Prevalence of chronic pain following suburethral mesh sling implantation for post-prostatectomy incontinence

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Abstract

Purpose: To evaluate postoperative pain and complications following AdVance™/AdVance™ XP male sling implantation.

Materials and Methods: A multi-center retrospective medical notes review of patients implanted for bothersome post-prostatectomy incontinence was conducted. All patients were telephoned to provide further information on pain or further complications related to their surgery. Statistical evaluation utilized logistical regression analysis. Additionally, a literature review was conducted reviewing pain outcomes following AdVance™/AdVance™ XP implantation.

Results: One-hundred and twenty-seven men were reviewed over an 8-year period. The mean age was 70 years, with mean follow up 52 months. Of those with mild stress urinary incontinence, 45 (79%) had a successful outcome compared to 42 (72%) in the moderate group. Twenty-nine (23%) men reported postoperative pain, with a mean maximal pain score of 6 (range: 0–10). The majority of pain resolved within 4 weeks (19/29 men). A further seven patients resolved by 3 months. Only three men (2.3%) had chronic pain greater than 3 months, which all resolved by 1 year. Men less than 65 years were more likely to suffer pain (p = 0.009). Acute urinary retention occurred in 23 (18%) men and correlated significantly with postoperative pain (p = 0.04). Overactive bladder symptoms, severity of incontinence or radiotherapy were not correlated with postoperative pain. In our cohort, there were no extrusions, divisions, or explantations.

Conclusion: Approximately a quarter of men experience pain in the early postoperative period. However, the severity and rates of chronic pain (>3 months) are low (2.3%) but all settle within a year.

KEYWORDS
male sling, pain, post-prostatectomy, suburethral sling, urinary incontinence
1 | INTRODUCTION

In 2018, the UK paused the use of vaginal mesh to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP) due to increasing reports of severe and sometimes life-altering complications, including extrusions and chronic pain. In the USA, the Food and Drug Administration banned all transvaginal synthetic mesh for POP and raised the risk classification for management of female SUI. It has been widely acknowledged that there is a lack of long-term efficacy and safety data with female mesh implants. Two studies reported pain in 6.4% and 13% of women at 7 and 10 years follow up, respectively, following mesh insertion. UK Health Episodic Data has shown a 9.8% complication rate within 5 years, with most occurring within the first 2 years postoperatively. However, there has been little robust long-term safety data for the use of synthetic mesh implants for male SUI.

The male sub-urethral sling is a less invasive alternative for mild to moderate SUI than the artificial urinary sphincter (AUS) (Boston Scientific). There are both fixed and adjustable types, with the most common being the transobturator retropubic AdVance™XP (Boston Scientific), which has been implanted into 70,000 men worldwide. This was introduced as the AdVance™ system in 2007. The mechanism of action is proposed to be distinct from female mesh implants. It works by repositioning the urethral sphincter proximally, increasing the functional urethral length and allowing the sphincter a backboard to co-apt against. This may provide less compression but more dynamic support.

In a recent meta-analysis of 64 studies including 72 patient cohorts implanted with several types of both fixed and adjustable male slings, pain was the most common complication. In total, 37 (1.3%) out of 2887 who had a fixed male sling, and 17 (1.5%) out of 1116 whom had an adjustable sling suffered with chronic pain that persisted after 3 months. The severity, management and duration of pain were not always reported. Twenty studies were found to mention pain outcomes from AdVance™/AdVanceXP™ systems as a secondary outcome but most studies did so with minimal detail and with only short to medium term follow up. In light of the recent controversy around female mesh implants, we analyzed male sling pain outcomes and complications from three tertiary referral centers and in addition reviewed the literature on the subject.

2 | MATERIALS AND METHODS

All men were offered a male sling as alternative to an AUS after at least 12 months of conservative therapy. This included pelvic floor exercises and pharmacological treatment for overactive bladder (OAB) symptoms if present.

We retrospectively reviewed the medical notes or electronic record of all men who had an AdVance™/AdVance™ XP implantation at each center. Data on demographics, surgical history, functional outcomes, complications and pain outcomes at last follow up were collected. Complications including acute urinary retention (AUR), de novo OAB symptoms, as well as the procedure success rates were also collected. Mild incontinence was defined as 0–2 pads/24 h, moderate incontinence as 3–5 pads/24 h and severe incontinence >5 pads/day. Outcomes were defined using number of pads and categorized as successful (one pad or less for reassurance) or failed (two or more pads use). Patients were followed up at 3 months, 12 months and yearly thereafter. All patients were then telephoned to provide additional detail on the presence of postoperative pain, location and duration of pain, pain score (verbal rating scale 0–10) and any intervention for the pain. Patients were also asked if they had any complications since their last follow up. Table 1 illustrates the questions asked at telephone follow up. Postoperative pain was divided into acute (<4 weeks), prolonged (4–12 weeks), and chronic pain (>12 weeks). At all three institutions, implantation of the AdVance™/AdVance™ XP system was performed by standardized technique.

Statistical analysis was conducted by multiple logical regression model using Python’s statsmodels packages with Anaconda Navigator (Anaconda, 2016). Statistical significance was a $p < 0.05$.

A literature search was also performed in PubMed using keywords “AdVance™ XP,” “AdVance™,” and “Male Sling” in April 2020. The search was limited to English and those with abstracts. Articles reporting outcomes from implantation of AdVance™ XP or AdVance™ slings, in particular related to pain, were included in the discussion and formulated into Table 2. Those studies providing updates to cohorts already published, the latest version was included for review.

All studies were registered with their local audit department.

3 | RESULTS

Over an 8-year period, 127 men had implantation of AdVance™/AdVance™ XP system across the three institutions (mean age 70 years). Nine men were previously excluded as they were uncontactable for follow up. Center 1 implanted 40 men, 62 men in center 2 and 25 men in center 3. Table 3 shows baseline characteristics of our cohort. The mean follow up was 52 (range: 3–112)
months. The majority had SUI following radical prostatectomy (97%), whilst 12% had prior pelvic radiotherapy. Eighty-nine (70%) patients had documented pad weights that averaged 238 g/24 h (range: 5–3000 g).

### 3.1 Functional outcomes

Of the group with mild SUI, 45 (79%) had a successful outcome compared to 42 (72%) in the moderate group. Only three patients (60%) had a successful outcome in the severe incontinence group.

### 3.2 Postoperative pain

In total 29 (23%) men reported postoperative pain, with center 1 encountering 12 (30%), center 2 had 13 (20%) and center 3 had 4 (16%). In 19/29 men (66%) this pain resolved within 4 weeks, whereas in 7 men (24%) it resolved within 3 months. There were 3 men (10%) where pain persisted beyond 3 months. Chronic pain was thus observed in the whole cohort in 3 out of 127 patients (2.3%) all of which resolved within 1 year. Pain scores were collected in 22 of the 29 men with a mean maximal postoperative pain score of 6 (range: 0–10). The most common location was the perineum (n = 16), followed equally by the groin and scrotum (n = 5 each). A further two experienced abdominal and one reported penile base pain. Patients were treated with simple analgesia only, except 4 who required codeine-based medication. Of those with previous radiotherapy only two men reported postoperative pain (13%) compared with 27 (24%) of those in the non-radiotherapy group, this was not statistically significant (p = 0.2). Men aged less than 65 years were significantly more likely to suffer from postoperative pain than their older counterparts (p = 0.009). Severity of incontinence did not predict pain outcome (mild incontinence p = 0.42 and moderate incontinence p = 0.9).

### 3.3 Acute urinary retention

Twenty-three (18%) men suffered AUR following sling implantation on their first postoperative day after catheter removal. The maximum duration of indwelling catheter was 6 weeks postoperatively (median 7 days; range: 2–42 days). Nine men converted to clean intermittent self-catheterization (CISC) with normal voiding re-established by 8 weeks in 7. One man required intradetrusor onabotulinumtoxin A therapy for persistent OAB symptoms and became CISC dependent thereafter. One man performs clean intermittent self-dilation for previous stricture disease. AUR correlated significantly with the presence of sling-related postoperative pain (p = 0.04). The functional success rate for those with AUR was 89% compared with 76% in the non-AUR cohort. However, this was not statistically significant (p = 0.268).

### 3.4 Overactive bladder symptoms

Forty-one men suffered with OAB pre-operatively whilst 18 (14%) men developed de novo OAB symptoms. Forty-nine patients were managed successfully with medications, with one declining further management. Eight patients, two with de novo and six with pre-existing OAB, went on to have intradetrusor onabotulinumtoxin A for refractory
| Paper                  | Year | Number of men | Sling (AdVance™ or AdVance™ XP) | Mean follow up (months) | Mean pain score (VAS/VRS at peak) | Location                    | <3 Months, N (%) | >3 Months, N (%) | If duration not stated, N (%) |
|-----------------------|------|---------------|---------------------------------|-------------------------|----------------------------------|-----------------------------|------------------|-----------------|-----------------------------|
| This study            | 2020 | 127           | AdVance™XP                      | 52                      | 6                                | Perineal, Scrotum, Groin, Abdomen, Penis | 26 (20)          | 3 (2.30 All resolved by 52 weeks) | -                           |
| Barnard et al.¹       | 2014 | 46            | AdVance™                        | 12                      | -                                | Perineal                     | 8 (17)           | 1 (2)           | -                           |
| Bauer et al.²         | 2015 | 115           | AdVance™ XP                     | 36                      | 0.6                              | -                            | -                | -               | -                           |
| Berger et al.³        | 2011 | 26            | AdVance™ XP                     | 12                      | 3                                | Perineal                     | 4 (19.2)         | -               | -                           |
| Collado et al.⁴       | 2017 | 94            | Both                            | 49                      | -                                | Perineal-scrotal              | -                | -               | 5 (5.3)         |
| Cornel et al.⁵        | 2010 | 36            | AdVance™                        | 12                      | 2.8                              | -                            | 36 (100)         | -               | -                           |
| Cornu et al.⁶         | 2014 | 236           | Both                            | 21                      | -                                | Perineal                     | -                | -               | AdVance™ (5) AdVance™ XP (2) |
| Grabbert et al.⁷      | 2019 | 115           | AdVance™ XP                     | 48                      | 0.5                              | -                            | All resolved      | -               | -                           |
| Husch et al.⁸         | 2018 | 294           | Both                            | AdVance™ 34 AdVance™ XP 52 | 0.4                              | Perineal, Genitals, Symphysis, Groin | -                | -               | AdVance™ 2 (1.8) AdVance™ XP 3 (1.6) |
| Kowalik et al.⁹       | 2015 | 30            | AdVance™                        | 39                      | -                                | -                            | -                | -               | 2 (6)           |
| Li et al.¹⁰           | 2012 | 66            | AdVance™                        | 24                      | -                                | -                            | -                | -               | 3 (5)           |
| Meuller et al.¹¹      | 2012 | 32            | AdVance™                        | 9                       | -                                | -                            | -                | 1–sling explanted | -                           |
| Rehder et al.¹²       | 2012 | 166           | AdVance™                        | 36                      | -                                | Perineal                     | 78 (50%) Resolved at 6 months | -               | -                           |
| Serra et al.¹³        | 2013 | 61            | Both                            | 28                      | -                                | Perineal                     | 5 (8)            | -               | -                           |
| Strum et al.¹⁴        | 2013 | 95            | AdVance™                        | 30                      | -                                | Pelvic                       | -                | -               | 3 (3)           |
| Sullivan et al.¹⁵     | 2018 | 77            | AdVance™                        | 6                       | -                                | Perineal                     | 4 (5)            | -               | -                           |
| Torrey et al.¹⁶       | 2013 | 37            | Advance™                        | 17                      | -                                | Scrotum lower extremity      | -                | -               | 7 (19) 4 (11) |
| Wright et al.¹⁷       | 2017 | 52            | Advance™                        | 92                      | -                                | -                            | -                | -               | 5 (10)          |

*(Continues)*
symptoms. One patient had a partial response to posterior tibial neurostimulation. OAB was not correlated with the presence of postoperative pain (p = 0.324). Eleven (23%) men who had pre-existing OAB were found to have resolution of symptoms following sling implantation.

### 3.5 | Sling related complication

There were no sling extrusions, divisions, or explantations during the mean 52 (3–112) month follow up.

### 3.6 | Further complications

Four men suffered with recurrent urinary tract infections, with one patient awaiting laser excision of an eroded prostatectomy suture at the vesico-urethral anastomosis. One patient suffered a scrotal hematoma. One patient had antibiotics for a wound infection.

### 3.7 | Further surgery

Fourteen men went on to have an AUS, with a further one offered but declined. Another patient went on to receive an adjustable transobturator male system sling.
4 | DISCUSSION

The Independent Medicine and Medical Review Safety Review Group in the UK has reported on female pelvic mesh use. It makes note of the lack of long term follow up and subsequent likely under-reporting of pain and complications following implantation. The concern has also involved the use of male mesh implants. The differences in pelvic anatomy and theoretical modes of action of the male sling have been debated. More detailed data on pain and complication rates in male slings is required.

The lack of a central register for woman with mesh implants may have led to under-reporting of complication data. At our institutions, we keep a prospective database of all patients implanted with AdVance™/AdVance™ XP slings and we build on our outcomes and complications previously published. The AdVance™/AdVance™ XP sling is the most commonly used male sling in the UK and our reported success rates with AdVance™/AdVance™ XP systems for mild and moderate incontinence, 79% and 72%, respectively, are in keeping with published literature.

This study presents a mean 52 (3–112) month follow up for functional, complication and pain outcomes. This, as far as the authors are aware, represents the longest follow up data with rigorous pain outcomes for the AdVance™/AdVance™ XP male slings systems. The occurrence of postoperative pain following implantation of male slings varies considerably. Table 2 shows the reported data on pain outcomes in the AdVance™/AdVance™ XP systems within the literature. Eleven of the studies provided no insight into the duration of the pain, with only five reporting pain scores. The rate of pain varied from 1.6% to 100% immediately following surgery. The wide variation in postoperative pain incidence is evidenced by the following two studies; Husche et al. found that 1.8% and 1.2% of men with AdVance™/AdVance™ XP slings, respectively, suffered with pain, although the duration of pain is not stated, whilst Cornel et al. found that 100% of men suffered pain in the immediate postoperative period. However, all pain had resolved by 3 month follow up. Furthermore, Rehder et al. found nearly 50% of men suffered postoperative pain in the perineum. The latter two studies specifically assessed pain with either a “visual analog scale” for pain or “verbal rating scale of pain.” It is unclear how Husche et al. elicited pain outcomes and therefore a significant risk of underreporting may exist. Of those studies that reported on duration of pain only two men were found to have persistent pain lasting for greater than 6 months. Additionally, Meuller et al. reported the need to explant a sling for intractable perineal pain and sling displacement in one patient. It is not known when this occurred after surgery or if it resolved the pain and follow up was only 9 months. There are significant numbers of series where duration of pain was not reported. The majority reported post sling pain resolved within 6 months following surgery. In our cohort, all patients were pain free at 1 year. Indeed, the majority of pain resolved within the first 4 weeks. Only three (2.3%) suffered with chronic pain, which all resolved at 1 year. This is data that can be used to appropriately counsel patients pre-operatively.

Although AUR did not predict a more successful continence outcome in our data, it did show significance with men suffering postoperative pain ($p < 0.05$). The reasons for this association are not clear. It is possible that pain perception may be associated with the use of indwelling or intermittent catheterization. The pathophysiology of pain in those with temporary retention in our view could be related to the tape tension and the degree of invagination of the bulbar spongiosus. The degree of postoperative bleeding, edema or inflammation may also contribute to the pain response. Additionally, poor tissue handling and excessive tissue cautery cannot be underestimated in its impact on postoperative pain.

In this study, age has been shown to be the most significant predictive factor for postoperative pain, with those aged less than 65 years significantly more likely to suffer postoperative pain ($p < 0.01$). It is difficult to explain this from a physical perspective. We know that younger men suffer more from a distress effect following radical treatment for prostate cancer. A study reported increase distress effect from urinary, bladder, and sexual dysfunction at a younger age, with anxiety being a key factor. These factors may contribute to the subjective experience of pain postoperatively.

The management of pain is poorly reported but, in our cohort, all were treated with oral medications (paracetamol/NSAIDs or codeine). Berger et al. describes the use of bupivacaine injections to the perineum in five (19.2%) patients for immediate postoperative pain. All pain resolved spontaneously by 4 weeks. Only five studies reported pain scores, that were all low (0.3–3). Although not always stated, these pain scores may well have been reported at first follow up, that is, 3 months. Pain scores are more useful if the time point that the pain occurred is known. This study found a higher mean maximal pain score of 6 (out of 10). This may be due to obtaining the pain score at the time the patient had maximal pain, rather the pain score at a dedicated time point.

The most common location of pain is around the incision in the perineum followed by the groin and more
rarely the scrotum. This is replicated within our data. Interestingly, one study found lower limb pain in 11% of men, which was not found in this or in other studies.15

Previous radiotherapy has been shown to correlate with poorer continence outcomes.15 However, our analysis has shown that radiotherapy does not appear to predict pain postoperatively although this may be due to our relatively small cohort of men that underwent radiotherapy (n = 15).

A previous study found that 16 out of 35 men failed their initial trial without catheter. These patients had a significantly higher dry rate compared to those that passed their first trial without catheter (100% and 26%, respectively).16 Our study did not find a relationship between AUR and success.

In our cohort whilst 14% developed de novo OAB, the majority of those who required non-medication management (e.g., onabotulinum toxin A) were those with pre-existing OAB. Eleven men who had OAB pre-operatively found this resolved following implantation of the sling.

With over 4 years follow up, it is important to note that our institutions have not experienced any sling exposure or extrusion. This is in comparison to the 7% exposure/extrusion rate reported for vaginal mesh implants at 10 years of follow-up.2

The major limitation of this study is its retrospective nature. Although both medical notes and telephone follow up were used, recall bias may affect the veracity of subjective measures, such as pain scores. Furthermore, we did not assess patients for the presence of pelvic pain pre-operatively. Nine patients were unable to be contacted and lost to follow up.

5 | CONCLUSION

There is still a lack of long-term prospective data regarding complications and pain outcomes with the AdVance™/Advance™ XP slings. However, this study has shown that rates of persistent postoperative chronic pain are low (2.3%) and in this cohort no cases of mesh extrusions were reported with medium term follow up. The male sling is a valuable management option for male SUI, and prospective registries should continue to collect data on pain and complications.

CONFLICT OF INTERESTS

Arun Sahai, Sachin Malde, and Findlay MacAskill have received an unrestricted educational grant by Boston Scientific.

AUTHOR CONTRIBUTIONS

Arun Sahai contributed to conception and design. Findlay MacAskill, Kieron Sheimar, Denossshan Sri, and Bogdan Toia contributed to acquisition of data. Findlay MacAskill, Sachin Malde, and Arun Sahai contributed to drafting manuscript. Arun Sahai, Sachin Malde, Jeremy Ockrim, Jai Seth, Tamsin Greenwell, Davendra Sharma, Claire Taylor, and Rizwan Hamid contributed to critical revision. Findlay MacAskill contributed to statistical analysis.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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**SUPPORTING INFORMATION**

Additional Supporting Information may be found online in the supporting information tab for this article.

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