Pharmacology Section

To Compare the Effect of Camylofin Dihydrochloride (Anafortin) with Combination of Valethamate Bromide (Epidosin) and Hyoscine Butyl-N-Bormide (Buscopan) on Cervical Dilation

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# ABSTRACT

**Background:** Various drugs have been tried to hasten cervical dilatation so that problems and hazards of prolonged labour both for the mother and fetus are minimised without increasing maternal or perinatal mortality and morbidity.

**Aims and Objectives:** To compare the effect of camylofin dihydrochloride with combination of valethemate bromide (epidosin) & hyoscine N butyl bromide (buscopan) on cervical dilatation, evaluate the incidence of side effects and to look for neonatal outcome.

**Material and Methods:** Two hundred cases were included of primigravidae or multigravidae with gestational age of 37 to 40 weeks with full term with single foetus, vertex presentation and no major antenatal complication of women in labour, admitted to labour room of gynaecology Department, Government Medical College, Patiala, India, was studied and divided into 2 groups Group A–100 Cases – labour accelerated by camylofin

dihydro chloride and Group B–100 Cases–labour accelerated by valethemate bromide (epidosin) and hyoscine N butyl bromide.

**Observations:** The mean age, parity and period of gestation in Anafortan group was  $24.13 \pm 3.60$  years, 49% primigravidae and 51% multigravidae and  $38.81 \pm 1.09$  weeks, while that in Epidosin + Buscopan group was  $24.43 \pm 3.42$  years, 45%primigravidae and 51% multigravidae and  $38.94 \pm 1.09$  weeks respectively. The difference was insignificant and both the groups were comparable.

**Results:** Mean duration of Active phase of 1st stage of labor was 141.40  $\pm$  55.41 minutes in Anafortan group and 181.46  $\pm$  75.58 minutes in Epidosin + Buscopan group. Mean rate of cervical dilatation according to active phase of first stage was 3.33  $\pm$  1.03 cm/hours in Anafortan group and 2.69  $\pm$  1.03 cm/hr in Epidosin + Buscopan group. The difference between the two groups is highly significant (p < 0.01) thus it is concluded that Anafortan hastened the rate of cervical dilatation.

Key words: Cervical dilatation, labour, Anafortan, Buscopan, Epidosin

# INTRODUCTION

The painless and short labor has been a cherished desire of every woman and goal of obstetrics is a pregnancy that resulted in healthy infant and minimally traumatised mother [1]. Labor is a multi–factorial process that involves myometrial contraction, cervical ripening and in dilatation, and then expulsion of the fetus and placenta in an orderly manner. The first stage of labor in a primigravidae lasted for 12–16 hours and in a parous woman usually 6–8 hours. There is a general consensus of opinion to classify labor lasting over 24 hours as prolonged labor. The progress of labor is assessed by progressive dilatation and effacement of the cervix and the descent of the presenting part [2].

The problems and hazards of prolonged labor, both for mother and fetus have been recognized for many years. Therefore attempts to accelerate labor and thereby shorten the duration of labor, without jeopardizing maternal or fetal interests would have been warranted [3].

Cervical dilatation is one of the important factors which determines the duration of labor and is the resultant of all the driving forces of uterine contraction acting against passive tissue resistance [4]. There are many causative factors associated with prolonged dilatation stage of labor, such as initial state of cervix, rate of cervical dilatation, intensity of uterine contractions, presentation, cephalopelvic disproportion, constitutional characteristics, and parity of the parturient. During pregnancy there is a pronounced softening of cervix, caused by increased vascularity and edema of the entire cervix, together with hypertrophy and hyperplasia of cervical glands [2].

Active management of labor is a part and parcel of modern obstetrics. There are various mechanical and pharmacological methods by which the cervical dilatation can be facilitated e.g., sweeping of membranes and stretching of the cervix causes local release of prostaglandins resulting in reduction in the need for formal induction of labor, amniotomy, cervical application of relaxin, estradiol and hylase, prostaglandins in various formulations for induction of labor, especially PGE2 gel for cervical ripening. Oxytocin is proven to induce and augment labor. Buscopan (Hyoscine Butyl-N-Bromide) and Scopolamine have been used for pain relief and shortening of labor. Epidosin (Valethemate bromide) has neurotropic and musculotropic actions, resulting in relaxation of cervical musculature leading to guick dilatation of cervix and shortened labor. Drotaverine hydrochloride shortens duration of the dilatation stage of labor [4]. Anafortan (Camylofin Dihydrochloride) is a selective PDE-4 enzyme inhibitor which facilitates cervical effacement and dilatation, accelerates labor, regulates the autonomic system and thereby prevents disordered progress of labor.

## MATERIAL AND METHODS

The present study was conducted in our department and 200 full term pregnant woman were included in this study, after the

RESULTS

approval of the ethics committee of the institution. Primigravidae or multi–gravidae with gestational age of 37 to 40 weeks with full term pregnancy, with single fetus, vertex presentation and no major antenatal complication were included in the study and informed consent was taken from them. Those who developed any complications during labor, necessitating caesarian section or any other interference, and contracted pelvis, multiple pregnancy and malpresentation were excluded.

Aseptic per vaginal examination was done to note the dilatation and effacement of cervix. Duration of first stage of labor was calculated from time of injection to the time of full cervical dilatation. Fetal heart sounds were auscultated every half hourly to note the rate and rhythm. Frequency and intensity of uterine contractions were also noted. Cervical dilatation and station of fetal head by per vaginal examination was noted every four hourly. They were divided into 2 groups.

The Study group comprised of 100 cases in which a single dose of intra-muscular injection of Camylofin Dihydrochloride (Anafortan) was given to the patients at cervical dilatation of 3cm.

The control group comprised of 100 cases, intra-muscular injection of Valethemate bromide (Epidosin) (1 amp) + injection Hyoscine N-Butyl bromide (Buscopan) (1 amp) were given at half hourly interval of 3 doses, at cervical dilatation of 3cm.

Both the groups were compared for duration of first stage of labor and mean rate of cervical dilatation to study the drug effectiveness and its side effects. The mean age, parity and period of gestation in Anafortan group was  $24.13 \pm 3.60$  years., 49% primigravidae and 51% multigravidae and  $38.81 \pm 1.09$  weeks, while that in Epidosin + Buscopan group was  $24.43 \pm 3.42$  yrs., 45% primigravidae and 51% multigravidae and  $38.94 \pm 1.09$  weeks respectively. The difference was insignificant and both the groups were comparable for the study in relation to age, parity and period of gestation [Table/Fig-1].

Mean duration of Active phase of 1st stage of labor was 141.40  $\pm$  55.41 minutes in Anafortan group and 181.46  $\pm$  75.58 minutes in Epidosin + Buscopan group. The difference between the two groups was highly significant (p < 0.01). Thus Anafortan shortens the duration of active phase of first stage of labor [Table/Fig-2].

Mean rate of cervical dilatation according to active phase of first stage was  $3.33 \pm 1.03$  cm/hr in Anafortan group and  $2.69 \pm 1.03$  cm/hour in Epidosin + Buscopan group. Again the difference between the two groups is highly significant (p < 0.01) thus it was concluded that Anafortan hastened the rate of cervical dilatation [Table/Fig-3].

Mean duration of Injection delivery interval was  $172.05 \pm 60.82$  minutes in Anafortan group and  $211.89 \pm 75.86$  minutes in Epidosin + Buscopan group. The difference between the two groups was statistically highly significant (p < 0.01), concludes that Anafortan shorten the injection delivery interval [Table/Fig-4].

Study	Injection Delivery Interval (in min)					
	Study Group	Control Group	t value	p value		
Age	24.13 ± 3.60	24.43 ± 3.42	0.27	> 0.05		
Parity	Primi 49 Multi 51	Primi 45 Multi 55	0.25	> 0.05		
Gestation	38.81 ± 1.09	38.94 ± 1.09	0.83	> 0.05		
Table (Fig. 4). Comparison of and postation						

[Table/Fig-1]: Comparison of age, parity and gestation

Study	Active Phase of 1st stage (in min)					
	Study Group	Control Group	t value	p value		
Asholter et al., (1953)	232	372				
Warke et al., (2003)	215	334				
Present Study	141.40 ±55.41	181.46 ± 75.58				
Primigravidae	154.48 ±60.24	215.55 ± 88.36	3.94	<0.01		
Multigravidae	128.82 ±47.61	153.05 ± 47.66	2.60	<0.05		

[Table/Fig-2]: Comparison of duration of active phase of first stage of labor

Study	Rate of Cervical dilatation (in cm/hrs.)					
	Study Group	Control Group	t value	p value		
Asholter et al., (1953)	1.81	1.12				
Warke et al., (2003)	1.92	1.18				
Present Study	3.33 ± 1.03	2.69 ± 1.03	4.34	<0.01		
Primigravidae	$3.06 \pm 0.98$	2.28 ± 0.89				
Multigravidae	3.59 ± 1.02	3.03 ± 1.02				
[Table/Fig-3]: Comparison of rate of cervical dilatation						

Injection Delivery Interval (in min) Study t value Study Group **Control Group** p value 377.56 Warke et al., (2003) 257.16 Present Study 172.05 ± 60.82 211.89 ± 75.86 Primigravidae 187.53 ± 62.89 248.37 ± 86.34 3.92 <0.01 <0.05  $248.37 \pm 86.34$ 181.15 ± 48.79 2.39 Multigravidae

[Table/Fig-4]: Comparison of the injection delivery interval

CONCLUSION

## DISCUSSION

Active management of labor has gone a long way in decreasing maternal morbidity and perinatal mortality. The findings of the present study are consistent with the findings of research done by Asholter et al., [5] and Warke et al., [6] Mean age, gestational age and gravidity in the present study in both the groups was comparable and there was no statistically significant difference.

In the present study mean duration of active phase of labor in Anafortan group was  $141.40 \pm 55.41$  minutes and in Epidosin + Buscopan group was  $181.46 \pm 75.58$  minutes. The present study showed that the duration of active stage of labor was shorter in the study group as compared to the control group. The results of the present study are comparable to the study of Warke et al., [6] and Asholter et al., [5].

Rate of cervical dilatation was more in Anafortan group and difference between the two groups was statistically highly significant (p < 0.01) as in [Table/Fig-3]. In the study of Asholter et al., [5] the rate of cervical dilatation in the study group was 1.81 cm/hr and 1.12 cm/hr in the control group. Therefore the results of the present study are comparable to the study of Asholter et al., [5] and Warke et al., [6].

The injection delivery interval was shorter with Anafortan group as compared to Epidosin + Buscopan group. The results of the present study are comparable with that of Warke et al., [6]. The difference between the two groups was insignificant.

## It was concluded that Anafortan is a potent and effective drug to shorten the first stage of labor. Its effect on shortening duration of labor is significantly better than Epidosin + Buscopan group. However both the drugs have almost similar side effects and have no effect on uterine activity. Both the drugs have no effect on second and third stage of labor as regards to duration or complications. The difference between the two groups as regards to instrumental delivery was insignificant. Neonatal outcome was not affected in both the groups.

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FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: Apr 11, 2013 Date of Peer Review: Jun 18, 2013 Date of Acceptance: Jul 07, 2013 Date of Online Ahead of Print: Jul 22, 2013 Date of Publishing: Sept 10, 2013