Original Research Article

Tramadol in perioperative shivering in patients undergoing caesrean section under regional anaesthesia

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Abstract

Background: Shivering can be unpleasant and physiologically stressful for the patients. The incidence of post-operative shivering is more in obstetric patients. Many physical and pharmacological interventions are used to decrease the incidence and severity of post anaesthetic shivering. Among pharmacological interventions, tramadol, a synthetic opioid is found effective in many studies, with the advantage of causing less respiratory depression and sedation. **Methods:** The present study was undertaken at St Martha's hospital Nrupatunga road, Bangalore. Atotal of 240 obstetric patients of ASA G 1 and 2, posted for elective and emergency caesarean section under regional anaesthesia, who developed subsequently shivering were studied. Patients were randomly divided into three groups. Group 1(80 patients who have received 0.25mg /kg), Group 2 (80 patients who have received 0.5mg/kg), Group 3 (80 patients who have received 1mg/kg). The attending anaesthesiologist observed for cessation of shivering and the time elapsed from treatment to the time shivering subsided. If shivering did not subside by the end of 15 minutes, treatment was considered ineffective.Statistical analysis of the data was done by Anova, chi Square, Kruskal Wallis test, fisher exact test. **Results:** Statistical analysis revealed significantly better response with Tramadol 0.5mg /kg (90%) and tramadol (1mg /kg), compared with 0.25mg/kg (25%) of tramadol. Vitals were not altered in any of the groups and none of the above doses induced significant sedation or unduly affected the APGAR scores of the new born. **Conclusion:** From the above study it can be concluded that 0.5mg/kg is the minimum effective dose of tramadol for control of shivering in obstetric patients.
Key Words: caesrean section.

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INTRODUCTION

Regional anaesthesia is a safe and popular anaesthetic technique for caesarean section. Around 40 -60 % of patients, under regional anaesthesia develop shivering.[1] Shivering increases metabolic rate and oxygen consumption up to 100-600%, it also increases intraocular pressures and intracranial tension. It interferes with monitoring, it can be detrimental to patients with low cardiac reserve[1] The incidence of shivering is high in obstetricpatients, it can be unpleasant and physiologically stressful for the patient. Many pharmacological agents like pethidine, clonidine, magnesium sulphate, amitriptyline, dolasetron are used to control shivering, these drugs have side effects like respiratory depression, bradycardia,hypotension etc[2] Among pharmacological agents, tramadol has been found effective in many studies with less side effects like respiratory depression, bradykinesia and hypotension[2]. Tramadol has potential use in controlling shivering in obstetric patients and

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hence is emerging as a new and safe drug to be used for the treatment of post anaesthetic shivering[3].

MATERIALS AND METHODS

The present study was undertaken at the St Martha'shospital, Nrupatungaroad, Bangalore during the period of December 2013 to December 2014. Institutional ethical committee approval was obtained, informed written consent was taken from all the patients. 240 ASA G 1 and G2, obstetric patients, who underwent elective and emergency caesarean section under regional anaesthesia, who subsequently developed shivering were studied. Patients belonging to the following classes were excluded from the study, those with significant cardiovascular,renal, hepatic, and respiratory disease, patients who are hypersensitive to tramadol, those with initial body temperature of >38 º c or <36.5 ºc, history of alcohol and substance abuse, who have received pethidine for labour pain, and who do not give valid consent. After noting down ambient temperature and baseline vitals, subarachnoid block was given, a standard double layered blanket was used to cover the patients and vitals were monitored throughout.Parturient who developed shivering after subarachnoid block were included in the study. A total of 240 cases fitting the above criteria were studied. They were randomly divided into one of the three groups.

Statistical Methods: Statistical analysis of the data was done by ANOVA, Chi-square, Kruskal Wallis test,Fisher exact test.

RESULTS

Table 1: Comparison of age in years

Age in years	Group I		Group II		Group III	
	No	%	No	%	No	%
18-20	17	21.3	10	12.5	6	7.5
21-25	44	55.0	51	63.8	51	63.8
26-30	15	18.8	11	13.8	16	20.0
31-35	4	5.0	8	10.0	7	8.8
Total	**80**	**100.0**	**80**	**100.0**	**80**	**100.0**
Mean ± SD	**23.29±3.52**		**23.98±3.11**		**24.40±3.15**	

There is no significant difference in the age distribution between the four groups. The mean age is 23 years in group 1 and 2 and 24 years in group 3.

Table 2: Comparison of parity

Parity	Group I		Group II		Group III	
	No	%	No	%	No	%
Primi	45	56.3	42	52.5	40	50.0
Multi	35	43.8	38	47.5	40	50.0
Total	**80**	**100.0**	**80**	**100.0**	**80**	**100.0**

There is no significant difference in the parity distribution between the groups (P=0.728).

Table 3: Comparison of baseline parameters among the three groups

Baseline variables	Group I	Group II	Group III	Significance
Axillary temperature	36.85±0.27	36.83±0.34	36.83±0.28	F=0.168; p=0.848
Room temperature	26.00±0.14	26.01±0.18	26.02±0.19	F=0.205; P=0.815
Pulse rate	77.93±7.77	77.71±7.66	77.78±8.22	F=0.015; p=0.985
SBP (mm Hg)	118.95±8.60	118.7±9.61	120.9±8.69	F=1.440; p=0.239
DBP (mm g)	69.10±7.72	69.15±8.76	70.99±7.92	F=1.394; p=0.250
SPO2(%)	98.48±0.49	98.43±0.59	98.49±0.64	F=1.361; p=0.258

There is no significant difference in the baseline parameters between the groups.

Table 5: Comparison of Height of block in three groups of patients studied

Height of block	Group I	Group II	Group III
T8	2 (2.5%)	1(1.3%)	1(1.3%)
T6	11(13.8%)	6(7.5%)	8(10.0%)
T4	67(83.8%)	73(91.3%)	70(87.5%)
Total	**80(100.0%)**	**80(100.0%)**	**80(100.0%)**

Inference Height of block is statistically similar between three groups with P=0.707Height of the block achieved was adequate, it was at T4 for majority of patients.

Table 6: Comparison of distribution of shivering grade

Grade of shivering	Group I		Group II		Group III	
	No	%	No	%	No	%
Grade I	46	57.5	43	53.8	38	47.5
Grade II	34	42.5	37	46.3	42	52.5
Total	**80**	**100.0**	**80**	**100.0**	**80**	**100.0**

Distribution of grade of shivering is similar between three groups (P=0.441).

Table 7: Distribution of Response

Response	Group I (n=80)		Group II (n=80)		Group III (n=80)	
	No	%	No	%	No	%
No	60	75.0	8	10.0	5	6.3
Yes	20	25.0	72	90.0	75	93.7

In distribution of response, statistically significant improvement is seen in group 2 and 3 when compared to group 1. The difference in the response rate is not statistically significant between group 2 and 3.

Group I vs Group II (25% vs 90%); □2=69.156; P<0.001**

Group I vs Group III (25.0% vs 93.7%);□2=78.301; P<0.001**

Group II vs Group III (90.0% vs 93.7%); □2=0.754; P=0.385.

Table 8: Distribution of time of response

Response	Group I (n=80)	Group II (n=80)	Group III (n=80)
Response (mean ± SD) min	4.80±0.29	2.28±0.37	1.67±0.37

There is statistically significant decrease in the response time among the groups.

Group I vs group II; P<0.001** Group I vs Group III; P<0.001**

Gr II vs Group III; P<0.001**

The response time has decreased from group 1 to group 3 doses.

Comparison of response between groups

Table 9: Subjective assessment of improvement

Improvement scale	Group I (n=80)		Group II (n=80)		Group III (n=80)	
	No	%	No	%	No	%
Grade 0	45	56.2	3	3.8	3	3.8
Grade I	20	25.0	6	7.5	4	5.0
Grade II	15	18.8	71	88.7	73	91.2

There is statistically significant improvement in group 2 and 3 when compared to group 1. Subjective assessment of improvement is higher in group 2 and 3 when compared to group 1.

Table 10: Incidence of recurrence

Incidence of recurrence	Group I (n=80)	Group II (n=80)	Group III (n=80)
% of recurrence	40.0%	27.8%	26.7%

Group I vs Group II; P<0.001**Group I vs Group III; P<0.001**Group II vs Group III; P=1.000. Higher incidence of recurrence noted in group 1 when compared to group 2 and 3.

Table 11a: Comparison of pulse rate in three groups of patients

PR	Group I	Group II	Group III
0 minute	77.20±5.90	76.46±5.22	74.81±7.05
10 minutes	77.79±6.99	76.55±7.22	74.11±7.25
20 minutes	77.30±6.62	76.48±6.87	74.45±7.35
30 minutes	77.21±6.63	76.38±6.86	74.44±7.34
P value	0.524	0.984	0.255

Table 10: Incidence of recurrence

Incidence of recurrence	Group I (n=80)	Group II (n=80)	Group III (n=80)
% of recurrence	40.0%	27.8%	26.7%

Group I vs Group II; P<0.001**Group I vs Group III; P<0.001**Group II vs Group III; P=1.000 Higher incidence of recurrence noted in group 1 when compared to group 2 and 3.

Table 11b: Comparison of SPO_2 in three groups of patients

Spo_2	Group I	Group II	Group III
0 minute	98.45±0.90	98.63±0.72	98.63±0.79
10 minutes	98.45±0.98	98.54±0.86	98.75±0.72
20 minutes	98.51±0.87	98.54±0.90	98.73±0.63
30 minutes	98.47±0.86	98.49±0.89	98.63±0.62
P value	0.851	0.873	0.263

Table 11c: Comparison of SBP in three groups of patients

SBP (mm Hg)	Group I	Group II	Group III
0 minute	110.23±8.93	111.05±7.94	114.18±7.17
10 minutes	110.55±8.61	123.5±112.2	114.3±7.09
20 minutes	110.34±9.01	111.28±8.04	114.18±7.22
30 minutes	110.32±9.11	111.26±8.14	114.12±7.12
P value	0.714	0.389	0.876

Table 11d: Comparison of DBP in three groups of patients

DBP (mm Hg)	Group I	Group II	Group III
0 minute	66.65±8.04	67.08±8.96	64.85±7.68
10 minutes	66.30±8.11	66.90±8.66	64.88±7.74
20 minutes	66.50±8.04	67.03±8.46	65.40±7.88
30 minutes	66.49±8.14	67.13±8.42	65.41±7.83
P value	0.239	0.847	0.131

Table 11e: Comparison of Temperature in three groups of patients

Temperature	Group I	Group II	Group III
0 minute	35.66±0.25	36.12±0.35	36.00±0.23
10 minutes	35.65±0.23	36.11±0.31	36.12±0.39
20 minutes	35.67±0.24	36.11±0.31	36.01±0.23
30 minutes	35.17±0.23	36.12±0.30	36.11±0.23
P value	0.472	0.911	0.110

There is no statistically significant difference in the vital parameters of the patient after administration of the drug.

Table 12: Comparison of adverse effects in three groups of patients

Adverse effects	Group I (n=80)	Group II (n=80)	Group III (n=80)	P value
Nausea	11(13.8%)	20(25.0%)	15(18.8%)	0.216
Vomiting	15(18.8%)	23(28.8%)	24(30.0%)	0.175
Pruritis	0	3(3.8%)	4(5.0%)	0.167
Dry mouth	0	0	0	-

There is no clinically significant difference between the groups in the incidence of adverse effects.

Table 13: Comparison of Sedation among the three groups of patients

Sedation	Group I (n=80)	Group II (n=80)	Group III (n=80)	P value
Grade I	2(2.5%)	2(2.5%)	4(5.0%)	0.736
Grade II	0	0	0	-
Grade III	0	0	0	-

There was no difference in the incidence of sedation between the groups and none of the patients had clinically significant sedation or respiratory depression.

able 14: Comparison of timing of administered in three groups of patients

Drug administered	Group I (n=80)	Group II (n=80)	Group III (n=80)	P value
Before	19(23.8%)	17(21.3%)	14(17.5%)	0.648
After	62(77.5%)	64(80.0%)	66(82.5%)	0.759

Table 15: Comparison of Apgar score in three groups of patients

Apgar score (<7)	Group I (n=80)	Group II (n=80)	Group III (n=80)	P value
0 min	8 (10.0%)	12(15.0%)	10(12.5%)	0.671
5 min	0	1(1.3%)	3(3.8%)	0.328

There is no significant difference in the APGAR scores among the groups when drug was administered before the extraction of the baby. Regional anaesthesia is emerging as safe and popular technique both in elective and emergency situations in the modern obstetric anaesthesia practice.

DISCUSSION

Regional anaesthesia is emerging as safe and popular technique both in elective and emergency situations in the modern obstetric anaesthesia practice. Incidence of post anaesthesia shivering is high in obstetric patients.[5] Shivering continues to be a common problem faced by the anaesthesiologist during intra operative and post-operative periods. Shivering occurs both during general and regional anaesthesia. Unfortunately, there is no gold standard drug or definitive strategy drawn in management of this commonly encountered problem. Shivering is a very unpleasant experience for the patients receiving comforts of modern anaesthesia. At times it is described as a sensation worse than surgical pain. It is physiologically stressful; it increases oxygen consumption, which may go up by 100-600%. It increases intra ocular and intracranial pressures. It interferes with routine monitoring like ECG, pulse oximeter and NIBP. It causes tension on suture lines. Shivering is detrimental to patients with low cardio respiratory reserve. It is uncomfortable to the patients as well as to the operating room personnel, especially during regional anaesthesia.[6,,7,5,8] The exact mechanism of development of post anaesthesia shivering is not known. Many hypotheseslike, perioperative heat loss, stress, the direct effect of certain anaesthetics, hypercapnia and hypoxia, uninhibited spinal reflexes, pain, early recovery of spinal reflex activity and sympathetic over activity.[6,3] Many physical methods like, active and passive warming systems, warming of inspired air, warming systems for IV fluids, blood and its products are tried in many studies, these methods require use of specialised equipment, which is not economically feasible and practical in all clinical settings.[1] Pharmacological methods are cost effective when compared to physical methods. There is no single gold standard drug for treatment of shivering. Many drugs like, Pethidine, Doxapram, Clonidine, Ketanserin, Propofol, Physostigmine, Nefopam, Alfentanil and Sufentanil are tried with success rates ranging from 30-95 %. Pethidine and clonidine are most commonly studied drugs. Clonidine is associated side effects like bradycardia and hypotension, and Pethidine is associated with nausea and vomiting and respiratory depression.[1,3] Tramadol is a novel analgesic, it has Opioid effect mediated via the mu-receptor, with minimal effect on kappa and delta receptors. Tramadol inhibits 5- HT3 reuptake and promotes its release. It also inhibits synaptosomal noradrenaline reuptake.[8] Electrophysiologic, neurophysiologic and neuropharmacological experiments in animals have established the role of Noradrenaline and 5HT3 in the control of body temperature. Activation of nucleus Raphe Magnus, where 5-HT3 acts as a neurotransmitter has inhibitory effect on shivering. It is thus possible that anti shivering effect of Tramadol is mediated by its effect on these receptors. So, many authors have postulated that, Tramadol is likely to have better clinical utility as a anti shivering drug when compared to Pethidine, whose anti shivering effect is postulated to be mediated through kappa receptors.[8] In treating anaesthesia induced shivering in obstetric patients respiratory depression in the mother and depressant effect on foetus has to be considered. Tramadol has been used as an analgesic for labour pain without adversely affecting the mother or new born. With its pharmacodynamic advantagein causing less respiratory depression and sedation, with its unique status of not being a controlled drug, it has potential use in the control of shivering in the obstetric suite, because it is more convenient and, theoretically, safer than meperidine.[3] Tramadol and Meperidine are approximately equipotent with respect to analgesia. The minimum effective dose of Meperidine for control of shivering is found to be 0.35 mg/kg.Although the ant shivering and analgesic effects of these two agents may be mediated via different receptors, it is postulated that Tramadol may control shivering at doses < 1 mg.kg -1.[9,3] Many studies have demonstrated the usefulness of Tramadol in control of shivering, studies have also demonstrated that,

Tramadol is more effective in treatment of shivering when compared to other drugs like Pethidine and amytriptyline.[10,9,6,7,11,12,3] Different doses of Tramadol from 0.2 mg/kg to 3mg/kg were used to control postoperative shivering in different studies.[13,9,14,15] In the present study we randomly administered 0.25 mg/kg(group1) 0.5mg/kg(group2) and 1mg/kg(group3) to groups of 80 patients each, of ASA physical status 1 and2 who were posted for elective and emergency caesarean section under spinal anaesthesia, and who in the due course of anaesthesia developed shivering and requested treatment for the same. Attending anaesthesiologist assessed the disappearance of shivering and time taken for the shivering control from the time of drug administration. Participating parturient also subjectively assessed degree of improvement after administration of the study drug. 20 patients out of 80 (25%) in 0.25 mg/kg,72 patients out of 80 patients (90%) in 0.5 mg/kg and 75 patients out of 80 patients in 1mg/kg (93.7%) were found to have their shivering controlled. There was statistically significant difference between the response rate between group 1 when compared to group 2 and group 3. There was no statistically significant difference between group 2 and group 3. Parvin sajedi *et al* in2008 studied the effect of Tramadol in treatment of post anaesthetic shivering. They administered 0.2 mg/kg, 0.4 mg/kg,0.6 mg/kg,0.8 mg/kg and 1 mg/kg Tramadol to groups of 15 patients each. They noted that 80% of patients in group 0.2 mg/kg and 100% in all the other groups had shivering controlled. Though they could not demonstrate statistically significant difference between the groups, they could not rule out type 2 errors as their sample size was small, they concluded that, 0.4 mg/kg is the minimum effective dose required to control shivering. In the present study sample size was 80 patients in each group, hence we could demonstrate the statistically significant difference in response between 0.25 mg/kg and 0.5 mg/kg,1mg/kg.[9] Response time in the present study for group 1 is 4.80±0.29 min which is similar to study by Chen *et al* who noticed mean response time of 5.4±3.7 min with 0.25 mg/kg of Tramadol. Sajedi and co-workers in their study have found mean response time of 3.16±1.69 min with 0.2 mg/kg tramadol.[9,3] Response time in the present study for group 2 was 2.28±0. 37min.In study by Chen *et al* the mean response was 3.8+- 1. 5min.Talakoub *et al* studied the effect Tramadol 0.5 mg/kg and Pethidine 0.5 mg/kg on post anaesthetic shivering in parturient under spinal anaesthesia. In their study, time of cessation of shivering from the time of drug administration was 2.54±0.78 min. The time taken for cessation of shivering in the present study is almost similar to the above study.[6,3] In the present study response time for group 3 patients was 1.67±0.37 min. In study by Sajedi *et al* the response time they noted with 1 mg/kg Tramadol was2±0.97 min. Aditi dhimar *et al* conducted a study on 60 ASA grade 1 and grade 2 patients who developed shivering after regional anaesthesia, they compared the effect of Tramadol 1mg/kg with Pethidine 1 mg/kg. They concluded Tramadol is superior to Pethidine in control of shivering. In their study, the mean response time for Tramadol group was 1 min. The response time of present study is almost similar to the above study[9,1] In the present study there was a statistically significant decrease in the response time among the three groups of drugs. This finding is similar to that found by De Witte and co-workers. They found statistically significant delay in the onset of action between Tramadol 0.5 mg/kg and 1mg/kg, 2 mg/kg of Tramadol in controlling post anaesthetic shivering.[15] The vital parameters like PR, SBP, DBP, SPO2, body temperature did not show any significant change with the administration of Tramadol. This is in accordance with all the studies mentioned above. Studies have found that administration of Tramadol 0.2mg/kg to 3 mg/kg does not affect the haemodynamic and other vital parameters of the patients. One of thelimitations of the present study is that core temperature of the of the patients was not measured. The incidence of vomiting in the present study was 18.8% for group 1, 28.8% for group 2, and 30.0% for group 3. Mild facial pruritus was noted in 3.8% patients in group 2 and 5.0% in group 3. No other side effects were noted in any groups of patients. Talakoub *et al* in their study, have found 19.4% incidence of nausea in 0.5mg/kg tramadol group. Aditi dhimar *et al* have found the incidence of nausea and vomiting with 1mg/kg of Tramadol as 6.6%. This variation in the incidence of nausea and vomiting among the studies can be due to difference in the rate of injection of the drug. The rate of injection of the drug is known to affect the incidence of nausea and vomiting. In the present study we slowly injected the drug over 2 minutes.[1,6] There was no statistically significant effect in the APGAR scores of the new-borns between the three groups. One of the limitations of the present study was, we did not compare the effect of the drug with placebo. Studies by chen *et al*, Atashkhoyi.s *et al*, Zahidi *et al* Javaherforoosh *et al*, Talakoub *et al*, Tsai *et al* have shown that Tramadol does not affect the APGAR of the new born, when administered to mother before extraction of the baby[10,5,6,11,16] In the present study it was found that recurrence of shivering was, 40.0% in group 1, 27.8% in group2, 26.7% in group 3. chen *et al* in their study found 58% recurrence of shivering in 0.25 mg/kg Tramadol group and40% recurrence in 0.5 mg/kg Tramadol group. Aditi *et al* in their study noted a 10% incidence of recurrence with Tramadol 1mg/kg. They administered 0.5 mg/kg of Tramadol to the patients who had recurrence,

and noted that shivering stopped completely. Since Tramadol does not cause significant respiratory depression, it can be safely used in management of recurrence of shivering. The probable reason for recurrence of shivering could be result of low concentration of the active drug, when hypothermia is still persisting and individual variations in the core temperature. Till date it is not clear whether higher shivering grades require higher doses of the drug.[1] This study did not control tightly the various factors which might influence the incidence of shivering, like the temperature of drugs and intravenousfluids and temperature of the operating room. However, this should not have affected the validity of comparisons. First, the current study focused on the response after treatment, rather than the incidence of shivering. Second, by randomisation, the three study groups had been subjected to a similar degree of influence of these factors. The present study has not performed a direct comparison between Tramadol and Pethidine. However, Tramadol does have advantages over Pethidine in that it is not a controlled drug and it causes less respiratory depression and sedation than other Opioids at equivalent dosages. Patients receiving Pethidine iv for control of shivering during extradural anaesthesia were more drowsy at two and five minutes after injection, although there was no difference in level of consciousness at later intervals. Some parturient developed recurrence of shivering after initial control with Tramadol. Further studies are indicated to compare these two agents directly to substantiate these possible differences. Synergism in the anti-shivering properties of these two agents is also possible, as their effects are likely mediated via different receptors. It might also be interesting to investigate the effect of repeating Tramadol administration in various dosages should shivering recur.

CONCLUSION

From the findings of the study it can be concluded that 0.5 mg/kg is the minimum effective dose of Tramadol for control of shivering in obstetric patients. Administration of Tramadol does not alter the vital parameters of the patients.

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