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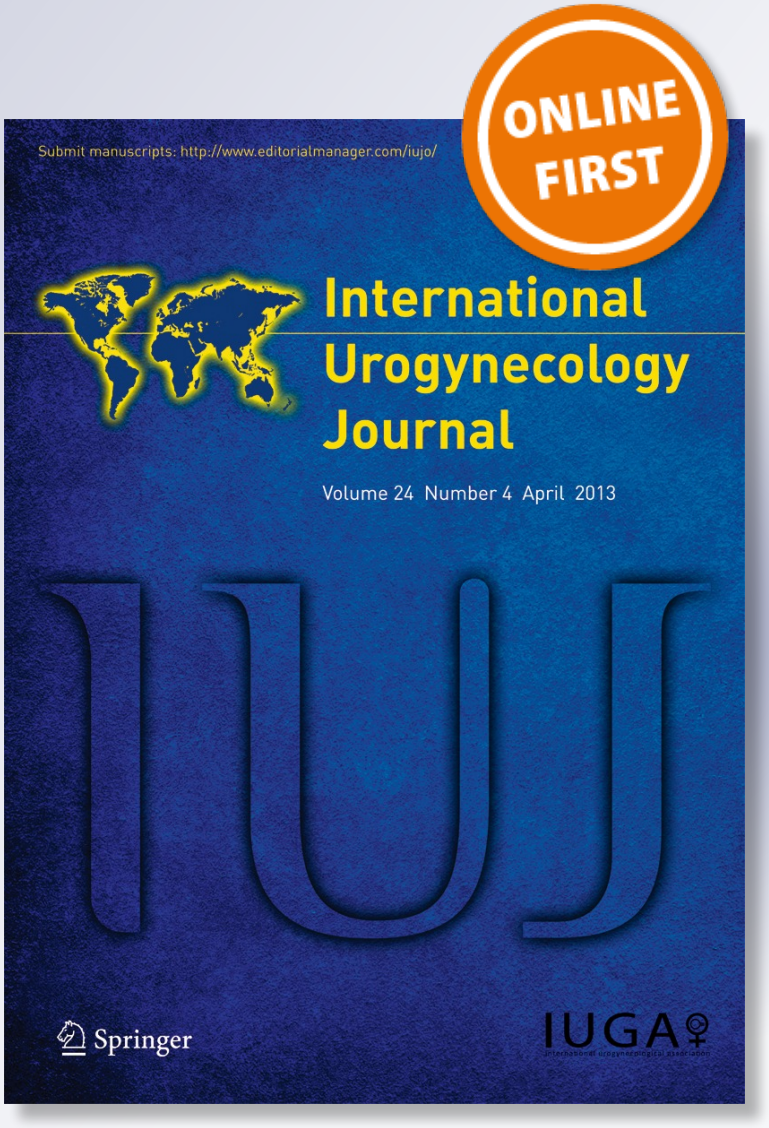

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ORIGINAL ARTICLE

The cube pessary: an underestimated treatment option for pelvic organ prolapse? Subjective 1-year outcomes

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Abstract
Introduction and hypothesis Pelvic organ prolapse (POP) is a common condition. The use of pessaries for conservative management of POP is widespread. However, there are little data on the use of cube pessaries. The aim of our study was to evaluate whether self-therapy with the use of vaginal cube pessaries in women with POP can be a well-tolerated, first-line treatment.
Methods In a prospective case series, 87 women who suffered from symptomatic POP, stages II–IV, were instructed in self-treatment with a vaginal cube pessary. Differences were analyzed using Wilcoxon's rank sum test or Fisher's exact test.
Results A pessary could be fitted in 84/87 patients (96.6 %); 6 women were lost to follow-up. The remaining 78 patients (92.9 %, median age 60 years) completed the study. Sixteen women (20.5 %) chose not to continue with the pessary treatment. For these patients, general well-being decreased from a median numeric rating score (NRS) of 4.5 (3–6) to 2.0 (1–3, $p<0.001$). In those who continued treatment, general well-being increased from a median NRS of 3.0 (2–5) to 8.0 (7–10, $p<0.001$) after 1 year of use. The majority of patients (53) in the present study rated pessary self-care use as "very easy" or "easy" (85.5 %). The Patient Global Impression of Improvement (PGI-I) was 2.0 (1–3) at follow-up examination. There were no complications or adverse effects of pessary use.
Conclusions Conservative self-treatment with vaginal cube pessaries might be a feasible treatment option for women who suffer from POP.

Keywords Uterine descensus · Cystocele · Pessary · Conservative treatment · Pelvic floor insufficiency

Introduction

Pelvic organ prolapse (POP) is a common condition, with an overall incidence of >10 % in the female population of the Western world. Up to 50 % of parous women develop some degree of POP in their life [1]. Although nonsurgical treatment options, including vaginal pessaries, exist, surgery is frequently performed in these patients [2]. However, up to 10 % of women who undergo a surgical procedure for prolapse require a second procedure [3]. Moreover, a recent trial demonstrated that nearly two thirds of women with symptomatic prolapse would initially opt for conservative management, including the use of vaginal pessaries [4].

The most common indication for vaginal pessary use is support and repositioning of prolapsed pelvic organs [5–7]. The main aims are to prevent worsening of the prolapse [8], to ameliorate prolapse symptoms, and to avoid the need for surgery [9]. Long-term success rates of up to 86 % have been reported [10, 11].

A survey among gynecologists in the USA revealed that a vast majority (86 %) of gynecologists prescribed pessaries.

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Vaginal ring pessaries were used most often and were deemed the easiest to use [7]. Accordingly, some authors consider cube pessaries a second choice only [12]. It has been confirmed that the cube pessary has been used only very rarely [6]. Hence, data on the efficacy of the cube pessary are scarce.

A large percentage of pessary complications have been reported to be due to long-term insertion [13]. It thus has been postulated that removing and replacing the device regularly, i.e., on a daily basis, would prevent many of the adverse effects [13, 14]. This consideration also applies to the ring pessary, although one of its major advantages has reportedly been the opportunity to retain the ring in the vagina for long periods [14]. Another disadvantage of the cube pessary that has been postulated is that it has to be taken out before sexual intercourse [5]. This, however, is also true of Gellhorn pessaries, which are the second most often used pessary [5].

We thus considered it appropriate to test the cube pessary as a first-line treatment option. There is a lack of studies in the literature that evaluate patient satisfaction and continuation rates of cube pessaries. Thus, we aimed to prospectively evaluate these issues in women with symptomatic POP.

Materials and methods

Patient population and study design

Between January and December 2011, 87 women with symptomatic POP (of at least stage II, see below) were enrolled in a prospective study at the Unit for Urogynecology at the Petz-Aladár Teaching Hospital, Department of Obstetrics and Gynecology, Györ, Hungary. All patients had been informed about both surgical treatment options and treatment with a vaginal pessary. They were invited to participate in the present study designed to evaluate the vaginal cube pessary as a first-line treatment and were informed that a surgical intervention would still be possible subsequently in case of dissatisfaction with the conservative treatment. All patients were offered another type of pessary if they declined participation in the study or discontinued the study.

Women were excluded from the study if they had any of the following contraindications to pessary use: undiagnosed vaginal bleeding, vaginal erosions, active infections of the vagina, dementia, or restricted mobility that would render the patients unable to use the device by themselves.

The main study objective was to evaluate patients' satisfaction with vaginal cube pessary use on a self-care basis and continuation rates after 1 year of use. As a second objective, we focused on risk factors for discontinuation. The study was approved by the Institutional Review Board of the Petz-Aladár Teaching Hospital, Györ, Hungary (IRB number 76-1-21/2011). Written, informed consent was obtained from all patients.

Details on pessary use

Patients were introduced to self-therapy using perforated vaginal cube pessaries (Arabin™ GmbH & Co, Witten, Germany, Fig. 1) during the daytime. A cube pessary retains its position in the vagina by suction of its six concave surfaces on the vaginal wall and daily removal and replacement are necessary as the suction can lead to erosions of the vaginal walls.

During the first study visit, we emphasized that this kind of pessary therapy is similar to wearing eyeglasses: pessaries and eyeglasses are medical devices, are used during the day, and can eliminate the symptoms immediately. The pessary is cheap and easy to use without any serious complications when used correctly.

The size of the pessary is specified in "Charrière" gauge: 0, 1, 2, 3, 4, and 5 correspond to diameters of 25, 29, 32, 37, 41, and 45 mm, respectively. The size was individually adapted for each woman and had to be sufficiently large so as not to fall out, but not so large as to cause the patient any sensation of pressure or discomfort with the pessary. At the initial visit, the patient was examined in both the recumbent and the standing position, during relaxation and straining. After insertion of the pessary, every patient had to test the device for 20 min: they had to walk, climb several steps, and empty the urinary bladder. Afterward, the pessary was considered to be of the correct size if the patient did not report any feeling of discomfort and the pessary was still placed correctly when she was examined in a standing position. After successful fitting, patients were informed in detail on how to use the vaginal device by themselves and to remove the pessary daily using the following method: each woman was advised to lift her left leg and place it on a small pedestal (or something similar), pull the pessary's thread down with her non-leading hand until it becomes tight, then go in between the device and the vaginal wall with her index or middle finger in order to unseal the vacuum and to remove the pessary afterward. All patients were advised to leave the pessary out overnight and for sexual intercourse.

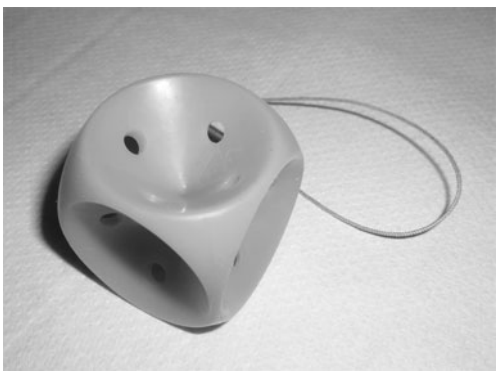

Fig. 1 The Arabin vaginal cube pessary

Postmenopausal women were advised to use about one third of an applicator dose every second day of an estriol cream with the pessary, which amounts to about 0.15 mg estriol. Every other day, the women were told to use a vaginal vitamin C-containing nonhormonal cream. Premenopausal women were told to use the vitamin C-containing cream only.

Baseline examination and follow-up visits

Patients were examined prior to treatment initiation. Patients were not followed up routinely until 1 year after treatment initiation, but they were offered the possibility of contacting the first author at any time, if necessary. Hence, additional consultations and examinations were performed according to the patients' individual needs, and this was also true for those patients who stopped using the pessary due to de novo symptoms.

In the course of the initial study visit, POP was assessed during a gynecologic examination based on the International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Stages were assigned according to the leading edge of the prolapse [15]. The women were asked to report general well-being on a numeric rating scale (NRS; 0 = worst imaginable general well-being, 10 = best imaginable general well-being). A detailed history of the patients was obtained [including age, parity, body mass index (BMI), and prolapse-associated symptoms]. We focused on the symptom load, including vaginal bulging (complaint of bulging toward or through the vaginal introitus), pelvic pressure (complaint of increased heaviness or dragging in the suprapubic area and/or pelvis), low backache (complaint of low, sacral backache, associated temporally with POP), increased bladder sensation (complaint that the desire to void during bladder filling occurs earlier or is more persistent than in previous experience), and bladder emptying problems (urinary hesitancy: complaint of delay in initiating micturition; slow urine stream: complaint of a urine stream perceived as slower compared to previous performance) [15]. At follow-up, patients were asked about subjective outcomes by the first author based on a questionnaire (Fig. 2), since there are no validated, standardized, urogynecologic quality of life questionnaires in the Hungarian language, and this is in accordance with previous studies [16, 17]. This included a rating of the process of pessary insertion on an NRS (1 = "very easy," 5 = "very difficult") and of general well-being on an NRS, as mentioned above, as well as the Patient Global Impression of Improvement (PGI-I), in which they could rate their condition now compared with their condition before beginning treatment (1 = very much better, 7 = very much worse) [18]. The type and size of the vaginal pessary inserted were also recorded. The women were also asked about compliance. All examinations were performed by the same investigator (Z.N.).

During the follow-up examination, we also focused on possible side effects of pessary use, including bleeding, vaginal excoriations, ulcerations, fistulas, and impactions in the vagina. The women were also asked whether they had experienced de novo stress incontinence that had been masked by the prolapse [5]. All women were informed that they could attend the outpatient clinics with any concerns or problems for short-term control during the whole study period at any time.

Statistical analysis

Variables are described by frequencies and mean±standard deviation or mean and range. Differences between values before treatment initiation and 12 months afterward were analyzed using Wilcoxon's rank sum test. Differences between nonmetric variables were analyzed using Fisher's exact test. A p value <0.05 was considered statistically significant. Statistical analysis was performed using SPSS 15.0.1 for Windows (SPSS Inc, 1989–2006).

Results

Pessary fitting and patient characteristics

All women who were offered participation in the study agreed to do so. A pessary could be fitted in 84/87 patients (96.6 %), whereas in 3/87 patients (3.4 %) it was not possible to successfully fit a pessary. These three women had already undergone a vaginal hysterectomy with both anterior and posterior colporrhaphy and anterior repeat colporrhaphy. The genital hiatus was large, the length of the vagina short, and consequently the cube pessaries did not remain in place. Of those with successful pessary fitting, six women were lost to follow-up (7.1 %). The remaining 78 patients (92.9 %) completed the study.

Details on the demographic characteristics of these women are shown in Table 1. Sixteen women (20.5 %) had already undergone gynecologic surgery: posterior colporrhaphy (n=1), anterior colporrhaphy (n=2), both anterior and posterior colporrhaphy (n=2) or vaginal hysterectomy (n=11); and eight patients had already undergone anterior and/or posterior colporrhaphy. The leading structure of POP was the anterior compartment in 27 women [34.6 %; n=11 for Pelvic Organ Prolapse Quantification (POP-Q) stage II, n=16 for stage III], the apical compartment in 45 patients (57.7 %; n=6 for stage II, n=18 for stage III, n=21 for stage IV), and the posterior compartment in 6 cases (7.7 %; n=3 for stage II, n=3 for stage III). Sixty-two patients (79.5 %) reported being sexually active.

The Charrière gauge of the fitted pessaries was 1 in 11 (14.1 %), 2 in 17 (21.8 %), 3 in 35 (44.9 %), 4 in 13 (16.7 %), and 5 in 2 (2.6 %) women.

Fig. 2 Questionnaire used for evaluation of patient satisfaction at follow-up

1. Do you want to continue using the cube pessary as a self-care therapy?

O yes O no

2. The process of pessary insertion is for you

O 1 = very easy O 2 = easy O 3 = moderate

O 4 = difficult O 5 = very difficult

3. How did the symptom of vaginal bulging change during pessary use?

O 0 = no vaginal bulging before treatment initiation

O 1 = improved O 2 = no change O 3 = worsened

4. How did urinary disorders (increased bladder sensation or emptying problems) change during pessary use?

O 0 = no urinary disorders before treatment initiation

O 1 = improved O 2 = no change O 3 = worsened

5. How did the symptom of pelvic pressure/low back pain change during pessary use?

O 0 = no pelvic pressure/low back before treatment initiation

O 1 = improved O 2 = no change O 3 = worsened

6. How did sexual satisfaction change during pessary use?

O 0 = no vaginal bulging before treatment initiation

O 1 = improved O 2 = no change O 3 = worsened

7. On a scale from 0 – 10 (0= worst imaginable general well-being; 10= best imaginable general well-being), how would you rate general well-being? _____

8. On a scale from 0 – 7 (1= very much better; 7= very much worse), how would you rate your condition now compared with how it was before beginning treatment (PGI-I)? _____

Continuation rates and subjective outcomes

All women confirmed to have used the pessary every day and to have routinely taken out the pessary overnight as well as for sexual intercourse for the complete treatment period. Sixteen women (20.5 %) chose not to continue with the pessary treatment. They attended our department 2–4 weeks after the initial visit and underwent an early termination visit. They all opted for surgery as an ongoing treatment. For these patients, general well-being decreased from a median NRS of 4.5 (3–6) to 2.0 (1–3, $p<0.001$). All of these patients stopped using the pessary due to de novo symptoms, i.e., stress urinary incontinence ($n=10$, 62.5 %), vaginal discomfort ($n=5$, 31.3 %), or both ($n=1$, 6.3 %). None of the patients reported that they stopped using the pessary because of the trouble of removing the pessary every day. Table 2 shows a comparison between continuers and discontinuers.

Accordingly, a continuation rate of 79.5 % (62/78) was achieved. In continuers, the general well-being had increased from a median NRS of 3.0 (2–5) to 8.0 (7–10, $p<0.001$). The PGI-I was 2.0 (1–3) at follow-up examination. When including those patients who had been lost to follow-up in an intention-to-treat analysis, the overall continuation rate was 73.8 % (62/84).

Table 1 Baseline characteristics of all patients who started pessary treatment and completed the study ($n=78$)

Characteristic	Median (range)
Age (years)	60 (42–84)
Body mass index (kg/m^2)	24.2 (19.4–25.0)
Parity	2 (0–3)
	n (%)
Premenopausal patients	15 (19.2)
Pelvic pressure/low backache	54 (62.1)
Vaginal bulging	58 (66.7)
Increased bladder sensation	44 (52.4)
Bladder emptying problems (urinary hesitancy, slow urine stream)	33 (37.9)

The subjective outcome in the 62 continuers was as follows: 60 patients (96.8 %) had reported foreign body sensation at treatment initiation; 59/60 (98.3 %) reported that it had improved. Pelvic pressure/low backache had originally been found in 45 women (72.6 %); it had improved in 41/45 patients (91.1 %). At the initial visit, all patients had reported urinary disorders (increased bladder sensation or emptying problems) with some kind of relief having been reported by 21/62 (33.9 %). Of the 43 women (69.4 %) who were sexually active, 23 (53.4 %) reported no change in their sex life while 20 (46.5 %) reported an improvement following pessary use. During the study period of 1 year, 12/62 women (19.4 %) attended our department for only one interim visit after a median of 214 days (range 92–305 days). All of these women reported a feeling of vaginal discomfort that was completely relieved after the pessary had been switched to a smaller model (from Charrière 3 to 2 in eight cases and from Charrière 2 to 1 in four cases). None of the 62 patients reported suffering from vaginal bleeding. At the final visit, the gynecologic examination revealed no complications, including vaginal excoriations, ulcerations, fistulas, and impactions in the vagina.

Discussion

In this case series, a vaginal cube pessary could be fitted in 96.6 % of patients. This is comparable to the majority of published studies reporting successful fitting rates of >85 % [19]. Usually, the correct size is arrived at by trial and error. In the literature, however, there is no agreement about how to define successful pessary fitting. While some authors consider fitting successful if the patient perceives a pessary as comfortable when retained during Valsalva and voiding at the initial visit, others suggest that the criteria should be whether a patient continues to use the pessary until the next follow-up examination or when the provider could place a finger between the pessary and the vaginal walls and the subject could stand, cough, and strain with the pessary retained [19, 20]. In this case series, we defined fitting as successful if the woman retained the pessary after 20 min of walking and climbing steps and after miction. The pessary had to be found in the correct position in the standing patient, and the patient had to report feeling comfortable with it. We consider this an applicable and adequate method, since it combines objective and subjective measures, and an early examination after a short "real-life test" was performed.

Risk factors that have been reportedly responsible for unsuccessful pessary fitting are short vaginal length, a large genital hiatus, prior history of hysterectomy, and prior surgical repairs of POP [21, 22]. In the present study, we also observed all of these factors in the three women with unsuccessful fitting.

Notably, the compartment and stage of POP have not been reported to have any influence on successful fitting of other pessary types. In the present data set, a risk factor analysis could not be performed due to the limited number of patients who could not be fitted with a cube pessary. In accordance with previous reports, we suggest that the clinician can recommend a pessary in women with all types and grades of prolapse severity [22].

In the literature, the ring pessary is most commonly used, followed by the Gellhorn pessary [23]. For these, the most frequent complications are bleeding, vaginal excoriations, and ulcerations and impactions in the vagina. Occult urinary incontinence has been reported in 36–72 % of women after insertion of a pessary [5]. One of the major advantages of the ring pessary is supposedly the ability to retain the ring in the vagina for long periods without the need for daily removal [5]. However, up to 56 % of patients reported at least one side effect, including a foul smell, vaginal discharge, bleeding, pain, and constipation [24]. It has been suggested that these symptoms of irritation could be prevented if the patients were willing and able to remove, clean, and replace the pessary themselves [13]. However,

Table 2 Comparison between continuers and discontinuers: patient characteristics and risk factors for discontinuation

	Discontinuers (n=16)	Continuers (n=62)	p
Age (years)	65.5 (49–85)[a]	64.0 (40–84)[a]	0.294
Body mass index (kg/m^2)	25.1 (20.2–25.0)[a]	24.2 (19.4–23.1)[a]	0.485
POP-Q stage of the leading compartment	III (II–IV)[a]	III (II–IV)[a]	0.762
Premenopausal women	2 (12.5)[b]	13 (21.0)[b]	0.723
Parity	2 (0–2)[a]	2 (1–3)[a]	**0.040**
Size of the initial pessary (Charrière gauge)	3 (1–5)[a]	3 (1–5)[a]	0.481
Pelvic pressure/low backache	9 (56.3)[b]	45 (72.6)[b]	0.234
Previous hysterectomy and/or colporrhaphy	7 (43.6)[b]	9 (14.5)[b]	**0.041**
Pessary insertion (1 = very easy, 5 = very difficult)	3 (2–5)[a]	2 (1–3)[a]	**<0.001**

Significant p values are shown in boldface

[a]Data are provided as median (range)

[b]Data are provided as n (%)

this seems to obviate the above-mentioned hypothesized advantage of the ring pessary. In comparison, in our patient population, we could not find any adverse effects caused by local irritation after 1 year of use. This is likely due to the fact that all women removed the pessary on a daily basis. However, 16 women (20.5 %) suffered from de novo symptoms, including urinary incontinence and vaginal discomfort, and thus chose to discontinue the pessary use. Risk factors for discontinuation were (1) a lower number of deliveries and (2) previous hysterectomy and/or colporrhaphy (see Table 2), putting the women at risk for developing the above-mentioned de novo symptoms.

Notably, all women who chose not to continue with the pessary treatment attended our department at least 4 weeks after the initial visit for an early termination visit. In a large study by Lone et al. [11], the vast majority of failures (73.8 %) also occurred within the first 4 weeks. However, 15 % of failures occurred within 1–6 months after treatment initiation. Since we present the first study on cube pessary use, we cannot explain this difference.

The continuation rate of 79.5 % is comparable to findings of studies on other types of pessaries. In the literature, continuation rates of 50–80 % have been reported [15]. In our data set, continuers revealed a significant increase in general well-being. This is comparable to the high satisfaction rates, ranging from 70 to 92 %, for medium-term use of other pessary types [16, 17, 25].

The increased well-being was accompanied by relief of various symptoms. Vaginal bulging and pelvic pressure/low backache, in particular, likely become better by using a cube pessary. Sexual satisfaction had increased in about 50 % of women who had reported dissatisfaction before pessary treatment. It has already been reported that, in sexually active women who were fitted with a pessary, a significant increase in frequency and satisfaction of sexual activity was found [12, 16, 23]. Again, this has been thought to be another advantage of ring usage because of the patients' ability to continue penetrative intercourse. In contrast, the cube pessary has to be removed prior to penetrative sexual intercourse [5]. However, our data suggest that the cube pessary is comparable to the ring pessary in terms of sexuality. This might be due to the fact that the leading structure of the POP remains in situ and thus is not prolapsed after removal of the pessary, i.e., directly before intercourse. Therefore, there is no anatomical barrier for penetration and women might feel less insecure about their body once the POP is no longer visual. The improvement in sexual satisfaction is of particular importance, since the majority of women (79.5 %) in our patient population were sexually active.

It has already been suggested that, with daily pessary removal, follow-up could be on an annual basis [13]. We can affirm this suggestion. However, in our study, all women had been informed about the possibility of unplanned interim visits in case of any complaints. Only 19.4 % of the patients needed such an interim examination due to a feeling of vaginal discomfort. This symptom was relieved after a smaller model had been fitted, and all of these women continued with the therapy.

In accordance with previous suggestions [13, 14], we feel that teaching a patient how to remove and replace the pessary herself and providing extensive information about pessary use increases women's autonomy. Notably, the majority of patients in the present study rated pessary use as "very easy" or "easy" (85.5 %).

The anatomical outcome after cube pessary use was not among the objectives of our study. However, as stated above, we observed that, in about 20 % of patients, the pessary had to be switched to a smaller model within 1 year of use. This suggests that the size of the vaginal capacity had decreased in these women. We hypothesize that the need for a smaller pessary might be a sign of an anatomical improvement, i.e., a decrease in the POP-Q stage. We observed the same phenomenon in a patient with postpartum POP (stage III cystocele and rectocele, stage II uterine descensus based on the IUGA/ICS joint report [15]), who achieved complete recovery with a combined conservative treatment that included a cube pessary, neurostimulation, and pelvic floor muscle training with vaginal weights [26]. Due to the combination of methods, it is difficult to comment about the extent to which the pessary contributed to the results. However, it has also been reported that there may be a decrease in the size of the genital hiatus with continued pessary use. This decrease is detected even after 2 weeks of continuously wearing a pessary. Thus, it is likely that pessaries reduce the load of the prolapsed vagina/pelvic organs on the levator ani muscles and perineum, enabling tissue recovery that results in a smaller genital hiatus [27], and this might also be true for the cube pessary, at least in some patients.

In the literature, vaginal pessaries have been proposed as a useful alternative to surgery in the management of symptomatic POP, especially for patients who are poor surgical candidates, have not completed childbearing, or who do not desire surgical correction. For the first time, we evaluated outcomes for the vaginal cube pessary after 1 year of use.

The results have to be interpreted within the limitations of the study. We did not use standardized questionnaires for the assessment of urogynecologic symptoms, since there are none available in the Hungarian language. However, the lack of such detailed outcome parameters affects only a secondary study objective, since the major aim was to evaluate the continuation rate and overall patient satisfaction and not possible improvements in the POP-Q stage. There is no information on vaginal length and the size of the genital hiatus and, thus, they cannot be evaluated as risk factors for discontinuation. Notably, the median BMI was quite low (median 24.2 kg/m^2). Due to the study design, it cannot be

concluded whether this had an influence on the success of pessary therapy. We can only say that discontinuers and continuers did not differ significantly in terms of BMI (Table 2).

In conclusion, our data suggest that the cube pessary is a feasible alternative for treatment of POP and should be considered a first-line treatment option. Vaginal bulging, urinary disorders, and pelvic pressure/low backache are symptoms likely to be relieved with cube pessary use. The vaginal cube pessary does not negatively interfere with sexual activity and may even improve sexual functioning as a whole. The main reasons for discontinuation are de novo stress incontinence and vaginal discomfort. However, studies comparing the cube pessary to other types of pessaries are warranted in order to confirm or disprove previous assumptions that consider the cube pessary of limited use.

Conflicts of interest None.

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