# A Randomised Controlled Study of Intramuscular Camylofin Dihydrochloride vs Intravenous Hyoscine Butylbromide in Augmentation of Labour

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## Abstract

Aims and objectives-to study and compare the effectiveness of injection Camylofin and injection Hyoscine in accelerating active phase of the 1st stage of labour in uncomplicated pregnancies. Second was to study the effects of the two drugs on 2nd and 3rd stage of labour and to study the adverse drug reactions on the mother and fetus. Method- This was randomized controlled prospective study.150 Primigravida in the age group 18 to 30 years with gestational age 37 to 40 weeks were included. The cases were divided into 3 groups Group I consisted 50 women which was Control Group. Group II consisted of 50 women who were given injection Camylofin intramuscular. Group III consisted of 50 women who were given injection Hyoscine intravenous. Result-There was significant reduction in duration of active phase of labour and improvement in the rate of cervical dilatation with Camylofin compared to Hyoscine butylbromide. There were no maternal, fetal side effects associated to these drugs.

***Index terms***— camylofin, hyoscine, active phase of labour.

## 1 I. Introduction

abour is one of the important and memorable events in a woman's life. Labour is a multifactorial process, which involves myometrial contraction, cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly manner. Liggins 1 has stated that any hypothesis for the initiation of labour is incomplete unless it includes the satisfactory explanation for the structural changes in the cervix. During pregnancy, the contractility of the myometrium is usually diminished to accommodate and protect the growing products of conception, whereas the cervix forms a tight sphincter to ensure the integrity of pregnancy. Close to term, myometrial activity increases and the cervix undergoes biochemical changes. This is called cervical maturation and ripening. Cervix plays essentially a passive role as an innocent obstruction and is acted upon by all the forces of labour. Cervical dilatation is the result of all the driving forces of uterine contractions acting against passive tissue resistance. The dilatation of the cervix is one of the effective end results of these forces and in this role it serves to reflect the process of labor. 2 Cervical dilatation is one of the important factors which determines the duration of labour and is the resultant of all the driving forces of uterine contraction acting against tissue resistance. Failure of the cervix to dilate in labour can cause prolonged labor. Prolonged labour can lead to increased maternal and neonatal mortality and morbidity. Active management of labour versus physiological expectant management, has shown to decrease the occurrence of prolonged labour. Various drugs have been tried in the past to reduce the tone of the cervical cells. Antispasmodics are drugs that are usually taken to relieve cramps. They work either by direct relaxation of muscle or by interfering with the message sent by the nerves to the muscle to contract. It is thought that these drugs may help with opening the womb (dilatation of the cervix), when given during labour as a preventative or a treatment strategy. This would shorten the time spent in labour. Evidence was sought to support this idea. Majority of these drugs were found to have ill effects on the fetus and the mother as well.

The modern obstetricians are now in search of a new drug which has got the role of beneficiary effect on the dilatation of internal os with minimal side effects on the fetus and mother. Administering antispasmodics during labour could also lead to faster and more effective dilatation of the cervix. Interventions to shorten labour, such as antispasmodics, can be used as a preventative or a treatment strategy in order to decrease the incidence of prolonged labour. As the evidence to support this is still largely anecdotal around the world, there is a need to systematically review the available evidence to obtain a valid answer.

# 2 II. Aims and Objectives

# 3 To study and compare the effectiveness of Injection

Camylofin and Injection Hyoscine in accelerating active phase of the 1st stage of labour in uncomplicated pregnancies in terms of duration of active phase of labour, cervix dialatation 2. To study the effects of the two drugs on 2 nd and 3 rd stage of labour.

3. To study the adverse drug reactions on the mother and fetus.

# 4 III. Materials and Methods

This study was conducted at a General Hospital from September 2011 to September 2013.Total number of cases-150 primigravidae. This was randomized controlled prospective study. Approval from ethical committee of the Institute was taken prior to the study. Women with term gestation, in active labour were chosen by simple randomization for the administration of drugs and written informed consent for the same was taken.

# 5 a) Inclusion Criteria

Primigravida in the age group 18 to 30 years with gestational age 37 to 40 weeks were included. All patients had singleton foetus with vertex presentation, spontaneous onset of labourin active phase of labour with intact membrane. Activephase of labour will be defined as 4 cm cervical dilatation with uterine contractions 3 contractions in l0 minutes each lasting for 30 sec.

# 6 b) Exclusion Criteria

Any antenatal pregnancy complications like preeclampsia, eclampsia, cephalopelvic disproportion, premature rupture of membranes, placenta previa, placenta abruption, preterm labour, abnormal presentation, multiple pregnancy, Medical disorders, induced labour, Known hypersensitivity to drug were excluded.

The cases were divided into 3 groups Group I: Consisted of 50 women who were given none of the cervical dilatation drugs i.e. Control Group. Group II: Consisted of 50 women who were given injection Camylofin (Anafortan) IM during labour at an interval of 1 hour upto a maximum of 4 injections. Group III: Consisted of 50 women who were given injection Hyoscine (Buscopan) IV at an interval of 1 hour upto a maximum of 4 doses. History was taken. General physical, systemic, per abdomen and vaginal examination was done and drugs were given according to the group to which the patient belonged. Labour was monitored clinically and plotted partographically. Any side effects were noted and treated accordingly. After the delivery of the placenta, cervix and vagina were inspected to exclude any trauma to the cervix and vagina. Following parameters were recorded in every patient-Duration of active phase (1st stage) of labour. Rate of cervical dilatation. Duration of 2nd stage. Duration of 3rd stage. Mode of delivery side effectsmaternal and fetal. 3rd stage complications. Neonatal condition at birth -baby weight and Apgar. The results observed were analyzed using biostatistical tests like Chi-square test and compared with that of other studies. Mode of delivery was comparable in all three groups. In Control group, 2% cases developed cervical tear. In Camylofin group, 2% cases developed retained placenta (however no PPH) and 2 % cases developed secondary arrest of dilatation of cervix. In Hyoscine group, 2% cases developed cervical tear and 2 % cases developed secondary arrest of dilatation of cervix. (2013).Maximum number of patients in both group I and group II were between 38-39 weeks.( 56% and 52% respectively). In group III, 38 % patients were in between 38-39 weeks and 42 % were in between 39-40 weeks. The average period of gestation in all three groups is 39 weeks. In a study by Singh KC et al 5 , the average period of gestation was 38.6 weeks, which is comparable to the present study. Parity has an important influence on the duration of labour. Most of the studies have included only primigravidae. To remove this confounding factor, in the present study also we have included only primigravidae.

# 7 IV. Observations

In present study mean Duration of active phase labor in group I was 185.38 min , in group II was 118.04 , in group III was 129.74 indicating that Camylofin is more efficacious in reducing duration of active phase of 1 st stage of labour.

In a study by Himangi 3 (2003), et al mean duration of active phase of labor was shorter in Camylofin group (3 hours, 35 minutes) than placebo group (5 hour, 34 minutes).The difference between Control group and Camylofin group in terms of the duration of active phase of labour is 67.34 min which is statistically significant, that between Control group and Hyoscine group is 65.34 min which is statistically significant, that between Camylofin group

and Hyoscine group is 11.74 min which also is statistically significant. The difference between Control group and Camylofin group, Control group and Hyoscine group and Camylofin group and Hyoscine group is not statistically significant with regard to the duration of 2nd stage of labour. There is significant shortening of the 3rd stage of labour in Camylofin group when compared to Control group and Hyoscine group while there was no significant difference between Control and Hyoscine group. This significant shortening of 3rd stage of labour in Camylofin group could not be attributed to any known factor. (Table 3)

In present study mean cervical dilatation rate is significantly more in Camylofin group (3.14

# 8 VI. Summary

The study was conducted in the Department of Obstetrics and Gynaecology of a general Hospital, between September 2011 to September 2013.150 primigravidae were selected. Majority of the cases were in the age group of 21-25 yrs. On statistical analysis, appropriate selection of all three groups was confirmed with regards to age, period of gestation. Among primigravidae who received injection camylofin the mean duration of active phase of labour is 118.04 min. The rate of cervical dilatation being 3.14 cm/hr. In Inj. Hyoscine group, the mean duration of active phase of labour is 129.74 min, the rate of cervical dilatation being 2.78 cm/hr, whereas in control group the mean duration of active phase labour is 185.38 cm/min and the rate of cervical dilatation 1.97 cm/hr. Both the drugs have been found to shorten the duration of active phase of labour, but the shortening caused by camylofin was more when compared to Hyoscine. No serious side effects were observed with both the drugs. Transient side effects like tachycardia, dryness of mouth, giddiness were observed in both the groups. There was no difference in mode of delivery, birth weight of the newborn and Apgar scores at 1 min and 5 min. There were no significant fetal side effects in both the groups. Hence both the drugs did not interfere with utero placental circulation.

# 9 VII. Conclusion

The following conclusions were drawn from this study: 1. Both camylofin and Hyoscine butylbromide are effective in reducing the duration of active phase of labour and improving rate of cervical dilatation. 2. There is significant reduction in duration of active phase of labour and significant improvement in the rate of cervical dilatation with Camylofin compared to Hyoscine butylbromide. Thus, Camylofin is more efficacious in augmenting the active phase of labour. 3. The number of patients having drug induced minor side effects are comparable with both drugs. These drugs cause no major maternal side effects. 4. There are no fetal/neonatal side effects associated to these drugs. 5. There are no adverse effects of these two drugs on 2 nd and 3 rd stage of labour. Thus, effective shortening of the duration of labour was achieved without any significant detrimental effects to the mother and the newborn. Camylofin is better in achieving the end result. Hence, it can be used in modern obstetrics to relieve spasm and to hasten the rate of cervical dilatation and thereby promote safe delivery. However, it is recommended that the better results obtained with Camylofin should be verified with studies including large number of subjects.

So we can say that in modern obstetrics no women should be allowed to suffer in pain and agony of labor. Labor should be considered as a pleasurable moment in the life of every pregnant women. Drugs which hasten labor should be welcomed by both obstetrician and the laboring mother. [1] [2]

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| Age in years | Group I (Control) | | Group II (Camylofi | |
|---|---|---|---|---|
| | No. | % | No. | % |
| 18 -20 | 2 | 4 | 8 | 16 |
| 21 -25 | 24 | 48 | 31 | 62 |
| 26 -30 | 24 | 48 | 11 | 22 |
| Total | 50 | 100 | 50 | 100 |
| Mean ± SD | 25.10±2.91 | | 23.08±2.65 | |
| Gestational age in wks | | | | |
| 37wks to 37 wks+6days | 9 | 18 | 6 | 12 |
| 38wks to 38wks+6days | 28 | 56 | 26 | 52 |
| 39wks to 40wks | 13 | 26 | 18 | 36 |
| Total | 50 | 100 | 50 | 100 |

Majority of the patients in control group (96%) were in the 21-30 yrs age group, those in Camylofin group(62%) in 21-25 yrs age group and those in Hyoscine group in 21-30 yrs age group.(Table I).Mean age in Control group was 25.10 year, in Camylofin group was 23.08, in Hyoscine group was 25.10.

Majority of the women in Control group and Camylofin group were between 38 and 39 weeks of gestation (>50%), those in Hyoscine group were between 39 and 40 weeks of gestation (42%).Period of gestation is statistically similar among the three groups with p=0.108 (Not significant)

Figure 1: Table 1 :

**2**

| | Group I(control) vs. Group II (Camylofin) | GroupI (control) vs. Group III (Hyoscine) | Group II(Camylofin) vs. Group III (Hyoscine) |
|---|---|---|---|
| Difference | | | |
| Duration of 1st stage (active phase) of labour (min) | 67.34 | 65.34 | -11.74 |
| Duration of 2nd stage of labour (min) | 0.78 | -1.41 | -2.18 |
| Duration of 3rd stage of labour (min) | 3.71 | 1.14 | -2.57 |
| P value | | | |
| Duration of 1st stage (active phase) of labour (min) | <0.001** | <0.001** | 0.013* |
| Duration of 2nd stage of labour (min) | 0.707 | 0.322 | 0.068+ |
| Duration of 3rd stage of labour (min) | <0.001** | 0.443 | 0.019* |

Figure 2: Table 2 :

**3**

| Mean | SD |
|---|---|

Figure 3: Table 3 :

**4**

| MODE OF DELIVERY | Group I (control) | | Group II (Camylofin) | | Group III (Hyoscine) | |
|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % |
| FTND | 45 | 90 | 47 | 94 | 45 | 90 |
| Instrumental | 2 | 4 | 1 | 2 | 2 | 4 |
| LSCS | 3 | 6 | 2 | 4 | 3 | 6 |
| Total | 50 | 100 | 50 | 100 | 50 | 100 |
| LABOUR COMPLICATIONS | | | | | | |
| Atonic PPH | 0 | 0 | 0 | 0 | 0 | 0 |
| Cervical or vaginal tear | 1 | 2 | 0 | 0 | 1 | 2 |
| Retained placenta | 0 | 0 | 1 | 2 | 0 | 0 |
| Sec arrest of dilatation | 0 | 0 | 1 | 2 | 1 | 2 |

Figure 4: Table 4 :

**5**

| | MATERNAL SIDE EFFECTS | | | | | |
|---|---|---|---|---|---|---|
| | GroupI(control) | | GroupII (Camylofin) | | GroupIII (Hyosc | |
| | No. | % | No | % | No | % |
| dry mouth | 0 | 0 | 4 | 8 | 2 | 4 |
| Tachycardia | 0 | 0 | 1 | 2 | 1 | 2 |
| nausea/vomiting | 0 | 0 | 4 | 8 | 1 | 2 |
| Giddiness | 0 | 0 | 1 | 2 | 4 | 8 |
| Drowsiness | 0 | 0 | 1 | 2 | 2 | 4 |
| Flushing | 0 | 0 | 0 | 0 | 1 | 2 |
| Hypotension | 0 | 0 | 0 | 0 | 1 | 2 |
| Present | 0 | 0 | 7 | 14 | 8 | 16 |
| FETAL / NEONATAL SIDE EFFECTS | | | | | | |
| tachycardia /bradycardia | 1 | 2 | 0 | 0 | 2 | 4 |
| Meconium stained liquor | 1 | 2 | 1 | 2 | 0 | 0 |
| low Apgar | 0 | 0 | 1 | 2 | 1 | 2 |
| Present | 2 | 4 | 2 | 4 | 3 | 6 |

In Camylofin group maternal minor side effects were present in 14% cases while in Hyoscine group in 16% cases. Fetal or neonatal side effects were present in Control group in 4% cases while in Camylof 4% cases developed fetal side effects. In Hyosc group 6% cases developed fetal side effects.

Figure 5: Table 5 :

**6**

| Fetal outcome | Control group | Camy group |
|---|---|---|
| Birth weight (kg) | 2.95±0.19 | 2.86± |
| Apgar score at 1 min | 7.86±0.57 | 7.82± |
| Apgar score at 5 min | 8.90±0.46 | 8.84± |

Mean birth weight was 2.95 kg in Control grou

2.86 kg in Camylofin group and 3.02 kg in Hyoscine group. Mean Apgar score at 1 min in Control group and Hyoscine group was 7.86 and 7.82 in Camylofin group. Mean Apgar score at 5 min in Control and Hyoscine group was 8.90 and 8.84 in Camylofin group.

V. Discussion

Friedman, Phillpot, O' Driscol and others hav

worked extensively on management of labour and partogram. These studies have given us the concept of active management of labour. Modern Obstetricians are now in search of new drugs, which have got the sole beneficiary effect on the dilatation of the internal os with minimal side effects on fetus and the mother. Drotaverine hydrochloride, camylofin dihydrochloride are musculotropic agents -phosphodiesterase type IV inhibitors, structurally related to papaverine. They have mild
anticholinergic effects and act directly on smooth muscle cells, inhibiting spasm.(Sommers 2 2002) Valethamate bromide and hyoscine butyl bromide (Buscopan) are anticholinergic agents which act as antagonists of acetylcholine at muscarinic receptors, inhibiting muscle spasm of smooth muscles innervated by the parasympathetic nerves(Sommers2 2002 and Samuels 3 2009)

Calcium channel blocking effects, no

Active management of labour has gone a long way in decreasing maternal morbidity and perinatal mortality.

Figure 6: Table 6 :

instrumental delivery. Delivery by LSCS was 6%, 4% and 6% respectively. In a study by Himangiet al 4 92% of patients had normal vaginal delivery, 4% had instrumental delivery and 4% had LSCS in Camylofin group. Incidence of side effects were statistically similar in two groups (14% in Camylofin group and 16% in Hyoscine, $p>0.05$).In Hyoscine group, 4% developed dryness of mouth, 2% developed transient tachycardia, 2% developed nausea, 8% developed giddiness, 4% developed drowsiness.
Mean birth weight was 2.95kg in control group and 2.86 in Camylofin group and 3.02 in Hyoscine group.0% in control group, 2% in Camylofin group, 2% in Hyoscine group had low Apgar score.2% in control group (one case because of meconium stained liquor), 4% in Camylofin group (two cases because of meconium stained liquor and instrumental delivery), 4% in Hyoscine group (two cases because of instrumental delivery). In various other studies too birth weight and Apgar were not affected by the drugs. The present study concluded that both the drugs are free from fetal side effects.

Figure 7:

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