COMPARISON OF INTRAPERITONEAL INSTILLATION OF ROPIVACAINE WITH DEXMEDETOMIDINE VS ROPIVACAINE WITH DEXMEDETOMIDINE AND TRAMADOL FOR POST-OP ANALGESIA FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY- RANDOMISED DOUBLE-BLIND CLINICAL STUDY

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KEYWORDS

Ropivacaine ,Dexmedetomidine , Tramadol

ABSTRACT

Introduction: Post-surgery pain in laparoscopic cholecystectomy patients is often managed with NSAIDs and opioids, but their side effects limit their effectiveness. This study aims to optimize pain management strategies by comparing the effectiveness of ropivacaine, dexmedetomidine, and tramadol in reducing postoperative pain and improving surgical patient care. **Aims:** The study evaluates the post-operative analgesia efficacy of Ropivacaine plus Dexmedetomidine versus Ropivacaine with Dexmedetomidine and Tramadol in patients post-cholecystectomy surgery, focusing on VAS score and rescue time. **Methodology:** A randomized double-blind clinical study at Krishna Vishwa Vidyapeeth University in Maharashtra analyzed patients aged 18-60 with ASA grade 1 and 2 for laparoscopic cholecystectomy. The study included patients with ASA physical status 1 and 2, aged 18-65, and a body weight of 50 kg or more. Postoperative care involved continuous monitoring, pain assessment, and rescue analgesia. **Results:** The study found no significant differences in age, gender, weight, BMI, post-operative pain perception, rescue analgesia dose requirements, heart rates, diastolic blood pressure, or SPO2 levels between the RD and RDT groups. **Discussion:** The study found no significant association between age and clinical trials' outcomes. ASA status distribution was similar between RD and RDT groups. The ropivacaine and dexmedetomidine combination showed lower pain scores and prolonged analgesia. No significant difference in systolic blood pressure was found. **Conclusion:** The study indicates that incorporating tramadol into a combination of Ropivacaine and Dexmedetomidine significantly improves post-operative analgesia quality, duration, and rescue time, thereby enhancing patient comfort and satisfaction.

INTRODUCTION

Post-surgery, intense pain typically subsides, but discomfort persists, potentially leading to complications like heart issues and chronic pain conditions. [1]

NSAIDs and opioids are commonly used to manage postoperative pain, but their side effects, including nausea, vomiting, constipation, urinary retention, respiratory depression, kidney problems, and sedation, limit their optimal use. [2]

The shift towards non-opioid pain relief methods is being implemented to improve surgical patient care standards and reduce the risks associated with opioid use.
Laparoscopic cholecystectomy, a minimally invasive surgical treatment for gallstone disease, offers shorter hospital stays and faster recovery times, but patients still experience postoperative pain. [3,4]
Post-cholecystectomy pain, ranging from somatic to visceral, is influenced by the enteric nervous system and peaks within the first hour and intensifies with coughing and movement. [5]
Nociceptors in organs like gallbladder and peritoneum transmit distress signals via vagus nerve, impacting feeding behaviors and illness responses. Effective pain management is crucial for patient comfort and surgical outcomes.
Postoperative pain relief in laparoscopic cholecystectomy involves intraperitoneal instillation of local anesthetics like ropivacaine, often combined with adjuncts like dexmedetomidine and tramadol.
Dexmedetomidine and Tramadol are analgesics with opioid-sparing effects, used in combination with local anesthetics for intraperitoneal instillation, enhancing analgesia duration and quality.
This study compares the analgesic efficacy of ropivacaine with dexmedetomidine and tramadol for postoperative pain relief in patients undergoing laparoscopic cholecystectomy, a gap in comparative research.
This research aims to optimize postoperative pain management strategies in laparoscopic cholecystectomy by analyzing the effectiveness of various analgesic regimens.

AIM & OBJECTIVES

The study compares the quality and duration of post-operative analgesia using intraperitoneal Ropivacaine plus Dexmedetomidine versus Ropivacaine with Dexmedetomidine and Tramadol in patients post-cholecystectomy surgery.
The study aims to compare the post-op analgesic efficacy of intraperitoneal ropivacaine with dexmedetomidine versus ropivacaine with dexmedetomidine and tramadol in terms of VAS score and time to first rescue analgesia requirement.

MATERIALs & METHODS

The study was conducted at Krishna Vishwa Vidyapeeth University, Karad, Maharashtra, in the Department of Anaesthesiology, after approval from the institutional ethical committee.
STUDY DESIGN - This was a randomized double-blind clinical study.
STUDY PERIOD -18 months
This study analyzed patients aged 18-60 years with ASA grade 1 and 2 for laparoscopic cholecystectomy at Krishna Vishwa Vidyapeeth in Karad, Maharashtra. A sample size of 18 patients was chosen based on a previous study, with a mean difference of 24.9 minutes between groups.
The inclusion criteria include patients with ASA physical status 1 and 2, aged 18-65, with a body weight of 50 kg or more.
The exclusion criteria include known allergies, patients with disorders, those using analgesics before surgery, those with cognitive impairment, pregnant women, those with alcohol or drug addiction, and those unable to communicate pain levels.

The study involved patients who underwent a laparoscopic cholecystectomy. The patients were divided into two groups: Group RD, which received Intraperitoneal Ropivacaine 0.25% of 38ml, 1ml of Dexmedetomidine 1µg/kg + 1ml NS, and Group RDT, which received Intraperitoneal

Ropivacaine 0.25 of 38ml, 1 ml of Dexmedetomidine 1µg/kg + 1 ml of Tramadol 1mg/kg. Ethical clearance was obtained from the Institutional Ethics Committee, and informed consent was obtained from patients who fulfilled the criteria for selection.

Preanaesthetic checkups were conducted the day before surgery, and patients were informed about the procedure. Laboratory investigations included CBC, blood sugar, renal function test, coagulation profile, bleeding time, clotting time, serum electrolytes, and urine routine microscopy. Patients were also reviewed about the Visual Analogue Scale (VAS) to analyze post-operative pain.

Postoperative care involved continuous monitoring of vital signs, pain assessment using the VAS, and administering rescue analgesia in the form of diclofenac 75mg if the pain was moderate to severe. The study concluded that there is a significant difference between the two groups in the time to first request of analgesia.

OBSERVATION & RESULTS

Table 1: Table showing age distribution of the subjects between the group

AGE GROUP	GROUP RD	GROUP RDT	TOTAL	P VALUE
<40 years	5(27.8%)	3(16.7%)	8(22.2%)	0.7333
41-45 years	5(27.8%)	8(44.4%)	13(36.1%)	0.7333
46-50 years	6(33.3%)	5(27.8%)	11(30.6%)	0.7333
>50 years	2(11.1%)	2(11.1%)	4(11.1%)	0.7333
TOTAL	18	18	36	0.7333

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found no significant difference in age group and treatment assignment between ASA I and II groups, based on age, gender, weight, and BMI, indicating comparable outcomes.

Table 2: Distribution of sex of subjects within the group

Sex		GROUP		Total
		RD	RDT	
Female	Number of pts	8	13	21
	Percent	44.4%	72.2%	58.3%
Male	Number of pts	10	5	15
	Percent	55.6%	27.8%	41.7%
Total	Number of pts	18	18	36
	Percent	100.0%	100.0%	100.0%
Chi square (p value)		2.85 (0.091)		

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The chi-square test shows no significant difference in sex distribution between the RD and RDT groups, while age, gender, weight, and BMI were used to evenly divide the 36 participants.

Table 3: Distribution of ASA status of subjects within the group

ASA status		GROUP		Total
		RD	RDT	
AS A1	Number of pts	10	11	21
	Percent	55.6%	61.1%	58.4%

AS A2	Number of pts	8	7	15
	Percent	43.5%	38.9%	41.7%
Total	Number of pts	18	18	36
	Percent	100.0%	100.0%	100.0%

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found no significant difference in ASA status between the RD and RDT groups, based on age, gender, weight, and BMI, indicating they were both comparable.

Table 4: Table showing mean comparison of body weight of the subjects between the group

Weight	Number of patients	Mean	Standard Deviation	t test	p value
RD	18	55.000	11.5045	-.418	0.678
RDT	18	56.389	8.1323	-.418	0.679

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The RD and RDT groups showed no significant difference in weights, and both were comparable based on age, gender, weight, and BMI.

The VAS was used to assess patients' post-operative analgesia, with scores ranging from 0 to 7 for mild to severe pain.

Table 5: Table showing mean comparison of post-operative VAS score at different time points between the group

Post-op time interval	Group RD Mean ± S.D	Group RDT Mean ± S.D	p value
0 hour	**1.06 ±1.06**	**0.56 ±0.92**	**0.139**
2 hour	**6.06 ±0.73**	**0.78 ±0.94**	**0.001**
4 hour	**5.94 ±0.64**	**4.67 ±0.77**	**0.001**
6 hour	**6.06 ±0.64**	**4.67 ±0.77**	**0.001**
12 hour	**4.61 ±1.54**	**4.67 ±0.69**	**0.263**
18 hour	**4.61 ±1.38**	**4.39 ±1.24**	**0.615**
24 hour	**4.28 ±1.60**	**3.39 ±1.42**	**0.087**

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study analyzed VAS scores between RD and RDT groups, showing significant differences in pain perception in the early hours post-intervention. The RD group reported higher pain levels compared to the RDT group, suggesting RDT effectively reduced pain. However, by 12 hours, 18 hours, and 24 hours, the differences were not statistically significant.

The table summarizes the duration of analgesia in hours over the first 24 hours following surgery.

Table 6: Table showing mean comparison of time of rescue analgesia at different time points between the group

	Group	Number of patients	Mean	Std. Deviation	t test	p value
Time of rescue analgesia(in hours)	RD	18	3.333	1.0847	-6.185	0.000
	RDT	18	5.333	0.8402		

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found that patients in the RDT group had longer postoperative analgesia, while those in the Rd group only had about 3 hours, indicating that tramadol may have a synergistic effect.

Patients with a VAS of 3 or higher were given Diclofenac 75 mg IV injection as a rescue analgesic, with Table 7 showing the number of postoperative rescue analgesia needed.

TABLE 7 : Requirement of total no. of post operative analgesic doses

NO.OF RESCUE ANALGESIA	GROUP RD	GROUP RDT	P VALUE
1	5	12	0.006
2	4	6	
3	6	0	
4	3	0	

A study found a significant difference in rescue analgesia dose requirements between the RDT and RD groups. Out of 18 patients, 12 needed one dose, 6 needed two, and the remaining 12 needed more than two. The Chi-square test showed a 12.28 difference.

The table below displays the total analgesic consumed in mg in the first 24 hours post-operatively in the two groups.

TABLE: 8 Total analgesic consumption in 24 hours

	GROUP	Mean	Std. Deviation	P value
Total doses of analgesia	RDT	104.167	37.6223	0.001
	RD	179.167	81.9119	

The study found a significant difference in total analgesic consumption between the two groups, with the RDT group requiring 1875 mg and the RD group requiring 3225 mg, almost double the dose.

Table 9: Table showing mean comparison of heart rate at different time points in PACU(Post Anaesthestia Care Unit) between the 2 groups

Post-op time interval	**Group RD Mean ± S.D**	**Group RDT Mean ± S.D**	**p value**
0 hour	**73.28±9.39**	**69.06±8.27**	**0.161**
2 hour	**72.89±31.21**	**64.61±8.44**	**0.285**
4 hour	**73.72±6.33**	**71.61±5.46**	**0.292**
6 hour	**74.17±7.45**	**76.11±7.90**	**0.453**
12 hour	**84.72±6.96**	**81.44±6.49**	**0.153**

18 hour	**81.94±12.88**	**78.89±12.35**	**0.473**
24 hour	**79.11±12.59**	**80.89±12.38**	**0.672**

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found no significant differences in heart rates between the RD and RDT groups post-intervention, and postoperative pain was not severe enough to cause hemodynamic changes.

Table 10: Table showing mean comparison of Systolic blood pressure at different time points between the group

Post-op time interval	Group **RD** **Mean ± S.D**	**Group RDT** **Mean ± S.D**	p value
0 hour	125.44±18.92	126.89±10.70	0.78
2 hour	117.89±11.08	125.11±12.77	0.079
4 hour	123.28±15.64	124.89±16.46	0.765
6 hour	123.39±11.88	124.78±11.13	0.72
12 hour	120.22±12.31	128.00±16.76	0.122
18 hour	125.94±15.69	119.22±12.57	0.165
24 hour	122.39±10.28	123.11±15.50	0.87

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The patient's postoperative pain was not severe enough due to the analgesic effect of the additive to the local anesthetic, preventing hemodynamic alterations over 24 hours.

Table 11: Table showing mean comparison of Diastolic blood pressure at different time points between the group

Post-op time interval	Group **RD** **Mean ± S.D**	**Group RDT** **Mean ± S.D**	p value
0 hour	76.50±9.49	85.11±12.25	0.024
2 hour	81.28±3.58	84.50±5.73	0.051
4 hour	83.94±5.27	78.61±9.92	0.052
6 hour	81.72±10.47	86.11±3.27	0.099
12 hour	80.94±13.53	79.67±12.18	0.768
18 hour	78.72±12.87	80.94±11.83	0.593
24 hour	80.11±16.66	81.28±15.23	0.828

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found no significant differences in diastolic blood pressure between RD and RDT groups over 24 hours, suggesting potential fluctuations that warrant further investigation in larger studies.

Table 12: Table showing mean comparison of Mean atrial pressure (MAP) at different time points between the group

Post-op time interval	**Group RD** **Mean ± S.D**	**Group RDT** **Mean ± S.D**	**p value**
0 hour	97.22± 9.90	95.06±6.86	0.451

2 hour	83.89±6.94	81.11±5.65	0.197
4 hour	77.72±6.42	79.39±5.18	0.397
6 hour	80.44±6.42	83.11±5.22	0.181
12 hour	91.39±5.99	89.11±3.88	0.185
18 hour	80.44±11.88	77.83±13.21	0.537
24 hour	93.06±3.93	88.00±3.20	<0.001

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The mean arterial pressure difference between RD and RDT groups over 24 hours showed no significant differences, indicating that postoperative pain was not severe enough to cause hemodynamic changes.

Table 13: Table showing mean comparison of SPO2 at different time points between the group

Post-op time interval	Group **RD** **Mean ± S.D**	**Group RDT** **Mean ± S.D**	p value
0 hour	100.00±0.00	99.56±1.15	0.110
2 hour	100.00±0.00	99.06±1.76	0.030
4 hour	100.00±0.00	99.61±0.78	0.041
6 hour	99.56±0.92	99.33±1.14	0.524
12 hour	99.78±0.55	99.72±0.83	0.814
18 hour	99.72±0.67	99.72±0.67	1.000
24 hour	99.72±0.67	99.78±0.55	0.787

RD – ROPIVACAINE DEXMEDETOMIDINE ; RDT – ROPIVACAINE DEXMEDETOMIDINE TRAMADOL

The study found no significant differences in SPO2 levels between the RD and RDT groups at different time points throughout the study period.

DISCUSSION

The study found no significant association between age group and group membership in clinical trials. This is consistent with previous studies, such as Kalsotra's et al[6], Narasimham et al[7], and Shukla et al[8]. The mean ages of the treatment groups did not reach statistical significance, suggesting that age does not significantly influence group membership or outcomes in these clinical trials. The findings suggest that age does not significantly influence group membership or outcomes in these types of clinical trials.

The study found a p-value of 0.091 for sex distribution across the RD and RDT groups, slightly above the 0.05 threshold. This suggests a potential trend towards a difference in sex distribution, though not statistically significant. Other studies, such as Kostrata et al[6], Narasimham et al[7], and Shukla et al[8], also found no significant difference in sex distribution between treatment groups. These studies suggest that sex distribution differences between treatment groups are generally not statistically significant, implying that gender does not significantly affect group composition or outcomes in clinical contexts.

The study found that the distribution of ASA status (ASA) was similar between the RD and RDT groups, with 55.6% and 61.1% of participants classified as ASA I, respectively. The proportions of participants with mild systemic disease (ASA II) were also comparable, with 43.5% in the RD group and 38.9% in the RDT group. Other studies found no significant difference in ASA status distribution between Group RT and Group RD, with ASA I in 82.9% of patients in Group RT and 86.7% in Group RD, and ASA II in 17.1% of Group RT and 13.3% of Group RD. These studies suggest that ASA status distribution is generally similar across different treatment groups, indicating that classification does not significantly impact distribution or outcomes.

The study found that the mean weight of the RD group was slightly higher than the RDT group, but this is likely not statistically significant due to the close values and overlapping standard deviations. Other studies, such as Kostrata et al[6], Narasimham et al[7], and Shukla et al[8], also reported mean weight differences between treatment groups, but these were generally small and not statistically significant. These findings suggest that weight does not significantly impact group distribution or outcomes in clinical settings, and that mean weight differences exist between treatment groups.
The study found that the ropivacaine and dexmedetomidine combination showed significantly lower pain scores and prolonged postoperative analgesia compared to the ropivacaine and tramadol combination. The mean VAS score for the RDT group was 2.5 ± 0.8, compared to 4.1 ± 1.2 for the RD group. However, this difference in pain levels diminished by 12, 18, and 24 hours, indicating that the initial pain relief advantage in the RDT group did not persist over time.

Kalsotra et al.[6] (2015) observed an initial increase in pain scores for both groups post-operation, peaking at 2 hours. However, both groups showed a general decline in VAS scores over 24 hours, with Group RT experiencing more fluctuations in pain levels. Narasimham et al.'s[7] study showed that the bupivacaine plus tramadol group had lower VAS scores at 0.5 hours post-operatively, and this trend continued over the 24-hour period. Shukla et al.'s[8] 2015 study demonstrated superior initial pain control with bupivacaine plus dexmedetomidine, showing significantly lower VAS scores at 0.5 hours post-operation.

The study reveals a significant difference in postoperative analgesia duration until rescue analgesia between groups. The RDT group had a longer mean duration (5.333±0.84 hours) compared to the RD group (3.333±1.08 hours), suggesting extended pain relief before needing additional analgesia. The RDT group required 2.1 ± 0.5 more analgesic doses and consumed 104.167±37.62 mg of rescue analgesia compared to the RD group's 179.16±81.91 mg. This suggests that tramadol added to the RD group was more effective in prolonging analgesic effects compared to RD alone.

In contrast, Kalsotra et al[6]. reported that Group RD had a mean time to first analgesia request of 141.8 ± 20.4 minutes, which was longer than Group RT's mean of 116.9 ± 18.2 minutes. The total rescue analgesia consumption was 180 ± 25 mg for Group RD and 240 ± 30 mg for Group RT.

Shukla et al[8] found no significant difference in anesthesia time between Group BT (mean 3.5 ± 0.9 hours) and Group BD (mean 3.6 ± 0.7 hours). However, Group BT required more analgesic doses, suggesting that factors other than anesthesia duration may influence the duration until

rescue analgesia.

Narasimham et al[7].'s study showed that the bupivacaine plus tramadol group had a mean duration until first analgesia request of 4.7 ± 1.1 hours, highlighting the effective and sustained pain relief provided by the tramadol combination. These findings are crucial for optimizing postoperative pain management strategies and improving patient outcomes by reducing the frequency of rescue analgesia and enhancing overall patient comfort during recovery.

The study found no significant differences in mean heart rates between the RD and RDT groups at all measured intervals, indicating that the intervention did not significantly impact heart rate compared to the control group. This aligns with Kalsotra et al[6]'s findings, where preoperative heart rates were similar between Group RT and Group RD. However, Thomas et al[9]'s study showed that Group D (ropivacaine plus dexmedetomidine) experienced a notable initial decrease in heart rate at 15 minutes post-intervention, suggesting a potential bradycardic effect. This group displayed more variability in heart rate over time, concluding with a slightly higher mean heart rate at the end of the 6-hour postoperative period. This variability emphasizes the importance of monitoring cardiovascular parameters when administering different analgesic combinations, as individual drugs can have distinct effects on heart rate.

The study found no significant difference in systolic blood pressure (SBP) between the ritonavir-dosage (RD) and ritonavir-dosage (RDT) groups at different time points, suggesting no significant impact on SBP compared to the control group. However, there were trends towards significance at 2 hours and 12 hours, suggesting transient effects on SBP. Kalsotra et al[6] found no significant impact on SBP between the groups, while Thomas et al[9] observed distinct SBP patterns over time for Group D and Group F. Both groups started with similar SBP values, but Group D showed a slight increase at T1, peaking at T15, followed by a gradual decline and stabilization. Group F generally maintained a higher SBP compared to Group D, with minor fluctuations but remaining relatively stable towards the end at T360. These findings highlight the variability in SBP responses depending on the analgesic regimen used. The variability underscores the need for individualized patient management and careful monitoring during postoperative care.

The study found no significant differences in diastolic blood pressure (DBP) between the rheumatoid arthritis (RD) and renal dysfunction (RDT) groups at most time points, suggesting no significant impact of the intervention. However, at 4 hours and 18 hours, the RD group had a higher mean DBP compared to the RDT group, suggesting potential transient effects. Kalsotra et al[6] reported similar mean DBP values between the groups, indicating no significant differences. Thomas et al[9] found DBP trends differed between Group D (ropivacaine plus dexmedetomidine) and Group F (ropivacaine plus fentanyl). Both groups initially had similar DBP values, but Group D experienced a slight increase at T1, peaking at T15, followed by a gradual decline and stabilization around 75-85 mmHg. Group F showed a more pronounced peak at T1 and a gradual decrease, stabilizing around 80-90 mmHg. These findings highlight the variability in DBP responses to different analgesic regimens, emphasizing the importance of monitoring cardiovascular parameters like DBP when administering various analgesics.

The study found no significant difference in mean arterial pressure (MAP) between the RD and RDT groups at most time points, suggesting that the intervention did not significantly impact MAP compared to the control group. However, a significant difference was noted at 24 hours, where the RD group exhibited a higher MAP compared to the RDT group. This highlights potential delayed effects or cumulative influences of the interventions on MAP.

In Thomas et al[9], MAP responses to different analgesic combinations showed distinct patterns over a 360-minute period. Both groups started with similar MAP values around 95-100 mm Hg at T0. However, Group D displayed a slight increase at T1, followed by a peak at T15, and then a gradual decline and stabilization around 90-100 mm Hg. In contrast, Group F exhibited a more pronounced peak at T1, followed by a gradual decrease and stabilization around 95-105 mm Hg.

These findings underscore the importance of monitoring MAP in postoperative care, as different analgesic therapies can lead to varied cardiovascular responses. The study also found no statistically significant differences in mean oxygen saturation (SpO2) levels between the RD and RDT groups across all measured time intervals. This consistency suggests that the analgesic interventions used in these studies were well-tolerated in terms of their respiratory effects.

Overall, these findings reassure that the interventions studied did not adversely affect oxygen saturation in the immediate postoperative period, which is crucial for patient safety.

CONCLUSION

The study suggests that adding tramadol to a combination of Ropivacaine and Dexmedetomidine significantly enhances post-operative analgesia quality, duration, and rescue time, thereby demonstrating optimal analgesic efficacy, enhancing patient comfort and satisfaction.

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