ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
Index Copernicus Value: 68 . 16
PubMed - National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 5, Issue –4, July - 2020, Page No. : 41 - 45

Comparative Study of Dortavarine and Valethamate Bromide in Cervical Dilation in Labour

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Citation this Article: Dr B. S.Meena, Dr. Teena Jain, Dr. Rajkumar Jain, "Comparative Study of Dortavarine and Valethamate Bromide in Cervical Dilation in Labour", IJMSIR- July - 2020, Vol – 5, Issue - 4, P. No. 41 – 45.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: To compare the efficacy of drotaverine and valethamate bromide in shortening the duration of first stage of labour.

Methods: The present study was conducted in the department of obstetrics and gynecology, S. M.S Medical College and Associated Group of Hospitals, Jaipur, Rajasthan. Total of 100 patients were included in the study with 50 patients in each of the two groups. In this study the effects of Drotaverine hydrochloride (Group A) and Valethamate bromide (Group B) on cervical dilatation were compared.

Results: The mean drug delivery interval was 102.18±77.58 mins in Group A and 131.26±93.11 mins in Group B. The difference was statistically highly significant ($p < 0.001$). The mean requirement of drug in Group A was 1.23±0.62 doses whereas in Group B it was 4.23±1.41 doses and this difference was found statistically highly significant ($p < 0.001$).

Conclusions: Drotaverine hydrochloride is found to be better than valethamate bromide in shortening the duration of active phase of labor in primigravidae. Drotaverine was found to be a better drug, hence, can be used to reduce the agony of the laboring woman without any significant side effects on the mother or the fetus.

Keywords: Labor, Drotaverine, Valethamate (epidosin)

Introduction

Of all the journeys ever we make, the most dangerous is the very first one we make through the last 10cms of the birth canal. In the strategy of labour, the duration of the labour which has great influence on both maternal and perinatal morbidity. Years ago when watchful expectancy was the attitude of midwives, prolonged labour increased the risk of dehydration, ketoacidosis, infection traumatic deliver y and fetal morbidity vix, hypoxia, infection. Modern times, "Active Management" trends towards curtailing the total duration of labour compatible with the safety of the mother and foetus. [1]

Labour is a multifactorial process which involves myometrial contraction; cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly

manner. The first stage of labour in a primigravida lasts about 12 – 16 hours and in a parous woman 6 – 8 hours.

Prolonged labour has been a dreaded problem for obstetricians. The most common cause of prolonged first stage of labour is cervical spasm leading to cervical dystocia. Many times it is observed that inspite of good uterine contractions, cervix fails to dilate or dilates very slowly. This is functional cervical dystocia. Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the first stage of labour are welcome by both obstetricians and women.

Drotaverine, an isoquinoline derivative, inhibits specifically phosphodiesterase IV (PDE IV) which in turn increases the intracellular concentration of cAMP and cGMP and causes smooth muscle relaxation. Inj. Drotaverine Hydrochloride 40m is given intramuscularly. Valethamate is a mixture of diphenylpiperidino-propane ethylaisamide HCL. It has atropine like parasympatholytic action, Papaverine – like action on plain muscle and antihistaminic action. The drug reduces the hyperexcitability of parasympathetic system and lowers the spasm of smooth muscle system. Each ampoule of valethamate bromide F 08 mg is given intravenously.[2]

Epidosin (valethamate bromide) is also an antispasmodic which helps in cervical dilatation due to its neurotropic or atropine like action and musculotropic or papaverine like action. Hence this study was carried out to compare the efficacy of Inj. Drotaverine with Inj Valethmate on duration of active phase of labour, the rate of cervical dilation and its effect on mother and foetus.

Material and Methods

Study design: Prospective randomized clinical trial.

Inclusion criteria: Women having normal singleton pregnancy at 38 – 41 weeks gestation, with vertex presentation, intact membranes and spontaneous onset of labor included in the study.

Exclusion criteria: Patients with

- Previous uterine scar..
- Cephalopelvic disproportion.
- Grand multiparity.
- Antepartum haemorrhage.
- Twin pregnancy.
- Preterm labour

Sampling methods: Random sampling

Data collection: Cases eligible for study were randomly enrolled in study Group A and B.

Group A: Cases where injection drotaverine containing 40 mg was administered intravenously during active phase of labor at an interval of 2 hours up to a maximum of 3 injections

Group B: Cases where injection valethamate containing 8mg was administered intravenously in active phase of labour at intervals of 30 minutes up to a maximum of 6 injections.

Vital parameters were monitored and progress of labour was assessed. Close watch on fetal heart rate was kept. Injection delivery interval, mode and time of delivery were noted Apgar at 1 and 5 minutes after birth and NICU admission was noted. Mode of delivery, maternal and fetal outcome was compared to know the efficacy of drotaverine and valethamate on cervical dilatation and in shortening the duration of active stage of labor.

Data Analysis: To collect required information from eligible patients a pre-structured pre-tested Proforma will be used. For data analysis Microsoft excel and statistical software SPSS will be used and data will be analyzed with the help of frequencies, figures,

proportions, measures of central tendency, appropriate statistical test.

Result

Table 1: Distribution of cases according to baseline characteristic

	Group-A	Group-B	p-value
Age in Yrs	22.12±2.78	22.16±2.72	>0.05
Gestation age	38.54±1.05	38.15±0.87	>0.05
Bishop Score	10.15±1.37	10.12±1.58	>0.05

The present study was carried out in 100 parturient women. In this study, the majority of subjects were between 21-25 years of age in both the groups. The mean maternal age was 22.12±2.78 years in Group A and 22.16±2.72 years in Group B making the groups comparable for age. The mean period of gestation was 38.54±1.05 and 38.15±0.87 weeks in Group A and Group B respectively which was comparable. The mean Bishop Score in group A was 10.15±1.37 while in Group B it was 10.12±1.58 and the difference was found statistically insignificant (p >0.05) and the both groups were comparable for study.

Table 2: Distribution of cases according to injection delivery interval (IDI) & number of doses of drug administered.

	Group-A	Group-B	p-value
Injection delivery interval (IDI)	102.18±77.58	131.26±93.11	<0.001
Number of doses of drug administered	1.23±0.62	4.23±1.41	<0.001

The mean drug delivery interval was 102.18±77.58 mins in Group A and 131.26±93.11 mins in Group B. The difference was statistically highly significant (p <0.001). The mean requirement of drug in Group A was 1.23±0.62 doses whereas in Group B it was 4.23±1.41 doses and this difference was found statistically highly significant (p <0.001).

Table 3: Distribution of cases according to Apgar score at 5 minuteS

	Group-A	Group-B	p-value
Injection delivery interval (IDI)	8.52±0.53	8.12±0.12	>0.05

Mean Apgar 8.52±0.53 and 8.12±0.12 at 5 minutes in Group A and B respectively and the difference was found insignificant (p >0.05).

Table 4: Distribution of cases according to side effects

	Group-A	Group-B
Tachycardia	4(8.00%)	6(12.00%)
Dryness of mouth	1(2.00%)	6(12.00%)
Headache	2(4.00%)	0(0.00%)
Cervical tear	3(6.00%)	2(4.00%)
Nausea / Vomiting	3(6.00%)	5(10.00%)
Vertigo	3(6.00%)	5(10.00%)

Study observed that in Group A, 8.00% subjects complained of tachycardia, 4.00% developed headache and 2.00% had dryness of mouth. 6.0% patients had cervical tear, 6% cases had nausea/vomiting. In Group B, 12.00% patient had complained of tachycardia and dryness of mouth, 4% cases had cervical tear, 10.00% cases had nausea/vomiting.

Discussion

Labor is one of the most important events in a woman's life. Prolonged labor has implications for both the mother and the fetus. Reducing the length of labor is a

highly desirable goal of intrapartum care, from the perspective of both maternal and fetal well-being.[4]

Cervical dilatation is one of the important factors which determines the duration of labor and is resultant of all driving forces of uterine contractions acting against passive tissue resistance. [5]

Cervical ripening, expressed as remodeling of the cervical connective tissue, has been proved to be necessary for an uncomplicated vaginal delivery.[6]

In this study, the age of patients was between 20-35 years. The mean maternal age was 22.12±2.78 years in Group A and 22.16±2.72 years in Group B making the groups comparable for age. The mean period of gestation was 38.54±1.05 and 38.15±0.87 weeks in Group A and Group B respectively which was comparable. The mean Bishop Score in group A was 10.15±1.37 while in Group B it was 10.12±1.58 and the difference was found statistically insignificant (p >0.05) and the both groups were comparable for study. This was comparable to the studies done by Sharma et al, Nagaria et al, Kaur et al, Naga et al, Kalhon et al, Edessy et al and Patil et al and related to the average age of marriage and child bearing in study area.[7-13]

Mandal and Molla study, in their study reported that the mean duration of active phase of labour in drotaverine group was 123.12±37.82 and 102.75±36.90 min in primigravida and multigravida respectively whereas in valethamate group results were 156.30±45.10 and 139.98±45.89 min respectively.[14] There was a statistically significant reduction in the duration of active phase of labor in both primigravida and multigravida given drotaverine when compared with valethamate bromide. Drotaverine was significantly more effective than valethamate. The results were comparable to present study. The drug delivery interval was slightly better with valethamate bromide in the present study as compared to when the drugs were given in the studies of like Selvaraj et al, Madhu et al, Sharma et al. [7,8,15]

Drugs used in the study are known to cause minor side effects in the mother. In this Group A, 8.00% subjects complained of tachycardia, 4.00% developed headache and 2.00% had dryness of mouth. 6.0% patients had cervical tear, 6% cases had nausea/vomiting. In Group B, 12.00% patient had complained of tachycardia and dryness of mouth, 4% cases had cervical tear, 10.00% cases had nausea/vomiting. Similar results were observed by Selvaraj et al, Madhu et al, Sharma et al. [7,8,15]

Conclusions

Drotaverine hydrochloride is found to be better than valethamate bromide in shortening the duration of active phase of labor in primigravidae. Drotaverine was found to be a better drug, hence, can be used to reduce the agony of the laboring woman without any significant side effects on the mother or the fetus.

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