Effect of Epidosin Forte in Cervical Dilatation in Labour : A Placebo-Controlled Study

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Summary: The present study aimed at finding out the effect of double dose of Inj Epidosin (16 mg of Valethamate bromide) on duration of labour in uncomplicated primigravidae and multigravidae.

One hundred and fourteen randomly selected uncomplicated primi and multigravidae in established labour with cervix 3 cm. dilated, and having contractions of at least 2 per 10 mins were taken up for the study. Inj. Epidosin forte (16mg) was given intramuscularly every ½ an hour for 3 doses. Another 100 randomly selected primi and multigravid parturients receiving Inj. placebo in the same schedule served as control. Age, parity distribution, and duration of gestation were comparable in both the groups.

Monitoring was done clinically and results were plotted on partographs. Excluding the latent phase of labour, average duration of active phase of 1st stage of labour was 4.22 hrs. in primigravidae and 3.84 hrs. in multigravidae in the trial group. Rate of cervical dilatation was 1.42 cm/hr. in primigravidae and 1.56 cm/hr. in multigravidae. 2nd and 3rd stages of labour remained unaffected. No significant maternal and foetal complications were recorded.

Inj. Epidosin forte promises to be a good drug for acceleration of 1st stage of labour and a good answer for the problem of functional cervical dystocia.

Introduction

Efforts to cut short the duration of labour has been continuing in modern obstetrics. With the wide acceptance of active management of labour, primarily advocated as early as 1969 by O Driscoll et al (1984), concern over the problem of functional cervical dystocia has justifiably grown over the years. More and more clinical trials have been devoted to acceleration of labour. Curtailing the duration of labour has thwarted to a considerable extent the risks of prolonged labour, e.g. dehydration, infection, keto-acidosis etc. A shortened 1st stage of labour is naturally of bilateral advantage, both to the obstetrician and to the patient.

In the present study, the authors have observed the effect of intramascular Epidosin forte (16 mg) on duration of labour in uncomplicated primi and multigravidae.

Materials and Methods

This prospective study was carried out at North Bengal Medical College Hospital, Siliguri, West Bengal, from January'97 to July'97.

One hundred and fourteen uncomplicated primigravidae & multigravidae were randomly selected, and they were divided into the following two groups.

Group-I (Trial Group):
Patients receiving Inj. Epidosin forte-2ml (containing 16 mg of Valethamate bromide) intramuscularly ½ hourly x 3 such, n=114 comprising of 80 primigravidae and 34 multigravidae.

Group-II (Control Group):
Patients receiving Inj. Placebo 2 ml intramuscularly ½ hourly x 3 such, n=100 comprising of 72 primigravidae and 28 multigravidae.

In both the trial and control groups, age, parity distribution and period of gestation were comparable, as shown in Tables I, II & III.

Table-I
Age distribution

Age (Years)	Trial group %	Control group %
20	11.4	10
20-25	56.1	59
25-30	25.4	27
30	7.1	4

Table – II
Gravidity Distribution

Gravidity	Number	
	Trial group (%)	Control group
1	80 (70%)	72
2	22 (19.3%)	18
3	8 (7%)	6
4 or more	4 (3.5%)	4

Table-III
Period of gestation

Gestation in weeks	Group-I N=114	Group-II n=0
37	6	5
37-38	28	23
39-40	74	68
41	6	4
41	nil	nil

Patients excluded from the study were

(i) organic lesion in the cervix, which may be responsible for organic cause of cervical dystocia.
(ii) obstetric complications, e.g. severe PET, Placenta Praevia, cephalopelvic disproportion, malpresentation etc.
(iii) leaking membranes.
(iv) patients in latent phase of labour.

Patients were included in the study only when they were in active phase of labour, with cervix 3 cm. dilated, and uterine contraction at least 2 per 10 mins.

Monitoring of the patients

Monitoring was done clinically. Uterine contractions, dilatation of the cervix, descent of the presenting part, and FHR were recorded in a partograph maintained from the beginning. Side effects of the drug were noted carefully. B.P. check up was done every 2 hours. Inj, oxytocin was used wherever needed, both in the trial as well as in the placebo group. P/V examination was done every 2 hours and findings were recorded. The mode of delivery and 3rd stage complications, and Apgar Score at 1 min. and 5 min. were noted.

Results

Age & Gravidity distribution and period of gestation of patients are noted in Table I, II & III.

Duration of 1st stage (active phase) is shown in Table-IV

Table-IV
Duration of Ist stage of Labour(active phase)

	Trial Group	Control group
Primigravida	2 hrs to 9.5 hrs (mean 4.22 hrs)	5.2 hrs to 15 hrs (mean 7.34 hrs)
Multigravida	1.58 hrs to 7.83 hrs	4.42 hrs to 11 hrs (mean 6.3 hrs)

Duration of 1st stage is reduced by approximately 40% in the trial group when compared to control group, both in primi and multigravidae. Duration of 2nd stage of labour was unaffected both in primi and multi when compared to control group. The mean duration of 2nd stage was 1.87 hours and 1.2 hours in primi and multi in control group and 1.82 hours and 1.06 hours in primi and multi in trial group respectively. No difference was noted in 3rd stage of labour in both trial and control group. Rate of cervical dilatation and mode of delivery are shown in Table V & VI

Table-V
Rate of Cervical Dilatation

	Trial group	Control group
Primigravida	1.42 cm/hr	1.08 cm/hr.
Multigravida	1.56 cm/hr	1.27 cm/hr.

Table-VI
Mode of Delivery

	Forceps/Ventouse		C.S	
	Trial gr.	Control gr.	Trial gr.	Control gr.
Primi	2	3	2	7
Multi	nil	1	1	3

In both the cases requiring ventouse extraction in primigravidae in trial group, there was no sign of foetal distress. Ventouse was indicated because of lack of bearing down efforts.

In both the cases requiring C.S. in primigravidae in trial group, there was foetal tachycardia consequent upon maternal tachycardia. Apgar score was 7, but promptly became normal on resuscitation of the newborn.

Foetal distress was encountered in two primigravidae and one multigravida in the control group. Of the total 7 cases of LSCS in the control group, 4 were because of failure of progress of labour.

Trial was abandoned in one case because of high fever of the mother.

Apgar Score: No significant difference was noted between the trial and the control group. Side effects observed are shown in Table-VII

Table-VII
Side Effects of Epidosin Forte

	N	%
Maternal - Tachycardia	18	15.8%
Fever	1	0.8%
Dryness of mouth	12	10.5%
Foetal tachycardia	2	1.6%

Maternal tachycardia and dryness of mouth were the commonest side effects observed. However, foetal tachycardia occurred in two cases only. No foetal distress was observed.

Discussion

Steinmann (1953) first reported use of Efosin in the management of cervical dystocia. Ulrich Beck (1956) first reported reduction of 1st stage of labour by 18-30% by using Inj. Epidosin 8 mg I.M.

Epidosin, belongs to the group of esters with a quarternary N-atom with the formula (CH_3 CH_2 CH_2 CH_2 COO CH_2 CH_2 $N(C_2H_5)_2$ CH_3) Br It has both neurotropic (atropine like) and musculotropic (Papaverine-like) action. It acts by blocking cholinergic receptors and the ganglia and also by direct musculotropic action. Its antispasmodic action is equal to that of atropine without producing the undesirable side effects of atropine as it is more easily detoxicated. Its effect on circulation, salivary secretion and the eye is much less than that of atropine. Its use in shortening the duration of labour was subsequently described by Shrivastava et al (1979), Desai et al (1984), Trivedi & Shah (1987) and Puri et al (1988). Baser et al, (1993) and Kaur et al (1995) evaluated the effect of intravenous infusion of epidosin in labour, and compared the results with intramuscular administration. They were of the opinion that intravenous infusion of epidosin is superior to intramuscular administration in reducing the duration of labour, without significant increase in side effects for mother and baby. In our study, double dose (16 mg) epidosin, used intramuscularly yielded comparable results in reducing the duration of 1st stage of labour, both in primi and multigravidae without significant increase in maternal and foetal side effects (Table – VIII). Therefore, intravenous infusion may be avoided for shortening duration of active phase of 1st stage of labour. The slightly better results as observed in the series of Baser et al (1993) and Kaur et al, (1995) may be due to the stage of cervical dilatation when epidosin was administered (Table – VIII).

According to the observations of Baser et al (1993) I/M epidosin is likely to have unsatisfactory effect in patients who have a thick uneffaced cervix. This was later corroborated by Kaur et al (1995). However, in the present study, using double dose (epidosin forte containing 16 mg of Valethamate bromide) we have not experienced significant increase in the number of cases of cervical dystocia in this group, though there is a need for further studies for corroboration. Maternal and foetal side effects were also not

Table-VIII
Comparison of different series: Effect of Epidosin

Author	Inj. Epidosin	Mode of administration	At cervical dilatation	Duration of active phase of 1st stage of labour Hours	
				Primi	Multi
Srivastava et al 1979	8 mg	IM	4 Cm	5.62	2.95
Baser et al 1993	16 mg	I/V infusion	2.5-3.5 cm	3.5	-
Kaur et al 1995	24 mg	I/V infusion	3-4 Cm	3.7	
Present series 1997	16 mg	IM	3 cm	4.22	3.84

increased significantly in any series including the present study.

Conclusion:

In conclusion, there was a significant reduction in the duration of active phase of 1st stage of labour, both in primi and in multigravidae by using epidosin forte intramuscularly without significant increase in side effects for mother and the baby. Further studies are worthwhile in this respect.

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