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Original research article

Patient choice of adjunctive nonpharmacologic pain management during first-trimester abortion: a randomized controlled trial☆,☆☆

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ABSTRACT

Objective: To determine if offering patients a choice of adjunctive nonpharmacologic pain management during first-trimester aspiration abortion results in lower pain scores when compared with standard care.
Study design: We enrolled women receiving first-trimester aspiration abortion at the University of Hawaii. We randomized patients to standard care (control) or standard care plus a choice of nonpharmacologic pain management options (intervention). Standard care was ibuprofen 800 mg orally at least 30 min preprocedure, lidocaine paracervical block and anticipatory guidance from the provider. We measured pain on a 100-mm visual analog scale immediately postprocedure with adequate sample size to detect a 20-mm difference in pain scores.
Results: Seventy-four women participated in the trial and reported an overall mean pain score of 61.9±27.0. Participants in the control and intervention groups reported similar overall mean pain scores (control 60.6±28.8, intervention 63.3±28.5). We found procedure time, complications, provider-perceived case difficulty and patient satisfaction with pain management to be similar between groups. Providers underestimated participant pain compared to participants' own scores (mean physician estimate of participant pain: 46.3±18.5, mean participant pain score: 61.9±27.0, $p<.01$). Intervention group participants most frequently selected ambient music (59%) as the nonpharmacologic intervention. Forty-one percent (15/37) of participants in the intervention group chose more than one nonpharmacologic intervention.
Conclusions: Participants in the control group reported similar pain scores to participants in the intervention group. Procedure time and difficulty were similar between the two groups.
Implications: Incorporating patient choice into a nonpharmacologic pain management model did not result in lower pain scores. This approach did increase the patient's visit time. Abortion providers frequently use nonpharmacologic pain management in the United States, and these techniques did not negatively impact patient pain scores in our study.

1. Introduction

Approximately 90% of abortions performed in the United States occur in the first trimester, and the majority are office- or clinic-based aspiration procedures. [1, 2] Patients commonly report moderately severe pain during office-based abortion, but it is a short procedure and pain returns to baseline within 30 min [3, 4].

Patients and providers choose a pain management regimen for first-trimester abortion based on preference, risks, costs and effectiveness [5, 6]. Paracervical block is associated with lower morbidity than sedative anesthesia and does not increase procedure or recovery time. However, the efficacy of paracervical block is limited, and the injection itself is painful [7, 8]. Other interventions, such as intravenous opioids and oral sedatives, are effective but require intravenous line placement, licensed personnel and a recovery room, all of which add cost, time and risks to the procedure. [8]

The appeal of nonpharmacologic adjuncts comes from their potential to improve pain without a substantial increase in risk or cost. Approximately 90% of respondents to a nationwide abortion provider survey indicated that they use at least one adjunctive nonpharmacologic technique during first-trimester abortion [6, 9, 10]. While the prevalence of these practices indicates that providers see some value in their use, to date, the evidence of the effectiveness of nonpharmacologic pain management

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techniques is conflicting. Prior studies found that offering nonpharmacologic techniques did not result in lower pain scores, but patients in these studies did report that they found the techniques helpful and recommended their future use [11].

The evidence about nonpharmacologic pain management during abortion is not conclusive but does offer guidance about next steps for research. Ambient music has been shown to be effective in other surgical settings and may be preferable to music played through headphones [12–14]. Meditation can regulate emotions and reduce pain, even among people who have never meditated before [15–17]. Clinical and qualitative abortion research also indicates that support from a compassionate staff member can have a meaningful impact on a patient's experience [13, 18, 19].

Freedom of choice and control reduce anxiety and improve satisfaction in health care settings. [20–22]. Choice appears also to increase analgesic effect even when the treatment options are both placebos [23]. Considering the evidence favoring patient choice, we hypothesized that the act of choosing a nonpharmacologic intervention, rather than the particular intervention itself, could be associated with lower maximum pain scores during abortion.

2. Materials and methods

We conducted this randomized controlled trial at the Women's Options Center at the University of Hawaii Department of Obstetrics, Gynecology and Women's Health in Honolulu, Hawaii. The University of Hawaii Human Studies Program Institutional Review Board approved the study, and we registered the trial at clinicaltrials.gov (NCT02590146).

As this is an academic practice, faculty, family planning fellows and obstetrics and gynecology residents provide patient care. Standard office practice for first-trimester surgical abortion pain management includes administration of a nonsteroidal anti-inflammatory drug (NSAID), usually ibuprofen 800 mg orally administered at least 30 min before the procedure, and lidocaine 1% 20 mL paracervical block injected at 2 points (4 and 8 o'clock). No patients received cervical priming with osmotic dilators or misoprostol. Physicians provided verbal anticipatory guidance and reassurance as appropriate.

2.1. Eligibility and randomization

We enrolled patients if they were at least 14 years old, were English speaking and had consented for an in-office surgical abortion or miscarriage management for a pregnancy with a gestational age of less than 14 weeks. Patients aged 14–17 years required parental consent for participation in the study. We did not enroll patients who requested that a companion be present for the procedure.

A statistician not associated with the study conducted the randomization using computer-generated blocked random assignment to control or intervention. The statistician then placed the assignments in sequentially numbered, opaque, sealed envelopes, and one of two investigators opened the envelope after obtaining participant consent for the study. In an effort to minimize bias, we did not inform participants of the primary study hypothesis during the consent process, but we instead informed participants that the study aimed to compare the effectiveness of nonpharmacologic pain management techniques versus standard office practice.

2.2. Intervention

One of two investigators (MST, KS) conducted standardized preprocedure counseling for every participant. During this counseling, the procedure was described, step-by-step, in relation to sensations and discomfort that could be expected (Appendix A). Participants in the control group then had a surgical abortion according to standard office protocol.

Investigators then completed a pain management discussion with participants in the intervention group. The investigator asked the participant to recall previous painful procedures and techniques she found helpful in managing that pain. The intention of this part of the intervention, which took approximately 5–7 min and used a structure recommended in clinical guidelines for abortion providers, was to encourage the participant to feel empowered and engaged in her pain management [5]. This counseling also prepared the participant to think about the nonpharmacologic adjuncts that she might be interested in using.

Participants could choose ambient music, physical contact (hand or shoulder holding), provider step-by-step narration of the procedure, a guided imagery meditation or a focused breathing exercise. Ambient music played from the participant or investigator's phone through a streaming service connected to a Bluetooth speaker, and the participant chose the music played. The investigator provided physical contact. The investigators offered a selection of noncopyrighted meditation and breathing recordings based on length, tone and appropriateness to the setting.

Participants could choose one or multiple of these pain management adjuncts, or they could propose their own alternative methods. The investigator emphasized that the choice belonged to the participant. If participants chose multiple interventions that were auditory (e.g., guided imagery and music), both could be offered simultaneously, with volume adjusted to allow the spoken elements to be heard. After choosing their preferred pain control adjunct(s), the investigator provided the intervention while the abortion otherwise followed the standard office protocol.

2.3. Data collection

All participants completed a paper-based 100-mm visual analog scale (VAS) to assess baseline pain. The scale was labeled with anchors of 0 (*no pain*) and 100 (*worst pain ever felt*). Participants also reported baseline anxiety on a 100-mm VAS which was labeled with anchors of 0 (*no anxiety*) and 100 (*worst anxiety ever felt*) and completed the State–Trait Anxiety Inventory (STAI), which assesses both acute (state) and general (trait) anxiety. Previous abortion studies have used this inventory to evaluate anxiety in relation to pain [4, 12]. We obtained demographic information and an abbreviated medical history noting known predictors of increased pain during abortion [4, 24]. As many people in Hawaii identify as multiracial, participants were able to select every race category they identified with in addition to selecting their ethnicity.

Immediately following the completion of the procedure, we collected VAS scores for overall procedural pain. At 10 min postprocedure, participants completed a VAS of current pain and overall satisfaction with their pain management during the abortion. A member of the study team who had not participated in the preprocedure counseling or intervention collected these data points to limit social desirability bias. We noted length of procedure (speculum insertion through speculum removal or until initiation of IUD insertion). Within 15 min of the procedure, providers completed a Likert scale evaluating procedure difficulty and a VAS estimating their perception of the participant's pain level during the procedure. We did not follow up with participants after their procedure day.

2.4. Sample size and statistical analyses

The primary outcome was the difference in pain scores between the control and intervention groups on the immediate postprocedure 100-mm VAS for overall pain. We determined a 20-mm difference to be a clinically meaningful finding. To find this difference with 80% power and a 2-sided alpha of .05 required 34 participants per group. In anticipation of potential dropout of 10%, we enrolled 6 additional participants for a total of 74 participants. Secondary outcomes included pain at 10 min postprocedure, overall satisfaction with pain control, procedure length and the provider's rating of overall procedure difficulty.

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