## **ORIGINAL ARTICLE**

# Compare the Analgesic Effectiveness of Oral Tramadol Versus Intravenous Analgesic for Pain Management after Cesarean Section

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## ABSTRACT

**Objective:** To examine the effectiveness of oral tramadol in term of postoperative pain and compare it with intravenous analgesics in patients underwent cesarean sections.

Study Design: Randomized controlled trial

**Place and Duration of Study:** Department of Gynaecology and Obstetrics, Services Institute of Medical Sciences Lahore from 1<sup>st</sup> March 2019 to 31<sup>st</sup> August 2019.

**Methods:** Two hundred and twenty patients undergoing lower segment cesarean section were enrolled in this study. All the patients were divided equally in to two groups. Group I contains 110 patients and received oral tramadol and group II with same number of patients received intravenous analgesics. Pain score was examined and compare between two groups by using Visual Analogue Scale (VAS) at 2, 6, 12 and 24 hours postoperatively. Adverse effects of drugs were examined and compare between both groups.

**Results:** The mean age of patients in group I and II was 30.02±5.24 years and 30.65±5.05 years. No significant difference was observed in term of pain score between both groups at 2 hours p-value >0.05 (group I 6.42±2.25, group II 6.36±1.98). At 6 hours mean pain score in group I patients was 4.85±1.68 and in group II it was 3.06±0.74, a significant difference was observed with p-value <0.001. At 12 and 24 hours no significant difference was observed between both groups regarding mean pain score with p-value >0.05. Drowsiness was the commonest adverse effect in both groups [(group I 16 (14.55%), group II 14 (12.73%)]. No significant difference was observed regarding adverse effects of drugs between both groups with p-value >0.05.

**Conclusion:** Oral tramadol is safe and effective for the management of postoperative pain and should be used as an alternate of intravenous analgesics.

Keywords: Cesarean section, Postoperative pain, Oral tramadol, Intravenous analgesics

# INTRODUCTION

Inadequately treated postoperative pain can contribute significantly to morbidity of surgical patients, resulting in the delay of patients' recovery and ability to return to daily functional activities.<sup>1</sup> Early recovery is especially important for a patient who is expected to take care of her newborn shortly after an operative procedure. Evidence from studies done in high income settings has demonstrated that inadequately treated pain after cesarean section is associated with an increased incidence of chronic pain<sup>2</sup> and post-traumatic stress syndrome.<sup>3</sup>

low-income countries, postoperative In pain management can be particularly challenging for several reasons including the expectation of postoperative pain by patients (thereby making no effort to request for pain relief) and the high patient-to-nurse ratio that limits assessment of pain and administration of adequate pain relief medication.<sup>4</sup> Early mobilization is a key factor to prevent the risk of thrombo-embolic disease. Pain has a multifactorial origin, hence it may be difficult to achieve effective pain control with a single drug.<sup>5</sup> Various agents, routes, modes exist for the treatment of postoperative pain. Historically opioids are most commonly administered analgesia. Pain, pruritus, nausea/vomiting, sedation and respiratory depression are concerning issues that complicate postoperative opioid usage.6,7

Tramadol is an atypical, centrally acting analgesic, acts as a weak opioid agonist, and also as a serotonin and

noradrenaline reuptake inhibitor and is an effective postoperative analgesic.<sup>8,9</sup> Non-steroidal anti-inflammatory drugs (NSAIDs) have beneficial effect on postoperative analgesia; addition of NSAIDs has been shown to potentiate opioid effect, decrease opioid consumption and also, is devoid of adverse effects of opioids.<sup>10,11</sup> Piroxicam, NSAID, has long half-life, extensive protein binding which allows for its once a day dosing.<sup>12</sup> The present study was conducted aimed to examine the efficacy of oral tramadol and compare with intravenous analgesics for pain management after cesarean sections.

# MATERIALS AND METHODS

This randomized controlled trial was conducted at Department of Gynaecology and Obstetrics, Services Institute of Medical Sciences Lahore from 1st March 2019 to 31st August 2019. A total of 220 women whom were undergoing lower segment cesarean section were enrolled. Patient's detailed demographics including age, weight and clinical examination were recorded. Women who refused to participate in the study, hypersensitivity to study medications, any systemic contraindications to the use of study medications, history of peptic ulcer disease or gastro intestinal bleeding, opioid use for the past month, history of selective serotonin reuptake inhibitors use, cases of eclampsia/pre-eclampsia, significant pulmonary or cardiovascular disease, and those with any intraoperative complications were excluded. All the patients were divided

equally in to two groups. Group I contains 110 patients and received oral tramadol and group II with same number of patients received intravenous analgesics. Tramadol 50mg and dimenhydrinate 20mg dose was given to group I patients immediately after cesarean section, then 50mg of tramadol capsule was given at 2, 6, 12 and 24 hours. In group II intravenous nalbuphine 4mg with dimenhydrinate 20mg was given to all the patients. Diclofenac 75mg were given as the rescue analgesia. Pain score was examined and compare between two groups by using Visual Analogue Scale (VAS) at 2, 6, 12 and 24 hours postoperatively. Adverse effects of doses were examined and compared between two groups.

The data was entered and analyzed by SPSS 24. Chisquare and student's 't' test was done to compare the pain score between two groups. P-value <0.05 was taken as significant.

#### RESULTS

The mean age of patients in group I and II was 30.02±5.24 years and 30.65±5.05 years. Mean weight in group I patients was 68.28±6.45 kg and in group II it was 69.55±6.04 kg. In group I mean systolic BP was 115±2.8 mmHg and in group II it was 117.2±3.8 mmHg. Mean diastolic BP in group I was 73.2±1.89 mmHg and in group II it was 72.09±3.48 mmHg. No significant difference was observed between both groups regarding age, weight and BP with p-value >0.05 (Table 1). When postoperative pain was analyzed by VAS, no significant difference was observed in term of pain score between both groups at 2 hours p-value >0.05 (group I 6.42±2.25, group II 6.36±1.98). At 6 hours mean pain score in group I patients was 4.85±1.68 and in group II it was 3.06±0.74, a significant difference was observed with p-value <0.001. At 12 and 24 hours no significant difference was observed between both groups regarding mean pain score with pvalue >0.05 (Table 2).

Table 1: Demographics of all the patients

Variable	Group I	Group II	P-value
Age (years)	30.02±5.24	30.65±5.05	0.62
Weight (Kg)	68.28±6.45	69.55±6.04	0.08
Systolic BP (mmHg)	115±2.8	117.2±3.8	0.06
Diastolic BP (mmHg)	73.2±1.89	72.09±3.48	0.07

Table 2: Comparison of pain score between both groups

Pain score	Group I	Group II	P-value
At 2 hours	6.42±2.25	6.36±1.98	0.6
At 6 Hours	4.85±1.68	3.06±0.74	0.04
At 12 Hours	2.05±0.8	2.01±0.2	0.3
At 24 Hours	1.28±0.02	0.90±0.42	0.06

Table 3: Comparison of adverse effects between both groups

Adverse Outcomes	Group I	Group II	P-value
Drowsiness	16 (14.55)	14 (12.73)	
Nausea	12 (10.91)	10 (9.09)	>0.5
Abdominal pain	3 (2.73)	1 (0.91)	

According to the adverse effects of doses, we found that drowsiness was the commonest adverse effect in both groups [(group I 16 (14.55%), group II 14 (12.73%)], followed by nausea (group I 12, group II 10) and abdominal

pain (group I 3, group II 1). No significant difference was observed between both groups (p=>0.05)

## DISCUSSION

Pain after surgical interventions is the most common complication found all over the world. Many of treatment modalities have been used for prevention of postoperative pain.<sup>13</sup> After cesarean section the most common complication is pain and this can lead to high morbidity. Postoperative pain is described to severe, moderate and mild pain and many of analgesic treatments have been applied to reduce the postoperative pain. Intravenous analgesics with NSAIDs are considered as a treatment of choice for the prevention of postoperative pain.14,15 In present study we compare the analgesic efficacy of oral tramadol with intravenous analgesics in patients undergoing cesarean sections. During the study period 220 patients whom were received lower-segment cesarean section and met the inclusion criteria were analyzed. Patients were randomly divided in to two groups, each groups consist of 110 patients. Group I received Oral Tramadol and group II received intravenous nalbuphine. No significant difference was observed between both groups regarding age, weight and blood pressure with p-value >0.05. A study conducted by Banapura et al<sup>16</sup> regarding efficacy of tramadol and tramadol plus piroxicam for pain management after cesarean section, in which they reported that the mean age of tramadol only group was 25.41±3.94 years and in other group it was 24.41±3.4 years. No significant difference was observed regarding BP and weight of patients between both groups.

In the present study, postoperative pain analyzed by VAS, no significant difference was observed in term of pain score between both groups at 2 hours p-value >0.05 (group I 6.42±2.25, group II 6.36±1.98). At 6 hours mean pain score in group I patients was 4.85±1.68 and in group II it was 3.06±0.74, a significant difference was observed with p-value <0.001. At 12 and 24 hours no significant difference was observed between both groups regarding mean pain score with p-value >0.05. A study conducted by Habib et al<sup>17</sup> regarding efficacy of oral tramadol and intravenous analgesics for pain management after cesarean section and they reported no significant difference between both groups at 4 and 12 hours (p=>0.05), while a significant difference was noted at 8 hours in which patients who received intravenous analgesics had less pain at 8 hours as compared to oral tramadol group (p=<0.05).

Duan et al<sup>18</sup> reported that efficacy of intravenous tramadol versus intravenous hydromorphone for prevention of postoperative pain, in the tramadol and hydromorphone groups exhibited equivalent incision pain NRS at different time points (*P*>0.05). Visceral pain in the tramadol group was higher than that in the hydromorphone group at postoperative 4 hours (2.9 [1.2] vs 2.3 [1.4], *P*=0.011) and 8 hours (2.4 [1.1] vs 1.8 [1.1], *P*=0.028).

Studies on oral tramadol are limited in postoperative caesarean patients. Wilder-Smith et al<sup>19</sup> conducted a study on intramuscular tramadol and diclofenac when given in combination has betterpain relief and time to first analgesic demand was reduced.

In the current study, we found that drowsiness was the commonest adverse effect in both groups [(group I 16 (14.55%), group II 14 (12.73%)], followed by nausea (group I 12, group II 10) and abdominal pain (group I 3, group II 1). No significant difference was observed between both groups (p=>0.05). These results were comparable to several previous studies regarding analgesic efficacy of different medication doses.<sup>20-22</sup>

#### CONCLUSION

Postoperative pain is one of the worst conditions and can lead to higher morbidity in patients after cesarean sections. Early and better management may helps to reduce complications rate. We concluded from this study that oral tramadol is safe and effective for the management of postoperative pain and should be used as an alternate of intravenous analgesics.

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