Original Research Article

# Single dose intravenous paracetamol versus intravenous tramadol in orthopedic surgeries: A randomized study

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## Abstract

**Objective:** 1) To compare the duration as well as quality of analgesia after a single dose Intravenous Paracetamol and Tramadol. 2) to compare the side effect of two drugs. **Method:** The present study was carried out on 120 patients from 20 to 55 years of both sexesunder going lower limborthopedic surgeries at GMC Akola, belonging to ASA I and ASA II. Of those 60 were allocated in study group (receiving Paracetamol) and 60 in control group (receiving Tramadol).Pain was assessed with visual analogue scale (VAS) at different postoperative interval. Analysis was done by using SPSS**. Results:** Both groups were comparable in demographic data. The difference in the duration of analgesia in both groups was statistically significant. The duration of total analgesia in both groups was comparable. Effective analgesia in Paracetamol group was longer than Tramadolgroup. In Paracetamol group side effects were observed less than in Tramadol group. **Conclusion:** This study concludes that Paracetamol is more effective in duration and quality of analgesia than tramadol.

**Key Words:** Effective analgesia, Tramadol and Paracetamol.

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## INTRODUCTION

Severe acute postoperative pain itself can easily hinder early physiotherapy, which is the most important factor for successful postoperative orthopaedic surgeries[1], this is again more important for mobilizing patient in lower limb surgeries. Successful recovery from surgery includes comprehensive management of post-operative pain.[2] Postoperative pain paves the way for a host of complications in major surgeries.[3] Pain is a predictable component of any surgical procedure, and postsurgical pain is commonly treated ineffectively. Inadequately treated postoperative pain may result in pain and suffering, as well as multiple physiological and psychological consequences[4] Tramadol, a synthetic opioid of the aminocyclohexanol group, is a centrally acting analgesic with weak opioid agonist properties, and effects on noradrenergic and serotonergic neurotransmission. In addition, these opioids and nonopioids modes of action appear to act synergistically.[5] Tramadol is an isomeric drug, of which the (+) enantiomer is a weak mu-opioid agonist with an analgesic potency about 1/10$^{th}$ that of morphine.[6] Paracetamol is effective for mild to moderate pain and an effective component in multimodal analgesia. It can also be used in more severe pain such as postsurgical pain. And providing palliative care in advanced cancer patient. It mechanism of action is inhibition of cyclooxygenase (COX) and recent finding suggest that it is highly selective for COX-2.[7] Maximal plasma concentration following intravenous infusion of 1gm of intravenous paracetamol is about 30mg /liter (200umol/lit) occurring at 15mins after the start of infusion.[8] Peak analgesia

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effect of I.V paracetamol occurs in 1hr with duration of approximately 4 to 6 hrs.[9] Considering all these points present study was undertaken to compare duration and quality of analgesia between Paracetamol and Tramadol.

## MATERIALS AND METHODS

Present study was a prospective randomized control trial carried on 120 patients who were undergoing lower limb orthopedic surgeries of both the sexes in the age group of 20 to 55 years. During the period of July 2017 to Dec 2017.

Ethical Committee approval and written informed consent from the patients was obtained prior to the study.

**Patients were divided into two groups**

- Group I: Received I.V Paracetamol 1 g in 100 ml NS infused over 15 min, 15 min prior to the end of surgery.
- Group II: Received I.V Tramadol 100mg slow IV in 100ml NS infused over 15 min, 15 min prior to the end of surgery.

**Inclusion Criteria:** American Society of Anaesthesiologist (A.S.A.) grade I and II patients, aged 20-55yrs, undergoing lower limb surgery under spinal anaesthesia, emergency or elective scheduled to last less than 180 minutes, and willing to participate in study.

**Exclusion Criteria:** Patient with refusal, patient with allergic to tramadol or paracetamol, morbidly obese patients, chronic alcoholic, serum bilirubin >1.8mg/dl, SGOT/SGPT >150, Coagulopathy, k/c/o renal disorders. Preoperatively detailed medical, surgical history, allergies were noted. Preoperative detailed general and systemic examination was done and vitals recorded and necessary investigations were done. Demographic data like age, weight (kg), height (cm) obtained for each case. The patients were familiarized with the 10 cm visual analogue scale (V.A.S) for pain during the pre-anesthetic visit. Patients were kept fasting for 6-8hrs prior to anesthesia. After shifting the patients to operation theatre, baseline monitoring of E.C.G, noninvasive blood pressure, oxygen saturation, and respiratory rate were recorded. A 20 Gauge i.v. line was established. All patients were preloaded with 10ml/kg of lactated Ringer solution over 15-20 minutes. The patients were randomly assigned to one of the study groups. The study drugs were prepared by an anesthetist not involved in patient assessment. All patients received spinal anesthesia with 3ml of 0.5% heavy Bupivacaine. Visual analogue scale was obtained post operatively at 30min, 1, 2, 4, 6 and 8 hrs. VAS as 0 as no pain and 10 worse pain. If VAS score is more than 5 then I.V Diclofenac 75mg was used as rescue medicine in both the groups. Postoperative hemodynamic parameters like heart rate, blood pressure and side-effects like nausea, vomiting was evaluated at regular intervals

**Statistical Analysis:** All values are reported as mean ± SD. Differences were considered statistically significant at a probability value $P<0.05$, $P<0.001$. All statistical analyses were performed with IBM SPSS Statistics version 19.0 (IBM Corporation, Somers, NY) {10}.

## RESULTS

**Table 1:** Details of demographic features as well as duration of surgery

| Parameter | Group 1 (Receiving paracetamol) | Group II (Receiving Tramadol) |
|---|---|---|
| Age | 38.4 ± 8.4 | 36.8 ± 6.9 |
| BMI | 24.6 ± 2.8 | 23.8 ± 3.1 |
| Male / femaleratio | 1.8 | 1.5 |
| Duration of surgery | 1.5 ± 0.4 | 1.4 ± 0.6 |

**Table 2:** Mean VAS score at the end of 30min, 1, 2, 4, 6 and 8 hrs.

| Time | VAS score Group 1 (Receiving paracetamol) (Mean ± S.D) | VAS score Group II (Receiving Tramadol) (Mean ± S.D) | Test of significance (P value) |
|---|---|---|---|
| 30 min | 0.5 ± 0.2 | 0.7 ± 0.3 | P > 0.05 |
| 1 hr | 1.0 ± 0.2 | 2.7 ± 0.4 | P < 0.05 |
| 2 hr | 2.1 ± 0.5 | 2.9 ±0.7 | P > 0.05 |
| 4 hr | 2.7 ± 0.3 | 3.4 ± 0.2 | P > 0.05 |
| 6hr | 2.4 ± 0.4<br>15 rescue dosages | 2.1 ± 0.6<br>23 rescue dosages | P > 0.05<br>$X^2$= 2.46, P > 0.05 |
| 8 hr | 1.6 ± 0.7<br>28 rescue dosages | 1.9 ± 0.6<br>37 rescue dosages | P > 0.05<br>$X^2$= 2.71, P < 0.05 |

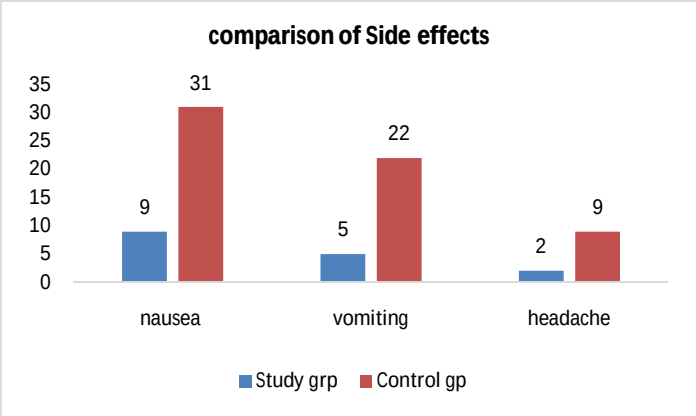


**Figure 1:** Side effects in both the grops

Table-1 gives details of demographic features as well as duration of surgery. The mean age in study group was 38.4± 8.4 and in control group was 36.8± 6.9. Mean BMI in study group was 24.6±2.8 and in control group was 23.8±3.1. Also male female ratio was 39/21 i.e1.8 in study group and 36/23 i.e. 1.5. Which are not statistically significant. Hence both the groups are comparable. Duration of surgery mean±SD was 1.5±0.4 hour in study group which is similar to that 1.4 ± 0.6 hours control group. Table-2 gives mean VAS score at the end of 30min, 1, 2, 4, 6 and 8 hrs. VAS score was comparatively better at all the times in study group than in control group. And significantly different at 1 hour i.e. mean ± SD is 1.0 + 0.2 in study group and 2.7 ± 0.4 in control group. VAS score decreased in both study and in control group at 6 and 8 hours because rescue medication was given to them whose VAS score was more than 5. Number of rescue medication given at the end of 6 hours was to 15(25%) in study group while it was 23(61.7%) in control group, which was not statistically significant ($X^2$= 2.46, P > 0.05) but comparatively less dosages were required in study group. And at the end of 8 hours rescue medication was given to 28(46.7%) in study group and 37(61.7%) in control group which was statistically significant ($X^2$= 2.71, P < 0.05) means less no of dosages were required in study group than in control group.

Figure 1 shows the no of episodes of side effects in study and in control group. Nausea was experienced in 9(15%) in study group while in 31(51.6%) in control group, vomiting was experienced in 5(8.3%) in study group while in 22(36.6%) in control group and headache experienced in 2(3.3%) in study group while in 9(15%) in control group. Which was statistically significant. Hence it is proved that paracetamol produce less no of side effects than tramadol.

## DISCUSSION

Our study demonstrate that IV Paracetamol is safe and effective non-opioid analgesics for the treatment of postoperative pain in patients undergoing lower limb orthopedic surgery. In the present study it was found that pain score (VAS) was lower at all the times in study group (receiving Paracetamol) than in control group (receiving Tramadol). And regarding the pain score ratings patient with Paracetamol group had significantly lower pain score in 1 Hr than those with Tramadol group. Similar findings were seen in study of Aghamir SK *et.al*[11], Uysal HY *et.al*[12] and Mohammed Shahid,*et. al* [13] In present study requirment of rescue medications was lower in the Paracetamolgroup than that of Tramadol group and it was stastiscally significant at 8 Hr.28(46.7%) in study group and 37(61.7%) in control group asked for rescue medications at 8 Hr which was stastically significant. Hence IV Paracetamol reduces the requirement of NSAIDS toan extent that NSAIDS related adverse effects are reduced. Similar findings were given by Dejonckheere *et.al.*[14] and Alfano G *et.al.*[15] Different findings were noted in study done by Hale YarkanUysal *et.al*[16] may be because their study participants were children. Reported adverse effects in post-operative pain study may reflect number of factors. Adverse effects may be due to residual effects of anaesthesia and surgery. To remove this confounding factor all patients received injection ondansetron 4mg intraoperatively. In present study number of patients experiencing side effects were significantly less in Paracetamol group than that of in the Tramadol group. Similar findings were seen in the study of Aghamir SK *et.al*[11], Similar side effects were seen in KumariUsha Rani *et.al.* [17]

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