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Original Research Article

Auricular acupressure and auricular acupuncture as an adjunct for pain management during first trimester aspiration abortion: A randomized, double-blinded, three-arm trial

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ABSTRACT

Objectives: To measure pain and anxiety during first trimester uterine aspiration when using auricular acupressure or acupuncture as an adjunct to usual care.
Methods: This randomized, double-blinded, three-arm trial enrolled patients undergoing an aspiration procedure for an induced abortion, a miscarriage, or other abnormal intrauterine pregnancy. Trial participants received auricular acupressure, auricular acupuncture, or placebo immediately prior to their procedures. The study began with 1:1:1 randomization, but later overenrolled into the acupressure group after providing retraining for greater fidelity to that intervention. All participants received ibuprofen and a paracervical block. Participants reported pain and anxiety levels via visual analog scores (0–100). Our analysis compared pain scores of those receiving acupressure versus placebo, and those receiving acupuncture versus placebo.
Results: We randomized 177 participants over nine months and excluded data from four participants. We analyzed data from 70 participants who received acupressure, 51 who received acupuncture, and 52 who received placebo. The groups had similar baseline characteristics, including baseline pain and anxiety scores. For acupressure, acupuncture, and placebo groups, respectively, immediate post-procedure median pain scores were 50, 55, 47.5 ($p = 0.88$); maximum pain scores during the procedure were 77, 79, 79.5 ($p = 0.96$); postprocedure anxiety scores were 26, 28, and 21 ($p = 0.47$). The acupressure group results were similar before and after retraining.
Conclusions: Receiving auricular acupressure or acupuncture did not result in lower pain or anxiety scores among women undergoing vacuum aspiration compared to a placebo group.
Implications: The results of this trial were null, thus differing from our previous study that had shown a benefit from auricular acupuncture. Given the conflicting results, incorporating these acupuncture techniques into abortion practice would be premature.

1. Introduction

Of the estimated 862,320 abortions performed in the United States in 2017 [1], most (91%) were performed at <13 weeks, and vacuum aspiration accounted for the majority [2]. Many first trimester vacuum aspirations are performed in outpatient settings with a paracervical block and nonsteroidal anti-inflammatory drugs (NSAIDs) as the only analgesics because moderate sedation and general anesthesia may be too expensive or not readily available [3]. In 2018, The National Academy of Medicine highlighted the existing research gap in optimizing pain management during aspiration procedures [4]. Opioids, anxiolytics, and anticonvulsants, for first trimester vacuum aspirations do not improve pain control [5–9].

Data regarding the effectiveness of non-pharmacological approaches (i.e., relaxation techniques, doulas) to reduce pain during first trimester vacuum aspiration is inconclusive [4, 7, 10].

Nonpharmacological approaches are worth considering as we seek to identify better approaches to minimize the pain women

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experience during an aspiration procedure. In a prior randomized controlled trial at this medical center, participants who received auricular acupuncture as an adjunct to paracervical block and ibuprofen reported lower pain and anxiety scores during first-trimester vacuum aspiration [11]. That trial used a modified battlefield acupuncture (BFA) protocol with 5 points on each ear, including cervix and uterus acupoints [11]. BFA is a type of auriculotherapy created with the goal of delivering rapid pain relief in the military battlefield [12, 13]. The initial findings were particularly promising because the BFA protocol is said to be easily taught. The Uniformed Services University of the Health Sciences (USUHS), a United States military medical school, teaches BFA in two 2-hour sessions [14]. Certain states, however, limit the provision of acupuncture in the clinical setting by requiring far more extensive training and certification. New York, for example, requires 300 hours of training for physicians and over 3000 for nurses to be licensed to provide acupuncture [15, 16].

Using auricular acupressure with adhesive seeds or beads, instead of with acupuncture needles, may prove to be a useful alternative to auricular acupuncture because states do not have stringent training requirements for acupressure provision. Using auricular acupressure achieved pain reduction during labor in a systematic review that included a small number of trials with high heterogeneity [17], but no prior studies have evaluated the effectiveness of acupressure for vacuum aspiration pain management. This study aimed to evaluate auricular acupressure for abortion pain and anxiety control, and to replicate the previous findings of a randomized controlled trial that evaluated auricular acupuncture compared to placebo and usual care.

2. Materials and methods

This randomized, double-blinded, placebo-controlled, three-arm trial took place at a single abortion practice at Columbia University Irving Medical Center (CUIMC). The CUIMC Institutional Review Board approved the study protocol. Study enrollment occurred from March 2019 to December 2019.

Patients seeking an aspiration procedure were eligible for this study if they were age 18 years or older, spoke English or Spanish, had pregnancies less than or equal to 13 0/7 weeks gestation, and were willing to be randomized. We excluded individuals with congenital anomalies or infections of the ear, with ear piercings that interfered with administering the interventions, and those with allergies or contraindications to adhesives, gold, ibuprofen, or lidocaine. Bilingual research staff approached patients after clinic registration, explained the study, determined eligibility, and obtained written consent.

After enrollment, we used a preprogrammed electronic tablet to collect and transmit interview data directly to the Research Electronic Data Capture (REDCap) database. A research assistant collected demographic information, reproductive health history, and worst degree of pain associated with menstruation (on a 4-point scale). We also elicited history of depression or anxiety, medication for depression or anxiety in the previous 24 hours, and acupuncture history (ever/never). To ensure understanding of the 100-mm visual analog scale (VAS) to measure pain and anxiety, participants used the tablet to test the scale with a standardized question. Participants then used the same scale to report their baseline pain (anchors: 0 = no pain, 100 = worst possible pain) and anxiety levels (anchors: 0 = anxiety, 100 = worst possible anxiety) within an hour prior to the procedure.

After the enrollment interview, participants underwent usual clinical care, including a pelvic examination, an ultrasound for pregnancy dating, and consent for the aspiration procedure. All received ibuprofen 800 mg orally about 1 hour before the procedure. Immediately before each aspiration procedure, research staff provided the study auriculotherapist with a sequentially numbered, sealed, opaque envelope containing the treatment group assignment. The participant, research assistant, and clinician performing the aspiration procedure all remained masked to the treatment assignment.

The three intervention groups were (1) auricular acupressure plus usual care, (2) auricular acupuncture plus usual care, and (3) placebo plus usual care. Eight clinicians (5 attending Family Planning Specialists, 2 family planning fellows, and one gynecology nurse practitioner) served as the study auriculotherapists and performed the interventions. Each had received a 2-hour standardized training on applying the modified BFA protocol (Appendix A); this training included didactic instruction and supervised hands-on practice led by a physician who is board-certified and licensed to practice medical acupuncture (MAG). After initial training, each study auriculotherapist completed weekly home practice and sent photographs of placed acupoints to the trainer for evaluation of accurate point location and bead placement. If the trainer identified inadequate placement, she provided feedback to ensure accurate placement.

The eight study auriculotherapists all followed a standardized script to describe the intervention to participants. To support masking, the script noted that the treatment may or may not be felt. After cleaning both ears with alcohol, the study auriculotherapist placed either single-use gold-plated 1.2-mm diameter acupressure beads on a 7.6mm adhesive base (Lhasa Oms Inc, Weymouth MA), single-use 0.2 mm gauge 1.2 mm length Pyonex acupuncture press needles on a 12-mm adhesive base (Seirin-America Inc, Weymouth MA), or 10-mm inert adhesive patches (placebo). The study auriculotherapist placed the beads, press needles, or patches at the designated acupoints, out of the participant's view. When applying each acupressure bead, the study auriculotherapist stimulated the corresponding acupoint by pressing the bead for 10 seconds. We placed the placebo inert adhesive patches to the designated acupoints because in the previous study both the placebo group that received adhesive patches as well as the group that received usual care alone (no adhesive patches) reported the same level of pain [11]. After placements were complete, the study auriculotherapist covered the participant's ears with a surgical cap to maintain blinding.

All participants then received a paracervical block using lidocaine 1% 20 mL (injected at 12, 4, and 8-o'clock), and underwent uterine aspiration by an attending gynecologist, family planning fellow, or gynecology resident. Immediately following procedure completion, defined as speculum removal, the research assistant returned to ask the participant to score current pain, maximum pain during the procedure, and current anxiety using the same 100-mm VAS used at baseline. Participants also responded to satisfaction questions using a Likert scale (1 = very poor, 5 = very good), and reported which of the three treatments they believed they received. After data collection, participants received a $25 gift card for study participation. The research assistant collected procedure details from the aspiration abortion provider, including the indication for aspiration (induced abortion, miscarriage, or other abnormal intrauterine pregnancy). "Other abnormal intrauterine pregnancy" includes molar pregnancy, retained products of conception, or possible ectopic pregnancy. Finally, to further support masking, someone other than the research assistant or the aspiration abortion provider removed the intervention.

The primary trial objective was to evaluate the effectiveness of auricular acupressure as an adjunct to usual care (ibuprofen and paracervical block) for pain management for first trimester aspiration abortion. We compared pain VAS scores between participants randomized to receive auricular acupressure and partic-

ipants randomized to receive placebo patches. The secondary objective was to replicate the prior trial, by comparing pain VAS scores between the auricular acupuncture and the placebo patch group. Finally, we compared anxiety scores for both the acupressure group and the acupuncture group against the placebo group.

We sought to identify a clinically relevant, between-group difference in maximum reported pain of at least 20-mm on the 100-mm VAS scale. To identify an effect size of at least 20-mm, with a pain standard deviation of 30 (calculated from the previous acupuncture study [11]), 80% power, and a two-sided alpha of 0.05, this study required 47 participants in each treatment group, for a total of 141 participants. An individual not involved in any other study activities determined the randomization schedule using a 1:1:1 allocation ratio in blocks of 6. During study team meetings, we identified a loss of fidelity to the acupressure treatment protocol, and thus we retrained all the study auriculotherapists. The problem we identified was that the study auriculotherapists, when applying acupressure beads, in many cases did not press on each acupoint for at least 10 seconds. To achieve sufficient participants for analysis, we increased the number randomized to 175, and changed the allocation ratio to 3:1:1 (favoring acupressure) during the latter part of the study (after retraining).

We used IBM SPSS Statistics for Windows, version 26 (IBM, Armonk, NY, USA) for analysis. We compared demographic and baseline characteristics using χ^2 tests and analysis of variance (ANOVA) as appropriate. We used nonparametric tests to compare the VAS pain and anxiety scores.

We registered the study with ClinicalTrials.gov (NCT03896022).

3. Results

Study staff screened 324 patients of whom 110 declined to participate or were ineligible for the study. Thirty-seven women who gave consent and enrolled did not undergo randomization mainly because no eligible procedure took place ($n = 30$); these patients decided to receive intravenous sedation or to have a medication abortion. In addition, occasionally the study auriculotherapist was not available at the time of the procedure ($n = 4$), or the woman withdrew from the study after consent ($n = 3$). Thus, we randomized 177 participants. We subsequently excluded 4 participants, all from the acupressure group: one withdrew from the study after randomization and 3 did not have a procedure that day. The final analysis included 173 participants: 70 participants in the acupressure group, 51 in the acupuncture group, and 52 in the placebo group (Fig. 1).

Table 1 demonstrates that the baseline characteristics of the participants were similar across the three groups. Self-reported anxiety history was more common in the placebo group ($p = 0.025$), but otherwise the groups were well-balanced. Table 1 also presents the baseline pain and anxiety scores. Pre- and postretraining acupressure groups differed only in the indication for aspiration procedure; induced abortion was more common in the initial group than in the postretraining group (74% vs 53%, $p = 0.03$).

The median VAS scores for postprocedure pain, maximum pain during procedure, and postprocedure anxiety were similar (Table 2). The acupressure protocol retraining did not result in lower pain or anxiety outcomes (Table 2). Calculating the difference between baseline pain and maximum pain for each woman,

Table 1
Baseline characteristics of participants randomized to acupressure plus usual care, acupuncture plus usual care, or placebo plus usual care during first trimester aspiration abortion ($n = 173$)

Variable	Acupressure ($n = 70$)	Acupuncture ($n = 51$)	Placebo ($n = 52$)
Age	31.4±6.6	31.5±6.2	30.3±6.2
Parity			
0	14 (20)	19 (37.3)	16 (30.8)
1	21 (30)	14 (27.5)	17 (32.7)
2+	35 (50)	18 (35.3)	19 (36.5)
Pregnancy type			
Induced abortion	44 (62.9)	30 (58.8)	32 (61.5)
Miscarriage	18 (25.7)	16 (31.4)	14 (26.9)
Other abnormal pregnancy[a]	8 (11.4)	5 (9.8)	6 (11.5)
Race/ethnicity[b]			
Hispanic	55 (78.6)	33 (64.7)	42 (80.8)
Non-Hispanic White	4 (5.7)	4 (7.8)	4 (7.7)
Non-Hispanic Black	8 (11.4)	9 (17.6)	2 (3.8)
Other (Asian)	3 (4.3)	5 (9.8)	2 (3.8)
Insurance			
Medicaid	49 (70)	34 (66.7)	39 (75.0)
Commercial	21 (30)	17 (33.3)	13 (25.0)
Education[b]			
<High school	11 (15.7)	7 (13.7)	8 (15.4)
Completed high school	13 (18.6)	12(23.5)	11 (21.2)
Some college	22 (31.4)	7 (13.7)	14 (26.9)
Bachelor or More	23 (32.9)	25 (49.0)	19 (36.5)
Occupation			
working	51 (72.9)	37 (72.5)	30 (57.7)
school	5 (7.1)	2 (3.9)	2 (3.8)
both	4 (5.7)	3 (5.9)	2 (3.8)
neither	10 (14.3)	9 (17.6)	18 (34.6)
Anxiety history	7 (10)	4 (7.8)	13 (25.0)
Depression history[b]	9 (12.9)	7 (13.7)	11 (21.2)
Acupuncture history	10 (14.3)	11 (21.6)	11 (21.2)

All data are presented as mean ± standard deviation, n (%), or median (Interquartile range).

[a] "Other abnormal pregnancy" refers to retained products of conception, diagnostic procedure to rule out ectopic pregnancy, or molar pregnancy.

[b] Two participants declined to report race/ethnicity in the placebo group; one participant declined to report the highest level of education obtained in the acupressure group; one participant declined to report history of depression in the acupuncture group.

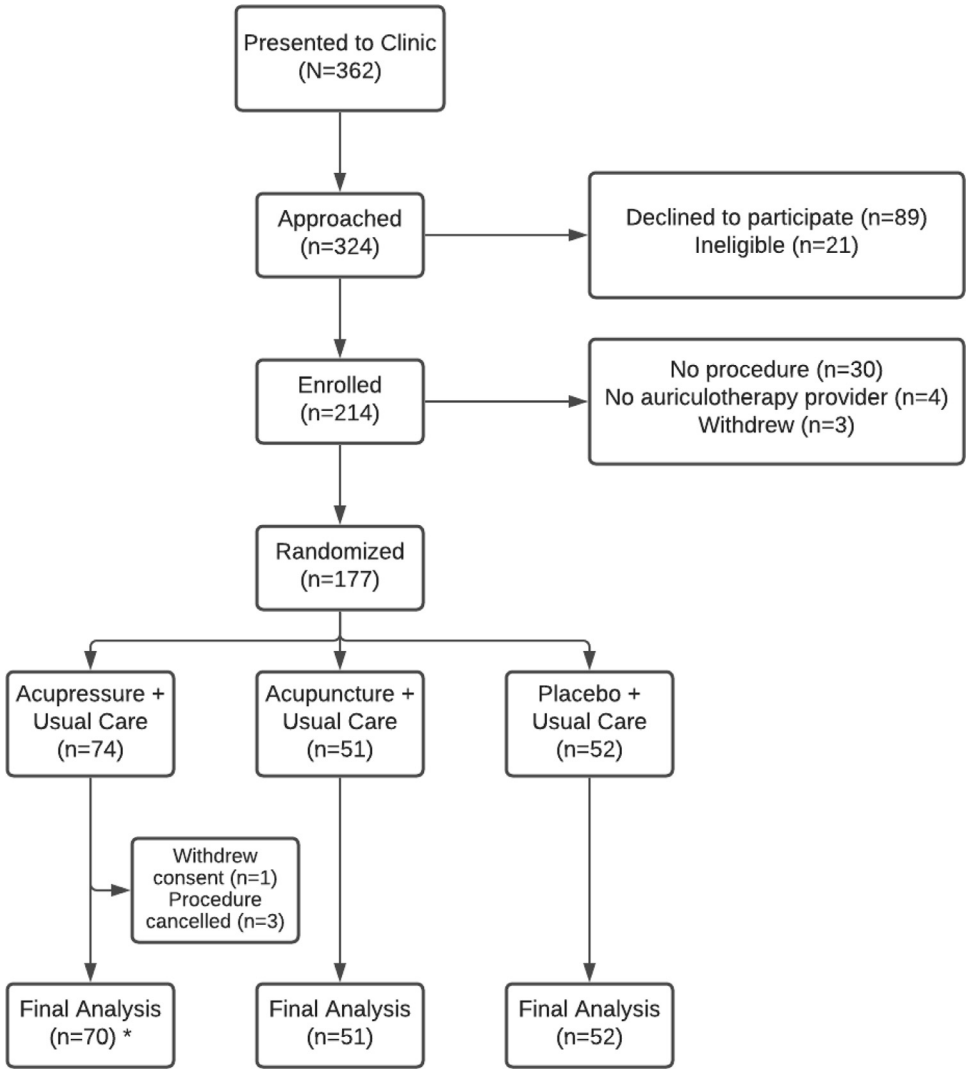

Fig. 1. Participant flow chart for trial of women randomized to acupressure plus usual care, acupuncture plus usual care, or placebo plus usual care during first trimester aspiration abortion. *37 participants were randomized to acupressure prior to protocol retraining.

Table 2
Pain and anxiety scores[a] recorded immediately following aspiration abortion among participants randomized to acupressure plus usual care, acupuncture plus usual care, or placebo plus usual care ($N = 173$)

Variable	Acupressure plus usual care ($n = 70$)			Acupuncture plus usual care ($n = 51$)	Placebo plus usual care ($n = 52$)	p-value[c]
	Acupressure (all)	*Preretraining*[b] *($n = 34$)*	*Postretraining ($n = 36$)*			
Median baseline pain[d]	7.5 (0,26)			10 (0,41)	7 (0,25)	0.59
Median postprocedure pain	50 (23, 75.5)	*47 (23.8, 73.5)*	*50 (17, 78.5)*	55 (28, 78)	47.5 (31.3, 73)	0.88
Median maximum pain during procedure	77 (53.8, 94.5)	*76 (53.8, 94)*	*78 (51.5, 95.5)*	79 (50,100)	79.5 (57, 100)	0.96
Median baseline anxiety[d]	50 (23.5,72)			54 (24,73)	42.5 (5,74)	0.44
Median postprocedure anxiety	26 (12.8, 50)	*29.5 (10.85, 50)*	*21 (13, 50)*	28 (10, 65)	21 (0, 56)	0.47

All data are presented as median (Interquartile range).
[a] Immediately following procedure completion, defined as speculum removal, the research assistant asked the participant to score current pain, maximum pain during the procedure, and current anxiety on a 100-mm VAS (anchors: 0 = no pain/anxiety, 100 = worst possible pain/anxiety) - the same scaled used at baseline.
[b] We identified a loss of fidelity to the acupressure treatment protocol, and thus we retrained all the study auriculotherapists.
[c] p-value obtained by Kruskal-Wallis Test.
[d] Participants reported their baseline pain and anxiety levels on a 100-mm VAS within an hour prior to the procedure.

and then comparing these differences between the groups yielded similar results (Appendix B.).

Most (144/173, 83%) randomized participants received the intervention from 2 study auriculotherapists, a Family Planning Fellow (JDO) and a gynecology nurse practitioner (AT). Pain and anxiety scores were similar between participants who received the interventions from JDO/AT or the other study auriculotherapists. Results were also similar when we stratified the analyses according to the baseline characteristics shown in Table 1 (data not shown).

We assessed baseline characteristics for association with pain and anxiety scores and found that history of a prior induced abortion, having a high school education or less, and having a provider with greater experience was not associated with lower pain or anxiety scores. Dysmenorrhea, however, was associated with higher maximum pain during procedure (66, 77, 82, 94 for none, mild, moderate, and severe dysmenorrhea respectively, $p = 0.05$).

We identified no auriculotherapy-related adverse events. At exit from the study, 86%, 88%, and 79% of participants in the three treatment groups rated their overall rating of care as very good ($p = 0.29$). Only one participant gave an overall rating of care as merely "acceptable." About half of the participants (46% auricular acupressure; 53% auricular acupuncture; 44.2% placebo) rated the "degree to which my pain was controlled" as good or very good ($p = 0.63$). Thirty-three percent of participants in auricular acupressure group, 55% in the auricular acupuncture group, and 67% in the placebo group correctly identified their treatment assignment ($p < 0.001$).

4. Discussion

This randomized, 3-arm trial found that auriculotherapy using acupressure or acupuncture did not result in lower pain or anxiety scores during first-trimester uterine aspiration compared to inert placebo patches. Participants receiving acupressure plus usual care versus those receiving placebo plus usual care had similar scores for postprocedure pain, maximum pain during the procedure, and post-procedure anxiety.

The prior study performed in the same clinical practice found a 30-point pain reduction and a 20-point anxiety reduction with auricular acupuncture [11]. In contrast, this study found no benefit. Given the discrepancy in the trial results, we compared the studies to identify any systematic differences. Both studies enrolled women from the same clinical practice, although the practice location had changed to a different building after the first study was completed. The attending physicians and practice protocols were the same in both studies. The patient populations were highly similar in the 2 studies. The research protocols for eligibility, enrollment, and data collection were the same between the studies. In contrast, the auriculotherapists in the first study included one licensed acupuncturist with years of experience and one obstetrician gynecologist trained and precepted on site by that acupuncturist. This present study included eight auriculotherapy providers; all received a 2-hour standardized group training with at-home practice including submitting photographs to assess accuracy of point location and treatment placement, but this group did not receive extended, ongoing one-on-one training and precepting during the trial. Participants in the first study may have benefitted from the skills of a highly experienced licensed acupuncturist, but the second (less experienced) acupuncturist who was a family planning fellow in that study achieved similar reported pain scores as the mentoring acupuncturist [11]. Perhaps years of experience would lead to superior results, and if so, those results would not be as easy to replicate in an abortion setting without including an experienced, licensed acupuncturist on the treatment team.

In both studies, participants entered VAS scores directly into an electronic tablet linked to a REDCap database, which should preclude problems with data integrity. The investigators analyzed both studies with a prespecified analysis plan and kept the group assignments blinded until the analysis was complete to minimize bias. After recognizing the discrepant results, we extracted the original data from the first study from the locked Redcap database, and reanalyzed the data. Our reanalysis yielded the same results without finding any errors. We also audited the previous database and were able to confirm that no changes were introduced after the participants entered their pain and anxiety scores. A minor difference in data collection is that in the first study, participants saw the number they were selecting on a vertical VAS scale, but in the present study, we used a horizontal VAS scale that did not display numbers to participants.

In the present study, we did not find an association between lower pains scores and factors previously found to be associated with lower pain scores during first trimester uterine aspiration (high school education or less, prior induced abortion, and abortion provider with greater experiences) [18]. We confirmed, however, that participants with a history of severe dysmenorrhea reported more procedure pain.

Women in both the acupuncture and placebo groups were likely to correctly guess their treatment assignment. If recognizing their treatments mattered, one might expect their reported pain scores to differ. In particular, one might expect those who received acupuncture to expect a greater benefit, and those who received placebo to expect less benefit, but as their reported pain scores were so similar, this bias appears unlikely.

The present trial benefitted from an experienced team that had carried out trials of abortion pain interventions in the same practice setting. Using Redcap allowed us to validate the data from the previous study and have confidence in both results. A limitation of the intervention here appears to be the brief training; when we planned this study, we were hopeful that brief training in the modified BFA protocol might be sufficient to achieve the favorable results observed in the previous trial. However, limited training did not achieve any benefits for the individuals in this trial.

The discrepancy between this study and the initial study highlights the importance of having results from more than one trial prior to widespread dissemination and training of a novel intervention. Given our findings, it is at best premature to incorporate these auriculotherapy techniques into abortion practice. Exploring other nonpharmacologic approaches to pain management during vacuum aspiration and other gynecologic procedures remains worthwhile since additional pharmacologic therapy has not been shown to result in lower pain scores during vacuum aspiration.

Declaration of competing interest

JDO - None, **EM** – None, **MAG** - Consultant to Bayer - Consultant, Oxford University Press – Book Royalties, **CLW -** Consultant to Merck, Bayer, AbbVie, Mayne, and TherapeuticsMD. Research support from Sebela and Medicines360, all managed through Columbia University.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.contraception.2021.02.005.

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