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A Surgeon's Guide to the Various Antibiotic Dips Available During Penile Prosthesis Implantation

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Abstract

Purpose of Review Inflatable penile prosthesis (IPP) is a treatment for erectile dysfunction. IPPs have undergone improvements; however, post-surgical infections still occur. Furthermore, the type of pathogens infecting the implants has changed recently from Gram-positive to Gram-negative bacteria and fungi due to advances in antibiotic dips targeting the skin flora. To protect against infection, the AMS 700 is pre-coated with InhibiZone (mixture of Rifampin/Minocycline) and the Coloplast Titan, with several antibiotic dip options of differing efficacies. This review discusses strategies to decrease the infection rates in implant surgery, focusing on antibiotic dips.

Recent Findings Current research endorses the use of rifampin/gentamicin as the most studied combination; however, some studies have utilized different dips for additional coverage including the InhibiZone on the AMS 700.

Summary With the increasing prevalence of diabetes and Gram-negative organisms, there is a need to develop strategies for increased coverage against infections. Controlled studies with different antibiotic combinations are needed to identify the ideal cocktail to decrease infection.

Keywords IPPs (inflatable penile prosthesis) · Antibiotic dips · Penile implant infections · Penile implant surgery

Introduction

The AUA and EUA guidelines for antibiotic prophylaxis for inflatable penile prostheses only cover about 62–86% of microorganisms involved in infection cases [1•]. The rise in comorbid conditions has led to more cases of a variety of bacterial and fungal infections. Diabetes as a comorbid condition has been linked to an increased risk of infection [2]. With the rise in diabetes in the general population, diabetic patients undergoing implant surgeries are at a higher risk of fungal infection [3]. Therefore, fungal infection coverage should be further investigated as current antibiotic dips, such as the combination of rifampin/gentamicin, have limited coverage against fungi [4]. Future usage of a fluconazole or amphotericin in conjunction with a rifampin/gentamicin dip should also take into account that rifampin, a strong inducer of the CYP3A4, may necessitate a higher dosage of the fluconazole or amphotericin for an adequate antifungal activity [5]. Fungal infections are still only one component of the changing landscape of implant infections. In addition to diabetes, the recently changing pathogens on implants necessitate a closer look into the antibiotic practices currently and for future improvement. The goal of this review is to summarize current and future antibiotic practices and to highlight the need for further studies.

History of the Penile Prosthesis

Erectile dysfunction affects over 50% of men between the ages of 40–70 [6]. As the number of men affected by this condition continues to grow, so has the need for the inflatable penile prosthesis (IPP). Penile prosthetics have been in use since the sixteenth century, when wood was utilized to create an artificial penis for a traumatic penile amputee [7]. The first published account of an alloplastic penile implant was in 1952 by Goodwin and Scott [8]. Building on this idea, the 1960s found the field of prosthetics moving towards the use of penile rods [9]. In particular, silicone rubber was developed for

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human implantation and was determined to be satisfactory for use in penile implants [9]. In 1973, Scott published an article describing the use of an inflatable penile implant. The implant was inflatable through hydraulic mechanisms and contained three parts: a reservoir, a pump, and two cylindrical inflatables that better mimicked the physiologic mechanisms of an erection [10]. Scott's invention led to the creation of the AMS 700 in 1983 [11]. This initial design has been modified over the years with additions such as lock-out valves which prevent auto-inflation and novel modifications to the pump to aid those with limited dexterity to pump their devices [12, 13]. However, the AMS was not alone in the race to create the ideal penile prosthetic. 1983 also saw the creation of the Bioflex penile prosthesis from the company Mentor (Coloplast) [11].

Strategies to Decrease Risk of Infections

Infection is the most dreaded complication of penile prosthetics, as it almost always results in removing the full implant [14]. Therefore, a surgeon must be diligent about the threat of infection before, during, and after surgery. There are a plethora of microorganisms that can infect an implant. Historically, almost 80% of infections were caused by Gram-positive bacteria [15]. In particular, *Staphylococcus epidermidis* was found to be the most common cause of infection, which generally occurred due to the creation of biofilms on the implant [16]. Another 20% of infections were found to be caused by Gram-negative bacteria such as *Escherichia coli*, *Serratia*, and *Proteus mirabilis* [17]. These Gram-negative infections have resulted in very severe complications when a synergism between anaerobic microorganisms occurred in patients [18]. Furthermore, some studies have found infections of fungal origin, especially in those with preexisting diabetes or other conditions [18]. Infections generally follow a time of development based on the infectious agent. A study found that isolated anaerobic infections generally progress the most rapidly and therefore have the highest rates of salvage (71%) when compared with Gram-negative (59% salvage rate) and Gram-positive (64% salvage rate) infections [19].

As AMS and Coloplast continued to create optimal, more efficient implants, they began to focus more closely on decreasing the risk of infection. In year 2000, AMS delivered a prosthesis with an external surface coating of a combination of rifampin and minocycline, known as InhibiZone [20]. A study performed a few years later showed that it reduced infectious complications from 1.61 to 0.68% [21]. Furthermore, the AMS 700 with InhibiZone was approved by the FDA in July 2009 as the only inflatable penile prosthetic with clinical evidence of decreasing the rate of revision surgeries due to infection [20]. Coloplast took steps to prevent infection as well, introducing a hydrophilic coating in 2004, which allowed the antibiotics to adhere to and elute out of the implant surface. With this coating capability, infection rates fell by 1 to 2% in first-time implant recipients with no other risk factors of infection [22].

Recent Changes in the Pattern of Infections Affecting IPPs

More recently, the nature of infectious agents is changing. There has been a reduction in infections caused by coagulase-negative Gram-positive infections such as *Staphylococcus epidermidis*. However, isolates of fungi, *E. coli*, and other Gram-negative bacteria are on the rise in infected and uninfected implants. There has also been an increase in the unique isolates that form the biofilm [23], which allows for the protection and nurturing of bacteria. Recent research and attention has been given towards biofilms and their role in infection creation on implants [24]. Furthermore, the increased prevalence of diabetes [25] in the general population has brought about new challenges regarding infection and has caused the increase in fungal infections seen in implants [26]. The rise of comorbid diseases and different infectious culprits highlights the changing landscape of penile prosthetic infections. This necessitates further exploration of anti-infection prophylaxis used by surgeons in implant surgery. Antibiotic dips must be suitable for combatting a variety of bacteria and fungi, and surgeons must adapt to the changing landscape of pathogens.

In Vitro Studies Evaluating IPPs and Antibiotics

AMS 700, unlike Coloplast, is coated with minocycline and rifampin and is called InhibiZone [20]. InhibiZone works by eluting these antibiotics over time into the surrounding tissue. The manufacturer highlights this time to be around 14 days. The combination of minocycline and rifampin was first studied in implanted vascular catheters [27]. The inhibitory activities of catheters coated with minocycline and rifampin against the Gram-positive bacteria *Staphylococcus epidermidis*, *S. aureus*, and *Enterococcus faecalis* strains were significantly better than those of catheters coated with vancomycin. Meanwhile, the inhibitory activities against Gram-negative bacilli and *Candida albicans* were comparable to those of catheters coated with ceftazidime and amphotericin B [28]. Both of these studies were done in vitro. Additionally, many studies have tested the efficacy of InhibiZone for penile implants. Similar results were found as with other implantable devices, and an overall 50% reduction in penile implant infections was found with its use [29]. A recent in vitro study was performed to determine whether the use of additional antibiotics would augment the antibacterial capabilities of InhibiZone. This study found that the addition of certain

antibiotics such as ciprofloxacin and ampicillin helped enhance the broader bactericidal effects against less-common infections such as Gram-negative infections of *Proteus mirabilis* and *E. coli* [30••]. The zone of inhibition was also increased against Gram-positive bacteria. This study also tested whether the amount of time the implant was dipped in the antibiotic solution would affect efficacy. When tested on *S. aureus*, 30-s incubation times with Ampicillin were more effective than 60-min incubation times. With ciprofloxacin, the trend was more variable and was dependent on the strain of bacteria. This study suggests that an extended period of time in the antibiotic dip may cause InhibiZone to leach out into the solution; however, more studies must be done to determine the significance of this assessment.

Current Antibiotic Dip Practices

Infection rates due to penile implants have been reduced by some surgical practices such as less skin contact and shorter operating times [31, 32]. However, antibiotic prophylaxis is a necessity in fighting infection. According to the AUA, antibiotic prophylaxis is recommended when the potential benefit outweighs the risk. Aztreonam and a first/second-generation cephalosporin or vancomycin should be used as prophylaxis for these implant surgeries for no more than 24 h [33]. The need for proper antibiotic coating has been repeatedly proven throughout the years, and recent studies have identified the standard practice for dips.

A chart review was performed to determine if there were any differences between the type of bacterial cultures on antibiotic-coated and on non-coated, uninfected implants at the time of revision surgery. The review examined the charts of 71 patients undergoing revision surgery and included those with both Coloplast and AMS-type implants. The study found that the non-coated implants had significantly more positive cultures of bacteria than those found on antibiotic-coated implants. The study went on to postulate that antibiotic coatings may help prevent late infections on implants, especially those after revision surgery. This may be because once the bacteria have seeded the area, they may infiltrate the post-revision implant and the surrounding area [34•]. This illustrates the need for antibiotic dips for the prevention of infections not only after first-time implant surgery but also after revision surgery many years in the future. Similarly, a multicenter study compared the rate and variety of bacterial presence on coated versus non-coated penile implants. The study found that although the infection-retardant coated implants had a lower percentage of positive cultures; the type of bacteria found had more variety, possibly due to the reduction in *Staphylococcus* genus bacteria. Furthermore, all the bacterial isolates were susceptible to a tetracycline (in place of minocycline) and rifampin combination [35••]. Both of these studies highlight the presence of *S. epidermidis* in both infected and non-infected implants; however, they indicate the actual differences in bacteria present on the infected versus uninfected implants to be in the Gram-negative and fungal infection categories.

From a surgeon's standpoint, Coloplast device usage leaves more room for preference in terms of the antibiotic dip utilized during surgery. The use of Rifampin has a similar origin to that of the InhibiZone Dip [27] and has further been studied in silicone grafts mimicking a penile prosthetic material [36]. The use of gentamicin has been incorporated due to its extensive Gram-negative coverage [37]. Gentamicin was found to be an effective antibiotic for the hydrophilic coating of Bioflex, a component of Coloplast's outer material [38]. In 2004, Gentamicin was studied further in connection with this hydrophilic coating, which was found to be more effective in in vitro studies at preventing bacterial colony growth when compared with non-coated. The study also found the coating with gentamicin or vancomycin to be more effective than no coating in vivo in rats [39].

Several studies have shown that the combination of gentamicin and rifampin is a highly effective antibiotic dip. In 2008, the combination of gentamicin/rifampin was compared with gentamicin/bacitracin and with InhibiZone for in vitro antibacterial capability. The study found that gentamicin/rifampin, which was comparable to InhibiZone inhibition, created a larger zone of inhibition against both *S. epidermidis* and *E. coli* when compared with gentamicin/bacitracin [40]. A separate study compared the combination of rifampin/gentamicin, vancomycin/gentamycin, and InhibiZone for infection rates. That study found that both AMS with InhibiZone and Coloplast Titan with rifampin/gentamicin had lower infection rates when compared with vancomycin/gentamycin-coated Coloplast Titan. The authors of that study thus strongly recommended that Coloplast Titan implants be coated with a combination of rifampin/gentamicin solution [41]. A further in vitro study comparing two concentrations of rifampin/gentamicin-soaked Coloplast Titan and AMS with InhibiZone was performed in 2010. Both of the rifampin-based solutions (rifampin 10 mg/mL with gentamicin 1 mg/mL and rifampin 1 mg/mL with gentamicin 1 mg/mL) were superior to AMS with InhibiZone in terms of the zone of inhibition created. Specifically, rifampin 10/gentamicin 1 was shown to have excellent coverage against *S. epidermidis* and *E. coli* [42].

A 2011 study that reviewed various antibiotic dips did not include the combination of rifampin/gentamicin. That study compared InhibiZone with Coloplast dipped in trimethoprim/polymyxin B ophthalmic solution, trimethoprim/sulfamethoxazole-infusion solution, Bacitracin, rifampicin/minocycline, or rifampin/trimethoprim/sulfamethoxazole. The zone of inhibition for all the dips (except Bacitracin) was superior to that of InhibiZone when inhibiting against *S. epidermidis*, *S. lugdunensis*, *S. aureus*, *Pseudomonas*, and *Enterococcus*. The authors recommended trimethoprim/

sulfamethoxazole as the optimum dip due to broad-spectrum effectiveness, ease of handling, and cost [43]. The combination of rifampin/gentamicin, however, appears to be more widely used and has been studied in much greater detail than the dips suggested in this article.

Apart from gentamicin's application as an antibiotic dip, it has been recently studied as a prophylaxis during penile prosthesis implantation as well. A study states that the higher dose (5 mg/kg) preoperative gentamicin should be used to lower the infections rates. Furthermore, the higher dose does not have more toxicity than the conventional lower dose amounts [44]. This study reinforces the efficacy of gentamicin in preventing the IPP disease, regardless of usage route.

The use of antibiotic dips is further reinforced by the recent recommendation from the International Consultation on Sexual Medicine which states that the use of antibiotic coating has been found to reduce infection rates [45]. To summarize the current practices of antibiotic coatings, AMS is coated with InhibiZone, and Coloplast Titan is recommended to be coated with rifampin/gentamicin at concentrations of 10 mg/mL rifampin/1 mg/mL gentamicin to 1 mg/mL rifampin/1 mg/mL gentamicin (based on extensive literature and research). Table 1 summarizes current dip studies.

Future Studies

The changing landscape of pathogens which infect implants has led to the investigation and re-evaluation of the antibiotic dips used for penile implant surgeries.

Table 1 Pertinent findings and bacteria studied, organized by author and anti-infection dip of concern

Author	Anti-infection dips studied	Bacteria studied	Pertinent findings
Li H (1998) [36]	Rifampin 40 mg/mL/minocycline 25 mg/mL Amikacin 30 mg/mL Vancomycin 60 mg/mL	*S. aureus* *S. epidermidis*	Rifampin/minocycline larger ZOI than amikacin and vancomycin
Hellstrom (2003) [38]	Gentamicin 2 mg/mL/bacitracin 100 U/mL	*S. aureus* *S. epidermidis* *E. coli* *P. aeruginosa*	Gentamicin/bacitracin greater ZOI than saline against *S. epidermidis*
Dhabuwala (2004) [39]	Gentamicin 160 mg/L/vancomycin 1 mg/mL	*S. epidermidis*	Gentamicin/vancomycin reduces *S. epidermidis* colony counts by 41%
Dhabuwala (2008) [40]	InhibiZone Rifampin 10 mg/mL/gentamycin 1 mg/mL Bacitracin 50 U/mL/gentamycin 1 mg/mL	*S. epidermidis* *E. coli*	Rifampin/gentamycin and bacitracin/gentamycin both have greater ZOIs than InhibiZone
Dhabuwala (2010) [42]	InhibiZone Rifampin 10 mg/mL/gentamycin 1 mg/mL/ vancomycin 2 mg/mL rifampin 10 mg/mL/gentamycin 1 mg/mL Rifampin 1 mg/mL/gentamicin 1 mg/mL/ vancomycin 2 mg/mL Rifampin 1 mg/mL/gentamycin 1 mg/mL Rifampin 10 mg/mL Bacitracin 50 units/mL/gentamycin 1 mg/mL	*S. epidermidis* *E. coli*	The zone of inhibition produced by both R10/G1 and R1/G1 is the greatest and exceed that produced by InhibiZone by 40% to 56% for *S. epidermidis* and 33% for *E. coli*.
Dhabuwala (2011) [41]	InhibiZone Trimethoprim/polymixin B ophthalmic solution Trimethoprim/sulfamethoxazole infusion solution Bacitracin Rifampicin/minocycline Rifampin/trimethoprim/sulfamethoxazole	*S. epidermidis* *S. lugdunensis* *S. aureus* *Pseudomonas* *Enterococcus*	All dips except bacitracin showed ZOI ≥ InhibiZone for most organisms. Author recommends TMP/SMX due to ease of handling and broad spectrum
Chanyi, RM (2018) [30]	Gentamycin 15 μg/mL Ampicillin 100 μg/mL Tetracycline 10 μg/mL Kanamycin 50 μg/mL Erythromycin 25 μg/mL Ciprofloxacin 10 μg/mL	*E. coli* *S. aureus* *S. epidermidis* *P. mirabilis*	Ampicillin best for Gram-positive *S. aureus* and *S. epidermidis* while ciprofloxacin is best for Gram-negative *E. coli* and *P. mirabilis*

However, the use of antibiotic dips may also be affected by other factors. Significantly, the use of dorsal nerve block with bupivacaine liposome injectable suspension (Exparel) has been proven efficacious for pain management after the implantation of an inflatable penile implant [46•]. With the incorporation of bupivacaine in penile implantation taking root amongst many surgeons, current research is being performed to determine if bupivacaine administration can compromise the antimicrobial effects of antibiotic dips. An in vitro analysis was performed to evaluate clinical outcomes of the Coloplast Titan hydrophilic coating dipped in 0.75% ropivacaine and 0.5% Marcaine (bupivacaine). The study compared drug-elution profile and microbial zone of inhibition in the hydrophilic coating with antibiotic in those receiving anesthetic versus those not receiving anesthetic. The in vitro release kinetics showed that passive drug elution was above the minimum inhibitory concentration and that the patient's pain scores were greatly reduced with the administration of the anesthetic [47••]. Building on this study, more research should be done to test the effects of bupivacaine. Specifically, bupivacaine should also be studied in AMS with InhibiZone as well as Coloplast Titan with rifampin/gentamicin concentrations. Studies on the anti-Gram-negative coverage with and without bupivacaine in antibiotic dips may also be warranted to reflect the changing landscape of bacteria in implant infections.

Conclusion

From the inception of penile prosthesis implantation, clinicians and scientists have worked tirelessly to perfect the implant [7]. With an aging population and a decrease in the stigma surrounding erectile dysfunction [48], the management of erectile dysfunction may include an increase in the number of penile implant surgeries performed each year. The prevention of infection from these surgeries has also been a long-standing goal. In fact, aside from negative outcomes involving consent and surgical performance, postoperative infections have been associated with over 30% of penile prosthesis litigation against urologists [49]. An improved surgical technique, augmentation of prophylactic antibiotics, and environmental infection control have all been heavily studied and modified. Thus, to prevent infection, antibiotic dip augmentation is the final frontier. For the AMS 700 with InhibiZone, further research must be performed to determine whether the addition of supplementary antibiotics for broader coverage will improve the outcomes. For the Coloplast Titan we recommend a combination of rifampin/gentamicin, between the concentrations of 10 mg/mL rifampin with 1 mg/mL gentamicin and 1 mg/mL rifampin with 1 mg/mL gentamicin, as the antibiotic dip.

Compliance with Ethical Standards

Conflict of Interest Soum D. Lokeshwar, Joshua Bitran, and Vinayak Madhusoodanan each declare no potential conflicts of interest.

Bruce Kava is a consultant for Endo and Coloplast.

Ranjith Ramasamy is a consultant for Coloplast, an investigator for Boston Scientific and Direx, and an advisory board member and investigator for Endo and Aytu Biosciences.

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- •• Of major importance

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