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Research Article

What does an Ointment Add to Usual Vulvar Diseases' Treatments?

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ABSTRACT

Objective: This study assessed the impacts of an ointment on treatment efficacy, side effects and global tolerance of most common vulvar diseases.

Methods: This observational study enrolled patients with Lichen Sclerosus (LS) and psoriasis who were still symptomatic despite maintenance therapy (topical steroids) the tested ointment was added to unchanged maintenance treatment. Patients with Condyloma Acuminata (CA), treated with liquid nitrogen and/or imiquimod applied tested ointment during healing phase. Patients suffering from vulvodynia used the ointment in addition to their multidisciplinary treatment. All patients were examined during 2 consecutive visits. subjective and objective clinical scores, tolerance, Dermatology Life Quality Index (DLQI) and auto-evaluation questionnaires were evaluated at each visit.

Results: Eighty-one patients completed the study: 26 LS, 6 psoriasis, 33 CA and 16 vulvodynia. There were significant reductions in global symptom and clinical scores for LS (-80.61% and -59.20% respectively, mean follow-up 66 days) and psoriasis (-82.88% and -82.80% respectively, mean follow-up of 51 days). For LS, a 75% decrease for symptom and clinical scores was reached by respectively 76.9% and 23% of patients. The DLQI decreased by 40.17% for LS and 76.92% for psoriasis. Use of ointment resulted in low post-treatment scores for CA (Symptom score (0-50):1.03, clinical score (0-24):1.85, mean follow-up of 21 days). For all diseases, auto-evaluation questionnaires answered 'totally or rather agree' to following questions: immediate comfort 79-88%, persistent comfort 75-100%, diminishes pruritus/burning sensations 75-100%, non-irritant 88-100%. Tolerance was good for all except two patients (one CA, one vulvodynia).

Conclusion: Our results indicated the complementary effects of an ointment added to treatments for vulvar lichen sclerosus, psoriasis, condyloma acuminata and for vulvodynia. Ointment is a good complement to TS treatments in dermatology, and skin protection enhances healing after aggressive treatments. Ointment simple formulation contributes to the good tolerance on vulvar skin.

Keywords: Ointment; Emollient; Lichen Sclerosus; Condyloma Acuminate; Vulvodynia; Genital Psoriasis; Vulvar Disease

INTRODUCTION

Normal vulvar skin is subject to various irritant factors (friction, occlusion, urine, etc.) [1]. Most vulvar diseases provoke vulvar skin alterations because of underlying inflammation (dermatosis, vulvodynia) and/or destructive treatments (genital warts). It is well known and described in dermatology that skin diseases may benefit from the addition of skin care to medical treatment. However, very few studies of this approach have been published for vulvar diseases.

Lichen sclerosus (LS) is the most common vulvar skin disease, causing pruritus, burning sensation, pain (soreness), and dyspareunia. One-third of patients reported severe impairment of Quality of Life (QoL) [2]. Vulvar LS is a relapsing disease (relapse rate 50% at 1.3 years, 84% at 4 years post-treatment) [3]. Patients with vulvar LS require lifetime surveillance and topical steroid (TS) treatment. The ultra-potent clobetasol propionate is the most frequently used treatment, but Mometasone Fuorate (MMF) has similar efficacy [4,5]. These topical steroids may alter skin barrier function and result in steroid induced dermatitis.

After a three month initial attack phase, symptom improvement is incomplete (47.3%) and complete reversal of clinical signs

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is rare (21.4%) [6]. To prevent relapse and scarring, and to help prevent malignant change, a proactive long-term treatment (e.g. twice weekly application of TS) strategy is recommended [7-9]. However, most patients remain symptomatic, with some activity of their LS, despite the maintenance therapy [10]. Recent guidelines recommend combining emollient and barrier preparation with the steroid treatment, as for any dermatosis, but this does not rely on published vulvar clinical studies [11].

During psoriasis, 33-63% of women will develop genital psoriasis [12]. It causes pruritus, pain, burning sensation, and dyspareunia. It typically expresses as flares but may become chronic and impair QoL and sexual health [13]. Treatment includes use of long term, sequential or intermittent application of moderate to potent TSs. However, these steroids are often not potent enough to induce a complete response, and thus to completely relief patients from their symptoms (pruritus mainly) [1]. Patients should avoid trigger factors associated with the koebner phenomenon. Emollient use is recommended during extra-genital psoriasis to reduce treatment-induced irritation and maintain therapeutic results [14]. No such recommendation is published for vulvar psoriasis.

Development of condyloma acuminate (CA) remains the most frequent sexually transmitted infections (STI). CA can be located on external genital organs and the perianal region. All treatments for CA are aggressive to the skin, especially liquid nitrogen (LN) and imiquimod. Imiquimod induces some combination of vulvar erythema, inflammation that sometimes includes erosion and ulceration. It seems that irritation parallels efficacy, but it also frequently diminishes adherence to treatment [15]. The precise role of complementary healing cream has never been tested.

Vulvodynia affects 7-10% of women worldwide. 2003 International Society for the Study of Vulvovaginal Diseases (ISSVD) terminology defines vulvodynia as vulvar discomfort (e.g. burning pain) that occurs without visible findings or a specific, clinically identifiable, neurological disorder [16]. Treatments for this neuropathic pain syndrome are complex, and a multidisciplinary approach is recommended [17]. Vulvar care measures include avoiding irritating factors and emollient soap substitute use [9]. Hydrating and/or protective cream could diminish friction and procure some relief, but most patients experience intolerance to emollients possibly related to increased local inflammation or a nocebo effect.

Our objective was to evaluate the complementary effects of an ointment applied during treatment of the most common genital conditions above mentioned, targeting clinical parameters and quality-of-life characteristics.

MATERIALS AND METHODS

This mono-centric observational study was performed at the Institut Alfred Fournier (Paris, France). Inclusion was based on first-raw visits. All patients filling the inclusion and exclusion criteria during the observational period entered the study. The goal was to evaluate a once to twice daily topical emollient (paraffinum liquidum, petrolatum, paraffinum, tocopheryl acetate; Deumavan ® Intimate Hygiene Salve Natural, Kaymogyn GmbH, Freiburg im Breisgau, Germany) application added to the usual care protocol (TS for LS and psoriasis, AL and/or imiquimod for CA, multidisciplinary approach for vulvodynia). Patients were instructed to maintain use of their usual toilet and washing products.

Patients were examined at the initial visit (T0) and a second visit (T1), except for vulvodynia who were examined only at T0. Investigators used Visual Analog Score (VAS) to score symptoms (0-10) and clinical signs (0-4). The scoring system was modified from Borghi et al. [6,18]. Investigator global assessment (IGA) was quantified by a global assessment of improvement from baseline (score 0: complete improvement to 6: worse) at T1 for women with LS and psoriasis. Same women with LS or psoriasis completed a dermatological QoL questionnaire (DLQI) at T0 and T1.

After giving informed consent, women with LS, psoriasis, or CA had illustrative photos taken at each consultation. All patients completed an auto-evaluation questionnaire (adapted to the pathology with seven common questions) at T1. The responses “totally agree” and “rather agree” were rated as favorable responses. Tolerance was evaluated at T1 for all women. Protocol is summarized in Table 1.

Inclusion/exclusion criteria and objectives

Pregnant or lactating women, women applying cosmetic or hormonal topical treatments, and patients with known hypersensitivity to an ingredient of the tested product were excluded from the study.

For the vulvar LS group, we selected patients who already completed the active treatment phase with TS, who were under maintenance therapy (usually TS twice weekly), who were still symptomatic despite the treatment and whose examination discovered a LS with moderate activity which did not require an intensification of the TS steroid (LS without signs of infection or signs of severity (e.g. leukoplakia, ulceration) and who did not apply any moisturizing cream. LS diagnosis was based on clinical observation of typical clinical signs. Patients were asked not to modify their TS treatment and only to add the ointment once to twice daily.

As there was only one changing parameter, we could reasonably attribute modifications of clinical signs and/or symptoms to the ointment. The T1 visit was expected at 30 days after T0. At each visit, information on age, date of diagnosis, topography, and frequency of TS were recorded. Six symptoms (pruritus, burning sensation, dyspareunia, discomfort, sensation of dryness, spontaneous pain) were recorded using a modified Global Symptoms Score (mGSS).

Table 1: Protocol.

Contents	T0			T1				
	Symptom score	Clinical score	DLQI	Symptom score	Clinical score	IGA	DLQI	Auto-evaluation questionnaire
Lichen sclerosus	+	+	+	+	+	+	+	+
Psoriasis	+	+	+	+	+	+	+	+
Condyloma acuminata	+	+	-	+	+	-	-	+
Vulvodynia	+	+	-	-	-	-	-	+

Ten clinical signs (pallor/whiteness, dryness, sclerosus/atrophy/synechia, lichenification, hyperkeratosis, erosions, fissures, erythema, purpura) were recorded using a modified Global Clinical Score (mGCS). The numbers (%) of patients with improvement scores ≥ 75% (mGSS75, mGCS75) and ≥ 50% (mGSS50, mGCS50) were recorded. IGA was performed at T1. The DLQI scoring was completed at T0 and T1 and auto-evaluation questionnaire (13 questions) at T1. Clinical pictures were taken at T0 and T1 with the consent of the patients.

The primary objective was to determine if there were statistically significant improvements in mGSS and mGCS scores between T0 and T1 (Wilcoxon statistical score, $p<0.05$).

Criteria to include patients with vulvar psoriasis were similar to the ones for LS. They were patients who had finished the active treatment phase, who were regularly treated with TS (maintenance therapy) to prevent relapses but who were still symptomatic. Patients applying moisturizing cream were not included. A psoriasis diagnosis was made on based typical clinical signs. Testing included a vulvo-vaginal swab to exclude candidiasis if suspected. The T1 evaluation was expected at D30 after T0. Scores (mGSS, IGA, and DLQI) and auto-evaluation questionnaire were like the LS protocol. The clinical signs recorded in the psoriasis GCS (pGCS) were desquamation, dryness, lichenification, erosions, fissures, and erythema. The DLQI scoring was completed at T0 and T1 and auto-evaluation questionnaire (13 questions) at T1. Clinical pictures were taken at T0 and T1 with the consent of the patients

Patients with exophytic or papular CA on the external genital area, without signs of infection (candidiasis) and without prior treatment within the preceding month, were included. Application of LN (T1 after 7 days) or imiquimod (T1 after 30 days), or both, were proposed depending on the extent of the CA and prior treatment use. The information collected on CA was CA topography, five symptoms using a CA GSS (mGSS without dyspareunia), and six clinical signs (desquamation, dryness, erosions, fissures, erythema, edema) using a CA GCS. The auto-evaluation questionnaire (15 questions) was completed at T1. The primary objectives for liquid nitrogen were to improve healing and to improve tolerance for treatment with imiquimod. Therefore, the analysis was used to determine if minimal changes in scores were obtained at T1.

The information collected for the vulvodynia groups at T0 were symptoms (mGSS) and treatments used. The clinical examination was, by definition, normal for the patients in this group. The diagnosis was made following the ISSVD definition [16]. The expected T1 was 30 days. The primary objective was to determine tested-product tolerance using the self-evaluation questionnaire (12 questions). Our study follows the principles of the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using the R software application [19]. Quantitative scores at D0 and after numbers of days of application were compared using Wilcoxon test for paired data. The frequencies of positive answers to questions were evaluated using Chi-square tests.

RESULTS

One hundred and six patients were included in the study from July 2017 to March 2018. Nineteen of these patients were lost to follow-up (8 LS, 3 psoriasis, 4 CA, 4 vulvodynia) and six had a deviation from the study protocol (stopped tested product prematurely: 4 LS, 1 CA, 1 vulvodynia). Eighty-one patients complied with the protocol and were evaluated (26 LS, 6 psoriasis, 33 CA, 16 vulvodynia) (demographic and clinical data at T0 are presented in Table 2).

In the LS group, the patients were followed for a mean time of 60 days (24-120 days). The results for the analysis of the clinical data are presented in Table 3. Steroids applied for maintenance therapy were: Clobetasol propionate 0.05% (n=19), betamethasone dipropionate 0.05% (n=5), diflucortone valerate 0.1% (n=1) and betamethasone valerate 0.1% (n=1). All patients kept the same steroid at the same posology during study. They all applied the ointment once to twice daily. Except for dyspareunia, spontaneous pain and sclerosus/atrophy/synechia, the improvements of each criterion and of global scores were statistically significant.

Seventy-six points nine percent (20/26) attained mGSS75 and 23% (6/26) attained mGCS75: 84.6% (22/26) attained mGSS50 and 65.3% (17/26) attained mGCS50. A total of 73% of patients (19/26) attained an IGA ≥ 2 (complete+excellent+marked improvement i.e., ≥ 75%). The DLQI questionnaire was completed by 21 patients. The mean score decreased significantly, by 40.17% ($p<0.01$), from 5.57 (SD 4.28) to 3.33 (SD 2.98).

Tolerance was rated good by all patients. Representative photographs are shown (Figure 1a and 1b).

Patients with psoriasis were followed for a mean time of 51

Table 2: Results for demographic and clinical data at time 0 (T0): mean [range]. Durations are expressed in years. Duration of treatment and frequency per week concern TS, topical steroids; mGSS, modified Global Symptoms Score (pruritus + burning sensations + dyspareunia + discomfort + dryness sensation + spontaneous pain).

Content	Lichen sclerosus	Psoriasis	Condyloma acuminata	Vulvodynia
n	26	6	33	16
Age(years)	63 [39-83]	57 [24-79]	42 [21-68]	57.94 [37-83]
Duration of symptoms	6.59 [0.4-40]	3.08 [0.5-10]	1.24 [0.08-10]	4.77 [0.41-30]
Time from diagnosis	4.81 [0.25-40]	1.19 [0.5-6]	1.65 [0-10]	0.97 [0-10]
Duration of treatment	1.74 [0.25-10]	2.02 [0.5-6]	-	-
Frequency per week	2.57 [1-7]	1.5 [0.5-2]	-	-
Sexual intercourse number (%)	9 (34.6%)	3 (50%)	-	9 (56.2%)
Urinary incontinence n (%)	8 (30.7%)	2 (33.3%)	-	-
mGSS	17.65 [3-35]	24.33 [12-32]	1.97 [0-18]	18.94 [2-38]

Table 3: Clinical results for patients with Lichen Sclerosus.

Content	T0 scores	T1 scores	T1-T0 (%)
Pruritus	3.23 (3.29)	0.72 (1.65)	-77,71**
Burning sensations	3.58 (2.94)	0.38 (0.94)	-89,24**
Dyspareunia	1.92 (3.47)	0.96 (2.29)	-50
Discomfort	3.85 (2.68)	0.73 (1.31)	-81**
Dryness sensation	4.46 (2.75)	0.58 (0.95)	-87,07**
Spontaneous pain	0.62 (1.63)	0.07 (0.39)	-87,50
mGSS	**17.65 (10.12)**	**3.42 (3.92)**	**-80.61****
Palor, whiteness	2.46 (1.21)	1.5 (0.95)	-39.06**
Dryness	2.62 (0.94)	0.27 (0.53)	-89.71**
Sclerosis Atrophy Synechia	1.88 (1.18)	1.73 (1.15)	-8.16
Lichenification	0.62 (0.9)	0.08 (0.27)	-87.5**
Hyper-keratosis	0.58 (0.99)	0.15 (0.26)	-73.33*
Erosions	0.65 (1.13)	0.12 (0.43)	-82.35*
Fissures	0.69 (0.97)	0.04 (0.2)	-94.44**
Erythema	1.19 (1.2)	0.5 (0.76)	-58.06**
Purpura	0.81 (1.23)	0.31 (0.79)	-61.9*
mGCS	**11.5 (5.1)**	**4.69 (2.71)**	**-59.2****

Note: *p<0.05; **p<0.01. All score values are first cited as mean values, followed by standard deviation ().

mGSS: modified Global Symptoms Score; mGCS: modified Global Clinical Score.

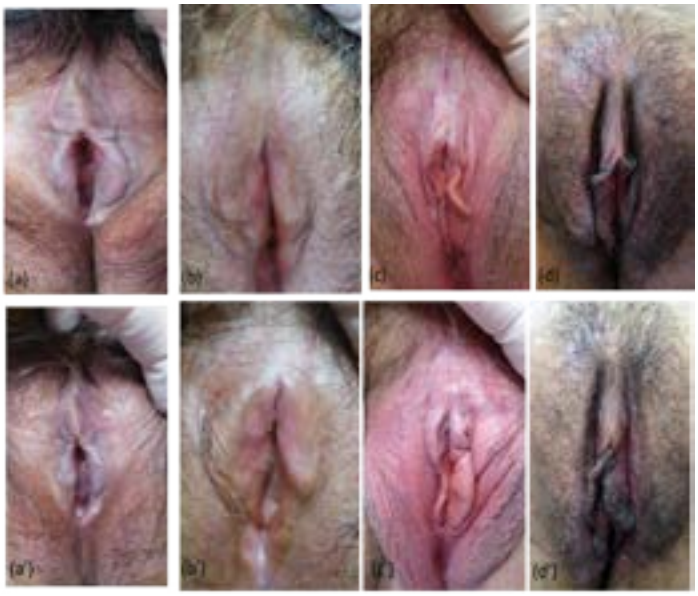

Figure 1: Illustrative photos of patients with lichen sclerosus (LS) and psoriasis, at time 0 (T0) and time 1 (T1). a, b:LS at T0; c, d:psoriasis at T0. a', b':LS at T1; c', d':psoriasis at T0. GCS (Global Clinical Score), a: 12, a': 7 (-41.6%); b: 12, b': 5 (-58.3%); c: 19, c': 4 (-78.9%); d: 16, d': 3 (-81.2%).

days (27-83 days). Topical steroids applied were betamethasone dipropionate 0.05%+calciprotriol 50 µg/g for one patient, fluticasone propionate 0.05% for one patient and betamethasone dipropionate 0.05% for 4 patients. The mean mGSS decreased from 24.33 (range 12-34) to 4.17 (range 0-11) (-82.88%; p<0.05) and the mean pGCS decreased from 10.70 (range 4-19) to 1.83 (range 0–4) (-82.80%; p<0.05). IGA ≥ 2 was reached by 6/6 patients. DLQI decreased by 76.92%, from 9.75 (SD 6.94) to 2.25 (SD 2.06). Tolerance was rated good by all patients. Representative photographs are shown (Figure 1c and 1d).

The patients with CA were treated using LN (n=21), imiquimod (n=9), or LN+imiquimod (n=3). The mean time to follow-up was 21.06 days (6-75 days; 9.47 days for LN and 41.33 days for imiquimod). At T1, the mean GSS and GCS values were 1.03 (SD 1.69; range 0-6) and 1.85 (SD 1.75, range 0-5), respectively. Tolerance was evaluated as good for all except one patient who was treated using LN and experienced pruritus.

The mean time to follow-up in the group of patients with vulvodynia was 74.6 days (range 28-150 days). The mean mGSS value at T0 was 18.94. Tolerance was rated good by all patients except one: this patient experienced transient tingling. The results for six questions common for the four-different auto-evaluation questionnaires are presented in Table 4.

DISCUSSION

This observational study is the first one to evaluate the benefits of the addition of an ointment to regular treatments of usual vulvar conditions. Our objective was to quantify the effects of an ointment with a simple formulation and a lipidic phase that would maximize efficacy, tolerance and provide a protective effect. Observations were added to regular follow-up visits. The ointment was added to complement proactive treatment with TS for LS and psoriasis (TS application usually twice a week) in women complaining of residual symptoms but without any clinical signs requiring intensifying TS treatment. It was also added to physical (LN) or medical (imiquimod) treatment for CA and as part of the multidisciplinary approach for vulvodynia treatment.

In the LS and psoriasis groups, one-third of the patients suffered from urinary incontinence which may aggravate signs and symptoms [7]. We studied the effects of treatment on three major symptoms (from GSS, pruritus, burning sensations, dyspareunia [6,18]) and added pain, dryness sensation, and discomfort, which are frequently cited by patients (mGSS). The mean mGSS value was greater for the psoriasis group than the LS group. After use of the ointment, it decreased significantly. For the LS group, the results were statistically significant for all symptoms except for pain

Table 4: Results for synthesis of similar questions used between auto-evaluation questionnaires.

Questions present in all questionnaires / % totally + rather agree	Lichen sclerosus	Psoriasis	Condyloma acuminata	Vulvodynia
Immediate comfort	88%*	80%	79%*	81%*
Persistent comfort	92%*	100*	73%*	75%
Diminishes pruritus burning sensations	80%*	100*	82%*	75%
Rich enough and adapted consistency	92%*	80%	85%*	100%*
Non-irritant	100%*	100%*	88%*	94%*
Globally satisfying	96%*	80%	82%*	88%*

Note : *p<0.05

(very low initial level of 0.62) and dyspareunia (-50%), consistent with Borghi et al.'s results [18]. They assessed a topical product and a nutritional supplement containing avocado and soybean extracts for the treatment of LS at 12- and 24-week follow-ups. Their protocol differed from ours. No TS was applied before or during the study period.

We compared the percentage of patients who had decreases of 50% and 75% of GSS. Borghi et al. found 55% and 35%, respectively, for these two outcomes vs. 80.7% and 65.3%, respectively, in our study population [18]. The difference may be explained by the TS maintenance therapy used in our study population. Murina et al. studied soft foam use for the supportive treatment of LS (n=43) [20]. Twenty-one patients were treated with MMF 0.1% for 4 weeks, then twice weekly for 4 weeks in combination with a moisturizing cream; 22 patients were treated with MMF for 20 days, then with a soft foam. At 8 weeks, there were statistically significant reductions in the severity of symptoms in both groups.

The authors concluded that the tested product could be an effective adjunct treatment for LS via its moisturizing effects and reductions in factors associated with epithelial disruption. A controlled, randomized, double-blind study compared silk briefs 'Dermasilk' vs. standard cotton briefs in patients affected by LS (n=42) [21]. The patients were treated with clobetasol propionate 0.05% plus moisturizer, daily for 6 months. Patients in both groups experienced symptomatic relief of soreness and itching. The number of patients with pruritus decreased significantly at 1 month in the tested group. All these studies suggest that the addition of an emollient or special underwear tends to improve the symptoms of LS patients treated with TS.

Gottlieb et al. developed a new symptom scoring system (Genital Psoriasis Symptoms Scale) that includes symptoms (itch, pain, discomfort, stinging, burning) and clinical signs (redness, scaling, cracking) (each scored 0-10) [22]. Our mGSS differed moderately: stinging was not included, and we added dyspareunia and dryness sensation. To our knowledge, no studies of the symptoms of genital psoriasis and emollient use have been published. Paulsen et al. compared aloe Vera gel use to a placebo (n=41) in a study of cutaneous extra-genital psoriasis [14]. The score sum of erythema, infiltration, and desquamation decreased in 72.5% of the aloe Vera-treated sites and in 82.5% of the placebo-treated areas from week 0 to week 4.

We also assessed changes in clinical signs in the patients with LS or psoriasis. In the LS group, mGCS decreased significantly by 59.2%. Each item decreased significantly except for sclerosus/atrophy/synechia, which is known to be stable under treatment. A total of 65% of the patients attained mGCS50; 23% attained mGCS75. Borghi et al. obtained 52.4% and 28.6%, respectively, according to their global score (5 of our 9 criteria: erythema, leukoderma (pallor), sclerosus/scarring/atrophy, hyperkeratosis, and purpura/erosion) [18]. Murina et al. used a global severity score (0-3) and also found a statistically significant decrease in vulvar signs [20]. Fissures and erosions were the two clinical signs that showed the most improvement across both groups of patients in D'antuono et al. study [21]. Erythema had the greatest improvement in the group of patients who used 'Dermasilk'.

Genital LS and psoriasis result in considerable impairment on QoL [13,23]. A study of Dutch patients with LS found that the mean DLQI score was 11.92 [23]. In patients with psoriasis, the DLQI score increased to 8.7 if genital involvement compared to 4 if not [13]. In our study, the women were under treatment and the initial mean DLQI scores were lower for the LS (5.57) and similar for the psoriasis groups (9.75). During the study, mean DLQI score decreased by 40.17% in the LS group (statistically significant) and by 76.92% in psoriasis group. In our study, the low symptom and clinical scores after treatment (1.03 and 1.85 respectively) suggested that the ointment likely provided soothing and healing effects for the patients with CA (n=33). Tolerance was good for all patients except one patient treated for CA (transient pruritus after LN) and one treated for vulvodynia (transient tingling). Tolerance was the only criteria tested for vulvodynia patients because the complexity of the multidisciplinary approach did not allow a specific efficacy evaluation of the ointment. No patients stopped using the ointment because of intolerance or side effects.

This study had some limitations. Because of the inclusion criteria for psoriasis (i.e., TS maintenance therapy), only six patients were included as we mostly see patients during flares and no previous treatment. This study did not include a control group, but the comparison of clinical symptoms and signs before and after adding an ointment or any other cosmetic product to an unchanged therapeutic protocol is a typical approach used for studies of other general dermatosis (e.g., atopic dermatitis) [24].

CONCLUSION

Our results illustrated the indications and effects of an ointment added to the usual treatments for vulvar LS, psoriasis, CA, and vulvodynia. When added to maintenance therapy with TS for vulvar LS and psoriasis treatment, the ointment improves symptoms, some clinical signs, and QoL characteristics, and thus may improve adherence of patients to this very long-term treatment. It reduces the irritation and side effects of topical genital warts treatments and, again, may improve adherence. Although patients suffering from vulvodynia often experience negative reactions to any topical product, tested ointment was very well tolerated during this study. Good tolerance is a prerequisite for the use of any topical product for the treatment of vulvar diseases.

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