The MiniArc sling for female stress urinary incontinence: clinical results after 1-year follow-up

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Introduction

It is estimated that urinary incontinence (UI) affects 10-40% of the female population aged 15-64 years and has an even higher incidence after 65 years of age (1-3). UI is defined as the uncontrolled and involuntary leakage of urine (4) and is associated with a reduction in quality of life (QoL) for women of all ages (1-3). To assess this reduction, QoL questionnaires are commonly used and focus on the consequences of urinary incontinence (5-9). Stress urinary incontinence (SUI) is described as urinary incontinence following increase of abdominal pressure as in sneezing or coughing and is due to a weakening of the muscles and connective tissue of the pelvic floor.

The wide acceptance of surgery with mid-urethral slings (MUS) as intervention for SUI is due to the effectiveness, rapidity, and minimal invasiveness of the techniques so far. After the first-generation (the tension-free vaginal tape, TVT) and second-generation (the trans-obturator tape, TOT, and the tension-free vaginal tape–obturator, TVT-O) tapes, the industry developed third-generation vaginal tapes like the MiniArc (introduced in 2007 by American Medical Systems) and TVT-Secur (introduced in 2006 by Women's Health & Urology, Ethicon, Johnson & Johnson). The TVT, TVT-O, and the TOT all show cure rates ranging from 84 to 100% after a minimum follow-up of 1 year (10).

The MiniArc uses self-fixating tips and is performed with a single incision in the anterior vaginal wall. With this design, the procedure aims to accomplish minimal tissue damage by lowering the number of incisions from three to one. Also, needle penetration of the obturator foramen or the retropubic space is avoided, thereby minimizing tissue and (potential) organ damage.

Studies of the MiniArc (11-18) show a variance in success rate (range, 69.1-91.4%), after a minimum follow-up of 1 year. Although these studies all assess the cure rate of the MiniArc, only the articles of De Ridder et al. and Pickens et al. (11;18) discuss the impact on everyday functioning and QoL.

It is important to mention that no restrictions were made regarding the study population on the base of severity of SUI, age, BMI, etc. The aim of this study is to perform a 1-year postoperative evaluation of the treatment of SUI using the MiniArc sling with a focus on the efficacy, quality of life, and daily functioning.

Material and methods

A prospective study was performed at the Department of Gynecology of the Flevo Hospital, Almere. In this hospital, 77 primary interventions with the MiniArc were performed by one gynecologist (IMC) from March 2008 to November 2009.

The patient population consisted of women aged 29-82 years who all had clinically established predominant SUI. If a patient was suspected of having urge incontinence due to detrusor overactivity, full urodynamics were performed. In the case of identified detrusor instability, the patient was subsequently excluded from the study. Patients were asked to complete questionnaires preoperatively and 1 year postoperatively.
Inclusion criteria were predominant SUI and a minimum follow-up of 1 year post-surgery. Exclusion criteria were predominant urge incontinence and previous surgery for SUI. It is important to mention that the tape was positioned against the urethra without compression, but the overall placement of the MiniArc was tighter than the traditional MUS. This study was approved by the medical ethics review board of the Flevo Hospital, Almere.

Outcome

Failure of the procedure was defined as persistent SUI, stated by the patient in the questionnaire as loss of urine upon exertion, coughing, or sneezing. Patients not reporting any amount of leakage were considered cured. A post voidal residual volume of 150 ml was considered as the maximum acceptable and treated with Ubretid (5 mg/day) and/or (self) catheterization.

Questionnaire

The questionnaire used has been validated by the Dutch Association for Obstetrics and Gynecology in cooperation with the Dutch Association of Urology to evaluate the impact of urinary incontinence. The questionnaire consists of 47 multiple choice questions and is divided in five sections that evaluate physical condition (health status), micturition status, defecation status, coping of the patient (emotional status), and sexual functioning.
The first part consists of the 5-Dimensional EuroQol instrument (EQ-5D) (19). The EQ-5D is specifically designed to evaluate five different subcategories of the patient's current physical condition (mobility, self-care, daily activities, pain/complaints, mood) and is scored from 1 (no complaints) to 3 (serious complaints). The first part also includes a Visual Analog Scale (VAS), as well as a QOL scale to evaluate the overall health status of the patients.
The next parts evaluate the micturition status using the Urogenital Distress Inventory (UDI) (7), the coping behaviour of the patients using the Incontinence Impact Questionnaire (IIQ) (7), and the defecation status using the Defecation Distress Inventory (DDI) (20). The final part assesses sexual functioning with sections of the Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire-SF (PIS-Q short form, limited to five questions (21)). The IIQ and UDI were scored using the different domains as described by van der Vaart et al. (9).

The postoperative questionnaire was identical to the preoperative questionnaire except for the first question which assessed the improvement/deterioration post-surgery with the Patient Global Impression of Improvement (PGI-I) (22).

Statistical analysis

Results of both pre- and postoperative questionnaires were scored, and for the UDI, IIQ, and DDI, outcomes were converted to a scale ranging from 0 to 100 (higher= negative). Statistics were performed in SPSS release 17 (SPSS Inc., Chicago, IL, USA). P values <0.05 were considered statistically significant. For multiple comparisons, a Bonferroni correction was conducted after the paired samples *t*-test.

Results

All patients screened for SUI and eligible for surgery with the MiniArc were asked to participate in our study and complete the preoperative questionnaires. Of the operated patients, 77 filled in the preoperative questionnaire and were thus eligible to be included in this study. Clinical characteristics of this patient group are described in Table 1.

Table 1 Clinical characteristics of patients treated with the MiniArc, n=77

Age	52.1±12.6 (range, 29–80)
BMI	28.2±6.1 (range, 17, 63–50, 43)
Parity	2.3±0.9 (range, 1–6)
None	4 (5%)
1–3	68 (88%)
4, >4	5 (7%)
Education	3.4±1.7

Values are given as mean ± SD or percentage. Education rated from 1 (primary school) to 7 (university degree). BMI Body mass index in kilograms per square meter

After 1 year, these 77 patients were sent a copy of the postoperative questionnaire of which 57 were returned (74%). No differences were found in baseline characteristics between responders and non-responders. Of the 77 patients who had primary surgery with the MiniArc, 10 (13%) were anesthetized locally and 67 (87%) had general anaesthesia.

Complications were seen in 6 of 77 patients (8%) and resulted in one cleaving of the MiniArc due to deteriorating urge incontinence. Other complications were dehiscence of the wound (one patient) and a large residue (two patients, 300-600 ml; two patients,

150-300 ml). At the 6 week check, all patients had normal emptying of their bladder. Further investigation showed that the dehiscence was due to a post-surgery hematoma and did not cause any problems after the first week. Success and complications over time are visualized in Table 2.

Table 2 Success and complication rate through time, n=77

	Complications	Success rate[a]	Response[b]
First quartile	2	41.2% (7/17)	17/19=89%
Second quartile	2	50.0% (6/12)	12/19=63%
Third quartile	2	42.9% (6/14)	14/19=74%
Fourth quartile	0	42.9% (6/14)	14/20=70%
Total	6	Mean, 44.0 % (25/57)	Total, 57 patients

Patients divided in quartiles (77/4=19 patients per quartile, 20 in the fourth), chronological order. a: Patient not experiencing any amount of leakage 1 year after surgery, b: Response after 1 year

One-year post-surgery, 44% of the patients stated to be completely continent (Table 3). The patient's subjective satisfaction was scored ranging from "very much better" to "very much worse," using the PGI-I. After 1 year, 68% of the patients rated their current situation as either being "very much better" or "much better." The other 32% stated little improvement or even deterioration of their SUI in comparison to their preoperative status (Table 3).

Table 3 PGI-I, 1 year post-surgery

Very much better	16 (D=13, 3=ND)	(28%)
Much better	23 (D=11, ND=12)	(40%)
A little better	10 (D=1, ND=9)	(17.5%)
No difference	6 (D=0, ND=6)	(10.5%)
A little worse	0	
Much worse	1 (D=0, ND=1)	(2%)
Very much worse	1 (D=0, ND=1)	(2%)
Total	57	
Dry (success)	25 (44%)	
Not dry (failure)	32 (56%)	

Values are given as mean ± SD D dry, ND not dry

Preoperatively the overall QoL mean score was 4.6 with a standard deviation of 0.9. One year after surgery, the QoL did not differ from pre-surgery. The VAS did also not differ significantly1 year after surgery.

The EQ-5D score did not show a significant difference in comparison to the pre-operational status. The part of the questionnaire concerning the micturition status was scored using the UDI (five subcategories). After 1 year, all five subcategories showed an improvement (Table 4).

Table 4 Comparison of pre- and post-operational scores of patients treated with the MiniArc,

	Pre-surgery n=77	1-year, n=57	p value[b]
QoL scale [1–6]	4.6±0.9	4.9±1.0	ns
EQ-5D	0.82±0.19	0.86±0.19	ns
VAS	73.8±17.2	77.3±13.3	ns
Incontinence-related distress (UDI)			
Discomfort/pain	26.6±23.9	13.2±20.1	0.009[a]
Urinary incontinence	58.9±24.1	23.4±25.0	0.000[a]
Overactive bladder	30.7±24.6	13.7±18.7	0.000[a]
Obstructive micturition	26.2±24.8	17.0±23.3	0.024[a]
Genital prolapse	8.4±15.9	3.8±10.0	0.000[a]
Impact on everyday functioning (IIQ)			
Mobility	50.7±18.9	40.0±18.4	0.003[a]
Emotional	49.9±18.3	37.1±14.7	0.000[a]
Physical	40.2±16.1	32.6±12.6	ns
Social	34.3±13.2	29.6±10.7	ns
Embarrassment	53.0±21.6	41.0±17.9	0.006[a]
Defecation disorders (DDI)			
Constipation	11.2±19.8	9.4±15.8	ns
Painful defecation	9.3±18.0	7.3±15.8	ns
Fecal incontinence	7.1±16.8	7.6±16.4	ns
Flatus incontinence	18.6±25.7	23.4±26.0	ns

Values are given as mean ± SD. The p values were Bonferroni corrected. Scale from 1 (no complaints) to 100 (a lot of complaints). Preoperative compared to 1-year postoperative (n=57). QoL: Quality of life from 1 (very bad) to 6 (excellent), VAS: Visual Analog Scale (1–100), EQ-5D EuroQol-5 Dimensions, ns: not significant a: P value <0.05 was considered statistically significant, b: Paired-samples *t*-test, UDI, IIQ, and DDI

The final part of the questionnaire discussed the distress caused by the incontinence and the impact on everyday functioning using the IIQ (five subcategories). Three out of the five items were significantly improved after 1 year, indicating a decrease in distress caused by SUI. The DDI, as expected, showed no differences pre- and post-surgery. The sexuality part (PIS-Q SF, not shown in a table) did not show any relevant differences pre- and postoperatively

No differences were found in baseline characteristics between the "success" and "failure" patients (Table 5). However, it was found that a BMI of 35 or higher was negatively related to the success rate of the MiniArc (Table 6).

Table 5 Clinical characteristics of failures versus success 1 year after MiniArc (n=57), p<0.05= significant

	Success (dry) (n=25)	Failure (not dry) (n=32)	p value[a]
Age	52.0±12.0 (range, 36–79)	56.0±13.5 (range, 29–80)	0.248
BMI	27.2±4.1 (range, 19.5–33.5)	29.70±7.6 (range, 17.9–50.4)	0.122
Parity	2.0±0.8	2.3±1.0	0.200
None	1 (4%)	1 (3%)	
1–3	23 (92%)	29 (91%)	
>4	1 (4%)	2 (6%)	
Education	3.7±1.7	3.3±1.7	0.309

Values are given as mean ± SD or percentage. Education rated from 1 (primary school) to 7 (university degree). BMI Body mass index in kilograms/square meter [a]Independent-samples *t*-test

Table 6 Sub-categorical success and improvement rates 1-year post-surgery

	Success (dry)				Success (dry)	p value[a]
Complete population	44% (n=57)	vs.	BMI≥35 kg/m^2	(n=7)	0%	0.000[b]
Complete population	44% (n=57)	vs.	Age≥65 years	(n=15)	33%	0.347
Complete population	44% (n=57)	vs.	Parity≥3	(n=14)	40%	0.181
	Improved		**Improved**			**p value[b]**
Complete population	86% (n=57)	vs.	BMI≥35 kg/m^2	(n=7)	57%	0.023[a]
Complete population	86% (n=57)	vs.	Age≥65 years	(n=15)	73%	0.200
Complete population	86% (n=57)	vs.	Parity≥3	(n=14)	86%	0.368

Values are given as percentages. BMI Body mass index, Improved as stated in questionnaire (independent of success). [a]Independent-samples *t*-test, [b]Statistically significant.

Discussion

This prospective single-center study was designed to evaluate the efficacy, safety and impact on quality of life of the MiniArc procedure in women with SUI. Of the 57

evaluated patients, after 1 year, 32 (56%) stated that they were still experiencing SUI, thus indicating failure of the MiniArc. After 1 year, the PGI-I showed an improvement in 68% of the patients (Table 3). Following surgery, an improvement was seen in everyday functioning, as well as a significant drop in incontinence related distress. The DDI part of the questionnaire did not show any significant improvements but was not specifically associated with SUI. For the significant change in the subcategory "genital prolapse" of the UDI, no explanation could be found, but the improvement could be accredited to a decrease of complaints in general. Complications were seen in 6 of 77 patients (8%). The rate of complications and success did not show any significant improvement in time (Table 2). There are certain limitations to this study that need to be addressed.

At present there is an ongoing discussion about the amount of compression with which the mini-slings should be positioned against the urethra. Up to now, no consensus seems to be reached about a standardized method to place these mini-slings as effectively as possible.

Because all the surgeries in this study were performed by one gynecologist (IMC), this could partly explain the lower success rate. However, the gynecologist that performed the surgery is an experienced specialist in MUS surgery, as well as an AMS trained instructor for the placement of the MiniArc. Nevertheless, we recommend this study to be repeated in a multicenter setting using comparative patient groups.

The second limitation is the subjective definition of failure in this study. This subjective measurement, however, does provide information about the experience of the patient over a longer period of time. So, despite the fact that clinical tests after 1 year (Cough Stress Test (CST), pad test, urodynamic investigation) would have guaranteed objectivity, these investigations would merely reflect a measurement at one point in time. We therefore feel that our definition of cure (and failure) is valid to use

Thirdly, it is possible that a misinterpretation of the questions regarding the different types of incontinence could have resulted in inaccurate results. At least part of the patients indicating persistent SUI after 1 year could in fact be experiencing (de novo) urge incontinence. Although we feel that the question in the UDI regarding SUI is clear, clinical tests will be needed to further validate the results and exclude a possible bias.

The major advantage of this study is that multiple questionnaires were used to assess the different improvement or deterioration aspects post-surgery. According to the International Continence Society and the International Consultation on Incontinence, the UDI and the IIQ are recommended as grade A condition specific questionnaires to be used in research (23).

Furthermore the PGI-I and the PIS-Q are recommended by the International Urogynecological Association as validated SUI outcome measures (24). The extensiveness and many different aspects of the questionnaires should make this study valid to offer urologists and gynecologists reliable information.

Due to the fact that prior to the first included patient, our gynecologist had only performed five MiniArc interventions, a learning curve was expected. However, upon analysing the success and failure rates, no improvement in cure and complication rate was found (Table 2). The absence of a learning curve should lead to more reliable and valid results.

For our comparison with other studies, a literature research was conducted in PubMed using the terms "SUI" and "Mini Arc." The found studies for the MiniArc showed success rates ranging from 69% to 91% (11;12;14-17) and are visualized in Table 7. Our 1-year analysis showed different results with a success rate as low as 44%. It is clear that the success rate of our study is exceptionally low, but two other studies (Sottner et al. (17) and Debodinance et al. (12)) also present low rates of success.

Table 7 Other MiniArc studies ranked by number of patients

Study	Number of patients	Success rate (percentage)	Definition of success	Follow-up
Kennelly, MJ, et al. [15]	188	90.6	Negative CST	1 year
Jiménez Calvo J, et al. [14]	135	91.9	Negative CST	495 days (mean)
Pickens RB et al. [18]	120	93.5[a]	Subjective: no leakage	1 year
Hogewoning, CRC, et al.[a]	77	44[a]	Subjective: no leakage	1 year
De Ridder, D, et al. [11]	75	85	Negative CST	1 year
Debodinance, P, et al. [12]	72	69.1	Negative CST	1 year
Moore, RD, et al. [16]	61	91.4	Negative CST	1 year
Sottner, O et al. [17][a]	38	76.7[a]	Subjective: no leakage	19 months

a No objective outcome measures

Variances between subjective and objective outcomes are common in literature, but results are conflicting (25-29). No statement can be made whether subjective success rates deviate from objective ones in either a negative or positive way. Future research should include both objective and subjective measurements that can then be either analysed separately or combined.

Characteristics of the patient population could also partly explain the disappointing success rate. In this study, no restrictions were made based on the severity of SUI and BMI whereas certain other studies leave out patients with a BMI >35 kg/m2. The differences between the "success" and "failure" population are visualized in Table 5 and do not show any significant differences in clinical characteristics.

If the population is further subdivided in specific categories (Table 6), it is shown that a BMI of 35 kg/m^2 or more is an indication for a lower success rate, but higher age (≥65) or a higher number of parities (≥3) is not related to lower rates of success. Improvement

rates in Table 6 also show that a BMI ≥35 kg/m^2 is a significant negative factor in this research population.
The 20 patients (26%) that were lost to follow-up could play a significant part in the accuracy of the evaluation as well, although their characteristics did not show any differences from the participating group.

Conclusion

The 1-year follow-up of the anti-incontinence treatment using the MiniArc single incision sling revealed a high rate of failure (56%), while showing improvement in 68%.

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