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Original Research Paper

A STUDY TO ASSESS THE EFFICACY OF ERECTOR SPINAE PLANE BLOCK (ESPB) FOR POST OPERATIVE ANALGESIA IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA

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ABSTRACT:

Background and aims: The erector spinae plane block (ESPB), a recent regional analgesic technique, has been used to manage acute pain after different thoracic and abdominal surgeries. Primary objective of this study was to compare the duration of effective analgesia and secondary objectives were to evaluate total amount and number of rescue analgesics in 24 hours, haemodynamic changes, and adverse effects. **Methods:** This prospective, randomized, double blind study was conducted on total of 100 patients of 18 to 60 years of age belonging to ASA class I & II, scheduled for laparoscopic cholecystectomy were randomly allocated into 2 groups - Group C (n=50) received 15 ml NS and Group R (n=50) received 0.25% ropivacaine 15 ml on each side for ESPB. **Results:** The duration of analgesia was statistically significantly longer in Group R (734.68 ± 64.98 min.) as compared to Group C (97.36 ± 21.08 min.) ($p < 0.05$). Total amount and number of postoperative analgesic (inj. diclofenac in mg) requirement was statistically lesser in Group R ($P < 0.05$). Postoperatively MAP and HR up to 8 hour was statistically higher in Group C. There was no significant difference in the mean VAS score between the two groups in early hours but overall, the VAS score was lower in Group R as compared to Group C at all time interval. There was no significant difference in adverse events and complications. **Conclusion:** Bilateral ESPB with ropivacaine 0.25% provided effective postoperative analgesia and hemodynamic stability and markedly decreased postoperative analgesic consumption in patients undergoing laparoscopic cholecystectomy.

Keywords: Ropivacaine, Erector spinae plane block, Laparoscopic cholecystectomy.

INTRODUCTION:

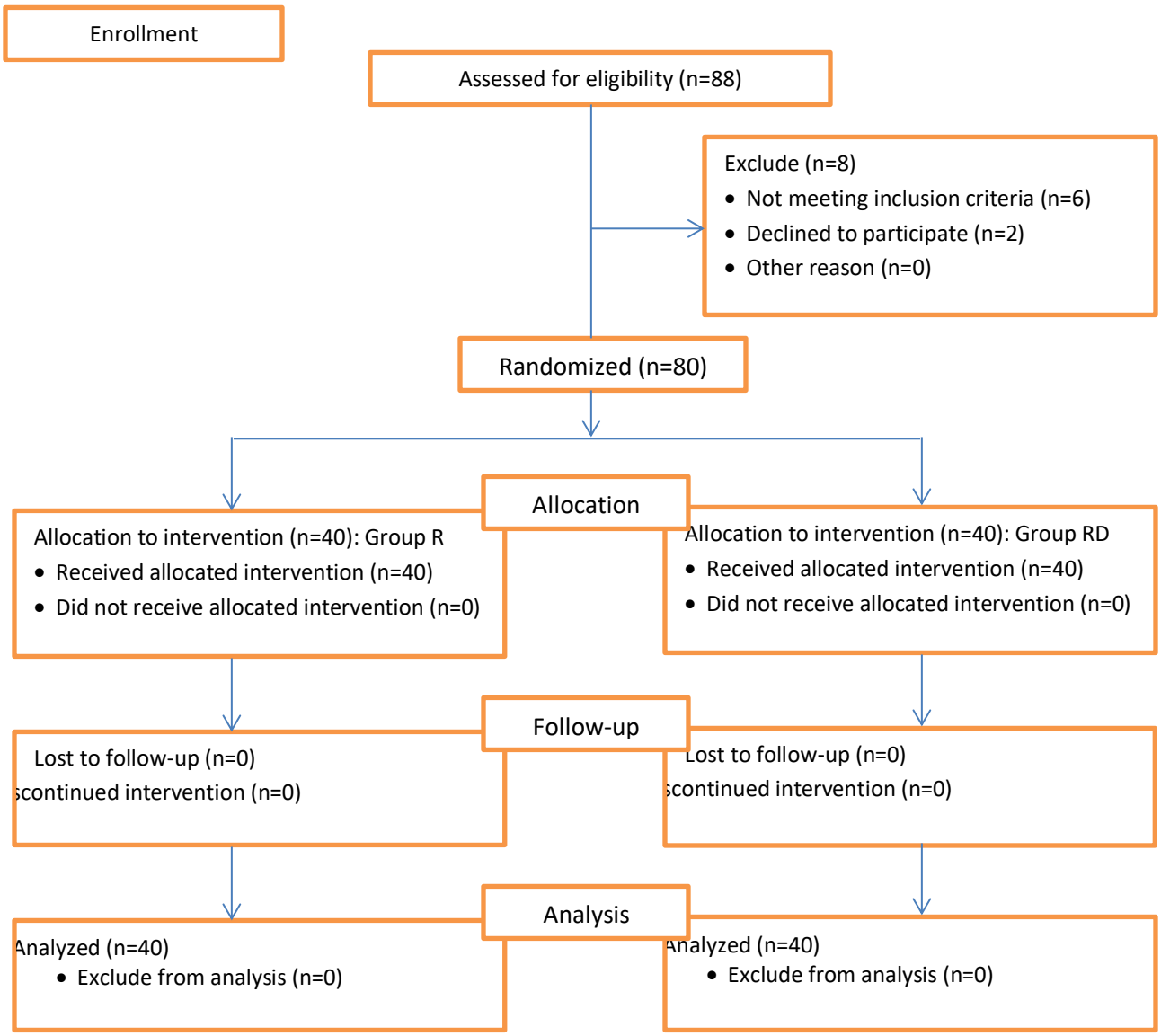
In the present era most accepted surgical technique for cholelithiasis is laparoscopic cholecystectomy in comparison to open cholecystectomy, due to its well-known advantages like less post-operative pain, shorter hospitalization and faster functional recovery. Early postoperative pain is a major obstacle for early postoperative ambulation leading to increased risk of venous thromboembolism and respiratory complications and prolongs hospital stay.[1] There are chances of developing chronic regional pain syndromes due to inadequately treated postoperative pain.[2]Laparoscopic cholecystectomy is also associated with stress response induced by surgery and anaesthesia. Anaesthetic maneuvers like direct laryngoscopy, tracheal intubation and extubation involve severe sympathetic stimulation. Moreover, the pneumoperitoneum and carbon dioxide insufflations required in laparoscopic surgeries lead to

increase in plasma nor-epinephrine, epinephrine levels and plasma renin activity.[3]All these changes lead to reduce cardiac output due to increase in heart rate, blood pressure, systemic and pulmonary vascular resistance. The reverse Trendelenburg position required for surgery leads to diminished venous return and thereby further reduction in cardiac output.[4] The haemodynamic changes predispose the myocardium to ischemia that may be life threatening in a vulnerable patient. The main goal of modern anaesthesia practices, therefore, plan to prevent sympathetic discharge and provide haemodynamic stability perioperatively. For this purpose, various drugs like opioid analgesics, benzodiazepines, beta blockers, calcium channel blockers and vasodilators have been used. In last few years the use of α2 agonists in anaesthesia practice increases because of their anxiolytic, sedative, sympatholytic and analgesic sparing properties. Multimodal analgesia regimens such as parenteral opioids, nonsteroidal anti-inflammatory drugs or local wound infiltration with local anaesthetics, have been tried to reduce overall pain and postoperative complications of patients undergoing laparoscopic surgeries.[5] Despite their efficacy, with all parenteral medications, there are associated adverse effects. In this modern era of surgery, intraperitoneal instillation of local anaesthetic agents has become an important method to control postoperative pain, nausea, vomiting, and reduced hospital stay. The local anaesthetic agents provide antinociception by affecting nerve membrane-associated proteins and by inhibiting the release and action of prostaglandins which stimulates the nociceptors and cause inflammation. Intraperitoneal instillation of 0.2% ropivacaine provide effective analgesia, in addition to this, we added either dexmedetomidine or fentanyl to compare the antinociceptive efficacy if mixed with ropivacaine. Dexmedetomidine blocks the release of substance P in the nociceptive pathway at the dorsal root level and increases the conductance through potassium channels by action on inhibitory G protein,.[6] The erector spinae plane (ESP) block is a newer regional anaesthetic technique that can be used to provide analgesia for a variety of surgical procedures or to manage acute or chronic pain. The technique of ESPB is relatively easy to perform, minimal or no sedation is required and can be performed outside the operative area. The ESP block is possible either using a single injection technique or via catheter placement for continuous infusion. This block was firstly used in 2016 to manage thoracic neuropathic pain in a patient with metastatic disease of the ribs and rib fracture. [7] Since then, the block has been reported to have been used successfully in a multitude of procedures including thoracotomies, percutaneous nephrolithotomies, ventral hernia repairs, and even lumbar infusions. [8] The erector spinae block is achieved by injecting the local anaesthetic solution between the erector spinae muscles (ilicostalis, longissimus, spinalis from lateral to medial) and transverse process. The local anaesthetic diffuses into the paravertebral space through spaces between adjacent vertebrae and blocks both the dorsal and ventral branches of thoracic spinal nerves. [9,10]In the current study, we evaluated the efficacy of ESP block by using 0.25% ropivacaine in patients undergoing laparoscopic cholecystectomy under general anaesthesia, in terms of postoperative duration of analgesia, intensity of pain, time to request for first rescue analgesic, total rescue analgesic consumption, hemodynamic changes and adverse effects and complications.

METHODS:

After the approval from institutional ethical committee and written informed consent, this prospective randomized double-blinded study was conducted in 100 patients between the age group of 18 to 60 years belonging to American Society of Anaesthesiologist physical status I and II, Mallampatti grade I & II and who gave valid informed consent undergoing laparoscopic cholecystectomy. Patients not satisfying inclusion criteria, lack of written informed consent, BMI >35 kg/m^2, skin infection at the puncture site, severe coagulopathy, hypersensitivity to diclofenac, or local anaesthetic agents, cardiovascular and respiratory disease, chronic liver disease and renal failure, any neurological and psychiatric illness, long term diabetic patients on medication or insulin, preoperative opioid or non-steroidal anti-inflammatory drugs for chronic pain treatment and pregnant female and lactating mother were excluded from the study. We screened 120 patients for this prospective double blind, randomized & placebo-controlled trial. As the inclusion criteria were not fulfilled, we excluded 20patients from our study. Hence a total of 100 patients were recruited & allocated in to

two groups of 50 each. All these patients finished the study and were available for follow up & data collection (Fig-1). The study population was randomly divided into two groups with 50 patients in each group using computer generated tables of random numbers. Group C (*n*=50) –Was given preoperative normal saline 15 ml on each side in ESP block Group R (*n*=50) –Was given preoperative ropivacaine 0.25%, 15ml on each side in ESP block Thorough preoperative evaluation was done according to standard protocol and relevant demographic data was collected from all the patients before surgery. All the study patients were instructed about the use of the VAS score before induction of anaesthesia (VAS score 0 - no pain, VAS score 10 - worst possible pain). The sitting position was used for erector spinae plane block as it allows easy identification of landmarks and greater comfort to the patient. The spinous process of T7 vertebra and a point 3 cm lateral to it was marked before performing the block. Under aseptic precautions, the needle (22-gauge, 8–10 cm short beveled needle) was inserted and advanced perpendicular to the skin in all planes to contact the transverse process of the vertebra. The needle tip lies between the erector spinae muscle and transverse process. After negative aspiration, a volume of 15 ml of 0.25% ropivacaine was injected on each side in 3–5 ml aliquots.After injecting the total 30 ml of study drug (15 ml each side) Patient was shifted to operation theatre where anaesthesia was administered by a blinded anesthesiologist. On arrival to operating room, an 18gauge intravenous (IV) cannula was inserted and I.V. fluid was started. Then monitoring of heart rate (HR), noninvasive blood pressure (NIBP), oxygen saturation (SpO_2) electrocardiography (ECG) was applied and baseline values were recorded. All patients were premedicated with injection glycopyrrolate 0.004 mg/kg and injection fentanyl 2 µg/kg. Preoxygenation with 100% oxygen (O_2) was done for 3 min. General anaesthesia was induced with injection propofol 2.0 mg/kg followed by succinylcholine 1.5 mg/kg to facilitate orotracheal intubation. A cuffed orotracheal tube of appropriate size was used for tracheal intubation. Anaesthesia was maintained with oxygen and sevoflurane (1-2%). The loading dose of atracurium (0.5 mg/kg) was given followed by Intermittent bolus of atracurium (0.1 mg/kg) was used to achieve adequate muscle relaxation. Minute ventilation was adjusted to maintain normocapnia (end tidal carbon dioxide [$EtCO_2$] between 35 – 40 mm Hg) and $EtCO_2$ was monitored.After completion of surgery reversal was given by using injection glycopyrrolate (0.008 mg/kg) and injection neostigmine (0.05 mg/kg). Then after achieving the adequate return of muscle power and respiration trachea was extubated and patient shifted to recovery room.The intensity of postoperative pain was recorded for all the patients using VAS score at 0 min, 30 min, 1, 2, 4, 6, 8, 12, 24 h after surgery. Patients who reported VAS $\geq$ 3 were given diclofenac 75 mg intramuscularly as rescue analgesia and this time was considered as duration of analgesia. The various hemodynamic parameters recorded in postoperative period up to 24 hours. Patients who complain of nausea or vomiting were given injection ondansetron 4 mg IV. Total dose of rescue analgesia and adverse or side effects over 24 h post-operatively were also noted.



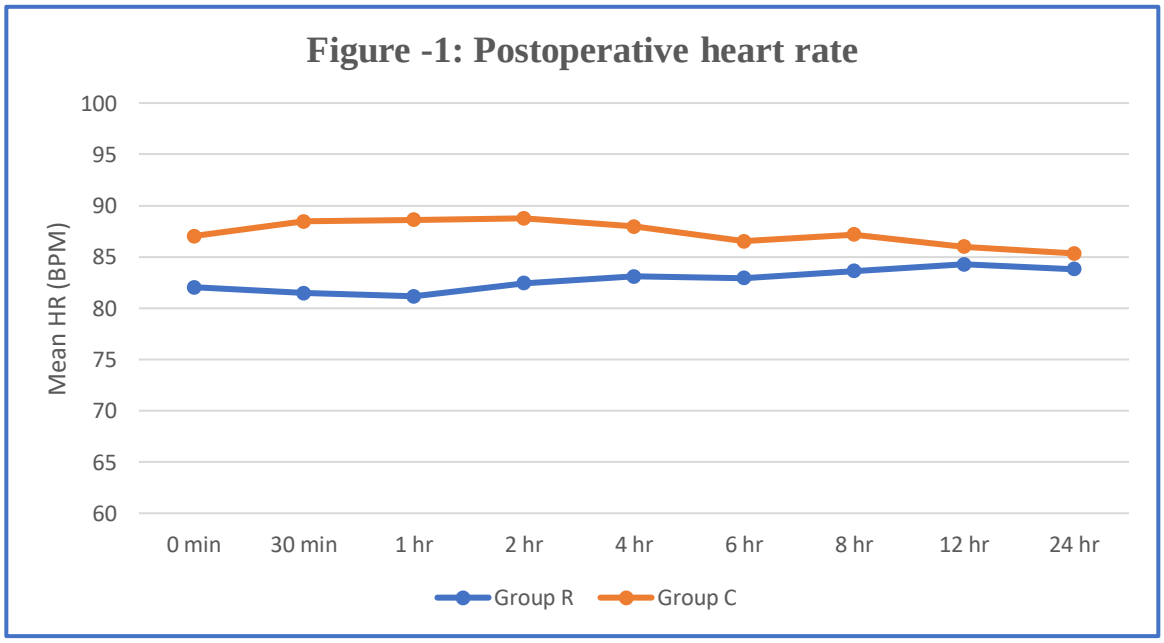
Comparison of demographic data (age, sex, weight and ASA physical status) and duration of surgery showed no significant difference between the groups. (Table-1).**Figure-1: Consort flow chart** Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) version 21 (SPSS Inc, Chicago,USA). Level of significance was ascertained by chi square and student t- test. *P* value <0.05 was considered statistically significant and *P* < 0.001 was considered highly significant.

RESULTS:

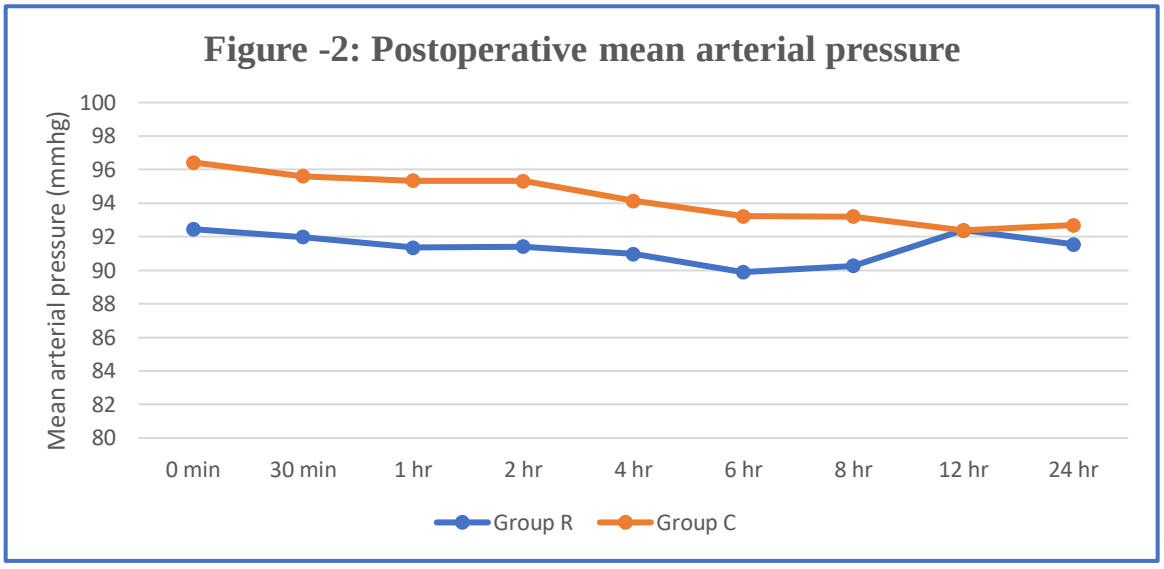
Table – 1: Demographic profile			
Patient`s characteristics	Group – R (n=50)	Group – C (n=50)	P value
Age (years) (Mean ± SD)	43.14 ± 13.87	42.94 ± 12.95	0.941
Sex (M/F ratio)	10/40	7/43	0.594
Weight (kg.)(Mean ± SD)	62.38 ± 5.54	63.32 ±4.84	0.368
ASA PS (I/II) (Ratio)	44/6	40/10	0.413
Duration of surgery (min)(Mean ± SD)	67.20 ± 13.97	66.90 ± 15.22	0.918

The distribution of baseline vital data was comparable among the groups (Table -2).

Table – 2: Baseline vital parameters			
	Group – R (n=50) (Mean ± SD)	Group – C(n=50) (Mean ± SD)	P value
Heart rate (BPM)	85.72 ± 10.48	84.94 ± 9.91	0.703
Systolic blood pressure (mmHg)	124.78 ± 9.73	125.22 ± 8.77	0.813
Diastolic blood pressure	77.80 ± 8.94	79.28 ±6.92	0.357
Mean arterial pressure (mmHg)	92.82 ± 8.11	94.59 ± 6.36	0.227
SpO_2	99.70 ± 0.54	99.60 ± 0.61	0.387



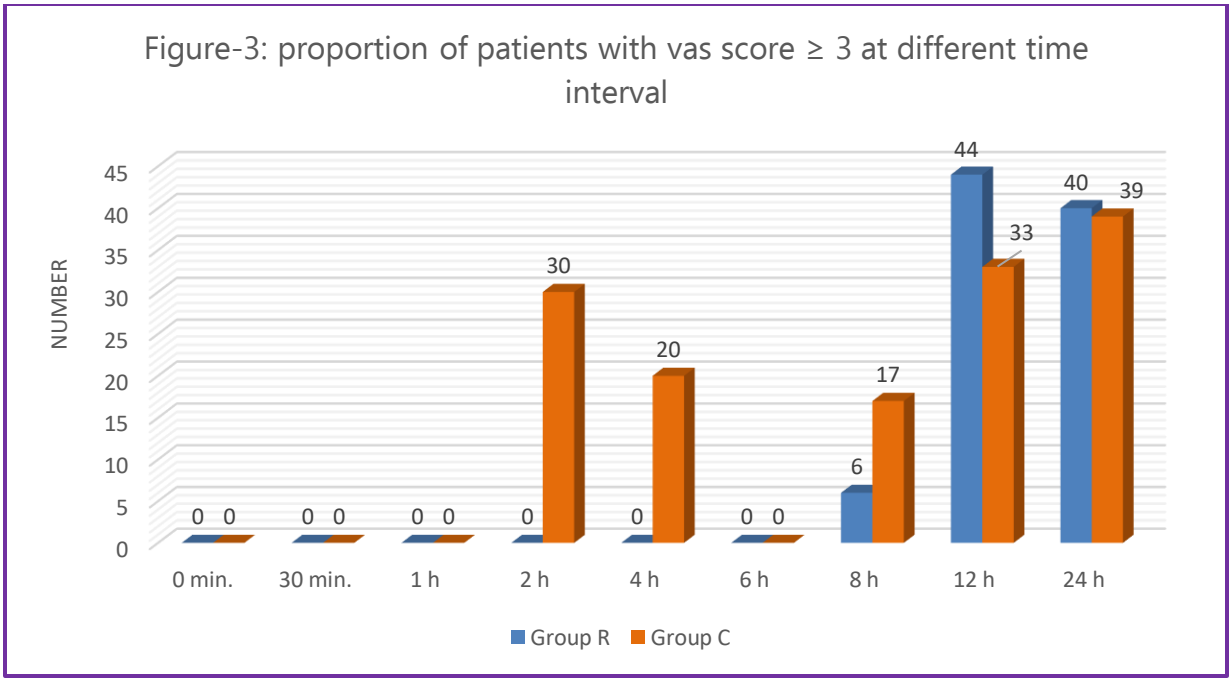
Intraoperatively hemodynamic parameters between the two groups were comparable. In the postoperative periods there was significantly increased heart rate in group C as compared to group R up to 8 hours after surgery (p>0.05). After that there both the groups were comparable. (Fig-1). There was significantly increased mean of mean arterial pressure in group C as compared to group R up to 8 hours after surgery (p>0.05). After that there both the groups were comparable.(Fig-2)



Up to 30 minutes after extubation both groups were comparable as the VAS score was not statistically significant. Statistically significant differences were found in pain (assessed by the VAS) among the groups from 1st hr to 12th hr except at 6th hr due to the effect of rescue analgesia. At all time intervals there were lower score in the Group R than Group C. (Table-3).No patient had VAS pain score ≥3 till first 6 hours in group R and till first 1 hours in group C. In group R earliest complaint of VAS score ≥3 was in 8th hour whereas in group C it was in 2nd hour. (Figure-3).

Table – 3: comparison of post - operative mean vas score

Time	Group R		Group RD		Result (p value)
	Mean	SD	Mean	SD	
0 min	1.04	0.20	1.06	0.47	0.782 (NS)
30 min	1.06	0.24	1.18	0.39	0.067 (NS)
1 hr	1.10	0.30	1.34	0.48	**0.0034 (S)**
2 hr	1.14	0.35	2.60	0.49	**<0.0001 (S)**
4 hr	1.40	0.53	2.02	0.89	**<0.0001 (S)**
6 hr	1.78	0.42	1.68	0.47	0.265 (NS)
8 hr	1.98	0.51	2.28	0.57	**0.0060 (S)**
12 hr	2.88	0.33	2.66	0.48	**0.0089 (S)**
24 hr	2.80	0.40	2.78	0.42	0.808 (NS)



The mean duration of analgesia in Group R was significantly longer than in Group C, i.e., 734.68 ± 64.98 min and 97.36 ± 21.08 (P < 0.0001), respectively (Table-4).

Table – 4: Mean duration of analgesia

Mean total duration of analgesia (minutes.)	Group R		Group C	
	Mean	SD	Mean	SD
	734.68	64.98	97.36	21.08
Result (p value)	**< 0.0001 (S)**			

The mean amount of rescue analgesic (Diclofenac in mg) used was statistically higher in group C (210.00 ± 30.30 mg.) as compared to group R (135.00 ± 30.30 mg.) (p<0.0001). In group R total number of doses required was 90 in comparison to group C where it was 140. Mean number of doses required in group R was 1.80 ± 0.40 and in group C was 2.80 ± 0.40, which was statistically significant(Table-5).

Table – 4: Mean duration of analgesia

Number of Analgesia doses	**Group R**			**Group C**			**Result (p value)**
	N	**%**	**Total doses**	**N**	**%**	**Total doses**	
1	10	20.00	10	0	0	0	**0.0027 (S)**
2	40	80.00	80	10	20.00	20	**0.0001 (S)**
3	0	0	0	40	80.00	120	**0.0027 (S)**
Total	50	100.00	90	50	100.00	140	
Mean no. of doses required	1.80 ± 0.40			2.80 ± 0.40			**<0.0001 (S)**
Mean amount of diclofenac used	135.00 ± 30.30 mg.			210.00 ± 30.30 mg.			**<0.0001 (S)**

Perioperative adverse effects were not statistically significant among the groups (Table -5).

Table – 4 perioperative adverse effects

Adverse effects	Group R		Group RD		P value
	No.	%	No.	%	
Nausea/vomiting	2	4.0	5	10.0	0.433 (NS)
Shoulder Pain	1	2.0	2	4.0	0.556 (NS)

DISCUSSION:

Pain following laparoscopic cholecystectomy reaches a peak within the first few hours following the operation but diminishes during the next 2 or 3 days. Some patients experience a rather painful early post-operative period and coughing and mobilization particularly aggravate the pain. Early pain after laparoscopic cholecystectomy is a complex process and includes different pain components secondary to different pain mechanisms , such as surgical trauma to the abdominal wall, trauma associated with gall bladder removal, abdominal distention by pneumoperitoneum using carbon dioxide etc. Therefore, pain should be treated multimodally.[11] According to Prospect (Procedure Specific Postoperative Pain ManagemenT) group (an international group of leading pain specialists and surgeons) various analgesic modalities have been tried for postoperative analgesia in laparoscopic cholecystectomy eg, use of non-steroidal anti-inflammatory drugs (NSAIDs); pre-emptive analgesic regimens; intraperitoneal local anaesthetics; infiltration of the incision site with local anaesthetics; and regional anaesthesia techniques including thoracic epidural and paravertebral block techniques. There were many controversial results in the literature about almost every method except regional techniques.[12] Epidural analgesia was proven to be successful for achieving postoperative analgesia in laparoscopic cholecystectomy; but due to recommendations based on the principles of evidence-based medicine, it was not recommended for routine use because lack of evidence concerning rational cost-benefit ratio. *Naja et al.* [13]reported that when used as complementary to general anaesthesia, bilateral paravertebral block may improve postoperative pain relief. Paravertebral block was adequate for this indication but it is an advanced technique and associated with risk for serious complications like inadvertent vascular puncture (6.8%); hypotension (4.0%); hematoma (2.4%);signs of epidural or intrathecal spread (1.0%); pain at site of skin puncture (1.3%); pleural puncture (0.8%); pneumothorax (0.5%). ESPB is a newly defined, relatively safe and promising regional anaesthesia technique. *Hannig et al.*[14] reported ESPB use for laparoscopic cholecystectomy in adults. Conventionally, ultrasound guided erector spinae plane block (ESPB) has been used for postoperative pain management in lumbosacral spine and laparoscopic cholecystectomy surgeries. Two case reports were published of landmark guided erector spinae plane block (LESB) i.e. *Dey S et al (2020)*[15], who used landmark guided continuous erector spinae plane block: an adjunct for perioperative analgesia in a patient with difficult back operated for total hip arthroplasty. And *Goel VK et al*[16] who used landmark guided erector spinae plane block as a part of multimodal analgesia in thoracolumbar spine surgeries. In our study we used Erector Spinae Plane Block for post operative analgesia in patients undergoing laparoscopic cholecystectomy as described by *Vadera et al*[17]under general anaesthesia.In our study there was no significant difference in demographic profile i.e., both Group R and Group C were comparable with respect to age, sex,weight, ASA physical status I/II and duration of surgery. In both groups baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and SpO_2 were comparable with p value > 0.05 which was statistically insignificant. All the haemodynamic parameters were comparable and remained stable throughout the whole intraoperative period which depicted the favorable safety profile of ropivacaine used in ESPB. Studies done by *Altıparmak B et al*[18] and *Singh S et al* [19]also showed same results.In the postoperative periods there was significantly increased HR, SBP, DBP and MAP in group C as compared to group R up to 8 hours after

surgery (p>0.05). After that both the groups were comparable. Results of our study coincides with studies done by *Ibrahim M et al* [20], *Aksu C et al* [21], *Altıparmak B et al* [18]. No patient had VAS pain score ≥3 till first 6 hours in group R and till first 1 hours in group C. Statistically significant differences were found in VAS scores among the groups from 1st hr to 12th hr except at 6th hr due to the effect of rescue analgesia. At all-time intervals there were lower score in the Group R than Group C. *Hamed MA et al*[22] and *Altıparmak B et al* [18] also found that VAS scores were lower in ESPB group as compared to control group.

In our study, we observed that the mean duration of analgesia was statistically prolonged in Group R (734.68 ± 64.98min.) as compared to Group C (97.36 ± 21.08min.) (p<0.0001).*Wang Q et al* [23] found that the duration of analgesia in group RD (505.1±113.9) was longer than that in group R (323.2±75.4) (P<0.001). *Ibrahim M et al* [20] compared the OSTAP block with EPSB for opioid usage during the first 24 h after laparoscopic cholecystectomy and found that the mean duration of analgesia was 384.0 ± 55.0 min in ESP group as compared to control group (266.0 ± 31.0 min) and OSTAP group (343.0 ± 51.0 min) which was statistically significant.In group R total number of doses required was 90 in comparison to group C where it was 140. Mean number of doses required in group R was 1.80 ± 0.40 and in group C was 2.80 ± 0.40, which was statistically significant (p value = <0.0001).The mean amount of rescue analgesic (Diclofenac in mg) was statistically higher in group C as compared to group R (210.00 ± 30.30 mg and 135.00 ± 30.30 mg. respectively)(p<0.0001). We observed, 2 patients experienced nausea and vomiting and 1 patient experienced shoulder pain in Group R. Whereas 5 patients experienced nausea and vomiting and 2 patient experienced shoulder pain in Group C and none of the patient experienced bradycardia, pruritus, hypotension, sedation and respiratory depression in both groups.So, the occurrence of side effects in both the groups were not statistically significant

CONCLUSION:

From our study we concluded that landmark guided ESP block with ropivacaine appears to be an effective procedure for postoperative analgesia in laparoscopic cholecystectomy surgeries as the block increased the pain free postoperative period and decreased the requirement of rescue analgesics in first 24 hours postoperatively with stable haemodynamics and no clinically or statistically significant side effects when compared with ESPB with placebo or normal saline alone. So, we concluded that bilateral ESPB with ropivacaine 0.25% provided effective postoperative analgesia and haemodynamic stability and markedly decreased postoperative analgesic consumption in patients undergoing laparoscopic cholecystectomy.

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