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ORIGINAL PAPER

Comparative study between intrathecal fentanyl and dorsal penile nerve block for controlling postoperative pain after inflatable penile prosthesis implantation

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Summary *Objectives: To compare the efficacy of intrathecal fentanyl and dorsal penile nerve block for postoperative pain management in patients undergoing inflatable penile prosthesis (IPP).*
Patients and methods: A prospective single-center study included 80 patients amenable to IPP. Patients were divided equally into two groups. Group I included 40 patients who were managed with spinal anesthesia with intrathecal fentanyl before undergoing IPP. Group II comprised 40 patients who received spinal anesthesia with dorsal penile block before IPP. Study groups were compared regarding postoperative VAS (Visual Analog Scale) scores, total narcotics consumption, patient satisfaction levels, and perioperative complications.
Results: The study groups were comparable regarding baseline patients' criteria. The operative time was comparable between the study groups, with group I and group II having respective median times of 64 minutes (interquartile range: 55-78) and 67 minutes (interquartile range: 56-81) (p = 0.65). Additionally, both groups demonstrated similar distributions in IPP implant cylinder and reservoir size (p = 0.9). Postoperative pain was higher in group I, with a statistically significant difference (p < 0.001). Eight patients in group I (20%) called the physician's office asking for pain medication, compared to two patients in group II (5%) (p = 0.04). 85% of patients in group II were highly satisfied compared to 50 % in group I (p = 0.003). We reported a 5% complication rate in group I compared to 2.5% in group II (p = 0.6).
Conclusions: The present study found that the dorsal penile nerve block offers superior postoperative pain control and patient satisfaction compared to intrathecal fentanyl for patients undergoing inflatable penile prosthesis insertion.

KEY WORDS: Penile prosthesis; Penile block; Intrathecal fentanyl; Postoperative pain.

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INTRODUCTION

Inflatable penile prosthesis (IPP) represents a gold-standard surgical treatment for medically refractory erectile dysfunction (1). Postoperative pain control after IPP surgery can be enhanced by targeting nerve endings and receptors in penile tissues. The dorsal penile nerve, formed by converging nerve fibers, carries signals through the pudendal nerve to the spinal cord (S2-S4), then to the thalamus and sensory cortex. Anesthesia can be applied at various points along this pathway, including the dorsal nerve, perineal nerve, pudendal nerve, and S2-S4 nerve roots (2). Several studies explored intraoperative analgesia for postoperative pain control. *Raynor et al.*, for instance, found that the *dorsal penile nerve block* (DPNB) reduced early postoperative pain but did not impact postoperative narcotic use (3). Additionally, *Xie et al.* studied the effectiveness of a combination of penile dorsal nerve and ring blocks, while *Hsu et al.* investigated the efficacy of a crural block. Both studies noted a decrease in early postoperative pain, although rates of postoperative narcotic use were not reported (4, 5).
The opioid fentanyl, possessing lipophilic properties, exhibits rapid onset and demonstrates up to 20 times greater potency when administered via the intrathecal route in comparison to the intravenous route (6). However, the use of intrathecal fentanyl has been linked to an increase in intravenous opioid requirement during the postoperative period, potentially attributable to subtle opioid tolerance or opioid-induced hyperalgesia (7). Additionally, it has been noted that intrathecal fentanyl doses exceeding 0.25 µg/kg may reach a "*ceiling effect*," indicating that higher doses do not enhance intraoperative analgesia and may amplify adverse effects (8).
Our study compares intrathecal fentanyl and dorsal penile nerve block for controlling postoperative pain in patients undergoing insertion of an inflatable penile prosthesis.

PATIENTS AND METHODS

A concurrent cohort study was conducted at the Urology and anesthesia *Departments, Faculty of Medicine, Al-Azhar University, Cairo, Egypt*. The study spanned from February 2022 to February 2024 and included 80 eligible patients

for elective inflatable penile prosthesis implantation with ASA I, II, and III at the facility. The study protocol received approval from the institutional review board. Informed written consent was obtained from all participants in compliance with ethical guidelines and regulations to ensure patient safety and confidentiality.

Inclusion criteria

IPP was considered for patients with ED after the failure of conservative therapy, including phosphodiesterase inhibitors, alprostadil urethral suppositories, vacuum erection devices, and intracavernosal injections.

Exclusion criteria

Patients with ASA IV and coagulopathy were excluded from the study.

The study cohort was divided into two equally sized groups. The patients were prospectively allocated to treatment groups without randomization. The choice between intrathecal fentanyl or DPNB was made through mutual agreement by the patients and physicians. Group I consisted of 40 patients who underwent spinal anesthesia with intrathecal fentanyl before undergoing IPP. In comparison, Group II comprised 40 patients who received spinal anesthesia with DPNB before IPP.

Anesthesia technique

Upon establishing an *Intravenous* (IV) line, a pre-load of normal saline was administered before the initiation of spinal anesthesia. Cardiorespiratory monitoring, including *heart rate* (HR), peripheral oxygen saturation (SPO2), and *blood pressure* (BP), was commenced for all patients. In the case of group, I, spinal anesthesia was induced using a 25-gauge BD Quinck spinal needle following the sterilization of the back and identification of the anatomical landmark. The needle was then inserted using a paramedian approach at the L3-4 intervertebral lumbar space level. Upon successful confirmation of *cerebrospinal fluid* (CSF) flow, a combination of 15 mg (3 ml) of heavy bupivacaine and 0.25 mcg/kg (0.5 ml) of Fentanyl was intrathecally injected.

For group II, spinal anesthesia induction involved the use of 3.5 ml (3 ml heavy bupivacaine plus 0.5 ml water for injection), followed by a dorsal penile nerve block performed by inserting an 18-gauge needle connected to a 20 CC syringe between the suspensory ligament and the base of the penis. A total volume of 20 bupivacaine was injected at the 2- and 10-o'clock positions (10 ml for each side) for the right and left dorsal penile nerves. All penile implant procedures were conducted by a single surgeon using a penoscrotal approach, employing Coloplast titan and Rigicon prostheses.

Postoperative pain assessment was conducted using a *visual analog scale* (VAS) after the IPP surgeries at 2, 4, 8, 12, 16, 20, 24 and 36 hours. Patient satisfaction was evaluated using the 5-point Likert scale, ranging from dissatisfied (1) to completely satisfied (5).

Outcome

In the comparative analysis of the study groups, the parameters considered encompassed patients' demographics, postoperative *Visual Analog Scale* (VAS) scores, total narcotics consumption, patient satisfaction levels regarding postoperative pain management, and perioperative complications according to *Modified Clavien Classification System* (MCCS) (9).

Statistical analysis

We analyzed the data using the *Statistical Package for Social Science* (SPSS) software, version 29 (SPSS Inc., Chicago data. The descriptive statistics included percentages, frequencies, means, and medians. We compared categorical variables between the two groups using the Fisher exact test. Additionally, for normally and abnormally distributed continuous variables, we used the Student's t-test or the Mann-Whitney U test, respectively. Statistical significance was defined as a two-tailed p-value of less than 0.05.

RESULTS

Group I included 40 patients who underwent spinal anesthesia with intrathecal fentanyl before undergoing IPP, while Group II included 40 patients who received spinal anesthesia with dorsal penile block before IPP. The study groups were comparable regarding baseline patients' criteria, as depicted in Table 1. The smoking status and prevalence of prior prostatectomy, pelvic radiation therapy, Peyronie's disease, diabetes, and hypertension were similar across the study groups (p = 0.87). The operative time was comparable between the study groups, with group I and group II having respective median times of 64 minutes (interquartile range: 55-78) and 67 minutes (interquartile range: 56-81); the between-group difference was not statistically significant (p = 0.65). Additionally, both groups demonstrated similar distributions in implant cylinder size and reservoir size (p = 0.9), as shown in Table 1.

As measured with the VAS score, post-operative pain was higher in group I, with a statistically significant difference

Table 1.
Comparison between the study groups regarding baseline patients' criteria.

Parameter	Group I (n = 40)	Group II (n = 40)	P-value
Age, median (IQR)	59 (51-72)	59 (52-70)	0.72
BMI, median (IQR)	29 (24-32)	29 (23-33)	0.62
Etiology/comorbidities, N (%)			0.87
DM	33 (82.5%)	35 (87.5%)	
HTN	21 (52.5%)	20 (50%)	
Smoking	18 (45%)	19 (47.5%)	
Peyronie's disease	6 (15%)	5 (12.5%)	
Prostatectomy	1 (2.5%)	1 (2.5%)	
Radiotherapy	1 (2.5%)	0	
Implant Cylinder size (cm), N (%)			0.93
< 18	4 (10%)	5 (12.5%)	
18-19	13 (32.5%)	11 (27.5%)	
20-21	15 (37.5%)	17 (42.5%)	
≥ 22	8 (20%)	7 (17.5%)	
Reservoir Size ≥ 100cc	13	14	0.91
Operative time (minutes), median (IQR)	61 (45-80)	63 (45-76)	0.65

Table 2.
Comparison between the study groups regarding postoperative outcomes.

Parameter	Group I (n = 40)	Group II (n = 40)	P-value
VAS score, mean ± SD			
2 hours	1.8 ± 0.52	1.73 ± 0.59	0.55
4 hours	3.7 ± 0.76	1.85 ± 0.62	< 0.001
8 hours	4 ± 0.72	3 ± 0.64	< 0.001
12 hours	5.3 ± 1.6	3.6 ± 1	< 0.001
16 hours	6.2 ± 1.8	2.8 ± 1	< 0.001
20 hours	7.5 ± 1	3.9 ± 0.6	< 0.001
24 hours	7.5 ± 0.9	4 ± 0.7	< 0.001
36 hours	6.4 ± 1	3.8 ± 0.5	< 0.001
Post operative calls for pain meds, N (%)	8 (20%)	2 (5%)	0.04
Hospital stay in hours, median (IQR)	35 (34-39)	35 (33-38)	0.82
Patients satisfaction with 5-point Likert scale, N (%)			0.003
Low satisfaction (1-2)	10 (25%)	2 (5%)	
Intermediate satisfaction (3)	10 (25%)	4 (10%)	
High satisfaction	20 (50%)	34 (85%)	
90-days complications according to MCCS, N (%)			0.6
Total	2 (5%)	1 (2.5%)	
Wound seroma (IIIb)	1 (2.5%)	0	
Device Infection (IIIb)	1 (2.5%)	1 (2.5%)	

MCCS: Modified Clavien Classification System.

($p < 0.001$), as shown in Table 2. Eight patients in group I (20%) called the physician's office asking for pain medication, compared to two patients in group II (5%) with a statistically significant difference ($p = 0.04$).
Regarding patients' satisfaction with post-surgery pain control, 85% of patients in group II were highly satisfied compared to 50 % in group I. On the other hand, 25% of group I reported low satisfaction on the 5-point Likert scale compared to 5% in group II, with a significant p-value ($p = 0.003$) (Table 2).
The 90-day perioperative complication rates were comparable between the study groups, as shown in Table 2. We reported a 5% complication rate in group I compared to 2.5% in group II ($p = 0.6$).

Discussion

Pain control after IPP surgery has been well studied and includes a multimodal analgesic approach that utilizes combinations of different non-opioid analgesics (10). Given the significant impact of the opioid epidemic, there is a growing emphasis on reducing narcotic use in postoperative care. Consequently, nerve blocks are increasingly employed in urological procedures as an essential strategy for achieving this goal (11).
There are multiple studies about the intra-operative use of local anesthesia to improve pain control during penile prosthesis surgery. *Nagao and colleagues* studied the utilization of dorsal penile nerve block with 10 mL of bupivacaine as a single pain control approach during non-inflatable prosthesis insertion in 20 patients at a mean follow-up of 3.4 years; they did not report any patient with chronic penile pain (12).
Ghanem and Fouad reported a series of 159 patients who received a dorsal penile nerve block for anesthesia during implantation of a penile prosthesis; additional general anesthesia was reported in 1.8%, and 5% of their cohort required additional local anesthesia (13). However, they did not report postoperative pain control.
Raynor and colleagues investigated the efficacy of dorsal penile block in pain control compared to placebo after 30 penile prosthesis implants; they found that VAS scores were significantly lower in patients with penile block (14).
In their study, *Gürkan and colleagues* compared an ultrasound-guided penile nerve block administered to patients undergoing implantation under spinal anesthesia and a control group who did not receive local anesthesia. The results indicated that patients who received the penile nerve block exhibited lower VAS scores and reduced opioid consumption during all observed time intervals up to 24 hours (15).
Numerous studies have indicated that the use of intrathecal fentanyl in combination with bupivacaine results in reduced requirements for intraoperative supplemental analgesia, a decreased incidence of intraoperative nausea/vomiting, and an extended duration until the first analgesic request (30).
The aggregated data from 14 studies revealed an 8% incidence of pruritus in patients administered intrathecal fentanyl, in contrast to 0.6% in the placebo cohort (30).
In the present study, we conducted a comparative analysis of the effectiveness of dorsal penile block and intrathecal fentanyl in managing postoperative pain among patients undergoing inflatable penile prosthesis insertion. Our findings indicate that DPNB demonstrated superior efficacy in pain reduction, accompanied by a significant decrease in postoperative narcotic usage and greater overall patient satisfaction. There were no adverse events with intrathecal fentanyl, and the incidence of perioperative morbidities was comparable to DPNB.

Limitations of the study

The current study introduces a novel prospective comparison between dorsal penile block and intrathecal fentanyl. However, it is essential to note that the study has certain limitations, such as the absence of randomization and a relatively small sample size.

Conclusions

Our research illustrates that the dorsal penile block offers superior postoperative pain management and patient satisfaction compared to intrathecal fentanyl for patients undergoing inflatable penile prosthesis insertion.

Ethical approval

All procedures conducted in this study complied with the Institution and National Research Committee's ethical standards, the 1964 Declaration of Helsinki, and its subsequent amendments or equivalent ethical standards. The institutional review board approved the protocol for the current study of the *Anesthesia Department* at the *Faculty of Medicine, Al-Azhar University Hospital*.
Informed written consent was obtained from all participating patients.

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