

Penile prosthesis in the medically complex patient: a narrative review

Andries Van Huele^{1,2}[^], Koenraad Van Renterghem^{1,3,4}

¹Department of Urology, Jessa Hospital, Hasselt, Belgium; ²Department of Urology, Ghent University Hospital, Ghent, Belgium; ³Hasselt University, Hasselt, Belgium; ⁴Department of Urology, University Hospital Leuven, Leuven, Belgium

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Correspondence to: Andries Van Huele, MD. Department of Urology, Jessa Hospital, Salvatorstraat 20, 3500 Hasselt, Belgium; Department of Urology, Ghent University Hospital, Ghent, Belgium. Email: andries.vanhuele@ugent.be.

Background and Objective: Penile prosthesis surgery is considered a safe and effective treatment for patients with erectile dysfunction. Implantation in the medically complex patient can be a challenge. The benefits of treatment must outweigh the possible risks or complications. A description of possible problems and how to cope with them is given in this narrative review.

Methods: Literature search was performed in January 2023 using different search prompts in PubMed. These articles, excluding non-English and non-full text articles, were listed by the two authors and afterwards, the most relevant ones were included.

Key Content and Findings: This article is divided into five important topics. We evaluated different comorbidities such as spinal cord injury, diabetes mellitus and cardiovascular disease, in which preoperative work-up and counseling is of significant importance. A detailed description of these comorbidities and how to handle these can be found in each section. In addition to the preoperative aspect in organ transplant patients, problems during surgery can arise, e.g., with the reservoir placement. Similarly, in patients with previous pelvic surgery, an ectopic reservoir placement can prevent possible complications.

Conclusions: Preoperative diagnostics are crucial and prosthetic surgery should be done by an experienced high-volume surgeon with a diverse range of surgical techniques at his disposal.

Keywords: Penile prosthesis; spinal cord injury (SCI); diabetes mellitus (DM); organ transplant; reservoir placement

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Introduction

Penile prosthesis surgery is the most common surgical procedure regarding erectile dysfunction (ED). Due to technological advances over the last few decades, it is regarded as a safe and effective treatment. One of the most important endpoints for penile implant surgery is patient satisfaction, with studies showing satisfaction rates higher than 85–90% (1,2). This outcome can be influenced by some preoperative variables, such as Peyronie's disease, obesity, prior surgery and patient age (3).

When the decision for penile implant surgery is made, the benefits of treatment must outweigh the possible risks or complications. In the medically complex patient, these possible harms can be of such importance that it could change treatment choices.

[^] ORCID: 0000-0002-3159-8012.

| Items | Specification |
|--------------------------------------|---|
| Date of search | 2 January 2023 to 31 January 2023 |
| Databases and other sources searched | PubMed |
| Search terms used | MeSH: penile prosthesis, spinal cord injury, diabetes mellitus, cardiovascular disease, organ transplant, prostatectomy |
| | Free text: reservoir placement, pelvic surgery |
| Timeframe | Due to the lack of evidence in some parts, all publication dates were considered, although there was a preference for articles from the last decade |
| Inclusion and exclusion criteria | Inclusion: clinical trial, meta-analysis, randomized controlled trials, review, systematic review |
| | Exclusion: language other than English, no full text |
| Selection process | Both authors (A.V.H., K.V.R.) did an elaborate literature research independently. After all articles were merged, duplicates were removed and the most relevant articles were kept for the manuscript |

 Table 1 The search strategy summary

This review article will describe some of the most common comorbidities in patients indicated for penile implant surgery. Because this series of reviews has already covered subjects such as priapism and Peyronie's disease, we will categorize this article into five parts: (I) spinal cord injury (SCI); (II) diabetes mellitus (DM); (III) cardiovascular disease (CVD); (IV) previous organ transplant; (V) previous pelvic surgery. We will discuss in each section the main problems and how to cope with them. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/ view/10.21037/tau-23-71/rc).

Materials and methods

A review of literature was performed using all relevant publications derived from PubMed. Literature was searched in January 2023. MeSH terms used were "penile prosthesis", "spinal cord injury", "diabetes mellitus", "cardiovascular disease", "organ transplant" and "prostatectomy". Additional queries were "reservoir placement" and "pelvic surgery". All non-English and non-full text articles were excluded. No publication date filter was used. Most recent articles were preferred for inclusion. Relevant references from the selected articles were also included. Both authors performed literature review independently and afterwards these number of articles were combined (*Table 1*). We listed the authors' recommendations at the end of each section.

SCI

SCI may lead to a set of different disabilities, including some important urologic problems. Most importantly, these include neurogenic urinary tract dysfunction and ED (4). The extent of ED depends mainly on severity and level of the SCI, with reports mentioning that 93% of patients are able to achieve erections suitable for intercourse when using Sildenafil if one or more pathways are preserved (4). A penile prosthesis is an option in patients with SCI who are non-responders for conservative treatments, which is more often the case in patients with lower levels of SCI (4).

Apart from ED, a penile prosthesis could also be indicated for patients who have urinary symptoms, who need a "condom" catheter or intermittent self-catheterization. A systematic review showed that approximately 33% of SCI patients had a penile implant solely for the indication of urinary symptoms (5).

An important fact to keep in mind in this patient group is that (I) these patients often have a limited dexterity and (II) they have an altered or diminished sensibility of their genital region. These facts are important for choice of type of prosthesis and create necessity for meticulous followup. Studies regarding penile prostheses in SCI include two types of implants: malleable and inflatable (4).

Clinical practice and literature show that in SCI patients, a significantly higher number compared to the general patient population receive a malleable implant (5). The most important factor is the easier use in patients with reduced dexterity. However, both types of implants could be considered.

An inflatable prosthesis could be considered if the patient has a good hand coordination or if the partner is willing to operate the device. It is more prone to mechanical or technical problems in comparison to the malleable implant due to the complexity of the components. A malleable prosthesis is indeed easier in use in the SCI population but literature shows that erosion rates are higher (5-7). Possible explanations could be due to the fact that inflatable prostheses are deflated most of the time (reducing chance of erosion) and because malleable prostheses are often placed for concomitant urinary symptom control in which reduced sensitivity could lead to tissue damage (e.g., when using intermittent catheterization or indwelling catheters).

A lot of studies about penile implants in patients with SCI are outdated. This means the results from these studies have a chance of not being representative for current practice (5). A systematic review by Pang et al. mentioned the appearance of a higher infection rate compared to the non-SCI group (0-9.1% vs. 0.8-5.7%). This could be related to altered blood supply in the penile region, urinary tract infections (catheter, neurogenic bladder), diminished wound healing, reduced mobility and lowered sensation (5). Another study by Kim et al. including SCI patients receiving a malleable prosthesis showed that complications occurred in 16.7% of patients and patient satisfaction was 79.2% (8). A study by Zermann et al.-with long-term follow-upshowed an infection rate of 5%. Perforation rate was different in subgroup analysis. The highest rate was seen in the malleable group, and the lowest in the inflatable penile prosthesis (IPP) group (respectively 18.1% vs. 0%) (9).

Author recommendations

Patients with SCI seem to have more risk for prosthesisrelated complications according to a limited amount of studies. Preoperative counseling regarding other indications such as urinary symptoms and limited dexterity or sensibility is of utmost importance. When feasible, we suggest the implantation of an IPP due to limited evidence of less erosion rates.

DM

DM is a chronic, multi-organ affecting disease. Up to half of patients have ED to some level (10). Device infection is

the most feared complication after penile implant surgery, as the implant needs to be removed. This topic is already described in a previous review article of this series (10).

In this paragraph, we will focus on risk of infection in DM patients. Diabetic patients have impaired defense mechanisms—including angiopathy, leukocyte dysfunction, neuropathy, etc.—which in theory results in a higher chance of infection (10).

There are different studies regarding the risk of infection in diabetic patients. Infectious diseases in general are more frequent in uncontrolled DM (11). While some studies show a threefold risk in penile implant infection, others conclude no difference (10,12,13). For example, an evaluation of the New York Statewide Planning and Research Cooperative System database withheld in their multivariate analysis DM as a risk factor for infectious complications for IPPs (3% in the diabetic group, 2% in the non-diabetic group, P<0.001) (14). Additionally, a multicentric prospective study by Habous et al. concluded that a high HbA1c level was associated with higher rates of implant infection. A receiver operating characteristic (ROC) curve was published in which a HbA1c level of 8.5% was proposed to predict infection with 80% sensitivity and 65% specificity (15). A recent meta-analysis suggests that DM is associated with a significant higher risk of penile implant infection compared to a non-DM patient [odds ratio (OR) 1.53, 95% confidence interval (CI): 1.15-2.04] (10). In contrast, a systematic review concluded no significant difference in infection prevalence between DM and non-DM patients. They mentioned however that since the implementation of antibiotic-coated implants from 2001 onwards, infection rates reduced significantly (16).

Author recommendations

Evidence regarding infectious complications in the DM patient population is still debatable (17). However, patients with poorly controlled disease are considered at risk, which results in our suggestion that there should be blood sugar testing and a good diabetic control preoperative to implant surgery. Large prospective studies or registries—such as the recently enrolled PHOENIX trial—could give us some more answers on the matter, e.g., on a possible HbA1c cut-off value (18).

CVD

The goal of this paragraph is to assess the perioperative

cardiovascular risks in penile implant surgery and to evaluate perioperative anticoagulation use.

A significant number of patients with ED will have concomitant CVD or it could be a marker for future cardiovascular events (19,20). A preoperative cardiovascular risk stratification can be done with different nomograms, such as the CHA2DS2-VASc [congestive heart failure, hypertension, age (\geq 75 years), DM, stroke, vascular disease, age (65–74 years), and sex category] score for risk for stroke or the HAS-BLED [hypertension, abnormal renal and liver function, stroke, bleeding, labile INR (international normalized ratio), elderly, drugs or alcohol] score for risk of major bleeding (17).

The Princeton Consensus Conference (I, II, III) is dedicated to treating ED and preserving cardiovascular health (21-23). The first Conference focused on stratification of patients by cardiac risks associated with sexual acts based on pre-existing CVD (23). The second Conference expanded previous recommendations regarding risk factor evaluation and lifestyle management. New information was given regarding medical therapy in patients with concomitant CVD (21). The third Conference updated their previous existing recommendations and additionally focused on cardiovascular risk assessment in patients with ED and no known CVD (predictive value of vasculogenic ED) (22). The European Association of Urology (EAU) guidelines included a flowchart derived from the Princeton consensus where patients are categorized in three groups based on cardiac risk. They recommend a cardiologist consultation in the high risk and stratify the intermediate risk group with a stress test (24).

A large retrospective study by Lacy *et al.* found that both hypertension and peripheral vascular disease were associated with increased risk for revision surgery or explant (hazard ratio 1.27, 95% CI: 1.12–1.43; hazard ratio 1.25, 95% CI: 1.10–1.41, respectively) (25). Other smaller retrospective studies showed no association between hypertension and prosthesis failure or revisions (26,27). Overall, data regarding penile implant surgery and peripheral vascular disease or hypertension is limited.

Special attention must be given to patients receiving antiplatelet or anticoagulant medication. According to the AUA, penile implant surgery is classified as a high risk for bleeding (28). A recent article by Dimitropoulos *et al.* reviewed different recommendations and guidelines regarding the perioperative management of antithrombotic medication in urologic surgery (29). They evaluated quality with the AGREE II (Appraisal of Guidelines for REsearch and Evaluation) instrument, with the EAU clinical practice guidelines having had the highest score (83.3 points). They recommend stopping antiplatelet therapy five days prior to surgery while the ideal moment to stop anticoagulants depends on the specific type (29,30).

Masterson *et al.* proposed a simplified preoperative checklist for penile implant surgery. They state in the preoperative setting there is need for: (I) cardiology/ medical clearance; (II) urine culture; (III) HbA1c <10; (IV) stop antiplatelet seven days prior to surgery. However, they state that they are also comfortable for doing surgery under aspirin 81 mg (31).

Author recommendations

In patients with a significant cardiovascular history, preoperative work-up together with a cardiologist and anesthesiologist should be performed, e.g., based on the Princeton Consensus Conference (22). The checklist by Masterson *et al.* is a simple and easy to use preoperative tool, including the medical clearance by a cardiologist and a guide for anticoagulant or antiplatelet medication (31).

Prior organ transplant patients

There is much debate regarding penile implant surgery in patients with previous organ transplants. The most feared complication is infection, e.g., due to immunosuppressive treatment (32). Literature withholds conflicting and limited results. Different small series, such as those of Kabalin *et al.*, Sidi *et al.* and Hill *et al.* concluded no significant difference in prosthesis-related complications (33-35). Other studies showed higher rates of complications such as infection and mechanical failure (36,37).

The study by Sun *et al.* compared 26 patients with solid organ transplantations with penile prosthesis implantation with 26 non-transplant patients. They saw no significant difference between the two groups in regards of infection (4% *vs.* 0% in the control group). The reoperation rates were the same (11.5% *vs.* 11.5% in the control group) (38).

Another study by Cuellar *et al.* included 211 patients of which 46 had pelvic organ transplantation. Transplant patients had significantly more complications in total than non-transplant patients (22% vs. 7.9%, P<0.01). The risk for prosthesis infection was similar in their study (4.3% vs. 4.2% in the control group). They concluded that the higher complication ratio can be attributed to reservoirrelated complications in IPP (three-piece) due to multiple

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surgeries for the organ transplantation itself. In patients with no retroperitoneal reservoir, complication ratio in total was not significantly higher in organ transplant patients (39). Aggregate data analysis showed no difference in noninfectious complications but interestingly did show a significant difference in future surgical injury in the organ transplant group (32).

Author recommendations

Despite some prejudices about infection risk in patients with previous organ transplant surgery, limited studies show no infectious related difference. When a three-piece IPP is placed, care must be taken in future organ transplant surgery to avoid reservoir-related complications by placing the reservoir in an ectopic position, e.g., submuscular.

Previous pelvic surgery

Previous abdominal surgery could be a perioperative problem regarding reservoir placement in a three-piece IPP. Reservoir placement is one of the most controversial technical subjects regarding IPP placement. Different approaches for reservoir placement are described in literature. The golden standard in patients with no previous abdominal surgery is placement in the space of Retzius through an extraperitoneal approach. Placement in this space avoids intra-abdominal complications and allows a low-pressure space for the reservoir (40). Access could be obtained through a separate suprapubic incision or in the same—e.g., in the penoscrotal approach—incision via the inguinal canal or the external oblique muscle fascia (41). The fascia transversalis could be perforated with the finger, sharp or with a nasal speculum (42-44).

Henry *et al.* stressed the importance of an empty bladder through a catheter in regards of the anatomical measures in the retropubic space (45).

Due to previous surgery—such as radical prostatectomy, radical cystectomy or colorectal surgery—the Retzius space could be compromised which could result in a higher risk of complication, e.g., damage to iliac vessels, bladder or intestines (41).

More and more publications arise regarding alternative techniques. Ectopic placement of the reservoir could be beneficial in patients with previous pelvic surgery. The term "ectopic" is defined as reservoir placement outside of the space of Retzius. The term can be interpreted broadly. These locations include intra-abdominal, high-submuscular or subcutaneous placement (46,47). The ectopic positioning has gained popularity, also due to technical advances in the reservoirs itself such as the low-profile and lock-out valves (40,48).

The high-submuscular placement was popularized by Morey *et al.* (47). In this technique, the reservoir is placed underneath the belly of the rectus muscle. It is an ideal place for the reservoir due to it being outside the abdomen or pelvis, and being separated from important anatomical structures due to the fascia transversalis (49). Different studies reported low palpability and high patient satisfaction (50,51). Preliminary data from the PROPPER study showed that none of the patients with a submuscular reservoir mentioned palpability or auto-inflation, which is also a concern for different urologists in ectopic reservoir placement (49).

A cadaveric study showed variable anatomical locations of the reservoir when the high submuscular technique was intended. Different additional precautions such as ultrasound-guided placement or a step-by-step standardized technique can be used for better positioning (52).

Author recommendations

Ectopic placement of the reservoir should be considered in patients in which the space of Retzius is impaired. A highvolume surgeon should have different techniques in his/her armamentarium.

Conclusions

Penile implant surgery is considered a safe and effective treatment for ED. However, due to its elective character, its safety must be warranted in the medically complex patient. In this review article, we selected some common comorbidities and potential problems. Overall, preoperative diagnostics and counseling are of utmost importance in making treatment decisions. The high-volume surgeon should know how to cope with perioperative problems, e.g., in patients with previous pelvic surgery.

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Footnote

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