

Enhanced Recovery Protocol Decreases Postoperative Opioid Use after Penile Inversion Vaginoplasty

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Background: Penile inversion vaginoplasty (PIV) entails considerable soft-tissue dissection to the perineal region and involves complex tissue rearrangement. This study examines the role of an enhanced recovery after surgery (ERAS) pathway after PIV in reducing opioid use and controlling postoperative pain.

Methods: A retrospective study of 50 transfemale patients who underwent PIV at a single institution from June 2021 to January 2023 was completed. The study compared 2 groups of patients who were given different postoperative pain management regimens: group A received standard postoperative analgesics and group B received ERAS. Variables such as postoperative pain scores on the numeric pain rating scale (0–10), use of opioid medication, length of hospital stay, and patient comorbidities were recorded and compared across the 2 groups.

Results: The average hospital stay length was 4.92 (± 0.85) days. Group A had a slightly longer average stay compared with group B. The average pain level in both groups was 4.25 (SD ± 1.51). Group A exhibited a slightly higher average pain level of 4.31 (± 1.53), whereas group B exhibited 4.16 (SD ± 1.51) ($P = 0.77$). Although pain levels did not significantly vary between the 2 groups, there was a statistically significant decrease in the amount of opioid medication used in group B with a P value of 0.009.

Conclusions: ERAS protocol is effective in decreasing opioid usage in the immediate postoperative setting after PIV. (*Plast Reconstr Surg Glob Open* 2024; 12:e6279; doi: 10.1097/GOX.0000000000006279; Published online 8 November 2024.)

INTRODUCTION

Gender dysphoria is a diagnosis that indicates distress from the incongruence between an individual's self-identified gender and sex assigned at birth.¹ The dysphoria experienced by transgender individuals can lead to emotional and physical distress, which can be alleviated by gender affirmation surgery.² Gender-affirming surgery has exponentially increased by roughly 400% from 2015 to

2019, according to a study that used the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database.³ This study also indicated that of 4505 gender-affirming procedures, 16% were male-to-female bottom procedures.³

Penile inversion vaginoplasty (PIV) requires complex tissue rearrangement and entails significant soft-tissue dissection to the perineal region, including scrotal skin graft harvest, orchiectomy, penectomy, dissection penile inversion fasciocutaneous flap, and creation of neo clitoris and neovaginal space.⁴ The full-thickness scrotal skin graft is harvested using electrosurgery. It is then tabularized and utilized for the lining of the neovagina. Patients are admitted after surgery, and poorly controlled pain may contribute to reluctance toward ambulation, prolonged stays in the hospital, impaired physical function and quality of life, slow recovery, prolonged opioid use during and after hospitalization, and increased cost of care.^{5–8} A vast majority of patients, approximately 80%, who undergo surgery are prescribed opioids for postoperative pain relief.^{9–11}

Furthermore, pain is a leading cause of opioid use disorder after surgery, and its misuse varies between different

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procedures.^{9,10,12} Although opioid analgesics can be therapeutically beneficial when used properly, their overuse may contribute to the opioid crisis.^{9,13} The current opioid epidemic is one of the most severe public health crises in US history, with the Centers for Disease Control and Prevention reporting that 1 million people have died from drug overdoses since 1999, and 75% of drug overdose deaths in 2021 involved opioids.¹² Furthermore, according to the National Center for Health Statistics at the Centers for Disease Control and Prevention, in 2022 alone, there were nearly 108,000 deaths involving drug overdose, and around 15,000 were related to prescription opioids.¹⁴

Research in recent years has investigated different approaches for minimizing opioid overuse.¹⁵ These studies include enhanced recovery after surgery (ERAS) protocols, epidural analgesia, and transversus abdominis plane block, which have been shown to decrease the use of opioid administration.^{4,8,16–19} ERAS protocol involves systemic nonopioid analgesics, such as acetaminophen, nonsteroidal anti-inflammatory drugs, and gabapentinoids, combined with regional and local anesthetics.⁸ Many studies of the ERAS protocol showed a decrease in the reliance on opioid medications, reduced complications, and shortened the length of stay by 30%–50%.^{8,20}

ERAS protocols began to emerge in the plastic surgery literature in 2013, with a series of articles exploring their application in abdominal wall reconstruction, microvascular breast reconstruction, implant-based reconstruction, abdominal-based microsurgical breast reconstruction.^{21–28} However, recent research has expanded its focus on gender-affirming surgery.^{8,16,25} Despite this progress, the literature specifically addressing gender-affirming surgery, notably PIV, remains scarce. Therefore, the central aim of this study is to compare the levels of self-reported pain and opioid use with the implementation of an ERAS protocol after PIV.

METHODS

After institutional review board approval, a retrospective chart review was conducted to identify patients who underwent PIV from June 2021 to January 2023. The inclusion criteria included all patients who underwent primary PIV. Patients undergoing zero-depth vaginoplasty or revision vaginoplasty were excluded. Demographics, comorbidities, length of hospital stay, complications, and the cumulative pain experienced during the hospitalization were recorded. The average and maximum daily pain levels reported by patients were calculated. Pain levels were recorded using the Numeric Pain Rating Scale, which assesses pain on a 0–10 grading system, with 10 representing the worst pain.²⁹ In our institution, a pain level above 6 is considered severe. Pain assessments were conducted by nurses every 8 hours with additional assessment performed if the patient requested pain medication for breakthrough pain. Administration of nonopioid analgesics, and both oral and intravenous opioid medications throughout the hospitalization period were recorded for each patient. To facilitate comparisons and ensure a standardized measurement of opioid use, the total quantity of opioids administered to patients during

Takeaways

Question: Our study evaluates the effectiveness of an enhanced recovery after surgery (ERAS) pathway in reducing opioid use and controlling postoperative pain after penile inversion vaginoplasty (PIV) surgery for transgender patients.

Findings: This retrospective comparative study revealed that the implementation of an ERAS protocol, defined as a standardized multimodal pain management and postoperative care protocol, leads to a significant decrease in opioid medication usage with equivalent pain control compared with a standard postoperative analgesic regimen after gender-affirming PIV.

Meaning: An ERAS protocol was effective in decreasing opioid usage in the immediate postoperative setting after PIV compared with a typical postoperative analgesic regimen.

the postoperative period was converted into morphine milligram equivalents (MMEs).^{8,18}

At our institution, 2 plastic surgeons conduct PIV procedures, each with several years of experience in the care of patients undergoing gender affirmation surgery. One surgeon adopted the ERAS protocol for postoperative care, whereas the second surgeon continued using the conventional protocol. Patients were assigned to group A or group B, depending on whether they were treated with conventional or ERAS protocols.

The conventional protocol consisted of oral acetaminophen (1000mg) as needed for mild-to-moderate pain and oral or intravenous opioids as needed for severe pain. In the ERAS protocol, patients received 1 dose of ketorolac (15 mg) at the end of the surgery and scheduled oral acetaminophen (1000mg) every 6 hours, gabapentin (300mg) every 8 hours, and celecoxib (200mg) or ibuprofen (400–600mg) every 6 hours until discharge. In severe pain, oral or intravenous opioids were administered as needed (Table 1). Complications were classified as major or minor. Minor complications were those

Table 1. Pain Medication for Standard and ERAS Protocols

Standard Protocol	ERAS Protocol
As needed:	Scheduled:
Mild to moderate pain	Oral
Oral	Acetaminophen 1000mg every 6h
Acetaminophen (1000mg)	Gabapentin (300mg) every 8h
Severe pain	Celecoxib (200mg) or Ibuprofen (400–600mg) every 6h
Oral	Intravenous
Oxycodone (5–10mg)	Ketorolac 15mg (1 dose)
Hydromorphone hydrochloride (0.3–1mg)	
Tramadol (25–100mg)	
Intravenous	As needed:
Meperidine hydrochloride (25 µg)	Oral
Fentanyl citrate (25 µg)	Oxycodone (5–10mg)
Hydromorphone hydrochloride (0.2–1mg)	Intravenous
Morphine INJ (2mg)	Hydromorphone hydrochloride (0.2–1mg)
	Fentanyl citrate (25 µg)

Table 2. Patient Characteristics

	Group A (n = 25)	Group B (n = 25)	P
Age, y (mean ± SD)	35.41 ± 12.37	36.40 ± 15.83	0.81
Count of comorbidities	21	13	0.21
BMI, kg/m ² (mean ± SD)	26.59 ± 5.65	27.96 ± 5.79	0.40
Smoking history	9 (36%)	8 (32%)	0.77

Table 3. Patients Comorbidities

Comorbidities	Group A	Group B	P
Hypertension	4 (16%)	3 (12%)	1
Diabetes	2 (8%)	0	0.48
Cardiovascular	9 (36%)	5 (20%)	0.34
Respiratory conditions (COPD/asthma)	6 (24%)	5 (20%)	1

COPD, chronic obstructive pulmonary disease.

Table 4. Pain Score and Hospital Length Stay

	Group A (SD)	Group B (SD)	P
Hospital stay, d	5.08 ± 0.57	4.76 ± 1.05	0.12
Average pain	4.31 ± 1.53	4.16 ± 1.51	0.77
Maximum pain	7.84 ± 1.59	7.76 ± 1.48	0.855

that could be treated conservatively in outpatient settings, such as surgical site infection (SSI), wound dehiscence, minor hematoma, granulation tissue around the vaginal canal, introitus, labia, and clitoris.^{30,31} Major complications were categorized as those requiring return to the operating room or hospitalization for medical interventions.^{32,33} Examples of major complications included expanding hematoma and infection.³⁴

Continuous variables were described by means and SDs, and categorical variables by percentages. The Kolmogorov-Smirnov test assessed whether the sample data significantly deviated from a normally distributed population. As the sample was normally distributed, the two-tailed paired *t* test was performed for statistical analysis to compare the reported pain levels, the total opioid consumption, and the complications in each group. The Fisher test was performed to compare the comorbidities between groups. Statistical analysis was performed using the R Project for Statistical Computing (R Foundation for Statistical Computing, Vienna, Austria) with a significance defined as a *P* value less than 0.05.

RESULTS

A total of 50 patients who underwent PIV between June 2021 to January 2023 met the criteria for inclusion in this study. There were 25 subjects in each group. Patient demographic and comorbidity characteristics are described in Table 2. The sample data closely approximated a normal distribution (*P* = 0.9715). The average patient age in group A was 35.41 ± 12.37 and 36.40 ± 15.83 in group B. Patient's body mass index (BMI) was an average of 26.59 ± 5.65 in group A and 27.96 ± 5.79 in group B. In both cohorts, none were current smokers. There were former smokers in each cohort of patients [*n* = 9 (36%) in group A and *n* = 8 (32%) in group B]. Comorbidity characteristics of

cohorts, as described in Table 3, were assessed as hypertension, diabetes, cardiovascular, and respiratory (chronic obstructive pulmonary disease/asthma). There was no difference between the 2 groups in age, BMI, smoking history, or comorbidities (*P* > 0.05).

Table 4 displays the details of pain scores and hospital stay. The average hospital stay was 4.92 days ± 0.85. Group A exhibited a slightly longer average hospital stay, approximately 5.08 ± 0.57 days. In contrast, group B had an average of 4.76 ± 1.05 days (*P* = 0.12). Using the numeric pain rating scale ranging from 0 to 10, the sample average level of postoperative pain reported was 4.25 ± 1.51. Group A exhibited a slightly higher average pain level of 4.31 ± 1.53, whereas group B exhibited 4.16 ± 1.51 (*P* = 0.77). The average maximum postoperative pain level in both groups was 7.8 ± 1.52. Group A showed a slightly higher maximum pain level, 7.84 ± 1.59, versus 7.76 ± 1.48 of group B (*P* = 0.855). When assessing the use of opioid medications, a substantial reduction in MMEs used was observed in the ERAS group (Fig. 1). Specifically, group A had a mean MME of 271 ± 213, whereas group B demonstrated a notably lower mean MME of 138 ± 112, with a statistically significant difference (*P* = 0.009).

Table 5 describes the percentage of complications between groups. Patient average follow-up was 267.72 ± 141.45 days. Group A exhibited a 4% incidence of minor hematoma compared with 2% in group B. Major hematoma was observed exclusively in group A at 6%. Stenosis occurred in 8% of group A patients and 14% of group B patients. Surgical site infections affected 8% in group A and 6% in group B, whereas minor tissue necrosis was evenly distributed at 6% in both groups. Total canal graft loss was documented in 2% of patients in groups A and B. Dehiscence was the most common complication, with a 12% occurrence in group A and a higher rate of 28% in group B. Only 3 patients in group A exhibited major

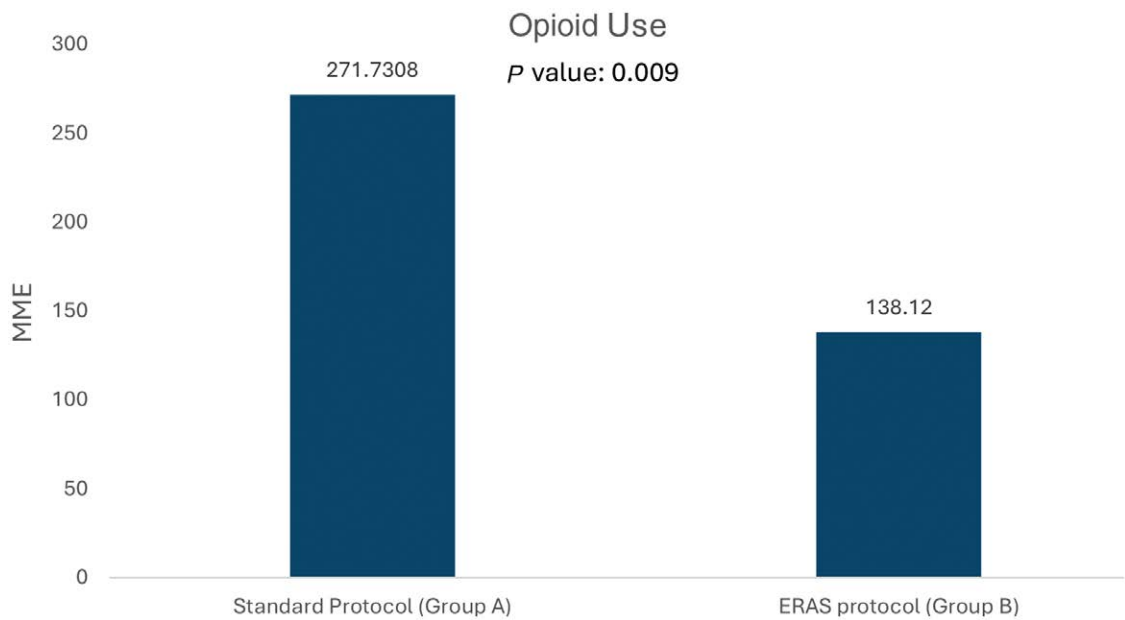


Fig. 1. Opioid medication use.

Table 5. Patient Complications

Complications	Group A	Group B
Minor hematoma	2 (4%)	1 (2%)
Major hematoma	3 (6%)	0
Stenosis	4 (8%)	7 (14%)
Surgical site infection	4 (8%)	3 (6%)
Minor tissue necrosis	3 (6%)	3 (6%)
Dehiscence	6 (12%)	14 (28%)
Partial graft loss	5 (10%)	6 (12%)
Total graft loss	1 (2%)	1 (2%)
Any major complication	3 (6%)	0
Intraoperative complication	0	1 (2%)
Count of minor complications ($P = 0.75$)	18 (36%)	19 (38%)

complications, which were all hematomas. Overall, the rate of minor complications in group A was 36% and 38% in group B, results were not statistically significant ($P = 0.75$).

DISCUSSION

Opioids have been the cornerstone of pain management in the perioperative period. Despite its mainstay and traditional use, opioids can lead to long-term misuse.¹³ The transgender population is recognized as a vulnerable group, with the 2015 US Transgender Survey revealing that 34% of respondents reported drug misuse.⁹ Considering the at-risk population, the current state of the opioid epidemic, and the need for adequate postoperative pain control, it is paramount that pain management protocols are investigated and optimized to control pain while also minimizing opioid use among the transgender population undergoing surgery.³⁵

In plastic surgery, ERAS protocols have been implemented primarily in breast reconstruction, which showed a decrease in hospital stay and inpatient opioid use without

increasing complications.^{21,26} In these studies, there was no difference in overall major complications and hematomas between patients managed with ERAS versus traditional pathways.^{21,22,26}

Our study emphasizes the ERAS pathway after PIV, comparing the levels of self-reported pain and levels of postoperative opioid use, along with the complications between 2 groups of patients receiving different pain management protocols. The enhanced recovery protocol implemented in group B effectively reduced the use of opioids for pain management, showcasing the potential benefits of this approach, with a statistically significant difference ($P = 0.009$).

Pain plays a crucial role in assessing patient comfort and recovery. Uncontrolled pain may lead to slow rehabilitation and prolonged hospitalization.⁵⁻⁸ Furthermore, some studies indicate that ineffectively managed acute pain after surgery increases the risk of developing prolonged postoperative pain.^{32,36} In our study, both groups experienced similar levels of postoperative average and maximum pain. However, our study showed a decrease of

almost 50% ($P = 0.009$) in MMEs with the introduction of multimodal ERAS regimen.

These findings are consistent with a growing body of literature on ERAS for gender affirmation surgery.¹⁶ Bedar et al¹⁶ assessed the effects of the ERAS protocol in patients who underwent facial feminization surgery. All 3 primary measures of total perioperative opioid usage, patient-reported pain scores, and total length of inpatient stay experienced a decrease with ERAS compared with a non-ERAS protocol.¹⁶ Moreover, Faulkner et al³⁷ demonstrated the reduction of opiate prescriptions after implementing the ERAS protocol in the outpatient postoperative setting in various breast reconstruction procedures such as gender-affirming chest/breast surgery.

Furthermore, Tirrell et al⁸ reported incorporation of ERAS protocol after PIV; however, they did not compare ERAS protocol versus conventional pain management. They assessed whether the use of intravenous patient-controlled analgesia (PCA) compared with nonpatient-controlled anesthesia (NCA), in the setting of perioperative ERAS protocol, impacts pain control and opioid consumption on patients after PIV.⁸

They discovered that the use of PCA was associated with increased opioid consumption with no additional benefit for pain control. Their NCA group experienced a 54% reduction in postoperative inpatient opioid use while reporting similar average pain scores from the postoperative day 1–6 for both PCA and non-PCA cohorts.⁸ Moreover, the PCA group had longer hospital stay.⁸ They suggest that the reduction in opioid consumption is more likely attributable to the adoption of the NCA approach, and sustained pain control is associated with ERAS protocol.⁸ Multiple studies have evaluated the application of nerve blocks and epidural anesthesia in an effort to improve postoperative pain and opioid usage after vaginoplasty surgery.^{4,18,19,38} Both our cohorts received surgical field block with a mixture of liposomal bupivacaine and marcaine hydrochloride. Further research is warranted to compare ERAS protocol with nerve blocks in optimizing pain management and opioid utilization.

Common complications in PIV were hematomas, stenosis, infections, graft loss, and dehiscence. Overall, the count of any minor complications in group A was 18 (36%) and 19 (38%) in group B, results were not statistically significant ($P = 0.75$). Even though the findings suggest some difference in hospital stay between the 2 groups, Group A had 5.08 ± 0.57 days in contrast, and group B had an average of 4.76 ± 1.05 days; this was not statistically significant ($P = 0.12$). This might be attributed to the small sample size, and with ERAS protocol, patients are typically discharged on the third day after surgery. Further investigation should be warranted to assess complications in a bigger sample size.

Even though our study was limited in its retrospective nature and small sample size, it is the only study that assesses ERAS protocol as a tool to decrease postoperative opioid use after PIV. One limitation of our study was that patients in groups A and B were operated on by 2 different surgeons, which may have impacted the pain levels and the amount of opioid use between the 2 groups. Further analysis with a larger, randomized sample would be essential

to solidify our findings. A larger sample size could explain slight variations in complications, hospital stay, and pain scores. Another limitation of our study is that we did not examine history of chronic pain medication use, which can potentially influence inpatient pain scores and opioid usage. Our study was limited to only inpatient use of the ERAS protocol. Future studies are needed to assess prolonged pain and opioid use in this patient population, as these factors could potentially impact adherence to the dilation schedule and alter the risk of losing the depth of the vaginal canal.^{12,32,36}

The transgender patient population carries several known risk factors for opioid use, including a higher proportion of mental health diagnoses, stigma, discrimination, and healthcare barriers.^{16,35,39,40} Over the course of their gender affirmation journey, they may undergo many procedures and encounter many opportunities for opioid overuse.¹⁸ Thus, effective pain management and efforts to decrease opioids in PIV are crucial. An ERAS protocol following PIV may be one modification to a surgical practice that helps protect these patients while also optimizing patient care.

CONCLUSIONS

This study emphasizes the importance of tailored postoperative care and pain management strategies for transfemale and gender diverse patients undergoing gender-affirming PIV. Incorporating ERAS protocol resulted in a substantial reduction in opioid usage without compromising the patient's pain level. These findings contribute to the ongoing effort to optimize the postoperative experience and enhance the overall well-being of patients undergoing gender-affirming surgical procedures. Moreover, these findings are important among transgender patients, due to higher risks of substance misuse. Further research may elucidate the underlying factors driving these observed differences and provide additional insights for future clinical practice.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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