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CONSERVATIVE THERAPY IS AN EFFECTIVE OPTION IN PATIENTS WITH LOCALIZED INFECTION AFTER PENILE IMPLANT SURGERY

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Abstract

INTRODUCTION—Traditionally penile implant (PI) infections have been managed by removal with immediate or delayed replacement. Recently, interest has been focused on conservative therapy (CT) using antibiotic therapy.

AIM—To investigate the success rate and predictive factors affecting the outcome of CT in PI infection patients.

METHODS—Patients diagnosed with early, localized PI infection were considered candidates for CT. Exclusion criteria included temperature >37.5 Celsius, WBC >13,000/μL and appearance of any sign of sepsis. In patients with purulent drainage, culture swabs were taken and an antibiotic

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was chosen based on sensitivity results. Oral antibiotics were used until the local infection was completely resolved. Patients were evaluated weekly during this process.

RESULTS—37 patients were retrospectively reviewed and constituted the study population. Mean age was 58.1 (range37–85; standard deviation 9.9) years. All were diabetic. Mean BMI was 31.8 (range 24–47; SD 5.0). PI was malleable in 33 and inflatable in 4 cases. Culture results (n=19) included: Staph epidermidis (42 %), Pseudomonas (21%), E coli (21%) and Staph aureus (16%). Four of thirty seven patients needed the PI removed due to CT failure and onset of systemic symptoms, at a mean time-point of 75±1.8 days after CT commencement. In men who were cured, mean time to complete healing was 49 (range 29–97; SD 15.8) days. Two of thirty seven patients (5%) had PI removal because of persistent penile pain despite complete wound healing, at a mean time point of 128±2.5 days after CT commencement. All men managed conservatively resumed sexual intercourse.

CONCLUSIONS—CT of localized PI infection appears to be a viable option for such patients with the majority of patients retaining their implant and resuming sexual activity.

Keywords

Penile prosthesis; implant; infection; conservative therapy; surgery; salvage

INTRODUCTION

Penile prosthesis implantation has a major role in treatment of organic erectile dysfunction (ED), even in the era of effective and safe oral medications [1]. Improvements in penile prosthesis design have extended the long-term survival of implants. The improved design of prostheses has led to their increased mechanical survival and decreased complications. Still one of the most devastating complications is infection, having an incidence of 1–4%, in fresh cases with minimal risk factors, but this can reach up to 20% in complicated high risk patients and when penile reconstruction is accompanied the repair as reported in large series of implants [2,3,4].

The previous classic approach called for immediate removal of the entire device followed by a lengthy course of IV and oral antibiotics with attempted re-implantation 3–6 months later. The main disadvantage of this approach is the intracorporal fibrosis that occurs leading to penile length loss and increase in difficulty with future implant surgery later.(5) Salvage procedures have been proposed that allow placement of a new penile prosthesis at the same time as removal of the infected device. (6) The principles of salvage are to remove any foreign material entirely lest any organisms attached to any remnant material continue to be protected in the biofilm. Thorough cleansing and vigorous irrigation of the cavities, is aimed at eradicating the organisms. After that, the wound is presumed to be sterile and a new implant may be placed. (6)

Bacterial colonization with positive cultures and visible bacterial biofilm have been shown to be present on clinically uninfected penile prostheses at revision which raises the question as to whether low grade implant infection need to be removed at all (7). Recently,

conservative therapy using antibiotic therapy has received increased interest as successful CT saves patients from needing invasive surgery and is a much less costly approach.

We aimed to investigate the success rate and predictive factors affecting the outcome of CT in PI infection patients.

METHODS

This study was run in three specialized centers for andrological and urological surgery in Saudi Arabia. Penile surgery is done in a day case well equipped hospital designed for penile and cosmetic surgery. Infection control protocols are strictly applied. Surgeries are done by high volume experts, local or international visitor (≥70 implants/year). Follow up is supervised by the surgeon himself or one of the consultants in his team. The patient is routinely come to the office next day after surgery to remove the bandage and/or catheter(if still in place) then recheck at day 7,14 and 30 postoperatively. After complete healing, usually in 6^{th} week visit the patient is taught how to use the implant and is allowed for sexual activity, then follow up visits at 3,6,12,18, 24,30 and 36 months. If the patient encountered any problem related to his implant any time starting from early postoperative period and ongoing, he can contact his doctor at once and schedule an emergency appointment.

Study Population

Between June 2011 and July 2014, patients diagnosed with early, localized PI infection were considered candidates for CT. Patients who showed signs of infection postoperatively were enrolled in this study. The diagnosis of PI infection was established when one or more of the following signs and symptoms were found during the period between the first week after surgery up to 6 months postoperatively: penile erythema, tenderness, swelling, wound dehiscence, fluctuance, erosion, discharge, or persistent pain. Patients' demographics, comorbidities, preoperative, operative notes and postoperative data were collected.

Management Algorithm

Any systemic symptoms related to the PI infection (temperature ≥37.5°C, leukocytosis, skin necrosis) were excluded from the CT management pathway. In patients with purulent drainage, culture swabs were taken and the antibiotic was chosen based on sensitivity results. In patients without discharge or negative culture results, the standard was to give Cefatriaxone 1g parenteral injection once daily for 10 days then switch over to oral antibiotics (amoxicillin and clavulanate potassium) were used until the local infection was completely resolved. Patients were evaluated weekly during this process, but they were instructed to contact their physician at once if they developed one or more of obvious systemic symptoms (fever, chills, malaise) and increasing penoscrotal pain. If the patient, at any time during CT, developed signs of sepsis or systemic symptoms (temperature higher than 37.5 Celsius *(99.5F),* rigors, malaise, continuous local unresolved pain and leucocytosis more than 13,000), immediate surgical intervention was performed.

Statistical Analysis

Descriptive statistics was used to describe the study group and calculate proportions, means and standard deviations. To identify possible predictors of CT failure we used Chi square test for discreet variables and Independent sample T-test for continuous variables. A p-value less than 0.05 was considered significant, for all comparisons.

RESULTS

Patient Population

In this study the total number of implants was 411 implants. The percentage of infected implants according to the criteria mentioned in our study was 9%. 37 patients were retrospectively reviewed and constituted the study population. Mean age was 58.1 (range 37–85; SD 9.89) years. All were diabetic with a mean Hb_{A1C} 9.2% (range 6.0–11.2%; SD 1.36). Mean BMI was 31.8 (range 24–47; SD 5.03). PI was malleable in 33 and inflatable in 4 cases. The malleable implants used were the Genesis (Coloplast, Minneapolis, MN, USA) and the inflatable implants used: two of them were the Titan OTR (Coloplast, Minneapolis, MN, USA), and the other two were AMS 700 LGX (American Medical Systems, Minnetonka, MN, USA).

Sixteen of 37 patients were smokers (43%) and 30 patients had Peyronie's disease (81%). Four cases were revision implants, one case had severe fibrosis after priapism, and 12 cases were described as difficult procedures because of moderate to severe Peyronie's disease. Implanting the prosthesis was enough to straighten the penis in the majority of Peyronie's patients, some of them needed modelling, some needed plaque excision and no one needed grafting.

Infection Data

The local signs of infection were described as erythema, penile/scrotal tenderness or swelling in 14 patients; incision discharge in 10 patients; ulcerative area on incision with discharge in 9 patients; and one patient had superficial gangrenous patches in glans and frenulum. Culture was done in the 19 patients who had purulence; the remaining 18 patient had no discharge. Culture results (n=19) are presented in Table 1.

Outcomes

The mean time to complete healing in those without the need for prosthesis removal (wound closure, absence of erythema, tenderness or swelling) was 49 days (range 29–97; SD 15.8). Four of 37 patients needed surgical intervention and the PI(3 were Genesis and one Titan OTR) was removed due to failure to respond and onset of systemic symptoms at a mean time-point of 75}1.8 days after CT commencement. Another two patients underwent PI removal(one Genesis and one AMS 700 LGX) because of persistent penile pain despite complete wound healing at a mean time point of 128}2.5 days after CT commencement. The remaining 31 had complete infection resolution and resumed their normal sexual activity, yielding a CT success rate of 83.8%. Follow up after successful CT ranged from 6–30 months with an average of 14.6 months. For summary of outcome see figure 1.

Infection with Pseudomonas had the worst prognosis as all 4 cases infected with this organism failed CT. The other two cases in whom the implants had to be removed because of continuous pain in spite of complete healing, were swabbed intraoperatively. Culture results in those two cases were positive for Staph epidermidis and E coli. There was not a significant difference in age between the responders and the non-responders to CT therapy. The mean age of the 6 patients with failure was 61.3 years compared to 57.5 years in the 31 not requiring removal (p=0.39). Two of the thirty-seven patients had chronic renal insufficiency and were on dialysis. Those two patients failed to respond to CT. Five of the six patients undergoing PI removal had Peyronie's disease, 4 of them described as having severe fibrosis. Diabetes control was not a predictor of response to CT: Hb_{A1C} was 9.2% in the CT failure group and in those who responded well to CT (p=0.97).

DISCUSSION

The numbers of PI performed annually has increased due to the large numbers of patients treated for prostate cancer, increasing prevalence and severity of diabetes and the metabolic syndrome, and patients becoming refractory or dissatisfied with PDE5 inhibitors.(8) Like all implanted devices, PI are subject to the risk of postoperative infection. The incidence of PI infections in the literature has varied significantly. Efforts to decrease the infection rate include use of perioperative antibiotics, antiseptic scrubs, DM control/low HBA1c, sterile urine culture, Intact healthy skin, skin shaving immediately, before surgery, minimization of OR traffic, prolonged skin scrub, double gloving, meticulous surgical technique, "No-touch" technique, coated implants: antibiotic coating/hydrophilic coating, copious irrigation with antibiotics during surgery, and much more.(8,9) With the advent of the infection-retardant coated prosthesis, infection rates appear to have diminished.(10–12)

Despite all of these measures, some PI still become infected. PI infection is a dreaded complication associated with significant financial costs and patient morbidity. (9) Following PI removal and re-implantation, the long-term results are likely to be inferior. Although the immediate salvage re-implant of infected PI is a well-accepted procedure with less patient morbidity, such surgery is more costly and potentially more morbid than CT for such patients.

In our centers the average cost of malleable penile implant is $6000 and the inflatable implant $13,500(total cost for the whole procedure). If we compared the average daily cost of CT of about $15–20 multiplied for 48 days (average time healing), this cost is approximately 15% of re-implanting a malleable prosthesis.

Henry and colleagues found a positive culture rate of 70% in cases of implant repair with no preoperative signs or symptoms of clinical infection.(13) The published data showed that most IPPs have bacteria present at the time of revision of clinically uninfected implants indicating that the infection can be controlled, even with persistent colonization without achieving complete bacterial eradication, which makes CT a feasible and safe option (14). If we look at our data choosing the CT for PI infection instead of surgical intervention, we find an excellent success rate of 84%. This high success rate is probably attributable to careful selection of candidates for CT. An important finding of the present study is that high success

rate of CT was without any serious complication related to this approach to any of the 37 patients in the study. The safety of CT was probably a result of careful monitoring and prompt implant removal with the earliest sign of treatment failure. The 31 responders who resumed their normal sexual activities did not require another operation, and avoided the potential hazards of anesthesia and increased risk of postoperative complications after salvage surgery.(15) Another important point is that a secondary implant is usually smaller and the eventual long-term results is usually not as good.(15)

Supporting our data, the very recent report (presented at AUA 2014) by Henry et al reporting an excellent success rate of CT in 15 patients with PI infection and complete resolution of symptoms in a mean of 76 days in 13/15 patients. They concluded that observation maybe an option for patients with local signs/symptoms of PI infection, even with pus drainage, that has traditionally warranted immediate surgical intervention. (14)

Pseudomonas as a causative organism had the worst prognosis as the four cases caused by this organism failed CT (100% failure). This finding may be logical if we look at the high virulence of this organism and resistance to therapy. If we look at the published data in orthopedic surgery, we find that pseudomonas infections were also associated with a worse outcome [16]. Pseudomonas *Aeruginosa* is known to be particularly difficult to eradicate due to its extended biofilm-producing capacities, its natural resistance to a variety of antimicrobial agents and development of rapid resistance even during ongoing therapy. (16,17)

2/37 patients had chronic renal failure and were on hemodialysis. Those two patients failed to respond to CT (100% failure). There is no data available on this issue in penile implant surgery except that recipients of renal transplants appear not to be at increased risk of complications when doing implant surgery (15). Data from orthopedic prosthetic surgery suggests increasing risk of perioperative and postoperative morbidity and mortality in patients on hemodialysis. (18,19)

Interestingly, HbA1C level was not a predictor in response to CT. There was no significant difference between the group who responded well to CT (n=31) compared to those who did not (n=6) (p=0.97). This may be explained by the fact that all patients with an infected implant were diabetic. Probably because the number of infections was low. Yet – only 1 of the six infected cases – had a normal HBA1C level. All the rest ≥7.8. Four cases had >9.5%. That may be an important signal.

The majority of our implanted patients during the study period (81%) were diabetics, and a significant percentage of them were uncontrolled (HbA1c ≥7). It is not a surprise that those 37 patients who got implant infection are uncontrolled diabetics with other risk factors and comorbidities. Although it was published before that HA1c is not a predictor in penile prosthesis infection by Wilson and colleagues (20) in a large series of implants, our protocol in general not to operate on HA1c more than 10% except in rare occasions.

The clinical implications of these data are obvious. To be able to reliably offer a conservative approach to a penile implant infection, while resulting in a prolonged course of antibiotics – it saves patients from the cost, discomfort and potential complicated salvage surgery. Twenty

percent of salvaged implants get infected (5) and thus this approach is not ideal and not guaranteed to salvage the implant. As we have pointed out the cost savings is high and none of our patient suffered any deleterious consequences of protracted antibiotic therapy, such as Clostridium difficile infection. While all implant infection patients had overt signs of implant infection, we excluded those patients with signs of tissue deterioration or systemic symptoms. Of note, our patient population is relatively unusual with an extremely high rate of diabetes in this study population (100%) and often poorly controlled diabetes (mean HB_{A1C} of 9%).

This study is not without limitations. Firstly, it is not a randomized control but ethically we believe that such a randomization process would be challenging. The study population is small but fortunately implant infections rates are relatively low at our center and we have twice the number of patients presented by Henry et al (manuscript not yet published). Only 19/37 patients had cultures obtained. Finally, defining localized infection is somewhat subjective as is the decision to remove the implant. However, our surgeons have extensive experience with penile implant surgery and while some may argue that some of these infections were superficial wound infections all patients' symptom or signs in our opinion suggestive of an implant infection. As a strength, we had the ability to administer the antibiotic protocol in a consistent fashion with very regular patient follow-up (weekly).

CONCLUSIONS

In this preliminary report, in a small population of PI infections, conservative therapy of infection appears to be a viable option, with the majority of patients retaining their implant and resuming sexual intercourse. We think that this approach is safe and should be offered to all patients with PI infection without systemic symptoms or tissue changes.

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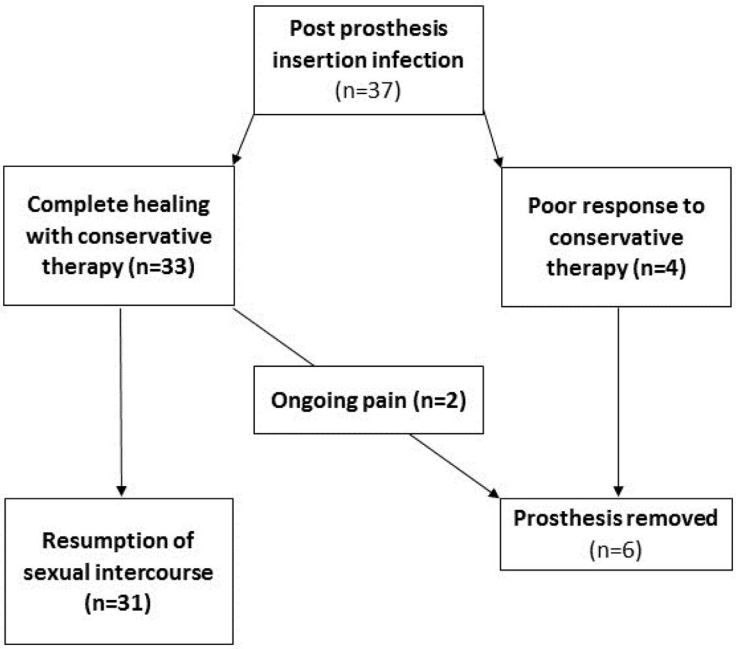

Figure 1.
Patient Outcomes

Table 1

Cultured Organisms

Organism	Number (%) of Patients
Staph epidermidis	8 (42%)
Pseudomonas	4 (21%)
E-Coli	4 (21%)
Staph aureus	3 (16%)