Aegean Journal of Obstetrics and Gynecology 4/1

Aegean Journal of Obstetrics and Gynecology

Original Article

The association of intravenous antispasmodics (hyoscine-N butyl bromide) injection with obstetric lacerations at vaginal delivery

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ABSTRACT

Objective: To study whether hyoscine-N butyl bromide injection affects the incidence of obstetric lacerations at vaginal birth.

Materials and Methods: This retrospective cohort study consists of 15806 term pregnant women who undergone vaginal delivery, in Tepecik Training and Research Hospital, İzmir between January 2018 and December 2020. Patients who received intravenous injection of Hyoscine-N-butylbromide during the active period of labor were compared with those who did not in terms of the incidence of obstetric laceration.

Results: The data of a total of 9216 deliveries meeting the study criteria were analyzed. Hyoscine-N-butylbromide was used in 4014 of these deliveries (HBD), and it was not used in 5202 of these deliveries. In both primigravid and multigravida patients in the HBD group, the first stage of delivery was found to be shorter than in patients who did not receive spasmolytics ($p < 0.001$). There was no difference between the groups in terms of the second stage of labor. Intravenous injection of Hyoscine-N-butylbromide in the active phase of labor significantly reduced 1st and 2nd degree obstetric lacerations in primigravid patients but had no effect on 3rd and 4th degree obstetric lacerations.

Conclusion: Hyoscine-N-Butylbromide shortens the active phase of labor and reduces minor obstetric lacerations in primigravid women.

Keywords: obstetric lacerations; spasmolytic; vaginal delivery; Hyoscine-N-Butylbromide

ARTICLE INFO

Doi: 10.46328/aejog.v4i1.110

Article history:

Received: 07 January 2022

Accepted: 02 February 2022

Introduction

The main purpose of the active management of labor strategy is to shorten the delivery time without increasing the mortality and morbidity of the mother and baby [1]. Because, as the labor prolongs, it increases in postpartum hemorrhage, sepsis, fetal distress and obstetric lacerations [2,3]. Randomized studies have demonstrated the safety and efficacy of an active birth management strategy [4]. For this purpose, mechanical, pharmacological and non-pharmacological methods have been used to accelerate the first stage of labor. Interventions to shorten labour, such as antispasmodics, can be used as a preventative or a treatment strategy in order to decrease the incidence of prolonged labour.

A prospective study by Sirohiwal found that administration of hyoscine-butyl bromide suppositories during labour significantly shortened the duration of the first stage of labour [5]. Hyoscine-N-butylbromide is a muscarinic antagonist acting as a cervical spasmolytic. Antispasmodics are commonly administered during labour in both developing and developed countries. The most commonly used agent for this purpose in our clinic is hyoscine-butyl bromide (Molit ampoule; Adeka, Istanbul, Turkey)

Hyoscine-butyl bromide is an antispasmodic and anticholinergic drug. It is a muscarinic antagonist that acts as a spasmolytic especially in the cervical tissue. In addition, since it does not cross the blood-brain barrier, it has no central anticholinergic effects. It quickly diffuses into tissues shortly after intravenous administration and binds to cholinergic receptors with high affinity [6].

Antispasmotics are used in the active phase of labour in many centers.

However, data showing the relationship between antispasmotics and obstetric lacerations are insufficient. To the best of our knowledge, this is the first study examining the effect of Hyoscine-butyl bromide on the incidence of the various obstetric lacerations. It includes a large cohort of deliveries in a single tertiary medical center.

In this study, we compared obstetric lacerations in patients who received Hyoscine-N-butylbromide injection during the active period of labor with those who did not.

Material and methods

Design and setting of the study

This retrospective cohort study consists of term singleton pregnant women who applied to Tepecik Training and Research Hospital between January 2018 and December 2020 and gave vaginal delivery.

All data of the patients were obtained from computer-based hospital records and partographs. The study was approved by the local institutional ethic committee (Registry no:2021/02-13).

Our primary aim is to evaluate the effect of antispasmodics applied in the active phase of labor on obstetric lacerations. For this purpose, pregnant women who were administered antispasmodic and not applied in the active phase of labor were divided into two groups by scanning the patient databases.

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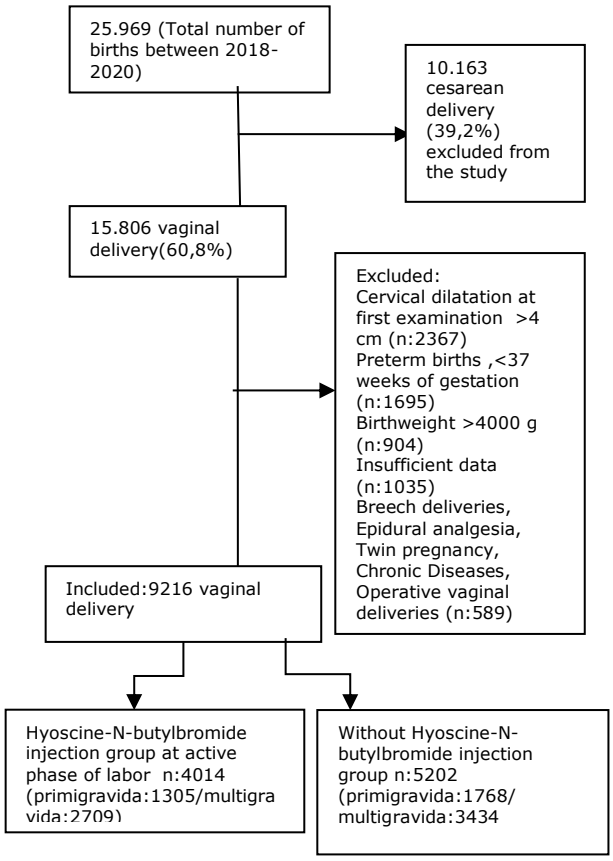
Primigravida and multigravida singleton pregnancies were included in the study. All fetuses were in vertex position.
The hospitalization period of the patients in the delivery room, cervical dilatation and effacement, the time of transition to the active phase, the duration of the 1st and 2nd stage of birth, whether the induction was taken, the time of antispasmotic administration, the time of delivery, whether episiotomy was applied, vaginal and vulvar lacerations and degrees, pre-postpartum hemoglobin values recorded from partographs. Neonatal Apgar scores were determined 1 and 5 min after birth.
Most of the deliveries that we did not include in the study consisted of pregnant women who had cervical dilatation> 4cm in their first vaginal examination and who started the active phase before hospitalization (n:2367).
In addition, we excluded preterm deliveries (<37 weeks of gestation n: 1695), Birthweight >4000 gr deliveries (n: 904) and deliveries with insufficient data in their records (n: 1035). The flow diagram of the participants and other excluded criteria are shown in Figure 1.
Based on the patient partograph records, the patients who received Hyoscine-N-butylbromide injection in the active phase of vaginal delivery and those who were not applied were compared in terms of delivery times and obstetric lacerations.
Management protocol of normal labour
The first stage of labour consists of a latent phase and an active phase. The latent phase is characterized by gradual cervical change and the active phase is characterized by rapid cervical change. Active phase is defined as cervical dilatation of 4 cm and effacement 50% and regular uterine contractions occurring (2-3 contractions every 10 min). For women in the second stage with minimal (<1 cm) or absent descent after 60 to 90 minutes of pushing and uterine contractions less frequent than every 3 minutes, we begin oxytocin augmentation.
In our clinic, vaginal deliveries are followed by midwives and assistant physicians. First examination and ultrasound imaging are performed by obstetricians. Approximately half of obstetricians in our clinic routinely use intravenous hyoscine-butyl bromide to accelerate cervical dilation in the active phase of labor. Iatrogenic amniotomy was performed for patients who did not have spontaneous membrane rupture when cervical ripening was 8 cm. The patient's vaginal examinations and medical treatments are recorded on the partographs.
We use the perineal massage and hands-on technique to prevent precipitous expulsion of the newborn, which can lacerate the perineum and anal sphincter [7]. We ask the woman to pant or make only small expulsive efforts when the head is fully crowning and delivery is imminent; this prevents the head from being propelled through the perineum. We use one hand to maintain the head in a flexed position and control the speed of crowning and use the other hand to ease the perineum away from the path of the emerging head. Episiotomy is reserved for deliveries with a high risk of severe perineal laceration, significant soft tissue dystocia, or need to facilitate delivery of a possibly compromised fetus.
If there is need for episiotomy, we preferred mediolateral episiotomy over midline episiotomy because of the association of midline episiotomy with increased risk of injury to the anal sphincter complex.
We actively manage the third stage because active management reduced the risk of severe postpartum blood loss and blood transfusion compared with expectant management. We use controlled cord traction to facilitate separation and delivery of the placenta. Uterine massage and oxytocin injection also may be performed.
After delivery, cervix, vagina, and perineum were evaluated by obstetricians in terms of obstetric lacerations.
The degrees of obstetric lacerations were recorded on partographs.
We use the classification system recommended by the American College of Obstetricians and Gynecologists (ACOG) [8]. Briefly, first-degree perineal lacerations involve only the perineal skin, second-degree perineal lacerations involve the perineal muscle but not the anal sphincter, third degree perineal lacerations
involve the anal sphincter complex and fourth-degree perineal lacerations involve the anal sphincter complex and the anal epithelium.
In first-degree lacerations, if the anatomy is intact or there is no bleeding, we did not require suturing. Severe perineal lacerations were repaired by an experienced obstetrician.
Statistical analysis
All calculations and statistical analyses were performed using SPSS ver. 17 for Windows (SPSS Inc., Chicago, IL). Continuous variables were compared by Student's t-test and nominal variables were compared by the Chi-squared test. p-value <0.05 was considered statistically significant.

Results

A total of 25969 births took place in our clinic between January 2018 and December 2020. 39.2% of deliveries are caesarean and 60.8% are vaginal. 9216 patients who had vaginal delivery and met our study criteria were included in the study.
According to the data in computer-based hospital records and partographs, 4014 patients in the active phase of labor (primigravida: 1305 / multigravida: 2709) received Hyoscine-N-butylbromide injection, while 5202 patients (primigravida: 1768 / multigravida: 3434) were not administered antispasmotic (Figure 1).
Figure 1. The flow diagram of the participants



The demographic data of the study population are shown in Table 1. Patients in multigravida predominate in both groups. There were no significant differences in terms of

maternal age, BMI, parity, gestational age, birthweight between the two groups. 44% of the patients in the HBD group and 42% of the patients who were not spasmolytic were induced with oxytocin (p = 0.45).
The mean duration of the first stage of labor was 199±50.1 minute in the primigravid subjects in the study group compared with 241±50.6 minute in the control group (p<0,003). The mean duration of the first stage of labor was 180,3±47.4 minute in the multigravid subjects in the study group compared with 231±50.3 minute in the control group (p<0,001). Hyoscine-N-butyl bromide injection shortened the active phase of labor by 43 minutes in primigravid pregnant women and 51 minutes in multigravid pregnant women.

Table 1. The demographic data of the groups

	Hyoscine-N-butylbromide injection group(n:4014)	Control group (n:5202)	p value
Maternal age (years)	28 ±6,1	29 ±5,8	0,56
Gestational age (weeks)	39,1 ±1,4	39,3 ±1,8	0,78
BMI (kg/m2)	25 ±4,3	24 ±5,2	0,34
Nulliparity	1305(32%)	1768(34%)	0,45
Birthweight, g	3314 ±340	3270 ±395	0,33
Augmentation of labor with oxytocin	1780(44%)	2215(42%)	0,45
ΔHgb(mg/dl)	*1,3 ±0,8*	*1,5 ±0,3*	*0,21*
Apgar score at 1 min	*8.1±0.78*	*8.2±0.49*	*0,15*
Apgar score at 5 min	*9.1±0.48*	*9±0.71*	*0,45*

Data are presented as mean ± standard deviation,or %.

ΔHgb level: Difference between prepartum and postpartum hemoglobin values

There were no significant differences in the times for the second stages of labor (Table 2). The groups could not be compared in terms of the third stage of birth due to insufficient registration.

Table 2. Comparison of both groups in the first and second stage of labor

		Hyoscine-N-butylbromide injection group(n:4014)	Control group (n:5202)	p value
First stage of labor(activ	Primigravid subjects	199,3±50,1	242±50,6	0,004
	Multigravid subjects	180,3±47,4	231,1±50,3	<0,001
Second stage of labor,minut	Primigravid subjects	21±7,4	19±8,1	0,2
	Multigravid subjects	13±4,4	14±5,4	0,4

Data are presented as mean ± standard deviation

First degree laceration was detected in 36.1% of our deliveries (n: 3331), second degree laceration in 16.5% (n: 1528) and severe laceration in 0.9% (n: 87). In the active phase of labor, primigravida applied Hyoscine-N-butylbromide was found to be statistically less than first-degree and second degree perineal lacerations in the control group (p: 0.03; p: 0.01). There is no difference between the two groups in terms of 3rd and 4th degree obstetric lacerations in primigravida pregnant. women. (Table 3)
When the groups were compared, the effect of Hyoscine-N-butylbromide administration on obstetric lacerations in multigravida pregnant women was not detected.
The difference between prepartum hemoglobin and postpartum 1st day hemoglobin values of pregnant women was shown as ΔHgb. There was no significant difference between the two groups in ΔHgb values (p: 0.21). There were no significant differences in terms of Apgar scores at 1 and 5 min.

Table 3. Comparison of obstetric laceration grades

		Hyoscine-N-butylbromide injection group(n:4014)	Control group (n:5202)	p value
First-degree perineal lacerations	Primigravid subjects	579 (44%)	894 (51%)	0,007
	Multigravid subjects	856	1002	0,34
Second-degree perineal lacerations	Primigravid subjects	239 (18%)	411 (23%)	0,006
	Multigravid subjects	398	480	0,8
Third-degree perineal lacerations	Primigravid subjects	18	21	0,67
	Multigravid subjects	14	17	0,56
Fourth-degree perineal lacerations	Primigravid subjects	4	6	0,8
	Multigravid subjects	3	4	0,76
Episiotomies	Primigravid subjects	331 (259	429 (24 %)	0,4
	Multigravid subjects	510	627	0,5

Data are presented as n (%)
Bolded values are statistically significant.

Discussion

As a result of the retrospective examination of the computer-based medical records of the pregnant women for whom we applied the same birth management model from a single center; we found that applying Hyoscine-N-butylbromide injection in the active phase of labor reduced 1st and 2nd degree obstetric lacerations in primigravida pregnant women. We found that antispasmodic use reduced the minor laceration rate by 12% in primigravida pregnant women. There was no difference between the groups in terms of severe obstetric lacerations. This study also showed us that antispasmodic administration shortens the active phase of the first phase of labor in both primigravida and multigravida pregnant women.
Our most important advantage in our study was that we managed all multiparous and primipara pregnant women in

a single center with the same delivery strategy.
To our knowledge, this is the first large retrospective study examining the effect of Hyoscine-N-butylbromide administration on obstetric lacerations in the active phase of labor.
Active management of labour versus physiological, expectant management, has shown to decrease the occurrence of prolonged labour. In this management protocol, antispasmotics are widely used to increase cervical dilatation and effacement and shorten delivery time. Many studies have shown that the use of Hyoscine-N-butylbromide in the active phase of labor is effective in shortening the delivery period. Especially the lack of central anticholinergic effects and the absence of maternal and fetal side effects in studies have made the use of this antispasmotic widespread [9].
In a recent Cochrane analysis, Twenty-one trials (n = 3286) were included in the review. Seventeen trials (n = 2617) were included in the meta-analysis [9]. Antispasmodics used included valethamate bromide, hyoscine butyl-bromide, drotaverine hydrochloride, rociverine and camylofin dihydrochloride. Most studies included antispasmodics as part of their package of active management of labour. Thirteen trials (n = 1995) reported on the duration of first stage of labour, which was significantly reduced by an average of 74.34 minutes when antispasmodics were administered (mean difference (MD) -74.34 minutes; 95% confidence Interval (CI) -98.76 to -49.93). Seven studies (n = 797) reported on the total duration of labour, which was significantly reduced by an average of 85.51 minutes (MD -85.51 minutes; 95% CI -121.81 to -49.20). Six studies (n = 820) had data for the outcome: rate of cervical dilatation. Administration of antispasmodics significantly increased the rate of cervical dilatation by an average of 0.61 cm/hour (MD 0.61 cm/hour; 95% CI 0.34 to 0.88). Antispasmodics did not affect the duration of second and third stage of labour.
In our study, the duration of the first stage of delivery was reduced by 43.3 minutes in primipara pregnancies and 51.8 minutes in multiparous pregnancies when the deliveries administered Hyoscine-N-butylbromide injection were compared with the control group. According to the results in the meta-analysis, the use of antispasmotic appears to reduce the first stage of labor more than our study. This is because we did not include patients who reached an active phase without being hospitalized. There was no difference between the groups in terms of the second stage of labor. We could not evaluate the third stage of birth due to insufficient medical records. When we evaluated both groups in terms of neonatal outcomes, we found that the use of antispasmotic did not affect Apgar scores in the 1st and 5th minutes. In this respect, our study supports the literature. [10]
Although studies have shown that antispasmotics accelerate cervical dilatation and shorten the 1st stage of labor, there is no study showing its relation with obstetric lacerations. Only decreases in hemoglobin values were evaluated in these studies.
Singh et al. showing no significant difference in risk for postpartum haemorrhage between intervention and control groups (RR 2.46; 95%CI 0.20 to 30.17) [11]. In our study, when the value difference between the prepartum and postpartum hemoglobin values of the patients was compared between the groups, we did not find a significant difference. (p = 0.21).
In our clinic, postpartum obstetric lacerations are recorded in the patient files by obstetricians. In the last meta-analysis evaluating obstetric laceration risk factors, (651934 women of whom 15366 [2.4%] had severe lacerations) the strongest risk factors for severe lacerations included forceps delivery (OR, 5.50; 95% CI, 3.17–9.55), vacuum-assisted delivery (OR, 3.98; 95% CI, 2.60–6.09), midline episiotomy (OR, 3.82; 95% CI, 1.96–7.42), and increased fetal birth weight. Based on the same meta-analysis data, other risk factors include Asian ethnicity (OR, 2.74; 95% CI, 1.31–5.72), epidural anesthesia (OR, 1.95; 95% CI, 1.66–2.32), and persistent occiput posterior position (OR, 3.09; 95% CI, 1.81–5.29). [12].
We did not include births that are risk factors for obstetric lacerations in our study. However, since persistent occiput posterior position is not recorded in our files, we could not evaluate these patients separately.
First degree laceration was detected in 36.1% of our deliveries (n: 3331), second degree laceration in 16.5% (n: 1528), and severe laceration in 0.9% (n: 87). The low rate of severe obstetric laceration compared to metaanalysis may be due to the high rate of multiparous patients (66%), our hands-on technique at birth and our antenatal perineal massage. Minor obstetric laceration decreased by 12% in primiparous pregnant women who received 20 mg Hyoscine-N-butylbromide injection in the active phase of labor. However, use of antispasmotic did not affect the incidence of 3rd and 4th laceration in primipara pregnant women.

As expected, the incidence of laceration in multiparous pregnant women is lower than in primipara pregnant women. Hyoscine-N-butylbromide injection shortened the delivery time in multiparous pregnant women more than primipara. However, this procedure did not reduce the incidence of obstetric laceration in multiparous pregnant women.
There are several limitations in our study. The most important of these was to define confunders associated with obstetric lacerations due to the retrospective design of the study.. We excluded preterm deliveries, birthweiht> 4000 g, operative vaginal deliveries, pregnancies who were administered different medications during delivery and pregnancies with chronic diseases, twin pregnancies, non-cephalic presentations and vaginal deliveries after cesarean section.
Another limitation of this study is that side effects in pregnant women who are applied antispasmotic are not recorded in the files. Maternal adverse effects of antispasmotics such as tachycardia, mouth dryness, headache, nausea, vomiting, dizziness, giddiness, cervical laceration, flushing of face and postpartum haemorrhage were recorded in previous studies. In our study, we evaluated only postpartum hemorrhage among these side effects by calculating the difference between prepartum hemoglobin values. We found no significant difference between both groups. (P = 0.21). Kirim et al. showed in their placebo-controlled double-blind study that Hyoscine-N-butylbromide administration was not a risk for postpartum hemorrhage. [13]
In conclusion, Hyoscine-N-butylbromide injection has a protective effect against minor obstetric lacerations in primigravids.

Disclosure

Authors have no potential conflicts of interest to disclose.

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