

Clinical Study of the Acceptability of a New Sanitary Pad “LAURIER-F®” in Thailand

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Abstract

Background: The use of sanitary pads often causes contact dermatitis (sanitary pad dermatitis).

Some possible causes of sanitary pad dermatitis are over-hydration by occlusion, irritation by menstrual blood, infestation of bacteria and friction with surface materials. Modern disposable sanitary pads were developed to reduce those causes. In this study, we examined the effects of a new sanitary pad product on subjects with skin eruptions in Thailand.

Methods: The subjects of this study were healthy adult women with symptoms of sanitary pad dermatitis assessed by a gynecologist. The test sanitary pad was “LAURIER-F®” (Kao Corporation, Tokyo, Japan, commercially available in Japan) and the control was each subject’s

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favorite sanitary pad. This was a crossover clinical usage study over the course of two menstrual periods. The diagnosis of eruptions and subjective symptoms was assessed by a gynecologist during two menstrual periods using each type of sanitary pad and between those menstrual periods (Control phase).

Results: Although we previously evaluated skin eruptions with sanitary pad usage after the end of the menstrual period, it is well known that sanitary pad dermatitis recovers rapidly after the end of the sanitary pad use. Due to the diagnosis of skin eruptions during the menstrual period, the preventive effects of “LAURIER-F®” on sanitary pad dermatitis were clearly detected by a doctor’s evaluation. The results suggest that sanitary pad users realize skin care effects of “LAURIER-F®” because their subjective symptoms also showed a similar tendency.

Conclusion: The tested “LAURIER-F®” sanitary pad did not cause a serious sanitary rash. Its surface is soft with good blood absorption. The gynecologist assessed collectively that the “LAURIER-F®” sanitary pad is highly effective to reduce sanitary pad dermatitis compared with conventionally used ones. It is considered that the characteristic features of the “LAURIER-F®” sanitary pad, such as softness, low-irritancy and high absorbency, are important factors to exert its efficacy.

Introduction

Some reports have shown that the long-term use of disposable sanitary pads can lead to contact dermatitis (1-3). Possible causes of sanitary pad contact dermatitis include over-hydration by occlusion, irritation by components of menstrual blood, infestation of bacteria and friction with the surface materials. Modern disposable sanitary pads were developed to reduce those causes. While the use of sanitary pads is now global, there may be some differences in the environments or cultures of sanitary pad users and/or in their skin sensitivity according to races between countries or regions. Recently, several reports evaluated the suitability of sanitary pads by regional differences in usage practice, ethnicity and climate. Clinical studies of sanitary pads in

practical usage have been conducted in the USA (4, 5), Germany (6), Greece (7), Sweden (8, 9), Ukraine (4), Mexico (4), Nigeria (10) and China (11), and the results of those studies have provided much information. However, some of those studies used healthy subjects with no symptoms and showed unclear effects of improved products, because the initial scores of eruptions were low (5, 11). In this study, we confirmed the effects of a new sanitary pad product on subjects with skin eruptions in Bangkok, Thailand, which belongs to a tropical monsoon climate, and whose main ethnicities are Thai and Thai-Chinese. The Test product was “LAURIER-F®” (Kao Corporation, Tokyo, Japan, commercially available in Japan), which has a non-woven unique surface sheet that reduces over-hydration and

physical stimulation. A recent clinical study in Japan showed improvement effects on skin eruptions and subjective symptoms (12, 13). While the previous evaluation period was after menstruation, this time we evaluated the product during menstruation for a more proper diagnosis.

Materials and Methods

Testing facility, Ethical Committee

approval and informed consent

This study was performed during March 5, 2013 to March 12, 2014 at Gynecology clinic, Thammasat University hospital, Thailand. This study adhered to the Helsinki Guidelines and was approved by the Institutional Research Ethics Committee of the Kao Corporation. All subjects provided written informed consent.

Subjects

The subjects studied were 22 healthy Thai females aged 20-40 years (31 ± 2 , mean \pm SD) who met the following criteria.

Inclusion criteria were as follows:

1. Individuals with a history of regular menstrual cycles for the last year (Regular is defined as a 26-30 day cycle for each month) and have a menstruation period of at least 3 days.
2. Individuals with any symptoms of itchiness or offensive sensations such as sweatiness or scraping. A gynecologist checked the symptoms of mild sanitary pad dermatitis and eliminated subjects with no symptoms during their menstrual period when using sanitary pads.
3. Regular users of sanitary pads.

Exclusion criteria were follows:

1. Individuals using any systemic medications to treat microbe infections, any medicated antipruritic or antifungal topical products to the genital area or oral antibiotics within 2 weeks of the baseline measurements.

2. Individuals with symptoms that require a doctor's care.

3. Individuals with an uncontrolled disease, such as diabetes, hypertension, hyperthyroidism or hypothyroidism.

4. Individuals who were pregnant, nursing or planning to become pregnant during the study.

Materials

The Test sanitary pad ("LAURIER-F®", Kao Corporation, Tokyo, Japan. commercially available in Japan) and

control sanitary pads (each subject's Favorite sanitary pad) were used in this study. The Test sanitary pad has a non-woven unique surface top sheet which is designed to reduce the skin area in contact with the top sheet. This product is highly breathable and has a strong capillary force and a soft dome shape.

Study design

This was a crossover clinical usage study over the course of two menstrual periods. Diagnosis of eruptions and subjective symptoms were assessed by a gynecologist during two menstrual periods using each sanitary pad and between those menstrual periods (the Control phase). Figure 1 shows the study schedule.

Clinical scoring by a gynecologist

Diagnosis of eruptions

Degrees of papulae, edema,

erythema, maceration, fissuring and scaling were assessed by a gynecologist using the following five-grade scale: 0=none, 1=slight, 2=mild, 3=moderate, 4=severe in the genitocrural region, external genitals, lower abdomen and perianal area.

Subjective symptoms

The gynecologist asked each subject to assess her functional signs of itching, stinging, burning sensation and skin wetness, using the five-grade scale noted above.

Statistical analysis

For diagnostic and subjective evaluations, the Friedman test with Tukey's post-hoc analysis was used. *: $p < 0.05$, **: $p < 0.01$.

Results

Out of the 28 subjects recruited, 6

subjects withdrew from the study because they had no eruptions in their first clinical scoring by the gynecologist. Twenty-two subjects (Age: 21-39, average: 31.0 ± 5.4 years) completed the test and their results were analyzed. Their Favorite sanitary pads were: Sofy (Uni-Charm): used by 11 subjects, Modess (Johnson and Johnson): used by 10 subjects, and Laurier (Kao): used by 1 subject.

The menstrual cycle characteristics and sanitary pad habits of the subjects are shown in Table 1. There were no significant differences between the Favorite sanitary pads and "LAURIER-F®" on menstrual period duration, average usage time per pad or number of products used / menstrual period.

The results of the clinical

evaluation are shown in Table 2. With regards to the lower abdomen, all subjects evaluated had no skin eruptions throughout the test period, which indicated that none of the subjects had a systemic skin disease. In other regions of the body, significant increases in scores of eruptions (except fissuring and maceration in external genitals and perianal area) were observed in the Favorite sanitary pad usage than in the control phase or in the “LAURIER-F®” sanitary pad usage. No significant difference was observed between the control phase and the “LAURIER-F®” sanitary pad usage.

The results of subjective symptoms are shown in Table 3. For all evaluated regions of the body except the lower abdomen, the scores of itching, stinging, burning sensation and skin wetness for the

Favorite sanitary pad increased significantly compared to the control phase. No significant differences in the scores of subjective evaluations were observed between the “LAURIER-F®” sanitary pad and the control phase. There were significant differences in the scores of subjective evaluations between the “LAURIER-F®” sanitary pad and the Favorite sanitary pad.

Discussion

Regarding the suitability of sanitary pads, several studies have reported that the daily use of sanitary pads causes no clinically significant adverse reactions in healthy subjects (4, 7). They concluded that the sanitary pads are highly useful, but some cases reported that sanitary pads induced sanitary pad dermatitis (1-3, 14). It would be a great distress for patients to develop

sanitary pad dermatitis constantly and to have to use sanitary pads during each menstrual period. Sanitary pad dermatitis is classified together with diaper dermatitis as an irritant contact dermatitis, an inflammation of the skin manifested as erythematous dermatitis with papulae, fissuring, itching and/or stinging. Since the pathogenic mechanisms of the contact dermatitis are still unclear, some possible causes are thought to be over-hydration by occlusion, irritation by components of the menstrual blood, infestation of bacteria, friction with the surface material and individual sensitivities of vulvar skin. We attempted to clarify whether the vulvar skin symptoms of contact dermatitis will be ameliorated with improved sanitary pads that address those causes of contact dermatitis.

For this purpose, we used “LAURIER-F®” sanitary pads designed especially for sensitive skin, with a non-woven unique patterned indented surface sheet which reduces the contact area between sanitary pads and vulvar skin to improve over-hydration and physical stimulation. Although a previous clinical study using the “LAURIER-F®” sanitary pads in Japan showed preventive effects on sanitary pad dermatitis (12, 13), the local environment (temperature and humidity), usage habits and differences in skin characteristics between races had a potential impact on the test results. In the current study, we performed the clinical test in Thailand, which has a tropical monsoon climate, and whose main ethnicities are Thai and Thai-Chinese. For objective and proper evaluation, diagnosis by

a doctor was set as the evaluation axis and subjects were selected who had skin symptoms at their vulvar area, assessed by actual clinical examination while they used their Favorite sanitary pads. While in our recent study, we evaluated skin eruptions immediately after menstruation was completed, it would be difficult to assess those eruptions because sanitary pad dermatitis resolves rapidly after the use of sanitary pads stops. Since we evaluated the skin symptoms during the menstrual period for the first time, the current study clearly detected the preventive effects of “LAURIER-F®” on sanitary pad dermatitis. Subjective symptoms also showed significant improvement, suggesting that the subjects felt actual benefits of the skin care effect of the “LAURIER-F®”. After finishing the

study, all subjects had a good impression of the tested product. They did not develop any skin irritation from using this product, especially on the last day of their period with minimal bleeding, and the product’s surface was not too dry as when using the conventional one. And also on heavy days, the subjects felt clean and not too humid or irritated. They felt more confident when using the test product compared to their Favorite conventional product, which they usually felt aware of blood leakage and contamination of their clothes. This meant good blood absorption of the test product.

Most of the skin irritations from using the conventional sanitary pads were on both sides of the groin, usually from the paper-like surface of the sanitary pad wings. These made the surface area of the folding

wings too hard and dry and irritated the skin around the groin. The soft and thin wings of the “LAURIER-F®” sanitary pad helps decrease the physical irritation of the skin. Although the tested product’s wings usually folded on themselves, the skin irritation was not severe.

In conclusion, this “LAURIER-F®” sanitary pad did not cause a serious sanitary rash. Its surface is soft with good blood absorption. The gynecologist assessed collectively that the “LAURIER-F®” sanitary pad is highly effective to reduce sanitary pad dermatitis compared with conventionally used sanitary pads. It is considered that the characteristic features of the “LAURIER-F®” sanitary pad, including its softness, low-irritancy and high absorbency, are important factors to exert its

efficacy.

What is already known on this topic?

The use of sanitary pads often causes contact dermatitis (sanitary pad dermatitis). Recently, several reports evaluated the suitability of sanitary pads by regional differences in usage practice, ethnicity and climate. Clinical studies of sanitary pads in practical usage have been conducted in the USA, Europe, China and Japan. However, some of those studies used healthy subjects with no symptoms and showed unclear effects of improved products, because the initial scores of eruptions were low.

What this study adds?

In this study, the effects of new sanitary pad product on subjects with skin eruptions was confirmed in Thailand, which

belongs to a tropical monsoon climate, and whose main ethnicities are Thai and Thai-Chinese. Since the test product has a non-woven unique surface sheet that reduces over-hydration and physical stimulation, it is highly effective to reduce sanitary pad dermatitis compared with conventionally used sanitary pads. And also we evaluated the skin symptoms during the menstrual period for the first time, the current study clearly detected the preventive effects of new sanitary pad product on sanitary pad dermatitis.

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Declaration of interest

No conflict of interest exists regarding any financial arrangements in this paper. This study was funded by Kao Corporation, Tokyo, Japan.

References

1. Eason EL and Feldman P. Contact dermatitis associated with the use of Always sanitary napkins. *Can Med Assoc J* 1996; 154:1173-1176.
2. Wakashin K. Sanitary napkin contact dermatitis of the vulva: location-dependent differences in skin surface conditions may play a role in negative patch test results. *J Dermatol* 2007; 34:834-837.
3. Rademaker M. Allergic contact dermatitis to a sanitary pad. *Australas J Dermatol* 2004; 45:234-235.

4. Farage M, Elsner P and Maibach H. Gynecol Scand 1994; 73:486-491.
Influence of usage practices, ethnicity and climate on the skin compatibility of sanitary pads. Acta Gynecol Obstet 2007; 275:415-427.
5. Fujimura T, Sato N, Takagi Y, Ohuchi A, Kawasaki H, Kitahara T, Takema Y and Rizer RL. An investigator blinded cross-over study to characterize the cutaneous effects and suitability of modern sanitary pads for menstrual protection for women residing in the USA. Cutan Ocul Toxicol 2011; 30:205-211.
6. Hanke-Baier P, Johannigmann J, Levin RJ and Wagner G. Evaluation of vaginal and perineal area during the use of external sanitary protection throughout the menstrual cycle. Acta Obstet
7. Farage MA, Katsarou A, Tsagrioni E, Bowtell P, Meyer S, Deliveliotou A and Creatsas G. Cutaneous and sensory effects of two sanitary pads with distinct surface materials: a randomized prospective trial. Cutan Ocul Toxicol 2005; 24:227-241.
8. Runeman B, Rybo G, Larkö O and Faergemann J. The vulva skin microclimate: influence of panty liners on temperature, humidity and pH. Acta Derm Venereol 2003; 83:88-92.
9. Runeman B, Rybo G, Forsgren-Brusk U, Larkö O, Larsson P and Faergemann J. The vulvar skin microenvironment: influence of different panty liners on temperature, pH and microflora. Acta Derm Venereol 2004; 84:277-284.

10. Stadler M, Tischler H, Wambebe C, Osisanya T and Farage MA. An investigator-blind, single-center, controlled, parallel group study to confirm the suitability of sanitary pads for menstrual protection in an ethnic Nigerian population. *Cutan Ocul Toxicol* 2006; 25:273-279.
11. Xuemin W, Sato N, Chao Y, Na L, Fujimura T, Takagi Y, Nojiri H, Kitahara T and Takema Y. Cutaneous and sensory effects of two types of sanitary pads with different surfaces in the Shanghai, Chinese population. *Cutan Ocul Toxicol* 2011; 30:212-216.
12. Sato N, Toyoshima Y, Takagi Y, Ogawa A, Ohkouchi K, Kikuchi K, Kumasaka K, Saijo S, Hosokawa M, Watabe M and Tagami H. Clinical study on the preventive effects of skin care napkin “Laurier F®” on sanitary napkin dermatitis. *Skin Res* 2007; 6:300-308.
13. Yonei N, Satoh N, Takagi Y, Yamamoto Y and Furukawa F. The effect of sanitary napkin (Laurier F®) on the skin condition and the QOL of women with napkin dermatitis. *Aesthetic Dermatology* 2009; 19:60-67.
14. Margesson LJ, Contact dermatitis of the vulva. *Dermatol Ther* 2004; 17:20-27.

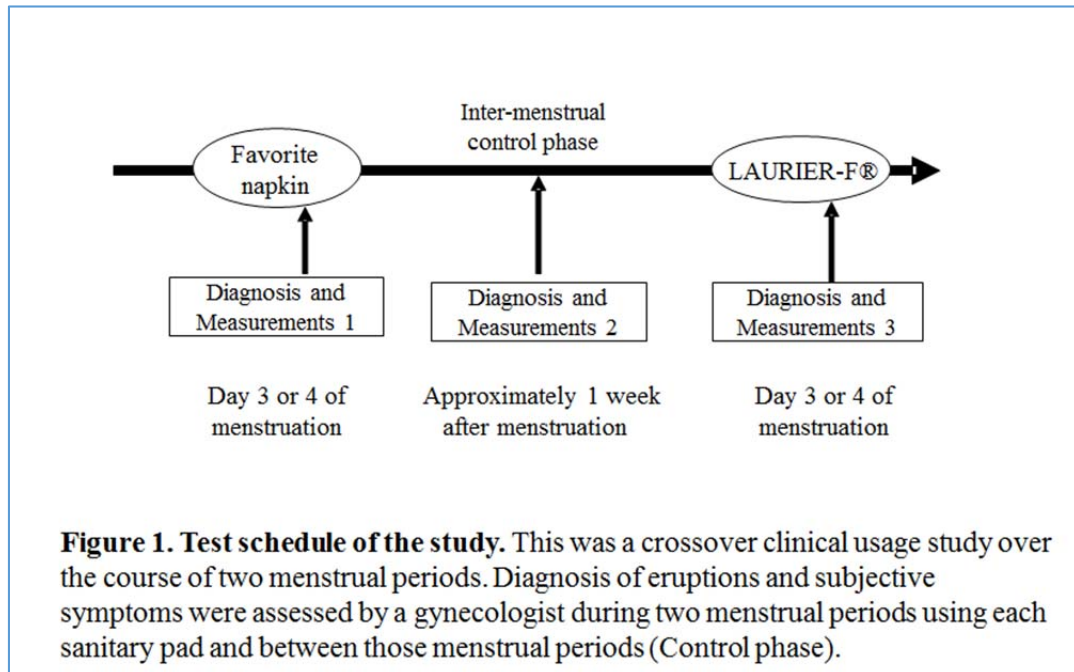


Table 1. Menstrual cycle characteristics and sanitary napkin habits

	Menstrual period duration (days)	Average using time per pad (hours)	Number of product used /menstrual period
Subject's favorite sanitary napkin	4.9 ± 0.9	4:10 ± 0:39	22.0 ± 8.1
LAURIER-F®	4.6 ± 0.7	3:51 ± 0:38	24.0 ± 8.1

Region	Objective signs	Score			Significance		
		Favorite napkin	Control phase (non-menstrual phase)	Laurier-F®	Control phase vs. Favorite napkin	Control phase vs. Laurier-F®	Favorite napkin vs. Laurier-F®
Genitocrural region	Papula	1.14	0.00	0.00	**	n.s.	**
	Edema	1.86	0.05	0.09	**	n.s.	**
	Erythema	2.18	0.05	0.23	**	n.s.	**
	Maceration	0.36	0.00	0.00	*	n.s.	*
	Fissuring	0.18	0.00	0.00	n.s.	n.s.	n.s.
	Scaling	0.86	0.00	0.00	**	n.s.	**
External genitals	Papula	0.27	0.00	0.00	*	n.s.	*
	Edema	1.00	0.00	0.00	**	n.s.	**
	Erythema	1.68	0.00	0.05	**	n.s.	**
	Maceration	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Fissuring	0.18	0.00	0.00	n.s.	n.s.	n.s.
	Scaling	0.32	0.00	0.00	*	n.s.	*
Lower abdomen	Papula	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Edema	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Erythema	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Maceration	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Fissuring	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Scaling	0.00	0.00	0.00	n.s.	n.s.	n.s.
Perianal area	Papula	0.32	0.00	0.00	*	n.s.	*
	Edema	0.73	0.00	0.00	**	n.s.	**
	Erythema	0.91	0.05	0.05	**	n.s.	**
	Maceration	0.05	0.00	0.00	n.s.	n.s.	n.s.
	Fissuring	0.23	0.00	0.00	n.s.	n.s.	n.s.
	Scaling	0.45	0.00	0.00	*	n.s.	*

Region	Subjective symptoms	Score			Significance		
		Favorite napkin	Control phase (non-menstrual phase)	Laurier-F®	Control phase vs. Favorite napkin	Control phase vs. Laurier-F®	Favorite napkin vs. Laurier-F®
Genitocrural region	Itching	2.59	0.05	0.18	**	n.s.	**
	Stinging	1.36	0.00	0.00	**	n.s.	**
	Burning sensation	1.18	0.00	0.00	**	n.s.	**
	Skin wetness	1.36	0.00	0.00	**	n.s.	**
External genitals	Itching	1.86	0.00	0.05	**	n.s.	**
	Stinging	0.64	0.00	0.00	**	n.s.	**
	Burning sensation	0.86	0.00	0.00	**	n.s.	**
	Skin wetness	0.82	0.00	0.00	**	n.s.	**
Lower abdomen	Itching	0.05	0.00	0.00	n.s.	n.s.	n.s.
	Stinging	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Burning sensation	0.00	0.00	0.00	n.s.	n.s.	n.s.
	Skin wetness	0.00	0.00	0.00	n.s.	n.s.	n.s.
Perianal area	Itching	1.27	0.05	0.05	**	n.s.	**
	Stinging	0.73	0.00	0.00	**	n.s.	**
	Burning sensation	0.36	0.00	0.00	**	n.s.	**
	Skin wetness	1.32	0.00	0.05	**	n.s.	**