GYNECOLOGY

Doulas for surgical management of miscarriage and abortion: a randomized controlled trial

Susan F. Wilson, MD, MSc; Elizabeth P. Gurney, MD, MPH; Mary D. Sammel, ScD; Courtney A. Schreiber, MD, MPH

BACKGROUND: Women undergoing office-based surgical management of a failed or undesired pregnancy often report fear of pain and anxiety pertaining to the procedure. Doulas are trained to specifically address women's physical and emotional needs in obstetric care, and recently have extended their practice to support women through all pregnancy outcomes.

OBJECTIVE: We sought to evaluate the impact of doulas on patients' physical and emotional responses to surgical management of a first-trimester failed or undesired pregnancy under local anesthesia.

STUDY DESIGN: In this nonblinded, randomized trial, women received doula support or routine care during office uterine aspiration for failed or unwanted pregnancies in the first trimester. The primary outcome was pain measured on a 100-mm visual analog scale. Secondary outcomes included satisfaction, emotional state, sense of personal empowerment, and ability to cope immediately and 1 month after the procedure, as well as medical assistants' assessment of the doula's utility. A sample size of 35 per group (N = 70) was planned to detect a 20% difference in pain score.

RESULTS: From April 2014 through January 2015, 129 women were screened and 70 were randomized. The 2 study groups were similar on all baseline characteristics. The primary outcome was not different between the doula and control groups (pain score 70.7 ± 24.5 mm vs 59.7 ± 32.5 mm, $P = .11$, respectively), even after controlling for procedure indication ($P = .20$). While 97% of women who received doula support reported this helped with their experience, there was no statistically significant difference in satisfaction, emotional response, sense of empowerment, or perceived ability to cope between the 2 groups of women immediately following or 1 month after the procedure. Of all study participants, 72% reported that it was important to have someone with them during the procedure, but that the support person did not have to be a doula.

CONCLUSION: Doula support during office uterine aspiration for failed or undesired pregnancies is well received and desired by women undergoing this procedure despite no significant effect on physical comfort or emotional responses related to the procedure. This may suggest an unmet psychosocial need for procedure-related support among such women.

Key words: abortion, abortion doula, doula, lay support person, miscarriage

Introduction

The national focus on high-value care challenges physicians to provide the best possible patient care while maintaining low costs. Office-based uterine evacuation is cost effective, but without systemic anesthesia, patient discomfort and stress could adversely impact the value equation. Because fear of pain and anxiety often compound preexisting feelings of sadness, guilt, and uncertainty at the time of office-based uterine evacuation procedures for first-trimester miscarriage and abortion care, elevating the patient experience requires addressing these feelings.[1-3] In addition to routine use of anti-inflammatory medications and local anesthesia, verbal distraction from clinicians ("verbicaine"); pharmacologic aids such as benzodiazepines, fentanyl, and nitrous oxide; and music therapy may help women through the procedure.[4-7] The inclusion of a support person in office-based procedures has been perceived favorably by patients, but is often not offered for logistical or safety concerns.[8-10]

Doulas, nonmedical individuals trained to provide emotional support, coping strategies, and relaxation techniques, have been shown to improve obstetric, neonatal, and postpartum outcomes, and to favorably influence women's perceptions of pain, satisfaction, and anxiety during labor and delivery.[11-15] Recently, full-spectrum doulas have expanded these techniques to assist women experiencing all types of pregnancy outcomes, including pregnancy loss and abortion.[16,17] Because many doulas work as volunteers, their services may be cost-effective.

Research on the impact of doulas for the management of pregnancy loss and abortion is limited, but encouraging. In a randomized controlled trial assessing the impact of doulas on pain experienced during first-trimester surgical abortions, women who received doula support largely recommended their use in future procedures (96.2%), and required significantly less support from staff than women who received routine care (2.9% vs 14.7%, $P < .01$).[18] These results suggest doulas may provide social or psychological support during office uterine aspiration. To more fully understand doulas' potential role(s) in surgical management of a first-trimester pregnancy under local anesthesia, the objectives of this study were to both evaluate physical discomfort as well as anxiety and other psychometric responses of women undergoing this procedure with and without doula support.

Materials and Methods

We conducted a nonblinded, randomized controlled trial to evaluate the impact of doulas on patients' level of physical discomfort and psychological response at the time of surgical management of a first-trimester undesired or failed pregnancy under local anesthesia, and 1 month later. The institutional

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review board at the Hospital of the University of Pennsylvania approved the study protocol prior to recruitment on Dec. 24, 2013 (project #819173; ClinicalTrials.gov, www.clinicaltrials.gov, NCT02165540). The Penn Family Planning and Pregnancy Loss Center is a referral location for women who present to an obstetrician or the emergency department at our institution with symptoms of a possible early pregnancy loss (bleeding and/or cramping), and for women with an undesired pregnancy. Women who were 18 years of age or older, presenting with a first-trimester failed or unwanted pregnancy, who desired office uterine evacuation for management of their pregnancy, and were willing to participate in randomization to doula support or routine care were eligible. Women who were pregnant as a result of sexual assault, and women who were not able to communicate in English were excluded from the study.

A clinic physician determined subject eligibility after obtaining a history, physical examination, and ultrasound as needed; the physician then introduced the study to eligible women. If interested, a research coordinator discussed the study, obtained written consent, and enrolled the woman in her private clinic room. A preprocedure questionnaire included demographic information, history of an office uterine evacuation, menstrual and psychiatric history, and the following previously published and validated scales to assess various emotional conditions: a 10-item assessment of current emotional state (anxiety, doubt, anger, depression, regret, shame, guilt, fear, happiness, relief [scored on a Likert scale of 1-10; higher value indicates feeling that emotion more]); an assessment of partner, family, and friends' support (scored on a Likert scale of 1-10; higher value indicates feeling more support); a 28-item brief cope score measuring a woman's emotional ability to cope with an event by assessing coping skills in denial, active coping, self-distraction, behavioral disengagement, humor, and religion (scored on Likert scales of 1 = I haven't been doing this at all to 4 = I've been doing this a lot, and averaging responses; higher score indicates greater perceived ability to cope); and a 28-item empowerment score measuring a woman's perceived sense of empowerment related to an event by assessing function in the 5 topic areas of self-esteem/self-efficacy, power/powerlessness, autonomy, optimism/control over future, righteous anger (scored on Likert scales of 1 = strongly agree to 4 = strongly disagree, and averaging responses; higher score indicates greater perceived empowerment).[19-22] Seven questions regarding knowledge and perceptions of doulas (scored on a Likert scale of 1 = strongly agree to 5 = strongly disagree) developed and validated among women obtaining abortions at New York University were used with written consent from researchers at New York University.

Subjects were randomized to either the experimental (doula) or control (routine care) group. A balanced randomization was performed by the principle investigator using a computer-generated scheme in permutated blocks, with randomization assignment concealed in numbered, opaque, sealed envelopes. The envelopes were sequentially opened after subject enrollment and baseline questionnaire completion by the research coordinator. Routine care consisted of verbal reassurance given by the physician and medical assistant in response to concerns and questions expressed by subjects during their procedures. Our clinic does not allow a patient's support person to be present during procedures. Doula support was provided by 3 volunteers who were recruited via e-mailing local reproductive justice groups. All volunteers were initially naïve to providing support around surgical management of first-trimester pregnancy, and received 2-day training in full-spectrum doula care from the registered nurse of the Penn Family Planning and Pregnancy Loss Center who herself was trained by the Doula Project, a full-spectrum doula organization founded in New York City in 2007.[17] The training included personal values clarification exercises, introduction to the social context of abortion care, and skills training in best practices for working with patients receiving highly stigmatized care. All doulas underwent a supervised period in which they were observed and mentored by the trainer, before providing doula support alone; this supervised period varied between 1-3 patient visits depending on the doula's comfort and preference. Doulas-in-training did not support study participants until their training was complete. The 3 doulas in this study were white, female, and <40 years of age. Doulas were not compensated for participating in the study.

Uterine evacuation was performed in accordance with the standard clinic protocol at the Penn Family Planning and Pregnancy Loss Center (manual aspiration <11 weeks' gestation, electric aspiration 11-13 weeks' gestation) by a physician who regularly performs these procedures. All subjects received 600 mg of ibuprofen prior to the procedure, a paracervical block of 20 mL of 1% plain lidocaine containing 3.5 U of vasopressin at the start of the procedure, and an abdominal heat pack during the procedure. For subjects in the experimental group, the doula entered the room and met privately with the patient for 5-10 minutes prior to the procedure. The doula remained at the bedside to provide physical support (eg, hand-holding, massage) and verbal support (eg, breathing techniques, guided visualization) through the procedure and during recovery. No medications were typically given after the procedure.

Within 30 minutes of procedure completion, the research coordinator administered the postprocedure questionnaire. This questionnaire consisted of a 100-mm visual analog scale (VAS) to assess maximum pain during the procedure, satisfaction with the procedure experience (scored on a Likert scale of 1-10), the same 10-item assessment of the current emotional state, 28-item empowerment score, and perception of the doula for support, if randomized to that group. Participants were compensated $10 cash for their time. Research coordinators contacted participants 1 month after the procedure by telephone