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The Association Between Perception of Sensitive Skin and Objective and Subjective Measures in Women with Urinary Incontinence

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Abstract

Purpose: To determine the prevalence of perceived sensitive skin in urinary incontinent women, and explore associations with objective and subjective measures.

Methods: A sensitive skin questionnaire was administered to 122 predominantly obese, frequent urinary incontinent women normally using protective underwear and recruited from the general population in St. Petersburg, Florida and San Antonio, Texas between October 2013 and February 2014. Their sensitive skin perception was compared with: 1) genital erythema, transepidermal water loss (TEWL) in the population, and subgroups of diabetic/menopausal status, and 2) product-related experiences.

Results: Population of 72% postmenopausal, 82% non-diabetic women, reported overall (62%), facial (50%), genital (41%), and body (39%) skin sensitivity. No statistical differences or trends found with diabetic/menopausal profile. Sensitive skin perception corresponded to higher (worse) erythema and TEWL scores over time, with some statistically significant differences for TEWL: overall buttock site on Day 14 (p=0.02), non-diabetic buttock (p=0.03), postmenopausal buttock (p=0.01) and labia majora (p=0.03) sites at Day 7 and at the buttock (p=0.01) site on Day 14. There was a statistically discernable perceived irritation due to products used in the genital area for subjects with perceived sensitive skin (p<0.05), and sensitive skin subjects were more likely to avoid certain ingredients and look for claims related to sensitive skin (p<0.01).

Conclusions: Based on this study, no association was seen between perception of sensitive skin and diabetic/ menopausal status. Skin sensitivity was associated numerically with higher (worse) erythema and TEWL scores, some reaching statistical significance. Sensitive skin consumers were more likely to experience product irritation used in the genital area, avoid certain ingredients, and look for sensitive skin claims. The diabetic population was small in this study, and a larger study is needed for final conclusion.m.

Keywords: Female; Diabetic; Erythema; Protective underwear; Sensitive skin; Urinary incontinence

Introduction

Sensitive skin represents a complex clinical challenge for dermatologists, and other skin care professionals. It is defined as patient report of prickling, burning or tingling sensation, due to physical, chemical, psychological, or hormonal factors, which may not include clinical signs or objective skin health measures expected in inflammatory or allergic reactions [1]. Sensitive skin has been reported throughout the body [2], and its pathophysiology is poorly understood [3-6]. Despite methodological differences (questionnaires used, anatomical sites investigated), epidemiological studies across industrialized world, including United States, United Kingdom, and France show the general population majority report sensitive skin, with higher prevalence in women vs. men [7].

Involuntary bladder control loss, termed urinary incontinence (UI), is a common health problem, especially among women. Rough female population prevalence estimates range from 5% to 69% globally [8]. Cultural differences, willingness to report, and methodological research differences are factors impacting the variation. Most studies report any UI prevalence in 25% to 45%, with 10% of adult women reporting at least weekly urine leakage [9]. Known risk factors for UI include increased body mass index (BMI), diabetes, and aging [9]. Several cross-sectional studies document an association between depression and incontinence [9], and urinary incontinent women have been shown to have a high overall perception of sensitive skin [10].

Treatment options for UI range from conservative lifestyle interventions, such as pelvic floor muscle training to more invasive

treatments as pharmaceuticals and surgery [9]. Some women manage UI with absorbent products; therefore, it is important for manufacturers to understand self-perception of sensitive skin to develop better products targeted for this population.

A previous investigational study evaluated the protective underwear impact on objective and subjective assessments in women self-reporting frequent involuntary bladder leakage (defined as: ≥ 1 leakage a day ≥ 5 days a week, wearing ≥ 1 moderate or maximum absorbency protective underwear a day). The population was postmenopausal (72%) and non-diabetic (82%), with a subgroup of premenopausal (28%) and diabetic (18%) subjects [11]. Women completed sensitive skin questionnaire about the history and nature of their sensitive skin, as well as product-related experiences. They were randomized to use either a currently marketed or experimental adult incontinence (AI) product with unique odor neutralizing technology for 14 consecutive days. Objective measurements: 1) expert grading of genital erythema at

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labia majora, labia minora, mons pubis, perineum, buttocks, and inner thigh as control, and 2) transepidermal water loss (TEWL) at labia majora, buttocks, and inner thigh as control. Measures at Baseline, Day 7 (Middle of treatment) and Day 14 (End of treatment). In this study, we were interested in investigating perceived sensitive skin prevalence, and association with objective and subjective measures. Since vulvovaginal symptoms in postmenopausal subjects may include irritation, burning, itching, etc. [12], and skin complications (infections and other disorders) and slower wound healing are common in people with diabetes [13], we also wanted to explore the impact of menopausal and diabetics status on these associations.

Materials and Methods

Study subjects, design, and procedures

Participants in a previous prospective trial had been administered a questionnaire prior to treatment to determine their sensitive skin self-perception. The prospective trial is described elsewhere, and the protocol and written subject information were approved by an Independent Central Institutional Review Board (Liberty, #13.09.0011) [11]. Briefly, incontinent women were recruited from the general population in St. Petersburg, Florida and San Antonio, Texas between October 2013 and February 2014. Subjects were asked demographic, medical/medication history, and inclusion/exclusion questions to determine their eligibility for the trial. Subjects were ambulatory (did not need assistance changing clothes and therefore study product), non-pregnant females \geq 18 years of age, with general good health (if diabetic, most recent HbA1c score <8%), and reported using moderate or maximum absorbency protective underwear for incontinence. Subjects reported frequent involuntary bladder leakage, defined as \geq 1 episode a day \geq 5 days a week, and reported using a \geq 1 product a day [11]. Urinary incontinence type (Stress, urgency, mixed, other) was not documented. Enrollment targeted ≤ 15% Fitzpatrick Skin Type V and VI [14], 20% Type II diabetics. Exclusion criteria included: currently using antibiotics, chemotherapeutics, antihistamines, antiinflammatories, corticosteroids, having any skin abnormalities that could interfere with interpretation of test results, kidney disease, current hematuria, and evidence of urinary tract or genital infection. Subjects agreed to refrain from activities impacting test results, such as: 1) shaving, using depilatories, or applying skin care preparations in pubic or buttocks area, 2) using tobacco, alcohol, caffeine or having sexual intercourse 2 hours before study visits, and 3) vigorous (sweat producing) exercise, swimming and sun exposure.

Baseline assessments included a self-perception skin questionnaire used to identify individuals with sensitive skin, and to understand the history and nature of their sensitive skin [2,15-18]. Subjects described their overall skin sensitivity, and facial, body and genital areas using the same 4-point scale. Some questions were regarding product-related experiences, and other questions about shopping decisions. Subjects were randomized and stratified into two groups (based on reported number of protective underwear used, presence of diabetes, waist measure), receiving experimental or marketed reference maximum absorbency protective underwear. Products were worn (nonmenstrually for premenopausal women) for urine leakage protection (\leq 24 hours/day) for 14 consecutive days [11].

The primary outcome measure was visual skin grading at the following sites: mons pubis, labia majora, labia minora, perineum, buttocks, and inner thighs (control area outside of the protective underwear). TEWL (VapoMeter SWL-4; Delfin Technologies, Ltd., Finland) was measured at labia majora, buttock, and inner thigh (control area). Both erythema grading and TEWL measures were

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taken at Baseline, Day 7, (Middle of treatment) and Day 14 (End of treatment). Visual assessments and TEWL measures were completed by qualified health professionals experienced in visual grading. One evaluator per site, blinded to product assignment, conducted all visual grading and TEWL assessments. TEWL was conducted at the Florida site exclusively (n=98) under proper environmental controls (Temperature 70° ± 2°F and 40% ± 5% Relative Humidity). The same TEWL instrument and operator were used.

Statistical analysis

Subjects were categorized as 'sensitive' or 'not sensitive' skin based on sensitive skin question responses. Those assessing themselves as 'very sensitive,' moderately sensitive,' or 'slightly sensitive' were 'sensitive skin.' Subjects assessing themselves as 'not sensitive' were 'not sensitive skin.' Descriptive statistics for the self-perceived 'sensitive' and 'not sensitive' skin groups were summarized. For numerical variables such as TEWL and Erythema, differences between groups were analyzed with Generalized Linear Mixed Models using the GLIMMIX procedure (SAS*, Version 9.4, Cary, North Carolina, USA). Group comparisons on categorical variables (such as diabetic and menopausal status) were analyzed with Fisher's Exact test. All comparisons were two-sided with a significance level of 0.05.

Results

Demographics

The demographics of the entire test population are shown in Table 1. The subject population was comprised of one hundred twenty-two women; aged 22-84 years (mean age of 56 years), with the majority (80%) of subjects from the Florida site. Overall mean Body Mass Index (BMI) was 33.8 ± 7.02 (SD) kg/m² (obese), and subjects were primarily Caucasian (79%) and Non-Hispanic (86%), or Black (19%). The demographics across both perceived sensitive and not sensitive skin were comparable.

Baseline characteristics

The baseline characteristics of the entire test population are shown in (Tables 1 and 2), (Figures 1 and 2). The majority of subjects in the test population were non-diabetic (100 subjects, 82%) and postmenopausal (88 subjects, 72%), and a majority (74 subjects, 62%) perceived themselves as having some degree of overall sensitive skin. There were no statistical differences found for the perception of overall sensitive skin (p=0.82) or for genital, body or face sensitivity (p=0.49, p=0.65, and p=0.82, respectively) between subjects recruited from the Florida and Texas sites. The baseline characteristics across both sensitive and not sensitive skin were comparable, except for those self-reporting sensitive skin had a significantly higher (p<0.0001) incidence of reported family members with sensitive skin (43%) versus not sensitive skin (9%). Almost all subjects (97%) did not experience doctor-confirmed skin allergies. The majority of subjects reported having sensitive skin for more than 10 years, with no or very little change in their skin sensitivity over time (Table 2). Weather was the predominant reason for why subjects thought they had sensitive skin.

Association between perceived skin sensitivity and diabetic and menopausal status

Sixty-two percent of the entire test population reported some degree of sensitive skin overall, and some degree of facial (50%), genital (41%) and body (39%) sensitivity (Figure 1). The severity of sensitivity experienced was low, with almost all subjects reporting their skin as either 'Not Sensitive' or 'Slightly Sensitive' (range of 85-95%) overall

| Demographic Measure/ Statistic | Sensitive (N=74)ª | Not Sensitive (N=46) | Overall (N=122) | | | | |
|--|----------------------|-------------------------|-----------------|--|--|--|--|
| Age | | | | | | | |
| Mean (SD) | 56.1 (10.87) | 55.7 (14.31) | 56.0 (12.16) | | | | |
| Min-Max | 22.0-81.0 | 27.0-84.0 | 22.0-84.0 | | | | |
| Median | 55 | 55.5 | 55 | | | | |
| Body Mass Index (kg/m ²) | | | | | | | |
| Mean (SD) | 34.4 (6.57) | 32.6 (7.65) | 33.8 (7.02) | | | | |
| Min-Max | 17.6-53.0 | 19.6-56.3 | 17.6-56.3 | | | | |
| Median | 34.1 | 31.5 | 33.6 | | | | |
| Diabetic | | | | | | | |
| No | 62 (83.8%) | 36 (78.3%) | 100 (82.0%) | | | | |
| Yes | 12 (16.2%) | 10 (21.7%) | 22 (18.0%) | | | | |
| Menopausal Status | | | | | | | |
| Post | 55 (74.3%) | 31 (67.4%) | 88 (72.1%) | | | | |
| Pre | 19 (25.7%) | 15 (32.6%) | 34 (27.9%) | | | | |
| Race | | | | | | | |
| American Indian or Alaskan Native | 3 (4.1%) | 0 (0%) | 3 (2.5%) | | | | |
| Black | 17 (23.0%) | 5 (10.9%) | 23 (18.9%) | | | | |
| Caucasian | 54 (73.0%) | 41 (89.1%) | 96 (78.7%) | | | | |
| Ethnicity | | | | | | | |
| Hispanic | 9 (12.2%) | 8 (17.4%) | 17 (13.9%) | | | | |
| Non-Hispanic | 65 (87.8%) | 38 (82.6%) | 105 (86.1%) | | | | |
| Family member with sensitive skin? | | | | | | | |
| No | 42 (57.5%) | 42 (91.3%) | 85 (70.8%) | | | | |
| Yes | 31 (42.5%) | 4 (8.7%) | 35 (29.2%) | | | | |
| Skin allergies confirmed by a doctor? | | | | | | | |
| No | 70 (94.6%) | 46 (100%) | 117 (96.7%) | | | | |
| Yes | 4 (5.4%) | 0 (0%) | 4 (3.3%) | | | | |
| ^a Subjects were asked the following question, "Some people have skin that is more sensitive than others. How would you describe your skin?" | | | | | | | |

^b Two subjects did not answer the overall sensitivity question

° n=98 from St. Petersburg, Florida, n=24 from San Antonio, Texas

Table 1: Demographics and Other Baseline Characteristics of the test population and by perceived skin sensitivity status. and across body, facial and genital body sites (Figure 1). There were no statistical differences or trends for sensitive skin profiles regardless of diabetic or menopausal status (Figure 2).

Association between perceived skin sensitivity and objective measurements

Perception of sensitive genital skin was generally associated with higher erythema and TEWL (higher is worse) scores over time

| Measure ^a | Number of Subjects | Percentage of Subjects | | | | | | |
|---|--------------------|------------------------|--|--|--|--|--|--|
| Why do I have sensitive skin? ^b | | | | | | | | |
| Rash | 13 | 18.57% | | | | | | |
| Burning,stinging,itching | 8 | 11.43% | | | | | | |
| Weather | 28 | 40.00% | | | | | | |
| Items that rub | 11 | 15.71% | | | | | | |
| Other | 10 | 14.29% | | | | | | |
| Sensitive skin length of time ^c | | | | | | | | |
| Less than 6 months | 6 | 8.22% | | | | | | |
| 6-11 months | 8 | 10.96% | | | | | | |
| 1-5 years | 11 | 15.07% | | | | | | |
| 6-10 years | 9 | 12.33% | | | | | | |
| Greater than 10 years | 39 | 53.42% | | | | | | |
| Changed over the years? ^d | | | | | | | | |
| Much less | 8 | 10.96% | | | | | | |
| Little less | 18 | 24.66% | | | | | | |
| No change | 27 | 36.99% | | | | | | |
| Little more | 18 | 24.66% | | | | | | |
| Much more | 2 | 2.74% | | | | | | |
| ^a These questions were only applicable to those subjects self-declaring to have sensitive skin | | | | | | | | |

^b 70 subjects answered 'Why do I have sensitive skin' question.

° 73 subjects answered 'Sensitive skin length of time' question.

^d 73 subjects answered 'Changed over the years' question.

Table 2: Descriptive Summary for subjects with self-declared sensitive skin.

Figure 1: Self-assessed description of skin type among all respondents. A total of 122 subjects completed the sensitive skin questionnaire at baseline to self-assess details of their skin sensitivity. Subjects who assessed themselves as 'Very Sensitive,' 'Moderately Sensitive,' or 'Slightly Sensitive' were classified as having 'Sensitive skin.' Subjects who assessed themselves as 'Not Sensitive' were classified as having 'Not Sensitive skin.' The majority of subjects self-declared themselves as having sensitive skin (62%) overall. The percentage of subjects responding as having sensitive skin for the facial, body and genital body sites was: 50%, 39%, and 41%, respectively.

Self-assessed Description of Skin Type Body N=73 (60.8%) V=60 (49.6%) V=44 (36.4%) 60 V=41 (34.2%) 40 N=16(13.2%) N= 4 (33%) Percentage of Respondents N= 2 (1.7%) (0.8%) 20 N= 1 N=72 (59.5%) N=56 (46.7%) N=46 (38.3%) 60 N=38 (31.4%) 40 N=16(13.3%) N= 8 (6.6%) N=3(2.5%) 1.7%) 20 N=2(.) o Very Sensitive Very Sensitive Slightly Sensitive Moderately Sensitive Slightly Sensitive Not Sensitive Not Sensitive Moderately Sensitive Sensitivity Level

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|---|------|---|----|---|
| | • | | | |

as compared to those who did not perceive their genital skin as sensitive. For the entire test population, the only significant difference between the sensitive and non-sensitive groups was the TEWL score at the buttock site on Day 14 (p=0.02), (Figure 3). For diabetes status breakout, TEWL score at the buttock site on Day 14 for the sensitive group was significantly higher for the non-diabetic subgroup than for the not-sensitive group (p=0.03), (Figure 4). For menopausal status breakout, there were no statistically significant differences found in the

premenopausal population between sensitive and not sensitive subjects; however, TEWL scores were significantly higher for sensitive versus the not sensitive group at the buttock (p=0.01) and labia majora (p=0.03) sites on Day 7 and at the buttock (p=0.01) and inner thigh - control (p=0.04) sites on Day 14 (Figure 5) for the postmenopausal population.

Product-related experiences

Subjects were asked if they experience irritation due to products



Figure 2: Self-assessed description of skin type among diabetic and menopausal status for all respondents. Diabetic and menopausal status were explored to understand the association of these characteristics on perception of sensitive skin. Using a two-sided Fisher's exact test for the group comparisons, there were no statistical differences or trends between the sensitive skin profiles between diabetics (Yes) and non-diabetics (No) as well as between postmenopausal (Post) and premenopausal (Pre) subjects.



Figure 3: Erythema and TEWL mean profile based on perceived genital sensitivity per anatomical site. There were no statistical differences or trends across all anatomical sites graded for erythema, and a statistically significant difference (p<0.05) at Day 14 for buttock TEWL (Subjects perceiving themselves as having sensitive genital skin had higher, or worse, TEWL scores).

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Figure 4: Erythema and TEWL mean profile based on perceived genital sensitivity per anatomical site for the subgroup of diabetic (n=22 with 12 sensitive and 10 not sensitive) and non-diabetic (n=98, 62 sensitive and 36 not sensitive) subjects. There were no statistical differences across all anatomical sites for erythema, and a statistically significant difference (p<0.05) at Day 14 for non-diabetic sensitive genital skin subjects at buttocks site for TEWL (Subjects perceiving themselves as having sensitive genital skin had higher, or worse, TEWL scores).



Figure 5 : Erythema and TEWL mean profile based on perceived genital sensitivity per anatomical site for the subgroup of postmenopausal (Post, n=86 with 55 sensitive and 31 not sensitive) and premenopausal (Pre, n=34, 19 sensitive and 15 not sensitive) subjects. There were no statistical differences for sensitive skin profiles and menopausal status for erythema, and statistically significant differences (p<0.05) for labia majora and buttock postmenopausal TEWL (Subjects perceiving themselves as having sensitive genital skin had higher, or worse, TEWL scores).

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used in the genital area (Table 3). Subjects who had some degree of genital skin sensitivity had a statistically significant higher percentage of experiencing skin irritation in the genital area after use of panty liners, incontinence pads, soaps and undergarments/clothing products versus those subjects who did not perceive themselves as having sensitive skin (p=0.03).

Subjects were asked two general questions about shopping decisions (Table 4). Subjects who perceived their skin as having some degree of sensitivity were more likely to avoid certain ingredients (p=0.04) and look for claims related to sensitive skin (p<0.0001) as compared to subjects who do not perceive their skin as sensitive.

Discussion and Conclusion

Prevalence of self-perceived sensitive skin in this population of majority postmenopausal women with frequent UI was 62% (74 subjects out of 120), which is similar to that reported in the literature [8]. The majority of subjects in this study had long standing perceived sensitive skin (more than 10 years) with a consistent level of severity over time. The numerical profile of perceived sensitive skin overall and for facial, genital and body areas was slightly lower, but followed the same trend reported previously in a large epidemiological study (n=1039) conducted with the same questionnaire in individuals with at least 5 years of perceived sensitive skin [2]. In contrast, the profile of self-perceived genital sensitivity reported previously in light UI women was higher than reported in this study, possibly influenced by the light UI women's participation in a focus group [10]. Both this and the previous study with light UI women [10] report lower self-perception of genital sensitivity than reported in the general population. A couple of possible explanations for this phenomenon are that women with UI may be more focused on managing urine leakage, or on maintaining a higher level of hygiene related to urine leakage versus a higher concern with sensitive skin.

Based on this study, neither menopausal status, nor diabetic status appeared to influence sensitive skin perception either overall, or at different anatomical sites. That said, the number of diabetic women in particular were very low, and a study should be conducted with a larger population of diabetics to confirm. Results based on menopausal status are contrasted with results of a previous epidemiological

| Variables | | Answer = Yes | | | | Answer=No | Divalue | |
|-------------------------------------|--------------|---------------|--------|------------|-----------|-------------|-------------|-------------|
| Factor | N of Answers | Sensitivity | Always | Frequently | Sometimes | Total | Never | ver P-value |
| Experience genital irritation after | er use? | | | | | | | |
| Menstrual Pads | 404 | Not Sensitive | 0 | 0 | 4 | 4 (11.76%) | 30 (88.24%) | 0.0129 |
| | 121 | Sensitive | 1 | 3 | 6 | 10 (41.67%) | 14 (58.33%) | |
| Danatu Linawa | 440 | Not Sensitive | 0 | 0 | 5 | 5 (8.77%) | 52 (91.23%) | 0.0000 |
| Panty Liners | 119 | Sensitive | 0 | 1 | 15 | 16 (43.24%) | 21 (56.76%) | 0.0002 |
| la continenza Dada | 400 | Not Sensitive | 0 | 0 | 5 | 5 (7.81%) | 59 (92.19%) | <0.0001 |
| Incontinence Pads | 120 | Sensitive | 0 | 2 | 18 | 20 (47.62%) | 22 (52.38%) | |
| - | 110 | Not Sensitive | 0 | 0 | 2 | 2 (5.56%) | 34 (94.44%) | 1 |
| lampons | 119 | Sensitive | 0 | 1 | 0 | 1 (5.00%) | 19 (95.00%) | |
| | 400 | Not Sensitive | 0 | 1 | 3 | 4 (7.02%) | 53 (92.98%) | 0.0074 |
| Feminine wipes | 120 | Sensitive | 0 | 0 | 10 | 10 (28.57%) | 25 (71.43%) | |
| | 110 | Not Sensitive | 0 | 0 | 7 | 7 (11.11%) | 56 (88.89%) | <0.0001 |
| Soaps | 116 | Sensitive | 0 | 1 | 19 | 20 (50.00%) | 20 (50.00%) | |
| | 110 | Not Sensitive | 0 | 1 | 5 | 6 (10.53%) | 51 (89.47%) | <0.0001 |
| Deodorants | 119 | Sensitive | 1 | 0 | 17 | 18 (47.37%) | 20 (52.63%) | |
| | 101 | Not Sensitive | 0 | 0 | 5 | 5 (10.64%) | 42 (89.36%) | 0.4921 |
| Douching Products | 121 | Sensitive | 1 | 0 | 4 | 5 (17.24%) | 24 (82.76%) | |
| | 100 | Not Sensitive | 0 | 0 | 6 | 6 (10.53%) | 51 (89.47%) | 0.004 |
| Perfumes/Colognes | 120 | Sensitive | 0 | 1 | 12 | 13 (36.11%) | 23 (63.89%) | |
| Toilet Paper | | Not Sensitive | 0 | 0 | 1 | 1 (1.56%) | 63 (98.44%) | 0.0001 |
| | 121 | Sensitive | 0 | 0 | 11 | 11 (26.83%) | 30 (73.17%) | |
| | 101 | Not Sensitive | 0 | 0 | 6 | 6 (9.38%) | 58 (90.63%) | <0.0001 |
| Undergarments/Clothing | 121 | Sensitive | 0 | 1 | 17 | 18 (45.00%) | 22 (55.00%) | |

Table 3: Comparison of self-declared genital sensitivity and response to experiencing genital irritation due to products.

| Variables | Self-assessed Sensitivity | | | | | | |
|--|---------------------------|-------------|---------------|---------|--|--|--|
| Answer | N of Answers | Sensitive | Not Sensitive | P-value | | | |
| Are there ingredients you avoid? | | | | | | | |
| No | 100 | 67 (90.54%) | 46 (100.0%) | 0.0400 | | | |
| Yes | 120 | 7 (9.46%) | 0 (0%) | 0.0428 | | | |
| Look for claims such as safe for sensitive skin? | | | | | | | |
| No | 116 | 32 (45.07%) | 40 (88.89%) | <0.0001 | | | |
| Yes | 110 | 39 (54.93%) | 5 (11.11%) | | | | |
| ^a In the questionnaire, subjects were asked about shopping habits. A two-sided Fisher's Exact test was conducted to determine if the sensitive and not sensitive groups differed. | | | | | | | |

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study conducted in Cincinnati, Ohio in which sensitive genital skin perception increased with postmenopausal status [19]. This indicates regional differences potentially influence sensitive skin perception.

Genital skin irritation due to products was reported to occur infrequently in this study, with majority reporting occurrence of "Never' or 'Sometimes.' This is a similar profile as reported previously [10] for both light UI women and their age-matched controls, indicating this phenomenon is probably not specific to UI women. The self-reported irritation profile for subjects with self-perceived sensitive genital skin was statistically higher than those reporting to not have sensitive genital skin across almost all categories, including: panty liners, menstrual pads, incontinence pads, and undergarments/clothing. This, however, may not be a clinically meaningful difference, since overall scores were low. On the other hand, subjects who subjectively perceived their skin as having some degree of sensitivity were more likely to be consumers who avoid certain ingredients and look for claims related to sensitive skin as compared to subjects who do not perceive their skin as sensitive.

There was a continuous trend of numerically higher (higher scores are worse results), but not statistically significant erythema scores. TEWL scores for sensitive skin subjects were also higher (higher scores are worse results) both overall and in subgroups of diabetic and postmenopausal subjects, although few statistical differences or trends overall were seen. Previous literature concluded no significant differences between menopausal status in healthy women (unknown urinary incontinence status) and TEWL scores [12,20]. TEWL and erythema results in this study between premenopausal and postmenopausal subjects were overall similar numerically; however, there were some statistical differences between TEWL postmenopausal sensitive and not sensitive subjects.

Limitations for the present study include the study was not sized to distinguish differences in sensitive vs. not sensitive skin, but was part of a separate study comparing skin health effects between an experimental and marketed reference protective underwear. Results are generalizable for frequent UI sufferers who normally use protective underwear; however, generalization for incontinent sub-types (Stress, urgency, other) are unknown as this information was not collected. The study was conducted in Florida and Texas for warmer, more consistent environmental conditions for testing; therefore, responses to the sensitive questionnaire should be considered with this regional context.

Based on this study:

• No association was seen between perception of sensitive skin and with diabetic or menopausal status. The diabetic population was small in this study for any conclusion, and there is a need to conduct a larger study.

- No firm association was seen between perception of sensitive skin and objective measures of erythema or TEWL. However, an interesting finding is that genital skin sensitivity was associated with higher erythema and TEWL scores (higher is worse) both overall and across diabetic and menopausal status subgroups, with some TEWL scores reaching statistical significance.
- There was a statistically discernable perceived irritation due to

products used in the genital area for subjects with perceived genital sensitive skin.

• Subjects with sensitive skin perception were more likely to be consumers who avoid certain ingredients and look for claims related to sensitive skin as compared to subjects who do not perceive their skin as sensitive.

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