Serial Membrane Sweeping at Term in Planned Vaginal Birth After Cesarean

A Randomized Controlled Trial

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OBJECTIVE: To estimate the effect of serial membrane sweeping on the onset of labor in women who planned vaginal birth after cesarean (VBAC).

METHODS: Women at term with one transverse lower segment cesarean delivery who were suitable for and who planned VBAC were approached to participate. Participants were randomly assigned to weekly membrane sweeping or weekly vaginal assessment for Bishop score until delivery. Participants and delivery providers were blinded to the allocated treatment. Standard obstetric care was given to all participants. The primary outcome was onset of labor which was defined as the presence of spontaneous regular and painful contractions that cause cervical dilation to at least 3 cm or prelabor rupture of membranes. Secondary outcomes included induction of labor and repeat cesarean delivery.

RESULTS: One hundred eight women were randomly assigned to membrane sweeping and 105 to control. The spontaneous labor rate was 78.5% compared with 72.1% (relative risk [RR] 1.1, 95% confidence interval [CI] 0.9–1.3; *P*=.34), the induction of labor rate was 12.1% compared with 9.6% (RR 1.3, 95% CI 0.6–2.8; *P*=.66), and the all-cause cesarean delivery rate was 40.2% compared with 44.2% (RR 0.9, 95% CI 0.7–1.2; *P*=.58) for the membrane sweeping and control groups, respectively. Gestational age at delivery (mean±standard deviation) of 39.6±1.0 weeks for the membrane sweeping group compared with 39.6±0.9 weeks for the control group (*P*=.84) was no different.

CONCLUSION: Serial membrane sweeping at term in women who planned VBAC has no significant effect on the onset of labor, pregnancy duration, induction of labor, or repeat cesarean delivery.

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LEVEL OF EVIDENCE: I

Membrane sweeping at term is effective in expediting delivery and reducing the need for formal induction of labor.[1] Recent guidance suggests that membrane sweeping can be offered at term to promote labor and avoid induction of labor for prolonged pregnancy.[2,3] Induction of labor is associated with a failed trial of vaginal birth after cesarean (VBAC) resulting in a repeat cesarean delivery.[4] Induction of labor and scarred uteri are associated with uterine rupture, which in turn massively increases the risk of neonatal mortality.[5] The rates of cesarean delivery in women undergoing planned VBAC were 33%, 26%, and 19% for induced, augmented, and spontaneous labor groups, respectively.[6] The risk of uterine rupture for planned VBAC delivery was 102, 87, and 36 per 10,000 attempts for induced, augmented, and spontaneous labor groups, respectively.[7]

Induction of labor at planned VBAC is acceptable after careful counseling and risk assessment,[8–10] but misoprostol should not be used.[8,10] The Bishop score is inversely correlated with successful induction of labor at planned VBAC.[11]

Prolonged pregnancy (after 39 weeks of gestation) after a previous cesarean delivery is associated with stillbirth.[12] Prior cesarean delivery is also associated

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with an excess risk of explained stillbirths.[13] However, other studies have not demonstrated an increased risk of subsequent stillbirth after a cesarean delivery.[14,15]

A PubMed search (http://www.ncbi.nlm.nih.gov/pubmed/) that used the terms *previous cesarean* and *membrane sweeping* without any limits from 1966 until May 2, 2009, did not identify any article. There is a paucity of data within the context of membrane sweeping after a cesarean delivery.

Promoting earlier onset of labor within term in women planning VBAC can be advantageous, because the need for induction of labor may be avoided, and prolongation of pregnancy further into late term with its risk of stillbirth may be reduced. We hypothesize that serial membrane sweeping is effective in initiating labor in women planning VBAC. The objective of our research, therefore, was to estimate the effect of serial membrane sweeping on the onset of labor in women who planned VBAC.

MATERIALS AND METHODS

The trial was conducted in a university hospital located in Kuala Lumpur, Malaysia. More than 5,000 women deliver at our center each year. In a recent report from our center, 1,000 consecutive women with one previous cesarean delivery who were suitable for VBAC were identified over a 3.5-year period from 2002 to 2005. A total of 76.8% of these women underwent planned VBAC, and 71.2% of those who attempted VBAC were delivered vaginally.[16] Many women who delivered at our center fulfilled eligibility criteria of this study and our provider base was also supportive of planned VBAC.

Ethical approval for the trial was obtained from the Medical Ethics Committee of the University of Malaya Medical Center. This study was performed in compliance with the Declaration of Helsinki. All participants provided written informed consent. The trial ran from September 2007 to November 2008.

Women with one transverse lower segment cesarean scar, a singleton pregnancy, cephalic presentation, intact membranes, and gestational age more than 36 weeks who were agreeable to VBAC and passed specialist assessment for VBAC were approached to participate at their routine antenatal visit. Exclusion criteria were obstetric contraindications to VBAC (eg, placenta previa, suspected macrosomia, suspected cephalopelvic disproportion, abnormal fetal lie, and obstructive pelvic masses).

Guidance data from a previous trial of membrane sweeping in women who planned VBAC was not available for sample size calculation. The spontaneous labor rate in women who underwent a trial of VBAC in our center was 87.5%.[17] A Cochrane review indicates 1 in 8 (12.5%) would not require formal induction of labor if membrane sweeping were performed,[1] hence we estimated a 98% spontaneous labor rate with serial membrane sweeping and with alpha at 0.05 and power at 80%, sample size calculation indicated 95 subjects would be required in each arm. Allowing for a 10% dropout rate, at least 211 women were needed for an adequately powered study.

Investigators recruited participants with the support of other specialist staff to counsel participants on suitability for VBAC. After consent, participants were randomly allocated by the sequential opening of numbered sealed opaque envelopes indicating "Sweep" or "No Sweep." These numbered envelopes were prepared by an author (M.H.) in blocks of 50 using a computer-generated randomization sequence (available online at http://www.random.org/).

Immediately after randomization, women assigned to "sweep" had their cervix stretched and membranes stripped from the lower uterine segment in the manner as previously described.[18] Women assigned to "no sweep" had a gentle vaginal examination for their Bishop score.

Weekly follow-up sessions based at the antenatal clinic with the investigators were arranged to repeat membrane sweeping or vaginal examination until delivery. The Bishop score was recorded at each session. Blinding of participants and delivery providers was effected by a policy of not revealing allocated treatment to them unless requested for an important clinical need. There was no request to unblind during the trial. All participants received standard management by delivery providers.

In our center, induction of labor for prolonged pregnancy is typically offered at 41 weeks of gestation.[19] Induction of labor for diabetes that required drug treatment is offered at 38 weeks and for gestational diabetes adequately controlled by diet, induction of labor is offered at 40 weeks.[20] Upon prelabor rupture of membranes, women were offered either immediate uterine stimulation, typically with oxytocin, or expectant inpatient management for up to 24 hours.[21] All women with a previous cesarean delivery who were offered formal induction of labor were counseled about a higher risk of scar rupture and of unplanned cesarean delivery and the option of a planned repeat cesarean delivery was given.

Our labor ward setup was fully compliant with recent major guidelines[10,22] for the conduct of a trial of labor after cesarean. The labor during planned VBAC was continuously monitored by electronic cardiotocography. Our protocol for planned VBAC permitted

induction of labor with vaginal dinoprostone, augmentation of labor with oxytocin, and no specific time limit for a trial of labor, and the decision on emergency cesarean delivery was made at the discretion of the faculty provider on duty.[16]

The primary outcome was the onset of spontaneous labor. Spontaneous labor was defined as 1) regular painful contractions that resulted in cervical dilation of at least 3 cm of or 2) confirmed prelabor rupture of membranes.[23] Other outcome measures were cesarean delivery, formal induction of labor, recruitment to delivery interval, gestational age at delivery, gestational age at delivery 40 weeks or more and 41 weeks or more, number of membrane sweep or control sessions conducted, Bishop score at each session, unscheduled hospitalization, significant antepartum hemorrhage, prostaglandin and oxytocin use, maternal fever intrapartum and postpartum, blood loss at delivery, duration of hospitalization, epidural analgesia and neonatal outcomes of umbilical artery blood pH, Apgar score at 5 minutes, and birth weight.

Data were entered into statistical software package SPSS 15 (SPSS Inc., Chicago, IL). Analysis was by intention to treat. Normal distribution of continuous data was checked with the one-sample Kolmogorov-Smirnov test. Normally distributed continuous data were analyzed with the Student *t* test. Two-by-two categorical data sets were analyzed with Fisher exact test and larger categorical data sets with the χ^2 test. Ordinal data and nonnormally distributed continuous data were analyzed with the Mann-Whitney *U* test. Kaplan-Meier survival curve analysis was performed to compare recruitment-to-delivery interval (cases that did not result in spontaneous labor were censored) and the Cox-Mantel log rank test was used to analyze the survival distributions. All tests were two-tailed and $P<.05$ was considered significant.

RESULTS

Two hundred thirteen women were recruited: 108 women were randomly assigned to membrane sweeping and 105 to control vaginal examination. Two women (one each from membrane sweeping and control arms) were lost to follow-up, because they did not deliver at our center and attempts to make contact were unsuccessful. This left 211 women for analysis. All participants received their allocated treatment.

The flow of participants through the trial is shown in Figure 1.

Table 1 shows the characteristics of the participants in the two trial arms. Participants in the membrane sweep and control arms were similar ($P>.05$) in their characteristics.

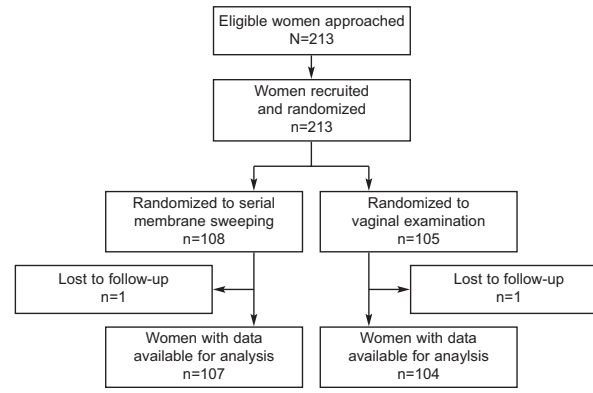

Fig. 1. Trial recruitment flowchart.

Hamdan. Serial Membrane Sweeping in Planned VBAC. Obstet Gynecol 2009.

Table 2 shows the analysis of the primary outcome of spontaneous onset of labor. Spontaneous onset of labor rate was 78.5% compared with 72.1% (relative risk [RR] 1.1, 95% confidence interval [CI] 0.9–1.3); $P=.34$) for membrane sweeping and control arms, respectively; there was no significant difference. The proportion of participants offered induction of labor was 14% compared with 16.3% (RR 0.9, 95% CI 0.5–1.6; $P=.7$) and who took the offer on and underwent induction of labor was 12.1% compared with 9.6% (RR 1.3, 95% CI 0.6–2.8; $P=.66$) for membrane sweeping and control arms, respectively. The overall planned cesarean delivery rate was 9.3% (membrane sweep) compared with 16.3% (control) (RR 0.6, 95% CI 0.3–1.2; $P=.15$). Of the planned cesarean deliveries before onset of spontaneous labor, 23 of 29 (79.3%) were due to maternal preference.

Analyses of secondary outcomes are listed in Table 3. All-cause cesarean delivery rate was not significantly different at 40.2% compared with 44.2% (RR 0.9, 95% CI 0.7–1.2; $P=.58$) for membrane sweeping and control, respectively. The indications for repeat cesarean delivery were similar. Mean (±standard deviation) recruitment-to-delivery interval at 16±8 days compared with 16±7 days ($P=.98$) and mean gestational age at delivery of 39.6±1.0 weeks compared with 39.6±0.9 weeks ($P=.84$) were virtually identical. Bishop score tended to be more favorable at subsequent treatment sessions in the membrane sweeping arm, but the median number of treatment sessions and the presenting cervical dilatation at the birth admission were no different. Epidural analgesia during labor was more commonly used by the membrane sweeping arm (31.8% compared with 19.2% $P=.04$). Frequency of unscheduled hospitalizations, significant antepartum bleeding, dinoprostone

Table 1. Characteristics of 213 Women After One Cesarean Delivery Randomly Allocated to Weekly Membrane Sweeping or Gentle Vaginal Examination

	Membrane Sweep (n=108)	Vaginal Examination (n=105)	*P*
Age (y)	30.7±3.5	31.5±3.9	.11
Gravidity	3 [1]	2 [2]	.68
Parity	1 [1]	1 [1]	.81
Any prior vaginal delivery	36 (33.3)	37 (35.2)	.78
Prior vaginal birth after cesarean	23 (21.3)	23 (21.9)	1.0
Ethnicity			.43
Malay	74 (68.5)	68 (64.8)	
Indian	18 (16.7)	24 (22.9)	
Chinese	13 (12.0)	8 (7.6)	
Others	3 (2.8)	5 (4.8)	
Interval since cesarean (y)	3.5±2.3	3.7±2.6	.62
Gestational age at recruitment (wk)	37.3±0.4	37.3±0.4	.62
Height (cm)	156±6	155±6	.38
Weight at recruitment (kg)	71±12	71±14	.97
Body mass index	29±5	29±5	.92
Bishop score at recruitment	1 [1]	1 [2]	.18
Indication for previous cesarean			.99
Failure to progress	33 (30.6)	32 (30.5)	
Nonreassuring fetal status	33 (30.6)	30 (28.6)	
Malpresentation	25 (23.1)	13 (22.8)	
Others	17 (15.7)	17 (16.2)	

Data are mean±standard deviation for continuous data, median [interquartile range] for ordinal data, and n (%) for categorical data.

Analysis by Student *t* test for continuous data, Mann Whitney *U* test for ordinal data, Fisher exact test for 2×2 categorical data sets, and χ^2 test for larger categorical data sets.

use for induction of labor, oxytocin use in labor, maternal fever, postpartum hemorrhage, and the duration of hospital stay were similar. Neonatal outcomes were also no different. No participant had a uterine rupture.

Kaplan-Meier survival curve analysis of recruitment-to-delivery interval, after censoring cases that did not result in spontaneous labor, showed no difference between the trial arms (Cox-Mantel log rank test, *P*=.82).

Post-hoc analysis stratifying women according to those with and without prior vaginal birth did not show a major difference in their response to serial membrane sweeping with regard to spontaneous onset of labor rate or to all-cause cesarean delivery. In women without prior vaginal births, comparing membrane sweeping with control, spontaneous onset of labor rate was 49 of 71 (69%) compared with 42 of 68 (61.8%) (RR 1.1, 95% CI 0.9–1.4; *P*=.38 and all-cause cesarean delivery rate was 37 of 71 (52.1%) compared with 41 of 68 (60.3%) (RR 0.9, 95% CI 0.6–1.2; *P*=.39). In women with prior vaginal birth, comparing membrane sweeping with control, spontaneous onset of labor was 35 of 36 (97.2%) compared with 33 of 36 (91.7%) (RR 1.1, 95% CI 0.9–1.2; *P*=.61) and all-cause cesarean rate was 6 of 36 (16.7%) compared with 5 of 36 (13.9%) (RR 1.2, 95% CI 0.4–3.6; *P*=1.0). Our post-hoc analysis showed that women with prior vaginal delivery generally had better outcome as expected.[9]

DISCUSSION

Serial membrane sweeping at term in women who planned VBAC did not increase the rate of onset of spontaneous labor or expedite delivery. Our findings are in contrast to the Cochrane meta-analysis of 22 membrane sweeping trials with its conclusion of reduced duration of pregnancy and with RR 0.59 of the pregnancy continuing to beyond 41 weeks with membrane sweeping.[1] Serial membrane sweeping resulted in a nonsignificant RR 1.1 (95% CI 0.9–1.3) for spontaneous onset of labor in our study. Indeed, there were proportionately more pregnancies delivered at or beyond 40 and 41 weeks in the membrane sweeping arm, although these differences were not significant.

The definition of spontaneous onset of labor used in this study included prelabor rupture of membranes.[23] Post-hoc analysis showed a more marked effect of membrane sweeping if the definition of labor was confined to achieving spontaneous regular painful uterine contractions and a cervical dilation of at least 3 cm. Spontaneous onset of labor rate was 75.7% compared with 63.5% (RR 1.2, 95% CI 1.0–1.43; *P*=.07), but this difference was also nonsignificant. Our data suggest that the effect, if any, of serial membrane sweeping to promote onset of labor in women planning VBAC is more modest than demonstrated by the Cochrane meta-analysis, but the trials covered by the Cochrane review typically enrolled low-risk women.[1]

Cesarean delivery rate was also no different, with serial membrane sweeping RR 0.9 (95% CI 0.7–1.2) in our study. The Cochrane meta-analysis[1] similarly did not demonstrate a significant reduction in cesarean delivery rate, with membrane sweeping RR 0.9 (95% CI 0.7–1.15), their relative risk is very similar to ours. Our study was not powered to estimate the

Table 2. Primary Outcome

	Sweep (n=107)	Control (n=104)	RR (95% CI)	*P*
Spontaneous labor*	84 (78.5)	75 (72.1)	1.1 (0.9–1.3)	.34
Contracting and cervix 3 cm or more dilated	81 (75.7)	66 (63.5)		
Prelabor rupture of membranes	3 (2.8)	9 (8.7)		
Not in spontaneous labor	23 (21.5)	29 (27.9)		
Offered indicated† induction of labor	15 (14)	17 (16.3)	0.9 (0.5–1.6)	.70
Accepted	13 (12.1)	10 (9.6)	1.3 (0.6–2.8)	.66
Opted for planned cesarean	2 (1.9)	7 (6.7)		
Planned cesarean‡	8 (7.5)	12 (11.5)		
Overall planned cesarean	10 (9.3)	19 (16.3)	0.6 (0.3–1.2)	.15

RR, relative risk; CI, confidence interval.
Data are n (%) except where otherwise indicated. Analysis by Fisher exact test.
* Spontaneous labor defined as having achieved regular contractions and cervical dilatation of at least 3 cm or confirmed prelabor rupture of membranes regardless of cervical or contraction status.
† Indications for induction of labor: postmature (18 total, 9 in each group), gestational diabetes (8 total, 6 in sweep and two in control group), nonreassuring fetal status (four in control group), pregnancy induced hypertension (one in control group), others (one in control group).
‡ Indications for planned cesarean delivery: (women offered induction of labor for obstetric indications but opted for planned cesarean delivery were excluded from this group) maternal request only (14), nonreassuring fetal status (two), preeclampsia (one), malpresentation (one), others (two).

effect of serial membrane sweeping on cesarean delivery.

We attempted to maintain blinding of the participants by performing vaginal examinations for their Bishop score in the control group. This measure should also eliminate the pure effect of vaginal examination, if any, as opposed to membrane sweeping in promoting onset of labor. Membrane sweeping is more uncomfortable than obtaining the Bishop score,[1,18] and therefore, the degree of blinding within the participants achieved by performing a control vaginal examination is probably incomplete.

The Bishop score was more favorable in the serially membrane swept arm at the second and fourth weekly sessions ($P<.01$ at both these sessions) and borderline at the third session ($P=.06$). It should be noted that the attrition rate was high from weekly session to weekly session as participants were delivered in the interim. The same investigator obtained both the Bishop score and performed the membrane sweeping. This protocol raised the possibility of investigator bias for the Bishop score. Also, because the Bishop score was obtained at the same time as membrane sweeping within a single digital vaginal procedure, there was the potential for the perceived cervical dilation subscore to be inflated by cervical stretching during membrane sweeping.[18] Cervical dilation was no different during the initial vaginal examination at hospitalization for birth when this was assessed by blinded delivery providers. Hence, the finding of more favorable Bishop scores at later treatment sessions in the membrane swept arm should be interpreted with some circumspection.

Epidural analgesia use was significantly higher in women assigned to serial membrane sweeping. There is no clear rationale for this effect because induction of labor rate, cervical dilation at hospitalization for birth, and oxytocin use during labor were similar across both trial arms. Given the multiple secondary outcomes assessed, there is the possibility of a type 1 statistical error with this analysis.

Our study has other limitations. A significant proportion of participants changed their mind about attempting VBAC. Although appropriately selected VBAC is supported by major guidelines,[9,10,22] when faced with the prospect of labor, induction of labor, or uterine stimulation for PROM, 29 of 211 (14%) of our participants opted for repeat cesarean delivery. These dropouts would reduce the power of our study as well as complicate interpretation of the overall repeat cesarean delivery rates. Our trial protocol was pragmatic, and given the diversity of opinion among obstetricians on the role of induction of labor in VBAC,[24] these dropouts were ethically unavoidable, because maternal choice must be given. Our participants are also heterogeneous, comprising lower-risk women with prior vaginal birth as well as women without vaginal birth who were at increased risk of unplanned repeat cesarean and uterine rupture.[9] Given the favorable outcome of planned VBAC in women with prior vaginal birth[9] (this observation was also supported by our post-hoc analysis), inclusion of these lower-risk women may have further reduced power.

Although a significant reduction in cesarean delivery rate in high-risk women without prior vaginal

Table 3. Secondary Outcomes

	Sweep (n=107)	Control (n=104)	RR (95% CI)	*P*
Maternal outcome				
Mode of delivery				.83
Spontaneous vaginal	60 (56.1)	54 (51.9)	1.1 (0.8–1.4)	.58
Instrumental vaginal	4 (3.7)	4 (3.8)		
Cesarean delivery	43 (40.2)	46 (44.2)	0.9 (0.7–1.2)	.58
Indication for cesarean				
Nonreassuring fetal status	15 (34.9)	15 (32.6)		.66
Failure to progress	12 (27.9)	9 (19.6)		
Maternal choice or request	13 (30.2)	16 (34.8)		
Malpresentation	2 (4.7)	2 (4.3)		
Others	1 (2.3)	4 (8.7)		
Number of sweep/control sessions	2 [1]	2 [1]		.75
Bishop score				
Session 2	2 [2] (n=81)	1 [1] (n=87)		<.01
Session 3	2 [2] (n=52)	1 [2] (n=45)		.06
Session 4	3 [1.5] (n=18)	1 [1] (n=11)		<.01
Session 5	3 [0] (n=1)	0 [0] (n=1)		*
Cervical dilation on admission for labor or induction of labor (cm)	2.5±1.9 (n=92)	2.4±1.7 (n=86)		.69
Hospital admission (unscheduled) after randomization	3 (2.8)	2 (1.9)	1.4 (0.2–8.6)	1.0
Reported significant antenatal vaginal bleeding after randomization	3 (2.8)	3 (2.9)	1.0 (0.2–4.7)	1.0
Prostaglandin for labor induction	5 (4.6)	2 (1.9)	2.4 (0.5–12)	.45
Oxytocin for induction or augmentation	14 (13.1)	9 (8.7)	1.5 (0.7–3.3)	.38
Intrapartum fever 38°C or more	2 (2.2) (n=90†)	3 (3.7) (n=82†)	0.6 (0.1–3.5)	.67
Postpartum fever 38°C or more	10 (9.9) (n=101‡)	6 (6.1) (n=99‡)	1.6 (0.6–4.3)	.44
Delivery blood loss (mL)	375±184	346±148		.22
Postpartum hemorrhage (500 mL or more)	21 (21.2) (n=99)	23 (23.5) (n=98)	0.9 (0.5–1.5)	.73
Recruitment to delivery interval (d)	16±8	16±7		.98
Gestational age at delivery (wk)	39.6±1.0	39.6±0.9		.84
Gestational age at delivery 40 wk or more	44 (41.1)	42 (40.4)	1.0 (0.7–1.4)	1.0
Gestational age at delivery 41 wk or more	14 (13.1)	8 (7.7)	1.7 (0.7–3.9)	.26
Duration of hospital stay for birth (d)	2.4±1.9	2.4±1.5		.78
Epidural analgesia in labor	34 (31.8)	19 (19.2)	1.7 (1.1–2.8)	.04
Neonatal outcome				
Birth weight (kg)	3.2±0.4	3.3±0.4		.63
Umbilical cord artery pH at birth	7.31±0.06	7.30±0.06		.35
Umbilical cord artery pH less than 7.1	1 (0)	(0)	§	.49
Apgar score at 5 min	10 [0] (n=100)	10 [0] (n=101)		.31
Apgar score 6 or less at 5 min	0 (0) (n=100)	0 (0) (n=101)	§	§

RR, relative risk; CI, confidence interval.

Data are mean±standard deviation for continuous data, median [interquartile range] for ordinal data, and n (%) for categorical data except where otherwise specified. Analysis by Student *t* test for continuous data, Mann Whitney *U* test for ordinal data, and Fisher exact test for 2×2 categorical data sets.

* No meaningful analysis, because only one patient in each group.

† Intrapartum maternal temperature not recorded in planned cesarean delivery, and some data are missing.

‡ Some data are missing.

§ Relative risk not calculable, because at least one cell with zero value.

birth was not demonstrated, using our post-hoc analysis data for all-cause cesarean delivery rate of 52.1% (membrane sweeping) compared with 60.3% (control), we calculated that a powered study of serial membrane sweeping would require 574 women in each arm.

Serial weekly membrane sweeping at term in women who planned VBAC was not associated with significantly increased spontaneous onset of labor rate or improved secondary outcomes. However, further study of membrane sweeping in high-risk women without prior vaginal birth and planning VBAC may be warranted, because these women are at the highest risk of unplanned repeat cesarean deliveries and uterine rupture in the event of formal induction of labor.

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