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A 10-Year Audit of Penile Prosthesis Insertion

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Abstract

Introduction

Penile prosthesis (PP) insertion is the gold standard surgical treatment option for men with refractory Erectile Dysfunction (ED). PP insertion is considered effective but has a well-documented array of complications. Our aim was to assess outcomes following single-surgeon insertion of PP for ED within an Irish cohort.

Methods

Following review of the Hospital In-Patient Enquiry (HIPE) system, a retrospective chart review of all patients who underwent PP insertion over a 10-year period from 2008-2017 inclusive was performed, and an electronic database was analysed for results.

Results

One-hundred-and-eleven PPs were inserted in 96 patients. The most common aetiology for ED in our cohort was post-prostatectomy, affecting 25 (26%) patients. The most frequently implanted device was a 3-piece inflatable PP (3p-IPP) (AMS 700^{TM}; American Medical Systems Inc., Minnesota, USA) and the peno-scrotal approach was utilised in the majority of patients (86, 77.5%). No intraoperative complications were recorded. Twelve (12.5%) patients developed peri-operative complications. Thirteen (13.5%) patients required device revision, the majority for device failure. Of the 71 patient satisfaction responses, 61 (85.9%) patients were satisfied with their PP.

Conclusions

This single-surgeon retrospective audit of PP surgery demonstrates complication rates in-line with internationally published data. Patients should be adequately counselled regarding possible complications, including device failure and erosion. PP insertion should be considered for suitable patients with refractory ED.

Keywords: Penile prosthesis, erectile dysfunction, penis surgery.

Introduction

The community prevalence of ED in the general male population is estimated to be in the region of 40% for those aged 40, and 70% for those aged 70[1.] Despite the availability of medical therapies, including oral phosphodiesterase type 5 inhibitors and intraurethral, topical or intracavernosal alprostadil, implanted penile prostheses (PP) remain a very relevant treatment option, as many men become refractory to medical therapy or seek a more effective and permanent therapy.

PPs are also a useful treatment adjunct in men who have significant penile curvature or fibrosis, men with priapism who have not responded to initial therapies, along with those who have phalloplasties and in some renal transplant patients[2,3].

Since their initial appearance in 1970, significant progress has been made in improving the reliability and quality of devices, and in making them more user-friendly. This, coupled with greater surgical experience and techniques to reduce infection rates and operative time, means improved patient outcomes[4,5]. There is international evidence demonstrating that PPs are efficacious, safe and result in good patient satisfaction levels[6-8],, although little has been published within an Irish population. The European Association of Urology Guidelines apply a strong rating for its recommendation of offering PP (if other treatments fail or based upon patient preference)[9]. The current American Urological Association guidelines also advise strongly that men with ED should be informed of the option of PP implantation[10].

Patient selection is a key component to successful outcomes; the patient must be well-motivated, with reasonable manual dexterity (especially for an inflatable device) and must be made aware of the potential complications and limitations of surgery[11].

A range of PPs are available on the international market, but there are no head-to-head studies that demonstrate superiority of one implant over another[12]. The three-piece inflatable penile prosthesis (3p-IPP) is considered the gold standard by many urologists and has the highest patient satisfaction rating[2,13] – this consists of an abdominal reservoir, a scrotal pump and dual cylinders placed in the corpus cavernosa. Semi-rigid, or malleable prostheses are also useful in more complex patient cohorts[13]. The main producers of inflatable protheses at present are Boston Scientific, who in 2015 acquired American Medical Systems (AMS) [AMS Inc, Minnesota, USA]. They produce a two-piece inflatable device (AMS Ambicor™) and a number of three-piece inflatable devices (e.g. AMS 700 CX ™; AMS 700 LGX ™; AMS 700 CXR ™). Coloplast (Humlebæk, Denmark) also produce three-piece inflatable devices (Titan ™; Titan OTR NB ™; Titan Zero Degree ™), as do Zephyr (Zephyr Surgical Implants, Switzerland) who produce the ZSI 475 ™. Semi-rigid devices frequently used include AMS Spectra™, AMS Tactra™, Coloplast Genesis™, and the Zephyr ZSI 100™.

In this study, we report a single-surgeon, single-centre 10-year experience of PP insertion.

Methods

A retrospective chart review of all patients who underwent PP insertion in a single tertiary-referral public teaching hospital was performed over the 10-year period from 2008-2017 inclusive. The Hospital In-Patient Enquiry (HIPE) system was utilized to obtain a register of patients who underwent PP surgery. In addition, theatre lists for the 10-year period were obtained, retrospectively reviewed and cross referenced to HIPE data. An electronic database was then analyzed for results. Of note, the principal surgeon in this study also performs this procedure in 2 additional private institutions, but the study was performed solely in this single public institution.

Each procedure was carried out in a similar manner. With insertion of 3p-IPP, the most frequently used device in our cohort, the following surgical steps were followed.

Pre-operatively, the patient has skin swabs and urine analyzed to out rule significant contamination or infection. They have a full medical work-up to ensure they are infection free systemically, paying particular heed to their cutaneous and urinary systems. The morning of their procedure, patients have a full body wash on the ward with Chlorhexidine Gluconate 4% weight/volume (w/v) cutaneous solution. They receive Gentamicin and Vancomycin (as per local microbiology protocol) intravenously on induction of anesthesia, and PP cases are performed as the first operation of the day. Lower abdominal and pubic hair is shaved, and patients undergo a further 10-minute pre-operative scrub with Chlorhexidine Gluconate 4% w/v cutaneous solution. Theatre traffic is minimized. When possible, a representative from the medical device company attends the procedure to aid with the device preparation. Surgeons use double-gloving and a non-touch technique. A catheter is inserted to allow urethral identification and to decompress the bladder. A penoscrotal (or infrapubic) approach is taken and operative time is minimized where possible. Meticulous hemostasis is ensured to reduce the risk of hematoma and infection, and therefore, no blind dissection is performed. The corpus spongiosum is laterally retracted and dissection through Dartos/Buck's fascia is performed to identify the tunica albuginea. The corpus cavernosa are incised and dilated bilaterally - proximally towards the crus and distally towards the glans. A Furlow is used to measure each corpus.

The cylinder size is then selected and components (reservoir, pump and cylinders) prepared. An antimicrobial coating is used if the patient is deemed higher risk for infection (e.g. revision procedure, immunosuppressed patient). The cylinders are inserted via each corporotomy and the reservoir is implanted by creating a defect in the transversalis fascia to the pre-vesical space. The pump is implanted in the most dependent part of the scrotum. An inflate/deflate test is then carried out, tubing connected, and a final inflate/deflate test performed. If required, the reservoir volume is adjusted at this point.

Each layer is closed, and a supportive dressing is applied with the device partially inflated. The penis is affixed to the abdominal wall overnight and the catheter is removed the following day. Patients are given verbal and written post-operative instructions, including advice to pull down on the pump in the scrotum numerous times per day, and to begin cycling the device four weeks post-operatively. Intercourse is advised from six weeks post-operatively.

The patient is seen back at the outpatient clinic for a post-operative review at 3 weeks, 6 weeks (for device activation), 3 months, 6 months and 12 months – and further reviews occur if required or on request. All patients are issued with a device identification card which they are advised to carry on their person.

Results

Over the study period, 111 PPs were inserted in 96 patients. The median patient age at time of PP insertion was 60.0 years [range: 33.4-80.2 years]. The peno-scrotal approach was used most frequently (86, 77.5%). The median length of stay for patients was 2.6 days [range: 2-5 days]. The catheter was usually removed on the first post-operative day, but patients were not discharged until they were voiding with confidence, had their pain well-controlled and were freely mobilizing.

The most frequently encountered reason for our cohort's ED was radical prostatectomy (N = 25, 26%), cardiovascular disease (N = 17, 17.7%) and diabetes mellitus (N = 15, 15.6%) [Table 1]. Ninety-six 3p-IPPs (75 AMS 700^{TM} devices and 21 Coloplast Titan^{TM} devices) and 15 semirigid prostheses (11 AMS Spectra^{TM} and 4 Coloplast Genesis^{TM}) were inserted.

No intraoperative complications were recorded. Twelve (12.5%) patients developed post-operative complications including hematoma and infection [Table 2]. Four patients developed mild transient haematuria that was presumed to be due to urethral contusion – these patients were managed by extending their catheterization period, but no further perioperative issues arose in this cohort. Thirteen (13.5%) patients required at least 1 revision procedure – 11 patients required one revision for device failure (8) or erosion/infection (3), and 2 patients required a re-revision procedure. Of these 2 patients, one developed infection of both of his first two devices and the second patient was dissatisfied with his erectile function following insertion of his malleable prosthesis but then suffered device failure of his 3p-IPP. Of note, 8 of the 13 patients (61.5%) who required a revision procedure had been fitted with the AMS 700^{TM} prosthesis, which has since been recalled due to complications resulting in device failure.

Of the 8 patients with device failure, 2 of these were felt to be due to kinking of the tubing, 1 was due to tubing becoming disconnected from the reservoir, and 1 was due to migration of the reservoir. The other 4 patients did not have the failed device component definitively recorded in their medical records.

Regarding patient follow-up, the median follow-up was 14 months. Overall patient satisfaction was reviewed in the outpatient clinic at the 6-month post-operative review. Patients were asked "How would you rate your overall satisfaction with the PP on a scale from 1 to 5 (with 1 being very dissatisfied, 2 being dissatisfied, 3 being neither satisfied nor dissatisfied, 4 being satisfied and 5 being very satisfied)?"

There were 71 recorded responses from the 96 patients in the study [Figure i]. Sixty-one (85.9%) patients were either satisfied or very satisfied overall. Three (4.2%) patients were very dissatisfied or dissatisfied with their outcome. Two of these patients had experienced device failure and the third had developed Floppy Glans Syndrome.

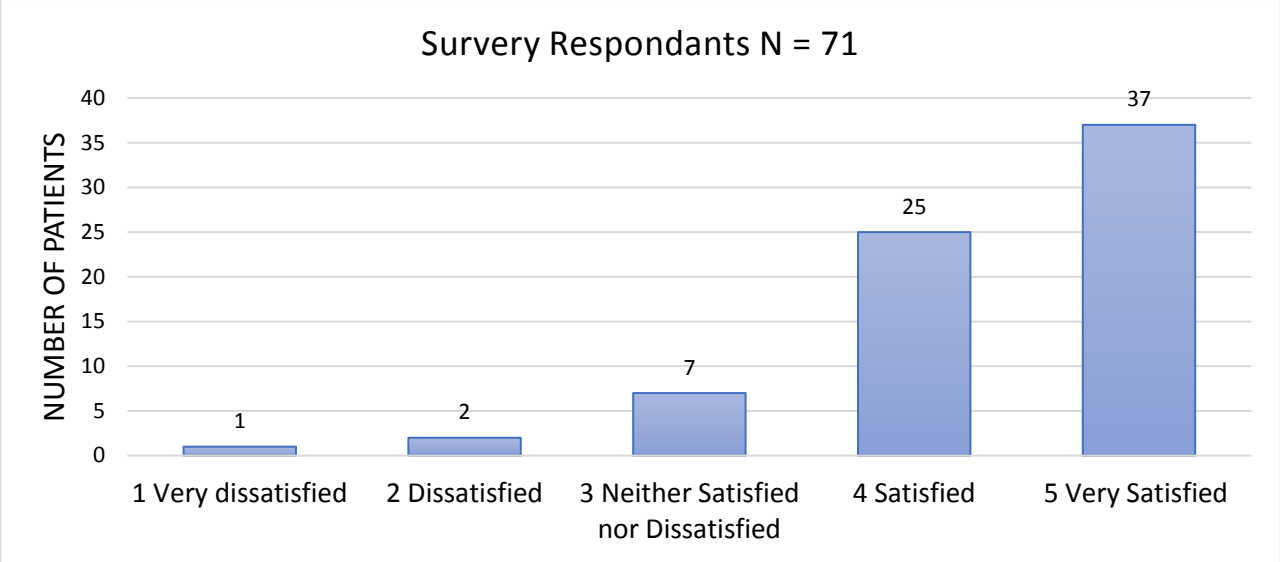
Table (1) Chief Aetiology of Erectile Dysfunction.

Chief Aetiology of ED	**Patient Numbers N=96**
Prostatectomy	25 (26.0%)
Cardiovascular disease	17 (17.7%)
Diabetes Mellitus	15 (15.6%)
Other pelvic surgery / radiation	8 (8.3%)
Neurological disease	8 (8.3%)
Priapism	5 (5.2%)
Trauma	5 (5.2%)
Other	13 (13.5%)

Table (2) Peri-operative complications by Clavien-Dindo[14] classification.

Peri-operative complications	**Clavien Dindo Classification**	**Patient Numbers**
Hematoma	IIIB (Complication requiring surgical intervention under general anaesthesia)	4
Hematuria	I (Complication deviating from normal post-operative course, not requiring pharmacological treatment)	4
Infection (superficial)	II (Complication requiring pharmacological treatment)	3
Pulmonary Embolism	IVa (Life threatening complication with single organ dysfunction)	1

Figure (3) Overall Satisfaction with Penile Prosthesis.



Discussion

The PP is a useful tool in the urologist's armamentarium when dealing with the patient with refractory ED. Intensive pre-operative and post-operative counselling is recommended, as realistic expectations need to be set, and a well-motivated patient is crucial in the rehabilitation phase post-operatively. Meticulous attention should be paid to the peri-operative period - including patient preparation, intraoperative factors and post-operative recovery in order to minimize complications.

To the author's knowledge, there have been no published series to date regarding the Irish experience at PP insertion. Challenges that our team encountered in running a PP service include difficulties in ring-fencing inpatient beds for what is considered benign, elective and expensive surgery, and difficulties in obtaining funding to acquire a psychologist and/or nurse specialist, which would greatly add to the patients' experiences and outcomes.

Our results, however, demonstrate that overall, patients are satisfied with their PP and our outcomes are in-keeping with international published literature[6-8]. In previous literature assessing Irish patient cohorts, it is clear that sexual dysfunction, particularly post cancer-surgery, poses a significant challenge for some men[15], and definitive treatments are a welcome adjunct in their treatment algorithm.

Regarding the limitations of this paper, its retrospective nature and relatively small patient numbers may have affected the accuracy of our outcomes. Ideally, we would have had a formal questionnaire that examined different domains of sexuality, such as the quality of life and sexuality with penile prosthesis (QoLSPP)[16] for each patient and their partners, and a longer median follow-up would have been preferable in order to identify late failure of devices. Also, patient cross-over from the public hospital that the procedures were performed into other institutions means that some data may not have been captured adequately.

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Declaration of Conflicts of Interest:
The authors have no conflicts of interest to declare.

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