

# Comparison of cervical massage with membrane sweeping for pre-induction cervical ripening at term; a randomized controlled trial

S S Yaddehige<sup>a</sup>, H D Kalansooriya<sup>b</sup>, M F M Rameez<sup>c</sup>

## Abstract

**Introduction:** Membrane sweeping is a common method of pre induction cervical ripening. However, this may not be possible if the cervical os is closed. Cervical massage has been proposed as an alternative under these circumstances. Whilst there are a large number of clinical trials which endorse the effectiveness of membrane sweeping, the effectiveness of cervical massage in comparison with membrane sweeping has not been researched.

**Objective:** To compare the effectiveness of cervical massage as a ripening method in post dated pregnancies prior to induction of labour against membrane sweep in tertiary care hospital in Sri Lanka.

**Methods:** A total of 165 singleton low risk pregnancies at 40 weeks +4 days gestation between August 2013 and May 2014 were included in the study. All these women were assessed to have Modified Bishop Score (MBS) less than 4. These women were randomly assigned to either undergo cervical massage, membrane sweeping or neither of these procedures as the control group. The favorability of the cervix was measured by a change in the MBS 48 hours after the intervention. Complications such as rupture of membrane, intrapartum infection, postpartum infection and neonatal morbidity were also assessed.

**Results:** There were no significant differences in the mean age and MBS at recruitment in the primigravidae and multigravidae, between the three study groups. There was a significant increase in the mean MBS after intervention in the cervical massage group (in primigravidae 6.4, 95% CI 4.8-8.0, in multigravidae 7.2, 95% CI 6.1-8.4) and membrane sweeping groups (in both primigravidae and multigravidae 7.6, 95% CI 6.2-9.0) compared to control group (in primigravidae 5.3, 95% CI 4.0-6.5, in multigravidae 4.8, 95% CI 3.8-5.8. Hence the change in the MBS post intervention was significant in both primigravidae and multigravidae. Adverse effects and neonatal morbidity were similar in all three groups with the exception of cardiotocographic abnormalities which were reported more often in the control group.

**Conclusion:** Cervical massage and membrane sweeping showed significant effect on improvement of the MBS at term as pre induction cervical ripening method. The complication rates with cervical massage are comparable to membrane sweeping. Cervical massage is hence an effective and safe alternative to membrane sweeping when the latter cannot be performed owing to a closed cervical os.

**Key words:** cervical massage, membrane sweeping, modified bishop score

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<sup>a</sup> Registrar in Obstetrics and Gynaecology in Bedford Hospital NHS Trust, United Kingdom.

<sup>b</sup> Consultant Obstetrician and Gynaecologist, Teaching Hospital Mahamodara, Sri Lanka.

<sup>c</sup> Senior Lecturer in Obstetrics and Gynaecology, Faculty of Medicine, University of Ruhuna, Sri Lanka.

Correspondence: SSY, e-mail: <[samanthayaddehige@yahoo.com](mailto:samanthayaddehige@yahoo.com)>

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 <https://orcid.org/0000-0001-5112-1206>

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## Introduction

Induction of labour is the artificial initiation of labour before its spontaneous onset, to deliver the foeto-placental unit. The frequency of induction varies from one region to another and from one institution to another. On average, approximately 10% of all deliveries result from induction of labour, ranging from 1.4% in Niger to 35.5% in Sri Lanka<sup>1,2</sup>. It is a well proven recommendation that the cervical ripening methods should be used before induction of labour, if the MBS is less than 6. Among all the non-pharmacologic methods, only the mechanical methods have proven efficacy for cervical ripening or induction of labour<sup>3,4</sup>.

Membrane sweeping is a simple method to promote cervical ripening and is widely practised all over the world. The ideal timing of membrane sweeping to ensure effectiveness is still unclear<sup>5</sup>. Membrane sweeping leads to an increase in prostaglandin metabolites such as PGF<sub>2α</sub> and phospholipase A<sub>2</sub> in the cervix locally. A similar increase is also seen in the maternal circulation. These prostaglandin metabolites mediate cervical ripening. This may also lead to the onset of spontaneous labour<sup>6,7</sup>.

The improvement in MBS of the cervix subsequent to membrane sweeping reduces the need for oxytocic agents in the induction of labour. However, membrane sweeping may be associated with pain and discomfort, vaginal bleeding, prelabour rupture of membranes and ascending infection<sup>3,4</sup>. Membrane sweeping may not be possible when the cervical os is closed as the examining finger cannot be admitted into the cervix. The National Institute of Health and Care Excellence in the United Kingdom (NICE) recommend cervical massage as an alternative in this situation<sup>4</sup>.

Although membrane sweeping and cervical massage has been in practice, the effectiveness of cervical massage has, thus far, not been compared to the better established practice of membrane sweeping. A number of studies on membrane sweeping have mentioned cervical massage as an alternative however the effectiveness of cervical massage has not been compared with membrane sweeping<sup>8,9</sup>. This trial compares the effectiveness of cervical massage with cervical membrane sweeping as regards its effectiveness. As a secondary objective, the study also compares the

maternal and neonatal morbidity associated with the two procedures.

## Materials and methods

This was a single blinded randomized controlled trial. The trial was conducted in Teaching Hospital Mahamodara, Galle, Sri Lanka, from the 01 August 2013 to the 03 May 2014. Ethical approval was obtained from the Committee of Ethical Review, Faculty of Medicine, University of Ruhuna, Sri Lanka. The study was registered in the Clinical Trial Registry Sri Lanka under Registration No: SLCTR/2014/001<sup>10</sup>.

The study included women with low risk singleton pregnancies with an MBS of less than or equal to 4 at 40+4 weeks gestation whose dates were confirmed with an ultrasound scan. Mothers with medical or obstetric complications including multiple pregnancies, previous cesarean deliveries, fetal growth restriction, and any contraindication to vaginal delivery were excluded from the study. Informed written consent was obtained from participants who met the inclusion criteria and agreed to participate in the trial.

A total of 165 participants were recruited consecutively during this study period and randomized into three groups. The three groups included Group I (cervical massage), Group II (membrane sweep), and Group III (control). The control group had neither of these procedures prior to induction of labour.

Based on the study by Boulvain (1999)<sup>20</sup> where the efficacy for cervical ripening or induction of labour (positive outcome) in the control group was about 25%. Increase in this proportion to 50% would be of clinical importance in both intervention groups. Therefore size of difference of clinical importance would be 25%; 80% statistical power at 95% significance level. Thus the total sample size was 165 (55 in each of the treatments and control groups) will be sufficient to detect a clinically important difference of 25% between groups.

Randomization was carried out by stratified randomization using a random number table. Serially numbered opaque envelopes were made up by an investigator who had no involvement in the clinical interventions during the study. The process of randomization to analysis is shown in Figure 1.

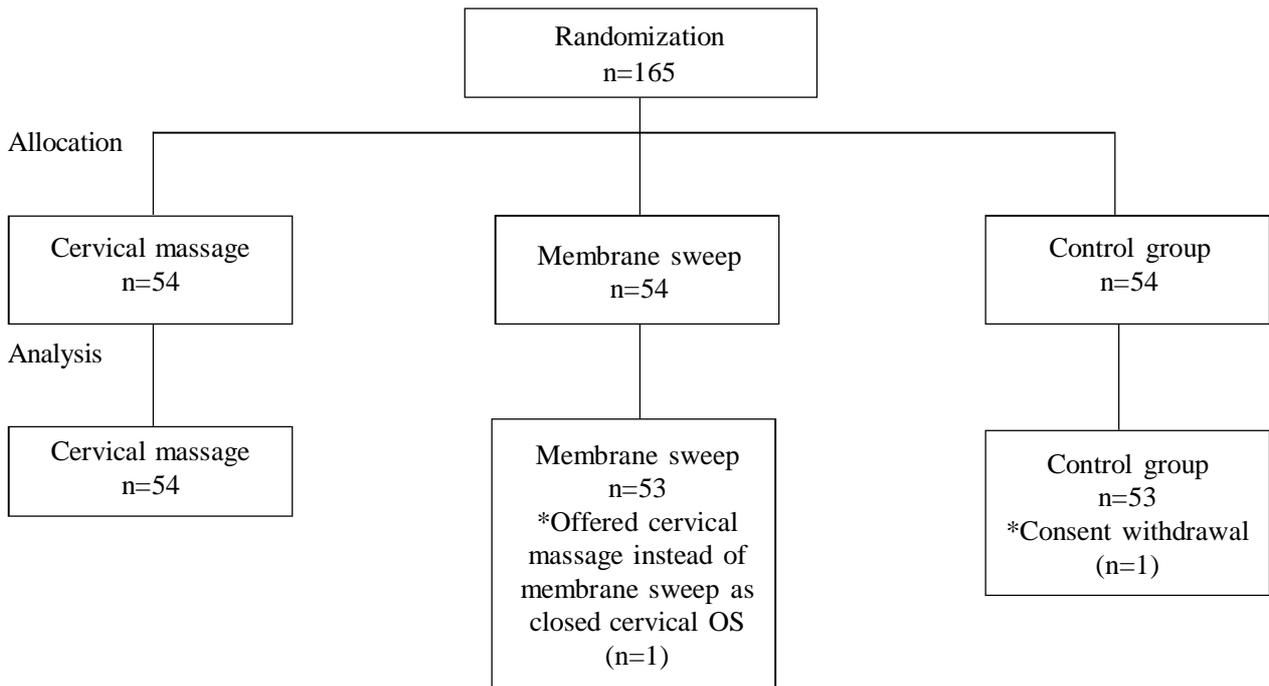


Figure 1. Flow diagram of the study participant.

The initial intervention (membrane sweeping or cervical massage) was carried out by the first investigator who was not blinded. While women randomized to the control group had no intervention performed, those randomized to cervical massage underwent the procedure using a technique described in a previous study as pushing and massaging movement around the vaginal fornices for 15 seconds<sup>5</sup>. Membrane sweeping was performed as per standard technique is duly randomized women. Aseptic technique was adhered to during all interventions. Fetal wellbeing was monitored in accordance with the unit’s standard protocol.

Forty-eight hours after the intervention, a second investigator who was blinded to the intervention performed a cervical assessment and recorded the MBS. The second investigator also determined the subsequent intervention required to induce labour as per the standard protocol of the unit. Spontaneous onset of labour was defined as mothers who established labour before 48 hours of the first intervention.

Basic demographic characteristics, mean MBS, the occurrence of fever and birth weight in each of the

three groups, were described as mean and 95% confidence interval and compared using ANOVA. Other maternal and neonatal outcomes such as mode of delivery, prelabour rupture of membrane, cardio-tocograph abnormalities, premature babies unit (PBU) admission and neonatal intensive care unit admission were presented in proportions and compared using the chi-square test.

### Results

A total of 165 participants were recruited to the study. Two participants were excluded from the analysis. One participant selected for the membrane sweeping group underwent cervical massage instead of membrane sweeping owing to a closed cervical os. One participant withdrew consent after randomization into the control group. Therefore, fifty-five participants were randomized to the cervical massage group, 54 to the membrane sweeping group and 54 to the control group. There was no significant difference in the distribution of basic demographic characteristics such as age and MBS at recruitment, among the three groups in primigravidae and multigravidae (Table 1).

**Table 1. Population demographics at baseline (n=163)**

	Cervical massage	Membrane sweeping	Control	<i>p</i> Value
<b>Primigravidae</b>	n=28	n =28	n=28	
Age in years:				
Range	20 - 35	19 - 34	17 - 32	0.19
Mean	25.93	23.82	24.89	
95% CI	24.06 - 27.80	22.35 - 25.29	23.30 - 26.56	
MBS at recruitment				
Mean	2.8	3.18	3.04	0.40
95% CI	2.51 - 3.20	2.83 - 3.53	2.69 - 3.22	
<b>Multigravidae</b>	n=27	n=26	n=26	
Age in years:				
Range	24 - 35	23 - 39	24 - 39	0.95
Mean	30.41	30.08	30.31	
95% CI	29.12 - 31.69	28.36 - 31.79	28.60 - 32.01	
MBS at recruitment				
Mean	2.89	3.31	3.27	0.30
95% CI	2.66 - 3.12	3.06 - 3.56	2.98 - 3.30	

MBS – Modified Bishops Score

95% CI – 95% Confidence Interval

Although numerically more participants in the cervical massage and membrane sweeping appeared to have established spontaneous onset of labour within 48 hours of intervention than in control group. Percentages are more in primigravidae than in the multigravidae. However, the difference is not statistically significant (primigravidae;  $p=0.22$  and multigravida;  $p=0.78$ ). Table 2 shows outcomes within 48 hours of intervention.

Analyses of primary outcomes after 48 hours of interventions were listed in Table 3. Mean MBS after

48 hours of intervention were compared with the control group and showed a significant change in the MBS in the primigravidae (Group1; 6.4, Group 2; 7.3, Group 3; 5.3,  $p=0.04$ ) and multigravidae (group1; 7.2, Group 2; 7.6, Group; 4.8,  $p=0.003$ ). Considering the favourability for induction of labour, higher proportion of participants in both group 1 and group 2 were in both primigravidae and multigravidae were favourable for induction of labour. However this difference was not statistically significant in primigravidae group ( $p=0.07$ ) and in multigravidae the difference was significant ( $p=0.022$ ).

**Table 2. Outcomes within 48 hours of intervention**

	Cervical massage	Membrane sweeping	Control	<i>p</i> Value
<b>Primigravidae</b>	n=28	n=28	n=28	
Spontaneous onset of labour (%)	12 (42.9)	10 (35.7)	6 (21.4)	0.22
<b>Multigravidae</b>	n=27	n=26	n=26	
Spontaneous onset of labour (%)	7 (26.9)	8 (30.76)	6 (22.2)	0.78
NNT	8	9		

NNT – Number Needed To Treat

**Table 3. Bishop Score after 48 hours  
(n=114, excluding mothers who established spontaneous labour)**

	Cervical massage	Membrane sweeping	Control	<i>p</i> Value
<b>Primigravidae</b>	n=18	n=18	n=22	
Mean MBS (95% CI)	6.4 (4.8-8.0)	7.6 (6.2-9.0)	5.3 (4.0-6.5)	0.04
Cervix favourable for induction (%)	7 (43.7)	13 (72.2)	9 (40.9)	0.07
<b>Multigravidae</b>	n=21	n=18	n=19	
Mean MBS (95% CI)	7.2 (6.1-8.4)	7.6 (6.2-9.0)	4.8 (3.8-5.8)	0.003
Cervix favourable for induction (%)	14 (66.7)	14 (77.8)	4 (21)	0.022

MBS – Modified Bishops Score

Cervix favourable for induction – MBS >7

Comparison of mean MBS after 48 hours of intervention were compared in the Table 4. The mean Modified Bishop Score after 48 hours of intervention showed a statistically significant difference between primigravidae and multigravidae in Group 1 and 2. There was no significant difference in the improvement achieved in the MBS in either the cervical massage or the membrane sweep groups.

Secondary outcome measures are shown in Table 5. There was a statistically significant increase in the number of participants requiring PGE2 for cervical

ripening among multigravidae (p=0.01) in the control group (24.1%) as compared to the intervention groups (6.9% in each). However, there was no difference among primigravidae (p=0.14). Statistically significant higher number of Cardiotocogram (CTG) abnormalities were noted among participants in the control group (8/28) than in both intervention groups in primigravidae (p=0.01). This difference was not significant in multigravidae (p=0.4). There was a significant difference in the proportion of development of pyrexia in labour or PROM in participants in both primigravidae and multigravidae.

In addition, there were no significant differences in neonatal outcomes between intervention groups in control group in two arms.

**Table 4. Comparisons of mean MBS after 48 hours of intervention in each group**

	SEM	95% CI	<i>p</i> Value
<b>Primigravidae</b>			
Group 1 vs Group 2	0.99	-3.23 - 0.76	0.2
Group 1 vs Group 3	0.95	-0.81 - 3.0	0.02
Group 2 vs Group 3	0.92	0.4 - 4.1	0.01
<b>Multigravidae</b>			
Group1 vs Group 2	0.80	-1.93 - 1.30	0.6
Group 1 vs Group 3	0.79	0.80 - 3.8	0.004
Group 2 vs Group 3	0.82	1.06 - 4.37	0.002

SEM – Standard error of mean

**Table 5. Secondary outcome measures in each group**

	Cervical massage	Membrane sweeping	Control	<i>p</i> Value
<b>Primigravidae</b>				
	28	28	28	
Need of vaginal PGE <sub>2</sub> (%)	9 (16.1)	4 (7.1)	11 (19.6)	0.14
Intra partum fever (%)	2 (2.4)	3 (3.6)	1 (1.2)	0.58
Postpartum fever (%)	2 (2.4)	3 (3.6)	2 (2.4)	0.85
CTG abnormalities (%)	1 (1.2)	2 (2.4)	8 (9.5)	0.01
PROM (%)	3 (3.6)	5 (6.0)	2 (2.4)	0.45
Apgar score < 7 in 5 minute	0	1 (1.2)	1 (1.2)	0.59
NICU/PBU admission	1 (1.2)	1 (1.2)	2 (2.4)	0.76
<b>Multigravidae</b>				
	27	26	26	0.68
Need for vaginal PGE <sub>2</sub> (%)	4 (6.9)	4 (6.9)	14 (24.1)	0.01
Intra partum fever (%)	1 (1.3)	1 (1.3)	2 (2.5)	0.75
Postpartum fever (%)	1 (1.3)	2 (2.5)	1 (1.3)	0.76
CTG abnormalities (%)	2 (2.5)	4 (5.1)	5 (6.3)	0.4
PROM (%)	4 (5.1)	4 (5.1)	2 (2.5)	0.64
Apgar score < 7 in 5 minute	0	0	2 (2.5)	0.12
NICU/PBU admission	1 (1.3)	2 (2.5)	1 (1.3)	0.75

CTG – Cardiotocogram. PROM – Prelabour ruptures of membrane. NICU – Neonatal intensive care unit. PBU – Premature birth unit. PGE<sub>2</sub> – Prostaglandin E<sub>2</sub>.

## Discussion

The current study showed that cervical massage is as effective as membrane sweeping, in achieving cervical ripening for induction of labour at term in both primigravidae and multigravidae, although spontaneous onset of labour following intervention did not show any statistically significant difference. This finding is probably due to the fact that sample size is inadequate and duration of cervical massage was not adequate to detect the true difference in the current study. The objective of the study was to achieve the adequate ripening of cervix to enable induction with currently practised method of artificial rupture of membrane and start of oxytocin infusion. Therefore since the authors had no prior experience in the use of cervical massage for ripening of the cervix and lack of evidence of the duration of cervical massage, 15 seconds of massage duration was used in this preliminary study.

The observation that the change in mean MBS after 48 hours of cervical massage and membrane sweep was statistically significant when compared with the control group. Further mean MBS after 48 hours of cervical massage was not significantly different from that of membrane sweep, indicates that both interventions are effective for pre induction cervical ripening. The current study showed mean MBS after 48 hours of intervention in both intervention groups were above the recommended level for induction of labour. This will provide the opportunity to consider cervical massage as alternative to membrane sweep when the cervical os is closed. This finding was in line with the study conducted in Switzerland, Michel Boulvain et al have shown that the proportion of women requiring induction of labour following membrane sweep as opposed to no intervention was lower (49% vs 60%)<sup>11,12</sup>. Similar study done in United States of America by Kathleen Putuam et al in 2011 showed different findings from those already published as well as findings to our study. However in their study few women who needed cervical massage instead of membrane sweeping showed similar outcomes to the membrane sweeping group<sup>13</sup>.

Proportion of participants requiring prostaglandin for induction of labour was higher in the control group as compared to either of the intervention groups. This reached statistical significance among the multigravidae. Allott HA et al in 1993 noted similar findings in their study where 8% of women undergoing membrane sweeping required prostaglandins as opposed to 18.8% in the control group<sup>14</sup>.

There was a slight increase in the occurrence of prelabour rupture of membrane (PROM) in the women who underwent membrane sweep (6%) as compared to the cervical massage (3.6%) and the control group (2.4%). This difference was not demonstrated among the multigravidae. Intrapartum and postpartum fever was also not significantly different in the various groups. This finding is in keeping with other studies in literature<sup>8,17,18,19</sup>.

It was also shown in the current study that cervical massage and membrane sweep would not adversely affect the neonatal outcomes. This is in keeping with other studies in literature<sup>17,18,19</sup>.

Thus, there was no substantial evidence that cervical massage exaggerates the maternal or neonatal adverse outcomes in the current study. Therefore this study showed maternal and neonatal outcomes were comparable in cervical massage and membrane sweeping. Thus cervical massage is a safe intervention with regards to risk of infection, prelabour rupture of membrane. However, the acceptability of the participants was not assessed in this study.

## Conclusions and recommendations

Cervical massage can be considered as a reasonable option for pre induction cervical ripening at term mothers as an alternative to membrane sweeping especially when the cervical os is closed and the latter is not possible.

The authors recommend a larger multicenter trial based on the outcome of this trial to further explore the above findings.

## Limitations

The standard technique for cervical massage is not defined in the literature and the 15 second interval to perform cervical massage in this trial was chosen arbitrarily. A longer duration of massage may, however, lead to more effective outcomes and needs to be explored in further studies.

Seeking references from literature for this paper was a challenge as there are very few trials exploring cervical massage and indeed none comparing cervical massage with membrane sweep.

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## Authors' contributions

SSY was the principal author and conceived the topic for this manuscript and both HDK and MFMR have done the review. All authors have critically revised and approved the final version of the manuscript.

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