A Comparative Study on Effectiveness of Drotaverine on **Cervical Dilatation during Labor**

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Abstract

Background:

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. Drotaverine hydrochloride is a non-anticholinergic isoquinoline derivative which acts by elevating intracellular cyclic Adenosine Mono Phosphate (cAMP) and cyclicGuanosine Mono Phosphate (cGMP) promoting smooth muscle relaxation.

Materials And Method:

This was a prospective study done at NMCH Obs. & Gyn. department Patna. 200 patients in labour were selected based on various inclusion and exclusion criteria. 100 cases of women in active phase of labor received injection drotaverine hydrochloride 40 mg (group i) and 100 cases of women did not receive any drug (group ii). Variables like maternal age, interval between administration of drug and delivery, mode of delivery, apgar score at 5 minutes, NCU (Neonatal Care Unit) admission and neonatal outcomes were recorded. Results:

The mean interval between drug adminstration to delivery in primipara and multipara in group i was 3.15 hours and 2.21 hours while in group ii was 4.3 hours and 3.70 hours respectively. The mean interval between drug administration and delivery was shorter in both groups of multipara. In group i, 96% had normal delivery and 4 % had vaccum delivery and in group ii 90% and 10% had normal delivery and vacuum delivery respectively. None of the participants had caeseraian section. There were no perinatal mortalities. *Conclusion: Drotaverine is a potent and safe cervical dialator.*

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Introduction : I.

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. The rate of cervical dilatation is one of the most important factor that determines the duration of labor and is the result of all driving force of uterine contraction acting against passive tissue resistance¹.Modern times, "Active Management" trends towards curtailing the total duration of labour compatible with the safety of the mother and foetus².

Labor is a multifactorial process which involves myometrial contraction, cervical ripening and dilatation, expulsion of fetus and placenta in an orderly manner. The first stage of labor lasts for about 12-16 hours in primigravida and for 6-8 hours in multigravida³. Active phase of labor is said to commence when cervical dilatation is of 3-4cm or more in the presence of regular uterine contraction. Active phase in nulli-para lasts for an average of 5 hours, where as in multi-para it is 3.5 hours. Pharmacological agents are used to facilitate the cervical dilatation in harmony with good uterine contractions for smooth progress of labor⁴.

Drotaverine is a non-anticholinergic iso-quinoline derivative. It acts by inhibiting phosphodiesterase-4 selective to smooth muscle, elevates intracellular cAMP and cGMP and promotes smooth muscle relaxation due to change in membrane ionic fluxes and membrane potential. It has been used orally as well as parenterally for intestinal, renal, bilary and uterine spasms and do not have anticholinergic side effects. Adverse effect reported are headache, dizziness, constipation, flushing and hypotention¹ is mainly excreted by non-renal route and has half-life of 7-12 hours⁵.

II. Materials And Method:

This was a hospital based prospective comparative study. The study was conducted at Nalanda Medical Collage and Hospital, Patna, a tertiary level hospital. Duration of study was one year. Data were collected from 1st May 2020 to 30th April 2021.

Inclusion criteria

- Primigravida multigravida up to 4th gravida.
- Age 18-30 years
- Period of gestation 37-42 weeks
- Singleton pregnancy with cephalic presentation
- Uterine contractions of 2-3 in 10 min lasting for 3040 sec
- Cervical dilatation around 3cms and 25-50% effaced
- Pelvis was adequate

Exclusion Criteria

Pregnant woman with

- Multiple Fetuses
- fetal demise
- fetal anomaly
- pre-eclampsia, eclampsia
- chronicsystemic diseases
- induced labor or augmented labor
- preterm labor
- premature ruptures of membrane

Total of 200 cases were enrolled in the study. 100 patients were given injection drotaverine hydrochloride (40 mg) intravenously at an interval of 2 hours upto max of 3 injections (group i) and 100 patients were not given drotaverine hydrochloride (group ii).

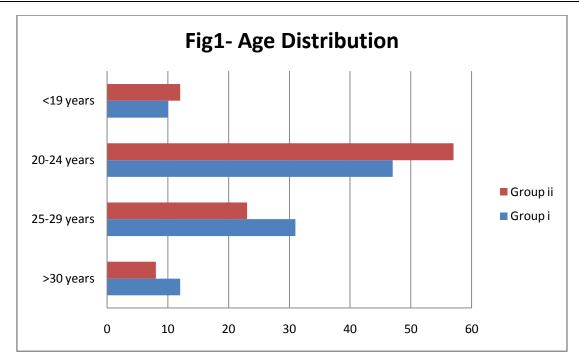
On admission detailed history was taken, complete general physical examination was made. Careful obstetric examination confirmed the lie, presentation, position of the foetus and FHP. Vaginal examination was made and the state of cervix (Dilatation, consistency and effacement) station of the vertex and type and adequacy of the pelvis was noted. Investigations including Hemoglobin level, Blood group and Random Blood Sugar (RBS) were done.

Continuous monitoring of maternal and fetal conditions were done by duty doctor/duty staff. Fetal heart rate was recorded every half an hour in early active first stage of labor and every 15 minutes in advanced first stage of labor. In the second stage, fetal heart rate was recorded every five minutes and in the pushing phase after every contraction. Per vaginal examination was done every 4 hours.. All the progress of labor were graphically recorded in Partograph.

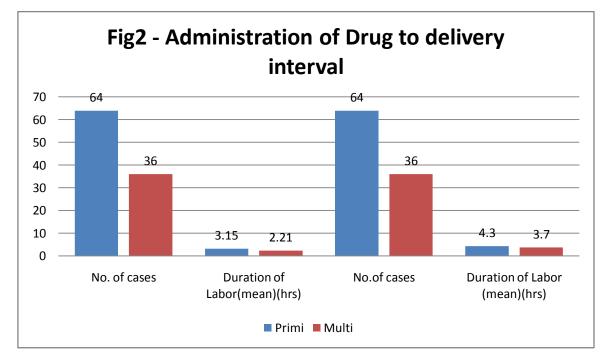
Hospital protocol was followed in cases of slow progress of labor. Amniotomy with or without syntocinone drip was used in cases of slow progress of labor. Mother and baby were followed up till discharge. Data analysis was done using SPSS program and was depicted as tables, diagrams, and chart.

III. Results:

Our study revealed that there was no significant difference in age group between two groups. Most of the women were in the age group of 20-24 years (52%), 27% were in the age group 25-29 years, 11% in less than 19 years group and 10% in more than 30 years group (figure 1).



Total duration of time taken from administration of drotaverine up to delivery was recorded in hours. In group i the time taken in primipara was 2.4 - 4.1 hours (mean 3.15 hrs) and 1.18 -2.6 hrs (mean 2.21hrs) in multipara. In group ii it was 2.36-6.21hrs in primipara (mean 4.3 hrs) and 3.1-4.4 hrs (mean 3.70hrs) in multipara mean. There was significant difference in interval between administration of drug to delivery among the two groups in both primipara and multipara (Figure 2).



Ten patient (10%) in group i required oxytocin augmentation without amniotomy and twenty patient (20%) in group ii needed oxytocin augmentation among which three cases also required amniotomy. (Table 1). In group i, 4 cases had vacuum delivery for fetal distress in second stage of labor while 10 cases (4 for

prolonged second stage and 6 for fetal distress) had vacuum delivery in group ii. Four babies were admitted for meconium aspiration syndrome in group i, 4babies with birth asphyxia and 6 babies with meconium aspiration syndrome wereadmitted to NCU in group ii (Table 2).

All babies were born alive. There was no any neonatal mortality in the study (Table 3).

Augumentation With	Group i		Group ii	
Augumentation with	Ν	%	Ν	%
Amniotomy	00	00	6	6
Syntocinone	10	10	20	20

Table 1: Need for augmentation of labor by amniotomy with or without syntocinon

Augumentation With	Group 1		Group ii		
	Ν	%	Ν	%	
Amniotomy	00	00	6	6	
Syntocinone	10	10	20	20	

Neonatal Outcome Admission to NCU	Group	i	Group ii		
Nonatal Outcome Admission to Ne O	N	%	Ν	%	
Birth Asphyxia	00	00	4	4	
Meconium aspiration Syndrome	4	4	6	6	

Table 2: Admission of newborn in NCU

Table	3:	Neonatal	Outcome	
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Neonatal Outcome	Group i		Group ii		
	Ν	%	Ν	%	
Alive	100	100	100	100	
Still Birth	00		00		
Neonatal Death	00		00		

IV. **Discussion:**

In this study there was no significant difference in age group between the two groups. No side effects were observed in patients who received drotaverine hydrochloride.

There was significant difference in time interval between drug adminstration to delivery in the two groups. The mean interval between drugadminstration to delivery was shorter in cases of multipara in comparision to primipara in both groups. The mean duration in primipara was shorter in the drotaverine group compared to the primipara in the control group. Similar observation was found by Sharma JB et al^3 where the mean injection to delivery interval was 194 min in primipara and 412.8 min in control group.

Decrease in first stage of labor can be attributed to the action of drotaverine. Study by Veronica Irene Yuel et et al.⁶ have shown drotaverine hydrochloride to be a superior cervical dilatating agent than other antispasmodics like epidosin or buscopan.Majumder S et.al.⁷ concluded that drotaverine causes more rapid acceleration and in their study the first stage of labor was 176.67+/-91.69 min.

In group i of our study, two had vacuum delivery for fetal distress in second stage of labor while 5 cases had vacuum delivery in group ii (2 for prolonged second stage and 3 for fetal distress). None of the cases in any of the two group had cesarean section. This may be due to the fact that the cases selected were already in established labor and they had no other high risk factors. The mode of delivery in drotaverine group of our study was vaginal in 100% of the cases which is similar to J.B. Sharma et. al³. Our findings of vaginal delivery as predominant mode of delivery is similar to these studies and is likely due to careful selection of the cases.

There was no baby with apgar score less than 3 in both group. There were 4 babies delivered by vacuum for fetal distress in group i. 10 babies had apgar score less than 7 in group ii.

In Group i, 4 babies were admitted for meconium aspiration syndrome while in group ii, 4 babies with birth asphyxia and 6 babies with meconium aspirationsyndrome were admitted to NCU. All babies were born alive. There was no any neonatal mortality.

Conclusion: V.

The administration of drug drotaverine hydrochloride is effective in shortening duration of active phase of labor in both primigravidae and multigravida with no major fetomaternal side effects. To concludedrotaverine is the drug of choice in active management of labor for a convenient and shorter delivery.

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