



EFFECT OF INTRAMUSCULAR DROTAVERINE HYDROCHLORIDE AND CAMYLOFIN DIHYDROCHLORIDE ON CERVICAL DILATATION IN FIRST STAGE OF LABOUR

Dr. Shiva

Senior Resident at Department of Obs. and Gynae PMCH, Patna.

Dr. Chitra Sinha*

Associate Professor at Department of Obs. and Gynae PMCH, Patna. *Corresponding Author

ABSTRACT

Introduction: Labour is one of the most important aspect of a woman's life. Its duration affects not only the mother but also the foetus. Cervical dilatation is one of the most important factors which determines the duration of labour. Hence, there is a need to find a cervical dilator which optimizes the rate of cervical dilatation and also has no adverse effect on the mother and the foetus. The prolonged duration of labour affects the pregnant woman by exposing her to maternal exhaustion, increased chance of instrumental delivery, infection, and post partum haemorrhage.

Aim: To compare and evaluate the rate of cervical dilatation from onset of true labour pain to full dilatation of cervix in women receiving intramuscular Drotaverine hydrochloride and Camylofin dihydrochloride.

Type of study: Prospective study

Study period: 2 years (April 2019 to March 2021)

Material And Methods: This study is conducted in department of Obstetrics and Gynaecology of Patna Medical College & Hospital, Patna, amongst women attending antenatal clinic and emergency obstetric unit. This study is conducted in 100 women who are randomly divided into 2 groups of 50 each. Group I comprised of 50 women who are administered Drotaverine hydrochloride and Group II comprised of rest 50 women who are administered Camylofin dihydrochloride.

Result: This study is carried out to compare the efficacy of Drotaverine hydrochloride and Camylofin dihydrochloride on cervical dilatation. Mean cervical dilatation rate is significantly more in Group II than in Group I. Time interval from administration of drug to delivery is significantly more in Group I than in Group II. Significantly more women delivered after first dosage in Group II than in Group I.

Conclusion: Both the drugs have been found to be effective in reducing the duration of labour and pain. Out of the two drugs involved in the present study, Camylofin dihydrochloride is more effective than Drotaverine hydrochloride in reducing the duration of labour.

KEYWORDS : Drotaverine hydrochloride, Camylofin dihydrochloride, Cervical dilatation

INTRODUCTION

The progress of labour is assessed by dilatation of cervix and descent of presenting part. The normal rate of cervical dilatation is 1cm/hr in primigravida and 1.5cm/hr or more in multigravida.

MATERIALS AND METHODS

This study is carried out in department of Obstetrics and Gynecology of Patna Medical College & Hospital. This is a prospective study over a period of 2 years from April 2019 to March 2021. Total 100 women are selected for this study. Informed consent is taken from all participants.

These women are randomly divided into 2 groups of 50 each.

Group I- 50 women in labour are selected for Drotaverine hydrochloride

Group II- 50 women in labour are selected for Camylofin dihydrochloride.

Group I: Drotaverine hydrochloride- Women in this group received 40mg of the drug intramuscularly. Second and third dose are repeated at an interval of 2hrs.

Group II: Camylofin dihydrochloride - Women in this group received 25mg of the drug intramuscularly. Second and third dose are repeated at an interval of 2hrs.

The rate of cervical dilatation is recorded every 2hrs and progress of labour is assessed by partogram.

Drug Details

1. Drotaverine Hydrochloride - Chemically it is 3,4,6,7 tetra ethoxy-1-benzyl 1,2,3,4 tetra hydroisoquinolone hydrochloride. It has got spasmolytic action on smooth muscle cells. It binds to the surface of smooth muscles and alters its membrane potential and permeability. Each ampoule of Drotaverine injection contains 40mg of Drotaverine Hydrochloride. Usually 3 dosages are given two hours apart. It has no embryotoxic and teratogenic effect. In rare cases headache, nausea, vertigo, and hypotension may occur. No other adverse drug reaction has been observed.
2. Camylofin Dihydrochloride- It is an antimuscarinic drug. It is a smooth muscle relaxant with both anticholinergic action as well as

direct smooth muscle action. It inhibits phosphodiesterase type IV which leads to increased cyclic AMP and eventually reduces cytosolic calcium. Each ampoule of Camylofin injection contains 25mg of Camylofin Dihydrochloride. It is given by IM route up to a maximum of 3 dosages. It is moderately toxic when given by IV route, oral or other routes. It should be given with caution in women with thyrotoxicosis, obstructive airway disease, during cardiac surgery, elderly, or those with fever. It may cause skin rashes, other allergic reactions and rarely atropine like side effects.

Inclusion Criteria

1. Cephalic presentation
2. Singleton Pregnancy
3. Full term gestation (38-41 weeks)
4. Primigravida
5. Women with true labour pain
6. Age 19-30 years

Exclusion Criteria

1. Known hypersensitivity to drugs
2. Antepartum haemorrhage
3. Pre-eclampsia, eclampsia
4. Any obstetric complications
5. Medical disorders

OBSERVATION AND RESULTS**Table – 1: Booked/unbooked Women**

Booked/ Unbooked	Drotaverine		Camylofin	
	No	%	No	%
Booked	35	70	35	70
Unbooked	15	30	15	30
Total	50	100	50	100

Distribution of booked/unbooked women is statistically similar in both the groups. 70% patients were booked in each group.

Table – 2: Age Distribution

Age in Years	Drotaverine		Camylofin	
	No	%	No	%
19-22	4	8	6	12
23-26	35	70	32	64

27-30	11	22	12	24
Total	50	100	50	100
Mean +/- SD	25.06 +/- 2.14	24.98 +/- 2.37		

Table – 3: Period Of Gestation

Period of Gestation	Drotaverine		Camylofin	
	No	%	No	%
38-39 week	17	34	14	28
40-41 week	33	66	36	72
Total	50	100	50	100
Mean +/- SD	39.82 +/- 0.96		39.94 +/- 0.91	

Table – 4: Number Of Injections Required

Number of injections required	Drotaverine		Camylofin	
	No	%	No	%
1	4	9.09	33	75
2	31	70.45	6	13.63
3	9	20.45	5	11.36
Total	44	100	44	100
Mean +/- SD	2.11 +/- 0.53		1.36 +/- 0.67	

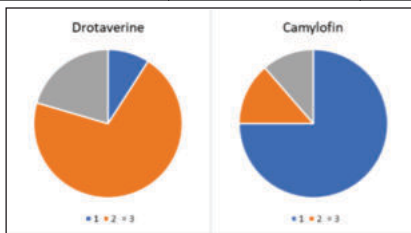


Figure – 1: Number Of Injections Required

75% patients in Camylofin group delivered after one injection while only 9.09% patients in Drotaverine group delivered after one injection. On an average 1.36 injections of Camylofin are required as compared to 2.11 injections of Drotaverine in the study. Number of injections required for Camylofin is lower than Drotaverine with p value 6.75×10^{-8} which is statistically significant.

Table – 5: Rate Of Cervical Dilatation In Cm/hr

Cervical Dilatation rate (cm/hr)	Drotaverine		Camylofin	
	No	%	No	%
1-1.5	11	25	5	11.36
1.5-2	28	63.63	30	68.18
>2.0	5	11.36	9	20.45
Total	44	100	44	100
Mean +/- SD	1.68 +/- 0.29		1.79 +/- 0.27	

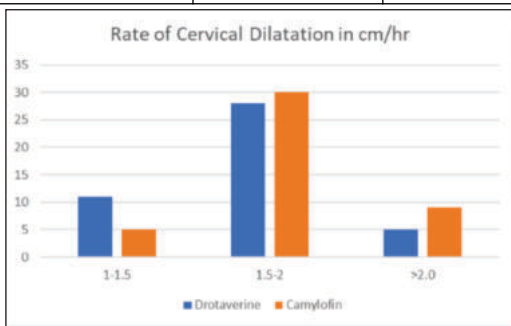


Figure – 2: Rate Of Cervical Dilatation

The mean cervical dilatation rate for Camylofin is 1.79 cm/hr as compared to 1.68 cm/hr of Drotaverine. The dilatation rate for Camylofin is higher with a p-value of 0.032972 making it statistically significant.

Table 6: Side Effects In Women Of The Two Groups

Side Effects	Drotaverine		Camylofin	
	No	%	No	%
Nausea	1	2.27	1	2.27
Vomiting	0	0	2	4.54
Dryness of Mouth	0	0	2	4.54
Foetal Tachycardia	2	4.54	0	0

Headache	1	2.27	0	0
Hypotension	1	2.27	0	0

11.36% patients in each group developed side effects. There was no statistically significant difference in side effect noted in both the groups at a significance of 5%.

Table 7: Time Interval From Administration Of Drug To Delivery (in Minutes)

Time interval from administration of drug to delivery (minutes)	Drotaverine		Camylofin	
	No	%	No	%
<200	12	27.27	20	45.45
200-300	26	59.09	21	47.72
>300	6	13.63	3	6.81
Total	44	100	44	100
Mean +/- SD	236 +/- 62.48		211 +/- 61.11	

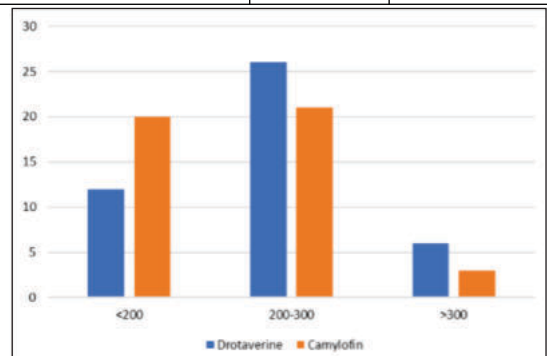


Figure – 3: Time Interval From Administration Of Drug To Delivery (in Minutes)

Mean time interval from administration of drug to delivery is significantly more in Drotaverine Group (236.36 minutes) than in Camylofin Group (211.36 minutes) with p value 0.030592.

Table 8: Mode Of Delivery

Mode of Delivery	Drotaverine		Camylofin	
	No	%	No	%
Vaginal	41	82	37	74
Assisted	3	6	7	14
LSCS	6	12	6	12
Total	50	100	50	100

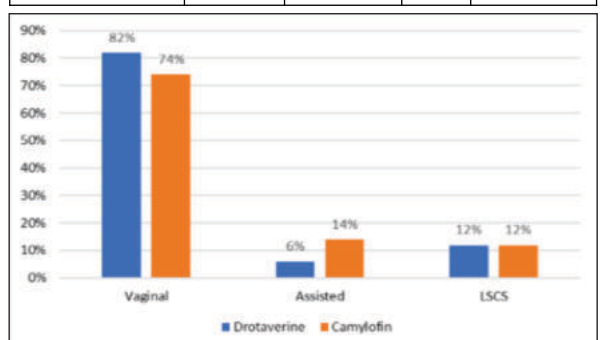


Figure – 4: Mode Of Delivery

12% patients in both the groups had LSCS (3 patients for foetal distress and 3 patients for arrest in first stage of labour in both the groups)

DISCUSSION

From the above study, this can be concluded that:

- The rate of cervical dilatation was more in Group II than Group I. This rate is also statistically significant (1.79 cm/hr vs 1.68 cm/hr) with P value = 0.032972.
- Time interval from administration of drug to delivery was significantly more in Group I than in Group II, 236.36 minutes vs 211.36 minutes with P value = 0.030592
- No foetal side effects were seen.

4. No major maternal side effects were seen.

CONCLUSION

Labour must be a pleasurable moment in the life of a pregnant woman. Any drug that ensures this must be welcomed by the obstetrician and labouring mother. Both the drugs have been found to be effective in shortening the duration of labour.

In the present study, Group II drug i.e. Camylofin has been found to be more efficacious than Group I drug i.e. Drotaverin in shortening the duration of labour.

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