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

Inc, Cary, NC). In all cases, $P < .05$ was considered statistically significant.

Results

During the study period, there were a total of 3802 deliveries of which 1067 were inductions. A total of 194 Foley catheters were used for cervical ripening in women who met inclusion criteria (Figure 1). Women were principally excluded because of the requirement of catheter placement by obstetrician/gynecologist residents of PGY2−4. We included only these providers to homogenize the clinical experience of the participating providers.

Twenty-nine women declined to participate, and 31 women were excluded for undocumented reasons. Overall, 134 women were consented and randomized, with 11 women subsequently excluded from the study by the institutional review board. A total of 123 total women entered statistical analysis.

Women who received the Foley catheter with a stylette (n = 62) vs without a stylette (n = 61) did not differ by age, race/ethnicity, body mass index, nulliparity, gravidity, history of vaginal delivery or cesarean delivery, gestational age, cervical dilation, admission Bishop score, indication for induction, resident PGY, route of delivery, or chorioamnionitis (Table 1).

No significant differences between the treatment and control groups were detected in log-transformed insertion time ($t_{105} = 0.38$; $P = .70$), patient-assessed pain level ($t_{120} = 0.88$; $P = .38$), or odds of insertion failure ($\chi^2 = 0.33$; $P = .57$; Table 2). Across all random-intercepts models, no significant interaction effects were detected (Table 3).

Following the removal of interactions, models revealed all 3 outcome variables as unrelated to stylette use, nulliparity, and history of vaginal delivery. Insertion time and failure, however, were significantly influenced by cervical dilation. For each 1 cm increase in dilation, insertion time decreased 21% and odds of failure decreased 71%.

Resident PGY also significantly influenced insertion time, with greater time required of physicians with less experience. The mean insertion time for PGY4 residents was 51% shorter than for PGY2 residents. Difference in times of PGY2 and PGY3 residents was not statistically significant, but modeling suggested a 34% shorter mean insertion time for PGY3 than PGY2 residents.

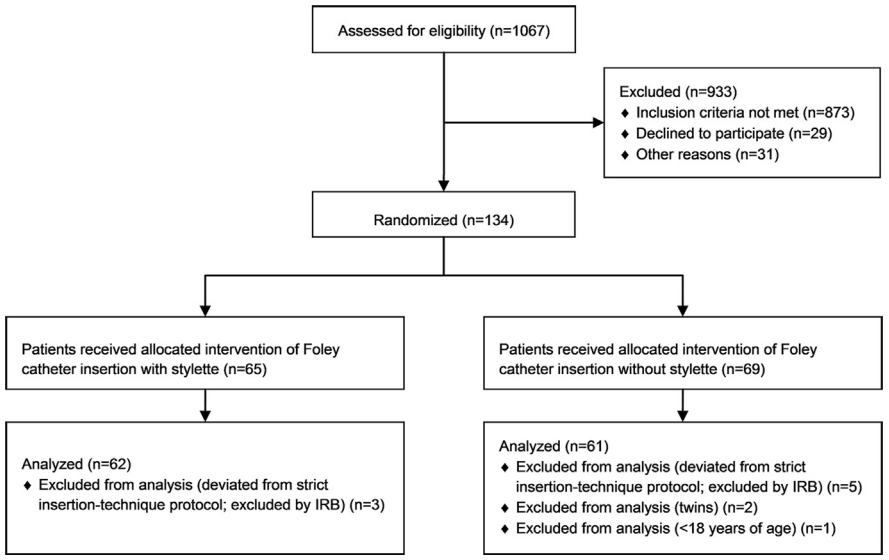
Descriptive summaries of outcomes by stylette use and confounder subgroup strongly supported the statistically significant results of the models (Table 2 and Figure 2). However, several prominent patterns, although not statistically significant, were revealed. Although median insertion times within the treatment and control groups were extremely similar, the mean time for Foley catheter insertion with stylette exceeded the mean time for insertion without stylette in all but 1 subgroup examined and overall. Insertion times associated with the use of the stylette also demonstrated greater variability and number of outlying values. In contrast, in all subgroups and overall, patient-assessed pain levels were less variable (coefficient of variation, 0.54 vs 0.74), and failure rates were numerically lower with the use of the stylette.

Along with overall lower odds of failure in the treatment than control group, women in the treatment group may have differentially benefited from the use of the stylette through greater reduction in failure when multiparous (38%) vs nulliparous (7%), with a history of vaginal delivery (30%) vs without (18%), and with closed (32%) vs open (22%) cervix. Also, visual comparisons of summarized outcomes between failed and successful insertion attempts highlighted the importance of achieving success on the first insertion attempt because both duration and associated pain were distinctly less when successful (Table 4). Lastly, resident experience may have influenced failure rate as values dramatically decreased from PGY2 to PGY4.

Comment

Use of a stylette to guide the placement of the Foley catheter during cervical ripening did not significantly affect the time taken for insertion, patient-assessed pain level, or odds of insertion failure, even after accounting for nulliparity, history of vaginal delivery, cervical dilation, route of delivery, chorioamnionitis,

FIGURE 1
Flow chart of subject inclusion, randomization, and reasons for exclusion



Most women were not eligible for the study because catheters were placed by providers other than second-, third-, and fourth-year obstetric-gynecology residents.

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TABLE 1
Baseline characteristics and labor outcomes of women in treatment and control groups

Characteristic	Treatment: stylette (n = 62)	Control: no stylette (n = 61)	*P* value[a]
Age, y, mean (SD)	26.9 (5.56)	26.9 (6.98)	1.00
Race/ethnicity, n, %			.33
White non-Hispanic	15 (24.2)	8 (13.1)	
African-American non-Hispanic	38 (61.3)	41 (67.2)	
Hispanic/Latina	6 (9.68)	10 (16.4)	
Delivery BMI, kg/m^2, mean (SD)	36.2 (8.76)	34.6 (8.95)	.32
Nulliparous, n, %	30 (48.4)	28 (45.9)	.78
Gravidity, mean (SD)	2.95 (2.61)	3.02 (2.67)	.89
History of cesarean delivery, n, %	5 (8.06)	9 (14.8)	.24
History of vaginal delivery, n, %	30 (48.4)	28 (45.9)	.49
Gestational age, wks, mean (SD)	38.3 (2.34)	39.1 (1.71)	.06
Cervical dilation, cm, mean (SD)	0.78 (0.64)	0.84 (0.64)	.64
Admission Bishop score, mean (SD)	3.34 (1.96)	2.97 (1.61)	.25
Primary indication for induction, n, %			.17
Elective for post-EDC	11 (17.7)	18 (29.5)	
Maternal disease	33 (53.2)	23 (37.7)	
Fetal indications	18 (29.0)	20 (32.8)	
Route of delivery, n, %[b]			.28
Normal spontaneous vaginal	35 (56.5)	42 (68.9)	
Vacuum-assisted vaginal	4 (6.5)	4 (6.6)	
Low-transverse cesarean delivery	23 (37.1)	14 (23.0)	
Chorioamnionitis, n, %	9 (14.5)	6 (10.0)	.45
Resident year, n, %			.66
PGY2	22 (35.5)	22 (36.1)	
PGY3	14 (22.6)	10 (16.4)	
PGY4	26 (41.9)	29 (47.5)	

BMI, body mass index; *EDC*, estimated date of confinement.

[a] Significance level of Pearson's χ^2 test of independence, Student *t* test, or Wilcoxon's rank sum test; $P < .05$ suggests difference between treatment and control groups; [b] The route of delivery is missing for 1 woman of the control group in whom induction was halted; she was discharged home prior to delivery.

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and physician experience. Unsurprisingly, we found that cervical dilation and PGY of the performing resident physician significantly affected insertion time.

Per 1 cm increase in dilation, insertion time decreased 21% and the odds of failure decreased 71%. Mean insertion times of PGY3 and PGY4 residents were 34% and 51% shorter, respectively, than PGY2 residents, suggesting greater time was required of physicians with less experience. Decreasing insertion time with increasing experience was not a gradual process for all residents because PGY3 residents demonstrated the greatest variability in times. These findings highlight that even as little as 1–2 years of practice in catheter placement and a 1 cm increase in cervical dilation by the start of labor can significantly improve catheter insertion outcomes.

Although few studies have focused on the techniques used for Foley catheter placement, general patterns reported on catheter insertion time, patient-assessed pain level, and insertion failure are comparable with those reported in this study. For instance, our overall insertion time using the digital method of insertion without a stylette (median, 1.88 min; IQR, 1.33–3.12) was similar to that reported by Jonsson et al[7] (median, 2 minutes; IQR, 1.5–3).

To our knowledge, no study has examined patient pain levels associated with stylette use in Foley catheter insertion. However, in their attempts to assess the effects of speculum vs digital methods of insertion on pain level, Jonsson et al[7] recorded patient-assessed (subjective) pain measurements using the same scale (0–10).

In our study, the median pain level recorded without the stylette was 4 (IQR, 1–7), which was a slightly higher than the results of Jonsson et al[7] (median, 3; IQR, 1–5). Their report states that catheters were placed by attending physicians, without mention of experience level, but we observed no obvious patterns in pain level due to physician experience. Quite possibly, residents-in-training are able to quickly grasp the technical elements of the insertion procedure but require experience beyond residency to develop the gentle, steady approach needed to achieve lower pain levels.

Another study, by Erekson et al,[6] suggested that stylette use during the insertion of a Foley catheter increases the probability of success. Success of catheter placement with a stylette was evaluated in their study only after the provider failed to place a catheter using either speculum or digital methods without a stylette. Erekson et al deemed all placements successful and concluded that the ease of insertion using the stylette makes it a valuable, possibly preferable method of catheter insertion.

Although we did not detect statistically significant differences in failure rate between the treatment and control groups, we did observe numerically

TABLE 2
Descriptive and inferential statistics for catheter insertion outcomes by confounder subgroup and use of the stylette

Outcome and confounder subgroup	n	Overall	Treatment: stylette	Control: no stylette	*P* value[a]
Insertion time[b]					
Overall	107	1.78 (1.25–3.23)	1.72 (1.25–3.30)	1.88 (1.33–3.12)	.70
Parity					
Nulliparous	50	1.89 (1.33–2.75)	2.08 (1.33–3.38)	1.78 (1.23–2.46)	
Multiparous	57	1.72 (1.25–3.28)	1.55 (1.23–3.08)	1.96 (1.35–3.39)	
History of vaginal delivery					
Yes	51	1.72 (1.25–3.30)	1.55 (1.23–3.08)	1.96 (1.35–3.58)	
No	56	1.89 (1.29–2.96)	2.08 (1.29–3.44)	1.95 (1.23–2.46)	
Cervical dilation					
Closed cervix (0 cm)	28	2.07 (1.53–3.26)	1.86 (1.29–2.94)	2.38 (1.83–3.48)	
Open cervix (> 0 cm)	79	1.68 (1.25–3.08)	1.68 (1.25–3.38)	1.70 (1.21–2.58)	
Resident year					
PGY2	35	3.08 (1.78–4.60)	3.19 (1.97–4.60)	3.00 (1.68–3.70)	
PGY3	22	1.76 (1.25–2.72)	1.50 (1.25–2.00)	2.17 (1.83–4.62)	
PGY4	50	1.46 (1.08–2.02)	1.38 (1.13–2.09)	1.56 (0.93–1.95)	
Patient pain level[b]					
Overall	122	4.66 (4.13–5.20)	4.90 (4.22–5.58)	4.43 (3.59–5.27)	.38
Parity					
Nulliparous	57	4.67 (3.89–5.45)	4.52 (3.51–5.53)	4.82 (3.56–6.08)	
Multiparous	65	4.66 (3.91–5.42)	5.25 (4.29–6.21)	4.09 (2.91–5.27)	
History of vaginal delivery					
Yes	58	4.69 (3.88–5.50)	5.30 (4.28–6.32)	4.04 (2.75–5.32)	
No	64	4.64 (3.91–5.37)	4.52 (3.57–5.46)	4.76 (3.61–5.91)	
Cervical dilation					
Closed cervix (0 cm)	37	5.27 (4.26–6.28)	5.40 (4.06–6.74)	5.12 (3.44–6.79)	
Open cervix (> 0 cm)	85	4.40 (3.76–5.04)	4.66 (3.85–5.47)	4.16 (3.16–5.16)	
Resident year					
PGY 2	43	4.51 (3.62–5.41)	5.57 (4.31–6.83)	3.50 (2.29–4.71)	
PGY 3	24	4.79 (3.57–6.01)	5.00 (3.37–6.63)	4.50 (2.28–6.72)	
PGY 4	55	4.72 (3.88–5.57)	4.31 (3.32–5.30)	5.10 (3.72–6.49)	
Failure of insertion method[b]					
Overall	123	16/123 (13.0%)	7/62 (11.3%)	9/61 (14.8%)	.57
Parity					
Nulliparous	58	8/58 (13.8%)	4/30 (13.3%)	4/28 (14.3%)	
Multiparous	65	8/65 (12.3%)	3/32 (9.4%)	5/33 (15.2%)	
History of vaginal delivery					
Yes	58	7/58 (12.1%)	3/30 (10.0%)	4/28 (14.3%)	
No	65	9/65 (13.8%)	4/32 (12.5%)	5/33 (15.2%)	

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(continued)

TABLE 2
Descriptive and inferential statistics for catheter insertion outcomes by confounder subgroup and use of the stylette *(continued)*

Outcome and confounder subgroup	n	Overall	Treatment: stylette	Control: no stylette	*P* value[a]
Cervical dilation					
Closed cervix (0 cm)	37	9/37 (24.3%)	4/20 (20.0%)	5/17 (29.4%)	
Open cervix (> 0 cm)	86	7/86 (8.1%)	3/42 (7.1%)	4/44 (9.1%)	
Resident year					
PGY 2	44	9/44 (20.5%)	4/22 (18.2%)	5/22 (22.7%)	
PGY 3	24	2/24 (8.3%)	1/14 (7.1%)	1/10 (10.0%)	
PGY 4	55	5/55 (9.1%)	2/26 (7.7%)	3/29 (10.3%)	

[a] Significance level of Student *t* test for insertion time and pain level and Pearson's χ^2 test of independence for odds of insertion failure; $P < .05$ suggests difference between treatment and control groups; [b] Displayed measurements include median (interquartile range) insertion time in minutes for successful insertion attempts only, mean (95% confidence interval) patient pain level on a scale of 0—10, and number of insertion failures from total number of attempts (rate as percentage). The pain level of 1 successful attempt was inadvertently not recorded.

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lower failure rates when a stylette was used. Lack of a significant difference in our study may be due to greater statistical power needed for detection or may also rest on inherent differences in study design. Erekson et al[6] studied an extremely small sample of women (n = 16), and, because catheter insertion without a stylette failed, the sample was inherently biased toward success with the stylette.

Examination of failed insertion attempts within our control group revealed that several catheters were subsequently successfully placed using a stylette (56% of failed attempts; Table 4). A total of 4 amniotomies occurred, all of which involved a stylette, whether it was the initial or subsequent treatment technique. Overall, failed catheter insertion attempts took longer and resulted in greater patient pain than successful attempts. Excessive time was the most common reason cited for a failure regardless of stylette use. Based on our data, one can infer that if it takes longer than 2 minutes to insert the catheter, it is less likely to be successful and more likely to cause pain.

Our study has numerous strengths. First, it was a RCT, designed to investigate a technique widely used in labor and delivery units but infrequently studied. Previous studies have investigated the techniques used after placement of the Foley catheter, such as determining saline volume for balloon inflation,[8,9] adjusting tension on the tape,[10] deciding when to add pharmaceutical agents,[11,12] and timing the removal of the Foley catheter.[13] However, little focus has been given to techniques used during insertion, and, until now, no RCT has been conducted to study outcomes related to stylette use.

Second, we outlined a protocol for Foley catheter insertion and strictly enforced its use with all subjects to minimize confounding effects. Any deviation from the protocol reported to the institutional review board as a major study violation led to the subject's removal from the study.

Lastly, despite the recognition of some sample size limitations (see below), our study comprised a sample size that was 3—7 times larger than any prior study of similar catheter insertion outcomes.[6,7] Moreover, > 95% power was achieved for insertion time and pain level outcomes due to a smaller SD within each group. We also designed the study based on a priori hypotheses concerning variability in outcomes, which led us to incorporate a meaningful set of potential confounders and physician heterogeneity into our analyses.

Our study also has some limitations. First, we did not enroll enough subjects to achieve sufficient power for every test performed or to obtain sufficiently precise effect estimates in our models. Whereas we detected some statistically significant patterns (ie, insertion time and failure rate each by cervical dilation, insertion time by resident PGY), we observed a greater number of statistically nonsignificant but prominent patterns, including differences in outcomes among groups (ie, failure rates by stylette use, failure rates by resident PGY) and interactions between stylette use and covariates in the models (ie, stylette × nulliparity, stylette × history of vaginal delivery, stylette × cervical dilation). To statistically detect the current treatment-control difference in failure rate of 3%, we would have needed 3814 patients.

We also did not enroll enough subjects to study outcomes with inherently low event rates or representing subcategories of an outcome, such as inadvertent amniotomy as a reason for failure. Although our study was prospective, only 63% of eligible women were included. Moreover, because of the nature of the intervention, providers could not be blinded to the catheter insertion technique used. Patients were also not blinded. Therefore, knowledge of whether a stylette was used could have biased reports of discomfort.

TABLE 3
Measures of effects in models of insertion time, patient pain level, and failure of the insertion method used

Model and explanatory variables	Insertion time		Patient pain level		Failure of insertion method	
	Effect size[a]	*P* value	Effect size[b]	*P* value	Effect size[c]	*P* value
Model 1						
Stylette						
Stylette	1.92 (−19.3 to 28.8)	.87	1.36 (0.72−2.56)	.34	0.75 (0.25−2.27)	.61
No stylette	Reference		Reference		Reference	
Nulliparous						
Nulliparous	0.17 (−20.6 to 26.3)	.99	0.99 (0.53−1.86)	.98	1.25 (0.42−3.77)	.69
Multiparous	Reference		Reference		Reference	
Interaction[d]		.80		.14		.73
Model 2						
Stylette						
Stylette	1.99 (−19.3 to 28.9)	.87	1.36 (0.72−2.56)	.34	0.76 (0.25−2.29)	.62
No stylette	Reference		Reference		Reference	
History of vaginal delivery						
Yes	−2.59 (−22.9 to 23.0)	.82	1.03 (0.55−1.93)	.92	0.80 (0.26−2.41)	.68
No	Reference		Reference		Reference	
Interaction[d]		.63		.12		.89
Model 3						
Stylette						
Stylette	−0.52 (−20.7 to 24.8)	.96	1.37 (0.72−2.58)	.33	0.70 (0.22−2.25)	.55
No stylette	Reference		Reference		Reference	
Cervical dilation	−20.8 (−34.2 to −4.67)	.01	0.65 (0.39−1.08)	.09	0.29 (0.10−0.86)	.03
Interaction[d]		.35		.35		.75
Model 4						
Stylette						
Stylette	0.61 (−19.8 to 26.2)	.96	1.35 (0.71−2.54)	.36	0.75 (0.25−2.27)	.61
No stylette	Reference		Reference		Reference	
Resident year						
PGY2	Reference		Reference		Reference	
PGY3	−33.7 (−58.9 to 6.93)	.09	1.20 (0.51−2.87)	.36	0.33 (0.05−2.02)	.23
PGY4	−51.0 (−69.0 to −22.7)	.003	1.09 (0.54−2.21)	.91	0.41 (0.11−1.56)	.19
Interaction[d]		.35		.10		1.00

[a] Effect size represents the percentage change in insertion time per 1 unit increase in continuous explanatory variables and the percentage difference between reference and nonreference categories of categorical variables; [b] Effect size represents the odds ratio, measuring the proportion of odds of less pain remaining per 1 unit increase in continuous explanatory variables and from reference to nonreference categories for categorical variables; [c] Effect size represents the odds ratio, measuring the proportion of odds of insertion failure remaining per 1 unit increase in continuous explanatory variables and from reference to nonreference categories for categorical variables; [d] When $P > .05$, the interaction term was removed from the model and no respective effect sizes were estimated.

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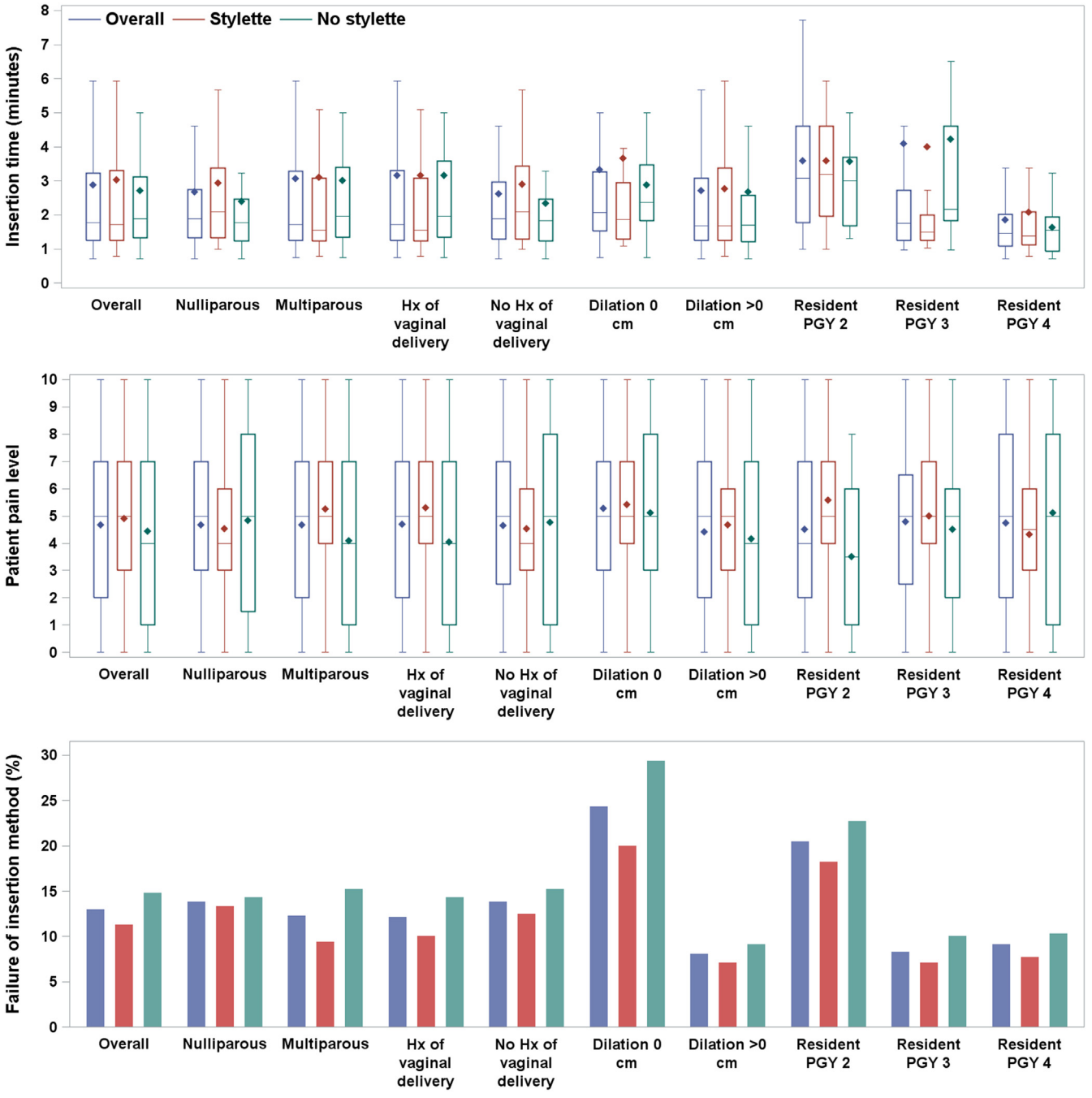
Additionally, insertion time and failure may have been influenced by providers who struggled without the stylette and aborted their insertion attempts earlier, knowing they could try again using the stylette.

Lastly, women within our study sample were selected from a single, urban site and were largely African-American and obese, which may not be generalizable to other populations.

FIGURE 2
Summaries of variables for women overall and in treatment and control groups



Box-and-whisker and bar plot summaries of insertion time, pain level, and insertion failure for women overall and in treatment (stylette) and control (no stylette) groups. The box-and-whisker plots (top and middle graphs) show mean (*diamonds*) and median (*horizontal lines within boxes*) insertion times and pain levels. Upper and lower limits of each box represent the interquartile range, whereas error bars include all values within 1.5 times the interquartile range. Outliers outside of this range are not shown (insertion time only).

Hx, history; *PGY*, postgraduate year.

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Many obstetrical providers strongly prefer one technique of digitally inserting transcervical catheters over the other (ie, with a stylette or without a stylette), believing the technique leads to greater success in catheter placement. Our study results suggest neither technique as credibly superior for reducing insertion time, patient pain level, or failure of

TABLE 4
Lengths of time and pain levels for failed (n = 16) and successful (n = 107) insertion attempts with explanations for failures

Catheter insertion outcome	Failed attempts		Successful attempts	
	n	Statistic	n	Statistic
Time of insertion attempt, min, median (IQR)				
Overall	14[a]	5.03 (3.80–10.0)	107	1.78 (1.25–2.23)
Treatment: stylette	7	6.55 (3.80–11.6)	55	1.72 (1.25–3.30)
Control: no stylette	7	5.00 (3.00–7.18)	52	1.88 (1.33–3.12)
Pain level for insertion attempt, mean (95% CI)				
Overall	16	7.38 (6.39–8.36)	106[a]	4.25 (3.69–4.82)
Treatment: stylette	7	7.14 (5.19–9.10)	54	4.61 (3.90–5.32)
Control: no stylette	9	7.56 (6.22–8.89)	52	3.88 (3.00–4.77)
Failure of insertion method, explanation and subsequent treatment				
Treatment: stylette				
Excessive insertion time	5	Misoprostol used (n = 3); catheter placed by senior resident (n = 1); catheter placed without stylette (n = 1)		
Amniotomy	2	Induced with oxytocin (n = 2)		
Control: no stylette				
Excessive insertion time	8	Catheter successfully placed with stylette (n = 5); catheter placed by senior resident (n = 1); attempted with stylette leading to amniotomy, then induced with oxytocin (n = 1); attempted with stylette unsuccessfully, then misoprostol used (n = 1)		
Excessive pain with insertion	1	Catheter placed with stylette leading to amniotomy, then induced with oxytocin (n = 1)		

[a] The insertion times of 2 failed attempts and pain level of 1 successful attempt were inadvertently not recorded.

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catheter placement. It may be true, however, that an individual provider has better outcomes when they use the technique with which they are more comfortable.

Moreover, nonsignificant but noticeable trends in the catheter insertion outcomes of specific subgroups suggest that, although stylette use may add time to the overall insertion procedure, its use may also minimize variability in patient pain levels and decrease insertion failure. A stylette may also be helpful if the provider is unsuccessful in placing a catheter without the use of one. ■

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