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Original Article

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UK practice for penile prosthesis surgery: baseline analysis of the British Association of Urological Surgeons (BAUS) Penile Prosthesis Audit

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Objectives

To undertake a prospective multicentre national audit of penile prosthesis practice in the UK over a 3-year period.

Patients and Methods

Data were submitted by urological surgeons as part of the British Association of Urological Surgeons Penile Prosthesis National Audit. Patients receiving a penile prosthesis (inflatable or malleable) were included as part of a prospective registry over a 3-year period. Data were validated and then analysed using a software package (Tableau).

Results

A total of 1071 penile prosthesis procedures were included from 22 centres. The three commonest aetiological factors for erectile dysfunction were diabetes, prostate surgery and Peyronie's disease. Of the recorded data, inflatable penile prostheses were the commonest devices implanted, with 665 devices used (62.1%), whereas malleable prostheses accounted for 14.2% of the implants. Recorded intra-operative complications included urethral injury (0.7%, $n = 7$), corporal perforation (1.1%, $n = 12$) and cross-over (0.6%, $n = 6$). Known postoperative complications were recorded in 9.8% of patients (74/752), with the two most frequently reported being postoperative penile pain ($n = 11$) and scrotal haematoma ($n = 14$).

Conclusion

This baseline analysis is the largest prospective registry of penile prostheses procedures to date. The data show that, over the 3-year collection period in the UK, there are now fewer surgeons performing the procedure, together with a reduction in the number of centres. Peri-operative complications were infrequent, and the rate of implant abortion (e.g. as a result of urethral injury) was very low. Further follow-up data will be required to publish long-term outcomes and patient satisfaction.

Keywords

penile prosthesis, audit, erectile dysfunction, complications, national database

Introduction

The prevalence of erectile dysfunction (ED) in the UK was reported as 13% in the MALES study, and increases with age [1]. The Massachusett's Male Aging Study reported a prevalence of 9.6% for complete ED [2]. Aetiological factors, such as major pelvic surgery, diabetes, Peyronie's disease and cardiovascular disease, are common, although the majority of patients with ED will respond to pharmacological interventions such as oral phosphodiesterase-5 inhibitors or intra-urethral/intracavernosal prostaglandins. However, the response to pharmacotherapies will often become refractory as a result of progression in neurovascular dysfunction due to the underlying aetiology. This may be either attributable to conditions such as diabetes, vascular disease or secondary to specific events such as priapism or major pelvic surgery.

Penile prosthesis surgery offers a surgical option for men with end-stage ED who have failed pharmacological treatment options, and have attempted or exhausted mechanical options

such as vacuum erection devices. Guidance on treatment pathways and the criteria by which to select patients for penile prosthesis surgery are available to clinicians in England [3] and reflect similar guidance for both UK [4] and European practice [5].

The two main types of penile prosthesis that are available in UK practice are the inflatable (three- or two-piece) or the semi-rigid (or malleable) prosthesis. The first inflatable device was launched in 1973 and was made of a Dacron-reinforced silicone elastomer. Since then, penile prostheses have undergone a number of developments in both the design of the components as well as the biomaterials used to construct the implant. Mechanical failure rates have gradually reduced [6], and the introduction of additional features such as a lock-out valve on the inflatable devices has reduced the incidence of auto-inflation [7].

Another concern is prosthesis infection, which requires removal of the device and is a serious complication. The introduction of antibiotic-coated implants (Inhibizone®) by Boston Scientific/American Medical Systems, as well as hydrophilic coatings on the Coloplast Titan implants, allow the implant to be soaked in an antibiotic solution of the surgeon's own preference, and have both reduced the infection rate by 83% [8,9].

More recent modifications to the inflatable prostheses include newer pumps, which allow patients to deflate the device after 3–4 s of squeezing the deflate button. There is also the option of ectopic reservoir placement superficial to the fascia transversalis or posterior to the rectus muscle, which has been aided by the introduction of flatter reservoirs such as the AMS Conceal®. This is particularly useful in patients who have undergone major pelvic or transplant surgery.

A previous retrospective audit of penile prosthesis practice in the UK, spanning a 2-year period, was published in 2006, and provided data relating to surgeon and centre caseload [10]. Recent registries have also been published from North America and Italy which allow comparative data in terms of comorbidities and surgeon volume [11,12].

In 2016 the BAUS National Penile Prosthesis Audit was developed to allow surgeons to enter their data prospectively online, including demographic and procedure-specific data relating to penile prosthesis surgery. The present paper describes the baseline data, which have been analysed over a 3-year period, and provides an overview of current UK practice for penile prosthesis surgery.

Methods

An online registry was developed by BAUS in collaboration with the BAUS Section of Andrology and Genitourethral Surgery. The fields were collated using similar data from that recorded on the patient information forms (PIFs), which are supplied by the manufacturers and are usually completed by the implanting surgeon at the time of surgery. Additional outcome data in relation to complications and prosthesis satisfaction and use for sexual intercourse were also included.

Prospective data collection commenced in January 2016 using an online resource: baus.e-dendrite.com, with each implanting surgeon having a unique log-in.

Data analysis covering a 3-year period up to December 2018 was performed. Data analysis was performed using a statistical software package (Tableau, Seattle, WA, USA). The initial baseline analysis was performed to provide an overview of the patient demographics, implant preference, peri-operative complications and surgeon and centre volume.

Results

Between January 2016 and December 2018, data on a total of 1071 penile prosthesis procedures were entered into the BAUS penile prosthesis audit. The numbers of implants, surgeons and centres year on year are shown in Table 1. High-volume centres were classified as those performing more than 50 procedures per year (n = 2). Over the 3-year period the number of prostheses implanted remained relatively consistent, although the number of surgeons implanting the devices reduced over the same time period.

Surgeon and Centre Caseload

Primary procedures comprised the bulk of the workload, with 817 procedures recorded as being a primary procedure. The majority of the prostheses (n = 747) were performed by surgeons at consultant grade (69.7%). The number of centres performing penile prosthesis surgery reduced from 22 in 2016 to 19 in 2017, and by 2018 there were 13 centres performing the operation. There was a corresponding decline in the number of surgeons performing penile prosthesis surgery, from 27 in 2016 to 20 in 2018.

Regional Variation in the UK

Table 2 shows the regional variations in the UK according to NHS regions.

Table 1 Number of consultants performing the procedure and the corresponding number of centres.

Year	*n*	%	Surgeons, *n*	Centres, *n*
2016	350	32.68	27	22
2017	393	36.69	22	19
2018	328	30.63	20	13
Grand Total	1071	100.00	34	28

Table 2 Regional variations within the UK for all implants recorded.

Region	*n*	%	Surgeons, *n*	Centres, *n*
East England	13	1.21	1	1
East Midlands	66	6.16	3	2
London North	634	59.20	8	2
London South	57	5.32	2	2
North East	22	2.05	1	2
North West	90	8.40	5	3
Scotland	82	7.66	3	4
South Central	1	0.09	1	1
South West	16	1.49	2	3
Wales	49	4.58	2	2
West Midlands	20	1.87	1	1
Yorkshire + Humberside	21	1.96	5	5
Grand Total	1071	100.00	34	28

Patient Demographics

The median (range) age of the patients was 55 (18–100) years. Preoperative American Society of Anaesthesiologists (ASA) grade was recorded in 465 cases, with the majority classified as ASA grade II. This reflects the common risk factors recorded for patients undergoing prosthetic surgery. The commonest group in this cohort were those with diabetes (19%), followed by men undergoing a prostatectomy (10.7%). The distribution of aetiologies for the underlying ED are listed in Table 3.

Prosthesis Subtypes used in the UK

Of the 665 inflatable penile prostheses entered in the registry, the model of the prosthesis was specified in 541 cases. The Coloplast Titan Touch was recorded as the most commonly used penile prosthesis (65.1% [n = 352]). This was followed by the AMS 700CX, used in (20.9% [n = 113]) of cases. The distribution of the inflatable penile prosthesis models used is shown in Table 4. The two-piece Ambicor inflatable prosthesis was used in 18 cases.

Of the 152 malleable prostheses recorded, 125 were Coloplast Genesis prostheses.

Antibiotic Regimens

Preoperative antibiotics were recorded in 57% of cases. The commonest combination used was co-amoxiclav and gentamicin (79.8%), followed by combinations of teicoplanin and co-amoxiclav or gentamicin and cefuroxime.

Postoperative antibiotics were recorded as being routinely administered in 66% of cases.

Table 3 Major aetiological factors for patients undergoing penile prosthesis surgery.

Aetiology	*n*	%
Diabetes	204	19
Prostatectomy	115	10.7
Peyronie's	111	10.4
Priapism	67	6.2
Neurological	22	2
Trauma	18	1.7

Table 4 Types of penile prosthesis used in UK practice.

	n	%
Inflatable prosthesis		
Ambicor	18	3.3
AMS 700CX	113	20.9
AMS CXR	6	1.1
AMS LGX	7	1.3
Coloplast Narrow Base	23	4.3
Coloplast OTR	22	4.1
Coloplast Titan Touch	352	65.1
Grand Total	541	100.0
Malleable prosthesis		
AMS	7	4.6
Coloplast	125	82.2
Not recorded	20	13.2
Grand Total	152	100.0

Use of Drains and 'Mummy Wrap'

Following insertion of the implant, surgeons have the choice of using drains and a compression dressing, such as a 'mummy wrap'. Surgeons were specifically asked to state the type of dressing or drain used following implant insertion and according to the type of implant. A 'mummy wrap' was used in 78.15% of recorded cases of inflatable prostheses (Table 5), with drains used in 76.6% of cases (Table 6).

Peri-operative Complications

Intra-operative Complications

Known postoperative complications were recorded in 9.8% of cases (74/752), with the two most frequently reported being postoperative penile pain (n = 11) and scrotal haematoma (n = 14). There were five prosthesis infections recorded within 30 days.

Surgeons were also asked to record intra-operative complications such as urethral injury or corpus cavernosum perforation (proximal or distal). A total of seven cases of urethral injury were recorded, of which six were during a

Table 5 Mummy wrap

Type of implant	Yes		No		Total
	n	%	*n*	%	
Malleable	99	78.57	27	21.43	126
Inflatable	372	78.15	104	21.85	476
Grand Total	471	78.24	131	21.76	602

Table 6 Drain use according to the type of prosthesis.

Type of implant	Drain inserted				Total
	Yes		No		
	n	%	*n*	%	
Malleable	45	35.43	82	64.57	127
Inflatable	370	76.60	113	23.40	483
Grand total	415	68.03	195	31.97	610

primary procedure. Proximal corporal perforation was recorded in nine cases, of which eight were primary procedures. Distal perforation was recorded in two cases, with a further case which did not specify the site of the perforation. Cross-over was recorded in six cases (0.6%).

Discussion

This multicentre prospective study provides a baseline analysis of penile prosthesis practice in the UK and includes data from 1071 penile prostheses inserted over a 3-year period.

The demographic data shows a median age of 55 years, with the commonest aetiologies for ED being diabetes, prostate surgery and Peyronie's disease. In North America the PROPPER study [11] reported a mean age of 63 ± 10 years.

The aetiology is in keeping with previous published registries, with the commonest factors being radical prostatectomy in the North American registry [11] and also the Italian registry [12].

Diabetes was listed as a comorbid factor or sole factor in 19% of patients in the total cohort. Excluding the 368 patients where the aetiology was not recorded, this comprises 29% of patients undergoing penile prosthesis surgery. Patients undergoing prostatectomy comprised 10.7% of the cohort, or 16.4% when patients with no recorded aetiology were excluded from the data analysis. This is in contrast to the PROPPER study in 1019 patients from 11 centres in North America, which reported the commonest aetiology being radical prostatectomy (28%), followed by diabetes (21.6%). Using the INSIST-ED registry [12], in which multicentre data in Italy wascollected, a baseline analysis of 367 procedures , found that previous pelvic surgery was be the commonest aetiology (35.8%), followed by Peyronie's disease (21.3%) and then diabetes (12.6%).

There are an estimated 4.5 million men with diabetes in the UK, which is a higher prevalence than that in Italy, and this could possibly account for the variation in the aetiology. The irreversible neuropathy and vasculopathy associated with diabetes often leads to pharmacological failures at an earlier age in diabetes, with a consequent resistance to non-surgical therapies for ED.

Despite the increasing use of robot-assisted nerve-sparing procedures, prostatectomy is still associated with neural injury secondary to a combination of traction, neuropraxia and diathermy injury [13]. Although there can be partial recovery with time, the present study, together with the PROPPER and INSIST-ED data, confirms that prostatectomy is still a significant risk factor for the development of end-stage ED.

Peyronie's disease has a peak incidence in the fifth decade, and also has a vasculogenic aetiology. A penile prosthesis is considered a suitable option where there is a significant penile curvature in conjunction with ED refractory to oral or intracavernosal pharmacotherapy. In this study, 10.4% of patients were reported to have a history of Peyronie's disease, with 71% of this group undergoing an inflatable penile prosthesis. A penile prosthesis offers the advantage of treating both ED and penile curvature simultaneously, thus restoring sexual function. The curvature may be successfully treated at the time of surgery during corporal dilatation or by the technique of penile modelling, and there may also be further straightening over time as the device is cycled.

In the UK the two major suppliers of penile prostheses are Coloplast and Boston Scientific. The majority of the procedures recorded were inflatable devices comprising 62.1% of the total number of cases. Inflatable devices offer better concealment and softer cylinders, and are available as three- or two-piece inflatable devices. There is no separate reservoir with the two-piece device as the fluid is contained in the posterior part of the cylinders, and they can therefore be useful where intra-abdominal/intra-peritoneal surgery needs to be avoided, for example, previous extensive pelvic surgery or transplant surgery. In the present analysis, only 3.3% of inflatable devices were two-piece Ambicor devices.

The Coloplast Titan inflatable penile prosthesis was used in 52.9% of cases. This is in contrast to the previous UK audit published in 2006 where the AMS 700CX implant was the commonest three-piece inflatable prosthesis used, with 139 implants recorded (33.7% of the total). The market share has remained consistent for the AMS 700CX. The data from 2006 recorded five different inflatable prosthesis models available and these were used in the 2-year period of the study. Ten years later, six models have been recorded, of which the AMS 700CX is the only model which has remained. Modifications of the angle of the exit tubing and changes in the pump have led to Coloplast initially releasing the Coloplast OTR, followed by the Coloplast Titan Touch, with the previous versions now obsolete.

Malleable prostheses comprised only 14.2% of the total implants used, reflecting the patient/surgeon preference for the inflatable devices. Similarly in the INSIST-ED study, 13.5% of primary procedures used a malleable prosthesis. In the PROPPER study, only 1% of devices were malleable prosthesis. Although malleable prostheses are technically

easier to perform and cheaper than the inflatable devices, it is clear that the preference is still for the hydraulic devices in the UK.

The majority of the procedures were performed by consultants (69.7%), with only 12.2% recorded by sub-consultant grade surgeons as the primary surgeon. This reflects the limited training and exposure to complex andrological procedures in the UK such that trainees in dedicated andrology units are the ones most likely to gain suitable training sufficient to perform the procedure independently.

The favoured surgical approach for a primary inflatable penile prosthesis is the penoscrotal approach, with only one UK surgeon recording the infrapubic approach. For malleable penile prosthesis procedures which can also be performed using the penoscrotal, infrapubic or subcoronal approach, the majority were again performed using the penoscrotal approach.

Reservoir placement into the Retzius space can be undertaken using a separate inguinal incision, or it can be placed blindly through the same penoscrotal incision. Previous pelvic surgery can make blind reservoir insertion difficult and potentially hazardous, and the submuscular ectopic placement of the reservoir is now becoming increasingly popular. The registry showed that, when recorded, the open reservoir insertion was used in 23% of procedures with the majority having undergone previous pelvic surgery. Blind reservoir insertion was favoured in higher-volume centres.

Intra-operative complications were recorded to assess the frequency of urethral or corporal perforation as there is little in the published literature relating to these complications. Although distal urethral perforation requires abandonment of the procedure, corporal perforation can be salvaged by redilatation, use of a 'hitch stitch' or repair of the perforation. Similarly, distal cross-over can be rectified intra-operatively by redilatation aided by an additional dilator on the contralateral side.

Over the study period there has been no significant increase in the number of penile prostheses inserted in the UK, although the number of surgeons and centres offering this surgery has reduced dramatically. This may be multifactorial, and reflect training, increasing sub-specialization amongst trainee urologists, funding constraints, and the UK healthcare system's desire for centralized and higher-volume centres for complex work.

In 2016, penile prosthesis surgery in the UK was performed in 22 centres by 27 surgeons. By the end of 2018 this had decreased to 13 centres and 20 surgeons performing the procedure. This represents a 51% reduction in the number of UK centres over a 3-year period. The previous UK audit published in 2006 recorded 76 surgeons performing the surgery, with only four surgeons performing more than 20 procedures per year.

National Health Service funding for penile prosthesis surgery in England has undergone a significant change over this time period, with some units submitting individual funding requests to local commissioners in order to undertake the surgery, whilst others have been centrally funded via NHS England. The penile prosthesis commissioning pathway [3] has now provided guidelines for the management of ED and penile prosthesis as end-stage surgery. The changes in centralized funding have not affected Wales, Scotland or Northern Ireland.

Previous studies have also suggested that revision rates for penile prosthesis procedures and mechanical failure are higher when performed by low-volume surgeons, compared to high-volume surgeons who had fewer peri-operative complications [14]. However, the recorded complications were low and suggests that the procedures are not associated with the high complication rates previously reported.

One of the limitations of the present study is that the follow-up data at present does not allow a complete analysis, and therefore the impact of surgeon and centre case volume on surgical outcomes is unclear. However, a future sub-analysis is planned.

Other limitations of the present study include reliance on the implanting surgeons to accurately enter their data for each implant. It is likely that the numbers have been underestimated. The alternative source to verify the number of procedures undertaken in the UK is the Hospital Episodes Statistics data which also code for attention to the prosthesis as an implant insertion and indicate that 540 procedures were performed in 2016, 515 procedures in 2017 and 525 in 2018. However, the present baseline data still provide an independent overview of the current practice in the UK and the change in practice since the last audit in 2006.

This study has used data entered onto a national registry independent of the manufacturers, who themselves collect data via the PIF, but analyse these data independently of each other, and do not publish this in the public domain. The PROPPER registry recorded data from high-volume centres only using AMS implants and therefore has limitations in terms of reporting exclusively on one implant manufacturer in North American practice. This BAUS audit provides an overview of all the implant subtypes from 22 centres in the UK, irrespective of the type of implant or manufacturer.

Conflict of Interest

Mr Muneer reports other fromColoplast, other from Boston Scientific Board, outside the submitted work.

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Abbreviations: ASA, American Society of Anaesthesiologists; ED, erectile dysfunction; PIF, patient information form.

Appendix 1

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