

Comparison of Efficacy of Intravenous Paracetamol Versus Intravenous Tramadol for Postoperative Analgesia in Surgeries under General Anaesthesia

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Abstract

Introduction: The under treatment of postoperative pain is recognized as an important issue to the anesthesiologists and treating surgeons despite of improvement in mechanisms and introduction of acute pain services. **Aim:** To compare analgesic properties of Intravenous Paracetamol and Tramadol for postoperative analgesia in lower abdominal surgeries under general anesthesia. To study the adverse effects of Tramadol and Paracetamol. **Materials and methods:** It is a randomized study done in 100 patients ASA grade 1 and 2 of either sex, 20 to 60 years of age who underwent lower abdominal surgery under general anaesthesia. It was conducted to compare the efficacy of IV Paracetamol and IV Tramadol for postoperative analgesia. Group 1 received Intravenous Paracetamol and group 2 Intravenous Tramadol 15 min before the end of the surgery and the study drug was administered every 6th hourly for 24 hours. Patients were monitored for pain at 0, 2, 4, 6, 8, 10, 12 and 24 hours postoperatively. Also the time of first dose of rescue analgesia and number of doses of rescue analgesia given was noted. Side effects like nausea and vomiting was also observed. **Results:** Found that the pain scores were significant at 2 hours and 4 hours (except in the early postoperative period) and pain scores decreased over time in both the groups. About 60% of the patients in the Tramadol group had nausea and vomiting sensation at 0 hours, 12% at 2 hours, 14% at 4 hours, 48% at 6 hours, 26% at 8 hours respectively whereas in Paracetamol group about 4% of the patients had nausea at 2 hours, 4% at 4 hours and 2% at 6 hours. The rescue analgesia in the form of morphine was required in 22% of the patients of Paracetamol group at 0 hour, 32% at 2 hours and 2.0% at 10 hours after surgery. But Tramadol group required additional rescue analgesia in 10% of the patients. Total doses of rescue analgesic required by the Paracetamol group was 1.04 (\pm 0.2) and in group 2 (Tramadol) was 1.0 (\pm 0). There was no significant difference between Paracetamol and Tramadol groups. **Conclusion:** Paracetamol is as effective as Tramadol when used for postoperative pain relief in patients for lower abdominal surgeries except in the early postoperative period.

Keywords: Tramadol; Paracetamol; Postoperative analgesia.

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Introduction

Pain serves a biological function. It signals the presence of damage or disease within the body.

Acute postoperative pain is a complex physiologic reaction to tissue injury, visceral distension or disease. Its manifestation of autonomic, psychological and behavioral responses results

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in unpleasant, unwanted sensory and emotional experience. Despite advances in knowledge of pathophysiology of pain, pharmacology of analgesics and development of effective techniques for postoperative pain control, many patients continue to experience considerable discomfort [1].

Postoperative pain is a result of surgery, specially involving the body cavities, large joint surfaces and deep tissues. The severity and frequency of postoperative pain depends upon the site affected, nature and extent of the surgery. The under treatment of postoperative pain is recognized as an important issue to the anesthesiologists and treating surgeons despite of improvement in mechanisms and introduction of acute pain services. The available literature shows that up to 75% of the patients after surgery have reported pain and 80% of the patients experienced the severe pain at some time during the hospital stay. Another survey also demonstrated that 70% of the approximately still complain of moderate or severe pain during the postoperative period [2].

Poorly controlled postoperative pain mainly results in increased catabolism, increased cardiorespiratory work, immunosuppression and coagulation disturbances [3]. Pain and postoperative nausea and vomiting prolong recovery and discharge times and contribute to unexpected admission after ambulatory surgery. Higher levels of postoperative pain can result in poor patient satisfaction, impair quality of recovery and increase in healthcare costs [9]. The goal of optimizing the postoperative pain is to relieve patients suffering early mobilization, shortened hospital stay, reduced costs and side effects and thereby reduces the burden on patients health and pocket.

The quality of postoperative patient care depends critically on effective pain management, which includes accurately assessing pain and monitoring the patient's response to treatment. Inadequate postoperative pain treatment can contribute to unnecessary discomfort, increased morbidity, delayed discharge, and unanticipated readmission to hospital.

The Paracetamol is an effective analgesic for mild to moderate pain with a favourable adverse effect profile [3]. It is an effective adjuvant to opioid analgesia and reduction in opioid requirement by 20–30% when combined with regular regimen of oral or rectal Paracetamol. Intravenous Paracetamol is a soluble diethyglycidyl ester of Paracetamol. It acts on both central and peripheral components of pain pathways. It is found to be a good drug in relieving

the postoperative pain and has no side effects like nausea and vomiting and it is well tolerated by patients. However, except for oral Paracetamol, there is a marked discrepancy between the extent to which Paracetamol is used and available evidence for an analgesic effect in postoperative pain.

Intravenous Tramadol is also a potent analgesic which is a synthetic 4-Phenyl piperidine analog of codeine. It is a centrally acting atypical opioid with low affinity for μ receptors. It is also a weak inhibitor of reuptake of norepinephrine and serotonin and is a good analgesic in postoperative pain. It is reported adverse effects include nausea, dizziness, sleepiness, dry mouth, sweating and lowering of seizure threshold. Its advantages over other narcotic drugs are that it causes less respiratory depression than morphine and codeine and does not share the propensity of non-steroidal anti-inflammatory drugs (NSAIDs) to provoke asthma, gastrointestinal mucosal damage and renal impairment.

However, the studies comparing the efficacy between the Paracetamol and Tramadol are scant in India and across the world. Most of the studies available are western studies. Hence, it was decided to take up this study in the context of this part of country. This study mainly focuses on comparison of effects, efficacy and side effects of these two different drugs.

Materials and Methods

A randomized controlled study was undertaken in the Department of Anesthesia in order to study the analgesic efficacy of Tramadol and Paracetamol. An informed bilingual, written consent was obtained from the patients before they were enrolled in to the study. A total of 100 patients undergoing surgeries under general anaesthesia were included in the study as study subjects. The inclusion and exclusion criteria were as follows:

Inclusion Criteria: Patients of ASA grade I & II, Age group of 20 to 60 years Undergoing surgeries under general anesthesia.

Exclusion Criteria: Patients allergic to Tramadol or Paracetamol, Liver dysfunction, Advanced renal dysfunction, Drug abuse, Patients belonging to ASA III and IV, Patients less than 20 years and more than 60 years, Difficulty in communication.

The study subjects were divided two equal groups:

Group I: 50 patients received intravenous

Paracetamol (15-17 mg/kg).

Group II: 50 patients received intravenous Tramadol (1.5 – 2 mg/kg).

The patients enrolled were randomly assigned to groups by marking on the slips of papers. The slips picked randomly to group the patient. The patients thus selected were administered with their first dose of the drug 15 minutes before the end of the surgery and 6th hourly for 24 hours. If adequate pain relief is not achieved with the study drugs or VAS > 4 intravenous morphine (0.1 mg/kg) was administered as a rescue analgesic and the efficacy of the study drugs were compared respectively. Patients were also instructed to request pain medication from the nurse whenever they required pain relief and not to wait for their next schedule pain assessment. The patients were followed subsequently assessed for the level of pain by using the VAS scores at 0, 2, 4, 6, 8, 10, 12 and 24 hours. All the data so obtained was meticulously documented and statistically analyzed. VAS score was compared between two groups using Student T test of unequal variances. Chi-square test was used to study the association between different parameters measured.

Results

A randomized controlled trial was undertaken in 100 patients who have undergone lower abdominal surgeries were divided in to two equal groups. One group received Paracetamol and another group received Tramadol. In Group 1 (Paracetamol), 34% of the patients were males and 66% of the patients were females. Since the Tramadol group was sex matched, 34% were males and 66% were females.

Table 1: Distribution of the study groups according to age group

Age group	Group 1	Group 2
21 – 30 years	20 (40.0)	17(34.0)
31 – 40 years	11(22.0)	13(26.0)
41 – 50 years	9 (18.0)	16(32.0)
51 – 60 years	10 (20.0)	4 (8.0)
Mean ± SD	37.3 ± 11.4	36.7 ± 10.4
Z value	0.257	
p value, Sig	0.56, NS	
Weight		
Mean ± SD	57.6 ± 5.0	59.1 ± 4.8

The mean age of Paracetamol group was 37.3 years and Tramadol group was 36.7 years. There was no significant difference between the two groups and hence they were comparable in all respects. However, there was no statistically

significant difference in weight between group 1 and group 2 patients (Table 1).

Table 2: Distribution of the study groups according to VAS scores

VAS scores	Group 1	Group 2	Z value	p value, Sig
0 hours	3.1 ± 1.1	2.8 ± 0.9	1.496	0.438, NS
2 hours	3.2 ± 1.4	2.6 ± 0.5	2.72	0.008, Sig
4 hours	2.0 ± 0.7	2.5 ± 0.5	4.454	0.000, Sig
6 hours	2.2 ± 0.6	2.5 ± 0.5	1.619	0.109, NS
8 hours	2.2 ± 0.6	2.2 ± 0.7	0.585	0.56, NS
10 hours	2.2 ± 0.6	2.4 ± 0.5	1.421	0.158, NS
12 hours	2.3 ± 0.6	2.1 ± 0.6	1.459	0.148, NS
24 hours	2.2 ± 0.6	2.1 ± 0.7	0.742	0.46, NS

The mean VAS scores at 0, 2, 4, 6, 8, 10, 12 and 24 hours in group 1 (Paracetamol) group were 3.1, 3.2, 2.0, 2.2, 2.2, 2.2, 2.3 and 2.2 respectively. The mean VAS scores for group 2 (Tramadol) were 2.8, 2.6, 2.5, 2.5, 2.2, 2.4, 2.1 and 2.1 respectively. There was a significant difference between the VAS scores of group 1 and group 2 at 2 hours and 4 hours (Table 2).

Table 3: Distribution of the study groups according to use of rescue analgesia

Rescue analgesia	Group 1	Group 2
0 hours	11 (22.0)	5 (10.0)
2 hours	16 (32.0)	0
4 hours	0	0
6 hours	0	0
8 hours	0	0
10 hours	1 (2.0)	0
12 hours	0	0
24 hours	0	0

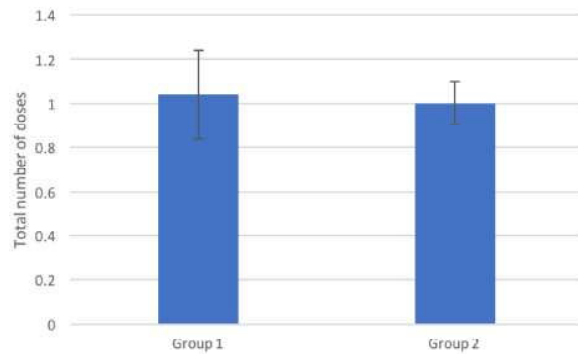
The rescue analgesia in the form of morphine was required in 22% of the patients of Paracetamol group at 0 hour, 32% at 2 hours and 2.0% at 10 hours after surgery. But Tramadol group required additional rescue analgesia in 10% of the patients (Table 3).

Table 4: Distribution of the study groups according to Nausea and vomiting in groups

Nausea and Vomiting	Group 1		Group 2	
	Frequency	Percent	Frequency	Percent
0 hours	0	0	30	60.0
2 hours	2	4	6	12.0
4 hours	2	4	7	14.0
6 hours	1	2	24	48.0
8 hours	0	0	13	26.0
10 hours	0	0	0	0
12 hours	0	0	0	0
24 hours	0	0	0	0

Tramadol is a drug known to result in nausea and vomiting. About 60% of the patients of Tramadol

group had nausea and vomiting sensation at 0 hour, 12% at 2 hours, 14% at 4 hours, 48% at 6 hours and 26% at 8 hours had nausea and vomiting sensation. In Paracetamol group about 10% of the patients had nausea at 4% at 2 hour, 4% at 4 hours and 2% at 6 hours (Table 4).



Graph 1: Total doses of rescue analgesia needed in the study group

Total doses of rescue analgesic required by the Paracetamol group was 1.04 (± 0.2) and in group 2 (Tramadol) was 1.0 (± 0). There was no significant difference between Paracetamol and Tramadol groups (Graph 1).

Discussion

Postoperative pain specially involves the body cavities, large joint surface and deep tissues as a result of surgery. The site of surgery, nature and extent of surgery decides the severity and frequency of pain. The postoperative pain is often under treated as emerged as an important issue for the anesthesiologists and treating surgeons even with improvement in the mechanism and introduction of acute pain services. The available literature shows that up to 75% of the patients after surgery have reported pain and 80% of the patients experienced the severe pain at some time during the hospital stay. Another survey also demonstrated that 70% of the approximately still complain of moderate or severe pain during the postoperative period.

Poorly controlled postoperative pain mainly results in increased catabolism, increased cardiorespiratory work, immunosuppression and coagulation disturbances. Pain and postoperative nausea and vomiting prolong recovery and discharge times and contribute to unexpected admission after ambulatory surgery. Higher levels of postoperative pain can results in poor patient satisfaction, impair quality of recovery and increase in healthcare costs.

Paracetamol has emerged as an effective

analgesic for mild to moderate pain with adverse effect profile. The use of Paracetamol reduces the opioid requirements by 20-30% when combined with regular dose of oral or rectal Paracetamol. Intravenous Paracetamol mainly acts on both central and peripheral components of pain pathways. The available literature has shown that it relieves postoperative pain with minimal adverse effects and also well tolerated by the patients. However, except for oral Paracetamol, there is a marked discrepancy between the extent to which Paracetamol is used and available evidence for an analgesic effect in postoperative pain.

Intravenous Tramadol has been emerged as an important and potent analgesic now-a-days. It mainly acts centrally and also a weak inhibitor of reuptake of norepinephrine and serotonin. But the reported adverse effects include nausea, dizziness, sleepiness, dry mouth, sweating and lowering of seizure threshold. Its advantages over other narcotic drugs are that it causes less respiratory depression than morphine and codeine and does not share the propensity of non-steroidal anti-inflammatory drugs (NSAIDs) to provoke asthma, gastrointestinal mucosal damage and renal impairment.

This study was mainly taken up to compare the efficacy of Paracetamol and Tramadol as postoperative analgesic. Hence, a randomized controlled study was undertaken in the Department of Anesthesia. About 100 patients who have undergone surgery for lower abdominal surgeries were divided in to two equal groups. One group received Paracetamol and another group received Tramadol.

Timing of Administration of First Dose of the Drug

In our study, the drug under the study was given 15min before the end of the surgery and subsequently the drug was administered every 6th hourly for 24 hours, and the patient was assessed for the level of pain by using the VAS score at 0, 2, 4, 6, 8, 10, 12 and 24 hours.

In a similar study done by Mustafa Arslan et al. [5] the study drug was administered 10 min before the skin incision and the level of pain was assessed by using the VAS scores at 15, 30 min and 1, 2, 4, 6, 8, 12 and 24 hours after the end of the surgery. In a study done at Bomay by Manish Kela et al. [6] patients received the study drug at the end of the surgery, and the doses were repeated every 8th hourly till 48 hours postoperatively and pain was

assessed using the VAS scale. In a study done by Lahtinen P et al. [7], patient received the study drug at 6 hours intervals for 72 hours.

Dosage

In our study, we used the drugs IV Paracetamol and IV Tramadol. IV Paracetamol was given at 15-17 mg/kg and IV Tramadol 1.5-2 mg/kg body weight. The study drug was given 15 min before the end of the surgery and repeated at every 6 hours for 24 hours. In a comparative study done by Manish Kela et al. [6], the patients were divided into two groups of 30 each. One group received Inj. Paracetamol (20 mg/kg) and the other group received Inj. Tramadol (2 mg/kg). In a comparative study done by Uysal HY et al. [8] the patients were divided into two groups, Paracetamol group received 15 mg/kg of IV Paracetamol and Tramadol group received 1.0 mg/kg IV Tramadol.

Analgesia

In our study, the mean VAS scores for Paracetamol were between 2.2 to 3.1 from immediate postoperative time to 24 hours after operation. The VAS scores of Tramadol were significantly different at 2 hours and 4 hours. The pain scores decreased over time in both the groups. In a comparative study by Cattbriga et al. [9], done for over 72 hours, patients who received Paracetamol had significantly less pain at the time point of 12 hours, 1 (0-6) vs. 2 (1-10) $p=0.0041$, 18 hour 1 (0-5) vs. 2 (0-8) $p=0.0039$, 24 hour 1 (0-5) vs 2 (0-8) $p=0.0044$. The pain scores progressively decreased in both the groups over the time, and there was no significant difference in pain 30-72 hours after operation. During a deep breath, the Paracetamol group had significantly less pain than placebo group only 12 hours after operation. A study done by Manish Kela et al. [6], observed that the mean score of VAS scale at rest and deep inspiration between the two groups was similar and the difference was not significant. At the end of 24 hours, mean VAS score had a significant reduction in both the groups and the difference was not significant.

Additional Analgesic Requirement

Paracetamol in this study needed additional analgesic especially immediately after surgery. Comparatively, less number of patients of Tramadol group needed additional analgesics. The rescue analgesic in the form of morphine was required in 22% of the patients of Paracetamol group at 0 hour,

32% at 2 hours and 2% at 10 hours after surgery. The total doses of rescue analgesic required by the Paracetamol group was 1.04 (± 0.2) and in Tramadol group was 1.0 (± 0). In a comparative study between IV Paracetamol and Tramadol done by Manish Kela et al. [6], 6.7% of Paracetamol group and 13.3% in the Tramadol group required rescue analgesic.

Adverse Effects

Tramadol is a drug known to result in nausea and vomiting. Majority of the patients in Tramadol group had sense of nausea and vomiting. About 60% of the patients in the Tramadol group had nausea and vomiting sensation at 0 hours, 12% at 2 hours, 14% at 4 hours, 48% at 6 hours, 26% at 8 hours respectively whereas in Paracetamol group about 4% of the patients had nausea at 2 hours, 4% at 4 hours and 2% at 6 hours. In a similar study by Manish Kela et al. [6] about 10% of the subjects in the Paracetamol group and 13.3% in the Tramadol group suffered nausea and vomiting. In a study done by Cattabriga et al. [9], it was observed that PONV was a very unusual adverse event, it was observed in three patients (6%) of Paracetamol group and in one patient (2.12%) in the placebo group.

Conclusion

Paracetamol is as effective as Tramadol when used for postoperative pain relief in patients for lower abdominal surgeries except in the early postoperative period. Incidence of postoperative nausea and vomiting is more with Tramadol when compared to Paracetamol.

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