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Research Article

Comparison between Mechanical induced Cervical Dilatation in Previous Scar Woman in 2nd Trimaster 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-canter, 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 (806%), 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 methods[(1)]. 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 studied[(2)]. A trial comparing 30 mL and 60 mL balloons showed no differe-nces in maternal and neonatal outcomes[(3)].

Hygroscopic dilators have been reported to be safe and effective in trials comparing them to pharmacologic methods [(4)]. 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 induction [(5)].

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

of 80% in Foley balloon and 84% in Dilapan-S. Total sample size=200 participants who had been chosen randomly according to the following inclusion criteria: previous one or two lower segment Cesarean-section woman, single baby not multiple-birth pregnancies (either IUFD or viable with lethal CFMF), and gestational age of baby from 16 to 24 weeks. While exclusion criteria were women with medical disorders e.g. (DM, HTN, Asthma etc.), previous three or more than two scars previous myomectomy, previous uterine scar like (previous repair of rupture uterus –previous myomectomy-previous repair of perforation ect, women who have coagulation defect, and women who have placenta low implanted or near internal os.

Then pregnant women presenting to our unit for management of 2nd trimesteric miscarriage, and who met inclusion and exclusion criteria counselled for treatment options, advantages and drawbacks of each and consent. Then, they were none randomly assigned in a 1:1 ratio to either Dilapan-S (DS) or Foley balloon (FB). Group A: 76 women had been scheduled for induction with unfavorable cervix, will be assigned from 24 to 36 hours of Dilapan-S for cervical ripening. Group B: 126 women had been scheduled for induction with unfavorable cervix, assigned from 48 to 72 hours of Foley balloon (intra-uterine balloon catheter) inflated with 30 -50 mL saline & prophylactic antibiotics.

A complete history was taken from patients including personal, past, family, obstetric and menstrual history. Detailed examination, such as general, abdominal, and local examination. Basic investigation includes, laboratory investigation (CBC-PT-PC-urea – creatinine – FBS- 2HPP), and Ultrasound to locate site of placenta. Then local examination to assess cervix (position, dilatation, effacement) and exclusion of any abnormality like polyp or previous tear. The cervix was visualized with a sterile vaginal speculum and cleaned with Betadin. The rods were inserted into the cervical canal under direct visualization as per the manufacturer's instructions for use (one or 2 maximum). The patient was instructed to report any excessive bleeding, pain, or other concerns and not to inform if the rods slipped. The dilators were left in place for at least 12 hour but no longer than 24 hour for the first and no longer than 12 hour for the second (total time for both maximum 36 hour). Patients remained in the hospital but were allowed to ambulate, shower, and perform regular activity as long as a reactive. If the cervix remained unfavorable after extraction of the dilators <2 cm dilated and not more than 30% effaced), a second round of DS was used, in this case for a maximum of 12 hours.

Statistical analysis

Data was collected, coded then entered as a spread sheet 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.

Results

This present study was a single-canter, non-randomized, open-label trial conducted on participants who had been non- randomly allocated to either Dilapan-S (DS) or Foley balloon (FB) groups. Figure (1) demonstrated the final included women in each trial arm in the current study, they were (74) in the DS group, (124) in the FB group. Table (2) and Figure (2) demonstrated a comparison of primary outcome of induction of termination between Dilapan-S versus Foley balloon. 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 (806%), p-value= 0.131], in Dilapan-S and Foley balloon groups respectively.

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

		Treatment group			*P-value*
		Foley balloon N= 124	**Dilapan-S N= 74**	**Total N= 198**	
Total Time of Induction	**Mean ±SD**	61.63 ±19.06	34.66 ±10.06	51.55 ±20.87	**<0.001***
	Min - Max	27 - 96	16 - 53	16 - 96	

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

		Treatment group		Total N= 198	*P-value*
		Foley balloon N= 124	**Dilapan-S N= 74**		
	Failure of cervical ripening	24 (19.4%)	9 (12.2%)	33 (16.7%)	0.131
	Success of cervical ripening	100 (80.6%)	65 (87.8%)	165 (83.3%)	

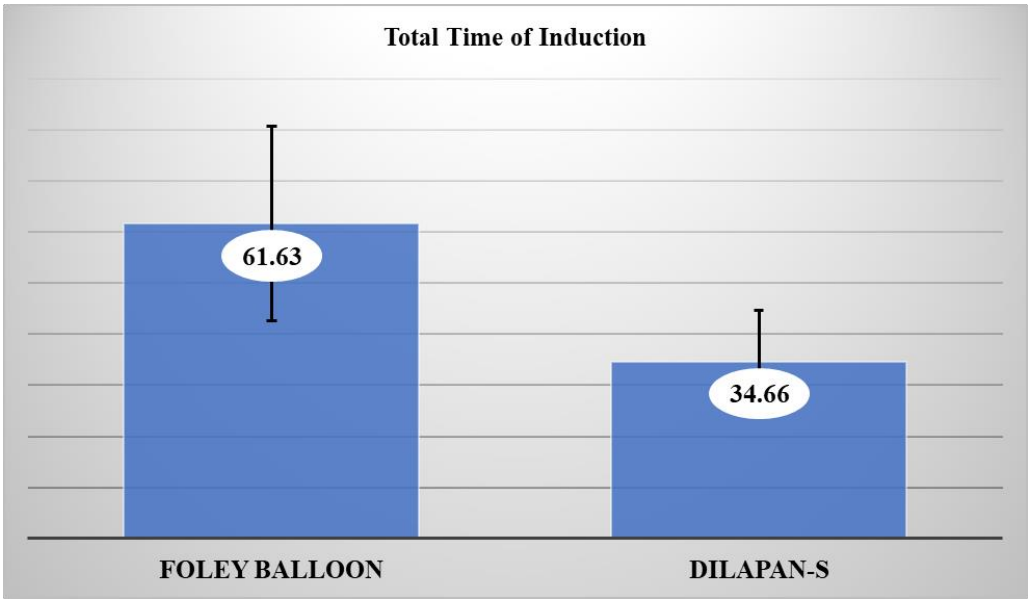

Figure (1): Total Time of Induction of termination with Dilapan-S versus Foley balloon.

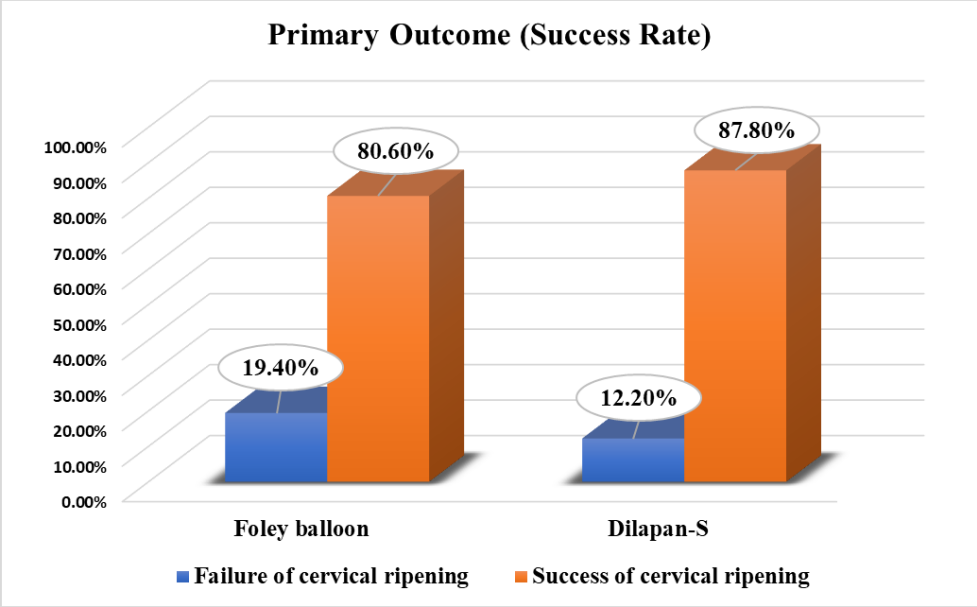

Figure (2): Distribution of the studied women by Primary Outcome of Induction of termination according to Different Methods of Induction.

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 [(2], 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

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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