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A systematic review of non-invasive modalities used to identify women with anal incontinence symptoms after childbirth

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Mr. Stephen Radley is a director and shareholder of ePAQ Systems Limited, an NHS spin-out technology company, largely owned by Sheffield Teaching Hospitals NHS Foundation Trust. Mr. Radley did not collect or analyse the data included in this systematic review.

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TG Gray: Project Development, Data Collection, Management and Analysis; Manuscript Writing

H Vickers: Data collection, Manuscript Editing

G.L. Jones: Methodological advice, Data analysis, Manuscript Editing

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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 in 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 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], Faecal 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