

## ERECTILE DYSFUNCTION

# Intraoperative Use of Betadine Irrigation is Associated With a 9-Fold Increased Likelihood of Penile Prosthesis Infection: Results From a Retrospective Case-Control Study



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## ABSTRACT

**Introduction:** Infection remains a persistent complication of penile prosthesis (PP) surgery. Despite popularity of Mulcahy's PP washout protocol, Betadine has known tissue toxicity.

**Aim:** We evaluated PP infection rate based on the type of intraoperative irrigation used,  $1/2$  strength Betadine vs vancomycin/gentamicin.

**Methods:** We reviewed a prospective database of men undergoing primary, revision, and salvage PPs. No other changes to operative or perioperative techniques occurred after the change in irrigation solution. Univariate and logistic regression analyses were used to evaluate differences in infection rate with use of Betadine vs vancomycin/gentamicin irrigation. Potential confounders were reviewed.

**Main Outcome Measure:** The primary outcome was rate of PP infection before and after change of intraoperative irrigation.

**Results:** From 2014 to 2018, 217 patients underwent PP placement at our institution by a single surgeon; of whom, 21 (9.7%) experienced an infection (primary = 10 [7.1%], revision = 11 [17.19%], salvage = 0 [0%]). Overall, 152 (70%) received irrigation with Betadine and 65 (30%) with Vancomycin/Gentamicin. Univariate analysis demonstrated significantly increased infection rates with Betadine irrigation (odds ratio [OR]: 4.64,  $P = .006$ ) and with revision surgery (OR: 2.68,  $P = .02$ ). Significance of increased infection rate with Betadine was maintained (OR: 9.3;  $P = .025$ ) after controlling for age, body mass index, Charlson comorbidity index, smoking, diabetes, primary vs revision/salvage, prior penile surgery, use of ectopic reservoir, and adjunctive glanulopexy.

**Conclusions:** Changing from intraoperative Betadine to vancomycin/gentamicin solution dramatically reduced infection rates among men undergoing PP placement in both primary and revision cases. We hypothesize that differences in infection rate may relate to the relative toxicity or non-sterile nature of Betadine. **Manka MG, Yang D, Andrews J, et al. Intraoperative Use of Betadine Irrigation is Associated With a 9-Fold Increased Likelihood of Penile Prosthesis Infection: Results From a Retrospective Case-Control Study. Sex Med 2020;8:422–427.**

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**Key Words:** Penile Prosthesis; Infection; Irrigation; Betadine

## INTRODUCTION AND OBJECTIVE

Penile prostheses (PPs) remain the gold standard for medically refractory erectile dysfunction with high overall success and

satisfaction rates. These devices are among the most reliable medical devices in use currently with more than 95%, 5-year and 80%, 10-year mechanical survival rates.<sup>1</sup> However, infection remains a persistent complication of PP surgery, which in a small percentage of cases necessitates device removal and can be devastating for patients. Although variable, the most common source of infection is thought to occur from skin contamination, usually *Staphylococcus epidermidis*, at the time of implant placement and persists within a biofilm around the device.<sup>2</sup> Less common, more virulent organisms such as *Pseudomonas*, *Serratia*, *Staphylococcus aureus*, and *Escherichia coli* may cause infection leading to more rapid spread and possible development of severe

Received February 11, 2020. Accepted May 26, 2020.

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<https://doi.org/10.1016/j.jsxm.2020.05.010>

systemic illness.<sup>3</sup> Revision PP procedures or PP placement associated with concomitant reconstructive surgery have been found to be associated with higher rates of infection, whereas diabetes, immunosuppression, and spinal cord injury remain debatable causes.<sup>3,4</sup>

Many perioperative techniques have been described to reduce the risk of infection with PPs. For instance, antibiotics are routinely given perioperatively, although there is no consensus on ideal duration of prophylaxis.<sup>5</sup> In addition, the development of AMS InhibiZone device and the hydrophilic coating of Coloplast devices have been shown to reduce rates of infection.<sup>6–10</sup> In regards to skin cleansing, a Cochrane review has demonstrated that chlorhexidine alcohol solutions had lower rates of surgical site infections than alcohol-based povidone-iodine.<sup>11</sup> Intraoperatively, the no-touch technique originally described in 2011 uses a drape after initial dissection to cover all skin surfaces, as well as new gowns, gloves, and instruments.<sup>12</sup> Single-surgeon series have suggested a reduction in infection using this technique.<sup>13</sup> Washout protocols, as described by Mulcahy for clinically infected prostheses, have led to reduced infection rates in uninfected prosthesis revision likely because of the ubiquitous presence of prosthetic biofilms.<sup>14–17</sup> However, the antiseptics commonly used in washout protocols can have cytotoxic effects, and recent literature highlights the need for additional evidence to guide PP implanters as to the most safe yet effective irrigant regimens.<sup>18</sup>

In our surgical practice, we experienced persistently elevated infection rates with both primary and revision PP cases despite using a complete no-touch technique, voluminous irrigation, antibiotic-impregnated devices, postoperative antibiotics, alcohol-based skin cleansers, and multiple other intraoperative considerations. Beginning in November 2016, we changed the type of intraoperative irrigation from 5% Betadine to vancomycin/gentamicin without any other changes to operative or perioperative protocols. We subsequently noted a dramatic and immediate anecdotal reduction in the rate of postoperative infections.

Given reduction in postoperative infections noted in our practice, the objective of the current manuscript was to compare infection rates based on type of irrigation performed at the time of both virgin and revision PP surgery and to evaluate for other potentially contributing factors.

## MATERIALS METHODS

### Study Cohort

The study cohort consisted of a consecutive single-surgeon series from a detailed, prospectively maintained database of men undergoing primary, revision, and salvage PPs at our institution from January 2014 through April 2018, with complication and outcomes data reviewed through January 2019. All men who agreed to receive periodic surveys were contacted at 3, 6, 12, 24, 36, 60, and 120 months postoperatively to identify complications including infections

managed at outside facilities. Medical records were also reviewed for all men in the cohort to identify phone communications, emergency department visits, and clinical visits in an attempt to more accurately capture true complication rates. The database included demographic, clinical, pathophysiologic, and operative variables. Beginning in May of 2018, a new provider was hired into our practice and began doing all PP cases at our institution, thus providing a minimum 9-month follow-up for all surgical cases. Cases performed by the new provider are not included in this series. The study was approved by the Mayo Clinic Institutional Review Board.

### Surgical Technique

PP placement is performed through a penoscrotal incision in a “no-touch” fashion as previously described.<sup>4</sup> Briefly, the patient is prepped with chlorhexidine, after which the penis and scrotum are brought through a small hole in the Iodophor-impregnated drape. A 14-French Foley catheter is placed, and the penis, scrotum, and catheter are prepped again with chlorhexidine. Liposomal bupivacaine is then used to create a penile ring block and to infiltrate the planned incision. An initial dissection is performed through the dartos at which time all surgical team members regown, and the instruments used to this point are considered contaminated and placed to the side. A 3M, 10-10 drape is placed over the incision, and the Scott retractor and hooks are placed through the 10-10 drape to completely exclude all skin edges from the surgical field. The remainder of the case is performed using traditional, penoscrotal approach techniques. In this cohort, the majority of patients received InhibiZone-coated infrapubic AMS 700 devices (Boston Scientific) with pump tubing custom-tailored. A small percentage of cases used Coloplast Titan devices presoaked in Bactrim solution, as well as Coloplast Genesis and AMS Spectra malleable devices. Irrigation (Betadine 10% diluted 50:50 with normal saline to achieve 5% concentration or vancomycin 1 g/gentamicin 80 mg in 1 L normal saline) is used liberally throughout the case (of note, before practice change, Betadine was used in all cases including first-time implants) to irrigate the scrotum and region of reservoir. No surgical drains were used, and all cases were performed as outpatient, same-day procedures.

### Outcomes and Statistics

The primary outcome was rate of PP infection before and after change of intraoperative irrigation. Secondary outcomes were rates of infection based on type of surgery (primary, revision, and salvage) as well as associations between other patient and surgical variables, including patient demographics (age and body mass index [BMI]), comorbidities (Charlson comorbidity index, smoking, and diabetes), and surgical variables (primary vs revision/salvage, prior penile surgery, ectopic reservoir placement, and adjunctive glanulopexy). Salvage surgery was defined as a case in which the patient had a prior PP in place that was subsequently explanted.

Statistical analyses were performed using JMP Pro 14.1.0 (SAS Institute, Inc), with 2-tailed *P*-values <.05 considered significant. Univariate and multivariate logistic regression analyses were used to evaluate differences in infection rates with use of Betadine vs vancomycin/gentamicin irrigation as well as to control for potential confounders.

## RESULTS

A total of 217 patients (mean age 65 years) underwent PP placement at our institution from January 2014 through April 2018. Baseline demographic and operative variables are presented in Table 1. Mean follow-up for the overall cohort was 3.0 years. There were no significant differences between irrigation cohorts, with the exception of a higher percentage of primary surgeries in the vancomycin/gentamicin group (81.5% vs 58.6%) and higher percentage of revisions in the Betadine group (36.2% vs 13.9%).

Overall, there were 21 infections (9.7%) identified. When stratified by surgery type, there were 10 (7.1%) infections among primary PP placements, 11 (17.19%) among revisions, and 0 (0%) among salvage surgeries. A total of 152 (70%) patients received irrigation with Betadine and 65 (30%) with vancomycin/gentamicin. Univariate analysis demonstrated significantly increased infection rates with Betadine irrigation (odds ratio [OR]: 4.64, *P* = .006) and with revision surgery (OR: 2.68, *P* = .02, Figure 1). Figure 2 further demonstrates the temporal association of infections and the change from Betadine to vancomycin/gentamicin. Yearly infection rates were reported in 8 (15.1%) of 53 patients in 2014, 5 (8.7%) of 57 patients in 2015, 7 (13.5%) of 52 patients in 2016, 1 (2%) of 51 patients in 2017, and none (0%) of 4 patients for 2018. The elevated infection rate with Betadine persisted after controlling for age, BMI, Charlson comorbidity index, smoking, diabetes, primary vs revision/salvage, prior penile surgery, use of ectopic reservoir, and adjunctive glanulopexy (OR: 9.3; *P* = .025). The elevated infection rate with revision surgery also persisted after controlling for age, BMI, Charlson comorbidity index, smoking, diabetes, prior penile surgery, use of ectopic reservoir, and adjunctive

glanulopexy (OR: 3.26; *P* = .047). There was no difference in infection rate between AMS and Coloplast devices (*P* = .3).

A subset analysis of infection by irrigation was performed based on type of surgery performed: primary, revision, or salvage. Among men undergoing primary PP placement, there was a lower rate of infection with vancomycin/gentamicin irrigation (1 of 53, 1.9%) than with Betadine (10 of 89, 11.2%); however, this difference did not reach statistical significance (*P* = .089). With PP revision surgery, there was also a lower rate of infection with vancomycin/gentamicin irrigation (0 of 9, 0%) than with Betadine (11 of 55, 20%) which also did not reach statistical significance (*P* = .18) because of insufficient power. There were no infections among salvage procedures in our cohort.

## DISCUSSION

Despite well-known precautions against PP infection such as use of alcohol-based skin cleansers, antibiotic-impregnated devices, no-touch technique, and others, infection remains a significant challenge for prosthetic urologists.<sup>2,3</sup> To our knowledge, the current data are the first to directly compare the use of Betadine vs antibiotic intraoperative irrigation during PP implantation on infection rate. It is worth mentioning that all other controllable surgical factors were held constant including surgeon operative time. We found Betadine to be associated with a significantly higher infection rate. This held true on multivariate analysis when controlling for demographics, comorbidities, and surgical variables. These findings were readily apparent when viewing infection rates chronologically, suggesting that infections were not due to intangible factors such as surgeon learning curve or others. These results were congruent with our clinical impressions that the introduction of the change in irrigation fluid led to an immediate and noticeable decline in infection rates.

These findings are clinically relevant given the widespread utilization of Betadine during prosthetic revision and infected salvage procedures. Mulcahy originally popularized the concept of salvaging a clearly infected PP and described the use of intraoperative irrigation with Betadine, hydrogen peroxide, and

**Table 1.** Patient demographics and operative variables

Variable	Overall	Betadine	Vanc/Gent	<i>P</i> -value
Age, mean (SD)	65.53 (10.14)	65.34 (9.84)	65.96 (10.86)	.68
Body mass index, mean (SD)	30.29 (4.45)	30.29 (4.53)	30.28 (4.33)	.99
Charlson comorbidity index, mean (SD)	2.37 (1.98)	2.28 (1.90)	2.56 (2.16)	.33
Diabetes mellitus, %	31.63	32.45	29.69	.74
Smoker, %	44.04	40.45	51.61	.16
Glanulopexy, %	10.14	12.5	4.62	.08
Ectopic, %	35.94	35.53	36.92	.87
Primary placement, %	65.44	58.55	81.53	.001
Revision surgery, %	29.49	36.18	13.85	.001
Salvage surgery, %	4.61	4.61	4.62	1.00

SD = standard deviation; Vac/Gent = vancomycin and gentamicin irrigation solution.

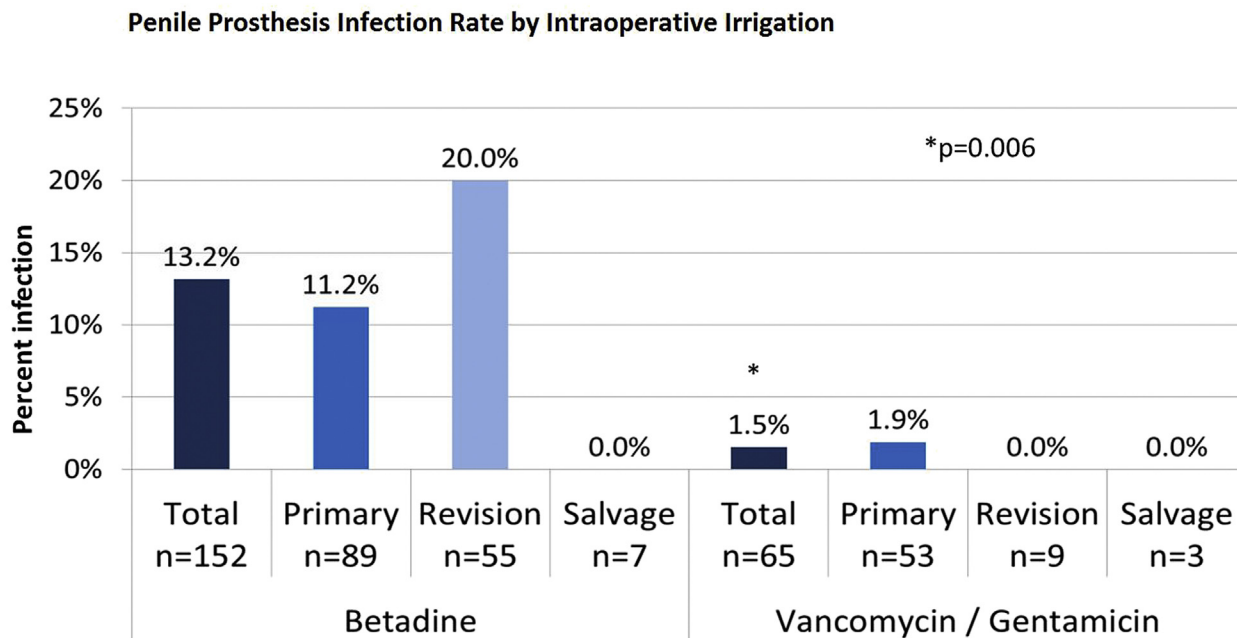


Figure 1. Inflatable penile prosthesis infection rate by intraoperative irrigation.

triple antibiotic solution.<sup>17</sup> As an interesting historical note, the selection of these agents was arbitrary based on what was available that appeared to be anti-infective and occurred after the resident on Mulcahy’s service indicated that he had recently performed a washout procedure on an infected joint during an orthopedics rotation.<sup>17</sup> Pan et al<sup>18</sup> have more recently performed a review of these antiseptic solutions used in PP surgery including Betadine, hydrogen peroxide, and chlorhexidine gluconate and highlight cytotoxic effects of Betadine and particularly of hydrogen peroxide. Further studies have confirmed reduced inflatable penile prosthesis infection rates with aggressive surgical

site washout at the time of revision.<sup>12</sup> Widespread use of Betadine was the basis to routinely use Betadine even in first-time inflatable penile prosthesis cases. Other specialties have also relied on Betadine irrigation during prosthetics procedures, most notably orthopedics who routinely uses this in virgin total hip and knee arthroplasty. Within the orthopedic literature, the impact of Betadine irrigation on infection rate has been met with mixed results with a large retrospective review of more than 11,000 cases showing no difference when compared with no irrigation.<sup>19</sup> More recently, irrigation with normal saline irrigation found similar results to the traditionally described

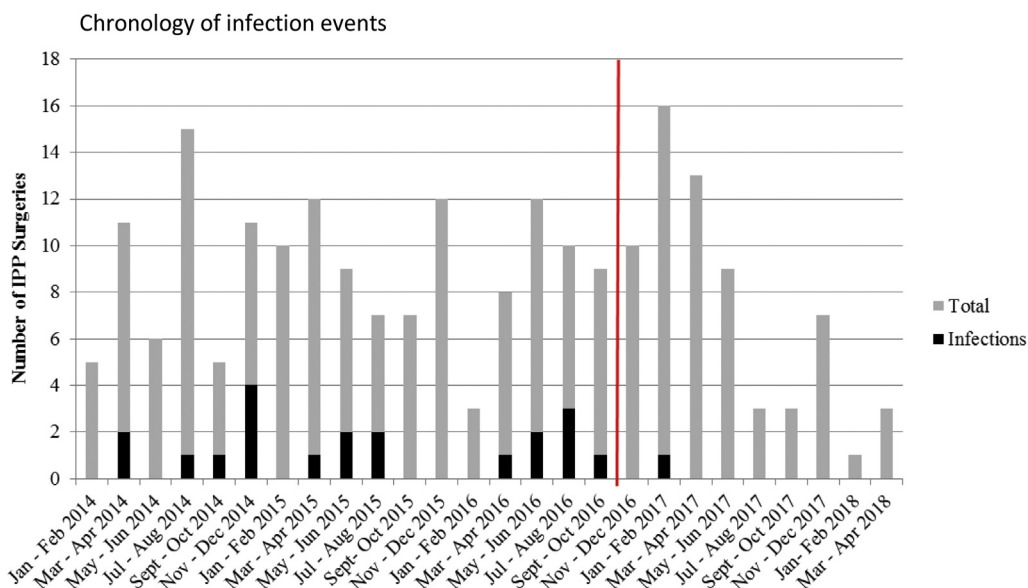


Figure 2. Chronology of infection events. Note: Red line indicated transition from use of Betadine to vancomycin/gentamicin irrigation.

procedures, suggesting that the mechanical process of lavage is likely most important factor for reducing infections rather than the specific agents selected.<sup>14</sup>

Although the underlying mechanism for increased infections with Betadine is not clear, multiple studies have consistently shown toxic effects of povidone-iodine to various tissues, with the overall extent of toxicity dependent on the tissue itself, concentration, and time applied.<sup>20–23</sup> In vivo research shows significant tissue toxicity with a Betadine concentration at or higher than 1% (we used 5% strength).<sup>24,25</sup> Glick et al<sup>20</sup> evaluated the absorption and toxicity of povidone-iodine when used as a continuous irrigant within the mediastinum and reported severe chemical pericarditis with marked acute inflammation and fat necrosis of adipose and myocardium tissues. At a cellular level, Balin and Pratt<sup>21</sup> demonstrated in vitro toxicity of varying dilutions of povidone-iodine to fibroblasts, indicating retarded growth and leading to a recommendation to avoid use of the irrigant in open wounds. Similarly, in the colorectal literature, surgeons are cautioned against using povidone-iodine for peritoneal lavage in concentrations more than 1% because of reports of sclerosing encapsulating peritonitis leading to morbidities including inability to fashion planned ileoanal pouch and small-bowel obstruction requiring reoperation.<sup>22</sup> In the case of PPs, we hypothesize that Betadine leads to scrotal tissue toxicity with subsequent necrosis and impaired immune function and thus provides an ideal milieu for bacterial growth.

It is also notable that in the present study, it is not clear if the changes in infection rates are related to the toxicity of Betadine, or the beneficial effects of vancomycin/gentamicin. However, given that other published series have reported a 1–3% infection rate among primary cases (using varied or no irrigants) and our elevated baseline rate of 11.2%, this would suggest that the infections were more likely secondary to the Betadine. Similarly, the baseline infection rate in the present study (20%) was similar to other published series of revision cases.<sup>7,9,17,26,27</sup> This similarity may relate, in part, to the routine use of Betadine during many salvage protocols (as popularized by Mulcahy).<sup>17</sup>

The current series has several notable limitations, including a lack of randomization and inadequate numbers to independently assess primary and revision cases. The procedures were also performed by a high-volume implanter at a tertiary referral center, which may not be representative of a typical prosthetic practice. Despite these limitations, the present study has several notable strengths, including its prospective registry design, zero patient attrition, relatively large number of cases, and common technique/protocol for surgical procedures. The current manuscript also reports findings that may significantly impact clinical practice, as Betadine is commonly used in revision and salvage prosthetic surgery and may be a directly modifiable step to reduce infections. A recent trial suggests that chlorhexidine may be a more logical choice for irrigation at time of implant exchange.<sup>28</sup> Orthopedic literature specifically examining intraoperative irrigation has also found antibiotic irrigation effective for prevention of infection, and

chlorhexidine has been shown to be a safe alternative to Betadine as well as effective in biofilm eradication even at low concentrations.<sup>29–31</sup> Further study is warranted to determine if these findings can be replicated in other clinical series that routinely use Betadine during the intraoperative procedure, particularly in the revision and salvage setting.

## CONCLUSIONS

Changing intraoperative irrigation solutions from Betadine (10%) to vancomycin/gentamicin significantly reduced infection rates among men undergoing PP placement. Although further study is warranted, these findings would suggest that surgeons who routinely use Betadine (including during revision cases) should consider the concentration used or perhaps an alternative irrigation solution.

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*Conflict of Interest:* The authors report no conflicts of interest.

*Funding:* None.

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