

EFFECT OF (HYOSCINE BUTYLBROMIDE) ON THE DURATION OF THE FIRST STAGE OF ACTIVE LABOR IN FULLTERM PREGNANT WOMEN

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ABSTRACT

Background: Prolonged labor contributes to increased perinatal and maternal morbidity. Active management of labor reduces the number of cesarean deliveries, the number of prolonged labor, and the duration of labor without having any adverse effects on the mother and the fetus. **Objective:** The aim of this study was to determine the effect of HBB on the duration of the first stage of active labor in full term pregnant women. **Methods:** The study was a Randomized Control Trail carried out at Tishreen University Hospital in Lattakia-Syria during the period between (2021-2022). study included 143 pregnant women in full term with spontaneous onset of labor. The patients were divided into two groups, study group: 73 pregnant women, They received (20mg of hyoscine butylbromide diluted in 9 ml of saline solution) slowly intravenously. Placebo Group: 70 pregnant patients, received placebo (10 mls of intravenous normal saline). The mean duration of the first stage of active labor was compared between the two groups. **Results:** The observed mean duration of the first stage of labor was significantly shorter ($P = 0.002$) in the Hyoscine butyl-bromide group (4.36 ± 2.4 h) than in the Placebo group (5.49 ± 2.8 h). There was no significant difference between the two groups in the mean duration of the second and third stages of labor (28.9 ± 10.8 vs. 32.1 ± 11.3 min, $p=0.3$. And 6.2 ± 2.03 vs. 6.7 ± 3.2 min, $p=0.4$, respectively). The median APGAR scores at the 1st and 5th minutes were also comparable (8.4 ± 0.9 vs. 8.6 ± 1.1 , $p=0.1$. And 9.3 ± 0.4 vs. 9.5 ± 0.3 , $p=0.2$, respectively). the side effects of HBB were seen in the two groups, but difference between the both groups was not statistically significant (p value > 0.05). **Conclusion:** HBB reduced the duration of first stage of labor in pregnant women without adverse maternal and neonatal complications. It is recommended that HBB to be given to women in active phase of labor to reduce the incidence of prolonged labor.

KEYWORDS: Duration of first stage; , Hyoscine Butyl-bromide, Prolonged labor.

INTRODUCTION

The duration of the first phase of labor takes about 12–16 hours for the first pregnancies and 8–12 hours for multiparous women.^[1] Labor is said to be prolonged when the duration of the active phase last more than 16 hours in primigravida and 12 hours in multiparous women.^[1] Prolonged labor contributes to increased perinatal and maternal morbidity. There is an increased incidence of maternal distress, postpartum hemorrhage, and sepsis.^[1,2] Active management of labor reduces the number of cesarean deliveries, the number of prolonged labor, and the duration of labor without having any adverse effects on the mother and the fetus.^[2] Intervention with drugs is among the option used for active management of labor.

Smooth muscle relaxants inhibit impulses in the form of spasm that impairs the effective cervical dilatation.^[3] Hyoscine N-butyl-bromide (HBB) is a derivative of hyoscine, which is extracted from the leaves of the Dubosia tree found mainly in Australia. It has been in use for over 50 years, for treatment of dysmenorrhea, pelvic spasm (e.g during hysterosalpingography), abdominal cramps, hypersalivation and motion sickness.^[3-4] Hyoscine-N- butylbromide (HNBB) belongs to the parasympatholytic group of drugs and is a semisynthetic derivative of scopolamine. It is an effective antispasmodic drug without the untoward side effects of atropine. HNBB acts primarily by blocking the transmission of neural impulses in the intraneural parasympathetic ganglia of abdominal organs, apparently inhibiting cholinergic transmission in the synapses of the

abdominal and pelvic parasympathetic ganglia, thus relieving spasms in the smooth muscles of gastrointestinal, biliary, urinary tract, and female genital organs, especially the cervicouterine plexus, thus aiding cervical dilatation and thus reducing the duration of labor.⁽⁶⁾ Hyoscine has been used by obstetricians in many countries to accelerate the first stage of labor.^[3] The mechanism by which it acts in the context of labor has not yet been evaluated and evidence of its efficacy has been largely anecdotal.

MATERIALS AND METHODS

Study area

The study was conducted at the labor ward of Tishreen University Hospital in Lattakia-Syria for one year (2021-2022).

Study design

It was randomized control trial.

Inclusion criteria

- 1- Age: 18–41 years old.
- 2- Gestational age = 37-42 weeks.
- 3- singleton pregnancy.
- 4- vertex presentation.
- 5- spontaneous active phase of labor (cervical dilatation \geq 4cm).

Exclusion criteria

- 1- Multiple fetus.
- 2- Malpresentation.
- 3- preterm labor.
- 4- cephalopelvic disproportion.
- 5- previous uterine scarring, previous cesarian section.
- 6- Medical conditions associated with pregnancy e.g. preeclampsia, diabetes mellitus.
- 7- Contraindications for hyoscine butylbromide which include known allergy to hyoscine or other atropinics (e.g., atropine, scopolamine).
- 8- antepartum hemorrhage.
- 9- Oxytocin induction or augmentation.
- 10- Patients who underwent epidural anesthesia or other types of analgesia.

METHODS

Patients who met the inclusion criteria were asked to participate in the study and a verbal consent was obtained from each patient after explaining thoroughly the nature and the scope of the study.

For each patient

1. Complete history was taken to exclude allergy to hyoscine butylbromide, medical disorders with pregnancy (preeclampsia, diabetes mellitus, heart disease ...etc.) and any contraindication for vaginal delivery.
2. General examination of the patients including (Pulse, blood pressure, temperature).

3. Obstetric abdominal examination including fetal lie, fetal presentation, head station and uterine contractions.
4. Vaginal examination including cervical dilatation, effacement and position, state of fetal membranes, presenting part, position of fetal head and pelvic adequacy.
5. Obstetric ultrasound to detect fetal gestational age, fetal birth weight amount of liquor, site of placental attachment and fetal heart rate.

The patients were divided into two groups.

Study Group(HBB): included 73 pregnant patients. They received (20mg of hyoscinebutylbromide diluted in 9 ml of saline solution) slowly intravenously.

Placebo Group: included 70 pregnant patients. received placebo(10 mls of intravenous normal saline).

Data analysis

Data was analyzed with SPSS version 20. Descriptive characteristics of the respondents were obtained. Independent sample t test was used to compare the mean duration of stages of labor between HBB group and placebo.

Chi-square test was used to compare between the two groups. A p-value of < 0.05 was considered statistically significant.

RESULTS

A total of 143 women were recruited for this study. Of these, 73 women received HBB group (20mg of hyoscine butylbromide diluted in 9 ml of saline solution) and 70 women received placebo (10 mls of intravenous normal saline). The mean age of women that received HBB was 24.6 ± 4.4 years, while the mean age for those that received placebo was 25.1 ± 3.2 years. There was no statistically significant difference between the mean age of the two groups ($P > 0.05$). The mean gestational age was 38.4 ± 1.4 weeks and in placebo group was 38.6 ± 1.6 weeks, thus selection of patients in both groups were similar [Table 1]. The mean duration of the first stage of labor was 4.36 ± 2.4 hours in the HBB group, while it was 5.49 ± 2.8 hours in the placebo group and this difference was statistically significant ($P < 0.05$). The mean duration of 2nd and 3rd stages of labor among the HBB group and placebo were not statistically significant* [Table 2+]. The median Apgar score in the 1st minute among HBB and placebo group were 8.4 ± 0.9 and 8.6 ± 1.1 respectively ($P = 0.1$), and in the 5th minute it was 9.3 ± 0.4 in the HBB group, while it was 9.5 ± 0.3 in the placebo group ($p = 0.2$). There were no statistically significant differences in the 1st and 5th minute Apgar scores between the two groups * [Table 3+]. The side effects of HBB were seen in the both groups, but there were no statistically significant differences between two groups concerning side effects ($p \text{ value} > 0.05$) * [Table 4+].

Table 1: Patient's characteristics.

Patient's Groups Characteristics	HBB group (Mean ± SD)	Placebo group (Mean ± SD)	P-value
Age (years)	24.6±4.4	25.1±3.2	0.8
Gestational Age(weeks)	38.4±1.4	38.6±1.6	0.5

Table 2: The mean duration of the stages of labor.

Stage of labor	HBB group (Mean ± SD)	Placebo group (Mean ± SD)	P-value
First stage (h)	4.36±2.4	5.49±2.8	0.002
Second stage (min)	28.9±10.8	32.1±11.3	0.3
Third stage (min)	6.2±2.03	6.7±3.2	0.4

Table 3: The median Apgar scores in each group.

Apgar score	HBB group (Mean ± SD)	Placebo group (Mean ± SD)	P-value
at one minute	8.4±0.9	8.6±1.1	0.1
at five minutes	9.3 ±0.4	9.5±0.3	0.2

Table 4: prevalence of HBB side effects in each group.

Side effects	HBB group (%)	Placebo group (%)	P-value
Dry mouth	4(5.5%)	2(2.9%)	0.2
Tachycardia	6(8.2%)	4(5.7%)	0.9
Vomiting	13(17.8%)	10(14.3%)	0.8
Facial flushing	2(2.7%)	1(1.4%)	0.2
Nausea	10(13.7%)	7(10%)	0.6

DISCUSSION

The management of normal labor is both an art and a science. Prolongation of labor is one such dilemma that every obstetrician tries to avoid. The ultimate aim of the obstetrician is to accomplish the delivery in the shortest possible time without compromising maternal and fetal safety. For decades, health providers have worked for shortening the duration of painful labor. Reduction of cesarean sections and other fetal and maternal complications is also an important aspect of labor management.^(7) Active management of labor was introduced in 1960s as a method to prevent prolonged labor. Prolonged labor is one of the most important risk factors for perinatal compromise and, if caused by obstructed labor, it carries the risk of uterine rupture, postpartum hemorrhage. The two major factors that determine duration of labor are uterine contractility and rate of cervical dilation.^(8) HBB has been used to shorten the duration of labor in different studies.^[2,1]

The mean duration of labor in the first stage of labor among the HBB group was 4.36±2.4 hours, while it was 5.49±2.8 hours in the placebo group. This difference was statistically significant (P = 0.002). HBB reduced the mean duration of labor in this study. The results of this study are similar to the findings by Samuels et al. in Jamaica.^[1]

Similarly, Movahed et al. in Iran found a significant reduction in the duration of first stage of labor among women who received HBB.^[10]

There was no difference in the duration of second and

third stages of labor among the HBB and placebo groups in this study. This is similar to the findings by Al- Khishali et al. in Iraq and Movahed et al. in Iran.^[10,11] This showed that HBB acts mainly on the smooth muscles of the cervix and does not interfere with the contractile function of the uterus.^(10) This is important as it obviates the concern regarding an excessively rapid second stage which can predispose to both maternal complications like perineal lacerations and neonatal complications, such as intracranial hemorrhage due to rapid, uncontrolled decompression of the fetal head at delivery.^[1]

It is however different from the study by Alani in Iraq where there was reduction in the duration of second and third stages of labor.^[12] We reported an Apgar score at the first minute of 8.4±0.9 and 9.3 ± 0.4 at 5 min in the HBB group, and 8.6±1.1 at the first minute and 9.5±0.3 at 5 min in the placebo group. Just like in other studies.^[13] our results show no adverse effects on the fetus, which were evaluated by the APGAR at 1 and 5 min.

In the present study the drug did not have adverse effects on the neonates. Similar outcome was obtained by study done by Kirimet al.^(7) Tewari et al.^[13]

In their study concluded that the drugs did not interfere with utero-placental circulation.

In the present study, side effects of HBB were seen in the both groups. The most common side effects seen were nausea and vomiting. Difference between the HBB group and placebo was not statistically significant (p value >

0.05). So in the present study the drug did not have any adverse maternal side effects, which is comparable to study supported by Samuel et al.^[1]

CONCLUSION

HBB reduced the duration of first stage of labor in the pregnant women without adverse maternal and neonatal complications. There was however, no significant difference in the durations of the second and the third stages of labor and neonatal APGAR scores.

Recommendation

- 1- It is recommended that HBB to be given to women in active phase of labor to reduce the incidence of prolonged labor.
- 2- The recommended dose is 20 mg intravenously.
- 3- Further studies using different routes of administration of Hyoscine butylbromide should be conducted to compare the effect of the drug.

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