J. of Obst. & Gyn. of India Vol. 52, No. 3 : May/June 2002 Pg 76-79

Effect of Drotaverine on Cervical Dilatation : A Comparative Study with Epidosin (Valethamate Bromide)

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Summary

The present study is designed to evaluate the effect of drotaverine, a superior smooth muscle relaxant, on cervical dilatation, and compare its efficacy with epidosin. The study was carried out on 150 patients which included both primigravidae and multigravidae who were at term in the early active phase of labor. The average rate of cervical dilatation in primigravidae with inj. drotin, an isoquinoline derivative was 2.05 cm/hr and with inj. epidosin 1.53 cm/hr. In multigravidaes it was 3.68 cm/hr and 2.00 cm/hr respectively. The average time taken from 3cm to full dilatation of cervix was 3 hrs 25 min with drotaverine and 4 hrs 35 min with Epidosin in primis and in multis 1 hr 45 min and 3 hrs 30 min. in multis.

The average duration of first stage of labour in primis was 7 hours 36 minutes with inj. drotin and 9 hour 3 minute with inj. epidosin. The incidence of maternal side effects were 2% in cases where inj. drotaverine was administered and 8% with Inj. Epidosin. The average number of drotaverine injections required in primis were 2.1 and in multigravidae 1.3, whereas number of epidosin injections were 4.15 in primis and 3.16 in multigravidae.

Introduction

In the process of labor, polarity of the uterus is maintained by active contraction of upper uterine segment. The driving forces of uterine contractions act upon the cervix which plays the role of an innocent obstruction due to passive tissue resistance. Overacting of circular muscle fibres of cervix results in cervical spasm which may be increased in presence of inflammation, injury or fibrosis of cervix or due to fear tension pain syndrome. Various drugs like antispasmodics, tranquillizers, prostaglandins and psychotherapeutic methods have been tried but majority of these were found to have ill effects on the mother and the fetus.

Leroy et al. (1990) found that type IV Phosphodiesterase (PDE) enzyme is present in increased concentration in third trimester in myometrium suggesting its contribution in regulation of uterine motility. Hence selective PDE IV inhibitors like drotaverine may help facilitate dilatation of cervix. Drotaverine, an isoquinoline derivative, is a superior smooth muscle relaxant which acts specifically on spastic sites and corrects the CAMP and calcium imbalance relieving smooth muscle spasm (Each ampoule Inj. Drotaverine contains 40 mg Drotaverine hydrochloride which can be given via IV or IM route).

Epidosin (valethamate bromide) is an ester with a quarternary N-atom having spasmolytic action. By virtue of its anticholinergic, parasympatholytic (Ambiye et al 1985) and musculotropic action, it relieves spasm of the smooth muscle of cervix facilitating smooth dilatation. Each ampoule contains valethamate bromide F 8 mg which can be given by I.V. route, continuous I.V.

infusion or deep I.M. route.

Material and Methods

This study was conducted on patients at term in early labour and included both primigravidae and multigravidae fulfilling the following criteria : full term pregnancy with vertex presentation and already in active phase of labour with cervix about 2-3 cms dilated and effaced (maximal length upto 10 mm) and having 2-3 uterine contractions every 10 minutes lasting for 30 seconds.

Patients with mechanical causes of nondilatation of cervix, with associated malpresentation and those on antihypertensive therapy were excluded from this study.

Complete history taking, general physical examination, abdominal examination and bimanual examination which included conditions of cervix in terms of dilation, effacement and consistency, presence or absence of membrances, presenting part and its station were noted along with a pelvic assessment .

Patients were distributed in 3 groups A,B. and C of 50 each. Group A included cases where none of the cervical dilation drug was administered during labour. Group B included patients where Inj. epidosin was given I.V. during labour at an interval of 30 minutes to 1 hour upto a maximum of 6 injections. Group C included the cases where Inj. Drotaverine was given intravenously during labor at an interval of 2 hours upto a maximum of 3 injections. Amniotomy was carried out at 4-5 cms dilatation. If desired rate of contractions were not achieved, oxytocin drip was started. Monitoring of pulse, blood pressure, uterine contractions, progress and descent of presenting part, cervical dilatation and FHS was done. Maternal side effects like tachycardia, fever, flushing of skin, dryness of mouth, nausea, vomiting were noted. Mode of delivery, duration of I, II, III stage of labor and fetal outcomes were noted and tabulated.

Observation and Discussion

Of the 150 cases, 79% (119) were from urban and 21% (31) from rural areas. 67% (100) cases were from middle socioeconomic status and 33% (14) cases from low socioeconomic status. While 49% (74) were primigravid, 46% (69) were multigravid and 5% (7) were grand multiparae.

The minimum time taken for full diatation of cervix was observed in Group C. (Table I). The average time taken for full dilatation in Group C was less than in Group B in the cases of primis ($P<0.05$ i.e. highly significant). Comparison of average time required in Group C and Group A in primis was significant $P<0.05$ i.e significant and in multis i.e. highly significant $P<0.001$. Average rate of cervical dilatation for Group C as compared to Group B showed significant difference in primis and highly significant findings in multis. This shows that drotaverine is a highly effective cervical dilatating agent as compared to epidosin and Control group.

Table I
Average Rate of Cervical Dilatation in Relation to Parity

Parity	No. of Cases	Avg. time interval between 3 cm and Full dilatation	S.D.	Avg. rate of Cervical Dilatation
Group A				
Primigravida	24	6 hrs 13 min.	72.27	1.13
Multigravida	24	4 hrs 56 min.	43.72	1.42
Grandmultigravida	2	3 hrs 15 min.		2.15
Group B				
Primigravida	26	4 hrs 35 min	124.52	1.53
Multigravida	22	3 hrs 30 min.	69.55	2.00
Grandmultigravida	2	2 hrs		3.50
Group C				
Primigravida	24	3 hrs 25 min	109.59	2.05
Multigravida	23	1 hrs 45 min.	49.47	3.68
Grandmultigravida	3	1 hrs 50 min.		3.82

These findings are consistent with those obtained by Demter and Turi (1998) who reported average time taken for 3 cm to full dilatation to be 183.6± 121.1 min. in Drotaverine group and in controls 236±138.6 min. Our findings are also consistent with the findings of Puri et al (1988) who noted that in primis the average rate of cervical dilatation was 1.1 cm/hr without any drug and 2.2 cm/hr with epidosin.

The average duration of IInd and IIIrd stages was not affected by administration of drotin and neither there was increase in the frequency of hemorrhagic complications.

In all the three groups, we observed that the time utilized for full dilatation was less when membranes were absent (Table II).

When membrane were present, the time needed for full dilatation in group B was less than that needed in Group A (P<0.001) and in Group C less than that in group B (P<0.001), all the values being highly significant statistically. Thus with the membranes present, time utilized for full dilatation was least in drotaverine group. In cases with absent membranes also, the time utilized for full dilatation was minimum in Group C (P<0.001 i.e. highly significant), intermediate in Group B (P<0.001 i.e. highly significant) and maximum in Group A. The difference between the time taken for full dilatation in Group B and Group C is also statistically highly significant (P<0.001) again pointing to the better efficacy of drotaverine in its effect on cervical dilatation than epidosin.

We observed that the maximum number of epidosin injections required was 6 while that of drotaverine was 3. Only single injection was required in 46% cases of group C while in Group B 8% cases had one injection (Table III).

The difference in number of injections required in both primi and multigravidae between Group B and C was statistically significant (P<0.001) showing better efficacy of drotaverine.

Most of the cases in both groups delivered normally. Two cases of group A and 1 case of group C underwent LSCS but the indications were not pertaining to drug administration. Three cases of group A and 2 cases each of group B had forceps delivery.

Table II
Effect of Presence of Absence of Membranes on Cervical Dilatation

Membranes (Present / Absent)	No. of Cases	%	Avg. time interval between 3 cm and full dilatation	Avg. rate of cervical dilatation cm/hr
Group A				
Present	41	82	5 hrs 44 min.	1.22
Absent	9	18	4 hrs 22 min	1.60
Group B				
Present	41	82	4 hrs 14 min	1.65
Absent	9	18	2 hrs 54 min	2.41
Group C				
Present	39	78	2 hrs 58 min	2.36
Absent	11	22	1 hrs 24 min	5.0

Table III
Comparison of Number of Intravenous Injection Given in Different Group

Group	No. of Cases	No. of Injections	Average no. of Injection	S.D.
Group B				
Primigravida	26	1-6	4.5	1.43
Multigravida	24	1-5	3.16	1.09
Group C				
Primigravida	24	1-3	2.1	0.85
Multigravida	26	1-2	1.3	0.48

In Group B, 8% cases exhibited side effects while in Group C only 2% cases had side effects in the form of tachycardia, fever and hypotension. Cervical tear was noted in 2% cases of Group A and atonic PPH in 2% cases of Group A and B each. Average duration of after pains in Group C was 72 minutes less than in group A and 68 minutes less than in Group B but these differences were not statistically significant. There was no adverse effect of ediposin or drotaverine on fetus as Apgar score was 8/10 in 98% in Group A and B and 100% in Group C.

Conclusion

Drotaverine is a superior cervical dilatation agent significantly reducing the duration of labor without any ill effects on the mother or the neonate. We strongly advocate its use to reduce the agony which the mother faces during child birth.

References

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