Original Article

Efficacy of Hyoscine Butyl Bromide Versus Drotaverine Hydrochloride Among Primiparous Women in Term of Mean Duration of Active Phase of First Stage Labor

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Abstract

Objective: To determine the efficacy of Hyoscine butyl bromide versus drotaverine hydrochloride, in term of time duration of active phase of first stage of labor among primiparous women.

Material and Methods: This comparative study was performed at the Obstetrics & Gynecology Department, Lady Willingdon Hospital, Lahore within the duration of 6 months from September 2017 to February 2018. All the primigravida females with 38-42 weeks of gestational age from the last menstrual period (LMP) with singleton pregnancy and cephalic presentation, and in the active-phase of first-stage >3cm dilatation were registered in the study. Patients were grouped into two categories. Group 'A' patients were administered with 10 mg I/v Hyoscine Butyl bromide at 3-4cm dilatation and doses were repeated consecutively after each hour up to a maximum concentration of 3 doses, in terms of cervical dilatation. Group-B was directed with 40mg of Drotaverine I/v at 3-4cm dilatation, doses were repeated consecutively after 2 hours according to cervical dilatation up to a maximum concentration of 3 injections. After every half hour, monitoring of uterine contractions, vital signs and fetal cardiac rate was performed. Labor progress was estimated by cervicogram. The primary-outcome i.e. course of time of active phase of labor's first stage in both groups was documented in pre-intended proforma.

Results: Overall 100 cases were enrolled (50 cases per group). Mean age of group A was 27.3+3.4 years and 25.7+2.8 years of group B. Mean durations for active-phase of labor's first stage was significantly lesser among Hyoscine Butyl bromide administered patients contrasted to drotaverine hydrochloride administrated patients as; 159.42+6.22 minutes in group "A" and 199.77+8.43 minutes in group B, P-value of 0.008.

Conclusion: It was concluded that both drugs showed favorable efficacy of first stage labour's active phase time duration among primiparous patients, while the Hyoscine Butyl Bromide is more effective in reduction of this time duration as compared to Drotaverine hydrochloride.

Key words: Primipara, Hyoscine Butyl bromide, Drotaverine, duration of first stage of labor.

Cite this article as: Janjua M, Wajid R, Shaukat S. Efficacy of Hyoscine Butyl Bromide Versus Drotaverine Hydrochloride Among Primiparous Women in Term of Mean Duration of Active Phase of First Stage Labor. J Soc Obstet Gynaecol Pak. 2019; Vol 9(1):46-50.

Introduction

Labor is a physiological set of events in which conception production (i.e. umbilical cord, placenta, membranes, and fetus) are delivered from the uterus.[1] Labor is one of the most difficult lifetime

Authorship Contribution: [1]Drafting the work or revising it critically for important intellectual content, [2]Final approval of the version to be published, [3] participated in the acquisition and data analysis.

Funding Source: none

Conflict of Interest: none

Received: Jan 19, 2019

Accepted: April 11, 2019

journeys, which is all about negotiating the diameters of the birth canal. The duration of labor has innumerable effects on fetomaternal outcome. Since ancient times, prolonged labor has led to deleterious effects on mother and fetus.[2] Prolonged labor is a significant contributor to the increasing rates of C-section and may increase these rates up to 6 times.[3] Both the laboring female and the obstetrician would prefer to complete the delivery process in the least possible time without putting the fetal and maternal safety at risk.[4] Cervical maturation is a crucial event in the process of preterm or term labor. The cervical maturation initiates at the initial stage of pregnancy and progresses with the time approaching to the delivery. The major variations occur in extracellular matrix. Many substances are important in the process of cervical maturing; they include prostaglandins, inflammatory cytokines and nitrous oxide. Progesterone has a sedating role in cervical maturation.[5] Cervical dilatation can be achieved with alterations in connective tissue, by gradual thinning and effacement of uterine cervix and by regular and effective uterine contractions. When active-phase starts, a progressive increase occurs in uterine contractions in every aspect, resulting in dilatation of cervix. Active-phase of first-stage is also known as "dilatation phase of labor".[6] First stage of labor can be reduced in its duration by active administration. This idea was proposed by obstetricians in Dublin. Active administration implies to active control during labor by the Obstetrician.[7] During effective management of the labor including fruitful uterine contractility and softening of cervix is imperative. Sometimes, in spitefulness of the best contractions and cervix dilatation is countered by spasm caused by inhibitory impulse. Sometimes, antispasmodics are used to overcome the spasm and hasten the cervical dilatation. It results in reduction in duration of labor.[8] The agent of choice for spasmolytic should be the one which reduces the time period of 1st-stage of labor, does not interfere with myometrial activity and other stages of labor and does not bear any fetomaternal complication.[9] This study has been conducted to determine the effectiveness of Hyoscine Butyl bromide versus Drotaverine hydrochloride in terms of time reduction of first stage labor's active phase among primigravida females at term. Not many studies have been done before in Pakistan, so it will generate local data and the better of the two drugs will be used in future for the said purpose.

Methodology

This study was comparative and was done at the Obstetrics & Gynecology Department, Lady Willingdon Hospital. Study duration was 6 months from September 2017 to February 2018. All the Primigravidae with 38-42 weeks of gestation from last menstrual period with singleton pregnancy and cephalic presentation and in active-phase of 1st-stage >3cm dilatation were incorporated in this study. Every female with excessive liquor, bleeding during pregnancy, medical disorders, intrauterine fetal death and cephalopelvic disproportion was excluded from this study. An informed consent from the patients was taken to include their data in study. The subjects were divided into two categories, first coming subjects were provided two folded slips marked as A and B on them. Group 'A' patients were administered 10 mg I/v Hyoscine Butyl bromide at 3-4cm dilatation and doses were repeated consecutively after each hour upto a maximum concentration of 3 doses, in terms of cervical dilatation. Group-B was directed 40mg of Drotaverine I/v at 3-4cm dilatation, repeated consecutively after 2 hours according to cervical dilatation to a maximum concentration of 3 injections. After every half hour, monitoring of uterine contractions, vital signs and fetal cardiac rate was performed. Labor progress was estimated by cervicogram. The primary-outcome i.e. time duration of the active phase of labor's first stage in both groups was documented in pre-intended proforma.

Data analysis was done by computer software SPSS version 20. Mean and standard deviation were recorded for age and duration of active phase. As a test of significance, Student T Test was applied and p-value ≤ 0.05 was considered as significant.

Results

Overall 100 cases (50 /group) were studied. In relation to age group, most of the subjects; 54% of A-Group and 52% in B-Group were found in age group 20 to 25 years, while 34% in Group-A, and 30% in Group-B were found with 26-30 years of age group, and only 12% in Group-A and 18% cases in

Group-B were aged between 31-35 years. The mean age was recorded insignificant as 27.3±3.4 years and 25.7±2.8 years of group A and B respectively, p-value 0.547. Table I

Gestational age of the patients was compared in both groups, 68%(n=34) in Group-A and 58% (n=29) in Group-B were between 38-40 weeks of gestation, 32 %(n=16) in Group-A and 42 %(n=21) in Group-B were between 41-42 weeks of gestation, these findings of gestational age were statistically insignificant, p-value 0.300. Table II.

According to the comparison of time duration of the active-phase of labor's first stage, Hyoscine Butyl bromide administrated group showed shorter mean of time as 159.42±6.22 minutes in Group-A and 199.77±8.43 minutes in Group-B, this time duration was significantly lesser in group A p-value 0.008 Table III

Table I: Age comparison among both study groups (n=100)

Age groups (years)	*Group-A (n=50)*	*Group-B (n=50)*	*p-value*
	Frequency (%)	*Frequency (%)*	
20-25	*27(54.0%)*	*26(52.0%)*	
26-30	*17(34.0%)*	*15(30.0%)*	*0.547*
31-35	*06(12.0%)*	*9(18.0%)*	
Mean and S.D.	*27.3+3.4 years*	*25.7+2.8 years*	

Table II. Patients distribution according to gestational age among both groups (n=100)

Gestational age	**Group-A (n=50)**	**Group-B (n=50)**	*p-value*
	No. of Patients	*No. of Patients*	
38-40 weeks	*34(68.0%)*	*29(58.0%)*	
41-42 weeks	*16(32.0%)*	*21(42.0%)*	*0.300*
Total	*50(100.0%)*	*50(100.0%)*	

Table III: Duration of active phase of first stage of labour of both groups

	Group-A (n=50)	**Group-B (n=50)**	**P value**
	"Mean±SD"	**"Mean±SD"**	
Duration	159.42±6.22 minutes	199.77±8.43 minutes	0.002

Discussion

Primipara females undergo prolonged labor more frequently than multipara. In underdeveloped countries such as India and Pakistan, prolonged labor plays a significant role in perinatal and maternal mortality and morbidity. Prolonged obstructed labor and ruptured uterus can possibly represent three quarters of overall maternal deaths, and significant perinatal mortality has been associated with obstructed labor. Vesico-vaginal fistula, a dreaded sequlae of prolonged labor, has been seen to occur in significant numbers in developing countries.[10] O'Driscoll at Dublin, presented the perspective of active management of labor and this has led the obstetricians to change their views about the administration of 1st stage of labor. Active administration of labor correlates with a low prevalence of cesarean section and prolonged labor.[7] We planned this study to contrast the time duration of the active-phase of labor's first stage when the patient was administered Hyoscine Butyl chloride in comparison to Drotaverine hydrochloride. Hyoscine Butyl Bromide is derived from Tree Dubosia which is present in Australia and has a known antispasmodic action. It blocks cholinergic impulses especially cervicouterine plexus and aids in dilatation of cervix. After intravenous injection, the action starts in 10 minutes, achieves peak concentration in an hour and the duration of action is an hour.[11] Drotaverine Hydrochloride is a strong antispasmodic agent which acts on smooth muscles. It is used for reducing cervical spasm during labor. It inhibits phosphodiesterases hydrolyzing cAMP, so as to increase CAMP levels, reducing uptake of calcium cells and modifying the distribution of calcium across the cells. The pharmacological dose of Drotaverine is not able to stop uterine action but relaxes the muscles of lower uterine segment.[12] Mode of action was investigated by Corsen et al, which was found in suppository and intravenous routes. Ideal time for management was 2.5 to 3 centimeters and no deleterious effect was seen at the dose of 30 mg. [13]

The results of our study reveal that large part of the patients of both groups were aged from 20 to 25 years and mean age 27.3±3.4 years and 25.7±2.8 years respectively, these findings were similar to

Kausar U et al.[18] Jogi SR et al[14] also found comparable findings regarding age.In this series time duration of the active-phase of labor's first stage was 159.42±6.22 minutes in Group-A and 199.77±8.43 minutes in Group-B; with a P value of 0.008, showing a significant difference. Jogi SR and Bashir S compared the efficacy and safety of Drotaverine and Hyoscine Butyl Bromide in reducing the duration of 1st-stage of labor and found a significant difference ($p < 0.05$). These results are consistent with our findings.[14,15] Our findings were also in agreement with Sirohiwal et al, Aggarwal et al, Tevari and Kauser et al. All these studies reported significant decline in duration of 1st-stage of labor when Hyoscine Butyl bromide was used in comparison with Drotaverine. In these studies, the mean age of the patients and the mean gestational age followed the same pattern as that in our study, therefore strengthening our results. [16, 11.17,18]

We also noted a significant variance in our patients managed with Hyoscine contrasted to those without intervention as; the subjects managed with Hyoscine had a significant short time of the first and second stage of the labor. These outcomes were same as observed in studies done by S Ashraf, Qatari, Makovandi and Samuels et al.[19-22] The hypothesis of this study regarding difference in time period of first stage of labor's active phase is found to be justified in light of results of the current study. It is also supported by national and international studies. However, Singh reported some incidence of PPH because of uterine atony by using of spasmolytics when Drotaverine hydrochloride was used. This figure of 18% is significant and may discourage the use of Drotaverine in labor. Most of the contemporary studies do not report any such side effect for use of Hyoscine in Labour.[23] The strength of the study lies in the fact that the success of Hyoscine in shortening of second stage of labor could help in avoiding neonatal and maternal sepsis, needed for opioid analgesia and chances of fetal distress. These factors could make this agent useful in our set up. In this study adverse fetomaternal outcome not studied which can possibly further enhance the acceptability and validity of these drugs in the treatment of first stage of labor. Though, further trials can possibly be conducted to meet this limitation.

Conclusion

It was observed that both drugs are effective in reduction of "time duration of active phase of first stage labour" among primiparous patients, while the Hyoscine Butyl Bromide is more effective in reduction of this time duration as compare to Drotaverine hydrochloride. Further studies are required on this comparison including adverse fetomaternal outcome.

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