Effect of Paracervical Block Volume on Pain Control for Dilation and Curettage.o

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Protocol:

We conducted a multi-site, randomized single-blinded clinical trial comparing pain control at the time of cervical dilation with two different paracervical blocks in patients undergoing D&C in the first trimester for either induced abortion or early pregnany loss (EPL) management. The study took place from October 2018 to December 2020 at the University of California, San Diego (UCSD) and the University of California, Los Angeles (UCLA). The institutional review board of the University of California, Los Angeles approved the protocol and relied on the IRB approval of the University of California, San Diego. Consort guidelines were used for reporting.

After performing a history, physical examination, and ultrasound if indicated, and completing informed consent for clinic D&C under minimal sedation, participants were recruited by a separate study team member. Written informed consent for the study was then obtained. We included participants ages 18 years and older presenting to UCSD or UCLA outpatient family planning clinics with an undesired pregnancy or early pregnancy loss measuring <11 weeks 6 days gestation on ultrasound, who speak English or Spanish and desire to have a clinic D&C. We excluded patients with pregnancy of unknown location, inevitable or incomplete abortion (defined as absence of a gestational sac on ultrasound and/or open cervical os), desire for general anesthesia or IV sedation, history of chronic pain conditions, and history of any medical comorbidities that are a contraindication to performing the procedure in the clinic setting. We also excluded patients if they declined or had an allergy to ketorolac, oral midazolam, or any component of the paracervical block or if they took any pain medication or misoprostol the day of the procedure.

Before the procedure, the study team member enrolling the participants performed a baseline survey detailing the participant's age, race, ethnicity, obstetric history, history of cervical procedures, baseline pain using the 100mm VAS and the GAD-7, a validated measure of anxiety.[14] The participant then received 60mg IM ketorolac, 10mg oral midazolam, and 500mg PO azithromycin 30-35 minutes prior to the procedure perstandard practice at the UCSD clinic.

Randomization was stratified by site and was performed using 85 blocks of 4 and 6 which were varied randomly. A statistician not involved in enrollment prepared sequential, sealed, numbered, opaque envelopes containing a card with computer-generated assignment. The envelopes were chosen in consecutive order by research assistants at the time of randomization, and the participant's initials were written on the envelope. The physician performing the procedure (which consisted of residents, fellows, and attendings) then opened the envelope and prepared the designated paracervical block, as it is standard practice for physicians to prepare their own paracervical blocks prior to performing any D&C in-clinic. The low volume block contained 20mL of 1% lidocaine (diluted in saline), and the high-volume paracervical block contained 40mL of 0.5% lidocaine (diluted in saline). The paracervical block in both arms contained 2U Vasopressin and 2mL of 8.4% sodium bicarbonate. The contents of each paracervical block were drawn from their respective vials, mixed in a sterile cup, and drawn into 2 separate 20mL syringes (10mL in each syringe for the lower volume block). The physician brought the paracervical block on a covered tray into the clinic room where the procedure was performed and the study participant and team member assessing the outcomes were blinded to study group. The block technique was standardized. Before placement of the tenaculum, 2mL of the designated block was injected on the anterior lip of the cervix. The remainder of the block (either 18 mL or 38 mL depending on the group) was then injected paracervically at four points around the cervix at the cervico-vaginal junction, initially injecting half of the block superficially and advancing to a depth of three centimeters and injecting the remaining block, which is consistent with prior literature.[5,15,16] The duration of the injection was timed. We waited 3 minutes between completing the injection and starting the cervical dilation. The procedures were performed with manual uterine aspiration (MUA). To better standardize the impact of any verbal

interaction on pain during the procedure, the physician performing the suction D&C was given a standard script to inform the patient of each next step. A member of the study team, who was blinded to the type of paracervical block, presented the VAS to the participant and asked the participant to mark level of pain at baseline, speculum insertion, paracervical block placement, cervical dilation, immediately after uterine aspiration, 10 minutes after the procedure, and overall pain. Additionally, after paracervical block placement, the participant was asked about side effects. The study coordinator recorded the duration of the procedure.

After the procedure, the clinician answered a brief questionnaire detailing any adverse events or challenges related to either the paracervical block or the D&C. The clinician also noted how much cervical dilation was performed, the size of the suction cannula used for uterine aspiration, 113 if a repeat aspiration was needed for an incomplete D&C after examination of the products of conception, if an intrauterine device (IUD) was placed and their level of training. The participant indicated overall pain and answered questions about satisfaction with pain control.

Statistical Analysis Plan:

The primary outcome was difference in median pain scores on the VAS during cervical dilation. The secondary outcomes were differences in median pain scores at block placement, uterine aspiration, 10 minutes after the procedure, overall pain, and side effects. Analyses were performed among each study strata (induced abortion and EPL) and in the overall cohort. Bivariate comparisons were analyzed using chi-squared tests or Fischer's exact tests for categorical variables and t-tests or Wilcoxon rank-sum tests for continuous variables as appropriate. The primary outcome (pain score at time of cervical dilation) was evaluated per intent-to-treat analysis. Rates of minor side effects (transient lightheadedness, tinnitus, circumoral tingling, and a metallic taste in the mouth) and major adverse events (seizure and cardiopulmonary arrest) were recorded.

We performed univariate and multivariate analyses for each potential confounder with the outcome of interest to determine which predictors to include in the multivariable analysis for each pain point and included covariates associated with a p-value of <0.20. All analyses were performed using RStudio (2021).

Prior literature suggests that a 13-mm to 20mm difference in pain is clinically meaningful. Similar studies of paracervical blocks during D&C procedures have found a standard deviation in the VAS of 26mm, which was used to calculate the effect size.[15,16]. We estimated that to detect a more subtle 15mm or greater difference in pain at the time of cervical dilation with 80% power and a two-sided alpha of 0.05, a total of 104 participants was required. Therefore, the study was powered to detect a 15mm difference in pain control in the overall cohort. This allowed for the power to detect a 20mm or greater difference in pain at the time of cervical dilation within each strata (induced abortion and EPL).