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Comparative study between IV paracetamol and tramadol for post-operative analgesia in patients undergoing laparoscopic cholecystectomy

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Abstract
Introduction: Efforts to use safer drug with minimal side effects for postoperative analgesia are growing day by day for surgeries of shorter duration or which may require day care only, search for ideal agent has been a never ending process. The aim of the present study was to compare the efficacy of intravenous Paracetamol and Tramadol for postoperative analgesia in patients undergoing laparoscopic cholecystectomy.
Materials and Methods: This study was done at Department of General Surgery, Mamata Medical College, Khammam, Telangana India. Sixty ASA-I or II patients between 18-55 years of age, scheduled for laparoscopic cholecystectomy were randomly allocated to two groups of 30 each. Group A received IV infusion of paracetamol 1g in 100 ml solution, while Group B received IV infusion of Tramadol 100 mg in 100 ml NS at 0 (first complain of pain postoperatively), 6, 12 and 18 hours respectively. Pain intensity was measured by a 10 point Visual Analogue Scale (0→no pain and 10→worst imaginable pain) VAS at T (0) →just before analgesic administration, at 0.5, 1.5, 3, 6, 12, 18 and 24 hours thereafter, in addition to HR, SBP, DBP.
Results: During postoperative follow-up intervals, paracetamol showed significantly lower VAS scores as compared to tramadol at 1.5 hour, 3 hour, 6 hour, 12 hour and 24 hour follow up intervals. One patient in tramadol group had nausea postoperatively (p>0.05). No adverse effect attributable to paracetamol was noticed.
Conclusion: Intravenous Paracetamol can be advocated as an effective and safe analgesic agent for postoperative pain relief.

Keywords: Non-steroidal anti-inflammatory drugs, postoperative pain, visceral pain, VAS score

Introduction

Laparoscopic cholecystectomy is regarded as a day-care procedure that requires a shorter duration of hospital stay. Pain significantly reduces after laparoscopic cholecystectomy approach and it shorten the recovery period, therefore, reducing discharge time from 1 to 3 days to same day discharge with an earlier return to a normal life [1]. Studies have shown that laparoscopic surgery too causes postoperative pain in at least one-third of the patients and these patients have been seen taking more analgesics to alleviate pain. The type of pain after laparoscopy differs from laparotomy which results mainly in parietal pain (abdominal wall), patients complain more of visceral pain after operative laparoscopy [2].

Different treatments have been proposed to relieve pain after laparoscopy. The choice of different drugs, the timing and route of their administration as well as the dosages are variable. Opioids and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are generally used for management of postoperative pain after laparoscopic cholesystectomy. However, the clinical importance of infiltration of wounds with local anaesthetic agents, their intraperitoneal application, as well as the choice and dosages of these agents still remain controversial [3].

Paracetamol is the most commonly prescribed analgesic for the treatment of acute pain. Its major advantages over NSAIDs are its lack of interference with platelet function and safe administration in patients with a history of peptic ulcers or asthma [4]. The main mechanism of action of Paracetamol is considered to be the inhibition of cyclooxygenase (COX) and recent findings suggest that it is highly selective for COX-2. Paracetamol is metabolised primarily in the liver into non-toxic products.

Researches have shown that besides its effective analgesic properties, paracetamol administered during perioperative period supports effective and speedy recovery in patients undergoing laparoscopic cholecystectomy [5].

Tramadol is a synthetic opioid which belongs to aminocylohexanol group, is an analgesic with central effect and weak opioid agonistic properties. Tramadol possesses weak agonist actions at the μ-opioid receptor with additional monoaminergic activity. This drug is also effective on noradrenergic and serotonergic neurotransmission. However, tramadol has shown to be failing in ensuring optimal analgesia in moderate to severe pain [6].

Materials and Methods

The prospective comparative study carried out in the Department of General Surgery, Mamata General Hospital, Khammam, Telangana from November 2021 to November 2023 with a total of 60 patients admitted to surgery ward. Study was approved by institutional ethics committee and written informed consent was obtained from all patients participating in the study.

Study Population: Patients came with complaint of pain abdomen during the study period are subjected for abdominal examination and ultrasonography abdomen and who were positive included in the study.

Inclusion Criteria

- Symptomatic cholelithiasis patients above age of 188 years.
- Patients fit for general anasthesia.
- Patients willing to participate in the study.

Exclusion Criteria

- Pregnant and lactating patients, patients with known allergy to Tramadol or Paracetamol.
- Patients on chronic analgesic medications.
- Patients with significant coronary artery disease or ischemic myocardial disease.
- Drug or alcohol abuse, chronic pulmonary disease, renal failure, hepatic dysfunction, haemorrhagic disorder were excluded from the study.

Method of Collection of Data

The study will comprise a minimum of 60 patients with diagnosis of cholelithiasis admitted in Mamata General Hospital underwent laparoscopic cholecystectomy were randomly divided in two groups of 30 each. GROUP-A receives IV 1 gram paracetamol infusion and GROUP-B receives IV tramadol 100mg in 100 ml NS. Informed consent will be taken from patients before beginning of the study. Ethical committee clearance will be taken prior to the study

Statistical Analysis: Chi-square test, Student t-test and p-values <0.05 was considered significant. The observations made during above study were recorded on a proforma and the results obtained were analysed by appropriate statistical tests such as Chi-square test, Student's t-test and $p<0.05$ was considered significant.

Results

Table 1: Baseline data of both the groups were matched for age, weight, height, BMI and gender

S. N.	Variable	Group A	Group B	Significance of difference
1.	Mean Age ± SD (yrs)	43.17±9.13	42.90±10.45	t=0.105; p=0.917
2.	Mean Weight ± SD (kg)	56.20±8.51	59.63±7.15	t=1.692; p=0.096
3.	Mean Height ± SD (cm)	154.97±10.52	157.03±9.38	t=0.803; p=0.425
4.	Mean BMI ± SD (kg/m^2)	23.37±2.58	24.17±1.97	t=1.346; p=0.184
5.	Male: Female	16:14	16:14	χ^2=0; p=1

The study compared two groups, Group A and Group B, in terms of age, weight, height, BMI, and gender distribution. The results showed no significant differences in age, height, BMI, or gender distribution between the groups. While weight had a numerical difference, it did not reach statistical significance. These findings suggest that demographic factors are unlikely to confound the study's main comparisons between Group A and Group B (Table 1).

Table 2: Comparison of mean SBP between two groups at different time intervals

S. N.	Time interval	Group A (n=30)		Group B (n=30)		Significance of difference	
		Mean	±SD	Mean	± SD	T	"p"
1.	T_0	131.60	8.46	131.73	9.20	-0.058	0.954
2.	T_1	126.40	10.92	126.00	10.69	0.143	0.886
3.	T_2	123.17	7.92	124.20	8.76	-0.479	0.634
4.	T_3	129.73	7.18	130.27	8.05	-0.271	0.787
5.	T_4	133.20	6.45	135.53	7.21	-1.321	0.192
6.	T_5	124.77	6.99	125.87	7.67	-0.581	0.564
7.	T_6	127.67	8.19	128.07	5.77	-0.219	0.828
8.	T_7	127.47	6.26	128.87	9.16	-0.691	0.492

At baseline (T_0), mean SBP in Group A was 131.60±8.46 mm of Hg as compared to 131.73±9.20 mm of Hg in Group B, showing the 'between group' difference not to be significant statistically (p=0.954). At T_1, mean SBP in Group A was 126.40±10.92 mm of Hg as compared to 126.00±10.69 mm of Hg in Group B. At T_2, both the groups showed a slight decrease in mean SBP, 123.17±7.92 (Group A) and 124.20±8.76 (Group B). This was followed by an increase in both the groups at T_3 and T_4 intervals. At T_5 interval, both the groups showed the mean SBP values close to baseline values, followed by a slight increase at T_6 interval which remained almost stabilized at T_7. At T_7, mean SBP in Group A was 127.47±6.26 mm of Hg as compared to 128.87±9.16 mm of Hg in Group B. At none of the time intervals, the difference between two groups was significant statistically ($p>0.05$)

Table 3: Comparison of mean DBP between two groups at different time intervals

S. N.	Time interval	Group A (n=30)		Group B (n=30)		Significance of difference	
		Mean	±SD	Mean	±SD	T	"p"
1.	T_0	79.40	6.83	78.83	8.31	0.288	0.774
2.	T_1	78.13	5.74	78.03	5.60	0.068	0.946
3.	T_2	75.37	7.62	75.40	7.75	-0.017	0.987
4.	T_3	71.38	10.72	73.97	8.12	-1.052	0.297
5.	T_4	88.77	6.94	91.80	6.17	-1.789	0.079
6.	T_5	83.13	7.95	84.03	8.45	-0.425	0.672
7.	T_6	75.87	6.87	75.77	8.37	0.051	0.960
8.	T_7	76.80	6.47	77.20	5.40	-0.260	0.796

For DBP- At baseline (T_0), mean DBP in Group A was 79.40±6.83 mm Hg as compared to 78.83±8.31 mm Hg in Group B. At T_1 mean DBP in Group A was 78.13±5.74 mm of Hg as compared to 78.03±5.60 mm of Hg in Group B. At T_2, both the groups showed a slight decrease in mean DBP to reach at 75.37±7.62 (Group A) and 75.40±7.75 (Group B). At T_3, a further decrease in mean DBP was observed, taking the mean value in Group A to 71.38±10.72 mm of Hg as compared to 73.97±8.12 mm of Hg in Group B. This was followed by an increase in both the groups at T_4 interval followed by a decrease at T_5 and T_6 intervals. At T_6 interval, both the groups showed the mean DBP values close to baseline values followed by a slight increase at T_6 interval which remained almost stabilized at T_7. At none of the time intervals, the difference between two groups was significant statistically (p>0.05).

Table 4: Comparison of Change in heart rate in two groups as compared to baseline

S. N.	Time interval	Group A				Group B			
		MD	SE	"t"	"p"	MD	SE	"t"	"p"
1.	T_1	-5.60	1.33	4.20	<0.001	-3.87	1.28	3.02	0.005
2.	T_2	-1.73	1.58	1.10	0.281	0.67	1.64	-0.41	0.687
3.	T_3	-0.17	2.00	0.08	0.934	3.00	2.09	-1.43	0.163
4.	T_4	9.53	1.50	-6.37	<0.001	11.63	1.45	-8.04	<0.001
5.	T_5	9.17	2.14	-4.29	<0.001	12.00	2.26	-5.30	<0.001
6.	T_6	-2.73	2.14	1.28	0.212	2.17	2.02	-1.07	0.292
7.	T_7	-0.93	2.06	0.45	0.654	2.07	0.55	-3.72	0.001

As compared to baseline, mean change in heart rate was maximum at T_4 interval in Group A and T_5 interval in Group B. In Group A, at all time intervals, except at T_4 and T_5, mean heart rate was lower as compared to baseline but it was significant statistically only at T_1. At T_4 and T_5 intervals, in both the groups, mean heart rate was significantly higher as compared to baseline. In Group B, mean heart rate was lower than baseline only at T_1 interval and the difference was significant (p=0.005). At all the other intervals, mean heart rate was higher than baseline, but the increase was significant statistically only at T_4, T_5 and T_7 intervals.

Table 5: Comparison of mean VAS scores between two groups at different time intervals

S. N.	Time interval	Group A (n=30)		Group B (n=30)		Significance of difference	
		Mean	± SD	Mean	±SD	T	"p"
1.	T_0	6.30	0.99	6.20	1.30	0.336	0.738
2.	T_1	3.10	0.61	3.47	0.51	-2.537	0.014
3.	T_2	2.53	0.63	3.03	0.93	-2.443	0.018
4.	T_3	3.03	0.67	3.23	0.77	-1.071	0.289
5.	T_4	3.53	0.68	4.20	0.66	-3.837	<0.001
6.	T_5	3.43	0.63	3.97	0.93	-2.610	0.012
7.	T_6	2.93	0.83	3.03	1.03	-0.414	0.681
8.	T_7	2.20	0.61	2.53	0.68	-1.996	0.051

At baseline (T_0), mean VAS score in Group A was 6.30±0.99 as compared to 6.20±1.30 in Group B, thus showing no significant difference between the two groups (p=0.738). However, at T_1 and T_2, mean VAS score in Group A (3.10±0.61 and 2.53±0.63 respectively) was significantly lower as compared to that in Group B (3.47±0.51 and 3.03±0.93 respectively). At T_3, mean VAS score in Group A (3.03±0.67) was lower as compared to that in Group B (3.23±0.77) yet the difference was not significant statistically (p=0.289). At all the other time intervals, Group A had mean VAS scores lower than Group B, but the difference was not significant statistically at T_6 and T_7 intervals (p>0.05).

None of the patients in either group required rescue analgesic. Only one (3.3%) case in Group B complained of nausea and vomiting. The patient was managed with inj Ondansetron 4 mg i.v. No other side effect was noticed in either of the two groups.

Discussion

Postoperative pain management is a critical aspect of patient care, especially in procedures like laparoscopic cholecystectomy (removal of the gallbladder through small incisions), which are often performed as day-care surgeries. Managing postoperative pain effectively is not only essential for the patient's comfort but also influences their recovery and the overall cost of healthcare. In laparoscopic surgeries, such as cholecystectomy, patients may experience various types of pain, including incisional pain (pain

at the surgical site), intra-abdominal pain (pain within the abdomen), or referred pain (pain felt in the shoulder tip area). The causes of this pain are multifaceted and can result from damage to abdominal structures, visceral (internal organ) trauma, inflammation, or irritation of the peritoneum (the lining of the abdominal cavity) due to the presence of carbon dioxide gas used during the surgery [7].

Traditionally, healthcare providers have used non-steroidal anti-inflammatory drugs (NSAIDs) and opioids to manage postoperative pain. However, there is ongoing debate about their effectiveness, and these drugs come with potential side effects and risks [8]. As a result, alternatives like paracetamol (acetaminophen) and tramadol have gained popularity for pain management in laparoscopic cholecystectomy and similar surgeries [9]. In the study you mentioned, researchers compared the pain-relieving effects and side effects of intravenous (IV) paracetamol and tramadol when administered to patients undergoing laparoscopic cholecystectomy under general anesthesia [10].

The study found that both paracetamol and tramadol effectively reduced pain scores within a short time after administration [11]. Patients' pain scores, as measured on the Visual Analogue Scale (VAS), improved significantly, shifting from acute pain (VAS score ≥5) to mild or bearable pain (VAS score ~3) within 30 minutes of receiving the medications [12]. Interestingly, paracetamol generally outperformed tramadol in terms of pain control over various follow-up intervals. This suggests that paracetamol may be a slightly more effective pain management option for patients undergoing laparoscopic cholecystectomy [13]. Furthermore, the study examined vital signs such as blood pressure and heart rate. Initially, both groups of patients (paracetamol and tramadol) experienced increases in blood pressure and heart rate, likely due to the stress response triggered by surgery [14]. However, the impact of tramadol on these vital signs was relatively mild, suggesting that tramadol's pain relief properties may have contributed to stabilizing these parameters. It's important to note that neither group of patients required additional pain relief (rescue analgesia), indicating that both paracetamol and tramadol were effective at controlling postoperative pain in this study [15].

In summary, the study's findings suggest that intravenous paracetamol is a safe and effective option for managing postoperative pain in patients undergoing laparoscopic cholecystectomy. While both paracetamol and tramadol are viable choices, paracetamol demonstrated slightly better pain control and may be preferred for this type of surgery. The study also highlights the importance of further research into drugs with fewer side effects and optimal pain-relieving efficacy in postoperative care.

References

1. Kum CK, Wong CW, Goh PM, Ti TK. Comparative study of pain level and analgesic requirement after laparoscopic and open cholecystectomy. Surgical Laparoscopy Endoscopy & Percutaneous Techniques. 1994 Apr 1;4(2):139-41.
2. Michaloliakou C, Chung F, Sharma S. Preoperative multimodal analgesia facilitates recovery after ambulatory laparoscopic cholecystectomy. Anesth Analg. 1996;82:44-51.
3. Ure BM, Troidl H, Spangberger W, Dietrich A, Lefering R, Neugebauer E, *et al*. Pain after laparoscopic cholecystectomy. Surgical Endoscopy. 1994;8(2):90-96.
4. Joris J, Cigarini I, Legrand M. Metabolic and respiratory changes after cholecystectomy performed via laparotomy or laparoscopy. Br J Anaesth. 1992;69:341-45.
5. Lepner U, Goroshina J, Samarütel J. Postoperative pain relief after laparoscopic cholecystectomy: A randomised prospective double-blind clinical trial. Scandinavian Journal of Surgery. 2003;92:121-24.
6. Sachs CJ. Oral analgesics for acute nonspecific pain. Am Fam Phys. 2005;71:913-18.
7. Hyllested M, Jones S, Pedersen JL, Kehlet H. Comparative effect of paracetamol, NSAIDs or their combination in postoperative pain management: A qualitative review. Br J Anaesth. 2002;88:199-214.
8. Salihoglu Z, Yildirim M, Demiroluk S, Kaya G, Karatas A, Ertem M, *et al*. Evaluation of intravenous paracetamol administration on postoperative pain and recovery characteristics in patients undergoing laparoscopic cholecystectomy. Surg Laparosc Endosc Percutan Tech. 2009;19(4):321-23.
9. Choudhari AH, Uppal R. A comparison between intravenous paracetamol plus fentanyl and intravenous fentanyl alone for postoperative analgesia during laparoscopic cholecystectomy. Anesthesia Essays and Research. 2011;5(2):196-200.
10. Dejonckheere M, Desjeux L, Deneu S, Ewalenko P. Intravenous tramadol compared to propacetamol for postoperative analgesia following thyroidectomy. Acta Anaesthesiol Belg. 2001;52(1):29-33.
11. Alexander JI. Pain after laparoscopy. Br J Anaesth. 1997;79:369-78.
12. Jackson SA, Laurence AS, Hill JC. Does post laparoscopy pain relate to residual carbon dioxide? Anaesthesia. 1996;51:485-87.
13. Comyn DJ. Proceedings of the 9th World Congress of Anesthesiologists. Washington, DC. Minimizing pain after laparoscopy; c1988 May. p. A4.
14. Lehmann KA. Tramadol in acute pain. Drugs. 1997;53(2):25-33.
15. Le Blanc-Louvry I, Coquerel A, Koning E, Maillot C, Ducrotté P. Operative stress response is reduced after laparoscopic compared to open cholecystectomy: the relationship with postoperative pain and ileus. Dig Dis Sci. 2000;45(9):1703-13.

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