Infection Retardant Coated Inflatable Penile Prostheses Decrease the Incidence of Infection: A Systematic Review and Meta-Analysis

Sree Harsha Mandava, Ege Can Serefoglu, Matthew T. Freier,* Steven K. Wilson† and Wayne J. G. Hellstrom‡,§

From the Department of Urology, Tulane University, New Orleans, Louisiana, and Institute for Urologic Excellence (SKW), Indio, California

Purpose: This systematic review was done to compare the effectiveness of infection retardant coated inflatable penile prostheses vs noncoated devices.

Materials and Methods: We systematically reviewed PubMed® and Galileo® to identify all relevant case studies. The postoperative infection incidence rate was compared for coated and noncoated inflatable penile prostheses to determine whether coating the implant affects the rate of surgical implant infection.

Results: Included in analysis were 14 clinical case studies in a total of 9,910 patients with a first time implant, including 5,214 inflatable penile prostheses without an infection retardant coating and 4,696 coated inflatable penile prostheses impregnated with minocycline/rifampin (3,158), rifampin/gentamycin immersion (181), vancomycin/gentamycin immersion (181) and a hydrophilic coating only (1,176). For noncoated vs coated prostheses the infection rate was 2.32% vs 0.89% ($p < 0.01$), including 0.63%, 0.55%, 4.42% and 1.11% for minocycline/rifampin, rifampin/gentamycin immersion, vancomycin/gentamycin immersion and hydrophilic coatings, respectively.

Conclusions: This analysis documents a significant advantage of using coated compared to noncoated inflatable penile prostheses to prevent postoperative device infection. Infection retardant coatings that allow antibiotics to elute off the device components decrease the incidence of device infection by approximately 50%. Future studies must address novel techniques, such as preventing bacterial adhesion, to further decrease infectious etiologies.

Key Words: penis, penile prosthesis, infection, anti-bacterial agents, postoperative complications

Abbreviations and Acronyms

A/C = infection retardant coated
ED = erectile dysfunction
H/C = hydrophilic coated
IPP = inflatable penile prosthesis
M/R = minocycline/rifampin
N/C = noninfection retardant coated
PVP = polyvinylpyrrolidone
R/G = rifampin/gentamycin
V/G = vancomycin/gentamycin

Submitted for publication February 14, 2012.

* Financial interest and/or other relationship with Coloplast.

† Financial interest and/or other relationship with American Medical Systems, Coloplast and NeoTract.

‡ Financial interest and/or other relationship with American Medical Systems, Auxilium, Coloplast, Cook, Endo, Johnson & Johnson, Lilly USA, Medtronic, National Institutes of Health, Slate Pharmaceutical, Theralogix and VIVUS.

§ Correspondence: Department of Urology, Tulane University SOM, 1430 Tulane Ave., New Orleans, Louisiana 70112 (telephone: 504-988-5372; FAX: 504-988-5059; e-mail: whellst@tulane.edu).

Erectile dysfunction is defined as the inability to achieve or maintain erection during sexual performance.[1] ED is a multifactorial disorder with etiologies encompassing neurogenic, psychological, pharmaceutical and mixed vascular causes.[2] Recommendations from authorities, such as the European Association of Urology guidelines, list a penile prosthesis as the tertiary and definitive treatment modality for ED.[3] However, certain candidates may directly elect surgical implantation after discussing all treatment modalities with the surgeon as a result of patient dislike/preference or qualification.

In the last 40 years advances in prosthetic technology have resulted in more physiological designs with fewer complications and greater patient satisfaction.[4] With more than 20,000 penile prosthesis implantations performed annually in the United States, this surgical procedure occupies an impor-

0022-5347/12/1885-1855/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2012.07.022
Vol. 188, 1855-1860, November 2012
Printed in U.S.A.

tant place in the armamentarium of urologists who treat ED.[5]

Historically, the first implants were made of wooden splints and not necessarily intended for sexual intercourse.[6] In 1936 innovations by the Russian surgeon Borgoraz using rib cartilage to support the penis[6] led to the development in 1949 of the first acrylic subcutaneous penile prosthesis.[7] Further advancement evolved to 3-piece inflatable implants in 1973, which are currently used today.[4]

Prosthetic infection remains an important, devastating complication associated with this surgery and manufacturers have introduced new strategies to decrease this risk. Historically, before infection retardant coating availability, device infection was attributed to coagulase negative Staphylococcus species, predominantly S. epidermidis and S. lugdunensis, introduced at implantation.[8] However, several recent reports of infection in coated devices demonstrated that bacterial species differ in coated implants, ie S. aureus and Enterobacter aerogenes.[9]

After these species gain access, the bacteria attempt to adhere to the device surface and produce a protective layer of extracellular polymers, termed biofilm.[10] This layer has 2 effects. The biofilm 1) sequesters bacteria from the defensive mechanisms of the body and 2) provides a safe environment in which to exchange genetic material, thereby increasing the chance of antibiotic resistant strains.[8] While not all biofilm formation leads to infection, more than 90% of IPP infections now develop in year 1 after implantation with the highest rate during the first 3 to 6 months due to contributing factors such as biofilm.

In January 2001 a major advance was the introduction by AMS® of the impregnated IPP with M/R.[4] Similarly, in late 2002 Mentor® Corporation introduced the method of coating an IPP with hydrophilic PVP at the manufacturing plant and then immersing the device in aqueous solution in which antibiotics were added immediately before surgical implantation.[8] This type of coating was specifically developed to decrease bacterial adhesion by creating a lubricious surface and allowing the implanting physician the flexibility to choose which antibiotic to add to the aqueous solution before surgical implantation.

The medical literature attests that these advancements effectively decrease infection complications.[11–25] However, to our knowledge a meta-analysis has not been done to evaluate these innovations.

We systematically reviewed the penile prosthetic literature to confirm statistically whether A/C IPPs significantly decrease the rate of postoperative infection in patients compared to noncoated devices.

MATERIALS AND METHODS

Identification/Search Strategy

We included all case-control and retrospective studies published on the incidence of IPP related infection. We searched the PubMed and Galileo electronic databases from 1985 to the present using the key search words antibiotic coated, antibiotic impregnated, penile prosthesis, complications and infection. Reference lists from retrieved documents were also searched. Computer searches were supplemented with a manual search. Two of us (SHM, ECS) independently screened all citations and abstracts selected by the search strategy to identify potentially eligible studies (fig. 1). Studies that incorporated risk factor based populations and/or specific population subsets, ie patients with diabetes or spinal cord injury, were excluded from analysis because they were beyond the scope of this investigation. Our goal was to determine IPP infection rates in the typical populace and not selective demographics.

Participant Data Sources

Study inclusion criteria were adult male patients undergoing first time IPP placement. The scope of participant selection included studies of the infection rate in males from the general population without selective etiologies. Patient groups undergoing revision were excluded from

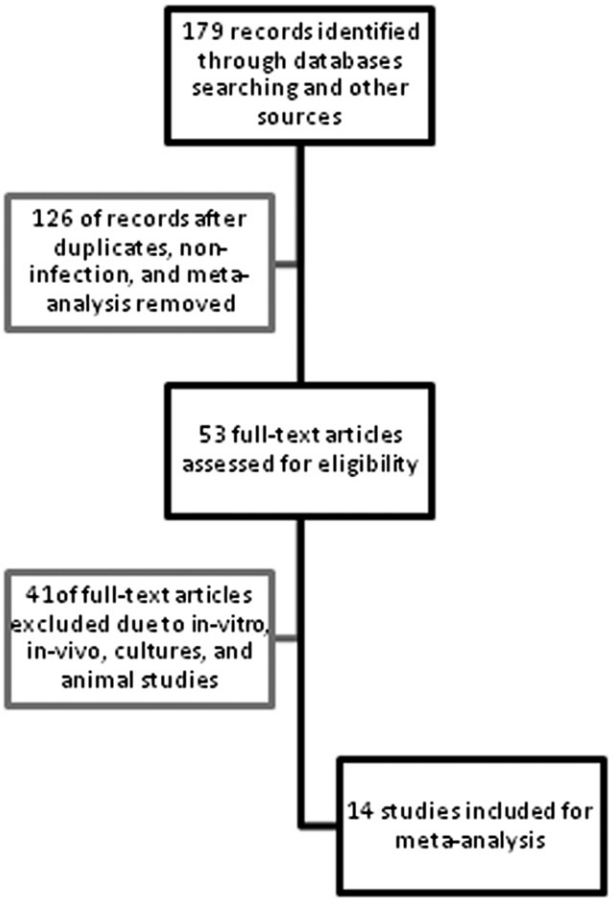

Figure 1. Flow diagram of systematic review