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STUDY TO KNOW THE COMPARISON OF 13-cis RETINOIC ACID GIVEN SYSTEMICALLY IN 20MG AND 40MG DOSE FOR THE ACNE VULGARIS TREATMENT AND ITS SAFETY AND EFFICACY

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Abstract:
Objective: *To determine the efficacy and safety of of 13-cis-retinoic acid in two different doses of 20mg and 40mg for the acne vulgaris treatment.*
Study Design: *An Observational Study*
Place and Duration: *The Study was performed in the Dermatology department of Services Hospital, Lahore for the period of 6 months from December 2016 to May 2017.*
Materials and methods*: From the dermatology ward 60 patients for study purpose with moderate to severe acne vulgaris were selected. They randomly divided two groups. Group I received 20 mg of systemic 13-cis retinoic acid daily and 40 mg of system II daily for 6 months. For acne severity assessment was done using Global Acne Classification System (GAGS). Improvement in patients Clinically was measured at the doctor's admission scale, up to 24 weeks every two months. Safety was assessed at baseline and at the end of treatment based on side effects and laboratory abnormalities.*
Results: *In all patients, a significant dose-result in lowering of acne lesions was observed within 2 months after the beginning of treatment. In Group I, 30 patients had a 70% clearence at 8 weeks, 90% at 16 weeks, 100% clean at 6 months, and in 4 patients residual pits occurs. Six women received the Diane 35® prescription, which is still an acne outbreak, in 6 months. 26 of 30 patients in Group II at 8 weeks had 90% Results and a 100% clear at 16-24 weeks. Slight scarring was observed in 24 weeks of treatment in six weeks. Three female patients continued to receive a new rash and were given Diane 35® after 24 weeks and the dose increased upto 60 mg / day in a male patient, which eliminated rumen at Thirty two weeks. The two group's results were unimportant (p> 0.5). The side effects observed were dryness, chelitis and peeling at the back, mostly group II. Mild mood changes were observed in 3 female patients.****Conclusion:*** *For the treatment of acne vulgaris 13-cis retinoic acid is effective and safe. A fast-paced reaction is observed, but works up to 20 mg / day up to 40 mg / day for up to 24 weeks*
Keywords: *Acne vulgaris, 13-cis retinoic acid.*

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INTRODUCTION:

In young adults and adolescent especially, acne vulgaris is a very common condition. With this disease there is no associated mortality, but there is often psychological significant morbidity. Because of this expensive and repetitive for a long time, these are highly expensive. For acne effective treatment is important to prevent psychological distress and facial scars. For Years people have been able to control pimples in some patients, such as antimicrobials, tretinoin, benzoyl peroxide, and so on. They use topical and systemic acne medications such as; However, you should not prescribe a anti-acne conventional treatment for long time, with recurrent nodulocytic and complications such as acne, pigmentation and scarring. The use of modalities such as antiandrogens is a compound that produces a miraculous response to acne vulgaris for short time period and its uses gender-cis retinoic acid and prevents complications. Studies have shown that 13-cis retinoic acid cause changes in the composition of skin superficial lipids. These alterations are the result of a significant lowering of sebaceous gland activity. In sebaceous glands Cis retinoid acid has a unique performance, but it is a mystery because the cell does not attach to the retinoic acid receptor or retinoic acid binding proteins. The anti-diabetic molecular basis activity is not fully understood. 13-retinoic acid is safe and potent in suppressing and inhibiting sebaceous production of sebaceous glands in vivo by reducing the size of sebaceous glands by proliferating the sebaceous glands by 90% reduction of basal sebocytes. Half life is between 8-38 hours. Through the placenta 13-cis retinoic acid passes and is a potent teratogenic cause. urine and Feces are thrown. The drug epidermal level is minimum and there is no continous accumulation in the serum or the deep. After leaving the treatment, the serum will disappear within four weeks. In lowering microbial flora 13- cis retinoic acid play a significant role. This reduction lasts for a period of time after cessation of treatment. This study was conducted to evaluate the safety and efficacy of 13-cis retinoic acid at systemic doses of 20 mg / kg and 40 mg / kg for severe and moderate acne treatment.

MATERIALS AND METHODS:

From Dermatology department of Services Hospital, Lahore for the period of 6 months from December 2016 to May 2017 and 60 patients with acne vulgaris in moderate and severe from were selected. Their acne was was classified in the Global Acne Classification System (GAGS). All medium and severe acne patients groups were selected. The two random groups were divided into I and II group. 30 patients in Group I received 20 mg of 13-cis retinoic acid (Ro-accutane®) in 30 patients and 40 mg of 13-cis retinoic acid in group II. They were followed up every 24 weeks for 8 weeks every 24 weeks.

Patients were assessed using an acceptable medical assessment scale every 2 months for up to 24 weeks. Clinical improvement was rated as follows: 1: >80% is excellent, 2: good at 50%); 3: medium (30% - 50%); 4: light (& lt; 30%); and no change in 5. Any side effects have been observed. At the beginning and at the end of the study, laboratory studies such as liver profile and lipid profile were done. For statistical analysis Chi-square test was used.

RESULTS:

The results were recorded in 60 patients (group I and II 30 patients) at the end of the study. No patients were followed With moderate and severe acne. The global acne score (GAGS) for patients was used in both groups. In group I Twenty-four patients showed good results (> 50%) at 2 months, at 16 weeks excellent 90% results were noted, and at 24 weeks 100% clear with mild residual pits. 6 patients who had mild parenchyma, one pre-stage healing and continuous new eruption, used Diane35® after 24 weeks. 26 patients in group II at 8 weeks showed a 90% clearance and at 4 months 100% clearance and 6 months. In 3 female patients with mild effusion, there was continuous contusion up to 24 weeks with recovery, and in a male patient 13 ± cis retinoic acid dose was increased to 1 mg / kg and 32 weeks. The difference between the two groups results Statistically was not significant (p> 0.5). However, a fast-paced response was observed in patients in group II (Table 1).

Table 1 Comparison of improvement in two groups during 24 weeks of follow-up.

	8 weeks	16 weeks	24 weeks
Group I (n=24)	60%	90%	100%
Group II (n=26)	90%	100%	100%

Side effects observed in each follow-up were 100% leprosy in one patient, itching and peeling in 30% and myalgia. Gravity is greater in group II. Softeners were applied as a treatment for desquamation and cheilitis. Three patients in Group II frequently noticed mood changes, which continued during the treatment. At the beginning of the study and at the end of the treatment, laboratory studies such as the liver and lipid profile were not evident in all patients. With moderate to severe acne vulgaris shown in Figure 3.

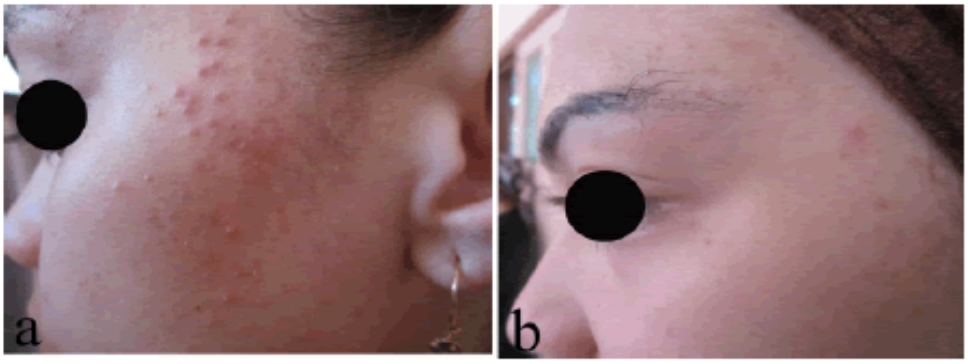

Figure 3: A female patient with moderate acne vulgaris.

DISCUSSION:

13-cis retinoic acid is effective in the acne vulgaris treatment. Facial injuries were faster than back and body. It is comparable to that reported by Farrell. The side effects observed were similar to those reported previously with this drug.The serum lipid profile at the beginning and at the end of treatment was not significant. This is described by Farreli3 and Katz et al. The presented data is exactly the opposite. Hyperlipidemia appears to be due to dozzine, and patients have received a higher dose of 13-cis retinoic acid than patients. Depression is an important side effect that affects both physicians and patients. Our three patients in Group II frequently showed emotional changes, but none of them complained of depression during treatment. Low dose, close family ties, appropriate choice of the patient may be some criteria for such an answer. 13-Retinoic acid is expensive and creates a financial burden for many families. For this reason, a low dose of 20 mg / day, a cost of 1/3, and reduced costly use of various topical modalities in antibiotics and relapses over many years. Treatment begins earlier, the results are so good that one looks like a person's pigmentation and post-acne scars. Even 20 mg / day was worrying about the cost of our patients, but in the past everyone was too tired and ill to clean their pills because they had completed the treatment and even had a new rash. Therapy is complete. productivity and tolerance

CONCLUSION:

Our results Shows that 13-cis retinoic acid alters the treatment of acne vulgaris. Elimination of acne lesions was predominant. Excellent recovery in both groups showed that 20 mg / day was as effective as 40 mg / day in our study.

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