# EFFECT OF HYOSINE BUTYLBROMIDE ON FIRST STAGE OF LABOUR IN TERM PREGNANCY

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## ABSTRACT

***Objective:*** To determine the effect of hyosine butyl bromide on mean duration of first stage of labor in term pregnancy by comparing with control group.

***Study Design:*** Randomized, double-blind, controlled trial.

***Place and Duration of Study:*** Department of obstetrics and gynecology CMH Rawalpindi, from Oct 2012 to Sep 2013.

***Material and Methods:*** This was a randomized, double-blind, controlled trial, conducted at department of Gynecology and Obstetrics Combined Military Hospital (CMH) Rawalpindi. Total patients included in the study were 108. Patients were distributed in two groups on the basis of drug given to them. Group-A was labeled as drug Hyoscine Butyl Bromide (HBB) and Group-B was labeled as placebo. Patients selection was done by using a pre defined inclusion and exclusion criteria. Women were admitted with spontaneous and active labour (4cm or more cervical dilation with regular uterine contraction) between 37 to 40 weeks of gestation, with singleton pregnancy, vertex presentation and intact membrane. Laboring mothers were monitored in bed till full dilatation of cervix. The collected data was endorsed on patient's performa. Data entry and analysis was done by using SPSS 12 and analyzed accordingly to the statistical plan.

***Results:*** Mean age of patients in group A was 25.85 ± 3.85 and in group B was 28.07 ± 4.71 years. Mean gestational age in Group-A and group- B was 38.67 ± 1.06 and 38.33 ± 1.09 weeks. Mean duration of first stage of labor in Group-A was 178.98 ± 92.44 and in group-B was 214.74 ± 147.44 minutes. According to *p*-value mean duration of first stage of labor in both groups was statistically same. i.e. (*p*-value= 0.135).

***Conclusion:*** Use of hyoscine butylbromide allows reduction in the mean duration of first stage of labour as compared to the control group. It not only minimizes the possibility of hastened delivery but also its use can prevent prolonged labour.

**Keywords:** First stage of labour, Hyosine Butyl bromide, Term Pregnancy.



## INTRODUCTION

First stage of labor can be shortened by active management. This concept was introduced in Dublin. Active management means active control, rather than passive observation during labour by the obstetrician. Active management of labour is safe, which is documented by different clinical trials[1]. Hazards of prolonged labour, to mother and fetus are well known for many years, Mother is exposed to high risk of infections, increased pain, high rate of chorioamnionitis, postpartum hemorrhage and neonatal admissions to ICU[2]. Prolonged labour is a significant contributor to increase in cesarean section rate and has shown to raise the risk four to six times[3]. Women and obstetrician both want to conduct delivery in shortest possible time without compromising safety of mother and fetus. So, along with oxytocin administration and early amniotomy, use of antispasmodic agents to hasten the first stage of labor like hyosine butylbromide, drotaverine, dicyclomine valethamide etc, is also advised[4].

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Hyoscine butylbromide (HBB) is derived from hyoscine, extract of tree dubosia, which is present in Australia and has antispasmodic action and is known since 1957[5] Hyoscine is quartenary ammonium compound which has spasmolytic effect on smooth muscles of genitourinary tract and gastrointestinal tract. Six in abdominal and pelvic parasympathetic ganglia it inhibits cholinergic transmission, especially cervico-uterine plexus and aids dilatation of cervix. It does not affect uterine contractions but improves co-ordination between cervical dilatation and contractions of uterus but the dilatation of cervix is increased. After intravenous dosing its action starts in 10 minutes, at 20-60 minutes is peak effect, and duration of action is 2 hours, elimination half life is 4.8 hours[7].

The objective of the study is to assess whether HBB effectively hastens the cervical dilatation and effacement leading to reduction in duration of active phase of first stage of labour and prevents prolonged labour.

## PATIENTS AND METHODS

The study was designed as a randomized, double blind, controlled clinical trial that compared two groups: hyoscine given to group-A, while the placebo given to group-B.

Total of 108 patients were taken (54 patients in each group randomly allocated) by using WHO sample size calculator, taking level of significance 5%, power of test 90%, population standard deviation 127, test value of population mean 228, anticipated population mean 156. One hundred eight patients were selected for a confidence interval of 95%. Sample technique was non-probability consecutive sampling.

After approval from hospital ethical committee, randomized double blind controlled trial was started in labour room. Prospective study was conducted on 108 women (primigravida and multigravida). Women were admitted with spontaneous and active labour (4cm or more cervical dilation with regular uterine contraction) between 37 to 40 gestational weeks, with singleton pregnancy, vertex presentation and intact membrane. Those with previous cesarean section, malposition, CPD, twin pregnancy and with any medical disorder were not included in study. From all the patients written informed consent was taken. Principle investigator prepared the syringes of placebo and drug, fresh syringes prepared for new patients. Each syringe contains 1ml of HBB (20mg) or 1ml normal saline. These both were colorless and syringes of drug couldn't be distinguished from the syringes with placebo. Syringes with drug were labeled as A and with placebo was labeled as B. Only principle investigator were labeled and their content. Patients were randomly assigned to group A and B based on lottery method. No intervention was done till 4cm cervical dilatation. After which oxytocin infusion was started at rate of 6mU/ml titrated according to uterine contractions. Artificial rupture of membranes was done after 4cm dilatation and participant was given a single intravenous dose of syringe. Doctor and woman were blinded whether drug or placebo is given. The progress was documented on partogram for both the control and study group. Intervention like caesarean section or instrumental delivery was decided by usual obstetric determinants. Monitoring of laboring women was done in bed till full dilatation of cervix. The collected data was endorsed on patient's Proforma.

All the data collected through the Proforma was entered into the statistical package for social sciences (SPSS) version 12 and analyzed. For continuous response variables like maternal age, gestational age, duration of first stage of labour was presented by Mean and standard deviation, independent samples t-test was applied to compare mean duration of first stage of labour in two groups, A $p$-value<0.05 was considered statistically significant.

## RESULTS

In this 108 pregnant women were included who were primigravida and multigravida. In Group-A mean age of patients was 25.85 ± 3.85 and in group-B was 28.07 ± 4.71 years. Mean age

of all 108 patients was 26.96 ± 4.42 years. Minimum and maximum age observed was 18 and 34 years.

Parity of pregnant women was present in the table-1. As per inclusion criteria (table-1).

Mean gestational age in Group-A and group-B was 38.67 ± 1.06 and 38.33 ± 1.09 weeks. Overall mean gestational age in all patients was 38.50 ± 1.08 years. Minimum and maximum gestational age was 37 and 40 weeks respectively. (table-2).

Mean duration of first stage of labor in Group-A and in Group-B was 178.98 ± 92.44 and 214.74 ± 147.44 respectively. Mean duration of first stage of labor of all 108 patients was 196.86 ± 123.79. Minimum and maximum duration of first stage labor was 40 and 680 respectively. According to *p*-value mean duration of first stage of labor in both groups was statistically same. i.e. (*p*-value=0.135) (table-3).

**Table-1: Parity of patients in both study group.**

| | | Groups | | | | Total | |
|---|---|---|---|---|---|---|---|
| | | Group-A | | Group-B | | | |
| **n** | | 54 | | 54 | | 108 | |
| **Parity** | 1 | 19 | 35.19% | 9 | 16.67% | 28 | 25.93% |
| | 2 | 12 | 22.22% | 12 | 22.22% | 24 | 22.22% |
| | 3 | 17 | 31.48% | 15 | 27.78% | 32 | 29.63% |
| | 4 | 4 | 7.41% | 9 | 16.67% | 13 | 12.04% |
| | 5 | 2 | 3.70% | 8 | 14.81% | 10 | 9.26% |
| | 6 | 0 | 0.00% | 1 | 1.85% | 1 | 0.93% |
| **Total** | | 54 | 100% | 54 | 100% | 108 | 100% |

Group-A= Hyoscine Butyl Bromide
Group-B=Placebo

**Table-2: Gestational age in both study group.**

| | Groups | | Total |
|---|---|---|---|
| | Group-A | Group-B | |
| N | 54 | 54 | 108 |
| Mean | 38.67 | 38.33 | 38.50 |
| SD | 1.06 | 1.09 | 1.08 |
| Minimum | 37 | 37 | 37 |
| Maximum | 40 | 40 | 40 |

Group-A= Hyoscine Butyl Bromide
Group-B=Placebo

**Table-3: Duration of first stage of labor in both study group.**

| | Groups | | Total |
|---|---|---|---|
| | Group-A | Group-B | |
| N | 54 | 54 | 108 |
| Mean | 178.98 | 214.74 | 196.86 |
| SD | 92.44 | 147.44 | 123.79 |
| Minimum | 40 | 40 | 40 |
| Maximum | 512 | 680 | 680 |

Group-A= Hyoscine Butyl Bromide
Group-B=Placebo
*p*-value= 0.135 (Insignificant: *p*-value>0.05)

## DISCUSSION

Women and obstetrician both want to conduct delivery in shortest possible time without compromising safety of mother and fetus. Hyoscine butyl bromide is a quaternary ammonium derivative; it is spasmolytic for the smooth muscle of the biliary, gastrointestinal

and genitourinary tracts. HBB is rapidly distributed (t1/2 = 29 minutes) after intravenous administration. It does not cross the blood–brain barrier, and has low affinity for plasma proteins; it is cleared through kidneys. Its exact mechanism of action in labour is not yet known[1].

This study results are important for many reasons. Short first stage of labour has potential benefits i.e. reduction in incidence of puerperal sepsis, chorioamnionitis, neonatal sepsis, which are all increased with prolonged labour. Need for opioid analgesia is reduced, that can lead to respiratory depression in neonates. Moreover, duration of the painful labour will be reduced and women will be relieved.

Modes of action and uses of hyoscine were studied by Corsen et al, and most rapid action was found with suppository and intravenous routes. most appropriate time for administration was at cervical dilatation of 2.5 to 3cm, and no harmful effects seen with dose of 30 mg[8].

The effect of atropine and HBB in reduction of pain and length of the first stage of labour was compared in a randomized single blind clinical trial named Hyoscine-N-butylbromide versus atropine as labour accelerant and analgesic. Mean length of the first stage of labor was 218.5 min (SD: 81.4) in hyoscine versus 339 min (SD: 83.3) in atropine group ($p$<0.001)[9].

In this study duration of labour in the first stage with Hyoscine Butyl Bromide was 178.98 ± 92.44 and in control group it was 214.74 ± 147.44. With hyoscine butyl bromide a reduction of 30-40% in length of labour is reported by many authors[6–10].

Sirohiwal et al. reported that HBB leads to a significant difference in length first stage of labour[11] Samuels et al. found that duration of first stage of labour is reduced by 31.7% after intravenous HBB without any harmful effect to neonate and mother[1]. Aggarwal et al. found out that 40mg HBB relieves pain in labour by 35.6%[7]. Qahtani & Hajeri evaluated that HBB reduces duration of labour by 23.3%[12].

Makvandi et al. found that HBB reduces first stage of labour significantly without maternal or fetal side effects[13]. Tewari et al , used 40 mg HBB intravenously first time and length of labor was reduced by 5 hours 12 minutes[14].

The shortening of the first stage of labor is very important as it leads to reduction of duration of severe pain associated with dilatation of cervix. More over reduced duration of labour is important for women with hypertension, placental insufficiency, oligohydramnios and sickle cell anemia[15-17].

Our study reveals that hyoscine butyl bromide leads to a significant decrease in duration of first stage of labor. The main action of Hyoscine butylbromide is on cervix and it does not promote uterine contractions. It does not affect second stage of labour. It also suggests that there is no effect of uterine contractions in postpartum period.

## CONCLUSION

On the basis of our study results and similar data of other clinical trials, it is concluded that hyoscine butylbromide allows reduction in mean duration of first stage of labor as compared to control. i.e. Hyoscine Butyl Bromide: 178.98 ± 92.44 vs. Control group: 214.74 ± 147.44 minutes. So with the use of Hyoscine Butyl Bromide prolonged labour can be prevented.

## CONFLICT OF INTEREST

The authors of this study reported no conflict of interest.

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