Comparison of the Analgesic Efficacy of IM Tramadol with IM Piroxicamin Post-Operative Lower Segment Caesarian Section **Patients**

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ABSTRACT

Aim: To compare the analgesic efficacy of IM tramadol with IM piroxicam in postoperatively cesarean section.

Study design: Randomized controlled trial

Place and duration of study: Bakhtawer Amin Memorial Hospital, Multan from 1st September 2019 to 29th February 2020

Methods: Two hundred and ten patients with lower segment cesarean section were enrolled in this study. Patients were divided into two equal groups. Group A consist of 105 patients and received IM piroxicam and group B with 105 patients received IM tramadol. Pain scores were analyzed byusing visual analogue scale at 0, 4,8,12 and 24 hours postoperatively.

Results: Mean age in both groupspiroxicam and tramadol were 27.24+/3.25 and 26.98±3.70 years. No significant difference was observed regarding postoperative pain by VAS between both groups at postoperatively 4,8,12 and at 24 hours. Significant reduction was observed at 0,4,8,12 and 24 hours. No significant difference was observed regarding side effects such as sedation, nausea, vomiting and fever between both groups. Patient's satisfaction rate was higher in piroxicam as compared to tramadol.

Conclusion: IM piroxicam is more effective than IM tramadol regarding postoperative pain in cesarean section, however no significant difference was observed regarding side effects of both groups.

Keywords: Cesarean section, Postoperative pain, Piroxicam, Tramadol.

INTRODUCTION

Post-operative pain is inevitable following major surgery, resulting from surgical trauma and handling of tissues. 1 The inadequate relief of post-operative pain has adverse physiological effects resulting in delay of patient recovery and return to daily activities.2. Caesarean delivery patients have even more compelling reasons to achieve optimal post-operative pain relief than other surgical patients since inadequate pain control impairs breastfeeding and delays maternal-infant bonding. It is usually relieved by opioids or non-steroidal anti-inflammatory drugs (NSAIDs) but with an additional challenge that the drug used should be safe during lactation.3

Various rescue analgesics have been used to treat post-operative pain relief; NSAIDs are the mainstay of this treatment. NSAIDs inhibit the synthesis of prostaglandins both in the spinal cord and at the periphery, thus diminishing the hyperalgesic state after surgical trauma. NSAIDs are useful as the sole analgesic after minor surgical procedures and may have a significant opioidsparing effect after major surgery.4 NSAIDs have many adverse effects like nausea and present a significant GI bleeding risk, along with a risk of a variety of renal complications, and myocardial infarction and other serious cardiovascular complications⁵.

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Tramadol, acentrally acting analgesic has opioid and non-opioid modes of action, both acting synergistically⁶. It has been shown to provide effective analgesia after both intra-muscular and intravenous routes of administration in post-operative pain^{7,8}. NSAID are also used for postoperative pain relief and commonly used are diclofenac, ketorolac, piroxicam, lornoxicam, selective cyclooxygenase (COX-2) inhibitors like etoricoxibandparecoxib9. Few studies have been carried out to compare the efficacy and tolerability of opioid and NSAID especially tramadol versus piroxicam for management of post-operativepain¹⁰. We conducted present study with aimed to compare the postoperative analgesic effectiveness of IM piroxicam with IM tramadol in patients with cesarean section.

MATERIALS AND METHODS

This randomized controlled trial was conducted at Bakhtawer Amin Memorial Hospital, Multan from 1st September 2019 to 29th February 2020. Patient's detailed demographics including age, body mass index and blood pressure were recorded after taking written consent from all the patients. Patients with no consent, patients with hypersensitivity, preeclampsia, eclampsia patients, patients with CVD and patients with pulmonary disease were excluded. Patients were divided equally into two equal groups. Group A consist of 105 patients and received IM piroxicam 20mg and 100 mg tramadol received by group B

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with 105 patients at 0,4, 8,12 and 24 hours. Postoperative pain was examined by Visual Analogue Pain scale VAS and compares the findings between both groups. Side effects of medication and patient's satisfaction between both groups were examine and compared. All the data was analyzed by SPSS 24. Chi-square test was done to compare the pain score, side effects and patient's satisfaction between two groups. P-value <0.05 was taken as significant.

RESULTS

The mean age of patients in group A and B was 27.24±3.25 years and 26.98±3.70years, no significant difference was observed between both groups with p>0.05.In group A mean BMI was 23.06±2.42 kg/m² and in group B it was 22.86±2.05 kg/m², no significant difference was observed regarding body mass index between both groups with p value >0.05.Mean systolic and diastolic BP in group A was 110.71±10.42 mmHg and 76.64±8.56 mmHg. Mean systolic and diastolic BP in group B was 111.02±9.78 mmHg and 75.81±7.88 (Table 1).

A significant reduction of pain score between both groups was observed at 4,8,12 and 24 hours with p<0.05.No significant difference was observed between both groups at 4,8,12 and at 24 hours in term of pain score between both groups with p-value >0.05 (Table 2). Regarding side effects of medication we found no significant difference between both groups p-value >0.05 (Table 3).

Table 1: Comparison of demographic information

Variable	Group A	Group B	P value
Age (Yrs)	27.24±3.25	26.98±3.70	0.06
BMI (kg/m ²)	23.06±242	22.86±2.05	0.072
Systolic BP(mmHg)	110.71±10.42	111.02±9.78	0.12
DiastolicBP(mmHg)	76.64±8.56	75.81±7.88	0.08

Table 2: Comparison of pain between both groups

Variables	Group I	Group II	P value
Baseline	7.78±1.24	8.02±0.6	N/S
At 4 hours	5.02±1.36	5.34±1.16	N/S
At 8 Hours	2.24±0.43	2.82±0.92	N/S
At 12 Hours	1.02±0.1	1.56±0.8	N/S
At 24 Hours	0.76±0.25	0.84±0.32	N/S

Table 3: Comparison of side effects of medication between both groups

Side effects	Group I	Group II	P value
Sedation	12 (11.43)	17 (16.19)	
Nausea/Vomiting	14 (13.33)	13(12.38)	>0.05
Fever	10 (9.52)	11 (10.48)	

Table 4: Comparison of patient's satisfaction

Patient's satisfaction	Group A	Group B	P value
Very Satisfied	60(57.14)	55(52.38	N/S
Satisfied	30(28.57)	20(19.05)	N/S
Neutral	12(11.43)	20 (19.05)	N/S
Not Satisfied	3 (2.86)	10 (9.52)	N/S

Regarding patient satisfaction 60 patients in group A and 55 patients in group B was very satisfied, 30 patients in group A and 20patients in group B was satisfied, 12 patients in group A and 20 patients in group B were neutral,

3 patients in group A and 10 patients in group B were not satisfied (Table 4).

DISCUSSION

Postoperative pain is severe complications and these complications effected maternal and neonatal health when women underwent cesarean section. It is one of the most frequent complications found all over the world. 11 In postoperative pain different medications are mainly used for patients to give relief, here we compare the analgesic efficacy of IM piroxicam with IM tramadol after lower segment cesarean section. In this regard 210 patients were observed and divided equally into two groups. Group A received IM piroxicam and group B received IM tramadol. The mean age of patients in group A and in group B was 27.24±3.25years and 26.98±3.70years. In group A mean BMI was 23.06±2.42 mmHg and in group B it was 22.86±2.05 mmHg. No significant difference was observed regarding age and body mass index between both groups with p value >0.05. These results were comparable to many of previous studies in which majority of patients were in the age group 25-30 years whom underwent cesarean sections and average weight was 72kg. 12,13

In present study no significant difference was observed in term of pain score at 0 hour between both groups (group A 7.78±1.24 and group B 8.02±0.6)at 4 hours p-value >0.05 (group A 5.02±1.36, group B5.34±1.16). At 8 hours mean pain score in group A patients was 2.24±0.43 and in group B it was 2.82±0.92. At 12 hours mean pain score between group A and B was (1.02±0.1 and 1.56±0.8). No significant difference observed at 24 hours with p-value >0.05(group A 0.76±0.25 and group B 0.84±0.32). A study conducted by Thippeswamy et al¹⁴ reported that no significant difference was observed regarding postoperative pain by VAS at 12 and 24 hours between IM tramadol group and IMpiroxicam group, however a significant difference was observed at 2,4 and 8 hours with p-value <0.05.

A Study conducted by Farshchi and Ghiasi¹⁵ regarding analgesic efficacy of piroxicam analgesia versus tramadol in post cesarean section pain management, in their study no significant difference was observed between both medication groups regarding pain at 0, 6, 12 and 24 hours with p-value >0.05.

Another study by Mala et al¹⁶ regarding effectiveness of opioid analgesic and compare with multimodal analgesic, in their study mean VAS scores of the patients in Pentazocine group was lower, hence better pain relief, than Tramadol group at all time periods. The mean VAS score of the patients in Pentazocine+Piroxicam was lower than Tramadol+Piroxicam group.

We found no significant difference regarding adverse effect of medication between tramadol and piroxicam group. These results showed similarity to other previous studies in which sedation, nausea/vomiting and fever were the frequent side effects^{17,18}.

CONCLUSION

IM piroxicam is more effective than IM tramadol regarding postoperative pain in cesarean sections, however no significant difference was observed regarding side effects of both groups. However, patient's satisfaction was more in proxicam than tramadol.

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