Pain perception with cervical tenaculum placement during intrauterine device insertion: a randomised controlled trial

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ABSTRACT

Introduction 'Slow' and 'cough' techniques for tenaculum placement are commonly used. This trial sought to determine if one method of placement resulted in less pain for patients.

Methods This study was a randomised controlled trial of patients presenting for intrauterine device placement. Sixty-six participants were randomised to tenaculum placement via the 'slow' method (closure of tenaculum over a 5-s period) versus the 'cough' method (closure of tenaculum at the time of patient's cough). The primary outcome was pain at time of tenaculum placement measured on a 100 mm visual analogue scale. The study was powered to detect a 16 mm difference in pain. Secondary outcomes included pain with insertion and provider satisfaction with tenaculum grasp. Pain scores were analysed with Wilcoxon rank-sum test.

Results Sixty-six women were enrolled, 33 randomised to each group. Demographics were similar in each group. The primary outcome of pain with tenaculum placement showed a median pain score of 44 (IQR=21, 63) with slow placement and 32 (IQR=19, 54) with cough placement. There was no significant difference in pain scores between methods of tenaculum placement (p=0.16). There was no significant difference in overall pain scores (p=0.12). Provider satisfaction was not associated with one method of placement (p=1). Pre-procedure anxiety was significantly associated with pain at the time of tenaculum placement (p=0.01).

Conclusions Neither the slow method nor cough method is superior for pain reduction or provider satisfaction. Pain with tenaculum use is significantly associated with anxiety.

Clinical trial registration NCT02969421.

Key messages

- The single-toothed tenaculum is used for many gynaecological procedures. Many providers assume the method of tenaculum placement impacts pain perception but there are no studies to support that assumption.
- We found no difference in pain scores when comparing the method of tenaculum placement, suggesting providers can use the method more preferable to them.
- Anxiety was associated with increased pain during tenaculum placement.

INTRODUCTION

The goals of office-based gynaecological procedures are two-fold: to safely and successfully perform the procedure, and to offer adequate patient comfort. A multimodal approach may be most effective in achieving adequate pain control.[1 2] Improving patient comfort during office-based procedures remains a priority.

The single-toothed tenaculum is used for stabilisation, traction and to decrease the flexion of the uterus to ease passage of instruments into the endometrial cavity. Few studies directly compare placement methods to decrease patient pain.[1] Commonly described strategies for reduction of pain with tenaculum placement include slow placement of the tenaculum over a number of seconds, having the patient cough while the cervix is quickly grasped, use of atraumatic tenaculums, and/or application of local anaesthetics.[1] In a previous study evaluating pain with intrauterine device (IUD) insertion Doty and Maclsaac conducted a randomised controlled trial (RCT) to compare the use of the vulsellum to a single-tooth tenaculum, finding no difference between groups.[3]

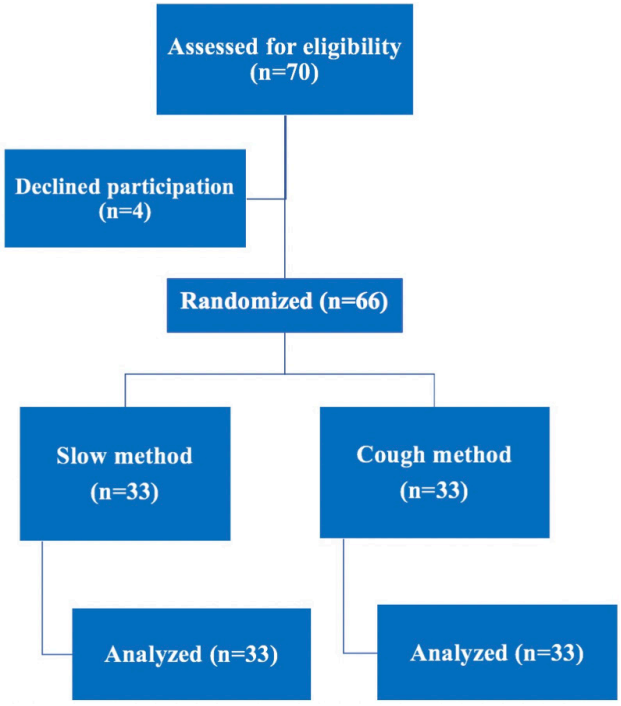

Figure 1 Study flow diagram.

Goldthwaite *et al* investigated the effect of local anaesthetics on pain at the time of tenaculum placement. They found that women who received lidocaine injection had lower mean pain levels at tenaculum placement but higher mean pain levels during injection compared with lidocaine gel.[4]

Slow tenaculum placement versus placement at the time of patient cough are two commonly described and taught methods of tenaculum placement. Both methods are utilised by providers based on preference or training. We chose to directly compare these methods since there is no evidence that identifies superiority of one method over the other.

Our study compared slow tenaculum placement versus the cough method, and their effects on procedural pain at time of IUD placement. Provider satisfaction with tenaculum placement and overall pain with IUD insertion were measured as secondary outcomes. Based on anecdotal experience, we hypothesised that slow tenaculum placement is less painful to patients and would offer higher provider satisfaction scores.

METHODS

This single-site RCT was conducted from January 2017 to March 2017 at Duke University Medical Center Gynecology Clinic. The study protocol was approved by the Duke University Health System Institutional Review Board. All participants completed informed consent. This study was registered at www.clinicaltrials.gov (Identifier NCT02969421).

We recruited English-speaking women aged 18 years and older who were having an IUD inserted during their clinic visit. Participants were excluded if they could not provide informed consent, did not speak English, or were having an additional procedure done at the time of IUD insertion. Potential participants who met eligibility criteria were recruited on the day of their procedure. Enrolment and informed consent were obtained by study-approved personnel.

The following demographics were obtained from each participant: age, parity, race, ethnicity, highest level of education, number of caesarean sections, body mass index, history of chronic pain, daily narcotic use, and anxiety score based on Generalised Anxiety Disorder 7 (GAD7) questionnaire. Patients with GAD7 scores 0–4 were labelled as not anxious, GAD7 scores 5–9 were labelled as mildly anxious, GAD7 scores 10–14 were moderately anxious, and GAD7 scores 15–21 were severely anxious. The GAD7 tool was calculated prior to start of procedure.

All IUDs were placed by obstetrics and gynaecology residents or faculty members in the clinic. The following information was collected from each provider: level of training, uterine position, and how many attempts were made at tenaculum placement. First- and second-year resident providers were considered novice providers, while third-year residents and above were considered expert. A first-year resident has completed medical school but are currently completing their first of 4 years of obstetrics and gynaecology training.

Randomisation was achieved using computer-generated random numbers (randomization.com) in blocks of 11. Participants were then assigned to their group once they had been enrolled in the study. This was not a blinded study for either the patient or the provider placing the tenaculum and IUD. Providers were informed prior to the procedure which method the patient would receive and were given instructions on how to place the tenaculum.

A single-tooth tenaculum was used in the placement of all IUDs. Each participant was placed in the standard dorsal lithotomy position. The tenaculum was placed on the anterior lip of the cervix using the following standardised protocol. If the participant was randomised to the slow method, the tenaculum was closed on the anterior lip of the cervix to the first ratcheted click over a 5-s period. If the participant was randomised to the cough arm, the participant was asked to give one strong cough. This first cough served as a test cough. The participant was then asked to cough again and at this cough the tenaculum was placed on the anterior lip of the cervix. No local anaesthetic was placed on the cervix prior to tenaculum placement.

Provider satisfaction with tenaculum placement was also assessed. The provider was asked to rate their satisfaction with grasp achieved by tenaculum placement on a 5-point Likert scale: 1: not at all satisfied, 2: slightly satisfied, 3: moderately satisfied, 4: very satisfied, 5: extremely satisfied. Optimal grasp was defined as a score ≥4, while suboptimal grasp was defined as

Table 1 Descriptive statistics for patient characteristics by method of tenaculum placement

Characteristic	Slow placement (n=33)	Cough method (n=33)	Total (n=66)
Age (years) (median (IQR))	25 (21, 31)	27 (23, 32)	26 (22.2, 31)
Body mass index (median (IQR))	26.4 (23, 36.5)	24.8 (22, 38.1)	26.1 (22.2, 37.6)
Race (n (%))			
Black or African American	13 (39.4)	9 (27.3)	22 (33.3)
White or Caucasian	13 (39.4)	19 (57.6)	32 (48.5)
Other	7 (21.2)	5 (15.2)	12 (18.2)
Hispanic or Latino (n (%))	7 (21.2)	6 (18.2)	13 (19.7)
Previous births (n (%))			
0	19 (57.6)	14 (42.4)	33 (50.0)
1	6 (18.2)	7 (21.2)	13 (19.7)
>1	8 (24.2)	12 (36.4)	20 (30.3)
Number of caesarean sections (n (%))			
0	28 (84.8)	27 (81.8)	55 (83.3)
1	5 (15.2)	4 (12.1)	9 (13.6)
>1	0 (0.0)	2 (6.1)	2 (3.0)
Highest level of education (n (%))			
Some high school	4 (12.1)	3 (9.1%)	7 (10.6%)
High school/GED	4 (12.1)	5 (15.2)	9 (13.6)
Some college	14 (42.4)	14 (42.4)	28 (42.4)
Completed college	2 (6.1)	5 (15.2)	7 (10.6)
Greater than college	9 (27.3)	6 (18.2)	15 (22.7)
History of chronic pain (n (%))	31 (93.9)	26 (78.8)	57 (86.4)
Daily opioid (pain medicine) use (n (%))	2 (6.1)	4 (12.1)	6 (9.1)
GAD7 score (n (%))			
No anxiety (0–4)	15 (45.5)	16 (48.5)	31 (47.0)
Mild anxiety (5–9)	6 (18.2)	9 (27.3)	15 (22.7)
Moderate anxiety (10–14)	8 (24.2%)	4 (12.1%)	12 (18.2%)
Severe anxiety (15–21)	4 (12.1%)	4 (12.1%)	8 (12.1%)

GAD7, General Anxiety Disorder 7 ; GED, general educational development.

a score ≤3. A grasp would be considered suboptimal if too little tissue was held at the time of tenaculum closure, limiting the traction that could be placed on the uterus.

Our primary outcome was pain at the time of tenaculum placement measured on a visual analogue scale (VAS). Our secondary outcome was overall pain with IUD placement. Participants recorded their pain on the VAS scale prior to procedure start, at the time of speculum placement, at the time of tenaculum placement, and then finally with the overall procedure. We measured pain using a continuous 100 mm VAS, where 0 represented no pain and 100 represented the worst imaginable pain. The following cut-off points on the pain VAS have been recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm) and severe pain (75–100 mm).[5] Todd *et al*, in addressing the question of clinical significance of VAS scores, found that 13 mm (95% CI 10 to 16) is the minimum mean change on a standard 100 mm VAS that should be considered clinically significant for acute, traumatic pain.[6] This finding was later validated in a prospective, observational cohort study by Gallagher *et al*.[7] We chose a 16 mm difference on a 100 mm VAS as value of clinical significance. In order to detect a 16 mm difference with 90% power and alpha of 0.05, we calculated that a total sample size of 66 was needed.

The data were collected on paper and then managed with Research Electronic Data Capture (REDcap) hosted at Duke University School of Medicine.

Patient demographics were summarised using median and IQR for continuous variables (age and body mass index) and frequency and percentage for categorical variables (race, ethnicity, parity, number of caesarean sections, education level, history of chronic pain, daily narcotic use, and GAD7 score)

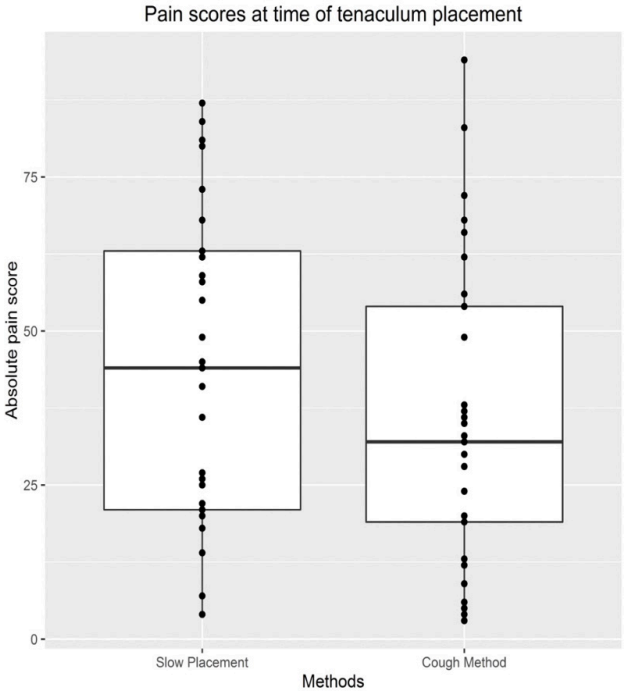

Figure 2 Pain scores on visual analogue scale at time of tenaculum placement.

by tenaculum placement methods. Pain at tenaculum placement and overall procedure pain scores were compared between groups using Wilcoxon rank-sum test. Provider's satisfaction with tenaculum grasp was measured on a 5-point Likert scale. Satisfaction levels were dichotomised into optimal grasp (Likert 4 or 5) and suboptimal grasp (Likert 1, 2 or 3) and compared between groups using Fisher's exact test. Potential associations between pain at tenaculum placement and patient demographics or physician experience were subsequently analysed using Wilcoxon rank-sum tests or Kruskal-Wallis tests. All analyses were performed in R 3.3.1 (R Core Team, 2016).

Patient and public involvement

There was no direct patient and public involvement.

RESULTS

A total of 70 women were assessed for eligibility. Four women declined to participate. Sixty-six women were enrolled and randomised between 10 January 2017 and 23 February 2017. All 66 women were included for analysis, with 33 in each group (figure 1). All women received their randomised method. Baseline characteristics for participants were summarised and appeared similar between tenaculum placement methods (table 1).

Pain scores at time of tenaculum placement are shown in figure 2. The VAS pain score medians were 44 (IQR=21, 63) in the slow placement group and 32 (IQR=19, 54) in the cough method group; this difference was not statistically significant (p=0.16). Because we saw no statistical difference in pain scores between randomisation groups, the groups were combined for assessment of other potential confounders of pain scores. These comparisons of tenaculum pain are presented in table 2. We observed that anxiety level was significantly associated with increased tenaculum pain scores (p=0.01). Patients with no/mild anxiety reported a median score of 29 (IQR=18.2, 54.8) while patients with moderate/severe anxiety reported a median score of 54 (IQR=32, 66.5). There was no

Table 2 Comparing tenaculum pain scores by level of training, parity, anxiety, chronic pain, race and education

Parameter	Comparison groups	N	Median (IQR)	P value
Methods	Slow placement	33	44 (21, 63)	0.16
	Cough	33	32 (19, 54)	
Provider's level of training	First/second-year resident	13	32 (18, 55)	0.42
	Third/fourth-year resident, attending	53	36 (20, 62)	
Parity	Nulliparous	33	38 (19, 62)	0.75
	Multiparous	33	35 (20, 58)	
Anxiety	No or mild anxiety	46	29 (18.2, 54.8)	0.01
	Moderate or severe anxiety	20	54 (32, 66.5)	
History of chronic pain	History of chronic pain	9	62 (36, 72)	0.10
	No history of chronic pain	57	32 (20, 56)	
Race	Black or African American	22	36.5 (26.5, 59)	0.65*
	White or Caucasian	32	34 (19, 56)	
	Other	12	29 (18, 62)	
Education	High school/GED	16	40 (26, 68)	0.33
	College/graduate degree	50	32.5 (20, 56)	

*Kruskal-Wallis test.
GED, general educational development.

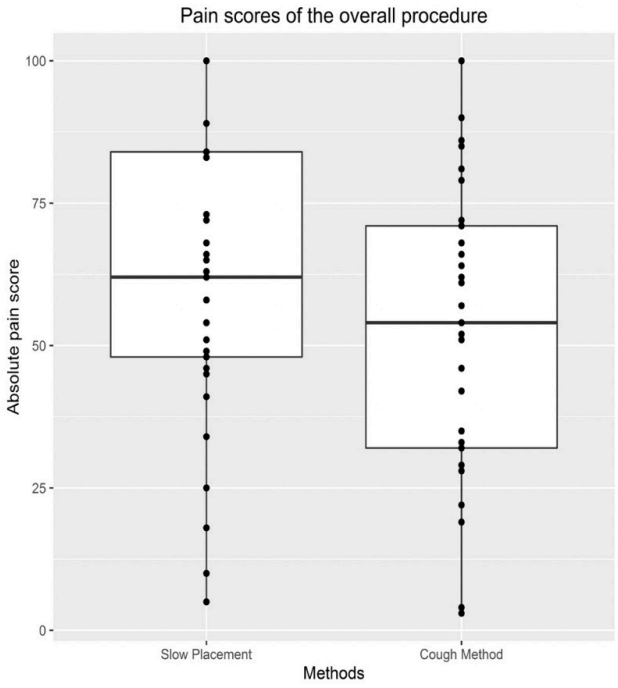

Figure 3 Pain scores on visual analogue scale for overall intrauterine device insertion procedure.

evidence of differences in pain scores in other comparisons shown in table 2.

Overall pain scores after procedure completion are shown in figure 3. The scores did not differ by group, with a median pain score for overall pain of 62 (IQR=48, 84) in the slow placement group and 54 (IQR=32, 71) in the cough method group (p=0.12).

Provider satisfaction with tenaculum grasp was dichotomised into optimal and suboptimal grasp. We observed that 26/33 (79%) providers in the slow placement group had optimal grasp compared with 27/33 (82%) providers in the cough method group. There was no association between optimal grasp and method of tenaculum placement (p=1). Similarly, optimal grasp was not associated with provider's level of training (p=0.71). There were 10/13 (77%) providers in the novice group who had optimal grasp compared with 43/53 (85%) in the expert group.

DISCUSSION

The method of tenaculum placement was not associated with differences in pain scores at the time of IUD insertion. We found that provider satisfaction with tenaculum grasp was not affected by method of placement. The VAS pain scores in our study were comparable to scores reported in previous studies for tenaculum placement.[3 4] Although the studies referenced considered a minimum VAS score of 13 mm as clinically significant, 16 mm was the upper limit of the 95% CI and was chosen to power our study. Similar to previous studies, we did observe a difference in pain perception related to general anxiety.[4 6] Previous studies suggest a difference in pain with IUD insertion based on vaginal parity.[8] We did not confirm this finding in our study. A study by Speedie *et al* comparing pain and ease of use of two different stabilising forceps during IUD insertions similarly found no difference in pain between groups but acknowledged that a larger study may demonstrate clinically significance differences in women's experience of pain.[9]

A major strength of this study is that it was a randomised trial performed at a single site with providers that placed IUDs using the same protocol. Our results are generalisable as this study included providers with varying experience, patients from various backgrounds with very minimal exclusions, and did not restrict IUD type. Thirteen distinct providers were involved in placement and two distinct IUD types were utilised. Another strength was the use of the VAS. In the absence of a gold standard for pain measurement, the VAS has grown in popularity due to ease of administration, good test-retest reliability, and its ability to detect pain.[10 11] Finally, the major strength of this study is its importance in clinical practice. The majority of providers in the USA are commonly taught to use the tenaculum in one of two ways, slowly or via the cough method. Despite anecdotal beliefs about which method is superior, they have not previously been compared directly.

One limitation of this study was the decision to not blind patients to their intervention. This could have been accomplished by having all patients cough despite method of tenaculum placement. In that scenario, some patients would have it placed quickly at the time of the cough and others would have it placed slowly after the cough without being aware of which method they received. However, providers who practise the cough method assume the distraction obtained at the time of a cough may account for some of the decreased pain sensation, so if patients were blinded in this manner, we might have introduced a confounding factor in measuring pain between groups. To counter this, however, results were likely to have been unaffected by the unblinded nature of this study since it is unlikely that participants were biassed to the belief that one method was better than the other.

An additional limitation is the potential for unmeasured confounders. Since we observed a significant difference between anxiety and reported pain, anxiety level or the use of anxiolytics may have impacted scores in both groups. Similarly, the presence of a support person,[10] use of narcotics, anxiolytics, type of IUD, or prior IUD insertion may have been additional confounders.

In conclusion, our findings suggest that providers can use the method most preferable to them for tenaculum placement.

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