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ORIGINAL ARTICLE

Penoscrotal versus minimally invasive infrapubic approach for inflatable penile prosthesis placement: a single-center matched-pair analysis

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Abstract

Purpose To compare perioperative results, safety and efficacy profile in patients receiving inflatable penile prosthesis (IPP) via penoscrotal (PS) or minimally invasive infrapubic (MII) approach for erectile dysfunction.

Methods A matched-pair analysis was performed including 42 patients undergoing IPP implantation via PS ($n = 21$) or MII ($n = 21$) between 2011 and 2016. Clinical and surgical data were prospectively collected. Patients' and partners' outcomes were assessed by the International Index of Erectile Function (IIEF), Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) and Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaires.

Results Mean (SD) operative time was 128 (40.6) min in group PS and 91 (43.0) min in group MII ($p = 0.041$). Complications occurred in 3/21 (14%) and 2/21 (10%) patients in groups PS and MII ($p = 0.832$). Overall, no differences were observed concerning the device utilisation ($p = 0.275$). However, in group MII 4/21 (19%) patients were able to resume sexual activity prior to 4 postoperative weeks, while in group PS no patient was ($p = 0.012$). Mean (SD) scores for questionnaires were similar between groups PS and MII: IIEF [20.9 (7.3) vs. 20.7 (4.8); $p = 0.132$], patient EDITS [76.0 (25.6) vs. 74.7 (20.8); $p = 0.256$] and partner EDITS [72.5 (29.1) vs. 73.1 (21.4); $p = 0.114$]. Similarly, QoLSPP showed comparable results among the groups PS and MII: functional domain [3.9 (1.4) vs. 4.0 (1.2); $p = 0.390$], personal [4.0 (1.2) vs. 4.1 (1.0); $p = 0.512$], relational [3.7 (1.5) vs. 3.9 (1.2); $p = 0.462$] and social [4.0 (1.2) vs. 3.9 (1.2); $p = 0.766$].

Conclusions PS and MII demonstrated to be safe and efficient techniques, leading to high level of both patients and partners satisfaction. Additionally, the minimally invasive infrapubic approach showed a shorter operative time and a tendency for a faster return to sexual activity.

Keywords Erectile dysfunction · Inflatable penile prosthesis · Penoscrotal approach · Minimally invasive infrapubic approach

Abbreviation

ED Erectile dysfunction
IPP Inflatable penile prosthesis
PS Penoscrotal approach
MII Minimally invasive infrapubic approach

Introduction

Erectile dysfunction (ED) is a common condition, with a prevalence of 52% in non-institutionalised men aged 40–70 years. Obesity, diabetes mellitus, dyslipidaemia, metabolic syndrome, lack of exercise, and smoking represent the main risk factors to develop ED as well as previous pelvic surgery such as radical prostatectomy [1].

For men with ED alone, inflatable penile prosthesis (IPP) is considered as a third-line therapy after inadequate response, inability or refusal to use phosphodiesterase-5 inhibitors, intraurethral or intracavernosal injections, and vacuum erection devices [2].

Currently, approximately 80% of IPPs are placed by penoscrotal approach [2]. Therefore, the latest represents the most

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employed technique for IPP insertion, providing the supposed advantage of improving ability to secure the pump in the dependent portions of the scrotum, corporal exposure and visualisation of urethra to minimise the risk for nerve damage during surgery.

With regard to infrapubic approach, since its introduction, the inherent difficulty with pump placement together with limited corporeal exposure and increased risk of injury to sensory nerves of the penis have potentially limited the widespread of this technique over time [3].

In light of this, a novel minimally invasive infrapubic approach has been recently developed: it minimises not only the abdominal incision, but also the length of the corporotomies with the aim of a safer and faster prosthesis placement [4].

However, to date, no technique has demonstrated to be superior to the other in terms of safety, efficacy and quickness to recover sexual life. Indeed, in the literature studies comparing the penoscrotal and infrapubic approaches are scarce and provide only limited data on patients' follow-up [5–7].

The objective of the present study is to compare in the "best case scenario" perioperative results, safety and efficacy profile after IPP implantation via penoscrotal approach (PS) or minimally invasive infrapubic (MII) approach.

Materials and methods

Data from our prospectively maintained password-secured institutional database of implanted patients were obtained. Excluded from the study were those patients with urinary incontinence, simultaneous surgery for congenital or acquired (Peyronie's disease) recurvatum, previous urethral or penile surgery and lack of follow-up data.

We identified 21 patients undergoing IPP implantation via newly introduced MII from June 2011 to January 2016. A contemporary matched-pair cohort of 21 patients undergoing PS was selected for comparison. All procedures were performed by an experienced single surgeon, who's performed 76 implants in our institution during the period, and at least the same number of implants in other institutions whose data were not accessible or not collected at the time of this study.

Hospital Ethics Committee approval was obtained and it conforms to the provisions of the Declaration of Helsinki. All patients gave written informed consent to have their data collected in our institutional database and used for the present and future studies.

The PS was performed in the classical fashion [8]. With the patient placed in 30° Trendelemburg position (Fig. 1a), a longitudinal skin incision is performed at the level of the median raphe of the scrotum (Fig. 1b) to achieve optimal exposition of the ventral surface of the corpora cavernosa

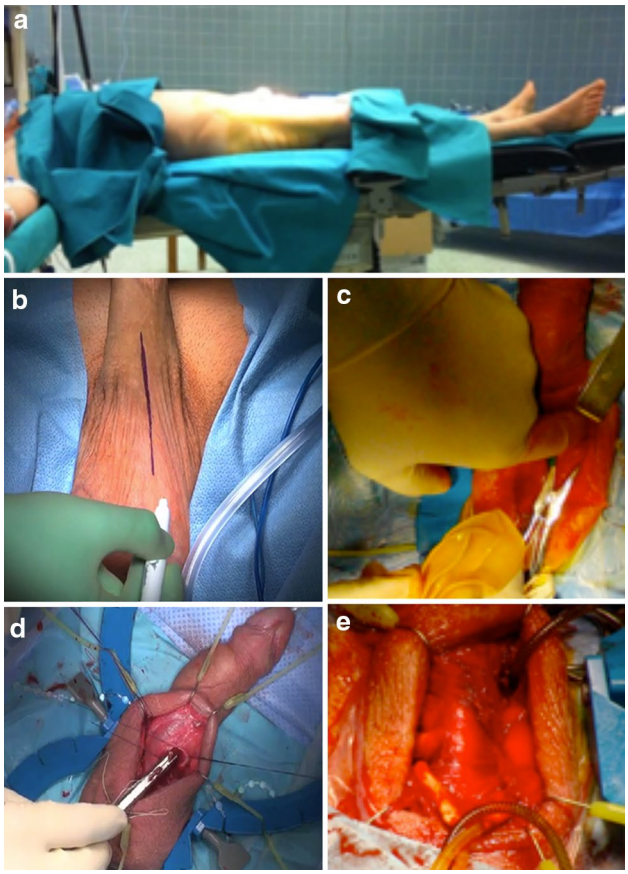

Fig. 1 Penoscrotal approach. **a** Patient's position, **b** penoscrotal incision, **c** reservoir placement using Killian's speculum. **d** dilatation of the corpora cavernosa, **e** closed corporotomies after device placement and pump placement

(CC). The index finger is then used to bluntly dissect the tissues until the tunica albuginea and access the CC. Exposure is maintained with a Scott retractor. At this point, the reservoir is placed (Fig. 1c). The index finger goes towards the external inguinal ring, enters the ring, perforates the fascia transversalis and, through an 8-cm long Killian Speculum the Reservoir is placed into the space of Retzius. Two large suspension stitches in 2-0 vycril are placed on each CC. The corporotomies are performed as proximal as possible, and they should not exceed 1.5 cm in length, to avoid device herniation. Dilatation of the CC is performed with Furlow retractor and, eventually, Hegar probes (Fig. 1d), the device is then placed in the usual fashion. Finally, the Dartos fascia is opened to place the pump into the scrotum (Fig. 1e). The penoscrotal incision is closed in layers.

The MII technique was performed as previously described by Perito [4]. At the beginning, an artificial erection by injecting saline in the CC is performed (Fig. 2a) to identify any pathology needing correction, and to facilitate subsequent dilatation of those and identification of the dorsal nerve. An infrapubic 3 cm skin incision followed by 1.5 cm

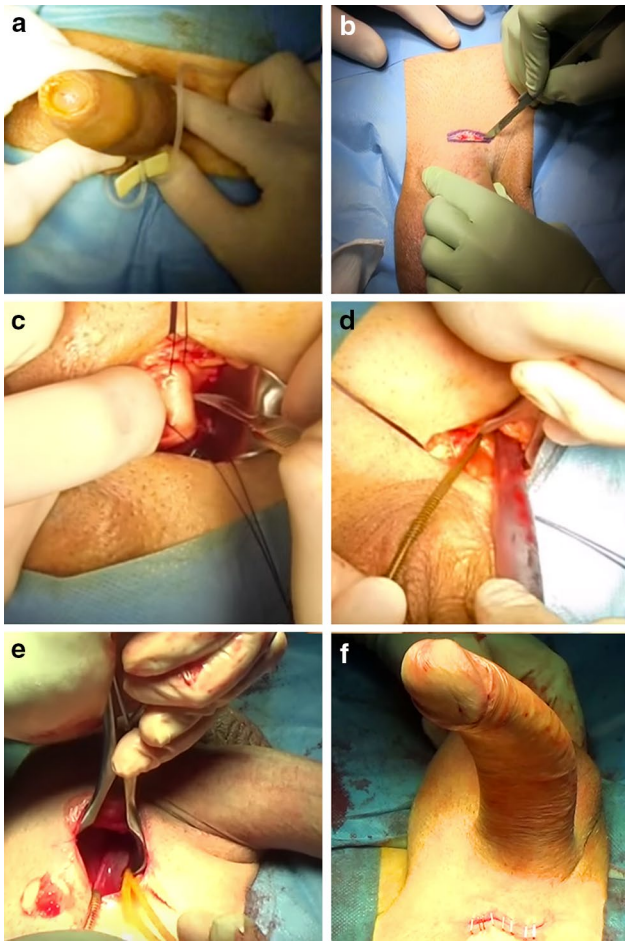

Fig. 2 Minimally invasive infrapubic approach. **a** Hydrodilatation of the penis, **b** infrapubic incision, **c** corpora cavernosa incision with n.12 scalpel, **d** reservoir placement, **e** pump placement, **f** final result

bilateral corporotomy incision is performed (Fig. 2b, c). Using the Furlow introducer, the proximal and distal CC are measured and dilated. A 3½ inches Killian speculum is used to develop the space for the reservoir. This is usually placed posterior to transversalis fascia (Fig. 2e). After exposure, cylinders are placed in the usual way. Once again, the Killian speculum allows the development of the sub-dartos pouch into dependant portion of scrotum to place the pump (Fig. 2d). After performing the hydraulic test, corporotomies and, then, skin incision are closed (Fig. 2f).

Prevention of perioperative infections included accurate alcohol-based intraoperative scrub and antibiotic prophylaxis (2nd generation cephalosporin or aminoglycoside) according to recent guidelines [2, 9].

A transurethral Foley catheter was inserted before skin incision and then removed on the 1st POD.

All patients were implanted an AMS 700 LGX (AMS, Minnetonka, MN, USA) three-piece IPP. In cases where a supplementary surgical access for reservoir placement was necessary because of post-surgical adhesions [10], it was placed in the subcutaneous space, when the patient's anatomy allowed, or between the transversalis fascia and rectus abdominis muscle according to previously published techniques [11, 12].

At the end of surgery, a scrotal drainage was left in place and removed at discharge. Patients were discharged on the 1st POD and instructed to wait 4 weeks after surgery before using their implant [13].

All patients were invited to fill in validated self-administered questionnaires to evaluate various aspects of post-prosthesis sexual life at 6-month follow-up. Specifically, questionnaires included: Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) [14], Quality of Life and Sexuality with Penile Prosthesis Questionnaire (QoLSPP) [15], International Index of Erectile Function (IIEF-SF) [16]. Complications were allocated using the modified Clavien classification [17].

All patients had 12-month minimum follow-up.

Statistical analysis

Data are reported as frequency and percentage for categorical variables and as mean and standard deviation for continuous variables. Mann–Whitney and χ^2 tests (or the Fisher exact test) were used to compare continuous and categorical variables among groups. Statistical analysis was performed using SPSS v.20.0 (IBM, Armonk, NY, USA). All reported p values are two sided and statistical significance was set at $p < 0.05$.

Results

In total, 42/76 (55%) patients met inclusion criteria and were included in our analysis. Mean (SD) age was 62.0 (6.4) and 65.5 (5.9) years in group PS and MII ($p = 0.623$), respectively.

Previous cancer treatment by radical prostatectomy or radical cystectomy was the main cause of ED, with 10/21 (48%) and 7/21 (33%) patients in the groups PS and MII, respectively.

Two of the 21 (9%) patients in group PS and 1 of the 21 (5%) in group MII required a supplementary incision for reservoir's placement due to previous pelvic surgery not permitting safe digital access to the space of Retzius. No intraoperative complication occurred. Further baseline and perioperative characteristics are summarised in Table 1.

Mean (SD) follow-up was 37.8 (21.4) months. Postoperative complications occurred in 3/21 (14%) and 2/21 (10%) patients (p = 0.832), respectively. They were represented by 4 Clavien grade I (postoperative pain) and 1 grade II (urinary tract infection).

Table 1 Baseline and perioperative characteristics

	Overall ($n = 42$)	Group PSA ($n = 21$)	Group MIIA ($n = 21$)	p
Age, years, mean (SD)	63.6 (6.3)	62.0 (6.4)	65.5 (5.9)	0.623
BMI[a], kg/m^2, mean (SD)	27.7 (4.4)	27.7 (3.6)	28.7 (5.2)	0.315
ED duration, months, mean (SD)	24.1 (25.6)	23.1 (27.9)	25.7 (28.4)	0.715
Diabetes mellitus, *n* (%)	8 (19)	6 (29)	2 (10)	0.258
Previous pelvic surgery, *n* (%)				0.742
For prostate cancer	15 (36)	8 (38)	7 (33)	
For bladder cancer	2 (5)	2 (10)	–	
Previous Pelvic Radiation Therapy	3 (7)	1 (5)	2 (10)	0.591
Previous ED treatment, n (%)				0.139
PDE5-I	7 (17)	5 (24)	2 (10)	
ICT[b]	17 (40)	11 (52)	6 (29)	
Vacuum device	5 (12)	–	5 (24)	
None	15 (36)	5 (29)	10 (48)	
Additional access for reservoir, *n* (%)	3 (7)	2 (10)	1 (5)	0.817
Mean operative time, min (SD)	116.6 (44.4)	128.8 (40.6)	91.0 (43.0)	0.041
Complications, *n* (%)				0.832
Clavien I–II	5 (12)	3 (14)	2 (10)	
Clavien III–IV	–	–	–	

[a]Body mass index

[b]Intracavernous injections

Concerning the use of the device, notably, none of the patients in group PS was able to restart sexual intercourse prior to 4 weeks after surgery, while at the follow-up visit 4/21 (19%) in group MII reported that they were able ($p = 0.012$), although advised by the physician to activate it only after 4 weeks. Overall, most patients restarted sexual activity after 6 weeks [12/21 (57%) and 10/21 (48%) patients in groups PS and MII, respectively; $p = 0.254$]. The frequency of device activation was similar among the groups ($p = 0.587$), with the majority of patients (48% in both groups) using it at least once a week. Further details about IPP utilisation are shown in Table 2.

After surgery, a perceived variation in penile length was observed in 15/21 (71%) patients in both groups ($p = 0.725$). Conversely, only 3/21 (14%) patients in group PS and 8/21 (38%) patients in group MII reported changes in penis circumference ($p = 0.055$) (Table 2).

According to the EDITS questionnaire, a high overall patients' satisfaction was observed, with a mean (SD) score of 75.4 (23.3) and no differences between groups PS and MII ($p = 0.256$). Interestingly, partner's version showed similar results (Table 3).

QoLSPP results showed to be comparable among the groups. When analysing per single domain, mean (SD) score for functional was 4.0 (1.3) [group PS 3.92 (1.4), group MII 4.0 (1.2); $p = 0.390$], personal 4.0 (1.1) [group PS 4.0 (1.2), group MII 4.1 (1.0); $p = 0.512$], relational 3.8 (1.4) [group PS 3.7 (1.5), group MII 3.9 (1.2); $p = 0.462$] and social 4.0 (1.2) [group PS 4.0 (1.2), group MII 3.9 (1.2); $p = 0.766$] (Table 3).

Discussion

IPP implantation represents a valuable option in men with drug-refractory ED in terms of both patient's and partner's satisfaction. Overall, it has shown to be a safe and effective treatment using both penoscrotal and infrapubic approach [2].

However, in the current literature studies comparing the outcomes of those approaches are scarce. In particular, authors reports only on complications [6] or perioperative results, such as the prosthesis length, type and filling of the reservoir, and few others surgeon-related variables [5].

To the best of our knowledge, this is the first study comparing perioperative results as well as satisfaction outcomes after IPP implantation using PS or MII approaches.

In our study, IPP implantation showed to be a feasible and safe procedure with both techniques, confirming what emerges from the available literature [2, 18–22]. Moreover, the minimally invasive infrapubic technique showed a shorter operative time ($p = 0.041$) and allowed a faster return to sexual activity after surgery ($p = 0.012$). Notably, no difference in infection rates occurred between the groups, supporting the hypothesis that infection occurrence is not

Table 2 Use of the device

	Overall ($n = 42$)	Group PSA ($n = 21$)	Group MIIA ($n = 21$)	p
First activation after surgery, *n* (%)				0.275
< 4 weeks	4 (9)	–	4 (19)	
> 4 but < 6 weeks	15 (37)	8 (38)	7 (33)	
6 or more weeks	22 (52)	12 (57)	10 (47)	
Never	1 (5)	1 (5)	–	
Frequency of device utilisation, *n* (%)				0.587
On daily basis	2 (5)	1 (5)	1 (5)	
More than once a week	16 (38)	7 (33)	9 (43)	
Once a week	20 (48)	10 (48)	10 (48)	
Once a month or less	2 (5)	1 (5)	1 (5)	
Never	2 (5)	2 (10)	–	
Self-estimated variations of the penis				
In length				0.725
No variation	12 (29)	6 (29)	6 (29)	
Gained	5 (12)	1 (5)	4 (19)	
Lost	25 (59)	14 (67)	11 (52)	
In circumference				0.481
No variation	31 (74)	18 (86)	13 (62)	
Gained	5 (12)	0 (0.0)	5 (24)	
Lost	6 (14)	3 (14)	3 (14)	

Table 3 IPP efficacy and patients' satisfaction

	Overall ($n = 42$)	Group PSA ($n = 21$)	Group MIIA ($n = 21$)	p
QoLSPP domain				
Functional, mean (SD)				0.390
Prosthesis adequacy	4.1 (1.1)	4.0 (1.2)	4.3 (0.9)	
Ease/simplicity of use	4.2 (1.1)	4.1 (1.3)	4.5 (0.7)	
Duration of implant	4.2 (1.2)	4.1 (1.4)	4.4 (0.8)	
Penile rigidity	3.2 (1.5)	2.9 (1.7)	3.4 (1.5)	
Fulfilment of expectations	4.0 (1.3)	3.8 (1.4)	4.1 (1.0)	
Personal, mean (SD)				0.512
Sexual desire	3.9 (1.2)	3.7 (1.4)	4.1 (1.1)	
Liveliness and wit	4.1 (1.2)	3.9 (1.3)	4.3 (0.9)	
Security	4.0 (1.2)	3.8 (1.4)	4.2 (0.9)	
Sexual experience	4.0 (1.0)	4.0 (1.2)	4.2 (0.8)	
Relational, mean (SD)				0.462
Well-being of the couple	4.1 (1.2)	4.0 (1.2)	4.2 (1.0)	
Frequency of orgasms	3.9 (1.5)	3.6 (1.7)	3.9 (1.4)	
Frequency of sexual intercourse	3.6 (1.3)	3.6 (1.4)	3.9 (1.4)	
Partner satisfaction	3.5 (1.8)	3.2 (1.9)	3.6 (1.8)	
Social, mean (SD)				0.766
Daily life	3.9 (1.2)	3.8 (1.3)	4.1 (1.0)	
General well-being	4.1 (1.0)	4.0 (1.1)	4.2 (0.7)	
Feeling like others	3.9 (1.4)	4.0 (1.2)	4.0 (1.3)	
EDITS score, mean (SD)				
Patient	75.4 (23.3)	76.0 (25.6)	74.7 (20.8)	0.256
Partner	72.9 (25.4)	72.5 (29.1)	73.1 (21.4)	0.114
IIEF-5, mean (SD)	20.8 (6.2)	20.9 (7.3)	20.7 (4.8)	0.132

necessarily reduced when the operative time is shortened, as indicated by previous studies [23].

In our centre, patients were discouraged to use the device for intercourse or masturbation prior to the 4th postoperative week. Nonetheless, in group MII a number of patients reported to have used the device earlier than advised (Table 2). These findings are far from those previously reported by Henry et al. [20] and Goldstein et al. [24] (41 and 25% of patients had resumed intercourse prior to 4 weeks after surgery, respectively). Possible explanation could be a wider adherence of the patients to physician's prescriptions. In addition, the lower number of patients in our study might also affect this figure.

Overall, post-implantation satisfaction is a complex issue. It is related to several factors, including the degree of postoperative pain/swelling, the presence or absence of complications, cosmetic outcome, device concealability and function, ease of use and partner acceptance.

In fact, despite overall low complication rate and good functional results [14, 15, 18, 19, 25], a proportion of men still remain dissatisfied with the implant also in the setting of technical success [25]. In this context, the surgical access surgeons employed for IPP implantation may affect the level of satisfaction among patients.

In the present study, to analyse the level of satisfaction after surgery, the EDITS questionnaire was administrated to both patients and partners [14], while IIEF questionnaire was used as a litmus test to evaluate prosthesis function. Questionnaires were administered 6 months postoperatively to minimise possible confounding factors. In fact, at this time of follow-up, patients are expected to have an adequate expertise in using the prosthesis and postoperative complaints including pain or swelling are generally resolved [26].

In our experience, the level of general satisfaction with the device was consistent with previously published data [25, 27–29], also in the subset analysis of frequency of the sexual activity [27]. Specifically, partner's satisfaction resulted to be strictly linked to patient's satisfaction in both groups, confirming Vakaloupulos findings [27].

After the development of QoLSPP by Caraceni and Utizi in 2014 [15], patients were asked to fill in also this questionnaire. Indeed, the QoLSPP questionnaire is the only available tool that correlates prosthesis function with perceived sexual and general Quality of Life. Therefore, patients operated prior to this date ($n = 19$) were contacted and asked to fill the questionnaire during the early 2015. The present results show that IPP implantation achieved an indisputable positive impact both on patients' and on partners' Quality of Life. In particular, we observed no differences about the perceived fulfilment of expectations ($p = 0.390$), satisfaction with the prosthesis ($p = 0.462$) and overall well-being ($p = 0.766$) between the two approaches.

In addition, the results indicate that placing IPP via PS or MII showed no difference in the subgroup of patients perceiving an increased penile length ($p = 0.767$). On the contrary, in MII group we observed a tendency for a higher number of patients perceiving an increased penile circumference compared to the PS group ($p = 0.058$). This partially opposes the findings of Trost et al. [5], even if only from patients' perspective.

With regard to safety profile, no technique showed to be superior over another (complication rate was 14% for PS and 10% for MII; $p = 0.76$). Overall, our complication rate appears to be higher than those reported by other authors [20–22, 24, 30]. However, such a difference might be partly attributed to the strict methodology of data collection in our study. First, we assessed complications not only during the intra-operative and early postoperative phase, but over the entire duration of follow-up. Second, any deviation from the perioperative standard was classified as a complication, including clinically insignificant events requiring no treatment.

The present study has some limitations. Although data were collected prospectively, the analysis is retrospective and, thus, subject to the inherent limitations of retrospective analyses. The relatively small number of patients analysed could represent another limiting factor.

Therefore, we aimed at comparing the two approaches in the "best case scenario" (same implanted prosthesis model, only first time implanted considered in the analysis, exclusion of patients with Peyronie's disease and incontinent patients).

Conclusions

Penoscrotal and minimally invasive infrapubic approaches demonstrated to be safe and efficient techniques for IPP implantation, leading to high level of both patients' and partners' satisfaction. In particular, minimally invasive infrapubic approach showed a shorter operative time, without compromising the safety of the procedure, and a tendency for a faster return to sexual activity. However, a greater number of patients and a longer follow-up are needed to draw definitive conclusions.

Authors' contributions PG, GA: protocol/project development; GDL, AL, AG, GG: data collection or management; GBDP: data analysis; PG, EDB, CC, GBDP: manuscript writing/editing.

Compliance with ethical standards

We disclose any conflict of interest such as consultancies, stock ownership or other equity interests, patents received and/or pending, or any commercial relationship which might be in any way considered related to the submitted article. All authors have made a significant

contribution to the findings and methods in the paper and have read and approved the final draft. Hospital Ethics Committee approval was obtained and it conforms to the provisions of the Declaration of Helsinki. All patients had given written informed consent and anonymity was preserved. The work has not already been published and has not been submitted simultaneously to any other journal.

Disclosures The authors declare that they have no conflict of interest.

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