

Cervical Ripening by Foley's Catheter balloon versus locally applied Prostaglandin E2: A Randomized Clinical Controlled Trial

Thesis

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List of Abbreviations

ACOG	American College of Obstetricians and Gynecologists
AHFS	American Society of Health- System Pharmacists
AJC	Apical junctional complex
Apgar score 5 min	Apgar score after five minutes
BMI	Body mass index
C/S	Cesarean section
C1	Carbon 1
C4	Carbon 4
cm	Centimeter
COX-1	Cyclooxygenase-1
COX-2	Cyclooxygenase-2
CTG	Cardiotocograph
EASI	Extra-Amnionic Saline Infusion
ECM	Extracellular matrix
EDD	Expected delivery date
EFM	External fetal monitoring
EFW	Estimated fetal weight
EO	External Os
ER	Estrogen receptor
FHR	Fetal heart rate
FMJ	Fibromuscular junction
GA	Gestation age
gm	Gram
h	Hour(s)
HS	High significant

IDI	Induction-delivery interval
IL	Interleukin
IM	Intramuscular
IO	Internal Os
IOL	Induction of labor
ISMN	Isosorbide mononitrate
IV	Intravenous
LMP	Last menstrual period
mg	Milligram
min	Minute(s)
ml	Milliliter
mu	milliUnit
mu/min	mili unite per minute
NE	Not estimable
NICE	National Institute for Health and Clinical Excellence
NICU	Neonatal Intensive Care Unit
NO	Nitric Oxide
NOS	Nitric Oxide Synthase
NS	Not significant
P	Probability
Pap	Papanicolaou
PG	Prostaglandin
PGD2	Prostaglandin D2
PGE2	Prostaglandin E2
PGF2	Prostaglandin F2
PGI	Prostaglandin I
PGI2	Prostaglandin I2
PPH	Post partum heamorrhage
RCT	Randomized controlled trial

S	Significant
SCE	Simple columnar epithelium
SD	Standard deviation
sec	Second(s)
Sig.	Significant
SIUP	Single intrauterine pregnancy
SMA	Smooth muscle actin
SPSS	Statistical package for the social sciences
SSE	Stratified squamous epithelium
TENS	Transcutaneous nerve stimulation
TNF	Tumor necrosis factor
t-test	Student's t test
US	Ultrasound
Vs	Versus
Wks	Weeks
X2	Chi-square test
Yrs	Years

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Introduction

Cervical ripening refers to a process of preparing the cervix for induction of labor by promoting effacement and dilatation as measured by Bishop's score **(Laddad et al., 2013)**.

If the continuation of pregnancy is a threat to the life of the fetus, mother or both, the labor is induced to deliver the fetus. There has been a substantial increase incidence of induction of labour during the past few decades **(Wijepala and Najimudeen, 2013)**.

Induction of labor is the artificial initiation of labor before its spontaneous onset to deliver the feto-placental unit. The rate of induction steadily from 12.9% in 1991–1992 to 19.7% in 1999–2000. The rate reached a high of 23.7% in 2001–2002, decreased slightly to 21.8% in 2004–2005, and has since remained steady **(Chauhan and Ananth, 2012)**.

Labor is commonly induced in response to a number of fetal and maternal situations, including post term pregnancy and preeclampsia without the onset of spontaneous contraction. Potential effect of induction is an increased risk of caesarean delivery and its complications

(Sujata et al., 2012). Accepted indications for labor induction can be divided into maternal and fetal indications. The former include: hypertensive disorders of pregnancy such as preeclampsia/eclampsia, and other medical complications such as pregestational and gestational diabetes, and chronic pulmonary or renal disease **(Khamaiseh et al., 2012).** The latter include: `chorioamnionitis, intrauterine fetal growth restriction, postdates pregnancy, isoimmunization, and fetal anomalies **(Wing, 2006).** In addition to oligohydramnios **(Keepanasseril et al., 2007)** and abnormal results of antepartum surveillance **(Owolabi et al., 2005).**

When the cervix is unfavourable, cervical ripening is recommended to increase the likelihood of successful induction **(Sujata et al., 2012).**

To date, Bishop's score remains the standard method to predict the duration and outcome of induced labor. However, the preinduction subjective and several studies have demonstrated a poor predictive value for the outcome of induction especially in women with a low Bishop's score **(Selhi and Surapanenl, 2010).**

The success of induced labor depends on the degree of ripening of the cervix, which can be best assessed

objectively by inducibility score as developed by Bishop **(Laughon et al., 2012)**.

Induction of labor should be simple, safe, effective and non invasive. The Successful of induction defined as stimulation of regular uterine contractions before the spontaneous onset of labor leading to cervical dilation and subsequent delivery. Induction of labor depend on consistency and compliance of the cervix **(Krishna et al., 2012)**.

Agents used in cervical ripening include extra amniotic Foley's catheters, osmotic dilators, oxytocin, relaxin, sweeping of membranes, estrogen gel and prostaglandins (PGE1, PGE2, and PGF2 α) **(Owolabi et al., 2005)**.

Ripening of cervix may be achieved by both pharmacological and non-pharmacological method **(Jozwiak et al., 2012)**. The pharmacological preparation includes the prostaglandins and misoprostol. Prostaglandin E2 (PGE2) or dinoprostone which is unstable at room temperature and requires refrigeration **(Sujata et al., 2012)**.

Currently the most commonly used method is intra-cervical application of Prostaglandin E2 (**Kelly et al., 2013**).

Non-pharmacological method includes the transcervical use of Foley's catheter for cervical ripening and induction of labor. Embrey and Mollison first described using a transcervical Foley's catheter for cervical ripening. Obed and Adewele documented its effectiveness by increasing Bishop's scores in women with unripe cervix (**Sujata et al., 2012**). Catheter appears to induce labor not only through direct mechanical dilatation of cervix but also by stimulating endogenous release of Prostaglandin (**Sujata et al., 2012**).

Mechanical methods are used to dilate the cervix, but may also increase prostaglandin and/or oxytocin release by causing localised inflammation (**Henry et al., 2013**).

The naturally occurring prostaglandin E2 (PGE2) is known in medicine as dinoprostone. It has important effects in labor (softens cervix and causes uterine contraction). Transcervical Foley's catheter potential mechanisms of cervical ripening include mechanical dilation of cervix as well as release of endogenous prostaglandins from the fetal membranes. The use of a transcervical Foley's catheter for