CHAPTER 8

PREDICTORS OF UNSUCCESSFUL PESSARY FITTING IN WOMEN WITH PROLAPSE:
A CROSS-SECTIONAL STUDY IN GENERAL PRACTICE

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International Urogynecology Journal, 2016
ABSTRACT

Introduction and Hypothesis
Prolapse is a common condition. There is inconsistency between predictors of unsuccessful pessary fitting in urological/gynaecological clinics. Research in general practice is scarce. The aim was to estimate the proportion of women with a symptomatic prolapse with unsuccessful pessary fitting in general practice, and to identify characteristics associated with unsuccessful pessary fitting.

Methods
Cross-sectional study in general practice (n = 20) among women (≥55 years) with symptomatic prolapse (n = 78). Multivariable logistic regression analysis was used to identify predictors of unsuccessful pessary fitting.

Results
In total, 33 (42%) women had unsuccessful pessary fitting. Factors associated with unsuccessful pessary fitting were age (OR 0.93 per year [95% CI 0.87 to 1.00]), BMI (OR 1.14 per kg/m² [95% CI 1.00 to 1.30]), and having underactive pelvic floor muscles (OR 2.60 [95% CI 0.81 to 8.36]).

Conclusions
Pessary fitting was successful in 58%, indicating that pessary treatment might be suitable for many but not for all women with a symptomatic prolapse in general practice. The condition of the pelvic floor probably plays a role in the success of pessary fitting, as evidenced by the association with underactive pelvic floor muscles, and BMI. The association with age might reflect the higher acceptance of conservative treatments for prolapse in older women. This is the first study about predictive factors for unsuccessful pessary fitting in general practice. Therefore, further research should seek to confirm these associations before we can recommend the use of this information in patient counselling.
INTRODUCTION

Prolapse is a common condition. In a community survey, 75% of Dutch women aged 45–85 years had at least some degree of prolapse, and the prevalence of typical prolapse symptoms (i.e., seeing or feeling a vaginal bulge) has been reported to be about 3%–12%. Besides vaginal bulging, prolapse can cause a variety of pelvic floor symptoms, including a feeling of pelvic pressure or heaviness, pelvic pain, and urinary or faecal incontinence or obstruction. In addition, prolapse can negatively affect daily activities, sexual function, and quality of life. Prolapse is therefore a significant problem.

Treatment options for symptomatic prolapse are the insertion of a vaginal pessary, PFMT or reconstructive surgery. One year after treatment, research has shown no differences between pessary treatment and surgery in the improvement of urinary, bowel, or sexual function, as well as quality of life parameters. Reconstructive surgery is not always possible or preferable because of the high rates of comorbidity and frailty among older women, and the high risk of recurrence. Pessary treatment can easily be offered in general practice, which is less expensive, generally closer to a patient’s home, and is generally easier to access compared to secondary care. Physicians can offer pessaries to the majority of patients with prolapse because there are very few contraindications. However, rates for successful pessary fitting range from 41% to 86%, indicating that pessary treatment is not suitable for all women.

Research into the predictors of unsuccessful pessary fitting is scarce in general practice. Many studies have been performed in urological or gynaecological clinics, but their results cannot be extrapolated to general practice because of the potential for selection bias. In addition, the predictors of unsuccessful fitting have been inconsistent between studies. The predictors include a short vagina and wide vaginal hiatus, genital hiatus/total vaginal length (GH/TVL) ratio >0.8, lower POP-Q stage, posterior wall prolapse, previous prolapse repair and hysterectomy, coexistent stress urinary incontinence, increased parity, age 65 years or younger, and smoking. The scarcity of studies and the inconsistency of the results is surprising given that knowledge about the fitting rate and predictors of success are important to general practitioners when counselling patients about appropriate treatment. Further evidence is needed to facilitate informed choice based on individualized estimates of the risk of failure. Therefore, we aimed to estimate the proportion of women with symptomatic prolapse, at or beyond the hymen, in general practice, who cannot be successfully fitted with a pessary. In addition, we aimed to identify the characteristics of those patients (including the findings during pelvic examination) that are associated with unsuccessful pessary fitting.
METHODS

Study design
We report on secondary analyses of data from a randomised controlled trial on the effects and cost-effectiveness of conservative treatments for prolapse in older women in general practice. The trial was conducted between October 2009 and December 2012 and was approved by the Medical Ethics Committee of the University Medical Centre Groningen, the Netherlands (METc2009.215). All participants provided written informed consent. An extensive description of the design is provided elsewhere.18

Participants
Women, registered in a general practice in the northern part of the Netherlands (n = 20 practices), who screened positive for ≥1 pelvic floor symptoms related to prolapse on a postal questionnaire were invited for a clinical assessment. Pelvic floor symptoms included urinary incontinence, vaginal bulging, pelvic heaviness/pressure, or vaginal splinting required to start or complete micturition or defecation. During the clinical assessment women underwent a gynaecological examination using the POP-Q system to assess the degree of prolapse. In total, 162 women (aged ≥55 years) with a symptomatic prolapse, where the leading edge was at or beyond the hymenal remnants (advanced POP-Q stage 2 or stage 3), were randomised to pessary treatment or PFMT. This study only includes those women who were assigned to pessary treatment.

Outcomes
The primary outcomes were the proportion of women with unsuccessful pessary fitting and the factors associated with unsuccessful pessary fitting.

Pessary fitting procedure
A research physician who was trained in fitting pessaries chose the pessary size and format. The first choice was an open ring pessary, followed by a ring pessary with support. If a ring pessary could not be fitted, a Shaatz or Gellhorn pessary was tried. All pessaries were made of silicone (Milex, Chicago, IL, USA). A pessary was considered to be the correct size when the physician could place a single finger between the pessary and the vaginal wall, the prolapse was reduced to above the hymen, it felt comfortable to the patient, and it was retained during a Valsalva manoeuvre and coughing in both the supine and standing positions. After two weeks, an appointment was scheduled to evaluate the fit. Participants in whom the pessary fell out or who experienced discomfort within the first two weeks were refitted with a different type or size of pessary and reviewed again after two weeks. A maximum of three
attempts was made to achieve successful pessary fitting. Successful pessary fitting was defined as the ability to wear the pessary for two weeks without any discomfort, regardless of the number of the pessary trials. Women were taught, if desired, to perform self-care of a pessary.

Selection of predictors of unsuccessful pessary fitting
The selection of candidate predictors to be included in a prediction model was based on a review of the literature review. The following potentially relevant predictors were considered for the multivariable logistic regression model: age (years), birth weight of the heaviest child given birth to (kg), hysterectomy (yes/no), other pelvic floor surgery (yes/no), BMI (kg/m$^2$), underactive or inactive pelvic floor muscles (yes/no) according to the ICS classification, POP-Q stage, genital hiatus (GH; cm), total vaginal length (TVL; cm) and the most prolapsed compartment (anterior wall, posterior wall or uterus/vault).

Measurements
A standardized interview was conducted to collect data about patient characteristics, comorbidity, and the medical and obstetric history of the participants. Women underwent a uroghynaecological examination using the POP-Q system to assess the degree of prolapse and the genital hiatus and total vaginal length.$^{19}$ The function of the pelvic floor muscles was assessed by digital vaginal palpation in the supine position. Pelvic floor muscle function was categorised as normal, underactive, overactive, or inactive according to the classification system of the International Continence Society (ICS). It was defined as normal when the voluntary contraction (VC) was normal/strong, the voluntary relaxation (VR) was complete, and both involuntary contraction (IC) and involuntary relaxation (IR) were present. Pelvic floor muscle function was defined as underactive when VC was absent/weak, VR was complete, IC was absent/present and IR was present. Overactive pelvic floor muscle function was defined as VC being absent/weak/normal/strong, VR being absent/partially present, and both IC and IR being absent/present. Inactive pelvic floor muscle function was defined as an absent VC, complete VR, and both and absent IC and IR.$^{20}$ Four research physicians were trained by an experienced urogynecologist in performing the POP-Q measurement and to assess the pelvic floor muscle function. All clinical assessment were performed by one of these four research physicians. The PFDI-20 was used to assess pelvic floor symptoms,$^{21}$ with higher scores indicating more distress. This questionnaire is divided into three subscales: the POPDI-6, for prolapse symptoms; the CRADI-8, for colorectal/anal symptoms; and the UDI-6, for urinary symptoms.
Analyses
Multivariable logistic regression analysis was used to identify independent predictors of unsuccessful pessary fitting. A manual backward-elimination approach with all candidate predictors was followed to arrive at a model that included only the strongest predictors. We used the Akaike Information Criterion, which corresponds to a p-value of ≥ 0.157 as the criterion for removal from the model. Calibration of the multivariable model, or the extent of agreement between the predicted and observed unsuccessful fitting was evaluated with the Hosmer and Lemeshow goodness-of-fit test. A calibration plot was created to display the concordance between the observed and predicted probabilities of unsuccessful pessary fitting. Discriminatory performance, or the ability of the model to distinguish between women with successful and unsuccessful pessary fitting was evaluated by the area under the ROC curve. ORs and 95% CIs are given, unless otherwise stated.

All statistical analyses were performed using IBM SPSS for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Patients
Of the identified participants, 3 women were excluded because there were missing values for birth weight of the heaviest child (n = 2) and the most prolapsed compartment (n = 1), leaving 78 women for the analysis (<5% incomplete cases). The characteristics of the study population are presented in Table 1.

In total, 45 women (58%) had a successful fitting. Of these, 30 women were fitted with an open ring pessary, 14 with a ring pessary with support, and 1 with a Shaatz pessary. In the remaining 33 women (42%), pessary fitting was unsuccessful because it was not possible to find a properly fitting pessary in 21 women (64%). Patient-related reasons were the cause of non-fitting in 12 women (36%): an increase in or the development of urinary incontinence (n = 4), emotional resistance to pessary fitting/treatment (n = 4), discomfort during intercourse (n = 2), increased vaginal discharge (n = 1; the patient found it bothersome and was unwilling to use topical oestrogens), and urinary tract infection (n = 1; the patient related the infection to the pessary treatment). Median number of consultations was 1.0 (IQR 1.0-2.0) for women with successful pessary fitting and 2.0 (IQR 2.0-3.0) for women with unsuccessful fitting.

Multivariable analysis of unsuccessful pessary fitting
From the selected candidate predictors, GH and TVL were excluded since all patients in the study had a vaginal length >6 cm and a genital hiatus <5 cm. The candidate predictors
## TABLE 1 CHARACTERISTICS OF THE STUDY POPULATION: WOMEN WITH SUCCESSFUL AND UNSUCCESSFUL PESSARY FITTING

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Successful pessary fitting</th>
<th>Unsuccessful pessary fitting</th>
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<tbody>
<tr>
<td></td>
<td><strong>n = 45</strong></td>
<td><strong>n = 33</strong></td>
</tr>
<tr>
<td>Age (years), median (IQR)</td>
<td>65.9 (59.5–71.3)</td>
<td>63.3 (57.9–67.0)</td>
</tr>
<tr>
<td>BMI (kg/m²), median (IQR)</td>
<td>25.3 (22.5–28.1)</td>
<td>26.7 (24.3–28.1)</td>
</tr>
<tr>
<td>Parity, median (IQR)</td>
<td>2.0 (2.0–3.0)</td>
<td>2.0 (2.0–3.0)</td>
</tr>
<tr>
<td>Education level, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower education</td>
<td>21 (47)</td>
<td>12 (36)</td>
</tr>
<tr>
<td>Intermediate education</td>
<td>8 (18)</td>
<td>11 (33)</td>
</tr>
<tr>
<td>Higher education</td>
<td>16 (36)</td>
<td>10 (30)</td>
</tr>
<tr>
<td>Charlson Index, median (IQR)</td>
<td>0 (0–1)</td>
<td>0 (0–0.5)</td>
</tr>
<tr>
<td>Sexually active, n (%)</td>
<td>18 (40)</td>
<td>23 (70)</td>
</tr>
<tr>
<td>Having a partner, n (%)</td>
<td>34 (76)</td>
<td>27 (82)</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>21 (47)</td>
<td>18 (55)</td>
</tr>
<tr>
<td>Birthweight of heaviest child, median (IQR)</td>
<td>3.8 (3.2–4.0)</td>
<td>4.0 (3.5–4.5)</td>
</tr>
<tr>
<td>Hysterectomy, n (%)</td>
<td>7 (16)</td>
<td>9 (27)</td>
</tr>
<tr>
<td>Other pelvic floor surgery, n (%)</td>
<td>4 (9)</td>
<td>4 (12)</td>
</tr>
<tr>
<td>≥1 first-degree relative with prolapse, n (%)</td>
<td>16 (36)</td>
<td>21 (64)</td>
</tr>
<tr>
<td>PFDI-20 score, median (IQR)</td>
<td>54.2 (28.1–77.1)*</td>
<td>61.5 (45.3–96.1)*</td>
</tr>
<tr>
<td>POPDI-6 score, median (IQR)</td>
<td>12.5 (8.3–25.0)</td>
<td>16.7 (8.3–33.3)*</td>
</tr>
<tr>
<td>CRADI-8 score, median (IQR)</td>
<td>12.5 (0.8–18.8)*</td>
<td>18.8 (7.1–29.7)</td>
</tr>
<tr>
<td>UDI-6 score, median (IQR)</td>
<td>20.8 (12.5–36.5)*</td>
<td>29.2 (18.8–41.2)</td>
</tr>
<tr>
<td>Most prolapsed compartment, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior wall</td>
<td>36 (80)</td>
<td>29 (88)</td>
</tr>
<tr>
<td>Posterior wall</td>
<td>7 (16)</td>
<td>4 (12)</td>
</tr>
<tr>
<td>Uterus/vault</td>
<td>2 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Underactive/inactive pelvic floor muscles, n (%)</td>
<td>31 (69)</td>
<td>26 (79)</td>
</tr>
<tr>
<td>Genital hiatus (cm), median (IQR)</td>
<td>3.0 (2.0–3.0)</td>
<td>3.0 (2.0–4.0)</td>
</tr>
<tr>
<td>Total vaginal length (cm), median (IQR)</td>
<td>9.0 (8.0–10.0)</td>
<td>9.0 (8.0–10.0)*</td>
</tr>
</tbody>
</table>

*2 missing items; †1 missing item

‘hysterectomy’ and ‘other pelvic floor surgery’ were combined into one variable (pelvic floor surgery) to enlarge the number of cases for this variable. Table 2 shows the results of the final multivariable logistic regression analysis, including all variables with a p-value <0.157. Variables in this final model were age (OR 0.93 per year [95% CI 0.87 to 1.00]), BMI (OR 1.14 per kg/m² [95% CI 1.00 to 1.30]), and underactive or inactive pelvic
TABLE 2 PREDICTORS OF UNSUCCESSFUL PESSARY FITTING AFTER MULTIVARIABLE LOGISTIC REGRESSION

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Univariable LR* OR (95% CI)</th>
<th>Multivariable LR OR (95% CI)</th>
<th>MLR p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per year)</td>
<td>0.94 (0.88 to 1.00)</td>
<td>0.93 (0.87 to 1.00)</td>
<td>0.046</td>
</tr>
<tr>
<td>Birthweight of heaviest child (per kg)</td>
<td>1.80 (0.86 to 3.77)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic floor surgery (versus no pelvic floor surgery)</td>
<td>1.31 (0.46 to 3.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (per kg/m²)</td>
<td>1.09 (0.97 to 1.23)</td>
<td>1.14 (1.0 to 1.30)</td>
<td>0.056</td>
</tr>
<tr>
<td>Underactive/inactive pelvic floor muscles (versus normal pelvic floor muscle function)</td>
<td>1.68 (0.59 to 4.78)</td>
<td>2.60 (0.81 to 8.36)</td>
<td>0.11</td>
</tr>
<tr>
<td>POP-Q stage 3 (versus stage 2)</td>
<td>0.96 (0.36 to 2.55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior wall prolapse (versus posterior wall)</td>
<td>1.41 (0.38 to 5.29)</td>
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</tbody>
</table>

*Univariable associations of all candidate predictors in the full model. A manual backward-elimination approach with all these candidate predictors in the model was followed to arrive at a final model that included only the strongest predictors. The Akaike Information Criterion (p-value of ≥ 0.157) was used as the criterion for removal from the model.

Discrepancies in floor muscles (OR 2.60 [95% CI 0.81 to 8.36]). Calibration of the final multivariable model was evaluated with the Hosmer and Lemeshow goodness-of-fit test (p = 0.81); the calibration plot displayed concordance between the observed and predicted probabilities of unsuccessful pessary fitting (plot not shown). Discrimination of the final model was evaluated with the area under the ROC curve (0.69 [95% CI 0.57 to 0.80]).

**DISCUSSION**

**Main findings**
In this study in women with a symptomatic prolapse at or beyond the hymen in general practice, pessary fitting (typically open ring) was unsuccessful in 42% (33/78). The success rate of 58% is consistent with previous reported successful fitting rates of 41%–86%. The factors associated with unsuccessful pessary fitting in this study were lower age, higher BMI, and underactive or inactive pelvic floor muscles.

**Strengths and limitations**
This is the first study about predictors of unsuccessful pessary fitting in general practice. The use of multivariable logistic regression to identify independent predictors for unsuccessful fitting elaborates on existing studies based on univariate regression.
analysis, which do not provide information on independent relationships.\textsuperscript{9,13-15}

When interpreting the results of this study, potential study limitations should be taken into account. Characteristics that were associated with unsuccessful pessary fitting, vary between studies, with few characteristics identified consistently. This complicated the pre-selection of the most important candidate predictors for our prediction model. The rule of thumb that logistic regression models should be used with a minimum of 10 events per predictor variable (EPV) is based on very few simulation studies in which only the numbers of events was varied.\textsuperscript{23} Vittinghoff and McCulloch conducted a large simulation study of other influences on confidence interval coverage, type I error, relative bias, and other model performance measures. They concluded that the rule of thumb of a minimum of 10 events per variable can be relaxed based on the finding that model performance problems were uncommon with 5-9 EPV, and still observed with 10-16 EPV. Based on this and the exploratory nature of our study we decided to use five EPV. In addition, the Akaike Information Criterion ($p \geq 0.157$) was used as the criterion for removal from the model to prevent the possibility that a true predictor would be missed and to reduce the extent of overfitting (i.e. over-optimism of the model).\textsuperscript{22,24}

\textbf{Interpretation}

In our study with women aged 55 years and older, higher age was negatively associated with unsuccessful pessary fitting in the final multivariate logistic regression model which means that in our study, which was explorative, the risk of unsuccessful pessary fitting decreased with increasing age. Evidence about the association is conflicting: some studies did not find an association between age and the likelihood of unsuccessful pessary fitting (e.g. \textsuperscript{9,14-16}) whereas others found age 65 years or younger to be a predictor of unsuccessful pessary fitting.\textsuperscript{11} Older women are more likely to choose pessary treatment over reconstructive surgery\textsuperscript{25,26} and higher age has been shown to be a good predictor of continuation of pessary use in successfully fitted patients.\textsuperscript{27,28} This might indicate that the acceptance and appreciation of pessary treatment for prolapse is higher in older women. Health care providers could therefore try pessary treatment in women of all ages, but especially in older women.

In our study, a higher BMI was associated with unsuccessful fitting. This has been found before.\textsuperscript{15} An explanation for this might be that increased pressure on the pelvic area in women with a high BMI, impedes pessary fitting. However, some studies report a lack of association of BMI with unsuccessful pessary fitting.\textsuperscript{12,14} This means that this association needs further exploration.

Women with underactive or inactive pelvic floor muscles, compared to those with normal pelvic floor function, had a higher likelihood of unsuccessful fitting. It is
conceivable that underactive pelvic floor muscles provide insufficient support to the pessary, which in turn results in the pessary falling out. This finding is different from the results of the two other studies that looked at the role of pelvic floor muscle strength in pessary fitting and in which no association was found.\textsuperscript{11,12} A possible explanation for these conflicting results might be the differences in the definition and measurement of underactive pelvic floor muscles.

We did not find an association between severity of prolapse and the likelihood of an unsuccessful pessary fit. We also did not find an association between the most prolapsed compartment (anterior wall, posterior wall, or uterus/vault) and unsuccessful pessary fitting. Although this is in accordance with previous studies\textsuperscript{9,14,15} our study may have lacked power to detect an association because of the low number of patients with the posterior wall as the leading edge of the prolapse (n = 11). So far, there is controversy regarding the effectiveness of a pessary for posterior wall prolapse since a pessary uses the pelvic floor as support base and its supportive effect was therefore thought to be presumably anteriorly. To date, there is insufficient evidence to state that a posterior wall prolapse is a risk factor for unsuccessful pessary fitting. The effect of a wide genital hiatus or a short vagina on pessary fitting could not be studied because of a lack of patients with these conditions in our sample. In primary care women with a prolapse often have a normal hiatus width and vaginal length. Patients referred to secondary or tertiary care settings may show more frequently a hiatus > 5 cm or a vaginal length < 6 cm.

The discriminatory performance of our final multivariable regression model was moderate and the calibration seemed to be good. Information about the discrimination and calibration is relevant to estimate the performance of a prediction model. This study was performed to generate hypotheses about predictive factors for unsuccessful pessary fitting in general practice rather than to arrive at a prediction model to be used in clinical practice. Information about the independent risk factors for unsuccessful pessary fitting is therefore of greater interest than the performances of the final multivariable logistic regression model. Future research should address the observed risk factors and seek to confirm these associations, preferably in a larger population. Until then, the association between the identified predictors and fitting failure is insufficiently strong to advise against pessary use in women with those predictors.

**Conclusions**

This study showed that pessary fitting was successful in 58% of women with a symptomatic prolapse in general practice. This indicates that pessary treatment might be suitable for many but not all women with a symptomatic prolapse. This study was
performed to generate hypotheses about independent risk factors for unsuccessful pessary fitting in general practice. Our results indicated that lower age, higher BMI and underactive or inactive pelvic floor muscle function were associated with a higher risk of unsuccessful pessary fitting. As this was the first study about predictive factors for unsuccessful pessary fitting in general practice, further research is needed to confirm the associations we found and prediction models have to be validated in other primary care populations. Only then we can use predictors of fitting failure in counselling women about pessary use.
REFERENCES


