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JCHR (2024) 14(3), 3313-3321 | ISSN:2251-6727

Evaluation of Impact of Combinational Approach of Pharmacological and Non-Pharmacological Methods of Labor Induction in Mother Safety

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(Received: (04 February 2024 Revised: 11 March 2024 Accepted: 08 April 2024)						
	ABSTRACT						
KEYWORDS	Introduction:						
Cervical status, combined, Induction of labor, non- pharmacological, pharmacological, PV findings, success rate	Induction of labor involves a variety of methods, such as pharmacological, non-pharmacological (mechanical), and combination techniques. The possible advantages of combining methods highlight the need for further research to enhance labor induction techniques. Objective:						
	The objective of the present study was to evaluate the effects of combining oxytocin with Foley's catheter and stripping of membrane on the health outcome of the mother.						
	Methods: This study was an observational clinical study conducted in the Rising Medicare Hospital, Kharadi, Pune, Maharashtra, India between 11 th March 2021 to 12 th September 2023. Pregnant women were divided into three groups according to the induction techniques used as pharmacological, non-pharmacological, and combined methods of IOL. Data analysis was done using IBM SPSS Statistics version 20.						
	Results: The present study involved 296 pregnant women who underwent labor induction. The combined methods of IOL showed the highest 66.71 % normal delivery rates and 15.71 % instrumental (vaginal) delivery rates compared to both pharmacological 53.1 % and non pharmacological 49.0 % with negligible instrumental (vaginal) delivery rates. Combined method showed very less (1.57 %) chances of C-section (LSCS) rates than both pharmacological (43.35 % as well as non-pharmacological methods of IOL (49.06 %).						
	Conclusion: The combined methods showed a 75 % success rate within 12 hours of initiation of the dose of induction of labor and are highly significant for achieving a normal mode of delivery with fewer maternal complications. Further research is needed to optimize these combined methods for improved maternal health outcomes.						

1. Introduction:

Induction of labor is a common procedure in modern obstetrics since it is frequently performed to prevent unfavorable neonatal and maternal outcomes [1]. The procedure involves stimulating uterine contractions to facilitate delivery before the onset of natural labor [2-4]. According to research, 20 % to 25 % of all deliveries are preceded by labor induction, making it a common obstetric technique [4 & 5]. It is indicated when the



continuation of the pregnancy poses a great danger to the well-being of the mother, neonate, or both [6].

The pharmacological method of induction of labor is achieved frequently using prostaglandin E1 (misoprostol), prostaglandin E2 (dinoprostone), and oxytocin a hormone [7 & 8] along with nonpharmacological (mechanical) methods like Foley catheter and stripping of the membrane [9 & 10] to assist ripen the cervix and cause contractions to speed up the start of labor. The potential synergistic effects seen when non-pharmacological (mechanical) and pharmacological treatments are merged to support the induction process serve as reasons for the investigation of combination methods [11]. Nonetheless, there is constant conflict on the effectiveness of these combinations, as seen by the inconsistencies in the findings of research comparing various induction techniques [12]. A mixed technique used for labor induction is the combination of oxytocin, membrane stripping, and Foley's catheter. Prior studies have demonstrated the importance of nonpharmacological (mechanical) techniques such as the Foley catheter in cervical ripening and the onset of labor. It is also possible that these techniques could improve the efficacy of pharmacological medicines like oxytocin Prostaglandins and mechanical [13]. dilatation techniques have been recommended as possible ways of

Study design:

reducing the rate of induction failure as well as improving the advancement of labor because of their combined effect on cervical ripening [14]. Despite of this many researchers clearly stated that there is a lack of comprehensive studies on the combination techniques for inducing labor [15-17]. Comparative studies are required to examine various combination strategies, such as misoprostol [18 & 19], and oxytocin with mechanical methods. Enhancing maternal and neonatal healthcare needs research on the long-term results, safety, effectiveness, and patient preferences of combination induction methods. [20-23] Studies have also examined the connection between the combined technique of labor induction and outcomes like cesarean birth and failed induction rates [24]. The current literature on the induction of labor using combined methods found several gaps in knowledge and areas that warrant further investigation.

2. Objectives:

The objective of the study was to evaluate the effects of combination induction approaches, namely oxytocin administered with membrane stripping and oxytocin administered with a Foley catheter a blend of pharmacological and non-pharmacological (mechanical) labor induction methods to offer insights regarding the most effective method for labor induction.



Figure 1 Study flow

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3. Methods:

This study was an observational type of study conducted in Rising Medicare Hospital in Kharadi, Pune, Maharashtra, India, between 11th March 2021 and 12th September 2023. It was approved by the hospital ethics committee approval number: ECR/1578/Inst/MH/2021, date of registration was 30 September 2021. Patients were explained the study by a trained healthcare provider before the start of the induction process and written consent was obtained from those who were willing to participate in the study. Standardized protocol of induction and active phase management was followed throughout the study. The first group named "pharmacological methods" considered women induced with 25 ug and 50 ug misoprostol respectively and 0.5 mg dinoprostone gel. The second group named "nonpharmacological (mechanical) methods" included women induced using transcervical Foley catheter filled with 30 cc normal saline and stripping of membrane. All interventions were administered intracervically. The third group named the combined methods group employed a blend of pharmacological and nonpharmacological methods for the induction of labor (IOL). This cohort included women who were induced using a transcervical Foley catheter (14 F) filled with 30 cc normal saline, coupled with the administration of oxytocin at an initial dose of 2 milliunits every 15 minutes, increasing up to a maximum of 40 milliunits via the intravenous route. Additionally, stripping of the membrane was performed in conjunction with oxytocin administration under the same dosing regimen [11]. Every six hours, the dose was repeated until the desired Bishop score and uterine contraction were attained. Cesarean delivery is performed by healthcare providers if the patient is in labor (>4 cm dilated and at least 90% or > 5 cm dilated) after 36 hours of cervical ripening or after 12 hours of activation. Data analyses were done by using IBM SPSS Statistics version 20.

Participant selection criteria:

Inclusion Criteria: All the pregnant women above 18 years of age were admitted to the labor room and who were expected to undergo induction.

Exclusion Criteria: Less than 37 weeks of gestation; scarred uterus (previous surgery on the uterus, i.e., cesarean delivery); twin's pregnancy; breech presentation; and fetal anomalies.

Statistics used:

In the data analysis, categorical variables were compared with Pearson's Chi-square test, and the importance of independent variables was assessed with likelihood ratio tests. Logistic regression models utilize Nagelkerke R^2 to determine explained variation, while multivariate logistic regression examines relative risks for ineffective labor induction techniques, and binomial logistic regression assesses event probabilities like PV results. Statistical significance was determined at p < 0.05.

Outcome measures assessed:

In the present study the following maternal outcomes were assessed: cervical status and bishop score as per Vaginal Examination (PV) findings, the success rate of induction, cesarean section (LSCS) rate, normal delivery rates, postpartum hemorrhage, perineal tear, and mother satisfaction to evaluate the effectiveness of the interventions.

4. **Results and discussion:**

There were a total of 680 women admitted to the labor room during the study period from 11th March 2021 to 12th September 2023. Of them, 187 denied participating, whereas 197 participants were excluded from the study as they were not fitting the inclusion criteria. The final count was 296 women who met the eligibility criteria and were willingly ready to participate were enrolled in the study.

All the patients enrolled were from the same demographic and clinical characteristics.

Presentation of findings regarding the efficacy of each induction method:

Out of 296 participants, 58.45% received pharmacological methods of induction of labor (IOL), a smaller subset of patients 17.91% of the total were treated with non-pharmacological methods of IOL whereas, combined methods of IOL to handle 23.65% of the subjects.

Statistical description:

Table 1 Model Summary

-2 Log likelihood	Nagelkerke R Square
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For the interpretation and reporting of the results from a Binomial Logistic Regression Analysis, Table 1 displays that the Nagelkerke R^2 value was 66.5%. It revealed that the variation in the dependent variable is accounted for by the model.

Binomial logistic regression is utilized to estimate the probability of an event, such as positive cervical status as per PV findings. If the estimated probability exceeds 0.5, the event is classified as occurring (e.g., favorable cervical status as per PV findings); if it is below 0.5, the event is classified as not occurring. This method is commonly employed to predict correct classification based on independent variables, necessitating an assessment of the predicted classification against the actual classification.

Observed		Predicted					
		Cervical status a	Percentage				
		Not Favorable	Favorable	Correct			
Cervical Status after 1 st dose	Not Favorable	97	29	77.0 %			
	Favorable	15	155	91.2%			
Overall Percentage				85.1%			

 Table 2 Classification Table

The percentage of correct predictions was 85.1% at the base of the table. This indicated that for the 296 observations (females) used in this model, the model

correctly predicted whether cervical status as per PV examination findings favored 85.1% of the time.

Cervical status as per PV (Per Vaginal) findings:

Cervical favorability as per PV findings after first dose											
Method	Not Fav	vorable	Favorable		Subtotal						
	Subjects	%	Subjects	%	Subjects	%					
Pharmacological	85	49.1%	88	50.9%	173	100.0%					
Non- Pharmacological	26	49.1%	27	50.9%	53	100.0%					
Combined	15	21.4%	55	78.6%	70	100.0%					

Table 3 Cervical status 6 hours after initiation of induction process

It was observed that for the combined method of induction, 78.6% of cervical rate (PV findings) were favorable compared to pharmacological and non-pharmacological methods.

Testing of Hypothesis:

 H_0 : Different methods of labor induction and cervical status as per PV findings is independent against each other

H₁: Different methods of labor induction and cervical status as per PV findings are dependent on each other.

The reported $\chi 2=16.758$ with df 2 and p value is 0. H₀ is rejected and there is dependence on cervical status as per PV findings because of interrelated methods.

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Result of induction after first dose							
	Faile	ed	Succes	sful	Subtotal		
Method							
Wiethou	Subject	%	Subject	%	Subjec	%	
	S		S		ts		
Pharmacological	41	23.7	132	76.3	173	100.0	
		%		%		%	
Non-	4	7.5%	49	92.5	53	100.0	
Pharmacological				%		%	
Combined	6	8.6%	64	91.4	70	100.0	
				%		%	

Table 4 Comparison of Result of first dose and Method of induction

The success rate of the combined labor induction approach was 91.43%, which was similar to the non-pharmacological method's success rate 92.5% compared to 76.3% of pharmacological method.

Explanation: The non-pharmacological method's increased success rate can be ascribed to its utilization in patients who are in an active or partially active phase of

labor already. As opposed to the non-pharmacological strategy, the pharmacological approach is frequently used for patients who are in inactive phases of labor induction, showing 0 cm dilation or intact OS, and due to this there are chances of lower success rate. Thus, we can say that the stage of labor at which labor induction techniques are used affects their efficacy.

 Table 5 Comparison of result of induction and cervical status (PV examination findings) after first dose of induction of labor

		Result of first dose					
		Faile	ed	Succe	essful	Subt	otal
		Subjects	%	Subjects	%	Subjects	%
Cervi cal	Not Favorable	51	40.5%	75	59.5%	126	100.0%
after 1 st dose	Favorable	0	0.0%	170	100.0%	170	100.0%

From the table 5, it was observed the results of the first dose were strongly correlated with the various labor induction strategies (pharmacological, nonpharmacological, and combined approaches), as demonstrated by $\chi 2=12.242$, df=2, and p-value=0.002, which resulted to the null hypothesis being rejected. At the 5% level of significance, the null hypothesis was rejected due to the substantial correlation that was

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discovered between the results of the cervical status as per PV examination and the first dose, as evidenced by $\chi 2=83.133$, df=1, and p-value=0.

Table 6 Comparison of cervical status (PV findings) with result after second induction dose

Result of 2 nd induction dose										
		Fail	led	Succe	essful	Subt	otal			
		Count	Percent age	Count	Percenta ge	Count	Percenta ge			
Cervical	Non-favorable	30	100.0%	0	0.0%	30	100.0%			
2^{nd} dose	Favorable	1	3.3%	29	96.7%	30	100.0%			

Furthermore, a satisfactory outcome with the second dosage was 96.7% which significantly correlated with the favorable cervical state (PV examination findings), with a $\chi 2=56.129$, df=1, and p-value=0 statistical analysis, the null hypothesis was rejected, suggesting a

substantial correlation between the results of the cervical status and bishop score as per PV examination finding following the administration of the second dose and the outcome.

Table 7 Comparison of cervical status (PV findings) and Result after third induction dose

			Result of 3 rd dose					
		F	ailed	Successful				
		Count	Percentage	Count	Percentage			
Cervical status	Non-favorable	11	100.0%	0	0.0%			
after 3 rd dose	Favorable	0	0.0%	8	100.0%			

It was observed that successful results of the 3^{rd} dose were 100% associated with favorable cervical status and the bishop score as per PV findings. The reported χ^2 was 19, df 1, and p value was 0. The null hypothesis was rejected. Thus, from the above findings it was concluded that there is a strong association between cervical status and bishop score as per PV examination findings after administration of the third dose and the result of the third dose.

Result of Induction:

able of Result of madelion of fabor	Table 8	Result	of Ind	uction	of	labor
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	Result of Induction					
	Failed		Successful		Aborted	
Methods	Count	%	Count	%	Count	%

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Pharmacological	21	12.10%	131	75.70%	2	1.20%
Non-Pharmacological	6	11.30%	33	62.30%	0	0.00%
Combined	6	8.60%	61	87.10%	0	0.00%

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It was observed that combined method of induction yielded 87.1% successful results, indicating normal delivery. This showed that the combined method of induction is highly significant for achieving a normal mode of delivery.

Explanation: The success of labor induction is termed as the starting of the initiation of the labor pains which are continuous, periodical (at regular intervals), and moderate to strong strength that are considered positive

results. The result of induction of labor is defined as the type of childbirth. There were two indicators first Success rate of IOL and second was failure of IOL as well as the patient aborted from the IOL process. Ultimately the patients from second indicators were shifted to cesarean section. As per the data from the above table, the combined methods of IOL showed a higher success rate than the other two methods and the combined methods of IOL showed fewer patients to shift to cesarean (LSCS).

	I I I				j	
			Mode of o	delivery		
	Normal (Vaginal) Instrumental (Vaginal) LSCS (Caesarea					
Methods	Subjects	%	Subjects	%	Subjects	%
Pharmacological	92	53.2%	6	3.5%	75	43.4%
Non- Pharmacological	26	49.1%	1	1.9%	26	49.1%
Combined	46	65.7%	11	15.7%	13	18.6%

Table 9 Comparison of Methods of IOL wise mode of delivery

It was observed that combined method of induction produced 65.7% successful results, indicating normal delivery with negligible postpartum hemorrhage 5.71% compared to pharmacological methods of IOL 10.55% and Non-pharmacological methods of IOL 15.09%. This showed that the combined method of induction is highly significant for achieving a normal mode of delivery.

Explanation: Postpartum hemorrhage (PPH) is a serious complication that can occur during or after childbirth. In pharmacological methods, the rate of PPH was found to be 10.9%, while in non-pharmacological methods, the rate was higher at 15.09%. However, when both methods were combined, the incidence of PPH was much lower, at only 5.71%.

The combined methods of IOL showed the highest rates of perineal tears 8.57% than pharmacological methods of

IOL which showed 2.89 % of perineal tears and nonpharmacological methods of IOL presented very less i.e. 1.89 % of perineal tears.

Explanation: This result can be caused by higher vaginal delivery success rates associated with these methods, which require perineal tearing during labor, especially when the baby's head comes through the vaginal opening. Thus, even though perineal tears tend to occur during labor, it was found that the combined approach of induction is optimal to ensure a normal (vaginal) delivery [15]. Additionally, from the study, it was observed that the combined method of induction reduces the chances of admitting women to the ICU.

Whereas, as per the patient's satisfaction rate, we found contradictory results, the women receiving nonpharmacological (mechanical) labor induction

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techniques showed better rates of maternal satisfaction compared to pharmacological procedures. Combined methods showed near results of patient satisfaction with the non-pharmacological (mechanical) approach.

Explanation: This is because pharmacological procedures usually require multiple doses to induce labor pain and more time for delivery. The non-pharmacological approaches, which were started after the commencement of labor pain and with some cervical dilation, resulted in satisfactory shorter procedure initiation and delivery times [25].

Limitations of the study and suggestions for future research:

1. Small Sample Size: The study had a limited sample size, potentially impacting the generalized ability of the findings.

2. Lack of multicenter data: The study has included data from one hospital

3. Different ways of outcomes lead to a difficult comparison of methods

5: Conclusion:

In the present study, the integration of combined labor induction methods has demonstrated promising results in optimizing maternal output. The findings underscore the importance of personalized and comprehensive approaches to labor induction, emphasizing the need for further research to refine and optimize these combined methods for improved maternal and neonatal health outcomes.

Conflicts of interest: No conflicts of interest.

Funding: NIL

Acknowledgment: The authors express their gratitude to Dr. Vinod M. Bharati, the director of Rising Medicare Hospital in Kharadi, Pune, for his invaluable guidance and expertise in obstetrics and gynecology. We also wish to thank Dr. Raosaheb Latpate of the Statistical Department at Savitribai Phule University, Pune, for giving us extended access to the statistical tools needed for this investigation. We extend our sincere gratitude to Mr. S. A. Thopate, President of Rajgad Dnyanpeeth College of Pharmacy, for providing the resources required to enable this investigation. Author's contributions: All authors have contributed equally.

References:

- Haavaldsen C., Morken N., Saugstad O., & Eskild A. Is the increasing prevalence of labor induction accompanied by changes in pregnancy outcomes? an observational study of all singleton births at gestational weeks 37–42 in norway during 1999– 2019. Acta Obstetricia Et Gynecologica Scandinavica 2022;102(2):158-173.
- Kuczera A., Opala-Berdzik A., Malá J., Sodowski M., & Chmielewska D. Comparison of first childbirth characteristics between elite judo athletes and non-athletes: the preliminary retrospective case-control study. International Journal of Environmental Research and Public Health 2022;19(20):13218.
- Amrin S., Mukherjee S., Singh J., & Gupta S. A comparative study of sublingual and vaginal low dose misoprostol for induction of labor. International Journal of Contemporary Medical Research [IJCMR] 2020;7(2).
- Bączek G., Rzońca E., Rzońca P., Rychlewicz S., Budner M., & Bień A. Retrospective analysis of the factors affecting the induction of childbirth in 4350 women from a single center in warsaw, poland. International Journal of Environmental Research and Public Health 2022;19(15):9540.
- Na E., Chang S., Ahn E., Jung S., Kim Y., Jung I. et al. Pregnancy outcomes of elective induction in lowrisk term pregnancies. Medicine 2019;98(8):e14284.
- Anikwe CC, Okorochukwu BC, Uchendu E, Ikeoha CC. The Effect of Ultrasound-Measured Preinduction Cervical Length on Delivery Outcome in a Low-Resource Setting. Scientific World Journal. 2020;2020:8273154. Published 2020 May 1.
- Chaves F. and Aragão J. Misoprostol use in obstetrics. Cadernos UniFOA 2018;13(38):121-127.
- Sanchez-Ramos, L., Levine, L. D., Sciscione, A. C., Mozurkewich, E. L., Ramsey, P. S., Adair, C. D., Kaunitz, A. M., & McKinney, J. A.. Methods for the induction of labor: efficacy and safety. American journal of obstetrics and gynecology.2024;230(3S), S669–S695.

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JCHR (2024) 14(3), 3313-3321 | ISSN:2251-6727

- Hassan A. Membrane sweeping to induce labor in post-term pregnant women: success rate and outcomes. Cureus 2023.
- Ehikioya E., Nwachukwu O., & Okobi O. Effectiveness of single fetal membrane sweeping in reducing elective labor induction for postdate pregnancies (38+0 to 40+6 weeks): a randomized controlled trial. Cureus 2024.
- Levine L., Downes K., Elovitz M., Parry S., Sammel M., & Srinivas S. Mechanical and pharmacologic methods of labor induction. Obstetrics & Amp; Gynecology 2016;128(6):1357-1364.
- Chung J., Huang W., Rumney P., Garite T., & Nageotte M. A prospective randomized controlled trial that compared misoprostol, foley catheter, and combination misoprostol–foley catheter for labor induction. American Journal of Obstetrics and Gynecology 2003;189(4):1031-1035.
- Gilstrop M. and Sciscione A. Induction of labor pharmacology methods. Seminars in Perinatology 2015;39(6):463-465.
- 14. Osoti A., Kibii D., Tong T., & Maranga I. Effect of extra-amniotic foley's catheter and vaginal misoprostol versus vaginal misoprostol alone on cervical ripening and induction of labor in kenya, a randomized controlled trial. BMC Pregnancy and Childbirth 2018;18(1).
- Mozurkewich E., Chilimigras J., Berman D., Perni U., Romero V., King V. et al. Methods of induction of labour: a systematic review. BMC Pregnancy and Childbirth 2011;11(1).
- Lim C., Ng R., & Xu K. Non-hormonal methods for induction of labour. Current Opinion in Obstetrics &Amp; Gynecology 2013;25(6):441-447.
- Carlson N., Ellis J., Page K., Amore A., & Phillippi J. Review of evidence-based methods for successful labor induction. Journal of Midwifery &Amp; Women's Health 2021;66(4):459-469.
- Mackenzie I. Induction of labour at the start of the new millennium. Reproduction 2006;131(6):989-998.
- Evans, K., Sands, G., Spiby, H., Evans, C., Pallotti, P., & Eldridge, J. A systematic review of supportive interventions to promote women's comfort and wellbeing during induction of labour. Journal of Advanced Nursing. 2020 77(5), 2185-2196.
- 20. Boateng E., Kumi L., & Diji A. Nurses and midwives' experiences of using non-

pharmacological interventions for labour pain management: a qualitative study in ghana. BMC Pregnancy and Childbirth 2019;19(1).

- Aziato L., Kyei A., & Deku G. Experiences of midwives on pharmacological and nonpharmacological labour pain management in ghana. Reproductive Health 2017;14(1).
- Dowswell T., Kelly A., Livio S., Norman J., & Alfirević Z. Different methods for the induction of labour in outpatient settings. Cochrane Database of Systematic Reviews 2010.
- 23. Anarado A., Ali E., Nwonu E., Chinweuba A., & Ogbolu Y. Knowledge and willingness of prenatal women in enugu southeastern nigeria to use in labour non-pharmacological pain reliefs. African Health Sciences 2015;15(2):568.
- Tadesse T., Assefa N., Roba H., & Baye Y. Failed induction of labor and associated factors among women undergoing induction at university of gondar specialized hospital, northwest ethiopia. BMC Pregnancy and Childbirth 2022;22(1).
- 25. Guzewicz, A., & Sierakowska, M. Comparative Analysis of Pharmacological and Non-Pharmacological Methods for Labor Induction: Implications for Maternal Satisfaction and Delivery Times. Journal of Obstetrics and Gynecology Research. 2022; 47(3), 321-328.

