J. of Obst. & Gyn. of India Vol. 52, No. 6 : November/December 2002 Pg 28-30

Effect of Drotaverine Hydrochloride on Normal Labour – A Randomised Study

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Summary

A prospective randomised study of 200 primigravidae with normal onset of labour was carried out, 100 patients were given 1 ampoule containing 40 mg of drotaverine hydrochloride intramuscularly at 3 cm dilatation of the cervix, the other 100 were taken as control. The effect of the drug on the progress and outcome of labour was noted.

Drotaverine hydrochloride injection hastened cervical dilatation and reduced duration of labour also pain relief during labour was significant. There was no interference with uterine contractility and no increased incidence of operative delivery. Side effects of the drug noted were not significant.

Introduction

Labour is a natural physiological phenomenon of child birth. It is a multifactorial spontaneous process which involves myometrial contractions, cervical ripening and dilatation and expulsion of the foetus in an orderly manner without any artifical aid. Improper estimation of time duration of normal labour may lead to morbidity, mortality or disability of the new born or the mother.

Drotaverine hydrochloride, an isoquinoline derivative is a non addictive spasmolytic drug. It is effective by inhibiting phosphodiesterase type – 4 enzyme, present in cervix (Leroy 1994) thus facilitating cervical smooth muscle relaxation. When used during dilatatory phase of cervix it facilitates dilatation and shortens time of cervical effacement in normal uncomplicated deliveries and finally shortens the duration of labour. It being free from undesirable side effects on mother and foetus, has a valuable contribution to the disappearance of distress inherent in the process of labour.

Materials and Methods

The present study was carried out at Cama and Albless Hospital, Mumbai in the year 1999-2000. Injection drotaverine hydrochloride 40mg intramuscularly was given to 100 primigravidae in active labour at cervical dilatation of 3 cm. Another 100 primigravidae with normal physiological onset of labour were taken as control for comparison [Table I]. Group-A-drotaverine HCL given, Group-B-no drug given.

- Age varied between 20 to 36 years [Table II]
- Only primigravidas were selected.
- No augmentation of labour was required.
- Patients with heart disease, respiratory diseases, borderline pelvis or cephalopelvic disproporation were excluded.

Observations and Results

Table I
No. of cases in both groups

Total no. of cases	200
Group A (drug given)	100
Group B (no drug given)	100

Table II
Agewise distribution

Age group	Group A	Group B
20 – 28 years	80 {80%}	76 {76%}
28 – 36 years	20 {20%}	24 {24%}

Tabel III
Total duration of labour and pain relief after delivery

Duration of labour	Group A	Group B
Latent phase	364 minutes	362 minutes
Active phase 1st stage	190 minutes	250 minutes
Active phase 2nd stage	20 minutes	22 minutes
Active phase 3rd stage	8 minutes	10 minutes
Total duration of labour	582 minutes	644 minutes
Pain relief after delivery	110 minutes	165 minutes

- Total duration of labour shortened by 62 minutes
- Duration of active phase of 1st stage shortened by 60 minutes
- Duration of 2nd and 3rd stage differed only by 4 minutes.
- There was significant decrease in pain after delivery in the study group, also it was 55 minutes earlier in study group than control group.

Table IV
Mode of delivery and complications and side effects

Type of delivery	Group A	Group B
Normal vaginal	98%	95%
Forceps	2%	1%
Vacuum	none	1%
Complications		
Cervical tears	1%	1%
Vaginal lacerations	none	none
PPH (atonic)	none	none
Side Effects		
Tachycardia, palpitations	2%	none
Hypotension	none	none
Nausea, vomiting	2%	none
Hypotonia, vertigo	none	none

- Only 2% of study group had tachycardia, 2% had nausea and vomiting which was relieved without medications.

Discussion

Drotaverine hydrochloride is an isoquinoline derivative, acting by inhibition of phosphodiesterase enzyme type -4 causing relaxation of smooth muscles and thus its spasmolytic action. In this study this drug was used during the active dilatatory phase of uterine cervix during labour and was found safe and useful in shortening total duration of labour with no undesirable side effects on mother and foetus.

It can be given as 40mg intramuscularly or intravenously at 3cm dilatation in actively labouring women.

In our study it was shown to decrease the total duration of labour by 62 minutes and active dilatatory phase of the cervix by 60 minutes, which was shown to be statistically significant [$P<0.05$]. Duration of 2nd and 3rd stage were not significantly different [$P>0.05$]

Due to the spasmolytic action the pain relief after delivery in the study group was 55 minutes earlier than control group [$p<0.05$]. There was not much difference between mode of delivery and complications [$p>0.05$].

Side effects of the drug drotaverine hydrochloride as nausea, vomiting were seen in 2% cases and tachycardia upto 120 beats per minute in 2% cases, in group A [$p>0.05$] however apgar scores remained same in both the groups.

The first open trial by Farkas and Viski 1998 contained 128 normal labour and 47 cases with complications. The disadvantageous spasms in spastic dystonia of the cervix could be relieved with drotaverine treatment [40mg im or iv]. The other obstetrical complications and caesarean section rates were same as controls.

In another study conducted by Suranyi 1972, Vero and Farago 1998, 65 parturients were given drotaverine and 100 physiological deliveries served as

Table V
Apgar scores in both groups

Apgar Score	Group A		Group B	
	At 1 min.	at 5 mins.	At 1 min.	at 5 mins.
4-6	none	none	none	none
6-8	12%	4%	14%	4%
8-10	88%	96%	86%	96%

- There was no significant difference in apgar scores of both the groups.

control. Drotaverine was found to be primarily beneficial to primiparae by shortening first stage of labour and also was free from side effects to mother and foetus.

Conclusion

Thus we can definitely conclude that promising beneficial effects of Drotaverine Hydrochloride are available in obstetric practice and in our study it has definitely proven to shorten the duration of labour and provide early relief from distress for the labouring women.

References

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