



A COMPARATIVE STUDY OF COMBINATION OF VAGINAL MISOPROSTOL AND FOLEY'S BULB V/S VAGINAL MISOPROSTOL ALONE FOR CERVICAL RIPENING AND INDUCTION OF LABOUR.

Obstetrics & Gynaecology

Dr. T. Rishma Sri Teja Postgraduate, Department of Obstetrics & Gynaecology, Alluri Sitarama Raju Academy of Medical Sciences Eluru, Eluru District Andhra Pradesh 534005 India

Dr. K. Vandana Professor and HOD, Department of Obstetrics & Gynaecology, Alluri Sitarama Raju Academy of Medical Sciences Eluru, Eluru District Andhra Pradesh 534005 India

ABSTRACT

Introduction: The induction of labor (IOL), involves stimulating uterine contractions before spontaneous labor begins. Augmentation refers to enhancing spontaneous but inadequate contractions. IOL often begins with cervical ripening using prostaglandins to soften and widen the cervix. This method has gained popularity over the last two decades, now accounting for about 27% of births. **Aims and Objective of the Study:** To compare the cervical ripening in combination of vaginal misoprostol and foley's bulb v/s vaginal misoprostol alone. To compare induction to delivery interval in combination of vaginal misoprostol and foley's bulb v/s vaginal misoprostol alone. **Material and Methods-** This is a Randomized control study comparing foley's bulb along with vaginal misoprostol and vaginal misoprostol alone in cervical ripening and induction of labour in patients attending the outpatient clinic in the department of Obstetrics and Gynaecology, ASRAM medical college, in the period of Aug 2022- Aug 2024 were enrolled in this study. **Statistical Analysis:** Collected data entered in Microsoft excel 2019 and analyzed using epi info software. Criteria for statistical significance was P value less than 0.05. Women were randomly divided into two groups: 50 in each group
Group 1: Received only vaginal misoprostol (25 micrograms every 4 hours, up to a maximum of 6 doses).
Group 2: Received vaginal misoprostol (same protocol as Group 1) and had a Foley bulb catheter inserted, filled with saline, and secured with light traction.

Results: Twelve patients in the misoprostol alone group were taken upon for lower segment cesarean section and nine patients in the combined group underwent LSCS. The mean value of the 12th hour bishop score was higher in the combined group. The time at which induction was started and the delivery time were noted for each patient in both the groups and the time interval was tabulated. An average time of 18 hours with a standard deviation of 2.5 hours were seen in the misoprostol alone group. A shorter average time period of 15 hours with a standard deviation of 2 hours was seen in the combination group. **Conclusion:** The comparison study's findings demonstrates that using Foley's in addition to vaginal misoprostol reduces the amount of time needed from induction until birth. These findings further imply that, in the event of an immature cervix, the combination of Foley's and vaginal misoprostol may be helpful in achieving an efficient and safe delivery.

KEYWORDS

INTRODUCTION

The induction of labor (IOL), involves stimulating uterine contractions before spontaneous labor begins. IOL often begins with cervical ripening using prostaglandins to soften and widen the cervix. This method has gained popularity over the last two decades, now accounting for about 27% of births.

"Augmentation" refers to enhancing spontaneous but inadequate contractions. IOL is considered when continuing the pregnancy poses risks or is requested by the pregnant woman. Both pharmacological methods (e.g., prostaglandins like misoprostol, oxytocin) and mechanical methods (e.g., Foley bulb) can be used alone or in combination for induction.

There is increasing use of IOL globally, including the use of misoprostol, a synthetic prostaglandin E1 analogue known for its affordability and versatility, despite being unlicensed for IOL. Misoprostol can be administered orally, vaginally, or buccally. Mechanical methods like the Foley bulb work by mechanical pressure and enhanced prostaglandin synthesis, offering benefits like reversibility and fewer side effects.

The study discussed investigates the combined use of the Foley bulb and misoprostol, versus misoprostol which may enhance cervical ripening and shorten delivery time. Although the ideal method for induction remains uncertain, combining mechanical and pharmacological techniques shows potential for improved outcomes.

Aim and Objectives Of the Study

- To compare the cervical ripening in combination of vaginal misoprostol and foley's bulb v/s vaginal misoprostol alone.
- To compare induction to delivery interval in combination of vaginal misoprostol and foley's bulb v/s vaginal misoprostol alone.

METHODOLOGY

This is a Randomized control study comparing foley's bulb along with vaginal misoprostol and vaginal misoprostol alone in cervical ripening and induction of labour in patients attending the outpatient clinic in the department of Obstetrics and Gynaecology, ASRAM medical college, in the period of Aug 2022- Aug 2024 were enrolled in this study.

Statistical Analysis

Collected data entered in Microsoft excel 2019 and analyzed using epi info software. Criteria for statistical significance was P value less than 0.05. The study followed a detailed protocol to evaluate the effectiveness of labor induction using misoprostol alone versus a combination of a Foley bulb and vaginal misoprostol.

Study Groups: Women were randomly divided into two groups: 50 in each group

Group 1: Received only vaginal misoprostol (25 micrograms every 4 hours, up to a maximum of 6 doses).

Group 2: Received vaginal misoprostol (same protocol as Group 1) and had a Foley bulb catheter inserted, filled with saline, and secured with light traction.

Inclusion Criteria

- Women with singleton viable gestation
- 1) 34 weeks gestation or greater (due to indications)
 - 2) Cephalic presentation of fetus
 - 3) Intact membranes
 - 4) Unfavorable cervix (bishop score 6 or less)
 - 5) Adequate pelvis
 - 6) Reactive fetal heart pattern
 - 7) Those who gave consent

Indications for induction :

- 1) Postdates
- 2) Preeclampsia
- 3) Chronic hypertension
- 4) Gestational hypertension
- 5) Pregestational diabetes, Gestational diabetes
- 6) Foetal demise
- 7) Antepartum bleeding

Exclusion Criteria:

- 1) Foetal malpresentation.
- 2) Multi foetal gestation.
- 3) Spontaneous labour.
- 4) Contraindications to prostaglandins.
- 5) Non reassuring fetal heart rate tracing.
- 7) Previous cesarean other uterine surgeries.
- 8) Contracted pelvis.

RESULTS

Mode of Delivery

Twelve patients in the misoprostol alone group were taken upon for lower segment cesarean section and nine patients in the combined group underwent LSCS. The mode of delivery did not have any significant effect with the cervical ripening time.

Table 1 : Mode of Delivery

MOD	Misoprostol		Foley's bulb + misoprostol	
	N	%	n	%
NVD	38	76.0	41	82.0
LSCS	12	24.0	9	18.0

Bishops Score at 12 Hour

By evaluating the cervical dilatation, length, consistency and position along with the station of fetal head the Bishop's score was calculated at 12 hours. All patients had a favourable score. The mean value of the 12th hour bishop score was higher in the combined group and was statistically significant with a P value less than .05.

Table 2 : Bishop's Score at 12 Hours

Parameter	Misoprostol			Foley's bulb + misoprostol		
	Mean	SD	Median	Mean	SD	Median
Bishop's	8.54	1.05	8	10.52	1.50	8
P value	<0.001					

Induction to Delivery Time

The time at which induction was started and the delivery time were noted for each patient in both the groups and the time interval was tabulated. An average time of 18 hours with a standard deviation of 2.5 hours were seen in the misoprostol alone group. A shorter average time period of 15 hours with a standard deviation of 2 hours was seen in the combination group which on calculation the T test revealed a significant correlation.

This data itself invariably proves that the time for cervical ripening is comparatively 3 hours less when a foleys catheter along with vaginal misoprostol was used rather than vaginal misoprostol alone

Table 3 : Induction to Delivery Time

Parameter	Misoprostol		Foley's bulb + misoprostol	
	Mean	SD	Mean	SD
Time for induction to delivery time (hrs)	18.9	2.5	15.8	2.0
P value	<0.001			

DISCUSSION

Physiology of Cervical Ripening

The cervix is primarily made of connective tissue (collagen, elastic fibers, glycosaminoglycans) with a small amount of smooth muscle (10-15%).

The extracellular matrix contains collagen types I, III, IV, proteoglycans, and glycosaminoglycans (e.g., hyaluronic acid, dermatan sulfate), which provide rigidity and strength to the cervix.

Cervical Ripening Involves

Structural changes in collagen fibrils (disorganization, solubility changes) caused by enzymes like matrix metalloproteinases (MMPs).

Dynamic remodeling of collagen rather than its degradation.

Biochemical Changes

During ripening, hydrophilic hyaluronic acid replaces chondroitin and dermatan sulfate, leading to increased water content in the cervix. This weakens collagen's structural integrity and enhances pliability for labor

Regulation of Cervical Ripening

Inflammatory mediators (e.g., prostaglandins, metalloproteinases, nitric oxide, cytokines like IL-1, IL-8, TNF- α) are crucial in initiating and maintaining cervical ripening.

Mechanical Effects

Fetal descent and cervical stretching cause connective tissue remodeling and trigger IL-8, PGE2, and collagenase release.

Induction of Labor

Artificially stimulates uterine contractions via medications or surgical methods to achieve vaginal delivery.

Augmentation

Enhances pre-existing uterine contractions to improve labor progression.

Cervix Favorability

The Bishop score quantifies cervical favorability for predicting the outcome of labor induction.

Parameters	score			
	0	1	2	3
Cervix				
• Dilatation(cm)	Closed	1-2	3-4	5+
• Cervical length(cm)	>4	2-4	1-2	<1
• Consistency	Firm	medium	soft	-
• Position	Posterior	Midline	Anterior	-
Head station	-3	-2	-1.0	+1,2

Total score (3); favorable score 6-13; unfavorable score 0-5

Methods of Cervical Ripening

Mechanical: Foley balloon catheter, membrane stripping, and dilators.

Surgical: Amniotomy.

Medical: Prostaglandins (e.g., Misoprostol and Dinoprostone), Oxytocin, and Nitric oxide donors.

Misoprostol

A prostaglandin E1 analogue commonly used for cervical ripening and labor induction.

- Advantages: Cost-effective, stable at room temperature, and fewer systemic side effects compared to alternatives.
- Dose: 25 micrograms vaginally every 4 hours, up to labor onset or favorable cervix.
- Risks: Uterine tachysystole, meconium-stained liquor, rarely, uterine rupture.

Intracervical Foley's Catheter

Mechanisms: Gradual dilation of the cervix and prostaglandin release triggered by separating the decidua from the amnion with balloon volumes (30–80 mL) Benefits: Lower cost, reduced uterine tachysystole risk.

CONCLUSION

The comparison study's findings demonstrates that using Foley's in addition to vaginal misoprostol reduces the amount of time needed from induction until birth. These findings further imply that, in the event of an immature cervix, the combination of Foley's and vaginal misoprostol may be helpful in achieving an efficient and safe delivery.

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