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Research Article

Complications of Inflatable Penile Prostheses Implantation Classified according to the Modified Clavien System

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Introduction. In patients with erectile dysfunction (ED), inflatable penile prosthesis (IPP) surgery is regarded as the gold standard treatment in medically refractory cases or where its conservative treatment options are contraindicated. Despite improvements in surgical technique and implanted materials, IPP surgery retains a substantial complication rate. The aim of the study was to record and grade the postoperative complications of IPP implantation according to a modified Clavien system. *Methods*. A total of 60 three-piece IPP implantations were performed between 2007 and 2013 by a single surgeon. The primary outcome was to stratify the early (first 30 days) complications into five categories using the modified Clavien-Dindo classification system. A secondary aim was to record the long-term adverse events and to identify possible factors related to complication occurrence. *Results*. Overall, there were 21 (35%) postoperative complications in 17 of 60 men (28.3%), with 15 adverse events occurring early after surgery. In terms of late complications, there were six (10%) major complications managed by either revision surgery or removal of the prosthesis. *Conclusion*. This study utilizes a validated morbidity scale thus overcoming problems of previous studies reporting IPP surgery complications. The modified Clavien classification system easily aids in assessing and comparing accurately patients' postoperative complications, thus improving management and prevention.

1. Introduction

Erectile dysfunction (ED) is highly prevalent in certain groups of population. Penile prosthesis implantation is the gold standard in treatment of ED when medical therapy either fails or is contraindicated or unwanted by the patient. Over the last 30 years, several penile implants have been developed to improve the penile rigidity in conjunction with a better cosmetic result [1]. Moreover, surgical techniques and antibiotic coverage of the newer implants have improved safety and both patient and partner satisfaction. In spite of these improvements, however, operative complications remain that can be severe and include increasing morbidity and hospitalization cost.

There is a need for an objective postoperative complications reporting system to improve the quality of health service and to facilitate cost reduction and patient satisfaction by reducing postoperative morbidity. The Clavien-Dindo classification distinguishes surgery complications based on the type of therapy needed to correct the complication, thus distinguishing postoperative complications that may appear similar but are actually quite different in terms of postoperative morbidity, costs, and patient satisfaction. The modified system published in 2004 includes seven grades (grades I–V) with 2 subgroups for grades III and IV [2]. Grade I includes any deviation from the normal postoperative course without need for special treatment except general therapeutic regimens like antiemetics, antipyretics, analgesics, diuretics, and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. Grade II includes complications requiring special pharmacological treatment. Blood transfusions and total parenteral nutrition are also

included here. Grade III includes complications that need special surgical, endoscopic, or radiological intervention and is divided depending on general anaesthesia needs in two subgroups IIIa and IIIb, respectively. Grade IV includes life-threatening complications (including CNS complications: brain haemorrhage, ischaemic stroke, and subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management. It is divided into IVa and IVb depending on whether there is a single- or multiorgan dysfunction, respectively. Finally grade V complication is patient death. If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

Although the Clavien system has been accepted as a valid and reproducible grading system, its use is not widespread in the urology community [3]. Indeed, there are no reports in the literature of this classification grading in regard to penile prosthesis implantation.

The aim of this original study was to evaluate the complications of penile prosthesis implantation in a single tertiary center, by utilizing the modified Clavien system, and to report the late complications (30 days postoperatively) and their management.

Table 1: Etiology of erectile dysfunction.

Etiology of ED, *n* (%)	
Diabetes mellitus	13 (21.7)
Previous radical prostatectomy	21 (35.0)
Vascular disease	6 (10.0)
Neurogenic	8 (13.3)
Peyronie's disease	3 (5.0)
Traumatic	2 (3.3)
Unidentified	7 (11.7)

Table 2: Types of implanted prosthesis.

Penile implants	
Implant type	Number implanted, *n* (%)
AMS 700 CX (3-piece)	29 (48.3)
AMS 700 InhibiZone (3-piece)	8 (13.3)
AMS LGX (3-piece)	9 (15.0)
Mentor Titan (3-piece)	14 (23.3)
Total	**60** (**100**)

AMS = American Medical Systems.

2. Materials and Methods

Between January 2007 and May 2013, 60 consecutive patients underwent primary IPP implantation. The mean patient age was 55.48 ± 13.13 years at the time of surgery and mean follow-up was 41.32 ± 27.29 months. In three postradical prostatectomy patients, simultaneous implantation of penile prostheses and artificial sphincter devices was performed. All surgeries were performed by a single surgeon in a tertiary center of North Greece.

For patients undewent nerve sparing radical prostatectomy, the preimplantation rehabilitation protocol, included a trial of four tablets of a PDE 5 inhibitor with a repeat of four more tablets of another PDE 5 inhibitor after a second consultation in case of primary failure. In case of secondary failure the patient was proposed to receive a PDE 5 combination treatment and if it failed again, the patient was proposed to go to intracavernosal injections or vacuum device treatment. If the patient did not accept or discontinued for various reasons this kind of treatment, then an inflatable penile implant was offered.

Patients, who underwent non-nerve sparing radical retropubic prostatectomy, were offered intracavernosal injections for the first two postoperative years and then they were asked to turn to PDE 5 inhibitors. In case of oral treatment failure, patients who did not wish to continue with injections had an offer of a vacuum device or an inflatable penile prosthesis.

The study patients were admitted the day before surgery and antibiotic prophylaxis was started the day of admission. All implants were placed through penoscrotal approach. The patients were discharged on the first postoperative day with instructions for receiving antibiotics for one week and proper clean of the surgical wound. They were further instructed to return for evaluation in the outpatient clinic in the seventh postoperative day unless a complication presented earlier.

Patients were instructed that they would be able to engage in sexual intercourse by the end of the first postoperative month. Complications were recorded in detail either in the outpatient clinic or emergently. The study was authorized by the Ethical Review Committee of G. Gennimatas General Hospital of Thessaloniki. Prior to enrollment, each patient was informed about the study purposes and written consent was obtained.

Patients and implant characteristics, details of the etiology of the ED, and postoperative complications were recorded. Complications occurring within 30 days of surgery (early complications) were ranked according to the modified Clavien classification system and stratified into five categories of severity. Complications occurring after this period were characterized as late complications. Statistical data was analyzed by using the software IBM SPSS version 20.0.0 (International Business Machines Corp., Chicago, Illinois).

3. Results

The main diseases contributing to the etiology of ED of the authors' patients were diabetes mellitus and previous radical prostatectomy (Table 1). Four types of three-piece inflatable prosthesis were used (Table 2).

Four of the study's patients were lost to follow-up, while two study patients died from unrelated causes after the first postoperative month. There were 21 (35%) postoperative complications in 17 procedures. Of these complications, 71.42% occurred in the early period after implantation, while 28.6% had late onset. The authors' had only one intraoperative complication consisting of septum perforation and crossover of the cylinder in a patient with micropenis and refractory

Table 3: Early complications classified according to the modified Clavien system.

Early complications		
Grade	Complications	Management
I	Hematoma akin to "boxer shorts"	No
	Scrotal hematoma	Bedside opening
	Glans bowing ("Concorde syndrome")	No
	Reservoir dislocation	No
II	Acute epididymitis	IV antibiotics
	Wound infection with positive culture	IV antibiotics
	Fever of unknown origin	Antibiotics
	Severe balanoposthitis	Topical cream + oral antibiotics
	Scrotal dermatitis	Topical cream + oral antibiotics
	Febrile urinary tract infection	IV antibiotics
IIIa	Glans bowing ("Concorde syndrome")	Plastic repair under regional anesthesia
IIIb	Prosthesis infection	Surgical removal
	Reservoir dislocation	Surgical reposition
	Acute abdomen due to bowel injury	Removal of reservoir and colostomy
IVa	None	
IVb	None	
V	Death due to acute myocardial infarction	

ED. One cylinder was managed to be implanted and the patient was followed up for 14 months.

3.1. Early Complications. Fifteen early postoperative complications (25%) occurred in 60 procedures. The majority were minor, graded I and II of the modified Clavien scale. The authors' addressed six minor inflammatory complications (10%) that were managed by oral, intravenous, or topical antibiotics. One additional case of hematoma, akin to "boxer shorts", occurred in a patient with severe coronary heart disease who was then treated with a dose of 7500 IU of tinzaparin immediately after the operation per a conservative management approach. However, this patient later required decompression of a large scrotal hematoma by bedside opening due to severe discomfort. Furthermore, there was also one case of floppy glans ("SST deformity") and one case of reservoir dislocation after strong cough in the first postoperative day. Neither patient desired to have surgical repair and had been treated with conservative management.

In contrast, two similar complications required surgical intervention pursuant to patient demand. Another case of SST deformity was repaired under local anesthesia (grade IIIa) and a patient with reservoir herniation underwent surgical reposition (grade IIIb). One implant was removed on the 14th postoperative day due to early infection in a young paraplegic patient (grade IIIb). Moreover, a case of acute surgical abdomen (due to bowel perforation) that presented on the second postoperative day also occurred. This complication was consequent to a bowel injury during reservoir placement in a patient with radical cystectomy and ileal neobladder reconstruction due to invasive bladder cancer. The management in this case included removal of the reservoir and temporary colostomy (IIIb). Finally, a postoperative death due to acute myocardial infarction occurred on the seventh postoperative day in a 57-year-old diabetic man with known history of coronary arteries heart disease. The overall rate of early major complications (grades III–V) was calculated at 8.33% (Table 3).

3.2. Late Complications. A total of four patients (6.66%) underwent revision surgery. Two patients (3.33%) asked for revision despite good prosthetic results due to penile size. One of these patients requested revision due to dissatisfaction with the penile size requested for IPP increase in corporal length and one, who had an AMS CX 700 IPP implanted, requested a size upgrade of the implant to an AMS LGX (American Medical Systems, Minnetonka, MN). The third patient also experienced a successful revision after erosion and protrusion of the right cylinder at 12 months after initial implantation. The fourth patient presented with micropenis (stretched length: 5 cm) and ED due to severe pelvis and testis injury at the age of four. During the initial implantation, the surgeon only had an AMS CMX size 12 available, which was too large. During the attempt to place the first cylinder, the surgeon struggled with septum perforation and crossover but was able to insert only one cylinder for implantation. Simultaneously, the patient underwent suspensory ligament ligation to gain some length. Unfortunately, after 14 months of satisfactory sexual life, the patient experienced erosion and protrusion of the cylinder. A revision was attempted by replacing the IPP with an AMS CXM size 10, but this was impossible due to severe scarring and narrowing of the corpora cavernosa and intracavernosal length of no more than 5 cm. This patient could not have even a malleable implant, since the only available malleable implant in our department was the AMS Spectra with a minimum available girth of 9.5 mm per cylinder. We did not use preoperative vacuum device treatment to enhance penile postoperative

length, since we had not any experience and also there is not much in the literature about it.

In four other patients (6.66%) the device was removed, but they did not wish for revision. Two of these patients (3.33%) had the IPP removed due to infection, at three and 28 months postoperatively, respectively, and the remaining two patients' IPPs were removed due to mechanical failure, at 12 and 24 months postoperatively, respectively.

Excluding the two unsatisfied patients, there were six (10%) major complications in the late postoperative period (Table 3).

4. Discussion

IPP implantation is the last and definitive treatment choice for refractory erectile dysfunction or where conservative therapies are contraindicated. IPP implantation is usually a straight-forward operation. The satisfaction rates are the highest among all other ED treatments for both patients and partners [4, 5].

Complications of IPP implantation, while infrequent, can become serious and may be accompanied by severe morbidity and decreased satisfaction. These complications can be intraoperative or postoperative. Intraoperative complications include perforation of the tunica albuginea during dilatation of the corpora or perforation of the septum, with or without urethral injury, which can result in cavernosal crossover [6]. Depending on the size and location of perforation, the surgeon must determine whether continuation or cessation of the operation is appropriate.

Minor postoperative complications consist of wound hematomas and superficial wound infection. The most frequent and severe postoperative complication is infection, which always requires removal of the implant. Indeed, diabetics and neurological patients are in the highest risk for this complication. Revision surgery for any reason also carries a greater risk of infection [7].

To combat this infection risk, several measures are taken to reduce infection rates, including thorough washing on the day before surgery; admission on the day of surgery; shaving and scrubbing in the theatre; pre- and postoperative antibiotics; and a focus on completing the procedure as efficiently as possible so as to avoid trafficking in the theatre. Since antibiotic impregnated IPPs were introduced, the total infection rate declined from 2.5% to less than 1% for primary operations [8]. Other major postoperative complications include mechanical failure: erosion and protrusion of cylinders; "S-shaped" deformity of the penis; and glans deflection (SST deformity). Almost all of these postoperative complications require surgical repair.

Using a standardized system to report procedure-related complications has a number of advantages. It improves the quality of care by informing patients of the efficacy and safety of the procedure based on reliable data. Moreover, it helps surgeons to compare their results and improve both their technique and the management of those complications. And most importantly, because of the wide release of new inflatable penile implants, a uniform data reporting system is needed to compare the occurrence of complications among these products to aid surgeons in the most appropriate device choice [3, 9].

The Clavien complication grading system is a severity grading system developed by Clavien et al. and published in 1992. This complication grading system ranks complications based on the magnitude of the intervention(s) required to treat them and whether those complications cause permanent injury or death. In 2004, the Clavien complication grading system was modified to include more observational/conservative treatment complications [2, 10].

In the field of urology, many surgical procedures have been evaluated with the use of Clavien-Dindo grading system. This grading system offers user facility and an objective measurement that has enjoyed increasing acceptance in many centers [3, 11]. Various papers have studied penile prosthesis implantation complications, but heretofore, no publications have utilized the Clavien-Dindo grading system [12–14].

Beyond the Clavien system, many other complication severity grading systems have been proposed. Recently, Beilan et al., encouraged by the results of general surgery colleagues, used the postoperative morbidity index (PMI) in 11 common urologic procedures. This is a new quantitative severity-weighing of postoperative complications, where an index of 0 indicates no complication in any patient and an index of 1 indicates that all patients who underwent a specific procedure died. To calculate the PMI for each operative procedure, the severity of all the complications for all patients who underwent the corresponding procedure are totaled and then divided by the total number of patients. The PMI of inflatable penile prosthesis was calculated to 0.093 with a severity index of 0.336, falling within the median range of the 11 procedures [12].

In the authors' IPP implantation series, the severe complications that demanded surgical intervention or resulted in severe morbidity were SST deformity in two patients (3.34%); herniation of the reservoir in two (3.34%); removal of the IPP due to infection in three (5%); erosion and protrusion in two (3.34%); mechanical failure in two (3.34%); bowel perforation in one (1.67%); and one death due to myocardial infarction (1.67%). The authors' complication rates are aligned with the literature.

Minervini et al. reported the outcomes of 504 penile prostheses implanted in 447 men from 1975 to 2000. Of those, 81 were three-piece IPP [1]. They reported infection in 15%; mechanical failure in 13.7%; and erosion in 7.5%. Sadeghi-Nejad reviewed the complications of IPP implantation and found that mechanical malfunction occurred in 10.3% of AMS implants and 0.8%–3.1% of Coloplast implants (Coloplast, Minneapolis, MN). Infection occurred in 0.68–1.06 of InhibiZone or hydrophilic-coated devices at 6 months and one year, respectively. Corporal perforation/erosion appeared in 1%–11%, more often distally, and glans bowing up to 10% [6].

In this study, the Clavien-Dindo grading system revealed that most patients had grade I and grade II complications that accounted for approximately 26.6% and 40% of all early complications, respectively. Grade III complications occurred in four patients. Unfortunately, although the authors did not face grade IV events, they did experience one grade

V complication. The statistical analysis did not yield any preoperative factors associated with a higher percentage of complication occurrences.

One weakness of this grading system, particularly as it pertains to IPP implantation, is the noninclusion of delayed events—for example, mechanical failure and prosthesis removal due to infection. However, it should be noted that late onset complications were separately reported in our study. In the authors' view, with procedures like penile prosthetic surgery, all complications can be included in this grading system, even beyond the 30th day postoperatively.

As a caveat, this study has some limitations. This study is restricted to a small sample of patients treated in a low volume center; sixty patients is admittedly a small number to demonstrate the wide range of complications for a specific surgical procedure. However, the authors believe that the detailed record of complications, combined with the prospective nature of the study, can counterbalance this limitation. Undoubtedly, further large prospective studies utilizing Clavien-Dindo grading should be performed to evaluate the real range of related complications in penile prosthesis surgery. As an additional factor, the main surgeon took part in recording patient complications and their management, which may yield some reporting bias. Without dispute, surgeons tend to underestimate their negative outcomes. To minimize this bias, two more authors reviewed the results by reexamining the hospital files and interviewing all participants.

5. Conclusions

Conclusively, IPP implantation is the definitive solution for ED treatment and yields higher rates of both sexual partners' satisfaction. Although, it is usually a straightforward operation, there remain severe complications and much corresponding advice to treat or prevent them. Ranking these complications by an objective grading system, such as Clavien-Dindo, helped the authors evaluate the safety of the procedure generally. The system also allows the surgeon in specific circumstances (e.g., Peyronie's disease) to analyze learning curves of surgical techniques, by providing a basis for internal quality control, and to standardize surgical errors, thereby improving management and prevention.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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