"COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA "

By

DR. TIRUVEEDHI N A ASRITHA CHOUDHARY

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTRE, KOLAR, KARNATAKA

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR

MASTER OF SURGERY

IN

OBSTETRICS AND GYNAECOLOGY

Under the Guidance of

Dr. MUNIKRISHNA.M

PROFESSOR,HEAD OF DEPARTMENT

DEPARTMENT OF OBSTETRICS & GYNECOLOGY

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

SRI DEVARAJ URS MEDICAL COLLEGE

TAMAKA, KOLAR-563101

ALMA MATER

SRI DEVARAJ URS MEDICAL COLLEGE

R.L. JALAPPA HOSPITAL AND RESEARCH CENTRE

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA"** is a bonafide and genuine research work carried out by me, DR TIRUVEEDHI N A ASRITHA CHOUDHARY , under the guidance of **DR. MUNIKRISHNA.M ,** Professor, Head of department, Department of Obstetrics and Gynecology at Sri Devaraj Urs Medical College, Tamaka, Kolar.

I hereby solemnly affirm that the contents of this dissertation have not been submitted earlier in a candidate for any degree elsewhere. The university is permitted to have legal rights for subsequent uses.

Date:

DR TIRUVEEDHI N A ASRITHA CHOUDHARY
POST GRADUATE STUDENT
DEPT. OF OBSTETRICS & GYNECOLOGY

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA"** is a bonafide research work done by **DR. TIRUVEEDHI N A ASRITHA CHOUDHARY** in partial fulfillment of the requirement for the degree of MASTER OF SURGERY in Obstetrics and Gynecology**.**

Date:

Place: Kolar

Dr. MUNIKRISHNA.M
Professor, head of department,
Department of
OBSTETRICS
&GYNECOLOGY
Sri Devaraj Urs Medical College,
Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

ENDORSEMENT BY THE HEAD OF THE DEPARTMENT, PRINCIPAL / HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA"** is a bonafide research work done by **DR. TIRUVEEDHI N A ASRITHA CHOUDHARY** under the guidance of **DR. MUNIKRISHNA. M ,** Professor, head of department , Department of Obstetrics and Gynecology.

I am pleased to forward this dissertation to Sri devaraj Urs Academy of higher education and research , Tamaka, Kolar, Karnataka.

R. MUNIKRISHNA.M
Professor & HOD Department of OBG
Sri Devraj Urs Medical College,
Tamaka, Kolar

DR. K. PRABHAKAR
Principal
Sri Devraj Urs Medical College,
Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

ETHICS COMMITTEE CERTIFICATE

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH

SRI DEVARAJ URS MEDICAL COLLEGE

Tamaka, Kolar

INSTITUTIONAL ETHICS COMMITTEE

Members

1. Dr. D.E.Gangadhar Rao, (Chairman) Prof. & HOD of Zoology, Govt. Women's College, Kolar.
2. Dr. Sujatha.M.P, (Member Secretary), Prof. Department of Anesthesia, SDUMC
3. Mr. Gopinath Paper Reporter, Samyukth Karnataka
4. Mr. G. K. Varada Reddy Advocate, Kolar
5. Dr. Hariprasad S. Prof. Dept. of Orthopedics. SDUMC
6. Dr. Abhinandana R Asst. Prof. Dept. of Forensic Medicine, SDUMC
7. Dr. Ruth Sneha Chandrakumar Assoc. Prof. Dept. of Psychiatry, SDUMC
8. Dr. Usha G Shenoy, Asst. Prof., Dept. of Allied Health & Basic Sciences SDUAHER
9. Dr. Munilakshmi U Asst. Prof. Dept. of Biochemistry, SDUMC
10. Dr.D.Srinivasan, Assoc. Prof. Dept. of Surgery, SDUMC
11. Dr.Shilpa M D Assoc. Prof. Dept. of Pathology, SDUMC

No. DMC/KLR/IEC/75/ 2023-24 Date: 10/04/2023

PRIOR PERMISSION TO START OF STUDY

The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the synopsis entitled **"Comparision Of Intracervical Double Foleys Catheter Vs Intravaginal Misoprostol Alone For Induction Of Labour In Multigravida"** being investigated by **Dr.Tiruveedhi N A Asrithachoudhary & Dr.Munikrishna.M** in the Department of OBG at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

Member Secretary

Member Secretary
Institutional Ethics Committee
Sri Devaraj Urs Medical College
Tamaka, Kolar

Chairman

CHAIRMAN
Institutional Ethics Committe
Sri Devaraj Urs Medical College
Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, TAMAKA, KOLAR, KARNATAKA.

COPY RIGHT

DECLARATION BY THE CANDIDATE

I hereby declare that the Sri Devaraj Urs Academy of Higher Education and Research, Kolar, Karnataka, shall have the right to preserve, use and disseminate this dissertation/thesis in print or electronic format for academic /research purposes.

Sigaature of candidate:

Date: **Dr. TIRUVEEDHI N A ASRITHA CHOUDHARY**

Place: Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH
TAMAKA, KOLAR, KARNATAKA, INDIA 563103

CERTIFICATE OF PLAGIARISM CHECK

Title of the Thesis/Dissertation	**COMPARISON OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA**
Name of the Student	**Dr. TIRUVEEDHI N A ASRITHA CHOUDHARY**
Registration Number	22OG1072
Name of the Supervisor / Guide	Dr. MUNIKRISHNA .M
Department	OBSTETRICS AND GYNECOLOGY
Acceptable Maximum Limit (%) of Similarity (PG Dissertation /Ph.D. Thesis)	10 %
Similarity	03%
Software used	TURNITIN
Paper ID	2680534313
ORCID ID	0009-0009-9739-7293
Submission Date	20/05/2025

T. Asritha Choudhary

Signature of Student

Signature of Guide/Supervisor

Professor & HoD
Obstetric and Gynaecology
Sri Devaraj Urs Medical College
Tamaka, Kolar.

HOD Signature

Professor & HoD
Obstetric and Gynaecology
Sri Devaraj Urs Medical College
Tamaka, Kolar.

21/5/25

University Librarian
University Library
Learning Resource Centre
SDUAHER, Tamaka
KOLAR-563103

PG Coordinator

PG Coordinator
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103

PLAGIARISM CERTIFICATE

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH
TAMAKA, KOLAR, KARNATAKA, INDIA 563103

CERTIFICATE OF PLAGIARISM CHECK

Title of the Thesis/Dissertation	**COMPARISON OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA**
Name of the Student	**Dr. TIRUVEEDHI N A ASRITHA CHOUDHARY**
Registration Number	22OG1072
Name of the Supervisor / Guide	Dr. MUNIKRISHNA .M
Department	OBSTETRICS AND GYNECOLOGY
Acceptable Maximum Limit (%) of Similarity (PG Dissertation /Ph.D. Thesis)	10 %
Similarity	03%
Software used	TURNITIN
Paper ID	2680534313
ORCID ID	0009-0009-9739-7293
Submission Date	20/05/2025

Signature of Student

Signature of Guide/Supervisor

Professor & HoD
Obstetric and Gynaecology
Sri Devaraj Urs Medical College
Tamaka, Kolar.

HOD Signature

Professor & HoD
Obstetric and Gynaecology
Sri Devaraj Urs Medical College
Tamaka, Kolar.

University Librarian
University Library
Learning Resource Centre
SDUAHER, Tamaka
KOLAR-563103

PG Coordinator

PG Coordinator
Sri Devaraj Urs Medical College
Tamaka, Kolar-563103

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	Dr. Tiruveedhi N A Asritha Choudhary
Assignment title:	PG Dissertation - 2025
Submission title:	COMPARISON OF INTRACERVICAL DOUBLE FOLEYS CATHETER ...
File name:	OPROSTOL_ALONE_FOR_INDUCTION_OF_LABOUR_IN_MULTIG...
File size:	1.01M
Page count:	123
Word count:	18,868
Character count:	106,329
Submission date:	20-May-2025 04:04PM (UTC+0530)
Submission ID:	2680534313

Document Viewer

Turnitin Originality Report

Processed on: 20-May-2025 16:05 IST
ID: 2680534213
Word Count: 18868
Submitted: 1

COMPARISON OF INTRACERVICAL DOUBLE FOLEYS CAT... By Dr. Tiruveedhi N A Asritha Choudhary

Similarity Index	Similarity by Source	
3%	Internet Sources:	2%
	Publications:	2%
	Student Papers:	0%

include quoted | include bibliography | excluding matches < 14 words | mode:
quickview (classic) report | print | refresh | download

1% match (Internet from 19-Nov-2024)
https://lucris.lub.lu.se/ws/portalfiles/portal/199536947/Avhandling_Mahdi_Amini_LUCRIS.pdf

<1% match (Internet from 09-Apr-2023)
https://www.jbumdc.bahria.edu.pk/index.php/ojs/issue/download/44/62

<1% match ("2017 ACR/ARHP Annual Meeting Abstract Supplement", Arthritis & Rheumatology, 2017)
"2017 ACR/ARHP Annual Meeting Abstract Supplement", Arthritis & Rheumatology, 2017

<1% match (Internet from 20-Mar-2025)
http://thejas.com.pk

<1% match (Montacer Hafsi, Eya Kristou, Fathi Mraihi, Dalenda Chelli, "Tunisian Pregnant Women Benefiting from Cervical Ripening in the Third Trimester", IntechOpen, 2025)
Montacer Hafsi, Eya Kristou, Fathi Mraihi, Dalenda Chelli, "Tunisian Pregnant Women Benefiting from Cervical Ripening in the Third Trimester", IntechOpen, 2025

<1% match (Kumari, Anshu. "Comparative Study of Pharmacological and Combined Pharmaco-Mechanical Method of Induction of Labour - A Randomised Study", Rajiv Gandhi University of Health Sciences (India), 2023)
Kumari, Anshu. "Comparative Study of Pharmacological and Combined Pharmaco-Mechanical Method of Induction of Labour - A Randomised Study", Rajiv Gandhi University of Health Sciences (India), 2023

<1% match (Internet from 12-Nov-2024)
https://indianfertilitysociety.org/wp-content/uploads/2024/07/POR-guidance-print-version-2july24.pdf

<1% match (Internet from 30-May-2023)
https://inajog.com/index.php/journal/article/download/1662/

Professor & HOD
Obstetric and Gynaecology
Sri Devaraj Urs Medical College
Tamaka, Kolar.

University Library
Learning Resource Centre
SDUAHER, Tamaka
KOLAR-563103

<1% match (Internet from 21-Feb-2024)
http://ijo.rjournals.org

<1% match (Internet from 24-Jul-2015)
http://nursing.cu.edu.eg

<1% match ()
Neeraj, Kulkarni, "Misoprostol with Foleys Versus Misoprostol Alone For Induction of Labour in Term Primigravidas: A Prospective Randomized Controlled Trial", 2017

<1% match (Internet from 01-Oct-2023)
https://www.science.gov/topicpages/h/hospital+workers+exposed.html

<1% match (Kehl, S, J Ziegler, E Schleussner, B Tuschy, S Berlit, J Kirscht, F Hägele, C Weiss, J Siemer, and M Sütterlin. "Sequential use of double-balloon catheter and oral misoprostol versus oral misoprostol alone for induction of labour at term (CRBplus trial): a multicentre, open-label randomised controlled trial", BJOG An International Journal of Obstetrics & Gynaecology, 2014.)
Kehl, S, J Ziegler, E Schleussner, B Tuschy, S Berlit, J Kirscht, F Hägele, C Weiss, J Siemer, and M Sütterlin. "Sequential use of double-balloon catheter and oral misoprostol versus oral misoprostol alone for induction of labour at term (CRBplus trial): a multicentre, open-label randomised controlled trial", BJOG An International Journal of Obstetrics & Gynaecology, 2014.

<1% match (Internet from 03-Dec-2021)
https://synapse.koreamed.org/articles/1144690

<1% match (Internet from 01-Nov-2023)
https://www.easpublisher.com/get-articles/3720

<1% match (Internet from 13-Feb-2024)
https://www.jogcr.com/article_710186_d3246f5be5acd424b7fbd033726fa5aa.pdf

COMPARISON OF INTRACERVICAL DOUBLE FOLEYS CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA ABSTRACT Background and Objectives Approximately 20-25% of pregnancies globally require IOL for various maternal and foetal causes, making it a substantial obstetric intervention. Optimal procedures for multigravida women are not yet well-defined, despite the fact that mechanical and pharmacological methods of induction are well-established. In order to induce labour in multigravida women, this study compared the two methods of using an intracervical DFC with an IVM and looked at the effects on both the mother and the baby. Methodology This study took place at the RL Jalappa Hospital and Research Centre in Kolar, India, over the course of 18 months. Thirteen women who were multigravida (two or three pregnancies) and had full-term pregnancies (37 to 42 weeks) and needed to start labour were part of the study. In Group A, 65 women were given IVM, and in Group B, 65 women were given a DFC. It was chance how the two groups were put together. The study was limited to women who had reactive NST, intact membranes, a singleton pregnancy, and a cephalic appearance. It was important that the new MBS was less than or equal to 5. In the first group, two interconnected Foleys tubes were put in. The proximal balloon was used to fill the internal os with 80 ml of saline, and the distal balloon was used to fill the vagina. A misoprostol boost was started if the MBS stayed below 6, and oxytocin boost was used if it was greater than or equal to 6. The women in Group B were given 25 µg of misoprostol intravenously every four hours until the cervix was deemed good (MBS ≥6), labour started, or the maximum dose of 100 µg (4 doses) was reached. If needed, oxytocin would then be given to help with labour. The major outcomes that were looked at were the mode of delivery, the time from induction to the active phase, and the outcomes for both the mother and the

ACKNOWLEDGEMENT

First and foremost, I thank God for giving me his endless blessings and giving me the strength both mentally and physically during my post-graduation and to make this dissertation book possible.

I would like to acknowledge all those who have supported me, not only to complete my dissertation but helped throughout my post-graduation course.

I wish to express my heart full indebtedness and owe a deep sense of gratitude to my mentor and guide, **Dr. MUNIKRISHNA.M** Professor, head of department, Department of Obstetrics and Gynecology for being very helpful throughout the study and offered his utmost patience, invaluable guidance and unwavering support , constant encouragement to fully understand and complete this study and also with respect to every aspect of my professional life. Through his vast professional knowledge and expertise, he ensured that I understand everything before I apply the information in my study. Without his constant supervision and advice, the completion of this dissertation would have been impossible. As head of department for providing necessary infrastructure, academic guidance and for facilitating a conductive research environment.

I am sincerely thankful to **Dr. VIMARSHITHA**, Associate Professor Department of Obstetrics and Gynecology, for encouraging me to the highest peak, paying close and continuous attention towards me to finish all tasks, and also providing her kind support, valuable suggestions, immense patience, and great care. Her precious advice on both the dissertation work as well as the path of my career has been priceless.

I wholeheartedly acknowledge **Dr.SHEELA.S.R**, Professor in the Department of Obstetrics and Gynecology, for their valuable teachings of perseverance, professional ethics, moral support, and commitment. Their precious advice on both the dissertation as well as on my career was invaluable.

I sincerely thank all the assistant professors **Dr. K A V Y A R A N I , DR,DIVYA J PATIL, DR AASHRITHA,DR NANDINI, DR ACHALA, DR BHAVYA, DR YAMINI** in the Department of OBG, SDUMC, Kolar, for their constant guidance and encouragement.

I express my sincere thanks to my fellow post graduates **DR.SUSHMITHA, DR.AKSHAYA,DR.YASASWINI, DR SWEETHA, DR.LAKSHMI PRIYA, DR.BHAVANA, DR. RAVALI,** and DR.SWETHAMRUTHA for their unflinching

Support, for staying with me and bearing with me through all the deadlines. And heartfelt thanks to my beloved Juniors for their co-operation and help in carrying out this study.

I thank all the staff nurses who are our pillars of support. Special thanks to all labour room staff for their help and support throughout my study.

I express my profound gratitude to my beloved parents **Mr.V VARA PRASAD TIRUVEEDHI, Mrs. SOUJANYA** and my brother **SUDARSAN SREERAM** for always inspiring me, for giving me continuous encouragement, unfailing support, and unconditional love throughout my life.

I thank my grandparents **Mr.SAJJA RAJAGOPALA RAO, Mrs. SAJJA SEETHA KUMARI**, for their constant moral support and for giving their time whenever I have needed it most.

I thank the lovely supportive stars of the family, **Mr. SAJJA CHAITHANYA Mr. ROHITHA SAJJA** for constantly entertaining me and keeping up the good spirit.

I would like to thank lovely support **Mr. BOLLA KAMAL CHAITANYA** for staying with me in times of need and giving me continuous motivation in finishing my study on time and keeping up to good spirit.

Last but not least, I extend my gratitude towards all the patients who agreed to participate in this study; without their precious support, it would not be possible to conduct this research.

DR TIRUVEEDHI N A ASRITHA CHOUDHARY

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
IOL	INDUCTION OF LABOUR
CR	CERVICAL RIPENING
DFC	DOUBLE FOLEYS CATHETER
FHR	FETAL HEART RATE
MMPS	MATRIX METALLOPROTEINASES
PGE2	PROSTAGLANDIN E2
PGE1	PROSTAGLANDIN E1
NICU	NEONATAL INTENSIVE CARE UNIT
LMP	LAST MENSTURAL PERIOD
NST	NON STRESS TEST
PPH	POST PARTUM HAEMORRHAGE
GA	GESTATIONAL AGE
RCT	RANDOMIZED CONTROL TRIAL
IVM	INTRAVAGINAL MISOPROSTOL
FI	FAILED INDUCTION
MSL	MECONIUM STAINED LIQUOR
CS	CAESAREAN SECTION
MBS	MODIFIED BISHOP SCORE

ABSTRACT

Background and Objectives

Approximately 20-25% of pregnancies globally require IOL for various maternal and foetal causes, making it a substantial obstetric intervention. Optimal procedures for multigravida women are not yet well-defined, despite the fact that mechanical and pharmacological methods of induction are well-established. In order to induce labour in multigravida women, this study compared the two methods of using an intracervical DFC with an IVM and looked at the effects on both the mother and the baby.

Methodology

This study took place at the RL Jalappa Hospital and Research Centre in Kolar, India, over the course of 18 months. Thirteen women who were multigravida (two or three pregnancies) and had full-term pregnancies (37 to 42 weeks) and needed to start labour were part of the study. In Group A, 65 women were given IVM, and in Group B, 65 women were given a DFC. It was chance how the two groups were put together. The study was limited to women who had reactive NST, intact membranes, a singleton pregnancy, and a cephalic appearance. It was important that the new MBS was less than or equal to 5. In the first group, two interconnected Foleys tubes were put in. The proximal balloon was used to fill the internal os with 80 ml of saline, and the distal balloon was used to fill the vagina. A misoprostol boost was started if the MBS stayed below 6, and oxytocin boost was used if it was greater than or equal to 6. The women in Group B were given 25 μg of misoprostol intravenously every four hours until the cervix was deemed good (MBS ≥6), labour started, or the maximum dose of 100 μg (4 doses) was reached. If needed, oxytocin would then be given to help with labour. The major outcomes that were looked at were the mode of delivery, the time from induction to the active phase, and the outcomes for both the mother and the baby.

Results

Age, GA, and pre-induction MBSs were all spread out similarly across the study's groups at the start. With 39 women (60.0%) reaching active labour within 6 hours in Group A, the induction-to-active phase intervals were noticeably shorter than those in Group B, where only 17 women (26.2%) managed the same feat. Group A also had better total induction-to-delivery intervals; 51 out of 102 women in Group A (78.5%) gave birth within 12 hours, while only 46 out of 102 women in Group B (70.8%) did so. A total of 42 women (64.6%) in the DFC group did not need any misoprostol, indicating a significant reduction in the need for this medication.

The two groups' oxytocin augmentation needs were similar: forty women (61.5% of the total) vs. forty women (64.6% of the total). Group A had a somewhat lower rate of CS (5 women [7.7%] vs. 7 women [10.8%]), but both groups had comparable rates of vaginal deliveries (58 women [89.2%] vs. 57 women [87.7%]). It is worth mentioning that the reasons for CS varied. Only three women in Group B (representing 42.9% of CS) experienced a FI. Group A had a tendency toward better APGAR scores in neonatal outcomes (55 newborns, or 84.6%, had ideal scores compared to 51 neonates, or 78.5%, in Group B). The most remarkable discovery was that there was a markedly decreased occurrence of amniotic fluid stained with meconium in Group A (9 women, or 13.8%) when compared to Group B (23 women, or 35.4%), with equivalent variations in the causes of NICU admission.

Conclusion

The results show that compared to IVM alone, the intracervical DFC is the best approach for inducing labour in women who have given birth more than one baby. The advantages of the mechanical approach included lower rates of meconium-stained amniotic fluid, more efficient induction, more reliable labour commencement, and fewer CS due to unsuccessful induction. Particularly for multigravida patients, where the optimization of IOL methods for fast cervical ripening, dependable labour onset, and minimizing of foetal problems is stressed, these results have significant clinical implications for obstetric practice.

Keywords

Labour Induction; Multigravida; Foleys Catheter; Misoprostol; Cervical Ripening; Meconium-Stained Amniotic Fluid; Caesarean Section Rate

KEY TO MASTER SHEET

SI.NO.	PARAMETER	CODING
A.	**S.NO**	
B.	**STUDY GROUP:**	
	FOLEYS	1
	CATHETER	2
	MISOPROSTOL	
C.	**MATERNAL AGE**	
	19-20	1
	21-25	2
	26-30	3
	31-35	4
E.	**Parity**	
		1
	MULTIGRAVIDA	
D.	**Gestational age**	
	37w- 38+6 days	1
	39 w -39+6 days	2
	40 w – 40 + 6 days	3
	41 w – 41+6 days	4

F.	**Pre induction modified bishop's score:** 2 3 4 5	 1 2 3 4
G.	**GROUP A : FURTHER MISOPROSTOL REQUIRED** NOT REQURIED 1 2 3 4	 1 2 3 4 5
H.	**GROUP B : NUMBER OF DOSES** 1 2 3 4	 1 2 3 4

I.	**INDUCTION TO ACTIVE STAGE INTERVAL** 1 TO 6 HOURS 7 TO 12 HOURS > 12 HOURS	 1 2 3
J.	**INDUCTION TO DELIVERY INTERVAL** <12 HOURS	 1
	13 TO 24 HOURS 25 TO 36 HOURS	2 3
K.	**MODE OF DELIVERY :** VAGINAL DELIVERY ASSISTED VAGINAL DELIVERY CEASAREAN SECTION	 1 2 3
L.	**INDICATION FOR C- SECTION** NOT SIGNIFICANT FETAL DISTRESS FAILED INDUCTION NON-PROGRESSION OF LABOUR	 0 1 2 3

M.	**OXYTOCIN AUGMENTATION REQUIREMENT:**	
	NOT REQUIRED	1
	REQUIRED	2
N.	**LIQUOR**	
	CLEAR	1
	MECONIUM-STAINED LIQUOR	2
	APGAR AT 1 MINUTE	
	>/=7	1
	<7	2
P.	**APGAR AT 5 MINUTE**	
	>/=9	1
	<9	2
Q.	**NICU ADMISSION**	
	YES	1
	NO	2

MASTER SHEET – GROUP A

SI.NO A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	1	1	1	1	1	1	-	1	1	1	0	1	1	1	1	2
2	1	2	2	1	2	1	-	1	1	1	0	1	1	1	1	2
3	1	1	1	1	2	1	-	1	1	1	0	1	1	1	1	2
4	1	3	2	1	1	1	-	1	1	1	0	1	1	1	1	2
5	1	2	2	1	2	1	-	1	1	1	0	1	1	1	1	2
6	1	3	1	1	2	2	-	2	1	1	0	1	1	1	1	2
7	1	1	2	1	1	1		2	2	1	0	1	1	1	1	2
8	1	2	2	1	3	1	-	2	1	2	0	1	1	1	1	2
9	1	4	1	1	1	1	-	2	1	1	0	1	1	1	1	2
10	1	1	3	1	3	1	-	1	2	1	0	1	1	1	1	2
11	1	2	3	1	3	1	-	1	1	1	0	1	1	1	1	2
12	1	2	1	1	1	1	-	1	1	1	0	1	1	1	1	2
13	1	1	3	1	2	1	–	1	1	1	0	1	1	1	1	2
14	1	2	3	1	4	2	-	2	1	1	0	1	1	1	1	2
15	1	4	1	1	2	1	-	1	1	1	0	1	1	1	1	2
16	1	3	2	1	4	1	-	1	1	1	0	1	1	1	1	2
17	1	1	2	1	2	1	-	1	1	1	0	1	1	1	1	2
18	1	2	1	1	1	1	-	2	1	1	1	2	1	1	1	2
19	1	2	2	1	2	1	-	2	1	1	0	2	1	1	1	2
20	1	4	1	1	3	1	-	1	2	1	0	2	1	1	1	2
21	1	3	2	1	2	1	–	1	1	1	0	2	2	1	1	2
22	1	2	1	1	2	1	-	1	1	1	0	1	1	1	1	2
23	1	3	2	1	3	1	-	1	1	1	0	1	1	1	1	2
24	1	1	2	1	2	1	-	1	1	1	0	1	1	1	1	2
25	1	2	1	1	3	1	-	1	1	1	0	1	1	1	1	2
26	1	2	2	1	2	2	-	1	1	1	0	1	1	1	1	2
27	1	2	3	1	2	2	-	1	1	1	0	1	1	1	1	2
28	1	1	1	1	3	4	-	1	1	1	0	1	1	1	1	2
29	1	2	3	1	3	5	-	2	1	1	0	1	1	1	1	2
30	1	3	1	1	4	5	-	1	1	1	0	1	1	1	1	2
31	1	2	3	1	4	2	-	2	2	1	1	1	1	1	1	2
32	1	4	1	1	2	1	-	1	1	1	0	1	1	1	1	2
33	1	1	2	1	2	1	-	1	1	2	0	1	1	2	2	1
34	1	2	2	1	3	1	-	1	1	1	0	1	1	2	2	1
35	1	2	3	1	2	1	-	1	1	1	0	1	1	2	2	1
36	1	3	2	1	2	1	-	1	1	1	0	2	1	2	2	1
37	1	1	2	1	2	1	-	1	1	1	0	2	1	2	2	2

38	1	4	2	1	3	1	-	1	1	1	0	2	1	2	2	1
39	1	2	2	1	3	1	-	1	1	1	0	2	1	1	1	2
40	1	3	2	1	1	2	-	2	1	1	0	1	1	1	1	2
41	1	2	2	1	3	2	-	2	1	1	0	1	1	1	1	2
42	1	1	3	1	3	1	-	1	1	1	0	1	2	1	1	2
43	1	3	2	1	3	1	-	2	1	1	3	1	1	1	1	2
44	1	3	3	1	2	1	-	1	1	1	0	1	1	1	1	2
45	1	1	2	1	2	1	-	3	1	1	0	2	1	1	1	2
46	1	2	3	1	2	1	-	1	1	3	0	1	1	1	1	2
47	1	2	2	1	2	1	-	3	1	1	0	2	2	1	1	2
48	1	3	2	1	3	1	-	1	1	1	0	2	2	1	1	2
49	1	2	1	1	4	1	-	1	1	1	0	1	1	2	2	1
50	1	3	2	1	1	1		3	1	1	3	1	1	2	2	1
51	1	3	2	1	4	2	-	1	2	1	0	1	1	1	1	2
52	1	3	1	1	2	2	-	1	2	1	0	1	1	1	1	2
53	1	2	2	1	3	1	-	1	2	1	0	1	2	1	1	2
54	1	3	2	1	3	1	-	1	1	1	0	2	2	1	1	2
55	1	3	1	1	3	2	-	3	1	3	0	2	1	1	1	2
56	1	2	2	1	3	5	-	3	1	1	0	2	1	1	1	2
57	1	2	3	1	3	2	-	3	1	1	0	2	1	1	1	2
58	1	2	3	1	4	3	-	3	1	1	0	2	1	1	1	2
59	1	2	3	1	4	4	-	3	2	1	0	2	1	2	2	1
60	1	3	3	1	3	2	-	3	2	1	0	2	1	1	1	2
61	1	3	3	1	3	5	-	3	3	1	0	2	2	1	1	2
62	1	1	1	1	3	5	-	3	3	1	0	2	2	1	1	2
63	1	2	3	1	3	2	--	3	3	3	0	2	2	1	1	2
64	1	3	1	1	3	3	-	3	2	3	1	2	2	1	1	2
65	1	2	1	1	3	3	-	3	3	3	0	2	2	2	2	1

MASTER SHEET – GROUP B

SI.NO A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	2	1	1	1	2	-	1	1	1	1	1	1	1	1	1	2
2	2	1	1	1	1	-	1	1	1	1	1	1	1	1	1	2
3	2	1	1	1	2	-	2	1	1	1	1	2	1	1	1	2
4	2	2	1	1	1	-	2	1	1	1	1	1	1	2	2	1
5	2	3	2	1	3	-	2	1	1	1	1	1	1	1	1	2
6	2	2	2	1	3	-	2	1	1	1	1	1	1	2	2	1
7	2	3	1	1	4	-	1	2	1	1	1	1	1	1	1	2
8	2	1	1	1	4	-	1	1	1	1	1	1	1	2	2	1
9	2	1	1	1	4	-	3	1	1	2	1	1	1	1	1	2
10	2	2	2	1	2	-	1	1	1	1	1	1	1	1	1	2
11	2	3	3	1	2	-	1	1	1	1	2	1	1	1	1	2
12	2	3	1	1	3	-	3	2	1	1	1	1	1	1	1	2
13	2	1	1	1	3	-	2	3	1	1	1	1	2	2	2	1
14	2	4	1	1	4	-	2	3	3	1	1	1	2	2	2	1
15	2	4	3	1	1	-	3	3	1	1	1	1	2	1	1	2
16	2	4	1	1	3	-	3	3	3	3	1	1	2	1	1	2
17	2	1	2	1	3	-	4	2	1	1	3	2	1	1	1	2
18	2	3	1	1	4	-	4	2	1	1	1	2	1	1	1	2
19	2	3	2	1	3	-	1	1	2	1	1	1	1	1	1	2
20	2	1	1	1	3	-	1	1	2	1	1	1	2	2	2	1
21	2	4	2	1	1	-	1	3	1	1	1	1	1	1	1	2
22	2	1	1	1	4	-	1	1	2	1	2	1	1	1	1	2
23	2	3	2	1	2	-	1	2	1	1	2	1	2	1	1	2
24	2	3	2	1	2	-	1	1	2	3	1	1	1	1	1	2
25	2	3	1	1	4	-	1	2	1	1	1	1	1	1	1	2
26	2	1	2	1	1	-	1	2	2	1	1	1	1	2	2	1
27	2	4	2	1	3	-	1	3	1	1	1	1	1	1	1	2
28	2	2	1	1	3	-	3	3	2	1	1	1	1	1	1	2
29	2	4	3	1	1	-	2	2	2	1	3	2	1	1	1	2
30	2	2	1	1	3	-	2	3	1	1	1	2	1	1	1	2
31	2	4	3	1	2	-	3	2	1	3	1	2	1	2	2	1
32	2	2	2	1	2	-	3	3	1	1	1	2	1	1	1	2
33	2	3	3	1	3	-	2	2	2	1	1	2	1	1	1	2
34	2	2	2	1	2	-	2	3	1	1	1	2	2	1	1	2
35	2	2	3	1	3	-	2	2	1	1	1	2	1	1	1	2
36	2	3	3	1	3	-	3	3	1	1	1	2	2	2	2	1
37	2	2	3	1	2	-	3	2	1	3	1	2	1	1	1	2
38	2	3	1	1	2	-	1	2	1	3	1	2	1	1	1	2
39	2	3	1	1	2	-	1	2	1	1	1	2	1	1	1	2
40	2	2	2	1	1	-	3	1	1	3	1	2	2	1	1	2

41	2	3	1	1	3	-	1	1	1	1	2	2	2	1	1	2
42	2	2	2	1	1	-	3	3	1	1	1	2	2	2	2	1
43	2	4	2	1	3	-	2	1	1	3	1	2	1	1	1	2
44	2	2	1	1	2	-	3	3	2	1	1	2	1	1	1	2
45	2	3	3	1	3	-	2	2	2	1	1	2	2	1	1	2
46	2	2	1	1	3	-	3	2	2	1	1	2	2	2	2	2
47	2	2	2	1	2	-	2	3	1	1	1	2	1	1	1	2
48	2	2	3	1	2	-	2	3	1	1	1	2	1	1	1	2
49	2	3	3	1	2	-	2	2	3	1	3	2	1	1	1	22
50	2	4	3	1	3	-	4	2	1	1	1	2	2	1	1	2
51	2	4	2	1	3	-	3	2	1	1	1	2	2	2	2	2
52	2	2	2	1	3	-	3	3	1	1	1	2	2	1	1	2
53	2	2	2	1	2	-	3	2	1	1	1	2	1	1	1	2
54	2	3	3	1	2	-	3	2	1	1	1	2	1	1	1	2
55	2	2	3	1	2	-	3	3	2	1	1	2	1	2	2	2
56	2	2	2	1	3	-	2	3	1	1	1	2	1	1	1	2
57	2	2	2	1	3	-	3	2	1	1	1	2	1	1	1	2
58	2	2	2	1	2	-	2	2	1	1	1	2	1	2	2	2
59	2	2	3	1	2	-	4	2	1	1	1	2	2	1	1	2
60	2	3	3	1	2	-	2	2	1	1	1	2	2	1	1	2
61	2	2	2	1	2	-	3	2	1	1	1	2	2	1	1	2
62	2	3	2	1	4	-	4	3	2	1	1	2	2	1	1	2
63	2	2	2	1	3	-	2	2	3	1	1	2	2	1	1	2
64	2	3	2	1	3	-	2	2	3	1	1	2	2	1	1	2
65	2	2	2	1	3	-	2	2	3	1	1	2	2	1	1	2

INTRODUCTION

When the mother's and the baby's safety are at risk during a natural delivery, or when the likelihood of labour beginning on its own is low, IOL becomes an essential tool in the obstetric toolbox. Medical practitioners have explored many mechanical and pharmacological techniques to improve mother and newborn outcomes throughout the process of CR and labour onset[1–3] Effective IOL needs careful evaluation of patient-specific characteristics and potential intervention risks; thus, doctors have traditionally relied on numerous techniques to prepare the cervix for birth.. [4–6]

As an alternative to pharmaceutical interventions, mechanical approaches, especially intracervical Foley catheter techniques, have become more prevalent. By using controlled artificial dilatation to start cervical changes, these methods make it safer to start labour. [7–9] Contrary to this, misoprostol and other drugs have recently been criticized for speeding up the opening of the cervix and the start of labour. [10–12] Comparing how well these methods work has become an important area of study for experts who want to find the best techniques for different groups of patients. [13–15]

Multigravida women are different when it comes to the therapeutic setting of methods used to start labour. These women may react differently to CR treatments than primigravida because of their history of giving birth. [16–18] Individual diversity in cervical response and labour development need complex treatments that take into account physiological variables and prior reproductive experience. [19–21] The significance of tailored intervention approaches that prioritize maternal and foetal health while also being safe and successful has recently come to light in the scientific literature. [22–24]

Beyond simple mechanical or drug-based methods, there are many complicated ways to IOL. To help with CR and getting IOL, recent literature has shown that combination treatments, which use more than one method. The purpose is to make IOL more controllable and reliable among pregnant mothers. The researchers made up for the flaws of individual approaches among these mothers.[25–27] In this method, several determinants need to be considered, including GA, cervical viability, health status of antenatal mothers, as well as any risks that might come with different types of surgical procedure.

It is important to look at the results of IOL treatments from the point of view of both the mother and the baby. It is very important to keep problems to a minimum during delivery, but the delivery itself needs to happen right away. A well-known method is the intracervical Foley device. The IVM also works in a similar way but has its own perks. How well these methods work compared to each other in women who have had more than one pregnancy is an important area of ongoing medical research that has implications for clinical practice and patient care procedures.

This study adds to our knowledge by comparing the intracervical DFC with the IVM for IOL in multigravida women. The goal of this study is to provide evidence-based information to make decisions and improve maternity intervention methods by thoroughly looking at how well CR works, how labour progresses, and look for the outcomes in both the mother and the baby.

OBJECTIVES

1. To assess the effectiveness of intracervical DFC and IVM for IOL in multigravida.
2. To compare the maternal and foetal outcome between these groups

REVIEW OF LITERATURE

The Epidemiological Context of IOL

IOL is an important method in delivery of baby, but how often and how it is used differs from country. This in-depth study looks into the statistical background of IOL by looking at national and global levels, clinical signs, demographic differences, frequency in multigravida mothers, as well as ethical implications.

Global and Regional Trends in IOL Rates

In the last decade, the rate of IOL has been increasing globally. Several things are driving this trend, such as better medical technology along with induction methods, as well as a greater focus on the health status of mother and baby. IOL rates in high-income countries have levelled off because of their attempts to get the best results while cutting down on unnecessary measures. Lower as well as middle-income countries, are slowly but surely seeing their induction rates rise. This is because more people can get health care as well as rules are being followed more consistently in those countries.[28]

Regional differences are caused by differences in healthcare systems, cultural differences, as well as financial status. For example, the rate of IOL is lower in Southeast Asia and Africa than it is in Europe and North America. This is because people in those countries prefer to have babies normally unless they have to for medical reasons. These differences show how important it is to have healthcare plans that are tailored to each area.[29]

Indications for IOL in Clinical Practice

Multiple clinical indicators are considered while deciding whether or not to induce labour in order to maximize maternal and foetal outcomes. Some common causes include factors such as gestational diabetes, foetal growth restriction, post-term pregnancy, and preeclampsia. It is crucial to weigh the advantages of induction against any dangers in order to make sure that treatments are justified and supported by evidence, according to medical recommendations. [30]

Shared decision-making as well as patient preference are two aspects of induction that have recently come to light in research. Health care practitioners can boost patient happiness and compliance with treatment plans by including them in decision-making. [31]

Demographic Variations in IOL Methods

The methods of IOL are greatly affected by demographic considerations. Clinical decisions are influenced by important factors such as age, parity, and socioeconomic situation. Induction is more common among younger women and those from higher socioeconomic backgrounds, for example, because these groups tend to have easier access to healthcare and to desire medicalized birthing experiences. [28] Another aspect is cultural, for example, some groups value old ways of healing more than modern medicine. The development of culturally sensitive healthcare policies that honour patient autonomy while guaranteeing safety and efficacy requires a thorough understanding of these demographic variances. [31]

Prevalence of IOL in Multigravida Populations

When multigravida women (women who have had more than one pregnancy) think about starting labour, they may face some unique problems. The number of inductions is based on the patient's obstetric history and any problems that have happened during earlier pregnancies. Evidence suggests that cumulative risk factors, such as uterine scarring or prior CS, may increase the incidence of induction for multigravida women. [32] Inducing labour in women who have given birth more than one time necessitates weighing the pros and cons, with an eye toward protecting the health of the mother and the unborn child while limiting interventions that are not absolutely essential. Better results and happier patients can be achieved when multigravida patients have individualized treatment programs that take their specific needs into account.

Ethical and Clinical Considerations in Intervention Selection

Patient safety and autonomy are of the utmost importance when making ethical and therapeutic decisions about IOL procedures. Ethical standards stress the importance of patients being well-informed about the potential benefits and drawbacks of various induction techniques before giving their consent. Interventions are more likely to be effective if they take the patient's values and preferences into account. [33]

Cervical readiness, maternal health, and foetal condition are clinical criteria that determine the choice between mechanical procedures like Foley catheters and pharmaceutical treatments like misoprostol. In order to help doctors make decisions based on research that

maximize results while protecting patients' rights, the World Health Organization has put out detailed guidelines. [34]

Physiological Mechanisms of CR

The physiology of CR is very complicated and very important for a baby to be born fit. There are biological, hormonal, and physical changes that happen in the cervix that get it ready for enlargement and effacement.

Anatomical and Biochemical Changes During Cervical Preparation

During pregnancy, the cervix changes in shape and biology in important ways to get ready for giving birth. Because of changes in the make-up of connective tissues, the cervical tissue goes through changes in its structure that make it softer and more flexible. The collagen fibers that usually keep the cervix stable rearrange and shrink, which makes it less stable.[35]

The biological process of CR is marked by an increase in the activity of MMPs and other enzymes that break down collagen and other parts of the extracellular matrix. This enzyme action is very important for getting the cervical stroma ready for opening. Increasing the production of hyaluronic acid makes tissues more hydrated and soft, which also helps with the changes that need to happen in the cervical spine for labour to happen.[36]

Hormonal Influences on Cervical Maturation

Hormones play a big role in controlling how the cervix grows and develops. Oestrogen and progesterone are the main hormones that control changes in the cervix. During pregnancy, the amounts of these hormones change. Oestrogen makes the cervix more flexible and softer by encouraging the production of glycosaminoglycans and MMPs.

An increase in oestrogen activity occurs shortly after progesterone, which is typically inhibitory to uterine contractions, goes through a functional withdrawal. To get the cervix ready for labour, this hormone interaction is essential. The peptide hormone relaxin also helps the cervical mucosa to restructure and becomes more flexible as the mucosa ripens.[37]

Biomechanical Processes of Cervical Dilation

As labour advances, a biomechanical process called cervical dilatation takes place. The process entails physically opening the cervical canal and extending the muscles inside it so the foetus may pass through. The cervical tissue's viscoelastic qualities alter due to biochemical and hormonal variations, which impact this process. [38]

The biomechanical process of cervical dilation is made possible by the uterine contractions, which push on the cervix and encourage its slow opening. In order for the cervix to dilate, the cervical fibres must be sufficiently remodelled to endure the mechanical stresses of labour. [39] Effacement is a process of narrowing the cervix that helps with dilatation as labour advances. A less difficult and more effective delivery is possible only via this biomechanical change, which lowers the level of resistance inside the cervical canal.

Factors Affecting Cervical Favourability

Hormonal, metabolic, and mechanical variables are among the many that impact cervical favourability, which is often measured by the MBS. Important hormones like relaxin and oestrogen promote cervical softening and dilatation by increasing hydration and facilitating the breakdown of collagen fibres. [40]

MMPs are biochemically involved in cervix remodelling, a process that makes the cervix more malleable by degrading components of the extracellular matrix. The release of prostaglandins, which help break down collagen and make the neck area more flexible, supports this process even more.

Mechanical factors, such as movements of the uterus and pressure from the baby's head, help CR. These forces help to open up and close off the cervix by stretching and shrinking it in order to get it ready for birth. When these things work together, the cervix is ready for labour, which lowers the risk of problems during delivery.[41]

Physiological Differences Between Primigravida and Multigravida Women

Physiological differences in CR affect how to start labour in primigravida (women who are pregnant for the first time) and multigravida (women who have already had children). For primigravida mothers, making sure that their cervix ripens properly takes more time as well as care because it is often stiffer along with less flexible. This is because the collagen fibres are thicker and also the uterine environment is less experienced.[42]

When it comes to hormones as well as pressure, a cervix that has been through more than one birth is often more sensitive. Multigravida women usually have cervical tissue that is more pliable and less resistant, which means that the ripening and dilation processes go more smoothly. [43]

The need for customized methods of inducing labour is highlighted by these physiological variations. Because their cervical circumstances are more favourable during multigravida,

multigravida women may react well to gentler induction approaches, but primigravida women may benefit from therapies that increase cervical favourability, including the injection of prostaglandins or mechanical dilators.[44]

Mechanical CR Techniques

There have been great advancements in mechanical CR procedures, which allow for safe and efficient means of prepping the cervix for IOL. The process of inserting an intracervical Foley catheter, its mechanism of action, and its historical evolution is all covered in this topic.

Historical Development of Mechanical Dilation Methods

In the early 1900s, a number of devices were made that were meant to widen the cervix. These were the first mechanical CR treatments. As the first tools for mechanical dilation, metal dilators were very dangerous because they could put a lot of stress on the neck. In the end, safer and more flexible alternatives, like the DFC, took their place.

In the middle of the 20th century, the Foley catheter was created. It allowed the cervical tissue to age in a controlled and gradual way. This DFC totally changed mechanical cervical dilatation. Instead of the old methods, the Foley tube could be put into the cervical opening and saline could be slowly pumped into it to press on the cervix. With the help of this development, automatic dilation techniques became safer and the chance of damaging the cervix was greatly reduced.[45]

The DFC has been improved over the past few years by making it more efficient and more comfortable for patients. This is possible thanks to improvements in balloon design and filling methods. Because of these changes, it is now an important part of CR treatments, especially for women whose cervix is not in good shape.[46]

Intracervical Foley Catheter: Mechanism of Action

What the intracervical DFC does is manually mimic the pressure that the baby's head feels during labour. This lets CR happen. Once the tube is in the cervical canal, a set amount of saline is added to the balloon. This amount is normally between 30 and 80 mL. The continuous pressure from this swelling causes the cervical tissue to get bigger and lose its shape.

The pressure of the bubble causes biological messengers called prostaglandins to be released, which helps the weakening and remodelling of the cervical spine even more. The cervix is

prepared for IOL by an accelerated ripening process aided by both direct mechanical pressure and pharmacological stimulation.

Furthermore, the cervix is encouraged to progressively open by the presence of the catheter, which reduces resistance and makes it easier for the foetus to slip through after delivery. Mechanical CR is facilitated by the Foley catheter because of its steady and regulated pressure.

Techniques of Foley Catheter Insertion

A Foley catheter may be easily inserted for CR, and the operation can be done either in an outpatient or hospital environment. First, the cervical position and dilatation are evaluated via a sterile examination. After that, the catheter is slowly advanced down the neck canal until the balloon is placed slightly outside the internal os.

After positioning, the balloon is filled to the required pressure using a sterile saline solution. We take special care to make sure the patient is not uncomfortable, and that the inflation is equal. Taping the catheter to the patient's thigh secures it in place, and it stays there for a certain amount of time—usually 12 to 24 hours—or until the catheter is expelled on its own, which means the cervical dilation is enough. [47]

Different insertion approaches, including as digital and speculum-guided procedures, have been investigated. The use of digital insertion, which involves guiding the catheter directly with the fingers instead of a speculum, is just as successful as the latter, and it also makes the patient more comfortable. [48]

Biomechanical Principles of Mechanical Cervical Preparation

Mechanical cervical preparation is based on biomechanical concepts that allow for dilatation and effacement of the cervix with the use of controlled pressure. The Foley catheter and other mechanical devices induce physical changes in the cervical tissue that are similar to the pressures applied by the foetal head during labour by applying circumferential pressure. By increasing cervical compliance and speeding up collagen breakdown, this pressure triggers the secretion of local prostaglandins.

By rearranging collagen fibers and increasing hydration of the cervical stroma, mechanical dilatation causes structural changes that make the cervix more malleable. If we want a more efficient and painless delivery, we must undertake this biomechanical shift to lower cervical resistance.

Advantages and Limitations of Mechanical Methods

Among the many benefits of mechanical CR techniques is the fact that they do not involve the use of pharmaceuticals, which considerably lowers the likelihood of systemic adverse effects. One adaptable alternative for CR is mechanical treatments, which are often well-tolerated and may be employed in numerous therapeutic settings, including outpatient care. [49] Having said that, there are limits to these strategies. Infection may occur if aseptic procedures are not meticulously followed, and mechanical device placement might be painful. Furthermore, certain populations may need additional pharmaceutical medicines since mechanical ripening is not as successful, for example, in cases when the cervix is abnormally large. [50]

As a safe and effective substitute for pharmaceutical therapies, mechanical approaches continue to be an important part of CR procedures, despite these limitations. [51]

Comparative Efficacy of Different Mechanical Interventions

The success of mechanical CR therapies varies from one device to the next and from one clinic setting to the next. An efficient mechanical device that promotes cervical ripening and shortens the time to delivery is the Foley catheter, which is one of the most often utilized. The Foley catheter offers a fair combination of effectiveness and safety, particularly in multigravida women, according to studies comparing it to other mechanical procedures such cervical osmotic dilators. [52]Researchers have also looked at how well mechanical and pharmaceutical methods work side by side. Mechanical methods are better than drugs like misoprostol because they are easier to control and take longer to work. This way, you can avoid hyperstimulation and other side effects. Method selection is often dictated by clinical preferences and patient-specific considerations. [53]Finally, a reliable and versatile method for inducing labour is mechanical cervical ripening. Clinicians may improve mother-and child-health outcomes by customizing therapies based on patients' unique biomechanical principles, strengths, weaknesses, and comparative efficacy.

Pharmacological IOL Methods

In cases when the mother's body does not produce labour on its own or when an early birth is required for medical reasons, the use of pharmacological treatments to induce labour is an important part of pregnancy management.

Prostaglandin-Based Interventions

Because of their effects on cervix softening and uterine contraction stimulation, prostaglandins are vital in IOL. On a clinical level, the two most prevalent agents are PGE2 and misoprostol, a synthetic version of PGE1. These chemicals improve uterine contractility and CR by binding to certain receptors in the myometrium and cervix. [54] A large body of research confirms the safety and effectiveness of prostaglandins as an induction agent for labour. While intracervical or intravaginal administration is the usual method for PGE2, misoprostol has many administration options (oral, sublingual, buccal, and vaginal). By reducing the need for further procedures like oxytocin augmentation or caesarean birth, these medicines are especially helpful for women with an unfavourable cervix. [31]

Misoprostol: Pharmacological Properties

The distinctive pharmacological characteristics of the prostaglandin E1 analogue misoprostol make it an efficient induction of labour medication. Binding to prostaglandin receptors in the uterus causes a rise in calcium influx and muscular contraction, which is its mode of action. This process helps the labour process forward by causing the cervix to ripen and the uterus to contract. [55]

In areas with low resources, misoprostol is especially useful since it remains active even when left at room temperature, making it easier to administer and more accessible. Furthermore, it is widely used for IOL due to its inexpensive cost and excellent effectiveness. Possible side effects, like vaginal hyperstimulation and tachysystole, need to be closely watched while it is being used.[54]

Administration Routes and Dosage Protocols

Giving IVM for IOL can be done in a number of different ways and doses. These doses are provided to each patient's needs. It works well in controlled settings because it is quickly absorbed as well as easy to take by mouth. Most of the time, 20 to 25 µg is administered every two hours until labour starts.

When the drug is given vaginally, it comes into direct touch with the cervix, which makes the softening action and also stronger. The amount is changed based on how the patient reacts, but the standard vaginal dose is 25 µg every four to six hours among the pregnant mothers. The sublingual as well as oral routes are less common in clinical practice, but they offer a choice that blends the benefits of fast absorption with ease of administration.

To find a good balance between safety and efficiency, dose schedules need to be carefully thought out. Most of the time, smaller doses are better to avoid hyperstimulation. However, in some cases, higher doses may be needed to speed up induction. It is very important to keep checking on the baby while the mother is on misoprostol to make sure that both she and the baby are healthy.

Mechanism of CR and Uterine Stimulation

IOL works better with misoprostol, a manufactured prostaglandin E1 that helps the uterus contract, and the lining of the cervix open up. It works by attaching to cervix and myometrium prostaglandin receptors. The interaction causes the intracellular calcium levels to rise, which in turn causes the muscles to contract and the collagen to break down, resulting in a cervix that is easier to dilate. [53]

The success of misoprostol in inducing labour is due to its ability to mimic the natural start of labour by improving uterine contractility and cervical effacement. Having a short half-life and fast absorption are two of its pharmacokinetic properties that make it useful in both hospital and community settings. [56]

Comparative Efficacy of Different Pharmacological Agents

There are many drugs on the market that can start labour, and each one works in a different way. Studies have shown that the most often used drugs, PGE2 and misoprostol, are equally efficient in increasing CR and beginning labour. Nonetheless, misoprostol often provides more leeway in terms of administration methods and dose regimens, allowing for better customization to meet patient demands. [57]

Although both PGE2 and misoprostol work, research show that misoprostol has the potential to be better in certain situations owing to its affordability and room temperature stability. The fact that misoprostol may be taken orally, vaginally, sublingually, or buccally makes it quite versatile in the clinic, meeting the needs of patients with varying preferences and different types of medical situations. [53]

Safety Considerations and Potential Maternal-Foetal Complications

The dangers associated with pharmacological induction procedures must be carefully handled, despite the fact that they are often safe. Uterine hyperstimulation, a side effect of misoprostol and other uterotonics, may, in very rare instances, induce uterine rupture or foetal

discomfort. To reduce these dangers, it is vital to administer the medication carefully and check the foetus continuously. [58]

Extreme caution is necessary when using misoprostol outside of its approved indications, especially at larger dosages. To reduce the risk of side effects, it is recommended to start with lower dosages and modify them according to the patient's reaction, as per the guidelines. In addition, in order to disclose possible adverse effects and get informed permission, thorough patient counselling is required. [59]

Excessive bleeding or infection are potential consequences for the mother, especially in cases when the amniotic sac is torn for a long time. Constant vigilance and preparedness to act in the event of problems are required for the fetus due to the possibility of issues including irregular heart rates. When making clinical judgments about pharmaceutical IOL, it is essential to properly weigh the risks and benefits.[60]

Combining Mechanical and Pharmacological Methods

A multi-pronged strategy for CR and IOL may be achieved by combining mechanical and pharmacological approaches. While pharmaceutical medicines like misoprostol trigger uterine contractions, mechanical procedures like the Foley catheter physically expand the cervix. Mechanical dilatation may provide an environment where pharmaceutical medicines can work more effectively, which is why combining both treatments makes sense. [61]

Synergistic Effects of Multi-Modal Interventions

Mechanical and pharmacological techniques of IOL may work together to increase their efficacy. Time to delivery, number of treatments needed, and mother satisfaction may all be improved with a multi-modal approach. [62]

Because the mechanical approach gets the cervix ready, the pharmaceutical method may operate better, and the induction process runs more smoothly; this is called synergy.

Potential Advantages of Integrated Approaches

There are a number of benefits to using an integrated strategy. Because it prepares the cervix and promotes contractions, it may shorten the induction-to-delivery time and decrease the frequency of CS. [63] By integrating different approaches, healthcare practitioners may better meet the unique requirements of each patient, which may lead to better results and a more positive overall experience. [64]

Clinical Protocols for Combined Interventions

The use of a Foley catheter and a modest dosage of misoprostol are common components of clinical procedures for combination treatments. In order to manually widen the cervix, the Foley catheter is inserted first, and then misoprostol is administered to induce contractions. The power of this combination to speed up the birthing process is good for both the mother and the baby. [65]

Emerging Research on Combination Strategies

More research is always being done to find better ways to blend mechanical and pharmacological methods and to figure out when to use each one. In difficult circumstances, such those involving multigravida individuals, recent research suggests that combining these approaches might improve CR and IOL. The significance of tailoring treatment plans to meet the specific requirements of each patient is highlighted by this study. [66]

It is a good idea to use both mechanical and drug-based treatments for IOL together, as this takes advantage of the best parts of both. Healthcare practitioners may improve outcomes for moms and their newborns by learning about the synergistic effects and possible benefits. These combination therapies will continue to be more successful as research and clinical procedure development continue.

Maternal Outcome Parameters

This study compares the use of intracervical DFC with that of IVM to induce labour in women, with an emphasis on those women who have given birth more than once.

Labour Progression Characteristics

An essential metric for determining the efficacy of IOL techniques is the rate of labour advancement. Because of its efficacy in stimulating uterine contractions, the prostaglandin E1 analogue IVM is often used for CR and induction. On the other hand, a foley catheter inserted into the cervical canal may help the labour process forward by manually widening the cervix. [1]

When compared to mechanical means alone, studies show that misoprostol often speeds up the labour progression since it directly stimulates uterine contractions, resulting to a more rapid cervical dilation. [67] The use of mechanical and pharmacological treatments together, including misoprostol and Foley catheters, may enhance labour progression more effectively. [14]

Induction-to-Delivery Interval

Another important metric for evaluating the efficacy of IOL techniques is the induction-to-delivery interval. Compared to mechanical techniques, the induction-to-delivery timeframe is usually shorter when using misoprostol because of its pharmacological activity. Taking misoprostol makes the uterus contract quickly, which speeds up the process of getting into active labour. [68]

Recent meta-analyses suggest that a Foley catheter may further reduce the time between induction and birth by combining the mechanical effect of dilatation of the cervix with the drug effect of misoprostol. [9] For multigravida women, whose cervixes may be in a more favourable position to begin with, this combination has shown to be an efficient means of shortening the length of labour.[69]

CS Rates

When comparing induction techniques, the rate of CS is an important outcome characteristic to consider, as a lower rate is usually better. The risk of uterine hyperstimulation with IVM use is increased, which in turn increases the possibility of a CS owing to foetal distress.[1] Instead, a mechanical approach employing a Foley catheter usually leads to a more regulated development of labour, which might lessen the likelihood of hyperstimulation and a future CS. [70]

Combining these approaches, according to the research, might provide a more well-rounded strategy, reducing the dangers that could be present with each technique alone. In one study, researchers found that using a Foley catheter with misoprostol reduced the induction-to-delivery time without increasing CS rates, compared to using misoprostol alone. [9]

Maternal Complications

One major worry with inducing labour is the possibility of problems for the mother. Uterine hyperstimulation, which raises the chance of uterine rupture and foetal discomfort, is one of the risks associated with IVM, a prostaglandin E1 analogue that is useful for CR. [9] Instead, the motorized intracervical Foley catheter is less likely to cause hyperstimulation. However, some people may find it painful because it is inserted into the cervix.[70]

Studies show that using a Foley catheter with misoprostol may lower the chance of uterine hyperstimulation compared to using misoprostol alone. This is true whether the catheter is

used alone or with misoprostol. Improved safety and efficacy in IOL are also possible outcomes of this combined strategy.[71]

Pain Management and Intervention-Related Discomfort

Because mechanical and pharmacological techniques of inducing labour may be painful, pain management is an important part of the process. One potential side effect of misoprostol is that it speeds up the start of contractions, which may make labour more painful and uncomfortable. [72]

Although the Foley catheter is less likely to induce uterine hyperstimulation, the mere presence of the catheter and its manipulation inside the cervix may nevertheless produce pain. To alleviate the pain that commonly accompanies these procedures, pain management techniques like epidural analgesia are often used. The success of IOL and the happiness of the mother depend on the availability of effective pain medication. [73]

Psychological Aspects of IOL

An important but sometimes disregarded component of maternal outcomes is the psychological effect of inducing labour on women. How a woman feels about her agency and the quality of her labour are both affected by the induction technique she chooses. The quick action of misoprostol could make labour more severe, whereas the slow cervical dilatation with the Foley catheter might be seen as more manageable. [74]

How a woman feels mentally and emotionally throughout labour affects how she gives birth and how happy she is with the outcome. Women might feel more in control and have less anxiety if they are involved in making decisions regarding their induction technique and given enough information, according to research. [61] To meet the psychological needs of women going through IOL, healthcare professionals should make it a point to talk to and help these women.

Foetal and Neonatal Outcome Assessment in IOL

IOL is a common medical treatment, so it is important to know how it affects the baby and the mother. Using IVM versus intracervical DFC for IOL in multigravida women, this section examines FHR monitoring during induction, APGAR score analysis, neonatal adaptation indicators, short-term and long-term neonatal outcomes, rates of NICU admission, and potential risks to neonates related to interventions.

FHR Monitoring During Induction

During IOL, measuring the FHR is essential for determining the foetal health. Intracervical DFC and IVM are both used to induce labour, but they have differing effects on the patterns of the FHR. The pharmacological action of misoprostol has the potential to induce uterine hyperstimulation, which in turn might create FHR patterns that are not encouraging. Therefore, in order to quickly identify any negative consequences, continuous FHR monitoring is crucial. [75]

Mechanical induction methods, such as the Foley catheter, tend to provide more regulated outcomes, which may mean fewer cases of aberrant FHR patterns. Still, these approaches must be used regularly to measure FHR to guarantee the protection of the foetus. [76]

APGAR Score Analysis

One of the most important ways to evaluate a baby's health just after delivery is using the APGAR score. It takes five things into account: look, heart rate, facial expression, level of activity, and breathing rate. There is no evidence that using a Foley catheter or misoprostol to induce labour improves APGAR scores, according to studies that compared the two. Most newborns get good APGAR scores at 5 minutes post-delivery using either approach, which is typically successful. [77]

Although there is an increased risk of uterine hyperstimulation with misoprostol, which might impact neonatal outcomes, this risk can be reduced with proper dose and monitoring. The Foley catheter's automatic method helps keep baby results stable, with few cases of low APGAR scores. [78]

Neonatal Adaptation Indicators

One of your main goals as a baby should be to help them get used to their new environment, both inside and outside the womb. Respiratory effort, thermoregulation, and general physiological stability are important measurements to take note of. Because of its fast onset of action, misoprostol may cause uterine hyperstimulation, which in turn might cause newborn adaption problems such as respiratory distress or the need for neonatal intensive care. [1]

Fewer cases of newborn adaption difficulties are seen while using the Foley catheter because of its progressive cervical dilation procedure, which lessens the probability of rapid

physiological alterations. This mechanical technique helps the newborn adjust more easily whether used alone or with misoprostol. [79]

Short-Term and Long-Term Neonatal Outcomes

The effectiveness and safety of IOL procedures are greatly affected by neonatal outcomes. Foley catheters and IVM have both been linked to different degrees of newborn complications in the short run. The pharmacological effect of misoprostol causes uterine hyperstimulation, which may potentially cause foetal discomfort and necessitates prompt intervention. [56] A more mechanical and slow induction is provided with the Foley catheter, on the other hand, which may result in more stable initial newborn outcomes. [33] While further study is needed to fully understand the implications, it seems that IOL methods do not have a substantial long-term effect on infant health. When properly overseen and controlled, these approaches are widely thought to be risk-free. [80]

NICU Admission Rates

Rates of admission to NICUs shed light on how babies adjust right after birth. Studies show that misoprostol is slightly more linked to NICU stays because it increases the risk of uterus hyperstimulation and baby pain. [81] Because it can start labour more gently, the Foley catheter is linked to a lower rate of babies being admitted to the NICU. [77] Still, when good baby tracking is in place, the rates of admission to the NICU do not vary much between the two methods, which means they are both safe to use. [82]

Potential Intervention-Related Neonatal Risks

With every technique of inducing labour, there is a worry about intervention-related hazards. While effective, misoprostol may cause uterine hyperstimulation, which, if left unchecked, can cause foetal discomfort and raise the chance of a CS. [83]

However, if not implanted and managed properly, the Foley catheter may induce pain and infection while posing less of a danger of uterine hyperstimulation. Both approaches must be carefully considered and closely monitored to ensure that the neonate is not put at danger. [84]

Risk Stratification and Patient Selection in IOL

Inducing labour is an essential element of obstetric treatment, especially for women who have given birth more than once. For the best results, it is important to weigh all of the benefits and downsides of both intracervical DFC and IVM.

Criteria for IOL

Medical, obstetric, and foetal reasons are often part of the rationale for inducing labour. When there are more hazards than advantages to carrying the pregnancy to term, induction may be considered. Foetal growth limitation, gestational hypertension, preterm membrane rupture, and post-term pregnancy are common conditions. [75] Misoprostol or a Foley tube can both be used for cervical softening, but the choice between the two may rely on the specifics of the patient. [85]

Patient-Specific Risk Assessment

To find the best way to start labour, doctors need to carefully look at the patient's risk factors. Some things that might have an effect are the mother's other health problems, scars on the uterus, and a history of caesarean birth. After having surgery on the uterus, women are often not told to take misoprostol because they have a higher chance of having their uterus burst. [86] But since it is a mechanical process, the Foley tube might work better in some situations. [87]

Influence of Maternal Characteristics

The effectiveness of inducing labour is greatly affected by maternal factors like as age, parity, and cervical condition. Induction failure and the need for a CS are more common in mothers who are older and who have adverse cervical conditions. [77] In situations when CR is necessary, the pharmacological mechanism of misoprostol may be successful, and the Foley catheter can be helpful for physically dilating the cervix. [11]

GA Considerations

The time and technique of induction are greatly affected by GA. When it is going to be more than 41 weeks before the due date, doctors may suggest induction to avoid the risks of bringing a baby to term. [88] The choice may be changed depending on the condition of the fetus and the mother's readiness, but both misoprostol and Foley tubes are used at different stages of pregnancy. [85]

Contraindications and Limitations of Interventions

There are limits and contraindications to every IOL technique. Women who have had uterus surgery or CS in the past should not use misoprostol since it increases the risk of uterine rupture. AI[69] The risk of uterine hyperstimulation and foetal discomfort is another possible limitation. [88] In situations when the cervix ripens quickly, the Foley catheter may not be as successful as other, safer options. [89]

Ultimately, while deciding between intracervical DFC and IVM to induce labour, it is important to take into account the following factors: induction criteria, patient-specific risks, maternal features, GA, and known contraindications. A individualized plan that takes these things into account may be good for both the mother and the baby.

Technological and Methodological Advances in IOL

Emerging Technologies in IOL

The goal of new IOL technology is to make the procedure safer and more effective. To lessen the likelihood of uterine hyperstimulation caused by pharmaceutical medicines like misoprostol, mechanical techniques, such as innovative balloon catheters, are being developed to provide CR that is more regulated. [90] More precise predictions of induction success are also possible because to developments in ultrasonography and elastography-based cervical evaluation, which in turn allows for more individualized treatment plans.[91]

Digital Monitoring and Predictive Modelling

With the use of real-time data provided by digital monitoring and predictive modelling, IOL is undergoing a remarkable transformation. In order to optimize healthcare treatments, researchers are creating digital twins, which are virtual representations of patients, to model and forecast the development of labour. [92] Clinicians may now anticipate possible difficulties and modify treatments based on predictive analytics that use data from electronic foetal monitoring and other digital inputs. [93]

Personalized Intervention Strategies

IOL is one area where personalized medicine is taking center stage. Induction procedures are now customized based on patient-specific criteria such maternal age, cervical condition, and prior obstetric history. [94] Healthcare practitioners are able to make real-time adjustments to strategy by using machine learning models to forecast outcomes, like as poor APGAR scores. [95] Improving maternal and newborn outcomes while decreasing the number of needless procedures is the goal of personalized therapies.

Future Research Directions

Current techniques of IOL are being studied in order to find ways to make them better, and new technologies are also being investigated. In order to develop more specific treatments, there is a rising interest in identifying the genetic and molecular variables that affect the

effectiveness of IOL. [96] To further guarantee that innovations are in line with patient-centered care, studies are required to investigate patients' perspectives and preferences. [97]

Potential Technological Innovations

The creation of wearables and smart gadgets that continually track physiological indicators and provide physicians feedback is one example of a possible technology advancement in IOL. With these gadgets, doctors might monitor the mother's health, the baby's health, and the uterus's activity in real time, potentially transforming the way labour is handled. [98] On top of that, AI and ML will be very helpful in making models that can predict problems during labour and suggest the best ways to help. [99]

Comparative Analysis of Intervention Methods in IOL

When choosing between mechanical (Foley catheter) and drug-based (IVM) techniques, it is important to think about what the patient needs and how safe and beneficial each method is.

Systematic Comparison of Mechanical vs. Pharmacological Methods

Inducing labour begins with CR and continues with uterine contractions, which may be achieved mechanically with a Foley catheter or pharmacologically with misoprostol. In contrast to pharmaceutical medications, mechanical procedures physically dilate the cervix, which may lessen the likelihood of uterine hyperstimulation. [100] There is a danger of overstimulation when using pharmacological approaches to induce contractions via hormonal pathways, but these methods may be more successful in certain clinical settings.[90]

Meta-Analytical Insights

Meta-analyses are a great way to learn more about how safe and effective different ways of inducing labour are. Both methods work, but study has shown that the Foley tube is safer for some groups because it causes less uterine hyperstimulation than misoprostol. [85] If, on the other hand, your cervix is easy to open, misoprostol may help more women go into labour in less than a day. [81]

Evidence-Based Recommendations

Individualized treatment that considers the patient's clinical history, cervical status, and preferences is emphasized in evidence-based recommendations. To find the sweet spot between safety and effectiveness, a mix of techniques may be suggested, including starting CR with the Foley catheter and then stimulating contractions with misoprostol. Clinicians and

patients must work together to make decisions, and patients should be informed about the advantages and disadvantages of each treatment option. [101]

Clinical Practice Guidelines

In order to standardize treatment and enhance results, clinical practice guidelines provide frameworks for the use of induction procedures. Due to its safety profile, the Foley catheter is often recommended by guidelines for women with an unfavorable cervix or a history of CS. [62]Misoprostol works, but it is usually only used when the cervix is in a better position or when the induction needs to happen quickly. [102]

Limitations of Existing Research

A lot of research has been done, but there are still gaps in the books. Because many studies only use small samples, the results can not be applied to a larger group of people. [103] There is no way to come to a clear conclusion because the study methods, patient groups, and result measures are all so different. Long-term studies of what happens to the baby and the woman need to be done in order to fully understand the effects of each induction method. [85]

Gaps in Current Knowledge

The area of IOL still has a lot of unanswered questions. The effects of induction techniques on mother health and long-term child development have received little scientific attention. Additional research is needed to fully understand how to include patients' preferences and experiences into therapeutic decision-making. In order to advance clinical practice, it is essential to fill these gaps via high-quality research.

Relevant articles

1. A groundbreaking investigation on the effectiveness of misoprostol for CR and IOL was carried out by Wing et al. (1995, United States). Misoprostol was investigated as a potential new pharmaceutical intervention in the field of obstetric care. Women needing IOL made up the research population, and the primary goal was to determine the best dose and method of administration. The reviews of outcomes centered on CR, the progress of labour, as well as the reactions of pregnant women and newborn. This mothed included a number of IVM treatments with different doses. The experts said that IVM showed a lot of potential as a CR agent in their study. This set the stage for future drug-based ways of starting labor.[12]
2. This study looked at the differences between an IVM and a transcervical Foley device for CR before induction. The study looked at pregnant women who had already given birth more than once. The group size was big enough to allow for a full clinical evaluation. The two different treatments that the researchers used were mechanical cervix opening with a Foley tube and drug ripening with misoprostol. Results were judged based on the shape of the cervix, the length of labour, and clinical signs between the mother and the baby. The results suggest a more sophisticated approach to IOL methods. They show that misoprostol sped up CR and the Foley tube was safer with a lower risk of overstimulating the uterus. [5]
3. In this . Nigeria studied how an intracervical DFC and an IVM worked when it was time to start labour and soften the cervix. The study group was made up of carefully picked women who had given birth more than once and needed help with labour so that the sample number would be statistically significant. The intervention plans compared using a DFC and a IVM to soften the cervix. There were records on how often the CR happened, how long the labour lasted, any problems the mother had, and how the baby behaved. There were fewer risks for both the mother and the baby during the Foley tube method, which led to a more controlled cervical change. The study showed that IVM made the cervical soften more quickly.[68]
4. In this study a review on IVM for CR and to start IOL. In this meta-analysis, a large group of studies from a variety of clinical settings were included. In the intervention study, the best ways to give IVM, how well it works, and safety in use were observed. In the result, a lot of clinical signs were carefully looked at, like how well CR worked, how

labour went, maternal complications, and how the baby turned out. The review mentioned the role of misoprostol in maternal processes. It included both its pros and cons, as well as changes in how it is used in real life.[2]

5. When it came to CR and IOL, Oliveira et al. (2010, Brazil) did an RCT that compared IVM with a cervical DFC. The study focused on women who were already pregnant and needed help with labour. Rates of cervical opening, lengths of labour, problems the mother had, and how the baby reacted were all part of the result reports. The Foley tube provided a more stable cervical change with fewer risks for both the mother and the baby. On the other hand, misoprostol was found to speed up the start of labour, according to the study.[18]
6. a DFC along with IVM to using IVM by itself. The international study project, which brought together many studies, gave a full assessment of IOL methods. In the conclusion, CR effectiveness, labour development times, baby outcomes, maternal complications, and other outcomes were observed. According to this review, using a DFC along with IVM led to better CR outcomes, lower CS rates, and lower risks of uterine hyperstimulation that are linked to IVM.[7]
7. a study that looked at IOL with and without IVM. The study gave a thorough analysis of IOL methods by combining the data of several studies conducted around the world. In the control study, ways to speed up CR using medicine and artificial means were compared. Rates of cervical dilation, progress in labour, problems, and traits of birth were all parts of the mother and baby outcomes that were looked at in detail in the outcome reviews. Researchers said that IOL techniques that used both mechanical and drug-based methods had benefits such as lowering the number of C-sections and making things easier for both moms and kids.[13]
8. This study did a meta-analysis to see how well IVM alone worked compared to an intracervical DFC for CR. In this review, they have compared several studies to provide lot of information about IOL strategies. There was a comparison between therapies that only used one method and treatments that used both hardware and medicine. In the conclusion, CR effectiveness, labour development times, baby outcomes, maternal outcomes, and other problems were noticed. The meta-analysis found that the combination approach increased CR, lowered the number of C-sections, and provided better, more controlled ways to start labor.[9]

9. This study compared the methods of IOL. They used an intracervical DFC in conjunction with IVM to methods that involved IVM alone. Methods for CR that included both mechanical and pharmaceutical interventions were contrasted in the intervention study among several studies they have compared. Cervical dilation efficacy, labour progression times, problems in mothers after delivery, and newborn outcomes were documented in this review. Both DFC and IVM combinedly enhanced CR, shortened labour duration, CS rate reduced, and overall induction outcomes in multigravida mothers.[70]
10. Orr and their colleagues did a meta-analysis to compare different CR methods, with a focus on combination approaches for IOL. The use of oxytocin and prostaglandins with a DFC was one of the many variations they have tried. They have observed that when different types of treatments were used together, especially those that used the DFC with prostaglandins or oxytocin, the study found the best clinical outcomes. In particular, the combined ways greatly decreased the incidence of CS compared to treatments that only used one strategy. They also increased the general effectiveness of IOL and made sure that the cervical opening lasted longer.[24]
11. The study looked at a group of fat women who were not pregnant. They have compared using a transcervical DFC with IVM to using IVM alone. A lot of attention was paid to the CR process, when labour started, how the baby responded, problems with the mother, and other results in the reviews. It was found that the mix of mechanical and drug methods greatly improved both the preparation of the cervix and the process of labour. Notably, the process suggested a more controlled and patient-specific approach to IOL in groups of patients who are having trouble by reducing the problems that could come up with drug therapies alone.[104]

MATERIALS AND METHODS

Study Design and Study Setting

The RL Jalappa Hospital and Research Centre in Kolar, Karnataka, India, was the site of this prospective comparison study.

Study Period

The study was conducted over an 18-month period,

Inclusion Criteria

- Maternal age between 19-35 years
- GA between completed 37 to 42 weeks
- Multigravida status (Gravida 2 or Gravida 3)
- Singleton pregnancy
- Cephalic presentation
- Intact membranes
- MBS less than or equal to 5
- Reactive NST

Exclusion Criteria

- Primigravida status
- Intrauterine foetal death
- Previous caesarean section or uterine surgeries (myomectomy or hysterotomy)
- Malpresentation
- Preterm gestation
- Multiple gestation
- Placenta previa, vasa previa, or active genital herpes
- Contracted pelvis
- Any contraindication to vaginal delivery

Sample Size Estimation

The study looked at 195 Canadian women who had already given birth more than once and found big differences between the groups in terms of how long it took for the foley catheter group to reach full term (16.2 ± 9.2 hours) and the PGE2 group (27 ± 14.8 hours).[3] With

these numbers, the method was used to find the smallest sample size that was needed, with a 99% confidence interval and 95% power.

$N = 2SD^2 (Z\alpha/2 + Z\beta)^2/d^2$

Where $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (2.58 for 99% confidence level),

$Z\beta$ is the critical value of the Normal distribution at β (1.28 for 90% power),

SD is the standard deviation from the previous study population variance, and

d is the largest difference between two means.

This calculation yielded a minimum requirement of 65 participants per group, with a total of 130 participants completing the study.

Intervention

Participants were alternately allocated to two intervention groups:

Group A (DFC Group): N= 65

DFC were put into the cervix with long forceps, and then they were moved up to the level of the internal os. We inflated the proximal Foley balloon with 80 ml of saline at the internal os. Meanwhile, we drew out the distal balloon (cervico-vaginal) and inflated it with 20 ml of saline until we could see it. Following the removal of the speculum, the cervico-vaginal balloon was inflated to a final pressure of 80 ml. The two catheters were gently secured to the inside of the thigh using tape. The balloons were deflated and removed if the rats did not exhibit spontaneous ejection within 12 hours. Both before and just after the catheter was inserted or removed was the MBS evaluated. Misoprostol induction was started if the MBS remained below than 6. We administered oxytocin augmentation if the MBS was 6 or above.

Group B (IVM group): N=65

Every four hours, or until a favorable cervix was achieved (MBS ≥6), active labour began, or a maximum cumulative dosage of 100 μg (4 doses) of misoprostol was reached, participants were given 25 μg of misoprostol into the posterior fornix of the vagina. As soon as the cervical circumstances improved, oxytocin augmentation was started according to clinical indications.

Sampling Method

A non-probability consecutive sampling strategy was used in the investigation. To keep group numbers equal and the study feasible in a clinical context, participants were randomly assigned to Group A or Group B after they were admitted to the labour ward.

Data Collection Procedure

Every participant had their complete obstetric history, results of prenatal exams, demographic information, and exact GA determined after they gave their written informed permission. Early ultrasonographic dating was used to calculate GA for individuals who did not have accurate LMP data. Abdominal examination for evaluation of presentation, FHR, and uterine contractions was part of the comprehensive obstetric evaluation that also included a general clinical examination. The vaginal exam was used to determine the first MBS and pelvic adequacy. To ensure the foetal well-being before induction began, obstetric ultrasonography and a NST were performed.

A standardized partogram was used to track the progress of labour throughout the active phase, and continuous cardiotocographic monitoring was maintained throughout the induction and labour process. To track the improvement of the MBS, cervical evaluations were carried out every six hours. When clinically required, oxytocin augmentation was administered in accordance with institutional standards, with dosage titration depending on uterine response and FHR patterns.

Some of the things that were tracked over time were how long it took from the induction phase to the active phase, how long it took from the active phase to delivery, how much oxytocin was needed, the method of delivery, the APGAR scores at 1 and 5 minutes, the rates of admission to the NICU, the reasons for admission, the type of amniotic fluid (clear or meconium-stained), and any problems that the mother had, like PPH.

"FI" in Group A was defined for this study as situations where either the mechanical method failed to achieve enough cervical dilation or when misoprostol was required because the catheter alone did not produce adequate CR.

Bishop Score

Standardized evaluation of cervical preparation for induction was carried out using the modified Bishop scoring system. These five parameters—cervical dilatation, effacement, station, consistency, and position—are evaluated by this established obstetric evaluation technique. There is a maximum possible score of thirteen parameters, with scores ranging from zero to two or three. According to this research, a score of 5 or below was deemed unfavourable and necessitated measures to help the cervical lining mature, but a score of 6 or above was deemed favourable for inducing or augmenting labour. Several validation studies have shown that the bishop scoring system is very reliable and valid for predicting whether a vaginal birth will be successful.

Data Analysis

Data were analysed using Statistical Package for Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were utilized to summarize demographic characteristics and baseline parameters. Continuous variables were expressed as means with standard deviations or medians with interquartile ranges based on their distribution patterns. Categorical variables were presented as frequencies and percentages.

Primary outcome measures included induction-to-active phase interval, induction-to-delivery interval, and mode of delivery.

Secondary outcomes encompassed oxytocin augmentation requirements, misoprostol dosage required, APGAR scores, NICU admission rates and indications, meconium-stained amniotic fluid incidence, and maternal side effects.

The study statistician was blinded to group allocation during analysis to reduce potential analytical bias.

RESULTS

Table 1: Demographic Distribution by Maternal Age Categories Among Study Participants

Age group (Years)	Group A		Group B		p value
	n = 65	%	n = 65	%	
19 - 20	13	20.0	10	15.4	0.521
21-25	28	43.1	25	38.5	
26-30	19	29.2	20	30.8	
≥31-35	5	7.7	10	15.4	

The age distribution analysis reveals comparable demographic patterns between the two intervention groups. In Group A, the majority of participants (n=28, 43.1%) were within the 21-25 years age range, followed by 26-30 years (n=19, 29.2%), with fewer participants in the ≤20 years (n=13, 20.0%) and ≥31-35 years (n=5, 7.7%) categories. Similarly, Group B demonstrated peak frequency in the 21-25 years category (n=25, 38.5%), followed by 26-30 years (n=20, 30.8%), with lower representation in both the younger and older categories (≤20 years: n=10, 15.4%; ≥31 years: n=10, 15.4%). The demographic homogeneity between groups facilitates valid comparative analysis by minimizing potential age-related confounding factors on IOL outcomes.

Figure 1: Demographic Distribution by Maternal Age Categories Among Study Participants

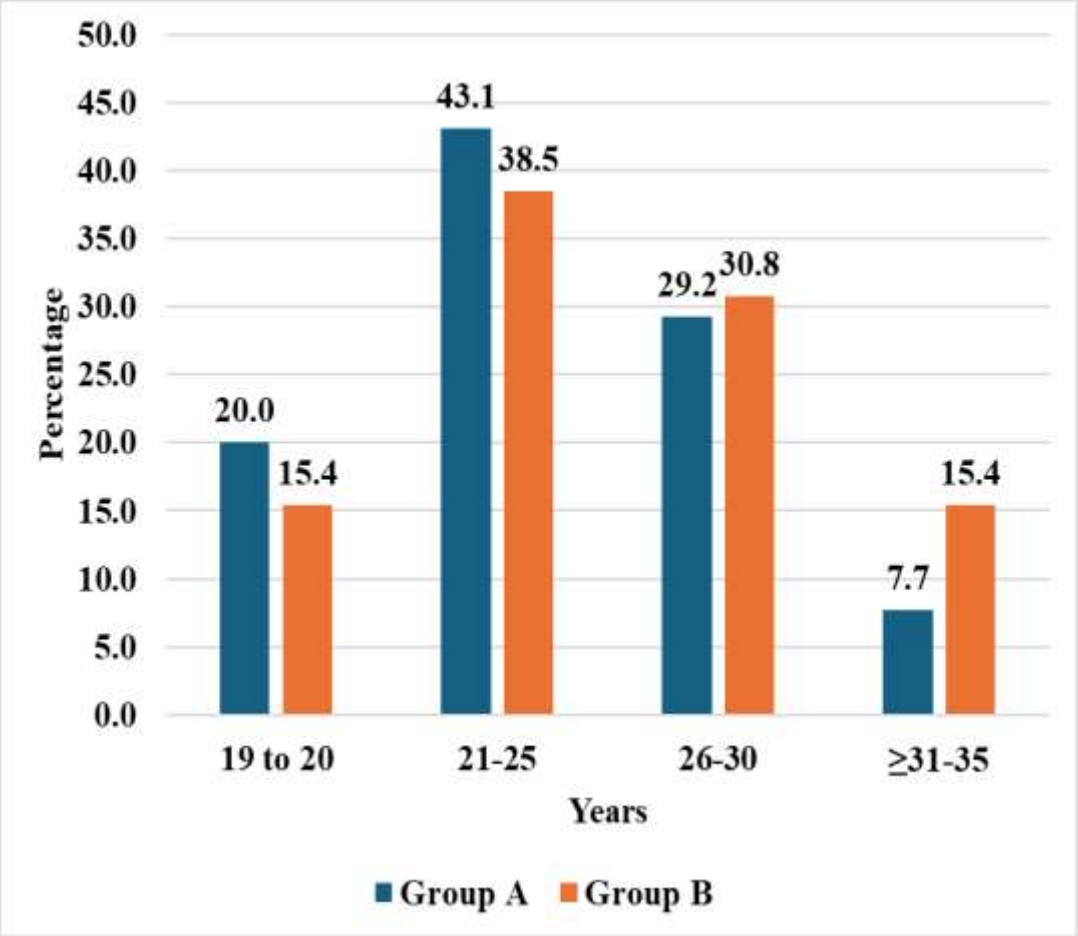


Table 2: Gestational Age Distribution in the Study Population

Gestational age in weeks	Group A		Group B		p value
	n = 65	%	n = 65	%	
37-38 weeks + 6 days	19	29.2	22	33.8	0.851
39- 39 weeks + 6 days	29	44.6	27	41.5	
40- 40weeks + 6 days	17	26.2	16	24.6	
41 – 41 weeks + 6days	0	0.0	0	0.0	

GA assessment at time of intervention demonstrates similar distributions across both study groups. The predominant GA in both groups was 39-39 weeks + 6 days (Group A: n=29, 44.6%; Group B: n=27, 41.5%), followed by early-term pregnancies at 37-38 weeks + 6 days (Group A: n=19, 29.2%; Group B: n=22, 33.8%), and late-term pregnancies at 40-40 weeks + 6 days (Group A: n=17, 26.2%; Group B: n=16, 24.6%). Notably, no post-term pregnancies (41-41 weeks + 6 days) were included in either study arm. This GA distribution confirms comparable baseline characteristics between groups, enhancing the validity of subsequent outcome comparisons.

Figure 2: Gestational Age Distribution in the Study Population

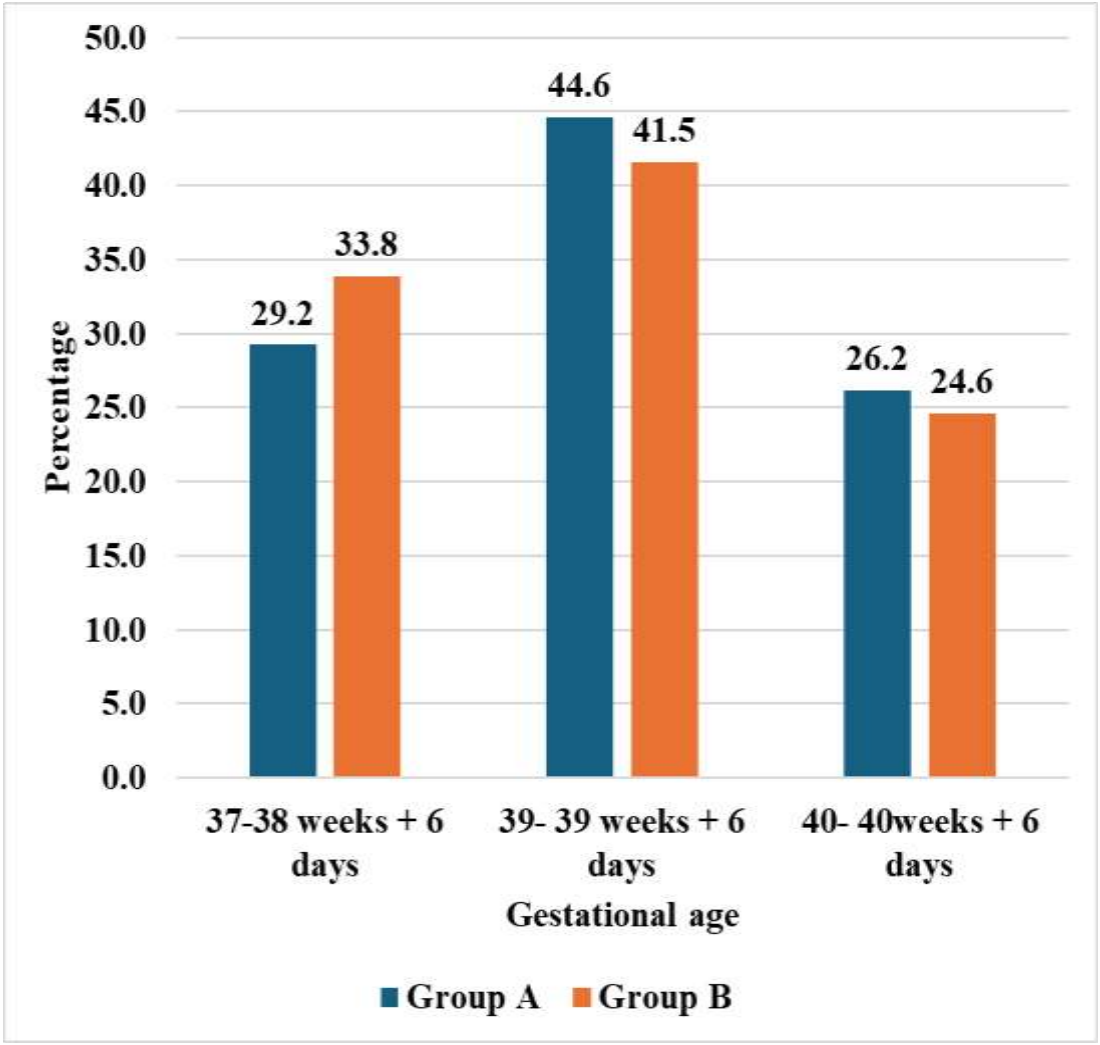


Table 3: Pre-induction MBS in the Study patients

Preinduction-modified BISHOP SCORE	Group A		Group B		p value
	n = 65	%	n = 65	%	
2	8	12.3	8	12.3	1.000
3	23	35.4	23	35.4	
4	26	40.0	26	40.0	
5	8	12.3	8	12.3	

Pre-induction cervical assessment utilizing the modified Bishop scoring system reveals identical distributions between intervention groups, establishing equivalent baseline cervical conditions. In both Group A and Group B, the most frequent MBS was 4 (n=26, 40.0% in each group), followed by a score of 3 (n=23, 35.4% in each group), with equal frequencies of scores 2 and 5 (n=8, 12.3% in each group). This methodological consistency in baseline cervical assessment is critical for valid comparative analysis of induction efficacy, as pre-induction cervical status significantly influences induction-to-delivery intervals and overall procedural success rates.

Figure 3: Pre-induction MBS in the Study patients

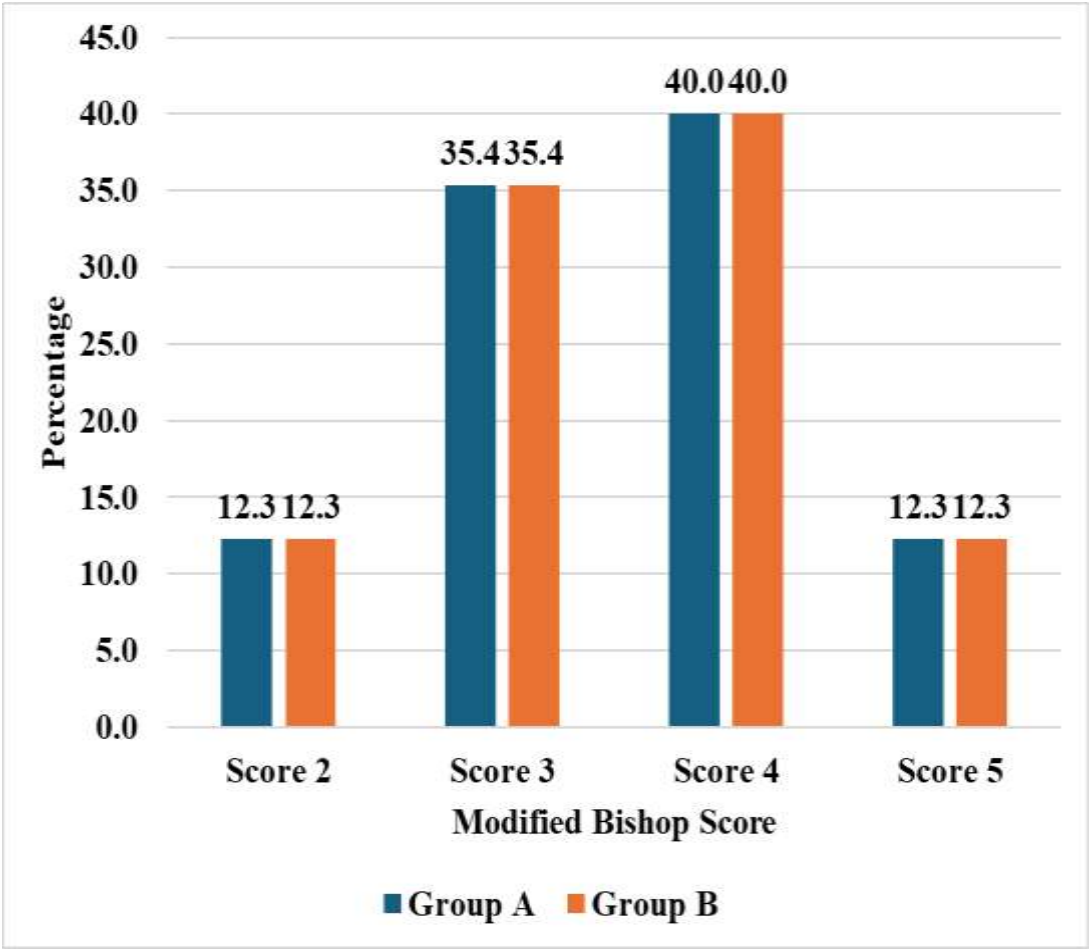


Table 4: Distribution of Induction Methodologies Among Multigravida Patients in the Comparative Study

Group	Initial induction method	Further required	Misoprostol
A	Foley catheter induction	Yes	23
		No	42

In Group A (DFC), 23 participants (35.4%) necessitated supplementary induction modalities beyond the initial mechanical approach, while 42 participants (64.6%) achieved adequate CR without additional methodological interventions.

Group B (IVM) demonstrated significantly different intervention patterns. While 25 participants (38.5%) required alternative induction methodologies beyond initial misoprostol administration, 47 participants (72.3%) required additional doses of misoprostol beyond the initial dose, with only 18 participants (27.7%) achieving adequate CR with a single misoprostol dose.

Table 5: Mode of Delivery in study population

Mode of Delivery	Group A		Group B		p-value
	n = 65	%	n = 65	%	
Vaginal	58	89.2	57	87.7	0.713
Assisted Vaginal	2	3.1	1	1.5	
Caesarean Section	5	7.7	7	10.8	

Analysis of delivery mode outcomes demonstrates comparable success rates between interventional methodologies. Spontaneous vaginal delivery was achieved in the majority of both cohorts (Group A: n=58, 89.2%; Group B: n=57, 87.7%). Assisted vaginal delivery rates were less in both groups (Group A: n=2, 3.1%; Group B: n=1, 1.5%). The caesarean section rate was slightly lower in Group A (n=5, 7.7%) compared to Group B (n=7, 10.8%), though this difference did not reach statistical significance. These delivery outcome distributions suggest comparable efficacy between mechanical and pharmacological induction methods in achieving vaginal delivery in the multigravida population.

Figure 4: Mode of Delivery Outcomes in study population

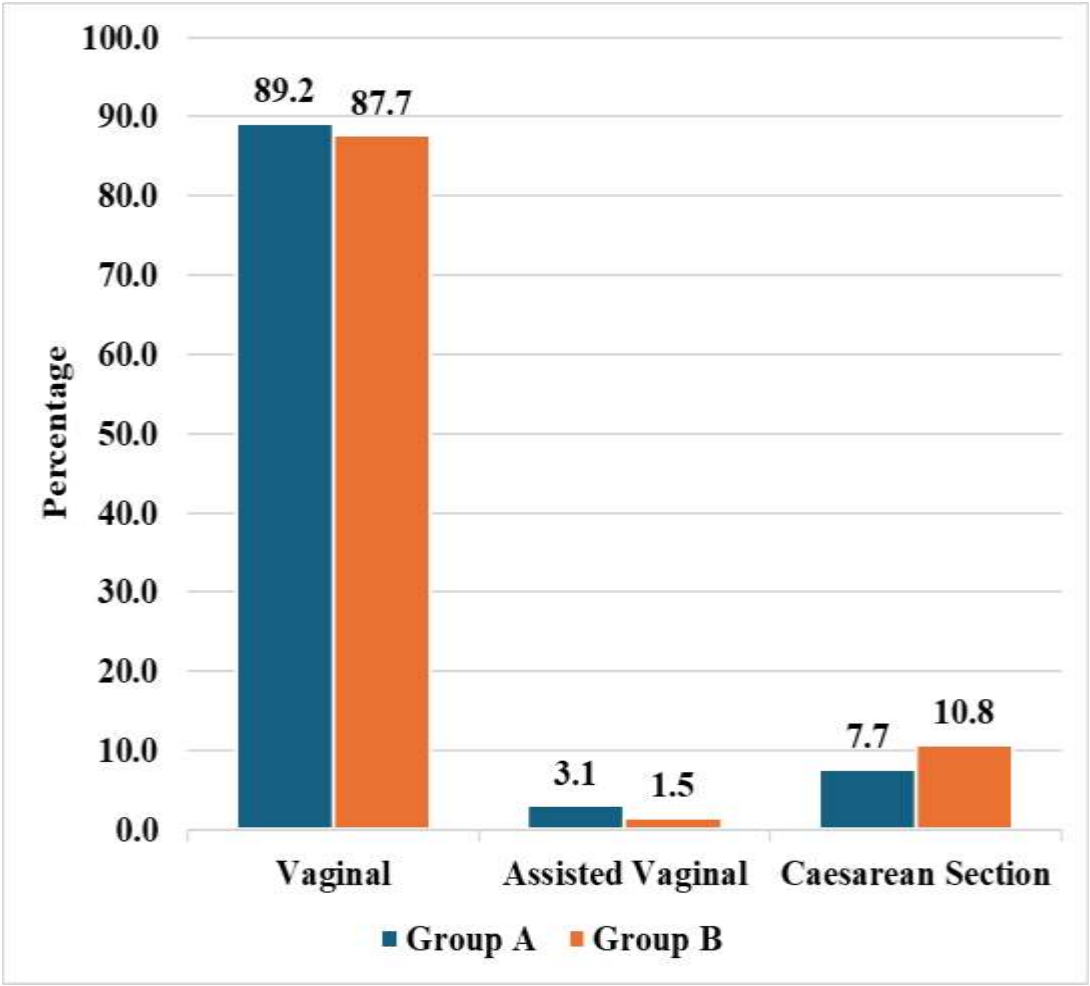


Table 6: Indications for Caesarean Section in the Study Population

Indications for Cesarean Section	Group A		Group B		p-value
	n = 5	%	n = 7	%	
Foetal distress	3	60.0	4	57.1	0.08
Failed induction	0	0.0	3	42.9	
Non progression of labour	2	40.0	0	0.0	

Analysis of caesarean section indications reveals significant variations in the aetiology of operative intervention between groups. In Group A (n=5), foetal distress represented the predominant indication (n=3, 60.0%), followed by failure of labour progression (n=2, 40.0%).

Conversely, in Group B (n=7), foetal distress remained the leading indication (n=4, 57.1%) but was accompanied by a substantial proportion of FI cases (n=3, 42.9%) where maximal misoprostol dosing failed to achieve adequate CR or labour initiation.

Table 7: Misoprostol Dosage Requirements in group A in the Study Population

Doses of misoprostol required (25 mcg)	**Group A**	
	n = 65	**%**
Not required	42	64.6
1 dose	12	18.5
2 doses	5	7.7
3 doses	2	3.1
4 doses	4	6.1

In Group A, where Foley catheter was the primary induction method, 42 participants (64.6%) did not require misoprostol supplementation. Among those receiving misoprostol in this group, most required only a single dose (n=12, 18.5%), with decreasing frequencies requiring multiple doses (2 doses: n=5, 7.7%; 3 doses: n=2, 3.1%; 4 doses: n=4, 6.1%).

Table 8: Misoprostol Dosage Requirements in group B ***in the Study Population***

Doses of misoprostol required (25 mcg)	**Group B**	
	n = 65	**%**
1 dose	18	27.7
2 doses	22	33.8
3 doses	20	30.8
4 doses	5	7.7

In Group B, where misoprostol was the primary induction agent, the most common requirement was 2 doses (n=22, 33.8%), followed closely by 3 doses (n=20, 30.8%), with fewer patients requiring only 1 dose (n=18, 27.7%) or the maximum 4 doses (n=5, 7.7%).

Table 9: Induction-to-Active Phase Interval Among Study Participants

Induction to active phase interval (hrs)	Group A		Group B		p-value
	n (65)	%	n (65)	%	
1 to 6	39	60.0	17	26.2	0.001
7 to 12	12	18.5	29	44.6	
>12	14	21.5	19	29.2	

In Group A, the majority of participants (n=39, 60.0%) transitioned to active labour within 6 hours of induction, with smaller proportions requiring 7-12 hours (n=12, 18.5%) or >12 hours (n=14, 21.5%). Conversely, Group B demonstrated a longer median interval, with the majority requiring 7-12 hours (n=29, 44.6%), followed by >12 hours (n=19, 29.2%), and only a minority (n=17, 26.2%) achieving active phase within 6 hours. This temporal distribution suggests potentially greater efficiency of mechanical dilation methods in achieving CR and labour initiation in the multigravida population.

Figure 5: Induction-to-Active Phase Interval Among Study Participants

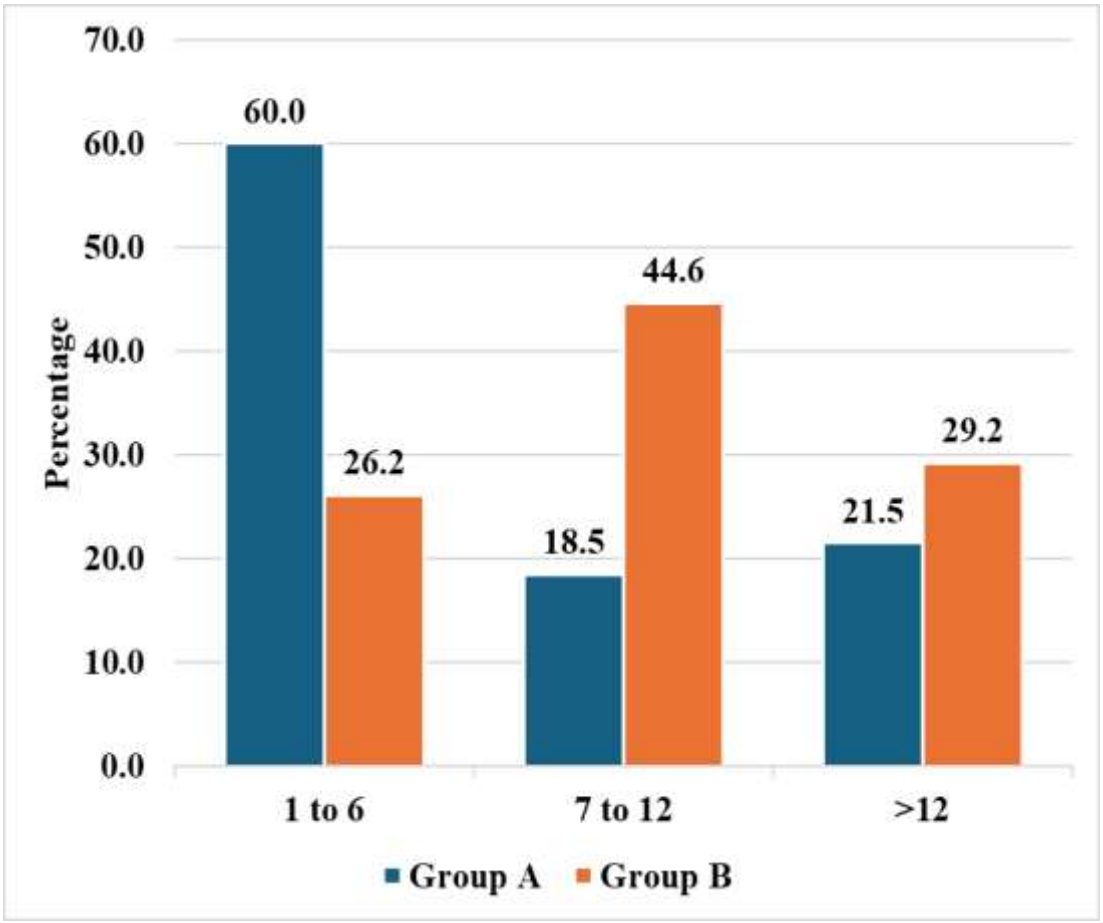


Table 10: Induction-to-Delivery Interval Among Study Participants

Induction to delivery interval (hrs)	Group A		Group B		p-value
	n = 65	%	n = 65	%	
≤12	51	78.5	46	70.8	0.591
13-24	10	15.4	13	20.0	
25-36	4	6.2	6	9.2	

The induction-to-delivery interval analysis demonstrates comparable overall efficiency between intervention methodologies, with slight temporal advantages in the Foley catheter group. In both groups, the majority of deliveries occurred within 12 hours of induction initiation (Group A: n=51, 78.5%; Group B: n=46, 70.8%). 13-24-hour inductions occurred in 10 participants (15.4%) in Group A compared to 13 participants (20.0%) in Group B. Similarly, 25-36 hours induction processes were slightly less frequent in Group A (n=4, 6.2%) compared to Group B (n=6, 9.2%). This distribution suggests a modest temporal advantage with mechanical dilation methodologies, though the overall efficacy profiles remain comparable.

Figure 6: Induction-to-Delivery Interval Among Study Participants

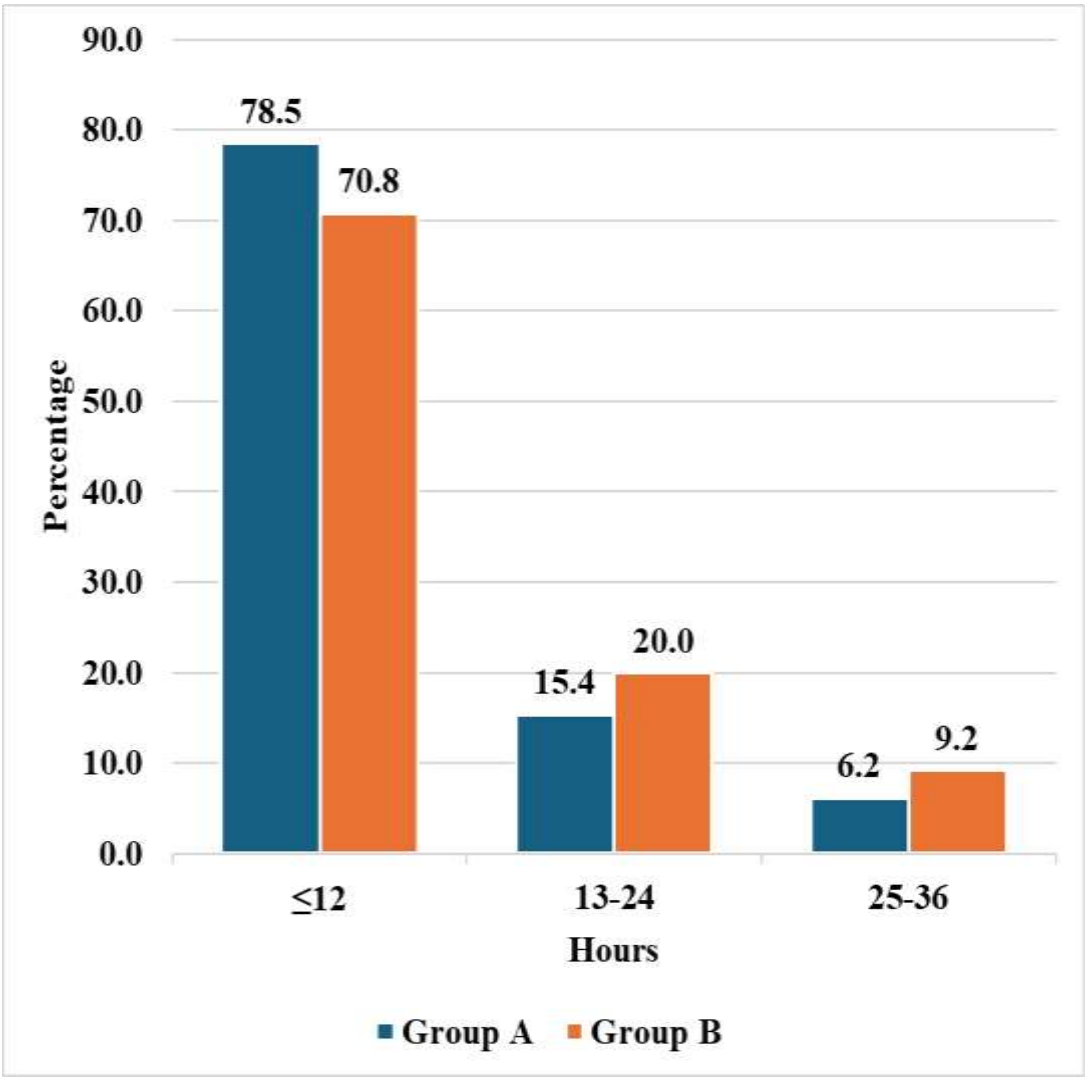


Table 11: Active Phase-to-Delivery Interval Distribution Among Study Participants

Active phase-to-delivery interval (hrs)	Group A (N=65)		Group B (N=65)		P-value
	n = 65	%	n = 65	%	
< 6	43	66.2%	37	56.9%	0.283
6-12	18	27.7%	21	32.3%	
> 12	4	6.1%	7	10.8%	

The temporal progression from active labour phase to delivery demonstrates modest variations between intervention methodologies, though without reaching statistical significance (p=0.283). In Group A (DFC), the majority of participants (n=43, 66.2%) completed the active phase and achieved delivery within 6 hours, with decreasing proportions requiring 6-12 hours (n=18, 27.7%) or >12 hours (n=4, 6.1%). Similarly, in Group B (misoprostol), most participants delivered within 6 hours of reaching active phase (n=37, 56.9%), followed by those requiring 6-12 hours (n=21, 32.3%), with a minority experiencing prolonged active labour exceeding 12 hours (n=7, 10.8%).

Figure 7: Active Phase-to-Delivery Interval Distribution in Hours Among Study Participants

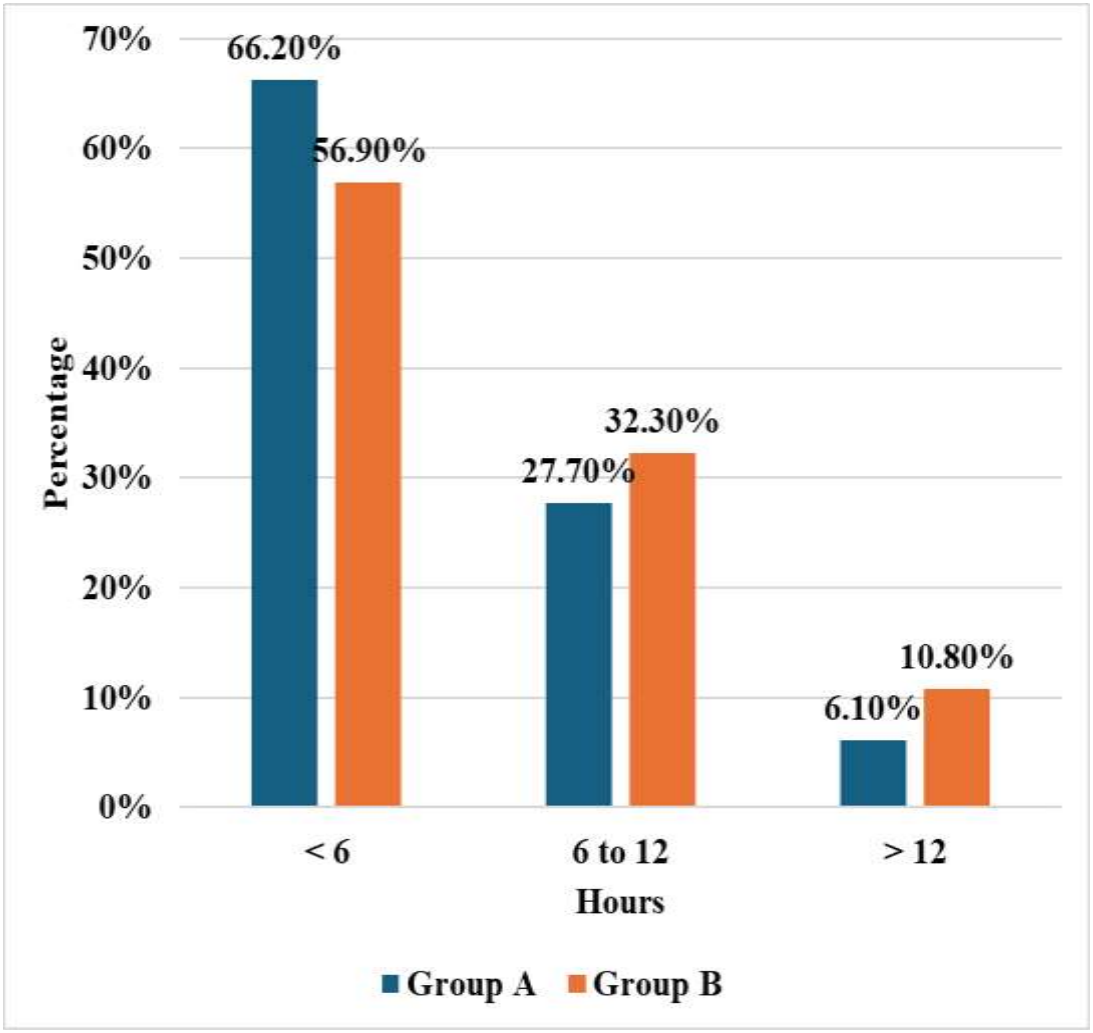


Table 12: Oxytocin Augmentation required in the Study group

Oxytocin augmentation requirement	Group A		Group B		p-value
	n = 65	%	n = 65	%	
Required	42	64.6	40	61.5	0.716
Not required	23	35.4	25	38.5	

Analysis of oxytocin augmentation requirements reveals similar distributions between intervention groups. In Group A, 42 participants (64.6%) required oxytocin augmentation following the initial induction with Foley catheter, compared to 40 participants (61.5%) in Group B who required oxytocin following initial misoprostol administration. Correspondingly, 23 participants (35.4%) in Group A and 25 participants (38.5%) in Group B achieved adequate labour progression without requiring oxytocin augmentation.

Figure 8: Oxytocin Augmentation required in the Study group

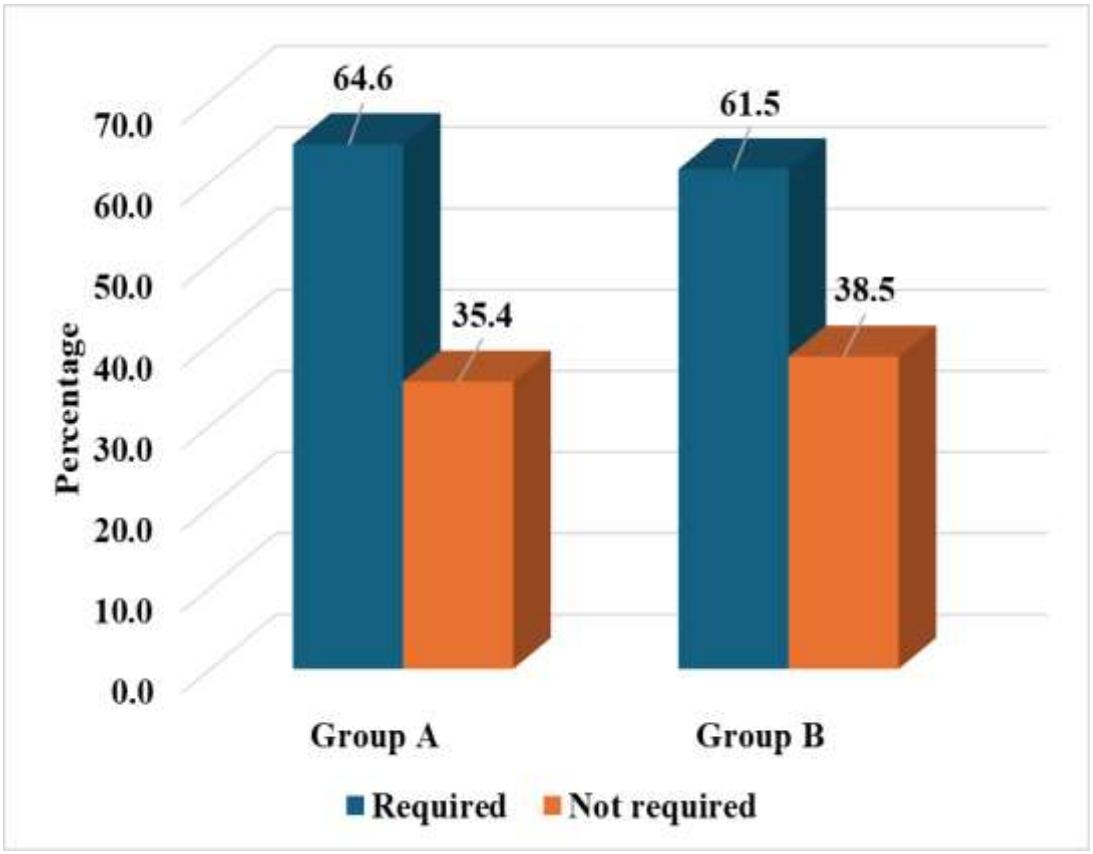


Table 13: Meconium Staining of Amniotic fluid Incidence in study population

Liquor	Group A		Group B		p-value
	n = 65	%	n = 65	%	
Meconium stained	9	13.8	23	35.4	0.004
Clear	56	86.2	42	64.6	

In Group A (DFC), MSL was observed in 9 participants (13.8%), with the majority (n=56, 86.2%) exhibiting clear amniotic fluid throughout labour. Group B (misoprostol) demonstrated a substantially higher incidence of meconium staining (n=23, 35.4%), with correspondingly fewer participants (n=42, 64.6%) exhibiting clear amniotic fluid during the intrapartum period (p-value 0.004).

Figure 9: Meconium Staining of Amniotic fluid Incidence in study population

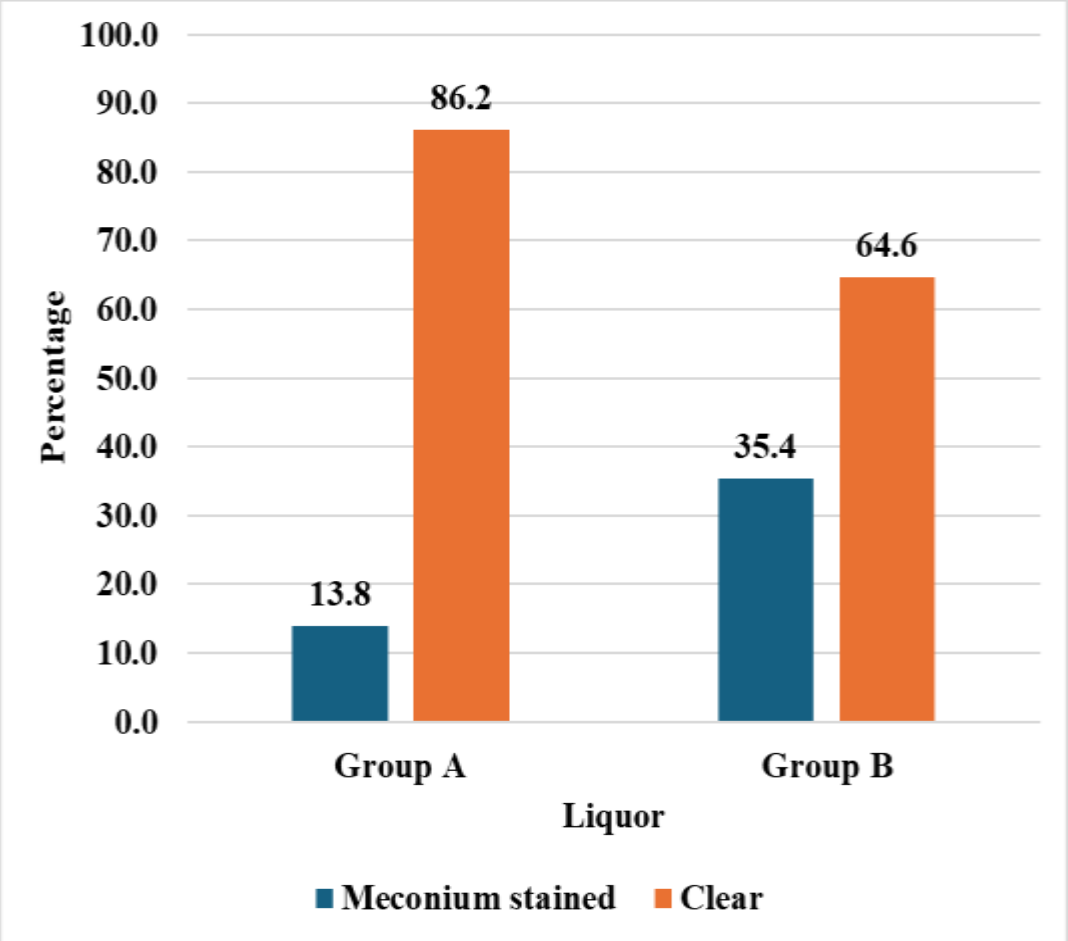


Table 14: Maternal Complication in study population

Maternal complications	Group A		Group B		p-value
	n = 65	%	n = 65	%	
Post partum Haemorrhage	1	1.5	2	3.1	0.559
Nil	64	98.5	63	96.9	

Assessment of maternal complications demonstrates better safety profiles with both induction methodologies. PPH occurred in 1 participant (1.5%) in Group A compared to 2 participants (3.1%) in Group B, though this difference did not reach statistical significance. This distribution indicates comparable maternal safety profiles between mechanical and pharmacological induction methods, with both demonstrating low complication rates in the multigravida population.

Figure 10: Maternal Complication Rates in study population

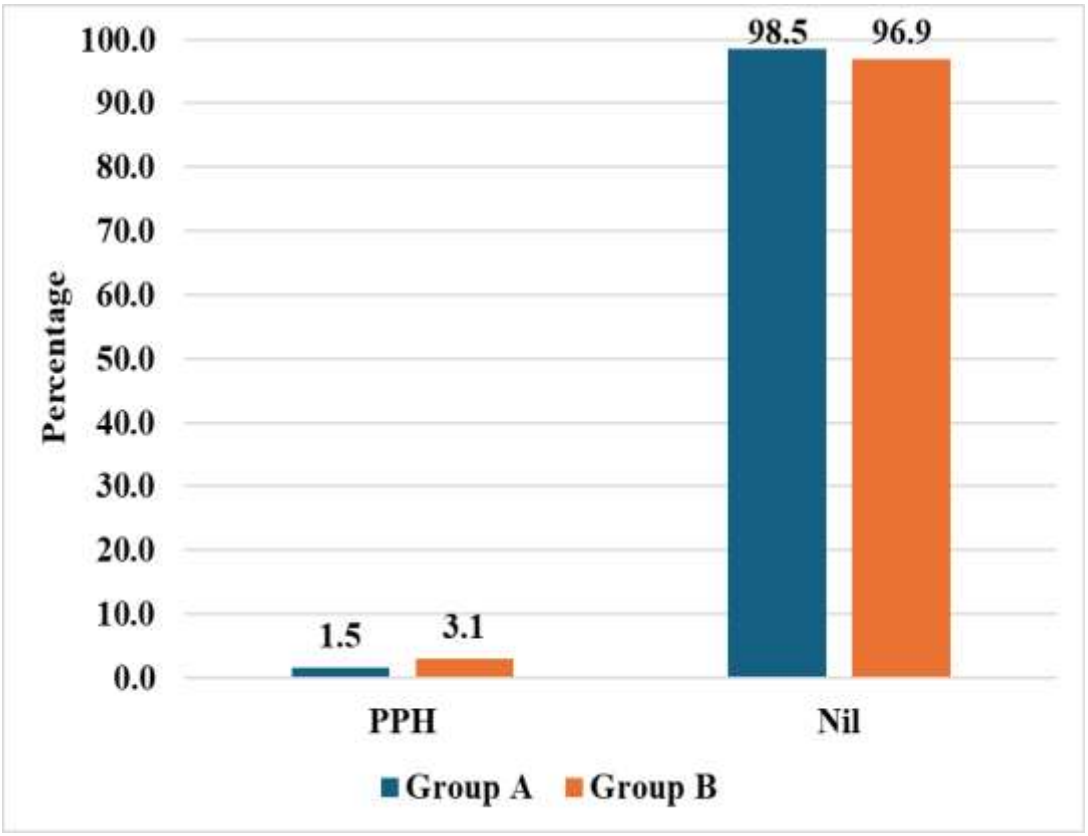


Table 15: APGAR Score at 1 and 5 Minutes in the neonates in the study population

APGAR score	Group A		Group B	
	n = 65	%	n = 65	%
At 1minute				
≥7	55	84.6	51	78.5
< 7	10	15.4	14	21.5
At 5 minutes				
≥9	55	84.6	51	78.5
< 9	10	15.4	14	21.5

The analysis of neonatal outcomes utilizing standardized APGAR scoring demonstrates generally favourable results with both induction methodologies, with slightly superior outcomes in the Foley catheter group. At both 1-minute and 5-minute assessments, 55 neonates (84.6%) in Group A achieved optimal APGAR scores (≥7 at 1 minute; ≥9 at 5 minutes), compared to 51 neonates (78.5%) in Group B. Correspondingly, suboptimal APGAR scores were observed in 10 neonates (15.4%) in Group A versus 14 neonates (21.5%) in Group B. While these differences did not reach statistical significance, they suggest a potential trend toward improved neonatal outcomes with mechanical dilation methodologies, possibly attributable to the reduced pharmacological exposure and potentially decreased incidence of uterine hyperstimulation.

Table 16: NICU Admission Rates in the study

NICU admission	Group A		Group B		p-value
	n = 65	%	n = 65	%	
Yes	9	13.8	10	15.4	0.8039
No	56	86.2	55	84.6	

The analysis of NICU admission requirements demonstrates comparable outcomes between both induction methodologies. In Group A, 9 neonates (13.8%) required NICU admission compared to 10 neonates (15.4%) in Group B. Correspondingly, 56 neonates (86.2%) in Group A and 55 neonates (84.6%) in Group B did not require specialized neonatal intensive care. This distribution suggests comparable neonatal safety profiles between mechanical and pharmacological induction methods, with no statistically significant differences in NICU admission rates.

Figure 11: NICU Admission Rates in the study

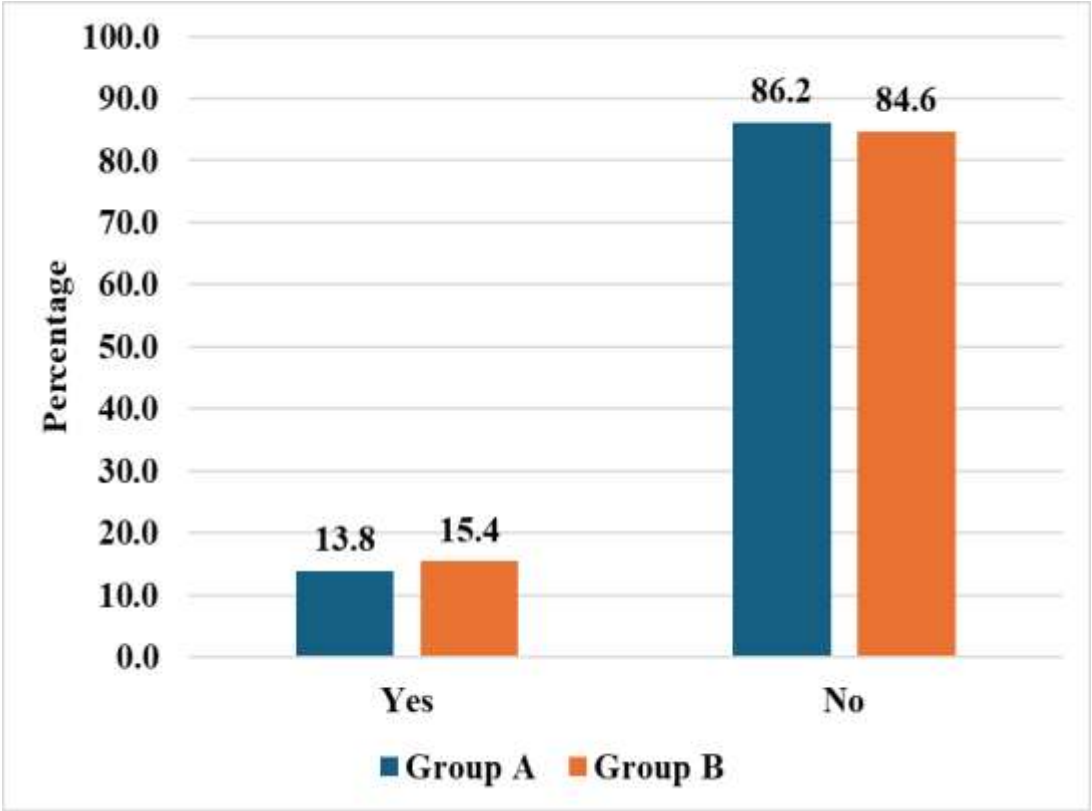
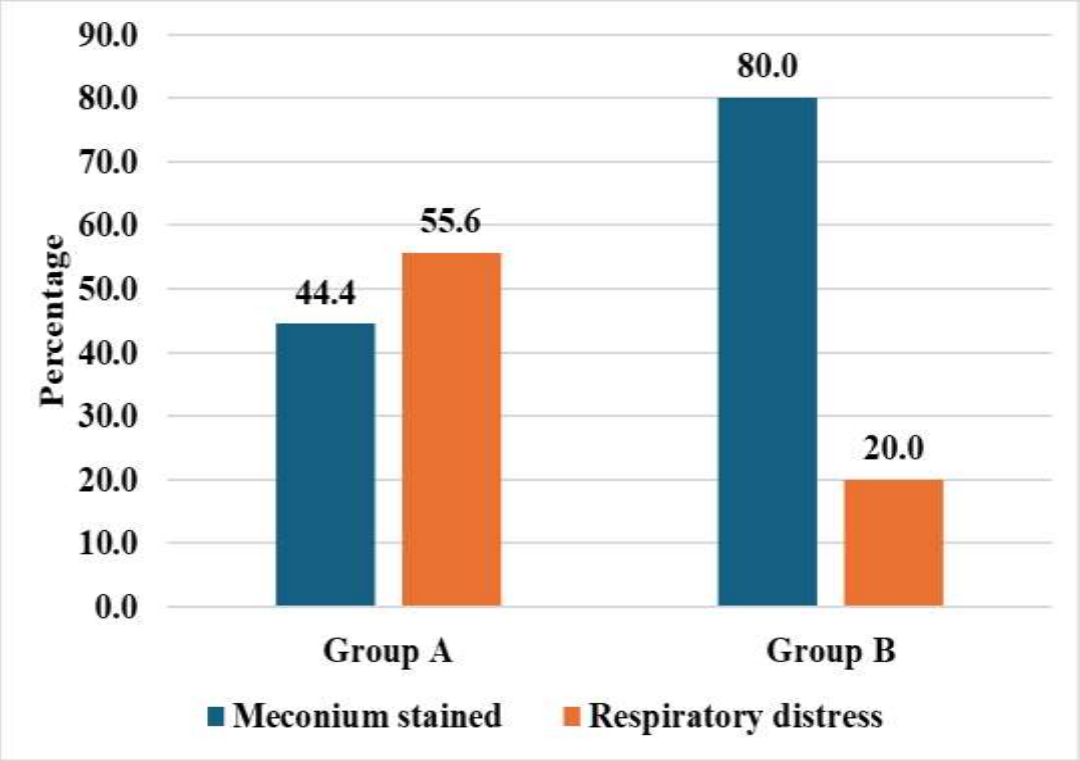


Table 17: Indications of NICU Admissions in the Study

Indications for NICU admission	Group A		Group B		p-value
	n = 9	%	n = 10	%	
Meconium stained in Amniotic fluid	4	44.4	8	80.0	0.108
Respiratory distress	5	55.6	2	20.0	

Detailed analysis of NICU admission indications reveals notable variations in the aetiology of neonatal complications between intervention groups. In Group A (n=9), the common indications for NICU admission were respiratory distress (n=5, 55.6%) followed by meconium staining in amniotic fluid (n=4, 44.4%). Conversely, in Group B (n=10), meconium staining represented the predominant indication (n=8, 80.0%), with respiratory distress accounting for a substantially smaller proportion (n=2, 20.0%).

Figure 12: Indications of NICU Admissions in the Study



Summary

- Maternal age (predominantly 21-25 years: 43.1% vs. 38.5%), GA (primarily 39-39+6 weeks: 44.6% vs. 41.5%), and pre-induction MBSs (predominantly score 4: 40.0% in both groups) were all observed to be homogeneous in both study groups.
- The DFC group exhibited a significant temporal efficacy, with 60.0% of participants attaining active labour within 6 hours, compared to 26.2% in the IVM group ($p<0.05$).
- The DFC group facilitated a more rapid delivery, with 78.5% of participants delivering within 12 hours compared to 70.8% in the IVM group, during the induction to delivery interval.
- The DFC group had slightly lower caesarean rates (7.7% vs. 10.8%), while both methods achieved comparable vaginal delivery rates (89.2% vs. 87.7%).
- The DFC group group necessitated significantly less additional induction agent, with 64.6% requiring no misoprostol and 18.5% requiring one dose of misoprostol. while both groups necessitated oxytocin augmentation (64.6% vs. 61.5%).
- The IVM group was the sole group to experience FI, accounting for 42.9% of caesarean deliveries. The mechanical method did not exhibit any primary induction failures.
- The incidence of meconium-stained amniotic fluid was considerably lower in the DFC group group (13.8% vs. 35.4%, $p<0.01$).
- The DFC group demonstrated a higher rate of optimal APGAR scores, with 84.6% attaining this level compared to the IVM group's 78.5%. The rates of admission to the NICU were comparable (13.8% vs. 15.4%) in both the study groups.
- The IVM group had a higher proportion of NICU admissions due to meconium-related complications on comparison to DFC group (80.0% vs. 44.4%).
- The safety profiles of both methods in the study were exceptional, with very minimal PPH (1.5% vs. 3.1%) and no other complications.

DISCUSSION

This study helps us improve induction methods for this special group of pregnant women by looking at how well and safely intracervical DFC and IVM for IOL work in women who have already given birth. The study makes it possible to compare things by using baseline factors that are similar, like age distribution, GA, and pre-induction cervical evaluations using MBS.

The study found that mechanical induction using a DFC cut the time it took to go from induction to the active phase by a large amount compared to drug induction with misoprostol. Along these lines, only 26.2% of women in the IVM group were actively labouring within 6 hours of being induced, while 60.0% of women in the DFC group were. Researchers from Canada (Manly et al., 2020) looked at 195 women and found that women who were induced with a Foley catheter had significantly faster induction-to-delivery times (16.2 ± 9.2 hours vs. 27 ± 14.8 hours, $p<0.001$) than women who were induced with prostaglandins. That is why our results are the same as those of these other studies. [3] These results show that mechanical induction methods give a consistent time advantage in multigravida, and this is true in a number of different places.

Notable among our results is the fact that the group treated with DFCs needed fewer further interventions. Misoprostol was not necessary for 64.6% of the Foleys cohort, and of those who did need it, the majority (18.5%) only needed a single dosage. The IVM group, on the other hand, required a total of 64.6% more than two or three doses. These results are in line with those of an Indian study by Garg et al. (2022) that found that a single dose of IVM administered with an intracervical Foley catheter resulted in more efficient CR than multiple doses of misoprostol administered alone. The study included 120 women. [14]

With 78.5% of patients delivering within 12 hours compared to 70.8% in the IVM group, the DFC group showed a little temporal advantage in the total induction-to-delivery interval study. This disparity did not achieve statistical significance, but it does show a decrease in overall induction length that is clinically meaningful. The results of this study partially support the findings of Filho et al. (2010), a Brazilian RCT including 240 women, who found that the combination of a Foley catheter and oxytocin reduced the average time to delivery when compared to IVM (12.8 ± 6.2 hours versus 19.6 ± 11.3 hours, $p<0.001$). [103] A possible

explanation for the more noticeable temporal disparities might be because Filho's inquiry included both nulliparous and multiparous women, which is different from our study.

In terms of delivery mode, both intervention approaches showed that vaginal birth was the preferred route with low rates of instrumental delivery. The rate for the DFC group was 89.2%, and the rate for the IVM group was 87.7%. A study by Fox et al. (2011) looked at 1,603 patients from 5 RCTs and found that the Foley catheter was linked to a lower risk of caesarean birth compared to IVM (7.7% vs. 10.8%; relative risk 0.72, 95% CI 0.52-0.98). [85] Similarly, a meta-analysis of 2,702 women from 8 RCTs conducted by Kemper et al. (2021) indicated that the incidence of caesarean deliveries were similar when oral misoprostol was used compared to a Foley catheter (20% vs 22%, adjusted RR 0.92, 95% CI 0.82-1.04). [77]

Our research found that various groups had varied patterns of caesarean section indications, which is a really important result. There were no instances of main induction failure among the women who had CS in the DFC group; instead, these procedures were carried out because of foetal distress (60.0%) or labour not progressing (40.0%). In contrast, 42.9% of CS in the IVM group were due to FI, which is defined as the failure to produce sufficient CR or the commencement of labour despite the maximum dosage of misoprostol. Consistent with these results, Beta et al. (2013) found in a Polish retrospective analysis of 160 women that pharmaceutical procedures resulted in a higher rate of induction failure (6.8% vs 15.3%, p=0.03), whereas mechanical methods had a lower rate. [86]Since our DFC group did not have any main induction failures, we may conclude that mechanical approaches, perhaps by dilating the cervix directly instead of depending on biochemical ripening processes, may provide more reliable CR in multigravida.

One of the most noteworthy results of our research is the noticeably greater incidence of amniotic fluid stained with meconium in the IVM group (35.4% vs 13.8%, $p<0.01$). In light of the possible consequences linked to meconium-stained drinks, this significant difference has significant therapeutic implications. In a randomized controlled study including 491 women, Levine et al. (2016) discovered that mechanical induction techniques were linked to lower rates of meconium passing than pharmacological approaches (15.7% vs 24.4%, p=0.04). Our results are in line with these findings. [65] The physiological difference between the two methods may be due to the fact that the prostaglandin-mediated uterine contractions of misoprostol may cause the foetus to react more negatively to the abrupt mechanical dilatation that the DFC achieves.

This idea is further supported by the varied pattern in the causes of NICU admissions. Although both groups had similar rates of NICU hospitalizations (13.8% for the DFC group and 15.4% for the IVM group), the IVM group had 80.0% of NICU admissions due to issues including meconium, whereas the DFC group had only 44.4%. Jozwiak et al. (2013) of the Netherlands also found that there were fewer cases of NICU admissions when Foley catheter induction was used instead of IVM (relative risk 0.82, 95% CI 0.65-1.04). However, their study did not specifically classify the causes of these admissions.[61]

Importantly, compared to the IVM group, 84.6% of infants in the DFC group had optimum APGAR ratings, suggesting a trend toward better neonatal outcomes. Tarimo et al. (2022) conducted a machine learning analysis in Tanzania that found that misoprostol use was a significant predictor of low APGAR scores at five minutes. Their study included 1,884 singleton vaginal deliveries following induction, and the adjusted odds ratio was 2.1 (95% CI 1.2-3.7).[95] Reducing uterine hyperstimulation, which has been linked to pharmacological induction medications, may explain why mechanical induction approaches are connected with better infant outcomes.

PPH was uncommon in the DFC group (1.5% vs. 3.1% in the IVM group), and no additional problems were seen in either intervention group, indicating great maternal safety. These results are in line with those of a RCT conducted by Eikelder et al. (2016) in the Netherlands. In this RCT, which included 1,845 women, the researchers found that oral misoprostol and Foley catheter had similar maternal safety profiles. There were no significant differences in pregnancy complications, such as PPH (8.3% versus 7.1%, p=0.36). [74]

Both groups needed oxytocin augmentation at about the same rate (64.6% in the DFC group and 61.5% in the IVM group), suggesting that the two methods were equally effective in starting the labour process. This finding is a little different from what Tuuli et al. (2013) found in their study of 944 women in the US over time. When they used the Foley catheter to start labour, oxytocin was needed more often (87.1% vs. 62.8%, $p<0.001$) than when misoprostol was used.[67] It is possible that the difference between our data and Tuuli's research, which only looked at women who had more than one pregnancy, is because Tuuli's study looked at both types of women.

The special attention to the misoprostol dose pattern that was observed in our research. When misoprostol was necessary, the majority of individuals in the group that used the DFC as their main induction strategy only needed one dosage (18.5% of the entire cohort), and very few

needed more than one. The main IVM group, on the other hand, required a total of 64.6% more than two or three doses. According to this pattern, mechanical dilation may physically disturb cervical tissue and make prostaglandin receptors more accessible, creating an environment that makes the cervical mucosa more receptive to later prostaglandin injection. This finding is in line with what Priyadarshini et al. (2019) in India discovered in their comparative study of 200 women. They discovered that when misoprostol was combined with an intracervical Foley catheter, fewer doses of misoprostol were needed compared to when misoprostol was used alone (1.2 ± 0.4 versus 2.5 ± 0.8, $p<0.001$). [105]

There is mounting evidence that suggests combining mechanical dilatation with pharmaceutical augmentation, as seen in a portion of our research participants (35.4% who received a DFC with misoprostol). In a RCT involving 150 women, Aduloju et al. (2016) from Nigeria showed that using a Foley catheter in conjunction with IVM reduced the time it took from induction to delivery (8.4 ± 4.1 hours versus 14.6 ± 5.2 hours, $p<0.001$) and improved the outcomes for CR. [16] On a similar note, Orr et al. (2020) conducted a network meta-analysis of 70 RCTs involving 19,772 participants. They found that combining a Foley catheter with prostaglandins was more effective than using either method alone for a successful vaginal delivery within 24 hours (relative risk 1.35, 95% CI 1.24-1.47). [24]

Additional discussion is warranted in view of new material regarding the significantly greater meconium passage rate in the IVM group. Comparing misoprostol alone to an intracervical Foley catheter plus misoprostol resulted in substantially lower rates of meconium-stained amniotic fluid (relative risk 0.72, 95% CI 0.56-0.93), according to a systematic review and meta-analysis conducted by Yin et al. (2023). The trial included 12 RCTs with 3,178 participants. [70] In line with our own findings, this study implies that mechanical approaches may have a physiological benefit in lowering foetal stress responses during IOL. One possible explanation is that mechanical techniques cause cervical dilatation more gradually than prostaglandins, which, especially at larger cumulative dosages, may cause more severe uterine stimulation.

In terms of clinical efficiency, the fact that our DFC group did not have any main induction failures is a very noteworthy discovery. In a RCT of 110 women with foetal growth limitation, Chavakula et al. (2015) found that using a Foley catheter resulted in fewer unsuccessful inductions than misoprostol (5.5% vs 18.2%, $p=0.04$). This conclusion is in agreement with our observations. [88] One major therapeutic benefit of mechanical approaches

for improving induction procedures is their dependability in regularly starting the CR process, even when further augmentation is needed.

Clinical Significance

This study's results provide important information for improving IOL procedures for women who have given birth more than once. Significant implications for clinical resource use and patient experience arise from the observed efficiency of the DFC in promoting faster CR and transition to active labour (60.0% within 6 hours compared to 26.2% with misoprostol). This time savings has the ability to improve the allocation of resources on the labour ward in overcrowded obstetric units, shorten the total length of admissions, and lower cumulative drug exposure.

The fact that the mechanical induction group did not have any main induction failures is a very important clinical result. It seems that the DFC group may provide more dependable induction of labour in multigravida individuals, as they eliminated unsuccessful induction as a caesarean rationale. However, overall, the rates of caesarean deliveries were similar across approaches. For patients with major comorbidities that increase surgical risks or in cases when a rapid birth is required but a caesarean section is preferred, this dependability may be a lifesaver.

Among the most clinically relevant results of this research is the much-decreased frequency of meconium-stained amniotic fluid linked to mechanical induction (13.8% vs 35.4%, $p<0.01$). Neonatal outcomes may be profoundly affected by meconium aspiration syndrome and other possible consequences of meconium transit. The clinical significance of this difference is further underscored by the similar pattern of NICU admission aetiologies. In the IVM group, 80.0% of hospitalizations were related to meconium problems, whereas in the DFC group, the equivalent figure was 44.4%. Preferential use of mechanical induction techniques to reduce hazards may be especially helpful for clinicians caring for patients who already have risk factors for foetal compromise.

Significant implications for drug exposure optimization arise from the fact that the mechanical induction group required fewer doses of misoprostol. This method significantly decreases cumulative prostaglandin exposure, as 64.6% of patients with DFCs do not need misoprostol and the majority of patients only require a single dosage. Patients with a history of fast labour, substantial uterine scarring, or prior uterine surgery may be at increased risk

for prostaglandin-associated complications, therefore this decrease may be especially helpful in these cases.

Mechanical dilatation and pharmaceutical augmentation when required provides a clinically balanced technique that takes use of both treatments, as shown in this study's procedure. There is some evidence that the first mechanical dilatation makes the cervical environment more receptive to later prostaglandin delivery, which might optimize effectiveness while reducing drug needs. It is possible to tailor intervention titration according to clinical response using this sequential, adaptable method.

Both procedures were shown to be quite safe for mothers, however the mechanical induction group had somewhat better newborn outcomes (84.6% with ideal APGAR scores compared to 78.5%), which might be good for the baby's health. Mechanical induction techniques may provide a more physiologically benign approach to labour onset in multigravida, maybe by avoiding the high uterine stimulation frequently linked with prostaglandins. This conclusion is supported by the lower meconium passing rates.

All things considered, these results lend credence to the idea that a DFC placed intracervically is the way to go when inducing labour in multigravida patients, especially in cases when the mother and baby are concerned about a speedy CR, a safe beginning of labour, and the best possible outcome for the baby.

CONCLUSION

This prospective comparative study demonstrates that intracervical DFC offers significant advantages over IVM alone for IOL in multigravida women. The DFC group exhibited better induction efficiency with significantly more rapid progression to active labour phase and modestly reduced overall induction-to-delivery intervals compared to IVM group. While both methods achieved comparable vaginal delivery rates, the DFC group demonstrated a slightly reduced caesarean section rate. In the present study, the incidence of meconium-stained amniotic fluid was significantly higher in the misoprostol-only group (35.4%) compared to the Foley catheter induction group. Regarding maternal and neonatal outcomes, our findings demonstrated excellent safety profiles with both induction methodologies, though with notable advantages for the mechanical approach. The DFC group exhibited lower rates of PPH and improved neonatal outcomes with 84.6% of neonates achieving optimal APGAR scores compared to 78.5% in the IVM group. Additionally, when NICU admission was required, the aetiology was less frequently related to meconium complications in the DFC group. In this study, among multiparous women who underwent induction of labour, the use of intracervical DFC was found to be more effective and preferable compared to misoprostol, suggesting that it should be considered the method of choice.

STRENGTH OF THE STUDY

Maternal age, GA, and pre-induction cervical evaluation using MBS were all statistically equal in all groups, confirming the thorough uniformity of baseline data. This consistency in methodology reduces the likelihood of confounding factors that can invalidate comparisons. Compared to single balloon procedures, the use of a DFC is a technological improvement that might lead to improved mechanical dilation effectiveness. A multi-dimensional efficacy evaluation is provided by the study's thorough outcome assessment, which includes metrics for maternal outcomes, APGAR scores, rates of NICU admission, and specific reasons for hospitalization, among other things.

RECOMMENDATIONS

Several suggestions for future clinical and scientific work are derived from the results of the study. When quick CR is needed or when limiting the danger of meconium-stained amniotic fluid is clinically relevant, the ideal induction approach for multigravida women is an intracervical DFC. For optimal efficiency and safety profiles, it may be best to use a progressive induction strategy that starts with mechanical means and then moves on to pharmaceutical augmentation if necessary. RCTs with higher sample sizes that are able to distinguish between maternal and newborn complications should be the primary emphasis of future studies. In order to get important health economic insights, studies should compare, and contrast induction strategies based on cost-effectiveness indicators and patterns of resource consumption. Important patient-centered metrics are presently underrepresented in the literature; thus, it would be beneficial to investigate patient-reported outcomes such as satisfaction, pain perception, and psychological effect of various induction regimens. Furthermore, to further optimize protocols, studies should investigate the ideal sequential timing of mechanical and pharmacological approaches in mixed protocols. Finally, there are important gaps in our understanding of how to manage clinically problematic induction settings that may be filled by doing RCTs that focus on high-risk subpopulations that were not part of this analysis.

SUMMARY

- This prospective comparative study investigated the efficacy and safety profiles of intracervical DFC versus IVM for IOL in multigravida women.
- The study was conducted at RL Jalappa Hospital and Research Center, Kolar, over an 18-month period, enrolling 130 multigravida women (gravida 2-3) with term pregnancies (37-42 weeks) requiring IOL. Participants were allocated to either Group A (n=65, DFC) or Group B (n=65, IVM) using an alternate assignment methodology.
- Both groups demonstrated comparable baseline characteristics including maternal age, GA, and pre-induction cervical assessment via modified Bishop scoring, establishing methodological homogeneity and minimizing potential confounding variables.
- Results demonstrated significantly shorter induction-to-active phase intervals in the mechanical induction group, with 60.0% of participants achieving active labour within 6 hours compared to 26.2% in the IVM group.
- Total induction-to-delivery intervals were also more favourable in the DFC group, with 78.5% delivering within 12 hours versus 70.8% in the IVM group.
- The DFC group required substantially fewer misoprostol doses, with 64.6% requiring none, 12 cases required only a single dose (18.5%), with decreasing frequencies requiring multiple doses (2 doses: n=5, 7.7%; 3 doses: n=2, 3.1%; 4 doses: n=4, 6.1%). In Group B, where misoprostol was the primary induction agent, the most common requirement was 2 doses (n=22, 33.8%), followed closely by 3 doses (n=20, 30.8%), with fewer patients requiring only 1 dose (n=18, 27.7%) or the maximum 4 doses (n=5, 7.7%).
- Mode of delivery analysis revealed similar vaginal delivery rates (89.2% vs. 87.7%), with slightly lower caesarean rates in the DFC group (7.7% vs. 10.8%). Notably, caesarean indications differed significantly between groups, with FI occurring exclusively in the IVM group (42.9% of caesarean deliveries) and no cases in the DFC group. This finding suggests greater reliability of mechanical methods in

consistently initiating the labour process, even when subsequent augmentation is required.

- Maternal safety profiles were excellent in both intervention groups, with low rates of PPH (1.5% vs. 3.1%) and no other complications observed.
- The most striking finding was the significantly lower incidence of meconium-stained amniotic fluid in the DFC group (13.8%) compared to the IVM group (35.4%, $p<0.01$). This substantial differential has important clinical implications given the potential complications associated with MSL.
- The analysis of NICU admission requirements demonstrates comparable outcomes between both induction methodologies. In Group A, 9 neonates (13.8%) required NICU admission compared to 10 neonates (15.4%) in Group B.
- Meconium-related complications constituted 80.0% of NICU admissions in the IVM group compared to 44.4% in the DFC group, suggesting that pharmacological induction may be associated with increased foetal stress responses compared to the more gradual mechanical dilation achieved with DFC.
- Neonatal outcomes demonstrated a trend toward improved APGAR scores in the DFC group (84.6% with optimal scores vs. 78.5%), though this difference did not reach statistical significance.
- The mechanical method offers advantages in induction efficiency, reliability of labour initiation, reduced caesarean rates from FI, and significantly lower rates of meconium-stained amniotic fluid.

LIMITATION

While 130 participants (65 in each group) is a sufficient number to draw valid conclusions about the main outcomes, it may not be large enough to discern differences in less common secondary outcomes such maternal problems. While the alternative assignment process does a good job of maintaining equal group sizes, it is not as robust as genuine randomization and might introduce selection bias. It may be difficult to apply the results to other healthcare systems due to the study's single-center design, which may have distinct patient demographics and clinical practice patterns. Because the treatments were not blinded, healthcare practitioners and participants might have been vulnerable to performance and detection bias when evaluating subjective results.

Although the study followed sound methodology, it does not apply to high-risk pregnancies that are clinically difficult and may require optimal induction protocols, such as those with abnormal foetal presentations, prior caesarean deliveries, multiple gestations, or growth restriction. We do not know much about the possible developmental effects of various induction techniques since there was no long-term neonatal follow-up. Lastly, the study's practical clinical application may have been improved by a cost-effectiveness analysis comparing the groups' resource use. This is especially important in healthcare settings with limited resources, where optimizing efficiency is of the utmost importance.

REFERENCES

1. Abdi N, Alavi A, Pakbaz F, Darabi H. Vaginal misoprostol versus intracervical Foley catheter for cervical ripening in postdate primigravid women: a randomized clinical trial. BMC Pregnancy Childbirth. 2021 Jul 27;21(1):533.
2. Hofmeyr GJ, Gülmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database Syst Rev. 2003;(1):CD000941.
3. Manly E, Hiersch L, Moloney A, Berndl A, Mei-Dan E, Zaltz A, et al. Comparing Foley Catheter to Prostaglandins for Cervical Ripening in Multiparous Women. J Obstet Gynaecol Can. 2020 Jul;42(7):853–60.
4. Kaur A, Santosh, Kaur P, Manpreet. Induction of Labour with intracervical Foley's catheter and intravaginal Misoprostol. Int J Curr Res Med Sci. 2018;4(1):43–50.
5. Adeniji OA, Oladokun A, Olayemi O, Adeniji OI, Odukogbe AA, Ogunbode O, et al. Pre-induction cervical ripening: transcervical foley catheter versus intravaginal misoprostol. J Obstet Gynaecol J Inst Obstet Gynaecol. 2005 Feb;25(2):134–9.
6. Agarwal M, Kose V. Comparative study of vaginal misoprostol and intra cervical Foley's catheter for pre-induction cervical ripening at term. Int J Reprod Contracept Obstet Gynecol. 2017 Mar 30;6(4):1283–7.
7. Chen W, Xue J, Gaudet L, Walker M, Wen SW. Meta-analysis of Foley catheter plus misoprostol versus misoprostol alone for cervical ripening. Int J Gynaecol Obstet Off Organ Int Fed Gynaecol Obstet. 2015 Jun;129(3):193–8.
8. Chowdhary A, Bagga R, Jasvinder Kalra null, Jain V, Saha SC, Kumar P. Comparison of intracervical Foley catheter used alone or combined with a single dose of dinoprostone gel for cervical ripening: a randomised study. J Obstet Gynaecol J Inst Obstet Gynaecol. 2019 May;39(4):461–7.
9. Lee HH, Huang BS, Cheng M, Yeh CC, Lin IC, Horng HC, et al. Intracervical Foley Catheter Plus Intravaginal Misoprostol vs Intravaginal Misoprostol Alone for Cervical Ripening: A Meta-Analysis. Int J Environ Res Public Health. 2020 Mar;17(6):1825.
10. Olasinde A, Aboyeji AP, Omokanye LO, Ogunlaja OA, Lawal BO, Olasinde YT, et al. A comparison of transcervical foley catheter and intravaginal misoprostol for cervical

ripening and labour induction in a tertiary hospital in North-Central Nigeria. Res J Health Sci. 2024 Aug 12;12(3):189–97.

11. Osoti A, Kibii DK, Tong TMK, Maranga I. Effect of extra-amniotic Foley's catheter and vaginal misoprostol versus vaginal misoprostol alone on cervical ripening and induction of labour in Kenya, a randomized controlled trial. BMC Pregnancy Childbirth. 2018 Jul 12;18(1):300.
12. Wing DA, Rahall A, Jones MM, Goodwin TM, Paul RH. Misoprostol: an effective agent for cervical ripening and labour induction. Am J Obstet Gynecol. 1995 Jun;172(6):1811–6.
13. Nasioudis D, Kim SW, Schoen C, Levine LD. Maternal and neonatal outcomes with mechanical cervical dilation plus misoprostol compared to misoprostol alone for cervical ripening; a systematic review of literature and metaanalysis. Am J Obstet Gynecol MFM. 2019 May;1(2):101–11.
14. Garg R, Bagga R, Kumari A, Kalra J, Jain V, Saha SC, et al. Comparison of intracervical Foley catheter combined with a single dose of vaginal misoprostol tablet or intracervical dinoprostone gel for cervical ripening: a randomised study. J Obstet Gynaecol J Inst Obstet Gynaecol. 2022 Feb;42(2):232–8.
15. Gomez HB, Hoffman MK, Caplan R, Ruhstaller K, Young MHH, Sciscione AC. Buccal vs vaginal misoprostol combined with Foley catheter for cervical ripening at term (the BEGIN trial): a randomized controlled trial. Am J Obstet Gynecol. 2021 May;224(5):524.e1-524.e8.
16. Aduloju OP, Akintayo AA, Adanikin AI, Ade-Ojo IP. Combined Foley's catheter with vaginal misoprostol for pre-induction cervical ripening: A randomised controlled trial. Aust N Z J Obstet Gynaecol. 2016 Dec;56(6):578–84.
17. Kalambe M, Jungari ML, Nair PP, Shrivastava D. Combination of Misoprostol with Transcervical Foley's Catheter Compared to Misoprostol Alone for Cervical Ripening at Term and Labour Induction in Tertiary Care Hospital: A Randomized Trial. Indian J Forensic Med Toxicol. 2020 Oct 7;14(4):6836–40.
18. Oliveira MV de O e, Oberst PV, Leite GKC, Aguemi A, Kenj G, Leme VD de T, et al. [Cervical Foley catheter versus vaginal misoprostol for cervical ripening and induction of labour: a randomized clinical trial]. Rev Bras Ginecol E Obstet Rev Fed Bras Soc Ginecol E Obstet. 2010 Jul;32(7):346–51.

19. Amin* JV, Gokhale AV, Shah VH, Rajani AJ. Comparison of oral mifepristone with intracervical foleys catheterisation for induction of labour in term pregnancy: A randomized control trial. Indian J Obstet Gynecol Res. 10(3):242–6.
20. Anjali, Jain S, Pasrija S, Kille HC. Labour induction with combined low-dose oral misoprostol and Foley catheter vs oral misoprostol alone at term gestation—a randomized study. AJOG Glob Rep. 2022 Aug 1;2(3):100060.
21. Ferdausi M, Rahman A, Geeti S, Shoma Chockroborty S, Zaman N, Siddika A. Effectiveness of combined use of misoprostol with intracervical catheter for induction of labour: a randomized control trial. Int J Reprod Contracept Obstet Gynecol. 2023 Mar 28;12(4):832–9.
22. Eser A, Ozkaya E, Abide CY, Eser T, Eser GY, Abike F, et al. Transcervical Foley balloon catheter and vaginal prostaglandin E2 insert combination vs. vaginal prostaglandin E2 insert only for induction of labour at term: a randomized clinical trial. Arch Gynecol Obstet. 2019 Feb;299(2):451–7.
23. Kashanian M, Bahasadri S, Nejat Dehkordy A, Sheikhansari N, Eshraghi N. A comparison between induction of labour with 3 methods of titrated oral misoprostol, constant dose of oral misoprostol and Foley catheter with extra amniotic saline infusion (EASI), in women with unfavorable cervix. Med J Islam Repub Iran. 2019;33:115.
24. Orr L, Reisinger-Kindle K, Roy A, Levine L, Connolly K, Visintainer P, et al. Combination of Foley and prostaglandins versus Foley and oxytocin for cervical ripening: a network meta-analysis. Am J Obstet Gynecol. 2020 Nov;223(5):743.e1-743.e17.
25. Kadu NA, Shiragur S. Comparison of Intracervical Foley's Catheter With Vaginal Misoprostol Versus Intravaginal Misoprostol Alone for Cervical Ripening and Induction of Labour. Cureus. 15(9):e44772.
26. Manku H. Comparative study of foley's catheter and misoprostol versus mifepristone and misoprostol in induction of midtrimester abortions: a retrospective study. Int J Res Med Sci. 2024 Nov 30;12(12):4533–40.
27. Nipanal HV, Talawar SR, Uppar P, Susmitha S. Comparison of Efficacy of Pervaginal Misoprostol, Intracervical Foley Catheter, Intracervical Dinoprostone on Induction of Labour. J South Asian Fed Obstet Gynaecol. 2024 Mar 6;16(S1):S11–5.

28. Rahman R. Literature Survey on Factors Influencing the Caesarean Section (CS) Delivery in Bangladesh: Evidence from Global [Internet]. [Amsterdam]: Vrije Universiteit; 2023. Available from: https://bibalex.org/baifa/Attachment/Documents/DyrdKvvzE3_20231122130609735.pdf
29. Nabila M, Baidani A, Mourajid Y, Chebabe M, Abderraouf H. Analysis of Risk Determinants of Neonatal Mortality in the Last Decade: A Systematic Literature Review (2013–2023). Pediatr Rep. 2024 Sep;16(3):696–716.
30. Aquino CI, Tivano A, Sala FD, Colagiorgio S, Scalisi L, Alemu TE, et al. The "Ideal Birth": The Occurrence of Severe Perineal Lacerations, Related Factors and the Possibility of Identifying Patients at Higher Risk. Healthcare. 2024 Dec 22;12(24):2584.
31. Maguire C. A comparison of maternal satisfaction with the use of osmotic dilators as opposed to balloons as a method of induction of labour: A literature review [Internet] [Thesis]. Hochschule für Angewandte Wissenschaften Hamburg; 2024 [cited 2025 Mar 27]. Available from: https://reposit.haw-hamburg.de/handle/20.500.12738/15249
32. Devy SR, Diah Indriani, Budi Prasetyo, Hari Basuki Notobroto, Lutfi Agus Salim, Muhammad Ardian Cahya Laksana, et al. Determinants of Caesarean Section Decision in Indonesia: A Systematic Review. J Promkes. 2024 Mar 8;12(1):129–38.
33. Amini M. Labour induction strategies with misoprostol- Evaluating oral, sequential and outpatient protocols for improved outcomes [Internet]. [Sweden]: Lund University; 2024. Available from: https://lup.lub.lu.se/search/files/199536947/Avhandling_Mahdi_Amini_LUCRIS.pdf
34. Organization WH. WHO recommendations on induction of labour, at or beyond term. World Health Organization; 2022. 48 p.
35. Giovannetti OP. Clinical Anatomy of the Cervix: Characterization Within the Context of Iatrogenic Outcomes Following LEEP [Internet]. [Canada]: Queen's University; 2023 [cited 2025 Mar 27]. Available from: https://www.proquest.com/openview/0d3eec00ded2faffd862162fa88222a3/1?cbl=18750&diss=y&pq-origsite=gscholar
36. Russu MC, Ghelmene AE, Stănculescu RV, Nastasia Ş, Russu MC, Ghelmene AE, et al. Abnormal Cervical Remodeling Early Depiction by Ultrasound Elastography: Potential Opportunities for Preterm Birth Prevention and Delay. In: Childbirth - Clinical

Assessment, Methods, and Management [Internet]. IntechOpen; 2023 [cited 2025 Mar 27]. Available from: https://www.intechopen.com/chapters/88488

37. Taylor-Cousar JL, Shteinberg M, Cohen-Cymberknoh M, Jain R. The Impact of Highly Effective Cystic Fibrosis Transmembrane Conductance Regulator Modulators on the Health of Female Subjects With Cystic Fibrosis. Clin Ther. 2023 Mar 1;45(3):278–89.
38. Rivera BSN, RN A. Reducing Caesarean Sections with Peanut Ball Use: A Quality Improvement Project. DNP Proj [Internet]. 2024 Jul 1; Available from: https://digitalcommons.sacredheart.edu/dnp_projects/74
39. Manfrè L, De vivo EA, Zini C, Ventura F, Hirsch JA. PERCUTANEOUS INTERSPINOUS DEVICES TREATMENT IN PATIENTS AFFECTED BY LUMBAR SPINAL CANAL STENOSIS: A PRELIMINARY STUDY EVALUATING DURAL SAC USING WEIGHT BEARING MRI, BEFORE AND AFTER THE TREATMENT. Eur J Musculoskel Dis 2024. 1-10;European Journal of Musculoskeletal Diseases(13):1.
40. Nomura S, Sakamoto H, Ghaznavi C, Inoue M. Toward a third term of Health Japan 21 – implications from the rise in non-communicable disease burden and highly preventable risk factors. Lancet Reg Health – West Pac [Internet]. 2022 Apr 1 [cited 2025 Mar 27];21. Available from: https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(21)00286-8/fulltext
41. McDonald SA, Qendri V, Berkhof J, de Melker HE, Bogaards JA. Disease burden of human papillomavirus infection in the Netherlands, 1989–2014: the gap between females and males is diminishing. Cancer Causes Control. 2017 Mar 1;28(3):203–14.
42. Prakasiwi SI, ARIYANI SIPLM. Proceedings of the 2nd Lawang Sewu International Symposium on Health Sciences: Midwifery (LSISHS-M 2023). Springer Nature; 2024. 219 p.
43. Oladapo-Akinfolarin TT, Mayowa O, Maduagwu MC, Fyneface C, Bartimaeus EAS. Effect of Gravidity on Atherogenic Indices in Normotensive and Hypertensive 3rd Trimester Pregnant Women.
44. Putri FD, Sebayang SM, Novitasari D. The Differences in Pre-Caesarean Anxiety Levels Between Primigravida and Multigravida Patients. Java Nurs J. 2025 Feb 28;3(1):65–74.

45. Wharton LK, and Anumba DOC. Techniques for detecting cervical remodeling as a predictor for spontaneous preterm birth: current evidence and future research avenues in patients with multiple pregnancies. J Matern Foetal Neonatal Med. 2023 Dec 15;36(2):2262081.
46. Premkumar A, Manthena V, Vuppaladhadiam L, Van Etten K, McLaren H, Grobman WA. The use of adjunctive mechanical dilation at the time of induction termination and adverse health outcomes: a systematic review. Am J Obstet Gynecol MFM. 2024 Feb 1;6(2):101263.
47. Yahea IA. Pre-induction cervical ripening by Foley's catheter in relative indication of caesarean section. Tobruk Univ J Med Sci. 2024;7(1):1–6.
48. Baradwan S, Alshahrani MS, AlSghan R, Sabban H, Khadawardi K, Alyafi M, et al. Digital versus speculum insertion of Foley catheter for labour induction: A systematic review and meta-analysis of randomized controlled trials. J Gynecol Obstet Hum Reprod. 2024 May 1;53(5):102770.
49. Félix J, Bartosch C, Matias A. Unlocking the Cervix: Biological Mechanisms and Research Gaps in Preterm Birth. Cureus [Internet]. 2024 Nov 1 [cited 2025 Mar 27]; Available from: https://www.cureus.com/articles/302802-unlocking-the-cervix-biological-mechanisms-and-research-gaps-in-preterm-birth
50. Shahabuddin Y, Murphy DJ. Cervical ripening and labour induction: A critical review of the available methods. Best Pract Res Clin Obstet Gynaecol. 2022 Mar 1;79:3–17.
51. Mokhtarpour S, Sahhaf F, Vahedi L, Sani A. Evaluation of mechanical and nonmechanical methods of cervix ripening in women with pre-labour rupture of membranes: a randomized controlled trial. Am J Obstet Gynecol MFM. 2023 Apr 1;5(4):100868.
52. Khan H, Buaki-Sogo MA, Barlow P, Vardanyan R, Zatorska A, Miller G, et al. Efficacy of pharmacological and mechanical cervical priming methods for induction of labour and their applicability for outpatient management: A systematic review of randomised controlled trials. Eur J Obstet Gynecol Reprod Biol. 2023 Aug 1;287:80–92.
53. Aishwarya R, Divya S, Shivaranjani KS, Sharanya H, Rasik NM. Comprehensive systematic review of pharmacological interventions for labour induction: mechanisms, efficacy, and safety. Int J Acad Med Pharm. 2023;5(5):749–54.

54. Jindal J, Launer D, Richards GC, Dernie F. Preventable maternal deaths in England and Wales, 2013-2023: a systematic case series of coroners' reports [Internet]. medRxiv; 2024 [cited 2025 Mar 27]. p. 2024.07.09.24310137. Available from: https://www.medrxiv.org/content/10.1101/2024.07.09.24310137v1
55. Dayal AK, Skupski D, Lu L, Bejerano S, Chan-Akeley R, Velagala D, et al. 980 Prevention of Obstetric Hemorrhage in Moderate and High Risk Patients: Addition of Prophylactic Misoprostol. Am J Obstet Gynecol. 2024 Jan 1;230(1):S517–8.
56. Socha MW, Flis W, Pietrus M, Wartęga M. Results of Induction of Labour with Prostaglandins E1 and E2 (The RIPE Study): A Real-World Data Analysis of Obstetrical Effectiveness and Clinical Outcomes of Pharmacological Induction of Labour with Vaginal Inserts. Pharmaceuticals. 2023 Jul;16(7):982.
57. Sanchez-Ramos L, Levine LD, Sciscione AC, Mozurkewich EL, Ramsey PS, Adair CD, et al. Methods for the induction of labour: efficacy and safety. Am J Obstet Gynecol. 2024 Mar 1;230(3, Supplement):S669–95.
58. Gallitelli V, Franco R, Guidi S, Zaami S, Parasiliti M, Vidiri A, et al. Off-label use of drugs in pregnancy: A critical review of guidelines, current practices, and a clinical perspective. Int J Gynecol Obstet [Internet]. [cited 2025 Mar 27];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/ijgo.70076
59. Pereira KV, Pacheco CO, Alves IA, Haas SE. A Systematic Patent Review (2008-2023) for Treatment in Pregnancy. Curr Med Chem. 2024 Nov 1;31(38):6288–305.
60. Arage MW. Labour Induction. In: New Aspects in Caesarean Sections [Internet]. IntechOpen; 2023 [cited 2025 Mar 27]. Available from: https://www.intechopen.com/chapters/86679
61. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BWJ, Irion O, Boulvain M. Mechanical methods for induction of labour - Jozwiak, M - 2012 | Cochrane Library. [cited 2025 Mar 27]; Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001233.pub2/abstract
62. Marconi AM. Recent advances in the induction of labour. F1000Research. 2019 Oct 30;8:F1000 Faculty Rev-1829.
63. Murano M, Chou D, Costa ML, Turner T. Using the WHO-INTEGRATE evidence-to-decision framework to develop recommendations for induction of labour. Health Res Policy Syst. 2022 Nov 7;20(1):125.

64. Vogel JP, Gülmezoglu AMM, Hofmeyr GJ, Temmerman M. Global Perspectives on Elective Induction of Labour : Clinical Obstetrics and Gynecology. [cited 2025 Mar 27]; Available from: https://journals.lww.com/clinicalobgyn/abstract/2014/06000/global_perspectives_on_elective_induction_of_labour.12.aspx
65. Levine LD, Downes KL, Elovitz MA, Parry S, Sammel MD, Srinivas SK. Mechanical and Pharmacologic Methods of Labour Induction: A Randomized Controlled Trial. Obstet Gynecol. 2016 Dec;128(6):1357.
66. Polónia-Valente R, Costa S, Coimbra C, Xavier J, Figueiredo R, Ferraz T, et al. Labour induction with a combined method (pharmacologic and mechanical): A randomized controlled trial. J Gynecol Obstet Hum Reprod. 2023 Nov 1;52(9):102649.
67. Tuuli MG, Keegan MB, Odibo AO, Roehl K, Macones GA, Cahill AG. Progress of labour in women induced with misoprostol versus the Foley catheter. Am J Obstet Gynecol. 2013 Sep 1;209(3):237.e1-237.e7.
68. Owolabi AT, Kuti O, Ogunlola IO. Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labour. J Obstet Gynaecol J Inst Obstet Gynaecol. 2005 Aug;25(6):565–8.
69. Al-Rawaf SA, Mousa ET. Comparison of Vaginal Misoprostol Alone versus a Combination of Vaginal Misoprostol and Intracervical Foley Catheter for Inducing Labour. J Obstet Gynecol Cancer Res. 2024 Jan 22;9(1):88–94.
70. Yin J, Li Y, Chen Y, Wang C, Song X. Intracervical Foley catheter plus intravaginal misoprostol compared to intravaginal misoprostol-only for cervical ripening: A systematic review and meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2023 Feb;281:76–84.
71. Rezk MAA, Sanad ,Zakaria, Dawood ,Ragab, Emarh ,Mohamed, and Masood A. Comparison of intravaginal misoprostol and intracervical Foley catheter alone or in combination for termination of second trimester pregnancy. J Matern Foetal Neonatal Med. 2015 Jan 2;28(1):93–6.
72. Sue J. The Prescription Drug Guide For Nurses. McGraw-Hill Education (UK); 2008. 232 p.
73. Dobrek L. Lower Urinary Tract Disorders as Adverse Drug Reactions—A Literature Review. Pharmaceuticals. 2023 Jul;16(7):1031.

74. Eikelder MLG ten, Meent MM van de, Mast K, Rengerink KO, Jozwiak M, Graaf IM de, et al. Women's Experiences with and Preference for Induction of Labour with Oral Misoprostol or Foley Catheter at Term. Am J Perinatol. 2016 Jun 24;34:138–46.
75. Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol–Foley catheter for labour induction. Am J Obstet Gynecol. 2003 Oct 1;189(4):1031–5.
76. Londero AP, Fichera A, Orabona R, Cagnacci A, Prefumo F. Timing of caesarean delivery for foetal heart rate abnormalities in hypertensive pregnancies induced with oral misoprostol or Foley catheter: Secondary analysis of a randomized clinical trial. Int J Gynecol Obstet. 2024;166(1):373–80.
77. Kemper JI, Li W, Goni S, Flanagan M, Weeks A, Alfirevic Z, et al. Foley catheter vs oral misoprostol for induction of labour: individual participant data meta-analysis. Ultrasound Obstet Gynecol. 2021;57(2):215–23.
78. Noor N, Ansari M, Ali SM, Parveen S. Foley Catheter versus Vaginal Misoprostol for Labour Induction. Int J Reprod Med. 2015;2015(1):845735.
79. Zheng R, Du L, Zhu X, Zhang X, Han W, Yang Z. Clinical comparison of vaginal misoprostol combined with a foley balloon versus vaginal misoprostol alone for inducing labour: a prospective cohort study. BMC Pregnancy Childbirth. 2025 Mar 15;25:295.
80. Lausman A, Kingdom J. How and when to recommend delivery of a growth-restricted fetus: A review. Best Pract Res Clin Obstet Gynaecol. 2021 Nov 1;77:119–28.
81. ten Eikelder MLG, Mast K, van der Velden A, Bloemenkamp KWM, Mol BW. Induction of Labour Using a Foley Catheter or Misoprostol: A Systematic Review and Meta-analysis. Obstet Gynecol Surv. 2016 Oct;71(10):620.
82. Kruit H, Tihtonen K, Raudaskoski T, Ulander VM, Aitokallio-Tallberg A, Heikinheimo O, et al. Foley Catheter or Oral Misoprostol for Induction of Labour in Women with Term Premature Rupture of Membranes: A Randomized Multicenter Trial. Am J Perinatol. 2016 Mar 31;33:866–72.
83. Backes C, Markham K, Moorehead P, Cordero L, Nankervis C, Giannone P. Maternal preeclampsia and neonatal outcomes. J Pregnancy. 2011;2011:214365.

84. Weyessa N, Bogale T, Ewnetu M, Goedert M, Jira L, Yenuse S, et al. Institutional Newborn Death and Associated Factors in Assossa and Metekel Zone Public Health Facilities in Benishangul Gumuze Regional State, Ethiopa [Internet]. Rochester, NY: Social Science Research Network; 2022 [cited 2025 Mar 27]. Available from: https://papers.ssrn.com/abstract=4027433
85. Fox N, Saltzman D, Roman A, Klauser C, Moshier E, Rebarber A. Intravaginal misoprostol versus Foley catheter for labour induction: a meta-analysis. BJOG Int J Obstet Gynaecol. 2011;118(6):647–54.
86. Beta J, Issat T, Nowicka MA, Jakimiuk AJ. Risk factors for caesarean section after using the Foley catheter for labour induction. Ginekol Pol [Internet]. 2013 [cited 2025 Mar 27];84(5). Available from: https://journals.viamedica.pl/ginekologia_polska/article/view/46033
87. Draycott T, van der Nelson H, Montouchet C, Ruff L, Andersson F. Reduction in resource use with the misoprostol vaginal insert vs the dinoprostone vaginal insert for labour induction: a model-based analysis from a United Kingdom healthcare perspective. BMC Health Serv Res. 2016 Feb 10;16(1):49.
88. Chavakula PR, Benjamin SJ, Abraham A, Londhe V, Jeyaseelan V, Mathews JE. Misoprostol versus Foley catheter insertion for induction of labour in pregnancies affected by foetal growth restriction. Int J Gynecol Obstet. 2015 May 1;129(2):152–5.
89. El-Halaby AED, El-Shamy ES, El-Kelani O, El-Fattah TA. Comparison between intracervical Foley catheter plus misoprostol and misoprostol alone for labour induction. Menoufia Med J. 2019 Dec 31;32(4):1393–6.
90. Gupta J, Baev O, Duro Gomez J, Garabedian C, Hellmeyer L, Mahony R, et al. Mechanical methods for induction of labour. Eur J Obstet Gynecol Reprod Biol. 2022 Feb 1;269:138–42.
91. Feltovich H, Hall TJ, Berghella V. Beyond cervical length: emerging technologies for assessing the pregnant cervix. Am J Obstet Gynecol. 2012 Nov 1;207(5):345–54.
92. Bai J, Kang X, Wang W, Yang Z, Ou W, Huang Y, et al. A multimodal model in the prediction of the delivery mode using data from a digital twin-empowered labour monitoring system. Digit Health. 2024 Sep 1;10:20552076241304934.

93. Hamilton EF, Zhoroev T, Warrick PA, Tarca AL, Garite TJ, Caughey AB, et al. New labour curves of dilation and station to improve the accuracy of predicting labour progress. Am J Obstet Gynecol. 2024 Jul 1;231(1):1–18.
94. Thayer SM, Cohen SY, Williams SAS, Stevenson L, Stewart K, Goodman B, et al. Optimizing induction of labour: the Birth Efficiency and Satisfaction Induction of Labour (BEST induction of labour) study. Am J Obstet Gynecol MFM [Internet]. 2024 Nov 1 [cited 2025 Mar 27];6(11). Available from: https://www.ajogmfm.org/article/S2589-9333(24)00233-7/abstract
95. Tarimo CS, Bhuyan SS, Zhao Y, Ren W, Mohammed A, Li Q, et al. Prediction of low Apgar score at five minutes following labour induction intervention in vaginal deliveries: machine learning approach for imbalanced data at a tertiary hospital in North Tanzania. BMC Pregnancy Childbirth. 2022 Apr 1;22(1):275.
96. D'Souza R, Ashraf R, Foroutan F. Prediction models for determining the success of labour induction: A systematic review and critical analysis. Best Pract Res Clin Obstet Gynaecol. 2022 Mar 1;79:42–54.
97. Evans K, Sands G, Spiby H, Evans C, Pallotti P, Eldridge J. A systematic review of supportive interventions to promote women's comfort and well-being during induction of labour. J Adv Nurs. 2021;77(5):2185–96.
98. Erickson EN, Gotlieb N, Pereira LM, Myatt L, Mosquera-Lopez C, Jacobs PG. Predicting labour onset relative to the estimated date of delivery using smart ring physiological data. Npj Digit Med. 2023 Aug 19;6(1):1–13.
99. Scamell M, Meades R, Foya V. Embodiment and the technologies of induction of labour. Midwifery. 2024 Nov 1;138:104144.
100. Vaan MD de, Eikelder ML ten, Jozwiak M, Palmer KR, Davies-Tuck M, Bloemenkamp KW, et al. Mechanical methods for induction of labour - de Vaan, MDT - 2019 | Cochrane Library. [cited 2025 Mar 27]; Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001233.pub3/abstract
101. Carlson N, Ellis J, Page K, Dunn Amore A, Phillippi J. Review of Evidence-Based Methods for Successful Labour Induction. J Midwifery Womens Health. 2021;66(4):459–69.
102. Bonsack CF, Lathrop A, Blackburn M. Induction of Labour: Update and Review. J Midwifery Womens Health. 2014;59(6):606–15.

103. Filho OBM, Albuquerque RM, Cecatti JG. A randomized controlled trial comparing vaginal misoprostol versus Foley catheter plus oxytocin for labour induction. Acta Obstet Gynecol Scand. 2010;89(8):1045–52.
104. Viteri OA, Tabsh KK, Alrais MA, Salazar XC, Lopez JM, Fok RY, et al. Transcervical Foley Balloon Plus Vaginal Misoprostol versus Vaginal Misoprostol Alone for Cervical Ripening in Nulliparous Obese Women: A Multicenter, Randomized, Comparative-Effectiveness Trial. Am J Perinatol. 2021 Aug;38(S 01):e123–8.
105. Priyadarshini A, Jaiswar SP, Singh A, Singh S. Comparative outcome of induced labour by intracervical Foley catheter with misoprostol versus misoprostol alone. J Comp Eff Res. 2019 Jan;8(1):55–9.

ANNEXURE

PATIENT INFORMATION SHEET

TITLE: COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA.

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY.

- Details-In patients presenting beyond 37 weeks gestation, induction of labour will be done with either 25μg intravaginal misoprostol or double foleys with misoprostol.

- Patients in this study will have to undergo complete general physical examination, obstetric examination, routine blood investigations such as complete blood count, viral serology, urine routine and random blood sugar levels. To assess the fetal wellbeing a cardiotocograph and an obstetric ultrasound with biophysical profile will also be done.

- If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

- There is no compulsion to agree to participate.you are requested to sign/provide thumb impression only if you voluntarily agree to participate in the study. All information collected from you will be kept confidential and will not be disclosed to any outsider.

- Your identity will not be revealed. You will not reveive any monetary benefits to participate in this research. This informed consent document is intended to give you a general background of study. Please read the following information carefully and discuss with your family members. You can ask your queries releated to study at any time during the study.

- If you are willing to participate in the study you will be asked to sign an informed consent form by which you are acknowlwdging that you wish to participate in the study and entire procedure will be explained to you by the study doctor.

- You are free to withdraw your consent to participate in the study anytime without explanation and this not change your future care.

- For any further clarifications you are free to contact the investigator.

Principal investigator:
Dr. T.N.A.Asritha
Choudhary.
Mobile no: 7337325739.

,

PATIENT INFORMED CONSENT FORM

SRI DEVARAJ URS MEDICAL COLLEGE & RESEARCH CENTRE, TAMAKA, KOLAR

COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA.

- I Mr./Mrs. _____have been explained in my own understandable language, that I will be included in a study which is **"COMPARISION OF INTRACERVICAL DOUBLE FOLEYS CATHETER VS INTRAVAGINAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR IN MULTIGRAVIDA** have been explained that my clinical findings, investigations findings will be assessed and documented for study purpose.
- I have been explained my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.
- I have been explained about the interventions needed possible benefits and adversities due to interventions, in my own understandable language.
- I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.
- I have principal investigator mobile number for enquiries.
- I in my sound mind give full consent to be added in the part of this study.

Signature of the patient:	Signature of the witness:
Name:	Name:
	Relation to patient:
Date:	Date:
Place:	Place:

Investigator signature:

(Signature & Name of Pt. Attendant) (Signature/Thumb impression & Name of patient) (Relation with patient)

Witness 1:

Witness 2:

(Signature & Name of Research person /doctor)

PROFORMA

Personal Details:

NAME:

AGE:

IP NO.:

DATE OF ADMISSION:

DATE OF DELIVERY:

DATE OF DISCHARGE:

OBSTETRIC SCORE:

ADDRESS:

PHONE NO:

BOOKED/ UNBOOKED:

LMP:

EDD:

GESTATIONAL AGE:

CHIEF COMPLAINTS:

OBSTETRIC HISTORY:

PRESENT PREGNANCY: T1

T2

T3

MARITAL H/O:NCM/CM

MENSTRUAL H/O:

PAST HISTORY:

FAMILY HISTORY:

PERSONAL HISTORY:

GENERAL EXAMINATION:

SYSTEMIC EXAMINATION:

PALLOR/ICTERUS/CYANOSIS/CLUBBING/LYMPHADENOPATHY/EDEMA.

CVS:

RS:

VITALS:

PR-

BP-

PER ABDOMINAL EXAMINATION:

DIAGNOSIS:

INDICATION FOR INDUCTION:

DATE & TIME OF INDUCTION:

PV & MODIFIED BISHOP SCORE:

REVIEW PV &MODIFIED BISHOP SCORE:

INDUCTION TO ACTIVE PHASE INTERVAL:

INDUCTION- DELIVERY INTERVAL:

OYTOCIN ACCELERATION:YES /NO:

DATE AND TIME OF DELIVERY:

WOMEN DELIVERED: <24HOURS / 24 - 48HOURS / >48HOURS

MODE OF DELIVERY: LABOUR
/ FORCEPS/ VACUUM / CAESAREAN

INDICATION FOR CAESAREAN: FAILED INDUCTION/ FETAL DISTRESS
/ NON PROGRESS OF LABOUR
BABY DETAILS:

MALE/ FEMALE

BIRTH WEIGHT:

APGAR SCORE: 1' - 5' –

NICU ADMISSION: YES / NO, IF YES REASON FOR ADMISSION

PN STAY AND FOLLOW UP:

ರೋಗಿಗಳ ಮಾಹಿತಿ ಹಾಳೆ:

- ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: ಮಲ್ಟಿ ಗ್ರಾವಿಡಾದಲ್ಲಿ ಪ್ರಸವ ಪ್ರಚೋದನೆಗಾಗಿ ಇಂಟ್ರಾ ಸರ್ವಿಕಲ್ ಡಬಲ್ ಫೋಲೀ ಬಲೂನ್ ಕಯೂಥೆಟರ್ ಗೂ ಇಂಟ್ರಾ ವಾಜಿನಲ್ ಮಿಸೋಪ್ರೊಸ್ಟೋಲ್ ನ ಹೋಲಿಕೆ
- ಅಧ್ಯಯನದ ಸ್ಥಳ: ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಕೋಲಾರ.
- ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ, ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಟಮಕ ಕೋಲಾರ
- ವಿವರಣೆ: ೩೭-೪೨ ವಾರಗಳ ಗರ್ಭಾವಸ್ಥೆಯನ್ನು ಹೊಂದಿರುವ ರೋಗಿಗಳಲ್ಲಿ, ಹೆರಿಗೆಯ ಪ್ರಚೋದನೆಯನ್ನು ೨೫ug ಇಂಟ್ರಾ ವಾಜಿನಲ್ ಮಿಸೋಪ್ರೊಸ್ಟೋಲ್ ಅಥವಾ ಮಿಸೋಪ್ರೊಸ್ಟೋಲ್ ನೊಂದಿಗೆ ಡಬಲ್ ಫೋಲೆ ಬಲೂನ್ ನೊಂದಿಗೆ ಮಾಡಲಾಗುತ್ತದೆ.
- ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ಸಂಪೂರ್ಣ ಸಾಮಾನ್ಯ ದೈಹಿಕ ಪರೀಕ್ಷೆ, ಪ್ರಸೂತಿ ಪರೀಕ್ಷೆ, ಸಂಪೂರ್ಣ ರಕ್ತದ ಎಣಿಕೆ, ವೈರಲ್ ಸ್ಥಿತಿ, ಮೂತ್ರದ ದಿನಚರಿ ಮತ್ತು ಯಾದೃಚ್ಛಿಕ ರಕ್ತದ ಸಕ್ಕರೆಯಂತಹ ಸಾಮಾನ್ಯ ರಕ್ತ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಗಾಗುತ್ತಾರೆ. ಯೋಗಕ್ಷೇಮವನ್ನು ನಿರ್ಣಯಿಸಲು ಕಾರ್ಡಿಯೋಟೋಕೋಗ್ರಾಫ್ ಮತ್ತು ಬಯೋಫಿಸಿಕಲ್ ಪ್ರೊಫೈಲ್ ನೊಂದಿಗೆ ಪ್ರಸೂತಿಯ ಅಲ್ಟ್ರಾಸೌಂಡ್ ಅನ್ನು ಸಹ ಮಾಡಲಾಗುತ್ತದೆ.
- ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ, ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮ್ಮಿಂದ ಅಥವಾ ಜವಾಬ್ದಾರರಾಗಿರುವ ವಯಸ್ಕರಿಂದ ಮಾಹಿತಿಯನ್ನು (ಪ್ರಮಾಣಿತ ಪ್ರಶ್ನಾವಳಿ ಪ್ರಕಾರ) ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಬಂಧಿತ ಇತಿಹಾಸವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ಭಾ

• ಒ ಗ್ವಹಿಸಲು ಫ್ಪ ಪ್ ಕಳಳ ಖಲು ಯಾವುದೇ ತ್ತು ಯವಿಲ್ಟ . ನಿ ಜ ೋವು ಸವ

ಭಾ ಯಂಪ್ ಾಿ ಾ ಜ ೋರಣೆಯಿಂದ ಅ್ಯ ಯನದಲ್ಲಿ ಗ್ವಹಿಸಲು ಪ್ಪೆ ಪ್ವರೆ ಮಾತ್ ಾ ಹಚು ಬರಳಿನ ಗುರುತ್ತನ ನ ಸಹಿ ಮಾಡಲು/ ದಗಿಸಲು ನಿಮಮ ನ್ನು ವಿನಂತಿಸಲಾಗಿದೆ. ನಿಮಿಮ ಾ ಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲಾ ಾಪ ಮಾಹಿತಿಯನ್ನನ ಗೌಪ್ಯ ವಾಗಿ ಇರಿಸಲಾಗುತ್ ಾಇ ದೆ ಮತ್ತು ಯಾವುದೇ ಹರಗಿನವರಿಗೆ ಬಹಿರಂಗ್ಪ ಾ ಡ ಸಲಾಗುವುಲ್ಟ .

• ನಿಮಮ ಗುರುತ್ತನ ನ ಬಹಿರಂಗ್ಪ ಾ ಡಸಲಾಗುವುಲ್ಟ . ಈ ಸಂಶೋಧ್ನನ ಯಲ್ಲಿ ಭಾ ಗ್ವಹಿಸಲು ನಿ ಜ ೋವು ಯಾವುದೇ ವಿತಿಃ ಾ ಜ ೋಯ ಪ್ ಾ ಯೋಜನಗ್ಳನ್ನನ ಮರುಪ್ಡಡ ಯುವುಲ್ಟ . ಈ ತಿಳುವಳಿಕೆಯುಳಳ ಸಮಮ ತಿಯ ಡಾಕುಯ ಯ ಮಂಟ್ ನಿಮಗೆ ಸಿ ಮಾನಯ ಅ್ಯ ಯನದ ಹಿನೆಃ ಲೆಯನ್ನನ ನಿ ಜ ೋಡಲು ಉದೆ ಾ ಜ ೋಶಸಲಾಗಿದೆ. ದಯವಿಟ್ಟಿ ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನನ ಎಚಚ ರಿಕೆಯಿಂದ ಓ್ಡ ಮತ್ತು ನಿಮಮ ಕಯಟಿ ಂಬ ಸದಸಯ ರಂ್ದಗೆ ಚಚ್ಚಿ ಸು . ಅ್ಯ ಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇಸಮಯದಲ್ಲಿ ಅ್ಯಯನಕೆಕ ಸಂಬಂಧಿಸು ದನಿಮಮ ಪ್ ಾ ಶ್ನು ಗ್ಳನ್ನನ ನಿ ಜ ೋವು ಕಳಬಹುದು

• ನಿ ಜಭ ೋವು ಅ್ಯ ಯನದಲ್ಲಿ ಗ್ವಹಿಸಲು ಸು ದಧ್ ರಿದಾ ರೆ ತಿಳುವಳಿಕೆಯುಳಳ ಸಮಮ ತಿಯ ನಮೂನೆಗೆ ಸಹಿ ಹಾಕಲು ನಿಮಮ ನ್ನು ಕಳಲಾಗುತ್ ಾಇ ದೆ ಮತ್ತು ಅದರ ಮೂಲ್ಕ ನಿ ಜ ೋವು ಅ್ಯ ಯನದಲ್ಲಿ ಗ್ವಹಿಸಲು ಬಯಸ್ತತಿಃ ಾ ಜ ೋರಿ ಎಂದು ಫ್ಪ ಪ್ ಕಳುಳ ತಿಃ ಾ ಜ ೋರಿ ಮತ್ತು ಸಂಪೂರ್ ಾಪ ಕಯ ಯಿವಿಧ್ನವನ್ನನ ಅ್ಯ ಯನ ವೈದಯ ರು ನಿಮಗೆ ವಿವರಿಸ್ತತ್ತು ರೆ.

• ವಿವರಣೆಯಿಲ್ಟ ದೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅ್ಯಯನದಲ್ಲಿ ಭಾ ಗ್ವಹಿಸಲು ನಿಮಮ ಒ

ಫ್ಪಪ್ ಗೆಯನ್ನನ ಹಿಂಪ್ಡಡ ಯಲು ನಿ ಜ ೋವು ಸವ ತಂತ್ ಾ ರಾಗ್ದಿ ಾ ಜ ೋರಿ ಮತ್ತು ಇದು ನಿಮಮ ಭವಿಷ್ಯ ದ ಕಳಜಿಯನ್ನನ ಬದಲಾಯಿಸ್ತವುಲ್ಟ .

• ಯಾವುದೇ ಹಚಿ ಚ ನ ಸಪ್ ಷ್ಿ ಾ ಜ ೋಕರಗ್ ಿಳಿಗ್ ಾ ಗಿ ನಿ ಜ ೋವು ತಿ ಖಾಯ ಯ ರಿಯನ್ನನ ಸಂಪಿ ಸಲು ಮುಕು ರಾಗ್ದಿ ಾ ಜ ೋರಿ.

• ಪ್ ಾ ಧ್ನನ ತಿ ಖಾಯ ಯ ರಿ: ಡಾ. ಟ್ವನಾಟ ಆಶಾ ಾತ್ ಮೊಬೈಲ್ ಸಖ್ಯ ಯ : 7337325739. ಚೌಧಾ .

ಮಾಹಿತಿನೋಡಿದಒಪ್ಪಿ ಗೆನಮೂನೆ

- ಶಾ ಂಶ್ಯೋ ದೇವರಾಜ್ ಅರಸ್ತ ವೈದಯ ಕೋಯ ಕ ಯೋಜು ಮತ್ತು ಸಂಶೋಧ್ನನ ಕಂದಾ , ಕ್ಷ, ಕೋಲಾರ
- ಮಲ್ಟಿ ಗ್ರಾವಿಡಾದಲ್ಟಿ ಪ್ಂಶ ಸವ ಪ್ಂಶ ಚೋದನೆಗ್ಂಶ ಗಿ ಇಂಟ್ರಾ ಸವಿಾಕಲ್ ಡಬಲ್ ಫ್ಲೋಲ್ಟಿ ರೋಸ್ ಕಯು ಥೆಟರ್ VS ಇಂಟ್ರಾವಾಜಿನಲ್ ಮಿಸೊಪ್ರಾ ಸೊಂಶ್ಯಾ ಂಶ್ಯೋನ್ನ ಹೋಲ್ಟಿಕೆ • ರೋಗಿಯ ಫ್ಲಪ್ ಗೆ
- ಪ್ಂಶ ಕರರ್ ಸಂಖ್ಯೆಯ :

- ನಾನು ಮೇಲ್ಟಿನ ಮಾಹಿತಿಯನ್ನನ ಓದಿದೆ ಂಶ್ಯೋನೆ ಅಥವಾ ಅದನ್ನನನನಗೆ ಓದಲಾಗಿದೆ ಮತ್ತುನನ್ನ ಸವ ಂಶಂತ್ ತಿಳುವಳಿಕೆ ಷೆಯಲ್ಟಿ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ಅದರ ಬಗೆಂ´ ಪ್ಂಶ ಶ್ನೆ ಗ್ಳನ್ನನ ಕಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ ಮತ್ತುನಾನು ಕಳಿದ ಯಾವುದೇ ಪ್ಂಶ ಶ್ನೆ ಗ್ಳಿಗೆ ನನ್ನ ತೃಪ್ತಿಕರ ಗೆ ಉತ್ಂಶರ ರಿಸಲಾಗಿದೆ. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಟಿ ಯಾವುದೇ ಸಮಯದಲ್ಟಿ ಫ್ಲಪ್ ಗೆಯನ್ನನ ನಿರಾಕರಿಸ್ತವ ಅಥವಾ ಅದನ್ನನ ಹಿಂತ್ಂಶ ಗೆದುಕಳ್ಳುಳ ವ ಹಕ್ಕ ನ್ನು ನಾನು ಹಂಂದಿದೆ ಂಶ್ಯೋನೆ ಮತ್ತು ಇದು ನನ್ನ ಚಿ ಕಿತ್ಸಾ ಯ ಮೇಲೆ ಯಾವುದೇ ರಿಣಾಮ ಬೋರುವುಂದಿಲ್ಟ ಎಂದು ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳಸಮಮ ತಿ ನಮೂನೆಯ ಪ್ಂಶ ತಿಯನ್ನನ ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನನಗ್ವಹಿಸ್ತವವರಿಗೆ ದಗಿಸಲಾಗಿದೆ.

- ನಾನು ಅಧಿಮಾಡಿಕಂಡಿದೆ ಂಶ್ಯೋನೆ ಈ ಅಧ್ಯಯನದಲ್ಟಿ ಗ್ವಹಿಸಲು ನಾನು ಸವ ಯಂಪ್ಂಶ ಂಶ್ಯೋರಣೆಯಿಂದ ಸಮ ಮತಿಸ್ತತ್ತಾ ಂಶ್ಯೋನೆ

- ನಾನು ಅಧಿಮಾಡಿಕಂಡಿದೆ ಂಶ್ಯೋನೆ. ಈ ಅಧ್ಯಯನದಲ್ಟಿ ಗ್ವಹಿಸಲು ನಾನು ಸವ ಯಂಪ್ಂಶ ಂಶ್ಯೋರಣೆಯಿಂದ ಸಮ ಮತಿಸ್ತತ್ತಾ ಂಶ್ಯೋನೆ

- ಫ್ಟ್ಟ. ಅಟಂಡಂಟನ ಸಹಿ ಮತ್ತು ಹೆಸರು)

(ಸಹಿ/ಹೆಬಬ ಬ ರಳಿನ ಗುರುತ್ು ಮತ್ತು ರೋಗಿಯ ಹೆಸರು) (ರೋಗಿಯಂØಗಿನಸಂಬಂಧ್)

- ಸಿ ಕೆ 1:
- ಸಿ ಕೆ 2

(ಸಂಶೋಧ್ನನ ವಯ ಕು/ವೈದಯ ರ ಸಹಿ ಮತ್ತು ಹೆಸರು)