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Evaluation of the long-term effect and complication rate of single-incision slings for female stress urinary incontinence

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ABSTRACT

Objective: To evaluate the long-term outcomes of single-incision midurethral slings (SIMS) in real-life practice.

Study Design: This retrospective, single-arm, patient cohort study was performed in a large Dutch teaching hospital, including 397 consecutive women who underwent a SIMS-procedure between 2009 and 2018. Data were obtained through questionnaires and patient record study. Subjective improvement was the primary outcome, defined as a Patient Global Impression of Improvement (PGI-I) of '(very) much better'. Secondary outcomes were subjective cure rate (defined as a negative Urogenital Distress Inventory - item 4 'Do you experience involuntary urine leakage related to physical activity, coughing or sneezing?'), complication rate and sling failure (defined as the need for additional research or treatment for persisting stress urinary incontinence (SUI)). All data was analysed with a statistical significance level of 5%.

Results: The mean follow-up time was 54 months. All patients received SIMS (Ajust® or Altis®). Of all respondents, 75% reported a (very) much improved burden of disease. The subjective cure rate was 61%. In 93 patients a total of 120 complications were registered. In 10% of patients a sling failure was observed, 76% of these failures appeared in the first two years post-surgery.

Conclusion: This study showed that, in real life practice, SIMS are both effective and safe over a long period of time.

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Introduction

Worldwide 6.1% of women suffer from stress urinary incontinence (SUI) [1].

The first-line treatment of SUI is conservative management with pelvic floor therapy and lifestyle modifications, predominantly regarding weight reduction [2]. Mid-urethral sling (MUS) procedures are considered the gold standard in the surgical treatment of SUI, if first line treatment is insufficient. Three types of MUS exist. The first MUS was the retropubic tension-free vaginal

tape (RMUS) with an efficacy of 92%. It is associated with a risk of injury of the bladder, bowel and major vessels [3]. Transobturator mid-urethral slings (TMUS) have a lower risk of bladder injury, but are associated with thigh, groin and hip pain [3–5]. Single-incision midurethral slings (SIMS) have been available since 2006 [6]. These slings do not perforate the adductor muscles, and are experienced by patients as a less painful procedure, but are as effective as TMUS in curing SUI [3].

There are many studies on the short-term effects of the SIMS, but there are few studies reporting the long-term effects [3].

The primary aim of this study is to evaluate the long-term effect and complication rate of the SIMS.

Materials and methods

This retrospective, single-arm, patient cohort study evaluating the effect and complication rate of SIMS was conducted at the pelvic care centre of the Isala Hospital in Zwolle, the Netherlands. The study was designed as a quality assurance measure for treatment

Abbreviations: UI, Urinary incontinence; UUI, Urge urinary incontinence; SUI, Stress urinary incontinence; MUI, Mixed urinary incontinence; UDS, urodynamic studies; MUS, Mid-urethral sling; RMUS, Retropubic mid-urethral sling; TMUS, Transobturator mid-urethral sling; SIMS, Single-incision midurethral sling.

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already established. Approval from the Medical Ethics Committee was given under number 200425.

All consecutive patients who underwent a SIMS procedure between November 1st 2009 and November 1st 2018 were included in this study. A pure selection on SIMS procedure could be made based on hospital registry, as all treatments in the Netherlands are registered in codes. This study included women with pure SUI, MUI with predominant SUI and women who underwent combined surgery (e.g. for prolapse repair and SUI). Diagnoses were made following hospital protocol, based on anamnesis, bladder diary, uroflowmetry and a positive urine cough stress test. Urodynamic studies (UDS) were performed if indicated. The SIMS used during this period were the Ajust[®] and the Altis[®]. All patients had a follow-up visit six weeks after surgery. Further follow-up visits were only scheduled if the physician or patient deemed them necessary. Three different gynaecologists performed the procedures. All three had prior experience with this type of surgery.

All women received an invitation for this study by mail, along with the consent form and the following questionnaires: the Urogenital Distress Inventory (UDI) [7]; the Patients Global Impression of Improvement (PGI-I) [8]; the Sandvik Incontinence Severity Index (ISI) [9]; and a Satisfaction Visual Score (SVS) for the received treatment, ranging from 0 (completely dissatisfied) to 10 (completely satisfied). No reminders were sent. Patients gave written informed consent to participate in this study.

To investigate a non-response bias, a subgroup analysis was conducted to test the representativeness of the respondents, compared to the women who did not respond to the questionnaire [10].

The primary outcome was subjective improvement, which was considered with PGI-I scores of 'much better' or 'very much better' [8].

The secondary outcomes were subjective cure rate, complication rate and sling failure. The subjective cure rate was defined as a negative response to UDI-item 4 'Do you experience involuntary urine leakage related to physical activity, coughing or sneezing?' [7,9].

Complications, sling failures and patient characteristics were retrieved by conducting a patient record study for the entire patient group, both responders and non-responders. The following ten complications were defined, based on the medical records: urinary tract infection (UTI) within six weeks post-operative, recurrent UTI (three or more urinary tract infection per year after placement of the sling), urinary retention (requiring clean intermittent catheterization (CIC)), exposure of the tape (observed by a clinician), removal of an exposure or the (partial) removal of the sling, de novo urge urinary incontinence (UUI), de novo urgency, pain in the operation area, perioperative complications and additional complications. In combined surgery, it was examined whether or not the complications were SIMS-surgery related.

A sling failure was defined as persistent SUI with the indication for additional diagnostic tests or treatment. This additional treatment could consist of a re-operation or injections with a bulking agent.

Patient characteristics consisted of demographic and surgery characteristics. Demographic characteristics were age, BMI, smoking, diabetes, parity, type of urinary incontinence (UI), UDS and previous incontinence therapy. Surgery characteristics consisted of whether or not sling surgery was combined with another operation, type of combined surgery, method of anaesthesia, follow-up time and presence of complications. Combined surgery was divided into two categories; 'major surgery' and 'minor surgery'. 'Major surgery' included prolapse surgery, different types of hysterectomy and colorectal surgery. 'Minor surgery' included sterilisation, surgery at the vulva, cervical loop excision, endometrial

ablation, removal of small exposures of previously placed vaginal mesh and the insertion of an intrauterine device (IUD).

Statistics

The statistical analyses were performed with SPSS Statistics for Windows: version 24.0 or version 25.0 (SPSS Inc., Chicago, IL, USA). The baseline characteristics were analysed with the use of Descriptive Statistics.

We compared the characteristics from the participants and the non-responders, derived from the medical files, to test the representativeness of the study sample. For this, we applied the independent Samples T-tests, Mann-Whitney U Tests, Chi-square Tests and Fisher's Exact, depending on the distribution of outcomes.

We used all available data; participants with incomplete responses were not excluded. Consequently, numbers for different outcomes will differ, and valid percentages are presented.

Complication rates were compared for women who underwent a combined surgery and those with SIMS only, using the Chi-squared test. Finally, we compared statistically significant patient characteristics between women with and without complication, and with and without sling failure, using the Mann-Whitney U test. The significance level was set at 5%.

Results

Patient characteristics

Of 397 patients invited, 190 (47.9%) responded to the questionnaire. This group was representative for the entire population, except for their lower BMI ($P = 0.035$). The shortest follow-up time was 18 months and the longest follow-up time was 126 months, with a mean follow-up time of 54 months. The median follow-up time was 50 months. UDS were performed in 188 patients (47.4%). A total of 15 patients had received previous incontinence treatment before their SIMS surgery: one patient was treated with botulinum toxin injections, ten patients were previously treated with a bulking agent; nine of these with Bulkamid[®] and one with Urolastic[®], and four patients had received previous incontinence surgery; one was treated with a RMUS, one with a TMUS and two patients were treated with a Burch colposuspension procedure. Patient characteristics of both respondents and non-responders are provided in [Table 1](#).

Questionnaires

A subjective improvement rate was observed in 138 (75%) of the participants, and subjective cure in 115 patients (60.8%). A satisfaction score of 8 or higher was observed in 126 patients (69.6%).

Using the ISI score, 49 patients (26.5%) were completely continent and 64.9% of patients were either continent or had slight involuntary UI. It was observed that 154 patients (85.6%) would choose this surgery again and that 160 patients (87.4%) would recommend this surgery to someone else. The results of the questionnaires are provided in [Table 2](#).

Complications and failures

All complications and failures were retrieved from patient records. We registered 119 complications in 93 patients (23.4%) ([Table 3](#)). A total of fourteen patients (3.5%) required re-operation due to one or more complications. Recurrent UTI occurred to 21 patients and 19 patients had a single UTI. Seventeen patients had urinary retention requiring CIC. Twelve patients used

Table 1
Patient characteristics.

Variable	Respondents (N = 190)	Non-respondents (N = 207)	P-value	Total (N = 397)
Demographic characteristics				
Age (yr), mean ± SD	50.6 ± 10.9	49.8 ± 11.8	0.463*	50.2 ± 11.4
BMI (kg/m ²), mean ± SD	26.5 ± 4.7	27.6 ± 5.2	0.035*	27.1 ± 5.0
Smoking, n (%)	19 (10.0)	20 (9.7)	0.662**	39 (9.8)
Diabetic, n (%)	9 (4.7)	9 (4.3)	0.852*	18 (4.5)
Parity, mean ± SD	2.4 ± 0.9	2.5 ± 1.1	0.596***	2.5 ± 1.0
Type of UI			0.119**	
SUI, n (%)	103 (54.2)	96 (46.4)		199 (50.1)
MUI, n (%)	87 (45.8)	111 (53.6)		198 (49.9)
UDS, n (%)	82 (43.2)	106 (51.2)	0.109**	188 (47.4)
Previous treatment, n (%)	4 (2.1)	11 (5.3)	0.094**	15 (3.8)
Surgery characteristics				
Combined surgery, n (%)	32 (16.8)	41 (19.8)	0.446**	73 (18.4)
Major surgery, n (%)	17 (53.1)	30 (73.2)		47 (64.4)
Minor surgery, n (%)	15 (46.9)	11 (26.8)		26 (35.6)
Type of anaesthesia			0.119**	
General, n (%)	55 (28.9)	78 (37.7)		133 (33.5)
Spinal, n (%)	28 (14.7)	33 (15.9)		61 (15.4)
Sedation, n (%)	107 (56.3)	96 (46.4)		203 (51.1)
Follow-up time (months), mean ± SD	55.2 (24.5)	52.9 (22.4)	0.346*	54.0 (23.5)
Presence of complications, n (%)	44 (23.2)	49 (23.7)	0.904**	93 (23.4)

BMI: Body Mass Index; UI: Urinary Incontinence; SUI: Stress Urinary Incontinence; MUI: Mixed Urinary Incontinence; UDS: UroDynamic Studies.

*Independent Samples T-test.

**Chi-square Test.

***Mann-Whitney U Test.

Table 2
Patient reported outcomes after Single Incision Sling.

Item	N	Measure
PGI-I, % [95%-CI]	184	75.0 [68.1, 81.1]
Satisfaction ≥ 8, % [95%-CI]	181	69.6 [62.4, 76.2]
UDI Total, mean (SD)	189	39.4 (38.4)
UDI SUI, mean (SD)	188	20.9 (24.7)
UDI UUI, mean (SD)	189	15.2 (17.8)
UDI Prolapse, mean (SD)	189	10.3 (12.5)
Item 4 'No', % [95%-CI]	189	60.8 [53.5–67.9]
ISI, % [95%-CI]	185	26.5 [20.3–33.5]
Choose surgery again, % [95%-CI]	180	85.6 [79.6–90.3]
Recommend surgery, % [95%-CI]	183	87.4 [81.7–91.9]

PGI-I: Patient Global Impression of Improvement; UDI: Urogenital Distress Inventory; ISI: Sandvik Incontinence Severity Index.

Table 3
Complications stated in patient records (N = 397).

Complications	% of total patients	Number of patients requiring re-operation (N = 14** (3.5%))
Total	23.4*	
Recurrent UTI	5.3	–
UTI	4.8	–
Urinary retention	4.3	2
Pain	3.5	6
Sling exposure	2.5	9
De Novo urgency	2.5	–
De Novo UUI	2.0	–
Perioperative	1.0	–
Other	0.5	1

*A total of 119 complications was found in 93 patients, thus individual complication percentages do not add up to the total percentage **Re-operation numbers do not add up to 14, as some patients had multiple reasons for re-operation.

CIC for a period of 6 weeks or less and five patients required CIC for a longer period of time. Fourteen patients experienced post-operative pain. Six patients underwent a (partial) SIMS removal because of this complaint. In ten patients a sling exposure was observed, one of these was treated conservatively. De novo urgency arose in ten patients and de novo UUI arose in eight patients. Four perioperative complications occurred: in three patients the attachment of the sling failed and in one patient a small urethral lesion occurred. There were two patients with other complications. One patient was unknowingly pregnant during surgery and one patient had a detached anchor after surgery and required a re-operation. There was no significant difference in complication rate between patients with and without combined surgery (22.2% vs. 28.8%, P = 0.233, Chi-Square Test) or between 'major' and 'minor' combined surgery (P = 0.181, Chi-Square Test). In the division between patients with SUI or MUI (25.1% vs. 21.7%), no significant difference in complication rate was observed (P = 0.423, Chi-Square Test). There was also no significant difference between patients with (26.7%) or without (23.3%) previous incontinence treatment (P = 0.763, Chi-Square Test). The mean BMI in the patients with and without a complication was similar (27.4 ± 5.1 vs. 27.0 ± 5.0; P = 0.488, Mann-Whitney U test).

Of 38 patients (9.6%) a sling failure was reported in their medical record. Six patients received a new tape due to their failure, two of these patients first received Bulkamid® injections. Seventeen patients only received additional Bulkamid® injections. The earliest failure occurred within the first month and the latest at 93 months. 63.2% of the failures were observed within the first year and 76.3% within the first two years. In the patients with a failure the mean BMI was 29.3 ± 5.7 and in the patients without a failure 26.8 ± 4.9 (P = 0.006, Mann-Whitney U test). No significant difference in failure rate between patients with and without combined surgery or in the division between 'major' and 'minor' surgery was observed. A significant difference (P = 0.000) in failure rate was found between patients with SUI (4.0%) and MUI (15.2%) and between patient who had or had not received previous treatment (26.7% vs. 8.9%, P = 0.045, Fisher's Exact Test) (Table 4).

Table 4
Failure rate stated in patient records (N = 397).

Groups	Presence of failures N (%)	P-value
Total population	38 (9.6)	–
Non-respondents	27 (13.0)	0.014*
Respondents	11 (5.8)	
No combined surgery	33 (10.2)	0.381*
Combined surgery	5 (6.8)	
Minor surgery	1 (3.8)	0.649**
Major surgery	4 (8.5)	
SUI	8 (4.0)	0.000*
MUI	30 (15.2)	
No previous treatment	34 (8.9)	0.045**
Previous treatment	4 (26.7)	

*Chi-square Test.

** Fisher's Exact Test.

Discussion

This study examined the long-term efficacy and complication rate of SIMS in real life practice. With a mean follow-up of 4.5 years, we found that the majority of women were satisfied with this treatment and reported subjective improvement.

With a subjective improvement observed in three-quarters of patients and a subjective cure in about two-thirds, our results were less positive than the short term outcome one year after Ajust® and two years after Altis® placement [4,11]. This might be explained by the longer mean follow-up in the current study, as it is known that patient satisfaction rates decline over time [6,12]. Comparing these results with a meta-analysis of retropubic and TMUS, the RMUS has a significantly higher subjective improvement and cure rate: 97% (95% C.I. = [−0.2924, −0.1476]) and 89.1% (95% C.I. = [−0.3728, −0.1932]) respectively. However, the outcomes of the TMUS are similar with this study with a subjective improvement rate of 76.1% (95% C.I. = [−0.0842, 0.0622]) and a subjective cure rate of 64.1% (95% C.I. = [−0.1234, 0.0574]) (13). White et al. found a subjective improvement rate of 89.4% of their SIMS population and 86.1% of their TMUS population. However, these results are with a loss-to-follow-up of approximately 25%, which could greatly impact the results. With missing data counting as treatment failure, a subjective improvement rate of 66.0% for the SIMS and 66.4% for the TMUS group was found [14].

The overall complication rate in this study is similar to the complication rate found by Kocjancic et al [11]. Re-operation rates of 3.5% of SIMS and 2.8% of TMUS are consistent with our population [14]. The pain rate in this study was 3.5% and the TMUS is associated with a groin pain rate of 6.3% (95% C.I. = [0.0068, 0.0492]). These findings are consistent with Schweitzer et al. [4]. In this study 2.5% of the total population had a sling exposure, which is comparable to other studies, with exposure rates for SIMS ranging between 0.0% and 3.5% [6,11,12]. This is also comparable with the exposure rate of 2.4% of patients with a TMUS and 2.1% of RMUS [13]. White et al. found an exposure rate of 2.8% for their SIMS group vs. 5.0% in their TMUS group [14]. One patient in this study had a small urethral lesion, this is comparable with the 0.2% bladder or urethral perforation observed with the TMUS (95% C.I. = [−0.0046, 0.0066]), but significantly less than the 5.0% observed with the RMUS (95% C.I. = [−0.0563, −0.0377]) [13]. Unspecified perioperative complications were observed in 11.7% of patients with a TMUS and in 13.0% of patients with a RMUS, while they were found in only 1% of patients in this study (95% C.I. = [−0.1285, −0.0855] and 95% C.I. = [−0.1417, −0.0983] respectively) [13].

With 9.6%, sling failure was observed less often than five years after the placement of the MiniArc® [12]. The patient population in

our study is younger (50.2 y vs. 54.6 y, 95%-CI [1.92, 6.88]), it has, however, a higher BMI (27.1 vs. 25.0, 95%-CI [−3.14, −1.06]) [12]. With higher age and higher BMI in their study population, Kocjancic et al found a failure rate of 12.1% for the Altis® (95%-CI [−0.0417, 0.0917]) [11]. In patients with a TMUS, repeated surgical interventions for UI were recorded in 9.4% of patients, which is similar to our results. However, only 1.5% of patients who had a RMUS, needed a reintervention for persistent SUI [13]. In this study patients with MUI had a significantly higher chance of sling failure than patients with pure SUI, which corresponds with current literature [15]. As patients with MUI also suffer from another type of incontinence, it is imaginable that their reported urinary loss after treatment is related to their UUI component. The retrospective nature of this study makes it impossible to further investigate whether the remaining incontinence was indeed a failure of the treatment or was related to their UUI. Patients who had received previous treatment for their SUI also had a significantly higher failure rate. It is known that patients with previously failed incontinence surgery have a higher risk of persistent SUI after secondary treatment [15].

This study has some strengths and limitations to address. The strengths of this study were the focus on patient satisfaction, long term follow-up and the availability of a large cohort. Most studies [3,11,12] assess the objective dryness of the patient with a cough test. However, subjective cure rate and patient satisfaction are considered of greater importance than objective dryness [16]. This study focused on patient satisfaction and the subjective cure rate and is, therefore, in line with the upcoming need for patient centred care [17]. An important quality of this study is its longer follow-up period than most other studies, with a mean follow-up time of 4.5 years and a maximum of 10.5 years [3]. Therefore it sustains and improves our current knowledge on the long-term effect of the SIMS. The patient population was a non-selected population of women. The total number of included patients was 397, which, in comparison to other studies about SIMS, can be considered as a large cohort [4,6,11,12,18].

The limitations of this study were the representativeness of the respondents, the retrospective nature of the study and the chance of non-response bias. The respondents to the questionnaire were not representative with respect to their BMI. We found that patients with a failure had a significantly higher BMI than patients without a failure (29.3 vs. 26.8). Obesity might contribute to the occurrence of a sling failure, the increase of five units in BMI is associated with a 60–100% increase in SUI risk. However, obesity alone is not sufficient to cause sling failure [12,19]. The retrospective nature of this study may have biased the diagnosing of complications, since all complications were obtained from patient records. It is possible that not every complication was recorded appropriately, or that a patient with a complication did not present themselves at our hospital. Furthermore, the long-term follow-up may have resulted in recall bias. This study was a single postal mail shot, no reminders were sent. Approximately half of the patients responded to the questionnaires, thus there is a chance of non-response bias [10].

Our study also has some implications for further research. This study focuses on current practice, but the majority of patients in this study received an Ajust® and unfortunately, the Ajust® has been withdrawn from clinical practice by C.R. Bard, Inc. in 2018. Because of the small population size of the Altis® group in this study, it is difficult to obtain statistically significant results. However, the data suggest that there is no difference in cure or complication rate between the Ajust® and the Altis®. In addition, both the Ajust® and the Altis® are similar adjustable SIMS with the same product characteristics, except for the insertion devices. Still, additional high quality evidence is needed on the long-term follow-up of SIMS currently in use. Specifically a prospective study with

well-defined outcome measures and a 5 to 10 year follow-up could provide the evidence needed to prove the safety, efficacy and patient satisfaction of SIMS.

Conclusion

Compared with the RMUS, the SIMS showed lower subjective improvement and cure rates, but also fewer complications. Compared with the TMUS, the SIMS showed similar subjective improvement and cure rates, and fewer complications. We concluded that the long-term patient satisfaction is good and that the SIMS used in our hospital are effective and safe at the long-term, with high patient satisfaction and subjective improvement.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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