

THE EFFECT OF HYOSCINE BUTYLBROMIDE ON 1ST STAGE OF LABOUR IN TERM PREGRENCACY

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ABSTRACT

Objective: To determine the effect of hyoscoine butylbromide in shortening active phase of 1st stage of labour without adverse effects in mother and fetus.

Study Design: Randomized, double- blinded placebo controlled trail.

Place and Duration: Labour ward of PNS SHIFA hospital for duration of 06 months from 1st Jan 2008 to 30 June 2008

Patients and Method: One hundred pregnant women both primigravida and multigravida in active phase of spontaneous labour (an active phase is defined as 3 cm or more cervical dilatation with regular uterine contraction) were included in the study. Either drug or placebo was given intravenously once the women entered active labour. Progress of labour was plotted on partogram student 't' test was applied for comparison of two groups.

The duration of 1st stage of labour was main outcome. Secondary outcome measures included duration of second and third stages of labour, blood loss at delivery, and apgar score in neonates between the two groups.

Result: In patient receiving hyoscine butylbromide the active phase of 1st stage of labour was 194.8 ± 87.3 mins as compared to placebo group where active phase 1st stage of labour was 282.3 ± 92.3 . There was significant difference in duration of active phase 1st stage in both groups of (87.5 mins), There was no significant change in duration of second and third stage of labour, no difference in blood loss, and apgar score in both groups.

Conclusion: Hyoscine butylbromide is effective significantly in reducing duration of 1st stage of labour in primigravida and multigravida with term pregnancy and it is not associated with any adverse out come in mother or neonate.

Keywords: Cervix, dilatation, hyoscine butylbromide (HBB), Primigravida, multigravida.

INTRODUCTION

The concept of active management of 1st stage of labour was introduced in Dublin to shorten the length of labour¹ the problems and hazards of prolonged labour, to, both for mother and foetus have been recognized for many years the mother is exposed for high risk of infection, ketosis and obstructed labour while the foetus faces the danger of infection, asphyxia and excessive cranial moulding². O'Driscoll at the national Maternity Hospital, Dublin, Introduces the concept of active management of labour³. This has influenced the obstetrician to change their approach regarding managing 1st stage of labour⁴⁻⁹.

Active management of labour is associated with low incidence of prolonged labour, low

incidence of instrumental delivery low risk of caesarean section⁹, low risk of fetal asphyxia and excessive cranial moulding.. The safety of active management has been demonstrated by several prospective randomized trial involving over 3000 women¹⁰. The shorter duration of labour from admission to delivery has also been consistently reported in numerous study of women treated with active management protocol¹⁰.

Spasmolytic drugs are frequently employed to overcome cervical spasm to reduce the duration of labour^{11,12}. Hyoscine (also known as scopolamine) butyl bromide is a quaternary ammonium compound which exert spasmolytic action on smooth muscle of gastrointestinal tract and genitourinary tract¹³⁻¹⁵. It belongs to Para sympatholytic group of drugs has anti cholinergic action but no central action it does not cross blood brain barrier and is devoid of untoward side effect of atropine¹⁶.

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(HBB) act primarily by blocking transmission of neural impulses in the intra neural parasympathetic ganglia of abdominal organ apparently inhibiting the cholinergic transmission in the synapses.

The specific objective of this project was to assess whether the hyoscine butyl bromide (in the form of buscopan) is effective in hastening cervical effacement and dilatation thus shortening the duration of 1st stage of labour. We also intend to determine with the use of Hyoscine Butyl Bromide in the first stage of labour is associated increase in complications such as increase in blood loss, and decrease in neonatal APGARSCORE.

PATIENTS AND METHODS

Double blind, randomized controlled trial conducted in labour ward of PNS SHIFA hospital. This was a prospective study carried on hundred pregnant women (primigravida and multigravida) admitted with spontaneous and active labour (3 cm or more cervical dilation with regular uterine contraction) between 37 to 40 weeks of gestation from Jan 2008 till June 2008. Study was designed to evaluate the efficacy of hyoscine butyl bromide on 1st stage of labour women with normal singleton pregnancy at 37 - 40 weeks of gestation with vertex presentation intact membrane and spontaneous onset of labour were included in the study. Those with uterine scar, malpresentation, cephalopelvic disproportion, twin gestation and with any medical disorder are excluded from study. This study was approved by hospital ethical committee.

Women are recruited from labor room, informed consent was taken. Adequate opportunity was provided at that time for the women to voice any questions or concerns regarding the study.

Women included in the study were all 18 years or older, were at term, and had no chronic or pregnancy induced illnesses. No woman had any contraindication to vaginal delivery, and all women were in established, spontaneous labour. Established labour was defined as the presence of regular uterine contraction associated with progressive cervical effacement and dilatation.

The syringes containing the drug and placebo were prepared by the principal investigator, under aseptic conditions and on a rolling basis (i.e fresh batches were prepared as additional participants were enrolled). Each syringe contained either 1 ml of hyoscine butyl bromide (20 mg) or 1 ml of normal saline; both liquids are colorless, so the syringes containing the drug were indistinguishable from those containing placebo.

A computer program was used to generate a random sequence of numbers. Sequentially numbered, sterile syringes were then prepared using the random numbers to determine content: placebo or hyoscine. Only the principal investigator knew the correlation between the labels of the syringes and their contents, and this was only shown after the study was completed. Participants received the contents of syringes as a single dose, given intravenously, when they were assessed as being in labour, with cervical dilatation of 5cm, as confirmed and documented by either a certified midwife or a resident in the Obstetrics and Gynecology program. The woman and the caregivers were blinded as to whether the active drug or placebo was being administered.

The progress of the participants was closely documented, with the conduct of labour for both the drug and control groups in accordance with our normal labour ward protocol, which is based on the principle of active management. Thus routine amniotomy was performed for all women in established labour who were found or have cervical dilatation of 3 cm or more, and who had not had spontaneous rupture of membranes. Oxytocin augmentation was initiated if the initial progress of labour (as assessed through partographs) was unsatisfactory. Intervention through instrumentation or caesarean delivery was dictated by the usual obstetric determinants. Labouring mothers were monitored in bed, and the use of electronic cardiotocography assisted in the monitoring of fetal wellbeing.

All data sheets (containing the raw data obtained during the study) were collected by the principal investigator and kept in a combination locked filing drawer in her office.

At the end of the study, the data were disaggregated by the participants and their data into the appropriate groups (drugs or placebo).

Data analysis was performed by using SPSS (statistical program for social sciences) version- 10.0. For continuous response variables like maternal age ,gestational age, duration of 1st, 2nd and 3rd stages of labour, blood loss and apgarscore at 1 and 5 minutes were presented by Mean \pm Standard deviation and Student's -t- test was applied to compare these variable between two groups. Proportions of parity status between two groups were compared by applying Chi- square test. Statistical significance was considered if $p < 0.05$.

RESULTS

The mean age of 50 women who were recruited as placebo was 27.2 ± 5.03 years and of 50 women who underwent Hyoscine Butylmide was 25.9 ± 4.5 years that have shown statistically insignificant difference of mean age between two groups ($p = 0.183$). Mean gestational age of two groups was also statistically equal ($p = 0.935$). Majority of both groups (72%) were multiparous (para 2-5) as detailed in table-1.

Mean duration of 1st stage labor of 50 women who underwent Hyoscine Butylmide was significantly shorter than placebo group (194.8 ± 87.3 vs. 282.3 ± 92.3 , $p < 0.001$), however mean duration of 2nd and 3rd stages were statistically insignificant between two groups (Table-2).

Mean blood loss in both groups was observed almost similar in both groups. Mean apgar score at 1 minute among neonates of 50 placebo women was 7.98 ± 0.98 that was slightly but insignificantly less than the mean apgar score (8.06 ± 0.98) among neonates of 50 women who underwent Hyoscine Butylmide ($p = 0.684$), however desirable good apgar score was thus revealed in both groups. Mean apgar score at 5 minutes was also desirable and insignificant in both groups (0.112) as detailed in table 2.

DISCUSSION

Hyoscine butylbromide, in the form of Buscopan has been used to shorten the duration of labour in several hospitals. Whereas its analgesic properties are probably negligible in

Table-1: Comparison of demographic variables between placebo and drug groups:

Variables	Placebo (n = 50)	Hyoscine Butylmide (n = 50)	p-value
Age (years)	27.2 \pm 5.03	25.9 \pm 4.5	0.183
Gestational age (weeks)	38.44 \pm 1.16	38.42 \pm 1.3	0.935
Parity			
▪ Primi (0-1)	11 (22)	12 (24)	0.863
▪ Multiparous (2-5)	36 (72)	36 (72)	
▪ Grand Multiparous (>5)	3 (6)	2 (4)	

Values at age and gestational age in Row 2, 3 are Mean \pm Standard deviation. Values given in parentheses are percentage.

Table-2: Comparison of outcome between placebo and drug groups:

Variables (mean \pm SD)	Placebo (n = 50)	Hyoscine Butylmide (n = 50)	p-value
1st stage labor (minutes)	282.3 \pm 92.3	194.8 \pm 87.3	0.001*
2nd stage labor (minutes)	26.66 \pm 14.35	24.32 \pm 14.8 2	0.424
3rd stage labor (minutes)	8.20 \pm 3.03	8.64 \pm 2.91	0.461
Blood loss	129.12 \pm 50.0	129.48 \pm 75. 4	0.978
Apgar score at 1 minute	7.98 \pm 0.98	8.06 \pm 0.98	0.684
Apgar score at 5 minutes	9.94 \pm 0.24	9.84 \pm 0.37	0.112

*Shows statistically significant difference at 5% level of significance

the context of labour, its value lies in the reduced time spent in the first stage, and consequently the reduced overall time spent in the pain by the labouring mother. Although its use is fairly widespread, the evidence for its efficacy in our population has been largely anecdotal, up until now. A review of the literature showed only a few other studies relation to hyoscine butylbromide and its use in labour. Most of these were conducted 20-30 years ago none was randomized and double-blinded studies, and none was conducted in population similar to ours.

Our study have shown potential benefits of a reduced first stage time, a reduced incidence of chorioamnionitis, neonatal sepsis, and puerperal; sepsis, all of which are increased

in women with prolonged labour. These results are comparable with studies of Saamuels et al¹.

Reduced need for repeat doses of opioid analgesia, which is associated with neonatal respiratory depression, is also a major benefit of a shorter labour process, This is particularly true in regions where epidural analgesia is not widely available, so opioid medication are used with increased frequency. Additionally, we are fairly certain that any intervention which can safely reduce the amount of time spent in the painful process of parturition will be greatly appreciated by our women.

The reduction in first – stage time may also prove to be of particular importance in the context of women with borderline placental reserve, as may be encountered in women with hypertension (both chronic and Gestational) , which is quite common in our population, Prolonged labour in these women may result in the fetoplacental reserves being depleted, with consequent signs of fetal distress, and the increased possibility of an abdominal delivery. Shortening the labour time could conceivably help prevent some of these surgical interventions; however, these potential benefits will need to be confirmed by further prospective studies, since none of our women had any of these conditions.

Our study has demonstrated that hyoscine butylbromide causes a significant reduction in the first stage of labour for one hour and twenty seven minutes. Our results are comparable with Sirohiwal and, Dahiya¹² and Raghavan¹³. However, we also demonstrated that there was no statistical difference in duration of second and third stage of labour, amount of blood loss and APGARSCORE in both groups, implying that the action of hyoscine butylbromide is primary on the cervix, and not so much on promotion of uterine activity. This is important, as it obviates the concern regarding an excessively rapid second stage.

CONCLUSION

Based on the results of our study, and noting the supportive data from similar clinical trials, we conclude that Hyoscine butylbromide is effective in significantly reducing the duration of the first stage of labor and that it is not associated with any obvious adverse outcomes in mother or neonate. Further long – term evaluation will be necessary to fully evaluate the scope of benefits that this reduction may confer.

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