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"COMPARATIVE STUDY OF INTRAVENOUS TRAMADOL VERSUS RECTAL TRAMADOL FOR POST OPERATIVE ANALGESIA IN PATIENT UNDERGOING CAESAREAN SECTION UNDER SPINAL ANAESTHESIA"

Anaesthesiology

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ABSTRACT

Aim: Aim of the study was to Intravenous Tramadol versus Rectal Tramadol for post operative analgesia in patient undergoing caesarean section under Spinal Anaesthesia.

Material & Methods: The study was comparative, randomized, prospective and hospital-based and conducted on ninety obstetric patients aged from 20 to 40 years, comes in ASA class I and II undergone for caesarean section after obtaining written consent. In this study ninety obstetric patient divided in two groups Group I and Group R 45 patients in each group to receive intravenous Tramadol (Group I) 1.5-2 mg/kg (Max 100mg) or rectal Tramadol(Group R) 1.5-2 mg/kg (Max 100mg) at the end of surgery. Pain measurement was performed using visual analogue scale. First onset of pain, VAS score, rescue analgesic requirement and side effects noted. Rescue analgesia was given when VAS was ≥4.

Results: Demographic parameters were comparable in both groups. Mean duration of analgesia in Group R was longer i.e. 640±77.46 minute as compared to 456±94.35 minute in Group I which was statistically highly significant (P value<0.001). Requirement of rescue analgesia was less in Group R than Group I. Also incidence of postoperative nausea and vomiting was less in Group R than Group I.

Conclusion: We conclude that rectal Tramadol is better alternative to intravenous Tramadol for postoperative analgesia in caesarean section patients.

KEYWORDS

Analgesia, Intravenous Tramadol, Rectal Tramadol.

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[1] Postoperative pain is important in causing psychological trauma to the patient. Patients who undergo caesarean section should achieve more post-operative pain relief other than surgical patients because of different factors related to the operation.[2] For pain relief various group of drugs such as Opioids and NSAIDs are used.[3] Tramadol has a unique dual action of pain relief, acting both as a central opiate agonist and CNS reuptake inhibitor of norepinephrine and serotonin. Tramadol exist as 2 enantiomers with analgesic properties, both with different mechanisms of action. (+)-Tramadol and its metabolite O-desmethyltramadol (M1) act as mu-receptor agonists altering the release of nociceptive neurotransmitters.[4] Tramadol used by different routes such as intravenous, intramuscular, rectal or local infiltration etc. have analgesic efficacy with different duration and variable incidence of side effects.[5,6] In this study, we compared intravenous Tramadol versus rectal Tramadol in caesarean section for post-operative analgesia, duration and side effect.

MATERIAL AND METHODS

The study design was comparative, randomized, prospective, single blind and hospital-based. After approval from Institutional ethical committee, the study was conducted on ninety obstetric patients aged from 20 years to 40 years and comes in ASA class I and II undergone for caesarean section after obtaining written informed consent from all patients. Patients having prior history of allergy to any of the drugs, cardiovascular, renal, hepatic, respiratory, anorectal and neurological disease comes under ASA> II were excluded from the study. All patients were explained about the procedure and visual analogue scale (VAS). Pain measurement was performed using a VAS, a 10 cm line with 0 cm equaling no pain and 10 cm worst pain ever felt.[7] All 90 patients were divided randomly into two groups of 45 each as Group I for intravenous and Group R for rectal route of tramadol. After taking patient on operation table multi-para monitor applied and baseline parameter noted. Intravenous line secured with 18 Gauge intravenous cannula and infusion of ringer lactate started with injection Metoclopramide 10 mg and injection Ranitidine 50 mg were given to all patients. Spinal anaesthesia given with 25 gauge spinal needle in L3- L4 interspaces with 0.5% Bupivacaine heavy 12 mg with desired level of T4 achieved. At the end of surgery Tramadol 1.5-2 mg/kg (Max 100 mg) given intravenously to Group I patients and 100 mg Tramadol suppository inserted per rectally in Group R patients for postoperative analgesia. This was considered 0 hour. Parameters like PR, MAP, SPO2 were monitored at interval of 0, 1, 2, 4, 6, 8, 10, 12 hours after the end of surgery. Post operatively, time of first onset of pain was noted. Also VAS score noted at 0, 1, 2, 4, 6, 8, 10, 12 hours. If patient have pain during this period (VAS>4) inj. Diclofenac 75 mg in 100 ml NS was given as rescue analgesia. During these hours side effect (nausea, vomiting, others) were also noted and appropriate treatment was given.

RESULTS

Demographic data like age and weight of patient in both the groups was similar. Tables 1 and 2 show the postoperative VAS scores in group I and group R, respectively. Table 3 shows the time and frequency of the rescue analgesia requirement. Table 4 shows the total duration of analgesia, which was 456±94.35 and 640±77.46 min with the Group I and Group R, respectively. It was statistically highly significant **(*P*<0.001).** Postoperative nausea and vomiting was less in Group R than Group I showing in Table 5. No other side effect noted.

Table 1: VAS for Group I

VAS	1 hr	2hr	4 hr	6 hr	8 hr	10 hr	12 hr
0	12	9	0	0	0	0	0
1	33	35	0	0	0	10	0
2	0	1	6	1	1	1	2
3	0	0	36	34	19	27	43
≥4	0	0	3	10	25	7	0

Table 2: VAS for Group R

VAS	1 hr	2hr	4 hr	6 hr	8 hr	10 hr	12 hr
0	14	16	0	0	0	0	0
1	31	20	2	0	0	0	0
2	0	9	25	17	5	1	0
3	0	0	18	28	37	28	31
≥4	0	0	0	0	3	16	14

Table 3: Rescue Analgesia requirement (No. of patients) (%)

Time	Group I	Group R
1 hr	0(0.0%)	0(0.0%)
2 hr	0(0.0%)	0(0.0%)
4 hr	3(6.7%)	0(0.0%)
6 hr	10(22.2%)	0(0.0%)
8 hr	25(55.6%)	3(6.7%)
10 hr	7(15.6%)	16(35.6%)
12 hr	0(0.0%)	14(31.1%)

Table 4: Duration of analgesia (in min)

	Group I	Group R	p-value
Mean± SD	456.00± 94.35	640.00±77.46	**<.001**

Table 5: Side Effects (No. of patients (%)

	Group I	Group R
Nausea	4(8.9%)	2(4.4%)
Vomiting	10(22.2%)	3(6.7%)

DISCUSSION:

This study evaluates the role of tramadol by two different routes in caesarean section. Postoperative pain is associated with grave psychological trauma, resulting in a restless and uncooperative patient. It thus seems that tramadol may be suitable to treat postoperative pain, but after intravenous route, peak concentrations are reached rapidly and this has been associated with postoperative nausea and vomiting. Rectal administration of Tramadol is an alternative in this situation. In our study we also introduced tramadol immediately after induction to avoid patient discomfort. A rectal dose of 1.5–2.0 mg/kg is therapeutic. Therefore, a dose of 100 mg was used in our study for suppository.

We studied VAS score in both Groups (**Table 1 &2**) and gave rescue analgesic at score of 4 or more than 4. As per our study during 0 to 2 hr, VAS score < 3 hence, there was no need of rescue analgesia in both Groups. At 4 hour, 6.7% (3 patients had VAS score >4) of the patients needed first rescue analgesic in Group I whereas no patients in Group R needed it. At 6 hours, 22.2% (10 patients had VAS score >4) of the patients needed rescue analgesic in Group I whereas no patients in Group R needed it.At8 hours, 55.6 %(25 patients had VAS score >4) of the patients needed rescue analgesia in Group I whereas 6.7% (3 patients had VAS score >4) of the patients in Group R needed it. By the end of 10 hours, remaining 15.6% (7 patients had VAS score >4) of the patients needed rescue analgesia in Group I and 35.6% (16 patients had VAS score >4) of the patients in Group R needed it. By the end of 12 hours, 31.1% (14 patients had VAS score >4) patients in Group R received rescue analgesia. As per my study, it was observed that 100% patients received rescue analgesia by the end of 10 hour in Group I while 73.4% patients of Group R received rescue analgesia by the end of 12 hr and remaining 26.6% patients in Group R was not needed rescue analgesia during 0 t0 12 hours (**Table 3**). Thus, number of patients in Group R having VAS score >4 was less as compared to Group I.

Duration of analgesia was prolong in Group R compared to Group I as mean+ SD in Group I was456+ 94.35 min and Group R was 640+ 77.46 which was statistically highly significant (P<0.001) and observed by time for need for first rescue analgesic and percentage of patients who required it in both groups **(Table: 4)**. Side effect like Nausea and vomiting were complained more in Group I as compared to Group R. As per the study 4 patients(8.9%) of Group I and 2 patients (4.4%) of Group R had complained about nausea and 10 patients (22.2%) of Group I and 3 patients (6.7%) in Group R had vomiting and no patients from both Groups was complained for any other side effect and all were responded to injection Ondansetron (IV 4mg). **(Table: 5)**

Gadani HN et al[6] found significantly prolonged duration of analgesia in rectal group against intravenous tramadol group (504±146.96min vs. 426±80.36min). Also they found 15% incidence of PONV in intravenous tramadol group as against 5% in rectal suppository group. **Patel SJ et al**[8] found that 45% of the patients needed first rescue analgesic at 6 hour in intravenous tramadol group whereas only 5% of the patients in rectal tramadol group needed it. By the end of 10 hrs all 100% patients received rescue analgesic in intravenous tramadol group and 65% patients in suppository group which was a significantly lower proportion .Thus the duration of analgesia was prolonged in Rectal Group with less side-effect. **Padol Y et al**[9] found that Duration of postoperative analgesia was prolonged with the rectal route compared to intravenous administration and noted nausea and vomiting were lower with the rectal route. **Zwaveling J *et al***[10]showed the pharmacokinetics of rectal Tramadol in postoperative paediatric patients. They found that difference in Tramadol clearance between children and adults after rectal administration in contrast to IV administration no difference in clearance between the two ages Group was found. They studied that after the 2 mg/kgdose of Tramadol, it increases therapeutic concentration and it could be correlated with the duration of analgesia

CONCLUSION:

Since the duration of analgesia was prolonged with Group R which was observed by time for need of rescue analgesia and percentage of patients who required it in both Groups. Hence we concluded that Rectal route of Tramadol is safe, noninvasive and better alternative for pain relief in caesarean section with minimal side effect.

Limitation of the study:

The study had small number of research cases. Involvement of large number of cases would strengthen the statistical validity. Postoperative analgesia studied only for 12 hours with the single dose of Tramadol via intravenous and rectal routes. Elaboration of postoperative nausea-vomiting may require large sample size. In our study, only obstetric patients who were undergoing caesarean section were included. So the result cannot be generalised to other lower abdominal surgeries.

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