Foley catheter placement for induction of labor with or without stylette: a randomized clinical trial

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BACKGROUND: Foley catheters are used for cervical ripening during induction of labor. Previous studies suggest that use of a stylette (a thin, rigid wire) to guide catheter insertion decreases insertion failure. However, stylette effects on insertion outcomes have been sparsely studied.

OBJECTIVE: The purpose of this study was to compare catheter insertion times, patient-assessed pain levels, and insertion failure rates between women who received a digitally placed Foley catheter for cervical ripening with the aid of a stylette and women who received the catheter without a stylette.

STUDY DESIGN: We conducted a randomized clinical trial of women aged $\geq$ 18 years who presented for induction of labor. Inclusion criteria were singletons with intact membranes and cephalic presentation. Women received a computer-generated random assignment of a Foley catheter insertion with a stylette (treatment group, n = 62) or without a stylette (control group, n = 61). For all women, a standard insertion technique protocol was used. Three primary outcomes were of interest, including the following: (1) insertion time (total minutes to successful catheter placement), (2) patient-assessed pain level (0–10), and (3) failure rate of the randomly assigned insertion method. Treatment control differences were first examined using the Pearson's test of independence and the Student *t* test. Per outcome, we also constructed 4 regression models, each including the random effect of physician and fixed effects of stylette use with patient nulliparity, a history of vaginal delivery, cervical dilation at presentation, or postgraduate year of the performing resident physician.

RESULTS: Women who received the Foley catheter with the stylette vs without the stylette did not differ by age, race/ethnicity, body mass index, or any of several other characteristics. Regression models revealed that insertion time, patient pain, and insertion failure were unrelated to stylette use, nulliparity, and history of vaginal delivery. However, overall insertion time and failure were significantly influenced by cervical dilation, with insertion time decreasing by 21% (95% confidence interval [CI], 5–34%) and odds of failure decreasing by 71% (odds ratio, 0.29; 95% CI, 0.10–0.86) per 1 cm dilation. Resident postgraduate year also significantly influenced insertion time, with greater time required of physicians with less experience. Mean insertion time was 51% (95% CI, 23–69%) shorter for fourth-year than second-year residents. Statistically nonsignificant but prominent patterns in outcomes were also observed, suggesting stylette use may lengthen the overall insertion procedure but minimize variability in pain levels and decrease insertion failure.

CONCLUSIONS: The randomized trial suggests that, even after accounting for nulliparity, history of vaginal delivery, cervical dilation, and physician experience, Foley catheter insertions with and without a stylette are equivalent in insertion times, patient pain levels, and failure of catheter placement.

Key words: catheter, cervical dilation, Foley, pain level, physician experience, randomized clinical trial, stylette

Cervical ripening, the softening, thinning, and dilating of the cervix during labor induction, commonly incorporates use of a transcervical Foley catheter.[1] The American Congress of Obstetricians and Gynecologists describe the Foley catheter as an acceptable induction agent because it has demonstrated high efficacy and safety across several studies.[1,2] Advantages over pharmaceutical ripening agents (eg, prostaglandins) include low cost, stability at room temperature, and reduced risk of uterine tachysystole with or without fetal heart rate changes.[3] Additionally, Foley catheters can be used to induce labor in women with histories of cesarean delivery or other major uterine surgeries.[4]

Despite the use of Foley catheters in clinical practice since it was first described in 1967,[5] a paucity of data exists regarding placement protocols. Typically, a Foley catheter is inserted using direct visualization of the cervix during a sterile speculum examination or blindly during a digital cervical examination. For digital placement, the literature describes insertion both with and without the aid of a stylette.[6] The stylette, also known as a rigid catheter guide or urethral manipulator, is placed inside the Foley catheter, and the unit is slid along the operator's hand into the cervical ostium, and then the stylette is removed.

Despite the stylette's intended purpose of easing catheter insertion, the advantages vs disadvantages of its use, have not been studied. A PubMed search, using the terms, Foley, cervical ripening, and stylette, indicates that there have been no randomized clinical trials (RCTs) on the topic.

In our practice, Foley catheter placement is performed with a speculum or blindly with digital placement. Among providers who place the catheter blindly, a seemingly-even split in preference for vs against use of the stylette has been observed. With a lack of external evidence and no institutional clinical preference, our goal for this RCT was to investigate the effects of a stylette use on the outcomes associated with Foley catheter insertion during blind, digital placement.

Our specific objectives were as follows: (1) compare catheter insertion times, patient-assessed pain levels, and insertion failure rates between groups of

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women receiving the Foley catheter for cervical ripening with vs without the stylette, and (2) quantify stylette effects while also accounting for heterogeneity among providers and the modifying effects of potential confounders.

Materials and Methods

We conducted a RCT to investigate the effects of stylette use on catheter insertion outcomes. The trial was approved by the local institutional review board (number 13-46E). The study population included all women aged $\geq$ 18 years who presented for induction of labor to Aurora Sinai Medical Center during June 2013 through December 2014.

Inclusion in the study further required that women were cared for by obstetrician/gynecologist residents postgraduate year (PGY) 2−4, induced via Foley catheter bulb, had a singleton pregnancy, had intact membranes, and had cephalic presentation. We excluded women cared for by PGY1 residents to ensure that residents within the study already had catheter placement experience. We estimated that residents placed 30 transcervical catheters during PGY1.

We designed our study for the comparison of outcomes between 2 groups. The treatment group was defined as women who received the Foley catheter via digital placement with a stylette and the control group was defined as women who received the catheter via digital placement without a stylette. We powered our study for the detection of difference in insertion time. A sample size of 64 women per group (128 women total) was determined necessary to detect a difference in mean catheter insertion time of 0.5 minutes with normally distributed responses, SD of 1, alpha of 0.05, and power of 0.80.

We also considered a log normal distribution for highly right-skewed responses with similar parameters and found that 58 women per group (116 women total) were needed. Ultimately we targeted the greater of the 2 sample size estimates and randomly assigned women to treatment and control groups using a computer-generated sequence of group identifiers with a 1:1 allocation. For application in the clinical setting, treatment and control group identifiers were concealed within envelopes and available per woman, following consent by a resident physician or research coordinator, in the same sequence as generated.

Women were positioned in the dorsal lithotomy position in the labor bed with feet on stirrups and bottom of bed detached. All inductions used a 22 French Foley catheter and a 5 French stylette if within the stylette group. After insertion, the catheter was filled with 50 mL of water and tugged back against the internal ostium until snug; the tail was then taped to the inside thigh under tension.

The primary outcomes of interest in this study depended on this protocol and included recording insertion time (total minutes to successful catheter placement), patient-assessed pain level (scale of 0−10), and failure of the insertion technique used. Using a stopwatch operated by a nurse in the room, measurement of insertion time began when the provider's fingers entered the vagina and ended at full inflation of the catheter balloon. Pain level was determined by verbally asking patients to assess their pain following taping of the catheter tail.

Failure was defined as inadvertent amniotomy, excessive time in placement (subjectively determined by the provider placing the catheter), or excessive patient pain (subjectively determined by the provider but based on patient response).

Variables hypothesized as potential confounders of the stylette effect on these primary outcomes included age, race/ethnicity, body mass index, nulliparity, gravidity, history of vaginal delivery and cesarean delivery, gestational age, cervical dilation, admission Bishop score, indication for induction, and PGY of the performing resident physician.

To describe our study population and assess equivalency in characteristics between the treatment and control groups, we computed frequencies and means with 95% confidence intervals (CI), as appropriate per variable type. Differences in proportions and means between the groups were tested using a Pearson's χ^2 test of independence and a Student t test (or Wilcoxon's rank sum test), respectively. In all cases, test assumptions of sample independence and normality (of original or transformed data) were satisfied.

We examined the effects of the stylette use by testing for treatment-control differences in mean insertion time (natural log transformed) and patient-assessed pain level using a Student t test and in odds of insertion failure using a Pearson's χ^2 test of independence. For each outcome of interest, we also constructed four regression models to examine the fixed main and interaction effects of stylette use and 1 covariate. Models tested the significance of stylette use while adjusting for other variable effects.

Covariates in the 4 models included nulliparity (nulliparous vs multiparous), a history of vaginal delivery (yes vs no), cervical dilation at presentation (centimeters), and resident PGY (2 vs 3 vs 4). Response distributions included the log normal (normal distribution with natural log-transformed response) for catheter insertion time, multinomial for pain level, and binomial for insertion failure. Following backtransformation or exponentiation of parameter estimates, model results were interpreted as the percentage change in insertion time, ratio of odds of less pain, and ratio of odds of failure of the insertion technique used. Unobserved outcome heterogeneity was captured by individual resident physicians, each of which defined a separate random variable and intercept in the model.

To display the statistically significant effects revealed in the regression models, as well as highlight nonsignificant trends, we summarized catheter insertion outcomes overall by use of stylette and by stylette use within confounder subgroup. Basic descriptive statistics, box-and-whisker plots, and bar plots were used. Descriptive statistics included mean with 95% CI, coefficient of variation (SD divided by the mean), and median with interquartile range (IQR), as appropriate per response variable. We performed all analyses using SAS statistical software (version 9.4; SAS Institute