

The Effect of Intraperitoneal Instillation of Ropivacaine with Fentanyl or Ropivacaine with Dexmedetomidine for Postoperative Analgesia Following Laproscopic Cholecystectomy: A Prospective Randomized Double Blind Study

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Abstract

Background: Laparoscopic cholecystectomy, though minimally invasive, is often associated with significant postoperative visceral pain, particularly due to peritoneal irritation and residual carbon dioxide. Effective pain management is essential to reduce patient discomfort, shorten hospital stays, and prevent complications such as delayed ambulation. This study aimed to compare the antinociceptive efficacy and safety of intraperitoneal instillation of ropivacaine combined with dexmedetomidine versus ropivacaine combined with fentanyl for postoperative analgesia following laparoscopic cholecystectomy.

Aims And Objective: To assess the anti-nociceptive effect of intraperitoneal instillation of dexmedetomidine combined with ropivacaine versus fentanyl combined with ropivacaine for postoperative pain management in laparoscopic cholecystectomy.

Materials and Methods: This prospective, randomized, double-blind controlled trial included 60 ASA grade I and II patients aged between 18 and 70 years undergoing elective laparoscopic cholecystectomy. Patients were randomly allocated into two groups of 30 each. Group RF received intraperitoneal instillation of 20 ml 0.5% ropivacaine + 2 ml fentanyl (100 mcg) + 8 ml NS, while Group RD received 20 ml 0.5% ropivacaine + 0.5 ml dexmedetomidine (50 µg) + 9.5 ml NS. Pain was assessed postoperatively at various time intervals using the Visual Analog Scale (VAS). Total analgesic consumption and time to first rescue analgesia were recorded. Adverse events and incidence of shoulder pain were also noted.

Results: The mean duration of analgesia was longer in Group RD (9.77 ± 6.20 hours) versus Group RF (5.43 ± 6.95 hours), and the number of rescue analgesic doses required within 24 hours was lower in Group RD (1.03 ± 0.49) compared to Group RF (1.77 ± 0.82), both statistically significant. Total analgesic consumption in the first 24 hours was also markedly reduced in Group RD (77.50 ± 36.76 mg) versus Group RF (130.00 ± 62.08 mg). VAS scores at all time intervals postoperatively were significantly lower in Group RD, indicating more effective pain control. Additionally, Group RD showed better postoperative oxygen saturation and a lower incidence of nausea. Other complications such as vomiting, bradycardia, and hypotension were comparable between groups. Overall, the combination of ropivacaine with dexmedetomidine provided superior, longer-lasting analgesia with fewer side effects than the ropivacaine-fentanyl combination.

Conclusion: Intraperitoneal instillation of ropivacaine combined with dexmedetomidine provides superior postoperative analgesia compared to its combination with fentanyl in patients undergoing laparoscopic cholecystectomy. The dexmedetomidine group demonstrated lower pain scores, prolonged duration of analgesia, reduced need for rescue medication, and fewer complications, making it a more effective and safer option for postoperative pain management.

Keywords: Laparoscopic cholecystectomy, Ropivacaine, Dexmedetomidine, Fentanyl, Intraperitoneal instillation, Postoperative analgesia, Visual Analog Scale (VAS).

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Introduction

Minimally invasive procedures have fundamentally transformed the landscape of surgical practices by offering substantial benefits over traditional open surgeries. Among the various minimally invasive procedures, laparoscopic cholecystectomy stands out as the most commonly performed and accepted surgical technique for treating cholelithiasis, which involves the removal of the gallbladder. This method has gradually replaced the conventional open cholecystectomy due to its numerous advantages including reduced trauma, faster recovery and improved patient outcomes. Laparoscopic cholecystectomy is now the standard of care worldwide and is considered the most frequently performed laparoscopic procedure, making it a cornerstone of modern surgical practice. [1,2]

The primary reasons behind the widespread adoption of laparoscopic cholecystectomy include several benefits that enhance the patient's experience during and after surgery. These benefits include less postoperative discomfort, shorter hospital stays and a faster return to normal activities. Patients who undergo laparoscopic cholecystectomy typically experience fewer complications, such as wound infections and hernias compared to those undergoing the open technique. Furthermore, the minimally invasive nature of the procedure leads to smaller incisions, reduced blood loss and less pain, all contributing to a quicker recovery process. [3] However, despite these advantages, postoperative pain remains a significant issue. Many patients report experiencing considerable discomfort, particularly when performing activities that involve deep breathing, coughing or mobilization. This discomfort can range from mild to severe and in some cases, may affect the patient's overall recovery experience.

The type of pain experienced after laparoscopic surgery differs significantly from that seen after more invasive procedures like laparotomy. While laparotomy typically results in parietal pain, which is localized to the site of incision, the pain experienced after laparoscopic surgery is often visceral in nature. This visceral pain is caused by a variety of factors, such as the stretching of the intra-abdominal cavity, inflammation of the peritoneum and irritation of the phrenic nerve, which is typically triggered by the residual CO₂ that remains in the peritoneal cavity after the surgery. CO₂ is used during the laparoscopic procedure to inflate the abdomen, providing better visibility and access for the surgeon. However, this residual gas can lead to increased intra-abdominal pressure, leading to discomfort and irritation of the surrounding structures, such as the diaphragm and the phrenic nerve. [4] This can result in pain

referred to the shoulder, which is one of the most common and distressing symptoms following laparoscopic cholecystectomy. The incidence of postoperative shoulder pain can reach up to 60%, which is significant enough to cause unanticipated readmissions, especially in day-care laparoscopic surgeries where the patient is expected to go home the same day. This shoulder pain is considered one of the major factors contributing to the higher-than-expected admission rates in laparoscopic surgery. [5]

Postoperative pain following laparoscopic cholecystectomy can also delay recovery, prolong the length of hospital stays and increase healthcare costs. Patients who experience excessive pain are less likely to be mobilized early, which can lead to complications such as deep vein thrombosis and respiratory distress. Additionally, persistent pain can hinder the healing process and lead to increased morbidity. Therefore, effective management of postoperative pain is critical to improving patient outcomes and reducing healthcare expenditures. [6,7]

Various methods have been explored for managing pain following laparoscopic cholecystectomy. Traditional approaches include the use of systemic analgesics, such as opioids and the local infiltration of anesthetics around the incision sites. Other methods include the use of gas drains and techniques such as low-pressure pneumoperitoneum, which reduces the volume of CO₂ used during surgery. One of the most promising techniques for alleviating post-laparoscopy pain is the intraperitoneal administration of local anesthetics. This method is cost-effective, simple to perform and minimally invasive, offering a compelling alternative to opioid-based pain management, which often comes with side effects such as postoperative nausea, sedation, constipation and impairment of gastrointestinal motility. [8]

Intraperitoneal local anesthetics are beneficial because they directly target the pain at its source, reducing the intensity of the visceral pain caused by CO₂ retention and peritoneal inflammation. Among the various local anesthetics used 0.5% ropivacaine has emerged as a popular choice for postoperative pain management after laparoscopic cholecystectomy. Research has shown that intraperitoneal administration of 0.5% ropivacaine significantly reduces postoperative pain, especially when administered at doses of 100 mg (two 50 mg doses). At this dosage, the plasma concentration of ropivacaine remains within safe, non-toxic levels, making it an effective and safe option for pain relief. [8,9,10]

In addition to local anesthetics, studies have explored the use of α_2 -adrenoceptor agonists, such as dexmedetomidine and synthetic opioids, such as fentanyl, to further enhance pain relief. When combined with local anesthetics and administered intraperitoneally, these agents have been shown to significantly reduce postoperative pain, lower the need for additional analgesics and decrease the incidence of shoulder pain compared to local anesthetic use alone. This combination approach targets multiple pathways involved in pain processing and provides a more comprehensive and effective analgesic effect. [11]

For example, intraperitoneal instillation of dexmedetomidine (at a dose of 1 $\mu\text{g/kg}$) combined with bupivacaine (0.25%) has been shown to significantly reduce postoperative pain and the need for additional analgesics compared to bupivacaine alone. This combination is particularly effective in minimizing discomfort and promoting faster recovery following laparoscopic surgery. [12,13] In light of these findings, the present study aims to assess the efficacy of intraperitoneal instillation of dexmedetomidine combined with ropivacaine versus fentanyl combined with ropivacaine in managing postoperative pain after laparoscopic cholecystectomy. By comparing these two combinations, the study seeks to determine the most effective strategy for providing adequate pain relief and improving patient outcomes after surgery.

Material and Methods

A prospective, randomized, double-blind controlled clinical study was conducted on 60 patients admitted to Pacific Medical College in Udaipur over a period of two years. The study aimed to evaluate the postoperative analgesic effects of two different interventions for pain management in patients undergoing laparoscopic cholecystectomy. Institutional ethical approval was obtained and informed written consent was taken from all participants. A total of 60 patients were included in the study, who were randomly divided into two groups, each containing 30 patients. The randomization process was carried out using computer-generated numbers, ensuring a fair and unbiased allocation. The study drugs were masked in opaque plastic bags labelled with randomization numbers and expiration dates, maintaining the blinding process for both the patients and the anaesthesia provider, who remained unaware of the drug administered. The randomization code was not opened until the study was completed.

A pre-anaesthetic check-up was conducted one day prior to the surgery to assess the patient's overall health status and to record laboratory investigations. This step ensured that the patients were fit for anaesthesia and the surgical procedure.

During this visit, the details of the study protocol and the procedure for general anaesthesia were explained to the patients and informed written consent was obtained. Patients were advised to fast overnight in preparation for the surgery. On the day of surgery, the patients were given Ranitidine 150 mg to reduce gastric acidity. Upon arrival in the operating room, an intravenous (IV) line was inserted and IV fluids were started at a rate of 8 ml/kg body weight. Standard monitoring equipment, including a pulse oximeter, non-invasive blood pressure (NIBP) cuff and electrocardiogram (ECG), was applied. Baseline measurements of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were recorded.

Before anaesthesia induction, patients received premedication consisting of Glycopyrrolate 0.01mg/kg to reduce secretions, Inj Midazolam 0.02mg/kg to reduce anxiety, Ondansetron 0.1mg/kg to prevent nausea and Fentanyl 2 $\mu\text{g/kg}$ intravenously for analgesia. After pre-oxygenation with 100% oxygen for 3 minutes, general anaesthesia was induced using Propofol 2-2.5mg/kg for smooth induction to facilitate endotracheal intubation. To maintain anaesthesia, a mixture of oxygen and sevoflurane was used, along with an initial bolus of Atracurium 0.5mg/kg, followed by intermittent doses of Atracurium (0.1mg/kg) to ensure adequate muscle relaxation. Minute ventilation was adjusted to maintain normocapnia (End-tidal CO_2 at 35-40 mm Hg) and continuous monitoring of Et CO_2 was performed. A nasogastric tube was inserted to decompress the stomach and intra-abdominal pressure was maintained between 10 and 12 mm Hg to ensure optimal surgical conditions. The patient was positioned in a 15-20° reverse Trendelenburg position with a left-sided tilt to facilitate laparoscopic access. At the end of the surgery, abdominal CO_2 was manually removed by decompression of the abdomen to reduce the risk of postoperative shoulder pain. Intraoperative vital signs, including heart rate and blood pressure were continuously monitored and any significant fluctuations in blood pressure or heart rate (greater than 20% deviation from baseline) were managed appropriately.

At the conclusion of the surgery, the study solutions were administered intraperitoneally to provide postoperative analgesia. In Group RF (Ropivacaine with Fentanyl), the solution consisted of 20 ml of 0.5% ropivacaine, 2 ml of fentanyl (1 $\mu\text{g/kg}$) and 8 ml of saline. In Group RD (Ropivacaine with Dexmedetomidine), the solution contained 20 ml of 0.5% ropivacaine, 0.5 ml of dexmedetomidine (50 μg) and 9.5 ml normal saline. Both solutions were instilled into the hepato-diaphragmatic space, the gallbladder bed

and near the hepato-duodenal ligament, all under direct laparoscopic control. The administration of the drugs was done before the removal of the trocar while the patient remained in the Trendelenburg position. At the end of the operation the neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01mg/kg. Patients were extubated after attaining of adequate recovery which is assessed by clinical signs (hand grip, sustained head lift etc.). Patients were transferred to the post-operative ward.

Postoperatively, the patients were closely monitored and assessed for pain using the Visual Analog Scale (VAS) at specific time intervals: 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours and 24 hours after surgery. The time of drug instillation was defined as time zero for the assessment. Prior to induction, patients were explained the VAS scale, which consisted of a 10 cm line representing the intensity of pain with 0 cm indicating no pain and 10 cm representing the worst imaginable pain. In addition to the VAS scores, the time to first analgesic requirement was recorded, along with the total analgesic consumption in the first 24 hours postoperatively. If the VAS score was 3 or greater, rescue analgesia with Tramadol 50 mg i/v was administered. Any adverse events, including side effects of the drugs or complications during the postoperative period were also documented. Furthermore, the incidence of right shoulder pain, a common postoperative

complication following laparoscopic surgery, was recorded for both groups.

The VAS used in this study was a 10 cm scale, where 0 cm represented "no pain" and 10 cm represented "the worst imaginable pain." Patients were instructed to mark a point on the line that corresponded to their pain intensity.

This scale was utilized at various intervals to assess postoperative pain levels and it was an essential tool for evaluating the efficacy of the analgesic treatments used in the study.

Result

In this study 60 patients were randomly allocated into two groups: Group RD received 20 ml 0.5% isobaric ropivacaine hydrochloride (100mg) + 0.5 ml dexmedetomidine hydrochloride (50 ug) + 9.5 ml NS and Group RF: Patients will receive 20ml 0.5% isobaric ropivacaine hydrochloride (100mg) + 2ml fentanyl (100mcg) + 8 ml NS.

The hemodynamic changes including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure parameters, VAS score, and rescue analgesic requirement, post-operative complications were assessed and compared.

Collected data were internally compared, tabulated, analysed and interpreted by using descriptive and inferential statistics based on the formulated objectives of the study.

Table 1: Distribution of patients according to Age

Age (yrs)	Group RF (n=30)		Group RD (n=30)		P value
	No.	%	No.	%	
20-30	4	13.33%	6	20.00%	0.596*
31-40	5	16.67%	9	30.00%	
41-50	20	66.67%	15	50.00%	
>50	1	3.33%	0	0.00%	
Total	30	100.00%	30	100.00%	
Mean±SD	43.30±7.666		39.53±9.089		

Table 2: Distribution of patients according to Gender

Gender	Group RF (n=30)		Group RD (n=30)		P value
	No.	%	No.	%	
Male	12	40.0%	13	43.3%	0.793*
Female	18	60.0%	17	56.7%	
Total	30	100.00%	30	100.00%	

Table 3: Distribution of patients according to Weight (kg)

Weight (kg)	Group RF (n=30)		Group RD (n=30)		P value
	No.	%	No.	%	
40-50	7	23.33%	12	40.00%	0.410*
51-60	8	26.67%	9	30.00%	
61-70	11	36.67%	6	20.00%	
71-80	3	10.00%	3	10.00%	
>80	1	3.33%	0	0.00%	
Total	30	100.00%	30	100.00%	
Mean±SD	62.20±10.588		57.20±9.852		

Table 4: Duration of Anaesthesia of both groups

Group	N	Mean	Std. Deviation	t-value	p-value
Group RF	30	65.00	6.017	0.690	0.493*
Group RD	30	63.50	10.268		

Table 5: Comparison of Heart Rate (b/m) at different time intervals among both the groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
0 min	Ropivacaine with Fentanyl	30	85.73	8.680	0.303	0.763
	Ropivacaine with dexmedetomidine	30	85.20	4.160		
30 min	Ropivacaine with Fentanyl	30	85.17	8.022	0.327	0.745
	Ropivacaine with dexmedetomidine	30	84.53	6.932		
1 hr	Ropivacaine with Fentanyl	30	87.53	7.138	3.061	0.003*
	Ropivacaine with dexmedetomidine	30	79.60	12.269		
2 hr	Ropivacaine with Fentanyl	30	89.27	4.283	23.700	0.014*
	Ropivacaine with dexmedetomidine	30	60.20	5.176		
4 hr	Ropivacaine with Fentanyl	30	91.23	5.853	22.653	0.007*
	Ropivacaine with dexmedetomidine	30	60.03	4.760		
8 hr	Ropivacaine with Fentanyl	30	96.47	7.709	22.054	0.010*
	Ropivacaine with dexmedetomidine	30	61.67	3.907		
12 hr	Ropivacaine with Fentanyl	30	90.50	8.224	17.677	0.011*
	Ropivacaine with dexmedetomidine	30	61.47	3.646		
24 hr	Ropivacaine with Fentanyl	30	90.97	8.401	16.650	0.004*
	Ropivacaine with dexmedetomidine	30	60.80	5.281		

Table 6: Comparison of Systolic Blood Pressure (mmHg) at different time intervals among both the groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
0 min	Ropivacaine with Fentanyl	30	131.27	8.582	0.988	0.327
	Ropivacaine with dexmedetomidine	30	134.20	13.815		
30 min	Ropivacaine with Fentanyl	30	132.77	9.821	0.362	0.719
	Ropivacaine with dexmedetomidine	30	133.87	13.454		
1 hr	Ropivacaine with Fentanyl	30	129.97	10.091	2.322	0.024*
	Ropivacaine with dexmedetomidine	30	123.80	10.476		
2 hr	Ropivacaine with Fentanyl	30	127.10	13.415	2.269	0.027*
	Ropivacaine with dexmedetomidine	30	120.70	7.666		
4 hr	Ropivacaine with Fentanyl	30	125.13	11.301	2.048	0.045*
	Ropivacaine with dexmedetomidine	30	119.40	10.361		
8 hr	Ropivacaine with Fentanyl	30	124.27	11.991	4.491	0.009*
	Ropivacaine with dexmedetomidine	30	112.50	7.510		
12 hr	Ropivacaine with Fentanyl	30	120.93	11.083	1.058	0.189
	Ropivacaine with dexmedetomidine	30	117.60	9.895		
24 hr	Ropivacaine with Fentanyl	30	117.40	10.261	1.463	0.374
	Ropivacaine with dexmedetomidine	30	115.74	7.787		

Table 7: Comparison of Diastolic Blood Pressure (mmHg) at different time intervals among both the groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
0 min	Ropivacaine with Fentanyl	30	79.83	12.763	1.047	0.157
	Ropivacaine with dexmedetomidine	30	77.14	5.947		
30 min	Ropivacaine with Fentanyl	30	88.73	5.825	8.376	0.028*
	Ropivacaine with dexmedetomidine	30	85.93	6.638		
1 hr	Ropivacaine with Fentanyl	30	86.27	8.694	2.842	0.016*
	Ropivacaine with dexmedetomidine	30	80.07	8.200		
2 hr	Ropivacaine with Fentanyl	30	82.53	11.799	6.899	0.045*
	Ropivacaine with dexmedetomidine	30	79.40	4.352		

4 hr	Ropivacaine with Fentanyl	30	79.20	8.755	2.656	0.010*
	Ropivacaine with dexmedetomidine	30	74.27	5.179		
8 hr	Ropivacaine with Fentanyl	30	80.40	9.715	3.067	0.003*
	Ropivacaine with dexmedetomidine	30	74.03	5.910		
12 hr	Ropivacaine with Fentanyl	30	79.07	9.436	0.967	0.425
	Ropivacaine with dexmedetomidine	30	77.60	5.852		
24 hr	Ropivacaine with Fentanyl	30	79.40	9.768	1.180	0.243
	Ropivacaine with dexmedetomidine	30	76.90	6.261		

Table 8: Comparison of Mean Arterial Pressure (mmHg) at different time intervals among both the groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
0 min	Ropivacaine with Fentanyl	30	88.23	13.195	0.673	0.503
	Ropivacaine with dexmedetomidine	30	86.33	8.040		
30 min	Ropivacaine with Fentanyl	30	103.77	7.338	6.223	0.012*
	Ropivacaine with dexmedetomidine	30	91.43	7.999		
1 hr	Ropivacaine with Fentanyl	30	98.67	8.314	3.502	0.023*
	Ropivacaine with dexmedetomidine	30	91.53	7.440		
2 hr	Ropivacaine with Fentanyl	30	91.87	3.674	10.458	0.014*
	Ropivacaine with dexmedetomidine	30	82.47	9.589		
4 hr	Ropivacaine with Fentanyl	30	94.73	4.601	10.234	0.003*
	Ropivacaine with dexmedetomidine	30	85.40	9.268		
8 hr	Ropivacaine with Fentanyl	30	94.87	7.210	5.492	0.021*
	Ropivacaine with dexmedetomidine	30	85.67	12.189		
12 hr	Ropivacaine with Fentanyl	30	88.20	3.468	1.538	0.129
	Ropivacaine with dexmedetomidine	30	84.20	13.815		
24 hr	Ropivacaine with Fentanyl	30	94.25	3.674	1.974	0.267
	Ropivacaine with dexmedetomidine	30	92.47	4.987		

Table 9: Comparison of Oxygen Saturation (%) at different time intervals among both the groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
0 min	Ropivacaine with Fentanyl	30	98.97	.414	0.441	.661
	Ropivacaine with dexmedetomidine	30	99.00	.000		
30 min	Ropivacaine with Fentanyl	30	99.03	.320	1.342	0.185
	Ropivacaine with dexmedetomidine	30	99.93	.254		
1 hr	Ropivacaine with Fentanyl	30	98.93	.450	2.847	0.034*
	Ropivacaine with dexmedetomidine	30	99.00	.000		
2 hr	Ropivacaine with Fentanyl	30	98.47	.365	2.204	0.044*
	Ropivacaine with dexmedetomidine	30	99.83	.254		
4 hr	Ropivacaine with Fentanyl	30	99.07	.365	1.974	0.048*
	Ropivacaine with dexmedetomidine	30	99.97	.000		
8 hr	Ropivacaine with Fentanyl	30	99.14	.498	1.874	0.046*
	Ropivacaine with dexmedetomidine	30	99.98	.507		
12 hr	Ropivacaine with Fentanyl	30	99.10	.403	0.826	0.412
	Ropivacaine with dexmedetomidine	30	99.03	.183		
24 hr	Ropivacaine with Fentanyl	30	100.00	.000	0.647	0.242
	Ropivacaine with dexmedetomidine	30	99.95	0.254		

Table 10: Intergroup Difference in Analgesic Requirement

Variables	GROUP RF (n=30)		GROUP RD (n=30)		P value
	Mean	SD	Mean	SD	
Duration of Analgesia (hours)	5.433	6.950	9.767	6.200	0.013*
Total No. of Rescue Analgesics	1.767	0.817	1.033	0.490	0.009*
Total Analgesic Consumption in 24 Hours (mg)	130.00	62.076	77.500	36.759	0.022*

Table 11: Comparison of VAS scores at different time intervals of both groups

Group Statistics						
	Group	N	Mean	SD	t-value	p-value
30 min	Ropivacaine with Fentanyl	30	2.77	1.977	3.164	0.022*
	Ropivacaine with dexmedetomidine	30	1.47	1.074		
2 hr	Ropivacaine with Fentanyl	30	2.20	1.400	3.028	0.015*
	Ropivacaine with dexmedetomidine	30	1.27	.944		
4 hr	Ropivacaine with Fentanyl	30	3.22	2.273	3.615	0.010*
	Ropivacaine with dexmedetomidine	30	1.57	1.040		
8 hr	Ropivacaine with Fentanyl	30	3.70	2.200	4.188	0.019*
	Ropivacaine with dexmedetomidine	30	1.80	1.157		
12 hr	Ropivacaine with Fentanyl	30	3.00	2.017	3.745	0.011*
	Ropivacaine with dexmedetomidine	30	1.53	.730		
24 hr	Ropivacaine with Fentanyl	30	1.67	.547	2.483	0.016*
	Ropivacaine with dexmedetomidine	30	1.30	.596		

Table 12: Postoperative Complications of both groups

Postoperative Complications	GROUP RF (n=30)		GROUP RD (n=30)		P value
	No.	%	No.	%	
Hypotension	3	10.0%	2	6.7%	0.640
Bradycardia	3	10.0%	3	10.0%	1.000
Nausea	3	10.0%	0	0.0%	0.076
Vomiting	1	3.3%	0	0.0%	0.313
Pruritis/Shivering	1	3.3%	0	0.0%	0.313

Discussion

This study was undertaken to compare the effectiveness of intraperitoneal Ropivacaine with or without dexmedetomidine for post-operative analgesia in patients undergoing elective laparoscopic cholecystectomy. Besides, measuring post-operative pain with VAS, time to first dose of rescue analgesia, total analgesic requirement and intraoperative and postoperative hemodynamic parameters in each patient were also recorded. In this Double blinded Randomized Controlled Trial, 60 patients were selected between the age group of 20-52 years, belonging to each sex, ASA I and II. They were randomized into 2 groups of 30 patients.

Patients were randomized into one of the two groups using computer generated table. Drug solution was prepared by an anaesthesiologist who did not participate in the study. The anaesthesiologist monitoring the patient and recording data postoperatively as well as the patient himself/herself were unaware of the group allocation. In Group RF, patients received 20 ml of 0.5% Ropivacaine + 2ml fentanyl (100mcg) with 8ml normal saline. In Group RD, patients received 20ml of 0.5% Ropivacaine with dexmedetomidine (50ug) diluted in 9.5ml normal saline.

Demographic Characteristics: The demographic parameters like age distribution, gender distribution were similar in two groups and were comparable. This helped to eliminate the variability due to demographic differences which could lead to error in interpretation of data.

Age: In our study, the mean age in the ropivacaine with fentanyl (RF) group was 43.30 ± 7.67 years, while the ropivacaine with dexmedetomidine (RD) group had a slightly younger mean age of 39.53 ± 9.09 years. Although not statistically significant, the difference reflects a slightly younger demographic in the RD group.

Across the reviewed literature, several studies reported comparable mean ages. Thomas et al. (2022) [14] documented a mean age of 37 years in the dexmedetomidine group and 37.58 years in the fentanyl group, closely matching the age distribution in our study. Praveena et al. (2019) [15] documented a mean age of 37.3 ± 9.2 years in the ropivacaine with fentanyl and 36.1 ± 9.4 years in the ropi with dexmedetomidine group. Sarvesh et al. (2018) [16] reported a mean age of 37.37 ± 11.25 years in the RD group and 35.37 ± 10.88 years in the ropivacaine-only group, showing a slightly younger cohort overall. Goswami et al. (2019) [17] noted mean ages of 37.9 ± 6.85 years in the RD group and 36.3 ± 5.65 years in the control group, again indicating a younger population compared to our RF group. Khare et al. (2023) [18] presented a mean age of 40.83 ± 10.27 years in the intravenous dexmedetomidine group and 41.43 ± 9.37 years in the intraperitoneal group, highly comparable to both our study groups. Jaiswal et al. (2022) [19] included patients with a mean age of 38.1 ± 8.73 years in the RD group and 39.3 ± 7.55 years in the ropivacaine-only group. Roat et al. (2023) [20] reported a mean age of 39.6 ± 9.3 years in the levobupivacaine-dexmedetomidine group and 40.1 ± 8.9 years in the ropivacaine-

dexmedetomidine group, placing their cohort in the same age band as ours. Soni et al. (2022) [21] had a mean age of 38.9 ± 10.56 years in the RD group and 39.3 ± 9.78 years in the R group, again aligning with the general adult population we studied. Kalsotra et al. (2019) [22] reported a mean age of 42.5 ± 7.5 years in the RD group, 43.1 ± 6.8 in the RT group, and 41.7 ± 7.9 in the ropivacaine group providing a close match to our RF group and slightly older than our RD group.

Gender: In our study, females constituted a higher proportion in both groups, with 60.0% in the Ropivacaine with Fentanyl (RF) group and 56.7% in the Ropivacaine with Dexmedetomidine (RD) group, while males comprised 40.0% and 43.3% respectively. The association between gender and group distribution was statistically non-significant ($p = 0.793$), indicating that gender did not influence analgesic outcomes. This observation is echoed in several studies. Praveena et al. (2019) [15] enrolled 80 patients undergoing laparoscopic cholecystectomy, reporting a similar female predominance though without emphasizing any gender-specific analgesic response. Modir et al. (2021) [23] included 138 patients, again with a notable female majority and stated that there were no significant differences in complications or pain response between males and females. Similarly, Thomas et al. (2022) [14] also observed a greater representation of female patients across both the dexmedetomidine and fentanyl groups, attributing this trend to the overall higher incidence of gallstone disease among women but did not find any gender-dependent variability in postoperative analgesic efficacy. In line with these findings, Soni et al. (2022) [21] and Kalsotra et al. (2019) [22] also reported no significant gender-related differences in analgesic duration or VAS scores, reinforcing the idea that the choice of adjuvant whether dexmedetomidine or fentanyl rather than sex, plays a more decisive role in postoperative pain outcomes following laparoscopic cholecystectomy.

Weight: In our study, the mean weight of patients was 62.20 ± 10.588 kg in Group RF and 57.20 ± 9.852 kg in Group RD, which was statistically not significant ($P = 0.410$), indicating comparable baseline characteristics in terms of weight. These findings are consistent with multiple previous studies. Acharya R et al. (2016) [24] reported similar mean weights of 57.63 ± 5.6 kg in Group R and 58.05 ± 5.32 kg in Group RD with no significant difference. Similarly, Oza VP et al. (2016) [25] found the mean weight to be 59.5 ± 7.93 kg in Group B and 57.08 ± 8.15 kg in Group B+D, again with a statistically non-significant result ($P > 0.05$). Sethy AK et al. (2018) [26] reported mean weights of 60.7 ± 10.5 kg in Group B and 62.4 ± 8.7 kg in Group BD, which also showed no

significant difference. In a study by Bindra TK et al. (2017) [27], the mean weight was 64.42 ± 6.70 kg in Group I and 58.84 ± 3.36 kg in Group II, which too was not statistically significant ($p = 0.303$). Shukla U et al. (2015) [13] compared three groups like Group B (63.00 ± 9.72 kg), Group BT (63.50 ± 8.96 kg) and Group BD (62.90 ± 9.60 kg). Their p-values for intergroup comparisons were 0.8115, 0.773 and 0.963, respectively. These results underscore that weight variations, while present are commonly non-significant in well-randomized clinical trials involving regional or local anesthetic techniques.

Duration of Anaesthesia: In our study, the duration of anaesthesia was defined as the interval between the initiation of anaesthetic induction and the time of tracheal extubation. This measurement reflects the total intraoperative time under anaesthetic effect and is an important parameter for ensuring consistency in surgical exposure and drug metabolism across groups. The mean duration of anaesthesia in Group RF was 65.00 ± 6.017 minutes, while in Group RD, it was 63.50 ± 10.268 minutes. The difference between the groups was not statistically significant ($P = 0.493$), confirming that both groups had a comparable anaesthesia exposure time. These findings are well-aligned with previously published literature. For instance, Shukla U et al. (2015) [13] reported similar anaesthesia durations across three groups: 68.00 ± 11.40 minutes in Group B, 68.00 ± 10.90 minutes in Group BT, and 67.00 ± 11.00 minutes in Group BD, with non-significant p-values of 0.841, 0.684, and 0.5510, respectively. This reinforces the observation that minor variations in anaesthesia duration are statistically inconsequential when patient groups are otherwise well-matched. Furthermore, Kang H et al. (2010) [28] reported a mean anaesthesia duration of 68.88 ± 13.81 minutes in Group C and 68.03 ± 11.89 minutes in Group I, indicating no significant difference between groups. Similarly, Kim TH et al. (2010) [29] documented anaesthesia times of 66.6 ± 15.20 minutes in Group C and 68.50 ± 11.40 minutes in Group I, again reporting no significant variation ($p = 0.658$).

Hemodynamic Vitals: In our study, mean heart rate (HR) at the baseline (0 min) was similar between groups: 85.73 ± 8.68 bpm in the Ropivacaine with Fentanyl (RF) group and 85.20 ± 4.16 bpm in the Ropivacaine with Dexmedetomidine (RD) group with no statistical significance. However, from 1 hour onward until 24 hours, the RD group demonstrated a statistically significant reduction in heart rate compared to the RF group. At 1 hr, the HR was 87.53 ± 7.13 bpm (RF) vs. 79.60 ± 12.27 bpm (RD) ($p = 0.003$) and this downward trend continued consistently at 2 hr, 4 hr, 8 hr, 12 hr and 24 hr ($p < 0.05$, confirming that

dexmedetomidine provides superior hemodynamic stability and sympatholysis compared to fentanyl. This finding is consistent with several studies with Thomas et al. (2022) [14] observed significantly lower heart rates in the RD group up to 6 hours post-instillation, attributing this to the central sympatholytic action of dexmedetomidine. Modir et al. (2021) [23] also reported no significant heart rate differences during surgery but noted better postoperative pain scores and reduced opioid needs in the RD group, indicating stable intraoperative and postoperative vital parameters. Sarvesh et al. (2018) [16] documented more stable HR trends with dexmedetomidine in TAP block, supporting its autonomic modulatory effect even outside intraperitoneal use. Jaiswal et al. (2022) [19] found that heart rate remained lower in the dexmedetomidine group across all intervals post-block, with a significant difference up to 8 hours, aligning with the pattern in our study. Soni et al. (2022) [21] and Goswami et al. (2019) [17] also confirmed significantly lower postoperative heart rate values in RD groups, enhancing the reliability of our findings regarding cardiac profile regulation by dexmedetomidine.

In our study, baseline systolic blood pressure (SBP) and diastolic blood pressure (DBP) were comparable between the ropivacaine with fentanyl (RF) group and the ropivacaine with dexmedetomidine (RD) group, with no statistically significant differences. However, from 1 to 8 hours postoperatively, the RD group consistently showed significantly lower SBP and DBP values indicating better hemodynamic stability with dexmedetomidine. The differences were statistically significant at all measured intervals, supporting the superior blood pressure control offered by RD in the early postoperative phase. This pattern indicates more stable and lower SBP and DBP values in the RD group consistent with dexmedetomidine's α_2 -agonist sympatholytic properties. These findings align closely with multiple published studies by Thomas et al. (2022) [14] reported lower postoperative SBP and DBP values in the RD group up to 6 hours after surgery, confirming significant hemodynamic moderation by dexmedetomidine. Jaiswal et al. (2022) [19] showed similar blood pressure-lowering effects, with dexmedetomidine offering improved intraoperative and postoperative hemodynamic stability compared to ropivacaine alone. Soni et al. (2022) [21] noted no significant difference in baseline SBP or DBP but consistently lower mean postoperative values in the RD group, particularly during the early recovery phase, validating its cardiovascular regulatory role. Roat et al. (2023) [20], although comparing levobupivacaine+DEX vs ropivacaine+DEX, observed stable SBP and DBP in both groups, with the RD combination still offering effective cardiovascular moderation.

Kapoor et al. (2023) [30] (RD vs RK vs R) observed more stable intraoperative and postoperative blood pressure trends in the RD group. Their median SBP and DBP remained within safer ranges even up to 8 hours postoperatively, mirroring our trend. Sharma et al. (2024) [31] reported no statistically significant difference in SBP and DBP intraoperatively but noted better postoperative VAS scores and analgesic profiles in the RD group, indirectly indicating reduced sympathetic drive. Kalsotra et al. (2019) [22] also noted lower SBP and DBP values in RD vs R groups at various postoperative intervals, attributing it to dexmedetomidine's central sympatholysis. Praveena et al. (2019) [15] and Sarvesh et al. (2018) [16] documented lower SBP and DBP values in RD groups across several postoperative time points with no episodes of significant hypotension, reinforcing dexmedetomidine's controlled cardiovascular modulation.

In our study, mean arterial pressure (MAP) at baseline was comparable between the ropivacaine with fentanyl (RF) and ropivacaine with dexmedetomidine (RD) groups, with no statistically significant difference. However, from 30 minutes to 8 hours postoperatively, the RD group consistently demonstrated significantly lower MAP values. This reflects better hemodynamic modulation with dexmedetomidine, which is attributed to its central α_2 -adrenergic agonist activity that reduces sympathetic outflow and stabilizes cardiovascular responses. The trend of reduced MAP in the RD group highlights its role in maintaining perioperative cardiovascular stability without causing hypotensive episodes. These findings align closely with Thomas et al. (2022) [14] reported a significantly lower MAP in the RD group compared to the RF group in the first 6 hours postoperatively, confirming dexmedetomidine's effectiveness in blunting sympathetic responses. Jaiswal et al. (2022) [19] showed consistent reductions in MAP in the RD group during both intraoperative and postoperative periods, aligning with the cardiovascular stability observed in our study. Soni et al. (2022) [21] noted reduced MAP in the RD group at several intervals postoperatively, contributing to smoother recovery and less requirement for rescue medications. Roat et al. (2023) [20] found comparable MAP control in both levobupivacaine+DEX and ropivacaine+DEX groups, with dexmedetomidine contributing to stable hemodynamic profiles across variations in local anesthetic choice. Kapoor et al. (2023) [30] observed that patients receiving RD had significantly better control over postoperative MAP, particularly in the early recovery phase, reinforcing our study's pattern of cardiovascular moderation. Sharma et al. (2024) [31] did not find statistically significant differences in MAP between

RD and R groups intraoperatively, but improved VAS scores and reduced analgesic use in the RD group indicated better overall homeostasis. Kalsotra et al. (2019) [22] documented lower MAP in the RD group compared to both ropivacaine alone and ropivacaine-tramadol groups at multiple intervals, supporting the autonomic stability provided by dexmedetomidine. Praveena et al. (2019) [15] and Sarvesh et al. (2018) [16] also showed decreased MAP trends in RD groups across several measurement points, confirming dexmedetomidine's central role in achieving cardiovascular stability without adverse hypotension.

In our study, baseline SpO₂ levels were similar between the RF and RD groups with no statistically significant difference. However, from 1 to 8 hours postoperatively, the RD group showed marginally higher SpO₂ values at multiple intervals. These differences were statistically significant during the early postoperative phase. Although the clinical difference was small, this trend suggests better preservation of respiratory function and oxygenation in patients receiving dexmedetomidine, potentially due to its minimal respiratory depressant effect compared to opioids. These findings are consistent with Thomas et al. (2022) [14] reported stable and slightly better SpO₂ levels in the RD group, emphasizing dexmedetomidine's favorable respiratory profile compared to fentanyl, which can cause mild respiratory depression in sensitive individuals. Jaiswal et al. (2022) [19] observed no significant desaturation episodes in either group but noted higher consistency of SpO₂ values in the RD group during early recovery, aligning with our results. Soni et al. (2022) [21] documented similar findings, stating that SpO₂ remained well-maintained in all patients but the RD group showed less variability postoperatively indicating more stable oxygenation. Kapoor et al. (2023) [30] noted no significant respiratory compromise in any group but highlighted the absence of SpO₂ drops in the RD group, which supports the observation that dexmedetomidine, unlike opioids does not suppress respiratory centers. Sharma et al. (2024) [31] did not find significant differences in SpO₂ between groups but supported the safety profile of RD in terms of respiratory outcomes, as no hypoxia or desaturation episodes were reported in either group. Kalsotra et al. (2019) [22] and Sarvesh et al. (2018) [32] also confirmed that patients receiving dexmedetomidine maintained stable SpO₂ postoperatively, supporting its safety in preserving oxygenation without requiring respiratory support.

Intergroup Difference Analgesic Requirement

Time to first request for analgesic [Duration of Analgesia (hours)]: In our study, the mean duration of analgesia defined as the time from

intraperitoneal instillation of the study drug to the first request for analgesia (VAS >3) was significantly longer in the RD group (9.767 ± 6.200 hours) compared to the RF group (5.433 ± 6.950 hours) with a p-value of 0.013. Singh D et al. (2013) [32] reported a similar trend with a duration of 264.00 ± 120.00 min in the Ropivacaine group compared to 24.60 ± 10.50 min in the saline group using the same dose as ours (0.5%, 20 ml). Das NT et al. (2017) [33] found even longer analgesia with 13.47 ± 1.38 hours in the Ropivacaine group, although they used a higher dose (35 ml of 0.375%, i.e., 131 mg). In contrast, Acharya R et al. (2016) [24] reported shorter durations (487.7 ± 40.96 min in RD vs. 242.5 ± 19.84 min in R), possibly due to the use of only 19 mg ropivacaine and lower dexmedetomidine dose. Chiruvella S et al. (2016) [34] also found significantly shorter durations (126 ± 24 min in RD vs. 59 ± 13 min in R) likely influenced by their use of 15 mg ropivacaine in laparoscopic hysterectomy patients, which differs from our laparoscopic cholecystectomy cases.

Further supporting the analgesic benefits of dexmedetomidine, Rapolu S et al. (2018) [35] reported 7.61 ± 0.56 hours in Group BD vs. 5.81 ± 0.71 hours in Group B ($p = 0.0001$) and Oza VP et al. (2016) [25] found durations of 14.5 ± 1.86 hours in Group BD vs. 13.06 ± 1.09 hours in Group B, both using larger volumes (50 ml of 0.25% bupivacaine). Similarly, Sethy AK et al. (2018) [26] observed 310 ± 32.5 min in BD and 165.5 ± 30.8 min in B groups ($p < 0.05$), despite using 75 mg bupivacaine. Overall, studies consistently show that the addition of dexmedetomidine prolongs the duration of analgesia compared to local anesthetic alone, though differences in drug concentration, volume and surgical procedure explain the variation in absolute durations.

Total No. of Rescue Analgesics: In our study, intramuscular injection of Diclofenac 75 mg was administered as rescue analgesia when the Visual Analogue Scale (VAS) score was ≥ 3 . The mean number of rescue analgesic doses required was significantly lower in the ropivacaine with dexmedetomidine (RD) group (1.033 ± 0.490) compared to the ropivacaine with fentanyl (RF) group (1.767 ± 0.817) with a statistically significant p-value of 0.000. This indicates better and prolonged postoperative analgesia in the RD group, reducing the need for additional pain relief. Similar trends were observed in previous studies. Singh D et al. (2013) [32] reported a higher requirement in the Normal Saline group (3.84 ± 0.75) than in the Ropivacaine group (2.72 ± 0.46) demonstrating the analgesic effectiveness of ropivacaine. Oza VP et al. (2016) [25] found that the mean number of rescue doses was significantly lower in the Bupivacaine-Dexmedetomidine (BD) group (1.76 ± 0.20) compared to the Bupivacaine (B) group (2.56 ± 0.16), while Rapolu S et al.

(2018) [35] observed 1.93 ± 0.32 doses in the BD group versus 2.12 ± 0.53 in the B group with statistically significant results ($p < 0.05$). These findings collectively support the conclusion that the addition of dexmedetomidine to local anesthetics reduces the requirement for rescue analgesia, offering improved postoperative pain control compared to both plain local anesthetics and placebo.

Total Analgesic Consumption in 24 Hours (mg):

In our study, the total analgesic consumption within 24 hours was significantly lower in the ropivacaine with dexmedetomidine (RD) group (77.500 ± 36.759 mg) compared to the ropivacaine alone (R) group (130.00 ± 62.076 mg) with a p-value of 0.000. This indicates that the addition of dexmedetomidine to ropivacaine significantly reduces the overall need for analgesics in the postoperative period. This finding is consistent with previous studies. Kang H et al. (2010) [28] reported a lower fentanyl requirement in the Ropivacaine group compared to the normal saline group. Acharya R et al. (2016) [24] found total analgesic consumption to be 183.75 ± 44.78 mg in Group R and 61.88 ± 37.55 mg in Group RD, while Chiruvella S et al. (2016) [34] reported 175 ± 75 mg in Group R and 95 ± 15 mg in Group RD—both using intravenous diclofenac 75 mg when VAS ≥ 4 . Singh A et al. (2013) [36] observed similar trends with 148.50 ± 41.46 mg in the normal saline group, 97.34 ± 46.69 mg in the ropivacaine group and 83.82 ± 24.52 mg in the ropivacaine-fentanyl group. In all these studies, the reduction in analgesic consumption was statistically significant ($p < 0.05$), reinforcing the efficacy of combining ropivacaine with adjuvants like dexmedetomidine or fentanyl.

A similar pattern was seen in studies involving bupivacaine. Shukla U et al. (2015) [13] found 175 ± 75 mg in Group B, 85 ± 35 mg in Group BT, and 45 ± 15 mg in Group BD (using intramuscular diclofenac 75 mg when VAS ≥ 3). Sethy AK et al. (2018) [26] reported total paracetamol consumption as 3.6 ± 0.4 gm in Group B and 1.2 ± 0.8 gm in Group BD. Ahmed B et al. (2008) [12] recorded morphine consumption as 24 ± 1 mg in Group B, 13 ± 2.0 mg in Group B+M, and 12 ± 1.0 mg in Group B+D, with 1 mg IV morphine administered when VAS ≥ 3 .

All these studies demonstrated statistically significant reductions ($p < 0.05$) in total rescue analgesic use when an adjuvant was added to the local anesthetic. Thus, our findings are in agreement with the broader evidence base, confirming the analgesic-sparing effect of combining ropivacaine or bupivacaine with adjuvants like dexmedetomidine.

Vas at Different Time Interval: In our study, the VAS scores in the ropivacaine with dexmedetomidine (RD) group were significantly lower at all measured postoperative intervals compared to the ropivacaine with fentanyl (RF) group. At 30 minutes, the VAS score in the RF group was 4.07 ± 1.28 versus 2.50 ± 1.36 in RD ($p < 0.001$). Similar differences were observed at 2 hours (4.40 ± 1.36 vs 3.07 ± 1.18), 4 hours (4.70 ± 1.24 vs 3.37 ± 1.07), 8 hours (4.93 ± 1.20 vs 3.30 ± 1.15), 12 hours (4.30 ± 1.01 vs 2.80 ± 1.13) and 24 hours (3.60 ± 0.85 vs 2.13 ± 0.73), all with $p < 0.001$. This clearly demonstrates that dexmedetomidine provided superior and longer-lasting postoperative analgesia compared to fentanyl. These findings are supported by Chiruvella S et al. (2016) [34] observed significantly lower 24-hour VAS scores in the RD group (1.86 ± 0.46) compared to the R group (4.7 ± 0.94) with each time interval from 30 minutes to 24 hours showing statistically significant lower scores in the RD group. For example, at 1 hour VAS was 5.80 ± 0.10 in R vs 2.14 ± 0.36 in RD, and at 24 hours it was 3.04 ± 0.82 in R vs 1.02 ± 0.61 in RD ($p < 0.05$), closely matching our pattern of sustained pain relief.

Acharya R et al. (2016) [24] also reported significantly lower VAS scores in the RD group at 4, 8, 12, and 24 hours postoperatively. At 24 hours, VAS was 2.1 ± 0.66 in R vs 1.6 ± 0.71 in RD ($p = 0.00$), confirming the prolonged analgesic effect of dexmedetomidine. While early time points (up to 2 hours) showed no significant difference, later intervals were consistent with our observations. Thomas et al. (2022) [14] found VAS scores significantly lower in the RD group throughout the first 24 hours.

At 2 hours, the RD group had 3.2 ± 1.1 compared to 4.5 ± 1.2 in the RF group, and at 24 hours, RD scored 2.0 ± 0.8 vs 3.6 ± 0.9 in RF reflecting similar magnitude and trend as in our results. Soni et al. (2022) [21] demonstrated significantly lower scores at all intervals up to 24 hours: VAS at 30 minutes was 2.67 ± 2.00 (R) vs 1.65 ± 1.29 (RD), at 4 hours 3.08 ± 2.20 vs 1.69 ± 1.46 and at 24 hours 1.86 ± 0.96 vs 1.28 ± 0.62 , all $p < 0.05$. Sharma et al. (2024) [31] also showed lower VAS values in RD vs RF at 6h, 12h, and 18h: at 12h, median VAS was 40 mm in RF vs 17 mm in RD; at 24h, 51 mm in RF vs 25 mm in RD, all highly significant ($p < 0.0001$). Kapoor et al. (2023) [30] found RD group had significantly lower VAS scores than both RK and R groups throughout 24 hours affirming dexmedetomidine's enhanced analgesic profile. Jaiswal et al. (2022) [19], Kalsotra et al. (2019) [22] and Praveena et al. (2019) [15] all observed consistently lower VAS scores in the RD groups across 24 hours, attributing it to the synergistic peripheral and central analgesic effects of dexmedetomidine.

Postoperative Complications: In our study, the incidence of postoperative complications was generally low and comparable between the two groups. However, bradycardia occurred similar among both the groups. Other complications such as nausea, hypotension, vomiting and pruritis were minimal in RD group. These results are in agreement with Acharya R et al. (2016) [24] observed postoperative complications including nausea, vomiting and shoulder tip pain.

Among these, vomiting was significantly less in the RD group compared to the R group ($p = 0.07$), supporting our finding of lower gastrointestinal side effects with dexmedetomidine. Singh A et al. (2013) [36] noted that pruritus, emetic symptoms and hypotension were non-significant across groups, but bradycardia was significantly higher in the ropivacaine-fentanyl group ($p = 0.002$), and shoulder pain was significantly higher in the normal saline group ($p < 0.0001$), aligning with our observation of better cardiovascular stability in the RD group. Shukla U et al. (2015) [13] reported higher rates of nausea (17.5%), vomiting (12.5%), and shoulder pain (70%) in the B group compared to BD (nausea 7.5%, vomiting 0%, shoulder pain 12.5%), closely reflecting our pattern of reduced side effects with the use of dexmedetomidine. Sethy AK et al. (2018) [26] documented that postoperative side effects like nausea, vomiting, and shoulder pain were significantly lower in the BD group (2, 3, 2 cases respectively) compared to the B group (8, 6, 6 cases), reinforcing the lower complication rate seen in our RD group. Rapolu S et al. (2018) [35] found that while nausea and vomiting were comparable, the incidence of shoulder tip pain was significantly lower in the B+D group (14%) compared to the B group (40%), supporting our observation of fewer complications with RD. Oza VP et al. (2016) [25] reported nausea/vomiting in 6% of Group B and 8% of Group B+D, and shoulder pain in 12% of Group B vs 4% in Group B+D. Notably, no cases of hypotension, bradycardia, or sedation were observed in either group, indicating good overall safety, which mirrors our findings.

Thomas et al. (2022) [14] reported a higher incidence of postoperative nausea and vomiting (PONV) in the fentanyl group compared to dexmedetomidine, attributing it to the opioid-sparing effects and antiemetic properties of dexmedetomidine. Soni et al. (2022) [21] also observed lower rates of nausea and vomiting in the RD group, noting that fentanyl-related side effects such as PONV and sedation were more common in the comparator groups. Sharma et al. (2024) [31] found that dexmedetomidine was associated with fewer episodes of nausea and vomiting, with no cases of hypotension or bradycardia, supporting the safety of the RD combination even in higher-risk

populations. Kapoor et al. (2023) [30] reported that while bradycardia and hypotension were observed in the RD group, they were not clinically significant or persistent, and the overall adverse event profile was more favorable than in other groups. Praveena et al. (2019) [15] and Acharya R et al. (2016) [34] also noted a reduction in opioid-related side effects in the RD groups, with better tolerance and fewer incidences of nausea and vomiting compared to fentanyl-based combinations. Chiruvella S et al. (2016) [34] observed a lower incidence of nausea, vomiting, and sedation in the dexmedetomidine group compared to ropivacaine alone, supporting shivering. However, bradycardia was similar in both the groups, suggesting equally effect in both groups.

Conclusion

Our study demonstrates that the intraperitoneal instillation of ropivacaine combined with dexmedetomidine (RD group) provides superior postoperative analgesia compared to ropivacaine with fentanyl (RF group) in patients undergoing laparoscopic cholecystectomy. The RD group experienced significantly longer duration of analgesia, reduced need for rescue analgesics, and lower total analgesic consumption within 24 hours. Hemodynamic parameters, including heart rate, systolic and diastolic blood pressure, and mean arterial pressure, were more stable in the RD group, particularly during the early postoperative period. Additionally, VAS scores were consistently lower in the RD group across all time intervals, indicating more effective pain control. Oxygen saturation was also marginally better in the RD group at several points. Postoperative complications were less in RD group. Overall, dexmedetomidine appears to be a more effective and safer adjuvant than fentanyl when combined with ropivacaine for intraperitoneal instillation, offering better pain relief and improved patient outcomes.

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