

North American Consensus Document on Infection of Penile Prosthesis

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OBJECTIVE	To issue a consensus document on the prevention, management, and research of infection associated with penile prostheses, as neither professional associations nor governmental entities have issued guidelines that are specific to this infection.
METHODS	Sixteen North American experts on infection of penile prostheses were identified and assembled to select and discuss certain issues related to infection of penile prostheses. After performing an extensive search of clinically important issues in published reports, the 16 experts met twice in person to finalize the selection, discuss the issues that were deemed most important, and issue pertinent recommendations.
RESULTS	Although many subjects relevant to infection of penile prostheses were initially identified, the experts selected 10 issues as currently being the most important issues and for which there exists some support in the published data. The examined issues involved prevention, management, or research of infections associated with penile prostheses.
CONCLUSION	In the absence of pertinent guidelines, the consensus document issued by experts in the field of prosthetic urology is anticipated to improve the quality of patient care, streamline the prevention and management of infected penile prostheses, and stimulate collaborative research. Although this consensus document could serve as best practice recommendations, the lack of adherence to these recommendations would not indicate improper care. UROLOGY 82: 937–942, 2013. Published by Elsevier Inc.

Of the tens of millions of American men with erectile dysfunction, up to 25,000 of them currently undergo implantation of inflatable penile prostheses each year in the United States.¹ Infection is the most common serious complication of

implanted penile prostheses, as it can result in prolonged and repeated hospitalizations, multiple operations, additional comorbid conditions owing to secondary interventions, and loss of work. Although the average rate of infection of virgin penile prostheses in patients at low risk of infection does not exceed 2%-3%, the likelihood of infection can be several folds higher in those who have replacement prostheses, undergo repeated surgical procedures, or with underlying medical conditions that predispose to infection, or a combination of these.²

Unfortunately, neither professional associations nor governmental entities have issued guidelines or even best practice recommendations that are specific to the prevention and management of infection of penile prostheses. The lack of established guidelines could be attributed, at least in part, to the relatively low rate of infection of penile prostheses (as compared, for example, with a 10%-20% incidence of catheter-associated urinary tract infection) or the relatively small absolute number of cases of infection of penile prostheses that occur each year in the United States (\leq a thousand cases of infected penile prostheses vs hundreds of thousands of episodes of catheter-associated urinary tract infection), or a combination of both.³ The purpose of this communication is to provide

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Table 1. Examined issues

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- (A) Prevention of infection
- (1) Perioperative systemic antibiotic prophylaxis
 - (2) Antiseptic cleansing of the skin
 - (3) Preoperative showering or bathing
 - (4) Preoperative scrubbing of patients' skin
 - (5) Surgeons' scrubbing vs hand rubbing
 - (6) Surface modification of prostheses
- (B) Management of infection or colonization
- (1) Salvage strategy
 - (2) Revision procedure
- (C) Future research
- (1) Limitations of research
 - (2) Microbiology of infection
-

a consensus document on the prevention, management, and research of infection associated with penile prostheses.

MATERIALS AND METHODS

A total of 16 North American (14 Americans and 2 Canadians) experts on infection of penile prostheses (including 15 practicing urologists and 1 infectious disease specialist) agreed to participate in this endeavor. All assembled experts have implanted penile prostheses in a large number of patients or frequently called on to help manage infection of penile prostheses, or both, and have published and lectured on this subject.

Of the dozens of issues related to infection of penile prostheses that were initially identified as being possibly suitable for discussion, the experts selected for further examination 10 issues that were regarded as being most important and for which there exists some support in the published data. As shown in Table 1, the 10 examined issues focused on prevention, management, or research of infections of penile prostheses. A comprehensive Medline search was performed using the MeSH index headings from January 2000 through March 2013 (Table 2). The expert panel did not rely on letters and abstracts. The experts described their practices, expressed their preferences, and stated the scientific basis or clinical logic for their recommendations. Because there exist minimal published data for many examined issues, the panel was not expected to qualify the strength of the issued recommendations.

RESULTS

The expert panel selected and discussed the following 10 issues that belong to the 3 categories of prevention of infection (6 issues), management of infection (2 issues), and future research (2 issues).

Prevention of Infection

Although the overall rate of infection of penile prostheses is not that high, these infections can lead to serious medical sequelae, tragic psychologic trauma, and disastrous economic consequences. Because 1 case of infection of penile prostheses is one too many, preventing these infectious complications is a top priority.

Table 2. MeSH index headings used for Medline search

Penile AND implant (OR prosthesis) AND antibiotic
 Penile AND implant (OR prosthesis) AND prophylaxis
 Penile AND implant (OR prosthesis) AND systemic AND antibiotic AND prophylaxis
 Penile AND implant (OR prosthesis) AND antisepsis (OR antiseptic)
 Penile AND implant (OR prosthesis) AND shower
 Penile AND implant (OR prosthesis) AND scrub
 Penile AND implant (OR prosthesis) AND surface
 Penile AND implant (OR prosthesis) AND antimicrobial (OR Inhibizone OR rifampin OR minocycline)
 Penile AND implant (OR prosthesis) AND salvage (OR salvaging OR removal OR replacement OR no removal)
 Penile AND implant (OR prosthesis) AND revision
 Penile AND implant (OR prosthesis) AND colonization
 Penile AND implant (OR prosthesis) AND biofilm
 Penile AND implant (OR prosthesis) AND capsule
 Penile AND implant (OR prosthesis) AND infection (OR infected)

Perioperative Systemic Antibiotic Prophylaxis.

Background. The American Urological Association Practice Guidelines Committee indicated that there were insufficient data to formulate a guideline on antimicrobial prophylaxis for urologic surgery and issued in 2007 a Best Practice Policy Statement on Urologic Surgery Antimicrobial Prophylaxis that was updated in 2008.⁴ Taking into consideration that no randomized controlled trials had assessed the type and duration of systemic antibiotic prophylaxis for “implanted urologic prostheses”, the American Urological Association Best Practice Policy Statement recommended the use of a first- or second-generation cephalosporin (or vancomycin) and an aminoglycoside (or aztreonam) for ≤ 24 hours. Our expert panel was also cognizant of the fact that guidelines from other surgical associations and quality-focused organizations recommended stopping systemic antibiotic prophylaxis within 24 hours after surgery.⁵ Not unexpectedly, there exist no prospective or retrospective data that assess the choice and duration of systemic antibiotic prophylaxis around the time of implanting penile prostheses. This helps explain the great variation in perioperative practices among urologists who implant penile prostheses.⁶

Recommendation. There was a consensus among the experts to provide antimicrobial coverage against gram-positive (mainly staphylococci) and gram-negative bacteria and to continue antibiotics, preferably intravenously while patients still hospitalized, for at least 24 hours after surgery. Although most experts preoperatively administer vancomycin rather than cephalosporins that are inherently inactive against methicillin-resistant *Staphylococcus aureus* (MRSA), the panel unanimously expressed the need to adjust the choice of vancomycin vs a cephalosporin on the basis of the prevalence of MRSA in the individual hospital and community. Preoperative administration of systemic antibiotics must be timed to allow therapeutic antibiotic levels before making the surgical incision in blood and manipulated tissues. All expert

urologists provided oral antibiotic prophylaxis for 5-14 days postoperatively. A variety of oral antibiotics (including quinolones, cephalosporins, penicillins, and sulfa drugs) are currently being used for postoperative prophylaxis. However, in environments in which MRSA is prevalent, the consensus among experts was to use trimethoprim-sulfamethoxazole (bactrim) in patients with no allergy to sulfa drugs, in which case doxycycline could be used.

Antiseptic Cleansing of the Skin.

Background. The panel acknowledged the variability of practices when cleansing the patients' skin before implanting penile prostheses. A randomized, controlled, multicenter study showed that patients embarking on clean-contaminated surgery have a significantly lower rate of surgical site infection if their skin is preoperatively cleansed with chlorhexidine-alcohol vs aqueous povidone-iodine.⁷ Another randomized clinical trial in patients undergoing clean, clean-contaminated, or dirty surgery also demonstrated the superior protection afforded by chlorhexidine-alcohol vs aqueous povidone-iodine.⁸ A single quasi cross-over study suggested that antiseptic cleansing of the patients' skin with chlorhexidine-alcohol may reduce the rate of infection of penile prostheses.⁹ Furthermore, in a recent randomized controlled trial, chlorhexidine-alcohol was superior to povidone-iodine in eradicating skin flora at the surgical skin site before genitourinary prosthetic implantation.¹⁰

Recommendation. The panel unanimously recommended cleansing of the patients' skin with alcohol-based antiseptic preparation whenever available, with the understanding that aqueous but not alcohol-based preparations would be applied to mucosal membranes. The alcohol-based antiseptic preparation should be allowed to dry for at least 3 minutes before making the surgical incision.

Preoperative Showering or Bathing.

Background. Although a bit controversial, extensive recent assessments in Cochrane reviews¹¹ and meta-analysis¹² disclosed no convincing evidence that preoperative showering or bathing with certain agents (chlorhexidine, povidone-iodine preparations, soap and water, and so forth) reduces the incidence of surgical site infection. Although a randomized, controlled, multicenter trial demonstrated a significant reduction in the incidence of surgical site infections because of *Staphylococcus aureus* among nasal carriers who preoperatively received for 5 days chlorhexidine bodily wash daily and nasal mupirocin twice a day as compared with no intervention, the degree of protection afforded by chlorhexidine alone is unknown.¹³ The value of this strategy of preoperative showering or bathing has not been examined in patients receiving penile prostheses.

Recommendation. The panel agreed that patients with poor skin condition should receive a preoperative shower or bath. However, there was a unanimous agreement

among the experts that, in the absence of relevant data, the operating urologist has the ultimate say as to whether patient should shower or bath, with which agent(s), and for how long.

Preoperative Scrubbing of Patient's Skin.

Background. Preoperative local scrubbing of the patient's skin has been generally studied much less than preoperative showering or bathing, and there exist no pertinent data specific to penile prostheses. A prospective cohort study in patients receiving artificial urinary sphincters (not penile prostheses) showed that scrubbing the patient's skin with 4% chlorhexidine for 5 minutes twice a day for 5 days reduces perineal colonization by 4 folds as compared with the usual hygiene practice of cleansing the skin with soap and water, but this study did not assess the effect on clinical infection.¹⁴

Recommendation. The panel acknowledged the lack of data comparing the effect of preoperative scrubbing vs showering or bathing vs no skin preparation on the occurrence of infection of penile prostheses. As is the case with the strategy of preoperative showering or bathing, the panel unanimously stated that the operating surgeon would determine the need, type, and duration of preoperative scrubbing of patients' skin.

Surgeons' Scrubbing Vs Hand Rubbing.

Background. There exists an emerging trend for surgeons scrubbing their hands with aqueous preparations before the first surgery of the day, then hand rubbing with an alcohol-based preparation before subsequent surgeries unless their hands become grossly dirty. This strategy, however, has not been assessed at the time of implanting penile prostheses. Furthermore, there are no strong comparative data to indicate that the use of various antiseptic preparations for scrubbing (including chlorhexidine, povidone-iodine, and chloroxylenol) or hand rubbing with various alcoholic-based solutions significantly affects the occurrence of surgical site infection. Surgical hand antisepsis with alcohol-based hand rubbing for 1.5 minutes vs 3 minutes resulted in comparable bacterial reduction.¹⁵

Recommendation. In the absence of convincing data, the panel experts unanimously recommended that urologists scrub their hands before the first surgery of the day and whenever their hands become grossly dirty. However, the experts could not reach an agreement as to whether the hands of urologists implanting penile prostheses should, after the first surgery of the day, be routinely scrubbed instead of being rubbed, and with which antiseptic preparation.

Surface Modification of the Penile Prosthesis.

Background. Penile prostheses that are antimicrobial-impregnated (with minocycline and rifampin) or antibiotic-dipped (by bonding various antibiotics such as gentamicin plus rifampin to a hydrophilic surface that contains polyvinyl pyrrolidone) were shown in retrospective

studies to cut down on average the rate of infection by at least half, as compared with control nonmodified prostheses. The efficacy of surface modification was documented with long-term follow-up,^{16,17} in diabetics,^{2,18} with replacement implantation,¹⁹ in combination with a no touch technique,²⁰ and in a meta-analysis.²¹ Not unexpectedly, the requirement for a large sample size prohibits the performance of sufficiently powered randomized controlled trials that would compare the clinical efficacy of these 2 types of surface-modified penile prostheses.

Recommendation. Although there are established factors (including diabetes mellitus, replacement surgery, spinal cord injury, severe vascular insufficiency, active infection, and so forth) that clearly predispose to infection of penile prostheses, the expert panel acknowledges the fact that infection can still occur and cause serious complications in patients at a low risk for infection. Accordingly, the experts unanimously recommended the use of surface-modified penile prostheses, whenever available, possible, and free of allergic reactions. The choice to use one type of antimicrobial-modified prosthesis vs another ought to be based on factors including allergic reactions to the used antibiotics, likelihood of antimicrobial coverage against infecting pathogens, durability of antimicrobial activity, and historic success when applying a certain surface modification not just to the penile prostheses but also to other types of foreign devices.

Management of Infection or Colonization

A number of other surgical specialties, including orthopedics and vascular surgery, commonly practice the 2-stage surgical management of infected implants by first removing the infected prosthesis, possibly placing antimicrobial-containing spacers or beads, and then implanting a new prosthesis at a later time when infection is deemed to have been cured. Although delayed replacement of infected penile prostheses can decrease the penile size because of corporal fibrosis, a recently reported patient initially received a calcium sulfate spacer that contains vancomycin and tobramycin, then subsequently had a successful and uneventful replacement of the penile prosthesis 6 weeks later without corporal fibrosis.²² However, at the present time, most urologists perform a single-stage “salvage” procedure during which the infected penile prosthesis is removed, the surgical field is washed, and a new penile prosthesis is placed. These observations prompt the analysis of 2 important issues related to the management of infected or colonized penile prostheses.

Salvage Strategy.

Background. Vigorous intraoperative mechanical and antimicrobial irrigation is a key to successful salvage of infected penile prostheses. The original protocol for salvage irrigation that comprised removal of all foreign materials, a 7-step antimicrobial wound irrigation (including 3 steps using antibiotics and 4 steps using

antiseptics), changing the operating setup, insertion of a new prosthesis, and a 1-month postoperative course of an oral quinolone was successful in 82% in highly selected cases.²³ A subsequent smaller study that used the same 7-step antimicrobial wound irrigation, but did not mention the change in operation setup or the 1-month course of oral quinolone, reported a similar degree of efficacy of 87% in also highly selected patients.²⁴ Some experts shared their nonpublished lower rates of success when using such irrigation protocols. The efficacy of these original or modified irrigation protocols has not been compared with other irrigation strategies. Because most infected penile prostheses currently undergo a single-stage salvage procedure rather than a 2-stage surgical replacement, it is essential to maximize the chance of cure.

Recommendation. The expert panel unanimously acknowledged the fact that a salvage procedure is more likely to fail in the presence of factors such as sepsis, purulence, extruded device, urethral perforation, and uncontrolled diabetes mellitus. That is why the experts recommended that infected patients should be involved in making the decision as to whether a salvage procedure should be performed. There was a universal recommendation by the panel to remove the whole penile prostheses if any component is clinically infected. A vigorous mechanical (to remove biofilm) and antimicrobial irrigation (aimed at eradicating bacterial presence) is essential in salvage surgery. However, some experts opined that modified (using different antimicrobials and, perhaps, using a lower concentration of potentially tissue-irritating antiseptics) or more practical (less irrigation steps) versions of the original irrigation protocol, or both, could also be protective. All experts recommended the use of systemic antibiotics guided by the results of intraoperative cultures for 2-4 weeks after surgery.

Revision Procedure.

Background. Even in the absence of clinical infection, mechanically failed components of penile prostheses can become grossly covered by biofilm or colonized by biofilm-embedded bacteria.^{25,26} Because intraoperative bacterial cultures are reportedly less likely to be positive after irrigation than before, and taking into consideration that bacterial absence could correlate with revision-free survival,²⁵ antimicrobial washout is commonly,²⁷ but not always,²⁸ done.

Recommendation. Although the experts expressed split opinions as to whether some but not all colonized components of the penile prostheses could be left in place in the absence of clinical infection, they unanimously agreed on the need for antimicrobial irrigation. Regardless, the components' spaces should be irrigated with antimicrobials before placing new components. Despite the absence of supporting data, all experts opined that a 5-7-day course of properly selected oral antibiotics would be appropriate after surgical revision for

noninfectious reasons. Although intraoperative cultures are not routinely obtained from patients undergoing revision surgery, the antimicrobial profile of colonizing organisms detected by intraoperative cultures could help guide the choice of postoperative systemic antibiotics.

Future Research

Limitations of Research. Although randomized controlled trials are a superior methodology in the hierarchy of evidence, the relatively small number of penile prostheses that are inserted each year combined with the relatively low rate of infection, makes it almost impossible to conduct randomized controlled trials on the prevention or management of infection of penile prosthesis. For instance, it takes 5028 evaluable patients to have a sufficiently powered study that would demonstrate a significant reduction in the rate of infection when comparing an experimental preventive strategy with a 1% rate of infection vs a baseline rate of infection of 2% in the control group.²⁹ Even if the baseline rate of infection in the control arm is higher, at 3% or 4%, and the experimental arm has an infection rate of 1.5% or 2%, respectively, it would still be prohibitive to conduct an adequately powered randomized trial of 3328 or 2478 evaluable patients, respectively.²⁹ Another limitation to conducting randomized controlled studies is that, according to the Centers for Disease Control and Prevention guidelines, surgical site infection in patients with indwelling prostheses needs to be assessed at 1 year as compared with only 1 month in surgical patients without an implanted prosthesis.³⁰ Not even a cross-over study design may yield itself well to the study of patients with penile prostheses. This helps explain why most studies that assess infection of penile prostheses are cohort or observational studies.

Microbiology of Infection. It would be important to determine whether exposure to certain systemic or local antibiotics changes the microbiology of infection of penile prostheses. Because this issue would be difficult to examine in a prospective fashion, it would be best assessed in a retrospective multicenter study that has 3 objectives: (1) compare the current vs past microbiology of infection of penile prostheses, (2) assuming a change in microbiology is detected, it would be important to explore whether changes in the microbiology of infection of penile prostheses simply reflect the hospital-wide microbiology alterations over time rather than the use of certain antibiotics, and (3) potentially update the optimal choice of antimicrobials for prevention and treatment of infection.

COMMENT

This consensus document is not intended to address all issues related to prevention, management, and research of infection of penile prostheses. Instead, the expert panel decided to focus on certain clinically important issues. We did not include in the consensus statement universally applied preventive practices, such as limiting traffic

in the operating room, optimizing control of diabetes mellitus, and postoperative sealing of wounds. We discussed but excluded from the consensus statement important but rather controversial issues such as insertion of drains and handling of hair (clipping vs shaving). This presented information and issued recommendations in the consensus document do not sanction the off-label use of products.

CONCLUSION

The issued North American Consensus Document on Infection of Penile Prostheses aims at enhancing prevention of infection, optimizing management of established infection, and stimulating collaborative research. In the absence of existing guidelines, the recommendations listed in this consensus document could serve as best practice recommendations. Lack of adherence to these recommendations does not indicate improper care.

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EDITORIAL COMMENT

This consensus statement will be a valuable reference for the penile prosthetic implanter to consult to prevent and manage

penile prosthesis infection. The authors are made up of leaders in sexual medicine and an authority in infectious disease. With up to 25,000 patients undergoing penile prosthesis implantation and an expected infection rate of 2%-3%, or higher in complex cases, managing infection is a considerable challenge, and we are best served by avoiding it altogether when possible.^{1,2} The fact that the authors did not assign levels of evidence to their recommendations speaks to the quality of the available evidence. In most cases, expert opinion is the best guidance we have. The authors point out methodological challenges of performing randomized trials with limited case numbers and a relatively rare outcome.

All urologists whether they implant prosthetics should be concerned about the epidemic of antibiotic resistance and the paucity of new antimicrobial drugs in development. Fewer new antimicrobials are being delivered to the market place. Between 1962 (nalidixic acid) and 2000 (linezolid) no new classes of antimicrobials were developed; drugs that entered the market place during this time were simply modifications of available molecules.³ Most large pharmaceutical companies no longer invest in antimicrobial research and development, given the long lead time to market place (up to 20 years), the cost (\$1 billion), and a market potentially limited by regulatory constraints.

The Health and Human Services Department of the United States is providing \$40 million to drug maker GlaxoSmithKline to help develop agents that will combat antibiotic resistance or those used for bioterrorism.⁴ The government program could give up to \$200 million over the next 5 years to the company. A similar program in Europe is underway with AstraZeneca and GlaxoSmithKline with companies working together to pool resources and research data. In addition, creating a stream-lined, faster drug approval process similar to those used for orphan drugs to treat rare conditions is being considered for antimicrobials. Finally, tighter regulation of distribution and marketing will be needed to protect these new antimicrobials from overuse and the development of resistance. Urologists will want to monitor the landscape of antimicrobial development and resistance closely as this dilemma evolves.

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