"EFFECT OF SWEEPING OF MEMBRANES AT INITIATION OF FORMAL INDUCTION OF LABOUR - A ONE YEAR RANDOMISED CONTROLLED TRIAL"

By

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In Partial Fulfillment
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M. S.
(OBSTETRICS AND GYNAECOLOGY)

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I hereby declare that this dissertation entitled **"EFFECT OF SWEEPING OF MEMBRANES AT INITIATION OF FORMAL INDUCTION OF LABOUR - A ONE YEAR RANDOMISED CONTROLLED TRIAL"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. (Mrs.) JYOTSNA C. SHRAVAGE** **MD, DGO, FICOG** Professor, Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum – 590 010.

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LIST OF ABBREVIATIONS USED

CRH	-	Corticotropin-releasing hormone
DHEA-S	-	Dehydroepiandrosterone sulfate
EDFL	-	End Diastolic Fibre Length
GAG	-	Glycosaminoglycan
HCG	-	Human chrionic gonadotrophin
KLES	-	Karnataka Lingayats Education Society
LSCS	-	Lower Segmant Cesarean Section
MCP-1	-	Monocyte chemotactic protein-1
PAF	-	Platelet activating factor
PG	-	Prostaglandins
PGE1	-	Prostaglandin E1
PGE2	-	Prostaglandin E2
PGF2α	-	ProstaglandinF2α
PGFM	-	Prostaglandin F Metabolites
RCOG	-	Royal College of Obstetricians and Gynecologists
WHO	-	World health organisation

ABSTRACT

Background and objectives

To evaluate the induction to delivery interval and mode of delivery in subjects who undergo membrane sweeping at initiation of formal induction of labour.

Methods

Randomized controlled trial conducted at KLES Dr Prabhakar Kore Hospital and Medical Research Center, Belgaum. Patients requiring induction and willing for the same were screened for the selection criteria and included in the study. Patients were then randomized into Sweep and Nonsweep categories as per the computer generated randomization chart. In Sweep group Bishop's score was noted and then membranes are swept before induction with cerviprime whereas, those in the Nonsweep category underwent induction with cerviprime without sweeping after noting the initial Bishop's score. Progress of labour in active phase was monitored by WHO partogram (2000).

Results

Sixty (35 nulliparas and 25 multiparas) subjects in Sweep and 60 (36 nulliparas and 24 multiparas) subjects in Nonsweep were analysed. Nulliparas, in sweep category, mean induction to delivery interval was 9.88±5.40hrs versus 18.88±6.83hrs in nonsweep category (p=0.0001). In multiparas the mean induction to delivery interval is 15.19±8.50hrs in Nonsweep and 8.33±6.79hrs in sweep (p=0.0001). Twenty five out of 35 nulliparas in sweep category went in for vaginal delivery (71.43%), whereas 17 out of 36 nulliparas in Nonsweep cases

had vaginal delivery (47.22%; p=0.038). All multiparas in sweep group had vaginal delivery whereas 12 out of 24 in Nonsweep had vaginal delivery (50%; p<0.001). The induction to delivery interval in nulliparas with Bishop's score ≤4 in sweep category was 9.19±5.42hrs as compared to 14.61±4.99hrs in nonsweep (p=0.0001).

Conclusions and interpretation

The induction to delivery interval and vaginal delivery rates in nulliparas and multiparas is significantly less in sweep category. In nulliparas, with unfavourable cervical score the induction to delivery interval is significantly less in sweep.

Key words: Delivery; Induction; Sweeping of membranes;

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INTRODUCTION

Induction of labour is artificial initiation of labour before its spontaneous onset, for the purpose of delivery of fetus placental unit.[1] Induction of labour is the most common obstetric intervention accounting for approximately 20% of deliveries.[2]

Induction is being practiced since centuries, where it was indicated in cases of fetal death but there is a sea of change in the indications for induction of labour since the last 50 to 60 years. Now induction of labour is advocated in circumstances or condition where the intrauterine environment is detrimental for growth and maturation of the fetus or for maternal indications.

Induction of labour is like a rapier or a double edged sword wherein one edge of the blade is always towards the users neck, in other words the more we try to interfere with the normal spontaneous onset of labour there are increased chances that we may land up into rough water like increased cesarean sections, increased rate of instrumental deliveries or chorioamniotis, psychological disturbances.[3]

Therefore elective inductions (that is for convenience) cannot be recommended.[4]

Elective induction does not appear to increase the rate of cesarean section when the guidelines are met. Electively inducing labour with a low Bishop's score increases the risk of cesarean section, especially in nulliparas.[5]

Society of Obstetricians and Gynaecologist in Canada (SOGC) states that induction of nulliparas is associated with twice the chance of cesarean birth compared with spontaneous labour.[6]

Most methods of inducing labour before the last half century involved mechanical manipulations, including Galvinism, repeated pressurised douches, extra-amniotic aqua picea, tents, bougies and catheters. The issue of threats, incantations and chants was doubtless popular when nothing else was at hand, while the administration of potions and later castor oil, quinine and posterior pituitary extract were also utilized.[7]

There is a gradual evolution in the technique for induction of labour; dietary delicacies and verbal threats gave way to physical stimulations like cervical stimulation, amniotomy and sweeping of membranes which finally gave way to sophisticated pharmacological manipulations using oxytocin and prostaglandins.

Exact knowledge about the physiological process involved in initiation of spontaneous parturition is still at large, so the chances of successful induction is still not guaranteed.

There has been increasing emphasis ,during the past decades, to search for a concrete answer for successful induction. Safety, success, and patient satisfaction continue to be the major objectives with economic evaluations now becoming a significant factor in the search for the ideal induction method.

Sweeping of membrane is believed to release endogenous prostaglandins which ripens the cervix leading to onset of labour, through initiation of self perpetuating prostaglandin cascade.[8]

Several randomized trial have evaluated sweeping of membrane with conflicting results and conclude that although sweeping of membranes promotes onset of labour, it does not seem to produce clinically important benefit on maternal neonatal outcome when used as a method for induction of labour but it does promote onset of labour and reduce the duration of pregnancy and rate of postterm pregnancy. Also it should not be the method of choice in urgent induction but means to decrease formal induction.

Cochrane Database System Review 2009 concluded that routine use of sweeping of membranes from 38 weeks of pregnancy was onwards does not seem to produce clinically important benefit.[9]

The search for a safe and efficient method of induction continued and it received the boost in 1960's,with the advent of prostaglandins, which were extensively evaluated and by 1980 prostaglandins have become the established and most effective means of labour induction.

Other formal method of induction, that is pharmacological agents have been studied, but individually they are not efficient and do not always guarantee a successful outcome.

Moreover use of rapidly acting inducing agent like prostaglandins were associated with increased chances of hyperstimulation, fetal distress, uterine rupture.[10,11]

Therefore the present concept of use of combined approach to harness the synergetic effect of two modes of labour induction has evolved.

Amniotomy and intravenous oxytocin warrant attention but available literature does not really support the value of this combined approach.[12]

Amniotomy with oxytocin should not be used as a primary method of induction of labour unless there are specific contraindications to the use of vaginal PGE2, in particular the risk of uterine hyperstimulation.[2]

The search for an induction method that modulates the unfavourable to favourable cervix without stimulating uterine contractions and improves the ultimate outcome of labour almost eliminating risk to the fetus remains the Holy Grail. Sweeping of membranes (a non pharmacological method) alone is an effective but not a very efficient method of labour induction on the other hand pharmacological method of induction such as induction with PGE1 and E2, oxytocin do not always result in successful outcome, but are associated with potential risk factors of iatrogenic prematurity, uterine hyperstimulation, non reassuring fetal Nonstress test (NST), greater likelihood of operative delivery.

Hence membrane sweeping at initiation of formal induction of labour needs to be assessed with regard to shortend induction to delivery interval and outcome of labour.

OBJECTIVES

Objectives of the present study were;

Primary objective

To evaluate the induction to delivery interval in subjects who undergo membrane sweeping at initiation of formal induction of labour in comparison to those patients who are categorized into nonsweep category.

Secondary objective

To determine the percentage of successful vaginal delivery in subjects with sweeping of membrane at initiation of formal induction of labour in comparison to subjects who are in no sweep category.

REVIEW OF LITERATURE

Fetus at term is on a springboard ready to leap into the rough sea of tough humanity. The first journey of life, which is arguably the shortest journey, may will prove to be the most precarious journey ever undertaken".

Uterine smooth muscles are governed by the laws of nature; one of which is Frank Starling's Law – which states that force of contraction of smooth muscle is directly proportional to End Diastolic Fibre Length (EDFL). Myometrial smooth muscle is inherently a contractile tissue; which is evident when isolated strips of myometrium when placed in isotonic water bath contact rhythmically without stimuli even in presence of PG synthetase inhibitor.[13]

Pregnancy is maintained by (1) cervical factors and (2) uterine factors

1. Cervical factors[14]

The cervix is essential in maintaining uterine stability during pregnancy. To achieve this, the maintenance of cervical shape and consistency is imperative since cervical 'ripening' is a physiological process occurring throughout the later weeks of pregnancy and is completed with the onset of labour. When delivery is necessary and ripening has not had time to occur, or has failed to be initiated, this natural process has to be accelerated.

The cervix possesses a unique construction to enable it to perform its various roles. It consists predominantly of a stroma of connective tissue that can be subdivided into a superficial loose zone and a deeper dense stromal zone.

The main elements of this connective tissue are collagen together with a small amount of elastic tissue and an even smaller component of muscle fibres. The collagen is composed of dense regular fibrils arranged in parallel bundles held together by cross-links, with a few interspersed mast cells and other cellular elements. The ground substance is composed of proteoglycan complexes consisting of glycosaminoglycan side chains (GAGs) on core proteins linked to a hyaluronic acid chain that bind tightly. The dominant GAGs in the cervix are dermatan sulphate and chondroitin sulphate, both of which contain hyaluronic acid conferring additional binding strength and have hydrophilic properties.

Fibroblasts with numerous long cytoplasmic processes radiating from one cell body to another, possibly similar to myometrial gap junctions, infiltrate the ground substance. With the advance of pregnancy, increased vascularity is seen and the fibroblasts become secretory, white cells and macrophages migrate out of vessel walls into the cervical stroma with an increase in water content. There is a reduction in collagen content and a relative increase in the glucuronic acid-containing GAG heparin sulphate that binds much less strongly. Enzymatic breakdown of collagen fibrils by collagenases/matrix metalloproteinases produced by fibroblasts and polymorphonuclear leukocytes alongside leukocyte elastase, which catabolises elastin, leads to increased cervical compliance. The precise mediation and inter-relationships remain to be elucidated, but the prostaglandins and their synthase inhibitors are closely implicated with the known increase observed as pregnancy advances. Significantly there is reasonably strong evidence that the process of cervical ripening will occur without any detectable uterine contractions being stimulated. Cytokines, notably IL-8, or platelet

activating factor (PAF), and monocyte chemotactic protein-1 (MCP-1) have been proposed as possible interactants in the remodelling process involved in cervical ripening, as has nitric oxide, synthesised by macrophages, myometrium and the cervix.

2. Uterine factors[15]

Uterus is maintained in quiescence stage throughout pregnancy probably due to following factors:

- Action of estrogen and progesterone via intracellular receptors.
- Myometrial cell plasma membrane receptor mediated increase in cAMP.
- Generation of cGMP.
- Modification of myometrial cell ion channel.

So phase 'O' or quiescence phase is maintained by several independent pathway. Any defect in any of the pathway many trigger the onset of labour.

As yet, the precise role, if any, for these agents in this physiological process remains to be elucidated.

A switch from contractions which are low frequency and low intensity but long lasting to contractions which are more frequent, with high intensity occurs before progressive cervical effacement and dilatation and regular uterine contraction.

The exact trigger for the onset of labour is unknown.

But the possible causes for onset of labour are;[16]

Following theories were postulated:

Hormonal factors

- Oestrogen theory:
    - During pregnancy, most of the oestrogens are present in a binding form. During the last trimester, more free oestrogen appears, increasing the excitability of the myometrium and prostaglandins synthesis.
- Progesterone withdrawal theory:
    - Before labour, there is a drop in progesterone synthesis leading to predominance of the excitatory action of oestrogens.
- Prostaglandins theory:
    - Prostaglandins E2 and F2α are powerful stimulators of uterine muscle activity. PGF2α was found to be increased in maternal and foetal blood as well as the amniotic fluid late in pregnancy and during labour.
- Oxytocin theory:
    - Although oxytocin is a powerful stimulator of uterine contraction, its natural role in onset of labour is doubtful. The secretion of oxytocinase enzyme from the placenta is decreased near term due to placental ischaemia leading to predominance of oxytocin's action.

- Foetal cortisol theory:
    - Increased cortisol production from the foetal adrenal gland before labour may influence its onset by increasing oestrogen production from the placenta.

Mechanical factors

- Uterine distension theory:
    - Like any hollow organ in the body, when the uterus in distended to a certain limit, it starts to contract to evacuate its contents. This explains the preterm labour in case of multiple pregnancy and polyhydramnios.
- Stretch of the lower uterine segment:
    - By the presenting part near term.

Most probable sequence of events are;

1. Uterine stretch receptors and parturition[15]

Considerable evidence is accumulating to support this hypothesis that fetal growth in an important component is activation of onset of labour.

Fetal growth and amniotic fluid pressure acts as a common activation pathway of stretch receptors on myometrium which in turn induce specific contractions associated protein, increase gap junction protein and oxytocin receptors.

This make the uterus more responsive to uterotonics which appear late in gestation at the time of labour.

2. Action of fetal cortisol on parturation[17]

At term fetal adrenal glands weigh the same as those in adults with daily production of 100 to 200 mg/day of steroids. Fetal cortisol level increase during last week of gestation. Which also causes increase production of DHEA-S.

CRH is synthesized in maternal / fetal hypothalamus but identical CRH in synthesized in placenta in relatively large amount at term and this CRH is proposed to;

1. Fetal cortisol production, positive feedback and CRH production.
2. High levels of cortisol modulate myometrial contractility by stimulating the membrane to increase PG synthesis.
2. CRH stimulate C-19 steroid synthesis leading to increased substrate for placental aromatization, resulting in shift in estrogen to progesterone ratio leading to loss of quiescence secondary to expression of contractile proteins.

There are instances where this natural spontaneous onset of labour need to be interfered artificially in maternal or fetal interest, a procedure called induction of labour.

The history of the induction of labor is largely limited by the failure of man-midwives and physicians to recognize the need or the desirability for it. The procedures used in the induction of labor are reviewed. As far back as 1595 a

Reverend Maister Alexis of Piemont was advocating a long list of medicaments said to stimulate the uterus. These included juniper berries, cinnamon, castor oil, and amber in white wine. In 1735, a Dr. Henry Bracken recommended that in order to procure an early labor an unctuous application, such as oil of sweet almonds, should be applied warm and with a bunch of feathers to "the privities and vagina." In a mid-19th century edition of the works of Aristotle it is stated that the midwife should let the waters break on their own. The contributions of Denman of the Middlesex Hospital to the induction of labor at the end of the 18th century lay not so much in his advocacy of artificial rupture of the membranes as such, but for his ability to recognize the need for it and for his effort thereby to forestall disproportion and secure an easier delivery with a smaller and more premature head.[18] Denman's method has stood the test of time. There followed in the course of the last century a series of more ruthless physical attacks upon the genital tract of the expectant mother which persisted until the 1930s.Induction protocol has undergone a dramatic change after the advent of inducing agents like oxytocin, prostaglandins and our understanding of mechanism of labour.

A retrospective study concluded that elective induction should be discouraged in the nulliparous woman, since the rate of Caesarean delivery is increased with elective induction.[19]

A case control study did not find elective induction itself to be predictive of Caesarean delivery.[20]

But a meta analysis of early trials concluded that there is no benefit to elective induction and there is no place for it in term pregnancy.[21]

The American College of Obstetricians and Gynecologists suggests that labour may be induced for logistic reasons, including risk of rapid labour, distance from hospital, and psychosocial reasons.[22]

Rate of induction of labor in increasing all through out the world and accounts for 20% of women undergoing labour.[2]

Indications for induction of labour are;[23,24,25]

1. Accepted absolute indications
    a. Hypertensive disorders
        i. Preeclampsia
        ii. Eclampsia
    b. Maternal medical conditions
        i. Diabetes mellitus
        ii. Renal disease
        iii. Chronic pulmonary disease
    c. Prelabour rupture of membranes
    d. Chorioamnionitis.
    e. Fetal compromise
        i. Fetal growth restriction
        ii. Isoimmunisation
        iii. Oligohydroamnius
    f. Fetal demise
    g. Prolonged pregnancy (> 42 weeks)
2. Relative indications include;

a. Hypertensive disorders
    i. Chronic hypertension
b. Maternal medical conditions
    i. Cholestasis of pregnancy
c. Polyhydroamnious

Methods of induction of labour [26]

a. Mechanical methods
    - Membrane stripping
    - Amniotomy
    - Mechanical dilators like laminaria tents
    - Transcervical ballon catheter with extraamniotic saline infusion.
b. Pharmacological method
    - Oxytocin
    - Prostaglandins
        - PG E2 (Dinoprostone gel)
        - PG E1 (Misoprostol)
    - Others
        - Estrogen
        - Relaxin
        - Hyaluronic acid
        - Progestrone receptor antagonist.

Induction of labour by medicinal method has been practiced since time immemorial but in it received a boost in 1948; Theoband and associates described their use of posterior pituitary extract, oxytocin by intravenous drip for labour induction. Five years later, oxytocin was the first polypeptide hormone synthesized by Du Vigneaud and associates.[27]

Since then world has not remained the same with the advent of prostaglandins in the inventory of present day obstetricians to induce labour.

Prerequisites for induction of labour are;[28]

Until induction is done for circumstances where pregnancy cannot be continued in view of maternal or fetal indications the following criterias are to be confirmed:

1. Confirmation of gestational age and fetal lung maturity. Criteria for which are;
    a. Clinical
        i. More than or equal to 39 weeks period of gestation in patient with regular cycles from the first day of last menstrual period.
        ii. Fetal heart tones has been documented for more than 20 weeks by non electronic fetoscope or for more than 30 weeks by Doppler ultrasound.
    b. Laboratory determinants
        i. More than or equal to 36 weeks has elapsed since a positive serum HCG test.

ii. Ultrasound estimation of gestational age is considered accurate if it is based on Crown rump length obtained at six to 11 weeks or Biparietal diameter obtained at less than 20 weeks.

c. Fetal pulmonary maturity: Term gestation can be confirmed if two or more of above criteria are present. If it cannot be confirmed then the parameters for fetal pulmonary maturity are

i. Lecithin / sphingomyelin ration more than 2:1.

ii. Presence of phosphotidyl choline more than or equal to 500 ng/ml in non diabetic mother (more than or equal to 1000 ng/ml in pregestational diabetic patient).

For assessment of cervical status, Bishop EH, proposed a scoring system to determine the favorability of cervix for induction of labour which was modified by Calder AA, Bernard JE in 1991 and the scoring system is as follows.[29]

Table 1: Bishop Scoring System Used for Assessment of Inducibility

Score	Factor				
	Dilatation (Cm)	**Effacement (%)**	**Station (3 to +3)**	**Cervical consistency**	**Cervical positions**
0	Closed	0–30	–3	Firm	Posterior
1	1–2	40–50	–2	Medium	Midposition
2	3–4	60–70	–1	Soft	Anterior
3	5	> 80	+1, +2	—	—

A score of four or less is generally regarded as unfavourable cervix and warrants cervical ripening.[14]

Recent reports have confirmed early studies that emphasized that the state of the cervix was the most important predictor of success, leaving little doubt that ripening of the cervix greatly facilitates labour and increases the likelihood of vaginal delivery.[30,31]

RCOG recommended vaginal prostaglandins for limitations of cervical ripening or labour induction for both unfavourable and favorable cervix. PGE2 tablets (3 mg six to eighth hourly to a maximum dose of 6 mg) are recommended in preference to PGE2 gel (2 mg for multiparous women with modified Bishop's score of less than four or 1 mg for all others; repeated sixth hourly to a maximum dose of 4 mg).[2]

A meta-analysis suggests that labour must be induced in an unripe cervix, prostaglandins can decrease the likelihood of failed induction, decrease the incidence of prolonged labour and increase the chances of a spontaneous vaginal delivery.[32]

Prostaglandins results in dissolution of collagen bundles and increase in submucosal water content of cervix. Prostaglandins are capable not only of inducing cervical ripening but also stimulating uterine contractions resulting in labour, hence they may be more efficient than other agents such as oxytocin which rely mainly on stimulating uterine contractions.[33]

Intravaginal or intracervical administration of exogenous PGE_2 (dinopros tone) is the most widely used pharmacologic method to promote cervical ripening and labour induction.[34,35]

Cochrane reviewers studied the use of prostaglandins for cervical ripening on labour induction. Compared with placebo, use of vaginal prostaglandins increased the likelihood that a vaginal delivery would occur within 24 hours.

Additionally, the rate of cesarean section was comparable in all studies. Prostaglandins are associated with an increased risk of uterine rupture and should not be used as part of a trial of labour with a previous uterine scar.[36]

Three types of prostaglandins are available for clinical use; PGE1, PGE2 and PGF2α.These can be administered by various routes but vaginal PGE2 is widely used and recognized as a standard method of labour induction.[37]

Royal College of Obstetricians and Gynaecologists (RCOG) recommends all women should be offered sweeping of membranes prior to induction of labour.[2]

Sweeping of membranes refers to digital separations of chorioamniotic membrane from the wall of cervix and lower uterine segment.[2]

This procedure was first reported by Hamilton in 1810 in England which is presumed to cause a release of endogenous prostaglandins from the adjacent membranes and cervix.[38]

McColgin et al[39] showed that there was a significant increase in uterine contractile activity immediately after membrane sweeping. The levels of plasma PG after membranes sweeping alone were approximately one tenth those achieved during active labor, which might sufficiently augment labor and improve delivery outcome.

Kashanian M et al concluded that sweeping of membranes at 39 weeks of gestation does not have any significant clinical effect on duration of pregnancy nor there is any clinically significant difference as far as bleeding, meconium stained liquor or puerperial fever.[40]

Garner O et al concluded that Bishop scores assigned 24 hours after prostaglandin installation and membrane sweeping does not have a significant difference and the proportion of women entering active labour or delivering within 24 hours were similar in prostaglandin and membrane sweep group.[41]

Lee et al conducted a study to evaluate the role of prostaglandins in the onset of human parturition. Result obtained stated that;[42]

- Amniotic fluid PG secretion remained unchanged with advancing gestation till 36 weeks of gestation.
- But an abrupt increase in amniotic fluid PG was observed before the onset of labour at term.
- Cases without labour at term median amniotic fluid PGF2α and concentration increase with advancing gestation.
- At the onset of labour the degree of cervical dilatation was significantly associated with higher concentration of PGF2 α.

Cochrane database systemic review 2008 compared vaginal PGE2 and F2α and concluded that there was insufficient data to make a meaningful conclusion for comparison of PGE2 and F2α.[43]

Recent data as per Cochrane Systemic Review 2009 states that oral prostaglandin consistently resulted in more frequent gastrointestinal side effects, as well as there was a trend which favoured oxytocin for induction of labour when compared with oral PGE2.[44]

Oral PGE2, Intravenous PGE2 and Intracervical PGE2 should not be used for induction of labour.[2]

Cochrane database 2009 stated that intracervical prostaglandins are effective when compared with placebo but appear inferior to intravaginal prostaglandins.[45]

Magham F et al concluded that daily membrane sweeping when compared to daily dinoprostone, resulted in greater Bishop's scores on admission to labour and delivery, fewer hour from admission to delivery and fewer labour induction at 42 weeks.[46]

Boulvian M et al concluded that while sweeping of the membranes reduces the interval to spontaneous onset of labour, there is no evidence of a reduction in maternal or neonatal morbidity. When used as a means of induction of labour, the reduction in the use of formal methods must be balanced against women's discomfort and other side effects attributable to the procedure.[47]

Foong LC et al evaluated if sweeping of membrane during induction of labour in beneficial and came to the conclusion that sweeping of membranes during induction of labour had beneficial effect on labour and delivery which appeared to be limited to nulliparas with unfavourable cervix.[48]

Similarly Peng Chiang Tan et al showed in a study designed to evaluate "membrane sweeping at initiation of formal labour induction that patient with membranes swept had higher spontaneous vaginal delivery rates, shortend induction to delivery interval, decreased oxytocin use and improved patients satisfaction as compared to non sweep with induction.[49]

METHODOLOGY

The present study was conducted in Department of Obstetrics and Gynaecology, KLES Dr Prabhakar Kore Hospital and Medical Research Center, Belgaum This randomized controlled trial was conducted over a period of one year during January 2008 to December 2008.

Type of study

Randomized controlled trial.

Study period

This randomized controlled trial was conducted over a period of one year during January 2008 to December 2008.

Source of data

Participants admitted at labour room of KLES Dr Prabhakar Kore Hospital and Medical Research Center, Belgaum for induction with cerviprime, and satisfying the selection criteria and willing to give consent for participation in the trial.

Sample size

Present study was conducted on 60 sweep and 60 non sweep participants.

Sampling procedure

Subject to inclusion and exclusion criteria based on the past records, the number of cases likely to report in our department was estimated to be around 144 per year. Based on this information the total sample size was decided to be 120. Out of which two groups would be made by randomization, by computer generated randomization chart, into "sweep" with a sample of 60 subjects and "non-sweep" category with 60 subjects.

Selection criteria

Inclusion Criteria

- Term (37 weeks – 42 weeks).
- Singleton fetus.
- Cephalic presentation
- Membranes intact.

Exclusion criteria

- Previous LSCS.
- IUD
- Gross fetal anomalies
- Placenta previa.
- Cervical dilatation <1 cm.

Ethical Clearance

The ethical clearance was obtained from Review Board of Jawaharlal Nehru Medical College, Belgaum.

Procedure

After preliminary evaluation and deciding about induction with cerviprime and screening for selection criteria the participants were explained about the study and written and informed consent was obtained (Annexure-I). Participants were then randomized into sweep and non sweep category. Further they were examined and data collected as per predesigned and pretested proforma.

Sweep category

Just before formal induction Bishop's score was noted and then a finger was introduced into the cervical canal into lower uterine segment and membranes swept from lower uterine segment by circular movement of finger introduced. Then cerviprime gel was instilled into the cervical canal.

Nonsweep category

Gentle vaginal examination done to note the Bishop's score and cerviprime gel instilled immediately into cervical canal.

Monitoring

- Electronic fetal heart rate monitor applied to all patients.
- Uterine contractions and fetal heart rate was monitored.

- Reevaluation done after six hours and if contractions were inadequate then next dose of cerviprime gel was put into cervical canal. Maximum of three doses of cerviprime gel put into cervical canal sixth hourly. Patient was taken up for emergency LSCS in view of maternal or fetal indication. Once patient goes into active labour, (cervical dilatation of more than or equal to four cm) the labour was monitored as per standard management protocol according to WHO partogram (2000).

Statistical analysis

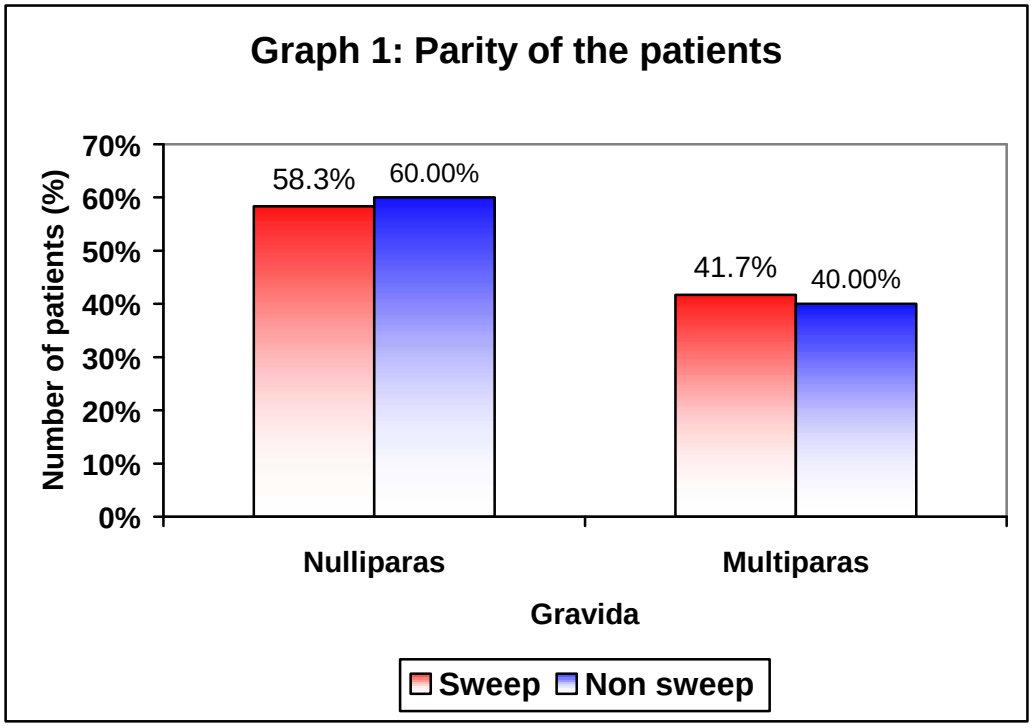
For Quantitative variables the mean and standard deviation was calculated and comparison of the parameters was done by using Student t test.

For qualitative variables percentage was calculated and comparison was done by using the test of proportion and Chi square test.

RESULTS

Table 2: Parity of the patients

Parity	Sweep		Non Sweep	
	Number	Percentage	Number	Percentage
Nulliparas	35	58.33%	36	60.00%
Multiparas	25	41.67%	24	40.00%
Total	60	100%	60	100%

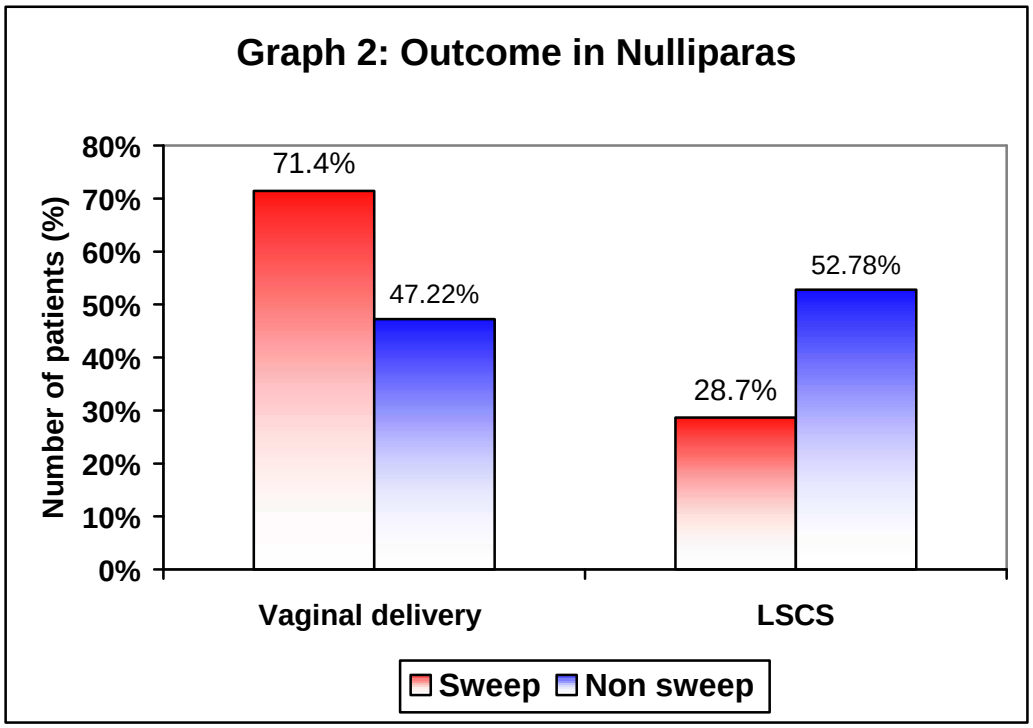


In our study 120 patients were recruited. 60 (35 Nulliparas and 25 Multiparas) in sweep category and 60 (36 Nulliparas and 24 Multiparas) in non sweep were analysed.

Table 3: Outcome in Nulliparas

Type of Delivery	Sweep		Non Sweep	
	Number	Percentage	Number	Percentage
Vaginal	25	71.43%	17	47.22%
LSCS	10	28.67%	19	52.78%

p=0.038 (Significant)

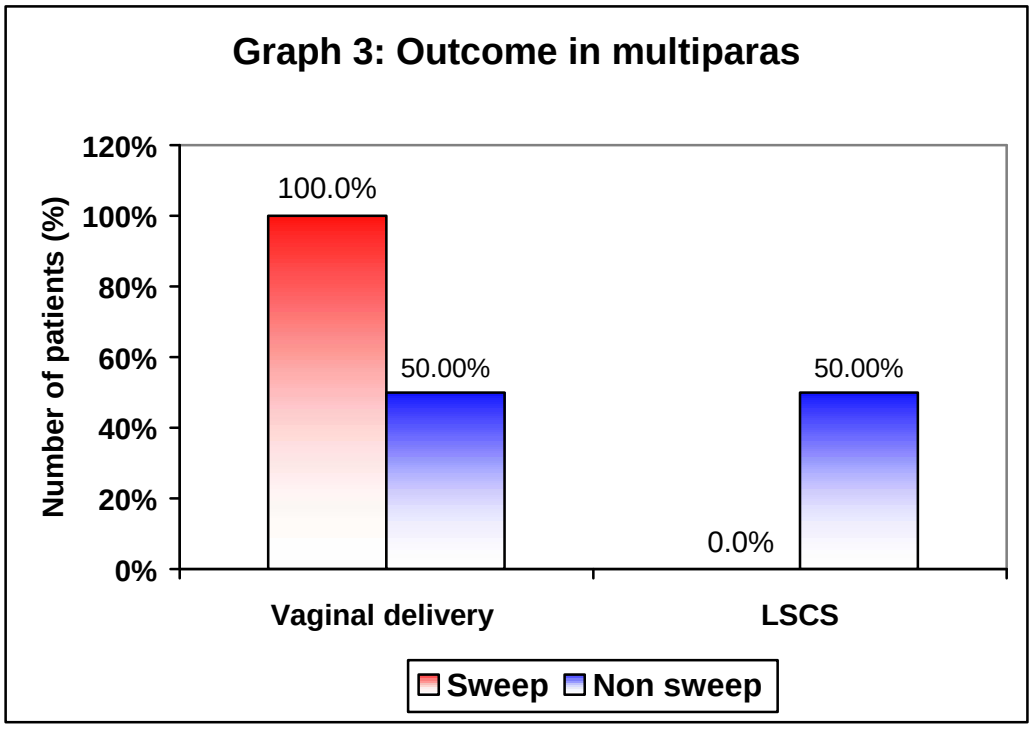


Nulliparas with sweep category had 35 subjects, 25 had vaginal delivery and the remaining 10 underwent LSCS. In non sweep category, out of 36 Nulliparas; 17 had vaginal delivery and 19 had LSCS. 71.43% of Nulliparas in sweep category underwent vaginal delivery whereas only 47.22% of Nulliparas had vaginal delivery in Non sweep category, with a P value of 0.038 which is significant.

Table 4: Outcome in multiparas

Delivery	Sweep		Non Sweep	
	Number	Percentage	Number	Percentage
Vaginal	25	100%	12	50%
LSCS	0	0%	12	50%

p<0.001 (Significant)

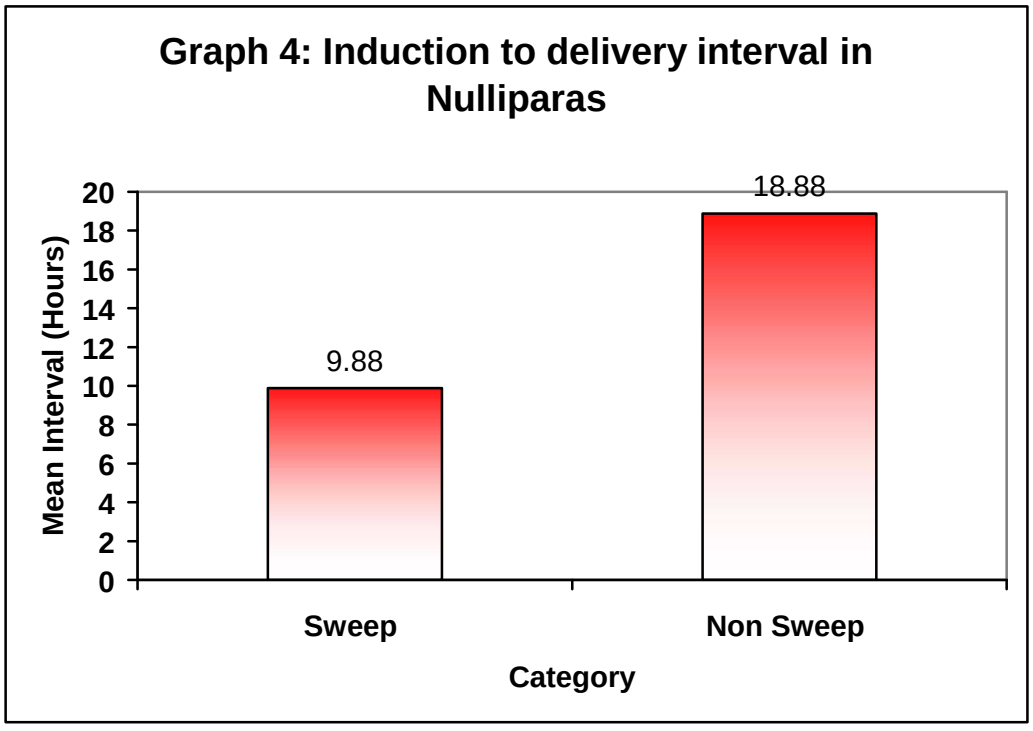


In multiparas out of 25 patients in sweep category all had vaginal delivery where as only 12 out of 24 underwent vaginal delivery in non sweep category. 100% multiparas in sweep category underwent vaginal delivery where as only 50% multiparas in non sweep category had vaginal delivery; p value= 0.001(Significant).

Table 5: Induction to delivery interval in Nulliparas

Category	Induction to delivery interval (Hours)	
	Mean	**S.D.**
Sweep	9.88	5.40
Non sweep	18.88	6.83

p=0.0001 (Significant)



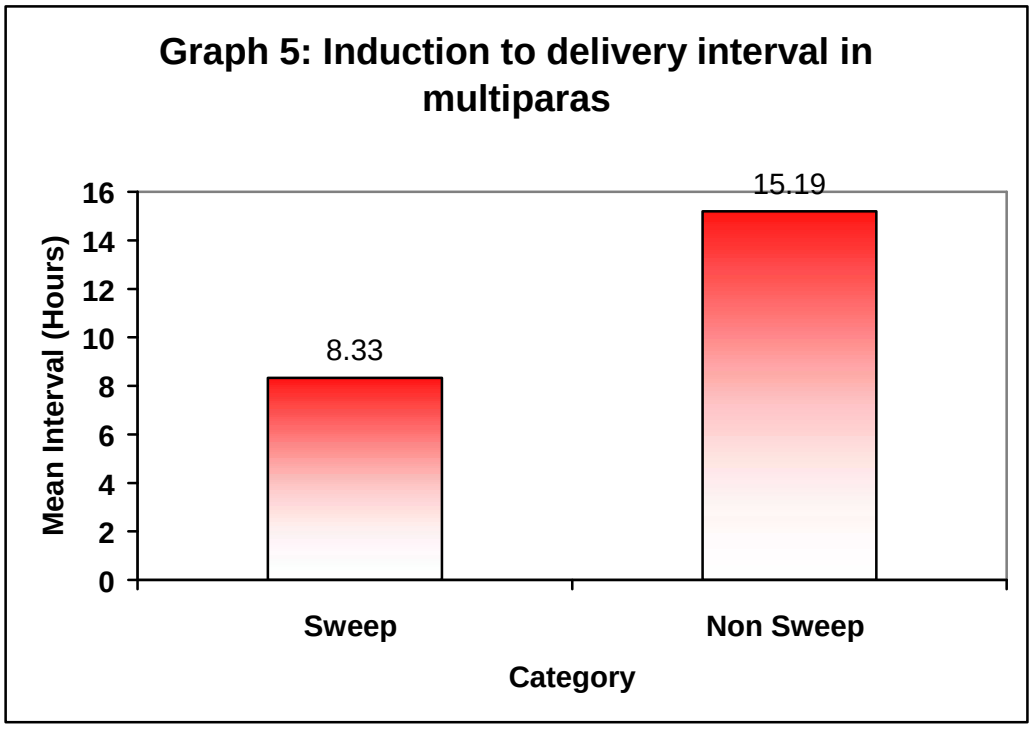
In nulliparas with vaginal delivery the mean induction to delivery interval in sweep category is 9.88 ± 5.40 hours and in nonsweep is 18.88 ± 6.83 hours with a P value of 0.0001.

Inference: Nulliparas with vaginal delivery in sweep category require statistically less induction to delivery interval as compared to nonsweep category.

Table 6: Induction to delivery interval in Multiparas

Category	Induction to delivery interval (Hours)	
	Mean	**S.D.**
Sweep	8.33	6.79
Non sweep	15.19	8.5

p=0.0001 (Significant)



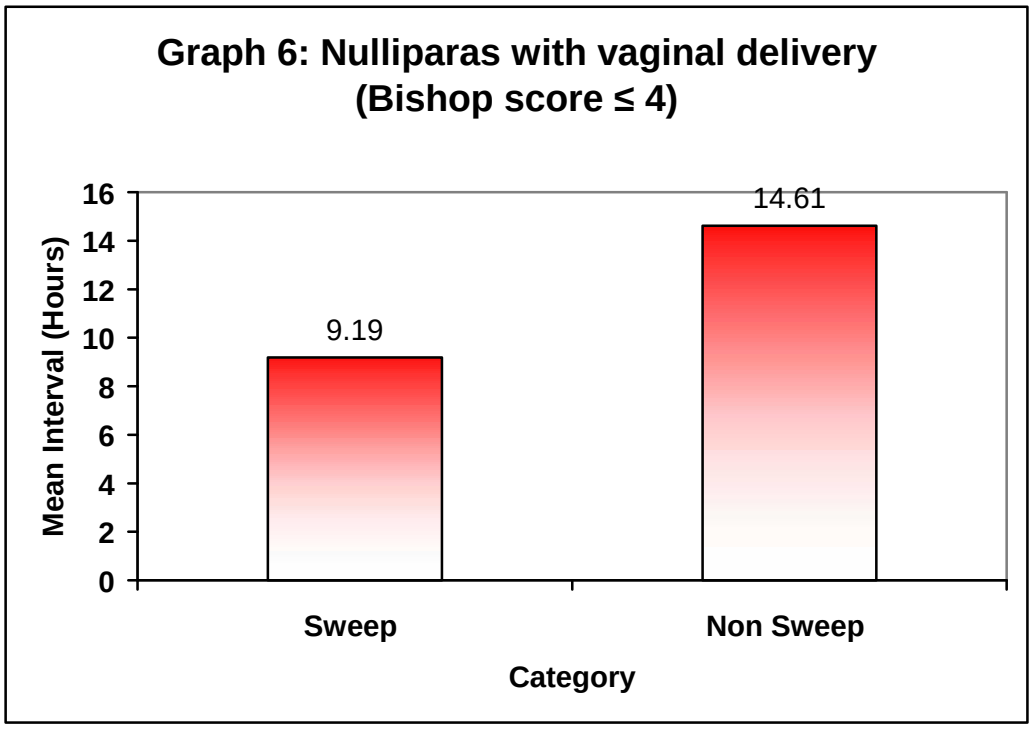
In multiparas with vaginal delivery the induction to delivery interval in sweep is 8.33 ± 6.79 hours and 15.19 ± 8.50 hours in nonsweep category with p value of 0.0001.

Inference: Multiparas with vaginal delivery in sweep category require significantly less induction to delivery interval.

Table 7: Nulliparas with vaginal delivery (Bishop score ≤ 4)

Category	Induction to delivery interval (Hours)	
	Mean	**S.D.**
Sweep	9.19	5.42
Non sweep	14.61	4.99

p=0.0001(Significant)

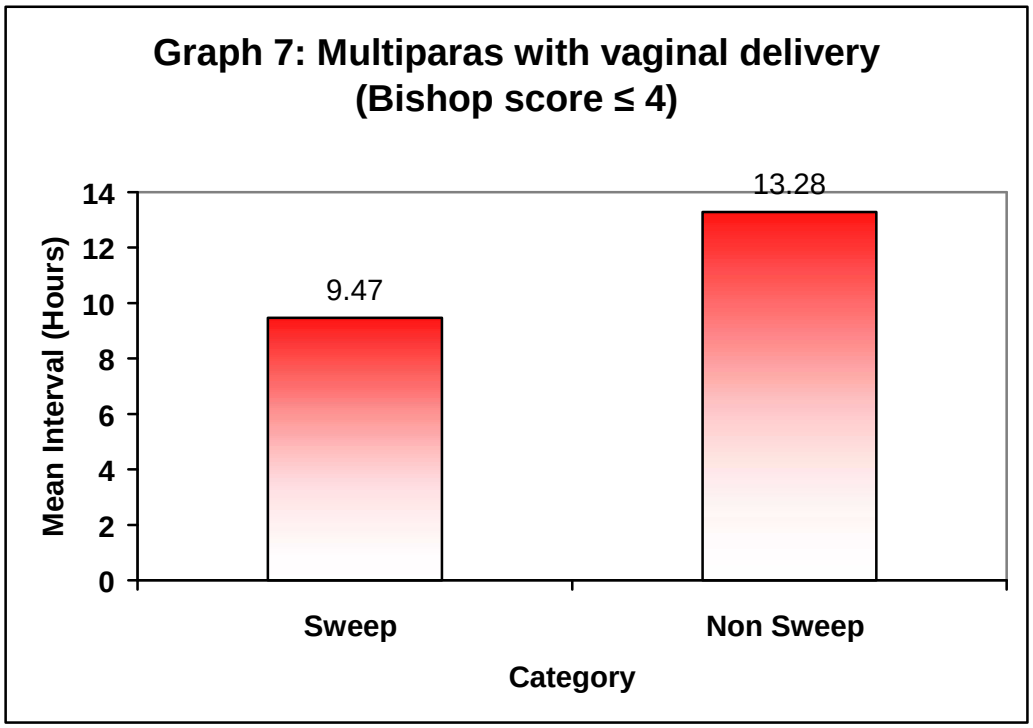


Data was also analysed with respect to Bishop's score. In nulliparas with vaginal delivery (Bishop's score less than equal to four), induction to delivery interval in sweep category was 9.19 ± 5.42 hours and in nonsweep category was 14.61 ± 4.99 hours with a p value of 0.0001. Inference: Significantly less induction to delivery interval is required in patient with unfavorable Bishop's score in sweep category in the recruited nulliparas.

Table 8: Multiparas with vaginal delivery (Bishop score ≤ 4)

Category	Induction to delivery interval (Hours)	
	Mean	**S.D.**
Sweep	9.47	7.22
Non sweep	13.28	7.66

p=0.118 (Not significant)



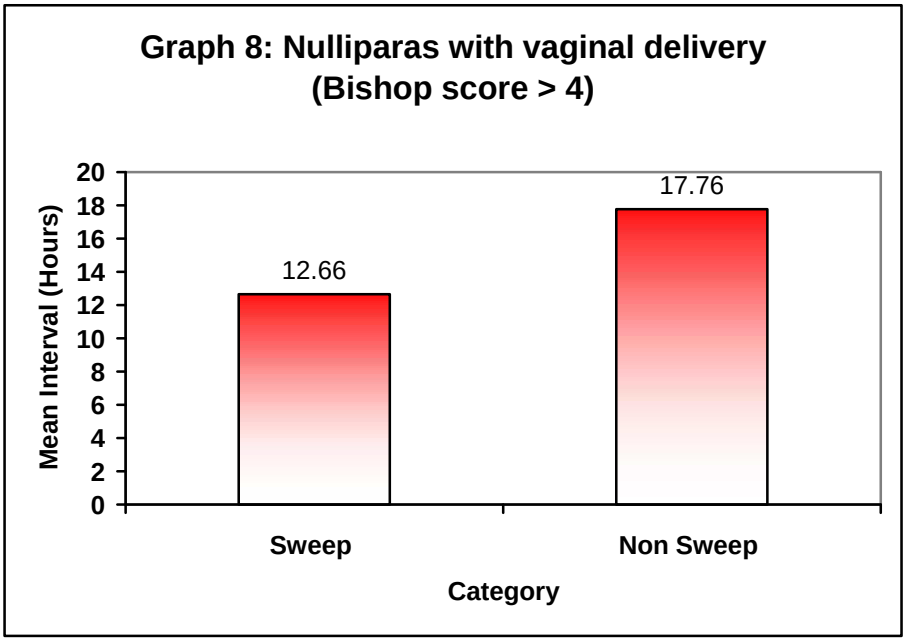
In multiparas with vaginal delivery with Bishop's Score less than or equal to four, induction to delivery interval was 9.47 ± 7.22 hours in sweep whereas subjects in nonsweep required 13.28 ± 7.66 hours with a P value of 0.118.

Inference: Although multiparas with unfavorable Bishop's Score required less induction to delivery interval but the difference was not statistically significant.

Table 9: Nulliparas with vaginal delivery (Bishop score > 4)

Category	Induction to delivery interval (Hours)	
	Mean	**S.D.**
Sweep	12.66	4.79
Non sweep	17.76	7.18

p=0.200 (Not significant)



In nulliparas with Bishop's Score more than four, induction to delivery interval was 12.66 ± 4.79 hours in sweep category. Whereas it was 17.76 ± 7.18 hours in non sweep category with P value of 0.20. Inference: Although nulliparas with a favourable Bishop's Score requires less induction to delivery interval but the difference was not statistically significant.

In the recruited multiparas with vaginal delivery with initial Bishop's score of >4, there were only 5 participants in sweep category and 2 subjects in non sweep category.So the sample size was not adequate to comment about the significance of the study.

DISCUSSION

The ability of prostaglandin E_1, E_2, $F_{2\alpha}$ to stimulate the uterus to contract at any time of gestation and to interrupt pregnancy at any stage has led to number of studies on their possible role in physiological activation of uterus during parturition.

This hypothesis is supported by the fact that PG synthetase inhibitors can inhibit preterm labour and delay parturition. It is further substantiated by the marked rise in amniotic fluid levels of PGE2 and PGF2α during term labour and rise in circulating levels of PGF Metabolites (PGFM) during advanced labour which also suggests a role for prostaglandin in mechanism of labour.

All uterine tissue have the capacity to synthesise prostaglandins but the spectrum varies from tissue to tissue. The capacity to synthesis PGs from endogenous substrates exists long before labour begins and there is no marked change in this ability at the onset of labour, so availability of substrate is not a limiting factor. Therefore it is safe to assume that in vivo conditions, prostenoid synthesis is kept at bay by inhibitory factors which are withdrawn during parturition; or the stimulatory factors which increase the rate of production of PG at onset of labour.[50]

Vaginal examination, particularly sweeping of membrane, manipulation of cervix or rupture of membranes is known to cause rapid and sustained levels of amniotic fluid PGs. [51]

This discovery clinched the imagination of present day obstetricians who were keen to find a safe and efficient method of induction of labour.

The additive beneficial effects of membrane sweeping with insertion of vaginal prostaglandin gel has been demonstrated by Doane and Mccarty , who showed that when compared with no intervention, sweeping alone or PG gel alone; the combined approach reduces post term pregnancy.[52]

Foong et al, in a randomized controlled trial of membrane sweeping in conjunction with formal labour induction demonstrated a reduction in caesarean delivery rate, induction to delivery interval. This was confined to nulliparas, in which subjects assigned to sweep had mean induction to delivery interval of 13.6 ± 1.4 hours and in non sweep had 17.3 ± 1.2 hours with a vaginal delivery rates of 83.3% in sweep and 58.2% in nonsweep.[49]

Choing et al in a similar study concluded that in nulliparas with sweep; the induction to delivery interval was 14 hours where as it was 19 hour in nonsweep with a vaginal delivery rates of 69% in sweep and 56% in non sweep.[50]

Our study was compared with the above two studies and the result is as follows:

	Foong et al	**Chiong et al**	**Our study**
Induction to delivery interval in nulliparas with sweep	13.6 ± 1.4 hrs	14 hrs	9.88 ± 5.40 hrs
Induction to delivery interval in nulliparas with non sweep	17.3 ± 1.2 hrs	19 hrs	18.88 ± 6.83 hrs
Nulliparas with vaginal delivery with sweep	83.3%	69%	71.43%
Nulliparas with vaginal delivery with nonsweep	58.2%	56%	47.22%

In our study the cervix was mechanically dilated during sweeping of membranes and at the same time uniform administration of PG E2 analogues in all cases further enhanced the cervical dilatation and shortened the induction to delivery interval in sweep category.However in the above two studies they have followed different induction protocol for favourable and unfavourable cervical scores. They used PGE2 analogue for unfavourable cervix and amniotomy with oxytocin for favourable cervical score and hence the difference in induction to delivery interval.

Significant reduction in induction to delivery interval and increase in vaginal delivery rates in both nulliparas and multiparas in subjects with sweep category can be accounted for, by the fact that in participants in sweep category

the initial cervical dilatation was more as compared to initial cervical dilatation in nonsweep subjects and since initial cervical dilatation is the best predictor for operative delivery, the vaginal outcome rates were less in non sweep category. Sweeping results in mechanical dilatation due to disruption in collagen fibres in the cervical stroma which offers less resistance to further dilation.[53,54] Cervical sweeping also releases endogenous PG and amnion sweeping is known to release many substances (prostaglandins $PGF_{2\alpha}$ and endocervical phospholipase A_2) that soften the cervix. Further, sweeping with simultaneous administration of PG E2 analogue results in their additive or synergestic effect accounting for their beneficial effect with respect to decreased induction to delivery interval and improved delivery outcome both in nulliparas and multiparas.

This was probably the reason for the significant decrease in mean induction to delivery interval in nulliparas with Bishop's score of ≤ 4 in sweep category as compared with nonsweep category.

The mean duration of induction to delivery interval in nulliparas, in non sweep and nulliparas with vaginal delivery in sweep category were comparable.

However the sample size in all these studies were relatively small and only a larger trial would achieve the appropriate power to confirm the difference.

CONCLUSION

The mean induction to delivery interval was significantly less both in nulliparas and multiparas in sweep category.

Significantly more number of nulliparas and multiparas in sweep category undergo vaginal delivery.

There is significant decrease in induction to delivery interval in nulliparas with Bishop's Score less than or equal to four in sweep category.

There is no significant difference in induction to delivery intervals in multiparas with Bishop's Score less than equal to four.

Nulliparas with Bishop's Score more than four although requires less induction to delivery interval but the difference is not statistically significant.

SUMMARY

In the present study we assessed the effect of sweeping of membranes at initiation of formal induction of labour. This was a randomized controlled trial conducted at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2008 to December 2008.

The summary of our study was:

1. Total of 120 participants were enrolled who were randomized into two groups as per a computer generated randomization chart into “sweep” with 60 subjects and “nonsweep” with 60 subjects.

2. In sweep category 35 were nulliparas and 25 multiparas and in nonsweep category 36 were nulliparas and 24 multiparas.

3. 71.43% of recruited nulliparas in sweep category underwent vaginal delivery whereas only 47.22% of recruited nulliparas had vaginal delivery in Non sweep category, with a P value of 0.038 which is stastistically significant.

4. In mutiparas out 25 patients in sweep category all underwent vaginal delivery accounting for 100%, whereas only 12 out of 24 underwent vaginal delivery in non sweep category which is about 50% of the subjects enrolled; P value of 0.001 which is significant.

5. In nulliparas with vaginal delivery the mean induction to delivery interval in sweep category was 9.88 ± 5.40 hours and in nonsweep category was

18.88 ± 6.83 hours; with a P value of 0.0001; which was significantly less in sweep category.

6. In multiparas with vaginal delivery the induction to delivery interval in sweep category was 8.33 ± 6.79 hours and 15.19 ± 8.50 hours in nonsweep category with a P value of 0.0001; which was significant.

7. Nulliparas with vaginal delivery (Bishop's score less than equal to four), induction to delivery interval in sweep category was 9.19 ± 5.42 hours and in nonsweep category was 14.61 ± 4.99 hours with a P value of 0.0001.Suggesting significantly less induction to delivery interval is required in nulliparas with unfavorable Bishop's score in sweep category.

8. Multiparas with vaginal delivery with Bishop's Score less than or equal to four the mean induction to delivery interval was 9.47 ± 7.22 hours in sweep whereas subjects in nonsweep required 13.28 ± 7.66 hours with a P value of 0.118; which was not statistically significant.

9. In the recruited nulliparas with Bishop's Score more than four, the induction to delivery interval was 12.66 ± 4.79 hours in sweep category, whereas it was 17.76 ± 7.18 hours in non sweep category with P value of 0.20.

Sweeping of membranes is simple, non invasive method to initiate the pathway to activate parturition process and the prostaglandins released ripen the cervix, and this effect is further enhanced by simultaneous administration of PGE2 analogues which significantly decrease the induction to delivery interval

and effect increased vaginal delivery rates in participants in sweep category in both nulliparas and multiparas. This benefit is statistically significant in individuals who are nulliparas with a unfavourable cervix in sweep category. Therefore sweeping of membranes should be offered to all patients at initiation of formal induction of labour for better delivery outcome and decreased induction to delivery interval.

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ANNEXURE I - CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Please help to serve you better ….

"A randomized control trial to determine the effect of membrane sweeping at initiation of formal labor induction as compared to labor induction alone", conducted by Dr. Amit Srivastava, Post Graduate in M.S. Obstetrics and Gynaecology J.N. Medical College, Belgaum under the guidance of Dr. J. C. Shravage M.D., Professor, Department of Obstetrics and Gynaecology, under KLE University, Belgaum.

The purpose of research is to determine the efficacy of sweeping of membrane in conjunction with induction of labor as compared to induction of labour alone.

Respected Madam we request you to please participate in our study as you are eligible for it. Your participation in this research is voluntary and your decision whether to participate or not in this study will in no way affect your relationship with J.N.M.C. If you decide to participate you are absolutely free to withdraw at any point of time.

During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Procedure Involved

If you agree to participate in the study, then you will be randomly assigned to either of the two groups.

- Study group : were membrane sweeping will be done at initiation of formal labour induction. Membrane sweeping is done by gentle vaginal examination were membrane from the lower uterine segment will be swept before induction.

- Control Group: where only formal labour induction will be done.

Risks and Benefits

Sweeping of membrane is a bit painful procedure which may result in rupture of membranes and bleeding per vagina. But is also associated with shorter induction to delivery interval and increased vaginal delivery rates when done in conjunction with induction of labor.

Alternatives

Even if you decline to participate in the study, your management protocol will not be changed.

Privacy and Confidentiality :

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to publish results

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Compensation

In the event of injury or complication related to the study, treatment will be made available to you through KLES Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. In case of any complication or injury please do feel free to contact Dr. Amit Srivastava. PG M.S. Obstetrics and Gynaecology, KLESH and MRC, Belgaum Phone No.9886172203.

Questions

In case you have any questions related to the study, you can contact Dr. Amit Srivastava on Mob: 98861 72203.

In case you have any question about your rights as a study participant, you can contact Dr. V.D. Patil (0831-2471350).

Consent for participation in research trial

I, Mrs _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____

Witness Name : _____

Signature: _____

Investigators Name: _____

Signature: _____

Date: _____ Place: _____

ANNEXURE II

PROFOMA

"A ONE YEAR RANDOMISED CONTROLLED TRIAL OF EFFECT OF MEMBRANE SWEEPING AT INITIATION OF FORMAL INDUCTION OF LABOUR".

Investigator: Dr. Amit Srivastava

Guide: Dr. J. C. Shravage **M.D.**

Name & Address of the patient:_____

_____

Age of the patient: _____ Years IP. No._____

BRIEF HISTORY

USG Findings

Investigations

Inclusion criteria:

- Period of gestation :
- Singleton : Y/N
- Cephalic Presentation : Y/N

- PROM : Y/N
- FHR Present : Y/N
- Previous LSCS : Y/N
- Previous Stripping Done: Y/N
- Placenta Previa : Y/N
- Fetal Anomaly : Y/N
- Cervical dilatation <1cm: Y/N

Time of Stripping

Time of Installing

1. **Cerviprime**
    - 1st dose
    - 2nd dose
    - 3rd dose
2. **Misoprostol**
    - 1st dose
    - 2nd dose
    - 3rd dose

Time of Delivery

Dose of Oxytocin Used

Complications if any

Outcome

- Vaginal delivery
- Caesarian section
- Reason for LSCS

Fetal Outcome

- Apgar score

  1 Min

  5 Min

- Meconeum stained liquor : Y / N

NICU Admission

ANNEXURE III - MASTER CHART SWEEP GROUP

NON SWEEP GROUP

KEY TO MASTER CHART

FD	-	Fetal distress
GA	-	Gestational Age
Hb%	-	Hemoglobin percentage
IP. No.	-	Inpatient number
IUGR	-	Intrauterine growth retardation
LSCS	-	Lower Segment Cesarean Section
NICU	-	Neonatal intensive care unit
NPL	-	Non progress of labour
OLIGO	-	Oligohydramnios
PD	-	Post datism
PIH	-	Pregnancy induced hypertension
POLY	-	Polyhydramnios
Rh –VE	-	Rh factor negative
S NO	-	Serial number
V	-	Vaginal

S.NO.	IP NO.	AGE (YEARS)	INDICATION	GA (WEEKS)	Hb%	BLOOD GROUP	PARITY	CERVIPRIME	CYTOTEC	BISHOP SCORE	INTERVAL	OXYTOCIN	COMPLICATION	VAGINAL	LSCS	INDICATION FOR LSCS	APGAR SCORE 1	APGAR SCORE 2	MECONEUM	NICU
1	256546	24	IUGR	37.71	10.5	O+	1	1	-	6	14.02	3	-	V	-	-	7	9	-	-
2	257503	20	PIH	37.71	10.0	O+	1	3	1	3	24.95	-	-	V	-	-	7	9	-	-
3	258277	19	PIH	37.29	10.0	A+	1	3	-	5	18.08	5	-	V	-	-	7	9	-	-
4	258492	21	PIH	40.00	11.0	O+	1	1	-	7	5.08	-	-	V	-	-	7	9	-	-
5	260149	26	PD	40.57	11.0	AB+	3	1	-	4	4.60	3	-	V	-	-	7	9	-	-
6	260324	20	MS	37.14	10.0	O+	2	2	-	4	7.42	-	-	V	-	-	7	9	-	-
7	260813	26	PIH	40.29	10.5	B+	1	2	-	4	4.33	-	-	-	LSCS	FD	7	9	M	NICU
8	261955	25	PD	40.71	11.5	A+	2	1	-	4	3.07	-	-	V	-	-	7	9	-	-
9	263044	20	PD	41.57	10.0	O+	1	3	-	4	18.05	-	-	V	-	-	7	9	-	-
10	263095	20	PIH	37.29	12.0	O+	1	1	-	4	8.82	3	-	V	-	-	7	9	-	-
11	272997	25	PD	41.14	10.0	O+	1	2	-	4	9.87	-	-	V	-	-	7	9	-	-
12	276518	28	PIH	40.29	10.0	O-	1	1	-	3	7.67	-	-	V	-	-	7	9	M	-
13	267081	19	PIH	39.00	8.0	B+	1	3	-	3	17.05	5	-	-	LSCS	NPL	7	9	M	-
14	267644	23	PD	42.29	11.0	O+	1	2	-	3	14.00	3	-	V	-	-	7	9	-	-
15	287617	30	PIH	38.86	13.9	A+	1	1	-	4	8.58	-	-	V	-	-	7	9	-	-
16	276952	23	PD	40.86	12.0	A+	2	1	-	3	8.58	-	-	V	-	-	7	9	-	-
17	280736	23	IUGR	37.14	12.0	O-	2	2	-	4	8.17	-	-	V	-	-	7	9	-	-
18	269911	30	PD	40.86	11.0	B+	5	1	-	6	5.37	2	-	V	-	-	7	9	-	-
19	270931	25	PD	41.00	9.0	B+	3	3	1	3	27.08	5	PPH	V	-	-	7	9	-	-
20	271890	20	PD	38.14	10.0	O+	1	3	-	4	40.08	10	-	-	LSCS	NPL	7	9	-	-
21	269275	24	IUGR	37.14	12.0	O+	3	1	-	3	31.00	10	-	V	-	-	7	9	-	-
22	274828	21	PD	41.86	11.0	O+	1	1	-	4	5.78	-	-	V	-	-	7	9	-	-
23	276277	21	PIH	41.29	9.5	A+	1	1	-	4	9.42	3	-	V	-	-	7	9	-	-
24	275607	21	PIH	39.14	12.0	AB+	1	2	-	3	8.63	-	-	V	-	-	7	9	-	-
25	279374	22	PD	42.00	10.0	AB+	2	2	-	4	9.57	-	-	V	-	-	7	9	-	-
26	279685	25	IUGR	38.71	12.0	AB+	4	1	-	5	2.57	-	-	V	-	-	7	9	-	-
27	280419	20	PIH	40.57	10.8	A+	1	3	2	2	27.17	-	-	-	LSCS	NPL	7	9	-	-
28	284584	21	-	37.00	10.5	A+	2	1	-	5	2.42	-	-	V	-	-	7	9	-	-
29	287698	21	IUGR	37.71	11.0	A-	2	1	-	3	7.87	-	-	V	-	-	7	9	-	-
30	284611	32	IUGR	39.86	11.0	B+	3	1	-	5	4.00	-	-	V	-	-	7	9	-	-
31	284662	26	IUGR	38.00	11.0	O+	3	1	-	3	6.27	-	-	V	-	-	7	9	-	-
32	284706	22	PD	41.43	11.5	AB+	1	1	-	5	11.87	-	-	V	-	-	7	6	M	-
33	288666	22	PD	41.43	12.5	O+	2	1	-	3	3.67	-	-	V	-	-	7	9	-	-
34	289414	30	PD	40.71	10.3	O+	1	2	-	2	13.23	-	-	-	LSCS	FD	7	9	-	-
35	288560	25	PD	40.29	10.5	O+	2	1	-	2	10.83	-	-	V	-	-	7	9	-	-

S.NO.	IP NO.	AGE (YEARS)	INDICATION	GA (WEEKS)	Hb%	BLOOD GROUP	PARITY	CERVIPRIME	CYTOTEC	BISHOP SCORE	INTERVAL	OXYTOCIN	COMPLICATION	VAGINAL	LSCS	INDICATION FOR LSCS	APGAR SCORE 1	APGAR SCORE 2	MECONEUM	NICU
36	290805	20	PD	40.71	11.0	O+	1	2	-	2	10.50	-	-	-	LSCS	FD	7	9	-	-
37	291607	24	PD	41.14	12.0	B-	2	1	-	4	10.33	5	-	V	-	-	7	9	-	-
38	295572	21	-	40.57	12.5	A+	1	1	-	3	9.17	5	-	V	-	-	7	9	-	-
39	298498	21	PD	41.14	10.0	0+	1	1	-	6	3.25	-	-	-	LSCS	FD	7	9	-	-
40	291101	21	-	39.86	11.0	A+	1	1	-	4	5.33	-	-	V	-	-	7	9	-	-
41	300383	30	PD	42.00	13.0	B+	3	1	-	3	11.17	5	-	V	-	-	7	9	-	-
42	300525	24	PD	41.00	9.8	B+	1	1	-	3	2.22	-	-	V	-	-	7	9	-	-
43	291194	28	-	40.29	11.5	A+	2	2	-	4	10.58	5	-	V	-	-	7	9	-	-
44	292508	21	PD	41.00	9.5	A+	2	1	-	4	1.83	-	-	V	-	-	7	9	-	-
45	292324	28	PD	41.00	12.5	-	1	3	-	3	13.15	-	-	-	LSCS	NPL	7	9	-	-
46	293670	28	OLIGO	41.00	7.0	O+	4	1	-	5	4.33	-	-	V	-	-	7	9	-	-
47	293628	22	IUGR	40.29	10.0	A+	1	3	-	3	14.92	-	-	V	-	-	7	9	-	-
48	294036	20	PD	40.86	12.0	B+	1	1	-	3	7.00	3	-	V	-	-	7	9	-	-
49	294620	20	PD	41.00	10.0	O+	3	1	-	4	9.00	5	-	V	-	-	7	9	-	-
50	292457	21	PD	40.00	10.0	O-	1	1	-	4	6.83	-	-	-	LSCS	FD	7	9	-	-
51	292416	19	IUGR	39.71	10.0	B+	1	1	-	4	5.25	-	-	V	-	-	7	9	-	-
52	294298	25	IUGR	39.43	11.0	O+	2	1	-	4	5.67	-	-	V	-	-	7	9	-	-
53	300535	22	PD	42.00	10.0	AB+	1	1	-	4	2.22	-	-	V	-	-	7	9	-	-
54	306149	25	PIH	41.71	10.7	O+	3	1	-	4	5.75	-	-	V	-	-	7	9	-	-
55	309230	20	OLIGO	40.29	11.0	AB-	1	1	-	4	4.83	-	-	V	-	-	7	9	-	-
56	309857	20	PD	41.14	11.5	A+	1	3	2	3	22.50	-	-	-	LSCS	FL IND	7	9	-	-
57	309817	28	PD	40.14	11.0	B+	2	1	-	4	7.00	-	-	V	-	-	7	9	-	-
58	310689	25	PD	40.86	12.8	B+	1	1	-	5	14.25	10	-	V	-	-	7	9	-	-
59	301719	19	PIH	40.43	10.5	B+	1	1	-	4	6.50	5	-	V	-	-	7	9	-	-
60	309900	22	PD	40.07	12.0	AB +	1	1	-	3	10.50	5	-	V	-	-	7	9	-	-

S.NO.	IP NO.	AGE (YEARS)	GA (WEEKS)	INDICATION	Hb%	BLOOD GROUP	PARITY	CERVIPRIME	CYTOTEC	BISHOP SCORE	INTERVAL	OXYTOCIN	COMPLICATION	VAGINAL	LSCS	INDICATION FOR LSCS	APGAR SCORE 1	APGAR SCORE 2	MECONEUM	NICU
1	257924	26	37.00	PIH	10.40	AB+	4	1	-	3	10.10	-	-	-	LSCS	FD	7	9	-	NICU
2	258260	20	37.00	IUGR	12.00	A+	1	3	-	4	18.08	-	-	-	LSCS	NPL	7	9	-	-
3	257625	20	37.00	IUGR	11.00	A+	1	2	-	5	11.57	-	-	-	LSCS	FD	7	9	-	-
4	260045	24	37.00	-	10.00	A+	2	2	-	7	15.25	-	-	-	LSCS	FD	7	9	M	-
5	261963	23	39.14	PIH	12.20	O+	2	1	-	4	1.68	-	-	-	LSCS	FD	7	9	-	NICU
6	261781	21	37.14	PIH	9.20	A+	2	1	-	2	9.60	-	-	-	LSCS	FD	6	9	M	NICU
7	262177	20	40.86	PD	10.20	-	1	2	-	5	15.50	-	-	V	-	-	7	9	-	-
8	263048	26	38.29	PIH	11.00	B+	1	2	-	5	13.17	-	-	V	-	-	7	9	-	-
9	263715	21	37.29	IUGR	10.50	A-	1	2	-	2	12.40	-	-	V	-	-	7	9	-	-
10	264587	23	39.86	IUGR	12.00	B+	1	1	-	2	6.50	-	-	-	LSCS	FD	7	9	-	-
11	266354	24	37.57	IUGR	12.00	B+	3	3	-	4	18.78	-	-	V	-	-	7	9	-	-
12	265939	23	37.14	IUGR	10.00	O+	2	1	-	3	17.08	5	-	V	-	-	7	9	-	-
13	266303	29	37.14	PIH	11.00	B+	1	2	-	3	16.43	3	-	V	-	-	7	9	-	-
14	267026	25	38.29	PIH	11.00	AB+	1	3	-	2	17.90	-	-	-	LSCS	NPL	7	9	-	N
15	267363	20	40.00	PIH	11.60	A+	1	1	-	4	1.75	-	-	-	LSCS	FD	6	9	-	-
16	267758	25	41.57	PIH	10.50	AB+	1	2	-	4	11.58	-	-	-	LSCS	CPD	7	9	M	-
17	268640	24	39.86	IUGR	11.00	B+	1	3	3	5	47.92	5	-	-	LSCS	NPL	7	9	-	-
18	267986	20	39.57	PIH	10.50	O+	2	2	-	4	22.40	2	-	V	-	-	7	9	M	-
19	268698	22	40.71	-	10.50	A+	2	3	-	5	18.57	5	-	-	LSCS	NPL	7	9	-	-
20	268735	19	40.00	PD	10.60	B+	1	3	1	5	26.83	-	PPH	V	-	-	7	9	-	-
21	280427	22	38.71	PIH	9.00	B-	1	1	-	5	3.08	-	ABR	-	LSCS	FD	7	9	-	-
22	280254	20	38.14	PIH	10.00	-	1	2	-	3	8.37	-	-	-	LSCS	FD	7	9	-	N
23	282002	20	40.14	IUGR	8.00	AB+	2	1	-	7	7.97	-	-	V	-	-	7	9	-	-
24	282387	21	39.57	POLY	10.80	A+	2	1	-	4	11.03	-	-	-	LSCS	FD	5	8	-	-
25	283968	27	37.00	OLIGO	10.00	O+	3	3	-	3	15.22	-	-	V	-	-	7	9	-	-
26	285033	20	42.00	PD	9.00	A-	1	1	-	6	18.87	3	-	V	-	-	7	9	-	-
27	268733	19	40.14	PIH	10.00	-	1	3	-	5	24.55	2	-	V	-	-	7	9	-	-
28	268876	20	42.14	PD	9.80	A+	1	3	-	5	21.25	-	-	-	LSCS	-	7	9	-	-
29	285633	23	42.00	PD	10.00	O+	1	2	-	2	12.45	-	-	V	-	-	7	9	-	-
30	290133	23	40.57	PD	11.00	B+	3	1	-	3	6.03	-	-	V	-	-	7	9	-	-
31	290450	19	40.14	PD	11.00	B+	1	2	-	3	11.17	-	-	-	LSCS	FD	7	9	-	-
32	280675	19	38.86	IUGR	11.00	O+	1	3	-	3	23.08	-	-	V	-	-	7	9	-	-
33	281597	20	39.14	IUGR	10.00	AB+	1	3	-	3	18.20	-	-	V	-	-	7	9	-	-
34	290701	25	40.71	PD	11.00	O+	1	2	-	4	12.58	-	-	-	LSCS	FD	7	9	-	-
35	295152	27	40.29	-	12.00	B+	2	2	-	4	13.57	-	-	-	LSCS	NPL	7	9	-	-

S.NO.	IP NO.	AGE (YEARS)	GA (WEEKS)	INDICATION	Hb%	BLOOD GROUP	PARITY	CERVIPRIME	CYTOTEC	BISHOP SCORE	INTERVAL	OXYTOCIN	COMPLICATION	VAGINAL	LSCS	INDICATION FOR LSCS	APGAR SCORE 1	APGAR SCORE 2	MECONEUM	NICU
36	295648	20	41.71	PD	10.50	B+	1	1	-	2	11.83	10	-	-	LSCS	FD	7	9	-	-
37	301767	25	41.14	PD	11.00	O+	3	1	-	3	4.42	-	-	V	-	-	7	9	-	-
38	290871	22	37.86	IUGR	11.00	O+	2	1	-	3	7.00	-	-	-	LSCS	FD	7	9	-	-
39	292357	22	41.00	PD	11.00	O+	1	3	-	2	19.83	-	-	V	-	-	7	9	-	-
40	292621	30	41.00	PD	9.00	A+	2	1	-	3	16.20	10	-	-	LSCS	FD	7	9	-	-
41	292287	25	40.43	RH -	11.50	A-	1	3	1	3	27.22	-	-	-	LSCS	FD	7	9	-	-
42	294298	25	39.43	IUGR	11.40	O+	2	1	-	4	5.67	-	-	V	-	-	7	9	-	-
43	285570	24	40.29	PD	11.00	B-	2	3	2	4	27.17	5	-	V	-	-	7	9	-	-
44	291612	21	40.00	IUGR	10.00	A+	2	1	-	4	28.58	-	-	V	-	-	7	9	-	-
45	294428	28	41.00	PD	10.00	O+	3	1	-	5	9.00	-	-	V	-	-	7	9	-	-
46	295141	19	39.43	IUGR	11.50	B+	1	2	-	5	20.58	-	-	-	LSCS	FD	7	9	-	-
47	296722	19	42.57	PD	11.50	AB+	1	1	-	4	7.63	-	-	-	LSCS	FD	7	9	-	-
48	297602	21	39.86	PIH	13.00	O-	1	2	-	3	13.75	-	-	V	-	-	7	9	-	-
49	298859	35	37.57	PIH	13.00	O+	2	1	-	4	11.33	-	-	-	LSCS	FD	7	9	-	-
50	304477	19	41.43	PD	12.50	B+	1	1	-	5	7.67	-	-	V	-	-	7	9	-	-
51	304754	25	39.00	PP	13.00	O+	2	1	-	4	6.42	-	-	-	LSCS	NPL	7	9	-	-
52	305332	22	39.57	PIH	11.40	AB+	1	3	2	4	36.25	-	-	V	-	-	7	9	-	-
53	305330	18	39.00	IUGR	9.00	AB-	1	2	-	3	13.75	-	-	-	LSCS	FD	7	9	-	-
54	305987	25	37.00	IUGR	12.00	O+	1	3	1	4	24.50	-	-	V	-	-	7	9	-	-
55	306263	22	38.43	PIH	10.00	A+	1	3	-	4	21.42	-	-	V	-	-	7	9	-	-
56	307855	23	39.86	PIH	11.00	O+	1	3	4	3	51.00	-	-	-	LSCS	NPL	7	9	-	-
57	307977	19	38.86	IUGR	9.00	B+	1	2	-	4	8.50	-	-	-	LSCS	FD	7	9	-	-
58	308932	25	39.14	OLIGO	10.00	A+	1	3	-	4	16.08	-	-	V	-	-	7	9	-	-
59	309558	25	39.57	IUGR	10.00	A+	2	2	-	5	11.00	-	-	-	LSCS	CD PL	7	9	-	-
60	309860	40	37.29	PIH	10.00	A+	2	2	-	4	20.00	-	-	V	-	-	7	9	-	-

ANNEXURE IV – RANDOMIZATION CHART

1_____

- SWEEP
- NONSWEEP 256546

2 _____

- SWEEP
- NONSWEEP 257503

3 _____

- NONSWEEP
- SWEEP 257625

4 _____

- NONSWEEP
- SWEEP 257924

5 _____

- SWEEP
- NONSWEEP 258277

6 _____

- NONSWEEP
- SWEEP 258260

7 _____

- SWEEP
- NONSWEEP 258492

8 _____

- NONSWEEP
- SWEEP 260045

9 _____

- SWEEP
- NONSWEEP 260149

10 _____

- SWEEP
- NONSWEEP 260324

11 _____

- SWEEP
- NONSWEEP 260813

12 _____

- NONSWEEP
- SWEEP 261781

13 _____

- NONSWEEP
- SWEEP 261963

14 _____

- SWEEP
- NONSWEEP 261955

15 _____

- NONSWEEP
- SWEEP 262177

16 _____

- NONSWEEP
- SWEEP 263048

17 _____

- SWEEP
- NONSWEEP 263044

18 _____

- SWEEP
- NONSWEEP 263095

19 _____

- NONSWEEP
- SWEEP 263715

20 _____

- NONSWEEP
- SWEEP 264587

21 _____

- NONSWEEP
- SWEEP 265939

22 _____

- NONSWEEP
- SWEEP 266303

23 _____

- NONSWEEP
- SWEEP 266354

24 _____

- NONSWEEP
- SWEEP 267026

25 _____

- NONSWEEP
- SWEEP 267363

26 _____

- SWEEP
- NONSWEEP 267081

27 _____

- SWEEP
- NONSWEEP 267644

28 _____

- NONSWEEP
- SWEEP 267758

29 _____

- NONSWEEP
- SWEEP 267786

30 _____

- NONSWEEP
- SWEEP 268640

31 _____

- NONSWEEP
- SWEEP 268698

32 _____

- NONSWEEP
- SWEEP 268733

33 _____

- NONSWEEP
- SWEEP 268735

34 _____

- NONSWEEP
- SWEEP 268876

35 _____

- SWEEP
- NONSWEEP 269275

36 _____

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120 subjects randomized into 2 blocks