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Original Research Article

A randomized comparative study of effect of intramuscular valathemate bromide (epidosin) and intramuscular camylofin dihydrochloride (anafortan) on cervical dilatation in labour

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ABSTRACT

Background: Our aim is to search for a good cervical dilating agent which is not only more efficacious in cervical dilatation but also effective in relieving pain during labour with no or very little harmful effects on mother and foetus.
Methods: The type of study was simple randomized comparative study. The present study was conducted in R. N. T. Medical College, Udaipur between October 2019 and December 2020. 118 patients were selected randomly. Two groups were made each consisting of 59 patients. First group received intramuscular camylofin dihydrochloride, second group received intramuscular (IM) valethamate bromide. Patients included in study group were: primigravidae/multigravidae, singleton full term gestation (37-40 weeks) with vertex presentation, cervical dilatation of ≥3 cm and patient excluded from study group with preclampsia, eclampsia, antepartum haemorrhage, any obstetric complications: cephalo pelvic disproportion, abnormal presentations.
Results: Mean duration of active phase of first stage of labor was shorter in group I (313.17 minutes) than in group II (356.3 minutes) but not statistically significant. Mean cervical dilatation rate was significantly more in group I (2.02 cm/hour) than group II (1.81 cm/hour). Anafortan was effective in pain relief with mean pain score 5.31±1.06 while mean pain score for epidosin group was 7.37±1.07.
Conclusions: In our study we observed that intramuscular camylofin dihydrochloride (anafortan) was more efficacious than IM valethamate bromide (epidosin) in shortening the duration of labor as well as in pain relief.

Keywords: Cervical dilatation rate, Pain relief in labour, Anafortan, Epidosin

INTRODUCTION

Pain during the labour has always been a great fear for pregnant women. Every woman is desirous of short labour with minimal pain. Every woman expects from obstetrician that her pregnancy results in healthy baby with minimal trauma during labour.[1] Labor is a multi–factorial process that involves myometrial contraction, cervical ripening, cervical dilatation, and then expulsion of the fetus and placenta in an orderly manner. 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] 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.[5] Epidosin (valethemate bromide) has neurotropic and musculotropic actions, resulting in relaxation of cervical musculature leading to quick dilatation of cervix and shortened labor.[16] Drotaverine hydrochloride shortens duration of the dilatation stage of labor.[6]

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 and fascilitate painless labour.[13] Visual analog scale has been best method to measure pain during labour.[14]

Objectives

Objectives of the study was to compare the effect of IM valethamate bromide and IM camylofin dihydrochloride on: rate of cervical dilatation, duration of active phase of 1st stage of labour, mode of delivery, total duration of labour and to find out the efficacy of the above drugs in shortening the duration of labour, to study the adverse drug reactions on the mother and foetus, to study relief of pain in mother during labour.

METHODS

Study setting

The present study was conducted at Pannadhay Zanana Hospital, RNT Medical College, Udaipur between October 2019 and December 2020.

Study design

Hospital based simple randomized comparative Analytical study between IM valathamate bromide and IM camylofindihydrochloride on cervical dilatation in labour. Maximum two doses (two vials) of each drug will be given two hours apart.

Study population

Primigravidae or multi–gravidae with gestational age of 37 to 40 weeks with full term pregnancy, with singleton fetus, cephalic presentation and no major antenatal complication

Sample size

Sample size calculated using N master software for estimating the difference between two means.[1,2]

Data analysis was done by using Microsoft excel version 2010 and statistical package for social sciences version 24 (SPSS 24).

Table 1: Standard deviation.

Standard deviation in valathamate group	**0.681**
Standard deviation in camylofin group	0.384 (20% of mean cervical dilatation was considered as SD)
Estimated difference between 2 means	0.2
Desired confidence level (1- α) %	95
Required sample size	59 in each group

Method of procedure

118 primigravidae or multigravidae with full term pregnancy in labour (3 cm cervical dilation) were selected by simple randomization and divided into two groups. First group received intramuscular camylofin dihydrochloride, second group received IM valethamate bromide. Maximum two doses of each drug given two hours apart.

Selection criteria

Primigravidae/multigravidae, age group 18-35 years, singleton full term gestation (37-40 weeks), vertex presentation, cervical dilatation of ≥3 cm, membranes intact/ruptured, spontaneous and induced labour. The participants had to be willing to sign a consent form in accordance with international and national ethics regulation.

Exclusion criteria

Women with preclampsia, eclampsia, antepartum haemorrhage, any obstetric complications: cephalo pelvic disproportion, abnormal presentations, twin pregnancy, medical disorders: renal and hepatic dysfunction, cardiac disease, diabetic pregnancy and obstructive airway disease, known hypersensitivity to drug.

RESULTS

118 patients were selected randomly. Two groups were made each consisting of 59 patients.

First group received intramuscular camylofin dihydrochloride, second group received IM valethamate bromide.

Table 2: Distribution of cases.

Group	No. of patients
Camylofin dihydrochloride (anafortan)	59
Valethamate bromide (epidosin)	59

The difference in the age groups in two groups is not statistically significant (p value of 0.458).

Highest number of patients were between 21-25 years (49.2% in anafortan group and 64.4% in epidosin group respectively) (Table 2).

Table 3: Age distribution of patients.

Age in years	Anafortan		Epidosin	
	No	%	No	%
15-20	13	22.03	8	13.56
21-25	29	49.15	38	64.41
26-30	17	28.81	13	22.03
Total	59	100.0	59	100.0
Mean±SD	23.6±2.97		23.20±2.71	

Mean duration of active phase of first stage of labor was shorter in anafortan group (313.17 minutes) than in epidosin group (356.3 minutes) and it was found to be statistically significant with p value of 0.024.

Mean duration of second stage of labor was 32.5 minutes in anafortan group and 37.09 minutes in epidosin group and it was found to be statistically significant with p value of 0.028. Mean duration of third stage of labor was 6.14 minutes in anafortan group and 6.09 minutes in epidosin group but it was found to be not statistically significant with p value of 0.902.

Mean of total duration of labor was shorter in anafortan group (351.84 minutes) than in epidosin group (398.4 minutes) and it was found to be statistically significant with p value of 0.017 (Table 4).

Table 4: Comparison of stage 1, 2, 3 and total labor of patients studied.

Variables (minutes)	Anafortan	Epidosin	P value
Stage I labour (active phase) (AIST MIN.)	313.17±121.03	356.27±70.74	0.024
Stage II labour	32.53±10.66	37.09±11.13	0.028
Stage III labour	6.14±1.98	6.09±2.07	0.902
Total labor	351.84±123.79	398.36±71.26	0.017

Mean cervical dilatation rate observed in anafortan group (2.02 cm/hour) was more than that in epidosin group (1.81 cm/hour) and was found to be statistically significant with p value of 0.024 (Table 5).

Mean induction delivery interval was significantly more in epidosin group (246.94 minutes) than that in Anafortan group (223.53 minutes) and found to be statistically significant with p value of 0.044 (Table 5).

Table 5: Rate of cervical dilation in centimeter/hour.

Cx rate (cm/ hour)	Anafortan		Epidosin	
	No	%	No	%
1-1.5	7	20.3	11	19.6
1.5-2.0	25	55.9	28	50
>2.0	26	23.7	17	30.4
Total	58	100.0	56	100.0
Mean±SD	2.02±0.55		1.81±0.44	

Table 6: Induction delivery interval in minutes.

IDI (minutes)	Anafortan		Epidosin	
	No.	%	No.	%
<200	23	39.6	11	20
200-300	30	51.7	33	60
>300	5	8.6	11	20
Total	58	100.0	55	100.0
Mean±SD	223.53±59.28		246.94±63.07	

25.9% patients in anafortan group had pain score of <5 while only 3.6% of patients had pain score <5 in epidosin group. 72.4% of patients had pain score 5 to 7 in anafortan group while its 47.3% of patients in epidosin group. Only 1.7% of patients had pain score more than 7 in anafortan group while 49.1% of patients in epidosin group had pain score >7. Anafortan was effective in pain relief with mean pain score 5.31±1.06 while mean pain score for epidosin group was 7.37±1.07 which was found to be statistically significant with p value of 0.000 (Table 7).

Table 7: Pain score by visual analogue score.[14]

VAS pain score	Anafortan (n=58)		Epidosin (n=55)	
	No.	%	No.	%
<5	15	25.9	2	3.6
5 to 7	42	72.4	26	47.3
>7	1	1.7	27	49.1
Mean score	5.31±1.06		7.37±1.07	

1.7% of patients in anafortan group had instrumental or assisted vaginal delivery while 5.1% of patients in epidosin group had instrumental delivery which is not statistically significant (p value=0.220). 6.8% of patients in epidosin group had lower segment cesarean section (LSCS) (two patients for non-progression of labor and two patients for fetal distress) while only 1.7% of patients had LSCS in anafortan group, one patient for foetal distress.

In present study 6.7% of patients in camylofin group and 8.5% of patients in epidosin group had third stage complication (p value=0.799). 3.3% in camylofin group had atonic postpartum hemorrhage (PPH) and 3.3% had vaginal tear. On the other hand in the epidosin group 3.3% had atonic PPH, 1.7% had third degree perineal tear, 1.7% had cervical tear.

DISCUSSION

Active management of labor has gone a long way in decreasing maternal morbidity and perinatal mortality. Various characteristics of the study are being discussed below.

The mean age of patients in group I is 23.6 and in group II is 23.2. Thus both the groups are comparable wit In present study mean duration of active phase labor was shorter in camylofin group (313.17 minutes) than in valethamate group (356.3 minutes) and was found to be statistically significant with p value of 0.024 with respect to the distribution of age of patients.

In a study by Mishra et al mean duration of active phase of labor was shorter in valethamate bromide group (275 minutes) than in control group (373 minutes).On the other hand In a study by Asholter et al mean duration of active phase of labor was shorter in camylofin group (3 hour, 52 minutes) than placebo group (5 hour, 6 minutes).[10] Similarly In a study by Himangi et al mean duration of active phase of labor was shorter in camylofin group (3 hour, 35 minutes) as compared to that in placebo group (5 hour, 34 minutes).[2]

In present study mean cervical dilatation rate is significantly more in camylofin group (2.02 cm/hour) than valethamate group (1.81 cm/hour) with p value of 0.024. There are very few studies on comparison between camylofin and valethamate for cervical dilatation, but individual studies on camylofin and valethamate are available.

In the study by Shridhar et al, mean rate of cervical dilatation in camylofin group was found to be 3.14 cm/hour whereas In a study by Himangi et al, mean rate of cervical dilatation in camylofin group was found to be 1.92 cm/hour which is comparable to the present study where the rate of cervical dilatation in camylofin group is found to be 2.02 cm/hour.[2,8] On the other hand in a study by Sharma et al, the rate of cervical dilatation in valethamate group was found to be 1.86 cm/hour which is comparable to present study where rate of cervical dilatation in valethamate group is found to be 1.81 cm/hour.[1]

Incidence of side effects were statistically similar in two groups with p value=1.000, 10.2% patients in each group developed side effects. In the present study 1.6% of patients developed nausea, 1.6% patients developed vomiting, 1.6%patients had dryness of mouth in anafortan group. 1.6% of patients had foetal distress while 3.2% patients developed maternal tachycardia in aanafortan group. Nausea, vomiting, headache, hypotension was observed in 1.6% of patients respectively in the epidosin group. 3.2% of patients develop foetal distress in epidosin group.

Mean blood loss is statistically similar in both groups 290.7 ml in camylofin group and 277.11 ml in valethamate group, maximum number of patients had blood loss in the range of 200-300 ml in both the groups 46% in group one whereas 45.8% in group two.[15]

25.9% patients in anafortan group had pain score of <5 while only 3.6% had pain score <5 in epidosin group. 72.4% had pain score 5 to 7 in anafortan group while its 47.3% in epidosin group. Only 1.7% had pain score more than 7 in anafortan group while its 49.1% in epidosin group.

Anafortan was effective in pain relief with mean pain score 5.31±1.06 while mean pain score for epidosin group was 7.37±1.07 which is statistically significant with p value of 0.000.[14]

There is no known study available so far for comparison of pain score in labour, this is first of its kind study.

Limitations

This study had three main limitations. In our study, first we studied the incidence of LSCS in two groups which was found to be comparable in both the groups. So to avoid confusion in calculation of the duration of active phase, second and third stage of labor, rate of cervical dilatation, and injection delivery interval and pain score by visual analogue scale, patients who had LSCS were excluded from these statistics. Second was that we measured pain score in labour by visual analogue scale in which pain is measured on a scale by noting facial expressions and discomfort felt by patient as there is no instruments to measure the actual pain felt parturient mother during labor. And last was small size of study population.

CONCLUSION

From the above study hence it can be concluded that no women should be allowed to suffer in pain and agony of labor. Labor should be considered as a pleasurable moment in the life of every pregnant women. Drugs which hasten labor should be welcomed by both obstetrician and the laboring mother. Hence the two drugs are effective in shortening the duration of labor. But intramuscular camylofin dihydrochloride (anafortan) was more efficacious than IM valethamate bromide (epidosin) in shortening the duration of labor as well as in pain relief. Both the drugs camylofin dihydrochloride and valethamate bromide can be used to hasten the labour.

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