

A COMPARATIVE STUDY OF EFFICACY OF HYOSCINE BROMIDE (IV) VERSUS TRAMADOL (IM) VERSUS PARACETAMOL (IV) ON CERVICAL DILATATION IN ACTIVE LABOUR

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ABSTRACT

Labour is a natural process, which involves a series of regular and progressive uterine contractions causing effacement and dilatation of cervix leading to birth of the baby. In order to minimise the perinatal morbidity and mortality caused by the prolonged labour, several drugs have been tried to hasten the process of cervical dilatation and this study in one such exercise.

AIM OF THE STUDY

- 1) To compare the efficacy of Hyoscine Bromide (IV) vs. Tramadol (IM) vs. Paracetamol (IV) on cervical dilatation in active labour.
- 2) To compare the duration of active phase of labour.

150 full-term women with gestational age 37-42 weeks, primi and multi singleton pregnancy with cephalic presentation in active labour were included in the study. Cases were divided into 3 groups - Group A: 50 cases of labour accelerated by Hyoscine Bromide 20 mg (IV), Group B: 50 cases of labour accelerated by Tramadol 50 mg (IM) and Group C: 50 cases of labour accelerated by Paracetamol 500 mg (IV).

Mean duration of active phase of 1st stage of labour was 3 hrs. 8 mins. (primi) and 2 hrs. 3 mins. (multi) in Hyoscine Bromide group and 4 hrs. 8 mins. (primi) and 3 hrs. 5 mins. (multi) in Tramadol group and 4 hrs. 2 mins. (primi) and 2 hrs. 5 mins. (multi) in Paracetamol group.

Mean rate of cervical dilatation was 1.5 cm/hr (primi) and 2.6 cm/hr (multi) in Hyoscine Bromide group, 1.2 cm/hr (primi) and 1.6 cm/hr (multi) in Tramadol group and 1.3 cm/hr (primi) and 1.6 cm/hr (multi) in the Paracetamol group. The difference between the groups A and B and A and C is significant ($p=0.0001$) and thus it is concluded that Hyoscine Bromide hastened the rate of cervical dilatation and reduced the duration of active phase of 1st stage of labour.

Divide the abstract into materials and methods, results and conclusion.

KEYWORDS

Cervical Dilatation, Active Phase of 1st Stage, Paracetamol, Tramadol, Hyoscine Bromide.

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INTRODUCTION: Labour is a natural process, which involves a series of regular and progressive uterine contractions causing effacement and dilatation of cervix leading to birth of the baby. The duration of first stage of labour in a primigravida usually lasts about 12-16 hrs. and in multigravida it is 6-8 hrs.

Labour is said to be prolonged if the duration of first stage exceeds 24 hours. The progression of labour is assessed by a partogram in which the effacement and dilatation of cervix and descent of presenting part are noted in a systemic manner.

Prolonged labour leads to maternal fatigue, foetal distress, intrapartum asphyxia, postpartum haemorrhage, all of which require early detection. Causes for prolonged first

stage of labour are multifactorial such as extremes of maternal age, intact membranes, rate of cervical dilatation, adequacy of uterine contractions, presenting part, clinical adequacy of pelvis, constitutional characteristics and parity.

Pain during childbirth is one of the most excruciating pain experiences that women encountered in their lives (Eriksson et al 2006).¹ Reference number should be written here and references, author should be mentioned in the bibliography. Fear of childbirth has been associated with a longer first and second stage of labour and dissatisfaction with the childbirth experience (Saisto et al 2001).² It has also been implicated in women's requests for caesarean sections and a resultant increased rate of caesarean sections (Eriksson et al 2006).¹

Nulliparous women generally experience more pain during early labour while multiparous women may experience more pain during the late first stage and the second stage of labour as a result of rapid foetal descent (Sheiner et al 1999).³ The ideal obstetric analgesic should provide potent analgesic efficacy with minimal maternal and neonatal adverse effects (Bricker and Lavender, 2002).⁴

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Epidural analgesia offers the best pain relief for many women in labour, but it requires trained staff (Bricker and Lavender; 2002).⁴ Woman who does not wish to have an epidural analgesia, administration of simple and less invasive alternative has been tried (Khooshideh and Shahriari, 2009).⁵

The drug to be used during labour should fulfil the following criteria: It should not have any depressant action on the course of labour. It should not have any adverse effect on the foetus and mother.

Several studies, which included both primigravid and multigravid women have shown that intravenous application of Hyoscine Bromide (20–40 mg) during the active phase of labour increases cervical dilatation (Aggarwal P et al, Iravani et al)^{6,7} and decreases duration of the first stage of labour.^{8,9,10} Hyoscine Bromide, an antispasmodic, extracted from leaves of the Duboisia tree found mainly in Australia. Hyoscine butylbromide has selective action on the cervicouterine plexus and brings about cervical dilatation and at the same time does not affect the uterine contractions (Obama 1957).¹¹ On the contrary, there can be an increased coordination in contractions thus helping to hasten normal labour (Richter 1953).¹² It acts by inhibiting cholinergic transmission in the abdominal and pelvic parasympathetic ganglion, thus relieving spasm in the smooth muscle of the gastrointestinal, biliary, urinary, and female genital organs, especially the cervicouterine plexus and thus aiding cervical dilation (Baracho et al, 1984;¹³ Hotwani and Ainapure, 2000¹⁴). It does not cross the blood-brain barrier; therefore, no central action is seen, thus the frequency and severity of side effects on the sweat and salivary glands; eyes and heart are less compared to atropine at the therapeutically administered dose (Baracho et al 1984).¹³ The maternal side effects of hyoscine-n-butylbromide include dry mouth, facial flushing, dryness of the skin, photophobia, loss of concentration, urinary retention and constipation and in neonates, it may cause tachycardia (Davenport et al 2005).¹⁵

Tramadol is a synthetic analogue of codeine and a weak opioid agonist acting centrally by modifying transmission of pain impulse by altering monoamine reuptake mechanisms (Khooshideh and Shahriari, 2009)⁵ intravenously or intramuscularly and it is principally metabolised in the liver and 90% of it is in urine (Lee et al, 1993).¹⁶ Its main side effects are observed in the central nervous system. It can be administered orally, rectally, (dizziness, drowsiness, fatigue, headache, sedation), gastrointestinal system (nausea, vomiting, dryness of mouth, constipation), cardiovascular system (orthostatic dysregulation and tachycardia) and respiratory system (respiratory depression). Central and respiratory depressant effects of Tramadol are due to high doses and maybe antagonised by Naloxone. Tramadol crosses the placenta and its concentration in the umbilical venous serum is approximately 80% of maternal level (Hussein et al 1987).¹⁷ In neonates, there are less incidence of neonatal respiratory depression (Khooshideh and Shahriari, 2009)⁵ and lack of gastrointestinal side effects (Faisal et al 2006).¹⁸

Paracetamol spacing has been widely used for over a century as an effective analgesic and as an antipyretic agent, the mode of analgesic action of which has still not been fully elucidated, but probably is a centrally-acting drug, which inhibits prostaglandin synthesis has recently been made available as intravenous preparation. Various studies have proved intravenous paracetamol as effective analgesic agent, which is safe, effective, inexpensive and requires no special monitoring. However, there are no significant trials regarding paracetamol analgesic effect on labour pain in women. If proved to be an effective analgesic agent in labour, paracetamol being inexpensive and simple to administer could be a boon agent of obstetric analgesia in developing countries.

MATERIALS AND METHODS: This study was conducted in Chengalpattu Medical College, Chengalpattu, for a period of 3 months from January 2016 to March 2016 after approval from Institutional Ethics Committee.

Study Method: This prospective study was carried out on 150 pregnant women irrespective of parity with gestational age of 37–42 weeks with single foetus, vertex presentation with no major antenatal complications admitted in our department.

Sampling Frame: Patients selected for the study were randomly allocated into three groups:

Group A: 50 cases, Labour accelerated spacing by Hyoscine Bromide 20 mg IV, avoid short forms.

Group B: 50 cases, Labour accelerated by Tramadol 50 mg IM.

Group C: 50 cases, Labour accelerated by Paracetamol 500 mg IV.

The selection of patients for the study was on the basis of history and examination. A detailed history was taken for each patient followed by a meticulous general and systemic examination. An obstetric examination was carried out to determine the fundal height, lie, presentation, uterine contractions and foetal heart sounds. This was followed by per vaginal examination and the dilatation effacement and position of cervix, presenting part, its position status of membranes and adequacy of pelvis was assessed.

Every patient was subjected to haemoglobin estimation, Blood group and Rh typing and urinalysis.

Inclusion Criteria:

- 1) Pregnant woman irrespective of parity of Gestational age 37–42 weeks.
- 2) Pregnancy without antenatal complications.
- 3) Full Term with single viable foetus with cephalic presentation.
- 4) Active phase of labour (>4 cm dilatation or >50% effacement).

Exclusion Criteria:

- 1) Gestational age less than 37 completed weeks.
- 2) Post term.
- 3) Associated foetal malformations.
- 4) Malpresentation and Multiple gestations.
- 5) Scarred uterus.
- 6) Foetal demise.
- 7) Cephalopelvic disproportion.
- 8) High risk Pregnancy-Placental insufficiency (Hypertension, Preeclampsia, Diabetes, Chronic renal disease, Connective tissue disorders).

Patients in study groups received the respective injections fulfilling the following criteria:

- 1) Good uterine contractions.
- 2) Cervix 4 cm dilated with Effacement of cervix minimum 50%.

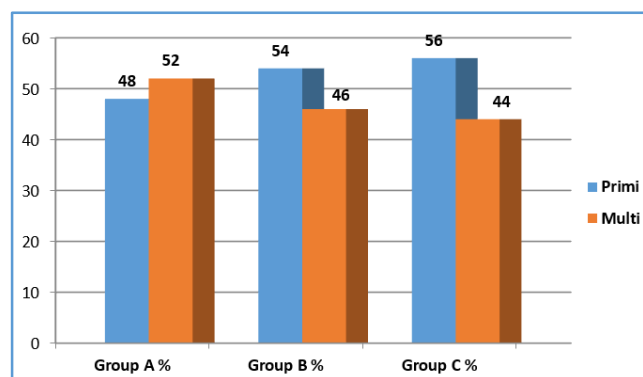
The progress of labour was monitored and observations were plotted on a partogram. In the present study, zero time of partogram was taken to be at the onset of active phase of labour (as judged by the presence of good uterine contractions, cervical dilatation of mins. 4 cm and effacement 50% or more). Subsequently, dilatation of cervix was plotted on the cervicograph. The descent of head was assessed in relation to station of presenting part to ischial spines. The time of rupture of membranes was noted and colour of liquor recorded. The uterine contractions were assessed; foetal heart rate was monitored every half an hour in active phase of labour and plotted over the partogram.

The time between injection and full dilatation of cervix was taken as the duration of active phase of labour. Drug to delivery interval was noted. Outcome of labour and indication for operative interference if any was noted.

RESULTS:

Sl. No.	Parity	Group a	%	Group b	%	Group c	%	Total
1	Primi	24	48	27	54	28	56	79
2	Multi	26	52	23	46	22	44	71
P value = 0.706								

Table 1: Distribution of Cases in Respect to Parity



Graph 1

Primiparas contributed to 48% in Group A, 54% in Group B and 56% in Group C. Multiparas contributed to 52%, 46% and 44% in Group A, B and C, respectively. The distribution was significant with a p value of 0.706.

Sl. No.	Group	PRIMI	MULTI
1	A	1.55±0.1	2.6±0.23
2	B	1.24±0.8	1.68±0.12
3	C	1.33±0.09	1.67±0.1

Table 2: Analysis of Cases in Respect to Rate of Cervical Dilatation (cm/hr)

Sl. No.	Comparison	P Value	Significance
1	A and B	0.0001	Significant
2	A and C	0.0001	Significant
3	B and C	0.635	Not Significant

Table 3: Significance among Groups in Respect to Rate of Cervical Dilatation (cm/hr)

The rate of cervical dilatation from 4 cm to full dilatation of cervix was calculated.

The mean rate of cervical dilation in the active phase of labour in primi in study Group A was 1.5 cm/hrs., in Group B was 1.2 cm/hrs. and in Group C was 1.3 cm/hrs.

In Multi, the mean rate of cervical dilatations in Group A was 2.6 cm/hrs.; in Group B, it was 1.6 cm/hrs.; and 1.6 cm/hrs. in Group C.

The results were significant when Groups A and B and A and C were compared (p value = 0.0001) and insignificant when Groups B and C were compared (p value= 0.635).

Sl. No.	Group	PRIMI	MULTI
1	A	3.87±0.26	2.32±0.21
2	B	4.82±0.32	3.57±0.26
3	C	4.51±0.32	2.59±0.25

Table 4: Analysis in Relation to Duration of Labour (Hours)

Sl. No.	Comparison	P value	Significance
1	A and B	0.0001	Significant
2	A and C	0.0001	Significant
3	B and C	0.316	Not Significant

Table 5: Significance among Groups in Relation to Duration of Labour (Hours)

The duration of active phase of labour was taken from 4 cm dilatation to full dilatation of cervix. Hence, in both Primipara and Multipara spacing, the duration of active phase of labour was shortened in Group A.

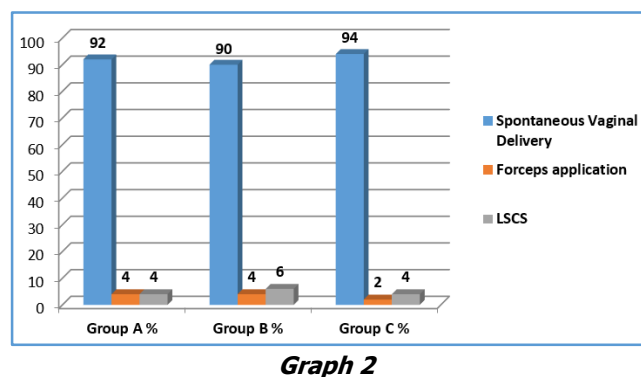
In Multipara, the mean duration of active phase was 2.3 hrs. in Group A, 3.5 hours in Group B and 2.5 hrs. in Group C.

In Primipara, the mean duration of active phase was 3.8 hrs. in Group A while it was 4.8 hrs. in Group B and 4.5 hrs. in Group C.

The results were significant when Groups A and B and A and C are compared (p value=0.0001) and insignificant when Groups B and C were compared (p value= 0.316).

Sl. No.	Outcome of labour	Group a	%	Group b	%	Group c	%
1	Spontaneous Vaginal Delivery	46	92	45	90	47	94
2	Forceps application	2	4	2	4	1	2
3	LSCS	2	4	3	6	2	4

Table 6: Analysis in Relation to Outcome of Labour



DISCUSSION: The use of Hyoscine Bromide in obstetric practice dates back to years. Observations have been recorded as early as 1950s frame the sentence properly.

Studies on obstetric uses are based on the extension of specific spasmolytic action on the intramural vagal ganglia of the abdominal organs thus making spasmolytic action by inhibiting the neural impulse in this pathway.

The actions of Hyoscine Bromide in labour are based on the observations that the cervix is supplied by parasympathetic and the body of uterus by sympathetic nerve supply and this functional antagonism is synergistic to uterine contractions.

Hyoscine Bromide has selective action on the cervicouterine plexus and brings about cervical dilatation and at the same time does not affect the uterine contractions. On the contrary, there can be an increased coordination in contractions thus helping to hasten normal labour.

In the present study, 150 patients in active labour were randomly selected and studied. The study group consisted in all 79 primipara and 71 multipara. They were divided into 3 groups A, B and C. In the present study, the duration of active phase of first stage of labour and the mean rate of cervical dilatation was considered and noted.

It was observed that the Mean duration of active phase of 1st stage of labour was 3 hrs. 8 mins. (primi) and 2 hrs. 3 mins. (multi) in Hyoscine Bromide group; 4 hrs. 8 mins. (primi) and 3 hrs. 5 mins. (multi) in Tramadol group and 4 hrs. 2 mins. (primi) and 2 hrs. 5 mins. (multi) in Paracetamol group.

Mean rate of cervical dilatation was 1.5 cm/hr (primi) and 2.6 cm/hr (multi) in Hyoscine Bromide group, 1.2 cm/hr (primi) and 1.6 cm/hr (multi) in Tramadol group and 1.3 cm/hr (primi) and 1.6 cm/hr (multi) in Paracetamol group. The difference between the groups A and B and A and C is significant (p=0.0001).

You have repeated the results part again.

You have to compare with the latest studies and discuss her studies carried out in the past reflect the action of Hyoscine Bromide in shortening the first stage of labour and thereby bringing about a reduction in total duration of labour.

In the study of Bhattachaiya et al¹⁹ (1985): 50 patients (all primipara) were divided into study and control group of 25 patients each. In this study, the total duration of first stage, second stage and third stage was observed. The mean duration of labour in primi study group was 5.21 hrs. and in control group was 8.88 hours. The reduction shown was 3.67 hours. They concluded that hyoscine butylbromide was an effective cervical dilator in primipara and was specifically useful in a spastic cervix with good uterine contractions.

Baracho et al¹³ (1984) studied the effect of hyoscine butylbromide on labour in 50 patients (25 primipara and 25 multipara). The total duration of labour in primi study group was 7.11 hrs. (which was 2.02 hrs. less than that in primi control group) in his study. The duration of active phase was recorded separately. It was 3.5 hrs. in primi study group and 2.4 hrs. in multistudy group. In the controls, the mean duration of active phase was 4.83 hrs. and 3.78 hrs., respectively. These findings are consistent with those of the present study. Don't use brackets.

In study by Bhattacharya et al,¹⁹ the cervical dilatation rate was found to be 1.92 cm/hr in primi study group and 1.7 cm/hr in primi control group. In the study by Baracho et al,¹³ the cervical dilatation rate was 1.85 cm/hr in primi study group and 1.35 cm/hr in primi control group. In multipara, it was 3.11 cm/hr in study group and 2.04 cm/hr in control group.

In the present study, Mean rate of cervical dilatation was 1.5 cm/hr (primi) and 2.6 cm/hr (multi) in Hyoscine Bromide group, 1.2 cm/hr (primi) and 1.6 cm/hr (multi) in Tramadol group and 1.3 cm/hr (primi) and 1.6 cm/hr (multi). The difference between the groups A and B and A and C is significant (p=0.0001).

Thus, it is concluded that Hyoscine bromide hastened the rate of cervical dilatation and reduced the duration of active phase of 1st stage of labour.

CONCLUSION: The following conclusions are drawn from the study:

1. Hyoscine Bromide is an anticholinergic drug, which effectively brings about cervical dilatation in the first stage of labour.
2. There is demonstrable shortening of active phase of labour and faster rate of cervical dilatation in patients receiving the drug Hyoscine Bromide.
3. There were no significant side effects on the mother and baby.

As evidenced in our study, Hyoscine Bromide scores over Tramadol and Paracetamol in shortening the duration of first stage of labour and hastening cervical dilatation. All the patients responded well to the drug and the duration of labour was considerably shortened spacing. Hence, it can be used in Modern obstetrics to relieve spasm and to hasten the rate of cervical dilatation and thereby promoting safe delivery.

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