Randomized controlled trial of prevention of perineal trauma by perineal massage during pregnancy

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OBJECTIVE: The aim of the study was to evaluate the effectiveness of perineal massage during pregnancy for the prevention of perineal trauma at birth.

STUDY DESIGN: Pregnant women with (n = 493) and without (n = 1034) a previous vaginal birth from 5 hospitals in the province of Québec, Canada, participated in this single-blind, randomized, controlled trial. All participants received oral and written information on the prevention of perineal trauma. Women in the experimental groups were requested to perform a 10-minute perineal massage daily from the 34th or 35th week of pregnancy until delivery.

RESULTS: Among participants without a previous vaginal birth, 24.3% (100/411) from the perineal massage group and 15.1% (63/417) from the control group were delivered vaginally with an intact perineum, for a 9.2% absolute difference (95% confidence interval 3.8%-14.6%). The incidence of delivery with an intact perineum increased with compliance with regular practice of perineal massage (χ^2 for trend 13.2, $P = 0.0003$). Among women with a previous vaginal birth, 34.9% (82/235) and 32.4% (78/241) in the massage and control groups, respectively, were delivered with an intact perineum, for an absolute difference of 2.5% (95% confidence interval –6.0% to 11.0%). There were no differences between the groups in the frequency of sutured vulvar and vaginal tears, women's sense of control, and satisfaction with the delivery experience.

CONCLUSION: Perineal massage is an effective approach to increasing the chance of delivery with an intact perineum for women with a first vaginal delivery but not for women with a previous vaginal birth. (Am J Obstet Gynecol 1999;180:593-600.)

Key words: Perineal massage, perineal trauma, randomized controlled trial

Women frequently incur perineal trauma while giving birth, particularly at the first delivery. The most common cause is episiotomy, which produces trauma similar to a spontaneous second-degree perineal tear. Recent randomized, controlled trials[1-7] have provided evidence that routine episiotomy not only is ineffective but may be harmful. Despite the decreased risk of perineal trauma when the use of episiotomy is restricted, about 50% of women who are delivered without episiotomy have a laceration requiring multilayer closure.[8-11]

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Interventions to reduce the risk of episiotomy and perineal tearing are highly desirable. Women who are delivered with an intact perineum have less perineal pain immediately and 3 months after delivery, report better sexual functioning at 3 and 6 months post partum, and have stronger pelvic floor musculature.[12-14] Perineal massage, performed by a woman or her partner during the last weeks of pregnancy, has been advocated by midwives to increase perineal elasticity. However, the efficacy of this technique in reducing trauma has never been adequately demonstrated. Most studies of perineal massage[15-21] suffer from small sample size and important methodologic limitations.

After carrying out a pilot study[20] to test our proposed methods, we planned this clinical trial to determine for women with and without a previous vaginal delivery whether perineal massage during pregnancy would increase the likelihood of delivery with an intact perineum. Secondary objectives included evaluation of the effects of perineal massage on the rate of episiotomy, the severity of perineal lacerations, and the occurrence of vulvovaginal tearing. In addition, we assessed whether perineal massage increased women's sense of control during labor and delivery and their satisfaction with the experience.

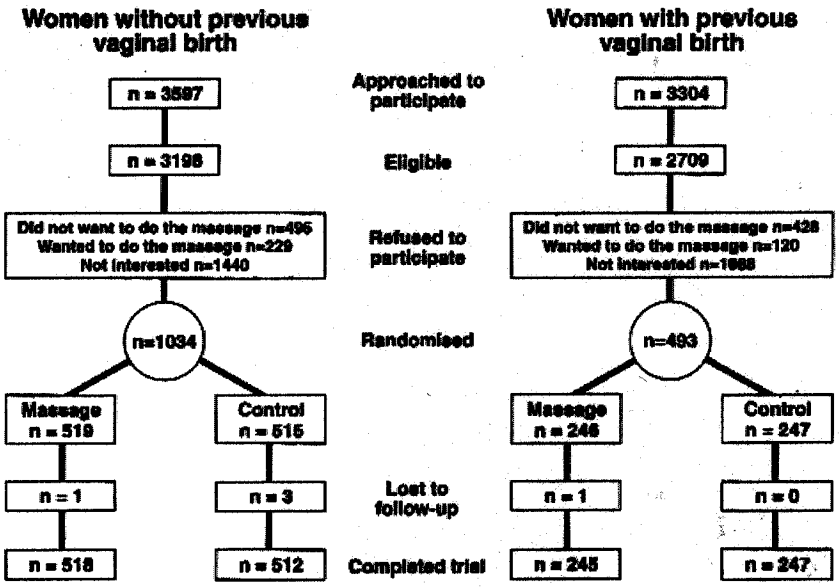

Fig 1. Perineal massage trial profile.

Material and methods

Participants. The study sample consisted of pregnant women being delivered in 5 teaching hospitals in the province of Québec, Canada. The study was approved by the research ethics committees at all participating centers. From September 1994 through December 1995, 3304 women with and 3597 women without a previous vaginal birth were approached to participate at prenatal visits or at third-trimester ultrasonographic or blood testing (Fig 1). Women were excluded for the following reasons: high risk of cesarean delivery, including previous cesarean delivery for cephalopelvic disproportion; multiple gestation; placenta previa; severe fetal growth restriction; breech presentation; preeclampsia (n = 182 among women without previous vaginal birth and n = 205 among women with previous vaginal birth); nonparticipating physicians (n = 129 and n = 246, respectively); outbreak of genital herpes during the current pregnancy (n = 11 and n = 1, respectively); and unknown or other reasons, including inability to speak French or English, inability to understand the instructions, and already doing the massage (n = 77 and n = 143, respectively). Eligible women were randomly assigned between 30 and 35 weeks' gestation.

Randomization and blinding. The randomization scheme was centrally developed with a table of random numbers and balanced in blocks of 4 or 6. Randomization was stratified by history of previous vaginal birth, specialty of the attending physician (family physician or obstetrician-gynecologist), and hospital. Sets of sealed, sequentially numbered, opaque envelopes were sent to each participating center. After they gave written consent, participants were randomly assigned to the experimental or the control group by the research nurse according to instructions contained in the envelope. No breaches of sequential assignment occurred.

All participants were instructed not to reveal their group assignment to their doctors. Similarly, physicians were asked not to inquire about their patients' study groups. Both women and physicians completed questionnaires after the delivery asking whether the study group had been divulged to the delivering physician. If either the physician or the woman said that the group assignment had been disclosed, we considered blinding to have failed.

Interventions. All participating physicians were provided with written information on the importance of maintaining a restrictive policy on episiotomy. In addition, we sent monthly reports to all participating physicians giving their personal episiotomy rate, the global rate of episiotomy in the study, and a reminder of the importance of maintaining a restrictive policy.

Women who agreed to participate met with the research nurse and were provided with oral and written information from the current medical literature about episiotomy and perineal trauma during delivery. Participants completed a baseline questionnaire regarding sociodemographic characteristics, obstetric history, and attitudes and intentions toward labor and delivery. For women with previous vaginal delivery, the medical record from the last delivery was obtained to provide accurate information about previous perineal trauma and other obstetric factors.

Women in the control group otherwise received usual obstetric care. Women in the experimental group received

the information provided to those in the control group and were also taught the technique of perineal massage by the nurse by means of a foam model, diagrams, and written instructions (available on request). Perineal massage requires approximately 10 minutes daily. It consists of introducing 1 or 2 fingers 3 to 4 cm deep into the vagina and applying and maintaining pressure, first downward for 2 minutes and then for 2 minutes to each side of the vaginal entrance. Women were given a bottle of sweet almond oil (Rougier Inc, Montreal, Quebec, Canada) to use for lubrication. They were asked to do perineal massage daily starting at 34 to 35 weeks' gestation.

To encourage compliance the nurse telephoned each woman assigned to the massage group 1 week and 3 weeks after random assignment. Participants were asked to fill out a daily diary indicating whether they or their partners had actually done the massage. A postpartum self-administered questionnaire asked all participants (in both massage and control groups) whether, for how many weeks, for how many days a week, and by whom massage had been done. We calculated correlations between the 2 instruments for the total number of weeks of massage and the proportion done by the partner. All Pearson correlation coefficients were >0.86.

Degree of compliance was calculated from the diary as the proportion of days massage was done between the starting day assigned by the nurse (either the date of random assignment or, if random assignment occurred earlier, during the 34th week of pregnancy) and the date of delivery. Women for whom no diary was available were considered to have complied less than a third of potential days.

Outcome measures. At the time of the birth decisions about the mode of delivery and the use of episiotomy were made by the resident or attending physician. Immediately after delivery the physician completed a standardized form about the state of the perineum, including details on episiotomy, perineal lacerations, and sutured vulvovaginal lacerations other than perineal. The primary outcome measure was the proportion of women who were delivered with an intact perineum, either with no laceration or with an unsutured first-degree tear. A nurse collected obstetric and neonatal data from the mothers' and babies' charts. All participants completed a self-administered questionnaire within a few days of delivery addressing the experience with perineal massage, their feelings of control, and their satisfaction with the delivery, as assessed with adapted versions of the Labor and Delivery Satisfaction Index[22] and the Labour Agentry Scale.[23]

Statistical analysis. On the basis of statistical reports from the participating hospitals, approximately 18% of primiparous women and 40% of multiparous women were being delivered with an intact perineum. Sample sizes were calculated to provide 90% power to detect an absolute difference of 10% in the proportion of women being delivered vaginally with an intact perineum in the group without and an absolute difference of 15% in the group with a previous vaginal birth ($\alpha = .05$, 2-sided). The sample size was increased by 20% for women without a previous vaginal birth and 5% in women with a previous vaginal birth to take into account an expected loss because of cesarean delivery. Thus the final sample sizes were 976 and 512, respectively. Analysis was by intention to treat, and results were calculated separately for women without and with previous vaginal birth. For the analysis of perineal and vulvovaginal outcomes, it was decided a priori in the research protocol to exclude women delivering by the cesarean route because it was not possible in these cases to assess the effect of delivery on perineal integrity. The difference between the groups in perineal outcome divided into 5 categories (intact perineum, sutured first-degree tear, second-degree tear, episiotomy, and third- and fourth-degree tears) was assessed with a χ^2 test with 4 degrees of freedom. If statistical significance was established, this was further partitioned to explore the contribution of various categories to the difference.[24] Absolute differences and 95% confidence intervals were calculated for the primary outcomes. The χ^2 test or the Fisher exact test was used to compare categoric data. The χ^2 test for trend was used for compliance subgroup analysis. Means and SDs were compared with Student *t* test and medians were compared with the Kruskal-Wallis test.

Results

A total of 1034 women without a previous vaginal birth and 493 with ≥1 previous vaginal birth were randomly assigned. Five were unavailable for follow-up (Fig 1). Baseline characteristics of women were similar in the experimental and control groups (Table I). In women with ≥1 previous vaginal birth, the type of delivery, the birth weight, the length of second stage of labor, and the perineal outcome recorded at the most recent delivery were similar between study groups. Exclusion of women unavailable for follow-up and those who were delivered by the cesarean route did not modify the comparability of the study groups.

Sixty-six percent of women without a previous vaginal birth assigned to perineal massage performed the massage ≥4 times/wk for ≥3 weeks; more than 85% massaged on at least a third of the assigned days (Table II). Compliance with perineal massage was slightly lower among women with ≥1 previous vaginal birth. At least a third of the massages were done by the partner in 48% and 34% of women without and with previous vaginal births, respectively. Extremely few participants in the control groups performed perineal massage.

There were no significant differences between the overall study groups (Table III), nor were there any after restricting analysis to vaginal births, type of delivery, gestational age at delivery, length of second stage of labor, birth weight, use of epidural anesthesia, and type of health professional attending the birth.

Table I. Baseline characteristics of women according to study group

Characteristics	*Women without previous vaginal birth*		*Women with previous vaginal birth*	
	Massage (n = 519)	*Control (n = 515)*	*Massage (n = 246)*	*Control (n = 247)*
Age (y, mean ± SD)	28.0 ± 4.9	27.9 ± 4.7	31.1 ± 4.1	30.7 ± 4.5
Educational level (y, mean ± SD)	15.4 ± 3.1	15.5 ± 3.0	15.4 ± 3.0	15.1 ± 3.1
Height (cm, mean ± SD)	163.3 ± 6.3	163.3 ± 6.5	163.6 ± 6.0	164.2 ± 5.8
Previous cesarean delivery (%)	5.8	4.9	4.1	2.8
≥2 previous vaginal births (%)	NA	NA	23.4	27.9
Gestational age at random assignment (wk, mean ± SD)	33.1 ±1.2	33.0 ± 1.3	33.0 ± 1.4	32.9 ± 1.3
Prenatal care by obstetrician-gynecologist (%)	72.8	72.4	74.4	74.9
Intention to breast-feed (%)	79.8	77.1	50.1	49.9
Ever heard of perineal massage (%)	51.9	48.1	51.9	48.1
Good to very good previous knowledge of perineal massage (%)	11.6	14.0	18.3	13.8
Important to very important to be delivered without an episiotomy (%)	72.9	68.9	61.8	58.9
Important to very important to be delivered without epidural anesthesia (%)	40.2	44.1	41.9	41.7

NA, Not applicable.

Among women who were delivered vaginally, perineal massage made a difference in perineal outcome for women without previous vaginal birth ($\chi^2_4 = 12.7$, $P = .01$; Table IV). The proportion of these women who were delivered vaginally with an intact perineum was 61% higher in the massage group (24.3%) than in the control group (15.1%), an absolute difference of 9.2% (95% confidence interval 3.8%-14.6%; $\chi^2_1 = 11.1$, $P = .001$). Among all randomly assigned women, the incidence of intact perineum was 19.3% (110/518) in the massage group and 12.3% (63/512) in the control group ($P = .002$). Fewer women without a previous vaginal birth in the massage group (35.0%) than in the control group (40.5%) had an episiotomy, but this difference did not achieve statistical significance ($\chi^2_1 = 0.1$, $P = .71$). All episiotomies were median, except for 2 mediolateral episiotomies in the control group. Perineal massage had no statistically significant effect on the risk of third- and fourth-degree perineal lacerations (10.5% and 12.5% in the massage and control groups, respectively) or on the risk of extension of episiotomy into the anal sphincter. Women in the massage group who practiced perineal massage less than a third, a third to two thirds, and more than two thirds of the assigned massage days were delivered with an intact perineum in 20.0%, 23.0%, and 27.5% of cases, respectively (χ^2 for trend 13.2, $P = .0003$).

Among women with ≥1 previous vaginal birth, the difference in perineal outcome was not statistically significant ($\chi^2_4 = 0.90$, $P = .92$). The proportions of women who were delivered vaginally with an intact perineum were similar in the 2 groups (absolute difference 2.5%, 95% confidence interval –6.0% to 11.0%; $\chi^2_1 = 0.34$, $P = .56$); including all those with ≥1 previous vaginal birth, the incidences of intact perineum were 33.5% (82/245) in the massage group and 31.6% (78/247) in the control group ($P = .65$). Among those in the massage group who practiced perineal massage less than a third, a third to two thirds, and more than two thirds of the assigned massage days, 35.1%, 35.7%, and 33.8%, respectively, had an intact perineum (χ^2 for trend 0.18, $P = .67$). Perineal massage had no effect on the risk of sutured vulvovaginal lacerations other than perineal lacerations in women without or with a previous vaginal birth (III).

Blinding was well maintained. Among women without previous vaginal birth, study group assignment was revealed by either the woman, the physician, or both in 38 cases (9.3% of vaginal births) in the massage group and 22 cases (5.3% of vaginal births) in the control group. Unblinding occurred among 13 (5.6%) and 10 (4.2%) of the women with previous vaginal birth in the massage and control groups, respectively.

Among women without a previous vaginal birth, the median scores on the Labour Agentry Scale were 5.61 and 5.56 in the massage and the control groups, respectively ($P = .03$); the median scores on the Labor and Delivery Satisfaction Index were 5.31 and 5.36, respectively ($P = .07$). Similar results were obtained among women with previous vaginal birth (median Labour Agentry Scale scores were 5.31 for massage and 5.14 for control, $P = .03$; median Labor and Delivery Satisfaction Index scores were 5.94 in the massage group and 6.06 in the control group, $P = .28$). These differences are not clinically significant. In the massage group 80% of women without a previous vaginal birth and 77% of women with ≥1 previous vaginal birth said that they

Table II. Characteristics of perineal massage practice according to study groups

Characteristics of perineal massage practice	*Women without previous vaginal birth*		*Women with previous vaginal birth*	
	Massage (n = 518)	*Control (n = 512)*	*Massage (n = 245)*	*Control (n = 247)*
Returned diary (%)	90.2	NA	85.0	NA
Returned postpartum questionnaire (%)	97.1	98.6	95.5	98.8
Massaged ≥1 time* (%)	97.9	6.1	94.7	4.5
Massaged ≥4 times/wk for ≥3 wk* (%)	65.6	2.9	57.1	1.6
Days with massage† (mean ± SD)	22.7 ± 11.0	NA	20.1 ± 11.4	NA
Weeks with ≥4 massages† (mean ± SD)	3.9 ± 2.0	NA	3.5 ± 2.1	NA
Compliance with massage † (%)				
<1/3 of potential days	22.6	NA	33.9	NA
1/3-2/3 of potential days	38.4	NA	35.5	NA
2/3 of potential days	39.0	NA	30.6	NA
Proportion of massages performed by partner†(%)				
0%-33%	52.4	NA	65.6	NA
34%-66%	9.4	NA	4.6	NA
≥67%	38.2	NA	29.7	NA

NA, Not applicable.
* Data for the massage group were taken from the diary or, if no diary was returned, from the postpartum questionnaire; data for the control group came from the postpartum questionnaire.
†Data were taken from the diary.

would perform perineal massage if they were to have another baby. Furthermore, 87% and 89%, respectively, would recommend perineal massage to another pregnant woman.

Comment

Our study showed that perineal massage is effective in increasing the likelihood that women having their first vaginal birth will be delivered with an intact perineum. Furthermore, we observed a dose-response effect; increasingly regular practice of perineal massage was associated with an increasing likelihood of maintaining an intact perineum. The effect of perineal massage is explained mainly by a reduction in sutured first-degree tears and episiotomy. Although most of the postpartum morbidity associated with perineal lacerations is due to third- and fourth-degree tears, there is evidence of a reduction in perineal pain immediately and 3 months after delivery, of better sexual functioning at 3 and 6 months' post partum, and of a stronger pelvic floor musculature with intact perineum than with sutured first- and second-degree perineal trauma.[12-14] Thus women without previous vaginal birth who practiced perineal massage could expect to decrease the risk of postpartum morbidity associated with sutured perineal lacerations. On the other hand, women undergoing a second or subsequent vaginal delivery had only a 2.5% increase in maintenance of an intact perineum, which is neither statistically nor clinically significant.

The increased frequency of delivery with an intact perineum among women without a previous vaginal birth may result from 2 factors: a beneficial effect of massage on perineal tissue and a greater motivation to collaborate with the birth attendant in maneuvers to avoid perineal trauma, such as slow, controlled delivery. We can reasonably assume that women in the control and massage groups were similarly motivated at enrollment because the groups were randomly assigned and the baseline data were comparable. Additional motivation in maintaining perineal integrity in the massage group should not be considered as a contaminating factor, but rather as part of the pathway by which the practice of massage acts to prevent perineal trauma.

Achievement of the lowest possible rate of episiotomy is necessary to permit observation of any effect of massage on the perineum. Some earlier studies on perineal massage were completely undermined by this problem.[17, 18] To that end we provided written and oral information about the most recent research evidence on episiotomy to both pregnant women and their physicians. Episiotomy rates among the women without a previous vaginal birth in the study centers fell from >50% before the study to 38% during the study.

Blinding was also crucial. If the delivering physician knew the patient's study group, a different degree of care might be taken to avoid maternal trauma at delivery. At the time of delivery, physicians knew the assigned study group for only 7.3% of women with no previous vaginal birth and 4.9% of those with ≥1 previous vaginal birth. We do not believe that unblinding explains the increased rate of delivery with an intact perineum. Among women without previous vaginal birth, if we hypothetically attribute perineal trauma to all unblinded deliveries of women from the massage group, the difference in the rate of delivery with an intact perineum between massage and control groups remains statistically significant ($P = .01$).

Table III. Labor and delivery characteristics other than perineal and vulvovaginal outcomes according to study groups

	Women without previous vaginal birth				
	Massage (n = 518)		*Control (n = 512)*		
Outcomes	*No.*	*%*	*No.*	*%*	*Statistical significance*
Type of delivery					
Spontaneous	282	54.4	289	56.4	$P = .86$*
Vacuum extraction	59	11.4	59	11.5	
Forceps	70	13.5	69	13.5	
Cesarean section	107	20.7	95	18.6	
Gestational age at delivery (wk, mean ± SD)	39.2 ± 1.5		39.2 ± 1.5		$P = .79$
Duration of second stage of labor† (min, mean ± SD)	89.9 ± 63.4		85.9 ± 60.7		$P = .35$
Mean birth weight (g, mean ± SD)	3388 ± 501		3346 ± 449		$P = .16$
Delivered with epidural anesthesia (%)	416	80.3	411	80.3	$P = .99$
Delivered by					
Obstetrician-gynecologist	344	66.4	329	64.3	$P = .70$‡
General practitioner	98	18.9	99	19.3	
House staff, nurse, other	76	14.7	84	16.4	

*Three degrees of freedom, χ^2 test.
†Calculated for vaginal births only.
‡Two degrees of freedom, χ^2 test.

Table IV. Perineal and vulvovaginal outcomes among women with vaginal delivery according to study group

	Women without previous vaginal birth				
	Massage (n = 411)		*Control (n = 417)*		
Outcomes	*No.*	*%*	*No.*	*%*	*Statistical significance*
Perineal outcome (%)					
Intact perineum (no suture)	100	24.3	63	15.1	$P = .01$*
First-degree tear (single-layer suture)	60	14.6	77	18.5	
Second-degree tear (multilayer suture)	97	23.6	96	23.0	
Episiotomy (no extension)	111	27.0	129	30.9	
Third- or fourth-degree tear without episiotomy	10	2.4	12	2.9	
Third- or fourth-degree tear with episiotomy	33	8.0	40	9.6	
Sutured tears other than perineal(%)					
Periurethral	25	6.1	35	8.4	$P = .20$
Labia minora	38	9.3	34	8.2	$P = .57$
Hymen	11	2.7	12	2.9	$P = .86$
Outer half of vagina	40	9.8	40	9.6	$P = .94$
Deeper half of vagina	17	4.1	16	3.8	$P = .83$

*Four degrees of freedom, χ^2 test, with third- or fourth-degree tear with or without episiotomy comprising 1 category.

Although the research nurses worked diligently to encourage a high level of compliance, this was difficult to achieve, particularly among women with ≥1 previous vaginal delivery. Our study participants represented a specific group of motivated women who were well educated on perineal massage and were receiving ongoing encouragement. Compliance in the general pregnant population in the context of actual clinical practice or prenatal classes is therefore unlikely to be higher. Because most women in the massage groups intended to practice perineal massage during another pregnancy and would recommend it to another pregnant woman, however, perineal massage appears to be a highly acceptable procedure to pregnant women. Furthermore, motivation to practice perineal massage may be increased now that we have demonstrated its effectiveness.

We speculated that doing perineal massage might increase women's feelings of control and satisfaction with the birth experience. On the other hand, there was the risk that investment of substantial time and effort to avoid perineal trauma could increase dissatisfaction if trauma nevertheless ensued. The measures that we used were unable to detect any differences between the massage and the control groups. It is likely that aspects of intrapartum care

Women with previous vaginal birth				
Massage (n = 245)		Control (n = 247)		
No.	%	No.	%	Statistical significance
213	86.9	227	91.9	P = .33*
14	5.7	10	4.0	
8	3.3	4	1.6	
10	4.1	6	2.4	
39.1 ± 1.4		39.2 ± 1.3		P = .43
31.8 ± 38.2		26.2 ± 27.3		P = .07
3506 ± 470		3475 ± 487		P = .47
130	53.1	140	56.7	P = .42
140	57.1	143	57.9	P = .97‡
55	22.5	53	21.5	
50	20.4	51	20.7	

Women with previous vaginal birth				
Massage (n = 235)		Control (n = 241)		
No.	%	No.	%	Statistical significance
82	34.9	78	32.4	P = .92*
54	23.0	54	22.4	
63	26.8	66	27.4	
35	14.9	41	17.0	
1	0.4	1	0.8	
0	0	1	0.8	
12	5.1	17	7.1	P = .37
17	7.2	16	6.7	P = .81
0	0	2	0.8	P = .50
4	1.7	8	3.3	P = .26
2	0.9	4	1.7	P = .69

other than perineal massage during pregnancy were major determinants of the sense of control and satisfaction.

Earlier studies of perineal massage[15-20] were largely inconclusive. In Avery and Burket's first clinical study[15] 140 (87.5%) of the 160 participants initially randomly assigned were excluded from the analysis; in the ensuing study of Avery and Van Arsdale[16] participants chose their own study group (massage or no massage). Our pilot study[20] and others[17-19] were too small to detect any clinically important difference between study groups. Shipman et al[21] recently published a randomized clinical trial of perineal massage with methods much like those described in our own pilot study.[20] In a population of 682 nulliparous women delivering vaginally, they found a 6.1% statistically nonsignificant reduction in perineal trauma with perineal massage ($P = .07$). Only a third of the women fully complied with perineal massage, and 15% did not massage at all. After adjustment for birth weight and maternal age, however, the difference reached statistical significance ($P = .02$). The results of this trial suggested a possible benefit of perineal massage with respect to the incidence of perineal trauma among nulliparous women. Our study confirmed that finding.

With the diminishing use of episiotomy, birth attendants will have to rediscover the art of helping women through delivery without perineal trauma. Our study has shown that regular practice of perineal massage, starting at 34 to 35 weeks' gestation, is effective in helping women approaching their first vaginal delivery achieve this goal.

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