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Original Research Article

A Randomised Prospective Study of Hyoscine-N Butyl Bromide Rectal Suppository and IV Drotaverine on Cervical Dilatation in Labour

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Conflict of interest: Nil

Abstract

Background: Whenever labor is prolonged, the mother suffers from Exhaustion, postpartum hemorrhage, and sepsis. Also, the fetus morbidity is increased due to fetal distress and birth asphyxia. So, use of pharmacological agents to reduce the duration of labor is justified.

Objective: To compare the rate of cervical dilatation and duration of the active phase of labor with rectal buscopan and injection of Drotaverine

Methods: The study was conducted in Government Rajaji Hospital, Madurai in 195 pregnant women who were admitted with term pregnancies in the active phase of labor. The women were randomized into three groups. Group A patients were the control group, who were not given any drug for cervical dilatation, Group B patients were given, 40 mg of intravenous Drotaverine, and Group C patients were put on Buscopan rectal suppository 10 mg.

Result: It was seen that in Primigravida, the mean rate of cervical dilatation was 2.47 cms/hr. in Group A compared to 3.12 cms./hr. in Group B and 3.92 cms/hr. in Group C. With both Drotaverine and Hyoscine, the rate of cervical dilatation was faster than control group[.[p value<0.001]. With Hyoscine, the rate of cervical dilatation was faster than Drotaverine [p value - 0.0151]. In primigravida, the duration of active phase was 188.4 minutes in the control group, 130 minutes in Drotaverine group and 103 minutes in the Hyoscine group. Duration of the active phase was reduced both in patients who received Drotaverine as well as Hyoscine when compared to the control group[p-value < 0.001]. Hyoscine was more effective in reducing the duration of the active phase in primigravida compared to Drotaverine. [p value 0.0219]. In multigravida, there was no reduction in the duration of of the active phase with use of both Hyoscine and Drotaverine. In multigravida, there was no difference in the rate of cervical dilatation with both drugs. Most of the subjects delivered vaginally.No serious side effects were noted in both the drug groups.

Conclusion: With use of Hyoscine butyl bromide in Primigravida, the rate of cervical dilatation was significantly increased when compared to Drotaverine. Also the duration of active phase of labor was shortened in primigravida with use of Hyoscine, when compared to Drotaverine.

Whereas in multigravida, there was no significant difference between both the groups in rate of cervical dilatation and duration of active phase of labor.

Keywords: Multigravida, postpartum hemorrhage, and sepsis, Drotaverine, Buscopan

Introduction

Whenever the progression of labor is poor, both the morbidity and mortality of the mother and neonate is increased. Usually there will be an underlying pathology which cannot be identified in all cases. But we can reduce the duration of labour by increasing the rate of cervical dilatation by using pharmaceutical agents. In this way the complications of Prolonged labor like Maternal exhaustion, Postpartum hemorrhage, sepsis, fetal distress and Birth Asphyxia (Denker 2009)

The protocol for Active management of labour in India was first developed by Dr. Daftary. It reduces both pain and duration of labor (Yeul 2008)

- Programmed labour protocol includes 4 pillars or components which are.
- Use of oxytocic to ensure adequate contraction of uterus.
- Use of Antispasmodics to facilitate dilatation of cervix.
- Analgesics to provide optimal relief from pain during labor.
- Use of partogram to assess how labor is progressing.

study was conducted in Govt. Rajaji Hospital, Madurai during the period August 2022 to November 2022.This study is a randomized control study on 195 pregnant women with term pregnancy in active labour were randomized into three groups.

Group A [Control Group]

Only Oxytocin

Group B

Oxytocin + Inj.Drotaverine 40mg I.V HRLY [MAX. 3 DOSES]

GROUP C

OXYTOCIN + HYOSCINE RECTAL SUPPOSITORY 10MG HRLY

[MAX 3 DOSES]

Inclusion Criteria

Women with full term gestation with vertex presentation with –

a) Cervical dilatation of 4cms
b) Cervical effacement of 50% or more
c) Membranes intact / ruptured.
d) Spontaneous and induced labour

Exclusion Criteria

a) Preterm labour.
b) Abnormal presentation
c) Antepartum hemorrhage
d) Cephalopelvic disproportion
e) Multiple pregnancy
f) anaemia Hb% < 8gms
g) heart disease
h) pregnancy induced hypertension.
i) previous LSCS
j) k/c/o myasthenia gravis
k) k/c/o hypersensitivity to the drug

Procedure

We took history of the patient, performed general examination and abdominal examination. We did per vaginal examination and

administered medications based on the group. We then monitored labour clinically and partographically.we did per vaginal examination Before administering each medication, or sooner if rupture of membranes, patient bearing down, or

significant changes in the foetal heart rate occurred. If there was any side effects such as tachycardia, dryness of mouth, flushing, headache, Hypotension, nausea, vomiting and pain at injection site and treated accordingly

In all patients we recorded the following

1. Duration of active phase of first stage of labour
2. Rate of cervical dilatation
3. Mode of delivery

Statistical Tools (To be included at the end of Materials and Methods)

We collected the information for all the selected cases and recorded in a Master Chart. We did data analysis with the help of computer using **Epidemiological Information Package (EPI 2010)** developed by Centre for Disease Control, Atlanta.

Using this software, we calculated the range, frequencies, percentages, means, standard deviations, chi square, and "p" values.

We examined the significance of the difference between the quantitative and qualitative variables using the Kruskal-Wallis chi-square test and the Yate's chi-square test, respectively.

We took a 'p' value less than 0.05 to denote significant relationship.

Results

Table 1: Age distribution

SBP at	No.of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
Upto 20 years	3	4.6	6	9.2	4	6.2
21-25 years	33	50.8	19	29.2	31	47.7
26-30 years	24	36.9	29	44.6	21	32.3
31-35 years	3	4.6	8	12.3	8	12.3
>35 years	2	3.1	3	4.6	1	1.5
Total	65	100	65	100	65	100
Range	19 – 37		19 - 39		20 – 36	
Mean	25.7		26.8		25.7	
SD	3.7		4.6		3.8	
‘p’ value between 3 groups	0.1707 Not significant					
Group A & B	0.1104 Not significant					
Group A & C	0.7539 Not significant					
Group B & C	0.1023 Not significant					

Most of the patients in the three groups were in 20 to 30 age group [73% to 87%]. 4.6 % in Group A, 9.2% in Group B, 6.2 % in C were less than 20 years.3.1 % in Group A, 4.6 % in Group B, 1.5 % in C were more than 35 years. All groups are comparable with respect to age distribution.

Table 2: Obstetric score

Obst. Score	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
Primi	34	52.3	35	53.8	32	49.2
Multi	31	47.7	30	46.2	33	50.8
'p' value between Group A & B	0.861 Not significant					
Group A & C	0.8607 Not significant					
Group B & C	0.7256 Not significant					

49 to 54 % were primipara and 46 to 51 % were multipara in three groups. There was no statistical difference among the groups with regards to parity.

Table 3: Antenatal complication

AN. Complications	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
Anaemia treated	2	3.1	32	3.1	2	3.1
Bronchial asthma	1	1.5	1	1.5	-	-
GDM	5	7.7	1	1.5	4	6.2
Hypothyroid	1	1.5	1	1.5	3	4.6
IUGR	1	1.5	-	-	-	-
Old PT.	-	-	1	1.5	-	-
Oligohydromnios	-	-	-	-	1	1.5
Prolonged pregnancy	1	1.5	2	3.1	-	-
PROM	5	7.7	6	9.2	5	7.7
RH negative	1	1.5	3	4.6	3	4.6
Total cases with complications	**16***	**24.6**	**16***	**24.6**	**17**	**29.2**
Total cases without complications	**49**	**75.4**	**49**	**75.4**	**48**	**73. 8**
'p' value between						
Group A & B	1.0 Not significant					
Group A & C	0.8409 Not significant					
Group B & C	0.8409 Not significant					

*Some cases had more than one complication

73 to 75.4 % of the cases were without antenatal complications. 24.6 % to 29.2 % were with antenatal complications. There was no significant difference between the three groups with respect to antenatal complications.

Table 4: Duration Of Active Phase In Primigravida

Duration of delivery e-phase	Duration (minutes)		
	Group A	Group B	Group C
Primi			
Mean	188.4	130.0	103.7
SD	102.6	51.1	36.8
'p' value between			

3 groups	**<0.0001 Significant**
Group A & B	**<0.0001 Significant**
Group A & C	**<0.0001 Significant**
Group B & C	**0.0219 Significant**

In primigravida, the duration of active phase was 188.4 minutes in control group, 130 minutes in Drotaverine group and 103 minutes in Hyoscine group. Duration of active phase was reduced both in patients who received Drotaverine as well as Hyoscine when compared to control group[p value < 0.001]. Hyoscine was more effective in reducing the duration of active phase in primigravida compared to Drotaverine. [p value 0.0219]

Table 5: Duration of Active Phase In Multigravida

Multi			
Mean	146.5	150.8	145
SD	78.2	79.2	84.1
'p' value between 3 groups	0.9136 Not significant		
Group A & B	0.7134 Not significant		
Group A & C	0.8186 Not significant		
Group B & C	0.6539 Not significant		

In multigravida, the mean duration of active phase was 146.5 min in Group A compared to 150.8 min. in Group B and 145 min in Group C. The difference were not statistically significant.

Table 6: Rate Of Cervical Dilatation In Primigravida

Rate of cervical dilatation	**Rate of cervical dilatation**		
	Group A	**Group B**	**Group C**
Primi			
Mean	2.47	3.12	3.92
SD	1.3	1.14	1.36
'p' value between 3 groups	<0.0001 Significant		
Group A & B	<0.0001 Significant		
Group A & C	<0.0001 Significant		
Group B & C	0.0151 Significant		

In primigravida, the mean rate of cervical dilatation was 2.47 cms/hr. in Group A compared to 3.12 cms./hr. in Group B and 3.92 cms/hr. in Group C. With both Drotaverine and Hyoscine, the rate of cervical dilatation was faster than control group[.[p value<0.001]. With Hyoscine, the rate of cervical dilatation was faster than Drotaverine compared to Group B[p value -0.0151].

Table 7: Rate of Cervical Dilatation in Multigravida

Multi			
Mean	3.02	3.11	3.24
SD	1.37	1.35	1.46
'p' value between			

3 groups	0.8397 Not significant
Group A & B	0.7859 Not significant
Group A & C	0.5801 Not significant
Group B & C	0.7353 Not significant

In multigravida, the mean rate of cervical dilatation was 3.02 cms/hr in Group A compared to 3.11cms/hr in Group B and 3.24 cms /hr in Group C. The difference was not statistically significant between any Group.

Table 8 : Duration of delivery – Second stage

Duration of delivery(second stage)	Duration (minutes)		
	Group A	Group B	Group C
Range	4 – 68	5 - 60	1 – 90
Mean	22.3	21.6	24.6
SD	14.3	10.2	20.4
'p' value between 3 groups	0.9096 Not significant		
Group A & B	0.8183 Not significant		
Group A & C	0.9925 Not significant		
Group B & C	0.6131 Not significant		

The duration of second stage was 22.3 minutes in the control group compared to 21.6 minutes in Drotaverine group amd 24.6 minutes in Hyoscine group. The difference was not statistically significant.

Table 9: Duration of delivery – Third stage

Duration of delivery- Third stage	Duration (minutes)		
	Group A	Group B	Group C
Range	4 – 10	4 - 10	4 - 30
Mean	5.46	5.38	6.18
SD	1.1	1.23	4.42
'p' value between 3 groups	0.5481 Not significant		
Group A & B	0.3233 Not significant		
Group A & C	0.8261 Not significant		
Group B & C	0.3111 Not significant		

The mean duration of III stage was 5.46 minutes in control group Compared to 5.38 minutes with Drotaverine group and 6.18 minutes with Hyoscine group. difference was not statistically significant.

Table 10: Number of doses

No. of doses	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
0	65	100	-	-	-	-
1	-	-	42	64.6	35	53.9
2	-	-	21	32.3	19	29.2

3	-	-	2	3.1	11	16.9
Range	0		1 - 3		1 - 3	
Mean	0		1.38		1.63	
SD	-		0.55		0.76	
Group B & C	0.084 Not significant					

There was no significant difference between the two experimental groups with regard to no.of doses.

Table 11: Maternal side effects

Side effects	**No. of cases**					
	Group A		**Group B**		**Group C**	
	No	**%**	**No**	**%**	**No**	**%**
Dryness of mouth	-	-	-	-	3	4.6
Flushing	-	-	3	4.6	-	-
Giddiness	-	-	3	4.6	-	-
Headache	-	-	1	1.5	-	-
Shivering	1	1.5	-	-	-	-
Tachycardia	-	-	2	3.1	4	6.2
Vomiting	1	1.5	-	-	-	-
Total cases with side effects	**2**	**3.1**	**9**	**13.8**	**7**	**10.8**
Total cases without side effects	**63**	**96.9**	**56**	**86.2**	**58**	**89.2**
'p' value between						
Group A & B	0.0586 Not significant					
Group A & C	0.0821 Not significant					
Group B & C	0.7895 Not significant					

13.8 % of the cases in Group B had adverse effects compared to 10.8% in Group C and 3.1% cases in control Group.With Buscopan, 6.2% patients had tachycardia and 4.2% patients had dryness of mouth. With Drotaverine, 4.6% patients had flusing of face and giddiness. The adverse effects were not statistically significant.

Table 12 :Mode of delivery

Mode of delivery	**No. of cases**					
	Group A		**Group B**		**Group C**	
	No	**%**	**No**	**%**	**No**	**%**
Labor natural	60	85.7	52	74.2	56	80
Outlet forceps	3	4.28	1	1.4	3	4.28
Vacuum	1	1.42	13	18.7	6	8.57
LSCS	6	8.5	4	5.71	5	7.14
Total	70	100	70	100	70	100

8.5% in group A, 5.7% in group B and 7.1% in group C went were LSCS.

Table 13: Birth weight

Birth weight (in kgs)	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
≤ 2.5 kgs	11	16.9	8	12.3	8	12.3
>2.5 kgs	54	83.1	57	87.7	57	87.7
Range	1.9 - 3.7		1.9 - 3.85		2.08 - 3.7	
Mean	2.86		2.91		2.89	
SD	0.37		0.39		0.36	
'p' value between 3 groups	0.758 Not significant					
Group A & B	0.4917 Not significant					
Group A & C	0.7024 Not significant					
Group B & C	0.6405 Not significant					

The mean birth weight among the three groups were between 2.86 to 2.91 kg. The three groups are comparable with respect to Birth weight.

Table 14: APGAR score

APGAR Score	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
5	-	-	1	1.5	-	-
6	2	3.1	3	4.6	1	1.5
7	12	18.5	14	21.5	13	20
8	43	66.2	32	49.3	48	73.9
9	8	12.3	15	23.1	3	4.6
Range	6 – 9		5 - 9		6 – 9	
Median	8		8		8	
Mean	7.88		7.88		7.82	
SD	0.65		0.88		0.53	
'p' value between 3 groups	0.6511 Not significant					
Group A & B	0.7799 Not significant					
Group A & C	0.4862 Not significant					
Group B & C	0.384 Not significant					

Mean APGAR SCORE was 7.88 in Group A and B, compared to 7.82 in Group C. The difference was not statistically significant.

Table 15: NICU admissions

NICU admissions	No. of cases					
	Group A		Group B		Group C	
	No	%	No	%	No	%
Yes	11	16.9	13	20	13	20

No	54	83.1	52	80	52	80
'p' value between Group A & B	0.8212 Not significant					
Group A & C	0.8212 Not significant					
Group B & C	1.0 Not significant					

16.9 % Neonates in Group A were admitted in NICU compared to 20% in Group B and C. There was no significant difference in the NICU admission between the three groups.

Table 16: Postpartum complications

Post-delivery complications	**No.of cases**					
	Group A		**Group B**		**Group C**	
	No	**%**	**No**	**%**	**No**	**%**
Atomic PPH	1	1.5	2	3.1	2	3.1
Disorder of sexual development	-	-	1	1.5	-	-
Retained placenta bits	-	-	-	-	1	1.5
Treated with oxytocin/prostadin	-	-	-	-	2	3.1
Total cases with side effects	**1**	**1.5**	**3**	**4.6**	**5**	**7.7**
Total cases without side effects	**64**	**98.5**	**62**	**95.4**	**60**	**92.3**
'p' value between						
Group A & B	0.3096 Not significant					
Group A & C	0.1039 Not significant					
Group B & C	0.3589 Not significant					

Discussion

Duration of active phase of labor in primigravida

Group A –188. 4 minutes.

Group B -130. 4 minutes.

Group C –103.7 minutes.

Drotaverine and hyoscine usage in primigravida decreased the length of the active phase. The Hyoscine group has a significantly shorter duration. Hence, hyoscine is more efficient at shortening labour in primigravida.

Duration of Active Phase of Labour in Multigravida

The mean duration of active phase was 146.5 min in Group A compared to 150.8 min in Group B and 145 min in Group C. The difference were not statistically significant.

Rate of Cervical Dilatation in Primigravida

In primigravida, the mean rate of cervical dilatation was 2.47 cms/hr. in Group A compared to 3.12 cms./hr. in Group B and 3.92 cms/hr. in Group C. Comparing group A and group B, there was a noticeable rise in cervical dilatation in both groups. When compared to Group B, Group C's cervical dilatation rate significantly increased.

Rate of Cervical Dilatation in Multigravida

In multigravida, the mean rate of cervical dilatation was 3.02 cms/hr. in Group A compared to 3.11cms/hr. in Group B and 3.24 cms /hr in Group C. The difference was not statistically significant between any Group

Duration of Second Stage of Labour

Group A – 22.3 min

Group B – 21.6 min

Group C – 21.6 min.

The present study shows no reduction in the duration of second stage with use of Hyoscine and Drotaverine

Duration of Third Stage of Labor

Present Study

Group A – 5.46 min.

Group B – 5.38 min.

Group C –6.18 min.

The present study shows no reduction in the duration of third stage with use of Hyoscine and Drotaverine

Mode of Delivery

8.5% in group A, 5.7% in group B and 7.1% in group C went were LSCS. The results were not statistically significant.

Conclusion

When compared to Drotaverine, Hyoscine Butylbromide significantly improves the rate of cervical dilatation in primigravida. Drotaverine is less effective than hyoscine butylbromide at shortening the active phase of labour. Hyoscine Butyl Bromide and intravenous drotaverine have no impact on cervical dilatation or the length of the active phase of labour in multigravida. During the usage of both medications, there were no major adverse maternal effects. With use ofboth drugs, APGAR score were identical. There were no significant neonatal negative effects.

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