Infectious complications in penile prosthesis implant

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Abstract

Penile prosthesis implant is a safe and effective option in patients with drug resistant erectile dysfunction (both oral and injectable) and when all other options are ineffective for various reasons. Infection of device may be immediate (also more than 6 weeks after surgery) or late (also less than 2 months) but regardless of when it occurs, it is hard to manage and correct for both patient and surgeon. While the incidence of infection following first implant is very low and has decreased progressively during the past four decades to a current estimated rate of up to 3%, in cases of re-implant surgery the rate can reach as high as 18%. We undertook a systematic review of all issues relating to prosthesis infection, including causes and risk factors, methods of prevention, and management; we realized a critical revision of the theme of infection as complication of penile prosthesis implant.

Keywords: Penile Prosthesis Implant, Infection, Complication, Explant, Treatment

Summary of Recommendations/Findings

Surgeon should follow strictly pre-, intra- and post-operatively any possible recommendations to reduce the risk of device's infection. All of them, with associated Oxford level of evidence, are listed in table 1 and table 2.

1. Introduction

Erectile dysfunction affects more than 150 million men across the world, and as life expectancy rises, this pathology and its management will be of increasing research interest [1]. Penile prosthesis implant is a safe and effective option in patients with drug-resistant erectile dysfunction when all other options are not working or are inapplicable. Since the first presentation of this approach almost 70 years ago, the available devices and the surgical technique have evolved to their current design and standard [2], [3]. Surgical implant procedures are now safe surgeries with excellent results in terms of satisfaction (98%), a relatively low complication rate, and a 15-year revision-free survival of 59.7% [4]. Penile Prosthesis Infection (PPI) nevertheless still represents one of the worst complications of andrologic surgery, and when it occurs, the possibility of prosthesis' explantation or a salvage procedure (re-do surgery) are concrete. While the incidence of infection after de novo implant is relatively low, at 1%–3%, in cases of revision surgery the risk of device infection increases to 10% while in diabetic patients it has even been reported to reach 18% [5], [6]). Infections are associated with morbidity for patients and with a high healthcare cost that exceeds the cost of the first implant by more than sixfold [7], [8]. Many risk factors and strategies for avoidance of salvage surgery have been identified over the years.

Here we critically review the literature regarding PPI with the aim of casting light on the causes and risk factors, methods of prevention, and management and identifying topics for further investigation.

Table 1: Oxford Levels of Evidence regarding the association between patient-related factors and risk of infection following penile prosthesis implant

PATIENT-RELATED FACTORS		LEVEL OF EVIDENCE
Preoperative antiseptic cleansing	No increased benefit of preoperative cleansing with chlorhexidine [9]	1
Smoking	Reduction of infection with cessation (at last 4 weeks) [10]	1
HIV	No increased risk of infection [11]	1
S.aureus nasal carriage	Increased risk of infection if nasal carriage present at time of surgery [12]	2
Treatment of nasal S.aureus carriers	Decreased risk of infection [13]	2
Revision surgery	Increased risk of infection with respect to initial surgery (10%–13.3% Vs 1%–3%) [14]	2
Diabetes	Increased risk of infection [15]	3
Hemoglobin A1C Level	Controversial	3
History of radiation therapy	No increased risk of infection [16]	3
Spinal cord injury	Increased risk of infection [17]	3
Obesity	No increased risk of infection [18]	3
Circumcision	No increased risk of infection if concomitant [19]	3
Immunosuppression	Controversial	3
Age >75 years	No increased risk of infection [20]	4
Intermittent self-catheterization	No increased risk of infection but more studies are needed [21]	4

2. Materials and Methods

A systematic and exhaustive review of the literature on PPI published over the past 20 years was undertaken using MEDLINE – National Library of Medicine database and Google Scholar. We considered all papers that addressed infectious complications in patients undergoing PPI surgery, with emphasis on causes, detection, diagnosis, and management. The review included articles published between January 1, 1990, and March 1, 2019. Only articles in English were considered. Keywords used and cross-linked were: penile prosthesis implant, erectile dysfunction, surgical treatment, surgery, complication, causes, diagnosis, medical treatment, early detection, antibiotic therapy, biofilm formation, prevention of infection, surgical treatment, savage therapy, conservative surgery, de novo surgery and complication, re-do surgery and complications, risk factor, implant and diabetes, implant and hair removal, implant and Hb1Ac, implant and drainage, implant and risk factors, implant and complications, and future perspectives. On this basis we identified more than 80 articles and then further selected from among them according to the author. More recent papers, up to March 2019, and all studies eligible for inclusion had to target reports on keywords selected.

Table 2: Oxford Levels of Evidence regarding the association between surgical factors and risk of infection following penile prosthesis implant

SURGICAL FACTORS		LEVEL OF EVIDENCE
Operative site scrubbing with chlorhexidine	Reduced risk of infection in comparison with other solutions [22]	1
Hair Removal	No increased risk of infection comparing the use or razor Vs clippers [23]	1
Hand cleansing	No difference between cleansing solutions [24]	2
Antibiotic-impregnanted implant and coating choice	Reduced risk of infection with impregnation and minocycline/rifampin or rifampim/gentamicin [25]	2
Postoperative drain placement	No effect on infection rates [26]	3
“No touch” technique of prosthesis	Reduced risk of infection [27]	3
Surgeon experience	Reduced risk of infection when the surgery is performed by skilled surgeons [28]	3
Institutional protocols to reduce infection	Reduced risk of infection [29]	3
Surgical approach (penoscrotal vs infrapubic)	No difference [30]	4

3. Results and Discussion

3.1 Risk Factors and Prevention of PPI

Many of the selected articles addressed the prevention and treatment of PPI, and many analyzed all relevant pre- and peri-operative factors associated with PPI. Although such factors have been well studied, there is no clear consensus worldwide on certain topics, including the use of postoperative antibiotic therapy. According to the American Urological Association (AUA) best practice statement, antibiotic prophylaxis should be discontinued 24 hours after surgery but the panel accepted that consideration should be given to extended antibiotic therapy in order to reduce the risk of biofilm formation. Unfortunately, this suggestion is not supported by strong literature evidence [31]. Both the AUA and the European Association of Urology (EAU) guidelines recommend preoperative antibiotic administration but a recent large multicenter study by Gross et al. [32] investigating the microorganisms involved in PPI suggested that the choice of antibiotics to be administered does not cover the pathogens isolated in 14%–38% of cases. Due to the isolation of Candida species in 11% of cases, these authors proposed the administration of an additional antifungal agent such as fluconazole or vancomycin and piperacillin-tazobactam to cover 100% of the identified microorganisms.

In order to prevent PPI by inhibiting prosthesis microbial attachment, the two main penile prosthesis manufacturers use a hydrophobic coating for devices in order to create a physical barrier. The use of antibiotic impregnated implants was found by Carson et al. [33] to reduce the rate of initial revision due to PPI from 2.5% (when using nonimpregnated implants) to 1.1% at 7.7 years of follow-up. Other speculative methods to prevent biofilm formation or protein adhesion to the biofilm have recently been discussed in a paper by Herati et al. [34].

Hematoma is another complication associated with an increased risk of infection. It usually presents in the early postoperative period, with an incidence ranging from 0.2% to 3.6% and allows blood and fluids to collect [35]. Partial cylinder inflation and a mummy wrap (wrapping of the genitalia) are commonly employed to reduce the risk of bleeding and hematoma formation, thereby reducing the risk of infection [36], [37]. The combination of compressive dressing and closed-suction drainage is associated with a statistically significant reduction in the rate of hematoma formation to 0.9% [38].

Tables 1 and 2 present the Oxford levels of evidence regarding the relation between a wide variety of patient-related and surgical factors and risk of infection. The paper by Holland and Kohler [39] exhaustively explored this topic and critically analyzed the strongest studies addressing such factors.

Measures to prevent infection can be divided into preoperative, perioperative (or intraoperative), and postoperative. Surgeons have at their disposal many strategies to avoid PPI, and high-quality surgery requires that all appropriate measures are taken. If PPI occurs despite these measures, other causes should be carefully investigated and treatment instituted immediately. Here it should be noted that we found no papers that addressed the postoperative measures to be followed by patients once at home following discharge, we miss data in this field. We consider that correct wound management and hygiene, the appropriate use of antibiotics and anti-inflammatory agents, the local application of ice, and the use of suspensory or wrap-around underwear may help to reduce the risk of PPI. Sometimes the infection may have causes other than the surgical; for example, a patient with poor control of his comorbidities (e.g., diabetes) or inadequate hygiene will be at higher risk of infection than a patient who carefully respects the surgeon's instructions regarding postoperative care. A patient with an uncontrolled diabetes with blood level of glycaemia (more than 200) and Hb1aC of 9%–10% or more is a patient who fails to take care of himself and will more probably not take care of the wound or prosthesis or comply with medical treatment after surgery. Further research is needed into the standardization of pre-, peri-, and postoperative measures: guidance on these measures needs to be clear to both surgeons and patients.

3.2 Presentation and Management of PPI

The development of a PPI is the worst danger associated with penile prosthesis implant. PPI usually does not respond to local antibiotic treatment but rather requires removal of the entire device, with almost invariable loss of erectile function to the extent that it is not possible to rectify thus making the patient resistant to any treatment for erectile dysfunction [40]. PPI can present in two different ways: a less aggressive, relatively silent form with local symptoms that is due to *Staphylococcus epidermidis* (up to 80% of cases) or other coagulase-negative bacteria, and an "aggressive" form with more systemic effects that is due to *E. Coli; St. Aureus; Klebsiella; Serratia* or *Pseudomonas* [41]. Both forms can lead to prosthesis infection and extrusion in the absence of adequate and prompt treatment. The majority of infections are secondary to bacterial seeding before or during surgery; once the prosthesis is attacked by bacteria, the bacteria secrete the various components of the biofilm, which technically impedes antibiotic penetration and reduces phagocytosis [42], [43]. This makes prosthesis salvage procedures difficult. Conservative salvage procedures represent the first step when infection is detected, but not everybody is eligible for this approach. Various conditions, including cylinder migration (to any site), erosion of the corpora cavernosa or corpus spongiosum, and sepsis and necrosis in a patient with comorbidities such as uncontrolled diabetes, require revision surgery as soon as possible, with cylinder or prosthesis removal and thorough irrigation of the implant site. It is also well known that antibiotic therapy is ineffective once a clinically evident PPI occurs and surgery should be mandatory. Failure to act promptly may worsen both the local situation and the final results, but no study has addressed this issue exhaustively. If it is not appropriately identified and managed, even a silent infection will leave patient and surgeon to explant surgery and re-do surgery. For several reasons, including technical ones, many propose the implantation of a new prosthesis at the time of explant surgery. A penis uninhabited by the cylinder will lead to fibrosis formation and shortening of the penis (by up to 2 inches) [40]; in these circumstances, reimplant surgery is technically demanding and the use of a vacuum device after explant may help in obtaining good results and reducing fibrosis and the shortening of the penis. Nevertheless, although it may be technically harder, delayed reimplant surgery perhaps currently remains safer than immediate re-implant surgery. While newer techniques of salvage have demonstrated increased success[1], further strong studies are required to identify ways in which the techniques and strategies for immediate salvage procedures can be further enhanced, thereby enabling full exploitation of their benefits relative to delayed re-implantation, namely enhanced cost effectiveness, greater technical ease, and reduced risk of penis shortening.

4. Further Research

We miss papers addressing post-operative clear recommendations (wound/prosthesis manage) for patients, we need a consensus regarding post-operative antibiotic use and we should consider strong studies on salvage procedures and techniques.

5. Conclusion

Penile prosthesis implant is a safe procedure with a relatively low risk of infection in the case of a first implant. When infection does occur, prosthesis explant may be required, with distress for the patient and the need for further complex surgery with an attendant increased healthcare cost. There are various risk factors for infection and while many of them have been well studied, PPI still occurs. Further studies are

required to establish additional possible risk factors and clarify how to reduce risk. We consider that efforts are also needed to identify all postoperative measures that a patient should follow closely once at home.

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7. Conflict of Interest

The authors declare no conflict of interest.

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