Use of Chlorhexidine Gluconate Irrigation Solution to Prevent Postoperative Infection in Inflatable Penile Prosthesis: a Cost-effectiveness Analysis

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Abstract

Inflatable penile prosthesis (IPP) placement for erectile dysfunction carries a risk of postoperative infection. This risk can be mitigated with intraoperative irrigation with antibiotic solutions. One such irrigant, chlorhexidine gluconate (CHG), has recently been introduced into the field of urology for IPP surgery. This investigation aimed to construct a Markov Model using established data from literature to define the incremental cost of complications following IPP and the range of infection rates at which CHG could serve as a cost-effective approach. The model produced found the incremental cost of infection/mechanical failure to be several thousand dollars when utilizing standard antibiotic regimens of Rifampin/Gentamicin ($2 483) and Vancomycin/Gentamicin ($3 066). However, if CHG irrigation is utilized instead, cost savings of several hundred to over a thousand dollars are observed, so long as CHG maintains below a 2.8% infection rate. The lower baseline cost and potential for equivalent or superior infection prevention with CHG make it an intriguing option for use in IPP surgeries.

Introduction

Inflatable penile prosthesis (IPP) remains the gold standard for treatment of medication refractory erectile dysfunction. A major complication of inflatable penile prosthesis is infection, historically occurring in approximately 3% of cases at 1 year [1]. Though uncommon, post-operative infection can necessitate surgical revision or explant. In order to decrease infection risk, intraoperative antibiotic irrigants are used to flush each corpus cavernosum and coat the device. Traditionally, Vancomycin/Gentamicin or Rifampin/Gentamicin have been used [2]. A new irrigant, Irrisept (chlorhexidine gluconate CHG) has recently been introduced into the field of urology for IPP surgery. CHG has success as a comparable alternative to antibiotic irrigants in other implant-based procedures. In implant-based breast reconstruction, CHG irrigation decreased odds of infection by 2.4-fold when compared to standard triple antibiotic solution (gentamicin, cefazolin, bacitracin) [3]. This is cost effective across a range of surgical specialties including breast implantation, orthopedic joint replacement, and colorectal surgery. As CHG irrigant is a new addition to the field of urology, clinical trials to determine infection rate are ongoing. This investigation aimed to estimate the range of IPP infection rates at which CHG could serve as a cost-effective approach.

Materials And Methods

A Markov model was constructed to estimate the cost effectiveness of CHG in IPP surgery. The model included baseline estimates described below: probability of mechanical failure, probability of infection with different irrigants, cost for IPP revision, cost for mechanical failure revision, and cost for different irrigants. Once these values had been established, either from literature review or internal estimates, a Markov model was constructed using TreeAgePro 2022 to analyze cost-effectiveness of different irrigants used for IPP procedures (TreeAge Software, LLC Williamston, MA, USA). After IPP placement, our repetitive decision tree fed patient cohorts into success, infection, or mechanical failure. A time horizon of 5 years was utilized for this project as the scope of this project was aimed at the shorter-term outcomes

from this procedure, rather than the entire device lifespan. Cohorts were run through one cycle of the decision tree. Sensitivity analysis was then conducted to calculate an estimate of infection rates at which CHG serves as a cost-effective strategy.

Mechanical failure rates are variable based on IPP model type, surgeon experience, and the time frame following placement to measure failure. To fit the aim of this study, a 5-year time frame was utilized with an average failure rate of 10% [4].

IPP infection rates were obtained from published irrigation protocols including: 0.55% for Rifampin/Gentamicin, 4.42% for Vancomycin/Gentamicin [2]. The infection rate when using CHG as an intra-operative irrigant has yet to be established. Therefore, this variable was analyzed during sensitivity analysis at an infection rate range of 0.25–6%.

All irrigation costs were obtained via internal cost estimates from the University of Nebraska Medical Center (One 500cc bottle of Irrisept ($65), Rifampin/Gentamicin ($319.60), Vancomycin/Gentamicin ($175.35)). Baseline estimates of primary implant surgical costs were not otherwise included as these were not influenced by irrigant type. The cost of infectious or mechanical failure complications was determined from established literature of revision surgeries. Median costs of revision for infection were found to be $11 252 and for mechanical failure $8 602 [5].

Results

In this Markov model (Figure A), under all conditions where IPP infection rate was less than 2.8%, CHG irrigation was cost effective compared to standard antibiotic irrigation. The incremental cost of infection or mechanical failure for a patient undergoing IPP was found to be $2 483 when utilizing Rifampin/Gentamicin and $3 066 for Vancomycin/Gentamicin (Figure B). Sensitivity analysis found that CHG was more cost-effective than Rifampin/Gentamicin below a 2.8% infection rate and more cost-effective than Vancomycin/Gentamicin below a 5.3% infection rate (Figure B). Above these infection rates, CHG was no longer a cost-effective option.

A savings table was created using varied CHG infection rates compared to fixed infection rates with Rifampin/Gentamicin or Vancomycin/Gentamicin (Table A). At CHG infection rates of 0.5-3%, per case savings were observed from $70 to $520 compared to Rifampin/Gentamicin. At CHG infection rates of 0.5-5%, per case savings were observed from $90 to $1 102 compared to Vancomycin/Gentamicin.

Discussion

Infections after IPP surgery are frustrating and costly. This study demonstrates a definite target window where CHG irrigant serves as a cost-effective modality for infection prevention. This finding was attributed to a lower incremental complication cost seen when using CHG compared to commonly used irrigation methods like Vancomycin/Gentamicin and Rifampin/Gentamicin, so long as an infection rate of less than 2.8% was observed.

Traditionally, infection rates following IPP placement have a moderate degree of variation based on whether the penile prosthesis is coated or non-coated/hydrophilic and on the compounds impregnated into the penile coating. A previous study displayed infection rates of 2.32% for non-coated prostheses and 0.89% for coated prostheses [2]. Therefore, if CHG demonstrates a similar performance in infection prevention to historically used regimens, it will serve as a cost-effective intervention.

While CHG clinical trials in prosthetic urology are ongoing, it has been employed in other surgical fields. CHG utilization in orthopedic surgery as a washing solution for joint arthroplasty performed very similarly to standard betadine wash, with no significant difference in the rate of wound complications or return trips to the operating room [6]. The field of plastic surgery has also used CHG for breast pocket irrigation prior to implant-based breast reconstruction. In this arena, CHG displayed significantly lower rates of both total complications (22.4% vs. 31.8%, p = 0.006) and infections (6.4% vs. 12.7%, p = 0.006) when compared to a triple-antibiotic solution, although this came at the cost of an increased rate of delayed wound healing (2.9% vs. 0.3%, p = 0.006) [3].

CHG use in urology for IPP placement is likely to be effective. Common bacteria in IPP infection include *E. coli*, coagulase-negative *Staphylococcus* spp, *S. aureus*, *P. aeruginosa*, *K. pneumoniae*, *Candida*, and Group B *Streptococcus* spp [7, 8]. In lab studies, CHG has shown > 99% efficacy against these common pathogens [9, 10]. If this trend continues into the implementation phase in the operating room, a cost reduction of several hundred dollars may be observed as seen in Table 1. Urologists will need to study if CHG use has any effect on delayed healing rates as observed in plastic surgery.

One of the limitations to this study is the limited nature of the modeling time frame. A 5-year cycle length run for one cycle was configured into the Markov decision tree which excludes any observed differences in outcomes past the 5-year time frame. This investigation was also entirely based on best-case modeling. No IPP clinical trials are completed yet. Another limitation to this study involves not factoring in potentially increased infection rates during salvage operations for penile prosthesis. Previous studies have shown that revision surgeries for mechanical failure, infection/erosion, or patient dissatisfaction have been associated with infection rates ranging from 5.7–10% [11, 12]. The Markov analysis used in this study did not factor in the potential for continued health care costs following initial salvage for infection/mechanical failure. The decision tree treated each salvage procedure as having a 100% success rate. Lastly, this study did not take into consideration quality-adjusted life years during cost-effectiveness analysis. QALYs are a routine measurement in cost-effectiveness analysis as they can serve as a balance between the overall cost-savings in dollars and patient satisfaction/quality of life. Unfortunately, utility values for health states following IPP surgery are limited and dated, and therefore excluded from this study. Future investigation of cost-effectiveness for CHG or any other irrigants will need to have an assessment of QALY, to then balance the weight of direct financial benefit with potentially different patient experiences following IPP placement.

Inflatable penile prosthesis for erectile dysfunction after first-line treatment failure serves as an effective management strategy. However, along with surgical intervention comes the expense of a more invasive

intervention that carries a risk for infection. Intracorporeal irrigation using CHG has a lower baseline cost than other standard intraoperative antibiotic regimens and has a potential for equivalent or superior infection prevention, making it an intriguing option for use in IPP surgeries. While the infection rates obtained from other surgical fields when using CHG are promising, clinical studies are underway to investigate this for IPP placement.

Declarations

Data Availability Statement

The data utilized in this study can be found within the published articles corresponding to each citation. The data generated from this study was under full control of the authors. TreeAge software was utilized for data analysis and additional background data can be furnished by the corresponding author if requested.

Acknowledgements

No external assistance was required for this project. Sources for references listed were obtained via online journal institutional access though through the University of Nebraska Medical Center, College of Medicine.

Author Contribution Statement

Conceived/Designed work - CD, SM. Literature Review - SM, MK. Model creation and data analysis - SM, CD. Manuscript written and revised by SM, CD, MK.

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No financial assistance was received in support of this study.

Ethical Approval

No ethical approval was required for this study as no experimentation with individuals was conducted. All data used to formulate models was obtained from existent literature.

Competing Interests

No competing financial interests or otherwise in relation to this work were present.

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Table

Table is available in the Supplementary Files section.

Figures

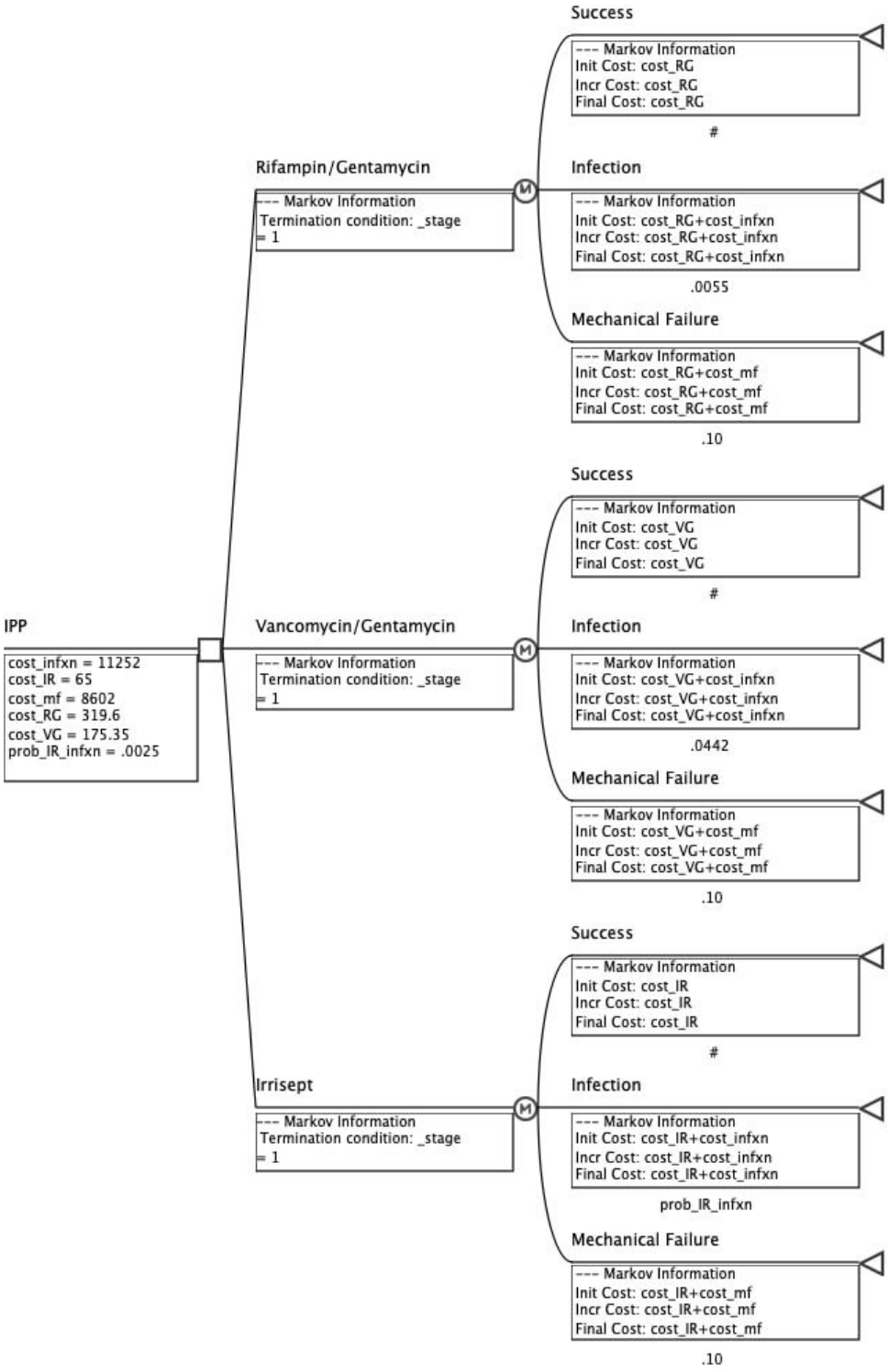

Figure 1

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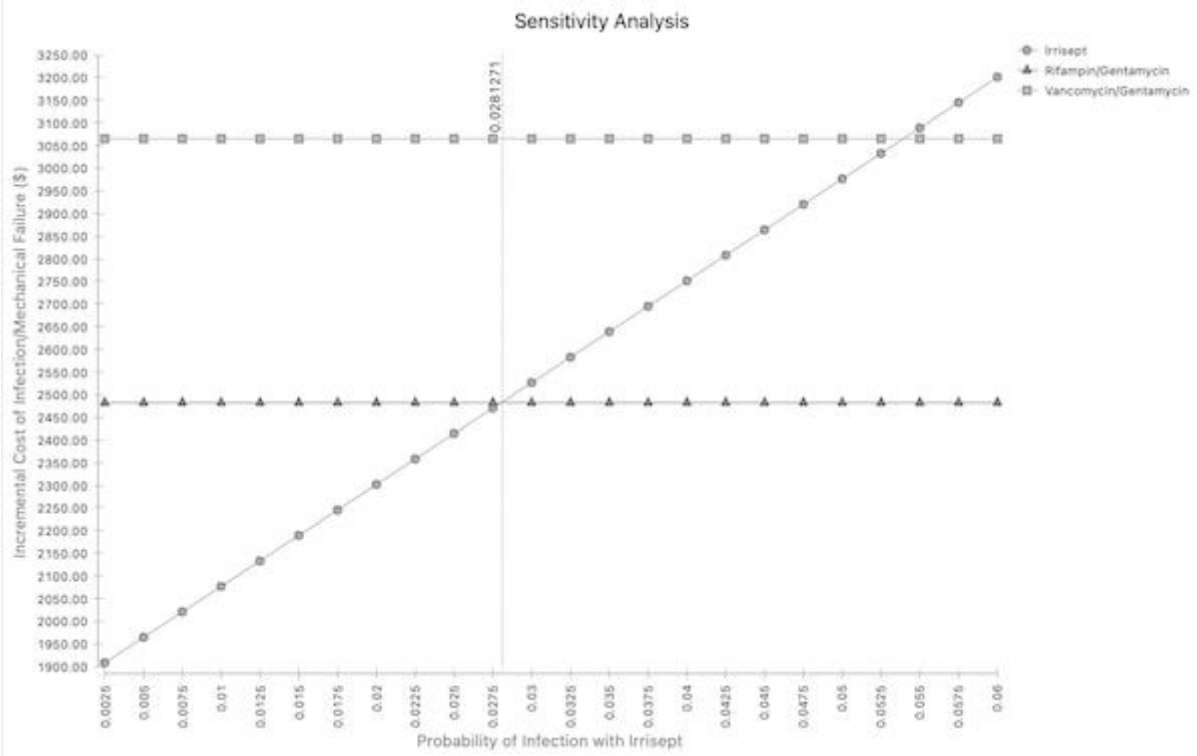

Figure 2

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Supplementary Files

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- TableCostReduction.jpg