Comparative Evaluation of Postoperative Analgesia with Tramadol and Pethidine following Caesarean Section

M. Ravishankar, S. Parathasarathy, B. Hemavathy, P. Saravanan and Asha Oumachigui

ABSTRACT

Fifty patients scheduled for Caesarean section under spinal anaesthesia with lignocaine were taken up for the study. The aims of this randomised study was to compare the efficacy of intramuscular Pethidine with intramuscular Tramadol for postoperative analgesia and to compare the side effects of the drugs with a special mention to maternal fetal interaction. Postoperatively, patients received Pethidine 1 mg per kg body weight (Group I) or Tramadol 1.5 mg per kg body weight (Group II), intramuscularly. Pain relief by Numerical Rating Scale system and side effects were noted by a blinded observer. After decoding, it was observed that pain relief was similar in both groups till the third dose, after which it was significantly better in Group II ($p<0.05$). No significant differences in pulse rate, blood pressure, respiratory rate and ABG values were identified. The less sedative action of Tramadol was not proved. There was no significant difference in the side effects between the two groups, including APGAR scoring of the newborn and mother-baby interaction.

KEY WORDS : Postoperative analgesia
Surgery : Caesarean section
Analgesics : Tramadol, Pethidine

Tramadol, a synthetic 4-phenyl piperidine analogue of codeine is a central analgesic with a low affinity for opioid receptors[1]. It can be administered orally, intramuscularly or intra-venously for the treatment of acute pain of intermediate or severe intensity. It exerts its analgesic action through two modes[2] : a direct action on opioid receptors, where its M1 metabolite has a higher affinity than the parent compound and secondly, modulation of central manoaminergic pathways. Studies have shown that the cardiorespiratory depressant effect of Tramadol is less than other opioids like morphine[3].

Most of the side effects like nausea, vomiting, dizziness are comparable with stronger opioids[4]. It is claimed to be less sedative than other available opioids. In the face of frequent non-availability of drugs such as morphine and pethidine, we have been forced to resort to drugs such as buprenorphine and pentazocine. In this context, tramadol appears to be a suitable option. It has got low addiction potential[5,6] and hence freely available in the market. Further no adverse effects have been reported in the newborn when used in the lactating mother.

These features prompted us to take up this study to compare the efficacy of intramuscular pethidine with intramuscular tramadol for postoperative analgesia in patients undergoing caesarean section under regional anaesthesia and also compare the side effects of the drugs.

PATIENTS AND METHODS

A total of fifty patients of ASA I and II presenting for elective or emergency caesarean section were taken up for the study. All the patients were explained about the study.

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the pain and the sedation scores preoperatively. Informed consent was taken from all patients. The study was approved by the hospital research and ethical committee. A routine preoperative evaluation was done and the following categories of patients were excluded from the study : (i) Patients with pre-existing cardiorespiratory diseases (ii) Those who have received either narcotics or sedatives in the process of labour, (iii) Those presenting with foetal distress and (iv) Those who were below 140 cm in height.

A conventional subarachnoid anaesthetic using 1.0 ml of 5% hyperbaric ligocaine at L2-L3 space was used in all the patients. Intraoperative management was based on generally accepted guidelines. The following patients were then excluded from the study : Patients who received narcotics, sedatives or supplemental general anaesthesia intraoperatively patients who suffered persistent hypotension due to any reason.

After conclusion of surgery, the patients were monitored and the time of regression of two spinal segments was noted. This is designated as '0' hour. The pulse rate, blood pressure, respiratory rate were noted and PaO_2, SaO_2, $PaCO_2$ were measured in all patients. At this time patients were randomly allotted to either of the groups. Group I patients received pethidine 1 mg per kg bodyweight and the Group II patients received tramadol 1.5 mg per kg bodyweight intramuscularly. The drug was repeated every six hours irrespective of the patient status. The initial drug administration was done by one of the authors who entered the name and hospital number of the patient along with the dose administered on a slip of paper, enclosed it in an envelope and handed it over to the staff nurse to repeat the dose 6th hourly. After administration of the 3rd dose the cover was sealed and handed over to the author.

The rescue analgesic was in the form of 10 mg i.v. pethidine every 10 minutes, when patients complained of pain. The following variables were noted for 18 hours after the first injection by an observer, who is totally blinded to the drug : pulse rate, blood pressure and respiratory rate were noted every three hours and at 45 minutes following each injection. $PaCO_2$, PaO_2 and SaO_2 were noted 45 minutes after the first and the last injections. Pain score by Numerical Rating Scale (NRS) was measured at 3 hour intervals and 45 minutes after each injection, and side effects such as nausea and vomiting, if any, were recorded. A sedation score was maintained at 3 hour intervals and 45 minutes after each injection as follows :

I. Awake, restless and complaining of pain
II. Awake, restless
III. Awake, comfortable
IV. Asleep, arousable
V. Asleep, arousable only to persistent call or touch.

Any additional analgesia in the form of incremental pethidine was noted.

The parameters were charted in a proforma. At the conclusion of the study, the sealed covers were opened and patients' data were grouped accordingly and were subjected to statistical analysis using Student's 't' test.

RESULTS

All the fifty patients received subarachnoid block with 1 ml of 5% hyperbaric lignocaine solution. Surgery was completed in all cases within the duration of the block comfortably. All the delivered babies had 5 minutes Apgar score of more than eight. The mean age of patients in pethidine group was 24.9 and that of tramadol was 25.5 years.

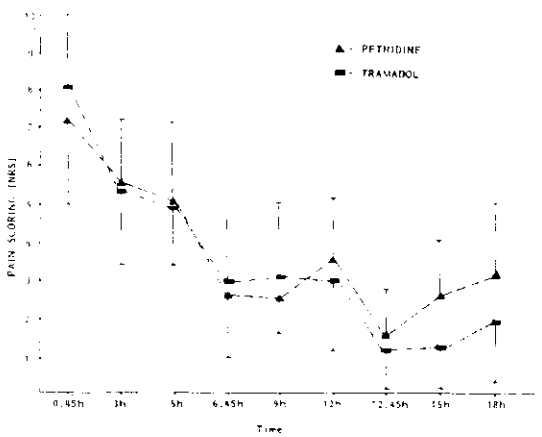

Fig.1 : Comparison of pain scoring (NRS) in group I and Group II

Both drugs caused insufficient analgesia after the first dose (Fig.1). Eighteen patients in pethidine group and 19 in tramadol group received incremental pethidine (rescue

analgesic) between 1st and 2nd dose. Average dose of the rescue analgesic was 20 mg in the pethidine group and 18.4 mg in the tramadol group. Pain scores after second dose with both drugs were comparable and similar till the third dose. After the third dose, pain scores in tramadol group

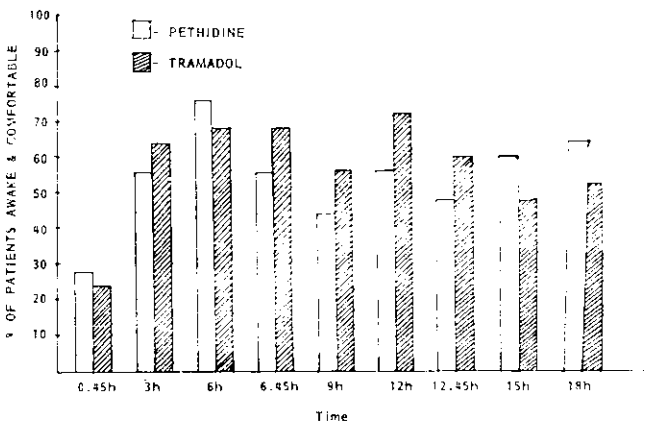

Fig.2 : Comparison of % of awake and comfortable patients in Group I and II

were lower than the pethidine group ($p<0.05$). The number of patients who were awake and comfortable (sedation score 3) were comparable in both groups (Fig.2).

The number of patients with sedation score 4 were comparable in both groups till the 3rd dose. There was a significant increase in number of patients who were asleep and arousable (sedation score 4) in the tramadol group after the third dose. There was only one recorded score of 5 which was in the pethidine group and one of score 2 in the tramadol group.

Vomiting as a side effect was seen in two patients of pethidine group and one of the tramadol group.

The pulse rate and the blood pressure (systolic) showed no significant difference except that the decrease in pulse rate was more in the tramadol group which could be considered clinically insignificant.

The respiratory rate of both groups of patients decreased during the study period. However there was no significant difference between the groups. There was no significant difference in the values (PaO_2, SaO_2 and $PaCO_2$) between the two groups (Table-1), eventhough a fall in the mean PaO_2 was found in the tramadol group after the third dose. The minimum PaO_2 measured was 49 mm Hg which was found in the pethidine group. The patient was asymptomatic and was supplemented with oxygen for 1-2 hours.

All the fifty babies were active and feeding well through out the study period. No difference was observed with feeding pattern or the mother-baby interaction.

DISCUSSION

Postoperative analgesia is an essential component of an ideal perioperative anaesthetic care. There are innumerable ways of achieving it, the use of parenteral narcotics being the commonest one. Tramadol, a codeine derived analgesic with its potential pharmacodynamic advantages, can be used for postoperative pain relief. In this study, the patients undergoing caesarean section were selected to standardise the type of incision and the intensity of postoperative pain and to test the hypothesis that the decreased sedative action of tramadol with satisfactory analgesia may improve mother-baby relationship than a sleeping mother.

In our study, the analgesic effect of the drugs (pethidine 1 mg per kg and tramadol 1.5 mg per kg) was similar upto

Table - 1

ABG values in the two groups (mean)

Time in hrs.	$PaCO_2$(mmHg)		PaO_2(mmHg)		SaO_2(%)	
	Pethidine	Tramadol	Pethidine	Tramadol	Pethidine	Tramadol
0.00	28.67	30.29	102.56	99.64	97.81	97.71
0.45	31.19	30.89	92.79	99.95	96.35	97.74
12.45	32.19	32.28	96.16	87.82	97.01	96.58

12 hours postoperatively but better analgesia with tramadol was found in the next 6 hours. This goes along with the proposed mechanism of predominant M receptor action with multiple doses and the increased formation of the M1 metabolite the major contributor of the M receptor effects. The necessity and the amount of rescue analgesic used were also similar in the two groups in this study. But along with this, the sedation scores which were comparable in the first 12 hours were found to be more in the next 6 hours in the tramadol group. To put it the other way, tramadol caused more sedation and better analgesia after the 3rd dose. This fact is against the hypothesis that it is a milder sedative with attractive efficacy. Alon et al found that intramuscular tramadol 50 mg was significantly less potent than buprenorphine 0.3 mg[7]. Rathgeber decribed that pain relief after abdominal surgery was good and similar when he used repetitive intramuscular doses of either 100 mg tramadol or 30 mg pentazocine[8]. Paravicini et al, in their studies have described tramadol as an analgesic with minimum effect on cardiorespiratory systems[9]. Rothe and Brather reported 3 cases of naloxone sensitive respiratory depression after intraoperative use of higher doses of tramadol[10]. In our study the cardiovascular variables and the respiratory rate were similar and comparable in both groups, except a statistically insignificant fall in PaO_2 after the 3rd dose of tramadol. $PaCO_2$ was normal and similar in both the groups. The incidence of vomiting was insignificant in both groups.

To conclude, tramadol 1.5 mg per kg is equianalgesic with pethidine 1 mg per kg, the potency of tramadol increasing with repetitive doses. The fact that it is a milder sedative cannot be proved. The other side effects were similar and insignificant.

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