

A Study on the Efficacy of Single Dose Intravenous Paracetamol and Intravenous Fentanyl for Intraoperative and Postoperative Pain Relief in Dilatation and Evacuation

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Abstract

Background and Aims: Dilatation and evacuation is a common Obstetrics day care procedure. However, it is a painful experience for the woman both during the intraoperative and postoperative period. Hence the purpose of this study was to compare single dose intravenous Paracetamol and intravenous Fentanyl for intraoperative and postoperative pain relief in dilatation and evacuation. *Materials and Method:* Sixty female patients were randomly included and divided into two groups of 30 patients each. Group P received intravenous (IV) paracetamol 15 mg/kg in the preoperative waiting area 15 min before starting the procedure. Group F received IV fentanyl 2 mcg/kg at induction of anaesthesia. Intraoperative and postoperative vitals along with postoperative pain scores on a numerical rating scale at 5, 15, and 30 min intervals after surgery were recorded. *Results:* Pain scores observed with paracetamol were not significantly different from that of fentanyl. Side effects were observed less with paracetamol. *Conclusion:* The study demonstrates the usefulness of IV paracetamol which may be as effective as fentanyl in dilatation and evacuation procedures without the major side effects of fentanyl. Paracetamol is also more cost effective.

Keywords: Dilatation and Evacuation; Pain Relief; Paracetamol; Fentanyl.

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Introduction

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual tissue damage or described in terms of such damage [1]".

Adequate pain relief should be considered as a basic human right. Failure to relieve pain is morally and ethically unacceptable. Providing rapid and effective relief of pain remains a humanitarian issue, whereas allowing patients to suffer as a result of inadequate analgesia may be considered a breach of fundamental human rights [2,3,4].

Patients subjected to inadequate pain relief are often unable to breathe adequately, cough effectively, move enough even to attend to their own needs or participate in the rehabilitation and hence they experience the feeling of helplessness, fear and anxiety.

The term Dilatation and Evacuation (D and E) is used to describe all techniques of transcervical operative uterine evacuation performed in the first trimester of pregnancy before the 12th week of gestation [5]. D and E is a painful procedure and so good pain relief is necessary apart from avoiding untoward vagal responses.

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D and E is commonly performed as a day care procedure in obstetrics. Due to requirement of early discharge, this procedure requires an anaesthetic technique than can provide rapid recovery [6].

Various groups of drugs are now available for controlling intra-operative and post-operative pain. These include opioids like fentanyl, acetaminophens like paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs) like diclofenac, alpha 2 adrenergic agonists like clonidine, N-methyl-D-aspartate (NMDA) receptor blockers like ketamine and local anaesthetics like bupivacaine.

Fentanyl is a potent synthetic opioid analgesic with a rapid onset, short duration of action. It is a strong agonist at μ - opioid receptors. Fentanyl decreases the anaesthetic requirement of other anaesthetic agents by providing antinociceptive effects that the intravenous agents do not provide⁷. It is suggested that a plasma concentration of approximately 1 ng/ml would be necessary for postoperative pain relief. Its adverse effects are respiratory depression, pruritis, skeletal and thoracic muscle rigidity [8] which may delay discharge, especially in day care surgeries. It is neither freely available nor cost effective.

Paracetamol is a commonly used non-opioid analgesic commonly used for the treatment of acute pain [9]. It is an effective and safe component in multimodal analgesia in combination with opioids and NSAIDs. Paracetamol has a different mechanism of action compared with other analgesics like opiates and NSAIDs which have considerable adverse effects [10]. Side effects of intravenous paracetamol are rare. These include rash, blood disorders and hypotension on infusion.

Materials and Method

Institute Ethics Committee clearance was obtained before commencement of the study. A prospective, randomized, interventional study was done between August 2015 and September 2017. All patients were subjected to a thorough pre- anaesthetic evaluation and relevant laboratory investigations were carried out. The patients were explained about the study in the language which is feasible to them and informed consent was obtained. The study was conducted on 60 American Society of Anaesthesiologist I and II fit patients (30 in each group) scheduled for elective and emergency Dilatation and Evacuation under general anaesthesia.

All patients were thoroughly evaluated pre-

operatively. All necessary and relevant laboratory and other investigations were carried out. All patients were kept nil per oral for 6 hours prior to surgery. In the pre-operative room, the patient's pulse and blood pressure were taken with the patient lying comfortably in supine position. Patients were explained about assessment of pain by Visual Analogue Scale (VAS) 0-10 scales. The interpretation of pain scores was assessed as follows: 0 - no pain, 1-4 mild, 5-7 moderate and 8-10 - severe.

Group P received IV paracetamol 15 mg/kg in the preoperative area 15 min prior the start of surgical procedure.

The conduct and technique of general anaesthesia was same for both groups. After application of standard monitoring (non-invasive blood pressure [NIBP], electrocardiogram (ECG), and pulse oximetry (SpO₂), patients were premedicated with Inj. Glycopyrrolate 0.004mg/kg, Inj. Midazolam 0.02mg/kg and Inj. Ondansetron 0.1mg/kg. In addition to this, patients in Group F received 2mcg/kg body weight of fentanyl. Patients were preoxygenated for 3 minutes with 100% oxygen. Intravenous Propofol 1-2mg/kg body weight was used for induction of anaesthesia.

Ventilation was maintained with Bain's circuit and appropriate sized face mask.

Anaesthesia was maintained with O₂ + N₂O + Isoflurane (0.8%-1%). Readings were observed and noted every 3 minutes from the start of the procedure until the end. Inadequate pain control during the surgical procedure was assumed if heart rate, blood pressure or respiratory rate increased by 20% above the baseline. The rescue analgesia consisted of Inj.fentanyl 25mcg increments in the intraoperative period for both the paracetamol and fentanyl groups.

At the completion of the surgery, patients were allowed to regain consciousness and were transferred to the recovery room once they responded to verbal command

In the recovery room pain score according to the Visual Analogue Scale were recorded at intervals of 5, 15 and 30 minutes in each group. If pain scores were greater than 5, rescue analgesic of fentanyl 25mcg increments were given. The total dose of rescue analgesic aliquots was noted and recorded. In addition to this, the rest of the vital parameters (pulse, blood pressure, oxygen saturation and ECG) were monitored in the recovery room.

Adverse effects were noted and treated in each group accordingly.

Thus, the efficacy of postoperative pain relief in both the groups were assessed.

Patients were transferred to the ward once the vital parameters were stable.

Statistical Analysis

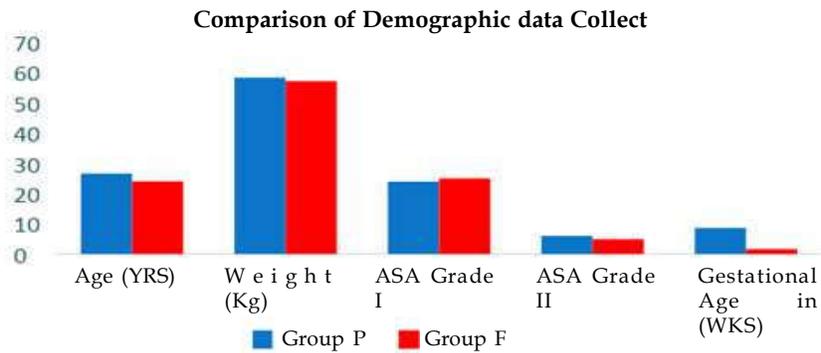
All the results obtained in both the groups were tabulated and compared clinically as well as statistically. All the data were expressed as mean with standard deviation (SD).

The quantitative data was analysed using test of significance based on "Z" test. Inferences and conclusions of the study were drawn based on the statistical analysis. p values < 0.05 was taken as significant and p value <0.001 as highly significant.

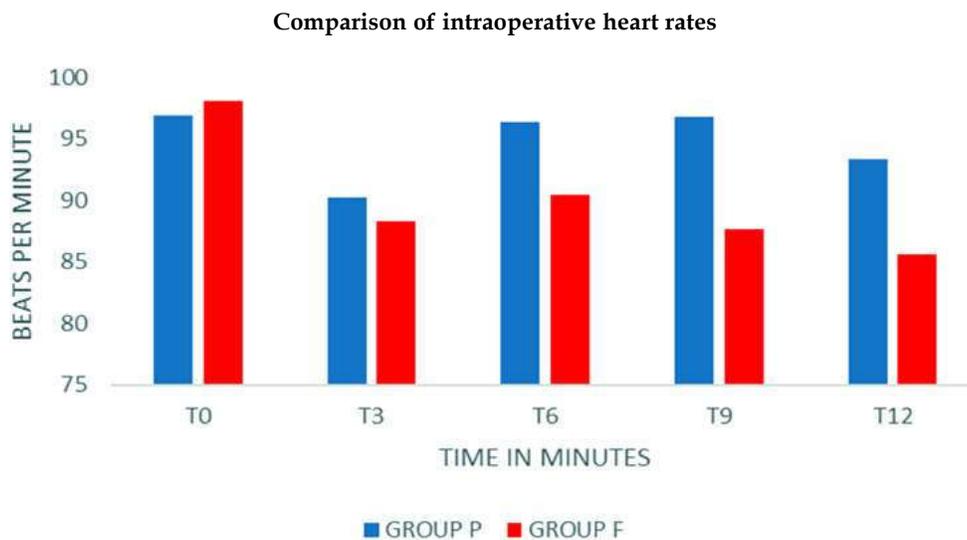
Sample size was calculated using Winpepi statistical package at a significance level of 5% with power 80%. A total sample size of 60 cases (30 cases in each group was obtained).

Results

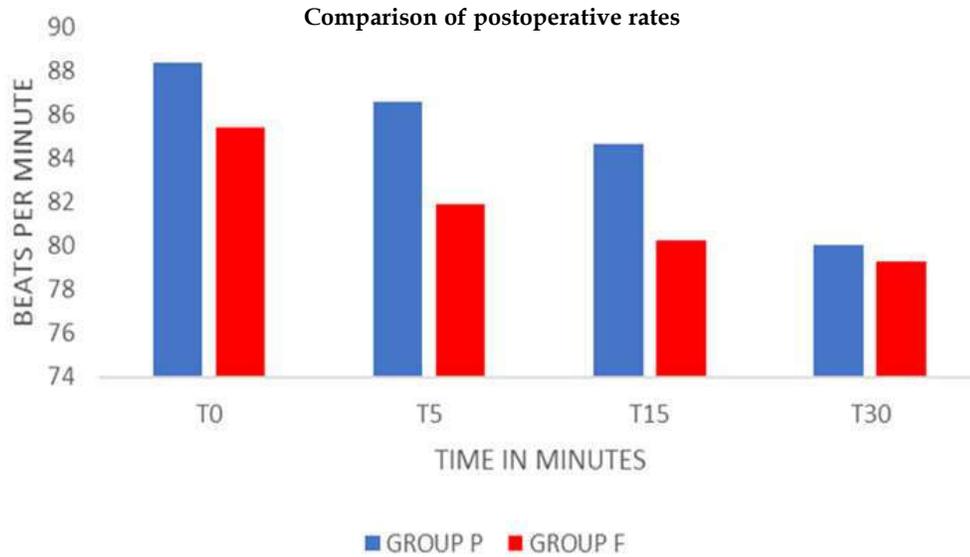
A total of 60 patients who underwent D&E requiring general anaesthesia were studied. They were randomly allocated in IV fentanyl and paracetamol group. There was no drop out during the study. It was observed that there was no significant difference between the groups with respect to age, weight, period of gestation and ASA status of the patients (Graph 1 to 13).



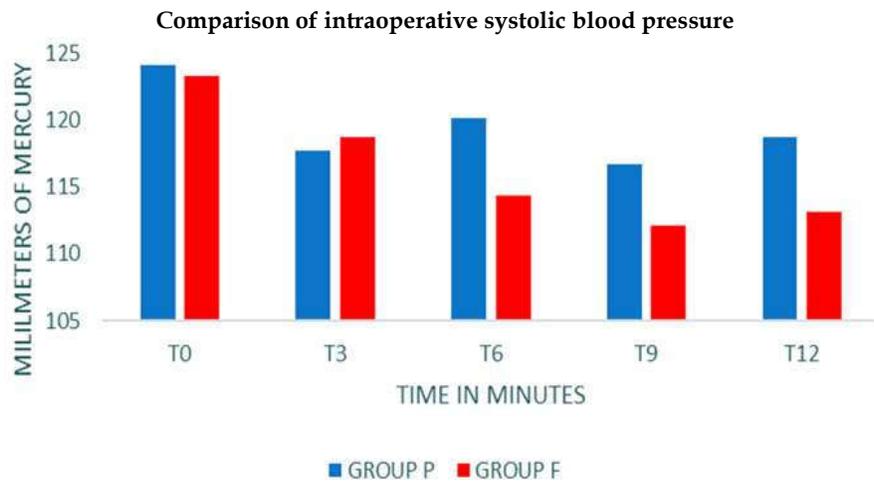
Graph 1: Comparison of Demographic data



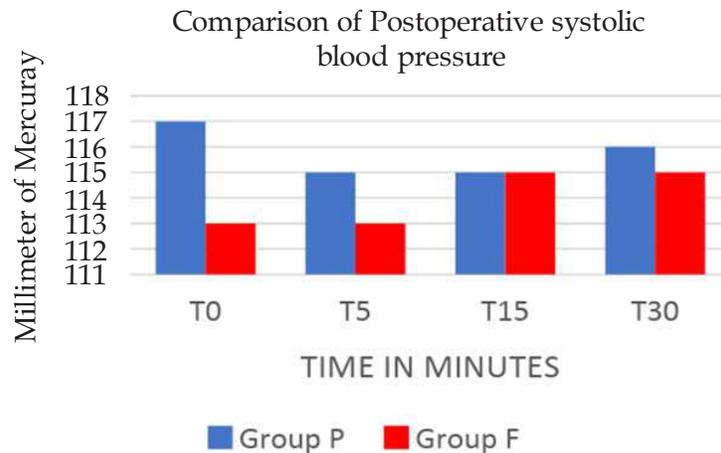
Graph 2: Comparison of intraoperative heart rates



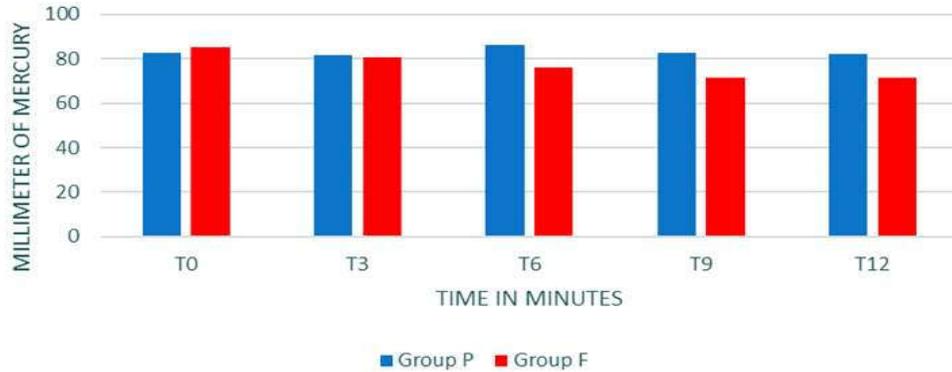
Graph 3: Comparison of postoperative heart rates



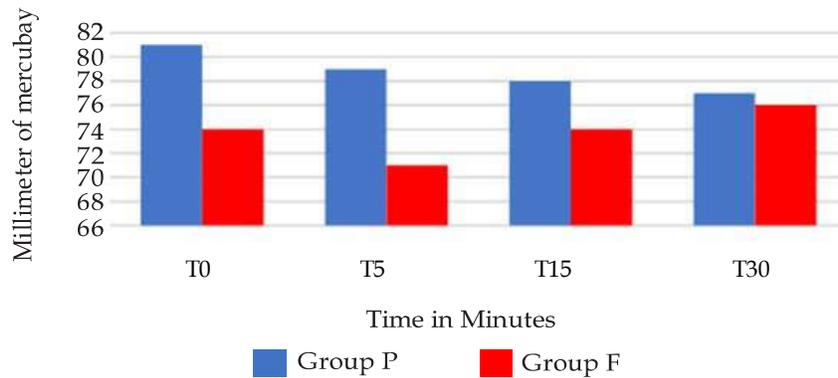
Graph 4: Comparison of intraoperative systolic blood pressure



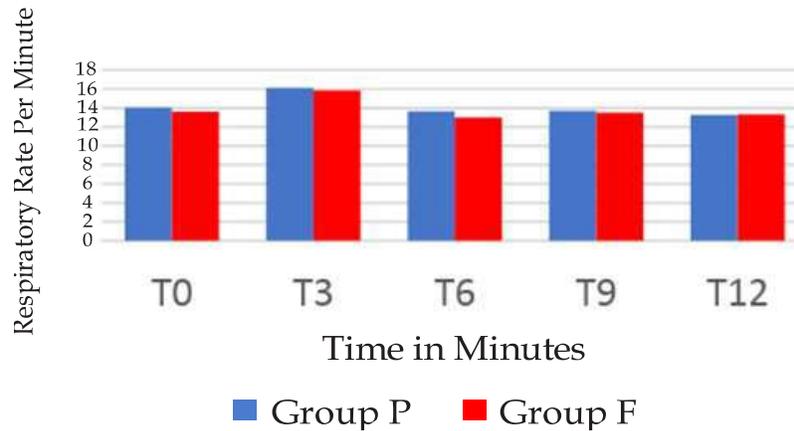
Graph 5: Comparison of postoperative systolic blood pressure



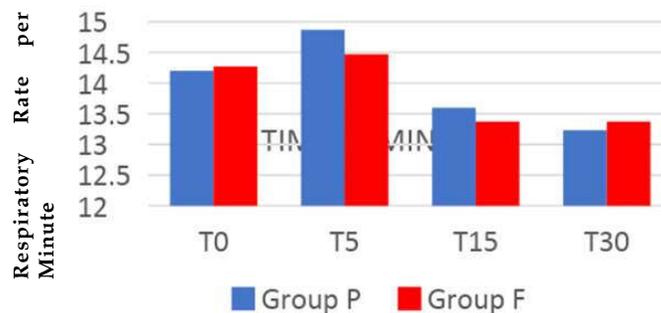
Graph 6: Comparison of intraoperative diastolic blood pressure



Graph 7: Comparison of postoperative diastolic blood pressure



Graph 8: Comparison of intraoperative respiratory rate



Graph 9: Comparison of postoperative respiratory rate

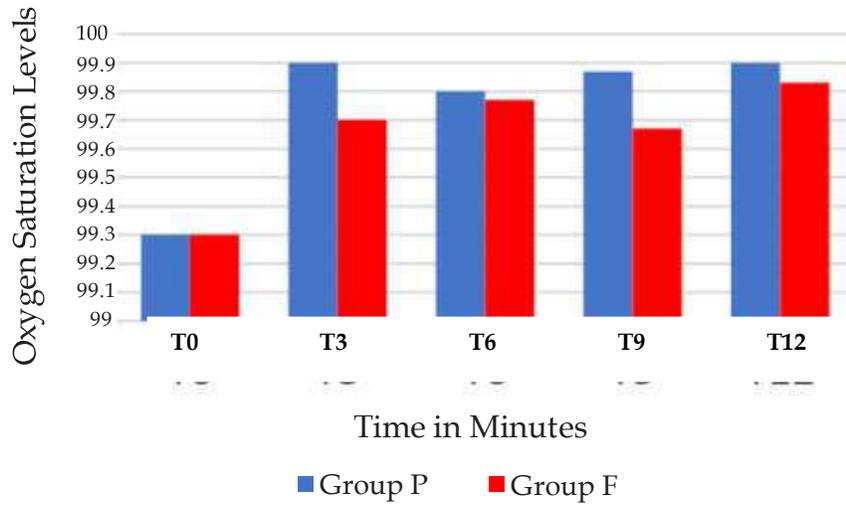


Table 10: Comparison of intraoperative saturation levels

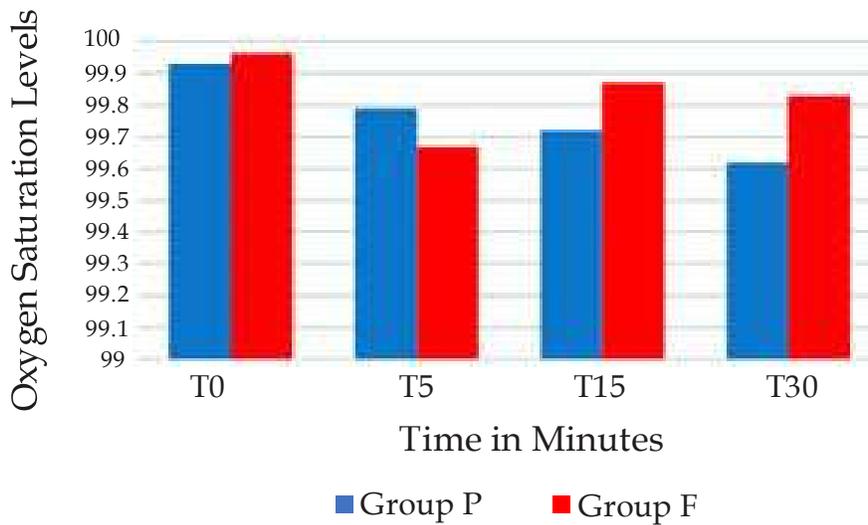
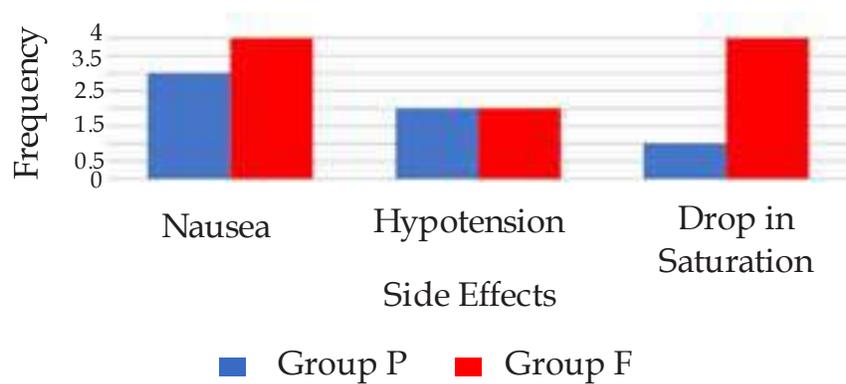
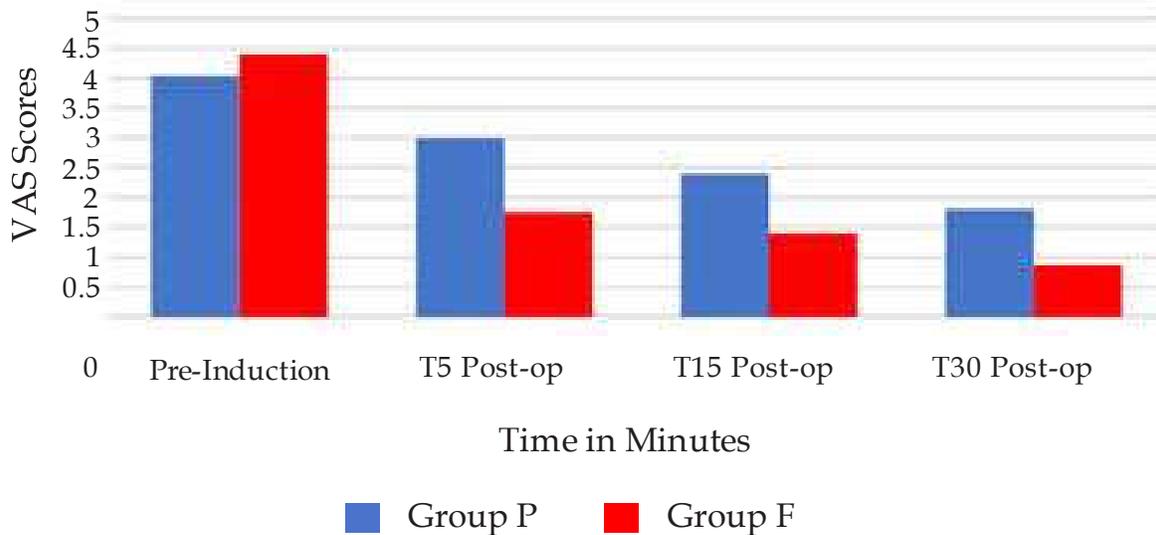


Table 11: Comparison of postoperative saturation levels



Graph 12: Comparison of side effects of the two drugs



Graph 13: Comparison of Visual Analogue Scale

Discussion

Pain in the intraoperative and postoperative period can lead to emotional and mental trauma with unpleasant sensory experience. Pain is precipitated by surgery and is often associated with autonomic, endocrine, metabolic, physiological and behavioural response. Relief of pain is of paramount importance to the patient as it causes discomfort and also leads to delayed mobilization with its associated complications and longer duration of stay in the hospital.

With a good analgesic treatment plan, not just the anxiety associated with the procedure but also the morbidity, cost and length of hospital stay is reduced. Although dilatation and evacuation is a brief procedure, it is associated with mild to moderate pain.

Fentanyl is a short acting synthetic opioid commonly used for intraoperative and postoperative pain relief in a day care procedure. Fentanyl is highly lipid soluble and acts rapidly. Its onset of action is in 2 minutes and duration of action is 30-60 mins. Its adverse effects are respiratory depression, pruritis, skeletal and thoracic muscle rigidity.

Paracetamol is a non-opioid analgesia. It is an effective and safe drug for managing mild to moderate pain. Its main advantage being that it is devoid of side effects commonly seen with the use of opioid analgesics.

Sinatra et al. [11] compared IV paracetamol with placebo after orthopaedic lower limb surgery. They found that IV paracetamol administered over a 24-h period in patients with moderate to severe pain after orthopaedic lower limb surgery provided

rapid and effective analgesia and was well-tolerated.

El-Hamamsy M, El-Kawaly H, Aziz hegazy M [12] in 2016 studied the post-operative use of intravenous paracetamol versus that of intravenous fentanyl in patients who were posted for lower limb orthopaedic surgeries. Their study showed that intravenous paracetamol was as good an analgesic as fentanyl and also improved the ability of the patients to be mobilized quicker with fewer adverse effects.

Memis D, Inal M, Kavalci G, Sezer A, Sut N [13] concluded in their study that not only did paracetamol reduce the use of opioids, the time to extubate the patient post-operation was reduced and the opioid related adverse effects were reduced in patients who received paracetamol. Early extubation in the paracetamol group was explained by reduced sedation as compare to the opioid group.

Ali M, Shamim F, Chughtai S. et al. [14] studied the difference between intravenous paracetamol and fentanyl for intraoperative and postoperative pain relief in dilatation and evacuation. The study concluded that there was no significant difference in the postoperative period at postoperative time intervals of 5, 15, 30 minutes. However, in our study, postoperatively mean heart rate in group F was significantly lower during the first 15 minutes postoperatively as compared to group.

Talmage D et al. [15] observed a significant drop in the heart rates of their study patients who were given Inj. Fentanyl during induction of anaesthesia. They attributed this bradycardia to the central vagotonic effects of fentanyl.

Thus, in our study Inj. Paracetamol proved to reduce intraoperative and postoperative pain in the patients undergoing Dilatation and Evacuation as seen with satisfactory VAS scores. Pain relief with Paracetamol was similar to that with Inj. Fentanyl but without respiratory depression or major side effects of Fentanyl.

Conclusion

Our study validates the use of a single dose of Inj. Paracetamol given intravenously at 15 mg/kg body weight for intraoperative and postoperative pain relief management in Dilatation and Evacuation as there was stable haemodynamic profile, no respiratory depression, no significant complications of the drug and a good VAS score.

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