ORIGINAL RESEARCH PAPER

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CLINICAL STUDY OF EFFICACY OF DROTAVERINE HYDROCHLORIDE ON DURATION OF FIRST STAGE OF LABOUR

KEY WORDS: Drotaverine hydrochloride, Duration of Labour, cervical dilatation

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ABSTRACT

Labour is a natural physiological phenomenon of child birth, which involves myometrial contraction; cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly manner. This clinical study was undertaken in the Department of Obstetrics and Gynecology, Government Medical College and Hospital, Miraj. To compare the duration of active stage of labour in treated and control group and to study any interference on uterine contractility with inj. Drotaverine hydrochloride. The present study deals with 400 cases in active labour (≥4 cm cervical dilatation) who were treated with i/v Drotaverine HCl. 400 similar cases were taken as control. The cases were taken up when cervical dilatation was between ≥ 4 cm. Only normal cases were taken up and presence of any complication what so ever was ruled out before selection. Regarding the duration of labour, the observation showed that the mean duration of first stage (i.e. ≥4 cm up to full dilatation) was 2.44 hrs in the treated group and 4.56 hours in the control group. This shows that the mean reduction of duration of first stage was 2.12 hours. The rate of cervical dilatation was 2.51 cm/hr in the treated group and 1.38 cm/hr in the control group, which was faster by 1.13 cm/hr in the Drotaverine group and the rate cervical dilatation, was still faster in multi gravida (3.12 cm/hr) as compared to primi gravida (2.43cm/hr)

INTRODUCTION:

Labour is a natural physiological phenomenon of child birth, which involves myometrial contraction; cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly manner.[1]

In the past obstetricians largely accepted labour as subjective to wide natural variations and management was done only when secondary complications developed. Professor O'Driscoll at the National Maternity Hospital, Dublin (1973), introduced the concept of "active management of labour", and this has influenced obstetricians to change their outlook regarding first stage of labour. Its aim was to accelerate labour thereby shortening the duration of labour, reduce maternal and fetal distress, anticipation and management of complications. Active management with new forms of pharmacological and surgical interventions are now common and they have transformed our labour wards and made the ugly nightmare of prolonged labour a buried memory of the past.[2].

The cervical dilatation which occurs during a contraction a centrifugal pull is exerted on the cervix leading to distention, a process referred to as cervical dilatation. It has been proved that cervical dilatation is one of the important factors which determine the duration of labour. Many a times it is observed that inspite of good uterine contractions; cervix fails to dilate or dilates very slowly. This is functional cervical dystocia.[3]

Drotaverine Hydrochloride is a new addition to cervical dilators. It was initially used in Europe for spasmodic conditions like ureteric and biliary colic but its use to facilitate cervical dilatation was studied first by Chinoin Pharmaceuticals (Hungary) and was launched in Hungary in 1963.[4]

Drotaverine, a benzyl isoquinoline derivative has excellent smooth muscle relaxant properties. It inhibits enzyme phosphodiesterase IV which leads to increase in cAMP level which in turn decreases the availability of free intracytoplasmic calcium ions leading to smooth muscle relaxation. One of the major benefits of Drotaverine is its safety during pregnancy and not associated with any teratogenic effect.[5]

Drotaverine HCl, has its main effect on the cervix facilitating its dilatation and can only be used for augmentation of labour, in patients with established labour preferable with 4cm dilatation and good uterine contraction.[6]

Material and Methods

The present study was based on evaluation of effect of Drotaverine hydrochloride in the first stage of labour as against a control group. The study group comprising of 400 cases and control group comprises of 400 cases. This study was carried out in the Department of Obstetrics and Gynaecology of the Government Medical College and Hospital, Miraj., for 4 years from June 2018 to June 2022.

SELECTION OF CASES:

(a) Patient admitted in labour room
(b) 400 patients were selected at random in study group
© 400 patients were selected at random in control group
Study Group–A: 400 number with intravenous injection of Drotaverine HCl.
Control Group–B: 400 numbers.

Inclusion Criteria:

- Age in between 18–30 years.
- Both primi gravida and multi gravida
- Term pregnancy - gestational age between 37–41 weeks with patient being sure of LMP.
- Singleton, vertex presentation with intact membranes.
- Patient must be in active phase of labour with well established uterine contraction (3/10 min.) and cervical dilatation 4 cm with an effaced or a partially effaced cervix.
- Pregnancy without any medical, surgical or obstetrical complications.

Exclusion Criteria:

- Patients with medical, surgical, obstetrical complications - pre- eclampsia, APH, Heart, kidney or liver disease etc.
- Any maternal and foetal complications which require

operative and other interventions during first stage e.g. maternal distress, foetal distress, CPD.

After selection of cases, a baseline clinical examination was performed:

- General physical examination, obstetrical examination like uterine contraction, cervical dilatation, FHR and maternal vital signs like pulse, B.P was recorded in the partograph.
- After starting the i/v line, 1 amp. of Drotaverine HCl (40mg) i/v was injected slowly, repeated after 1-2hrs. If necessary up to a maximum of 3 doses.
- Vaginal examination was carried out at an interval of 1hrs and finding was noted.
- The vital signs of mother and foetus was continuously monitored and noted down the side effects or adverse reactions if any.
- Amniotomy was avoided.
- The injection to delivery interval (time from 4cm dilatation to delivery of baby) was noted in all cases.
- Mode of delivery was recorded. Forceps/ventouse was applied when required.
- Duration and complication of the third stage of labour was recorded.
- Newborns were examined for Apgar score at 1 minute and 5 minutes and their birth weight was noted down.
- Similar observations were made for the control group and plotted accordingly in the partograph.

RESULTS

In the present series, 400 patients in active labour with cervical dilatation 4 cm were taken up for study where 2 cc Inj. Drotaverine HCl (40mg) was Injected intravenously for labour acceleration up to a maximum of 3 dosage. A control group of 400 patients were also taken randomly fulfilling the same criteria. Labour was managed with composite MODIFIED WHO PARTOGRAPH.

***Age distribution of patients:**

It has been found that the maximum numbers of patients (70%) were in the age group of 21—25 years in the treated group and 74% in control group.

***Parity:**

Out of 400 patients 70% were primigravida and 30% were multigravida.

***Duration of gestation:**

Highest number (42%) of the patients from treated group and 40% from the control group were in the gestational period of 40 weeks.

TABLE NO. 01: CERVICAL DILATATION AT 0 HOUR:

CERVICAL DILATATION (in cm)	DROTAVERINE HCl		CONTROL	
	NUMBER OF CASES	PERCENTAGE (%)	NUMBER OF CASES	PERCENTAGE (%)
4.0	320	80.00	328	82.00
4.5	48	12.00	48	12.00
5.0	32	8.00	24	6.00
TOTAL	400	100.00	400	100.00

TABLE NO. 02: DURATION OF LABOUR

DURATION OF LABOUR (Hour : Minutes)	STUDY GROUP	CONTROL GROUP
First Stage (4cm)		
Range	1.15-6	2.50-10.50
Mean	2.44 0.73	4.56 1.37
Second Stage:		
Range	10-90	24-95
Mean	41.72	41.44
Third Stage:		
Range	3-10	4-11
Mean	5.56	6.26

It is observed that the total duration of labour is reduced to a great extent in the treated group. The first stage of labour is reduced by 2.12 hours. Individually, the second and third stage is not very different in both the groups with maximum affection in the 1st stage of labour. It is observed that the duration of 1st stage is less in multi gravida as compared to Primigravida

TABLE NO. 03: RATE OF CERVICAL DILATATION

GROUP	MEAN RATE OF CERVICAL DILATATION (cm/hour)
Drotaverine	2.51 0.88
Control	1.38 0.38

The mean rate of cervical dilatation in the treated group is 2.51 cm/hour and in the control group it is 1.38 cm/hour. So, in the treated group the mean rate of cervical dilatation is faster by 1.13 cm/hour.

TABLE NO. 04: INJECTION DELIVERY-INTERVAL

GROUP	NUMBER OF CASES	MEAN (Hours : Mins)
Drotaverine:	400	3.218
Primi	280	3.82
Multi	120	2.62
Control	400	5.37

it has been observed that the mean injection delivery interval in the treated group is 3.218 hours and in the control group it is 5.37 hours. So, in the treated group there was a mean reduction of delivery interval by 2.16 hours.It is evident from the above table that majority of patients (70%) required two injections to achieve the required results.

SIDE EFFECTS OF THE DRUG:

Headach,Dryness omouth,Tachycardia,Hypotension!Nausea and vomitting. Side effects were also very minimum with only 4 patients in the treated group developed headache, hypotension and nausea and vomiting against three in control group

MODE OF DELIVERY:

It is evident that the highest number of cases in both the groups delivered vaginally with or without episiotomy. Forceps application was same in both the groups. Only 8 patients in the treated group and 12 in the control were delivered by caesarean section, due to foetal distress and prolonged labour and not due to any ill effect of the drug.

DISCUSSION:

In the present era, the obstetrician as well as the parturient prefers childbirth to be accomplished in shortest possible time. In prolonged labour, the incidences of maternal distress like- dehydration, keto-acidosis, PPH etc are more with resultant increase in maternal morbidity. Foetus on the other hand is also exposed to higher risks of infection, asphyxia, intra-cranial stress etc. So with newer methods of monitoring the mother and foetus during the antenatal, intranatal and postnatal period, the hazards of child bearing is receding progressively.Labour acceleration has emerged as a method of reducing the duration of labour minimizing the incidence of prolonged labour with its ill effects on the mother and foetus.

The rate of cervical dilatation in the present series was found to be enhanced in the study group treated with Drotaverine HCl 2.51cm/hour compared to 1.38 cm/hour in the control group so the treated group is faster by 1.13 cm/hour.

The available literature shows the details of the rate of cervical dilatation and found to be faster in the treated group

in comparison to the control group. Similar results were observed in studies conducted by Sharma J.B et. al.,[7] Singh K. C et. al.,[8] and Madhu C. et. al.[9]

In the present study the duration of 1st stage of labour shown to be very much reduced than the control group. Similar results were observed in studies conducted by Sreekumar S. et. al.,[10] and Singh K. C. et al.,[8]

CONCLUSION :

From the present study, it may be concluded that intravenous Drotaverine HCl has important role in hastening cervical dilatation in active phase of labour. In a country like ours, where intense monitoring of labour with modern electronic gadgets is as yet not uniformly available to the whole population, where communication is still poor, hospital beds are far too less, manpower too meager, such a method will be of utmost help to the obstetricians.

Simplicity of the method and its safety render it liable to be used to advantage by non-specialist because of minimal adverse drug reactions. Earlier referral could be achieved because of earlier detection of abnormal labour by partograph. Thus it ensures reduction of maternal and foetal morbidity and mortality by preventing prolonged labour.

Thus we can definitely conclude that promising beneficial effects of Drotaverine HCl are available in Obstetric practice and in our study it has definitely proven to shorten the duration of labour (active phase), without affecting the uterine contraction and providing early relief from distress for the labouring women.

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