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ORIGINAL PAPER

Immediate insertion of a soft penile prosthesis as a new option for a safe and cost-effective treatment of refractory ischemic priapism

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Summary *Objective: The aim of this study is to assess the management of refractory ischemic priapism (IP) by the immediate insertion of a soft penile prosthesis (sPP).*

Patients and methods: We identified men affected by IP who underwent early sPP placement from May 2017 to October 2019. All patients underwent a detailed medical history review; intraoperative, postoperative features and adverse events were recorded. We evaluated the penile lengthening and bending, presence of complementary erection, ability to have sexual intercourse, postoperative sexual life satisfaction (International Index of Erectile Function [IIEF] questionnaire - question number 5). A cost-analysis was included.

Results: A total of six patients were identified. Median time (range) since onset was 78 (48-108) hours with a mean age (SD) of 33 (6.9) years. Median operative time (range) was 82 minutes (62-180). No complications were recorded. Median follow-up was 9 months (range 3-17). No significant loss of penile length, neither penile angulation was recorded. Despite a transient reduction of penile sensitivity, all patients reported satisfactory sexual intercourse (mean score question number 5 from IIEF-5 of 4). The cost of sPP was € 1769,00 with a surgery-related reimbursement fee from the National Health System of € 3856,75.

Conclusions: The insertion of a sPP for patients with refractory IP results in immediate pain relief, preservation of sexual function and penile size, with a higher surgery reproducibility in an emergency. In addition to this, financial and resource burdens of IP on the health-care system can be potentially reduced.

KEY WORDS: *Priapism; Soft tutors; Penile prosthesis; Virilis; Ischemic priapism; Early implantation.*

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INTRODUCTION

Ischemic priapism (IP) is a pathological condition presenting itself as a persistent erection marked by the rigidity of the corpora cavernosa with little or no cavernous arterial inflow accounting for more than 95% of all priapism episodes (1). Beyond 4 hours, IP is considered a compartment syndrome which severely compromises cavernous circulation, leading to progressive destruction of cavernous sinusoids and consequently smooth muscle cells necrosis. Emergency medical intervention is required, treated on a flaccid, non-painful state, to minimize potential irreversible consequences, such as corporal fibrosis and permanent *erectile dysfunction* (ED) (2-3). Episodes lasting < 36 hrs may still respond to corporal blood aspiration and α-adrenergic agents, e.g. phenylephrine, unlike in delayed cases (> 72 h) that then often require surgical intervention, creating a permanent shunt between the cavernous bodies and the glans or the spongious urethra (4-5). It is intuitable that all patients affected by ischemic priapism lasting over 36 hours, have no chance to regain any erectile function (not even supported by drugs) (6).

In the light of this, early *penile prosthesis* (PP) implantation in refractory IP has been proposed by some Authors (1-7). Actually, with the immediate PP insertion of either malleable and inflatable, can offer many advantages for these patients: resolving painful erection, providing sufficient rigidity for satisfactory intercourses, and counteracting inevitable penile shortening, which are cavernous fibrosis consequences (8, 9). Moreover, the immediate implant of PP is easier to perform while, rather than if delayed which may be technically challenging, with higher complication rates and the need to implant downsized cylinders (9).

In case of the acute PP insertion, the technical complexity of surgery, the cost-related issue and the possible unavailability of the devices in many centers or in emergency settings must be considered as critical points.

In this study, we report our experience with the use of particular non-inflatable prosthesis, made of soft silicon (sPP), in the surgical management of a refractory IP.

PATIENTS AND METHODS

In this retrospective study, we identified men affected by IP attending our emergency department in a tertiary referral center from May 2017 to October 2019 who underwent early sPP placement.

The patient's work-up consisted of: a) detailed medical history review for sickle cells disease, malignancy, hematological conditions such as thrombophilia or other hemoglobinopathies, assumption of pharmaceutical compounds or illicit drugs; b) general physical and androlog-

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ical examination; c) comprehensive laboratory tests, including a complete blood count, white blood count with blood cell differential, platelet count, coagulation profile and fetal hemoglobin assessment; d) cavernosal blood sample for gas analysis.
Intraoperative, postoperative features and adverse events were recorded. Follow-up was based on a standard internal protocol that consisted of scheduled re-evaluations, considering the following items: postoperative question number 5 from IIEF-5, the onset of penile bending (if any), presence of complementary erection, ability to have sexual intercourse, possible penile shortening and any troubles in genital sensitiveness. The healthcare-related costs of treatment were included in this analysis.
This study was conducted according to the guidelines and principles of the Declaration of Helsinki and the standard ethical conduct of research involving humans; after the approval from the *Ethical Committee for this Clinical Research*, all patients signed an informed consent agreeing to supply their anonymous data for this and for future studies.

Surgical technique and technical considerations

The SPP insertion was performed by the same experienced surgical team. A longitudinal incision, along the scrotal raphe, is made 1 cm below the penoscrotal junction. A Scott or Lone-star retractor is helpful in maintaining the exposure. A traction stitch through the glans penis is mandatory to obtain adequate stretching of the cavernous bodies. After dissection of the dartos layer, the urethra is identified and laterally mobilized; a bilateral longitudinal corporotomy (at least 3 cm) is then performed on the ventral aspect of two corpora cavernosa. The use of blunt scissors within the corpora, under direct vision, helps to minimise the risk of urethral injury or crossover, not infrequent in the case of extensive fibrosis of the apex. Bleeding is generally minimal and any coarse clots are evacuated. After an extensive corporal irrigation with antibiotic solution, the insertion of the soft medical-grade silicone *Virilis I*™ (*Giant medical, Cremona, Italy*) axial implant (Ø 10 mm) is performed, shaping and adapting its length to that of the corpora cavernosa, in the maximal stretch condition.
The limited diameter of the prosthetic cylinders allows the peripheral displacement of the residual erectile tissue, making it possible for the subsequent realization of a complementary erection. Bilateral corporotomy are closed with running sutures. In our practice, a closed suction drain is always inserted.

Results

A total of six patients underwent the sPP insertion for refractory IP treatment. Median time (range) since onset was 78 (48-108) hours with a mean age (SD) of 33 (6.9) years. Three cases were referred from other centers after having had unsuccessful conservative management with aspiration and intracorporal injection of alpha-adrenergic agonists. Two of the patients reported a medical history of sickle cells disease; all of them denied the assumption of either any pharmaceutical compound or illicit drugs. In one case, a new diagnosis of sickle cell disease was made. Low-flow priapism was confirmed with the gas evaluation of cavernosal blood, revealing blood hypoxia and acidosis in all cases. Median operative time (range) was 82 minutes (62-180). No intraoperative complications and no subsequent infection were recorded. Median follow-up was 9 months (range 3-17).
No significant loss of penile length, neither penile angulation or apical extrusion was recorded. Despite a transient reduction of penile sensitivity, all patients have been satisfied with the results of the surgery (mean score question number 5 from International Index of Erectile Function of 4), and all were successfully engaging in satisfactory sexual intercourse.
The cost of sPP was € 1769,00 with a surgery-related reimbursement fee from the National Health System of € 3856.75. Cost analysis comparing different types of PP are reported in Table 1.

Table 1.
Cost-analysis comparing different types of penile prosthesis (please note that the reported costs may vary in different centers and between different Countries).

	Surgery-related national health service reimbursement	Penile prosthesis cost	Potential economic benefit
Soft penile prosthesis	€ 3856,75	€ 1768,00 (4% VAT included)	+ € 2088,75
Malleable penile prosthesis	€ 3856,75	€ 2600,00 (4% VAT included)	+ € 1256,75
3-piece inflatable penile prosthesis	€ 3856,75	€ 7964,51 (4% VAT included)	- € 4107,76

Discussion

The aim of the present study was to evaluate the outcomes of sPP placement surgery for men with refractory or delayed IP in an emergency situation, as a possible alternative to the traditional inflatable or malleable implants. Albeit the number of treated patients is limited, the sPP implantation seem to be an effective option for the surgical treatment of IP, with a low risk of complications and high patient satisfaction. Of clinical importance, our results revealed no significant loss of penile length or de-novo angulation at the follow-up. To the best of our knowledge, this is the first report on the use of this device in a priapism setting, with a reduction of surgery-related technical expertise required and National Public Health-care costs.This strategy could be an attractive chance for patients to maintain, at least in part, their natural erectile response. If case of unsatisfactory rigidity for penetration at follow-up, the sPP can be replaced by an upsized hydraulic PP with no risk of penile retraction.
As this is an emergency condition requiring immediate intervention, the treatment for recent onset IP episode is sequential, going from conservative measures such as aspiration of cavernous blood and irrigation with saline solution to surgical shunts, while in cases with > 36 hours onset, even if surgical interventions can obtain detumescence, the benefits of preserving erectile function are scarce (10). To date, relative indications for immediately implanting a PP in acute IP include (1):

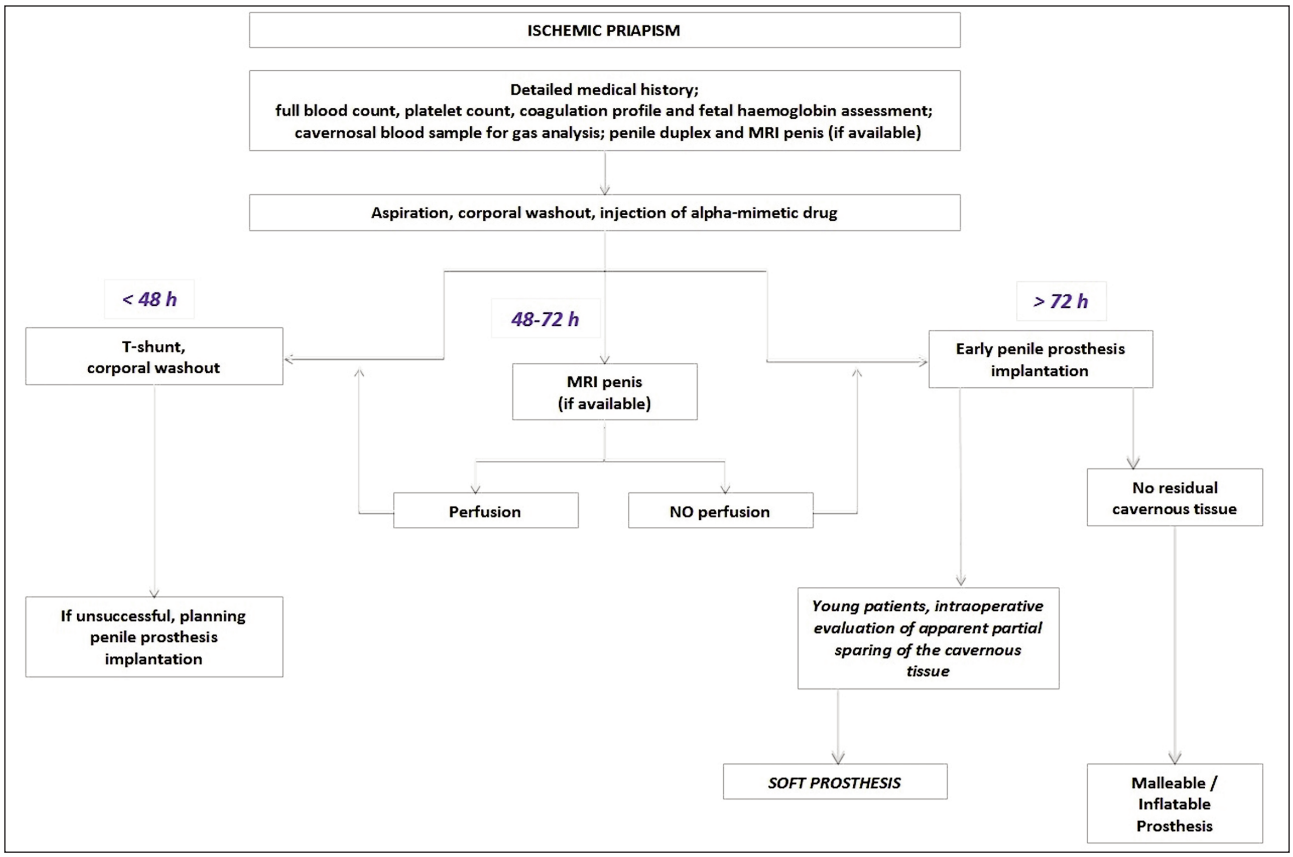
Table 2.
Soft penile prosthesis in a refractory ischemic priapism setting: key points.

· Cheaper devices
· Costs fully covered by the surgery-related National Health Service reimbursement
· Higher availability of the device in an emergency setting
· Simpler and faster surgery
· Prompt pain resolution
· Maintain penile size
· Good coital function (association of residual erection)
· In case of later inflatable penile prosthesis exchange, later upsizing of the cylinders is allowed

- ischaemia that has been presented for more than 36 hours;
- failure of aspiration and sympathomimetic intracavernous injections;
- failure of distal and proximal shunting (although in delayed cases, implantation might be considered ahead of shunt surgery)
- MRI or corporal biopsy evidence of corporal smooth muscle necrosis.

The early versus delayed placement of a PP has been a topic of debate. The immediate insertion of a penile prosthesis has been recommended to avoid the difficulties and complications presented with delayed surgery in the presence of corporal fibrosis.
Early surgery also offers the opportunity to maintain penile size, which is inevitably compromised by delayed surgery (7). During early PP implantation, the corporal dilatation is generally easy; however, distal perforation can occur in 6% of patients who have previously undergone previous needles and shunt procedures, especially when a malleable device is placed (11, 12). Moreover, a six-fold infection rate higher than virgin implant has been reported, with a 12% of revision rate at 16 months (9-13). On the other hand, delayed insertion of PP must face inevitable penile fibrosis which is particularly challenging even for experienced surgeons.
This often results in penile shortening, in a down-sized PP, in complication rates as high as 65%, a 30% of infection rate, and a PP survival – for inflatable devices – of 50% at 1 year (13, 14). No clear indication on the ideal type of implant to be used in priapism setting has been given. In the largest series reported by *Ralph* in 2009, 86% underwent the immediate insertion of a malleable device (7). In addition to this, *Zacharakis et al.* noted, in patients that previously underwent malleable PP placement for IP, a median upsize of 1 cm at the time of implant exchange and a patient satisfaction rate of 90% after 3 months (15). On the other hand, *Sedigh et al.*

Figure 1.
Proposed algorithm for the management of Ischemic Priapism (adapted from Zacharakis et al. (9).
MRI: Magnetic resonance imaging.



remarked the cosmetic and functional superiority of inflatable PP, leading to a higher satisfaction rate (11).
In the light of this, placing a malleable device followed by an inflatable prosthesis exchange means to subject the patient to 2 separate operations (11).
The authors also proposed a copious antibiotic use and a conscious and aggressive sizing of the prosthesis placement against the risk of prosthetical infection and loss of length (11).
The advantages of using sPPs in a prolonged IP are shown in Table 2. These flexible devices were first proposed by *Louis Subrini* in 1982 and then successively popularized by *Austoni et al.* in 2005 for the treatment of Peyronie's disease, with the goal of avoiding penile retraction typically caused by traditional surgery for this condition (16, 17). The idea of sPP as ideal prosthetic model for treating IP comes from our thirty-year experience with the use of these prostheses in the treatment of Peyronie's disease where they represent a good option, incorporating technical simplicity and surgical time-sparing, offering good aesthetic and functional results. A pre-operative MRI, when available, can provide useful features regarding the state of the residual erectile tissue. In this context, these findings must be integrated with the macroscopic aspect of the tissue observed intraoperatively: in young patients, with apparent partial sparing of the cavernous tissue, a sPP could represent a less invasive solution than a malleable or inflatable prosthesis allowing greater acceptance by the patient who, thanks to the complementary erection, could benefit from a lower psychological impact deriving from this condition (Figure 1).
As also recently underlined by *Zaazaa et al.*, cavernous tissue preservation and subsequent tumescence would transform the implant's artificial erection to a more normal physiological and satisfactory one, with higher satisfaction rate (18). Potential economic benefits in positioning a malleable penile prosthesis in an IP context have been suggested by *Tausch et al.* (19). Although they ruled that prosthesis itself represents only 5% of the total cost treating these patients, specifically $3.850, the surgery results in a durable cure that provides relief in all cases without need for prolonged treatment of subsequent erectile dysfunction. In addition to this, a considerable consumption of health-care resources was stressed with an average US $ 83.818, whereas in 4 emergency room visits, 2 hospital admissions, 1.5 shunt procedure, 5 irrigation and drainage have been included in the analysis (19). The present case series has shown how convenient the use of sPPs is and can potentially reduce the financial and resource burdens of IP on the health-care system. The potential economic benefits must be interpreted considering different limitations: shunt procedure is not included in this analysis.
Moreover, the costs of PP can vary between different hospitals and different Countries. In addition to this, the reimbursement fee from the *National Health System* may also vary in different regions of our Country, sometimes falling to € 1800.00. Despite this, sPP placement is completely covered by the surgery-related reimbursement of the National Health-care System and for this reason the devices can always be available in the operating rooms even in an emergency situation.

Conclusions

The insertion of a sPP for patients with refractory (delayed) IP results in immediate pain relief, preservation of sexual function and penile size, with a higher surgery reproducibility in an emergency situation. The case series reported shows a low risk of complications and high patient satisfaction. In addition to this, financial and resource burdens of IP on the health-care system can be potentially reduced.

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