

PREOPERATIVE DILATATION OF THE CERVIX AT LEGAL ABORTION WITH A SYNTHETIC, FAST-SWELLING HYGROSCOPIC TENT

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Abstract. Preoperative dilatation of the cervix at first trimester legal abortion has been shown to facilitate the vacuum aspiration procedure and to reduce pre- and postoperative complications as well as late sequelae. The present study represents a clinical trial in which a new synthetic hygroscopic tent, Dilapan®, has been evaluated. Dilapan tents of different diameters with different durations of cervical exposure were tested on a case material of 450 nulliparous women. It was found that treatment with 4 mm tents during 3–4 h or 3 mm tents during 16–20 h produced a cervical dilatation that allowed an easy evacuation of the uterus with a minimum of complications. The advantage of this particular tent is its property of rapid swelling.

Legal abortion by vacuum aspiration (VA) represents one of the most common surgical interventions in the gynecological departments of countries with liberal abortion legislation. An obvious problem in this context relates to pre- and postoperative complications. Inadvertent perforation of the cervical canal or uterine corpus and incomplete evacuation of the uterus resulting in endometritis-salpingitis are still embarrassingly common consequences of first-trimester legal abortions (1, 2). The incidence of such complications depends on many factors, among others positive cervical culture of *Chlamydia trachomatis*. However, a long, narrow and stiff cervix resistant to rapid instrumental dilatation, generally represents the basic technical problem (6, 7).

Preoperative dilatation of the cervix by hygroscopic tents, such as Laminaria, has been shown to reduce these complications significantly. The rate of postabortive pelvic inflammatory disease (PID) found in a recent study of 519 women in Sweden was 2.9% in the group preoperatively dilated by Laminaria, but 12.2% among the controls ($p < 0.001$). The risk of acquiring PID was greater in those patients whose gestational age was 10–12 weeks, than in those at 6–9 weeks (8, 9, 10). Similar results have been obtained by using a synthetic sponge-like tent, Lamigel (11, 12). There seems to be no doubt that preoperative dilatation alters the situation so that a VA becomes a technically simple procedure—even in the hands of a junior gynecologist—and that the incidence of postoperative complications is significantly reduced.

The traditional Laminaria tent is useful in this context but has also the disadvantage of being of biological origin (dried and compressed seaweed) and difficult to manufacture to precise specifications. The Laminaria tents are also characterized by slow swelling and generally require 15–20 h to accomplish adequate dilatation of the cervix. A new synthetic hygroscopic tent made from a polyacrylate-based hydrogel (Dilapan®) has recently been developed and tested (13, 14). These tents have the shape of a firm rod with a diameter of 3 or 4 mm and are characterized by rapid swelling following absorption of moisture from the surrounding tissue to the extent that the cervix attains significant dilatation within 3–4 h following insertion.

The present study represents a clinical trial where Dilapan tents of different diameters and different durations of treatment have been evaluated regarding their usefulness as cervical dilators in current abortion routines.

CASE MATERIAL AND METHODS

The total case material included 450 unselected nulliparous women in the 10th–12th week of gestation admitted for legal abortion on an out-patient basis. Gestational age was estimated from their menstrual history, by pelvic examination and in some cases ultrasound. Cultures for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were carried out at their first visit approximately one week before termination of pregnancy. Women with positive cultures were treated with oral doxycycline preoperatively or, in some cases, with i.v. doxycycline infusion started postoperatively. All women were treated for at least 10 days.

Table I. Treatment groups and basic clinical data (mean \pm SD)

Group	Diameter of tent (mm)	Duration of treatment (hrs)	No. of cases	Age (yrs)	Week of pregnancy
A.	4	3-4	200	23.8 \pm 4.3	10.8 \pm 1.0
B.	4	16-20	50	24.2 \pm 6.0	11.0 \pm 0.9
C.	3	3-4	25	23.6 \pm 4.8	10.5 \pm 1.0
D.	3	16-20	178	22.7 \pm 4.8	11.0 \pm 0.9

Following cleansing of the vagina with a 2% chlorhexidine solution, a Dilapan tent (Gynotech, Inc., Lebanon, New Jersey, USA (Menox AB, Göteborg, Sweden) was inserted into the cervical canal so that the tip of the dilator was well above the internal os. Patients were consecutively distributed into four treatment groups.

- A) 4 \times 65 mm tent, dilatation during 3-4 h under supervision in the hospital.
- B) 4 \times 65 mm tent, dilatation during 16-20 h at home.
- C) 3 \times 55 mm tent, dilatation during 3-4 h under supervision in the hospital.
- D) 3 \times 55 mm tent, dilatation during 16-20 h at home.

The tent was removed under i.v. anesthesia and the degree of cervical dilatation estimated by passing Hegar dilators of increasing diameter. At the point when the largest Hegar dilator tested passed the internal os without resistance, this was recorded as the cervical diameter achieved. If it was judged to be needed, further dilatation to 10 or 11 mm was accomplished using Hegar dilators. The VA was carried out in accordance with the conventional routines of the Department. One and the same physician was responsible for insertion of the tents and performance of the VA in accordance with a rotating system with change of physician every 3-4 weeks. Discomfort in terms of pain during dilatation was defined as pain requiring analgetic drugs. All volunteers participating in this study were questioned as to their postoperative symptoms and examined at a follow-up visit 3 weeks after the legal abortion.

The study had been approved by the Medical Ethics Committee of the Faculty of Medicine in Göteborg and all patients gave their informed consent. Statistical calculations were carried out using Student's t-test.

RESULTS

Basic clinical data are given in Table I. There was no significant difference between the treatment groups regarding maternal age or week of pregnancy.

The mean cervical diameters achieved using Dilapan tents of different initial diameters and different durations for the dilatation are shown in Table II. Treatment with 3 or 4 mm tents during 16-20 h resulted in a cervical dilatation that allowed insertion of a suction cannula 10 mm in diameter without resistance. When the treatment period was reduced to 3-4 h, the 4 mm tents still produced a dilatation of 8.4 \pm 1.2 mm and the 3 mm tents 7.9 \pm 0.7 mm. There was a significant difference ($p < 0.01$) in cervical dilatation between the 4

mm and 3 mm tents, in the case of both the 3-4 and 16-20 h treatment. However, although the cervical diameter achieved was smaller with a shorter treatment period, the tents changed both the tensile properties and the resistance of the cervix so that the degree of dilatation required could be easily accomplished with a few Hegar dilators.

Insertion of the tents was generally easy, but failed in 2-5% of the cases (Table III). These failures were due to anatomical irregularities at the level of the internal os, a markedly anteverted corpus, or simply fear of pain in some teenage girls.

Dysmenorrhea-like pain following exposure to 4 mm Dilapan tents for 3-4 h (group A) occurred in 7% of the cases but did not represent any significant clinical problem, considering the short period of dilatation and the possibility of administering analgesics under supervision in the hospital (Table III). The incidence (12.3%) and duration of pain, however, was more of a problem when using 4 mm tents remaining in the cervix for 16-20 h (group B). In some instances this pain appeared early following insertion of the tent and in other cases not until several hours after application. The 3 mm tents behaved differently in this respect in that only 4.6% ($p < 0.05$) of the women felt mild dysmenorrheic pain. As a matter of fact the 3 mm tents did not cause any noticeable inconvenience despite 16-20 h of exposure.

There was an impression at the beginning of the study that women suffering from primary dysmenorrhea experienced more pain during dilatation than did

Table II. Cervical diameter following preoperative dilatation with Dilapan

Group	Diameter of tent (mm)	Duration of treatment (hrs)	Dilatation achieved (mean \pm SD)*
A.	4	3-4	8.4 \pm 1.2
B.	4	16-20	11.3 \pm 1.2
C.	3	3-4	7.9 \pm 0.7
D.	3	16-20	9.6 \pm 1.2

* A < B $p < 0.01$; A > C $p < 0.05$
B > D $p < 0.01$; C < D $p < 0.01$

non-dysmenorrhoeic subjects. This hypothesis was analysed in some detail. 17% of the women in group A suffered from moderate to severe primary dysmenorrhoea subsequent to menarche. However, these subjects did not experience more pain during dilatation than the eumenorrhoeic women in group A.

Removal of the tent after completion of dilatation was carried out under general anaesthesia and immediately before the VA operation. Difficulties at extraction and fragmentation of the tent occurred, particularly in patients treated with 4 mm tents for 16–20 h (B vs. A, C or D, $p < 0.05$). Usually, however, the fragments were easily removed with forceps and suction at VA. Extraction of the tents in groups A, C and D could be accomplished without any noteworthy difficulty.

The incidence of postoperative endometritis—salpingitis among the total number of women in whom the cervix had been dilated preoperatively with Dilapan was 3.2%. Positive Chlamydia cultures were found in 27 of the 450 cases (6%) and there was no difference in the rate of positive cultures between the different treatment groups. The 27 women with positive cultures were treated with doxycycline and one patient developed PID postoperatively. Only one case of positive *Neisseria* culture was found. Peroperative complications, in terms of cervical or uterine perforation, did not occur in any of the cases in the Dilapan-treated group.

DISCUSSION

The resistance of the cervix to mechanical dilatation with metal dilators, on the basis of well-known clinical experience, may be divided into three phases: (1) an initial low resistance phase reflecting the elastic properties of the tissue, (2) a phase of firm resistance when the metal dilator has to be held under pressure for

some time against the internal os, and (3) a phase of sudden decreasing resistance when further dilatation may become comparatively easy. The biomechanical and biophysical mechanisms behind these phenomena are complex, including consequences of physical laws (e.g. the law of Laplace) and the so called visco-elastic creep (15). If dilatation proceeds into phase 3 when the resistance decreases, there may be a risk of microfractures and lacerations of the connective tissue, in some cases causing long term sequelae such as cervical incompetence (7, 16, 17). A gradual preoperative dilatation of the cervix by hygroscopic tents prohibits such injuries and facilitates the VA procedure.

However, facilitation of the VA procedure after preoperative dilatation of the cervix with hygroscopic tents is not only dependent on the mechanical effect achieved but also on the biochemical and ultrastructural alterations in the cervical connective tissue. These alterations include an increase in the plasma metabolite of $\text{PGF}_{2\alpha}$ (12), probably an increased local production of prostaglandins and a disintegration and dissolution of collagen fibrils resulting in the softening and increased distensibility of the cervix (18).

The present investigation was initiated as an open study using 4 mm tents for 16–20 h. From experience, this protocol was subsequently changed to comprise alternative treatment schedules. Unfortunately it was at that point difficult to convert the design of the investigation into a controlled study. However, the volunteers included in the different treatment groups of the present study did not differ with regard to mean age, parity (nulliparae) and gestational age (10–12 weeks). Members of the permanent staff of physicians in the Department were instructed regarding the protocol of the study, including principles for evaluation of the cervical diameter after removal of the tent. In accordance with a rotating system, one and the same physician was in charge of the legal abortion service during 3–4 week periods.

Evacuation of the conceptus in the 10th–12th week of pregnancy generally requires use of a VA cannula 10 mm in diameter. It is evident from this study that exposure of the cervix to 4 mm as well as 3 mm Dilapan tents during a period of 16–20 h resulted in the desired degree of dilatation.

However, a major advantage of Dilapan tents is their rapid swelling which results in a significant degree of dilatation within 3–4 h and hence the possibility of carrying through dilatation and VA in sequence during the course of half a day. The degree of dilatation after 3–4 h corresponded to 8.4 ± 1.2 mm (4 mm tent) and

Table III. Problems encountered at preoperative cervical dilatation with Dilapan

Group	Failed insertion (%)	Pain during treatment* (%)	Fragmentation of tent on withdrawal** (%)
A.	4.2	7.2	2.4
B.	2.0	12.3	8.2
C.	5.8	4.0	0
D.	4.4	4.6	0.5

* B > D $p < 0.05$

** B > A $p < 0.05$

7.9 ± 0.7 mm (3 mm tent). As a consequence of the softening effect of the Dilapan tents, the required diameter (10 mm) could easily be achieved by using one or two metal dilators.

At present, three different types of tents are available on the market: Laminaria, Lamichel and Dilapan. Current literature indicates that any of these hygroscopic devices is useful for the purpose of facilitating the VA operation. The clinical usefulness of the traditional Laminaria tent was recently compared with that of Dilapan in a controlled study. It was found that dilatation for a period of 3–4 h with Laminaria tents resulted in a mean cervical diameter of 6.7 mm, whereas Dilapan 4 mm tents achieved 9.4 mm (14). Another controlled trial, comparing Dilapan and Lamichel (13th–16th week of gestation, 20 h of cervical exposure) showed that Dilapan induced a significantly ($p < 0.001$) higher degree of dilatation than the Lamichel tent (24). A recent Swedish study showed, on the other hand, that the Lamichel tents seemed to attain their maximum cervical dilatation after 4 h and that the mean diameter after 16 h tended to be smaller (12).

It may be concluded that the types of hygroscopic tents available on the market differ with regard to advantages and disadvantages. As far as the Dilapan tent is concerned it seems obvious that this device provides a more rapid cervical dilatation than Laminaria and Lamichel and that it swells gradually during the course of at least 20 h.

Dysmenorrhea-like pain during the course of dilatation in first-trimester pregnancies is a problem when using 4 mm tents that are in the cervix for 16–20 h. However, short-term exposure of the cervix to 4 mm tents or long-term exposure to 3 mm tents did not cause any noticeable inconvenience.

Primary dysmenorrhea has been shown to be associated with increased production of $\text{PGF}_{2\alpha}$ by the endometrium, with uterine hypercontractility and ischemia (19, 20, 21). The role of the cervix in the pathogenesis of dysmenorrheic pain is rather obscure. It is possible that pain at dilatation by hygroscopic tents is due to stimulation of the cervical pain receptors during increased tension. The present results showed that women with primary dysmenorrhea did not experience more pain at cervical dilatation with Dilapan than non-dysmenorrheic subjects. It has been shown that dilatation by Laminaria tents is accompanied by small, moderately frequent, painless contractions (22). The reason why Dilapan tents cause dysmenorrheic pain in some women may be that these tents induce more frequent and forceful uterine con-

tractions and hence local prostaglandin synthesis and release, not only from the cervix but also from the endometrium.

The 4 mm tents had a tendency to get entrapped in the cervix following long-term dilatation, resulting in fragmentation at extraction in 8% of the cases. In most such cases, however, the fragments could easily be removed at the subsequent VA. In this context it should be emphasized that the tent should be extracted by gentle, straight pulling, not by rotation. The extraction of 4 mm tents 3–4 h after insertion, or of 3 mm tents following 16–20 h, was not associated with any problems.

The incidence of per- and postoperative complications following legal abortion has previously been evaluated in many controlled studies. The results indicate that preoperative dilatation of the cervix with hygroscopic tents helps lower the frequency of PID. The reason is probably that preoperative dilatation of the cervix facilitates the operation from a technical point of view and, hence, that less residual tissue remains in the uterine cavity as substrate for the invasion of micro-organisms (1, 23). A factor having a significant influence on the rate of postoperative PID is the occurrence of a positive Chlamydia culture (3, 4, 5). The present study was not in the first place aimed at evaluating postoperative complications. However, previous experience in this Department, including analyses of the rate of postabortive PID among first-trimester legal abortion patients—approximately 1000 cases a year, has shown a significant decrease in the incidence of PID (from 14% in 1976 to 6–8% in 1982–86) following the introduction of Chlamydia screening and treatment with doxycycline and a further decrease after the introduction of preoperative dilatation of the cervix. The rate of PID in the present study corresponded to 3.2%. Moreover, our incidence of uterine perforation varied between 0.1 and 0.5% during preceding years but not a single case of uterine or cervical perforation occurred among the 450 women dilated with Dilapan tents.

Opinions may differ regarding the best method of accomplishing preoperative dilatation of the cervix. However, judging on the basis of controlled trials comparing different types of tents and our own experiences comparing different diameters and treatment periods with Dilapan, it seems that 4 mm tents produce an extensive and rapid dilatation to the extent that VA can be carried out 3–4 h following insertion. To have the abortion procedure completed during the course of a few hours is particularly important for some women

because of their family situation or transport and travel problems.

Hospitals in densely populated areas may prefer to complete their legal abortion operations early in the morning. Under these circumstances the 3 mm tents can be applied in the afternoon, the patient can go home and return the next morning for the abortion. With this protocol, it is our experience that the Dilapan tent does not cause any noticeable inconvenience for the patient. It is easy to extract and the degree of cervical dilatation achieved corresponds to the degree of dilatation required.

One final comment; young nulliparous women generally have a considerably anteverted uterus in addition to a narrow, retroverted cervix. If the Dilapan tents were made slightly curved during manufacture, this would facilitate their insertion into the cervix.

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REFERENCES

- Jerve H, Fylling P. Therapeutic abortion. *Acta Obstet Gynecol Scand* 1978;57:237-40.
- Moberg P, Sjöberg B, Wijkvist N. The hazards of vacuum aspiration in late first trimester abortion. *Acta Obstet Gynecol Scand* 1975;54:113-18.
- Möller B, Ahrons S, Laurin J, Mård P-A. Pelvic infection after elective abortion associated with Chlamydia trachomatis. *Obstet Gynecol* 1982;59:210-13.
- Westergaard L, Philippsen T, Scheibel J. Significance of cervical Chlamydia trachomatis infection in postabortal pelvic inflammatory disease. *Obstet Gynecol* 1982;60:322-5.
- Giertz G, Kallings I, Nordenvall M, Fuchs T. A prospective study of Chlamydia trachomatis infection following legal abortion. *Acta Obstet Gynecol Scand* 1987;66:107-09.
- Sirtman DA, Cates W. In: Complications from legally induced abortion: A review. *Obstet Gynecol Surv* 1979;34:177-81.
- Hulká JF, Higgins O. Trauma to the internal cervical os during dilatation for diagnostic curettage. *Am J Obstet Gynecol* 1961;82:913-17.
- Jonasson A, Larsson B, Bygdeman S, Forsum U. The influence of cervical dilatation by Laminaria tent and with Hegar dilators on the intrauterine microflora and the rate of postabortal pelvic inflammatory disease. *Acta Obstet Gynecol Scand* 1989 (in press).
- Evaldsson GR, Fianu S, Jonasson A, Larsson B, Nord CE, Ölund R. Does the hygroscopic property of the Laminaria tent imply a risk for ascending infection in legal abortions? *Acta Obstet Gynecol Scand* 1986;65:257-61.
- Bryman I, Granberg S, Norström A. Reduced incidence of postoperative endometritis by the use of Laminaria tents in connection with first trimester abortion. *Acta Obstet Gynecol Scand* 1988;67:323-5.
- Nicolaides KH, Welch CC, MacPherson MBA, Johnson IR, Filshie GM. Lamicel: A new technique for cervical dilatation before first trimester abortion. *Br J Obstet Gynaecol* 1983;90:475-9.
- Norström A, Bryman I, Hansson HA. Cervical dilatation by Lamicel before first trimester abortion: A clinical and experimental study. *Br J Obstet Gynaecol* 1988;95:372-6.
- Chvapil M, Droegemüller W, Meyer T, Macsalka R, Stoy W, Suchi T. New synthetic Laminaria. *Obstet Gynecol* 1982;60:729-33.
- Darney PD, Dorward K. Cervical dilatation before first-trimester elective abortion: A controlled comparison of Metereprost, Laminaria and Hypan. *Obstet Gynecol* 1987;70:397-400.
- Atienza ME, Burkman RT, King TN. Forces associated with cervical dilatation at suction abortion: Qualitative and quantitative data in studies completed with a force-sensing instrument. In: Naftolin F, Stubblefield PG, eds. *Dilatation of the uterine cervix*. New York: Raven Press, 1980;343-50.
- Hulká JF, Lefler HT, Anglone A, Lachenbruch PA. A new electronic force monitor to measure factors influencing cervical dilatation for vacuum curettage. *Am J Obstet Gynecol* 1974;120:166-9.
- Liu DTY, Black MM, Melcher DH, Melville HAH, Cameron S, Morgan J. Dilatation of the parous non-pregnant cervix. *Br J Obstet Gynaecol* 1975;82:246-49.
- Ölund A, Jonasson A, Kindahl H, Fianu S, Larsson B. The effect of cervical dilatation by Laminaria on the plasma levels of 15-keto-13,14-dihydro-PGF_{2α}. *Contraception* 1984;30:23-27.
- Lundström V, Gréen K. Endogenous levels of prostaglandin F_{2α} and its main metabolites in plasma and endometrium of normal and dysmenorrhoeic women. *Am J Obstet Gynecol* 1978;130:640-5.
- Lundström V, Gréen K, Wijkvist N. Prostaglandins, indomethacin and dysmenorrhoea. *Prostaglandins* 1976;11:833-7.
- Åkerlund M. Pathophysiology of dysmenorrhoea. *Acta Obstet Gynecol Scand* 1979; Suppl. 87:27-32.
- Jonasson A, Larsson B. Contractile activity in the human uterine cervix and corpus during cervical dilatation by Laminaria tent in first trimester legal abortions. *Acta Obstet Gynecol Scand* (in press).
- Sweet RL, Gibbs RS. Postabortal infection and septic shock. In: Sweet RL, Gibbs RS, eds. *Infectious diseases of the female genital tract*. Baltimore: Williams & Wilkins, 1985:142-54.
- Wells E. Cervical dilatation. A comparison of Lamicel & Dilapan. In: *Abortion Service: Contribution to the Nation's Health 11th Annual National Abortion Federation Meeting*. Salt Lake City, Us, May 18-19, 1987.