

Laminaria versus Dilapan osmotic cervical dilators for outpatient dilation and evacuation abortion: Randomized cohort comparison of 1001 patients

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OBJECTIVE: Our purpose was to compare the clinical experience in using Dilapan osmotic dilator and *Laminaria japonicum* as overnight osmotic cervical dilators in second-trimester dilation and evacuation abortion with respect to measurable outcome variables, including complication rates.

STUDY DESIGN: A cohort comparison was performed of 1001 patients receiving alternate preoperative treatment with either osmotic dilator after initial randomization until this number had been reached in the series.

RESULTS: Few significant differences were found in the two cohorts with respect to blood loss, procedure times, and overall complication rates. However, patients receiving the Dilapan dilator were at least twice as likely to experience problems in cervical dilation or problems resulting from poor dilation or disintegration of the device than were patients receiving *Laminaria japonicum*. Although more patients receiving laminaria experienced amniotic fluid embolism or disseminated intravascular coagulation syndrome, these problems could not be attributed to the type of osmotic dilator used.

CONCLUSION: Both osmotic dilators are acceptable for use in overnight dilation in this procedure, but the Dilapan dilator is more likely to disintegrate, retract, or present minor problems associated with poor dilation. (Am J Obstet Gynecol 1994; 171:324-8.)

Key words: Laminaria, Dilapan, abortion, evacuation

Preoperative cervical dilation with hygroscopic materials such as *Laminaria japonicum* has become the standard of practice for abortions performed after the first trimester in the United States. Controversy continues, however, over the length of preoperative dilation time and the choice of materials. The recent introduction of a synthetic osmotic dilator, Dilapan (Gynotech Industries, Middlesex, N.J.), offers the alternative of using a manufactured, highly controlled material with a predictable response.¹ Although pilot studies and one controlled trial have been published, the numbers are too small to permit adequate evaluation or comparison between the synthetic dilator and laminaria.^{2,5} Another problem is that most case series of multiple laminaria application for cervical dilation have used a 2-day procedure, which increases the possibility of introducing confounding factors that make accurate comparison difficult.^{4,5}

The current study attempts to provide a side-by-side study of *Laminaria japonicum* with Dilapan in a standardized overnight treatment to permit accurate and valid comparison in second-trimester dilation and evacuation abortion patients.

Methods

A total of 1247 patients were included in the study, 246 of whom were excluded from the final analysis because of failure to meet the study criteria or the presence of confounding factors (including performance of some cases by a different physician). Entry criteria included gestational age 13 to 25 menstrual weeks as confirmed by ultrasonographic diagnosis. The first patient in the trial was chosen by consulting a table

of random numbers, and a coin was flipped to select her treatment. After that, treatments alternated with each patient. Patients were informed that they would receive either treatment. No patients declined to participate in the study.

Exclusion criteria included history of cervical surgery or presence of cervical scarring, multiple cesarean sections, serious intercurrent illness, or active vaginal bleeding. More than 200 patients whose procedures were performed by a physician in training were excluded because, although outcome variable results were within acceptable limits, they showed more variability according to physician identity than variability resulting from treatment alternatives under study. The majority of cases excluded for this reason fell in the last 300 cases studied. Also, any patient who was judged to require multiple applications of dilators for safety reasons was dropped from the study. Those who were so judged before preoperative treatment was begun were replaced with the next patient. Those for whom this judgment was made after the first dilator application occurred were not replaced in the series. A total of 1001 patients, all of whose procedures were performed by a single physician (W.M.H.), were included in the final study.

Patients who were admitted to the study received preoperative evaluation of gestational age by ultrasonography, preoperative counseling, physical examination, and preoperative placement of one or more cervical dilators. Alternate patients received *Laminaria japonicum* or Dilapan. In all cases the cervix was sounded through the internal os to determine patency and direction and the hygroscopic dilators were dipped in nitrofurazone ointment before placement. The number of dilators used was determined principally by the degree of resistance of the patient's cervix. Force was not used, but the goal was the maximum number that could be placed easily until resistance was noted. No forcible manual dilation occurred before placement of laminaria (thick) or Dilapan. Two goze sponges that were coated with nitrofurazone ointment were gently placed against the cervix to prevent expulsion of the dilators. The dilators were left overnight for periods ranging from 18 hours to 24 hours. On the following day a dilation and evacuation abortion was performed with local anesthesia according to previously established protocols.^{6,7}

After removal of the vaginal packing gauze and dilators under direct vision, specially designed dilators⁷ were used to ascertain the degree of hygroscopic dilation attained and to augment this to the degree possible. Dilation was carried up to the point of mild resistance and no more. If bulging membranes were visible, no supplemental manual dilation was performed. At this point membranes were ruptured and a No. 12 cle3ar plastic cannula was inserted into the uterine cavity to permit amniotic fluid to drain as completely as possible, to minimize the risk of amniotic fluid embolism. The amount of fluid was measured. This permitted measurement of actual blood loss after the procedure. Fetal age was determined postoperatively by criteria previously established.⁸

Blinding was not possible because only one physician was available for most of the series to apply the dilators, to remove them, and to perform the abortions. However, the same method was used for all patients. We studied a large number of patients over a long period of time to reduce or eliminate sources of systematic bias in the study population.

Independent variables studied were Dilapan versus laminaria treatment, length of gestation, number of dilators used, length of time dilators were in place, and degree of manual dilation. Dependent (outcome) variables studied were blood loss, procedure length, and problem or complication rate. Statistical studies were performed with SPSS (SPSS, Inc., Chicago) and a hand calculator.

Results

Of the 1001 patients receiving a single overnight treatment of hygroscopic dilators, 505 received one or more Dilapan, whereas 496 received one or more *Laminaria japonicum*.

The mean and median ages of all patients were 22 and 21 years, respectively. The mean age of Dilapan patients was 22 years, and mean age of laminaria patients was 22.4 years. The mean number of previous pregnancies was one for both groups. The mean gestational length for all patients was 18.5 menstrual weeks, with 18.5 weeks for the Dilapan group and 18.4 weeks for the laminaria group. Only 5.5% of the patients came from Boulder County; 72.2% of all patients came from within Colorado, and 27.8% came from outside Colorado. Three percent of all patients had visited the clinic for one abortion previously, and eight patients (0.8%) had made two previous visits. The follow-up contact rate for all patients was 78.2% ($n = 783$). There was no difference in the two groups in the follow-up rate (Dilapan group 77.2%, laminaria group 79.2%, not significant).

From one to five Dilapan were used for patients receiving this treatment (mean 2) and from one to 10 laminaria were used for patients receiving this treatment (mean 3.7). Mean duration of treatment for both groups was 22.3 hours (Dilapan group 22.4 hours, laminaria group 22.2 hours, not significant). The mean amount of supplemental manual dilation needed, up to 61.5Fr (Hern/Pratt dilators), was the same for both groups. Supplemental dilation was used for 74.2% of all cases but more often for patients receiving laminaria (77.5%) than those receiving Dilapan (70.9%).

Mean procedure time for all patients, counting from the beginning of manipulation or insertion of instruments into the cervix, was 719 minutes, with a median of 6 minutes. The mean procedure time for the Dilapan group was 7.7 minutes, and the mean procedure time for the laminaria group was 8.1 minutes (not significant). The mean overall blood loss for both groups was 139 ml, with a median of 100 ml (range 5 to 1500 ml), but there was no significant difference between the means of the two groups (Dilapan 136 ml, laminaria 143 ml).

Analysis of variance of procedure time by week of gestation showed the differences in the treatment effect of the two groups to be insignificant ($p = 0.074$). Similarly, there was no significant difference between the two groups in blood loss by week of gestation ($p = 0.073$).

Regression analysis of the effects of independent variables on procedure time showed that 23% of the variability was related to gestational length ($p < 0.001$) and 1% to the degree of manual dilation ($p < 0.001$). The treatment (Dilapan vs laminaria) ($p = 0.08$), the number of hygroscopic dilators ($p = 0.54$), and the duration of dilator treatment ($p = 0.72$) had no significant effect on the dependent variable. Essentially the same results were

observed for blood loss, where 15% of the variability was accounted for by gestational length ($p < 0.001$) and 2% by degree of manual dilation ($p = 0.0$). Treatment (Dilapan vs laminaria) had no significant effect on blood loss ($p = 0.20$) nor did the number of hygroscopic dilators used ($p = 0.063$) or the length of time the dilators were in place ($p = 0.31$).

Problems and complications. Various problems and complications were noted and coded for analysis. These included such observations as heavy bleeding (undefined), poor uterine tone, cervical laceration, reaspiration, retained tissue, poor dilation to no dilation, expulsion of the device, and amniotic fluid embolism – disseminated intravascular coagulation syndrome. A prominent category (not a complication per se) was “retracted/fractured” to describe the fate of the device at removal. In this category a retracted laminaria was noted only on one occasion, and no laminaria disintegrated. On the other hand, one of these problems occurred with Dilapan on 30 occasions (retracted 8, fractured 21, both 1). Fragmented or retracted Dilapan were recovered in all cases with ordinary instruments such as forceps and uterine curettes. Poor dilation to no dilation was noted in 11 instances for Dilapan and 13 instances for laminaria.

These categories were collapsed to three for the purpose of comparison: amniotic fluid embolism-disseminated intravascular coagulation syndrome, “cervical dilation deficiency,” and postoperative infection. Forty-seven patients receiving Dilapan experienced these problems or complications (4.7%) compared with 32 (3.2%) of the patients receiving laminaria. Forty-four of the Dilapan patients (1.8 times as many) experienced a problem or complication characterized as (or caused by) a “cervical dilation deficiency” (including problems with severe bleeding, uterine atony, or reaspiration) in comparison with 24 in the patients receiving laminaria (relative risk 1.73, 95% confidence interval 1.1 to 3.1). A narrow definition of “cervical dilation deficiency” shows a higher relative risk (2.3, $p < 0.05$) for this problem for patients receiving Dilapan (Table I), usually in cases in which the cervix was somewhat rigid and permitted only one Dilapan. There was no other discernible pattern in the distribution of these problems in time elapsed in the study or gestational age.

The small difference seen in the larger proportion of laminaria patients receiving supplemental dilation may be related to the more rapid increase in Dilapan size, a probable factor in the more frequent difficulty of fragmentation with Dilapan in patients with a relatively rigid cervix.

Few genuine complications occurred that could be characterized by treatment alternative. Seventy-seven patients (7.7%) experienced minor complications, and three patients (0.3%) receiving laminaria experienced a major complication that could not be attributed to the material used for dilation (Table I). All three of the latter patients experienced amniotic fluid embolism or disseminated intravascular coagulation syndrome requiring transfusion. Two patients (one each treated with Dilapan and laminaria) experienced amniotic fluid embolism but without disseminated intravascular coagulation requiring transfusion.

There were two cases of twin gestation in each treatment group, one case of placenta previa with heavy bleeding in the laminaria group, and one oxytocin reaction in the Dilapan group.

Table I. Complications

	Laminaria	Dilapan	Relative Risk	95% Confidence interval
Minor				
Amniotic fluid embolism – disseminated intravascular coagulation syndrome (no transfusion)	1	1	1.0	0.9 – 1.1
Heavy bleeding (> 450 ml, with or without uterine atony)	3	4	1.3	0.3 – 5.8
Cervical dilation deficiency (poor to no dilation; fractured or retained dilator)	14	33	2.3	1.3 – 4.5
Reaspiration (retained products of conception)	7	7	1.0	0.9 – 2..9
Postoperative infection	6	2	0.3	0.1 – 0.8
Major				
Amniotic fluid embolism – disseminated intravascular coagulation syndrome requiring transfusion	3	0*		

* Overall relative risk for amniotic fluid embolism-disseminated intravascular coagulation syndrome for Dilapan patients was 0.25 (95% confidence interval -0.1296 to + 0.6296, $p < 0.05$).

Fig. 1. Fragmented Dilapan devices



Comment

In general, very few differences were observed in the results for patients receiving either device. The principal outcome variables, blood loss and procedure time, showed statistically and clinically insignificant differences, including those classified by week of gestation. The most commonly observed difference was in the number of instances of fragmentation and retraction of the Dilapan devices (Fig. 1). Fragmentation of Dilapan has been reported previously,³ and although it did not lead directly to any serious complications in this study it is the most common and vexing problem in using the device. On the other hand, the manufacturer has not described or recommended overnight use, as occurred in this study. It is possible that using the Dilapan in conjunction with several laminaria, as some practitioners informally report, would yield different or more trouble-free results. There is no evidence that the Dilapan fragments themselves are harmful, but the recovery of them is time consuming and stressful for both the patient and the operator. The danger in this problem lies in the risk of a secondary complication incurred while trying to recover the Dilapan.

Although the relative risk of amniotic fluid embolism-disseminated intravascular coagulation syndrome requiring transfusion was zero for the Dilapan patients in this series, the larger number of this event among laminaria patients (3 vs 0) was not attributable in any obvious way to the type of dilator used or to the amount of supplemental dilation required. The severity of the problem appeared to be almost exclusively related to the random occurrences of low-lying placentas that permitted disruption before complete evacuation of amniotic fluid and fetal parts.

The differing rates in the extremely small number of postoperative infections between the two groups was statistically significant but did not appear to be related to the dilator device and was not clinically significant. These rates may have been related to the presence of mild preexisting vaginal infections that did not respond to routine postoperative prophylactic antibiotic treatment.

It is remarkable that in this series no cases of uterine perforation occurred and only one minor case of cervical laceration occurred. Uterine trauma was minimal.

Although the outcomes and complication rates of this series compare favorably with previous series that used a 2-day serial multiple laminaria application,^{4, 6} my consistent clinical impression, confirmed by the "cervical dilation deficiency" category of problems or complications was that the single overnight application of multiple osmotic dilators gives less satisfactory results than the 20-day dilation protocol that I have reported previously.^{4, 6} A proper comparative study of these two protocols, however, remains to be completed and reported.

REFERENCES

1. Chavpil M, Droegemueller W, Meyer T, Macsalka R, Stoy V, Suci T. New synthetic laminaria. *Obstet Gynecol* 1982;60:729-33.
2. Blumenthal PD. Prospective comparison of Dilapan and laminaria for pre-treatment of the cervix in second trimester induction abortion. *Obstet Gynecol* 1988;72:243-6.

3. Hern WM. Cervical treatment with Dilapan prior to second trimester dilation and evacuation abortion. *Am J Gynecol Health* 1993;7:15-8.
4. Hern WM. Outpatient second-trimester D & E abortion through 24 menstrual weeks' gestation. *Adv Planned Parent* 1981;16:7-13.
5. Stubblefield PG. Laminaria and other adjunctive methods in second trimester abortion. In: Berger GS, Brenner WE, Keith LG, eds. *Second trimester abortion: perspectives after a decade of experience*. Boston: John Wright PSG, 1981:135-61.
6. Hern WM. Serial multiple laminaria and adjunctive urea in late outpatient dilation and evacuation abortion. *Obstet Gynecol* 1984;63:543-9.
7. Hern WM. *Abortion practice*. Boulder, Colorado:Alpenglo Graphics, 1990:122-56.
8. Hern WM. Correlation of fetal age and measurements between 10 and 26 weeks of gestation. *Obstet Gynecol* 1984;63:26-32.

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