Comparison between Mechanical induced Cervical Dilatation in Previous Scar Woman in 2nd Trimester Abortion Non-Randomized Controlled Study

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Abstract
Background and objective: Mechanical strategies incorporate the insertion of a balloon catheter or placement of a hygroscopic dilator. Balloon catheters were utilized within the larger part of past trials comparing mechanical and pharmacologic strategies. The objectives of this study were to compare the efficacy and safety of hygroscopic dilators and balloon catheters for ripening of the cervix in induction of labor. Methods: This study was a single-center, non-randomized, open-label trial conducted on participants who had been non-randomly allocated to either Dilapan-S (DS) or Foley balloon (FB) groups. The present study was conducted on 200 women, who had been selected randomly from attendants of the obstetrics and gynecology department at the Minia Maternity University Hospital in the period between October, 1st 2020 and September, 1st 2021. Results: The percentage of success rate was higher among the Dilapan-S group, however; there was non-statistically significant difference between both trial arms, [65/74 (87.8%) vs. 100/124 (80.6%), p-value= 0.131], in Dilapan-S and Foley balloon groups respectively. Conclusion: Dilapan-S is safe, effective induction method at second trimester termination with outcome comparable to Foley’s balloon catheter in the cervical preparation. Both Dilapan-S and Foley’s catheter have equivalent efficacy, lower risk of hyperstimulation and no clear evidence of increased infection risk.

Keywords: Balloon, Catheter, Dilator, Dilapan-S, Foley.

Introduction
Mechanical methods include insertion of a balloon catheter or placement of a hygroscopic dilator, of which the former is more commonly applied. In fact, balloon catheters were used in the majority of previous trials comparing mechanical and pharmacologic methods¹. While single and double balloon catheters are used, trials comparing these types have shown no substantial difference in clinical outcomes. The effects of different balloon sizes have also been studied². A trial comparing 30 mL and 60 mL balloons showed no differences in maternal and neonatal outcomes³. Hygroscopic dilators have been reported to be safe and effective in trials comparing them to pharmacologic methods⁴. In fact, dilators are more commonly used for pregnancy termination at early stages than for labor induction at term. We have not found any large-scale trials comparing the use of a hygroscopic dilator and other modalities for labor induction⁵.

Patients and methods
This present study was non-randomized, conducted on participants who had been selected randomly from attendants of the obstetrics and gynecology department at the Minia Maternity University Hospital during the period from (1/10/2020) to (1/9/2021). Sample size was based on an inferiority margin of 10%, 90% power, and an estimated frequency of vaginal delivery
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Statistical analysis
Data was collected, coded then entered as a spreadsheet using Microsoft Excel 2016 for Windows, of the Microsoft Office bundle; 2016 of Microsoft Corporation, United States. Data was analyzed using IBM Statistical Package for Social Sciences software (SPSS), (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp). The Kolmogorov-Smirnov test was used to verify the normality of distribution. Continuous data was expressed as mean ± standard deviation, median & IQR while categorical data as numbers and percentage. A statistical value <0.05 was considered as significant.

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Table (1): Total Time of Induction of termination with Dilapan-S versus Foley balloon; (N= 198):

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foley balloon</td>
<td>Dilapan-S</td>
</tr>
<tr>
<td>N= 124</td>
<td>N= 74</td>
</tr>
<tr>
<td>Mean ±SD</td>
<td>Mean ±SD</td>
</tr>
<tr>
<td>Min - Max</td>
<td>Min - Max</td>
</tr>
<tr>
<td>61.63 ±19.06</td>
<td>34.66 ±10.06</td>
</tr>
<tr>
<td>27 - 96</td>
<td>16 - 53</td>
</tr>
</tbody>
</table>

<0.001*

Table (2): Distribution of the studied women by Primary Outcome of Induction of termination according to Different Methods of Induction; (N= 198):

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Foley balloon</td>
<td>Dilapan-S</td>
</tr>
<tr>
<td>N= 124</td>
<td>N= 74</td>
</tr>
<tr>
<td>Failure of cervical ripening</td>
<td>24 (19.4%)</td>
</tr>
<tr>
<td>Success of cervical ripening</td>
<td>100 (80.6%)</td>
</tr>
</tbody>
</table>

Figure (1): Total Time of Induction of termination with Dilapan-S versus Foley balloon.
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Discussion

Abortion during the second trimester of pregnancy accounts for 10-15% of abortions performed worldwide (6). Dilation and evacuation (D&E) is the preferred method of second-trimester abortion in most parts of the developed world. Cervical preparation is recommended for dilation and curettage (D&C) after 12 weeks gestation and is standard practice for D&E beyond 14 weeks gestation (7).

Women with previous CS had an increased risk of uterine rupture than patients with unscarred uterus, so IOL in these patients should be done after thorough and detailed counseling with both patient and their relatives (8). Many studies evaluated different methods of labor induction when the cervix is unfavorable, these methods were classified roughly into either pharmacological or mechanical methods (3). Although misoprostol (PGE1) is widely used for labor induction, it has a high incidence of uterine hyperstimulation and subsequent rupture uterus which is a nightmare for misoprostol users, especially in women with CS, so misoprostol is not recommended in those patients (9,10).

There are three mechanical methods for cervical ripening: osmotic dilators, the transcervical Foley catheter, and other devices designed specifically for cervical ripening (11). All methods are thought to work by both directly dilating the cervix and by causing natural prostaglandin and/or oxytocin release (12). There is a lack of compelling evidence suggesting increased risk of uterine rupture because mechanical devices can also be readily removed when needed and are stable at room temperature (13).

Foley’s catheter induces labor by both mechanical dilatation and stimulating endogenous release of prostaglandins (14). Osmotic dilators exist in three main forms: laminaria tents, Lamicel T M, and Dilapan-ST M. DilapanT M, a hygroscopic dilator rod made from hydrophilic polymers, was used in abortion procedures in 1982 (12), but felt to be inferior to laminaria due to reports of fragmentation (15,16). Dilapan-S works by producing an outward mechanical force in addition to prostaglandin release, causing collagen degradation that leads to cervical

Figure (2): Distribution of the studied women by Primary Outcome of Induction of termination according to Different Methods of Induction.

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softening (17). Problems with fragmentation have not been reported with Dilapan-S and it is estimated to exert close to its maximum effect within 4-6 hours but continues to expand for up to 24 hours (18).

**Conclusion**

Dilapan-S is safe, effective induction method at second trimester termination with outcome comparable to Foley’s balloon catheter in the cervical preparation. Both Dilapan-S and Foley’s catheter have good safety profile. They have equivalent efficacy, lower risk of hyperstimulation and no clear evidence of increased infection risk. While both Dilapan-S and Foley’s catheter have minimal adverse events, the advantages of Dilapan-S over Foley’s Catheter include no protrusion from the introitus, no need to keep under tension and improve the patient satisfaction. It is easy to insert and remove.

Insertion of Dilapan-S does not require skilled medical personnel whereas insertion of Foley’s Catheter requires skill. Dilapan-S being equally effective as the Foley’s Catheter in cervical ripening and induction of termination in second trimester, is a good alternative to Foley’s Balloon Catheter with good safety profile.

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**Conflict of interest:** None.

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