# Efficacy of Dilapan S compared to foley balloon in preinduction cervical ripening—a noninferiority trial

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**BACKGROUND:** The need for induction of labor is increasing in present obstetric practice. The available non-pharmacological methods for cervical ripening at term are Foley balloon and Dilapan-S. With the gaining popularity of Dilapan-S worldwide, there are very few clinical trials conducted in India to evaluate its effectiveness.

**OBJECTIVE:** To compare the efficacy of Dilapan-S and Foley balloons for pre-induction cervical ripening.

**STUDY DESIGN:** This single-center randomized non-inferiority trial included primi- and multi-gravida women between 37 and 41 weeks of gestation and unfavourable cervix with a Bishop's score between 0 and 2. Using a random number table, patients were assigned to study Group 1 Dilapan-S and to control Group 2 Foley balloon. Dilapan-S or Foley balloon was inserted intracervically and assessed for dilation after 12 hours. Patients with unfavourable dilatation were further provided prostaglandins (PgE 1 and 2) for further augmentation of induction. Primary outcome measures included improvement in Bishop's score, and mode of delivery, followed by time to delivery from intervention, use of other augmentation methods, and maternal and neonatal outcomes.

**RESULTS:** After screening, 296 patients with Bishop score less than 2, (148 in each group) were enrolled in the study. The number of patients who had vaginal delivery was comparable between both groups ($p$=.72), and so were the maternal outcomes. Two cases of cord prolapse occurred with Foley balloon. Group 2 showed significant improvement in Bishop's score ($p$<.001), and Group 1 had a significantly higher use of augmentation with PgE1 ($p$-.01) and PgE2 ($p$<.001). The number of contractions was significantly lower in Group 1 ($p$<.001), and contraction intensity was higher in Group 2. There was no significant difference in cesarean delivery for failed induction of labor between the groups ($p$=.72). Based on the primary outcome measure, Dilapan-S was found to be non-inferior to the Foley balloon.

**CONCLUSION:** Dilapan-S is non-inferior to Foley balloon in achieving pre-induction cervical ripening in term pregnancies, and therefore Dilapan-S can be suggested as an alternative in clinical practice with minimal risks.

**Key words:** cervical ripening, Dilapan-S, Foley balloon, labor induction, noninferiority

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Patient consent- Written informed consent was taken from all participants in either Tamil (local language) or English.

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## Introduction

In developing countries, an estimated 500 women die every year due to complications in labor.[1] In India, labor induction is prevalent among 22% of the pregnant population.[1]

Labor induction itself could increase the risk of maternal and neonatal morbidity and mortality.[1] Labor induction is usually indicated for women to terminate pregnancies with increased perinatal risks, for post-term pregnant women, for fetal growth restriction (FGR), or for conditions such as hypertension and diabetes.[2,3] However, there is an increase in demand for elective induction of labor due to various non-medical indications such as avoiding pregnancy-related pain, and also due to the increased availability of cervical ripening agents.[2]

Labor induction is performed either mechanically or pharmacologically. An unfavorable Bishop's score indicated by a digital cervical exam based on cervical dilation, position, cervical consistency, and fetal station, suggests using cervical ripening agents.[4,5] Mechanical dilators include Foley balloons and Cook catheters, while, prostaglandins are commonly administered as pharmacological cervical ripening agents.[4]

Dilapan-S is an alternative mechanical synthetic osmotic dilator manufactured using an anisotropic xerogel, that absorbs fluids from surrounding tissues of the cervical canal to induce radial pressure on the cervical wall, dilating and softening the cervix.[6] It was approved by the United States Food and Drug Administration (USFDA) for third-trimester use in 2015.[7]

Dilapan-S has previously been reported to be as effective as Foley balloons and pharmacological methods for term pregnancies with better maternal and fetal safety, and patient satisfaction.[6–10] However, there are very few

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**Why was this study conducted?**

Labor induction has been rising among Indian women. Despite being as effective as a Foley balloon, the effectiveness of Dilapan-S has been understudied in India.

**Key findings**

Maternal outcomes and the number of vaginal deliveries were comparable among women who used Foley balloon or Dilapan-S. Two cases of cord prolapse were observed in the Foley balloon group and the number of contractions was significantly lower among the Dilapan-S group.

**What does this add to what is known?**

Dilapan-S can be prescribed as a safer alternative to Foley balloon in India, without the risk of umbilical cord prolapse.

studies that have compared the efficacy of Dilapan-S with Foley balloon for term pregnancies in India, a topic of interest given the increasing prevalence of Caesarean section deliveries.[10,11] Therefore, we conducted a randomized trial to compare the efficacy of Dilapan-S with the commonly used Foley balloon for pre-induction cervical ripening in term-pregnant women. This study could provide evidence for an alternative and cost-effective method in Indian states for preinduction cervical ripening.

## Materials and methods

### Study setting and design

This was a single-centre randomized trial. The study was approved by the Institutional Human Ethics Committee (IHEC: 19/389). Written informed consent was obtained from all participants before randomization.The trial is registered in the Clinical Trial Registry of India (CTRI/2020/06/0260272020).

### Study population-inclusion and exclusion criteria

This noninferiority trial included primi- or multigravida women near-term (37 −41 weeks)with singleton pregnancies, with a cephalic presentation and an unfavorable cervix based on Bishop's score (between 0 and 2),[5] scheduled for labor induction. Any participants with a history of cesarean delivery were excluded from the study. The CONSORT flow diagram summarizing the recruitment and selection of participants is given in Figure 1.

### Sample size

Considering the percentage of normal delivery in the Foley group to be 71% and that in the Dilapan-S group to be 76%, with a non-inferiority limit (d) of 10% from the DILAFOL trial, a sample size of 148 in each group was arrived at using an online sample size calculator.[12]

### Randomization and procedure

Using a random number table, patients were randomized into the intervention and control groups; Group 1 was the interventional group allotted to Dilapan-S, and the control group (Group 2) was assigned to the Foley balloon. Neither the patients nor the researchers were blinded to the allotment.

A Dilapan-S or Foley balloon was inserted intracervically in patients in the respective groups, under aseptic conditions. Depending on the dilatation, 1 to 3 Dilapan-S were inserted. Patients in both groups were assessed for dilation after 12 hours and were further augmented using prostaglandin E1 (PgE1) Misoprostol or PgE2 if no spontaneous labor was achieved. Other augmentation modes were decided based on Bishop's score.[5] Both Dilapan-S and Foley balloon were removed after 12 hours without waiting for spontaneous expulsion. Oxytocin was started for patients with a Bishop's score ≥ 6. For primigravida 5 units and multigravida 2.5 units of oxytocin in 500 mL of Ringer-Lactate solution was started at 16 mL/h and titrated to get adequate contractions.

### Outcomes

The primary outcome measure was the efficacy of Dilapan-S when compared with the Foley balloon determined based on differences in the change in Bishop's score, delivery mode, number of contractions, time to delivery from insertion of device, and augmentation methods. Secondary outcome measures included adverse maternal and neonatal outcomes with Dilapan-S and Foley balloon.

### Statistical analyses

The data was analyzed using SPSS Ver 29. Categorical data were represented as frequency and percentage, and continuous data as mean and standard deviation (SD).Student's t-test and chi-square tests were employed to assess the difference in variables between the two groups. A *p*-value less than .05 was considered statistically significant.

## Results

### Baseline characteristics of patients in both groups

After screening, a total of 296 patients were found eligible for the study, and 148 were randomly assigned to Group 1 and Group 2. The median (IQR) maternal ages of the patients in Groups 1 and 2 were comparable at 26 (4) and 26 (18) years, respectively.

The baseline variables of the patients in both groups are compared in Table 1. Most of the patients in both groups were primigravida (Group 1-91.2%, Group 2-93.2%) and had a Bishop's score of 0 (Group 1-70.9%, Group 2-81.1%). Gestational diabetes mellitus (22.3%, n=33) and fetal growth restriction (29.7%, n=44) were significantly higher among the patients in Dilapan-S Group 1 ($p$=.001).

### Efficacy of Dilapan-S compared to Foley balloon

The modes of delivery were comparable between the groups ($P$=.72), with the majority of them achieving normal vaginal delivery (Group 1-63.5%, n=94; Group 2-65.5%, n=97). However, the need for augmentation using PgE1 ($P$=.01) and PgE2 ($P$<.011) was significantly higher among Group 1 (Table 2).

**FIGURE 1**
**CONSORT flow diagram**

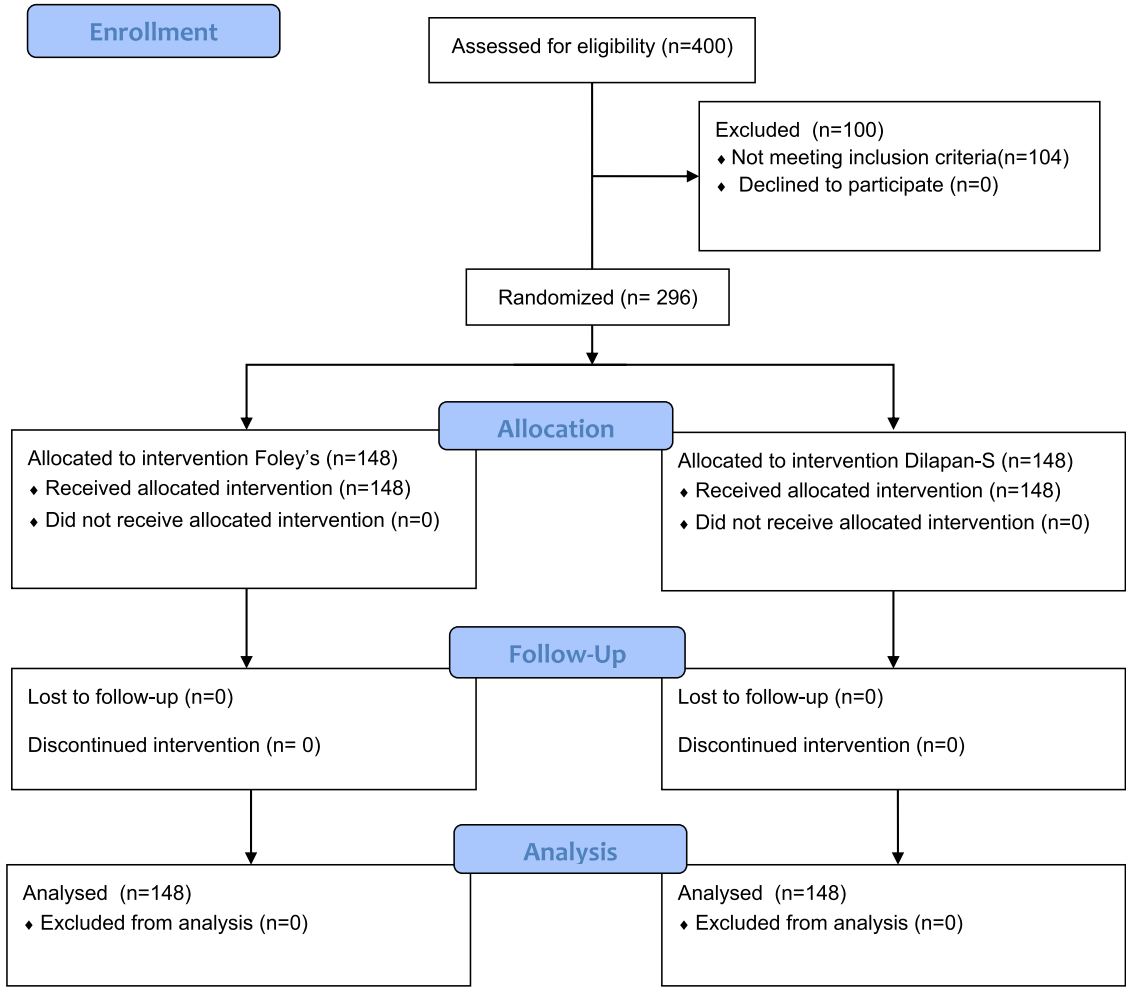


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**TABLE 1**
**Comparison of baseline variables of patients in Group 1 (Dilapan-S) and Group 2 (Foley balloon)**

| Variable | Category | Dilapan-S, N=148 (%) | Foley balloon, N=148 (%) | *P*-value |
|---|---|---|---|---|
| Gravida | Primi | 135 (91.2) | 138 (93.2) | .51 |
| | Multi | 13 (8.8) | 10(6.8) | |
| GDM | Present | 33 (22.3) | 13 (8.8) | .001[a] |
| PIH | Present | 15 (10.1) | 10(6.8) | .29 |
| FGR | Present | 44 (29.7) | 21(14.2) | .001[a] |
| Bishop's score | 0 | 105 (70.9) | 120 (81.1) | .12 |
| | 1 | 38 (25.7) | 25(16.9) | |
| | 2 | 3 (2.0) | 3(2.0) | |
| | 3 | 2 (1.4) | 0(0.0) | |
| Maternal age | Median (IQR) | 26 (4) | 26 (18) | .74[MW] |
| Gestational age | Median (IQR) | 38.5 (3) | 39 (2) | .08[MW] |

Abbreviations: GDM-gestational diabetes mellitus, PIH-pregnancy-induced hypertension, FGR-fetal growth restriction.

[a] Indicates significance at $P<.05$; [MW] - Mann-Whitney U-test.

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**TABLE 2**
**Comparison of induction requirements between Group 1 (Dilapan-S) and Group 2 (Foley balloon)**

| Augmentation method | No. needed for induction | Dilapan-S, N=148 (%) | Foley balloon, N=148 (%) | Total | *P*-value |
|---|---|---|---|---|---|
| PgE2 | 0 | 47 (31.8%) | 118 (79.7%) | 165 (55.7%) | <0.001[a] |
| | 1 | 51 (34.5%) | 23 (15.5%) | 74 (25%) | |
| | 2 | 50 (33.8%) | 7 (4.7%) | 57 (19.3%) | |
| PgeE1 | 0 | 27 (18.2%) | 51 (34.5%) | 78 (26.4%) | 0.01[a] |
| | 1 | 49 (33.1%) | 26 (17.6%) | 75 (25.3%) | |
| | 2 | 36 (24.3%) | 30 (20.3%) | 66 (22.3%) | |
| | 3 | 28 (18.9%) | 33 (22.3%) | 61 (20.6%) | |
| | 4 | 5 (3.4%) | 6 (4.1%) | 11 (3.7%) | |
| | 5 | 2 (1.4%) | 2 (1.4%) | 4 (1.4%) | |
| | 6 | 1 (0.7%) | 0 | 1 (0.3%) | |

[a] Indicates significance at *P*<.05.

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Among other factors that were compared, the number of contractions (defined as the contractions from the introduction of Folley ballon or Dilapan-S till it was removed), was significantly lower in Group 1 (*P*<.001) (Table 3), and contraction intensity was higher in Group 2. A significantly longer time to delivery from insertion of the device was also observed among Group 1 patients (Figure 2). There was no significant difference in cesarean delivery for failed induction of labor between the groups(*P*=.72) (Figure 3). Postintervention, a significantly higher improvement in Bishop's score was observed among Group-2 patients who received Foley Balloon (*P*<.001) (Figure 4).

Based on the absolute difference in proportion (-0.2, 95% Confidence interval 0−4) of the primary outcome measure, that is, vaginal delivery, Dilapan-S appears non-inferior to Foley's balloon with both the upper and lower bounds above the noninferiority margin of -10% (Figure 5).

## Adverse maternal and neonatal outcomes

The incidence of adverse outcomes such as postpartum hemorrhage, fever, and urinary retention were minimal in both groups and did not differ significantly between groups (Table 4). Postpartum hemoglobin levels were also comparable between groups (*P*=.84).

Similarly, neonatal outcomes in terms of Apgar score at 1 minute (*P*=.08), 5 minutes (*P*=.05), and the birth weights of the babies (*P*=.71) were not significantly different between groups. However, there were 2 cases of umbilical cord presentation in Group 2, where the cord presented with intact membrane while removing Foleys. In both cases the amniotic fluid levels were normal and the head was fixed at the beginning of induction.

## Discussion

While there is gaining popularity of Dilapan-S as an effective method for pre-induction cervical ripening, very few randomized trials have been conducted in India comparing its efficacy to that of established methods like Foley balloons/catheters.

## Principal findings and results

In the present study, Dilapan-S appeared noninferior to the Foley balloon in inducing labor for women with unfavourable cervix near-term. This was consistent with a recent randomized controlled trial by Saad et al.,[7] who

**TABLE 3**
**Difference in the number of contractions between Group 1 (Dilapan-S) and Group 2 (Foley balloon)**

| No. of contractions | Dilapan-S | Foleys | Total | *P*-value |
|---|---|---|---|---|
| 0 | 112 (75.7%) | 30 (20.3%) | 142 (48.0%) | <.001* |
| 1 | 9 (6.1%) | 17 (11.5%) | 26 (8.8%) | |
| 2 | 18 (12.2%) | 47 (31.8%) | 65 (22.0%) | |
| 3 | 6 (4.1%) | 44 (29.7%) | 50 (16.9%) | |
| 4 | 3 (2.0%) | 10 (6.8%) | 13 (4.4%) | |

* Indicates significance at *P*<.05. No. of contractions: Contractions from the introduction of Foley balloon or Dilapan-S till it was removed.

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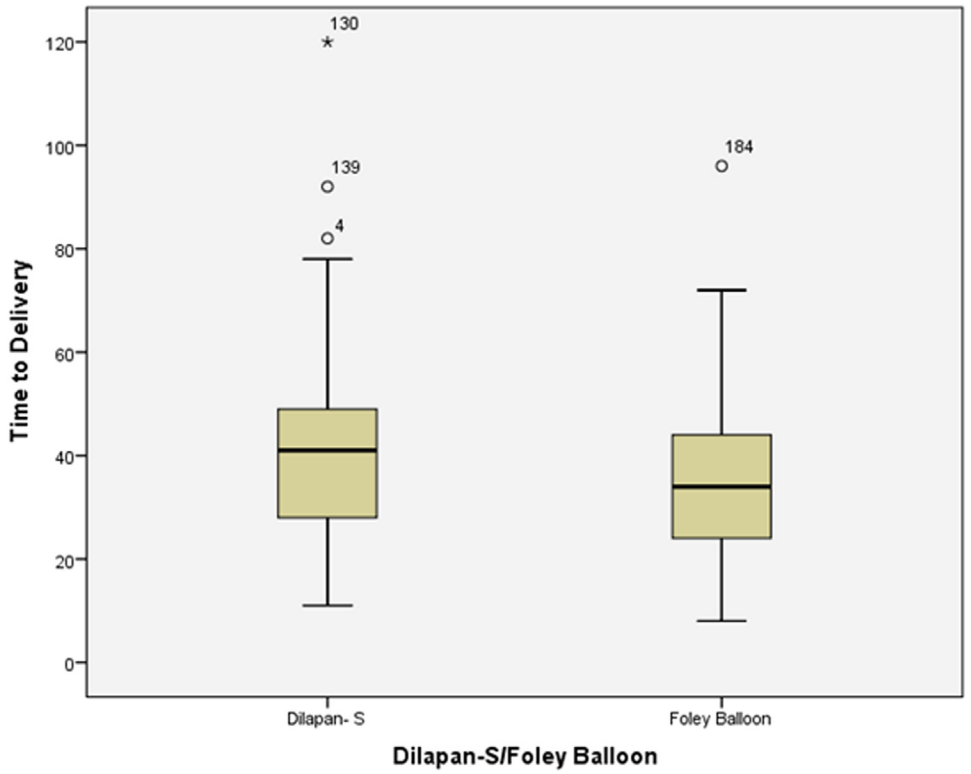
**FIGURE 2**
**Time to delivery from insertion of device among patients who received Dilapan-S and Foley balloon**

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also established the non-inferiority of Dilapan-S for preinduction cervical ripening when compared to the Foley balloon. In the present study, the majority of the patients in both groups, who used Foley balloon or Dilapan-S, underwent normal vaginal delivery, with significant improvement in Bishop's score noted among women in the Foley balloon group. While Saad et al,[7] reported significant improvement in Bishop's score in the Dilapan-S group, another randomized trial by Gupta et al.,[8] comparing Dilapan-S with pharmacological induction using dinoprostone showed the latter to improve Bishop's score. Baev et al.[13] also reported improvement in Bishop's score with combination treatment using Dilapan-S and mifepristone, than those who received only Dilapan-S. This inconsistency in Bishop's score improvement needs exploration in further studies.

The time to delivery from the time of insertion of device was longer among the Dilapan-S group. A longer, though insignificant, induction to delivery duration was reported by Baev et al.,[13] among patients who received only Dilapan-S, compared to those who received Dilapan-S and mifepristone. The number and intensity of contractions were observed to be significantly lower in the Dilapan-S group in the present study. Though this is consistent with a historical study,[14] a recent multicentre observational study reported no significant difference.[10] However, participants in another study by Gupta et al.[8] reported contractions of lower frequency and intensity, and therefore better satisfaction with Dilapan-S when compared to a dinoprostone. We also found the need for augmentation using pharmacological methods like PgE1 and PgE2 significantly higher in the Dilapan-S group. This has also been noted in other studies.[7,13] On the other hand, mechanical methods of induction reduce the risk of uterine hyperstimulation and serious maternal or fetal outcomes.[6]

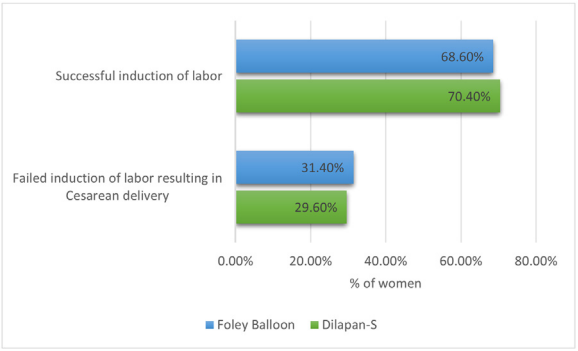
Maternal outcomes were comparable between the groups with minimal adverse events in the present study, similar to other studies.[7–10] Additionally, patient satisfaction has been reported with the use of Dilapan-S in different studies, in terms of its insertion, comfort after insertion, ability to sleep, and performance of desired activities.[6,15]

In the present study, 2 cases of cord presentation were observed in Foley group requiring emergency cesarean delivery. Cord prolapse was previously reported in a study conducted in Japan, where the use of balloons increased the risk of umbilical cord prolapse.[16] This highlights the improved safety profile of Dilapan-S with reduced risk of adverse events. [17]

## Research and clinical implications

Overall, on par with existing literature, no superiority could be established with

**FIGURE 3**
**Failed induction of labor between groups was not significantly different**

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the use of Dilapan-S when compared to Foley balloons for preinduction cervical ripening. The study findings, though from a single centre are consistent with most other studies concluding the non-inferiority of Dilapan-S when compared to Foley balloon. We saw that there was a higher number of vaginal than cesarean deliveries among the study population, with lower uterine contractions and no risk of umbilical cord prolapse, underlining its potential as a good alternative for pre-induction cervical ripening. This study adds to the existing literature on non-inferiority and therefore, probable recommendation of Dilapan-S as an alternative to the Foley balloon and other pharmacological induction methods. These results provide valuable insight into obstetric practice, in the form of evidence-based decision-making regarding cervical ripening methods for term pregnancies. Obstetricians must consider different factors like Bishop's score, to make an optimal choice that also limits the use of excessive augmentation methods, and reduces maternal and neonatal risks.

## Limitations and future directions

While the study presents findings consistent with other studies, limitations such as its single-center nature, small sample size, and lack of blinding may limit its generalizability and introduce biases. Additionally, the exclusion of women with a prior history of cesarean delivery could have resulted in selection bias and limited generalizability to pregnant women. Another limitation of the study is the lack of feedback from

**FIGURE 4**
**Improvement in Bishop's score among patients who received Dilapan-S and Foley balloon**

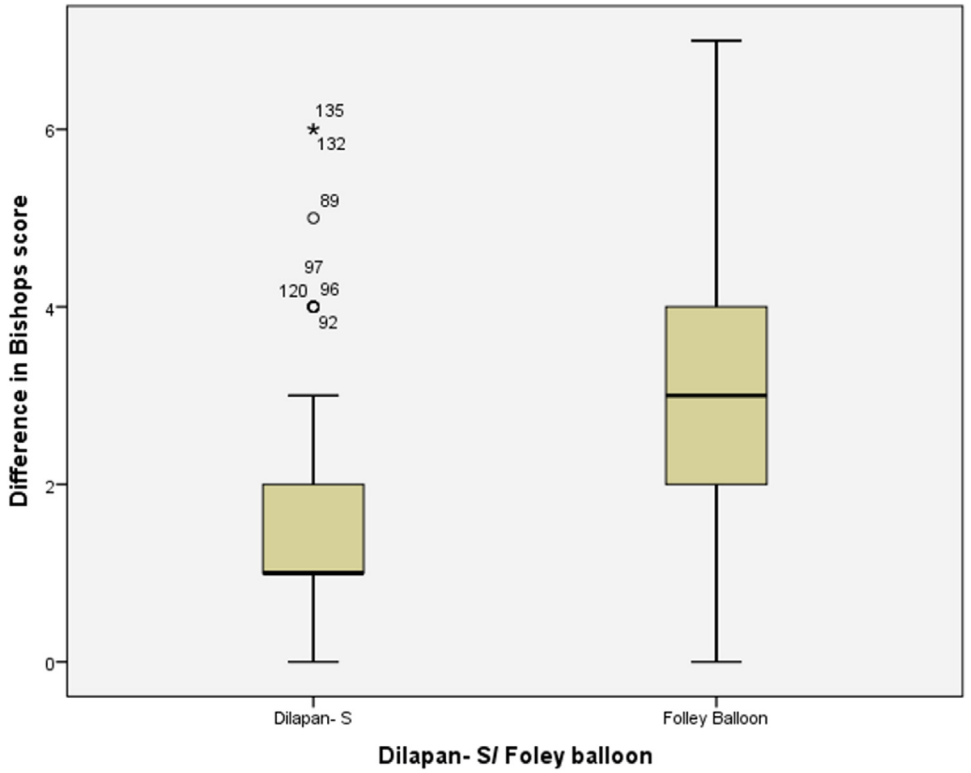


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**FIGURE 5**
**Absolute difference in the proportion of vaginal deliveries among Dilapan-S and Foley balloon**

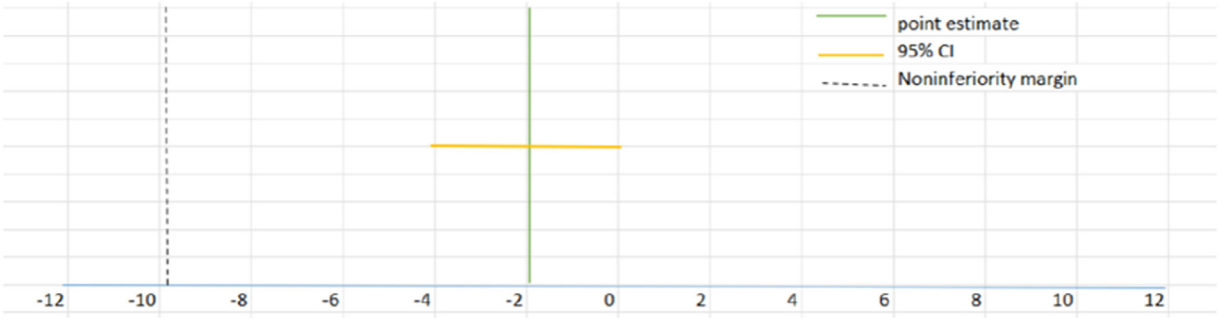


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**TABLE 4**
**Difference in maternal outcomes between Group 1 (Dilapan-S) and Group 2 (Foley balloon)**

| Outcomes | Dilapan- S, N=148 (%) | Foley Balloon, N=148 (%) | *P*-value |
|---|---|---|---|
| Postpartum hemorrhage | 16 (10.8) | 13 (8.8) | .56 |
| Fever | 6 (4.1) | 4(2.7) | .52 |
| Urinary retention | 0 (0) | 2(1.4) | .16 |

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patients regarding their experience or satisfaction with the use of Dilapan-S or Foley balloon. Also, the study analysis did not adjust for factors such as parity, fetal size, and gestational age. Furthermore, the presence of adverse outcomes in the current study was lower, however, it is not generalizable due to the small sample size.

Future multicenter trials must be conducted with a larger sample size to allow for stratified randomization and further evaluate the efficacy, maternal and neonatal outcomes, safety, and patient satisfaction using Dilapan-S to provide robust evidence for clinical practice.

## Conclusion

Dilapan-S demonstrates noninferiority to the Foley balloon with a margin of -10% for achieving pre-induction cervical ripening in near-term women with an unfavorable cervix. Despite differences in Bishop's score improvement and augmentation needs, both methods displayed similar maternal and neonatal outcomes, emphasizing their comparative safety profiles. ■

## CRediT authorship contribution statement

**Krishna Priya Leela:** Writing – original draft, Investigation, Funding acquisition, Data curation, Conceptualization. **Maheswari Somasundaram:** Writing – original draft, Methodology, Investigation. **Zinia T. Nujum:** Validation, Software, Formal analysis, Data curation. **Latha Maheshwari Subbarayan:** Writing – review & editing, Validation, Project administration, Conceptualization. ■


## ACKNOWLEDGMENTS

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