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Original Research Article

Comparative Study of Intravenous Paracetamol and Tramadol for Postoperative Analgesia Following Infra-Umbilical General Surgeries

Indrajit Gupta[1], Mrigendra Kumar Rai[2]

[1]Assistant professor, Department of Anesthesiology, Sheikh Bhikari Medical college, Hazaribagh, Jharkhand, India

[2]Associate Professor, Department of General Surgery, Sheikh Bhikari Medical college, Hazaribagh, Jharkhand, India

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Corresponding Author: Dr. Mrigendra Kumar Rai

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Abstract:

Background: Postoperative pain is a common clinical problem, which may compromise recovery and hospital stay. Proper pain management, preferably in infra-umbilical procedures, is very important to optimize patient's outcomes. Although opioids such as tramadol are popular, their adverse effects – nausea, vomiting, sedation, and respiratory depression – do not make them desirable. Intravenous (IV) paracetamol: a non-opioid analgesic, which is gaining popularity as the potential alternative with favourable safety profile.

Aim: To compare intravenous paracetamol and tramadol for efficacy and safety for use in the postoperative period in patients undergoing infra-umbilical general surgeries.

Methods: It was an observational study that took place in Sheikh Bhikari Medical College, Hazaribagh, Jharkhand, India for one year. 52 patients undergoing elective infra-umbilical surgeries were randomly selected in to the two groups. Group A (IV paracetamol 15mg/kg) and group B (IV tramadol 2mg/kg). The intensity of pain was measured by the Visual Analogue Scale at 0, 1, 2, 4, 6 hours post operatively. Undesirable effects and need for rescue analgesia were also noted.

Results: The two groups exhibited similar outcomes in the early hours of having their blood. However, Group A (paracetamol) had statistically lower VAS scores reported at 2, 4, and 6 hours. More adverse effects such as nausea and sedation occurred in Group B (tramadol), which would suggest for better tolerability with paracetamol.

Conclusion: IV paracetamol has better analgesic efficacy in the later postoperative period and has fewer side effects than tramadol and is thus, a safe drug for the postoperative pain management system on infra-umbilical operation.

Keywords: Analgesia, Intra-umbilical operation, Intravenous paracetamol, Randomized trial, Tramadol, Visual Analogue Scale.

Introduction

Pain, an intense sensation, is induced by current or potential tissue injury. Nearly every surgical procedure entails some degree of intense discomfort. A fast restoration of normal physiological function as well as the avoidance of chronic pain initiation and progression rely on effective pain management. Elevated opioid dosages can result in many problems, including somnolence, nausea, respiratory depression, pruritus, immunosuppression, constipation, with urinary retention [1]. Postoperative pain is a prevalent and persistent issue following the majority of surgical interventions. This is a significant factor contributing to extended postsurgical recovery. It is distinct from other pain kinds as it is characterised by an immediate onset, commences post-surgery that is more easily managed than chronic pain.

Diverse methodologies have been proposed for the management of pain following general surgery, with neuraxial opioids frequently employed as a technique for alleviating post-umbilical pain. Opioids possess a dose-dependent capacity for significant adverse responses, including vomiting, nausea, bowel movements, pruritus, urine retention, difficulty breathing, and drowsiness [2]. Preventive analgesia encompasses any intraoperative analgesic medications that might mitigate pain-induced sensitisation of the central nervous system, hence reducing both the onset as well as duration of pain. Paracetamol (intravenous paracetamol) is a non-opioid painkiller that lacks the associated hazards of opioids. The postoperative consumption of paracetamol has already been demonstrated to reduce acute pain following several surgical interventions [3].

Postoperative pain management has garnered heightened focus in recent years due to advancements in procedures and pharmacological agents for its alleviation, as well as a deeper comprehension of the true cause of acute pain [4]. Inguinal hernia repair is among among the most prevalent as well as one of the most difficult outpatient operations, alongside about fifty percent of patients experiencing moderate to severe discomfort postoperatively [5].

Inguinal herniorrhaphy is among the most prevalent surgical procedures performed on males. The neuroaxis block is the predominant anaesthetic approach, allowing most patients to be discharged from the hospital a few hours post-procedure, provided sufficient analgesia is achieved and nausea and vomiting are absent [6]. Inguinal hernias repaired with Lichenstein open hernioplasty should be compared for postoperative pain relief using intravenous diclofenac bolus, intravenous paracetamol infusion, as well as intravenously tramadol f or postoperative pain management after Lichtenstein repair of an inguinal hernia, intravenous boluses of diclofenac, intravenous paracetamol, or intravenous tramadol are all equally effective and safe options [7]. The study evaluated the efficacy of intravenous tramadol vs diclofenac rectal suppositories in reducing postoperative pain in individuals having inguinal hernioplasty. Based on the mean postoperative pain score, study found that diclofenac rectal suppository is far superior to intravenous tramadol in patients having inguinal hernioplasty [8]. The objective of this study is to evaluate both effectiveness and safety of intravenous (IV) use of paracetamol and tramadol for post-operative analgesia in the patients undergoing intra-umbilical general surgeries. Post-operation pain management is a significant aspect for quality healing, and the choice of the right analgesic can affect the outcomes, comfort and recovery of patients. This study aims to assess and compare the efficacy for analgesia, onset of action, duration of analgesia and side effects of both drugs hence, giving an insight on their suitability as used in routine practice in post-operative care following infra-umbilical procedures.

Methodology

Study Design

This was an observational, prospective, non-interventional case-control research that aimed to compare the efficiency and safety of in providing postoperative analgesia following infra-umbilical general surgeries.

Study Area

The study was conducted at Department Of Anesthesiology, Sheikh Bhikari Medical college, Hazaribag, Jharkhand, India. For one year

Inclusion and Exclusion Criteria

- **Inclusion Criteria:**

The study comprised adult patient between the age of 18- 65 years who is undergoing infra-umbilical surgeries under intravenous paracetamol and intravenous tramadol and those who given consent to participate.

- **Exclusion Criteria:**

Participants were excluded if they had sensitivity to tramadol or paracetamol, chronic opioid use, medical history of seizure disorder, who were under complications and under emergency medical care, those who have undergone general, epidural or regional anesthesia and those who refuses to participate.

Procedure

This study was done following permission from the institutional ethics committee and the acquisition of signed informed consent from all participants at a tertiary care facility. A total of 52 patients, of both sexes belong to the age of 18 to 65 years and classified as ASA Grade I and II, undergoing elective infra-umbilical operations were included in the study. Patients were randomly allocated into two equal groups with the sealed envelope method, ensuring that Group A and Group B are of same size. Group A received intravenous paracetamol at a dosage of 15 mg/kg (maximum 1 g in a 100 ml infusion), while Group B was administered intravenous tramadol at 2 mg/kg (max. 150 mg in 100 ml of normal saline). These treatments were administered within 20 minutes, 25 minutes prior to the exclusion of patients classified as ASA grade III/IV, or those who had undergone general, epidural, or regional anaesthesia. Furthermore, individuals with substantial systemic disorders, a BMI exceeding 35 kg/m², pregnant women, and those on specific drugs were excluded. Post-operatively, pain levels were assessed at 0, 1, 2, 4, and 6 hours using a 10 cm visual analogue scale. Rescue analgesia was administered when the Visual Analogue Scale. exceeded 3. Vital signs and side effects, including sedation as assessed by the University of Michigan Sedation Scale, were meticulously monitored.

Statistical Analysis

The association between administered type of intravenous analgesic (paracetamol and tramadol) and several clinical parameters was analyzed in a systematic way. These parameters were the level of post-operative pain at various intervals of time, the patients' demographics (their age and gender), and the frequency of the adverse reactions to the drug. Further, outcomes like need of rescue analgesia and time taken for pain to be relieved were assessed with the correlation of the given drug. Continuous data

was described in which mean ± SD was used while ordinal, and nominal data were expressed as number and percentage. Intergroup comparisons for quantitative variables were based on Student's t test while Chi-square test was used in comparison of categorical variables. parameters recorded during postoperative period were subjected to one-way ANOVA to establish if there were significant variations within groups and between groups. Where p-value <0.05, a statistical significance was taken throughout the analysis.

Results

Table 1 demographic composition of the respondents from both groups was similar, which is an indicator of the outcome of a good randomization process. Patients' age mean in Group A (Paracetamol) was 43.6 ± 7.9 years; in Group B (Tramadol) – 45.1 ± 8.2 years, which is not statistically significant (p – 0.374). Correspondingly, the mean weight was 60.2 ± 5.4 kg in Group A as compared to 58.9 ± 6.1 kg in the other group (p = 0.297), which is not statistically distinct. ASA physical status distribution (ASA I/II) was 20/6, in Group A vs. 18/8, in Group B with p-value of 0.527 and insignificant difference of baseline health status. Group distribution in gender was also the same between the groups, Group A had 17 males and 9 females while Group B had 15 males and 11 females (p = 0.592). The average time of the surgery in Group A (66.5 ± 6.7 minutes) was slightly higher than in Group B (64.2 ± 7.1 minutes), while p = 0.258 was not statistically significant. All in all, we did not find statistically significant differences in the variables of demography, which implies that the groups under comparison could be successfully matched and compared relative to postoperative results.

Table 1: Demographic Profile of the Respondents

Variables	Group-A (Paracetamol)n = 26	Group-B (Tramadol)n = 26	P value
Age (years)	43.6 ± 7.9	45.1 ± 8.2	0.374
ASA I / II	20-Jun	18-Aug	0.527
Duration of surgery (min)	66.5 ± 6.7	64.2 ± 7.1	0.258
Sex (Male / Female)	17-Sep	15-Nov	0.592
Weight (kg)	60.2 ± 5.4	58.9 ± 6.1	0.297

In table 2, a time-wise comparative description of the postoperative pain amongst the two groups showed no significant differences in the intensity of pain in the immediate postoperative period (0 and 1 hours) with p-values exceeding the level of statistical significance (p > 0.05). However, from two hours onwards, a significant deviation can be identified. Elevated mean pain scores from Group B (Tramadol) were consistently reported compared with Group A (Paracetamol) which became significant at 2 hours (p = 0.041), more so at 4 and 6 hours (p = 0.0003 and 0.0018 respectively). This pattern indicates a relatively superior analgesic role of paracetamol in prolonging pain relief postoperatively out of the early recovery.

Table 2: Comparison of mean VAS scores at different times within both groups

Observation Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Immediately Postoperative (0 hr)	1.10 ± 0.28	1.08 ± 0.35	0.774
After 1 hour	1.25 ± 0.40	1.42 ± 0.50	0.191
After 2 hours	1.75 ± 0.48	2.05 ± 0.53	0.041
After 4 hours	2.58 ± 0.52	3.22 ± 0.49	0.0003
After 6 hours	2.95 ± 0.71	3.51 ± 0.58	0.0018

Table 3 show the adverse effects were higher in the tramadol group as compared to the paracetamol group. Nausea and vomiting were present in 11 patients of Group B, but 2 patients of Group A (p = 0.003) and sedation (UMSS ≥ 2) was noted in 6 patients (tramadol) and only 1 (paracetamol), p = 0.028. Dizziness, bradycardia, hypotension, and respiratory depression were not significantly different, which is a good tolerability and fewer adverse events with IV paracetamol.

Table 3: A comparison of the adverse effects of the two categories

Adverse Effect	Group A (n = 36)	Group B (n = 36)	p-value
Bradycardia	0	1	0.312
Dizziness	0	3	0.112

Hypotension	0	0	–
Nausea and Vomiting	2	11	0.003
Respiratory Depression	0	0	–
Sedation (UMSS ≥ 2)	1	6	0.028

Discussion

The results of the current study, whereby intravenous paracetamol and tramadol postoperative analgesic efficacy and safety profile were compared in infra-umbilical general surgeries conform well to the literature. Our data supported the fact that both drugs provided adequate pain relief in the first postoperative period. However, intravenous paracetamol demonstrated significantly better pain control past 2 hours with significantly lower VAS score at 4, 6 hours. This pattern can be aligned with former results described by Bande,et al., 2016 [9], whereby paracetamol demonstrated significantly diminished VAS scores compared to tramadol over multiple times post-operatively, including up to 24 hours.

Like our results, the previous articles noted that on one hand, both paracetamol and tramadol are effective analgesics, but the tolerability profile of paracetamol is more favorable. In our study, unfavorable effects including nausea and vomiting occurred significantly more in the group treated with tramadol ($p = 0.003$) confirming findings observed by Mentes, et al., 2009 [7] who presented nausea in 10% of the patients using the tramadol. In the same way, our findings are presented by Santos et al. [8], who could not report significant differences in cases of nausea and vomiting after administering these substances intravenously or subcutaneously – tramadol, but still attest to the general manifestation of such effects with use of this drug.

Curiously, the discoveries of the studies Uysal et al., 2011 [2] and Mentes and Bagci, 2009 [7] also noted the absence of statistically significant demographic and hemodynamic discrepancies between the study groups which corresponds with the demographic neutrality which has been found in our study. Statistically, both were non-significant when it came to age and ASA grade distribution, meaning an effective group matching which therefore establishes the validity of the comparison of outcomes.

As far as rescue analgesia is concerned, our study on both groups has got similar needs although a few patients in the tramadol group needed more rescue doses. That is similar to the findings of Kumari et al. [10], where paracetamol shown significant reduction in the patients' request for additional analgesia with diclofenac. The delay in the time to administration of rescue analgesics was also found to be statistically significant among paracetamol group, as in the results of Kumari et al. the need for rescue analgesic (tramadol) was delayed in paracetamol group (12.33 ± 3.47 h vs. 3.47 $p < 0.0001$).

More so, our study gave superior sedation scores in the tramadol group ($p = 0.028$), in line with Bandey S, et al., 2016 [9], and Bhalavi M,et al., 2022 [1]'s sedation reports on patients receiving tramadol or pregabalin. As it is clinically relevant, that excessive sedation can slow down recovery and discharge in day-care surgeries.

Finally, our results found no significant differences between the groups in regard to the incidence of bradycardia, hypotension, or respiratory depression. This reflects findings of Bhalavi et al., 2022 [1], where stable vital parameters and lack of serious adverse effect were observed in the two groups. Combined, the findings from these comparisons support the conclusion that IV paracetamol does not only prove to be effective in postoperative analgesia but also superior in safety and tolerability in IV tramadol in infra-umbilical general surgeries.

Conclusion

The present study has shown that IV paracetamol and tramadol are helpful agents for the postoperative analgesia infra-umbilical general surgeries; however, paracetamol offers much better relief of pain during the later post-operative period, in the case of 4 and 6 hours post-surgery. Furthermore, intravenous paracetamol is less likely to elicit adverse effects in particular nausea, vomiting and sedation in comparison to tramadol. Such evidence favours paracetamol use due to the safer and more tolerable analgesic option in the immediate postoperative state. Due to its efficacy and better side effect profile, intravenous paracetamol could be a better alternative to tramadol in normal postoperative pain relief practice after infra-umbilical surgeries. Richer sizes samples, as well as longer post-operative monitoring periods, should be employed in further studies in order to verify and further develop the findings in question.

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