

Randomized Trial of Dilapan and Laminaria as Cervical Ripening Agents Before Induction of Labor

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A randomized trial was conducted to evaluate the comparative effectiveness of Dilapan cervical dilators and *Laminaria japonicum* as cervical ripening agents before induction of labor at term. Patients with Bishop scores of 4 or less and a fetal or maternal indication for induction at 34 or more weeks' gestation were eligible for the study. The outcome variables of interest were Bishop score upon removal of the devices, number of devices used, induction-to-delivery time, and induction-to-complete dilatation time. In the Dilapan group, an average of 4.3 devices per patient was used, compared with 9.7 devices in the laminaria group ($P < .01$). Among patients who eventually achieved complete dilatation, the mean (\pm SD) time for the Dilapan group was 10.8 ± 6.1 hours, compared with 14.7 ± 9.2 hours with laminaria. For women undergoing induction of labor at term with an unripe cervix, Dilapan appeared to be a preferable alternative to *Laminaria japonicum* because its use may result in a shorter induction-to-delivery interval with fewer devices required to obtain significant cervical ripening. (*Obstet Gynecol* 75:365, 1990)

The role that a ripe cervix plays in predicting successful induction of labor has long been recognized.¹⁻³ Because of this, a number of researchers have sought to identify means of artificially achieving cervical ripening to improve the likelihood of a successful induction.²⁻¹² Although a variety of methods have been tried, no single uniformly safe and reliable method has emerged. Recently, the Dilapan synthetic dilator, a slender stick of polyacrylonitrile hydrogel measuring 4×65 mm, was found useful for cervical pre-treatment before second-trimester abortion and was thought to hold promise for achieving cervical ripening before the induction of labor in term pregnancy.¹³ We conducted this study to evaluate the safety and efficacy of this new synthetic cervical dilator as compared with a more traditional dilator, *Laminaria japonicum*.

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Materials and Methods

Between January 1987 and January 1988, 97 women brought to Michael Reese Hospital for induction of labor were eligible for participation in the study, according to the following requirements: gestational age 34 or more weeks, no known fetal anomalies, intact membranes, vertex presentation, and no previous cesarean delivery.

Upon admission to the labor corridor, subjects gave a history and had a physical examination. Upon vaginal examination, a Bishop score was assigned.³ After obtaining informed written consent in accordance with Institutional Review Board guidelines, we randomized subjects with a Bishop score of 4 or less to receive either the *Laminaria japonicum* (Dilateria; Milex Corp., Chicago, IL) or Dilapan (polyacrylonitrile hydrogel; Gynotech Corp., Lebanon, NJ) cervical dilators. Randomization was accomplished by having women randomly choose a blank envelope from a stack of identical envelopes each containing a group assignment. There were 25 envelopes for each group. Those whose Bishop scores were more than 4 were considered to have "ripe" cervixes and were assigned to a comparison group. Demographic and obstetric data obtained for all patients included age, parity, gestational age, number of previous abortions, and indication for induction.

For subjects assigned to receive either laminaria or Dilapan, preparation of the vagina and cervix was performed on the evening before induction using povidone-iodine, followed by insertion of the devices. Women in the Dilapan group received as many devices as could comfortably be tolerated, but not more than six. The devices were placed in the endocervical canal, followed by a povidone-iodine-soaked sponge placed in the vagina as a pack. For the laminaria group, as many devices (of assorted sizes) as could be comfortably tolerated were placed in the endocervical canal,

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followed by a povidone-iodine-soaked sponge as described above. Insertions were performed by senior residents experienced in the placement of laminaria who were instructed in the placement of Dilapan by one of the authors (PDB). Insertions were performed under the supervision of an attending physician. Any difficulty in the insertion of devices was noted and recorded. The subjects were then sent to the obstetric floor, where they rested for the night.

The next morning, the women were returned to the labor rooms, the devices were removed, and the Bishop score reassessed. Induction of labor using oxytocin was then begun according to the standard protocol used at our institution. Oxytocin at a concentration of 10 U/250 mL of normal saline was infused at a rate of 1 mU/minute for 30 minutes. If there was no evidence of fetal compromise, the rate of infusion was increased by 2 mU/minute at 30-minute intervals until contractions occurred every 2–3 minutes. All labors were monitored electronically. When clinically appropriate, amniotomy was performed in the active phase of labor with the cervix dilated 5 cm or more. If indicated, internal fetal monitoring devices were placed. Vaginal examinations were performed as needed. We recorded the time at which complete cervical dilatation was achieved and the delivery time for each woman.

Outcome variables recorded were change in Bishop score, induction-to-delivery interval, induction-to-complete dilatation interval, cesarean and vaginal birth rates, and the total number of devices used per subject. Statistical analyses were performed using the following: 1) Wilcoxon or Mann-Whitney tests for nonparametric data (ie, change in Bishop score), 2) χ^2 to test for associations between categorical variables, 3) *t* tests for determining statistical significance between normally distributed variables, and 4) analysis of variance for testing multiple means. $P < .05$ was considered statistically significant.

Results

Characteristics for the laminaria, Dilapan, and comparison groups did not differ in any clinically relevant ways (Table 1). In the two groups that received devices, the number of devices used per subject was appreciably different (Table 2). The indications for induction in the study groups were a variety of obstetric complications including postmaturity (15), intrauterine growth retardation (eight), pregnancy-induced hypertension (eight), gestational diabetes (seven), and other (three). Chi-square analysis of the indications for induction between groups showed no statistically significant differences.

There were no complications associated with device

Table 1. Patient Characteristics

Variable	Treatment group		"Ripe" cervix	P
	Dilapan	Laminaria		
No. of subjects	23	18	57	
Maternal age	23.5 ± 5.98	21.2 ± 5.1	28.2 ± 6.5	NS
Gestational age	39.6 ± 2.7	39.8 ± 2.3	39.8 ± 1.8	NS
Parity	0.8 ± 1.2	1.0 ± 1.4	1.0 ± 1.0	NS
Bishop score before	2.6 ± 0.9	2.4 ± 1.2		NS

NS = not significant.

Values are presented as mean ± SD.

insertion or removal in any subject; nor were there any cases of intrapartum pyrexia or infection. Consistent with our previous experience with Dilapan,¹³ these devices seemed subjectively easier to insert, requiring less force and gliding through the cervix more easily than laminaria.

Table 2 presents the induction-to-complete dilatation intervals and the induction-to-delivery intervals for the three groups. Analysis of variance and multiple regression analysis controlling for parity and gestational age demonstrated a statistically significant difference in the mean induction-to-complete dilatation times among the three groups. Statistical contrasts among the three groups showed a significant difference between the group with ripe cervixes and the laminaria group. The 4.1-hour difference between the Dilapan and the laminaria groups was not statistically significant ($P = .07$), but suggests a trend of clinical importance. The induction-to-delivery intervals displayed in Table 2 show a time difference among the three groups similar to that

Table 2. Selected Outcomes in the Three Groups

Variable	Treatment group		"Ripe" cervix
	Dilapan	Laminaria	
Bishop score			
Before	2.6 ± 0.9	2.4 ± 1.2	
After	6.4 ± 1.7	5.6 ± 2.4*	5.4 ± 0.9
Difference	3.9 ± 1.6	3.2 ± 2.3	
No. of devices per patient	4.3 ± 0.71	9.8 ± 3.1	
Induction-complete dilatation time (N = 20)	10.8 ± 6.1	14.7 ± 9.2	9.6 ± 5.9 (N = 54)
Induction-delivery time	11.6 ± 6.0	15.5 ± 7.7	10.4 ± 6.0
% of group with vaginal delivery	85.7	76.5	92.7

Device-related outcomes are presented as mean ± SD. Times are presented as mean hours ± SD.

* $P < .05$ for change in Bishop score for both groups (Mann-Whitney test)

† $P < .05$ among the three groups (analysis of variance) and $P < .001$ using multiple linear regression and controlling for parity and gestational age.

found for the time to complete dilatation. The second stage of labor in each group was also similar in duration.

The Bishop scores for the three groups, shown in Table 2, had changed appreciably upon removal of the devices in both of the device-receiving groups. For both groups, the change in Bishop score was statistically significant. Although the average Bishop score after removal was slightly higher in the Dilapan group than in the laminaria group, this small difference has no clinical importance.

As shown in Table 2, the proportion of patients who eventually required cesarean delivery was somewhat different among the three groups, but these differences were not statistically significant. There were no adverse effects on the mother or fetus in either of the study groups.

Discussion

The purpose of this study was to explore the usefulness of the Dilapan cervical dilator as a cervical ripening agent. Compared with laminaria, Dilapan appears to be effective. It may offer advantages in terms of the number of devices required to effect cervical ripening, as reflected by changes in the Bishop score. There was a trend toward shorter intervals required to reach complete dilatation with Dilapan than with laminaria and, when compared with a group of patients with "ripe" cervixes, Dilapan seemed to produce cervical changes and results more closely resembling a ripe cervix than did laminaria. The reason for this is not clear, but may be partly due to the fact that Dilapan is more predictable than laminaria in terms of the final diameter of the expanded device and the time required to reach that diameter. It may also be that Dilapan, in addition to its purely hygroscopic effect on the cervix, affects cervical collagen more profoundly than laminaria, resulting in a cervix that more closely resembles a "ripe" one.

Because of our previous experience with the Dilapan device, we arbitrarily chose six as the maximum number of these devices allowed per patient.¹³ This constraint makes statistical comparisons of the number of devices used in each group inappropriate. Nevertheless, despite the arbitrary limit on the number of Dilapan devices allowed per patient, it is valuable to know that an average of 4.3 ± 0.7 of these devices accomplished a change in Bishop score and an induction-to-complete dilatation interval similar to those with an average of 9.8 ± 3.1 laminaria. In addition, the difference in number of devices placed per patient has important implications with respect to patient discomfort, trauma to the cervix, and cost. At the time this

study was conducted, the cost per device for a center making large purchases was approximately \$2.25 for laminaria and \$4.00 for Dilapan. Thus, in this study, the average cost of cervical pre-treatment with laminaria was approximately \$20.25, compared with approximately \$17.00 using Dilapan.

Although the induction-to-delivery time has been the standard by which a successful induction has been judged, the induction-to-complete dilatation time was considered a more appropriate index by which to assess the effect of the devices on the cervix and the length of labor. By using the induction-to-complete dilatation time as the primary measure of effect, we reduced confounding by factors such as fetal size, fetal position, pelvic dimensions, and effectiveness of pushing. These factors can significantly affect the overall length of labor, especially in the second stage, and might therefore obscure the effect of the devices in facilitating complete cervical dilatation.

Recently, use of prostaglandin E₂ gel (PGE₂) has been advocated for cervical priming before induction of labor.^{8,10,14} Although a number of studies have demonstrated its efficacy, PGs are not approved for this use in the United States. In addition, when PGs have been used to ripen the cervix before induction of labor, serious adverse effects such as fetal distress, occult onset of labor, and tetanic uterine contractions have occasionally been observed.^{10,11} To our knowledge, no previous studies have compared Dilapan with PGE₂ in the obstetric setting. However, the recent report of Ferguson et al¹⁴ allows some comparisons. In their study, which was methodologically similar to this one, an average induction-to-complete dilatation interval of 9 ± 5.5 hours was observed in the PGE₂-treated group, remarkably similar to the 10.8-hour interval observed in our report. The changes in Bishop scores in the two studies are also quite similar—3.5 reported by Ferguson et al and 3.8 for the Dilapan group in this study. Thus, it seems that Dilapan and PGE₂ may both be effective as cervical ripening agents before the induction of labor.

This preliminary study demonstrates the potential usefulness of Dilapan in the obstetric setting, specifically for pre-induction ripening of the cervix. However, before this device finds its place in the obstetric armamentarium, further randomized trials are necessary to directly compare Dilapan with PG-related methods of cervical ripening.

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