International Journal of Medical and Health Research
ISSN: 2454-9142
Impact Factor: RJIF 5.54
www.medicalsciencejournal.com
Volume 4; Issue 11; November 2018; Page No. 178-181

Drotaverine hydrochloride versus hyoscine butyl bromide in first stage of labour

Supriya Patil[1], Yamini S Patil[2*]
[1-2] Department of obstetrics and gynecology, Krishna institute of medical sciences, Karad, Maharashtra, India
[*] Corresponding Author: Yamini S Patil

Abstract
This study was done to compare the efficacy of drotaverine hydrochloride and hyoscine butyl bromide in first stage of labour. The prospective randomized control trail was done to understand the effects of drotaverine and hyoscine in cervical dilatation and thus duration of first stage of labour. Study evaluated the side effect profit of both the drug and overall patient acceptance of the two. The study population of 300 patients was divided into three groups. One group was given injection Drotaverine 1 amp iv single dose, second was given injection Hyoscine butylbromide 1 amp iv single dose in active phase of labour, and the third group did not receive any anti-spasmodic. Periodic evaluation of cervix, uterine contractions a foetal heart sounds were done for each complaint of the patients was noted. Approximate blood less in third stage of labour was noted. In this research topic, each group was further subdivided into nulliparous and multiparous, and all the main outcome measures were calculated for each such group. The ages of patients in all three groups in both nulliparous and multiparous patients are comparable. The dilatation on admission of patients in all three groups of both nulliparous and multiparous patients are comparable. All three groups of both nulliparous and multiparous patients are comparable in terms of dilatation at injection or detection of active phase.

Keywords: labour, hyoscine butylbromide, drotaverine hydrochloride, nulliparous

Introduction
Majority of the obstetricians use anti-spasmodic agents like drotaverine hydrochloride and hyoscine butylbromide in an attempt to increase the rate of cervical dilatation. By this study, my aim was to find out whether these drugs are actually effective or whether they are just placebos for the surgeons. Cervical dilatation is measured by per vaginal examination and expressed in centimeters.

Aims and Objectives
To study the effect of hyoscine butylbromide and drotaverine hydrochloride on the duration of first stage of labour. To study the maternal side effects and neonatal outcome with these drugs.

Review of Literature
Labour is defined as the process of expulsion of viable products of conception from the womb, through the vagina, into the outer world. The production of uterine contractions requires an increase in myometrial intracellular calcium concentration. This occurs by influx of calcium from the outside of the myocyte through calcium channels or by release of calcium deposited in the endoplasmic reticulum. The activity of MLCK is central to the process of muscle contraction and most pharmacological agents used to stimulate or inhibit uterine contractions operate through metabolic pathways that lead to this enzyme. Cervix undergoes more extensive remodeling prior to initiation of contractions. This involves connective tissue changes and is termed cervical ripening. The total amount and composition of proteoglycans and glycosaminoglycans within the matrix are altered which promotes ripening. At the end of pregnancy, before and during early stages of labour, collagenase activity in the extra-cellular matrix increases, and there is increased fibroblastic production of hyaluronic acid, a hydrophilic molecule. As a consequence of these changes the collagen content decreases and the water content of the cervix increases. There is infiltration of the extra-cellular matrix by inflammatory cells particularly neutrophils and macrophages with production of cytokines, metalloproteinases and prostaglandins. The cervix becomes soft and can be stretched be the pressure of the foetal presenting part and the pulling effect of the uterine contractions. The trigger for the initiation of cervical ripening is unknown although there is substantial evidence indicating a role for sex steroid hormones and prostaglandins. The role of sex steroid hormones is evidenced by the administration of progesterone antagonists such as RU486, a powerful inductor of cervical ripening. Also, there is laboratory evidence demonstrating the ability of estradiol to stimulate collagen degradation. Prostaglandins are powerful pharmacologic inductors of cervical ripening and may play a central role in the physiology of the process. Prostaglandins modulate the fibroblastic activity and induce production of hyaluronic acid with mobilization of water into the extra-cellular matrix and promote changes in the glycoprotein composition of the cervix. They also have the ability to mobilize leukocytes and macrophages into the extra-cellular matrix that will be responsible for the production of enzymes that will cause changes in the cervical ground substance. An insufficient remodeling of the connective tissue in the cervix and isthmus uteri may contribute to slow progress of labour [1].
Asphyxia from the long labour itself. Cerebral damage caused

by pressure against the foetal head Injury as a result of difficult forceps rotations and extractions. Rupture of the bag of waters long before delivery. This may result in amniotic fluid being infected and in turn pulmonary and general infection in the foetus. Prolonged labour exerts a deleterious effect on the mother. The severity of the damage increases progressively with the duration of the labour, the risk rising sharply after 24 hrs. There is a rise in the incidence of uterine atony, lacerations, hemorrhage, infections, maternal exhaustion and shock. The high rate of operative deliveries aggravates maternal dangers. Different studies have shown that smooth muscle content of the cervix varies from 5-20%. This is being explained as the physiological basis for aiding dilatation of cervix by various smooth muscle spasmolytics. In obstetrics, there has always been an effort to reduce the duration of labour and reduce maternal and foetal suffering. Our aim as obstetricians is to deliver a healthy baby to a healthy mother and make the process of child-bearing as comfortable as possible. In 1962, Ferron M published a study on use of dihexyverine in obstetrics [2].

This study attempted to evaluate the effect of dihexyverine HCl (Metaspas), an anticholinergic and direct smooth muscle relaxant (spasmolytic), in shortening the first stage of labour. One hundred and five patients constituted the series: 31 were primiparae, 27 secundiparae and 47 multiparae. The majority of these (95) received one intramuscular injection (10 mg.) of dihexyverine. Alphaprodine (Nisentil), 40 mg., was administered in all but 10 cases, since dihexyverine has no analgesic action. Seventy-five control patients were used: 25 were primiparae, 25 secundiparae and 25 multiparae. Alphaprodine alone was administered to these control patients. The length of time for dilatation from 4 cm. to 10 cm. was the selected criterion. In the control group, the average time for complete cervical dilatation was 4 hours, 10 minutes. In the group treated by dihexyverine, complete dilatation was achieved in 1 hour, 16 minutes. On the average, the first stage of labour was 2 hours and 54 minutes shorter with dihexyverine; the clinical effect begins 10-30 minutes after administration. The only side effect encountered was a skin rash in one patient. In 1975, Salzmann KD published a study on digital dilatation [3]. In 1975, Mitrani *et al* published a study on use of propranolol in dysfunctional labour [4]. In 2001, Sharma J B, Pundir P, Kumar A published a study on drotaverine hydrochloride versus Valethamate bromide in acceleration of labour [5].

They concluded that both intramuscular drotaverine hydrochloride and valethamate bromide are effective in acceleration of labour; however, drotaverine accelerates labour more rapidly and is associated with less side effects. In 2004, Singh KC, Jain P, Goel N published a study on drotaverine hydrochloride for augmentation of labour [6]. They concluded that Drotaverine hydrochloride is safe and effective in accelerating labour, but not effective in lessening labour pain. In 2005, Sirohiwal D *et al* studied the efficacy of hyoscine butyl bromide suppositories as a cervical spasmolytic agent in labour [7]. They concluded that Hyoscine-N-butyl bromide (HBB, Buscopan) suppositories were highly effective in shortening the duration of the first stage of labour. In 2007, Roy A, Patra KK, Mukhopadhyay S, Guha S Published a study of drotaverine hydrochloride on first stage of labour and pregnancy outcome [17].

Materials and Methods

Source of data: the source of data is patients admitted in Krishna hospital, KIMS, Karad. A total of 300 cases are selected by simple random sampling method. 100 patients are alloted to each study group: Group A will receive inj. Drotaverine 40 mg iv at 3-4 cm dilatation if admitted in active phase of labour and at first examination if already more than 4 cm dilated. Women in group B will receive 1 ampule inj. Hyoscine 20 mg iv instead of inj. Drotaverine. Women in group C will not receive any antispasmodic. Breech, absent membranes, h/o encirclage, preterm labour and IUD. Active but not aggressive management protocol will be followed for all women in labour. Artificial rupture of membranes will be done at 4-5 cms. Only one dose of antispasmodic will be given in the study. Cervical assessment every two hours or earlier if indicated will be done. Amount of bleeding in III stage of labour will be noted. Women's pulse rate will be measured hourly and every 15 min for one hour after injection of antispasmodic. Continuous FHR monitoring for high risk patients and every 15 minutes for low risk patients will be done after taking an initial NST. Pearson's chi square test was used to analyse the data. This test is used to test for proportion in the groups with respect to a categorical variable such as age, delivery time, duration of various stages of labour. P value: if the P value is less than 0.05, we can conclude that the means are not equal and the difference is statistically significant.

Observation and Results

The study comprised of 300 patients randomly allocated into 3 groups: Group A: receiving Drotaverine. Group B: receiving Hyoscine Group C: no anti-spasmodics These groups were studied as given in the methodology and compared as follows.

Table 1: Association between Ages of Nulliparous Patients in Each Group

Age Group		St Group			Total
		Drotaverine	Hyoscine	Control	
Less than 21 Yrs	Count	12	15	15	42
	Percent	28.6%	35.7%	35.7%	100.0%
21 to 25 Yrs	Count	35	31	33	99
	Percent	35.4%	31.3%	33.3%	100.0%
26 to 30 Yrs	Count	3	3	2	8
	Percent	37.5%	37.5%	25.0%	100.0%
More than 30 Yrs	Count	0	1	0	1
	Percent	0.0%	100.0%	0.0%	100.0%
Total	Count	50	50	50	150
	Percent	33.3%	33.3%	33.3%	100.0%

As shown in table 1, the ages of patients in all three groups in both nulliparous and multiparous patients are comparable. The P value in nulliparous patients is 0.819 and in multiparous patients is 0.255. Both these values are more than 0.05 and hence statistically not significant.

Table 2: Associations Between Dilatation on Admission of Nulliparous Patients In Each Group

Dilatation on Admission		St Group			Total
		Drotaverine	Hyoscine	Control	
Less than 2 cm	Count	13	9	10	32
	Percent	40.6%	28.1%	31.3%	100.0%
2 to 4 cm	Count	28	32	22	82
	Percent	34.1%	39.0%	26.8%	100.0%
5 to 7 cm	Count	9	9	18	36
	Percent	25.0%	25.0%	50.0%	100.0%
Total	Count	50	50	50	150
	Percent	33.3%	33.3%	33.3%	100.0%

As shown in tables 2, the dilatation on admission of patients in all three groups of both nulliparous and multiparous patients are comparable. The P value in nulliparous patients is 0.127 and in multiparous patients is 0.125. Both these values are statistically not significant.

Table 3: Association Between Dilatation on Injection In Nulliparous Patients of Each Group (Dilatation on Detection of Active Phase In Control Group)

Dialation on inj		St Group			Total
		Drotaverine	Hyoscine	Control	
Upto 4 cm	Count	33	28	28	89
	Percent	37.1%	31.5%	31.5%	100.0%
5 to 6 cm	Count	17	22	22	61
	Percent	27.9%	36.1%	36.1%	100.0%
Total	Count	50	50	50	150
	Percent	33.3%	33.3%	33.3%	100.0%

As shown in tables 3, all three groups of both nulliparous and multiparous patients are comparable in terms of dilatation at injection or detection of active phase. The P value in nulliparous patients is 0.501 and in multiparous patients it is 0.919. both these values are not statistically significant.

Table 4: Association Between Duration Of Injection To Full Dilatation In Nulliparous Patients With Injection At 3 - 4 Cm Dilatation (Duration Of Active Phase In Control Group)

duration bet inj to full dilatation		St Group			Total
		Drotaverine	Hyoscine	Control	
Less than 2 Hrs	Count	2	0	0	2
	Percent	100.0%	0.0%	0.0%	100.0%
2 to less than 3 Hrs	Count	11	6	8	25
	Percent	44.0%	24.0%	32.0%	100.0%
3 to less than 4 Hrs	Count	12	9	5	26
	Percent	46.2%	34.6%	19.2%	100.0%
4 to less than 5 Hrs	Count	4	4	7	15
	Percent	26.7%	26.7%	46.7%	100.0%
5 and above	Count	4	9	8	21
	Percent	19.0%	42.9%	38.1%	100.0%
Total	Count	33	28	28	89
	Percent	37.1%	31.5%	31.5%	100.0%

As shown in tables 5, there is no statistical difference between the duration of injection to full dilatation or active phase in all three groups of both nulliparous and multiparous patients. The P value in nulliparous patients is 0.219 and in multiparous patients is 0.803. Both these values are not significant.

Table 6: Association Between Duration of Injection to Full Dilatation In Nulliparous Patients With Injection At 5 - 6 Cm Dilatation (Duration Of Active Phase In Control Group)

duration bet inj to full dilatation		St Group			Total
		Drotaverine	Hyoscine	Control	
Less than 2 Hrs	Count	12	5	6	23
	Percent	52.2%	21.7%	26.1%	100.0%
2 to less than 3 Hrs	Count	2	8	8	18
	Percent	11.1%	44.4%	44.4%	100.0%
3 to less than 4 Hrs	Count	2	5	5	12
	Percent	16.7%	41.7%	41.7%	100.0%
4 to less than 5 Hrs	Count	1	3	2	6
	Percent	16.7%	50.0%	33.3%	100.0%
5 and above	Count	0	1	1	2
	Percent	0.0%	50.0%	50.0%	100.0%
Total	Count	17	22	22	61
	Percent	27.9%	36.1%	36.1%	100.0%

As shown in tables 6 and 14, there is no statistical difference between the duration of injection to full dilatation or active phase in all three groups of both nulliparous and multiparous patients. The P value in nulliparous patients is 0.177 and in multiparous patients is 0.944. Both these values are not significant.

Discussion

The study is a randomized control study which compares the drugs drotaverine hydrochloride and hyoscine butylbromide with control group. Tehalia Manpreet *et al*. Average time from injection to full dilatation was 103.4 min in nullipara, 117.09 min in multipara with drotaverine and 59.88 min in nullipara, 60.48 min in multipara in hyoscine group. P.Bhattacharya and S G Joshi's study out of 100 cases, 29 patients had less than 4 hours and 52 patients had 4 to 8 hours and 19 had more than 8 hours injection to delivery interval. In control group, 8 patients were less than 4 hours and 33 had 4-8 hours, 59 patients had more than 8 hrs injection delivery interval.

Conclusions

APGAR score of all babies in the study was more than 7 after 5 minutes of birth. So, we conclude that there is minimal role of anti-spasmodics in shortening the duration of first stage of labour. However, both these drugs are safe and can be used with minimum side- effects. There is no significant difference between the side effect profiles of both drugs.

Refeerences

1. Granström L, Ekman G, Malmström A. Insufficient remodelling of the uterine connective tissue in women with protracted labour. Br J Obstet Gynaecol. 1991; 98(12):1212-6.
2. Ferron M. Preliminary study on the use of dihexyverine in obstetrics: Can Med Ass J. 1962; 84:1121-3
3. Salzmann KD. a labour saving manouvre. JR Coll Gen Pract. 1975; 25(155):409-16
4. Mitrani A, Oettinger M, Abenader EG, Sharf M, Klein A. Use of propranolol in dysfunctional labour: BJOG. 1975; 82(8):651-5
5. Sharma JB, Pundir P, Kumar A. Drotaverine hydrochloride versus valethamate bromide in acceleration

of labour: Int J Gynaec Obstet. 2001; 74(3):255-60
6. Singh KC, Jain P, Goel N, Saxena A. Drotaverine hydrochloride for augmentation of labour: Int J Gynaec Obstet. 2004; 84(1):17-22
7. Sirohiwal D, Dahiya KDC. Efficacy of hyoscine N butyl bromide suppositories as a cervical spasmolytic agent in labour: Austr NZ J Obstet Gynaec. 2005; 45(2)128:9
8. Roy A, Patra KK, Mukhopadhyay S. Study of drotaverine on first stage of labour and pregnancy outcome: J Indian Med Ass. 2007; 105(8):450-52