

Vaginal pessaries in urinary incontinence: integrative review

Pessários vaginais na incontinência urinária: revisão integrativa

Pesarios vaginales em la incontinência urinaria: revisión integrada

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ABSTRACT

Objectives: To analyze the types of pessaries, indications and impact in the treatment of urinary incontinence (UI). **Methods:** This is an integrative review with publications from 2007 to 2017 indexed in the Biblioteca Virtual em Saúde, Medical Literature Analysis and Retrieval System Online databases, Scopus Info Site, Cumulative Index to Nursing and Allied Health Literature and Web of Science. **Results:** Eight articles were selected. The pessaries indicated were the dish, ring, Uresta®, and Contiform®. The reduction or resolution of stress UI in women was observed by analysis of objective parameters such as urodynamic evaluation and quality of life questionnaires. Economic viability was highlighted. Disability, difficulties in use, discomfort, and maintenance of urinary losses were evidenced among the reasons for non-adherence. Advanced prolapse and short vaginal length were predictive of failure. Adverse events were identified in low incidence: urinary retention and leukorrhea. **Conclusion:** Pessary therapy is effective in the treatment of SUI when accompanied by trained professionals. Individual characteristics and perceptions about the device are determinants of therapeutic success. Studies of greater sampling, follow-up time and quality, as well as stimulation to national publications, are necessary for the investigation of objective measures of UI, clinical and demographic factors in relation to the success of the pessary.

DESCRIPTORS: Urinary incontinence; Pessaries; Nursing; Stomatherapy.

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RESUMO

Objetivo: Analisar os tipos de pessários, as indicações e o impacto no tratamento da incontinência urinária (IU). **Métodos:** Trata-se de revisão integrativa com publicações de 2007 a 2017 indexadas nas bases de dados Biblioteca Virtual em Saúde, Medical Literature Analysis and Retrieval System Online, Scopus Info Site, Cumulative Index to Nursing and Allied Health Literature e Web of Science. **Resultados:** Selecionaram-se oito artigos. Os pessários indicados foram prato, anel, Uresta® e Contiform®. A redução ou resolução da IU de esforço (IUE) em mulheres foi observada por análise de parâmetros objetivos, como avaliação urodinâmica e questionários de qualidade de vida. Destacou-se viabilidade econômica. Evidenciaram-se desajuste, dificuldades no uso, incômodo e manutenção de perdas urinárias entre os motivos de não adesão. Prolapso avançado e comprimento vaginal curto foram preditivos de insucesso. Identificaram-se eventos adversos em baixa incidência: retenção urinária e leucorreia. **Conclusão:** A terapia pessária é eficaz no tratamento da IUE quando acompanhada por profissionais capacitados. Características individuais e percepções sobre o dispositivo são determinantes no sucesso terapêutico. Estudos de maior amostragem, tempo de seguimento e qualidade, bem como estímulo a publicações nacionais, são necessários para investigação de medidas objetivas de IU, fatores clínicos e demográficos em relação ao sucesso do pessário.

DESCRIPTORES: Incontinência Urinária; Pessários; Enfermagem; Estomoterapia.

RESUMEN

Objetivo: Analisar los tipos de pesarios, indicaciones e impacto en el tratamiento de la Incontinencia Urinaria (IU). **Método:** Se trata de una revisión integrada con publicaciones de 2007 a 2017 organizado en la base de datos: La Biblioteca Virtual en Salud; Medical Literature Analysis and Retrieval System Online; Scopus Info Site; Cumulative Index to Nursing and Allied Health Literature; Web of Science. **Resultados:** Se seleccionaron ocho artículos. Los pesarios indicados fueron plato, anillo, Uresta® y Contiform®. La reducción o resolución de las pérdidas urinarias en mujeres con IU de esfuerzo fueron observadas por análisis de parámetros objetivos, como el estudio urodinámico y cuestionarios de calidad de vida. Se destacó la viabilidad económica. Se evidenció desajuste, dificultades en el uso, incómodo y mantenimiento de pérdidas urinarias entre los motivos de no adhesión. Prolapso de órganos pélvicos avanzado y tamaño vaginal corto fueron predictivos de fracaso. Se identificaron eventos adversos en baja incidencia: retención urinaria y flujo vaginal. **Conclusión:** La terapia con pesarios es eficaz en el tratamiento de la IU de esfuerzo cuando esta acompañada por profesionales capacitados. Características individuales y percepciones sobre el dispositivo son determinantes en el éxito de la terapia. Estudios de mayor muestreo, tiempo de seguimiento y calidad, bien como el estímulo a las publicaciones nacionales son necesarios para la investigación de medidas objetivas de IU, factores clínicos y demográficos en relación al éxito de los pesarios.

DESCRIPTORES: Incontinencia Urinaria; Pesarios; Enfermería; Estomaterapia.

INTRODUCTION

By 2018, an estimated 120 million men and 301 million women are suffering from urinary incontinence (UI), involuntary loss of urine^{1,2}. In the United States, in 2000, US\$ 14.2 billion, about US\$ 801 per non-institutionalized person, was spent on UI treatment, with US\$ 553 million in productivity burdens³. In women, a prevalent population, stress UI predominates, associated with physical activity, sneezing or coughing, and mixed (MUI), urgency and stress¹. The literature indicates impairment of quality of life (QoL); a Brazilian study identified a serious impairment in daily living activities in 63.9% of women suffering from SUI⁴ and U.S. study linked UI to increased risk for depression and disability⁵.

Pessaries, minimally invasive intravaginal devices, are described as a UI treatment option for women of any age group, especially those who wish to avoid or have

contraindications to surgical treatment^{1,6-8}. Among other advantages, they have a relatively low cost and risk, provide immediate relief of symptoms, and the possibility of being used in addition to other conservative therapies, such as exercises of the pelvic floor musculature^{1,6-8}. The earliest reports of pessaries date back to Ancient Egypt associated with pelvic organ prolapse (POP) treatment⁹, an indication that remains up to date^{1,6}. In evolution, there are reports of half pomegranate soaked in vinegar (350 BC), string-wrapped sponges wrapped in wax and covered with oil or butter (1559 AD), up to current silicone models⁹.

Despite the advantages observed in the clinical treatment of UI by means of pessaries, they are suspected to be underutilized. This question is justified by the current panorama of underreporting and neglect in the care of people with IU allied to the incipient theoretical and practical training of health professionals about this clinical condition, often restricted to postgraduate courses, and lack of randomized

controlled studies that support clinical practice, based today mainly on the opinion of experts, occasionally conflicting^{1,10,11}. In this context, this review study aims to analyze the types of pessaries, indications and the impact on the treatment of UI in order to provide subsidies for this clinical practice.

METHODS

The integrative review was used as a method of searching and summarizing the evidence for its ability to gather and synthesize relevant information from studies with different methodological designs, providing a critical and comprehensive assessment of the subject in order to support clinical practice based on evidence and point out gaps¹².

This review was developed and described in six methodological steps, according to Mendes et al.¹². In the first step, the following guiding question was elaborated: what is the evidence about the use of vaginal pessaries in the treatment of UI?

In the second step, represented as a flowchart (Fig. 1), the databases to be studied, the search or sampling strategies, and the inclusion and exclusion criteria of studies were determined. The literature review was carried out at the index databases Biblioteca Virtual em Saúde (BVS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Scopus Info Site (Scopus), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Web of Science. Different search strategies with the controlled descriptors (MeSH/DeCS), article indexing tools and search facilitators were used: Incontinência Urinária/Urinary Incontinence/Incontinencia Urinaria, Pessários/Pessaries/Pesarios, and their synonyms, uncontrolled descriptors:

Incontinence, Urinary, and Pessary. Among the controlled descriptors, we used the Boolean operator AND and, among the uncontrolled descriptors, OR.

Intervention/experimental studies (randomized, non-randomized clinical trials and community intervention studies), cohort, case-control and systematic review published from 2007 to 2017 in national and international journals in the English, Spanish and Portuguese languages were included in the sample, consistent with the objectives and guiding question of this study. Repeated or no full-text articles were excluded. The articles were independently peer-reviewed.

The third step consisted in the categorization of the sample with the following information extracted from the selected studies: reference, type of study, subjects, type of incontinence, type of pessary, time of follow-up of therapy, reasons for failure, adverse events, conclusions and limitations of the study. In the fourth step, from the analysis of this database, the evaluation of the sample that originated the results was developed. In the fifth stage, the discussion or interpretation of the results was carried out. Finally, in the sixth stage, were constructed the synthesis document and the presentation of this revision.

RESULTS

Eight articles were selected, according to the flowchart shown in Fig. 1. Despite the selection of 46 articles for reading in full, 38 had as main theme the application of pessaries for treatment of pelvic organ prolapse and were excluded.

Tables 1 and 2 present the characteristics and relevant data selected by the reviewers for this study.

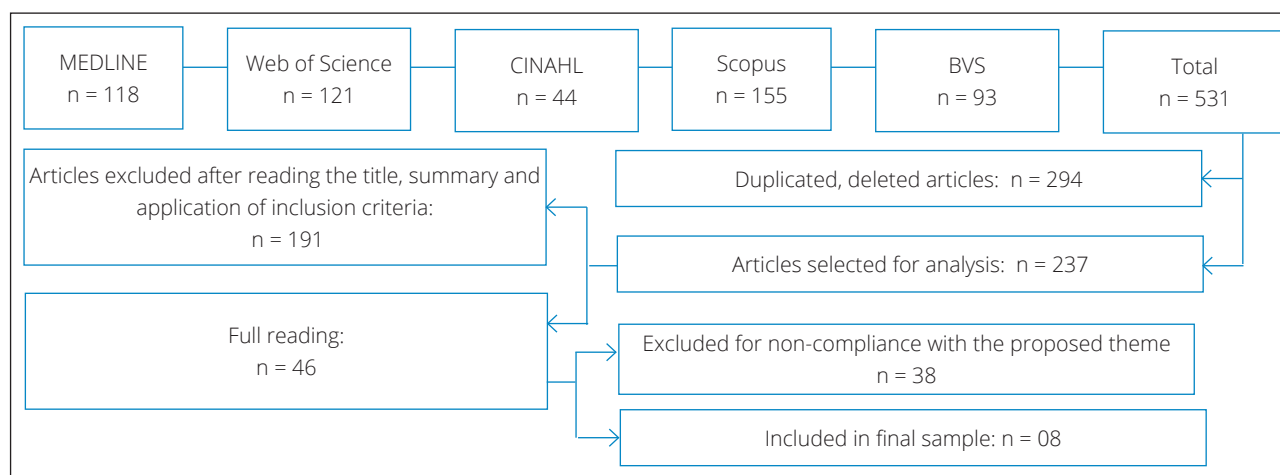


Figure 1. Flowchart of the selection process of the articles according to the databases. Campinas/São Paulo, Brazil.

Table 1. Distribution of selected studies according to the article number, title, author, year, period, type of study, subjects, type of incontinence, type of pessary and follow-up time. Campinas/State of São Paulo, 2018.

Number of the article	Title	Author (year)/ Journal	Type of study	Subject*/Type of incontinence	Type of pessary/ Follow-up time
1	Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women	Farrell et al. (2007)/ Am J Obstet Gynecol	Longitudinal	32/SUI or MUI	Uresta®/12 months
2	Effects of the incontinence dish pessary on urethral support and urodynamic parameters	Noblett et al. (2008)/ Am J Obstet Gynecol	Longitudinal	33/SUI	Dish/during urodynamic evaluation
3	Restoration of continence by pessaries: magnetic resonance imaging assessment of mechanism of action	Komesu et al. (2008)/ Am J Obstet Gynecol	Almost experimental	15/SUI	Dish/during urodynamic evaluation and resonance imaging
4	Update: the "Contiform" intravaginal device in four sizes for the treatment of stress incontinence	Allen et al. (2008)/Int Urogynecol J	Longitudinal	37/SUI and MUI	Contiform®/ 4 weeks
5	Incontinence pessaries: size, POPQ measures, and successful fitting	Nager et al. (2009)/ Int Urogynecol J	Intervention	266/SUI	Dish or ring/ not specified
6	A trial of continence pessary vs. behavioral therapy vs. combined therapy for stress incontinence	Richter et al. (2010)/ Obstet Gynecol	Longitudinal	446/SUI or MUI	Dish or ring/ 12 months
7	Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence	Kenton et al. (2012)/ Female Pelvic Med Reconstr Surg	Intervention	295/SUI or MUI	Dish or ring/ 3 months
8	Short-term Uresta efficacy (SURE) study: a randomized controlled trial of the Uresta continence device	Lovatsis et al. (2017)/ Int Urogynecol J	Intervention	36/ SUI or MUI	Uresta®/during the Pad test

*Women. SUI: Stress urinary incontinence; MUI: mixed urinary incontinence with a predominance of stress symptoms.

Table 2. Distribution of articles regarding article number, results and conclusions, reasons for failure and adverse events, and study limitations. C

N of the article	Results and Conclusions	Reasons for failure/Adverse events (AE)	Limitations of the study
1	Uresta® significantly reduced urinary incontinence (UI); Easy to use, with improved quality of life (QoL); Results demonstrated with objective measures: Pad test, Incontinence Impact Questionnaire (IIQ) and Urogenital Distress Inventory (UDI); Mechanism of action: mechanical support to the urethra; The need for larger, prospective, comparative studies with placebo effect control and analysis of interfering factors in the success of therapy.	Fall of the pessary, discomfort, disliked maintenance of urinary losses. Greater parity: predictive of difficulty in adjustment./AE: none.	Small number of participants; absence of control group.
2	Pessary in plate solved the majority of UI cases; Results demonstrated in the urodynamic evaluation and Q-tip test; Most of the women were satisfied; Mechanism of action: enhancement of urethrovaginal junction support an increase of maximum urethral closure pressure; Studies are needed to evaluate the bladder emptying function related to the risk of urinary retention.	Maintenance of urinary losses, discomfort Advanced pelvic organ prolapse (POP): predictive of failure/EA: reduction of the mean flow rate by 2 mL/s.	Urodynamic evaluation does not faithfully mimic the conditions of real life.
3	In magnetic resonance and urodynamic evaluation, the following mechanisms of continence of the pessary in the plate were observed: reduction of the posterior urethrovaginal angle, reduction and blunting of the bladder neck, increase in functional length and urethral resistance.	No record/AE: no record.	Insufficient sample for significant analysis.
4	Contiform® significantly reduced UI; Economically viable; Results demonstrated with Pad test de 24 h, UDI, IIQ and St. George score (20-point index scale of incontinence).	Fall of the pessary, difficulty in removal. Small vaginal length or introitus and prior gynecologic surgery: predictors of failure/AE: urinary retention.	Not pointed.
5	The majority of women with effort UI without advanced pelvic organ prolapse (POP) may succeed in pessary therapy if accompanied by trained professionals.	Unwillingness to use, mismatch, pain. Small vaginal length: predictive of failure/AE: no record	Results do not apply to women with advanced POP.
6	Pessary therapy is an alternative to behavioral therapy for patients who desire non-surgical management of SUI and are unable or resistant to pelvic floor muscle training (PFMT). Combination therapy was not superior to single therapy. Results demonstrated with Global Impression of Improvement (PGI-I), Pelvic Floor Distress Inventory (PFDI) and Patient Satisfaction Question (PSQ). Studies are needed to investigate barriers to adherence to these treatments.	Unwillingness to use, maladjustment, urinary losses/AE: leucorrhoea.	Not pointed.
7	Behavioral and pessary treatment are equivalent and clinically effective and important in the treatment of SUI, the choice depends on individual characteristics and preferences. Results demonstrated by QOL questionnaires: PFDI, Pelvic Floor Impact Questionnaire (PFIQ), Urinary Incontinence Diagnosis (QUID). Need for studies investigating clinical factors associated with the success of conservative treatment.	No record/AE: No record.	Not pointed.
8	Uresta® is effective in the treatment of SUI by reducing objective measures of UI evaluated by Pad test. Need for studies that evaluate subjective results and long-term patient satisfaction.	No registry/AE: none	Short-term evaluation.

DISCUSSION

For purposes of analysis and discussion of the identified articles, three categories were created: limitations of the literature, types of pessaries and indications for UI treatment and impact on treatment (positive and negative aspects).

Category 1: Limitations of the literature

The final sample of this review consisted of eight scientific articles selected by the inclusion and exclusion criteria previously established.

Regarding the origin of the studies, all were published in the English language and in international journals. As for the year of publication, the highlight was the year of 2008, with 37.5% of publications, followed by 12.5% in 2007, 2009, 2010, 2012 and 2017, observing a decrease in the number of publications. As for the methodological approach, it was found that 50% corresponded to longitudinal studies, 38% to intervention studies and 12.5% to almost experimental ones. Regarding the time of follow-up and evaluation of the therapy, 25% followed for 1 year, 12.5% for 3 months, 12.5% for 4 weeks, 37.5% during the exams and 12.5% did not specify.

According to the literature, the shortage of articles with a higher level of evidence related to the topic, coupled with the high prevalence of small-group studies (62.5% of the studies involved up to 37 women) and limited follow-up time, demonstrated that pessary therapy is in the process of consolidation as science and discovery by patients and health professionals^{1,9,12,13}, who are transposing sophisms of pessary inefficiency in the treatment of UI^{13,14}. Thus, studies of greater sampling, follow-up time and quality, as well as a stimulus to national publications, absent in this study, are necessary, although the Brazilian scientific literature grows above the world average¹⁵.

Category 2: Types of pessaries and indications for UI treatment

Pessary is indicated in the literature as a non-surgical treatment option for SUI^{6,14}. It was evidenced in this study that all the selected studies treated women with SUI and 62.5% also with MUI, with a predominance of stress symptoms. In the treatment of these dysfunctions, the pessaries in ring, with button and holder, dish and Uresta were prescribed in

other studies⁶, consistent with the data of this review, when the following indications were observed: pessary in dish (62.5%), in ring (37.5%) and three worked with specific devices, Uresta® (25%) and Contiform® (12.5%).

According to the literature¹, in this study, pessary therapy was indicated as an alternative to the training of pelvic floor muscles (PFMT) for patients who desired non-surgical management of SUI and were incapable or resistant to PFMT. Both therapies were considered clinically equivalent and combined therapy was not superior to single therapy. PFMT is indicated as a first line conservative treatment regardless of age because the integrity of this musculature is very relevant in the mechanism of continence¹.

Category 3: Impacts on treatment (positive and negative aspects)

As observed in the literature^{8,14,16}, Positive aspects such as economic viability; ease of insertion, fitting and withdrawal; low incidence of complications; adverse effects and discomfort, therefore low risk, are present in this review and are associated with the successful treatment of UI with pessaries, as well as their adherence. All studies reported resolution or reduction of urinary loss, attesting to the efficacy of the therapy. Some demographic and clinical aspects are mentioned in the literature as positive data regarding therapeutic success: being elderly, being postmenopausal, presenting less parity and not being a smoker¹⁶.

In the present review, length (<7 cm) or small vaginal introitus, greater parity, advanced POP and previous gynecological surgeries were characterized as predictive of failure. In two studies, adverse events with low incidence were also identified: vaginal discharge and urinary retention. Other unsuccessful factors reported in the literature are a cognitive deficit, high body mass index (BMI), and mobility restrictions, such as those caused by rheumatoid arthritis^{17,18}.

In this review, the following reasons for non-adherence were identified: mismatch (25%); fall of the pessary (25%); disliked or unwilling to use (37.5%); difficulty of removal or insertion (12.5%); maintenance of urinary losses (37.5%); pain or discomfort (37.5%). Consonant to the literature, these results and the lack of specialized support influence the treatment negatively^{1,14,16,18-20}. With the trend towards

decentralization of care to people with UI for primary care, in order to democratize access to treatment, specialist or trained nurses are indicated as the ideal professionals to promote this care in a holistic and person-centered way and their family, social and economic structure^{1,21}. However, it is believed that the reasons related to non-adherence are much more complex and are related to the capacity of resources and structuring of the health system, knowledge of the patient, of the health professional and their perceptions regarding pessaries^{15,21,22}.

It was observed in the present review that two articles demonstrated the efficacy of the pessaries through the urodynamic study, whose purpose is to investigate the functioning and dysfunctions of the urinary tract¹. In this study, elementary mechanisms of pessary action were evidenced: stabilization, an increase of resistance and urethral functional length, as already exposed in the literature^{6,20}. Among the main results, the reduction of the posterior urethrovesical angle was identified in the Q-tip test; in the urodynamic evaluation, the increase of the maximum urethral closure pressure. Other objective measures, in addition to urodynamic parameters such as Pad test and QOL and incontinence questionnaires, are prone to assess pessary therapy in order to make it scientific.

CONCLUSION

Data from the present study suggest that pessary therapy is effective in the control and treatment of SUI and MUI, with predominance of effort symptoms as long as

they are accompanied by trained professionals. However, the particular characteristics of each woman and their perceptions directly influence the success of the therapy, which is still in process of being consolidated as science and discovery by patients and health professionals. The structuring of the health system and the guarantee for resources that are fundamental for democratization of access to therapy. The number of publications of intervention, cohort and case control studies and systematic reviews is incipient. Major sample studies, follow-up time and quality, as well as the encouragement to national publications are required for investigation of objective UI measures, clinical and demographic factors related to the success of pessary therapy.

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CONTRIBUTION OF AUTHORS

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