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NEW DRUG FORMULATIONS FOR ACNE VULGARIS – PATHOGENESIS BASED TREATMENT OF ACNE VULGARIS

Sukmawati Tansil Tan¹, Yohanes Firmansyah²

¹Department of Dermato-Venereology, Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia

²General Practitioner, Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia

Correspondence Author:

Yohanes Firmansyah, MD, AIFO-K Tarumanagara University, Jakarta, Indonesia

Telp: (+62) 812-9793-4375

E-mail: yohanesfirmansyah28@gmail.com

Address: Jl. Letjen S. Parman No. 1 Jakarta Barat 11440, Indonesia

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Abstract

Acne vulgaris is an inflammatory condition that affects the pilosebaceous glands on a localized basis. According to the Indonesian Cosmetics Dermatology Study, the prevalence of acne vulgaris increased between 2006 and 2009. Young women between the ages of 14-17 years have a prevalence of 83-85 percent, while men between the ages of 16-19 years have a prevalence of 95-100 percent. Acne vulgaris has a significant physical and psychological impact on adolescent sufferers. Accuracy in the treatment of acne vulgaris is critical because it has an impact on the patient's recovery and prognosis. A topical anti-acne cream containing retinoids, antibiotics, and corticosteroids is one of the best options because it contains all of the components necessary to treat acne. The purpose of this study was to ascertain the proportion of acne vulgaris sufferers in adolescents aged 14-19 years with mild, moderate, and severe acne levels prior to and following intervention, to ascertain the relationship between intervention and reduction in the severity of acne vulgaris, and to ascertain the proportion of acne vulgaris sufferers in adolescents who received intervention and experienced a reduction in the severity of acne vulgaris. This study is a retrospective cohort study conducted at the Indra Clinic. The sample of this study was the entire group of adolescents aged 14-19 years with acne vulgaris who came to the study site in the 2016-2017 period and met the inclusion criteria. The formulation observed was a combination of anti-acne cream with the active ingredient clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%, with the comparative drug being a standard regimen containing 0.05% tretinoin. The dependent variables in this study were treatment success (improved or not) after 4 weeks intervention, side effects during treatment, and post-treatment symptoms. The results indicated the cure rate was 87,6 percent for the 97 respondents who received a combination formulation containing Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%, compared to a 71,0 percent cure rate for the 93 respondents who received standard therapy containing Tretinoin 0.05% (p-value : 0,008).

Keywords: Acne vulgaris; Tretinoin; Clindamycin; Dexamethasone

INTRODUCTION

Acne vulgaris is a common chronic skin disease that causes inflammation of the pilosebaceous glands or localized inflammation. The majority of cases of acne vulgaris present with a variety of pleomorphic lesions ranging in severity from blackheads to papules, pustules, and nodules. Acne typically strikes women earlier than men, owing to the effects of puberty and hormones.¹⁻³

Acne affects 37% of African American and 32% of Hispanic women, 30% of Asian women, 24% of Caucasians, and 23% of Indian women, respectively.

Adolescents have a fairly high prevalence, ranging from 47 to 90%. According to the Indonesian Cosmetics Dermatology Study, 60% of the population suffered from acne in 2006, 80% in 2007, and 90% in 2009. This demonstrates that the prevalence of acne vulgaris is increasing year after year. Adolescent females aged 14-17 years have a prevalence of 83-85%, while males aged 16-19 years have a prevalence of 95-100%. Acne is caused by four factors: hyperproliferation of the follicular epidermis, which results in follicular obstruction; excessive sebum production;

inflammation; and *Propionibacterium acnes* (*P. acnes*) activity.⁴⁻⁹

Acne vulgaris is a multifactorial disease that is influenced by genetics, ethnicity, race, diet, climate, environment, skin type, hygiene, cosmetic use, psychological stress, infection, and occupation. The face, shoulders, upper superior limb, chest, and back are all areas of predilection. Although acne vulgaris is not a dangerous disease, it has a significant physical and psychological impact on sufferers, particularly adolescents, and can result in anxiety, depression, and a loss of self-confidence. Accuracy and rapidity in treating acne vulgaris are critical steps because they can have an impact on the patient's recovery and prognosis¹⁰⁻¹²

The most effective acne management strategy entails limiting bacteria growth with antibiotics, reducing inflammation with corticosteroid medications, and inhibiting micro comedo formation with retinoids. The use of topical medications in the form of a combination anti-acne cream is one of the best options because it combines all of the components necessary to treat acne. Additionally, the researchers chose the combination of anti-acne creams because they were inexpensive, non-invasive, and easy to apply to patients, with fewer side effects than other therapies.^{2,13,14}

The purpose of this study is to evaluate the efficacy of a new treatment regimen that contains Klindamisin 3%, Tretinoin 0.05%, dan Deksametason 0.05% and to compare it to standard therapy, which contains Tretinoin 0.05%,

METHOD AND MATERIAL

This study is a retrospective cohort study conducted at the Indra Clinic. The sample of this study was the entire group of adolescents aged 14-19 years with acne vulgaris who came to the study site in the 2016-2017 period and met the inclusion criteria. The minimum sample size required was 123 respondents with the sampling

technique using non-random consecutive sampling / total sampling. The inclusion criteria were 14-19 years of age, suffering from acne vulgaris in the facial area regardless of skin type. Exclusion criteria were incomplete medical records, as well as respondents with other skin diseases on the face such as atopic dermatitis, contact, rosacea, viral infections, impetigo, fungal infections, acneform eruptions and respondents suspected of having allergies to the active substances contained in the anti cream combination. acne.

The formulation observed was a combination of anti-acne cream with the active ingredient clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%, with the comparative drug being a standard regimen containing 0.05% tretinoin. The dependent variables in this study were treatment success (improved or not) after 4 weeks intervention, 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 Peason 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 190 individuals who had acne vulgaris. There were 97 respondents who received new formulation of acne cream (clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%) and 93 respondents who received standard Tretinoin 0.05% therapy. Table 1 summarizes the demographic characteristics of each group of patients.

Table 1. Demographic Characteristics of Respondents

Variable	Treatment		p-value
	Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05% N : 97 responden	Tretinoin 0.05%, N : 93 responden	
Age	26,57 (9,85)	26,78 (10,05)	> 0,05
Sex			
• Male	29 (29,9%)	17 (18,3%)	> 0,05
• Female	68 (70,1%)	76 (81,7%)	

The therapy was administered for four weeks before being re-examined at the subsequent visit. The cure rate was 87,6 percent for the 97 respondents who received a combination formulation containing Combination of Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%, compared to 93 respondents who received standard therapy containing

Tretinoin 0.05%, obtained a 71,0 percent cure rate. The Chi Square with Yates Correction statistical test revealed a difference in the degree of clinical improvement between formulation therapy when compared to standard therapy (p-value: 0.008). There were no significant side effects between the 2 groups during the use of treatment.

Table 2. Therapeutic Effectiveness between 2 Treatment Regimens

Parametric	Clinically after 4 week		p-value
	Remission in <4 week	Persistent	
Combination of Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%	85 (87,6%)	12 (12,4%)	0,008
The standard regimen of Tretinoin 0.05%,	66 (71,0%)	27 (29,0%)	

DISCUSSION

The findings of this study corroborate those of a study published in India by Sarvajnamurthy et al. about Synchronizing Pharmacotherapy in Acne with Clinical Care Review. This study indicates that the combination of tretinoin and antimicrobials, particularly clindamycin, is critical and should be considered first-line therapy for moderate to severe acne. Tretinoin, which acts as a keratolytic, aids in the penetration of antimicrobials into the pilosebaceous unit, which is colonized by *P. acnes* bacteria, thereby increasing the drug's effectiveness. According to Ashley, William, Tushar, and

Steven, the primary goal of combination therapy with retinoids and antimicrobials as a topical acne treatment is to target multiple aspects of acne pathogenesis that monotherapy cannot. Clindamycin and Tretinoin have been combined to target multiple aspects of acne pathogenesis. Tretinoin is a comedolytic and anti-inflammatory agent, whereas clindamycin is an antimicrobial agent that inhibits the growth of *Propionibacterium acnes*. The combination of these two drugs has been shown to be significantly more effective at reducing acne lesions than monotherapy treatment. According to Thiboutot et al., the combination of clindamycin and topical

retinoids has also been shown to accelerate lesion healing and decrease antimicrobial resistance to *Propionibacterium acnes*.¹⁵⁻¹⁸

According to Rianyta, Purwastyastuti, Sri, and Larisa's research, topical corticosteroids are frequently used as anti-inflammatory agents and it is believed that when combined with Tretinoin, they can reduce the irritating side effects of Tretinoin without exacerbating acne vulgaris exacerbation. Coman et al. conducted a four-week study in which they used a combination of Tretinoin and topical corticosteroids on one half of the face and a non-comedogenic moisturizer on the other half. The results indicated that 86 percent of respondents reported improved results on the half of the face when using a combination of Tretinoin and topical corticosteroids; additionally, no irritation side effects were observed, which is thought to be due to corticosteroids' anti-inflammatory effect.¹⁹

CONCLUSION

The Combination therapy of Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05% has been shown to provide a greater level of clinical improvement than standard Clobetasol therapy. The cure rate was 87,6 percent for the 97 respondents who received a combination formulation containing Clindamycin 3%, Tretinoin 0.05%, and Dexamethasone 0.05%, compared to a 71,0 percent cure rate for the 93 respondents who received standard therapy containing Tretinoin 0.05% (p-value : 0,008).

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