Bohbot and Druckmann, J Genit Syst Disor 2016, 5:3
DOI: 10.4172/2325-9728.1000158

Journal of Genital System & Disorders

Research Article A SCITECHNOL JOURNAL

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] (lichens, psoriasis), iatrogenic causes (like contact dermatitis due to local antibiotics, antiseptics, 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.

***Corresponding author:** Bohbot JM, Ph Dr, Institute Fournier 25, Boulevard Saint Jacques, 75014 Paris – France, Tel: 0033140782619; E-mail: jmbohbot@msn.com

Received: March 01, 2016 **Accepted:** June 07, 2016 **Published:** June 14, 2016

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 vulviti). 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-administrated 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-administrated 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. Were excluded pregnant women, patients with clinical or biological symptoms of ano-genital infections and all patients using local medications (anti-infectious and/or anti-inflammatory 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.

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 candidiasis

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)

6 Anitis

4 noninfectious isolated Anitis

2 antis associated with vulvitis

2 other etiologies

1 sine materia vulvar pruritus

1 case isolated non-infectious vulvar cracks due to itch-scratch cycles

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.

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.

Table 1: Clinical score at baseline.

Symptoms	Nb patients (80)	Score	Mean Score
Pruritus	80	247	3.08
Burning	78	173	2.21
Pain	65	148	2.27
Erythema	45	156	3.46
Oedema	32	80	2.5
Skin lesions	70	180	2.57

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

Symptoms	Score at baseline*	Score at month 2 (evolution %)	Score at month 4 (evolution %)	Score at Month 6 (evolution %)
Pruritus	247	106 (-57.1)	85 (-64.7)	54 (-77.2)
Burning	173	68 (-60.7)	38 (-77.2)	22 (-84.4)
Pain	148	63 (-57.4)	38 (-72.5)	22(- 83.6)
Erythema	156	60 (-61.5)	34 (-77.9)	17(-88.6)
Oedema	80	14 (-82.5)	3 (-96)	1(-98.6)
Skin lesions	180	75 (-58.33)	40 (-76.7)	24 (-85.5)
Total score	**984**	**386* (-60.8)**	**238** (-74.9§)**	**148*** (-84.8§)**

§the scores of patients who stopped the study have been withdrawn

* p=0.38 (CI 95 %)

** p=0.21 (CI 95 %)

*** p=0.026 (CI 95 %)

Statistics: Pearson's test by SPSS-IBM for Windows

The duration of the study was deliberately long because in a preliminary study of 100 patients, the ointment application for 2 weeks had shown a partial improvement of symptoms, particularly in patients with dermatosis (lichen, psoriasis, irritative dermatitis). Finally, a long study helps identify patients' adherence to the product by observing the percentage of discontinuation or patients lost.

This results were obtained with the twice a day recommendation to apply the ointment but we assume that a 3-4 times application per day might be even more beneficial.

At baseline, all diseases requiring specific treatment were excluded. This is the case of clinically patent infectious diseases. If in doubt, a cyto-bacteriological examination has ruled out patients with infection and thus liable to anti-infectious therapy.

Diagnosis of genital dermatosis included in the study was taken clinically. Indeed, in most cases, biopsy is not necessary [8-11] whether in women or in men: in a study of the etiologies of balanitis among 226 men [12], a biopsy was performed in 10% of cases with excellent histo-clinical correlation (79%).

According to observance

4 patients out of 80 decided to break off the study and we lost sight of 1 patient after 4 months: a 25 yo woman with a post-infectious (candidiasis) vulvitis: pruritus, burning and vulvar cracks. At baseline, her CGS was 13, at visit 1 (after 2 months) her CGS was only 2 and at visit 2 (Month 4) her score was nil.

The proper observance of the protocol can be interpreted as positive regarding the effectiveness of the ointment.

According to clinical results

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 case 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 month.

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.

Acknowledgement

This study has been conducted thanks a grant of Kaymogyn GmbH. Material: Deumavan Natur –Kaymogyn GmbH 65203 Wiesbaden Germany/ Distributor in France-Hiramed.

References

1. Fischer GO (1996) The commonest causes of symptomatic vulvar disease: a dermatologist's perspective. Australas J Dermatol 37: 12-18.
2. Lambert J (2014) Pruritus in Female Patients. Biomed Res Int 541867.
3. Edwards S (1996) Balanitis and balanoposthitis: a review. Genitourin Med 72: 155-159.
4. Ryan C, Sadlier M, De Vol E, Patel M, Lloyd AA, et al. (2015) Genital psoriasis is associated with significant impairment in quality of life and sexual functioning. J Am Acad Dermatol 72: 978-983.
5. Haefner HK, Aldrich NZ, Dalton VK, Gagné HM, Marcus SB, et al. (2014) The impact of vulvar lichen sclerosus on sexual dysfunction. J Womens Health (Larchmt) 23: 765-770.
6. Barnes L, Kaya G, Rollason V (2015) Topical corticosteroid-induced skin atrophy: a comprehensive review. Drug Saf 38: 493-509.
7. Johnson E, Groben P, Eanes A, Iyer P, Ugoeke J, et al. (2012) Vulvar skin atrophy induced by topical glucocorticoids. J Midwifery Womens Health 57: 296-299.
8. Croxtall JD, Plosker GL (2009) Sertaconazole: a review of its use in the management of superficial mycoses in dermatology and gynaecology. Drugs 69: 339-359.
9. Veraldi S, Milani R (2008) Topical fenticonazole in dermatology and gynaecology: current role in therapy. Drugs 68: 2183-2194.
10. Spring S, Pratt M, Chaplin A (2012) Contact dermatitis to topical medicaments: a retrospective chart review from the Ottawa Hospital Patch Test Clinic. Dermatitis 23: 210-213.
11. Bunker CB, Shim TN (2015) Male Genital Lichen Sclerosus. Indian J Dermatol 60: 111-117.
12. Fistarol SK, Itin PH (2013) Diagnosis and Treatment of Lichen Sclerosus: An Update Am J Clin Dermatol 14: 27-47.
13. Andreassi L, Bilenchi R (2014) Non-infectious inflammatory genital lesions. Clin Dermatol 32: 307-314.
14. Pearce J, Fernando I (2015) The value of a multi-speciality service, including genitourinary medicine, dermatology and urology input, in the management of male genital dermatoses. Int J STD AIDS 26 : 716-722.

Author Affiliation

Top

Institute Fournier 25, Boulevard Saint Jacques, 75014 Paris, France