



Advances in Infection Prevention Strategies for Penile Prosthesis Surgery

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Abstract

Purpose of Review To describe recent advances in infection prevention strategies for penile prosthesis surgery.

Recent Findings Improvements in surgical technique, antibiotic prophylaxis, prosthetic device design, and patient selection have globally reduced penile prosthesis infection rates. However, current societal antibiotic prophylaxis guidelines may fail to cover all organisms implicated in penile prosthesis infections, particularly fungal and anaerobic pathogens.

Summary Although significant strides have been made in reducing penile prosthesis infections, further education and research efforts are needed to continue to prevent this infrequent, but devastating complication. This review discusses recent advances in penile infection understanding and prevention.

Keywords Erectile dysfunction · Penile prosthesis · Infection control

Introduction

Erectile dysfunction (ED) is a prevalent and potentially distressing urologic condition affecting nearly 70% of men by age 70 [1]. Inflatable penile prosthesis (IPP) surgery is widely accepted as the definitive treatment option for men with ED unresponsive to oral, intraurethral, and intracavernosal pharmacotherapy [2, 3]. Although IPP placement is an invasive surgical procedure, it is highly effective and associated with excellent long-term patient and partner satisfaction outcomes [4, 5]. However, IPP surgery is not

without surgical risk. Despite improvements in device design and operative technique over the last four decades, IPP infections remain a dreaded complication for both patients and surgeons [6].

Population studies have shown that IPP infections occur in 1–3% of men receiving de novo implants and 5–18% of men undergoing revision surgery [7–9]. These infections can result in severe emotional and physical harm, loss of sexual function, increased healthcare utilization and costs, as well as considerable medicolegal consequences for providers [10–12]. In addition, device infections can result in decreased patient satisfaction and prolonged time to achieving penetrative intercourse secondary to required infection control and salvage procedures [13].

IPP infections can be grouped into two categories: immediate and indolent processes [14]. Immediate infections are less common and typically occur within 8 weeks of surgery with patients presenting with surgical site edema, erythema, purulent drainage, and possibly fever or sepsis [14, 15]. More frequently, however, patients develop an indolent infection typically occurring within a year of surgery, but sometimes longer [14]. These patients can present with persistent vague symptoms, including chronic pain, sinus tract development, and fixation of the pump to the scrotal skin, which should heighten clinical suspicion for a smoldering infection [14, 15]. As such,

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infection prevention has become a key focus among urologists commonly performing this procedure.

The purpose of this review is to provide an update on recent advances in infection prevention strategies in penile prosthesis surgery. We begin with a brief review of penile prosthesis infection pathophysiology and risk factors of this complication.

Infection Pathophysiology

Immediate IPP infections classically occur when a device comes into contact with skin flora during placement, resulting in seeding of the corporal space [9]. Infections secondary to hematogenous spread from concomitant procedures may be responsible for late or indolent infections [16]. Once introduced into the corporal space, bacterial and fungal organisms adhere to the device and begin to multiply and secrete a biofilm [17]. Biofilm is a complex matrix of extracellular polymers that facilitate organismal growth, further pathogen adherence, and antibiotic resistance through gene swapping and reduction of antibiotic penetration [18, 19]. Simultaneously, the body seals the device in a dense surgical capsule which further limits the immune response and efficacy of antibiotics [20]. Consequently, capsule excision, surgical removal of the device, and antibiotic washout are necessary to clear an IPP infection [21]. Of note, biofilm-forming organisms include *Staph epidermidis*, *Staph aureus*, *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Candida albicans* [22]. Multicenter investigations have shown that 25% of IPP infections are polymicrobial, while 11.1%, 10.5%, and 9.2% are caused by *Candida*, anaerobes, and methicillin-resistant *Staph aureus*, respectively [23••].

Infection Risk Factors

Risk factors for IPP infection are well known and can be categorized into patient and procedural characteristics. Patient-specific factors include medical co-morbidities, behavioral issues, and socioeconomic status [24, 25]. In 1995, Wilson and Delk examined 1337 consecutive IPP surgeries and found no significant increased risk of device infection among diabetics [26]. However, recently in 2019, Lipsky et al. observed a 1% increased risk of device infection associated with diabetes when examining 14,969 men undergoing IPP surgery (3% vs. 2%, $p < 0.002$); their results remained statistically significant after multivariate adjustment [27]. In addition, a recent multicenter review found that 83% of fungal IPP infections occurred in patients who were diabetic or obese, ultimately further raising concern for diabetes and metabolic syndrome as a risk factor for IPP infections [28•]. However, peri-operative diabetes control appears to be a more

definitive risk factor for IPP infection. Patients with a blood glucose > 200 mg/dL at the time surgery have more than a four-fold risk of IPP infection compared to those under tight glycemic control [29]. Prior research has also shown that patients with HIV, spinal cord injury, *Staph aureus* nasal carriage, and who are chronically immunosuppressed are at significantly increased risk for IPP infection [26, 29, 30]. In terms of behavioral risk factors, patients who smoke or misuse at least one substance (e.g., alcohol, marijuana, cocaine) at the time of surgery are at increased risk of IPP infection [29, 30]. Similarly, homelessness has been shown to increase IPP infection risk 12-fold [29].

Certain procedural characteristics may put ED patients at even higher risk for IPP infection. Most notably, infection rates are substantially higher for device revision surgeries; up to an 18% increased risk of infection compared to new implants has been reported [26, 31]. Revision surgeries may be particularly susceptible to infection due to the tissue changes that occur after initial IPP placement, including the presence of a de-vascularized surgical capsule that may reduce the effectiveness of intravenous antibiotics and the host immune response. Increased operative time and case complexity may also place patients at increased risk of IPP infection [32]. The infection rate in patients requiring extensive corporal reconstruction for Peyronie's disease, fibrosis, or a neophallus approaches 22% for these lengthy cases [33]. Further, the climate in which IPPs are placed may also be a risk factor. A recent multi-center study found that IPP infections occurred more commonly in the month of June and when average daily temperatures were greater than 55 °F [34]. Lastly, there is growing evidence that IPP infection rates may correlate with urologist experience. Onyeji et al. found that patients undergoing IPP placement by low volume urologists were approximately 2 times more likely to require reoperation for infection compared to high-volume implanters [35].

Infection Prevention Strategies

IPP infection prevention strategies are composed of a combination of evidence-based research, expert opinion, and frequent practices employed by high-volume implanters (which may or may not be supported by clinical evidence). Below, we discuss infection prevention strategies for the pre-operative, intra-operative, and post-operative settings and specifically for the placement of new devices. Table 1 summarizes infection prevention strategies that should be considered by urologists prior to performing IPP surgery.

Pre-operative Prevention

In the office, ED patients electing for IPP placement should be counseled on the risks and benefits of surgery, particularly as

Table 1 Infection prevention strategies that should be considered prior to IPP surgery

Pre-operative
1. Patient selection. Exercise caution in following high-risk patients:
a. Diabetics
b. Anticoagulated
c. Polysubstance abuser
d. Immunocompromised
e. Spinal cord injury
f. Complex surgery
i. Revision/Salvage
ii. Reconstruction/Peyronie's
iii. Female-to-male transgender
iv. Concomitant artificial urinary sphincter
2. Thorough physical exam negative for infection
3. Medical Optimization
a. HbA1c
b. Blood sugar
c. Charlson Comorbidity Index
d. Anticoagulation
4. Drug abuse and smoking cessation
5. Urine culture particularly for patients with neurogenic bladders
6. Pre-operative Hibiclens/Chlorhexidine scrub
7. Referral to high-volume surgeon
8. Consider pre-operative antibiotic prophylaxis
9. Patient education including risk of infection and necessary post-operative care
Intra-operative
1. Careful surgical site preparation: Chlorhexidine
2. Reduce operative time
3. Reduce operative room traffic
4. Hair removal using clippers
5. No-touch technique, i.e., minimizing skin contact
6. Perioperative or irrigative antibiotic and antifungal prophylaxis along with use of antibiotic-impregnated or implants with hydrophilic coatings
Post-operative
1. Hematoma prevention:
a. Mummy wrap/compressive dressing
b. Post-operative inflation
c. Closed suction drainage
2. Antibiotic prophylaxis
3. Early discharge
Revision surgery
1. Culture device by needle aspiration or direct swabbing
2. Administer broad-spectrum antibiotics and antifungals based on local antibiogram/guidelines and clinical judgement
3. Ensure proper washout for explant/salvage

they pertain to the individual risk factors discussed above. Pre- and post-operative instructions should be reviewed with patients in detail to ensure understanding. As part of the pre-

operative assessment, a thorough physical exam should be conducted to assess for open sores or signs of fungal rash involving the groin, perineum, penis, or scrotum. Candidal infections in particular may be responsible for up to 11% of IPP infections and can easily be treated with oral fluconazole prior to surgery [23••]. Evidence of cellulitis or folliculitis can also be addressed with oral antibiotics with broad skin-flora coverage. A complete blood count and urine culture should be obtained to assess for underlying or asymptomatic urinary tract infection. However, prior research has shown little correlation between pre-operative urine culture results and the bacteriology of prosthetic device infections [36].

Currently, there is no evidence to support the utility of obtaining a hemoglobin A1c prior to surgery as there is no lab value cut-off useful in predicting increased risk for IPP infection. Alternatively, hemoglobin A1c may be a useful indicator to identify patients who require more support in achieving adequate glucose control in the peri-operative setting. Further, nasal swab testing should be performed to identify patients harboring *Staph aureus*. A large randomized, placebo-controlled, multicenter trial performed by Bode et al. showed that pre-treating nasal *Staph aureus* carriers with mupirocin and washing with chlorhexidine prior to surgery resulted in significantly fewer deep surgical site infections compared to placebo (0.9% vs. 4.4%) [37]. However, the benefit of pre-operative chlorhexidine washes in preventing surgical site infections has recently been called into question [38]. Until more data are available, all IPP patients should be instructed to bathe with chlorhexidine leading up to their procedure and *Staph aureus* carriers should be treated with mupirocin.

In the pre-operative area, patients should again be thoroughly examined to assess for signs of infection that may require postponement of surgery. If the planned surgical site is clear, patients should receive intravenous antibiotics prior to proceeding to the operating room. Both the American Urological Association and European Association of Urology have published guidelines for broad perioperative antibiotic coverage to prevent IPP infection [39, 40]. However, a recent multi-center retrospective study of IPP infections showed that these guidelines may be insufficient and ineffective in 14–38% of cases [23••]. The authors found a high rate of infections secondary to *Candida* (11.1%), anaerobes (10.5%), and methicillin-resistant *Staph aureus* (9.2%) that were not covered by guideline-recommended antibiotic practices [23••]. As such, broader pathogen coverage that includes fungal and anaerobic organisms is likely needed to achieve adequate prophylaxis in IPP surgery.

Intra-operative Prevention

One of the most important innovations in prosthesis design has been the development of infection-resistant coatings.

Coloplast devices now have a hydrophilic coating allowing for antibiotic impregnation when bathed in antibiotic solutions prior to placement (Fig. 1). Similarly, AMS devices are now coated with a mix of rifampin and minocycline. A 2012 meta-analysis by Mandava et al. found that this device innovation alone globally reduced the incidence of IPP infections by 50% [41]. In addition to improvements in device design, greater surgeon and surgical team experience has been found to be associated with reduced infection risk. Prior research has shown that high-volume implanters have lower infection rates compared to urologists performing IPP surgery less frequently [35]. This difference may be explained by increased comfort with IPP infection prevention strategies and shorter operative times among high-volume implanters [42]. Similarly, having an operative team familiar with the goals and steps of the procedure may reduce infectious complications, particularly when utilizing an IPP-specific surgical checklist prior to incision [43].

Preparation of the operative site should be performed with chlorhexidine-alcohol solution. Surgical site preparation with povidone-iodine has repeatedly been found to be inferior to chlorhexidine-alcohol in terms of surgical site infection risk and reducing bacterial volume [44, 45]. Once prepped, the patient should be draped in a sterile fashion to facilitate a “no-touch” technique to minimize device contact with the skin [46]. Multiple glove exchanges should then be performed at each critical point in the procedure to further reduce the risk of introducing skin flora into the corporal space. Additionally, throughout the procedure, anesthesia staff should be encouraged to maintain normothermia and adequate oxygenation as both have been shown to be beneficial in reducing infection risk [47, 48]. At completion of the case, the patient’s penis and scrotum should be bandaged with a Mummy wrap to prevent post-operative hematoma. This technique has been shown to simultaneously reduce hematomas and associated IPP infections by 83% [29]. Other common techniques for hematoma prevention include partial device inflation, tight corporotomy closure, and surgical drain placement. Finally, other untested

techniques to decrease intra-operative infection risk may include cleansing the urethra with betadine prior to incision, washing the external Foley catheter with alcohol after seating of the catheter balloon, minimizing operating room traffic, and maintaining IPP-specific operative teams.

Post-operative Prevention

Provider survey results have shown that IPP patients are commonly discharged home with a course of oral antibiotics, commonly levofloxacin and cephalexin [40]. However, there is no evidence to support or oppose this practice at this time. In the absence of local or systematic signs of infection, antibiotic administration more than 24 h after surgery has been shown to provide no additional benefit across a variety of surgeries [49]. However, the combination of prosthetic device implantation and the location of the surgery in the groin may necessitate the need for extended post-operative antibiotic coverage in IPP patients. Future research is needed to comprehensively investigate this practice.

Prevention for Revision Surgeries

Patients with suspected IPP infections should be admitted for observation, obtainment of culture data (e.g., wound, urine, and blood), and intravenous antibiotics. Cross-sectional imaging may also be warranted to assess the extent of infection, including involvement of the reservoir. If an infection is suspected, device explantation and surgical site washout are required to obtain source control and remove residual biofilm. After explantation and washout, temporary placement of a malleable prosthesis should be considered to preserve the corporal space for future IPP re-implantation. Prior research has shown high infection-free rates among patients undergoing Mulcahy salvage procedures (see below), followed by immediate temporary malleable device placement (Fig. 2) [50, 51].



Fig. 1 Example of a three-piece inflatable prosthesis



Fig. 2 Example of one cylinder of malleable penile prosthesis

Of note, the Mulcahy protocol introduced in 1996 is often used for device salvage and consists of explantation, surgical site washout with hydrogen peroxide, and betadine solution, followed by re-implantation [52]. However, a recent critical appraisal of antiseptic irrigation has challenged the conventional use of 1.5% hydrogen peroxide and 5% betadine solution due to cytotoxicity and lack of clinical efficacy [53]. Diluted povidone-iodine solution (0.35–3.5%) may have more robust antimicrobial activity against recurrent IPP infections [53]. Similarly, data from a small single-center study suggests that surgical site washout with vancomycin and gentamicin may be superior to the traditional Mulcahy salvage procedure [54].

Future Research

It is challenging to conduct randomized clinical trials to assess the effectiveness of different IPP infection prevention strategies, particularly due to the resources and number of patients needed to perform such high-quality studies. However, we should continue to encourage multicenter research efforts to facilitate large, nationally-representative studies to establish best practices in IPP surgery. Despite recent advances in infection prevention strategies, IPP infection rates are still too high and significant opportunity exists to further reduce the prevalence of this devastating complication. Moving forward, we need to evaluate the role of expanded antibiotic coverage to address *Candida*, anaerobes, and methicillin-resistant *Staph aureus*. In addition, substantial research is required to understand which common, but untested, infection control practices (e.g., post-operative antibiotics, reducing operating room traffic) employed by high-volume implanters are beneficial in preventing IPP infections. Our ultimate goal should be to develop a safe and systematic methodology that can be utilized by all urologists performing IPP surgery to obtain the lowest possible infection rates.

Conclusion

IPP infections are an infrequent, but devastating complication for both surgeons and patients. Substantial advances have been made over the last 40 years to reduce infection rates, including improvements in IPP device design, surgical technique, and antibiotic prophylaxis. However, current urologic societal guidelines may fail to recommend appropriate prophylaxis for frequent causative organisms in IPP infection, including *Candida* and anaerobes. Significant opportunity exists to further reduce the incidence of IPP infections through continued multicenter, collaborative research endeavors and educational efforts.

Compliance with Ethical Standards

Conflict of Interest Dr. Rezaee, Dr. Butaney, and Dr. Thirumavalavan each declare they have no conflicts of interest to disclose. This research study was not supported financially.

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Research Involving Human Participants and/or Animals This article does not contain any studies with human or animal subjects performed by the author.

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