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Original Article

Comparison of Analgesic Efficacy of the Non-Opioid Analgesics Following Abdominal Hysterectomy

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ABSTRACT

Objectives: Present study was conducted to compare the post-operative analgesic duration, efficacy and side effect profile of diclofenac, paracetamol and ketorolac (injectable non-opioids) for postoperative pain relief in patients undergoing abdominal hysterectomy under spinal anesthesia.

Methods: 120 patients undergoing total abdominal hysterectomy under spinal anesthesia, satisfying the study criteria were included in the study and divided into 3 groups to receive 1ml (75mg) Diclofenac (group A), 100ml (1000mg) Paracetamol (group B) and 1ml (30mg) Ketorolac (group C). 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 were compared and occurrence of adverse effects noted.

Results: Overall mean postoperative VAS scores were significantly ($p<0.05$), better with (group C: Ketorolac) and VAS scores were not significantly different between Group A and Group B. Duration of analgesia was significantly ($p<0.05$) more in the group C as compared to group A and Group B. No clinically significant side effects were recorded.

Conclusion: In patients undergoing abdominal hysterectomy, the IV administration of a single dose of ketorolac 30mg provides significantly better pain control in the early postoperative period compared with other non-opioids (diclofenac and paracetamol) without any significant adverse events.

KEYWORDS: Analgesia, Bromage Scale, Diclofenac, Ketorolac, Paracetamol, Visual Analog Scale.

INTRODUCTION

Postoperative pain always remains a prime concern for surgeons and anesthetists for favorable patient's recovery and procedure's outcome. Effective analgesia is important for early ambulation and reducing postoperative hospital stay, thereby reducing the burden on patient's health care. Abdominal hysterectomy is associated with moderate-to-severe postoperative pain.[1,2] Opioid analgesics are the traditional first-line medication in this setting but may induce unwanted side effects, such as nausea and vomiting, sedation, and respiratory depression. Several studies have shown that non-opioid analgesics (Paracetamol, NSAIDs) provide effective pain relief in patients with acute postoperative pain, either as a substitute for or as an adjunct to opioid analgesia.[3-5]

Different classes of analgesics exert their effects through different mechanisms. Their side effects (e.g. respiratory depression with opioids or enteropathy with nonsteroidal antiinflammatory drugs [NSAIDs] tend to be different and may be dose related.

Besides opioids, nonsteroidal anti-inflammatory drugs (NSAIDs) play an important role in this clinical setting. Their analgesic effect is based on a diminished prostaglandin synthesis by inhibition of the cyclooxygenase (COX) enzyme in the arachidonic acid metabolism. Among non-opioid analgesics diclofenac, paracetamol are most commonly used. There are enough studies available on post-operative analgesia using different NSAIDs alone or in combination for surgeries done under general anesthesia but scarce data was

available regarding analgesic efficacy of NSAIDs for surgeries done under regional anesthesia.

We therefore designed the present study to compare the post-operative analgesic duration, efficacy and side effect profile of diclofenac, paracetamol and ketorolac (injectable non-opioids) for postoperative pain relief in patients undergoing abdominal hysterectomy under spinal anesthesia.

MATERIALS AND METHODS

Present study was a prospective randomized double blind study, in which 120 patients of ASA status 1 or 2 aged between 18-65 years undergoing elective abdominal hysterectomy under spinal anesthesia in Santosh Medical College & Hospital, Ghaziabad, UP, India. After obtaining ethical clearance, 120 patients undergoing total abdominal hysterectomy under spinal anesthesia, satisfying the study criteria were included in the study. Patients with hepatic, cardiac or renal disorder, patients with co-morbid diseases like bronchial asthma, morbid obesity, contraindication to spinal anesthesia, history of known hypersensitivity to any drugs used in study, patients with history of acid peptic disease and procedures which were converted to general anesthesia were excluded from the study. A detailed history and preanesthetic checkup was done on previous day of the surgery. Written informed consent was taken prior to scheduled operation from the patient/patient's relatives.

After informed consent, patients were assigned randomly to one of three study groups. Randomization was performed using a sealed opaque envelope with a computer-generated block random allocation (http://www.randomizer.org/). 3 groups of 40 patients in each group were formed.

Group A: Received 1ml (75mg) Diclofenac diluted in 100ml NS.

Group B: Received 100ml of (1000mg) Paracetamol.

Group C: Received 1ml (30mg) Ketorolac diluted in 100ml NS.

All study drugs were infused intravenously over 20 mins. The drug solutions was administered to all patients in a double blind manner, where by neither the person who gave the injections nor the observer who assessed the various parameters was aware of the drug used. The group assignment code was retained until the conclusion of the study. To ensure patient safety, however, a sealed opaque envelope containing the name of the drug was kept with the patient in the operating room, the postoperative care unit and on the ward to permit immediate unmasking if necessary.

Patients involved in the study were premedicated with intravenous 1mg midazolam. 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 at 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 intra venously 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 were noted.[6] Collected data analyzed by analysis of variance test (ANOVA). (P value <0.05) was taken to be statistically significant. The statistical software SPSS version 19.0 was used for the analysis of data.

RESULTS

Patient's demographic data and duration of surgery are listed in Table 1, which shows that there was no significant difference in the groups (p >0.05) with respect to age, height and duration of surgery.

Overall mean postoperative VAS scores were significantly (p<0.05), better with (group C: Ketorolac) and VAS scores were not significantly different between Group A and Group B (Table 3). Table 4 shows that the duration of analgesia was significantly (p<0.05) more in the group C as compared to group A and Group B. No clinically significant side effects were recorded.

Table 1: Demographic characterstics among Groups

	Group A	Group B	Group C	P value
Age	56.43 ± 4.89	55.12± 5.13	55.78 ± 4.78	p >0.05, NS
Weight	57.87 ± 5.11	56.95 ± 5.13	58.04 ± 4.69	p >0.05, NS
Height	157.86 ± 4.95	159.07 ± 4.92	158.74 ± 4.16	p >0.05, NS
Duration of surgery	122.3 ±11.42	121.8 ± 11.84	122.7 ± 11.74	p >0.05, NS

S: Significant; NS: Not significant

Table 2: Bromage Score.

Time (mins)	Group A	Group B	Group C	P value
0	2.73 ± 0.7	2.79 ± 0.32	2.85 ± 0.4	p >0.05, NS
60	1.61 ± 0.63	1.76 ± 0.39	1.85 ± 0.21	p >0.05, NS
120	0.73 ± 0.47	0.72 ± 0.51	0.68 ± 0.47	p >0.05, NS

S: Significant; NS: Not significant

Table 3: VAS Score

Time (mins)	Group A	Group B	Group C	P value
0	0.24 ± 0.39	0.22 ± 0.4	0.17±0.37	p >0.05, S
60	1.43 ± 0.57	1.45 ± 0.48	0.96 ± 0.42	p >0.05, S
120	2.26 ± 0.58	2.19 ± 0.78	1.9 ± 0.4	p >0.05, S
180	3.02 ± 0.57	2.98 ± 0.43	2.61 ± 0.43	p >0.05, S

S: Significant; NS: Not significant

Table 4: Duration of Analgesia.

	Group A	Group B	Group C	P value
Duration of Analgesia	194.8 ± 19.89	201.75 ± 18.96	274.9 ± 12.89	p >0.05, S

S: Significant; NS: Not significant

DISCUSSION

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.

Postoperative pain causes marked distress and anxiety and is a major factor affecting patient's recovery from anaesthesia and treatment outcome following surgical procedure. Despite major improvements in understanding of acute pain pathophysiology over the past decade, majority of patients (approximately 80 percent) undergoing surgical procedures experience mild to severe postoperative pain.7 In our study we found that group C 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.[8] in their study compared diclofenac and ketorolac for postoperative analgesia; after knee arthroscopy found ketorolac to be better than diclofenac.[8] Kumar G & Sherif Lalso demonstrated similar results.[6]

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.9 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.[10] But in this study both the drugs administered intramuscularly compared to our study where it is administered IV.

In conclusion, in patients undergoing abdominal hysterectomy, the IV administration of a single dose of ketorolac 30mg provides significantly better pain control in the early postoperative period compared with other non-opioids (diclofenac and paracetamol) without any significant adverse events.

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