ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
Index Copernicus Value: 49. 23

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 3, Issue –3, June - 2018, Page No. : 104 - 110

Drotaverine Hydrochloride Verses Hyoscine Butyl Bromide in Augmentation of Labour among Nulliparous Women

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Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Background: Prolonged labour is an important risk factor for both maternal morbidity and perinatal compromise.[5] Minimizing the duration of labour without compromising fetomaternal wellbeing is a desirable outcome in all labour and delivery units.Since most of the prolonged labours are among the nulliparous women, the current study was done to compare the safety and efficacy of intravenous drotaverine hydrochloride against intravenous hyoscine butyl bromide in augmentation of labour among nulliparous women.

Aims & Objectives

AIM: To study and compare the efficacy and safety of Drotaverine hydrochloride and hyoscine-N-butyl bromide in the augmentation of labour among nulliparous women

Objectives

1. To compare the efficacy of Drotaverine hydrochloride and Hyoscine-N butyl bromide in hastening cervical dilatation and thus in shortening the duration of labour.
2. To compare the side effects of both the drugs on the mother.
3. To compare the side effects of both the drugs on the newborn.

Materials and Methods: The Government RSRM lying in hospital is a 500 bedded hospital dedicated to Obstetrics Gynaecology and Neonatology. It is a maternity and women's health hospital attached to Stanley Medical College. On an average 10000 babies are delivered per year.

Study Population: Nulliparous women admitted in spontaneous active labour to the labour ward at Government Raja Sir Ramasamy Mudaliar Lying in Hospital, Stanley Medical College from March 2015 - August 2015. These women were selected according to Inclusion and Exclusion criteria.

Results: Drotaverine group when compared to control group showed a reduction in the duration of active phase by 50.92 minutes among nulliparous women which is statistically significant.

Hyoscine group when compared to control group showed a reduction in the duration of active phase by 64.94 minutes among nulliparous women which is statistically significant.

Drotaverine group when compared to Hyoscine showed a reduction in the duration of active phase by 14 minutes among nulliparous women which is statistically

significant.

Conclusion: Both Drotaverine hydrochloride and Hyoscine Butyl bromide is effective in shortening the duration of first stage of labour by virtue of faster cervical dilatation there by helping in augmentation of labour among the nulliparous women.

Key words: drotaverine hydrochloride ,intravenous hyoscine butyl bromide & augmentation of labour

Introduction

Prolonged labour is an important risk factor for both maternal morbidity and perinatal compromise.[5] Minimizing the duration of labour without compromising fetomaternal wellbeing is a desirable outcome in all labour and delivery units. Since most of the prolonged labours are among the nulliparous women, the current study was done to compare the safety and efficacy of intravenous drotaverine hydrochloride against intravenous `hyoscine butyl bromide in augmentation of labour among nulliparous women.

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Materials And Methods

Study Design: Prospective interventional comparative study

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Study Population

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Sample Size & Sample Technique

A total of 600 nulliparous women were selected according to the Inclusion and

Exclusion criteria.

Inclusion Criteria

a) Primiparous Women 18-35 years of age

b) Singleton term fetus (gestational age between 37-41 weeks 6 days)

c) Vertex Presentation

d) Spontaneous onset of labour in active phase of labour (cervical dilatation of 3-4 cm)

e) Intact membranes

f) No contraindication for vaginal delivery

g) No chronic or pregnancy induced illnesses h) Informed and written consent

Exclusion Criteria

a) Women <18 and >35 years of age b) Multiparous

c) Multiple gestation

d) Cephalopelvic disproportion e) Malpresentation

f) Induced labour

g) Cervical dilatation of >4 cm h) Ruptured membranes

i) Previous uterine scarring

j) Chronic or pregnancy induced illnesses k) Antepartum Haemorrhage

l) Non reassuring fetal status

m) Hypersensitivity to Drotaverine or Hyoscine

A detailed history was taken and a thorough physical

examination was done. A

written informed consent was obtained from all the eligible participants. These

600 women were randomly assigned into 3 groups namely A, B, C with each group having 200 women each.

Group A - Control Group

Women in this group belongs to control group. Hence progress of labour was monitored using a partogram.

Group B - Drotaverine Group

These women received single dose of Inj. Drotaverine 40 mg intravenously at the onset of spontaneous active labour which is cervical dilatation of about 3-4 cm and the progress of labour was monitored using a partogram.

Group C - Hyoscine Group

These women received single dose of Inj. Hyoscine 20 mg intravenously at the onset of spontaneous active labour which is cervical dilatation of about 3-4 cm and the progress of labour was monitored using a partogram.

Artificial rupture of membranes was done under antibiotic cover. A partogram was maintained throughout the labour for every patient to monitor the progress of labour. Vaginal examination was done every 2hrs or earlier if required. Oxytocin infusion was started and titrated according to uterine contractions.

Vitals monitoring and progress of labour was monitored which includes uterine contractions, progress and descent of presenting part, cervical dilatation and fetal heart sounds using a partogram.

The 3 groups of patients were observed to record the primary and secondary outcomes. The observations that were noted are the time of onset of active labour (is the time at which the drug is given), time of full cervical dilatation, time of delivery of the baby and placenta.

The primary outcome that are noticed are the duration of I, II, III Stage of labour and cervical dilation rate. Secondary outcome that are analysed are the mode of delivery, maternal drug side effects, third stage complications and neonatal outcome (APGAR at 1 minute and 5 minutes, NICU admission). Both the primary and secondary outcomes were compared among groups.

Results & Analysis

This study was undertaken at Government RSRM Lying in hospital, Stanley Medical College, Chennai. 600 Nulliparous women were selected and divided in to three groups namely Group A or the Control Group, Group B or the Drotaverine Group and Group C or the Hyoscine Group. Each group was monitored as mentioned in the methodology of the dissertation and the observations were tabulated and analyzed.

Oxytocin Augmentation

Table 1: Oxytocin Augmentation

Oxytocin		Group			Total
		Control	Drotaverine	Hyoscine	
Yes	Count	121	103	95	319
	% within Oxytocin	37.9%	32.3%	29.8%	100.0%
	% within Group	60.5%	51.5%	47.5%	53.2%
No	Count	79	97	105	281
	% within Oxytocin	28.1%	34.5%	37.4%	100.0%
	% within Group	39.5%	48.5%	52.5%	46.8%
Total	Count	200	200	200	600
	% within Oxytocin	33.3%	33.3%	33.3%	100.0%
	% within Group	100.0%	100.0%	100.0%	100.0%

60.5%, 51.5%, and 47.5% from control, drotaverine and hyoscine group required oxytocin infusion drip to establish active uterine contractions. This was about 319 patients of the total study groups constituting 53.2%.

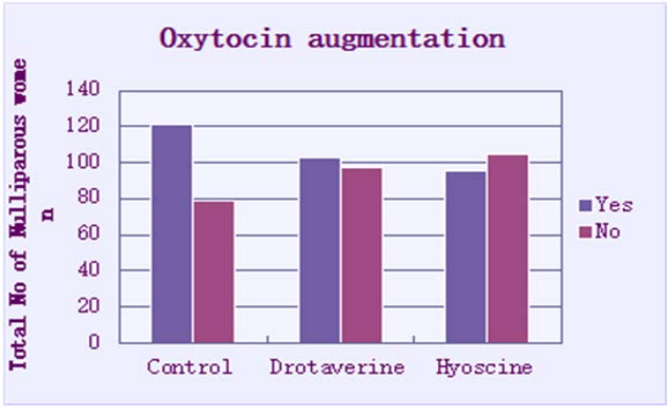

Chart 1: Oxytocin Augmentation

Duration of Active Phase of Labour

Table 2: Duration of active phase of labour (min).

Group	N	Mean	Std. Deviation	P value
Control	184	213.51	25.874	.000
Drotaverine	180	162.58	19.828	
Hyoscine	181	148.57	31.033	
Total	545	175.12	38.186	

In the control group the mean duration of active labour was 213.51 minutes. In the Drotaverine group it was found to be 162.58 minutes. In the Hyoscine group the mean duration of active labour was found to be 148.57 minutes.

Table 3: Duration of active phase of labour (min) – Multiple Comparisons

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.
Control	Drotaverine	50.92(*)	2.725	.000
	Hyoscine	64.94(*)	2.721	
Drotaverine	Control	-50.92(*)	2.725	
	Hyoscine	14.01(*)	2.736	
Hyoscine	Control	-64.94(*)	2.721	
	Drotaverine	-14.01(*)	2.736	

The difference among all the three groups within one another was found to be significant. The mean duration of active stage of labour was significantly lower than the control group when compared to the Drotaverine and the hyoscine group. When compared to Drotaverine the hyoscine group had statistically significant difference in the mean duration of active stage of labor.

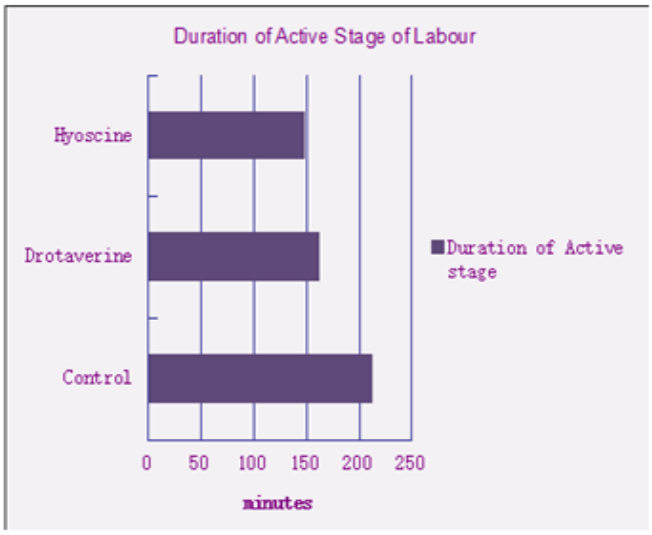

Chart 4: Duration of active phase of labour (min)

Cervical Dilatation Rate

Table 5: Cervical dilatation Rate.

Group	N	Mean	Std. Deviation	Std. Error	Sig.
Control	184	1.7090	.19099	.01408	.000
Drotaverine	180	2.2427	.23811	.01775	
Hyoscine	181	2.5146	.45396	.03374	
Total	545	2.1528	.46038	.01972	

In the control group the rate of cervical dilatation was 1.7090 cm/hr. In the

Drotaverine group it was found to be 2.2427 cm/hr. In the Hyoscine group the rate of cervical dilatation was found to be 2.5146 cm/hr. This was found to be statistically significant.

Table 6: Cervical dilatation Rate – Multiple comparisons.

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.
Control	Drotaverine	-.5337(*)	.03307	.000
	Hyoscine	-.8056(*)	.03302	
Drotaverine	Control	.5337(*)	.03307	
	Hyoscine	-.2719(*)	.03320	
Hyoscine	Control	.8056(*)	.03302	
	Drotaverine	.2719(*)	.03320	

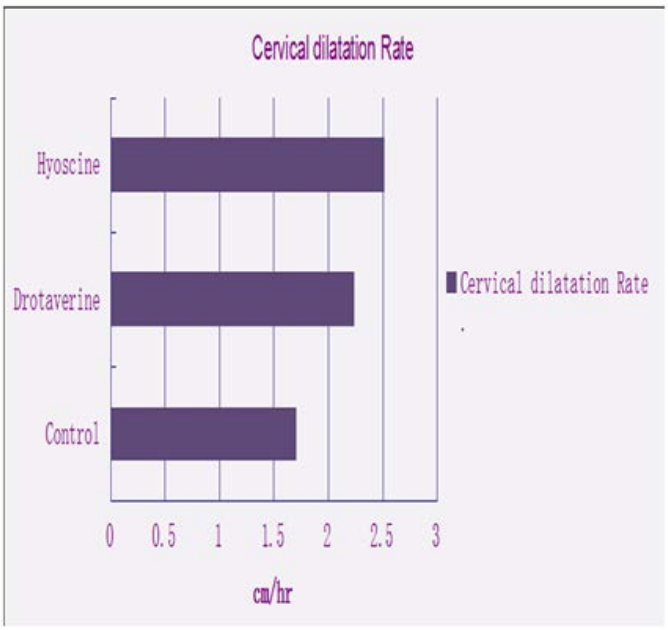

Chart 5: Cervical dilatation Rate.DURATION OF II STAGE OF LABOUR

Table 10: Duration of II stage of labour (min).

Group	N	Mean	Std. Deviation	Std. Error
Control	184	50.19	8.547	.630
Drotaverine	180	48.61	7.858	.586
Hyoscine	181	49.60	8.241	.613
Total	545	49.47	8.233	.353

Duration of III Stage Of Labour

Table 11: Duration of III stage of labour (min).

Group	N	Mean	Std. Deviation	Std. Error
Control	184	9.09	.734	.054
Drotaverine	181	9.09	.705	.052
Hyoscine	181	9.06	.776	.058
Total	546	9.08	.738	.032

There was no significant difference in the duration of third stage of labour among all the three groups.

Mode of Delivery

Table 12: Mode of delivery.

Mode of delivery		Group			Total
		Control	Drotaverine	Hyoscine	
VD	Count	174	166	172	512
	% within Mode of delivery	34.0%	32.4%	33.6%	100.0
	% within Group	87.0%	83.0%	86.0%	85.3%
OVD	Count	10	14	9	33
	% within Mode of delivery	30.3%	42.4%	27.3%	100.0
	% within Group	5.0%	7.0%	4.5%	5.5%
LSCS	Count	16	20	19	55
	% within Mode of delivery	29.1%	36.4%	34.5%	100.0 %
	% within Group	8.0%	10.0%	9.5%	9.2%
Total	Count	200	200	200	600
	% within Mode of delivery	33.3%	33.3%	33.3%	100.0 %
	% within Group	100.0%	100.0%	100.0%	100.0m%

Majority of the women in all the groups had vaginal deliveries. It constituted about 85.3% of the entire 600 patients. There was no significant difference in the incidence of vaginal deliveries.Operative vaginal deliveries constituted 5.5% of the total number of deliveries. The difference in their incidence in all the three groups were found to be insignificant, the indication for them being either maternal exhaustion or fetal distress.LSCS constituted 9.2% of the total deliveries. The indication for LSCS was either fetal distress or Failure to progress.

Summary

This prospective interventional comparative study was done among 600 nulliparous women to compare the efficacy of intravenous Drotaverine hydrochloride and

Hyoscine butyl bromide in augmentation of labour.

For these nulliparous women who were in active labour with 3-4cm cervical dilatation, artificial rupture of membranes was done and was randomly divided into three groups. Oxytocin infusion was initiated if the initial progress of labour was unsatisfactory

Drotaverine group when compared to control group showed a reduction in the duration of active phase by 50.92 minutes among nulliparous women which is statistically significant.

Hyoscine group when compared to control group showed a reduction in the duration of active phase by 64.94 minutes among nulliparous women which is statistically significant.

Drotaverine group when compared to Hyoscine showed a reduction in the duration of active phase by 14 minutes among nulliparous women which is statistically significant.

The cervical dilatation rate was 1.70 cm/hr, 2.24 cm/hr, 2.51 cm/hr in control group, drotaverine group, and hyoscine group respectively which was statistically significant.

There was no significant change in the duration of II stage of labour among all the three groups.

In Control group 87% of women had spontaneous vaginal delivery, 5% of women had forceps delivery and 8% of women had caesarean section. In Drotaverine group 83 % of women had spontaneous vaginal delivery, 7% of women had forceps delivery and 10% of women had caesarean section. In Hyoscine group

86 % of women had spontaneous vaginal delivery, 4.5% of women had forceps delivery and 9.5% of women had caesarean section. Drotaverine and Hyoscine did not influence the mode of delivery.

There was no significant change in the duration of III stage of labour and maternal complications among all the three groups.

The side effects observed in both the groups were insignificant. There was no difference in perinatal outcome among the groups.

Conclusion

1. Both Drotaverine hydrochloride and Hyoscine Butyl bromide is effective in shortening the duration of first stage of labour by virtue of faster cervical dilatation there by helping in augmentation of labour among the nulliparous women.

2. Hyoscine butyl bromide is a superior cervical dilatation agent as compared to

Drotaverine hydrochloride.

3. Of the two drugs Hyoscine butyl bromide seems to be more effective than Drotaverine hydrochloride in augmentation of labour among the nulliparous women.

4. Both Drotaverine and Hyoscine didn't affect the duration of second and third stage of labour.

5. Both the drugs didn't show any major increase in operative vaginal delivery or cesarean section rate.

6. Both the drugs didn't show any increase in third stage complications.

7. Both the drugs had no significant maternal or fetal adverse effects.

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