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Laparoscopic radical prostatectomy with the simultaneous implant of a penile prosthesis: Ten years follow up

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Summary

Introduction: Even today, despite technological evolution, erectile dysfunction remains the most feared complication after radical prostatectomy surgery especially for patients who report pre-existent refractory erectile dysfunction (ED) and patients in whom there is a high risk of extracapsular disease, such as any cT2c or cT3, who undergo non-nerve sparing radical prostatectomy (RP). To overcome this issue, Khoudary et al. performed the first simultaneous placement of a penile prosthesis during open RP in 1997, aiming at an early return to sexual function without any impact on oncological outcomes and without significant adverse effects. Ten years ago we performed laparoscopic extraperitoneal RP and simultaneous penile prosthesis implantation (PPI) on ten patients in order to preserve the full length of the penis and to improve their satisfaction and quality of life (QoL) increasing the chances of ED resolution.

Objectives: Aim of this study is to illustrate the ten years follow up of this case series which has no terms of comparison in the world. Oncological and functional results were analyzed.

Materials and Methods: In 2013 10 patients underwent simultaneous PPI (with an AMS InhibiZone prosthesis). Patients were evaluated by means of urological visits, questionnaires, and objective measurements before surgery, at discharge from the hospital, on postoperative days 21 to 28, each 3 months for the first year, and each year thereafter. The main outcome measures were biochemical recurrence-free rate, penile length and quality of life.

Results: Eight patients with mean age 71 (range 66-75) were reached at the 10-year follow-up; one patient died of acute infarction 10 years after surgery and another one died of disease 7 years after surgery. Partners had, currently, mean age 60 (range 37-71). Mean preoperative PSA was 9.3 (6.3-13.7) and mean PSA at 10 years was 0.08 (range 0.01-1.2).

International index erectile function IIEF before surgery was 11 (range 9-14) and 23 (range 22-25) at 10 years. Partner satisfaction rating increased from 7 (post-surgical) to 8 at 10 years. Penis length was unchanged after 10 years: mean intraoperative length was 9 cm (range 8.5-9.5) and mean length at 10 years was 8.8 cm (range 8-9.5).

Conclusions: In our cases, laparoscopic radical prostatectomy with the simultaneous implant of a penile prosthesis demonstrate to be an interesting option to offer to selected and highly motivated patients. Outcomes like preservation of the penis length, resuming of normal sexual activity 21 days after surgery, partner satisfaction and oncological safety at 10-year fol-

low-up make it a valid surgical technique to be proposed in clinical practice if performed by an experienced team in prosthetic surgery.

KEY WORDS: Radical Prostatectomy; Erectile dysfunction; Penile prosthesis; Andrology; Quality of life.

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INTRODUCTION

Radical prostatectomy (RP) is the most common treatment option for men with localized prostate cancer worldwide, being related to excellent and reproducible cancer control rates. Although progress has been made in *nerve sparing* (NS) surgery, *erectile dysfunction* (ED) still remains a common long-term complication after RP. To overcome this issue, Khoudary et al performed the first simultaneous placement of a penile prosthesis during open RP in 1997, aiming at an early return to sexual function without any impact on oncological outcomes and without significant adverse effects (1). We describe a case series of patients who underwent laparoscopic extraperitoneal RP combined with PPI (during 2013) to evaluate the impact of this treatment strategy on preserving the full dimensions of the penis and improving patients' sexual *Quality of life* (QoL) (2). Aim of this study is to illustrate the ten years follow up of this case series which has no terms of comparison in the world. Oncological and functional results were analyzed.

MATERIALS AND METHODS

Ten patients underwent simultaneous *penile prosthesis implantation* (PPI) (with an AMS InhibiZone prosthesis) and laparoscopic RP in 2013. They were evaluated by means of urological visits, dedicated questionnaires inherent in QoL and sexual function, objective measurements before surgery, at discharge from the hospital, on postoperative days 21 to 28, each 3 months for the first year, and each year thereafter for 10 years. The main outcome measures were biochemical recurrence-free rate, penile length, and quality of life. All procedures were performed according our standard practice. All patients and their partners underwent sexual counselling with a

clinical sexologist, both before surgery, in order to assess their motivation to undergo such a procedure, and after surgery, in order to investigate their level of satisfaction with the results. The study was conducted in line with the STROBE statement (<http://www.strobe-statement.org>). Due to the retrospective nature of the study in Italy, it did not require approval by the local ethics committee.

Nevertheless, it was conducted in line with the Good Clinical Practice guidelines and the ethical principles laid down in the latest version of the Declaration of Helsinki.

Data collection

All patients were evaluated with penile measurements and questionnaires which were administered before surgery, at discharge from the hospital, on postoperative days 21 to 28, each 3 months for the first year, and each 6 months thereafter. At the time of surgery, the following parameters were recorded: the patient's and partner's age, the Charlson comorbidity index, preoperative prostate-specific antigen levels, Gleason score, penile length, clinical prostate cancer stage (through an abdominal *computed tomography* (CT) scan and skeletal scintigraphy), estimated blood loss, *visual analogue scale* (VAS) pain scores, analgesic use, duration of hospital stay, and surgical complications, according to the Clavien-Dindo classification.

Penile length measurements

Penile length was evaluated through a manual measurement of the fully stretched penis in the flaccid state. The length was obtained from the pubis to the tip of the penis and made in centimeters (3).

Questionnaires

Patients completed dedicated questionnaires for satisfaction and the 36-Item Short Form Health Survey (SF-36) questionnaire. Patients' satisfaction was evaluated using *patient-reported outcomes* (PROs). QoL was measured using an Italian version of the SF-36 Health Survey, a test particularly suitable for chronic conditions. A year after surgery patients and their partners were also asked to rate their level of sexual satisfaction on a scale of 1 to 10, with 1 meaning "completely unsatisfactory" and 10 meaning "maximum level of satisfaction". We decided to use the PROs tool instead of the International Index of Erectile Function questionnaire because the aim of the present study was to evaluate the impact of laparoscopic extraperitoneal RP with simultaneous PPI on patients' satisfaction (1).

Surgical procedure

All laparoscopic RP procedures were performed by a single experienced uro-oncological surgeon (RB). All penile prostheses were placed by a single surgeon with high-volume experience in PPI surgery (NM). Upon conclusion of the prostatectomy and after removing the prostate via access through a Hasson trocar we manually positioned the reservoir. The pneumo-Retzius was redetermined and the positioning of the reservoir optimized between the bladder and pubis. We then made a penile-scrotal incision and isolated the internal inguinal ring with a blunt incision as far as the external fascia of the rectal-abdominal muscles that was crossed by fine-tip forceps, the path of which was simultaneously monitored from the laparoscopic access. The reser-

voir tube, previously plugged with a special titanium plug, was then dislocated to the penile-scrotal incision. The reservoir was then inflated and its location checked once again. A pelvic drain was positioned and removed on day 1. After ensuring haemostasis, the implant was positioned. The two cylinders were initially positioned following bilateral cavernosotomy, followed by the pump that was placed at the level of the scrotum, and subsequently tubing were connected. The prosthesis was then almost fully activated for the first 24 hours with a compressive bandage. All patients stayed for 4 hours in a nurse-operated recovery room. The drain was removed on day 1 and patients were discharged from the hospital on day 4. On day 10, retrograde and voiding cystography was carried out after removing the bladder catheter. Activation of the prostheses took place between day 21 and day 28.

Ethical considerations

The present study was conducted as a consecutive case series in which patients who received a similar treatment were followed and all outcomes were recorded and analyzed. Even though the case series had a descriptive study design, the local ethical committee was informed about the study.

RESULTS

Among patients that were enrolled in this study with a median age of 71 years, one died of acute infarction 10 years after surgery (group no adjuvant therapy) and another died of disease 7 years after surgery (group radiotherapy after surgery). According to the Clavien-Dindo classification, the first patient reported a severe complication: migration of the reservoir into the bladder, which was resolved without prosthesis removal. This occurred even though the reservoir had been placed under vision. A CT scan was carried out, and it demonstrated a lesion on the superior wall of the bladder due to a pressure ulcer formed by the reservoir near a bladder diverticulum. The reservoir was then removed from the bladder and changed through laparoscopic access. The bladder wall was then repaired and a catheter was placed. 2 After 7 days, the catheter was removed and the patient was discharged after cystography. No prosthesis infections occurred (Table 1).

Table 1.
Post-surgery penile length measurements.

Time	Median penile length (cm)
Intraoperative	9.0 (8.5-9.5)
12 mo	9.0 (8-9.7)
24 mo	9.0 (8.2-9.7)
36 mo	9 (8-9.5)
48 mo	9 (8-9.5)
60 mo	9 (8-9.5)
72 mo	9 (8-9.5)
84 mo	9 (8-9.5)
96 mo	9 (8-9.5)
108 mo	8.8 (8-9.5)
120 mo	8.8 (8-9.5)

Values are presented as median (range). Mo: months.

Oncological outcomes

Over a median follow-up of 120 months 3 patients were disease-free without adjuvant therapy, and 4 were on hormonal therapy; 1 of the latter group had to undergo radiotherapy after surgery.

Penile length at the time of surgery and at the follow-up visits

The median penile length at the time of the surgery was 9 cm. Post-surgery penile length measurements showed the preservation of the full dimensions of the penis compared to the preoperative measurements. No statistically significant differences were found between the preoperative penile length measurements and the follow-up measurements. However, a reduction of 0.5 cm was observed in only 20% of the patients, although no patients described having problems with their penile dimensions (Table 2).

Table 2.
Clinical, laboratory and demographic characteristics.

Characteristic	Value
Patients	10 (2 died)
Age (y) (at 120 mo)	71 (66-75)
PSA (pre-surgery)	9.3 (6.3-13.7)
PSA (post surgery) (at 120 mo)	0.08 (0.01-1.2)
IIEF score (pre-surgery)	11 (9-14)
IIEF score (post-surgery) (at 120 mo)	23 (22-25)
Partner's age (y) (at 120 mo)	60 (37-71)

Values are presented as number only or median (range). PSA: prostate-specific antigen; IIEF: International Index of Erectile Function.

Quality of life evaluation

The pre-surgery SF-36 median value was 97 (range, 96-98). According to post-surgical sexual counselling with a clinical sexologist, all patients were satisfied with their penile implants, and the couples' level of sexual satisfaction was rated a median of 8 (range, 7-10) at follow-up 1. The median post-surgery SF-36 score was 99 (range, 97-99). A statistically significant difference was found between the pre-surgery and post-surgery SF-36 scores ($p = 0.02$) (Table 3).

Table 3.
Questionnaire and quality of life results at enrolment and at last follow-up.

Variable	Quality of life result
SF-36	
Pre-surgery (enrolment)	97 (96-98)
Post-surgery (120 m)	99 (97-99)
Sexual satisfaction scale	8 (7-10)

Values are presented as median (range). SF-36: 36-Item Short Form Health Survey.

DISCUSSION

In the 1990s, Clough et al. suggested the integration of plastic surgery techniques with breast-conserving treatments for breast cancer. In the urological setting, in 1997 Khoudary et al performed a combination procedure of

open non-nerve-sparing retropubic RP and PPI in 50 men. This group was compared with a group of 72 men who went RP alone during the same time interval. No significant differences were noted in the preoperative patient variables. The mean operative time for prosthesis insertion was 82 minutes, and the mean time to sexual intercourse was 12.7 weeks. No prosthesis infections occurred, with a mean follow-up of 1.7 years. Four men (8%) required revision of their inflatable penile prosthesis. There were no significant differences between the combination procedure and RP alone with regard to estimated blood loss, length of hospital stay or analgesic use. Men who chose the simultaneous placement of a penile prosthesis with RP reported greater overall QoL (1).

In the present paper we reported the results of simultaneous PPI and RP performed from June 2013 to June 2014 in 10 patients who completed the study follow-up period (median, 32.2 months). No difference was found between the time of surgery and the 2-year follow-up evaluation in terms of penile length. The pre-surgery 36-Item Short Form Health Survey (SF-36) median score was 97 The and median postoperative SF-36 score was 99 at 3 months follow-up (2). Patients were satisfied with their penile implants, and couples' level of sexual satisfaction was rated median 8. Post-surgery penile length measurements showed the preservation of the full dimensions of the penis compared to the preoperative measurements. No prosthesis infections occurred, over a median follow-up of 120 months. In light of these results, laparoscopic extraperitoneal RP with simultaneous PPI could be proposed to selected and very motivated patients because:

- medicated AMS InhibiZone [American Medical Systems, Inc. (AMS), Minnetonka, MN, USA] penile prostheses reduce the risk of prosthesis infections. Moreover, the extraperitoneal approach is preferable in order to keep the prosthesis reservoir located in a place with a low risk of infection (3);
- simultaneous PPI preserves penile length; c) combined procedure reduces the duration of hospitalization and allows patients to quickly resume sexual activity. A faster return to a satisfactory sexual life could have a positive impact on QoL and on the couple's well-being (4).

Some aspects of this study should be considered, in particular the fact that all surgical oncological procedures were performed by a single dedicated surgeon and all prosthesis implantations were performed by the same surgeon with a high-volume experience. Moreover, the psychological counselling support and the involvement of the partner in the surgical decision-making process should be considered strengths of this study. The main limitation of this study is the fact that it was a consecutive case series. However, our findings could serve as a basis for planning future studies. The majority of our patients had low- or intermediate-risk cancers and they could have undergone complete nerve-sparing resection, which in experienced hands, does not result in high positive margin rates. However, all patients reported stable ED with no benefits from PDE5i or intracavernous therapy. For this reason, we did not consider this treatment strategy to be overtreatment. Finally, the inclusion of a psy-

chologist in the patients' care should be considered a strength of this study. Psychological support during the PPI is a key means of improving adherence to the follow-up and overall outcomes.

We believe that laparoscopic extraperitoneal RP can be considered an optimal surgical technique that offers considerable safety margins for the simultaneous implantation of a tricomponent penile prosthesis, even though simultaneously performing 2 surgical procedures may increase the risk of complications. The hospitalization length is no longer than that required for normal surgery, and the additional costs of the prostheses can be easily amortized by avoiding the costs of a second surgical operation for the penile implant and avoiding the postoperative use of prostaglandins for penile erection.

The main complications of prostate cancer surgery are ED and urinary incontinence. Several patients received an artificial sphincter for urinary incontinence. The presence of a penile implant is not a contraindication for artificial sphincter implantation. The cuff can be placed through the perineal approach in the bulbar urethra or over the bladder neck in particular cases. The reservoir can be placed on the opposite site of the penile implant reservoir and the pump in the opposite part of the scrotum.

CONCLUSIONS

The aim of this study is to evaluate the outcome of simultaneous PPI and RP. The ideal candidates are those who report pre-existent refractory ED and patients in whom there is a high risk of extracapsular disease, such as any cT2c or cT3, who undergo non-nerve sparing RP. A simultaneous procedure would avoid two admissions, reduce hospitalization time and guarantee a faster recovery of sexual function, preventing the otherwise unavoidable loss of penile length. Since the urologist does not need to preserve the neurovascular bundles, as the penile implant will take care of postoperative rigidity, RP can be

performed more radically from an oncological point of view, thus reducing the risk of recurrence and metastasis, especially in patients with high risk disease. In conclusion, simultaneous PPI with RP provides early sexual rehabilitation, improving patients' QoL, without compromising surgical outcomes. However, larger series will be necessary, to better identify the patients who are more likely to benefit from nerve sparing surgery and postoperative penile rehabilitation from those who would be more likely to develop refractory ED post RP and would therefore benefit from simultaneous PPI.

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DECLARATIONS

Ethical approval: The case series has been approved by the local medical research ethics committee. Protocol number 78901.

Availability of data and material: The datasets used and/or analyzed during the current study are available upon reasonable request from the corresponding author.

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