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LITERATURE REVIEW

Evaluating the effect of pessaries on quality of life in the management of stress urinary incontinence in women

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Abstract

Stress urinary incontinence (SUI) can have a detrimental effect on quality of life (QoL). The controversy over surgical vaginal mesh, and the subsequent suspension of its use, have reinforced the importance of exploring non-surgical approaches to the treatment of this condition. Well-documented conservative measures include physiotherapy and pelvic floor muscle training, which are key parts of the management strategy for SUI. Additionally, national and international guidelines advocate the use of pessaries for symptomatic improvement in women with SUI. However, there is a lack of current research supporting the effectiveness of, and patient compliance and satisfaction with pessary use in the treatment of SUI in the UK, thus restricting its availability in National Health Service settings. Consequently, it is a challenge for healthcare professionals to provide patients with evidence-based guidance on pessary use for SUI. The focus of this literature review is to examine the available evidence regarding the efficacy of this treatment modality, and its effect on the QoL of women with mixed urinary incontinence with dominant SUI or SUI alone. A detailed literature search covering the period from 2003 to 2020 was completed, and seven relevant publications were identified. The limitations of the papers included variations between pessary brands, pessary management instructions and additional treatments combined with the pessary use. The findings of this literature review indicate that there is a role for pessaries as part of a holistic multidisciplinary approach in the management of SUI. However, future trials are needed in order to develop the guidelines on pessary selection and long-term management.

Keywords: pessary, quality of life, stress urinary incontinence.

Introduction

Stress urinary incontinence (SUI) is defined as the involuntary loss of urine during physical exertion, or an increase in intra-abdominal pressure while coughing or sneezing (NAFC 2018). In such cases, the normal positive urethral closure mechanism is overcome in the absence of detrusor contraction (Haylen *et al.* 2010). Estimates of the rate of urinary incontinence among adults vary from 2% to 55%, and increase with age (Thom *et al.* 2005). Epidemiological figures vary widely between studies; however, commonly cited projections by Buckley & Lapitan (2009) report that urinary incontinence affects 25% of the adult population, with prevalence higher in women than men. This has been attributed to variations in definitions of diagnostic criteria and the study designs used. Stress urinary incontinence appears to be the most common type of urinary incontinence in women (Minassian *et al.* 2008), and there is evidence that as many as one in three women are affected (Magon *et al.* 2011) and that it may have detrimental effects on quality of life (QoL) (Kwon *et al.* 2010).

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Between 2008 and 2017, 100 516 patients had a tape insertion procedure for SUI in England (NHS Digital 2018). Last year, The Independent Medicines and Medical Devices Safety Review, chaired by Baroness Cumberlege, published large volumes of evidence documenting the harmful side effects of pelvic mesh in the treatment of SUI (Cumberlege 2020). As a result, the National Institute for Health and Care Excellence (NICE 2019) has extended the high-vigilance restriction period with regard to vaginal mesh in the treatment of SUI. In practice, this means that conservative measures such as physiotherapy and pessary fitting are being more frequently considered. All surgical procedures for SUI carry a risk of infection, voiding dysfunction or unsuccessful outcome, and these also often involve long waiting times (Ellington *et al.* 2015). Welk & Alhothi (2015) estimated that one out of every 30 women may require a second procedure for mesh removal or revision. As such, NICE (2019) recommended that all non-surgical options should be exhausted prior to surgery, and suggest pessaries as a possible treatment option to prevent incidents of SUI (e.g. during exercise).

Pessaries, also known as containment or mechanical devices, are utilized intra-vaginally to correct bladder neck instability or an anatomical defect (Al-Shaikh *et al.* 2018). These mechanisms are a cost-effective, minimally invasive, non-surgical treatment option for SUI (Gorti *et al.* 2009). Worldwide clinical guidelines remain conflicted regarding the efficacy of pessary use in the management of SUI (Al-Shaikh *et al.* 2018). In a systematic review, Ayeleke *et al.* (2015) reported that there is insufficient evidence to determine the effectiveness of the use of mechanical devices in conjunction with pelvic floor muscle training (PFMT). A Cochrane Review by Lipp *et al.* (2014) found that using pessaries may be superior to no treatment, but the evidence remains weak. There is limited evidence to support the superiority of one type of mechanical device over another, or one modality such as PFMT over pessary use (Lipp *et al.* 2014). The American College of Obstetricians and Gynecologists and the American Urogynecologic Society (ACOG 2015) guidelines state that pessaries that selectively support the bladder neck may be effective for some patients, but there is no objective measure of the efficacy of this approach (Al-Shaikh *et al.* 2018). A reduction in QoL is a significant predictor of individuals with urinary incontinence seeking treatment (Huang *et al.* 2007), and studies have shown that identifying the link between QoL and incontinence is crucial to the success of early interventions (Kang *et al.* 2010). Despite valid and reliable condition-specific tools for measuring QoL, a discussion continues about how best to interpret the data and how to extend the findings of research to clinical practice (Kwon *et al.* 2010).

The current ambiguity in the available literature might contribute in part to the limited prescription of mechanical devices by physiotherapists for this patient group. In line with the NICE guidelines, current clinical practice is for all patients with SUI to receive PFMT, a home exercise plan, and diet and lifestyle advice (NICE 2019). An onward referral to a gynaecology team for possible pessary insertion can be advised, or patients can purchase their own without referral, if this is deemed appropriate. The efficacy of pessaries as a conservative form of treatment to improve the QoL of the population with SUI is unclear (Farrell *et al.* 2007). Therefore, the aim of the present literature review is to answer the following research question: How effective are pessaries for improving the QoL of individuals with SUI?

The evidence for the use of pessaries, and the impact of these devices on the QoL of females who present with SUI is critically evaluated. The conclusions will inform recommendations for future patient care.

Materials and methods

A systematic literature search was completed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher *et al.* 20093). The inclusion criteria for the literature review were formed by the characteristics of the study population, intervention, control, outcome, study design and time (PICOST) (Table 1). The PICOST framework was chosen because Rios *et al.* (2010) correlated it with better reporting quality in randomized controlled trials (RCTs). The framework was used to generate search terms and identify relevant papers (Fig. 1). Studies relevant to the proposed research question were identified on electronic medical databases using population and intervention search terms (Table 2). The search was limited to randomized and controlled trials published in English from 2003 to 2020. Studies in which subjects had suffered a prolapse greater than grade II, faecal incontinence or urge dominant urinary incontinence, as measured by validated outcome measures such as the Questionnaire for Urinary

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Table 1. Population, intervention, control, outcome, study type and time (PICOST) criteria (Rios *et al.* 2010): (SUI) stress urinary incontinence; and (IIQ-7) Incontinence Impact Questionnaire, Short Form

Variable	Details
Population	Female subjects with SUI or mixed incontinence with dominant SUI
Intervention	Incontinence pessary or containment device
Comparison	No pessary management Pelvic floor muscle training instruction
Outcome measures:	
primary	Subjective measures of quality of life (e.g. IIQ-7)
secondary	Validated outcome measure of urinary incontinence Objective measures (e.g. urodynamics and pad weight test)
Study type	Randomized controlled trials or controlled clinical trials
Time	2007–2018

Incontinence Diagnosis, urodynamics and bladder frequency charts, were excluded from the review since these conditions require alternative first-line treatment modalities. Methodological quality was appraised using published validated critical appraisal tools, i.e. the Critical Appraisal Skills Programme checklist (CASP 2018) and the Physiotherapy Evidence Database (PEDro) scale (Maher *et al.* 2003). The PEDro scale has been deemed to be a valid measure of the methodological quality of clinical trials (De Morton 2009). Studies identified by population and intervention search terms were then screened for relevance against the inclusion (Table 1) and exclusion criteria, and evaluated using the aforementioned appraisal tools. Those with a PEDro score of $\leq 3/10$ were excluded from final analysis (see "Appendix 1", Table 5).

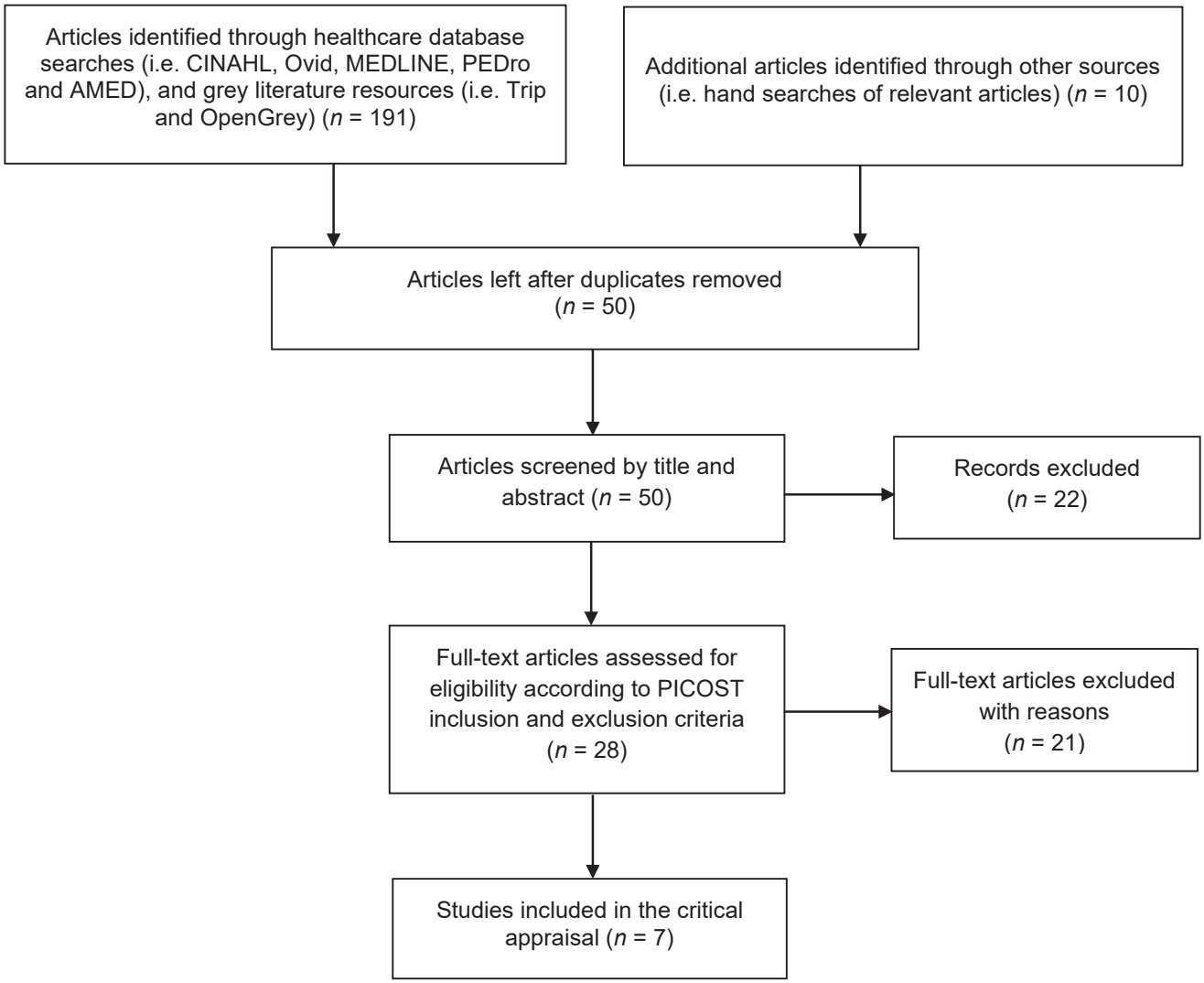

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart demonstrating the literature search strategy (Moher *et al.* 2009; PRISMA 2009): (CINAHL) Cumulative Index to Nursing and Allied Health Literature; (MEDLINE) Medical Literature Analysis and Retrieval System Online; (PEDro) Physiotherapy Evidence Database; (AMED) Allied and Complementary Medicine Database; and (PICOST) population, intervention, control, outcome, study type and time.

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Table 2. Search strategy: (CINAHL) Cumulative Index to Nursing and Allied Health Literature; (MEDLINE) Medical Literature Analysis and Retrieval System Online; (PEDro) Physiotherapy Evidence Database; (AMED) Allied and Complementary Medicine Database; (SUI) stress urinary incontinence; and (NICEE) National Institute for Health and Care Excellence

Variable	Details
Databases	CINHAL, Ovid, MEDLINE, PEDro, AMED, Trip, OpenGrey
Search terms	Population: "female", "urinary incontinence", "SUI", "mixed urinary incontinence", "SUI dominant" Intervention: "pessary", "intraurethral device", "intravaginal device", "mechanical device", "containment device", "vaginal device", "intrauterine device" Outcome: "quality of life"
Inclusion criteria	Adult, female, diagnosed with SUI or SUI-dominant mixed urinary incontinence, English, 2003–2020
Exclusion criteria	Pregnancy, urinary urgency studies, overactive bladder syndrome, urge urinary incontinence, urgency, studies including previous vaginal surgery, studies using pessary for pelvic organ prolapse, PEDro score < 3/10
Additional search strategies	Hand search of reference lists for available articles Search of available grey literature using the Trip database, NICE guidelines and OpenGrey

Results

Seven studies that all reported improvements in QoL with pessary use were identified for critical appraisal. These were classified into two groups: controlled trials comparing QoL changes before and after pessary fitting within the same group of patients (Table 3); and RCTs comparing QoL changes with pessary use to PFMT or no treatment (Table 4). Both groups were deemed appropriate for the first author's (S.B.'s) research proposal because multimodal treatments are reflective of daily clinical practice.

Discussion

Pessaries are a non-surgical option in the management of SUI, and are recommended for occasional use by NICE (2019). However, the published literature on the efficacy of these devices in the enhancement of QoL is inconclusive. The present literature review supports the hypothesis that pessaries can improve QoL in the population with dominant SUI, but further RCTs are required because there is a mixed evidence base with regard to the efficacy and impact of these devices on QoL. Two studies did not find a significant improvement in QoL with pessary use in comparison to no treatment (Cornu *et al.* 2012) and PFMT (Kenton *et al.* 2012). Morris & Moore (2003), Allen *et al.* (2008), Ziv *et al.* (2009), Richter *et al.* (2010) and Shayo *et al.* (2020) reported statistically significant and clinically important improvements in QoL following pessary use when within-group paired analysis was calculated.

Richter *et al.* (2010) and Kenton *et al.* (2012) found that PFMT was as effective as pessary use in enhancing QoL. These results were drawn from a large multicentre RCT called the Ambulatory Treatments for Leakage Associated with Stress (ATLAS) trial. Furthermore, Richter *et al.* (2010) found that combining pessary use with PFMT was as beneficial as PFMT alone, and both were superior to pessary use alone. This is relevant to current clinical practice since pessaries are often prescribed in conjunction with physiotherapy and PFMT. However, Richter *et al.* (2010) also reported that participants continued to receive interventions after the end of the trial if their symptoms persisted into the follow-up period. Additionally, if they were in the combined group, individuals could continue in the trial while receiving only one of the treatments, but were still included in their initial group allocation, which led to an inaccurate representation of the results. Furthermore, despite data being drawn from the same ATLAS trial, there are differences in the presentation of the datasets. Richter *et al.* (2010) reported nine participating clinical sites. In contrast, Kenton *et al.*'s (2012) study involved only seven sites, but they did not indicate which had been excluded or why, and used the same number participants, thereby compromising the validity of their findings. The results from Richter *et al.* (2010) should be viewed with caution because of possible methodological inconsistencies within the study design. In line with the NICE (2019) guidelines, the multimodal treatment interventions in the ATLAS trial are similar to those defined by the first author (S.B.), and therefore, of clinical relevance to the present literature review.

Richter *et al.* (2010) and Kenton *et al.* (2012) did not compare pessary use with no treatment; rather, control groups typically also received advice on PFMT and continence strategies. Such trials are likely to underestimate the effect of pessary use (a type II error), which would suggest that the true impact of these devices on QoL

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Table 3. Controlled trials: (SUI) stress urinary incontinence; (IQR) interquartile range; (SF-12) 12-Item Short Form Survey; (IIQ-7) Incontinence Impact Questionnaire, Short Form; (UDI-6) Urinary Distress Inventory, Short Form; and (PFIQ-UIQ) Urinary Impact Questionnaire of the Pelvic Floor Impact Questionnaire

	References			
Variable	Morris & Moore (2003)	Allen *et al.* (2008)	Ziv *et al.* (2009)	Shayo *et al.* (2020)
Design	Single centre, two-arm controlled trial	Tertiary urogynaecology unit, two-arm controlled trial	Two clinical sites, two-arm controlled trial	Two-arm controlled cross-sectional community-based trial conducted in four centres
Population (*n*)	41 with SUI divided into two groups: mild and moderate/severe	52 with SUI as the main complaint	60 with SUI only (> 8 on Sadvik's four-level severity index)	48 with SUI only, confirmed by stress test
Age group (years)	46 (mild) 47 (moderate)	45 (median) IQR = 41–54	18–70	18–90
Location	Australia	Australia	Israel	Hai, Rombo and Same districts, Kilimanjaro Region, Tanzania
Intervention	Taught to use self-fitting device by nurse, 3 weeks wearing device continuously or intermittently (as patient preferred)	Taught to use self-fitting device by nurse and video taken home, 4 weeks wearing device continuously (apart from two participants who were to use it only during exercise)	Device was worn for 8 h a day over 28 days while performing activities of daily living, cough vigorously 10 times and jump in place 50 times with a full bladder once during the day before voiding	Fitted with continence pessary by nurse, taught self-management, and instructed to remove, clean and reinsert every month
Control/comparison	Baseline measurements	Baseline measurements	Baseline measurements (7-day control period)	No containment device/baseline
Drop-out (*n*)	Unclear	28	10	13
Outcome measure	24-h pad test SF-12 IIQ-7 UDI-6	24-h pad test St George score IIQ-7 UDI-6	IIQ-7 UDI-6 Leak score Participant's perception of incontinence	UDI-6 PFIQ-UIQ
Follow-up	Baseline and 4–6 weeks	Baseline and 4 weeks	Baseline, and 14 and 28 days	Baseline, and 3 and 12–18 months

Table 4. Randomized controlled trials (RCTs): (SUI) stress urinary incontinence; (PFMT) pelvic floor muscle training; (PGI-I) Patient Global Impression of Improvement; (UDI-6) Urinary Distress Inventory, Short Form; (PFIQ-UIQ) Urinary Impact Questionnaire of the Pelvic Floor Impact Questionnaire; (USP) Urinary Symptom Profile; (QUID) Questionnaire for Urinary Incontinence Diagnosis; (CONTILIFE) Quality of Life Assessment Questionnaire Concerning Urinary Incontinence; (ITT) intention to treat; and (QoL) quality of life

	Reference		
Variable	Richter *et al.* (2010)	Cornu *et al.* (2012)	Kenton *et al.* (2012)
Design	Nine clinical sites, three-arm RCT	Multicentre prospective RCT	Seven clinical sites, three-arm RCT
Population (*n*)	446 with SUI or predominant SUI randomly assigned into three groups: continence pessary ($n=149$), behavioural therapy ($n=146$) or combination therapy ($n=151$)	55 with SUI or mixed UI with predominant SUI randomly assigned into two groups: control ($n=26$) or treatment ($n=29$)	446 with SUI or predominant SUI randomly assigned into three groups: continence pessary ($n=149$), behavioural therapy ($n=146$) or combination therapy ($n=151$)
Age (years)	18–89	29–85	18–89
Location	USA and England	France	USA and England
Intervention	Continence pessary group and behavioural group (four visits at biweekly intervals for PFMT and additional strategies for active use of muscles to prevent SUI) over an 8-week treatment period	The first treatment group wore a device for a minimum of 6 h a day for 14 days; the remaining patients were treated with the device for another 14 days	Continence pessary over an 8-week treatment period
Control/comparison	Combined group (pessary and behavioural therapy) over an 8-week treatment period	No containment device/baseline	Behavioural therapy over an 8-week treatment period
Drop-out (*n*)	39 (pessary), 22 (behavioural therapy) and 18 (combined)	2 (control) and 12 (intervention)	39 (pessary) and 22 (behavioural therapy)
Outcome measure	PGI-I UDI-6 Bladder diary Patient satisfaction questionnaire	Bladder diary USP 24-h pad test CONTILIFE	UDI-6 PFIQ-UIQ QUID
Follow-up	Baseline, and 3, 6 and 12 months	Baseline, and 14 and 28 days	Baseline and 3 months
Data analysis	ITT	ITT and per-protocol analysis	ITT
Results	At 3 months, QoL in the combined group was significantly better than in pessary-only arm (PGI-I, $P=0.02$; UDI-6, $P=0.05$), but not better than that in the behavioural therapy group (PGI-I, $P=0.49$; UDI-6, $P=0.42$); this was not sustained at the12-month follow-up	After the 14-day trial, there was an improvement in CONTILIFE scores, but this was not statistically significant; the mean relative variations of USP subscores, apart from those for dysuria, were more significant in the pessary group	There was a significant within-group improvement in QUID, PFDI and PFIQ-UIQ scores compared to baseline ($P<0.0001$) for both groups; there was no statistical difference in QoL between the pessary and behavioural therapy arms ($P>0.2$)

may be larger than calculated. This may explain the lack of a significant difference between pessary use and PFMT treatment (Richter *et al.* 2010; Kenton *et al.* 2012). Kenton *et al.* (2012) did attempt to address this issue by comparing baseline QoL scores to those at a 3-month follow-up, which showed a significant within-group improvement ($P<0.0001$) in both groups. This is relevant to the first author's (S.B.'s) clinical practice because PFMT for a minimum of 3 months is recommended as a first-line treatment modality for SUI (NICE 2019).

Based on the work of O'Sullivan *et al.* (2004), Morris & Moore (2003) categorized their patient population into two groups on the basis of the severity of urine leakage: mild and moderate/severe. However, the latter authors did not find a significant improvement in Urinary Distress Inventory (UDI) scores for mild SUI at the 4–6-week follow-up. A plausible explanation is that the mild group encountered the ceiling effect with regard to the outcome measure, i.e. it was not accurate enough to measure changes in QoL for these participants. Because of the subjective nature of measures of QoL and the inability to blind patients to the treatment intervention, there is an increased risk of reporter bias, i.e. patients may have believed the treatment to be more effective than it was (Greenhalgh 2014). The weight of the examiner's expectations may have a positive impact on a patient's answers in non-blinded studies. This can produce the Hawthorne and Rosenthal effects, the latter being a special branch of the Pygmalion effect that pertains to

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experimenter bias (Holman *et al.* 2015). The Hawthorne effect arises when participants alter their behaviour because they are taking part in a study, which can positively influence the results (Gosall & Gosall 2015). The Rosenthal effect may account for the better results reported by patients when greater expectations are put on them (Holman *et al.* 2015). This phenomenon may explain better performance in non-blinded studies.

When the categorization used by O'Sullivan (2000) is applied to Allen *et al.* (2008), an improvement in UDI scores in the group with mild SUI was apparent. This inconsistency between studies could be explained by the longer duration of the Allen *et al.* (2008) trial. It could also be explained by potential recall bias in Morris & Moore (2003) since follow-up data were not collected until 1–3 weeks after the trial had ended. Morris & Moore (2003) did not indicate whether the participants in their study continued to use pessaries as per the initial instructions, or whether subjects relied on their memories, which could have affected the reliability of the results. Both studies used the same brand of pessary (Contiform, Contiform International Pty Ltd, Kingsgrove, NSW, Australia), albeit it in a variety of sizes depending on patient comfort, and had the same nurse continence advisor fitting the pessary and teaching self-management of the device. This standardization of interventionist and pessary brand improves the internal validity of results by reducing confounding variables (Haneuse 2016).

The length of time that the pessaries were used for was not standardized across the seven studies, and in some cases, the device may not have been worn for long enough to have an effect on QoL. Participants were able to self-manage insertion and removal depending on menstruation, sexual intercourse and patient choice (see "Appendix 1", Table 6). Cornu *et al.* (2012) reported the shortest daily use and follow-up period. This could have led to underestimation of the results (a type II error) because the participant may not have used the pessary for enough to feel the benefits; given the subjective nature of the QoL measures, this is extremely important (Banerjee *et al.* 2009).

None of the seven studies reviewed described whether participants who received a pessary sought additional treatment outside of the trial. If so, this could have positively affected the outcome, i.e. although QoL improved, this might not have been a result of the pessary, but rather, it could have been caused by the additional treatment instead. This is otherwise known as a false positive or type I error, i.e. a significant effect is found, but there is not actually one present and the result has occurred by chance.

The controlled trial of Ziv *et al.* (2009) included an additional standardized assessment with high-impact activities (i.e. running, jumping and vigorously coughing). The evidence shows that high-impact exercises are associated with SUI (Fozzatti *et al.* 2012). Therefore, this additional exertion is likely to be provocative of SUI, and may enhance subjective measures at baseline, especially if the patient is not used to doing these activities. Higher baseline measures (e.g. a severely impacted QoL) may increase the chance of developing a false-positive result because there is more likely to be significant progress (Banerjee *et al.* 2009). This may explain the statistical improvements reported in the studies by Ziv *et al.* (2009) and Shayo *et al.* (2020) in comparison to the other trials (Cornu *et al.* 2012; Kenton *et al.* 2012) in which no statistical significance was found.

Richter *et al.* (2010), Kenton *et al.* (2012) and Cornu *et al.* (2012) used a power calculation for sample size prior to commencing their studies. Recruitment failed to meet this number, which had a negative impact on statistical power and may have increased the risk of a false negative, i.e. the research conclusion fails to show a significant improvement in QoL when, in fact, there was one. Additionally, the high drop-out rate in these trials may have had a negative impacted on statistical output (Bell *et al.* 2013) by reducing the statistical power of the studies and/or the balance of variables between the study groups. Combined with per-protocol statistical analysis, this may have increased the risk of attrition bias (i.e. the unequal loss of participants from the groups) within the studies (Mansournia *et al.* 2017). Per-protocol analysis helps to show the true effect of a treatment because it only includes the participants who have completed the full protocol, but it is not as frequently used as intention-to-treat (ITT) analysis (Gosall & Gosall 2015). Richter *et al.* (2010), Cornu *et al.* (2012) and Kenton *et al.* (2012) all completed ITT analysis, which provides unbiased results by addressing missing data (McCoy 2017). Despite producing more-conservative results, ITT analysis provides findings that are most likely to be reflected in everyday clinical practice (Gupta 2011).

Morris & Moore (2003), Allen *et al.* (2008) and Shayo *et al.* (2020) issued the participants

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in their studies with reusable pessaries, but the trials by Ziv *et al.* (2009) and Cornu *et al.* (2012) involved single-use disposable devices. This may have had an impact on whether patients decided to continue to use the pessaries or not because of the environmental impact and potential cost implications. All of the studies reviewed (Morris & Moore 2003; Allen *et al.* 2008; Ziv *et al.* 2009; Richter *et al.* 2010; Cornu *et al.* 2012; Kenton *et al.* 2012; Shayo *et al.* 2020) were conducted in countries where private healthcare is dominant, and this reduces the generalizability of these results to National Health Service (NHS) settings in the UK.

Three studies (Richter *et al.* 2010; Kenton *et al.* 2012; Shayo *et al.* 2020) reported long-term follow-up at 12 months; however, Kenton *et al.* (2012) did not fully document these results.

Morris & Moore (2003), Allen *et al.* (2008), Ziv *et al.* (2009) and Shayo *et al.* (2020) assessed QoL with validated outcome measures, i.e. the Incontinence Impact Questionnaire, Short Form (IIQ-7) and the UDI (Uebersax *et al.* 1995). Harvey *et al.* (2001) questioned the validity of using the IIQ-7 and UDI to assess the population with SUI in the absence of a urodynamic diagnosis, stating that neither the long nor short versions of the questionnaires correlate with the severity of urinary incontinence, as shown by the pad test. This may increase the risk of generating statistically significant results for the impact of pessaries on QoL when, in fact, there is no difference (Banerjee *et al.* 2009). All of the studies reviewed (Morris & Moore 2003; Allen *et al.* 2008; Ziv *et al.* 2009; Richter *et al.* 2010; Cornu *et al.* 2012; Kenton *et al.* 2012; Shayo *et al.* 2020) employed multiple outcome measures and involved many subgroup analyses. The practice of analysing large volumes of statistics in order to find any possible relations is known as data dredging (Gosall & Gosall 2015), and it can lead to the creation of significant results when, in fact, there are none.

All of the studies (Morris & Moore 2003; Allen *et al.* 2008; Ziv *et al.* 2009; Richter *et al.* 2010; Cornu *et al.* 2012; Kenton *et al.* 2012; Shayo *et al.* 2020) used self-reported outcome measures to record patient QoL, and this may have reduced the risk of researcher bias (Althubaiti 2016).

Richter *et al.* (2010) and Kenton *et al.* (2012) reported the results of stratified permuted block randomization. Stratified randomization addresses confounders by ensuring that there is a symmetrical distribution of symptom severity (Pourhoseingholi *et al.* 2013). It also minimizes selection bias and improves the reliability of the results (Sverdlov & Rosenberger 2013). Additionally, Richter *et al.* (2010) reported blinding of the research personnel, which reduces the risk of ascertainment bias, and also documented the allocation of concealment, which is a safeguard against selection bias after randomization (Karanicolas *et al.* 2010). Richter *et al.* (2010) and Kenton *et al.* (2012) both completed assessor-blinded studies, reducing the risk of detection bias (Karanicolas *et al.* 2010). Clinicians who are blinded to the study hypothesis and intervention arm are less likely to project their attitudes and beliefs onto participants (Schulz & Grimes 2002).

Richter *et al.* (2010) and Kenton *et al.* (2012) analysed a large RCT ($n = 446$) of good methodological quality (PEDro scores = 7/10 and 5/10, respectively) that failed to find any statistically significant superiority of pessaries over PFMT. Therefore, this calls into question whether the cost of the pessary and the inconvenience to the patient would be worthwhile in this case. Unfortunately, despite providing details of the statistical analyses and *P*-values, none of the papers included in the present literature review reported effect sizes, and therefore, it is difficult to determine the clinical significance of any improvement (Coe 2002). Furthermore, none of the authors provided sufficient information about their approach to data testing to allow a thorough critical evaluation. It was assumed that the data were not normally distributed because non-parametric testing was completed (Vickers 2005) (see "Appendix 1", Table 7). Two studies involved telephone follow-up with the practitioner (Richter *et al.* 2010; Cornu *et al.* 2012), but there was no indication that data collectors were blinded to assignment to treatment groups, which may have introduced researcher bias by encouraging positive results. The researchers did not state whether the telephone call was supervised or scripted, or who conducted it, which also increases the risk of researcher bias (Greenhalgh 2014). The remaining studies (Morris & Moore 2003; Allen *et al.* 2008; Ziv *et al.* 2009; Kenton *et al.* 2012; Shayo *et al.* 2020) did not report how data were collected at follow-up (e.g. telephone, mail or online), and therefore, it is difficult to assess any possible bias. Three studies (Allen *et al.* 2008; Ziv *et al.* 2009; Cornu *et al.* 2012) reported possible conflicts of interest and bias because funding was provided by industries or personnel involved in the manufacture of the pessaries.

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Limitations

The limitations of the present literature review include: the mixed baseline continence statuses and histories of pelvic surgery that were reported; the variations in the brand of the pessaries; and the length of time that the devices were used by the participants in the various trials. The analysis followed the principles of a systematic review, but it was undertaken alone by the first author (S.B.). Future systematic reviews would benefit from the inclusion of high-quality randomized crossover trials that involve large sample sizes and standardized monitoring of patients over time. Randomized controlled trials of larger populations conducted in NHS settings are also required. Patients on waiting lists could represent the control group, and standardization of the length of use, the longevity of any effect on QoL and a qualitative research methodology (e.g.) for measuring QoL should be explored. Since QoL is ambiguous and emotionally dependent, interpretative phenomenological analysis would be a useful qualitative methodology because it is designed to provide evidence of the personal lived experience of women with SUI (Smith & Osborn 2015).

Conclusions

The present literature review provides tentative support for the use of pessaries as a means of improving the QoL of female patients with SUI.

There is no consensus on the most appropriate mode of management, type of pessary or length of pessary use for a population of females with SUI. The literature does not give unequivocal support to pessaries fitted by a healthcare professional and left *in situ* in contrast to devices that are self-managed by patients. There is a need for future research to investigate the effect of self-management of pessaries versus physician-fitted pessary insertion on QoL, waiting list times, cost-effectiveness and patient satisfaction.

The present authors suggest that best practice may involve individualized PFMT alongside intermittent pessary use. The implications for the first author's (S.B.'s) own practice would include collaborative working with the multidisciplinary continence team in order to audit current conservative management strategies locally, and propose a pilot pathway for physiotherapists to prescribe and fit pessaries.

Declaration of interest

Following completion of the present literature review, the first author (S.B.) took part in research into a new containment device for SUI, the Uresta bladder support (Resilia Inc., Shediac, New Brunswick, Canada), which was funded by iMEDicare Ltd (Watford, UK). Completed in January 2021, this work investigated the long-term compliance and success rates of self-managing patients who used the device.

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Appendix 1

Table 5. Physiotherapy Evidence Database (PEDro) scores for trials included (N.B. the eligibility criteria do not contribute to the total score): (+) criterion met; and (–) criterion not met

	Reference						
Variable	Morris & Moore (2003)	Allen *et al.* (2008)	Ziv *et al.* (2009)	Richter *et al.* (2010)	Cornu *et al.* (2012)	Kenton *et al.* (2012)	Shayo *et al.* (2020)
Eligibility criteria	+	+	+	+	–	+	+
Random allocation	–	–	–	+	+	+	–
Concealed allocation	–	–	–	+	–	–	–
Baseline comparability	+	–	+	–	+	+	+
Blind subjects	–	–	–	–	–	–	–
Blind therapists	–	–	–	–	–	–	–
Blind assessors	–	–	–	+	–	+	–
Adequate follow-up (85%)	–	+	–	+	–	–	+
Intention-to-treat analysis	–	–	–	+	+	–	–
Between-group comparison	+	+	+	+	+	+	+
Point estimates and variability	+	+	+	+	+	+	+
PEDro score	3/10	3/10	3/10	7/10	5/10	5/10	4/10

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Table 6. Study interventions

Reference	Pessary instruction	Length of intervention	Learning time/attempts to fit	Pessary fitter
Morris & Moore (2003)	Allowed to leave *in situ* for 3 weeks, or to insert/remove it on a daily basis and before sexual intercourse	3 weeks	Patient had two attempts to insert and remove pessary at same appointment	Nurse
Allen *et al.* (2009)	Remove it on a daily basis and before sexual intercourse	4 weeks	Patient had between two and three attempts to insert and remove at same appointment	Nurse
Ziv *et al.* (2009)	Inserted for 8 h a day, but this could be interrupted for menstruation or as per patient convenience; changed on daily basis	28 days	14 days	Unclear
Richter *et al.* (2010)	Worn continuously for 8 weeks	8 weeks	Three clinic visits at 1–2-week intervals	Physician or nurse
Cornu *et al.* (2012)	Inserted for 6 h a day (maximum = 24 h), and changed on daily basis	28 days	Unclear	Unclear
Kenton *et al.* (2012)	Worn continuously for 8 weeks	8 weeks	Three clinic visits at 1–2-week intervals	Physician or nurse
Shayo *et al.* (2020)	Worn continuously for 3 months; removed once a month by user, cleaned and reinserted	18 months	Unclear; patient was taught by nurse on day of fitting	Nurse

Table 7. Statistical data analysis: (ANOVA) analysis of variance

Reference	Statistical test
Morris & Moore (2003)	Wilcoxon signed-rank test and Mann–Whitney *U*-test
Allen *et al.* (2008)	Mann–Whitney *U*-test
Ziv *et al.* (2009)	Student's *t*-test with Tukey's adjustment for multiple comparisons, mixed-model analysis
Richter *et al.* (2010)	Mantel–Haenszel test or ANOVA, logistic regressions
Cornu *et al.* (2012)	Student's *t*-test or Wilcoxon signed-rank test, χ^2 test
Kenton *et al.* (2012)	χ^2 test or two-sample *t*-test, paired *t*-test, one-way ANOVA
Shayo *et al.* (2020)	Fischer's exact text or χ^2 test, Wilcoxon signed-rank test

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