Research article

The effectiveness of twice versus once-only membrane sweeping among uncomplicated primi gravidae at 40 weeks of gestation – A randomized controlled trial

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Abstract

Objective

To assess the effectiveness and acceptability of twice versus once-only Artificial Sweeping of Membrane (ASM) among uncomplicated primigravidae at 40 weeks of gestation in a tertiary care hospital in Sri Lanka.

Methods

A randomized controlled trial was performed among 240 uncomplicated primigravidae with ≤5 Modified Bishop's Score (MBS) at 40 weeks of gestation at teaching hospital Kandy from August 2013 to May 2014. Following randomization both groups received ASM at 40 weeks of gestation and the intervention group received a repeat ASM after 48 hours (40 weeks +2 days). The MBS was re-assessed at 40 weeks +5 days. Participants who did not have spontaneous onset of labor (SOL) at 40 weeks +5 days were managed according to the ward policy of cervical ripening and Induction of Labor (IOL). Perceived discomfort, acceptability of the method, neonatal, maternal and labour outcomes were assessed.

Results

More participants in the intervention group established SOL within 48 hours compared to the controls (61.6% vs. 45%, RR=1.37, 95% CI=1.1-1.7, NNT=6). However, the difference of the mean MBS among the participants who had not delivered at 40+5 days, between the two groups was not statistically significant [mean MBS=6.36 (SD=1.94) in intervention group and 6.03 (SD=0.84) in control group; p=0.354].

There was no significant difference among the participants who would recommend either method to another patient (75% in intervention vs 79.1% in control groups, RR=0.94, 95% CI=0.8-1.1) and who would accept either method during a subsequent pregnancy (72.5% in both groups, RR=1, 95% CI=0.9-1.2). Participants who required IOL at 40 weeks +5 days was significantly lower among the intervention group (38.4%; compared to 55% in controls) with RR=0.69 (95% CI=0.5-0.9). There were no significant differences in neonatal, labour outcomes, and maternal complications between the groups.

Conclusions and recommendations

Twice sweeping of membrane reduced the need of IOL and increased progression towards SOL at 40 +5 days. Acceptability of twice sweeping is not different from sweeping once. We recommend twice membranes sweeping as first line management for induction for women at 40 weeks gestation.

Key words: ASM, SOL, induction, acceptability

Sri Lanka Journal of Obstetrics and Gynaecology
2018; **40:** 78-84

DOI: http://doi.org/10.4038/sljog.v40i4.7869

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Received 30 October 2018 and revised version accepted 10 December 2018.

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Competing interest: The authors report no conflict of interest

Introduction

Sweeping of the membranes (SOM) is a simple technique that may positively affect the shift from maintenance of pregnancy to the initiation of labour. This simple procedure has been used for a long time and is useful to prevent post-term pregnancy, though the ideal timing of the procedure is unclear. The aim of SOM is to initiate spontaneous onset of labour (SOL) through a flow of physiological events, which eventually would lead to decreased requirement of formal induction of labour (IOL)[1]. This method can be regarded as a safe, cheap and cost-effective method in the local low-resourced setting, where majority of mothers belong to the lower middle social class and thus are unable to afford expensive methods of induction, needing intense monitoring which require trained skilled human resource. Even though extensive evidence exists on SOM, studies focusing on when and how frequently it should be performed, maximum effectiveness and acceptability of the method is sparse and would be of immense value[2].

The normal gestational age has been shown to be shorter among Asian and African women, compared to European women. The median gestation at delivery following spontaneous labour of an Indian fetus was found to be 39 weeks. Therefore, fetal maturation would occur earlier in Asian and African women[3, 4, 5]. South Asian women have highest perinatal mortality rate at all gestational ages and it is found to be the highest at term[6]. These observations suggest that the complications of post-maturity would occur sooner among the Asians. As a result, considering the timing of induction, it will be more acceptable to opt for it at 40+7 weeks even though in similar European settings it is done at 42 weeks. In addition, local literature was not common on the effectiveness of single versus multiple SOM. Aiming to bridge this knowledge gap, this study was conducted to assess the effectiveness and acceptability of twice versus once only membrane sweeping among uncomplicated prime gravida at 40 weeks of gestational age.

Methods and materials

The study was conducted at the Teaching Hospital Kandy, where approximately 5000 women deliver each year. A single blinded randomized control trial was conducted from August 2013 to May 2014 among Primi gravida mothers with a singleton live fetus at 40 weeks of gestation, whose dates have been confirmed by ultrasound scan. Women with intact fetal membranes, Modified Bishop's score (MBS) ≤5 and cephalic presentation fetuses were selected for the study. Women with grand multiparity, antepartum haemorrhage, pre-labour rupture of membranes, placenta praevia, cephalopelvic disproportion, diagnosed with any medical disorder, had undergone previous caesarean section or having a uterine scar and fetal distress were excluded from the study.

Sample size calculation for the study was based on the findings of Miranda et al. (2006), where multiple sweeping of membranes resulted in SOL among 41% of the intervention group and 23% of the control group; 80% statistical power, at 95% significance level and considering 10% non-response rate. Thus, the calculated sample size was 114 per group. The current study was conducted among 120 participants each in the intervention and control group.

All eligible women were invited to participate in the study and informed written consent was obtained from those who were willing to participate.

Randomization sequence generation

A computer assisted predetermined block randomization sequence was generated.

Randomization, allocation concealment and implementation

According to the randomization sequence, sealed envelopes were prepared to recruit the participants to the respective intervention and control arm of the study. The process of randomization is shown in Figure 1.

Allocation concealment was further assured by an Intern Medical Officer being independently engaged in the recruitment and a Senior Medical Officer in the allocation process.

Blinding

The participants of the study were kept blinded about the objectives of the study.

Intervention

Both experimental and control groups received membrane sweeping at 40 weeks of gestation and only one group (experimental group) received another membrane sweeping after 48 hours (40+2 days). Assessment of MBS at the recruitment and the first

sweeping was performed by the principal investigator (PI) using the standardized method. Sweeping after 48 hrs and measurement of the modified Bishop score at the time of second membrane sweeping was done by a separate equally-trained (as the PI) medical doctor (a senior registrar).

Outcome assessment

Primary outcomes of the study included the assessment of the proportion of mothers that progressed to SOL following SOM and the acceptability of the methods. The MBS was assessed by the PI at 40+5 days who was blinded to both the groups. All mothers in both groups who did not go into labor at 40+5 days were managed according to the unit policy of cervical ripening and labor induction at 40+5 days.

Two different methods were used to assess their perceived pain during the SOM procedure. Initially, the participants were asked to grade the perceived pain during the SOM according to a likert scale, ranging from painless, minimal pain, moderate pain and severe pain. They then evaluated their pain based on the Visual Analog Score (VAS), which is a scale ranging from zero (no pain) to 10 (most severe pain) points (ref). Patient acceptability was evaluated by assessing whether she would recommend either procedure (twice or once only SOM) to another, and by her acceptance of undergoing either procedure during her next pregnancy.

Neonatal outcomes were measured by assessing the Apgar score, antibiotic use during postnatal period and admission to the neonatal intensive care unit. A fever chart for all the study participants was maintained after recruitment by nursing officers. Having a fever of 100.4 °F or more lasting for more than 24 hours was considered as maternal fever. Any bleeding following SOM was recorded. All the outcomes were documented in a data form attached to the maternity record issued at the time of recruitment.

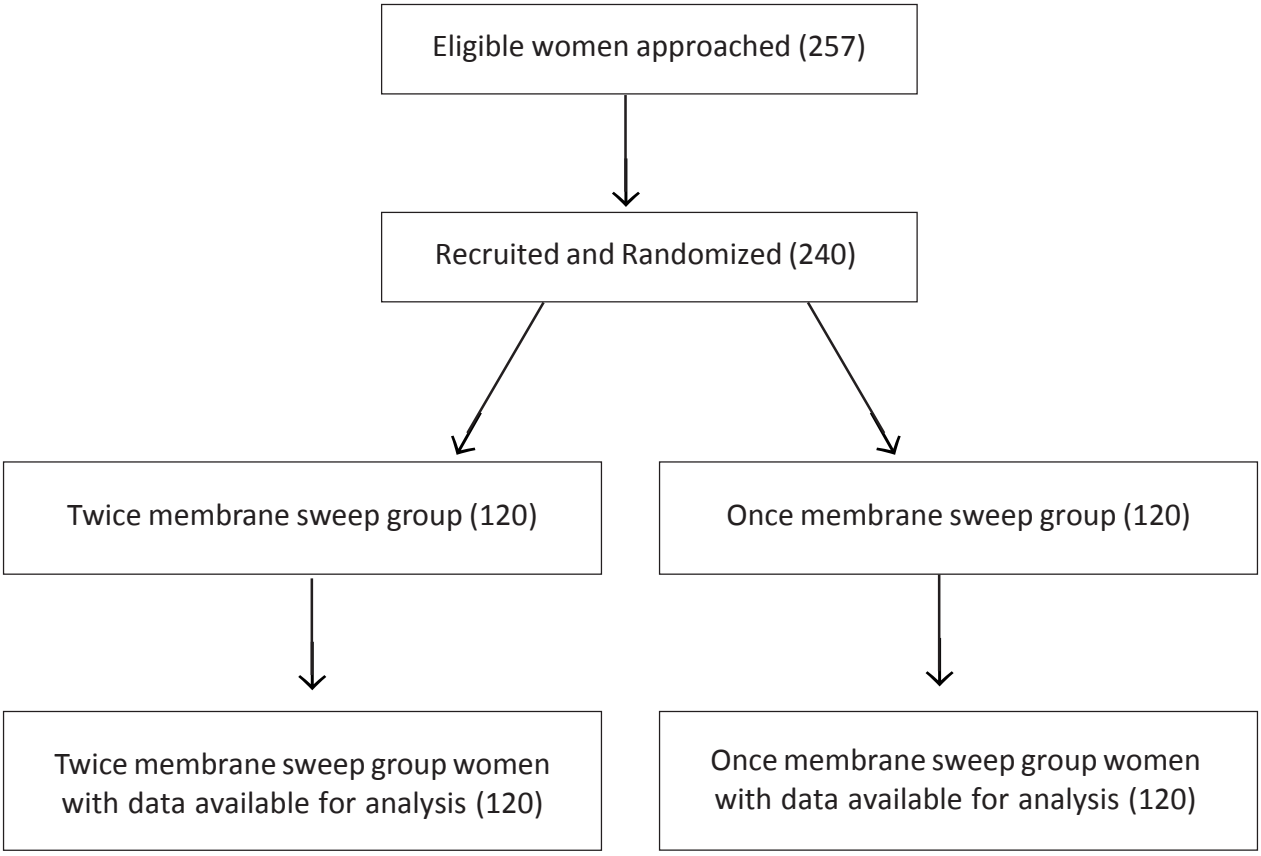

Figure1. **The process of randomization.**

Data analysis

The study was analyzed on the basis of intention-to-treat analysis. Relative risk (95% CI) was calculated as an effect measure. Bivariate analysis included independent t test and Chi Square test accordingly at 0.05 significance level.

Ethical approval for the study was obtained from the Ethical Review Committee of the Kandy Medical Society.

Results

The study was conducted among 240 participants and comparison was made among the participants who underwent a single (control group; n=120) versus twice (experimental group; n=120) SOM. Basic characteristics of the participants in the two trial arms such as age, ethnicity, parity and Bishop Score were similar (p>0.05) at the time of recruitment.

Analyses of primary outcomes are listed in Table 2.

Table 1. Comparison basic characteristics among study and experimental groups

	Twice ASOM	Once ASOM	Significance
Age	25.5 (SD=4.68)	25.71 (SD=4.53)	P=0.76
MBS	≤ 5	≤ 5	P>0.05
Ethnicity:			
Sinhalese	105 (87.5%)	100 (83.4%)	P>0.05
Muslims	11 (9.2%)	13 (10.8%)	
Tamils	04 (3.3%)	7 (5.8%)	

Table 2. Primary outcome of twice vs. single membrane groups

	Twice ASOM (n=120)	Once ASOM (n=120)	Significance
Spontaneous onset of labour	74 (61.6%)	54 (45%)	RR=1.37 95% CI=1.1-1.7, NNT=6 P=.01
Bishop's scores change	31 (67.3%)	38 (57.5%)	X^2=7.7 df=1, P=0.21
MBS at 40 +5 days	6.36 (SD=1.94)	6.03 (SD=0.84)	t=0.93, df=1, P=0.354
Recommending to another	90 (75%)	95 (79. 2%)	RR=0.94, 95% CI=0.8-1.1 P=0.443
Acceptability of ASOM	87 (72.5%)	87 (72.5%)	RR=1, 95% CI=0.9-1.2 P=1

A significant proportion of women in the intervention group progressed to SOL at 40+5 days (61.6%) compared to controls (45%); with RR=1.37 (95% CI=1.1-1.7, p=0.01) and 5.99 (95% CI) Number Needed to Treat (NNT). The Bishop Score was changed in 67.3% of the intervention group and 57.5% of the controls nevertheless, this difference was not statistically significant (X^2=7.7, df=1, p=0.21). There was no statistical difference in the mean MBS among the participants in the two groups at 40+5 days (those who did not experience SOL) (t=0.93, df=1, p=0354) as well.

Considering the acceptability of the ASOM, a higher proportion of participants 79.2% in the control group would recommend ASOM to another compared to the intervention group (75%), although this difference was not significant RR=0.94 (95% CI=0.8-1.1p=0.443). The difference of the proportion of participants accepting ASOM for her subsequent pregnancy among the two groups was not significant as well (p=1.00).

Secondary outcome measures are shown in Table 3. Mean duration from recruitment to the delivery time

Table 3. Secondary outcome of twice Vs single membrane group

	Twice ASOM (n=120)	Once ASOM (n=120)	Significance
Need of formal induction	46 (38.4%)	66 (55%)	RR=0.7 (95% CI 0.5-0.9) P=0.01
Augmentation of labour	48 (40%)	57 (47.5%)	RR=0.8 (95% CI 0.6-1.1) P=0.24
Complain of pain	112 (93.6%)	103 (84.9%)	RR=1.1 (95% CI 1-1.1) P=0.06
Comparison of bleeding	32 (26.7%)	23 (19.2%)	RR=1.39 (95% CI 0.8-2.2) P=0.17
Maternal fever	7 (5.8%)	3 (2.5%)	RR=2.23 (95% CI 0.6-8.8) P=0.1
PROM	16 (13.3%)	11 (9.2%)	RR=1.5 (95% CI 0.7-3.0) P=0.3
NICU admission	11 (9.1%)	10 (8.3%)	RR=1.1 (95% CI 0.5-2.5) P=0.82
Meconium stained liquor	6 (5%)	5 (4.1%)	RR=1.21 (95% CI 0.36-4.1) P=0.76
Neonatal fever	6 (5%)	6 (5%)	RR=1 (95% CI 0.3-3.0) P=1
IV Antibiotics use newborn	6 (5%)	4 (4.1%)	RR=1.5 (95% CI 0.4-5.2) P=0.518
Apgar scores at 5 min < 7	2 (1.7%)	2 (1.7%)	RR=1 (95% CI 0.1-6.9) P=1

in the intervention and control groups were 4.13 (SD=1.17) and 5.0 (SD=1.13) days respectively, which showed no significant difference (p=0.716). In the intervention group, 38.4% required IOL compared to 61.6% in the control group at 40+5 days, and this difference was statistically significant (X^2=6.69, df=1, p=0.01), with a NNT=6. There was no significant difference in the proportion of participants required augmentation of labour at 40+5 days between the groups (p=0.242).

In addition, there were no significant differences in neonatal outcomes between the experimental and control groups.

Of the participants of intervention group, 93.3% had suffered from pain during the SOM compared to 85.8% of controls. However, this difference was not statistically significant (X^2=3.62, df=1, p=0.06). The finding was similar using the VAS (t=0.56, df=1, p=0.574). Twice SOM had no significant effect on bleeding during SOM, and maternal outcomes as well.

Discussion

The current study showed that the twice SOM results in to progression towards SOL resulting in lower requirement of formal IOL compared to once only SOM at 40 weeks of gestation, although the acceptance of either method did not show any statistical significant difference.

Currently available evidence in literature suggest that the efficacy of membrane sweeping is likely to be low at an early gestational age since the major problems are associated beyond 42 weeks of gestation. Therefore, intervention to be usually initiated at 40 weeks. On the other hand, earlier maturation of fetuses is also expected at Asian settings[3,4,5]. Hence, the current study was designed to assess the effectiveness and acceptability of twice versus once-only membrane sweeping among uncomplicated prime gravidae at 40 weeks of gestational age. Most literature are based on studies that compared none versus single or serial SOM. In contrast, twice membrane sweeping to single sweeping was compared in this study. NICE guideline recommendation when and how frequently it should be performed to get maximum effectiveness and acceptability[2].

The current study showed that the occurrence of delivery after 40+5days was substantially low when the membranes were swept twice compared to a single sweeping. This finding was in line with the findings of a study done in Netherland which showed that serial membrane sweeping around 41 weeks of gestation reduces the number of post-term pregnancies (RR=0.57, 95% CI=0.46-0.71, NNT=6)[7]. It further increased natural onset of labour prior to 42 weeks and spontaneous vaginal delivery among parous women[7].

Pain, discomfort and mild vaginal bleeding are expected to be associated with membrane sweeping which can adversely affect its acceptability. According to a study done by Boulvain et al. (2013), approximately 70% of mothers experienced significant discomfort[8], which was similar to the findings of the current study. However, a higher proportion of participants in the current study had perceived pain during the procedure. This difference in the findings could be due to the methodological differences in the studies, as the current study included only primigravidae.

There's no consensus among researchers about the ability of SOM to lower the requirement for formal IOL. A meta-analysis of 14 randomized clinical trials depicted that regular use of striping of membranes at 38 weeks or later does not appear to result in clinically significant benefits[1]. In contrast, our study found that twice SOM reduces the requirement of IOL. However, it is shown that striping membranes for mothers at 41 weeks appear to lower the incidence of induction of labour[9,10,11]. In addition, the findings of the current study and findings of a study done in Hong Kong[12] show that SOM reduces the duration between the recruitment to the delivery.

The sweeping of membranes did not affect intra-partum characteristics like duration of labour and the mode of delivery in previous studies. Similar observations were made in this study as well. Caesarian section rate and instrumental delivery rate were comparable in both groups which were similar to findings with previous studies[7,12].

One concern of membrane sweeping is the possibility of infection, which could cause chorioamnionitis. But none of the patients in the present study had clinical features suggestive of chorioamnionitis. It was observed that the occurrence of prelabour rupture of membranes among the two groups in the current study was comparable and this is in agreement with many other on sweeping[7,8,12].

It was also shown in the current study that the SOM would not adversely affect the neonatal outcomes, which is similar to the findings of other studies[7,12].

Thus, there was no substantial evidence that striping of membranes exaggerates the risk of maternal or neonatal adverse outcomes in the current study. This study showed that maternal or neonatal outcome were comparable in twice and single membrane sweeping. Membrane sweeping is a safe intervention with regard to the risk of premature ruptured membranes, peri partum infection and vaginal bleeding. However, a substantial number of mothers experienced discomfort during this procedure.

Conclusion and recommendation

Multiple membrane sweeping can be considered as a reasonable option in a term mother as it has been proven to be a safe procedure which does not increase the risk of maternal or neonatal adverse outcomes even though a substantial number of women reported discomfort during this procedure. Twice SOM was effective to reduce the need of formal IOL and increase the chances of progressing towards SOL at 40+5days.

However, majority of the women were willing to accept this as a method of induction during next pregnancy and for recommending the method to others as well. Therefore, this study recommends multiple membrane sweeping to be used as the first option for women reaching 40 weeks of pregnancy. Also, further studies using different frequencies of SOM at different recruitment intervals are recommended. Furthermore, multicenter studies utilizing larger samples are recommended.

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