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Original Research Article

Comparison of Dexmedetomidine and Fentanyl as Adjuvant for Bupivacaine in Ultrasound Guided Erector Spinae Block for Laproscopic Cholecystectomy: Prospective Observational Study

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Abstract:

Objective: This prospective observational study aimed to compare the efficacy of dexmedetomidine and fentanyl as adjuvants to bupivacaine in ultrasound-guided erector spinae block for postoperative pain management following laparoscopic cholecystectomy.

Methods: The study included two groups. Group 1 received dexmedetomidine, and Group 2 received fentanyl. Demographic data and baseline characteristics were analyzed, revealing a significant age difference between the groups. ASA physical status categories 1 and 2 were similarly distributed, indicating comparable baseline health statuses. While baseline cardiovascular parameters were comparable, significant differences in diastolic blood pressure and respiratory rate were noted. Clinical parameters, including heart rate, systolic and diastolic blood pressure, were assessed at various time points postoperatively. Numerical Rating Scale (NRS) scores for pain assessment were analyzed over the study period. The time interval from the injection of local anesthetic until the first demand for analgesic or the need for postoperative pain management (MNT) was compared between the groups. Total tramadol consumption and the incidence of postoperative nausea and vomiting were also assessed.

Results: Group 1 exhibited varying heart rates compared to Group 2 at 2, 4, 6, 12, and 24 hours postoperatively. Significant differences in diastolic blood pressure at 2 hours suggested early divergence between the groups. NRS scores showed significant variations at 2, 4, 6, and 12 hours, indicating distinct effects of dexmedetomidine and fentanyl on pain perception. Group 1 demonstrated a significantly longer duration until the first demand for analgesic compared to Group 2. Total tramadol consumption was comparable between the groups, suggesting similar efficacy in controlling postoperative pain. The occurrence of postoperative nausea and vomiting did not significantly differ, but a trend in Group 1 suggests further exploration.

Conclusion: Dexmedetomidine and fentanyl as adjuvants to bupivacaine in ultrasound-guided erector spinae block exhibit differential effects on hemodynamic parameters and pain management. Dexmedetomidine prolonged the duration until the first demand for analgesic, indicating potential benefits in postoperative pain control. Total tramadol consumption and the incidence of postoperative nausea and vomiting were comparable, warranting further investigation into potential clinical implications. These findings contribute to the understanding of optimal adjuvant selection for enhanced postoperative pain management in laparoscopic cholecystectomy patients.

Keywords: Dexmedetomidine , Erector spinae plane block, Fentanyl , Institutional Review Board.

Introduction

An interfascial plane block called the erector spinae plane block (ESPB) works by successfully depositing a local anesthetic between the erector spinae muscle and the transverse process. ESPB is a straightforward and secure substitute analgesic method for treating adults and children with acute postsurgical, posttraumatic and chronic neuropathic thoracic pain. Clinical research have already shown its effectiveness in reducing discomfort around incisions. It is possible to do the ESP block using ultrasound guidance. The focus is the transverse process, which is clearly identifiable and situated at a reasonable distance from the pleura and significant arterial or neurological systems. One advantage is that deep analgesia may be obtained with only one puncture. Another significant benefit of the ESP block seems to be its ability to offer both visceral and somatic analgesia. Effective postoperative analgesia is achieved with ESP block when it is administered at the T 7 level for abdominal surgery

and at the T 4 and T5 level for breast and thoracic surgery. There are two reasons why a laproscopic cholecysectomy could hurt. The first is parietal pain from a skin incision and the second is visceral pain from the trauma of gallbladder excision [1].

This block may be applied relatively far from the surgical zone and in a seated, lateral decubitus or prone position. It is crucial to use strategies that extend the duration of analgesia using peripheral nerve blocks given with a single injection since it is not always feasible to admit patients to a ward with peripheral nerve catheters that are implanted. Today, it is acknowledged that dexmedetomidine is a strong α2(alfa2) agonist that may be used in addition to regional anesthesia and analgesia. It may lengthen the time of the nerve block. When used with a local anesthetic, it causes anesthestic with very little side effects. Few studies have compared the effectiveness of fentanyl and dexmedetomidine as adjuvants with bupivacaine for erector spinae block [2].

This study aimed to analyse whether dexmedetomidine is superior to fentanyl when used as adjuvant for bupivacaine in USG guided erector spinae block to control postoperative pain after laparoscopic cholecystectomy.

Objective

Primary objective of the study was to compare the efficacy of dexmedetomidine and fentanyl when used as adjuvant for bupivacaine in US guided erector spinae block to control postoperative pain after laproscopic cholecystectomy.

Hypothesis of the study was dexmedetomidine when used as an adjuvant with bupivacaine was more efficient than fentanyl in controlling postoperative pain of laproscopic cholecystectomy.

Materials and Methods

Type of Study: Prospective observational study

Study Setting: The study was conducted in the the Department of Anaesthesiology and the Department of General Surgery at Government Medical College, Kottayam.

Study Period: The study spanned 6 months from the approval of the Institutional Review Board (IRB).

Sample

Sample size calculation was performed using the formula: Sample**,**

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \, SD^2 \, (r+1)}{d^2}$$

$Z_{\alpha/2}$ = standard normal deviate for two-tailed test based on alpha level = 1.96 Z_{β} = standard normal deviate for one-tailed test based on beta level = 0.84
r = ratio = $n_2/n_1 = 1$

SD= average SD of NRS 3 hours postoperatively of the two groups= $\frac{(SD_1+SD_2)}{2}$

$= \frac{(1.25+1)}{2} = 1.125$

d = difference in NRS 3 hours postoperatively between the two groups= 1 from the study done by Freideriki Sifak et al

The calculated sample size was 20 in each group, resulting in a total sample size of 40.

Participants: ASA 1 and ASA 2 female patients, aged 18-65, undergoing elective cholecystectomy were included. Patients were grouped based on the adjuvant used: Group I (Dexmedetomidine) and Group II (Fentanyl).

Inclusion Criteria:

1. Adult female patients aged 18-65 years.
2. Patients belonging to ASA 1 and ASA 2.

Exclusion Criteria: Patients were excluded if they refused erector spinae block, had coagulopathy, bradycardia, cardiac conduction block, were on β-adrenergic antagonist or an antiplatelet agent, had a history of allergy to any of the drugs used. Exclusion criteria also included central neuropathy, BMI >35 kg/m², uncontrolled diabetes mellitus, significant cardiopulmonary disease, or psychiatric disease.

Sampling Method: Convenient sampling was employed until the required sample size was reached.

Study Tools:

1. Proforma
2. Numerical Rating Scale (NRS)

Study Procedure: After obtaining Institutional Review Board clearance, a comparative study was conducted at the Department of Anaesthesiology, Government Medical College, Kottayam. Patients planned for laparoscopic cholecystectomy were interviewed during routine pre-anaesthetic check-up. Information was collected on sex, age, weight, history of co-morbid illness, and presence of any exclusion factors. A clinical airway assessment using the Mallampatti classification was performed. Routine blood investigations, ECG and chest X-ray were conducted. Informed written consent was obtained.

All eligible patients were kept fasting for 8 hours and received tablet alprazolam 0.25mg, tablet ranitidine 150 mg and tablet metoclopramide 10 mg at night and in the morning of surgery.

In the pre-operative room, intravenous access was secured and fluids were initiated. Patients were explained in detail about the anesthesia procedure and the Numerical Rating Scale (from 0-10). Patients were allocated into two groups, Group 1

(Dexmedetomidine) and Group 2 (Fentanyl). An assistant prepared the study drugs. Patients received either 0.25% bupivacaine 20 mL on each side with .5 µg/kg dexmedetomidine or 0.25% bupivacaine 20 mL with .5 µg/kg fentanyl (F), deep to the erector spinae muscle adjacent to transverse processes.

General anesthesia was standardized for all patients in both groups. Premedication included Inj. Fentanyl 2 mcg/kg i/v, Inj. Midazolam 0.02 mg/kg i/v, and Inj. Glycopyrrolate 10mcg/kg i/v. After 3 minutes of pre oxygenation with 100% of Oxygen, Anaesthesia was induced with 2mg/kg of propofol and vecuronium 0.1mg/ kg intravenously then mask ventilated for 3 minutes and oral intubation was done with an appropriately sized cuffed oral endotracheal tube. Anesthesia was maintained with nitrous oxide: oxygen in the ratio 4:2. Muscle relaxation was achieved by vecuronium at a maintenance dose of 1/5th of the loading dose. Intraoperative monitoring included continuous electrocardiography, noninvasive blood pressure, pulse oximetry (SpO2) and end-tidal carbon dioxide. IV Ondansetron 4mg was administered 30 min prior to the end of surgery and then 8 hours in the postoperative period. Intraoperative analgesia was provided with inj. paracetamol 15mg/kg. At the completion of surgery, when spontaneous attempts appeared, the neuromuscular block was reversed with IV Neostigmine 50 µg/kg and Glycopyrrolate 10 µg/kg. After the patient became fully conscious, the trachea was extubated. In the recovery room, monitoring was continued with pulse rate, blood pressure, and SpO2. In the postoperative period, the quality of analgesia was determined by the NRS scale at intervals of 0, 2, 4, 6, 12, and 24 hours. Patients were asked to circle the number between 0 and 10 (0: no pain, 10: worst pain). The duration of analgesia was determined by the time interval from the injection of local anesthetic until the first demand for analgesic in minutes. Rescue analgesia was provided with injection paracetamol 1 gm infusion. Additionally, total tramadol consumption in milligrams and postoperative nausea and vomiting (PONV) were assessed during the postoperative period up to 24 hours. Heart rate and blood pressure were also assessed.

Data Analysis:

The collected data was coded and entered into a Microsoft Excel sheet and subsequent analysis was conducted using SPSS statistical software version 22. Quantitative variables were summarized using the mean and standard deviation (SD), while categorical variables were presented as frequencies and percentages. To compare quantitative variables between the two groups, an independent sample t-test was performed. The paired t-test was employed to assess changes in parameters between baseline and the end of the follow-up period. The association of different qualitative variables between the groups was tested using the Chi-square test or Fisher's exact test, as appropriate. A significance level of $p<0.05$ was considered statistically significant in all analyses

Results

1. Demographic data and base line characteristics among the study groups

The study groups, comprising Group 1 administered with dexmedetomidine and Group 2 with fentanyl, were analyzed for demographic data and baseline characteristics. Group 1 exhibited a mean age of 41.32 ± 6.1 years, while Group 2 had a mean age of 41.1 ± 9.4 years, showing a statistically significant age difference ($p = 0.01$), indicating dissimilarity in age distribution ASA physical status categories 1 and 2 were similarly distributed across both groups ($p = 0.5$), indicating comparable baseline health statuses. Additionally, no significant differences in weight and BMI ($p = 0.908$ and $p = 0.548$, respectively) suggested similarity in baseline body weight and mass index. Comparable baseline cardiovascular parameters were observed for heart rate and systolic blood pressure ($p = 0.194$ and $p = 0.651$ respectively). Notably, a significant divergence in diastolic blood pressure ($p = 0.005$) and respiratory rate ($p = 0.012$) indicated differences in these baseline parameters between the two groups. (Table 1)

Table 1: Demographic data and base line characteristics among the study groups

Variable	Group		P value
	Group 1-dexmedetomidine	Group 2-fentanyl	
AGE	41.32±6.1	41.1±9.4	0.01
ASA 1 2	 8 11	 10 10	0.5
WEIGHT	68.11± 6.181	66.65± 7.013	0.908
BMI	26.79 ±2.840	26.79 ±2.840	0.548
HR	80.68 ±10.662	77.00 ±13.955	0.194
SBP	118.79 ±9.925	123.15 ±10.854	0.651
DBP	77.58 ±9.179	75.50 ±5.216	0.005
RR/mint	14.68 ±1.827	15.10± 1.071	0.012
P-value < 0.05 (significant) P-value > 0.05 (non-significant)			

2. Clinical parameters at the different study groups over the study period

The clinical parameters were assessed at different time points for the two study groups (Group 1 - dexmedetomidine and Group 2 - fentanyl). Regarding heart rate, a statistically significant difference was observed at 2 hours (p = 0.007), 4 hours (p = 0.008), 6 hours (p = 0.04), 12 hours (p = 0.01), and 24 hours (p = 0.01) between the groups. Specifically, Group 1 exhibited varying heart rates compared to Group 2 at these time points. However, no statistically significant differences were noted in systolic blood pressure (BP) between the groups across all time points. In contrast, diastolic BP showed a significant difference at 2 hours (p = 0.02), suggesting a divergence between the two groups at this early time point. Overall, these findings imply that while heart rate differences were prominent throughout the study period, systolic BP remained comparable between the groups, except for a significant diastolic BP difference at 2 hours. (Table 2)

Table 2: Clinical parameters at the different study groups over the study period

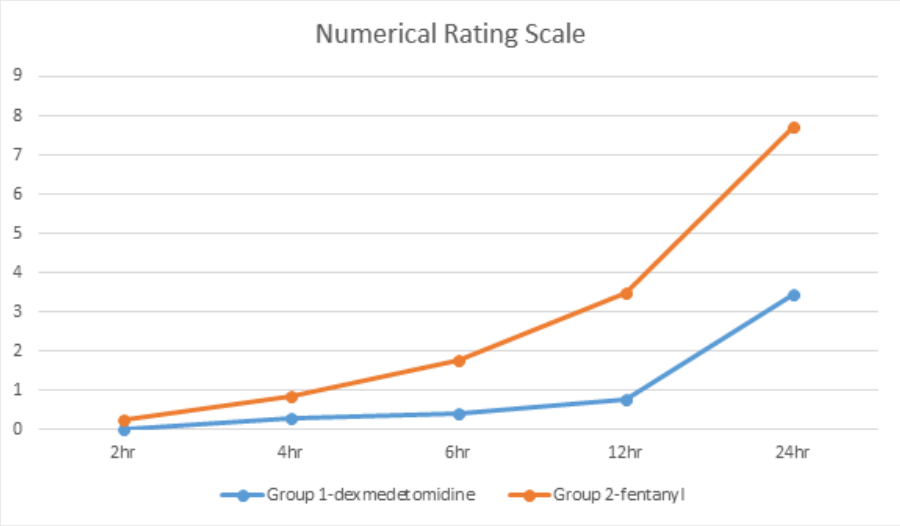
Variable	Characteristics	Group		P value
		Group 1-dexmedetomidine	Group 2-fentanyl	
Heart Rate	**2hr**	77.95 ±10.385	77.75± 5.399	0.007
	4hr	75.80 ±10.501	78.50± 5.247	0.008
	6hr	77.30 ±9.979	80.05± 5.744	0.04
	12hr	76.70 ±10.839	82.65± 4.082	0.01
	24hr	82.65 ±11.165	81.32 ±4.042	0.01
Systolic BP	**2hr**	117.35 ±9.593	121.90 ±9.915	0.9
	4hr	116.90 ±8.466	124.0±10.643	0.3
	6hr	117.30 ±8.706	125.0±10.613	0.2
	12hr	118.45 ±8.401	124.05±7.302	0.3
	24hr	123.10 ±7.461	124.37±7.595	0.6
Diastolic BP	**2hr**	76.15 ±8.343	76.85±4.487	0.02
	4hr	76.40 ±8.382	75.60±6.336	0.1
	6hr	76.15 ±8.190	76.80±5.502	0.1
	12hr	76.25 ±7.946	77.90±6.181	0.5
	24hr	78.20 ±7.388	76.95±7.043	0.7
P-value < 0.05 (significant) P-value > 0.05 (non-significant)				

3. Mean Numerical rating scale to access the pain at the different study groups

The mean Numerical Rating Scale (NRS) scores for pain assessment in different study groups (Group 1 - dexmedetomidine and Group 2 - fentanyl) over the study period were analyzed. At various time intervals postoperatively, significant differences were observed in NRS scores between the groups. Specifically, at 2 hours (p = 0.00), 4 hours (p = 0.003), 6 hours (p = 0.00), and 12 hours (p = 0.05), the NRS scores demonstrated statistically significant variations, indicating a notable difference in pain perception between the two groups during these time points. However, at 24 hours postoperatively, the NRS scores did not exhibit a statistically significant difference (p = 0.5) between Group 1 and Group 2. These results suggest that dexmedetomidine and fentanyl may have distinct effects on pain management, with significant differences observed at earlier time intervals.

Table 3: Mean Numerical rating scale to access the pain at the different study groups

Variable	Characteristics	Group		P value
		Group 1-dexmedetomidine	Group 2-fentanyl	
NRS	2hr	0.00±0.000	0.25±0.444	0.00
	4hr	0.30±0.470	0.55±0.826	0.003
	6hr	0.40±0.503	1.35±1.268	0.00
	12hr	0.75±0.786	2.75±1.209	0.05
	24hr	3.45±0.887	4.26±0.806	0.5
P-value < 0.05 (significant) P-value > 0.05 (non-significant)				



4. The time interval from the injection of local anesthetic at the different study groups

The time interval from the injection of local anesthetic until the first demand for analgesic or the need for postoperative pain management (MNT) differed significantly between the two groups. Group 1 (17.05±3.634) exhibited a longer duration compared to Group 2 (7.21±1.316), with a statistically significant difference (p = 0.01). This suggests that the administration of local anesthetic in Group 1 resulted in prolonged analgesia, delaying the onset of the first demand for analgesic.

In terms of total tramadol consumption in milligrams, no statistically significant difference was found between Group 1 (55.00±48.395) and Group 2 (107.89±47.910) (p = 0.9). This indicates that the overall tramadol usage for pain management was comparable between the two groups, suggesting similar efficacy in controlling postoperative pain.

Regarding postoperative nausea and vomiting, the occurrence did not significantly differ between the groups, with 6 cases in Group 1 and 1 case in Group 2 (p = 0.09). While not reaching statistical significance, this trend suggests a potential difference in the incidence of postoperative nausea and vomiting between the two groups. Further investigation may be warranted to explore these findings.

Table 4: The time interval from the injection of local anesthetic at the different study groups

Variable	Characteristics	Group		
		Group 1-dexmedetomidine	Group 2-fentanyl	P value
T-interval injection of local anaesthetic till first demand of analgesic/mnt		17.05±3.634	7.21±1.316	0.01
Total tramadol consumption in milligrams"		55.00±48.395	107.89 ± 47.910	0.9
Post-operative nausea and vomiting	Yes No	6 14	1 18	0.09
P-value < 0.05 (significant) P-value > 0.05 (non-significant)				

Discussion

Laparoscopic cholecystectomy (LC) does not require advanced techniques, and its performance has therefore rapidly spread worldwide. However, postoperative pain management, particularly early postoperative pain, remains a matter of concern for several anesthesiologists and surgeons. To reduce the postoperative pain in patients undergoing lap cholecystectomy various modalities have been used, one such modality is erector spinae plane block. Erector spinae plane block (ESPB) is a novel posterior thoracic wall block that the local anesthetics is injected locally in the deep erector spinae muscle surface, as a part of multimodal analgesia. Given that erector spinae muscles anatomically situated along the thoracolumbar spine, ESPB promotes an extensive craniocaudal spread. [3,4]

Previous studies have shown that ESPB can provide effective analgesia in breast, chest, and abdominal surgery, and in thoracotomy. [3–7] Emerging research demonstrated that ESPB can be employed as a simple and safe alternative analgesic technique to address acute post-surgical, posttraumatic, and chronic neuropathic thoracic pain in adults1 and children. [8,9]

Ultrasound is a non-invasive visualization technology that helps capture the anatomical structure of target tissues; it can help guide the direction and depth of anesthesia puncture needles, thus reducing the risk of complications. [10,11]

Adjuvants to local anesthetics such as fentanyl. [13] and dexmedetomidine, [7,12] may improve the quality and duration of peripheral nerve block effects. Adding an adjuvant, such as dexmedetomidine or fentanyl, to a nerve block improves its quality and reduces perioperative opioid consumption. Since it is not always feasible to admit patients to a ward with indwelling peripheral nerve catheters, it is imperative to employ methods to increase the duration of analgesia with single-shot peripheral nerve blocks.

Dexmedetomidine, a new highly selective α2-agonist, is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects. Various studies have compared dexmedetomidine and fentanyl with isobaric bupivacaine intrathecally. [14,15] But there is a paucity in literature in studies comparing efficacy of dexmedetomidine vs fentanyl as adjuvant to bupivacaine in erector spinaeblock. Hence the need for this study.

The current study investigated the comparative efficacy of dexmedetomidine and fentanyl in postoperative pain management, highlighting several noteworthy findings. Baseline differences in age, diastolic blood pressure, and respiratory rate were observed between the two groups, suggesting variations in physiological parameters. Throughout the study, Group 1 (dexmedetomidine) exhibited significant differences in heart rate at various time points, while systolic blood pressure remained comparable, except for a notable diastolic blood pressure difference at 2 hours. Pain assessment using the Numerical Rating Scale indicated significant differences in perception at multiple early time intervals, suggesting distinct effects of dexmedetomidine and fentanyl on pain management. Group 1 also demonstrated a significantly longer duration until the first demand for analgesic, emphasizing prolonged analgesia with dexmedetomidine. However, total tramadol consumption and the incidence of postoperative nausea and vomiting did not differ significantly between the groups.

Comparing these findings with other relevant studies provides valuable insights. Gao et al. [15] explored dexmedetomidine as an adjuvant for ropivacaine in erector spinae block for video-assisted thoracoscopic surgery (VATS). Their results align with our study, indicating prolonged sensory block duration and effective acute pain control with dexmedetomidine. Mostafa et al. [16] investigated ultrasound-guided erector spinae plane block in laparoscopic bariatric surgery, reporting decreased analgesic consumption without significant impact on postoperative pulmonary functions, consistent with our findings of prolonged analgesia duration. Rao et al. [17] compared nalbuphine and dexmedetomidine as adjuvants to ropivacaine in erector spinae plane block for VATS, highlighting reduced postoperative pain, total PCA use, and rescue analgesia, aligning with our observations. Sifaki et al. [18] and Jian et al. [19] also supported the efficacy of erector spinae plane block with dexmedetomidine in laparoscopic cholecystectomies and thoracoscopic wedge resection, respectively. Additionally, Wang et al. [20] demonstrated that adding dexmedetomidine to ropivacaine for erector spinae plane block prolonged postoperative analgesia without increasing adverse effects, supporting our study's findings.

Conclusion

The present study reveals a significant difference in the duration of erector spinae block between the use of dexmedetomidine and fentanyl, with dexmedetomidine exhibiting a longer duration. This finding underscores the potential superiority of dexmedetomidine as an adjuvant in regional anesthesia, suggesting extended analgesic effects compared to fentanyl. The observed difference in block duration may have implications for postoperative pain management, highlighting dexmedetomidine's potential to provide prolonged pain relief in the context of erector spinae block. Further research and exploration of the specific mechanisms underlying this difference are warranted to optimize the utilization of dexmedetomidine in enhancing the efficacy of regional anesthesia.

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