Comparing Single-Incision Midurethral Sling with Bulking Agents for Female Stress Urinary Incontinence

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Comparing Single-Incision Midurethral Sling with Bulking Agents for Female Stress Urinary Incontinence: Rationale for a Non-Randomized Controlled Trial

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Keywords
Stress urinary incontinence · Single-incision midurethral sling · Bulking agent · Patient preference · Patient satisfaction

Abstract
Objectives: Midurethral slings are considered the gold standard for the surgical treatment of stress urinary incontinence (SUI), with an efficacy up to 80%. Another therapeutic option is the use of bulking agents, which create an artificial mass in the urethral submucosa, with an efficacy varying from 64% to 74%. Although bulking agents have a lower risk of complications than midurethral sling surgery, they are mainly used in case a midurethral sling is not an option or if midurethral sling surgery failed to cure stress urinary incontinence. In this study, we offer all patients with SUI in secondary care a choice between a single-incision midurethral sling procedure and treatment with a bulking agent. We want to examine patient preference and patient satisfaction for both procedures. We expect that offering both interventions in combination with standardized counselling will result in high patient satisfaction. ***Design:*** In this non-randomized controlled trial, 266 patients will be objectively counselled for both interventions, after which all patients will choose between single-incision midurethral slings and polyacrylamide hydrogel (PAHG), followed by the standard care procedure for women with SUI. ***Participants/Materials, Setting, Methods:*** From January 1, 2021, onward, all consecutive adult patients (between 18 and 80 years of age) attending the outpatient gynaecology department with objectively confirmed, moderate to severe SUI will be eligible for enrolment in this non-randomized study. The primary outcome is patient satisfaction at 1 year, measured by the Patient Global Impression of Improvement; secondary outcomes are patient satisfaction at 3 months, objective and subjective cure at 3 months and 1 year, adverse events, postoperative pain, and cost-effectiveness. Differences in outcome measures will be assessed through logistic and linear

Trial Registration: This study is retrospectively registered at the Dutch Trial Registry on March 22, 2021, under the number NL9353.

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regression analyses, both unadjusted and adjusted with covariate adjustment using the propensity score. ***Results:*** No results are available yet. ***Limitations:*** The major disadvantage of this study design is the potential confounding bias. We intend to eliminate this bias by applying propensity scoring. ***Conclusion:*** By designing a non-randomized patient preference trial, we not only expect to demonstrate high patient satisfaction with both interventions but also provide insight into the possible role of PAHG-injections in the treatment of female SUI as a first-choice non-conservative treatment.

Introduction

Worldwide, an estimated 154 million women suffer from stress urinary incontinence (SUI), which is the involuntary loss of urine during moments of increased intra-abdominal pressure, for example, coughing, sneezing, and physical exertion [1]. SUI has a significant burden on quality of life of patients and has significant financial repercussions for society. Worldwide over $12 billion is annually spent on conservative and surgical therapy [2]. Conservative management includes pelvic floor muscle therapy and lifestyle modifications, predominantly regarding weight reduction [3]. If this is insufficient, urologists and gynaecologists can offer surgical treatment [4, 5].

Traditionally, the Burch colposuspension was the gold standard procedure, but nowadays, midurethral slings are considered the gold standard, with an efficacy as high as 90% [4–6]. There are three different techniques to place midurethral slings. The first technique is the retropubic approach, originally described as the tension-free vaginal tape (TVT) [4, 5]. This technique carries the risk of bladder perforation during surgery [7]. The second approach, the transobturator route, has an almost zero risk of bladder perforation but is associated with more groin pain as compared to the retropubic TVT [8]. The groin pain is most likely due to perforation of the external obturator and adductor muscles of the upper leg. The third approach is the single-incision midurethral sling (SIMS). The SIMS does not penetrate the obturator muscles and is, therefore, less painful compared to the transobturator route, with the benefit of reducing the risk of bladder perforation as compared to the retropubic TVT. The SIMS is as effective as TVT in curing SUI [9]. Another advantage is that SIMS can be placed under procedural sedation with local anaesthesia [10].

However, due to long-term complications of vaginal mesh surgery, such as erosions and pain, and an increasing number of legal claims, medical authorities have published warnings about the use of mesh, including midurethral slings, and new guidelines in the United Kingdom advise to consider midurethral slings only if alternative surgical procedures are not suitable [11, 12]. In the Netherlands, midurethral sling surgery is still the gold standard, but the search for other treatment options continues.

A completely different approach in the treatment of SUI consists of the use of bulking agents [13]. Bulking agents create an artificial mass in the urethral submucosa and, according to this hypothesis, improve urethral coaptation to restore continence [13–21]. In the Netherlands, polyacrylamide hydrogel (PAHG, Bulkamid®) is nowadays used for urethral injections. PAHG is biocompatible, non-biodegradable, non-allergenic, non-migrational, atoxic, stable, and sterile. A recent systematic review supports the use of PAHG in SUI patients and reports a more favourable safety profile compared to other bulking agents [22]. Urethral bulking therapy is minimally invasive in nature, and treatment does not require hospitalization [13, 17–20]. The procedure can be performed solely under local anaesthesia.

The efficacy of PAHG-injections in treating SUI varies from 64% to 74% depending on the patient characteristics [13, 17–20]. Urethral injections have a lower risk of complications than midurethral sling operation, and PAHG has shown a very low risk of serious adverse events [13, 16–21, 23]. Bulking therapy has no negative effect in case of subsequent midurethral sling operation.

The Cochrane review on urethral injection therapies concluded that injection therapies are inferior to surgery at 1-year follow-up but have a better safety profile [21]. Studies with a direct comparison of urethral injection treatment and SIMS in women with pure SUI have not been conducted. Recently, a Finnish study group showed that TVT was superior to PAHG-injections in curing SUI (objective cure 91% vs. 54%) [23]. However, patient satisfaction ("would you choose this procedure again?") was comparable in both groups (97% and 89%, respectively). Moreover, there were no complications in the PAHG group versus 6 reoperations in the TVT group. Based on these outcomes, authors suggested that bulking agents could be offered as a good alternative to surgical intervention. Currently, in the Netherlands, bulking agents are mainly used in women with SUI in whom earlier sling placement has failed to cure SUI or is considered unwanted or not possible (e.g., in women with dysfunctional voiding or suffering from cognitive disorders). A recent

review highlighted the possible role of bulking agents in (short-term) treatment, in addition to emphasising the need for evaluation of the quality of life for patients with surgical treatment for SUI [6].

We hypothesise that bulking agents can be successfully offered to all women with SUI after shared decision-making, thus not limiting their use, for example, to older and fragile patients. We expect that providing patients with clear and concise information about both treatment modalities will result in high patient satisfaction for both interventions.

Materials and Methods

We will conduct a non-randomized prospective patient preference study, comparing midurethral sling surgery with the use of bulking agents in women with SUI. As no comparison has been made between SIMS and bulking agents in the treatment of SUI, this prospective study compares SIMS (Altis®) and PAHG (Bulkamid®) injections. This study measures the patient satisfaction of incontinence interventions based on their personal preferences.

Setting

All participants will be patients of the outpatient gynaecological clinics of Isala hospital, Zwolle, and St. Antonius hospital, Nieuwegein, The Netherlands.

Population

From January 1, 2021, onwards, all consecutive patients between 18 and 80 years old who meet the following inclusion criteria will be screened for eligibility in this study:

- Pure or predominant SUI (e.g., on a weekly basis, more incontinence episodes related to physical exercise, coughing, or sneezing as compared to incontinence associated with a feeling of urgency).
- SUI is confirmed with a stress test during physical examination.
- Moderate to severe incontinence as identified by use of the Sandvik score.
- Women should be able to understand the Dutch language both verbally as well as in writing.

All potential patients who meet the following criteria will be excluded:

- A post-voiding bladder volume of more than 100 mL as determined by ultrasound (Bladderscan®).
- History of anti-incontinence surgery.
- Genital prolapse stage 2 (Ba >0) or more according to the POP-Q classification [24].
- Patients' desire for future pregnancy and childbirth.
- Comorbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classifications, up to the anaesthetist and physician to decide if eligible for SIMS surgery.
- Recurrent lower urinary tract infection (≥3 times/year).
- Patients with a limitation to comprehend the informed consent, such as a history of current major psychiatric illness, a history of chronic or current neurological disease, or poor cognitive function, as subjectively assessed by the physician.
- Patients with poor understanding of the written Dutch language.
- Neurogenic bladder due to chronic or current neurological disease.

Intervention

All eligible patients with SUI will receive standardized counselling for both the Altis® SIMS and Bulkamid® PAHG-injections, after which they will decide which intervention they prefer. Patients will receive their preferred treatment but can receive additional treatment if this fails. After failure of the Altis® SIMS, additional Bulkamid® PAHG-injections can be given and vice-versa. Salvage treatment with Bulkamid® PAHG-injections has an efficacy of 75% [25]. Retrospective data on sling surgery after bulking agents showed a subjective cure rate of 60.5% [26].

Single-Incision Midurethral Sling

The Altis® SIMS placement (shown in Fig. 1) will be performed under conscious sedation with local anaesthesia. This beholds sedation with propofol, combined with alfentanil or remifentanil, and the local application of levobupivacain 15 mL 0.25%, mixed with a short-acting aminoamide anaesthetic to ensure rapid anaesthetic effects within minutes (mepivacain) on both sides of the urethra. During surgery, women will be in the lithotomy position. After inserting the tape, a pair of Mayo scissors is placed between the tape and the urethra, to ensure a tension-free status. After adjustment of the tape, the scissors are removed. Then the tape is secured, and the incision is closed. Before the operation, prophylactic antibiotics (metronidazol 500 mg and cefazoline 2 g IV) will be given. The patient will be discharged after 2–4 h follow-up with post-void residual volume less than 150 mL. Limitation of heavy physical work for 5 days is recommended.

PAHG-Injections

In an outpatient setting under local anaesthesia (3.4 mL ultracaine and instillagel, two injections on both sides of the urethra), a urethroscopy will be performed (shown in Fig. 2). Under direct vision, four transurethral injections (0.2–1 mL) will be placed at 2, 5, 7, and 10 o'clock at the midurethral level. After the intervention, the patient urinates to empty the bladder. Limitation of heavy physical work for of 1 day is recommended. After 6 weeks, a telephonic follow-up is scheduled, and if the patient is unsatisfied with the result, additional injections can be injected.

Standard Care

The standard care procedure for women with SUI consists of 3 visits to the outpatient clinic: at baseline, 3-month follow-up, and 1-year follow-up, according to the Dutch guideline of the Use of Implants in Genital Prolapse and Urinary Incontinence Surgery [27]. The collected data are shown in Table 1. Post-operative pain is measured with a VAS scale and the use of painkillers up to 3 days after intervention.

After 5 years, an additional follow-up consultation is scheduled, outside the scope of standard care. This follow-up consultation is voluntary, and patients will receive a travel allowance.

Outcome Measures

The primary outcome is patient satisfaction at 1-year follow-up after SIMS procedures or PAHG injections. This is recorded by the Patient Global Impression of Improvement (PGI-I) (see Table 2):

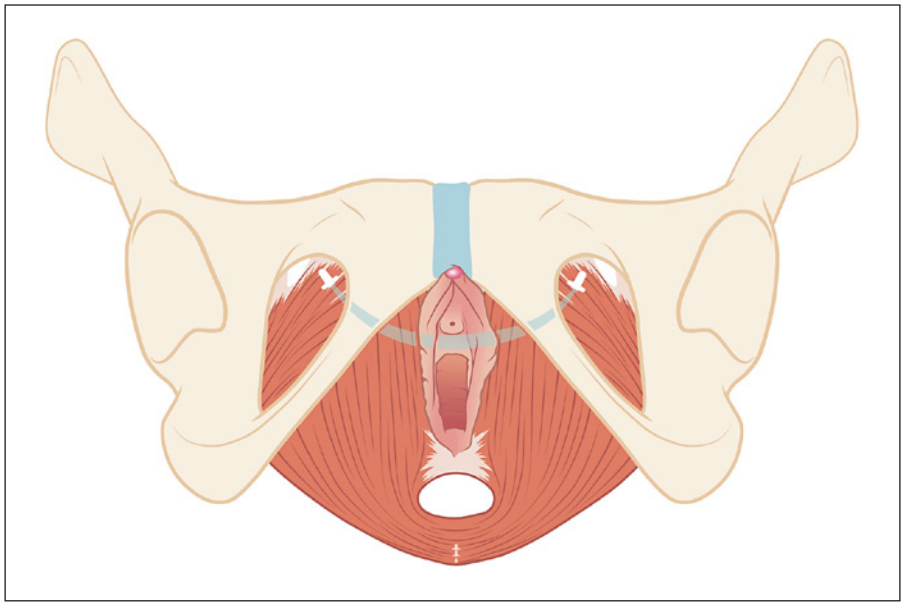

Fig. 1. Schematic image of Altis® SIMS insertion.

Table 1. Data collection

Data	Baseline (digital/in person)	6-week follow-up (phone)	3-month follow-up (digital/in person)	6-month follow-up (mail)	1-year follow-up (digital/in person)
Medical history	X				
Stress test	X		X		X
48 h bladder diary	X				
Uroflow measurement and residual volume	X				
Sandvik ISI	X		X		X
PFDI-20	X		X		X
EQ-5D-5L	X		X		X
iPCQ				X	
iMCQ				X	
IIQ-7	X		X		X
PGI-S	X				
PGI-I			X		X
Surgical complications		X	X		X
Satisfaction questionnaire		X	X		X
Post-operative pain during the first 3 days			X		
Experiencing pain			X		X
Length of sick-leave			X		
Need for additional treatment		X	X		X

ISI, Incontinence Severity Index; PFDI-20, Pelvic Floor Distress Inventory; EQ-5D-5L, EuroQol 5D-5L; iPCQ, iMTA Productivity Cost Questionnaire; iMCQ, iMTA Medical Consumption Questionnaire; IIQ-7, Incontinence Impact Questionnaire; PGI-S, Patient Global Impression of Severity; PGI-I, Patient Global Impression of Improvement.

a seven-point Likert scale with the following responses: "very much worse," "much worse," "a little worse," "no change," "a little better," "much better," and "very much better." Patient satisfaction is set as the percentage of patients that responded with "much better" or "very much better" [28].

The secondary outcomes are as follows:

1. Patient satisfaction at 3 months

Patient satisfaction will also be assessed at 3 months, using the PGI-I.

2. Subjective cure of SUI at 3 months and 1 year

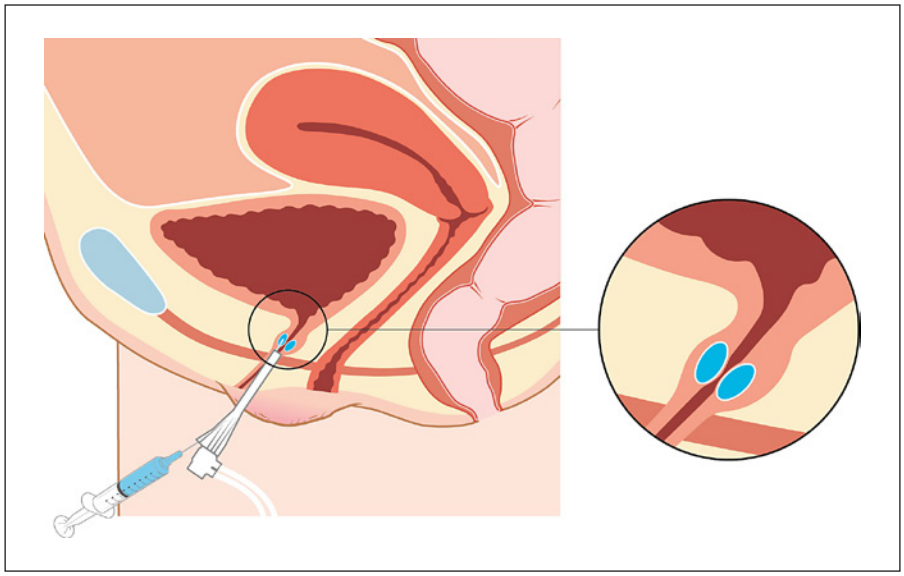

Fig. 2. Schematic image of Bulkamid® PAHG injections.

Subjective cure is assessed with one question of the Pelvic Floor Distress Inventory (see online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000529407) [29]. In the PFDI-20, the question regarding SUI ("do you ever experience urine loss while coughing, sneezing, or performing physical exercise?") should be answered with "no."

3. Objective cure of SUI at 3 months and 1 year

Objective cure is assessed with a standardized stress test. After checking that the bladder volume is at least 300 mL, a stress test will be performed as part of routine post-operative care.

4. Adverse events during and after the procedure at 3 months and 1 year

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the trial procedure. Adverse events are collected in standardised form in an outpatient setting, with the possibility to report additional options by the participant.

A serious adverse event is any untoward medical occurrence or effect that results in death, is life threatening (at the time of the event), requires hospitalisation or prolongation of existing inpatients' hospitalisation, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator. An elective hospital admission will not be considered a serious adverse event.

5. Post-operative pain diary

The post-operative pain will be assessed with a 100-mm Visual Analogue Scale (VAS pain) with the extremes "no pain at all" and "the most extreme pain imaginable" (see Supplementary material). All women will be operated under local anaesthesia, and the SIMS group will receive additional conscious sedation. All women are intended to leave the hospital the same day, unless otherwise indicated. During the first 3 days after surgery, participants are asked to record the mean daily pain on a VAS scale, before going to sleep, and to record the type and number of painkillers used in the last 24 h.

Table 2. Patient Global Impression of Improvement (PGI-I)

Check the number that best describes how your post-operative condition is now, compared with how it was before you had the surgery
1. Very much better
2. Much better
3. A little better
4. No change
5. A little worse
6. Much worse
7. Very much worse

6. Cost-effectiveness of the intervention

In the economic evaluation, the primary aim will be to estimate the societal costs of both interventions. The secondary aim will be to estimate the cost of utility.

All direct medical cost items related to both procedures will be registered on a patient level using the cost questionnaires iMTA Productivity Cost Questionnaire (iPCQ) and iMTA Medical Consumption Questionnaire (iMCQ) at 6-month follow-up (available on https://www.imta.nl/questionnaires/). Cost items will be valued according to the Dutch standard guidelines for economic evaluations. Direct medical costs comprise visits to the gynaecologist, GP, physical therapist, and other health care providers; operation time; costs of necessary surgical equipment and personnel; medication; and incontinence pads. Direct non-medical costs include travelling expenses and productivity losses and will be measured using a short patient questionnaire. These cost components will be valued according to the Dutch standard guidelines for economic evaluations.

The cost utility analysis will be performed based on EuroQol 5D-5L (EQ-5D-5L) defined utilities (see online suppl. material) [30]. In both groups, utility will be measured at baseline, at 3 months, and at 1 year. In order to value the EQ-5D-5L profiles, the Dolan algorithm

will be used [31]. The use of the EQ-5D-5L as a generic measure in economic evaluations facilitates the comparability of (cost-effectiveness) results across different studies and interventions [32]. Results of the cost-utility analysis will display the additional costs or savings of both procedures, in order to gain one quality adjusted life year. The time horizon of this study will be 12 months. Therefore, the analysis will not include discounting of costs and effects. Bootstrap re-sampling will be performed on the cost and on the cost and effect (utility) pairs in order to calculate confidence intervals [33].

Participant Timeline

Enrolment of patients started on January 1, 2021, and continues until enough patients are included. All patients will be approached in an outpatient setting. They will receive standard counselling for both intervention options from their gynaecologist. After at least 1 week, they will have an interview by phone with their gynaecologist to confirm their choice of intervention. Afterwards, they will sign an informed consent for monitoring of their data. From the day of the intervention, all participants will keep a pain diary for 3 days. The participants in the PAHG group will receive another interview by phone 6 weeks after their intervention to review the outcomes. If needed, a second intervention with PAHG can be scheduled before the first follow-up visit. At 3 months after their initial intervention, all participants will visit the outpatient clinic for their first follow-up visit. If needed, a second intervention with either PAHG or SIMS can be scheduled as soon as possible. At 1 year after their initial intervention, all participants will visit the outpatient clinic for their second follow-up. This is the last follow-up included in the standard care of SUI. At 5 years after their initial intervention, all patients will be asked to visit the outpatient clinic one last time for the long-term follow-up of their interventions.

Participants can leave the study at any time for any reason without any consequences if they wish to do so. Their records will be used anonymously for intention-to-treat analysis.

Assignment of Intervention

All participants are able to choose the intervention of their preference.

Blinding

Blinding is not feasible.

Data Collection

Most patient-reported outcomes are collected through electronic questionnaires that are linked to the electronic medical records of patients. Data are available to the treating physician, and to the researcher, through an automated data extraction of these questionnaires. The pain diary will be kept on paper and will be entered in a CRF by the researcher, who is not involved in the further treatment. Finally, the treating physician will collect data on side effects using a standardised form that is part of routine care, which is obligatory according to the Dutch guideline [27].

Sample Size

The sample size calculation is based on a RCT with a non-inferiority design, with adjustment for dropout. Assuming a success rate of 89.2% in PGI-I [10], and a 10% non-inferiority margin, with a statistical power of 80% at an alpha of 5%, we would need 120 patients in each group. As women will receive their preferred treatment, we expect different group sizes. Inclusion will continue until the smallest group is 120. A 10% dropout rate was assumed, thus needing a minimum of 133 patients per group. The total patient population will consist of a minimum of 266 patients.

Statistical Methods

Categorical baseline characteristics will be presented as numbers and percentage, continuous baseline characteristics will be presented depending on normality, as mean with standard deviation or as median with interquartile range. Normality will be conformed with a histogram. In the univariate analyses, the trial groups will be compared with regard to the baseline patient characteristics including the primary outcome and secondary outcome measures, following an intention-to-treat approach.

The effect of the two types of treatment modalities on the primary and secondary outcomes will be evaluated in, respectively, a logistic or a linear regression analysis. Unadjusted analyses will be followed by covariate adjustment using the propensity score [34]. Propensity scores will be estimated in case the following potential confounding variables (baseline severity of incontinence, BMI, age, menopausal status, or physician) are indeed proven to be confounders [35].

Discussion

In this non-randomized prospective patient preference study, we intend to compare SIMS surgery with PAHG injections based on patient preferences. This study is designed to determine the role of PAHG in the care of SUI and to highlight the importance of policy based on patient preferences.

This design was chosen for several reasons. Patient preference studies measure the preferences of patients in a standardised and quantitative manner and are designed to provide insights into the preferences and acceptability of different treatment options [36–38]. The results of a patient preference trial alone cannot display the relative efficacy of a treatment for any patient. Therefore, these results have to be supported by additional evidence. It does, however, give insights into being a viable option for patients and provide evidence of efficacy compared to baseline measurements [39]. These insights are used to ensure decisions from guidelines align with the preferences and needs of patients. A representative patient preference study can provide more insights to health technology assessment bodies than patient testimonies alone [36]. However, patient preference studies are not much used in health technology assessment, as focus is laid mainly on cost-utility analysis [40]. This study combines those two approaches to create a complete view of both patient and social values in order to implement a patient-centred approach in the care of SUI.

Patient-centred care is increasingly important in medical policy making [41]. While this study is designed to determine the role of PAHG in the care of SUI, it is also

meant to highlight the importance of policy based on patient preferences. Today, there are only a few patient-centred care studies in urogynaecological care [39, 42, 43]. Patient-centred care is defined as care that respects and is responsive to individual patient preferences, needs, and values, while ensuring that patient values guide all clinical decisions [44]. This study implements this definition in the care for women with SUI, a care that is slowly moving from stigma to the spotlight. Taylor et al. brought forward the lack of leadership to broadly implement patient-centred care in incontinence care [45].

Even though this study focuses on surgical methods, it is important to note that there are also promising non-surgical methods in use for the treatment of SUI. A recent Cochrane review analysed 84 meta-analyses on the conservative management for SUI, from 14 different reviews [46]. Vaginal cones and pelvic floor muscle therapy with and without biofeedback have significant beneficial effects, substantiated with high-certainty evidence. In the context of patient-centred care, these non-surgical therapies should be offered to the patient before proceeding towards more invasive treatments. Drug therapy with duloxetine is also a possible therapy, but it is less effective than pelvic floor muscle therapy and less cost-effective tha surgical therapies [47].

This study design ensures an improvement in proactive care management as patients get to choose their own interventions. This means that a shared decision-making process is included in the design of this study, which improves patient empowerment [48].

This patient-centred approach is compatible with the principle of "personal care": a physician's first obligation is solely to the patients' well-being [49]. In many clinical research designs, there is a risk to fail adherence to this principle, as the participant's interest becomes secondary to the physician-researcher's interests. This is one of the reasons not to choose for a randomised controlled trial, as randomization is a key example of this shifting of interests. The argument that randomization is acceptable with treatments with the same efficacy or with unknown superiority does not apply in our study, as PAHG-injections are proven to be less effective than SIMS in curing SUI [10, 23]. In a randomised controlled trial, a shared-decision making process would also be impossible, thus diminishing patient empowerment [48].

In addition to being unethical, it is also a possibility that patient preferences are so strong that they refuse randomisation. In that case, only patients without a strong preference are included, which could imply less motivated participants, possibly causing a bias and resulting in an unrepresentative patient cohort [37–39]. Therefore, no randomization was applied in this study design. The major disadvantage of this non-randomized, non-inferiority study design is the potential confounding bias [50]. In non-randomized designs, baseline imbalance is to be expected [38, 39]. We intend to eliminate this bias with propensity scoring [34]. We will identify potential confounding variables based on literature. During the analyses, we will check whether these potential confounding variables are indeed confounders. Afterwards, we will perform a covariate adjustment analyses using propensity scoring for those confounding variables. With this design, we expect not only to provide insights on the patient satisfaction and preferences of both treatments but also on the possible role of PAHG-injections in the treatment of female SUI.

Statement of Ethics

This study was approved by the Medical Ethical Committee (METC) of the Isala Hospital, Zwolle, The Netherlands, under the number 201114. All patients will receive objective counselling for both interventions from their gynaecologist and have to sign an informed consent form before entering the study.

Conflict of Interest Statement

Engberts and Van Eijndhoven are consultants for Coloplast (tutor training surgical skills of gynaecologists). The other authors have no conflicts of interest to declare.

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Author Contributions

N.J.E. Osse, M.K. Engberts, M.H. Blanker, and H.W.F. Van Eijndhoven developed the trial, in discussion with M.E.A. Schonewille and W.M. Klerkx. N.J.E. Osse led the writing of the paper, assisted by M.E.A. Schonewille. Drafts were commented on by M.K. Engberts, M.H. Blanker, W.M. Klerkx, and H.W.F. Van Eijndhoven. All authors have read and approved the manuscript.

Data Availability Statement

No data are associated with this article. All future data from this study will be made available on request. Further enquiries can be directed to the corresponding author.

References

1 Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. BJU Int. 2011;108(7):1132–8.
2 Sun Z, Wang X, Lang J, Xu T, Zhang Y, Kang J, et al. Comparison of outcomes between single-incision sling and transobturator sling for treating stress urinary incontinence: a 10-year prospective study. Neurourol Urodyn. 2019;38(7):1852–8.
3 Bo K, Frawley HC, Haylen BT, Abramov Y, Almeida FG, Berghmans B, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Int Urogynecol J. 2017;28(2):191–213.
4 Saraswat L, Rehman H, Omar MI, Cody JD, Aluko P, Glazener CM. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst Rev. 2020;1:CD001754.
5 Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013;24(8):1265–9.
6 Monti M, Fischetti M, Di Pinto A, Santangelo G, Giannini A, D'Oria O, et al. Update on surgical treatment of female stress urinary incontinence. Minerva Ginecologica. 2021;73(2):140–4.
7 Nambiar A, Cody JD, Jeffery ST, Aluko P. Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev. 2017;7:CD008709.
8 Laurikainen E, Valpas A, Aukee P, Kivela A, Rinne K, Takala T, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol. 2014;65(6):1109–14.
9 Schweitzer KJ, Milani AL, van Eijndhoven HWF, Gietelink DA, Hallensleben E, Cromheecke GJ, et al. Postoperative pain after adjustable single-incision or transobturator sling for incontinence: a randomized controlled trial. Obstet Gynecol. 2015;125(1):27–34.
10 Engberts MK, Schweitzer KJ, van Eijndhoven HWF, Cromheecke GJ, Naber HR, Huub van der Vaart C. A prospective observational cohort study of the Ajust® single incision sling performed under conscious sedation with local infiltration. Neurourol Urodyn. 2019;38(6):1632–9.
11 Urogynecologic FDA. Surgical mesh: update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse; 2011.
12 Chapple CR, Cruz F, Deffieux X, Milani AL, Arlandis S, Artibani W, et al. Consensus statement of the European urology association and the European urogynaecological association on the use of implanted materials for treating pelvic organ prolapse and stress urinary incontinence. Eur Urol. 2017;72(3):424–31.
13 Leone Roberti Maggiore U, Alessandri F, Medica M, Gabelli M, Venturini PL, Ferrero S. Outpatient periurethral injections of polyacrylamide hydrogel for the treatment of female stress urinary incontinence: effectiveness and safety. Arch Gynecol Obstet. 2013;288(1):131–7.
14 Kerr LA. Bulking agents in the treatment of stress urinary incontinence: history, outcomes, patient populations, and reimbursement profile. Rev Urol. 2005;7(Suppl 1):S3–11.
15 Kuhn A, Stadlmayr W, Lengsfeld D, Mueller MD. Where should bulking agents for female urodynamic stress incontinence be injected? Int Urogynecol J Pelvic Floor Dysfunct. 2008;19(6):817–21.
16 Klarskov N, Lose G. Urethral injection therapy: what is the mechanism of action? Neurourol Urodyn. 2008;27(8):789–92.
17 Lose G, Sorensen HC, Axelsen SM, Falconer C, Lobodasch K, Safwat T. An open multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and mixed urinary incontinence. Int Urogynecol J. 2010;21(12):1471–7.
18 Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012;23(10):1373–8.
19 Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014;192(3):843–9.
20 Mouritsen L, Lose G, Moller-Bek K. Long-term follow-up after urethral injection with polyacrylamide hydrogel for female stress incontinence. Acta Obstet Gynecol Scand. 2014;93(2):209–12.
21 Kirchin V, Page T, Keegan PE, Atiemo KO, Cody JD, McClinton S, et al. Urethral injection therapy for urinary incontinence in women. Cochrane Database Syst Rev. 2017;7:CD003881.
22 Hoe V, Haller B, Yao HH, O'Connell HE. Urethral bulking agents for the treatment of stress urinary incontinence in women: a systematic review. Neurourol Urodyn. 2021;40(6):1349–88.
23 Itkonen Freitas AM, Mentula M, Rahkola-Soisalo P, Tulokas S, Mikkola TS. Tension-free vaginal tape surgery versus polyacrylamide hydrogel injection for primary stress urinary incontinence: a randomized clinical trial. J Urol. 2020;203(2):372–8.
24 Bump RC, Mattiasson A, Bø K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996;175(1):10–7.
25 Daly CME, Mathew J, Aloyscious J, Hagen S, Tyagi V, Guerrero KL. Urethral bulking agents: a retrospective review of primary versus salvage procedure outcomes. World J Urol. 2021;39(6):2107–12.
26 Koski ME, Enemchukwu EA, Padmanabhan P, Kaufman MR, Scarpero HM, Dmochowski RR. Safety and efficacy of sling for persistent stress urinary incontinence after bulking injection. Urology. 2011;77(5):1076–80.
27 NVOG. Gebruik van implantaten bij genitale prolaps- en urine-incontinentiechirurgie. 2020.
28 Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol. 2003;189(1):98–101.
29 Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with Pelvic Floor Disorders (PFDI-20 and PFIQ-7). Am J Obstet Gynecol. 2005;193(1):103–13.
30 M Versteegh M, M Vermeulen K, M A A Evers S, de Wit GA, Prenger R, A Stolk E. Dutch tariff for the five-level version of EQ-5D. Value Health. 2016;19(4):343–52.
31 Dolan P. Modeling valuations for EuroQol health states. Med Care. 1997;35(11):1095–108.
32 Greiner W, Weijnen T, Nieuwenhuizen M, Oppe S, Badia X, Busschbach J, et al. A single European currency for EQ-5D health states. Results from a six-country study. Eur J Health Econ. 2003;4(3):222–31.
33 Wolowacz SE, Briggs A, Belozeroff V, Clarke P, Doward L, Goeree R, et al. Estimating health-state utility for economic models in clinical studies: an ISPOR good research practices task force report. Value Health. 2016;19(6):704–19.
34 Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivariate Behav Res. 2011;46(3):399–424.
35 Benedetto U, Head SJ, Angelini GD, Blackstone EH. Statistical primer: propensity score matching and its alternatives. Eur J Cardiothorac Surg. 2018;53(6):1112–7.
36 Bouvy JC, Cowie L, Lovett R, Morrison D, Livingstone H, Crabb N. Use of patient preference studies in HTA decision making: a nice perspective. Patient. 2020;13(2):145–9.
37 Torgerson DJ, Sibbald B. Understanding controlled trials: what is a patient preference trial? BMJ. 1998;316(7128):360.
38 Kowalski CJ, Mrdjenovich AJ. Patient preference clinical trials: why and when they will sometimes be preferred. Perspect Biol Med. 2013;56(1):18–35.
39 Brewin CR, Bradley C. Patient preferences and randomised clinical trials. BMJ. 1989;299(6694):313–5.

40 Mott DJ. Incorporating quantitative patient preference data into healthcare decision making processes: is HTA falling behind? Patient. 2018;11(3):249–52.
41 Constand MK, MacDermid JC, Dal Bello-Haas V, Law M. Scoping review of patient-centered care approaches in healthcare. BMC Health Serv Res. 2014;14:271.
42 Ganz PA. Delivering on the promise of patient-centered care. J Natl Compr Canc Netw. 2015;13(4):495–7.
43 Tseng EK, Hicks LK. Value based care and patient-centered care: divergent or complementary? Curr Hematol Malig Rep. 2016;11(4):303–10.
44 Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century.. Washington (DC): The National Academies Press; 2001.
45 Taylor DW, Cahill JJ. From stigma to the spotlight: a need for patient-centred incontinence care. Healthc Manage Forum. 2018;31(6):261–4.
46 Todhunter-Brown A, Hazelton C, Campbell P, Elders A, Hagen S, McClurg D. Conservative interventions for treating urinary incontinence in women: an overview of Cochrane systematic reviews. Cochrane Database Syst Rev. 2022;9(9):CD012337.
47 Capobianco G, Madonia M, Morelli S, Dessole F, De Vita D, Cherchi PL, et al. Management of female stress urinary incontinence: a care pathway and update. Maturitas. 2018;109:32–8.
48 Bravo P, Edwards A, Barr PJ, Scholl I, Elwyn G, McAllister M, et al. Conceptualising patient empowerment: a mixed methods study. BMC Health Serv Res. 2015;15:252.
49 Appelbaum PS, Roth LH, Lidz CW, Benson P, Winslade W. False hopes and best data: consent to research and the therapeutic misconception. Hastings Cent Rep. 1987;17(2):20–4.
50 Middleton LJ. Falling in the margin: randomised controlled trials with a non-inferiority design. BJOG. 2021;128(12):1916.