Title:

Pain perception with cervical tenaculum placement during office procedures: A randomized controlled trial

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Introduction

Gynecology is undergoing a transformation in the location of care delivery. As a result of technological innovations, procedures are migrating from the hospital and ambulatory surgical center to the office setting. There are numerous advantages to office-based procedures. They include reduced patient expenses, improved scheduling convenience, favorable provider reimbursement, enhanced continuity of care, and patient satisfaction.[1] However, success of office-based procedures is based on numerous factors such as patient selection, physician competency, teamwork and communication, along with adequate and safe anesthesia.[2]

The goal of most office-based procedures is twofold: (1) to be able to safely and successfully perform the procedure, and (2) patient comfort. The experience of pain is influenced not only by physical factors but also by psychological and social factors. Regardless of procedure type, anxiety, depression, and a woman's anticipation of the pain she will experience are strong predictors of the pain experienced during office gynecologic procedures. For procedures that involve cervical dilation and passage of a device or cannula through the internal os of the cervix, a history of dysmenorrhea, nulliparity, and postmenopausal status are associated with increased pain.[3]

The importance of patient counseling and patient selection remains pivotal in success of in-office procedures.[4] Numerous studies have focused on optimal pain control during in-office procedures analyzing analgesia, anesthesia, anxiolytics, combination regimens, local anesthesia, and nonpharmacologic techniques. The indisputable evidence thus far supports the idea that a multimodal approach may be most effective in achieving adequate pain control.[3,4] However, what steps can we take with our procedural methods to further improve patient comfort.

In most gynecologic procedures involving cervical and uterine instrumentation, the single-toothed tenaculum is used for stabilization and traction, and allows descent of the uterus within the speculum. Most importantly, the tenaculum decreases the flexion of the uterus and eases passage of instruments into the endometrial cavity. Tenaculum placement generally precedes insertion of intrauterine devices, removal of intrauterine devices, endometrial biopsy, uterine aspiration, and hysteroscopy. Despite the very frequent use and importance of the tenaculum, few studies directly compare methods to decrease pain with tenaculum placement.[3]

Commonly described strategies for tenaculum placement include slow placement of the tenaculum, having the patient cough while the tenaculum is placed, use of atraumatic tenaculums, and/or application of local anesthetics.[3]

Doty et.al published a randomized control trial of 80 women randomized to the use of vulsellum or a single-tooth tenaculum during IUD insertion. Their primary outcome was reported pain. They found pain scores at the time of tenaculum placement to be the same in both groups.[5]

Goldthwaite et.al investigated the effect of local anesthetics on pain at the time of tenaculum placement. Seventy-four women were randomized to receive 1% lidocaine intracervical injection or topical application of 2% lidocaine gel to the cervix immediately prior to tenaculum placement. The primary outcome was pain at time of tenaculum placement. They found that women who received injection had lower mean pain levels at tenaculum placement but higher mean pain levels with study drug application. Both outcomes were statistically significant.[6]

The two commonly described strategies for tenaculum placement, slow versus having the patient cough while the tenaculum is placed are utilized by providers based on preference and/or their previous training. There is no published study that compares these methods to one another. Doty and Goldthwaite utilized each method separately. In Doty's study that compared tenaculum type, patients were asked to cough at time of vulsellum or single-tooth tenaculum placement, no local or systemic analgesic was used, and pain was measured using a 100-mm visual analog scale.[5] In Goldthwaite's study that compared lidocaine injection versus jelly, the tenaculum was closed slowly over 3 seconds and pain was rated using a 100-mm visual analog scale.[6] Our study aims to compare these strategies, slow tenaculum placement versus the cough method, and their effects on pain at time of placement. Provider satisfaction with tenaculum placement will be measured as a secondary outcome. Overall pain with IUD insertion will also be a secondary outcome. I hypothesize that slow tenaculum placement is less painful to patients and offers higher provider satisfaction scores.

Methods and Materials

Randomized controlled trial from December 2016 to April 2017 at Duke University Medical Center Gynecology Clinics.

Data to be collected from each subject prior to randomization:
-Age
-Parity
-Race
-Highest education level achieved
-Number of cesareans
-BMI
-History of chronic pain
-Daily narcotic use
-GAD7 Score

Inclusion criteria:
-Women ages 18 years and older
-Undergoing IUD placement
-English or Spanish speaking

Exclusion criteria:
-Primary language other than English or Spanish

Sample size determination
Visual analog scale (VAS) is a continuous scale comprised of a horizontal or vertical line, usually 10 centimeters (100 mm) in length, anchored by 2 verbal descriptors, one for each symptom extreme. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 100). The respondent is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity. Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0-100. The following cut 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).[7] Todd et.al in their quest to address the question of clinical significance of VAS scores, found that 13 mm is the minimum mean change on a standard 100-mm visual analog pain scale that should be considered clinically significant for acute, traumatic pain.[8] This finding was later validated in a prospective, observational cohort study by Gallagher et.al.[9]

We have chosen a 16 mm difference on a standard 100-mm visual analog pain scale as value of clinical significant. In order to detect at least a 16 mm difference with 90% power and alpha of .05, we estimated a total sample size of 66.

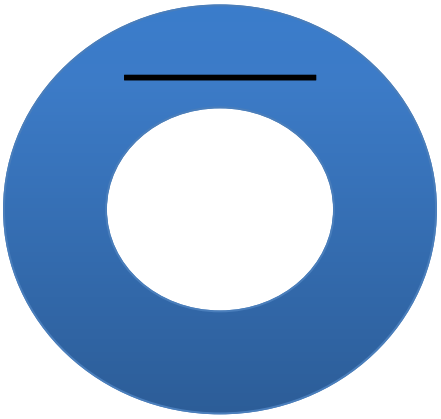
Randomization:
All patients meeting study criteria will be randomized using computer generated random numbers (randomization.com). This is not a blinded study so patients and providers will be aware of the group each subject is randomized to. This randomization will be revealed prior to speculum placement.

Procedure at time of IUD insertion:
A single-tooth tenaculum will be used in placement of all IUDs. Each subject will be placed in the standard dorsal lithotomy position. To start data collection, each subject will be asked to rate their baseline pain. After speculum placement, and adequate visualization of the cervix by the provider, the subject will be asked to rate their pain using a 100-mm visual analog scale. The provider will then place the tenaculum on the anterior lip of the cervix closing to the first ratcheted click over a 5 second period. At this point, the subject will be asked to rate their pain using a 100-mm visual analog scale. If the subject was randomized to the cough arm, the subject will be asked to give one strong cough. This first cough will serve as a test cough. If provider is pleased by the strength of the patient's cough, the subject will then be asked to cough again and at this cough the tenaculum will be placed on the anterior lip of the cervix. Only one test cough will be allowed. At this point, the subject will be asked to rate their pain using a 100-mm visual analog scale. All subjects will be asked to rate their overall pain at the completion of the procedure. The provider will be asked to rate their satisfaction with tenaculum placement on a Likert-type 5 point satisfaction scale. 1: not at all satisfied, 2: slightly satisfied, 3: moderately satisfied, 4: very satisfied, 5: extremely satisfied.

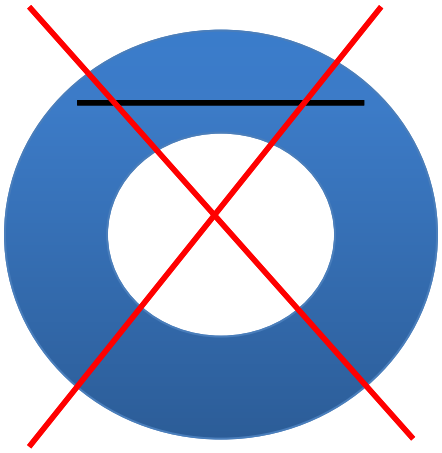
A script will be read by the provider during the process of IUD insertion. The script reads as follows.

Provider Says: First, we will place each foot in its footrest. Please lay back and slide your bottom downward towards me. I will tell you when to stop. On your scoring sheet, please mark your pain at this time.
Provider does: Place speculum and achieve adequate visualization of the cervix.
Provider says: On your scoring sheet, please mark your pain at this time.
Provider does: Clean cervix. Place tenaculum on anterior lip of cervix in accordance to your randomized group.

Slow Method
The tenaculum is to be placed on the anterior lip of the cervix.
After visualization of the anterior lip of the cervix, open the tenaculum and close it slowly over 5 seconds to the first ratcheted click. No more than 1 cm of cervix should be grasped between your tenaculum teeth.



Maximum amount of cervix to grasp



Too much cervix grasped

Cough Method
The tenaculum is to be placed on the anterior lip of the cervix.
After visualization of the anterior lip of the cervix, ask the patient to give a strong cough. If you are pleased with the cough (cervix remained in view during cough), then ask the patient to cough once more. During the cough, the open tenaculum should be closed on the anterior lip of the cervix to the first ratcheted click. No more than 1 cm of cervix should be grasped between your tenaculum teeth.

Provider says: On your scoring sheet, please mark your pain at this time.
Provider does: Sound uterus, place IUD, cut strings, remove speculum.
Provider says: On your scoring sheet, please mark your pain at this time.

Subject Compensation – Subjects will be given $10 incentive for participation in this study.

Consent Process – Participants will be given adequate time for consent, will be consented in private areas, and will not receive undue influence from study staff to participate. They will be told that declining to participate will not affect their access to healthcare. Steps will be taken to

ensure their privacy. If a participant cannot read the consent or is blind, the consent will be read to them. Subjects who cannot give legal consent will be excluded.

Study Interventions – Not an intervention study. Tenaculum placement will be done as per standard of care procedure.

Risk/Benefit Assessment: No additional risk is placed on the patient by participation in this study as the use of tenaculum is standard procedure. Possible complications include those related to IUD insertion, which is the purpose of their visit. These standard risk include bleeding, infection, uterine perforation, failure of IUD for contraception, need for further procedures at time of removal.

Subjects will be monitored for the standard time after IUD insertion, which is usually until they are able to sit up right and ambulate without lightheadedness or dizziness. Any adverse events will be reported to the IRB per IRB policy. Under this protocol, any time a patient has a post-procedure complication, the attending physician who performed the procedure should be notified. Additionally, we have requested in the consent form that patients contact their provider who performed the procedure, should a complication occur in order to capture patients who may present to outside emergency departments.

There is no direct benefit for any individual subject. The potential knowledge to be gained from this project may make a significant contribution to clinical practice.

Costs to the Subject –Participation will not result in any costs to subjects.

Data collection:
REDCap, web-based password-protected relational database will be created prior to study initiation. All patients consented for the study will have a REDCap generated subject ID code. This code will be used for subject identification. The REDCap database will also store the following information from each subject ID; age, parity, race, level of education, the patient's pain responses, and provider satisfaction.

Statistical analyses:
We will compare groups on the primary outcome of pain using T-tests versus Wilcoxon test pending the normality of the results. We will compare groups on the secondary outcome of provider satisfactions with placement using Chi-square test or Fisher's exact test. We will evaluate for potential correlations based on patient demographics and physician experience.

Privacy, Data Storage & Confidentiality – All paper data will be kept secured in a locked cabinet in Dr. Beverly Gray's office. The data will be retained until the conclusion of the data analysis, then destroyed per IRB guidelines. Only the PI and the personnel listed will have access to the paper data.

During data collection, subject identifiers and relevant data elements will be recorded in the RedCap database. Then, study-specific identification numbers will be assigned to each subject. Prior to dissemination of any information in this database beyond the DUMC's secure servers or firewall, all identifiers will be stripped from the database and data will only be referenced by the study-specific identification numbers. Deidentified data exported from RedCap will be stored in an excel spreadsheet, on a secure network folder managed by the department of Obstetrics and Gyneoclogy in on a secure server behind the Duke University Medical Center firewall. Only study staff listed as key personnel with the IRB will have access to the study folder. The name of the secure network folder will be the same as the IRB protocol number.

A master log, which links the study-specific identification number to the study subject, will be generated. The master log will be stored on the same secure network server mentioned in the above paragraph.

Any publications or presentations that result from this research will not identify any subjects individually, and will present data in aggregate form only.

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