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Original Research Article

Comparison of effect of perioperative infusion of lidocaine vs dexmedetomidine on post-operative pain in patients undergoing laparoscopic cholecystectomy

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ABSTRACT

Background: Growing concerns regarding opioid-related side effects and complications have prompted alternative analgesic modalities for post-operative pain in laparoscopic cholecystectomy. This study aimed to compare the efficacy of Lidocaine and Dexmedetomidine infusions administered intraoperatively by evaluating post-operative VAS scores, hemodynamic parameters, recovery profiles, total number of rescue analgesics required, and any side effects of the study drugs between the two groups.

Materials and Methods: Interventional, double-blind, randomized study on 66 ASA I/II class patients aged 18 to 60 years of both genders. These Patients were randomized to Group L (Lidocaine) and Group D (Dexmedetomidine). Hemodynamic Parameters were noted at pre-defined time frames intra/post-operatively. Post-operative Visual Analogue Scale Score and Richmond Agitation Sedation Score monitoring was done.

Results: The study did not result in any significant hemodynamic event, indicating the safety of both Lidocaine and Dexmedetomidine. Moreover, both drugs were found to be effective in managing post-operative pain but mean VAS was found to be significantly lower in Group D as compared to that in Group L at 120 min follow-up only ($p<0.05$). The recovery characteristics were also similar for most of the evaluation periods, further reinforcing the safety and effectiveness of these drugs.

Conclusion: It can be inferred that perioperative infusion of both Lidocaine and Dexmedetomidine effectively delayed the post-operative rescue analgesic need, with similar recovery profiles. However, of the two, Dexmedetomidine had a slight edge over Lidocaine in terms of analgesic effect and recovery profile.

1. Introduction

The demand for laparoscopic procedures has surged due to their ability to reduce surgical scarring, shorten hospital stays, promote early mobilization, and speed up recovery times.[1] Post-operative pain management is a critical aspect of patient care following laparoscopic cholecystectomy, as it significantly impacts recovery and satisfaction.[2] Various analgesic strategies are employed to alleviate pain effectively while minimizing adverse effects.[3] Traditional opioid-based analgesia has raised concerns due to side effects and complications, leading to the exploration of alternative strategies.[4] Lidocaine, Dexmedetomidine, ketamine, gabapentinoids, and magnesium sulfate are some non-opioid analgesics used in laparoscopic cholecystectomy patients.[5]

This study compares the efficacy of intra-operative Lidocaine and Dexmedetomidine infusions in managing post-operative pain in laparoscopic cholecystectomy. Lidocaine, a local anaesthetic, is known for its analgesic,

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anti-inflammatory, and anti-hyperalgesic properties.[6] Dexmedetomidine, an alpha-2 adrenergic agonist, offers sedative, anxiolytic, and analgesic effects, making it a valuable adjuvant in post-operative pain management.[7] Despite their widespread use, there is limited comparative data on the efficacy of these agents in reducing post-operative pain, specifically in patients undergoing laparoscopic cholecystectomy.

Comparing intra-operative Lidocaine and Dexmedetomidine infusions for post-operative pain management in laparoscopic cholecystectomy is essential to determine the most effective and safe option. Both drugs offer significant analgesic and opioid-sparing effects, but they differ in their side effect profiles and impacts on recovery.[8] By evaluating these differences, clinicians can optimize pain management protocols, enhance patient outcomes, and minimize post-operative complications.

This study aimed to compare the effects of perioperative infusions of Lidocaine and Dexmedetomidine on post-operative pain in patients undergoing laparoscopic cholecystectomy. We hypothesized that there would be no significant difference between the two groups in terms of post-operative Visual Analogue Scale (VAS) scores, hemodynamic parameters, and recovery profiles. The primary outcome measures were post-operative VAS scores and hemodynamic parameters. The secondary outcome measures included recovery profiles, total number of rescue analgesics required, duration of post-operative analgesia, time to first rescue analgesia, and the incidence of adverse effects associated with the study drugs.

2. Materials and Methods

This study was approved by the institutional ethics Committee (registration no.- ECR/717/inst.U.P./2015/RR-21) dated 21 January 2023 and registered on clinicaltrial.gov (CTRI/2024/04/064953) before enrolment of the first patient. This prospective randomized study was conducted on 66 adult patients of either sex, aged 18-60 years, ASA physical status I and II, undergoing laparoscopic cholecystectomy under general anaesthesia. Exclusion criteria were Body Mass Index >30kg/m^2, pregnant or lactating women, patients having sinus bradycardia or heart blocks, patients on steroids, and a history of allergy to study drugs. The sample size was calculated based on a previous study, assuming a mean difference in heart rate (effect size) of 5 bpm, with a 95% confidence interval, a significance level (α) of 0.05, β = 20%, and a statistical power of 80%. A total of 66 patients were required, with 33 subjects in each group.[9]

Written informed consent for participation in the study and anesthesia was obtained from all patients. The Visual Analogue Scale (VAS) was explained to each patient, and baseline parameters, including heart rate, oxygen saturation, and mean arterial blood pressure, were recorded. Randomization was performed using a computer-generated random number table, and patients were allocated into two groups of 33 each: Group L and Group D. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes. The study drugs were prepared in identical syringes by an anesthesia resident who was not involved in data recording or analysis. The anesthesia providers administering the infusions were blinded to the treatment allocation.

Group L (Lidocaine Group, n=33) received a bolus of 1.5 mg/kg lidocaine over 10 minutes prior to laryngoscopy, followed by a continuous IV infusion of 2 mg/kg/hr until the end of surgery. Group D (Dexmedetomidine Group, n=33) received a bolus of 1 μg/kg dexmedetomidine over 10 minutes prior to laryngoscopy, followed by a continuous IV infusion of 0.4 μg/kg/hr until the end of surgery. General anesthesia was standardized for all patients using propofol, fentanyl, vecuronium, and isoflurane. Vital parameters, including heart rate, mean arterial pressure, oxygen saturation, and end-tidal carbon dioxide, were recorded every 5 minutes for the first 10 minutes and every 15 minutes thereafter until the end of surgery.

Upon removal of the trocars, the study drug infusions were discontinued. Isoflurane administration was stopped after the final skin suture. Neuromuscular blockade was reversed using neostigmine and glycopyrrolate. Extubation was performed once the patient demonstrated adequate spontaneous ventilation, the ability to open their eyes, and responsiveness to verbal commands from the anesthesiologist. After extubation, patients were transferred to the Post-Anesthesia Care Unit (PACU) for further monitoring and management.

All patients were kept in the Post Anesthesia Care Unit for 12 hours, and pain was assessed at 15mins, 30mins, 1hr, 2hr, 4hr, 8hr, and 12hrs post-operatively using a Visual Analogue Scale Score (VAS Score). Sedation was assessed using the Ramsay Sedation Score when the patient was shifted to PACU. Inj. diclofenac 1.5 mg kg-1 I/V was given as first rescue analgesic when the VAS score >3. Further analgesia was supplemented with Injection Tramadol 50mg I/V if wanted. Total post-operative analgesic consumption in 12 hours was recorded. Any incidence of post-operative nausea/vomiting was recorded. The recovery profile was assessed 12 hours post-operatively with appropriate scoring.

Data analysis was conducted using IBM SPSS Statistics version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as numbers (percentages). The Chi-Square test was used to compare categorical variables, and the independent samples t-test was applied for continuous data. A p-value of less than 0.05 was considered statistically significant.

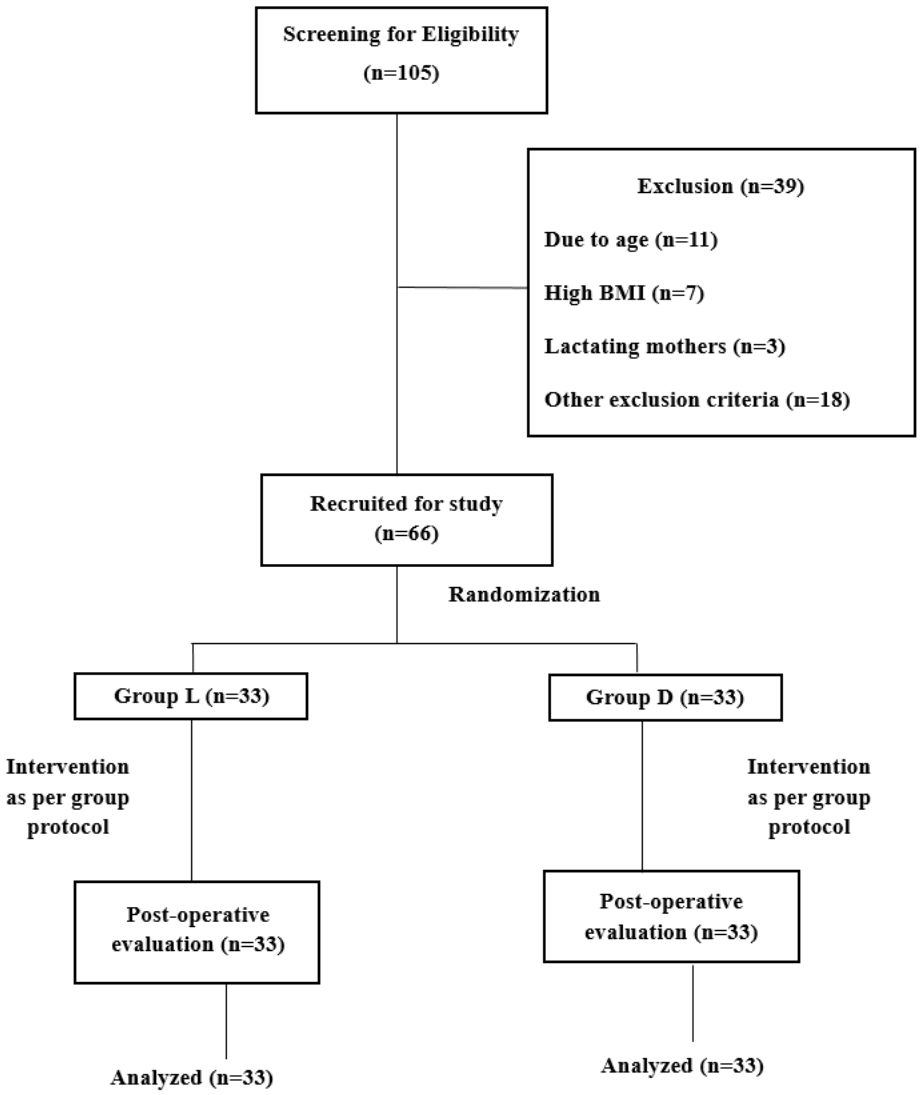

Diagram 1: Consort flow chart for the study

3. Results

Demographic variables reveal that both groups were comparable in age, height, weight, BMI, ASA-PS classification, and sex composition. (Table 1)

The HR and MAP were recorded at baseline, after pneumoperitoneum for 5 minutes, 10 minutes, every 15 minutes, and post-extubation.

During intraoperative periods, at all the time intervals, MAP was lower in Group D as compared to that in Group L, and this difference was also significant statistically at 10-, 30-, and 75-min time intervals (Table 2).

During intraoperative periods, the Mean HR difference between the two groups was found to be statistically insignificant ($p>0.05$) at all time intervals (Table 3).

During different intervals of post-operative periods, mean VAS scores ranged from 0.33±0.54 (12 hours) to 2.94±0.86 (75 min) in Group L as compared to 0.33±0.54 mmHg (12 hours) to 2.76±1.06 (60 min) respectively in Group D. Mean VAS was found to be significantly lower in Group D as compared to that in Group L at 120 min follow-up only ($p<0.05$) (Table 4).

Residual sedation was evaluated via Ramsay Sedation scores (RSS) and assessed simultaneously as VAS evaluation. Mean RSS ranged from 1.7±0.17 (12 hr) to 2.48±0.67 (0 min) in Group L, as compared to 1.72±0.53 (12 hours) to 2.67±0.78 (0 min), respectively, in Group D. At none of the follow-up intervals, the difference between the two groups was significant.

During the first 12 post-operative hours, 54.5% of patients in Group L needed Diclofenac compared to 39.4%

Table 1: Demographic profile and baseline characteristics

S. No.	Characteristic	Group L(Lidocaine) (n=33)		Group D (Dexmedetomidine) (n=33)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	Age (years)	39.94	11.59	37.12	8.43	1.130	0.263
2.	Male: Female	10 (33.3%): 20 (66.7%)		6 (18.2%): 27 (81.8%)		c^2=1.320; p=0.251	
3.	ASA 1: ASA 2	17 (51.5%): 16 (48.5%)		20 (60.6%): 13 (39.4%)		c^2=0.554; p=0.457	
4.	Diagnosis: Cholelithiasis	33	100%	33	100%	c^2=0; p=1.000	

Table 2: Evaluation of mean arterial pressure (in mmHg) at different intraoperative time intervals

S. No.	Time	Group L			Group D			Significance	
		n	Mean	SD	n	Mean	SD	't'	'p'
1.	0 min	33	92.30	12.43	33	95.82	10.79	1.23	0.22
2.	5 min	33	97.6	15.0	33	92.1	12.9	1.611	0.112
3.	10 min	33	97.6	19.6	33	89.8	9.6	2.068	**0.043**
4.	15 min	33	90.9	13.6	33	85.0	11.9	1.884	0.064
5.	30 min	33	90.8	7.7	33	86.0	10.1	2.167	**0.034**
6.	60 min	33	93.2	7.0	33	90.0	9.2	1.598	0.115
7.	75 min	31	98.6	8.2	28	93.5	9.5	2.189	0.**033**
8.	90 min	9	94.2	5.2	7	95.3	6.5	-0.364	0.721

Table 3: Evaluation of heart rate (in beats per minute) at different intraoperative time intervals

S. No.	Time	Group L			Group D			Significance	
		n	Mean	SD	N	Mean	SD	't'	'p'
1.	0 min	33	83.39	13.18	33	87.67	11.18	1.42	0.16
2.	5 min	33	85.21	11.32	33	79.94	13.06	1.753	0.084
3.	10 min	33	78.67	11.03	33	76.18	12.78	0.846	0.401
4.	15 min	33	77.94	10.40	33	74.52	11.65	1.260	0.212
5.	30 min	33	75.94	9.19	33	73.55	12.02	0.909	0.367
6.	60 min	33	74.52	9.34	33	73.03	12.31	0.552	0.583
7.	75 min	31	76.07	11.01	28	77.61	11.10	0.535	0.595
8.	90 min	9	86.00	6.00	7	79.00	11.96	1.535	0.147

Table 4: Evaluation of post-operative visual analogue score (VAS) at different time intervals

S. No.	Time	Group L (n=33)		Group D (n=33)		Significance	
		Mean	SD	Mean	SD	't'	'p'
1.	0 min	2.67	0.60	2.36	0.65	1.971	0.053
2.	30 min	2.73	0.63	2.67	0.82	0.338	0.736
3.	60 min	2.94	0.86	2.76	1.06	0.763	0.448
4.	120 min	2.88	0.96	2.21	0.65	3.303	0.002
5.	4 hr	2.09	1.16	1.70	1.24	1.337	0.186
6.	8 hr	1.00	0.56	1.03	0.85	0.171	0.864
7.	12 hr	0.33	0.54	0.33	0.54	0.000	1.000

of patients in Group D. No significant difference in the mean time to rescue analgesia was seen between the two groups.

None of the patients required tramadol in either of the two groups. The incidence of PONV was 21.2% in Group L compared to 18.2% in Group D. For none of these outcomes, the difference between the two groups was significant statistically. (Table 5)

The duration of analgesia was 434.48 ± 287.39 minutes for Group A and 501.00 ± 284.17 minutes for Group B. The difference between the groups was not statistically significant (Table 5).

4. Discussion

Decreased post-operative pain is one of the significant advantages of laparoscopic cholecystectomy. However, patients still report pain in the post-operative period, especially during the first few hours, which may adversely affect the patient's recovery profile.[10] Therefore, targeted

Table 5: Need for post-operative rescue analgesic need duration of post-operative analgesia and incidence of post-operative nausea and vomiting

S. No.	Outcome	Group L (n=33)		Group D (n=33)		Statistical significance	
		No.	%	No.	%	c2	
1.	No. of patients requiring first rescue analgesia up to 12 hrs	18	54.5	13	39.4	1.521	0.218
2.	Mean time to first rescue analgesia±SD	165.71±83.22 (n=18)		163.85±11.49 (n=13)		t=0.05	p=0.959
3.	Duration of Analgesia±SD	434.48±287.39		501.00±284.17		t=0.945	p=0.348
4.	Tramadol need	0	0	0	0	-	-
5.	PONV	7	21.2	6	18.2	0.096	0.757

strategies are required to reduce post-operative pain and improve the patient's overall experience. The present study was conducted to compare the efficacy of perioperative intravenous infusion of Lidocaine and Dexmedetomidine on post-operative analgesia and intraoperative hemodynamics in patients undergoing laparoscopic cholecystectomy.

In this study, Dexmedetomidine and Lidocaine were equally effective in terms of intraoperative hemodynamic parameters, post-operative analgesic efficacy, and recovery profile. The VAS scores, time to first rescue analgesia, and total rescue analgesic dose consumed were comparable in both groups.

No significant difference in VAS scores was observed between the two groups at various post-operative follow-up intervals, except at 120 minutes, where the VAS score was lower in the Dexmedetomidine group compared to the Lidocaine group. These findings align with those of Choi et al. and Ibrahim et al., who also did not find significant differences in VAS scores between the two groups throughout the post-operative period.[11,12] Therefore, the analgesic efficacy of both drugs was comparable up to approximately 2 hours post-operatively. The lower VAS at the 120-minute time interval in the Dexmedetomidine group can be attributed to its longer half-life (120-180 minutes) compared to Lidocaine (60-90 minutes). After 120 minutes, VAS scores were assessed at 4-hour intervals, at which point most patients had received rescue analgesia, which could explain the comparable VAS scores thereafter.

In contrast to our observations, Vidushi et al. and Roy et al. reported that Dexmedetomidine provided better post-operative analgesia, with lower VAS scores and reduced total post-operative analgesic consumption compared to Lidocaine.[13,14] This discrepancy could be due to our study utilizing intraoperative nitrous oxide and intravenous paracetamol, which enhanced analgesic efficacy in both groups during the immediate postoperative period. Additionally, our study performed postoperative pain assessments at more frequent intervals during the initial hours compared to the studies of Vidushi et al. and Roy et al.

In our study, Diclofenac was used as the first-line rescue analgesic. Both study groups were comparable in terms of the duration of analgesia, time to first rescue analgesia, and total rescue analgesic dose. Tramadol was not required in any case.

Similar to our findings, Ibrahim et al. reported comparable times to first rescue analgesic consumption between Dexmedetomidine (35.67 minutes) and Lidocaine (33.53 minutes).[12] However, the time observed in their study was much shorter than in our study. In our study, the mean time to first rescue analgesia was 165.71 ± 83.22 minutes in the Lidocaine group and 163.85 ± 11.49 minutes in the Dexmedetomidine group. This discrepancy may be attributed to differences in the type of surgeries performed in their study, which involved major abdominal surgeries.

Thus, the analgesic efficacy of both drugs was comparable, likely due to their ability to modulate the inflammatory response caused by tissue injury, resulting in pain suppression.[14]

The study participants in Group D had significantly lower mean diastolic blood pressure (DBP) and mean arterial pressure (MAP) compared to Group L at most intraoperative intervals. Dexmedetomidine is known for its sedative, analgesic, sympatholytic, and anxiolytic effects, which are responsible for blunting cardiovascular responses during the perioperative period. These findings are consistent with the studies by Ghosal et al.[10] and Roy et al.[14]

When comparing heart rate (HR) between the groups, we found no significant differences at most time intervals, except at the 5-minute mark, where Group D exhibited a lower HR. This could likely be due to the loading dose of Dexmedetomidine. A similar trend was observed in studies conducted by Singh et al. and Vidushi et al. no significant differences in sedation scores or side effects were observed between the groups at any post-operative time intervals.[13,15]

The limitations of this study include its small sample size, single-center design, non-inclusion of a control group, and the inability to measure plasma levels of the individual drugs. The absence of a control group limits the ability to determine whether observed changes are specifically due to the intervention, thus posing threats to internal validity

and introducing potential bias due to the lack of a baseline for comparison. Similarly, the small sample size reduces the study's statistical power, increasing the risk of Type II errors and making it more difficult to detect a true effect, if one exists. This also affects the generalizability of the findings, limiting their applicability to broader populations or settings.

5. Conclusion

Both perioperative infusions of Lidocaine and Dexmedetomidine were effective in managing intraoperative hemodynamics and post-operative pain, with comparable sedation scores and recovery profiles. However, Dexmedetomidine provided a slight advantage over Lidocaine in terms of analgesic effect and recovery. These results suggest that either medication can be used effectively for post-operative pain management, with a preference for Dexmedetomidine due to its potentially better outcomes. Future research is needed to optimize dosing regimens and explore combination therapies, ideally with a larger sample size, to validate these findings and confirm their generalizability.

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None.

7. Conflict of Interest

None.

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