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*Original Research Article*

# Effect of Intravenous Drotaverine Hydrochloride on the Active Phase of Labour and Fetomaternal Outcome: A Prospective Randomized Controlled Trial

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***Abstract:*** A prospective randomized single-blind controlled trial was conducted in the labour room of a tertiary care teaching hospital in eastern India from May 2013 to September 2014. A total of 110 parturients in active labour fulfilling predefined inclusion criteria were randomized into a drug group (drotaverine hydrochloride 40 mg intravenously) and a control group (normal saline). Labour progress was monitored using a modified WHO partogram. Primary outcome was rate of cervical dilatation. Secondary outcomes included duration of stages of labour, injection-to-delivery interval, mode of delivery, maternal complications, neonatal outcomes, and drug-related adverse effects. Statistical analysis was performed using SPSS version 20, with $p < 0.05$ considered significant Out of 110 participants, 97 completed vaginal delivery and were included in final analysis (drug group = 49; control group = 48). The mean rate of cervical dilatation was significantly higher in the drug group compared to the control group in both primiparous women (2.08 ± 0.52 vs 1.48 ± 0.41 cm/hour; $p < 0.001$) and multiparous women (2.35 ± 0.45 vs 1.59 ± 0.31 cm/hour; $p < 0.001$). The duration of the active phase of labour and the injection-to-delivery interval were significantly shorter in the drotaverine group ($p < 0.001$). There was no significant difference in the duration of the second and third stages of labour between the two groups. Apgar score at 1 minute was significantly better in the drug group ($p < 0.001$), while Apgar score at 5 minutes showed no significant difference. No significant maternal complications or drug-related adverse effects were observed, and no neonatal morbidity or NICU admissions were reported.

*Keywords*: Drotaverine hydrochloride; Active labour; Cervical dilatation; Labour acceleration; Partogram; Randomized controlled trial; Maternal and neonatal outcomes

## 1. INTRODUCTION

Prolonged labour is associated with increased maternal and neonatal morbidity. Pharmacological agents that facilitate cervical dilatation without adversely affecting uterine contractility may shorten labour duration and improve outcomes. Drotaverine hydrochloride, a phosphodiesterase-4 inhibitor with smooth muscle relaxant properties, has been proposed as a cervical spasmolytic agent during labour. This study has been conducted to determine the efficacy of Drotaverine hydrochloride as a potent cervical dilator when used in reducing duration of active phase of labour and also to determine maternal and fetal outcome.

## 2. AIMS AND OBJECTIVES

- To study the effect of Drotaverine hydrochloride 40 mg intravenously in accelerating dilatation of cervix in active phase of labour.
- To study its effect on duration of active phase of labour.
- To study any maternal complications.
- To study fetal outcome.

## 3. MATERIALS AND METHODS

**STUDY AREA**

The study was conducted in the labour room of the Department of Obstetrics and Gynecology, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata.

**STUDY POPULATION**

The study was conducted among parturients in labour room for vaginal delivery after satisfying the exclusion-inclusion criteria.

**INCLUSION CRITERIA**:

1. Singleton pregnancy in primipara or multipara with no antenatal complication.
2. Gestational period of 37 – 42 weeks.
3. Cephalic presentation.
4. No medical or obstetrical complications.
5. Spontaneous onset of labour.
6. No apparent cephalopelvic disproportion.
7. Cervical dilatation of 4 cm.
8. Cervical effacement of around 75 %.
9. Women in active phase of labor with uterine contractions at least 2 in 10 minutes lasting for 25-30 seconds.
10. Clear liquor on artificial rupture of membrane at 4 cm cervical dilatation.
11. Reassuring cardiotocograph (CTG).

**EXCLUSION CRITERIA**

1. Multiple pregnancy.
2. Fetal malpresentation.
3. Preterm labour.
4. H/o caesarean section in the past.
5. History of any uterine anomaly/surgery or cervical surgery in the past.
6. Known hypersensitivity to any drugs or any contraindications to drotaverine like cardiac or renal disease.
7. Thick meconium stained liquor.
8. Non-reassuring or abnormal cardiotocograph.(CTG).
9. Any h/o receiving spasmolytics in last 48 hrs.

**STUDY PERIOD:**

1st May 2013 - 1st September 2014.

**STUDY DESIGN:**

Prospective randomized single-blinded control trial.

**SAMPLE SIZE :**

Considering alpha error to be 5%, power of the study is 90% , 55 samples were taken in each group *i.e.* 110 sample size was taken.

**STUDY TOOLS**

1. 2 ml of Drotaverine Hydrochloride 40 mg : **Drug group**
2. 2 ml of normal saline (0.9%) : **Control group**
3. Modified WHO partogram.

## 4. METHODOLOGY

Parturients fulfilling exclusion inclusion criteria were allocated into Drug group and Control group after taking consent by randomization.

1. Complete review of history.
2. General examination of the patients including (pulse, blood pressure, temperature).
3. Obstetric Abdominal examination including lie, presentation, engagement; fetal heart rate, uterine contraction, adequacy of liquor.
4. Vaginal examination under aseptic conditions to assess cervical dilatation, effacement, state of amniotic membranes, presenting part, position, station, color of liquor and pelvic adequacy.
5. Assessment of the frequency and duration of uterine contractions. Fetal wellbeing was monitored through cardiotocography.(CTG).
6. Low amniotomy was done at 4 cm cervical dilatation and the colour of liquor was noted.
7. Pretested random number table was used for randomization. Single blinding technique was used. Each participant was randomly given a prefilled syringe with 2 ml of the study medication solution (either Drotaverine Hydrochloride or normal saline). Each participant received the selected syringe slowly intravenously over 2 minutes at 4 cm cervical dilatation in supine position. Participant receiving the drug (drotaverine hydrochloride 40 mg iv) formed Drug group and participant receiving placebo (normal saline 0.9% iv) formed Control group.
8. Uterine contractions was monitored half hourly. In absence of adequate uterine contractions, oxytocin infusion was started (5 IU Oxytocin in 500 cc of Ringers Solution IV drip) by titration method until complete regulation of uterine contraction (4 contractions/10 mins lasting for 30 seconds). If the contractions were adequate, no interference was done.
9. Partographic representation of labour was done.
10. Cervical effacement and dilatation in addition to station and position of fetal head were

recorded every two hours by vaginal examination.

11. A) In case of poor progress: Cephalopelvic disproportion (CPD) and uterine inertia were excluded.- Urgent Caesarean-section was undertaken in case of cephalopelvic disproportion.

**- Uterine inertia:** adjustment of the dose of Oxytocin IV drip via titration method until complete regulation of uterine contraction.

B) If there was good progress, no interference was done.

Those women requiring caesarian section were excluded from the study.

The following parameters were monitored:

1. Progress of labour with partogram

a. Frequency and duration of uterine contractions clinically by abdominal palpation every 30 minutes during labor.
b. Cervical dilatation and effacement were recorded every 2 hours by vaginal examination.
c. Station and position of the presenting part at the same time.

2. Maternal wellbeing: Pulse, blood pressure any other complications.

3. Fetal well being: Fetal heart rate was recorded every 15 minutes, Colour of amniotic fluid at every examination, APGAR score was recorded at 1 and 5 minute after birth.

**Outcome**:

1. The duration of the active phase of first stage of labour ,second stage and also third stage of labor.
2. The duration of injection( Drotaverine or placebo) to birth time of the baby
3. Mean dilatation of cervix per hour.
4. Mode of delivery.
5. APGAR score at 1 and 5 minutes.
6. Any complications during delivery like postpartum haemorrhage, cervical tear etc were noted.
7. Any side effect of the drug was noted

The mother and the baby were followed up for 48 hours following delivery.

**Data Collection**:
Maternal characteristics, labor information and fetal outcome were prospectively collected in a grand chart.

**Data analysis**
Categorical variables were expressed as number of patients and percentage of patients and compared across the two groups using Pearson's Chi Square test for Independence of Attributes.

Continuous variables were expressed as Mean ± Standard Deviation andcompared across the 2 groups using unpaired t test.The statistical software SPSS version 20 has been used for the analysis.An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

**Institutional ethical committee** clearance has been obtained.

## 5. RESULTS AND ANALYSIS

TABLE 1- DISTRIBUTION OF THE SUBJECTS ACCORDING TO MODE OF DELIVERY

| | GROUP | | |
|---|---|---|---|
| MODE | CASES (%) | CONTROL (%) | Total (%) |
| VAGINAL | 49 (89.19) | 48 (87.17) | 97 (54.64) |
| CESAREAN | 6 (10.91) | 7 (12.73) | 13 (8.44) |
| Total | 55 (100) | 55 (100) | 110 (100) |

Note: Values within bracket denotes percentage.

Cases and Control, each comprises of 55 subjects.

Out of them, 6 (10.91%) of the Drug group and 7 (12.73%) of the Control group underwent cesarean section. So, the Drug group comprised of 49 subjects while the Control group comprised of 48 subjects.

TABLE -2 DISTRIBUTION OF SUBJECTS ACCORDING TO AGE ( IN YEARS)- RANGE AND MEAN

| AGE IN YEARS | GROUP | | |
|---|---|---|---|
| | DRUG | CONTROL | Total |
| Mean | 25.39 | 26.17 | 25.77 |
| Std. Deviation | 4.252 | 4.710 | 4.478 |
| Minimum | 18 | 18 | 18 |
| Maximum | 37 | 39 | 39 |

p – value- not significant

The Drug group had subjects with a mean age of 25 years while the

Control group had subjects with a mean age of 26 years.

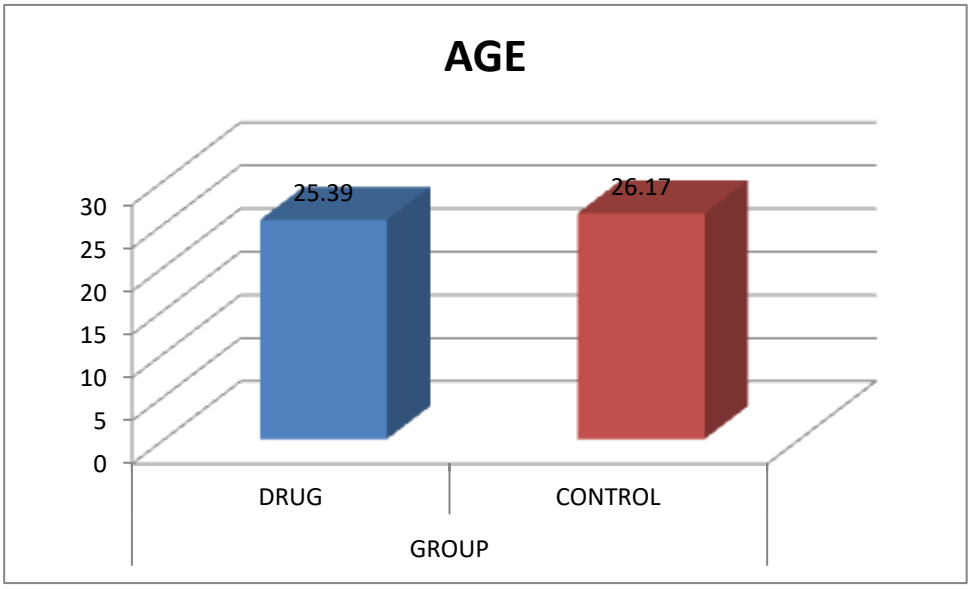



TABLE-3 DISTRIBUTION OF SUBJECTS ACCORDING TO STRATIFICATION OF AGE GROUPS

| | GROUP | | | | |
|---|---|---|---|---|---|
| AGE | DRUG | CONTROL | Total | p Value | Significance |
| 18-20 | 8(16.33) | 5(10.42) | 13(13.4) | 0.602 | not significant |
| 21-30 | 36(73.47) | 36(75) | 72(74.23) | | |
| 31-40 | 5(10.2) | 7(14.58) | 12(12.37) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N.B- age in years. Numbers within brackets denotes percentages.

Majority of the subjects 72 (74.23%) were in the age group between 21 and 30 Years both Drug and Control group.

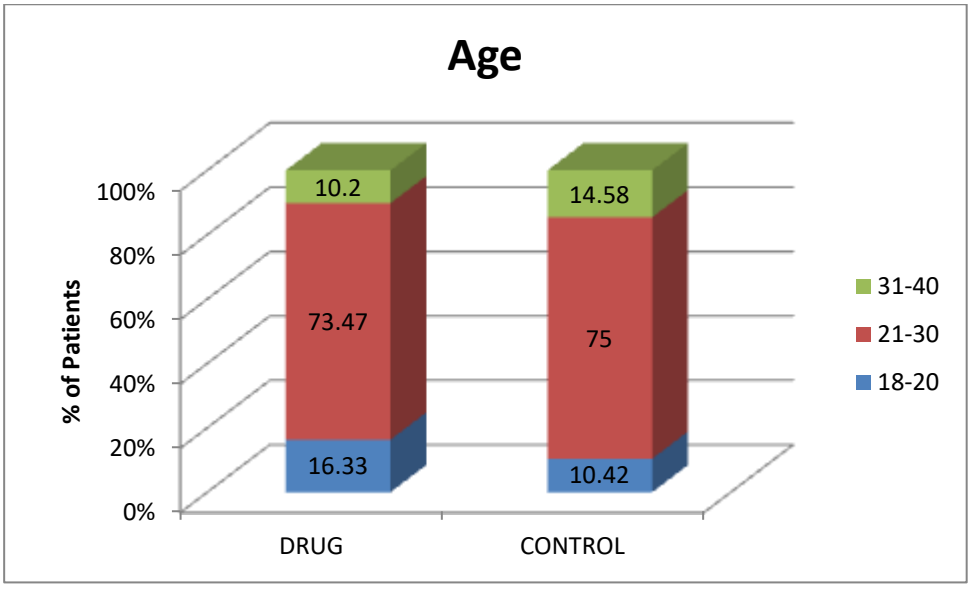



TABLE-4 DISTRIBUTION OF SUBJECTS ACCORDING TO PARITY

| | GROUP | | | | |
|---|---|---|---|---|---|
| PARITY | DRUG | CONTROL | Total | p Value | Significance |
| PRIMI | 27(55.1) | 26(54.17) | 53(54.64) | 0.926 | not significant |
| MULTI | 22(44.9) | 22(45.83) | 44(45.36) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N.B- VALUES WITHIN BRACKETS DENOTES PERCENTAGE.
In the Drug group, 27 ( 55.1%) subjects were primipara and 22 (44.9%) subjects were multipara while in the Control group 26 (54.17%) subjects were primipara and 22 (45.36%) subjects were multipara.

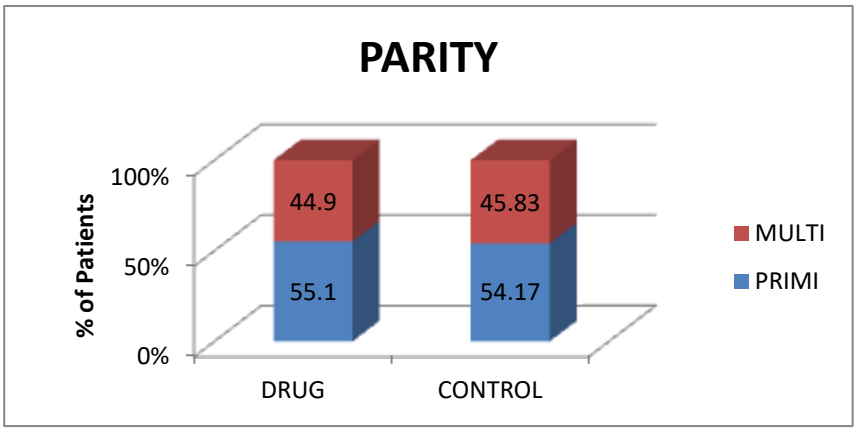



TABLE-6 DISTRIBUTION OF SUBJECTS ACCORDING TO GESTATIONAL AGE

| | GROUP | | | | |
|---|---|---|---|---|---|
| Gestational Age | DRUG | CONTROL | Total | p Value | Significance |
| 37-37+6/7 | 14(28.57) | 17(35.42) | 31(31.96) | 0.059 | not significant |
| 38-38+6/7 | 13(26.53) | 20(41.67) | 33(34.02) | | |
| 39-39+6/7 | 18(36.73) | 11(22.92) | 29(29.9) | | |
| > = 40 | 4(8.16) | 0(0) | 4(4.12) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N.B-GESTATIONAL AGE IS IN WEEKS. VALUES WITHIN BRACKETS DENOTES PERCENTAGE.
Majority of the subjects 33 (34.02%) had spontaneous onset of labour at 38-<39 weeks period of gestation. Only 4 (4.12%) subjects were postdated (>=40 weeks) and were a part of the drug group (8.16%).

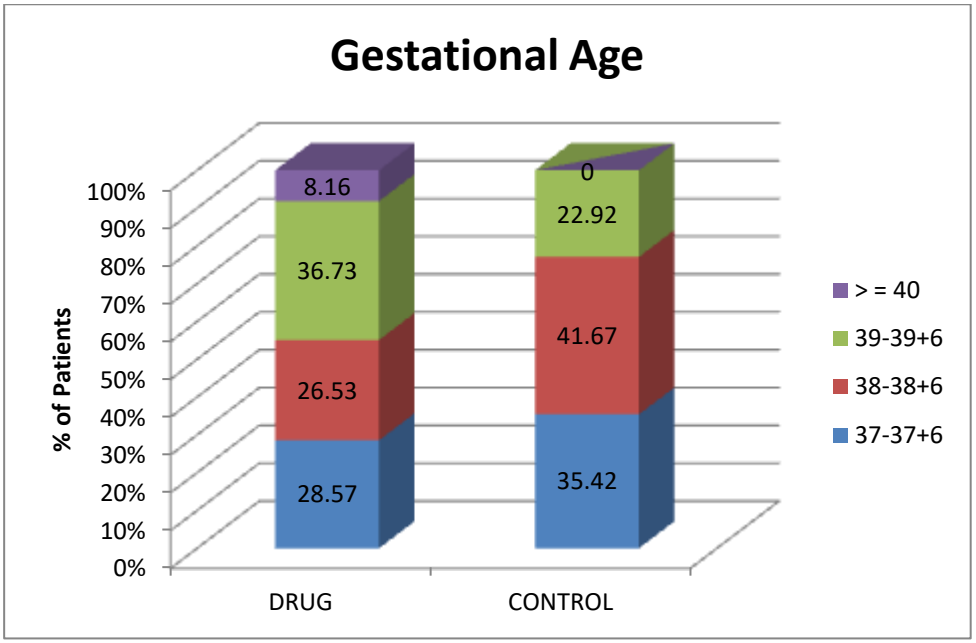



TABLE-7 DISTRIBUTION OF SUBJECTS ACCORDING TO MEAN DURATION OF THE ACTIVE PHASE IN MINUTES

| PARITY | | | Duration of Active Phase in Minutes |
|---|---|---|---|
| PRIMI | DRUG | Mean | 179.07 |
| | | Std. Deviation | 37.93 |
| | CONTROL | Mean | 250.38 |
| | | Std. Deviation | 57.81 |
| | | p Value | <0.001 |
| | | Significance | significant |
| MULTI | DRUG | Mean | 158.18 |
| | | Std. Deviation | 33.75 |
| | CONTROL | Mean | 225.00 |
| | | Std. Deviation | 36.45 |
| | | p Value | <0.001 |
| | | Significance | significant |

N.B-Std= STANDARD DEVIATION.

VALUES WITHIN BRACKETS DENOTES PERCENTAGE.

The average duration of the active phase of first stage of labor was 179.07+/-37.93 mins (2 hrs 59 mins +/- 37 mins) in the Drug group and 250.38 +/- 57.81 mins (4 hrs 10 mins +/- 57 mins) in primipara patients.While in multipara patients, the mean duration was 158.18 +/- 33.75 mins (2 hrs 38 mins+/- 33 mins) in the Drug group and 225.00+/- 36.45 mins (3 hrs 45 mins +/- 36 mins) in the Control group. Both the values for primi and multi were found to be statistically significant (< 0.001).

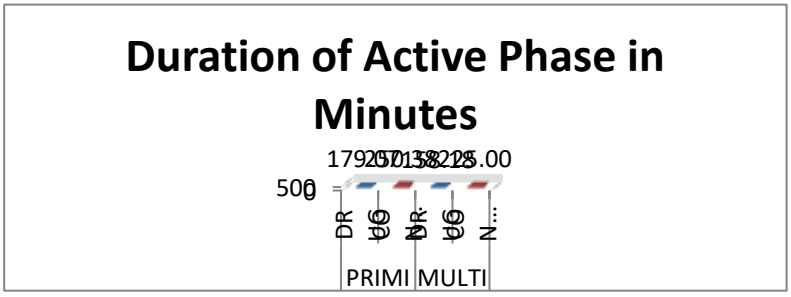
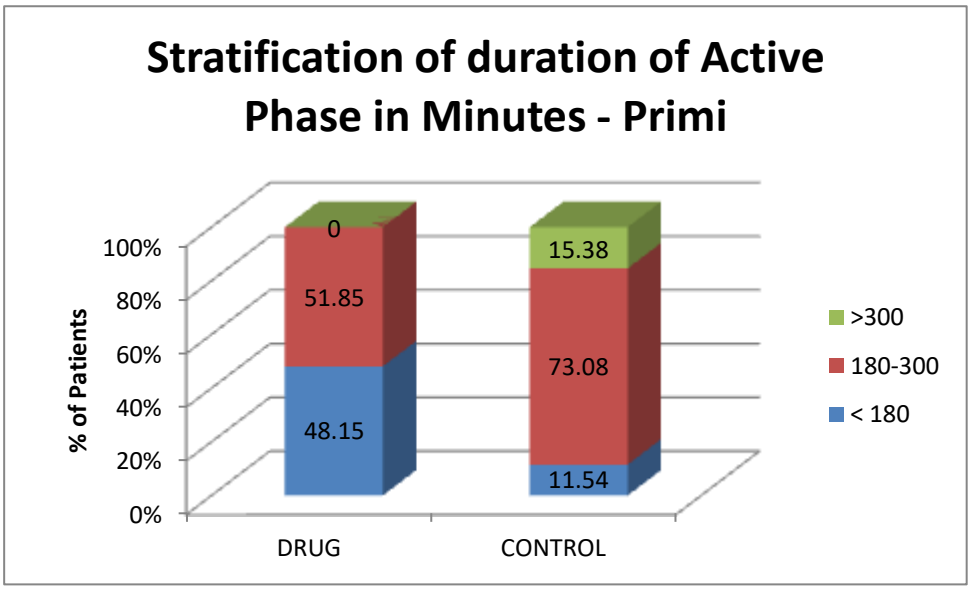


TABLE-8 DISTRIBUTION OF ACTIVE PHASE OF LABOR IN MINUTES ACCORDING TO STRATIFICATION OF THE DURATION

| PARITY | | | GROUP | | | | |
|---|---|---|---|---|---|---|---|
| | | | DRUG | CONTROL | Total | p Value | Significance |
| PRIMI | Duration of Active Phase in Minutes | < 180 | 13(48.15) | 3(11.54) | 16(30.19) | 0.004 | Significant |
| | | 180-300 | 14(51.85) | 19(73.08) | 33(62.26) | | |
| | | >300 | 0(0) | 4(15.38) | 4(7.55) | | |
| | Total | | 27(100) | 26(100) | 53(100) | | |
| MULTI | Duration of Active Phase in Minutes | < 180 | 17(77.27) | 3(13.64) | 20(45.45) | <0.001 | Significant |
| | | 180-300 | 5(22.73) | 19(86.36) | 24(54.55) | | |
| | Total | | 22(100) | 22(100) | 44(100) | | |

N.B VALUES WITHIN BRACKETS DENOTES PERCENTAGE.

It was seen that 13 (48.15%) of the primipara and 17 (77.27%) of the multipara were fully dilated within 3 hours in the Drug group. But in the Control group, 3 (11.54%) of the primipara and 3 (11.54%) of the multipara were fully dilated within 3 hours.The values were found to be statistically significant (p=0.004) for primi and also(p= < 0.001) for multipara. Only 4 subject who were primi para and belonged to the Control group required >5 hrs to get fully dilated.



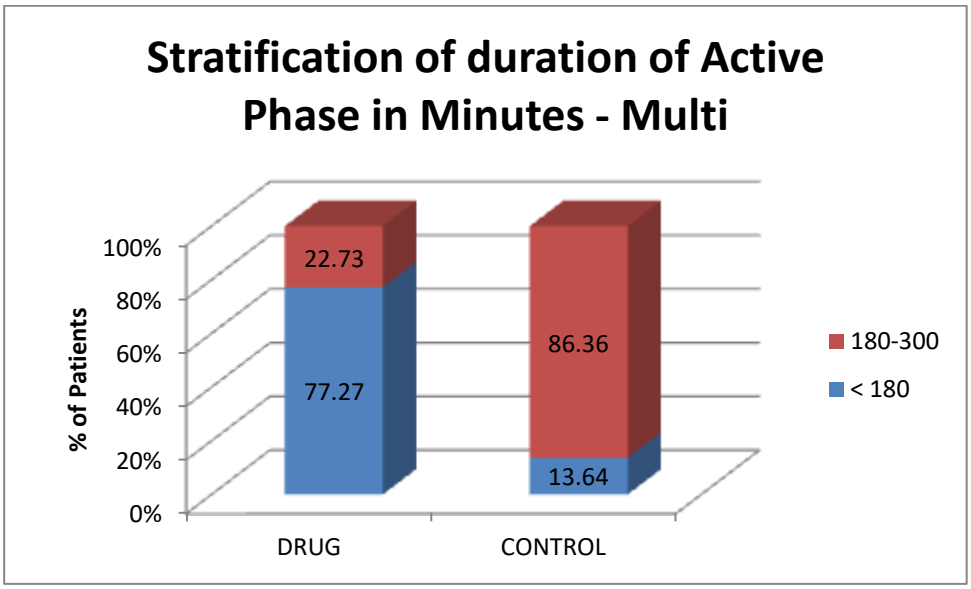



TABLE-8 DISTRIBUTION OF SUBJECTS ACCORDING TO MEAN DURATION OF SECOND STAGE IN MINUTES

| PARITY | | | Duration of Second Stage |
|---|---|---|---|
| PRIMI | DRUG | Mean | 32.41 |
| | | Std. Deviation | 11.04 |
| | CONTROL | Mean | 37.12 |
| | | Std. Deviation | 7.91 |
| | | p Value | 0.081 |
| | | Significance | not significant |
| MULTI | DRUG | Mean | 29.32 |
| | | Std. Deviation | 5.37 |
| | CONTROL | Mean | 30.59 |
| | | Std. Deviation | 6.44 |
| | | p Value | 0.480 |
| | | Significance | not significant |

N.B-Std= STANDARD DEVIATION.ALL VALUES ARE IN MINUTES.

The duration of second stage of labor was slightly less in Drug group (32.41+/-11.04 mins in primi and 29.32+/-5.37 mins in multipara) in comparison to Control Group (37.12 +/-7.91 mins in primi and 30.59 +/-6.44 mins in multipara).The values were not found to be statistically significant.

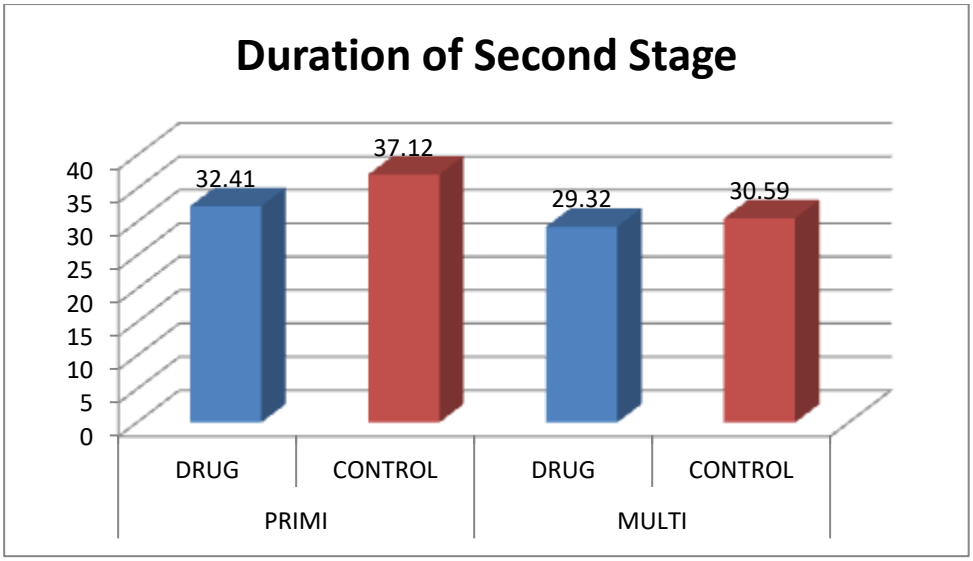



TABLE-9 DISTRIBUTION OF SUBJECTS ACCORDING TO THE THIRD STAGE OF LABOR IN MINUTES

| PARITY | | | Duration Of Third Stage |
|---|---|---|---|
| PRIMI | DRUG | Mean | 5.63 |
| | | Std. Deviation | 1.15 |
| | CONTROL | Mean | 5.85 |
| | | Std. Deviation | 1.46 |
| | | p Value | 0.551 |
| | | Significance | not significant |
| MULTI | DRUG | Mean | 5.36 |
| | | Std. Deviation | 0.85 |

| | | | |
|---|---|---|---|
| | CONTROL | Mean | 5.68 |
| | | Std. Deviation | 1.21 |
| | | p Value | 0.318 |
| | | Significance | not significant |

N.B-Std= STANDARD DEVIATION.ALL VALUES ARE IN MINUTES.

The duration of third stage of labour showed almost no difference among Drug group and Control group, both in primipara and multipara and thus showed no statistical significance.

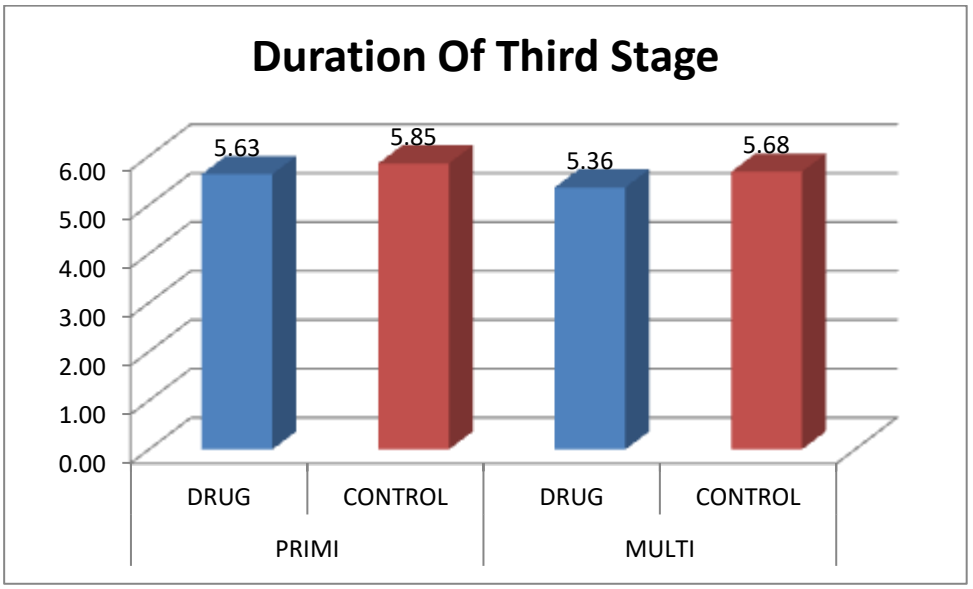



TABLE-10 DISTRIBUTION OF SUBJECTS ACCORDING TO THE TIME INTERVAL BETWEEN INJECTION AND BABY DELIVERY IN MINUTES

| PARITY | | | Time Interval Between Injection and Baby Delivery |
|---|---|---|---|
| PRIMI | DRUG | Mean | 211.48 |
| | | Std. Deviation | 41.44 |
| | CONTROL | Mean | 289.42 |
| | | Std. Deviation | 63.39 |
| | | p Value | <0.001 |
| | | Significance | significant |
| MULTI | DRUG | Mean | 187.73 |
| | | Std. Deviation | 36.22 |
| | CONTROL | Mean | 254.91 |
| | | Std. Deviation | 39.01 |
| | | p Value | <0.001 |
| | | Significance | significant |

N.B-Std= STANDARD DEVIATION.ALL VALUES ARE IN MINUTES.

The time interval between injection and delivery of the baby was found to be 211.48+/-41.44 mins (3 hrs 31 mins +/- 41 mins) in the Drug group and 289.42+/-63.39 mins (4 hrs 49 mins+/- 1 hr 3 mins) in the Control group for primi para. The values were found to be statistically significant. (p< 0.001).For multipara subjects, the time interval was found to be 187.73+/- 36.22 mins(3 hrs7 mins+/-36 mins) in the Drug group and 254.91 +/-39.01mins (4 hrs 14 mins +/-39 mins). The values were found to be statistically significant (p<0.001).

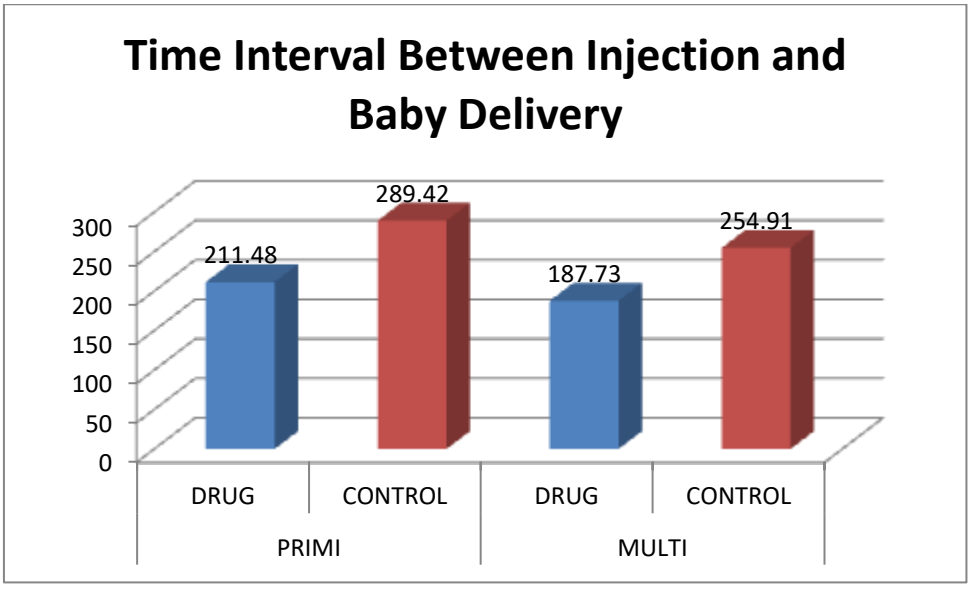



TABLE-11 DISTRIBUTION OF SUBJECTS ACCORDING TO CERVICAL DILATATION RATE IN CM/HOUR

| PARITY | | | RATE |
|---|---|---|---|
| PRIMI | DRUG | Mean | 2.08 |
| | | Std. Deviation | 0.52 |
| | CONTROL | Mean | 1.48 |
| | | Std. Deviation | 0.41 |
| | | p Value | <0.001 |
| | | Significance | Significant |
| MULTI | DRUG | Mean | 2.35 |
| | | Std. Deviation | 0.45 |
| | CONTROL | Mean | 1.59 |
| | | Std. Deviation | 0.31 |
| | | p Value | <0.001 |
| | | Significance | Significant |

N.B Std=STANDARD DEVIATION. VALUES ARE IN CM/HOUR

The mean rate of dilatation was found to be2.08+/-0.52 cm/hr in Drug group and 1.48 +/- 0.41 cm/hr in Control group in case of primipara .It was found to be statistically significant (p<0.001).The mean rate of dilatation was found to be 2.35 +/- 0.45 cm/hr in Drug group while 1.59+/- 0.31 cm/hr in Control group in case of multipara. It was found to be statistically significant (p<0.001).

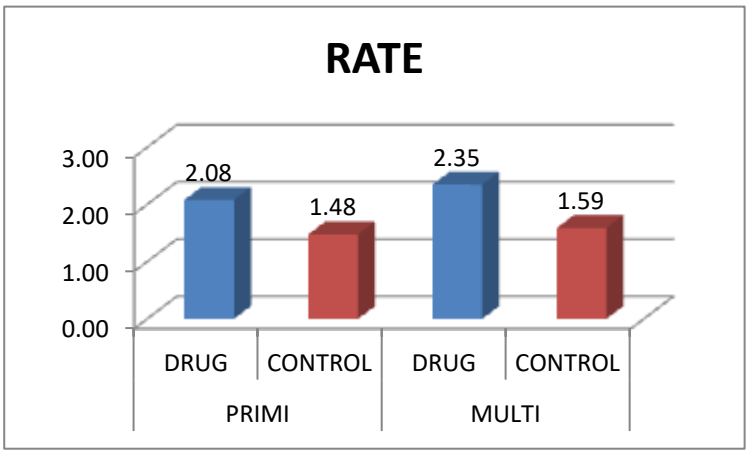


TABLE-12 DISTRIBUTION OF SUBJECTS ACCORDING TO APGAR SCORE AT 1ST MINUTE

| | GROUP | | | | |
|---|---|---|---|---|---|
| Apgar Score at 1 Minute | DRUG | CONTROL | Total | p Value | Significance |
| <7 | 4(8.16) | 21(43.75) | 25(25.77) | <0.001 | significant |
| 7-10 | 45(91.84) | 27(56.25) | 72(74.23) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N.B VALUES WITHIN BRACKETS DENOTES PERCENTAGE.

The 1 minute APGAR score was found to be statistically significant in the Drug group in comparison to the Control group.($p<0.001$).

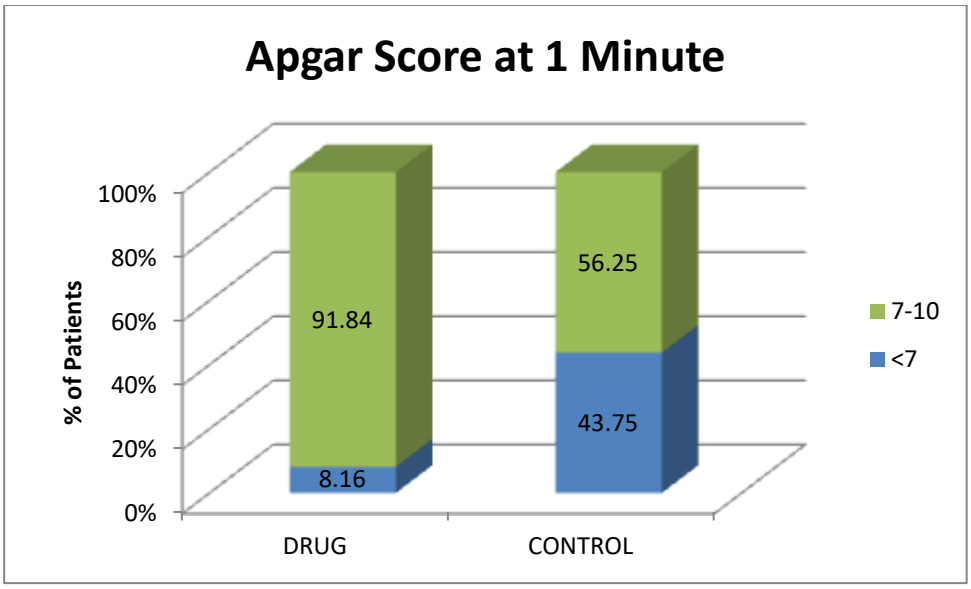



TABLE 13-DISTRIBUTION OF SUBJECTS ACCORDING TO APGAR SCORE AT 5 MINUTE

| | GROUP | | | | |
|---|---|---|---|---|---|
| Apgar Score at 5 Minutes | DRUG | CONTROL | Total | p Value | Significance |
| <7 | 0(0) | 3(6.25) | 3(3.09) | 0.075 | not significant |
| 7-10 | 49(100) | 45(93.75) | 94(96.91) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N. .B- VALUES WITHIN BRACKET DENOTES PERCENTAGE.

The 5 minute APGAR score was not found to be statistically significant in the Drug group in comparison to the Control group .Only 3 babies (6.25%) in the Control group had APGAR score less than 7.

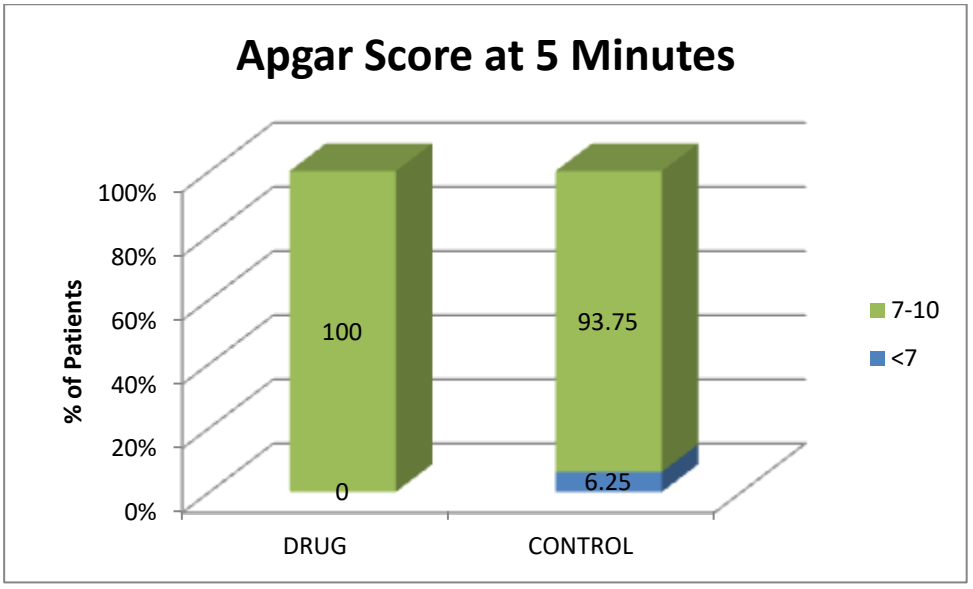
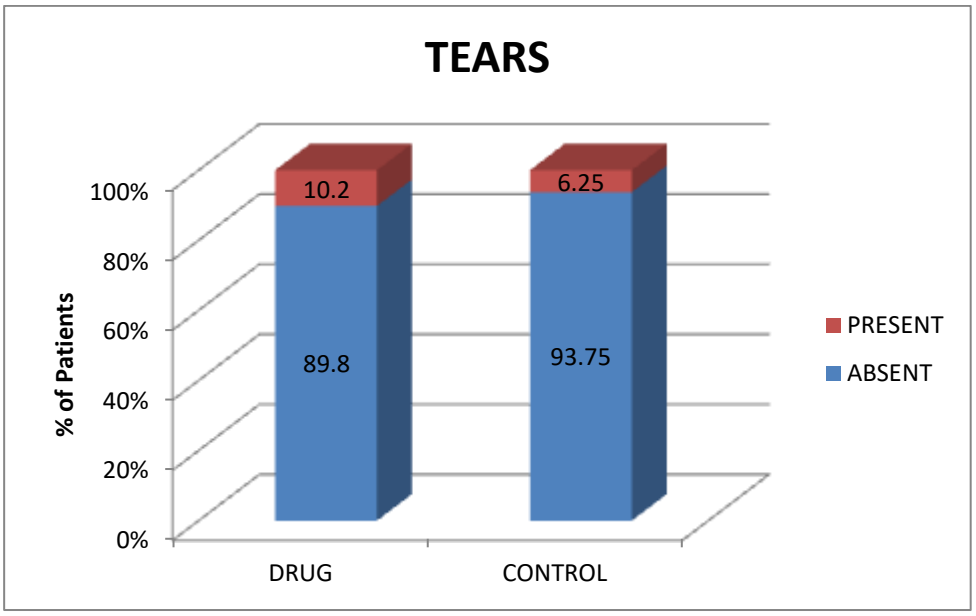



TABLE-13DISTRIBUTION OF SUBJECTS ACCORDING TO MATERNAL COMPLICATION

i) TEARS

| | GROUP | | | | |
|---|---|---|---|---|---|
| TEARS | DRUG | CONTROL | Total | p Value | Significance |
| ABSENT | 44(89.8) | 45(93.75) | 89(91.75) | 0.479 | not significant |
| PRESENT | 5(10.2) | 3(6.25) | 8(8.25) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

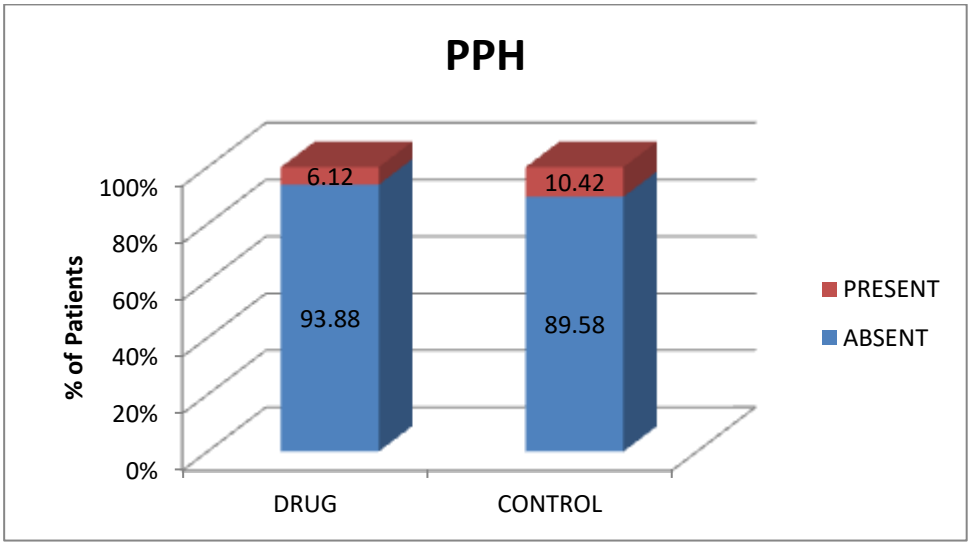
N.B VALUES WITHIN BRACKET DENOTES PERCENTAGE.




ii) PPH

| | GROUP | | | | |
|---|---|---|---|---|---|
| PPH | DRUG | CONTROL | Total | p Value | Significance |
| ABSENT | 46(93.88) | 43(89.58) | 89(91.75) | 0.442 | not significant |
| PRESENT | 3(6.12) | 5(10.42) | 8(8.25) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

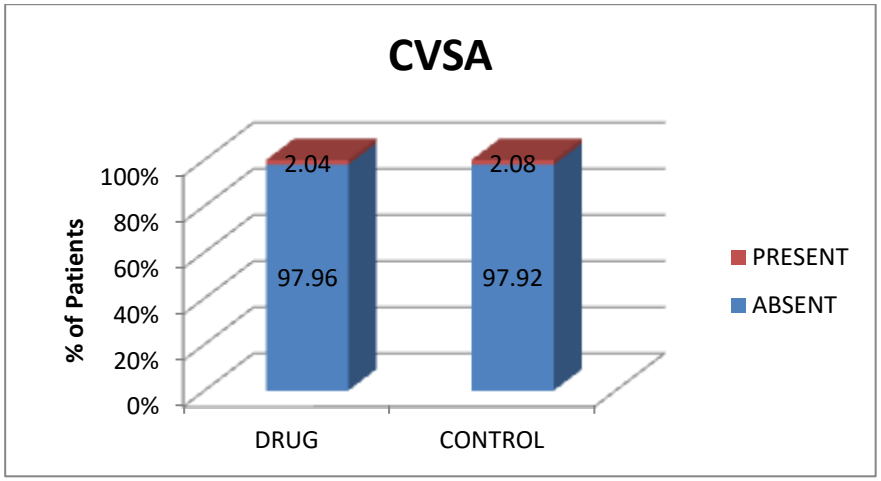
N.B VALUES WITHIN BRACKET DENOTES PERCENTAGE.




iii)CARDIOVASCULAR ABNORMALITY (CVS-A)

| | GROUP | | | | |
|---|---|---|---|---|---|
| CVSA | DRUG | CONTROL | Total | p Value | Significance |
| ABSENT | 48(97.96) | 47(97.92) | 95(97.94) | 0.988 | Not Significant |
| PRESENT | 1(2.04) | 1(2.08) | 2(2.06) | | |
| Total | 49(100) | 48(100) | 97(100) | | |

N.B VALUES WITHIN BRACKET DENOTES PERCENTAGE




There was no statistically significant difference in incidence of Tear (cervical tear, vaginal laceration, paraurethral tear) between the 2 groups. There was no statistically significant difference in incidence of PPH( atonic) and any cardiovascular abnormality ( CVS-A) between the 2 groups. Only 1 case of ventricular ectopic was found in the control group.

TABLE 14- DISTRIBUTION OF SUBJECTS ACCORDING TO INDICATION OF CESAREAN SECTION

| | GROUP | | |
|---|---|---|---|
| INDICATION | DRUG | CONTROL | Total |
| NPOL | 5(73.33) | 5(71.43) | 10(76.92) |
| MSL | 1(16.67) | 2(29.17) | 3(23.08) |
| Total | 6(100) | 7(100) | 13(100) |

N.B-VALUES WITHIN BRACKETS DENOTES PERCENTAGES.NPOL=NON PROGRESSION OF LABOR. MSL=MECONIUM STAINED LIQUOR.

5 (73.33%) of the Drug group and 5 (71.43%) of the Control group required cesarean section for Non Progression of labor (NPOL).1 (16.67%) of the Drug group and 2(29.17%) of the Control group required cesarean section for Meconium stained liquor (MSL)

## 5. DISCUSSION

110 subjects were chosen for the study. They were in the active phase of labour and fulfilled the inclusion criteria. Their consent was taken. They were randomized into Drug group and Control group, each comprising of 55 subjects.Out of them, 6 (10.91%) of the Drug group and 7 (12.73%) of the Control group underwent cesarean section. So, the Drug group comprised of 49 subjects while the Control group comprised of 48 subjects.

The Drug group had subjects with a mean age of 25 years while the Control group had subjects with a mean age of 26 years. Majority of the subjects 72 (74.23%) were in the age group between 21 and 30 years. In the Drug group, 27 (55.1%) subjects were primipara and 22 (44.9%) subjects were multipara while in the Control group 26 (54.17%) subjects were primipara and 22 (45.36%) subjects were multipara.

Majority of the subjects 33 (34.02%) had spontaneous onset of labor at 38-<39 weeks period of gestation. Only 4 (4.12%) subjects were postdated (>=40 weeks) and were a part of the drug group (8.16%).

All the subjects underwent selective amniotomy at 4 cm cervical dilatation in the active phase of labor and received 2 ml of prefilled solution intravenously. The Drug group was administered 40 mg of Drotaverine hydrochloride while the Control group received normal saline.

The following parameters were monitored:

- Progress of labour was assessed with partogram.
- Maternal and fetal well being was monitored.

The results were tabulated and statistical significance was calculated with the help of SSPS 20.

The average duration of the active phase of first stage of labor was 179.07+/-37.93 mins (2 hrs 59 mins +/- 37 mins) in the Drug group and 250.38 +/- 57.81 Mins (4 hrs 10 mins +/- 57 mins) in the Control group in primipara patients.While in multipara patients, the mean duration was 158.18 +/- 33.75 mins in the Drug group and 225.00+/-36.45 mins (3 hrs 45 mins +/- 36 mins) in the Control group. Both the values for primi and multipara were found to be statistically significant(< 0.001). It was seen that 13 (48.15%) of the primipara and 17(77.27%) of the multipara were fully dilated within 3 hours in the Drug group. But in the Control group, 3 (11.54%) of the primipara and 3 (11.54%) of the multipara were fully dilated within 3 hours.The values were found to be statistically significant (p=0.004) for primi and also (p= < 0.001) for multipara. Only 4 subject who were primi para and belonged to the Control group required >5 hrs to get fully dilated.

The duration of second stage of labour was slightly less in Drug group(32.41+/-11.04 mins in primi and 29.32+/-5.37 mins in multipara) in comparison to Control Group (37.12 +/-7.91 mins in primi and 30.59 +/-6.44 mins in multipara).The values were not found to be statistically significant.

The duration of third stage of labour showed almost no difference among Drug group and Control group, both in primipara and multipara and thus showed no statistical significance.

The time interval between injection and delivery of the baby was found to be 211.48+/-41.44 mins (3 hrs 31 mins +/-41 mins) in the Drug group and 289.42+/-63.39 mins (4 hrs 49 mins+/- 1 hr 3 mins) in the Control group for primi para. The values were found to be statistically significant (p< 0.001).

For multipara subjects, the time interval was found to be 187.73+/- 36.22 mins(3 hrs7 mins+/-36 mins) in the Drug group and 254.91 +/-39.01mins( 4 hrs 14 mins +/-39 mins). The values were found to be statistically significant (p<0.001) The mean rate of dilatation was found to be 2.08+/-0.52 cm/hr in the Drug group and 1.48 +/- 0.41 cm/hr in the Control group in case of primipara.

It was found to be statistically significant (p<0.001. The mean rate of dilatation was found to be 2.35 +/-0.45 cm/hr in Drug group while 1.59+/- 0.31 cm/hr in Control group in case of multipara. It was found to be statistically significant (p<0.001).

The 1 minute APGAR score was found to be statistically significant in the Drug group in comparison to the Control group.(p<0.001).

The 5 minute APGAR score was not found to be statistically significant in the Drug group in comparison to the Control group .Only 3 babies((6.25%) in the Control group had APGAR score less than 7.

There was no statistically significant difference in incidence of Tears (cervical tear, vaginal laceration, paraurethral tear) between the 2 groups. There was no statistically significant difference in incidence of PPH( atonic) and any cardiovascular abnormality ( CVS-A) between the 2 groups.

Only 1 case of ventricular ectopic was found in the control group.

No incidence of any side effects related to the drug was found.

## 6. CONCLUSION

- Drotaverine is effective in shortening the duration of active phase of uncomplicated labor at term, both in primi and multipara.
- Drotaverine does not cause any increase in the incidence of operativedelivery or complication like postpartum haemorrhage.
- Drotaverine does not alter the second or third stage of labor
- The use of Drotaverine in pharmacological dose of 40 mg is not associated with any significant maternal or adverse effects.

Drotaverine is a new aid in the management of uncomplicated labour at term for a safer and convenient outcome with a shorter delivery time.

## 7. LIMITATIONS

1. Study of Drotaverine on cases with maternal or fetal complications has not been done.
2. Effect of Drotaverine on intact membrane or cases with spontaneous rupture of membrane has not been studied.
3. Oxytocin has been used in some of the subjects with inadequate uterine contraction, no separate study of the subjects receiving oxytocin has been done.
4. No long term follow-up of the neonates has been done in the study.

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