THE COMPARISON OF CERVICAL RIPENING DOUBLE BALLOON AND HIGROSCOPIC DILATOR (DILAPAN–S®) IN LABOR INDUCTION

Doğum İndüksiyonunda Servikal Olgunlaştırıcı Çift Balon ile Higroskopik Dilatörün (Dilapan – S®) Karşılaştırılması

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ABSTRACT

Objective: The aim of this study was to compare the cervical ripening double balloon and hygroscopic dilator in labor induction.

Material and Methods: This is a retrospective single-center study conducted in a tertiary center. Pregnant women at or after 37 weeks with induction indication were included in this study. A total of 113 patients were included in the study. Pregnant women were divided into two groups as balloon and dilator. The two groups were compared in terms of obtetric outcomes such as bishop score change, oxytocin requirement, vaginal delivery rate, delivery time, apgar score and patient comfort.

Results: There was no difference between the groups in terms of age, body mass index, gestational week and parity. Vaginal birth rates in Dilapan-S® and balloon catheter groups were 51% and 54.2%, respectively. The total duration of the labor was longer in the dilator group but the third stage was shorter. Patient comfort was significantly higher in the Dilapan group.

Conclusion: Hygroscopic dilator and cervical ripening double balloon methods have similar results in terms of efficacy and safety and are equally effective in induction of labor.

Keywords: *Balloon; Birth; Dilapan; Dilator; Hygroscopic Induction*

ÖZET

Amaç: Bu çalışmanın amacı doğum indüksiyonunda Servikal olgunlaştırıcı çift balon ile higroskopik dilatörün karşılaştırılmasıdır.

Gereç ve Yöntemler: Bu çalışma tersiyer merkezde yapılan retrospektif tek merkezli bir çalışmadır. 37 hafta ve sonrasında olan ve indüksiyon endikasyonu olan gebeler bu çalışmaya dahil edilmiştir. Çalışmaya toplam 113 hasta alındı. Gebeler balon grubu ve dilator grubu olmak üzere iki gruba ayrıldı. İki grup bishop skor değişikliği, oksitosin gereksinimi, vajinal doğum oranı, doğum zamanı, apgar skoru ve hasta konforu gibi obstetrik sonuçlar açısından karşılaştırıldı.

Bulgular: Gruplar arasında yaş, vücut kitle indeksi, gebelik haftası ve parite açısından fark yoktu. Dilapan-S® ve balon kateter gruplarında vajinal doğum oranları sırasıyla %51 ve %54,2 idi. Doğumun toplam süresi dilatör grubunda daha uzundu ancak üçüncü aşama daha kısaydı. Dilapan grubunda hasta konforu anlamlı derecede yüksekti.

Sonuç: Doğum indüksiyonu kararı verilen hastalarda higroskopik dilatör ve servikal olgunlaştırıcı çift balon yöntemleri etkinlik ve güvenlik açısından benzer sonuçlara sahiptir ve eşit derecede etkilidir.

Anahtar Kelimeler: *Balon; Dilapan; Doğum; Higroskopik Dilatör; İndüksiyon*

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INTRODUCTION

The procedures in which the uterus is artificially stimulated to initiate labor are, together, termed 'labor induction'(1). There are a broad range of methods for labor induction, among which oxytocin or prostaglandin administration, or manually rupturing the amniotic membrane, are some of the most common. As the natural course of labor is being disrupted, potential complications of induced delivery include hemorrhage, switching to Caesarean section, uterine hyper-stimulation and uterine rupture. Rates of labor induction among full-term pregnancies are as high as 25% in developed countries (2-3).

Cervical maturation is one of the major determinants directly influencing the success of labor induction, and failed induction due to an unripe cervix is not uncommon (4). Cervical maturity is assessed by the Bishop score, developed by Edward H. Bishop in 1964 and based on the vaginal examinations of 500 multiparous women who underwent spontaneous delivery after 36 weeks' gestation (5). Numerous studies have established the correlation between the Bishop score and induction success (6-7). Therefore, various chemical and mechanical methods are implemented to increase the Bishop score, ripen the cervix, prepare it for labor and render it amenable to oxytocin induction (8-10).

The cervical ripening double balloon catheter (Cook®) is an 18F mechanical dilatation instrument, bearing two balloons with a maximum inflation of 80cc each. The balloons are designed to be inflated separately, one inside the uterus and the other inside the vagina, just exterior to the external cervical os (11). Dilapan-S® is a hygroscopic osmotic dilator made of aqua acrylic hydrogel. This rigid gel stick absorbs fluids and increases in volume, thereby dilating the cervix. After 4-6 hours, the 3 mm and 4 mm Dilapan-S® sticks expand to 8.3-10 mm and 10-12.5 mm, respectively. Dilapan-S® also stimulates endogenous prostaglandin release, leading to collagen degradation and cervical softening (12,13). The aim of this study is to compare the effect of dilapan-S and cervical ripening double balloon catheter in labor induction.

There is no study in the literature comparing Dilapan-S® and cervical ripening double balloon catheter (Cook®) in labor induction until this study is performed. In this respect, this study is capable to add new information to the literature.

MATERIAL AND METHODS

This study was approved in April 2014 by the Educational Planning and Ethics Committee (7 May 2014, No:194) of Etlik Zübeyde Hanım Women's Health Research and Training Hospital and the Etlik Zubeyde Hanım Hospital Local Ethics Committee. Pregnant patients who were followed and treated in Etlik Zubeyde Hanım Hospital perinatology ward, and who underwent labor induction for any reason between May and December 2014, were included in the study. In May 2014, our hospital initiated use of the hygroscopic dilator, Dilapan-S®, and data collection forms intended to record the detailed information of patients who received balloon or Dilapan-S® application. Patient records were retrospectively evaluated in January 2015. Patient satisfaction was performed by asking the patients to evaluate how much pain they fell during the application and after the application to the end. Patients were asked to rate the pain they felt for each condition from one to ten.

Data were obtained from a total of 113 patients who underwent either of the two mechanical cervical ripening methods for any reason. These patients were divided into two groups for analysis: those who received the cervical ripening double balloon (1st group, n=41) and those who received the hygroscopic dilator (2nd group, n=72). The study was conducted in the perinatology ward and the delivery room.

In accordance with hospital policy, all pregnant patients to receive induction of labor, for any reason, are informed about the procedure, and their written informed consents are obtained. Upon admission, every patient undergoes an initial ultrasonographic and pelvic examination. Ultrasonographic evaluations are carried out using Voluson 730 Expert (General Electric Medical Systems) and a 2.5-7.5MHz convex transabdominal probe. Following the assessment of fetal well-being and uterine activities through a nonstress test (NST), one of the medical or mechanical induction methods is implemented in the presence of any indications that induced labor is necessary. In this research, the patients who underwent Dilapan-S® or cervical ripening double balloon (Cook®) administration were studied.

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Study Groups

A. Hygroscopic Dilator Group (1st Group)

Hygroscopic dilators (4 x 65 mm) have been used in our hospital since May 2014. The patients' pre-application examination findings and Bishop scores were recorded. For patients with Bishop scores less than five, the cervix was visualized using an appropriate speculum and wiped with 10% povidone-iodine, followed by the insertion of two, saline moistened hygroscopic dilators (one at a time) until they passed through the external and internal os. The dilators were left inside the cervical canal for 12 hours.

B. Cervical Ripening Double (Cervicovaginal+Uterine) Balloon Catheter Group (2nd Group)

The patients' pre-application examination findings and Bishop scores were recorded. The cervical ripening balloons were applied, inflated 80 cc each, and strapped to the patients' legs. The balloons were removed after 12 hours, if they did not displace themselves spontaneously. If they displayed spontaneously vaginal examination was performed and patient followed as normal labor process. Continuous fetal monitoring was performed during the procedure. The patient was transferred to the delivery room for further follow up, if:

1. Abnormal fetal heart traces (fetal tachycardia, bradycardia, late decelerations, severe variable decelerations, loss of variability) were detected.
2. Abnormal uterine contractions (tachysystole, hypertonus, hyperstimulations) were detected.
3. Cervical dilatation was 5 cm, and active labor occurred.

Statistical Analiysis

Continuous variables were defined with the mean ± standard deviation (SD), and categorical variables with numbers and percentages, as appropriate. Proportions were compared using the chi-squared test. P value<0.05 was considered statistically significant. The Statistical Package for the Social Sciences (SPSS) was used for statistical analysis (version 21.0, SPSS Inc.; Chicago, IL, USA). Normal distribution was evaluated with the Kolmogorov-Smirnov Test and skewness and kurtosis values were used when necessary. The statistical analysis was performed using Fisher's exact test.

RESULTS

A total of 113 pregnant women, who were followed up in the Perinatology Ward of Etlik Zübeyde Hanım Women's Health Research and Training Hospital and who underwent mechanical labor induction by either hygroscopic dilator or cervical ripening double balloon catheter methods, were included in this study.

Of the 113 patients, 41 (36.3%) were administered the hygroscopic dilator, and 72 (63.7%) were administered the cervical ripening double balloon catheter.

The average age of the patients was calculated to be 27.9 ± 5.75 (range: 17-43). The values were 25.5 ± 3.92 (range: 18-34) for the hygroscopic dilator group and 29.3 ± 6.05 (range: 17-43) for the cervical ripening double balloon group. Age characteristics were similar between the two groups (p>0.05).

Data were obtained from these 113 patients and evaluated. The distribution of the cases, according to the implemented method, is given in Table 1.The study groups were found to be similar regarding body mass indices (p=0.560), gestational age at the time of induction (p=0.458), and parity (p=0.831).

Tablo 1. Various characteristics of the study groups

	Hygroscopic dilator (n = 41) (mean ± SD)	Balloon (n =72) (mean ± SD)	p value
Parity	1.52 ± 0.40	1.67 ± 0.48	0.831
BMI (kg/m2)	30.10 ± 3.40	31.74 ± 4.80	0.560
Gestational age (week)	39.00 ± 6.46	39.61 ± 1.82	0.458

Açıklama: SD: Standard deviation, BMI: Body mass index

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Tablo 2. İndications for labor induction

İndications	**Dilapan-S**		**Balloon**	
	N	**(%)**	**N**	**(%)**
Postterm pregnancy	18	43.9	31	43.1
Postterm pregnancy + oligohydramniosis	3	7.2	1	1.4
Rh incompatibility	1	2.4	1	1.4
Oligohydramniosis	10	24.4	20	27.8
Polihydramniosis	-	-	2	2.8
Hypertension	2	4.9	7	9.7
GDM	-	-	2	2.8
IUGR	-	-	4	5.6
SGA + oligohydramniosis	4	9.6	2	2.8
IUGR + oligohydramniosis	-	-	2	2.8
GDM + oligohydramniosis	1	2.4	-	-
Postterm pregnancy + Rh incompatibility	1	2.4	-	-
NRNST	1	2.4	-	-
Total	41	100	72	100

Açıklama: GDM: Gestational diabetes mellitus, IUGR: Intrauterine growth restriction, SGA: Small for gestational age, NRNST: Non-reactive nonstress test

The indications for labor induction, is given in Table 2.

The average total procedure times were significantly longer in the hygroscopic dilation group than in the double balloon catheter group (685.4 ± 293.2 min. vs. 574.5 ± 192.7 min.; p=0.018). The average time elapsed between initiation of induction and birth was 1357.5 ± 781.6 min. for the hygroscopic dilator group and 1117.3 ± 475 min. for the balloon catheter group, which were also significantly different. After ceasing induction, the balloon catheter group had shorter times before completing the delivery than the hygroscopic dilator group; however, the difference was statistically insignificant (544.8 ± 375.2 min. vs. 691.5 ± 624.1 min.; p>0.05) (Table 3).

The numbers of vaginal delivery cases in the study groups were limited (19 in the hygroscopic dilator group and 39 in the balloon catheter group). The durations of the first and second stages of labor were similar between the two groups, whereas stage three was found to be significantly shorter in the hygroscopic dilator group (p<0.05) (Table 4).

Pre-application Bishop scores of the two groups were also found to be similar (p>0.05); however, the groups revealed significantly different Bishop scores after completion of induction (p<0.05). The Bishop score changes in the double balloon catheter group were significantly better.

The rates of meconium detection in amniotic fluids during labor were 7.9% and 6.9% in the hygroscopic dilator and double balloon groups, respectively.

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Tablo 3. Duration of the procedures

	Hygroscopic dilator (mean ± SD)	Balloon catheter (mean ± SD)	p value
Average total procedure time (minutes)	685.4 ± 293.2	574.5 ± 192.7	0.018
Time interval between initiation of induction and birth (minutes)	1357.5 ± 781.6	1117.3 ± 475	0.046
Time interval between ceasing of induction and birth (minutes)	691.5 ± 624.1	544.8 ± 375.2	0.129

The difference between the two groups was not statistically significant (p=0.932).

The rates of oxytocin requirement during labor in the two groups were also compared, and a slight, but insignificant, difference was present (p>0.05).

Vaginal delivery rates in Dilapan-S® and balloon catheter groups were 50% and 54.2%, respectively. The difference was not statistically significant (p=0.532).

CPD, fetal distress, and failed induction were the most common indications of Caesarean delivery in both study groups. Caesarean indications were found to be similar between the groups.

The groups had similar gender distributions (p=0.992) and showed similar average birthweights (p=0.490).

First- and fifth-minute Appearance, Pulse, Grimace, Activity, and Respiration (Apgar) scores were similar between the groups. No patient in the hygroscopic dilator group, and only one in 72 in the double balloon catheter group, required neonatal resuscitation (p>0.05).

Maternal tachysystole was present in 2.4% and 9.7% of the patients in the hygroscopic dilator group and the double balloon catheter group, respectively. The difference was statistically insignificant (p>0.05).

Satisfaction survey

Upon completion of the induction, the patients were asked to assign a score for their pain—1 for minimum and 10 for maximum—to establish a measure of patient satisfaction and compare the two groups on this point. The average scores were 4.8 ± 0.7 (range: 1-9) for the hygroscopic dilator group and 7.6 ± 0.8 (range: 5-10) for the cervical double balloon catheter group. According to the survey results, the satisfaction levels were found to be significantly higher in the hygroscopic dilator group (p<0.001).

DISCUSSION

Mechanical cervical ripening applications are now proven to be as effective and safe as pharmacological methods, and they are currently increasing in popularity due to their several advantages.

Pre-application Bishop scores were similar between the two studied groups. After application, the patients' Bishop scores in the double balloon catheter group showed significant improvement.

Patient satisfaction was found to be significantly higher in the hygroscopic dilator group than in the double balloon catheter group.

If initiation of labor is necessary, for any reason, the obstetrician has three different approach alternatives: waiting for labor to begin spontaneously, delivering the baby through Caesarean section, or stimulating the uterus to create contractions and initiate labor. The last option is the most convenient in most cases. The function of the cervix in maintaining pregnancy to term is unquestionable. Likewise, cervix functions and cervical responses to labor induction seem to be the main checkpoints in labor initiation and maintenance (14,15). Inducing labor when the cervix is unripe will lead to increased delivery times and Caesarean section rates. Thus, cervical ripening will reduce, not only the time

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elapsed between commencing induction and birth, but also the need for Caesarean delivery (16). There are several methods to ripen the cervix, which may be divided into two main groups: mechanical cervical dilators and medical agents. Intravenous oxytocin is the most commonly used method today (15). Prostaglandin E1, another medical agent, is cheaper and easier to keep, and it is still being used at low doses. Currently, the prostaglandin E1 analogue misoprostol is reported as useful for labor induction when the cervix is unripe (17,18). However, a consensus on optimum administration routes and safe dose intervals has yet to be established (18,19). Prostaglandins used to be administered systemically; however, they are now being used locally. Their systemic absorption may lead to uterine hypertonia, nausea, and vomiting. To avoid these side effects, prostaglandin pessaries or gels are used by intravaginal, intracervical, or extra-amniotic routes (20, 21).

A small number of studies are available regarding the use of hygroscopic dilators in full-term pregnancies. Therefore, this study may comprise a substantial contribution to the literature.

The effectiveness and safety of different cervical ripening agents have been examined and compared in several studies. Fitzpatrick et al. (2012) studied 116 cases that applied Foley catheters, comparing the effects of fixed vs. incremental doses of oxytocin and reporting no significant difference regarding labor duration between the two groups (23.7 vs. 19.2 hours, respectively) (22).

Another study by Levy et al. (2004) compared the oxytocin augmentation requirements for cervical ripening when Foley catheters were inflated to 30cc and 80cc. They found that 90.4% and 69% of the patients needed oxytocin augmentation, respectively, and the patients belonging to the 80cc group had shorter labor durations ($p<0.05$) (23).

Most of the studies examining the effects of different labor induction agents accept the mode of delivery (i.e., vaginal or Caesarean) as the main outcome measure.

In this study, the vaginal delivery rate in the hygroscopic dilator group was 50% compared to 54.2% in the cervical ripening double balloon group, with no statistically significant difference ($p=0.532$).

Of the 113 patients included in this research, 41 underwent hygroscopic dilator, and 72 underwent cervical ripening double balloon; the study groups were established accordingly. Oxytocin administration rates were seemingly different between the two groups (65.8% in the hygroscopic dilator group vs. 55.6% in the double balloon catheter group), although there was no statistical significance ($p>0.05$). The Caesarean delivery rates in this study were higher than those found in similar studies (24,25).

The groups in this research showed similar pre-induction Bishop scores ($p=0.357$). The difference between pre- and post-induction Bishop scores was found to be 3.57 in the hygroscopic dilator group and 4.87 in the double balloon catheter group, which reveals that both methods were successful in improving the Bishop scores. A multidisciplinary study by Roztocil et al. (1996), which is one of the few in the literature that focuses on hygroscopic dilators, found a difference between pre- and post-priming Bishop scores of 3.32, which was similar to our results (26).

Tachysystole was recorded in one (2.4%) patient in the hygroscopic dilator group and seven (9.7%) patients in the double balloon catheter group ($p=0.259$).

Conflicting with previous reports, the rates were statistically similar between our study groups. In the study by Gelber et al. (2006), no tachysystole

Tablo 4. Duration of labor stages

Labor stages	Hygroscopic dilator (mean ± SD)	Balloon (mean ± SD)	p value
Stage 1 (minutes)	1212.6 ± 273.8	1029.1 ± 235.8	0.235
Stage 2 (minutes)	65.5 ± 64.1	74.2 ± 88.4	0.412
Stage 3 (minutes)	20.2 ± 8.1	39.6 ± 25.4	0.002
Total	19	39	

was encountered among their hygroscopic dilation patients. Pennel et al. (2009), on the contrary, found a tachysystole rate of 14%, which was again discordant with our findings (27,28).

The average one-minute Apgar scores in the hygroscopic dilator and double balloon catheter groups were 7.4 and 7.3, respectively.

Caesarean section rates were 50% and 45.8%, respectively, for hygroscopic dilator and double balloon catheter groups (p=0.532), which were higher than those of previous balloon catheter studies. In a randomized, controlled trial by Salim et al. (2011), the Caesarean delivery rate among double balloon catheter patients was reported to be 17.6%, and Foley and cervical ripening double balloon catheter methods were found to be similarly effective with higher Caesarean and operative vaginal delivery rates in the double balloon catheter group (25). Pennel et al. (2009) studied nulliparous pregnant women and reported a Caesarean delivery rate of 43% in double balloon catheter patients. They inferred these results to be a consequence of the patients having unripe cervices (27). Cromi et al. (2011) compared the Caesarean delivery rates of double balloon catheter implemented and of controlled-release dinoprostone vaginal ovule administered patients, and reported them to be 23.8% and 26.2%, respectively (24).

In our study, no infant was resuscitated in the hygroscopic dilator group, whereas one neonate required resuscitation in the double balloon catheter group. The resuscitated infant was followed up for two days in the neonatal care unit and was discharged from the hospital on the fifth day.

No case of postpartum endometritis, uterine rupture, chorioamnionitis, or fetal exitus occurred during our study.

In this study, meconium contaminated amniotic fluid rates were 7.3% in the hygroscopic dilator group and 6.9% in the double balloon catheter group (p=0.941).

CONCLUSION

The biggest limitation of this study is that it is retrospective. However, all of the data used in the study were collected by a single doctor.

There are a limited number of studies focusing on hygroscopic dilator administration in full-term, pregnant women. Further multicenter clinical studies, recruiting higher numbers of patients and applying better-defined criteria, are needed to standardize the hygroscopic dilation and double balloon catheterization procedures.

As a final word, for the active management of full-term pregnant patients with inappropriate Bishop scores, hygroscopic dilator and cervical ripening double balloon catheter methods bear comparable effectiveness and safety characteristics. According to our results, these two cervical ripening and labor induction methods are equivalent and replaceable. However, patient satisfaction levels seem to be higher for the hygroscopic dilation method. Further randomized, prospective, multicenter, controlled studies with larger patient populations are needed to clarify the important issues regarding neonatal outcomes and complications, such as uterine hyperstimulation, fetal distress, and the like.

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