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Comparison of Analgesic Effectiveness of Tapentadol and Tramadol in Relieving Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy Under General Anesthesia

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ABSTRACT

Various pharmacological interventions have aimed to address postoperative pain, however the search for optimal preemptive analgesic continues. In this assessment, it was sought to evaluate tapentadol and tramadol as preemptive analgesic, in order to identify the more effective option for managing postoperative pain. **Objective:** To compare the analgesic effectiveness of tapentadol and tramadol in relieving postoperative pain in patients undergoing laparoscopic cholecystectomy under general anesthesia. **Methods:** This quasi experimental study was conducted at Anesthesia Department of Mayo Hospital, Lahore from 30-11-2022 to 30-05-2023 after taking ethical approval from IRB. 60 individuals were enrolled after taking written informed consent, who were planned for laparoscopic cholecystectomy under general anesthesia. Patients were assigned to either group A (tramadol) or group B (tapentadol). Analgesic effectiveness was assessed in terms of time to first rescue analgesia, total rescue analgesic consumption in 24 hours, and VAS score at different interval postoperatively. **Results:** Mean time to 1st analgesia requirement calculated was 1.667±0.365 hours for group A and 4.46±1.45 hours for group B; p <0.0001. Mean total rescue analgesic (injection nalbuphine) consumption in group A and group B was 17.06±5.16mg and 8.4 ± 2.59mg, respectively (p <0.001). Mean of VAS score at different intervals noted was less in group B as compared to group A postoperatively, p <0.001. **Conclusions:** The findings of this study demonstrate that tapentadol 75 mg is more effective than tramadol 50 mg as preemptive analgesia in patients undergoing laparoscopic cholecystectomy.

INTRODUCTION

Postoperative pain following laparoscopic cholecystectomy is a common complaint, leading to prolonged hospital stay. Typically, pain is maximum within few hours after the surgery and then gradually subsides over a period of 2-3 days [1, 2]. Preemptive analgesia is strategy for preventing central neuro-sensitization by administering prophylactic anti-nociceptive measures prior to the start of surgical pain, it helps in minimizing postoperative pain and reduces the hyperactivity of spinal neurons, leading to decreased postoperative pain intensity [3]. Numerous pharmacological approaches have been explored to achieve the aforementioned goals. However, the quest for an "ideal preemptive analgesic" persists [4]. One challenge while managing postoperative pain, revolves around the reliance on opioids as powerful pain reliever and need for careful dosage control to mitigate their potential

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side effects [5].Tapentadol exhibits strong analgesic efficacy and is well tolerated for different intensities of pain following different types of surgeries [6] It functions as an agonist of μ-opioid receptor and acts as a norepinephrine reuptake inhibitor [7, 8]. Tramadol is a centrally acting analgesic and has dual mechanism of action by inhibiting the reuptake of norepinephrine and serotonin, as well as exerting a weak agonist effect on opioid receptors [9]. Tapentadol and tramadol were compared for their analgesic efficacy in multiple studies. One study found that tapentadol had better analgesic effect than tramadol after surgical removal of mandibular third molar, P <0.05 [10]. The efficacy of Tapentadol in mitigating pain has been substantiated through numerous trials conducted in both acute and chronic pain scenarios. Prior investigations have delved into the analgesic effectiveness of Tapentadol within a dosage range of 50 to 200 mg. However, its potential as a preemptive pain reliever remains unexplored. Consequently, the primary focus of the study is to assess the preemptive capabilities of tapentadol in comparison to tramadol, for. Notably, there is a lack of previous studies within the local population on this particular subject.

So, we are conducted this study to compare the analgesic effectiveness of tapentadol and tramadol in relieving postoperative pain in patients undergoing laparoscopic cholecystectomy under general anesthesia.

METHODS

This quasi experimental study was conducted at anesthesia department, KEMU, Mayo Hospital Lahore after taking ethical approval from IRB [111/PEC/RC/KEMU]. This study was done over a period of 6 months from 30-11-2022 to 30-05-2023. Sample size of 60 patients was calculated using significance level of 5%, power of test 80%. Expected mean value of total rescue analgesic consumption for intervention group is estimated to be 13.3 ± 22.5mg, while for control group, it is estimated to be 33.3±33 mg.[10] Sample size was calculated using formula; $n= Z\ \sigma^2(Ƶ1 - \alpha + Ƶ1 - \beta)^2 / (\mu_1 - \mu_2)^2$; where: n = required sample size per group=30, Z1–α= standard normal variate corresponding to the significance level (5%), Z1–β = standard normal variate corresponding to the power (80%), σ1,σ2 = standard deviations of the intervention and control groups, respectively and μ1, μ2 = expected mean values of total rescue analgesic consumption for the intervention and control groups. Patients selection was done using non-probability consecutive sampling. Total 60 patients aged 20 to 60 years of both genders with ASA status I & II, who were planned to undergo laparoscopic cholecystectomy under general anesthesia were included. Patients with uncontrolled diabetes (BSL > 200mg/dl), uncontrolled hypertension (BP >140/90mmHg), impaired liver function test (ALT/AST > 40IU/L), renal insufficiency (serum creatinine >1.5mg/dl), psychiatric illness, chronic pain or patients on analgesic medications, having allergy to opioids, alcoholics, and pregnant or lactating ladies were excluded. Written informed consent was taken from all patients and performing surgeons. During the pre-anesthetic assessment, the patients were provided with information regarding the Visual Analogue Scale for pain. Patients were divided into 2 equal groups; odd number assigned to group A (tramadol) and even numbers to group B (tapentdol). Tapentdol 75mg or tramadol 50mg based on the allocation in respective groups were administered to the patients 2 hours before the surgery. In the operating room, standard monitoring equipment was used to continuously measure ECG, heart rate, SpO2, non-invasive blood pressure, and EtCO2 levels. Routine general anaesthesia protocols were followed utilizing endotracheal tube intubation. Continuous monitoring of ECG, heart rate, NIBP, SpO2, and EtCO2 was performed throughout the surgery. Approximately 15 minutes before surgery completion, patients were given IV ondansetron (8mg) to prevent postoperative nausea and vomiting. In PACU, continuous monitoring of vital signs was performed. The starting point for the postoperative observation was marked when the patient regained consciousness and was able to respond to verbal commands. Injection paracetamol 1g IV TDS was given to all patients. However, rescue analgesia was given in the form of injection Nalbuphine at a dose of 0.1mg/kg (maximum 10mg) IV bolus whenever the patient reported VAS of greater than 3 for pain and time to first analgesia requirement was noted. The total amount of analgesic consumption within first 24 hours after surgery was recorded. Postoperative pain evaluations were conducted at specific time intervals by a blinded observer at 0, 2, 4, 6, 12, and 24 hours after completion of surgery. At 24-hour period end, total amount of analgesics consumed by each patient was recorded. All information recorded on preformed proforma. The data were enlisted into SPSS 26.0 for statistical analysis. Quantitative variables such as age, BMI, surgical time, and anesthesia time were showed as mean and SD. On the other hand, qualitative variables like gender, DM, and HTN, were presented as frequencies and percentages. Comparison among pain score using VAS scale at different intervals of both groups using independent sample t test, p-value was taken as ≤ 0.05 statistically significant.

RESULTS

Mean age in Group A and B calculated was 35.26 ± 5.65 years and 36.33 ± 6.12 years, respectively. In Group A 8 (26.7%) patients were male and 22 (73.3%) were female and in Group B 6 (20%) were male and 24 (80%) were female. Mean BMI of patients in Group A and B calculated was 25.6 ±

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4kg/m^2 and 26.9 ± 3.2kg/m^2, respectively. Mean duration of anesthesia in Group A and B noted was 107.30 ± 18.9 minutes and 106.3 ± 21.73 minutes. 67% patients in Group A and 70% in Group B belonged to ASA status I, while 33% and 30% belongs to ASA status II. Mean weight in group A and B calculated was 66.55 ± 5.43 and 65.23 ± 6.01, respectively.

Table 1: Demographic and Clinical Characteristics of Patients in Group A (Tramadol) and Group B (Tapentadol) (n=60)

Variables	Group A (Tramadol) Frequency (%)/ Mean ± SD	Group B (Tapentadol) Frequency (%)/ Mean ± SD		p-Value
Age (Years)	35.26 ± 5.65	36.33 ± 6.12		0.484
Gender	Male	8 (26.7%)	6 (20%)	0.541
	Female	22 (73.3%)	24 (80%)	
BMI (kg/m2)	25.6 ± 4.0	26.9 ± 3.2		0.168
ASA Status	I	20 (67%)	21 (70%)	0.781
	II	10 (33%)	9 (30%)	
Duration of anaesthesia (Minutes)	107.30 ± 18.9	106.3 ± 21.73		0.849
Weight (Kg)	66.55 ± 5.43	65.23 ± 6.01		0.375

As shown in table 2, mean time to first analgesia requirement noted was prolonged in group B as compared to group A (Group A: 1.67 ± 0.36 hours' vs Group B: 4.46 ± 1.45 hours; p<0.001 i.e. statistically significant). Mean total injection nalbuphine (mg) consumption in group A was more as compared to group B (17.06 ± 5.16mg and 8.40 ± 2.59mg, respectively; p <0.001 i.e. statistically significant).

Table 2: Comparison of Time to 1st Rescue Analgesia and Total Rescue Analgesic Consumption Among Groups (n=60)

Variables	Group A (Tramadol) Mean ± SD	Group B (Tapentadol) Mean ± SD	p-Value	95% CI
24-Hour Total Rescue Analgesic (nalbuphine) Requirement (mg)	17.06 ± 5.16	8.40±2.59	<0.001	6.550-10.770
Time to 1st Analgesia (Hours)	1.67 ± 0.36	4.46±1.45	<0.001	2.246-3.339

Mean of VAS score at different interval noted was higher in group A as compared to group B, and this difference was statistically significant p <0.0001 at 0hr, 2hr, 4hr, 6hr, 12hr and 24hr.

Table 3: Comparison of Vas Score at Different Interval Post-Operatively (n=60)

VAS Score at Different Intervals	Group A (Tramadol) Mean ± SD)	Group B (Tapentadol) Mean ± SD	p-Value
VAS Score at 0 Hour	4.60±1.06	0.86±0.50	<0.001
VAS Score at 2 Hours	3.70±0.74	3.10±0.60	<0.001
VAS Score at 4 Hours	3.76±1.38	2.13±0.89	<0.001
VAS Score at 6 Hours	2.20±0.40	2.73±1.22	<0.001
VAS Score at 12 Hours	3.76±1.38	1.20±0.96	<0.001
VAS Score at 24 Hours	2.20±0.40	0.43±1.00	<0.001

DISCUSSION

Effective pain management after laparoscopic cholecystectomy is crucial for enhancing recovery, reducing opioid consumption, and improving patient satisfaction [11]. Despite being minimally invasive procedure, LC can cause significant postoperative pain due to peritoneal distension, diaphragmatic irritation from residual CO_2, and port-site trauma [12]. Optimizing postoperative pain control not only facilitates early mobilization and discharge but also minimizes complications [13]. In current study, time taken for first analgesic administration in Post-Anesthesia Care Unit was significantly longer in tapentdol groups as compared to tramadol group 1.67 ± 0.36 hours vs 4.46 ± 1.45 hours (P < 0.001). Additionally, the total dose of injection Nalbuphine needed was significantly reduced in tapentdol group 8.40 ± 2.59mg vs tramadol group 17.06 ± 5.16mg. Studies have also highlighted the potential of tapentdol as effective analgesic option for postoperative pain relief in different surgical procedures [14].The use of tapentadol as preemptive analgesic in laparoscopic cholecystectomy has also shown promising results in reducing postoperative pain and need for rescue analgesics. A study by Yadav *et al.*, reported that a single preoperative dose of tapentadol significantly lowered perioperative analgesic requirements and improved pain scores in the immediate postoperative period.Specifically, their study found that total rescue analgesic consumption was 13.3 ± 22.5 mg in the intervention group compared to 33.3 ± 33 mg in control group, highlighting tapentadol's efficacy in managing acute pain with minimal side effects [10].The opioid-sparing effect of tapentadol makes it promising option for managing postoperative pain, potentially leading to quicker recovery and reduced hospital stays [15]. Tapentadol is not considered as first-line opioid, it represents a valuable option for patients who may benefit from its specific pharmacological profile, especially when considering individual patient factors and potential drug interactions [16]. Apart from LC, tapentadol has also gain favor in other laparoscopic procedures. It was found by Comelon *et al.*, that tapentadol found to have similar analgesic efficacy to oxycodone during the first 24 h after laparascopic hysterectomy [17].Premedication with analgesics in laparoscopic cholecystectomy is crucial for effective pain management and improved postoperative outcomes.Furthermore, employing multimodal analgesia approach, can further optimize pain relief while decreasing reliance on opioids [18]. This strategy not only improves patient comfort but also contributes to faster recovery and shorter hospital stays, making it valuable consideration in anesthetic regimen for laparoscopic cholecystectomy [19]. Furthermore, Putta *et al.*, found preemptive analgesics more effective as compared to postoperative

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pain management, in patients after LC [20].This study primarily focused on evaluating the effectiveness of tapentdol 75 mg compared to tramadol 50 mg as preemptive analgesia in patients undergoing laparoscopic cholecystectomy. However, the safety profile of both medications was not assessed, which limited the comprehensive understanding of their overall clinical utility.Additionally, long-term outcomes, potential side effects, and patient-reported satisfaction beyond the immediate postoperative period were not studied, leaving gaps in evaluating the broader implications of these analgesic strategies.

Future studies should address these aspects to provide a more holistic evaluation of tapentdol and tramadol in similar clinical settings.

CONCLUSIONS

The findings of this study demonstrate that tapentdol 75 mg is more effective than tramadol 50 mg as preemptive analgesia in patients undergoing laparoscopic cholecystectomy. Tapentdol not only reduced the need for postoperative rescue analgesia but also significantly prolonged the time to the first analgesic requirement, highlighting its superior efficacy in managing postoperative pain.

Authors Contribution

Conceptualization: AM, MHZ, AI
Methodology: AM, MHZ, AA, ZAC, AY
Formal analysis: SK, HW
Writing, review and editing: AA, ZAC, AI, SK

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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