AMNIOTOMY VERSUS NON AMNIOTOMY FOR SHORTENING SPONTANEOUS LABOUR

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE RULES AND REGULATIONS FOR MD BRANCH II (OBSTETRICS AND GYNAECOLOGY) DEGREE EXAMINATION OF THE TAMIL NADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI, TO BE HELD IN APRIL 2015

CERTIFICATE

This is to certify that the dissertation entitled**, "Amniotomy Versus Non Amniotomy for Shortening Spontaneous Labour**" is a Original work done by

Dr.V.Malarvizhi

Done under my guidance towards the MD Branch II (Obstetrics and Gynecology) Degree Examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai to be held in April 2015.

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Above all I thank God for His love and abundant grace.

Dmalar

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INTRODUCTION

Intentional artificial rupture of amniotic membranes or breaking of waters is one of the commonly performed procedure in modern obstetrics(1). It was first introduced by Thomas Denman, an English Obstetrician, in 1756(2). The primary aim of amniotomy is to increase contractions and shorten the duration of labour. With amniotomy, the production and release of local prostaglandins and oxytocin increases resulting in stronger contractions and quicker cervical dilatation. Amniotomy allows detection of meconium stained amniotic fluid and enables us to introduce internal fetal electrode and intra uterine pressure catheters for monitoring labour. In some centers, it is routinely performed in all women and in many centers it is used for treatment of prolonged labour (1). With the active management of labour protocol introduced by O'Driscoll in 1968, the use of amniotomy has been widely accepted as part of labour(3). Opponents of amniotomy argue that amniotic sac and fluid plays an important role in protecting the fetus against uterine contractions and helps in cervical effacement, dilatation and pre-stretching the perineum. However, there are number of potential but rare risks associated with amniotomy like cord prolapse, fetal heart rate abnormalities and sepsis. The Randomized Controlled Studies included in the Cochrane review (1) that compared outcomes in women who had amniotomy with outcomes in women who did not have amniotomy had variable inclusion criteria and hence have conflicting results. Thus, a need for a well-designed large study to look at the outcomes of this intervention has been identified as a research priority.

AIM

The aim of the of this randomized control study is to assess the effectiveness of routine amniotomy in reducing the duration of labour in women having spontaneous onset of labour.

PRIMARY OUTCOME

Duration of labour from the time of randomization to delivery in minutes between amniotomy group and non amniotomy group.

SECONDARY OUTCOME

MATERNAL OUTCOMES

1. Caesarean section.
2. Need for ARM.
3. Need for Oxytocin augmentation.
4. Hyperstimulation.
5. Need for amnio-infusion.
6. Chorio Amnionitis.
7. PPH.
8. Postpartum endometritis.

FETAL OUTCOMES

1. Cord prolapse
2. CTG abnormalities.
3. APGAR score at 5 minutes
4. NICU admission.
5. Neonatal Sepsis

REVIEW OF LITERATURE

HISTORY OF AMNIOTOMY:

Thomas Denman was the first to propose the use of amniotomy, otherwise called as “English operation” in 1794 for inducing labour. The purpose of amniotomy at that time was to induce labour to avoid disproportion(4). It was not a very popular procedure in those times as they believed that the amniotic sac and fluid serves as the wedge that cause cervical dilatation, helps the labour to progress and prevent cord prolapse(5). It is believed that pressure exerted by membranes on uterus stimulates oxytocin surge. They also believed that elective amniotomy increases the risk of puerperal infection. A new light was thrown on amniotomy when Eastman through his study, found that labour was 73% shorter in women who underwent elective amniotomy and the incidence of cord prolapse was 0.3%. (6)

STRUCTURE OF AMNION:

The amnion is a thin layer devoid of blood vessels. It consists of flat columnar cells which is attached to the basement membrane and connective tissue, containing macrophages. The amnion is contiguous over the umbilical cord and fetal skin. The amnion does not contain blood vessels but gets its nutrition from the amniotic fluid and chorionic vasculature. The amnion is passively attached to the chorion by internal pressure of amniotic fluid. (7).Electron microscopic studies disagree with existence of such distinct layers.(8)

The amniotic membrane is 0.2 mm – 0.5mm thick.

In 1962, Bourne(9) described five layers of amnion namely,

1. Epithelium
2. Basement membrane
3. Compact layer
4. Fibroblastic layer
5. Spongy layer

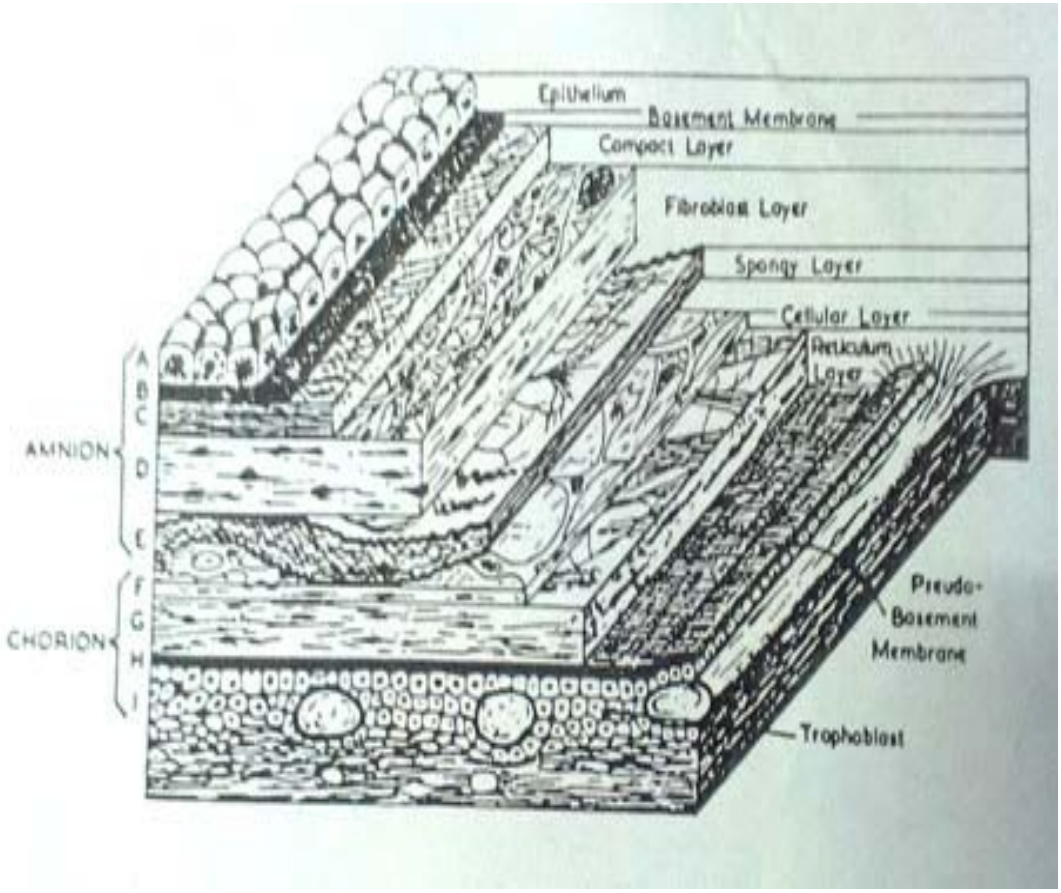


FIGURE 1 structure of amnion

EPITHELIUM

The epithelium which is the innermost layer, consists of single layer of cuboidal cells which contacts the amniotic fluid. The cells may be columnar over the placenta and flattened over the amnion reflection.

BASEMENT MEMBRANE

The basement membrane is a thin layer, consisting of network of reticular fibers.

COMPACT LAYER

The compact layer consists of dense network of reticular fibers.

FIBROBLAST LAYER

The fibroblast layer is the thickest layer and consists of loose fibroblast network embedded in reticulum.

SPONGY LAYER

The fifth and outer most layer is the spongy layer. It is derived from extra-embryonic celom and found between amnion and chorion and it allow the amnion to slide on the chorion.

ANATOMICALLY DISTINCT PORTIONS OF AMNION

1. Reflected amnions
2. Placental amnion
3. Amnion covering the umbilical cord
4. Fused amnion in twins

REFLECTED AMNION(10)

The amnion contiguous with the chorion leave is called reflected amnion.

PLACENTAL AMNION

The placental amnion overlies the fetal surface of the placenta and it is contiguous with fetal chorionic vessels.

AMNION COVERING THE UMBLICAL CORD

The third portion of amnion covers the umbilical cord .

FUSED AMNION

The forth portion is present only in diamnionic pregnancy and called as fused amnion.

GROSS EXAMINATION

Gross examination of amnion reveals a translucent structure that is easily separated from the underlying chorion. The strength of membrane is imparted by the layer of dense connective tissue to which the amnion epithelial cells are attached.

AMNION EPITHELIAL CELLS

The apical surface of amnionic epithelium is rich with highly developed microvilli. Microvilli plays an important role in transfer between the amniotic fluid and amnion. The epithelium is metabolically active. Amnionic epithelial cells synthesize prostaglandin E, fibronectin and tissue inhibitor of metalloproteinase. Towards term pregnancy, amniotic expression of endoperoxide H synthase increases. By prostaglandin production this amniotic epithelium participates in the final common pathway of labour initiation.

Epithelial cells respond to signals derived either from the fetus or the mother. These epithelial cells are responsive to various endocrine and paracrine modulators like oxytocin and vasopressin, both of which increase the PGE2 production. (10)

AMNION MESENCHYMAL CELLS

The major source of tensile strength of amnion is from compact layer. This compact layer is made up of interstitial collagen which is derived from mesenchymal cells.(10)

AMNION TENSILE STRENGTH

The amnion provides the major strength of fetal membranes. Its tensile strength is almost exclusively from compact layer, which is composed of cross-linked interstitial collagen 1 and 3 and lesser amount of collagen 5 and 6.

PHYSIOLOGICAL FEATURES OF AMNION

It is metabolically active layer. It is involved in solute and water transport to maintain homeostasis and the production of several hormones and peptides like endothelin-1, Parathyroid hormone related protein, Oxytocin, Prostaglandin E2 and PGF2 alpha.(11)(12).

TYPES OF AMNIOTOMY

1. Low amniotomy

2. High amniotomy

LOW AMNIOTOMY

Most commonly used procedure. It is otherwise called as English operation which was proposed by Thomas Denman in 1794. Thomas Denman was the first one to introduce amniotomy. It is rupture of forewaters or membranes lying below the presenting part.(13)

HIGH AMNIOTOMY

High amniotomy otherwise called as high water amniotomy. It was originally proposed by Hamilton in 1863 and reintroduced by Drew Smythe in 1930. Double curved silver catheter is used to puncture the membranes beyond fetal head.(13)

ADVANTAGES OF HIGH AMNIOTOMY

1. Reduces the risk of infection.
2. Reduces incidence of cord prolapse.

DIS ADVANTAGES OF HIGH AMNIOTOMY

1. Harm the fetus, placenta and mothers genital tract.
2. Used in polyhydramnios and floating head.

COMPLICATIONS OF AMNIOTOMY

1. Fetal
2. Maternal

FETAL COMPLICATIONS

1. Cord prolapse - At present incidence of cord prolapsed after amniotomy ranges between 0.0-0.7% (14)(15)
2. Fetal heart decelerations.
3. Bleeding from placenta previa or vasa previa.
4. Increased risk of HIV transmission.

MATERNAL COMPLICATIONS

1. Discomfort to patient.
2. Increased pain following procedure.
3. Chorio amnionitis.

ADVANTAGES OF AMNIOTOMY

1. Visualization of liquor colour to detect MSAF
2. Enables to introduce internal fetal electrode
3. Enables to introduce intrauterine pressure catheter.

VARIOUS INSTRUMENTS USED IN LOW AMNIOTOMY (2)

1. Kocher's
2. Dressing forceps
3. Long clamp
4. One blade of a disarticulated valsellum
5. A pair of long scissor

SPECIAL INSTRUMENTS

1. Currie's induction catheter
2. Titus special perforator

CURRENT DEVICES

1. Amnio hook
2. Baylor hook
3. Amniocot

INSTRUMENTS USED IN HIGH AMNIOTOMY

Double curve silver catheter with a blunt stylet

TECHNIQUES OF AMNIOTOMY

LOW AMNIOTOMY:

1. Amniotomy is usually performed blindly using the examination finger with any of the instruments mentioned above.
2. Direct visualization using an amnioscope. Advantages being the ability to avoid the fetal vessels in the membranes and reduces the risk of damage to the cervix.

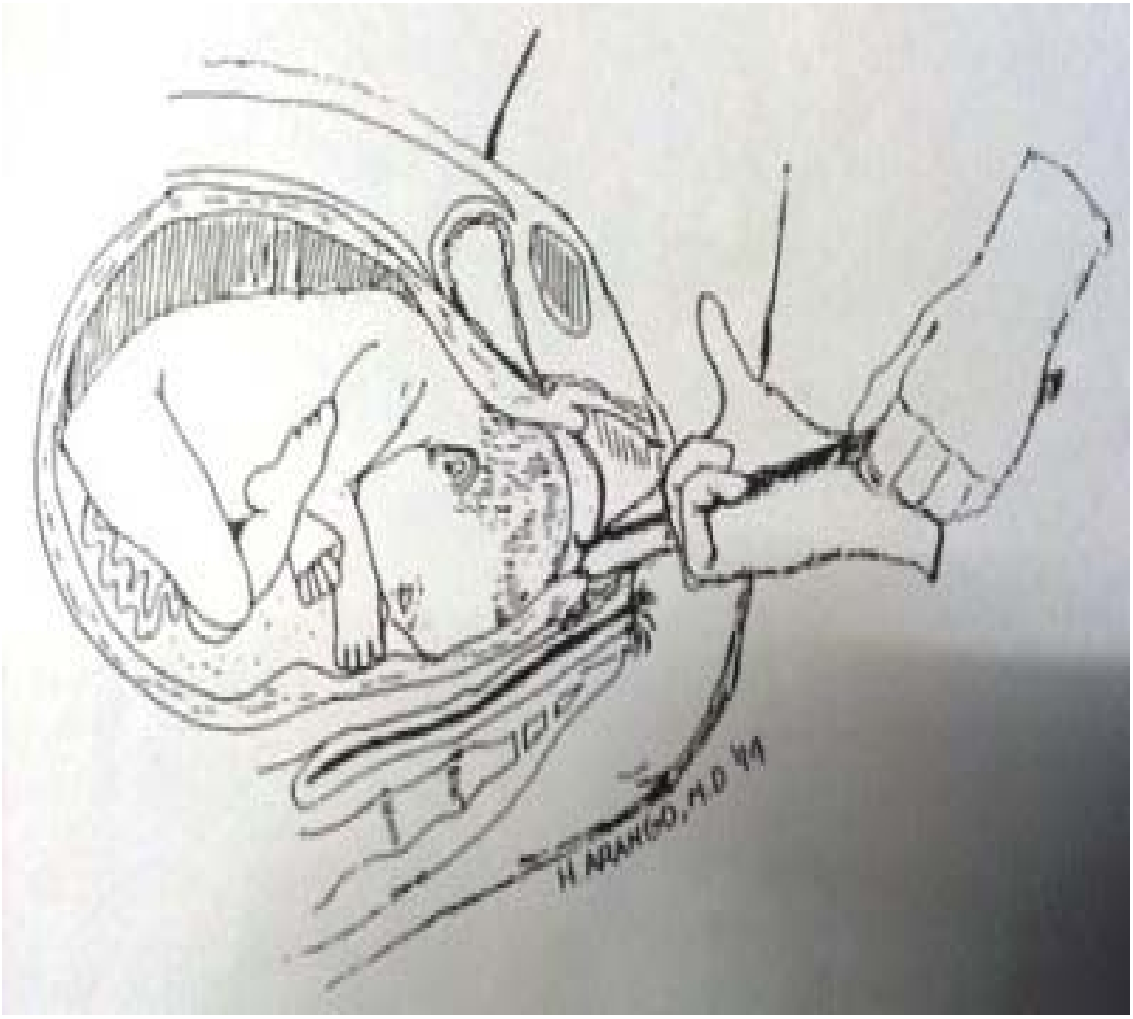


FIGURE 2: TECHNIQUE OF AMNIOTOMY

HIGH AMNIOTOMY

1. Double curve silver catheter with blunt stylet was introduced through the cervix and it is slided posteriorly between the membranes and the uterine wall and advances well above the presenting part.
2. The interior stylet is then advanced to puncture the membranes.

LABOUR

Labour is a normal physiological process. Labour involves integrated set of changes which occurs in a sequential manner in myometrium, cervix, and decidua. It is characterized by change in myometrial contractility pattern from contractures to contractions ,resulting a change from long lasting low frequency activity into high frequency, resulting in effacement and dilatation of cervix. (16)

STAGES OF LABOUR(10)(17)

1. Quiescent phase
2. Activation phase
3. Stimulation phase
4. Involution phase

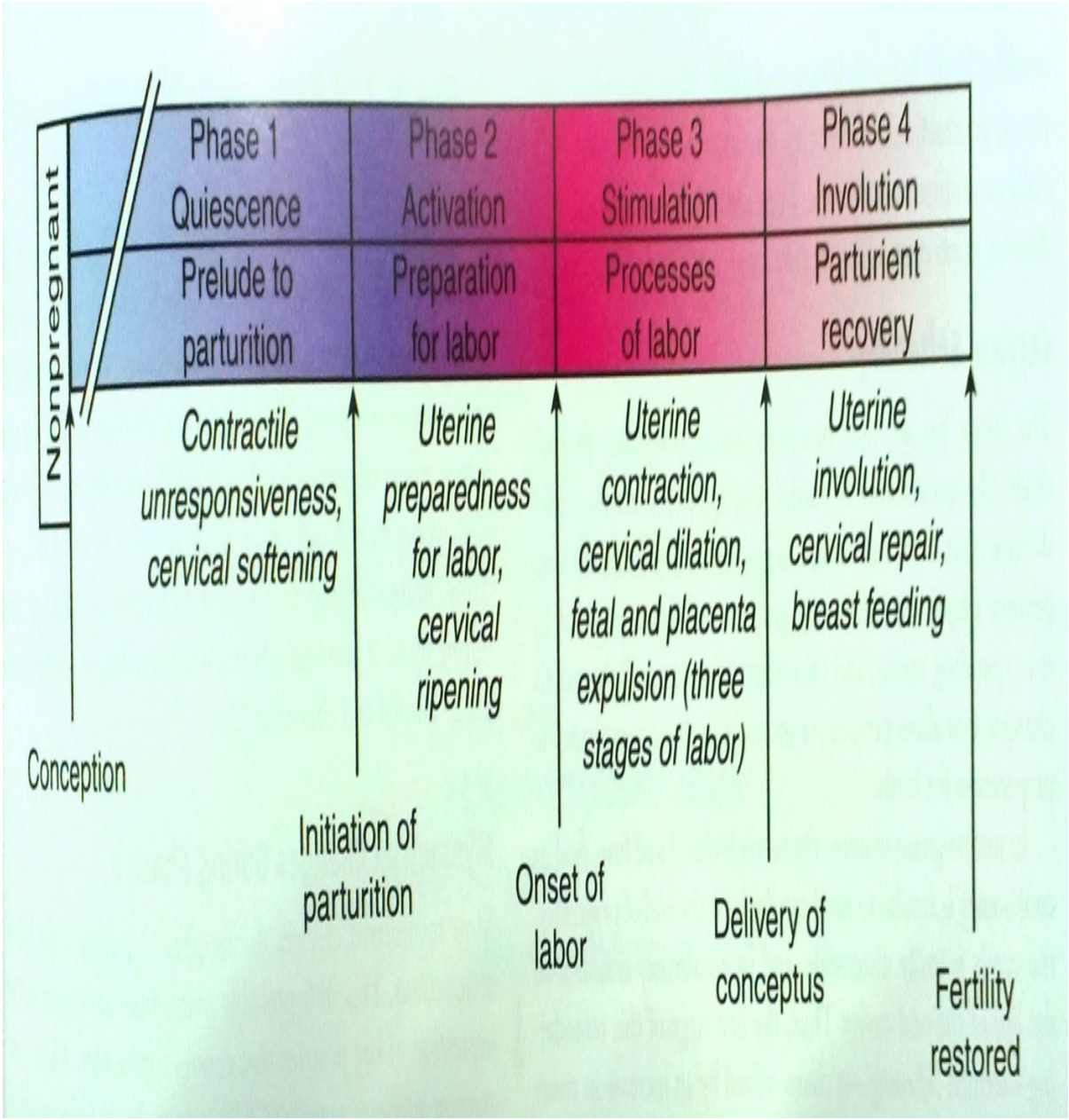


FIGURE 3: Stages of labour

QUIESCENT PHASE

Throughout pregnancy the uterus is kept functionally quiescent by variety of mediators like Progesterone, Prostacyclin-I, Relaxin, Nitric oxide, Parathormone related peptide, Vaso active intestinal peptide, Calcitonin gene related peptide.

ACTIVATION PHASE

Toward term uterus become responsive to uterotropins like estrogens. This is mediated by increased expression of contractile associated proteins, stimulation of specific ion channels, increase in gap junctions (connexin 43).Increase in gap junctions leads to electrical synchrony between myometrium leading to co-ordinated and effective uterine contractions.

STIMULATION PHASE

Uterotonic agonist like PG-E, PG-F2 alpha, Oxytocin acts on the primed uterus to contract. Following ARM oxytocin and prostaglandins are released and thus accelerates the stimulation phase and shorten the duration of labour.

INVOLUTION PHASE

Mediated by Oxytocin.

PROSTAGLANDINS

It plays an important role in parturition. It is produced mainly by fetal membranes-amnion, chorion and deciduas. PGs are responsible for synchronous uterine contractility, cervical effacement, increase in myometrial sensitivity to oxytocin by increasing gap junctions and increased oxytocin receptors in myometrium. Thus a prostaglandins act in stimulation phase of labour and accelerates it.

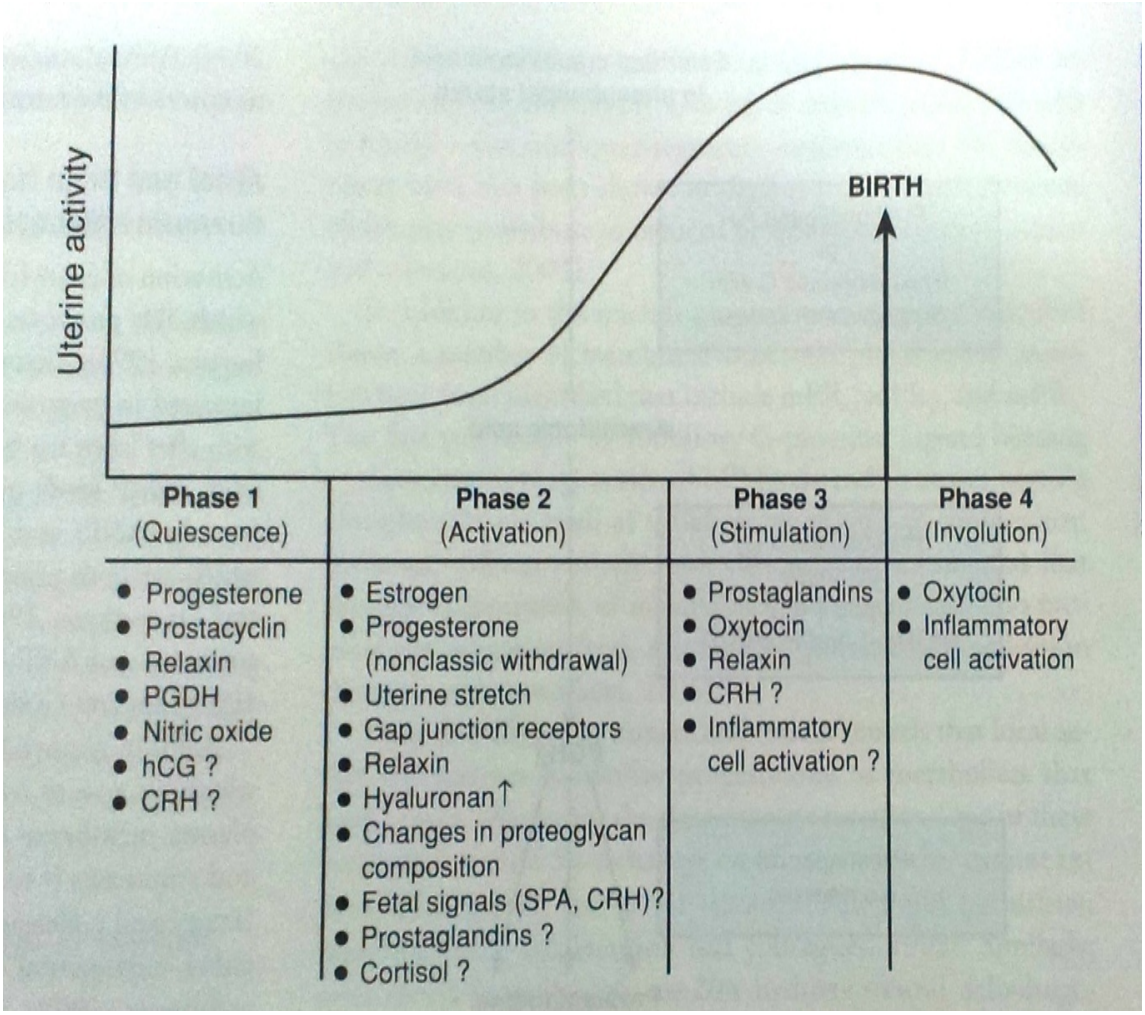


FIGURE 4: Hormones involved in phases of labour

Increased levels of PGs are seen before the onset of labour. This is mediated by increased synthesis of PGHS - 2 prostaglandin H synthase produced by fetal membranes. PGDH prostaglandin dehydrogenase is produced mainly by chorion. In pregnancy increased PGDH activity is seen preventing the PGs to reach the cervix and myometrium. At term the activity of PGDH decreases, and PGs are able to act on cervix and myometrium. Glucocorticoids increases the production of PGHS-2, and decreases the production of PGDH. Prostaglandin is the KEY factor for onset and progress of labour.

PHYSIOLOGICAL BASIS OF AMNIOTOMY IN LABOUR

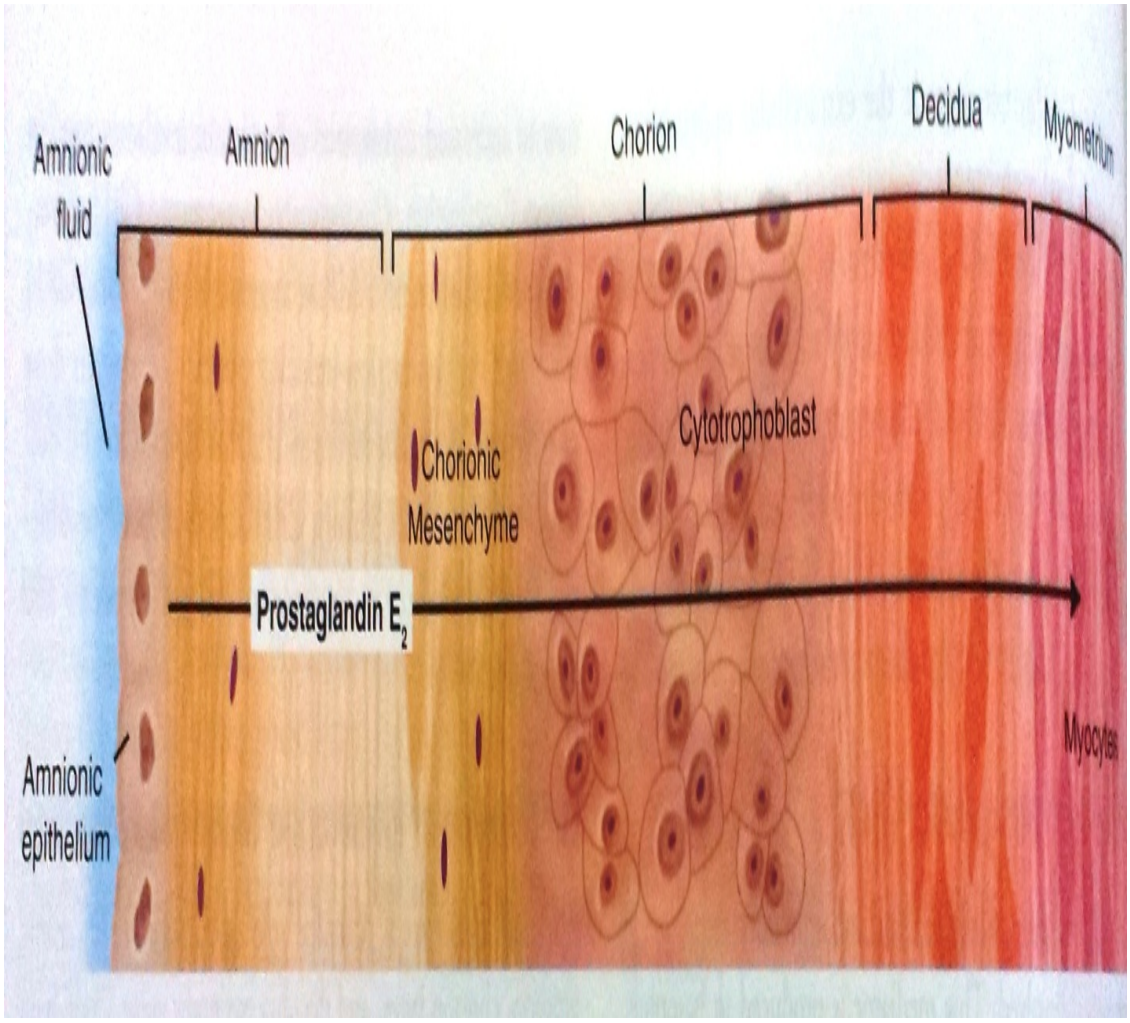


FIGURE 5: structure of amnion with prostaglandin release

Amniotomy increases the synthesis of prostaglandins which induces and accelerates the labour.

FLINT 1975

Flint and associates in 1975 reported that vaginal and cervical distension in labour releases oxytocin which further releases prostaglandins into the circulation. Ferguson's reflex leads to both oxytocin release and prostaglandin production. (18)

THORNTON

But further studies conducted by Thornton and co workers recognized that amniotomy did not result in the increase in oxytocin levels.(19)

SELLERS 1980

Sellers and associates in 1980 found that the surge of prostaglandin immediately after amniotomy was not responsible for labour onset and progress but the late surge of prostaglandin is involved in the progress of labour.(20)(21)(22)

MITCHELL 1977

Mitchell and colleagues in 1977 found that amniotomy increases uterine contractility. In their study patient were classified into three group:(23)

1. Vaginal examination
2. Vaginal examination with stripping of membranes
3. Amniotomy

Peripheral concentration of 13, 14 dihydro 15 keto prostaglandin F (PGFM) were measured before the procedure and 5 minutes after the procedure. They found that in all groups there is a significant increase in PGFM levels but it is more significant in the amniotomy group.

SELLERS STUDIES

Further studies conducted by Sellers and colleagues in Oxford found that PGFM was increased maximally in about 5 minutes after ARM and remained elevated for at least 30 minutes.(24)

Oxytocin concentration does not increase during this period and hence they concluded that PGFM increases after amniotomy is not preceded by increase in oxytocin concentration.

Further studies by the Sellers and associates from oxford concluded that in addition to PGF2alpha, PGE2 also plays an important role in the progress of labour (20)

HUSSELEIN 1983

Husselein and associates in 1983 conducted further studies on PGFM levels in labour. They included 23 pregnant women and checked blood PGFM levels before amniotomy, 15mins, 2hrs, 5hrs and 8 hrs after ARM and concluded that plasma PGFM 2 hours after amniotomy correlated with the progression of labour.(25)

MANNABE 1987

Mannabe and colleagues in 1987 conducted a study involving 12 nulliparous women and found that in 6 patients there was a sudden and progressive descent of the fetal head to the cervix with significant increase in the PGFM levels. They concluded that when amniotomy was done at a appropriate time there was increase in PGFM level which was partially due to the increased pressure of the head on the cervix.(26)

PRAAGH AND HENRIQUES 1964

Praagh and Henriques in 1964 conducted a study on the effect of amniotomy in patient with spontaneous labour versus induced labour. They found that two third of patients in both groups had increase in intensity and frequency of uterine contractions with increased Montevideo units after amniotomy. They also found that amniotomy helped to correct the contractility pattern when incordinate uterine axis existed.(27)

ACTIVE MANAGEMENT OF LABOUR PROTOCOL(28)(1)

With the introduction of active management of labour protocol by O'Driscoll and colleagues in 1968, amniotomy was widely and readily accepted as a part of labour management. It was first implemented at National Maternity Hospital in Dublin in 1968. The primary aim of the active management of labour protocol was to ensure labour progression and to intervene to decrease dystocia in first stage of labour and decrease the LSCS rate.

The policy of Active management of labour was to ensure that every primi gravid should deliver within 12 hours.

COMPONENTS OF ACTIVE MANAGEMENT OF LABOUR PROTOCOL O DRISCOLL 1984

1. Diagnosis of labour.
2. Early Amniotomy.
3. Frequent cervical examinations.
4. High dose of oxytocin for slow progress <1 cm / hour.

EARLY AMNIOTOMY AND OXYTOCIN AUGMENTATION

They are the two important key components of active management of labour protocol.

The incidence of prolonged labour was reduced to 3% and caesarian section was less than 10% by limiting the incidence of dystocia. Dystocia was the cause for increased rate of caesarian section .

EFFICACY OF ACTIVE MANAGEMENT OF LABOUR

1. Shorten the duration of labour.
2. Decreases maternal and neonatal infection rate without increase in maternal and neonatal morbidity.
3. Modest reduction in LSCS rate (28)

COCHRANE REVIEW ON EARLY AMNIOTOMY AND EARLY OXYTOCIN ON PREVENTION OF OR THERAPY FOR, DELAY IN FIRST STAGE OF LABOUR(29)

AIM

The main objective of this review is to estimate the effects of early augmentation with amniotomy and oxytocin for prevention of or therapy for delay in progress of first stage of labour.

It involves 14 RCTS and quasi randomized control trials involving 8033 women.

MAIN RESULTS

The unstratified analysis showed that the early intervention with amniotomy and oxytocin was associated with modest reduction in the risk of caesarean and shortens the duration of labour by 70 minutes.

Amniotomy has been practiced for many years but there is paucity of good evidence for its use in women in spontaneous labour, although it has been used as therapy for delay in progress of labour.

COCHRANE DATABASE SYSTEMIC REVIEW ON AMNIOTOMY FOR SHORTENING SPONTANEOUS LABOUR(30)

AIM

To determine the effectiveness and safety of amniotomy alone for routinely shortening all labour that starts spontaneously.

It included 15 RCTs involving 5583 women.

This was conducted mainly in UK , USA and CANADA

Primary analysis was done by intention to treat.

RESULTS

There was no clear statistically significant difference between women in amniotomy group and control group in length of first stage of labour (MD-20.43 minutes and 95% CI (95.93-55.06)

No statistically significant difference in LSCS rate (Relative risk 1.27, 95% CI (0.99-1.63)

No statistically significant difference in APGAR score of less than 7 at 5 minutes (RR 0.53 95% CI 0.28-1.00)

CONCLUSION

Amniotomy cannot be routinely recommended as a part of routine labour care and management.

DRAW BACKS OF COCHRANE REVIEW

1. Outcome may be influenced by inclusion criteria pertaining to cervical dilatation at which they are randomized .Large time interval between women randomized at 3cm and 6 cm. It is difficult to make recommendations based on this.

2. More than 30 -40% of women in amniotomy group underwent ARM at some point in time and their analysis was done by intention to treat analysis and not by per protocol analysis.

However there were 2 good quality studies included in Cochrane review showed definite decrease in duration of labour and decreases the frequency of dystocia without definite complications.

GARITE ET AL 1993(31)

Garite et al 1993 is one of the good quality study included in Cochrane review. This study was published in Am J Obstet Gynecol 1993.

This was a randomized control trial conducted at University of California Irvine Medical centre over a period of 4 years from 1988 to 1991.

AIM

Aim of the study was to evaluate the effects of routine elective amniotomy on severity and frequency of FHR patterns and on course of labour and the need for oxytocin augmentation.

Inclusion criteria were women in spontaneous active labour with intact membranes with vertex presentation at or below -2 station between 4-6 cm dilatation.
Exclusion criteria were patients having fetal distress or chorio amnionitis at admission and Pre -eclampsia.

Patients were randomized by consecutively numbered sealed envelopes generated by EPISTAT-random number computer programme.

459 patients were included of which 235 in amniotomy group, and 224 in intact group.
Average cervical dilatation at membrane rupture were 5.5 cm in amniotomy group and 8.1 cm in intact group.

It has been found that 17% of patients in intact group underwent amniotomy for arrest or protracted dilatation and 9% for fetal distress.

Statistical analysis was done by student t test or Fischer's exact test and intention to treat analysis was done.

Results were active phase of labour was shorter in amniotomy group compared to intact group (4 hours 35 minutes in amniotomy group vs 5 hours 56 minutes in intact group).

The need for oxytocin was twice as common in intact group compared to amniotomy group.

There was mild and moderate variable deceleration in amniotomy group but does not result in more severe decelerations or operative delivery.

So they concluded elective amniotomy shorten the active phase of labour and decreases the need for oxytocin.

FRASER ET AL 1993 (32)

This is another good quality study included in Cochrane review.

This study was published in The New England Journal of medicine 1993.

This study was conducted in 11 university affiliated teaching hospitals over a period of 3 years from 1989-1991.

AIM

To determine whether routine early amniotomy reduces the risk of dystocia for nulliparous women in spontaneous labour.

Inclusion criteria were term nulliparous women in spontaneous labour with intact membranes

Exclusion criteria were IUGR,Pre eclampsia ,GDM on insulin,cervical dilatation greater than 6 cm.

Randomization was centralized by telephone answering services and group stratification was done according to the degree of cervical dilation before randomization < 3 cm versus ≥3 cm.

925 patients were included in the study of which 462 were randomized to amniotomy group and 463 in conservative management group.

Dystocia was defined if mean cervical dilatation was less than 0.5 cm per hour atleast 4 hours after 3 cm cervical dilatation according to guidelines suggested by panel of the National Consensus Conference on aspects of Caesarean birth.

In conservative management group 51% underwent amniotomy out of which 77% was failure to progress, and 17% was done for fetal distress.

RESULTS

Dystocia was significantly less in amniotomy group (34% versus 45%,relative risk 0.8,95 % CI 0.6-0.9).

The median length of time from randomization to full dilatation was 136 minutes shorter in amniotomy group and less frequent use of oxytocin in amniotomy group (36% versus 41%, relative risk 0.9, 95%CI 0.8-1.0)

So they concluded that early amniotomy was an effective method shortening the duration of labour and reducing the frequency of dystocia in nulliparous and the LSCS rates were similar.

WETRICH 1970 (33)

This was one of the earliest RCT's included in Cochrane review. This study was conducted in University Hospitals, State University of Iowa, Iowa city. This study was published in Obstetrics and Gynecology May 1970.

AIM

The primary aim of the study was to establish the effect of Amniotomy on the course of labour.

INCLUSION CRITERIA

Primigravidas, normally progressive labour < 6 cm dilatation with intact membranes, vertex presentation which was fixed and applied to the cervix.

EXCLUSION CRITERIA

SPE, Diabetes, abruption placenta, Rh isoimmunization .

Randomization was done by blind draw Random assignment.

There were 32 patients included in this study, 16 women in each arm.

RESULTS

The average time taken from 6 cm to complete dilatation was 90.2 minutes in amniotomy group and 151.7 minutes in the spontaneously ROM group with a P value 0.01 which is statistically significant. No difference in the duration of second stage of labour and the mode of delivery was similar in both the groups.

CONCLUSION

Amniotomy at 6 cm dilatation in primigravida with normally progressive labour significantly shorten the labour because of the more rapid completion of the first stage of labour. There was no difference in the second stage.

LAROS 1972(34)

This was one of the RCT's included in Cochrane review. This study was conducted in University of Michigan Medical Centre, Ann Arbour and Wayne Country general Hospital Eloise, Mich. This study was published in Obstetrics and Gynecol May 1972.

AIM

To assess the effect of Amniotomy performed during the active phase of labour on the length of active phase of labour and the second stage of labour.

INCLUSION CRITERIA

Term gestation, Vertex presentation, between 5 cm and 8 cm dilatation with intact membranes were included in this study.

125 patients were included in this study, 70 in Amniotomy group and 55 in non amniotomy group.

The data were analyzed by Student's t test and x^2 test.

RESULTS

In primigravida the mean active phase was shorten by 40 minutes, second stage was shorten by 26 minutes and active phase and second stage was shorten by 60 minutes compared to control group. In multigravida the mean active phase was shorten by only 1 minute.

There were no significant between 2 groups with respect to non labour parameters.

CONCLUSION

Amniotomy performed in active phase of normal labour has minimal effect on subsequent labour events in multigravidas. In primigravida amniotomy slightly shortens the remainder of the active phase and second stage.

STEWART 1982 (35)

This was one of the RCT's included in Cochrane review. This was published in British Journal of Obstetrics and gynecology Jan 1982. This study was conducted at Royal Maternity Hospital Glasgow, Scotland, UK.

AIM

To compare the effect of early and late Amniotomy on the course and outcome of spontaneous labour.

Inclusion criteria were term singleton pregnancies with intact membranes with cervical dilatation ≤ 4 cm and cervical score of atleast 6.

There were total of 68 patients included in the study but 4 patients were excluded from the analysis. So total of 30 patients in amniotomy group and 34 in non amniotomy group. Analysis was done by student's t-test.

RESULT

The mean time interval from admission to full dilatation was 4.9 hours in amniotomy group and 7.0 hours in non amniotomy group with P value of 0.02 which was statistically significant.

CONCLUSION

The duration of first stage of labour was significantly shorter in early Amniotomy group.

BARRET 1992 (36)

This study was conducted at St James's University Hospital, Leeds, UK and was published in BJOG Jan 1992.

AIM

The main objective of the study was to compare the outcome of labour between early amniotomy and non amniotomy group in early established labour. Inclusion criteria were term singleton pregnancies with intact membranes with 4 cm cervical dilatation. 362 women were included in the study of which 183 in amniotomy group and 179 in the non amniotomy group

Randomization was done by numbered, sealed, opaque envelopes and analysis was done by student t -test or x^2 test.

RESULT

In primigravida the duration of first stage of labour was significantly shorten 9.7 hour versus 8.3 hour with a P value of 0.05 which was statistically significant. The duration of second stage remains unaffected.

CONCLUSION

Routine ARM slightly shorten the duration of labour but more epidural analgesia were needed suggesting that labour was painful.

UK AMNIOTOMY 1994(37)

This was a multi-centre Randomized control trial conducted at 6 centers at UK between January 1990 to December 1991.This was published in BJOG April 1994.

AIM

To measure the effect of routine Amniotomy on nulliparous labour. Inclusion criteria were nulliparous women in spontaneous labour with intact membranes between 3-4 cm dilatation. In 5 centers randomization was done by numbered sealed opaque envelope. At St James Hospital there was a programming error in computer randomization resulting in ratio of 4:3 instead of 1:1

Total of 1463 women were included in the study of which 782 were in early amniotomy group and 681 in non amniotomy group, imbalance being explained due to the error occurred at computer randomization.

RESULT

Mean duration of labour was 8.4 hours in early amniotomy compared with 9.4 hours in late amniotomy group.

CONCLUSION

Routine amniotomy has little effect on important outcomes except modest reduction in the duration of labour. Hence routine amniotomy should not be recommended but there was randomization error and not a good quality study included in Cochrane review.

AJADI 2006 (38)

This is one of the recent RCT included in Cochrane review.

AIM - To determine the effect of amniotomy on the outcome of spontaneous labour in low risk patients.

Inclusion criteria were low risk multiparous patients with spontaneous onset of labour with intact membranes between 4-5 cm dilatation.

Total of 128 women of which 64 were randomized to amniotomy group and 64 in no amniotomy group.

Result- The duration of labour was significantly shorter in amniotomy group (208 versus 292 minutes $p < 0.05$).

There was no difference on oxytocin requirement, LSCS rate and neonatal outcome. They conclude amniotomy shorten the duration of labour significantly.

SHOBEIRI 2007 (39)

This study was conducted at University affiliated teaching hospital Hamedan, Iran. This was a recent RCT included in Cochrane review.

AIM – To determine the effects of amniotomy on duration of labour.

Inclusion criteria were singleton term gestation, cephalic presentation, and intact membranes ≥ 3cm dilatation. Total of 80 patients, 40 in each group.

RESULTS

The mean time interval from randomization to full cervical dilatation was reduced by 170 minutes (215 min in amniotomy group versus 385 in control group, p value -0.001). Dystocia was significantly less frequent in amniotomy group (34% versus 45%, relative risk 0.8, 95% CI 0.6-0.9)

KARINE GAGNON –GERVAIS 2011 (40)

This was a Randomized control trial conducted at the University of Montreal, Montreal. This was published in American Journal of Obstetrics and Gynecology January 2011.

AIM

The primary outcome was to assess the effect of early amniotomy on delivery mode in patients undergoing IOL. The secondary outcome was the duration of labour.

Inclusion criteria were term singleton pregnancy with intact membranes admitted for IOL. Total of 143 women were included in this study of which 71 women were randomized to early amniotomy group and 72 in late amniotomy group. In early amniotomy group women underwent amniotomy concomitant with oxytocin infusion. In late amniotomy group oxytocin was started after randomization and amniotomy was done after 4 hours.

RESULT

In early amniotomy group oxytocin to delivery interval was significantly shorten compared with late amniotomy group in both primigravida and multigravidas.

CONCLUSION

Early amniotomy shorten the duration of labour with no difference in the LSCS rate.

GEORGE A MACONES 2012 (41)

This was an unblinded Randomized Control Trial published in American College of Obstetrics and Gynecology 2012.This study was conducted in Washington University in St. Louis and University of Pennsylvania. The aim of this study was to assess whether early amniotomy decreases the duration of labour or increases the proportion of subjects who are delivered within 24 hours in nulliparous patient who underwent labour induction.

Inclusion criteria were nulliparous women , singleton pregnancy, term gestation needing labour induction and Exclusion criteria were HIV infected patients, cervical dilatation > 4 cm at admission.

Total of 585 patients were Randomized 292 were randomized to Amniotomy group and 293 were randomized to 293 to standard management. Intention to treat analysis was done.

RESULT

Early amniotomy shortens the time to delivery > 2 hours (19 hours versus 21.3 hours) and increases the proportion of women delivers within 24 hours (68% versus 56%) and was not associated with increased complications.

EFFECT OF AMNIOTOMY ON MYOMETRIAL ELECTRIAL ACTIVITY (42)

This study was published in American Journal of Obstetrics and Gynecology 2013. This study was conducted at 3 medical centers namely Rabin Medical centres, Shaare Medical centre, Bnei Zion Medical centre at Isreal.

AIM

The primary aim of this study was to assess the uterine myometrial activity before and after Amniotomy using a novel technique of Electrical Uterine Myography (EUM).

This was a prospective study involving 23 women with term singleton pregnancy in active phase of labour between 4 to 8 cm dilatation. Electrical Uterine Myography was continuously measured for 30 minutes before Amniotomy and 30 minutes afer Amniotomy. EMU was measured using non invasive 9 channels recorder with an EMG amplifier and 3 dimensional sensor.

A scoring index was developed based on the period between contractions in seconds, power of contraction peaks in root mean square (RMS) and the movement of the centre of electrical activity in millimeter.

RESULT

Average power of contraction following Amniotomy was significantly enhanced compared to that of before (mean EUM measurements 3.21 ± 0.43 versus 3.44 ± 0.45, p value < 0.01).So they concluded that electrical uterine activity was increased following amniotomy in labour thus reinforcing that Amniotomy accelerates labour.

Table 1: Comparison between RCTS included in Cochrane review on Amniotomy for shortening spontaneous labour

Study name	Journal published	Sample size	Cervical dilatation at randomization	Primary outcome	Conclusion
Wetrich 1970	Obstetrics and gynecology volume 35, no5, may 1970	32 (16 in each arm)	6 cm	1 stage - shorten 2 stage- unaffected	ARM shortens the duration of labour by rapid completion of 1 st stage, second stage unaffected.
Laros 1972	Obstetrics and gynecology, volume 39,no5,may 1972	125(70 in ARM, 55 NON ARM)	5-8 cm	Mean active stage ,2 stage, both mean active and 2 stage duration shorten in primi ,Multi no difference	ARM does not accelerate the cervical dilatation in active phase of labour.
Stewart 1982	BJOG jan 1982, vol 89, pp 39--43	64 (34 in ARM, 30 in NON ARM)	≤ 4 cm	ARM shorten the duration of labour, decrease the need for oytocin augmentation	Supported the evidence of benefit from early amniotomy in improving the efficiency of labour.

Table 2: Comparison between RCTS included in Cochrane review on Amniotomy for shortening spontaneous labour

Franks 1990(43)	Journal of family practice 1990, 30; 49-52	53(26 in ARM,27 in NON ARM)	< 6 cm	ARM shorten the duration of labour	Shortens the duration of labour
Fraser 1991(44)	BJOG ,jan 1991, vol 98, pp 84-91	97 (47 ARM, 50 NON ARM) 38% -ARM in control group	3-5 cm	No significant difference in the interval from randomization to full dilatation	Failed to support the long held belief that early amniotomy is an effective method for reducing labour duration.
Barret 1992	BJOG jan 1992,volme 99,pp5-9	362(183 ARM,179 NON ARM) 46%-ARM in control group	4 cm	Significant decrease in duration of first stage of labour,no difference in 2 stage	Routine amniotomy results in slightly shorter duration of labour,but more epidural is needed suggesting labour is more painful

Table 3: Comparison between RCTS included in Cochrane review on Amniotomy for shortening spontaneous labour

Fraser 1993	N ENGL J MED 1993; 328(1145-9)	925(469 ARM, 463 ONARM), 51%-ARM in control group	3 or ≤3 cm	Significant decrease in duration of labour,decreases the duration of dystocia in primi,	Early amniotomy is an effective method of shortening the duration of labour and reducing the frequency of dystocia among nulliparous women in labour.
Garite 1993	AM J Obstet gynecol june 1993,168; 1827-32	459(235 ARM,224 NON ARM) 31%-ARM in control group	4-6 cm	Significant decrease in the active phase of labour, decreases the need for oxytocin augmentation	Elective amniotomy shorten the active phase of labour and decreases the need for oxytocin.
UK AMNIO TOMY 1994	BJOG 1994,volume101-pp307-309	1463(782 ARM, 681 NON ARM)	3-4cm	Significant decrease in mean duration of labour,no difference in LSCS rate	Beyond a modest shortening of labour,routine amniotomy has little effect on important outcomes ,shouldnot be recommended.

Table 4: comparison between RCTS included in Cochrane review on Amniotomy for shortening spontaneous labour

Blanch 1998(45)	BJOG, jan 1998,vol 105,pp 117-120	60 (1-ARM+Oxytocin,-2-ARM Only,3 Expectant Management)	Fully effaced, 3 cm	Encourage cervical dilatation and shorten dysfunctional labour- not statistically significant	Amniotomy alone without oxytocin shortens dysfunctional labour but not statistically significant.
Ajadi 2006	J obstet gynaecol 2006,oct 26(7)631-4	128(64 in each ARM)	4-5 cm	Significant decrease in duration of 1 stage	Amniotomy significantly reduces the duration of labour without affecting oxytocin requirement, LSCS rate, newborn outcome.
Shobieri 2007	International journal of gynecology and obstet 2007; 96(3), 197-8	80 (40 in each arm)	≥ 3cm	Significant decrease in duration of 1 stage of labour and dystocia, no difference in LSCS rate.	Amniotomy is an effective method of shortening the duration and reducing the frequency of dystocia.

THE WHO RECOMMENDATIONS FOR AUGMENTATION OF LABOUR **(still in press)**

The WHO Recommendations for augmentation of labour, does not recommend the use of ARM in spontaneous labour.

How where they have reiterated that this recommendations was based on low level of evidence, hence weak recommendations.

Thus there is need for large, well designed study that will give us clear answers to manage patients better.

METHODOLOGY

SAMPLE AND SETTING

This study was started in June 2014 and expected to complete in June 2015 at CMC Vellore. The study protocol was reviewed and approved by Institutional Review Board, Christian Medical College and Hospital, Vellore. Term pregnant women admitted to the labour room in spontaneous labour of the department of Obstetrics and Gynecology of the Christian Medical College and Hospital Vellore fulfilling the inclusion criteria and willing to participate were recruited in the trail. The study and the research procedure were fully explained to women and those who have given written consent were allowed to participate in the study. The consent was obtained in the regional language that the patient was conversant (annexure 4).

STUDY DESIGN

This trial is a randomized control trial (RCT) comparing the effects of amniotomy and non amniotomy on the duration of labour for women with spontaneous onset of labour.

SAMPLE SIZE

A sample size of 144 in each group will be sufficient to detect a clinically important difference of 1 hour duration of labour assuming a standard deviation of 3 hours using a independent't' test of the difference between means, a power of 80%, a significant level of 5%

The formula for the sample size for comparison of 2 means (2-sided) is as follows:

$$n = \frac{2 * \{Z_{(1-\alpha/2)} + Z_{1-\beta}\}^2 * \sigma^2}{d^2}$$

where

n = the sample size required in each group (double this for total sample).

σ= standard deviation of the primary outcome variable, 3 hour

d= size of difference of clinical importance, 1 hour

$Z_{(1-\alpha/2)}$ = desired significance level

$Z_{(1-\beta)}$ = desired power

$$n = \frac{2 * 7.84 * 3^2}{1}$$

n =144 in each arm

Block Randomization was used to allocate the women to either of the groups using varying block sizes 2, 4, 6 and 8 which was computer generated. Allocation

Concealment was done by the statistician by placing each allocation in separate identical opaque envelope consecutively with serial numbers of the subjects written outside the envelope.

PARTICIPANTS

All women in spontaneous labour with intact membranes were recruited in this trial if they fulfilled the following criteria

1. Low risk women.
2. Singleton pregnancy.
3. Vertex presentation.
4. Spontaneous labour.
5. Membranes intact.
6. Cervical dilatation 3-5 cm
7. 37 - 41 weeks of GA.

EXCLUSION CRITERIA

1. Previous bad obstetric history.
2. GDM on OHA's and insulin.
3. Pre-eclampsia
4. IUGR
5. Previous uterine surgery
6. Previous LSCS
7. Sero positive women
8. Para 4 or more.

MEASUREMENTS

The data collection was done in the data abstraction form (annexure 5) by the principal investigator of the study.

The following details were recorded specifically

1. Demographics-Age, height, weight, BMI, Gestational age, cervical dilatation at randomization, Position of the vertex, Station of the vertex.

2. Duration of labour-Time from randomization to delivery in minutes.

3. LSCS rate, need for ARM, need for oxytocin augmentation, CTG Abnormalities ,amnio-infusion, and cord prolapse.

4. PPH, Post partum endometritis, uterine hyper stimulation.

5. APGAR score, NICU admission, Neonatal sepsis.

When they are having good uterine contractions (3 contractions each lasting for 40-60 seconds in 10 minutes) per vaginal examination was done. If the cervical dilatation was 3-5 cm with intact membranes they were randomized by selecting the next serially numbered envelope.

The Randomization cannot be blinded to the treating obstetrician and the patients, since the rupture of membranes was obvious to the treating obstetrician and the patient.

INTER –OBSERVER BIAS

In order to overcome the inter-observer variation in determining the cervical dilatation, we cut out circles of varying diameters from 2-5 cm on a cardboard box and used this box while randomizing each patient. While examiner was doing per vaginal examination at randomization, his or her left hand was simultaneously introduced into the holes made in the box and the dilatation of cervix was compared to the diameter of the circle.

Demographic data and baseline characteristics were documented.

Thus the women were randomized to either one of the allocation

1. Amniotomy

2. Non amniotomy.

In labour all women had continuous fetal monitoring using cardiotocogram. Women were monitored for uterine contractions.

If required labour augmentation was done with oxytocin in aminotomy group. In non amniotomy group augmentation was done after the rupture of membranes at next PV. Per vaginal examination was done every 4 hours and Partogram was maintained. All further interventions was left to the discretion of the treating obstetrician.

OUTCOMES

PRIMARY OUTCOME:

The primary outcome was the duration of labour from the time of randomization to delivery in minutes.

SECONDARY OUTCOMES:

The secondary outcome was to evaluate the effectiveness of amniotomy in the need for oxytocin augmentation, need for ARM, FHR abnormalities and Caesarean section. We also assessed the maternal morbidities like post parum fever, post partum endometritis, postparum hemorrhage of greater than 500 ml blood loss.

The neonatal outcomes assessed were APGAR score of < 7 minutes, need for Resuscitation and NICU admission.

STATISTICAL ANALYSIS

Statistical analysis was carried out using commercial software SPSS (Statistical Package for social sciences) Version 16.0 or later. For continuous data, the descriptive statistics such as mean, median, standard deviation, minimum and maximum was presented. For categorical data, frequency and percentage were calculated and presented. The duration of labour between 2 arms were analyzed using Independent t test or Mann Whitney U test based on normality of the data. Association between mode of delivery and intervention was done by Chi Square test. For the data, Intention to treat analysis as well as per protocol analysis was done. Secondary outcomes were analyzed by Chi Square test.

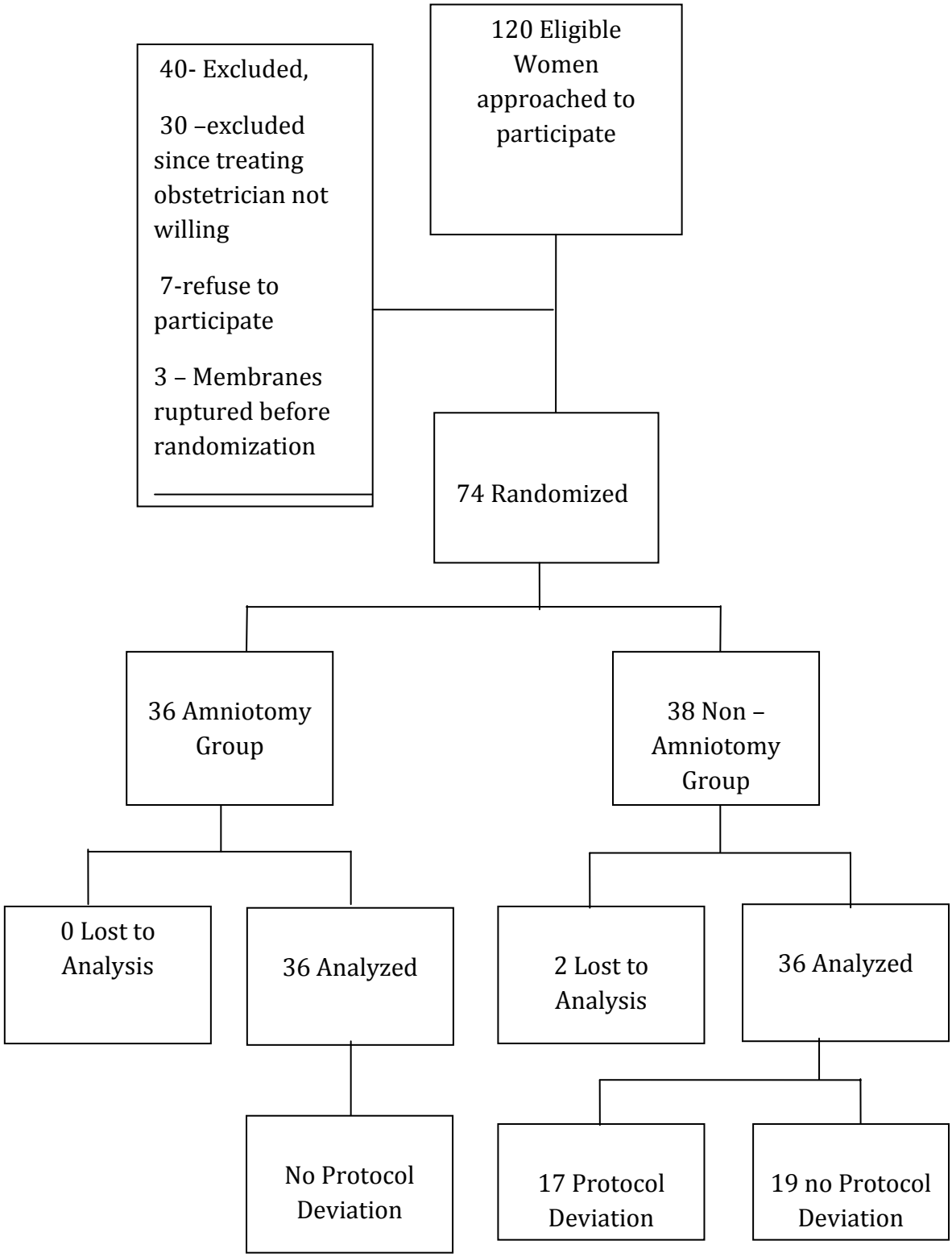
RESULTS

A total of 120 eligible women were approached to participate in this study. A total of 40 women were not randomized. Thirty women were excluded since the treating obstetrician was not willing, 7 refused to participate in the study due to fear even after repeated counseling, 3 women willing to participate in the study but ruptured the membranes before Randomization. So a total of 74 patients were randomized in this study. 36 women were randomized to Amniotomy group and 38 women in Non Amniotomy group.

In Non Aminotomy, two women were excluded from the analysis, one patient in whom labour was induced was mistakenly randomized into this study and the other was a women randomized to Non amniotomy group underwent amniotomy mistakenly. So 36 women were analyzed in each group.

In Amniotomy group, no women had protocol deviation, but in Non Amniotomy group, 17 had rupture of membranes at next per vaginal examination. 15 patients underwent amniotomy due to protracted labour, 2 patients had amniotomy for fetal distress to look for the colour of liquor.

FLOW CHART


120 Eligible Women approached to participate
40- Excluded,
30 –excluded since treating obstetrician not willing
7-refuse to participate
3 – Membranes ruptured before randomization
74 Randomized
36 Amniotomy Group
38 Non – Amniotomy Group
0 Lost to Analysis
36 Analyzed
2 Lost to Analysis
36 Analyzed
No Protocol Deviation
17 Protocol Deviation
19 no Protocol Deviation

BASELINE CHARACTERISTICS

Patient baseline characteristics prior to randomization showed no difference between the two groups. There was no significant difference in the maternal age, BMI, Gestational age between both groups.

The average age in the Amniotomy group 24.67 years with the range from 19-32 years.

The average age in the Non Amniotomy group 24.83 years ranging between 18-35 years.

AGE DISTRIBUTION

Table 5: Comparison of age between Amniotomy and Non amniotomy group

Group	Mean	SD	Minimum	Maximum
Amniotomy	24.67	3.7	19	32
Non-Amniotomy	24.83	3.5	18	35

Weight

The average weight in Amniotomy group was 58.83 kg, and the average weight in Non Amniotomy group was 61.18 kg.The lowest weight in amniotomy group was 47 kg and highest weight was 84kg.In non amniotomy group lowest weight was 44 kg and highest weight was 83kg.

Table 6: Comparison of weight between each groups

Group	Mean	SD	Minimum	Maximum
Amniotomy	58.83	7.76	47	84
Non Amniotomy	61.18	9.24	44	83

Height

The average height was 157 cm in Amniotomy group and 158 cm in Non Aminotomy group. In amniotomy group lowest height was 147 cm and highest height was 176 cm. In Non amniotomy group lowest height was 149 cm and highest was 170 cm.

Table 7: Comparison of height between each group

Group	Mean	SD	Minimum	Maximum
Amniotomy	157	3.20	147	176
Non Amnitomy	158	3.76	149	170

Body mass index

The mean body mass index in the Amniotomy group 23.67 kg/m^2 and in the non amniotomy group 24.39 kg/m^2.

Table 8: Distribution of BMI

Group	Mean	SD	Minimum	Maximum
Amniotomy	23.67	3.2	17.26	30.37
Non amniotomy	24.39	3.7	16.90	34.13

Table 9: Percentage distribution of BMI in Amniotomy and Non Amniotomy group

BMI	Amniotomy	Non amniotomy
Under weight (<18.5)	2.8%	8.3%
Normal weight (18.5-24.9)	55.6%	52.8%
Overweight (25-29.9)	38.9%	33.3%
Obesity (≥30)	2.8%	5.6%

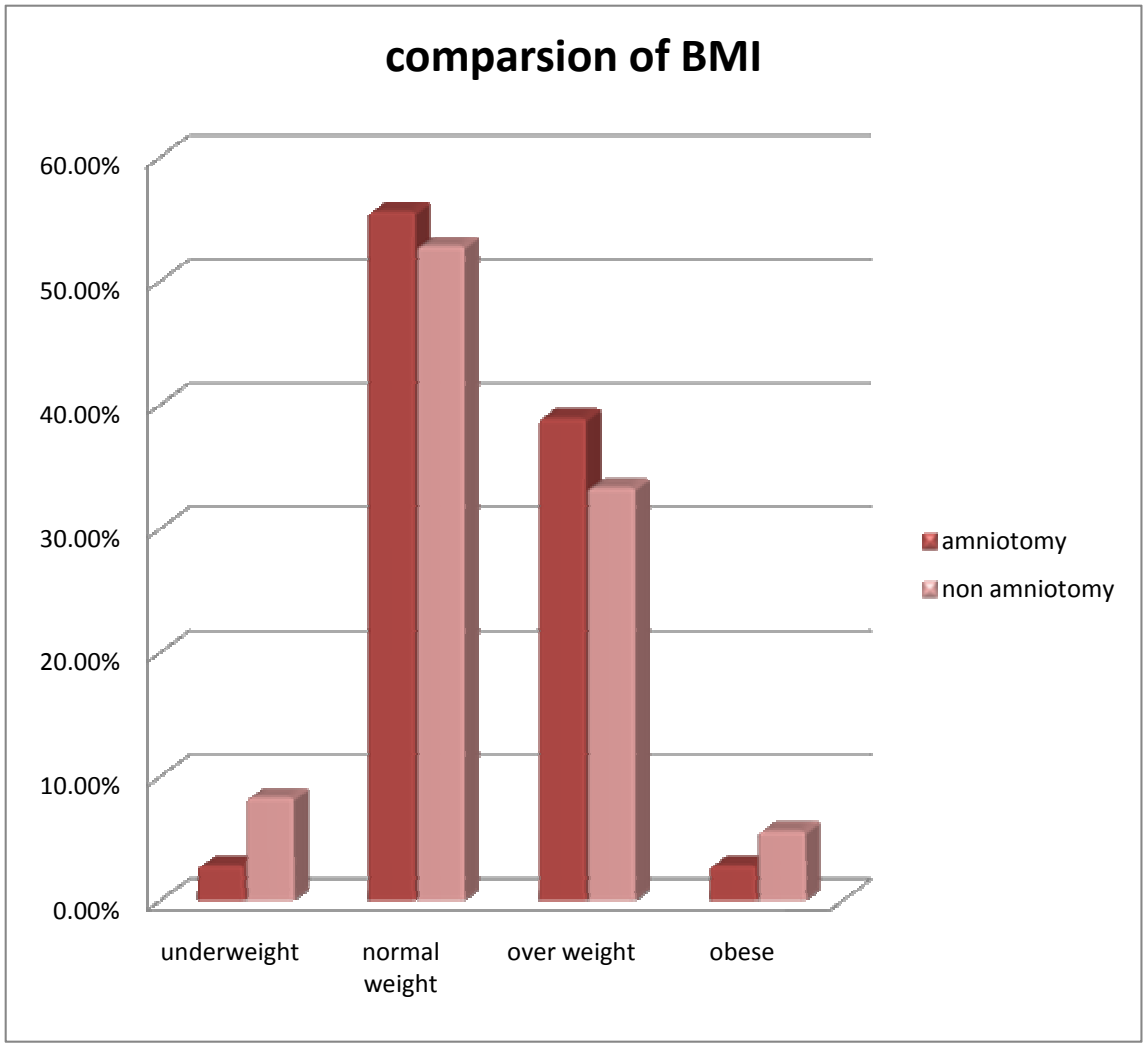


FIGURE 6: Comparison of BMI

GESTATIONAL AGE

Patients in the study were between 37 weeks and 41 weeks. The Mean Gestational age in Amniotomy group is 38.47 weeks and in non Amniotomy group is 38.86 weeks.

Table 10: Summary of gestational age

Group	Mean	SD	Minimum	Maximum
Amniotomy	38.4	0.878	37	41
Non Aminotomy	38.8	0.867	37	41

Distribution of parity

There were 44 nulliparous, 27 primiparous, 1 multiparous patients in the study inclusive of both groups.

In the Amniotomy group 61.1% were nulliparous 36.1% were primiparous and 2.8% were multiparous patients.

In Non Amniotomy group 61.1% were nulliparous 37.5% were primiparous and none multiparous

Table 11: Distribution of parity between each arm

Parity	Amniotomy	Non Amniotomy	Total
Nulliparous	22(61.1%)	22(61.1%)	44
Primiparous	13(36.10%)	14(38.9%)	27
Multiparous	01(2.80%)	00(0.00%)	01
Total	36	36	72

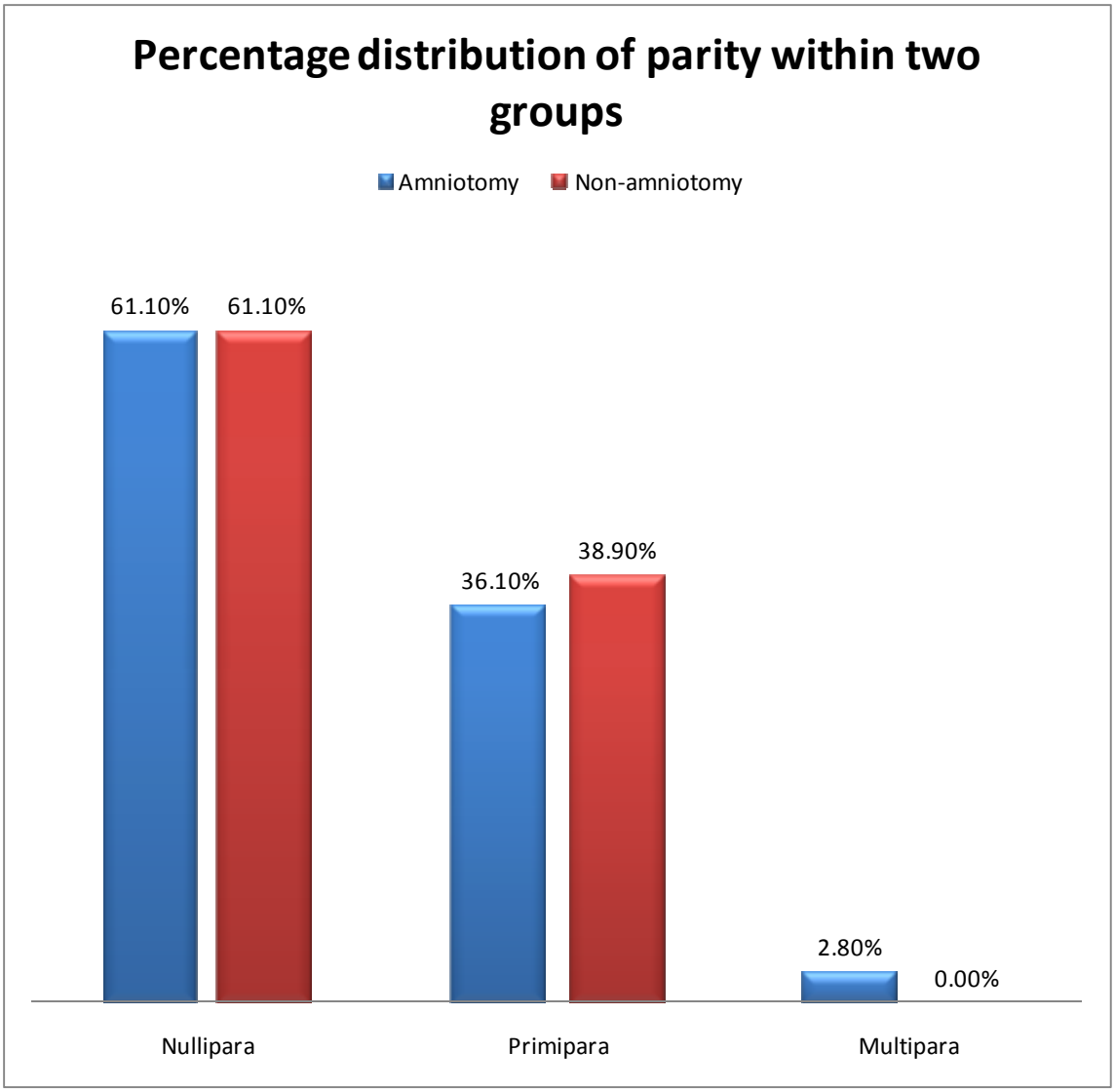


FIGURE 7: percentage distribution of parity within two groups

Cervical dilatation

In the Amniotomy group 41.7%were at 3cm, 27.8% at were at 4cm, 30.6% were at 5 cm cervical dilatation respectively.

In the non Amniotomy group 53.1% were at 3 cm, 31.9% were at 4 cm, 25% were at 5cm cervical dilation respectively.

Table 12: Comparison of cervical dilatation among both groups

Group	3 cm	4cm	5 cm	P-value*
Amniotomy	41.7%	27.8%	30.6%	**0.519**
Non amniotomy	43.1%	39.1%	25.0%	

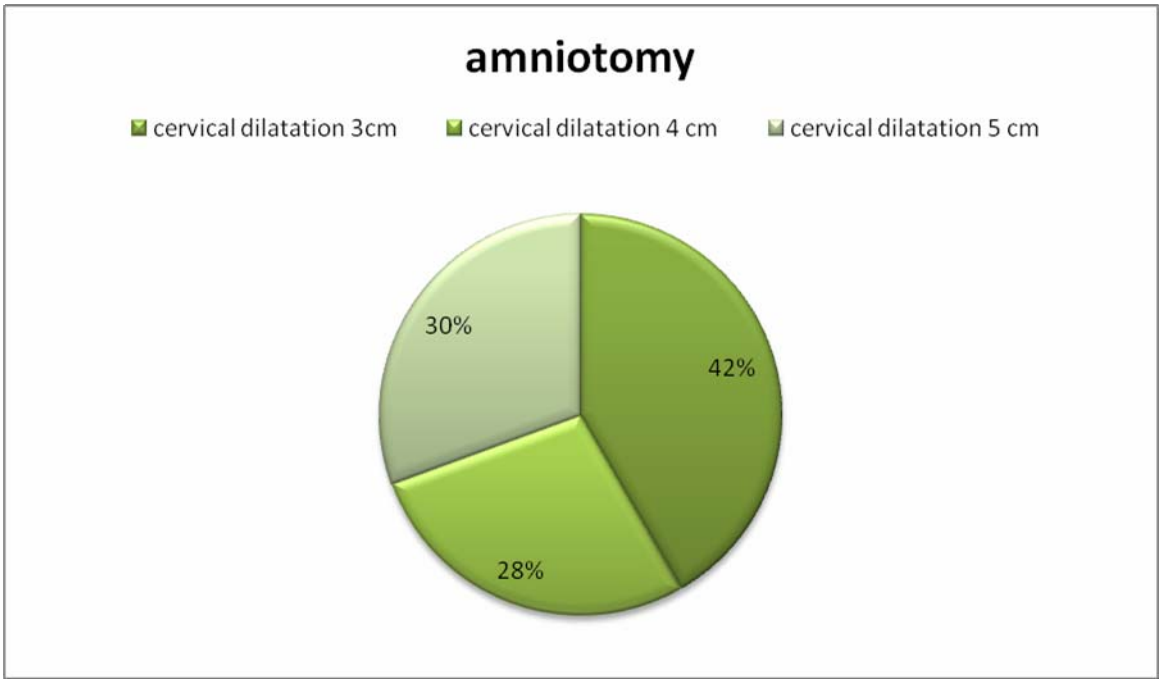


FIGURE 8: Cervical Dilatation in Amniotomy Group

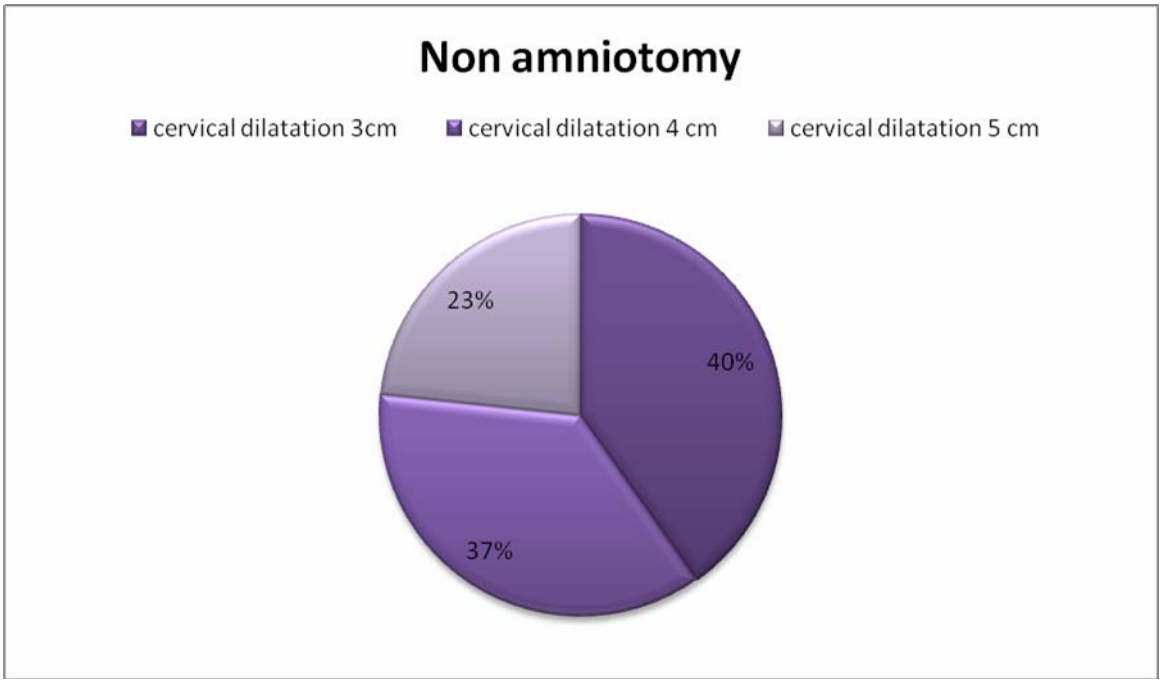


FIGURE 9: Cervical Dilatation in Non Amniotomy Group

Position of vertex

In Amniotomy group 44.4% were at occipito-anterior position,44.4% were at occipito-transverse position,8.3% were at occipito-posterior position.

In Non Amniotomy group 33.3% were at occipito-anterior position, 58.3% were at occipito-transverse position,5.6%were at occipito-posterior position.

Table 13: Comparison of position of vertex among both groups

Group	Occipito-Anterior	Occipito-Transverse	Occipito-Posterior
Amniotomy	44%	44.4%	8.3%
Non Amniotomy	33.3%	58.3%	5.6%

P value-0.486

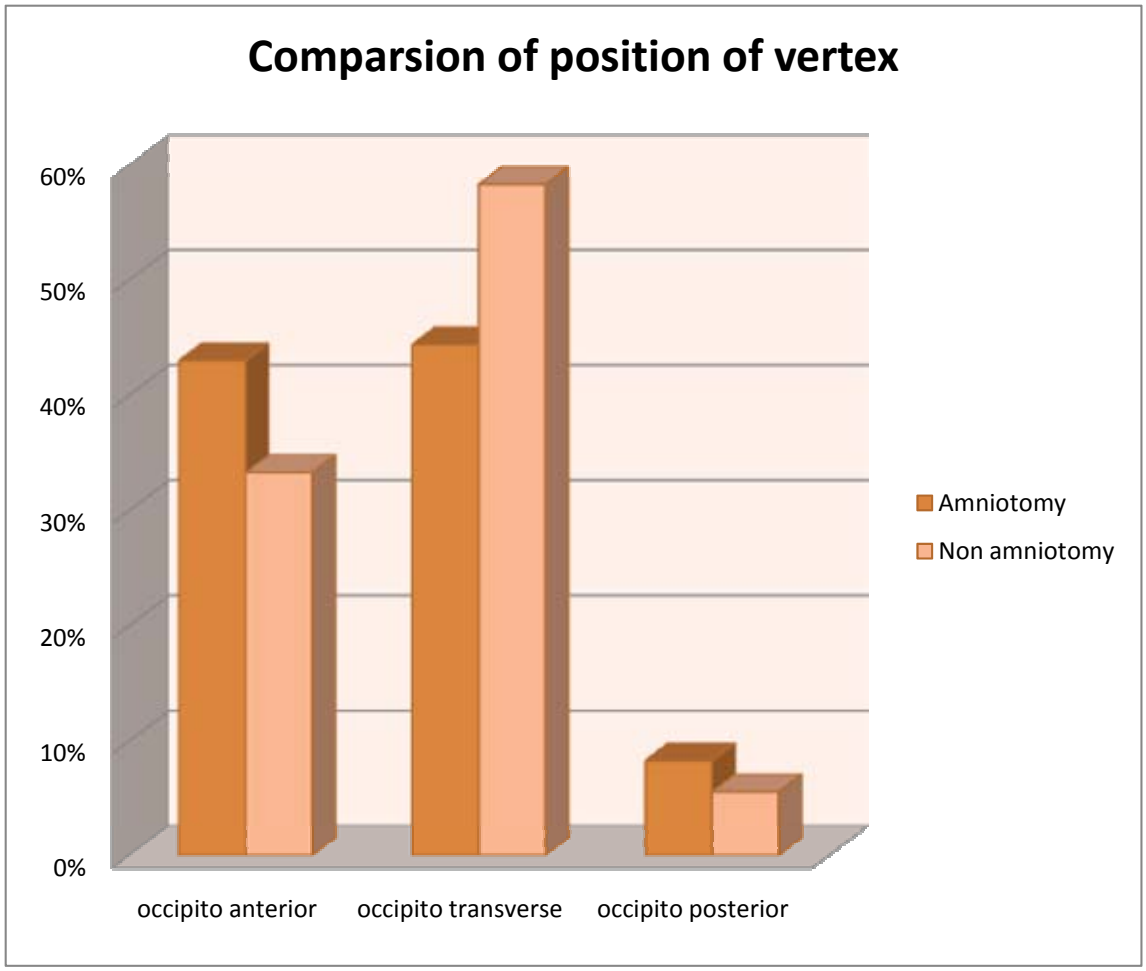


FIGURE 10: Comparison of position of vertex

Station of Fetal head

In the amniotomy group 36.1% were at -3 station,41.7% were at -2 station,16.7% were at -1%,5.6% were at 0 station respectively.

In Non Amniotomy group 50 % were at -3 station, 47.2% were at -2 station, none at -1 station, 2.8% at 0 station.

Table 14: Station of fetal head among both groups

Station of fetal head	Amniotomy	Non Amniotomy	P value
-3	36.1%	50.0%	0.064
-2	41.7%	47.2%	
-1	16.7%	0.0%	
0	5.6%	2.8%	

Table 15 : Comparison of Baseline Characters.

Baseline Characteristics	**ARM N=36**	**No ARM N=36**
Age in Years	24.7	24.8
BMI (Kg / m^2)	23.67	24.69
GA in Weeks	38.4	38.8
Nulli Parity	61%	61%
Cervical Dilatation		
3 cm.	41.7%	43%
4 cm.	28%	39%
5 cm.	37%	25%
Position of Vertex		
Occipito Anterior	43%	33.3%
Occipito Transverse	44.4%	58.3%
Occipito Posterior	8.3%	5.6%
Station – 3	36.1%	50%
- 2	41.7%	47.2%
Birth Weight in Grams	3042	3098
MSAF	25%	22.2%

Duration of labour

The primary outcome of this RCT was to calculate the duration of labour measured from the time of randomization to delivery in minutes between 2 groups.

The mean duration of labour in Amniotomy group was 276.19 minutes.

The mean duration of labour in Non Aminotomy group was 369.47 minutes.

The mean difference between the duration of labour between Amniotomy and Non Amniotomy group was 93.28 minutes.

Table 15: Duration of labour among both groups

Group	Mean	SD	Minimum	Maximum
Amniotomy	276.19	181.34	07	776
Non Amniotomy	369.47	222.23	54	893

P Value-0.065

In this study P value was not statistically significant. This is because the sample size is not completed and sample used to calculate the P value was 72 instead of 288. Even though P value was not statistically significant at the interim analysis, we expect the P value to show significant difference at the completion of sample size.

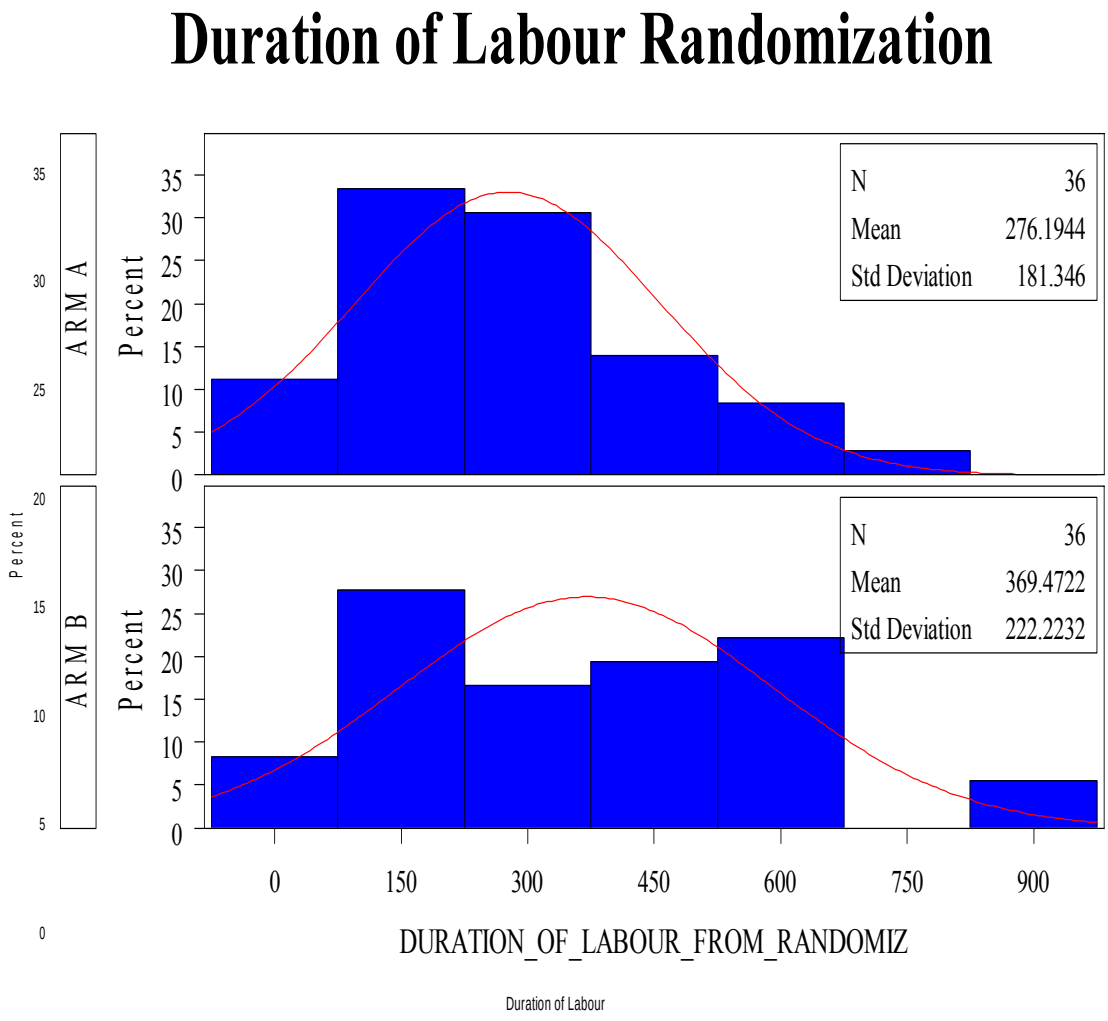


FIGURE 11: Comparison of duration Labour from Randomization to Delivery

Table 16: Duration of Labour per protocol analysis

Arm	N	Mean	Std Dev	Mini.	Maxi.	P Value*
Amniotomy	36	276.2	181.3	7.0000	776.0	
Non Amniontomy	19	234.2	158.3	54.0000	624.0	0.3983

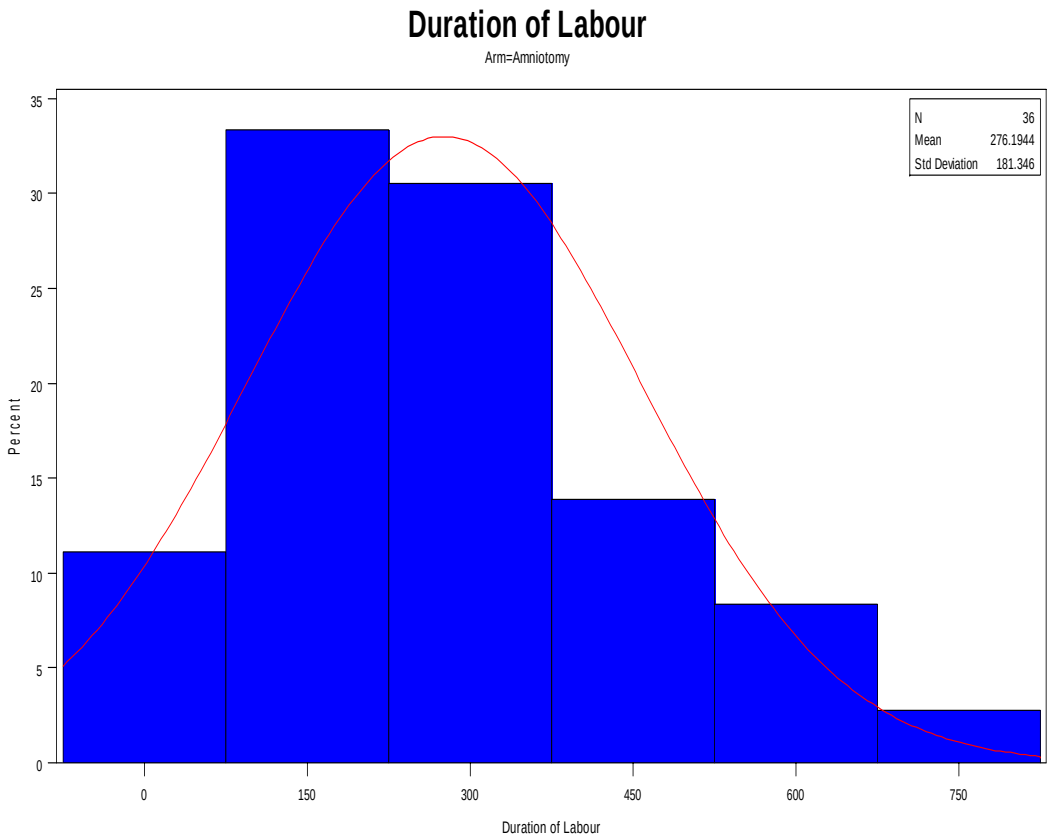


FIGURE 12: Duration of Labour in Aminotomy Group-per protocol analysis

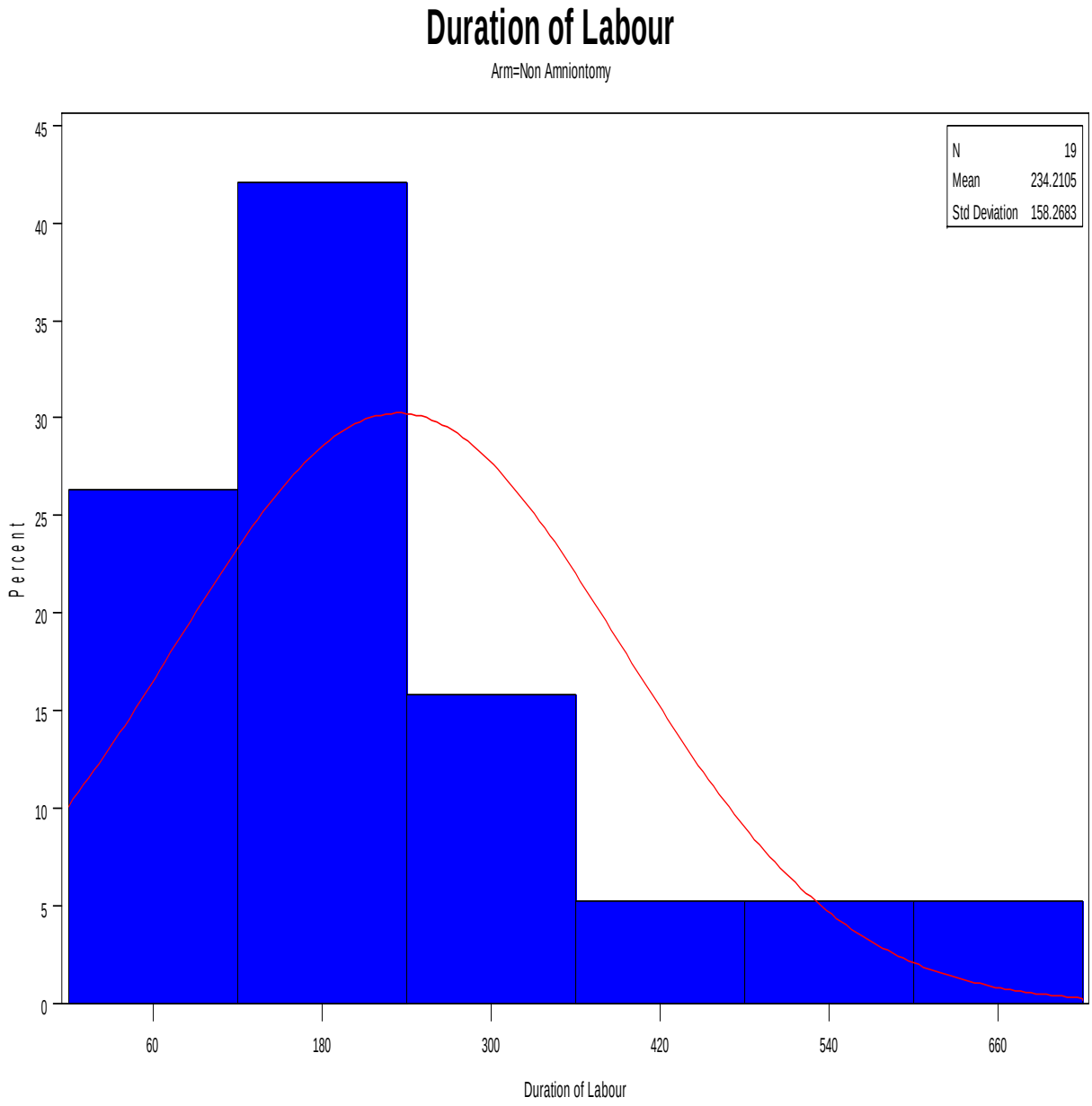


FIGURE 13: Duration of Labour in Non Aminotomy

CTG ABNORMALITIES

In Amniotomy group 25.0% were having abnormal FHR tracings, In Non Amniotomy group 22.2% were having abnormal FHR tracings.

Almost all the decelerations observed in this study were CATEGORY 2 and were Recurrent Variable Decelerations.

Table 16: Comparison of CTG Abnormalities between groups.

CTG Abnormalities	Amniotomy	Non Amniotomy	P value
Present	25%	22.2%	**0.781**
Absent	75%	77.8%	

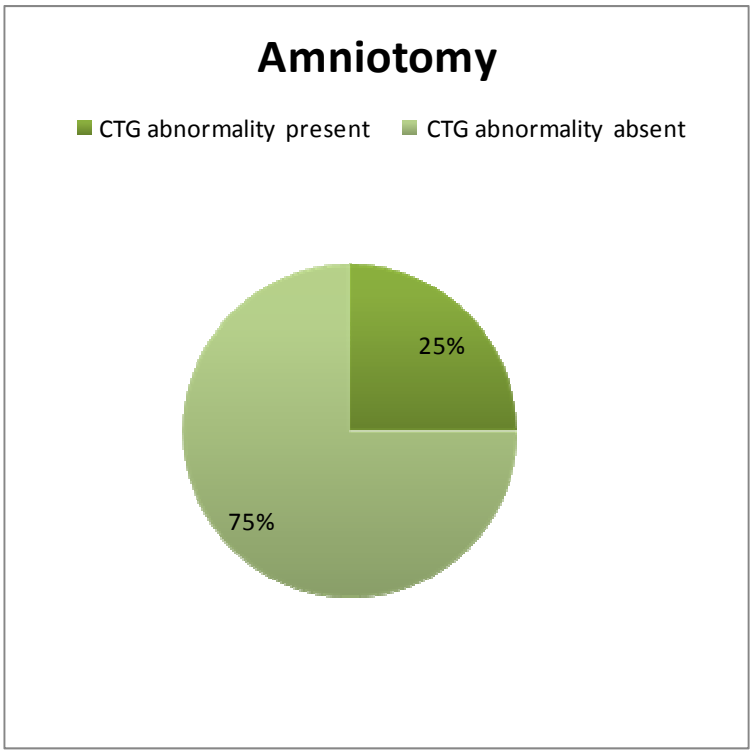


FIGURE 14: CTG Abnormality in Aminotomy Group

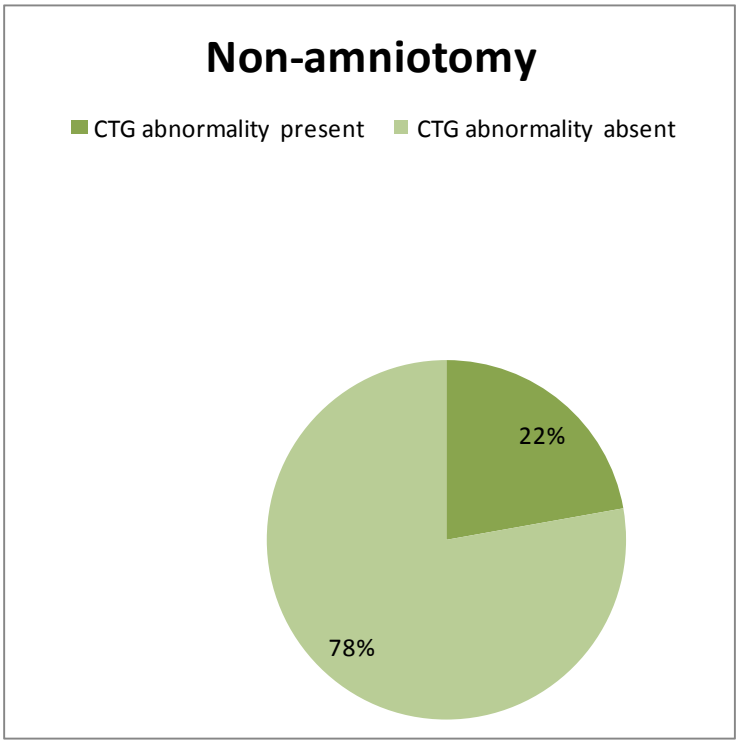


FIGURE 15: CTG Abnormality in Non - Aminotomy Group

COLOUR OF LIQUOR

In amniotomy group 80.6% were having clear liquor, 19.4% were having Meconium stained amniotic fluid (MSAF).

In Non Amniotomy group 86.1% were having clear liquor, 13.9% were having Meconium stained amniotic fluid (MSAF).

All most all of the Meconium stained amniotic fluid were of thin MSAF (Grade1, 2)

Table 17: Comparison of Colour of Liquor between groups

Colour of liquor	**Amniotomy**	**Non Amniotomy**	**P-value**
Clear liquor	80.6%	86.1%	**0.527**
MSAF	19.4%	13.9%	

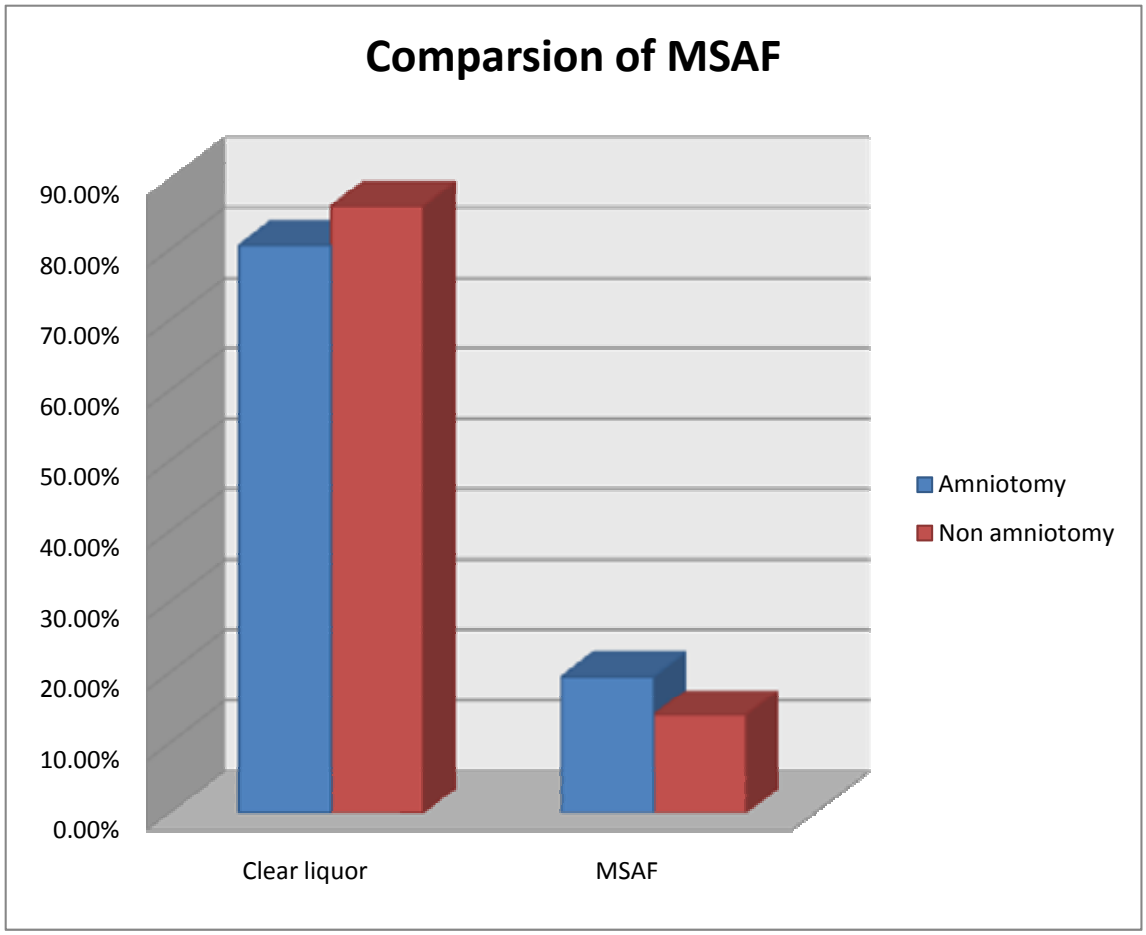


FIGURE 16: Comparison of MSAF between both Groups

OXYTOCIN REQUIREMENT

In amniotomy 41.7% were requiring Oxytocin for Augmentation of labour, 42.95 weren't requiring Augmentation.

In Non Amniotomy group 34.8% were requiring Oxytocin for Augmentation, 51.75 % weren't requiring Augmentation.

Table 18: Comparison of Oxytocin requirement among both groups.

Oxytocin required	**Amniotomy**	**Non Amniotomy**	**P value**
Yes	15 (41.7%)	8 (22.2%)	**0.077**
No	21 (58.3%)	28(77.8%)	

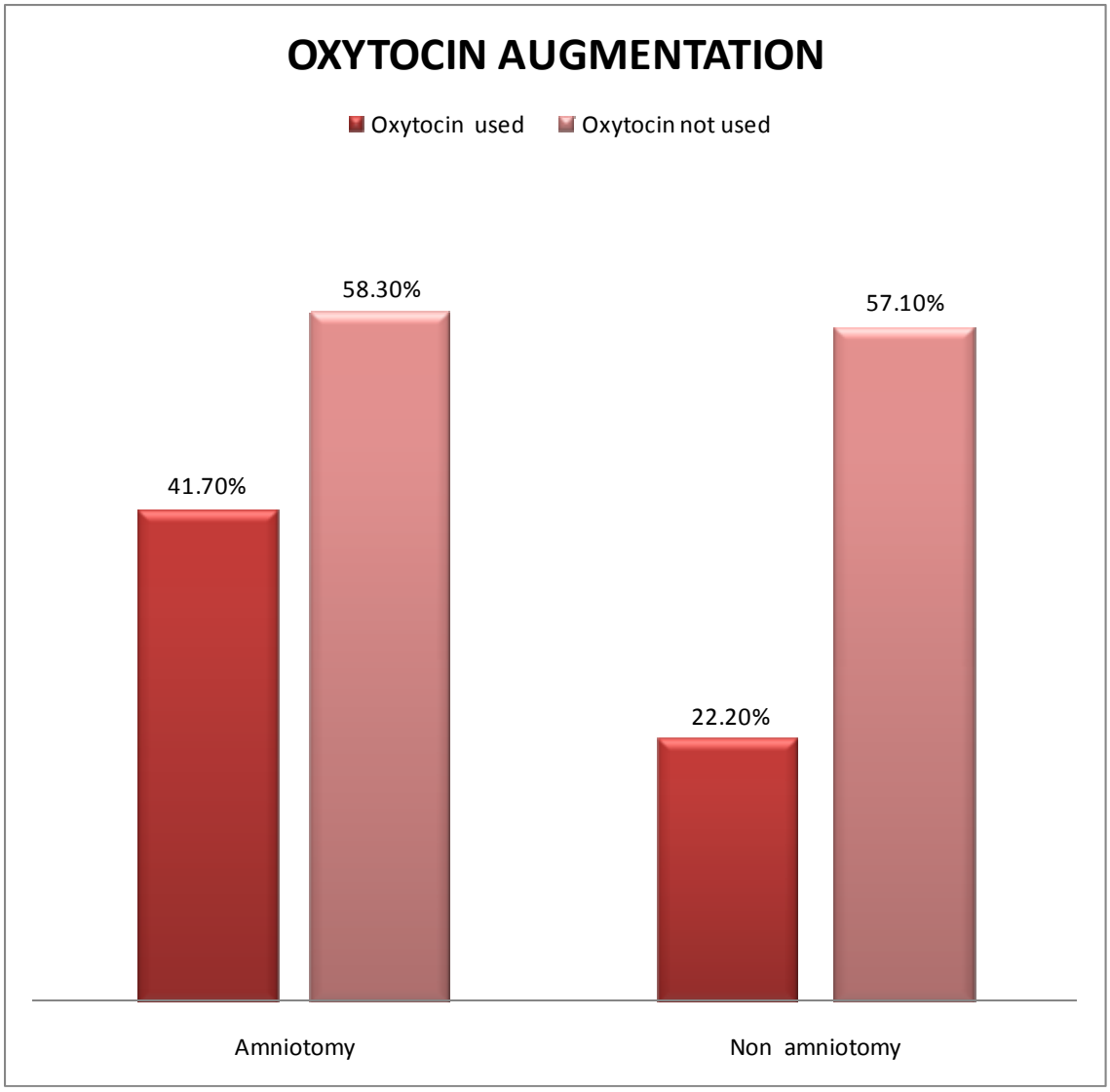


FIGURE 17: Oxytocin Augmentation

Units of oxytocin used

The median number of units of oxytocin used in Amniotomy and Non Amniotomy group was 2.5 units in each.

Table 19: Median of units of oxytocin required in each group.

	Median	**IOR**
Amniotomy group	2.500	2.5-2.5
Non Amniotomy group	2.500	2.5-2.5

AMOUNT OF OXYTOCIN USED

Amount of oxytocin used	**Amniotomy group**	**Non Amniotomy group**
2.5 U-100 ml	4 (26.7%)	4 (50.0%)
2.5 U-200 ml	6(33.4%)	2(25%)
2.5 U-300 ml	1(6.7%)	2(25%)
2.5 U-400ml	2(13.3%)	0 (0.0%)
2.5 U-500 ml	3 (20.0%)	0 (0.0%)

Amnioinfusion

In amniotomy group 8.3% were requiring amnio - infusion for CTG abnormality category 2 deceleration,

In Non Amniotomy group 2.8% were requiring amino - infusion for CTG abnormalities category 2 deceleration.

Table 20: Comparison of amnioinfusion requirement among both groups

Amnio-infusion required	Amniotomy	Non Amniotomy	P value
Yes	3 (8.3%)	1 (2.8%)	
No	33 (91.7%)	35(97.2%)	**0.303**
Total	36(100%)	36(100%)	

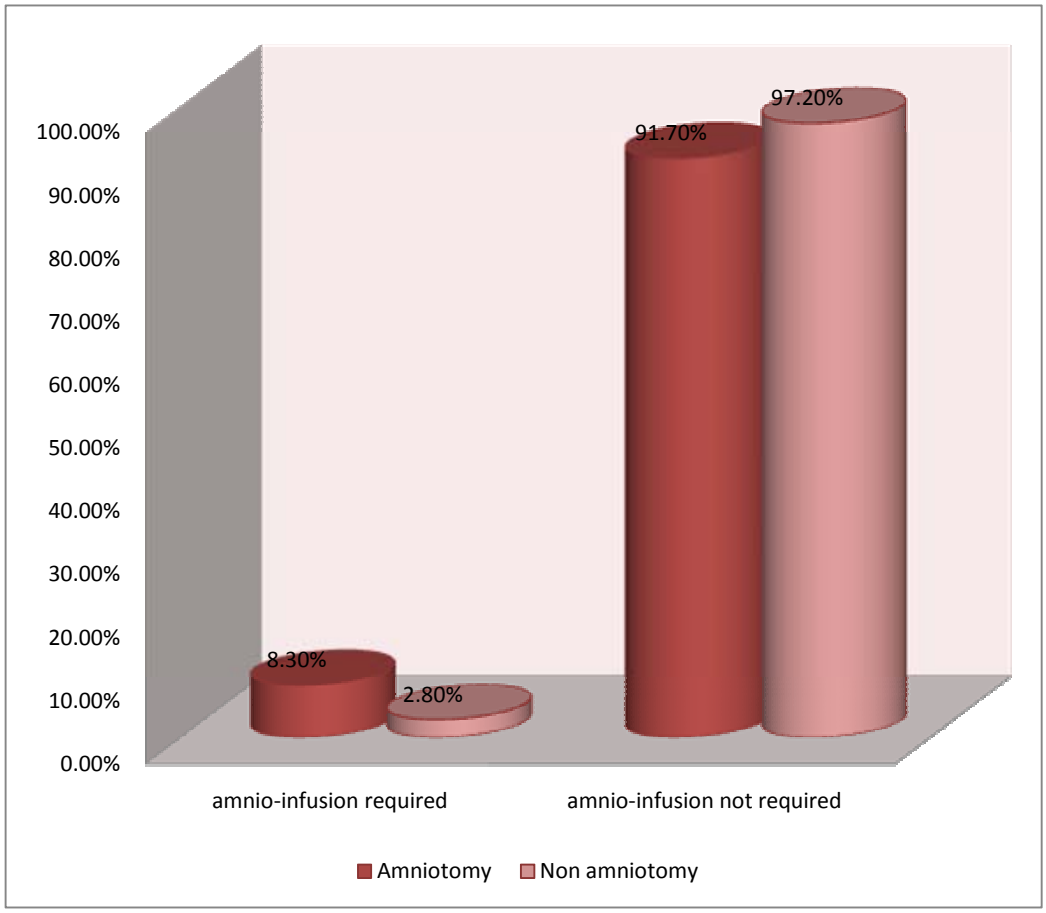


FIGURE 18: Comparison of Amnio infusion between both Groups

Mode of delivery

Among all the patients 54 delivered vaginally, 16 patients requiring assistance by instrument and 2 patients delivered by caesarean.

In amniotomy group 26 delivered vaginally, 09 patients requiring assistance by instrument and 1 patient delivered by caesarean.

In non amniotomy group 28 delivered vaginally, 07 patients requiring assistance by instrument and 1 patient delivered by caesarean.

Table 21: Comparison of mode of delivery among both groups

Mode of delivery	Amniotomy	Non Amniotomy	Total
Vaginal delivery	26 (72.2%)	28 (77.8%)	54(75%)
Instrumental	09 (25.0%)	07 (19.4%)	16(22.2%)
Caesarean section	01 (2.8%)	01 (2.8%)	02(2.8%)
Total	36 (100%)	36(100%)	72(100%)

P Value-0.850

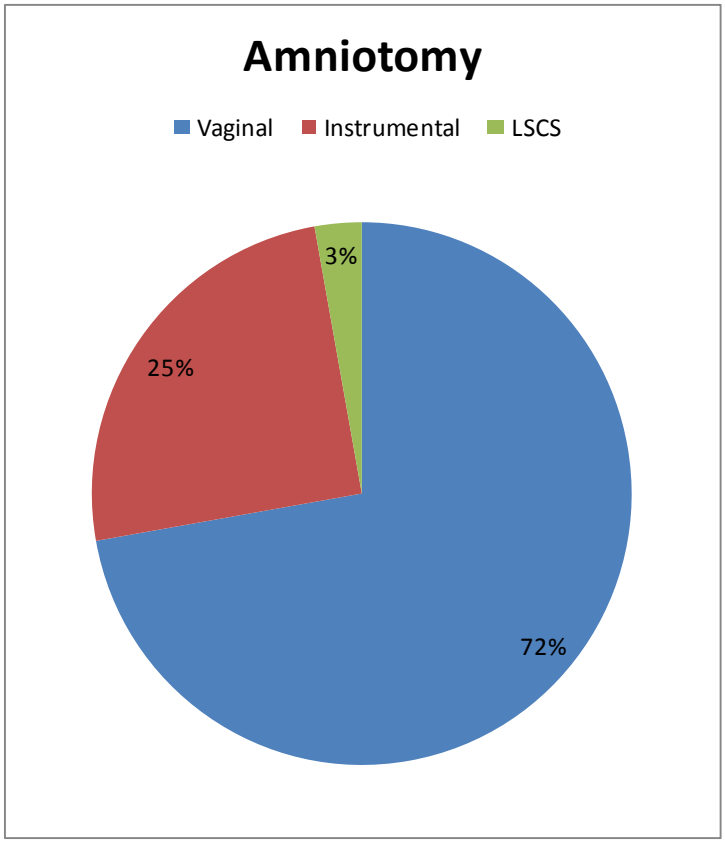


FIGURE 19: Mode of Delivery in Aminotomy

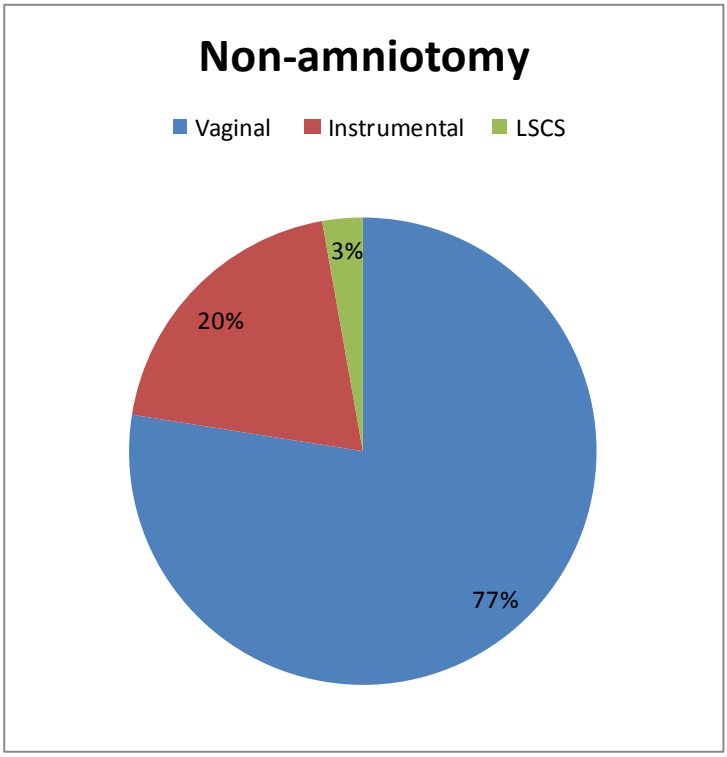


FIGURE 20: Mode of Delivery in Non Aminotomy

Post partum haemorrhage

In amniotomy group 11.1% had Post partum haemorhage, wheras in Non Amniotomy group 8.3% had PPH.

Table 22: Comparison of PPH among 2 groups

PPH	Amniotomy	Non amniotomy	P value
Present	4 (11.1%)	3(8.3%)	**0.691**
Absent	32(88.9%)	33 (50.8%)	

APGAR SCORE

In amniotomy group no neonate had APGAR score of < 7 at 5 minute, whereas in Non Amniotomy group 1 neonate had APGAR score of < 7

Table 23: Comparison of APGAR score between 2 groups

APGAR score at 5 minute	**Amniotomy**	**Non Amniotomy**	
< 7	0(0%)	1(2.8%)	**P value**
9	2(5.6%)	1(2.8%)	**0.513**
10	34(94.4%)	34(94.4%)	

BIRTH WEIGHT

In the amniotomy group the mean birth weight was 3042 gms and in the non amniotomy group the mean birth weight was 3098 gms

Table 24: Comparison of birth weight between 2 groups

Group	Mean birth weight (grams)	SD	Minimum	maximum	P value
Amniotomy	3042.8	344.3	2450	3840	**0.510**
Non amniotomy	3098.6	373.7	2400	3900	

Need for resuscitation

In amniotomy group no neonate need resuscitation, whereas in Non Amniotomy group 1 neonate needed resuscitation .

Table 25: Comparison of Resuscitation between 2 groups

Resuscitation	**Amniotomy**	**Non Amniotomy**	**P value**
Needed	0(0%)	2(5.6%)	**0.151**
Not needed	36(100%)	34(94.4%)	

NICU Admission

In both arms 1 neonate needed admission to NICU

Table 26: Comparison of NICU admission

NICU Admission	Amniotomy	Non Amniotomy	
Yes	1(2.8%)	1(2.8%)	**P value**
No	35(97.2%)	35(97.2%)	**1.000**

Neonatal complication

In amniotomy group 1 neonate had sepsis started on antibiotics.

In Non Amniotomy group1 neonate had respiratory distress on antibiotics, 1 neonate had clavicular fracture after suction cup delivery

Table 27: Comparison of Neonatal complication between both groups

Neonatal complication	Amniotomy	Non Amniotomy	
Sepsis	1 (2.8%)	0(0%)	**P value**
Respiratory distress	0(0%)	1(2.8%)	**0.389**
Others	0(0%)	1(2.8%)	

Table 28: Comparison of outcomes between both groups

Primary Outcome	**ARM N = 36**	**No ARM N=36**	**P – Value**
Duration of Labour from Randomization to Delivery	276 min.	370 min.	0.06
Secondary Outcomes			
CTG Abnormality	25%	22%	0.7
Amnioinfusion	1/36 (2.8%)	1/36 (2.8%)	0.03
Oxytocin Augmentation	15/3 (41.7%)	8/36 (22.2%)	0.07
Mode of Delivery LSCS	1/36 (2.8%)	1/36 (2.8%)	0.085
PPH	4/36 (11.1%)	3/36 (8.3%)	0.69
Postpartum Endometritis	0.0%	0.0%	0.0
NICU Admission	1/36 (2.8%)	1/36 (2.8%)	1.0
Neonatal Sepsis	1/36 (2.8%)	0/36 (0.0%)	0.3
Protocol Deviation	0.0%	17/36	0.39

DISCUSSION

Intentional artificial rupture of membranes is one of the commonly performed procedures in modern Obstetrics. The aim of this randomized control study is to assess the effectiveness of routine amniotomy in reducing the duration of labour in women having spontaneous onset of labour .Two Cochrane reviews with no clear inclusion criteria have been published. Both the reviews have conflicting evidence.

The drawbacks of Cochrane review were that outcome was influenced by poor quality studies. The studies had variable inclusion criteria. Cervical dilatation for inclusion was anything between3-8 cm. More than half of the women in the no amniotomy group needed amniotomy.

In our study the mean age of the patients was 25 years in both the groups and 61.1% in both the groups were nulliparous. The average body mass index was similar in both the arms (23.67kg/m^2 versus 24.69 kg/m^2).Women in both the groups belonged to a mean gestational age of 38 weeks. The Baseline characteristics were similar in both the groups confirming that randomization was followed.

At randomization in Amniotomy group 44.4% of them were in the occipito anterior position, 44% of them having occipito-transverse position and 8.3% having occipito-posterior. In non-Amniotomy 58.3% were having occipito-transverse position 33.3% of occipito-anterior and 5.6% of occipito-posterior positions.

The mean duration of labour in the Amniotomy group was 276.19 minutes and in non -Amniotomy group 369.47 minutes. The mean difference between both the groups was 93.28 minutes. However this was not found to be statistically significant with a P value of 0.06. This may be because the sample size could not be completed .

No women in Amniotomy group underwent protocol deviation whereas 17 out of 36 recruited women in non amniotomy underwent protocol deviation. The reason for protocol deviation in non Amniotomy were mainly prolonged labour and fetal distress. Out of 17 women 15 women underwent amniotomy at their next per vaginal examination due to prolonged labour and 2 women had fetal distress and underwent amniotomy to see the colour of liquor.More than 50% of women were requiring amniotomy in non amniotomy group.The data were analyzed by intention to treat analysis as well as per protocol analysis also.

The LSCS rate was similar between both groups (2.8% in both the arms). Thus there was no difference between both groups in the LSCS rate but it was not statistically significant since the P value was 0.850.

There were no difference in the number of women achieved vaginal and instrumental delivery between both the groups. One women in the non amniotomy group underwent LSCS the indication being protracted dilatation ,another women in

Amniotomy group underwent LSCS for arrest of dilatation were cervix remained 6 cm after 4 hours with good uterine contractions augmented with oxytocin.

The oxytocin requirement was more in Amniotomy group compared with that of non amniotomy group (65.2% versus 22.2%) with a P value of 0.06.Even though we except the oxytocin requirement to be less in Amniotomy group, it is increased. The reason for this may be due to the low threshold to start oxytocin following artificial rupture of membranes in our Institution.

The CTG abnormalities between both the groups were the same (25% versus 22.2%). The most common CTG abnormality found between both the groups as is commonly known were Category 2 decelerations. The decelerations were having mild to moderate recurrent variable decelerations. In this study no women had Category 3 decelerations.

Meconium stained amniotic fluid was slightly higher in Amniotomy group compared to non Amniotomy group (19.4% versus 13.9%) with a P value of 0.527. Amnio-infusion is one of the commonly used practice used in our Institution for Recurrent Variable Decelerations following Amniotomy, even though not practiced in many other centres. The requirement for Amnio infusion is increased in Amniotomy group compared to non amniotomy group (8.3% vs 2.8%) with a P value of -0.303 not statistically significant. This probably is instrumental in not increasing the LSCS rate.

In both the groups there was no women having Uterine Hyper stimulation with fetal heart changes and requiring Terbutaline.

In both the groups no women had Cord Prolapse so far. However the sample size was small.

The incidence of Post Partum Hemorrhage were same between both the groups (11.1% VS 8.3%). 4 women in Amniotomy group and 3 women in non Amniotomy group had PPH which were managed by Medical Management and no Surgical intervention needed.

In both the groups no women had Post Partum Endometritis, 1 women had post partum fever in non amniotomy group which was due to Urinary tract infection and responded to antibiotics.

The mean birth weight in each group was 3042 grams versus 3098 grams respectively. There was one neonate in non amniotomy group had APGAR score of < 7 at 5 minute.

One neonate in the non Amniotomy group was admitted in NICU with respiratory distress requiring antibiotics. One neonate in the amniotomy group was admitted to NICU with Meconium Aspiration Syndrome and was depressed at birth.

LIMITATIONS

This study was performed in a tertiary level hospital which serves more than 12,000 women in labour annually. Time factor was the major limitation in this study since the sample size was not completed. We did not have dedicated research personnel, a few patients were randomized outside the inclusion which could have been avoided. Some women were not included in this study since the treating Obstetrician were not willing. We have not recorded the cervical dilatation at which women underwent Amniotomy in Non amniotomy group and we suggest that it should have been done.

CONCLUSION

Our study did not complete the requested sample size. Our study found that amniotomy reduces the duration of labour by more than 1.5 hours compared with Non Amniotomy group. However this was not statistically significant. The rate of cesarean section was similar in both the groups. The need for Oxytocin augmentation is slightly increased in Amniotomy group. Amniotomy was required in more than 50% of patients in non Amniotomy group. There were more mild to moderate variable decelerations in the amniotomy group so an increase need for amnio-infusion. Amniotomy had no increase in the incidence of maternal and neonatal outcomes compared with non amniotomy group. However no statistical significance was present in any of these findings.

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ANNEXURES

ANNEXURE I – INSTITUTIONAL REVIEW BOARD CLEARANCE

ANNEXURE II – ORIGINALITY CERTIFICATE

ANNEXURE III – PATIENT INFORMATION SHEET

ANNEXURE IV – PATIENT CONSENT FORM

ANNEXURE V – PROFORMA

ANNEXURE VI – MASTER SHEET

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph D., FSMS, FRSS.,
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Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
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Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
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Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

July 14, 2014

Dr. V. Malarvizhi
PG Registrar
Department of Obstetrics and Gynecology Unit 5
Christian Medical College,
Vellore 632 004

Sub: **Fluid Research Grant Project:**
Effect of amniotomy on the duration of spontaneous labour (ARM study).
Dr. V. Malarvizhi, PG Registrar, Dr. Jiji Elizabeth Mathews, Dr. Santosh Benjamin,
Dr Anuja Abraham, Dr Swathi Rathore, Obstetrics and Gynecology Unit 5;
Dr B Antonisamy, Biostatistics, CMC, Vellore.

Ref: IRB Min No. 8918 [INTERVEN] dated 25.06.2014

Dear Dr. V. Malarvizhi,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Effect of amniotomy on the duration of spontaneous labour (ARM study)," on June 25th 2014.

The Committee reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. V. Malarvizhi, Jiji Elizabeth Mathews, Santosh Benjamin, Anuja Abraham, Swathi Rathore, B Antonisamy
3. Informed Consent form (English, Tamil & Hindi)
4. Information Sheet (English, Tamil & Hindi)
5. No of documents 1-4

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on June 25th 2014 at 9.45 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Name	Qualification	Designation	Affiliation
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Dr. Biju George	MBBS, MD, DM	Professor, Haematology, CMC, Vellore	Internal, Clinician
Dr. B. Poonkuzhali	MSC, PhD	Professor, Haematology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
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Dr. L Jeyaseelan,	M. Sc, PhD, FRSS	Professor, Biostatistics, CMC, Vellore	Internal, Statistician
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Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB.	External, Clinician
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Dr. P. Zachariah	MBBS, PhD	Retired Professor, CMC, Vellore	External, Scientist

IRB Min No: 8918 [INTERVEN] dated 25.06.2014

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Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. Jayaprakash Muliyil	BSC, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist
Dr. Vinitha Ravindran	PhD (Nursing)	Professor & Addl. Deputy Dean, College of Nursing, CMC, Vellore	Internal, Nurse
Mrs. Ruma Nayak	M Sc (Nursing)	Professor, Head of Paediatric Nursing & Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Binu Susan Mathew	MBBS, MD	Associate Professor, Clinical Pharmacology CMC, Vellore	Internal, Pharmacologist
Dr. Shirley David	M.Sc, PhD	Professor, Head of Fundamentals Nursing Department, CMC, Vellore	Internal, Nurse
Rev. Dr. T. Arul Dhas	M. Sc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL	Sr. Legal Officer, CMCH.	Internal, Legal Expert
Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

IRB Min No: 8918 [INTERVEN] dated 25.06.2014

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block; Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

The trial need to be registered with Clinical Trial Registry India (CTRI) http://ctri.nic.in before commencing.

The study has to report to Internal Data Safety Monitoring Board (DSMB) http://172.16.11.136/Research/IRB_Policies.html on quarterly basis.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Effect of amniotomy on the duration of spontaneous labour (ARM study)." on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

Yours sincerely

CHRISTIAN MEDICAL COLLEGE VELLORE INDIA

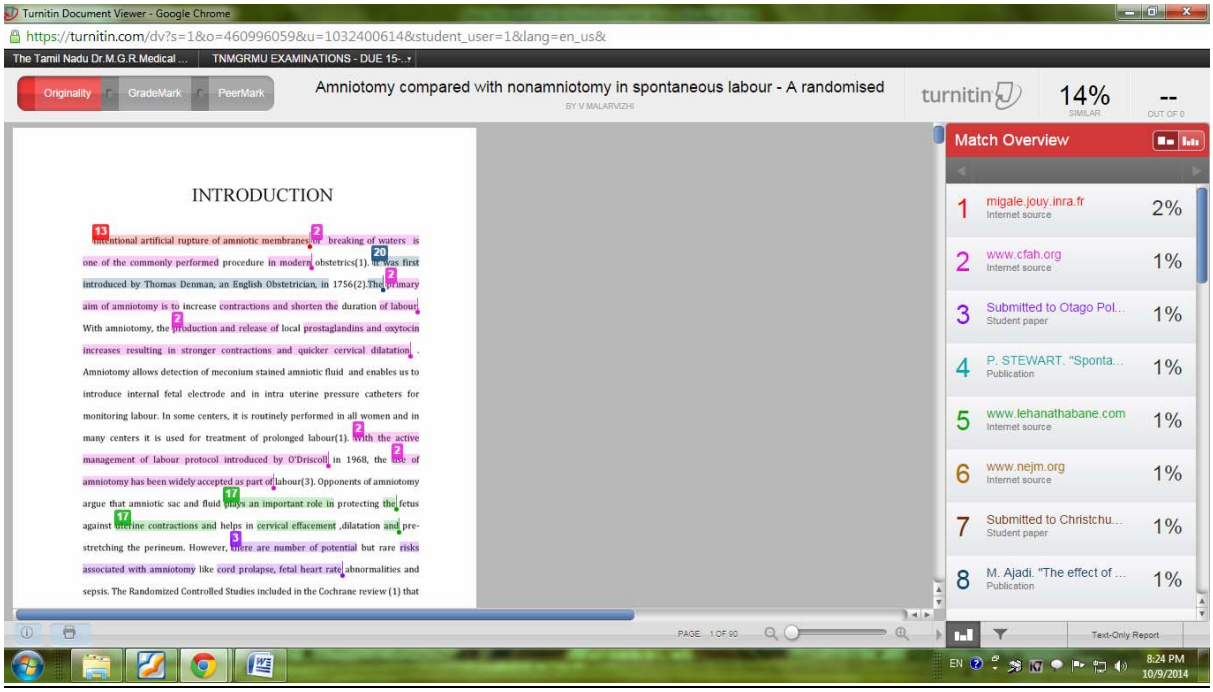
Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min No: 8918 [INTERVEN] dated 25.06.2014

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

ORIGINALITY CERTIFICATE



PATIENT INFORMATION SHEET

With normal labour pains, the baby with the bag of water around it in the uterus will push on to the opening of the uterus, dilate it and eventually result in the birth of the child.

Some doctors think that if the bag of waters around the baby is left intact, labour is less painful, less likely to cause infection, less likely to have caesarean section for fetal heart abnormalities.

Other doctors feel that breaking the bag of waters allows labour to be faster with a decrease in caesarean section. Unfortunately, research done in the past have several flaws and have not been able to help doctors make this decision. Doctors managing labour room usually make a decision based on what she or he thinks is best for the patient.

When you come to the labour room with normal labour pains, you may be invited to participate in a study that is comparing the effects of breaking the bag of waters around your baby with the effects of retaining the bag of waters around your baby.

If you agree to be part of this study and if you are in the active phase of labour i.e. after 3 cm upto 5 cm, we may either retain the membranes or break the waters depending on what the randomization envelope instructs the doctor.

You will have no benefit or additional risk by participating in this study.However, if for some reason you do not choose to be part of this study you will be at no disadvantage.You have the option of withdrawing from the study at any point without your medical care being affected.

INFORMED CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title:

Study Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth / Age:_____

Please initial box

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am

free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

PROFORMA

ARM TRIAL-ARM VERSES NON-ARM

DATA ABSTRACTION FORM

1. Name	_____		2. Serial Number	☐☐☐
3. Hospital Number				☐☐☐☐☐☐☐
4. Age (in years)				☐☐
5. Gestational age in weeks				☐☐ ☐
6. Parity				0 1 2 3 4
7. -Time of randomization before Cervical dilatation				☐☐ : ☐☐
8.Cervical dilatation at randomization				3 4 5
9. Position of Vertex				OP OA OT
10.Station				-3 -2 -1 0 1
11. Height in cms				☐☐☐
12. Weight in kgs				☐☐☐
13 .Cervix	1.Well applied	2.Not well applied		☐
14. Birth weight in gms				☐☐☐☐
15. Time from onset of labour to randomization				☐☐ : ☐☐
16. Randomization group				☐
1. ARM group				
2. Non-ARM group				
17 .Duration of labour from randomization to delivery				☐☐ : ☐☐
18.Oxytocin used	1.Yes	2.No		☐
19.If yes	i) 2.5	ii) 5	iii) 7.5	☐
	100 , 200 , 300 ,400 ,500 ml	100 ,200 ,300 ,400 ,500 ml	100 , 200 , 300 ,400 ,500 ml	
20.CTG abnormalities	1. Yes	2. No		☐
1) Before amnioinfusion				☐
2) After amnioinfusion				

21.If Yes	1. category-1	2. category-2	3. category-3	
22.Description of deceleration				
1.Early deceleration	2.Late deceleration	3.Variable deceleration		
4.Tachycardia	5.Complicated Tachycardia	6.Severe variable deceleration		
23 .Liquor colour	1.Clear	2.MSAF		
24.If MSAF is	1.Thick	Thin		
25.Amnioinfusion	1. Yes	2. No		
26.Mode of delivery	1.Normal	2.Instrumental	3.Lscs	
27.If Lscs,indication for the same				
1.Fetal distress	2.NRFS	3.Protracted dilatation		
4.Arrest of dilatation	5.Arrest of descent	6.Others specify		
28. Tachysystole	1. Yes	2. No		
29. Hyper tonus	1. 1-Minute	2. 2-Minute	3. No	
30. Points 28+29+Trace Abnormalities	1. Yes	2. No		
31. If Yes ,requiring terbutaline	1. Yes	2. No		
32.Cord prolapse	1. Yes	2. No		
33.PPH	1. Yes	2. No		
34. Blood Loss	1. Less then 500 ml	2. 500-1000 ml	3. 1000-1500 ml	
	4. 1500-2000 ml	5. Greater than 2000 ml		
35.Post partum fever	1. Yes	2. No		
36.Post partum endometritis	1. Yes	2. No		
37.Diagnosis of endometritis	1.Clinical	2.fever	3.antiblotics	
38.Outcome of the baby	1.Alive	2.Still birth	3.END	
39.Apgar score at 1 min and 5 min				
40.Need for resuscitation at birth		1. Yes	2. No	

41.If Yes ,extent of resuscitation			
42.Cord ph<7.2			
43.Admission to NICU	1. Yes	2. No	
44.Indication for NICU admission			
45.Neonatal complication			
1.Sepsis	2.Seizures		
3.need for antibiotics(with indication)	4.others-specify		
46.Patient satisfaction 1-5			
47.care giver satisfaction 1-5			
48.Time at protocol deviation			
49.Protocol deviation			
1. Yes			
2. No			
50. If yes, reason in Non -in ARM group			
1) ARM for abnormal trace			
2) ARM for prolonged Labour			
51.If yes reason in ARM group			
1) Patient Withdrawal			
2) care giver Withdrawal			

STA	HT IN	WT IN	CER	babyB	TIME F	D GR	DURA	OX	IF YES	C	IF YES(C	DESCRI	LIQ	IF MS	AM	MC	IF LSC	TACH	HYPE	POIN	IF TE	CORI	PPH	Bloo	POST	POST	DIAG	OUT	APG	APG	NEEI	IF YE	CORD F	AD	INDICA	NEO	PT S	CAR	TIME @	PROTO	IF YES F	IF YES IN ARM GROUP			LDS-I
-2	154	50.7	1	3110	6:00	2	171	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	5	5	2	888	888	888				999
-2	152	59	1	2640	7:15	1	134	1	1(100 m	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	5	5	2	888	888	888				12
-2	162	51.4	1	2850	7:00	1	330	1	1(200 m	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				12
-2	160	62.6	1	3400	2:00	2	345	2	888	1	2	3	2	2	2	1	888	2	3	2	2	2	2	1	2	2	888	1	4	7	1	INTU	7.02	1	DEPRES	3,4	4	5	2	888	888	888				12
-3	161	44.4	1	3320	3:50	2	200	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
0	153	48	1	2950	5:30	1	77	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	4	2	888	888	888				999
-2	164	51	1	3000	2:40	1	127	2	888	2	888	888	2	2	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	5	5	2	888	888	888	* LACERATION			10
-1	165	47	1	3380	7:30	1	362	1	1(200 m	1	2	3	1	888	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
-2	149	48.02	1	3050	7:30	2	439	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
-2	165	46	1	3260	4:10	2	229	2	888	1	2	3	1	888	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
-2	157	55	1	2890	10:30	1	526	2	888	1	2	3	1	888	1	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	5	5	2	888	888	888				11
-2	155	70.5	1	2800	2:45	2	60	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				999
-3	155	61	1	2930	3:45	1	374	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
-3	155	63.3	1	3390	7:00	2	354	2	888	1	2	3	1	888	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	4	5	5	15:00	1	2	888	*Left clavicula			11
-3	152	59	2	2470	6:30	1	355	1	1(100 m	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	3	4	2	888	888	888				12
-3	167	63.6	1	2880	10:15	2	566	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	1	2	2	2	888	1	9	10	2		888	2	888	0	4	5	3:30	1	2	888				999
-3	156	50.7	2	2940	6:00	1	182	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	4	2	888	888	888				999
-3	160	53	1	3460	8:30	2	616	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	23:30	1	2	888				12
-3	157	54	1	3330	7:00	2	389	2	888	2	888	888	2	2	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	4	21:30	1	2	888				12
-3	165	53	1	2580	5:30	2	253	2	888	1	2	3	2	2	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	21:30	1	1	888				12
-2	147	52.3	1	2860	12:00	1	87	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				12
-3	157	66.8	1	2870	9:00	1	309	2	888	1	2	3	1	888	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	9	2		888	2	888	0	4	5	2	888	888	888				999
-2	170	51.7	1	3120	7:45	2	611	2	888	2	888	888	2	2	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	23:45	1	2	888				12
-3	162	57.4	1	3770	9:40	1	378	2	888	1	2	3	1	888	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	2	5	2	888	888	888				999
-2	154	53	2	2880	7:00	1	206	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				12

-3	158	62	1	2710	6:55	2	488	1	1(300 n	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	5	5	13:00	1	2	888				12
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-2	165	66	1	3820	7:00	2	506	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
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-3	152	60	1	2930	2:00	2	351	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
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-2	167	84.7	1	2960	8:15	1	140	1	1(300 n	2	888	888	2	2	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
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-2	155	82	1	2830	3:30	2	377	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	10:30	1	2	888				12
-3	157	60.72	1	3380	6:00	2	610	1	1(300 n	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	19:30	1	2	888				999
-3	155	57	1	3730	9:00	2	624	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				12
-2	172	61	1	3450	6:30	1	131	2	888	2	888	888	2	2	2	1	888	2	3	2	2	2	1	2	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				11
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-2	155	68	1	2900	4:30	2	207	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	888	888	888				12
0	151	64.5	1	2750	6:25	1	168	2	888	1	2	3	2	2	2	2	888	2	3	2	2	2	2	1	2	2	888	1	9	9	2		888	2	888	0	4	5	2	888	888	888				999
0	165	66	1	3210	7:30	2	414	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	15:30	1	2	888				12
-3	160	65	1	3900	7:00	2	893	1	1(100 n	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	4	16:30	1	2	888				12
-2	150	48	1	2520	11:50	1	492	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	2	888	888				12
-3	162	73.9	1	3500	6:20	2	825	1	1(100 n	2	888	888	1	888	2	3	3	2	3	2	2	2	1	2	2	2	888	1	9	10	2		888	2	888	0	4	4	5:40	1	2	888				12
-2	164	83	1	3140	6:15	2	54	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	2	888	888				12
-3	162	62.5	1	3840	12:40	1	776	1	1(500 n	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	4	2	2	888	888				12
-3	153	68.1	1	3220	3:20	1	553	1	1(400 n	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	2	888	888				12
-2	159	54.8	1	2940	7:30	2	96	2	888	2	888	888	1	888	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	2	888	888				13
-2	158	54	1	3180	13:35	1	322	1	1(200 n	2	888	888	2	2	2	1	888	2	3	2	2	2	2	1	2	2	888	1	9	10	2		888	2	888	0	4	5	2	2	888	888				12
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