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PAIN RELIEF IN LABOR BY TRAMADOL HYDROCHLORIDE: EFFICACY & SAFETY

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ABSTRACT

Labor is considered to be one of the most painful experiences in life. There are several methods used for labor analgesia but there is a need of a safe & effective analgesics along with very simple to administer as most of the delivery conducted to primary healthcare in our country. The objective of this study wasto evaluate the analgesic efficacy and the tolerability of 50 mg tramadol intramuscularly in labor pain compared with placebo group. This hospital based prospective study was carried out in Department of Obstetrics and Gynecology at Bashundhara Addin Medical College Hospital, Keraniganj during the period of January 2019 to June 2020. 200 women in labor at term pregnancy who met the inclusion and exclusion criteria were enrolled. Theywere divided into Study Group (n=100) women in active labor received 50 mg Tramadol intramuscularly for analgesia. & Control Group (n=100) didn't received any analgesia. They were observed for time of onset analgesics effect; pain relief score; duration of drug to delivery interval; mode of delivery; adverse effect; fetal Apgar score & recorded. Pain relief was satisfactory (score II) in 51% in tramadol group & <1% in control group groups ($p < 0.001$). Duration of labor was significantly shorter in study group as compared to control group. There was minimal maternal side effects in study group and no significant difference in the incidence of fetal morbidity in both the groups. Tramadol is an effective and safe labor analgesic as well as it shortens the duration of labor.

KEYWORDS: Tramadol hydrochloride, labor analgesia, Pain relief score.

INTRODUCTION

Most women like to experience birth actively and as naturally as possible. Labor is a painful process and may be the most painful experience many women ever encounter.[1] The experience is different for each woman, and the different methods chosen to relieve pain depend upon the techniques available locally and the personal choice of the individual patient or health workers. Pain during labor is a physiological phenomenon. The evolution of pain during first stage of labor is associated with ischemia of the uterus during contraction as well as effacement and dilation of cervix.[2] In the second stage, pain is caused by stretching of the vagina, perineum, and compression of pelvic structures. However, pain sensation is a response of the total personality and is a subjective phenomenon. Adequate analgesia during labor is a benefit for the mother, has a positive influence on the course of labor and the state of the newborn child. The ideal analgesic in obstetrics should have potent opiate-like analgesic efficacy with minimal side effects.[3] Tramadol is a narcotic drug introduced in Germany 1971 is available throughout the world. It was introduced in India for the last couple of years.[4] It is a weak opioid analgesic Tramadol is a centrally acting analgesic agent belonging to the group of weak opioids.[5,6] Interestingly, some side-effects which are typical for opioids such as miosis, depression of the respiratory and cardiovascular system, constipation and urine retention are very rare or not relevant with therapeutic doses of tramadol.[7,8] The

onset of the analgesic effect of intramuscular tramadol is rapid and the effect lasts for 4-6 h. In a study of tramadol for pain relief in labor, reported that 50 mg tramadol given intramuscularly was effective in relieving labor pain in more than 60% of subjects; the effect began after about 10 min and lasted for as long as 45 min.[9] Therefore, the drug is of interest for the treatment of labor pain and could improve current analgesic therapy.[3] This trial is aimed to evaluate the analgesic efficacy and the tolerability of 50 mg tramadol intramuscularly in labor pain.

MATERIALS AND METHODS

It was a prospective study conducted in labor ward from January 2019 to June 2020 at Bashundhara Addin Medical College Hospital (BAMCH), Keranigang, Bangladesh. Two hundred pregnant women were allocated for this study. Criteria for inclusion were women in established labor, aged between 18 and 35 years & Pregnancy without obstetrical & medical complications.Excluded from the study were patients with a clinical history of a complicated pregnancy as diabetes mellitus, multiple pregnancy, intrauterine infection or placental insufficiency, pregnancy induced hypertension, bad obstetric history, preterm labor, previous caesarean section. A complete history, examination and all preliminary routine investigations were done. Procedure and side effects of the drug are explained. Informed consent for labor analgesia has taken from all patients & ethical clearance was obtained before study.

The 200 women were alternately divided into: Group A – Study Group: 100 women in active labor who received 50 mg Tramadol intramuscularly for analgesia. Group B – Control Group: 100 women in active labor whodidn't received any labor analgesia. During the procedure, monitoring of PR, BP and RR was recorded every hour and frequency, duration and intensity of contractions are noted and fetal heart rate is monitored every half an hour during the 1st stage of labor and every 15 minutes during the 2nd stage of labor, progress of labor checked periodically. A partogram is initiated. Patient enters into the study when cervix is effaced and 3 -5 cm dilated, 50 mg Intramuscular dose of tramadol is given. Pain relief of mother was assessed by Total pain relief scores (TOTPAR) obtained at 30 and 60 min , 2 hour & 4 hour after the administration of study drugs. Mode of delivery whether normal, instrumental or operative was studied. Any maternal side effects, if present are noted, perinatal outcome evaluated by Apgar score. All resuscitative measures for mother and baby were kept ready. Total duration of labor and injection delivery interval was calculated. The data was recorded in a predesigned questionnaires and analyzed by SPSS 26.0 software; for analysis chi-square test, Students T test were done where needed. P value <0.05 was assumed as significant.

RESULTS

The demographic characteristics of the subjects are summarized in **Table I**. There were no significant differences (P > 0.05) in tramadol group & control group. Mode of delivery of the patients are approximately in same proportion in both groups that is 93% in tramadol & 92% control groups of women had vaginal delivery. Similarly, near about same proportion of the women had emergency cesarean section (P>0.05). There was significant difference in mean duration of labor between two group (4.84 hours in tramadol group & 5.12 hours in control group). Here the mean drug-to-delivery interval was shorter in the tramadol group as compared to the controlgroup (31% vs 38%). This difference is statistically significant (P<0.05) **(Table II)**. A few of the side effects of tramadol like nausea, vomiting, dizziness, headache, sweating, restlessness was found in the study group only.

Table III shows the degree of pain relief. In the study group 15% patients was in score 0, i.e. no pain relief; 23%, 49% & 11% were in score I, II, III after 30min of administering tramadol compared to the control group in which 86% patients said no pain in relief. After one hour of administering tramadol in study group 11% patients was in score '0' followed by 19%, 55% & 15% was in score I, II & score III respectively. Whereas in the control group, 95%% patients was in score 0 followed by only 4% was in score I, 1% in score II& no one found in score III.

After Two & Four hours of administering tramadol in study group 15% patients was in score '0' followed by 17%, 54% & 15% was in score I, II & III respectively and 23%, 47% & 15% in score I, II & III. Whereas in the control group, 95% & 98% patients was in score 0at 2nd & 4th hour. Only 4%, 5% & 2% was in score I. Very negligible no. was in score II & no one found in score III which was statistically significant(P<0.05) This table showed Tramadol (50 mg) was much effective than no analgesia.

The mean Apgar score at 1st and 5th minutes in both the groups was not significant statistically. Only 2% babies were admitted to NICU in both groups due to perinatal asphyxia.

Table I: Epidemiological Analysis in between both groups.

Age group		
	Tramadol 50mg (n=100)	**Control group(n=100)**
<30 years	76 (76%)	72 (72%)
>30 years	24 (24%)	28 (28%)
Gravida		
Primi gravid	71 (71%)	67 (67%)
Multi gravid	29 (29%)	33 (33%)
Mode of delivery		
Vaginal delivery	93 (93%)	92 (92%)
Cesarean section	07 (07%)	08 (08%)

Table II: Duration of labor in hour.

>6 hours	15 (15%)	38 (38%)
4-6 hours	54 (54%)	49 (49%)
< 4hours	31 (31%)	13 (13%)
Side effects		
None	82 (82%)	_
Nausea	05 (05%)	_
Vomiting	03 (03%)	_
Fatigue	02 (02%)	_
Vertigo	03 (03%)	_
Dizziness	05 (05%)	_

Table III: Pain relief score.

(0 = no effect, I = insufficient relief, II = sufficient/good relief, III = complete relief).						
Study drug	**Pain relief score**	**0 min**	**30 min**	**1 hour**	**2 hour**	**4 hour**
Study group (Tramadol 50 mg)	**No (0)**	100	15	11	15	15
	Mild (I)	0	23	19	17	23
	Satisfactory(II)	0	49	55	54	47
	complete (III)	0	11	15	15	15
Control group (No drug)	**No (0)**	100	86	95	95	98
	Mild (I)	0	12	4	5	2
	Satisfactory(II)	0	2	1	0	0
	complete (III)	0	0	0	0	0

Table IV: APGAR scores at one and five minutes in both groups.

	Tramadol 50mg (n=100)		**Control group(n=100)**	
	1st min	**5th min**	**1st min**	**5th min**
Scores 8-10	93	94	95	97
Scores 6-7	07	06	05	O3
Need of NICU	02		O2	

DISCUSSION

Results of the current study have shown that the socio-demographic characteristics of pregnant women in both groups were similar at baseline. There was no statistically significant difference in the two groups regarding age& gravidity or mode of delivery. These results are similar to a study where the researchers compared analgesic efficacy of tramadol for pain relief in active labor with placebo.[15]

Pain is a subjective phenomenon and so its relief is difficult to measure. In the present study, the degree of pain relief was assessed by Total pain relief scores (TOTPAR). In majority of cases (80%), pain relief was within 1 hour with 50mg of tramadol I/M. Maximum analgesic action of the drug is up to 2 hours and wanes off by 4 hour. This is differ from theother studies such as 15 min[11], 10 min[15] and 15.89 min.[16] Duration of analgesia was 4.10hour.[11] These differences are probably due to dose discrepancy, where they use 100 mg tramadol for labor analgesia.

In study group satisfactory pain relief (Score-II) was 51% & complete relief (Score-III) 14%. Amongst

controls there was almost no relief of pain. In a study found moderate to good/satisfactory pain relief in 12% and 49% which was almost same of this study.[13] another study shown 58%[13], 54%[15] and 37%[16] of the parturient had good pain relief respectively. There was no significant difference in the mode of delivery of patients between two groups. Majority of patient (93% & 92%) Vaginal delivery was conducted in study & control group, rest underwent caesarean section (LSCS) for fetal distress in both groups. Another study reported 90% normal deliveries, 6% Instrumental deliveries and 4% LSCS.[11]

Patients who had vaginal delivery , the duration of labor ranged from 4-6 hours with mean value of 4.84 hrs in tramadol group & 5.12 hrs in control group. This was also found to be statistically significant (P<0.05). In a study there was significant shorter duration of labor in study group compared to control group which supports the present study is shown in the table.[4,10]

Anideal analgesic is the one that has no adverse effect on the fetus. In this study Apgar scores of most of the babies at 1st and 5th min were satisfactory although 06 % in tramadol group & 03% incontrol group were observed score 6-7 who delivered by LSCS due to fetal distress. It is not possible to attribute the cause of fetal distress to tramadol, as for doing so, it is ideal to access the plasma level of the drug in the baby. This is not done in our study. Another study observed that Apgar score was > 7 at 1 min (96%) and 5 min (100%).[11] Another study reported an Apgar score of more than 8 at 1 min in all neonates of the tramadol group.[12] In a study reported that Apgar scores of most of the babies at 1 min and 5 min were satisfactory, although 14% of the tramadol group and 10% of the placebo group were observed in score is 6-7.[13]

In this study 82% women showed no adverse effect. Nausea and dizziness found in only 5 % patient. In a study observed that sedation was the only side effect in 9% of tramadol group.[14] There was no significant change in the vital parameters like pulse, respiratory rate, and blood pressure in both groups.

CONCLUSION

In this study it is found that the therapeutic dose of tramadol (50 mg) I/M is a potent analgesic with rapid onset of action, quick metabolism and good pain relief score. Tramadol decreases the duration of labor and increases duration of analgesia with minimal side effects.

CONFLICT OF INTEREST

None.

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REFERENCES

1. Ohel I, Walfisch A, Shitenberg D, Sheiner E, Hallak M. A rise in pain threshold during labour: A prospective clinical trial. Pain., 2007; 132: S104-8.
2. Yarnell RW, McDoland JS. Obstetric analgesia and anesthesia. Current Obstetric and Gynecologic diagnosis and treatment. 10th edition, 2007; 29: 441.
3. Viegas OA, Khaw B, Ratnam SS. Tramadol in labour pain in primiparous patients. A prospective comparative clinical trial. Eur J Obstet Gynecol Reprod Biol. 1993; 49:131–5.
4. Shyamsundar B et al. Int J Reprod Contracept Obstet Gynecol, Jan, 2018; 7(1): 312-317
5. Arend L, Amim von B, Nijssen J, Scheele J, Flohe L. Tramadol and pentazocin in a double blind crossover comparison. Arzneim.-Forsch/Drug Res., 1978; 28(la): 199-208.
6. Friderichs E, Felgenhauer F, Jongschaap P, Osterloh G. Pharmacological Investigations on Analgesia and the Development of Dependence and Tolerance with Tramadol, a Strongly Acting Analgesic Arzneim.-Forsch/Drug Res., 1978; 28(la): l22-134.
7. Preston KL, Jasinski DR, Testa M. Abuse potential and pharmacological comparison of tramadol and morphine. Drug Alcohol Depend, 1991; 27: 7-17.
8. Cossmann M, Wilsmann KM. Application of Tramadol injection (TRAMALe) in acute pain: open trial to assess the acute effect and safety after a single parenteral administration. Therapeut News, 1988; Jahrgarg 1 30; 36,633-636. 13
9. Bitsch M, Emmrich J, Hary J, Lippach G, Rindt W. Obstetric analgesia with tramadol. Fortrschr Med., 1980; 16: 632-634.
10. Sharma UR, Verma RS. Use of Tramadol or Analgesic in normal and abnormal labour. J Obstet Gynecol India, 1999; 49(6): 67-9.
11. SudhaPatil, Somashekara SC, Veerabhadra Goud GK, Bhanurekha S, Jayanthi Reddy L, Deepa laxmi S; Tramadol analgesia in labor. Int J Pharm Biomed Res., 2012; 3(1): 49-51.
12. Bajaj P, Meena R, Prasad R; I/V tramadol for labor analgesia; The IndPract, 1997; 50: 1051-4.
13. M. Suguna, Shobha rani et al., Sch. J. App. Med. Sci., September, 2015; 3(6C): 2347-2350
14. Jain S, Arya VK, Gopalan, JainV; Analgesic efficacy of intramuscular opioids versus epidural analgesia in labor; Int J GynaecolObstet, 2003; 83(1): 19-27.
15. Meena J, Singhal P, Chaudhary D; Programmed labour; J Obstet Gynecol India, 2006; 56: 53-55.
16. Nagaria T, Acharya J; Pain relief in labor - tramadol versus pentazocine. J Obstet Gynecol India, 2006; 56: 406-409.