

Pain after midurethral sling; the underestimated role of mesh removal

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Introduction The primary aim of this study was to evaluate the results of midurethral sling (MUS) removal in women who have pain as their single complication of MUS.

Material and methods We performed a retrospective chart study supplemented with a cross sectional questionnaire. Women who underwent MUS removal for pain as the solitary reason for removal between 2004 and 2018 were included. Primary outcome was change in pain levels assessed by the visual analogue scale (VAS) pain score (range 0–10). Secondary outcome was the recurrence of stress urinary incontinence (SUI).

Results Twenty-six of 31 patients returned the questionnaire. Median medical file follow-up was 12 months (range 2–66) and 25 months (range 5–104) regarding questionnaires. VAS pain score dropped from 7.8 (SD 1.9) at baseline to 4.5 (SD 3.2) at follow-up ($p < .00$). Seven (23%) patients were pain-free. Patients undergoing partial vaginal resection ($n = 6$) had a VAS pain score decrease of 4.7 ($p = .02$) versus 2.7 ($p = .02$) for complete vaginal removal ($n = 14$). Twenty-three (89%) patients experienced SUI at follow-up, whereof 10 (45%) reported (almost) no incidents of SUI.

Conclusions MUS removal is a viable and safe option with a significant drop in VAS pain score in patients with chronic pain after MUS placement. A post-operative increase of SUI and a possible renewed wish for SUI treatment have to be considered. This should not be a reason to refrain from information and/or referral for surgical removal.

Key Words: stress urinary incontinence ↔ post-operative complications ↔ pain
↔ midurethral sling ↔ tape removal

INTRODUCTION

Female stress urinary incontinence (SUI) is a prevalent condition. In women aged 45–70 years the prevalence is around 29% [1]. The most frequently used surgical therapy is the insertion of a retropubic or transobturator midurethral sling (MUS) [2]. Reported five year complication rates after MUS placement are 2.7–9.8% [3, 4, 5]. Several studies reported rates of sling removal of approximately 3% and reoperation rate between 2.7% and 7.8% [4–8].

Pain without underlying causes, such as exposure or erosion, are responsible for 1–17% of sling removals [2, 4, 9, 10]. However due to a lack of proper complication registries, true incidence may be underestimated [11]. In a study identifying predictors of litigation among women with complications, pain after transvaginal mesh implantation was the main reason for litigation [12]. This reflects the large impact of pain on quality of life in patients after mesh placement with or without concomitant complications such as erosion or exposure.

Pain without an identifiable cause, like erosion or exposure, after MUS surgery can be challenging to manage. Treatment can be conservative or surgical. Conservative treatments include chronic analgesics use, local injection of analgesics and pelvic floor muscle training. Currently, surgical removal of MUS is mainly performed if conservative treatment fails. There are scarce data on the effectiveness of MUS removal in reducing pain. This study aimed to evaluate the results of sling removal in women with MUS related pain without any objectifiable reason for pain.

MATERIAL AND METHODS

This is an institutional review board approved retrospective single centre cohort study (File number 2018-4760, CMO region Arnhem-Nijmegen). We combined a retrospective chart review with a cross sectional questionnaire. All patients underwent MUS removal between November 2004 and June 2018. MUS resection was performed using different techniques: transection, partial or complete removal, by approach via the vagina or groin and in one or multiple sessions, depending on the local situation. The most important parameter for choice of technique was the location of the pain.

Primary outcome was the change of MUS related pain before and after MUS removal measured by the visual analogue scale (VAS) pain score (range 0–10). Secondary outcomes were recurrence of SUI, and the effect of partial versus complete removal on pain (VAS), the number of redo surgeries and determination of predictive factors for pain reduction. The definition of partial removal or complete removal was left to the discretion of the surgeon.

Inclusion criteria were surgery for solitary pain without a clear reason after MUS placement. Patients with vaginal, urethral or vesical MUS exposure or erosion or recurrent urinary tract infections were excluded.

Data collection

Pre and post-operative notes in the electronic medical files of all included patients were reviewed by two of the authors. Baseline demographics, SUI status and additional pain and SUI treatment were collected. A questionnaire was sent to all included patients; patients retrospectively scored their pre-operative pain and their current post-operative pain at follow-up. Furthermore, we noted the PGI-I scores, their current SUI status and relevant medical history. Complications were scored with respect to the Clavien-Dindo system [13]. Time in months to refer-

ral before 2008, between 2008 and 2011 and after 2011 were determined, because of the various FDA notifications to inform on the complication risks of mesh kits [14].

Statistical analysis

The χ^2 and Fisher exact test for categorical variables and paired and independent t-tests for continuous variables were used. Possible predictors for pain were analysed using linear regression analysis. Significance level was set at $p < 0.05$. Study data was collected using CASTOR a secure web-based application.

RESULTS

Thirty-one patients were included in the study. Twenty-six (84%) patients returned the questionnaire. Demographic data, MUS type, operating time, blood loss and number of surgeries are listed in Table 1. Median follow-up of the medical reports was 12 months (range 2–66) and of the questionnaires was 25 months (range 5–104). Median placement-to-removal interval was 15 months (1–141). This interval dropped from a median of 64 months (range 1–141) before 2011, to a median of 12 months (range 1–54) after 2011 ($p = .00$). More women had a transobturator tape removal (TOT, $n = 23$) than a transvaginal tape removal (TVT, $n = 10$). Intervals between MUS placement and removal according to the year of surgery is shown in Figure 1.

We categorized pain location in Table 2. Nineteen (61%) of the patients experienced pain at multiple sites of whom 16 patients required more than one surgical session for removal. The number of surgeries to remove tape at once or step-wise during subsequent surgeries differed with a range of 1 to 4 surgeries per patient. Fifteen (48%) patients were referred to our tertiary clinic, of whom 5 (38%) patients had undergone an attempt of MUS removal surgery before referral. At the end of the follow-up in this study, after all cumulative surgeries, 10 patients (32%) had a partial one sided vaginal tape removal, 18 patients (58%) had a complete vaginal tape removal, one patient (3%) had only a midline transection, one patient (3%) had a one sided groin removal, and one patient (3%) had a complete groin and vaginal removal. Using the patient global impression of improvement scale (PGI-I), 18 patients felt better in general whereas 7 patients remained stable or deteriorated in their general wellbeing.

Mean current VAS pain score was 4.2 (SD 3.2) ($n = 26$). Seven patients (23%) were completely free of pain. Twenty-two out of 26 patients (84.6%) could recall

a VAS pain score at baseline (after MUS placement but before removal). Mean VAS pain score dropped from 7.8 (SD 1.9) before removal to 4.5 (SD 3.2) at the end of the follow up ($p < .00$).

In Table 3 the change in VAS pain scores allocated by type of surgery and for the total group is shown. There was no statistically significant difference in partial vaginal versus complete vaginal removal ($p = .38$). At last clinical follow-up, as derived from medical records, 20 (65%) patients reached a self-re-

ported acceptable pain level, of whom 7 (23%) were completely pain free. Nine (29%) felt no change and 2 (7%) experienced an increase of pain.

Fifteen patients underwent some form of redo SUI treatment after removal, including a second MUS ($n = 12$), fascial sling ($n = 1$), Pelvicol implant ($n = 1$) and Burch colposuspension ($n = 1$). Of the patients who received a second MUS, seven (58%) had the second MUS placed concomitant with the removal surgery. At last clinical follow-up, 6 (86%) of these patients were almost pain free or reached an acceptable situation, 1 patient (14%) reported no decrease of pain and was referred for physical therapy. Five of the 6 patients that filled out the questionnaire, their VAS pain score pre-removal was 8.4 (SD 1.1) and at the end of the follow-up was 6.0 (SD 3.8), $p = 0.24$. Five patients had a MUS placed at a later date, with a median removal to placement

Table 1. Demographics of patients who underwent MUS removal

	Number of women (%)	Mean (SD)	Median (range)
Age at MUS placement	31 (100)	48 (8.8) years	49 (28–65) years
TVT	8 (26)	47 (10.1) years	46 (34–65) years
TOT/TVT-O	21 (68)	48 (8.1) years	50 (28–62) years
TVT-Abrevo	2 (6)	40 (15.6) years	40 (28–52) years
Multiple slings	2 (6)	48 (15.6) years	49 (37–59) years
Placement-removal interval	31	32 (34) months	15 months (1–141)
Before 2008	6	68 (48) months	68 (1–141) months
Between 2008-2011	5	51 (33) months	43 (9–86) months
After 2011	20	17 (16) months	12 (1–54) months
Total number of MUS related surgeries per patient (insertions and resections)	31 (100)	3.82	3.0 (2–9)
Total number of MUS resections per patient	31 (100)	1.67 (0.91)	1.0 (1–4)
Surgery time	30	33 (21) min	25 (10–93)
Blood loss	15	125 (147)	50 (0–450) ml

MUS – Mid Urethral Sling; TVT – trans vaginal tape; TOT/TVT-O – trans obturator tape; SD – standard deviation

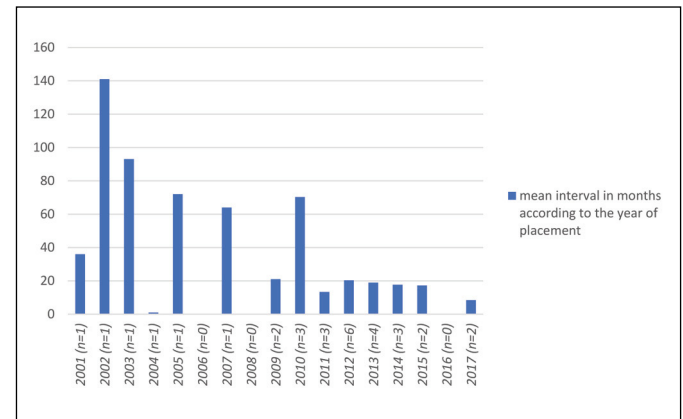


Figure 1. Interval between placement of MUS and (first) removal.

MUS – midurethral sling

Table 2. Locations of pain as reported by patients

Location of original pain	Frequency n (%)	Sling type n (%)			
		TVT	TOT	Multiple	
Side	Left side	9 (29)	1 (11.1)	7 (77.8)	1 (11.1)
	Right side	15 (48)	5 (33.3)	9 (60)	1 (6.7)
	Central	4 (13)	1 (25)	3 (75)	0 (0)
	Both sides	3 (9.7)	1 (33.3)	2 (66.7)	0 (0)
Site*	Vaginal	24 (77)	5 (20.8)	17 (70.8)	2 (8.3)
	Groin	17 (55)	5 (29.4)	11 (64.7)	1 (5.9)
	Abdominal	11 (36)	4 (36.4)	7 (63.6)	0 (0)
	Other	4 (13)	0 (0)	4 (100)	0 (0)
	Multiple sites	19 (61)	5 (26.3)	13 (68.4)	1 (5.3)

N – number; TVT – transvaginal tape; TOT – transobturator tape

* Different sites for pain mentioned by patients. Each patient can mention more than one site, which is reflected by the number of patients that mention multiples sites (61%).

Table 3. VAS pain scores according to the type of surgery

Surgery performed	Number	VAS pain score preoperative	VAS pain score postoperative	p
Partial vaginal removal	6	8.5 (SD 1.0)	3.8 (SD 2.9)	0.02
Complete vaginal removal	14	7.4 (SD 2.3)	4.7 (SD 3.0)	0.02
One sided inguinal removal	1	10	6	
Complete inguinal removal	1	8	3	
Total	26	7.8 (SD 1.9)	4.2 (SD 3.2)	<0.01

VAS – visual analogue scale; SD – standard deviation; p – p value

interval of 8 months (range 2–14). Their VAS pain score pre-removal was 8.5 (SD 1.0) and at the end of the follow-up it was 4.0 (SD 3.2), $p = 0.05$. Four of these patients were almost pain free. Two patients felt no change or were almost pain free and were referred for physical therapy. One patient who was almost pain free was referred to a pain management team. She reached a VAS pain score of 0. The endpoint of pain treatment at the last follow-up is listed in Table 4. Sixteen (52%) patients reached an acceptable situation at the last clinical follow-up, and this remained stable in the long-term.

Nineteen (61%) patients reported more severe SUI post-operatively, whereas 9 (29%) and 3 (10%) had stable or a decrease of SUI respectively. Out of the 10 patients who had partial vaginal removal, 5 (50%) reported an increase, 4 (40%) remained stable and 1 (10%) reported a decrease of SUI. In patients with complete vaginal removal ($n = 18$), 11 (61%) reported worsening, 5 (27%) remained stable and 2 (11%) had a decrease of SUI respectively. Worsening of SUI did not differ between partial vaginal versus complete vaginal removal ($p = .97$).

Twelve patients (39%) (partial $n = 7$, complete $n = 4$, groin $n = 1$) reached a self-reported acceptable situation regarding their SUI and required no additional

treatment at median follow-up of 53 months (7–140). Six (19%) patients did not want an additional SUI procedure mostly due to fear of pain recurrence or expected treatment effect. Four of these patients filled out the questionnaire and had no wish for new SUI treatment.

Questions regarding current SUI complaints were answered by 26 patients. Twenty-three (89%) patients experienced any degree of SUI. Median incontinence pad use was 3/day (range 0–10) ($n = 22$). Patients indicating that they experienced no or almost no incidents of SUI ($n = 10$), used 2 (range 0–5) pads/day. Of these patients, 3 patients had a second MUS placed and 1 had a biological sling placed. Patients who were bothered by their SUI ($n = 12$) used an average of 3.0 (range 1–10) pads/day. Of these patients 4 patients had a new MUS placed. The pad use of patients with incidents was significantly higher ($p = 0.04$).

The following possible risk factors associated with pain were collected: menopause ($n = 15$), prior hysterectomy ($n = 11$), tobacco use ($n = 3$), fibromyalgia ($n = 6$), diabetes ($n = 1$), dystrophy ($n = 2$), chronic abdominal pain ($n = 3$), bladder pain syndrome ($n = 2$), chronic pain ($n = 9$). None of these showed any significant correlation with pain.

We documented 4 complications within 30 days after MUS removal. There were 3 grade 1 complications (1 post-operative pain and 2 haemorrhages); two after complete vaginal removal and 1 after partial vaginal removal. One grade 2 complication (haemorrhage) occurred after complete vaginal removal.

DISCUSSION

In this paper we report on the results of MUS removal in women with solitary pain defined as pain without other objectifiable complications or reasons for pain. MUS removal resulted in a significant drop in pain score. Almost one out of four patients reported to be completely pain-free. Complication rates of MUS removal were low implying that MUS

Table 4. Acceptability of pain level and further treatments according to type of surgery

Pain outcome post-surgery	Surgery performed					Total
	Midline transection N (%)	Partial removal (left or right) N (%)	Complete vaginal removal N (%)	Groin removal N (%)	Complete vaginal and groin removal N (%)	
Acceptable	1 (6.3)	5 (43.8)	8 (37.6)	1 (6.3)	1 (6.3)	16
Pain medication		1 (50)	1 (50)			2
Pain management team		1 (20)	4 (80)			5
Physical therapy		3 (37.5)	5 (62.5)			8

N – number

removal surgery can be a safe procedure. Although 52% of patients reached an acceptable level of pain, 48% needed additional treatment. Comparable studies use different methods to study and record the change in pain [2, 15–23]. The heterogeneity of pain measurement and small cohort sizes make the comparison of studies and determination of optimal treatment difficult. Nevertheless, other studies also found a reduction in pain after MUS removal [20, 21, 22]. In our series, partial vaginal and complete vaginal MUS removal showed no significant difference in both pain scores and rates of recurrent SUI, which was also reported by Jambusaria et al. [24]. This suggests that it is not necessary to remove an MUS completely in every case. Danford et al. showed an association between chronic pelvic pain before MUS placement and increased risk of failure of the pain relieving procedure [19]. Our study could not identify predictive factors, possibly due to a low incidence of chronic pain patients in our cohort. When MUS removal was combined with new SUI treatment we recorded a higher VAS pain score at follow-up compared to patients who had SUI treatment at a later stage. This suggests a role for prioritizing pain treatment and postponing new SUI treatment until pain treatment is optimized, although this results in an extra surgical procedure. This should be considered when counselling patients. Our results are in line with the findings of Ramart et al who found that a third of patients develop significant SUI within a year after MUS removal, regardless of the extent or type of mesh removed [25]. Surgical therapy is often performed after failed conservative therapy. In the present study we did not assess the effects of conservative SUI treatments after MUS removal.

Currently there is no consensus on the best treatment or successive order of pain treatment. The challenge of pain treatment after MUS placement may result in a delay during which patients suffer unnecessarily. Therefore, we feel that MUS removal should not be considered only when conservative treatment fails. Comparable studies have used various methods to study change in pain after MUS revision [2, 15–20]. This heterogeneity, combined with small samples, makes the comparison of studies difficult and impedes the identification of an optimal treatment program.

In 2008, the FDA issued the first notification to inform the public on the complication risks of mesh kits. In 2011, the FDA issued a second notification which advised both patients and surgeons regard-

ing the risks concerning pelvic mesh surgery [14]. We noticed a significant drop in the time interval between placement and removal of MUS between the periods before and after 2011. This could be due to a higher awareness of possible complications [11] and less optimism regarding the chances of spontaneous resolution of pain over time, with quicker and better counselling of patients on MUS removal.

There are a few studies that report on the results of midurethral sling removal results only because of solitary pain. This study therefore clarifies the consequences of mesh removal in this particular group. We had a high response rate in our study of 84%, which guarantees a good representation of the group. Nevertheless, with this relatively small sample size, significant conclusions are hard to make. Limitations were the retrospectively obtained VAS pain scores, in which possible recall bias should be considered. We included only patients that underwent surgery as a treatment of pain after MUS placement and the patients who were treated conservatively. This implies an incomplete picture of the total group. The retrospective design of our study, resulting in non-systematic and incomplete data in the medical files should also be taken into account. With these limitations taken into account, we feel that in experienced hands MUS excision and removal is a viable alternative to conservative treatment which should be discussed with the patient. Proper counseling about conservative as well as surgical options should be considered earlier in the therapeutic algorithm. Especially if the use chronic addictive opioids, which don't cure the cause of the pain, are required [26].

CONCLUSIONS

In the case of pain after MUS, removal of the tape is a viable and safe option with a significant reduction of pain in patients without any identifiable cause. When considering MUS removal, a post-operative increase in SUI can be expected, which should be discussed beforehand. However, this should not be a reason to avoid the discussion or referral for surgical removal in case conservative treatment fails, or even as an alternative to conservative treatment. In terms of pain resolution, postponing new SUI treatment should be considered until pain treatment is optimised.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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