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RESEARCH

A Randomized Comparative Trial of Two Decision Tools for Pregnant Women with Prior Cesareans

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ABSTRACT

Objective: Evaluate tools to help pregnant women with prior cesareans make informed decisions about having trials of labor.

Design: Randomized comparative trial.

Setting: A research assistant with a laptop met the women in quiet locations at clinics and at health fairs.

Participants: Pregnant women ($N = 131$) who had one prior cesarean and were eligible for vaginal birth after cesarean (VBAC) participated one time between 2005 and 2007.

Methods: Women were randomized to receive either an evidence-based, interactive decision aid or two evidence-based educational brochures about cesarean delivery and VBAC. Effect on the decision-making process was assessed before and after the interventions.

Results: Compared to baseline, women in both groups felt more informed ($F = 23.8$, $p < .001$), were more clear about their birth priorities ($F = 9.7$, $p = .002$), felt more supported ($F = 9.8$, $p = .002$, and overall reported less conflict ($F = 18.1$, $p < 0.001$) after receiving either intervention. Women in their third trimesters reported greater clarity around birth priorities after using the interactive decision aid than women given brochures ($F = 9.8$, $p = .003$).

Conclusion: Although both decision tools significantly reduced conflict around the birth decision compared to baseline, more work is needed to understand which format, the interactive decision aid or paper brochures, are more effective early and late in pregnancy.

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In the United States in 2008, fewer than one in 10 women with prior cesareans had vaginal births after cesarean (VBAC) (Osterman, Martin, Mathews, & Hamilton, 2011). In a recent systematic review on the safety of VBAC, the authors reported that 74% of the women who had trials of labor delivered vaginally (Eden et al., 2012). This review included studies from the United States and other developed countries published between 1987 and 2009. The expert panel for the 2010 National Institutes of Health Consensus Development Conference for VBAC stated that one of their major goals was to "support pregnant women with one prior transverse uterine incision to make informed decisions" (Cunningham et al., 2010, p. 2). The panel identified the development and validation of decision-making tools that communicate risk in easily understood terms as a critical research priority. Authors of the latest Cochrane review on VBAC reported finding very few studies evaluating interventions to help women make decisions about trials of labor (Horey, Kealy, Davey, Small, & Crowther, 2013).

Decision aids including booklets, DVDs, and interactive computerized tools have been used to inform patients and support shared medical decision making for preference-sensitive decisions when more than one option for treatment is reasonable. They are designed to complement rather than replace counseling from a health practitioner (Stacey et al., 2014). In a Cochrane Review of 115 randomized controlled trials, patients exposed to decision aids reported feeling more informed and had less conflict around values or priorities related to the decision than patients in usual care (Stacey et al., 2014).

The long-term objective of our research was to help women make more informed decisions about

trials of labor. There are no standardized recommendations on how and when to counsel women who are faced with the option of trial of labor or scheduled repeat cesarean delivery. The trial of labor rate in the United States after 1996 was less than 50% (DiMaio, Edwards, Euliano, Treloar, & Cruz, 2002; Eden et. al., 2012; Gregory et al., 2008; Landon et al., 2006). We evaluated an evidence-based, computerized decision aid and two evidence-based childbirth brochures from the American College of Obstetricians and Gynecologist (ACOG) for effect on the decision-making process for trial of labor. We hypothesized that women using the decision aid would experience less decisional conflict around birth priorities than women who read the two brochures. We also explored the effect of the decision aid and brochures on route of delivery. For women who used the decision aid, we also summarized their birth priorities.

Methods

This randomized comparative trial was approved by the Oregon Health & Science University and Kaiser Permanente Northwest Institutional (KPNW) Review Boards. It is registered at clinical trials.gov.

Eligibility, Recruitment, and Sample Size

Pregnant women who had one prior cesarean and were eligible for VBAC participated one time in this study. Several approaches were used in recruiting this convenience sample. We identified potentially eligible women using the electronic medical records at Oregon Health & Science University (OHSU) and Kaiser Permanente Northwest and contacted women by phone. We also recruited using informational flyers placed in local county health clinics, at health fairs, and using newspaper advertisements. Pregnant women were eligible if they were age 18 years or older, could read English or Spanish, were pregnant with one fetus, had only one prior cesarean delivery, had a low transverse uterine scar, and their providers had given the option of trial of labor. Eligibility was verified during the phone recruitment or in person at the health fair. The women were compensated $25 for time, travel, and child care.

We selected a sample size of 64 per group to detect an effect size of 0.5 with a significance of $p \leq .05$ and power of 80% (Hulley et al., 2001). This was based upon estimates from a similar trial that measured decision conflict for colorectal screening (Dolan & Frisina, 2002).

We designed a decision aid to help women with prior cesareans decide whether to have trials of labor or elective repeat cesareans.

Setting

A research assistant with a laptop and printer met the women in a quiet location at any of five participating clinics from the following health systems in Oregon: OHSU, Multnomah County, and Kaiser Permanente. Additionally, women who were recruited at health fairs participated using a quiet desk with privacy near the health fair.

Procedures for All Women

After the women provided informed consent, the research assistant logged into the secured, randomization database to obtain the decision tool assignment (brochures or decision aid). The women were unaware of their intervention assignment. The consent form stated that they would be randomized to one of two formats of a computer program but did not describe the differences in formats. One program contained the preintervention baseline data collection screens, an interactive decision aid, and follow-up data collection screens. The other program contained the same baseline and follow-up data collection screens but a pause after baseline questions so the women could read two paper brochures instead of using a decision aid. All answers to baseline and follow-up questions on the user interface were set up for response using point-and-click with a mouse with options for the women to type in additional information.

The research assistant loaded the assigned program for all women and provided brochures to women assigned to that intervention. The research assistant was trained not to divulge details about the two formats. The women were randomized in blocks based on language (English or Spanish) and number of prior vaginal births (none, one, or more). The secured database was managed by the biostatistician who was offsite and did not meet with the women.

Brochures Group Intervention and Procedures

The research assistant gave the women randomized to the brochures group the most current ACOG brochures on VBAC published in August 1999 (ACOG, 1999) and cesarean birth published in January 2005 (ACOG, 2005). The women could

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