



## Research Article

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# Efficacy of Combined Low-Dose Hormonal Contraceptives in the Treatment of Acne Vulgaris-A Randomized Control Trial Study

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## Introduction

Acne vulgaris is a skin condition that affects a high number of teenagers and young adults. The pilosebaceous unit is impacted by this multifactorial inflammatory disorder. The understanding of acne pathogenesis is constantly changing. Sebum production, follicular hyper keratinization, complex inflammatory processes, and Propionibacterium acnes microbiological colonization are significant pathogenic elements that contribute to the onset of acne. Acne vulgaris has a substantial physical and psychological morbidity, including low self-esteem, poor self-image, scars, and depression. According to estimates, 12.6% of all dermatological treatment costs in the world go toward treating acne [1]. Due to this and referring the effects of acne and psychological affects to the adolescent it is quite important to focus on new research for efficacy in acne treatment.

**Aim of the study:** To verify the effectiveness of low-dose combined oral contraceptives in the treatment of acne vulgaris and to evaluate the quality of life of patients before and after treatment using the Acne-QoL questionnaire.

## Materials and Methods

The study included 143 girls aged 15-25 years diagnosed with Acne vulgaris of grades II, III, and IV according to the classification of the American Academy of Dermatology. The study took place to the period 2011-2017. Depending on the degree of acne, the patients were randomly divided into two groups: the intervention group applied low-dose combined contraceptives (20 mcg Ethinyl estradiol and 3 mg Drospirenone) while the control group received the standard treatment (local retinoid, oral antibiotic / doxycycline, local antibiotic/ erythromycin) The study groups were evaluated and compared 1, 3, and 6 months after the start of

treatment. To determine the impact of acne on the quality of life, the international Acne-specific quality of life questionnaire (Acne-QoL), validated in the Albanian language (the country where the study was conducted), was used.

## Results

The average age of the subjects was 17.4 years; 65.7% had mild-moderate acne (stage II-III) while 34.3% had severe acne (stage IV).

Low-dose combined contraceptives significantly reduced the number of acne lesions 6 months after treatment in subjects with stage II-III Acne vulgaris (71.4% vs. 22.2% in the control group), but not in those with stage IV acne (64% vs. 25% in the control group,  $P > 0.05$ , but the clinical significance is clear). Low-dose combined contraceptives significantly increased the proportion of girls cured 6 months after treatment in subjects with stage II-III acne (44.9% vs. 15.5% in the control group), but not in those with stage IV acne (28% vs. 16.7% in the control group). Meanwhile, the percentage of girls who improved was higher in the intervention group than in the control group, for each stage of acne, although statistical significance was not achieved in any case. Increasing acne severity was associated with a significant negative impact on the social aspect, while acne duration  $> 5$  years had a negative and significant impact on the emotional aspect and those related to acne symptoms. In conclusion, the current study scientifically evidenced that combined low-dose contraceptives are an effective treatment of moderate acne, being in direct correlation with the duration of treatment, whereas severe forms of acne vulgaris do not benefit significantly from treatment with low-dose combined contraceptives in 1- and 3-month regimens.

## Discussion

Our study evaluated the impact of Acne vulgaris on quality of life using the International Acne-Specific Quality of Life Questionnaire (Acne-QoL), which has been translated into Albanian language. To provide the most accurate interpretation, this questionnaire was assessed twice. At the first appointment, each subject answered the Acne-QoL questionnaire; seven days later, just before starting therapy, they did it again. Values between the first test and the follow-up test varied in an acceptable and satisfactory manner. We decided to retest after seven days based on research by Anderson and Rajagopalan, which effectively assessed test-retest reliability with intervals ranging from 3 to 7 days. It demonstrated that a retest interval of seven days was ideal [2]. During the results analysis stage of the study, we discovered an inverse correlation between the severity of facial acne and quality of life. These results were in line with the study carried out by Martin et al. [3]. The findings of our study reveal that despite this correlation, even subjects with minor forms of acne may experience major compromises in their self-confidence, ability to go out in public, and social and family interactions. In particular, for the role-emotional subclassifications and acne symptoms, our study found a negative association between the questionnaire score and the duration of the illness. In other words, the participants who had the condition for a shorter period had a higher quality of life. These findings were consistent with cohort research by Tan et al. [4] that discovered a lower quality of life in those who had acne for more than five years [4]. Numerous studies that have been published in the literature have indicated that acne has a detrimental impact on people's quality of life. The role-social and role-mental health domains were shown to be significantly influenced in a research of 111 patients with facial acne, whereas the role-emotional domain showed to alter if the patient was observed for a longer length of time than a year. On tests of mental health, subjects with conditions like facial acne scored worse than those with bronchial asthma, epilepsy, diabetes, headache, and arthritis [5]. In the 1990s, Gupta et al. [6] and Kellet et al. [7] found that subjects with acne had more severe symptoms of anxiety and depression than people with alopecia areata, atopic dermatitis, psoriasis, and the general population [6,7]. Smithard et al. [8] investigated 317 teenagers with acne between the ages of 14 and 16 in the United Kingdom, standardizing the subject's age by using the SQD (Strengths and Difficulties Questionnaire) scale that assesses mental health. Results showed that subjects with acne had a two-fold greater prevalence on the emotional subscale [8].

The effectiveness of combined oral contraceptives (COCs) containing estrogen in the management of acne has been evaluated in various clinical investigations. When compared to a placebo, Thiboutot D and al. assessed the effectiveness of low-dose COCs. The reduction in acne lesions, improvement, and the patient's overall clinical evaluation made up the primary result. After six months of low-dose COC treatment, the reduction was

statistically significant while a higher score was found in the patient's self-assessment questionnaire. This study demonstrated that moderate acne can be effectively and safely treated with low dose combined oral contraceptives [9]. Even in our study, a more pronounced progressive reduction in the number of acne lesions compared to the control group was found. Particularly 3 and 6 months after the beginning of treatment with 20 mcg Ethinyl estradiol and 3 mg Drospirenone, there was a more pronounced difference between the two groups. We got a statistically significant difference after 6 months of therapy. Meanwhile, for stage IV subjects according to the classification of acne severity from the American Academy of Dermatology, the difference between the two groups was not as apparent as in subjects with milder stages of acne. Probably the efficacy of adjunctive COC treatment in subjects with advanced acne vulgaris appears to be related to the duration of treatment. In the context of polycystic ovarian syndrome (PCOS), the most common form of treatment consists of ovarian suppression through COC treatment [10,11]. In our study, we independently evaluated the response to COC treatment of patients diagnosed with acne vulgaris and PCOS. All patients diagnosed with PCOS were part of the study group (under COC treatment). More pronounced compliance to the treatment of patients with concomitant PCOS was observed, regardless of the stage of the disease. This improvement was more pronounced for the three durations of treatment :1, 3, and 6 months and was more significant for stage II and III patients based on the classification of acne severity from the American Academy of Dermatology.

## Conclusion

- Acne-Specific Quality of Life Questionnaire validated in the Albanian language is a valid measure of psycho-morphometric evaluation of patients with acne vulgaris, applicable in the context of the culture of our country.
- Treatment decisions should be based on the clinical parameters, such as severity, extent, and duration of acne.
- Low-dose combined contraceptives are an effective and safe treatment of moderate acne vulgaris.
- The efficiency of the treatment with low-dose combined contraceptives is in a direct correlation with the duration of treatment.
- Severe forms of acne vulgaris do not benefit significantly from low-dose combined contraceptive treatment in 1- and 3-months regimens.

Patients with moderate acne and PCOS have more pronounced compliance with the treatment, regardless of the severity of the disease.

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