Satisfaction and Tolerability of Combination of Lactoserum and Lactic Acid on the External Genitalia in Thai Women

Amnuay Tansupasiri MD*, Apithan Puangsricharern MD**,
Ajcharaporn Itti-arwachakul MD**, Suvanna Asavapiriyanont MD**

** Obstetrics and Gynecology Infectious Unit, Department of Obstetrics and Gynecology, Rajavithi Hospital*
*** Department of Obstetrics and Gynecology, Rajavithi Hospital*

Objective: *The aims of this study were to assess the user satisfaction and tolerability of a combination of lactoserum and lactic acid on the external genitalia of Thai women.*
Material and Method: *Women who were over 18 years of age who came to gynecologic outpatient unit at Rajavithi Hospital from November 2004 to January 2005, without clinical manifestations of vulvovaginal irritation or infection were included.*

The exclusion criteria were women who had allergy to a combination of lactoserum and lactic acid, or any of the components of this product.

Clinical history was taken and gynaecological examination was performed. Those who met the eligible criteria were assigned to use one bottle of 150 ml combination of lactoserum and lactic acid on the external genitalia. Fisher's Exact test was used to compare the satisfaction between each group.
Results: *There were 300 patients equally dividing in 3 groups. Average age was 42.2 $\pm$ 9.8 years. The satisfaction percentage was more than 90 percent according to the evaluation criteria. There was no statistically significant difference between products. The tolerability were high percentage,only 3.3% of the patients used these products less than 7 days. 6 patients (2%) experienced discomfort resulting from these products and no statistically significant difference between products.*
Conclusion: *The combination of lactoserum and lactic acid demonstrated the high percentage of satisfaction and tolerability. Only 2% of patients experienced discomfort without any serious discomfort effects.*

Keywords: *Lactoserum, Lactic acid, Satisfaction, Tolerability*

J Med Assoc Thai 2005; 88 (12): 1753-7
Full text. e-Journal: *http://www.medassocthai.org/journal*

High levels of estrogens stimulate the deposit of glycogen in the vaginal epithelium, which is then fermented to acetic and lactic acids by epithelial cells and vaginal flora[1]. Recent studies support the hypothesis that vaginal bacteria are the main source of lactic acid in the vagina[2]. Among the microflora of the healthy vagina, Lactobacilli have been recognized as the predominant organisms in the vagina that can maintain a pH below 4.5[3]. This acidic environment reduces the risk of colonization by pathogens[4], therefore, it can sustain the healthy environment state. A rising level of vaginal pH to above 4.5 can lead to an overgrowth of anerobic bacteria causing bacterial vaginosis, which is the most common vaginal pathology worldwide[5]. Also an increase in vaginal pH is detrimental to the survival of lactobacilli;therefore, local acidification with lactic acid or lactobacilli is useful for restoration of the vaginal ecosystem.

The combination of lactoserum and lactic acid is presented in liquid form for external uses. Lactoserum is a natural substance which is extracted from milk. It is rich in mineral salts, metals and is at a pH of 5.2[6]. Lactic acid is an alpha-hydroxy acid that has been safely used as a peeling agent in the treatment of melasma[7]. Some

Correspondence to: Puangsricharern A, Department of Obstetrics and Gynecology, Rajavithi Hospital, Bangkok 10400, Thailand. Phone: 0-2354-8084, Mobile: 0-1626-3457

recent studies also showed the correlation between skin pH and the overgrowth of Staphylococcus aureus, colonized on skin, leading to changes in its barrier function causing atopic dermatitis[8]. Moreover, there is evidence that the pH of lactic acid acts against the growth of many microorganisms in the vaginal fluid[4,9]. Because the combination of lactoserum and lactic acid can be used as an disinfectant for skin, therefore, it has been widely used among Thai women as an intimate hygiene soap for over 10 years. A study from France showed that 40 women who had been using this antiseptic for a period of 8 weeks had good tolerance of the vaginal mucous membrane. In addition, bacteriological studies showed that at the end of treatment, the flora rapidly returned to normal in all patients[6]. This study aimed to assess the user satisfaction and tolerability of a combination of lactoserum and lactic acid when used once daily as a hygiene soap in Thai women for a 28 day period.

Material and Method

The open-label was survey conducted at Rajavithi Hospital from November 2004 to January 2005. Women who consulted their Gynecologists at the outpatient clinic for any medical conditions other than vulvovaginal signs and symptoms were recruited. The inclusion criteria were patients who were over 18 years of age, without clinical manifestations of vulvovaginal irritation or infection, gave written informed consent, and available for telephone contact for survey purposes. The exclusion criteria were women who had allergy to a combination of lactoserum and lactic acid or any of the components of a combination of lactoserum and lactic acid.

The combination of lactoserum and lactic acid 100 ml contained 0.9 gram of lactoserum, 1 gram of lactic acid, 3.5 qs ad pH, 100 ml qs ad, and fragrance. It was used for external vaginal wash, as a liquid soap, once daily for 28 consecutive days. User instructions were first poured approximately 2.5 ml (1/2 teaspoon) of a combination of lactoserum and lactic acid into the palm; second, applied in the external genital area; and then rinsed thoroughly with water.

Clinical history was taken and gynaecological examination was performed. Signs and symptoms of vulvovaginal infection such as abnormal vaginal discharge (copius, curd-like, yellowish, or foul-smelling), vaginal pruritis, tenderness and/or vulvar erythema, were evaluated. If these symptoms were present, the patients were excluded. Those who met the eligible criteria were asked to sign an informed consent of the ethical committee of the institute. Each patient was assigned to receive one bottle of 150 ml of a combination of lactoserum and lactic acid by simple randomization. They were instructed to use the products and began on the day of enrolment.

The survey was administered at Day 28 either by an outpatient visit or by telephone. Patients may come back anytime they experience any discomfort from the use of the products for the purpose of this study. The main evaluation criteria were user satisfaction with a combination of lactoserum and lactic acid. Satisfaction criteria composed of ease of use, ability to refresh, scent, cleansing ability, and overall assessment. Any discomfort resulting from the use of the product was reported as part of the tolerability criteria.

Statistical analysis

The continuous data was analyzed as mean $\pm$ standard deviation, and the categorical data were described as percentage. Using Fisher's Exact test, the comparison of satisfaction were performed between each type of a combination of lactoserum and lactic acid. A p-value less than 0.05 is considered statistically significant difference. All statistical analyses were performed by using STATA 8.0 program (Statacorp, Tx).

Results

There were 100 patients in each group using a combination of lactoserum and lactic acid, (Fragrance free, Sweet flora and Spring fresh scent). The average age of the women was 42.2 $\pm$ 9.8 years (range 21-71 years). All patients completed 2 visits by outpatient visit (69.3%) and phone interview (30.7%). One hundred and seventy patients (56.7%) used these products every day. Seventy-three patients (24.3%) used 15-28 days; 47 patients (15.7%) used 8-14 days, and 10 patients (3.3%) used 0-7 days.

Statistical analysis

The number and percentage satisfaction of the women according to the evaluation criteria is presented in Table 1, which included all participants in the presented study (n = 300). There was no statistically significant difference among women who used Fragrance free, Sweet flora or Spring fresh products in each category of evaluation criteria that included ease of use, ability to refresh, scent, cleansing ability, and overall assessment. Table 2 demonstrates the number and percentage of satisfaction on rating product in the population after excluding women who experienced

symptoms. The result was the same as the previous one that there was no statistically significant difference of satisfaction percentage among the 3 products of combination of lactoserum and lactic acid in all evaluation criteria.

Discomfort symptoms

There were 6 patients (2%) who experienced discomfort resulting from these products (5 in Sweet flora group and 1 in Spring fresh group). Discomfort symptoms were 2 itching, 2 abnormal vaginal discharge, 1 burning sensation, and 1 itching with fungal vaginosis. The side effect of these products was evaluated using the percentage of discomfort symptoms (Table 3). There was no significant difference among these 3 products. Women who used Fragrance free product had a 5% risk reduction of discomfort symptoms when compared with Sweet flora (RD 0.05, 95% confidence interval (CI) 0.007, 0.092), and 1% risk reduction when compared with Spring fresh (RD 0.01, 95%CI - 0.009, 0.29). However, there was no statistical significance in both comparisons. When compared with Sweet flora, women who used Spring fresh product had a 4% risk reduction without statistical significance (RD 0.04, 95% CI - 0.006, 0.087).

Discussion

The present study demonstrated the high percentage of satisfaction of all 3 types a combination of lactoserum and lactic acid product in gynaecologic out-patient women. There was 100% complete follow-up. Only 3% of the women used the products equal to

Table 1. Number and percentage of women on rating the product according to the evaluation criteria

Evaluation criteria	Total number	Number and percentage of satisfaction			p-value
		Fragrance free (%) n = 100	Sweet flora (%) n = 100	Spring fresh (%) n = 100	
1. Ease of use	300	100 (100)	99 (99)	99 (99)	1.000
2. Ability to refresh	300	99 (99)	100 (100)	100 (100)	1.000
3. Scent	300	93 (93)	97 (97)	96 (96)	0.482
4. Cleansing ability	300	98 (98)	100 (100)	100 (100)	0.331
5. Overall assessment	300	100 (100)	99 (99)	100 (100)	1.000

Table 2. Number and percentage of women on rating the product according to the evaluation criteria (excluding those who experienced any discomfort symptoms)

Evaluation criteria	Total number	Number and percentage of satisfaction			p-value
		Fragrance free (%) n = 100	Sweet flora (%) n = 95	Spring fresh (%) n = 99	
1. Ease of use	294	100 (100)	94 (98.9)	98 (98.9)	0.550
2. Ability to refresh	294	99 (99)	95 (100)	99 (100)	1.000
3. Scent	294	93 (93)	92 (96.8)	95 (95.9)	0.483
4. Cleansing ability	294	98 (98)	95 (100)	99 (100)	0.331
5. Overall assessment	294	100 (100)	94 (98.9)	99 (100)	0.323

Table 3. Number and percentage of women who experienced discomfort symptoms according to the products

Present of any discomfort symptoms	a combination of lactoserum and lactic acid, Product Supplied			p-value
	Fragrance free (%) n = 100	Sweet flora (%) n = 100	Spring fresh (%) n = 100	
No	100 (100)	95 (95)	99 (99)	0.051
Yes	0 (0)	5 (5)	1 (1)	

or less than 7 days. There was no difference of satisfaction and discomfort symptoms among these products. Fragrance free or Sweet flora or Spring fresh products were used according to the patient preference without any serious discomfort effects.

However, the possibility of exposure of each type of products was unequal because the patients were assigned by simple randomization. Moreover, there were some possible factors related to satisfaction and discomfort symptoms such as menopausal status, duration of applying time, and co-intervention with other soap/liquid soap that were not include in this study. These confounders caused inconclusive effects of a combination of lactoserum and lactic acid. The authors have no reason why women used the products less than 7 days. It may be due to the discomfortness with the products.

In conclusion, all 3 types of a combination of lactoserum and lactic acid demonstrated a high percentage of satisfaction and tolerability. Fragrance free, Sweet flora and Spring fresh products should be used according to the patient preference.

References

1. Donders GG, Bosmans E, Dekeersmaecker A, Vereecken A, Van Bulck B, Spitz B. Pathogenesis of abnormal vaginal bacterial flora. Am J Obstet Gynecol 2000; 182: 872-8.
2. Boskey ER, Telsch KM, Whaley KJ, Moench TR, Cone RA. Acid production by vaginal flora in vitro is consistent with the rate and extent of vaginal acidification. Infect Immun 1999; 67: 5170-5.
3. Redondo-L pez V, Cook RL, Sobel JD. Emerging role of lactobacilli in the control and maintenance of the vaginal bacterial microflora. Rev Infect Dis 1990; 12: 856-72.
4. Aroutcheva A, Gariti D, Simon M, Shott S, Faro J, Simoes JA, et al. Defense factors of vaginal lactobacilli. Am J Obstet Gynecol 2001; 185: 375-9.
5. Eschenbach DA. History and review of bacterial vaginosis. Am J Obstet Gynecol 1993; 169: 441-5.
6. Jacquet A, Roussilhes R, Anoufa S, Marteau C, Mallet F, Audebert A. Study of a new lactic acid and pH 5.2 lactoserum emulsion for feminine hygiene: results of a clinical study. Contracept Fertil Sex 1995; 23: 457-9.
7. Sharquie KE, Al-Tikreety MM, Al-Mashhadani SA. Lactic acid as a new therapeutic peeling agent in melasma. Dermatol Surg 2005; 31: 149-54.
8. Rippke F, Schreiner V, Doering T, Maibach HI. Stratum corneum pH in atopic dermatitis: impact on skin barrier function and colonization with Staphylococcus aureus. Am J Clin Dermatol 2004; 5: 217-23.
9. Andersch B, Lindell D, Dahlen I, Brandberg A. Bacterial vaginosis and the effect of intermittent prophylactic treatment with an acid lactate gel. Gynecol Obstet Invest 1990; 30: 114-9.

ความพึงพอใจและความคงทนในการใช้ยาแลคโตซีรัมร่วมกับกรดแลคติกฟอกล้างอวัยวะสืบพันธุ์ภายนอกของสตรีไทย

อำนวย ตัณฑ์ศุภศิริ, อภิธาน พวงศรีเจริญ, อัจฉราพร อิทธิอาวัชกุล, สุวรรณา อัศวพิริยานนท์

วัตถุประสงค์: เพื่อศึกษาความพึงพอใจและความคงทนในการใช้ยาของสตรีไทยในการใช้ยาแลคโตซีรัมร่วมกับกรดแลคติกฟอกล้างอวัยวะสืบพันธุ์ภายนอกของสตรีไทย

วัสดุและวิธีการ: สตรีไทยอายุ 18 ปีขึ้นไปที่มาตรวจภายในที่ห้องตรวจนรีเวช โรงพยาบาลราชวิถี ช่วงเดือน พฤศจิกายน พ.ศ. 2547 ถึงเดือนมกราคม พ.ศ. 2548 ที่ไม่มีอาการของโรคติดเชื้อหรืออาการระคายเคืองของอวัยวะสืบพันธุ์ ไม่มีประวัติแพ้ยาแลคโตซีรัมหรือกรดแลคติกหลังจากได้รับการซักประวัติและตรวจภายในแล้วพบว่าถูกต้องตามเกณฑ์จะได้รับยาแลคโตซีรัมร่วมกับกรดแลคติก 1 ขวด ปริมาตร 150 มิลลิลิตร เพื่อใช้ฟอกล้างอวัยวะสืบพันธุ์ภายนอก ใช้วิธีทางสถิติ Fisher's exact test เปรียบเทียบความพึงพอใจ

ผลการศึกษา: มีผู้ร่วมโครงการ 300 ราย แบ่งเป็น 3 กลุ่มเท่า ๆ กัน อายุเฉลี่ย คือ 42.2 $\pm$ 9.8ปี ผู้ใช้ยามีความพึงพอใจตามเกณฑ์การประเมิน มากกว่าร้อยละ 90 และไม่มีความแตกต่างในชนิดของกลิ่น อย่างมีนัยสำคัญทางสถิติ ผู้ใช้ยาส่วนใหญ่คงใช้ยานี้เป็นประจำ มีผู้ใช้ยานี้น้อยกว่า 7วัน เพียง ร้อยละ 3.3 เท่านั้น มีผู้ที่รู้สึกมีอาการระคายเคือง 6 ราย คิดเป็นร้อยละ 2 และไม่มีความแตกต่างที่มีนัยสำคัญทางสถิติของชนิดของกลิ่นที่ทำให้เกิดการระคายเคือง

สรุป: ผู้เข้าร่วมโครงการใช้ยาแลคโตซีรัมร่วมกับกรดแลคติกส่วนใหญ่มีความพึงพอใจและมีความคงใช้ยานี้สูงมีเพียงร้อยละ2 ที่มีอาการระคายเคืองจาการใช้ยานี้แต่เป็นอาการระคายเคืองที่ไม่รุนแรง