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Research Article

Epidural Dexamethasone and Epidural Tramadol for Postoperative Analgesia in Patients Undergoing Abdominal Surgeries: A Comparative Study

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ABSTRACT

Background: After surgery, systemic opioids are typically administered to relieve pain. The quest for an improved opioid never stops. In this trial, tramadol, an opioid, is utilized in opposition to dexamethasone. Dexamethasone has a potent anti-inflammatory activity and has proven to reduce morbidity after surgery. This study aims to investigate the effects of epidural bupivacaine combined with dexamethasone versus tramadol on postoperative analgesia in individuals undergoing lower abdomen procedures.

Material and methods: Two groups of sixty patients, ages 18 to 60, were assigned to elective lower abdominal operations performed under general anesthesia (group T and group D). In Group D (n=30), patients were given 8ml of 0.25% Bupivacaine with 2ml (8 mg) of Dexamethasone. In group T (n=30), patients were given 8ml of 0.25% Bupivacaine with 2ml (100 mg) of Tramadol. 10ml of medication was administered epidurally to each group at the onset of incisional wound closure. Patients were then extubated following reversal and moved to the postoperative care unit (POCU). An additional investigator, unaware of the group assignment, continued to observe and care for the patients. Hemodynamics were assessed every 15 minutes for the first hour followed by half hourly for 2 hours. Patients were evaluated and information was documented regarding the time first to rescue analgesia, which is defined as the interval between the end of block performance and the patient's initial request for rescue analgesia. Analgesia following surgery was recorded using a VAS (Visual Analogue Scale) score. VAS score and mean satisfaction score were recorded at 0, 1st, 3rd, 6th, and 12th postoperative hours.

Results: There were just slight variations in both groups' hemodynamics. The mean VAS was significantly lower in group D and the mean satisfaction score was better in group D. Requirement of analgesia and PONV was minimal in group D.

Conclusion: Therefore, for post-operative analgesia following abdominal procedures, epidural dexamethasone can be utilized as an adjuvant in comparison to epidural tramadol to 0.25% bupivacaine.

Keywords: Epidural Dexamethasone, Epidural Tramadol, Epidural Analgesia, Post-operative pain, Visual Analog scale, Abdominal Surgeries

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INTRODUCTION

Following surgical procedures, acute pain emerges from tissue injury and is anticipated to diminish during the recovery process, typically within three months. Beyond this timeframe, pain is categorized as chronic or persistent. Pain perception varies among individuals due to biological, psychological, and social factors. Surgical interventions cause tissue damage,

activating diverse pain pathways and triggering emotional responses such as fear and anxiety.

While many patients experience a reduction in pain and analgesic needs shortly after surgery, others may encounter a stable or worsening trajectory of pain intensity and medication requirements. The Perioperative Quality Improvement Programme (PQIP) 2017-2018 annual report 9 included data from 79 hospital sites across the UK. It highlighted that 48 and 19 percent of patients reported moderate or severe pain respectively at the surgical site within 24 h of surgery [1].

In addition to cardiac ischemia, venous thrombosis, arterial hypoxemia, and an increased hormonal reaction to the operation, the pain is unpleasant. The goal of postoperative analgesia is to promote early ambulation and function restoration while minimizing adverse effects and enhancing patient satisfaction. Inadequate pain management following surgery can hinder healing, raise medical expenses, and lower patient satisfaction.

Unmanaged postoperative pain can exacerbate certain pathophysiologies and raise patient morbidity and death rates. Reducing pain following surgery has the potential to lower perioperative morbidity and death [2]. A safe and efficient way to treat postoperative pain is with analgesia administered via an indwelling epidural catheter [3].

Since it prolongs analgesia, extending the duration of local anesthetic activity is frequently preferred. To improve and prolong the analgesic benefits of local anesthetics and lessen the need for and adverse effects of opioids, a variety of adjuvants are employed in regional anesthesia. Adjuvants such as midazolam, tramadol, morphine, dexmedetomidine, fentanyl, and steroids have been studied to optimize the effectiveness of epidural analgesia. Clonidine and adrenaline are two of the adjuvants that have been examined more [4,5].

Adjuvant medications such as ketamine and epidural neostigmine were also utilized [6,7]. Studies have shown that bupivacaine combined with systemic and local spinal corticosteroids can provide analgesia [8].

Excellent outcomes have been reported when administering opioids via the epidural route for the treatment of postoperative pain. Epidural analgesia eliminates these issues [9]. Postoperative analgesia is caused by the existence of opioid receptors at the spinal level and their blockage. For this objective, a variety of opioids have been employed, investigated, and contrasted. During the first post-operative day, the combined epidural opioid-local anesthetic gives adequate pain control; however, it is linked to nausea, vomiting, sedation, pruritus, urine retention, and respiratory depression [10].

Dexamethasone is a long-acting, high-potency glucocorticoid that has been used to prevent post-operative nausea. It has less mineralocorticoid impact. Single oral or intravenous(IV)[11]

doses of dexamethasone and other glucocorticoids have also been shown to enhance analgesia following a variety of surgeries. According to several investigations, the analgesic effectiveness of an epidural bupivacaine-dexamethasone admixture was nearly identical to that of bupivacaine-fentanyl, with the added benefits of opioid-sparing and antiemetic effects [12].

Tramadol is a synthetic 4-phenyl-piperidine analog that exhibits a synergistic anti-nociceptive effect. It is a racemic mixture of two enantiomers. While the (−) enantiomer is a strong inhibitor of norepinephrine synaptic release, the (+) enantiomer has a modest affinity for the opioids μ receptor and inhibits serotonin absorption. As a result, an opioid is produced that, while having an analgesic strength roughly equivalent to that of pethidine in certain trials, does not have any respiratory depressive effects.

Hence we are conducting this study to compare the efficacy of epidural dexamethasone and epidural tramadol as an adjuvant to 0.25% Bupivacaine for post-operative analgesia in patients undergoing abdominal surgeries.

Materials & Methods

Following ethical committee approval, a prospective, randomized, double-blinded, comparative study was conducted in the Department of Anesthesiology, Dr. D.Y. Patil Medical College, Hospital & Research Centre, Pimpri, Pune.

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Using WinPepi software, at a power of 80% and significance level of 5 %, the sample size calculated was 26 in each group concerning an article by Suhail Sidiq et.al [13] Considering the drop-off rate, we have taken the sample size as 30 in each group.

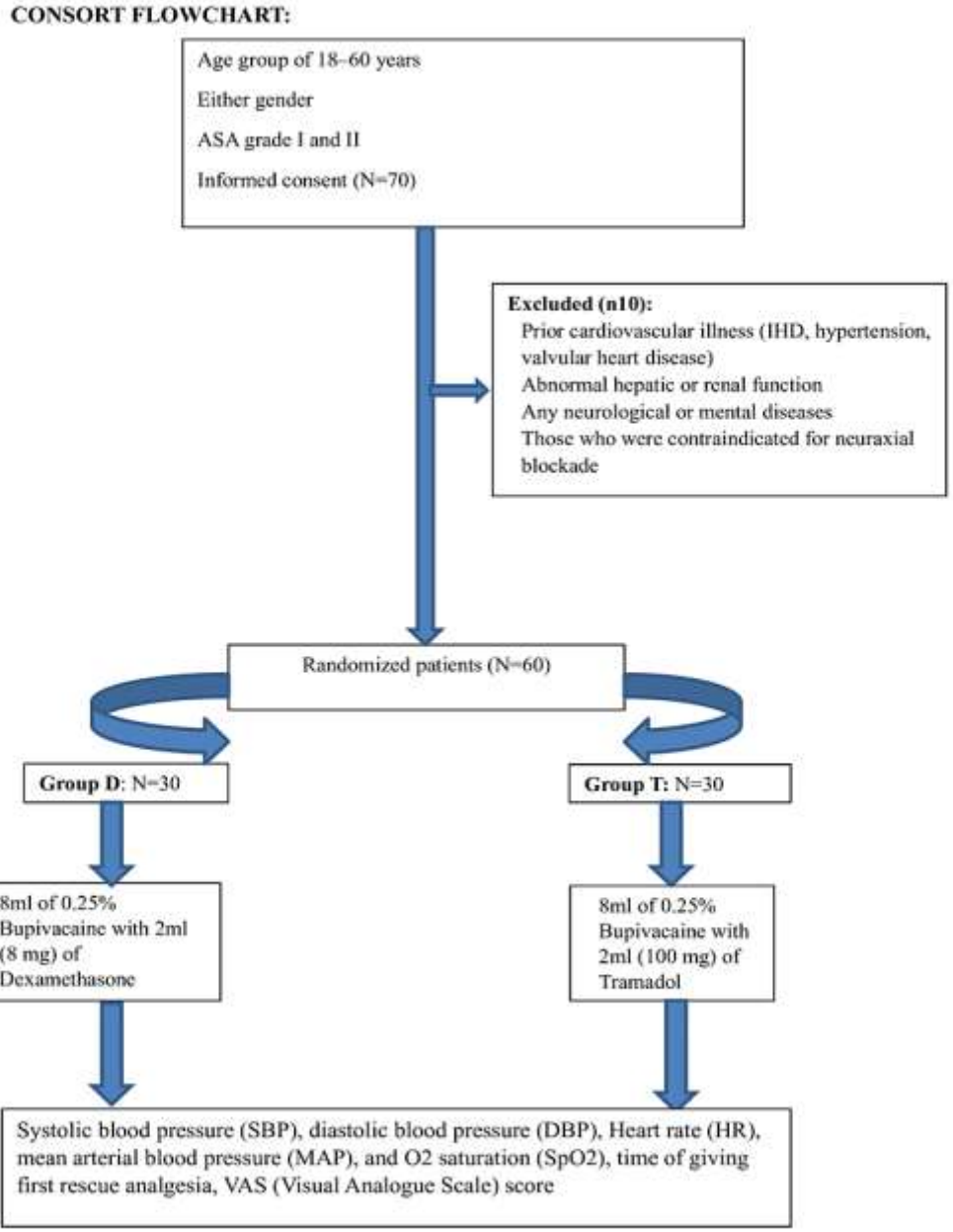

Figure 1: Flow chart

Patients with Physical status grades I and II who were between the ages of 18 and 60 and provided informed consent for the study were included in our analysis. Patients with prior cardiovascular illness (Ischemic heart disease, hypertension, valvular heart disease), abnormal hepatic or renal function, any neurological or mental diseases, or those who were contraindicated for neuraxial blockade were also eliminated. Patients scheduled for emergency procedures and those with a history of allergy to any of the medications utilized in our trial were also excluded. Surgeries included all types of abdominal surgeries like open cholecystectomy, abdominal hysterectomies requiring general anesthesia, supra umbilical hernias, renal transplant donor, pyeloplasty, supra umbilical incisional hernias, benign pancreatic lesion surgeries, and so on. The trial was thoroughly explained to the patients, and their informed written agreement to participate was obtained. At no

point during the study did the patients know their group assignment. Before surgery, all patients received instructions on how to record and utilize the visual analog scale (VAS). To reduce the risk of aspiration and other issues connected to anesthesia, all patients were placed on a strict fast for at least six hours before the operation. IV access in the operating room was obtained using a 20-gauge cannula. The following monitoring equipment was attached: an Electrocardiogram(ECG), non-invasive blood pressure, temperature probe, pulse oximeter, and heart rate monitor. Recorded were baseline parameters.

Using an 18-gauge Tuohy's epidural needle, epidural space was identified with the loss of resistance technique, and the catheter was inserted and secured at the desired level according to the surgery. A test dose consisting of 3 milliliters of 2% lidocaine and 1:200,000 adrenaline was utilized to rule out intravascular and subarachnoid injections.

General anesthesia was induced I.V. by Glycopyrrolate 0.2mg, Fentanyl 2 microg/kg, Propofol 2 mg/kg, and Succinylcholine 2mg/kg. The patient was intubated with an appropriate-size endotracheal tube and muscle relaxation was maintained with Vecuronium 0.1mg/kg. Afterward, maintained on 40% O2 in Air and isoflurane (0.7-1% end-tidal concentration) to maintain normocarbia at end-tidal CO2 between 35 and 40 mmHg. Using computer-generated random numbers, patients were randomly assigned using a therapy analysis approach into either group of thirty patients each.

Group D (n=30): Patients will be given 8ml of 0.25% Bupivacaine with 2ml (8 mg) of Dexamethasone. Group T (n=30): Patients will be given 8ml of 0.25% Bupivacaine with 2ml (100 mg) of Tramadol

Ten milliliters of medication were administered epidurally to each group at the onset of incisional wound closure. The research medications were produced by the pharmacy and administered in identical amounts of 10 milliliters to ensure blinding of the anesthesiologist, and data collection observers about the medication and dosage. 0.05 mg/kg neostigmine and 0.008 mg/kg glycopyrrolate were used to antagonize any remaining neuromuscular block after surgery. Patients were then extubated following reversal and moved to the postoperative care unit (POCU). An additional investigator, who was not aware of the group assignment, continued to observe and care for the patients.

We assessed heart rate (HR), Mean Arterial pressure (MAP), and Oxygen saturation (SpO2) every 15 minutes for the first hour followed by half-hourly for 2 hours. Patients were evaluated and information was documented regarding the time to first rescue analgesia, which is defined as the interval between the end of block performance and the patient's initial request for rescue analgesia. Analgesia following surgery was recorded using a VAS score.VAS (Visual Analogue Scale) scores were recorded at 0, 1st, 3rd, 6th, and 12th postoperative hours. Rescue analgesia of Epidural Top-ups was given either on the patient's request or if the Visual Analogue Scale(VAS) score = 5 or more than 5. A linear numerical scale was used to measure the satisfaction score, with 0 representing total discontent and 10 representing perfect satisfaction. The scores were recorded at 0, 1, 3, 6, and 12 hours after surgery. Vomiting and nauseous episodes were noted.

Data was collected and entered into a Microsoft Excel spreadsheet. IBM SPSS Version 22 was used for all of the analysis. The statistical analysis was done by using a parametric test and the final interpretation was by using the “Z” test (standard normal variant) with 95% significance. For qualitative data, the Chi-square test or Fischer's exact probability test was used and for quantitative data, the Student's t-test was used to draw inferences. P<0.05 was considered statistically significant.

Results

We included 60 patients randomized into two groups. Study groups were comparable in terms of demographic profile (table *1*).

Demographic factors		**Group D(Mean±S.D)**	**Group T(Mean±S.D)**	**P value**
Age (years) (Mean±S.D)		46.7±15.4	43.4±6.9	0.191
Sex	Male	12 (40%)	14 (46.7%)	0.795
	Female	18 (60%)	16 (53.3%)	
Weight (Kgs) (Mean±S.D)		60.6±11.6	63.2±11.3	0.387
Height (cms) (Mean±S.D)		159.9±4.5	161.4±5.3	0.263

Table 1: Demographic profile

Table *2* shows the comparison of Mean Arterial Pressure(MAP) in study groups and we found that Mean arterial pressure was statistically higher in group T compared to group D during intraoperative 45 minutes and 90 mins and also at post-operative 1 hour (p<0.05)

Time (h)		Group D (Mean±S.D)	Group T(Mean±S.D)	P value
Pre-operative	Baseline	101.2±7.1	99.7±6.4	0.408
Intra-operative	15 mins	101.1±6.3	99.7±6.4	0.081
	30 mins	96.2±6.1	98.8±5.7	0.093
	45 mins	94.4±6.1	97.8±5.3	**0.024***
	60 mins	97.9±5.04	100.4±5.2	0.061
	90 mins	94.8±4.4	97.4±4.4	**0.028***
	120 mins	93.3±5.7	95.5±5.5	0.126
Post-operative	0 hour	92.7±5.7	94.4±4.9	0.229
	1 hour	95.9±3.7	97.8±3.4	**0.048***
	3 hours	94.4±3.04	95.6±3.9	0.181
	6 hours	98.9±6.2	98.7±5.1	0.855
	12 hours	97.7±3.7	96.3±3.9	0.167

Table 2: Mean Arterial Pressure (MAP) (mmHg) in the two groups at different intervals of time (hours).
*Significant p-value (<0.05)

Table *3* shows the comparison of Heart rate (HR) in study groups and we found that Heart rate was statistically higher in group T compared to group D during the intraoperative and postoperative periods (p<0.05)

Time (h)		Group D(Mean±S.D)	Group T(Mean±S.D)	P value
Pre-operative	Baseline	87.6±11.2	89.3±7.3	0.491
Intra-operative	15 mins	77.2±5.9	84.8±11.6	**0.002***
	30 mins	75.3±6.2	86.7±10.9	**<0.001***
	45 mins	73.9±5.6	79.8±9.6	**0.006***
	60 mins	71.9±5.6	79.5±9.5	**<0.001***
	90 mins	79.6±9.7	80.6±9.6	0.7
	120 mins	79±9.6	85.5±5.9	**0.002***
Post-operative	0 hour	87.7±10.1	82±6.2	**0.011***
	1 hour	86.3±10.05	81.4±6.4	**0.029***
	3 hours	82.5±8.9	82.8±5.6	0.863
	6 hours	83.2±7.6	81.6±5.8	0.366
	12 hours	78.1±8.7	77.5±8.6	0.790

Table 3:: Mean Heart Rate (HR) in the two groups at different intervals of time (hours).
*Significant p-value (<0.05)

Table *4* shows the comparison of Visual Analogue Scale (VAS) scores in study groups and we found that Visual Analogue Scale scores were statistically higher in group T compared to group D during the postoperative period (p<0.05)

Post-operative Time (h)	Group D(Mean±S.D)	Group T(Mean±S.D)	P value
0 hour	3.43±0.504	3.43±0.504	1
1 hour	3.5±0.509	6.5±0.509	**<0.001***
3 hours	5.03±0.85	6.7±1.5	**<0.001***
6 hours	3.63±0.49	4.87±0.82	**<0.001***
12 hours	4.6±1.006	6.5±1.48	**<0.001***

Table 4: Mean Visual Analogue Scale (VAS) scores in the two groups at different intervals of time (hours).
*Significant p-value (<0.05)

Table *5* shows the comparison of mean satisfaction scores in study groups and we found that the mean satisfaction score was statistically higher in group D compared to group T at 1 hour post-operatively (p<0.05)

Post-operative Time (h)	Group D(Mean±S.D)	Group T(Mean±S.D)	P value
0 hour	8.33±1.5	8.23±1.5	0.797
1 hour	7.2±1.5	6.3±1.4	**0.026***
3 hours	8.9±0.7	9±0.83	0.499
6 hours	9.2±0.91	9.1±0.85	0.770
12 hours	8.8±1.02	8.3±1.1	0.059

Table 5: Mean satisfaction score in the two groups at different intervals of time (hours).
*Significant p-value (0.05)

Table *6* shows the comparison of the requirement of analgesia in study groups and we found that the requirement of analgesia was statistically higher in group T compared to group D during the postoperative period (p<0.05)

Post-operative Time (h)	Group D	Group T	P value
0 hour	0	0	-
1 hour	0	30	**<0.001***
2 hours	0	28	**<0.05***
3 hours	11	25	**<0.001***
6 hours	0	8	**0.005***
12 hours	7	23	**<0.001***

Table 6: Requirement of analgesia among study groups
*Significant p-value (<0.05)

Table *7* shows the comparison of Post Operative Nausea and Vomiting (PONV) in study groups and we found that the Post Operative Nausea and Vomiting was statistically more in group T compared to group D during the postoperative period (p<0.05)

PONV	Group D	Group T	P value
Yes	2	8	**<0.05***
No	28	22	
Total	30	30	

Table 7: Comparison of PONV in study groups
*Significant p-value (<0.05)

Discussion

Anaesthesiologist's top priority has been identified as providing effective pain control, which is crucial. The epidural method is widely used to manage pain following surgery. The epidural catheter can be used to treat post-operative pain following surgery and the regression of spinal analgesia [14]. When compared to systemic administration, opioids that act on spinal cord receptors offer a clear advantage in terms of greater analgesia quality, reduced sedation scores, preservation of physiological function, and superior outcomes. A study showed that Buprenorphine when added to bupivacaine gave early onset and long postoperative epidural analgesia than epidural butorphanol with bupivacaine [15]. According to a study, tramadol blocks impulses from entering the brain by indirectly activating postsynaptic á2-adrenoceptors, which results in monoaminergic spinal regulation of pain [16]. Most patients report a noticeable reduction in pain intensity after using dexamethasone, as it can significantly lessen discomfort [17].

Based on their demographics, the patients in the selected group were similar, and they were all continuously infused with 0.25% bupivacaine. In our study, pain was measured using self-reported data. When treating patients with acute or chronic pain, self-reports of discomfort are helpful [18]. By counting the number of top-ups or additional dosages that patients in both groups needed, the pain was also indirectly assessed.

Throughout the evaluation intervals, group T's mean satisfaction score and Visual Analogue Scale (VAS) score were statistically higher than group D's in our investigation, indicating that dexamethasone was successful in producing the desired amount of analgesia. Additionally, both groups showed a continuously declining pain VAS score from the first time to the end of the study period. This may be due to other unknown variables as well as the constant infusion at a sufficient volume.

This finding is supported by various studies. A study comparing patient-controlled epidural analgesia (PCEA) with continuous epidural analgesia (CEA) in adult surgical patients found that

PCEA patients were more satisfied with analgesia in two studies [19].

Additionally, a study on the use of tramadol as a local anesthetic adjuvant in epidural labor showed excellent maternal satisfaction in the tramadol group [20]. These findings collectively support the notion that Epidural dexamethasone may lead to higher patient satisfaction compared to Epidural tramadol in the context of postoperative analgesia.

In comparison to the group where just bupivacaine was utilized, Khafagy et al [21] discovered that the groups receiving Bupivacaine-fentanyl and Bupivacaine-dexamethasone had considerably lower VAS scores and greater patient satisfaction levels. Additionally, this investigation showed that the analgesic effectiveness of an epidural bupivacaine-dexamethasone mixture was nearly identical to that of bupivacaine-fentanyl.

The cited study found that VAS was statistically higher in epidural dexamethasone compared to epidural tramadol in patients undergoing abdominal surgeries during the post-operative period [22]. However, it is important to note that the cited study did not directly compare epidural dexamethasone and epidural tramadol. Instead, it compared epidural dexamethasone with a combination of epidural tramadol and ropivacaine [23]. Therefore, caution should be taken when interpreting the results. Other studies have shown that both epidural dexamethasone and epidural tramadol can be effective in reducing postoperative pain. A systematic review found that dexamethasone, when used along with local anesthetic, significantly reduces the VAS score and analgesic consumption. Another study found that epidural tramadol was effective for postoperative pain relief [24]. Overall, while the cited study found that the VAS score was statistically higher in epidural dexamethasone compared to epidural tramadol, other studies have shown that both epidural dexamethasone and epidural tramadol can be effective in reducing postoperative pain. Further studies directly comparing Epidural Dexamethasone and Epidural Tramadol are needed to confirm these findings.

Thomas S et.al [25] and Aditi Dhimar et al [26] reported preoperative epidural administration of dexamethasone 5 mg, with or without bupivacaine, reduces postoperative pain and morphine consumption. It also lessens postoperative pain and the need for analgesics.

Due to dexamethasone's effect on Chemoreceptor Trigger Zone(CTZ) and ability to inhibit vomiting, vomiting was reported as a side effect in a significantly higher number of patients in the epidural tramadol group of our study than in the epidural dexamethasone group, where only two patients reported vomiting. The comparison of hemodynamic parameters such as blood pressure, heart rate, and respiratory rate was observed during most assessment intervals in both groups. This suggests that the anti-inflammatory effects of tramadol, which inhibits the excitability of sensory neurons and releases pro-inflammatory neuropeptides, and dexamethasone, which causes vasoconstriction, are similar. Here, a novel way of analysis was applied to evaluate the analgesic efficacy of both medications.

Limitations:

The study had a relatively small sample size of 60 patients, with 30 patients in each group. A larger sample size would enhance the statistical power and generalizability of the findings. The study was conducted at a single center, which may limit the generalizability of the results to other settings with different populations, surgical procedures, and clinical practices. The study excluded patients with certain comorbidities and conditions. This may limit the applicability of the findings to a broader patient population. The study included patients undergoing various abdominal surgeries which may have different degrees of surgical trauma and postoperative pain intensity. The study followed patients up to 12 hours postoperatively. Longer-term follow-up would provide insights into the duration of analgesic effects and potential late-onset adverse events associated with epidural dexamethasone and tramadol. The study assessed outcome measures such as pain scores, satisfaction scores, and adverse events, other relevant outcomes such as long-term pain control, functional recovery, and opioid consumption were not evaluated.

Conclusions

The study found that both epidural dexamethasone and tramadol were effective in providing postoperative analgesia, but epidural dexamethasone was found to be more effective in reducing pain scores and prolonging the duration of analgesia. Therefore, the study concluded that epidural dexamethasone as adjuvant to 0.25% bupivacaine is a better option for postoperative analgesia in patients undergoing abdominal surgeries.

Conflicts of interests- Nil

Financial support and sponsorship- Nil

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