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Original Research

Timing and causative organisms associated with modern inflatable penile prosthesis infection: an institutional retrospective

Raevti Bole, MD[1], Engy Habashy, MD[1], David Yang, MD[1], Mohamed Ahmed, MBBCh[1], Landon Trost, MD[2], Matthew Ziegelmann, MD[1], Sevann Helo, MD[1], Tobias Kohler, MD[1,*]

[1]Department of Urology, Mayo Clinic, Rochester, MN 55905, United States
[2]Male Fertility and Peyronie's Clinic, Orem, UT 84057, United States
*Corresponding author: Mayo Clinic, Department of Urology, Rochester, MN. Email: kohler.tobias@mayo.edu

Abstract

Background: The advent of antibiotic-coated devices has reduced the rate of inflatable penile prosthesis (IPP) infections; however, this may have altered microbial profiles when infections do occur.

Aim: To describe the timing and causative organisms behind infection of infection retardant–coated IPPs in the context of our institution's perioperative antimicrobial protocols.

Methods: We retrospectively reviewed all patients undergoing IPP placement at our institution from January 2014 to January 2022. In all patients, perioperative antibiotic administration was congruent with American Urological Association guidelines. Boston Scientific devices are impregnated with InhibiZone (rifampin and minocycline), and all Coloplast devices were soaked in rifampin and gentamicin. Intraoperative irrigation was performed with betadine 5% irrigation prior to November 2016 and with vancomycin-gentamicin solution afterward. Cases involving prosthesis infection were identified, and variables were extracted from the medical record. Descriptive and comparative statistics were tabulated to identify clinical characteristics, including patient comorbidities, prophylaxis regimen, symptom onset, and intraoperative culture result. We previously reported an increased infection risk with Betadine irrigation and stratified results accordingly.

Outcomes: The primary outcome was time to infectious symptoms, while the secondary outcome was description of device cultures at the time of explantation.

Results: A total of 1071 patients underwent IPP placement over 8 years with an overall infection rate of 2.6% (28/1071). After discontinuation of Betadine, the overall infection rate was significantly lower at 0.9% (8/919) with a relative risk of 16.9 with Betadine ($P < .0001$). Primary procedures represented 46.4% (13/28). Of 28 patients with infection, only 1 had no identified risk factors; the remainder included Betadine at 71% (20/28), revision/salvage procedure at 53.6% (15/28), and diabetes at 50% (14/28). Median time to symptoms was 36 days (IQR, 26-52); almost 30% of patients had systemic symptoms. Organisms with high virulence, or ability to cause disease, were found in 90.5% (19/21) of positive cultures.

Clinical Implications: Our study revealed a median time to symptoms of just over 1 month. Risk factors for infection were Betadine 5% irrigation, diabetes, and revision/salvage cases. Over 90% causative organisms were virulent, demonstrating a microbial profile trend since antibiotic coating development.

Strengths and Limitations: The large prospectively maintained database is a strength along with the ability to follow specific changes in perioperative protocols. The retrospective nature of the study is a limitation as well as the low infection rate, which limits certain subanalyses from being performed.

Conclusion: IPP infections present in a delayed manner despite the rising virulence of infecting organisms. These findings highlight areas for improvement in perioperative protocols in the contemporary prosthetics era.

Keywords: antibiotic; implant; timing; culture; fungal; erectile dysfunction..

Introduction

For surgeons and patients alike, infections are a devastating and disheartening complication of inflatable penile prosthesis (IPP) implantation. Treatment of severe infection consists of prompt antibiotic administration and prosthesis removal, as well as washout of the corpora, scrotum, and reservoir spaces. To combat the initially high infection rate, the 2 major IPP manufacturers developed infection retardant–coated devices in the early 21st century.[1] Boston Scientific's American Medical Systems (AMS) devices are impregnated with InhibiZone, a proprietary mixture of rifampin and minocycline. Wilson et al showed a decrease in infection rate from 3% to 0% in primary nondiabetic implants following implementation of the coated AMS device. In comparison, Carson et al showed a decrease from 2.5% to 1.1% over almost 8 years of follow-up.[2,3] Yet, Coloplast's devices carry a hydrophilic coating allowing the surgeon to create a customizable dip.[4] Over an 11-year follow-up, Serefoglu et al found that only 1.4% of hydrophilic-coated devices required removal for infection vs 4.6% of their older counterparts.[5] Mulcahy and Carson further showed that patients with diabetes benefited from decreased infection risk. Nehra et al even found a lowered

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infection rate in revision surgery from 3.7% to 2.5%.[6,7] Existing data have not demonstrated a significant difference in infection rate between the device coatings.[8]

In addition to the absolute reduction in infection rate, many studies have shown a change in microbial virulence profiles when infections occur.[9] The *virulence* of an organism refers to the degree of pathology caused by an organism.[10,11] There is no precise definition for virulence, but there are some commonly accepted approaches to classify bacteria. The LD50 (lethal dose) measures the bacteria required to kill 50% of the host population, while the pathogenic potential measures the amount of bacterial load needed to cause symptoms.[12] An exact ranking of organisms by virulence is challenging because it is measured relative to a particular host model; however, virulence can be generally characterized as high or low. Low-virulence skin flora such as coagulase-negative *Staphylococcus* species dominated in the era before infection retardant–coated devices and was present in approximately 65% of infected devices in 1 study.[4,13] Device companies therefore designed IPP coatings to specifically combat skin flora. Virulent pathogens such as *Pseudomonas aeruginosa*, *Escherichia coli*, methicillin-resistant *Staphylococcus aureus* (MRSA), *Enterococcus*, anaerobes, and *Candida* are now increasingly more common culprits in coated-device infections.[14,15]

These organisms can cause different clinical symptoms based on their levels of virulence. Low-virulence bacterial infections are thought to present in a delayed fashion with symptoms localized to the prosthesis, while aggressive bacteria can cause rapid onset of systemic symptoms.[14]

We therefore sought to describe the timing and causative organisms behind IPP infections in the context of our institution's current perioperative antimicrobial protocols. Our primary objective was to evaluate the time to infectious symptoms, while a secondary objective was to describe device cultures at the time of explantation.

Methods

Following Institutional Review Board approval, we retrospectively reviewed a prospectively maintained database of all patients undergoing penile prosthesis surgery at our institution from January 2014 to January 2022.

Infection prevention protocol

All patients undergo preoperative urinalysis and culture to ensure absence of infection, as well as bladder scan to ensure no urinary retention. Typical perioperative antibiotic choice is consistent with current American Urological Association guidelines: aminoglycoside plus vancomycin or first-/second-generation cephalosporin or ampicillin/sulbactam or piperacillin/tazobactam. All other clinical factors being equal, we typically employ intravenous vancomycin and gentamicin. Intraoperative irrigation of the corpora and scrotum was performed with Betadine 5% before November 2016; however, all subsequent irrigations were performed with vancomycin (1 g) and gentamicin (80 mg) in 1 L of normal saline solution. Coloplast devices are soaked in rifampin and gentamicin solution while the Boston Scientific device is already impregnated with minocycline and rifampin. Following primary implant surgery, as is common practice among prosthetic surgeons, patients are discharged with 10 days of oral antibiotic.[16] This regimen is typically trimethoprim-sulfamethoxazole vs oral cephalosporin for those with sulfa allergies. Antibiotic selection for salvage surgery is based on intraoperative culture data when available.

Surgical technique

Our standard surgical technique has been previously described.[17] Briefly, surgical preparations are performed with chlorhexidine, followed by a 3M 1010 drape below the scrotum and finally blue surgical drapes. Prior to May 2018, our standard practice was to also cover the exposed skin with an iodophor-impregnated film; however, this step was not routinely performed in subsequent cases. After placement of a 14F Foley catheter, the genitals are again prepped, taking care to avoid urine spillage on the field. The remainder of the case is performed via the traditional penoscrotal approach.[17] A surgical drain is placed in the dependent scrotum and removed on postoperative day 1 following overnight observation in the hospital. Due to the COVID-19 pandemic, our practice has shifted to performing outpatient IPP surgery with rare exception. Currently, patients return on postoperative day 1 to have their drains removed in clinic.

Device selection at our institution has been based on surgeon preference. Prior to May 2018, all cases were performed by a single surgeon using Boston Scientific AMS devices. From May 2018 until present, cases have been performed by 3 different surgeons using primarily Coloplast Titan devices. All surgeons employ the penoscrotal surgical technique and perioperative antibiotic regimen just described. All surgeons had completed fellowship training in male sexual medicine at the time of these cases, and 3 of the 4 were <5 years into clinical practice at the beginning of the study.

Analysis

Each penile prosthesis infection was diagnosed clinically with either systemic symptoms of fever, chills, malaise, and hypotension or localized symptoms of purulent drainage, fluctuance, skin changes, or prolonged penile pain. All patients with a clinical diagnosis of prosthesis infection underwent device explantation and washout. All database cases resulting in penile prosthesis infection were identified, and relevant variables were extracted. No cases of infection were excluded. Cases were categorized as primary for first-time placement of an IPP in a patient not requiring any additional procedures. Complex primary cases were coded for patients with a first-time IPP and altered anatomy requiring an additional procedure, such as panniculectomy, mini-jupette, or Peyronie repair. Cases were categorized as revision surgery when an implant was being placed after explantation of a noninfected prosthesis. Salvage surgery was coded for IPP placements occurring after concurrent or delayed explantation and washout of an infected prosthesis. Descriptive and comparative statistics were tabulated to identify clinical characteristics, including patient comorbidities, prophylaxis regimen, symptom onset, and intraoperative culture result. Mann-Whitney *U* test was used to compare time to infectious symptoms. A P value $<.05$ was considered statistically significant. Statistical analyses were performed with JMP version 15.2.1 (SAS Institute Inc).

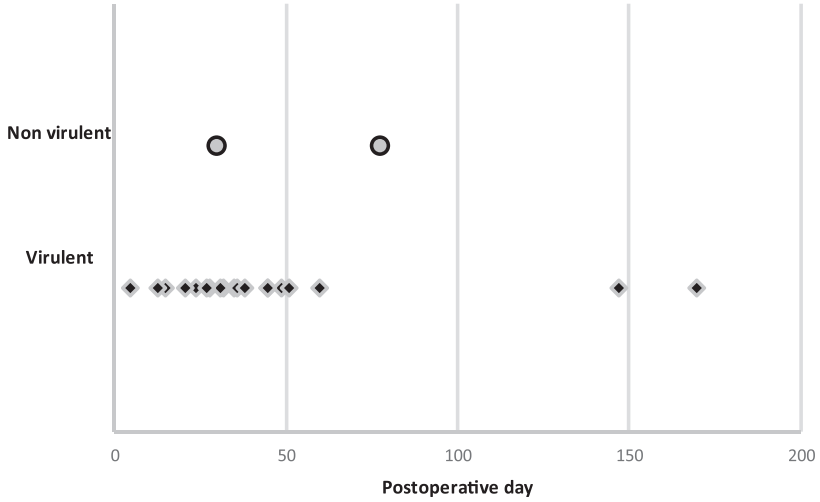

Figure 1. Time to symptoms based on virulence.

Results

A total of 1071 patients underwent IPP placement via a penoscrotal approach over 8 years. The rate of infection for all cases was 2.6% (28/1071). The infection rate in the Betadine cohort was 13.2% (20/152). Following discontinuation of Betadine, the overall infection rate was significantly lower at 0.9% (8/919), yielding a relative risk (RR) of 16.9 with Betadine ($P < .0001$). Demographic and clinical factors of the infection cohort are highlighted in Table 1. The median age of patients with an infected IPP was 66 years (IQR, 59-75), and the median body mass index was 28 (IQR, 25-30). Fifty percent of the patients had diabetes mellitus (14/28). First-time IPPs made up 46.4% (13/28) of the infections, composed of 11 straightforward primary placements and 2 complex primary placements. Revision (11/28, 39.3%) and salvage (4/28, 14.3%) placements made up the remainder. Of 28 infected patients, only 1 had no identifiable risk factors; the remainder included Betadine at 71.4% (20/28), revision/salvage at 53.6% (15/28; RR, 5.2; $P = .0001$), and diabetes mellitus at 50% (14/28; RR, 2.5; $P = .01$), as shown in Table 2. A subset analysis was performed to compare device coatings while excluding the known risk factors of Betadine irrigation and revision surgery; in this subset analysis of primary IPP placements, no difference was found in infection rate between InhibiZone and hydrophilic coating ($P = .48$).

At presentation, 28.6% (8/28) of patients had systemic symptoms, such as fever, chills, malaise, or hypotension, while the remainder had localized symptoms, such as prolonged pain, purulent drainage, or skin changes. Median time to infectious symptoms was 36 days (IQR, 26-52) overall and 35 days for virulent organisms (IQR, 27-48). There was no statistically significant difference in time to infectious symptoms between diabetic and nondiabetic patients ($P = .2$) or between patients undergoing primary and revision/salvage surgery ($P = .6$). Due to the small number of patients with nonvirulent causative organisms on intraoperative culture, a statistical comparison of time to symptoms based on virulence could not be made (Figure 1).

No growth was observed on 25% (7/28) of intraoperative cultures performed at the time of IPP explantation. *E coli* was present in 33.3% (7/21) of intraoperative cultures, fungus in 19% (4/21), MRSA in 19% (4/21), *Enterococcus* in 19% (4/21), and *P aeruginosa* in 14.3% (3/21). Polymicrobial growth was seen in 47.6% (10/21) of intraoperative cultures. Thus, 90.5% (19/21) of cases were caused by an organism with virulent features. Of note, none of the patients whose cultures grew fungus had a diagnosis of diabetes mellitus.

Discussion

Infection retardant coatings have been one of the many improvements made to IPPs over the years. This has led to a <1% rate of primary IPP infections.[8] However, growing evidence has shown that the era of coated implants has heralded a new roster of causative organisms as well. A review of IPP infections across 25 centers demonstrated that *Candida* species, anaerobes, and MRSA grew in nearly one-third of positive device cultures at the time of explantation, resulting in only 62%-86% coverage by the standard antibiotic guidelines of the American Urological Association and the European Association of Urology.[15] As all prosthetic surgeons are well aware, patient satisfaction is highly influenced by several factors, including complications such as device infection.[18] With this in mind, we examined our institutional experience with IPP infections to characterize the offending organisms and enhance our antimicrobial regimens. Our primary objective to determine timing of symptoms was born out of a desire to test the prevailing wisdom that virulent bacterial infections will present rapidly with systemic symptoms. This hypothesis has important implications for clinicians who face the diagnostic dilemma of whether a patient with an IPP truly has an infection and requires device explant.

It was interesting that among the intraoperative cultures demonstrating bacterial growth, virulent microorganisms were the causative organism in 90.5% (19/21) of cases. Despite this, >70% of patients still presented with only localized symptoms, including purulent drainage from the incision site, skin fixation of the pump, and unusually prolonged penile or scrotal pain.

The median time to presentation with infectious symptoms was between 1 and 2 months (36 days; IQR, 26-52). Prosthetic surgeons have traditionally believed that aggressive organisms will cause rapid and severe symptoms by penetrating the body's tissues rather than remaining localized.[19] In the days

Table 1. Demographics, antibiotic protocols, and culture results of patients with penile prosthesis infection.[a]

No.	Age, y	BMI	Type	Implant type	Irrigation solution	Discharge antibiotic	Systemic symptoms?	Culture result
1	81	25.1	Revision	Boston Scientific	Betadine	Bactrim	No	*Enterococcus faecalis*
2	81	25.1	Salvage	Boston Scientific	Betadine	Ertapenem	No	Polymicrobial (*Stenotrophomonas maltophilia*, *Candida glabrata*)
3	70	25.4	Primary	Boston Scientific	Betadine	Bactrim	No	NG
4	75	29.6	Revision	Boston Scientific	Betadine	Bactrim	No	MSSA
5	50	22.8	Primary	Boston Scientific	Betadine	Bactrim	No	MRSA
6	77	25.5	Revision	Coloplast	Betadine	Cephalexin	Yes	Polymicrobial (*E faecalis*, *Escherichia coli*, *C glabrata*)
7	84	28.3	Primary	Boston Scientific	Betadine	Bactrim	No	Polymicrobial (*Streptococcus agalactiae*, *Prevotella* sp, *Peptoniphilus* spp)
8	57	26.5	Revision	Boston Scientific	Betadine	Bactrim	Yes	Polymicrobial (reported as "skin flora")
9	59	30.4	Primary	Boston Scientific	Betadine	Bactrim	No	NG
10	74	28	Revision	Boston Scientific	Betadine	Bactrim	No	NG
11	61	30.2	Revision	Coloplast	Betadine	Bactrim	Yes	MDR *E coli*
12	75	32.1	Revision	Coloplast	Betadine	Bactrim	No	MRSA
13	55	26.5	Revision	Boston Scientific	Betadine	Bactrim	No	Vancomycin-resistant *Enterococcus*
14	65	30.7	Complex	Boston Scientific	Betadine	Bactrim	No	NG
15	61	24.4	Primary	Boston Scientific	Betadine	Cefdinir	Yes	Polymicrobial (skin flora, *E coli*, MRSA, anaerobic bacteria)
16	56	31	Revision	Boston Scientific	Betadine	Ciprofloxacin	No	NG
17	67	24.4	Primary	Boston Scientific	Betadine	Bactrim	Yes	Polymicrobial (*Candida lusitaniae*, *Staphylococcus lugdunensis*)
18	67	29	Salvage	Boston Scientific	Betadine	Cefdinir	No	NG
19	62	28.3	Primary	Boston Scientific	Betadine	Cefdinir	Yes	Polymicrobial (MDR *E coli*, *Pseudomonas aeruginosa*)
20	70	30	Primary	Boston Scientific	Betadine	Clindamycin	No	NG
21	59	28.2	Complex	Boston Scientific	Vancomycin, gentamicin	Cefdinir	No	*P aeruginosa*
22	85	23.4	Revision	Coloplast	Vancomycin, gentamicin	Cefdinir	No	*C glabrata*
23	65	28.5	Primary	Coloplast	Vancomycin, gentamicin	Bactrim	No	Polymicrobial (*S agalactiae*, *E faecalis*)
24	61	30.7	Salvage	Coloplast	Vancomycin, gentamicin	Bactrim	No	MDR *E coli*
25	30	31.2	Revision	Coloplast	Vancomycin, gentamicin	Cefdinir	No	*E coli*
26	56	33.3	Salvage	Coloplast	Vancomycin, gentamicin	Bactrim	Yes	MDR *E coli*
27	66	32.9	Primary	Coloplast	Vancomycin, gentamicin	Cefdinir	Yes	Polymicrobial (*Klebsiella pneumoniae*, MRSA)
28	80	27.3	Primary	Coloplast	Vancomycin, gentamicin	Ciprofloxacin	No	Polymicrobial (*P aeruginosa*, *Streptococcus anginosus*)

Abbreviations: BMI, body mass index; MDR, multidrug resistant; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*; NG, no growth. [a]Intravenous vancomycin and gentamicin were given for intraoperative surgical prophylaxis in all cases.

Table 2. Risk factors for infection in cohort of 28 patients diagnosed with penile prosthesis infection: a single-institution review of 1071 cases.

Risk factor	No. (%)
Diabetes mellitus	14 (50)
Revision surgery	11 (39.3)
Salvage surgery	4 (14.3)
Intraoperative Betadine irrigation use	20 (71.4)

before device coating, infections from less virulent organisms often presented indolently after 3 to 6 months or even longer.[13,20] Due to a small sample size of nonvirulent organisms, we could not assess for a statistically significant difference in time to infectious symptoms based on the organism's virulence. This being said, we do note that all 3 patients who developed infectious symptoms within 15 days of surgery were infected with virulent organisms, including multidrug-resistant *E coli*, vancomycin-resistant *Enterococcus*, and *Candida lusitaniae*. Again, only 1 of these patients had systemic symptoms at presentation.

Time to development of infectious symptoms was not significantly different for diabetic patients or those undergoing revision/salvage surgery vs primary placement. In the past, diabetes mellitus and complex IPP placement requiring penile reconstruction or straightening for Peyronie disease have been implicated as risk factors for infection.[21,22] While both these factors were associated with increased risk of infection in our study, their effect on the timing of infection has not been fully elucidated.

Humans are colonized with yeast; therefore, fungal infections can commonly infect medical devices such as heart valves, pacemakers, and catheters.[23] The incidence of IPP fungal infection ranges from 5% to 12% in the coated device era, which is consistent with our 19% rate of fungal organisms in positive cultures.[15,24,25] Gross et al published a multicenter study of IPP fungal infections and found that 83% of the patients in their database were either diabetic or overweight.[25] In contrast, none of our patients with fungal infections were diabetic, and their median body mass index was 24.8. However, we do note that 3 of the 4 (75%) occurred in revision or salvage cases.

We further examined the susceptibilities of the 21 positive cultures to our standard intraoperative and discharge antibiotic regimens; 19 patients had complete susceptibility data. Of the patients who had positive cultures, 31.6% (6/19) had cultures susceptible to all antibiotics given. Five patients (26.3%) had cultures that were not susceptible to any antibiotics given, and of these, 4 of 5 grew yeast. There were 11 patient cultures where the bacteria were nonsusceptible to the discharge antibiotics provided; 5 (45.5%) were primary implants: 3 primary and 2 complex primary. The other 6 (54.5%) cases were revision or salvage. Of these, 8 cultures would have been susceptible to ciprofloxacin, and 10 would have been susceptible to Levaquin with no difference between primary implants and revision/salvage cases.

We have implemented changes in our institutional perioperative antimicrobial protocols based on the current findings. We administer 1 dose of intravenous fluconazole at the time of IPP placement in patients undergoing complex primary, salvage, or revision surgery because 75% of our yeast IPP infections occurred in nonprimary implants. Following discharge, unless precluded by medication interactions or allergies, we now provide an oral fluoroquinolone to these nonprimary patients rather than our standard trimethoprim-sulfamethoxazole or cephalosporin prescription.

Of note, our institution did use a different protocol for intraoperative irrigation at the time of device placement before November 2016. We have published our findings showing that using Betadine irrigation resulted in a 9-fold increased likelihood of penile prosthesis infection in primary placements, from 1.9% to 11.2%.[26] Accordingly, 20 of the 28 infected IPP cases occurred between 2014 and 2016. Two of the 4 fungal infections occurred in 2014, 1 in 2016, and 1 in 2019. After the conclusion of this study, we transitioned to the use of Irrisept (0.05% chlorhexidine gluconate in sterile water) due to the antifungal and antibiofilm properties of this solution. Irrisept will be used for Coloplast device dip and intraoperative irrigation for all prosthetic cases going forward.

A major strength of this study is the large prospectively maintained database of prostheses from which the infection cases are identified, allowing for comparison of changes in perioperative protocols over time. Our study also has certain limitations, including the retrospective nature of the analysis, multiple surgeons, and the low rate of infection, which does not allow for certain subanalyses to be performed. The study surgeons do use the same surgical technique, which somewhat limits technical variation. We additionally acknowledge that antimicrobial susceptibility will differ by geographic location; therefore, our results may not be broadly generalizable to the rest of the country. However, we recommend that surgeons analyze their own series of IPP infections for trends in microbial profiles that could prompt changes in their institutional protocols. Finally 25% of intraoperative cultures resulted in no growth despite clinical symptoms of infection. As patients are typically started on empiric antibiotics prior to device explant, it is possible that this affected culture results. Additionally, traditional bacterial culture techniques are known to be ineffective at growing the majority of bacteria; thus, a negative culture does not necessarily imply the absence of clinical infection in the presence of symptoms. Reassuringly, the percentage of cultures with no growth in our study is consistent with prior publications in the prosthetic infection literature.[15]

Conclusion

These findings demonstrate that the onset of symptoms in penile prosthesis infection occurs in a delayed fashion between 1 and 2 months despite the rising prevalence of virulent organisms. Virulent organisms dominated 90% of positive intraoperative cultures in our series, confirming a microbial profile trend since the development of antibiotic-coated devices. These findings suggest that high-volume implanters need to reflect on their institutional perioperative antibiotic protocols in the contemporary prosthetic device era.

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