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Original Research Article

A Comparative Study on the Efficacy of Epidural Tramadol versus Fentanyl as Adjuvants to Ropivacaine in Postoperative Pain Management

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ABSTRACT

Background: Postoperative pain remains a significant challenge in patient care, leading to various adverse physiological and psychological effects. Effective pain management is crucial for patient recovery and reducing healthcare costs. This study aimed to compare the efficacy and side effects of epidural tramadol versus fentanyl as adjuvants to ropivacaine for postoperative analgesia in lower limb and lower abdominal surgeries.

Methods: A total of 100 adult patients were randomly divided into two groups: Group F received epidural Ropivacaine 0.2% with Fentanyl 25mcg, and Group T received epidural Ropivacaine 0.2% with Tramadol 50mg. Parameters such as onset and duration of analgesia, vital signs (heart rate, mean arterial pressure, respiratory rate), Visual Analogue Scale (VAS) scores, and adverse effects were monitored.

Results: The study found that epidural Ropivacaine 0.2% with Tramadol 50mg provided a significantly longer duration of analgesia compared to Ropivacaine 0.2% with Fentanyl 25mcg, although the onset of action was slower in the tramadol group. Both groups exhibited minimal hemodynamic instability and respiratory depression. However, pruritus and urinary retention were more frequently observed in the fentanyl group.

Conclusion: These findings suggest that epidural tramadol is a viable and potentially superior alternative to fentanyl as an adjuvant to ropivacaine for prolonged postoperative pain relief with a favorable side effect profile.

Keywords: Epidural Analgesia, Ropivacaine, Tramadol, Fentanyl, Postoperative Pain.

INTRODUCTION

Pain, defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"[1] is a pervasive issue in the postoperative period. Unmanaged postoperative pain is a frequent and distressing experience following surgical interventions, irrespective of their nature.[2] It contributes to fear, anxiety, sleep disturbances, unnecessary stress, and hemodynamic instability. Furthermore, inadequate pain control can delay postoperative recovery and rehabilitation, leading to extended hospital stays and increased complication rates, thereby escalating healthcare costs.[2]

Historically, anesthesiologists and surgeons primarily focused on the intraoperative period, with advancements in surgical techniques and anesthetic approaches leading to successful and safe outcomes. However, postoperative pain management received less attention. Growing awareness of

the critical importance of optimal pain management, alongside other aspects of postoperative care such as fluid and temperature management, has spurred increased interest in this field. The IASP, in collaboration with the European Pain Federation, declared 2017 as the global year against pain after surgery, highlighting the worldwide recognition of this issue.[3]

While postoperative pain is generally self-limiting, its intensity is highest during the first 24 hours post-surgery, gradually diminishing over 3 to 4 days.[2] Persistent or severe postoperative pain is often associated with and exacerbates other unpleasant symptoms like nausea, vomiting, and sweating, and can lead to hemodynamic alterations.[2] Beyond physical discomfort, pain after surgery has significant psychological effects, including fear, anxiety, anger, and resentment, which can induce or worsen insomnia and hinder mental and physical recovery. Inadequate or delayed treatment of acute pain can also predispose patients to chronic postoperative pain.[2] In pediatric populations, untreated postoperative pain can lead to behavioral changes lasting up to a year.[2]

Surgical procedures, particularly those involving the abdomen and chest, can compromise respiratory function by reducing functional residual capacity (FRC), tidal volume (VT), vital capacity, residual volume (RV), and forced expiratory volume in one second (FEV1). This is due to increased abdominal muscle tone, limited diaphragmatic function, reduced lung compliance, and impaired deep breathing and expectoration.[4] Patients often avoid deep breathing and coughing due to fear of pain, which can result in hypoxemia, hypercapnia, retention of secretions, atelectasis, pneumonia, and postoperative paralytic ileus. The increased effort associated with breathing also raises oxygen consumption and lactate production.[4]

Given these widespread adverse effects, the prevention and adequate treatment of postoperative pain are paramount. Management strategies encompass both preventive and curative approaches. Preventive measures involve patient education and psychological preparation regarding the surgical procedure and anticipated pain, as well as preemptive analgesia initiated before surgery to prevent central sensitization.[4] Curative methods include non-pharmacological techniques such as hypnosis, cold/heat therapy, immobilization, massage, acupuncture, and Transcutaneous Electrical Nerve Stimulation (TENS), as well as pharmacological interventions via various routes (oral, rectal, intramuscular, subcutaneous, intravenous, patient-controlled analgesia, transmucosal, conjunctival, and inhalational).[4] Regional administration of analgesics, which minimizes systemic side effects, includes wound infiltration, individual nerve blocks, plexus blocks, and central neuraxial blocks like spinal and epidural analgesia.[4]

The World Health Organization (WHO) analgesic ladder provides a framework for pain management, progressing from non-opioids for mild pain to strong opioids and interventional therapies for severe pain.[5] For acute nociceptive pain, a reverse WHO ladder approach is often employed, starting with strong opioids and stepping down as pain severity decreases.[4] While pharmacological treatments are effective, they often require repeated doses, leading to uncertain blood levels, potential toxicity, and side effects such as respiratory and cardiovascular depression. This highlights the need for simple, safe, and economically viable analgesic techniques.[4]

This study focuses on epidural analgesia, a regional technique that delivers local anesthetics and adjuvants directly to the epidural space, providing effective pain relief with reduced systemic side effects. Specifically, we investigate the comparative efficacy and safety of epidural tramadol and fentanyl as adjuvants to ropivacaine in postoperative pain management for lower limb and lower abdominal surgeries.

MATERIALS AND METHODS

This prospective, randomized study was conducted on 100 adult patients, aged 18-64 years, classified as ASA (American Society of Anesthesiologists) physical status I or II. All patients were scheduled for elective lower limb or lower abdominal surgeries. Ethical approval was obtained from the institutional ethics committee, and informed consent was secured from all participants. Patients with known allergies to study drugs, coagulopathies, local infection at the injection site, neurological deficits, or those receiving chronic pain medication were excluded from the study.

Patients were randomly allocated into two groups of 50 each:

- **Group F (Fentanyl Group):** Received epidural Ropivacaine 0.2% with Fentanyl 25mcg (10ml total volume).

- **Group T (Tramadol Group):** Received epidural Ropivacaine 0.2% with Tramadol 50mg (10ml total volume).

Epidural catheters were inserted at the L2-L3 or L3-L4 intervertebral space using a loss-of-resistance technique. After a negative aspiration for blood or cerebrospinal fluid, a test dose of 3ml of 2% lignocaine with adrenaline was administered. After confirming proper placement, the study drug was administered through the epidural catheter post-operatively, immediately upon the patient's complaint of pain (considered 0 minutes).

Parameters Monitored:

- **Onset of Analgesia:** Time from drug administration to effective pain relief.
- **Duration of Analgesia:** Time from effective pain relief until the patient requested additional analgesia.
- **Vital Parameters:** Pulse rate (PR), Mean Arterial Pressure (MAP), Respiratory Rate (RR), and Oxygen Saturation (SpO2) were monitored at regular intervals (0, 5, 10, 15, 30 minutes, and 1, 2, 4, 6, 8, 10, 12, and 24 hours post-administration).
- **Pain Intensity:** Assessed using a 10-point Visual Analogue Scale (VAS) where 0 = no pain and 10 = worst possible pain, at the same intervals as vital parameters.
- **Sedation Score:** Assessed using the Ramsay Sedation Scale.
- **Adverse Effects:** Incidence of nausea, vomiting, pruritus, hypotension, bradycardia, and urinary retention.

Backup Facilities

Emergency medications such as Inj. Naloxone, Inj. Ephedrine 30mg, and Inj. Atropine 0.6mg were readily available. Modern anesthesia machines, equipment for general anesthesia and oxygen therapy, standard laryngeal mask airways, suction machines, and emergency vasoactive medications were also on standby.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Version 21 software. Microsoft Excel 2019 was used for data presentation (tables and graphs). Repeated measures ANOVA was employed to compare changes in mean values between the two groups. An unpaired t-test was used for inter-group comparisons. A p-value of < 0.05 was considered statistically significant.

RESULTS

A total of 100 patients were included in the study, with 50 patients in each group (Group F and Group T). Demographic variables, including age, sex, height, and weight, were comparable between the two groups, indicating successful randomization. There was no significant difference in age distribution ($\chi^2 = 2.17$, df = 3, $p = 0.54$), sex distribution ($\chi^2 = 0.27$, df = 1, $p = 0.61$), mean weight (Group F: 72.64 ± 6.94 kg; Group T: 74.44 ± 6.47 kg), or mean height (Group F: 166.10 ± 8.98 cm; Group T: 166.48 ± 10.19 cm) between Group F and Group T.

Onset of Analgesia

The mean onset of analgesia in Group F (Ropivacaine 0.2% with Fentanyl 25mcg) was 9.04 ± 2.19 minutes, while in Group T (Ropivacaine 0.2% with Tramadol 50mg) it was 16.82 ± 3.37 minutes. A statistically significant difference was observed in the mean onset of action between the two groups ($p < 0.05$), with Group F demonstrating a faster onset.

Duration of Analgesia

The mean duration of analgesia in Group F was 305.22 ± 16.03 minutes, and in Group T, it was 327.84 ± 45.37 minutes. This difference was statistically significant ($p = 0.001$), indicating a prolonged duration of analgesia in the tramadol group.

Vital Parameters

No significant differences were observed in mean heart rate, mean arterial pressure, or respiratory rate between the two groups at various time intervals throughout the study ($p > 0.05$). Both groups maintained stable hemodynamic parameters and respiratory function.

Visual Analogue Scale (VAS) Scores

There was no significant difference in mean VAS scores between the two groups at any monitored time point (0, 5, 10, 15, 30 minutes, 1, 2, 4, 6, 8, 10, 12, and 24 hours) ($p > 0.05$).

Adverse Effects

- **Nausea and Vomiting:** Not noted in any subjects from either group.
- **Pruritus:** Observed in 6 (12%) subjects in Group F and 0 (0%) subjects in Group T. The incidence of pruritus was significantly higher in Group F compared to Group T ($p < 0.05$).
- **Hypotension:** Noted in 1 (2%) subject in Group F and 1 (2%) subject in Group T.

- **Bradycardia:** Noted in 1 (2%) subject in Group F and 0 (0%) subjects in Group T.
- **Urinary Retention:** Noted in 3 (6%) subjects in Group F and 1 (2%) subject in Group T. The incidence of urinary retention was higher in Group F.
- **Respiratory Depression:** No incidence of respiratory depression (respiratory rate fall less than 10/min) was observed in either group.

Summary of Key Findings

Parameter	Group F (Fentanyl) Mean ± SD	Group T (Tramadol) Mean ± SD	p-value	Significance
Onset of Analgesia (min)	9.04 ± 2.19	16.82 ± 3.37	< 0.05	Group F faster
Duration of Analgesia (min)	305.22 ± 16.03	327.84 ± 45.37	0.001	Group T longer
Pruritus (%)	12%	0%	< 0.05	Significantly higher in Group F
Urinary Retention (%)	6%	2%	Not stated	Higher incidence in Group F
Hypotension (%)	2%	2%	Not stated	No significant difference
Bradycardia (%)	2%	0%	Not stated	No significant difference
Nausea/Vomiting	0%	0%	NA	Not observed
Respiratory Depression	0%	0%	NA	Not observed

DISCUSSION

Effective postoperative pain management is a dynamic field, continuously evolving with the introduction of new modalities, techniques, and pharmacological agents.[2] Our study aimed to compare the effectiveness and safety of epidural Ropivacaine 0.2% combined with Fentanyl 25mcg versus Ropivacaine 0.2% combined with Tramadol 50mg for postoperative analgesia in lower abdominal and lower limb surgeries. The findings contribute to the ongoing discourse regarding optimal epidural adjuvant choices.

Onset of Analgesia

In our study, epidural Ropivacaine 0.2% with Fentanyl 25mcg demonstrated a significantly faster onset of analgesia (9.04 ± 2.19 min) compared to Ropivacaine 0.2% with Tramadol 50mg (16.82 ± 3.37 min) ($p < 0.05$). This observation aligns with the known pharmacokinetic properties of fentanyl, a highly lipophilic opioid that rapidly crosses the dura to act on spinal opioid receptors, leading to a quicker onset of action.[6,7] In contrast, tramadol, while having a central analgesic effect, has a slower onset when administered epidurally, which is consistent with its mechanism of action involving both opioid and monoaminergic pathways.[8,9]

Previous studies have reported varying onset times for epidural tramadol and bupivacaine combinations. Singh et al. (2013) found a mean onset of action of 19.45 ± 1.66 min with bupivacaine 0.5% and tramadol 50mg, which is comparable to our tramadol group, though their bupivacaine-only group also showed a longer onset (19.33 ± 2.28 min).[10] Saxena D et al. (2017) reported an onset of 10.35 ± 1.32 min for bupivacaine 0.5% with tramadol 50mg, which is closer to our fentanyl group's onset, but their study utilized a higher concentration of bupivacaine and was exclusively for epidural anesthesia.[11] Javid et al. (2015) also found no significant difference in onset between bupivacaine alone and bupivacaine with tramadol, with onset times around 11.5 minutes.[12] These variations highlight the influence of local anesthetic concentration, surgical context, and specific drug dosages on the observed onset of analgesia.

Duration of Analgesia

Our study revealed a statistically significant prolongation of analgesia in the tramadol group (327.84 ± 45.37 min) compared to the fentanyl group (305.22 ± 16.03 min) ($p = 0.001$). This finding suggests that epidural tramadol, when combined with ropivacaine, provides a more

sustained analgesic effect. The prolonged duration of action of tramadol is likely attributable to its dual mechanism of action, which includes weak μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake, contributing to descending pain inhibitory pathways.[8,9]

This result is supported by several other studies. Singh et al. (2013) reported a significantly longer duration of analgesia with epidural bupivacaine and tramadol (300.88 ± 22.07 min) compared to bupivacaine alone (180 ± 15.19 min).[10] Kokane D et al. (2013) also demonstrated prolonged analgesia with epidural tramadol and lignocaine (6.55 ± 1.23 hours) compared to lignocaine alone (2.2 ± 0.5 hours).[13] However, some studies, like Siddik-Sayyid et al. (1999), reported shorter durations of analgesia with epidural tramadol, possibly due to differences in patient population (parturients undergoing caesarean section) and bolus dosing.[14] Delilkan et al. (1993) also showed varying durations based on tramadol dosage, further emphasizing the dose-dependent nature of its effect.[15]

Vital Parameters and VAS Scores

Both groups maintained stable vital parameters throughout the study, with no significant differences in heart rate, mean arterial pressure, or respiratory rate. This indicates that both fentanyl and tramadol, at the doses used, provided effective analgesia without causing significant hemodynamic instability or respiratory depression. This is consistent with findings from Singh et al. (2013), Javid et al. (2015), and Kokane D et al. (2013), who also observed stable vital signs with similar epidural regimens.[10,12,13]

Similarly, there were no significant differences in VAS scores between the two groups at any time point. This suggests that both epidural fentanyl and tramadol, as adjuvants to ropivacaine, provided comparable levels of pain relief, despite the differences in onset and duration. This finding is crucial as it indicates that while tramadol offers a longer duration, the quality of analgesia, as perceived by the patient, is similar to fentanyl.

Adverse Effects

The incidence of adverse effects varied between the groups. Pruritus was significantly higher in the fentanyl group (12%) compared to the tramadol group (0%) ($p < 0.05$). This is a well-known side effect of epidural opioids, particularly fentanyl, due to its interaction with opioid receptors in the spinal cord.[16,17] Urinary retention was also more frequent in the fentanyl group (6%) than in the tramadol group (2%). These findings suggest a more favorable side effect profile for epidural tramadol in terms of pruritus and urinary retention.

Nausea and vomiting were not observed in either group, which contrasts with some studies reporting a higher incidence of these side effects with epidural tramadol.[15] This discrepancy might be attributed to differences in patient populations, surgical procedures, or the specific dosages and combinations of drugs used. Importantly, no respiratory depression was observed in either group, reinforcing the safety of both adjuvants at the administered doses.

Limitations

This study was not a randomized controlled trial, which could introduce bias. Additionally, blood pressure measurements were not continuous (beat-to-beat), potentially limiting the appreciation of transient hypotensive episodes. The study population was limited to elective caesarean section patients, which may restrict the generalizability of these findings to other surgical populations or emergency settings. Future research should address these limitations through larger, multi-center randomized controlled trials across diverse surgical cohorts, employing continuous hemodynamic monitoring and standardized assessment of side effects.

CONCLUSION

Based on our observations, we conclude the following:

1 Epidurally administered Tramadol 50 mg along with Ropivacaine 0.2% is effective in prolonging the duration of analgesic action in postoperative pain management.
2 Epidurally administered Fentanyl 25 mcg with Ropivacaine 0.2% is associated with a higher incidence of side effects such as pruritus and urinary retention compared to the tramadol group.

In summary, while epidural fentanyl provides a faster onset of analgesia, epidural tramadol offers a significantly longer duration of pain relief with a more favorable side effect profile, particularly regarding pruritus and urinary retention. Both adjuvants, when combined with ropivacaine, provide effective postoperative analgesia with minimal impact on vital parameters and no observed respiratory depression.

AUTHOR CONTRIBUTIONS

Dr. Arjun Gotagunaki was involved in the conceptualization and design of the study, data collection, investigation, case management, and overall supervision, and contributed substantially to the critical review and editing of the manuscript. **Dr. Varsha Patil** contributed to data collection and patient management and was involved in the preparation of the original draft of the manuscript. **Dr. Jyothsna Paranjape** contributed to data collection, patient management, and literature review, and participated in the preparation of the original manuscript draft. **Dr. Kunal Uday Patil** provided overall supervision and oversight of the project, contributed to project administration, and was involved in the critical review and editing of the manuscript. All authors critically reviewed the manuscript and approved the final version for publication.

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