Membrane sweeping prior to Induction of Labor: A Randomized Controlled Trial

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Abstract: Objective: to evaluate the effect of single membrane sweep at the commencement of labor induction on the induction-delivery interval and mode of delivery. **Patients and methods:** This randomized controlled prospective trial was conduct at Ain-Shams Maternity Hospital, Cairo, Egypt. The included women were recruited from women attending labor ward who were suited for labor induction. The included patients were randomized into one of two groups: Group 1 (study group): included 238 women who were subjected to membrane sweeping at initiation of labor induction. The control group included 234 women who were subjected to labor induction without any membrane sweeping. Labor induction was carried out by introduction of 50µg of misoprostol vaginal tablets in the posterior vaginal fornix. A 10 cm visual analog score (VAS) was obtained from the women immediately after initiation of labor induction. As soon as possible after delivery, another VAS was evaluated from the women to judge their perception of the birth process before their hospital discharge. The main outcome measures of our study were induction to delivery interval and mode of delivery. **Results:** A total of 472 women were finally analyzed. There was a statistically highly significant reduction in the mean induction to delivery interval among women of group 1 (number=194) compared to women of group 2 (number 157) [11.6±4.1 hours versus 17.2± 5.1 hours respectively, $P < 0.01$). Also, there was a statistically significant reduction in both cesarean delivery and operative vaginal delivery rates in group 1 when compared to group 2 [(44/238(18.5%) versus 77/234(32.9%), $P< 0.01$ and (2 /238(0.8%) versus 5/234(2.1%), $P< 0.01$, respectively]. A higher prevalence of spontaneous vaginal delivery was observed among women of group 1 when compared to women of group 2 (192 /238(80.7%) versus 152/234 (65%), $P< 0.01$, respectively]. **Conclusion:** Membrane sweeping at initiation of labor induction reduces the induction to delivery interval, decreases the rate of cesarean delivery and reduces the duration of oxytocin infusion and the dose of prostaglandins needed for induction. Although the procedure is associated with some discomfort, swept women expressed much more overall satisfaction of the birth process.

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1. Introduction

An induction of labor in women with an unfavorable cervix can lead to a failed induction in over 50% of all women [1]. One of the methods used to ripen an unripe cervix is membrane sweeping [1]. A number of investigations have looked at the benefits of cervical ripening by serial membrane sweeping in women with an unfavorable cervix [1]. Membrane sweeping is simple and quick methods which requires no equipment and probably needs only to be done at the commencement of formal labor induction. It contributes to release of endogenous prostaglandins [2]. Cochrane Reviews of membrane sweeping for induction of labor found that sweeping was associated with a reduction in interval to delivery time duration, a reduction in the frequency of post-term pregnancy, and a reduction in the necessity of other methods of labor induction. These reviews concluded that the use of membrane sweeping showed no differences in the risk for maternal or neonatal outcomes between control and membrane-swept groups [3]. Investigators reported no significant complication of the membrane sweeping and the method is found to be a safe procedure in terms of risk of prelabor ruptured of membranes, peripartum infection, and vaginal bleeding. Although, a large number of women found that this method caused significant embarrassment, swept women authenticated higher satisfaction with the birth process [2, 4]. As membrane sweeping is painful and prostaglandins release after sweeping lasts for at least 6 hours, repeat sweeping may not be important in labor induction where additional interventions are programmed within 6 hours [5].

As many trials have focused on the role of membrane sweeping as a sole method to induce labor, but only few ones investigated its role as an adjunctive prior to formal labor induction, the aim of the current study was to evaluate the effect of single membrane sweep at the commencement of labor induction on the induction-delivery interval and mode of delivery.

2. Patients and methods

This randomized controlled prospective trial was conduct at Ain-Shams Maternity Hospital, Cairo,

Egypt. Recruitment took place during the period from July 2009 to March 2010. The protocol of this study was approved by the hospital committee on human investigations on July 2009. An informed written consent has been obtained from all participants before recruitment in the study, and after explaining the aim and the procedures of the study and possible hazards. The included women were recruited from women attending labor ward who were suite for labor induction. The included patients were randomized into one of two groups: Group 1 (study group): included 238 women who were subjected to membrane sweeping at initiation of labor induction. The control group included 234 women who were subjected to labor induction without any membrane sweeping. Randomization was done by the use of sealed opaque envelopes. Pregnant women with a singleton living fetus, 37 weeks gestation or above calculated from a reliable last menstrual period, with cephalic presentation and intact membranes were recruited when they admitted to the delivery ward for labor induction. Previous uterine scar, intrauterine fetal death, known gross fetal anomalies, undiagnosed vaginal bleeding and/ or any contraindication of vaginal delivery were the exclusion criteria.

History taking, general examination and registration of the demographic data were done. . Women in both groups were examined at the morning of induction and the Bishop score was evaluated and recorded. Only those with Bishop ≤ 4 and required preinduction cervical ripening with prostaglandins were recruited in this study.

Women in group 1 had their cervix swept by introducing the examining finger as high as achievable past the internal cervical os and the membranes were swept off the lower pole of the uterus by a complete circular sweep of the finger, on one occasion clockwise and once anticlockwise. This was followed promptly by introduction of 50µg of misoprostol vaginal tablets in the posterior vaginal fornix. Women in group 2 had 50µg Misoprostol vaginal tablets in the posterior vaginal fornix without sweeping. For women in group 1, membrane sweeping was performed only at the initiation of labor induction, even if the induction process was continuing. Women allocated to group 2 did not have any sweeping in concomitance with labor induction.

A 10 cm visual analog score (VAS) was obtained from the women immediately after initiation of labor induction. A scaled ruler from 0 to 10 was given to all women and were asked to point by her finger on the number represents the pain after notifying them that 0 represents no pain and 10 represents intolerable sever pain. Bishop Score and uterine contractions were reassessed 4 hours later. Further dose of misoprostol 25µg or amniotomy may be performed, according to cervical dilatation and uterine contractions. Four hours later, reassessment was performed and if the cervix prevailed unfavorable, a final dose of misoprostol 25µg will be inserted vaginally. No further doses of misoprostol to be used after the 3rd dose. Again, reassessment was performed 4 hours later, women with unfavorable cervices and with non demanding indications was usually rested overnight and the process imitated the following morning. After amniotomy for labor induction, oxytocin was usually begun within 2 hours if contractions were inefficient. The beginning of labor induction was taken as time of insertion of the first dose of misoprostol. Once in established labor, (regular contractions and cervical dilatation ≥ 3 cm), vaginal assessment was usually done every 4 hours; unless otherwise indicated. Oxytocin was started for labor augmentation when labor progress fell below the action line in the partogram. As soon as possible after delivery, another VAS was evaluated from the women to judge their perception of the birth process before their hospital discharges. The scale ranged from 0 to 10, with 0 delineating very satisfied to 10 delineating very dissatisfied. This was also performed as the VAS for pain.

Outcome measures

The main outcome measures of our study were induction to delivery interval and mode of delivery. Other measures include; dose of prostaglandins used for induction, duration of oxytocin infusion, V.A.S results just after initiation of induction and after the delivery. Neonatal outcome measures included: meconium staining, Apgar score at 5 minutes and neonatal intensive care unit (NICU) admission.

Sample size justification

Based on an earlier study of *Tan et al.* which reported a significant increase in spontaneous vaginal delivery rates from 56% to 69% with sweeping, and a significant reduction in the induction to delivery interval (mean 14 hours compared with 19 hours), we calculated our sample size using the program STATA 10 [2]. Assuming a power of 80% and a level of significance of 5%, two hundreds thirty two women were needed in each group for an appropriately powered randomized study on the effect of membrane sweeping in conjunction with labor induction. The results were analyzed after having recruited 478 women in total.

Statistical methodology

Statistical analysis was performed using Microsoft Excel version 2010 and Statistical Package for Social Sciences (SPSS) for Windows version 15.0. Data was described as mean and standard deviation (SD) (for numeric parametric variables), or number and percentage (for categorical

variables). Difference between two independent groups was estimated using independent student's t-test (for numeric parametric variables), or chi-squared (for categorical variables). Significance level was set at 0.05.

3.Results

A total of 472 women were finally analyzed. Included women were randomly divided into 2 groups: group 1 [study group]: (n =238) and group 2 [control group] (n=234). The flow of women through the study is shown in figure 1. There were no statistically significant differences between women of both groups as regards age, body mass index (BMI), initial Bishop Score, parity, gestational age and different causes for labor induction (tables1,2).

There was a statistically significant reduction in both cesarean delivery and operative vaginal delivery rates in group 1 when compared to group 2 [(44/238(18.5%) versus 77/234(32.9%), $P< 0.01$ and (2 /238(0.8%) versus 5/234(2.1%), $P < 0.01$, respectively]. There was a statistically highly significant reduction in the mean induction to delivery interval among women of group 1 (number=194) compared to women of group 2 (number 157) [11.6±4.1 hours versus 17.2± 5.1 hours respectively, $P < 0.01$). A higher prevalence of spontaneous vaginal delivery was observed among women of group 1 when compared to women of group 2 (192 /238(80.7%) versus 152/234 (65%), $P < 0.01$, respectively].

There was a statistically highly significant reduction in the duration of oxytocin infusion in group 1 compared to the group 2 [(2.5±1.2 hours versus 3.3±1.6 hours respectively, ($P < 0.01$)]. The dose of misoprostol required for induction in the study group was statistically significant less than that needed in the control group [(72.6±28.3 µg versus 91.6±63.3 µg respectively, ($P < 0.01$)]. The VAS of pain immediately after sweeping was statistically significant higher in group 1 compared to group 2 [(3.4±1.1versus 1.9±0.8 respectively, ($P < 0.01$)]. Nevertheless, the VAS of birth process satisfaction obtained from the women to judge their perception of the birth process before their hospital discharges was statistically significant higher in group 1 compared to group 2 [(2.9±2.1versus 5±2.3 respectively, ($P < 0.01$)]. There was no statistically significant difference between both groups as regards indication of cesarean section (Table3). The current study found no significant difference between group 1 and group 2 regarding fetal outcomes (Table 4). The reduction of mean induction to delivery interval and mean duration of oxytocin infusion were statistically significant among nulliparas cases compared to nulliparas controls ($P < 0.01$). The mean dose of total misoprostol also significantly reduced among nulliparas cases compared to nulliparas controls ($P < 0.05$) (Table5). In the subgroup of multiparas, the mean induction to delivery interval and mean dose of misoprostol required for induction was significantly reduced compared to those of controls ($P < 0.05$), while, the reduction in the mean duration of oxytocin infusion among multiparas cases was statistically insignificant ($P > 0.05$) (Table 6). Data analysis in the subgroup of nulliparas also showed statistically significant reduction in cesarean delivery and operative vaginal delivery rates and a statistically significant higher percentage of spontaneous vaginal delivery rate ($P < 0.05$). There was a reduction in the mean rate of cesarean delivery and operative vaginal delivery in the subgroup of multiparas cases compared to controls. But this reduction was statistically insignificant ($P > 0.05$).

4.Discussion

The current study authenticated that, there was no statistically significant difference between both groups as regarding demographic characteristics (Table 1). This agreed with the studies of other investigators [2; 6; 7; 8].

All women included in this study had a Bishop score less than or equal 4. In other study, each group was subdivided to women with Bishop Score less than or equal 4, and others more than or equal 5 [2]. We have chosen this restriction to increase the homogeneity of the study group.

The current study involved 1 sweep at initiation of labor induction; this agreed with other studies [2; 6; 7].While other studies applied repeated sweeping until established labor [8]. Induction of labor was started immediately after sweeping in the women of group 1or after initial examination without sweeping in women of group 2, using vaginal prostaglandins. Vaginal prostaglandin was the universal method of induction in the current study.

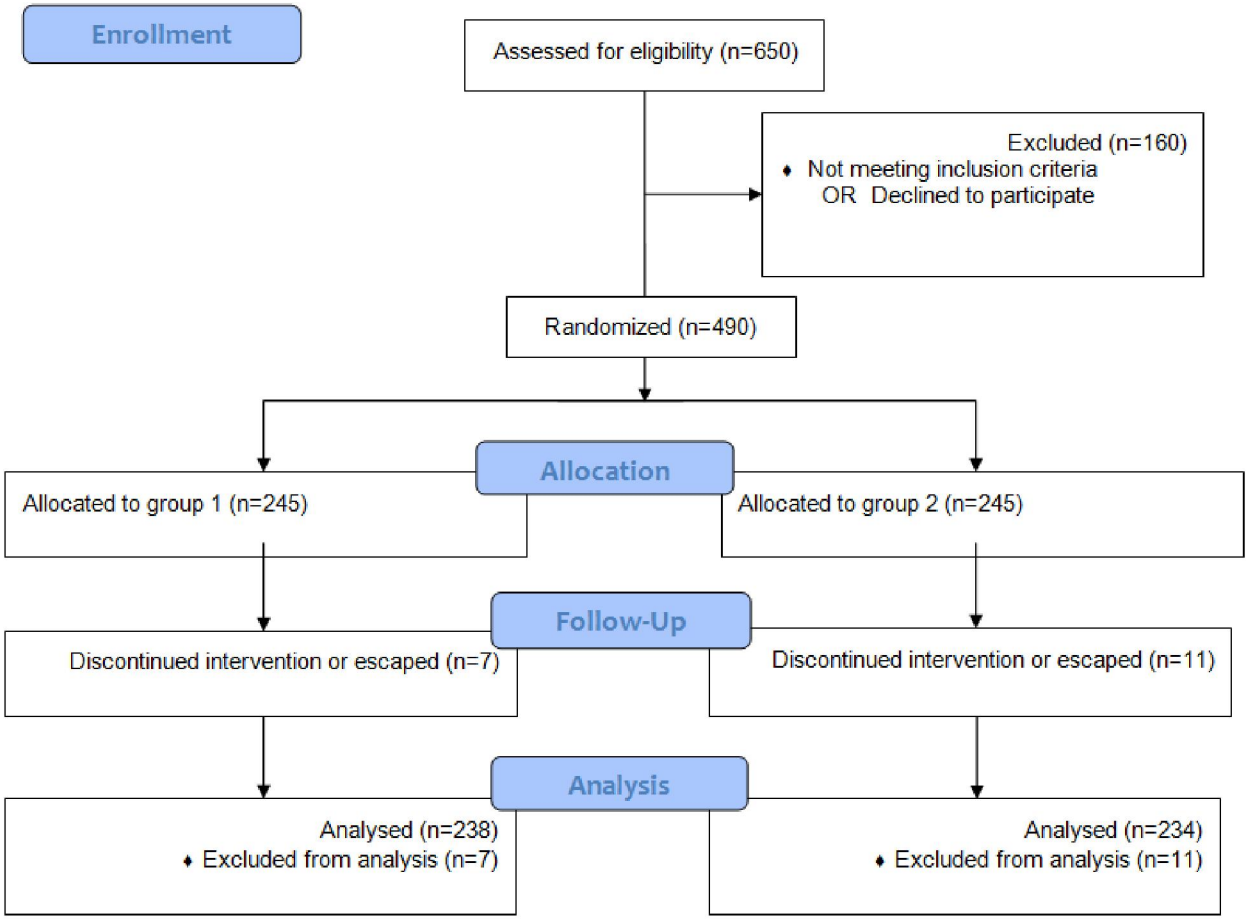

Figure 1: CONSORT FLOW DIAGRAM OF THE CURRENT STUDY.

Table (1): Comparison between group 1 and group 2 regarding the mean age, body mass index (BMI), parity, initial Bishop Score and gestational age.

	Group 1 (number=238) Mean SD	Group 2 (number=234) Mean SD	*P*¥
Age (years)	25.7 4.9	25.5 4.8	0.6
Body mass index (kg/m^2)	27.8 2.7	27.8 2.6	0.7
Bishop score	2.4 0.8	2.3 0.8	0.2
Parity	1.0 1.3	1.0 1.2	0.9
Gestational age (weeks)	40.8 1.2	40.6 1.4	0.1

SD: Standard deviation
¥Analysis using student's t-test.

Table (2): Comparison between group 1 and group 2 regarding the causes of labor induction¥.

	Group 1 (number=238) Number (%)	Group 2 (number=234) Number (%)	*P* value¥
Postdate	135 56.7	116 49.6	0.1
Decreased Kicks with non-reassuring CTG	37 15.5	40 17.1	0.7
Oligohydramnios	30 12.6	20 8.5	0.17
Preeclampsia	12 5.0	21 9.0	0.1
Other indications	24 10.1	37 15.8	0.07

CTG: Cardiotocography ¥Analysis using chi square test.

Table (3): Comparison between group 1 and group 2 regarding indications of cesarean section (CS).

Indication of CS	Group 1 Number=44 Number (%)	Group 2 Number=44 Number (%)	P value¥
Fetal distress	15 34.1	26 33.8	
Failed induction	25 56.8	44 57.1	0.1
Other causes	4 9	7 9.1	

¥Analysis using chi square test.

Table (4): Comparison between cases and controls as regards neonatal outcomes

	Group 1 Number=238	Group 2 Number=234	*P* value
Positive meconium staining¥.	236 (99.2%)	230 (98.3%)	0.3π
NICU admission¥.	43 18.1	41 17.5	0.8π
APGAR score Ω	8.6±0.5	8.5±0.7	0.1©

Data presented as number (%) ¥. or mean± Standard deviation Ω
NICU: Neonatal intensive care unit. π Analysis using chi square test. ©Analysis using student's t-test.

Table (5): Comparison between nulliparas cases and controls as regards the mean time of induction to delivery, mean dose of misoprostol and the mean infusion time of Oxytocin.

	Cases Number=117 Mean SD	Controls Number=116 Mean SD	*P* value¥
Induction to delivery (hours)	13.4 4.3	19.9 4.8	0.000
Misoprostol dose (µg)	83.9 25.0	104.0 85.7	0.01
Time of oxytocin infusion (hours)	2.4 1.4	3.9 1.2	0.000

SD: Standard deviation ¥Analysis using student's t-test.

Table (6): Comparison between multiparas cases and controls as regards the mean time of induction to delivery, mean dose of misoprostol and the mean infusion time of Oxytocin.

	Cases Number=121 Mean SD	Controls Number=118 Mean SD	*P* value¥
Induction to delivery (hours)	10.0 3.2	15.4 4.4	0.000
Misoprostol dose (µg)	61.7 27.0	79.4 21.8	0.000
Time of oxytocin infusion (hours)	2.73 0.9	2.95 1.8	0.2

SD: Standard deviation ¥Analysis using student's t-test.

This agreed with other study where only Cerviprime gel (dinoprostone prostaglandin) was used for induction [6]. While in other studies, prostaglandins were not the only method used for induction; amniotomy with oxytocin infusion was also used as a method for induction of labor in some women [2;7;8]. This also adds to the homogeneity of the study group and improves the reliability of the current study. The additive beneficial effect of membrane sweeping with vaginal prostaglandin has been demonstrated by *Doane and McCarty,* who showed that this combined approach reduced post-term pregnancies and antenatal visits [9]. The current study concluded that membrane sweeping statistically significant reduced the mean induction to delivery interval from 17.2 hours in group 2 to 11.6 hours in group 1. Secondary analysis based on subgroups of nulliparas and multiparas also showed statistically significant reduction in the mean induction to delivery interval in both nulliparas (13.4 hours in group 1[cases] versus 19.9 hours in group 2 [controls]) and multiparas (10.00 hours in group 1 versus 15.4 hours in group 2). *Fogsi,* reported that sweeping of membranes statistically significantly reduced the mean induction to delivery interval between women in group 2 and women in group 1 (9.80 hours versus 18.88 hours in primigravidas and 8.33 versus 15.19 in multiparas) [6]. This agreed with *Tan et al.* study which reported that sweeping of membranes statistically significantly reduced the

mean induction to delivery interval between the two groups; which was 14 hours in cases versus 19 hours in controls. In the subgroup of nulliparas; the mean induction to delivery interval was 19 hours in cases versus 26 hours in controls. While in multiparas; 9 hours in cases versus 11 hours in controls [2]. *Foong et al.* reported that the benefits of membrane sweeping appeared to be limited to nulliparas with unfavorable cervices who needed cervical priming with prostaglandins. These cases reported a shorter mean induction-labor interval than controls (13.6 versus 17.3 hours) [8]. The study of *Day et al.* showed that there was a trend toward shorter induction-to-delivery interval in cases than controls (18.7 hours versus 19.9 hours) [7]. The trend of shorter induction was more pronounced when comparing only women who delivered vaginally (15.5hours versus 17.4 hours). However, these trends were not statistically significant. In the current study, swept women had higher spontaneous vaginal delivery rate (80.7% compared with 65% in controls). The difference was statistically significant. This was also concluded in the subgroup of nulliparas (76.1% compared with 53.4%). There were a higher percentage of vaginal deliveries among multiparas cases compared with controls; but the difference was not statistically significant statistically. This disagrees with the study of *Fogsi* at which the difference was only statistically significant in multiparas (100% of swept multiparas had vaginal delivery compared with 50% in controls) [6]. This also disagrees with *Day et al* which reported no differences between cases and controls in mode of delivery [7]. This may be attributed to geographic and racial differences. *Tan et al.* found that Swept women had higher spontaneous vaginal delivery rate (69% compared with 56% in controls) [2]. This agreed with the current study. Swept women in the study of *Foong et al.* also had a statistically significant greater likelihood of better delivery outcome (vaginal delivery 83.3% versus 58.2%). This benefit was restricted to nulliparas [8]. Statistically significant benefit was demonstrated in oxytocin infusion duration in the current study. The duration of oxytocin infusion in cases was 2.5 hours compared with 3.3 hours in controls. In the subgroup of nulliparas the reduction of oxytocin infusion was statistically significant too (2.4 hours in cases versus 3.9 hours in controls). In multiparas, the reduction in the duration of oxytocin infusion was not statistically significant (2.73 hours versus 2.95 hours). This benefit was demonstrated by *Tan et al. (*2.6 hours compared with 4.3 hours) [2]. In nulliparas; *Tan et al.* reported a statistically significant difference between swept and non swept women as regarding oxytocin infusion (3.7 hours versus 6.1 hours). However, the difference was no longer statistically significant in multiparas (1.4hours versus 2.2 hours). This agreed with *other* study where the reduction of total oxytocin dose was limited to nulliparas (mean maximum dose 6.8 mU/minute versus 10.35 mU/minute) [8]. *Day et al.* reported no statistically significant difference between swept and non swept women as regarding total oxytocin usage [7]. Swept women in the current study required less mean dose of prostaglandins than controls (72.6µg of misoprostol; compared with 91.6µg) and this was statistically significant. *Tan et al.* reported that swept women also required less dose of prostaglandins (mean 1.2mg of dinoprostone compared with 1.3mg); but the reduction in prostaglandin dose was not statistically significant. However, this was statistically significant in the subgroup of multiparas (0.9 versus 1.1). Swept women in the current study expressed higher satisfaction with the birth process (VAS mean was 2.9 compared with 5 in controls) and this was statistically significant, even though sweeping was initially more painful; as the post sweeping VAS for pain was statistically significant increased (mean 3.4 compared with 1.9 in controls). The finding that sweeping is painful has been shown in other study (VAS for pain was 4.7 in cases compared with 3.5 in controls), also this study reported a statistically significant improvement of VAS for birth process satisfaction (mean 4.0 compared with 4.7) [2]. These results agreed with the current study. *De Miranda* reported that even among the women who described sweeping as painful; 88% of them reported that they would choose membrane sweeping again in the next pregnancy [10]. *Wong et al.* found that although membrane sweeping is safe, the majority of women felt uncomfortable during the procedure. However, this transient discomfort during the procedure was not reflected on their overall satisfaction of the labor process. This implies that the membrane sweeping is an accepted procedure to the patients. The compliance is not an issue against this procedure [11]. The current study reported that, there was no statistically significant difference between cases and controls as regarding neonatal outcomes. Other investigators showed similar neonatal outcomes [2; 8].

Conclusion

Membrane sweeping at initiation of labor induction reduces the induction to delivery interval, decreases the rate of cesarean delivery and reduces the duration of oxytocin infusion and the dose of prostaglandins needed for induction. Although the procedure is associated with some discomfort, swept women expressed much more satisfaction of the birth process.

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