Paracervical block with IUD insertion versus no paracervical block IRB

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Protocol Title:	Paracervical block versus no paracervical block during IUD insertion
Principle Investigator:	Pamela Berens
Co-Investigators:	Neda Jooya
Population:	50 Adults who present for IUD insertion at several UT Physicians Obstetrics and Gynecology clinics.
Number of sites:	Three: Dr. Patti Jayne Ross OB/GYN Continuity Clinic: UTPB Suite 350; UT Physicians Women's Center- TMC: UTPB Suite 250; UT Physicians Women's Center- Bellaire: 6700 West Loop South, Suite 450
Study duration:	October 2016 until completion (anticipated 1 year)
Subject duration:	20 minutes or less to place block and insert IUD

General information

We propose to compare paracervical block versus no local analgesia in women who present for IUD insertion. We will compare the patient's procedural pain level with tenaculum placement and IUD insertion using paracervical block versus no analgesia during the IUD insertion procedure..

Background Information

In the United States, approximately 7% of women used intrauterine devices (IUD) for contraception in 2012 (Guttamacher institute). To date, no standard method of pain control with IUD insertion has been proposed or adopted. IUDs have a less than 1% rate of failure depending on the type of IUD used and have a high rate of compliance. Some barriers to women obtaining the IUD are: cost and the perceived pain associate with IUD insertion including stimulation of cervical parasympathetic

and sympathetic nerve fibers and prostaglandin release. Some research has been done on the difference in pain experienced with IUD insertion using paracervical block with conflicting results (Mody, Cirik). In a study of nulliparous women, 2% topical lidocaine gel has been found to be effective for pain relief at the tenaculum site however it's use in a clinical setting is uncommon (Rapkin, et al). This study involved self-administration of the topical product prior to the procedure and may be distasteful to some patients. Despite the controversy regarding the effectiveness of various techniques for pain management, a recent revision of the U.S. Select Practice Recommendations for Contraception (2016) includes a recommendation that "paracervical block with lidocaine might reduce patient pain during IUD insertion."

We are interested in performing an open label randomized controlled trial of local block versus no local block in a group of women who present to the Dr. Patti Jayne Ross OB/GYN Continuity Clinic, the UT Physicians Women's Center, and the UT Physicians Women's Center- Bellaire for IUD insertion. Individual providers vary in their use of a local block for pain with IUD procedures. We will collect data on the vital signs of each woman undergoing an IUD insertion procedure. We also plan on collecting demographic information on each patient involved in the study. We plan on assessing the pain of each individual throughout each individual IUD insertion procedure using a visual analogue pain scale. Each patient will be randomized to receive either a paracervical block or no local analgesia. A standard protocol for administration of paracervical block will be delineated, distributed, and used for the study. Patient pain will be assessed prior to, during the placement of tenaculum, and after the procedure using the visual analogue scale tool.

The study will take place at the clinics mentioned above. IUD placement will be carried out by residents and faculty at the Memorial Hermann and LBJ Hospital Obstetrics and Gynecology residency programs rotating through the aforementioned clinics.

Objectives

We would like to compare patient pain perception in IUD insertion when using paracervical block versus no block. We aim to improve pain in this patient population.

Study Design

The study will be an open label randomized controlled trial. Each woman will be consented to the study and either randomized to receive paracervical block or routine care (no local analgesia). The level of pain of each woman will be assessed before the procedure but after placement of the speculum, during placement of the tenaculum, and after the procedure by using a visual analogue pain assessment scale. Vital signs will also be taken prior to and after completion of the procedure.

Each patient will be consented prior to the study.

We would like to assess the following in each of the study participants undergoing the IUD insertion procedure.

a) Age, race, gravity, and parity

b) Type of IUD received

c) Randomization status, i.e. whether each participant received a paracervical block or not

d) History of vaginal, pelvic, or cervical surgery

e) History of sexually transmitted infection or pelvic inflammatory disease

f) Vital signs (including but not limited to blood pressure, respiratory rate, pulse, and oxygen saturation) before and after the procedure

g) Patient rating of pain before, during tenaculum placement, and after the procedure.

h) Complications associated with IUD insertion procedure or block itself (i.e.: cervical stenosis requiring dilation, failure of IUD placement, bleeding)

i) Other pain medications taken by the patient on the day of but prior to the procedure

Study Population

Women of reproductive age, having IUD placed at the Dr. Patti Jayne Ross OB/GYN continuity clinic, The UT Physicians Women's Center, and the UT Physicians Women's Center- Bellaire during the study time.

Inclusion criteria:

Women of reproductive age between ages 18 and 52 who present for an IUD insertion procedure.

Exclusion criteria: Women less than age 18 and greater than age 52, women with current PID, women who are not good candidates for an IUD, and patients who have a Lidocaine allergy.

Women aged 18 and over will undergo a consent process prior to being enrolled in the study.

Study Procedures

Women who meet inclusion criteria who present to the abovementioned locations will be informed of the study, and those agreeing will be asked to sign a consent.

These patients will be informed that routine care for our practice is no analgesia. These women will then be randomized to either a group getting no analgesia during the IUD insertion procedure and those receiving a paracervical block with 1% Lidocaine prior to the procedure. An established protocol will be used for the paracervical block arm of the study. Patient vitals will be assessed 5 minutes prior to procedure and 5 minutes after procedure. Patient pain scale will be assessed after speculum placement but prior to any procedure, with tenaculum placement and after placement of the IUD. All complications associated with the IUD insertion procedure will also be analyzed as will failure to successfully insert the IUD.

The following paracervical block protocol will be used for this study:

Paracervical block protocol (Study arm)

Tools:
Speculum
10 cc syringe
1% Lidocaine
Single tooth tenaculum

1. Obtain consent and randomization
2. Perform pre-procedure vital signs
3. Insert the speculum into the vagina
4. Perform pain scale #1
5. Identify the cervix
6. Apply Betadine to the cervix and surrounding vaginal tissue
7. Insert the syringe into the cervico-vaginal junction at 12 o'clock (the anticipated tenaculum site). Inject 2 cc of Lidocaine at the tenaculum site on the cervix, making sure to first draw back on the plunger to ensure that the needle is not inserted into a blood vessel.
8. Place tenaculum at the anterior lip of the cervix at 12 o'clock
9. Perform pain scale #2
10. Inject 3 cc of 1% lidocaine and 4 and 8 o'clock position of the cervix. Ensure that you insert the syringe into the cervix at the cervico-vaginal junction and withdraw the plunger to ensure the needle is not inserted into a blood vessel prior to injecting.
11. Wait 3 minutes after last injection before starting IUD insertion procedure
12. Insert IUD
13. Perform pain scale #3
14. Cut IUD strings and remove all instruments from the vagina
15. Perform post procedure vital signs

Paracervical block protocol (Control Arm)

Tools:

Speculum
Single tooth tenaculum

1. Obtain consent and randomization
2. Perform pre-procedure vital signs
3. Insert the speculum into the vagina
4. Perform pain scale #1
5. Identify the cervix
6. Apply Betadine to cervix and surrounding vaginal tissue
7. Place tenaculum at the anterior lip of the cervix at 12 o'clock
8. Perform pain scale #2
9. Insert IUD
10. Perform pain scale #3
11. Cut IUD strings and remove all instruments from the vagina
12. Perform post procedure vital signs

Statistics

Demographic characteristics will be assessed and described using descriptive variables. Vital sign assessment and pain scale assessment will be described using numerical categories. A two tail T-Test will be used to assess the data and we will look for a 20% difference in the pain score.

Ethics

IRB approval will be sought with the University of Texas system.

Informed consent in writing will be obtained in English from each individual prior to enrollment. No coercion will be used. Recruitment and consent will be obtained by Dr. Jooya and a group of previously authorized and trained residents and attendings working out of the clinic.

Data handling and record keeping

Participant information will be stored on encrypted computers owned by Drs. Berens and Jooya.

Quality control and assurance

All data collection will be taken by previously authorized members of the aforementioned residency programs.

Publication plan

Results are planned for publication. Participants will not be notified of results.

Sources:

Mody et al. *Pain control for intrauterine device insertion: a randomized trial of 1% lidocaine paracervical block.* Contraception 86 (2012) 704-709.

Cirik et al. Paracervical block with 1% lidocaine for pain control during intrauterine device insertion: a prospective, single-blinded, controlled study. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2013 Sep;2(3);263-267

Rapkin RB, Achilles SL, Schwarz EB, et al. Self-Administered Lidocaine Gel for Intrauterine Device Insertion in Nulliparous women: A Randomized Controlled Trial. Obstet Gynecol. 2016 Sep;128(3):621-8.

Lopez LM, Bernholc A, Zeng Y, Allen RH, et al. Interventions for pain with intrauterine device insertion. Cochrane Database Syst Rev. 2015 Jul 29;(7):CD007373. Review

US. Selected Practice Recommendations for Contraceptive Use, 2016 MMWR July 2016/65(4);1-66.

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