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### Abstract

**Background:** Psoriasis is a chronic inflammatory skin disease characterized by persistent itching and a high rate of recurrence. Until now, the primary issue with these two diseases has been their inability to respond to therapy; thus, it is critical to develop an appropriate combination therapy for these two diseases. Due to the fact that psoriasis patients experience alternating periods of remission and exacerbation, dermatologists should tailor psoriasis treatment to the severity of the disease at the time it manifests, with the goal of extending remission and improving quality of life. Thus, it is critical to achieve maximum treatment efficiency in order to prolong the period of remission and improve quality of life. **Method:** This study is a study comparing the effectiveness of a new treatment therapy using a combination therapy of 0.05% Clobetasol with 3% liquor carbonis detergent and 2% salicylic acid compared to standard therapy, namely 0.05% Clobetasol. This study is a retrospective cohort therapy at the Indra Clinic. The samples of this study were all cases of psoriasis of the skin at Indra's clinic in the 2016-2017 period that met the inclusion criteria. The independent variable of this study was the drug formulation with the dependent variable in the form of clinical improvement and the appearance of side effects. **Results:** The cure rate was 86,2 percent for the 29 respondents who received the combination formulation, compared to 54,5 percent for the 22 respondents who received standard therapy containing Clobetasol 0.05 percent (p : 0,028). There were no statistically significant differences in adverse events between the two intervention groups. **Conclusion:** Innovative drug formulations (clobetasol 0.05% with 3% liquor carbonis detergent and 2% salicylic acid) for psoriasis are proven to be more effective and superior than standard therapies

**Keywords:** clobetasol; liquor carbonis detergens; salicylic acid; psoriasis

## INTRODUCTION

Psoriasis is a chronic inflammatory condition of the skin that is characterized by well-defined erythematous plaques that are rough, layered, and silvery white in color. This disease is chronic and recurrent, with the patient experiencing periods of remission and exacerbation on a regular basis. Psoriasis is the most common autoimmune disease, characterized by an abnormal activation of the cellular immune system<sup>1-6</sup>

Psoriasis prevalence varies significantly between countries, ranging from 0.09 percent to 11.43 percent, making it

a serious global problem affecting at least 100 million people. Around 10% – 25% of patients develop psoriatic arthritis, which causes joint pain and swelling. Psoriasis can affect both men and women of any age and frequently recurs.<sup>7,8</sup>

Psoriasis affects between 2% and 3% of the world's population, with men and women having an equal chance of developing it. The Asian race has a relatively low prevalence of psoriasis, estimated to be around 0.4 percent. There is a significant difference in the prevalence of psoriasis between African Americans and white

Americans, according to studies (1.3 percent vs. 2.5 percent ). Psoriasis is uncommon in children under the age of ten, peaking between the ages of fifteen and thirty. From January to December 2009, data on patient visits to the Dermatology and Venereology Polyclinic of Sanglah General Hospital in Denpasar revealed 156 new cases of psoriasis from 10,856 visits (1.4 percent ).<sup>5,9-12</sup>

Due to the possibility of developing psoriatic arthritis and a variety of other systemic diseases, psoriasis can result in significant morbidity. Around 10% – 30% of patients with psoriasis are at risk of developing psoriatic arthritis. Along with an increased risk of morbidity, patients with severe psoriasis faced an increased risk of mortality, with men dying 3.5 years earlier and women 4.4 years earlier than healthy subjects. Longitudinal studies indicate that spontaneous remission occurs with varying frequency in approximately one-third of psoriasis patients.<sup>4,5,13,14</sup>

Psoriasis management is complicated by a variety of factors that contribute to and influence the severity of the disease. It is critical to avoid triggers for this condition, which include physical trauma, infection, stress, seasonal and climate changes, beta blocker use, chloroquine use, alcohol use, and smoking. Due to the fact that psoriasis patients experience alternating periods of remission and exacerbation, dermatologists should tailor psoriasis treatment to the severity of the disease at the time it manifests, with the goal of extending remission and improving quality of life.<sup>15-18</sup>

Due to the critical nature of treatment efficiency in extending the duration of remission and improving quality of life, a new treatment formulation is required to

accomplish this goal. The purpose of this study is to evaluate the efficacy of a new treatment regimen that contains 0.05 percent clobetasol, 3% liquor carbonis detergent, and 2% salicylic acid, and to compare it to standard therapy, which contains 0.05 percent clobetasol.

## METHOD AND MATERIAL

This study was a retrospective cohort study that analyzed the comparisons between 2 treatment formulations. The population of this study were all cases of psoriasis on the skin at Indra's clinic in the period 2016-2017. The research sample is part of the study population that meets the inclusion criteria. The inclusion criteria in this study were a minimum age of 12 years and a diagnosis of psoriasis of the skin by a Dermatologist. The exclusion criteria in this study were incomplete medical record data or there was a history of allergy to drug content. The minimum sample size required is 20 samples for each treatment formulation group (type 1 error is 5% and type 2 error is 20%). The sampling method used was non random purposive sampling. The procedure of this study is to look at all patient medical record data from 2016 to 2017 and look for data on the diagnosis of psoriasis in the skin and the therapy given. The independent variable of this study was a treatment formulation for psoriasis in the skin in the form of clobetasol 0.05%, or a combination of 0.05% Clobetasol with 3% liquor carbonis detergent and 2% salicylic acid topically. The dependent variables in this study were treatment success (improved or not), side effects during treatment, and post-treatment symptoms. Analysis of research data is divided into two, namely descriptive data analysis and analytic data analysis. Descriptive data analysis includes the proportion (%) for the type of qualitative data and the distribution of centralized data (mean, SD, median, minimum, maximum). Analytical data



analysis used the comparative test for unpaired categorical data in the form of the Pearson Chi Square test, Chi Square with Yates Correction, or Fisher Exact in accordance with the applicable data provisions for each statistical test.

## RESULT

This study enrolled 51 individuals who had skin psoriasis. There were 29 respondents who received clobetasol formulation therapy (0.05 percent clobetasol with 3% liquor carbonis detergent and 2% salicylic acid) and 22 respondents who received standard clobetasol therapy. Table 1 summarizes the demographic characteristics of each group of patients.

**Table 1. Demographic Characteristics of Respondents**

Variable	Treatment		p-value
	Clobetasol Formulation N : 29 responden	Clobetasol 0,05% N : 22 responden	
Age	36,72 (17,7)	35,82 (20,4)	> 0,05
Sex			
• Male	15 (51,7%)	12 (54,5%)	> 0,05
• Female	14 (48,3%)	10 (45,5%)	

The therapy was administered for one week before being re-examined at the subsequent visit. The cure rate was 86,2 percent for the 29 respondents who received a combination formulation containing 0.05 percent clobetasol, 3 percent liquor carbonis detergent, and 2% salicylic acid, compared to 22 respondents who received standard

therapy containing 0.05 percent clobetasol. obtained a 54,5 percent cure rate. The Chi Square with Yates Correction statistical test revealed a difference in the degree of clinical improvement between psoriasis and formulation therapy when compared to standard therapy (p-value: 0.028).

**Table 2. Therapeutic Effectiveness between 2 Treatment Regimens**

Parametric	Clinically after 1 week		p-value
	Remission in <1 week	Remission in > 1 week	
Combination of 0.05% clobetasol with 3% liquor carbonis detergent and 2% salicylic acid	25 (86,2%)	4 (13,8%)	0,028
The standard regimen of 0.05% Clobetasol	12 (54,5%)	10 (45,5%)	

The assessment of adverse effects was conducted using two drug formulations. It was discovered that side effects consisted

solely of persistent itching and redness during drug use. The Fisher Exact test revealed no statistically significant difference

in adverse events between the two intervention groups.

**Table 3. Side effects between the 2 Treatment Regimens**

Variable	Drug Formulation		p-value
	Clobetasol Formulation N : 29 responden	Clobetasol 0,05% N : 22 responden	
Side effects			
• Persistent itching	2 (6,9%)	3 (13,6%)	> 0,05
• Redness	4 (13,8%)	5 (22,7%)	> 0,05
• Skuama	-	-	-
• Hyperpigmentation	-	-	-
• Hypopigmentation	12 (41,4%)	13 (59%)	> 0,05

## DISCUSSION

Psoriasis is a chronic, multisystem inflammatory disease characterized by abnormal skin differentiation and hyperproliferation as a result of immune system dysfunction. The skin becomes hyperresponsive during the course of the disease due to a failure to regulate the immune response and the formation of reactive memory cells that continuously recruit inflammatory mediators. Hyperplasia and hyperkeratosis occur as a result of chronic inflammation, resulting in the thickening of the skin and the formation of scales. This is a chronic disease that has a remission-exacerbation cycle and occasionally does not respond to therapy. Environmental, genetic, and immunological factors all have an effect on psoriasis. The elbows, knees, scalp, back, groin, and glans penis are frequently affected by red, scaly patches. Extracutaneous manifestations of psoriasis include nail involvement and psoriatic arthritis. Psoriasis severity is generally quantified using the Psoriatic Area and Severity Index (PASI) score or the Physicians' Global Assessment (PGA).<sup>1,19-24</sup>

Psoriasis treatment is determined by its severity. The management of this disease

is based on manipulating the immune system to reduce its activity and restore normal functioning. The first line of treatment for mild-moderate psoriasis is topical agents. The primary goals of therapy are symptom suppression and long-term disease severity modulation. Additionally, this topical therapy aims to improve overall quality of life with few side effects. The combination of corticosteroids and Liquor Carbonis Detergent has a favorable therapeutic response, and the availability of stain- and odor-reducing preparations has reintroduced this therapy into use. Additionally, it is known that anthralin, tazarotene, salicylic acid, phenol, and calcipotriene are effective when combined with corticosteroids. Retinoids, methotrexate, cyclosporine, 6-thioguanine, azathioprine, and hydroxyurea are used to treat severe cases. UVA and UVB phototherapy are also known to be effective.<sup>1,25,26</sup>

Different formulations of topical steroids have varying potencies. Its efficacy is proportional to the degree of steroid molecule penetration into the skin, which is influenced by the chemical structure of the steroid used. The dosage form and the state of the skin also have an effect on the drug's

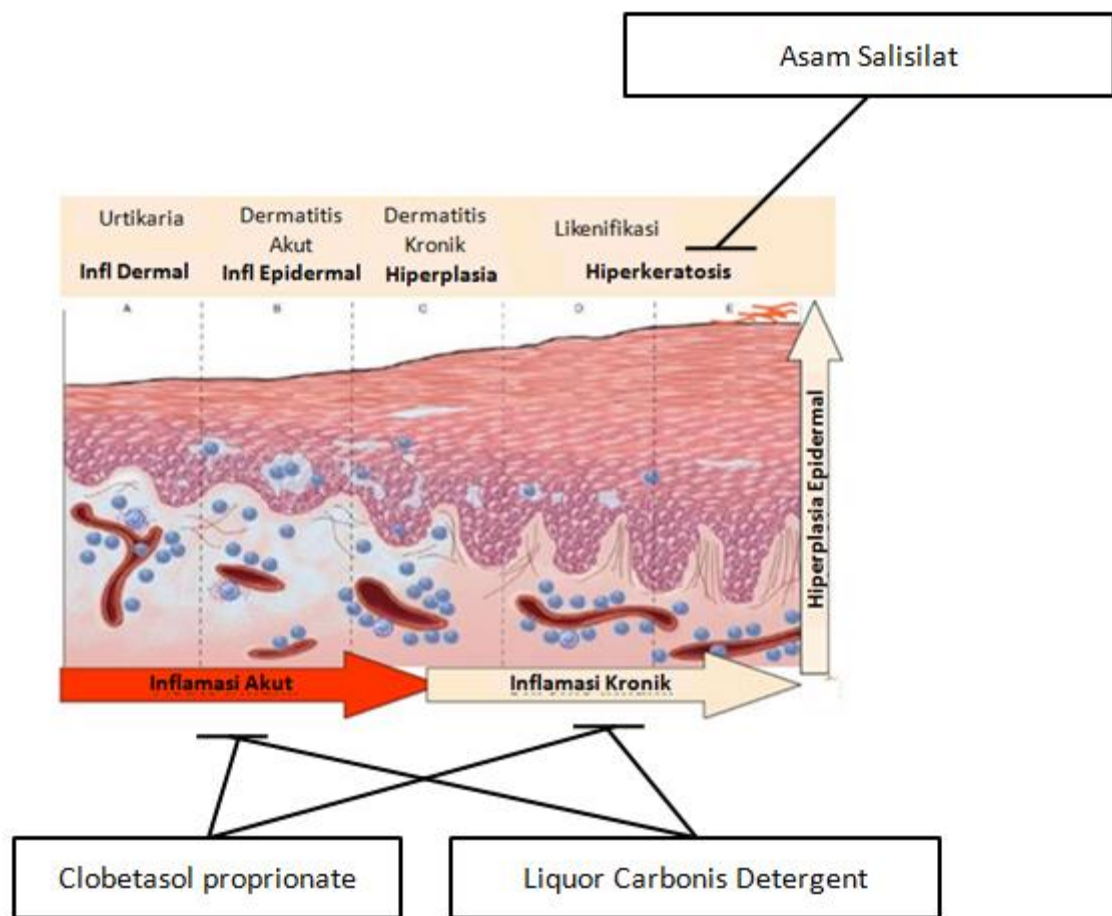
absorption. In children, low-potency steroids should be used. In adults, steroids should be of low to moderate potency. Clobetasol is a powerful anabolic steroid. It is typically used at a concentration of 0.05 percent in the treatment of skin diseases. Clobetasol is an anti-inflammatory agent that is used to treat a variety of skin conditions.<sup>27-31</sup>

Liquor Carbonis Detergent is derived from the primary condensation of coal. This preparation is believed to work by inhibiting DNA synthesis and keratinocyte proliferation. The topical detergent Liquor Carbonis acts as a keratolytic, antiacanthotic, photosensitizer, vasoconstrictor, antipruritic, and antimicrobial. In comparison to corticosteroids, this medication is effective for long-term management of mild to moderate psoriasis with fewer side effects and a lower risk of recurrence.<sup>32-34</sup>

Keratolytics are recommended as adjuvant therapy in psoriasis of mild to severe severity. The main goals of keratolytic use are hydration of the stratum corneum, desquamation of the skin, reducing itching, increasing penetration of topical drugs and phototherapy. Salicylic Acid (2-Hydroxybenzoic Acid / Orthohydrobenzoic Acid) is a member of the hydroxy acid group. Salicylic Acid can be extracted naturally or synthesized chemically. Topical salicylic acid functions as a keratolytic, comedilytic, reduces sebum production, antihyperplastic,

desmolytic, antimicrobial and anesthetic. Salicylic acid as a keratolytic has been widely researched and used. At concentrations of 5% and above, this preparation has a rapid and deep keratolytic effect that causes desquamation. The underlying mechanism is that salicylic acid reduces the intercellular cohesion between corneocytes by dissolving the intercellular material and decreasing the pH of the stratum corneum, resulting in increased hydration and softening.<sup>35-39</sup>

Based on a case study conducted by Frankel et al. entitled "Coal tar 2% foam in combination with a superpotent corticosteroid foam for plaque psoriasis: case report and clinical implications, as well as published in *J Clin Aesthet Dermatol*, a combination of Liquor Carbonis Detergent 2% with Clobetasol 0.05% gives good results. in psoriasis patients. The study by Jacobi et al. with the title "Keratolytics and emollients and their role in the therapy of psoriasis: a systematic review", and published in *Dermatol Ther (Heidelb)*, suggests salicylic acid administration reduces the severity of psoriasis with a rapid onset. Corticosteroid administration is accompanied by a liquor carbonis detergent and / or salicylic acid was also suggested in the studies of Brakeley, et al, Zhu et al, and Khandpur et al for use in the treatment of psoriasis.<sup>39-43</sup>



**Figure 1. Mechanism of keratolytic and anti-inflammatory action in psoriasis**

Effects of Clobetasol, Liquor Carbonis Detergent, and Salicylic Acid according to the pathogenesis of psoriasis. Psoriasis is based on the pathogenesis of chronic inflammation of the skin. (A) Urticaria is a response to acute inflammation that appears first due to inflammation of the dermis. (B) In acute dermatitis the inflammation continues on the epidermal layer. (C) If the dermatitis is chronic, there will be hyperplasia of the epidermal layer. (D) Over time hyperkeratosis occurs so that scales (E) appear on the skin as seen on lichenification. In the skin, Clobetasol propionate and Liquor Carbonis Detergent work by inhibiting inflammation so as to decide the course of the disease that leads to hyperplasia and hyperkeratosis. Salicylic Acid acts as a keratolytic which eventually removes the excess scales due to

hyperkeratosis. Through the combination of the three, the thickening and scales on the skin surface will gradually disappear.<sup>1,19-24</sup>

Ointments and serums are prepared in accordance with the standard for dermatological drug preparations. A combined psoriasis ointment is prepared by mixing 500 grams of Vaseline Album with Clobetasol 0.05–1.5 percent, Liquor Carbonis Detergent 3-5 percent, and Salicylic Acid 2–5%. Natrosol 20%, Clobetasol 0.05–1.5%, Liquor Carbonis Detergent 3-5%, and Salicylic Acid 2–5% are used in the serum. The mixture is diluted to a concentration of 100 percent aqua. The ointment and serum preparations are placed in a container designed for this purpose. Instructions for use, indications, contraindications, and adverse effects are included on the container.

Serum is intended for use on areas that are excessively hairy. Ointments can be used on hairy or non-hairy skin, but they will feel sticky when applied to hairy areas. By preparing these two types of preparations, maximum therapy can be delivered to the entire surface of the affected skin.

## CONCLUSION

The innovative therapy of a 0.05 percent Clobetasol mixture with 3% liquor carbonis detergent and 2% salicylic acid has been shown to provide a greater level of clinical improvement than standard Clobetasol therapy. The cure rate was 86,2 percent in the group receiving 0.05 percent Clobetasol mixed formulation innovation therapy combined with 3 percent liquor carbonis detergent and 2 percent salicylic acid, compared to 54,5 percent in the group receiving standard therapy containing 0.05 percent Clobetasol. There were significant differences between the two therapy groups, but there were no significant differences in side effects.

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