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Research Article

Maternal and Neonatal Morbidity Following Dinoprostone Alone Versus Dinoprostone Combined With Laminaria for Cervical Ripening In Women with Poor Bishop Score: A Randomized Controlled Trial

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ABSTRACT

Objective: To compare the maternal and neonatal morbidity following cervical ripening with dinoprostone alone and dinoprostone in combination with laminaria in women undergoing induction of labor with poor Bishop scores.

Study Design: Randomized controlled trial.

Place and Duration of Study: MCH Unit-II, Pakistan Institute of Medical Sciences, Islamabad. From February 2024 to August 2024.

Methodology: A total of 146 women at term with singleton pregnancies and unfavorable cervix (Bishop score ≤4) undergoing induction of labor were included in this study. Participants were randomized into two equal groups, where Group A received dinoprostone alone, whereas Group B received dinoprostone combined with laminaria for cervical ripening. The two groups were compared for cervical ripening outcomes, and maternal and maternal and neonatal morbidity.

Results: Women in Group B demonstrated significantly better cervical ripening than those in Group A, with higher post-ripening Bishop score (8.23±1.24 vs. 6.78±1.57; p<0.001), and shorter induction-to-active labor interval (8.47±2.74 vs. 10.56±2.59 hours; p<0.001) and induction-to-delivery interval (13.55±3.96 vs. 17.11±6.17 hours; p<0.001). Similarly, vaginal delivery was more frequent (84.9% vs. 69.9%; p=0.030), while cesarean section (15.1% vs. 30.1%; p=0.030) and failed induction (6.9% vs. 17.8%; p=0.044) were significantly lower in Group B compared to Group A. A comparable maternal and neonatal morbidity outcomes were observed between the groups (p>0.05, for all).

Conclusion: The addition of laminaria to dinoprostone improve cervical ripening, shorten labor duration, and reduce cesarean section and failed induction rates without increasing the maternal or neonatal morbidity.

Keywords: Bishop Score, Cervical Ripening, Cesarean Section, Dinoprostone, Induction of Labor, Laminaria.

INTRODUCTION

Induction of labor (IOL) is one of the most commonly performed obstetric procedures, accounting for approximately 20–25% of all deliveries worldwide.[1] IOL is performed when the continuation of pregnancy poses greater maternal or fetal risk than the delivery. The common causes leading to IOL are post-term pregnancy, gestational hypertension-related disorders, gestational diabetes mellitus (GDM), intrauterine growth restriction (IUGR), and prelabor rupture of membranes (PROM), oligohydramnios and various maternal medical disorders.[2] A successful IOL relies on the cervical favorability at the time of induction, conventionally assessed by the Bishop scoring system. A Bishop score of 5 or above generally predicts a favorable outcome, whereas a score of ≤4 is classified as a "poor" Bishop score. A low Bishop score is therefore linked to poor outcomes such as prolonged labor, failed induction, increased cesarean section (CS) rates, and higher maternal and neonatal morbidity.[3]

Cervical ripening is therefore a crucial initial procedure prior to IOL in women with an unfavorable Bishop score. Several pharmacologic and mechanical techniques are

available to induce cervical ripening with varying levels of efficacy.[4] The most common pharmacological methods include the use of dinoprostone, a prostaglandin E2 (PGE2), which acts on cervical fibroblasts and smooth muscle cells, thereby facilitating the breakdown of collagen fibers and increasing water content. In this way, dinoprostone helps to efface, soften, and dilate the cervix. The product is available in multiple formulations, including gel, pessary, and sustained-release vaginal inserts. Although proven to be effective and safe, dinoprostone alone may be insufficient to achieve adequate cervical ripening, particularly those with a Bishop score of ≤ 4. Moreover, it has been noted to cause prolonged induction time, uterine hyperstimulation, and induction failure in some women.[5,6]

Mechanical methods have been used for many years because of their effectiveness in cervical ripening and favorable safety profile. Laminaria, a hygroscopic dilator derived from seaweed, is commonly used for the purpose. It gradually absorbs moisture from the surrounding cervical tissue and expands within the cervical canal, exerting radial pressure which stimulates endogenous prostaglandin release, promotes collagen breakdown, and hastens effacement.[7] Use of prostaglandins in combination with mechanical dilators can therefore improve cervical remodeling, shorten the induction-to-delivery times and minimize the risk of operative delivery, however, the evidence is not consistent. These variations in outcomes are more prominent in the low-resource areas where significant variations are observed in obstetric practices.[8] This combination of mechanical and pharmacological approaches may offer synergistic benefits, potentially leading to improved cervical ripening and more efficient IOL, particularly in women with an unfavorable cervix.[9]

IOL remains an important concern for obstetricians as prolonged labor, failed induction, operative delivery, postpartum hemorrhage (PPH), uterine hyperstimulation, fetal distress, and neonatal intensive care unit (NICU) admissions contribute significantly to healthcare burden and adverse pregnancy outcomes. Identifying induction strategies that improve cervical ripening while minimizing complications is therefore of substantial clinical importance to decrease the maternal and neonatal morbidity associated with the delivery.[10]

It is therefore important to study the effectiveness and safety of using laminaria in combination with dinoprostone in our local population. This study was planned to determine the efficacy of using dinoprostone alone and dinoprostone plus laminaria on maternal and neonatal outcomes in women with poor Bishop scores. These results may serve to provide data to support clinical-decisions making and help to set the IOL protocol in obstetric care.

METHODOLOGY

This randomized controlled trial was conducted at the MCH Unit-II, Pakistan Institute of Medical Sciences, Islamabad, from February-2024 to August-2024. Ethical approval for conducting the study was obtained from the Ethical Review Committee of the hospital before commencement of the study. A written informed consent was obtained from all participants prior to their inclusion.

Sample size was calculated based on the proportion of patients requiring CS while assuming a CS rate of 31.8% in the dinoprostone alone group, and 12.1% in the dinoprostone combined with Laminaria group.[11] Using alpha as 0.05 and 80% power (two-sided), a minimum of 66 patients was required in each group. However, to account for 10% attrition, we enrolled 73 patients per group, giving a total sample size of 146 patients.

A total of 146 pregnant women aged 18 to 40 years with singleton pregnancies at term (≥37 weeks gestation), requiring IOL due to an unfavorable cervix (Bishop score of ≤4) were included in this study. Patients were included by use of consecutive sampling and randomized into two groups, Group A and Group B, through a computer-generated randomization method.

The exclusion criteria consisted of women with cephalopelvic disproportion, placenta previa, previous CS, malpresentation and multiple gestation. Moreover, cases of fetal congenital anomalies, active genital infections, or contraindications to vaginal delivery (VD) were also excluded from the study.

All the baseline demographics and obstetric characteristics were recorded for each patient including maternal age, gestational age (GA), parity, indication for IOL, and initial Bishop score.

Women in Group A received dinoprostone alone (3 mg vaginal tablet, inserted into the posterior vaginal fornix). As per the set institutional protocols, a repeat dose of dinoprostone was administered after 6 hours in cases where adequate cervical ripening or labor had not been achieved. Patients were monitored for

uterine activity and fetal well-being throughout the procedure. In Group B, women received dinoprostone in combination with laminaria insertion for cervical ripening. A single laminaria tent (5 mm diameter) was inserted aseptically into the endocervical canal and left in place for up to 12 hours or until spontaneous expulsion was observed. Cervical reassessment was performed following laminaria removal.[12] Dinoprostone was administered as described for Group-A. Oxytocin augmentation was started in both the groups, in cases where active labor was not achieved within 12 hours of the last dinoprostone dosage.

Patients in both the study groups were monitored by trained obstetric staff throughout the labor and repeat cervical assessment was performed during the period.

Primary maternal outcomes of the study included post-ripening Bishop score, induction-to-active labor interval, induction-to-delivery interval, mode of delivery (MoD), failed induction, uterine hyperstimulation, PPH, maternal fever, and chorioamnionitis. Neonatal outcomes included low birth weight (LBW) (Birth weight< 2500 g), Apgar score <7 at five minutes, NICU admission, meconium aspiration syndrome (MAS), and respiratory distress. All these data were collected and recorded using a structured proforma.

Cases where active labor was not achieved despite adequate cervical ripening and uterine contractions were labelled as failed induction.[13] Uterine hyperstimulation was considered when more than five contractions were observed in 10 minutes for 20 minutes or more, with or without fetal heart rate (FHR) changes.[14]

Data were analyzed using SPSS 26. Quantitative variables were presented as mean ± standard deviation (SD), while qualitative variables were expressed as frequencies and percentages. Independent sample t-test was employed for comparison of continuous variables, while Chi-square or Fisher's exact test was used in case of categorical variables. A p-value less than 0.05 was taken as statistically significant.

RESULTS

The mean age of women in this study was 28.02 ± 4.85 which ranged from 18 to 40 years, while the mean GA was 39.01 ± 1.19 weeks, ranging from 37 to 42 weeks. All the enrolled patients completed the study and their outcomes were included in study analysis. The group wise demographics and baseline clinical characteristics are shown in Table-I.

Table-I: Baseline Demographics and Clinical Characteristics. N = 146

Demographic and clinical variables		Group A (Dinoprostone) (n=73)	Group B (Dinoprostone+ laminaria) (n=73)
Age (Mean ± SD) years		27.36 ± 4.46	28.69 ± 5.15
Gestational age (Mean ± SD) weeks		39.11 ± 1.20	38.92 ± 1.19
Gravidity status	**Primigravida n (%)**	39 (53.42)	36 (49.32)
	Multigravida n (%)	34 (46.58)	37 (50.68)
Parity	**Nulliparous n (%)**	48 (65.75)	50 (68.49)
	Multiparous n (%)	25 (34.25)	23 (31.51)
Indications for IOL	**Post-dated (>40 weeks) n (%)**	25 (34.25)	28 (38.36)
	Gestational hypertension n (%)	16 (22.86)	14 (19.18)
	Gestational diabetes n (%)	9 (12.33)	8 (10.96)
	PROM n (%)	9 (12.33)	11 (15.07)
	Oligohydramnios n (%)	6 (8.22)	5 (6.85)
	Decreased fetal movements n (%)	4 (5.48)	3 (4.11)
	Fetal growth restriction n (%)	2 (2.74)	3 (4.11)
	Other medical/obs. indications n (%)	2 (2.74)	1 (1.37)
Baseline Bishop Score (Mean ± SD)		2.96 ± 0.72	3.04 ± 0.68

The data regarding cervical ripening and labor outcomes showed that the women in Group B demonstrated significantly greater improvement in cervical ripening compared to Group A (<0.001). This was also reflected in shorter Induction-to-active labor interval and

induction-to-delivery interval in Group B compared to Group A (<0.001 for both). Analysis of delivery outcomes showed significantly higher rate of VD and lower rate of CS and failed induction in Group B. All this was achieved without any significant increase in maternal morbidity including uterine hyperstimulation, PPH, maternal fever and Chorioamnionitis, as shown in Table-II.

Table-II: Comparison of Cervical Ripening and Maternal Outcomes. N = 146

Outcomes variables	Group A Dinoprostone (n=73)	Group B Dinoprostone+ laminaria (n=73)	p-value
Cervical ripening outcomes			
Bishop score after ripening (Mean ± SD)	6.78 ± 1.57	8.23 ± 1.24	<0.001
Induction-to-active labor interval (Mean ± SD) hours	10.56 ± 2.59	8.47 ± 2.74	<0.001
Induction-to-delivery interval (Mean ± SD) hours	17.11 ± 6.17	13.55 ± 3.96	<0.001
Delivery outcomes			
Vaginal delivery n (%)	51 (69.86)	62 (84.93)	0.030
Cesarean section n (%)	22 (30.14)	11 (15.07)	0.030
Failed induction n (%)	13 (17.81)	5 (6.85)	0.044
Maternal morbidity			
Uterine hyperstimulation n (%)	6 (8.22)	3 (4.11)	0.494
PPH n (%)	4 (5.48)	3 (4.11)	1.00
Maternal fever n (%)	5 (6.85)	4 (5.48)	1.00
Chorioamnionitis n (%)	2 (2.74)	1 (1.37)	1.00

Neonatal outcomes also showed overall favorable results in terms of LBW, APGAR <7 at 5 Min , NICU admission**,** MAS and respiratory distress with no statistically significant difference present between the two groups, as shown in Table-III.

Table-III: Comparison of Neonatal Outcomes. N = 146

Outcomes variables	Group A Dinoprostone (n=73)	Group B Dinoprostone+ laminaria (n=73)	p-value
Low birth weight n (%)	6 (8.22)	3 (4.11)	0.494
Apgar <7 at 5 Min n (%)	7 (9.59)	5 (6.85)	0.547
NICU admission n (%)	6 (8.22)	4 (5.48)	0.745
MAS n (%)	4 (5.48)	2 (2.74)	0.439
Respiratory distress n (%)	5 (6.85)	3 (4.11)	0.719

DISCUSSION

The findings of this study showed that the addition of laminaria to dinoprostone resulted in significant improvement in cervical ripening and labor outcomes among women undergoing IOL with poor Bishop scores. Women receiving this combination therapy achieved a higher post-ripening Bishop score (8.23±1.24 vs. 6.78±1.57; p<0.001), shorter induction-to-active labor interval (8.47±2.74 vs. 10.56±2.59 hours; p<0.001), and shorter induction-to-delivery interval (13.55±3.96 vs. 17.11±6.17 hours; p<0.001) compared to those receiving dinoprostone alone. The combination group demonstrated a significantly higher rate of VD (84.93% vs. 69.86%; p=0.030), and lower rates of CS (15.07% vs. 30.14%; p=0.030) and failed induction (6.85% vs. 17.81%; p=0.044). It is important that these benefits were achieved without any significant increase in maternal or neonatal morbidity. These findings support the concept of combining a mechanical cervical ripening method with a pharmacological agent to provide synergistic effects, resulting in more effective cervical ripening and improved labor outcomes. A number of earlier researches have discussed the role of this combined approach and reported varying effects on obstetric success, and morbidity profiles for the mothers and the neonates.

The utility of mechanical approach was studied by Behrashi M et al., who compared laminaria (mechanical) and misoprostol (a prostaglandin) for cervical ripening in 100 term women with an unfavorable cervix. Cervical dilatation during the first 6 hours was 4.4 times greater with laminaria (p=0.001), while the CS and uterine hyperstimulation were significantly more frequent with misoprostol (p=0.017). The study therefore concluded that mechanical technique using laminaria is an effective and safer method for cervical ripening in these cases.[15] Behnoud F et al. compared misoprostol alone with misoprostol plus laminaria in 90 women, who were undergoing second-trimester pregnancy termination. The combination group demonstrated significantly lower need for curettage (p=0.05), and shorter labor duration (p=0.04), and hospital stay (p=0.003). The authors concluded that the addition of laminaria improved cervical preparation and reduced procedure-related morbidity.[16] Additional evidence regarding the adjunctive role of laminaria was reported in studies evaluating second-trimester pregnancy termination. Sheikham and Amani conducted a randomized interventional study with 80 women with second-trimester pregnancies. The combination of vaginal misoprostol and laminaria achieved a complete abortion in 90% of cases compared to 85% with misoprostol plus letrozole. Despite this statistically non-significant difference, the findings suggested that laminaria may serve as a mechanical adjunct to pharmacological agents to enhance cervical ripening without increasing complications.[17] Mushtaq H et al. conducted a RCT by comparing laminaria plus dinoprostone with dinoprostone alone for cervical ripening in 132 women with unfavorable cervices. The combination group achieved a significantly higher modified Bishop score (8.9±0.74 vs. 8.1±0.33; p<0.001) and greater cervical ripening success (68.2% vs. 43.9%; p=0.005). Similarly, VD rates were higher, CS rates were lower, and neonatal Apgar scores were better in the combination group. The authors therefore concluded that laminaria combined with dinoprostone enhances cervical ripening and improves the overall induction outcomes.[11]

The present study, along with the previously available evidence, indicates that the use of laminaria in combination with dinoprostone is a useful approach to cervical ripening in women with poor Bishop scores. These improved IOL outcomes are achieved without any additional maternal or neonatal complications.

This study was performed at a single tertiary care center which may limit its validity over large scale. Furthermore, a relatively small sample size may not be able to detect significant differences between the less frequent maternal and neonatal complications. Studies with multicenter design and larger numbers of patients will help to confirm these findings, and to guide future obstetric practice guidelines.

CONCLUSION

Adding laminaria to dinoprostone appears to be a safe and effective method of cervical ripening in women undergoing IOL with poor Bishop scores. The combination improves cervical favorability, promotes efficient labor progression, increases VD rates, whereas it reduces the rates of CS and failed induction compared to dinoprostone alone. These benefits are obtained without increase in maternal or neonatal morbidity, suggesting a good safety profile. The results indicate that a cervical induction technique combining mechanical and pharmacological approaches optimize the IOL in women with unfavorable cervix.

Conflict of Interest

None.

Disclaimer

None.

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