

Foley's Catheter And Vaginal Misoprostol Versus Vaginal Misoprostol Alone For Labour Induction

Dr. Shikha Toshniwal¹, Dr. Saunitra Inamdar², Dr. Himanshi Agarwal³

Designation with affiliation of Authors:

1] Junior Resident, Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences Deemed University, Sawangi(Meghe), Wardha, shikhatoshniwal802@gmail.com , 8905669695

2] Professor, Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Science Deemed University, Sawangi(Meghe), Wardha, saunitrainamdar56@gmail.com, 9850307750

3] Junior Resident, Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences Deemed University, Sawangi(Meghe), Wardha, hagarwal2701@gmail.com , 9426480284

Corresponding author's name and address:

Dr. Shikha Toshniwal, First floor, Dept.of Obstetrics and Gynaecology
AVBRH, JNMC, Sawangi(Meghe)
Email: shikhatoshniwal802@gmail.com
Mob: 8905669695

ABSTRACT-

Background- *The labour induction becomes necessary when the continuing the pregnancy could result in maternal and fetal complications. Cervical ripening is essential for success of normal delivery, so attempts are made to ripen the cervix in a small span of time.*

Aim- *To study the comparative impact of "Transcervical Foley's Catheter with vaginal misoprostol on labour induction versus vaginal misoprostol alone" at or after 36 weeks of gestation.*

Method- *A cross- sectional study conducted in the rural area of India involves 120 full term pregnant females selected by systematic random sampling technique and the labour will be induced either by Foley's catheter along with misoprostol or misoprostol alone.*

Result - *In females induced with the Foley catheter along with vaginal misoprostol in both*

Primigravida and multigravida females, the time from induction to delivery is predicted to be substantially reduced.

Conclusion- Due to synergistic effect of intracervical Foley's catheter and vaginal misoprostol for cervical ripening and induction of labour, the time from induction to delivery interval will be reduced, prolongation of labour will be decreased and unnecessary caesarian section can be avoided.

Keywords- Foley's catheter, misoprostol, labour induction

INTRODUCTION :

Induction of labour are now commonly performed to decrease the maternal and fetal complications in cases where prolonged labour has more risks. For a good delivery, one of the key components is cervical ripening. For labour induction, various procedures for ripening the cervix are used. The use of oxytocin as a labour induction drug leads to a delay in the birth of the vagina and therefore leading to the caesarean section. The methods used for cervical ripening that ripen the cervix in a short period of time can also minimize the time interval between induction and childbirth (and ultimately lead to improved maternal and foetal outcomes(1). Although there is existence of other methods used for cervical ripening, but there is no as such concurrence to choose between proper labor induction for unripe cervix. We use "cervical Foley's catheter and vaginal misoprostol" for inducing labour and ripening of cervix (2-4) .The labour inducing techniques are practised clinically. The prolongation in induction to delivery time and failure of induction often leads to increase in rate of hospitalization stay and costs, maternal anxiety and leads to adverse maternal effects when vaginal delivery is not perceived (5). The collaborative effect of prostaglandin with mechanical dilatation often reduce the prevalence of failure of induction and intensify the progress of labor (6).

RATIONALE: The synergistic effect of intracervical "foley's catheter and vaginal misoprostol for cervical ripening and induction of labour", induction to delivery interval can be reduced, prolongation of labour can be decreased and unnecessary caesarian section can be avoided.

AIM:

The objective of the research is to compare the efficacy of vaginal misoprostol and transcervical foley catheter versus vaginal misoprostol alone in labour induction at or after 36 weeks of gestation.

OBJECTIVES:

The aims of this research are—

1. To study the effect of the foley's catheter and vaginal misoprostol for labour induction
2. To Analysis of the role of vaginal misoprostol in labour induction process
3. To Compare of foley's catheterization effect with vaginal misoprostol and vaginal misoprostol alone in labour induction

METHOD:

Study design: Cross Sectional Observational Study

Setting: Obstetrics and Gynaecology OPD , JNMC, A.V.B.R.H, DMIMS (Du), Wardha

Participants: A total of 120 subjects full-filling the inclusion and exclusion criteria will be admitted and monitored in the prelabour room. A detailed history will be taken to exclude any contraindications for induction of labour.

Variables: Case study will be done on 120 subjects and comparison between induction with “Foley’s catheter and vaginal misoprostol and vaginal misoprostol alone” will be done.

Data sources/ measurement :
Obstetrics OPD, Department Of Obstetrics And Gynaecology, DMIMS (DU), JNMC, Sawangi (M), Wardha, Maharashtra
Sample size = 120

Study Design : Observational Cross Sectional Study

Level of Significance: 5% (95% CI)

Power of the test : 80%

Side of the test : Two Sided

Statistical methods used : 1. Student’s unpaired t test 2. Chi square test

Inclusion Criteria includes:

1. Vertex Presentation
2. Singleton Pregnancy
3. Post term pregnancy
4. Less than 6 - Bishop’s score of
5. PET (pre- eclamptic toxemia)
6. Period of Gestation >36 weeks

Exclusion Criteria includes:

1. Placenta Previa
2. Known allergy to Misoprostol
3. Severe IUGR (intrauterine growth restriction)
4. Previous uterine scar
5. Severe oligohydramnios.
6. CPD
7. Prolonged PROM (>12 hrs)
8. Abnormal NST and Doppler findings on admission.

Quantitative variables:

Group A: (n=60) Tablet Misoprostol 25 mcg per vaginal tablet is administered for labour induction every 6 hours for a maximum of 4 doses.

Group B: (n=60) Foley's intracervical catheter (bulb inflated with 60 ml NS) and Misoprostol 25 mcg per vaginal tablet will be administered for labour induction every 6 hours for a maximum of 4 doses.

METHOD:

Ethical clearance will be obtained from the institutional ethical committee. Every woman will be clarified the type and purpose of the study, the need for induction and risks associated with the medication and the process of induction and informed consent will be taken before enrolling the patient into the study.

A total of 120 subjects full-filling the inclusion and exclusion criteria will be admitted and monitored in the pre labor room. A detailed history will be taken to exclude any contraindications for induction of labor. General examination, systemic examination and a thorough obstetric examination will be done. Pelvic examination will be done to see the adequacy of the pelvis and note the Bishop's score.

A baseline NST will be done for at least 10 minutes to rule out already existing compromised state of the fetus-in-utero. Routine investigations and an obstetric ultrasound and Doppler will be done to check for fetal wellbeing in addition to other parameters like gestational age, placental site including grading and liquor volume.

The patients will be grouped in 2 categories according to randomization no. -

Group A: Tablet Misoprostol 25 mcg

Group B: Tablet Misoprostol 25 mcg plus Foley's catheter (No. 16).

For subjects assigned to Group A, the Tablet Misoprostol 25 mcg will be placed intravaginally. For subjects assigned to Group B, first Foley's catheter 16F will be inserted intracervically with in the posterior fornix of vagina every 6 hourly for a maximum of 4 doses.

Speculum examination done to visualize of the cervix by sterile measures and avoiding contact of catheter with the adnexa. The catheter balloon will be inflated with 30cc of sterile normal saline solution after proper positioning is assured. Traction would be applied to the catheter until the internal cervical os is tensed against the balloon The catheter would then be stucked to the patient's inner thigh region for a period of 12 hours or before spontaneous expulsion. Antibiotic coverage will be given to avoid any infection. Along with it Tablet Misoprostol 25 mcg will be placed intravaginally in the vagina's posterior fornix every 6 hourly for a maximum of 4 doses. There will be tracking of patient symptoms, vital signs , uterine contractions and foetal heart rate patterns. The second and third stages will be managed as usual. Progress of labour will be monitored.

Delivery interval induction will be noted. If there is any indication of foetal risk or any other obstetric complications, labour will be cut short, as needed, by instrumental delivery or caesarean section.

APGAR scores at 1 and 5 minutes of birth weight, meconium aspiration, sepsis and other related complications will be identified shortly after delivery. The advice of the neonatologist would be sought in the event of complications. A NICU will be admitting all neonates with signs and symptoms of suspected sepsis.

It will be noted for neonatal morbidity and mortality. During their stay in the hospital, Both mother and child will be monitored.

EXPECTED OUTCOME/RESULTS:

Participants:

Group A: (n=60) Tablet Misoprostol 25 mcg per vaginally will be given for induction of labor every 6 hours apart upto 4 doses only

Group B: (n=60) Intracervical Foley's catheter (bulb inflated with 60 ml NS) along with Tablet Misoprostol 25 mcg per vaginally will be given for induction of labor every 6 hours upto maximum of 4 doses only

Descriptive data- induction to delivery interval

Outcome data: Case study will be done on 120 subjects and comparison between induction with intracervical Foleys catheter and misoprostol and misoprostol alone to establish the reduction in induction to delivery interval.

Discussion:

Induction of labour are commonly performed nowadays to decrease the maternal and fetal complications in cases where prolonged labour has more risks. For a successful delivery to take place, cervical ripening plays an important component. So different methods to ripen the cervix are been performed for labor induction.

In subjects with un-ripened cervix the desired process will reduce the Induction to Delivery interval without any complications to the mother and fetus. The need to deliver a patient with unripe cervix, to induce labour to increase the efficacy of labour are frequent problems to obstetrician.

Methods of induction: It includes the following -

1. Medication
2. Prostaglandins - Dinoprostone or Misoprostol can be given as Intravaginal, endocervical or oral route.
3. Oxytocin- Pitocin , synthetic oxytocin preparations Intravenous administration
4. Natural Induction - Many midwives or other holistic practitioners practise "natural" induction, which may involve the use to stimulate or advance a stalled labour of herbs, castor oil or other medically unorthodox agents.
5. Mifepristone.
6. Relaxin but not in use

2. Processes

- In Australia and UK, Membrane sweep or membrane stripping, or "stretch and sweep" is used during an per vaginal examination, the obstetrician moves their finger around the cervix , this will separate the membranes around the head from the cervix that will stimulate the release of prostaglandins that will accelerates labor.(7)
- Artificial rupture of the membranes
- Transcervical foleys catheter

Many of these prostaglandins have been shown to be very useful for cervical maturation and labour induction.

Prostaglandins are enzymatically derived lipid compounds from fatty acids that have discrete functions in the body. Each prostaglandin contains around 20 atoms of carbon with a five-carbon ring. When prostaglandin was first isolated by the Swedish physiologist Ulfvon Euler from seminal fluid in 1935, and independently by M.W. Goldblatt consider it as part of the secretions of the prostate.(8)

It was later discovered that many other tissues also secrete prostaglandins for different roles. E. J. Corey in 1969 reported the first total synthesis of prostaglandin PGF₂ α and prostaglandin PGE₂. (9) All nucleated cells except lymphocytes manufacture them. They function on platelets, endothelium, uterine and mast cells as autocrine and paracrine lipid mediators. They are synthesised from essential fatty acids (EFAs) in the cell and encourage cervical softening and promote myometrial contractions caused by oxytocin. For labour

induction, PGE₂ and PGF₂ have also been used. Prostaglandins have been used in the form of oral supplements, gels, pessaries and films in the cervix and vagina. While PGE₂ has long been used for ripening PGE₁ (misoprostone) has recently been tried. The misoprostol was cheap and does not require refrigeration unlike PGE₂. Misoprostol is extensively absorbed and the free acid (Misoprostol acid) which is responsible for its clinical function, is rapidly easily de-esterified.(10) Foleys balloon catheter causes cervical ripening by mechanical dilatation of cervix and by releasing prostaglandin from amniotic membranes. (11)Spontaneous expulsion of catheter correlates with 2-3cm dilatation of cervix. Failed labour induction and increased induction to delivery period are related to increased costs of hospitalization ,maternal and parental anxiety levels and when secure and timely vaginal delivery is not realized, adverse maternal and perinatal outcomes are likely to increase(12). A number of studies on use of different agents for cervical ripening and induction of labour were reported (13-16).

The synergistic impact of prostaglandin and mechanical dilatation on cervical maturation and improvement in combined labour approaches would decrease the occurrence of induction failures and increase labour improvement.

Limitations:

- 1) Foley's Catheter may not be used for prolonged period as chances of infection is high in pre mature rupture of membrane.
- 2) Misoprostol should not be used in previous C- section women because of increased rate of uterine rupture.

Interpretation: There exists a positive effect on induction-delivery interval when induction is done with both "intracervical Foley's catheter and vaginal misoprostol" in cases with high risk pregnancy.

REFERENCES:-

- [1] Barrilleaux PS, Bofill JA, Terrone DA, Magann EF, May WL, Morrison JC. Cervical ripening and induction of labor with misoprostol, dinoprostone gel, and a Foley catheter: a randomized trial of 3 techniques. *Am J Obstet Gynecol.* 2002 Jun;186(6):1124–9.
- [2] Jozwiak M, Bloemenkamp KWM, Kelly AJ, Mol BWJ, Irion O, Bouvain M. Mechanical methods for induction of labour. *Cochrane Database Syst Rev.* 2012 Mar 14;(3):CD001233.
- [3] Wing DA, Ham D, Paul RH. A comparison of orally administered misoprostol with vaginally administered misoprostol for cervical ripening and labor induction. *Am J Obstet Gynecol.* 1999 May;180(5):1155–60.
- [4] Zieman M, Fong SK, Benowitz NL, Banskter D, Darney PD. Absorption kinetics of misoprostol with oral or vaginal administration. *Obstet Gynecol.* 1997 Jul;90(1):88–92.
- [5] Baños N, Migliorelli F, Posadas E, Ferreri J, Palacio M. Definition of Failed Induction of Labor and Its Predictive Factors: Two Unsolved Issues of an Everyday Clinical Situation. *Fetal Diagn Ther.* 2015;38(3):161–9.
- [6] Levine LD, Sammel MD, Parry S, Williams CT, Elovitz MA, Srinivas SK. 5: Foley or Misoprostol for the Management of Induction (The ‘FOR MOMI’ trial): A four-arm randomized clinical trial. *Am J Obstet Gynecol.* 2016 Jan 1;214(1):S4.
- [7] Bouvain M, Stan CM, Irion O. Membrane sweeping for induction of labour. *Cochrane Database Syst Rev [Internet].* 2005 Jan 24 [cited 2020 Dec 4];2005(1). Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7032890/>
- [8] Flower RJ. Prostaglandins, bioassay and inflammation. *Br J Pharmacol.* 2006 Jan;147(Suppl 1):S182–92.
- [9] Total synthesis of prostaglandins F1.alpha., E1, F2.alpha., and E2 (natural forms) from a common synthetic intermediate | *Journal of the American Chemical Society [Internet].* [cited 2020 Dec 4]. Available from: <https://pubs.acs.org/doi/abs/10.1021/ja00711a083>
- [10] PubChem. Misoprostol [Internet]. [cited 2020 Dec 4]. Available from: <https://pubchem.ncbi.nlm.nih.gov/compound/5282381>
- [11] Rath W, Kehl S. The Renaissance of Transcervical Balloon Catheters for Cervical Ripening and Labour Induction. *Geburtshilfe Frauenheilkd.* 2015 Nov;75(11):1130–9.
- [12] Koelewijn JM, Sluijs AM, Vrijkotte TGM. Possible relationship between general and pregnancy-related anxiety during the first half of pregnancy and the birth process: a prospective cohort study. *BMJ Open [Internet].* 2017 May 9 [cited 2020 Dec 4];7(5). Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5623367/>
- [13] Deshmukh, S., M.L. Jungari, and U. Shrama. “Use of Pg-e 2 Gel for Cervical Ripening in Labour Induction.” *International Journal of Current Research and Review* 12, no. 14 Special Issue (2020): 110–13. <https://doi.org/10.31782/IJCRR.2020.110113>.
- [14] Sharma, S., and M. Tiwari. “Comparison of Intravaginal Misoprostol and Intramuscular Carboprost for Cervical Priming in the First Trimester of Medical Termination of Pregnancy.” *Journal of Datta Meghe Institute of*

Medical Sciences University 14, no. 4 (2019): 296–302.

https://doi.org/10.4103/jdmimsu.jdmimsu_154_19.

- [15] Singh, N., N. Acharya, P. Singh, K. Singh, and C.S. Gode. “Study of Mifepristone vs Misoprostol as Pre-Induction Cervical Ripening Agent in Term Pregnancy.” *International Journal of Pharmaceutical Research* 11, no. 4 (2019): 2030–34. <https://doi.org/10.31838/ijpr/2019.11.04.506>.
- [16] Acharya, N., A. Gadge, M. Agrawal, and M. Singh. “Mechanical Cervical Ripening with Foley Catheter Balloon: Rekindling a Forgotten Art.” *Journal of SAFOG* 10, no. 1 (2018): 1–4. <https://doi.org/10.5005/jp-journals-10006-1548>.