

Membrane Sweeping versus Dinoprostone Vaginal Insert in the Management of Pregnancies beyond 41 Weeks with an Unfavorable Cervix

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OBJECTIVE:

To determine the best method of cervical ripening to prevent postdate inductions in women with an unfavorable cervix at 41 weeks' gestation.

STUDY DESIGN:

Women presenting at 41 weeks' gestation with a Bishop score of ≤ 4 received daily dinoprostone (Cervidil) vaginal inserts (group I) or daily membrane sweeping (group II).

RESULTS:

One-hundred and eighty-two women were prospectively randomized with 91 women in each arm. The women in group II, membrane sweeping, had Bishop scores significantly greater on admission for delivery ($p < 0.001$), had less time elapsed from admission to delivery ($p = 0.018$), and had fewer labor inductions at 42 weeks ($p = 0.04$) than the women in group I, the dinoprostone group. In addition, a greater number of women in group II were admitted in spontaneous labor ($p = 0.006$) than in group I. Total antenatal costs for the membrane sweeping group was \$15,120 versus \$59,540 for the dinoprostone group.

CONCLUSION:

Daily membrane sweeping was more effective than dinoprostone administration with fewer postdate inductions at one-fourth the cost.

Postterm pregnancy, with a reported frequency of 3% to 12%,¹ is a gestation extending beyond 42 weeks (294 days from the last menstrual period). These gestations may be complicated by oligohydramnios, meconium-stained amniotic fluid, macrosomia, fetal dysmaturity syndrome, and perinatal death.^{2,3} Of women presenting with a Bishop score of ≤ 4 at 41 weeks, 63% will remain undelivered at 42 weeks' gestation.⁴

Dinoprostone (prostaglandin E₂) has been beneficial when used for preinduction cervical ripening in a variety of medical conditions.⁵ Dinoprostone vaginal inserts (Cervidil; Forest Pharmaceuticals, St. Louis, MO) commercially offer the advantages of a slow, reproducible release preparation (0.3 mg/hr over 12 hours) and a retrieval system that permits removal of the insert if hyperstimulation occurs. These inserts are also effective in promoting cervical ripening in term pregnancies.⁶ Compared with dinoprostone gel (Prepidil; UpJohn, Kalamazoo, MI), the vaginal inserts achieve ripening over a shorter period.⁷ Membrane sweeping has been used to ripen the unfavorable cervix and prevent postterm pregnancies.^{8,9} Membrane sweeping is inexpensive, safe,¹⁰ and easy to perform, but a comparison with dinoprostone vaginal insert has not been undertaken.

The purpose of this investigation was to compare the effectiveness of dinoprostone vaginal insert versus membrane sweeping, in women presenting at 41 weeks with an unfavorable cervix, in preventing inductions at 42 weeks' gestation.

MATERIALS AND METHODS

This investigation took place during an 18-month period, from January 1995 until June of 1996. All pregnant women, undelivered of fetus at 41 weeks' gestation, are routinely referred to the antenatal diagnostic unit for fetal evaluation by a nonstress test, and an evaluation of amniotic fluid volume is performed twice a week. In this investigation, we initiated antenatal testing starting at 41 weeks with twice weekly testing as has been suggested by some investigators.^{11,12} This was done despite evidence by a prospective study demonstrating no clear benefit to testing before 42 completed weeks.¹³

Because the risk of an adverse outcome clearly increases after 42 completed weeks, we have chosen this as our endpoint for an induction and delivery. Gestational age was confirmed by last menstrual period, uterine size on first examination, first auscultation of fetal heart tones, and nearly all our patients have an ultrasound before 20

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Table 1 Bishop Score

	Score			
	0	1	2	3
Dilation	0	1–2	3–4	5–6
Effacement (%)	0–30	40–50	60–70	80
Station	–3	–2	–1–0	+1–+2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid	Anterior	

Table 2 Maternal Demographics

	Dinoprostone	Membrane sweeping	<i>p</i> value
Maternal age (yr)	25.4 ± 4.2	24.9 ± 6.0	0.522
Race			0.642
White	60 (66%)	64 (70%)	
Black	12 (13%)	7 (8%)	
Asian	7 (8%)	6 (7%)	
Hispanic	12 (13%)	14 (15%)	
Parity			0.546
0	62 (68%)	55 (60%)	
1	20 (22%)	24 (26%)	
≥2	9 (10%)	12 (13%)	
Gestational age at start (wk)	41.05 ± 0.09	41.03 ± 0.07	0.068
Bishop score at entry	2.71 ± 0.99	2.88 ± 0.95	0.245

weeks' gestation. Any patients whose gestational age was uncertain were not included in this investigation. After an ultrasound to evaluate amniotic fluid volume and confirm placental location, a pelvic examination was performed and a Bishop score was assigned (Table 1). Women with a singleton pregnancy, vertex presentation, intact membranes, reassuring antenatal assessment, no contraindication to a vaginal delivery, and a Bishop score of ≤4 were eligible to participate in the investigation. Exclusion criteria included women whose gestational age was uncertain and those women not desiring to participate. This study was approved by the Institutional Review Board, and all participants signed an informed consent before entrance into the study.

Patients were randomly assigned to one of two groups by drawing a card, generated from a table of random numbers sealed in an opaque envelope. The first group were to have daily placement of a dinoprostone vaginal suppository (Cervidil) and the second group had daily membrane sweeping. The technique for membrane sweeping involved the separation of the membranes from the lower uterine segment with two circumferential sweeps of the examining finger. If the cervix did not permit entrance of the examining finger, the cervix was stretched by the examining finger daily until membrane stripping could be accomplished. All patients were examined by one of two examiners, blinded to group assignment to determine the daily Bishop score. Following the examination, the membranes were either stripped or the vaginal suppository was placed. Patients were examined on a daily basis until spontaneous labor, rupture of membranes, a Bishop score of ≥8 occurred (at which time patients were admitted for labor induction), or 42 weeks was attained, at which time all remaining patients were admitted for labor induction.

Women in the dinoprostone group had daily nonstress tests and amniotic fluid evaluation following placement of the prostaglandin. Patients were discharged from the hospital after a reassuring assessment and if any contractions were present after the contractions had begun to decrease in intensity and frequency. All patients were instructed to return to labor and delivery for regular contractions, rupture of membranes, fever, or decreased fetal movement.

A sample size and power calculation was performed, and it was determined that 90 women were sufficient (power of 0.80, α = 0.05, and β = 0.20) in each group to demonstrate a difference of interventions by 18% between the two groups. These calculations are based on

a previous study in which 17% of patients with an unfavorable cervix treated with daily membrane stripping would remain undelivered for another 7 days.⁴

Statistical analysis was performed by Student's *t*, χ-squared, and Fisher's exact tests where appropriate, and *p* < 0.05 was considered significant.

RESULTS

One-hundred and eighty-two women were prospectively randomized, with 91 entered into each arm of this study. All patients were highly motivated to be delivered, and although some patients complained that membrane sweeping was uncomfortable, none of the patients dropped out of the study after randomization. The participants were in their mid twenties, primarily white, of a low gravidity, and with similar gestational ages and Bishops' score on entrance into this investigation (Table 2). The Bishop score on admission to labor and delivery was greater in the membrane sweeping group (8.56 ± 2.5) than in the dinoprostone group (6.63 ± 2.55) (*p* < 0.001).

A greater number of women were admitted to labor and delivery in active labor in the membrane sweeping group, 63 of 91 (69%) versus 44 of 91 (48%) in the dinoprostone group (*p* = 0.009). Fewer of the membrane sweeping group, 4 of 91 (9%), had a labor induction at 42 weeks than the dinoprostone group, 13 of 91 (4%) (*p* = 0.041). The time interval from admission to delivery was shorter in the membrane sweeping group (10.8 + 6.9 hours) than in the dinoprostone group (13.3 + 6.7 hours) (*p* = 0.01). The gestational age on admission and increase in gestational age from study entrance to admission to labor and delivery, mode of delivery, and reason for operative delivery were similar among the two groups (Table 3). The birth weight, Apgar scores, neonatal disposition, and reasons for admission to newborn intensive care unit were not different between the groups (Table 4). Three patients developed postpartum endometritis,

**Table 3** Intrapartum and Postpartum Outcomes

	Dinoprostone	Membrane sweeping	<i>p</i> value
Reason for admission to L&D*			
Labor	44 (48%)	63 (69%)	0.006
SROM	24 (26%)	13 (14%)	0.065
Induction at 42 wk	13 (14%)	4 (4%)	.041
Other	10 (11%)	11 (12%)	1
Gest age at admission to L&D (wk)	41.49 ± 0.27	41.45 ± 0.21	0.273
Increase in gestational age from study admission to L&D admission (wk)	0.43 ± 0.26	0.41 ± 0.21	0.603
Bishop score on L&D admission	6.63 ± 2.55	8.56 ± 2.50	<0.001
Time elapsed from L&D admission to delivery	13.37 ± 7.62	10.80 ± 6.92	0.018
Mode of delivery			
Spontaneous vaginal	59 (65%)	67 (74%)	0.362
Cesarean section	25 (27%)	17 (19%)	
Forceps	7 (8%)	7 (8%)	
Reason for operative (cesarean or forceps) delivery			
CPD	16 (50%)	14 (58%)	0.282
Fetal distress	11 (34%)	5 (21%)	
Maternal exhaustion	5 (16%)	3 (13%)	
Transverse arrest	0 (—)	2 (8%)	

*Abbreviations: L&D, labor and delivery; SROM, spontaneous rupture of membranes; CPD, cephalopelvis disproportion.

Table 4 Neonatal Outcome

	Dinoprostone	Membrane sweeping	<i>p</i> value
Birth weight (gm)	3727 ± 47	3651 ± 446	0.268
Apgar score at 5 minutes	8.87 ± 0.34	8.81 ± 0.42	0.333
<7	0	0	
≥7	91 (100%)	91 (100%)	
Umbilical artery pH	7.23 ± 0.06	7.23 ± 0.51	0.506
<7.2	23 (25%)	22 (24%)	
≥7.2	68 (75%)	69 (76%)	
Neonate admission			
Well-born nursery	86 (95%)	90 (99%)	0.097
NBICU*	5 (5%)	1 (1%)	
NBICU admissions			
Neonatal depression	2 (40%)	0	0.494
Meconium	1 (20%)	1 (100%)	
Rule out sepsis	1 (20%)	0	
Transient tachypnea	1 (20%)	0	

*NBICU, newborn intensive care unit.

two in the cervidil group and one in the membrane sweeping group. All three patients had undergone abdominal delivery, had prolonged rupture of membranes, and had a large number of vaginal examinations with rupture of membranes.

The primary medical cost was for the dinoprostone. The dinoprostone costs \$120 per dose, and 229 doses were used in the 91 women for a total cost of \$27,480. The average cost of a nonstress test and amniotic fluid estimation with interpretation is \$140 per test. All 229 dinoprostone placements were followed by nonstress test and AFI at a cost of \$32,060. The membrane sweeping group had antenatal testing twice a week or a total of 108 tests at a cost of \$140 for \$15,120. Total antenatal cost for the dinoprostone group was \$59,540 compared with \$15,120 for the membrane sweeping group. Intrapartum costs are \$26 per hour. The dinoprostone group spent an average of 13.4 hours in labor for a cost of \$31,704 for the 91 patients. The membrane sweeping group spent an average of 10.8 hours in labor for a cost of \$25,552 for that group. Total antepartum and intrapartum cost for the dinoprostone group was \$91,244 compared with \$40,672 for the membrane sweeping group.

Comment

Few situations in pregnancy create more anxiety between an obstetrician and his patient than a postdate pregnancy. This anxiety, coupled with the known significant increase in perinatal morbidity and mortality of postterm pregnancies, has led to antenatal testing often beginning at 41 weeks and/or labor inductions. To minimize these anxieties and to decrease the number of inductions performed at 42 weeks, serial cervical ripening may play a role in the management of women with an unfavorable cervix at 41 weeks' gestation.

Prepidil (the intracervical dinoprostone gel) and Cervidil (vaginal dinoprostone suppository) are the two prostaglandin preparations currently approved by the FDA for cervical ripening. Both agents have been used to transform a rigid unyielding cervix to a softer, more distensible and pliable one. In this investigation, we compared the efficacy of the vaginal dinoprostone insert to membrane sweeping. Both methods were found to reduce the number of postdate inductions at 42 weeks. It has been observed that, in women beyond 41 weeks with an unfavorable cervix, 63% will remain undelivered 7 days later without cervical ripening.⁴ However, the membrane sweeping technique resulted in fewer 42-week inductions (4% vs 14%) with the Cervidil without an increase in the risks of complications attributed to membrane sweeping, which include rupture of the membranes, bleeding, or infection. The risk of infection and membrane rupture occurred more frequently in the Cervidil group, although it was not significantly different from the membrane sweeping group. No patients in either group had any unusual vaginal bleeding. A recent investigation¹⁴ suggests that a combined therapy of membrane sweeping and dinoprostone is superior in preventing postterm pregnancies than either is alone.

Membrane sweeping has been shown to ripen the unfavorable cervix^{8,9} but not all investigators agree that membrane sweeping is effective in changing the Bishops' score or in initiating labor.¹⁵ In the two investigations^{8,9} demonstrating success, 180 and 142 women were prospectively randomized with mean Bishop scores of 2.4 to 3.8, whereas, in the study showing no improvement, 150 randomized women¹⁶ with a mean Bishop score of 5 showed no difference when



compared with a control group. On analyzing these studies, all which entered patients at 38 weeks, the initial Bishop score was the only different component between investigations. This may suggest that the more unfavorable cervixes respond to membrane sweeping, whereas the more favorable cervixes do not change any differently than a control group would change. The success of the sweeping in our study may be influenced by the cervical unfavorability at the start (Bishop ≤ 4) shown in other studies^{8,9} and the frequency of the sweeping, which was done daily. Clearly, the low 4% induction rate in the membrane stripping group, when compared with a control group of women with similar Bishop scores at 41 weeks who did not have membrane sweeping or any other type of cervical ripening rate of 63% at 42 weeks,⁴ is evidence suggestive of the success of daily membrane sweeping.

The daily active management of women at 41 weeks with an unfavorable cervix results in fewer labor inductions, 4% in the membrane swept group and 14% in the dinoprostone groups, contrasted to 63%⁴ observed in untreated similar women. Daily membrane sweeping, when compared with daily dinoprostone, resulted in greater Bishop scores on admission to labor and delivery, fewer hours from admission to delivery, and fewer labor inductions at 42 weeks. Daily membrane sweeping appears to be superior to dinoprostone in the management of pregnancies with an unfavorable cervix at a combined antepartum and intrapartum cost that is less than one-half the cost of using the vaginal insert method.

References

1. Rayburn WF, Morley ME, Stempel LE. Antepartum prediction of the postmature infant. *Obstet Gynecol* 1982;60:148–53.
2. Lagrew DC, Freeman RK. Management of postdate pregnancy. *Am J Obstet Gynecol* 1986;154:8–13.
3. Yeh SY, Read JA. Management of postterm pregnancy in a large obstetric population. *Obstet Gynecol* 1982;60:282–7.
4. Magann EF, Chauhan SP, Nevils BG, McNamara MF, Kinsella J, Morrison JC. Management of pregnancies beyond 41 weeks' gestation with an unfavorable cervix. *Am J Obstet Gynecol* 1998;178:1279–87.
5. Keirse MJN, Phil D. Prostaglandins in preinduction cervical ripening: meta-analysis of worldwide clinical experience. *J Reprod Med* 1993;38:89–100.
6. Witter FR, Mercer BM. Improved intravaginal controlled-release prostaglandin E2 insert for cervical ripening at term. *J Matern Fetal Med* 1996;5:64–9.
7. Chyu JK, Strassner HT. Prostaglandin E2 for cervical ripening: a randomized comparison of Cervidil versus Prepidil. *Am J Obstet Gynecol* 1997;177:606–11.
8. McColgin SW, Hampton HL, McCaul JF, Howard PR, Andrew ME. Stripping of membranes at term: can it safely reduce the incidence of postterm pregnancies? *Obstet Gynecol* 1990;76:678–80.
9. Berghella V, Rogers RA, Lescale K. Stripping of membranes as a safe method to reduce prolonged pregnancies. *Obstet Gynecol* 1996;87:927–31.
10. Gupta R, Vasishta K, Sawhney H, Ray P. Safety and efficacy of stripping of membranes at term. *Int J Obstet Gynecol* 1998;60:115–20.
11. Bochner CJ, Williams J, Castro L, Medearis A, Hoblel CJ, Wade M. The efficacy of starting post-term antenatal testing at 41 weeks as compared with 42 weeks' of gestation. *Am J Obstet Gynecol* 1988;159:550–4.
12. Guidetti DA, Divon MY, Langer O. Postdate fetal surveillance: is 41 weeks too early? *Am J Obstet Gynecol* 1989;161:91–3.
13. Usher RH, Boyd ME, McLean FH, Kramer MS. Assessment of fetal risk in postdate pregnancies. *Am J Obstet Gynecol* 1988;158:259–64.
14. Doany W, McCarty J. Outpatient management of the uncomplicated postdate pregnancy with intravaginal prostaglandin E₂ gel and membrane stripping. *J Matern Fetal Med* 1997;6:71–8.
15. Naeye RL. Causes of perinatal mortality excess in prolonged gestations. *Am J Epidemiol* 1978;108:429–34.
16. Crane J, Bennett K, Young D, Windrim R, Kravitz H. The effectiveness of sweeping membranes at term: a randomized trial. *Obstet Gynecol* 1997;89:586–90.