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Douching for Perceived Vaginal Odor With No Infectious Cause of Vaginitis: A Randomized Controlled Trial

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■ Abstract

Objective. To demonstrate the effectiveness of medical-grade stainless steel Water Works Douching Device for treating abnormal vaginal odor in comparison with a commercially available over-the-counter plastic douching device.

Materials and Methods. In a multicenter study, 140 women with perceived vaginal odor with no vaginal infection were randomized to either Water Works or control group in a 1:1 ratio and were douched daily for 4 weeks. A visual analog scale (VAS) was used to assess the intensity of vaginal odor. Primary outcome included subject assessment of odor improvement and Nugent Gram stain score of vaginal secretions. Secondary outcome compared the efficacy and safety of Water Works with control douching device. Each patient underwent baseline, week 2, and week 4 visits.

Results. The final analytic sample consisted of 96 women. Success score at 4 weeks was 78% for the Water Works group and 38.5% for the control group. Mean VAS was significantly reduced, and Nugent and *Lactobacillus* scores were maintained in both groups. In the Water Works group, VAS was reduced from 7.3 ± 0.3 to 1.8 ± 0.6 ($p < .001$) after 4 weeks. In the control group, baseline versus 4 weeks VAS was 7.2 ± 0.3 and 3.4 ± 0.8 ($p < .003$).

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Conclusions. Women reported significant reduction of vaginal odor after douching with water for 4 weeks without any alteration of vaginal flora. The Water Works Douching Device was superior to over-the-counter device in reducing vaginal odor. ■

Key Words: bacterial vaginosis, douching, genital malodor

Malodorous vaginal discharge is a common problem in female patients attending care centers [1]. Although vaginal odor is rarely considered a serious disease, symptoms are extremely distressing to patients [2]. Bacterial vaginosis (BV) is the most common vaginal infection causing vaginal discharge or odor; however, no identifiable cause can be found in approximately a third of symptomatic women with malodorous discharge, and accordingly, no therapy is available for idiopathic vaginal odor [3–7].

Although the prevalence has declined, douching continues to be a common practice in the United States; however, its use is highly controversial. Approximately 22% of women of reproductive-age report vaginal douching and the prevalence rate is more than 2-fold higher among African American women [8, 9]. Douching is done to improve vaginal hygiene particularly in response to odor, after menses, to enhance sexual activity and is more prevalent among women with a higher number of lifetime sexual partners [10]. Although douching has been reported to result in a variety of adverse outcomes [11–16], possible benefits of douching are also suggested

[16–19]. In a pilot study, douching using a stainless steel device demonstrated significant reduction or elimination of vaginal odor [19]. Here we extend previous observations in a randomized study in women complaining of vaginal discharge and malodor, unassociated with any infectious cause of vaginitis, who douched with tap water using either Water Works Douching Device (WW) or a control commercial douching device. The goals of this prospective study were to verify the role of douching in reducing genital malodor and to evaluate whether the use of a stainless steel device was superior to a conventional plastic device.

MATERIALS AND METHODS

Study Design and Sample

A prospective, multicenter, double-blind randomized study was conducted at the outpatient clinic of 5 different medical centers in the United States. These included specialty vaginal infection clinics as well as general obstetric/gynecologic clinics. The study was reviewed and approved by institutional review boards at each study site. We approached women for enrollment if (1) they were seeking care at selected clinics and (2) their symptoms included self-reported vaginal odor. A total of 535 women were approached and invited to participate in the study. A total of 210 women consented (a response rate ~39%) and were screened to determine eligibility for randomization to treatment or control. Screening included a pelvic examination, a Pap smear (if results within the past 12 mo were not known), collection of a vaginal swab, abstraction of a medical history from chart and self-report, and completion by women of a visual analog scale (VAS; a 10-cm line used to assess the intensity of vaginal odor, 10 being the worst).

We used the screening data to exclude women in whom a potential reason could be identified for their perceived vaginal odor, such as vaginal infection (Table 1); the predominant reason was BV diagnosed by Amsel criteria ($n = 49$). We also excluded women who had social or medical issues that could interfere with participation in the intervention and follow-up evaluations. Finally, women who scored lower than 4 on the 10-point VAS rating scale for perceived vaginal odor were excluded ($n = 1$; Table 1). This was done to improve the ability of the VAS to discriminate between treatment and control subjects during the follow-up period; women beginning at the low end of the scale would have very little room for improvement. Numbers for each exclusion factor

Table 1. Study Treatment Exclusions: (A) At Screening and (B) After Enrollment

	Reason	<i>n</i>
Excluded at screening, <i>n</i> = 70		
Potential cause identified for vaginal odor (<i>n</i> = 61)	BV-positive (Amsel criteria)	49
	<i>Trichomonas</i> positive	8
	Human papillomavirus positive	1
	Symptomatic yeast infection (VVC)	1
	Obesity	2
Social or medical conditions likely to affect participation (<i>n</i> = 8)	Poor mental status	1
	Withdrew at enrollment	1
	Severe atrophic vaginitis	2
	HIV positive	1
	History of cervical cancer	1
Limited room for improvement (<i>n</i> = 1)	Pregnant	2
	VAS score < 4	1
Excluded after enrollment, <i>n</i> = 44		
	BV positive at visit 1 (Nugent/Gram stain)	21
	BV positive at visit 2 (Nugent/Gram stain)	6
	Abnormal Pap	8
	Sexually transmitted disease at visit 1	2
	Pregnancy test positive at visit 2	1
	Withdrawn from study at visit 2	2
	Lost to follow-up	4

listed in Table 1 sum to 70 total women excluded because some women met multiple exclusion criteria.

Study Procedures

All 140 eligible patients were randomized in a 1:1 ratio either to the Water Works (Abbott Research Group, Pittsburgh, PA) as investigational or to the over-the-counter douching device as the control group. Patients and the examining physician were both blinded to the subject's randomization assignment. Although devices are different in appearance, patients were blinded in that they were entirely unaware that 2 devices were distributed or that 1 device contained stainless steel. All patients were instructed how to use the treatment devices and asked to vaginally douche once daily for the 4-week study period, with the exception of the days of evaluation and menstruation. They were instructed to refrain from the use of other douches and intravaginal products (e.g., estrogen, feminine deodorant sprays, spermicides, tampons, and diaphragms) during the 4-week study period. Oral and intravaginal antibiotics or antifungal agents during the 4-week study periods were contraindicated.

All participating women underwent a pelvic examination at each of the 2 visits after randomization. At all visits, vaginal swabs were collected from the posterior and lateral vaginal fornix in all patients. At screening

and both of the follow-up visits, patients were asked to complete VAS for perceived vaginal odor (VAS, described above). In addition, each patient kept a brief diary where they recorded their own assessment of vaginal odor and other vaginal symptoms and tolerability of using the devices during the study period. They were instructed to report any adverse event noted during the study period.

Study Device and Douching Procedures

In Water Works, the nozzle is made of medical-grade stainless steel. The kit includes a customized water container and tubing. It is a gravity-fed douching device, listed as class I (21 CFR 884.5900) with the US Food and Drug Administration. The control device (CT) was a commercially available, over-the-counter douche device with a plastic nozzle. Instructions given were the same for both devices as befits a double-blind randomized trial. Women were instructed to use 32 oz of tepid tap water as a douching fluid hung in a container at approximately 3 ft above the vagina (eye level). The protocol specified a total douching time of approximately 2 minutes with instructions for constant manipulation of the douching device to make contact with all of the vaginal walls.

Measurement of Key Variables

Descriptive variables obtained at enrollment included self-report of age, parity, race/ethnicity, and clinical measurement of body weight and height (for body mass index computation). Obstetric and menopausal history of enrolled women was also obtained. To identify BV, vaginal swab specimens at screening and at the 2 follow-up visits were used for assessment of Amsel criteria, Gram stain for Nugent and *Lactobacillus* score, and yeast culture for mycotic infection. Lactobacilli were scored 1 to 4 using modified Nugent criteria. The vaginal pH was measured using pHDrion papers (Micro Essential Laboratory, Inc, Brooklyn, NY) color strips with a range of 4.0 to 5.5. Amsel criteria at each study site and Gram stain slides for Nugent score were sent to a central reference laboratory (Detroit Medical Center/Wayne State University laboratories). Urine for pregnancy test, OSOM (Genzyme Diagnostics, Framingham, MA), *Trichomonas* rapid test or *Trichomonas vaginalis* culture, and *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA tests were performed at visit 1. Herpes simplex virus culture was obtained at the screening visit as indicated. The primary outcome variable was the VAS for perceived vaginal order (the VAS score).

Analysis

The VAS scores at baseline, visit 2 (at week 2), and visit 3 (at week 4) were compared to determine the effectiveness of douching in each arm in treating the complaint of vaginal odor. Data on BV (Amsel and/or Nugent score criteria), Nugent score, *Lactobacillus* score, pH of vaginal swab specimens, and yeast infection were all evaluated as potential adverse effects of treatment to assess the safety and efficacy of the WW device. Using a paired *t* test, we examined the trends over time within each study arm for the VAS and cross sectionally at each follow-up visit to compare VAS scores between arms. In addition, we categorized the change in VAS during the study period with “success” defined as a decrease of 40% or higher (4 cm on the 10-cm scale). We compared the percentage of subjects who were a “success” in each arm using Fisher exact test for comparing binomial proportions [20, 21].

RESULTS

Table 2 describes the overall characteristics and by study arm. A history of past douching was reported by 61% of women to control vaginal symptoms such as odor, discharge, or itching. Most women used commercial douches containing water-vinegar solution; only a few used a medicated douche. Most women douched infrequently. Among the 140 women enrolled in the study, follow-up data comparing the 2 study arms were excluded from analysis for 44 women (Table 1). The main reason for exclusion was the identification of previously undetected BV based on a Nugent score of 7 or higher from the Gram stain assessment of the vaginal swabs at screening or at follow-up visit: 21 women at visit 1 and 6 women at visit 2.

Our analytic sample was 96 women: 48 in the WW arm and 48 in the CT arm. As expected from the eligibility and exclusion criteria, all 96 patients complained of strong vaginal odor at their baseline visit. Comparison of the 2 study groups similarly demonstrated identical clinical characteristics (data not shown). The mean \pm SD VAS score was 7.23 ± 1.6 in the WW group at the entry visit. Scores were significantly reduced after 2 weeks of douching to 3.89 ± 2.42 ($p < .005$). The VAS score was further reduced to 1.74 ± 2.08 ($p < .005$) after 4 weeks of douching. In the CT group, VAS score was 7.14 ± 1.67 at entry and was significantly reduced after 2 weeks of douching to 4.86 ± 2.31 ($p < .005$). The VAS score was further reduced to 3.38 ± 2.87 ($p < .05$) after 4 weeks of douching. Comparison between the treatment and control groups showed a significantly greater

Table 2. Demographics of Enrolled Participants (n = 140)

	Enrolled and randomized participants (n = 140)		
	Overall (n = 140)	Water Works (n = 68)	Control (n = 72)
Age, mean ± SD, y	41.7 ± 10.5	41.8 ± 11.1	41.6 ± 10.0
Body mass index, mean ± SD, kg/m ²	27.7 ± 4.6	27.1 ± 5.0	27.6 ± 4.2
Race/ethnicity, n			
Asian	1	1	0
Black	92	46	46
White	34	18	16
Hispanic	11	2	9
Other	1	1	0
Obstetric history, mean ± SD			
No. pregnancies	2.3 ± 1.7	2.1 ± 1.7	2.4 ± 1.8
No. children	1.7 ± 1.4	1.6 ± 1.5	1.7 ± 1.4
Menopausal status, n			
Childbearing age	95	47	48
Perimenopausal	7	4	3
Menopausal	10	3	7
Postmenopausal	28	14	14

improvement in the VAS score with the use of the WW device for 2 ($p = .049$) and 4 weeks ($p = .002$). The percentage of women in each group who scored less than 4 cm in the VAS scale at the end of the study was 85.4% (41/48) in the WW group and 58.3% (28/48) in the CT group ($p < .01$).

As described in Materials and Methods, a decline of 4 cm or a greater drop in the VAS score after 4 weeks of douching was categorized as a success reflecting a significant decrease in odor. The Fisher exact test comparing the overall success proportions (78% for the WW group versus 38.5% for the CT group) rejects the null hypothesis of no difference at a significance level less than .0001. The observed difference in success rates is 39.5%, and the true difference in success rates has an exact 95% confidence interval (CI) of 20.7% to 58.4%. We also examined the effect of intervention on complete resolution of vaginal odor defined as VAS score less than 1 at follow-up. The proportion of patients who experienced complete resolution of vaginal odor (VAS < 1) was 27 (56%) of 48 in the WW group and 14 (29%) of 48 in the CT group at week 4 ($p = .01$).

With regard to adverse effects of the intervention, we compared the WW and CT groups on progression to BV and changes in related variables during the study period. We found that 3.5% (3/86) of patients with normal flora (Nugent 0–3) and 50% (5/10) with intermediate flora developed BV at the end of the study (odds ratio = 0.04, 95% CI = 0.007–0.196). In the WW group, 28.6% (2/7) of patients with intermediate flora at baseline developed BV at the completion of follow-up, whereas in the control group, all 3 women with inter-

mediate flora at enrollment developed BV at the end of study. In the WW group at baseline and week 4, mean vaginal pH was 4.3 ± 0.3 and 4.4 ± 0.4 , whereas in the CT group, it was 4.3 ± 0.2 and 4.4 ± 0.4 ($n = 48$ in each group). Mean vaginal pH and Nugent score did not change from baseline values as determined at the end of study in either group.

Lactobacillus score was also maintained within the reference range. In the WW group at baseline and week 4, mean *Lactobacillus* score was 3.5 ± 1.3 and 3.4 ± 1.2 , whereas in the CT group, it was 3.8 ± 0.6 and 3.5 ± 1.3 ($n = 48$ in each group). After 4 weeks of douching, 3 (3/48) and 5 (5/48) subjects had developed BV in the WW and CT groups, respectively (relative risk = 0.6, 95% CI = 0.15–2.37).

Women with symptomatic yeast infection at enrollment were not permitted to participate in the study. Yeast cultures were positive in 12 (12/48) women in the WW group and in 13 (13/48) women in the CT group at the entry visit. At the end of 4 weeks of douching, none presented with symptoms of yeast infection, and culture became negative in 5 (5/12) women in the WW and 5 (5/13) women in the CT group (absolute risk reduction = 0.03, 95% CI = 0.35–0.42). A small number of subjects who had negative yeast cultures at baseline developed asymptomatic culture-positive yeast infection after 4 weeks of douching including 2 of 36 women in the WW group and 5 of 35 women in the CT group (relative risk = 0.39, 95% CI = 0.08–1.87). In addition to these measures, no major adverse effects or complications were reported by women in either device group. Patient's tolerance assessed from subject diary of the

devices was similar in the 2 groups as reflected by ease and comfort of use and lack of adverse effects.

DISCUSSION

This prospective study demonstrates that vaginal douching with tap water is effective in reducing unpleasant vaginal odor in women without an identifiable cause for the perceived odor.

Several cross-sectional studies have shown that frequent douching is associated with BV [3, 22–24]. A protective *Lactobacillus*-dominant vaginal flora is considered a major factor defining a healthy vaginal environment. An important issue in our study was whether frequent douching might wash away *Lactobacillus* and weaken vaginal defenses [20]. We note, however, that women in our study used only water as the douching product. Our short-term study demonstrated that daily douching with water for 1 month did not result in any increased risk of BV. In agreement with our observation, Glynn [25] showed that daily douching for 4 weeks was not associated with significant alteration in vaginal pH. Nugent, *Lactobacillus* score, and vaginal pH were maintained in our WW intervention group. In the control group, although the mean *Lactobacillus* score decreased from baseline after 4 weeks of douching ($p = .03$), it was still greater than 3, reflecting *Lactobacillus* predominance. In the present study, women who developed BV after 4 weeks of douching either had intermediate flora at baseline or had a history of recurrent BV. In a prospective analysis, Hutchinson et al. [26] similarly showed that douching increased the risk of developing BV among women with intermediate flora but not with normal flora. Again, in the present study, women with normal flora at baseline showed no association between daily douching with tap water for 4 weeks, in either study arm, and development of BV.

Our study did not observe any adverse effects such as pelvic pain or any unusual vaginal symptoms in either group. The intensity and methods of douching, especially douching with pressure, have been associated with adverse outcomes in a previous study [27]. Therefore, the risk of ascending infection from the pressure of douching may be greatest around the time of ovulation when the cervical os is gaping and the mucus is thin. However, in a recent study, Ness et al. [28] did not confirm a relationship between douching and either gonococcal or chlamydial genital infection or pelvic inflammatory disease. The Water Works douching device is designed so that the water is directed downward away from the cervical os and is gravity fed to avoid

ascending infection. Finally, in the present study, 25 (26%) of 96 asymptomatic yeast-positive women were enrolled and 10 (40%) of 25 women had negative yeast cultures at the end of the study period. No subject developed symptomatic yeast infection during the course of study. The American College of Obstetrics and Gynecology Guidelines state that douching is not effective for vaginitis but without specifically referring to genital odor. The guidelines also emphasized the increased risk for pelvic inflammatory disease, a complication not addressed in the present study [29].

The study has several additional limitations. Vaginal discharge and odor were self-reported by participants, and at present, there are no validated instruments for the assessment of vaginal odor. The small study population is another drawback. In addition, we could not rule out that unmeasured confounding factors might have influenced our results. However, the use of a randomized double-blind design should reduce the likelihood of confounding explaining our results. Most importantly, neither the beneficial nor adverse effects of long-term frequent douching were studied. Time to return of symptoms after discontinuation of douching was not studied. Particular strengths of our study included keeping both the subject and the investigator blinded to the study device. Other important strengths of the study include the use of consistent enrollment and data collection protocols, collection of detailed study diary completed by subjects, the use of an expert reference laboratory blinded to each woman's reported douching behavior, and the internal consistency shown between microbiologic outcomes.

CONCLUSIONS

This study is not meant to support widespread and long-term use of douching, and despite several studies emphasizing the harmful sequelae of douching, it is still a widely used feminine hygiene practice [22–24]. There is less agreement regarding douching for relief of genital odor, recognizing that solutions for vagina odor, not caused by vaginal infection, are not available. In this prospective multicenter randomized double-blind study, our data do not support a relationship between short-term douching and consequent vaginal infection in women with normal vaginal flora. We found that douching using water is valuable for the treatment of vaginal odor and much appreciated by symptomatic women and does not seem to interfere with maintenance of a normal vaginal ecosystem. The Water Works device with medical-grade stainless steel nozzle, when used

with water, was significantly better than the commercially available over-the-counter plastic douching device in reducing or eliminating self-reported vaginal odor.

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