

The Analgesic Effects of a Saddle Block with Intrathecal Morphine for Penile-Inversion Vaginoplasty: A Retrospective Study

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Background: Despite its association with severe postoperative pain, the use of regional anesthesia techniques for penile-inversion vaginoplasty surgery is understudied. This retrospective study aimed to assess the analgesic effects of a saddle block (ultra-low dose hyperbaric spinal anesthesia) with intrathecal (IT) morphine in transgender females undergoing penile inversion vaginoplasty.

Methods: We performed a single-centre, retrospective chart review of 72 patients who underwent penile-inversion vaginoplasty with or without saddle block with IT morphine at our institution over a 26-months period. All patients received standard multimodal intravenous analgesia, and the surgeon administered both a pudendal nerve block and a spermatic cord block as part of routine care. Our primary outcome was cumulative opioid consumption (oral morphine equivalent) at 24h postoperatively. Secondary outcomes included postoperative pain severity, duration of stay in the postoperative care unit and in-hospital, time to first opioid request and incidence of opioid- and block-related side effects.

Results: 30 patients received a saddle block with IT morphine and 42 patients received standard analgesia. We found no statistical difference in cumulative opioid consumption at 24h postoperatively (control group: 17.7 mg [5.6, 30.8] vs intervention group 12.5 mg [7.5, 22.5] P: 0.249). The addition of a saddle block was associated with clinically and statistically significant improvements in short-term postoperative pain-related outcomes in the recovery room, including mean and maximum pain severity scores, time to first analgesic request, and duration of stay. While no difference in pain scores was detected at the 24-hour time point, mixed-effects modelling demonstrated lower pain trajectories over time among patients in the intervention group, suggesting a time-dependent benefit. However, the significant time-by-group interaction ($p = 0.024$) indicates that the difference in pain scores between groups decreased over time. We found no differences in the rates of nausea and vomiting between groups. No saddle block procedure-related complications were reported.

Conclusion: This retrospective study suggests that despite no statistically significant difference in 24-hour opioid consumption, the addition of a saddle block with 100 mcg of IT morphine is associated with improved PACU pain scores, a longer time to first analgesic request, and a shorter PACU stay. These findings are hypothesis-generating and merit further investigation in a prospective double-blind randomized controlled trial.

Keywords: regional anesthesia, transition-related surgeries, acute pain, gender-affirming care

Introduction

Transition-related Surgery (TRS) encompasses all surgical procedures that help patients transition to their self-identified gender. Among transgender and gender diverse (TGD) individuals, TRS is associated with substantial improvements in well-being and quality of life, as well as decreased rates of gender dysphoria, depression, and suicidality.¹ With an

estimated prevalence of TGD individuals approaching 3% in the United States and increasing visibility in recent years, demand for TRS procedures is expected to rise.²

Penile Inversion Vaginoplasty (PIV), which is part of the TRS available for transgender females, is a complex procedure that involves penectomy, orchiectomy, clitoroplasty, vulvoplasty and the surgical invagination of the scrotum to create a vaginal vault.^{3,4} Owing to the rich innervation of the genitalia, penile-inversion vaginoplasty (PIV) is associated with moderate-to-severe pain during the first four days after surgery.⁵ Postoperative pain management can be further complicated by higher rates of depression, anxiety, and preexisting chronic pain reported among the transgender population.^{6,7} Up to 20% of patients undergoing PIV develop persistent postsurgical pain, along with a corresponding reduction in quality of life.⁸ Importantly, the severity of acute postoperative pain is a well-known modifiable factor that correlates with the risk of developing a persistent pain state.⁹

One of the most effective means of reducing the severity of acute postoperative pain and the development of chronic pain is the use of local anesthetic-based regional anesthesia techniques as part of a multimodal analgesic regimen.¹⁰ Unfortunately, the optimal perioperative care and pain management strategy for PIV is unknown, and literature on this topic is scarce. A recent systematic review examining the analgesic benefits of regional anesthesia in transition-related surgeries (TRS) found only four case reports, one case series and one cohort study.¹¹ In the setting of PIV surgery, regional anesthesia targeting the sacral plexus has been limited to traditional central neuraxial anesthesia (spinal and epidural) and a single-injection pudendal nerve block, which are undermined by lower extremity motor weakness and incomplete perineal coverage, respectively.^{5,12} Additionally, the use of lumbar or sacral Erector Spinae Plane (ESP) block for PIV has been described anecdotally in case reports.^{13,14}

By contrast, a saddle block, using an ultra-low dose but dense (“heavy”) spinal anesthesia to preferentially target the smallest sensory nerve fibres of the sacral plexus while sparing larger motor nerve fibres, has long been the standard of care for patients undergoing ambulatory perianal procedures at our home institution. Previous literature indicates that hyperbaric bupivacaine doses as low as 1.5 mg can achieve effective and reliable anesthesia for perianal procedures. However, reported dosing practices vary substantially, with described doses ranging from 1.5 mg to 7.5 mg.¹⁵ We have recently introduced the preoperative administration of a saddle block for our inpatients undergoing PIV. To synergistically prolong the analgesic effects of the saddle block without causing postoperative weakness for our PIV inpatients, we add low-dose intrathecal (IT) morphine. Morphine, a hydrophilic opioid, exhibits a slow decline in cerebrospinal fluid (CSF) concentration and a greater rostral spread compared to lipophilic opioids, resulting in a broader band of analgesia with a risk of delayed respiratory depression.^{12,16} At a dose of 100 mcg, analgesia typically lasts 18–24 hours, with a relatively low incidence of respiratory depression compared to higher doses.¹⁷ Literature supports the use of IT morphine as part of a multimodal analgesic regimen in abdominopelvic surgeries.^{18–21} Regardless of the dose, the current guidelines recommend at least 24-hours in-hospital monitoring following administration of IT morphine due to the potential of delayed respiratory depression.²²

While theoretically and anecdotally advantageous, a saddle block has not yet been formally evaluated in the setting of PIV. Therefore, this retrospective study aims to assess whether the addition of a saddle block with a low dose of IT morphine to standard multimodal analgesia provides superior analgesia compared to patients who do not receive a saddle block. We hypothesize that patients who received a preoperative saddle block with IT morphine will demonstrate superior analgesic outcomes over the first 24 hours postoperatively.

Material and Methods

This retrospective, single-centre study was conducted at Women’s College Hospital and was approved by the Hospital Research Ethics Board (REB) number: 2024–0022-E. The requirement for written consent was waived as this study was limited to preexisting data collected as part of the standard of care. Patient data confidentiality was strictly maintained, and all procedures were conducted in accordance with the ethical standards of the institutional research committee and with the Declaration of Helsinki. As patient consent to review their medical records was not required, all data were anonymized prior to analysis to ensure confidentiality. This study was conducted according to STROBE guidelines. All patients who underwent PIV with or without saddle block between February 2022 and April 2024 were considered for inclusion in our study. Exclusion criteria included opioid dependence (at least 30mg of oxycodone or equivalent per day),

contraindication to any of the components of multimodal analgesia, revision PIV and vulvoplasty. The primary data source was individual patient hospital records. The data sets for patients undergoing PIV during the period of interest were retrieved, and the relevant data were extracted.

The primary outcome of this study was the cumulative postoperative opioid consumption (converted to oral morphine equivalent – please see conversion table in [Supplementary Material 1](#)) in the first 24 hours. Secondary outcomes included total intraoperative opioid consumption, total in-hospital opioid consumption, time to first opioid request, no opioid request, duration of stay in Post-Anesthetic Care Unit (PACU), duration of postoperative hospital stay, mean and maximum in-hospital pain severity scores during PACU, first 24 hours and throughout hospital stay (Numeric Rating scale [NRS] ranging from 0=no pain to 10=severe pain), the incidence of opioid- and block-related side effects (nausea, vomiting, pruritus, respiratory depression, and postoperative neurological symptoms).

Saddle Block Technique

The saddle block with IT morphine was performed preoperatively by the attending anesthesiologist or directly supervised regional anesthesia fellow in a dedicated block procedure room. Patients were placed in a sitting position and received 1–2 mg of intravenous midazolam for anxiolysis. Under sterile technique, prior to injecting local anesthetic in the subcutaneous tissue around the target area, a 25 gauge Whitacre spinal needle is introduced in the lumbar region below the L3 level to reach the intrathecal space. After free-flowing CSF was confirmed, 0.4–1.0 mL of hyperbaric (“heavy”) bupivacaine 0.75% plus 100 mcg of morphine were injected into the intrathecal space. The dose of local anesthetic was based on the attending anesthesiologist’s preference. Immediately after injection, patients were placed in a seated position for a duration of 15 minutes to allow the hyperbaric local anesthetic solution to pool the sacral plexus.

Standard Care

All patients received general anesthesia (GA) using inhalational gas (sevoflurane) or total intravenous anesthesia (TIVA) with propofol. Hydromorphone and ketorolac were administered intraoperatively for analgesia based on hemodynamic responses and surgical stimuli. Intravenous ondansetron 4 mg and dexamethasone 8 mg were administered intraoperatively to all patients for postoperative nausea and vomiting (PONV) prophylaxis. Standard surgeon-administered local infiltration analgesia at the end of the procedure included a pudendal nerve block with a 20 mL 1.5:1 admixture of bupivacaine 0.5% with epinephrine 1:200,000 and lidocaine 1%, and infiltration of the surgical incision and spermatic cord with an additional 20 mL of the same admixture of local anesthetic.

Pain reported in the PACU was treated with nurse-administered intravenous (IV) fentanyl (25–50 mcg every 5 min, as needed), followed by IV hydromorphone (0.2–0.4 mg every 5 min, as needed), and/or oral oxycodone (5–10 mg every 2 hours, as required). If a total dose of 100 mcg of IV fentanyl or 2 mg of hydromorphone was reached during the PACU stay, administration of additional doses required approval from the attending anesthesiologist based on the patient’s level of sedation and pain severity. Patients were discharged from PACU after meeting institutional discharge criteria (Modified Aldrete Score). After PACU discharge, patients received a standard systemic analgesic regimen consisting of oral acetaminophen 1 g every 6 hours, IV ketorolac 15 mg every 6 hours on postoperative days 0 and 1, followed by oral celecoxib 200 mg every 12 hours beginning on postoperative day 2, and oral oxycodone 5–10 mg or oral hydromorphone 1–2 mg every 4 hours as needed.

Patients who received the saddle block with IT morphine received postoperative respiratory monitoring as per the American Society of Anesthesiologists guidelines and were followed by the Anesthesia team on the first postoperative day. Nurses in PACU and in-hospital units recorded NRS measurements. In general, NRS scores are measured by nurses every 30 minutes in PACU and every 2 to 4 hours during the in-hospital stay. No patients were excluded.

Statistical Analysis

Results for each group are reported as median (interquartile range [IQR]) and mean (standard deviation [SD]) for continuous outcomes or number (percentage) for binary outcomes. The Chi-squared or Fisher’s Exact tests were used for categorical data, while t-tests or Mann–Whitney *U*-tests were used for continuous data. The normality of continuous data

was assessed using the Kolmogorov–Smirnov test. Missing pain scores were treated as zero in a sensitivity analysis. We considered $P=0.05$ as the threshold of statistical significance.

Total opioid consumption within the first 24 hours was analyzed using univariable and multivariable linear regression models to identify independent predictors among age, BMI, surgery duration, and use of a saddle block. Repeated pain scores over 24 hours were analyzed using linear mixed-effects models with fixed effects for time, saddle block, and their interaction, along with a random intercept for each patient to account for within-subject variability. Regression coefficients (β) with 95% confidence intervals and p -values were reported, with statistical significance defined as $p < 0.05$.

Results

Complete data were available from the charts of 72 patients who met our inclusion criteria and were included in the analysis. Between February 2022 and April 2024, 30 patients received standard anesthetic care with a saddle block (2 patients received 0.4 mL, 18 received 0.5 mL, 5 received 0.6 mL, 2 received 0.7 mL, and 3 received 1 mL of hyperbaric bupivacaine 0.75% with 100 mcg of IT morphine), and 42 patients received standard anesthetic care without a saddle block. Patient characteristics are presented in Table 1.

Results of primary and secondary objectives are presented in Table 2. We found no statistically significant differences in opioid consumption during the first 24 hours postoperatively between patients who received a saddle block (12.5 [7.5, 22.5]) and those who did not (17.7 [5.6, 30.8]; $p=0.249$).

In the linear regression model assessing predictors of total 24-hour opioid consumption (expressed as morphine equivalents), no variable demonstrated a statistically significant association after multivariable adjustment. Although age and body mass index (BMI) showed a tendency toward reduced opioid requirements ($\beta = -0.485$, 95% CI -1.057 to 0.086 , $p = 0.10$; and $\beta = -0.721$, 95% CI -1.687 to 0.245 , $p = 0.15$, respectively), these relationships did not reach statistical significance. Similarly, neither the use of a saddle block nor surgery duration influenced total opioid consumption (Table 3).

We found clinically and statistically significant differences in favour of saddle block for short-term postoperative pain outcomes experienced in PACU, including mean and maximum NRS scores, time to first analgesic request, and duration

Table 1 Patient Characteristics

	All	No SB	SB	P-value
Patients	72	42	30	
Age (years)	29.5 [25.0, 38.0]	29.0 [25.5, 38.7]	30.5 [25.0, 36.7]	0.841
ASA class (I/II/III)	18/36/28	9/22/11	9/14/7	0.710
BMI (kg/m ²)	24.7 [21.4, 31.0]	24.39 [21.3, 28.2]	24.9 [21.5, 32.1]	0.410
Psychiatric disease*	39 (54.2)	21 (50.0)	18 (60.0)	0.549
Chronic pain*	2 (2.8)	2 (4.8)	0 (0.0)	0.628
Chronic opioid use*	1 (1.4)	1 (2.4)	0 (0.0)	1.000
Tobacco use*	9 (12.5)	7 (16.7)	2 (6.7)	0.366
Alcohol use*	4 (5.6)	2 (4.8)	2 (6.7)	1.000
Recreational drug use*	20 (27.8)	12 (28.6)	8 (26.7)	1.000
Duration of surgery (min)		269.5 [252.5, 282.7]	276.5 [261.2, 299.0]	0.057
Dose of hyperbaric bupivacaine 0.75%				
0.4mL			2 (6.6)	
0.5mL			18 (60)	
0.6mL			5 (16.6)	
0.7mL			2 (6.6)	
1mL			3 (10)	

Notes: *Self-reported patient data (yes/no) from standard anesthesia pre-operative assessment questionnaire. Data are presented as mean (standard deviation), median [interquartile range], or n (%). 2 patients received 0.4 mL, 18 received 0.5 mL, 5 received 0.6 mL, 2 received 0.7 mL, and 3 received 1 mL of hyperbaric bupivacaine 0.75% with 100 mcg of IT morphine.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, Body mass index; min, minutes; SB, saddle block.

Table 2 Results

	No SB (n=42)	SB (n=30)	P-value	Mean/Median Differences and 95% CI
Total 24h opioid (mg)	17.7 [5.6, 30.8]	12.5 [7.5, 22.5]	0.249	5.2 (95% CI 0.0, 16.2)
Total intraoperative opioid (mg)	21.0 [15.0, 30.0]	16.5 [12.0, 28.5]	0.370	4.5 (95% CI -4.5, 9.0)
Total in-hospital opioid (mg)	38.5 [15.0, 80.0]	32.5 [15.0, 67.5]	0.855	6.0 (95% CI -30.0, 33.7)
Time to first opioid request (min)	68.5 [46.5, 439.0]	482.5 [188.5, 1053.0]	0.047*	-414.0 (95% CI -767.9, -142.0)
No opioid request	8 (19.0)	2 (6.7)	0.249	
Duration of PACU stay (min)	125.5 [106.5, 169.5]	96.5 [79.0, 117.5]	0.001*	29.0 (95% CI 10.0, 57.0)
Duration of postoperative hospital stay (days)	2.9 [2.8, 2.9]	2.9 [2.8, 2.9]	0.307	0.0 (95% CI -0.02, 0.05)
Mean NRS in PACU	1.7 (1.6)	0.8 (1.4)	0.026*	0.8 (95% CI 0.1, 1.6)
Maximum NRS in PACU	3.0 (2.4)	1.6 (2.1)	0.014*	1.4 (95% CI -0.3, 2.5)
Mean NRS during first 24h	2.4 (1.5)	1.8 (1.3)	0.101	0.5 (95% CI -0.1, 1.2)
Maximum NRS during first 24h	5.2 (2.3)	4.7 (1.8)	0.284	0.5 (95% CI -0.4, 1.5)
Mean NRS throughout hospital stay	2.3 (1.5)	1.8 (1.3)	0.124	0.5 (95% CI -0.1, 1.2)
Maximum NRS throughout hospital stay	5.7 (2.3)	5.5 (1.8)	0.793	0.1 (95% CI -0.8, 1.1)
Nausea	18 (42.9)	19 (63.3)	0.140	
Vomiting	7 (16.7)	11 (36.7)	0.098	

Notes: * $p < 0.05$. Opioid consumption presented as oral morphine equivalent (mg). Data are presented as mean (standard deviation), median [interquartile range], or n (%).
Abbreviations: NRS, Numeric Rating Scale (/10); PACU, Post-Anesthetic Care Unit; SB, Saddle block.

Table 3 Linear Regression Model for Total 24h Opioids

	Univariable Estimate [95% CI] P value	Multivariable Estimate [95% CI] P value
Saddle block	-1.607 (-13.1, 9.882) 0.785	-1.798 (-13.6, 9.967) 0.765
Age	-0.58 (-1.116, -0.045) 0.037	-0.485 (-1.057, 0.086) 0.1
BMI	-0.919 (-1.827, -0.011) 0.051	-0.721 (-1.687, 0.245) 0.148
Surgery duration	0.013 (-0.184, 0.21) 0.897	0.07 (-0.131, 0.272) 0.497

Abbreviation: BMI, Body mass index.

of PACU stay. The median [IQR] number of measurements for pain scores by nurses was 4 [3,5] in PACU, and 6 [5,7.5] during the total stay over 24 hours.

We found no statistically significant differences in intraoperative or total in-hospital opioid consumption, no opioid request, duration of postoperative hospital stay, mean and maximum pain scores in first 24 hours and throughout hospital stay, as well as rates of nausea and vomiting. Nevertheless, in the mixed-effects model examining postoperative pain trajectories within 24 hours, patients who received a saddle block had statistically significantly lower pain scores compared with those who did not ($\beta = -0.937$, 95% CI -1.695 to -0.179, $p = 0.018$). However, the significant time-by-group interaction ($p = 0.024$) suggests that the difference in pain scores between groups decreased over time (Table 4). The sensitivity analysis, which imputed a zero pain score for the missing data, yielded very similar results (results not shown). No episodes of pruritus or respiratory depression and no saddle block procedure-related complications were reported.

Table 4 Association of Saddle Block with Pain Scores Over 24 hours

	Multivariable Estimate [95% CI] P value
Saddle block (Yes vs No)	-0.937 (-1.695, -0.179) 0.018
Time (hours)	0.073 (0.045, 0.102) <0.0001
Saddle block:Time (hours)	0.053 (0.007, 0.099) 0.024

Notes: Mixed effects model with interaction with saddle block and surgery duration. Time represents actual NRS measurement times (in hours) from 0 to 24 hours.

Discussion

The results of this retrospective study suggest clinically and statistically significant benefits in short-term postoperative pain outcomes for patients who received a saddle block for PIV. While all other short-and intermediate-term in-hospital outcome results uniformly signalled benefit in favour of saddle block with IT morphine, these differences did not reach statistical significance. Taken together, our retrospective findings are novel, encouraging, and merit further investigation.

There are several important observations to consider from our results. Firstly, it appears likely that the duration of analgesia following the saddle block with IT morphine is relatively short-lived in the setting of PIV. In our analysis, although pain scores at 24 hours postoperatively did not differ significantly between groups, the mixed-effects model revealed that patients who received a saddle block with intrathecal morphine experienced lower pain scores over the 24-hour postoperative period, but with a diminishing effect over time, suggesting a more pronounced effect in the early postoperative phase. Indeed, this has been our clinical experience in caring for these patients during the first postoperative night. To that end, we have recently increased the dose of local anaesthetic administered to 1 mL of bupivacaine 0.75% for all patients regardless of body habitus, with the intent to extend the duration of analgesia. However, for this study's retrospective dataset, we performed a post-hoc subgroup analysis of the 10 patients (33%) who received greater than 0.5 mL of bupivacaine 0.75% and found no additional statistically or clinically significant differences in any of the outcomes ([Supplementary Material 2](#)). We have not increased the dose of IT morphine further because 100 mcg is the dose beyond which the undesirable side effects have been shown to outweigh the analgesic benefits. Indeed, a retrospective case-control study investigating a high dose (250–300 mcg) IT morphine for PIV reported a decrease in some pain-related outcomes until postoperative day 2, however more than 50% of participants suffered from pruritus, hypotension, nausea, and vomiting.²³ Finally, we were pleased to find that none of our patients, regardless of the addition of a saddle block, suffered from moderate-to-severe postoperative pain which has been reported to accompany PIV. Previous retrospective studies investigating pudendal nerve block and intravenous patient-controlled analgesia (PCA) have reported cumulative 24-hour opioid requirements up to six times higher than what we found in our retrospective dataset, regardless of grouping.^{5,12,16} At least one reason for the difference in opioid consumption may be our surgeons' extensive infiltration, which includes a pudendal nerve block and spermatic cord block, both of which are routinely administered intraoperatively.

This study has several important limitations. First, the retrospective design introduces inherent risks of confounding and relies on the accuracy and completeness of documentation, which may affect the precision of recorded pain scores and opioid consumption. In addition, the sample size of 72 patients (42 without saddle block and 30 with saddle block) provided limited statistical power. A post-hoc analysis showed that the study had only 31% power ($\alpha = 0.05$) to detect the observed median difference of 5.2 mg in 24-hour opioid consumption, increasing the likelihood of a Type II error. Notably, a minimum median difference of 12.5 mg would have been required to achieve 80% power, suggesting that the current sample may not have been sufficient to detect smaller but potentially meaningful differences between groups. Post-hoc power estimates should be interpreted with caution, as they are dependent on the observed effect size and may be influenced by sampling variability. Moreover, our dataset is dynamic and not standardized. We recognize that no standardized saddle block protocol was employed for this comparison and the variability in the volume of local anesthetic used represents our department's attending preference that leads to variability and our learning curve. Similarly, we acknowledge the potential for historical control bias as the patients who received a saddle block underwent PIV more recently than those who did not. Moreover, the retrospective nature of our study hinders the assessment of patient-reported outcome measures (PROMs) to evaluate the actual clinical impact of an analgesic intervention. Finally, future studies should consider following up patients at three and six months to assess the impact of these strategies on persistent postsurgical pain.

In summary, this retrospective study suggests that despite no statistically significant difference in 24-hour opioid consumption, the addition of a saddle block with 100 mcg of IT morphine is associated with improved PACU pain scores, a longer time to first analgesic request, and a shorter PACU stay. These findings are limited by the retrospective design, small sample size, and protocol variability, and they support the need for further prospective, randomized evaluation.

Raw data were generated at Women's College Hospital. Derived data supporting the findings of this study are available from the corresponding authors LGA and RB on request.

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Disclosure

All authors declare no conflicts of interest in this work.

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