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Intra-peritoneal versus retropubic implantation of three-piece inflatable penile prosthesis: Patient-reported outcomes and complications

Alessandro Natali, Simone Grisanti Caroassai, Giovanni Tasso, Gianmartin Cito, Luca Gemma, Andrea Cocci, Francesco Sessa, Pierangelo Verrienti, Sergio Serni, Marco Carini and Augusto Delle Rose

Abstract

Introduction: The role of reservoir position was investigated in this series of patients treated with three-pieces penile prosthesis implantation (PPI). The outcomes and the patients' reported quality of life after insertion of the balloon in the retropubic space, or the Retzius's space (SOR), were compared with the outcomes of patients who received an intraperitoneal implantation (IP). The study aimed to analyze how the anatomy of the SOR influenced the long-term results of PPI, especially in patients who have been previously exposed to pelvic surgery or radiotherapy. The SOR has usually been identified as ideal for concealing and protecting the reservoir; nevertheless, an increasing rate of patients that ask for a PPI do not conserve the typical favorable characteristic of the SOR. In these cases, the tissue alteration can cause a higher rate of undesired events and can impair the satisfaction from device use. In the recent literature, few articles focus on the topic of reservoir position and very poor information is available about the results of the IP insertion.

Materials: Our cohort of patients was retrospectively inspected; the two different subgroups, according to the reservoir position (SOR or IP) were evaluated considering the pre-operative condition, the post-operative complication, the development of undesired events or uncomfortable sensations during the follow-up. The quality of life after PPI was observed as well, with a questionnaire specifically developed for patients treated with PPI. The surgical technique adopted for the intraperitoneal implantation was described.

Results: The results of penile prosthesis functionality and patients' and partners' reported quality of life (QoL) showed similar results between the two groups but greater satisfaction in the relational domain of the questionnaires adopted was described in the IP subgroup.

Conclusion: According to our observations, the IP reservoir insertion guarantees good functionality and lower rates of undesired events after PPI.

Keywords

Implantation, reservoir, inflatable, penile, prosthesis

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Introduction

Erectile dysfunction (ED) threatens male's fertility and quality of life worldwide,[1] with a prevalence reaching the 19.2%, a steep age-related increase (2.3%–53.4%) and a strong correlation with highly-incident comorbidities such as hypertension, diabetes, pelvic surgery, and lower urinary

Department of Urology, Careggi Hospital, University of Florence, Florence, Italy

Corresponding author:
Pierangelo Verrienti, Department of Urology, Careggi Hospital, University of Florence, Largo Brambilla 3, Florence 50134, Italy.
Emails: pierangelo.verrientimail.com; pierangelo.verrienti@unifi.it

tract symptoms (LUTS).[2] In the upcoming future an higher incidence of ED is expected, 325 millions of men, of which around 50% in the fifth to seventh decades will require a treatment.[3] The oral therapy with phosphodiesterase type 5 inhibitors (PDE5i) and the intracavernous therapy with PGE1 are the first and second level of treatment but not every patient will benefit, for patients unresponsive/intolerant to the oral and injective therapy the penile prosthesis implantation (PPI) can offer the definitive solution.[4]

The inflatable offer a more natural erection than semi-rigid prosthesis, the reservoir-balloon stores the liquid that fills the device and permits an on-demand activation.[5] Three different approaches are recognized and adoptable, according to patients features and surgeon experience: penoscrotal, infra-pubic and sub-coronal. Conversely, the choice between alternatives sites for the insertion of the reservoir has been investigated in the past but did not obtain relevant esteem, even if the patient's satisfaction and the functional outcomes can suffer a permanent impairment when an unfit space is selected to harbor the balloon.[6]

The retro-pubic space of Retzius (SOR), although traditionally used as the first-choice site for implantation, is not always conserving those properties functional to a valid balloon concealment and protection. The sub-muscular positions posterior to trasversalis fascia (PTF) or anterior to trasversalis fascia (ATF), are the most adopted alternatives for reservoir placement.

Namely, after radiotherapy or pelvic surgery the rate of reservoir-related undesired event can be increased.[7]

The grade of balloon palpability and the capacity to store the liquid for device deactivation, differs significantly according to the site of implantation. In a shrunken SOR, the balloon can lay superficial under the skin, or might get compressed in a fibrotic capsule, increasing the rate of bothering sensation. The alternative sites for retropubic reservoir implantation (RI) consider the creation of a pocket above the transversalis fascia, below the rectus abdominis muscle, not always approachable in presence of scarred tissue.

The intraperitoneal (IP) reservoir implantation, described more than 30 years ago by Schreiter in Germany,[8] showed good functional and satisfaction results, with an easy and reproducible implantation technique, but has not achieved a consistent celebrity. In this study thus, we aimed to describe the outcomes of IP vs. RI of three-piece inflatable penile prosthesis (PP) in a group of patients suffering from organic ED unresponsive to pharmacological treatments.

Material and methods

Study design

The study was conceived as monocentric retrospective evaluation of 52 patients undergoing inflatable PP placement between June 2014 and October 2017 for severe organic chronic ED, non-responder/intolerant to pharmacologic treatments (PDE5i/intracavernous PGE1) in a third level hospital. All the patients were searched in the institutional database for operative and pre/post-operative features. Data acquisition was based on the information collected during the outpatient visits. The follow-up was carried out at months 1, 3, 6, 12, and at least yearly. The overall patients were divided into two subgroups according to where the reservoir was inserted, group A included patients receiving a retropubic – SOR reservoir; group B comprised patients with an IP reservoir.

Participants and outcome measurements

Data on patients' age and medical history, including the cause of ED were collected pre- and post-operatively. ED was evaluated using the International Index of Erectile Function (IIEF-15)[9] and the Hospital Anxiety and Depression Scale (HADS)[10] questionnaires. The IIEF-15 scale classified the severity of ED as severe (IIEF-15 score $\leqslant$10), moderate (IIEF-15 score = 11–16), or mild (IIEF-15 score = 17–25). The HADS was used to determine levels of anxiety and depression that a patient was experiencing on a scale of 0 to 21 as normal (0–7), borderline abnormal (8–10), or abnormal (11–21). Patients with moderate or severe cardiovascular diseases, previous penile prosthetic surgery, and an Eastern Cooperative Oncology Group (ECOG) Performance Status higher than 1 were excluded. The AMS-LGX InhibiZone (Boston Scientific Corporation, Massachusetts, United States) PP was the device implanted in every patient, by an experienced team in andrological surgery. Intraoperative features such as operative time, PP length, and reservoir volume were collected. Post-operative complications were evaluated in accordance with Clavien-Dindo classification.[11] The level of patients' satisfaction was assessed using a subjective scale of satisfaction (from 0 to 5) and by the Patient Global Impression of Improvement (PGI-I).[12] PGI-I estimated the score that best described the postoperative condition, from 1 (very much better) to 7 (very much worse). During the preoperative counseling, the site for RI was discussed with the patient; for all the patients with an altered SOR, due to previous surgery or radiotherapy, the alternative (IP) allocation was recommended. During the follow-up period, the Quality of Life and Sexuality with Penile Prosthesis questionnaire (QoLSPP), developed by Caraceni et al., was adopted to evaluate patients' quality of life after PPI.[13] This questionnaire is composed by four domains (functional, personal, relational, and social) and considers: prosthesis functionality, relationship with partner, grade of satisfaction, relation with others, and self-image. Each domain's score is calculated on 3 to 5 questions, with responses structured according to a six-point (0–5) Likert scale.

The primary endpoint was the patients' satisfaction and functional outcomes according to different sites of RI,

Table 1. Preoperative characteristics.

	SOR	IP	"*p*" value
Patients, *n* (%)	13 (25%)	39 (75%)	
Age, median [IQR]	66.5 (66.3–69.8)	66.0 (62.0–70.5)	NS – 0.88
IIEF-15 preop, score; median [IQR]	9 [8–13]	9 [8–10.5]	NS – 0.76
HADS preop, score; median [IQR]	2.5 [1–3]	2 [1–3]	NS – 0.96
ECOG, score; median [IQR]	0 [0–1]	0 [0–0]	NS – 0.43
F-U time, months; mean [SD]	60.0 [26.16]	60.0 [20.1]	NS – 0.85
ED due to systemic disease, *n* (%)	2 (3.8%)	15 (28.8%)	NS – 0.74
ED due to Prior pelvic surgery, *n* (%)	9 (17.3%)	24 (46.1%)	NS – 0.74

IQR: inter-quartile range.

comparing the intra-peritoneal versus the retropubic. Secondary endpoints were the post-operative complications at short- and long-term follow-up period.

Surgical technique for reservoir implantation

Before incision, the skin was sterilized with Chlorhexidine and iodine solution for 5 min, the patient was supine in a 10° Trendelenburg position, the bladder was emptied. The institutional protocol was adopted for the preoperatory prophylaxis, with one-shot double antibiotic intravenously. The surgical technique for IP balloon insertion reproduced the steps of a laparoscopic first-trocar insertion. A 3 cm incision was done between umbilicus and iliac-spine, the retro-fascial space was achieved after incision of the aponeurosis of External Oblique and Transversalis fascia. The peritoneum layer was grasped with a clamp and opened under vision. If the digital exploration confirmed the absence of bowel adhesions to abdominal wall, the reservoir was inserted into the abdomen. After suturing the peritoneum and the fascia, the balloon was inflated and the linking tubes were left in the subcutaneous fat for the final connection. If the balloon was inserted in the SOR, the 3 cm incision was made 1 cm above the pubic bone and medially to the inguinal canal. The reservoir was inserted in a pocket created inside the fat tissue. According to the volume of cylinders, the balloon was inflated with a mean of 60 ml of saline solution both in case of IP and SOR insertion. The PP is left inflated during the first 24 h after surgery to favor hemostasis.

Ethical approval and statistical evaluation

All the patients signed an informed consent for the collection of their clinical information in our database. The present study was in line with declaration of Helsinki. The data collected were tabulated and analyzed in SPSS (IBM Corp. Armonk, NY). All the variables considered in the study were included in a Shapiro-Wilk test or a Chi-squared test to verify their distribution. Descriptive statistic and the tests for analysis were chosen according to the type and distribution of variables: *t*-Student, Mann-Whitney or Chi square test were adopted. The threshold for significance was set at $p < 0.05$.

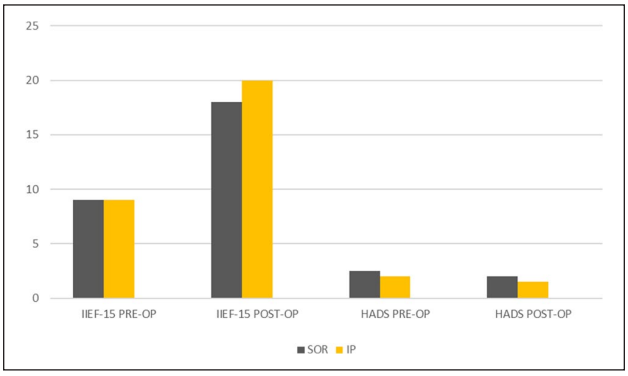

Figure 1. Pre and post-operative IIEF-15 and HADS scores comparing space of Retzius (SOR) versus intraperitoneal (IP) approach.

Results

A total of 52 devices were implanted: 39 patients (75%) had an IP reservoir, while 13 (25%) received a reservoir in SOR. The mean patients' age was 64 ± 6.3 years. As shown in Table 1, no statistical differences were found, concerning the age between the two groups. 35 patients (67.3%) had iatrogenic ED, due to radical prostatectomy, while 17 patients (32.7%) had organic ED due to neuro-vascular disorders.

The preoperative IIEF-15, HADS, and ECOG score were not differing among groups, Figure 1 summarizes the pre and post-operative scores in the two subgroups.

The mean follow-up period was 60 months for both groups. Globally, PPI was successful with an improvement in subjective patient's satisfaction in the two groups, although without significant differences. Subjective score was 4 and 3, respectively for IP and SOR group (p 0.14); median PGI-I score was 3 for SOR group and 4.5 for IP group (p 0.08), Figure 2 displays these results.

Regarding the QoLSPP score, statistically significant improvements for all domains were recorded in the two groups in favor of IP patients ($p < 0.03$). The histograms in Figure 3 describe the scores in different domains for the two groups. Analyzing the score's subgroups, only the relation domain showed a statistical significance ($p < 0.003$). Partner's satisfaction was the same between IP and SOR patients ($p = 0.5$).

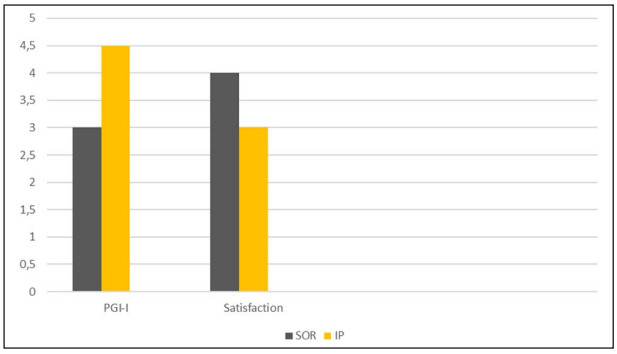

Figure 2. PGI-I and patient's satisfaction scores comparing space of Retzius (SOR) versus intraperitoneal (IP) approach.

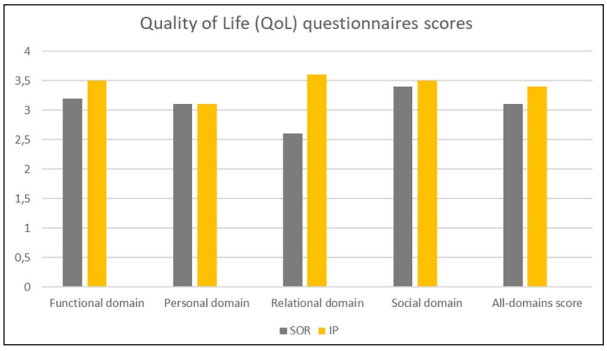

Figure 3. Quality of Life (QoL) questionnaires domains, comparing space of Retzius (SOR) versus intraperitoneal (IP) approach.

The mean overall operative time was 132 ± 47.4 min and 141 ± 33.8 min in SOR and IP group, respectively ($p = 0.21$). The mean time used for RI was 15 ± 13 min and 30 ± 12 min for SOR implantation and IP group, respectively ($p = 0.23$). Considering the two techniques, according to Clavien Dindo classification, no early (<90 d) post-operative complications, such as PPI infection, wound infection, bowel, bladder or vascular injury, were recorded. During the follow-up period, two patients (15.4%) of SOR group and three patients (7.7%) of IP group removed penile implant for mechanical failure (Clavien Dindo IIIb). No reservoir-related complications occurred during the follow-up in the two groups. Nine patients, of which three (23%) of SOR group and six (15.4%) of IP group described a reservoir perception in the first post-operative month but, at the sixth month control, reported to be satisfied and did not asked for corrections. Two patients (15.3%) of SOR group and one patient (2.6%) of IP group referred an uncomfortable palpability of the reservoir also many months after implant but a reservoir's replacement was not required. Table 2 shows the Quality of Life (QoL) questionnaires scores and Table 3 lists all the operative and peri-operative characteristics.

Discussion

Tailoring surgical therapy to meet the patient's features and will, means mastering different operative solutions to avoid complications and promote excellent results, even more on comorbid patients. The exploration of different alternative sites for RI during past and recent years led to a growing interest for the ectopic placement of PP reservoir, following the raising rate of men suffering from iatrogenic ED, with

Table 2. Quality of Life (QoL) questionnaires scores.

	SOR	IP	"*p*" value
Subjective satisfaction score, median [IQR]	3 [2.0–3.3]	4 [2.8–5]	NS – 0.14
PGI-I, score; median [IQR]	3 [2; 4]	4.5 [3; 6]	NS – 0.08
Partner satisfaction score, median [IQR]	3 [2; 4]	3 [2; 4]	NS – 0.50
All-domains score, mean (% of maximal score)	3.1 (61.0%)	3.4 (69.0%)	SS < 0.001
Functional domain; mean (% of maximal score)	3.2 (63.6%)	3.5 (70.5%)	NS – 0.06
Personal domain; mean (% of maximal score)	3.1 (62.7%)	3.1 (62.8%)	NS – 0.94
Relational domain; mean (% of maximal score)	2.6 (51.0%)	3.6 (71.8%)	SS < 0.001
Social domain; mean (% of maximal score)	3.4 (67.0%)	3.5 (69.7%)	NS – 0.34
All-domains, score >70% of maximal, *n* (%)	5 (38%)	20 (51%)	NS – 0.63
Functional domain, score >70% of maximal, *n* (%)	5 (38%)	23 (59%)	NS – 0.34
Personal domain, score >70% of maximal, *n* (%)	4 (31%)	9 (23%)	NS – 0.85
Relational domain, score >70% of maximal, *n* (%)	2 (15%)	27 (69%)	SS < 0.003
Social domain, score >70% of maximal, *n* (%)	7 (54%)	22 (56%)	NS – 0.87

IQR: inter-quartile range.

Table 3. Operative and postoperative characteristics.

	SOR	IP	"*p*" value
Operative Time, min; mean [SD]	132 [47.4]	141 [33.8]	NS – 0.21
PP length, cm; median [IQR]	18.8 [16.6–19.8]	16.0 [15.0–16.8]	NS – 0.36
Volume of the reservoir, ml; median [IQR]	50 [50–50]	55 [55–60]	NS – 0.09
Reservoir tangibility, *n* (%)	2 (15.3%)	1 (2.6%)	NS – 0.12
Painful use, *n* (%)	3 (23%)	2 (5%)	NS – 0.17
Absence of glans tumescence, *n* (%)	2 (15%)	11 (28%)	NS – 0.31
Penile length reduction, *n* (%)	2 (15%)	7 (18%)	NS – 0.83
Need for surgical revision, *n* (%)	2 (15.4%)	3 (7.7%)	NS – 0.24
Uneventful follow-up, *n* (%)	8 (61.5%)	28 (71.8%)	NS – 0.73

an altered SOR.[8] The sub-muscular positions, PTF or ATF, are the most adopted alternatives for reservoir placement.

Though ATF and PTF represents valid options in patients with history of pelvic surgery, herniations and a bothering palpability are not deniable complications.[14,15] According to Stember et al., 3.4% of patients with ATF reservoir feel reservoir in the first post-operative time and 0.45% required additional surgery for correction.[15] A modified ectopic placement into the "high sub-muscular space" (HSM), described by Morey et al., seems to reduce the risk of reservoir palpability and visibility.[16] However, a recent study compares the results of ectopic balloon insertion and SOR implants and reveals that immediately after surgery up to the 64.3% of patients feel their reservoir, around 20% of them don't report improvements after peri-reservoir capsule formation[17]; in the very thin candidates this latter rate would be even higher. Although in our series the first post-operative palpability of the reservoir is higher than in other studies, no patients needed surgical corrections. Moreover, subjective satisfaction was better in IP group rather than in SOR group. It has been reported that 1.34% of patients with ATF reservoir developed herniation into the inguinal canal, in our experience no patients of IP group had abdominal or inguinal reservoir's herniation.[14] As ectopic site, the reservoir may be intentionally placed within the peritoneal cavity; in addition to the precluding the auto-inflation of the prosthesis, the peritoneal cavity is known for not favoring the development of fibrosis. In fact, foreign bodies placed within the peritoneum have been reported to not stimulate capsule formation, and the large intraperitoneal space prevents the transmission of intra-abdominal pressure to the reservoir.[18] The lock-out valves introduction for PP considerably reduced the risk of auto inflation, a relevant drawback of ATF and PTF implantations, but this occurs still.[17,19] Different cases of reservoir migration from IP site have been described to require surgical correction. Moreover, cases of hernias caused by the balloon, tubing entanglement with bowels, peritonitis or intestinal erosions are the most feared complications. In our series we didn't recorded such a type of complications; neither has been reported a persisting ileum or changes in bowel habit.

Whether different studies emphasize the possible intra-abdominal reservoir migration, it must be considered that an asymptomatic migration can remain unrecognized without any type of sequelae and the rate of peritoneal migration can be much higher than those reported in literature as case-report.[14,20]

In our center the andrological surgery represent a tradition, with a considerable experience in PPI, the development of this technique was supported with solid evidence for both, a conserved functionality and an elevated reproducibility. The results of our IP implantations confirm a relevant benefit in terms of reservoir palpability, device functionality and patient's satisfaction. Surgeons should hence consider this alternative site to improve outcomes, especially in case of altered SOR. Nevertheless, to avoid abdominal ailment, reservoir migration or bowel entanglement the reservoir should be firmly fixed to the abdominal fascia.

Some consistent limitations have to be acknowledged for our study. Due to the retrospective nature of the study, a randomization to allocate patients in the two groups was not possible, but the preoperatory counselling was in favor of IP insertion in patients with an history of abdominal surgery. We aimed to collect information associated to functional outcomes and quality of life which possibly reveal some real-life surgery outcomes. However, further prospective larger studies are needed to better understand the more appropriate technique, able to optimize patients' and their partner satisfaction and QoL.

Conclusion

The IP reservoir implantation represent a feasible, safe and effective alternative to SOR reservoir placement, especially in patients with previous pelvic surgery. The IP approach showed to positively impact on patient's satisfaction and relational domains of questionnaires used in the study.

Declaration of conflicting interests

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ORCID iDs

Gianmartin Cito https://orcid.org/0000-0001-7526-4025

Pierangelo Verrienti https://orcid.org/0000-0002-7596-5961

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