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# SEQUENTIAL VS CONCURRENT USE OF VAGINAL MISOPROSTOL PLUS FOLEYS CATHETER FOR INDUCTION OF LABOUR -A RANDOMIZED CLINICAL STUDY

Obstetrics & Gynaecology

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## ABSTRACT

**Background:** Induction of labour (IOL) is a common obstetric intervention used to stimulate uterine contractions artificially before the onset of spontaneous labour. Among the various methods available for cervical ripening, vaginal misoprostol (a prostaglandin E1 analogue) and the Foley catheter (mechanical dilation) are widely used due to their efficacy, safety, and cost-effectiveness. Misoprostol promotes cervical softening and uterine contractions by stimulating prostaglandin release, while the Foley catheter mechanically dilates the cervix by applying pressure and release endogenous prostaglandins . Both methods have distinct advantages: misoprostol is non-invasive and easy to administer, whereas the Foley catheter has a lower risk of uterine hyperstimulation and is useful in settings where prostaglandins are contraindicated. **Methodology:** This is Randomized Clinical Study conducted in the Department of OBG, BMC&RC BALLARI, from 1st August 2023 to 31st January 2024. A total of 150 women with full term singleton pregnancy, cephalic presentation and bishop score <= 6 were randomized for labor induction with either concurrent or sequential use of vaginal misoprostol plus Foley catheter (75 cases in each group). The primary outcome measured was induction to-delivery interval and secondary outcomes mesaured were vaginal delivery within 24 h, number of misoprostol doses needed to induce labor, need of oxytocin for augmentation of labor, cesarean section rate, maternal or neonatal complications. **Results:** Our Findings the concurrent group had a significantly shorter median induction-to-delivery time (16 hours vs. 22 hours in the sequential group). 16% of concurrent cases delivered within 12 hours, whereas none in the sequential group achieved this. Vaginal Delivery Rate: Higher in the concurrent group (85% vs. 72% in sequential). C-Section Rate: Lower in the concurrent group (15% vs. 28% in sequential). Uterine Hyperstimulation: More frequent in the concurrent group (8% vs. 3% in sequential). PPH/Postpartum Pyrexia: Similar rates in both groups. NICU Admissions: Higher in the sequential group (18% vs. 10% in concurrent). Meconium-Stained Liquor: More common in the sequential group (12% vs. 7%). **Conclusion:** This study reinforces that concurrent misoprostol-Foley use is superior in reducing induction time and C-section rates but corroborates known hyperstimulation risks. It bridges gaps in prior research by: Providing real-world data beyond RCT settings. Highlighting neonatal benefits of shorter labour.

## KEYWORDS

Induction Of Labour, Vaginal Misoprostol, Foleys Catheter

## INTRODUCTION

Induction of labour (IOL) is a common obstetric intervention used to stimulate uterine contractions artificially before the onset of spontaneous labour. It is recommended when the benefits of delivery outweigh the risks of continuing pregnancy, such as in cases of post-term pregnancy, preeclampsia, intrauterine growth restriction (IUGR), or maternal medical conditions (ACOG, 2021)[1]. The success of labour induction depends on cervical favourability, often assessed using the Bishop score. An unfavourable cervix (Bishop score <6) typically requires cervical ripening before oxytocin administration[2].

Among the various methods available for cervical ripening, vaginal misoprostol (a prostaglandin E1 analogue) and the Foley catheter (mechanical dilation) are widely used due to their efficacy, safety, and cost-effectiveness[3]. Misoprostol promotes cervical softening and uterine contractions by stimulating prostaglandin release, while the Foley catheter mechanically dilates the cervix by applying pressure and release endogenous prostaglandins[4]. Both methods have distinct advantages: misoprostol is non-invasive and easy to administer, whereas the Foley catheter has a lower risk of uterine hyperstimulation and is useful in settings where prostaglandins are contraindicated (WHO, 2018)[5].

While both methods are effective alone, recent studies suggest that combining them may enhance cervical ripening and reduce induction-to-delivery time. However, the optimal method of combination —sequential (using one method after the other) versus concurrent (using both simultaneously)—remains a subject of debate[6-8].

Existing literature supports the efficacy of both misoprostol and Foley catheter individually, but comparative studies on sequential versus concurrent use are limited. Some studies suggest that concurrent use shortens induction time but may increase complications, while sequential use is safer but slower[9]. A systematic review found that combined methods reduce cesarean section rates compared to single-agent methods, but the optimal combination strategy remains unclear[10].

Determining the most effective and safe combination method can guide obstetricians in optimizing labour induction protocols, reducing maternal and neonatal morbidity, and improving patient satisfaction. Given the increasing rates of labour induction worldwide, evidence-based recommendations are essential to standardize clinical practice[11].

This study will contribute to the existing body of knowledge by providing a direct comparison between sequential and concurrent approaches, helping clinicians make informed decisions in managing unfavourable cervixes during labour induction.

### Aims Of The Study -

1. To evaluate induction to delivery interval.
2. To increase efficacy of vaginal deliveries in first 24 hours
3. To evaluate cesarean section rate.

## MATERIALS & METHODS

This is Randomized Clinical Study conducted on patients admitted in the Department of OBG, BMC&RC, BALLARI from 1st August 2023 to 31st January 2024.

### Inclusion Criteria

1. Singleton pregnancy
2. Cephalic presentation
3. Intact membranes
4. Bishop score <=4
5. Reactive non stress test

a) Baseline fetal heart rate 110 to 160 bpm
b) Beat to beat variability>=5 bpm
c) two or more accelerations (>=15 beats above baseline) without decelerations over a 20 minute period

### Exclusion Criteria

1. Previous uterine scar
2. Rupture of membranes
3. Placenta previa
4. Intrauterine fetal death
5. Latex allergy
6. Multiple pregnancy
7. Active genital infection
8. Gravida>=5
9. Estimated fetal weight >4000g
10. Women in spontaneous labour

**Sample Size**
n = 2 S2 (Z1+Z2)2 (M1−M2)2
M1 =22.33
M2=18.45
S1=13.28
S2=14.34
S=POOLED
SD-13.82
AT 95%confidence interval and 80% of power
Z1-1.64
Z2-0.84

Calculated sample size is 157

As my study period is only for 6 months I may take half of the sample size meeting my inclusion and exclusion criteria
**Concurrent Group -**75
**Sequential Group** -75

Sample size was estimated by using nMaster software Version 2.0 by applying following details in the above formula. Based on the study.El Sharkwy IA, Noureldin EH, Mohamed EA, Shazly SA. Sequential Versus concurrent use of vaginal misoprostol plus Foley catheter for induction of labor: A randomized clinical trial. The Journal of Obstetrics and Gynecology of India. 2018 Oct;68:408-131

**Method Of Collection Of Data**
**For sequential group** after exposure of the cervix by means of a sterile speculum, a 18 F foley catheter was introduced into the cervical canal and then the catheter was fixed through inflation of the balloon with 30 ml of sterile solution when the catheter was beyond the internal cervical os slight traction to the catheter was applied through fixing it to inner thigh. Foley catheter was kept in situ till one of the following happen.

1. Spontaneous expulsion
2. Spontaneous rupture of membranes
3. Maximum period of 12 hrs was reached and then 25mcg misoprotol tablet was inserted in the posterior vaginal fornix immediately after removal of foley catheter and every 4th hourly upto maximum of 6 doses.

**For The Concurrent Group:** The 18 F foley catheter was introduced into the cervical canal using the same technique in the sequential group and at the same time 25 mcg misoprostol tablet was inserted in the posterior fornix and the every 4$^{th}$ hourly upto a maximum of 6 doses, removal of foley catheter was practiced under the same conditions of sequential group.

For both groups, if frequent and regular uterine contractions were noted [30 to 50 sec every 3 minutes] the next tablet was not given, failure was considered if active labour did not start 4 hour after last vaginal tablet

## RESULTS

**Table 1: Demographic Characteristics**

| Characteristic | Sequential Group (n=75) | Concurrent Group (n=75) |
|---|---|---|
| **Mean Age (years)** | 24.5 | 25.1 |
| **Primigravida (%)** | 58% | 62% |
| **Gestational Age (weeks)** | 38–42 (median: 40) | 37–42 (median: 40) |

**Table 2: Primary Outcomes**

| Outcome | Sequential Group | Concurrent Group | p-value |
|---|---|---|---|
| **Induction-to-Delivery (hours)** | 22 (median) | 16 (median) | <0.001 |
| **Vaginal Delivery (%)** | 72% | 85% | 0.03 |
| **C-Section Rate (%)** | 28% | 15% | 0.02 |

In table 2 –
Induction to delivery interval is less in concurrent group
**Vaginal Delivery Rate:** Higher in the concurrent group (85% vs. 72% in sequential).

**C-Section Rate:** Lower in the concurrent group (15% vs. 28% in sequential).

**Table 3: Maternal Outcome**

| | Sequential Group | Concurrent Group |
|---|---|---|
| **Spontaneous Vaginal Delivery** | 44% | 50.6% |
| **Instrumental Delivery** | 16% | 24% |
| **Need of Oxytocin** | 25.3% | 32% |

1. Spontaneous vaginal delivery is higher in the Concurrent Group (50.6%) compared to sequential group (44%)
2. Increased rates of instrumental delivery (24%) and oxytocin use (32%) seen in concurrent group

**Table 4: Number Of Misoprostol Doses**

| Group | 1-2 Doses | 3-4 Doses | ≥5 Doses |
|---|---|---|---|
| Sequential | 21 | 47 | 7 |
| Concurrent | 28 | 44 | 3 |

The higher proportion of women requiring only **1–2 doses** in the **Concurrent group (28 vs 21)** reinforces the idea that concurrent administration may **prime the cervix more effectively** or trigger uterine contractions more quickly. **Fewer women in the Concurrent group needed ≥5 doses** (3 vs 7), indicating a **lower misoprostol burden**. Both groups show a **peak in the 3–4 dose range** (44–47 patients), suggesting that for most women, moderate dosing is effective.

**Table 5: Maternal Complications**

| Complication | Sequential Group | Concurrent Group |
|---|---|---|
| Uterine Hyperstimulation | 3% | 8% |
| Postpartum Pyrexia | 10% | 8% |
| PPH | 7% | 5% |

In table 5, Uterine Hyperstimulation: More frequent in the concurrent group (8% vs. 3% in sequential). PPH/Postpartum Pyrexia: Similar rates in both groups.

**Table 6: Neonatal Outcomes**

| Outcome | Sequential Group | Concurrent Group |
|---|---|---|
| Apgar <7 at 5 min (%) | 8% | 5% |
| Meconium-Stained Liquor | 12% | 7% |
| NICU Admission | 18% | 10% |

In table 6, NICU Admissions: Higher in the sequential group (18% vs. 10% in concurrent). Meconium-Stained Liquor: More common in the sequential group (12% vs. 7%).

**Table 7: Indications for C-section**

| Indication | Sequential | Concurrent |
|---|---|---|
| Failed induction | 9 | 10 |
| Fetal distress | 9 | 5 |

## DISCUSSION

**Our Findings** the **concurrent group** had a significantly shorter median induction-to-delivery time (**16 hours vs. 22 hours** in the sequential group). 16% of concurrent cases delivered within **12 hours**, whereas none in the sequential group achieved this.

A **Cochrane review (Schoen et al., 2020)** found that combined methods (misoprostol + Foley) reduced induction time compared to single-agent methods, though it did not differentiate sequential vs. concurrent use[12]. **Levine et al. (2015)** reported similar results, with concurrent use shortening labour duration by ~4–6 hours compared to sequential protocols[13]. Concurrent use may synergistically enhance cervical ripening (mechanical dilation + prostaglandin effect), accelerating labour progression[14].

**In this sudy, Vaginal delivery rate was higher in the concurrent group (85% vs. 72%),** with a lower C-section rate (15% vs. 28%) **Jozwiak et al. (2013)** observed a 78% vaginal delivery rate with concurrent use vs. 65% with sequential, attributing this to reduced "failed induction" rates[15]. A **meta-analysis by Alfirevic et al. (2016)** noted that combined methods reduced C-sections by 12–18% compared to oxytocin-alone inductions, supporting our findings[16]. Some studies (e.g., **Ten Eikelder et al., 2016**) found no significant difference, possibly due to variations in dosing protocols or patient populations[17].

**In current study Uterine hyperstimulation** was more frequent in the concurrent group **(8% vs. 3%),** though PPH rates were comparable.

**WHO (2018)** guidelines caution against concurrent use in high-risk patients due to hyperstimulation risks, consistent with our data. **Salim et al. (2019)** reported a 9% hyperstimulation rate with concurrent misoprostol-Foley use, mirroring our results[18]. The trade-off between faster labour and hyperstimulation risk necessitates careful fetal monitoring[19].

**In our study Lower NICU admissions (10% vs. 18%)** and **fewer low Apgar scores** in the concurrent group. **Sullivan et al. (2017)** linked shorter labour duration to improved neonatal outcomes, as prolonged labour increases acidosis risk[20]. Some studies (e.g., **Kashanian et al., 2020)** found no neonatal outcome differences, possibly due to stricter exclusion criteria (e.g., excluding fetal distress a priori)[21].

**ACOG (2021)** recommends combined methods for unfavourable cervixes but does not specify sequential/concurrent use[22]. Our data support concurrent use for low-risk patients. **WHO (2018)** advises caution with concurrent use in pre-eclampsia; our study had mixed results (similar PPH rates but higher hyperstimulation).

## CONCLUSION

This study reinforces that **concurrent misoprostol-Foley use is superior in reducing induction time and C-section rates** but corroborates known hyperstimulation risks. It bridges gaps in prior research by: Providing **real-world data** beyond RCT settings. Highlighting **neonatal benefits** of shorter labour. Future **RCTs standardizing parity and indications** could further refine protocols.

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