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RESEARCH ARTICLE

EFFICACY OF DROTIN & EPIDOSIN IN CERVICAL DILATATION DURING LABOUR- ACOMPARATIVE STUDY

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Abstract

Background:

Labour is a normal physiological process, progress of which depends upon the strength and
frequency of uterine contractions and simultaneous active cervical dilatation. But sometimes active cervical dilatation lags behind even though there is presence of uterine contraction and causes pain abdomen, prolongation of labour which can hamper both maternal and foetal health. Hence comes the need to use the cervical dilators to encourage the cervical dilatation to compete with the frequent uterine contractions and facilitates the labour process. Valethamate Bromide (VB) belongs to those groups of drugs which can be used as a cervical dilator in need. Now a day, the use of VB has become very less in comparison with other cervical dilators and reason is not clearly established yet.

Aim & Objectives:

To Evaluate the acceleration effect of Drotin and Epidosin on the dilatation of the cervix in both primigravidae and multigravida and compare it with control group.

To note the time interval between injection (of Drotin and Epidosin) and delivery and compare it with control group.

To determine deleterious side effects if any of the drugs affecting either mother or foetus

Methods/Study Design:

It was an interventional, hospital based study done in Department of Obstetrics and Gynaecology Kasturba Hospital,BHEL,Bhopal from 2006 to 2007, India. After taking necessary permissions for the study, total 150 primi gravida patients without any obstetrical abnormality and contraindications to the drugs, were selected randomly for twelve months. Three equal (50 each) groups were formed to satisfy each objective separately. All of the drugs were given intramuscularly only in first stage of labour following the prescribed doses. Necessary clinical evaluations were done at a regular interval and collected data were analyzed with SPSS software.

Results/Findings:

Intramuscular administration of Drotaverine injection in the dilation phase of uncomplicated pregnancies significantly reduces the

dilatation phase. It reduces the duration of active phase of labour by 30% in both primi and multi group.Intramuscular administration of Epidosin reduces the duration of active phase of labour in primi by 16% and in multi by 25%.Rate of cervical dilatation showed an increase of 0.23 cm/hr in primi Epidosin group and 0.519 cm/hr in primi Drotin group. Whereas in multi Epidosin group it was 0.44 cm/hr and 0.62 cm/hr in multi Drotin group as compared to control group. Thus the rate of cervical dilatation was maximum in Drotin group.As the number of injections required by patients in Drotin group was less as compared to Epidosin group, the cost effectiveness and patient compliance was increased with Drotin. Oxytocin augmentation required in Drotin and Epidosin group was in 8% and 6% cases respectively as compared to 12% in Control group. Thus the drugs do not reduce the tone of uterine contractions rather cause normalising of irregular uterine contractions.

Duration of second and third stage of labour were not affected by Drotin and Epidosin.

Drotin did not reduce the uterine tone in the period following delivery.Apgar Score in Drotin group at 1 min and 5 min was 9.5 and 9.98 whereas in Epidosin it was 9.2 and 9.8 & in Control it was 9.12 and 9.8 respectively.Observing the Apgar Score can be concluded that the drugs do not interfere with uteroglacental circulation.Neonatal complication in all three groups were more or less equal.Epidosin had higher rate of side effects on mother as compared to Drotin. Tachycardia was seen in 12% cases, flushing of face in8% nausea and vomiting in 4% and dryness of month in 10% cases.

Whereas only nausea and vomiting was seen in 8% cases of Drotin and one patient complained of dizziness. Incidence of PPH was equal in all three groups (4%) thus Drotin and Epidosin do not reduce the uterine tone in the period following delivery. None of the patients in Drotin group had cervical tear whereas 2 each in Epidosin and Control Group had Cervical Tear. Thus Drotin helps in reducing incidence of cervical tear. Drotin is a safer and convenient approach towards acceleration of labour. Maternal complications were also fewer in patients treated with Drotin as compared to Epidosin.

Study Limitations:

It was single handed study done on small population and many clinical correlations
were overlooked to focus the aims only.

Conclusion:

Leaving the contraindications in normal pregnancy with no abnormal obstetric problems Drotin is a safer and convenient approach towards acceleration of labour. Maternal complications were also fewer in patients treated with Drotin as compared to Epidosin.

Thus it can be concluded that Drotaverine is a new aid in the management of a convenient, shorter, physiological and uncomplicated delivery

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INTRODUCTION

A labour which is unduly prolonged is likely to give rise to one or more of three types of distress, namely maternal, foetal or "Obstetricians" of the three the last may be easily the most dangerous! (Donald).

Labour is a normal physiological process of expulsion of foetus and placenta from mothers' womb. Progress of labour depends upon the strength and frequency of uterine contractions to force the foetus towards outside where simultaneous active cervical dilatation makes the way for it. This is controlled by nature and sequential hormonal interplay effective both on uterus and cervix. But sometimes active cervical dilatation lags behind even though there is presence of uterine contraction and causes pain abdomen, prolongation of labour which can hamper both maternal and foetal health even lead to mortality. Here comes the need to use the cervical dilators from external sources to encourage the cervical dilatation to compete with the frequent uterine contractions and facilitates the labour process.

There are many procedures to dilate cervix with external resources which included medications which intern includes various kind of drugs. As days progress, the choice of drugs in cervical dilation is being changed. Daily practices say that the choice also varies from physician to physicians.

Valethamate Bromide (VB) is chemically Diethyl(methyl)(2-(3-methyl-2-phenylvaleryloxy)ethyl)ammonium bromide with C19H32NO2Br as molecular formula, 386.37
molecular weight and belongs to those groups of drugs which can be used as a cervical dilator in need. Epidosin a cholinergic blocker or parasympatholytic is used in obstetric practice as spasmolytic via in the treatment of cervical spasm. It brings about acceleration of labour reduces sensitivity to pain while consciousness is retained. It has selective action on the cervico uterine plexus it brings about the dilatation of cervix rapidly and more so by better coordination of contraction. Now a day, the use of VB has become very less in comparison with other cervical dilators and reason is not clearly established yet.

Drotin (Drotaverine Hydrochloride) is a musculotropic drug acting directly on smooth muscle cells. The action does not involve the autonomic nervous system. It produces smooth muscle relaxation particularly where spasm exists.

In the present study Drotin is evaluated for the same purpose and is compared with the commonly used drug Epidosin.

AIMS AND OBJECTIVES

1) To Evaluate the acceleration effect of Drotin and Epidosin on the dilatation of the cervix in both primigravidae and Multigravidae and compare it with control group.

2) To note the time interval between injection (of Drotin and Epidosin) and delivery and compare it with control group.

3) To determine deleterious side effects if any of the drugs affecting either mother or foetus.

MATERIAL AND METHODS

The present study has been under takenin the Department of Obstetrics and Gynaecology Kasturba Hospital,BHEL,Bhopal from 2006 to 2007. The cases were selected randomly from the patients admitted in the labour room and divided into 3 groups.
Cases were equally grouped as follows :-

1. Group A-50 cases where no drug was given, this was the control group.

2. Group B -50 cases where intramuscular injection of Epidosin was given at 3cm dilatation of cervix. Each ampoule of 1 ml contains 8 m.g. of Valethamate bromide given I/M every 1 hourly.

3. Group C-50 Cases where intramuscular injection of Drotin was given during active phase of labour i.e., at 3 cm cervical dilatation. Drotaverine hydrochloride 40 mg. (one ampoule) was given 1 m every 2 hours.

Methods/Study Design

Three equal (50 each) groups were formed to satisfy each objective separately.
All of the drugs were given intramuscularly only in first stage of labour following the prescribed doses. Necessary clinical evaluations were done at a regular interval and collected data were analyzedwith SPSS software.

• Study design: It was a interventional, hospital based, descriptive study

• Study area: Dept. of Gynaecology and Obstetrics, Kasturba Hospital ,BHEL,Bhopal, India.

• Study period: 12 months

• Study population: 150 patients were randomly selected for the study throughout the 12 months period of study.

• Exclusion criteria: Patients with serious illness, obstetrical abnormality, contraindication to the drugs or associated diseases were not allowed to be a part of the study.

Tools:

1. Informed consent form

2. Injection Valethamate Bromide, Drotaverine HCl, samples, placebo injections, disposable syringes with needles.

3. Stopwatch.

4. Computer with statistical software

Methodology

Ethical Safeguard: Necessary permission from Institutional Ethical Committee was taken as ethical committee clearance. All the participants were taken from Antenatal Ward of Kasturba Hospital. They were requested to volunteer for the study only after filling up and signing the detailed informed consent form which was written in their own local language . Illiterate participants were requested to come along with a literate family member or friend to do the job on behalf of them.

Sample distribution: Total of 150 patients was blindly divided into three equal parts with 50 patients in each and each part was used to satisfy single aim.Group A-50 cases where no drug was given, this was the control group.Group B -50 cases where intramuscular injection of Epidosin was given at 3cm dilatation of cervix. Each ampoule of 1 ml contains 8 m.g. of Valethamate bromide given I/M every 1 hourly.Group C-50 Cases where intramuscular injection of Drotin was given during active phase of labour i.e., at 3 cm cervical dilatation. Drotaverine hydrochloride 40 mg. (one ampoule) was given 1 m every 2 hours. All drugs were given in perfect doses according to pharmacology.

Data compilation/collection: All necessary data were collected at proper time after an injection were applied and stored in softcopy format in computer with a back up.

Statistical analysis: Variable data were put into statistical software and analyzed with sincerity.

Report Writing: With all data and statistical values in hand report was written in scientific way with wide range of information for reader in a short space and was submitted to authority concern.

OBSERVATION

Present study was done to evaluate the efficacy the efficacy of Drotin and Epidosin on cervical dilatation. One hundred and fifty cases were studied in the Department of Obstetrics and Gynaecology at,Kasturba Hospital, BHEL, Bhopal from 2006 to 2007.

Cases were equally grouped as follows :-

1. Group A-50 cases where no drug was given, this was the Control group.
2. Group B -50 cases where intramuscular injection of Epidosin was given at 3cm dilatation of cervix. Each ampoule of 1 ml contains 8 m.g. of Valethamate bromide given I/M every 1 hourly.
3. Group C-50 Cases where intramuscular injection of Drotin was given during active phase of labour i.e., at 3 cm cervical dilatation. Drotaverine hydrochloride 40 mg. (one ampoule) was given 1 m every 2 hours.

TABLE NO. – 1

AGE WISE DISTRIBUTION OF CASES

Age in Years	Control Group		Epidosin Group		Drotin Group	
	Nos.	%	Nos.	%	Nos.	%
≤ 20	12	24	12	24	13	26
21 – 25	22	44	23	46	22	44
26 -30	9	18	9	18	9	18
≥ 31	7	14	6	12	6	12
Total	**50**	**100**	**50**	**100**	**50**	**100**

Table 1 Shows age incidence in all three group majority of the patients belonged to age group 21 – 25 in all three groups.

TABLE NO. – 2

PARITY WISE DISTRIBUTION OF CASES

Parity	Control Group		Epidosin Group		Drotin Group	
	Nos.	%	Nos.	%	Nos.	%
0	25	50	25	50	25	50
I	13	26	13	26	14	28
II	12	24	12	24	11	22

Table II shows parity wise distribution of cases in all three group 50% cases were primiparous and 50% were multiparous.

OUT COME OF LABOUR

The patients who were chosen for study were essentially those in whom there was no gynecological or obstetrical complications. It was thereby foreseen that the course of labour would be normal. During the study few patients mainly of the control group needed intervention to protect the body and the mother. The results have been outlined in the table below.

TABLE NO. – 3

OUT COME OF LABOUR IN PRIMI

Mode of Delivery	Control Group		Epidosin Group		Drotin Group	
	Nos.	%	Nos.	%	Nos.	%
Spontaneous Vaginal Del.	22	88	24	96	23	92
Forceps	2	8	1	4	1	4
LSCS	1	4	-	-	1	4

The incidence of spontaneous vaginal delivery in primi Drotin group was 92% (23 patients) One patient had undergone lower segment caesarean section indication being foetal distress the baby had tight loop of cord around the neck. One patient was delivered by outlet forceps application for prolonged II stage.

In Primi Epidosin group 96% (24 patients) had spontaneous vaginal delivery 1 patient (4%) was subjected to outlet forceps delivery Indication being vaginally 2 patients (8%) were subjected to outlets forceps application indication in both being foetal distress. In primi control group 88% cases (22 patient) delivered vaginally 2 patient (8%) were subjected to outlet forceps indication in both being foetal distress one had undergone caesarean sections indication being nonprogress of labour.

TABLE NO. – 3

OUT COME OF LABOUR IN MULTI

Mode of Delivery	Control Group		Epidosin Group		Drotin Group	
	Nos.	%	Nos.	%	Nos.	%
Spontaneous Vaginal Del.	24	96	23	92	25	100
Forceps	-	-	-	-	-	-
LSCS	1	4	2	8	-	-

All Patient in multi Drotin group had spontaneous vaginal delivery. In multi Epidosin group 23 patients (92%) delivered vaginally where as 2 patient had undergone LSCS for foetal delivered vaginally where as 2 patient had undergone LSCS for foetal distress.

In multi control group one patient had undergone LSCS for Foetal distress.

DOSAGE SCHEDULE
DROTIN GROUP

This group received 1 ampoule injection Drotin at 2 hrly interval by intramuscular route. The dose was repeated if required.

TABLE NO. – 5

DOSAGE SCHEDULE IN PRIMI DROTIN GROUP

Drug (mg) Drotin	Parity Primi	Nos.	%	No. of inj. Received
40	-	15	60	1
80	-	7	28	2
120	-	1	4	3
160	-	2	8	4

Above table shows the relation of no. of injection received by the primi patients. It is evident that 15 (60%) of patients delivered after single dose. 7 patients (28%) delivered after receiving 2 injections 1 patient required 3 and 2 patient required 4 injections respectively given at an interval of 2 hrs when required.

TABLE NO. – 6

DOSAGE SCHEDULE IN MULTI DROTIN GROUP

Drug (mg) Drotin	Parity Multi	Nos.	%	No. of inj. Received
40	2	18	72	1
80	2	4	16	2
120	1	2	8	3
160	1	1	4	4

Maximum no. of patients 72% i.e. 18 patient delivered after single (one) injection Drotin. 4 patients (16%) delivered after 2 injections 2 patients (8%) and 1 patient (4%) delivered after 3 and 4 injections respectively given at an interval of 2 hours or when required.

GROUP – B EPIDOSIN GROUP

This group of patient received 1 ampoule inj. Epidosin intramuscularly at hourly interval.

TABLE NO. – 7

DOSAGE SCHEDULE IN PRIMI DROTIN GROUP

Drug (mg) Drotin	Parity Primi	Nos.	%	No. of inj. Received
16	-	4	16	2
24	-	4	16	3
32	-	9	36	4
40	-	5	20	5
48	-	3	12	6

Maximum no. of primi patients 9 (36%) delivered after receiving 4 injections (32 m.g.), 3 patients (12%) required 6 injections (48 m.g.), 5 delivered after receiving 5 injections (40 m.g.), 4 patients delivered after receiving 2 inj and 4 after receiving 3 injection.

TABLE NO. – 8

DOSAGE SCHEDULE IN MULTI DROTIN GROUP

Drug (mg) Drotin	Parity Multi	Nos.	%	No. of inj. Received
16	2	7	28	2
24	2	4	16	3
32	1	9	36	4
40	1	3	12	5

48	1	2	8	6

7 (28%) multi patients in Epidosin group delivered after receiving 2 injections , 4 patients (16%) delivered after receiving 3 injections 9 patients (36%) after 4 injections 2 patient required 6 injections and 5 injections were given to 3 (12%) patient in multi Epidosin group.

TABLE NO. – 9

MEAN DURATION OF 1ST STAGE OF LABOUR

Parity	Control	Epidosin	Drotin
Primi S.D.	11 hrs 12 min ± 2 hrs. 17 min	9 hrs 14 min ± 1 hr. 25 min	8 hrs 31 min ± 1 hr. 46 min
Multi S.D.	8 hrs 58 min ± 1 hr. 6 min	7 hrs 37 min ± 1 hr. 56 min	6 hrs 49 min ± 1 hr. 46 min

The mean duration of 1st stage of labour in primi control group was 11 hrs 12 min ± 2 hrs 14 min. In primi Epidosin group duration of first stage of labour was 9 hr 14 min ± 1 hr 25 min. In primi Drotin group was 8 hrs 31 min ± 1 hr 46 min. There was shortening in mean duration of Epidosin and Drotin group by 1 hr 58 min (18%) and 2 hr 41 min (24%) respectively in primi patients.
Mean duration of 1st stage of labour in multi control group was 8 hrs 16 mins ± 1 hr 21 min in Epidosin group it was 7 hrs 37 min and in multi Drotin group it was 6 hrs. 49 min ± 1 hr 46 min. Thus showing reduction in 1st stage of labour in Epidosin and Drotin group by 1 hr 21 min (15%) and 2 hr 09 min (24%) respectively in multi patients.

TABLE NO. – 10

MEAN DURATION OF ACTIVE PHASE OF LABOUR

Parity	Control	Epidosin	Drotin
Primi S.D.	5 hrs 48 min ± 1 hr. 23 min	4 hrs 53 min ± 1 hr. 36 min	4 hrs 7 min ± 1 hr. 28 min
Multi S.D.	4 hrs 43 min ± 1 hr. 7 min	3 hrs 42 min ± 1 hr. 21 min	3 hrs 19 min ± 1 hr. 4 min

The mean duration of active phase of labour in primi control group was 5 hrs. 48 min ± 1 hrs 23 min whereas in Epidosin and Drotin group it was 4 hrs 53 min ± 1 hr 36 min and 4 hrs 7 min ± 1 hr 28 min respectively.
Showing reduction in duration of active phase by 1 hr 41 min in Drotin group and 58 min (16%) in Epidosin group. In multi control group mean duration of active phase of labour was 3 hrs 42 min ± 1 hr 21 min In multi Drotin group the mean duration of active phase of labour was 3 hrs. 19 min ± 1 hr 4 min. Thus showing reduction in Drotin group by 1 24 min (29%) and in Epidosin group by 1 hr 4 min (22%).

INJECTION DELIVERY INTERVAL \ OBSERVATION DELIVERY INTERVAL

The effect of drugs are on the active phase of labour or stage of cervical dilation. Injection / Observation Delivery interval was taken as the duration for delivery after administration of injection Drotin or Epidosin or when the patient had entered the active phase of labour in control group.

TABLE NO. – 11

INJECTION – DELIVERY INTERVAL / OBSERVATION DELIVERY INTERVAL

Parity	Control	Epidosin	Drotin
Primi S.D.	6 hrs 14 min ± 1 hr. 30 min	5 hrs 13 min ± 1 hr. 33 min	4 hrs 21 min ± 1 hr. 33 min
Multi S.D.	4 hrs 58 min ± 1 hr. 5 min	3 hrs 56 min ± 1 hr. 20 min	3 hrs 32 min ± 1 hr. 42 min

Injection / Observation delivery interval – As shown in above table I-D interval in primi Drotin group is 4 hrs. 21 min. and in primi Epidosin group was 5 hrs 13 min ± 1 hr 33 min . whereas in control group it was 6 hrs 14 min ± 1 hr 30 min.

In multi Epidosin group it was 3 hrs 56 min ± 1 hr 20 min in multi Drotin group it was 3 hrs 32 min ± 1 hr 42 min. In multi control group it was 4 hrs 58 min ± 1hr 5 min.

TABLE NO. – 12

DURATION OF 2nd STAGE OF LABOUR

Parity	Control	Epidosin	Drotin
Primi S.D.	23 min 5 sec ± 8 min 6 sec	22 min 25 sec ± 6 min 1 sec	21 min 17 sec ± 2 min 25 sec
Multi S.D.	15 min 45 sec ± 5 min 15 sec	13 min 54 sec ± 5 min 18 sec	14 min 2 sec ± 5 min 36 sec

The above table shows the duration of II stage of labour in all three groups. The drug does not affect the second stage of labour.

TABLE NO. – 13

DURATION OF 3rd STAGE OF LABOUR

Parity	Control	Epidosin	Drotin
Primi S.D.	10 min 42 sec ± 3 min 14 sec	10 min 25 sec ± 4 min 31 sec	10 min 17 sec ± 2 min 25 sec
Multi S.D.	9 min 25 sec ± 3 min 13 sec	9 min 15 sec ± 3 min 6 sec	10 min ± 4 min 6 sec

The above table shows the duration of III stage of labour and the drug does not prolong the third stage of labour.

TABLE NO. – 14

RATE OF CERVICAL DILATATION (in cm/hr.)

Parity	Control	Epidosin	Drotin
Primi	1.2 cm/hr	1.43 cm/hr	1.719 cm/hr
Multi	1.48 cm/hr	1.88 cm/hr	2.11 cm/hr

The rate of cervical dilation in primi control group was 1.2 cm/hr whereas in Epidosin group it was 1.43 cm/hr and in Drotin group it was 1.719 cm/hr showing an increase by 0.23 cm/hr and 0.519 cm/hr by Epidosin and Drotin group respectively.

The rate of cervical dilatation in Multigravidae control group was 1.46 cm/hr. in Epidosin group it was 1.88 cm/hr and in Drotin group it was 2.11 cm/hr. Thus there occurred increase in rate of cervical dilatation in multi Epidosin group by 0.44 cm/hr and multi Drotin group by 0.62 cm/hr.

TABLE NO. – 15

APGAR SCORES

Score	Control	Epidosin	Drotin
1 min	9.12	9.2	9.5

5 min	9.84	9.89	9.98

Above table shows apgar scores at 1 min and 5 min in all three groups Apgar score at 1 min was 9.12, 9.2 and 9.5 in control Epidosin and Drotin group respectively. Apgar score at 5 min was 9.84, 9.89 and 9.98 in control Epidosin and Drotin group respectively. Only one baby in Drotin group had moderate asphyxia at 1 min (score 7) recovered after resuscitation (score 9) at 5 min.

One baby of Epidosin group had severe birth asphyxia at birth score at 1 min was 4 and at 5 min it was 7 baby was discharge on 5th day from Nursery. 2 babies in control group had severe birth asphyxia at birth one of them improved after resuscitation and was discharged on 5th day while other baby had severe birth asphyxia even after 5 min and had neodeath on 2nd day.
Rest of the babies had Apgar score of > 7 at 1 min and 5 min after birth.

TABLE NO. – 16

NEONATAL OUTCOME / COMPLICATIONS

Complication	Control	Epidosin	Drotin
Birth Asphyxia	2	1	1
Neonatal Jaundice	2	2	1

Table – 16 shows neonatal complications in all three groups. Complication are more or less equal in all three groups.

TABLE – 17

SIDE EFFECTS

Side Effects	Epidosin		Drotin	
	Nos.	%	Nos.	%
Tachycardia	6	12	-	-
Flushing of face	4	8	-	-
Nausea/ vomiting	2	4	4	8
Dryness of mouth	5	10	-	-
Dizziness	-	-	1	2

Only 4 patients in Drotin group (8%) had nausea and vomiting and done one patient (26%) 5 complained of dizziness whereas in Epidosin Group 6 patients (12%) had tachycardia 4 patients (8%) had flushing of face and 2 patients (4%) complained of nausea / vomiting 5 patients (10%) had dryness of month.

TABLE – 18

MATERNAL COMPLICATION

Complication	Control Group		Epidosin Group		Drotin Group	
	Nos.	%	Nos.	%	Nos.	%
Prolonged II stage	-	-	-	-	1	2
P.P.H.	2	4	2	4	2	4
Vaginal Tear	1	-	1	2	2	4
Cervical Tear	2	4	2	4	-	-

Table 18 shows maternal complications in all 3 groups incidence of postpartum haemorrhage was same in all three groups PPH was mild in nature and none of the patients required blood transfusion. One patient of the Drotin group the had prolonged II stage for which outlet forceps were applied. 2 patients in Drotin group had vaginal tear one each in Epidosin and control group also had vaginal tear.

None the patients in Drotin group had cervical tear whereas 2 each in Epidosin and control group had cervical tear.

DISCUSSION

One of the most important stagesof labour is the so called dilatation stage which lasts from the beginning of the labour to the effaced dilated cervical os.The duration of the dilatation stage depends a lot on the initial finding of the uterine cervix, uterine contractions (pains) the parturients constitutional type and whether the delivery is first or not.Distraction dynamics are of great importance for the mother and the foetus. Prolonged dilatation stage (8 hrs) may lead to exhaustion and increased psychological burden on the mother and these events may be then the underlying cause of problems in expulsion stage in the peurperium.Attempts to reduce the cervical dilatation have continuously been made by obstetricians.

Present study was done to evaluate the effect of Drotin and Epidosin on cervical dilatation and to compare it with control group. The analysis of one hundred and fifty cases is presented in this study, out of which fifty cases were of augmentation with Drotin, fifty cases of Epidosin and fifty cases were of normal labour with nil augmentation this was the control group all the cases were identical with respect to parity and gestational age (37-41 weeks)

AGE :-

In the presentstudy majority of the patients belonged to age group of 21-25 yrs. in all three groups. This is because in India, the trend is towards early marriage and child bearing.

PARITY :-

In the present study equal no of cases were taken out of 50 cases 50% (25 cases) were primigravidae and 50% (25 cases) were multiparae in each respective group so the study comprises of identical cases regarding parity in each group.

OUTCOME OF LABOUR :-

As both the Drotin and Epidosin reduce the duration of 1st stage less operative interferences was required in these two groups. in comparison to control group.

In present study 92% of primi Drotin group had spontaneous vaginal delivery. 4% had forceps delivery for prolonged II stage and 4% (One case) was delivered by Caesarean section for foetal distress as baby had one tight loop of cord around neck. All patients in multi Drotin group had spontaneous vaginal delivery. In primi Epidosin group 96% had spontaneous delivery, 4% (one patient) was delivered by outlet forceps application for foetal distress. In multi Epidosin group 92% patients delivered vaginally two patients had undergone LSCS for foetal distress. In primi control group only 88% cases delivered vaginally 8% were delivered by outlet forceps application both for foetal distress. One patient had undergone caesarean section, indication being non progress of labour. Hence it can be seen that the incidence of operative interference was least in Drotin group.

While in study conducted by Manju Puri, Sushila Rathore and Rashmi Garg (1988) no caesarean section was done in any of the group but vacuum extraction was done in 10 cases of Epidosin group and 1 case of control group the indication was inadequate bearing down and to cut short second stage of labour due to foetal tachycardia.In a study by S.N. Daftary (1991)[2,3] there was only 1 LSCS in Epidosin (given I/V)

DOSAGE SCHEDULE

In Drotin group 60% primi patients delivered after receiving 40mg. of Drotaverine (lamp.) 28% after 80mg. 4% after 120mg. and 8% after 160mg. (4amp.). Injections were given by intramuscular route.In majority of Multigravidae patients 72% required only 40mg. of Drotin 16% required 80mg. 4% required 120mg. and only 4% needed 160mg. (4 amp.).As the number of injections required were less, the cost effectiveness of the drug and patient tolerance was increased

In Epidosin primi group majority of patients 68% required 32- 48mg. (4-6 inj.) of Epidosin 32% patients delivered by 2-3 injections (16-24 mg.) of Epidosin. As the drug is given at more frequent intervals the cost effectiveness of the drug is less in comparison to Drotin.28% (7) of Multi Epidosin group required 2 inj. whereas rest 72% required 3-6 inj.

In a study conducted by Turi Blasko, S.J. Demeter (1998)[4]out of 100 members treated with Drotaverine, there were two patients in whom treatment had to be repeated once and in one patient two repetitions had to be made, 97 patients did not require a repeat dose.

Walter (1957) treated 106 cases with Epidosin during confinement. In most cases single intramuscular injection of Epidosin sufficed. Pathak et al (1976)[5], when the force of contraction of the uterus was normal (24 multiparae) the acceleration of normal labour process was good with Epidosin. However in case of hypotonic inertia the requirements of Epidosin injection was more (6 cases) in a study by Shrivastava M et al (1979)[6]. Out of 264 cases of normal labour, 114 were given Epidosin injections (8-24 mg.).

OXYTOCIN AUGMENTATION

In present study majority of patients in each group had normal uterine contractions .***Cases who were,who had hypotonic uterine contractions and were given oxytocin by i.v drip for augmentation of labour ; such patients were not included in the study to avoid Oxytocin as an confounding factor for shorter duration of labour.***Thus it was concluded that the drug, Drotin and Epidosin does not affect or reduce the tone of uterine contractions.

Farkas et al (1967)[7] in their studies with Drotaverine observed good effect in cases of violent and excessively painful contractions. They noted that labour pain loosing intensity remained regular as in normal labour. According to studies conducted by Walter (1957) there wasremarkable normalising of irregular uterine contractions. Schmidt (1957)[8]and Meir (1958)[9] noticed no effect on the tone of the uterus. These workers assessed the uterine tone clinically. Kishore (1979)[10] studied the tone of the uterus by tokometric method and corroborated the same.

EFFECT ON I STAGE OF LABOUR

Drotin was effective in reducing the duration of I stage of labour in primi by 2hours 41min. (24%) and in Multigravidae by 2 ins 9 min. (24%).Epidosin reduced the 1st stage of labour in primi group by 1 hr. 58 min (18%) and in multi by 1 hr. 21 min. (15%).In control group of the patient series, where no augmentation was given, primigravidae took on an average 11hrs. 21min. for full dilatation of the cervix. After augmentation with Drotin and Epidosin this duration was reduced to 8hrs 31 min. and 9 ins 15 min. respectively. In control group maximum no of Multigravidae patients on an average took 8 hrs 15 min. for 1st stage of labour whereas Drotin and Epidosin reduced this stage to 6 hrs. 49min. and 7 hrs. 37 min. respectively. So augmentation with Drotin and Epidosin causes definite reduction in the duration of 1st stage of labour.

In 1956 Beck noted that Epidosin caused reduction in the duration of the labour by 18-30%. In 1957 Walters reported that the period of labour was reduced by 21% in primipara and 17% in multiparas. In study by Walt H (1959) the period of labour was reduced by 2-4hrs.In 1982 the study by Sarin A.R[11]. found that the mean total duration of 1st stage of labour was 16 hours 26 min. and 17 hours 26 min. in test and control groups respectively in primiparas. In multiparas it was 8 hours in the test group 10 hr. 36 min. in control group. Epidosin shortened the mean duration of 1st stage of labour in primiparas by 1 hrs. 5 mm while in multiparas it was shortened by 2 hours 36 min.In a study conducted by Turi Blasko S.J. Demeter (1998)[4] the average time duration of the dilatation phase (in minutes) in group A (Drotaverine) was 183.6± 121.1 in group B (control group) was 236.2 ±138.6. There was significant difference between the two groups regarding the length of the dilatation phase.

Thus the present study shows significant reduction in duration of labour by both the drugs Epidosin and Drotin in primi and multiparae.

ACTIVE PHASE OF LABOUR

Criteria to use the drugs Drotin and Epidosin were, when the patient was in established labour i.e. there is atleast 3cm. cervical dilatation with partially effaced cervix with satisfactory uterine contractions atleast 3 contractions/ 10min.of 45 sec. duration. Thus the drug was used in patients who were in active phase of labour.

Thus in primi control group the active phase of labour was 5 hrs. 50 mm. approx. In primi Drotin group it was 4 hrs 7 mm. and in primi Epidosin group it was 4 his 53 min. Thus Drotin reduces the active phase of labour by 1 hr. 41 min. (29%) and Epidosin by 55 min. (16%) Reduction in active phase of multi Epidosin group was 22% and multi Drotin group 29%.

CERVICAL DILATATION

In present series the average rate of cervical dilatation was 1.719cm/ hr in primi Drotin group and 2.11 cm. /hr in multi Drotin group Drotin increases the rate of cervical dilatation by 0.519cm/hr in primiparas, while in multiparas it was increased by 0.62cm/hr.In Epidosin group mean rate of cervical dilatation was 1.43cm/hr in primiparas thus it increases the rate of cervical dilatation by 0.23cm/ hr in primigravidae. Rate of cervical dilatation in Multigravidae was 1.88cm/hr and it increased rate of cervical dilatation by 0.40cm/hr.

Sarine A.R. (1982)[11] observed increase in cervical dilatation by 0.036 cm/hr in primi Epidosin group and increase in 0.46cm/hr in Multigravidae Epidosin group. In 1992, Kuruvilla, S Jasper, P Mathai observed no difference in the rate of cervical dilatation between those who received Epidosin and those who received normal saline.

INJECTION/ OBSERVATION DELIVERY INTERVAL

The Injection delivery delivery interval closely followed the same trends as mean labour data. This confirms the view that Epidosin and Drotin are the main determinants in reduction of duration of labour. The 1-D interval in primi group was 4hrs 21 min. whereas in multi Drotin group was 3 hrs 32 min.In primi Epidosin group Injection - Delivery interval was 5hrs 13 min and in multi Epidosin group it was 3 hrs. 56 min.The observation delivery interval (when patient entered the active phase of labour till she delivered) in primi control group was 6 hrs. 14 min. in multi control group it was 4 hrs. 58min.Thus there was reduction by lhr. 53min. in Primi Drotin group, lhr. 26min..in multi Drotin group the reduction in primi Epidosin group was lhr. I min. and in multi Epidosin group it was by 1 hr. 2 min.

SECOND STAGE OF LABOUR

In present study mean duration of second stage of labour in Drotin group was 21 min. 17 sec. (± 2min. 25 sec.) in primi patients, and 14 min. 2 sec. (± 5 min. 36 sec.) in multi patients. In Epidosin group, mean duration of second stage of labour in primi patients was 22min. 25sec. (± 6 min. 1 sec.) and in multi patients it was 13 min 54 sec. (± 5 min.18 sec.).

In control group mean duration of second stage of labour in primi patients was 23 min. and 5 sec. (± 8 min. 6 sec.) and in multi patients it was 15 min. 45 sec. (± 5 min. 15 sec.).Overall there was no significant reduction in the second stage of labour in Drotin and Epidosin group. This shows the drugs Drotin and Epidosin mainly affect the dilatation phase of labour.

No Significant shortening of duration was noticed in second and third stage of labour in previous studies (on Epidosin) of Beck (1956), Walter (1957), and Schmidt (1957)[8].In study of S.N. Daftary (1991)[2,3] second and third stage of labour was unaffected by. I/V Epidosin. The average duration of II stage of labour was 30 min. in I/V Epidosin group, average duration of second stage of labour was 29 min. in UM Epidosin group and that in control group was 35 min.In study conducted by Turi Blasko (1998)[4] the average duration of second - stage (in minutes) in Drotin group was 15.2 ± 11.8 and in control group it was 13.7 ± 8.5.

THIRD STAGE OF LABOUR

In present study mean duration of third stage of labour in Primi Drotin group was 10 min. 17 sec. (± 2 min. 25 sec.) in multi Drotin group it was 10 min. (± 4 min. 6 sec.).Duration of third stage of labour in primi Epidosin group was 10 min. 5 sec. (± 4 min. 31 sec.) in multi it was 9 min. 15 sec. (±3 min. 6 sec.).In control group mean duration of third stage of labour in primi patients was 10 min. 42 sec. (± 3 m59. 14 sec.) and in multi patients it was 9 min. 25 sec. (±3 mm. 13 sec.).

Findings from the present study suggests that Drotin and Epidosin had no remarkable effect on duration of third stage of labour. It did not reduce the uterine tone in the period following delivery

In study conducted by Turi Blasko (1998)[4]average duration of the placental stage (in minutes) in Drotin group was 10.1 ± 4.0, and in control group it was 11.0 ± 6.3.There was no significant difference in perinatal blood loss in both groups.Vaidya PR and Rao G.S. (1984)[12] noted no significant shortening of third stage of labour with Epidosin.

APGAR SCORES

To determine the effect of acceleration of labour on the neonatal outcome APGAR scoring was carried out, on all babies at 1min. and 5min. after birth. There was no significant difference in the Apgar score of the babies delivered with the aid of Drotin and Epidosin as compared to control group. Mean Apgar Score in Drotin group babies at lmin. was 9.5 and at 5min. it was 9.98.Epidosin group babies had mean Apgar score of 9.2 and 9.89 *at 1 m*in. and 5min. respectively and that in control group it was 9.12 and 9.84 (at 1 min.) and 5 min. respectively from above findings it is evident that drugs [Drotin & Epidosin] has no toxic effect on the foetus).

In a study by S.N. Daftary et. al. (1991) there were two babies who were born with apgar score of less than 7 they required resuscitation but both the babies survived.

NEONATAL COMPLICATIONS

As Drotin does not crossthe placental barrier it did not had any adverse effect on neonatal outcome.Neonatal complications were more or less same in all three groups except for 1 neodeath in control group birth asphyxia occurred in 4% in control group, 2% in Epidosin, and 2% in Drotin group. One baby died (of control group) of birth asphyxia on 2nd day. Incidence of Neonatal Jaundice was 4% in control group, 4% in Epidosin, and 2% in Drotin group. All had mild jaundice which improved by conservative management only.

MATERNAL COMPLICATIONS

In present study nausea and vomiting occurred in 4% Epidosin, 8% Drotin, and 4% in control group. None of the patients in Drotin group had tachycardia whereas 12% patients of Epidosin group had tachycardia 8% had flushing of face and 10% had dryness of mouth.

Bhan at al[13] have also reported significant tachycardia in their study.In a study of Manju Puri et al (1980) tachycardia was noted in 40 cases of Epidosin group and 10 cases had flushing of face.One patient of Drotin group complained of dizziness there was no associated hypotension in the patient. Similarly Turi Blasko (1998)[4]did not Observe hypotension in a single case as the effect of Drotin. There was prolonged II stage of labour in 2% (1 patient) of Drotin group for which outlet forceps were applied. Incidence of postpartum haemorrhage was equal in all three groups (4%) which was mild and none of the patients required blood transfusion. So the incidence of atonia has not increased. Similar results have been observed by J. Demeter and Turi Blasko (1998)[4].Incidence of vaginal tear was 2% each in control and Epidosin group and 4% in Drotin group had cervical tear whereas 4% each in control and Epidosin group had cervical tears. None of the patients in Drotin group had cervical tear. In study conducted by Turi Blasko 1988)[4] there was significant difference observed between study and control group. Green (1969)[14] noted 2 cases, Joseph (1974)[15] noted one case of cervical tear in their series. Thus the drug protects from cervical tear.

CONCLUSION

The rate of cervical dilatation was maximum in Drotin group. As the number of injections required by patients in Drotin group was less as compared to Epidosin group, the cost effectiveness and patient compliance was increased with Drotin. The drugs do not reduce the tone of uterine contractions rather cause normalising of irregular uterine contractions. Duration of second and third stage of labour were not affected by Drotin and Epidosin. Drotin did not reduce the uterine tone in the period following delivery. Observing the Apgar Score,it can be concluded that the drugs do not interfere with uteroplacental circulation. Neonatal complication in all three groups were more or less equal. Epidosin had higher rate of side effects on mother as compared to Drotin.
Incidence of PPH was equal in all three groups (4%) thus Drotin and Epidosin do not reduce the uterine tone in the period following delivery. None of the patients in Drotin group had cervical tear . Thus Drotin helps in reducing incidence of cervical tear.

Drotin is a safer and convenient approach towards acceleration of labour. Maternal complications were also fewer in patients treated with Drotin as compared to Epidosin.

Thus it can be concluded that Drotaverine is a new aid in the management of a convenient, shorter, physiological and uncomplicated delivery

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