International Journal of Gynecology and Obstetrics 115 (2011) 61–64

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

The effect of "breathable" panty liners on the female lower genital tract

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ARTICLE INFO

Article history:
Received 12 February 2011
Received in revised form 17 April 2011
Accepted 30 June 2011

Keywords:
Bacterial vaginosis
Lactobacillus
Menstrual hygiene products
Vaginal discharge
Vulvovaginal candidiasis

ABSTRACT

Objective: To evaluate whether the use of "breathable" panty liners (BPLs) alters the normal vaginal flora, increases the incidence of bacterial vaginosis and/or vaginal candidiasis, or causes vulvar irritation. *Methods:* A randomized controlled trial assessed the vaginal ecosystem of women without complaints of vaginal discharge. The study group (n = 53) wore BPLs for 10–12 hours each day for 75 consecutive days, whereas the control group (n = 54) wore only their usual underwear. At each of 6 visits during 3 menstrual cycles, participants underwent gynecologic examination with colposcopic evaluation and pH measurement, in addition to assessment of vaginal microbial flora, intensity of inflammatory processes, and presence of vaginal candidiasis/bacterial vaginosis in Gram-stained smears. *Results:* After 75 consecutive days of BPL use, 40/44 (90.9%) and 42/44 (95.5%) women reported no complaints of vaginal discharge or vulvar itching/burning, respectively. There was no significant difference between the study group and the control group with regard to positive vaginal fungus cultures (5/44 [11.4%] vs 8/50 [16.0%]; $P = 0.7848$) or bacterial vaginosis (3/44 [6.8%] vs 2/50 [4.0%]; $P = 0.7974$) at the end of the study period. *Conclusion:* After 75 days of BPL use, there was no significant increase in vulvovaginal candidiasis, bacterial vaginosis, vulvovaginal irritation, or vulvovaginal inflammation.

1. Introduction

The use of panty liners has become a common habit among women seeking protection against menstrual blood stains on their clothing, non-menstrual vaginal discharge, and the release of genital odors at social events. To date, there have been few compelling studies published on the impact of wearing such panty liners, especially "breathable" variants, on the vaginal ecosystem. Modern women have been continuously going through changes in their lifestyle and increasingly have a key role in household income. In Brazil, 1 in 3 homes is supported solely by women [1], who perform, on average, approximately 10–12 hours of work per day. Such disproportionate workloads may negatively influence proper hygiene of the genital area, resulting in an increased likelihood of releasing secretions and odors in social situations. Women have increasingly begun to wear panty liners on a daily basis during the intermenstrual period to feel more self-confident and protected against vaginal odor. Approximately 50% of women in North America and western Europe use panty liners, with 10%–30% using them daily throughout the intermenstrual period; their ideal is staying clean and dry at all times [2].

Several studies have shown that the application of new hygiene practices can favorably or unfavorably affect the ecosystem of the mouth and vagina [3–5]. Changes in hygiene practice may alter the homeostatic condition of the vaginal mucosa, possibly resulting in altered concentrations of immunoglobulins, heat-shock proteins, and cytokines—which, in turn, could affect the occurrence of vaginal candidiasis, bacterial vaginosis, and irritation of mucous membranes and skin [6–9].

Since their inception, panty liners have undergone changes in shape, size, and composition to make them more appropriate for women's needs. One change, which was intended to improve the maintenance of temperature and humidity in the genital/perineal area, was the replacement of impermeable film barrier layers with breathable (i.e. air- and vapor-permeable) materials for pads used at times of low vaginal discharge (referred to as breathable panty liners [BPLs]) [10]. An average increase of 1 °C in the temperature of the outer labia was reported among women using panty liners with a plastic barrier, whereas no such increase was observed among BPL users [11,12].

Despite the high prevalence of panty liner use, few studies have assessed the effect on the vaginal ecosystem of frequent use for lengthy periods [5,13]. Furthermore, the few studies that have been carried out have analyzed the genital microflora of women who used panty liners with vapor-impermeable, rather than vapor-permeable, back sheets.

The aim of the present study was to evaluate whether the use of BPLs within the intermenstrual phase would alter the normal vaginal flora,

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0020-7292/$ – see front matter
doi:10.1016/j.ijgo.2011.04.016

influence vaginal inflammatory processes, affect the incidence of bacterial vaginosis and/or vaginal candidiasis, or cause vulvar irritation.

2. Materials and methods

The present randomized controlled trial—which was conducted from July 23 to December 17, 2010—involved women at a clinic specializing in genital infections at the Department of Obstetrics and Gynecology, State University of Campinas (UNICAMP), Campinas, Brazil. The inclusion criteria were as follows: 18–35 years of age; body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) less than 30; regular menstrual cycles; no complaints of vaginal discharge for more than 1 month; no continuous use of any drugs or medication; not pregnant; no use of intrauterine device or diaphragm; and no history of allergy or recurrent vaginal discharge.

After providing written informed consent, participants were randomly assigned to the study or the control group—according to a computer-generated randomization schedule. Food and transportation aid was provided for all participants. Three free BPLs were offered every day to the women in the study group, who were instructed to wear the panty liners on a daily basis—for 10–12 hours continuously (regardless of the number of changes)—for 75 consecutive days. Women in the control group were instructed to wear their usual underwear. During menstruation, however, patients were free to use their own pads or tampons. The study group used BPLs in addition to common tampons during this time. Participants were instructed not to make any changes to their eating, sexual, or hygiene habits, including during menstrual periods. Ethics approval was provided by the Research Ethics Committee of the study institution.

The BPLs were produced in an industrial plant following Good Manufacturing Practices and were distributed in packages of 3 panty liners per day; they were handed out at each visit, without any branding identification. The products were designed to absorb small amounts of intermenstrual vaginal fluid and were composed of cellulose fibers (absorbent core), thermoplastic adhesives, nonwoven polypropylene cover fabric, silicone release paper, and odor neutralizer. The breathable barrier comprised a polypropylene nonwoven fabric (Johnson & Johnson, São Paulo, Brazil).

Six visits were scheduled for clinical and laboratory assessments at 2-week intervals (between the 8th and the 12th day and between the 22nd and the 26th day of the menstrual cycle). At each visit, in addition to gynecologic examination with colposcopic evaluation and vaginal pH measurement (with colorimetric paper strip [Merck, Darmstadt, Germany]), vaginal contents were sampled for microscopic investigation of microbial flora, intensity of inflammatory processes, and presence of vaginal candidiasis/bacterial vaginosis in Gram-stained smears; the vaginal contents were transferred to 2 glass slides for wet mount and staining via Gram technique. At 3 visits (initial, intermediate, and final) vaginal swabs were collected with a sterile alginate swab for identification of *Candida albicans* in Sabouraud medium, following incubation at 37 °C for 7 days. Interviews, gynecologic examination, and sample collection were carried out by the same researcher (R.L.G.A.). Sample processing, and isolation and identification of bacteria and fungi were performed by the same microbiologist (J.E. Jr) at the Microbiology and Molecular Biology Laboratory at the Women's Integrated Healthcare Center, UNICAMP.

The microbiology examination identified 3 types of vaginal flora: type 1 (a dominance of Gram-positive bacilli); type 2 (a balance between lactobacilli and other bacteria); and type 3 (the absence of lactobacilli) [13]. Vaginal candidiasis was diagnosed based on the presence of fungi (pseudohyphae and spores) on a vaginal smear or following culture. The API 20 C AUX system (Biomerieux Vitek, Hazelwood, MO, USA) was used for the isolation and identification of fungal species.

The diagnosis of bacterial vaginosis was carried out according to the Nugent criteria [14]. Cases were considered positive if the Nugent score was higher than 7. Vaginal inflammation was characterized by the presence of 4 or more leukocytes (polymorphonuclear neutrophils) per 40x magnification field by optical microscopy. Complaints of genital itching/burning and other clinical findings (e.g. vulvar hyperemia) were recorded at each visit.

The results were analyzed using SAS version 9.02 (SAS Institute, Cary, NC, USA), taking the absolute and relative frequencies, means, and SDs of qualitative and quantitative variables. Bivariate analysis of association measures used the Pearson χ^2 or Fisher exact test for nominal variables. The significance level was 95%.

3. Results

Of the 200 women assessed for eligibility, 195 were allocated to an intervention; 143 women underwent their allocated intervention and 52 were excluded (for not attending the consultation [n = 27], inappropriate use of BPLs [n = 22], or pregnancy [n = 3]) (Fig. 1). In total, 107 women were included in the study (53 in the study group and 54 in the control group) because 36 women had inconclusive microbiological exams.

The study and control groups were homogenous in terms of age; education; skin color; gravidity; parity; number of abortions; smoking; BMI; frequency of weekly sexual intercourse; and use of contraceptive pills, condoms, and vaginal douching (Table 1).

Despite the participants entering the study without complaints of vaginal discharge, 6.5% (n = 7/107) were found to have bacterial vaginosis, 8.4% (9/107) had presence of hyphae in vaginal content, 10.3% (11/107) had intermediate vaginal flora, and none had a vaginal pH above 4.5. During the study period, the frequency of vaginal discharge reached 24.3% (26/107), that of bacterial vaginosis reached 13.1% (14/107), that of hyphae in vaginal content reached 12.1% (13/107), and that of vaginal pH above 4.5 reached 15.9% (17/107).

At the start of the study, bacterial vaginosis was present in 7.5% (n = 4/53) of the study group (Table 2); at the end of the study period, the frequency had decreased to 6.8% (n = 3/44). In the control group, the initial frequency of bacterial vaginosis was 5.6% (n = 3/54), compared with 4.0% (n = 2/50) at the end of the study. The frequency of vaginal candidiasis at the beginning of the study was 9.4% (n = 5/53) and 7.4% (n = 4/54) in the study and control groups, respectively; at the end of the study, these frequencies had increased to 11.4% (n = 5/44) and 16.0% (n = 8/50), respectively.

None of the participants reported vaginal discharge, vulvar hyperemia, or vulvar burning/itching at their first visit. At the end

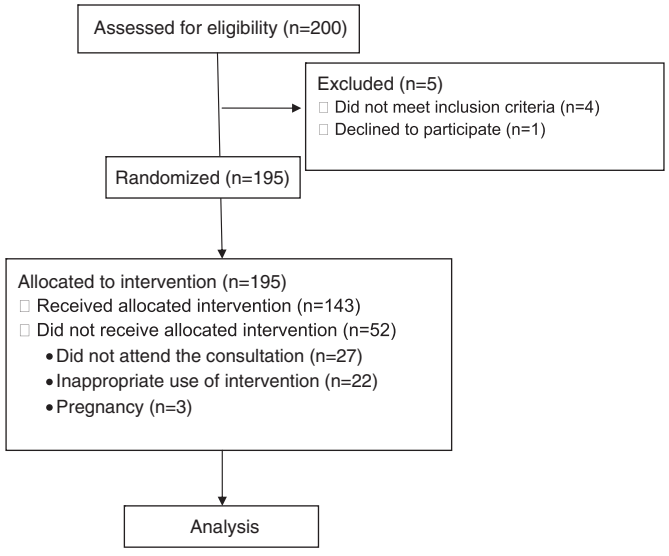

Fig. 1. Flow of participants through the study.