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Efficacy of SEBCLAIR® Cream for Moderate Seborrhoeic Dermatitis on The Face as An Adjuvant Therapy (Randomised Clinical Trial, Double Blind)

Inda Astri Aryani[1], Yulia Farida Yahya[1], Nina Roiana[1], Radema Maradong Ayu Pranata[1#]

[1]Dermatovenerology Department, Faculty of Medicine, Universitas Sriwijaya/
General Hospital Moh. Hoesin Palembang, Indonesia

#Correspondence : radema.pranata@googlemail.com

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Abstract

Background: Seborrhoeic dermatitis (SD) is a chronic papulosquamous inflammatory disease which resistant to medical treatment. Various treatment such as topical corticosteroid, antifungal and calcineurin inhibitor has been widely practiced and gives varying results

Objective: Our objective was to compare the efficacy of Sebclair® and topical hydrocortisone 2,5% for management of moderate SD on the face

Methods: A randomised clinical trial, controlled, double blind study was performed for four weeks. We assessed the efficacy and side effects of these topical treatment. The severity of SD was evaluated using Seborrhea Area Severity Index-Facial (SASI-F) score. The severity of pruritus was evaluated using Visual Analogue Scale. Demographic characteristics, baseline SASI-F and VAS were recorded in the medical record.

Results: A 34 patients (14 males, 20 females) with moderate SD on the face completed the four weeks study. The mean of SASI T2 and VAS score of the Sebclair® group was significantly lower than Hydrocortisone 2.5% group with p = 0.000 and p = 0.000 respectively. Tolerance between Sebclair® and Hydrocortisone 2.5% showed insignificant results (p = 1.000)

Conclusions: The longer application of Sebclair® was significantly more effective to improve moderate SD

Key words: Moderate seborrhoeic dermatitis, face, Sebclair®, hydrocortisone

1 INTRODUCTION

Seborrhoeic dermatitis (SD) is a chronic papulosquamosa inflammatory disease characterised by exacerbation, remission periods and resistant to medical treatment. It occurs in immunocompetent adult in 5% range of the entire population, generally 30-60 years old.[1,2] Although its prevalence is small, but 34 - 83% of SD occur in immunocompromised patients with risk factors. Recently, at least 50% of HIV patients have been encountered with SD.[3,4] Its also found in patients with Parkinson disease or patients receiving treatment such as haloperidol decanoate, buspirone, chlorpromazine.[4] The prevalence of SD in adults is higher, especially in the age range of 30-60 years old.[5] Various risk factors increase the clinical

severity of SD, it comorbidities with systemic disease such as diabetes mellitus, hypertension, Parkinson's disease, HIV infection, environmental conditions such as air-conditioned room, resulting in persistent and exacerbation. Until now, its pathogenesis is still unclear, factors associated with SD are *Malassezia spp*., skin surface lipid film (SSLF), sebaceous gland activity, and excess sebum production.[6,7] Some experts think excess sebum production is not a risk factor associated with SD. Other factors related to SD pathogenesis include immune responses, individual susceptibility, and neurogenic.[8] It factors resulting in impaired skin function and skin barrier thus increased host vulnerability.[9]

Seborrhoeic dermatitis appears in the area which contains many sebaceous glands, especially on face, nasal folds, central part of the face, eyebrows, head, chest and back, with a typical features of patches erythematous, oily and white-yellowish scale, smooth, accompanied by itch.[10]

Seborrhoeic dermatitis clinical severity assessed using score of Seborrhea Area Severity Index-Facial (SASI-F). SASI-F score is obtained by assessing the area involved, erythematous, scale, and face area involvement. The clinical severity score obtained after the calculation. The head area is divided into areas of scalp and face (including neck and ears), given equal weight for the purpose of calculating engagement score divided into 6 scores (0 = less than 1% ; 1 = 1 - 10%; 2 = 11-20%, 3 = 21-35%, 4 = 36- 50%, 5 = 51-75%; 6 = 76-100%).[3] Pruritus was assessed by VAS with a range 0 until 10

The treatment aims to decrease inflammation; reduce erythematous, scale, itching and prevention of exacerbation. Various SD treatment on the face has been widely practiced and gives varying results.[2] Topical treatment is the first choice in moderate SD, including corticosteroids (CS) such as 2.5% hydrocortisone. Topical CS cannot be given in the long term period because it causes skin atrophy and telangiectasis. Other topical treatments are 2% ketoconazole cream and tacrolimus cream. The application of tacrolimus cream must be careful and the price is quiet expensive.[11]

Sebclair® is a new non-steroid topical drug containing 1.2% bisabolol, 0.5% pyroctone olamine, 1% alglycera and 0.01% telmesteine. Sebclair® has an effect such as anti-inflammatory, anti-fungal and anti pruritus. Study by Micali (2015) in adult SD treated with Sebclair® for 4 weeks, double blind, with placebo as control, randomization (n = 60) evaluated clinical and erythematous skin by assessing IGA therapeutic results, assessing pruritus with VAS, showed significantly improved (decreased erythematous, scale) by 68% compared to placebo by 11%.[12]

2 METHODS

This was a randomised, double-blind, controlled study in adult patients with SD in the Dermatovenereology Outpatient Unit of General Hospital Dr. Mohammad Hoesin Palembang (RSMH) from June 2017 – March 2018. Inclusion criteria is patients aged ≥ 20 years old with moderate SD on the face. Exclusion criteria are patients with light or severe SD, allergic to the substances used in the study, patients with other dermatoses on the face, patients taking oral retinoid within 6 weeks before study; patients taking antibiotics, immunosuppression drugs, hormones (corticosteroids), contraceptives, and other vitamins within 4 weeks before study; patients using topical corticosteroids or antibiotics, facial wash

or makeup containing antibiotic or corticosteroid ingredients within 2 weeks before study; patients undergoing chemical peeling, laser and other aesthetic treatments within 4 weeks before study; patients who are pregnant, lactating, or planning to pregnant; patients with a diagnosis of drug eruption or have a lot of scar tissue on the face which complicates investigator evaluation or evaluation using the instrument (photo).

Informed concent was obtained from the patients. All the patients were subjected to history taking such as name, age, sex and occupation. The patients divided into Sebclair® group and hydrocortisone 2,5% group. Baseline data of SASI-F score and VAS were collected. Assessment of SASI-F, VAS and tolerance were collected every two weeks of follow up. The length of follow up duration is four weeks.

Data then analysed by Wilcoxon test, Mann Whitney U test and Fisher exact test. Ethical clearance had been approved for this study by the Local Ethical Committee.

3 RESULTS

A total of 34 patients from two groups were examined. The results showed that female (20 patients; 117,6%) are common than male in both groups (14 patients; 82,4%). Mean age in Sebclair® group is 31,53 ± 13,39 and mean age of hydrocortisone is 38,59 ± 14,34.

In the Sebclair® group, the median of VAS T0 and T1 are 3 and 2 respectively (p= 0,000). Median of VAS T1 with VAS T2 are 2 and 0 (p= 0,004) respectively. The median of SASI T0 and T1 in Sebclair® group are 3 and 2 (p=0,000) respectively, and the median of SASI T1 and T2 are 2 and 1 (p=0,000) respectively.

In the hydrocortisone 2,5% group, both of median of VAS T0 and T1 are 3 (p=0,008). Median of VAS T1 and T2 are 3 and 2 (p=0,005) respectively. The median SASI T0 and T1 are 3 and 2,5 respectively (p=0,000). Median SASI T1 and T2 are 2,5 and 2 (p=0,004) respectively.

Comparison of median VAS T1 in Sebclair® and Hydrocortisone 2,5% group are: 2 and 3 (p=0,009) respectively. Median VAS T2 in Sebclair® and hydrocortisone 2,5% group are 0 and 2 (p= 0,000) respectively. (**Table.1**)

Comparison of median SASI T1 in Sebclair® and Hydrocortisone 2,5% group are: 2 and 2,5 (p=0,057) respectively. Median SASI T2 in Sebclair® and hydrocortisone 2,5% group are 1 and 2 (p=0,000) respectively. (**Table.2**)

The tolerance in Sebclair® group was found in 1 patient who experienced mild irritation (5.9%) while in the hydrocortisone 2.5% group did not experience an irritation (p=1,000).

Tabel 1. VAS score of Sebclair® and Hydrocortisone 2.5% in patients with Seborrhoeic Dermatitis

VAS Value	Treatment		*p value*
	Median value (min-max) Sebclair®	Median value (min-max) Hidrokortison 2,5%	
T1	2 (0 – 3)	3 (1 – 4)	0,009
T2	0 (0 – 2)	2 (0 – 4)	0,000

Table 2. SASI score of Sebclair® and Hydrocortisone 2.5% in patients with seborrhoeic dermatitis

SASI value	Treatment		*p value*
	Median value (min-max) Sebclair®	Median value (min-max) Hydrocortisone 2,5%	
T1	2 (0 – 3)	2,5 (2 – 3,5)	0,057
T2	1 (0 – 2,5)	2 (1 – 3)	0,000

4 DISCUSSION

This study was compared Sebclair® cream with hydrocortisone cream 2.5% in patients with SD on face. This study assessed SASI, VAS and drug tolerance score on SD patients on face from March 2017 to February 2018. The sampling technique was randomised, double-blind, and controlled. A total of 34 study subjects with a DS diagnosis who met inclusion criteria were included as subject.

Based on demographic data, the most subjects in the two treatment groups is female, as many as 20 patients (64.7%). This is in accordance with study by Araya, et al (2015) in 166 patients obtained more female than men.[13] Yet another literature shows different results: male are more likely to suffer from DS than female.[14] This may be related to attention of the physical appearance more common in female than male, so female more often to seek the treatment.

In this study the mean age of SD subject in Sebclair® group is 31.53 ± 13.39 years old, whereas in Hydrocortisone 2.5% group is 38.59 ± 14.34 years old. This is in accordance with the average age of SD patients in the study by Oglio, et al (2015) is 30.7 years old.[14] Other studies reported mean age of SD patients 39.2 ± 17.7 years.[15] Study by Youn, et al (2016) reported the mean age of SD patient is 35.57 years old.[16] The severity of SD decreases with age, but some factors such as emotional stress and less rest often associated with occupational factors, especially in adult patients, will trigger SD induced expulsion of pro inflammation cytokines.[15]

Sebclair® group showed a significant decrease in SASI T1 score compared to baseline (p = 0.000) and SASI T2 compared to T1 (p = 0,000). Decreased pruritus with VAS score was also significant in VAS T1 compared to baseline (p = 0.000) and decreased VAS score on T2 compared to VAS T1 (p = 0,004). These results are in line with study by Oglio showing significant changes in erythema (p = 0.0001), desquamation (p = 0.0002), and pruritus (p = 0.0001) compared to baseline after 28 ± 2 days.[14] Sebclair® is a nonsteroid topical drug, containing 1.2% bisabolol, 0.5% ococheme olamine, 1% alglycera and 0.01% telmesteine. Bisabolol, telmesteine and alglycera work as anti-inflammatory and antipruritus plays a role in repairing skin barrier. Alglycera increase moisture in the extracellular matrix and has keratolytic effect by increasing desquamation in the corneocyte layer.[14] Piroctone olamine, an antifungal, is capable to penetrate the fungal membranes cell and forming a complex ions with iron, thereby inhibiting the fungal mitochondrial metabolism.[16]

In hydrocortisone 2.5% group, significant decreases were also obtained in the SASI T1 score compared to baseline (p = 0.000) and SASI T2 compared with T1 (p = 0.004). There was a significant decrease in VAS T0 score compared to VAS T1 (p = 0,008) and decreased VAS T1 score compared to VAS T2 (p = 0,005). The application of hydrocortisone for 12 weeks, effectively reduce SASI and VAS in 72 patients with moderate SD.[1] Other studies have shown the effectiveness of hydrocortisone in reducing SASI and VAS in week 4 of application.[11] Hydrocortisone works as anti-inflammatory thereby decreasing the proliferation of stratum corneum. This anti-inflammatory function also helps to improve the differentiation of corneocytes, so that increasing the skin barrier function and reduces *M. furfur* colonization in the skin.[17] On the other hand, long-term use of corticosteroids can cause side effects such as atrophy, telangiectasis, hypertrichosis and perioral dermatitis.[10]

The mean SASI T1 score was not significantly different in the two groups (p = 0.057). The mean score of SASI T2 in Sebclair® group was significantly lower than Hydrocortisone 2.5% group (p = 0.000). Sebclair® group also showed a significantly lower of VAS T2 than Hydrocortisone 2.5% group (p = 0.000). The results showed that the efficacy of Sebclair® in a short duration did not differ significantly with hydrocortisone, but Sebclair® group was significantly more effective (p = 0.000) after longer usage. There have been no case reported the efficacy of Sebclair® compared to Hydrocortisone 2.5%, but combination of active ingredient in Sebclair® may lead to better effectiveness in long-term treatment of SD.

Tolerance between Sebclair® and Hydrocortisone 2.5% of SD patients gave insignificant results (p = 1.000), although there was 1 patient with mild irritation to Sebclair® application. There have been few reports of Sebclair® side effects, but one study by Veraldi, et al (2008) reported 4 patients experiencing adverse effects of light erythema and slight burning.[18] Some of Sebclair® side effects include erythema, burning, itching and edema.[18]

5 CONCLUSION

It can be concluded that Hydrocortisone 2.5% and Sebclair® have the same effectiveness in short-term of DS treatment. Sebclair® is consider more superior than hydrocortisone 2,5% if the duration of application is longer. The application of long-term hydrocortisone 2.5% should be avoided to prevent side effects such as atrophy, telangiectasis, hypertrichosis and perioral dermatitis. Sebclair® may be considered as an

alternative therapy for both short and long term of DS treatment.

6 LIMITATION

This study has a limitation such as small sample size and short term of follow-up.

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There is no conflict of interest in this study.

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