

The Relationship Among Objectively Assessed Vulvar Erythema, Skin Sensitivity, Genital Sensitivity, and Self-Reported Facial Skin Redness

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ABSTRACT

Background: Sensitive skin is an area of considerable research interest. Although research has been performed in people who consider their skin to be sensitive, genital skin sensitivity has not been explored.

Objective: Determine whether women with prior dermatologist-assessed vulvar erythema exhibited greater irritation to sanitary pads, and whether such women considered their skin to be sensitive, based on self-reported reactions to products used on the face or genitalia.

Methods: A retrospective questionnaire was administered and post-hoc analysis performed on 2 subgroups of women who had participated in a prior randomized trial of sanitary pads: ie, those who presented either with or without preexisting vulvar erythema on clinical trial enrollment.

Results: Women with preexisting vulvar erythema were more likely to report facial redness induced by cosmetics compared with women without vulvar erythema. Despite the persistence of slightly higher erythema scores among women with preexisting vulvar erythema in a prospective sanitary pad trial, no correlation to self-reported genital sensitivity was found.

Conclusions: Women with preexisting vulvar erythema were no more likely to perceive their skin as sensitive. However, they might be a more sensitive population based on the persistence of slight vulvar erythema in a prospective trial and a correlation with self-reported facial erythema with cosmetics. Because vulvar erythema was assessed objectively, its correlation with self-reported facial but not genital sensitivity may reflect the fact that facial changes are more noticeable.

INTRODUCTION

Sensitive skin is an area of considerable research interest.^{1,2} Sensitive skin is

often defined by a propensity to sensory responses (stinging, itching, burning) or visible reactions (erythema, papules or vesicles, wheal and flare responses, dryness, scaling, desquamation) in response to topical exposures.³

Significant numbers of the general population consider their skin to be sensitive. A study performed in the United Kingdom found that 51.5% of women and 38.2% of men perceived their skin to be sensitive.⁴ Similar results were observed in the United States where 52% of those surveyed perceived themselves to have sensitive skin; the proportion was similar across African Americans, Asians, Euro-Americans, and Hispanics.⁵

No clear consensus exists in the literature on what criteria define sensitive skin. Several studies on sensitive skin have emphasized facial reactions because facial irritation can be detected visually⁶ and by biophysical measures,⁷ and stinging responses to lactic acid are elicited readily.⁸⁻¹⁰

People with sensitive skin differ in susceptibility to irritants at various body sites. For example, Green¹¹ found that some people were more sensitive to capsaicin on the face while others were more sensitive on the forearm.

Little published information exists on whether genital skin reactions are more prevalent in people who report having sensitive skin elsewhere. The skin of the vulva differs from skin at exposed body sites in its permeability and in its susceptibility to certain irritants.¹²⁻¹⁴ Britz and Maibach¹⁵ found that vulvar skin was significantly more reactive than forearm skin to benzalkonium chloride and maleic acid, but Elsnier et al¹⁶ found that the vulva was slightly less reactive than the forearm to low concentrations of sodium lauryl sulfate (SLS). The vulva also was less responsive to the irritant effects of SLS, venous blood, and menses when compared with the upper arm.¹⁷

Vulvar skin reactions to 2 menstrual pads were previously evaluated in a prospective clinical trial with participants drawn from the general population.¹⁸ No significant difference in the prospective development of vulvar erythema was found between groups allocated to the test and comparison pads.

The present investigation examines 2 subgroups of participants from the above-referenced prospective trial who presented either with or without vulvar erythema at study enrollment prior to being allocated to test and comparison products. It was hypothesized that women who presented with preexisting vulvar erythema might represent a subgroup with sensitive skin. The study goals were (1) to assess whether the subgroup with preexisting vulvar erythema at study entry continued to exhibit higher levels of erythema during the prospective phase of the sanitary pad trial, and (2) to examine whether the subgroup of women with preexisting vulvar erythema might report a propensity to skin reactions on the face or genitalia. Towards these goals, (1) the degree of vulvar erythema in the 2 subgroups over the course of the sanitary pad was compared, and (2) a retrospective questionnaire was administered to determine whether subgroups with and without preexisting vulvar erythema differed either in their perceived skin sensitivity or in their history of facial or genital skin reactions to topical products.

MATERIALS AND METHODS

This was a retrospective study of a subgroup of participants who had participated in an examiner-blind, randomized, prospective trial of sanitary pads in healthy women. The prospective trial was described in elsewhere.¹⁸ In brief, healthy, regularly menstruating women aged 18 to 45 were enrolled in a sanitary pad trial lasting 2 menstrual cycles. The trial compared a test pad with a fabric-

like surface layer with a comparison commercial pad. Participants used only the assigned menstrual pads for menstrual protection. Outcome measures in the pad trial were (1) visually assessed vulvar erythema as scored by the study examiner, a board-certified dermatologist, (2) subjective perceptions of pad-related irritation and comfort, and (3) overall product preference.

At enrollment (and prior to product group allocation) medical histories were obtained and the vulva was scored for preexisting erythema of the mons pubis, the labia majora, and the labia minora by a board-certified dermatologist who was trained and validated in using the standard 5-point scale for erythema, where "0" was no apparent cutaneous involvement and "4" was moderate-to-severe erythema.¹⁸ The scoring scale also was used during the prospective phase of the trial.

Similar scoring scales for erythema have been used successfully for many years in the evaluation of potential dermatological effects of menstrual pads and panty liners.¹⁹⁻²¹ Results from the Procter & Gamble laboratory indicated that visual scoring yielded results that were as reliable as bioengineering measures, such as measures of transepidermal water loss or of erythema via chromometer. In addition, several authors have demonstrated that trained graders can reliably detect evidence of irritation with equal or higher degrees of sensitivity to that of instrumental measures.²²⁻²⁷

For the present post-hoc investigation, 14 trial participants with visually discernible erythema on the labia majora at enrollment in the prospective trial (erythema scores of ≥ 0.5) formed a test subgroup for analysis; 19 trial participants with no discernible vulvar erythema at enrollment (erythema scores of "0") were randomly selected from among the full cohort of participants in the prospective pad trial to represent the control subgroup. These are referred

to as the vulvar erythema subgroup (n=14) and control subgroup (n=19), respectively.

Two analyses were performed. First, the degree of vulvar erythema in each subgroup during the prospective phase of the sanitary trial was compared regardless of product assignment. For this comparison, the scores on the labia majora, labia minora, and mons pubis of each participant were averaged and subgroup means were compared.

A retrospective questionnaire was administered to these subgroups to assess whether they perceived their skin to be sensitive and whether they had a history of skin reactions to topical products used on the face or genitalia. The questionnaire was an industry standard, and questioned a personal or family history of rhinitis, asthma, or eczema; perceptions of either facial or genital sensitivity; and whether symptoms were related to topical contact, environmental causes (cold, heat, pollution), lifestyle (diet, alcohol, stress); or the menstrual cycle.

Participants who considered their facial skin to be sensitive rated facial sensitivity on a scale of 0 to 3, with 0=not sensitive, 1=somewhat sensitive, 2=moderately sensitive, and 3=very sensitive. They noted the types of subjective symptoms (tightness, burning, stinging, itching, discomfort) and/or observable symptoms (dryness, scaling, reddening) that they experienced after cosmetic application, rating these symptoms on a scale of 0 to 3, with 0=none, 1=slight, 2=moderate, and 3=severe.

Participants indicated the presence or absence of genital sensitivity based on reported subjective or objective symptoms (itching, burning, erythema) after use of menstrual pads, topical skin cleansers (bars or liquids), or textiles (acrylic fabrics).

Mean vulvar erythema scores between vulvar erythema and control subgroups during the prospective phase of the sanitary pad trial were compared

Table 1. Vulvar Erythema Scores From a Prospective Trial of Sanitary Pads* for 2 Consecutive Menstrual Cycles in Subgroups of Participants Who Presented With or Without Preexisting Vulvar Erythema at Enrollment

		Erythema Scores [†] (Mean ± SE) (n=group size)			
		Prospective Phase			
Enrollment		First Menstrual Cycle		Second Menstrual Cycle	
Subgroup	(Preexisting Erythema Scores)	Menstrual Scores	Intermenstrual Scores	Menstrual Scores	Intermenstrual Scores
Preexisting vulvar erythema	0.31 ± 0.04 (n=14)	0.15 ± 0.03 (n=13)	0.21 ± 0.04 (n=13)	0.12 ± 0.03 (n=13)	0.13 ± 0.04 (n=12)
No preexisting erythema (control)	0.00 ± 0.00 (n=19)	0.04 ± 0.02 (n=19)	0.02 ± 0.01 (n=18)	0.05 ± 0.02 (n=18)	0.05 ± 0.02 (n=18)
Comparison	<i>P</i> <0.0001	<i>P</i> =0.0009	<i>P</i> <0.0001	<i>P</i> =0.0695	<i>P</i> =0.0809

Note: Number of participants changes throughout the study due to subject withdrawals.
^{*} The prospective trial was described in Farage M, et al.¹⁸
[†] Vulvar erythema scores reported as the group mean for scores averaged for 3 vulvar sites: the mons pubis, the labia majora, and the labia minora, regardless of product assignment during the prospective phase. Among erythema subgroup with preexisting erythema at enrollment, 6 individuals used a test product with a modified top layer and 8 used a commercial product. Among the subgroup without erythema at enrollment (control) 8 and 11 individuals used test and comparison products, respectively.

using differences of least squares means. For this comparison, scores for the mons pubis, labia majora, and labia minora of each individual were averaged to obtain an overall vulvar erythema score, and subgroup means were compared irrespective of product assignment. It was previously shown that the pads did not differ significantly in skin effects.¹⁸ Fisher exact test was used to compare subgroup responses to the questionnaire on skin sensitivity.

RESULTS

Persistence of Vulvar Erythema

Vulvar erythema during the prospective phase of the original sanitary pad trial was compared in the 2 subgroups that, prior to use of the sanitary pads, presented with (n=14) and without (n=19) vulvar erythema at enrollment. During the pad trial, the subgroup that presented with vulvar erythema at enrollment consistently exhibited statistically higher

mean erythema scores of the vulva during the prospective phase of the trial (Table 1). Vulvar erythema scoring was performed menstrually and intermenstrually for 2 consecutive menstrual cycles. However, the degree of erythema observed was very low—at each prospective evaluation, mean scores in the subgroup with preexisting erythema were <0.5 (where 0.5 is barely perceptible on a scale of 0 to 4). Notably, mean scores in the subgroup that presented with erythema at enrollment dropped during the prospective phase, indicating that pad use did not have a detrimental effect on skin condition. In the control subgroup without vulvar erythema at enrollment, mean scores during the prospective phase were negligible (≤0.05) indicating that most individuals in this subgroup continued to have had no perceptible erythema throughout the study.

It is also interesting to note that

Table 2. Summary of Responses to a Questionnaire on Facial and Genital Sensitivity Among Subgroups of Women Who Presented With (Vulvar Erythema Subgroup) or Without Preexisting Vulvar Erythema (Controls) on Enrollment in a Prospective Trial of Sanitary Pads

	Is Your Facial Skin Sensitive? (Positive Responses)	Positive Responses (Slight, Moderate, and Severe) for the Subjects Who Claim Facial Sensitivity								
		Subjective Signs (After Application of Cosmetics)					Objective Signs			
Subgroup		Tightness	Burning	Stinging	itching	Discomfort	Dryness	Redness	Scaling	
Vulvar Erythema (n=14)	6	4	1	2	2	1	4	6 *	1	
Control (n=19)	8	4	0	1	1	1	7	2	4	

The vulvar erythema subgroup (n=14) and the control subgroup (n=19) were asked to respond to a series of questions about facial sensitivity, as detailed in the Materials and Methods section. This table summarizes the responses of those individuals who indicated that their facial skin was "sensitive."
 *Significantly different using Fisher exact test.

when vulva erythema was analyzed per region (ie, only labia major, labia minora, or mons pubis), the same results were achieved.

Self-Reported History of Atopy

Based on questionnaire responses, no significant differences between the subgroups were found in their personal or family history of rhinitis, asthma, or eczema conditions linked to atopy. Most respondents did not appear to have a personal or family history of atopy (data not shown).

Self-Reported Facial and Genital Sensitivity in Relation to Objectively

Assessed Vulvar Erythema

The proportion of respondents with or without vulvar erythema at enrollment who claimed some degree of facial sensitivity did not differ (6 of 14 in the vulvar erythema subgroup versus 8 of 19 in the control subgroup) (Table 2). There was no difference between these subgroups in the factors reported to elicit facial skin reactions (topical contact, environmental factors, lifestyle, and menstrual cycle). Topical contact and environmental factors were most often cited as causative in both subgroups; no respondents claimed facial sensitivity linked to the menstrual cycle.

Among respondents who claimed facial sensitivity, a higher number in the

The Sensitivity Is Related to				Do You Have a Personal or Family History of						Do You Have Sensitivity of the Genital Area After Use of		
Contact Causes	Environmental Causes	Lifestyle Causes	Menstrual Cycle	Eczema (Personal)	Eczema (Family)	Rhinitis (Personal)	Rhinitis (Family)	Asthma (Personal)	Asthma (Family)	Sanitary Pads	Topical Cleansers	Textiles (Acrylic Fibers)
6	5	2	0	0	0	1	1	1	1	6	3	5
7	7	1	0	0	1	1	0	0	1	5	3	5

vulvar erythema subgroup described their facial skin as moderately or very sensitive (Figure 1), but this result was not significant. Most respondents who claimed facial sensitivity in either subgroup also reported genital sensitivity to sanitary pads and textiles (Table 2). Among those claiming facial sensitivity, when the specific signs and symptoms were assessed (Table 2), facial redness was reported by a statistically higher number of individuals in the vulvar erythema subgroup (6 out of 6, or 100% claiming facial sensitivity) compared with the control subgroup (2 out of 8, or 25% claiming facial sensitivity) ($P=0.001$). The reported degree of facial redness was slight or moderate (Figure 2).

The frequency of reported genital sensitivity to sanitary pads, topical cleansers, or textiles was not significantly higher among the subgroup with vulvar erythema (Figure 3).

DISCUSSION

This investigation was a post-hoc evaluation of 2 subgroups of participants in a prior prospective trial of sanitary pads lasting 2 menstrual cycles.¹⁸ The primary outcome measures in the prospective trial were vulvar erythema (objectively scored by a dermatologist) and subjective symptoms reported during pads use. No significant difference in skin effects was found between the sanitary pads.

Some participants in this trial pre-

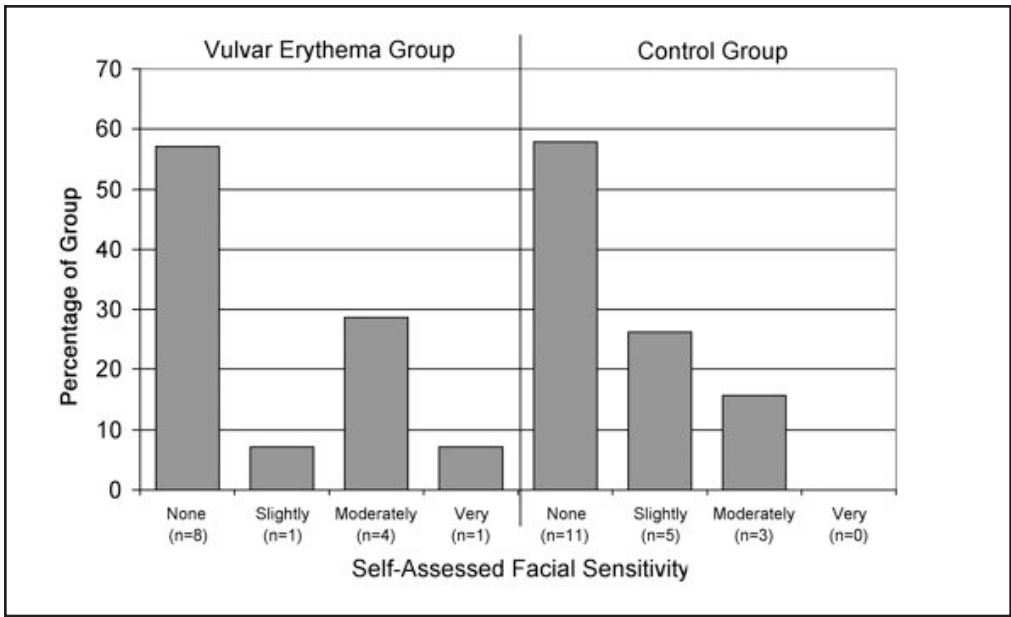


Figure 1. Relationship of vulvar erythema to self-reported sensitivity of facial skin. Prospective trial participants with vulvar erythema scores of ≥ 0.5 at enrollment (vulvar erythema subgroup, n=14) and a randomly selected control subgroup of participants with no erythema at enrollment (n=19) responded to a retrospective questionnaire on facial skin sensitivity. Participants rated symptoms associated with sensitive facial skin on a scale of 0 to 3, with 0=none or nonsensitive, 1=slight or somewhat sensitive, 2=moderately sensitive, and 3=very sensitive. The proportion of individuals in the vulvar erythema and no erythema (control) subgroups reporting facial skin sensitivity was compared. Differences did not reach significance ($P=0.238$).

sented with preexisting vulvar erythema on enrollment, prior to being allocated to sanitary pad use. It was hypothesized that these women might represent a sub-population with sensitive skin.

To test this hypothesis, the development of vulvar erythema was compared during the prospective trial in the subgroup of women who had presented with erythema at enrollment (vulvar erythema subgroup, n=14) and a control subgroup of randomly chosen participants (n=19) who presented with no discernible erythema. Subgroups were compared irrespective of product assignment. The vulvar erythema subgroup exhibited statistically higher erythema scores than the control subgroup, both menstrually and intermenstrually, throughout the prospective phase of the sanitary pad trial. This suggested that the vulvar erythema subgroup had a

measurably higher propensity to vulvar erythema than the controls, and it may indicate that the skin of the genitalia was more sensitive in these women based on objective measures. Nevertheless, these women tolerated the pads used in the trial, as the average intensity of vulvar erythema during the prospective phase dropped to levels below the barely perceptible range.

Self-reported genital skin and facial sensitivity in these subgroups were assessed by questionnaire. There was no difference between the subgroups in the proportion of respondents who reported facial sensitivity in response to cosmetics or genital reactions to sanitary pads, topical cleansers, or textiles. Women in the vulvar erythema subgroup were therefore no more likely to perceive their skin to be sensitive.

People who perceive their skin to be

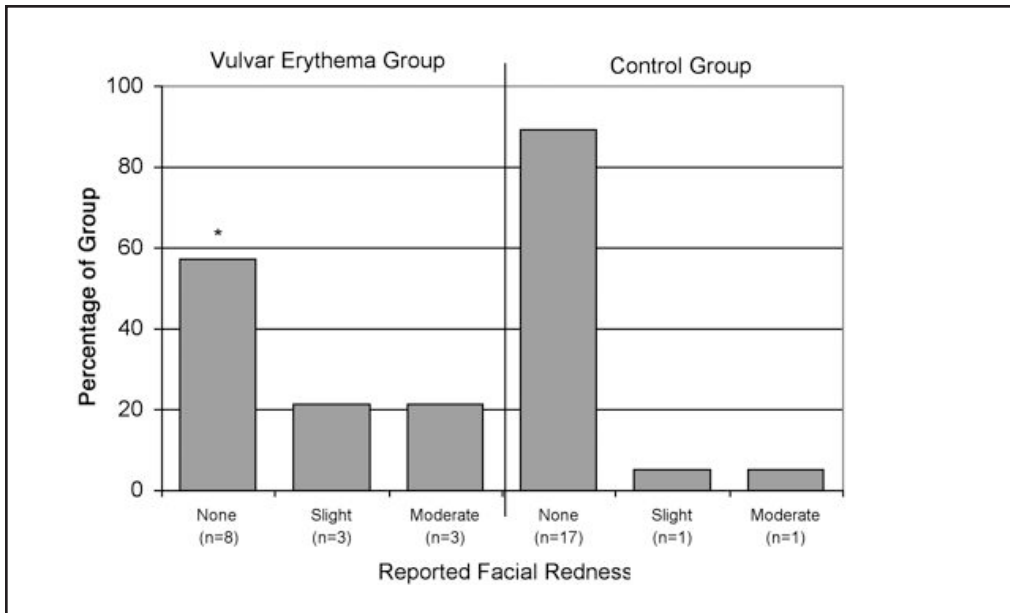


Figure 2. Relationship of vulvar erythema to reported facial redness (erythema) after topical product use. Prospective trial participants with vulvar erythema scores of ≥ 0.5 at enrollment (vulvar erythema subgroup, $n=14$) and a randomly selected control subgroup of participants with no erythema at enrollment ($n=19$) responded to a retrospective questionnaire on facial and genital skin reactions to topical products. Participants rated symptoms associated with sensitive facial skin on a scale of 0 (not sensitive) to 3 (very sensitive).

* Statistically higher frequency of reporting facial redness as a symptom ($P=0.047$).

sensitive report a variety of cutaneous and sensory reactions. A statistically higher proportion of those reporting “facial redness” (erythema) were in the vulvar erythema subgroup. The correlation between symptoms of erythema at both body sites supported the possibility that the subgroup of women with vulvar erythema at study inception was more likely to be prone to generalized erythematous reactions, a possible objective indicator of sensitive skin.

It is important to recognize that the degree of vulvar erythema exhibited by the subgroup in question was low, and it was scored by a trained dermatologist. The correlation with self-reported facial redness but not self-reported genital sensitivity may reflect the fact that women are more likely to see facial skin reactions than genital skin reactions. It is uncommon for women to closely observe the vulva, and they may not recognize skin changes unless they are severe and

create a bothersome sensation.

The definition of sensitive skin is broad, and the nature of the symptoms is highly variable. Symptoms range from visible signs of irritation (erythema, wheal and flare, and scaling) to subjective discomfort (burning, itching, stinging, and tightness). Self-reported symptoms are difficult to quantify, and often, there are no visible signs.²⁸ The statistical association of vulvar erythema and self-reported facial redness leads to the intriguing notion that manifestations of sensitive skin may be systemic for some individuals, regardless of body site or stimulus. A subpopulation with a propensity for skin erythema may have been identified, rather than sensory manifestations of sensitive skin that are more likely to elicit a self-perception of sensitivity.

Some caveats must be considered. The vulva is highly vascularized and may appear naturally rosaceous in some

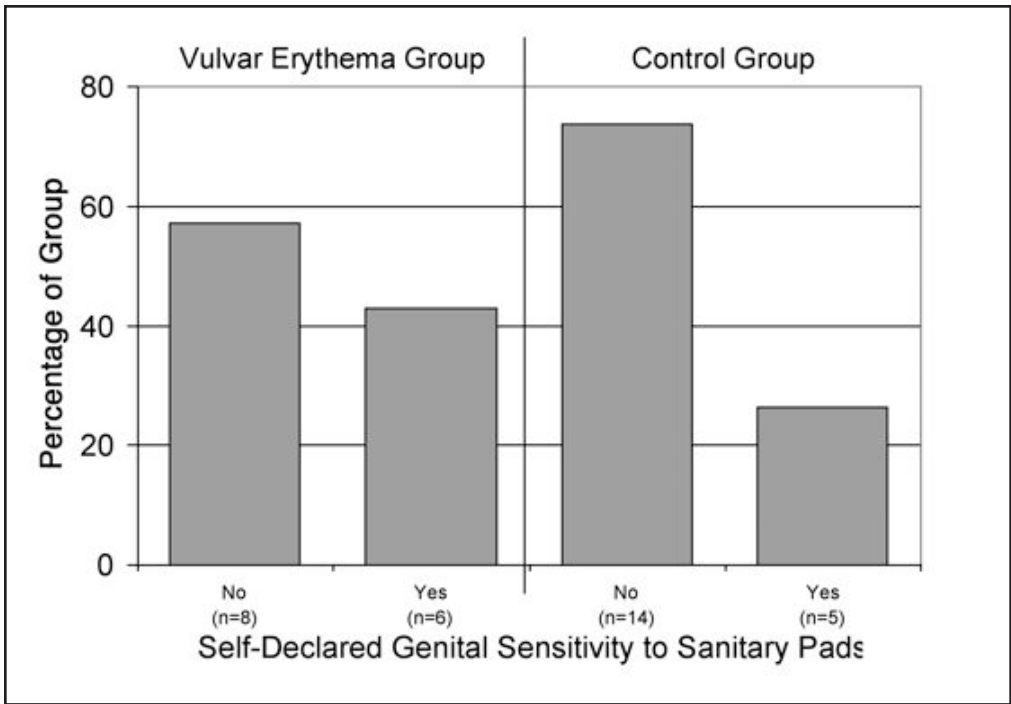


Figure 3. Relationship of vulvar erythema to reported genital sensitivity. Prospective trial participants with vulvar erythema scores of ≥ 0.5 at enrollment (vulvar erythema subgroup, $n=14$) and a randomly selected control subgroup of participants with no erythema at enrollment ($n=19$) responded to a retrospective questionnaire on genital skin sensitivity to sanitary pads, topical cleansers, and textiles. Subgroup differences in the number reporting genital sensitivity did not reach significance ($P=0.459$).

women. The possibility exists that for some of the women in the erythema subgroup, the degree of skin coloration exhibited was natural. However, the fact that average erythema scores for the subgroup dropped during the pad trial argues against skin coloration or pigmentation being a significant confounding factor. Second, the experience of skin sensitivity was self-reported and not independently confirmed by objective measures. However, the correlation of vulvar erythema with the specific symptom of facial redness (erythema) is noteworthy because it is a similar manifestation at a different site and because facial erythema, which is readily recognized, is unlikely to be erroneously reported.

In summary, a subgroup of women was found who presented with vulvar erythema on enrollment in a prospective sanitary pad trial consistently exhibited

higher vulvar erythema over the course of the study compared with controls who presented with no discernible erythema. Moreover, the presence of vulvar erythema in this subgroup was statistically associated with self-reported facial erythema. Taken together, these results suggest that certain women may be prone to erythematous skin responses at more than 1 body site, including the genitalia. Further research is needed to validate a possible relationship between a propensity to genital erythema and heightened erythematous reactions at other body sites and to determine whether this is an objective manifestation of skin sensitivity.

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