Feasibility and Acceptability of the Menstrual Cup for Non-Surgical Management of Vesicovaginal Fistula among Women at a Health Facility in Ghana

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Abstract

Background

Vesicovaginal fistula is a debilitating condition resulting from prolonged obstructed labor. Globally, at least 2 million women are estimated to be living with fistula with about 50,000 to 100,000 new cases each year. More than 90% of the global burden of fistula is in sub-Saharan Africa and South East Asia. Traditional management of fistula requires surgical repair. However, many women either do not have access to surgery, or access to surgery is delayed. These categories of patients have few or no options to control the constant urinary leakage. The vaginal menstrual cup is an insertable medical device approved for use in Europe and North America to collect menstrual flow. Because it collects fluid drainage from the vagina, it could also be used to control urine leakage in women with vesicovaginal fistula. While surgical management of fistula would remain the gold standard in treatment, the menstrual cup could be an alternative for women who do not have access to surgery or are poor surgical candidates.

General Aim

To evaluate the menstrual cup for short-term non-surgical management of vesicovaginal fistula.

Methodology

This study will examine the reduction in urinary leakage for women with vesicovaginal fistula who use the cup over a 2 hour period. Fistula patients recruited after community durbars will be invited to the hospital and offered enrollment. They will wear a sanitary pad for 2 hours and the pad will be weighed. The patients will then receive counseling on how to insert the cup in the vagina and will wear both the device and a sanitary pad for 2 hours. The second pad will also be weighed. The amount of urine leaked with and without the cup will be compared using a paired t-test. Addtionally, the women will answer a short questionnaire on the acceptability of the cup, and a physical exam will be carried out to assess safety with cup use. A purposeful sample of the patients will be recruited for in-depth interviews to share their experiences of coping with VVF and their acceptability of the menstrual cup device.

Expected Outcome

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The knowledge gained from this study may offer alternative temporizing management options for fistulas, especially for women who fail or are awaiting surgery, women who cannot access surgery, or are poor surgical candidates.

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Protocol

Step 1.
Approval was obtained from the Ethical and Protocol Review Committee of the School of Medicine and Dentistry, College of Health Sciences, University of Ghana, Legon (protocol number CHS-Et/M.9-P3.2/2015-2016) on 13 June 2016.

Step 2.
Without evidence from any previous application of the menstrual cup for reduction of urine leakage, a sample size calculation was developed within the study protocol that assumed a 50% reduction in leakage with use. Preliminary evaluation based on initial clinical observation and expert opinion suggested that a 65% reduction was a more appropriate estimate. With 80% power and an alpha of 0.05, a total of 11 participants were required.

Step 3.
Recruitment occurred from June to November 2016 and data collection was conducted from for two days in August to and two days in December 2016 at Mercy Women's Catholic Hospital in Ghana.

Step 4.
The trial was registered on clinicaltrials.gov after enrollment began, as the study team was not aware of this requirement for a small, non-randomized feasibility studyclinical trial (Clinical trial registration: NCT03414060) to determine the feasibility of a device, where the primary outcome measure relates to feasibility and not to health outcomes.

Step 5.

Study participants were identified during a VVF preoperative clinic. The subjects were introduced to the study, and if interested in participating, the eligibility criteria were reviewed. If eligible for enrollment, informed consent was obtained for study participation, and the participants was enrolled and given a subject ID.

Step 6.

If the number of potential patients at a single fistula camp exceeds the number required for the study, the study team should utilize randomization for enrollment. The study team member enrolling participants should ask the patients to pick pieces of paper on which either a 1 (=invited to enroll) or 0 (=not invited to enroll) is written. Patients who select the pieces of paper with a 1 will be invited to enroll and given a subject ID. This will avoid selection bias in enrollment of subjects.

Step 7.
Participants were taught hand hygiene, vaginal placement, removal techniques, and cup washing. They had ample opportunity to practice and were encouraged to ask questions. All instruction and

data collection occurred in the local language of the participant's choice

Step 8.
Participants were counselled to drink enough water to allow the free flow of colorless, odorless urine, and optimal hydration status was confirmed with a color chart.

Step 9.

Participants were given standardized sanitary pads to wear for two hours while walking around and carrying out their typical activities of daily living. It will be explained that they can use more than one sanitary pad if necessary. Each sanitary pad used in the two hours will be weighed and the dry pad weight subtracted from the wet pad weight.

Step 10.
Feasibility was assessed primarily by examining the potential effect at reducing urine leakage, the cup's safety, and users' acceptability of the device. Volume of urine leaked was measured via a 2-hour pad test. At baseline, participants wore sanitary pads within disposable underwear for two hours without physical activity restrictions. Each pad was weighed, and the dry weight subtracted from the wet weight to obtain the baseline volume (in ml) of urine leaked. Participants then inserted the menstrual cup for two hours, and the pad test was repeated.

Step 11.
After the cup and pads were removed, a non-study clinician examined the vaginal mucosa to assess safety outcomes, including erythema, edema/induration, erosion, and bleeding. Participants were read a structured questionnaire on demographics, perceived severity of leakage, perceived efficacy, and acceptability.

Step 12.
Additional feasibility factors were assessed throughout to inform the necessary steps of a future study, including rates of enrollment and consent and appropriateness of data collection.

Step 13.
Data were analyzed using Stata v.13. Independent and dependent variables were examined using univariate analyses to assess central tendency, normality, and distribution. The volume leaked at baseline and with the cup inserted were compared using a paired t-test.