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A STUDY OF THE EFFECT OF HYOSCINE BUTYL BROMIDE ON THE DURATION OF LABOUR

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ABSTRACT

Objective: The purpose of this study was to assess whether hyoscine butyl bromide is effective in improving cervical effacement and dilatation, thus reducing the duration of first stage of labour without causing any maternal and neonatal complications. Materials and **Methods:** It was a prospective, comparative, observational study. 80 women with term pregnancies in active labour were recruited for the study. They were allocated into 2 groups, study and control group each with 40 patients. The duration of active labour was taken from 3 cm dilatation to full dilatation of the cervix. The study group received 40 mg HBB as slow I V injection (over 1 – 2 min) given at hourly intervals up to a maximum of 3 doses starting at 3 cm dilatation. Results: The mean duration of active phase of labour was 109.28 ± 58. 42 minutes in the study group and 317.48 ± 108.9 in the control group. The difference between the 2 groups was statistically significant ($p< 0.001$). In 25 (62.5%) women, the onset of active labour to delivery interval was < 2 hours in the study group whereas it was only 2 (5%) in the control group. Similarly 2 (5%) women took > 4 hours after first injection of HBB to deliver whereas 29 (72.5%) women took > 4 hours after onset of active labour to deliver in control group (table 5). This was statistically significant ($p < 0.05$). There was no difference in the APGAR scores in the 2 groups. No significant adverse effects were noted in the group of women receiving HBB. **Conclusion:** HBB is a safe drug and is effective in significantly reducing the duration of labour.

KEYWORDS: first stage, hyoscine butyl bromide (HBB), labour, cervical dilatation.

INTRODUCTION

Every woman would appreciate a painless and short duration of labour. Labour is a process beginning with the onset of regular uterine contractions until the expulsion of the placenta. It involves myometrial contractions, cervical ripening and dilatation and then expulsion of the fetus and placenta in an orderly manner. The first stage of labour lasts for 12 – 16 hours in primigravida and 6 -8 hours in multigravida.

The hazards of prolonged labour have been well recognized. There is an increased incidence of maternal distress, PPH, infection, dehydration and operative interference. The baby may suffer from asphyxia, sepsis and neurological insult.[1]

Attempts to shorten the duration of labour, especially the first stage has been an endeavor for the past several years. Cervical dilatation and effacement is an important factor apart from the driving force of uterine contractions which determines the duration of labour. Among the various causes of prolonged labour, protracted dilatation and effacement of the cervix is a major contributor.

Various pharmacologic agents with different modes and sites of action have emerged aiming to prevent prolonged labour. There are a host of drugs used to obtain effective effacement and dilatation of the cervix. One such drug is hyoscine-butyl-N-bromide.

Hyoscine-butyl-N-bromide is a quaternary ammonium derivative which exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genitourinary tract. Several studies have shown that intravenous injection of HBB (20 – 40 mg) during the active phase of labour increases cervical dialatation and decreases the duration of the first stage of labour.

The objectives of this study were to assess whether HBB is effective in improving cervical effacement and dilatation, thus reducing the duration of first stage of labour. It was also intended to analyze whether the use of HBB has any associated increase in complications for the mother and foetus.

MATERIALS AND METHODS

This study was undertaken in the Department of Obstetrics and Gynecology, ESICMC & PGIMSR, Bangalore. 80 pregnant women in active labour admitted in the labour room between January 2014 to December 2014 were recruited for the study. The inclusion criteria were primi & multigravidae with gestational age of 37 – 40 weeks, singleton pregnancy with

vertex presentation expected to have spontaneous vaginal delivery. The exclusion criteria were scarred uterus, overdistended uterus (hydramnios, multiple pregnancy and large baby), antepartum hemorrhage, cephalopelvic disproportion, caesarean and instrumental delivery and known coagulation and medical disorders. After a detailed history taking, general physical and obstetric examinations were performed. Informed consent was taken from those who fulfilled the inclusion criteria. The study was approved by the institutional ethics committee.

The women who were in active labour were allocated into 2 groups, study and control group each with 40 patients. Active labour was defined by cervical dilatation of 3cm with uterine contractions at interval of 3 – 4 minutes lasting atleast 40 seconds. The duration of active labour was taken from 3 cm dilatation to full dilatation of the cervix. The study group received 40 mg HBB as slow IV injection (over 1 – 2 min) given at hourly intervals up to a maximum of 3 doses starting at 3 cm dilatation. The progress of labour was monitored and a partogram maintained for all participants. Labour was conducted according to labour room protocol. Oxytocin augmentation was done if the initial progress of labour was unsatisfactory in both groups. Fetal heart rate was monitored regularly and CTG assisted in monitoring. Duration of first stage was calculated from the time of injection of HBB to the time of full dilatation of cervix in the study group. Total duration of active phase of labour, rate of cervical dilatation, mode of delivery, injection – delivery interval, any complications in third stage, neonatal condition at birth, side effects of the drug were recorded in every patient and both groups compared.

RESULTS

A total of 80 women in active labour were chosen for the study. The age of patients in both groups ranged from 18 to 35 years. The numbers of primigravidae were 14 and 19 respectively in the study and control group whereas multigravidae were 26 and 21 respectively in the study and control group. The 2 groups were well matched with respect to baseline characteristics. (table 1).

Table 1 – Baseline characteristics of study and control group (mean +/- SD)

Age group	Study group N (%)	Control group N (%)	Total N (%)	p value
18 to 24 years	15 (37.5)	24 (60.0)	39 (48.8)	0.129
25-30 years	23 (57.5)	15 (37.5)	38 (47.5)	
31-35 years	2 (5.0)	1 (2.5)	3 (3.8)	
Total	40 (100)	40 (100)	80 (100)	

Parity	Study group N(%)	Control group N(%)	Total N(%)	p value
Primipara	14 (35)	19(47.5)	33(41.2)	0.256
Multipara	26(65)	21(52.5)	47(58.8)	
Total	40(100)	40(100)	80(100)	

The mean duration of active phase of labour was 109.28 ± 58. 42 minutes in the study group and 317.48 ± 108.9 in the control group. The difference between the 2 groups was statistically significant (p< 0.001) (table 2).

Table 2. Comparison of duration of active phase of labour (in minutes) in study and control group (n=80) (student t test).

Group	Mean duration of active labour minutes	Std. Deviation	Mean difference of duration of active labour	p value	95% confidence interval
HBB group	109.28	58.42	-208.2	<0.001	-247.1 – 169.2
Control group	317.48	108.97			

In 25 (62.5%) women, the onset of active labour to delivery interval was < 2 hours in the study group whereas it was only 2 (5%) in the control group. Similarly 2 (5%) women took > 4 hours after first injection of HBB to deliver whereas 29 (72.5%) women took > 4 hours after onset of active labour to deliver in control group. This was statistically significant (p < 0.05). (table 3).

Table 3. Distribution of onset of active labour to delivery interval in study and control group (n=80).

Onset of active labour to delivery interval	Study group N (%)	Control group N (%)	Total N (%)
< 2 hours	25(62.5)	2(5.0)	27(33.8)
2 to 4 hours	13(32.5)	9(22.5)	22(27.5)
>4 hours	2(5.0)	29(72.5)	31(38.8)
Total	40(100)	40(100)	80(100)

Chi square p value: < 0.001.

There was no statistical difference in the number of doses of HBB injection administered to primis when compared to multis in the study group (table 4).

Table 4. Distribution of study group according to parity and number of doses of HBB (N=40).

Number of HBB doses given	Multi N (%)	Primi N (%)	Total N (%)
1 dose	8 (30.8)	1 (7.1)	9 (22.5)
2 dose	9 (34.6)	7 (50)	16 (40)
3 dose	9 (34.6)	6 (42.9)	15 (37.5)
Total	26 (100)	14 (100)	40 (100)

Chi square p value: 0.228.

Table 5. Comparison of injection delivery interval (idt) in study group according to parity (N=40) (student t test).

Parity (N)	Mean idt (minutes)	Standard deviation	Mean ifference of idt	p value	95% confidence interval
Primigravida(14)	127.5	65.7	28.03	0.15	-10.5 to 66.6
Multigravida(26)	99.4	52.8			

Primigravidae in the study group had a mean injection delivery interval of about 127 minutes in comparison to multigravidae in the study group who had a mean injection delivery interval of about 99 minutes, but the difference was statistically not significant (p >0.05).

There was no difference in the APGAR scores in the 2 groups.

No adverse events or significant adverse effects (like dryness of mouth, tachycardia) were noted in the group of women receiving HBB.

DISCUSSION

The goal of obstetrics has always been a pregnancy which results in a healthy infant and minimally traumatized mother. The problems of prolonged labour are many and painless and short duration of labour is a cherished dream of every mother.

It is well documented that active management of labour which refers to the active control rather than passive observation reduces the complications of prolonged labour.[2, 3]

Hyoscine butyl bromide is one such drug which is being used with an aim to reduce the duration of labour. It is a parasympatholytic drug and is a semisynthetic derivative of scopolamine. HBB does not cross the BBB and plasma protein binding is low. It can be administered in various routes (IM, IV, rectal, oral).[4]

Several studies have shown that IM/IV application of HBB (20 – 40 mg) during active phase of labour increases cervical dilatation and decreases duration of first stage of labour.[5,6]

In a study by Aggarwal et al.[7] the injection delivery interval was between 2 – 4 hours in 84% of women in study group (mean duration 3 hours 46 minutes) while it was only 9% in the control group (mean duration 8 hours 16 minutes).

In a similar study by Samuels et al.[8] mean time for the first stage in the control group was 228 minutes, compared with 156 minutes in the HBB group, a difference of 72 minutes. This represents a decrease of 31.7% and was statistically significant (p = 0.001). There was no significant change noted in the time for the second and third stage of labour.

Tewari et al.[9] was the first to use 40mg of HBB intravenously and found that labour was shortened by 5hr12 min when compared to controls.

The results of the above study are comparable to the results of our study.

Similar to the above studies, there was also no difference in APGAR scores in the neonate in the 2 groups in our study. No significant adverse effect in the mother was noted.

CONCLUSION

HBB is a safe drug and is effective in significantly reducing the duration of labour. This is important because this helps in reducing the incidence of infection, neonatal sepsis and PPH which are all increased in women with prolonged labour. It is also safe with no untoward fetal or maternal effects.

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