ISSN: 2641-1687

**(9)** 

DOI: 10.32474/JUNS.2023.04.000186

# **Research Article**

# Mid to Long Term Results of Argus-T Adjustable Male Sling: Continence and Complications and Review of Literature

Javed R Burki1\* and John F Donohue2

- <sup>1</sup>Department of Urology, Medway Hospital NHS Trust, UK
- <sup>2</sup>Department of Urology, Maidstone and Tunbridge wells Hospital, UK
- \*Corresponding author: Javed R Burki, Department of Urology, Medway Hospital NHS Trust, UK

Received: 

April 17, 2023 

Published: 

April 20, 2023

#### **Abstract**

**Introduction:** Male urinary incontinence is a common condition after treatment intervention for prostate cancer and bladder outflow Obstruction. The aim of this study is to evaluate the mid to long term results of the Argus-T sling on incontinence, patient's quality of life and the associated complications.

**Methods:** Patients with ongoing stress urinary incontinence following radical prostatectomy and bladder outflow surgery were included in the study. Incontinence persisted despite conservative measures for a period of 12 to 18 months. Patients were assessed with a detailed history, bladder diary, flow test and residuals and patient reported 24-hour pad count. Argus-T adjustable sling was placed through midline perineal incision through the transobturator route.

**Results:** A total of 72 patients were included with a mean age of 66 +/- 5 years. Median follow-up was 5.2 years. All patients have been followed up for at least 3 years. The primary endpoint was padding usage. 76.5 % of patients used 0-1 pad. 50% of the patients were completely dry. Most complications happened in the early postoperative period. Three patients required explantation because of infection and one for ongoing inguinal pain.

**Conclusion:** Mid-term results for Argus-T adjustable sling as a surgical option for male patients with stress urinary incontinence after radical prostatectomy and bladder outflow surgery are encouraging.

Keywords: Argus-T; male urinary incontinence; prostate cancer

# Introduction

Prostate cancer diagnosis has been estimated at 1.4 million cases worldwide in 2020 and is the second most commonly diagnosed cancer in the male population [1]. Iatrogenic injury in association with radical prostatectomy or other bladder outlet surgeries is the most common cause of stress urinary incontinence [2]. 30 to 40% of patients who undergo prostatectomy report stress urinary incontinence. The incontinence volume and the degree of bother with incontinence can be quite variable. While most men recover with conservative measures over a period of 12 to 18 months following radical prostatectomy, persistent stress urinary incontinence can vary and is estimated at around 10% [3]. This can

adversely affect a patient's daily activities and quality of life [4]. Patients who have failed conservative measures like pelvic floor muscle exercises, lifestyle modification and biofeedback, continue to have stress urinary incontinence with an impact on quality of life are considered for surgical intervention.

The surgical treatment options include injection or bulking agents, male slings, placement of inflatable balloons and artificial urinary sphincter implantation. Over the last decades there is a large variety of bulbar urethral slings; both fixed and adjustable which are placed via trans obturator or retro public route. The short-term results of the slings are encouraging however the long-term results

are not known. The artificial urinary sphincter which is considered as a gold standard has shown favourable long-term results and has well established complication rates of infection (5%) mechanical failure and erosions (6%) and revision surgery rate of 21% and 50% within 5 and 10 years respectively [5]. The use of male slings for stress urinary incontinence has increased recently owing to the advantages of being a simpler and less invasive intervention and the lack of need for mechanical device manipulation by patients. To our knowledge there is no long-term data in a randomised clinical trial setting comparing artificial urinary sphincter to Argus-T sling. The aim of this study is to evaluate the mid to long term results of Argus-T sling on continence and complications.

#### **Materials and Methods**

### Study population

All patients included in the study were seen in the urology clinic with bothersome stress urinary incontinence. 85% of these patients had undergone radical prostatectomy. The study also included patients with stress urinary incontinence following HoLEP and TURP. Patients had undergone rigorous conservative management for at least 12 to 18 months before the procedure was offered. Patients with neurogenic bladder and urethral or bladder neck strictures were excluded from the study.

#### **Study assessments**

All patients seen in clinic with stress urinary incontinence filled a bladder diary for 3 days, performed a flow test and post void residual scan and patient reported pad count for 24 hours. All patients underwent a flexible cystoscopy and demonstrated residual sphincter function by voluntary contraction of the external urethral sphincter.

# **Argus-T system**

Argus-T system (Promedon, Cordoba, Argentina) was used in all patients which comprises of a silicone cushion attached to two silicone columns, once placed via trans-obturator route in position are held in place by two silicone rings. The sling tension is adjusted by releasing or tightening the silicone rings over the coned structure of the columns. The increased tension that the silicone cushion exerts over the urethra increases the urethral resistance.

## Surgical procedure

All the procedures were performed under general anaesthetic and patients received cefuroxime 1.5 g and gentamicin 160 mg prior to the procedure. Patients were placed in dorsal lithotomy position, shaved, prepped and draped. Urinary bladder was emptied, and retrograde leak point pressure was measured by using a simple standing column manometer and arterial line tubing attached to cystoscope as described by Bochoove-Overgauw [6]. A midline perineal 6 cm incision was performed and deepened through the fatty tissue till the bulbospongiosus muscle. Blunt dissection was then carried out towards the obturator foramen. The insertion of

adductor longus tendon was identified bilaterally and a small skin incision was made bilaterally 1 cm lateral and below the tendon. Argus-T placement needles were introduced through these small incisions, directed towards obturator foramen, and guided by the surgeon's finger. Silicone columns were attached and pulled back so that the silicone cushion lies snuggly over the bulbar urethra. Silicone rings were placed over the columns and tension was adjusted to achieve retrograde leak point pressure of 35 cm H2O after performing a cystoscopy [7]. A 16 French catheter was left in situ and the perineal and skin incisions were closed in layers. The catheter was removed the next day and patients were advised to mobilize and perform a flow test and post void residuals. They were assessed for sling adjustment and subsequently followed up in the continence clinic.

#### Results

A total of 81 patients underwent the procedure of which complete records were available for 78, which were included in the study. The mean age of patients was 66 +/- 5 years. All patients had failed conservative management over a period of at least 12 to 18 months following radical prostatectomy or bladder outlet surgery. All patients had used incontinence pads with a median of 6.2 (2-14) pads per 24 hours. Some patients were using a Conveen sheath in conjunction with pads when going out for long period. The mean retrograde leak point pressure prior to sling placement was 18.2 which increased to 37.5 after the procedure. The median follow-up time was 5.2 (3-10.8) years. 76.5% of patients reported the need for 0 to 1 pad per 24 hours. 36 patients (50%) were fully continent. Sling tension re-adjustment was performed in thirty- patients (41.6%). Of these 6/72 (8.3%) required a second sling tension re adjustment for incontinence. All patients had successful initial or subsequent trial without catheter.

Complications were seen during the first 6 months. This included UTI in 11.1 %. Perineal pain was reported in 41% percent of patients and a vast majority resolved with analgesics except one prolonged pain more than 6 months requiring explantation. Three patients had infections around the sling in the first 3 months and were treated with antibiotics and explantation. The silicone column in one patient snapped during second re adjustment and the sling was replaced. The explantation rate was 5.5 %. Two patients reported denovo OAB symptoms more than 6 months after sling placement. One patient required delayed sling readjustment after 4 years due to excessive weight loss. With this exception there was no change in pad requirement during the follow-up period. No urethral erosion was identified.

#### Discussion

This data suggests that Argus-T sling placement for stress urinary incontinence following radical prostatectomy and bladder outlet surgery leads to improvement in terms of pads use for incontinence, which remains mostly sustained over the duration of this study. To our knowledge there is no long-term head-to-head

results of a randomised controlled trial available for Argus-T sling versus an artificial urinary sphincter which is considered a gold standard. However, the long-term results for artificial urinary sphincter are well known as mentioned previously. Short term results of Argus-T sling reported previously have been encouraging with additional advantage of being able to adjust the sling, a less invasive procedure and patient preference for lack of need for the patient to manipulate the implant and maintenance of physiological voiding [8]. A few fixed and adjustable slings are being used for stress urinary incontinence. A systematic review and meta-analysis by Chen et all reported a cure rate of 60% for all types of slings [9]. More recently a systematic review of surgical treatment for post prostatectomy incontinence suggested preferential use of adjustable slings for those with mild to moderate incontinence and those who cannot or do not wish to have an artificial urinary sphincter [10].

We reviewed our Argus-T sling results in addition to review of literature in order to evaluate the results and complications of Argus-T sling in the mid to long term. A systematic search on Medline and Embase was conducted. Search was restricted to English language, duplicates and abstracts were removed. All studies related to Argus-T sling were reviewed by two authors independently and studies with follow-up of 22 months or more were included. All patients had mild to severe stress urinary incontinence and were treated with Argus-T sling placement. Studies were a series of prospective cases. The Argus-T arm results of a comparative multicenter analysis of Argus vs Argus-T were excluded because of small number, high radiotherapy rates (37.5%) and sling being used as salvage procedure (40.6%) [11]. The longest follow-up has been reported by Casteleijn et al at 5 years [12]. This was a prospective study of 78 patients with stress urinary incontinence following radical prostatectomy and a median follow-up of 38.4 months. He reported results of zero pads per day, more than 90% improvement on more than 50% improvement in incontinence. 26 patients completed 5 years of follow-up and 53% were dry and 71.5% had more than 90% improvement.

Sling explantation rate was 6.4%, of which two cases required reimplantation because of delayed silicone column transection after 2 and 3 years. Romano et al reported results of prospective study of 36 patients with stress urinary incontinence (mild to moderate 22% severe 78%) with a follow-up of 45 months [13]. Cure was defined as zero pad usage with a cure rate of 66%. He reported adjustment rate of 19.4% with explantation rate of 10.4%. Bauer et al has reported results of prospective study of 42 patients with stress urinary incontinence, using 7.1 pads per day with a follow-up of 28.8 months [14]. He defined cure as zero pads per day with a cure rate of 61.9%. He reported adjustment at 1.7 and an explanation rate of 4.8%. Siracusano et al has reported results of prospective study of 182 patients with stress urinary incontinence (mild 11.6%, moderate 52.7%, severe 35.8%) with a follow-up of 22 months [15]. Cure was defined as 0 to 1 pad, with a cure rate of

33%. He reported adjustment rate of 30% and an explanation rate of 9.3%. A collective review of our data and the aforementioned papers highlights the quality of evidence and small sample sizes. In addition, there is a variation and description of incontinence and definition of cure.

Allowing for these limitations a collective sample of 332 patients (range 36 to 182) over a mean follow-up period of 39.3 months (range 22-62.4), shows a mean cure rate of 61.78% (range 33% to 76.5%). The result from our data is compatible with the cure rates reported in the literature previously. Sling tension adjustment has been variably reported from 19.4% to 50% and 1.7 times. The authors have reported a case of silicone column breakdown during sling tension re adjustment, as two instances by Casteleijn et al however it was not clear if the column breakdown was spontaneous or during tension re adjustment. Sling explantation rate has been reported between 3% to 10.4% with a mean of 6.6%. Early complications of transient perineal pain and urinary retention were comparable to previous literature reports. Current data supports sustained results for Argus-T sling in the midterm with acceptable explantation rates. There is however a lack of strong evidence to support these results in the long term. The study has limitations in terms of sample size, design and being performed in a single centre. In addition, it focuses on one of the many slings used in practice- this being due to authors experience with the device. These limitations should be considered when designing future prospective studies on the subject.

## Conclusion

The evidence to support long term outcomes of Argus-T sling implantation is sparse, however in the midterm, given the limitations of sample size and study design continence rates and low explantation rates are encouraging.

## References

- Culp MB, Soerjomataram I, Efstathiou JA, Bray F, Jemal A (2020) Recent Global Patterns in Prostate Cancer Incidence and Mortality Rates. Eur Urol 77(1): 38-52.
- Bauer RM, Bastian PJ, Gozzi C, Stief CG (2009) Postprostatectomy incontinence: all about diagnosis and management. Eur Urol 55(2): 322-333.
- Herschorn S, Bruschini H, Comiter C, Grise P, Hanus T, et al. (2010) Surgical treatment of stress incontinence in men. Neurourol Urodyn 29(1): 179-190.
- Sanda MG, Dunn RL, Michalski J, Sandler HM, Northouse L, et al. (2008) Quality of life and satisfaction with outcome among prostate-cancer survivors. N Engl J Med 358(12): 1250-1261.
- Comiter CV, Dobberfuhl AD (2016) The artificial urinary sphincter and male sling for postprostatectomy incontinence: Which patient should get which procedure? Investig Clin Urol 57(1): 3-13.
- Bochove-Overgaauw DM, Schrier BP (2011) An adjustable sling for the treatment of all degrees of male stress urinary incontinence: retrospective evaluation of efficacy and complications after a minimal followup of 14 months. J Urol 185(4): 1363-1368.

- 7. Romano SV, Metrebian SE, Vaz F, Muller V, D'Ancona CA, et al. (2006) An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial. BJU Int 97(3): 533-539.
- Kumar A, Litt ER, Ballert KN, Nitti VW (2009) Artificial urinary sphincter versus male sling for post-prostatectomy incontinence--what do patients choose? J Urol 181(3): 1231-1235.
- 9. Chen YC, Lin PH, Jou YY, Lin VC (2017) Surgical treatment for urinary incontinence after prostatectomy: A meta-analysis and systematic review. PLoS One 12(5): e0130867.
- 10. Kretschmer A, Hübner W, Sandhu JS, Bauer RM (2016) Evaluation and Management of Postprostatectomy Incontinence: A Systematic Review of Current Literature. Eur Urol Focus 2(3): 245-259.
- 11. Loertzer H, Huesch T, Kirschner-Hermanns R, Anding R, Rose A, et al. (2020) Retropubic vs transobturator Argus adjustable male sling: Results from a multicenter study. Neurourol Urodyn 39(3): 987-993.

- 12. Casteleijn NF, Cornel EB (2021) Argus-T adjustable male sling: A followup study on urinary incontinence and patient's satisfaction. Neurourol Urodyn 40(3): 802-809.
- 13. Romano SV, Huebner W, Rocha FT, Vaz FP, Muller V, et al. (2014) A transobturator adjustable system for male incontinence: 30-month follow-up of a multicenter study. Int Braz J Urol 40(6): 781-789.
- 14. Bauer RM, Rutkowski M, Kretschmer A, Casuscelli J, Stief CG, et al. (2015) Efficacy and complications of the adjustable sling system ArgusT for male incontinence: results of a prospective 2-center study. Urology 85(2): 316-320.
- 15. Siracusano S, Visalli F, Favro M, Tallarigo C, Saccomanni M, et al. (2017) Argus-T Sling in 182 Male Patients: Short-term Results of a Multicenter Study. Urology 110: 177-183.



This work is licensed under Creative Commons Attribution 4.0 License

To Submit Your Article Click Here: Submit Article

**DOI:** 10.32474/JUNS.2023.04.000186



# Journal of Urology & **Nephrology Studies** Assets of Publishing with us

- Global archiving of articles
- Immediate, unrestricted online access
- Rigorous Peer Review Process
- Authors Retain Copyrights
- Unique DOI for all articles