OBJECTIVE: To estimate if membrane sweeping increases the rate of prelabor rupture of membranes.

METHODS: This randomized trial of term, uncomplicated pregnancies included 300 patients. Patients were randomly assigned into sweep or no-sweep groups, with patients and delivering providers blinded to group allocation. Only the examining provider in the clinic was unblinded to group allocation. Membranes were then swept or not swept at each weekly visit from 38 weeks of gestation onward, depending on the randomization. Data collected included parity, cervix examination at each visit, estimated gestational age at delivery, rupture of membranes, and maternal or fetal complications.

RESULTS: A total of 162 patients were randomly assigned to the membrane sweep group and 138 to the no-sweep group. There was no difference in baseline characteristics or obstetric and neonatal outcomes between the groups. The average gestational age at delivery and induction rate were not different. The overall prelabor rupture of membranes rate was not significantly higher in the membrane sweep group (12% compared with 7%) \((P=.19)\); however, patients with a cervix more than 1 cm dilated at time of membrane sweeping were more likely to have prelabor rupture of membranes if they were in the membrane sweep group (9.1% compared with 0%; relative risk 1.10, 95% confidence interval 1.03–1.18).

CONCLUSION: No benefit in gestational age at delivery or reduction of postmaturity occurred from membrane sweeping. Although the overall prelabor rupture of membranes rates were similar, patients with membrane sweeping occurring at more than 1 cm cervical dilation may be at increased risk of prelabor rupture of membranes.


LEVEL OF EVIDENCE: I

Membrane sweeping or stripping is a common practice in routine obstetrics for term pregnancies. The primary aim of membrane sweeping is to decrease the number of pregnancies which remain undelivered at 42 weeks (postmaturity), thereby decreasing the need for labor induction.\(^1\)\(^-\)\(^7\) This intervention has been shown to increase intracervical phospholipase A2 activity and plasma 13,14-dihydro-15-keto-prostaglandin F2\(_\alpha\), with a corresponding rise in contractions 3 hours after the intervention. These changes may stimulate labor.\(^8\)\(^,\)\(^9\) The reported side effects of membrane sweeping are increased maternal discomfort, mild bleeding, and irregular uterine contractions.\(^3\)\(^,\)\(^4\) Multiple studies have established membrane sweeping as a safe practice that does not increase maternal or fetal morbidity or mortality;\(^1\)\(^,\)\(^2\) however, no studies have evaluated prelabor rupture of membranes as a primary outcome. Prelabor rupture of membranes is most commonly defined as rupture of membranes before the onset of labor and...
occurs in 8% of term pregnancies. Since the introduction of membrane sweeping as a routine practice at Tripler Army Medical Center, we have anecdotally noted an apparent increase in prelabor rupture of membranes. It may be that the reduction in postmature pregnancies with membrane sweeping is in part due to an increase in prelabor rupture of membranes with subsequent labor induction.

A recent prospective trial found no increase in prelabor rupture of membranes, although assessment of prelabor rupture of membranes as an outcome variable was not added until midway through the study. A meta-analysis of membrane sweeping found 10 publications that analyzed prelabor rupture of membranes as a secondary outcome, although none of these studies sought to analyze prelabor rupture of membranes in their objectives. The meta-analysis found a relative risk for prelabor rupture of membranes of 1.14, but the finding was not statistically significant. The largest study included in the meta-analysis did find a significantly increased risk of prelabor rupture of membranes. The studies in the meta-analysis vary greatly in their incidence of prelabor rupture of membranes, ranging from 2–39% in the membrane sweeping groups and 2–26% in the control groups. This wide variation, the fact that these studies were not primarily designed to compare prelabor rupture of membranes rates, and the reported general population 8–10% prelabor rupture of membranes rate suggests limitations in the ability of this meta-analysis to detect a difference in prelabor rupture of membranes rates.

A Cochrane review of membrane sweeping suggests that this procedure provides little clinical benefit. If this intervention has minimal clinical benefit, it is important to evaluate all potential risks associated with it. Our aim was to address whether routine membrane sweeping increases prelabor rupture of membranes in a randomized controlled trial.

MATERIALS AND METHODS
We carried out a blinded, randomized controlled trial at Tripler Army Medical Center in Honolulu, Hawaii between March 2006 and May 2007. Patients with uncomplicated pregnancies were approached for enrollment in the study between 30–37 weeks of gestation. All patients had confirmation of gestational age by first-trimester crown rump length or mid-second-trimester biometry assessment. Additional inclusion criteria were singleton pregnancy, cephalic presentation, and anticipated vaginal delivery. Exclusion criteria fell into three main categories: indications for labor induction, indications for cesarean delivery, and contraindications to membrane sweeping. These included multiple gestation, placenta previa, placental abruption, pregestational or gestational diabetes, chronic or gestational hypertension, preeclampsia, any pregnancy with an indication for induction other than impending postmaturity, any pregnancy for which a cesarean delivery was planned, history of preterm delivery, history of vasa previa, active cervical infection, third-trimester vaginal bleeding, mülleri-an anomalies, severe fetal anomalies, and active genital herpes infection.

Upon obtaining written informed consent, patients were entered into a computer-generated randomizer program. Participants were randomly assigned to receive either weekly membrane sweeping or no membrane sweeping for the duration of the pregnancy after 38 0/7 weeks gestational age (Fig. 1). Several steps were taken to insure that participants, researchers, and providers were blinded to group allocation. Participants were not informed as to the group allocation. It was understood that many patients would realize which intervention they were receiving, but we felt that not informing the patients of their group allocation would increase the quality of the blinding process. Prior studies have shown membrane sweeping to be associated with increased maternal discomfort, mild bleeding, and irregular uterine contractions. It was recognized that not informing the patients of group allocation is not fully equivalent to patient blinding because full blinding is not possible in this type of study. Each patient was identified by a computer-generated sequential number that was placed in her chart. Upon seeing a patient who was enrolled in the trial during a routine prenatal appointment, the clinician would enter the participant number into a Web-based program that would tell the provider whether to sweep or not to sweep the membranes. These data were not included in the patient chart. A computer log was kept of all access through the program to the patient identifier to ensure no one but the clinician seeing the patient for routine obstetric appointments accessed her group assignment. Providers who admitted the patient to the labor and delivery unit were also blinded to the patient’s group allocation. The same restrictions were placed on the authors of this article until the end of the trial and the completion of all data collection. All data were collected and all chart analysis was done by the primary author, who was also blinded to the group allocations. Unblinding did not occur until the time of data analysis.

The trial was conducted in a teaching hospital setting. Clinical providers included resident physi-
cians, attending staff physicians, nurse practitioners, and certified nurse midwives. If a participant was assigned to the sweep arm of the trial, she received a cervix examination at every visit from 38 weeks of gestation until delivery. If the cervix was dilated, the provider swept a finger in a 360-degree fashion inside the cervix, thereby separating the lower uterine segment from the amniotic sac. If the cervix was closed, it was massaged as described by prior authors. If the participant was assigned to the no-sweep arm, a weekly cervix examination was performed from 38 weeks of gestation until delivery. Special effort was made on this examination not to stretch or manipulate the cervix. Data on cervical dilation, effacement, and fetal station were recorded at each visit from 38 weeks of gestation until delivery. Patients are assigned a single provider at our institution, and most patients had the same providers for the majority of their visits. When the patient’s assigned provider was unavailable, an alternative provider performed the examination.

Upon admission to labor and delivery, data were collected on the indication for admission, induction, estimated gestational age at delivery, prelabor rupture of membranes, cervical examination, and Bishop’s score. Subsequently, data were collected on labor outcomes, route of delivery, pregnancy complications, neonatal complications, group B streptococci status, and neonatal intensive care unit admissions. Prelabor rupture of membranes as an indication for admission was confirmed by Nitrazine Paper (Bristol-Myers Squibb, Princeton, NJ) testing, ferning test, and speculum examination. Prelabor rupture of membranes was defined as confirmation of ruptured membranes without contractions or contractions more than 10 minutes apart at the time of membrane rupture. If prelabor rupture of membranes occurred just before the patient presenting to the labor unit, the assessment of contraction frequency was made by tocodynamometer. If prelabor rupture of membranes occurred before the patient presenting to the labor unit, the assessment of contraction frequency was based on the patient’s subjective assessment of her contractions at the time of membrane rupture. Patients who did not enter labor or who had an indication for induction before 41 weeks of gestation had induction of labor during the 41st week.

Numerous prespecified analyses were performed on differences in demographics, obstetric outcomes, obstetric complications, and prelabor rupture of membranes rates. A post-hoc analysis was performed
to examine the effect of cervical dilation on prelabor rupture of membranes rates in the sweep and no-sweep groups. This subgroup analysis was performed comparing those with a cervical examination 1 cm or less dilation in the two groups and those with a cervical examination more than 1 cm dilation in the two groups at the clinic visit preceding admission to labor and delivery.

Data were analyzed on an intent-to-treat basis. Power analysis was based on data from a meta-analysis. We calculated a total of 300 patients (150 in each arm) required at an alpha error of 0.05 for an 80% chance of showing a 15% difference in prelabor rupture of membranes between the sweep and no-sweep arms. Parametric analyses were performed with a Student t test and nonparametric analyses were performed with a Mann-Whitney rank sum test. Normality of data were determined with a Shapiro-Wilk test. A Kruskal-Wallis one-way analysis of variance was used for multiple means comparisons. Differences in outcome rates were analyzed with a χ² or two-tailed Fisher exact test where appropriate. Relative risk and 95% confidence intervals were calculated where appropriate. All data were reported as means with their associated standard deviations. Data analysis was performed with SPSS software (SPSS Inc., Chicago, IL). The study protocol was approved by the human use committee at Tripler Army Medical Center, Honolulu, Hawaii.

RESULTS

Three hundred patients were enrolled in the trial between March 2006 and May 2007. During the study period, a total of 3,341 patients delivered at our facility. Thus, our study group represented 9% of our total patient population. No enrolled patients were subsequently found to be ineligible for the study. Seventeen patients in the no-sweep group and seventeen patients in the sweep group delivered after group allocation but before 38 weeks of gestation. Three patients in the no-sweep arm insisted upon having their cervices swept and their request was honored. No patients in the sweep group refused membrane sweeping. Patients who delivered before 38 weeks or insisted upon membrane sweeping were analyzed on an intent-to-treat basis.

The baseline characteristics of the groups were similar (Table 1). There were similar numbers of multiparous and nulliparous patients in each group. Racial demographics were similar between the groups. Both groups had a 25% group B streptococci (GBS) carrier status. Baseline cervical exams were also similar between the two groups. The sweep group

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Sweep Group (n=138)</th>
<th>Sweep Group (n=162)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age (y)</td>
<td>25.6±5.1</td>
<td>25.7±4.9</td>
<td>.72</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>62 (45)</td>
<td>79 (49)</td>
<td>.76</td>
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<tr>
<td>Parity</td>
<td>0.8±0.9</td>
<td>0.9±1.1</td>
<td>.86</td>
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<tr>
<td>GBS positive</td>
<td>35 (25)</td>
<td>41 (25)</td>
<td>1</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>.86</td>
</tr>
<tr>
<td>White</td>
<td>81 (59)</td>
<td>102 (63)</td>
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<tr>
<td>Pacific Islander</td>
<td>19 (14)</td>
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<td>African American</td>
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<td>19 (12)</td>
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</tr>
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<td>Hispanic</td>
<td>12 (9)</td>
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<td>Asian</td>
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<td>7 (4)</td>
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</tr>
<tr>
<td>Native American</td>
<td>2 (1)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (2)</td>
<td>6 (4)</td>
<td></td>
</tr>
<tr>
<td>Initial cervical dilatation (38 wk) (cm)</td>
<td>1.4±1.2</td>
<td>1.5±1.1</td>
<td>.41</td>
</tr>
</tbody>
</table>

GBS, group B streptococci.
Data are mean±standard deviation or n (%).

mean initial cervical examination on entry into the study (38 weeks of gestation) was 1.5 cm dilation, 44% effacement, and −2.9 station. The no-sweep group cervical examination was similar, with means of 1.4 cm dilation, 40% effacement, and −3.4 station. Twenty-five (15%) patients in the sweep group had cervical massage performed at least once, due to cervical dilation inadequate to sweep. Seventeen (10%) of these patients had cervical massage performed more than once. There were no cases of prelabor rupture of membranes in the week after a cervical massage examination (25 patients undergoing a total of 49 cervical massages).

There was no difference in prelabor rupture of membranes rates between the two groups (Table 2). Prelabor rupture of membranes occurred in 10 of 138 (7%) of patients in the no-sweep group and 19 of 162 (12%) of patients in the sweep group (P=.19). Prelabor rupture of membranes occurrences in both groups were clustered in the 39th and 40th weeks (78% in the sweep group and 60% in the no-sweep group). All patients who were diagnosed with prelabor rupture of membranes required oxytocin induction of labor. Four patients (2.9%) in the no-sweep group and four patients (2.4%) in the sweep group had prelabor rupture of membranes after randomization but before intervention. When all patients who delivered after randomization but before intervention were excluded from analysis, the prelabor rupture of membranes rate was 15 of 145 (10.3%) in the sweep group and 6 of 121 (5.0%) in the no-sweep group (P=.10).
When subgroups were analyzed based upon their cervical examination at the clinic visit before admission to labor and delivery, no differences in prelabor rupture of membranes occurred in the groups with 1 cm or less dilation. However, those who were more than 1 cm dilated were more likely to have prelabor rupture of membranes if they were in the membrane sweeping group. In this subgroup, membrane sweeping was associated with a 9.1% prelabor rupture of membranes rate compared with a 0% prelabor rupture of membranes rate in the no-sweep group (relative risk 1.10, 95% confidence interval 1.03–1.18).

There was no difference between the groups when other obstetric outcomes were compared. This included vaginal delivery rates, cesarean delivery rates, spontaneous labor, spontaneous rupture of membranes, labor induction, chorioamnionitis, endometritis, postmaturity, neonatal intensive care unit admission, and neonatal infection (Table 2). No difference was noted between the two groups for induction rate (32% compared with 25%; \( P = .15 \)). Chorioamnionitis rates were similar in GBS-negative patients between sweep and no-sweep groups (5% compared with 6%) and in GBS-positive patients between the groups (7% compared with 0%; \( P = .24 \)).

There were 14 impending postmature inductions in the two groups during the 41st week. For scheduling reasons, five pregnancies progressed to the 42nd week of gestation. There was no difference in postmaturity or impending postmature inductions between the two groups. The mean and median delivery dates were similar between the groups (Table 2). When the percentage of patients remaining pregnant at each day after 38 weeks was compared between the two groups, no advantage of early delivery was seen by membrane sweeping (Fig. 2). The mean time from study entry (38 weeks of gestation) until delivery was 11 days in both groups (\( P = 1 \)). The median time from study entry to delivery was 11 days in the no-sweep group and 12 days in the sweep group (\( P = .76 \)).

**DISCUSSION**

We performed a randomized controlled trial to evaluate the effect of membrane sweeping on prelabor...
rupture of membranes. Membrane sweeping did not result in an increase in prelabor rupture of membranes. The actual difference in prelabor rupture of membranes rates was 5% between the sweep and no-sweep groups, whereas our study was powered to evaluate for a 15% or greater difference. We performed a subgroup analysis of the effect of membrane sweeping on prelabor rupture of membranes based upon cervical dilation at the time of examination. Patients who were more than 1 cm dilated at their examination before admission were significantly more likely to have prelabor rupture of membranes if they underwent membrane sweeping (P < .05). Prelabor rupture of membranes rates were similar between the groups in the patients 0–1 cm dilated. It may be that a cervix 0–1 cm dilated is difficult to sweep adequately, and therefore an increase in prelabor rupture of membranes would not be seen in this group. If a difference in prelabor rupture of membranes does exist between sweep and no-sweep groups, it would most likely be seen in those patients who have the most appropriate cervical examination for adequate membrane sweeping, namely those who are more than 1 cm dilated at the time of examination.

Our study was undertaken to answer the question of whether membrane sweeping increases prelabor rupture of membranes. The rationale for performing membrane sweeping has been to reduce the number of postmature inductions. If postmature inductions are decreased at the cost of more inductions for prelabor rupture of membranes, this would defeat the ostensible benefit of the procedure. Because membrane sweeping can be uncomfortable for patients and takes additional clinical time to perform, if no clear clinical benefit is obtained, then the use of the procedure itself can be called into question. No previous study has been designed to primarily determine prelabor rupture of membranes rates. Among previous studies, definitions of prelabor rupture of membranes are either not given or not consistent with each other, and reported prelabor rupture of membranes rates have varied from 3% to 39%. Our overall finding that membrane sweeping does not increase prelabor rupture of membranes is consistent with the majority of published data.1–6,7,11,14 Goldenberg et al12 reported an increase in prelabor rupture of membranes from membrane sweeping; however, their rate of prelabor rupture of membranes in the sweep group was 39%, whereas ours was only 12%. This large discrepancy suggests a difference in the clinical diagnosis of prelabor rupture of membranes between the two studies. We are not aware of any studies which have evaluated the risk of prelabor rupture of membranes based upon cervical dilation at the time of membrane sweeping. Our findings suggest that patients at more than 1 cm dilation may be at increased risk for prelabor rupture of membranes as a result of membrane sweeping. However, this is a result of a subgroup analysis and requires verification in a study designed to address this possibility.

Our study and the literature to date show that membrane sweeping seems to be a safe practice.1 However, it must be noted that our study was not powered to appropriately compare the rates of rare outcomes, such as neonatal GBS sepsis, in membrane sweeping patients.

Potential weaknesses of this study include the definition of prelabor rupture of membranes. There is
no criterion standard test, or even agreed-upon definition, for prelabor rupture of membranes. Our definition of contractions less than 10 minutes apart at the time of membrane rupture was designed to be conservative and clinically applicable. Indeed, in reviewing the data, the majority of prelabor rupture of membranes patients did not have any uterine contractions at the time of diagnosis, making the diagnosis simple for the purposes of this study. All patients diagnosed with prelabor rupture of membranes in this study required subsequent induction of labor, adding validity to the diagnosis of prelabor rupture of membranes. Additionally, the prelabor rupture of membranes rates of 12% and 7% in the two groups is similar to the overall prelabor rupture of membranes rate of 10.5% at our institution for the year 2007, adding internal validity to our findings. When comparing our trial to others, differences in prelabor rupture of membranes definition may explain differences in outcomes.

The post-hoc analysis introduces additional tests which increase the likelihood of a false-positive result. However, it does provide interesting data on prelabor rupture of membranes rates in patients who undergo membrane sweeping at various cervical dilations, which may help guide future research.

Our trial had several strengths: the specific design to examine prelabor rupture of membranes, the extensive steps taken to blind the authors and delivery providers to group allocation, the randomized controlled design, and the maintaining of blinding until completion of all data collection. Additionally, our study included a large variety of obstetrics providers—attending physicians, resident physicians, midwives, and nurse practitioners—and therefore has wide clinical application.

In conclusion, we found no overall difference in prelabor rupture of membranes rates between those receiving membrane sweeping and those without membrane sweeping. However, a post-hoc analysis suggests that patients who are more than 1 cm dilated during membrane sweeping may be at increased risk of prelabor rupture of membranes. A prospective trial designed specifically to assess prelabor rupture of membranes rates in patients receiving membrane sweeping when the cervix is more than 1 cm dilated is warranted.

REFERENCES