ORIGINAL ARTICLE

Compare the Analgesic Efficacy of Oral Tramadol with Intravenous Analgesics on Postoperative Pain after Caesarean Section

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ABSTRACT

Aim: To compare the analgesic efficacy of oral tramadol with intravenous analgesic postoperatively in patients with caesarean section.
Study design: Randomized controlled trial
Place and duration of study: Department of Obstetrics & Gynaecology, Allama Iqbal Memorial Teaching Hospital, Sialkot from 1st June 2019 to 30th November 2019.
Methods: Two hundred and sixty patients with lower segment cesarean section were enrolled in this study. Patients were divided into two equal groups. Group I consisted of 130 patients and received oral tramadol and group II with 130 patients received Nalbuphine intravenously. Pain scores were compared using visual analogue scale at 4, 8 and 12 hours postoperatively. Patients with higher scores in group I were reverted to intravenous analgesia.
Results: No significant difference was observed regarding age and BMI in both groups. No significant difference was observed regarding postoperative pain by VAS between both groups postoperatively at 4 hours, and at 12 hours with p-value >0.05, but at 8 hours, oral group had significantly high pain score as compared to intravenous group (p- value 0.024). 13 patients in group I (oral group) required rescue intravenous analgesia at 8hours postoperatively while 3 patients in group II required rescue analgesia, so a significant difference was observed with p-value 0.02.
Conclusion: Oral tramadol is safe and effective in reducing postoperative pain.
Keywords: Tramadol, Nalbuphine, Analgesia, Lower segment Caesarean section

INTRODUCTION

Acute pain is a common complication after cesarean section. Post–cesarean pain management is important for both the mother and the newborn. When postoperative pain is managed well then the mother is better able to care for her newborn and bond with her child as early as possible.[1] In contrast, uncontrolled pain may delay bonding with the child and limit mobilization, further increasing the risk for thromboembolism[2,3]. Therefore, appropriate and effective analgesia is important following caesarean section. Analgesia administered to post-caesarean women must be effective and reliable, while remaining safe for both the mother and her newborn.

Pain is defined as an unpleasant sensory or emotional experience associated with actual or potential tissue damage, often evoked by external or internal noxiousstimulus[4,5]. Analgesic agents are the drugs possessing significant pain relieving mechanism by acting on the CNS or on peripheral pain receptors[6,7]. Opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are most commonly used agents for the post-operative pain, but they have their own advantages and disadvantages[8]. Although opioids are the main choice for acute postoperative pain, they are not devoid of undesirable side effects such as postoperative nausea and vomiting, sedation, and respiratory depression in higher doses[9,10].

Postoperative patients are given different opioids but most commonly used are tramadol or nalbuphine. Tramadol is a centrally acting, synthetic analgesic which is an opioid receptor agonist and serotonin nor-epinephrine reuptake inhibitor. It is approved for oral, intravenous and intramuscular administration and efficiently decreases moderate to severely moderate pain.[11]Nalbuphine is a mixed agonist-antagonist opioid analgesic that is a weak antagonist of mu receptors and partial agonist at kappa receptors. It is given intravenously and has a faster onset of action[12]. We conducted this study to compare the analgesic efficacy of oral tramadol with intravenous nalbuphine in patients with lower segment caesarean section.

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MATERIALS AND METHODS

This randomized controlled trial was conducted at Department of Obstetrics & Gynaecology, Allama Iqbal Memorial Teaching Hospital, Sialkot from 1st June 2019 to 30th November 2019. Informed consent taken from all patients.Patientsdemographics including age, body mass index and clinical examination for pain scoring were recorded.Patients with hypersensitivity to any of these two agents, pre-eclampsia, eclampsia, patients with Coronary Vascular Disease (CVD) and pulmonary disease were excluded. Patients were divided in two equal groups.Group I consisted of 130 patients and received tramadol 50mg orally at 4 and 8 hours and 100mg tramadol at 12 hours and group II with 130 patients who received intravenous nalbuphine4mg at 4, 8 and 12 hours. Postoperative pain was assessed by Visual Analogue Pain scale (VAS) and efficacy of pain relief assessed in both groups. Diclofenac

sodium 75mg was used as rescue analgesia.All the data was analyzed by SPSS 24. Chi-square and student t test were applied 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 31.25±4.74 years and 31.76±4.08 years. In group I mean BMI was 22.48±2.86 kg/m^2 and in group II it was 22.01±2.34 kg/m^2. No significant difference was observed regarding age and body mass index between both groups with p value >0.05 (Table 1).

No significant difference was observed in term of pain score between both groups at 4 hours post-operative with p-value >0.05. (Mean pain score group I,4.36±1.45, group II 4.16±1.20). At 8 hours post-operative, mean pain score in group I patients was 3.66±1.15 and in group II it was 2.96±1.36, a significant difference was observed with p-value 0.021. At 12 hours post-operative, no significant difference was observed between both groups regarding mean pain score with p-value >0.05 (Table 2).

Thirteen patients in group I (oral group) received rescue analgesia while 3 patients in group II received rescue analgesia, a significant difference was observed with p-value 0.02 (Table 3). Regarding side effects of medicationwe found no significant difference between both groups with p-value >0.05 (Table 4).

Table 1: Comparison of age and BMI in both groups

Variable	Group I	Group II	P value
Age (years)	31.25±4.74	31.76±4.08	0.09
BMI (kg/m^2)	22.48±2.86	22.01±2.34	0.1

Table 2: Comparison of pain score between both groups

Mean pain score	Group I	Group II	P-value
At 4 hours	4.36±1.45	4.16±1.20	> 0.05
At 8 Hours	3.66±1.15	2.96±1.36	0.021
At 12 Hours	2.82±1.1	2.76±0.8	> 0.05

Table 3: Need of rescue analgesia between both groups

Rescue analgesia	Group I	Group II	P-value
Yes	13 (10%)	3 (2.31%)	0.04
No	117 (90%)	127(97.69%)	

Table 4: Comparison of side effects of medication between both groups

Side effects	Group I	Group II	P-value
Dizziness	20(15.38%)	16(12.31%)	>0.05
Nausea/Vomiting	15(11.54%)	12(9.23%)	

DISCUSSION

Postoperative pain is one of the most frequent problem observed all around the world. Women undergoing caesarean section can experience severe complications and these complications have effects on both maternal and neonatal health[13]. Many medications have been used for prevention and treatment of postoperative pain, and here we compared the analgesic efficacy of oral tramadol with intravenously nalbuphine after lower segment caesarean section. Mean age of patients in our study was 31.25±4.74 years in group I and 31.76±4.08 years in group II.In group I, mean BMI was 22.48±2.86 kg/m^2 and in group II it was 22.01±2.34kg/m^2. These results were comparable to many of previous studies in which average age of patients was 30 years who underwent cesarean section and average weight was 75kg[14,15].

In present study no significant difference was observed in term of pain score between both groups at 4 hours and 12 hours. At 8 hours mean pain score in group I patients was 3.66±1.15 and in group II it was 2.96±1.36, a significant difference was observed with p-value 0.021.These results were similar to the study conducted by Habib et al[16] in which no significant difference was observed regarding postoperative pain by VAS at 4 and 12 hours between oral tramadol group and intravenously nalbuphine group, however a significant difference was observed at 8 hours with p-value <0.05.

A study conducted by Chi et al[17] regarding analgesic efficacy of PCA (patient controlled analgesia) versus tramadol in post caesarean section pain management also showed no significant difference between both medications regarding pain at 4, 8 and 12 hours with p-value >0.05. However, patients on Fentanyl had more movement-evoked pain and a higher sedation score at 4, 8, and 12 h postoperatively, as compared with the tramadol group.

Duanet al[18] reported in their study that patients in the tramadol and hydromorphine groups exhibited equivalent incision pain at different time points (*P*>0.05). Visceral pain in the tramadol group was higher than that in the hydromorphine 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).

Many of previous studies demonstrated that oral tramadol is safe and effective for post caesarean pain management and could be used as an alternate to intravenously analgesia such as nalbuphine and NSAIDs[19,20].

In present study regarding side effects of medication we found no significant difference between both groups p-value >0.05. These results were comparable to many previous studies[21,22].

CONCLUSION

No significant difference was observed between oral tramadol and intravenously nalbuphine for postoperative caesarean section pain relief. Oral tramadol is safe and effective for reducing pain after caesarean section with fewer side effects and can be used as an alternative to intravenous analgesics.

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