

**To Evaluate the Incidence of Side Effects of Camylofindihydrochloride with Combination of Valethemate Bromide (Epidosin) and Hyoscine – N - Butyl Bromide (Buscopan), on Mother and to Look for Neonatal Outcome.**

Sarbhjit Kaur\*, Paramjit Kaur, Surjit Kaur Bajwa, Surinder Kumari, and Manjit Kaur Mohi.

Department of Obst. And Gynae, GMC, Patiala, Punjab, India.

Research Article

ABSTRACT

Received: 17/07/2013  
Revised: 29/07/2013  
Accepted: 02/08/2013

**\*For Correspondence**

Department of Obst.and  
Gynae, GMC, Patiala, Punjab,  
India.

**Keywords:** camylofindihydrochl  
oride, epidosinbuscopan,  
neonatal.

Various drugs have been tried to hasten cervical dilatation so that problems and hazards of prolonged labor both for the mother and fetus are minimized without increasing maternal or perinatal mortality and morbidity. To evaluate the incidence of side effects of camylofindihydrochloride with combination of valethemate bromide (epidosin) & hyoscine N butyl bromide (buscopan), on mother and to look for neonatal outcome. Two hundred cases primigravidae or multigravidae with gestational age of 37 to 40 weeks with single foetus, vertex presentation and no major antenatal complication, admitted to labor room of gynaecology department of our institution and divided into 2 groups Group A-100 Cases - labor accelerated by camylofin dihydrochloride and Group B- 100 Cases - labor accelerated by valethemate bromide (epidosin) and hyoscine N butyl bromide. Various side effects and progress of labor and duration of various stages of labor was noted. Neonate was examined at birth and at 5 minutes for Apgar score. Vomiting occurred in 9% of Anafortan group and 10% Epidosin + Buscopan group. Dryness of Mouth occurred in 7% cases of Anafortan group and 10% cases of Epidosin + Buscopan group, followed by tachycardia which occurred in 2% cases of Anafortan group and 3% cases of Epidosin + Buscopan group. Apgar score at 1 minute in both the groups was similar i.e.  $7.97 \pm 0.22$  in Anafortan group and  $7.97 \pm 0.20$  in Epidosin + Buscopan group. The Apgar score at 5 minutes in both the groups was quite similar i.e.  $8.99 \pm 0.1$  in Anafortan group and  $8.97 \pm 0.14$  in Epidosin + Buscopan group, so the difference between the two groups is insignificant statistically.

INTRODUCTION

The goal of obstetrics is a pregnancy that results in a healthy infant and minimally traumatized mother. Much of the art of good obstetric care involves the delicate balance of avoiding caesarean delivery and its attendant complications. The painless and short labor has been cherished desire of every woman. Fear tension-pain syndrome is associated with labor and is a perpetual problem for the obstetricians. Fear and anticipation gives rise to natural protective tension in mind of the patient and increased tone in the muscle of the cervix. Excessive stimulation of the motor mechanism of the sympathetic nervous system increases the tone of the circular muscle fibers of the cervix. Resistance in these muscles produces pain by stimulating the sensory nerve endings in the uterus. Thus there is a disturbance in the polarity leading to incomplete relaxation of the uterus and spasm of the cervix [1].

It is a well-known fact that women have more painful and protracted labor now a day because of increasing modernization of life, which has resulted in reduction of capacity of pelvic musculature and relaxation of cervix, thus causing sub clinical and clinical dystocia. In the present age the attempts to accelerate labor and there by shorten its duration without jeopardizing maternal or foetal outcome is welcome to both the patient and the obstetrician. Uterine activity and rate of cervical dilatation are the two basic factors that determine the duration of labor. Various drugs have been tried over the last few decades, which accelerate labor either by increasing the uterine activity or by accelerating cervical dilatation [2].

Prolonged labor, either due to mechanical obstruction or due to inefficient uterine action, becomes a problem for the mother, the fetus, the attendant and the obstetrician. A baby born after prolonged labor subjected to intra uterine anoxia may be resuscitated with difficulty but alas, what would be the predicament of the parents if the milestones of the life of the baby develop slowly or the baby becomes retarded or spastic in the years to come. This is why some of the eminent gynecologists maintain, 'of all the journeys ever we make, the most dangerous one is the first one we take through the last 10 cm of the birth canal<sup>[3]</sup>. 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 <sup>[1]</sup>.

The use of antispasmodics is based on the hypothesis of innervation of uterus. According to this hypothesis the body of uterus is innervated by sympathetic chain and cervix by para- sympathetic. This functional antagonism is synergic in its effect on the uterine activity. An ideal antispasmodic for acceleration of cervical dilatation should have a prompt and long lasting action, no adverse effects on uterine contractility, and be free from the risk of uterine inertia. It should also have minimal side effects in the mother and the foetus<sup>[2]</sup>.

Various drugs have been tried to hasten cervical dilatation and minimize the pain without increasing maternal or perinatal mortality and morbidity like Valium, relaxin, drotaverine hydrochloride, Valethamate bromide, Hyoscine-N- Butyl bromide, Camylofindihydrochloride.

Epidosin: (Valethamate bromide) It is potent anticholinergic agent. It has a direct relaxant action on smooth muscle thus acting as antispasmodic and reducing the duration of labor. It is an antispasmodic and reduces the duration of normal labor<sup>[4]</sup>.

Buscopan: (Hyoscine N- Butyl bromide) It is a smooth muscle relaxant. It has selective spasmolytic effect on the parasympathetic innervation of the cervical os. It accelerates labor by dilating the cervical os<sup>[5]</sup>.

Camylofindihydrochloride:

Camylofin has a direct papaverine like spasmolytic action on the smooth muscle and a mild atropine like anticholinergic action, making it one of the most potent antispasmodics. It inhibits the enzyme phosphodiesterase, which in turn causes increase in concentration of cyclic AMP and smooth muscle relaxation. Due to its phosphodiesterase enzyme-IV- isoenzyme selectivity, this drug does not interfere with uterine contractility. Camylofindihydrochloride primarily acts on smooth muscles (Intestine, ureter, cervix) whereas its influence on glands, eyes, heart and circulation is slight and of no clinical significance. It has very mild anticholinergic side effects like dryness of mouth, dilatation of pupils, paralysis of accommodation and palpitations. In modern obstetrics, a drug that offers convenience and assures shortening of first stage of labor without compromising the mother or foetus, is a welcome drug. Camylofin accelerates labor by regulating the autonomic system. This facilitates the cervical effacement and dilatation. Hence it is a new indication of an old drug <sup>[2]</sup>.

## METHODOLOGY

The present study was conducted in our department and 200 full term pregnant women were included in this study, after the approval of the ethics committee of the institution. Primigravidae or multigravidae 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 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 was 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 Valethamate bromide (Epidosin) (1 amp) + injection Hyoscine - N-Butyl bromide (Buscopan) (1 amp) was given at half hourly interval of 3 doses, at cervical dilatation of 3cm. Complication of third stage of labor like prolonged duration, retained placenta and PPH, Maternal complications were noted. Examination of neonate and APGAR score was noted at birth and at 5 minutes.

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.

## RESULTS

Both the groups were comparable for study as regards age, gravidity, gestational age, and type of labour [spontaneous or induced].

Table (1) shows that both the groups neither adversely affected the uterine activity nor it resulted in uterine inertia.

**Table 1: Showing complications of Anafortan and Epidosin + Buscopan**

Complications	Group	
	Anafortan group	Epidosin+Buscopan
Uterine activity	Not affected	Not affected
Uterine Inertia	Nil	Nil
Cervical tear	1	-
MROP	1	2

**Table 2: Showing complications compare with warke et al**

Complications	Warke et al (2003)		Present Study	
	Study Group	Control Group	Study Group	Control Group
Uterine Activity	Not affected	Not affected	Not affected	Not affected
Uterine Inertia	Nil	Nil	Nil	Nil
Cervical Tear	1	1	1	-
MROP	-	-	1	2

Table (3) predicts that nausea occurred in 5% of Anafortan group and 3% of Epidosin + Buscopan group.

**Table 3: Showing side effects of Anafortan and Epidosin + Buscopan**

Side effects	Anafortan group (n = 100)		Epidosin+ Buscopan group (n = 100)	
	No.	%age	No.	%age
Nausea	5	5%	3	3%
Vomiting	9	9%	10	10%
Diarrhoea	-	-	-	-
Dryness of Mouth	7	7%	10	10%
Tachycardia	2	2%	3	3%
Headache	-	-	-	-
Vertigo	-	-	-	-
Flushing of face	-	-	-	-
Rash	-	-	-	-

**Table 4: Shows maternal side effects compare with warke et al**

Side Effects	Warke et al (2003)	Present Study	Control group
Dryness of Mouth	9%	7%	10%
Nausea	5%	5%	3%
Vomiting	6%	9%	10%
Drowsiness	1%	-	-
Transient Tachycardia	1%	2%	3%

There was one case of cervical tear in Anafortan group and none in Epidosin + Buscopan group.

Two cases required MROP in Epidosin + Buscopan group and one case in Anafortan group. The difference in the occurrence of various side effects was statistically insignificant.

**Table 5: Showing APGAR score at 1 minute**

Apgar Score	Anafortan Group		Epidosin + Buscopan Group	
	Number	%age	Number	%age
Upto - 7	2	2%	3	3%
8	98	98%	7	97%
9	-	-	-	-
Total	100	100%	100	100%
Range	6-8		6-8	
Mean ± SD	7.97 ± 0.22		7.97 ± 0.20	
t value			0.32	
p value			p>0.05	
Significance			NS	

**Table 6: Showing APGAR score at 5 minutes**

Apgar Score	Anafortan Group		Epidosin + Buscopan Group	
	Number	%age	Number	%age
Upto - 7	-	-	-	-
8	1	1%	2	2%
9	99	99%	98	98%
Total	100	100%	100	100%
Range	8-9		8-9	
Mean ± SD	8.99 ± 0.1		8.97 ± 0.14	
t value			0.58	
p value			p>0.05	
Significance			NS	

Vomiting occurred in 9% of Anafortan group and 10% Epidosin + Buscopan group. Dryness of Mouth occurred in 7% cases of Anafortan group and 10% cases of Epidosin + Buscopan group. Tachycardia occurred in 2% cases of Anafortan group and 3% cases of Epidosin + Buscopan group.

The difference in the occurrence of various side effects was statistically insignificant. Apgar score at 1 minute in both the groups is similar i.e 7.97± 0.22 in Anafortan group and 7.97± 0.20 in Epidosin + Buscopan group (table 5), so the difference between the two group is insignificant statistically. The Apgar score at 5 minutes in both the groups was quite similar i.e. 8.99 ± 0.1 in Anafortan group and 8.97 ± 0.14 in Epidosin +Buscopan group, so the difference between the two groups is insignificant statistically (table 6).

## 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 [9] and Warke et al [2] Mean age, gestational age and gravidity in the present study in both the groups is comparable and there was no statistically significant difference.

As shown in table 1 both the groups neither affected the uterine activity nor resulted in uterine inertia. Similar results were obtained in the study of Warke et al [2]. Cervical tear occurred in one case in Anafortan group and none in Epidosin + Buscopan group. Two cases required MROP in Epidosin + Buscopan group and one case in Anafortan group. Cervical tear occurred in one case each in both the groups and there were no major complication encountered in the IIIrd stage in the study of Warke et al [2]. The difference, of various side effects was statistically insignificant in the present study and is comparable to the study of Warke et al [2]. In the study of Jayashree et al [6] one multigravida given valethamate bromide developed cervical tear and one developed Para urethral tear and no major complication occurred in 3rd stage of labor.

In the present study vomiting was noted as the main side effect in both the groups i.e. 9% in Anafortan and 10% in Epidosin + Buscopan group followed by dryness of mouth, nausea and transient tachycardia (Table 3).

Warke et al [2] noted dryness of mouth as the main side effect followed by vomiting (6%), nausea (5%), drowsiness (1%), and transient tachycardia (1%) and comparable with our study (Table 4).

K Devinder et al and Kholsa AH [7, 8] noted maternal tachycardia in 28% of cases and 16% cases respectively and only 1% in our study which was statistically significant.

As shown in table 5 and 6 In Anafortan group 98% babies had Apgar score of 8 at birth and in Epidosin + Buscopan group 97% had Apgar score of 8 at birth. At 5 minutes 99% in Anafortan group and 98% babies in Epidosin + Buscopan group had Apgar score of 9. There was no fetal or neonatal mortality. The difference of Apgar score in both the groups at birth and at 5 minutes was not statistically significant and results were comparable with the study of Warke et al [2].

### CONCLUSION

It was concluded that both the drugs have almost similar side effects and have no effect on uterine activity&Neonatal outcome. Both the drugs have no effect on second and third stage of labor as regards to duration or complications. Therefore Anafortan is a potent and effective drug to shorten the duration labor.

### REFERENCES

1. Sharma M, Singh VK, Upreti S: Diazepam A valuable drug in labour. J Obstet, and Gynarcollnd 1978; 579-89.
2. Warke HS, Chauhan AR, Raut VS, Ingle KM. The efficacy of Camyl of in Dihydrochloride in acceleration of labor: a randomized double blind trial. Bombay Hosp J. 2003; 45(3): 420-4.
3. Ghosh AK, khara BN, Kanjilal J: Cervical partogram in primigravidae and accelerated labour. J. ObstetGynaecol Ind. 1998; 30(5) 789-93.
4. Krantz, Care. Cholinergic blocking agents. In: Pharmacologic principals of medical practice. 7th ed. Calcutta, India Scientific Book Agency; 1969.p. 408
5. Samal S, Balaji O. Place of Buscopan in acceleration of labour. J Obst and Gynae 1998; 34(1):8-10.
6. Srivastava M, Sarkar B, Kishore N. Effect of Epidosin on normal labor. J ObstetGynaecol Ind. 1979; 29(2): 384-8.
7. Kaur D, Kaur R: Comparison of drotaverine and epidosin in First stage of Labour. J ObstetGynecol Ind. 2003; 53(5).
8. Khosla AH, Bala I, Dahiya K. A comparative study of the efficacy of valethamate bromide with drotverine in normal labour. ObstetGynaecol India 2003; 53(6): 568-570.
9. Asholter C. Acceleration of parturition by Avacan. Medizinische.1953; 36:1164-6.