Systematic review of penile prosthesis infection and meta-analysis of diabetes mellitus role

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Abstract

Background: Infection is the most feared complication of penile prosthesis. Diabetes mellitus is a well known to increase risk of several kinds of infection, but its role upon penile prosthesis is not defined. The aim of this systematic review is to show the contemporary scenario of penile prosthesis infection and perform a meta-analysis about diabetes mellitus contribution to penile prosthesis infection.

Methods: the review was performed with no language or time limitation, in 10 data bases. There were included articles about male population who received a penile prosthesis with no model restriction, with a minimum follow up of one year and proper outcomes report.

Results: The mean incidence of infection after penile prosthesis implant ranged from 0.33 to 11.4%. In early 2000, after several improvements, the general incidence of infection was 3 to 5%. Then, the introduction of coated materials decreased infection to 0.3 to 2.7% . Also, no touch technique and centers of reference with high volume surgeons contributed to reduce infection rates. Meta-analysis showed that diabetes mellitus increases penile prosthesis infection with odds ratio of 1.56 (95% CI: 1.12 - 2.044).

Conclusions: Penile prosthesis infection decreased in the last decades, but remains an important cause of reoperation and it is related to lower prosthesis survival. Meta-analysis concludes that diabetes mellitus increases penile prosthesis infection and it should be considered as a risk factor.

Background

Implantable devices are frequently used in urological procedures. Penile prosthesis was introduced in the 1970s and it still remains the most effective treatment to erectile dysfunction refractory to oral and injectable drugs (1, 2). In the last 40 years several improvements in materials and surgical technique led it to satisfaction rates of 80 to 90% (3). Moreover, better erectile function and sexual satisfaction was reported among patients who opted by penile prosthesis than those who used sildenafil citrate and intracavernous injections (4). However, complications range from 7 to 20% (5), mostly related to mechanical malfunction, infection and erosion. The cost of penile prosthesis removal is estimated at about 10 thousand dollars, which is 6 fold higher than an initial implantation(6).

Surgical site infection is the most feared complication. It can cause pain, local abscess and even sepsis that requires prompt hospitalization and reoperation(7). After
removal, the cavernosum corpus fibrosis reduces penile length a girth and make a new prosthesis insertion much more difficult (8).

About 50% of patients with diabetes mellitus (DM) have some degree of erectile dysfunction and usually show less response to oral and intracavernous therapies. Diabetics correspond to 20% of penile prosthesis surgeries and are particularly prone to infection because of leucocyte disfunction and microangiopathy (9, 10). While some studies show a 3 fold increased risk of penile prosthesis infection in diabetics, other show no difference and it is still controversial whether DM increases the risk of penile prosthesis infection (10).

Many improvements in penile prosthesis materials reduced mechanical failures, but infection remained an important cause of reoperation, so there were many attempts to reduce infection in penile prosthesis throughout the past years (8, 11). The aim of this study is to gather wide information about penile prosthesis evolution regarding infections, summarize the contribution of technique and material improvements, present the current state of device infection and survival. We also present a meta-analysis of available data about diabetes mellitus contribution to penile prosthesis infection.

Methods

This review was performed with no language or time limitation, in order to gather all available data about penile prosthesis, in ten databases: Medline, PubMed, LILACS, IBECs, MEdCarib, CINAHL, Scopus, Web of Science, Embase and Cochrane Library. The search strategy included the terms: "penile prosthesis" or "penile implantation" and "postoperative complications", or "prosthesis-related infections" or "treatment outcome". It was performed following PRISMA statement, registered at PROSPERO with number CRD 42019117734 and had no founding resources.
All the articles had title and abstract assessed by two independent authors who selected relevant studies blinded from each other. Conflicting selection was resolved by a third and more experienced author. The included articles were about male population who received a penile prosthesis with no model restriction, a minimum follow up of one year and outcomes and complications properly reported. Studies had quality assessed using "Grading of Recommendations, Assessment, Development and Evaluations" (GRADE) framework(12). The evaluated outcomes were surgical site infection, prosthesis infection, prosthesis revision or removal. The outcomes were compared along time, techniques, prosthesis types and diabetes mellitus presence when available.

Exclusion criteria were case reports, articles about surgical technique and in vitro tests. All studies about transgender patients were also excluded as they assess a specific population and different surgical techniques. Studies focused on quality of life without outcomes assessment or those stating to have no complications were also excluded. Considering infection incidence, studies that started with less than a hundred patients were excluded due to the risk of underestimation of complications.

Each study had data extracted including author, publication year, study design, penile prosthesis type, number of patients, mean age, follow up, cause of erectile dysfunction, infection, reoperation, prosthesis removal or replacement. The data are presented as incidence ratio, with mean and standard deviation when available. Relation between diabetes mellitus and penile prosthesis infection is presented as odds ratio and meta-analysis was carried out using Open Meta for Macintosh version 12.11.14. Significance was adopted as p < 0.05 and 95% confidence interval.

Results

Literature overview
The research strategy was completed on January 2018 and turned out 4164 articles. After excluding 2012 duplicates, the 2152 articles had title analyzed by two different authors, who excluded yet 464 duplicates. The remaining had the abstract analyzed in order to exclude case reports, experimental studies, retrospective and small series. At the end 80 articles were fully assessed for eligibility and 41 included in the analysis. The study selection is showed in flow diagram - figure 01.

The literature about penile prosthesis is based upon prospective cohorts, retrospective studies and case series, most of them do not present controls or use historical data as controls. There is only one randomized trial available, which is about AMS 700 (American Medical Systems, Minneapolis, MN, USA) and Titan (Coloplast, Minneapolis, MN, USA) presented by Chung et al in 2013 (13). Both are inflatable and coated penile prosthesis and were evaluated for satisfaction, curvature correction for Peyronie's disease and mechanical survival. There were only 2 cases of infection from 138 patients with no report of group or time. Authors state that there was no statistical difference between groups and it was not designed to assess infection.

Decreasing infection strategies

The mean incidence of penile prosthesis infection ranged from 0.33 to 11.4%. In the 1980s and 1990s the incidence was variable; in early 2000 the general incidence of infection was 3 to 5% and after coating introduction it decreased to 0.3 to 2.7%.

In 2000, American Medical Systems introduced prosthesis with InhibiZone™, which consists in an antibiotic coating using minocycline and rifampicin that disperse in tissues around the implantable device and inhibit bacterial growth. Carson, in 2004, described results from manufacturer database showing that infection in penile prosthesis using InhibiZone™ was 0.28% while regular ones had 1.59% at 60 days postoperative (p 0.003). At 6 months, the incidence was 0.68% in coated group and 1.61% in control (p 0.005) (14).
In 2002 Mentor (now Coloplast) introduced the Titan, which was basically the Alpha-1 penile prosthesis with a hydrophilic coating that reduces bacterial adherence and can diffuse antibiotics when immersed into an antibiotic solution during surgery (15). In 2004, Wolter et al published data about infection and reoperation from Mentor’s database and FDA explantation reports. At one year follow up, the infection rate in Titan prosthesis implants was 1.06% (25/2357), while in non coated alpha-1 prosthesis was 2.07% (10/482) (p 0.033) (11).

The only prospective study with InhibiZone™ was carried out by Wilson et al (16), including 467 patients with at least one year follow up. Initially the study had a control group but the authors reported better outcomes in coated group and the control one was early discontinued. None of 223 non-diabetic patients had infectious complications, while 1.2% of diabetics patients (1/83) presented infection. In 2011, Carson et al published a large manufacturer’s database review, including more than 39 thousand implants, ninety percent of them coated with InhibiZone™, between 2001 and 2008 and followed up to 7.7 years. They found that the revision rate for all causes (not only due to infection) were significantly lower on coated implants (6.7% vs 12.5%, log rank p=0.002) (17). Dhabuwala et al, 2011, compared Titan immersed in Rifampicin 10mg/ml and Gentamicin 1mg/ml or Vancomycin and Gentamicin to AMS with InhibiZone™. There was no difference in infection rates between InhibiZone™ (1/77) and Titan with Rifampicin and Gentamicin (0/81), however the vancomycin and gentamicin group had 4.4% of infection (8/181) which was a significant difference to the other two groups (p<0.05) (18).

Prosthesis infection has been a feared complication because treatment involved removal of implanted material, irrigation and antibiotics. Tissue scaring and fibrosis of corporeal bodies replace spongy erectile tissues and cause penile shortening in most of the cases. That make a prosthesis reinsertion more difficult or even not feasible (16). To avoid those complications, Brant and Mulcahy presented a salvage surgery with removal of all implanted material, copious irrigation with a series of antibacterial solutions and immediate placement of a new prosthesis. They reported 82% of success in a 35 months mean follow up with 55 patients (19, 20). Wilson et al reported 122 salvage surgeries using
the antibiotic irrigation protocol combined to InhibiZone™ coated prosthesis and had 3.3% of infection in follow up. They compared to 39 salvage procedures without antibiotic washout protocol and using non coated prosthesis and had 10% of infections in this group (16).

The concept of “center of excellence” is widely used for heart and oncologic surgeries, based on the evidence that surgeons with a high volume of a specific surgery trend to have superior outcomes. In 2009, Henry et al introduced this concept to urological penile prosthetic surgery, comparing results of a single surgeon with more than 50 cases per year with a group of 10 general urologists. The single surgeon had shorter operative time (34 min versus 94 min, p<0.0001) and eight fold less reoperations (p 0.028) (21). High volume surgeons and high volume institutions have better infection rates as stated by the current recommendations from international consultation in sexual medicine(6, 22).

The most recent strategy was a technical improvement, presented by Eid in 2011, called the “no-touch” technique. It advocates the use of sterile antibiotic coated drapes over the skin to reduce contact of surgeon hands and materials to the skin(23). In 2012 the same authors achieved an infection incidence of 0.4% using coated material plus the innovative technique (24).

Diabetes mellitus and penile prosthesis infections

Diabetes mellitus is a well established risk factor for several infections, however its contribution to penile prosthesis infection is still controversial. Diabetics are more susceptible to infections because of impaired defense mechanisms, including leukocyte dysfunction and impaired mobilization to infection site due to angiopathy(9). Fallon and Ghanen reported a three fold higher risk of infection in diabetics, while Bishop et al
suggested glycosylated hemoglobin as infection predictor in early 1990s (25). However, Wilson et all (1995), in a retrospective study investigating risk factors for infection in 823 first implanted penile prosthesis found no difference regarding diabetes mellitus(26). However, three years later the same authors presented a prospective study with 114 diabetic and 275 non diabetic men and found out more infection in diabetic group (8.8% vs 4%) but it was not significant (p= 0.06) (9). Mulcahy and Carson (2011), in a review of manufacturer’s database, including 31341 men using coated penile prosthesis, reported that the general revision rate was significant higher in diabetics: 1.72% in diabetics versus 1.26% in non diabetics (p = 0.005)(10).

We summarized the available evidence about penile prosthesis infection in diabetics in a meta-analysis including 9041 diabetic patients and 36517 non diabetics. Meta-analysis shows that diabetes mellitus increases the incidence of penile prosthesis infection with an odds ratio of 1.47 (95% CI: 1.10 - 1.96; p 0.009) as showed in figure 2.

Infectious Agents

Skin resident organisms, most commonly coagulase-negative staphylococci (CoNS) historically caused around 65% of infections of penile prosthesis, followed by group B streptococci (15%) and Escherichia coli (8%) (26). However, Gross et al(27), in 2017, showed a shift from those findings from previous decades. Based on results of intraoperative cultures from prosthesis reoperations, they found out that the most common agents were: Staphylococcus aureus (20%), Escherichia coli (18%), CoNS (15%), Candida spp (11%), Group B Streptococcus spp (10%), Staphylococcus epidermidis (7%) and Pseudomonas aeruginosa (6%). They found 9% of methicillin resistant S. aureus and 14% to 38% of infections were not covered by current American Urological Association recommendations, neither by the European Association of Urology antibiotic guidelines. So, they suggest that antibiotic prophylaxis guidelines should be rediscussed.
Although traditional wisdom consider *Candida spp* as an opportunistic infection; the authors, instead, suggest it can be a real cause of prosthesis infection and might be even more common in diabetics and immunocompromised patients. The authors also consider that it is not possible to speculate whether these findings are related to coated prothesis, but it remains a possibility(27). In a recent review, Dawn *et al* (2017) also reported the increased incidence of *Enterococcus* species, *E. coli* and *Pseudomonas aeruginosa* causing penile prosthesis infection(28).

Henry *et al* (2008), collected swab cultures from 148 patients who had penile prosthesis revised due to mechanical problems, with no clinical signs of infection and found that positive cultures had significant lower revision free survival. They found 66% of positive swab cultures from liquid around de pump, after prosthesis removal, all spaces were washed out with antiseptic solutions of Mulcahy’s salvage protocol(19), then another sample of tissue was collected and cultures were yet 25% positive. During follow up patients with negative swab culture had longer revision free survival: mean 6.3 years while positive ones had 4.7 years (log rank p = 0.0162)(29).

**Discussion**

This revision presents important information from a wide variety of available articles in ten databases and brings contemporary data about penile prosthesis infectious complications. It resumes device and technique improvements that contributed to reduce infection and reoperations. Penile prosthesis infection has decreased in the last decades and it is not a frequent condition, but it is still an important condition. It is an important cause of reoperation and prosthesis removal, loss of function and costs(8, 30). Li *et al*(6), in a recent multicentric study, reported a direct medical cost of about 10 thousand dollars to remove an infected penile prosthesis. Considering that penile prosthesis with positive culture had lower revision-free survival, with a trend to have also more mechanical failure and the high prevalence of positive cultures even in patients with no clinical signs of infection, bacterial adhesion and colonization of prosthesis seem to be important issues yet.
Penile prosthesis development significantly reduced the incidence of mechanical complications, so recent research has been focused on infection avoidance. Coated materials represent an important step in that direction, but there is a lack of strong evidence about its effect. Most of the studies are supported by companies self reports database, which may lead to potential biases and the only prospective study presented by Wilson et al had good results, but discontinued the control group (16).

Diabetes is one of the main causes of erectile disfunction and it composes about 20% of patients receiving penile implants. It causes angiopathy and neuropathy, which reduces cavernous perfusion and parasympathetic activity required for cavernous smooth muscle relaxation. It is also associated with superoxide radicals production that impair nitrous oxide and ciclicic-GMP production and thus contributes to a worse response to oral therapy (10, 31). Even if there is conflicting data about DM role in penile prosthesis infection, the meta-analysis suggests it causes a significant risk. Bishop et al suggested that glycosylated hemoglobin was a predictor for prosthesis infection when above 11.5%(25). Recently, Li et al (2018) reported diabetes mellitus, HIV and Charles Comorbidity Index as factors associated to prosthesis removal(6).

We found that most of the studies were not designed to evaluate DM properly and there is a lack of information about diabetes treatments and glycemic control. Mohamed et al, (32) reported that all patients in his study had glycosylated hemoglobin inferior to 7.0%. Considering the contemporary trend to seek good glycemic control before elective surgeries it is possible that other studies also have a good glycemic control which was not reported and could be a bias. Mohamed’s findings suggest that diabetes presence may play an important role independently of its control. However none of the studies were powered to asses the role of diabetes time and treatments which may have importance along with glycemic control.

Reoperations are still frequent, ranging from 3 to 20%, so are positive cultures. Even considering only patients with no clinical sings of infection, the majority had positive cultures at the reoperation. It is comprehensive that it is not possible to achieve a
completely aseptic surgical field in these cases, which explains higher incidence of infection and lower prosthesis survival. Thus, coated devices may have the best indication in these cases along with field irrigation and antibiotic use. This approach can inhibit bacterial adherence and inhibit further infections.

There is an important shift in microorganisms agents causing prosthesis infection: from coagulase-negative streptococcus to *Staphylococcus aureus*, *Escherichia coli* and *Pseudomonas spp*. Moreover, nine percent of positive cultures included methicillin resistant *S. aureus* and this kind of resistant agent was never found in previous studies(27). It was a multi center study including the United States, Spain, United Kingdom, Argentina and Brazil so it might reflect a world wide trend. One can consider this change may reflect a consequence of the wide usage of antibiotics and the increasing use of antibiotic coated materials. Those data should be considered in future antibiotic prophylaxis protocols and studies about new biomaterials for penile prosthesis development.

This study is limited by the quality of available evidence, the lack of controls and studies based on manufacturer’s database and FDA reports, which may have standardization bias. However, considering the low incidence of infection, the number of patients necessary to show an incidence decrease would be to high. Considering a baseline infection rate of 3%, it is estimated that a prospective study would need about 3 thousand patients to show a 50% reduction on infection rate, or 34370 patients to show a 25% reduction(33). One can also consider the available evidence about coated materials superiority which could bring ethical issues to a trial(34). This is the largest revision about penile prosthesis infection to date, including references from 10 databases, which brings information from the current scenario of penile prosthesis infection and gather enough data to perform the first meta-analysis about diabetes mellitus role on penile prosthesis infection. The results encourage further studies to asses diabetic patients subgroup considering glycosylated hemoglobin levels, treatments in use, time elapsed from diabetics diagnose to surgery. Moreover the recent evidence showed a shift in bacterial species causing prosthesis infection and it would be interesting to investigate new materials and strategies to avoid them.
Conclusions

Penile prosthesis infection decreased in the last decades, but remains an important complication related to lower prosthesis survival. Meta-analysis concludes that diabetes mellitus increases penile prosthesis infection and it should be considered as a risk factor.

Declarations

**Ethical Statement:** The study was assessed by institutional board review which has approved the study with no informed consent due to its design.

**Informed consent and consent to participate:** Not applicable. There was no individual participants. As a systematic review, data was obtained from other studies with no patient identification.

**Consent for publication:** No applicable.

**Availability of data and material:** All data is fully provided. The subject of research was previous studies since it is a systematic review. All the studies are listed in a table and the full references are provided.

**Competing interests:** The Authors declare that they have no competing interests. All authors agree with BMC Urology editorial policies.

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Table

Due to technical limitations, table 1 is only available as a download in the supplemental files section.

Figures
Figure 1

Study flow diagram. Diagram shows methodological steps of the systematic review.
Figure 2

Forest plot Diagram showing articles included in meta-analysis. The overall result shows that diabetic patients have more infection of penile prosthesis than non-diabetics, with an odds ratio of 1.46 (p = 0.03).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.xls
- supplement2.tif