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Experience With Prophylactic Gentamicin During Penile Prosthesis Surgery: A Retrospective Comparison of Two Different Doses

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ABSTRACT

Background: Gentamicin has been determined to be active against a wide range of bacterial infections and has been commonly used as a preoperative antibiotic for inflatable penile prosthesis (IPP) implantation. However, the best dosing regimen to produce the safest optimal prophylactic effect remains to be determined.

Aim: To compare low- and high-dose gentamicin as prophylaxis during IPP implantation.

Methods: We retrospectively analyzed two groups of patients who underwent IPP placement from April 14, 2012 through April 13, 2016. Group 1 was composed of 490 patients who underwent IPP placement from April 14, 2012 through April 13, 2014 and received a low dose of preoperative gentamicin at 80 mg every 8 hours for 1 day. Group 2 was composed of 407 patients who underwent IPP placement from April 14, 2014 through April 13, 2016 and received a single high dose of preoperative gentamicin at 5 mg/kg. We compared the infection rates of IPP and any gentamicin-related toxicities. The same surgeon performed all procedures. All patients received additional vancomycin 1 g before incision and at 12 hours postoperatively.

Outcome: Demographic data and IPP infection rate were compared and potential toxicities from the higher dose of gentamicin were closely monitored.

Results: There were no significant differences in mean age, mean body mass index, and mean interval for IPP placement and IPP infection between the two groups. No toxicity was seen with the higher gentamicin dose. Six cases in group 1 (five de novo cases and one redo case, infection rate = 1.22%) and three cases in group 2 (two de novo cases and one redo case, infection rate = 0.74%) were found to have IPP infection. The infection rate in group 2 appeared to be lower than that in group 1, although a significant statistical difference was not achieved ($P = .057$).

Clinical Implications: These findings would help guide urologists in choosing an optimal preoperative gentamicin dose for IPP surgery.

Strengths and Limitations: This is the first study to report on the usage of high-dose preoperative gentamicin for IPP surgery but with limitations as a retrospective study.

Conclusions: Although not achieving a statistical difference, there was a trend for patients receiving a higher dose of preoperative gentamicin to have a lower IPP infection rate. No toxicity was encountered from the 5-mg/kg gentamicin dose. We recommend following prophylactic high-dose gentamicin guidelines. **Xie D, Gheiler V, Lopez I, et al. Experience With Prophylactic Gentamicin During Penile Prosthesis Surgery: A Retrospective Comparison of Two Different Doses. J Sex Med 2017;XX:XXX–XXX.**

Key Words: Penile Prosthesis; Preoperative Antibiotic; Gentamicin

INTRODUCTION

Inflatable penile prosthesis (IPP) placement is the gold standard for treating refractory erectile dysfunction. The potential risk of infection is less common because of improvements in device design and surgical protocols adhered to in the operating room.[1,2] However, IPP infection still occurs, leading to prolonged hospital stays, readmissions, and high health care costs.[3]

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Gentamicin has been determined to be active against a wide range of bacterial infections, mostly gram-negative bacteria including *Pseudomonas* species, *Proteus* species, *Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes,* and *Serratia* species and gram-positive *Staphylococcus* species.[4,5] It also has been determined to be an effective prophylactic antibiotic for IPP surgery.[3,6–13] However, the best dosing regimen to produce the safest optimal prophylactic effect remains to be determined. Obviously, there are concerns regarding the potential toxicities of high-dose gentamicin, mainly nephrotoxicity.[14–18] Most physicians adopt a fixed dosage of not more than 120 mg per person every 8 hours.[19] However, there are multiple studies showing that single high-dose gentamicin is safe and cost efficient, although its superiority in increasing tissue penetration and lowering the infection rate remains to be established.[15,20–25]

To help guide urologists in choosing an optimal preoperative gentamicin dose, we carried out this retrospective analysis to compare the IPP infection rates of low- and high-dose gentamicin prophylaxis and any possible treatment-related toxicities.

METHODS

After obtaining institutional ethics review board approval (Urological Research Network, 2016-04), we retrospectively analyzed two groups of patients who underwent IPP placement from April 14, 2012 through April 13, 2016. Group 1 consisted of 490 patients who underwent IPP placement from April 14, 2012 through April 13, 2014 and received a lower dose of preoperative gentamicin at a fixed dose of 80 mg followed by two more injections every 8 hours before being discharged. Group 2 consisted of 407 patients who underwent IPP placement from April 14, 2014 through April 13, 2016 and received a one-time higher dose of preoperative gentamicin at 5 mg/kg. The infection rates within the two groups were compared. All patients received additional vancomycin 1 g before incision and at 12 hours postoperatively.

In group 1, there were 441 de novo cases and 49 redo (removal and replacement or replacement) cases. In group 2, there were 357 de novo cases and 50 redo cases. Before the surgery, all patients were instructed to use Hibiclens soap two times per day for 3 days to wash the scrotal, penile, and perineal skin. IPP placement was performed through a penoscrotal approach using a lateral scrotal incision under general or regional anesthesia and using the "non-touch" technique, as previously described.[26] All procedures were performed by the same surgeon with consistent protocols including preoperative use of surgical cleanser, intraoperative antibiotic regimen for soaking the device and surgical field irrigation (combinations of gentamicin, vancomycin, and rapamycin), and surgical techniques. For redo cases, a peroxide solution was added for more extensive irrigation and complete device exchange was consistently executed. Potential toxicities from the higher dose of gentamicin were closely monitored after administration, including serum urea nitrogen and creatinine levels, and a query for signs of ototoxicity. All patients were admitted for observation for 1 day after surgery and were maintained on the intravenous antibiotics during their stay followed by 1 week of oral antibiotic at discharge. Patients were followed up 2 weeks, 6 weeks, and 6 months after surgery and then annually.

Table 1. Demographic data comparison

Item	Group 1 (low dose)*	Group 2 (high dose)†	*P* value
Patients, n	490	407	
Ratio of de novo cases, %	90	87.7	>.05
Ratio of redo cases, %	10	12.3	>.05
Age (y), mean	68.4	66.8	>.05
BMI (kg/m^2), mean	28.8	29.1	>.05
Diabetes, %	39.1	39.6	>.05
Hypertension, %	69.4	64.1	>.05
Chronic kidney disease, %	1.66	1.23	>.05

BMI = body mass index.
*Low dose of preoperative gentamicin.
†High dose of preoperative gentamicin.

Main Outcome Measures

Demographic data and IPP infection rate were compared. Potential toxicities from the higher dose of gentamicin were closely monitored. The mean values were compared using analysis of variance. Categorical variables were assessed with χ^2 test. A *P* value less than .05 was considered statistically significant.

RESULTS

As presented in Table 1, mean age for patients in group 1 was 68.4 years and mean age for patients in group 2 was 66.8 years. Mean body mass index was 28.8 kg/m^2 for group 1 and 29.1 kg/m^2 for group 2. Hypertension was present in 69.4% of patients in group 1 and 64.1% of patients in group 2. Diabetes was present in 39.1% of patients in group 1 and 39.6% of patients in group 2. Chronic kidney disease was present in 1.66% of patients in group 1 and 1.23% of patients in group 2. There were no significant demographic differences between the groups. No toxicity was seen with the higher gentamicin dose.

As presented in Table 2, 6 cases in group 1 (five de novo cases and one redo case, infection rate = 1.22%) and three cases in group 2 (two de novo cases and one redo case, infection rate = 0.74%) were found to have IPP infection. The infection rate in group 2 appeared to be lower compared with that in group 1, although a significant statistical difference was not achieved ($P = .057$). A similar finding was noted by comparison of infection rates for de novo cases within the two groups. The infection rate in group 1 for de novo cases was 1.15% and the infection rate for de novo cases in group 2 was 0.56%, although a significant statistical difference was not achieved ($P = .063$).