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Can topical applied patches adhere without causing irritation in Vulvar Lichen Sclerosus patients?

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Introduction

Vulvar lichen sclerosus (VLS) is a chronic inflammatory skin disease with a predilection for the anogenital area. It is estimated that up to 3 % (1:30) of perimenopausal/menopausal women have vulvar lichen sclerosus. The symptoms are dyspareunia, dysuria, perianal discomfort, pruritus and pain. Typical clinical signs is thinning of the skin, dyspigmentation, fissuring, ecchymoses, hyperkeratosis and inflammation. Topical coricosteriod is the gold stand of therapy and long-term treatment can reduce the disease-associated risk of spinocelluar carcinoma, which occurs in up to 6% of woman with Vulvar Lichen Sclerosus[1,2,3]
It presents clinically as areas of atrophy, edema, fissures, erosion and/or thickened hyperkeratotic plaques.[4] The initial treatment regimen consists of daily application of topical corticosteroids. Irritation from changes in microbiome and mechanical shear are thought to influence the disease severity.[3]
An adhesive patch has been developed to form a protective barrier over VLS lesions thereby potentially also contribute to pain relief.
The present study was conducted in order to explore the adhesion and tolerability of plain patches (without medication) when applied directly to VLS lesions.

Objectives

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Figure 1. Instruction for application of the patch

Materials & Methods

This was an open-label study. Eligible subjects were women (≥ 18 years) diagnosed with VLS which had signed an informed content. Pregnant or menstruating patients at the time of patch application were excluded.
The primary endpoint was applications of the patches and adhesion for ≥ 30 min. Secondary endpoints were frequency and intensity of adverse events collected during the investigation, subject's ability to apply patches correctly and understanding of the 'instructions for use' leaflet.
A visual analogue scale (VAS) for discomfort, pain, itching and burning was used at baseline, at 2 hours after application (or when the patch detached) and on day 2 (VAS 0 - 10, where 0 = no symptom and 10 = worst possible). At the same time physical examination grading redness, erosion and edema was performed (graded from 0 (no signs) to 4 (maximum)). Ten questions regarding the comfort, adhesion and the willingness to wear the patch containing medications was fulfilled day 2.

Activity	Timing
Activities Day 1	
Patient information and written informed consent	
Screening and Enrolment	
Assessment of mucosal irritation and subject VAS	
Instruction in applying patches and application of patches	Time 0
Cycling, walking, sitting down and laying down	Time 0-2 hours
Removal of one patch (if not detached)	Time 2 hours
Assessment of mucosal irritation and subject VAS	Time 2 hours
Assess adhesion time for patch 2	Time 2-14 hours
Night time application of one to two patches	Bedtime
Activities Day 2	
Assessment of mucosal irritation and subject VAS	Time 24 hours
Interview on optimised patch design for VLS	

Results

Twelve VLS patients aged 24 to 61 years (mean 55.1) were included. The majority had had VLS for more than one year (< 1 year (8.3%, n=1), 1-5 years (50%, n=6), 6-10 years (8.3%, n=1), > 10 years (8.3%, n=1), NA (25%, n=3))..

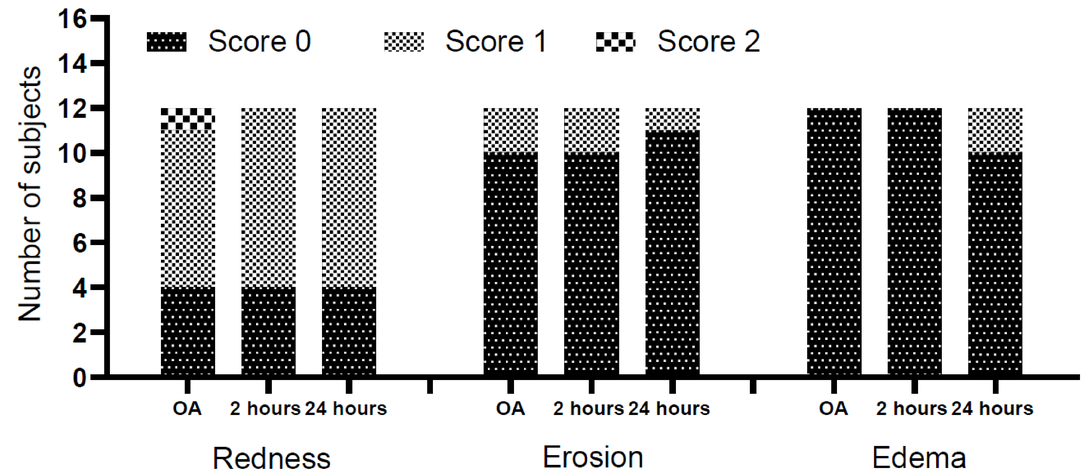

Figure 2. Mean scores for mucosal irritation accessed by the investigator. Signs of mucosal irritation are assessed using a 5-point scale (0-4), where 0 is normal and 4 is most extreme

Results (continued)

Baseline VLS symptoms by VAS scoring was as follows: pain (mean 2.6, range 0-7), itch (mean 3.8, range 0-10), burning (mean 3.3, range 0-8) and discomfort (mean 4.1, range 0-8) (Fig. 2).
All patients were able to apply the plain patch. The mean adhesion time was 9.5h on Day 1 and 10.0 h on Day 2. No AEs were reported. All subjects applied the patches correctly and were able to follow the leaflet instructions.
The measured VLS symptoms VAS scores (discomfort, pain, itching and burning) were lower 2 hours after application and on day 2 compared to baseline. In addition, for both redness, erosion and oedema, all subjects (except for 1) had scores of 0 or 1 on both day 1 and 2. For the physical examination of the mucosa and skin (vulva and anal area) 5 subjects (41.6%) had a shift from abnormal to normal for either skin or mucosa or both while no change were reported for the rest (58.3%) of the subjects. The overall response to the design of the patches was that they were easy and quick to apply.

Conclusion

The primary objective to investigate the adhesion time of the plain patches to VLS lesions was met as all subjects reported a successful application with a mean adhesion time for both morning and evening of more than 9 hours. For all symptoms of VLS the VAS scores were lower after patch application compared to prior to application indicating a reduction in the subjects' evaluation of the level of VLS symptoms after using the patch. No safety issues were reported and the patch were well tolerated when applied to sensitive VLS lesions.

Acknowledgement

MG and LSM received a grant from the Innovation Fund, Denmark.

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