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## RESEARCH ARTICLE

# EFFECT OF RECTAL HYOSCINE BUTYL BROMIDE SUPPOSITORIES ON FIRST STAGE OF LABOR

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Purpose: Prolong labour contributes to increased perinatal and maternal morbidity. Inhibitory impulses in the form of spasm often impair the dilatation of cervix and prolong the duration of labour. This study was undertaken to compare the effect of Hyoscine N Butylbromide [Buscopan] rectal suppository on duration of labour and rate of cervical dilatation. Method-400 patient were taken up for study. Of these 100 were primipara & multipara. In the multipara, only second para (OH=1001) were included to ensure comparability. 200 patients (100 primipara & 100 multipara), served as control. There were 59 patients in age group 15-20 yrs. and 114 patients in age group 21-25 yrs in study group. In the control group 52 patients were between 15-20 yrs of age and 117 patients between 21-25 years of age. Hyoscine butyl bromide suppositories were inserted per rectally (2) suppositories each containing 10 mg of drug) in study group. Mean duration of active phase of labor was taken from 3 cm dilatation to full dilatation of cervix. **Results** -In the study group mean duration of active phase was 3.43 his in primi and 1.79 hrs in multi. in the control group, mean duration of active phase was 4.5 hrs in primi and 3.42 his in multi respectively. Thus the active phase of labor was shortened by 1.07 hrs. in primi and 1.63 his in multi. The rate of cervical dilatation from 3 cm to full dilatation of cervix was calculated. The mean rate of cervical dilatation in the active phase of labor in primi study group was 2.04 cm/hr, while in multi study group was 3.91 cm/hr. In the control group, mean rate of cervical dilatation for primi & multi were 1.5 cm/hr & 2.04 cm/hr respectively. In the study group 98% of patients delivered vaginally among primipara and 99% of multipara delivered vaginally. In the controls, 97% of primipara delivers vaginally & 99% of multipara had vaginal delivery. Only 1 baby had 5 min. Apgar score less than 7 in study group. Very few and minor side effects of hyoscine butyl bromide were noted Dryness of mouth was noted in 13% and maternal tachycardia in

**Conclusion**: Buscopan was effective in reducing the duration of active phase of labour and rate of cervical dilatation. Buscopan because of its convenience of administration (as rectal suppository) can be an alternative in rural setups where trained medical personnel may not be available most of the times

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INTRODUCTION

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Prolonged labour, one anomaly, presents a picture of mental anguish and physical morbidity. The parturient is exposed to high risk of infection, dehydration, ketosis, exhaustion, operative interference and often accompanied by loss of morale. The baby suffers in form of intrapartum asphyxia, asphyxia, sepsis and subsequent neurological development may be adversely affected.

Active management of labour, as conceptualized by Prof. O' Driscoll (2), has been widely accepted and shown to be beneficial .Amniotomy, with the judicious use of oxytocin, has been shown to be beneficial in augmenting labour. Various other methods have also been used to augment labour and have been evaluated in studies.

Active management of labor reduces the number of cesarean deliveries (1-5), the number of prolonged labors, and labor duration, without having any adverse effects on the mother or the fetus .A hosts of pharmacological agents have emerged with different mode and site of action, aiming at prevention of prolonged labour. Among others, prolongation of first stage of labour is often due to protracted or arrest of dilatation of cervix.

Various drugs have been used so far to obtain effective dilatation of the internal os, majority of them were found to have its effect on the foetus and mother. Modern Obstetricians are now in search of new drugs, which have got the sole beneficiary effect on the dilatation of the internal os with minimal side effects on foetus and the mother. One such antispasmodic drug is Hyoscine butylbromide which has been used to shorten the duration of labor in many hospitals all over the world.

Hyoscine butylbromide is a quaternary ammonium derivative, which exerts a spasmolytic action on the smooth 4 muscle of the gastrointestinal, biliary, and genitourinary tracts. Hyoscine butylbromide belongs to a parasympatholytic group of drugs and it is a semisynthetic derivative of scopolamine, it has effective antispasmodic activity but devoid of side effects of atropine, it does not cross the blood brain barrier, it acts primarily by blocking the transmission of neural impulses in the parasympathetic ganglia of abdominal organs. An important advantage is that contractions are in no way affected, but due to better co-ordination of contractions, pace of cervical dilatation is increased. This drug can be given by parenteral route (intramuscular and intravenous) but these are painful and risk of sepsis is present. Rectal route of administration of hyoscine butyl bromide has remerged in past few years. Due to rich blood supply and rectal route entails minimum discomfort to the parturient woman while efficacy of drug is not compromised.

Several studies, which included both primigravid and multigravid women, have shown that intravenous application of HBB (20-40 mg) during the active phase of labor increases cervical dilatation ( $\underline{6},\underline{7}$ ) and decreases duration of the first stage of labor ( $\underline{8}$ - $\underline{11}$ ). When given in the latent phase, during which the contractions are still not strong, HBB actually delays the labor progress by decreasing the intrauterine tension ( $\underline{8}$ ). Even though the rectal route is less invasive and would allow administration even by the patients themselves, effects of HBB given as a rectal suppository have been rarely studied. All of these studies involved both primigravid and multigravid women, which could be problematic in labor trials (9,10).

The present study aims at establishing the effect of rectally administered hyoscine butyl bromide on cervical dilatation and its effect on mother and baby. The present study assessed the effects and safety of a single dose (20 mg) of HBB administered as a rectal suppository during labor, since such administration of HBB has been demonstrated to be less invasive and simpler, even possible by the patient herself. This study is an attempt to compare and evaluate the efficacy of Hyoscine butylbromide in the process of cervical dilatation and labour augmentation.

# AIMS AND OBJECTIVES

The present work was undertaken to assess.

- 1. The effect of Hyoscine N. Butyl Bromide on cervical dilatation.
- 2. To evaluate the efficacy of drug given by rectal route in reducing the duration of first stage of labour.
- 3. The effect on maternal and fetal outcome.

4. To note side effects if any.

# MATERIAL AND METHODS

The present study was undertaken in the Department of Obstetrics and Gynaecology, Kasturba Hospital, Bhopal, from 2006 to 2007.

Patients selected for the study were randomly allocated into two groups:

- a) Study Group: Consisted of 200 patients. Of these 100 were primipara and 100 were multipara.
- b) Control Group: Consisted of 200 patients. Of these 100 were primipara and 100 were multipara.

The selection of patients for the study was on the basis of history and examination. A detailed history was taken for each patient followed by a meticulous general and systemic examination. An obstetric examination was carried out to determine the fundal height, lie, presentation, uterine contractions and fetal heart sounds. This was followed by a per vaginal examination and the dilatation effacement and position of cervix, presenting part, its position status of membranes and adequacy of pelvis was assessed.

Every patient was subjected to hemoglobin estimation, Blood group and Rh typing and urinalysis.

#### **Inclusion Criteria:**

- 1. Primipara and multipara (only 1001 patients was included in study).
- 2. Full term singleton pregnancy with vertex presentation.

## **Exclusion Criteria:**

- 1. Scarred uterus
- 2. Fetal demise
- 3. Multiple pregnancy
- 4. Malpresentations
- 5. Cephalopelvic disproportion
- 6. Medical complication like heart disease, diabetes, asthma, myasthenia gravis, glaucoma, mega colon etc

Hyoscine butyl bromide suppositories containing 10 mg of hyoscine butyl bromide in each suppository base was used in the study group. Patients in study group received 2 suppositories of hyoscine butyl bromide on fulfilling the following criteria:

- i) Good uterine contractions
- ii) Cervix minimum 3 cm dilated
- iii) Effacement of cervix minimum 50%
- iv) Intact membranes.

After evacuation of bladder and bowel, the patient is placed in lithotomy position. The 2 suppositories are pushed, pointed end first into the rectum.

The progress of labour was monitored and observations were plotted on a partogram. In the present study, zero time of partogram was taken to be at the onset of active phase of labor (As judged by the presence of good uterine contractions, cervical dilatation of min 3 cm and effacement 50% or more).

Subsequently dilatation of cervix was plotted on the cervicograph. The descent of head was assessed in relation to station of presenting part to ischial spines. The time of rupture of membranes was noted and color of liquor recorded. The uterine contractions were assessed; fetal heart rate was monitored every half an hour in active phase of labour and plotted over the partogram.

Time of full dilatation of cervix and time of delivery of fetus was noted. Apgar score of baby at 1 min and 5 min was taken.

The time between insertion of hyoscine butyl bromide suppository and full dilatation of cervix was taken as the duration of active phase of labor. Drug to delivery interval was noted. Outcome of labor and indication for operative interference if any was noted.

# **OBSERVATION**

The present study was undertaken in Department of Obstetrics & gynecology, Kasturba Hospital, Bhopal from 2006 to 2007.

Four hundred patients were included in this study of these 200 were primipara and 200 were second para. Out of 200 primipara, 100 received Buscopan suppository (study group) and other 100 served as control group.

TABLE NO. 1

AGE WISE DISTRIBUTION OF CASES

S.No.	Age		Study	Group		Control Group				
		Primi		Multi		Primi		Multi		
		No.	%	No.	%	No.	%	No.	%	
1	15-20 yr	40	40	19	19	35	35	17	17	
2	21-25 yr	50	50	64	64	50	50	67	67	
3	26-30 yr	9	9	15	15	14	14	15	15	
4	> 30 year	1	1	2	2	1	1	1	1	

As shown above patients were divided into 4 groups according to age. Primiparas between 21-25 years contributed to 50% in both study and control group. In multiparas 64 % belonged to age group 21-25 years and 15% to age group 26-30 years.

TABLE NO. 2 DISTRIBUTION OF CASES ACCORDING TO PLACE OF RESIDENCE

S.No.	Place of		Study Group				Control Group				
	Residence	Primi	Primi Multi			Primi		Multi			
		No.	%	No.	%	No.	%	No.	%		
1	Rural	53	53	38	38	44	44	48	48		
2	Urban	47	47	62	62	56	56	52	52		

TABLE NO. 3

The place of residence was recorded as rural or urban. In the study group 53% of primiparas were from rural areas and 38% of multiparas were from rural areas. In the control group 44% of primiparas belonged to rural areas.

DISTRIBUTION OF CASES ACCORDING TO SOCIOECONOMIC STATUS

S.No.	Socioeconomic		Study	Group		Control Group				
	Class	Primi		Multi		Primi		Multi		
		No.	%	No.	%	No.	%	No.	%	
1	Class I	1	1	3	3	3	3	3	3	
2	Class II	11	11	9	9	9	9	10	10	

ſ	3	Class III	62	62	63	63	58	58	65	65
	4	Class IV	26	26	25	25	24	24	22	22

Prasad's classification was used in classifying patients as per socio economic status into four classes. Majority of patients belonged to class III and class IV in both study and control group.

TABLE NO. 4 ANALYSIS OF CASES IN RELATION TO DURATION OF ACTIVE PHASE

S.No.	Duration		Study	Group		Control Group				
	in hours	Primi		Multi		Primi		Multi		
		No.	%	No.	%	No.	%	No.	%	
1	1-4	82	82	99	99	62	62	88	88	
2	5-6	16	16	1	1	36	36	11	11	
3	7-8	-	-	-	-	-	-	-	-	
4	9-10	-	-	-	-	-	-	-	-	
5	> 10	-	-	-	-	-	-	-	-	
Mean Duration in hours		3.43	(3hrs.	1.79 (1hr.46min)		4.5 (4hrs.23min)		3.42	(3hrs	
		25m	nin)					25. r	nin)	

The duration of active phase of labor was taken from 3 cm dilatation to full dilatation of cervix.

In the study group, Buscopan suppositories were inserted per rectally at 3 cm of dilatation while no drug was used in control group.

In the study group, mean duration of active phase was 3.43 hrs while it was 4.5 hrs in control group, thus the active of labor was shortened by 1.07 hrs in primiparas.

In multipara mean duration of active phase was 1.79 hour in study group and 3.42 hours in the control group. Hence, in multipara the duration of active phase of labor was shortened by 1.63 hours.

TABLE NO. 5 ANALYSIS OF CASES IN RELATION TO RATE OF CERVICAL DILATATION

	Study Group	Control Group
Primigravida	2.04 cm/hr	1.5 cm/hr
Multigravida	3.91 cm/hr	2.04 cm/hr

The rate of cervical dilatation from 3cm to full dilatation of cervix was calculated.

The mean rate of cervical dilation in the active phase of labor in primi study group was 2.04 cm/hr while in multipara study group was 3.91 cm/hr.

In the control group the mean rates of cervical dilatation for primi and multi were 1.5 cm/hr and 2.04 cm/hr respectively.

TABLE NO. 6
ANALYSIS IN RELATION TO OUTCOME OF LABOR

S.No.	Duration in		Study Group				Control Group			
	hours	Primi		Multi		Primi		Multi		
		No.	%	No.	%	No.	%	No.	%	

1	Spontaneous Vaginal Delivery	98	98	99	99	97	97	99	99
2	Forceps Application	0	0	0	0	1	1	0	0
3	LSCS	2	2	1	1	2	2	1	1

In the present study 2 patients underwent LSCS in the study group for fetal distress and 98% had spontaneous vaginal delivery. In the primi controls, 97% had spontaneous vaginal delivery, 1 had outlet forceps application for prolonged second stage and 2 had LSCS (both for fetal distress).

Out of multipara, in the study group, 99% had spontaneous vaginal delivery and 1 patient underwent LSCS for deep transverse arrest. In the control group, only one patient underwent LSCS for fetal distress and 99% had spontaneous vaginal delivery.

TABLE NO. 7 ANALYSIS IN RELATION TO SIDE EFFECTS

S.No.	Side Effects	No.	%
1	Dryness of mouth	26	13
2	Maternal Tachy Cardia	6	3
3	Facial Flushing	4	2

13 % of patient experienced dryness of mouth, 3% of patients had tachycardia and 2% experienced facial flushing. In none of the patients fetal heart rate irregularities were noticed.

TABLE NO. 8 ANALYSIS IN RELATION TO APGAR SCORE OF BABY

S.No.	Apgar		Study	Group		Control Group				
	Score	Primi		Multi		Primi		Multi		
		No.	%	No.	%	No.	%	No.	%	
1	≤ 7	4	4	6	6	8	8	6	6	
2	8	10	10	18	18	20	20	16	16	
3	9	14	14	28	28	32	32	36	36	
4	10	72	72	48	48	40	40	42	42	

Majority of babies had 5 min Apgar score of 6 in the study group only 1 baby had 5 min. Apgar score of 6 (Patient had LSCS for fetal distress)

# **DISCUSSION**

The use of Hyoscine N Butyl bromide in obstetric practice goes back to years. Observations have been record as early as 1950s.

Studies on obstetric uses are based on the extension of specific spasmolytic action on the intramural vagal ganglia of the abdominal organs, thus making spasmolytic action by inhibiting the neural impulse in this pathway. Wick (195 demonstrated that it has pronounced spasmolytic effect, similar to that of hyoscine and atropine but without the undesirable side effects these alkaloids have on the salivary and sweat glands; the eye and the heart.

The actions of hyoscine butyl bromide in labor are based on the observations of Saigannik (1936) that the cervix is supplied by parasympathetic and the body of uterus by sympathetic nerve supply and this functional antagonism is synergistic to uterine contractions that is, the cervical dilatation stimulates uterine contractions. The uterine efficiency was increased not by increase in strength or frequency of contractions but due to the fact that same uterine contractions were rendered more effective by easing cervical dilatation and reducing cervical spasm.

Hyoscine butyl bromide has selective action on the cervicouterine plexus and brings about cervical dilatation and at the same time does not affect the uterine contractions (Obama 1957)<sup>12</sup>. On the contrary there can be an increased co-ordination in contractions, thus helping to hasten normal labor (Richter 1953).<sup>13</sup>

In the present study, 400 patients in active labor were studied of these 200 were primipara and 200 were multipara (only second para were included to ensure comparability). The study group consisted of 100 primipara and 100 multipara. They were given 2 suppositories each having 10 mg of hyoscine butyl bromide per rectally at 3 cm cervical dilatation, effacement of cervix 50% or more and good uterine contractions. In the present study, only the duration of active phase of labour was considered and the effect of the drug in shortening of in shortening of active phase of labor was noted. It was observed that the mean duration of first stage of labor was 3.43 hrs. in primipara who received hyoscine butyl bromide rectally, while in control group it was 4.5 hours. Thus the shortening in duration of active phase was 1.07 hrs. In multipara, the mean duration of for active phase of labor was 1.79 hours in study group and 3.42 hours in control group. Studies carried out in the past reflect the action of hyoscine butyl bromide in shortening the first stage of labor and thereby bringing about a reduction in total duration of labor.

In the study of Bhattachaiya et al (1985)<sup>14</sup>: 50 patients (all primiparas) were divided into study & control group of 25 patients each. In this study, the total duration of first stage, second stage & third stage was observed. The mean duration of labor in primi study group was 5.21 his and in control group was 8.88 hours. The reduction shown was 3.67 hours. They surmised that hyoscine butyl bromide was an effective cervical dilator in primipara and was specifically useful in a. spastic cervix with good uterine contractions. Baracho et all (1984) studied the effect of hyoscine butyl bromide on labor in 50 patients (25 primi paras & 25 multiparas. The total duration of labor in primi study group was 7.11 his (which was 2.02 his less than that in primi control group) in his study, the duration of active phase was recorded separately. it was 3.5 hrs in primi study group & 2.4 hrs in multi study group. In the controls, the mean duration of active phase was 4.83 his and 3.78 hrs respectively. These finding are consistent with those of the present study.

In study by Bhattacharya <sup>14</sup>, the cervical dilatation rate was found to be 1.92 cm/hr in primi study group & 1.7 cm/hr in primi control group. In the study by Baracho et all, the cervical dilatation rate was 1.85 cm/hr in primi study group and 1.35 cm/hr in primi control group. In multipara, it was 3.11 cm/hr in study group & 2.04 cm/hr in control group.

In the present study, the cervical dilatation rates were 2.04 cm/hr in primi study group and 1.5cm/hr in primi control group. In multipara, the cervical dilatation rate was 3.91 cm/hr in study group & 2.04 cm/hr in control group.

Thus rectally administered hyoscine butyl bromide has efficacy similar to that of parenterally administered drug in bringing about cervical dilatation.

When the outcome of labor was considered, in the study by Bhattachaiya et al<sup>14</sup>, the results were as follows. Of the study group, 4 patients underwent LSCS (indications were fetal distress in 2 patients, deep

transverse arrest and cervical dystocia). In the control group, 6 patients underwent caesarean section (3 for fetal distress. 3 for cervical dystocia) 6 patients in each group had forceps delivery. In the study by Baracho et al<sup>15</sup>, there was 1 caesarean section in primi study group (indication was deep transverse arrest) In the primi control group, 2 patients underwent- caesarean section (indications were fetal distress and failed forceps respectively); forceps application was done in 4 patients: 2 in primi study group & 2 in primi control group Vaccum extraction was performed in 2 patients, 1 in multi study group and 1 in multi control group respectively.

In the present study, in the study group, 2 patients underwent LSCS in the primi study group (indication: fetal distress) In the primi in control group. 2 patients underwent LSCS (indication: fetal distress) and 1 patient had outlet forceps delivery for prolonged second stage of labor. Out of multipara in the study group, I patient underwent caesarean section for deep transverse arrest. In the multi control group, there was one LSCS for fetal distress.

# **CONCLUSION**-The following conclusions are drawn from the study.

- 1. Hyoscine butyl bromide is an anticholinergic drug which effectively brings about cervical dilatation M the first stage of labor.
- The rectal route can be used with good results, with less discomfort to the patients and less chances
  of systemic or local infection due to good absorption of drug by vascular columnar epithelium of
  rectum.
- 3. There is demonstrable shortening of active phase of labor and faster rate of cervical dilatation in patients receiving the drug by the rectal route.
- 4. There were no significant side effects on the mother and baby.

We believe our study showed that HBB rectal suppository was effective in shortening the duration of labor without any significant detrimental effects to the mother and

the new born. Hyoscine butylbromide dilates the cervix more rapidly, and the duration of active phase was shorter in Hyoscine butylbromide group than control group Furthermore, the rectal administration of the drug is more convenient, absorption is faster, gastric irritation is avoided, and hepatic metabolism is partially bypassed.

Hyoscine butylbromide is better in achieving the end result. Hence it can be used in

Modern obstetrics to relieve spasm and to hasten the rate of cervical dilatation and thereby promoting safe delivery. Buscopan because of its convenience of administration (as rectal suppository) can be an alternative in rural setups where trained medical personnel may not be available most of the times

Further studies are necessary to fully evaluate the benefits of HBB, as well as its effect on women in induced labors or those with an active phase arrest or protraction disorders.

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