The usage of Gellhorn pessary in pelvic organ prolapse and in regards to success, continuity of use and effect on symptoms: a retrospective study of 2 years

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ABSTRACT

Introduction: Pelvic organ prolapse (POP) is a condition involving weakened pelvic floor muscles causing organs to protrude. Conservative POP treatment comprises pelvic floor exercises and vaginal pessaries. Besides conservative care, surgery is offered. However, surgery is invasive, risky and unsuitable for those with serious medical conditions. This study aims to assess the acceptance, success and outcomes of the Gellhorn pessary for POP treatment, especially in advanced cases.

Materials and Methods: The present study is a retrospective cohort study using hospital medical records (patient files) from October 2019 to November 2021 (for 2 years). This study was performed in Malaysian women (n=53) suffering from advanced stages of POP, in which Gellhorn pessaries of diameter (44-76mm) were inserted by trained personnel. Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7) were used to measure patients' symptoms and quality of life before and after Gellhorn pessary fitting. Patients were reassessed every three months for two years and their satisfaction scores were recorded.

Results: We observed a significant difference in pre-test (pre-fitting) and post-test (three months post-fitting) scores on all three subscales and the PFIQ-7 total score. Twenty-eight (52.83%) patients continued the use of Gellhorn pessary for at least 24 months, whereas 25 (47.20%) patients discontinued during this period. A retrospective analysis of the patients who discontinued Gellhorn pessary showed that 13 (24.52%) patients gave up the use of pessary for definitive surgery. It is noteworthy to mention here that only one out of the 13 patients who were awaiting surgery, chose surgery and the remaining 12 changed their mind after being fitted with the Gellhorn pessary. Seven (13.20%) patients declined reinsertion due to discomfort and voiding difficulties and refused further intervention, whereas three (5.66%) patients requested a ring pessary. Two (3.77%) patients, requested the removal of pessary due to vesicovaginal fistula and rectovaginal fistula (caused by an impacted pessary). The rate of continued use was 79.24% (42 patients) after 1st year and 52.83% (28 patients) at the end of two years.

Conclusion: In the current study, the Gellhorn pessary was used to treat stage 3 and 4 POP with significant symptom reduction post-fitting. More than half of the patients continued to use the pessary after 24 months of fitting. Therefore, the Gellhorn pessary can be used as a treatment strategy for stage 3 and 4 POP with reasonable acceptance in the Malaysian population.

KEYWORDS:
Pelvic organ prolapse (POP), Gellhorn pessary, Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7)

INTRODUCTION

Pelvic organ prolapse (POP) is characterised by pelvic floor muscle dysfunction that causes one or more organs to descend and causes a bulge in the vagina. The respective prolapse of an organ is called cystocele, urethrocele, uterine prolapse, rectocele and enterocele. Physiologically, pelvic floor muscles form a hammock supporting the organs in place. However, numerous factors compromise this support resulting in POP.[1] Globally, the prevalence of POP in women is on the rise due to the ageing population and could reach around 40% within a few years. Up to 54% of women with POP also have stress urinary incontinence.[2]

Conservative management of POP includes pelvic floor exercises and vaginal pessaries.[3] Apart from conservative management, there are surgical treatments available as well. However, surgery is an invasive procedure with many risks involved. Furthermore, relapse is also a factor that is quite high when POP is treated with surgery which can increase a patient's financial and mental health burden.[4] In some situations, patients have severe medical conditions or comorbidities that make them a poor candidate for surgery.[5] In such cases, the healthcare provider should inform the patients regarding alternative treatment options.

Vaginal pessaries belong to one of two main categories: supportive (ring pessary, etc.) or space-occupying (Gellhorn pessary, etc.).[6] Ring pessaries are generally easier to remove, lower the risk of erosions and require lesser visits to the clinic.[3] However, up to 56% of ring pessary users could experience complications such as extrusion, haemorrhage, severe vaginal discharge, pain and constipation, leading to a high discontinuation rate within one year.[7] Moreover, ring pessaries get dislodged easily in comparison to space-occupying Gellhorn pessaries, hence they are not suitable for

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advanced prolapse and the Gellhorn pessary could be more effective.[8,9]

The Gellhorn pessary is an effective and long-term treatment for POP because it creates suction against the proximal vagina, which supports the pelvic organs even in advanced-stage POP. The Gellhorn pessary can also be used as a treatment option for POP after other treatments fail.[10] It has a high success rate in patients with posterior compartment and stage 4 prolapse.[11] As per our clinical experience, support pessary is usually used in Malaysia as the mainstay amongst pessary types for the conservative management of POP while Gellhorn pessary is not widely used. Furthermore, as per our literature search (using google scholar and Pubmed databases using keywords Gellhorn pessary & Malaysia) Gellhorn pessary's acceptance and success rate is unknown in Malaysia. Therefore, an analysis of its acceptance, success rates and reasons for discontinuation is required. Our study will enable healthcare providers to make informed decisions regarding the use of the Gellhorn pessary and will contribute to shared decision-making between doctors and patients by facilitating personalised treatment planning. Moreover, our study could serve as the baseline for comparisons with other treatment modalities of POP.

MATERIALS AND METHODS

Study Design

The present study is a retrospective cohort study using hospital medical records (patient files).

Study Population

We conducted a retrospective clinical review of 61 patients of symptomatic POP with stages 3 and 4 from October 2019 to November 2021. Based on the inclusion and exclusion criteria, 53 women were selected. Due to the stage of prolapse in the selected patients, 27 patients were not able to fit a ring pessary, 13 patients had initially failed ring pessary fitting (for successful ring pessary fitting, the internal vaginal calibre must be wider than the vaginal opening to retain a ring pessary, and patients who had a wide introitus and were unable to retain the pessary were placed under the category of 'ring pessary failure') and 13 were awaiting surgery (who had their surgery scheduled for at least after three months). They were given the option of a Gellhorn pessary as an alternative to surgery or till the date of operation (see Table I).

Inclusion Criteria

Records of patients with stage 3 and stage 4 POP were included in this study with complete follow-up data for at least three months after their Gellhorn pessary fitting.

Exclusion Criteria

Patients who were sexually active were not part of the present study as space-occupying pessaries interfere with sexual activity. Any allergy history of the patients was also checked before the pessary fitting to ensure that none of them were allergic to silicone as the Gellhorn pessaries are usually made of silicone. Patients with atrophic vagina and erosion were also not fitted with the Gellhorn pessary because the Gellhorn pessary also has vaginal dryness, itching and erosion as its side effects which could cause further complications. Atrophic vagina and some erosions are often found in women with advanced stage POP, especially those who have used a ring pessary in the past so such patients were thence not routed for Gellhorn pessary fitting. Furthermore, patients with abnormal pap smears were also not fitted with Gellhorn pessary and were referred to the Oncology Department.

Pessary Type

Gellhorn pessaries manufactured by the Cooper Surgical, Inc. were used and the range of pessary diameter varied from 44 mm to 76 mm.

Pessary Fitting Procedure

Trained personnel inserted the Gellhorn pessary in patients with POP. We manually managed prolapse before the pessary fitting. Measurement between both sacrospinous processes and one finger breath of space between the pessary and the vagina determined the size of the pessary. We asked the patients to walk, cough, micturate and execute the Valsalwa manoeuvre to ensure the pessary did not expel during daily activities. After confirmation of in situ pessary placement, we recommended the patients return for a follow-up appointment in 2 weeks to record their symptoms and get a general evaluation of their condition. We changed the pessary size of patients who had discomfort. Retaining the pessary after 2 weeks without any complaints was considered a successful fitting. We collected data on every follow-up regarding symptoms, factors affecting satisfaction and refusal for pessary re-fitting.

Data Collection

We collected data from the medical records of patients who visited our urogynaecology unit for stage 3 and 4 POP. Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7) were used to measure patients' symptoms and quality of life before and after (at 3 months follow-up visit) Gellhorn pessary fitting. Patients came for a follow-up every three months for condition re-evaluation.

Numerous factors were reported (verbally) by patients that, according to them, were behind their doing away with Gellhorn pessary. These factors were then noted in their hospital record files. In a similar manner, we also asked the patients who continued the use of Gellhorn pessary for at least two years to verbally rate their satisfaction on a scale of 1 to 10 where 1 meant least satisfied and 10 meant extremely satisfied with the pessary. Their rating was again noted in their files.

Ethical Considerations

All the procedures used during this study adhered fully to the Malaysian Medical Association's (MMA) Code of Medical Ethics. Furthermore, Gellhorn pessary is a non-invasive management for third and fourth degree prolapses so patients were not exposed to higher levels of risk of harm. Informed consent question was part of the forms that patients filled before the procedure, so, only those patients' data were chosen who voluntarily allowed us. Therefore, institutional review board's exemption or waiver or consent was not needed in this retrospective study.

Table I:Patient characteristics, indications, main side effect and reasons for removal of Gellhorn pessary

		Primary Indication (n=27)	Postring pessary failure (n=13)	Awaiting Surgery (n=13)	Total (n=53)
Patient characteristics	Age (mean±SD)	63.33 (6.67)	64.62 (7.96)	61.77 (6.31)	63.26 (6.86)
	Parity (mean±SD)	3.88 (1.31)	3.54 (1.26)	3.31 (1.37)	3.66 (1.31)
	Prior surgery history	2 (7.40%)	2 (15.38%)	2 (15.38%)	6 (11.32%)
Duration	Completed 1 year	21 (77.77%)	9 (69.23%)	12 (92.30%)	42 (79.24%)
	Completed 2 year	13 (48.14%)	6 (46.15%)	9 (69.23%)	28 (52.83%)
Side Effects	Pain/discomfort	22 (81.48%)	10 (76.92%)	10 (76.92%)	Exp:42 (79.24%) Rmvd:5 (9.43%)
	Discharge	21 (77.77%)	13 (100%)	11 (84.61%)	Exp: 45 (84.90%) Rmvd:0 (0.00%)
	Bleeding	7 (25.92%)	1 (7.69%)	2 (15.38%)	Exp:10 (18.87%) Rmvd:3 (5.66%)
	Voiding Difficulty	3 (11.11%)	2 (15.38%)	0 (0.00%)	Exp:5 (9.43%) Rmvd:5 (9.43%)
	Defaecation difficulty	1 (3.70%)	1 (7.69%)	1 (7.69%)	Exp: 3 (5.66%) Rmvd:0 (0.00%)
	Impacted pessary/fistula	0 (0.00%)	1 (7.69%)	1 (7.69%)	Exp:2 (3.77%) Rmvd:2 (3.77%)
	Difficult removal and insertion	5 (18.51%)	2 (15.38%)	1 (7.69%)	Exp:8 (15.09%) Rmvd:8 (15.09%)
	Unexplained	1 (3.70%)	0 (0.00%)	1 (7.69%)	Exp:2(3.77%) Rmvd:2(3.77%)

Table II: Results of repeated measures t-test of PFIQ-7

	Pre-test		Post-test				
Measure	Mean	S.D.	Mean	S.D.	T	df	p
UIQ7	58.31	5.97	55.62	6.52	5.022	52	<0.01
CRAIQ7	56.43	6.50	53.58	6.41	4.227	52	<0.01
POPIQ7	93.08	2.93	54.66	22.07	12.873	52	<0.01
PFIQ7	207.82	10.12	163.86	22.73	14.115	52	<0.01

Analysis

All data were collected and measured. We estimated percentages of symptoms affecting satisfaction and of each factor influencing pessary discontinuation. The difference in symptoms before and after pessary fitting was assessed on PFIQ-7 using a repeated measures t-test. The statistical significance level used was $p<0.001$.

RESULTS

Gellhorn pessary fitting showed an initial success rate of 100%; retaining the pessary after two weeks without any complaints was considered a successful fitting. Information of the patient characteristics is shown in Table I. Furthermore, Figure 1 shows the outcome of our study. Twenty-eight patients (52.83%) preferred to continue the pessary after 24 months. A total of 25 patients (47.16%) discontinued the use of Gellhorn pessary. Out of these, 13 (24.53%) patients gave up the use of pessary for definitive surgery based on personal preference (reason not explicitly disclosed by patients), and seven patients (13.21%) refused reinsertion, whereas 3 (5.67%) patients requested a ring pessary due to discomfort and voiding difficulties. Two patients (3.77%) developed a fistula due to impacted pessary and discontinued the use of Gellhorn pessary. The number and percentage of patients who discontinued the use of Gellhorn pessary during the first and second year is shown in Figure 2. During the first year, 11 patients (20.75%) relinquished the use of the Gellhorn pessary, while 14 patients (26.42%) in the second year (a total of 25 patients or 47.17% in two years).

Many side effects of using Gellhorn pessary were reported (verbally) by the patients. These side effects (with percentage of patients who experienced them) were: discomfort (79.25%), abnormal vaginal bleeding (18.87%), voiding difficulties (9.43%), defaecation difficulties (5.66%), difficulties in re-fitting (15%), and fistula (3.77%). We tried to resolve these symptoms through conservative management, but still, a few of them got their pessaries removed owing to these side effects (for details see Table I).

It is noteworthy to mention here that initially 13 patients were fitted with Gellhorn pessary owing to the long waiting time for their scheduled surgery; only one (1.88%) patient (out of those initial 13) ultimately chose surgery. And the remaining 12 cancelled their surgeries after getting fitted with a Gellhorn pessary. This underscores the importance of Gellhorn pessary use as a viable alternative to surgery in the management of advanced POP. On the other hand, some (12 or 22.64%) patients got their pessaries removed and they opted for surgery although they were initially not awaiting surgery for their treatment.

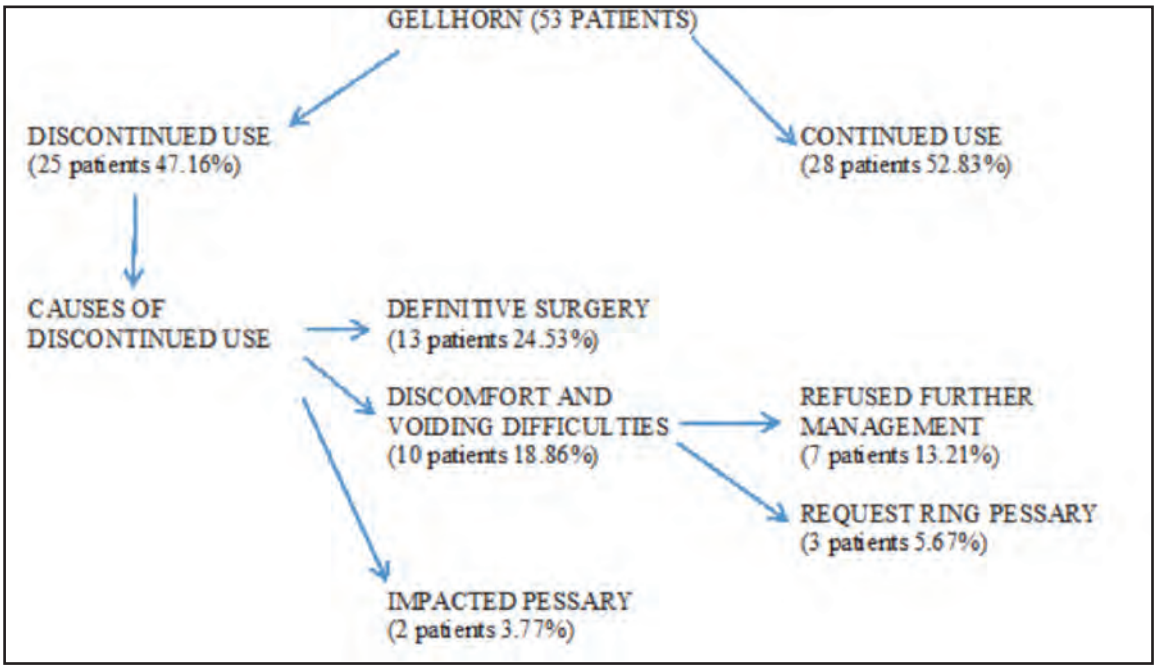

Fig. 1: Outline of the study.

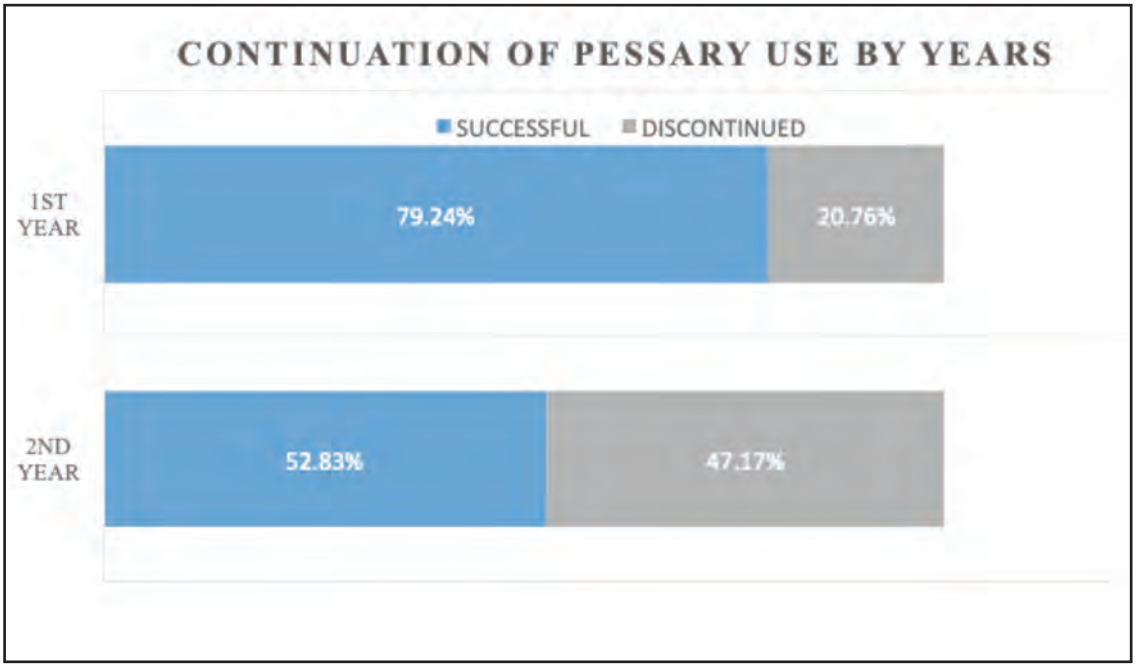

Fig. 2: The continuous use of pessary for the first and second year.

The patients who completed two years with Gellhorn pessary were asked to verbally rate their satisfaction with the pessary; a rating of 1 meant least satisfied and 10 meant highly satisfied.

Their answers showed that 68% of the patients chose 7, while 25% of patients described their satisfaction as 6 and only 7% described their satisfaction as 5.

No cut-off values were chosen to indicate the level of satisfaction, as lower rating meant less satisfaction and higher ratings meant higher satisfaction. The most frequent Gellhorn pessary sizes used were 57mm (46%), followed by 51mm (29%) and 64mm (15%).

Repeated measures t-test results of PFIQ-7 showed a significant improvement in the quality of life after the Gellhorn pessary fitting. Pre-test scores on all three scales

decreased significantly, i.e., on UIQ7 from 58.31(5.97) to 55.62(6.52), CRAIQ7 from 56.43(6.50) to 53.58(6.41), POPIQ7 from 93.08 (2.93) to 54.66 (22.07) and on the combined PFIQ-7 from 207.82 (10.12) to 163.86 (22.73) (see Table II).

Before Gellhorn's pessary fitting, the PFDI-20 showed a severity of distress score in 85% (45/53) of patients for Pelvic Organ Prolapse Distress Inventory 6 in patients suffering from POP while 15 % of patients experienced a moderate degree of distress for Pelvic Organ Prolapse Distress Inventory 6. We could not include the post-fitting results of PFDI-20 in this study because that data were incomplete to the extent that we were unable to calculate any meaningful results from it.

DISCUSSION

First-line treatment for POP comprises pelvic floor exercises and vaginal pessaries, regardless of age or type of prolapse.[12-14] In a recent Cochrane meta-analysis, women who used pessaries in conjunction with pelvic floor muscle training reported fewer symptoms of POP and improved quality of life.[3] Pessaries have been proven to effectively manage the symptoms of prolapse (PFDI-20 and PFIQ-7 scores) and improve self-perception of body image in a way similar to surgery.[15-17]

In the present study, 79.24% of women continued to use the Gellhorn pessary after the initial fitting during the first year, while the success rate of continuation was 52.83% in second year. Mao et al.[10] reported that difficulties associated with placement and removal influence the use of pessaries. More than 70% of discontinuity occurred within the first month of fitting due to the associated symptoms.[18] A long-term study indicated a decrease in the likelihood of sustained use over time.[19] The present study showed a discontinuity rate of 47.14% during second year. The symptoms affecting patient satisfaction were discomfort, abnormal vaginal bleeding, voiding difficulties, defecation difficulties, difficulties in re-fitting and fistula. Impacted pessary led to complications of vesicovaginal fistula and rectovaginal fistula in two patients (3.77%) and resulted in discontinuation of use. Management of vesicovaginal fistula involved the insertion of a silicon catheter and broad-spectrum antibiotics for 10 days. As for the rectovaginal fistula, the patient was given stool softener for one month and covered with broad-spectrum antibiotics for 2 weeks. These two patients refused any further intervention.

Patient-reported outcome measures, known as PROMs, are frequently used to evaluate and quantify the degree and severity of symptoms. The Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) are reliable tools for assessing the quality of life in women with POP. The PFIQ-7 is used to assess the effect of POP on quality of life, and PFDI-20 is used to check the extent of POP symptoms and related complaints.[20] All patients reported a significant improvement in their quality of life after the Gellhorn pessary fitting.

The current study shows that Gellhorn pessary is an effective alternative treatment option in the management of symptomatic third and fourth-degree prolapse. Discussion with patients regarding the pros and cons of pessary before fitting could improve the success rates as the adverse effects were manageable. Our findings suggest that Gellhorn pessary is a viable option for patients who are unwilling or unfit for surgery and have a third or fourth degree of POP. A strength of this study was our focus on the Gellhorn pessary with a long-term follow-up duration (up to 2 years).

LIMITATIONS OF THE STUDY AND FUTURE DIRECTIONS

The present study provides valuable insights into a novel phenomenon of Gellhorn pessary use in Malaysian population. However, there are certain limitations of the present study as well which should be addressed by future researchers. Firstly, the present study was a retrospective study with limited available data; therefore, it is recommended that future researchers should conduct prospective studies on this topic to further understand the factors affecting Gellhorn pessary use in Malaysia. Secondly, our study included a relatively small sample size of the continuation group, so future researchers should aim for a larger sample size. Thirdly and finally, we mainly utilised quantitative data in our study which has a built-in limitation of being restrictive. Future researchers should try and investigate the challenges and benefits of Gellhorn pessary use through qualitative research, i.e., interviews etc.

CONCLUSION

We conclude that Gellhorn pessary has a reasonable success rate and patience acceptance after two years of use. Most patients who continued the use of pessary showed good satisfaction and improved quality of life. This pessary can be used as a reasonable treatment option in conservative patient management of advanced prolapse before moving towards surgical management, increasing the available conservative treatment options in Malaysia. Our study paved a way towards non-surgical management of prolapse, exploiting space-filling pessaries in older women who are no longer sexually active and wish to manage their condition without surgery. All main side effects of Gellhorn pessary; pain, discharge, bleeding and fistula were conservatively managed.

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COMPETING INTEREST DECLARATION

The authors declare that there are no conflicts of interest.

REFERENCES

1. Wang CN, Chung DE. Etiology, diagnosis, and management of pelvic organ prolapse: overview. Female Genitourin Pelvic Floor Reconstr 2023; 507-18.
2. Wong JWH, Ramm O. Urinary incontinence and pelvic organ prolapse. Clin Obstet Gynecol 2021; 64(2): 314-20.
3. Bugge C, Adams EJ, Gopinath D, Stewart F, Dembinsky M, Sobiesuo P, et al. Pessaries (mechanical devices) for managing pelvic organ prolapse in women. Cochrane Database Syst Rev 2020; (11): CD004010.

4. Li B, Chen Q, Zhang J, Yu C, Zhang L, Chen L. A prospective study of pessary use for severe pelvic organ prolapse: 3-year follow-up outcomes. Arch Gynecol Obstet 2020; 301(5): 1213-8.
5. Radnia N, Hajhashemi M, Eftekhar T, Deldar M, Mohajeri T, Sohbati S, et al. Patient satisfaction and symptoms improvement in women using a vaginal pessary for the treatment of pelvic organ prolapse. J Med Life 2019; 12(3): 271-5.
6. Cundiff G. A survey of pessary use by members of the American Urogynecologic society. Obstet Gynecol 2000; 95(6): 931-5.
7. Van Der Vaart L, Vollebregt A, Milani A, Lagro-Janssen A, Duijnhoven R, Roovers J, et al. Pessary or surgery for a symptomatic pelvic organ prolapse: the PEOPLE study, a multicentre prospective cohort study. BJOG Int J Obstet Gynaecol 2022; 129(5): 820-9.
8. Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse. Am J Obstet Gynecol 2004; 190(2): 345-50.
9. Abdulaziz MM, Stothers L, Lazare D, Macnab A. An integrative review and severity classification of complications related to pessary use in the treatment of female pelvic organ prolapse. Can Urol Assoc J 2015; 9(5–6): E400-6.
10. Mao M, Xu T, Kang J, Zhang Y, Ai F, Zhou Y, et al. Factors associated with long-term pessary use in women with symptomatic pelvic organ prolapse. Climacteric 2019; 22(5): 478-82.
11. Ma C, Xu T, Kang J, Zhang Y, Ma Y, Liang S, et al. Factors associated with pessary fitting in women with symptomatic pelvic organ prolapse: a large prospective cohort study. Neurourol Urodyn 2020; 39(8): 2238-45.
12. Nygaard CC, Tsiapakidou S, Pape J, Falconi G, Betschart C, Pergialiotis V, et al. Appraisal of clinical practice guidelines on the management of obstetric perineal lacerations and care using the AGREE II instrument. Eur J Obstet Gynecol Reprod Biol 2020; 247: 66-72.
13. Pizzoferrato AC, Thuillier C, Vénara A, Bornsztein N, Bouquet S, Cayrac M, et al. Management of female pelvic organ prolapse—summary of the 2021 HAS guidelines. J Gynecol Obstet Hum Reprod 2023; 52(3): 102535.
14. Sansone S, Sze C, Eidelberg A, Stoddard M, Cho A, Asdjodi S, et al. Role of pessaries in the treatment of pelvic organ prolapse: a systematic review and meta-analysis. Obstet Gynecol 2022; 140(4): 613-22.
15. Schiavi MC, D'Oria O, Faiano P, Prata G, Di Pinto A, Sciuga V, et al. Vaginal native tissue repair for posterior compartment prolapse: long-term analysis of sexual function and quality of life in 151 patients. Female Pelvic Med Reconstr Surg 2018; 24(6): 419-23.
16. De Tayrac R, Antosh DD, Baessler K, Cheon C, Deffieux X, Gutman R, et al. Summary: 2021 International Consultation on Incontinence evidence-based surgical pathway for pelvic organ prolapse. J Clin Med 2022; 11(20): 6106.
17. Patel M, Mellen C, O'Sullivan DM, LaSala CA. Impact of pessary use on prolapse symptoms, quality of life, and body image. Am J Obstet Gynecol 2010; 202(5): 499.e1-499.e4.
18. Lone F, Thakar R, Sultan AH, Karamalis G. A 5-year prospective study of vaginal pessary use for pelvic organ prolapse. Int J Gynecol Obstet 2011; 114(1): 56-9.
19. Ramsay S, Tu LM, Tannenbaum C. Natural history of pessary use in women aged 65 – 74 versus 75 years and older with pelvic organ prolapse: a 12-year study. Int Urogynecol J 2016; 27(8): 1201-7.
20. Mikeltadze I, Täär K, Kadastik Ü, Soplepmann P, Rull K. Validation of the short forms of the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire in Estonian. Int Urogynecol J 2023; 34(9): 2235-40.