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Original Research Article

Efficacy of ultrasound guided erector spinae plane block with or without dexmedetomidine on the postoperative analgesia in patients undergoing laparoscopic cholecystectomy: a comparative study

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ABSTRACT

Background: A crucial problem in laparoscopic cholecystectomy, the most common intra-abdominal surgical procedure, is substantial postoperative pain despite improvements in anaesthesia and surgery. Many minor to medium level surgical procedures are associated with severe postoperative pain occurring in about 20-40% of the patients.
Methods: The study groups were divided into two, named group A and group B. In Group A, all the patients were received, bilateral Erector Spinae Plane Block (ESPB) with 19 ml of 0.375% Ropivacaine + 1ml of 0.9% NS (20 ml on each side) and in the Group B, all the patients were received, bilateral Erector Spinae Plane Block (ESPB) with 19 ml of 0.375% Ropivacaine + 1ml of dexmedetomidine (0.5mcg/kg) (20 ml on each side).
Results: Overall findings highlighted that Group B has superior pain control and hemodynamic stability as compared with Group B at multiple postoperative time intervals. Group A maintains higher heart rates and MAP values early on, suggesting different cardiovascular responses between the two treatment groups throughout the assessment period. None of the patients required atropine for treatment of bradycardia.
Conclusions: The study showed that addition of dexmedetomidine to ropivacaine for ESP block in laparoscopic cholecystectomy resulted in superior postoperative analgesia and a reduction in the total consumption of rescue analgesics. Dexmedetomidine had a more favourable impact on hemodynamic parameters indicating better cardiovascular stability perioperatively.

Keywords: Erector spinae plane block, Ropivacaine, Dexmedetomidine, Post operative analgesia

INTRODUCTION

A crucial problem in laparoscopic cholecystectomy, the most common intra-abdominal surgical procedure, is substantial postoperative pain despite improvements in anaesthesia and surgery.[1,2] Many minors to medium level surgical procedures are associated with severe postoperative pain occurring in about 20-40% of the patients. Severe pain is associated with decreased patient satisfaction, delayed postoperative ambulation, development of chronic postoperative pain, increased incidence of pulmonary and cardiac complications and increased morbidity and mortality. Among various surgical procedures, laparoscopic cholecystectomy is at 94th rank with average pain score (NRS) of 4.76.[1] Inadequately controlled postoperative pain continues to be

a widespread health care problem despite improved understanding of pain mechanisms, increased awareness of the prevalence of postsurgical pain, advances in pain-management approaches, and other focused initiatives aimed at improving pain-related outcomes in recent decades.[2]

Several regional anaesthesia techniques like thoracic epidural analgesia (TEA), paravertebral block, intercostal block, pectoral block and erector spinae plane block have been used to provide postoperative analgesia. Truncal blocks have emerged to be an attractive multimodal approach to pain control for a variety of abdominal surgeries. Wahal and his co researchers had commented that in ESP block, a single interfacial injection of 20 ml of 0.5% Ropivacaine at T5 level (3 cm from the midline) can result in sensory blockade from T3 to T9 over posterior thorax and T3 to T6 anterolateral thoracic area by blocking the ventral and dorsal rami of the thoracic spinal nerves.[3] Application of ultrasonography in regional anaesthesia has significantly improved the quality of nerve blocks and patient satisfaction.[3]

The ultrasound guided erector spinae plane block (ESPB) is a paraspinal interfacial plane block, first described by Forero et al.[4] This novel but simple technique been successfully applied in 2 cases of severe thoracic neuropathic pain as well as 2 cases of acute postsurgical pain. The local anaesthetic solution is deposited beneath the erector spinae muscle above the transverse process under ultrasound guidance and is technically easy to perform.

Various adjuvants are frequently added to local anaesthetics to prolong the duration of action. Dexmedetomidine being a flexible medication is being widely used in various clinical circumstances without further restricting only to the intensive care unit sedation.[5] Dexmedetomidine is seven times more selective alpha-2 receptor agonist compared to Clonidine with similar mechanism.[6] There are very few studies on the use of dexmedetomidine with local anaesthetic solution in ESP block.[7] No study has been conducted on the use of dexmedetomidine with local anaesthetic ropivacaine in ESP block in our ethnic population.

So, the present study was undertaken to study the efficacy of dexmedetomidine with local anaesthetic in erector spinae plane block for postoperative analgesia in patients undergoing laparoscopic cholecystectomy.

METHODS

A randomized double blinded study was conducted in the Department of Anaesthesiology, Regional institute of medical sciences (RIMS), Imphal, Manipur from April 2023 to March 2025 consisting of 60 patients totally. The permission of the Research Ethics Board, RIMS, Imphal, Manipur was obtained before initiating the study. Informed written consent were taken from all patients.

Inclusion criteria include, Patients of either gender, Age between 18 to 60 years, ASA (American Society of Anaesthesiology) category 2, MBI (Body Mass Index): 18 – 25 kg/m^2.

Exclusion criteria include, patient refusal and allergic to study drugs (Local anaesthetics), bleeding disorders – platelet count <50,000/ micro litre, prothrombin time >14 sec and international normalised ratio (INR) >1.5, local site infection and with neurological deficits of lower limb and torso, cardiac and respiratory diseases, chronic renal diseases, pregnancy, spinal deformity, and cognitive impairment.

The study groups were divided into two, named group A and group B. The total sample size was 60 (30 patients in each group). Patients were allocated by using computer generated randomization chart. In Group A, all the patients were received, ESPB with 19 ml of 0.375% Ropivacaine + 1ml of 0.9% NS (20 ml on each side) and in the Group B, all the patients were received, ESPB with 19 ml of 0.375% Ropivacaine + 1ml of dexmedetomidine (0.5mcg/kg) (20 ml on each side).

All patients received tablet alprazolam 0.5 mg at bedtime the night before surgery. Two hours prior to the procedure, intravenous access was established, and patients were administered injection pantoprazole 40 mg and injection metoclopramide 10 mg in the preoperative holding area. Maintenance fluids were initiated as per standard protocol.

On arrival in the operating room, standard monitoring was initiated, including heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), and electrocardiogram (ECG). After preoxygenation for three minutes, general anaesthesia was induced with Fentanyl l2 µg/kg, Propofol 2 mg/kg, and Succinylcholine 2 mg/kg to facilitate endotracheal intubation. Anaesthesia was maintained with Oxygen, Nitrous oxide, and Sevoflurane (0.6–1.5%), along with Vecuronium 0.08 mg/kg for muscle relaxation. Intermittent positive pressure ventilation was used to maintain end-tidal carbon dioxide ($EtCO_2$) between 30–35 mmHg. Intraoperative hypotension (SBP < 100 mmHg or < 80% of baseline) was treated with 100 ml of normal saline and 3 mg of mephentermine, while bradycardia (HR < 50/min) was managed with Atropine 0.3–0.6 mg.

After induction of general anaesthesia and endotracheal intubation, patients were positioned in the right lateral decubitus position. Under strict aseptic precautions, a linear ultrasound probe (Mindray M7 Premium, China; Linear transducer L12-4s) was placed in a parasagittal orientation approximately 3 cm lateral to the T7 spinous process. The ultrasound landmarks, including the T7 transverse process and the overlying trapezius, rhomboid, and erector spinae muscles, were identified. A stimuplex needle was inserted in an out-of-plane technique until contact was made with the T7 transverse process. After hydro dissection with 2–3 mL of normal saline and

confirming negative aspiration, 15 mL of the study drug was deposited in the interfacial plane beneath the erector spinae muscle. The procedure was repeated on the contralateral side to achieve bilateral block.

At the end of surgery, residual neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg. Patients were extubated and transferred to the post-anaesthesia care unit (PACU) for monitoring. Postoperative pain was assessed using the visual analog scale (VAS) at 0, 4, 6, 12, and 24 hours. Rescue analgesia (intramuscular diclofenac 75 mg+ intravenous paracetamol 10–15 mg/kg) was administered if the VAS score was ≥4. The total consumption of rescue analgesics in the first 24 hours was recorded, along with any adverse effects such as hypotension, bradycardia, nausea, vomiting, or shivering.

The measured variables were checked for the normality of their distribution with the Shapiro-Wilk test and Q-Q plot. Normally distributed, continuous variables were presented with mean±standard deviation (mean±SD), while continuous variables with non-parametric distribution and ordinal variables were presented with median and interquartile range (median, IQR). Qualitative or categorical variables were presented as numbers and percentages. The level of statistical significance was set at $p<0.05$. The statistical analysis of the results was performed using SPSS software version 27. Comparisons were performed among independent t-tests for independent variables in multiple groups with normal distribution, whereas non-parametric variables were checked with the Mann Whitney U test. Also, Chi-square test was performed to test the association between two categorical or nominal data.

RESULTS

Table 1 compares various parameters of the two groups tested with Group A and Group B. The mean age±SD of the Group A and Group B are 43.00±14.75 and 40.80±7.76, respectively. No statistically significant difference between the two groups was observed as revealed by the p-value. The mean weight of the group A is 62.20 kg, whereas the mean weight of the Group B is 61.67 kg. No significant difference in weight between the two groups. In both groups, the majority are female. In the ASA classification also, the majority, i.e., more than 70%, are ASA I. No significant associations were observed in both sex and ASA classification between the two groups. The duration of surgery was also the same between the two groups.

However, statistically significant differences were observed in the total dose of analgesic and duration of analgesia outcomes between the two groups.

Table1: Demographic characteristics, duration of surgery, duration of analgesia and total dose of analgesic consumed.

Variables	Group A	Group B	P value
Age in years	43±14.8	40.8±7.76	0.473
Sex			0.417
Male	5(16.7%)	7(23.3%)	
Female	25(83.3%)	23(76.7%)	
Weight	62.2±7.3	61.67±10.1	0.816
ASA I	22(73.3%)	25(83.3%)	0.884
ASA II	8(26.7%)	5(16.7%)	
Duration of surgery	48.3±8.4	47.1±11.8	0.634
Duration of analgesia	600(345-1440)	1440(1440-1440)	<0.01
Total dose of analgesic	1000 (0-1000)	0(0-0)	<0.01

Table 2 presents a comparative analysis of VAS scores at rest and VAS scores at cough between two groups tested with Group A and Group B at different time intervals (0, 4, 6, 12, and 24 hours).

At initial time, i.e., 0 hour, both groups reported no pain, having a median VAS score at rest of 0 with IQR (0-0), highlighting no statistically significant difference between them. A similar result was observed in the VAS score at cough at the same time interval between the groups (p=0.677). However, at 4 hours, a significant difference in both cases, i.e., the median VAS score at rest and the VAS score at cough were observed between the two groups. Such a pattern of significant difference in the VAS score at rest for two groups continued up to 24 hours. Whereas at the time of 12 hours, no significant difference between the two groups was observed in the VAS score at cough with p value=0.081. At 24 hours, a significant difference in the median VAS score was observed between the groups.

Overall, these findings highlighted that Group B has superior pain control and hemodynamic stability as compared with Group B at multiple postoperative time intervals.

Table 2: Comparative analysis of VAS at rest and at cough between group A and group B.

Time	VAS at rest			Vas at cough		
	Group A Median (IQR)	Group B Median (IQR)	P value	Group A Median (IQR)	Group B Median (IQR)	P value
0 hour	0(0 -0)	0(0-0)	0.317	0(0-0)	0(0-0)	0.677
4 hour	0(0-2)	0(0-0)	0.036	1(0-3)	0(0-0)	0.013
6 hour	2(0-2)	0(0-0)	0.000	3.0(0-6)	1 (0-1)	0.011
12 hour	1(0-2.0)	0(0-0)	0.003	2(1-3)	1(1-2)	0.081
24 hour	1(0 -1.0)	0(0-0)	0.001	2(1-2)	0.5(0-1)	0.001

Table 3: Comparative analysis of heart rate and mean arterial pressure between group A and group B.

Time	Heart rate			MAP		
	Group A Mean±SD	Group B Mean±SD	P value	Group A Mean±SD	Group B Mean±SD	P value
0 minute	78.8±12.6	81.9±10.8	0.299	96.1±11.3	95.8±10.3	0.915
5 minute	77.7±13.3	71.0±9.7	0.029	93.5±14.1	84.4±11.9	0.009
10 minute	77.5±12.5	66.7±7.7	<0.01	95.5±14.8	88.7±15.8	0.092
15 minute	76.7±12.8	63.5±8.3	<0.01	96.6±12.4	88.6±12.0	0.013
20 minute	78.6±12.3	60.2±7.3	<0.01	98.0±14.1	89.4±10.3	0.009
30 minute	80.7±14.1	61.2±8.1	<0.01	99.07±9.98	92.0±11.7	0.015
40 min	80.8±13.9	65.3±8.4	<0.01	98.9±10.9	89.2±11.2	0.001

Table 3, Figure 1 and 2 compared the heart rate and mean arterial pressure (MAP) measurements between the Group A and Group B at various time intervals. There was significant difference in both SBP and DBP between the two groups which was maintained till 40 minutes. Group A exhibited consistently higher blood pressure reading ($p<0.05$) as shown in Figure 3.

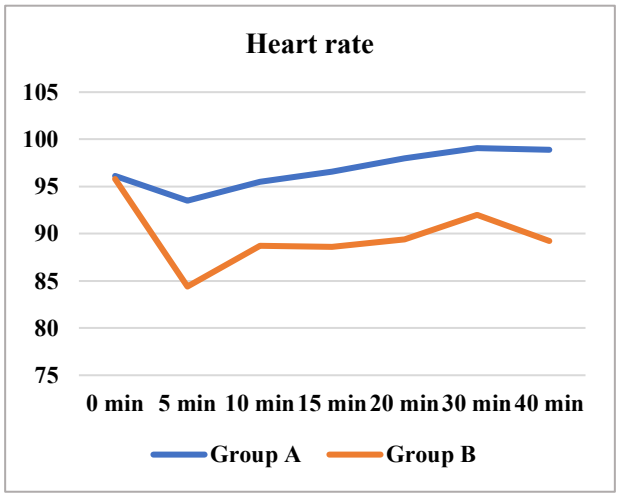

Figure 1: Comparison of heart rate between group A and group B.

At the initial time, i.e., 0 minutes, no significant differences in heart rate were observed between the two groups. A similar result was also observed in MAP. However, significant differences begin at 5 minutes, where the Group A shows a higher heart rate (77.7±13.3) compared to the Group B (71.0±9.7, p=0.029), and a similar trend is observed for MAP (Group A: 93.5±14.1 vs. Group B: 84.4±11.9; p=0.009).

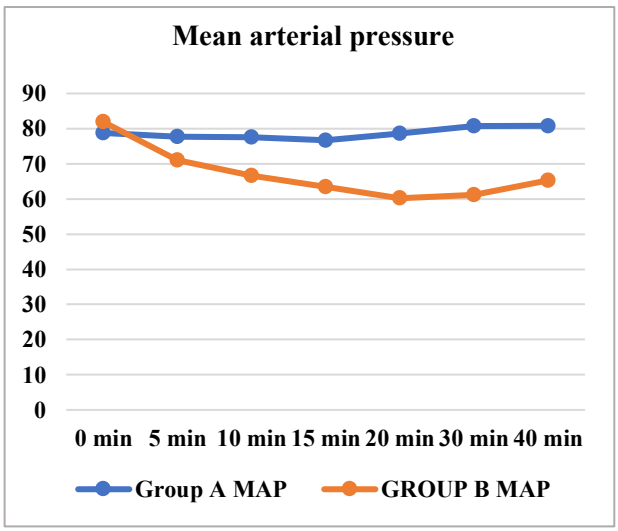

Figure 2: Comparison of MAP between group A and group B.

This pattern of different heart rates in between the groups remains at 10 minutes, 15 minutes, and 20 minutes. Significant variations in MAP are also noted at 15 minutes (p=0.013) and 20 minutes (p=0.009). Although the differences in heart rate remain significant up to 40 minutes, the MAP difference becomes highly significant at this time (p=0.001), while the heart rates for Group A and Group B do not differ significantly at 30 minutes.

Overall, these findings indicate that the Group A maintains higher heart rates and MAP values early on, suggesting different cardiovascular responses between the two treatment groups throughout the assessment period. However, bradycardia at 5 minutes was observed in one patient each from Group A and Group B. At 10 minutes in two patients belonging to Group A, bradycardia was observed. At 20 minutes fourteen patients from Group B underwent bradycardia. None of the patients required atropine for treatment of bradycardia.

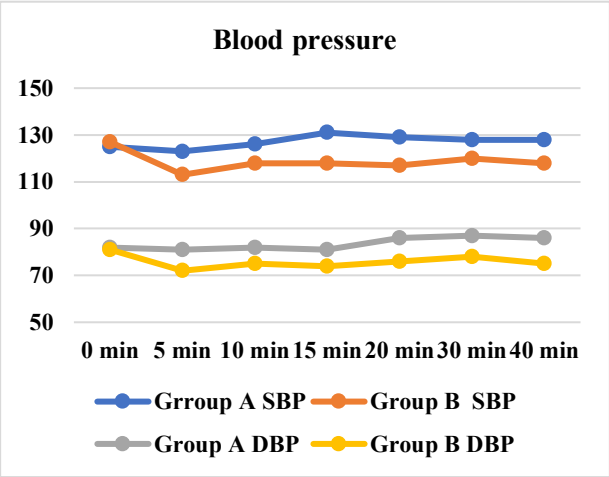

Figure 3: Comparison of SBP and DBP between Group A and Group B.

DISCUSSION

The erector spinae plane (ESP) block is a versatile and safe regional anaesthesia technique that provides effective analgesia for a wide range of surgical procedures. The use of adjuvants can further enhance the quality and duration of the block, reducing the need for systemic opioids and improving patient outcomes. Adjuvants in ESP block, such as dexamethasone, dexmedetomidine, clonidine, and buprenorphine, are used to prolong the duration of analgesia, enhance the quality of the block, and reduce postoperative opioid consumption. These adjuvants work by modulating inflammation, pain pathways, and receptor activity, making the ESP block more effective for managing acute and chronic pain.

Dexmedetomidine is a selective alpha-2 adrenergic agonist used as an adjuvant in regional anaesthesia for its sedative, analgesic, and sympatholytic properties. It prolongs the duration of nerve blocks, reduces postoperative pain, and decreases opioid requirements, while maintaining hemodynamic stability and respiratory function. Its use enhances patient comfort and recovery.

The study compared Group A (ropivacaine alone) and Group B (ropivacaine with dexmedetomidine) across demographic and clinical parameters. The mean age (Group A: 43.00±14.75 years; Group B: 40.80±7.76 years; p=0.473) and weight (Group A: 62.20±7.29 kg; Group B: 61.67±10.14 kg; p=0.816) showed no significant differences. Both groups had a majority of female participants (Group A: 83.3%; Group B: 76.7%) and ASA I classification (Group A: 73.3%; Group B: 83.3%), with no significant differences in sex (p=0.417) or ASA classification (p=0.884). As no statistically significant differences were observed, the two groups were comparable demographically.

The duration of surgery was also comparable between the two groups (Group A: 48.3±8.4 minutes vs. Group B: 47.1±11.8 minutes, p=0.634). However, significant differences were observed in the duration of analgesia (Group A: 600 minutes vs. Group B: 1440 minutes, p<0.01) and total dose of analgesics (Group A: 1000 mg vs. Group B: 0 mg, p<0.01), indicating that the Group B had a longer pain-free period and required fewer rescue analgesics.

The study compared postoperative pain scores (VAS) at rest and during coughing between the Group A and Group B at 0, 4, 6, 12, and 24 hours. At 0 hours, both groups reported no pain, with median VAS scores of 0 (IQR: 0-0) at rest and during coughing, showing no significant differences (p=0.317 and p=0.677, respectively). However, significant differences emerged at 4 hours, with the Group B showing lower median VAS scores at rest (0 vs. 0-2, p=0.036) and during coughing (0 vs. 1-3, p=0.013). This trend continued at 6 hours (rest: 0 vs. 2, p<0.01; cough: 1 vs. 3, p=0.011) and 12 hours (rest: 0 vs. 1, p=0.003), although no significant difference was observed in VAS scores during coughing at 12 hours (p=0.081). At 24 hours, the Group B maintained significantly lower VAS scores at rest (0 vs.1, p=0.001) and during coughing (0.5 vs. 2, p=0.001). These findings demonstrate that the Group B had superior pain control compared to the Group A across multiple postoperative time intervals.

In Sarvesh et al and Kumar et al the duration of postoperative analgesia assessed (4.8 hours:8 hours in ropivacaine vs ropivacaine and dexmedetomidine) and (8 hours:18.5 hours in ropivacaine vs ropivacaine and dexmedetomidine) while our study found (10 hours:24 hours in ropivacaine vs ropivacaine and dexmedetomidine).[8,9] This finding may be due to the different ethnicity of the two studies. Similarly, Hamed et al (19 ml bupivacaine 0.25%+1ml dexmedetomidine 0.5 µg/kg) reported a prolonged duration of analgesia in the ESPB+DEX group (18.5 hours) compared to the ESPB group (12 hours, p=0.044).[10] The similar prolonged duration of analgesia may be attributed to use of different concentrations of bupivacaine (0.25%) and ropivacaine (0.375%).

The study compared HR and MAP between the Group A and Group B at 0, 5, 10, 15, 20, 30, and 40 minutes. At baseline (0 minutes), no significant differences were observed in HR (Group A: 78.8±12.6 vs. Group B: 81.9±10.8, p=0.299) or MAP (Group A: 96.1±11.3 vs.

Group B: 95.8±10.3, p=0.915). However, significant differences emerged at 5 minutes, with the Group B showing lower HR (71.0±9.7 vs. 77.7±13.3, p=0.029) and MAP (84.4±11.9 vs. 93.5±14.1, p=0.009). This trend continued at subsequent time intervals, with the Group B maintaining significantly lower HR at 10 minutes (66.7±7.7 vs. 77.5±12.5, p<0.01), 15 minutes (63.5±8.3 vs. 76.7±12.8, p<0.01), and 20 minutes (60.2±7.3 vs. 78.6±12.3, p<0.01). Similarly, MAP was significantly lower in the Group B at 15 minutes (88.6±12.0 vs. 96.6±12.4, p=0.013) and 20 minutes (89.4±10.3 vs. 98.0±14.1, p=0.009). At 40 minutes, the Group B continued to show significantly lower MAP (89.2±11.2 vs. 98.9±10.9, p=0.001), while HR differences remained significant (65.3±8.4 vs. 80.8±13.9, p<0.01).

These results suggest that the Group B had better hemodynamic stability, with lower HR and MAP values throughout the assessment period.

In the present study Group B required no rescue analgesics (0 mg), while the Group A required a median dose of 1000 mg of paracetamol (p<0.01). This demonstrates the opioid-sparing effect of dexmedetomidine. Similar findings were reported by Kumari et al, where Group RD required less IV diclofenac (85.00±42.85) compared to Group R (110.00±42.85, p=0.028).[11] Wang et al also observed lower postoperative sufentanil consumption in Group RD compared to Group R (p=0.001).[12] Additionally, Hamed et al found that the ESPB+DEX group had significantly lower total postoperative Morphine consumption compared to the ESPB group (p=0.021).[10] These results collectively emphasize the opioid-sparing benefits of dexmedetomidine.

In the present study Group B had significantly lower VAS scores at rest and during coughing at 4, 6, 12, and 24 hours compared to the Group A (p<0.05). At 24 hours, the median VAS score at rest was 0 for Group B compared to 1 for Group A (p=0.001). These findings are consistent with Kumar et al, where Group RD had significantly lower VAS scores up to 16 hours postoperatively (p<0.05).[9] Similarly, Kumari et al reported significantly lower VAS scores at all time points in Group RD compared to Group R (p<0.05).[11] Wang et al also found lower NRS scores at rest and during coughing in Group RD at 12, 24, 36, and 48 hours (p<0.05).[12] These results collectively demonstrate that dexmedetomidine provides superior pain control across multiple postoperative time intervals.

In the present study Group B showed significantly lower HR and MAP values starting from 5 minutes (HR: 71.0±9.7 vs. 77.7±13.3, p=0.029; MAP: 84.4±11.9 vs. 93.5±14.1, p=0.009) and maintained this trend up to 40 minutes (HR: 65.3±8.4 vs. 80.8±13.9, p<0.01; MAP: 89.2±11.2 vs. 98.9±10.9, p=0.001). This suggests better hemodynamic stability with dexmedetomidine. These findings are consistent with Kumar et al, where Group RD showed significant reductions in HR, SBP, DBP, and MAP from the 15th minute onwards (p<0.05).[9] Kumari et al also reported significantly lower HR, SBP, DBP, and MAP in Group RD compared to Group R (p<0.05).[11] However, Wang et al found no significant differences in MAP or HR between Group R and Group RD (p=0.250 and p=0.099, respectively), suggesting that dexmedetomidine did not adversely affect hemodynamic.[12] Overall, the present study's findings align with most research groups, indicating that dexmedetomidine contributes to better hemodynamic stability.[9,11,12]

The findings of the present study are highly consistent with those of the research groups across all headings.[8-10] The addition of dexmedetomidine to ropivacaine consistently prolonged the duration of analgesia, reduced the need for rescue analgesics, provided superior pain control (as evidenced by lower VAS scores), and improved hemodynamic stability (lower HR and MAP values).

These results reinforce the efficacy and safety of dexmedetomidine as an adjuvant in regional anaesthesia.

Strength

The ultrasound-guided ESP block offers significant strengths, including precision, safety, and versatility. Real-time visualization ensures accurate needle placement and local anaesthetic spread, reducing the risk of complications such as pneumothorax or intravascular injection.

Limitations

The pain assessment done using VAS score is subjective. Hence study involving larger sample size covering various ethnic population groups is needed to come to a definitive conclusion.

CONCLUSION

The study showed that addition of dexmedetomidine to ropivacaine for ESP block in laparoscopic cholecystectomy resulted in superior postoperative analgesia and a reduction in the total consumption of rescue analgesics. Dexmedetomidine had a more favourable impact on hemodynamic parameters indicating better cardiovascular stability perioperatively.

ESPB with ropivacaine plus dexmedetomidine can be recommended for attenuation of stress response and postoperative analgesia for laparoscopic surgeries.

Summary

The randomized, double-blinded study, titled- Efficacy of Ultrasound-Guided ESPB with or without dexmedetomidine on postoperative analgesia in Patients undergoing laparoscopic cholecystectomy: A comparative Study, compared the efficacy of ultrasound-guided ESPB using 0.375% ropivacaine with and without dexmedetomidine for postoperative analgesia in patients undergoing laparoscopic cholecystectomy. Conducted over two years at the Department of Anaesthesiology, Regional Institute of Medical Sciences (RIMS), Imphal,

60 patients were divided into two groups: Group A received bilateral ESPB with 19 mL of 0.375% ropivacaine and 1 mL normal saline, while Group B received the same dose of ropivacaine with 1 ml (0.5 µg/kg) dexmedetomidine. The primary outcome was the duration of analgesia, with secondary outcomes including pain scores (VAS) at rest and during cough, rescue analgesic consumption, hemodynamic parameters, and side effects. Results demonstrated that Group B had significantly longer analgesia (1440 vs. 600 minutes, $p<0.01$), lower pain scores at all time intervals, reduced rescue analgesic use, and better hemodynamic stability, with no significant difference in side effects. The study concluded that dexmedetomidine as an adjuvant in ESPB significantly enhances postoperative analgesia and hemodynamic stability, offering a promising approach for pain management in laparoscopic cholecystectomy. Ethical approval was obtained from the Research Ethics Board, RIMS, Imphal (Approval No. A/206/REB-Comm (SP)/RIMS/2015/974/05/2023), and the study was registered with the Clinical Trials Registry of India (CTRI/2024/03/064503), ensuring compliance with ethical standards and transparency in reporting

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