

THE PATIENTS' PERSPECTIVE ON URETHRAL BULKING AGENTS AND MID-URETHRAL SLING SURGERY AS A PRIMARY TREATMENT OPTION FOR STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

Women with pelvic floor disorders (PFD) want to be informed on their treatment options and most women with the specific PFD urinary incontinence want to take part in treatment decision making (1). However, treatment options for stress urinary incontinence offered to women vary between institutes and treatment choices are mainly based on the experience and preference of the physician as well as on international guidelines, whereas the patients' perspective remains underexplored. Mid-urethral sling (MUS) surgery is often considered the first choice surgical option for SUI given its high cure rates and minimal invasive character. An alternative treatment for SUI is urethral injection therapy with a bulking agent (UBA), a treatment that is performed under local analgesia in an outpatient setting. Currently, most centers offer UBA only as a last resort intervention for women with complex or recurrent SUI, for women with a contra-indication for surgery or for women with intrinsic sphincter deficiency. Petrou et al. showed that women with SUI accept lower efficacy rates to undergo a less invasive treatment with UBA as compared to surgery (2). This suggests that the cure rate is not decisive in selecting the right treatment for the right patient. The objective of this study was to identify treatment decision-making factors between UBA and MUS-surgery in women indicated for primary treatment of SUI. A second objective was to explore if, and to what extent, women accept incontinence after treatment. Thirdly, we evaluated whether patients accept UBA as a primary treatment for SUI.

Study design, materials and methods

This qualitative study focused on patients' perspective on factors to take into account when choosing between UBA and MUS-surgery. Patients were recruited in a tertiary urogynecological center in the Netherlands. To be eligible, women had to be Dutch-speaking and had to seek a first treatment for SUI. Patients with predominant urgency incontinence or a history of MUS-surgery or UBA treatment were not eligible. The treatment decision-factors were determined by face-to-face interviews until data saturation was reached. The interview was guided by three open-ended questions with a framework of topics to discuss. The contents of the topic list was revised by an expert panel and the interview was first pilot tested on two patients. The interviews took place at the patient's home, as preferred by patients and took approximately 30-60 minutes. All interviews were audiotaped. The interview started by exploring if, and to what extent, women accept incontinence after treatment. Then, the interviewer informed participants on the procedures of MUS-surgery and UBA and their complications, withholding any information on efficacy. Using the topic list, the decision-making factors were explored when choosing between UBA and MUS-surgery. The topic list was modified when new factors emerged. Afterwards, the participants were informed about the efficacy of the treatment: 70% and 90% for UBA and MUS-surgery respectively. The efficacy was defined as subjective cure: no symptoms of urine leakage during laughing, sneezing, coughing and physical exercise. The interview evaluated how the difference in efficacy influenced the women's treatment preference. At the end of the interview, the woman's opinion on UBA as a primary treatment option was explored. All interviews were transcribed verbatim by the interviewer. Thematic analysis was done independently by two researchers as follows: 1. Reading the interviews line-by-line and mark the decision factors (open coding). 2. The relationship between the codes were identified by categories and subcategories by means of constant comparison (axial coding). 3. Finally, with an iterative process the categories were combined to develop domains (selective coding). Computer program MaxQda12 was used.

Results

After interviewing 20 women from November 2015 until July 2016 data saturation was reached. The mean age was 53 years (range 23-88), the majority was Caucasian, scored mild on the PGI-S, had pelvic floor muscle training, used anti-incontinence material and was sexual active. Data-analysis resulted in 20 treatment decision-factors that could be divided into 5 domains: personal -, procedural -, professional -, social- and external factors. Some women considered their symptoms not serious enough to undergo surgery and opted for UBA treatment. Others indicated that if the symptoms would decrease after UBA treatment, the situation would be good enough to accept. However, lack of confidence tended to arise out of unfamiliarity with the UBA treatment and was therefore a decision-factor to opt for MUS-surgery. The minimal invasive character of the procedure, a procedural factor, was a returning decision-factor to opt for UBA. The general or regional anesthesia and the incision of MUS-surgery was a major reason to opt for UBA. UBA treatment was seen as an intermediate step between conservative management and MUS-surgery and some patients wanted to preserve the most invasive procedure (MUS-surgery) for the last option. Also the risk of the procedure was very important to women. Women were especially worried about the safety of the material of UBA. The fear of fibrosis, infection or persistent pain after sling implantation was on the other hand a decision-factor to opt for UBA. Especially the inability to remove the sling completely caused fear. The majority of patients preferred UBA before information on efficacy, but afterwards a slight majority preferred MUS-surgery, a few remained indecisive. Six patients still preferred UBA and accepted a lower cure rate. Regarding the expectations about the treatment of women with SUI, it was noticed that women believed that 'becoming dry' would be wishful thinking. They accepted the consequences of giving birth and increasing age and did not expect that treatment could completely cure their incontinence symptoms. There was acceptance of persistent incontinence symptoms after treatment, as long as incontinence involved not more than drops requiring a maximum of one pad per day. The lower efficacy of UBA treatment did hold back women to believe that UBA should be offered as a primary treatment option. Women indicated that physicians should inform women about UBA treatment as a primary treatment option, so they can carefully weigh the benefits and disadvantages of both treatments and take an well-informed decision.

Interpretation of results

The broad variety of treatment-decision factors that are identified in this study, implicate that physicians should distance themselves from making assumptions about what patients want and carefully listen to identify the patients' preference and expectations. MUS-surgery is generally known as a minimally invasive procedure. However, in our study some patients preferred UBA because they considered the anesthesia and incision of MUS-surgery too invasive. Patients rated the outpatient setting, less postoperative pain and quicker recovery of UBA beneficial, but these factors were considered less important. Remarkable was that some patients did not change their preference for UBA after informing them about the difference in efficacy. This can be explained by the fact that women can be satisfied with a remaining form of incontinence after treatment. 'Becoming dry' is mostly not a goal for women with SUI. This corresponds to other literature, showing that treatment goals for incontinence are very personal and highly subjective (3). Potential limitations of this study are that the majority of the women scored 'mild' on the PGI-S and were receiving pelvic floor muscle training. These women could have been more positive towards UBA. Secondly, the success rates and re-intervention rates mentioned by the interviewer could be different from daily practice counseling. Thirdly, despite purposive sampling was used not all ethnicities were represented and cultural factors may have been underexposed. Finally, an interview is a snapshot of a women perspective and their perspectives may change over time.

Concluding message

This study shows that from a patients perspective urethral bulking agents should be offered to women with primary SUI, as some patients feel the advantages of a minimally invasive treatment outweigh the disadvantages of a lower cure rate. A broad variety of decision-factors determines a woman's preference for UBA or MUS-surgery. This should be kept in mind when tailoring treatment for SUI.

References

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