Thieme

Comparison of Vaginal Pessaries to Standard Care or Pelvic Floor Muscle Training for Treating Postpartum Urinary Incontinence: a Pragmatic Randomized Controlled Trial

Vergleich von Pessaren mit Standardversorgung (Rückbildungskurse) und Beckenbodenphysiotherapie zur Behandlung von postpartaler Harninkontinenz: eine pragmatische randomisierte kontrollierte Studie

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Schlüsselwörter

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ABSTRACT

Introduction

To compare three conservative treatment options, standard care, pelvic floor muscle training (PFMT), and vaginal pessaries, for postpartum urinary incontinence (UI) that are accessible to most patients and practitioners in a generalizable cohort.

Materials and Methods

A multicenter, open-label, parallel group, pragmatic randomized controlled clinical trial comparing standard care, PFMT, and vaginal cube pessary for postpartum urinary incontinence was conducted in six outpatient clinics. Sample size was based on large treatment effects (Cramers'

V > 0.35) with a power of 80 % and an alpha of 0.05 for a 3 × 3 contingency table, 44 patients needed to be included in the trial. Outcomes were analyzed according to the intention-to-treat principle. Group comparisons were made using analysis of variance (ANOVA), Kruskal-Wallis, and chi-square test as appropriate. P < 0.05 was considered statistically significant.

Results
Of the 516 women screened, 111 presented with postpartum UI. Of these, 52 were randomized to one of three treatment groups: standard care (n = 17), pelvic floor muscle training (n = 17), or vaginal cube pessary (n = 18). After 12 weeks of treatment, treatment success, as measured by patient satisfaction, was significantly higher in the vaginal pessary group (77.8 %, n = 14/18), compared to the standard care group (41.2 %, n = 7/17), and the PFMT (23.5 %, n = 4/17; $\chi^2_{2,n=52} = 14.55$; p = 0.006, Cramer-V = 0.374). No adverse events were reported. SUI and MUI accounted for 88.4 % of postpartum UI.

Conclusion
Vaginal pessaries were superior to standard care or PFMT to satisfyingly reduce postpartum UI symptoms. No complications were found.

ZUSAMMENFASSUNG

Einleitung
Ziel war es, 3 konservative Optionen zur Behandlung der postpartalen Harninkontinenz in einer verallgemeinerbaren Kohorte zu vergleichen. Verfügbare Behandlungsoptionen waren Standardversorgung (Rückbildungskurse), Beckenbodenphysiotherapie und Pessare, die den meisten Patientinnen und Behandelnden zur Verfügung stehen.

Material und Methoden
Es wurde eine multizentrische offene pragmatische randomisierte kontrollierte klinische Studie mit parallelen Gruppen durchgeführt. Die Outcomes nach Standardversorgung (Rückbildungskurse), Beckenbodenphysiotherapie oder Würfel-Pessaren zur Behandlung von postpartaler Harninkontinenz wurden in 6 Arztpraxen verglichen. Zum Nachweis eines großen Behandlungseffektes (Cramers V > 0,35) mit einer Teststärke von 80 % bei einem Alpha von 0,05 für eine 3 × 3-Kontingenztabelle wurde eine Stichprobengröße von mindestens 44 Patientinnen errechnet. Die Outcomes wurden nach dem Intention-to-treat-Prinzip analysiert. Die Gruppen wurden mithilfe der Varianzanalyse (ANOVA) sowie Kruskal-Wallis- und Chi-Quadrat-Test verglichen. Der p-Wert für die statistische Signifikanz betrug < 0,05.

Ergebnisse
Von den 516 untersuchten Frauen hatten 111 eine postpartale Harninkontinenz. Von diesen Frauen wurden 52 in jeweils eine der 3 Behandlungsgruppen randomisiert: Standardversorgung (Rückbildungskurse, n = 17), Beckenbodenphysiotherapie (n = 17) und Würfel-Pessare (n = 18). Nach 12 Wochen Behandlungszeit war der an der Patientinnenzufriedenheit gemessene Behandlungserfolg signifikant höher in der Pessar-Gruppe (77,8 %, n = 14/18) verglichen mit den Gruppen Standardversorgung (Rückbildungskurse, 41,2 %, n = 7/17) und Beckenbodenphysiotherapie (23,5 %, n = 4/17; $\chi^2_{2,n=52} = 14,55$; p = 0,006, Cramers-V = 0,374). Es gab keine unerwünschten Ereignisse. Belastungsinkontinenz und Mischinkontinenz machten 88,4 % der Fälle mit postpartaler Harninkontinenz aus.

Schlussfolgerung
Es stellte sich heraus, dass für eine zufriedenstellende Reduktion von Symptomen der postpartalen Harninkontinenz Pessare der Standardversorgung (Rückbildungskurse) und der Beckenbodenphysiotherapie überlegen waren. Komplikationen sind keine aufgetreten.

Abbreviations

ACOG	American College of Obstetricians and Gynecologists
BMI	Body Mass Index
ICS	International Continence Society
MUI	Mixed Urinary Incontinence
NICE	The National Institute for Health and Care Excellence
OAB	Overactive Bladder
PFMT	Pelvic Floor Muscle Training
PRECIS	Pragmatic Explanatory Continuum Indicator Summary
SUI	Stress Urinary Incontinence
UI	Urinary Incontinence

Introduction

Urinary incontinence (UI) is present in approximately 56 % of pregnant nulliparous women and in 33 % of all women in the first 3 months after delivery [1, 2]. Several studies have shown that stress urinary incontinence (SUI) accounts for around 66% of cases, whereas mixed urinary incontinence and overactive bladder syndrome make up around 25% and 10% of all cases, respectively [1, 3]. Three-quarters of women who have urinary incontinence after birth show a persistence of symptoms 12 years later [4]. Unfortunately, even this high prevalence has not changed the fact that most women are not sufficiently treated for urinary incontinence [5]. This is due to several facts: First, there is a persistent belief that UI is an inevitable, natural result of childbirth and is therefore

not necessarily seen as pathologic, even among health care providers [6, 7]. Second, a general screening for urinary incontinence during postpartum visits does not exist, and practitioners and future health care providers lack experience in treating UI [8, 9]. Third, only a small minority of less than 10% of women discuss urinary and fecal incontinence symptoms with their physicians during their postpartum check-ups [10].

Multiple treatment options for urinary incontinence exist and vary depending on the type of urinary incontinence and the patient's history and preferences. In postpartum women, conservative treatments remain the preferred choice over surgical treatments which are seldomly performed in the postpartum period given the risk of treatment failure in future pregnancies [11]. The treatment option that has been studied the most in pregnant and postpartum women is pelvic floor muscle training (PFMT) ante- and postnatally [11]. While continent women might benefit from antenatally started PFMT, results in women who are incontinent after giving birth are conflicting regarding the effect of PFMT on the persistence of urinary incontinence symptoms. In several countries, women benefit from postpartum exercise courses either in groups or individually. These courses are generally offered by midwives and in most cases do not solely address pelvic floor problems, but other issues as well. There is a lack of data on the extent to which PFMT could be more effective than postpartum exercise courses.

Vaginal pessaries are most often used to treat pelvic organ prolapse, but can also be used in the treatment of urinary incontinence [12, 13, 14]. Recent guidelines included vaginal pessaries as valid treatment options [15]. Their effectiveness is mostly attributed to their support of the anterior vaginal wall and the urethrovesical junction [16]. Of the different existing pessary types, none has been shown to be superior to the others in improving incontinence symptoms [17]. Only very few studies have investigated the use of pessaries for postpartum women. Recently, one prospective cohort study studied the compliance with the Restifem pessary [18]. 71% of the pessary users still used the pessary after 3 months but no comparison with other treatments was performed. In this study, we aimed to compare the use of vaginal pessaries to two conservative treatment options for postpartum urinary incontinence.

Materials and Methods

Study design and inclusion criteria

This study was a multicenter, open-label, parallel group, randomized controlled clinical trial comparing standard care to pelvic floor muscle training or vaginal pessary for postpartum urinary incontinence (trial number: NCT06031870). The protocol for this study was based on the PRECIS proposal (Pragmatic–Explanatory Continuum Indicator Summary) and aimed to be pragmatic, and a reflection of the usual clinical care for postpartum urinary incontinence [19]. Consistent with the PRECIS proposal, the study was designed so that participants represent general postpartum patients in gynecologic practices as much as possible.

Women were eligible for enrollment if they were 18 years or older, gave birth within the 12 weeks prior to the postpartum visit, reported postpartum urinary incontinence since delivery, and were able to understand and give consent in German. Exclusion criteria were treatment for postpartum urinary incontinence that started prior to inclusion and any neurologic disease that impairs bladder function.

The study was approved by the local institutional review board (the ethics committee of the Chamber of Physicians of the Land Rhineland-Palatinate, Germany; Study-ID: 2018–13832). An informed consent process was completed by all participants, with all patients providing written consent.

Study population and randomization

Patients were screened in six gynecologic medical offices in three German towns from June 2019 to July 2021. In Germany, postpartum check-ups are generally performed six to twelve weeks after birth and are paid for by the mandatory health insurance.

Women who attended their scheduled postpartum check-ups and met the inclusion criteria were asked to participate in the study. Those who consented answered a modified version of the 3IQ-questionnaire adapted to pregnancy [20]. The questionnaire consisted of the following questions:

1. Did you lose urine before pregnancy?
2. Did you lose urine during pregnancy?
3. Did you lose urine after pregnancy?

To each question, the patients were able to choose between the following answers:

1. When you were performing some physical activity, such as coughing, sneezing, lifting, or exercise?
2. When you had the urge or feeling that you needed to empty your bladder, but could not get to a toilet fast enough?
3. Without physical activity and without a sense of urgency?

Patients who presented with urinary incontinence, as determined by the 3IQ-questionnaire, were asked if they desired treatment, and those desiring treatment were randomized. Randomization was performed by the study centers in blocks of six in a 1–1–1 manner.

Intervention and follow-up

Patients who desired treatment were randomized to one of three treatment groups:

1. Standard care (Pelvic floor group exercise courses):
   Standard care consisted of a pelvic floor group exercise course led by a midwife, a physiotherapist, or an osteopath. Courses were in general once a week for a minimum of seven to a maximum of twelve weeks. The course was chosen by the patient, and the study team had no influence on the choice.
2. Pelvic floor muscle training:
   Twelve pelvic floor physiotherapy sessions were prescribed by the study physician. Pelvic floor physiotherapy was performed in individual courses by trained physiotherapists. The patient was free to choose the physiotherapist and the study team had no influence on the choice.

3. Intravaginal cube pessary:
   In the pessary group, all patients received a cube pessary (Dr. Arabin GmbH & Co. KG, Germany), which was individually adapted to each patient. These pessaries exist in sizes 0 (25 mm edge length) to 9 (75 mm edge length). Patients were instructed by a physician or a trained nurse on how to autonomously manage the pessary, including daily changing and cleaning. After one week of treatment, all patients had an office visit to check if fitting was correct and if autonomous handling of the pessary was feasible. Treatment duration was 12 weeks.

At the end of the 12-week treatment period, all study participants had another clinical check-up with outcome assessment. Patients who did not show up for the check-up were contacted by the study team by telephone. All treatments and appointments were paid for by the patients' health insurance, thus no additional costs arose for any patient.

Clinical data were recorded in the electronic patient file at each visit and basic information were derived from it.

Definitions

This study defines urinary incontinence in accordance with the International Continence Society (ICS) as "complaint of involuntary loss of urine" [21]. Subtypes of UI, including stress urinary incontinence (SUI), overactive bladder (OAB), and mixed urinary incontinence (MUI) are also defined according to ICS.

Outcomes

The primary outcome was patients' self-reported satisfaction with the treatment. Success of treatment was defined as the subjective reduction of incontinence symptoms as judged by the patient. We used a questionnaire consisting of one question with three possible replies: "Did the treatment reduce your incontinence symptoms?"

1. "No changes in urinary incontinence symptoms."
2. "Somewhat improved urinary incontinence symptoms."
3. "Satisfying reduction of urinary incontinence symptoms."

Patients who gave either answers 2 or 3 were considered successfully treated. Secondary outcomes were treatment complications and compliance with treatment; these were evaluated at the post-treatment visit.

Statistical analysis

The sample size was calculated based on the primary outcome measure and estimated using G-Power 3.1 [22]. Given the absence of any previous studies that use vaginal pessaries to treat postpartum urinary incontinence, estimation of the sample size was based on the fact that only large treatment effects would be considered clinically relevant. To find a large effect (> 0.35) with a power of 80% and an alpha of 0.05 for a 3 × 3 contingency table (three groups × 2 levels of satisfaction), 44 patients needed to be included in the trial.

All outcomes were analyzed according to the intention-to-treat principle. Patients who were lost to follow-up, did not finish the treatment, or refused to answer the post-treatment questionnaire were classified as treatment failure. A per-protocol-analysis was also carried out. This analysis only included women who completed the entire treatment protocol as planned, attended the post-treatment clinical check-up, and answered the post-treatment questionnaire.

Group comparisons were made using analysis of variance (ANOVA), Kruskal-Wallis, and chi-square test as appropriate. $P < 0.05$ was considered statistically significant. Cramers' V was used as a measure of the size of the association between treatment group and patient satisfaction with the treatment. For a 3×3 contingency table, a large effect was defined as $V \geq 0.35$. Statistical analyses were performed using SPSS 28.

Patient involvement

No patient was involved in the design and implementation of the study, including setting the research question and outcome measures, recruiting study participants, and disseminating the study results.

Results

Five-hundred and sixteen patients were screened at postpartum check-ups with 111 (21.5%) presenting with postpartum urinary incontinence (see ▶ **Fig. 1**). Of those 111 patients, 54 (48.6%) consented to participating in the trial. Two patients had to be excluded prior to randomization to a treatment group because they had already started a standard care treatment for postpartum urinary incontinence. A total of 52 participants were randomized to one of the three treatment groups: standard care (n = 17), PFMT (n = 17), or vaginal pessary (n = 18). Fitting of the pessaries was possible for all women in the pessary group without any notable issues. Twelve patients used a pessary size 0, four patients pessary size 1, and sizes 2 and 3 were used by one patient each.

▶ **Table 1** shows the basic characteristics of the three treatment groups. No differences were found between the three groups in terms of age (p = 0.957), parity (p = 0.303), BMI prior to pregnancy (p = 0.642), BMI after pregnancy (p = 0.924), weight gain during pregnancy (p = 0.066), or mode of delivery (p = 0.726).

Types of urinary incontinence

▶ **Table 2** shows the distribution of the different types of urinary incontinence before, during, and after pregnancy. While only 40.4% of study participants reported UI prior to pregnancy, 80.6% complained of UI during pregnancy. SUI was the most frequent type of UI in all groups prior to, during, and after pregnancy, and accounted for 61.9% of UI before, 69.0% during, and 61.5% after pregnancy. When also considering MUI, stress-related UI accounted for 85.7% of UIs before, 90.5% during, and 88.5% after pregnancy. No differences between the groups were found regarding the type of urinary incontinence before (p = 0.700), during (p = 0.881), or after pregnancy (p = 0.687).

▶**Table 1** Basic characteristics of the treatment groups. Percentages were calculated relative to group size.

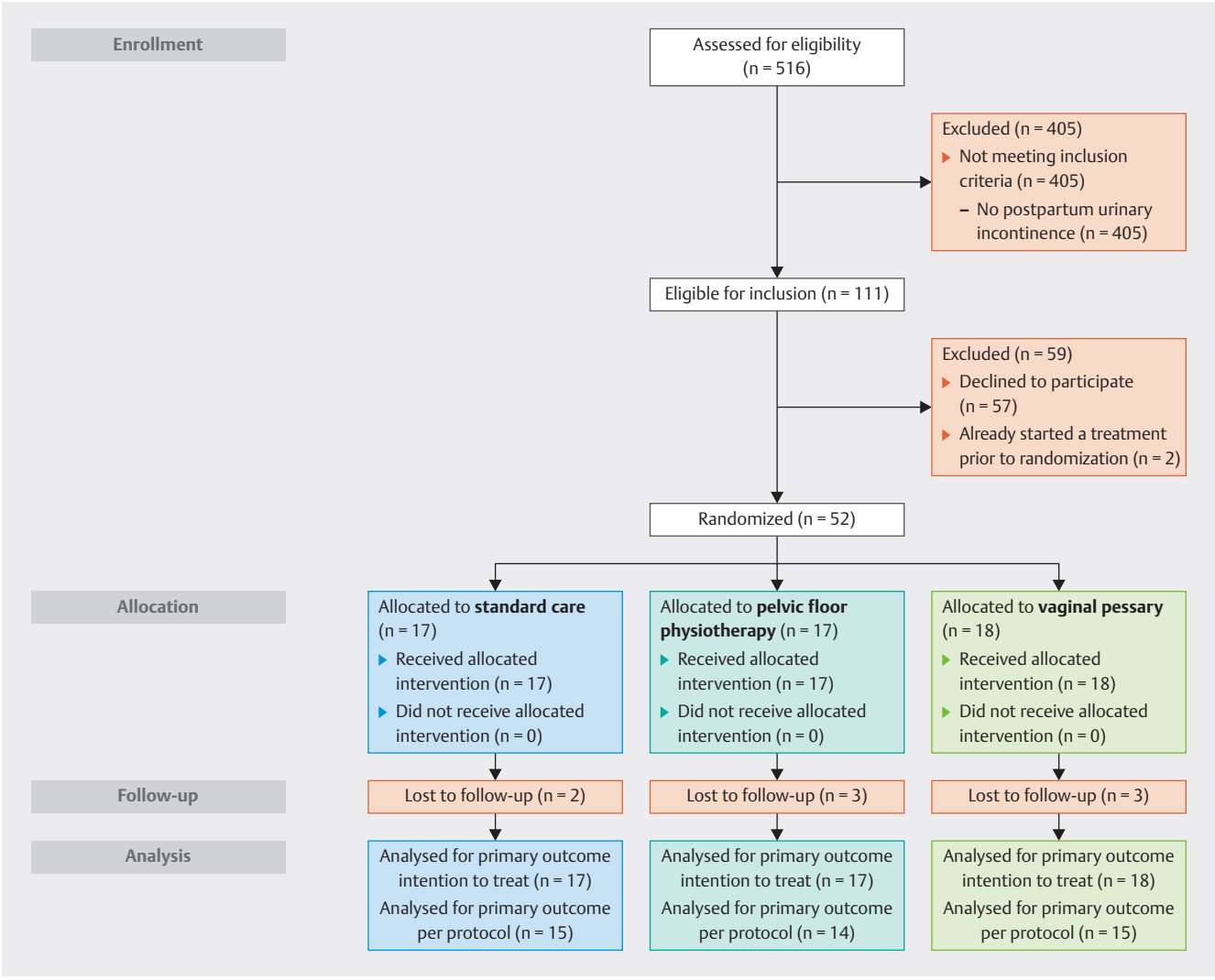
	Standard care (n = 17)	Pelvic floor physiotherapy group (n = 17)	Vaginal pessary group (n = 18)
Mean age (years; SD; range)	32.65 (SD 5.88; 21–44)	32.12 (SD 4.24; 24–40)	32.22 (SD 5.73; 21–44)
▪ 18–29 years (n; %)	5 (29.4)	3 (17.6)	4 (22.2)
▪ 30–34 years (n; %)	6 (35.3)	9 (52.9)	9 (50.0)
▪ 35–39 years (n; %)	4 (23.5)	4 (23.5)	3 (16.7)
▪ > 40 years (n; %)	2 (11.8)	1 (5.9)	2 (11.1)
Parity			
▪ Primiparous (n; %)	8 (47.1)	8 (47.1)	3 (16.7)
▪ Multiparous (n; %)	9 (52.9)	9 (52.9)	15 (83.3)
Mean BMI prior to pregnancy (kg/m^2; SD; range)	27.12 (4.40; 21.9–35.8)	29.30 (7.54; 16.5–47.5)	27.88 (7.66; 18.8–44.1)
▪ underweight (BMI < 18.5 kg/m^2; n; %)*	0 (0.0)	1 (6.3)	0 (0.0)
▪ normal weight (BMI 18.5–24.9 kg/m^2; n; %)*	9 (52.9)	4 (25.0)	8 (47.1)
▪ preobese (BMI 25.0–29.9 kg/m^2; n; %)*	3 (17.6)	5 (31.3)	4 (23.5)
▪ obese (BMI ≥ 30.0 kg/m^2; n; %)*	5 (29.4)	6 (37.5)	5 (29.4)
Mean BMI after pregnancy (kg/m^2; SD; range)	32.56 (3.88; 26.8–37.9)	33.00 (8.73; 18.4–54.8)	32.50 (7.60; 21.3–49.6)
▪ underweight (BMI < 18.5 kg/m^2; n; %)*	0 (0.0)	1 (6.7)	0 (0.0)
▪ normal weight (BMI 18.5–24.9 kg/m^2; n; %)*	0 (0.0)	1 (6.7)	3 (17.6)
▪ preobese (BMI 25.0–29.9 kg/m^2; n; %)*	5 (31.3)	3 (20.0)	4 (23.5)
▪ obese (BMI ≥ 30.0 kg/m^2; n; %)*	11 (68.8)	10 (66.7)	10 (58.8)
Mean weight gain during pregnancy (kg; SD; range)	14.81 (7.86; 10.6–19.0)	8.96 (6.82; 5.3–12.6)	12.38 (6.11; 9.3–15.4)
Mode of delivery			
▪ Vaginal delivery, n (%)*	15 (88.2)	16 (94.1)	15 (83.3)
▪ Spontaneous vaginal delivery, n (%)*	12 (70.6)	14 (82.4)	14 (77.8)
▪ Instrumental delivery, n (%)*	3 (17.6)	2 (11.8)	1 (9.6)
▪ Cesarean section*	2 (11.8)	1 (5.9)	3 (16.7)

BMI = Body mass index; SD = standard deviation.
* Total percentage might be slightly more or less than 100 % due to rounding.

▶**Table 2** Types of urinary incontinence prior to pregnancy, during pregnancy, and postpartum. Values are presented as numbers (percentages). Percentages were calculated for each time point.

Type of urinary incontinence	prior to pregnancy (n = 52)	during pregnancy (n = 52)	postpartum (n = 52)
SUI	13 (24.1)	29 (53.7)	32 (61.5)
OAB	1 (1.9)	2 (3.7)	5 (9.6)
MUI	5 (9.3)	9 (16.7)	14 (26.9)
Other types	2 (3.7)	2 (3.7)	1 (1.9)
No urinary incontinence	31 (59.6)	10 (19.2)	0 (0.0)

MUI = mixed urinary incontinence; OAB = overactive bladder; SUI = stress urinary incontinence.



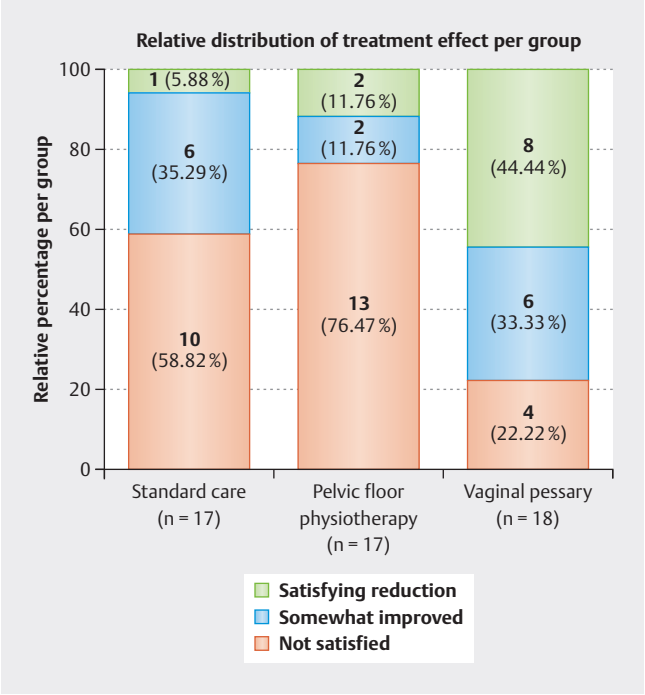
▶ **Fig. 1** CONSORT flow diagram.

Main findings

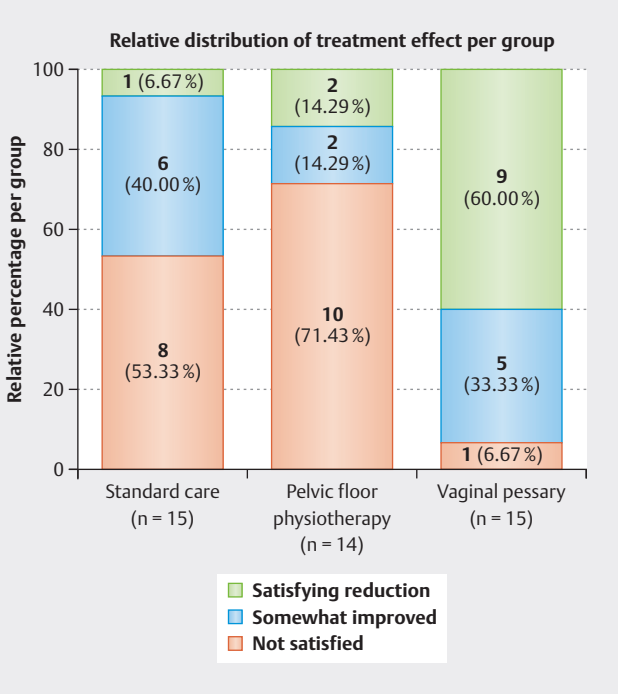
All women started treatment as allocated, but two women in the standard care group (11.8%), three in the pelvic floor physiotherapy group (17.7%), and three in the vaginal pessary group (16.7%) were lost to follow-up or did not finish the allocated treatment (see ▶ **Fig. 1**). No between-group differences in the rate of loss to follow-up was found (p = 0.878). There was no cross-over between groups.

In the intention-to-treat analysis (see ▶ **Fig. 2**), treatment success was found in 41.2% of patients in the standard care group (n = 7/17), 23.5% in the pelvic floor physiotherapy group (n = 4/17), and in 77. 8% in the vaginal pessary group (n = 14/18). A Chi-Square test revealed a strong statistically significant association between treatment group and patient satisfaction ($\chi^2_{2,n\,=\,52}$ = 14.55; p = 0.006, Cramer-V = 0.374). Post-hoc tests based on adjusted residuals indicated that in the pessary group, more participants than expected were satisfied with the treatment, while in the physiotherapy group, a higher frequency of dissatisfaction was observed. When looking at the exact responses of the satisfied participants, most were "somewhat satisfied". Specifically, in the standard care group, all but one patient reported being "somewhat satisfied" (n = 6/7) with the treatment, while half of the satisfied patients in the physiotherapy group were "somewhat satisfied" (n = 2/4). In the pessary group, 8 out of the 14 women who reported being satisfied were "somewhat satisfied", while 6 women were "satisfied". The per-protocol analysis yielded comparable results to the intention-to-treat analysis, and revealed also a strong statistically significant association between treatment group and satisfaction rate ($\chi^2_{2,n\,=\,44}$ = 18.40; p = 0.001, Cramer-V = 0.457; see ▶ **Fig. 3**).

No treatment complications, such as infections or pain during pessary insertion, were observed in any patient during the study period.



▶ **Fig. 2** Relative distribution of treatment effect per group in the intention-to-treat analysis. Percentages are indicated as relative to group size.



▶ **Fig. 3** Relative distribution of treatment effect per group in the per-protocol analysis. Percentages are indicated as relative to group size.

Discussion

Urinary incontinence is one of the most frequent ailments in the postpartum period [1]. It is more frequent in multiparous than in primiparous women [1, 2]. In this study, 21.5% of all women screened at the postpartum check-up presented with a UI, with almost half of them desiring treatment. This number may be underestimated, given the fact that some women may have already started or organized a treatment without mentioning it at the postpartum check-up. Screening of postpartum UI is infrequently performed during postpartum check-ups, even though a diagnosis can be made primarily based on patients' symptoms and, in most cases, without the need for further urodynamic evaluation before starting conservative treatment [5, 10].

In our study, vaginal pessaries were more effective than standard care or PFMT to treat postpartum urinary incontinence. Only a few studies have investigated the use of vaginal pessaries to treat urinary incontinence, and only one other study studied vaginal pessaries as a treatment for postpartum women [14, 18, 23, 24]. A Cochrane analysis from 2014 found insufficient evidence to recommend vaginal pessaries over PFMT for treating UI due to the lack of data [17]. In the ATLAS trial, Richter and colleagues compared ring or dish pessaries to behavioral therapy and combined therapy for treating SUI and found better results for behavioral therapy after three months, though these differences did not persist after a 12-month period [24]. Kiefner and colleagues studied the compliance of postpartum women with the Restifem pessary in a prospective cohort study [18]. Of 857 women who received a pessary, 209 women (24.4%) were followed for at least three months. Of these, 56.9% (n = 119) used the pessary initially, but compliance fell to 40.7% (n = 85) after three months. Improvement of symptoms was found in 72% of women with SUI and 66% with OAB. No comparison with other treatments was performed.

Pelvic floor muscle training is considered a first-line of treatment for urinary incontinence because of its effectiveness and quasi-absence of risks [25]. NICE and ACOG recommend starting PFMT as early as possible or at least at postpartum visits [26]. PFMT is an effective method to reduce urinary incontinence symptoms in non-pregnant women [27]. In postpartum women, a Cochrane analysis found PFMT to be less effective than in non-pregnant women [11]. The authors found no evidence that PFMT started after delivery for persistent UI achieved a significant reduction of symptoms. The only women who seemed to slightly benefit from PFMT were women without urinary leakage who started PFMT during pregnancy to prevent urinary incontinence. Additionally, no differences between group courses and individual physiotherapy were observed. All trials included in the analysis recommended either at least 30 minutes of PFMT per day or at least 100 muscle contractions per day. The authors hypothesized that postpartum women might have difficulty finding time to perform PFMT over the recommended duration, with childcare being a possible important distractor. In our study, 41.2% of women who received standard care, and only 23.5% of women in the PFMT group reported being at least somewhat satisfied with the treatment's effect after 12 weeks.

It is hypothesized that UI, especially SUI, develops as a result of an increased bladder neck mobility, which occurs during and after pregnancy due to physiological changes during pregnancy and

pelvic floor trauma incurred during childbirth [3]. Risk factors for UI during pregnancy in nulliparous women are pre-pregnancy obesity, pre-pregnancy UI, a maternal age of 35 years or older at the time of delivery, and childhood enuresis [1]. In our study, stress-related types of UI were found in more than 8 out 10 participating women, which is consistent with findings in other studies [28]. Pessaries are known to support the pelvic floor and thus the bladder neck by stabilizing the proximal part of the urethra above the level of the pelvic floor [14, 17]. Consequently, the maximum urethral closure pressure increases [13]. Even though in the ATLAS trial, continence pessaries were less effective in reducing incontinence than behavioral therapy, patients using the pessaries showed a reasonable satisfaction with the treatment [24]. In recent guidelines, vaginal pessaries should be recommended as a treatment option to women with stress urinary incontinence [15]. It is possible that, compared to non-pregnant women, the postpartum period is a sensible period in which stabilization of the bladder neck with intravaginal pessaries might be more effective than PFMT in reducing UI symptoms due to the recent pelvic floor trauma and physiological changes experienced.

Pessaries are widely used for the treatment of pelvic organ prolapse and fitting is successful in approximately 90 % of cases [14]. There is, to date, no pessary type that has been shown to be superior to other types of pessaries in treating urinary leakage. In our study, we only used cube pessaries. We are aware that cube pessaries are less often used than some other types, i.e. ring pessaries [29]. In a survey on the experience of pessary use among U.S. obstetrics and gynecology residents, only 19% of residents reported having experience with cube pessaries [30]. Nemeth and colleagues studied cube pessaries for pelvic organ prolapse and found that almost 80% of women continued the treatment after 12 months [31]. Importantly, the authors found no complications or adverse events during the study period. In our study, 16.7% (n = 3) discontinued the pessary treatment, but this discontinuation rate was not statistically different from the rate in the PFMT or standard care groups. Like Nemeth and colleagues, we did not find any adverse events or complications in the pessary group, or in any other treatment group. Our study design does not permit the evaluation of whether any one type of pessary is superior to the others in the treatment of UI. It is possible that most pessary types support the bladder neck efficiently enough during the postpartum period to reduce UI symptoms.

Treatment effects can be influenced by patients' accessibility to the treatment. In Germany, mandatory health insurance covers 98.6 % of the population [32]. All three treatments in this study were reimbursed by health insurance. Therefore, patients did not incur any costs as a result of participating in the study, and this permitted equal accessibility to the assigned treatment for all participants. Consequently, study participation and patient satisfaction rates are unlikely to have been influenced by financial constraints.

We aimed for a pragmatic study design to achieve generalizability of our results to the broader population. For this reason, the exclusion criteria were kept to a minimum, and all relevant conservative treatment options were included. We also did not intervene with the standard care or the PFMT treatments, because these are generally led by midwives, physiotherapists, or osteopaths, and practitioners have very little influence on the daily practice of these treatments. For these reasons, we hope that practitioners can identify the treatment options they have at their disposal for each of their patients in our trial. It is our belief that the design and findings of this study bring us closer to answering the question of which treatment option is more effective in treating urinary incontinence in postpartum women.

Limitations

Our study has several limitations. First, we did not include a sham treatment group. However, our aim was to compare the three most common treatment options available to practitioners for treating postpartum UI and not to test whether these are effective treatment per se. We also did not include a combined therapy group due to the lack of evidence that such treatment in non-pregnant women is superior compared to single-modality therapy [12]. Still, we recommend that further research investigate the effects of a combined therapy approach. Another limitation was the short follow-up period of 12 weeks. We decided to evaluate the treatment effect after this period because it represents the usual duration of postpartum standard care and PFMT in Germany and in other countries. Studies that investigated long-term follow-ups of pelvic floor muscle training for UI showed no beneficial effect [11]. Long-term treatment effects on postpartum UI should be investigated in future studies. Another factor in this particular cohort is that a certain number of women will get pregnant again, limiting the comparability of long-term observations in symptom persistence among members of the cohort. Finally, the sample size in this study was small since this was the first study comparing pessaries to standard care and physiotherapy. Even though we think that our cohort is representative of the general population concerned by this health issue, we think it is important to replicate the effect in a different sample.

Strengths

This is the first randomized controlled trial to compare vaginal pessaries to standard care or PFMT for the treatment of postpartum UI. The pragmatic approach addresses the issue of generalizability and allows practitioners to implement our results in their daily practice. Coverage of treatments by the mandatory health insurance reduces the risk of financial burden influencing the accessibility to the different treatments. Urinary leakage requires a symptom-based diagnosis, and patients' complaints or experiences should be the guidance for any treatment decisions. We therefore opted for a self-reported primary outcome to keep the evaluation of treatment success patient centered.

In summary, after 12 weeks of treatment, women who were treated with vaginal pessary for postpartum UI were significantly more often satisfied with the treatment's effect than those treated with the standard of care or PFMT. Loss-to-follow-up was low in all groups, and all three treatments options were found to be safe. The results of this study are reassuring for patients and practitioners in that, in addition to standard care and PFMT, vaginal pessaries could be a valid treatment option for women who present with postpartum UI. Given that this is the first study to compare

these treatments, further studies should be conducted to confirm this study's findings. Additionally, combined therapy approaches should be explored.

Conclusion

In this study, a treatment with vaginal pessaries resulted in a significantly higher satisfaction rate after 12 weeks of treatment in women with postpartum urinary incontinence compared to standard of care or pelvic floor muscle training. No adverse outcomes were observed and loss-to-follow-up was similar in all three groups.

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Clinical Trial

Registration number (trial ID): NCT06031870 | ClinicalTrials.gov (http://www.clinicaltrials.gov/) | Type of Study: multicenter, open-label, parallel group, randomized controlled clinical trial

Contributors' Statement

S. Lange: Project development, data analysis, manuscript writing.
E. Tabibi: Project development, data collection, data analysis, manuscript editing.
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Conflict of Interest

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