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Citation for final published version:

Ellul, Thomas, Bullock, Nicholas, Steggall, Martin and Brown, Gareth 2020. Perioperative management of patients undergoing penile prosthesis surgery in the UK: A survey of current practice. *Journal of Clinical Urology* 13 (5) , pp. 326-331. 10.1177/2051415820931263

Publishers page: <http://dx.doi.org/10.1177/2051415820931263>

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**Title:**

Perioperative management of patients undergoing penile prosthesis surgery in the United Kingdom: a survey of current practice

**Authors:**

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## **Abstract**

### Objectives:

This study aimed to define contemporary perioperative management of patients undergoing penile implant surgery in the United Kingdom.

### Materials and Methods:

All Consultant Urological Surgeons responsible for the insertion of penile prostheses in the UK were invited to complete an online survey comprising of 25 questions relating to surgeon demographics, patient selection, preoperative workup, intraoperative management and postoperative care. Anonymised responses underwent descriptive statistical analysis, with particular focus on measures employed to reduce the risk of perioperative infection.

### Results:

Of the 34 invited surgeons, 26 (76.5%) responded to the survey. The majority reported undertaking between 10 - 30 cases in 2018 (n=17; 65.4%). A total of 23 (88.5%) respondents reported employing a threshold for diabetic control, although the exact limit varied between surgeons. Most respondents (n=22; 84.6%) reported routinely sampling urine for microscopy, culture and sensitivity (MCS). All but one (n=25; 96.2%) reported routinely performing cavernosal washouts, with the most common solution being a mixture of gentamicin and vancomycin (42.3%). All reported routinely giving intravenous antibiotics on induction of anaesthesia and, although there was no clear consensus, most surgeons preferentially used an

aminoglycoside in combination with one other agent (including penicillins or teicoplanin).

**Conclusion:**

The variation in current perioperative management demonstrates a potential need for the development and introduction of evidence-based guidelines to standardise practice nationwide.

**Keywords:**

Andrology, Infection, Penile prosthesis, perioperative care, Urologic surgical procedures.

**Abbreviations:**

Erectile dysfunction (ED)

National Health Service (NHS)

United Kingdom (UK)

Glycated haemoglobin (HbA1c)

International Federation of Clinical Chemistry (IFCC)

Diabetes Control and Complications Trial (DCCT)

Microscopy, culture and sensitivity (MCS)

Methicillin-Resistant Staphylococcus Aureus (MRSA)

American Urological Association (AUA)

European Association of Urology (EAU)

Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS)



## **Introduction:**

Penile prostheses remain the mainstay of treatment for men with erectile dysfunction (ED) for whom medical therapies and external vacuum devices have been unsuccessful. They are an effective treatment and associated with high levels of patient satisfaction <sup>1</sup>. Although rare, the most significant postoperative complication in penile prosthesis surgery is infection, which necessitates removal and leads to a higher risk of future complications should a revision device be inserted <sup>2</sup>. Reported infection rates vary across different published series but are generally in the range of 1-3% for implantation of a new prosthesis and up to 18% following revision surgery <sup>2</sup>. <sup>3</sup>. A number of risk factors have been identified, including several that may be potentially modifiable, including poor glycaemic control, high body-mass index, immunosuppression, smoking, and concurrent urinary infection <sup>4</sup>. However, whilst various strategies have been proposed in an attempt to reduce perioperative infection rate, there remains no clear consensus on the optimal approach.

A survey of members of the Sexual Medicine Society of North America and the International Society of Sexual Medicine responsible for implantation of penile prostheses was undertaken in 2012 <sup>4</sup>. This demonstrated significant variation between the perioperative management of patients undergoing implant surgery amongst the 129 participants, the vast majority of whom were based in North America. Variability was observed in most aspects of perioperative practice, including undertaking preoperative urine culture and skin washes, as well as intraoperative hand and skin preparation, antibiotic usage and drain placement <sup>4</sup>. However, the authors did not investigate or report clinical outcomes, including perioperative infection rates, and therefore the effect of these prophylactic measures

is yet to be determined. Furthermore, there is a paucity of high-quality evidence within the literature to support such measures.

Despite the significance of perioperative infection, existing guidelines concerning antimicrobial prophylaxis in urological surgery outline a proposed regimen for all implanted prostheses collectively, rather than penile implants specifically, and do not provide guidance on other preventative methods such as skin preparation and cavernosal washouts. Furthermore, provision of prosthesis surgery in England is currently under review, with a recently published consultation document from NHS England (the organisation responsible for overseeing the services provided by the National Health Service in England) proposing substantial changes to the current service, including a reduction in the number of centres performing penile implant surgery from twenty-eight to four<sup>5</sup>. However, whilst these proposed changes are based on presumed variation in the number of procedures performed and a lack of standardisation between centres, the current state of practice in the United Kingdom (UK) remains unknown. The aim of this survey was therefore to review current practice amongst surgeons responsible for insertion of penile prostheses in the UK, with particular focus on measures employed to reduce the risk of perioperative infection.

## **Patients and methods:**

### *Instrument:*

A 25-question survey was designed using the Online Surveys web-based tool (Online Surveys, Bristol, UK; [www.onlinesurveys.ac.uk](http://www.onlinesurveys.ac.uk)). Questions were designed to capture the current state of practice across the full spectrum of perioperative management. These were divided into five sections, comprising questions relating to surgeon demographics, patient selection, preoperative workup, intraoperative management and postoperative care. In particular, several questions focused on aspects relating to theoretical reduction of perioperative infection, including the utilisation of preoperative skin swabs and urine cultures, the use of prophylactic antibiotics or skin washes, choice of implant bathing solution and corporal washes, and timing of discharge.

### *Participants:*

All Consultant Urological Surgeons responsible for the insertion of penile prostheses in the UK were invited to complete the survey via direct email communication, with a further invitation email sent after two weeks. All responses were captured anonymously.

### *Statistical analyses:*

Anonymised data were analysed using GraphPad Prism Version 8.0 (GraphPad Software, La Jolla, California, USA). All glycated haemoglobin (HbA1c) values reported in reported in International Federation of Clinical Chemistry (IFCC) units measured in mmol/mol were converted to Diabetes Control and Complications Trial



(DCCT) units measured in % to standardise responses and allow comparisons. All analyses were descriptive and no specific statistical tests were utilised in the comparison of subgroups.

## **Results:**

### *Current practice*

Of the 34 invited surgeons, 30 (88.2%) opened the invitation email and 26 went on to complete the survey, giving a response rate of 76.5%. Of these, 20 reported practicing in England, 4 in Scotland and 2 in Wales. Figure 1 demonstrates the number of cases performed by each respondent in the calendar year of 2018. The majority reported undertaking between 10 - 30 cases (n=17; 65.4%), with 5 (19.2%) performing less than 10 and 4 (15.4%) performing more than 30.

### *Patient selection*

5 questions pertained to patient selection. 15 respondents (57.7%) reported that they did not employ a maximum threshold for body-mass index (BMI), whereas 11 (42.3%) do not offer surgery for those patients with a BMI of greater than 30kg/m<sup>2</sup>. A total of 23 (88.5%) respondents reported employing a threshold for diabetic control, with glycated haemoglobin (HbA1c) as the metric of choice. The majority of surgeons employ a threshold HbA1c value of between 9.0 and 9.5% (75 – 80 mmol/ml) (n=9; 42.34.6%), with the overall distribution demonstrated in Figure 2. Only 1 surgeon (3.8%) reported requiring patients to cease smoking prior to surgery and none employed additional selection criteria for patients with spinal pathologies. A total of 21 (80.8%) reported no change in the preoperative management of patients taking corticosteroids, whilst 5 (19.2%) indicated that they preferentially defer surgery if possible, with one employing a prolonged course of postoperative prophylactic antibiotics in this patient group.

### *Preoperative workup*

5 questions related to preoperative practice. The majority of respondents (n=22; 84.6%) reported routinely sampling urine for microscopy, culture and sensitivity (MCS), with all stating they would undertake this at the time of preoperative assessment approximately 1 - 6 weeks prior to surgery. 16 (61.5%) reported obtaining skin swabs for MCS, with the majority specifically sampling the groin for presence of Methicillin-Resistant Staphylococcus Aureus (MRSA). No surgeons routinely prescribe prophylactic antibiotics to be taken preoperatively whilst 4 (15.4%) routinely prescribe topical antimicrobial agents, usually in the form of Naseptin cream (chlorhexidine dihydrochloride and neomycin sulphate). A total of 7 respondents (26.9%) reported instructing patients to undertake self-administered antimicrobial skin washes prior to surgery, with all employing a chlorhexidine based regimen.

### *Intraoperative management*

5 (19.2%) respondents reported routinely using antimicrobial impregnated skin drapes such as the 3M Ioban Antimicrobial Incise Drape. All reported routinely giving intravenous antibiotics on induction of anaesthesia and, although there was no clear consensus on the most appropriate regimen, half of respondents reported administering a combination of an aminoglycoside and beta-lactam agent, most commonly gentamicin and co-amoxiclav (augmentin), as shown in Figure 4. Similarly, all surgeons report performing preoperative hair removal, with 14 (53.8%) and 12 (46.2%) utilising razor and electric shaving methods respectively. Respondents reported using a variety of skin preparation solutions, as demonstrated

in Figure 3, with a total of 19 surgeons (73.1%) stipulating that skin preparation is performed for a minimum of 10 minutes.

Almost all surgeons reported routinely utilising a peno-scrotal surgical approach (n=25; 96.2%). Figure 5 demonstrates the type of solutions used for cavernosal washouts and the bathing of non-impregnated implants. All but one respondent (n=25; 96.2%) reported routinely performing cavernosal washouts, with the most commonly used formulation being a mixture of gentamicin and vancomycin (42.3%), followed by gentamicin alone (30.8%). Similar variation was observed with respect to implant bathing solution, with the commonest being a mixture of gentamicin and rifampicin (46.2%), followed by rifampicin or gentamicin alone (23.1% and 11.5% respectively). 3 surgeons (11.5%) reported that they only insert antibiotic-impregnated implants and thus do not utilise a bathing solution.

#### *Postoperative care*

17 respondents (65.4%) reported routinely leaving a drain following insertion of the prosthesis, with the majority (n=24; 92.3%) employing a compressive mummy-wrap dressing. 23 (88.5%) routinely discharge patients on oral antibiotics, with the choice of agent given in Figure 6. All but one respondent (n=25; 96.2%) reported admitting patients for one night following surgery, with the remaining surgeon discharging patients on the same day. Finally, 16 respondents (61.5%) reported that if a UK-wide guideline were developed they would use this to inform their practice.

## **Discussion:**

The provision of penile implant surgery in England is currently undergoing review and it is probable that a new service structure will be published imminently in an attempt to standardise and centralise practice throughout the country<sup>5</sup>. However, as the current state of practice in UK was unknown, these proposals are based on hypothetical variation in operative numbers and perioperative practice. In achieving an excellent response rate of 76.5% among all Consultant Urological Surgeons in the UK responsible for penile implant surgery, we have provided a comprehensive overview of contemporary practice not only in England, but also the other regions of the UK. These findings demonstrate considerable disparity, particularly with respect to patient selection and choice of skin and implant preparation solutions.

The majority of respondents (65.4%) reported performing between 10 and 30 implants last year. Only 4 (15.5%) respondents reported performing more than 30 implants. This volume of operative numbers in the UK and many European countries is in contrast to that seen in practice in the United States and is likely related to the nature of andrological practice within the UK<sup>6,7</sup>. Few surgeons in the UK practice 'pure' andrology and often surgeons will undertake general urology alongside andrological procedures. Furthermore in many regions, limits are set on the number of penile implants that may be performed due to NHS funding restrictions, thereby further reducing the overall number of cases performed nationwide.

Substantial variation in patient selection and preoperative workup was identified, especially in terms of diabetic control. A multicentre prospective assessment of preoperative HbA1c level in over 900 patients that underwent implant surgery

between 2009 and 2015 has recently been reported <sup>8</sup>. Infection rate was significantly higher in those patients with a high HbA1c level, with multivariable analysis identifying a level of 8.5% (~70 mmol/mol) able to predict infection with a sensitivity and specificity of 80% and 65% respectively <sup>8</sup>. Interestingly, 17 respondents (65.4%) in the current study employed an upper limit that was equal to or higher than this whilst 3 (11.5%) did not preclude patients from undergoing implant surgery based upon their diabetic control at all.

Variation in patient selection based on body-mass index (BMI) was also identified, with 11 (42.3%) respondents declining implant surgery for those patients with a BMI of greater than 30kg/m<sup>2</sup>. However, whilst obesity has been identified as an independent risk factor for surgical site infection in both colorectal and orthopaedic surgery <sup>9,10</sup>, this association has not been observed in terms of perioperative penile prosthesis infection after controlling for the presence of diabetes <sup>11,12</sup>. Despite this, levels of self reported satisfaction, as measured using a number of validated questionnaires including the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), have been found to be significantly lower in patients with a BMI of greater than 30kg/m<sup>2</sup> compared with the general implant population <sup>13</sup>. It is therefore possible that concerns over lack of satisfaction, rather than increased complication risk specifically, may be responsible for this observed variation in practice.

The majority of respondents did not routinely prescribe pre-operative prophylactic antibiotics, antimicrobial creams or skin washes, although most surgeons ensured that patients were pre-operatively screened with a urine culture and skin swabs (most commonly for MRSA). This was an interesting finding, as American Urological

Association (AUA) guidelines on antimicrobial prophylaxis for urological surgery currently state that implant surgery should not be performed in patients with active systemic, cutaneous or urinary infection <sup>14</sup>. However, it is unclear whether this requires screening or whether treating only symptomatic infection is indicated.

There was also variation in the solution used for surgical skin preparation. Yeung *et al.* have demonstrated that a chlorhexidine-alcohol solution is superior to povidone-iodine solutions for the prevention of infection when implanting <sup>15</sup>. However, the present study has identified that the most commonly chosen solution among UK surgeons was a combination of povidone-iodine with either chlorhexidine or alcohol, with only one respondent specifying that they routinely use a chlorhexidine-alcohol mixture. A similar variety of responses was noted for the preferred solution used to bathe implants prior to insertion. Lokeshwar *et al.* have previously reviewed the evidence regarding the efficacy of antimicrobial dips and concluded that the literature endorses the use of rifampicin/gentamicin solution <sup>16</sup>. However, only 46.2% of respondents in this survey reported routinely using this combination.

In a recent retrospective, multicentre review of 227 intraoperative cultures obtained at explantation or Mulcahy salvage of infected three-piece inflatable prostheses, Gross *et al.* identified candida, anaerobes and MRSA as the causative organism in nearly one third of positive cultures, although interestingly cultures were also negative in one third <sup>17</sup>. Such evidence may be used to guide choices of antibiotics to be given at induction of anaesthesia, with the AUA best practice statement on antimicrobial prophylaxis for urological surgery (published in 2008 and amended in 2012) recommending administration of an aminoglycoside with vancomycin or a

cephalosporin <sup>14</sup>. However, Gross *et al.* noted that the micro-organisms identified were not covered by the AUA or EAU antibiotic guidelines in 14% to 38% of cases, and furthermore established that the addition of fluconazole to vancomycin and piperacillin-tazobactam would allow for coverage of 100% of the infectious organisms identified <sup>17</sup>. With this disparity between published evidence and existing guidelines it is therefore unsurprising that the current study did not identify a consensus in the agent/s used by UK surgeons. Further research is therefore required to determine the most appropriate antibiotic to be given at induction and this will need to be region specific, depending upon local microbiological and antimicrobial resistance trends.

The main strength of this study is the high response rate among Consultant Urological Surgeons responsible for implant surgery in the UK, thus rendering the results representative of nationwide contemporary practice. However, there are also a number of limitations, most importantly the anonymous self-reported nature of responses, which cannot be independently verified and may be subject to recall bias. Secondly, as questions related to implanting practice overall, any differences in approach between virgin and revision cases, or between the insertion of malleable and inflatable prostheses, could not be assessed. Finally this study did not measure clinical outcomes and therefore it is not possible to comment on whether the techniques being utilised by surgeons are effective in reducing perioperative infection, even if not universally accepted or evidence based. Further studies, preferably in the form of randomised trials, are therefore required to robustly assess the impact of particular management steps on clinical outcomes such as infection rate.





### *Conclusion*

There is currently significant variation in the perioperative management of patients undergoing penile implant surgery in the UK, particularly with respect to preoperative patient selection and choice of skin and implant preparation solution, which presents a potential need for the development and introduction of national evidence-based guidelines to standardise practice.

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