The development and utility of electronic patient reported outcome measures in gynaecology

In support of submission for the degree of Doctor of Medicine (MD)

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1. Acknowledgements

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2. Abstract

Aims and Objectives: Patient reported outcome measures (PROMs) are tools which seek to ascertain patients' views of their symptoms, their functional status and their health-related quality of life, without interruption from a healthcare professional. Usually PROMs are questionnaires, they may include multiple choice components and/or free text answers. In order for the use of these tools to be considered reliable and valid in clinical practice, psychometric testing to provide evidence of reliability, validity and functionality should be undertaken. Electronic PROMs or ePROMs are such tools which are delivered electronically and completed on a computer or handheld device, often with responses uploaded onto the internet allowing remote completion and access of results.

The ePAQ system is an ePROM platform which utilises an online electronic response system for completion of PROMs. The original ePROM for which the ePAQ system was developed is ePAQ-Pelvic Floor (ePAQ-PF). This is a pelvic floor questionnaire widely used in clinical practice with excellent evidence foe reliability, validity and functionality.

This thesis aims to present a narrative on the development and utility of electronic patient reported outcome measures in gynaecology, including systematic literature reviews of existing tools prior to development/utilisation of ePROMs (**papers 1 and 2**), development and initial psychometric testing of two novel gynaecology ePROMs using the ePAQ system (**papers 3 and 4**) and discussion of the utility of ePROMs in gynaecology both as tools for clinical practice and in research (**papers 5, 6 and 7**).

Methods: Two systematic reviews following PRISMA guidelines and registered prospectively on the PROSPERO database (CRD42017082508 and CRD42017084710)

were undertaken. **Paper 1** was a systematic review of non-invasive modalities used to identify women with anal incontinence following childbirth; to assess the existing PROMs for this purpose with a view to deploying the ePROM ePAQ-PF for this purpose in a future study. **Paper 2** was a systematic review of PROMs, and their psychometric properties, used to assess body image in a urogynaecology patients. This was done to evaluate existing tools available, to inform development of a domain (area within a questionnaire) in ePAQ-PF to assess body image.

The development and initial psychometric testing of a two novel gynaecology ePROMs based on the ePAQ system is described in **papers 3 and 4.**

Three ethically approved retrospective cohort studies using data collected from ePAQ-PF as part of routine clinical practice are described in **papers 5-7**. Each of these papers deals with different symptom complexes and issues occurring in urogynaecology with the aim of presenting the utility of ePROMs in gynaecology both as clinical tools and research tools.
In **paper 5** the aim was to measure the prevalence of coital urinary incontinence (leakage of urine during sexual intercourse). In this study 2312 women completed ePAQ-PF in advance of their urogynaecology consultation. Logistic regression and Spearman's rank correlation evaluated associations between types of coital incontinence and different types of urinary incontinence (urgency incontinence and stress incontinence). Mann-Witney test evaluated the relationship between coital incontinence and self-reported quality-of–sex-life and self -avoidance and partner-avoidance of sex using data from ePAQ-PF. A subgroup analysis was undertaken to analyse outcomes in 84 women with coital incontinence undergoing tension free vaginal tape (an operation to treat stress incontinence).

In **paper 6** the aim was to use data from ePAQ-PF to assess the relationship between pelvic organ prolapse symptoms, subjective outcomes of surgery and body mass index (BMI) in women undergoing vaginal hysterectomy for treatment of prolapse. Pre- and post-operative data from ePAQ-PF were collected prospectively from 60 women undergoing vaginal hysterectomy for prolapse. Of these, 20 were normal weight (BMI 18.5 – 24.9), 20 were overweight (BMI 25 – 29.9) and 20 were women with obesity (BMI 30 – 34.9). The relationship between BMI and symptom scores for prolapse, impact on vaginal symptoms on quality of life and 'overall change in condition' was assessed. Pre- and post-operative symptom scores were compared using repeated mixed ANOVA test for BMI as a categorical variable (Normal, Overweight and Obese). Spearman's rank order correlation test was carried out to evaluate BMI as a continuous variable. All women underwent vaginal hysterectomy using a standardised technique.

ePAQ-PF uses a free test question to assess the concerns and treatment goals of patients completing this ePROM. All patients are asked: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?*'. The objectives of the study presented in **paper 7** were to undertake a content analysis of the free-text concerns and goals recorded by patients completing this item in ePAQ-PF and measure how these related to self-reported symptoms and health-related quality-of-life (HRQOL) data also recorded using ePAQ-PF. In total, 1996 consenting patients completed ePAQ-PF. Content analysis was undertaken of the free-text item responses. Key content themes were identified by the lead researcher, and three researchers read and coded all

recorded responses. Student's *t* test was used to compare ePAQ-PF domain scores for patients reporting concerns in the relevant domain with those who did not.

Results: Paper 1: 109 studies were included from 1602 screened articles. 36 studies utilising 15 different PROM instruments were identified. Mean response rates were 92% up to six weeks after childbirth. Non-personalised assessment modalities (PROMs) were associated with reporting of higher rates of anal incontinence compared to patient interview at all periods of follow up after childbirth, this was statistically significant between six weeks and one year after childbirth ($p<0.05$).

Paper 2: 17 studies were included from 3207 screened articles. Seven different PROMs used to assess body image in a urogynaecological population were identified. Two of these PROMs (Genital Self-Image Scale-20 and Body Image in Pelvic Organ Prolapse questionnaire) had good psychometric evidence for use but this was only in the context of women with prolapse. Evidence for validity and reliability was limited for the other five PROMs identified.

Paper 3 (development/testing of ePAQ-Vulva): Factor analysis identified five principal components. These were reviewed and amended to provide a putative domain structure of six domains. Internal reliability of these domains was assessed using Cronbach's alpha, producing values of 0.715 to 0.917. Inter-rater reliability of the picture items produced a Kappa statistic of 0.405. Spearman's rank showed moderate correlation between multiple choice answers and free-text concerns (r=0.364 – 0.462) in three of the six domains (Pain, Sex and Dyspareunia).

Paper 4 (development/testing of ePAQ-Menstrual, Pain and Hormonal (ePAQ-MPH)): Exploratory factor analysis identified 18 domains (Cronbach's α >0.7) and 30 redundant items. Test-retest analysis found acceptable intra-class correlations of 0.6–0.9 (p<0.05). Eight domains were compared with Menstrual Distress Questionnaire showing moderate or strong correlation in seven domains. Ten domains were compared with Women's Health Questionnaire, six of which showed moderate correlation. Mean QQ-10 Value and Burden scores were 76 and 25, respectively (SD=15.8 and 15.5). The mean completion time for ePAQ-MPH was 31 minutes. Confirmatory factor analysis of the revised version 2 instrument with 15 domains showed good model fit.

Paper 5: Prevalence of coital incontinence in the cohort was 30%. Symptoms of both urgency incontinence (p<0.005) and stress incontinence (p<0.005) were significantly and independently associated with both types of coital incontinence (orgasm & penetration). In women with coital incontinence compared with those without, there was significant self-avoidance of sex (p<0.0005), partner-avoidance of sex (p<0.0005) and impaired quality-of-sex-life due to sexual problems (p<0.005). Subgroup analysis of 84 women undergoing TVT showed significant improvement in all coital incontinence symptoms three months post-operatively.

Paper 6: Overall, 93% of women reported improvement in their condition. The main finding was that 'Overall change in condition' was negatively correlated with increasing BMI (r_s= -0.324, p=0.028). Irrespective of BMI, significant improvements were observed in symptoms

of prolapse and vaginal symptoms impact on health-related quality of life at three-months post operation.

Paper 7: 63% of participants who completed the questionnaire, recorded at least one free-text item. Content analysis identified 1560 individual concerns coding into the 19 ePAQ-PF domains. Symptom scores were significantly higher for patients reporting free-text concerns in 18 domains ($p<0.05$) indicating convergent validity of ePAQ-PF. Additional concerns relating specifically to body image were recorded by 11% of patients.

Conclusions: This narrative thesis presents good evidence for the use of ePROMs in gynaecology, both as clinical and research tools. Electronic patient reported outcome measures in gynaecology have an important role in supporting self- expression and increasing disclosure of potentially taboo or embarrassing symptoms. Their use as research tools is valuable allowing symptom complexes to be explored and outcomes after interventions measured accurately. Further research and development of ePROMs in gynaecology will be needed to support the NHS Long Term Plan.

3. List of abbreviations

AMED	Allied and complimentary MEdicine Database
ANOVA	Analysis of Variance
BMI	Body Mass Index
CINAHL	Cumulative Index to Nursing and Allied Health Literature
EMBASE	Excerpta Medica dataBase
ePAQ	Electronic Personal Assessment Questionnaire
ePAQ-MPH	Electronic Personal Assessment Questionnaire- Menstrual, Pain and Hormonal
ePAQ-PF	Electronic Personal Assessment Questionnaire- Pelvic Floor
ePAQ-Vulva	Electronic Personal Assessment Questionnaire- Vulva
ePROM	Electronic patient reported outcome measure
HRQoL	Health-related Quality of Life
MCQ	Multiple Choice Question
OAB	Overactive bladder
POP	Pelvic organ prolapse
POP-Q	Pelvic organ prolapse Quantification system
PRISMA	Preferred Reporting Items for Systematic reviews and meta-Analysis
PROM	Patient reported outcome measure

QQ-10	Questionnaire Quotient -10 item
SUI	Stress urinary incontinence

4. List of papers together with contribution to publications leading to MD thesis

Paper 1**: Gray TG, Vickers H, Jha S, Jones GL, Brown SR, Radley SC. A systematic review of non-invasive modalities used to identify women with anal incontinence symptoms after childbirth. International Urogynecology Journal. 2019;30(6):869-79.**

As the first author, I devised the systematic review with support from Dr Jha, registered the project (PROSPERO: CRD42017082508) and undertook the literature review, I was one of two reviewers to review all potentially relevant studies. I undertook all the data analysis. I wrote the manuscript. My co-author Dr. Vickers also reviewed the potentially relevant studies. The other authors reviewed papers where there was a disparity about whether these should be included in the data analysis and they also edited the manuscript.

Paper 2: **Gray TG, Sneyd R, Scurr K, Jones GL, Iles D, Jha S, Radley SC. Patient-reported outcome measures which assess body image in urogynaecology patients: a systematic review. International Urogynecology Journal. 2019;30(5):673-81.**

As the first author, I devised the systematic review, registered the project (PROSPERO: CRD42017084710) and undertook the literature review alongside Dr Sneyd and Dr Scurr. I was one of three reviewers to review all potentially relevant studies. I undertook all the data analysis. I wrote the manuscript. The other authors reviewed papers where there was

a disparity about whether these should be included in the data analysis and they also edited the manuscript.

Paper 3: **Gray TG, Alexander C, Jones GL, Tidy JA, Palmer JE, Radley SC. Development and Psychometric Testing of an Electronic Patient-Reported Outcome Tool for Vulval Disorders (ePAQ-Vulva). Journal of lower genital tract disease. 2017;21(4):319-26.** Ethical approval for the study was from the University of Sheffield, UK. Project registration number: 001980. As first author, I completed the data collection to assess the literature for patient reported outcome measures in vulval disease, I undertook collection of the pilot data for patient involvement, including all analysis. I was part of the panel which devised the items in ePAQ-Vulva and I collated and analysed the data for psychometric testing, alongside Dr Alexander and supported by Professor Jones. I wrote the paper, which was edited by my co-authors.

Paper 4: **Gray TG, Moores KL, James E, Connor ME, Jones GL, Radley SC. Development and initial validation of an electronic personal assessment questionnaire for menstrual, pelvic pain and gynaecological hormonal disorders (ePAQ-MPH). European Journal of Obstetrics & Gynecology and Reproductive Biology. 2019;238:148-56.**

Ethical approval was obtained from the Sheffield Local Research Ethics Committee (Reference number 09/H1308/21). As first author, I completed the data collection to assess the literature for patient reported outcome measures in menstrual disease, the initial study

data for version 1 of ePAQ-MPH was collected and analysed by Dr James and Professor Jones. I undertook data collection and analysis for version 2 of ePAQ-MPH, including for the confirmatory factor analysis alongside Professor Jones. I reviewed and restructured the PROM alongside Professor Radley and Professor Jones following the confirmatory factor analysis. I wrote the manuscript. My Co-authors edited the manuscript.

Paper 5: **Gray T, Li W, Campbell P, Jha S, Radley S. Evaluation of coital incontinence by electronic questionnaire: prevalence, associations and outcomes in women attending a urogynaecology clinic. International Urogynecology Journal. 2018;29(7):969-78.**

I arranged for ethical approval for this study, which was obtained from the University of Sheffield (Registration Number 011338). As first author I conceived the study, created the database for the study, collected the data, analysed the data alongside Dr Li and wrote the manuscript. My Co-authors contributed to writing sections of the paper and with manuscript editing.

Paper 6: **Gray T, Money-Taylor J, Li W, Farkas AG, Campbell P, Radley SC. What is the effect of body mass index on subjective outcome following vaginal hysterectomy for prolapse? International Neurourology Journal. 2019;23(2):1-8.**

I co-arranged for ethical approval for this study, which was obtained from the University of Sheffield (Registration Number 006343). The study was conceived by Dr Patrick Campbell. As first author I co-created the database for the study, co-collected the data, co-analysed

the data alongside Dr Li and wrote the manuscript. My Co-authors contributed to manuscript editing.

Paper 7: **Gray T, Strickland S, Pooranawattanakul S, Li W, Campbell P, Jones G, Radley S. What are the concerns and goals of women attending a urogynaecology clinic? Content analysis of free-text data from an electronic pelvic floor assessment questionnaire (ePAQ-PF). International Urogynecology Journal. 2019;30(1):33-41.**
I arranged for ethical approval for this study, which was obtained from the University of Sheffield (Registration Number 015337). As first author, I wrote the paper. I also conceived the study, created a database of free-text data and collected and analysed the data. My co-authors, Ms Strickland and Ms Pooranawattanakul also undertook collection of free text data. I wrote the manuscript. My Co-authors edited the manuscript.

5. Commentary

5.1 Introduction, background and systematic literature reviews

5.1.1 Patient reported outcome measures

Patient reported outcome measures (PROMs) are tools which seek to ascertain patients' views of their symptoms, their functional status and their health-related quality of life (HRQoL)[1]. An individual's beliefs and perspective on his or her condition, including personal goals and concerns are important to understand in any medical field. This is particularly true for intimate gynaecological and urogenital disorders, which may be taboo, embarrassing and have significant psychological and psychosocial components.

PROMs are completed by the patient without interpretation of the patient's response by a clinician or anyone else[2]. Their function as an outcome measure refers to the ability of these tools to compare patients' health at different times, measuring the effect a treatment or intervention has had on symptoms, functional status or HRQoL. PROMs are usually questionnaires, ideally completed by the patient, which allow for subjective data to be collected and measured in an objective way[3].

The use of PROMs in all areas of healthcare has become increasingly widespread[4,5] and their use in sensitive conditions, where patients may not disclose embarrassing symptoms is potentially invaluable[6-8]. Since 2009 the NHS has made it a requirement to collect PROM data

from patients before and after surgery for hip and knee replacements, varicose veins and groin hernias[5]. Increasingly, their use is being recommended in clinical practice and they are being integrated as part of standard clinical care in many areas.

PROMs were originally developed as tools for use in research studies, but their value and utility in clinical care is increasingly understood and development of PROM tools and usage thereof is steadily increasing.

5.1.2 Patient reported outcome measures in gynaecology

Gynaecology concerns disease of the female reproductive and genitourinary systems. Almost all the conditions in gynaecology have symptoms which are considered to be embarrassing or taboo in nature. Gynaecological conditions, such as heavy menstrual bleeding, pelvic pain, urinary incontinence and pelvic organ prolapse can have a profound and significant impact on HRQoL. There is good evidence that many patients do not seek help for intimate and potentially embarrassing symptoms, resulting in decreased HRQoL and delays in accessing care[7-9]. Using PROMs as a tool for assessment in gynaecological conditions, especially if administered indirectly (by post or by the internet), can potentially result in increased disclosure of embarrassing symptoms and their impact on HRQoL; allowing for a better assessment of health than a conventional history may be able to achieve. PROMs have been used in gynaecological disorders since the 1960s[10] and since the 1990s many tools (150+) have been developed and validated within urogynaecology, which concerns female pelvic floor dysfunction including urinary incontinence, pelvic organ prolapse, anal incontinence and sexual dysfunction.

5.1.3 Electronic Patient Reported Outcome Measures (ePROMs) and ePAQ-Pelvic Floor

One of the key disadvantages of paper based PROMs is the ability to review the data easily and look at patterns and trends across multiple groups of patients. In order to achieve this with paper based PROMs, the data needs to be entered by hand into a database which is time consuming and costly.

ePROMs offer patients the opportunity to complete the assessment when it is convenient for them and in their own home. This may mean that the answers to the questions asked are more honest and open as the patient may feel more comfortable in a non-medical setting and have a better opportunity to reflect on their symptoms[11] and the impact of these on function and HRQoL, compared to completing the PROM on paper in an outpatient clinic waiting room.

ePROMs also offer clinicians the opportunity to assess the patient remotely, via a virtual clinic. This has considerable benefits for follow-up patients who may be able to have a telephone consultation after completion of an ePROM at home to assess progress, rather than having to re-attend the outpatient department[12]. ePROM data could also be utilised to give tailored advice to patients on self-management, as well as providing healthcare professionals with detailed symptom and HRQoL data between scheduled appointments[13].

Previous research has found that electronic systems can gain better response rates and patients may find them easier and more satisfying to complete[14].

The first ePROM developed for use in gynaecology was the electronic Personal Assessment Questionnaire- Pelvic Floor (ePAQ-PF)[15]. This was previously a paper based tool, comprising a battery of validated paper based PROMS: the Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q)[16], Sheffield Prolapse Symptoms Questionnaire (SPS-Q)[17] and Female Sexual Function Index (FSFI)[18]. In development of ePAQ-PF, an expert panel reviewed the items included and revised the format of the instrument as well as adding items assessing impact, patients concerns, patient goals and patient questions.

ePAQ-PF is now utilised as a web-based instrument that provides a comprehensive assessment of a patient's pelvic floor symptoms and their impact on HRQoL. The instrument is completed on-line, prior to clinic attendance by 80% of users, or alternatively, using a touchscreen-computer or tablet in a private room in the urogynaecology clinic. Patients may choose to have their partner/family member present with them when they complete the questionnaire and if they complete it in the hospital a nurse can sit with them to support them if they wish. The majority of patients complete the questionnaire alone, unaided. Previous studies have shown that most patients find the questionnaire easy to use and a useful process which helps them to reflect and prepare for their consultation[6]. The mean completion time of ePAQ-PF, including the free-text components, is 26 minutes[15]. A questionnaire report may be printed or viewed

electronically for use by the attending clinician, supporting consultation, diagnosis and management[19].

The core element of ePAQ-PF comprises of standardised multiple-choice questions, which assess both the frequency and impact of pelvic floor symptoms across four dimensions: Urinary, Bowel, Vaginal and Sexual. Each item is presented on a separate screen, with individual 'help' pages and navigation buttons. Response options for all these items are on a four-point scale 'Never', 'Occasionally', 'Most of the time' or 'All of the time' and scored 0, 1, 2 or 3 respectively. The impact attributed to each of these symptoms is also recorded, using a standard sub-question *'How much of a problem is this for you?'* and graded as 'Not a problem', 'A bit of a problem', 'Quite a problem' or 'A serious problem' and scored 0, 1, 2 and 3 respectively. The degree of frequency and bothersomeness are thereby assessed for each symptom.

The electronic instrument automatically generates scores across 20 validated domains (areas assessing different themes within a PROM or questionnaire), providing graphic representation of these both the severity and the impact for each condition. Domain scores are derived by dividing the sum of all item scores in that domain by the total possible item score and multiplying this by 100 to produce a scale ranging from 0 (best possible health status) to 100 (worst possible health status)[15, 20]. In addition to the multiple-choice items within ePAQ-PF, the instrument also includes a free-text question which asks: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help,*

advice or treatment?'. Patients are invited to record up to three free-text responses, each of up to 100 characters.

Five of the papers incorporated into this narrative thesis are studies which use the ePAQ system developed for ePAQ Pelvic Floor. Two of the studies describe the development and initial psychometric testing of two novel gynaecology ePROMs using the ePAQ base format for software engineering and PROM production. Three further papers utilise data from ePAQ-Pelvic Floor for purposes of research in urogynaecology and demonstrate both the potential utility and value of PROMs for this purpose as well as within clinical practice.

5.1.4 Focused gynaecology PROMs systematic literature reviews: paper 1 and paper 2

In order to inform development of patient reported outcome measures, it is essential to have a deep awareness of the existing tools available for the same or similar purposes and the evidence of psychometric testing for these tools. Therefore, before using an existing tool for a new or different purpose or before developing a completely new PROM literature reviews should be undertaken. Ideally, these reviews should be systematic in nature using standardised methods of data collection, analysis and reporting of results. Paper 1 and Paper 2 of this thesis are systematic reviews undertaken to inform using an existing ePROM (ePAQ-PF) in a different way (**paper 1**) and developing new domain areas in an existing ePROM (**paper 2**).

Paper 1[21] of this thesis is a systematic review of non-invasive modalities (PROMs) used to identify women with anal incontinence problems following childbirth. Anal incontinence is the involuntary leakage of faeces or flatus. Anal incontinence following childbirth is prevalent and has a significant impact upon quality-of-life. At the present time, there is no standard assessment for women after childbirth using a PROM to identify these symptoms. This systematic review aimed to identify non-invasive modalities including all PROMs that have been used to identify women with anal incontinence following childbirth and assess response rates and reporting rates of anal incontinence for these modalities. The reason for undertaking this systematic review was to assess whether ePAQ-Pelvic-Floor may be a suitable tool to deploy for this purpose.

Ovid Medline, AMED, CINAHL, Cochrane Collaboration, EMBASE and Web of Science databases were searched for studies using non-invasive modalities to identify women with anal incontinence following childbirth, published from January 1966 to May 2018. Study data including type of modality, response rates and reported prevalence of anal incontinence were extracted and critically appraised.

In total, 109 studies were included from 1602 screened articles. Three types of non-invasive modality were identified: validated PROMs (n=36 studies utilising 15 different instruments, including ePAQ-Pelvic Floor in one study), non-validated PROMs (n=50 studies) and patient interviews (n=23 studies). Mean response rates were 92% up to six weeks after childbirth. Non-personalised assessment modalities (PROMs) were associated with reporting of higher rates of anal incontinence compared to patient interview at all periods of follow up after childbirth, this was statistically significant between six weeks and one year after childbirth ($p<0.05$).

This systematic review confirmed that PROMs can be used effectively after childbirth to identify women with anal incontinence and these are likely to be more effective than interviews with patients. The main strengths of this systematic review were the rigorous search strategy employed, which has identified the relevant studies, allowing identification of the PROMs available which have been used successfully to identify women with anal incontinence after childbirth. The limitations of this systematic review include the heterogeneity in the definitions used to describe anal incontinence symptoms in the studies included, which is some cases may have underestimated the prevalence of anal incontinence. Disparity in the definition, or lack of definition, of what constitutes obstetric anal sphincter injury may also have contaminated the results. The use of non-validated PROMs and patient interviews may have also resulted in over or under-reporting of anal incontinence symptoms. The small numbers of studies for the three different non-invasive modalities at various different points of follow-up may have resulted in type 2 statistical errors when comparing prevalence rates using paired *t* test. The use of a search strategy which excluded papers not published in English may have also resulted in missing non-invasive modalities potentially relevant to this systematic review. Grey literature searches were also not undertaken, this may have resulted in relevant conference abstracts being excluded. Nevertheless, this is an up to date systematic review which demonstrates the most appropriate PROMs to use for women with anal incontinence following childbirth. Further research aims to evaluate the use of ePAQ-Pelvic Floor (one of the validated PROMs identified in this review) in a large cohort of women following childbirth.

Paper 2[22] of this thesis is a systematic review of PROMs which have been used to assess body image concerns in women with urogynaecology and pelvic floor problems. It is well established that urogynaecological conditions can have a significant impact on body image[23-27]. This systematic review aimed to identify currently available PROMs used to assess body image within a urogynaecological population and to identify the most psychometrically robust and appropriate PROM tools to use in this context. This was undertaken following a study which identified that women using ePAQ-Pelvic Floor had body image concerns which were not addressed by this ePROM (**Paper 7** of this thesis)[28]. Ovid Medline, AMED, CINAHL, Cochrane Collaboration, EMBASE and Web of Science databases were searched from January 1966 to November 2018, to identify studies that had administered a PROM to assess body image to patients diagnosed with a urogynaecological condition. The information extracted and critically appraised included; study setting, PROM instrument used and the reported psychometric properties of the PROM.

In total, seventeen studies were included from 3207 screened articles. Seven different PROMs used to assess body image in a urogynaecological population were identified. Two of these PROMs (Genital Self-Image Scale-20[29] and Body Image in Pelvic Organ Prolapse questionnaire[30]) had good psychometric evidence for use but this was only in the context of women with prolapse. Evidence for validity and reliability was limited for the other five PROMs identified. The main strength of this systematic review was the rigorous and transparent search strategy employed, which allowed the identification of all the relevant studies and identifying seven PROMs used in a urogynaecology population. The review

was able to identify the most psychometrically robust tools available for use to assess body image within a urogynaecology setting.

The limitations of this systematic review were that the data was only as good as that which has been provided in the included studies. Not all the psychometric testing for each PROM may have been included, especially details about content validity, criterion validity and responsiveness, which were often not reported. To minimise the risk of bias and subjectivity with using the Oxford PROM group's appraisal system which was used to complete this systematic review[31], each reviewer independently extracted data on the quality of the psychometric properties and functionality of the included PROMs. The use of a search strategy which excluded papers not published in English may have also resulted in missing both instruments and related studies potentially relevant to this systematic review. This review has identified that further development and psychometric testing of PROMs to assess body image in urogynaecology, both for research purposes and clinical practice, is required. Likewise, further research to investigate the relationship between body image and urogynaecological symptomatology is required and developing valid, reliable and functional PROMs will be integral to this. The next stage is to develop and undertake psychometric testing of a domain to assess body image in the ePAQ-PF ePROM.

5.2 Development and psychometric testing of PROMs in gynaecology

5.2.1 Overview of development and testing of PROMs

The development of patient reported outcome measures should follow a set pattern. This includes the assessment of the views of both healthcare professionals and patients on the

development of the PROM, what items (questions or themes the PROM should cover) should be included and how it should work. Drafting of PROM items is undertaken and this process may be reviewed by both healthcare professionals and patients who are stakeholders in the development of the PROM. Once the PROM is completed it should be administered to a group of patients large enough to allow for psychometric properties which assess reliability, validity and functionality of the PROM to be appropriately evaluated. After initial testing of the PROM, further refinement of items and structure, taking into account the results of the psychometric testing, should be undertaken. A further or final version of the PROM may then be tested in a similar manner and the PROM revised as indicated until the reliability, validity and functionality are shown to be optimal. Only then should the instrument be used in clinical practice and as a research tool.

Paper 2[22] of this thesis is a systematic which identified all the currently available PROMs to assess body image in urogynaecology. One of the main findings of this systematic review was that of the seven tools identified by the review, only two had been appropriately tested in a urogynaecology population and had good evidence of reliability, validity and functionality. The other five tools had all been used in a research setting without adequate evidence of their ability to do the task they have been designed to do. The most frequently used instrument identified in this systematic review was the modified Body Image Scale (mBIS)[23], which was used in 11 studies[23,24,32-40]. This PROM was initially developed to assess body image concerns in relation to medical conditions or treatment in cancer patients and was adapted for use in patients with pelvic organ prolapse. This was done by simply changing questions regarding 'disease or treatment' from Hopwood's original body image scale[41] to questions regarding 'prolapse'. No evidence at all was provided for the

content validity of this tool in a urogynaecology population and the available evidence for its reliability and construct validity was very limited, despite it being the most widely used PROM to assess body image in a urogynaecology setting. For this tool to be considered valuable for research and use in clinical practice, further psychometric testing within a urogynaecology population would be required. This paper helps to underline the importance of robust PROM development and testing to ensure that the results it produces are not biased or inaccurate.

5.2.2 Patient involvement in the development of ePROMs

In order to ensure that a PROM truly captures the perspectives of patients, it is essential that patients are directly involved in the development of a PROM[42]. This is mainly because only patients will be able to determine which elements of health outcomes are important to them and if the PROM is able to access this information.

A large scoping review which aimed to review the different ways that patients are involved in PROM development, the extent to which patients are involved and whether patient involvement has increased over time found that in just over a quarter of the 189 included studies did not actively utilise any involvement from patients[43]. Of the PROM development studies which did include patients, 58% involved patients in item development, 51% involved patients in testing the comprehensibility or reading level of the PROM. In only 7% of the studies included were patients involved in each step of PROM development. The scoping review also found that patient involvement did not improve over time.

Paper 3[44] of this thesis is a PROM development study describing the development and primary psychometric testing of an electronic PROM to assess patients with vulval disorders. During the development of the ePROM concerned (ePAQ-Vulva), patients' views were sought on ePROM development in this area. A survey of six free text questions was completed by 62 patients with vulval disorders attending the vulval clinic at Sheffield Teaching Hospitals over a three-week period. Of the patients who completed the survey, 75% were positive about the idea of an electronic PROM to aid with the assessment of with vulval disorders, 74% of patients listed advantages ePROMs in this context, compared to 26% who listed disadvantages. There were two emerging key themes from advantages listed by patients completing the survey. These were the ability to express their feelings or concerns via the ePROM (35%) and the ability to receive information and knowledge about vulval-disorders via the ePROM (33%). The responses to the survey helped to inform the development of items within the PROM, alongside the expert panel and national guidelines. Patients were not involved in assessments of reading level for the ePAQ-Vulva PROM and were only involved at the very start of PROM production. Given the evidence for the benefits of patient involvement in PROM production, this lack of patient involvement could be seen as a limitation of paper 3 of this thesis.

Paper 4[45] of this thesis is also an ePROM development paper, concerning the development and initial psychometric testing of ePAQ-MPH (Menstrual, Pain and Hormonal). This is an ePROM designed to assess menstrual disorders, gynaecological pain syndromes and gynaecological hormone disorders. In order to guide development of PROM items, semi-structured interviews with 25 patients were conducted by a social scientist working as part

of the ePROM development team. These interviews were voice-recorded, transcripts made and then subjected to thematic content analysis[46]. The thematic content analysis identified the themes which were salient to the patients participating, including assessments of pain, the ability to say how much symptoms impacted on HRQoL and the inclusion of perimenopausal symptoms.

Measures of ePROM acceptability were assessed using another questionnaire based tool. In total, 279 women completing the ePAQ-MPH ePROM during the pilot phase also completed a validated questionnaire called Questionnaire Quotient 10-item (QQ-10). This is a tool which measures face validity (the degree to which the ePROM appears to measure what it is purporting to measure, from the patient's perspective in this case), feasibility and utility of the PROM (all from the patients' perspective)[47]. The QQ-10 tool produces a value score and a burden score, the greater the value score then the more acceptable the ePROM appears to be to patients. Conversely, the greater the burden score then the ePROM appears less acceptable to patients. Mean scores for Value and Burden in this ePROM development study for ePAQ-MPH were 76 (SD = 15.8) and 25 (SD = 15.5), respectively, suggesting high Value and low Burden for the majority of patients. Of the six items relating to Value, 'ease of use' and 'happy to complete again' were the most highly rated responses (92% and 90%, respectively). Of the four Burden items; 'The questionnaire is too long' was the most frequently reported response (25% of subjects). Therefore, patients were involved in both the development of the ePROM and in assessing acceptability. They were not involved in the revision and further psychometric testing of ePAQ-MPH, which may be a limitation of its development. This is of concern, because if an ePROM does not adequately

represent the patients' perspective, it can lead to patients failing to complete the ePROM, resulting in a negative impact on the validity[48].

5.2.3 Psychometric testing of patient reported outcome measures

Testing of psychometric properties of a PROM provides evidence that the instrument is working correctly and measuring what it purports to measure (validity) and doing this in a consistent and reproducible way (reliability). The ability of a PROM to accurately collect symptom data and HRQoL data is dependent on the strength of the psychometric properties of the instrument. The two most important psychometric properties are reliability and validity and the evidence for these two properties sits along a continuum whereby there can be no evaluation of these properties at all, up to full evaluation in the relevant study population. This means that it is not correct or proper to claim that a PROM is absolutely valid or reliable, as this is a continuous process[49]. This also means that to state that an instrument is 'validated', meaning psychometric testing has been completed and good evidence for validity, is incorrect. This statement simply means that the psychometric performance has been tested and may show promise. The more psychometric testing is done, then the more that patients and healthcare professionals can have confidence in the reliability, validity and functionality of the tool being considered.

Reliability assesses the extent to which a PROM tool yields consistent and reproducible results[50]. Internal reliability is the extent to which items within an instrument measure the same concepts[51]. It also ensures that no two items in a PROM are measuring exactly the same concept and may therefore be used as a tool for item reduction during PROM

development; with the aim of reducing the burden of completing the instrument. The Cronbach's α statistic is used to measure internal reliability. Scores greater than 0.7 indicate that items are measuring related constructs. Likewise, scores greater than 0.94 suggest a degree of item redundancy, and provide a basis for item reduction[44]. A further measure of reliability is test-retest reliability, which provides evidence of stability of the PROM. In test-retest reliability the patient completes the PROM on two separate occasions at least one week apart. Typically, Wilcoxon signed-rank test is used to measure any differences between Cronbach's alpha values for the two completions and then inter-class correlations are calculated.

Validity is the extent to which a PROM measures what it purports to measure[52]. This has to be absolutely specific to the population and setting[22]. For example, as in **paper two** of this thesis, a PROM designed to assess body image in cancer patients may not be reliable in a urogynaecology population. Broadly, there are three main types of validity. These are content validity, criterion validity and construct validity.

Content validity is extent to which a PROM measures appropriate content and includes a variety of attributes which make up the measured construct of the instrument[49]. This is represented by evidence of the adequacy and appropriateness of development of the material included in the PROM. Ideally, a plan for the content of the PROM should be made before the instrument is developed and the source of the content should be from focus groups or cognitive interviewing (with patients who would be using the PROM, but also

with experts in the field). A group of experts in the field can then further examine items and endorse the content validity and identify any gaps in content[49]. Face validity is where the content of a PROM is assessed in terms of how it is perceived by patients and experts with regard to its ability to measure what it is supposed to be measuring. If the PROM appears to measure what it is supposed to be measuring, this is evidence of face validity. It is a subjective judgement and there are different means of assessing this including interviews with patients/experts completing the PROM or questionnaire tools, such as QQ-10[47].

Criterion validity is when the extent to which the PROM agrees with an external standard measure, usually another PROM which has undergone psychometric testing and is used in clinical practice or research[49]. Correlation between the PROM and another (usually validated and well-established) PROM is usually measured using Spearman's rank correlation[22]. Often, during PROM development, if the concept of the tool is novel (as in **paper 3** of this thesis) there may not be an appropriate measure of criterion validity available.

Construct validity describes the relationship of a construct to other variables[52]. Convergent construct validity is the degree to which two measures of constructs that should be related, are in fact related. For example, the relationship between women who report urinary incontinence and quality of life, which would be anticipated to be related. This is often explored using correlation coefficients, whereby >0.5 indicates adequate convergent validity and <0.5 indicates adequate divergent validity (two concepts which should be

unrelated, are proven to be)[53]. Responsiveness of a PROM measures the instrument's ability to measure change, for example, before and after treatment[54].

Functionality, refers to the practical properties of a PROM and includes things such as acceptability, feasibility and reading level of the administration of the PROM. Strictly speaking, these are not psychometric properties per se. However, these details are often important in practical terms; ensuring that it is feasible for patients to complete the PROM and the it is user friendly. Details such as the completion rate (levels of missing data), number of items in the PROM, completion time and scored reading level provide evidence of the functionality of a PROM.

Paper 3[44] of this thesis describes the initial psychometric testing of ePAQ-Vulva, an ePROM developed for the assessment of patients with vulval disease. Initial psychometric testing of this novel ePROM was undertaken. Factor analysis is a statistical procedure which enables the underlying domains, or scales, of a patient-reported outcome measure/patient questionnaire to be determined and for appropriate measures of reliability and validity to be measured thereof[50]. In order to identify the domains of ePAQ-Vulva, factor analysis using Varimax rotation (a statistical procedure to identify domains in a PROM or questionnaire) was carried out. Cronbach's α was used to measure internal reliability. Convergent validity was partially assessed by comparing the multiple-choice PROM responses with the free-text items in the PROM recording patient concerns and goals. The free text comments were each reviewed to assess if the concern recorded by the patient

was assessed by a questionnaire item in a particularly domain. Free-text data for concerns were then categorized according to domain and the rank correlation coefficient with the relevant domain scores for quality of life calculated (Spearman's rank correlation).

During the evaluation period 98 vulval clinic patients completed the instrument either on-line prior to clinic attendance or in the vulval clinic at a touch screen computer in a private room. The average time to complete the questionnaire was 32 minutes.

Factor analysis indicated the presence of five components or domains. The expert panel reviewed and intuitively amended these components to provide a structure comprising of six clinically meaningful domains. Internal reliability of the six domains was assessed using Cronbach's α; all six domains achieved an alpha level of≥ 0.7. Inter-rater reliability of the picture items showed agreement between clinician and patient 54% of the time regarding the presence of symptoms. Agreement regarding absence of symptoms was 85%. The Cohen's Kappa measure of agreement for this was moderate at 0.405. Spearman's rank showed significant moderate correlation between multiple-choice components and free-text items in three of the five domains. The initial testing and validation of ePAQ-Vulva has provided some evidence of reliability and validity but the data analysed so far represent a relatively small sample in a single-centre specialist vulval clinic. ePAQ-Vulva therefore requires further testing, including confirmatory factor analysis of its domain structure in larger numbers of women. Changes will be made to the instrument to remove redundant items, though with some caution to ensure that clinical detail is not lost through item reduction. Further psychometric testing will then be undertaken in further ethically approved studies.

Paper 4[45] of this thesis regards the initial psychometric testing of ePAQ-MPH, a novel ePROM assessing menstrual disorders, gynaecological pain and gynaecological hormonal disorders. Again, psychometric testing consisted of exploratory factor analysis with Varimax rotation to identify a domain structure. The internal reliability of items that intuitively constituted a domain was also evaluated, whether loading collectively in the factor analysis or not. Items failing to be included in any domain were reviewed by the expert panel regarding their value and possible removal, this was in order not to prioritise statistical significance over clinical significance (and is a measure of face validity from the clinicians' perspective).

To measure criterion validity, a sample of 213 patients also completed two validated PROMs (Women's Health Questionnaire (WHQ)[55] and the Menstrual Distress Questionnaire (MDQ)[10]. These two PROMs were used as there is evidence for their validity and both instruments cover almost all the content incorporated in ePAQ-MPH. Scores from ePAQ-MPH were compared with salient domain scores from WHQ and MDQ using rank correlation to assess the degree of correlation. Test-retest reliability to evaluate stability over time was undertaken with 30 participants who completed ePAQ-MPH on two occasions, at least one week apart. Wilcoxon signed-rank test was used to measure differences between Cronbach's alpha values for the two completions and inter-class correlations were calculated.

Complete questionnaire data were obtained from 291 completions of ePAQ-MPH. Mean completion time was 31 minutes. Eighteen domains of ePAQ-MPH with Cronbach's alpha values of >0.7 were identified. Factor analysis demonstrated that the Menstrual dimension had two redundant items and identified six domains; the Pelvic Pain dimension had four

redundant items and five domains; the Hormonal dimension had seven redundant items and four domains. Within the hormonal dimension a putative polycystic ovary syndrome domain including items relating to hair loss, acne and hirsutism was evaluated; these items were tested for internal reliability and produced a Cronbach's alpha value of 0.42 suggesting that this was not a reliable domain. The final dimension of Non-menstrual Bleeding & Discharge (NMBD) had 5 redundant items and three domains were identified. All redundant items were removed from Version 1 of ePAQ-MPH (102 items reduced to 72 items). Test retest reliability of ePAQ-MPH was undertaken with 30 participants using Version 1 of ePAQ-MPH. Intra-class correlation coefficient values ranged from 0.45 to 0.9; the minimum accepted value of 0.5, was not achieved in the hormonal / sexual function domain (0.45). Interclass correlation >0.5 was seen in all other domains. For criterion validity of Version 1 of ePAQ-MPH, 180 patients completed the MDQ PROM and 213 completed the WHQ PROM. Two of the 18 domains of ePAQ-MPH (Version 1) had a relevant domain in both MDQ and WHQ. Eight domains were compared with MDQ showing moderate or strong correlation in seven domains. Ten domains were compared with WHQ, six of which showed moderate correlation**.**

Following this initial psychometric testing, all redundant items were removed from version 1 of ePAQ-MPH and the PROM restructured. To confirm the conceptual model of ePAQ-MPH, a confirmatory factor analysis (CFA) using Mplus version 8.0 (Muthen & Muthen, 2017, Los Angeles, CA) was undertaken by on 254 completed questionnaires (ePAQ-MPH Version 2)[56]. Overall, the findings suggested that that the ePAQ-MPH structure fits the data moderately well[57]. Having confirmed the conceptual framework for ePAQ-MPH, the PROM structure for patient administration was reorganised. The single NMBD domain (intermenstrual bleeding)

was relocated into the Menstrual dimension and the five domains relating to sexual function (menstruation and sexual function, dyspareunia, pain and sexual function and hormones and sexual function) were moved into a new Sexual dimension, thus version 3 of ePAQ-MPH was finalised. Initial psychometric testing of ePAQ-MPH has shown good internal reliability, test-retest reliability and criterion validity. The results of the initial psychometric testing has enabled remodelling of the instrument. The confirmatory factor analysis of the revised instrument has shown that the domain structure of ePAQ-MPH fits the data it is intended to collect moderately well and good model fit was also demonstrated, confirming the conceptual framework of the instrument. Whilst this paper reports the development of version 3 of ePAQ-MPH, to allow other research groups to scrutinise and review the data generated thus far, wider evaluation and psychometric testing of this latest and current version of ePAQ-MPH is now required in larger samples and in different settings, including tests of stability, tests of data quality, sensitivity and responsiveness to change. So far, ePAQ-MPH shows good potential as an ePROM; providing objective patient-based data which could be utilised for assessment, service evaluation and research.

5.3 The utility of ePROMs as research tools in gynaecology

5.3.1 Quantitative research using ePROMs in gynaecology

PROMs in gynaecology were first developed as research tools to measure the outcome following an intervention (or control) as part of a study. The value of using patient focussed tools as part of routine clinical care has become apparent over time, although there is still little agreement on which tools should be used in which settings.

Good quality research assessing patient outcomes depends on using PROMs which have good evidence for reliability and validity. Studies which use non-validated tools are at risk of creating biased and unreliable results. The tool used in the three gynaecology ePROM original research papers forming part of this thesis (**Paper 5**, **Paper 6** and **Paper 7**) all utilise ePAQ-Pelvic Floor which has excellent evidence for reliability and validity[6, 15, 20].

A key advantage of using an ePROM as part of routine clinical care, both at initial assessment and follow up after interventions, is that a large amount of data is prospectively collected and available for analysis. However, in order to ensure good research governance, it is essential that appropriate consent for use of the data in research is obtained from each patient, each time they complete the ePROM. In addition, each research project should be appropriately registered and approved. The final item in ePAQ-Pelvic Floor asks patients: "Are you willing to allow confidential use of your answers to this questionnaire for appropriate approved and regulated research, audit or service evaluation projects?". Only data from patients who answer 'yes' to this question is then able to be used in approved studies. Separate ethical approval for each of the three original research studies using ePAQ-Pelvic Floor data in this thesis was obtained in addition to the patients' individual permissions.

ePAQ-Pelvic Floor presents 132 items across four symptom dimensions. It is able to assess urinary symptoms, bowel symptoms, vaginal symptoms and sexual symptoms; all of these symptom areas are important in urogynaecology. The twenty scored domains each consist of three to five questions assessing symptoms and their impact on HRQoL. Thus, a very large amount of data is collected and processed. Each individual symptom question is

scored out of four and each domain (comprising three-six questions in related areas) is scored out of 100 using an algorithm. This system of quantitative data and scoring allows for symptoms occurring in different domains to be compared using statistical tests to measure associations. It also allows for symptom scores to be compared before and after an intervention. The datasets accumulated by ePAQ-Pelvic Floor are large, demonstrating statistical significance of associations and changes after intervention is both feasible and potentially very valuable.

Paper 5[8] of this thesis is a retrospective cohort study assessing the prevalence and associations of coital urinary incontinence in women attending the urogynaecology teaching clinic at Sheffield Teaching Hospitals, using data from ePAQ-Pelvic Floor. Coital incontinence is the complaint of involuntary loss of urine associated with sexual intercourse (coitus). This can be further divided into coital incontinence occurring with penetration at the start of intercourse and that occurring at orgasm[58]. The aim of the study was to accurately measure the prevalence of coital incontinence in women attending the urogynaecology clinic and evaluate the association between different types of coital incontinence and different types of urinary incontinence (stress incontinence and overactive bladder) and HRQoL. Previously it was thought that coital incontinence at orgasm was due to overactive bladder (OAB) (inappropriate bladder contractions causing leakage) and that incontinence at penetration was due to stress incontinence (SUI) (leakage with raised intra-abdominal pressure secondary to weakness of the muscles at the bladder neck. Data from 2212 patients who had completed ePAQ-Pelvic Floor and consented for use of their data was analysed. The results

showed that the prevalence of coital incontinence in the cohort was 30%. Symptoms of overactive bladder ($p<0.005$) and stress urinary incontinence ($p<0.005$) were *both* significantly and independently associated with both types of coital incontinence (orgasm & penetration). This was in contrast to the previously held view that coital incontinence at orgasm was only associated with overactive bladder. In women with coital incontinence compared with those without, there was significant self-avoidance of sex ($p<0.0005$), partner-avoidance of sex ($p<0.0005$) and impaired quality-of-sex-life due to sexual problems ($p<0.005$). The impact of this was significant in each group. Therefore, the symptom of coital incontinence may be a significant factor in sexual dysfunction in women with coital incontinence.

Paper 6[59] of this thesis was a retrospective cohort study using quantitative data from ePAQ-Pelvic Floor. The aim of this study was to assess the relationship between pelvic organ prolapse (POP) symptoms as assessed by ePAQ pelvic floor, subjective outcomes of surgery and the patients'' body mass index (BMI) in women undergoing vaginal hysterectomy for POP. The rationale for undertaking this study is that obesity is a significant risk factor for pelvic organ prolapse (POP), but the effects of obesity on outcomes of surgery for POP are poorly understood[60-63].

Pre- and post-operative data from ePAQ-Pelvic floor were collected prospectively from 60 women undergoing vaginal hysterectomy for POP. Of these women, 20 were normal weight (BMI 18.5 – 24.9), 20 were overweight (BMI 25 – 29.9) and 20 were women with obesity (BMI 30 – 34.9). The relationship between BMI and symptom scores for prolapse, impact on vaginal symptoms on quality of life and 'overall change in condition' was assessed. Pre- and

post-operative symptom scores were compared using repeated mixed ANOVA test for BMI as a categorical variable (Normal, Overweight and Obese). Spearman's rank order correlation test was carried out to evaluate BMI as a continuous variable. All women underwent vaginal hysterectomy using a standardised technique undertaken by four surgeons.

The results showed that 93% of women reported improvement in their condition. The main finding was that 'Overall change in condition' was negatively correlated with increasing BMI (r_s= -0.324, p=0.028). Irrespective of BMI, significant improvements were observed in symptoms of prolapse and the impact of vaginal symptoms on quality of life at three-months post operation. Therefore, with increasing BMI, women may be more likely to report lower levels of satisfaction following prolapse surgery, despite reporting equivalent improvements in symptoms compared to those with normal BMI. Previous studies have shown that BMI is known to affect how individuals perceive their general health and well-being with obese individuals reporting poorer levels of subjective health status[64-66]. Therefore, women with obesity may actually perceive change in their condition after prolapse surgery differently to women of normal weight. Reduction of weight prior to prolapse surgery could be considered in obese women to improve subjective outcomes of surgery.

The main limitations of this study were the short follow up period after surgery (three months) and lack of pre- and post-operative objective data, including pelvic organ prolapse quantification (POP-Q) scores, although this would have looked at objective outcomes which are now widely recognized to be less important than subjective outcomes[67, 68]. Of course, it is possible that patients who were not satisfied with their surgery may have disengaged from the follow up process and not completed the post-op questionnaire that was requested,

thereby introducing reporting bias. However, the comprehensive pre- and post-operative questionnaire data collected with ePAQ-Pelvic Floor from 60 patients undergoing vaginal hysterectomy for prolapse has permitted a detailed comparison of subjective outcomes between different BMI groups in this small study. The main recommendation following this small study could be that, because women with increasing BMI are likely to be satisfied to a lesser degree with the outcome of prolapse surgery, they should perhaps be counselled about this pre-operatively; or else weight loss prior to surgery be recommend. Future studies in this area should investigate the impact of obesity on outcomes of surgery for anterior and posterior compartment prolapse, assessing both subjective and objective outcomes, with long term follow up to assess the impact of BMI on prolapse recurrence in addition.

5.3.2 Qualitative research using ePROMs in gynaecology

Most PROMS used in gynaecology use multiple choice questions (MCQs) to assess for the presence of symptoms and their impact on function and HRQoL. Data collected using these types of questions provides quantitative data, but in reality it may lack both sensitivity and acuity required to individualise each patient's concerns and goals. This is especially important with regard to treatment which is often highly individualised and dependent on many different factors, such as personal preference and previous treatments[69].

The use of free text responses within PROMs, which allow the patient to provide their own written response to a question, can help to provide a qualitative component to the data collected and provides an important opportunity for the patient to express themselves.

ePAQ-Pelvic Floor uses free text components in this way. The penultimate item in ePAQ-Pelvic Floor is a free-text question: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?*'. The patient's free-text responses to this question are then presented at the very top of the structured report which the clinician uses to review the results prior to and during the consultation (face to face or virtual) with the patient. The purpose of using this free-text information is to give an additional qualitative and personalised component to patient assessment, alongside quantitative data from the closed MCQ elements of the ePAQ-Pelvic Floor.

Although free-text data are commonly included in patient reported outcome measures alongside quantitative components, these types of data are rarely used in research as components of free-text responses may vary in relevance to the research question posed[70] and analysis of qualitative data presents methodological challenges. Reading through free text comments and analysing/categorising them can be very time consuming and difficult to approach in a standardised way. As a result, free-text data are often neglected even though they may represent a potentially rich source of data, which can supplement, augment and compliment more traditional quantitative data[71].

Paper 7[28] of this thesis is a content analysis[46] of free-text data from ePAQ-Pelvic Floor. The objective of this study was to analyse themes and content of free-text concerns and goals recorded in response the free-text concerns and goals item and measure how these responses related to the quantitative data recorded in MCQ items in ePAQ-PF. A further objective was to identify any elements of urogynaecology care not currently addressed by

the ePROM. The main findings were the free-text component of ePAQ-PF was used by over 60% of patients completing the ePROM. The majority (x=90%) of themes which were identified from the content analysis fitted into the existing domain structure of ePAQ-Pelvic Floor. An important finding was that specific body-image concerns were recorded by 10% (n=136) of patients responding to the free-text question. Body image in urogynaecology is an issue which is not currently addressed by the MCQ items of ePAQ-Pelvic Floor. The most commonly reported patient goals identified by the content analysis related to seeking improvement or cure of urogynaecology conditions and improved physical or sexual function. As a result of this study a new domain to assess body image within ePAQ-Pelvic Floor has been developed and is currently undergoing psychometric testing which will be submitted for publication. **Paper 1**[21] of this thesis assessed the existing tools which can do this in a urogynaecology setting and was used to inform content validity of the new domain.

5.4 Using ePROMs to increase reporting of sensitive symptoms

It has previously been shown that ePROMs can increase discussion rates in consultations about sensitive symptoms. This was because patients had completed the ePROM in private and therefore felt better able to disclose potentially embarrassing symptoms. This then allowed the clinician to initiate a discussion with the patient about these sensitive symptoms and therefore devise a management strategy which aimed to address these issues. Using ePROMs therefore should be considered in symptom areas with sensitive,

taboo and potentially embarrassing symptoms, as patients may not disclose these symptoms, even when direct questioning is employed.

A good example of this is in **paper 5**[8] of this narrative thesis. The reported prevalence of coital urinary incontinence (leaking urine during sexual intercourse) in this study was 47% in women reporting urinary incontinence. This is the largest study to-date relating to coital incontinence in women attending a urogynaecology clinic. These results are comparable to a previous study in an earlier cohort of women from the same unit, which found a coital incontinence prevalence of 60% in women undergoing urodynamic studies for urinary incontinence[72].

A review of the literature shows that six previous studies have shown rates of coital incontinence in women with urinary incontinence to vary between 10% - 66%[72-77]. Including this study, three of these seven studies have assessed coital incontinence in women attending a urogynaecology clinic. The prevalence was 10%[74] when direct questioning was used to assess prevalence and 36%[73] and 47%[8] when a validated questionnaire was used. Four studies assessed the prevalence of coital incontinence in women undergoing urodynamics, these women are likely to have a more severe degree of coital incontinence. Two of these studies used direct questioning to assess this and both found a prevalence of 11%[77, 78]. The other two studies used validated (ePAQ-Pelvic Floor) or non-validated (author's own) PROMs to assess prevalence and found it to be 60%[72] and 66%[76] respectively. The substantially higher prevalence of coital incontinence in women undergoing urodynamics, compared with women attending a urogynaecology clinic, is likely to be a reflection of more severe symptoms in women undergoing urodynamics. It is

apparent that using a PROM, does significantly increase the disclosure of coital urinary incontinence and therefore the reported prevalence of coital incontinence, compared with direct questioning. This is likely to be due to embarrassment and the taboo nature of this intimate problem.

Similarly, in **paper 1**[21] of this narrative thesis, which assessed tools (including PROMs and ePROMs) available to identify women with anal incontinence symptoms following childbirth, the type of tool (PROM or patient interview) was shown to be a significant factor in the reported prevalence of anal incontinence symptoms in studies included. Lower rates of anal incontinence were observed when personalised data collection methods (i.e. face to face interview or telephone interview) were used, compared with non-personalised methods (PROM or ePROM). This important finding was demonstrated at both short and long-term periods of follow up and was found to be statistically significant at the six weeks to one year follow-up period. Interestingly, this finding mirrored those of systematic reviews of the prevalence of faecal incontinence where reporting of faecal incontinence symptoms was found to be lower when face-to-face and telephone interviews were used to assess these embarrassing symptoms, when compared to PROMs[79].

In a previous study, two of the main barriers to accessing care for anal incontinence were shown to be embarrassment and stigma which were manifested as deeply felt shame in violating a social taboo to not talk about bowel symptoms[80]. This means that many women living with anal incontinence symptoms after childbirth may not seek healthcare, despite a number of healthcare contacts during the post-natal period, such as routine postnatal follow up, infant vaccinations and development assessments; which lead to interactions

with healthcare professionals including midwives, health visitors and general practitioners. These contacts could present a number of opportunities where a PROM or ePROM could be administered routinely to identify women with anal incontinence symptoms; potentially enabling access to care for such affected women. Using ePAQ-Pelvic Floor in this context will be the subject of a further study.

As there is good evidence that ePROMs result in increased disclosure of taboo and embarrassing symptoms, it could be argued that their routine use in gynaecology should be mandatory; to enhances self-expression and improve access to care. This would require consensus and recommendations from governing bodies, making recommendations based on the available evidence.

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7. Published papers

7.1 Paper 1: **Gray TG, Vickers H, Jha S, Jones GL, Brown SR, Radley SC. A systematic review of non-invasive modalities used to identify women with anal incontinence symptoms after childbirth. International Urogynecology Journal. 2019;30(6):869-79.**

Abstract

Aim: Anal incontinence following childbirth is prevalent and has a significant impact upon quality-of-life. Currently, there is no standard assessment for women after childbirth to identify these symptoms. This systematic review aimed to identify non-invasive modalities that have been used to identify women with anal incontinence following childbirth and assess response rates and reporting rates of anal incontinence for these modalities.

Methods: Ovid Medline, AMED, CINAHL, Cochrane Collaboration, EMBASE and Web of Science databases were searched for studies using non-invasive modalities to identify women with anal incontinence following childbirth, published from January 1966 to May 2018. Study data including type of modality, response rates and reported prevalence of anal incontinence were extracted and critically appraised.

Results: 109 studies were included from 1602 screened articles. Three types of non-invasive modality were identified: validated questionnaires/symptom scales (n=36 studies

utilising 15 different instruments), non-validated questionnaires (n=50 studies) and patient interviews (n=23 studies). Mean response rates were 92% up to six weeks after childbirth. Non-personalised assessment modalities (validated and non-validated questionnaires) were associated with reporting of higher rates of anal incontinence compared to patient interview at all periods of follow up after childbirth, this was statistically significant between six weeks and one year after childbirth ($p<0.05$).

Conclusion: This systematic review confirms that questionnaires can be used effectively after childbirth to identify women with anal incontinence. Given the methodological limitations associated with non-validated questionnaires; the role of providing assessment for all women following childbirth using validated questionnaires to assess pelvic-floor symptomatology, including anal incontinence, should be considered.

Keywords: Anal incontinence, faecal incontinence, postnatal, patient reported outcomes, questionnaires

Brief Summary

This systematic review identified 14 validated patient reported outcome measures which could potentially be used routinely to identify women with anal incontinence symptoms after childbirth.

Introduction

Anal incontinence is a common condition affecting up to 20% of adult women [1]. It has a profound and significant effect on quality of life [2] and is associated with significant healthcare costs [3]. The joint International Urogynaecological Association/International Continence Society definition of anal incontinence symptoms include faecal incontinence; defined as involuntary loss of faeces (solid and/or liquid stool) and flatus incontinence; defined as involuntary loss of flatus [4].

The main aetiological factor in the development of anal incontinence in women is childbirth; causing injury either to the anal sphincter complex, pelvic nerves or both [5]. The condition often goes unrecognised at the time of delivery and, even when managed appropriately, can lead to lasting problems, which are also frequently unreported to healthcare providers [6].

Many women may perceive anal incontinence symptoms such as flatus incontinence to be normal following childbirth and barriers to accessing care in this context include shame and embarrassment, as well as a lack of knowledge of potential treatments; many of which are minimally invasive [7]. Many general practitioners are also unaware of treatments and local care pathways for women with anal incontinence following childbirth [8]. In the UK

and many other countries, there is currently no standardised assessment for women in the postnatal period to identify those who are affected by anal incontinence symptoms. This is despite a number of routine healthcare contacts during this time, including with midwives, general practitioners and health visitors; potentially yielding an opportunity for the condition to be assessed and appropriate access to care provided if indicated. There are a number of patient reported outcome measures and symptom scales available which could potentially be used in this context.

If women with anal incontinence symptoms are identified in a timely fashion after childbirth, there is an opportunity to offer them access to appropriate care. This may include physiotherapy and assessment in a functional bowel clinic under the care of a colorectal team with access to endoanal ultrasound scanning and manometry, followed by appropriate treatment.

The primary aim of this systematic review was to identify non-invasive modalities used to detect women with anal incontinence symptoms following childbirth. Secondary aims were comparison of response rates and prevalence rates of anal incontinence symptoms using the different types of modalities identified. It was anticipated that the non-invasive modalities would include tools such as questionnaires and patient-reported outcome measures, which are increasingly used in clinical practice to identify patients with sensitive and potentially embarrassing symptoms.

Methods

This systematic review of the literature followed the PRISMA guidelines [9] and was designed to capture studies where a population of women had been studied after childbirth and a non-invasive modality or tool was used to identify anal incontinence symptoms. This systematic review was registered prospectively on the PROSPERO database (registration number: CRD42017082508).

The study population was women following childbirth. The intervention studied was any non-invasive modality which enabled the identification of anal incontinence symptoms.

Ovid Medline, AMED, CINAHL, Cochrane library, EMBASE and Web of Science databases were searched using medical subject heading (MeSH) theme 'faecal incontinence' and the keyword 'anal incontinence' (which is not currently a MeSH theme). These were combined using Boolean AND operators with the following MeSH themes: 'prevalence', 'incidence', 'communication', 'decision making', 'surveys and questionnaires', 'access', 'pathway', 'care', 'antenatal', 'postnatal', 'computer/internet' for studies published between January 1966 and May 2018 (inclusive). Studies included were limited to adult female human subjects and were restricted to English language publications. Conference abstracts were excluded. The rationale for restricting to English language was to identify tools suitable for use in the UK population and also because the research team lacked the language skills and resources to translate those papers published in languages other than English.

Only studies that specifically assessed women following childbirth, or studies in which this group was identified separately within the results of the study were included. The following were excluded:

- Studies assessing prevalence in community-based adults
- Studies in which women had already been identified with anal incontinence following childbirth (interventional studies including women with known incontinence after childbirth)
- Studies which used invasive modalities, such as endoanal ultrasound or manometry

The primary outcome was the type of modality used to identify women with anal incontinence after childbirth. Secondary outcomes included response rates to the identified modalities and prevalence rates of anal incontinence reported following childbirth (including rates of incontinence to flatus, liquid stool and solid stool where reported) in order that the prevalence reported for the different types of modalities could be compared.

Two reviewers (TGG and SCR) independently reviewed all the abstracts identified by the literature search to identify papers of potential interest. All papers of potential interest to the review were obtained and read by two reviewers (TGG and HV) to identify those that were relevant. Studies were included only with the agreement of both reviewers following evaluation of full manuscripts. Any disparities were resolved by consensus and, if required, arbitration by a third reviewer (SJ). A manual search of the reference list of each manuscript was also conducted by both reviewers to identify further studies of relevance to the systematic review.

The same two reviewers independently extracted data from the included studies onto an electronic data collection form. These were compared and a summary table of consensus data was compiled. Critical appraisal of study quality was undertaken according to the principles of the STROBE statement for observational studies and Centre for Evidence Based Medicine questionnaires for cross-sectional surveys [10, 11], to assess the data quality of included studies similarly to methods used in previous comparable systematic reviews. Studies were scored out of four for data quality- one point being given for use of representative sampling, one point for response rate greater than 50%, one point for use of a self-administered and robustly validated assessment tool (administered in its original format and language of validation and not altered by the authors of the relevant study) and one point for 95% confidence interval for the estimated prevalence of anal incontinence of no more than 2%. Studies scoring 3+ were deemed to be of high quality.

Differences in the mean prevalence of anal incontinence were compared for the different modalities identified using paired t- test. A *p* value of less than 0.05 was considered statistically significant.

Results

A total of 1602 studies (excluding any duplicates) were identified for screening with 1296 discarded on title and abstract alone. Of the remaining studies, 306 manuscripts were reviewed in full with 109 studies ultimately being included for final analysis (figure 1). A total of 80,935 women were included in this systematic review. In total 33 of the 109 studies scored three or higher for data quality (Supplementary Tables 1, 2 and 3).

Three types of modality were used to identify anal incontinence symptoms in women following childbirth: validated patient-reported outcome measures or symptom scales (i.e. instruments that have undergone an element of psychometric testing) (36 studies- Supplementary Table 1) [2, 12-46], non-validated questionnaires (50 studies- Supplementary Table 2) [47-96] and patient interview, both face to face and telephone (23 studies- Supplementary Table 3) [97-119]. Of the 36 studies using a validated patient-reported outcome measure or symptom scale, 15 different instruments were used (Table 1).

The duration of follow up in the 109 studies varied between 38 days and 34 years. Eleven studies conducted follow-up within six weeks of delivery [12, 47-49, 64-66, 82, 97, 108-109], fifty two conducted follow up after six weeks and up to one year [13-21, 28-33, 40-41, 46, 50-58, 67-72, 83-86, 98-107, 110-115,119], sixteen studies conducted follow up between two and five years [22, 32, 42-45, 59-60, 73, 87-91, 94-95], and twenty six studies conducted follow up at greater than five years [2, 23-27, 33-38,61-63, 74-79, 92-93, 116-118]. Four included studies did not collect data on length of time to follow up after childbirth [39, 80-81, 96].

Seven studies did not report response rates to the modality used to assess anal incontinence symptoms in postnatal women [47, 57, 84, 93, and 99,111,119]. The mean response rate was 84% when follow up was at six weeks or less, 72% when follow up was between six weeks and one year, 70% when follow up was between two and five years and

68% when follow up was at greater than five years. Reported response rates for questionnaires and patient interviews were similar (Supplementary Table 4).

The populations of women in the studies included different characteristics, with four broadly different population types being identified: (1) Forty four studies included only primiparous women following different modes of delivery, including spontaneous vaginal delivery, instrumental delivery and caesarean section [12-27, 47-63, 97-107],) (2). Thirty seven studies included women with mixed parities and mixed modes of delivery [28-39, 64-81, 96, 108-112] (3). Twenty four studies included only women who had been diagnosed with obstetric anal sphincter injury (OASI) [42-45, 82-93, 113-118] (4). Four studies included only women who had undergone instrumental delivery with forceps or ventouse [46,94-95,119].

A variety of different definitions were used for anal incontinence in the studies. Generally, definitions were based on functional bowel symptom criteria or symptom severity scales. The reported rates for overall anal incontinence at different points of follow-up is shown in Table 2. Supplementary Tables 1-3 show anal incontinence prevalence for each study, including different rates for flatus incontinence, incontinence to liquid stool, incontinence to solid stool and overall anal incontinence (as per Sultan et al, 2017[4]) where reported in each study.

Overall reported rates of different types of anal and faecal incontinence varied between study populations and follow-up period. Reported prevalence of anal incontinence was higher when non-personalised assessment tools (questionnaires and patient-reported

outcome measures, both validated and non-validated) were used, compared with patient interview (Table 2). There were statistically significant differences in the prevalence of anal incontinence at follow up between six weeks and one year when validated and non-validated questionnaires were used, compared to patient interview (Table 3 and 4). At all other points of follow-up there was no statistically significant difference in prevalence of anal incontinence identified by the three different non-invasive modalities (Table 3-5).

Discussion

This is an up-to-date systematic review of non-invasive modalities which have been used to identify women with anal incontinence symptoms following childbirth and is the first to specifically assess the tools used for this purpose; identifying fourteen validated instruments that appear to be suitable. The present systematic review has also confirms that the prevalence of anal incontinence symptoms in women following childbirth is high, affecting up to 50% of first-time mothers in the first year after childbirth in studies published in 2014 and 2016 [16,19].

The strengths of this systematic review are the rigorous search strategy employed, which has identified the relevant studies, allowing identification of the non-invasive modalities available which have been used successfully to identify women with anal incontinence after childbirth. The limitations of this systematic review include the heterogeneity in the definitions used to describe anal or faecal incontinence symptoms in the studies included, which is some cases may have underestimated the prevalence of anal incontinence. Disparity in the definition, or lack of definition, of what constitutes obstetric anal sphincter

injury may also have contaminated the results. The use of non-validated questionnaires and patient interviews (supplementary tables 2 and 3) may have also resulted in over or under-reporting of anal incontinence symptoms. The small numbers of studies for the three different non-invasive modalities at various different points of follow-up may have resulted in type 2 statistical errors when comparing prevalence rates using paired *t* test. The use of a search strategy which excluded papers not published in English and the grey literature may have also resulted in missing non-invasive modalities potentially relevant to this systematic review.

Whilst there was a degree of heterogeneity in the definitions used to report anal incontinence in the studies included in this review, these definitions were based on functional bowel symptom criteria or symptom severity scales. Some studies had sought to only assess faecal incontinence (excluding flatus incontinence), potentially underestimating anal incontinence rates, and some had reported as 'faecal incontinence' rates which actually included flatus incontinence. When extracting data from all papers, the current IUGA/ICS definition of anal incontinence [4] was used (supplementary tables 1, 2 and 3). Flatus incontinence is the most common symptom in the spectrum of anal incontinence. Frank faecal incontinence of liquid or solid stool is less common, but has a greater impact on quality of life [120]. However, studies assessing patient preferences for end points in anal incontinence treatment have indicated that flatus incontinence, faecal frequency and faecal urgency are among the most bothersome symptoms, having a significant impact on quality of life [121] and are therefore it is important to include and assess for flatus incontinence in addition to faecal incontinence.

A number of studies (n=31) in this systematic review were published before Sultan's classification system for obstetric anal sphincter injury (OASI) was published and became well established in clinical practice [122]. The populations identified in this systematic review include studies which may contain a larger number of patients with either unrecognised or inadequately repaired third or fourth degree perineal tears, resulting in a higher rate of anal incontinence symptoms than would be expected with current practices. However, the reported rates of third and fourth degree perineal tears (obstetric anal sphincter injury) have actually risen in the last ten years [123,124]. This has previously been attributed in part to increased detection and reporting of third and fourth degree tears, however, this is also now considered to be due to inconsistencies in preventing OASI in different units, inconsistencies in midwifery and obstetric training and skills, lack of awareness of risk factors and the long-term impact of OASI and variations in practice between midwives and obstetricians [124]. Measures to help reverse this trend are being put in place with a current trial of a national care bundle devised by the Royal College of Obstetricians and Gynaecologists (UK) and supported by the Royal College of Midwives (UK) [125], which makes use of the increasing evidence for specific manual perineal protection maneuvers [126]. It is clear that women are currently at risk of anal incontinence following childbirth and there is currently a lack of interventions to identify such affected women following childbirth and help them to access care and treatment.

The type of modality used (validated questionnaire/symptom scale, non-validated questionnaire and patient interview) was shown to be a significant factor in the reported prevalence of anal incontinence symptoms in studies included in this systematic review

(Table 2). Lower rates of anal incontinence symptoms were observed when personalised data collection methods (face to face interview or telephone interview) were used, compared with non-personalised self-completed questionnaires (both validated and non-validated)(Tables 2-5). This was demonstrated at both short and long-term periods of follow up (Table 2) and was statistically significant at the six weeks to one year follow-up period (Tables 3 and 4). This finding mirrors those of systematic reviews of the prevalence of faecal incontinence [1] where reporting of faecal incontinence symptoms was found to be lower when face-to-face and telephone interviews were used to assess these embarrassing symptoms, when compared to self-completed questionnaires. Differences in the prevalence rates of anal incontinence between the different modalities did not reach statistical significance at the other points of follow up. This may be due to a type two statistical error due to the small sample sizes for these periods of follow up, compared to the six week-one year follow up period where the sample sizes were large enough to demonstrate a statistically significant effect.

It has previously been shown that using non-personalised methods (self-completed questionnaires), which may be perceived as less intimidating, results in increased rates of disclosure for urinary incontinence compared to patient interview [127, 128]. We would anticipate that this would also be the case for reporting of anal incontinence symptoms.

Two of the main barriers to accessing care for faecal incontinence in a recently published, well-designed qualitative study were embarrassment and stigma which were manifested as deeply felt shame in violating a social taboo to not talk about bowel symptoms [7]. This is

often compounded by normative thinking, with patients feeling that faecal incontinence may be a normal symptom following childbirth and a lack of knowledge about the condition and fear of investigation or treatment. Therefore, many women living with anal incontinence symptoms after childbirth may not seek healthcare. This is despite a number of healthcare contacts during the post-natal period, such as routine postnatal follow up, infant vaccinations and development assessments; which lead to interactions with healthcare professionals including midwives, health visitors and general practitioners. These contacts present a number of opportunities where a self-completed questionnaire could be administered routinely to identify women with anal incontinence symptoms; potentially enabling access to care for affected women. The relatively high response rates to the modalities evaluated in this systematic review (Table 1) suggest that using an appropriate questionnaire to assess pelvic floor symptoms, including anal incontinence in the first year after childbirth would result in good response rates in clinical practice.

The fifteen validated patient-reported outcome measures/symptom scales identified by this systematic review have all undergone psychometric testing in populations of women with anal incontinence. The comparison of psychometric properties of these instruments is outside the scope of this systematic review. Fourteen of these tools would appear to be suitable for identifying anal incontinence symptoms following childbirth. The Faecal Incontinence Quality of Life (FIQoL) questionnaire [129] is used to assess health related quality of life in patients previously identified as having faecal incontinence, rather than as a means to identify those with the symptom and is therefore not suitable for

administration to women following childbirth, unless they are known to have anal incontinence.

The Jorge and Wexner score [5], Vaizey incontinence score [130], Colorectal Anal Distress Inventory [131], Danish Anal Sphincter Rupture Questionnaire [132], St Mark's Score [133], Park's score [134], Bowel Symptom questionnaire[135],Fecal Incontinence questionnaire [136] , Anal Incontinence score [137] and Manchester Health Questionnaire [138](now modified Manchester Health questionnaire [139]) are all paper-based instruments which assess anal incontinence and bowel symptoms.

The Australian Pelvic Floor Questionnaire [140], Epidemiology of Prolapse and Incontinence Questionnaire [141] and the Personal Assessment Questionnaire (PAQ) [142] are comprehensive pelvic-floor questionnaires which are also paper-based, assessing prolapse, vaginal symptoms and urinary incontinence in addition to anal incontinence symptoms. The Personal Assessment Questionnaire (PAQ) [142] has subsequently been further validated in an electronic format (ePAQ) [143].

The validated questionnaires in this systematic review were administered to populations including ten different languages (Supplementary Table 1). All of the identified instruments had been previously validated in the language in which they were used for in this study. The majority of the symptom scales and validated questionnaires identified in this systematic review have also been validated in translated forms into multiple languages (Table 1).

When using patient reported outcome measures including questionnaires and symptom scales, it is important to use instruments that are psychometrically robust with evidence of their validity, reliability and functionality. This reduces bias and ensures the validity of results. Studies which use questionnaires that have not been validated for use in the population of interest may potentially be subject to measurement error and lack ability to measure changes in health status accurately [144]. Therefore, any conclusions drawn cannot be made with confidence. Where a validated instrument is available, it should be used in preference to a non-validated instrument.

In conclusion, this systematic review has identified three types of non-invasive modality which can be used to identify women with anal incontinence following childbirth. The key clinical message is that using non-personalised assessment methods (validated and non-validated questionnaires/symptom scales) is likely to be more effective than patient interview when assessing intimate and embarrassing symptoms such as anal incontinence; which is a prevalent symptom following childbirth, with a significant potential for impact on health related quality of life. Therefore, the role of a national standard assessment for all women following childbirth using validated questionnaires to assess for pelvic floor symptoms, including anal incontinence, should be considered. Validated questionnaires and symptoms scales should be used in preference to non-validated tools owing to the methodological limitations of using non-validated instruments. Further psychometric validation of the validated measures identified in this systematic review is required, in populations of postnatal women, before recommending their use as part of routine clinical practice in this context. The value and cost of using

appropriate validated tools to identify affected women, and subsequently providing access to care and support, also warrants further research.

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Tables and figures, including legends

Figure 1: PRISMA diagram showing selection of articles for review.

Supplementary Table 1: Summary of results for studies using validated patient reported outcome measures or symptom scales to identify anal incontinence after childbirth, including the language in which each study was undertaken.

Supplementary Table 2: Summary of results for studies using non-validated questionnaires to identify anal incontinence after childbirth.

Supplementary Table 3: Summary of results for studies using patient interviews to identify faecal incontinence after childbirth.

Table 1: List of validated patient reported outcome measures or symptom scales identified in this systematic review, including other languages of validation these measures are available in

Supplementary Table 4: Response rates for different follow up periods.

Table 2: Comparison of faecal incontinence type and response rates for non-personalised (PROM/questionnaire) and personalised (interview) modalities at different times of follow up.

Table 3: Comparison of mean prevalence rates reported for anal incontinence using validated questionnaires/symptom scales or patient interview

Table 4: Comparison of mean prevalence rates reported for anal incontinence using non-validated questionnaires/symptom scales or patient interview

Table 5: Comparison of mean prevalence rates reported for anal incontinence using validated questionnaires/symptom scales or non-validated questionnaires

Table 1: List of validated patient reported outcome measures or symptom scales identified in this systematic review, including other languages of validation these measures are available in

Validated patient reported outcome measure/symptom scale used	Validation paper reference	Format of PROM/Symptom scale	Number of studies using PROM/scale in present systematic review	Original language of validation	Subsequent Language(s) of validation
Jorge and Wexner score	Jorge and Wexner, 1993	Paper-based	17	English	Swedish, Danish, French, German, Spanish, Italian, Dutch, Turkish
Anal incontinence score	Pescatori et al, 1992	Paper-based	5	Italian	English, French, Norwegian
Colorectal Anal Distress Inventory (CRADI)	Barber et al, 2001	Paper-based	2	English	Finnish, Korean, Greek, Brazilian Portuguese, Spanish, Hebrew, Turkish, Chinese
Epidemiology of prolapse and incontinence questionnaire (EPIQ)	Lukacz et al, 2005	Paper-based	2	English	Spanish
Fecal incontinence questionnaire	Reilly et al, 2000	Paper-based	1	English	-
Australian Pelvic floor symptom questionnaire	Baesssler et al, 2009	Paper-based	1	English	Serbian, French, German
Bowel symptom questionnaire (BSQ)	Talley et al, 1995	Paper-based	1	English	-
St Marks Score	Maeda at el, 2007	Paper-based	1	English	Norwegian, French, German, Spanish, Italian, Dutch, Turkish
Vaizey incontinence score	Vaizey et al, 1999	Paper-based	1	English	French, German, Spanish, Italian, Dutch, Norwegian, Turkish
Park's score	Browning and Parks, 1983	Paper-based	1	English	Dutch
Personal Assessment Questionnaire (PAQ, now revised to ePAQ-Pelvic Floor)	Hiller et al, 2002 Radley et al, 2006	Electronic	1	English	Italian
Manchester Health Questionnaire	Bugg et al, 2001	Paper-based	1	English	-
Modified Manchester Health Questionnaire	Kwon et al, 2005	Paper-based	1	English	-

Danish Anal Sphincter Rupture Questionnaire (DASRQ)	Due and Ottensen, 2009	Paper-based	1	Danish	-
Faecal incontinence quality of life survey (FIQoL)	Rockwood et al, 2000	Paper-based	1	English	Spanish, Japanese, French, Turkish, Norwegian, German

Table 2

Modality used	**Number of studies**	**Response rate (mean±2SD)**	**Overall anal incontinence (mean±2SD)**
Studies with follow up at 6/52 or less after childbirth			
Validated questionnaire/PROM	1	**100%**	**21%**
Non-validated questionnaire	7	**92%±0.2%**	**22%±0.2%**
Patient interview (telephone/face to face)	3	**66%±0.4%**	**16%±0.1%**
Studies with follow up after 6/52 up to 1 year after childbirth			
Validated questionnaire/PROM	16	**65%±0.4%**	**27%±0.3%**
Non-validated questionnaire	18	**76% 0.3%**	**21% 0.4%**
Patient interview (telephone/face to face)	17	**74%±0.2%**	**12%±0.2%**
Studies with follow up between 2-5 years after childbirth			
Validated questionnaire/PROM	6	**66%0.5%**	**33%±0.2%**
Non-validated questionnaire	10	**74%±0.2%**	**38%±0.3%**
Patient interview (telephone/face to face)	0	**No Data**	**No Data**
Studies with follow up at greater than 5 years after childbirth			
Validated questionnaire/PROM	12	**62%±0.3%**	**26%±0.3%**
Non-validated questionnaire	11	**68%±0.3%**	**31%±0.4%**
Patient interview (telephone/face to face)	3	**91%±0.1%**	**22%±0.1%**

Table 3: Comparison of mean prevalence rates reported for anal incontinence using validated questionnaires/symptom scales or patient interview

Follow up Period after childbirth	Validated questionnaire (Mean prevalence of anal incontinence±2SD)	Patient interview (Mean prevalence of anal incontinence±2SD)	T value	P value	95% Confidence interval
6 weeks or less	21% (1 study)	16%±0.1% (3 studies)	1.0	0.500	-64.38 to 75.38
6/52 to 1 year	27%±0.3% (16 studies)	12%±0.2% (17 studies)	3.700	0.0021*	6.04 to 22.46
2-5 years	33%±0.2% (6 studies)	No data	-	-	-
>5 years	26%±0.3% (12 studies)	22%±0.1% (3 studies)	1.162	0.365	-30.57 to 17.57

Table 4: Comparison of mean prevalence rates reported for anal incontinence using non-validated questionnaires/symptom scales or patient interview

Follow up Period after childbirth	Non-validated questionnaire (Mean prevalence of anal incontinence±2SD)	Patient interview (Mean prevalence of anal incontinence±2SD)	T value	P value	95% Confidence interval
6 weeks or less	22%±0.2% (7 studies)	16%±0.1% (3 studies)	1.672	0.236	-8.07 to 18.34
6/52 to 1 year	21% 0.4% (18 studies)	12%±0.2% (17 studies)	2.391	0.029*	1.123 to 18.67
2-5 years	38%±0.3% (10 studies)	No data	-	-	-
>5 years	31%±0.4% (11 studies)	22%±0.1% (3 studies)	1.311	0.320	-15.74 to 29.54

Table 5: Comparison of mean prevalence rates reported for anal incontinence using validated questionnaires/symptom scales or non-validated questionnaires

Follow up Period after childbirth	Validated questionnaire (Mean prevalence of anal incontinence±2SD)	Non-validated Questionnaire (Mean prevalence of anal incontinence±2SD)	T value	P value	95% Confidence interval
6 weeks or less	21% (1 study)	22%±0.2% (7 studies)	2.011	0.295	-10.71to 14.71
6/52 to 1 year	27%±0.3% (17 Studies)	21% 0.4% (18 studies)	0.901	0.382	-7.41 to 18.23
2-5 years	33%±0.2% (6 studies)	38%±0.3% (10 studies)	1.571	0.178	-24.70 to 6.00
>5 years	26%±0.3% (12 studies)	31%±0.4% (11 studies)	0.621	0.552	-29.90 to 17.20

PRISMA Flow Diagram

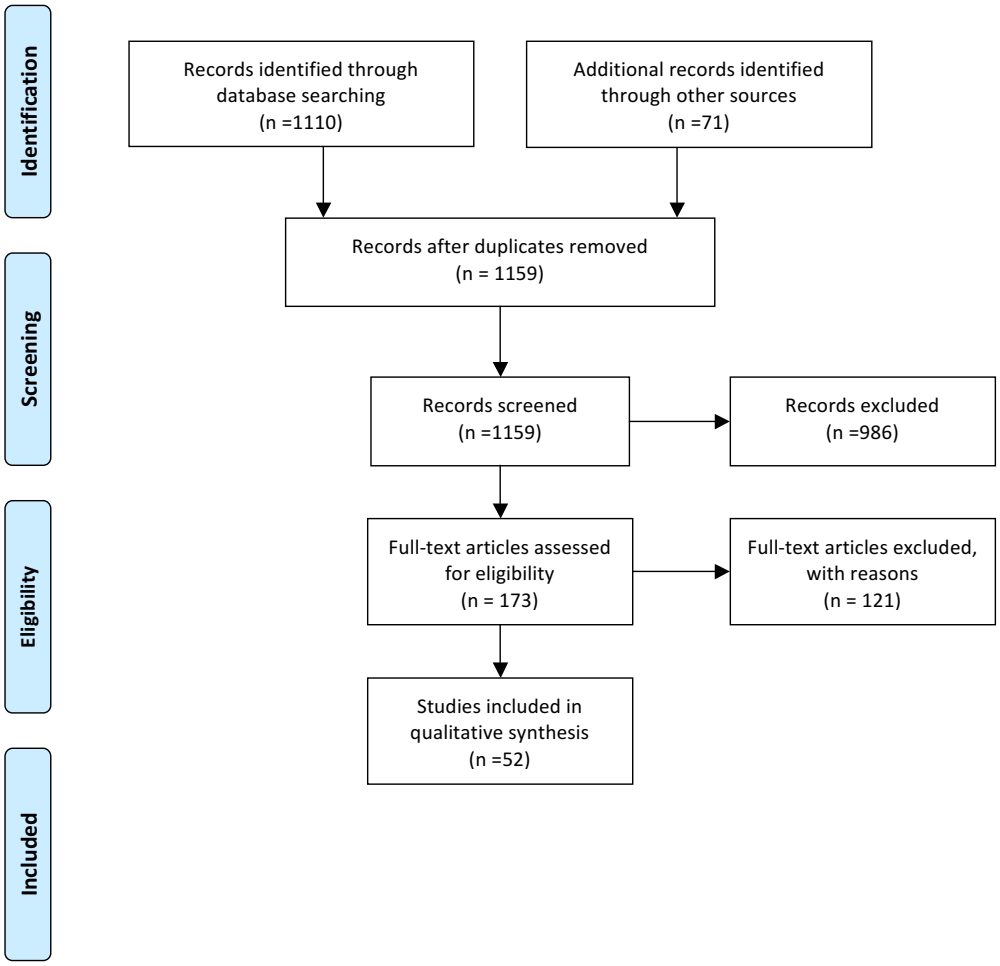

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Table 1

Type of modality: Validated patient reported outcome measures

Study	Study quality	Patient group	Participants	Follow-up	Modality	Language of questionnaire used in study	Response rate to modality	Flatus incontinence	Faecal incontinence (liquid stool)	Faecal incontinence (solid stool)	Overall anal incontinence i study (Sultan 2017)
	Primiparous women (all modes of delivery)										
	Follow up 6/52 or less										
Fynes et al, 1998	4	Primiparous women (all modes of delivery)	200	6 weeks	Anal incontinence score	English	100%	11.5%	Not reported	1.5%	21%
	Follow up >6/52 to 1 year										
Solans-Domènech et al, 2010	3	Primiparous women (all modes of delivery)	876	7 weeks	Jorge and Wexner Score	Spanish	88.2%	Not reported separately	Not reported separately	Not reported separately	7.3%
Frudinger et al, 2003	3	Primiparous women (all modes of delivery)	156	3 months	Jorge and Wexner questionnaire	English	95%	Not reported	Not reported	Not reported	27.6%
Donnelly et al, 1998	3	Primiparous women (all modes of delivery)	168	6 months	Anal incontinence score	English	76%	13%	Not reported	4%	13%
Rogers et al, 2014	3	Primiparous women (all modes of delivery)	474	6 months	Jorge and Wexner score	English	71%	Not reported separately	Not reported separately	9.4%	50.4%
Hatem et al, 2007	3	Primiparous women (all modes of delivery)	1355	6 months	Vaizey incontinence score	English	55%	Not reported	Not reported	Not reported	10.2%
Leeman et al, 2016	3	Primiparous women (all modes of delivery)	335	6 months	Jorge and Wexner questionnaire	English	74%	Not reported separately	Not reported separately	Not reported separately	49.7%
Johannessen et al, 2014	3	Primiparous women (all modes of delivery)	1030	1 year	St Mark's score	Norwegian	66%	5.8%	8.9%	4.5%	19%
Chan et al, 2013	3	Primiparous women (all modes of delivery)	328	1 year	CRADI	Chinese	74.2%	18.3%	4%	0.3%	18%
Durnea et al, 2014	3	Primiparous women (all modes of delivery)	872	1 year	Australian Pelvic floor questionnaire	English	72%	44.8%	7.2%	1.9%	44.8%
	Follow up 2-5 years										
Gartland et al, 2016	3	Primiparous women (all modes of delivery)	1102	4 years	Bowel Symptom Questionnaire (BSQ)	English	82%	43.4%	Not reported separately	1.5%	43.3%
	Follow up > 5 years										
Damon et al, 2005	3	Primiparous women (all modes of delivery)	74	6 years	Jorge and Wexner questionnaire	French	73%	13.5%	Not reported separately	Not reported separately	14.8%

Evers et al, 2012	2	Primiparous women (all modes of delivery)	937	7.5 years	Epidemiology of prolapse and incontinence questionnaire (EPIQ)	English	41%	19.3%	8.3%	1%	19.3%
Dolan et al, 2010	4	Primiparous women (all modes of delivery)	1861	20 years	Personal Assessment Questionnaire (PAQ)	English	62%	Not reported	Not reported	Not reported	11%
Nilsson et al, 2016	3	Primiparous women (all modes of delivery)	4203	21.5 years	Jorge and Wexner questionnaire	Swedish	65.2%	Not reported separately	Not reported separately	13.7%	13.7%
Gyhagen et al, 2013	4	Primiparous women (all modes of delivery)	5118	22 years	Jorge and Wexner Questionnaire	Swedish	65.2%	47%	8.9%	4.7%	47%
	Postnatal women (all parities and modes of delivery)										
	Follow up 6/52 to 1 year										
Soligo et al, 2016	3	Postnatal women (all parities and modes of delivery)	685	3 months	Jorge and Wexner questionnaire	Italian	53%	Not reported	Not reported	Not reported	10.4%
Torrisi et al, 2012	3	Postnatal women (all parities and modes of delivery)	744	3 months	Jorge and Wexner questionnaire	Italian	70.9%	12%	3.2%	1.1%	16.3%
Pinta et al, 2004	2	Postnatal women (all parities and modes of delivery)	99	4 months	Jorge and Wexner score	Finnish	10%	26.2%	3%	3%	26.2%
Guise et al, 2007	2	Postnatal women (all parities and modes of delivery)	8774	6 months	Fecal incontinence survey	English	40%	26.5%	9.4%	8.3%	29.2%
	Follow up 2-5 years										
Wagenius et al, 2003	3	Postnatal women (all parities and modes of delivery)	534	4 years	Anal incontinence score	Swedish	82%	21.3%	12.7%	3%	21.3%
	Follow up > 5 years										
Mous et al, 2008	3	Postnatal women (all parities and modes of delivery)	209	5 years	Park's classification	Dutch	84%	27%	5.7%	5.2%	27%
Baud et al, 2011	2	Postnatal women (all parities and modes of delivery)	258	6 years	Jorge and Wexner Score	French	36%	39.9%	12%	3.9%	39.9%
Handa et al, 2011	2	Postnatal women (all parities and modes of delivery)	1011	7.5 years	Epidemiology of prolapse and incontinence questionnaire (EPIQ)	English	48.2%	Not reported separately	Not reported separately	Not reported separately	11%
Altman et al, 2007	3	Postnatal women (all parities and modes of delivery)	395	10 years	Jorge and Wexner	Swedish	69%	27.6%	5.3%	1%	27.6%
Samarasekera et al, 2008	4	Postnatal women (all parities and modes of delivery)	175	14 years (mean)	Jorge and Wexner questionnaire Faecal incontinence quality of life scale (FIQoL)	English	60.9%	26%	15.4%	12%	26%
Faltin DL et al, 2006	3	Postnatal women (all parities and modes of delivery)	540	18 years	Jorge and Wexner score	French	77%	41%	7.6%	1.6%	41%
Soerensen et al, 2013.	3	Postnatal women (all parities and modes of delivery)	363	22.2 years	Jorge and Wexner Questionnaire	Danish	62.9%	21.1%	10.7%	2.5%	35%

	Variable follow up										
Fritel et al, 2007	3	Postnatal women (all parities and modes of delivery)	2640	Variable, not reported	Anal incontinence score	French	85%	28.6%	Not reported separately	9.5%	28.6%
	Postnatal women with obstetric anal sphincter injury										
	Follow up > 6/52 to 1 year										
Vaccaro et al, 2008	3	Postnatal women with obstetric anal sphincter injury	47	12 weeks	Jorge and Wexner score	English	60%	38%	11%	4%	43%
Andrews et al, 2009	3	Postnatal women with obstetric anal sphincter injury	43	1 year	Manchester Health Questionnaire	English	73%	5%	Not reported	Not reported	5%
	Follow up 2-5 years										
Norderval et al, 2004	3	Postnatal women with obstetric anal sphincter injury	150	2 years	Anal incontinence score	Norwegian	87%	35.3%	15.3%	8%	35.3%
Richter et al, 2015	2	Postnatal women with obstetric anal sphincter injury	138	2 years	Modified Manchester Health questionnaire	English	40.2%	19%	16%	13%	24%
Tin et al, 2010	2	Postnatal women with obstetric anal sphincter injury	325	2-5 years	Colorectal Anal Distress Inventory (CRADI)	English	25%	38.2%	19.7%	7.7%	38.2%
Jangö et al, 2016	3	Postnatal women with obstetric anal sphincter injury	1987	5 years	Danish anal sphincter rupture questionnaire	Danish	77%	22%	10.5%	2.9%	36.6%
	Postnatal women after instrumental delivery										
Fitzpatrick et al, 2003	4	Postnatal women after instrumental delivery	130	12 weeks	Jorge and Wexner questionnaire	English	55%	Not reported	Not reported	Not reported	45%

Table 2

Type of modality: Non-validated questionnaires

Study	Study quality	Patient group	Participants	Follow-up	Modality	Response rate in study	Flatus incontinence	Faecal incontinence (liquid stool)	Faecal incontinence (solid stool)	Anal incontinence (Sultan et al, 2017)
Primiparous women (all modes of delivery)										
Follow up to 6/52 or less										
Rieger et al, 1998	1	Primiparous women (all modes of delivery)	50	38 days (median), range 20-65 days	Self-administered questionnaire (author's own)	Non-reported	6%	Not reported	Not reported	20%
Zetterström et al, 1999	2	Primiparous women (all modes of delivery)	38	6 weeks	Self-administered questionnaire (authors own)	100%	18.4%	10.5%	2.6%	18.4%
Donnelly et al, 1998	3	Primiparous women (all modes of delivery)	312	6 weeks	Self-administered questionnaire (authors own)	100%	15.4%	Not reported	10.2%	24%
Follow up > 6/52 to 1 year										
Faltin et al, 2001	2	Primiparous women (all modes of delivery)	92	3 months	Self-administered questionnaire (authors own)	92%	17%	Not reported	3%	17%
Chaliha et al, 2001	3	Primiparous women (all modes of delivery)	161	3 months	Self-administered questionnaire (authors own)	56%	12.4%	1.8%	0.6%	12.4%
Faltin et al, 2000	2	Primiparous women (all modes of delivery)	144	4.5 months	Self-administered questionnaire (authors own)	96%	13.8%	4.1%	4.1%	15%
Hatem et al, 2007	2	Primiparous woman (all modes of delivery)	1291	6 months	Self-administered questionnaire (author's own)	52%	Not reported	Not reported	Not reported	20.6%
Fenner et al, 2003	1	Primiparous women (all modes of delivery)	831	6 months	Self-administered questionnaire (authors own)	29%	Not reported	Not reported	Not reported	21.7%
Zetterstrom et al, 1999	2	Primiparous women (all modes of delivery)	278	9 months	Self-administered questionnaire (authors own)	80%	26%	Not reported	Not reported	26%
Van Brummen et al, 2006	2	Primiparous women (all modes of delivery)	407	1 year	Self-administered questionnaire-authors own	93%	30.5%	Not reported separately	Not reported separately	30.5%
Svare et al, 2016	2	Primiparous women (all modes of delivery)	617	1 year	Self-administered questionnaire-authors own	85%	48%	18%	5%	48%
Follow up 2-5 years										
Koops et al, 2003	2	Primiparous women (all modes of delivery)	430	3-4 years	Self administered questionnaire (authors own)	70%	27.4%	18.8%	10.2%	27.4%
Pollack et al, 2004	2	Primiparous women (all modes of delivery)	242	5 years	Self-administered questionnaire-authors own	69%	34.2%	Not reported separately	4.9%	35.5%
Follow up > 5 years										
Nordenstam et al, 2009	2	Primiparous women (all modes of delivery)	231	10 years	Self-administered questionnaire-authors own	81%	31%	Not reported separately	5.6%	46%
Gyhagen et al, 2015	2	Primiparous women (all modes of delivery)	5236	20 years	Self-administered questionnaire-authors own	65.2%	Not reported	Not reported	Not reported	13.3%
Halle et al, 2016	2	Primiparous women (all modes of delivery)	1122	15-23 years	Self-administered questionnaire-authors own	52.8%	26%	8.6%	1.6%	26%
Postnatal women (all parities and modes of delivery)										
Follow up to 6/52 or less										
Rajeshkannan at al, 2013	2	Postnatal women (all parities and	540	6 weeks	Self-administered	95.2%	Not reported separately	Not reported separately	Not reported separately	16.5%

		modes of delivery)			questionnaire-authors own					
Hall et al, 2003	2	Postnatal women (all parities and modes of delivery)	50	6 weeks	Self-administered questionnaire (authors own)	96%	24%	Not reported	10%	24%
Abramowitz et al, 2000	3	Postnatal women (all parities and modes of delivery)	233	6-8 weeks	Self-administered questionnaire (authors own)	90%	10.4%	1.4%	1.8%	10.4%
Follow up > 6/52 to 1 year										
Hannah et al, 2002	2	Postnatal women (all parities and modes of delivery)	1596	3 months	Self-administered questionnaire (authors- own)	82%	7.8%	Not reported	0.9%	7.8%
Haadem et al, 1990	2	Postnatal women (all parities and modes of delivery)	36	3 months	Self-administered questionnaire (authors own)	!00%	25%	Not reported	2.7%	25%
MacArthur et al, 2001	2	Postnatal women (all parities and modes of delivery)	7879	3 months	Self-administered questionnaire (author's own)	71.7%	45.3%	Not reported	9.6%	45.3%
Eason et al, 2002	2	Postnatal women (all parities and modes of delivery)	948	3 months	Self-administered questionnaire-authors own	79%	25.5%	Not reported	3.1%	25.5%
Obioha et al, 2015	2	Postnatal women (all parities and modes of delivery)	230	3 months	Self-administered questionnaire-authors own	92%	10.4%	Not reported separately	3%	13.5%
Glazener et al, 1995	2	Postnatal women (all parities and modes of delivery)	438	1 year	Self-administered questionnaire (author's own)-faecal incontinence not asked about specifically	86%	Not reported	Not reported	Not reported	0.2%
Follow up 2-5 years										
Palm et al, 2013	2	Postnatal women (all parities and modes of delivery)	417	5 years	Self-administered questionnaire-authors own	69.2%	59%	18.4%	6%	59%
Follow up > 5 years										
Ryhammer et al, 1995.	2	Postnatal women (all parities and modes of delivery)	242	Eight years	Self-administered questionnaire (author's own)	80%	4.95%	Not reported	0.8%	4.95%
Fornell et al, 2005	2	Postnatal women (all parities and modes of delivery)	59	10 years	Self-administered questionnaire (authors own)	71%	13%	14.6%	21.9%	13%
Glazener et al, 2014	2	Postnatal women (all parities and modes of delivery)	471	12.7 years (mean)	Self-administered questionnaire (authors own)	63%	Not reported	Not reported	Not reported	16.5%
MacArthur et al, 2011	1	Postnatal women (all parities and modes of delivery)	3763	12 years	Self-administered questionnaire (authors own)	49%	Not reported	Not reported	Not reported	12.9%
Nygaard et al, 1997	2	Postnatal women (all parities and modes of delivery)	151	30 years	Self-administered questionnaire (author's own)	67%	68%	Not reported	41%	68%
Bollard et al, 2003	2	Postnatal women (all parities and modes of delivery)	92	34 years	Self-administered questionnaire-authors own	64%	31%	6%	4.4%	64%
Variable follow up										
McKinnie et al, 2005	2	Postnatal women (all parities and modes of delivery)	978	Variable	Self-administered questionnaire-authors own	97.4%	Not reported separately	Not reported separately	Not reported separately	13%
Goldberg et al, 2003	2	Postnatal women (all parities and modes of delivery) All had multiple pregnancy	733	Variable	Self-administered questionnaire-authors own	95.3%	25.2%	5.9%	1.6%	25.2%
Kunduru et al, 2015	2	Postnatal women (all parities and modes of delivery)	1373	N/A	Self-administered questionnaire-authors own	100%	Not reported	Not reported	Not reported	14.2%
Postnatal women with obstetric anal sphincter injury										
Follow up 6/52 or less										
Sultan, Kamm, Hudson, Bartram,1994	2	Postnatal women with obstetric anal sphincter injury	34	49 days (median) Range 42-651 days	Self-administered questionnaire (authors own)	68%	41%	8.8%	Not reported	41%
Follow up > 6/52 to 1 year										
Haadem et al, 1988	2	Postnatal women with obstetric	59	3 months	Self-administered	54%	28%	Not reported	Not reported	15%

		anal sphincter injury			questionnaire (authors own)					
Chaliha et al, 1999	1	Postnatal women with obstetric anal sphincter injury	549	3 months	Self-administered questionnaire (authors own)	Not reported	4.9%	0.5%	0.4%	5%
Uustal Fornell et al, 1996	2	Postnatal women with obstetric anal sphincter injury	51	6 months	Self-administered questionnaire (authors own)	94%	24%	16%	0%	40%
Mazouni et al, 2005	2	Postnatal women after instrumental delivery	159	1 year	Self-administered Questionnaire (author's own)	75%	7.5%	Not reported	Not reported	8.8%
Follow up 2-5 years										
Tetzschner et al, 1997	2	Postnatal women with obstetric anal sphincter injury	72	2-4 years	Self-administered questionnaire (authors own)	77%	25%	Not reported	17%	25%
Haadem et al, 1987	2	Postnatal women with obstetric anal sphincter injury	59	3.4 years	Self-administered questionnaire (author's own)	95%	25.4%	Not reported	6.7%	50.9%
Gjessing et al , 1998	2	Postnatal women with obstetric anal sphincter injury	35	3.5 years	Self-administered questionnaire-authors own	75%	34%	11.4%	11.4%	57%
Kumar, 2012	2	Postnatal women with obstetric anal sphincter injury	41	4-6 years	Self-administered questionnaire (authors own)	60%	26%	19.5%	4.9%	37%
Poen et al, 1998	2	Postnatal women with obstetric anal sphincter injury	117	5 years	Self-administered questionnaire (author's own)	75%	19.6%	5.1%	7%	40%
Follow up > 5 years										
Sørensen et al, 1988	2	Postnatal women with obstetric anal sphincter injury	24	6.5 years	Self-administered questionnaire (author's own)	96%	25%	13%	4%	42%
de Leeuw et al, 2002	1	Postnatal women with obstetric anal sphincter injury	34	19 years	Self-administered questionnaire-authors own	Not reported	35%	21%	24%	35%
Postnatal women following instrumental delivery										
Sultan et al, 1998	2	Postnatal women following instrumental delivery	44	5 years	Self-administered questionnaire (authors own)	73.8%	22.7%	11.3%	3.6%	22.7%
Johanson et al, 1999	2	Postnatal women following instrumental delivery	228	5 years	Self-administered questionnaire-form another author	74.5%	12.2%	4.4%	3%	20.2%

Table 3

Type of modality: Patient interviews

Study	Study quality	Patient group	Participants	Follow-up	Modality	Response rate to modality	Flatus incontinence	Faecal incontinence (liquid stool)	Faecal incontinence (solid stool)	Anal incontinence (Sultan et al, 2017)
Primiparous women (all modes of delivery)										
Follow up 6/52 or less										
Belmonte-Montes C et al, 2001	1	Primiparous women (all modes of delivery)	98	6 weeks	Patient interview	42%				21%
Follow up >6/52 to 1 year										
Meyer et al, 1998	2	Primiparous women (all modes of delivery)	149	9-11 weeks	Patient interview	80%	Not reported	Not reported	Not reported	5%
Groutz et al, 1999	2	Primiparous women (all modes of delivery)	300	3 months	Patient interview	Not reported	6.3%	Not reported	0.7%	7%
Farrell et al, 2001	2	Primiparous women (all modes of delivery)	315	6 months	Patient interview	45.7%	22.2%	Not reported separately	Not reported separately	22%
Borello-France D et al, 2006	2	Primiparous women (all modes of delivery)	759	6 months	Telephone interview	82%	21.2%	8.3%	4.7%	21.2%
Yang et al, 2010	2	Primiparous women (all modes of delivery)	1889	6 months	Telephone interview	77%	0.32%	0.11%	0.05%	0.69%
Jelovsek et al, 2013	2	Primiparous women (all modes of delivery)	759	6 months	Patient interview (telephone)	82%	Not reported	Not reported	Not reported	12%
Crawford et al, 1993	2	Primiparous women (all modes of delivery)	70	9-12 months	Patient interview (telephone)	37%	10%	3%	1.5%	10%
Lal et al, 2003	2	Primiparous women (all modes of delivery)	284	1 year	Patient interview (telephone)	85%	3%	Not reported	3.7%	3.7%
Brincat et al, 2009	2	Primiparous women (all modes of delivery)	151	1 year	Patient interview (telephone)	63%	Not reported separately	Not reported separately	Not reported separately	5.3%
Lipschuetz et al, 2015	2	Primiparous women (all modes of delivery)	198	1 year	Patient interview (telephone)	94%	Not reported separately	Not reported separately	Not reported separately	10.1%
Postnatal women (all parities and modes of delivery)										
Follow up 6/52 or less										
Sultan, Kamm, Hudson et al, 1993	2	Postnatal women (all parities and modes of delivery)	150	49 days postnatal (median) Range 35-105 days.	Patient interview	74%	Not reported	Not reported	Not reported	10%
Sultan et al, 1994	2	Postnatal women (all parities and modes of delivery)	105	6 weeks	Patient interview	82%	Not reported	Not reported	Not reported	16%
Follow up >6/52 to 1 year										
Tetzschner, Sørensen,Jønsson, Lose and Christiansen, 1997	2	Postnatal women (all parities and modes of delivery)	146	3 months	Patient interview	72%	2%	1%	Not reported	3%

Baydock et al, 2009	2	Postnatal women (all parities and modes of delivery)	632	4 months	Patient interview (telephone)	Not reported	Not reported separately	Not reported separately	Not reported separately	4%
MacArthur et al, 1997	2	Postnatal women (all parities and modes of delivery)	906	10 months	Patient interview	80%	Not reported	Not reported	Not reported	1.4%
Postnatal women with obstetric anal sphincter injury										
Follow up >6/52- 1 year										
Sørensen et al, 1993	2	Postnatal women with obstetric anal sphincter injury	38	3 months	Patient interview	100%	Not reported	Not reported	Not reported	23.7%
Walsh CJ, 1996	2	Postnatal women with obstetric anal sphincter injury	81	3 months	Patient interview	87%	12%	Not reported	7.4%	20%
Laine et al, 2011	2	Postnatal women with obstetric anal sphincter injury	455	10 months	Patient interview	77%	33%	Not reported separately	6%	38%
Follow up > 5 years										
Sze EH, et al, 2005 (A)	2	Postnatal women with with obstetric anal sphincter injury	148	5-10 years	Patient interview (telephone)	98%	Not reported separately	Not reported separately	Not reported separately	29.7%
Sangalli et al, 2000	3	Postnatal women with with obstetric anal sphincter injury	177	13 years	Patient interview (telephone)	86%	5.6%	7.3%	2.3%	15.2%
Size EH, 2005 (B)	2	Postnatal women with with obstetric anal sphincter injury	172	Variable 2.5-14 years	Patient interview (telephone)	90%	Not reported	Not reported	Not reported	19.7%
Postnatal women following instrumental delivery										
Sultan, Kamm, Bartram et al, 1993	1	Primiparous women undergoing instrumental delivery	43	5.3 months	Patient interview	Not reported	Not reported	Not reported	Not reported	20.9%

Supplementary Table 4

Follow up period	Number of studies in review reporting follow-up period	Total number of patients in studies reporting follow-up period	Median response rate	Mean response rate ± 2SD
Validated questionnaire/symptom scale (validated patient reported outcome measures)				
6 weeks or less	1	200	100%	100%
>6 weeks to 1 year	17	17473	71%	64.5%±0.4
2-5 years	6	4236	66%	80%±0.5
>5 years	12	15144	64%	62%±0.1
Non-validated questionnaires				
6 weeks or less	7	1257	96%	92%±0.2
>6 weeks to 1 year	18	15766	81%	76%±0.4
2-5 years	10	1685	75%	74%±0.2
>5 years	11	11425	66%	69%±0.3
Patient interview				
6 weeks or less	3	353	74%	66%±0.4
>6 weeks to 1 year	17	7175	80%	74%±0.3
2-5 years	[redacted]			
>5 years	3	497	90%	91%±0.1

7.2 Paper 2: Gray TG, Sneyd R, Scurr K, Jones GL, Iles D, Jha S, Radley SC. Patient-reported outcome measures which assess body image in urogynaecology patients: a systematic review. International Urogynecology Journal. 2019;30(5):673-81.

Abstract

Aim: Urogynaecological conditions can have a significant impact on body image. Patient-reported outcome measures (PROMs) are widely used in urogynaecology to assess symptoms and their impact on quality-of-life.

This systematic review aimed to identify currently available PROMs used to assess body image within a urogynaecological population and to identify the most psychometrically robust and appropriate PROM tools to use in this context.

Methods: Ovid Medline, AMED, CINAHL, Cochrane Collaboration, EMBASE and Web of Science databases were searched from January 1966 to November 2018, to identify studies that had administered a PROM to assess body image to patients diagnosed with a urogynaecological condition. The information extracted and critically appraised included; study setting, PROM instrument used and the reported psychometric properties of the PROM.

Results: Seventeen studies were included from 3207 screened articles. Seven different PROMs used to assess body image in a urogynaecological population were identified. Two of these PROMs (Genital Self-Image Scale-20 and Body Image in Pelvic Organ Prolapse questionnaire) had good psychometric evidence for use but this was only in the context of women with prolapse. Evidence for validity and reliability was limited for the other five PROMs identified.

Conclusion: Further development and psychometric testing of PROMs to assess body image in urogynaecology, both for research purposes and clinical practice , is required. Further research is also required to investigate the relationship between body image and urogynaecological symptomatology and developing valid, reliable and functional PROMs will be integral to this.

Keywords: Body image, patient report outcome measures, surveys and questionnaires

Brief Summary

This systematic review has identified two patient-reported outcome measures that could be recommended for use in assessment of body image in women with prolapse.

Introduction

Patient-reported outcome measures (PROMs) are well established in urogynaecology and are utilised both as clinical and research tools. PROMs provide patients' perspectives on their conditions, without interruption or influence from the clinician and can include assessments of condition-specific symptomatology and impact on health-related quality of life (HRQoL) [1]. Evaluation of PROMs through psychometric testing is deemed important for each population the specific tool is to be used, to ensure reliable and valid results.

PROMs are particularly valuable in urogynaecology, where conditions are often of a sensitive nature. PROMs are clearly shown to help self-expression, discussion and the disclosure of embarrassing or intimate conditions [2, 3]. Although the assessment of the impact of urogynaecological conditions on both sexual function and HRQoL is increasingly well understood, understanding the relationships, impact and outcomes of these conditions in relation to body image is a relatively new area of research within the subspecialty.

'Body image' refers to the mental picture that an individual has of themselves, which depicts not only details available to objective investigation by others (e.g. height, weight, hair colour etc.), but also details that have been learned about themselves, either from personal experiences or by internalising the judgments of others [4].
In addition, the term 'genital self-image' has also been used to describe the internal mental picture (body image) that an individual has of his or her external genitalia [4] and may include components such as appearance, attractiveness, scarring, function and the perceptions of others (including both partners, family and healthcare professionals).

Urogynaecological conditions including prolapse, urinary incontinence and perineal trauma [5 - 9] have been shown to have a negative effect on body-image as a whole, and specifically on genital self-image [10, 11]. Previous qualitative studies have also found that a significant proportion of new patients attending urogynaecology outpatient clinics have body image concerns [8, 12].

The aim of this systematic review was to identify from the existing literature the PROMs that have been used to assess body image within a urogynaecological population and also to identify the most psychometrically robust and appropriate PROM(s) to use in this context.

Methods

A systematic review of the literature using well established methodology [13] was undertaken. This followed the PRISMA guidelines [14] and was designed to capture studies where a population of women specifically with urogynaecology conditions had been administered a PROM which assessed body image. This systematic review was registered prospectively on the PROSPERO database (registration number: CRD42017084710).

The study population was women with urogynaecological conditions. In particular, this covered the following conditions: pelvic organ prolapse, urinary incontinence, faecal incontinence and sexual dysfunction.

The intervention studied was any PROM which assessed body image concerns. The comparison was the reported psychometric properties of the identified instruments in the included studies.

Ovid Medline, AMED, CINAHL, Cochrane library, Dissertations and theses (PhD only), EMBASE, PSYCHInfo and Web of Science databases were searched using medical subject heading (MeSH) theme "body image", combined with Boolean AND operators with the MeSH themes "patient reported outcome measures", "surveys and questionnaires", "urinary incontinence", "pelvic organ prolapse", "sex", "fecal incontinence" for studies published between January 1966 and November 2018 (inclusive). Studies included were limited to adult female human subjects and were restricted to English language publications.

In addition, the following journals were hand searched for relevant studies:

- International Urogynaecology Journal
- Neurourology and Urodynamics
- American Journal of Obstetrics and Gynecology
- BJOG: an international journal of obstetrics and gynaecology
- Quality of Life Research

Three reviewers (TGG, RS and KS) independently reviewed all the abstracts identified by the literature search to identify papers of potential interest. All papers of potential interest to the review were obtained and read by three reviewers (TGG, RS and KS) to identify those that were relevant. Studies were included only with the agreement of all three reviewers

following evaluation of full manuscripts. Any disparities were resolved by consensus and, if required, arbitration by a fourth and fifth reviewer (SCR and SJ). A manual search of the reference list of each manuscript was also conducted by the reviewers to identify further studies of relevance to the systematic review.

The same reviewers (TGG, RS and KS) independently extracted data from the included studies onto an electronic data collection form adapted from previous reviews of the psychometric properties of PROMs [13, 15]. The information extracted included study setting, population, PROM instrument used, the domains included in the PROM and the psychometric properties of the PROM. These were compared and a summary table of consensus data compiled.

Only studies that specifically included women with urogynaecological conditions, or studies in which this group was identified separately within the results of the study were included. The following were excluded: papers reporting clinician completed questionnaires or proformas, review articles or interim reports superseded by full reports. The primary outcome was the number of PROM tools used to assess body image in urogynaecological conditions. Secondary outcomes were evidence of reliability, validity and responsiveness of these tools in a urogynaecology population.

Psychometric properties including reliability and validity provide a level of evidence that an instrument works effectively and measures what it has been designed to measure. For this systematic review the psychometric properties of the identified PROMs were assessed

using data from studies where the instrument had been used within a urogynaecology population, providing evidence for its potential validity in this setting.

Reliability assesses the extent to which a PROM tool yields consistent and reproducible results [16]. Both internal consistency and test-retest reliability were assessed as measures of reliability in this review.

Validity describes the extent to which an instrument (PROM) measures what it purports to measure [17]. This is absolutely specific to the population and setting. Therefore, for example, a PROM designed to assess body image in cancer patients may not be reliable in a urogynaecology population. Construct validity describes the relationship of a construct to other variables [17]. This is often explored using correlation coefficients, whereby >0.5 indicates adequate convergent validity and <0.5 indicates adequate divergent validity [15, 17]. Other methods used to assess validity were evidence of criterion validity, where a correlation between the PROM and another (usually validated and well-established) PROM had been assessed. Content validity assessing the extent to which the PROM topic (or domain) had been described by the items (individual questions) with it, and usually involving patient groups, was also measured. Information on responsiveness (change before and after an intervention) was also collected.

Functionality, or details on practical properties, of each PROM was assessed by data reported on acceptability, feasibility and reading level of the administration of the PROM. Details of the type, size and range of the populations in which the identified PROMs were

administered was collected, as well as domains and scoring, to identify the most psychometrically robust PROM tools available to assess body image in urogynaecology patients.

Results

A total of 3207 studies (excluding duplicates) were identified for screening with 3158 being discarded on title and abstract alone. Of the remaining studies, 49 manuscripts were reviewed in full with 17 studies identified as meeting the inclusion criteria (**Figure 1**). This resulted in seven PROMs being identified that had been used in a urogynaecology population. A full summary of the seven PROMs is presented in **Table 1** and a full summary of the psychometric properties presented in each of the 17 studies is presented in **Table 2**.

In terms of population, 15 studies included women with pelvic organ prolapse (5, 6, 10, 18-29), one study also included patients with perineal trauma following childbirth as well as patients with prolapse [21], one study included patients with overactive bladder [30] and one study included patients attending a urogynaecology clinic but did not specify their symptomatology [11]. Two identified studies utilised two PROMs within their study design [10, 27]. A full summary of study setting and participants is reported in **Table 3**.

Two of the PROMS identified (modified Body Image Scale- mBIS and Body Image in Pelvic Organ Prolapse- BIPOP) were condition specific, each only able to be used in women with pelvic organ prolapse as the questions relate directly to this condition. One PROM (Body Exposure during Sexual Activities Questionnaire- BESAQ) was specific to a population of

women who were currently sexually active. The remaining four PROMs (Gential Self image Scale-20- GSIS-20, Body Esteem Scale- BES, Body Image Quality of Life Inventory- BIQLI and the Vaginal changes, Sexual and Body Esteem questionnaire- VSBE) were all generic instruments which could be to be used in any population of women, regardless of condition.

The seven PROMs identified varied considerably in their length, the domains covered and how they were scored. The number of items varied from 10-30, resulting in variations in the scope of the PROMs identified and in different completion times, all of which affect the acceptability, value and burden of a PROM.

Information on the psychometric properties of the identified PROMs was assessed following the methodology of the Oxford PROMS group [13] and replicated the methodology employed in previous systematic reviews [31]. This is a subjective method of appraisal, but is arguably a useful and helpful indicator of how comprehensively the psychometric properties have been assessed and provides an indication of the level of evidence for each PROM tool [31]. **Table 4** presents an appraisal of the psychometric properties and functionality of the identified PROMs which helps to indicate which tools can be best recommended for use in clinical practice within a urogynaecology setting.

Two of the PROMs (BIPOP and GSIS-20) identified had undergone formal psychometric testing in a population with pelvic organ prolapse and/or perineal trauma [21, 28]. Body Image in Pelvic Organ Prolapse is a 10 item PROM scored out of 50 which assesses how

pelvic organ prolapse directly affects body image perception. Good evidence in favour of reliability, content validity, construct validity and criterion validity was presented for the Body Image in Pelvic Organ Prolapse questionnaire (BIPOP). However, no data on responsiveness or acceptability was presented. The Genital Self Image Scale-20 is a longer 20 item PROM scored out of 40, and relates to body image in relation to genitalia. It has undergone formal psychometric testing in a population of women with pelvic organ prolapse and/or perineal trauma and good evidence in favour of reliability, content validity, construct validity, criterion validity, responsiveness and acceptability was presented [28].

None of the other five instruments identified (mBIS, BESAQ, BIQLI, VSBE and BES) had such comprehensive evidence of reliability or validity within a urogynaecological population (**Table 4**). Two of these instruments (VSBE and BES) had no evidence of reliability in a urogynaecological population presented and none of these five instruments had evidence of content validity for their use within a urogynaecological population. However, apart from the Body Image Quality of Life Inventory- BIQLI, all the tools identified had some good evidence in favour of construct validity in a urogynaecological population and all had some favourable evidence for acceptability presented.

Discussion

This systematic review of PROMs used within a urogynaecology population has identified seven instruments used for the assessment of body image. Of these, two instruments have been identified as suitable for use in women with pelvic organ prolapse (GSIS-20 and BIPOP) [21, 28]. Suitable PROMS to assess body image in other areas of urogynaecology,

including urinary and faecal incontinence or as part of a comprehensive PROM tool, were not identified.

The nature of urogynaecology, which includes a spectrum of related conditions such as urinary incontinence, pelvic organ prolapse, faecal incontinence and sexual dysfunction, often occurring concurrently, makes identifying a single PROM for use to assess body image across the whole subspecialty challenging. Issues to consider include the scope, length (and therefore burden) of the tools available and rationale for their administration in a urogynaecology population. Also, considering which aspects of body image to assess within a urogynaecological population is important. Whether this is an assessment of global body image satisfaction or specifically in relation to genital self-image or sexual function would impact on the choice of PROM.

The rationale for administration of PROMs in a clinical setting includes supporting individualised care as part of routine use in clinical practice, as well as service evaluation and research [32]. For this reason, it is essential to establish psychometric evidence of reliability, validity and feasibility of use of the tool intended for this purpose; especially if data are to be used for research purposes. The seven instruments identified in this systematic review have been developed for use in clinical practice and not purely as research tools. Only one of the PROMs identified has been developed specifically for a urogynaecology population (BIPOP) [28].

The body image in pelvic organ prolapse questionnaire (BIPOP) has been specifically developed and validated in a population of women with pelvic organ prolapse [28]. The study reported clear evidence of content validity, internal consistency reliability, construct validity, criterion validity and acceptability. Though no assessment of responsiveness was presented.

The Genital Self Image Scale-20 (GSIS-20) was not initially developed for use within a urogynaecological population, but has now undergone formal validation in a population of women with perineal trauma or pelvic organ prolapse [21]. The study reports good evidence for content validity, internal consistency reliability, construct validity, criterion validity, responsiveness and acceptability.

All of the other five PROMs identified in this systematic review have been developed and validated in different patient settings and all their published formal validation has been in non-urogynaecological populations. The most frequently used instrument identified was the modified Body Image Scale (mBIS), which was used in 11 studies [5, 6, 18-20, 22-26, 30]. This PROM was Initially developed to assess body image concerns in relation to medical conditions or treatment in cancer patients and was adapted for use in patients with pelvic organ prolapse. This was achieved by changing questions regarding 'disease or treatment' from Hopwood's original body image scale [33] to questions regarding 'prolapse'. This tool is therefore only able to be utilised in populations where patients with pelvic organ prolapse symptoms are assessed. No evidence has been provided for the content validity of this tool in a urogynaecology population and the

available evidence for its reliability and construct validity is very limited, despite it being the most widely used PROM to assess body image in a urogynaecology setting. Following its initial use in a urogynaecology population by Jelovsek et al in 2006 [5], ten further studies have utilised mBIS. However, in order for this tool to be considered valuable for research and use in clinical practice, further psychometric testing within a urogynaecology population is required.

The other four tools identified in this review, the Body Exposure during Sexual Activities Questionnaire (BESAQ), Body Esteem Scale (BES), Body Image Quality of Life Inventory (BIQLI) and Vaginal changes/Sexual and Body Esteem (VSBE) questionnaire are each all used in only one study; each time in a population of patients with pelvic organ prolapse. None of these four tools has been developed in a urogynaecology population and there is no evidence for content validity for these tools in a urogynaecology setting. There is some limited evidence for reliability for BESAQ [27] and BIQLI [27] and some good evidence for construct validity for BESAQ [27], VSBE [29] and BES [10]. However, more comprehensive formal psychometric testing in a urogynaecology population is recommended prior to using these instruments in clinical practice or research.

We did not identify any studies where a PROM tool has been used to assess body image in patients with stress urinary incontinence or faecal incontinence and only one study in which body image was assessed in patients with overactive bladder [30]. The relationship between conditions including stress urinary incontinence, overactive bladder, faecal incontinence *and* body image is clearly an area for further research. This requires the

development and psychometric testing of appropriate PROMs to assess this. The interplay between body image, sexual function and quality of life within urogynaecology populations is also an important area of future research.

Whilst the relationship between body image and pelvic organ prolapse is now becoming well established, there are still significant questions about how patients who report negative body image should be advised and managed. There is some evidence that body image improves following surgical intervention for prolapse [18, 22, 27] or the use of pessaries [20, 23], though studies which evaluate the value of counselling or cognitive behavioural therapy in this context are also needed, again demanding psychometrically robust PROMs which assess body image in the relevant urogynaecological setting.

The main strength of this systematic review is the rigorous and transparent search strategy employed, which has identified the relevant studies, allowing identification of seven PROM tools used in a urogynaecology population. We have been able to identify the most psychometrically robust tools available for use to assess body image within a urogynaecology setting.

The limitations of this systematic review are that the data is only as good as that which has been provided in the included studies. Not all the psychometric testing for each PROM may be included, especially details about content validity, criterion validity and responsiveness, which were often not reported. To minimise the risk of bias and subjectivity with using the

Oxford PROM group's appraisal system, each reviewer independently extracted data on the quality of the psychometric properties and functionality of the included PROMs. The use of a search strategy which excluded papers not published in English may have also resulted in missing both instruments and related studies potentially relevant to this systematic review.

Conclusions

This systematic review aimed to identify the most psychometrically robust patient reported outcome measures which could be used to assess body image in a urogynaecology population. Two of the identified PROMs (GSIS-20 and BIPOP) [21, 28] can be recommended for use in clinical practice, service evaluation and research for patients with pelvic organ prolapse. Development of a PROM/PROM(s) to identify and measure body image issues in other areas of urogynaecology including urinary incontinence and faecal incontinence is required.

Further research is required to investigate the relationship between body image and urogynaecological symptomatology, quality of life and sexual function and changes after interventions, which would valuably utilise such tools.

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No

Tables and figures, including legends

Figure 1: PRISMA diagram showing selection of articles for review.

Table 1: Summary of the content and scope of the seven PROMs identified in this systematic review

Table 2: Summary of the psychometric properties reported for each PROM in the 17 included studies in this systematic review

Table 3: Summary details of the study populations for each included study.

Table 4: Psychometric properties of PROMS identified by the systematic review, scored according to Preston et al (2015). Key to scoring: 0 not reported, - no evidence in favour, + some limited evidence in favour, ++ some good evidence in favour, +++ good evidence in favour.

Table 1

PROM name	Population for use	Number of times used in review	Number of items	Summary
The modified Body Image Scale	Condition specific-prolapse	11	10	Uses the same 10 questions as the Body Image Scale but substitutes "disease or treatment" to "vaginal prolapse" to make it more relevant to its patient cohort. Answers graded from "Not at all" to "Very much" in four steps.
Genital Self Image Scale - 20	Generic to women	3	20	20 questions assessing body image regarding female genitalia. Scored from 0-40 with an increased score indicating positive genital body image. 10 questions are scored 0-3 (graded) and 10 are 0-1 (yes/no).
Body Exposure During Sexual Activities Questionnaire	Condition specific-sexually active women only	2	28	A 28 item questionnaire assessing body image during sexual activities. Included genitalia specific questions. Answers graded from "never" to "always or almost always" in 5 steps.
Body Esteem Scale	Generic to women	1	30	A measure of "overall" body image. Divided into 3 categories – appearance, weight and attribution with 12, 9 and 9 items respectively. The items are graded in 5 steps from "never" to "always".
The Body Image Quality of Life Inventory	Generic to women	1	19	Assesses the impact body image has on quality of life. It uses 19 items each scored from -3 to +3 giving an overall mark between -54 and +54 with a higher score indicating a higher quality of life.
Body Image in Pelvic Organ Prolapse questionnaire	Condition specific-prolapse	1	10	A 10 item questionnaire that assesses how pelvic organ prolapse directly affects how women perceive their body image. 5 step grading from strongly agree to strongly disagree.
Vaginal Changes Sexual and Body Esteem	Generic to women	1	10	10 questions with Likert scale responses ranging from 1 (strongly agree), to 5 (strongly disagree).

Table 2: Summary of the psychometric properties reported for each PROM in the 17 included studies in this systematic review

Instrument/study	Reliability Cronbach's alpha Interclass correlation/Pearson's (*r*)	Validity Construct validity	Content/criterion validity	Responsiveness
The modified Body Image Scale (mBIS)				
Jelovsek et al (2006)	Cronbach's alpha 0.91	Body image correlated moderately (r=0.4) with quality of life and prolapse (r=0.3) and urinary (r=0.4) scores of the PFDI-20	Not reported	Not assessed
Barber et al (2007)	Not reported	Not demonstrated	Not reported	Not demonstrated
Lowenstein et al (2009)	Not reported	mBIS scores correlated moderately with POPDI scores (r=0.37) and PISQ scores (0.34)	Not reported	Not assessed
Lowenstiein et al (2010)	Not reported	Improvement in mBIS scores was significantly correlated with improvement in symptoms of prolapse (r=0.27) Patients with higher body image scores also had higher sexual function scores.	Not reported	Significant change in mBIS scores following treatment
Patel et al (2010)	Cronbach's alpha 0.89	mBIS scores improved significantly following the use of pessary for prolapse management	Not reported	Significant change in mBIS scores following treatment
Crisp et al (2013)	Not reported	mBIS scores significantly improved post-surgical management of prolapse and this was sustained at 24 weeks.	Not reported	Significant change in mBIS scores following treatment
Levin et al (2014)	Not reported	Statistically significant improvement in mBIS scores following treatment of OAB with Interstim	Not reported	Significant change in mBIS scores following treatment
Meriwether et al (2015)	Not reported	Changes in mBIS scores were significantly associated with BMI, comorbidity indices and satisfaction with pessary for management of prolapse	Not reported	Significant change in mBIS scores following treatment
Crisp et al (2016)	Not reported	mBIS scores showed significant improvement post op	Not reported	Significant change in mBIS scores following treatment
Lucacz et al (2016)	Not reported	Statistically significant improvement in mBIS scores postoperatively at 6, 12 and 24 months.	Not reported	Significant change in mBIS scores following treatment
Weidner et al (2017)	Not reported	Not demonstrated	Not reported	Not demonstrated
Genital Self Image Scale– 20 (GSIS-20)				
Zielinski, Kane-Low et al (2012)	Cronbach's alpha 0.79-0.89	Known group approach: significant correlation of GSIS-20 scores with participants considering genital cosmetic surgery	User group involvement. Clincian expert panel. Content validity index scores calculated.	Pearson's correlation for test-restest reliability= 0.88
Zielinski et al (2012)	Cronbach's alpha 0.89	GSIS-20 scores significantly lower (worse) than patients not diagnosed with prolpase	Positive correlation with BES scores (*r*=0.38)	Not assessed
Handezalts et al (2017)	Cronbach's alpha 0.85	GSIS scores significant associated with sexual function scores (FSFI)	Not reported	Not assessed
Body Exposure during Sexual Activities Questionnaire (BESAQ)				
Lowder et al (2010)	Cronbach's alpha 0.95	Statistically significant improvement in BESAQ scores following prolapse surgery Age significantly associated with BESAQ score	Not reported	Significant change in BESAQ scores following treatment
Body Esteem Scale (BES)				

Zielinski et al (2012)	Not reported	Positive correlation between sexual function scores (FSFI) and BES (*r*=0.34)	Positive correlation with GSIS-20 (*r*=0.38)	Not assessed
The Body Image Quality of Life Inventory (BIQLI)				
Lowder et al (2010)	Cronbach's alpha 0.97	No statistically significant change in BIQLI scores	Not reported	Not demonstrated
Body Image in Pelvic Organ Prolapse questionnaire (BIPOP)				
Lowder (2014)	Cronbach's alpha 0.92 Interclass correlation 0.80	Strong correlation (r=0.38 and r= 0.45) with scores for pelvic organ prolapse symptoms (PFDI-20, PFIQ-7)	Patient user group involvement and good evidence of face validity Strong correlation (r=0.70 and r=0.36) with body exposure during sexual activity (BESAQ) and Body image quality of life inventory (BIQLI)	Not assessed
Vaginal Changes Sexual and Body Esteem (VSBE)				
Zielinski (2009)	Not reported	Strong correlation (r=0.59) between severity of prolapse and VSBE	Not reported	Not assessed

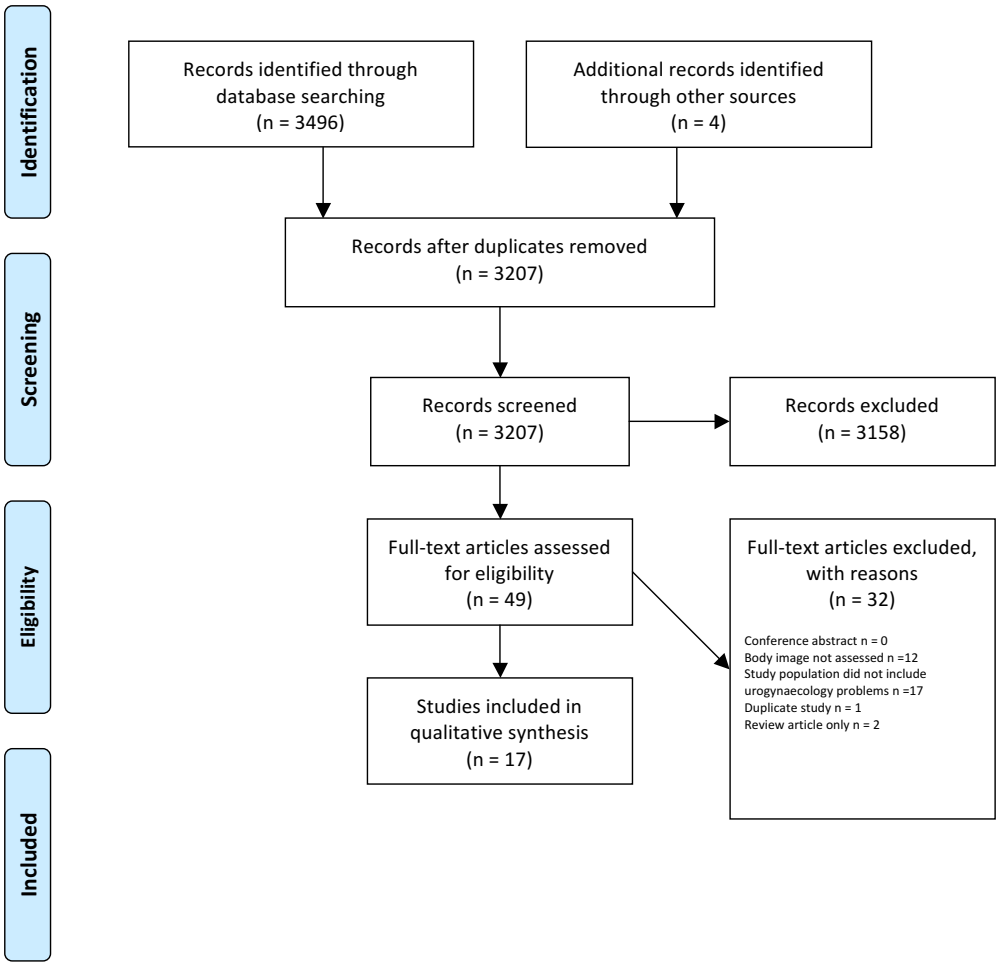
Table 3: Summary details of the study populations for each included study.

Instrument/study	Number of women in study	Study population
The modified Body Image Scale (mBIS)		
Jelovsek et al (2006)	47	Patients with advanced pelvic organ prolapse
Barber et al (2007)	70	Patients undergoing surgery for pelvic organ prolapse
Lowenstein et al (2009)	384	Patients with stage 2 or greater pelvic organ prolapse
Lowenstiein et al (2010)	239	Patients with stage 2 or greater pelvic organ prolapse
Patel et al (2010)	54	Patients with pelvic organ prolapse managed by pessary
Crisp et al (2013)	87	Patients with prolapse undergoing colpocliesis
Levin et al (2014)	28	Patients with overactive bladder
Meriwether et al (2015)	127	Patients with pelvic organ prolapse managed with a pessary
Crisp et al (2016)	81	Patients with prolapse undergoing colpocliesis
Lucacz et al (2016)	307	Patients undergoing surgery for pelvic organ prolapse
Weidner et al (2017)	283	Patients with pelvic organ prolapse stage 2 or greater
Genital Self Image Scale– 20 (GSIS-20)		
Zielinski, Kane-Low et al (2012)	277	Patients with stage 2 or greater prolapse (n=34). Patients with perineal trauma(n=51)
Zielinski et al (2012)	74	Patients with prolapse (n=13),, surgery for prolapse (n=24) and controls (n=37)
Handezalts et al (2017)	107	Patients attending a urogynaecology clinic
Body Exposure during Sexual Activities Questionnaire (BESAQ)		
Lowder et al (2010)		Patients with pelvic organ prolapse stage 2 or greater
Body Esteem Scale (BES)		
Zielinski et al (2012)	74	Patients with prolapse (n=13),, surgery for prolapse (n=24) and controls (n=37)
The Body Image Quality of Life Inventory (BIQLI)		
Lowder et al (2010)	64	Patients with pelvic organ prolapse stage 2 or greater
Body Image in Pelvic Organ Prolapse questionnaire (BIPOP)		
Lowder (2014)	201	Patients with pelvic organ prolapse symptoms
Vaginal Changes Sexual and Body Esteem (VSBE)		
Zielinski (2009)	13	Patients with pelvic organ prolapse

Table 4: Psychometric properties of PROMS identified by the systematic review, scored according to Preston et al (2015). Key to scoring: 0 not reported, - no evidence in favour, + some limited evidence in favour, ++ some good evidence in favour, +++ good evidence in favour.

PROM	Number of studies used in	Reliability	Construct Validity	Content Validity	Criterion Validity	Responsiveness	Acceptability
The modified Body Image Scale (mBIS)	11	++	++	0	0	++	++
Body Exposure during Sexual Activities Questionnaire (BESAQ)	1	++	++	0	0	++	++
Body Image in Pelvic Organ Prolapse questionnaire (BIPOP)	1	+++	++	++	+++	0	0
The Body Image Quality of Life Inventory (BIQLI)	1	++	0	0	0	0	++
Genital Self Image Scale–20 (GSIS-20)	3	+++	+++	+++	+++	+++	+++
Vaginal Changes Sexual and Body Esteem (VSBE)	1	0	++	0	0	0	+
Body Esteem Scale (BES)	1	0	++	0	++	0	++

Figure 1


Identification
Screening
Eligibility
Included
Records identified through database searching (n = 3496)
Additional records identified through other sources (n = 4)
Records after duplicates removed (n = 3207)
Records screened (n = 3207)
Records excluded (n = 3158)
Full-text articles assessed for eligibility (n = 49)
Full-text articles excluded, with reasons (n = 32)
Conference abstract n = 0
Body image not assessed n =12
Study population did not include urogynaecology problems n =17
Duplicate study n = 1
Review article only n = 2
Studies included in qualitative synthesis (n = 17)

7.3 Paper 3: Gray TG, Alexander C, Jones GL, Tidy JA, Palmer JE, Radley SC. Development and Psychometric Testing of an Electronic Patient-Reported Outcome Tool for Vulval Disorders (ePAQ-Vulva). Journal of lower genital tract disease. 2017;21(4):319-26.

Précis: There is a need to address outcomes assessment for patients with vulval disorders. A PROM (ePAQ-Vulva) has been developed, initial psychometric testing shows good potential.

Abstract

Objective: Development of an electronic patient reported outcome measure (PROM) specifically designed for vulval-disorders. Psychometric testing of the components of the questionnaire which assess vulval symptoms, sexual function and quality of life (QoL).

Method: Development and programming of the instrument (ePAQ-Vulva) was informed by national guidelines for the assessment of vulval-disorders, an expert panel and a survey of 61 vulval clinic patients. The PROM assesses frequency and impact of vulval symptoms, sexual function and QoL. It also records conditions and behaviours related to vulval-disorders and patient concerns/goals.

Scale generation and psychometric testing were undertaken for the vulval symptoms, sexual function and QoL components of the PROM with 91 participants: descriptive statistics**,** factor analysis and internal reliability of identified domains, agreement between free-text and multiple-choice items to assess convergent validity and inter-rater reliability of picture items was assessed.

Results: Descriptive statistics showed high floor effects for seven questionnaire items. Factor analysis identified five principal components. These were reviewed and amended to provide a putative domain structure of six domains. Internal reliability of these domains

was assessed using Cronbach's alpha, producing values of 0.715 to 0.917. Inter-rater reliability of the picture items produced a Kappa statistic of 0.405. Spearman's rank showed moderate correlation between multiple choice answers and free-text concerns (r=0.364 – 0.462) in three of the six domains (Pain, Sex and Dyspareunia).

Conclusions: ePAQ-Vulva offers the first patient reported outcome tool, specifically designed for vulval-disorders. The instrument requires further validation and testing, including evaluation of the stability, responsiveness and reliability.

MeSH Keywords: Vulva, Genitalia- female, patient-reported outcome measures, surveys and questionnaires, self report, telemedicine

Introduction:

Vulval-disorders encompass a diverse group of conditions affecting the visible areas of the external female genitalia.[1] Vulval-disorders negatively impact on quality-of-life, body-image, self-confidence, relationships and sexual function.[2] Adequate consultation time is essential to enable appropriate assessment of women with vulval-disorders. New-patient appointments within the National Health Service (NHS) in the UK are restricted to twenty-minutes. Taking a detailed history, physical examination, scheduling investigations, discussing possible diagnoses and treatment options, whilst making provision for women to freely express themselves about such intimate conditions is challenging.

Patient-reported outcome measures (PROMs) are questionnaires or instruments designed to provide means of measuring conditions, their impact and outcome following intervention, from the patient's perspective. The use of PROMs is increasingly widespread. Since 2009 the NHS has made it a requirement to collect PROMs data from patients before and after surgery for hip and knee replacements, varicose veins and groin hernias.[3] In 2013 The British Society for the Study of Vulval Disease (BSSVD) published 'Standards of Care for Women with Vulval Conditions.'[4] These standards recommend the routine collection of PROMs for all women with vulval conditions. However, despite this, there is no nationally recommended vulva-specific instrument for the collection of outcomes data.

A variety of PROMs have been described for use in women with vulval-disorders. These include three instruments specific to vulval cancer; Vulval Intra-epithelial Neoplasia Questionnaire (VIN-Q), [5] Functional Assessment of Cancer-Vulvar (FACT-V) [6] and Sexual Function Vaginal Changes Questionnaire (SVQ).[7] Examples of generic instruments used to assess components of vulval disorders include the McGill Pain Questionnaire (MPQ), [8] Dermatology Specific Quality-of-life (DSQL), [9] Dermatology Life Quality Index (DLQI), [10]

Female Sexual Distress Scale (FSDS) [11], Female Sexual Function Index (FSFI)[12] and Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction measure (PROMIS SexFS). [13]

The available instruments are therefore either specific to vulval cancer or non-specific to the vulva itself. The now archived Royal College of Obstetricians and Gynaecologists (RCOG) Guideline on the Management of Vulval Skin Disorders included an example of a pre-clinic vulval-disorders questionnaire.[14] This explores behaviors and co-morbidities that relate to vulval-disorders, but does not include assessment of symptoms, sexual function or quality-of-life.

The first aim of this study was to develop a PROM instrument specific for vulval-disorders, utilizing the potential benefits of an interactive electronic format in evaluating intimate and sensitive conditions, enhancing patient assessment and addressing the collection of PROMs data. The second aim was to undertake psychometric testing of the components of this instrument designed to assess vulval symptoms, sexual function and quality of life in this context.

Methods:

Ethical approval was obtained from the University of Sheffield University Research Ethics Committee (Project Number 001980).

Patient Survey

To assess women's perspectives regarding the concept of an electronic PROM, and inform the questionnaire content that would be important to women with vulval disorders, a survey of vulval clinic patients was undertaken over three weeks in January 2013. This survey included an explanation of the planned development of the PROM to help in the assessment of vulval conditions and included six free-text questions. (**Table 1**).

Platform technology

The platform technology used was first developed in urogynaecology to assess women with pelvic-floor disorders (ePAQ-Pelvic Floor), which has been extensively validated and used in clinical practice.[15-17]

Key elements of the system include introductory pages, explaining how to use the 'Help', 'Back', 'Next' and 'Skip' navigation functions. This eliminates accidental non-response to items, as progression is only enabled once a response has been selected. Items can be skipped automatically, depending upon responses to earlier screening questions. Sub-questions regarding the impact of symptoms are displayed if the particular symptom is reported. Responses from completed questionnaires are stored as numeric code in a secure central database, located behind a firewall on an NHS N3 server.

Item Generation

Design features of ePAQ-Pelvic Floor were incorporated in ePAQ-Vulva with entirely new content. Initial drafting of items was undertaken by a specialty trainee (TG) following Food and Drug Administration (FDA) guidance on PROM development.[18] Content was informed by RCOG guidelines for the management of vulval-disorders, findings from the literature review and responses from the 62 women attending the specialist vulval clinic who took part in the survey. An expert panel consisting of three consultant gynecologists (JAT/SCR/JEP) reviewed the items and further advised on content. An interactive pictorial item, using an image of the vulval area was also developed, enabling women to select areas of the vulva affected by pain and skin changes. Advanced prototypes of the instrument were prepared across six drafts, before converting to electronic format using the ePAQ questionnaire builder software. The first electronic prototype was again reviewed by the expert panel and refined across two further versions. The final version contained 64 items, of which 28 related to vulval symptoms, sexual function and associated quality of life issues. These items were subject to factor analysis in order to evaluate the domain structure of the instrument. The other items concerned conditions related to vulval disorders, behaviours potentially affecting vulval disorders, demographic details, the interactive picture item and free text concerns and goals. Items assessing conditions, behaviours and demographics were not subjected to psychometric assessment as part of this study.

Scale generation

To identify scales and evaluate psychometric properties for the items assessing vulval symptoms, sexual function and quality of life; the instrument was administered to consenting patients attending the vulval clinic at Sheffield Teaching Hospitals NHS Foundation Trust between December 2013 and January 2015. Data collected during the study period were analyzed using SPSS (IBM SPSS Statistics for Windows, Version 22.0, IBM Corporation, 2013, Armonk, New York).

During the study period, all women scheduled to attend the Vulval Clinic received a letter providing them with details of their appointment, inviting them to complete ePAQ-Vulva prior to attending. The letter included details about the nature and purpose of ePAQ-Vulva, along with a unique 16-digit voucher code which enables secure on-line completion. Subjects unable to complete on-line were invited to do so in clinic, using a touch screen kiosk in a private room. Data from each subject automatically populates a one-page summary and three-page detailed report, which can be viewed or printed for inclusion in patient case-notes.

Factor analysis is a statistical procedure which enables the underlying domains, or scales, of a patient-reported outcome measure/patient questionnaire to be determined.[19] In order to identify the domains of ePAQ-Vulva, factor analysis using varimax rotation was carried out. There is no consensus on the sample size required to carry out factor analysis. It has been recommended that five to ten times the number of subjects to items in the instrument is required. However, it has been shown that a ratio of 2:1 of respondents and variables is satisfactory and can produce the same results. [20] Therefore, instead of a power calculation, following a conservative pragmatic approach we aimed to recruit as many

women as possible to the study within the study time frame. [19] Of the 64 items in ePAQ-Vulva, 28 items were suitable for factor analysis. Not all items from ePAQ-Vulva were included, as each of the 28 items contained sub-questions, which explore the impact of each symptom/problem. Each of these items consisted of responses on a four-point scale, which were scored 0-3, giving continuous data suitable for factor analysis.

Descriptive statistics provided a baseline understanding of the data set generated from ePAQ-Vulva. This included the mean, median and floor/ceiling effects for each item. Floor and ceiling effects help assess content validity and show the proportion of individuals who score the greatest or least possible numeric value of a score/scale, and are considered present when more than 15% of participants score these values. High ceiling effects indicate that it will be difficult to measure changes in patients after an intervention has been undertaken. [21]

Internal reliability is the extent to which items within an instrument measure the same concepts.[22] It also ensures that no two items are measuring exactly the same concept and may therefore be used as a tool for item reduction; with the aim of reducing the burden of completing the instrument. Cronbach's α was used to measure this. Scores greater than 0.7 usually indicate that scale items are measuring related constructs, scores greater than 0.94 suggest a degree of item redundancy, and provide a basis for item reduction. This was considered for all items that did not statistically or intuitively fit into any of the domains identified from factor analysis and those that did not show good internal reliability.

Inter-rater reliability was assessed for picture items. This assesses the level of agreement between two or more raters assessing the same variable.[23] In order to establish whether the pictures items were useful for recording symptoms of vulval disease, a subgroup

of data from 17 women completing ePAQ-Vulva was assessed. The clinician reviewing the patient (JEP) completed a paper version of the picture item in the patient's notes, indicating where they considered the symptoms to be located after examination. The picture item was split into six fields, so that for 17 women there were 102 possible sites of agreement. For each site a binary score of either agreement "1" or disagreement "0" was given and Cohen's Kappa statistic was used to analyze the data. Disagreement was deemed to occur if a site was selected by the patient, but not by the clinician and vice versa.

Convergent validity is the degree to which two measures of constructs that should be related, are in fact related. This was partially assessed by comparing the multiple-choice responses with the free-text items recording subject's concerns and goals. The free text comments were each reviewed to assess if the concern recorded by the patient was assessed by a questionnaire item in a particularly domain. Free-text data for concerns were then categorized according to domain and the rank correlation coefficient with the relevant domain scores for quality of life calculated (Spearman's rank correlation).

Results

a. Patient Survey.

A total of 62 women completed the survey over the three-week period (**Table 1**). Altogether 91 women attending the clinic were invited to complete the questionnaire, giving a response rate of 68%.

Of women completing the survey, 75% were positive about the idea of an electronic online questionnaire to assess women with vulval disorders, 74% listed advantages of this and 26% listed disadvantages. Two key themes that emerged related to advantages of being

able to express their feelings or concerns (35%) and receiving information and knowledge about vulval-disorders (33%). When asked about possible advantages of an electronic questionnaire to clinic staff, 56% of respondents answering the question reported advantages of improved clinic staff communication with patients and their partners.

Table 1 - Survey questions and summary of results

b. ePAQ Vulva Structure and Dimensions

ePAQ Vulva comprises of 3 dimensions. The full structure and questions comprising ePAQ-Vulva as tested can be viewed as supplementary material online as an appendix to this paper.

1. **Vulval Symptoms dimension.**

Items assessing severity, frequency and impact of symptoms, including pain, soreness, itching, skin changes, effects on sexual function and activities of daily living (quality of life) **(Figure 1).**

Figure 1: Example of item in the Vulval Symptoms Dimension, assessing symptom frequency and impact, in this case itching.

Within this dimension are two items which present an interactive picture of the vulva to allow women to record both the loci of any vulval pain or soreness and vulval skin changes **(Figure 2).**

Figure 2: Vulval image allowing women to indicate areas affected by discomfort or pain.

2. Activities and conditions that may affect the vulva.

These items relate to activities and behaviors such as vulval washing regimens, as well as dermatological, rheumatological and inflammatory disorders associated with vulval conditions. This did not undergo psychometric testing.

3. Personal Data Dimension

Comprising of six items, recording age, body mass index (BMI), current medications and obstetric history. Within this dimension are two free-text items that allow women to record their personal concerns, goals and questions. The final 'consent' item asks whether the subject is willing to allow confidential use of their anonymised data for approved research.

c. Initial psychometric testing

Of the 153 women who were posted a voucher to complete ePAQ-Vulva, 98 (64%) completed the instrument either on-line prior to clinic attendance or in the vulval clinic at a

touch screen computer in a private room. The age range of the cohort was 22 – 89, with a mean age of 38. The average time to complete the questionnaire was 32 minutes (range 22 – 57 minutes).

Initially, factors (groups of items) which gained an Eigen value (raw sum of the squares) of 1 or more were retained. Factor analysis (principle component analysis using Varimax rotation) indicated the presence of five components or domains. These accounted for 42.0%, 11.8%, 7.6%, 5.7% and 3.6% of the variance. The expert panel (SCR, JEP, GJ and JAT) reviewed and intuitively amended these components to provide a putative structure comprising of six clinically meaningful domains.

Descriptive statistics showing the mode, median and floor/ceiling effects of 28 items from ePAQ-Vulva, including the frequency that each question was answered, can be seen in table two**.** Descriptive statistics of the 28 items found that some had large floor and ceiling effects and non-specificity, meaning that many women completing the questionnaire recorded a similar score and there was a lack of variance; these items were considered for modification or reduction when the PROM was revised. Internal reliability of the six domains was assessed using Cronbach's α; all six domains achieving an alpha level of≥ 0.7 (**Table 3**).

Table 2: Descriptive statistics for the 28 assessed items in ePAQ-Vulva: Mean, Standard Deviation, Floor and Ceiling effects. Items are scored from 0 to 3 (0= best possible health status, 3= worst possible health status)

Table 3: Internal reliability assessment of the six domains identified in ePAQ-Vulva: The six components resulting from Factor Analysis, Internal reliability testing and discussion with an expert panel. Showing items and resulting Cronbach's alpha statistic.

Inter-rater reliability of the picture items showed agreement between clinician and patient 54% of the time regarding the presence of symptoms. Agreement regarding absence of symptoms was 85%. The Cohen's Kappa measure of agreement was moderate at 0.405.

Spearman's rank showed significant moderate correlation between multiple-choice components and free-text items in three of the five domains. These were; vulval pain and soreness (r=0.364, p<0.005), dyspareunia (r=0.394, p<0.005) and vulval itching (r=0.462, p<0.005). Correlation between the other two domains (quality of life (r=0.022, p=0.84) and skin changes (r=0.071, p=0.50) was non- significant.

Discussion

ePAQ-Vulva combines detailed assessment of vulval symptoms, sexual dysfunction, quality-of-life, associated activities and medical conditions, as well as relevant issues such as BMI, parity, personal goals and patient questions. This presents the clinician with a large amount of information about both frequency and bothersomeness of symptoms, presence of conditions or behaviours related to vulval disorders and relevant demographic details. This information can enhance the acuity of a consultation as most components of the history will be included in the ePAQ-Vulva report. It is not intended to be a tool which gives a clinician a diagnosis, but rather an accurate and detailed assessment of symptoms and behaviours.

The instrument is designed to be completed prior to clinical consultation, to facilitate communication and enable women to feel more confident in exploring intimate conditions and concerns. Evidence suggests that electronic questionnaires can increase discussion rates in sensitive conditions and that patients may feel more comfortable exploring sensitive medical problems via electronic questionnaire than during face-to-face consultation.[24,25]

ePAQ-Vulva can also be completed prior to subsequent consultations, allowing comparisons with previous completions to assess treatment response and patient outcomes.

The initial testing and validation of ePAQ-Vulva has provided some evidence of reliability and validity. However, the data analysed thus far represent a relatively small sample in a single-centre specialist vulval clinic. The instrument therefore requires further testing, including confirmatory factor analysis of its domain structure in larger numbers of women, with a wider variety of vulval conditions. Although the age range of the cohort was 22 – 89, with a mean age of 38, many women attending vulval clinics are elderly, which may affect compliance with questionnaire completion. [25] Important psychometric properties, including test-retest reliability (stability), local dependency, item discrimination and responsiveness of the instrument have yet to be evaluated.

Of the six domains in the vulval symptoms dimension of ePAQ-Vulva, both skin changes and quality of life did not reach statistical significance in this study. This could be due to a lack of direct patient-involvement in the construction of the questionnaire items. Whilst some patient involvement supported initial development and testing of the instrument, due to the limited time-frame of the study, qualitative in-depth interviews with patients were not carried out.[3] Further work, such as cognitive interviewing with patients is proposed, gathering feedback on the current item pool, considering new items and strengthening the content validity.

Following the initial psychometric testing, changes will be made to the instrument to remove redundant items, though with some caution to ensure that clinical detail is not lost through item reduction; prioritising statistical significance over clinical detail may result in

the loss of important information needed for in-depth assessment.[26] Further psychometric testing will then be undertaken.

Inter-rater reliability for the picture items, was not shown to be statistically significant, using Cohen's Kappa. However, a measure of sensitivity may be reflected in the proportion of cases where there was agreement between clinician and patient (54%) and cases when both clinician and patient agreed regarding absence of symptoms (85%). This suggests that self-completed vulval image items may have high specificity but low sensitivity. Further research is required to better understand their reliability and value in clinical practice. Only fair inter-rater reliability was demonstrated in this initial study.

Completion times for ePAQ-Vulva are generally around 30 minutes which may be unacceptable for some users, particularly in busy under-resourced clinics and when patients fail to pre-complete the questionnaire at home. ePAQ-Vulva is shorter than its predecessor, ePAQ-Pelvic Floor, which has been found to be acceptable and valuable in clinical practice, though the potential older age of patients with vulvar disorders, with attendant lower levels of computer literacy and internet access may affect compliance.[15,17,]

The detail recorded in ePAQ-Vulva aims to form part of routine clinical assessment and a baseline for future comparison. A graphic illustration of changes across its component domains may be particularly helpful in monitoring long-term vulval conditions when reviewing patients at follow-up appointments.

The instrument aligns with BSSVD recommended standards of care through the routine collection of PROMS data, enabling subsequent interrogation of datasets through appropriately approved and regulated audit, service evaluation and research.[4] This may take

the form of local, as well as multi-center studies, when the analysis of larger volumes of data may be valuable.

Conclusions:

An individual's beliefs and perspective on his or her condition, including personal goals and concerns are important to understand in any medical field. This is particularly true for intimate urogenital disorders, which may be taboo, embarrassing and have significant psychological and psychosocial components. ePAQ-Vulva is the first instrument specifically designed for use in women with vulval-disorders. Although more testing is required, the instrument shows potential as a clinical tool. ePAQ-Vulva also has the potential to be used in providing objective patient-based data for service evaluation and research. The next step is to undertake wider psychometric testing of a revised instrument in larger samples and in different settings, including further assessments of its domain structure, responsiveness, reliability and validity.

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Figure 1: Example of item in the Vulval Symptoms Dimension, assessing symptom frequency and impact, in this case itching

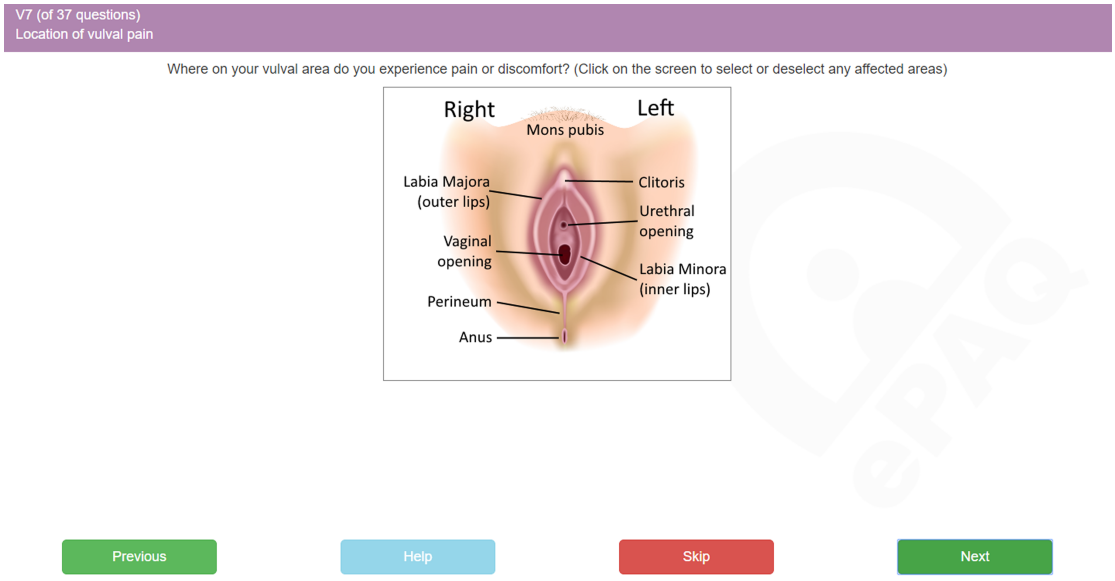

Figure 2: Vulval image allowing women to indicate areas affected by discomfort or pain.

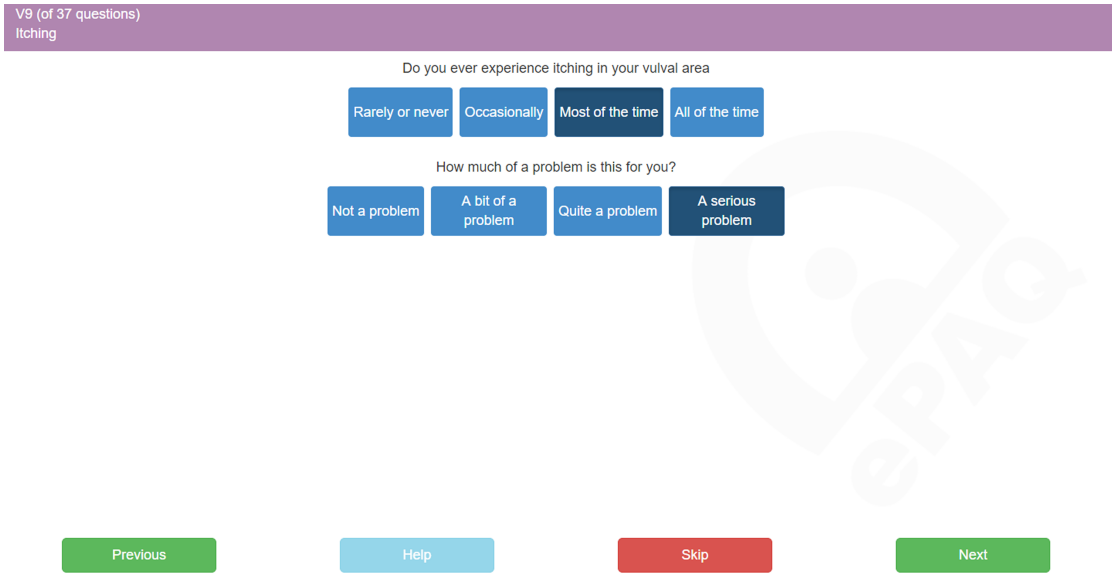

Table 1: Survey Questionnaire and summary of results

	Survey Question	Summary of responses
1.	**What do you think about the idea of a computerised online questionnaire to help assess women's feelings and concerns about their vulval condition and clinical care?** **Responses: n=60**	• Positive response -75% • Ambivalent response- 8% • Negative response- 17%
2.	**What key areas or issues do you think such a questionnaire should cover?** **Responses: n=52**	The answers were split into six categories based on the main themes covered by the various answers. Some patient answers included several themes. • 22.6% -symptoms/investigations/diagnosis. • 37.7% - addressing feelings/concerns. • 15.1% - management of their vulval disease. • 24.5% - information about their condition to be given through using the electronic questionnaire. • 15.1% - ability to record demographic information about themselves though the electronic questionnaire. • 20.8% said the electronic questionnaire should cover 'all areas' and didn't define anything more specific. • 5.7%- said that they 'did not know' or were 'not keen' on the questionnaire.
3.	**What do you think might be the advantages or disadvantages of this questionnaire to patients?** **Responses: n=51**	The answers were split into six categories based on the main themes covered by the various answers. Some patient's answers included several themes. Advantages listed included: • Providing information/knowledge to patients (33%), • Expressing their feelings or concerns (35%), • Confidentiality (2%), • Improved accessibility to the vulval clinic (20%). Disadvantages listed included • Providing too much information (10%), • Confidentiality concerns (4%), • Worsening access to vulval clinic (i.e. doing an electronic questionnaire instead of seeing a doctor/nurse) (10%).
4.	**What do you think might be the advantages or disadvantages of this questionnaire to the health care team?** **Responses: n=43**	89% of responses regarded advantages; 11% regarded disadvantages. Advantages listed included: • Improve staff training (7%), • Provide more accurate information to women based on the answers provided in the questionnaire (14%), • Improve clinic staff's communication with patients and their partners (56%), • Improve quality of care provided to patients (19%), • Help to collect information which can be used to improve the clinic service (14%). Disadvantages listed included: • Create extra work for clinic staff (12%), • Some patents wouldn't use the electronic questionnaire (2%).
5.	What sort of research studies do you feel might be carried out in relation to this project? **Responses: n=24**	• 42% felt that communication would be a suitable topic for research carried out in relation to the electronic questionnaire. • 41% felt that treatment/cures/prognosis would be a potential research topic in relation to the electronic questionnaire. • 21% felt that a research on the epidemiology of patients with vulval disease could be carried out using the electronic questionnaire. • 4% felt that research into the diagnosis of vulval disease could be carried out using the electronic questionnaire.
6.	Do you have any comments or suggestions about this project?	• Six patients (50%) said they wanted the questionnaire to help them get access to information about vulval disease. • One patient (8.3%) said they wanted the questionnaire to cover sexual function • Two patients. (16.7%) raised concerns about the questionnaire being electronic and the effect this would have on provision of face to face consultations.

Responses: n=12

- Four patients (33%) made comments stating that they felt that the questionnaire project was advantageous for them.

Table 2: Descriptive statistics summary for the 28 items in ePAQ-Vulva: Mean, Standard Deviation, Floor and Ceiling effects. Items are scored from 0 to 3 (0=best possible health status, 3= worst possible health status)

Item	n.	Mode	Median	Mean	Floor 0 (%)	1 (%)	2 (%)	Ceiling 3 (%)
DOMAIN 1 VULVAL PAIN								
V2a – Pain soreness frequency	98	2	2	1.64	11	30	39	17
V3a – Pain/ soreness affecting sleep	98	0	1	.81	40	40	15	3
V4a - Painkiller use	97	0	0	.46	63	25	7	2
V5a – Micturition pain	97	1	1	.85	33	51	8	5
V6a – Pain on defecation	97	0	0	.52	58	30	7	2
DOMAIN 2 – VULVAL ITCHING								
V9a – Itching: frequency	95	1	1	1.27	22	34	30	9
V10a – Itching and excoriation	95	1	1	1.03	31	39	15	9
V11a – Itching: scratching and bleeding	95	0	0	.41	63	26	5	1
V12a – Itching: sleep disturbance	95	0	1	.69	44	39	10	2
DOMAIN 3 – VULVAL SKIN CHANGES								
V13a – Skin pigmentation	95	1	1	1.28	25	31	19	15
V14a – Skin dryness	95	0	1	1.33	34	15	27	19
V15a – Skin tightness	95	0	1	1.13	41	21	12	20
V16a – Skin thickening	94	0	0	.48	63	15	6	5
V17a – Skin thinning	94	0	0	.77	56	9	13	11
DOMAIN 4 – DYSPAREUNIA: FREQUENCY								
V23a – Dyspareunia: frequency	93	3	3	1.98	12	13	4	37
V25a – Dyspareunia: post coital	92	1	1	1.49	15	19	12	17
V26a – Dyspareunia: dryness	92	0	1	1.46	21	13	8	21
V27a – Dyspareunia: reduced sensation	92	0	1	1.08	23	12	8	13
V28a Dyspareunia: tightness	92	0	1	1.24	26	14	8	16
V29a Dyspareunia: obstruction	91	0	0	.72	39	10	5	8
DOMAIN 5 – VULVA & SEX								
V30a Vulva and sex overall	91	3	3	2.15	11	7	6	39
V31a Vulva and sex avoidance	91	3	2	1.91	9	16	12	29
V32a Vulva and sex partner avoids	91	0	1	1.27	26	12	10	16
V33a Vulva and sex anxiety	91	3	2	1.79	16	8	12	28
DOMAIN 6 – ACTIVITIES OF DAILY LIVING								
V34 Vulval condition and enjoyment								

of life	91	3	2	1.83	15	19	18	35
V35 Vulval condition and physical activities	91	0	1	1.11	37	20	18	14
V36 Vulval condition and responsibilities	91	0	0	.57	61	14	6	8
V37 Vulval condtion and social activities	91	0	0	.66	55	17	10	7

Table 3: Internal reliability assessment of the six domains on ePAQ-Vulva: The 6 components resulting from Factor Analysis, Internal reliability testing and discussion with an expert panel. Showing items and their Cronbach's alpha statistic.

Item	**Cronbach's α**
DOMAIN 1 VULVAL PAIN V2a – Pain soreness frequency V3a – Pain/ soreness affecting sleep V4a - Painkiller use V5a – Micturition pain V6a – Pain on defecation	**0.786**
DOMAIN 2 – VULVAL ITCHING V9a – Itching: frequency V10a – Itching and excoriation V11a – Itching: scratching and bleeding V12a – Itching: sleep disturbance	**0.850**
DOMAIN 3 – VULVAL SKIN CHANGES V13a – Skin pigmentation V14a – Skin dryness V15a – Skin tightness V16a – Skin thickening V17a – Skin thinning	**0.715**
DOMAIN 4 – DYSPAREUNIA: FREQUENCY V23a – Dyspareunia: frequency V25a – Dyspareunia: post coital V26a – Dyspareunia: dryness V27a – Dyspareunia: reduced sensation V28a Dyspareunia: tightness V29a Dyspareunia: obstruction	**0.878**
DOMAIN 5 – VULVA & SEX V30a Vulva and sex overall V31a Vulva and sex avoidance V32a Vulva and sex partner avoids V33a Vulva and sex anxiety	**0.929**
DOMAIN 6 – ACTIVITIES OF DAILY LIVING V34 Vulval condition and enjoyment of life V35 Vulval condition and physical activities V36 Vulval condition and responsibilities V37 Vulval condition and social activities	**0.881**

7.4: Paper 4: **Gray TG, Moores KL, James E, Connor ME, Jones GL, Radley SC. Development and initial validation of an electronic personal assessment questionnaire for menstrual, pelvic pain and gynaecological hormonal disorders (ePAQ-MPH). European Journal of Obstetrics & Gynecology and Reproductive Biology. 2019;238:148-56.**

ABSTRACT

Objective

Menstrual disorders, pelvic-pain and gynaecological hormonal conditions in women can have a significant impact on quality-of-life. Reliable assessment and monitoring of these intimate conditions is challenging. Patient reported outcome measures (PROMs) can be invaluable in providing objective assessment, but no comprehensive PROM assessing all of these conditions and their impact on quality of life is currently available. The purpose of this study was to develop and undertake initial psychometric testing of a comprehensive interactive electronic patient reported outcome measure for these conditions.

Study design

A prototype electronic PROM (ePAQ-MPH) was developed following systematic literature review, semi structured interviews with 25 patients and expert panel review. Exploratory factor analysis was undertaken in 291 women attending a menstrual-disorders clinic; establishing a domain structure and enabling item reduction. Two validated PROMS (Women's Health Questionnaire and Menstrual Distress Questionnaire) were completed to assess criterion validity in 213 patients. Test-retest reliability was carried out in 30 women completing ePAQ-MPH at least one week apart. Patients' views on 'Value' and 'Burden' were assessed in 278 women using a validated 10-item survey measuring questionnaire utility (QQ-10). Confirmatory factor analysis (CFA) of the revised version of ePAQ-MPH following item reduction was undertaken in a different sample of 254 women.

Results

Exploratory factor analysis identified 18 domains (Cronbach's α >0.7) and 30 redundant items. Test-retest analysis found acceptable intra-class correlations of 0.6–0.9 (p<0.05). Eight domains were compared with Menstrual Distress Questionnaire showing moderate or strong correlation in seven domains. Ten domains were compared with Women's Health Questionnaire, six of which showed moderate correlation. Mean QQ-10 Value and Burden scores were 76 and 25, respectively (SD=15.8 and 15.5). The mean completion time for

ePAQ-MPH was 31 minutes. CFA of the revised version 2 instrument with 15 domains showed good model fit.

Conclusions

Whilst wider psychometric testing of the revised version of ePAQ-MPH is required, including in different settings and in assessments of data quality and responsiveness, initial analysis provides some evidence for reliability, validity and acceptability of this multi-dimensional electronic PROM. ePAQ-MPH shows potential for both patient assessment and roles in service evaluation and research.

KEYWORDS

Patient reported outcome measures, Menstruation, Pelvic Pain, Pre-menstrual syndrome, Quality-of-life

Condensation

ePAQ-MPH is a multi-dimensional electronic PROM. Initial psychometric testing shows some evidence for potential use for patient assessment, service evaluation and research.

INTRODUCTION

Menstrual disorders and associated pelvic pain and gynaecological hormonal symptoms are common and can have a profound and debilitating effect on health-related quality of life (HRQoL) [1-5]. There is often an overlap between heavy menstrual bleeding, pelvic pain and gynaecological hormonal symptoms such as premenstrual syndrome and perimenopausal symptoms [6].

The main aim of treatment for menstrual disorders is to improve HRQoL and therefore it is important that valid and reliable patient reported outcome measures (PROMs) are available to measure both symptoms and their impact on HRQoL.

PROMs are instruments designed to provide means of measuring conditions, their impact and outcome following intervention, from the patient's perspective. [7] The use of PROMs in all areas of healthcare has become increasingly widespread [8, 9] and their use in sensitive conditions, where patients may not disclose embarrassing symptoms is potentially invaluable [10-12].

A number of PROMs have been described for use in women with menstrual, pelvic pain and gynaecological hormonal disorders. However, existing instruments are either condition specific [13-15] or limited to one symptom area of menstrual disorders; specifically assessing heavy menstrual bleeding, [16-18] pelvic pain, [19] sexual function, [20] health related quality-of-life [21-24] or premenstrual syndrome alone. [25-28]. The majority of instruments are paper-based, adding a significant administrative burden to their use in clinical practice [29].

The objective of this study was to develop and undertake psychometric testing of a comprehensive electronic PROM instrument for women with menstrual symptoms, pelvic pain and gynaecological hormonal symptoms, including assessments of HRQoL and sexual function. The context of use (COU) for this PROM would be for both baseline assessment of women referred to secondary care in gynaecology with these conditions and when they are reviewed for follow up.

MATERIALS AND METHODS

Ethical approval was obtained from the Sheffield Local Research Ethics Committee (Reference number 09/H1308/21).

Instrument development

The platform technology (ePAQ) used to create this electronic PROM was first developed in urogynaecology [30]. Design features of ePAQ were incorporated into the new instrument, but with entirely new content.

To form a basis for sound content and face validity, development of the PROM started with a systematic literature review of existing women's health PROMs and semi-structured interviews with 25 patients conducted by a social scientist experienced in PROM development, these were voice-recorded, transcripts made and subjected to thematic content analysis [31].

Drafting of items, identified as relevant from both the systematic review and the content of the semi-structured interviews, was then undertaken following Food and Drug Administration (FDA) guidance on PROM development [32] and an initial paper-based prototype PROM was developed by an expert panel (two gynaecologists, social scientist and specialist nurse) before converting to a first electronic prototype comprising of 102 scored items. This PROM is called electronic Personal Assessment Questionnaire-Menstrual, Pain and Hormonal (ePAQ-MPH).

Eligible patients (female, age over 18, able to understand written English and attending the menstrual disorder outpatient clinic) were recruited into the study between August 2015-June 2016 and formal written consent was taken. Participants were asked to complete ePAQ-MPH followed by three paper based questionnaires which would assess acceptability and criterion validity. **Table 1** presents a flow chart detailing recruitment and completion rates.

Scale generation and internal reliability

ePAQ MPH was administered to 308 consenting female patients attending the menstrual disorders gynaecology clinics at Sheffield Teaching Hospitals. Data collected were analysed using SPSS (IBM, Version 22.0, IBM Corporation, 2013, Armonk, New York).

Psychometric testing consisted of exploratory factor analysis with Varimax rotation. Factor analysis is a statistical procedure which enables the underlying domains or scales of an instrument to be determined. Initially, factors (groups of items) which gained an Eigen value (raw sum of the squares) of >0.5 were considered as constituting potential domains,

each of which contained a minimum of three items [33]. A potential domain structure and redundant items were thereby identified.

Internal reliability is the extent to which items within an instrument measure the same concepts [34]. It also ensures that no two items are measuring exactly the same concept and may be used as a tool for item reduction. Cronbach's α was used to measure this; scores greater than 0.7 usually indicate that scale items are measuring related constructs. Items failing to be included in any domain were reviewed by the expert panel regarding their value and possible removal.

Criterion validity

Two-hundred and thirteen participants also completed the Women's Health Questionnaire [35] (WHQ) and the Menstrual Distress Questionnaire [36] (MDQ). These two PROMs were used as there is evidence for their validity and both instruments cover almost all the content incorporated in ePAQ-MPH. Scores from ePAQ-MPH were compared with salient domain scores from WHQ and MDQ using rank correlation to assess the degree of association.

Stability

Test-retest reliability to evaluate stability over time was undertaken with 30 participants who completed ePAQ-MPH on two occasions, at least one week apart. Wilcoxon signed-rank test was used to measure differences between Cronbach's alpha values for the two completions and inter-class correlations were calculated.

Patient experience and acceptability

Patients' views of ePAQ-MPH were evaluated for 279 participants using QQ-10, a validated 10-item instrument which measures face validity, feasibility and utility of PROM use during their clinical episode [37]. The established QQ-10 scoring algorithm for measuring value and burden in was used [37].

Instrument modification and confirmatory factor analysis

Following revision of the instrument and item reduction, to confirm the conceptual model of ePAQ-MPH, a confirmatory factor analysis (CFA) using Mplus version 8.0 (Muthen & Muthen, 2017, Los Angeles, CA) was undertaken on 254 completed questionnaires (ePAQ-MPH Version 2) from patients who had given consent for the use of their data via the PROM between January 2017-January 2018. Given the nature of the scales used in ePAQ-MPH the estimator chosen was weighted least squares means and variance adjusted (WLSMV). This estimator does not assume normally distributed variables and therefore has been argued as providing the best estimator for modelling categorical or ordered data [38]. A number of model fit indices were evaluated for confirmation of the CFA which included a chi-square, root mean square error of approximation (RMSEA), comparative fit index (CFI) and the Tucker–Lewis index (TLI). We should expect a non-significant chi-square for confirmation of the CFA ($p > 0.05$) [39]. The RMSEA, is a measure of fit [40]; a value < 0.05 suggests good model fit, although values < 0.08 are considered reasonable. The CFI ranges from 0 for a poor fit to 1 for a good fit. The TLI is another index for comparative fit. It can be interpreted in a similar fashion as CFI, but it can have a value outside of the range of 0 to 1. We should expect

good fit statistics for CFI and TLI to be > 0.95 although values exceeding 0.90 are considered acceptable.

RESULTS

ePAQ-MPH

ePAQ-MPH is completed online; patients use a unique 16-digit voucher code which is automatically generated and embedded in a posted clinic letter. This code is entered by the patient, along with their date of birth to log-in and pseudonymously complete the questionnaire on-line. Patients unable to complete the PROM at home can complete it in the menstrual disorders clinic using a touch-screen or tablet computer in a private room, with the support of a nurse if needed. Key elements of ePAQ-MPH include introductory pages, explaining how to use the 'Help', 'Back', 'Next' and 'Skip' navigation functions.

Each item is presented on one screen and presents stem questions relating to symptom frequency and severity, sub-questions regarding the impact of symptoms are displayed if the particular symptom is reported. Each item offers a four-point response scale (Figure 1). Domain scores are computed using a standard algorithm used in the urogynaecology version of ePAQ, providing scales from 0 (best health status) to 100 (worst heath status). Responses from completed questionnaires are stored as numeric code in a secure central database, located behind a firewall on a secure NHS N3 server.

Version one of ePAQ-MPH comprised four symptom dimensions: Menstruation, Pelvic Pain, Hormonal Conditions and Non-Menstrual Bleeding & Discharge. The PROM also included a

fifth non-scored Personal Data dimension, recording additional information, such as self-reported height and weight (computed BMI), previous hysterectomy, parity and free-text items relating to patient concerns and treatment goals. Each symptom dimension contains screening questions, identifying whether the participant is affected by symptoms from the relevant dimension. Therefore, the PROM only presents questions relevant to the symptoms the patient will be suffering from. For example, if a participant does not have periods, they will not be presented with questions about how heavy their periods are, how many days they bleed for etc. Data from each patient automatically populates a one-page summary (Figure 2) and detailed ePAQ-MPH report, with one page each for the raw data from each symptoms dimension which can be viewed on screen or printed for inclusion in patient case-notes.

Domain structure, internal reliability and item reduction

Complete questionnaire data were obtained from 291 of the 308 women in the study (94.5%). The age range was 22–63 years (mean 43). Mean completion time was 31 minutes. Eighteen domains of ePAQ-MPH with Cronbach's alpha values of >0.7 were identified. These domains each contained between 3–7 items and Cronbach's alpha values ranged from 0.70–0.96. A summary of internal reliability statistics for the 18 domains is shown in **Table 2**. Factor analysis demonstrated that the Menstrual dimension had two redundant items and identified six domains; the Pelvic Pain dimension had four redundant items and five domains; the Hormonal dimension had seven redundant items and four domains. Within the hormonal dimension a putative polycystic ovary syndrome domain including items relating to hair loss, acne and hirsutism was evaluated; these items were tested for internal reliability and produced a Cronbach's alpha value of 0.42 suggesting that this was not a reliable domain.

The final dimension of Non-menstrual Bleeding & Discharge (NMBD) had 5 redundant items and three domains were identified. A putative vaginal discharge domain within this dimension produced a Cronbach's alpha value of 0.46, again suggesting that this was not a reliable domain. All redundant items were removed from version 1 of ePAQ-MPH (102 items reduced to 72 items).

Test retest reliability

Test retest reliability was undertaken with 30 participants using version 1 of ePAQ-MPH **(Table 3)**. Intra-class correlation coefficient values ranged from 0.45 to 0.9; the minimum accepted value of 0.5, was not achieved in the hormonal / sexual function domain (0.45). Interclass correlation >0.5 was seen in all other domains.

Criterion validity

Of the 308 participants completing version 1 of ePAQ MPH, in order to assess criterion validity, 180 (58%) completed MDQ and 213 (69%) completed WHQ. No corresponding domains could be identified for two of the 18 ePAQ-MPH domains (Dyspareunia and Intermenstrual Bleeding), two of the 18 domains had a relevant domain in both MDQ and WHQ. Eight domains were compared with MDQ showing moderate or strong correlation in seven domains. Ten domains were compared with WHQ, six of which showed moderate correlation **(Table 4)**.

PROM Acceptability

A total of 279 (91%) women completed the QQ-10 instrument. Summary statistics for value and burden, as measured by QQ-10, are shown in **Table 5**. Mean scores for Value and Burden were 76 (SD = 15.8) and 25 (SD = 15.5), respectively, suggesting high Value and low Burden for the majority of patients. Of the six items relating to Value, 'ease of use' and 'happy to complete again' were the most highly rated responses (92% and 90%, respectively). Of the four Burden items; 'The questionnaire is too long' was the most frequently reported response (25% of subjects).

Revised instrument and confirmatory factor analysis

The revised version 2 of ePAQ-MPH (Table 6) consisted of four dimensions and fifteen domains containing 72 items, 30 redundant items having been removed and domain structure modified. The mean completion time of the revised instrument was 22 minutes.

Table 6 shows the fit indices for the CFA model for each ePAQ-MPH dimension.

For all dimensions, the p-value for the $\chi 2$ goodness of fit test was $p<0.001$ indicating that the overall model did not fit the data well; as should be expected from this test for CFA. The RMSEA was small ($p<0.005$) suggesting good model fit for the Menstrual, Hormonal and NMBD dimensions. The RMSEA was 0.086 for the pain domain suggesting a reasonable fit. The CFI and TFI values were > 0.95 for all dimensions indicating good model fit. Therefore, overall, the findings suggest that that the ePAQ-MPH structure fits the data moderately well. Having confirmed the conceptual framework for ePAQ-MPH, the PROM structure for patient administration was reorganised. The single NMBD domain (intermenstrual bleeding) was relocated into the Menstrual dimension and the five domains relating to sexual function

(menstruation and sexual function, dyspareunia, pain and sexual function and hormones and sexual function) were moved into a new Sexual dimension **(Table 7**).

Comment

ePAQ-MPH is a condition-specific ePROM which provides comprehensive assessment of symptomatology associated with menstrual disorders, pelvic pain and gynaecological hormonal conditions and their associated impact on sexual function and quality of life.

ePAQ-MPH combines detailed assessment of menstrual disorders, including heavy menstrual bleeding, cycle regularity, intermenstrual bleeding, dysmenorrhea, menopausal symptoms and pre-menstrual syndrome. The PROM also assesses non-cyclical pelvic pain and hormonal symptoms. For each dimension of ePAQ-MPH the impact of symptoms on HRQoL and sexual function is assessed. Due to the significant overlap between menstrual, pelvic pain and gynaecological hormonal conditions, the ability to assess for symptoms and their impact on HRQoL in all of these conditions simultaneously is potentially valuable.

The instrument aims to process, with graphic and concise presentation, a large volume of information regarding both frequency and bothersomeness of symptoms. This can then be used to enhance the acuity of a consultation through the inclusion of self-reported key components of a patient's presenting complaint and her perspective of her condition. This PROM is not intended to replace clinical consultation, but to assist and objectively augment the clinical assessment and diagnosis. The PROM could also be used in ethically approved research projects to assess both baseline symptoms and impact on HRQoL and change following intervention.

Initial psychometric testing of ePAQ-MPH has shown good internal reliability, test-retest reliability and criterion validity. The results of the initial psychometric testing has enabled remodelling of the instrument. The confirmatory factor analysis of the revised instrument has shown that the domain structure of ePAQ-MPH fits the data it is intended to collect moderately well and good model fit was also demonstrated, confirming the conceptual framework of the instrument.

The burden of ePAQ-MPH was low when assessed, despite the length of the PROM, for which the first iteration (version 1, prior to item reduction) was reported as being 'Too long' by 25% of patients. Completion times of twenty minutes may be unacceptable for some users, particularly in under-resourced clinics when patients have failed to pre-complete the questionnaire at home. However, ePAQ-MPH is considerably shorter than the previously developed 132 item urogynaecology PROM (ePAQ-Pelvic Floor), which has been found to be acceptable and valuable in clinical practice [30, 41-42]. ePAQ-MPH may be similarly useful as a clinical and research tool. Barriers to completing PROMs in clinical practice can include licensing costs and additional staff training needed to set such tools up. However, once in place they are often cheap and reduce consultation burden.

Limitations of this study are the lack of detailed demographic data for the 308 participants including race/ethnicity, first language spoken and educational level. A further limitation is whether the patients recruited, presented with a full range of the conditions that ePAQ-MPH aimed to address, including pre-menstrual syndrome, perimenopausal symptoms and non-

menstrual pelvic pain. The two PROMS used to assess criterion validity focus principally on HRQoL rather than symptomology [35, 36] therefore the domains compared were not directly measuring an identical concept. As this was a research project, requiring consent, women who were participants may have been more motivated to provide questionnaire responses and have a more positive attitude towards questionnaire completion. Another limitation is that women unable to understand written English were excluded from the study as were those lacking basic computer literacy and willingness complete the instrument in the electronic format.

Whilst this paper reports the development of version 3 of ePAQ-MPH in order to allow other research groups to scrutinize and review the data generated thus far, wider evaluation and psychometric testing of this latest and current version of the instrument is now required in larger samples and in different settings, including tests of stability, tests of data quality, sensitivity and responsiveness to change.

Cognitive interviewing will provide further assessment of content and face validity. So far, ePAQ-MPH shows good potential as a PROM; providing objective patient-based data which could be utilised for assessment, service evaluation and research.

Conflicts of interest statement: Professor Stephen Radley is a director and shareholder of ePAQ systems limited, an NHS spin-out technology company (www.epaq.co.uk). The other authors declare they have no conflicts of interest.
Both the ethical review board and all research participants were made aware of the potential for commercial use of ePAQ-MPH in the future.

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Table 1: Recruitment into study and completion rates for ePAQ-MPH and study questionnaires

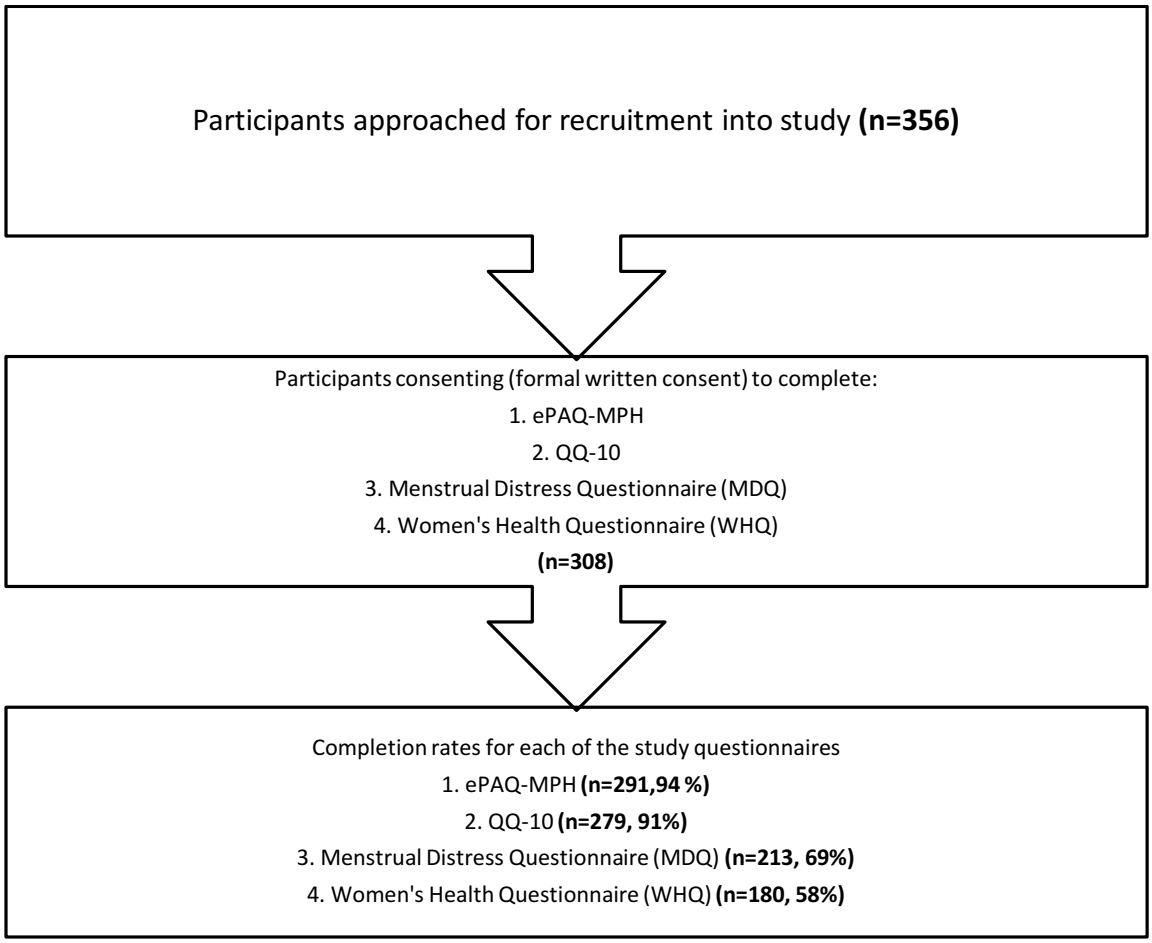


Table 2: Domain structure and internal reliability of ePAQ-MPH Version 1

Menstrual dimension		
Domains	**Summary of items**	**Cronbach's α**
Regularity	Irregularity, Regularity, Predictability	0.87
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days	0.78
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size	0.83
Protection	Leak onto clothes, Leak onto bedding, Pad change, Tampon change, Double protection	0.77
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.86
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.94
Pain dimension		
Domains	**Summary of items**	**Cronbach's α**
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve	0.84
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel	0.79
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction	0.80
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.92
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.96
Hormonal dimension		
Domains	**Summary of items**	**Cronbach's α**
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness	0.70
Pre- Menstrual Syndome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability	0.85
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.90
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.95
Non-menstrual bleeding and Discharge (NMBD) dimension		
Domains	**Summary of items**	**Cronbach's α**
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed	0.88
NMBD & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.93
NMBD & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.95

Table 3: Test retest reliability: ePAQ domains with first and second completion Cronbach's alpha, Wilcoxon signed rank test and intra-class correlations

Domain	First completion (Cronbach's alpha(number of completions))	Second completion (Cronbach's alpha(number of completions))	Intra-class correlation (2-tailed significance)
Menstrual dimension			
Regularity	0.87 (280)	0.87 (27)	0.87
Cycle length	0.78 (273)	0.64 (26)	0.80
Heavy Menstrual Bleeding	0.83 (275)	0.92 (28)	0.81
Protection	0.77 (129)	0.90 (16)	0.92
Menstruation & Sexual Function	0.86 (266)	0.89 (24)	0.76
Menstruation & Quality of Life	0.94 (281)	0.95 (27)	0.86
Pain dimension			
Dysmenorrhoea	0.83 (249)	0.82 (26)	0.80
Non-cyclical pain	0.79 (210)	0.73 (19)	0.88
Dyspareunia	0.80 (263)	0.74 (25)	0.84
Pain & Sexual Function	0.92 (262)	0.91 (24)	0.75
Pain & Quality of Life	0.96 (281)	0.95 (29)	0.88
Hormonal dimension			
Hypo-oestrogenism	0.70 (266)	0.72 (27)	0.90
Pre-Menstrual Syndrome	0.87 (264)	0.84 (28)	0.83
Hormones & Sexual Function	0.90 (235)	0.92 (23)	0.45
Hormones & Quality of Life	0.95 (271)	0.96 (29)	0.76
Non-menstrual bleeding & Discharge dimension			
Intermenstrual bleeding	0.88 (235)	0.89 (25)	0.68
NMBD & Sexual Function	0.93 (238)	0.94 (23)	0.70
NMBD and Quality of Life	0.95 (263)	0.85 (29)	0.58

Table 4: Criterion Validity for Salient ePAQ-MPH and Menstrual Distress Questionnaire (MDQ)/Women's Health Questionnaire (WHQ) domains and the Spearman's rank correlations

ePAQ-MPH domain	**Related MDQ domain**	**Spearman's rank (2-tailed significance)**
Menstrual Quality of Life	Behaviour Change Menstrual	0.46 (<0.001)
Dysmenorrhoea	Pain Menstrual	0.52 (<0.001)
Non-cyclical pain	Pain Postmenstrual	0.34 (<0.001)
Pain & Quality of Life	Behaviour Change Menstrual	0.42 (<0.001)
Hypo-oestrogenism	Autonomic Reactions Menstrual	0.40 (<0.001)
Pre-Menstrual Syndrome	Water Retention Premenstrual	0.38 (<0.001)
Hormones & Quality of Life	Behaviour Change Menstrual	0.48 (<0.001)
NMBD & Quality of Life	Behaviour Change Menstrual	0.12 (0.153)
ePAQ-MPH domain	**Related WHQ domain**	**Spearman's rank (2-tailed significance)**
Regularity	Menstrual	0.15 (0.041)
Cycle Length	Menstrual	0.24 (0.001)
Heavy Menstrual Bleeding	Menstrual	0.39 (<0.001)
Protection	Menstrual	0.27 (<0.001)
Menstruation & Sexual Function	Sex	0.36 (<0.001)
Hypo-oestrogenism	Vasomotor	0.49 (<0.001)
Pre-Menstrual Syndrome	Menstrual	0.47 (<0.001)
Hormones & Sexual Function	Sex	0.50 (<0.001)
Pain & Sexual Function	Sex	0.38 (<0.001)
NMBD & Sexual Function	Sex	0.26 (0.001)

Table 5: QQ-10 results for face validity/patient experience of ePAQ-MPH (version 1) including percentage and count for each response

Statement	% Strongly disagree (n)	% Mostly disagree (n)	% Neither agree or disagree (n)	% Mostly agree (n)	% Strongly agree (n)
Value					
1. Improved communication	1.4 (4)	6.1 (17)	14.0 (39)	57.9 (161)	20.5 (57)
2. Relevance	1.4 (4)	5.0 (14)	10.4 (29)	52.2 (145)	30.9 (86)
3. Ease of use	2.2 (6)	2.2 (6)	3.9 (11)	37.3 (104)	54.5 (152)
4. Comprehensive	1.1 (3)	6.8 (19)	12.6 (35)	47.1 (131)	32.4 (90)
5. Enjoyable	1.8 (5)	5.0 (14)	42.1 (117)	36.7 (102)	14.4 (40)
6. Happy to complete again	2.2 (6)	2.9 (8)	5.8 (16)	39.6 (110)	49.6 (138)
Burden					
7. Too long	10.9 (30)	24.3 (67)	40.2 (111)	18.5 (51)	6.2 (17)
8. Too embarrassing	43.5 (120)	30.4 (84)	23.9 (66)	2.2 (6)	0.0 (0)
9. Too complicated	41.1 (113)	42.2 (116)	14.5 (40)	1.8 (5)	0.4 (1)
10. Upsetting	68.1 (188)	17.4 (48)	13.0 (36)	1.1 (3)	0.4 (1)

Table 6: Dimensions and domain structure ePAQ-MPH Version 2 with associated fit indices for each dimension derived from confirmatory factor analysis

Menstrual dimension				
X^2	***df***	**RMSEA**	**CFI**	**TFI**
818.402	165	0.001	0.970	0.965

Domains	**Summary of items**
Regularity	Irregularity, Regularity, Predictability
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact

Pain dimension				
X^2	***df***	**RMSEA**	**CFI**	**TFI**
920.172	319	0.086	0.982	0.980

Domains	**Summary of items**
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact

Hormonal dimension				
X^2	***df***	**RMSEA**	**CFI**	**TFI**
889.560	168	0.001	0.963	0.958

Domains	**Summary of items**
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness
Pre- Menstrual Syndome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact

Non-menstrual bleeding and Discharge (NMBD) dimension			
X^2	***df***	**RMSEA**	**CFI**
15.250	2	0.005	0.998

Domains	**Summary of items**
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed

Table 7: Dimensions and domain structure ePAQ-MPH Version 3 following development of conceptual framework

Menstrual dimension	
Domains	**Summary of items**
Regularity	Irregularity, Regularity, Predictability
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
Pain dimension	
Domains	**Summary of items**
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
Hormonal dimension	
Domains	**Summary of items**
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness
Pre- Menstrual Syndome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
Non-menstrual bleeding and Discharge (NMBD) dimension	
Domains	**Summary of items**
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety

Figure 1

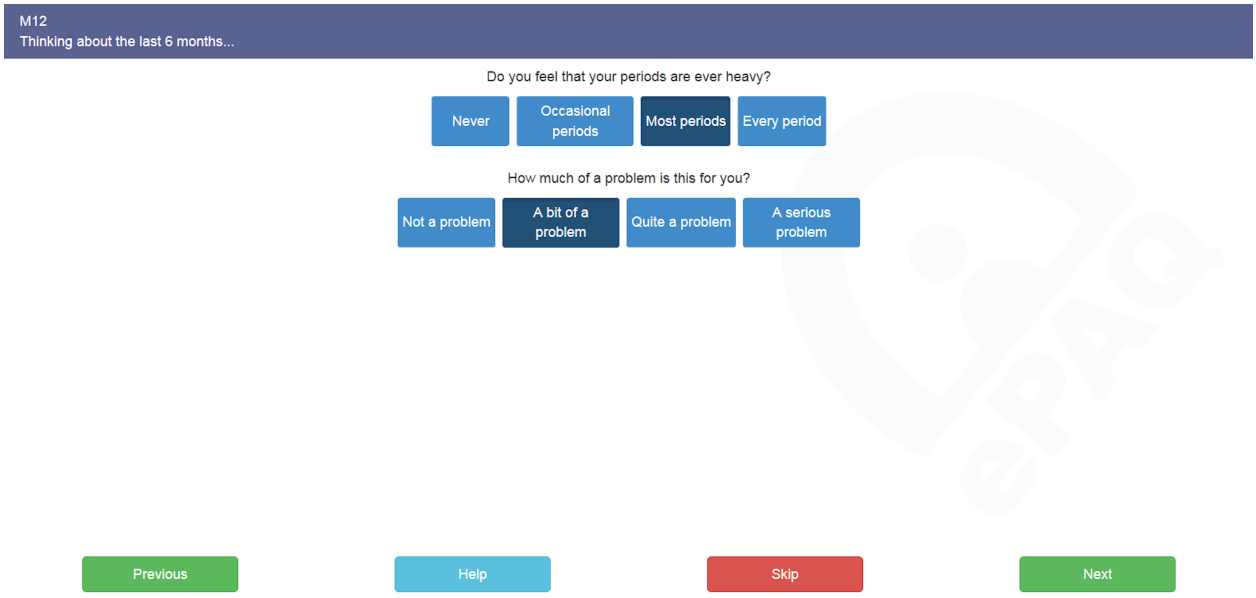
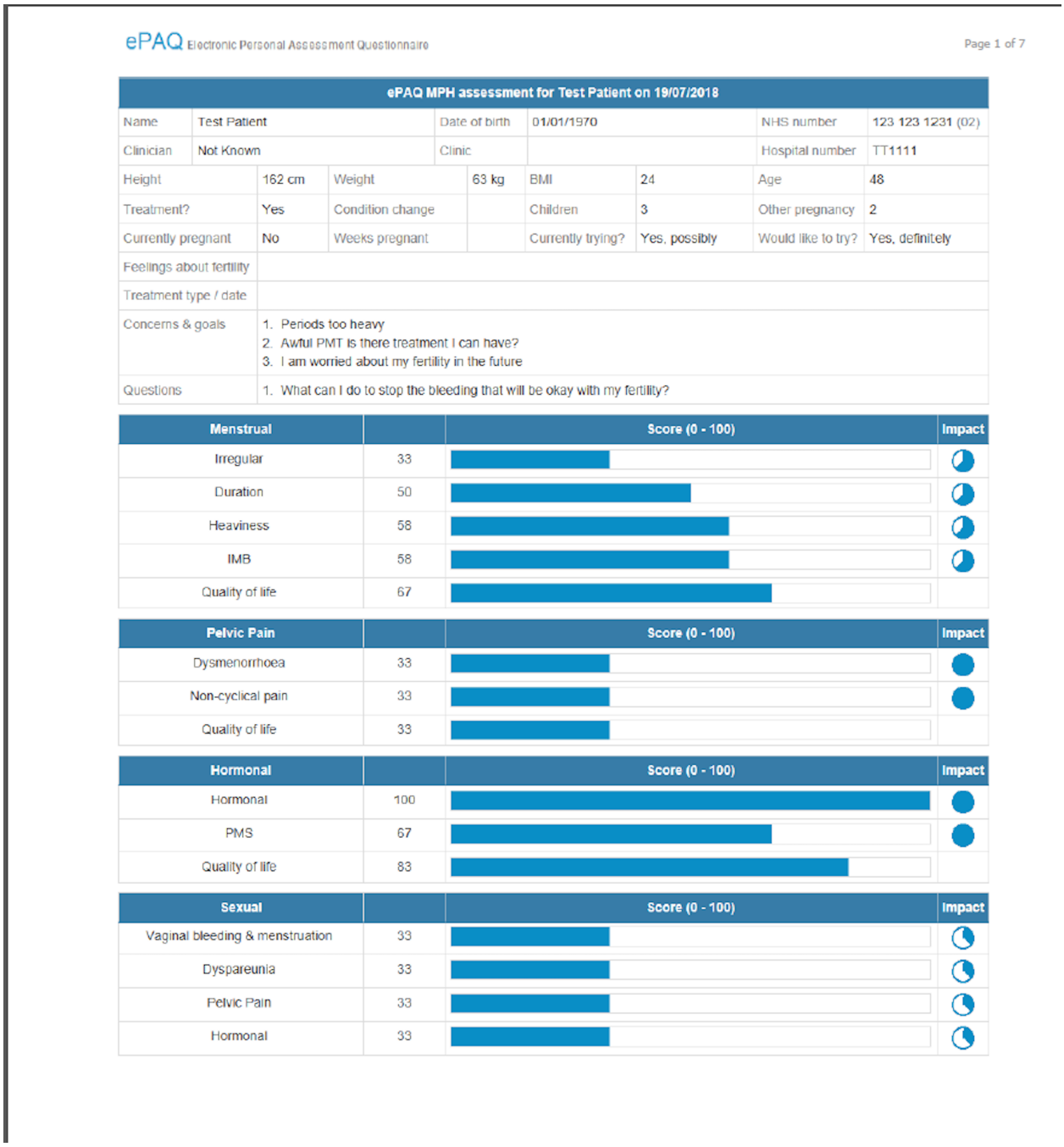

M12
Thinking about the last 6 months...
Do you feel that your periods are ever heavy?
Never
Occasional periods
Most periods
Every period
How much of a problem is this for you?
Not a problem
A bit of a problem
Quite a problem
A serious problem
Previous
Help
Skip
Next

Figure 2



ePAQ Electronic Personal Assessment Questionnaire

ePAQ MPH assessment for Test Patient on 19/07/2018

Name	Test Patient			Date of birth	01/01/1970	NHS number	123 123 1231 (02)
Clinician	Not Known			Clinic		Hospital number	TT1111
Height	162 cm	Weight	63 kg	BMI	24	Age	48
Treatment?	Yes	Condition change		Children	3	Other pregnancy	2
Currently pregnant	No	Weeks pregnant		Currently trying?	Yes, possibly	Would like to try?	Yes, definitely
Feelings about fertility							
Treatment type / date							
Concerns & goals	1. Periods too heavy 2. Awful PMT is there treatment I can have? 3. I am worried about my fertility in the future						
Questions	1. What can I do to stop the bleeding that will be okay with my fertility?						

Menstrual		Score (0 - 100)	Impact
Irregular	33		
Duration	50		
Heaviness	58		
IMB	58		
Quality of life	67		

Pelvic Pain		Score (0 - 100)	Impact
Dysmenorrhoea	33		
Non-cyclical pain	33		
Quality of life	33		

Hormonal		Score (0 - 100)	Impact
Hormonal	100		
PMS	67		
Quality of life	83		

Sexual		Score (0 - 100)	Impact
Vaginal bleeding & menstruation	33		
Dyspareunia	33		
Pelvic Pain	33		
Hormonal	33		

7.4: Paper 5: Gray T, Li W, Campbell P, Jha S, Radley S. Evaluation of coital incontinence by electronic questionnaire: prevalence, associations and outcomes in women attending a urogynaecology clinic. International Urogynecology Journal. 2018;29(7):969-78.

Abstract

Introduction

Coital incontinence is the involuntary leakage of urine during sexual intercourse and is divided into that occurring with penetration or orgasm. Mechanisms of coital incontinence are poorly understood. The aim of this retrospective study was to measure the prevalence of coital incontinence and evaluate the association between different types of coital incontinence with stress urinary incontinence (SUI), overactive bladder (OAB) and impact on quality-of-life in women attending a urogynaecology clinic.

Methods

2312 women completed ePAQ-PF in advance of their urogynaecology consultation. Logistic regression and Spearman's rank correlation evaluated associations between types of coital incontinence and OAB and SUI. Mann-Witney test evaluated the relationship between coital incontinence and self-reported quality-of–sex-life and self -avoidance and partner-avoidance of sex. Subgroup analysis analysed outcomes in 84 women with coital incontinence undergoing TVT.

Results

Prevalence of coital incontinence in the cohort was 30%. Symptoms of OAB ($p<0.005$) and SUI ($p<0.005$) were significantly and independently associated with both types of coital incontinence (orgasm & penetration). In women with coital incontinence compared with those without, there

was significant self-avoidance of sex ($p<0.0005$), partner-avoidance of sex ($p<0.0005$) and impaired quality-of-sex-life due to sexual problems ($p<0.005$). The impact of this was significant in each group. Subgroup analysis of 84 women undergoing TVT showed significant improvement in all coital incontinence symptoms three months post-operatively.

Conclusion Using an electronic questionnaire prior to consultation has identified coital incontinence as a prevalent symptom, having a significant impact on sexual life. Coital incontinence at orgasm and penetration are both significantly associated with SUI and OAB.

Keywords: coital incontinence, ePAQ-PF, questionnaire, computer interviewing, TVT, orgasm

Brief Summary:

Orgasm and penetration coital incontinence are prevalent complaints in women attending urogynaecology clinics and are both associated with OAB, SUI and impaired sexual function.

Introduction

Coital incontinence is a symptom occurring within the spectrum of urinary incontinence in women and is defined as the complaint of involuntary loss of urine associated with coitus. This can be further divided into coital incontinence occurring with penetration and that occurring at orgasm[1].

Coital incontinence is prevalent in women attending urogynaecology clinics [2, 3, 4] and has been shown to affect up to 60% of women with urinary incontinence [5]. Coital incontinence has been shown to have a negative impact on quality of life [6].

The precise mechanism and aetiology of coital incontinence remains incompletely understood, with conflicting evidence presented in previous studies regarding the association between coital incontinence and stress urinary incontinence (SUI) and detrusor overactivity (DO). Previously, it has been observed in urodynamic studies that coital incontinence with orgasm was more strongly associated with detrusor overactivity (DO), whereas coital incontinence with penetration more strongly associated with urodynamic stress incontinence (USI) [2, 7]. However, larger studies have suggested that urodynamic findings do not correlate well with orgasm or penetration coital incontinence [5, 8].

The objective of this study was to evaluate the prevalence of coital incontinence in women attending a urogynaecology clinic in a tertiary teaching hospital in the UK, and evaluate the association between different types of coital incontinence and SUI, OAB and quality of life. The impact of treatment with tension-free vaginal tape (TVT) on coital incontinence will be assessed as part of a subgroup analysis.

Methods

Women attending the urogynaecology unit at Sheffield Teaching Hospitals, UK, between January 2012 and September 2015 who had completed the electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) as part of their routine clinical care, prior to first assessment in the urogynaecology clinic, were included in the study. Ethical approval for this study was obtained from the University of Sheffield (Registration Number 011338)

ePAQ-PF is a web-based instrument, in the form of an electronic questionnaire, which provides a detailed assessment of a woman's pelvic floor symptoms and their impact [9-11]. The questionnaire can be completed online, prior to clinic attendance, or using a touch-screen computer terminal in a private room in the clinic. Computer interviewing using ePAQ-PF provides women with an opportunity to report symptoms of an intimate and sensitive nature, which may be difficult to express in a face-to-face consultation [12, 13].

The questionnaire comprises of four dimensions (areas of the questionnaire which assess different types of symptomatology): Urinary, Bowel, Vaginal and Sexual. Within each dimension are four to five scored domains. Domain scores are derived by dividing the sum of all item scores in that domain by the total possible item score and multiplying this by 100 to produce a scale ranging from 0 (best possible) to 100 (worst possible health status). Data for the present study were used anonymously from women who answered 'Yes' to the final item of the questionnaire, which seeks consent to allow confidential use of their answers for approved research projects.

Between January 2012 and September 2015, 2,905 women completed ePAQ-PF as part of their routine clinical care, prior to their first consultation in the urogynaeoclogy clinic. Two hundred and thirty two women (8%) declined consent for the use of their data for research, and a further 361 women did not complete the consent question. Therefore, data from 2,312 women were anonymised and transferred to SPSS (version 22) for analysis.

Table 1 shows the ePAQ-PF items included in the analyses of this study. Response options for all these items are on a four-point scale 'Never', 'Occasionally', 'Most of the time' or 'All of the time' and scored 0, 1, 2 or 3 respectively. The impact attributed to each of these symptoms is also recorded, using a standard sub-question *'How much of a problem is this for you?'* and graded as 'Not a problem', 'A bit of a problem', 'Quite a problem' or 'A serious problem' and scored 0, 1, 2 and 3 respectively. Frequency and bothersomeness are thereby assessed for each symptom. Figure 1 shows the ePAQ-PF item relating to coital incontinence. The domain score for OAB is derived from items 21 to 24 and that for SUI from items 28-32 (Table 1).

Both Spearman's rank and logistic regression were used to measure the association between coital incontinence symptoms (items Q101, Q102 and Q103) with symptoms of OAB and SUI (items Q21-32). Mann-Whitney Test was used to compare self-avoidance of sex, (Q98) partner-avoidance of sex (Q99) and interference of sex with enjoyment of life (Q122) in women with and without CI.

ePAQ-PF also includes a free-text question which asks: *'Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?'*. All free

text responses were reviewed to evaluate self-reporting of sexual concerns and goals, including free-text responses specifically related to coital incontinence.

Subgroup analysis was undertaken in 84 women who underwent tension-free vaginal tape (TVT) procedure, in order to evaluate whether treatment of SUI is associated with changes in coital incontinence. Data from consenting patients who underwent TVT between 2012 and 2015 and completed ePAQ-PF both pre- and three-months post operatively were included in the study. All women reported stress urinary incontinence and underwent urodynamics in line with ICS guidelines [14]. It is the usual practice at Sheffield Teaching Hospitals to complete urodynamic studies before undertaking surgery for stress urinary incontinence. Paired Student t Test was used to compare the pre- and post-operative OAB and SUI domain scores in women reporting coital incontinence pre-operatively. Wilcoxon signed ranks test was used to compare pre- and post-operative symptoms of CI.

Demographic details for consenting patients undergoing TVT were collected from the standardised anaesthetic pre-operative assessment and include body mass index (BMI), smoking status, hypertension, sleep apnoea, depression or anxiety, diabetes and American Society of Anesthesiologists (ASA) grade. Demographic data and co-morbidities were compared between patients reporting pre-operative coital incontinence and those who did not. BMI was compared using student *t* test. The proportion of hypertension, smoking, diabetes, sleep apnoea, depression and anxiety in patients reporting coital incontinence and those who did not was compared with Pearson Chi-Square and Fisher's Exact tests, depending on the prevalence of the co-morbidities. ASA scores were compared using the Mann-Whitney U test. The reasons for the four different statistical tests for demographic features, were the different data types: BMI was of continuous

data type, (student T test), ASA score was of ordinal data type (Mann-Whitney U test) and co-morbidity and smoking status of categorical data type (Pearson Chi-Square test or Fisher Exact test, depending the prevalence of each item).

Results

Prevalence of coital incontinence

Between January 2012 and September 2015, 2,312 women completed ePAQ-PF and gave consent for the use of their data. Of these, 1,573 completed Q_{101} regarding coital incontinence, of whom 477 (30.3%) reported the presence of this symptom. The overall prevalence of coital incontinence was 21% (477 of 2,312). The question on orgasm coital incontinence was answered by 1,533 women, of whom 369 (24.1%) reported the presence of this symptom (16% overall). The question of penetration coital incontinence was answered by 1,532 women, of whom 230 (15.0%) reported the presence of this symptom (10% overall).

The item on urinary incontinence was answered by 2,294 women, of whom 1,438 reported this symptom. Amongst those women reporting urinary incontinence, 946 answered the question on coital incontinence, of whom 451 (47.7%) reported the presence of the symptom. Of the women without urinary incontinence, 26 reported coital incontinence (1%).

Association between coital incontinence, SUI and OAB scores

Three binomial logistic regression models were used to explore the relationship between SUI and OAB symptoms with coital incontinence, orgasm incontinence and penetration incontinence. Symptoms of OAB ($p<0.005$) and SUI ($p<0.005$) were shown to be significant and independent predictors of coital incontinence.

Increasing OAB domain scores were associated with increasing odds of coital incontinence (OR=1.042 95%CI, 1.035 to 1.050, p <0.0005), orgasm incontinence (OR=1.035 95%CI, 1.028 to 1.042, p <0.001) and penetration incontinence (OR=1.038 95%CI, 1.030 to 1.045, p <0.001). Increasing SUI domain scores were associated with increasing odds of coital incontinence (OR=1.017 95%CI, 1.009 to 1.024, p <0.0005), orgasm incontinence (OR=1.011 95%CI, 1.004 to 1.019, p =0.003) and penetration incontinence (OR=1.024 95%CI, 1.015 to 1.033, p <0.001). These data are all statistically significant, but the magnitude of the effect is relatively low, possibly due to the large sample size.

Spearman's Rank Order Correlation showed similar results of moderate statistically significant association between coital incontinence symptom score with both SUI (Rs=0.410, p<0.001) and OAB (Rs=0.540, p<0.001); orgasm incontinence with SUI (Rs=0.339, p<0.001) and OAB (Rs=0.462, p<0.001); penetration incontinence with SUI (Rs=0.361, p<0.001) and OAB (Rs=0.443, p<0.001). These results are displayed as product plots in figure 2.

Coital incontinence with impact on sex

Mann-Whitney Test was used to compare reported self-avoidance of sex due to bladder problems, partner-avoidance of sex due to bladder problems and overall interference of sex with enjoyment of life and the impact of each of these in women who reported coital incontinence compared with those who did not. This showed significant self-avoidance of sex (p<0.0005), partner avoidance of sex (p<0.0005) and lower quality of life due to sexual problems (p<0.0005), compared with those without coital incontinence (Table 2).

Pre-operative symptom profiles in women undergoing TVT

Pre and post operative ePAQ-PF data were available for 84 women who gave consent for the use of their data. Coital incontinence was reported by 45 (54%). Table 3 shows a comparison of pre-operative symptom profiles between women with and without coital incontinence.

This analysis found that women reporting coital incontinence were significantly younger than those who did not (Mean age 48 vs. 55) ($t(67)= 3.448$, $p= 0.001$). The BMI of women reporting orgasm incontinence ($t(56)= -2.750$, $p=0.008$) and penetration incontinence ($t(57)= -3.205$, $p=0.002$) was significantly higher than that of patients without coital incontinence.

TVT outcome

Paired *t* test was used to compare pre-operative and post-operative OAB and SUI domain scores in all 84 women undergoing TVT and found significant improvement in all the symptoms analysed (Table 4). Wilcoxon signed rank test was used to conduct sub-group analysis in the 45 women undergoing TVT who reported coital incontinence pre-operatively (55%). This found significant improvement in the reporting of any coital incontinence, orgasm incontinence and penetration incontinence following TVT (table 5). Of the 45 patients with coital incontinence, 37 completed follow up at three months. Of these, 27 (72%) had improved nine (20%) reported no change and one (3%) worsened ($p<0.001$).

The association between cure of SUI following TVT and the presence of pre-operative coital incontinence (coital incontinence, orgasm incontinence and penetration incontinence) was analysed using Pearson Chi-Square test and Fisher's Exact test. The presence of coital incontinence pre-operatively was not associated with the outcome in terms of SUI ($X^2= 1.001$,

p=0.317); neither was pre-TVT orgasm incontinence status (X^2= 2.745, p=0.098) or pre-TVT penetration incontinence status (X^2= 1.983, p=0.159).

Free-text analysis

The free-text item relating to 'Greatest concerns' was completed by 1,261 women (55%), 24 of whom used free-text to report concerns regarding sexual function (1%). Four women explicitly reported coital incontinence, five said that they wanted to improve or resolve problems in their sex life, but did not detail the specific problem. Three women reported reduced sensation during sex and twelve reported painful sexual intercourse.

Discussion

The primary objective of this study was to investigate the prevalence of coital incontinence and its association with SUI, OAB and sexual function in women attending a urogynaecology clinic.

The main findings are that coital incontinence is reported by approximately one in five women attending urogynaecology clinics and is associated with avoidance of sexual activity. Coital incontinence is associated with both SUI and OAB, regardless of whether this occurs at orgasm or on penetration. Following TVT, 60% of women reported cure in coital incontinence.

The main weakness of this study is its observational nature and that data on other aspects of sexual function, sexuality and relationship status were not available. We are therefore unable to

comment on other factors which may affect sexual function and coital incontinence; including menopausal status and other physical and mental health issues. Detailed demographic data for the 2312 women are also lacking, including parity and ethnicity.

This is however the largest study to-date relating to coital incontinence in women attending a urogynaecology clinic, which has found a prevalence of 21% overall, 30% in women willing to answer questions about sexual function and 47% in women reporting urinary incontinence. The results are comparable to a previous study in an earlier cohort of women in our unit, which found a coital incontinence prevalence of 60% in women undergoing urodynamic studies for urinary incontinence [5].

Previous studies have shown rates of coital incontinence in women attending urogynaeoclogy clinics of up to 24%[2, 4] If the prevalence of coital incontinence is assessed only in women with urinary incontinence the rates have been shown to vary between 10% - 66% [5][6][15][16][17][18].

Including this study, three studies have assessed coital incontinence in women attending a urogynaecology clinic. The prevalence was 10% [15] when direct questioning was used to assess prevalence and 36% [6] and 47% when a validated questionnaire (KHQ or ePAQ-PF) was used. Four studies assessed the prevalence of coital incontinence in women undergoing urodynamics. Two of these studies used direct questioning to assess this and both found a prevalence of 11% [8][18]. The other two studies used validated (ePAQ-PF) or non-validated (author's own) questionnaires to assess prevalence and found it to be 60% [5] and 66% [17] respectively. The substantially higher prevalence of coital incontinence in women undergoing urodynamics,

compared with women attending a urogynaecology clinic, is likely to be a reflection of more severe symptoms in women undergoing urodynamics.

It is apparent that using a questionnaire, substantially increases disclosure and therefore the reported prevalence of coital incontinence, compared with direct questioning. This may be due to embarrassment and the taboo nature of this intimate problem.

Using ePAQ-PF to assess coital incontinence has the advantage of specifically enquiring about urinary coital incontinence and when it occurs- with orgasm or penetration. Other questionnaires used widely within urogynaecology do not assess coital incontinence as comprehensively. The Pelvic organ prolapse urinary Incontinence Sexual Questionnaire (PISQ) doesn't differentiate between faecal and urinary incontinence during intercourse and doesn't assess if the incontinence occurs with orgasm or penetration, the International Consultation on Incontinence modular Questionnaire- Short Form (ICIQ-SF) does not ask about coital incontinence or sexual issues at all and the Kings Health Questionnaire (KHQ), whilst it does assess the prevalence of coital urinary incontinence, doesn't distinguish between orgasm incontinence and penetration incontinence.

We found that orgasm coital incontinence was significantly associated with the reporting of both symptoms of both SUI and OAB. Likewise, penetration incontinence was also significantly associated with symptoms of both SUI and OAB. Studies have previously linked orgasm incontinence to OAB, demonstrating higher rates of detrusor overactivity during urodynamics in women with orgasm incontinence than in women with penetration incontinence [2, 7, 18]. Penetration incontinence has similarly been linked to stress urinary incontinence [15, 17].

However, larger and more recent studies have found no significant relationship between urodynamic diagnosis and penetration or orgasm incontinence [5]. It has also been shown that both Urodynamic Stress Incontinence (USI) and Detrusor overactivity (DO), but *not* DO incontinence, are both significantly associated with coital incontinence [8]. As seen in table four, both orgasm incontinence and penetration incontinence were significantly improved following TVT, suggesting a similar aetiology for coital incontinence in women with these symptoms.

There is a significant overlap between women who have coital incontinence at penetration and coital incontinence at orgasm, with 26% of women in our study group reporting both symptoms. Therefore, attempting to separate orgasm and penetration coital incontinence into different diagnostic groups may not be helpful or meaningful; many women have elements of both and the symptoms may not be indicative of distinct pathophysiological entities.

A previous anatomical study used MRI to measure the pubococcygeal line, hiatal width and levator descent to assess pelvic organ prolapse in 60 women with coital incontinence, compared with a control group of 30 women with urinary incontinence but no coital incontinence. No MRI features were identified that were significantly associated with coital incontinence in that study[17]. Proposed mechanisms for coital incontinence include increased abdominal pressure during intercourse, which may vary depending on position; increased abdominal pressure due to contraction of abdominal muscles during orgasm and straightening of the urethra during deep penetration [19]. The precise mechanism is however not fully understood.

Urinary incontinence is well known to cause sexual dysfunction [20-22]. It is clear from the present study that women with coital incontinence commonly avoid sex, their partners

commonly avoid sex with them and they have a significantly impaired sexual function compared with women without coital incontinence. In a study of 633 women with urinary incontinence, assessed using the King's Health Questionnaire (KHQ), women with coital incontinence were observed to have significantly worse scores in all KHQ dimensions and global score [6]. A logistic regression model in the study found that the only variable which demonstrated independent association with the KHQ global score was coital incontinence (*B*=10.1, 95% CI=1.7-18.5). A further study of 180 women using the Bristol Female Lower Urinary Tract Symptoms questionnaire and the Medical Outcomes Study Short Form (SF-36) questionnaire observed that women with coital incontinence had more health-related quality of life impairment than those without coital incontinence [23]. A qualitative study of 37 women scheduled for pelvic floor surgery using semi-structured interviews found that nine of the 37 women had experienced coital incontinence [24]. These women tried to avoid coital incontinence by emptying their bladders before intercourse and also avoided certain sexual positions, hurried through sex so that it would be over quicker, avoided orgasm and did self-directed pelvic floor muscle training. These measures were reportedly successful in four of the nine patients.

It is clear that coital incontinence causes embarrassment to women [25] and leads to avoidance of sex which in turn affects quality of life. Previous studies addressing the prevalence of coital incontinence and its associations have shown that coital incontinence is a rarely volunteered symptom. Only two of 400 women in Hilton's study paper [2] and one of 100 in Gordon's study [4] volunteered that they had coital incontinence prior to questioning. Urinary symptoms may be the presenting complaint in women who have an underlying sexual problem [25], it is therefore important to routinely enquire about coital incontinence in women attending the urogynaecology

clinic. In our study, of 2,312 women completing ePAQ-PF, only 1% used the free-text items to report a sexual problem, and only four recorded that they had coital incontinence using free text. It is also clear from the differing prevalence rates of coital incontinence in women with urinary incontinence observed in previous studies that using an appropriate questionnaire will help identify women experiencing this symptom. There is evidence that patients may feel more comfortable disclosing embarrassing or intimate issues through use of a computer questionnaire than during a conventional consultation [26]. By using a validated questionnaire to identify women experiencing coital incontinence, a more open and honest consultation can be afforded and more appropriate treatment planned. It has been shown that electronic questionnaires can increase discussion rates in women with urinary incontinence [8] and seems likely that this is also the case for coital incontinence.

Our study found significant improvement in SUI and OAB at three months follow-up in women undergoing TVT. There was also a statistically significant improvement in coital incontinence at penetration, orgasm and overall. Coital incontinence was not shown to be a predictor for poorer outcome at TVT in this study.

In previous studies, TVT has been shown to improve sexual function. In 2007 Jha et al reported improved sexual function at six months post-operatively in 54 women assessed using PISQ-12 [27]. The study showed that coital incontinence was significantly reduced after TVT, with 38 women being affected pre- and 15 post-operatively ($p<0.002$). In 2009 Bekker et al showed that women with coital incontinence show a significantly higher improvement in sexual function at three to twelve months post-op (61 TVT, 32 TVT-O and 43 TOT), compared with those without

coital incontinence [16]. The authors concluded that coital incontinence is a prognostic factor for improvement in sexual function after incontinence surgery.

Glavind et al in 2014 observed that in 51 women undergoing TVT, sexual function significantly improved and coital incontinence assessed by PISQ-12 was significantly reduced ($p<0.005$) at six months post-operatively [28]. The same authors subsequently published a follow-up study in this group, with 44 patients followed up at both at six months post TVT and again at a mean of four years and nine months [29], showing that sexual function and coital incontinence remained significantly improved at long-term follow-up, with no significant differences between six month and long term follow up.

In a previous study, Serati et al used antimuscarinics (tolteridine 4mg) to treat women with coital incontinence at orgasm, and observed inferiority in the treatment of OAB, compared with women without orgasm CI, supporting the view that incontinence at orgasm is either a marker of more severe detrusor overactivity or that it is more of a marker for SUI [18]. The improvement in coital incontinence post TVT lends support to this latter theory.

The demographics of the patients with coital incontinence in our study group undergoing TVT showed that younger age was a significant co-factor for coital incontinence, which is likely to be related to higher levels of sexual activity in this age group. Raised BMI was also a risk factor for both penetration and orgasm coital incontinence. This was also demonstrated in the study by Madhu et al [8], which also observed a significant association between coital incontinence and cigarette smoking and antidepressant use. High BMI is an established risk factor for urinary incontinence [30] and this is thought to be due to increased intra-abdominal pressure and

increased stress on the pelvic floor. This again points towards a stress related mechanism rather than a detrusor over activity mechanism for coital incontinence.

In conclusion, the present study has found coital incontinence to be highly prevalent and affects more than half of women with urinary incontinence. It is also a rarely volunteered symptom and even on direct questioning, women may not admit to coital incontinence. The value of questionnaires to help in the assessment of women in this context cannot be underestimated. Coital incontinence has a significant negative impact on sexual function and results in avoidance by both partners. Both coital incontinence at orgasm and penetration are significantly associated with both SUI and OAB. and should not be considered completely separate entities. TVT results in a significant improvement in coital incontinence symptoms and improves sexual function for women with SUI. Further studies, including multiple centres using ePAQ-PF, are needed to confirm and develop these findings. Further research into the precise mechanisms of coital urinary incontinence are required.

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Urinary dimension

- Q_{21} Do you suddenly get a strong urge to rush to the toilet to pass urine?
- Q_{22} When you get the urge to go, does urine start to leak before you can make it to the toilet?
- Q_{23} Does urine leak when you wash your hands or hear the sound of running water?
- Q_{24} Does urine leak when you are opening or unlocking your door to your home?
- Q_{28} Does urine leak when you cough?
- Q_{29} Does urine leak when you sneeze?
- Q_{30} Does urine leak when you exercise, lift things, jump or run?
- Q_{31} Does urine leak with movements such as standing up, bending down or getting dressed?
- Q_{32} Does urine leak when you are walking?

Sexual dimension

- Q_{98} Do you avoid sexual activity because of your bladder or urinary problems?
- Q_{99} Do you feel that your partner avoids sexual activity with you because of your bladder or urinary problems?
- Q_{101} Does urine leak when you have sexual intercourse?
- Q_{102} Do you leak urine when you have an orgasm?
- Q_{103} Does urine leak at the start of sexual intercourse?
  (i.e. on penetration)
- Q_{122} Overall, how much do sexual problems interfere with your enjoyment of life?

Table two
The frequency and impact of coital incontinence on self-avoidance and partner avoidance of sex and interference with enjoyment of life.

	Coital incontinence positive	Coital incontinence negative	*p*-value
Self-avoidance	365.74	586.34	$p < 0.0005$
Impact of self-avoidance	356.22	596.77	$p < 0.0005$
Partner-avoidance	411.92	515.84	$p < 0.0005$
Impact of partner-avoidance	407.53	520.74	$p < 0.0005$
Overall enjoyment of life	338.08	610.44	$p < 0.0005$
Impact of overall enjoyment of life	332.65	616.40	$p < 0.0005$

Table three: Comparison of pre-operative symptom profiles between women with coital incontinence and without coital incontinence, with details of statistical test used and significance level. Complete demographic details were available for 56 participants, 36 with coital incontinence and 23 without.

a. Coital incontinence

	Coital incontinence positive (n)	Coital incontinence negative (n)	Statistical test used	Significance
Age	48.3± 8.0	55.46± 8.8	*Student t Test*	$t(67)= 3.448$, $p= 0.001$
BMI	30.4± 5.6	28.0± 5.7	*Student t test*	$t(57)= -1.616$, $p= 0.112$
Hypertension	10/36	7/23	*Pearson Chi Squared Test*	$X^2(1)= 0.48$, $p=0.826$
Smoking	6/36	2/23	*Fisher exact test*	$p=0.464$
ASA (Mean rank)	29.13	31.37	*Mann Witney test*	$U=382.500$, $p=0.580$
Diabetes	0/36	2/23	*Fisher exact test*	$p=0.516$
Sleep apnoea	5/36	2/23	*Fisher exact test*	$p=0.694$
Depression	5/36	3/23	*Fisher exact test*	$p=1.000$
Anxiety	1/36	2/23	*Fisher exact test*	$p=0.554$

b. Orgasm coital incontinence

	Orgasm coital incontinence positive (n)	Orgasm coital incontinence negative (n)	Statistical test used	Significance
Age	49.0± 8.2	52.9± 9.3	*Student t Test*	$t(66)= 1.824$, $p= 0.073$
BMI	31.6± 5.9	27.7± 5.1	*Student t test*	$t(56)= -2.750$, $p= 0.008$*
Hypertension	10/28	7/30	*Pearson Chi Squared Test*	$X^2(1)= 1.071$, $p=0.301$
Smoking	5/28	2/30	*Fisher exact test*	$p=0.246$

ASA (Mean rank)	31.23	27.88	*Mann Witney test*	*U*=371.500, *p*=0.394
Diabetes	1/28	1/30	*Fisher exact test*	*p*=1.000
Sleep apnoea	3/28	3/30	*Fisher exact test*	*p*=1.000
Depression	6/28	3/30	*Fisher exact test*	*p*=0.290
Anxiety	2/28	1/30	*Fisher exact test*	*p*=0.605

c. Penetration coital incontinence

	Penetration coital incontinence positive (n)	Penetration coital incontinence negative (n)	Statistical test used	Significance
Age	50.2± 7.7	51.1± 9.6	*Student t Test*	*t*(67)= 0.370, *p*= 0.0713
BMI	32.6± 6.1	27.9± 4.9	*Student t test*	*t*(57)= -3.205, *p*= 0.002*
Hypertension	8/20	9/39	*Pearson Chi Squared Test*	X^2(1)= 1.846, *p*=0.174
Smoking	5/20	3/39	*Fisher exact test*	*p*=0.106
ASA (Mean rank)	34.43	27.73	*Mann Witney test*	*U*=301.500, *p*=0.109
Diabetes	2/20	0/39	*Fisher exact test*	*p*=0.111
Sleep apnoea	4/20	3/39	*Fisher exact test*	*p*=0.213
Depression	4/20	4/39	*Fisher exact test*	*p*=0.424
Anxiety	0/20	3/39	*Fisher exact test*	*p*=0.544

Table four: Paired *t* test was used to compare the pre-operative and post -operative OAB and SUI domain scores in all 84 women undergoing TVT.

	Pre-operative domain score	Post-operative domain score	Significance
OAB Domain of ePAQ-PF	30.59±19.46/100	18.99±19.70/100	$t(78)= 5.557$, $p< 0.001$
SUI Domain of ePAQ-PF	58.72±23.42/100	14.70±27.04/100	$t(77)= 12.032$, $p<0.001$

Table five

Wilcoxon signed ranks test was used to compare the pre-operative and post-operative symptoms of coital incontinence, orgasmic coital incontinence and penetrative coital incontinence. It showed that there was significant improvement in all the symptoms analysed.

	Positive pre-TVT	Improvement	Worsening	No change	Significance
Coital Incontinence	45/84	27/37	1/37	9/37	$Z = -4.639$, $p < 0.001$
Orgasm Coital Incontinence	35/84	20/26	0/26	6/26	$Z = -4.030$, $p < 0.001$
Penetration Coital Incontinence	25/84	14/19	0/19	5/19	$Z = -3.402$, $p = 0.001$

Fig.1 The electronic Personal Assessment Questionnaire-Pelvic Floor item relating to coital incontinence

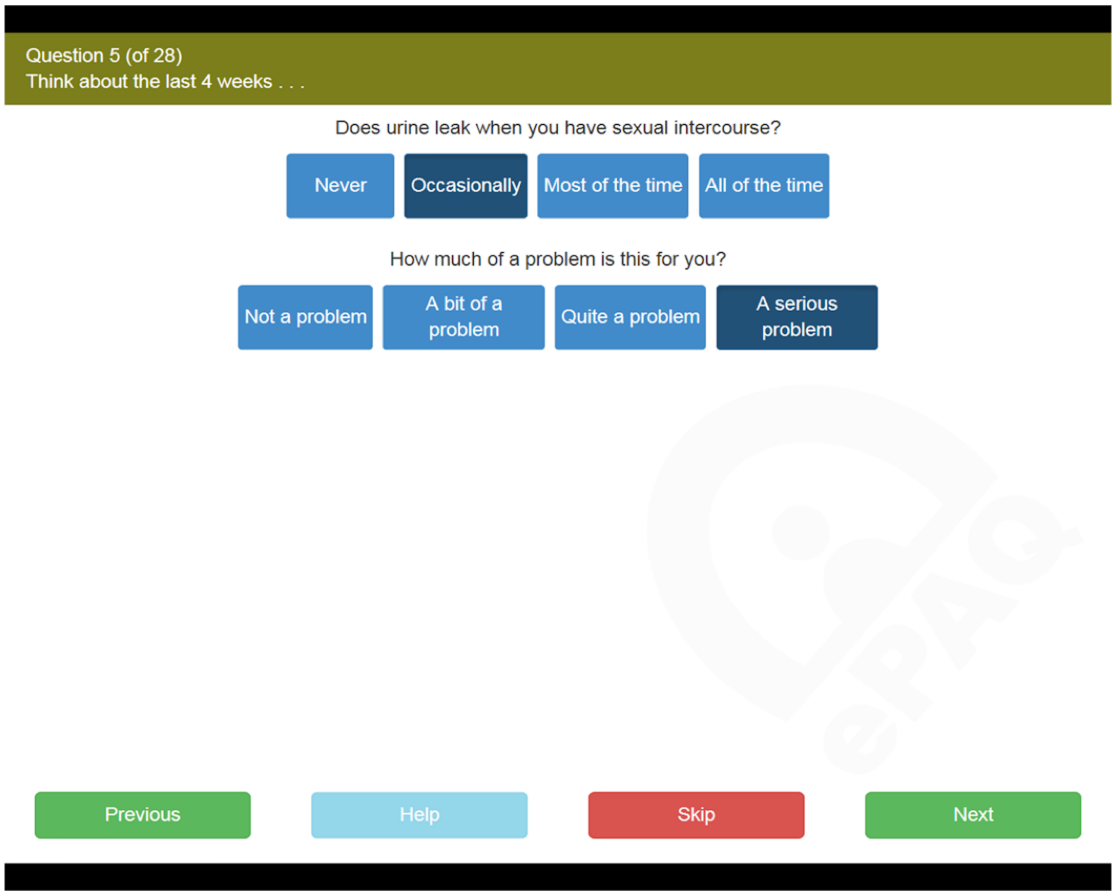
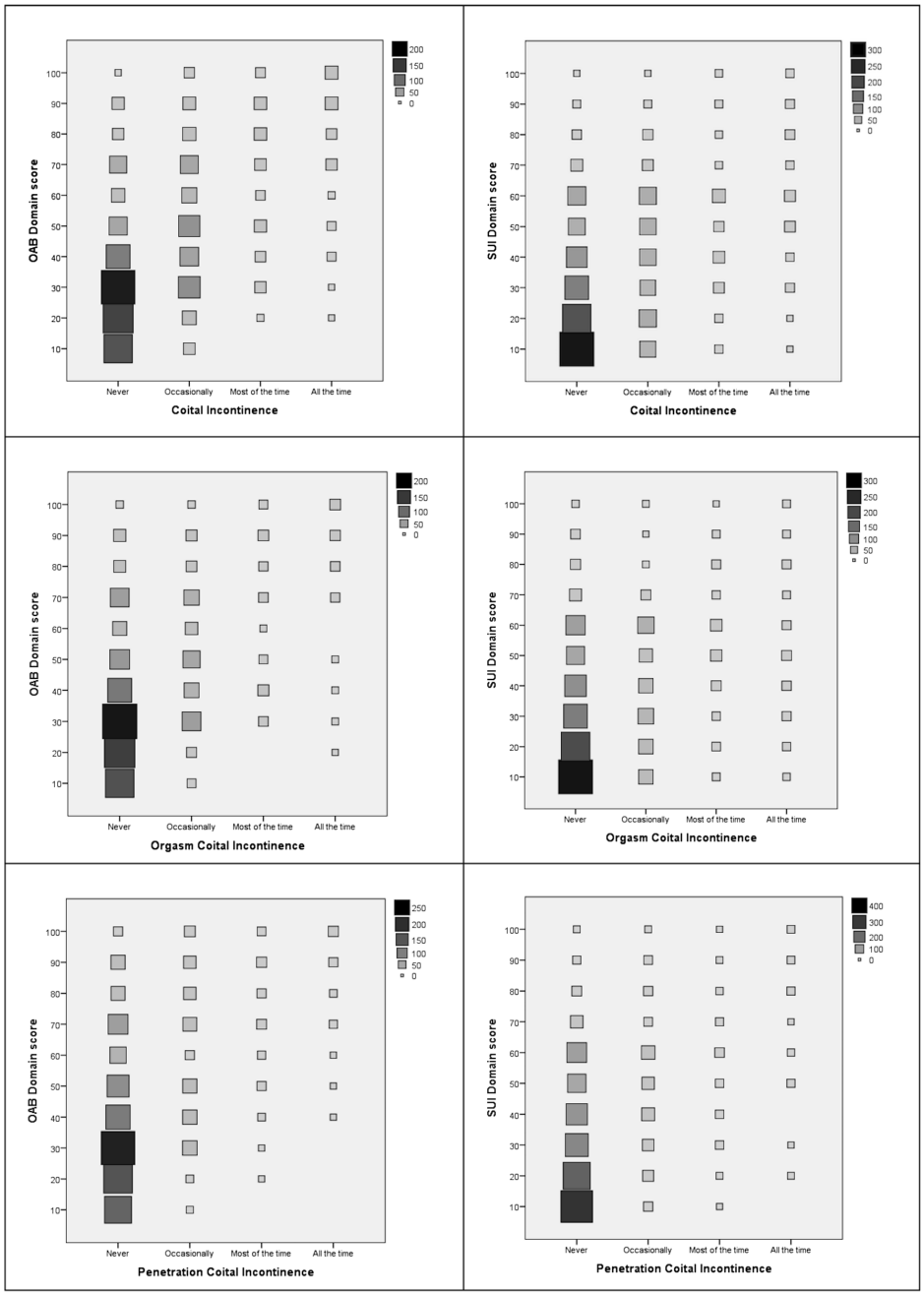


Figure 2: Product plots showing the correlation between domain scores for stress urinary incontinence (SUI) and overactive bladder (OAB) with overall reported coital incontinence, coital incontinence at orgasm and that at penetration. The shading of each square displayed varies depending on the number of patients reporting the specific frequency of coital incontinence symptoms (never, occasionally, most of the time, all of the time) and having a particular domain score (0–100)



7.6: Paper 6: Gray T, Money-Taylor J, Li W, Farkas AG, Campbell P, Radley SC. What is the effect of body mass index on subjective outcome following vaginal hysterectomy for prolapse? International Neurourology Journal. 2019;23(2):1-8.

Abstract

Purpose

Obesity is a significant risk factor for pelvic organ prolapse (POP), but the effects of obesity on outcomes of surgery for POP are poorly understood. The aim of this study was to assess the relationship between POP symptomatology, subjective outcomes of surgery and body mass index (BMI) in women undergoing vaginal hysterectomy for POP.

Methods

Pre- and post-operative data from a validated pelvic floor questionnaire (ePAQ-PF) were collected prospectively from 60 women undergoing vaginal hysterectomy for POP. Of these, 20 were normal weight (BMI 18.5 – 24.9), 20 were overweight (BMI 25 – 29.9) and 20 were women with obesity (BMI 30 – 34.9). The relationship between BMI and symptom scores for prolapse, impact on vaginal symptoms on quality of life (VS-QoL) and 'overall change in condition' was assessed. Pre- and post-operative symptom scores were compared using repeated mixed ANOVA test for BMI as a categorical variable (Normal, Overweight and Obese). Spearman's rank order correlation test was carried out to evaluate BMI as a continuous variable. All women underwent vaginal hysterectomy using a standardised technique.

Results

Overall, 93% of women reported improvement in their condition. The main finding was that 'Overall change in condition' was negatively correlated with increasing BMI (r_s= -0.324,

p=0.028). Irrespective of BMI, significant improvements were observed in symptoms of prolapse and VS-QoL at three-months post operation.

Conclusions

With increasing BMI, women are likely to report lower levels of satisfaction following prolapse surgery, despite reporting equivalent improvements in symptoms. BMI is known to affect how individuals perceive their general health and well-being with obese individuals reporting poorer levels of subjective health status. Women with obesity may perceive change in their condition after prolapse surgery differently to women of normal weight. Reduction of weight prior to prolapse surgery could be considered in obese women to improve subjective outcomes of surgery.

MeSH Key words

Obesity, Patient outcome assessment, Pelvic organ prolapse, Hysterectomy

Highlights

- Obesity is a risk factor for pelvic organ prolapse.
- Data on impact of BMI on outcomes of prolapse surgery is limited.
- Impact of obesity on subjective outcomes following hysterectomy was assessed.
- Women with obesity reported less impact of prolapse on quality of life (*p*=0.032).
- Increasing BMI is associated with poorer subjective outcome (p=0.028).

Introduction

Pelvic organ prolapse (POP) is a common condition for which the estimated lifetime risk of undergoing surgery is 12.6% [1]. Despite the global rise in the prevalence of obesity, defined as body mass index greater than or equal to 30, little is known regarding the relationship between obesity and surgical outcomes in this field [2].

An association between increasing obesity and prevalence of prolapse has been reported by several authors, including data from a number of large population-based surveys [3-8]. Obesity is recognised as a risk factor for progression of pelvic organ prolapse [9] and is the strongest identified risk factor for post-hysterectomy vaginal vault prolapse [10].

The impact of obesity on outcomes of prolapse surgery has been reported in relatively few studies. Anatomical and functional outcomes following abdominal sacrocolpopexy do not appear to be affected by obesity [11-13], whereas a study of women undergoing sacrospinous ligament fixation with anterior mesh repair reported less improvement in prolapse symptoms in the obese group [14].

The increasing prevalence of obesity is likely to lead to increasing prevalence of symptomatic POP. Improving our understanding of how obesity relates to perception and reporting of symptoms, impact on quality of life and outcomes of surgery will help to inform decision making and ensure that both clinicians and patients have a good understanding and realistic expectations of outcome. To our knowledge, the relationship between obesity and outcome following vaginal hysterectomy for uterine prolapse has not been reported. The aim of the present study was to compare subjective outcomes of surgery in women of normal weight, overweight and obesity, undergoing vaginal hysterectomy for POP, using prospectively collected data from a validated pelvic floor symptom questionnaire (ePAQ-PF) [15].

Materials and methods

The study included all women undergoing vaginal hysterectomy at Sheffield Teaching Hospitals NHS Foundation Trust, UK, during the three year study period who completed ePAQ-PF pre-operatively and three months post-operatively, with documented Body Mass Index (BMI) and patient consent for their data to be used for research.

Women who attend our unit complete the ePAQ-PF questionnaire as part of routine assessment. This provides detailed symptom and health-related quality of life (HRQoL) data, as well as recording BMI and patient consent for use of their data in research and service evaluation.

The electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) is a validated web-based interactive questionnaire which provides an in-depth evaluation of a woman's pelvic floor symptoms and their impact upon her HRQoL [15, 16]. The questionnaire can be completed online, or using a touch-screen computer terminal in clinic. The questionnaire presents up to 132 items and was designed to improve communication and detailed assessment by providing patients with an opportunity to report symptoms of an intimate and sensitive nature, many of which might be difficult to express face-to face [17, 18]. The questionnaire covers dimensions of urinary, bowel, vaginal and sexual function.

For this study, the following items from ePAQ-PF questionnaire were assessed.

Comparison of pre- and post-operative *vaginal prolapse domain scores* and *impact*. Domain score is a composite of responses to the following questions on the ePAQ questionnaire;

- Q_{84} Do you feel that something is dropping down inside your lower abdomen or vagina?

- Q_{85} Do you feel that your vagina is too loose or too lax?
- Q_{86} Do you feel a lump or bulge coming down in your vagina?
- Q_{87} Do you feel a lump or bulge that comes out of your vagina altogether, so that you can feel it or see it on the outside?

Response options are 'Never', 'Occasionally', 'Most of the time' or 'All of the time' and scored 0, 1, 2 or 3 respectively. Symptom impact is graded as 'Not a problem', 'A bit of a problem', 'Quite a problem' or 'A serious problem' and scored 0, 1, 2 or 3 respectively. Domain scores are calculated by dividing the sum of all item scores in the domain by the maximum total possible score and multiplying this by 100, to produce a scale ranging from 0 to 100. On this scale, a score of 0 indicates the best and 100 indicates the worst possible health status.

Analysis of pre- and post-operative responses to individual POP symptoms relating to;

'Awareness of something coming down (SCD)' (Q_{84})

'Vaginal laxity' (Q_{85})

'Awareness of a vaginal lump or bulge' (Q_{86})

Comparison of pre- and post-operative *vaginal symptoms quality of life* scores (VS-QoL) generated from responses to three questions;

'Overall, how much do vaginal problems interfere with your enjoyment of life?'

'Do you have any vaginal problems that interfere with physical activity?'

'Do you have any vaginal problems that interfere with social activity?'

Assessment of *overall change in condition* based on a validated 7-point scale; 0 = Very much worse, 1 = Much worse, 2 = A little worse, 3 = No change, 4 = A little better, 5 = Much better, 6 = Very much better.

Four surgeons carried out the hysterectomies included in this study, using a standardised technique. All women undergoing vaginal hysterectomy and vaginal wall repair had a procedure using absorbable suture materials only. No mesh inlays or non-absorbable suture materials were used as part of surgery. All women had Mc'Call's culdoplasty to unite the uterosacral ligaments in the midline and obliterate the deadspace where a potential enterocoele could form. The uterosacral ligaments were also fixed to the vault and tied across the midline. Concomitant native tissue anterior vaginal wall repair was undertaken if point Aa on the pelvic organ prolapse quantification grid was within 1cm of the hymenal ring. Likewise, concomitant native tissue posterior wall repair was undertaken if point Ap on the pelvic organ prolapse quantification grid was within 1cm of the hymenal ring. All patients who had a sacrospinous fixation had this undertaken with a Capio Slim™ device (Boston Scientific) and 2.0 PDS was the suture material used.

Ethical approval was obtained from The University of Sheffield. Data were anonymised and statistical analysis was undertaken using SPSS (version 22). Pre- and post-operative symptom scores were compared using a repeated mixed ANOVA test for BMI as a categorical variable (Normal: 18-24.9, Overweight: 25-29.9 and Obese: 30-35). Spearman's rank order correlation test was also carried out to evaluate BMI as a continuous variable.

Results

In total 60 women were included in the study and completed ePAQ-PF both pre-operatively and three months post operatively during the study period. Of these 60 women, 20 were of normal weight, 20 were overweight and 20 were women with obesity. The average age for the cohort was 63 (range 37 – 88 years). The average age in the normal BMI group was 63.2, in the overweight group it was 61.6 and in the obese group it was 64.8. The average parity for the cohort was 2.4. The average parity in the normal BMI group was 2.4, in the overweight group it was 2.5 and in the obese group it was 2.35. When assessed by student's t test, there was no significant difference in age for women with normal BMI compared with overweight BMI (p= 0.24), normal BMI compared to obese BMI (p= 0.33) and overweight BMI compared with obese BMI (p= 0.13). There was also no significant difference in parity when assessed by Student's t test for women with normal BMI compared with overweight BMI (p= 0.37), normal BMI compared to obese BMI (p= 0.42) and overweight BMI compared with obese BMI (p= 0.30). All women in the study had uterine prolapse grade 2 or more using the pelvic organ prolapse quantification system. There was no statistically significant difference in age, parity or grade of prolapse between the three groups. Characteristics of the three BMI groups are reported in **Table 1.**

Fifty-six women underwent vaginal hysterectomy with anterior or posterior repair, two of whom underwent concomitant sacrospinous ligament fixation. Four women underwent vaginal hysterectomy, without vaginal wall repair. No other concomitant procedures were undertaken. All the surgical procedures undertaken are reported in **Table 1.**

Vaginal symptoms quality of life (VS-QoL) scores

The pre-operative impact of prolapse on vaginal symptoms quality of life (VS-QoL) was significantly less in women with obesity when compared with women in the overweight group (p=0.026) and normal weight group (p=0.032) (**Table 2**). Significant improvements were observed in VS-QoL scores post-operatively in all BMI groups (**Table 2**). There was no significant difference in degree of improvement between different BMI groups (p=0.102).

Overall change in condition

Forty-six women (77%) answered the global rating of outcome question, of whom 93% (n=43/46) reported improvement in their condition. One woman felt that there was 'No change' and two women felt that their condition was 'A little worse'. Surgery resulted in improvement in overall condition in all groups: normal weight group (4.9 ± 0.3), overweight group (4.6 ± 0.9) and obese group (4.5 ± 0.8). Analysing BMI as a continuous variable, BMI was significantly correlated with global rating of outcome; women with the higher BMI reporting poorer overall outcome (Spearman's rank-order correlation r_s=-0.324, p=0.028).

Prolapse symptoms domain scores

Significant improvement was seen in the prolapse symptoms domain score for all BMI groups (**Table 3**). Data from all patients combined (n=60) showed 91% improvement, from 55 ± 18 to 6 ± 14 (p<0.0005). There was no significant difference in the degree of improvement of prolapse symptoms with increasing BMI (repeated mixed ANOVA test, p=0.57, Spearman's rank-order correlation test (r_s=-0.104, p=0.44)). There was no

significant correlation between pre and post-operative prolapse impact scores and BMI (repeated mixed ANOVA test, p=0.223).

Prolapse symptom scores

The two most commonly reported symptoms of prolapse were 'Awareness of something coming down' and 'Awareness of a lump', reported by 97% and 95% of women respectively. 'Vaginal laxity' was reported by 48% of women. Data from all patients combined showed significant improvement in all symptoms (**Table 4**). Further analysis demonstrated no significant difference in degree of improvement of individual prolapse symptoms between different BMI groups (repeated mixed ANOVA tests, p>0.05).

Discussion

The aim of this study was to investigate the impact of BMI on subjective outcomes of vaginal hysterectomy for POP. The main finding is that patient-reported perception of overall improvement in their condition following hysterectomy for prolapse is negatively correlated with increasing BMI.

As women with raised BMI appear to be less satisfied with subjective outcome of surgery for POP, the potential merits of delaying surgery on patients with significantly raised BMI and POP should be considered. The increased intra-abdominal pressure associated with obesity which leads to associated pressure on the pelvic floor is the theoretical mechanism implicating obesity as a risk factor for POP. Therefore, weight loss should lead to

improvement in symptomatic prolapse and as this study shows, may also lead to improved subjective outcomes following surgery after weight loss.

However, the impact of weight loss on POP still remains unclear. As part of the Women's Health Initiative (WHI) trial, which investigated health issues in women taking hormone replacement therapy; 16,608 women were followed up over a five-year period to investigate the relationship between weight change and POP [9]. Although this study observed an association between weight gain and POP progression, weight loss was not associated with prolapse regression but in fact with borderline worsening of uterine prolapse [9]. Likewise, the impact of bariatric surgery on POP has demonstrated conflicting results, with one study reporting significant reduction in prevalence of symptoms of POP from 54% to 18% at 1 year follow up [19], while other studies have shown no effect [20-22]. In contrast, a weight loss programme for women with stress urinary incontinence reported (SUI) that women who lost 5-10% of their body weight were significantly more likely to achieve substantial reduction in SUI symptoms than women in a control group [23]. There is also strong evidence that bariatric surgery has significantly beneficial effects on SUI [24].

A common rationale for delaying surgery in morbidly obese patients with POP whilst they lose weight is to reduce the risk of intraoperative complications. However, only one study has reported complications of prolapse surgery specifically related to BMI, finding that obesity was protective against blood loss, transfusion and long-term urinary retention [25]. The retrospective design of this study may have introduced selection bias as it possible that women with obesity may have been managed differently. Evidence of a significant increase in risks of immediate complications during prolapse surgery in obese patients is lacking.

A further potential rationale for recommending weight loss to patients with POP prior to surgery, is to reduce the risks of recurrence. A small retrospective study of 69 women found that BMI was a significant risk factor for surgical failure at one year [26] and obesity has been associated with significant risk of recurrent anterior vaginal wall prolapse following anterior colporrhaphy [27]. Conversely, a five-year prospective study of 376 women undergoing prolapse and incontinence surgery found no association between obesity and recurrence [28]. Moreover, a systematic review from 2015 found that though higher BMI was a significant risk factor for primary pelvic organ prolapse, it was not a significant risk factor for recurrent prolapse [29]. Therefore, delaying surgery for POP whilst patients lose weight may not be beneficial for reducing complications or recurrence of the prolapse.

Comparison of our findings with other studies is limited, as only a few papers have reported the impact of obesity on outcomes of prolapse surgery. Obesity does not appear to affect anatomical or functional outcomes in women undergoing abdominal sacrocolpopexy [11-13]. A study involving women undergoing sacrospinous ligament fixation with anterior mesh, employing Asian BMI categories (where obesity is classed as BMI $\geq$27.5), reported less symptomatic improvement in women with obesity [14]. Whereas these studies involved the use of synthetic mesh to treat vault prolapse, the present study related specifically to women undergoing vaginal hysterectomy for prolapse, so results are not directly comparable.

Since increasing BMI was associated with a lesser degree of overall improvement in condition and improvement in POP symptoms was not related to BMI, perception of outcome may be related to factors other than impact of prolapse surgery on prolapse symptoms. Body mass index affects how individuals perceive their general health and well-being [30] and

obesity is associated with impaired health related quality of life and poor levels of subjective health status [31]. A population survey of 2000 people in America reported decreased HRQoL with increasing obesity, even without the presence of chronic disease [31], and in a population survey of almost 10000 people in Australia who completed the Short Form Health Survey (SF-36), high BMI was associated with reduced levels of physical and mental well-being [32]. The assessment of 'overall change in condition' in the present study is a subjective measure of treatment outcome. Women with obesity may perceive change in their condition differently to women of normal weight.

The ePAQ VS-QoL score is generated from responses to questions relating to the impact of vaginal symptoms on physical and social activity and enjoyment of life. Women with obesity and POP reported significantly less impact of prolapse on their vaginal symptoms quality of life (VS-QoL) pre-operatively than normal weight or overweight patients, a possible explanation for this being a relationship between physical activity and BMI. Women with obesity may be less likely to engage in physical activity than women of normal weight and therefore report less impact of prolapse on their quality of life. This finding may relate specifically to prolapse as it contrasts with published reports of impaired health related quality of life with increasing BMI.

The main limitations of our study are the short follow up period (three months) and lack of pre- and post-operative objective data, including pelvic organ prolapse quantification (POP-Q) scores. It is possible that patients who were unsatisfied with their surgery may have disengaged from the follow up process and not completed the post-op questionnaire that

was requested, thereby introducing reporting bias. However, our comprehensive pre- and post-operative questionnaire data from 60 patients undergoing vaginal hysterectomy for prolapse has permitted a detailed comparison of subjective outcomes between different BMI groups in this small study.

In conclusion, we suggest that with increasing BMI, women are likely to be satisfied to a lesser degree with the outcome of prolapse surgery. This may have important implications in pre-operative counselling and management of patients. Future studies should investigate the impact of obesity on outcomes of surgery for anterior and posterior compartment prolapse, assessing both subjective and objective outcomes, with long term follow up to assess the impact of BMI on recurrence.

Conflicts of interest statement:

Professor Stephen Radley is a director and shareholder of ePAQ systems limited, an NHS spin-out technology company (www.epaq.co.uk). The other authors declare they have no conflicts of interest. No funding was received for this study

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Table legends

Table 1: Characteristics of patients in normal BMI group, overweight BMI group and obese BMI group (VH= vaginal hysterectomy, AR= anterior vaginal wall repair, PR= posterior vaginal wall repair and SSF= sacrospinous fixation).

Table 2. Pre and post-operative vaginal symptoms quality of life (VS-QoL) scores.

Table 3. Pre and post-operative prolapse symptoms domain score for each BMI group.

Table 4. Pre and post-operative prolapse symptoms (all BMI groups combined, n=60).

(Score 0 = Never, 1

= Occasionally 2 = Most of the time, 3 = All of the time)

Table 1. Characteristics of patients in normal BMI group, overweight BMI group and obese BMI group (VH= vaginal hysterectomy, AR= anterior vaginal wall repair, PR= posterior vaginal wall repair and SSF= sacrospinous fixation)

Normal group (BMI 18-24.9)				
[redacted]	BMI	Age	Parity	Surgical procedure
	21.5	37	2	VH + AR
	22.4	83	3	VH + AR
	23.3	62	2	VH + AR + SSF
	24.2	58	3	VH + AR
	24.2	73	3	VH + AR
	24.3	67	2	VH + AR +PR
	21.2	63	2	VH + AR
	23.5	64	3	VH + AR
	21.2	55	2	VH + PR + SSF
	22.5	49	2	VH + AR
	18.5	63	1	VH + AR
	21.2	65	2	VH + AR + PR
	20.6	66	2	VH + AR= PR
	21.2	72	2	VH + AR
	24.3	63	3	VH + AR+ PR
	23.5	61	4	VH + AR
	24.7	56	3	VH + AR
	24.1	62	2	VH + AR + PR
	24.2	60	1	VH + AR
	21.8	85	4	VH+ PR
AVERAGE	22.6	63.2	2.4	[redacted]
Overweight group (BMI 25-29.9)				
[redacted]	BMI	Age	Parity	Surgical procedure
	25.8	62	3	VH + AR
	27.7	48	5	VH + AR
	26.6	52	4	VH + AR
	27.5	56	3	VH + AR+ PR
	28.3	67	2	VH + AR
	28.3	68	2	VH + AR
	29.7	63	2	VH + AR+ PR
	26.7	68	2	VH + AR
	25.6	58	3	VH + AR
	28.2	56	2	VH + AR
	27.6	57	2	VH + AR+ PR
	29.6	63	1	VH + AR + PR
	27.5	65	2	VH + AR
	28.4	68	2	VH + PR+ SSF
	26.3	60	2	VH
	29.7	67	3	VH + AR
	26.6	64	3	VH + AR+ PR
	28.5	45	1	VH + AR
	26.2	49	2	VH + AR
	28.6	84	4	VH + AR +PR
AVERAGE	27.67	61	2.5	[redacted]
Obese group (BMI 30-35)				
	BMI	Age	Parity	Surgical procedure
[redacted]	30.6	82	2	VH + AR
	33.7	76	3	VH + AR
	34.9	53	2	VH + AR+ PR+ SSF
	35.0	62	3	VH + AR
	33.8	67	3	VH + AR + PR
	32.1	68	2	VH
	31.2	49	2	VH + AR
	33.2	62	3	VH + AR+ PR
	31.5	73	2	VH + AR + PR
	33.8	54	2	VH + AR
	34.3	73	1	VH + AR
	34.9	53	2	VH + AR
	33.5	76	2	VH
	32.7	42	2	VH + AR
	32.8	50	3	VH + PR
	33.8	64	4	VH + AR
	32.1	74	3	VH + AR
	34.8	63	2	VH + AR
	33.8	67	1	VH + AR + PR
	34.7	88	3	VH + PR
AVERAGE	33.36	64.8	2.35	[redacted]

Table 2. Pre- and post-operative vaginal symptoms quality of life (VS-QoL) scores.

BMI group	n	Pre-op score	Post-op score	Change in score	Percentage improvement	Significance
Normal weight	20	57 ± 27	10 ± 24	47 ± 39	82%	(p<0.0005)
Overweight	20	57 ± 26	10 ± 22	47 ± 34	82%	(p<0.0005)
Obese	20	31 ± 26	5 ± 15	26 ± 29	84%	(p<0.0005)

Table 3. Pre- and post-operative prolapse symptoms domain scores for each BMI group.

BMI group	n	Pre-op score	Post-op score	Change in score	Percentage improvement	Significance
Normal weight	20	60 ± 16	6 ± 18	54 ± 25	90%	(p<0.0005)
Overweight	20	55 ± 16	5 ± 13	50 ± 22	91%	(p<0.0005)
Obese	20	51 ± 21	7 ± 13	45 ± 25	88%	(p<0.0005)

Table 4. Pre- and post-operative prolapse symptoms, all BMI groups combined n=60
(Score 0 = Never, 1 = Occasionally 2 = Most of the time, 3 = All of the time)

Symptom	**Pre-op score**	**Post-op score**	**Change in score**	**Percentage improvement**	**Significance**
'Something coming down'	2 ± 0.7	0.3 ± 0.7	1.9 ± 0.9	95%	(p<0.0005)
'Vaginal lump'	2 ± 0.7	0.3 ± 0.8	1.8 ± 1	90%	(p<0.0005)
'Vaginal laxity'	1.04 ± 1.15	0.06 ± 0.23	1 ± 1.1	96%	(p<0.0005)

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Abstract

Introduction

Understanding patients' concerns and goals is essential for providing individualised care in urogynaecology.

The study objectives were to undertake a content analysis of free-text concerns and goals recorded by patients using an electronic pelvic-floor questionnaire (ePAQ-PF) and measure how these related to self-reported symptom and health-related quality-of-life (HRQOL) data also recorded using ePAQ-PF.

Methods

1996 consenting patients completed ePAQ-PF. Content analysis was undertaken of free-text responses to the item: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?*' Key content themes were identified by the lead researcher, and three researchers read and coded all recorded responses. Student's *t* test was used to compare ePAQ-PF domain scores for patients reporting concerns in the relevant domain with those who did not.

Results

In total, 63% of participants who completed the questionnaire, recorded at least one free-text item. Content analysis identified 1560 individual concerns coding into the 19 ePAQ-PF domains. Symptom scores were significantly higher for patients reporting free-text concerns in 18 domains ($p<0.05$). Additional concerns relating specifically to body image were recorded by 11% of patients. Key areas of importance emerging for personal goals included cure/improvement, better understanding, incontinence pad use, sexual-function and surgery.

Conclusion

Free-text reporting in ePAQ-PF is utilised by patients and facilitates self-expression and discussion of issues impacting on HRQOL. The significant relationship between recorded free-text concerns and ePAQ-PF domain scores suggests convergent validity for the instrument. Development and psychometric testing of a domain to assess body image is proposed.

Keywords: patient reported outcome measures, prolapse, incontinence, body image

Brief Summary:

Free-text reporting in ePAQ-PF is well utilised and relates significantly to the quantitative data recorded. Development of a domain to assess body image is required.

Introduction

Understanding patient's concerns of an illness and its treatment and their personal goals in terms of achieving a good health-related quality of life (HRQoL) is an important element of clinical management. This is particularly important in areas concerning sensitive conditions, as encountered in urogynaecology. Patients may not always divulge clear information about their symptomatology and what bothers them the most, particularly within the constraints of a conventional history and examination [1].

The use of technology has been shown to be of benefit in overcoming this problem. For example, computer interviewing in urogynaecology has been shown to provide patients with an opportunity to report symptoms of an intimate and sensitive nature, which may be difficult to express in a face-to-face consultation [2-4]. This means that their concerns can be more objectively assessed and appropriate investigation and treatment planned.

The use of patient reported outcome measures (PROMS) in urogynaecology is now well-established and their use is advocated in clinical practice [5], aiming to reliably and objectively quantify HRQoL and assess outcomes [2]. Most PROMS used in urogynaecology use multiple choice questions (MCQs) to assess symptoms and their impact. Data collected using these tools provides quantitative data about HRQOL and outcome, but may lack sensitivity and acuity required to individualise patient's concerns and goals, particularly with regard to treatment [6]. The electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) is a self-administered, interactive, web-based questionnaire which measures urinary, bowel, vaginal and sexual symptoms and their related impact [7,8,9]. The instrument is interactive and presents up to 132 items, depending on patients'

responses to screening items, providing both summary and detailed reports, reflecting the 4-dimensional assessment of urinary, bowel, vaginal and sexual conditions and their impact on HRQOL, which is used to inform and support healthcare consultations, document symptoms and monitor outcomes from the patient's perspective.

The penultimate item in ePAQ-PF is a free-text question: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?*' **(Figure 1)**. Free-text responses to this question appear at the top of the structured report **(Figure 2)** aiming to provide an additional qualitative, personalised component to patient assessment, alongside quantitative data from the closed MCQ elements of the instrument.

The objective of this study was to analyse themes and content of free-text concerns and goals recorded in response to this item, from new patients attending a urogynaecology clinic, and assess how these responses related to the quantitative data recorded in MCQ items in ePAQ-PF and to identify any elements not currently addressed by the questionnaire.

Methods

The principal methodology for this research study was content analysis [10]. This is a social science methodology used to examine patterns in communication in a systematic and replicable manner, in this case free text comments from a validated pelvic floor assessment questionnaire (ePAQ-PF).

Ethical approval for the study was obtained from the University of Sheffield, UK (project number 015337). Female patients attending the urogynaecology unit at Sheffield Teaching

Hospitals, UK, who completed ePAQ-PF during the study period (October 2013- September 2016) as part of their routine clinical care, prior to first assessment in the urogynaecology clinic and gave consent for use of their data for approved research, were included in the study.

ePAQ-PF is a web-based instrument that provides a comprehensive assessment of a patient's pelvic floor symptoms and their impact on HRQOL [7,9,11]. The instrument is completed on-line, prior to clinic attendance by 80% of users [7], or alternatively, using a touchscreen-computer or tablet in a private room in the urogynaecology clinic. Patients may choose to have their partner/family member present with them when they complete the questionnaire and if they complete it in the hospital a nurse can sit with them to support them if they wish. The great majority of patients complete the questionnaire alone, unaided. Previous studies have shown that most patients find the questionnaire easy to use and a useful process which helps them to reflect and prepare for their consultation [2]. The mean completion time of ePAQ-PF, including the free-text components, is 26 minutes [7]. A questionnaire report may be printed or viewed electronically for use by the attending clinician, supporting consultation, diagnosis and management.

The core element of ePAQ-PF comprises of standardised multiple-choice questions, which assess both the frequency and impact of pelvic floor symptoms across four dimensions: Urinary, Bowel, Vaginal and Sexual. Each item is presented on a separate screen, with individual Help page and navigation buttons. Response options for all these items are on a four-point scale 'Never', 'Occasionally', 'Most of the time' or 'All of the time' and scored 0, 1,

2 or 3 respectively. The impact attributed to each of these symptoms is also recorded, using a standard sub-question *'How much of a problem is this for you?'* and graded as 'Not a problem', 'A bit of a problem', 'Quite a problem' or 'A serious problem' and scored 0, 1, 2 and 3 respectively. The degree of frequency and bothersomeness are thereby assessed for each symptom.

The electronic instrument automatically generates scores across 19 validated domains, providing graphic representation of these both the severity and the impact for each condition. Domain scores are derived by dividing the sum of all item scores in that domain by the total possible item score and multiplying this by 100 to produce a scale ranging from 0 (best possible health status) to 100 (worst possible health status). [7, 8]

In addition to the multiple-choice items within ePAQ-PF, the instrument also includes a free-text question (item PD6 within the final *Personal Data Dimension*) which asks: '*Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?'.* Patients are invited to record up to three free-text responses, each of up to 100 characters.

Data for the present study were used anonymously from women who answered *'Yes'* to the final item of the questionnaire, which seeks consent to allow confidential use of their answers for approved research.

Data were anonymised and transferred to SPSS (version 22) for analysis. Free-text data were imported into Microsoft Excel (version 15.33). Content analysis of free-text data was conducted [10]. This approach was adopted because it is located more within a quantitative methodology and our aim was to count and record the number of concerns reported by the women and compare these against the current ePAQ-PF domain structure (e.g. looking at where there was convergence and divergence between the datasets). The lead researcher (TG) read and became thoroughly familiar with the comments recorded throughout the free-text data. These comments were then coded categorically according to the 19 domains of the ePAQ-PF instrument. Content not fitting into these categories, and therefore not assessed by ePAQ-PF, were then coded separately.

Free-text comments were then analysed coded independently by three members of the research team (TG, SS, SP) and any ambiguities were resolved by discussion. A similar approach was also undertaken by the lead researcher to analyse the text that patients had been reported for patient goals (TG). Again, these were then coded independently by two members of the research team (TG, SP) and any further ambiguities were resolved by discussion.

Student's *t* test was used to compare ePAQ-PF domain symptom frequency scores for patients reporting concerns in the relevant domains, compared with those who did not. Mann Witney test was used to compare the domain impact scores in the same manner.

Results

During the three-year study period, 2,498 women completed ePAQ-PF as part of their routine clinical care prior to their first consultation in the urogynaecology clinic. One hundred and ninety-nine women (8%) declined consent for the use of their data for research, and a further 303 did not complete the consent question. Therefore, data from 1,996 women were included in the study. Of these, 1266 (63%) recorded one or more response to the question: 'Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?'. During the study period, greater than 90% of patients attending the urogynaecology outpatients department at Sheffield Teaching Hospitals, UK completed ePAQ-PF. Reasons for non-completion have not been formally recorded or studied, but often relate to advanced age, computer literacy or lack of time to complete during the clinic.

Patient concerns

Five hundred and thirty-one patients (42%) recorded one concern, 472 (37%) recorded two concerns, 100 (8%) patients recorded three concerns and 102 (8%) recorded more than three. Sixty-one patients (5%) completing this item recorded free text content which did not relate to a concern or goal, for example, writing a question or making a statement about their care.

Content analysis identified 1560 components from recorded concerns which all coded into the 19 domains of ePAQ-PF.

Domain scores were significantly higher in 18 of the 19 ePAQ-PF domains for women reporting concerns in the salient domain, compared with those who did not (p<0.05) (**table 1**). Domain impact scores were also significantly higher in all 19 ePAQ-PF domains for those reporting concerns in the salient domain, compared with those who did not (p<0.05) (**table 1**).

Additional themes not coding into the existing ePAQ-PF domain structure were identified; 160 specific body image concerns were recorded by 136 patients. These body concerns were grouped into themes of smell (16.3%), scarring (6.9%), appearance (37.5%) and emotions (39.3%). The frequency of the most commonly used words or phrases used in relation to body image concerns is shown in **Table 2**.

Table 3 provides examples of some of the intimate concerns and goals recorded by patients in the study; 102 patients reported faecal incontinence, 23 reported coital urinary incontinence and 5 reported coital faecal incontinence. A word cloud, graphically illustrating the words most frequently used by women recording concerns about their condition was created (**figure 3)**.

Personal goals

Overall 85% of patients completing the free-text item recorded at least one goal. A total of 596 patients (47%) recorded one goal, 332 (26%) recorded two goals, 116 (9%) patients recorded three goals and 102 (3%) recorded more than three; 189 (15%) did not record a goal. Content analysis identified seven key themes related to personal goals: (1) Aiming for

cure or improvement, (2) better understanding of their condition, (3) to improve physical activity, (4) reduced use of incontinence pads, (5) improved sex life, (6) reduction in pain and (7) to undergo surgery.

Discussion

The primary objective of this study was to undertake a content analysis to assess themes emerging from free-text concerns and goals recorded in ePAQ-PF. The secondary objective was to assess how concerns recorded related to symptoms and HRQOL recorded in quantitative components of ePAQ-PF and thereby support a patient-focussed approach to updating and potentially introducing new elements to the questionnaire.

The main findings are that the free-text component of ePAQ-PF was used by over 60% of patients completing the instrument. The majority (90%) of themes identified from the content analysis fitted into the existing domain structure of the instrument. Specific body-image concerns were recorded by 10% (n=136) of patients responding to the free-text question, which are not currently addressed by the MCQ items of ePAQ-PF. The most commonly reported goals related to seeking improvement or cure of conditions, improved physical and sexual function and to undergo surgical treatment.

Free-text data are commonly included in patient reported outcome measures alongside quantitative components, though such data are rarely used in research as components of free-text responses may vary in relevance to the research question posed [12] and analysis

of qualitative data presents methodological challenges. As such, free-text data are often neglected as a potentially rich source of data, which can supplement, augment and compliment more traditional quantitative data [13].

The free-text concerns and goals questions of ePAQ-PF are presented towards the end of the questionnaire. This aims to ensure that patients have first completed the core MCQ component of the PROM, giving them the opportunity to reflect on their condition and then provide considered responses to these items. A previous qualitative study, using semi-structured interviews with 20 women completing ePAQ-PF observed that patients found the use of ePAQ-PF helped them better understand and have further insight into their condition and its impact on their HRQOL, in addition to giving them the confidence to disclose embarrassing personal issues [2]. Previous studies have also found that patients using electronic questionnaires, feel more comfortable when reporting embarrassing or taboo problems with this approach than during a consultation with a healthcare professional [2, 9, 14]. The content analysis of the concerns in this study recorded included a large volume of personal detail including faecal incontinence, coital urinary incontinence and coital faecal incontinence. All these symptoms are also incorporated in the MCQ component of ePAQ-PF. The fact that these patients felt sufficiently enabled to record these intimate symptoms using their own words, suggests that these symptoms are likely to be having a significant impact on their HRQOL and hence are seeking to ensure these concerns are addressed during the consultation and subsequent treatment.

In this study, we undertook a deductive approach, hypothesising that there would be significantly higher domain scores in ePAQ-PF for patients reporting a free-text concern in the salient domain, compared with those who did not which was observed from the analysis. In questionnaire psychometrics, convergent validity refers to the degree to which two different measures of constructs that theoretically should be related, are in fact related. This translates to the degree to which an instrument measures what it purports to measure [15] and is one component in establishing the overall construct validity of an instrument. The significant differences in domain scores between women recording free-text concerns in the salient domain compared with those who did not, provides evidence of convergent validity for ePAQ-PF and fulfils the objective of the study. We found that women reporting free-text concerns for a specific domain had significantly higher domain scores than those who did not in 18 of the 19 ePAQ-PF domains. The only domain which was not statistically significant was *Sex and bowel symptoms*. Only five women recorded a concern in this domain, and therefore the lack of statistical significance in this instance may have been due to the small sample size (Type 2 error) with effect not being detected due to very small numbers of concerns recorded for these less common, but intimate and taboo symptoms.

An important finding of this study was that 10% of concerns recorded related to body image issues, which are not currently assessed by ePAQ-PF. This supports previous research suggesting that many women who attend urogynaecology clinics have body image concerns [16, 17]. The analysis demonstrated that women were most concerned about smell, the presence of scars and the appearance of their pelvic area; often using emotive language to describe and express these concerns.

'Body image' refers to the mental picture that an individual has of themselves, which depicts not only details available to objective investigation by others (e.g. height, weight, hair colour etc.), but also details that have been learned about themselves, either from personal experiences or by internalising the judgments of others [18]. The term *Genital self-image* has also been used to describe the mental picture that an individual has of his or her external genitalia [18]. This may include components such as appearance, smell, function and the perceptions of others (including partners and healthcare professionals).

Pelvic floor disorders including urinary incontinence and pelvic organ prolapse have been shown to negatively impact on body image [16,17]. A previous qualitative study of patients completing a quantitative urogynaecology PROM (King's Health Questionnaire) also found that women reported body image concerns during the qualitative analysis, which were not covered by the quantitative components of the questionnaire [6]. Currently there is no specific instrument available which assesses body image exclusively in women with pelvic floor conditions. The definition of the female genitalia does not necessarily include the perineum, vagina and perianal region, which are often involved in pelvic floor conditions, including incontinence and pelvic organ prolapse. Therefore, a broader definition than *genital self-image* is required for the assessment of body image concerns experienced by women with pelvic floor disorders and we suggest that the term *Pelvic Body Image* may be more appropriate. Whilst ePAQ-PF provides a comprehensive and robust assessment of a women's pelvic floor symptomatology, it does not specifically address related body image

concerns. The authors propose further work to develop items in a new domain within ePAQ-PF, evaluating related body image issues.

The content analysis of goals in this study demonstrated that fewer patients mentioned cure compared with improvement in symptoms as a personal goal (29% vs 40%). This may suggest that patients do have realistic expectations about their treatment outcomes and the higher likelihood of *improvement* as compared to outright *cure* of their condition. Previous studies have observed that the majority of women with urinary incontinence and overactive bladder do have realistic expectations regarding outcome and are willing to accept improvement and tolerate ongoing minor lower urinary tract symptoms [19]. Previous studies have also identified similar themes when assessing personal goals in semi-structured interviews. Srikrishna et al (2009) identified goals around role limitation, physical activity, sexual function and less frequent use of incontinence pads [4]. Almost 10% of patient's goals recorded referred to sexual function, again confirming the impact that pelvic floor conditions have on sexual function and patient's desires for interventions to improve this.

The use of patient-orientated goals has been described as a more sensitive approach to counselling women and assessing outcome and identifying these goals via a PROM prior to initial consultation or discussions about investigation and intervention is a useful way to aid counselling and enhance shared decision making [20]. Structured questionnaires functioning as PROMS may lack the sensitivity to understand and individualise a patient's expectations with regard to treatment if they do not include free-text components which

aim to enhance self-expression. Providing an individualised summary report **(Figure 2)** which headlines personal goals, allows the consultation to focus on issues of greatest concern to the patient and therefore be most useful clinically. Electronic data capture via instruments such as ePAQ-PF might enable the development of personalised decision aids, using individual patient data, such as symptom profile, along with personal circumstances, concerns and goals to model information relevant and meaningful to the individual. This is important as women affected by pelvic floor disorders, including urinary incontinence and pelvic organ prolapse face challenging and complex decisions about their treatment.

The main limitations of this study are that not all patients completing ePAQ-PF provided a response to the free-text question. The length and quality of the free-text comments provided was also variable. Both issues are likely to be related to questionnaire fatigue; the time taken to complete the up to 132-item questionnaire. This may be exacerbated as the free-text item is positioned at the end of the instrument and this may have had an impact on data quality. Variation in literacy, patient engagement or a lack of significant ongoing concerns or goals may have also contributed to non-responses. It is also possible that presenting free-text items after the MCQ component of the questionnaire may have introduced recall bias by prompting free-text responses related to the most recent MCQ items. For example, the reporting of sexual dysfunction may have been favoured as this dimension immediately precedes the personal data dimension containing free-text items. In-depth semi-structured qualitative interviews would provide an alternative approach to eliciting information regarding concerns and goals, though face-to-face interview data may also prove unreliable, due to non-disclosure of sensitive issues; previous studies assessing both urinary incontinence and coital urinary incontinence have shown patients are

significantly less likely to disclose sensitive symptoms to an interviewer, as compared to a questionnaire [9, 1].

Detailed demographic data for the 1996 women are also lacking, including parity and ethnicity, menopausal status, prolapse grade, urodynamic findings and other physical and mental health issues. The comparison of domain scores for those reporting free-text concerns for the stress urinary incontinence (SUI) and overactive bladder (OAB) domains of ePAQ-PF with salient domain scores for patients not reporting concerns potentially did not include a number of patients with SUI and OAB symptoms. This is because patients (n=451) who reported urinary incontinence, did not report specific symptoms of overactive bladder or stress urinary incontinence. The authors were therefore unable to categorise these as such, so the numbers of patients reporting a concern for the stress urinary incontinence and overactive bladder domains of ePAQ-PF may have been underestimated. Nonetheless the scores in these two domains were still significantly different for both symptom frequency and impact for those reporting SUI or OAB concerns.

Despite the limitations of this observational study, its strengths include a large sample size, subject to a systematic analysis. This is the first paper to publish an in-depth analysis of free-text data from an electronic questionnaire used in routine clinical practice.

Currently, including free-text data within ePAQ-PF is a helpful way to provide an individualised qualitative element which will help to improve the acuity of the PROM when it is used in clinical practice, to facilitate discussion and aid shared decision making about treatment [9]. The patient's response to the open free-text question regarding concerns

and goals in ePAQ-PF is automatically populated in the summary report and appears as headline information, showing the clinician clear individual qualitative information about what is most concerning the patient and what their goals are regarding their condition. This helps to ensure that these concerns and goals can then be appropriately addressed during the consultation, as the report draws stark attention to them.

The main clinical implication of this study is that validated questionnaires used in clinical practice, including ePAQ-PF, can help to identify concerns and goals which relate to symptoms. Another clinical implication is that a significant proportion of patients attending a urogynaecology clinic will have body image concerns which may need to be addressed and development and use of questionnaires to identify these issues and their impact in urogynaecology patients needs to be considered.

Conclusions

The present study has found the free-text component of ePAQ-PF to be well utilised by patients and the concerns and goals recorded may be of value in guiding and focussing the subsequent consultation. Many of the concerns recorded related to intimate issues and helped to highlight the issues affecting patients HRQOL the most. The significant relationship between domain symptom frequency scores and domain impact scores with reporting of free-text concerns supports convergent construct validity of the instrument. A significant proportion of concerns recorded by patients related to body image, which is not currently assessed by ePAQ-PF and is an area of further, development and psychometric

testing. An individualised electronic patient decision aid to address patient goals could also be of value and is worthy of further research.

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Figure 1

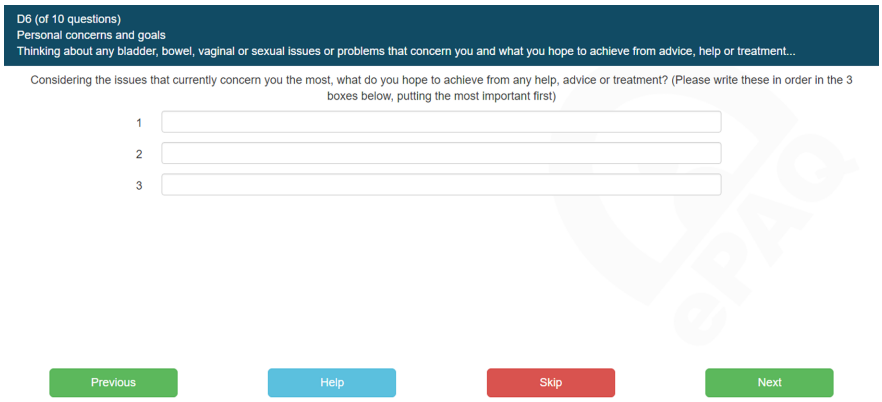
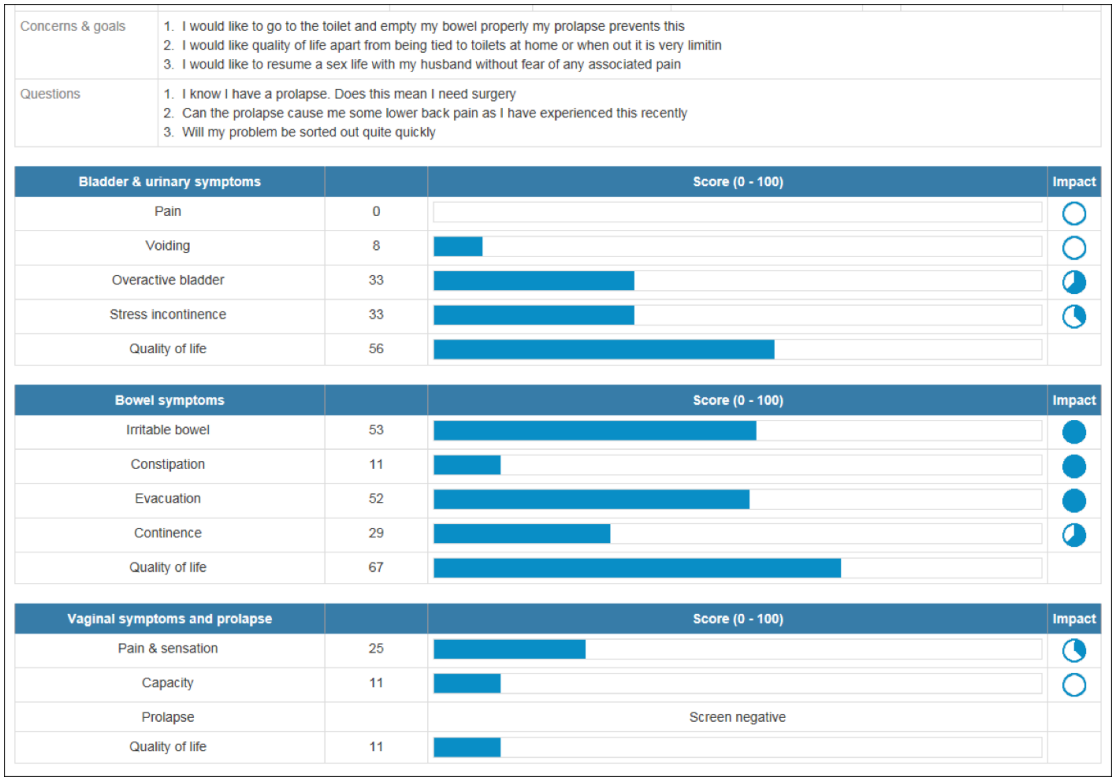


Figure 2



Concerns & goals	1. I would like to go to the toilet and empty my bowel properly my prolapse prevents this 2. I would like quality of life apart from being tied to toilets at home or when out it is very limitin 3. I would like to resume a sex life with my husband without fear of any associated pain
Questions	1. I know I have a prolapse. Does this mean I need surgery 2. Can the prolapse cause me some lower back pain as I have experienced this recently 3. Will my problem be sorted out quite quickly

Bladder & urinary symptoms		Score (0 - 100)	Impact
Pain	0		
Voiding	8		
Overactive bladder	33		
Stress incontinence	33		
Quality of life	56		

Bowel symptoms		Score (0 - 100)	Impact
Irritable bowel	53		
Constipation	11		
Evacuation	52		
Continence	29		
Quality of life	67		

Vaginal symptoms and prolapse		Score (0 - 100)	Impact
Pain & sensation	25		
Capacity	11		
Prolapse		Screen negative	
Quality of life	11		

Figure 3

Leakage
Urine
Pain
Sex
Bowel
Feel
Vagina
Prolapse
Toilet
Go
Bladder
Leak
Stool
Need
Problem
Out
Empty
Exercise
Walk
Stress
Control
Cough
Scared
Pelvic
Up
Sneeze
Open
Poo
Very
Uncomfort
Discomfort
Sore
Sexual
Anal
Constant
Incontinent
Lack
Sensation
Bloat
Being
Time
Lower
Unable
Intercourse
Down
Wind
Life
Sit
Help
Night
Area
Future
Fear
Wee
Bleed
Urinary
Urgency
Movement
Lump
Pad
Worry
Loose
Bulge
Floor
Run
Hold
Loss
Stop
Socialise
Ache
Embarassed
Constipated
Inside
Urge
Period
Full
Evacuate
Partner
Hard
Self
Push
Scar
Without
Sleep
Fall
Make
Loo
Work
Sharp
Weak
Flow
Take
Struggle
Smell
Drop
Skin
Wake
Active
Due
Use
Stand
Dryness
Jump
Concern
Abdomen
Severe
Strain
Lax
Lift
Wet
More
Frequency
Odour
Bad
Pee
Much
Sexual
Rush
Over
Dragging
Big

Table 1

Domain	Number of controls (number of patients not recording a concern in this domain)	Number of cases (patients recording a concern in this domain)	Mean symptom frequency score ± 2 S.D (controls)	Mean symptom frequency score ± 2 S.D (cases)	Domain score p value (Student's *t* test)	Modal symptom impact score (controls)	Modal symptom impact score (cases)	Impact score p value (Mann-Whitney)
Urinary dimension								
Stress urinary incontinence	1143	122	23.3±49.7	47.5±43.3	<0.005	0	3	<0.005
Overactive bladder	1197	68	23.1±41.7	41.7±39.2	<0.005	0	3	<0.005
Voiding dysfunction	1212	53	16.6±38.3	38.1±47.4	<0.005	0	2	<0.005
Urinary pain and sensation	1213	52	12.3±33.4	24.4±45.1	<0.005	0	2	<0.005
QoL Urinary	1132	133	33.0±66.12	66.3±59.0	<0.005	-	-	
Bowel dimension								
Constipation	1206	59	21.2±40.7	53.0±52.9	<0.005	0	2	<0.005
Irritable Bowel	1237	28	27.7±41.9	46.2±46.1	<0.005	0	2	<0.005
Bowel evacuation	1194	71	20.8±38.2	47.1±42.3	<0.005	0	3	<0.005
Bowel continence	1163	102	16.3±33.0	38.4±39.4	<0.005	0	3	<0.005
QoL Bowel	1235	30	22.6±60.0	53.7±71.5	<0.005	-	-	
Vaginal dimension								
Prolapse	857	408	16.5±45.4	54.6±52.0	<0.005	0	2	<0.005
Vaginal pain and sensation	1078	187	19.1±39.4	33.1±43.0	<0.005	0	2	<0.005
Vaginal capacity	1254	11	9.0±41.3	34.3±61.1	0.021	0	1	<0.005
QoL Vagina	1223	42	27.6±60.9	63.3±60.6	<0.005	-	-	
Sexual dimension								
Sex and urinary symptoms	1242	23	25.7±63.4	47.6±53.16	<0.005	0	3	<0.005
Sex & bowel symptoms	1260	5	15.2±53.09	36.6±19.2	0.072	0	2	0.001
Sex & vaginal symptoms	1223	42	36.2±69.0	64.4±46.6	<0.005	0	3	<0.005
Dyspareunia	1189	76	23.3±49.7	41.4±44.75	<0.005	0	3	<0.005
General sex life QoL	1217	48	41.9±57.42	66.1±52.0	<0.005	1	3	<0.005

Table 2

Emotional words /phrases used in relation to body self-image	Number of times repeated
Embarrassment	18
Worry	6
Fear	5
Lack of confidence/ Self-conscious	4
Depression	4
Gets me down	2
Shame	1
Mortifying	1
Anxiety	1
Scared	1
Distress	1
Mental effects	1
Feeling low	1
Mentally disturbing	1
Dirty	1
Ashamed	1
Paranoid	1
Miserable	1
Psychological effect	1
Overall unhappy	1
Annoying	1
Upsetting	1

Table 3

REAL CONCERNS AND GOALS FROM PATIENTS INCLUDED IN THE STUDY

"I would like to sleep without getting up 2-3 times each night"

"Being able to go out without having to know where the toilets are"

"The lump protruding out of my vagina and lack of sex and closeness with my husband. It is ruining my life"

"Urge incontinence"

"I have bowel leakage and splattering. I never know when I've finished opening my bowels. I never feel clean or empty properly. This is mentally disturbing and I feel dirty and ashamed, in fear"

"I have urine leakage when walking on uneven ground, urine leakage when lifting and carrying grandchildren, urine leakage when running and jumping and urine leakage when coughing and sneezing"

I am not able to urinate later in the day. I feel that I am not emptying my bladder, then going two minutes later. My bladder prolapse interferes with wiping bottom. I feel ugly"

"My bladder is hanging down, I can't go far without needing the toilet. I am avoiding sex, due to anxiety about my problem. I get depressed about my problem, I don't want it to spoil our relationship"

"I am unable to stop leaking when laughing. I feel the need to be close to a toilet. I need to wear pads. I hate having to get up during the night"

"The prolapse dragging makes me feel just rubbish. I don't feel in the mood for intercourse and don't feel feminine. I have concerns about ulceration on my prolapse"

"I leak urine when walking, running and walking on concrete. I don't have sex with my husband, he denies me sex because of his mistress"

8. Conclusions and areas for future research

Electronic patient reported outcome measures in gynaecology have an important role in providing patients with the opportunity to report their symptoms and the impact they may be having on both function and health related quality of life. ePROMs, such as ePAQ-Pelvic Floor, ePAQ-MPH and ePAQ-Vulva which are all delivered online allow patients to do this in the comfort of their own surroundings; supporting self- expression and increasing disclosure of potentially taboo or embarrassing symptoms. Utilisation of these tools is of particular importance in gynaecology, as this area of medicine deals with sensitive conditions which often have a profound and significant impact on health-related quality of life. It can be well argued that routine use of ePROMs such as ePAQ-Pelvic Floor, ePAQ-MPH and ePAQ-Vulva should be standard practice in the evaluation of both new and follow up patients, such is the level of evidence for their value.

It is clear that ePROMs used in gynaecology need to have undergone psychometric testing and have good evidence for their reliability, validity and functionality in clinical practice as well as in research. ePAQ-Pelvic Floor already has an excellent level of evidence for this and is widely used across many centres in the UK and as an outcome measure in research studies. Papers five, six and seven of this thesis help to build on this. The levels of evidence presented so far for ePAQ-MPH and ePAQ-Vulva provide some good evidence for reliability, validity and functionality. For ePAQ-Vulva further, psychometric testing including test-retest reliability (stability), local dependency, item discrimination and responsiveness of the instrument have yet to be evaluated. The instrument requires further assessments of its domain structure, responsiveness, reliability and validity. For ePAQ-MPH, wider evaluation and psychometric

testing of the latest and current version three of the instrument is required in larger samples and in different settings, including tests of stability, tests of data quality, sensitivity and responsiveness to change. Once these psychometric properties of ePAQ-Vulva and ePAQ-MPH have been assessed, there will be further evidence to support their routine use in clinical practice and research.

Through the work presented here in paper two and paper six, work has been undertaken to develop and test a new domain in ePAQ-Pelvic Floor which will be able to assess body image in a urogynaecology setting. This will be the first ePROM able to do this. Further research will evaluate this new domain of the ePAQ-Pelvic Floor ePROM and will allow the routine assessment of body image in patients attending the urogynaecology clinic. This will also allow ethically approved research studies to evaluate the relationship between body image, urogynaecology symptomatology and the effect of interventions, such as surgical treatments for incontinence or prolapse, on body image.

Likewise, the work undertaken in paper one of this narrative thesis has led to testing of ePAQ-Pelvic Floor in postnatal women, in order to identify pelvic floor symptomatology including anal incontinence. Using an ePROM in this context is a novel concept and the ethically approved eQuiPP study (Electronic Questionnaires in the Postpartum Period) will help to investigate and test this. The evidence presented in paper 1 and paper 5 regarding increased disclosure of embarrassing and taboo symptoms when PROMs are used has supported this next phase of work.

It is essential that high quality research evaluating the use of ePROMs in gynaecology continues, particularly work which examines the financial and costing benefits of using such tools, as well as assessments of psychometric properties, clinical outcomes and research outcomes. The NHS Long Term plan[81] states that ten years from now many patients will be offered a 'digital first' option for assessment when they have a healthcare interaction. It is likely that the remit of ePROMs in this context is going to increase exponentially. Therefore, high quality research both for ePROM development, including systematic reviews of psychometric properties of existing measures as well as psychometric testing of new tools, and research using data from ePROMs will similarly increase. The body of work presented in this thesis forms a small part of this overall narrative which will become increasingly important as we strive to delivery high quality healthcare for all.

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Published online: June 30, 2019
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What Is the Effect of Body Mass Index on Subjective Outcome Following Vaginal Hysterectomy for Prolapse?

Thomas Gray[1], John Money-Taylor[2], Weiguang Li[2], Andrew G Farkas[1], Patrick C. Campbell[3], Stephen C. Radley[1]

[1]Department of Urogynaecology, Sheffield Teaching Hospitals, Sheffield, UK

[2]University of Sheffield Medical School, Sheffield, UK

[3]Belfast City Hospital, Belfast, UK

Corresponding author: Thomas Gray Department of Urogynaecology, Sheffield Teaching Hospitals, c/o Tricia Kenyon, Level 4, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF, UK E-mail: Thomas.Gray@doctors.org.uk / Tel: +1447763686015
Submitted: January 12, 2019 Accepted after revision: May 1, 2019

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Title: What are the concerns and goals of women attending a urogynaecology clinic? Content analysis of free-text data from an electronic pelvic floor assessment questionnaire (ePAQ-PF)

Author: Thomas Gray, Scarlett Strickland, Sarita Pooranawattanakul et al

Publication: International Urogynecology Journal

Publisher: Springer Nature

Date: Jan 1, 2018

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Institution name	Sheffield Teaching Hospitals NHS Foundation Trust

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Dear Mr Farkas,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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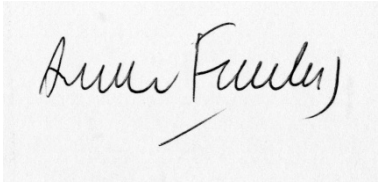
I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Andrew Farkas



Signed:

Date: 26.06.19

Dear Charlotte,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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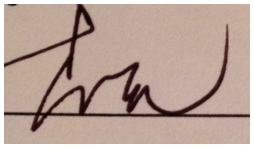
I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Charlotte Alexander

Signed: 

Date: 4/7/19

Dear Mr Iles,

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Regards

Thomas Gray

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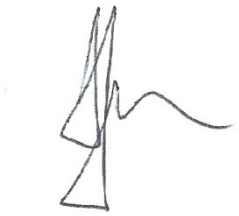
I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: David Iles

Signed:



Date: 07/07/19

Dear Dr James,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

Thomas Gray

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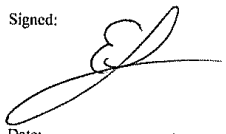
I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Ellie James

Signed:



Date: 15/07/19

Dear Professor Jones,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Georgina Jones

Signed: GEORGINA JONES

Date: 2/7/19

Dear Dr Vickers,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Holly Vickers

Signed: 

Date: 2/7/19

Dear Professor Tidy,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gynaecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: John Tidy

Signed:

Date: 8th July 2019

Dear Dr Palmer,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Julia Palmer

Signed:

Date: 26th June 2019.

Dear Dr Moores,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Karen Moores

Signed: KMoores.

Date: 02/07/19.

Dear Dr Scurr,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Kaia Scurr

Signed: 

Date: 26/06/2019

Dear Miss Connor,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Mary E Connor

Signed: 

Date: 1st July 2019

Dear Mr Campbell,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

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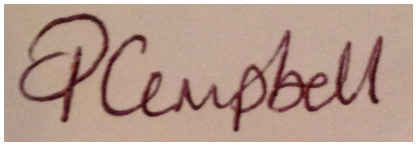
I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Patrick Campbell

Signed: 

Date: 4/7/19

Dear Dr Sneyd,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Thomas Gray

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Name: Rosie Sneyd

Signed:

Date:

15.07.2019

Dear Professor Brown,

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Regards

Thomas Gray

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Name: Steven Brown

Signed: 

Date: 29/6/19

Dear Professor Radley,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Stephen Radley

Signed:

Date: 26th June 2019

Dear Dr Jha,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Swati Jha

Signed:

Date: 4/7/19

Dear Sarita,

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Regards

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Name: Sarita Pooranawattanakul

Signed: 

Date: 26/6/19

Dear Scarlett,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

Thank you for your response and please contact me if there are any questions.

Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Scarlett Strickland

Signed: S. Cl

Date: 27/06/19

- 4 JUL 2019

Dear Dr Money-Taylor,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

Thomas Gray

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I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: John Money-Taylor

Signed: 

Date: 14/7/19

Dear Dr Li,

I am currently in the process of applying for an MD by publication at the University of Sheffield (on 'The development and utility of electronic patient reported outcome measures in gyanecology'). As a co-author on the papers listed below I would be grateful if you would allow me to include these papers in my submission. If you agree to this, could you please sign this document and return to me by email or by post to Dr Thomas Gray, Room 15, Level 4 Jessop Wing, Tree Root Walk, Sheffield Teaching Hospitals, S10 2SF.

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Regards

Thomas Gray

List of co-authored papers

1. **Gray T, Li W, Campbell P, Jha S, Radley S. Evaluation of coital incontinence by electronic questionnaire: prevalence, associations and outcomes in women attending a urogynaecology clinic. International Urogynecology Journal. 2018 Jul 1;29(7):969-78.**
2. **Gray T, Strickland S, Pooranawattanakul S, Li W, Campbell P, Jones G, Radley S. What are the concerns and goals of women attending a urogynaecology clinic? Content analysis of free-text data from an electronic pelvic floor assessment questionnaire (ePAQ-PF). International Urogynecology Journal. 2018 Jun 27:1-9.**
3. **Gray T, Money-Taylor J, Li W, Farkas AG, Campbell P, Radley SC. What is the effect of body mass index on subjective outcome following vaginal hysterectomy for prolapse? International Neurourology Journal. 2019;23(2):1-8. https://doi.org/10.5213/inj.1938016.008 pISSN 2093-4777 · eISSN 2093-6931**

I agree to the inclusion of the above listed published research article in Dr Thomas Gray's MD by publication thesis, to be submitted to the University of Sheffield.

Name: Weiguang Li

Signed: 

Date: