“Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction” - A Randomized control trial

A dissertation submitted in partial fulfilment of the rules and regulations for the MS Branch II (Obstetrics and Gynaecology) Degree examination of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, to be held in May 2020.

DECLARATION

I hereby declare that this dissertation titled **"Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction" - A Randomized control trial** is carried out by me under the guidance and supervision of Dr. Reeta Vijayaselvi, Associate professor, Obstetrics & Gynecology Unit – IV, Christian Medical College, Vellore. This dissertation is submitted in partial fulfillment of the requirement for the degree of M.S in Obstetrics and Gynaecology examination of the Tamil Nadu Dr.M.G.R. Medical University to be held in May 2020.

Dr.Sravani

Registration number- 221716408

CERTIFICATE

This is to certify that the dissertation entitled, **"Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction" - A Randomized control trial** is an original work done by

Dr. T SRAVANI

Done under my guidance towards the MS Branch (Obstetrics and Gynecology) Degree Examination of Tamil Nadu Dr. M.G.R Medical University, Chennai to be held in May 2020.

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CONTENTS

INTRODUCTION

Induction of labour (IOL) is a common obstetrical procedure done in pregnancy when continuing the pregnancy has more risks to the mother or fetus than benefits. The common indications for IOL are maternal medical complications like hypertension, diabetes, connective tissue disorders and fetal indications are intrauterine growth restriction, Oligohydramnios and non-reassuring fetal status. Most low risk pregnancies between 40 weeks to 41 weeks are induced if they have not got spontaneous labor according to Obstetrician's discretion. The induction rate in pregnancy is 9.6% globally and in more developed countries the induction rate is more having maximum of 35%. The induction rate in CMC is 40%. The cervix is assessed with BISHOP score to assess the possibility of vaginal delivery. The women with unfavorable BISHOP score are given ripening agents for 12 hours prior to induction of labour. The induction of labour not only doubles the caesarean rate but also increases infection rate and labour related other maternal and fetal complications. So, induction of labour is done only when it is indicated. In indicated women measures are taken to minimize the maternal and fetal complications like minimizing the pelvic examination, retaining the amniotic membrane till late in labour and using the Cardiotocograph (CTG) for fetal monitoring. Studies have shown the early amniotomy in spontaneous labour reduces the duration of labour and thereby reducing the infective morbidity to the mother and the baby without increasing the caesarean rate.

Late amniotomy is found to reduce the caesarean rate by reducing the failed induction by promoting more natural contraction, reducing cord compressions and CTG abnormalities and promoting cervical dilatation. The present literatures support both early and late amniotomy in induced patients who have reached the active phase of labour with cervical ripening agents. This study is designed to study the maternal and fetal outcomes in the early and late amniotomy in the induced low risk pregnancies who have not entered active phase with ripening agents.

AIM

The main aim of this randomized control trial is to assess the effectiveness of late amniotomy in reducing the caesarean delivery in comparison with early amniotomy in low risk pregnant women who undergo induction of labour.

Primary outcome

To compare the rate of caesarean section in Early versus Late amniotomy group.

Secondary outcomes

To compare the maternal and fetal outcomes like the following

Maternal outcomes:

1) Duration of lab our

2) Postpartum hemorrhage

3) Postpartum endometritis

4) Instrumental deliveries

5) Cord prolapse

Fetal outcomes:

1) Meconium stained liquor

2) APGAR score at 5 min

3) NICU admission

REVIEW OF LITERATURE

HISTORY OF IOL AND AMNIOTOMY:

Induction of labour history started from the time of Hippocrates with description of mammary stimulation and mechanical dilation of cervical canal(1). In the past IOL were used only for life threatening maternal conditions. But now a days it becomes a common procedure in obstetrics practice.

Amniotomy

Artificial rupture of membranes/ amniotomy popularly known as the 'English method', was 1st introduced by Thomas Denan in 1756 (2). Until 1906, amniotomy and mechanical methods remained the commonest methods for IOL. Then Sir Henry Dale invented that uterine contractions caused by extracts of posterior pituitary gland(crude preparation) (3)

Oxytocin, a synthetic octapeptide was 1st produced in 1953, which facilitated use of physiological drip of diluted intravenous oxytocin for IOL(4). In 1960- Alec Turnbull and Anne Anderson introduced 'oxytocin titration' method(5), From 1990 electrical intravenous infusion pumps introduced for accurate titration of oxytocin flow. In 1970 prostaglandins introduced into clinical practice for IOL(6)

TYPES OF AMNIOTOMY:

1. **Low amniotomy**: Introduced by Thomas Denmann. It is rupture of bag of membranes which lying below the presenting part. Most commonly used method.

   Instruments used for amniotomy:

   a. Kocher's
   b. Amnio hook
   c. Amniocot
   d. Baylor hook

2. **High amniotomy:** Rupture of hind water by using Drew smythe catheter. (7)

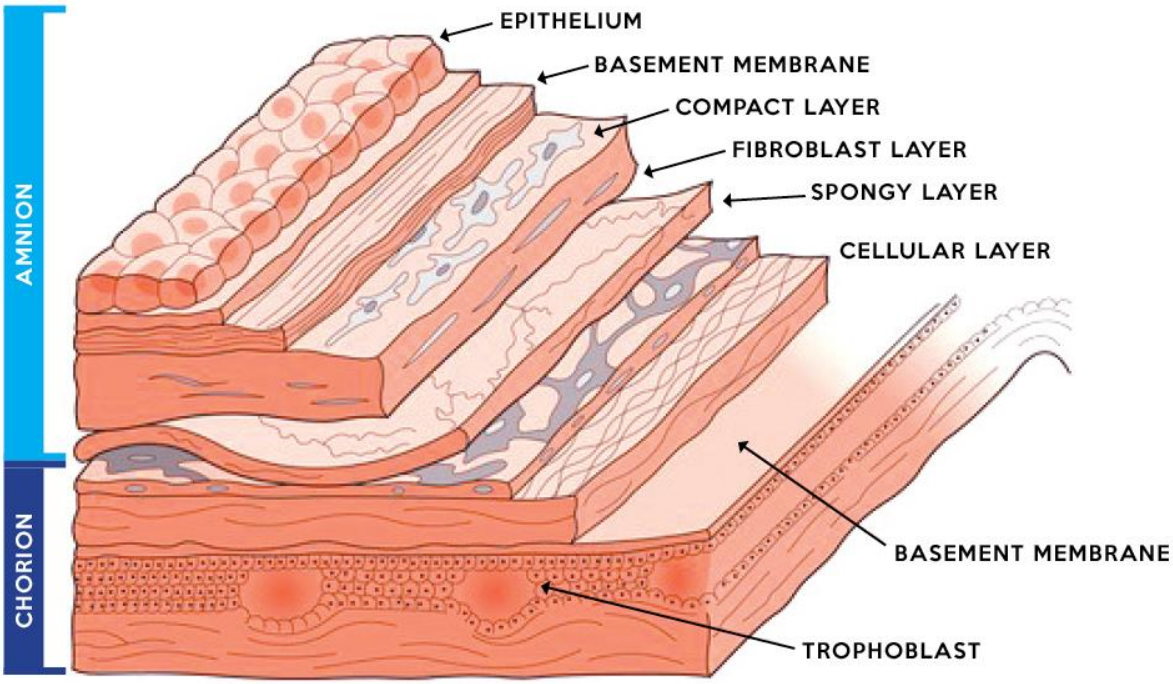
Structure of amnion:

Amniotic membrane (AM) or amnion is a thin avascular membrane on inner side of fetal placenta. It surrounds the embryo and is filled with amniotic fluid. On gross examination it is a transparent structure and easily separated from the underlying chorion. Thickness of amnion varies from 0.2mm-0.5mm

Bounet(1962), described 5 layers of amnion(8)

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

Structure of amnion



The amnion has been shown to have antifibrotic, anti-inflammatory, antiangiogenic and antimicrobial properties

Epithelium:

It is the innermost layer composed of single layer of cuboidal cells with microvilli present on its apical surface.

Basement membrane: Made up of collagen (type IV, V, VII), fibronectin, and laminin.

Stroma : (9)

This is divided into 3 contiguous layers

Compact layer: which is next to basement layer and provides tensile strength of membrane.

Fibroblastic layer: Thickest layer and made up of a loose fibroblast network embedded in reticulum.

Spongy layer: Outermost layer that is derived from extra embryonic celom and found in between amnion and chorion. It allows the amnion to slide over chorion.

Parts of Amnion:

1. Reflected amnion- part of amnion which is contiguous with the chorion.
2. Placental amnion- part of amnion which is covers the fetal part of placenta and it is contiguous with chorionic vessels.
3. Amnion covering the umbilical cord
4. Fused amnion in twin pregnancy- seen in diamnionic twins.

AMNION EPITHELIAL CELLS:

The apical surface of Amnionic epithelium with microvilli plays important role in transfer between amniotic fluid and amnion. This layer is metabolically active and these cells secrete Prostaglandin E2 (PGE2), Fetal fibronectin (fFn), tissue inhibitors of MMP1.

Epithelia cells respond to signals which derived from fetus or mother. These cells are responsive to paracrine and endocrine modulators i.e.: oxytocin and vasopressin, both of which increases the PGE2 (10). It also produces Brain natriuretic peptide (BNP) and corticotrophin releasing hormone, which are responsible for uterine quiescence. At term Epidermal growth factor which is a negative regulator of BNP is upregulated in the membrane, leads to onset of labour.

AMNION MESENCHYMAL CELLS:

Synthesizes interstitial collagen that compose compact layer, which is responsible for tensile strength of amnion. Mesenchymal cells also synthesize cytokines- IL-6 and IL8.

In cases of premature membrane rupture- mesenchymal cells may be a greater source of PGE2

Advantages of amniotomy:

1. To detect Meconium stained amniotic fluid (MSAF)
2. For Internal fetal monitoring- by intrauterine electrode
3. Enables to introduce intrauterine pressure catheter.

Complications of amniotomy:

I. Fetal complications:

1. Cord prolapse (Incidence – 0-0.7%) (11,12)
2. Fetal heart decelerations (13)
3. Increase in neonatal GBS infections

II Maternal complications

1. Increase in rate of LSCS (14)
2. Chorioamnionitis
3. Increased risk of HIV transmission (12)
4. Bleeding from placenta previa or vasa previa

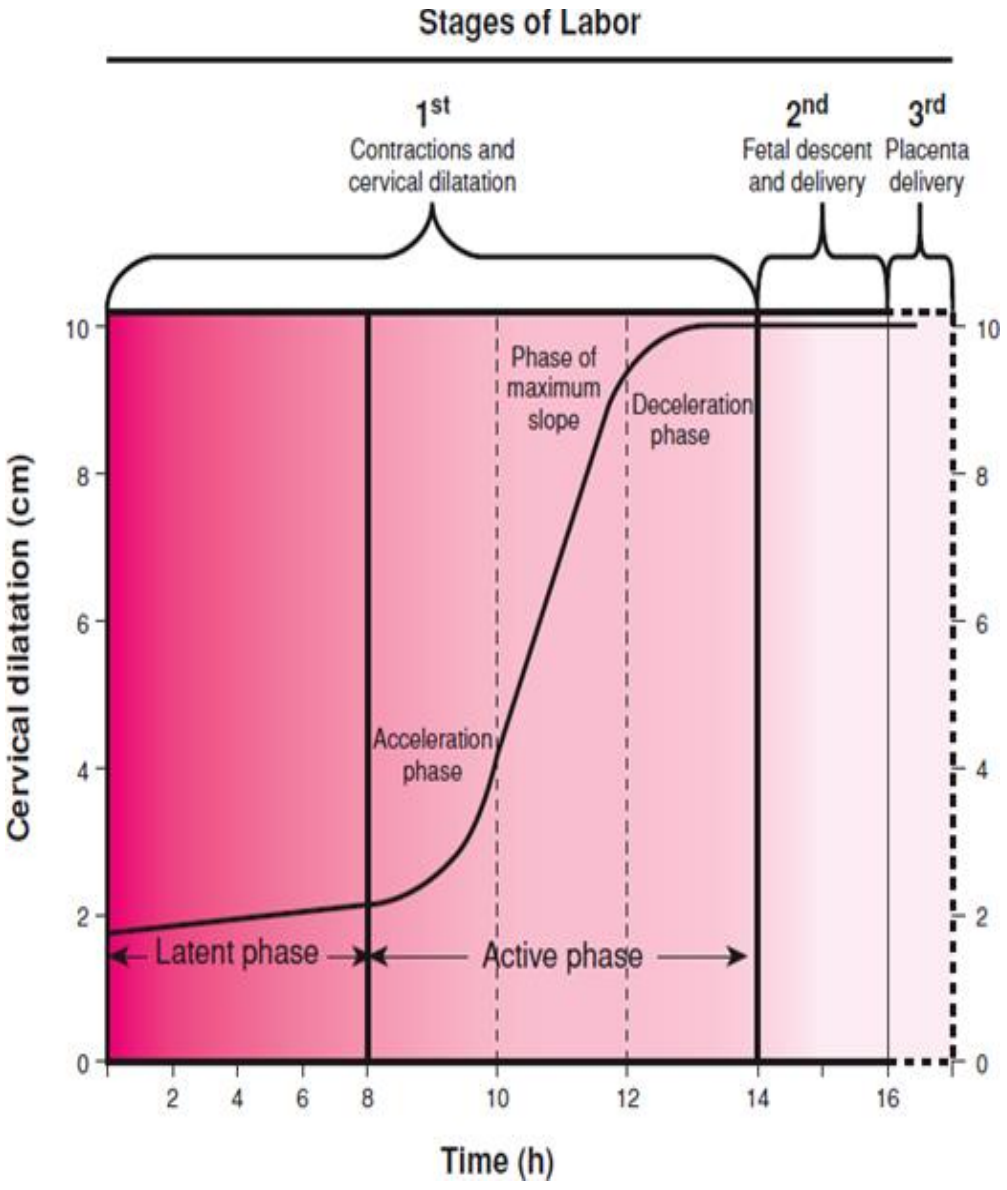
Physiology of normal labour:

Labour is a physiological process which **involves** sequential integrated set of changes in cervix, myometrium and decidua which results in delivery of fetus and placenta from the uterus through the vagina.(15)

Stages of normal labour:

Human labour divides into 3 stages:(16)

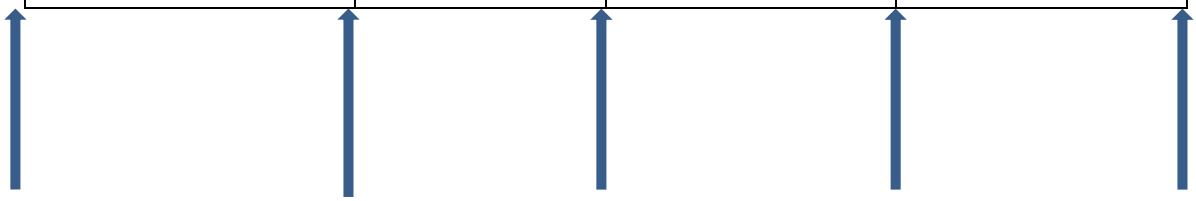
1. First stage which start with uterine contractions and ends with full cervical dilation (i.e.: 10cm dilatation).
2. 2nd stage: Stage of fetal expulsion (from full dilatation of cervix to delivery of fetus)
3. 3rd stage of labour: Delivery of placenta and membranes.



Phases of labour and hormones involved in each phase :(16)

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

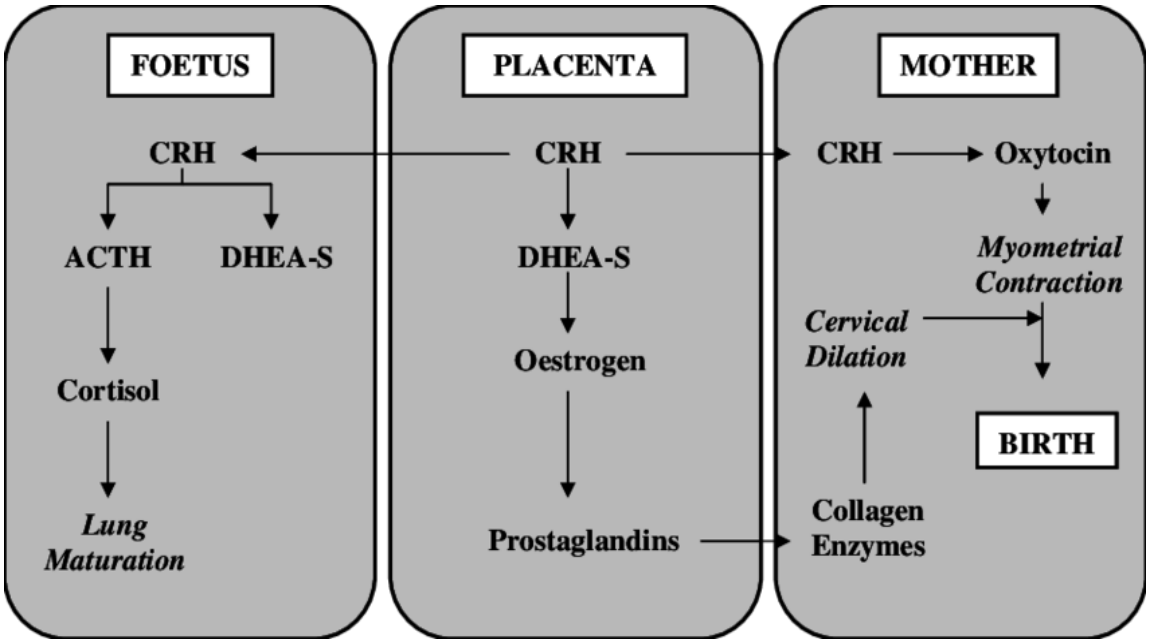
Phase 1 Quiescence	**Phase 2** Activation phase	**Phase 3** Stimulation phase	**Phase 4** Involution phase
Prelude to parturition	Preparation for labour	Process of labour	Parturient recovery
Contractile unresponsiveness	Uterine Preparedness for labour	Active lab our (3 stages of labour)	Uterine Involution
Inhibitors or tocolytics -progesterone, CRH, PGI2, Relaxin, NO, Human placental Lactogen.	Uterotropins- CAP, PGE2, PGF2	Uterotonics- Oxytocin prostaglandins	Oxytocin



Conception | Initiation of Parturition | onset of labour | delivery of conceptus | Fertility resumes

Role of CRH in physiology of labour: (17)

At term gestation there is an increased placental CRH production due to positive feed forward mechanisms from mother and fetus. Increased placental CRH causes changes in fetal cortisol level, phospholipids, fetal lung maturation, amniotic fluid proteins and myometrial receptor expression, which leads to activation of individual pathways to precipitate labour.



Mechanism of rupture of membranes in spontaneous labour: (10,18)

In 70% cases membranes remains intact till full dilatation of cervix (19).

Amnion is an inner layer fetal membranes which is the main source of Prostaglandin E2 (PGE2) production. PGE2 is responsible for softening and shortening of cervix. Chorionic membrane which acts as barrier between amnion and cervix produces Prostaglandin dehydrogenase (PDHG) enzyme, it causes breakdown of PGE2 and thus prevents cervical ripening and premature rupture of membranes. In normal pregnancy PGE2 and collagenases plays a vital role in rupture of membranes. At term chorion releases less PDHG, thus allows PG's to reach cervix and facilitate for cervical ripening (20,21)

IOL Definition: Induction of labour refers to methods used for the stimulation of uterine contractions to bring about delivery before the onset of spontaneous labour or after the period of viability. IOL is a therapeutic option when benefits of delivery to mother or fetus outweigh the risk of continuing the pregnancy.(22)

Success of IOL depends on cervical favorability. Bishop scoring system is a quantifiable method to predict the outcomes of IOL was introduced by Edward Bishop in 1964. Bishop score has sensitivity around 75% and positive predictive value of 83% for predicting vaginal delivery (23).

Bishop scoring system:

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	--	80	+1, +2	--

Cervical ripening may be indicated when cervix is unfavourable

(Bishop score< 6)

Indications of Induction of labour:(24,25)

1. Past dates
2. Chorioamnionitis
3. Premature rupture of membranes >34 weeks
4. Fetal compromise (Rh isoimmunization, severe fetal growth restriction, non-reassuring fetal status, oligohydramnios, fetal demise)
5. Maternal medical conditions: Chronic hypertension, gestational hypertension, pre-Eclampsia, diabetes mellitus, cholestasis of pregnancy, Twin gestation, previous LSCS)

Contraindications of IOL : (24,25)

1. Placenta previa/ vasa previa
2. Umbilical cord prolapse
3. Transverse lie or footing breech
4. Prior classical or inverted T uterine incision
5. Prior uterine surgeries: Transfundal uterine surgery, full thickness myomectomy, prior uterine rupture
6. Active genital herpes
7. Pelvic structural deformities associated with cephalopelvic disproportion
8. Invasive cervical carcinoma
9. Previous pelvic surgeries- vesicovaginal fistula/ rectovaginal fistula / 4^{th} degree perineal repair/ tracheloerrhaphy

Methods of Cervical ripening : (26)

1. Pharmacological (T. PGE1 or PGE2)
2. Sweeping of membranes
3. Mechanical methods

Pharmacological methods:

1. Misoprostol- oral 100/50mcg, vaginal – 25mcg every 6hrs(27,28)
2. Dinoprostone gel 0.5mg/ tablet 10mg every 6hrs maximum 3 doses in 24hours(28)

Associated with hyperstimulation and NRFS

SWEEPING OF MEMBRANES:

Stripping/ sweeping of the membrane was introduced by James Hamilton – 1810.

It increases local production of prostaglandins and subsequent lab our onset.(28)

Mechanical methods:

Foleys catheter balloon is used for IOL acts as mechanical dilator of cervix and stimulator of endogenous prostaglandins release from fetal membranes.(29)

Complications of induction of labour: (30)

1. Uterine hyperstimulation, NRFS
2. Failed induction
3. Cord prolapse
4. Uterine rupture

STUDIES SUPPORTING LATE AMNIOTOMY:

Anju Bala et al has done a randomized trial on early versus delayed amniotomy during labour induction with oxytocin in women with Bishop score of ≥6(31) in singleton pregnancy showed early amniotomy group has reduced induction delivery interval (IDI)(7.35 versus 11.66 hours with delayed amniotomy p=0.000)but higher caesarean section rate (10.7 versus 2.7% with delayed amniotomy p=0.0495). With early amniotomy, the proportion of women delivering within 12hours was higher (86.7 versus 60%, p=0.000) and the maximum oxytocin concentration used was lower (30.05 versus

39.68mU/min, P=0.001) as compared to delayed amniotomy. Intrapartum fever was similar in both groups.

A randomized control trial was done by **Ruamsap and Panichkul**(32) in labor unit of Phramongkutklao hospital. The objective of the study was to compare effect of early versus late amniotomy on duration of labour in first and second stage, the caesarean section rate and usage of analgesia in labour. This study was done between June 2013 to October 2013 and included 120-term nulliparous singleton with cephalic presentation. Pregnant women in this study were randomized into early amniotomy (performed when patients entered active phase with cervical dilatation 3-5cm) and late amniotomy (performed only for specific indications). There was no significant duration of first stage of lab our between both the groups (560.0 versus 637.5 min; p<1). The rate of caesarean section was higher among early amniotomy group as compared to late amniotomy group (43.3% versus 20%; p=0.006).

Faris Anwar Rasheed et al(33) conducted a prospective single blinded randomized controlled study in 210 nulliparous singleton pregnant women. This study was intended to study impact of early versus late amniotomy on duration of labour. This study showed higher rate of caesarean section in early amniotomy group compared to late amniotomy group (33.3% versus 15.2%, p=0.002). Early amniotomy shortens significantly the duration of first stage of labour (5.1 versus 7.8 hours, p=0.01) the rate of chorioamnionitis was significantly higher in early amniotomy group (12.4% versus 3.8%, p=0.036).

Levy et al. has done a randomized control study on comparison of early versus late amniotomy following cervical ripening with a Foleys catheter (34) on 154 women with singleton pregnancies at >38 weeks of gestation, vertex presentation with intact membranes, cervical dilatation of 1 cm or less and no regular contractions showed the rate of CS was significantly higher in early amniotomy group compared to late amniotomy group (25% versus 7.9% relative risk – 1.74, 95% CI 1.3 – 2.34) suggesting to postponed amniotomy until the women is in active labour to reduce the CS rate due to labour dystocia in these women.

A Retrospective cohort study by **Lee et al** on "Early Rupture of membranes" during induced labour as a risk factor for Cesarean delivery (35) included 500 term singleton nulliparous women who were admitted for labour induction showed CS rate was significantly higher in early amniotomy (<4cm cervical dilatation) group compare to late amniotomy (>4cm cervical dilatation) (24% versus 10%, P<0.01). The chorioamnionitis rate in two groups was similar.

A Retrospective cohort study was conducted in 19 US hospitals by **Battarbee et al** (36) to investigate association of early amniotomy with rate of caesarean section and maternal and neonatal morbidity. Among 228438 deliveries, of eligible 15525 women, 10421 (67%) had early amniotomy. Higher adjusted odds of cesarean rate were seen in early amniotomy group as body mass index increased. Neonatal morbidity is not seen in early amniotomy group. Median lab our induction was shorter (2.5 hour) in early amniotomy group.

Olfati et al (37) conducted a prospective cohort study in Kosar hospital of Qazvin (Iran) from 2008 to 2009, with Aim of research was to study effect of amniotomy on rate of caesarian section rate. They included singleton pregnant women with cephalic presentation and divided into two groups- Exposure amniotomy group (amniotomy < 3cm of cervical dilatation) and Unexposed group (amniotomy > 3cm of cervical dilatation). This study showed caesarean section rate was significantly higher in early amniotomy group with p value of – 0.001, Exposure group – 19(10.9%) vs. unexposed group 2(1.5%). This study also showed significant difference for non-progressive labour among two groups with P value of 0.001.

Li et al. (38) conducted a metanalysis to analyze the effects of early amniotomy on labour and fetal and neonatal health status, resulted in shorter duration of 1st stage of labour (94.9min shorter in early amniotomy group) and increase in caesarean rate with the odds ratio for caesarean section was 1.25, 95% CI (0.99-1.57)

Ibost et al. (39)conducted retrospective observational study from 2002 to 2007 to study the association of Intrapartum interventions and LSCS rate in low risk nulliparous women with spontaneous onset of labour. This study showed positive association between amniotomy and oxytocin augmentation and LSCS rate (Aor-1.89, 95% CI, 1050-2.21).

Other literature related to Amniotomy:

A Randomized control trial on the efficacy of early amniotomy in 585 nulliparous women who needs IOL by **Macones et al** (40) showed the CS rate was similar in early amniotomy group(ARM at <4cm of cervical dilatation) and late amniotomy group(ARM > 4cm) with P value of 0.75.

A Randomized controlled trial was conducted by **Mercer et al** (41) on early versus late amniotomy for labour induction in 2019 term singleton pregnancies with cephalic presentation, with intact membranes who needs IOL, without any maternal and fetal risk factors showed the chorioamnionitis rate was higher in early amniotomy group(22.6% vs. 6.8%, P=0.002) compared to late amniotomy group and the caesarean section rate was similar in both groups.

A Randomized clinical trial was done on early amniotomy after vaginal misoprostol for induction of labour by **Makerem et al** (42) on 320 singleton, term gestation, cephalic presentation with intact membranes who underwent vaginal misoprostol induction showed the CS rate (26.9 versus 34.4%) and chorioamnionitis rates were similar(6.8 versus 6.2%) in early and late amniotomy group which were statistically not significant.

A Randomized controlled trial to study the effect of amniotomy on the duration of spontaneous labour by **Vadivelu et al.** (43) on singleton term pregnancies, cephalic presentation , with spontaneous onset of lab our with regular and strong contractions, cervical dilation 3-5cm showed the duration of labour reduced significantly in amniotomy group compared to non-amniotomy group ($p < 0.001$), but there was no significant difference in caesarean section in both groups (p=0.159)

Gagnon – Gervais et al (44) conducted a Randomized control trial to evaluate the effect of early (EA, oxytocin infusion along with amniotomy) vs. late amniotomy (LA, amniotomy after 4 hours of oxytocin infusion) on mode of delivery in induced women showed no significant difference in rate of Caesarean section (18% vs. 17%, P= 0.91: among nulliparous: 3% versus 0% , p= 1.0: in parous women) but early amniotomy resulted in shorter duration of lab our from oxytocin to delivery time(12 versus 15hours, p=0.03).

Methodology

Sample and setting:

This study was conducted in department of Obstetrics and gynecology, CMCH, Vellore from June 2018 to august 2019. The study protocol was approved by Ethics committee and Institutional review board (IRB Min. No. 11185), Christian Medical College and hospital, Vellore. Study was registered in the Clinical trials registry of India (CTRI/2018/06/014586). Total number of women consented for trial was-585. A total of 450 women were randomized into two groups 1. Early amniotomy group and late amniotomy group. In each arm 225 women were included.

STUDY DESIGN:

This study is a prospective randomized control trail (RCT) to study the effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction.

SAMPLE SIZE

With reference to Hospital statistics (Christian Medical College, Vellore: November 2017) the rate of caesarean section among early amniotomy was found to be 22.5% excepting a reduction of 35% of 22.5% was found to be 14.6% with power at 80% and alfa error at 5% for two sided test for at least sample size of 382 in each arm.

Two Proportion - Hypothesis Testing - Large Proportion - Equal Allocation	
Proportion in Control group (Rate of LSCS)	0.225
Proportion in experimental group (35% Reduction of LSCS)	0.14625
Estimated risk difference	0.07875
Power (1- beta) %	80
Alpha error (%)	5
1 or 2 sided	2
Required sample size for each arm	382

Formula for Hypothesis testing of two large proportions - Equal allocation

Formula

$H_o : P_1 = P_2;$ $\quad\quad$ $H_a : P_1 \neq P_2$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\,\overline{P}\,(1-\overline{P})} + Z_{1-\beta} \sqrt{P_1\,(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Where,

$$\overline{P} = \frac{P_1 + P_2}{2}$$

P_1 : Proportion in the first group

P_2 : Proportion in the second group

α : Significance level

$1-\beta$: Power

METHODOLOGY IN DETAIL:

Low risk term gestation pregnant women who admitted in labour ward and obstetrics ward at CMCH for induction of lab our were screened for trial by using below criteria:

Inclusion criteria:

1. Singleton pregnancy
2. Vertex presentation
3. Term gestation
4. Membranes intact
5. Low risk pregnant women who needs induction of lab our (past date pregnancy, GDM on MNT)

Exclusion criteria: (At the admission to ward/ before cervical ripening)

1. Previous LSCS/ Previous uterine surgery
2. Antepartum hemorrhage
3. Medical complications which increases the rate of caesarian delivery (GDM on OHA/ Insulin, HTN, SPE, Eclampsia, PROM, Infertility treated, EFW>4kg, elderly gravida >35 years)
4. Seropositive women, HBs Ag positive
5. IUGR (Intrauterine growth restriction)
6. Multiple pregnancies
7. Polyhydramnios

8. Maternal fever at admission
9. Floating head
10. Grand multi (parity ≥4)
11. Previous bad obstetric history
12. Non reassuring fetal status before induction

Exclusion criteria at the time of induction after cervical ripening:

1. Tachysystole or hyper stimulation with ripening agent.
2. Women who entered active labour
3. Women who ruptured membrane
4. NRFS

Women who fulfilled the inclusion criteria were given patient information sheet and consent form. Consented pregnant women were randomized in labour room after cervical ripening. Patient and caregiver were not blinded to which group they belong to. All eligible women were allocated into two groups by using block randomization. Randomized slips were computer generated. Statistician has done allocation concealment. It was done by placing each allocation in separate identical envelops which were numbered consecutively with serial numbers.

CONSORT check list was followed. Patients were randomized into two arms 1. Early amniotomy (amniotomy along with oxytocin induction) 2.Late amniotomy (amniotomy after 6 hours of oxytocin infusion). All women were started on oxytocin infusion after cervical ripening.

They were monitored with continuous Cardio topography (CTG), oxytocin dose was titrated as per protocol and oxytocin was withheld if patient develops tachysystole, hyperstimulation and fetal heartbeat was non-reassuring. In non-reassuring CTG,(13) amniotomy done before 6 hours duration in the late amniotomy group and meconium stained amniotic fluid was checked. Pervaginal examination done 6^{th} hourly to assess progress in labour. Failed induction was considered when the women who did not enter the active phase of labour by 18 hours of oxytocin. Protracted dilatation and arrest of dilatation definitions were followed from standard guidelines. Maternal vitals and temperature recorded hourly. Patients who developed chorioamnionitis(45) were treated with inj. Ampicillin and Inj. Gentamycin. Postpartum hemorrhage is defined as blood loss of >500ml in normal vaginal delivery and >1000ml blood loss in LSCS(46). For Postpartum fever and endometritis, the recruited women were followed up in the ward till their discharge. The maternal and fetal outcomes are followed up from the chart and analyzed

MEASUREMENTS:

The data collection was done by primary investigator and entered in the data abstraction form (Annexure IV)

Following data was collected from all participants

1. Base line characters: Age, Gestational age, parity, height, weight, BMI, Bishop score, birth weight of baby
2. Mode of delivery and duration of delivery from randomization, colour of liquor
3. CTG changes, classification and interventions done for NRFS

4. Maternal outcomes: Chorioamnionitis, PPH, Postpartum fever, endometritis.
5. Fetal outcomes: Apgar score, need of resuscitation at birth, NICU admission.

OUTCOMES:

Primary outcome: Rate of caesarean section in Early versus Late amniotomy group.

Secondary outcomes: Duration of lab our, Postpartum hemorrhage, endometritis, instrumental deliveries, incidence deliveries, Meconium stained liquor, APGAR at 5min, NICU admission.

Statistical Analyses:

Statistical methods were used for the primary outcome include description of methods to estimate the strength of the effect (e.g.: Odds ratios, relative risks, etc.)

Statistical Methods:

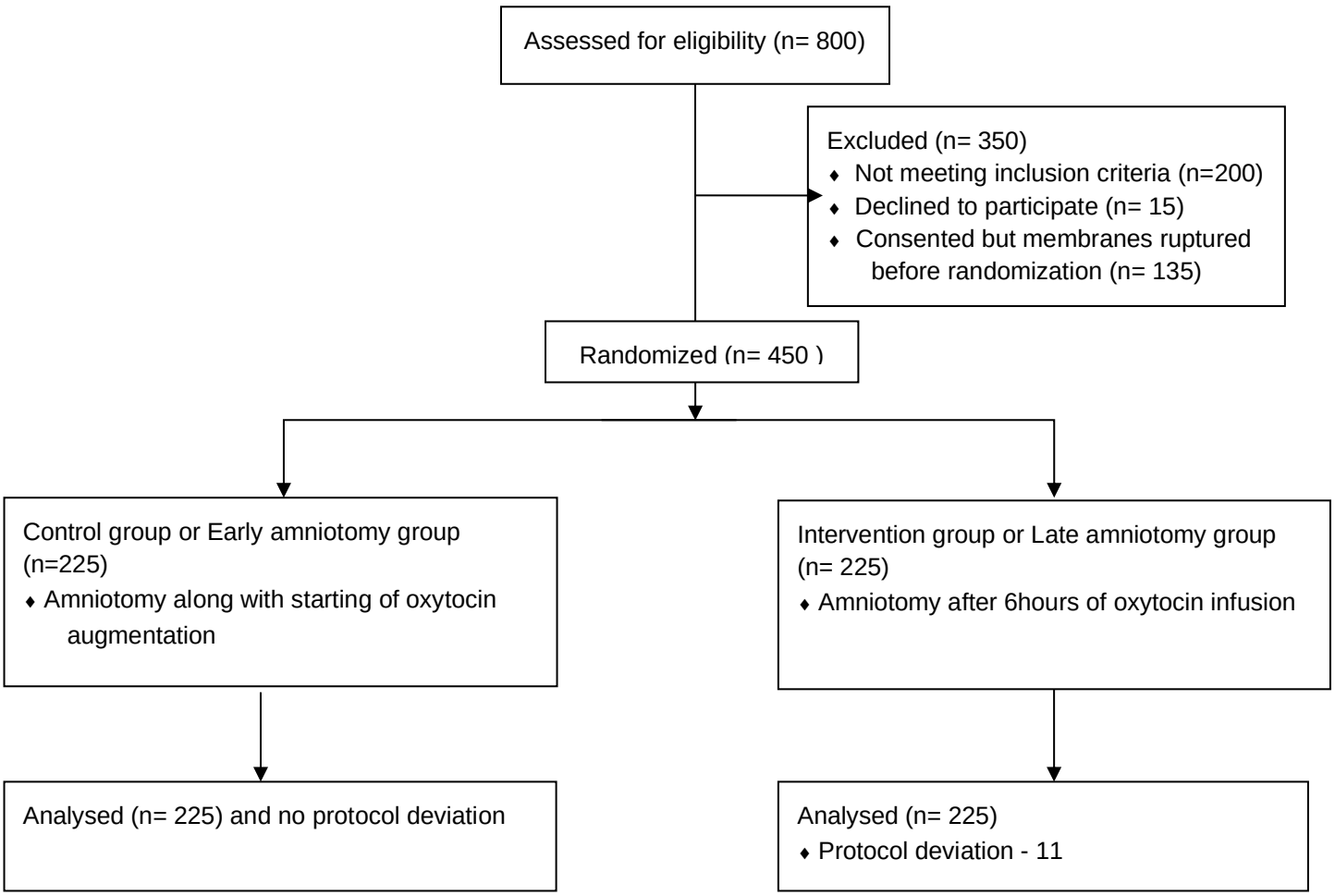
Data entry was done by using Epi Data 3.1. Data analysis was carried out by using SPSS 16.0 or higher. Descriptive statistics were reported by using Frequency and Percentage for categorical variables. Continuous variables were reported by using Mean±SD. Comparison between the Early amniotomy and Late amniotomy was done by using two independent sample t test after checking for normality for continuous variables. Categorical variables were reported by using Chi-square/Fisher's exact test. P value <0.05 was considered statistically significant.

RESULTS

A total of 600 eligible women were approached for consent to participate in this study. 15 women refused to participate, hence a total of 585 women were consented to participate in study at the time of induction. A total of 135 women who consented for participation in this study were excluded as they spontaneously ruptured membranes after cervical ripening and before randomization. Hence, only 450 women were randomized into two groups, in each group 225 women were included.

In early amniotomy group, no women had protocol deviation, whereas in delayed amniotomy group, 11 members had protocol deviation. For two women ARM was done before 6 hours of oxytocin infusion because of abnormal CTG findings and to look for colour of amniotic fluid. Rest 9 members had spontaneous rupture of membranes after randomization, hence included in analysis.

CONSORT FLOW CHART



BASELINE CHARACTERISTICS:

Baseline characteristics of study participants showed no difference between two groups. There was no significant difference in the maternal age, parity, gestational age, bishop score, body mass index, weight of baby between two arms.

Study participants were in the range of 18 years to 37 years.

AGE DISTRIBUTION:

Table 1: Comparison of age between early and late amniotomy group

Group	Mean	SD	Minimum	Maximum	
Early amniotomy	**25.80**	**3.537**	**18**	**37**	**P value 0.156**
Late amniotomy	**25.32**	**3.620**	**18**	**37**	

Table 2: Comparison of Gestational age in weeks between both groups

Group	Mean	SD	
Early amniotomy	**39.636**	**0.8562**	**P value: 0.511**
Late amniotomy	**39.583**	**0.8642**	

Table no .3 Distribution of Parity between each group

Parity	Early amniotomy	Late amniotomy	Total	
Primi gravida	155(68.9%)	144(64%)	299	
Multigravida	70(31.1%)	81(36%)	151	p-value 0.272
Total	225	225	450	

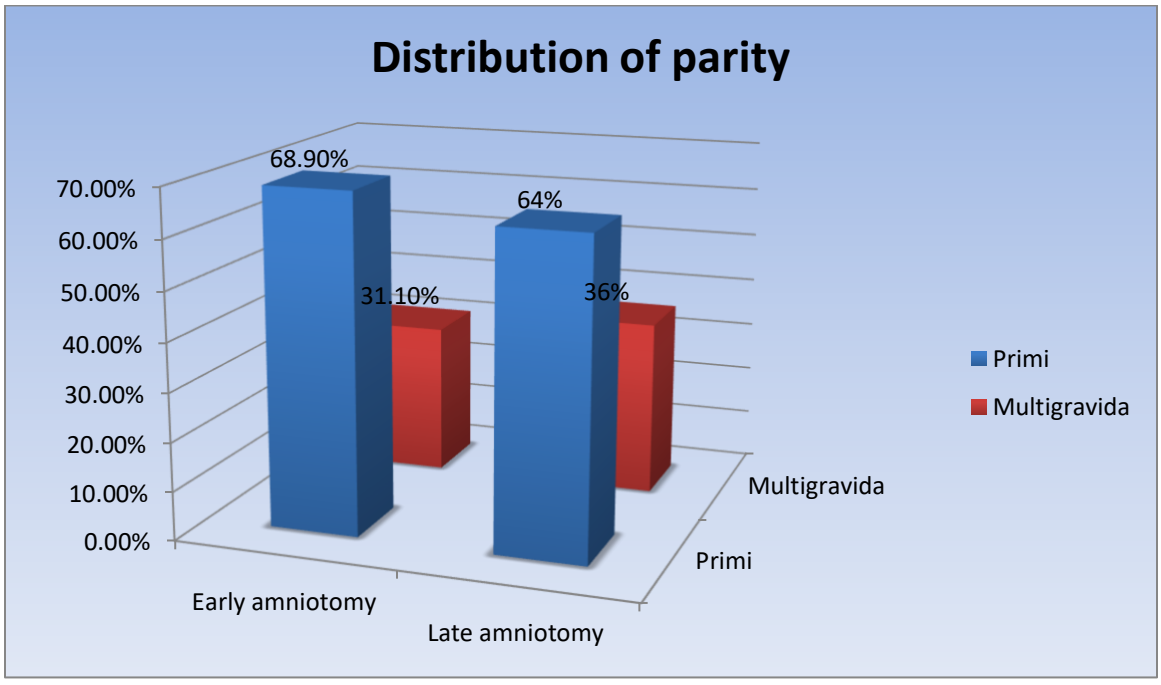


Table: 4

Comparison of Bishop score (at randomization) among two groups

BISHOP SCORE	Early amniotomy	Late amniotomy	
4/13	10(4.4%)	12(5.3%)	
5/13	133(59.1%)	138(61.3%)	
6/13	27(12%)	28(12.4%)	
7/13	23(10.2%)	20(8.9%)	P value=0.672
8/13	19(8.4%)	21(9.3%)	
9/13	13(5.8%)	6(2.7%)	

Method of cervical ripening among both groups

Most of study participants received Tab. PGE1 for cervical ripening, in early amniotomy group – 65.3% and late amniotomy group – 70.2%, followed by combined method (PGE1 +Foleys). There was no significant difference in method of cervical ripening among both arms.

Table: 5

Method of cervical ripening	**Early amniotomy N (%)**	**Late amniotomy N (%)**	
PGE1	**147(65.3%)**	**158(70.2%)**	**P- Value 0.655**
Foleys	**1(0.4%)**	**1(0.4%)**	
PGE1+Foleys	**77(34.2%)**	**66(29.3%)**	

Table: 6

Comparison of Height (in cm) of mother in both Arms

Group	Mean	SD	Minimum	Maximum	P-Value
Early amniotomy	158	5.639	145	175	0.243
Late amniotomy	158.61	5.501	145	176	

Table 7: Comparison of weight (in kg) between each group

Group	Mean	SD	Minimum	Maximum	P-value
Early amniotomy	70.79	11.377	50	106	0.63
Late amniotomy	70.28	11.3	47	114	

Table 8: Comparison of BMI in each arm

The mean body mass index in early amniotomy group 28.39 and late amniotomy group 27.92.

Group	Mean	SD	Minimum	Maximum	
Early amniotomy group	**28.3941**	**4.52361**	**17.51**	**28.39**	**P value: 0.256**
Late amniotomy group	**27.9245**	**4.222**	**18.37**	**27.92**	

Table 9: To compare weight of baby in each group:

There was no significant difference between weights of baby between both groups.

Group	Mean (weight)	Standard deviation	
Early amniotomy N= 225	**3071.16**	**396.115**	**p- value 0.906**
Late amniotomy N= 225	**3075.50**	**381.089**	

Table 10: BASELINE CHARACTERS:

Baseline characteristics	**Early ARM group**	**Late ARM group**	**P Value**
Age in years	25.8	25.32	0.156
BMI	28.39	27.9	0.256
GA in weeks(mean)	39.63	39.58	0.511
Parity			
Primi	68.9%	64%	0.272
Multiparity	31.1%	36%	
Bishop score			
4/13	4.4%	5.3%	
5/13	59.1%	61.3%	
6/13	12%	12.4%	0.672
7/13	23%	8.9%	
8/13	8.4%	9.3%	
9/13	5.8%	2.7%	
Method of induction			
T. PGE1	65.3%	70.2%	
Foleys	0.4%	0.4%	0.655
Combined method	34.2%	29.3%	
Weight of baby (in grams)	3071.1	3075.5	0.906

Table: 11

Duration of Labour from randomization to delivery (in minutes) among both arms:

Duration of labour was less in early amniotomy group with mean of 576.86 compared to late amniotomy with the mean of 635.66 with hour difference between the groups. There was a significant difference in duration of labour with P value of 0.049.

Group	**Mean**	**SD**	**Minimum**	**Maximum**	
Early amniotomy	**576.86**	**326.203**	**62**	**1521**	**P-value 0.049**
Late amniotomy	**635.66**	**305.964**	**60**	**1440**	

Table 12: Amount of oxytocin used in each arm

More oxytocin required in late amniotomy group compared to early amniotomy group.

Amount of oxytocin used	Early amniotomy	Late amniotomy	
2.5 units	112(59.9%)	75(33.3%)	
1st 5 units	76(33.8%)	113(50.2%)	
2nd 5 units	34(15.1%)	32(14.2%)	P value 0.001
7.5units	3(1.3%)	5(2.2%)	

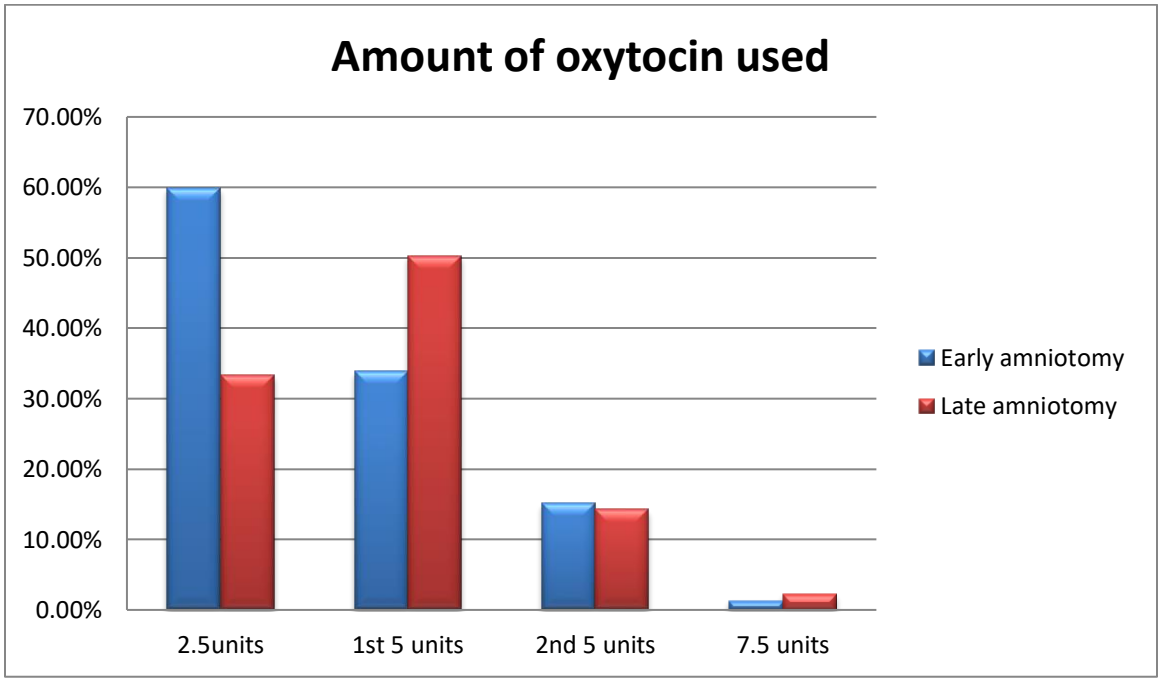


Table 13: Comparison of Intrapartum fever between two groups

There was no significant difference in Intrapartum fever among two study groups. In early amniotomy group 21 participants had Intrapartum fever whereas in late amniotomy group 12 participants had Intrapartum fever.

Intrapartum fever (>100.4F)	**Early amniotomy**	**Late amniotomy**	
Present	**21(9.3%)**	**12(5.3%)**	**P-value 0.104**
Absent	**204(90.7%)**	**213(94.7%)**	

Table 14: Comparison of CTG abnormalities between two groups

There was no significant difference in CTG abnormalities among two arms. In early amniotomy group 100 participants had fetal distress on CTG whereas in late amniotomy group 80 participants had CTG changes.

NRFS/ Fetal distress	**Early amniotomy N (%)**	**Late amniotomy N (%)**	**Total**	
Present	**100(44.4%)**	**80(35.6%)**	**180(40%)**	**P-value 0.54**
Absent	**125(55.6%)**	**145(64.4%)**	**270(60%)**	
Total	**225**	**225**	**450**	

Table 15: Comparison of Category II NRFS among two arms

Cat II NRFS	Early amniotomy N (%)	Late amniotomy N (%)	Total	
Present	91(40.4%)	77(34.22)	168(37.33)	P value: 0.1606
Absent	134(59.5%)	148(65.7%)	282(62.66)	
Total	225	225	450	

Table 16: Comparison of Category III NRFS among two groups

In Early amniotomy group nine participants showed Category III NRFS where as in late amniotomy group only three participants showed Category III NRFS changes on CTG. There was a significant difference in Category III NRFS among two groups.

Category III NRFS	Early amniotomy- N (%)	Late amniotomy- N (%)	Total N (%)	
Present	**9(4%)**	**3(1.33%)**	**12(2.66)**	**P value: 0.0143**
Absent	**216(96%)**	**222(98.66)**	**438(97.33)**	
Total	**225**	**225**	**450**	

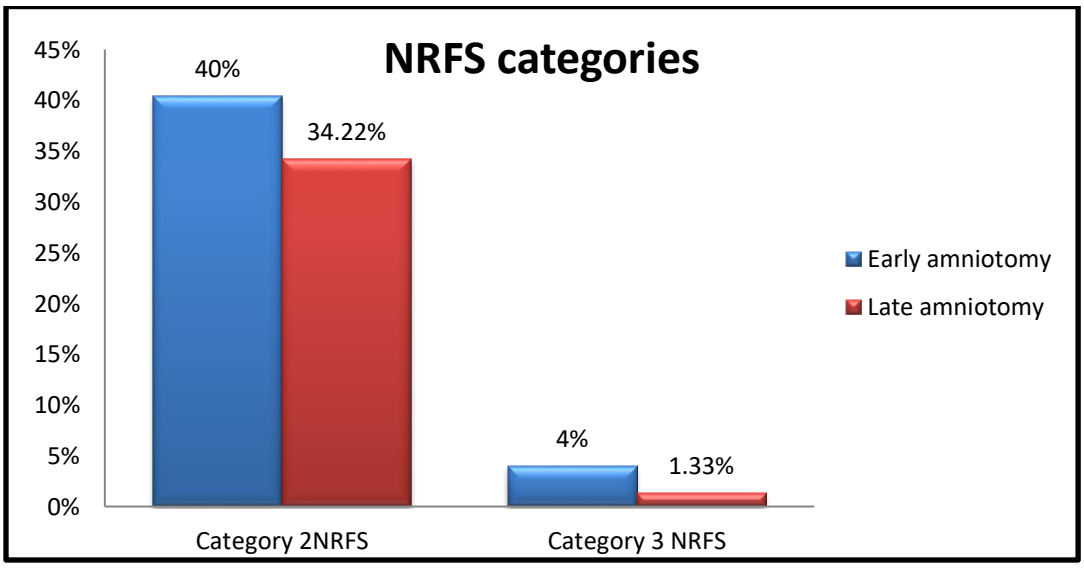


Table 17: Comparison of types of deceleration among two groups

Type of deceleration	Early amniotomy	Late amniotomy	Total	
Late decelerations	4(4%)	1(1.3%)	5	
Variable decelerations	85(85%)	73(91.3%)	158	
Tachycardia	8(8%)	3(3.8%)	11	P value
Prolonged decelerations	3(3%)	3(3.9%)	6	0.449
Total	100	80	180	

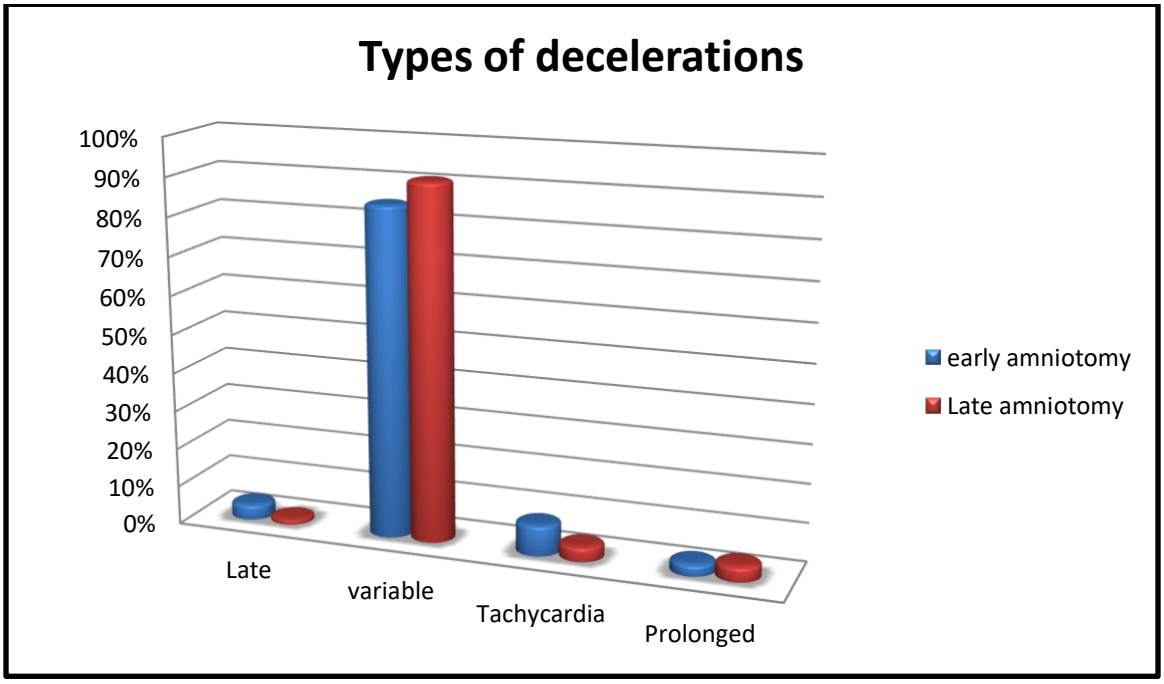


Table 18: Comparison of Amnioinfusion required in both arms.

In early amniotomy group 13 women required Amnioinfusion for variable decelerations when compared to 6 women in late amniotomy group.

Amnioinfusion required	**Early amniotomy- N (%)**	**Delayed amniotomy- N (%)**	
Yes	**13(5.8%)**	**6(2.7%)**	
No	**212(94.2%)**	**219(97.3%)**	**P- value 0.101**
Total	**225**	**225**	

Table 19:

Comparison of Tachysystole between two arms

In early amniotomy group 1.8% developed tachysystole whereas in late amniotomy group 2.7% had tachysystole. There was no significant difference in-between both arms.

Tachysystole	**Early amniotomy N (%)**	**Delayed amniotomy N (%)**	
Present	**4 (1.8%)**	**6 (2.7%)**	**P – Value 0.522**
Absent	**221 (98.2%)**	**219 (97.3%)**	

Table 20: Comparison of hypertonus between two arms

In early amniotomy group 5 women developed hypertonus for 1min whereas in delayed amniotomy 3 women developed hypertonus for 1 min and 2 women developed hypertonus for 2 minutes

Hypertonus		**Early amniotomy N (%)**	**Delayed amniotomy N (%)**	
Present	**1 min**	**5 (2.2%)**	**3 (1.3%)**	**P- Value**
	2 min	**0**	**2 (0.9%)**	**0.504**
Absent		**220 (97.8%)**	**220 (97.8%)**	

Table 21: Terbutaline requirement between two groups

There was no significant difference in terbutaline requirement among two groups.

In early amniotomy group six participants required terbutaline whereas in late amniotomy group five members required terbutaline.

Terbutaline required	**Early amniotomy N (%)**	**Delayed amniotomy N (%)**	
Yes	**6 (2.7%)**	**5 (2.2%)**	**P- Value** **0.76**
No	**219 (97.3%)**	**220 (97.8%)**	

Table 22: Comparison of colour of liquor (at amniotomy) among two arms

Colour of liquor	Early amniotomy N (%)	Delayed amniotomy N (%)	P-Value 0.216
Clear	214 (95.1%)	219 (97.3%)	
MSAF	11 (4.9%)	6 (2.7%)	
Total	225	225	

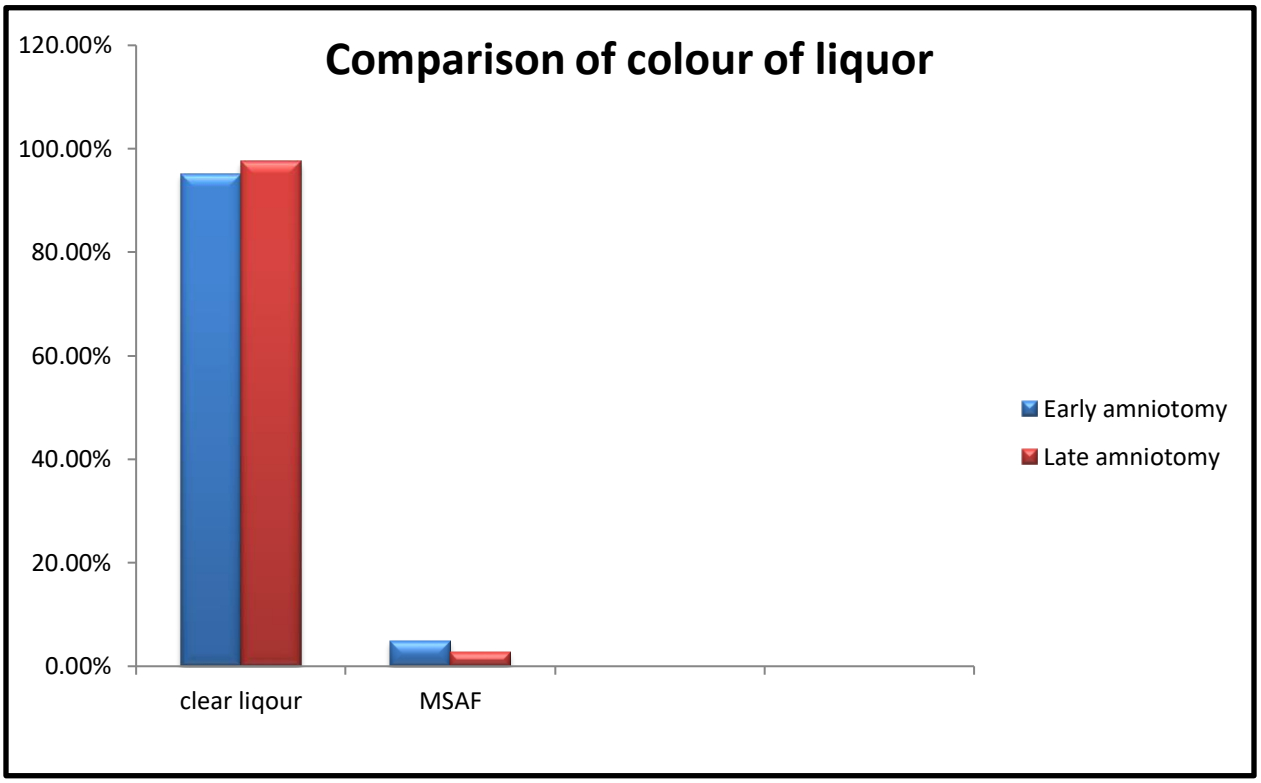


Table 23: Comparison of mode of delivery between two arms

Mode of delivery	Early amniotomy- N (%)	Delayed amniotomy N (%)	Total N (%)	
Normal vaginal delivery	102 (45.3%)	122 (54.2%)	224 (49.8%)	
Instrumental	60 (26.7%)	61 (27.1%)	121 (26.9%)	P Value 0.05
Caesarean	63 (28%)	42 (18.7%)	105 (23.3%)	
Total	225	225	450	

Figure: Mode of delivery in early amniotomy group

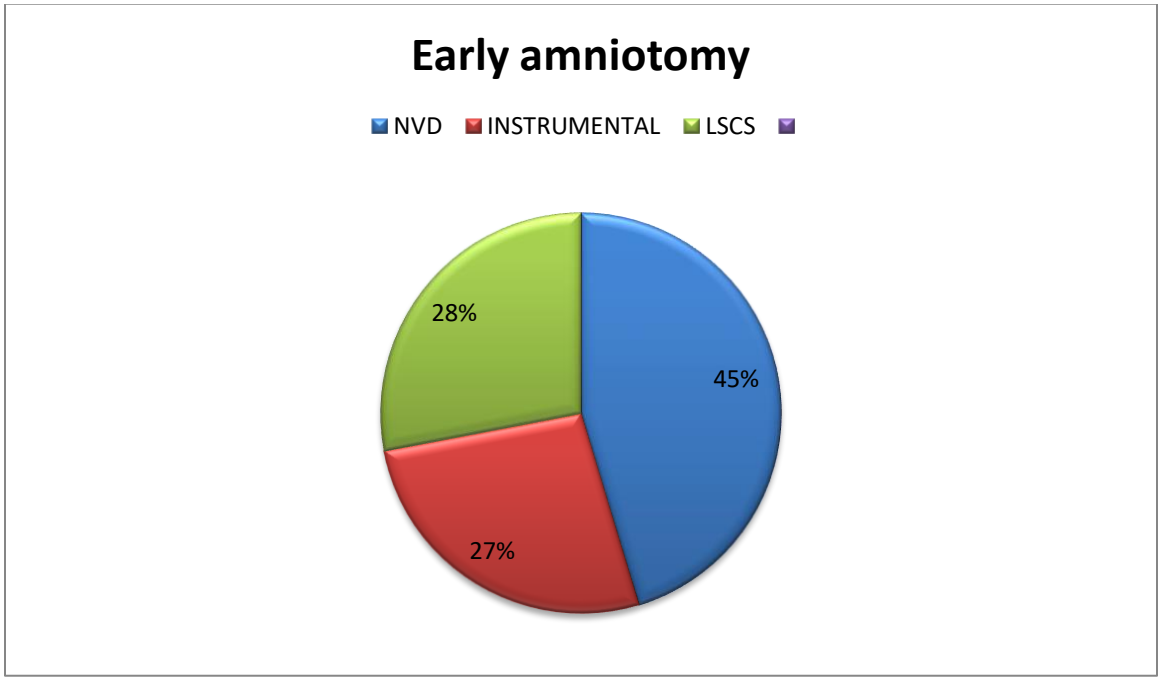


Figure: Mode of delivery in late amniotomy group

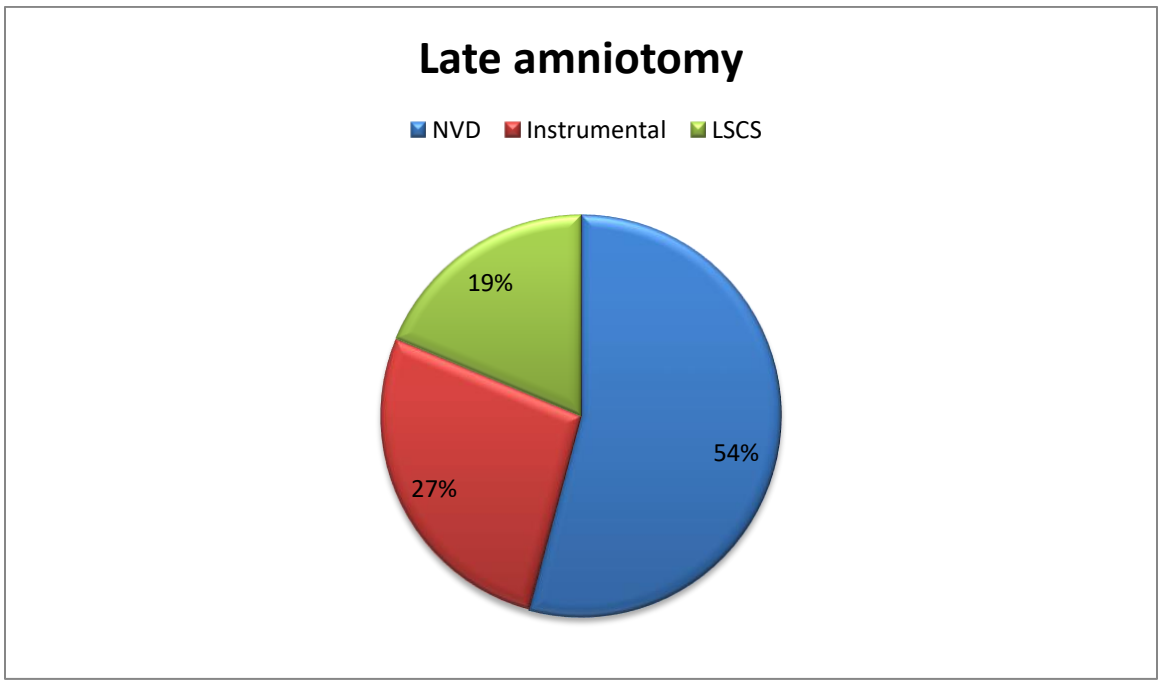


Table 24: –Normal vaginal delivery

Group	Normal vaginal delivery (N %)	Mean	95% CI	
Early amniotomy	102(45.9%)	0.4533	0.3882-0.5183	P Value 0.0593
Late amniotomy	122(54.95%)	0.5422	0.4771-0.6073	
Total (N)	222			

Table 25: Instrumental delivery

Group	Instrumental delivery (N %)	Mean	95% CI	
Early amniotomy	60(49.5%)	0.2666	0.2088-0.3244	P Value 0.9153
Late amniotomy	61(50.4%)	0.2711	0.2130-0.3291	
Total (N)	121			

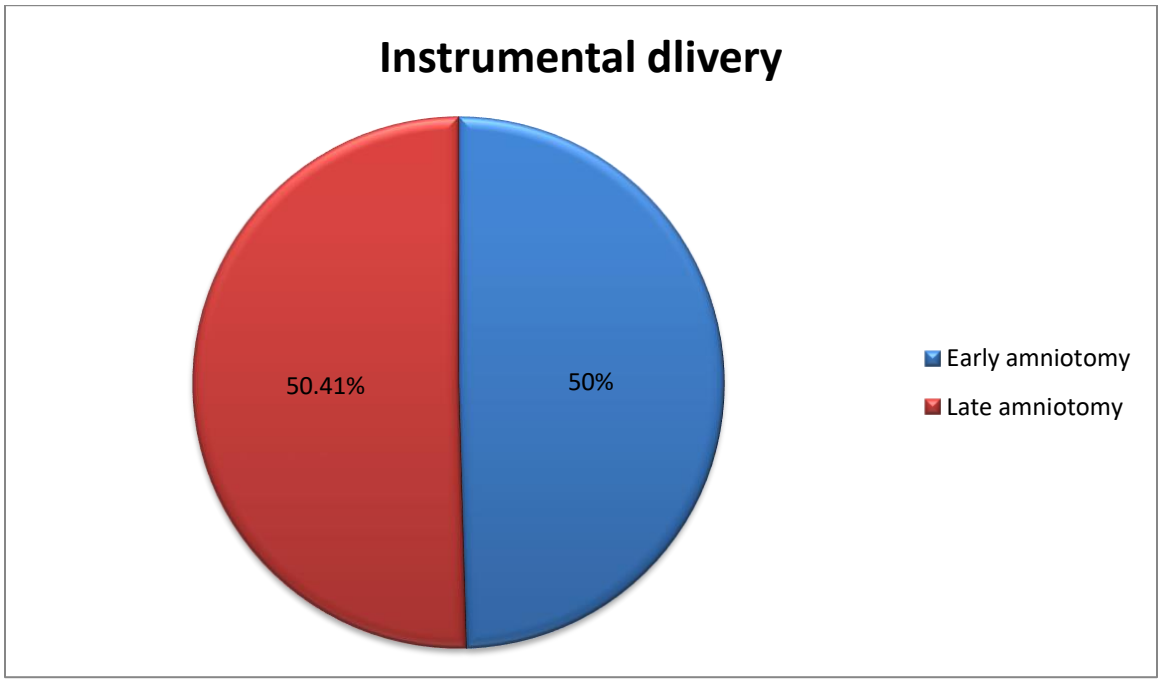


Table 26: Comparison of LSCS rate between two arms

In early amniotomy group 63 women underwent LSCS whereas in late amniotomy group only 42 women underwent LSCS. There was statistically significant difference in LSCS rate among two groups with P value of 0.0193.

Group	**LSCS (N %)**	**Mean**		
Early amniotomy	**63(60%)**	**0.28**	**95% C.I**	
Late amniotomy	**42(40%)**	**0.1866**	**0.0156 – 0.1710**	**P Value 0.0193**
Total (N)	**105**			

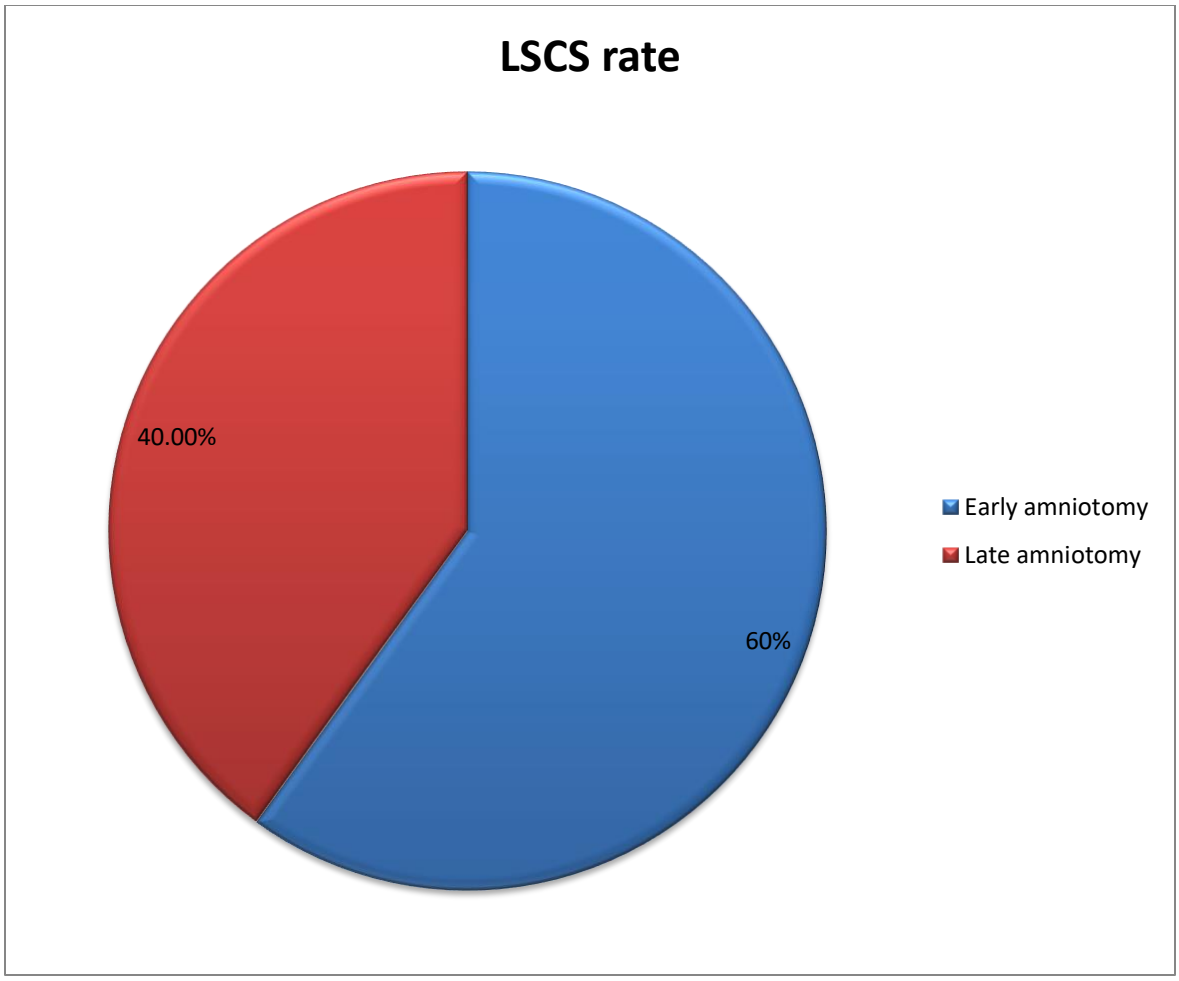

LSCS rate
40.00%
60%
Early amniotomy
Late amniotomy

Table 27: Comparison of indications of LSCS:

Indication of LSCS	Early amniotomy N (%)	Late amniotomy N (%)	P value
NRFS	37(58.7%)	16(38.1%)	0.0383
Arrest of dilatation	3(4.8%)	2(4.8%)	1.0000
Arrest of descent	1(1.6%)	2(4.8%)	0.3388
Failed induction	21(33.3%)	20(47.6%)	0.1416
Cord prolapse	0(0%)	1(2.4%)	-
Total	63	42	

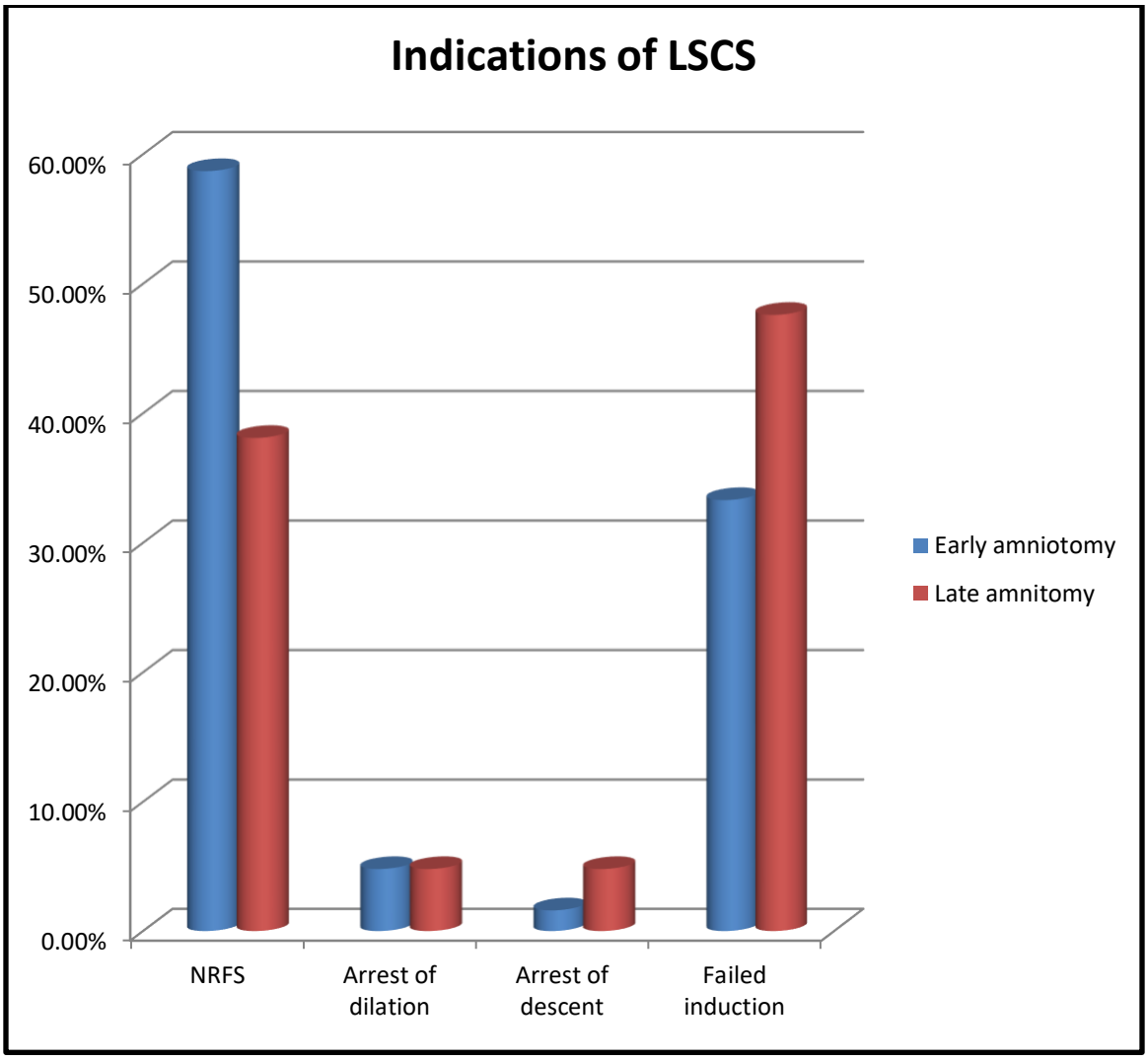

Indications of LSCS
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
NRFS
Arrest of dilation
Arrest of descent
Failed induction
Early amniotomy
Late amnitomy

Table 28: Comparison of PPH between two groups

In early amniotomy group 3.6% participants had postpartum hemorrhage and in late amniotomy group 4.4% had PPH. There was no significant difference in PPH among both arms.

PPH	**Early amniotomy group N (%)**	**Late amniotomy group N (%)**	**Total**	**P value**
Present	**8(3.6%)**	**10(4.4%)**	**18(4%)**	**0.63**
Absent	**217(96.4%)**	**215(95.6%)**	**432(96%)**	
Total	**225**	**225**	**450**	

Table 29: Comparison of postpartum fever among two arms

In early amniotomy group -10.7% of participants had postpartum fever and in late Amniotomy group- 6.2% of participants had postpartum fever. There was no significance difference among both groups.

Postpartum fever	**Early amniotomy N (%)**	**Late amniotomy N (%)**	**Total**	
Present	**24(10.7%)**	**14(6.2%)**	**38(8.4%)**	**P value**
Absent	**201(89.3%)**	**211(93.8%)**	**412(91.6%)**	**0.09**
Total	**225**	**225**	**450**	

Table 30: Comparison of postpartum endometritis between two groups

There was no significant difference in postpartum fever among two arms. In early amniotomy 4.9% of participants had postpartum endometritis where as in late amniotomy group 4.4% had postpartum endometritis.

Postpartum endometritis	**Early amniotomy N (%)**	**Late amniotomy N (%)**	**Total**	
Present	**11(4.9%)**	**10(4.4%)**	**21(4.7%)**	
Absent	**214(95.1%)**	**215(95.6%)**	**429(95.6%)**	**P value 0.823**
Total	**225**	**225**	**450**	

Table 31: Maternal outcomes

Maternal Outcomes	**Early amniotomy** N (%)	**Delayed amniotomy**	**P- Value**
PPH	**8 (3.6%)**	**10 (4.4%)**	**0.63**
Postpartum fever	**24 (10.7%)**	**14 (6.2%)**	**0.09**
Postpartum endometritis	**11 (4.9%)**	**10 (4.4%)**	**0.823**

Neonatal outcomes:

Table 32: Comparison of APGAR score at 5min:

There was no significant difference (P= 1.00) in APGAR score between two arms.

APGAR score at 5min	Early amniotomy N (%)	Late amniotomy N (%)	Total
6	**0**	**1(0.4%)**	**1(0.2%)**
8	**3(1.3%)**	**3(1.3%)**	**6((1.33%)**
9	**7(3.11%)**	**6(2.7%)**	**13(2.88%)**
10	**215(95.5%)**	**215(95.5%)**	**430(95.55%)**
Total	**225**	**225**	**450**

Table 33: Comparison of neonatal resuscitation among two groups:

In early amniotomy group 5 neonates required resuscitation and in late amniotomy group 3 neonates required resuscitation. There was no significant difference in neonatal resuscitation among two arms.

Resuscitation	**Early amniotomy N (%)**	**Late amniotomy N (%)**	**Total**	
Required	**5 (2.2%)**	**3 (1.3%)**	**8 (1.8%)**	
Not required	**220 (97.8%)**	**222 (98.7%)**	**442 (98.2%)**	**P value 0.724**
Total	**225**	**225**	**450**	

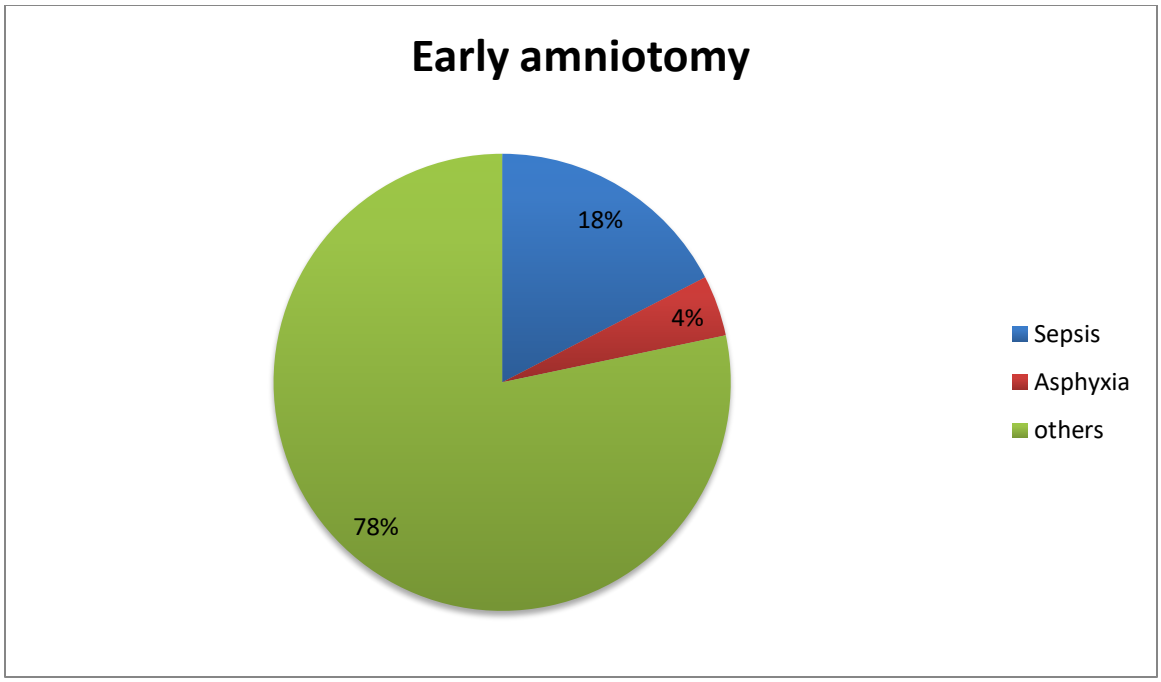
Table 34: Comparison of NICU admissions:

In early amniotomy group, 10.2% neonates admitted in NICU whereas in late amniotomy group -6.2% admitted in NICU. However, there was no significant difference among two arms.

Admission to NICU	**Early amniotomy N (%)**	**Late amniotomy N (%)**	**Total**	**P value 0.276**
Yes	**23(10.2%)**	**14(6.2%)**	**37 (8.2%)**	
No	**202(89.8%)**	**211(93.7%)**	**413 (91.7%)**	
Total	**225**	**225**	**450**	

Table 35: Comparison of indications of NICU admission (data taken at discharge of the baby)

Indication for NICU admission	Early Amniotomy	Late amniotomy	Total
Sepsis	4(17.4%)	1(7.1%)	5(13.5%)
Asphyxia	1(4.3%)	3(21.4%)	4(10.8%)
Others	18(78.3%)	10(71.4%)	28(75.7%)
total	23	14	37


Early amniotomy
18%
4%
78%
Sepsis
Asphyxia
others

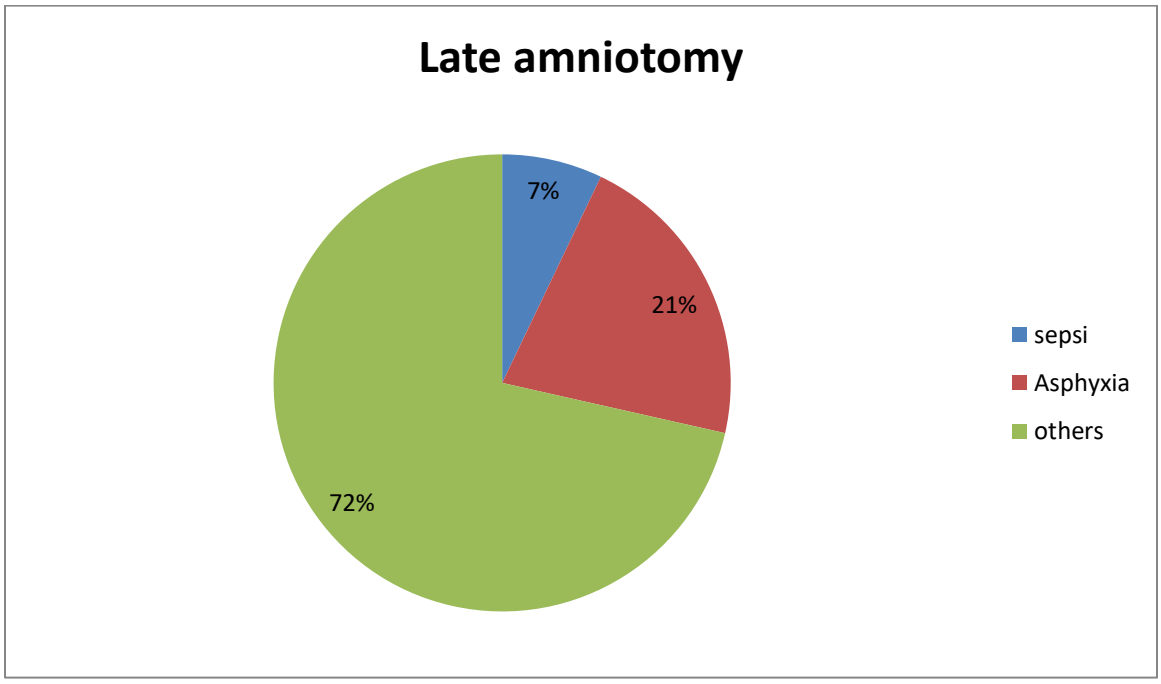

Late amniotomy
7%
21%
72%
sepsi
Asphyxia
others

Table 36: Comparison of protocol deviation in each arm

Protocol deviation	Early amniotomy N (%)	Late amniotomy N (%)	Total	
Yes	0	11(4.9%)	11(2.4%)	
No	225	214(95.1%)	439(97.6%)	P value 0.001
Total	225	225	450	

DISCUSSION

The increase in LSCS (Lower segment caesarean section) rate has been a global phenomenon due to increasing rate of induction of labour. According to WHO global survey on maternal and perinatal health, in 24 countries and nearly 300000 deliveries, showed that 9.6% of the deliveries involved labour induction(47). According to our National Family Health Survey (1992-1993 to 2015-2016) women undergoing LSCS rate has gone up from 10 to 30 %, raising the country's average caesarean section rates from 5 to 18 %. World Health organization advises that Caesarean section (CS) rates should not be more than 15% in the population. There is evidence that CS rate above 15% are not associated with additional reduction in maternal and neonatal mortality and morbidity. Indications of Caesarean section may be maternal or fetal (48). Induction of lab our (IOL)is associated with 2-3 fold increased risk of caesarean section (49). Risk factors for CS during IOL are macrosomia in baby, advanced gestational age, nulliparous women, and use of cervical ripening agents (50,51). Studies done in the past comparing early and late amniotomy showed either increase or no differences in the caesarean section rate and the population studied had different cervical dilatations, mostly 3-4 cm and above. We conducted this trial to assess the effects of delayed amniotomy (ARM after 6hrs of oxytocin infusion) on caesarean section rate in the group of women who have not entered active phase of labour at the time of oxytocin augmentation.

As chorioamnionitis has been associated with significant maternal and neonatal morbidity including postpartum hemorrhage, maternal and neonatal sepsis, infant's future development of cerebral palsy (52,53) research on interventions which impact rates of chorioamnionitis is also important. The aim of this study is to assess whether late amniotomy reduce the rate of caesarean section delivery when compare to early amniotomy in low risk pregnant women who undergo induction of labour.

In our study baseline characteristics of study participants showed no difference between two groups, conforming that randomization followed. The mean age of study participants was 25.8 vs. 25.32 and primigravida were 68.9% vs. 64 %. The average BMI was 28.39 in early amniotomy and 25.32 in late amniotomy group. Mean gestational age was 39.63 vs. 39.58. In this study, average weight of baby was 3071.1 versus 3075.5, with P value of 0.906.

In early ARM group 65.3% of women received Tab. PGE1 as cervical ripening agent as compared to 70.2% in late ARM group. Combined method (Tab. PGE1 + Foleys) was used for early group: 34.2% versus late group 29.3%. P value was 0.655 in method of induction.

At randomization, Bishop Score showed no significant difference between two arms. Majority of women reached bishop score of 5/13 after cervical ripening. Early amniotomy 59.1% versus 61.3% had bishop score of 5/13.

Duration of labour was less in early amniotomy group with mean of 576.86 compared to late amniotomy with the mean of 635.66. There was a significant difference in duration of labour with P value of 0.049. In our study, Labour duration was 1 hour shorter in early amniotomy group when compared to late amniotomy group. These results are in support to other studies like -Faris Anwar Rasheed et al (Early versus late: 5.1 versus 7.8 hours, p=0.01), Li et al showed significant difference in 1st stage of labour and Batterbee et al. showed shorter median labour induction time (2.5hours) in early amniotomy group. Anju Bala et al. showed high proportion of women delivered within 12 hours in early amniotomy when compared to delayed amniotomy group (Early versus late: 86.7 versus 60%). Marcer et al. (early versus late: 13.3 vs.17.8hours, P=0.001), Macones et al. (Early versus late: 19 versus 21.3hours, P=0.04), Makarem et al. (early versus late: 9.7 vs. 13.6hours, p=0.002), Gagnon Gervais et al. (Early versus late: 12vs.15hours, P=0.003) also showed short IDI in early amniotomy group. A RCT conducted by Vadivelu et al (43) in CMCH, Vellore to compare effect of amniotomy and non-amniotomy for shortening spontaneous labour also showed shorter duration of labour in early amniotomy group when compared to late amniotomy group (Early vs. Late : 235 versus 365, P<0.001).

The oxytocin requirement is more in late amniotomy group compared to early amniotomy group. P value was 0.001, which is statistically significant. In late amniotomy group participants required high concentration of oxytocin when compared to early amniotomy group. In our study in early amniotomy group -59.9% versus in late

amniotomy group 33.3% received 2.5 units of oxytocin, 33.8% versus 50.2% received 5u units of oxytocin and 15.1% versus 14.2% received 2nd pint of 5 units of oxytocin. Three participants in group 1 and 5 participants in group 2 needed 7.5 units of oxytocin. The results can be explained by early release of PG'S by amniotomy in early group.

Levi et al. (early versus late: 8.7 and 23%, RR: 1.69) and Mercer et al. (Early vs. late: 39 and 10%, P <0.001) showed increased intrapartum fever in early amniotomy group. However, in our study, there was no significant difference in Intrapartum fever between two study groups. In early amniotomy group, 9.3% had Intrapartum fever whereas in late amniotomy group 5.3% had Intrapartum fever.

In our study, there was no significant difference in CTG abnormalities among two arms (P Value: 0.54). In early amniotomy group, 44.4% had fetal distress on CTG whereas in late amniotomy group only 35.6% had CTG changes. In category II NRFS there was no significant difference among two arms, but in category III there was statistically significant difference with p value of 0.0143. In early group, 4% showed Category III NRFS where as in late amniotomy group 1.33% participants showed Category III NRFS changes on CTG. Though difference not met the statistical difference in Category II NRFS, the high number of fetal distress can be explained by cord compression because of amniotic fluid drains out in early amniotomy. There was no significant difference in Amnioinfusion among two arms, P value: 0.101, Early vs. late: 5.8% versus 2.7%

In our study among 450 participants total 10 women developed tachysystole (early vs. late amniotomy 4 vs. 6) with P value 0.522. In each arm five women developed hyper tonus (p value: 0.504). In our institute, injection Terbutaline is used for hyper stimulation of uterus. In early amniotomy group 2.7% and in late amniotomy group 2.2% participants received terbutaline injection. There was no significant difference between two groups (P value: 0.76). Meconium stained amniotic fluid (MSAF) was more in early amniotomy group when compared to late amniotomy group (Early versus late – 11 versus 6) with P value of 0.216.

Total 224 study participants underwent normal vaginal delivery (early versus late - 45.3% versus 54.2%), 121 participants had instrumental delivery (early versus late: 26.7% versus 27.1%), 105 women underwent caesarean section (28% versus 18.7%). P value for mode of delivery was 0.05. There was no difference in number of instrumental deliveries between both groups, but data analysis showed a greater number of normal deliveries in delayed ARM group compared to early amniotomy group.

The LSCS rate in early amniotomy group was more when compared to delayed amniotomy group (Early versus late – 63 versus 42). There was a statistically significant difference with P value of 0.0193. Some previous randomized control trials showed increase in LSCS rate in early amniotomy group when compared to late amniotomy group. Levy et al (early versus late: 25 vs. 7.9) and Bala et al (early vs. late: 10.7 vs. 2.7), Ruamsap and Panichkul (Early versus late: 43.3% versus 20%; P = 0.006), Faris Anwar Rasheed et al (early versus late: 33.3% versus 15.2%) along with other retrospective

studies like - Lee et al and Battarbee et al showed increased Lscs rate in early amniotomy group and Ibost et al. showed positive association between amniotomy and LSCS rate. Metaanalysis by Li et al. also showed increase in LSCS rate in early amniotomy group with the odds ratio of 1.25, 95% CI (0.99-1.57). Another cohort study conducted by Olfati et al. also showed significantly high LSCS rate in early amniotomy group with P value of 0.001.

In early amniotomy group most common indication of LSCS was NRFS, 37 women in this group had LSCS for NRFS, followed by failed induction- 21 women (33.3%), 5 women underwent LSCS for arrest disorders (arrest of dilatation, arrest of descent and protracted dilatation = 8%). No women had LSCS for cord prolapse in early amniotomy group.

In late amniotomy group 20 women (47.6%) had LSCS for failed induction, 16 women (38.1%) underwent LSCS for NRFS, five women had LSCS for arrest disorders (arrest of dilatation, arrest of descent and protracted dilatation = 12%). One participant underwent LSCS for cord prolapse (2.4%). In late amniotomy group number of women who had LSCS for failed induction were more when compared to early amniotomy, it might be correlates with defining failed induction in late amniotomy group only after 12 hours of amniotomy when compared to early amniotomy where failed induction taken after 18 hours of amniotomy.

In LSCS indications, NRFS was more in early amniotomy group and showed statistically significant difference with P value – 0.0383. Hence, there are more chances of fetal distress because of cord compression in early rupture of membranes, which increases LSCS rate.

In both groups, number of women who had PPH was almost similar with P value of 0.63, in early amniotomy group, 8 patients (3.6%) had postpartum hemorrhage and late amniotomy group 10 women had (4.4%) PPH. There was no significant difference in incidence of postpartum fever (early vs.late : 10.7%vs.6.2%) and postpartum endometritis (early versus late: 4.9% vs. 4.4%) among two groups.

In our study most of neonates had APGAR score of 10 at 5min. Only 1 baby had APGAR of 6 in late amniotomy group, but there was no significant difference in APGAR score between two groups. In early amniotomy group, 2.2% required neonatal resuscitation whereas in late amniotomy group 1.3% required neonatal resuscitation, but P value was 0.724. NICU admission was slightly more in early amniotomy group compared to late amniotomy group with P value of 0.276, which was not significant. Four neonates in early amniotomy group had neonatal sepsis compared to one neonate in late amniotomy group. No women in early amniotomy group underwent protocol deviation, but in late amniotomy group, 11 out of 225 underwent protocol deviation. For two women Amniotomy done before 6 hours of oxytocin for abnormal CTG findings to check meconium stained liquor and nine women had spontaneous rupture of membranes before 6 hours of oxytocin augmentation.

LIMITATIONS

- This study was performed in tertiary teaching hospital where it serves more than an average of 1200 to 1500 deliveries per month, so sample size was not completed by the investigator.

- This study included only low risk mothers who underwent induction of labour, hence these results cannot be extrapolated to all women who are undergoing IOL.

- To make the uniformity of protocol failed induction is considered 18hr from the time of oxytocin and not from the time of ARM, which resulted in more no of failed induction in Late amniotomy group.

- Most of the study participants after informed consent spontaneously ruptured membranes before randomization, because of this we could not able to complete expected sample size.

CONCLUSION

- This study showed increased LSCS rate in early amniotomy (Amniotomy along with oxytocin augmentation) when compared to delayed amniotomy group (amniotomy after 6 hours of oxytocin augmentation), which is statistically significant with P value of 0.0193.
- This study also showed a smaller number of NRFS as indication of LSCS in late amniotomy when compared to early amniotomy group. There was statistically significant difference in NRFS as an indication of LSCS between the two groups, P value: 0.0383.
- There was more category III NRFS who delivered by LSCS in early amniotomy group compared to late amniotomy group with P value of 0.0143.
- We also found that duration of labour was slightly less (1 hour) in early amniotomy group compared to late amniotomy group. Which is significant- 0.049
- The Amount of oxytocin required was less in early amniotomy group. Which is significant with P value of 0.001
- Maternal complications like chorioamnionitis, PPH, Postpartum fever, postpartum endometritis and fetal outcomes like sepsis, asphyxia, low APGAR score showed no significant difference among both groups.

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ANNEXURES

ANNEXTURE I – INSTITUTIONAL REVIEW BOARD CLEARANCE

ANNEXTURE II- PATIENT INFORMATION SHEET

ANNEXTURE III – PATIENT CONSENT FORM

ANNEXTURE IV- PROFORMA

ANNEXTURE V – MASTER SHEET

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

Ethics Committee Registration No: ECR/326/INST/TN/2013 Re Reg-2016 Issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. of India

Dr. George Thomas, M.B.B.S., D. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

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

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

May 31, 2018

Dr. T. Sravani,
PG Registrar,
Department of Obstetrics and Gynecology
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction – A randomized control trial.

Dr. T. Sravani (Emp. No. 21413), PG Registrar, Obstetrics and Gynecology, Dr. Reeta Vijayaselvi (Emp. No. 50600), Dr. Anju Abraham (Emp. No. 31916), Dr. Swathi Rathore (Emp. No. 31682), Dr. Liji David (Emp. No. 28567), Obstetrics and Gynecology, Mrs. Grace Rebekah (Emp. No. 32070) Biostatistics.

Ref: IRB Min. No. 11185 (INTERVEN) dated 28.02.2018

Dear Dr. T. Sravani,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board.

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

CC: Dr. Reeta Vijayaselvi, Professor, Department of Obstetrics and Gynecology, CMC, Vellore

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

May 31, 2018

Dr. T. Sravani,
PG Registrar,
Department of Obstetrics and Gynecology
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
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Ref: IRB Min. No. 11185 (INTERVEN) dated 28.02.2018

Dear Dr. T. Sravani,

The Institutional Review Board **(Silver**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction – A randomized control trial" on February 28, 2018.

The Committee reviewed the following documents:

1 IRB Application format
2. Information sheet and Informed Consent form
3. Cvs. Of Drs. Annie Regi, Sravani, Anuja, Liji, Reeta, Swati, Ms. Rebecca.
4. Data Collection Proforma.
5. No. of documents 1- 4.

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on February 28th 2017 at 9.45 am in the New IRB Room, Christian Medical College, Bagayam, Vellore 632002.

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

Dr. George Thomas, M.B.B.S., D. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

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

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB, Chennai	External, Clinician
Rev. Dr. T. Arul Dhas	MSc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore.	Internal, Clinician
Dr. L. Jeyaseelan	MSc, PhD, FSMS, FRSS	Professor & Head, Biostatistics, Secretary (Research Committee), IRB, CMC, Vellore	Internal, Statistician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
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
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Clinician
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor of Paediatrics, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Sujith J Chandy	MBBS., MD., PhD., FRCP (E)	Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Ashish Goel	MBBS, MD, DM	Professor, Hepatology, CMC, Vellore	Internal, Clinician
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMC, Vellore	Internal, Basic Medical Scientist

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

Dr. Prasanna Samuel	MSc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Abhay Gahukamble	MS, D Ortho, DNB(Ortho)	Associate Professor, Paediatric Orthopaedics, CMC, Vellore	Internal, Clinician
Dr. Suceena Alexander	MBBS, MD, DM	Associate Professor, Nephrology, CMC, Vellore	Internal, Clinician
Dr. Sathya Subramani	MD, PhD	Professor, Physiology, CMC, Vellore	Internal, Clinician
Dr. Shirley David	MSc, PhD	Professor, Head of Fundamentals Nursing Department, College of Nursing, CMC, Vellore	Internal, Nurse
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Mrs. Ilavarasi Jesudoss	MSc (N)	Professor, Head of Medical Surgical Specialty 3 and Deputy Nursing Superintendent, College of Nursing, CMC, Vellore.	Internal, Nurse

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction – A randomized control trial" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 20,000/- INR (Rupees Twenty Thousand Only) will be granted for 2 Years

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board.

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 11185 (INTERVEN) dated 28.02.2018

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INFORMATION SHEET

Title of study: Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction - A Randomized control trial.

Information: Around 30-40 % of the pregnancies end up in artificial stimulation of labour pain. Artificial stimulation of labour is done when the risk outweigh the benefits of continuing the pregnancy. This artificial stimulation is done if there is any complication in mother or fetus or in postdated pregnancies.

Artificial stimulation of labour is done by softening the cervix with vaginal or oral medication, followed by giving labour stimulant drug intravenously. The bag of membrane is ruptured simultaneously along with starting intravenous drug or can be done later when the laboring women reach active labour. Rupture of membrane exposes the uterus and the foetus to the outside environment and draining the fluid from the amniotic cavity increasing the chances of for operative delivery for fetal distress and infection to mother or baby during and after delivery. Studies done in the past has varied outcomes and hence we would like to conduct this study to find the benefits of delayed artificial rupture of membrane. The current practice in our hospital is rupturing the bag of membrane when the stimulant drug is given to the women.

If you agree to be part of this study, after ripening of cervix, either we rupture the bag of membranes along with the intravenous stimulant drug (i.e.: control group) or break the bag of membrane after 6hrs of starting the stimulant drug (i.e.: Intervention group). This depends on what the randomization envelop instruct the doctor.

You will have no benefit or additional risk by participating in this study. If there are any complications, it will be taken care of. 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.

For any query contact:

Dr. Sravani, Pg Registrar, OG-4 office, CMCH, Vellore

Informed Consent form to participate in a research study

Study Title: Effects of early versus late amniotomy on maternal and fetal outcomes in low risk induced pregnancies following cervical ripening for labour induction - A Randomized control trial.

Study Number: _____

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

Date of Birth / Age: _____

(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 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

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or thumb impression

Representative: _____

Date: _____/_____/_____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____

DATA COLLECTION PROFORMA:

Data abstraction form

	ARM TRIAL- EARLY AMNIOTOMY VERSUS LATE AMNIOTOMY	
1. Name		
2. Serial number		
3. Hospital number		
4. Age(in years)		
5. Gestational age in weeks		
6. Parity		
7. Cervical dilatation at randomization		
8. Position of cervix		
9. Length of the cervix		
10. Consistency of the cervix		
11. Station of vertex		
12. BISHOP SCORE		
13. Method of cervical ripening		
a. PGE1	b. Foleys	c. PGE1 and Foleys
d. No ripening agent		
14. Height in cm		
15. Weight in kgs at admission		
16. Birth weight of baby in grams		
17. Randomization group		
a. Early ARM group		
b. Delayed ARM group		
18. Duration of labour from randomization to delivery (min)		

19. Amount of Oxytocin used		
2.5 units	100,200,300,400,500ml	100,200,300,400,500ml
5 units (1st)	100,200,300,400,500ml	100,200,300,400,500ml
5 units (2nd)	100,200,300,400,500ml	100,200,300,400,500ml
7.5 units	100,200,300,400,500 ml	100,200,300,400,500 ml
20. Intrapartum fever (≥100.4F)	a. Yes	b. No
21. Fetal distress /NRFS	a. Yes	b. No
22. If yes	a. Category I	b. Category II
	c. Category III	
23. Description of decelerations		
a. Early deceleration	b. Late deceleration	c. Variable deceleration
d. Tachycardia	e. severe decelerations	f. others
24. Amnioinfusion required	a. Yes	b. No
25. Tachysystole	a. Yes	b. No
26. Hyper tonus		
a.1-minute	b. 2-minute	c. No
27. Points (25+26)	a. Yes	b. No
28. If yes, requiring terbutaline	a. Yes	b. No
29. Color of liquor	a. Clear	b. MSAF
30. If MSAF	a. Thick MSAF	b. Thin MSAF
31. Mode of delivery		
a. NVD	b. Instrumental	c. LSCS
32. If LSCS, indication for the same		
a. Fetal distress	b. NRFS	c. Protracted dilatation
d. Arrest of dilatation	e. Arrest of descent	f. Failed induction
g. Cord prolapse		
33. PPH	a. Yes	b. No
34. Blood loss	a. less than 500ml	b. 500-1000ml
	c. 1000-1500ml	d. 1500-2000ml
	e. Greater than 2000ml	
35. Blood transfusions	a. Yes	b. No
36. Postpartum fever	a. Yes	b. No
37. Postpartum endometritis	a. Yes	b. No

38. Diagnosis of endometritis		
a. Clinical	b. Fever	C. Antibiotics
39. Outcomes of the baby		
a. Alive	b. Still birth	c. END
40. Apgar score at 5min		
41. Need for resuscitation at birth	a. Yes	b. No
42. If yes Cord PH <7.2		
43. Admission to NICU		
44. If yes, indication for admission to NICU		
a. sepsis	b. Asphyxia	c. Others
45. Protocol deviation	a. Yes	b. No
46. If yes, in Late ARM group		
a. ARM for abnormal trace	b. Spontaneous rupture	c. Withdrawal
47. If yes reason in Early ARM group	a. Withdrawal	

amnio	tachy	hyper	point	color	msaf	delive	lscs	pph	bldlos	bldtra	postfe	poste	endo	outco	apgar	resus	cordp	nicu	nicuy	proto	latear	early
2	2	1	1	1		1		2	1	2	2	2		1	10	2		2		2		
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93	26	38	4	1	2	2	2	2	-3	5	1	149	88	2500	1	570	2	800	1	1	2	3
94	19	38	4	1	2	2	2	2	-3	5	1	156	65	2870	2	444	2	800	2	2		
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97	23	38	2	2	2	2	2	2	-3	5	1	158	60	3458	1	210	1	200	2	2		
98	22	40		1	3	2	0.5	2	-2	8	3	160	74	2960	2	120	1	200	2	2		
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104	32	39	5	2	2	2	2	2	-3	5	1	165	60	2780	2	450	2	600	2	2		
105	22	40	4	2	2	2	2	2	-3	5	1	159	48	2760	2	401	1	500	2	2		
106	29	39	2	2	2	2	2	2	-3	5	1	161	80	3070	1	368	1	400	2	2		
107	25	39	5	1	2	2	2	2	-3	5	1	152	55	2880	2	635	2	700	2	1	2	4
108	24	38	4	1	3	2	0.5	2	-3	8	3	166	57	2700	1	840	3	1200	2	2		
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110	27	40		1	2	2	2	2	-3	5	1	166	73	3330	1	300	1	400	2	2		
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112	24	40	1	2	2	2	2	2	-2	6	1	159	86	3020	2	300	1	300	2	2		
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114	29	39		2	3	2	2	2	-3	6	1	156	96	3050	1	331	1	400	2	2		
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