

Prospective Comparison of Dilapan and Laminaria for Pretreatment of the Cervix in Second-Trimester Induction Abortion

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Fifty-four women presenting for second-trimester induction abortion received either Dilapan synthetic dilators or laminaria for pretreatment of the cervix before induction abortion using intra-amniotic prostaglandin (PG) $F_{2\alpha}$. The two groups were similar with respect to age, parity, previous abortion, and gestational age. Neither group experienced any unusual complications. The same protocol for intra-amniotic $PGF_{2\alpha}$ (40 mg) was used in all patients except for three with histories of asthma, in whom PGE_2 vaginal suppositories (20 mg) were used as the induction agent. For the Dilapan group, an average of three devices was used, compared with an average of six in the laminaria group. The mean (\pm SEM) induction-abortion time for Dilapan patients was 10.9 ± 1.3 hours, compared with 16.1 ± 1.4 hours in the laminaria group, a statistically significant difference ($P < .05$). When nulliparous women were examined separately, the mean times were 11.0 ± 1.7 for Dilapan and 16.5 ± 1.6 for laminaria, a medically relevant and statistically significant difference ($P < .05$). Dilapan appears to be an effective alternative to laminaria that results in shorter induction-abortion intervals. (*Obstet Gynecol* 72:243, 1988)

Although dilation and evacuation (D&E) procedures have become increasingly common for termination of pregnancy between 13–18 weeks' gestation, many centers continue to perform induction abortion procedures. These procedures, defined here as those in which labor is induced to effect the abortion, rely on such abortifacients as intra-amniotic prostaglandin (PG) (either alone or in combination with urea), vaginal PGs (usually by gel or suppository) and, less commonly, oxytocin infusion.¹ In addition, because of the numerous reports demonstrating that cervical pretreatment with laminaria could reduce both the induction-abortion time and the likelihood of uterine rupture, many centers now use laminaria routinely

before amnioinfusion or the use of vaginal suppositories.^{2–11}

Recently a new synthetic dilator, the Dilapan dilator, was introduced for this use.⁵ The Dilapan dilator is a polyacrylonitrile hydrogel which expands more rapidly and, according to the manufacturer, more reliably than traditional laminaria. This report directly compares laminaria and Dilapan to evaluate their effectiveness in cervical pretreatment during induction abortion.

Materials and Methods

This open-label serial trial was conducted between September 1, 1985 and November 30, 1986. All patients presenting to the Mid-Trimester Abortion Unit of Michael Reese Hospital and Medical Center for whom an induction abortion was planned were eligible to participate. After giving informed written consent, the patient received either laminaria (Dilateria; Milex Corp., Chicago, IL) or Dilapan (Gynotech Corp., Lebanon, NJ) cervical dilators. Between September 1985 and March 1986, all patients received laminaria. As many devices (in a combination of sizes) as the patient could tolerate comfortably were placed intracervically on the evening before admission for an induction abortion. If fewer than three devices could be inserted at that time, a second set of laminaria were inserted on the morning of admission. From April 1986 to December 1986, all participating patients received Dilapan dilators. As with laminaria, as many devices as the patient could tolerate comfortably were inserted on the evening before admission. If fewer than two devices could be placed, a second set was inserted on the morning of admission. In all cases, the devices were allowed to remain in place until rupture of membranes or fetal expulsion, but no longer than 24 hours. None of the patients received any local or systemic medication at the time of insertion. In all cases, two Betadine-

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soaked gauze sponges were placed in the vagina as a pack. The author performed all insertions and all induction procedures.

One intra-amniotic injection of PGF_{2α} (Prostin F_{2α}; Upjohn Co., Kalamazoo, MI), 40 mg, was used as the abortifacient in all but four cases. In these instances, because of a history of asthma, serial PGE₂ suppositories, 20 mg (Prostin E₂; Upjohn Co.) were used. Any difficulty with either insertion or removal of the devices was recorded.

Patient characteristics such as age, parity, history of abortion, and gestational age were recorded for both groups. The induction-abortion interval, the number of devices used, and the number of sets of devices required were recorded for each patient. A nurse cared for each patient individually from the time the procedure began (injection or insertion of first suppository) to the end time (fetal expulsion). In addition, the author recorded any complications, such as hemorrhage requiring transfusion, unintended major surgery, and infection that was apparent during the induction. Infection was defined as temperature greater than 38.5C associated with foul-smelling amniotic fluid, white blood cell count greater than 16,000 cells/ μ L, and/or clinical evidence of endomyometritis post-expulsion.

A subgroup of patients received laminaria coated with a crudely prepared suspension of PGE (10 mg) in Betadine gel, which was inserted just before injection. These patients were originally included in the laminaria group but, because of the potentially confounding effects of the PG and the timing of insertion, were ultimately analyzed separately.

The most important outcomes in this study were induction-abortion times and the number of devices used per patient. Differences between means were compared statistically by *t* tests and analysis of variance.¹² In addition, 95% confidence intervals were constructed for the differences between means of induction-abortion time for the two laminaria groups compared with Dilapan.¹³

Results

Age, parity, and gestational age for the laminaria, Dilapan, and the subset of PGE-coated laminaria groups were similar, and showed no clinically relevant differences (Table 1). Although two patients in the laminaria group had experienced previous second-trimester abortions, compared with none in the Dilapan group, this difference was not statistically significant. Such a history may predispose to more rapid induction-abortion times, but these two patients had induction-abortion times similar to those of the

Table 1. Patient Characteristics by Treatment Group

Characteristic	Laminaria		
	Laminaria	+ PGE	Dilapan
No. of patients	25	12	17
Age	23.2 \pm 7.2	20.9 \pm 6.6	21.6 \pm 7.5
Gestational age	18.6 \pm 1.1	18.3 \pm 0.9	18.5 \pm 0.7
% nulliparous	80	67	76
Previous second-trimester abortion	0.1 \pm 0.3	0	0

PGE = prostaglandin E.

Data are expressed as mean \pm SD, except for parity.

other patients in their group, so they were included for statistical analysis.

The number of devices used per patient differed appreciably between the two groups (Table 2). Laminaria patients received an average of twice as many devices as did the Dilapan group (*P* < .01). When one considers patient discomfort with insertion, potential trauma to the cervix, and cost, the difference also has medical relevance. There were no complications of either insertion or removal for any patient. Subjectively, it was considerably easier to insert the Dilapan devices than the laminaria, and the patients in the Dilapan group seemed to tolerate the insertion better than their laminaria counterparts. One patient required a transfusion because of hemorrhage immediately after fetal expulsion, but there were no other complications.

Table 2 displays induction-abortion times for the

Table 2. Selected Outcome Variables by Treatment Group

Outcome variable	Laminaria		
	Laminaria	+ PGE	Dilapan
Total patients			
No. of devices	6.1 \pm 0.5	4.4 \pm 0.4	2.9 \pm 0.2*
Induction-abortion time (hr)	16.1 \pm 1.4	13.7 \pm 1.9	10.9 \pm 1.3 [†]
Nulliparous patients			
No. of patients	20	8	13
No. of devices	5.8 \pm 0.5	4.8 \pm 0.5	3.0 \pm 0.3*
Induction-abortion time (hr)	16.5 \pm 1.65	15.2 \pm 2.8	11.0 \pm 1.7 ^{†§}

PGE = prostaglandin E.

Data are expressed as mean \pm SEM.

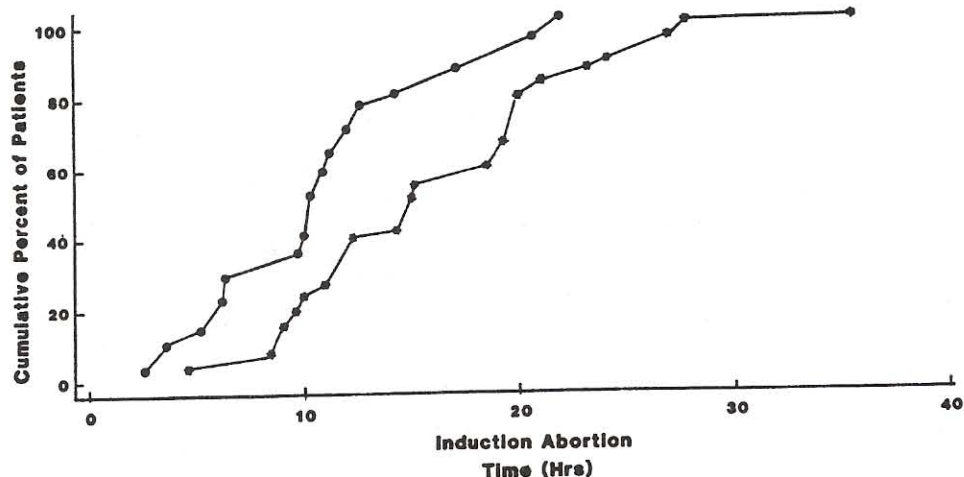
* *P* < .05 for difference between means, each laminaria group compared with Dilapan.

[†] *P* < .05 for difference between several means, by analysis of variance.

[‡] *P* < .02 for difference between laminaria and Dilapan (95% confidence interval = 1.37, 9.17); *P* > .10 for difference between laminaria + PGE and Dilapan (95% confidence interval = -1.94, 7.60).

[§] *P* < .02 for difference between Dilapan and laminaria (95% confidence interval = 2.14, 8.74); *P* > .10 for difference between Dilapan and laminaria + PGE (95% confidence interval = -2.33, 10.71).

Figure 1. Cumulative percent of patients successfully completing induction abortion over time for the untreated laminaria (asterisks) and Dilapan (circles) groups.



three treatment groups for both the total study group and nulliparous patients. Between the uncoated laminaria and Dilapan groups there was a difference of 5.27 hours for all patients and 5.44 hours for nulliparous patients. These differences are both statistically significant and medically relevant. Between the PGE-coated laminaria group and the Dilapan group, the induction-abortion times differed by 2.85 hours in the total sample and 4.18 hours for the nulliparas. These differences were not statistically significant, probably because of the relatively smaller sample and larger variance than for the untreated laminaria group, but suggest a trend. For the differences between the untreated laminaria group and the Dilapan group, the range of the confidence limit was not wide and excluded zero. This was true for the two parity-specific strata (all patients; nulliparas) and indicates both statistical significance and that the "true" difference probably fell within a narrow range. However, the mean difference for the PGE-coated laminaria group compared with Dilapan, as represented by the 95% confidence limit, was wider and included zero, indicating both the lack of statistical significance and the relatively greater variation in the induction-abortion times in the PGE-coated group.

Figure 1 shows the cumulative proportion of patients successfully completing the abortion over time for the laminaria and Dilapan groups. At almost any time, a higher proportion of the Dilapan patients had successfully completed the abortion. Thus, the Dilapan group completed the abortion earlier and, in half of the cases, avoided an overnight stay.

Discussion

This study was conducted to answer two relatively simple questions: 1) How would induction-abortion

times compare when Dilapan or laminaria were used for cervical pretreatment before induction abortion procedures? and 2) Would one device have advantages over the other?

When untreated laminaria are compared with Dilapan, the answer seems fairly clear. A considerable reduction was found in the induction-abortion time and in the number of devices used. Although not as dramatic or as statistically reliable, a difference also resulted between Dilapan and laminaria coated with PGE. In both instances, the difference favors Dilapan.

The reasons for these results are not clear, but may involve the more predictable properties of Dilapan compared with laminaria, particularly in relation to the final diameter of the expanded device and the shorter time required to reach that size.¹⁴ It may also be that Dilapan has a more pronounced effect on cervical collagen than laminaria, resulting in a softer, more pliable cervix.

Dilapan seems to have other advantages over laminaria. First, fewer Dilapan devices are needed, which results in less insertion time, less cervical trauma, less patient discomfort, and a greater likelihood that all devices will be placed properly in the cervix. All too often when multiple laminaria are inserted, only a few of them actually reach the level of the internal os, while the rest dangle uselessly from the external os or dilate the vagina.¹⁵ By using fewer but more reliable devices, this can be avoided. Second, the Dilapan were, at least subjectively, easier to insert than the laminaria. Dilapan devices become quite slippery when they are dipped in Betadine solution before insertion; they glide through the cervical canal more easily than identically inserted laminaria. Finally, the cost of cervical pretreatment may be less with Dilapan. For a center making large purchases, the costs are approximately \$2.25 and \$4.00 for laminaria and

Dilapan, respectively. Thus, assuming one uses three Dilapan and six laminaria per patient, the costs per procedure would be \$12.00 for Dilapan and \$13.50 for laminaria.

As abortion technology continues to improve, safer and more expeditious procedures result, especially for second-trimester gestations. This study demonstrates a potential improvement in cervical pretreatment. These results need to be confirmed and extended. In addition, given the apparent usefulness of Dilapan in the induction abortion setting, there are obvious implications for its use in the induction of labor.

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