

Serial Multiple Laminaria and Adjunctive Urea in Late Outpatient Dilatation and Evacuation Abortion

WARREN M. HERN, MD, MPH

The safety and clinical approach in late second-trimester outpatient dilatation and evacuation abortion is controversial. In this series, 1000 dilatation and evacuation abortions were performed on patients from 17 through 25 menstrual weeks' gestation in a private office outpatient facility. Each patient experienced serial multiple laminaria treatment over two days before abortion. Patients at 20 weeks' gestation or more also received adjunctive urea amnioinfusion on the day of the procedure. Three patients (0.3%) experienced major complications. Although a wide variety of clinical problems was encountered, procedure times were short, blood loss was generally low, and other complication rates were low. Recommendations for staffing and the prevention of complications are discussed. (*Obstet Gynecol* 63:543, 1984)

Several controversies surround the use of dilatation and evacuation methods in late second-trimester abortion. One concerns the safety of the method, which has tended to supplant amnioinfusion methods in early second-trimester abortion, even though only one randomized study has shown a lower complication rate than a commonly used amnioinfusion method.^{1,2} Several case series have shown relatively low complication rates in early second-trimester abortion by dilatation and evacuation.^{3,4} Little has been published concerning its application over 17 or 20 menstrual weeks.⁵⁻⁷

Another controversy concerns the method of dilatation, for which there has been only one comparative study.⁸ Some authors have advocated manual dilatation,⁹ whereas others have stressed the advantages of laminaria by single or serial multiple application.¹⁰⁻¹²

A third controversy concerns the safety of the setting, a question recently addressed by the United States Supreme Court. The authors of the most thorough analysis of the last question concluded that mortality data did not support performance of dilatation and evacuation abortion on an outpatient basis

past 16 weeks' gestation.¹³ The authors stressed in discussion and subsequent correspondence, however, that weakness of the mortality data and the prospect of further data could alter that conclusion.¹⁴

In published studies it has been shown that dilatation and evacuation could be performed on an outpatient basis either within a hospital setting or private extramural office throughout the second trimester with acceptably low complication rates.^{3,6,7} Few cases in these series, however, were included in the range from 17 weeks' gestation and above where the principal controversy lies.

The present report concentrates on results obtained in 1000 dilatation and evacuation abortions from 17 through 25 menstrual weeks' gestation performed in an ambulatory extramural setting at a single institution. The report reviews techniques used to enhance safety of the procedure, procedure variables by week of gestation, and overall complication rates.

Materials and Methods

All procedures were performed over a period of six years, ending December 1982 in a single private office outpatient abortion facility located across the street from a community hospital. The facility has been specially equipped and staffed to provide assistance for women seeking abortion through the second trimester of pregnancy. Patients receive individual counseling and support throughout their experience at the clinic. Real-time diagnostic ultrasound is performed on all patients during the preoperative evaluation.

Patients came from throughout the western half of the United States and Canada. Only 4.3% were from the local community, and 48.2% were from outside Colorado. Patient ages ranged from 12 to 45 years, with a median of 19.6. Sixty-six percent of the patients were experiencing their first pregnancy, and 83% were

From the Boulder Abortion Clinic, Boulder, Colorado.

having their first abortion. Preoperative estimates of fetal age ranged from 17 through 24 menstrual weeks, with sonographic biparietal diameter readings ranging from 31 through 57 mm.

Routine protocol after ultrasound evaluation and counseling included one to three laminaria placed in the cervix on day 1, replaced by four to 12 laminaria on day 2 at one sitting or at two sittings six hours apart, and dilatation and evacuation procedure on day 3. This protocol has been described in detail.¹² The decision concerning whether patients received one or two changes of laminaria on day 2 was determined principally by the length of gestation and rigidity of the cervix, with patients being evaluated on an individual basis.

In addition to the serial multiple laminaria treatment over more than 40 hours, patients in whom a diagnosis of 20 or more completed menstrual weeks' gestation was made received an intrauterine infusion of hyperosmolar urea approximately five hours before dilatation and evacuation on day 3. This protocol was followed on 425 patients, of whom ten experienced a procedure of fetal intrathoracic urea infusion under direct sonographic visualization. The latter procedure was used for a brief period for patients in whom a diagnosis of advanced gestation (23 to 24 weeks) was made. In these patients, it was found that a routine 80-g intraamniotic infusion was not effective in gestations at that advanced stage. The fetal intrathoracic injection procedure was abandoned because of inconvenience and lack of effectiveness when it was found that a larger quantity of intraamniotic urea produced satisfactory results.

Patients receiving an intraamniotic urea infusion were prepared and draped in the usual manner, and either a straight 18-gauge spinal needle or a 16-gauge catheter needle was used to obtain a free flow of amniotic fluid. At least 200 and up to 500–600 mL of amniotic fluid was removed by gravity flow by attaching a sterile intravenous extension tube to the hub of the indwelling needle or catheter and placing the distal tip of the extension tube below the level of the patient. After removal of an adequate quantity of amniotic fluid, either 80 g ($N=125$) or 120 g of hyperosmolar urea solution was then injected directly into the amniotic cavity. Initially, 80 g was used as a standard dose, but this was increased to 120 g for more advanced gestations. The amount subsequently adopted for all patients receiving urea amniocentesis was 120 g. A highly concentrated solution was created by using a 60% solution of 80 g as the solvent for the remaining 40 g. The volume of this solution was approximately 225 mL, and this determined the minimum amount of amniotic fluid to be removed before the injection.

After urea amniocentesis, patients were observed

for up to five or six hours for evidence of labor and/or fetal death as documented by Doppler ultrasound examination. Since only one or two Doppler examinations were performed during this time for each patient, the exact time of fetal death could not be studied. However, fetal death occurred within three or four hours in all but a few cases.

Patients experiencing active labor were taken to the procedure room where membranes were ruptured and the uterus was emptied. Fifteen to 20 minutes before the anticipated procedure time, each patient was given 50 to 75 mg of meperidine intramuscularly for light analgesia. The dilatation and evacuation procedure was performed under paracervical block anesthesia using 18 mL of 1% lidocaine without epinephrine. From 40 to 60 U of oxytocin were routinely added to 500 to 1000 mL of Ringer's lactate intravenous infusion upon delivery of the fetal skull, and 0.2 mg of methylergonovine maleate was given intramuscularly upon delivery of the placenta.

After removal of the most recent pack of laminaria, membranes were routinely ruptured, and amniotic fluid was drained off as completely as possible. One important reason for this maneuver was to reduce the risk of amniotic fluid embolism.^{15–17} With the exception of patients receiving urea, the fluid was measured and separated so that blood loss could be measured as accurately as possible. Amniotic fluid was not measured in patients receiving urea owing to the uncertainty introduced by the possible physiologic replacement of amniotic fluid volume after initial withdrawal and urea infusion; also, urea patients sometimes experienced ruptured membranes immediately before the dilatation and evacuation procedure, and fluid volume could not be measured. Blood loss was measured for all 1000 patients both by direct measurement of blood volume in the collecting basin or by removing clots with the gloved hand from the fluid in the basin and measuring the volume of the clots.

Procedure time was measured from the time the uterine cavity was entered with instruments or from the beginning of delivery of the fetus, whichever came first.

Examination of the tissue postoperatively included weighing the fetus and placenta separately and careful measurement of fetal parts including foot length, knee-to-heel length, and biparietal diameter. The method of measurement of fetal parts has been described and diagnosis of actual fetal age according to fetal foot length was made on the basis of previously established values.¹⁸

Patients were routinely observed in the recovery room for two hours or more, depending on patient response and the appearance of complications.

Ninety-eight percent of all patients received routine

antibiotic coverage after the dilatation and evacuation procedure. The standard protocol was 1 g of tetracycline immediately after the procedure followed by 500 mg every six hours for five days. The 2% of patients who did not receive antibiotics represented those who gave a history of antibiotic allergy, were on current medications for other reasons, or had some other contraindication such as vaginal moniliasis.

Patients were given strong encouragement to return for follow-up examination and were provided with forms to send in when they could not return in person for an examination. Efforts were made to arrange for follow-up with the referring or other local physician when the patient came from a long distance, and for the follow-up physician to return a brief report. Standard follow-up instructions included a recommendation for examination at one and at four weeks after the abortion. Follow-up contact was obtained for 77% ($N = 769$) of all patients, and 36% ($N = 359$) were seen in the clinic for at least one of the two recommended examinations.

Seventy-two percent of the procedures in the present report were performed by the author; the remainder were performed by four other physicians using similar techniques under the author's supervision. Comparative study of complication rates by physician and time series was not performed due to small numbers and numerous sources of bias. Complication rates by week of gestation were not analyzed for the same reasons.

Major complication is defined in the present report as major unintended surgery, hemorrhage requiring transfusion, or pelvic infection with two or more days of fever and a peak of at least 40C or with hospitalization for 11 or more days. A minor complication is defined as any operative or postoperative problem that requires reaspiration or suture of cervical laceration, infection indicated by uterine tenderness at follow-up examination responding to antibiotic therapy or a more than transitory fever of 38C or more, a total blood loss of 500 mL or more, and documented evidence of coagulopathy not requiring transfusion.

Results

The final estimate of gestational age as defined by fetal foot length ranged from 17 through 25 menstrual weeks; 48.3% of the pregnancies were from 17 through 19 menstrual weeks, and 50.6% were from 20 through 24 menstrual weeks. Twenty (2.0%) exceeded the intended gestational limit of 24 menstrual weeks by one week due to errors in the preoperative diagnosis.

Median dilatation and evacuation procedure time for

Table 1. Procedure Characteristics (All Patients)

Gestational age (wk from LMP)	No. of patients ($N = 1000$)	Median procedure time (min)	Median blood loss (mL)
17	117	7.5	102
18	178	7.0	102
19	181	7.4	150
20	91	8.0	154
21	137	7.8	151
22	153	8.4	150
23	70	9.7	102
24	53	10.2	100
25	20	15.5	109
Total	1000		

LMP = last menstrual period.

all cases was 7.9 minutes, and median blood loss was 149 mL with a mean of 172 mL. Procedure times were longer with pregnancies of more than 22 weeks' gestation, but blood loss was not increased (Table 1). Fetal weight ranged from 74 to 906 g, fetal foot length ranged from 23 to 49 mm, and biparietal diameter ranged from 32 to 63 mm.

Among patients receiving urea amnioinfusion, injection-to-procedure time ranged from 5.4 to 5.7 hours (Table 2), although some patients went into labor quickly and aborted within one or two hours after injection. There were no births of living fetuses. The exact time of fetal death after injection was not established in most cases, but it failed to occur after six hours in only a few cases.

Among the ten patients in whom fetal intrathoracic infusion of urea was performed, fetal death occurred immediately, but fetal tissue maceration was variable, and labor did not occur predictably as it did after amnioinfusion.

Table 2. Intraamniotic Urea Infusion Followed by Dilatation and Evacuation

Gestational age (wk from LMP)	No. of patients ($N = 415$)	Median amniotic fluid withdrawn (mL)	Median urea injected (g)	Median injection to procedure time (h)
20	40	280	104	5.4
21	96	227	83	5.3
22	142	300	118	5.4
23	64	327	118	5.2
24	53	378	120	5.5
25	20	328	119	5.7
Total	415			

LMP = last menstrual period.

Hemorrhage and Uterine Perforation

While blood loss was generally low and within acceptable limits, 2.1% of all patients experienced a blood loss of over 500 mL, and five of these experienced an operative blood loss of 1000 mL or more. These included one patient who experienced a spontaneous abortion on the evening of the second day of laminaria treatment and showed evidence of incipient shock upon arrival at the office. After initial treatment with colloid, volume replacement, and dilatation and curettage, 2 U of packed cells were given with immediate improvement and discharge from outpatient care.

Two other patients required transfusion. One experienced a uterine perforation during the dilatation and evacuation procedure in a pregnancy advanced to 23 weeks' gestation after urea amnioinfusion was unsuccessful. A perforation was suspected during the procedure, and the procedure was completed under direct ultrasound visualization without difficulty. After laparotomy and repair of a 2-cm posterior uterine defect, the patient recovered without incident. Another patient experienced delayed treatment for heavy vaginal bleeding four weeks after abortion and received 2 U of whole blood.

One patient in whom a reaspiration was attempted four weeks after abortion experienced a suspected perforation but developed no further symptoms or complications.

Infection

The patients in this series experienced an incidence of clinically identifiable infections of 0.6% (Table 3). The infection category includes one woman who developed transitory evidence of sepsis on the morning of

the procedure after serial multiple laminaria treatment in the presence of amniotic fluid leakage. She had received tetracycline during the laminaria treatment, but she experienced symptoms of sepsis after urea amnioinfusion. Sepsis symptoms disappeared after intravenous antibiotic therapy was begun, and the patient experienced no further complications.

Hospitalization

A total of six patients were hospitalized in the series, of whom only one, already described, was hospitalized for more than one night. Two patients were hospitalized for heavy postoperative bleeding due to uterine atony that was controlled before hospitalization. Another was hospitalized for heavy intraoperative bleeding accompanied by uterine atony and inability to remove the calvarium. Bleeding had stopped by the time of arrival at the hospital, and the fetal part was removed uneventfully several hours later.

Incomplete Procedures and Retained Tissue

Unsuspected retained tissue requiring treatment occurred in 0.7% of all patients. In 18 patients, the procedure could not be completed during the first attempt due to retained calvarium and, in one case, retained placenta. The treatment of choice in the case of trapped calvarium proved to be postponement of the procedure accompanied by oxytocin stimulation by intravenous infusion, followed in one or two hours by relatively easy forceps removal of the retained fetal part.

In approximately 5% of all patients, completion of a difficult procedure was assisted by the intraoperative use of real-time ultrasound. The ultrasound machine is set up at the side of the operating table with the screen facing the operator. The room lights are extinguished, leaving the operating lamp to light the perineum. The operator places the forceps tip in the lower uterine segment while maintaining countertraction on the cervix with a tenaculum, then watches the ultrasound screen for the outline of the forceps. The operator then approaches a fetal part, especially the calvarium, which has been displayed on the screen. The grasp of tissue is coordinated with the image on the screen. Confirmation of success can be obtained by rotating the tissue with the forceps or moving it downward toward the cervix.

Cervical Laceration

Three minor cervical lacerations occurred. All three were superficial and were adequately treated by one suture.

Table 3. Overall Complication Rates*

Major complications* (N = 3)	0.3%
Minor complications (N = 55)	5.5%
Clinically identifiable infections (N = 6)	0.6%
Unsuspected retained tissue requiring treatment (N = 7)	0.7%
Reaspiration within 1 wk (N = 3)	0.3%
Reaspiration beyond 1 wk (N = 4)	0.4%
Reaspiration within 6 hr, retained tissue (N = 20)	2.0%
Total blood loss of more than 500 mL (N = 18)	1.8%
1000+ mL (not including major complications) (N = 2)	0.2%
Cervical lacerations (N = 3)	0.3%
Coagulopathy (N = 1)	0.1%

* N = 1000.

† Major complication = major unintended surgery, hemorrhage requiring transfusion, pelvic infection with two or more days of fever and a peak of at least 40C or with hospitalization of 11 or more days.

Spontaneous Delivery

A total of two patients aborted spontaneously after laminaria treatment, both without assistance. One of these, already described, experienced severe bleeding and required transfusion.

Coagulopathy

One patient experienced a documented episode of disseminated intravascular coagulation (DIC) syndrome. The patient, whose 18-week pregnancy was terminated uneventfully, responded immediately to uterine reaspiration. Cause of the DIC is unknown, but hematometra due to uterine atony precipitated by a distended bladder is suspected.

Unusual Cases

In the present series, a wide variety of unusual circumstances were encountered that tended to complicate the procedure, but the author found that it was possible to manage within the framework of the protocol. Notably, there were three patients with didelphic uteri at 17, 20, and 23 weeks' gestation. Two twin pregnancies at 21 and 22 weeks' gestation were terminated by the usual protocol, except that in each case, methylene blue was used to distinguish between the two amniotic sacs. Urea (80 g) was injected into each amniotic sac. One patient with 18 weeks' amenorrhea but spotting was diagnosed preoperatively by ultrasound to have a hydatidiform mole. After serial multiple laminaria treatment and preoperative oxytocin infusion, the uterus was emptied quickly with a blood loss of approximately 500 mL.

Discussion

It must be emphasized that a key component of the late dilatation and evacuation procedure described here, whether supplemented or not by urea amnioinfusion, is serial multiple laminaria treatment over 24 to 48 hours. Through physiologic processes that may not be completely understood, this produces marked cervical softening and effacement in most cases. We have found that abbreviating this procedure by using only one laminaria treatment, for example, or by providing only 24 hours of multiple laminaria treatment (serial or not) in advanced gestations has not yielded optimum results in terms of blood loss, procedure times, uterine emptying, and patient comfort.

The use of urea in advanced pregnancies (greater or equal to 20 menstrual weeks' gestation) was adopted for several reasons. First, the fetal death and tissue

maceration obtained by this treatment makes evacuation much easier and therefore much less dangerous. The procedure is much more comfortable for the patient. The routine use of 120 g of hyperosmolar urea in a highly concentrated solution has proved to be highly and consistently effective.

Another consequence of urea amnioinfusion is the development of labor with dilatation and effacement of the cervix. Coming after greater or equal to 40 hours of serial multiple laminaria treatment, labor occurs consistently within a few hours after amnioinfusion. The wide dilatation and effacement appears to be the result of an interaction between the laminaria treatment and uterine irritation caused by the intraamniotic urea rather than a direct effect of the urea on the cervix as studied by Droegemueller et al.¹⁹ The dilatation and effacement adds to the safety and ease of the procedure by reducing the necessity of dilating the internal os from within by fetal parts as they are removed from the uterus. It sometimes permits delivery of a relatively intact fetus and placenta with virtually no blood loss.

It is necessary to emphasize that the late dilatation and evacuation procedure requires great caution, a high level of operator skill attained by gradual advancement from early to later gestations, and considerable time commitment on the part of the physician.

In our institution, both staffing and equipment have become more extensive and specialized as we accepted the more advanced gestations. One of the principal advantages of this procedure for patients (safety aside) is the freedom from having to experience unattended expulsion of a fetus that may or may not show signs of life.²⁰ Delivery of the fetus or uterine evacuation is performed by the physician under controlled conditions. Removal of the placenta and curettage is immediate; this reduces the risk of unusual bleeding or infection.²¹ Staffing requires the use of highly committed individuals who are expert in nursing, counseling, and patient support. Equipment includes the availability of a wide range of instruments appropriate to the procedure, real-time ultrasound, and adequate recovery space.¹²

The question of whether or not these procedures can or should be performed outside hospital settings is a complex one. The advantages of an outpatient setting include the possibility of a selected staff that is highly supportive, the availability of a full range of specialty instruments not usually available in community hospitals or even teaching hospitals, maintenance of patient confidentiality and informal procedures that reduce patient anxiety, availability of individual counseling throughout the patient's experience, reduced cost, fewer bureaucratic controls, reduced political vulnera-

bility, and greater flexibility in counseling, preoperative, and operating schedules.

There are no absolute requirements for routine hospital performance of late dilatation and evacuation procedures, although this option should be available in case of medical indications. Determination of the level of gestation at which the dilatation and evacuation is performed on an outpatient basis depends on the level of skill of the operator, the extent of preoperative preparation by use of laminaria and urea, the level of preparation reached by the facility in which the procedure will occur, and the proximity to a full-service hospital.

In the author's experience, there are several components to outpatient provision of late midtrimester abortion services that are essential. The patients must have absolute support from all members of the staff throughout the experience. Physicians should have specialized training and experience in the performance of this procedure. All patients should be routinely evaluated by ultrasound examination for diagnosis of fetal age, presentation, placental location, multiple gestations, and any abnormalities such as hydatidiform mole. A serial multiple laminaria preparation of the cervix should be performed over 40 to 48 hours before the dilatation and evacuation procedure. Specific appropriate instruments should be available in sufficient quantities.¹² Space for a routine minimum recovery period of two hours should be available within the facility. Tissue obtained through dilatation and evacuation should be inspected thoroughly by the operating physician or other specially trained person immediately after the procedure. Outpatient dilatation and evacuation in gestations greater or equal to 17 menstrual weeks' gestation should occur within 20 minutes of a full-service hospital (with blood bank, intensive care unit, and operating room) providing life-support ambulance service is immediately available. Physicians and administrators should recognize the emotional stress experienced by staff in assisting with or performing this procedure.^{22,23}

The level of safety achieved in this series, while it represents only the experience in a single institution and primarily the results of a single experienced operator, can be achieved by any conscientious physician or institution that makes the necessary commitment to the prevention of complications.

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Address reprint requests to:
Warren M. Hern, MD
Boulder Abortion Clinic PC
1130 Alpine Avenue
Boulder, CO 80302

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