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Comparative Study of the Efficacy of Intravenous Paracetamol and Intramuscular Paracetamol in Combination with Intravenous Tramadol for Post-Operative Analgesia in Open Appendectomy Patients

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ABSTRACT

Non-steroidal anti-inflammatory drugs and opioids are routinely used to mitigate post-operative pain., however these drugs are burdened by side effects. Tramadol and paracetamol are believed to be lacking in such side effects. To compare the efficacy of intravenous Paracetamol with intramuscular paracetamol in combination with intravenous tramadol for post-operative analgesia in open appendectomy patients. This was a randomized controlled double-blinded study. A total of 120 patients were selected and randomized into two groups of sixty patients each, Group A (Inj paracetamol 15mg/kg IM+Inj tramadol 50mg IV) and Group B (Inj paracetamol 1gm IV infusion+Inj tramadol 50mg IV was used) undergoing open appendectomy elective or emergency surgery under spinal anesthesia. Duration of analgesia after surgery, visual analog scale score and hemodynamic parameters were recorded. Statistical software SPSS 24.0 version IBM USA was used for data analysis. We observed that the mean duration of analgesia was better in Group A as compared to Group B which was statistically significant ($p < 0.05$). The VAS score was significantly less in Group A as compared to Group B at 5 and 6 hours after surgery. Post-operative complications were negligible in both the groups. Mean duration of analgesia was less in intravenous paracetamol group as compared to intramuscular group.

INTRODUCTION

Pain is a predictable component of any surgical procedure and post-operative pain is commonly treated ineffectively. Inadequately treated post-operative pain may result in pain and suffering, as well as multiple physiological and psychological consequences and successful recovery from surgery includes comprehensive management of post-operative pain^[1]. Post-operative pain paves the way for a host of complications in major surgeries like laparotomy, which can be deleterious. The ultimate goal of any surgical treatment is to attain an uneventful recovery from anesthesia and surgery for a better quality of life and outcome without any associated complications and sequella. These goals can be achieved only with concurrent suitable anesthesia^[2]. Advances in multi modal analgesia (MMA) have largely replaced conventional opioid based monotherapy, but continued reliance on opioids to manage post-operative pain may at least partly explain the inadequacy of conventional acute pain management^[3]. For decades now, opioids and non-steroidal anti-inflammatory drugs (NSAIDs) have been used and have not been entirely devoid of undesirable side effects like postoperative nausea and vomiting, respiratory depression, sedation, gastrointestinal bleeding renal injury etc. Paracetamol, known as acetaminophen, is the most commonly prescribed analgesic for the treatment of acute pain^[4]. With the advent of intravenous paracetamol, interest is now being shown as to its efficacy in mitigating pain especially against the backdrop of commonly used analgesics^[5]. Tramadol has been shown to provide effective analgesia after both IM and IV administration for the treatment of postoperative pain. While it is not recommended as a supplement to general anesthesia because of its insufficient sedative activity, tramadol has been successful in the treatment of postoperative pain. When low dose IV tramadol is combined with IV paracetamol, it not only achieved excellent analgesia, the incidence of postoperative nausea and vomiting was extremely low. Intravenous tramadol alone or co-administered with non-opioid medication (when needed) as a multi modal combination analgesia approach resulted in high patient satisfaction with their pain relief^[6]. Low doses of IV tramadol combined with IV paracetamol achieved excellent analgesia and the incidences of PONV was extremely low. These low doses of tramadol combined were enough to produce equivalent analgesia and at the same time reduced the side effects of using larger doses of tramadol^[7]. Postoperative pain following open appendectomy surgery is associated with prolonged hospitalization

duration. Post-operative incision site pain may be distressing to the patients. Non-narcotic analgesic options like paracetamol, tramadol, NSAIDs, infiltration analgesia, transverse abdominis blocks can be used to manage post-operative pain in appendectomy patients. There are no single studies that used combination of IM paracetamol and IV tramadol for postoperative analgesia. Hence, we decided this randomized double-blind study to elucidate whether IM paracetamol can be an alternative to IV paracetamol for postoperative analgesia in combination with IV tramadol for open appendectomy patients. The goal of this study is to compare the efficacy of intravenous paracetamol with intramuscular paracetamol in combination with intravenous tramadol for postoperative analgesia in open appendectomy patients.

MATERIALS AND METHODS

A comparative prospective randomized double-blind study was conducted at the tertiary care centre after approval from the Institutional Ethical Committee and consent from the patient. A total of 120 patients of either sex with inclusion criteria aged between 18 and 55 years, American Society of Anesthesiologists (ASA) physical status Classes I and II posted for elective and emergency open appendectomy surgery under spinal anesthesia. The study population was randomly divided into two groups with 60 patients in each group. Group A: patients with IM paracetamol 15mg/kg+IV tramadol 50 mg and Group B: patients with IV paracetamol 1gm infusion+ IV tramadol 50mg. All the patients were included after a thorough pre-anesthetic checkup including general, physical and systemic examinations. All patient's routine laboratory investigations like CBC, LFT, KFT, BSL, ECG and CHEST X-RAY were done. After obtaining informed consent, the patient is shifted to OT, IV access was secured with a 20 G cannula and crystalloids will be infused. Monitors ECG, NIBP and Spo2 probe were connected. Baseline Heart rate, blood pressure and Spo2 was measured. Spinal anesthesia was performed in sitting position with a 23 or 25 G Quincke spinal needle in the L3-L4/L4-L5 interstate (midline approach) with injection Bupivacaine 0.5% heavy 3cc was given to achieve desirable level of anesthesia. At the end of the surgery Group A received injection paracetamol IM 15 mg/kg+ injection tramadol 50mg IV and Group B received injection paracetamol 1 gm IV infusion +injection tramadol 50 mg IV. Patients were monitored with heart rate, blood pressure, pulse oximetry, ECG. Post-operative pain response was assessed with Visual analog scale score. Duration of analgesia was studied

in both the groups. Collected data were entered into a Microsoft Excel spreadsheet. Continuous variables were presented as Mean±SD. Categorical variables were compared by performing a chi2-square and an independent t-test. For small numbers, Fisher exact was used. $p < 0.05$ was considered as statistical significance. Statistical software SPSS 24.0 version IBM USA was used for data analysis. A p value of < 0.5 was considered as statistically significant.

RESULTS AND DISCUSSIONS

In our study, 60 patients in each Group A (IM Paracetamol) and Group B (IV Paracetamol) were studied to compare the duration of analgesia after surgery, VAS score and side effects. Postoperative pain not only affects the patient's operative outcome, well-being and satisfaction from medical care, but also directly affects the development of tachycardia, hyperventilation, decreases in alveolar ventilation, transition to chronic pain, poor wound healing and insomnia, which in turn may impact the operative outcomes^[8]. Individual variations in the response to pain are influenced by the genetic makeup, cultural background, age and gender^[9]. The practice of modern anaesthesiology has been developed from intraoperative period into perioperative period. Postoperative pain management is one of the most important components of adequate post surgical patient's care^[10]. The demographic characteristics in the present study included 120 patients (60 patients in each group) having ages between 18-55 years. In our study, the mean age of the patients from Group A and Group B was 28.45 ± 9.07 and 28.65 ± 9.46 years respectively. Mean duration of surgery of the patients from Group A and Group B was 93.25 ± 9.47 and 94.17 ± 9.79 minutes respectively. So, the patient's demographic characteristics in all the groups were comparable but all were not statistically significant ($p > 0.05$). We also compared hemodynamic responses in Group A and Group B. We observed statistically non-significant difference in the SBP at 6, 8 and 12 hours ($p > 0.05$). It means SBP was comparable in Group A as compared to Group B at 6, 8 and 12 hours. We observed statistically non-significant difference in the DBP at 4, 6, 8 and 12 hours ($p > 0.05$). We compared the PR between two groups at different time intervals. It is observed that the mean PR of Group A and Group B was almost similar at all the times ($P > 0.05$). It was also observed that there was no significant difference in the mean SPO2 of Group A and Group B at all the time intervals. Mean duration of analgesia after surgery of the patients from Group A and Group B was 316.17 ± 16.06 and 240.83 ± 7.43 minutes respectively.

We observed statistically significant difference with respect to duration of analgesia ($p < 0.05$). It means duration of analgesia was less in Group B as compared to Group A in our study. We compared the VAS between two groups at different time intervals. It is observed that there was effective analgesia till 4 hours. At 5 hours after the procedure mean VAS of the patients from Group A and Group B was 0.03 ± 0.26 and 2.0 ± 0.0 respectively. At 6 hours after the procedure mean VAS of the patients from Group A and Group B was 1.97 ± 0.26 and 2.0 ± 0.0 respectively. We observed statistically significant difference in the VAS at 5 and 6 hours ($p < 0.05$). It means VAS was less in Group A as compared to Group B comparing 5 and 6 hours. But it doesn't hold much clinical significance. The effects observed in both groups are nearly identical. At 8, 12 and 24 hours there was no significant difference in the VAS score between two groups ($p > 0.05$). Proportion of cases having vomiting as side effect in Group A were 6.7% as against 5% in Group B. We observed statistically non-significant difference with respect to cases of vomiting ($p > 0.05$). Shiv Kumar Singh^[7] conducted a study to elucidate the efficacy, safety and patient satisfaction of a simple combination of readily available medications (Shiv-mix) for perioperative analgesia, hemodynamic stability and postoperative recovery profile. This study presents use of a combination of easily available medication as part of multi modal analgesia. The study was carried out using a defined mixture of non-opioid medications in patients undergoing elective neuro surgical procedures. The components of these mixes include paracetamol, tramadol, lignocaine and magnesium sulphate. One of the mixes combined low dose IV tramadol with IV paracetamol. It not only achieved excellent analgesia, the incidences of PONV was extremely low in these cases. These low doses of tramadol combined were enough to produce equivalent analgesia and at the same time reduced the side effects of using larger doses of tramadol. Paracetamol itself is known to prevent PONV in a meta analysis by Apfel^[11]. Aimakhu^[12] conducted the study with the objective to compare the analgesic efficacy, patient satisfaction and side effects of intramuscular tramadol and paracetamol as pain relief among women in labor at University College Hospital (UCH), Ibadan, Nigeria. Their study showed that intramuscular paracetamol was as effective as intramuscular tramadol for providing moderate pain relief during active phase of labor. Khyati R Vaghela *et al.* conducted a comparative study of intravenous febrinil vial (150mg/ml) vs intravenous paracetamol (1gm/100ml) pint formulation for postoperative analgesia concluded

Table 1: Distribution According to Age Group

| | | Group A | | Group B | | Total | p |
|--------------------|-------|---------|-------|---------|-------|-------|-----------------------|
| | | No | % | No | % | | |
| Age group in years | <20 | 13 | 21.7 | 14 | 23.3 | 27 | 0.97, Not significant |
| | 21-30 | 28 | 46.7 | 26 | 43.3 | 54 | |
| | 31-40 | 13 | 21.7 | 12 | 20.0 | 25 | |
| | 41-50 | 5 | 8.3 | 7 | 11.7 | 12 | |
| | 51-60 | 1 | 1.7 | 1 | 1.7 | 2 | |
| Total | | 60 | 100.0 | 60 | 100.0 | 120 | |

Table 2: Comparison of Mean Duration of Surgery Between Group A and Group B

| Group | N | Mean | Std. Deviation | t | p | Inference |
|--------------------------------|----|-------|----------------|--------|------|-----------------|
| Duration of surgery in minutes | | | | | | |
| Group A | 60 | 93.25 | 9.47 | -6.207 | 0.09 | Not significant |
| Group B | 60 | 94.17 | 9.79 | | | |

Table 3: Comparison of Mean Duration of Analgesia After Surgery Between Group A and Group B

| Group | N | Mean | Std. Deviation | t | p | Inference |
|--|----|--------|----------------|--------|--------|--------------------|
| Duration of Analgesia after surgery in minutes | | | | | | |
| Group A | 60 | 316.17 | 16.06 | 32.974 | 0.0001 | Highly significant |
| Group B | 60 | 240.83 | 7.43 | | | |

Table 4: Comparison of Mean VAS Score Between Group A and Group B

| VAS | N | Mean | Std. Deviation | t | P | Inference |
|---------|----|------|----------------|---------|--------|--------------------|
| 0 hrs | | | | | | |
| Group A | 60 | 0.00 | 0.0 | | | - |
| Group B | 60 | 0.00 | 0.0 | | | |
| 1 hrs | | | | | | |
| Group A | 60 | 0.00 | 0.0 | | | - |
| Group B | 60 | 0.00 | 0.0 | | | |
| 2 hrs | | | | | | |
| Group A | 60 | 0.00 | 0.0 | | | - |
| Group B | 60 | 0.00 | 0.0 | | | |
| 3 hrs | | | | | | |
| Group A | 60 | 0.00 | 0.0 | | | - |
| Group B | 60 | 0.00 | 0.0 | | | |
| 4 hrs | | | | | | |
| Group A | 60 | 0.00 | 0.0 | | | - |
| Group B | 60 | 0.47 | 0.85 | | | |
| 5 hrs | | | | | | |
| Group A | 60 | 0.03 | 0.26 | -4.238 | 0.0001 | Highly significant |
| Group B | 60 | 2.00 | 0.00 | | | |
| 6 hrs | | | | | | |
| Group A | 60 | 1.97 | 0.26 | -59.000 | 0.0001 | Highly significant |
| Group B | 60 | 2.00 | 0.00 | | | |
| 8 hrs | | | | | | |
| Group A | 60 | 4.00 | 0.00 | -1.000 | 0.319 | Not significant |
| Group B | 60 | 4.00 | 0.00 | | | |
| 12 hrs | | | | | | |
| Group A | 60 | 5.97 | 0.26 | -1.000 | 0.319 | Not significant |
| Group B | 60 | 6.00 | 0.00 | | | |
| 24 hrs | | | | | | |
| Group A | 60 | 7.90 | 0.44 | -1.762 | 0.081 | Not significant |
| Group B | 60 | 8.00 | 0.00 | | | |

Table 5: Distribution According to Side Effects-Nausea

| | | Group A | | Group B | | Total | P |
|--------|-----|---------|-------|---------|-------|-------|-----------------------|
| | | No | % | No | % | | |
| Nausea | Yes | 9 | 15.0 | 11 | 18.3 | 20 | 0.62, Not significant |
| | No | 51 | 85.0 | 49 | 81.7 | 100 | |
| Total | | 60 | 100.0 | 60 | 100.0 | 120 | |

Table 6: Distribution According to Side Effects-Vomiting

| | | Group A | | Group B | | Total | P |
|----------|-----|---------|-------|---------|-------|-------|-----------------------|
| | | No | % | No | % | | |
| Vomiting | Yes | 4 | 6.7 | 3 | 5.0 | 7 | 0.69, Not significant |
| | No | 56 | 93.3 | 57 | 95.0 | 113 | |
| Total | | 60 | 100.0 | 60 | 100.0 | 120 | |

that paracetamol is a safe and effective treatment option in post-caesarean pain without any major side effects as compared to opioids and NSAIDs. Paracetamol vial is very economic and cheap option with same analgesic efficacy as compared to paracetamol pint^[13].

CONCLUSION

This randomized double-blind study conducted to compare the efficacy of intravenous paracetamol with intramuscular paracetamol in combination with intravenous tramadol for post-operative analgesia in

open appendectomy patients conclude that intramuscular paracetamol is as effective as intravenous paracetamol for postoperative analgesia. Intramuscular paracetamol is simple, cost-effective and readily available. Both the drug combinations were observed not to have any adverse effects.

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