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Original Research Article

EVALUATING THE EFFICACY OF PREEMPTIVE INTRAVENOUS PARACETAMOL VERSUS TRAMADOL FOR POSTOPERATIVE ANALGESIA: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background. Adequate postoperative pain management is crucial for promoting faster patient recovery, minimizing side effects, reducing mental and physiological burdens, and enhancing patient satisfaction. Aims: This prospective study aims to compare the preemptive use of Paracetamol and Tramadol, evaluating their effectiveness in managing postoperative pain. **Material & Methods:** Conducted in the Department of Anesthesiology of our tertiary care hospital from August 2019 to December 2019, this randomized controlled clinical trial included 60 patients aged 18 to 60 years with ASA I & II undergoing minor elective surgical procedures under general anesthesia (GA). Patients were randomly assigned to two groups: Group P received preemptive Paracetamol, and Group T received preemptive Tramadol hydrochloride. Premedication included inj. glycopyrrolate 0.2 mg and inj. Fentanyl 2µg/kg intravenously, 3 minutes before GA induction. Additionally, patients in Group P received inj. Paracetamol 15 mg/kg intravenously, while those in Group T received inj. Tramadol 2 mg/kg intravenously, 15 minutes before GA induction. Continuous vital signs monitoring was performed, and the number of analgesic doses, duration of surgery, and postoperative side effects at 24 hours were recorded. **Results:** Both groups were comparable in demographic profile and surgical procedure duration. Group P exhibited statistically significantly lower mean VAS scores (2.45±2.10) compared to Group T (3.83±2.96), with a lower number of rescue analgesics required (1.89±1.03 vs. 2.75±2.13, respectively) ($p<0.05$). **Conclusion:** Preemptive intravenous Paracetamol administration demonstrated effective and reliable postoperative pain control under general anesthesia. Postoperative VAS scores and the requirement for rescue analgesics were lower in the Paracetamol group compared to the Tramadol group.

Keywords: Paracetamol, Tramadol, Preemptive use, VAS scale

INTRODUCTION

Surgical procedures inflict pain, which continues in the post- operative period. **(1)** Failure to alleviate the pain may make the patient unable to breathe & cough adequately and perform daily activities. Inadequate pain control post-surgery cause significant physical & physiological trauma. It can result in long-term & medium term complications. These include hypoxemia, pneumonia, pulmonary embolism, psychological trauma, delay in improvement of bowel function, myocardial ischemia and infarction & urinary retention. **(2)** Pain is maximum during 48-72 hours postoperatively & decreases late on. Paracetamol effectively controls pain by inhibiting prostaglandin synthesis & cyclooxygenase (COX). It has a high safety profile as compared to other nonsteroid antiinflamatory drugs (NSAID). **(3)** Preemptive pain control involves the usage of analgesics, preoperatively thus beneficial in reducing the amount of anesthetic drugs & more effective pain control postoperatively. Arslan M et al in 2013 observed preemptive IV paracetamol to provide effective and reliable pain

control after cholecystectomy & reduced post-operative pain scores, the need for additional opioids. **(4)** Bandey S & Singh V 2016 showed paracetamol to exhibit lower VAS scores as compared to tramadol at follow up intervals. No side effects were noted with paracetamol while one patient in Tarmadol group experienced nausea. **(5)**

The present prospective study, aims to compare the preemptive use of Paracetamol and Tramadol, to evaluate their effectiveness on postoperative pain.

MATERIALS AND METHODS

This prospective randomized controlled clinical trial was conducted in the Department of Anesthesiology of our tertiary care hospital from August 2019 to December 2019. The study recruited 60 patients aged18 to 60 yrs with ASA I & II who were undergoing minor elective surgical procedures under general anesthesia (GA). An institutional ethical approval was sought & written informed consent taken. Patients with any allergy to study drugs, comorbid diseases, renal insufficiency, hepatic insufficiency, pregnant women were excluded from the study. Visual analogue scale was explained to the patients.

The patients were randomly allocated to two groups:

Group P: preemptive use of Paracetamol

Group T: preemptive use of Tramadol hydrochloride

Patients were premeditated with inj. glycopyrrolate 0.2 mg intravenously; inj. Fentanyl 2μ/Kg body weight intravenously, 3 minutes prior to induction of GA. In addition, patients of group P received inj. Paracetamol 15mg/kg intravenously and patients of group T received inj. Tramadol 2mg/kg intravenously 15 minutes prior to the induction of GA. Induction with inj. propofol 1.5 – 2.5 mg/kg body weight followed by oro-tracheal intubation with rocuronium 0.08 mg/kg body wt, using well-lubricated PVC tube. Anesthesia was maintained with 65 % nitrous oxide (N2O) with 35 % oxygen (O2) mixture plus isoflurane 0.5% to 0.8%.

Continuous monitoring of vitals was done. Measurement of urine output (hourly), blood loss was done & fluid replacement was done with crystalloids, if required with colloids. The patients were shifted to ward and monitored up to 24 hrs. Pain experienced by the patients was recorded using VAS Scale and for relieving of pain the same study drug was injected intravenously. The numbers of analgesic doses, duration of surgery, side effects 24 hrs postoperatively were noted.

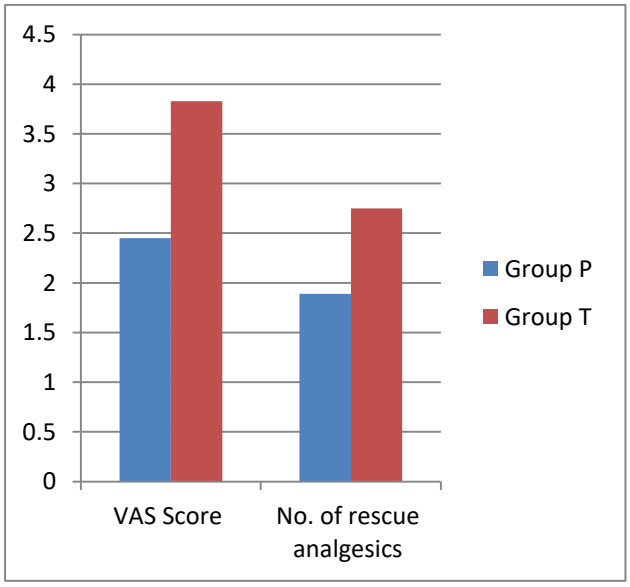
Statistical analysis

The collected data was tabulated in excel spreadsheet & put to statistical analysis. The data was expressed as mean and standard deviation. P value <0.05 was considered statistically significant.

RESULTS

Both groups were comparable with respect to their demographic profile, surgical procedure and duration. In Group P, the mean VAS scores were 2.45±2.10 and in Group T, it was 3.83±2.96. The mean VAS scores in Group P were statistically significantly lower than Group T ($p<0.05$). In Group P, the number of rescue analgesics required was 1.89±1.03 while in Group T, it was 2.75±2.13. The number of rescue analgesics in Group P were statistically significantly lower than Group T ($p<0.05$). (Fig 1)

Fig 1 Shows the VAS Scores and No. of rescue analgesics required in Group P & T



DISCUSSION

Preemptive analgesia is defined as an anti-nociceptive treatment that prevents the establishment of altered central processing of afferent input, which amplifies pain after surgery **(5)**. It was first proposed by Crile **(6)** in 1913 and spread by Wall and Woolf 7. Woolf stated that preemptive analgesia reduces the central sensory processing.**(7)** A study by Coderre et al. showed that preemptive administration of analgesics prevented the pain experienced after surgery & reduced postoperative pain as well. It avoids central sensitization & chronic

neuropathic pain, protective effect on the nociceptive system, which could significantly reduce the level of pain and decrease the risk for the development of chronic pain. **(8)** It is an important part of multimodal analgesia. Multimodal analgesia involves using analgesic adjuncts with different mechanisms of action for ensuring adequate postoperative pain management with minimum side effects. Preemptive analgesia is an important part of multimodal analgesia. **(9)**

In the present study, both groups were comparable with respect to their demographic profile, surgical procedure and duration. In Group P, the mean VAS scores were 2.45±2.10 and in Group T, it was 3.83±2.96. The mean VAS scores in Group P were statistically significantly lower than Group T ($p<0.05$). In Group P, the number of rescue analgesics required was 1.89±1.03 while in Group T, it was 2.75±2.13. The number of rescue analgesics in Group P were statistically significantly lower than Group T ($p<0.05$).

Accordingly, study by Arici S, Gurbet A et al. observed paracetamol 1 g preemptive use to provide good quality postoperative analgesia.**(10)** Aghamir et al. did a randomized controlled trial on 40 patients undergoing surgery under GA. Tramadol 100 mg & paracetamol 2 gm at post-op hour 0. The study concluded that paracetamol was insufficient in the control of pain as compared to tramadol.**(11)** Syeda S et al 2019 concluded pre-emptive I.V. paracetamol to be as effective as I.V. tramadol for postoperative analgesia ensuring early recovery & decreased incidence of postoperative nausea & vomiting in paracetamol group.**(12)** Aporado CB et al used low doses of tramadol (0.5mg/kg) pre-emptively to provide good intra operative analgesia in pediatric patients undergoing appendectomy & concluded that rescue analgesics were required to control the pain postoperatively.**(13)** Aweke et al 2018, demonstrated preemptive use of paracetamol-tramadol and paracetamol-diclofenac combination to decrease the total tramadol dosage & prolonging the time to first analgesic request as compared to paracetamol alone in patients undergoing laparotomy surgery.**(14)**

CONCLUSION

The present study concludes that pre-emptive administration of paracetamol has better efficacy than tramadol hydrochloride during surgery & also post-operatively, with lower number of analgesic doses, greater VAS reduction & no side effects.

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