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Original Research Article

Intravenous Paracetamol Vial and i.v. Pint for Postoperative Pain Management in Caesarean Section: A randomised Controlled Trial

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Abstract:

Background: Paracetamol is used as an analgesic in mild to moderate pain over opioids or NSAIDs due to lack of significant side effects.

Objective: To evaluate the efficacy of intravenous paracetamol vial and iv pint in alleviating postoperative pain & side effects in patients undergoing caesarean sections.

Methods: This clinical trial was prospective, randomized, and double-blinded. The patients were randomly divided into two groups: Group A (n:30): receiving IV Paracetamol 6.5 ml (1 gm) from vial (Febrinil,150mg/ml by MANISH Pharmaceuticals) diluted in 100 ml normal saline over 15 minutes. Group B (n:30): receiving IV Paracetamol 1gm from ready to use 1%w/v Paracetamol 100 ml pint (1% w/v, by ABBOTT pharmaceuticals) over 15 minutes. The primary endpoint was the assessment of pain at various intervals: 0, 1 minute, 5 minutes, 6 hours, 12 hours, 18 hours, and 24 hours. The secondary endpoint involved recording the quantity of rescue analgesic administered during the same timeframe.

Results: There was no statistically significant difference in VAS score between two groups ($p>0.05$). In group A, 4 patients and in group B, 5 patients required rescue analgesia. There were no significant differences in number of rescues in either group.

Conclusion: Both the formulations had comparable efficacy in alleviation of pain after caesarean section with minimal or no side effects. IV Paracetamol was observed to be more cost efficient than iv paracetamol pint.

Keywords: IV Paracetamol, Paracetamol Pint, Caesarean Section.

Introduction

Pain is defined as an unpleasant sensory and emotional experience that is linked to actual or potential tissue damage. [1] Effective management of pain, especially after surgery, is a significant concern for both healthcare providers and patients. Patients frequently ask about the pain levels they might encounter following a surgical procedure. Postoperative pain can adversely influence not only the patients' recovery, overall well-being, and satisfaction with medical care but also contribute to complications such as tachycardia, hyperventilation, reduced alveolar ventilation, the onset of chronic pain, impaired wound healing, and insomnia, all of which can further affect surgical outcomes. The way individuals respond to pain varies based on factors such as genetic predisposition, cultural influences, age, and gender. [2]

The administration of opioid medications for pain management during and post-surgery is a standard practice in anesthesia. However, these drugs can lead to adverse effects such as nausea, vomiting, sedation, and respiratory depression. To mitigate these side effects, it is recommended to concurrently use a nonopioid analgesic. Examples of such medications include nonsteroidal anti-inflammatory drugs like aspirin and acetaminophen. The primary action of these analgesics is to inhibit cyclooxygenase and prostaglandin synthesis, which plays a crucial role in preventing hypersensitivity and alleviating pain. [3]

Cesarean delivery ranks among the most frequently performed surgical procedures in obstetrics globally. Surgery is recognized as the primary and most predictable source of pain within hospital environments, with postoperative pain being a common expectation for individuals undergoing surgical interventions. Ensuring effective pain management in the postoperative phase is a critical concern for both patients and healthcare providers.[4] The prevalence of unrelieved pain following surgery is notably high, significantly affecting morbidity and mortality rates. This situation often results in extended hospital stays and increased readmission rates, thereby escalating healthcare expenses. Adequate pain management post-surgery is essential to avert adverse outcomes such as tachycardia, hypertension, myocardial ischemia, reduced alveolar ventilation, immobility, deep vein thrombosis, and impaired wound healing. [5]

As of now, at least two distinct types of cyclooxygenase (COX) have been recognized: Cyclooxygenase-1 (COX-1), which plays a role in platelet aggregation, hemostasis, and the protection of the gastric mucosa, and Cyclooxygenase-2 (COX-2), which is effective in managing pain, inflammation, and fever. Additionally, the recently identified COX-3 has been suggested as a key mechanism underlying the analgesic properties of acetaminophen. [6] Nonsteroidal anti-inflammatory drugs (NSAIDs) are generally effective for alleviating mild to moderate pain, and their efficacy has been acknowledged as complementary to opioids for managing moderate to severe pain. Recent research indicates that NSAIDs are effective for pain management, whether used alone or in conjunction with opioids, surpassing previous assumptions. [7] Thus, this randomised controlled clinical trial was conducted to evaluate the efficacy of iv paracetamol vial and iv paracetamol pint in alleviating postoperative pain & side effects in patients undergoing caesarean sections.

Material & Methods

This clinical study, which was prospective, randomized, and double-blinded, involved 60 female participants aged between 18 and 35 years, classified as American Society of Anaesthesiologists (ASA) I-III, who were scheduled for either elective or emergency caesarean sections under spinal anaesthesia. Exclusion criteria included patients with abnormal liver function tests (Serum bilirubin >2 mg%), chronic alcoholism, chronic malnutrition, dehydration, or known allergies to the study medication. Informed consent was obtained from each participant, and approval from the institutional ethical committee was secured. All participants were educated about the 0-10 point visual analogue scale (VAS), where (0) represents 'no pain' and (10) signifies 'excruciating pain.'

The patients underwent caesarean section by an experienced gynaecologist. Near the end of the caesarean section surgery, at time of skin closure injection paracetamol was given to all patients slowly over 15 minutes and subsequent doses 6 hours apart and patients were followed for 24 hours post caesarean delivery. The patients were randomly divided into Group A (n = 30) and Group B (n = 30).

Group A (n:30): receiving IV Paracetamol 6.5 ml (1 gm) from vial (Febrinil,150mg/ml by MANISH Pharmaceuticals) diluted in 100 ml normal saline over 15 minutes

Group B (n:30): receiving IV Paracetamol 1gm from ready to use 1%w/v Paracetamol 100 ml pint (1% w/v, by ABBOTT pharmaceuticals) over 15 minutes.

The primary endpoint was the assessment of postoperative pain at various intervals: 0, 1 minute, 5 minutes, 6 hours, 12 hours, 18 hours, and 24 hours. The intensity of pain was measured using the Visual Analogue Scale (VAS), which ranges from 0 (indicating no pain) to 10 (indicating the worst pain imaginable). The secondary endpoint involved recording the quantity of intravenous rescue analgesic administered during the same timeframe. Patients received intravenous rescue analgesic (diclofenac sodium 75 mg diluted in 10 ml) whenever their VAS score exceeded 4. Additionally, patients were monitored for hemodynamic parameters, and any side effects such as nausea, vomiting, skin rashes, hypersensitivity reactions, and pain at the injection site were documented as necessary.

Results

Both the groups were comparable in regards to age, height, weight & duration of surgery at baseline. ($p>0.05$) (Table 1) There was no statistically significant difference in VAS score between two groups ($p>0.05$) (Table 2). No statistically significant difference in number of rescue analgesia required in both the groups ($p>0.05$). (Table 3) In group A, 4 patients and in group B, 5 patients required rescue analgesia. 10% patients in Group A while 13.33% patients in Group B had complains of nausea vomiting. One patient (out of 30) in Group A and two in Group B had pain on injection site.

Table 1: Shows the Baseline characteristics

Time	Group A	Group B	P value
Age (yrs)	25.45±3.54	26±2.09	>0.05
Height (cm)	155.71±3.47	157.24±4.24	>0.05
Weight(kg)	62.54±5.34	61.7±6.54	>0.05
Duration of surgery(min)	65±16.8	67.23±115.4	>0.05

Table 2: Shows the VAS Scores at various time intervals

Time	Group A	Group B	P value
5 min	0	0	>0.05
6 hr	1.04±1.27	1.5±1.56	>0.05
12 hr	0.54±0.91	0.81±0.74	>0.05
18 hr	0	0	>0.05
24 hr	0	0.29±0.02	>0.05

Discussion

The Caesarean section is a significant public health concern as it ranks among the most frequently performed surgeries in obstetrics, with its prevalence rising due to factors such as increasing marital age, legal considerations, and the socio-economic status of the community. [7] Therefore, it is crucial to prevent postoperative complications associated with Caesarean sections. One of the most prevalent postoperative complications is pain following the surgery. Various methods, including medications, are available for managing this pain, each exhibiting different levels of effectiveness. [8]

Paracetamol, classified as a non-opioid analgesic, does not carry the potential risks associated with opioids. It has a well-documented history of safety, effectiveness, and tolerability in adult populations. The World Health Organization (WHO) recommends it as the first-line medication in the analgesic ladder for pain management. [9] The analgesic and antipyretic effects of paracetamol are believed to result from the inhibition of the COX-3 enzyme in the brain and a decrease in central nervous system prostaglandin E2 production. It can be utilized alone or in conjunction with other non-steroidal anti-inflammatory drugs (NSAIDs) to effectively alleviate postoperative pain. Its safety and tolerability present a significant advantage over alternative analgesics. [10] Unlike opioids, paracetamol does not induce sedation, respiratory depression, ileus, or constipation, and it is not linked to dependence or misuse. [11]

While paracetamol is generally well tolerated, it may occasionally lead to side effects such as nausea, vomiting, abdominal discomfort, diarrhea, and, in rare cases, liver toxicity. In the present study, we assessed the use of iv paracetamol and iv paracetamol pint for alleviating postoperative pain in Caesarean sections, and our findings indicated that pain relief was satisfactory in both groups. Minimal maternal side effects were observed in both the Groups.

In the present study, Both Group A & Group B, achieved satisfactory postoperative analgesia. No statistically significant difference in VAS score was noted in both the groups at different time intervals($p>0.05$). Similar results observed in Vaghela et al study. [12] The study also observed the cost effectiveness of Febrinil vial over ready-to-use pint formulation without much trouble involved in preparations. Therefore, clinical choices should be influenced by patient volume, resource availability, and the necessity for sterility and dosage precision. [12]

In our study, no significant side effect was noted. Three patients in both the group had nausea, 1 patient in group B had vomiting and 1 patient in each group had pain on injection. A 2016 study conducted by Usha Rani compared intravenous paracetamol and intravenous tramadol following caesarean sections, revealing that pain scores remained low in both groups at various time intervals, with the exception of the paracetamol group at 6 hours ($p=0.673$) and the tramadol group at 8 hours ($p=0.194$). The need for rescue analgesia was similar in both groups (16% vs. 10%, $p=0.372$). However, maternal side effects were more prevalent in the tramadol group (8% vs. 34%, $p<0.01$). [13]

In our study, there was no statistically significant difference in number of rescue analgesia required in both the groups ($p>0.05$), suggest that paracetamol provide adequate postoperative analgesia. In Usha Rani et al study, Eight out of fifty patients in Paracetamol group & 5 out of 50 in Tramadol group required rescue analgesia. This difference was non-significant. ($p>0.05$) [13]

Mustafaeva and Mizikov found that despite the high efficacy of tramadol, the quality of analgesia using IV paracetamol was almost five times better with fewer adverse effects. [14]

Muhammad Asghar Ali did a comparative study between iv paracetamol and fentanyl for intraoperative and postoperative pain relief in dilatation and evacuation and demonstrated the

usefulness of IV paracetamol which may be as effective as fentanyl in dilation and curettage procedures. [15]

Conclusion

A comparative analysis of IV Paracetamol vials and IV Paracetamol pints indicates that both formulations effectively provide the active ingredient for pain relief and reduction of postoperative pain following cesarian sections.

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