# Complications after male adjustable suburethral sling implantation

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## Abstract

***Introduction:*** *Argus suburethral sling implantation is a minimally invasive operation with the possibility to adjust the tension of the sling at any time after the procedure, which provides good treatment results for male stress urinary incontinence (SUI).*
***Aim:*** *To determine the predictive factors, the incidence, severity and timing of the onset of complications after Argus sling implantation for males with post-operative SUI.*
***Material and methods:*** *A total of 41 patients who underwent Argus sling implantation due to post-operative SUI were included. Median follow-up was 12 months. All complications were captured and graded according to severity and classified by timing of onset. Logistic regression analysis was performed to identify predictors of the most common side effects.*
***Results:*** *Overall 22 (54%) of 41 males have experienced 31 complications. Three (7%) patients have experienced only intra-operative, 16 (39%) patients only post-operative and 3 (7%) patients both intra-operative and post-operative complications. The most common intra-operative complications were bladder perforation (12%) and external iliac vein injury (5%), while post-operative complications were acute urinary retention (29%), infection (10%) and perineal pain (7%). Previous radiotherapy has significantly increased the risk of intra-operative complications, while a non-significant tendency was observed for younger age, previous androgen deprivation therapy and grade 3 SUI. In terms of severity, most post-operative complications were classified as grade 3 according to the modified Clavien-Dindo system.*
***Conclusions:*** *Argus sling implantation provides a tolerable complication rate, where acute urinary retention was the most common side effect. Previous radiotherapy significantly increases the risk of serious intra-operative complications.*

***Key words:*** *complications, urinary incontinence, treatment, male, adjustable suburethral sling.*

## Introduction

Male stress urinary incontinence (SUI) is one of the most common complications after prostate surgery. According to the literature, the incidence of SUI is up to 60% after radical prostatectomy and about 1% after transurethral resection of the prostate [1–5]. The leakage after prostate surgery has a huge negative impact on a male's physical and mental well-being [6]. The primary management of post-prostatectomy urinary leakage consists of various conservative treatment modalities, such as lifestyle changes and biofeedback, medications and physiotherapy [1, 2, 7]. Surgical approaches for male SUI treatment, including injections of bulking agents,

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insertion of inflatable balloons and implantation of synthetic slings, as well as urinary sphincters, should be considered at least 6–12 months post-operatively. Although the implantation of an artificial urinary sphincter is still considered a gold standard procedure for male SUI, due to the high costs of the procedure and a high complication rate, it has led to the development of alternative and more accessible surgical treatment modalities [7, 8].

In the 1970s Berry introduced the concept of a male sling, which was developed by Kaufman and Schaefer and resulted in a suburethral sling which is used today [9–11]. A sling implantation operation is a minimally invasive procedure with lower costs, and no manipulations with the device are needed during urination, making this procedure an attractive treatment option for SUI [12]. The results of a surgical technique using the male adjustable retropubic Argus sling were first described by Romano *et al.* in 2006 [13] and started to be used as a standard male SUI treatment procedure in our centre in 2008.

## Aim

The aim of our study was to determine the predictor factors, the incidence, severity and timing of the onset of complications for males undergoing adjustable Argus sling implantation for treatment of post-operative SUI.

## Material and methods

### Population

A retrospective descriptive study was performed on 41 males who underwent adjustable Argus sling implantation due to post-operative SUI between January 2008 and December 2019. SUI was defined as the complaint of any involuntary loss of urine on effort or physical exertion. The diagnosis was confirmed by symptoms and physical examination, including a cough test, at least 6 months after the surgery due to prostate cancer or benign prostatic disease. Urinalysis and urine culture, if needed, urogenital ultrasound with the measurement of post-void residual urine, uroflowmetry and cystoscopy with the reposition test were mandatory. Cystometry was performed only in males when mixed urinary incontinence was suspected. In individual cases, computed tomography and/or magnetic resonance imaging was performed. The indication for adjustable Argus sling implantation was SUI of grade 2 and 3. The surgery and the further follow-up afterwards at 3, 6 and 12 months and then annually was performed by a single experienced urologist. The outcome of the study was a new onset of unanticipated complications, defined as any deviation from the ideal post-operative course that was not inherent with the procedure. According to the time of onset, all complications were classified as intra-operative and post-operative. Post-operative complications were graded according to the modified Clavien-Dindo classification system [14]. The Argus sling adjustment operation performed for persistent or recurrent SUI after initial treatment was considered as a treatment efficacy outcome. Post-surgical urinary continence results were evaluated by symptoms, number of pads used per day and physical examination, including the cough test, after 6 months post-operatively as follows: completely dry (0–1 pad per day); improvement (number of pads decreased ≥ 50%) and treatment failure (number of pads decreased < 50%). To standardise reporting of surgical complications Martin criteria were used, while 10 of 10 criteria were fulfilled in our study [15].

### Surgical technique

For all patients, antibacterial prophylaxis with a single dose of intravenous cefuroxime 1.5 g and gentamicin 240 mg was applied before the surgery. Argus sling implantation was performed at the middle urethra by a retropubic approach according to the technique described by Roman (2006) [13, 16]. After insertion of needles, intra-operative cystoscopy with two different optics was performed. 12° optics were used to visualize and confirm the integrity of the urethra while 70° optics were used to inspect the urinary bladder intra-operatively. Retrograde urethral pressure and retrograde leak-point pressure were measured under the visual control using the cystoscope after implantation of the sling. Middle retrograde leak-point pressure was verified as between 25 and 40 cm $H_2O$. A bladder catheter was inserted for 48 h after the surgery. The patient's ability to void was evaluated after removal of the bladder catheter and the residual urine volume was measured.

### Statistical analysis

Descriptive statistics were used to characterise patients. The Shapiro-Wilk test was used to deter-

mine the normality of continuous variables. Continuous variables were compared by the *t*-test when normally distributed and by the Mann-Whitney *U*-test for non-normally distributed variables. Pearson's $\chi^2$ and Fisher's exact tests were used for comparison of qualitative variables, as appropriate. Logistic regression analysis was performed for the prediction of complications after the Argus sling implantation. Odds ratios and 95% confidence intervals (CI) have been calculated. Statistical analysis was performed using R version 3.4.4 (http://www.r-project.org/) and a *p*-value < 0.05 was defined as statistically significant.

## Results

The median time from prostate surgery to male adjustable Argus sling implantation was 4 (1–10) years. The clinical characteristics of the study cohort are provided in Table I. The median surgery time was 100 min (45–155 min), while the median hospitalisation time was 7 days (4–29 days). Patients who experienced any complication related to an Argus sling implantation were using a slightly greater mean number of pads per day due to SUI in comparison with patients who had not experienced compli-

**Table I.** Clinical characteristics of the study cohort

| Characteristic | All patients (*N* = 41) | Complications | | |
|---|---|---|---|---|
| | | No (*N* = 19) | Yes (*N* = 22) | *P*-value |
| Age, median (min.–max.) [years] | 70 (55–84) | 70 (59–78) | 68 (55–84) | 0.725 |
| Severity of incontinence: | | | | |
| Grade 2, *n* (%) | 32 (78.1) | 17 (89.5) | 15 (68.2) | 0.140 |
| Grade 3, *n* (%) | 9 (22.0) | 2 (10.5) | 7 (31.8) | |
| Number of pads used per day, median (min.–max.) | 3 (2–12) | 3 (2–5) | 4 (2–12) | 0.048 |
| Previous conservative treatment, *n* (%): | | | | |
| Medications | 36 (87.8) | 17 (89.5) | 19 (86.4) | NA |
| Pelvic floor training | 27 (65.9) | 10 (52.6) | 17 (77.3) | 0.115 |
| Electrostimulation | 3 (7.3) | 3 (15.8) | 0 (0.0) | 0.091 |
| Prostate pathology, *n* (%): | | | | |
| Prostate cancer | 39 (95.1) | 17 (89.5) | 22 (100.0) | 0.209 |
| Benign prostatic hyperplasia | 2 (4.9) | 2 (10.5) | 0 (0.0) | |
| Previous prostate surgery, *n* (%): | | | | |
| Open RP | 36 (87.8) | 16 (84.2) | 20 (90.9) | 0.573 |
| Laparoscopic RP | 1 (2.4) | 0 (0) | 1 (4.4) | |
| TURP | 3 (7.3) | 2 (10.5) | 1 (4.5) | |
| HoLep | 1 (2.4) | 1 (5.3) | 0 (0.0) | |
| Previous urethrotomy, *n* (%) | 8 (19.5) | 3 (15.8) | 5 (22.7) | 0.703 |
| Previous radiotherapy, *n* (%): | | | | |
| External | 4 (9.8) | 1 (5.3) | 3 (13.6) | 0.610 |
| Brachytherapy | 1 (2.4) | 0 (0.0) | 1 (4.5) | |
| Previous tape implantation, *n* (%) | 1 (2.4) | 0 (0.0) | 1 (4.5) | NA |
| Previous androgen deprivation therapy, *n* (%) | 4 (9.8) | 1 (5.3) | 3 (13.6) | 0.610 |

*HoLep – holmium laser enucleation of the prostate, max. – maximum, min. – minimum, N – number of patients, NA – not applicable, RP – radical prostatectomy, SD – standard deviation, TURP – transurethral resection of the prostate.*

cations (3.3 vs. 4.5, $p = 0.048$; Table I). Other baseline clinical and demographic characteristics were well balanced between patients with and without complications (all $p > 0.050$; Table I).

Overall 22 (53.7%) of 41 males have experienced 31 complications with the median follow-up of 12 months (6–108 months). Three (7.3%) patients have experienced only intra-operative, 16 (39.0%) patients only post-operative and 3 (7.3%) patients both intra-operative and post-operative complications. Six (14.6%) patients have experienced multiple complications. The incidence rates of complications and their severity are detailed in Table II.

On univariate logistic regression analysis previous radiotherapy to the prostate significantly increased the risk of intra-operative complications (OR = 16.5, $p = 0.010$), while a non-significant difference was observed for younger age (OR = 0.86, $p = 0.068$) and previous treatment with androgen deprivation therapy (OR = 8.25, $p = 0.062$). A non-significant tendency to have a higher risk of multiple complications was observed in patients with previous androgen deprivation therapy and grade 3 SUI (OR = 6.21, $p = 0.070$ and OR = 4.83, $p = 0.091$, respectively) (Table III).

In 6 (14.6%) out of 41 patients, seven intra-operative complications have been registered (Table II). Isolated bladder perforation caused by the needle passing the retropubic space occurred in 4 patients. In all the cases bladder perforation was diagnosed on intra-operative cystoscopy. The needle was reinserted immediately in the right position under cystoscopy. In all the cases the urinary bladder catheter was removed on day 7 post-operatively without any further consequences; however, in 1 patient urinoma associated with previous bladder perforation was diagnosed on day 14 post-operatively due to supra-pubic pain and leakage through the post-operative wound. In 2 patients the external iliac vein was injured during the Argus sling implantation. In one of these patients the external iliac vein injury was accompanied by bladder perforation. Due to bladder perforation the needle was reinserted immediately under the visual control of the cystoscope, but the external iliac vein injury was successfully reconstructed by the vascular surgeon without using any grafts 2 h after the surgery, when symptoms of acute bleeding occurred. In the other patient the external iliac vein injury was diagnosed 1 month after the surgery on MRI and treated conservatively. Both patients who experienced an external iliac vein injury have had previous radiotherapy and urethrotomy.

In 17 (41.5%) out of 41 patients, 24 post-operative complications have been diagnosed (Table II). In 10 (24.4%) patients, 12 acute urinary retention episodes were observed. In 1 (2.4%) patient, spontaneous micturition was restored after 2 days of intermittent urinary bladder catheterisation, while in 9 (22.0%) patients a sling loosening procedure under general anaesthesia on median seventh post-operative day was performed. During the loosening procedure the washers of the Argus sling on coned columns were released per 1 or 2 cones bilaterally and tension was adjusted

**Table II.** Complications and their severity after male adjustable Argus suburethral sling implantation

| Complication | All patients, *n* (%) (*N* = 41) | Clavien-Dindo grade (*N*) |
|---|---|---|
| Intra-operative: | 7 (17.1) | NA |
| Bladder perforation | 5 (12.2) | NA |
| External iliac vein injury | 2 (4.9) | NA |
| Post-operative: | 24 (58.5) | NA |
| Acute urinary retention | 12 (29.3) | 1 (1); 3b (11) |
| Local infection | 4 (9.8) | 3b (4) |
| Perineal pain | 3 (7.0) | 2 (3) |
| Obturator nerve neuralgia | 2 (4.6) | 2 (2) |
| External iliac vein thrombosis | 1 (2.3) | 2 (2) |
| Sepsis | 1 (2.3) | 4 (1) |
| Urinoma | 1 (2.3) | 3b (1) |

*N – number of patients, NA – not applicable.*

**Table III.** Logistic regression analysis for predictors of complications after male Argus sling implantation

| Pre-operative predictor | Complications | | | |
|---|---|---|---|---|
| | Overall | Intra-operative | Post-operative | Multiple complications (≥ 2) |
| | OR (95% CI); *P*-value | OR (95% CI); *P*-value | OR (95% CI); *P*-value | OR (95% CI); *P*-value |
| Age [ years] | 0.98 (0.89–1.08); 0.722 | 0.86 (0.72–1.01); 0.068 | 1.03 (0.93–1.14); 0.553 | 0.94 (0.82–1.08); 0.404 |
| Urinary incontinence (Grade 3) | 3.90 (0.71–22.11); 0.116 | 2.00 (0.30–13.22); 0.472 | 2.08 (0.47–9.31); 0.337 | 4.83 (0.78–30.01); 0.091 |
| Previous conservative treatment: | | | | |
| Medications | 0.74 (0.11–5.01); 0.762 | 0.19 (0.02–1.48); 0.113 | 1.07 (0.16–7.22); 0.943 | 0.65 (0.06–7.01); 0.719 |
| Pelvic floor training | 3.06 (0.80–11.73); 0.103 | 2.95 (0.31–28.14); 0.346 | 3.95 (0.90–17.40); 0.070 | 2.95 (0.31–28.14); 0.346 |
| Previous RP | 2.64 (0.50–13.93); 0.254 | 0.59 (0.10–3.31); 0.545 | 1.79 (0.34–9.48); 0.491 | 0.59 (0.10–3.31); 0.545 |
| Previous urethrotomy | 1.57 (0.32–7.66); 0.578 | 2.92 (0.59–14.41); 0.366 | 2.16 (0.36–8.65); 0.189 | 2.42 (0.36–16.34); 0.366 |
| Previous radiotherapy | 4 (0.41–39.37); 0.235 | 16.5 (1.93–140.85); 0.010 | 2.36 (0.35–15.93); 0.379 | 5.33 (0.67–42.23); 0.113 |
| Previous androgen deprivation therapy | 2.84 (0.27–29.90); 0.384 | 8.25 (0.90–75.79); 0.062 | 1.47 (0.19–11.59); 0.716 | 8.25 (0.90–75.79); 0.062 |

*CI – confidence interval, NA – not applicable, OR – odds ratio, RP – radical prostatectomy.*

to achieve retrograde urethral leak pressure within 30–40 cm $H_2O$ under the visual control of 12º optics. In 4 (9.8%) patients due to persistent local infection associated with the synthetic implant and resistance to antibacterial therapy, sling removal was performed. Three (7.0%) patients suffered from moderate perineal pain and recovered after 1 month with anti-inflammatory drugs. In 2 (4.6%) patients obturator nerve injury symptoms were diagnosed, which recovered with non-steroid anti-inflammatory drugs, gabapentin and physiotherapy. In 1 (2.3%) patient, after removal of the bladder catheter a urinoma was diagnosed, which required urinary bladder suturing and repositioning of the Argus sling. In 1 (2.3%) patient sepsis was diagnosed and intensive care was required. In 1 (2.3%) patient a post-thrombotic external iliac vein syndrome was diagnosed. The blood supply of the left lower extremity was evaluated on duplex scan by the vascular surgeon, where sufficient collateral circulation was detected and no intervention was required.

In 11 (26.8%) patients 13 cases of persistent or recurrent urinary incontinence were observed post-operatively. The median number of sling adjustments per patient was 1 (1–2). All patients have undergone sling tightening operation under general anaesthesia, while in 2 patients the procedure was repeated twice. Two patients have undergone a sling tightening operation in the short post-operative period, 3 patients at 6 months and the others later than 6 months. During the sling tightening procedure two unexpected mechanical issues with the medical device have occurred, when the silicone column of the sling was torn off. The sling fixing ring was captured on the rest of the column and laid down on the anterior abdominal muscle aponeurosis.

Readmission was required in 16 (39.0%) out of 41 patients, while 4 patients were re-hospitalised more than once. The re-intervention rate was 43.9%, while 12 (29.3%) out of 41 patients were re-operated on due to post-operative complications and 11 (26.8%) due to persistent or recurrent urinary incontinence.

According to our study results, the treatment was successful in 34 (82.9%) out of 41 patients after 6 months post-operatively. The median number of pads used per day post-operatively was 2 (0–6). During the physical examination negative cough test was observed in 29 (70.7%) patients. Twenty-three (56.1%) out of 41 patients were completely dry, 11 (26.8%) patients improved, and for 7 (17.1%) patients, treatment with the Argus suburethral sling implantation failed.

## Discussion

Post-prostatectomy SUI strongly affects a male's daily activity and impairs his quality of life [6]. Various surgical approaches and devices have been offered for patients, while implantation of an artificial urinary sphincter is considered as the gold standard

procedure [17–20]. Despite high treatment success rates (59–90%) [21], the availability of this treatment method is limited due to the high cost of the device. Furthermore, the implantation of an artificial sphincter is associated with a high incidence of infection and urethral erosion, while mechanical failure of the device has also been reported [21, 22]. Considering the possible surgical complications, the likelihood of mechanical device failure and the need for active manual control of the device during urination alongside the high cost of the artificial sphincter, it is often debilitating for many patients and leads to the decision to choose another type of treatment, especially in low- and middle-income countries [21]. Suburethral sling implantation could be a reasonable option for these patients, when a minimally invasive technique with a short learning curve is required, with no need for manual manipulation of the device and substantially lower costs [23, 24]. The main advantage of the Argus sling is the possibility to adjust and loosen tension at any time after the surgery.

A recent systematic review on male adjustable slings concluded that adjustable slings are effective for the treatment of post-prostatectomy SUI with a complications rate comparable to the artificial urinary sphincter [25]. The overall complication rate after male Argus sling implantation was reported as high as 83%, where 58% of all complications were graded as grade 3 according to the Clavien-Dindo classification [26]. According to our study the overall complications rate was 54%, where grade 3 complications were also predominant.

According to the literature, bladder and urethral perforation is reported in 5–6% of patients undergoing Argus sling implantation [13, 27, 28]. According to our study, bladder perforation was detected in 12% of patients, while in 5% of patients the external iliac vein was injured. It is generally known that previous radiotherapy to the prostate and urethrotomy are associated with higher risk of complications [16, 25, 29–32]. These findings are in line with our results, where all the patients with external iliac vein injury and most of the patients with bladder injury have had previous radiotherapy and urethrotomy.

Acute urinary retention is one of the most common complications (16–35%) in patients after adjustable Argus sling implantation [26, 27]. According to our data, acute urinary retention was observed in 24% of patients, which is comparable with the results reported in the literature. To avoid excessive tension on the urethra, intra-operative assessment of retrograde leak-point pressure of 40 cm of $H_2O$ was performed for all the patients intra-operatively. Despite this, acute urinary retention was detected for a substantial number of patients.

According to other authors, 3–13% of urethral erosions were detected [13, 27, 28]; meanwhile, we have not observed any urethral erosion in our study cohort, while 4 (10%) sling removal operations have been performed due to infection. According to the literature, the male adjustable Argus sling removal rate due to infection ranges from 11% to 35% [26–28]. 9–28% of patients may suffer from perineal pain, which is related to compression or intra-operative disruption of the superficial perineal nerves [26–28]. We observed a 7% rate of perineal pain and 10% rate of obturator nerve neuralgia post-operatively, while all the patients were treated conservatively. In some rare cases sling removal due to pain was described in the literature [27].

Twenty-seven percent of patients in our study underwent a sling tightening operation due to persistent or recurrent urinary incontinence, compared to 32–39% of patients reported in the literature [27, 28]. Recurrent urgency may occur in up to 14% of patients after male adjustable Argus sling implantation [26].

The treatment success rate after male adjustable Argus sling implantation is reported between 72 and 79% after a 26–45-month follow-up period [13, 27, 28], although there are data indicating that the "dry" status remains only in 17% of patients after three years of follow-up [26]. According to our study, treatment success was observed in almost 83% of patients after 6 months of follow-up.

The main limitation of our study is its retrospective and non-randomized nature. Secondly, the relatively small study cohort could also result in inability to determine more significant predictors of complications. Thirdly, no comparison with artificial urinary sphincter or other alternative treatment options was available. Despite these limitations, the strength of the present study is that all the patients were operated on and followed up by a single experienced urologist, which allowed us to use a standardised methodology.

## Conclusions

Male adjustable Argus sling implantation provides tolerable results in terms of complications,

where acute urinary retention is the most common. Previous radiotherapy significantly increases the risk of serious intra-operative complications, such as bladder and external iliac vein perforation. This minimally invasive procedure provides high treatment success rates, but carefully selected patients are the main cornerstone for good results.

## Conflict of interest

The authors declare no conflict of interest.

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