Original Article

Comparative Efficacy of Hyoscine-N-Butylbromide versus Drotaverine Hydrochloride in the Augmentation of Labor

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ABSTRACT

Objective: To compare the efficacy of Hyoscine-N-butylbromide versus drotaverine hydrochloride in the augmentation of labor.

Study Design: Double-blind, randomized controlled trial study

Place and Duration of Study: This study was conducted at the Gynecology Unit-I, Liquate University Hospital Hyderabad for the period of one year from February 2018 to January 2019.

Materials and Methods: This study was conducted on 270 women to compare the efficacy of Hyoscine-N-butyl bromide versus drotaverine hydrochloride in the augmentation of labor Gynecology Unit-I Liquate University Hospital Hyderabad. Women of reproductive age group between 18-35 years and gestational age between 37-40 weeks were included. All the data was analyzed in SPSS version 22.0.

Results: The average age of the patients was 21.45±5.42 years. Efficacy was significantly high in the drotaverine hydrochloride group than the Hyoscine-N-butylbromide group (73% vs. 41.8% p=0.0005).

Conclusion: Drotaverine hydrochloride appears to be effective in accelerating the first stage of labor.

Key Words: Active management of labor, Drotaverine hydrochloride, the first stage of labor, Hyoscine-N-butylbromide

Citation of article: Shuaib A, Bushra, Ghori A, Zardari AA, Sahito RM, Rekha. Comparative Efficacy of Hyoscine-N-Butylbromide versus Drotaverine Hydrochloride in the Augmentation of Labor. Med Forum 2021;32(1):76-80.

INTRODUCTION

Dublin introduced the principle of active management of labor to reduce delivery time while achieving or maintaining a low rate of cesarean section.[1]

Type in anything that you want. Then click Quill It on the right to paraphrase your input.[1] The achievement of effective labor leadership is well documented and the amount of caesareans delivered to organizations using protocols has been reduced.

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Received: July, 2020
Accepted: October, 2020
Printed: January, 2021

More than 3000 females have been tested in potential, randomized, clinical studies to demonstrate their safety. In countless surveys of females dealt with the effective leadership protocol, the smaller working time from entry to shipment has been continuously recorded.[1]

Hyoscine N-butyl bromide (HBB) inhibits cholinergic transmission into the pelvic abdominal parasympathetic ganglia to alleviate spasm in soft gastrointestinal, bile, urinary and women's issues, in particular in the cervical uterine plexus, and aid for cervical extension hyoscine.[2]

Active labor leadership decreases the number of cesarean shipments, long working hours and length of work, without negative impacts on mom or fetus.[3]

Spasmolytics, such as hyoscine-N-butyl bromide (HBB), are commonly used during this process.[4].

Several trials, involving both primigravida and multigravate females, have demonstrated that HBB (20-40 mg) intravenously improves cervical dilation during the active stage of the work.[2]

HBB effectively slows down the progression of the work by reducing intrauterine stress.[5] when provided in the latent phase, during which contractures remain unchanged. [6]

LA Samuels et al.[1] in their study compared the efficacy of hyoscine-N-butylbromide versus placebo in the augmentation of labour and reported that the decrease of 31.7% in the meantime for the first stage in the drug group as compared to control group.

In a study reported reported that there was a medium reduction of 15% in drotaverine for the duratio n of the first stage of labor in the group of drotaverines. So, that we could know which method is more effective shortening the duration of labour especially the first stage, in turn, we will be able to decrease the rate of cesarean section and other related morbidities of prolonged labour.

MATERIALS AND METHODS

This Double-blind, randomized controlled trial study was conducted on 270 women for the period of one year from February 2018 to January 2019 to compare the efficacy of Hyoscine-N-butylbromide versus drotaverine hydrochloride in the augmentation of labor Gynecology Unit-I Liquate University Hospital Hyderabad. A total of 270 women were enrolled in the Hyoscine-N-butylbromide group and drotaverine hydrochloride group by the double-blind randomized method. Women of reproductive age group (between 18-35 years) and gestational age between 37-40 weeks (gestational age determined by 1st-trimester scan), Primi gravida, Single live fetus in vertex presentation, booked cases, on regular follow up in antenatal clinic, and admitted in labour room, cervical dilatation of 3 – 5 cms and cervical effacement of ≥ or 50% were included in this study. Multiple pregnancies, women with co-morbidities i.e. hypertension, diabetes mellitus, Preterm labour, Abnormal presentation, and Cephalopelvic disproportion were excluded. Informed written consent regarding study protocol was taken from all the women. An approval from the hospital ethical review committee was obtained. Study subjects were divided into two groups of women: one group of women received the Hyoscine-N-butylbromide drug, while the other group received the drotaverine hydrochloride.

Sterile syringes were then numbered sequentially and ready with the random digits to determine their hyoscine or drotaverine chloride content. Participants were provided intravenously in a single dose of syringe content with 4–5 cm cervical dilation, which was verified and recorded by an Obstetrics and Gynecology patient. All the data was entered in the pre-designed proforma by the researcher herself.

Data Analysis: The collected data was entered on SPSS version 16. The frequencies and percentages were calculated for a mode of delivery and efficacy. Mean and the standard deviation was calculated for maternal age, gestational age, duration of the first stage of labor and rate of cervical dilatation. Stratification was done with regards to maternal age and gestational age to see the effect of these on outcomes by the chi-square test. $p \leq 0.05$ was considered significant.

RESULTS

A total of 270 women were enrolled in this study, 170 women in the hyoscine-N-butylbromide group and 100 women were in the drotaverine hydrochloride group. The average age of the patients was 21.45±5.42 years. The age distribution of women is presented in figure 4. Gestational age of 88% and 59% cases were between 37 to 38 weeks in the Hyoscine-N-butylbromide group and 82% and 41% were between 39 to 40 weeks in drotaverine hydrochloride group as presented in figure 5. Distribution of the first stage of labor and rate of cervical dilatation with respect to groups is presented in Figures 6 and 7 respectively.

The rate of vaginal delivery was 81% in the drotaverine hydrochloride group and 55.9% in the hyoscine-N-butylbromide group while the cesarean section was 19% in drotaverine hydrochloride group and 44.1% hyoscine-N-butylbromide group as shown in table 2.

Efficacy was significantly high in the drotaverine hydrochloride group than the hyoscine-N-butylbromide group (73% vs. 41.8% p=0.0005) as presented in table 3. With respect to age groups, efficacy was significantly high in the drotaverine hydrochloride group than the hyoscine-N-butylbromide group in 18-20 years of age (p=0.0005) and 21-25 years of age patients (p=0.005) as shown in table 4. Similarly, Efficacy was significantly high in the drotaverine hydrochloride group than the hyoscine-N-butylbromide group in those cases whose gestational age was 37 to 38 weeks (93.2% vs. 51.1% p=0.0005).

Table No.1: Comparison of baseline characteristics and other parameters between groups (n=270)

	Hyoscine-N-butylbromide Group (n=170)	Drotaverine hydrochloride Group (n=100)	P value
Age groups(years)			
18-20 years	57(33.5%)	35(35.0%)	0.0005
21-25 years	46(27.0%)	25(25.0%)	0.005
26-30 years	36(21.17%)	20(20.0%)	0.221
31-35 years	31(18.2%)	20(20.0%)	0.107
Gestational age (weeks)			
37-38	88(51.7%)	59(59.0%)	0.0005
39-40	82(48.2%)	41(41.0%)	0.589
Duration Of the First Stage Of Labour With			
>8h	95(55.8%)	20(20.0%)	0.003
6h to 8h	75(44.1%)	80(80.0%)	0.001
Rate Of Cervical Dialatation			
0.5 to 1cm/h	64(37.6%)	45(45.0%)	0.932
1.1 to 1.5cm/h	48(28.2%)	25(25.0%)	0.541
>1.5cm/h	58(34.1%)	30(30.0%)	0.051
Mode of delivery			
Vaginal delivery	95(55.9%)	81(81%)	
Caesarean section	75(44.1%)	19(19%)	0.0005
Efficacy:			
Yes	71(41.8%)	73(73%)	0.0005
No	99(58.2%)	27(27%)	0.0006

Table No.2: Comparison of Efficacy between Groups with Respect to Age Groups (n=270)

	Hyoscine-N-butylbromide group (n=170)			Drotaverine hydrochloride group (n=100)			P-Values
	n=170	Efficacy Yes (n=71)	Efficacy No (n=99)	n=100	Efficacy Yes (n=73)	Efficacy No (n=23)	
Age Groups							
18-20 Years	57	25(44%)	32(56%)	35	29(82.9%)	6(17.1%)	0.0005
21-25 Years	46	28(60.9%)	18(39.1%)	25	23(92%)	2(8%)	0.005
26-30 Years	36	12(33.3%)	24(66.7%)	20	10(50%)	10(50%)	0.221
31-35 Years	31	6(19.4%)	25(80.6%)	20	8(40%)	12(60%)	0.107
Gestational Age (Weeks)							
37 to 38	88	45(51.1%)	43(48.9%)	59	55(93.2%)	4(6.8%)	0.0005
39 to 40	82	26(29.5%)	56(68.3%)	41	15(36.6%)	26(63.4%)	0.589

DISCUSSION

The work protocol programming is focused on labor analgesia inclusion, active employment leadership and work event monitoring using partogram. Various drugs have been implemented as well as non-pharmacological techniques to shorten the length of work to decrease maternal and newborn diseases. In addition, different pharmacological agents were discovered to promote cervical dilation,[7] in relation to mechanical variables such as membranes,[8] cervical deformations and amniotomy. The function of oxytocin in employment increase was created world-wide, and hyaluronidase was also successfully applied cervically.[9] Phloroglucinol results in an average 34 percent decrease in the first phase of labor and a median 23 percent decrease in the second phase, compared with placebo organizations. [10]

Valethamide has neurotropic and musculotropic activities and contributes to the relaxation of cervical muscles, resulting in a rapid cervical dilution and reduced workload.[11] Hydrochloride drotaverine is a spasmolytic drug that inhibits phosphodiesterase IV selectively and accompanies a gentle calcium channel blocking action that facilitates cervix dilation.[12]

It has a non-renal path excreted and lasts between 7 and 12 hours in a half-life. It has benign maternal adverse events such as hypotension, vertigo, vomiting, and palpitation but is unrelated to fetal adverse effects.[13]

In the present study, it was observed that the gestational age of 88% and 59% cases were between 37 to 38 weeks in the Hyoscine-N-butylbromide group and 82% and 41% were between 39 to 40 weeks in drotaverine hydrochloride group. We observed 80 (6-8 hour) patients shortening the first stage in women who received the drotaverine hydrochloride group.

Hydrochlorid Drotaverine is an isoquinoline derivative that affects the membrane potential and permeability of smooth muscle cells by means of a strong spasmolytic effect.[14]

Different trials have demonstrated that work takes 54 and 218 minutes to shorten. A study showed an average 15% and 19 percent decrease respectively in the first and second phases of work.[15]

The muscarin antagnant is a cervical spasmolytic substance. No impact on either the length of the active work-phase or cervical dilation was observed in this study Hyoscine-N-butylbromide.

Al Dohami and al Matari,[16] did not report any distinction of cervical dilations, contrasting with those cited by Baracho and Kamat,[17] which indicated that complete working times were considerably decreased by 2 h and 1 h 37 min in Primigravida and Multigravida females.

Each of them. Bhattacharya and Joshi,[18] who indicated a substantial decrease in the length of work for Buscopan, also observed similar findings. The impact of the Buscopan suppositories on effective labour leadership was assessed and the length of work between the control and research organizations was significantly affected (368.05 ±133.0 min, compared to 123.86±68.87, respectively). During the second and third stages of work, there was no distinction.[12]

In the present study rate of vaginal delivery were 81% in the drotaverine hydrochloride group and 55.9% in the Hyoscine-N-butylbromide group while the cesarean section was 19% in drotaverine hydrochloride group and 44.1% Hyoscine-N-butylbromide group. In this study, efficacy was significantly high in the drotaverine hydrochloride group than the Hyoscine-N-butylbromide group. Similarly, Efficacy was significantly high in the drotaverine hydrochloride group than the Hyoscine-N-butylbromide group in those cases whose gestational age was 37 to 38 weeks (93.2% vs. 51.1% p=0.0005). A similar result was also observed.

Drying hydrochloride seems efficient in speeding up both the first and second phases of work. The effect will be greater if a 4 cm cervical dilation drug is given and after a second dose.

Drotaverine had no important impact on work pain, but most females experienced less pain during the fourth

phase of work. The medication did not have fetal side effects but the incidence of postpartum hemorrhage was boosted.

In Madhu et al.[14] study it was also observed that the average moment of service for the first injection to a child, 183.2 min in group Drotaverine as opposed to 206.5 min in Valethamate and 245 min in the control group, was statistically important in the average shipping moment.

The average cervical expansion rate (cm / h) was 3, 2.4 and 1.9 respectively in communities 1, 2 and 3, and statistically significant were these variations. The duration of the second and third phases of work did not differ statistically significantly.

In another study.[15] The acceleration of work is effective in both intramuscular drotaverin and valethamate bromide; however, drotaverine is accelerating labor and is associated with fewer side effects.

It has also been reported that drotaverine is highly efficacious in reducing the active work phase by accelerating cervical dilation and more efficient in the dilated colorectal colon than in the case of multigravida.

Much research has investigated the use of drugs to facilitate cervical dilatation. Drotaverine is a PDE inhibitor, selective for isoenzyme type IV. It works to correct the balance between cAMP and calcium and relieves muscle spasms.[12]

The high concentrations of PDE type IV are found in human myometrium during the third quarter and near term. Drotaverine metabolites inhibit PDE type IV isoenzyme is 10 times more potent than Drotaverine.

Drotaverine was statistically better than Valethamate and reduced work in the first stage by 11%. These findings confirm that other studies have demonstrated Drotaverine's high efficiency in increasing work.[15]

In our study, Drotaverine was superior to valethamate; however, both Drotaverine and Valethamate were equally efficient in a comparative study[15].

CONCLUSION

Drotaverine hydrochloride appears to be effective in accelerating the first stage of labor. The study showed that Hyoscine-N-butylbromide did not work more effectively. Efficacy was significantly high in drotaverine hydrochloride group than the Hyoscine-N-butylbromide group in those cases whose gestational age was 37 to 38 weeks. More randomized tests are required to analyze the associated effect of drotaverine and other methods before routine drug use during labor is recommended.

Author's Contribution:

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Conflict of Interest: The study has no conflict of interest to declare by any author.

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