

ORIGINAL STUDY

A predictive model of choosing pessary type for women with symptomatic pelvic organ prolapse

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Abstract

Objective: To investigate clinical factors including translabial ultrasound parameters, which are predictive for choosing pessary type (Ring or Gellhorn) in the fitting trial, and to establish a predictive model.

Methods: A retrospective study was conducted on symptomatic women with pelvic organ prolapse (POP) at the Pelvic Floor Disease Diagnosis and Treatment Center (Liaoning Province, China) between May 2018 and December 2020 who were successfully fitted with pessaries. This retrospective study was supplemented with a prospective cohort study on women seeking pessary for first-line treatment of POP at the above tertiary center between December 2020 and April 2021 for validation. Enrolled participants were grouped by their fitted type of pessary. Demographic and clinical parameters between groups, including pelvic organ prolapse quantification and translabial ultrasound, were analyzed using logistic regression. A receiver operating characteristic curve was calculated using predictive values obtained by regression as the predictor for choosing pessary type in the pessary fitting trial.

Results: The 181 participants included in the retrospective analysis were randomly divided into the “Development” and “Validation” datasets. In the “Development” set, multivariable logistic regression analyses showed that a younger age (odds ratio [OR]: 0.950; 95% confidence interval [CI]: 0.908-0.995; $P = 0.026$), a larger hiatal circumference on Valsalva (OR: 1.348; 95% CI: 1.103-1.647; $P = 0.004$), and a higher POP-Q stage (OR: 2.963; 95% CI: 1.210-7.255; $P = 0.017$) were independent predictors for successful fitting with the Gellhorn pessary. The predictive model was $P = \exp(Z) / [1 + \exp(Z)]$, $Z = -0.051 \times \text{Age (y)} + 0.298 \times \text{hiatal circumference on Valsalva (cm)} + 1.086 \times \text{pelvic organ prolapse stage (2, 3, or 4)} - 5.490$. The area under the receiver operating characteristic curves (AUC) was 0.776 ($P < 0.001$) and 0.705 ($P < 0.001$) based on the “Development” dataset and “Validation” datasets, respectively. The AUC was 0.815 ($P < 0.001$) based on the prospective cohort validation.

Conclusions: For severe POP, women with younger age and larger hiatal circumference, Gellhorn pessaries should be their first choice instead of ring ones in pessary fitting trials.

Key Words: Gellhorn pessary – Pelvic organ prolapse – Predictive model – Ring pessary with support – Ultrasound.

Pelvic organ prolapse (POP) is a common disease worldwide, which adversely affects a woman’s quality of life. In general, women with POP are treated by surgical or conservative management. The vaginal pessary has been used as a conservative treatment of symptomatic POP for thousands of years.¹ Vaginal pessaries can

immediately relieve prolapse and prolapse-related symptoms, and prevent the progression of prolapse after long-term use.² Due to its efficacy and safety, it is used as a first-line treatment for symptomatic POP.³ Pessaries can be categorized into the following two types: support and space-occupying, and they appear equally effective in relieving symptoms of genital

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prolapse and voiding dysfunction.⁴ Ring pessaries with support are the supporting type, and they are typically recommended for stage I and stage II prolapse and have the benefits of convenience and comfort.⁵ In contrast, Gellhorn pessaries are both supporting and space-occupying. They are often used to treat advanced prolapse cases; however, they are difficult for women to remove and reinsert.⁶ Sexual activity, degree of prolapse, and ability of the women to self-manage should be considered when choosing the type of pessary for women with POP. However, there is no consensus on the order of type in pessary fitting trials in practice. Fitting a pessary in clinical practice is currently guided by experience. Due to the convenience and comfort of the support pessary, physicians prefer to choose it as a first choice, and only when there is an unfitted size, do they use the Gellhorn pessary or other type of pessary for a retry. A previous study showed that the ring pessary with support was successfully fitted in women with advanced POP with a high success rate and few complications, so it was recommended as an initial fitting type in women with POP at any stage.⁷ However, refitting is time consuming and may become tedious when multiple fittings are attempted. Moreover, women who originally benefit from the Gellhorn pessary may stop the fitting trial after failed pessary fittings with a support pessary, then turn to surgery. It is therefore useful to screen out women who are more likely to be successfully fitted with a Gellhorn pessary, and for whom a Gellhorn pessary should be recommended as the first choice instead of a ring pessary with support.

A previous study has shown that a prior hysterectomy and the vaginal introitus width were identified as independent predictors of the pessary type used.⁸ Factors investigated in the previous study were demographic information and physical examination findings. However, these assessments are inadequate for clinical practice. Because of the development of sonography, translabial ultrasound (TLUS) has been increasingly used in the evaluation of POP, providing information about both the objective and functional anatomy.⁹ To our knowledge, the predictive value of TLUS findings for choosing pessary type in a pessary fitting trial of women with symptomatic POP has not been reported. Our aim was therefore to investigate clinical factors including TLUS parameters, which are predictive for choosing pessary type, and to establish a predictive model.

METHODS

With Institutional Review Board approval by the Shengjing Hospital of China Medical University (No. 2021PS170K), we undertook a retrospective study on women presenting with symptomatic POP, who visited the Pelvic Floor Disease Diagnosis and Treatment Center (Liaoning Province, China) between May 2018 and December 2020. Also, we prospectively recruited participants from the above tertiary center between December 2020 and April 2021 for validation. Informed consents were obtained from all participants included. Inclusion criteria consisted of participants who had chosen the vaginal pessary as first-line treatment and

had undergone TLUS before pessary insertion. Participants who failed to be fitted with any pessary, and to whom the Gellhorn pessary was used as first choice were excluded. All participants were examined and staged according to the International Continence Society Pelvic Organ Prolapse Quantification (POP-Q) system by one experienced urogynecologist (with ≥ 10 y experiences).¹⁰ To test the reproducibility of our predictive model, a split-sample internal validation scheme was adopted to develop and assess the factors and prediction models in the retrospective analysis. The included participants were randomly divided into the ‘‘Development’’ and ‘‘Validation’’ datasets in a 2:1 proportion. TLUS was conducted by the same experienced sonographer blinded to the pessary fitting results. The medical records including age, gravidity, parity, menopausal status, sexual activity, body mass index (BMI), history of hysterectomy, urinary incontinence symptoms, POP-Q stage, and TLUS parameters were recorded.

TLUS was undertaken with participants in dorsal lithotomy positions (after bladder emptying and defecation), using either a Voluson E8 (GE Healthcare, Chicago, IL) or a Resona 8 (Mindray Medical, Shenzhen, China) ultrasound system equipped with a curved-array transducer (4-8 MHz, 85° acquisition angle).¹¹ Volume acquisition was performed at rest, on maximum Valsalva maneuver, and on maximum pelvic floor muscle contraction (PFMC), as described by Dietz.¹² For acquiring effective and accurate volumes to analyze, at least three volumes were obtained during the Valsalva maneuver makeover for each participant, and each Valsalva maneuver was conducted for a minimum duration of 6 seconds without levator coactivation. Hiatal circumference (HC) and hiatal area (HA) were assessed on maximal Valsalva maneuver in the plane of minimal hiatal dimensions. In the mid-sagittal plane, the inferior margin of symphysis pubis (SP) was defined as the reference line. Using previously published criteria, significant cystocele, uterine prolapse, and rectocele on TLUS were defined as bladder descent to 10 mm or more below SP,¹¹ uterine descent to 15 mm or less above SP,¹³ and rectal ampulla descent to 15 mm or more below SP, respectively.¹¹ A downward displacement of abdominal contents into the vagina, dorsal to the anechoic bladder and ventral to the rectal ampulla, and anal canal was evidence of enterocele.⁹ The Levator ani muscle (LAM) was assessed using tomographic ultrasound imaging on volumes obtained at maximum PFMC at 2.5 mm slice intervals, from 5 mm below to 12.5 mm above the plane of minimal hiatal dimensions. LAM avulsion was defined as identification of abnormal insertion of the puborectalis muscle in at least three central slices.¹² In uncertain cases, measurements of the levator-urethra gap (LUG) were also taken as described by Dietz,¹⁴ and a cutoff of 23.6 mm for LUG was considered abnormal.¹⁵

At our treatment center, we typically offer expectant management, vaginal pessary, or surgical intervention during the first visit for symptomatic POP. One experienced and trained nurse conducted all the fittings for participants who opted for pessaries as first-line treatments. Two types of medical-grade

silicone pessaries were available, either a ring with support (51, 58, 64, 70, or 76 mm in diameter) or a Gellhorn design (51, 57, 64, 70, or 76 mm in diameter). Women were initially fitted with either pessary during the first visit. If a participant experienced discomfort or pain, insertion of a smaller size pessary was attempted, and a larger size was inserted if the pessary could not be retained. If the participant failed to retain any size, another type was immediately placed following the same procedure. Once comfortably fitted, the participant was asked to ambulate and void during the office visit. If the pessary was comfortably retained, the initial fitting was considered successful, and the participant or her caregiver was instructed on how to manage the pessary, including its regular removal, cleaning, and replacement. Generally, we recommend that at least once a week participants remove and clean their pessaries before going to bed and reinsert it the next morning. Removal of the pessary was also recommended before sexual activity regardless of the pessary type. Participants were scheduled to return to the center 2 weeks after the first visit to assess the fitting or sooner if they encountered a problem. Women who reported discomfort or expulsion were offered another size or type of pessary for refitting. They returned again after 2 weeks for a third visit. Follow-up visits were also scheduled as needed, until participants had tried both types and all sizes of pessaries available in our treatment center. Moreover, a pessary fitting was considered successful if a participant who was fitted with a pessary either in the initial fitting or in the refitting trials continued to use it for 2 weeks, regardless of the number of refittings. In our prospective cohort study, ring pessaries were fitted initially, and Gellhorn pessaries were offered as the second-line pessary only if the ring pessaries failed. Statistical analysis was conducted using SPSS Statistics, version 22.0 (SPSS, Chicago, IL) and Stata/SE 12.1 (StataCorp, College Station, TX). Quantitative data are presented as the mean \pm standard deviation (SD) or median (range). The Mann-Whitney U test was used for comparisons between the two groups. The associations between categorical variables were analysed using the chi-square test. Univariate and multivariate logistic regression of factors for choosing pessary type (Gellhorn vs Ring) in the pessary fitting trial was conducted. Variables identified as $P < 0.10$ using univariate analysis were entered into a multiple backward stepwise logistic regression model. The formula of the logistic regression model was: $P = \exp(Z)/(1 + \exp(Z))$, where $Z = b_1x_1 + b_2x_2 + \dots + b_kx_k + \text{constant}$, $x_1 \dots x_k$ were a collection of predictor variables, and $b_1 \dots b_k$ were regression coefficients determined by the development dataset using a least-squares approach, while P was the probability obtained by regression. The P value was calculated based on both development, validation, and prospective cohort datasets. A receiver operating characteristic curve (ROC) was calculated using the P value obtained by regression as the predictor for selecting the pessary type in the pessary fitting trial (Gellhorn vs Ring). The accuracies of the prediction models were measured using the area under the ROC curves (AUC). Sample size calculation was performed using the Tests for One ROC Curve in PASS,

version 15.0.5 (NCSS, LLC, Kaysville, UT). A value of $P < 0.05$ was considered significant.

RESULTS

Between May 2018 and December 2020, a total of 394 symptomatic women with POP tried pessaries after TLUS examination in our clinic. Among them, 21 women did not complete the fitting procedure, and 95 women tried the Gellhorn pessary as their first choice. After excluding these 116 women, 90 women had a successful fitting with a ring with support pessary, while 188 women had unsuccessful fittings. However, among those who failed to be fitted with ring pessaries with support, 91 women were successfully fitted with Gellhorn pessaries. In all, a total of 181 women successfully fitted with pessaries were included for analysis. The demographic and clinical characteristics, including POP-Q and TLUS findings, of the 181 women are shown in Table 1. The median age was 64.42 years, and the median parity was 2 (range: 0-8). The median BMI was 24.39 kg/m². Nearly all of the women (171, 94.48%) were postmenopausal, and none had undergone hormonal treatment. Twelve women (6.63%) had a history of hysterectomy. Of the 181 included women, 92 (51.69%) reported symptoms of urinary incontinence (UI). In terms of the POP-Q staging, 64 (35.36%) women were classified as stage II, 105 (58.01%) women as stage III, and 12 (6.63%) women as stage IV. A total of 145 (80.11%) women, 148 (81.77%) women, and 106 (58.56%) women were diagnosed as significant cystocele, uterine prolapse, and rectocele on TLUS examinations, respectively. The manifestation of LAM avulsion and enterocele was found in 12 (6.63%) and 8 (4.42%) women, respectively.

According to the successful fitting type of pessary, we sorted women into two groups: the ring with support pessary group (Ring group) and the Gellhorn pessary group (Gellhorn group). The included 181 participants were randomly divided into the "Development" and "Validation" datasets, with 121 women allocated to the "Development" set and 60 women to the "Validation" set. In the "Development" set, there were 61 women in the Ring group, and 60 women in the Gellhorn group. Univariate analysis was performed in the "Development" set between these two groups (Table 2, Fig. 1). The average age in these two groups was 66.93 ± 11.20 and 63.10 ± 10.66 years, respectively, and this difference was statistically significant ($P = 0.011$). In the Ring group, there were 28 (45.90%) women with stage II, 32 (52.46%) women with stage III, and only 1 (1.64%) case with stage IV prolapse, while in the Gellhorn group, there were 14 (23.33%) women with stage II, 44 (73.33%) women with stage III, and 2 (3.33%) women with stage IV prolapse, respectively. In stage II, the number of participants in the Ring group were twice those in the Gellhorn group, while in stage IV, it was exactly reversed. The difference of prolapse stage between these two groups was significant ($P = 0.032$). When comparing the TLUS parameters, we found that HC was 18.71 ± 2.20 cm and 20.39 ± 2.66 cm ($P = 0.001$), and HA was 24.41 ± 5.79 cm² and 28.82 ± 6.61 cm² ($P < 0.001$) in the Ring

TABLE 1. Characteristics of enrolled participants including the “Development,” “Validation,” and “Prospective” datasets

	Development set (N = 121) ^a	Validation set (N = 60) ^a	Prospective cohort (N = 63) ^a
Age, yrs	65.03 ± 11.06	63.18 ± 9.47	65.57 ± 9.36
Gravidity	3 (0, 8)	2 (0, 10)	3 (0, 8)
Parity	2 (0, 8)	1 (0, 5)	2 (0, 7)
BMI, kg/m ²	24.47 ± 2.93	24.24 ± 2.43	24.84 ± 2.53
Sexually active ^b			
Yes	31 (26.72)	14 (25.00)	15 (23.81)
No	85 (73.28)	42 (75.00)	48 (76.19)
Successful fitting type of pessary			
Ring	61 (50.41)	29 (48.33)	25 (39.68)
Gellhorn	60 (49.59)	31 (51.67)	38 (60.32)
Postmenopausal			
Yes	115 (95.00)	56 (93.33)	59 (93.65)
No	6 (5.00)	4 (6.67)	4 (6.35)
Previous hysterectomy			
Yes	10 (8.33)	2 (3.33)	5 (7.94)
No	111 (91.67)	58 (96.67)	58 (92.06)
History of urinary incontinence ^b			
Yes	60 (50.85)	32 (53.33)	29 (46.03)
No	58 (49.15)	28 (46.67)	34 (53.97)
POP-Q measurements			
Aa	1 (-1, 3)	1 (-2, 3)	1 (-2, 3)
Ba	2 (-1, 6)	1.75 (-2, 7)	1.5 (-2, 6)
C	-1 (-4, 6)	0.75 (-6, 7)	0 (-4, 6)
D	-3 (-4, 5)	-2 (-6, 7)	-2 (-4, 6)
Ap	-1 (-2, 3)	-1 (-2, 3)	-1 (-2, 3)
Bp	-1 (-2, 6)	-1 (-2, 4)	-1 (-2, 3)
Gh	5 (3, 6)	5 (3, 7)	4 (3, 6)
Pb	2 (2, 4)	2 (1, 3)	3 (2, 3)
TVL	8 (6, 8)	8 (5, 8)	8 (4, 8)
POP-Q stage			
II	42 (34.71)	22 (36.67)	20 (31.75)
III	76 (62.81)	29 (48.33)	39 (61.90)
IV	3 (2.48)	9 (15.00)	4 (6.35)
LAM Avulsion			
Yes	7 (5.79)	5 (8.33)	8 (12.70)
No	114 (94.21)	55 (91.67)	55 (87.30)
Enterocoele			
Yes	6 (4.96)	2 (3.33)	4 (6.35)
No	115 (95.04)	58 (96.67)	59 (93.65)
Cystocoele			
Yes	100 (82.64)	45 (75.00)	55 (87.30)
No	21 (17.36)	15 (25.00)	8 (12.70)
Uterine prolapse			
Yes	96 (79.34)	52 (86.67)	54 (85.70)
No	25 (20.67)	8 (13.33)	9 (14.29)
Rectocoele			
Yes	70 (57.85)	36 (60.00)	43 (68.25)
No	51 (42.15)	24 (40.00)	20 (31.75)
HC on Valsalva, cm	19.50 ± 2.55	18.95 ± 2.21	19.38 ± 2.06
HA on Valsalva, cm ²	26.60 ± 6.57	25.41 ± 5.71	26.36 ± 5.62

BMI, body mass index; HA, hiatal area; HC, hiatal circumference; LAM, levator ani muscle; POP-Q, Pelvic Organ Prolapse Quantification; SD, standard deviation.

^aData are given as mean ± SD, median (range), or *n* (%).

^bVariables have missing data.

and Gellhorn groups, respectively. However, we did not find any significant difference in menopausal status, sexual activity, gravidity, parity, BMI, symptoms of UI, prior hysterectomy, POP-Q measurements, and other TLUS findings.

All predictors with a value of $P < 0.05$ in the univariate analysis were assessed in the multivariable logistic regression analysis (Table 3); the results showed that a younger age (OR: 0.950; 95% CI: 0.908-0.994; $P = 0.026$), a larger HC on Valsalva (OR: 1.348; 95% CI: 1.103-1.647; $P = 0.004$), and the higher POP-Q stage (OR: 2.963; 95% CI: 1.210-7.255; $P = 0.017$) remained independent predictors for successful fitting with a Gellhorn pessary.

The logistic regression with variables included age, HC on Valsalva, and POP-Q stage was used to form the predictive model for choosing type of pessary (Gellhorn vs Ring). After coefficients were determined by the “Development” dataset using a least squares approach, the model was $P = \exp(Z) / [1 + \exp(Z)]$, $Z = -0.051 \times \text{Age (y)} + 0.298 \times \text{HC on Valsalva (cm)} + 1.086 \times \text{POP-Q Stage (2, 3, or 4)} - 5.490$. A ROC from the “Development” dataset is shown in Figure 2A, with an AUC of 0.776 (standard error = 0.046; $P < 0.001$). Discrimination of this model in the “Validation” dataset was also evaluated with the ROC (Fig. 2B), with an AUC of 0.705 (standard error = 0.071; $P < 0.001$).

TABLE 2. Demographic and clinical parameters of enrolled participants in relation to their pessary type in the “Development” dataset

	Ring group (N = 61) ^a	Gellhorn group (N = 60) ^a	<i>p</i> ^b
Age, yrs	66.93 ± 11.20	63.10 ± 10.66	0.011
Gravidity	3 (0, 8)	3 (1, 8)	0.681
Parity	2 (0, 7)	2 (1, 8)	0.710
BMI, kg/m ²	24.15 ± 3.06	24.78 ± 2.78	0.223
Sexually active ^c			0.349
Yes	13 (22.81)	18 (30.51)	
No	44 (77.19)	41 (69.49)	
Postmenopausal			0.414
Yes	57 (93.44)	58 (96.67)	
No	4 (6.56)	2 (3.33)	
Previous hysterectomy			0.178
Yes	3 (4.92)	7 (11.7)	
No	58 (95.08)	53 (88.3)	
History of urinary incontinence ^c			0.856
Yes	31 (51.67)	29 (50.00)	
No	29 (48.33)	29 (50.00)	
POP-Q measurements			
Aa	1 (-1, 3)	1 (-1, 3)	0.229
Ba	1.5 (-1, 6)	2 (-1, 6)	0.413
C	-1 (-4, 6)	0 (-4, 6)	0.286
D	-3 (-4, 4)	-3 (-4, 5)	0.623
Ap	-1 (-2, 1)	-1 (-1, 3)	0.137
Bp	-1 (-2, 6)	-1 (-1, 6)	0.330
Gh	5 (3, 6)	5 (3, 6)	0.157
Pb	2 (2, 4)	2 (2, 3)	0.167
TVL	8 (6, 8)	8 (6, 8)	0.266
POP-Q stage			0.032
II	28 (45.90)	14 (23.33)	
III	32 (52.46)	44 (73.33)	
IV	1 (1.64)	2 (3.33)	
LAM Avulsion			0.234
Yes	2 (3.28)	5 (8.33)	
No	59 (96.72)	55 (91.67)	
Enterocoele			0.414
Yes	4 (6.56)	2 (3.33)	
No	57 (93.44)	58 (96.67)	
Cystocoele			0.497
Yes	49 (80.33)	51 (85.00)	
No	12 (19.67)	9 (15.00)	
Uterine prolapse			0.282
Yes	46 (75.41)	50 (83.33)	
No	15 (24.59)	10 (16.67)	
Rectocoele			0.114
Yes	31 (50.82)	39 (65.00)	
No	30 (49.18)	21 (35.00)	
HC on Valsalva, cm	18.71 ± 2.20	20.39 ± 2.66	0.001
HA on Valsalva, cm ²	24.41 ± 5.79	28.82 ± 6.61	<0.001

BMI, body mass index; HA, hiatal area; HC, hiatal circumference; LAM, levator ani muscle; POP-Q, pelvic organ prolapse quantitation.

^aData are given as mean ± SD, median (range), or *n* (%).

^bMann-Whitney *U* test or Chi-square.

^cVariables have missing data.

For further validation, we prospectively recruited participants seeking a pessary as a first-line treatment for POP at our tertiary center. Sample size calculations were performed based on the results of our retrospective study. A sample of 21 women from the Ring group and 21 women from the Gellhorn group achieved 90% power to detect a 0.2760 difference between the AUC under the null hypothesis of 0.5000 and an AUC under the alternative hypothesis of 0.7760 using a two-sided *z* test at a significance level of 0.050. Between December 2020 and April 2021, a total of 114 women chose vaginal pessary as the first-line treatment for POP. Among them, 11 women had not finished their fitting

trial, and 40 women were unsuccessfully fitted with either pessary. There were 25 participants who had a successful fitting with a ring with a support pessary, while 38 participants were successfully fitted with Gellhorn pessaries. The demographic and clinical characteristics of the 63 women are shown in Table 1. The ROC from the “prospective cohort” dataset is shown in Figure 2C, with an AUC of 0.815 (standard error = 0.054; *P* < 0.001).

DISCUSSION

A vaginal pessary is a common treatment for POP, with 75% of specialized clinicians in the USA using it as first-line

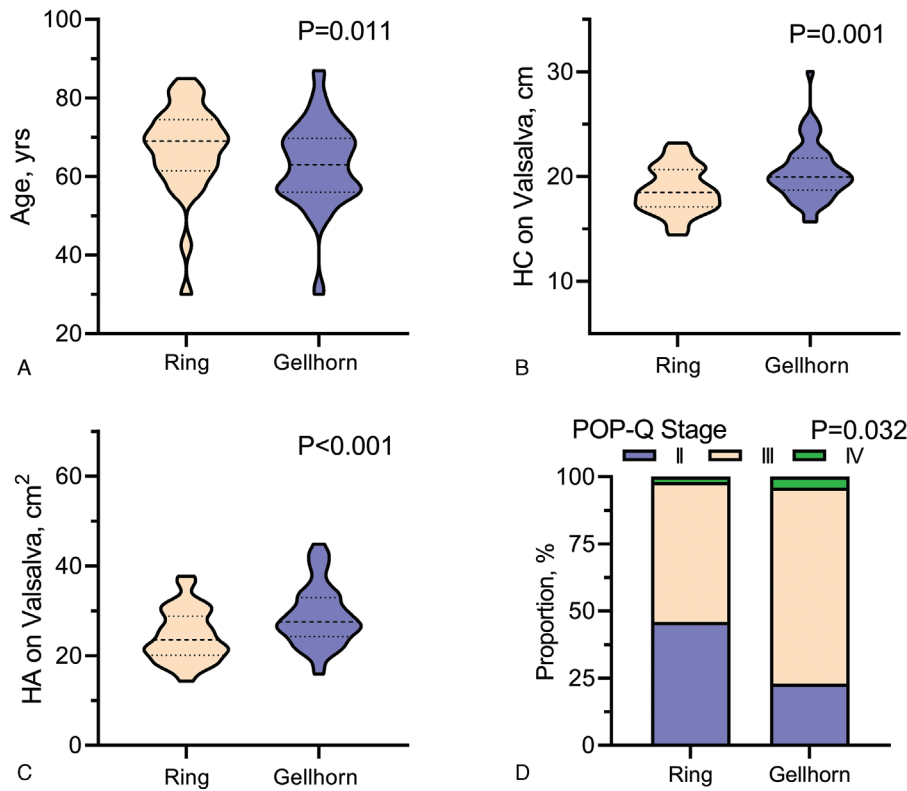


FIG. 1. Univariable analysis of factors between the Ring group and the Gellhorn group in the “Development” dataset. (A) Age. (B) HC on Valsalva. (C) HA on Valsalva. (D) POP-Q stage.

treatment.¹⁶ Fitting a pessary is currently guided by experience, and refitting is time consuming. Moreover, this process may cause women to mistakenly select surgery. Offering the appropriate type of pessary for the correct woman is therefore critically important in clinical practice. In the present study, we therefore retrospectively collected data on symptomatic women with POP referred to our urogynecology clinic who were successfully fitted with either the ring with support pessary or the Gellhorn pessary. We found that age, HC on the Valsalva maneuver examined by TLUS, and the POP-Q stage were associated with a successfully fitted pessary. In addition, we successfully established a predictive model and validated it in a prospective cohort study with an AUC of

0.815. When considering a woman’s information in the predictive model, we could estimate the chance of successful fitting with a Gellhorn pessary but unsuccessful fitting with ring pessaries in the fitting trial. So, for severe POP women with younger age and larger HC, a Gellhorn pessary should be their first choice instead of a ring with support pessary. When considering the type of pessary for women with POP, sexual activity should be taken into account, although there was no significant difference in sexual activity between the Ring group and the Gellhorn group. Therefore, for sexually active women, we can calculate their chance of a successful fitting with a Gellhorn pessary, but an unsuccessful fitting with a ring pessary. If the chance is high, we recommend trying the

TABLE 3. Logistic regression for successful pessary type in a pessary fitting trial based on the “Development” dataset

Characteristics ^a	Univariate analysis			Multivariate analysis ^b		
	OR ^c	95% CI	P	OR ^c	95% CI	P
Age	0.967	0.935-1.002	0.061	0.950	0.908-0.994	0.026
POP-Q stage (IV vs III vs II)	2.568	1.236-5.335	0.008	2.963	1.210-7.255	0.017
HC on Valsalva	1.355	1.123-1.635	0.002	1.348	1.103-1.647	0.004
HA on Valsalva	1.124	1.052-1.201	0.001	—	—	—

CI, confidence interval; HA, hiatal area; HC, hiatal circumference; OR, odds ratio; POP-Q, pelvic organ prolapse quantitation.

^aAll characteristics are calculated as continuous variables.

^bBackward step-wise logistic regression including all characteristics with $P < 0.10$ in univariate analysis (age, POP-Q stage, HC on Valsalva, and HA on Valsalva) and excluding characteristics with $P > 0.05$ in multivariate analysis.

^cGellhorn ($N = 60$) vs Ring ($N = 61$) (The smaller favors the Ring).

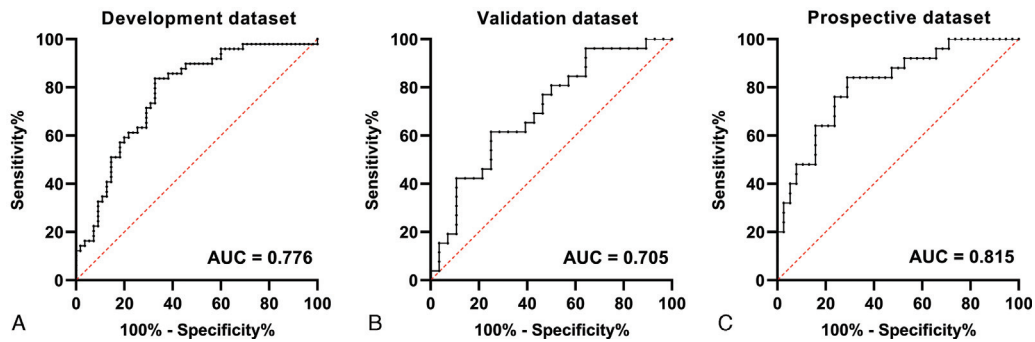


FIG. 2. The receiver operating characteristic curve curves for three datasets. (A) “Development” dataset. (B) “Validation” dataset. (C) “Prospective” dataset.

Gellhorn pessary first if the women are capable of self-care. If not, they can also choose to try ring pessaries, even with the high chance of failure. If both pessaries still fail, surgery may be indicated. For women who were unable to remove the Gellhorn pessary themselves, their caregivers were instructed on how to manage the pessary, they could also come to our treatment center for assistance. However, if the participant did not accept it, surgery was recommended. This information may improve fitting strategies and possibly reduce the time to find the right pessary for optimal comfort and fit. Besides, this may improve doctor–patient communication.

An earlier study showed that previous hysterectomy and vaginal introitus width were independent predictors of the pessary type used by the women (OR: 18.987; 95% CI: 2.033-177.358; OR: 2.665; 95% CI: 1.234-5.757).⁸ However, a previous hysterectomy was not confirmed as a predictor in our study. Although the earlier study was a prospective study, their sample size was smaller than ours. It has been suggested by some clinicians that previous hysterectomy narrows the upper vaginal diameter, making it more difficult to find a pessary that fits into the vaginal apex, but is large enough to be retained by the introitus.^{17,18} Unfortunately, due to the retrospective nature of our study, we did not have specific measurements of the vaginal introitus and apical width in our participants. A history of hysterectomy as a predictor of unsuccessful pessary fitting has been controversial.¹⁹⁻²¹ Further large sample prospective studies are therefore needed to confirm its value in the type of fitting to be used in a pessary trial.

In the present study, we showed that as the stage of POP increased, the successful fitting percentage decreased in the Ring group, but increased in the Gellhorn group, and the difference between the two groups was significant, which was consistent with other studies.^{20,22} Although our study did not support the manufacturer’s recommendations to limit ring pessaries to women with stage I and II prolapse and to use only Gellhorn or other space-filling pessaries in women with stage III and IV prolapse,^{23,24} we recommend that the Gellhorn pessary should be used as the first choice for women with advanced POP with younger age and larger HC. Ring pessaries are easily inserted and removed, even by older women with decreased manual dexterity. Furthermore, we found that participants in the Ring group were older than those in the

Gellhorn group, so age should be considered when offering different pessary types to women.

The most common reasons for pessary fitting failure were expulsion and discomfort, which were relatively objective. However, patients discontinued pessary therapy mostly due to more subjective reasons, such as too much trouble managing the pessary, inability to insert and remove the pessary, and a desire for surgery.^{25,26} Accordingly, the pessary fitting outcomes were largely determined by objective findings. Therefore, in addition to POP-Q parameters, the TLUS findings were also investigated in our study. It has been shown that women with a larger HA and HC on maximal Valsalva maneuver were more likely to be successfully fitted with Gellhorn pessaries. The levator hiatus is the largest potential hernial portal in the human body, and all POPs are herniations through the hiatus.²⁷ In a previous study, it has been reported that HA was associated with POP symptoms and signs.²⁸ The larger the HA and HC detected, the more severe the POP, and the more likely the Gellhorn pessary would be successfully fitted. The ring pessary with support is intended to have a supportive function. Hiatal overdistension makes it difficult to retain the pessary in the midportion of the vagina above the levator plate, resulting in a decrease in the likelihood of pessary retention.²⁰ The Gellhorn pessary may act by suction against the apical vagina. Therefore, the function of this pessary is less affected by the hiatal overdistension.

We developed a prediction model that included participant age, POP-Q stage, and TLUS findings. A ROC curve was obtained with an AUC of 0.776 in the “Development” set and 0.705 in the “Validation” set. In addition, an AUC of 0.815 was obtained in our prospective cohort validation. Our study was the first to establish a predictive model for choosing the type of pessary. The AUC was higher than any other study considering pessary as a POP treatment. Taking TLUS into account may contribute to this excellence.

Strengths of this study included the establishment of a prediction model. Furthermore, this study included TLUS, which can provide information about the objective anatomy and also the underlying functional anatomy. The limits of this study included its being a retrospective study at a single tertiary care center. Due to the retrospective nature of our study, we did not have specific measurements of the vaginal introitus, which was

found to be a risk factor in a previous study. The small sample size of our study is also a limitation as, larger studies may be able to find other predictors. In addition, there were only two available pessary types with limited sizes (51-76 mm in diameter). Our results may then merely apply to similar circumstances. Further prospective trials with larger sample and different ethnicities are needed to confirm these findings.

CONCLUSION

Age, POP-Q stage, and HC on TLUS were predictive for choosing pessary type. For severe POP women with younger age and larger HC, Gellhorn pessaries should be their first choice instead of ring ones in pessary fitting trials.

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