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ORIGINAL PAPER

Comparison of intraoperative and postoperative results after tricomponent penile prosthesis implantation under spinal *versus* local anaesthesia

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Summary ***Background: The aim of this paper was to compare the intraoperative and postoperative outcomes of two similar groups of patients who underwent three-component penile prosthesis implantation under spinal versus local anaesthesia.***

Materials and methods: We reviewed retrospectively the medical records of twenty consecutive patients who underwent three-component penile prosthesis implantation for erectile dysfunction under spinal anaesthesia (S-PPI) versus local anaesthesia (L-PPI) in the period between January 2023 and January 2025. As regards the assessment of the pain, the patient's requests of sedation due to pain complaining during the induction of the anesthesia and the following surgical procedure were assessed. The Visual Analogue Scale (VAS) was also used for pain assessment six hours and one day after the surgical procedure. A modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) validated questionnaire was used to evaluate patient satisfaction after the prosthesis implantation. Perioperative and postoperative complications were also assessed.

Results: There was no statistical difference in terms of age, BMI and etiology of erectile dysfunction among the two groups. As regards the assessment of the pain, a significantly higher request of sedation was assessed in the S-PPI group than in the L-PPI group of patients (10% versus 40%) due to discomfort during the local anaesthesia or the surgical procedure ($p < 0.05$). On the contrary, mean VAS scores of 6.0 and 6.5, 5.5 and 5 were reported by the S-PPI and L-PPI groups at 6 and 24 hours after surgery respectively, showing a similar degree of postoperative pain among the two groups of patients. The EDITS questionnaire scores showed no significant difference between the two groups in terms of patient satisfaction. As regards the complications, no significant difference was assessed between the two groups of patients.

Conclusions: Our preliminary outcomes showed that a three-component penile prosthesis implantation under local anesthesia can be successfully performed in terms of postoperative pain control, acceptable complication rates and remarkable satisfaction scores with respect to the same procedure under spinal anaesthesia. Concerning the perioperative pain control, a significantly higher request of sedation was reported in the L-PPI group of patients with respect to the S-PPI group due to discomfort during the induction of local anesthesia or the implant procedure. Basing on these aspects, we think that a three-component penile prosthesis implantation in local anaesthesia could be proposed in selected patients with comorbidities which contraindicated spinal or general anesthesia or in patients unwilling to undergo these types of anesthesia after a preoperative counselling regarding the pain control and the possible need of sedation.

KEY WORDS: *Penile prosthesis; Penile implantation; Anesthesia; Local; Erectile dysfunction.*

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INTRODUCTION

Penile prosthesis implantation represents a valid therapeutic option suitable for patients in whom a pharmacological approach is ineffective or contraindicated (1-3). Regardless of the type of implantation, several studies reported high (87-91%) patient and partner satisfaction rates suggesting that the satisfaction after prosthesis implantation is even higher than with oral medication or local therapy (4-6). In this setting, tricomponent penile prothesis represents the most used device which provided the highest success rate due to a better functional and aesthetic impact on patient sexuality than malleable or two-component inflatable devices (7-8). Generally, tricomponent prosthesis implantation is performed under spinal anesthesia with appreciable analgesia during and some hours after the procedure. However, some authors have already reported encouraging results following penile semi-rigid or two-component inflatable prosthesis surgery under local anesthesia, generally with intravenous sedation (9-12). More recently, our group reported the first implant of a three-component device under completely local anesthesia (13). Since this first encouraging experience, the implantation of a three component penile prosthesis in local anesthesia has become a rather common procedure at our institution with satisfying results. The aim of this paper is to compare the perioperative and postoperative outcomes with particular attention to the pain evaluation of the last ten three-component penile prosthesis implantations under spinal anaes-

thesia with the first ten implanted under local anaesthesia at the same institution by our surgical team.

Material and methods

Patient

We reviewed retrospectively the medical records of twenty consecutive patients who underwent three-component penile prosthesis implantation for erectile dysfunction in the period between January 2023 and January 2025. In particular, the first group of ten patients underwent the surgical procedure under spinal anaesthesia (S-PPI) while the second group in local anaesthesia (L-PPI). The characteristics of the patients are reported in Table 1. One expert surgeon, with more than 500 prosthesis implantations, performed all the procedures. AMS 700™ penile prosthesis device were implanted in all the patients' groups.

The same standardized perioperative procedure was performed for the two groups of patients as previously published (13) and summarized as follows.

As regards the infection control measures, preoperative antibiotic prophylaxis included intravenous administration of 1g vancomycin two times a day and 80 mg gentamicin once a day. The same schedule was repeated for two days after surgery and followed by oral levofloxacin 500 mg daily and amoxicillin/clavulanic acid twice a day for seven days. Shaving of the penoscrotal and abdominal area was performed in the pre-anesthesia room, close to the operatory theatre. Accurate disinfection of the scrotum, the perineum and the abdomen was achieved using iodopovidone solution. All components of the AMS 700™ LGX prosthesis were pre-coated with the antibiotic InhibiZone.

Concerning the anaesthesia protocols, the S-PPI patients underwent spinal anaesthesia with 12,5 mg of 0.5% hyperbaric bupivacaine and 15 mg of 0.5% levobupivacaine while the L-PPI patients underwent local anesthesia with administration by the urologist of an 80-20 mixture of 7.5% ropivacaine and 2% mepivacaine with adrenaline for both the penoscrotal and abdominal surgical sites. In particular, a 20 cc anesthetic mixture was injected into the infrapubic space on both sides along the mid-line of the penis. This infiltration provided an effective anesthesia of the afferent fibers of the dorsal nerve which innervate the dorsolateral portion of the penis. In order to anesthetize the afferent ventral portion of the penis, a mixture of 10 cc was also injected superficially at the level of the penoscrotal junction on both sides. This infiltration involved the superficial branch of the perineal nerve providing an anesthesia of both the ventral portion of the penis and the penoscrotal skin. Furthermore, some minutes later, after identifying the bulb of the urethra, another 10 cc mixture deep infiltration was performed bilaterally at the same level in order to anesthetize the deep branches of the perineal nerve, which innervates the urethra. As for the abdominal surgical site, a similar local anesthesia was administered 2 cm medially from the anterosuperior iliac spine at a depth of 2.5-4 cm. for the blockade of the iliohypogastric and ilioinguinal nerves which are quite superficially located between the internal oblique muscle and the aponeurosis of the transverse muscle. In case of patient's discomfort or pain during the induction of the anesthesia and the following surgical procedure, a sedation by the anesthetist was proposed.

Concerning the surgical procedure, we started with a "*inverted U shaped*" penoscrotal incision of approximately 4 cm. Using a Scott retractor, the skin and Colles' fascia were retracted to expose the corpora cavernosa. Buck's fascia was dissected to expose the tunica albuginea and two Vicryl 2-0 stay sutures were placed on both sides. A 3 cm corporotomy was then performed between the stay sutures on both sides and a dilatation using Hegar dilators from 8 to 13 Fr, was performed gently.

After measuring the cavernosal bodies, the cylinders of the AMS 700™ prosthesis were implanted. After confirming the functionality of the device, the corporotomies were closed using the longitudinal stay sutures. The housing for the activation and deactivation MS pump™ was created in the midline of the scrotum as an extra dermal pocket. A 5 cm cutaneous incision was then made 2 cm medially from the anterosuperior iliac spine at a depth of 2.5-4 cm. After the incision of the fascia, the muscle plane was developed with a blunt technique, reaching the transversalis fascia. The prosthesis AMS Conceal™ reservoir was introduced in a minimal pre peritoneal space in thirteen patients (85%) or into the peritoneal space in the remaining three patients (15%) due to severe adhesions after previous surgery. The reservoir was then inflated. Subsequently, a suprafascial passage of the reservoir tubes toward the scrotum was achieved to connect them to the pump using the quick-connect system. The activation of the prosthesis was then tested. Closure of the abdominal and scrotal surgical wounds followed. The prosthesis remained activated for 24 hours and was then deactivated, the catheter was removed after 30 hours. All the patients were discharged one or two days after surgery. They started to activate and deactivate the prosthesis device 10-15 days after surgery and experienced sexual intercourse one month after implantation.

As regards the assessment of the pain in the perioperative period, particular attention was addressed to the evaluation of patient's discomfort during the induction of the local or the spinal anaesthesia and during the surgical procedure. In particular, the patient's requests of sedation due to pain complaining during the induction of the anesthesia and the following surgical procedure were assessed. As regards the postoperative period, the Visual Analogue Scale (VAS) was used for pain assessment six hours and one day after the surgical procedure (14).

A validated questionnaire was used to evaluate patient satisfaction after the prosthesis implantation. This was the *Erectile Dysfunction Inventory of Treatment Satisfaction* (EDITS), which was modified and included six questions (15). This questionnaire evaluates the overall patient satisfaction, the degree to which the prosthesis met patient expectations, the likelihood of continued use, the ease of use, the confidence in the ability to engage in sexual activity and the patient-reported partner satisfaction. All EDITS questionnaires were administered at least 6 months from surgery. Mean responses to the 6-item EDITS questionnaire were compared between the two groups as a measurement of device and sexual satisfac-

tion. Perioperative and postoperative complications were also evaluated and compared between the two groups.
The data are given as the means ± *standard deviation* (SD). A t-test was used for comparisons between two groups with normal distribution. The categorical data are presented as numbers and percentages and were tested with a Chi-square test. Statistical significance was considered at the $p \leq 0.05$ level).

Results

The characteristics of the patients are summarized in Table 1. There was no statistical difference in terms of age, BMI and etiology of erectile dysfunction among the two groups. The surgical procedure was completed in all the patients following the same perioperative protocol.
As regards the assessment of the pain in the perioperative period, only one patient (10%) of the S-PPI group requested a sedation due to discomfort during the spinal anaesthesia while four patients (40%) of the L-PPI group requested a sedation due to a discomfort during the local anaesthesia or the surgical procedure. Thus, a significant greater discomfort was reported in the L-PPI group with respect to the S-PPI group ($p < 0.05$). On the contrary, concerning the postoperative period, mean VAS scores of 6.0 and 6.5, 5.5 and 5 were reported by the S-PPI and L-PPI groups 6 and 24 hours after surgery respectively showing a similar degree of postoperative pain among both groups of patients (Table 2).
The EDITS questionnaire scores are reported in Table 3. No significant difference was assessed between the two groups in terms of overall satisfaction, degree of expectations achievement, likelihood of continued use, ease of use, confidence in the ability to engage in sexual activity and patient-reported partner satisfaction.
As regards the complications, no significant difference was assessed between the two groups of patients. In particular, three patients (15%) reported only a hemorrhagic suffusion of the penis and scrotum (one patient of the L-PPI and two patients of the S-PPI groups, respectively) which spontaneously resolved within some days and didn't require any treatment. All the patients reported a mild abdominal discomfort in the position of the reservoir. This discomfort was worst among the patients who underwent surgery under spinal anaesthesia than in the patients who underwent surgery under local anesthesia

Table 1.
Preoperative characteristics of the patients.

	Group 1 (S-PPI)	Group 2 (L-PPI)	P-value
N° of patients	10	10	-
Age (years +/- SD)	55.2 +/- 7.41	56.1 +/- 6.88	0.12
BMI (Kg/m^2 +/- SD)	27.19 +/- 2.43	26.9 +/- 2.25	0.24
Etiology (n -%-)			
Previous pelvic surgery	4 (40%)	3 (30%)	0.51
Diabetes mellitus	2 (20%)	3 (30%)	
Induratio penis plastica	1 (10%)	3 (30%)	
Neurological disease	1 (10%)	1 (10%)	
Prosthesis replacement	1 (10%)	0	

S-PPI: spinal anaesthesia penile prosthesis implantation; L-PPI: local anaesthesia penile prosthesis implantation; BMI: body mass index.

Table 2.
Assessment of pain among the two groups of patients.

	Group 1 (S-PPI) (n -%)	Group 2 (L-PPI) (n -%)	P-value
Request of sedation (perioperative)	1 (10)	4 (40)	0.02
Mean VAS score (6 hours postoperative)	6.0	6.5	0.45
Mean VAS score (24 hours postoperative)	5.5	5	0.51

S-PPI: spinal anaesthesia penile prosthesis implantation; L-PPI: local anaesthesia penile prosthesis implantation; VAS: Visual Analogue Scale.

Table 3.
EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction) questionnaire data among the two groups of patients.

Questions	Answers	S-PPI (n -%)	L-PPI (n -%)	P-value
Overall, how satisfied are you with this treatment?	Very satisfied	2 (20)	3 (30)	0.41
	Somewhat satisfied	8 (80)	7 (70)	
During the past four weeks, to what degree has the treatment met your expectations?	Completely	2 (20)	2 (20)	-
	Considerably	8 (80)	8 (80)	-
How likely are you to continue using this treatment?	Very likely	9 (90)	8 (80)	0.49
	Moderately likely	1 (10)	2 (20)	
During the past four weeks, how easy was it for you to use this treatment?	Very easy	2 (20)	3 (30)	0.48
	Moderately easy	7 (70)	6 (60)	
	Neither easy nor difficult	1 (10)	1 (10)	
How confident has this treatment made you feel about your ability to engage in sexual activity?	Very confident	2 (20)	3 (30)	0.51
	Somewhat confident	8 (80)	7 (70)	
Overall, how satisfied do you believe your partner is with the effects of this treatment?	Very satisfied	2 (20)	1 (10)	0.46
	Somewhat satisfied	7 (70)	8 (80)	
	Neither satisfied nor dissatisfied	1 (10)	1 (10)	

S-PPI: spinal anaesthesia penile prosthesis implantation; L-PPI: local anaesthesia penile prosthesis implantation.

although there was no statistical difference. Discomfort was treated with ibuprofen 600 mg tablet twice a day for the first day and tended to disappear the day after surgery. None case of wound infection has been reported. As for the rest, the follow-up was uneventful in both groups of patients.

Discussion

The aim of this paper was to compare the outcomes of two groups of patients with similar preoperative characteristics who underwent three-component penile prosthesis implantation under spinal versus local anaesthesia by our surgical team. In particular, we focused our attention on the pain assessment among the two groups in order to verify the feasibility of the prothesis implantation under local anaesthesia with respect to the spinal anaesthesia procedure. Our outcomes showed no significant difference between the two groups in terms of postoperative pain, questionnaire satisfaction scores and complication rates. On the contrary, concerning the perioperative pain assessment, a significantly greater request of sedation was reported in the patients who underwent local anaesthesia with respect to spinal anesthesia due to discomfort before and during the respective procedures. Based on these aspects, we think that a three-component penile prosthesis implantation could be proposed even in local anaesthesia after a preoperative patient's counselling regarding the pain control and the possible need of sedation during the induction of local anesthesia or the implant procedure. Although these encouraging results, as already highlighted in our previous case report, some considerations should be mentioned (13).

We are aware that the implantation of three-component penile prosthesis under local anaesthesia should not be considered as a new gold standard for all the patients eligible for prothesis implantation. However, our results tend to confirm the role of this technique in particular patients with comorbidities which contraindicated spinal or general anesthesia or in patients unwilling to undergo these types of anesthesia.

Regarding the efficacy of the local anaesthesia procedure, our outcomes can be reproduced only using a similar adequate anaesthetic mixture (80-20 mixture of mepivacaine with adrenaline and ropivacaine), correct sites of infiltrations (penile and perineal innervations, iliohypogastric and the ilioinguinal nerves) and by a surgical team with extended skill in penile prosthetic procedure. Furthermore, the build of the patient must be considered because it can also hamper the efficacy of the anaesthetic infiltrations. In the present study, all the patients were rather thin and the procedure was rather easy with a "*blind technique*" but, in case of fat patients, the identification and anaesthetization of the nervous structures can be more difficult and then less effective. Actually, in these patients, the use of ultrasound guidance can help to target the anesthetic infiltrations (16, 17).

The patient must be counselled preoperatively regarding the need of his cooperation during a penile prosthesis implantation under local anesthesia and this aspect could limit the reproducibility of our technique, especially in anxious patients. Furthermore, although local anesthesia could be performed by the urologist, the participation of an anesthetist in the operatory room remains crucial in case a booster sedation or a general anesthesia became necessary.

Our outcomes can be limited by the retrospective design of the study and the limited patient groups. Further studies are still needed to explore the benefits of this approach in a larger patient population

Conclusions

Our preliminary outcomes showed that a three-component penile prosthesis implantation under local anesthesia can be successfully performed in terms of postoperative pain control, acceptable complication rates and remarkable satisfaction scores with respect to the same procedure under spinal anaesthesia. Concerning the perioperative pain control, a significantly greater request of sedation was reported in the patients who underwent local anaesthesia with respect to spinal anesthesia due to discomfort during the induction of local anesthesia or the implant procedure. Based on these aspects, we think that a three-component penile prosthesis implantation in local anaesthesia could be proposed, by expert surgeons, in selected patients with comorbidities which contraindicated spinal or general anesthesia or in patients unwilling to undergo these types of anesthesia after a preoperative counselling regarding the pain control and the possible need of sedation.

Declarations

Ethical approval and consent for participate: *A formal approval by an ethics committee was not acquired but the patients provided a written consent for the use of their anonymized clinical data which were collected during our daily activity according to the current clinical guidelines for the management or erectile dysfunction.*

The study was conducted in accordance with the Declaration of Helsinki and it is a retrospective analysis involving standard clinical practices which are part of routine care according to the current clinical guidelines for the management or erectile dysfunction.

Consent for publication: *The patients routinely provided written consent for the use of their anonymized clinical data for clinical research purposes.*

Availability of data and material: *All data generated or analyzed during this study are included in this manuscript.*

Competing interests: *The authors declare that they have no competing interests.*

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