

To study the efficacy and safety of Drotaverine hydrochloride in augmentation of labour

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Abstract

Background: Labor is a complex physiological process characterized by painful uterine contractions which bring about the delivery of fetus. Augmentation of labour is common clinical practice and various methods both pharmacological and non-pharmacological are available for the same. **Aims:** To assess the efficacy and safety of drotaverine hydrochloride for augmentation of labor. **Materials and Methods:** A total of 200 patients in active labor were included in the study after fulfilling the inclusion criteria. The patients were divided into 2 groups by simple randomization method. After a detailed history and examination Group A women received inj. Drotaverine intramuscularly every 2 hours for a maximum of three doses. Group B women did not receive injection and served as the control group. **Results:** Our study showed a significant reduction in the duration of active phase of first (I) stage of labor (Group A-164 mins and Group B- 296mins), with significant improvement in the rate of cervical dilatation (Group A- 2.5cm/hr and Group B- 1.38cm/hr). There were no reports of any serious adverse effects in both mother and the fetus. The most common side effects seen were nausea, vomiting (2%) and headache (1%). **Conclusion:** Thus, drotaverine can be safely used as a potent agent for augmentation of labor without any adverse effects on mother and the fetus.

Keywords: Augmentation of labor, Cervical dilatation, Drotaverine.

Introduction

Labor is a complex physiologic process characterized by painful uterine contractions which cause cervical dilatation and effacement followed by delivery of fetus. Augmentation of labor to shorten its duration and thereby reducing the pain and suffering of delivering woman is beneficial for both patients and obstetricians.

Various methods are available for the augmentation of labor like mechanical methods: sweeping of membranes, cervical stretching & amniotomy and pharmacological methods including oxytocin has been well established worldwide [1,2]. Buscopan and Scopolamine have been used for pain relief and shortening of labour; cervical application of hyaluronidase has also been used with some success. Various other pharmacological agents like diazepam and morphine have also been tried for pain relief, however majority of them were found to ill effects on the mother and the fetus.

In the 1960s, Drotaverine, a benzyl isoquinoline was introduced. Drotaverine hydrochloride is unique smooth muscle relaxant, acts by selectively inhibiting phosphodiesterase IV enzyme which is present in high concentration in myometrium near term, thus facilitating cervical dilatation during labor[2].

It has minimal maternal side effects like hypotension, vertigo, nausea and palpitation but free of any fetal or neonatal side effects. Our study aims to assess the use of drotaverine hydrochloride in accelerating the rate of cervical dilatation and thus reducing the duration of labor.

Aims and Objectives

To study the effectiveness of Inj. Drotaverine Hydrochloride with respect to:

- i. duration of labor
- ii. mode of delivery
- iii. maternal side effects
- iv. maternal and fetal complications

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Methodology

Study design: prospective clinical study

Setting: Department of OBG, ESIC Medical College and Hospital, Kalaburgi

Sample size: total of 200 patients, randomly divided in 2 groups of 100 each.

Study period: July 2017 to June 2108

Inclusion criteria

All the patients admitted in labor room with

- i. Full term pregnancy
- ii. Singleton fetus with cephalic presentation
- iii. in active stage of labor (cervical dilatation ≥ 4 cms and uterine contractions 3/10mins, each lasting for 30-40s)
- iv. pelvis adequate

Exclusion criteria

- i. any maternal or fetal complications requiring operative interventions.

On admission a detailed history is taken and a complete general physical and obstetric examination was done. Vaginal examination was done to note the cervical

Results

A total of 200 patients were included in the study, after fulfilling the inclusion and exclusion criteria. These women were then divided into two groups- A and B. Group A women received Inj. Drotaverine intramuscularly every 2hrs for maximum of 3doses, Group B women served as controls and did not receive any injection.

Majority of the women in both Group A and Group B were in the age group of 21-25years, 70% & 74% respectively as shown in Table 1. There was no statistical significant difference in the age and parity in the two groups as shown in Table 1 and Table 2.

From our study it has been observed that the average duration of active phase of labor was significantly reduced in the group A-2.44hrs as compared to the group B- 4.56hrs. However there was no significant difference in the durations of second and third stage of labor in both groups as shown in Table.3

The mean rate of cervical dilatation was 2.5cm/hr in group A. The rate of cervical dilatation in primigravida was 2.4cm/hr while in multi it was 3.12cm/hr. In group B the mean rate of cervical dilatation was 1.38cm/hr, in primigravida it was 1.2cm/hr and in the multi it was found to be 1.5cm/hr (Table 4).

Table-1: Age distribution.

Age in years	Group A	Group B
18-20	12	10
21-25	70	74
26-30	18	16
Total	100	100

dilatation & effacement, station & position of the head, membrane status and adequacy of pelvis.

Total of 200 patients were included in the study after fulfilling the inclusion and exclusion criteria. The patients were randomly divided in group A and group B. The patients in group A were given Inj. Drotaverine Hydrochloride 40mg intramuscularly at an interval of 2hrs upto a maximum of 3doses. Group B patients were not given any medications and served as control group.

Vaginal examination was done every 4hrs to assess the progress of labor. Augmentation of labor with oxytocin infusion or amniotomy was done if necessary, to achieve moderate uterine contractions. A partograph was maintained to note the progression of labor and for maternal and fetal surveillance during labor.

Mode of delivery, duration of II and III stages of labor and any complications were recorded. Neonatal APGAR scores at 1 and 5mins were assessed and any NICU admissions were noted.

The data collected were analysed by using IBM SPSS statistics. For statistical comparison, ANOVA test were used, where appropriate.

Table-2: Comparison of parity in both groups

Parity	Group A	Group B
Primi	70	70
Multi	30	30
Total	100	100

Table-3: Duration of stages of labour.

Duration of labor	Group A	Group B
Active phase, hr	2.44 ± 0.73	4.56 ± 1.37
Second stage, mins	27.72	30.44
Third stage, mins	5.56	6.26

Table-4: Comparison of rate of cervical dilatation

	Group A	Group B
Mean cervical dilatation, cm/hr	2.51 ± 0.88	1.38 ± 0.38
Mean cervical dilatation in primigravida	2.4 ± 0.44	1.2 ± 0.21
Mean cervical dilatation in multigravida	3.12 ± 0.6	1.5 ± 0.42

From Table.5 it was found that the mean injection to delivery interval was 3.2 hrs, in the primigravida it was 3.8hrs and in the multi 2.6 hrs. In our study majority of the patients (70%) required two injections to achieve the required results.

Table-5: Injection delivery interval

Group	No. of cases	Mean (hours : mins)
Drotaverine	100	3.218
Primi	70	3.82
Multi	30	2.62

Table-6: Mode of delivery.

Mode of delivery	Group A	Group B
Normal vaginal delivery	94	93
Forceps	4	4
Vacuum	-	-
LSCS	2	3

Table-7: Indication for LSCS in two groups.

Mode of delivery	Drotaverin HCL	Indication	Control group	Indication
LSCS	2	Fetal distress	2	Fetal distress
	-	-	1	Prolonged labor

Table-8: Complications of III stage of labour.

Complications	Drotaverine HCL	Control
Cervical tears	2	1
Lacerations	-	-
PPH(atonic)	1	2

Table-9: APGAR scores of neonates in two groups

Apgar score	Group A		Group B	
	1 minute	5 minute	1 minute	5 minute
4-6	-	-	-	-
7-8	6	4	8	4
9-10	94	96	92	96

Table-10: Side effects in two groups

Side effects	Drotaverine HCL	Control
Headache	1	-
Dryness of mouth	-	1
Tachycardia	-	1
Hypotension	1	-
Nausea & vomiting	2	1

Table-11: Comparative evaluation of efficacy and safety with previous studies

S. No	Authors	Drotaverine dose	Duration of Duration of active phase of I stage (in mins)	Rate of Cervical dilatation (cm/hr)	IDI (in mins)	Side effects
1	Simhasane H et al (2017)	40mg im, max-2doses 2hrly	P*- 233 M#- 149	P- 1.83 M- 2.8		T**- 10% V^ - 3%
2	Change de PR ¹⁵ (2016)		P- 110.7 M- 96.2	P- 3.8 M- 4.3		T-2%
3	Jogi SR (2015)	40mg im, max-3doses 2hrly	149.7	P- 2.5 M- 3.3	Avg- 176.7	T- 4% N- 1%
4	Aziz M ¹⁶ (2015)		P- 247 M- 199			N-4%
5	Palii et al (2013)		P-186 M- 148	P- 1.92 M- 2.46	Avg- 200	Nil
7	Khosla (2003) ¹⁴	40mg im	Avg. 175.92			Nil
8	JB Sharma et al ¹⁷ (2001)	40mg im, max-3doses, 2hrly	Avg- 193.9	Avg-2.04	Avg- 194	N- 4% T- 4%
9	Present study	40mg im, max-2doses, 2hrly	Avg-144	P- 2.4 M-3.1	Avg-180	T-nil V-nil

*P- primigravida, #M- multigravida, **T- tachycardia, ^V- vomiting

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Our study found no significant difference in the mode of delivery in both the groups as shown in Table 6. There were two cases of cervical tears in Group A and in the Group B there were 2 cases of PPH. However there was no significant difference in complications in both groups (Table 8). None of the neonates in both groups showed APGAR scores less than 8 at 1 or 5mins as shown in below Table 9.

There were no significant side effects in the treated group as compared to the control group. The common side effects experienced were nausea, vomiting, headache and giddiness (Table 10).

Discussion

Prolonged labour contributes to increased physiological burden on the mother as well as increases the perinatal morbidity and mortality. Thus, augmentation of labour to reduce the total duration of labor and thereby reducing the pain and suffering of laboring women is common clinical practice in modern obstetrics.

Various methods are available for augmentation both pharmacological and non pharmacological.

Our study aimed to evaluate the efficacy of injection drotaverine hydrochloride on duration of active phase of first stage of labor, cervical dilatation, its complications and safety in mother and neonate.

Farkas et al, was the first to conclude that drotaverine effectively reduces the cervical spasm,^[7] since then various studies have proven the efficacy of drotaverine in the augmentation of labour. Our study also proves the same.

In our study, total of 200 women were randomly divided in two groups, Group A (cases) and Group B (controls). Majority were primigravida in the age group of 21-25yrs, both the groups showed no statistical difference with respect to age or parity.

The average maternal age in our study are comparable to the studies done by Kaur D et al (2003), Batukan AC et al (2006)[8,9]. In our study, the average duration of active phase of labour was found to be 144mins, comparable to the results shown by Jogi et al and Nagaria(2009)[10,11].

The results of rate of cervical dilatation from our study were comparable to the studies done by Simhasane et al (2017)[12]and Jogi et al as shown in Table 11.

The injection to delivery interval was 180 mins which was not significantly different from other studies.

Our study showed no significant cases of nausea or tachycardia similar to the study done by Palii et al (2013) [13] and Khosla et al [14]

There were no reports of low APGAR scores in the neonates or NICU admissions in our study similar to study by Palii et al. [13].

Conclusion

From the above study we conclude that injection drotaverine significantly reduces the duration of active phase of labour with improvement in rate of cervical dilatation both in the primigravida as well as multigravida. Thus it can be safely used as potent agent for augmentation of labour without any serious adverse effects on mother or the neonate, as shown and proven by previous studies.

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Permission from IRB: Yes

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