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Efficacy of 3D-pore sanitary napkin on mild-to-moderate irritant contact dermatitis in the female genital area

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Abstract

Background: Women worldwide have their own strategies to cope with menstruation, and unhygienic menstrual practices often cause vaginal diseases. During menstruation, the skin is irritated by the remaining unabsorbed menstrual flow and sweat on sanitary pads. Irritation of vulvar skin by an external agent could cause contact dermatitis, which is an important contributor to vulvar diseases. Various sanitary napkins available today share similar materials. This study compared commonly used sanitary napkin among Indonesian women with 3D-pore sanitary napkin in terms of efficacy.

Methods: A randomized, controlled, single blind, crossover study of 72 participants who met the inclusion and exclusion criteria was conducted. Six areas were evaluated by dermatologists using the Grading Scale of Cutaneous Symptoms. The evaluation was performed in five visits.

Results: All participants were divided randomly into two groups. Eight of the 72 participants dropped out; thus, 64 participants completed the study. Scores at Visit-2 show a significant difference between group A (3D-pore napkin) and group B (comparator napkin). Group A shows better improvement. The difference in total score at first second visit until end visit from each napkin shows that the 3D-pore napkin reduces the score by 4.77 and the comparator napkin reduces the score by 3.10. The difference between these numbers is statistically significant. The specific area (external genitalia and perianal) of both groups is significantly reduced in visit 1 and visit 2. The 3D-pore napkin reduces wetness better than the comparator napkin.

Conclusion: The 3D-pore sanitary napkin significantly improves vulvar skin inflammation compared with the comparator napkin.

Keywords: 3D-pore sanitary napkin, commonly used napkin, female genitalia

Background

Menstrual hygiene practices are affected by cultural norms, parental influence, personal preferences, economic status, and socioeconomic pressures. Menstrual beliefs refer to misconceptions and attitudes toward menstruation within a given culture or religion.

Women worldwide cope with menstruation differently depending on personal preferences, availability of resources, economic status, cultural traditions and beliefs, education level and knowledge about menstruation. Practices related to menstrual hygiene are of major concern because of its health impact. Poor menstrual hygiene can cause toxic shock syndrome, and other vaginal diseases.¹

Vulvar disease is generally multifactorial, and contact dermatitis of the vulva is an important contributor to this disease. Although different agents have been implicated in vulvar dermatitis, the susceptibility of this tissue to inflammation caused by topical and micro traumatic agents may be underestimated.² Contact dermatitis is a skin inflammation caused by an external agent that acts as an irritant. Characteristic symptoms of contact dermatitis, such as vulvar itching and soreness, adversely affect the quality of life of affected women. This condition has a presentation of varying redness, swelling, and scaling. Erosions or frank ulcers with marked erythema and swelling may appear. The increased tendency toward irritant dermatitis may cause problems by itself or act as a risk factor for further development of other vulvar dermatoses.³ Common irritants include soaps, antiseptics, lubricants, spermicides, tampons, sanitary pads, and synthetic underwears. Irritant contact dermatitis may be due to poor hygiene habits or excess use of soap or prolonged wearing of wet swimming suits.⁴

Rashes or itching during menstruation has two major causes, namely, heat and dampness. Skin is irritated by the remaining unabsorbed menstrual flow and sweat on sanitary napkin.⁵

Disposable absorbent hygiene products, such as feminine pads, have evolved with the availability of advanced materials, and their superior functions over cloth napkins have improved the quality of daily lives. Although feminine pads and baby/adult diapers are used for different purposes, absorbent hygiene products share similar materials.⁶

Therefore, a study is needed to compare the efficacy of commonly used sanitary napkin by Indonesian women with 3D-pore sanitary napkin on mild-to-moderate irritant contact dermatitis.

Methods

The study design was a randomized, controlled, single blind, crossover study. Study duration: End of January 2018 until May 2018
Study site: Clinical site of PT Equilab International, Jakarta, Indonesia.

Inclusion criteria:

1. Healthy individuals
2. Age: 20–39 years
3. Gender: Female
4. Individuals with a history of regular menstrual cycles for the past year. (Regular is defined as 26–30 days \pm 3 days cycle for each month)

and have a minimum menstruation period of 3 days.

5. Individuals who experienced any symptom of itchiness or offensive senses (sweatiness or scrape) under the usage of feminine hygiene products during the last three menstrual periods before screening.

Exclusion criteria:

1. Use of any of the following:
 - Systemic medications for treating yeast infection within 2 weeks of baseline measurements;
 - Any medicated anti-pruritic or anti-fungal topical products to the genital area within 2 weeks of baseline measurements;
 - Oral antibiotics within 2 weeks of enrollment and for the duration of the study;
 - Participants may treat any developing conditions but must notify the clinic immediately;
2. Individuals with a symptom that needs doctor's care.
3. Individuals with uncontrolled diseases, such as diabetes, hypertension, hyperthyroidism, or hypothyroidism, as determined by the health questionnaire.
4. Pregnancy, nursing, or planning to become pregnant during the study as determined by the health questionnaire.
5. Concurrent participation in any other clinical usage study with the hospital.
6. Individuals who are currently participating or planning to participate in another clinical study with another research center or doctor's office.

Study procedures:

1. Participant information visit:
Oral and written information concerning the study, signing informed consent, pre-survey questionnaire, medical record, instruction for changing napkin (five times daily), and education for genital hygiene.
2. Evaluation visits: Skin assessments and monitoring by two to three dermatologists of any adverse events for each subject.

Evaluation:

Dermatologists performed skin assessment using the scoring system shown in Table 1.

Six areas were evaluated, including lower abdomen, external genitalia (right and left sides), genitocrural area (right and left sides), and perianal area. Lower abdomen was taken as reference, and the other five were evaluated at each visit.

Total subjects enrolled: 72 participants were divided randomly into two groups with comparable skin score and age. Eight of the 72 participants withdrew from the study; thus, 64 participants completed this study. Group A and B consisted of 31 and 33 participants, respectively. The trial protocol described in Figure 2 was approved by the ethical committee of the Medical Faculty of Universitas Indonesia. Results were considered significantly different at $p < 0.05$ (95% CI).

As shown in Figure 1, four evaluation visits (visit 2 to 5) as presented in Figure 1 were performed by dermatologists after eligibility assessment (visit 1). Evaluation visit 2 and 4 were conducted on the next day of the end of the menstruation cycle, whereas evaluation visit 3 and 5 were conducted 10 days after the end of the menstruation cycle.

Table 1. Grading scale of cutaneous symptom was examined at visit 1

Score	Papule/ Vesicle	Edema	Erythema	Maceration	Fissuring	Scaling	Others
0 None	Absent	Absent	Absent	Absent	Absent	Absent	Absent
0.5	One papule	Absent	Faint, barely perceptible erythema	Absent	Absent	Absent	Absent
1 Slight	A Few Papules	Barely perceptible erythema	Faint, but define erythema	Slight maceration	Slight fissuring	Powdery scales	Slight
2 Mild	Discrete mild papules	Mild edema	Definite erythema	Mild maceration	Mild fissuring	Definite fine flaky scales	Mild
3 Moderate	Generalized moderate papules or a few vesicles	Moderate edema	Intense erythema	Maceration with erosion	Deep fissuring	Coarse flaky scales	Moderate
4 Severe	Large area confluent papules and large vesicles	Moderate to severe edema	Very intense erythema	Maceration with large area of erosion and bleeding	Severe bleeding	Severe desqua- mation	Severe

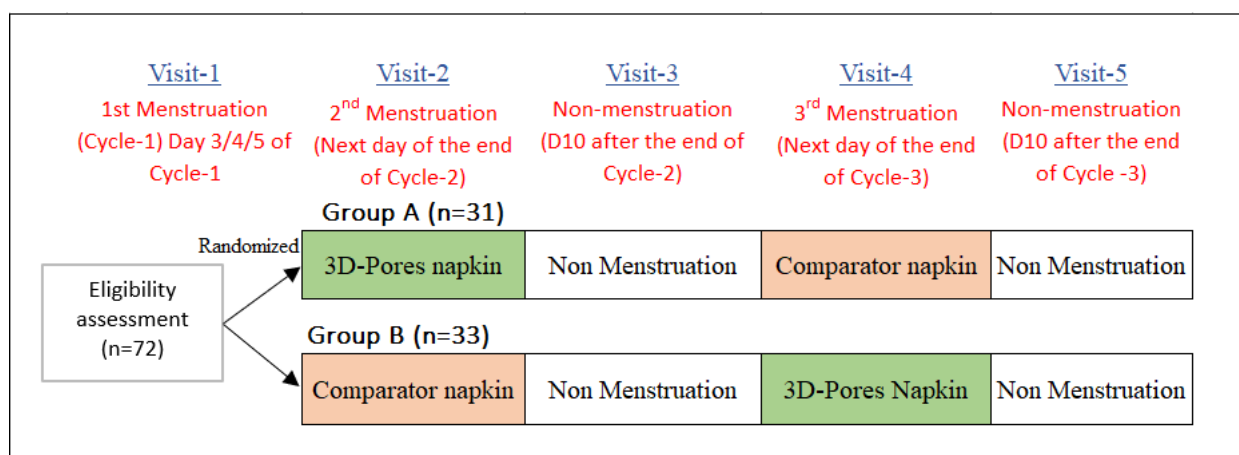


Figure 1. Trial protocol of the study

Table 2. Demography of subjects

	Group A n = 31		Group B n = 33	
	n	%	n	%
Age (years)				
20–29	10	32.3	11	33.3
30–39	21	67.7	22	66.7
Occupation				
Employee	8	25.8	14	42.4
Housewife	20	64.5	14	42.4
Entrepreneur	1	3.2	3	9.1
College student	2	6.5	2	6.1
Marital status				
Married	22	71.0	22	66.7
Not Married	9	29.0	11	33.3

Results

Demography

Demographic characteristic of both groups was similar, as shown in Table 2.

Clinical effect on vulvar skin

The clinical effect of using these napkins is shown in Figure 2. The baseline total score for group A was 10.87, and for group B was 11.12. These scores were similar with no significant differences. The most commonly seen clinical symptoms were varying degree of erythema (score 2 and 3) and papules. Most commonly seen locations were extra genital, genitocrural, and perianal areas.

The total score from visit 1 to 2 showed a significant decline in group A from 10.87 to 5.26 ($p < 0.0001$) and in group B from 11.12 to 7.38 ($p < 0.005$). This result translates into an improvement in clinical symptoms. Erythema intensity decreased from score 2 and 3 to score 1. Other skin lesions, such as papules, were also improved. This result indicated that the 3D-pore napkin and the comparator napkin could reduce vulvar skin irritation.

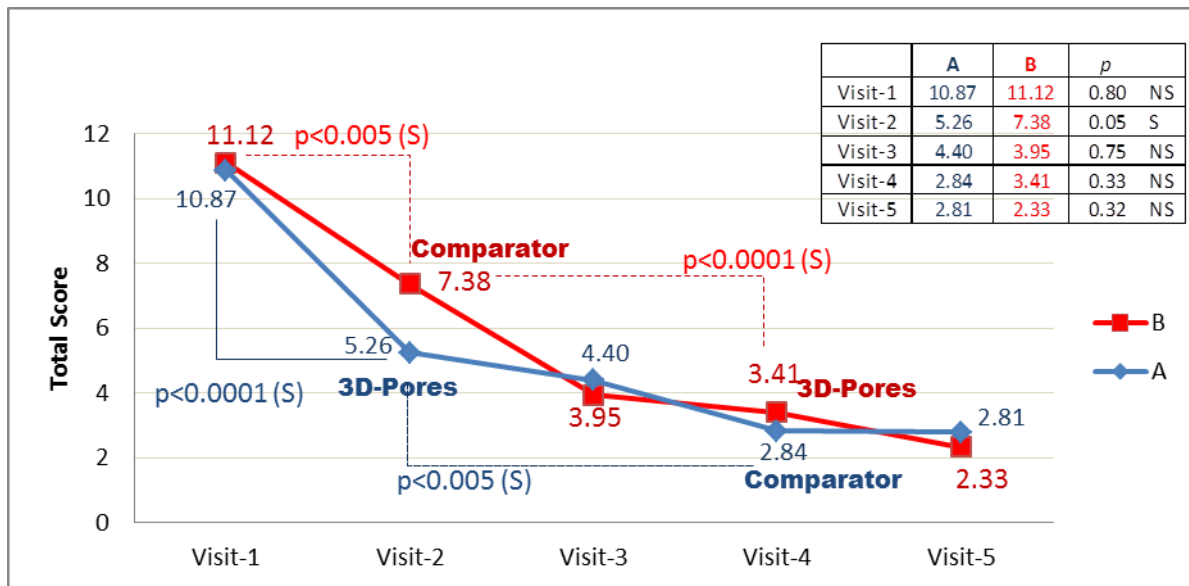
In the next cycle, after switching sanitary napkin, both groups still showed a declining score. From

visit 2 to 4, group A showed a decreasing score from 5.26 to 2.84 ($p < 0.005$). Group B showed a decline from 7.38 to 3.41 ($p < 0.0001$). Both of these declines were statistically significant, but the decline in group B was more significant than that in group A. Thus, the 3D-pore napkin could further improve the skin condition with reductions of all skin symptoms.

Comparison between groups A and B

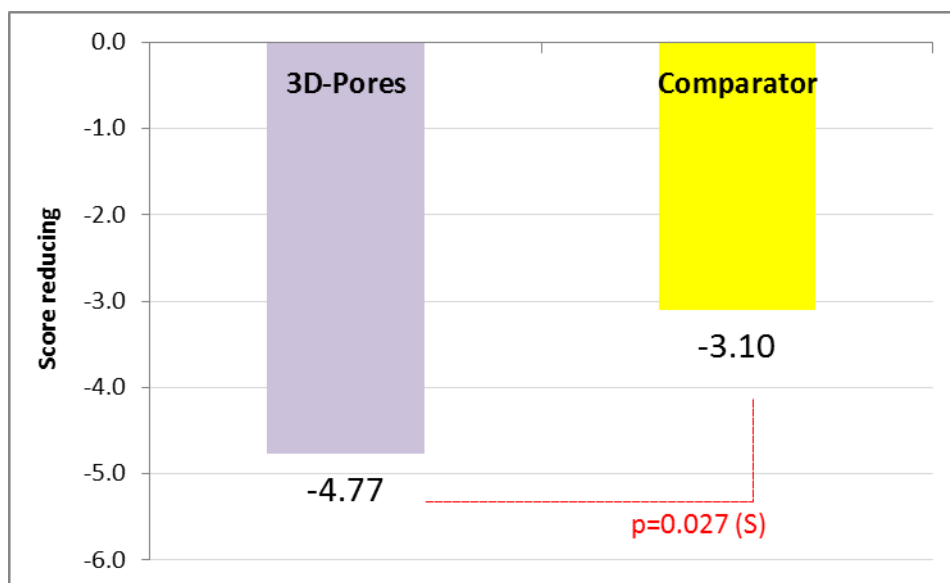
Figure 2 showed the comparison results of the two groups. Scores at visit 2 showed a significant difference between group A and B. Therefore, group A showed a better improvement after using the 3D-pores sanitary napkin compared to the comparator napkin. Scores at visit 4 were not statistically significant between the groups. This finding showed that both napkins could further improve skin condition from visit 2 to the same condition at visit 4.

Visit 1 and 3 were the condition 10 days at the end of the menstruation cycle. Visit 3 scores of both groups were much lower than baseline (visit 1), and the score was even lower at visit 5. Interestingly, these data showed that the skin condition had no improvement in between cycles (outside the menstruation period).



S: statistically significant (if $p < 0.05$), NS: not statistically significant

Figure 2. Comparison of skin condition between the two groups in each visit



S: statistically significant (if $p < 0.05$),

Figure 3. Overall total score using each napkin

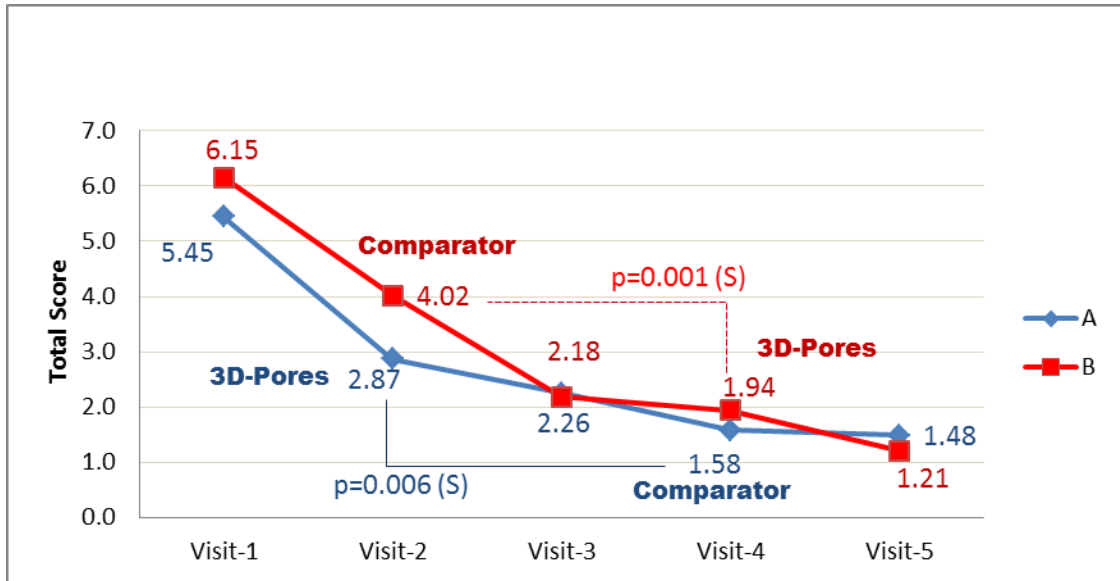
Overall effectiveness

In order to evaluate complete assessment the efficacy of each sanitary napkin; we calculated the difference in total scores from first visit (V1)–second visit (V2) and second visit until visit four (V2–V4) from each corresponding napkin as shown in Figure 3. Results showed that the 3D-pore napkin could reduce the overall score by 4.77, whereas the comparator napkin reduced the score by 3.10. The difference between these numbers was statistically significant. These results

suggested that the 3D-pore napkin could significantly improve vulvar skin conditions compared with the comparator napkin. No adverse event was reported during the study.

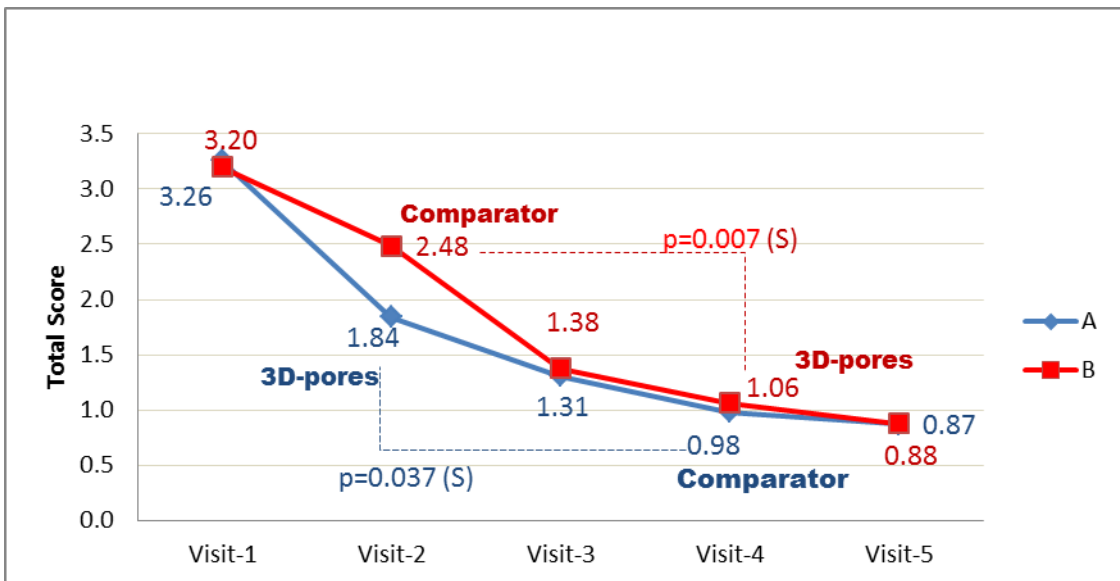
Specific areas

As mentioned in Figures 4, 5, and 6, the total score in specific areas such as the external genitalia and perianal was significantly reduced in both groups from visit 1 to 2. However, in the genitocrural area, the reduction was not statistically significant.



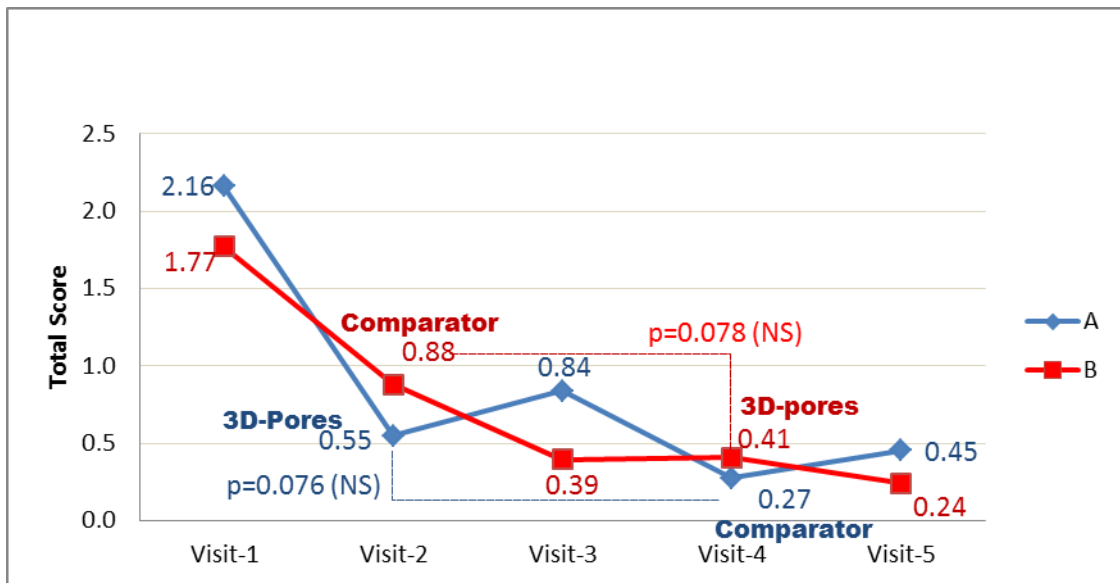
S: statistically significant (if $p < 0.05$), NS: not statistically significant

Figure 4. Average external genitalia score in group A and B



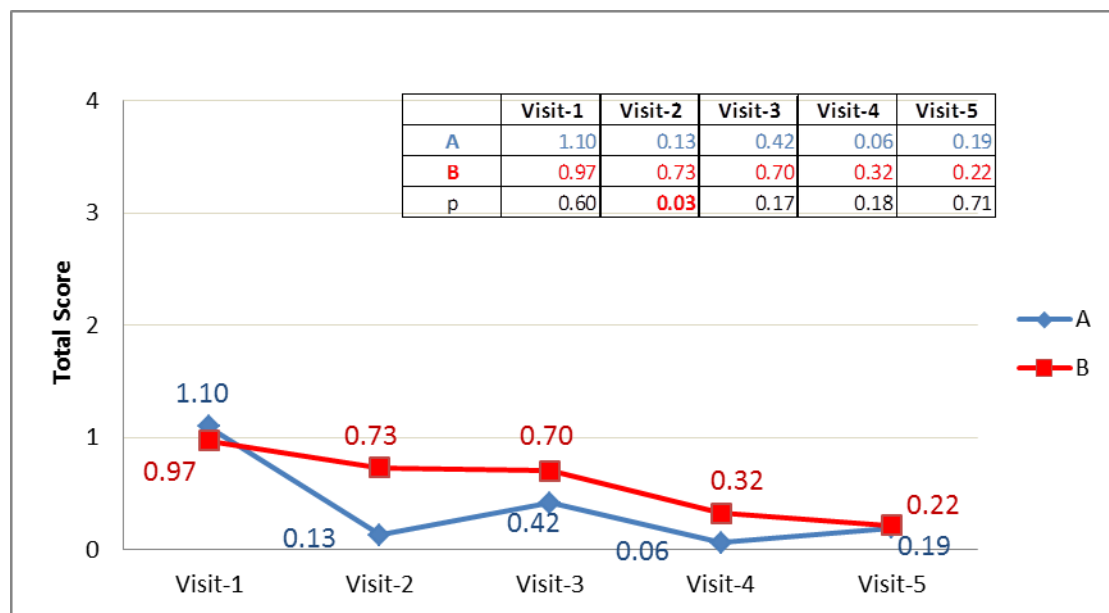
S: statistically significant (if $p < 0.05$), NS: not statistically significant

Figure 5. Average genitocrural area score in group A and B



S: statistically significant (if $p < 0.05$), NS: not statistically significant

Figure 6. Average perianal score in groups A and B



S: statistically significant (if $p < 0.05$), NS: not statistically significant

Figure 7. Skin wetness

Participants of the study were required to provide information subjectively on how they felt when using the napkins. Skin wetness was one parameter showing a significant difference in reducing wetness on visit 2. Thus, the 3D-pore napkin could reduce wetness better than its comparator, as shown in Figure 7.

Discussion

Vulvar skin irritation, which manifests as erythema, itching, or sometimes stinging or burning sensation, can be caused by many factors. It is a type of irritant contact dermatitis that is induced by wet local conditions and by friction caused by wearing a sanitary napkin. The resistance of the

skin to external irritation varies between different parts of the body; the skin of the genital area, covered by a thin stratum corneum, has low resistance to external and mechanical stimulation caused by wearing sanitary napkins.⁷

Disposable absorbent hygiene products have evolved for superior performance, enhancing the convenience of daily lives.⁶ Sanitary napkins should be absorbent, retain menstrual fluid, stop leakages, be aesthetically pleasant, prevent odor, stay in place, and provide comfort. They should also enhance every woman's health and lifestyle.⁸

The basic mechanism behind the function of a sanitary napkin should be elucidated to improve napkin technology. A sanitary napkin comprises multilayered structures in which each layer has a specific function to perform. It consists of three main layers: the top sheet, barrier layer and the absorbent core.⁵

a) Top sheet: This surface sheet has 3D pore protrusions that reduce the friction with the skin by decreasing the area that comes in contact with the skin. This structure further reduces the skin swelling by occlusion because of high air permeability at the interface with the skin, which has a large area of vacant space. In addition, this top sheet has the capillary force toward the under layer because of the coarse-to-fine structure caused by the higher fiber density of the under layer than the upper layer. Thus, it absorbs blood quickly and prevents blood from remaining on the skin, thereby suppressing swelling of the skin. These functions prevent and reduce skin irritation.

b) Absorbent core: It is interposed between the top sheet and the barrier layer, and its main function is to absorb and retain the fluid. Moreover, the absorbent core needs to be thin, soft, and flexible to provide comfort.

In this study, the 3D-pore napkin and the commonly used napkin improve vulvar skin irritation during and after menstruation. This improvement is due to the increased frequency of napkin changes from the usual practice of three times daily to five times daily. Furthermore, promoting education on genital skin hygiene can maintain healthier skin condition outside the menstruation period.

The 3D-pore napkin improves vulvar skin irritation and genital skin condition significantly because of its improved napkin technology. Specifically, its 3D-pore technology on the top sheet with a highly absorptive pad can ensure quick absorbance of

menstrual fluid and significantly reduce wetness.⁹ Therefore, it prevents contact between blood and the vulvar skin, thereby preventing and reducing skin irritation.

Skin condition in the genitocrural area does not show significant improvement possibly because this area is a natural occlusion; thus, the humidity is high in this area. The wetness is possibly increased by the underwear and clothing worn and also by the activity of the subject. Furthermore, this area is not covered by the napkin, thereby preventing the absorption of water or moisture.

Improvement of genital skin condition by increasing the frequency of napkin change during menstruation and by promoting knowledge and menstrual hygiene practices can enhance the quality of life of Indonesian women.

Conclusion

The 3D-pore sanitary napkin can significantly improve vulvar skin inflammation in comparison to the comparator napkin. With its 3D-pore technology, this new napkin can quickly absorb menstrual fluid and significantly reduce skin wetness, thereby preventing skin irritation. Moreover, promoting knowledge and menstrual hygiene practices can improve skin condition during and after menstruation.

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