

A COMPARISON OF KETOROLAC, DICLOFENAC AND PARACETAMOL FOR POSTOPERATIVE ANALGESIA FOLLOWING ABDOMINAL HYSTERECTOMY

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ABSTRACT

BACKGROUND

Abdominal hysterectomy is associated with moderate-to-severe postoperative pain. Among non-opioid analgesics diclofenac, paracetamol and ketorolac are most commonly used.

OBJECTIVES: The aim of this study was to compare the analgesic duration, efficacy and side effect profile of paracetamol, diclofenac and ketorolac administered intravenously in patients who underwent abdominal hysterectomy.

METHODS

In a prospective double-blinded study, in which 90 women undergoing elective abdominal hysterectomy under spinal anesthesia were randomly selected and divided into 3 groups to receive 1ml (75mg) Diclofenac (Group D), 1ml (30mg) Ketorolac (Group K) and 100ml (1000mg) Paracetamol (Group P). Two hours post spinal anesthesia, irrespective of completion of surgery study drug was administered intravenously. In post-operative ward analgesic, efficacy was assessed hourly using a visual analog scale (VAS), duration of motor blockade due to spinal anesthesia (Modified Bromage scale), time for rescue analgesia (VAS>4) were compared and occurrence of adverse effects noted.

STATISTICS

Collected data was analyzed using ANOVA.

RESULTS

The time taken to administer the first dose of rescue analgesic was significantly ($P < 0.05$) delayed in the group K (276mins). Overall, mean postoperative VAS scores were significantly better with (Group K) and VAS scores were not significantly different between other (Group P) and (Group D).

CONCLUSION

Ketorolac was a better post-operative analgesic compared to diclofenac and paracetamol.

KEYWORDS

Analgesia, Diclofenac, Hysterectomy, Ketorolac, Paracetamol.

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INTRODUCTION

Pain in the postoperative period is a critical factor that impedes recovery from surgery and anaesthesia.¹ Abdominal hysterectomy is associated with moderate-to-severe postoperative pain, which has unfavorable effects on patient's recovery and procedure's outcome.² Effective analgesia is important for early ambulation and postoperative hospital stay, thereby reducing the burden on patient's health and pocket.

Opioids remains the preferred choice for severe pain; however, the adverse effect of these class of drugs such as nausea, vomiting, sedation and respiratory depression is troublesome.³ Non-opioid analgesics (Paracetamol, NSAIDs) are commonly used alone or in combination with opioids for relieving post-operative pain. Among non-opioid analgesics diclofenac, paracetamol and ketorolac are most commonly used. There are enough studies available on post-operative analgesia for surgeries done under general anesthesia, not many for surgeries done under regional anesthesia.

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AIMS AND OBJECTIVES

The aim of this study was to compare the post-operative analgesic duration, efficacy and side effect profile of paracetamol, diclofenac and ketorolac administered intravenously in patients who underwent abdominal hysterectomy under spinal anesthesia with 0.5% bupivacaine.

SUBJECTS AND METHODS

This was a prospective randomized double-blind study in which 90 patients of ASA status 1 or 2 aged between 18-60 years, undergoing elective abdominal hysterectomy under spinal anesthesia in Father Muller Medical College Hospital. Patients with hepatic, cardiac or renal disorder; patients with co-morbid diseases like bronchial asthma, morbidly obese patients; patient whose height <150cm or >185cm, contraindication to spinal anesthesia, history of known hypersensitivity to any drugs; patients with history of acid peptic disease and procedures which were converted to general anesthesia and any administration of intraoperative analgesics were also excluded from the study.

After obtaining ethical clearance, 90 patients undergoing total abdominal hysterectomy under spinal anesthesia, satisfying the study criteria were included in the study. A detailed history and preanesthetic evaluation was done on previous day of the surgery. Written informed consent was taken prior to scheduled operation from the patient/patient's party. Patients were randomly allocated using closed envelope technique into 3 groups of 30 each. Group D received 1ml (75mg) Diclofenac diluted in 100ml NS. Group K received 1ml (30mg) Ketorolac diluted in 100ml NS.

Group P received 100ml of (1000mg) Paracetamol. All study drugs were infused intravenously over 20mins. The drug solutions was administered to all patients in a double-blind manner, whereby neither the person who gave the injections nor the observer who assessed the various parameters was aware of the drug used. Patients involved in the study were premedicated with intravenous 1mg midazolam. Patients were preloaded with intravenous infusion of Ringer lactate solution 10ml kg-1 over 20 minutes prior to surgery. Patient was shifted to the OT and Pulse oximeter, NIBP and electrocardiography monitors was connected.

For spinal anesthesia 3.5cc of 0.5% Bupivacaine is administered by inserting spinal needle at L2-L3 level with patient in left lateral position, under aseptic conditions using a 25G Quincke spinal needle. Time spinal anesthesia given and peak sensory level attained was noted. Achievement of sensory level of at least T6 was required, if not achieved patients were excluded from the study. Two hours post spinal anesthesia, irrespective of completion of surgery, study drug was administered intravenously over 20mins. Duration of surgery was noted.

Once the patient was shifted to post-operative ward, sensory block level was noted. Patient's recovery from motor blockade was assessed hourly using modified Bromage score. Severity of pain was assessed hourly using Visual analogue scale (VAS). VAS score >3 rescue analgesia 1mg Butorphanol IV was administered and time noted. This was taken as end point of the study. Throughout the study duration, any side effects caused by the study drug was noted. Collected data analyzed by ANOVA (p<0.05) was taken to be statistically significant. The statistical software SPSS version 18.0 was used for the analysis of data. Microsoft word and Excel were used to generate graphs and tables.

RESULTS

Patient's demographic data and duration of surgery are listed in Table 2, which shows that there was no significant difference in both the groups (p >0.05) with respect to age, height and duration of surgery.

Demographic Data and Duration of Surgery

| | Group D (n = 30) | Group K (n = 30) | Group P (n = 30) | p Value |
|---------------------|------------------|------------------|------------------|----------|
| Age | 55.88 ± 5.16 | 56.63 ± 5.99 | 56.63± 4.33 | 0.896 NS |
| Weight | 58.21 ± 4.97 | 59.12 ± 5.12 | 57.46 ± 4.23 | 0.723 NS |
| Height | 159.46 ± 5.3 | 159.81 ± 3.91 | 158.18 ± 5.14 | 0.609 NS |
| Duration of Surgery | 124.0 ± 13.36 | 123.1 ± 10.08 | 122.3 ± 13.40 | 0.933 NS |

Table 1: Age Distribution among Groups

Bromage Score (Post Op)

| Time (mins) | Group D (n = 30) | Group K (n = 30) | Group P (n = 30) | P Value |
|-------------|------------------|------------------|------------------|----------|
| 0 | 2.81 ± 0.4 | 2.93 ± 0.26 | 2.81 ± 0.4 | 0.608 NS |
| 60 | 1.69 ± 0.70 | 1.93 ± 0.26 | 1.81 ± 0.403 | 0.58 NS |
| 120 | 0.79 ± 0.42 | 0.5 ± 0.51 | 0.69 ± 0.47 | 0.276 NS |

Table 2: Bromage Score between the Groups in Post-Operative Ward

Table 2. shows that Bromage score assessed in 3 groups was statistically insignificant (p<0.05).

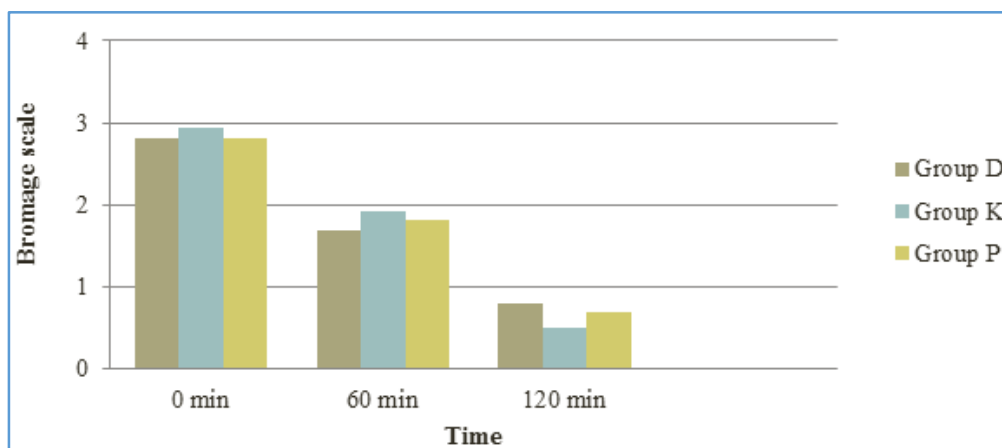


Fig. 1: Bromage Scale among Three Groups

Visual Analogue Score

| Time (mins) | Group D (n = 30) | Group K (n = 30) | Group P (n = 30) | P Value |
|-------------|------------------|------------------|------------------|----------------------|
| 0 | 0.25 ± 0.44 | 0.00 | 0.19 ± 0.4 | 0.119 NS |
| 60 | 1.44 ± 0.62 | 0.94 ± 0.25 | 1.44 ± 0.51 | 0.007 Significant |
| 120 | 2.31 ± 0.47 | 1.88 ± 0.34 | 2.25 ± 0.44 | 0.16 Significant |
| 180 | 3.07 ± 0.25 | 2.63 ± 0.5 | 3 | 0.02 Significant |
| 240 | 0 | 3 | 0 | - |
| 300 | 0 | 3 | 0 | - |

Table 3: VAS Score Between the Groups

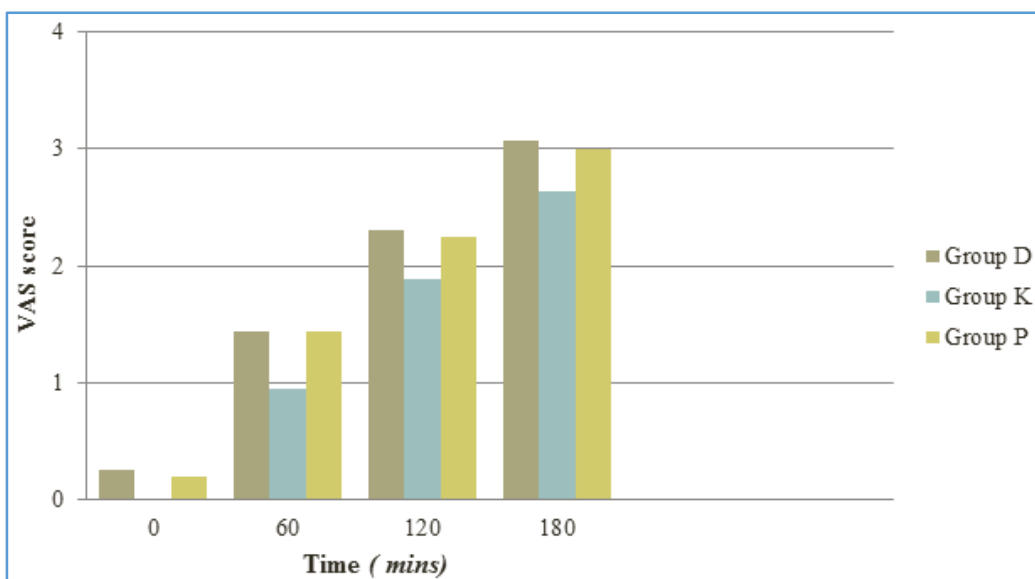


Fig. 2: VAS Score Between the Groups

Overall, mean postoperative VAS scores were significantly ($p < 0.05$) better with (group K) and VAS scores were not significantly different between Group P and Group D (Table 3).

Duration of Analgesia (Time for Rescue Analgesia)

| | Group D (n=30) | Group K (n=30) | Group P (n=30) | P value |
|-----------------------|----------------|----------------|----------------|-----------------------|
| Duration of Analgesia | 196.6 ± 21.07 | 276.5 ± 15.41 | 202.08 ± 20.14 | 0.0004 Significant |

Table 2: Duration of Analgesia Between the Groups

Table 2. shows that the time taken to administer the first dose of rescue analgesic was significantly ($p < 0.05$) delayed in the group K as compared to group D and group P (276 mins for group K, 202 mins for group P and 195 mins for group D). No clinically significant side effects were recorded. The results of this study demonstrate that ketorolac provides effective analgesia in post-operative period after total abdominal hysterectomy. Patients who received a single IV dose of ketorolac experienced pain relief that was superior to diclofenac and paracetamol based on VAS score and time required for rescue analgesia.

DISCUSSION

Postoperative pain causes marked distress and anxiety and is a major factor that affects recovery from anaesthesia and surgery. Despite major improvements in understanding of acute pain pathophysiology over the past decade, approximately 80 percent of patients undergoing surgical procedures experience mild-to-severe postoperative pain.⁴ In our study, we found that patients who received ketorolac 30mg IV had significantly better VAS score than the patients who received diclofenac 75mg IV or paracetamol 1gm IV. No significant side effects were noted among the groups.

Morrow et al., in their study compared diclofenac and ketorolac for post-operative analgesia after knee arthroscopy found ketorolac to be better than diclofenac. This result matches with our study findings.⁵ Forbes et al., evaluated ketorolac, ibuprofen, paracetamol, and paracetamol-codeine combination in postoperative oral surgery pain, found that ketorolac and ibuprofen both were superior to paracetamol with respect to post-operative analgesia.⁶

In a study conducted by Fredman et al., which compared ketorolac and diclofenac on post-laparoscopic cholecystectomy pain concluded that both ketorolac and diclofenac to be equally effective.

But in this study, both the drugs were administered intramuscularly compared to our study, administered IV.⁷ From the present study, it can be concluded that ketorolac 30mg IV showed better analgesic efficacy as compared to diclofenac 75mg IV and paracetamol 1gm IV for postoperative pain relief in patients undergoing abdominal hysterectomy under spinal anesthesia without any significant adverse events. However, long-term multicentric trials with more number of patients are required to address these issues further.

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