Efficacy and Tolerance of a New Ointment in Non-Infectious Vulvitis, Anitis and Balanitis

Bohbot JM* and Druckmann R

Abstract

Background: Vulvitis and/or ano-vulvitis are a common cause of consultation. These complaints are due to a broad-spectrum of diseases: infections, dermatosis, post-menopausal atrophy, iatrogenic cause. Balanitis have similar etiologies. In most cases, specific treatments demonstrate a good efficacy. However, when long or repeated courses of treatment are required, local side-effects can arise. We studied a new ointment to define its efficacy and tolerance in non-infectious vulvitis, anitis and balanitis.

Material and Methods: 60 women suffering from non-infectious vulvitis and/or anitis and 20 men with non-infectious balanitis or anitis were included. All patients had to apply the ointment twice a day for six months. Efficacy was evaluated by the evolution of a global clinical score (GCS) defined by the addition of scores (self-rated or after clinical examination) of clinical symptoms (pruritus, burning, pain, erythema, oedema and skin lesions). Patients were evaluated after 2, 4 and 6 months.

Results: 5 patients didn’t achieve the study (4 due to subjective non-sufficient results and one no-show). 59 patients (73.8%) had a reduction of the GCS higher than 75% including 25 (31.2%) who were totally free from symptoms at the end of the study. Tolerance was good to excellent.

Conclusion: This new ointment demonstrated its ability to reduce clinical symptoms linked to vulvitis, anitis and balanitis. It could be used either in first-line or as complementary or alternative medication to etiological medications.

Keywords
Vulvitis; Anitis; Balanitis; Non-steroid ointment

Introduction

Vulvitis and/or ano-vulvitis are common causes of consultation. Vulvitis is caused by a broad spectrum of diseases: uro-genital infections, dermatosis [1,2] (lichen, psoriasis), iatrogenic causes (like contact dermatitis due to local antibiotics, anti-cancer drugs, spermicides, and moisturizers [2] post cryotherapy or vulvar surgery) and atrophic vulvitis in post-menopausal women.

Clinical symptoms are often similar whatever the etiology: pruritus, burning, pain, erythema, lesions (cracks, lichenification due to itch-scratch cycles…), rarely and oedema.

Balanitis have similar etiologies than vulvitis. Up to 50% of balanitis are due to local infections [3], but dermatosis involved in balanitis are numerous: contact dermatitis, allergy, lichen, psoriasis….

The chronic diseases involved in either vulvitis or balanitis can have a serious impact on patients’ quality of life and sexual health. In a study including 354 patients [4] with active or a history of genital lesions of psoriasis, 39% reported genital pains, 42% dyspareunia and 43% said that they decreased their sexual activity. In a case-control study including 355 women [5], including 197 women with lichen sclerosus (LS), 95 healthy women and 43 women with candidiasis, an impact on sexual life has been reported: patients with LS have less frequent sexual activity and less satisfying sexual activity when compared with controls.

Many of vulvitis and balanitis need a long specific medication (i.e. infectious vulvitis or vulvitis due to dermatosis like psoriasis or lichens, atrophic vulvitis). Etiological medications have demonstrated a real efficacy in these cases. In case of dermatosis like psoriasis or lichen sclerosus, long-term treatment by topical corticosteroids treatment is required. It has been demonstrated that this chronic treatment could induce skin reduction and atrophy [6] especially in the vulvar area [7]. On the other hand, local antifungal treatment is responsible in irritations or contact dermatitis [8,9]. These side-effects often lead patients to use self-administered medications which worsen the situation.

For all these reasons, complementary and/or alternative symptomatic medication appears to be useful for patients’ wellbeing. Counseling for efficient product leads to avoid inappropriate self-administered medications.

Material and Methods
Ointment

The ointment* is made from highly purified lipids, free of additives such as parabens, stabilisers and preservatives. It’s composed with Paraffinum Liquidum, Petrolatum, Paraffinum, Tocopheryl Acetatevitamine E.

Inclusion/exclusion criteria

80 patients (60 women and 20 men) more than 18 years old, attending the consultation of Institute Fournier (Paris), affected with ano-genital discomfort due to various etiologies were included. We excluded pregnant women, patients with clinical or biological symptoms of ano-genital infections and all patients using local medications (anti-inflammatory and/or anti-inflamatory and/or moisturizers).

Female patients suffered from symptoms of vulvitis and/or Anitis. Male patients suffered from symptoms due to Anitis and/or balanitis.

At baseline, a score from 0 (no symptom to 5: severe symptom) was obtained from patients’ interrogation or physical examination: pruritus, burning, pain, erythema, oedema and skin lesions. A global clinical score (GCS) was obtained by addition of the score of each symptom.

All included patients were told to apply the ointment twice a day for 6 months.

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3 other visits were scheduled at months 2, 4 and 6 to evaluate efficacy (by measuring the CGS) and tolerance.

Approval and informed consent have been obtained from all patients

**Patients at Inclusion**

**Age of patients**

The average age of patients was 45.0 yo. (21 to 85 yo):

Male patients: 42.4 yo (21 to 72 yo)

Female patients: 45.8 yo (21 to 85 yo)

**Female etiologies**

- 24 dermatitis:
  - 11 cases of lichen
  - 5 irritative dermatitis
  - 6 psoriasis and seborrheic dermatitis
  - 2 Vulvodynia
- 14 post-menopausal symptoms (vulvar dryness and/or atrophy)
- 10 post-infectious ano-vulvitis
- 9 post recurrent candidiadiasis
- 1 post bacterial vaginosis

Among these 10 patients a vaginal sampling has eliminated an active infection.

- 4 post treatment vulvitis
- 2 post pelvic radiotherapy for ovarian cancer
- 2 post treatment for Condyloma (laser or cryotherapy)

**Male etiologies**

- 12 dermatosis
- 9 cases of lichen
- 2 allergic balanitis
- 1 isolated dryness of the glans
- 5 non-infections anitis
- 3 post-cryotherapy lesions

**Clinical score at inclusion**

The total of the 80 patients’ CGS was 984 at inclusion

Table 1 represents the scores according to clinical reported or observed symptoms.

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**Results**

**Intermediate visits: Month 2, Month 4**

All included patients attended the visit 1 after 2 months of ointment applications. The total CGS was 386 at month 2 vs. 984 at inclusion that is 60.7% of decrease. The rate of improvement was sharper in women (63.3%) than in men (53.9%).

In 70 patients, CGS decreases of 50% or more

In 1 patient, CGS decrease was between 25 and 50%

In 6 patients no decrease or a decrease less than 25% of CGS were reported.

3 patients decided to break off the study due to sufficient results: 2 men with lichen sclerosus and one woman with non-infectious vulvar cracks. Furthermore, 1 of these men and this woman reported mild adverse events: burning after each application.

77 patients out of 80 (18 men and 59 women) attended Visit 2, after 4 months of ointment applications. The CGS of these 77 patients was 238 vs. 948 at baseline (the CGS of patients who stopped the study have been withdrawn) that is decrease of 74.9%.

The improvement of CGS was upper to 50% (vs. CGS at baseline) in 62 patients.

6 out these 62 patients reported a total disappearance of symptoms: 5 women (2 post infectious vulvitis, 1 allergic vulvitis, 1 post-cryotherapy vulvitis and 1 lichen sclerosus) and 1 man with allergic balanitis. These 6 patients decided to carry on the study for 2 months more.

1 woman with post-infectious vulvitis decided to leave the study due to poor clinical results. This patient reported mild burning after each application.

**Final visit: Month 6**

75 patients out 80 attended the final visit after 6 months of ointment applications. 1 patient was lost to sight.

At Visit 3, the remaining 75 patients’ CSG was 148 vs. 922 at baseline (the CGS of patients who leaved the study were excluded) that is an improvement of 84.8% (Table 2).

5 patients didn’t achieve the study: 4 due to non-sufficient results and 1 no-show.

25 patients out of 75 had no more symptoms at V3 (33.3%).

34 patients out 75 (45.3%) improved their CGS more than 75%.

14 patients out 75 (18.6%) improved their CGS between 50 and 75%

2 patients (2.7%) had a poor improvement (less than 50%).

**Discussion**

**According to the design of the study**

We chose to conduct an open study as the ointment is not a treatment but has a symptomatic action, although skin repair was observed in many cases. Our goal was not to compare the ointment with specific medications but to determine the efficacy of this ointment towards symptoms of irritation.
The clinical results are generally very satisfactory: 59 of 80 patients (73.5%) had clinical improvement >75% (according to the CGS), 7 patients out of 80 (8.7%) had poor clinical results (decrease of CGS less than 50%). However, the results can be modulated based on etiologies.

**Lichen sclerosus:** 20 patients (9 men and 11 women) were included with the diagnosis of lichen sclerosus. 2 male patients decided to leave the study due to poor results.

At month 6, 8 patients out of 18 had no more symptoms like pruritus, burning or cutaneous cracks. However, the hyperkeratosis persisted.

At month 2, 12 patients out of 20 already reported a clinical improvement as high as 50% and 11 patients out of 20 (55%) reported a clinical improvement higher than 75% at visit 3 (6 months).

The ointment is not a treatment of lichen sclerosus, but these results demonstrate that this product may represent a useful enhancement to corticosteroids for these latter can be responsible in cutaneous adverse events in cases of lengthy treatment.

**Psoriasis and seborrheic dermatitis:** Only 6 patients (6 women) were included with psoriasis. All were clinically improved and 4 had an improvement of their CGS above 80%.

**Anitis:** 11 patients (6 women and 5 men) had anitis at baseline either isolated or associated with vulvitis in 2 cases. At visit 3, 1 man and 1 woman had no more symptoms. In all patients a clinical improvement (CGS higher than 50%) has been reported. 9 patients out of 11 reported an improvement higher than 50% as soon as the second month of applications. To prevent anal pruritus, this ointment can be used after passing a motion.

**Menopausal symptoms:** Out of the 14 patients with post-menopausal vulvitis (vulvar dryness and/or atrophy), 2 improved their CGS between 50 and 75% at 6 months. The other 12 patients had an improvement >75%. The improvement has been slow to get as at visit 1 (after 2 months) 4 patients had an improvement less than 50% and 10 between 50 and 75%.

Note that if the ointment has provided clinical improvement in the vast majority of cases, this improvement is getting longer in patients with chronic conditions (lichen sclerosus, symptoms associated with menopause) This justifies the implementation of long durations.

**With regards to tolerance:** The ointment was well tolerated since none of the 80 patients reported any serious adverse event or discontinued treatment because of side effects. 3 patients reported mild to moderate side effects (transient burning after application): 1 man suffering from lichen sclerosus and 2 women with post-infectious vulvitis [13,14].

**Conclusion**

Out of the 80 patients included in this study, 59 patients (73.7%) showed a clinical improvement higher than 75% including 25 (31.2%) with a complete resolution of their symptoms at the end of the study.

5 patients (6.2%) stopped the study (4 due to subjective poor results and 1 no show). Tolerance was good to excellent and the best results were achieved by longer lasting application with 6 months.

In conclusion, the ointment demonstrates its ability to improve genital symptoms linked to various etiologies in men and women and can be used either in first-line or as complementary or alternative medication to etiological medications (corticosteroids i.e.). Thus, by reducing genital symptoms, the ointment is likely to improve the quality of sexual and general life of our patients.

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**Table 1:** Clinical score at baseline.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Nb patients (80)</th>
<th>Score</th>
<th>Mean Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus</td>
<td>80</td>
<td>247</td>
<td>3.08</td>
</tr>
<tr>
<td>Burning</td>
<td>78</td>
<td>173</td>
<td>2.21</td>
</tr>
<tr>
<td>Pain</td>
<td>65</td>
<td>148</td>
<td>2.27</td>
</tr>
<tr>
<td>Erythema</td>
<td>45</td>
<td>156</td>
<td>3.46</td>
</tr>
<tr>
<td>Oedema</td>
<td>32</td>
<td>80</td>
<td>2.5</td>
</tr>
<tr>
<td>Skin lesions</td>
<td>70</td>
<td>180</td>
<td>2.57</td>
</tr>
</tbody>
</table>

**Table 2:** Evolution of clinical score between Visit 1, 2, 3 and baseline.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Score at baseline</th>
<th>Score at month 2 (evolution %)</th>
<th>Score at month 4 (evolution %)</th>
<th>Score at Month 6 (evolution %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus</td>
<td>247</td>
<td>106 (-57.1)</td>
<td>85 (-64.7)</td>
<td>54 (-77.2)</td>
</tr>
<tr>
<td>Burning</td>
<td>173</td>
<td>68 (-60.7)</td>
<td>38 (-77.2)</td>
<td>22 (-84.4)</td>
</tr>
<tr>
<td>Pain</td>
<td>143</td>
<td>63 (-57.4)</td>
<td>38 (-72.5)</td>
<td>22 (-83.6)</td>
</tr>
<tr>
<td>Erythema</td>
<td>156</td>
<td>60 (-61.5)</td>
<td>34 (-77.9)</td>
<td>17 (-88.6)</td>
</tr>
<tr>
<td>Oedema</td>
<td>80</td>
<td>14 (-82.5)</td>
<td>3 (-96)</td>
<td>1 (-98.6)</td>
</tr>
<tr>
<td>Skin lesions</td>
<td>180</td>
<td>75 (-58.3)</td>
<td>40 (-76.7)</td>
<td>24 (-85.5)</td>
</tr>
<tr>
<td>Total score</td>
<td>984</td>
<td>386 (-60.8)</td>
<td>238** (-74.9)</td>
<td>148*** (-84.8)*</td>
</tr>
</tbody>
</table>

* p=0.38 (CI 95 %)
** p=0.21 (CI 95 %)
*** p=0.026 (CI 95 %)

Statistics: Pearson’s test by SPSS-IBM for Windows
Acknowledgement

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References