

## EFFECT OF ISOTRETINOIN ON QUALITY OF LIFE IN PATIENTS WITH ACNE VULGARIS: A FOLLOW UP STUDY FROM A TERTIARY CARE CENTER

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### Abstract

**Background:** Acne vulgaris is a common dermatologic disorder that significantly affects psychosocial health and quality of life (QoL) of patients. Oral isotretinoin is effective in the clinical control of acne, but the relationship between this treatment and its psychosocial impact on the patient has not been completely investigated. The aim of present study is to assess the effect of isotretinoin on QoL in patients with acne vulgaris over the follow up of 6 months. **Materials and Methods:** Total 85 patients clinically diagnosed with moderate to very severe acne according to global acne grading system (GAGS) were included in the study. Evaluation of QoL was done using dermatology life quality index (DLQI) and cardiff acne disability index (CADI). After baseline evaluations, all the patients were prescribed with oral isotretinoin 0.5mg/kg/day. Follow up of patients was done at 3 months and 6 months of therapy. GAGS, DLQI, CADI were assessed and recorded at each follow up. **Result:** The mean age of patients was 21.41±4.39 years with predominance of females (70.59%) patients. The acne severity based on the GAGS showed a significant improvement at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline. The CADI scores showed a significant decrease at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 5 domains. The QoL as assessed by DLQI scores showed a significant decrease in score and improvement in QoL at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 10 domains. **Conclusion:** QoL appears to significantly improve among acne vulgaris patients after receiving oral isotretinoin therapy. However, further multicentric studies with ample sample size is needed to be conducted to validate the findings of this study.

## INTRODUCTION

Acne vulgaris is a common dermatological disorder with varying etiology. The clinical presentation might vary from moderate acne to a systemic illness that can leave scars. The complex interplay between the sebaceous gland production of sebum, follicular colonization, modulation in the keratinization process, and hormone dysfunction are some factors that play role in acne. Acne affects approximately 95% of 16–17-year-old females and 83–85% of 16–17-year-old males. While acne gets cured after adolescence, 42.5% of men and 50.9% of women still experience acne well into their twenties. 5% of women and 1% of males may experience the acne lesions even at age of 40 years. Acne is a leading cause for visit to dermatologists in India.<sup>[1]</sup>

Dermatological disorders are usually not life threatening but tends to cause significant psychological challenge to patients. Patients with dermatological disorders bear a unique psychological burden since they live with the stigma of their condition visible to the public and subject to everyday criticism. Psychological issues related to acne affect between 30% and 50% of teenagers. These issues include poor self-esteem, anxiety, body image issues, shame, social impairment, and aggression. In certain studies, the perception of body dysmorphism among acne patients is almost 21%. Patients with acne are often dissatisfied with treatment. Acne not only causes emotional anguish, but it also exacerbates anxiety and depression.<sup>[2]</sup> Isotretinoin is a systemic retinoid that affects sebaceous glands and is used to treat severe acne. The FDA authorized the isotretinoin in 1982 for

management of severe acne that is resistant to standard treatments, such as systemic antibiotics. Isotretinoin decreases sebum production and sebaceous gland size, which prevents keratinization and sebaceous gland activity.<sup>[3]</sup> Oral isotretinoin reduces sebum by up to 90%, which prevents the proliferation of propionibacterium acnes and normalizes keratinization. Dosage can vary; in general, 0.5–1 mg/kg/day is recommended for conventional acne (the European Medicines Agency; EMA), starting at a dose of 0.5 mg/kg/day, titrating up as tolerated and well received. In some patients with persistent acne (especially in the mature age group), and in cases where side-effects are not tolerated at the recommended doses, low doses and/or intermittent treatment have been advocated in the literature. Isotretinoin is used until complete recovery and for a further month of treatment, independent of the total cumulative dose that is reached.<sup>[4]</sup>

A study of cases between 1982 and 2000 reported 37 suicides, 110 hospitalizations due to depression with suicidal tendencies or suicide attempts, and 284 reports of patients with depression in patients treated with isotretinoin.<sup>[5]</sup> A large cohort study that compared isotretinoin users with users of oral antibiotics found no significant difference with regards to the risk of development of depression or psychosis.<sup>[6]</sup> The aim of present study is to assess the effect of isotretinoin on quality of life in patients with acne vulgaris over the follow up of 6 months.

## MATERIALS AND METHODS

**Study design:** Present study was hospital based, prospective, observational study with validated pre-structured questions. The study was conducted in the Department of Dermatology, Venereology and Leprosy (DVL), Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan. Total duration of study was twelve months. Total 85 patients clinically diagnosed with moderate to very severe acne according to GAGS severity and represented with failure of conventional therapy were included in the study. Pregnant patients or patients with allergic to isotretinoin were excluded from the study.

**Data collection:** Patients clinically diagnosed as moderate to severe acne were enrolled in the study after taking written consent. Demographic data,

detailed history and physical examination were recorded in a pre - structured proforma. The severity of the acne was evaluated using the Global Acne Grading System (GAGS). Evaluation of Quality of life was assessed using Dermatology life quality index (DLQI) and Cardiff Acne Disability Index (CADI). The I PLEGE program was explained to all the females under child bearing age group. Following investigations were done in the patients for evaluation of moderate to severe acne.

**Treatment protocol:** After baseline evaluation all the patients were prescribed oral isotretinoin 0.5mg/kg/day. Follow up of patients was done at 3 months and 6 months of therapy. GAGS, DLQI, CADI were assessed and recorded at each follow up.

**Statistical analysis:** Using SPSS 25.0, the statistical analysis was conducted. Frequencies and proportions were used to characterize qualitative variables. For quantitative variables results was reported as mean and standard deviation. For a categorical variable, frequency (percentages) was determined. For sociodemographic factors, descriptive statistics was employed, and chi-Square test was used to identify any statistically significant difference. Paired t-test was used to compare two groups. All tests were conducted with a 95% confidence interval and a significance level of 5%. The significance threshold for all statistical tests was set at 0.05.

## RESULTS

The age of patients included in our study ranged from 15 to 31 years with a mean age of 21.41±4.39 years. 41.18% patients were aged between 15-19 years, 41.18% patients were aged between 20-24 years, 5.88% patients were aged between 25-29 years, and 11.76% patients were aged between 30-35 years. Our study comprised of 70.59% females and 29.41% males. In our study, 17.65 individuals were housewives, 76.47% were students, and 5.88% were staff nurses [Table 1].

The acne severity based on the global acne grading system showed a significant improvement at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline [Table 2 and Figure 1].



Figure 1: Patients image at (A) Baseline (B) at 3 months and (C) at 6 months.

**Table 1: Sociodemographic characteristics of enrolled patients.**

Variable	Domain	Number	Percentage
Age distribution	Mean age	21.41±4.39 years	
	15-19 yrs	35	41.18
	20-24 yrs	35	41.18
	25-29 yrs	5	5.88
	30-35 yrs	10	11.76
Gender distribution	Female	60	70.59
	Male	25	29.41
Occupation	Housewife	15	17.65
	Staff nurse	5	5.88
	Student	65	76.47

**Table 2: GAGS severity score at 3 months and 6 months follows up as compared to baseline.**

Acne Severity	At Baseline		At 3 Months		At 6 Months		p Value (At 3 months)	p Value (At 6 months)
	N	%	N	%	N	%		
Mild	0	0	15	17.65	85	100	0.001	0.001
Moderate	40	47.06	55	64.71	0	0	0.001	0.001
Severe	35	41.18	15	17.65	0	0	0.001	0.001
Very Severe	10	11.76	0	0	0	0	0.001	0.001
Total	85	100	85	100	85	100		

**Table 3: CADI Score at 3 months and 6 months follow up as compared to baseline.**

CADI Score	At Baseline		At 3 Months		At 6 Months		p Value (At 3 months)	p Value (At 6 months)
	Mean	SD	Mean	SD	Mean	SD		
C1	2.471	0.609	1.588	0.495	0.588	0.495	0.001	0.001
C2	1.765	0.882	1	0.598	0.353	0.481	0.001	0.001
C3	1.294	1.021	0.765	0.734	0.176	0.383	0.001	0.001
C4	2.353	0.767	1.412	0.603	0.529	0.502	0.001	0.001
C5	2.353	0.481	1.471	0.502	0.647	0.481	0.001	0.001

**Table 4: DLQI Score at 3 months and 6 months follow up as compared to baseline.**

DLQI Score	At Baseline		At 3 Months		At 6 Months		p Value (At 3 months)	p Value (At 6 months)
	Mean	SD	Mean	SD	Mean	SD		
D1	2.765	0.427	1.765	0.427	0.882	0.324	0.001	0.001
D2	2.118	0.586	1.294	0.458	0.706	0.458	0.001	0.001
D3	2.235	0.734	1.294	0.669	0.706	0.458	0.001	0.001
D4	1.824	0.789	1.059	0.542	0.588	0.495	0.001	0.001
D5	1.941	1.169	1.176	0.862	0.706	0.669	0.001	0.001
D6	1.588	1.094	1.059	0.73	0.588	0.495	0.001	0.001
D7	1.471	1.042	0.882	0.68	0.647	0.481	0.001	0.001
D8	1.647	1.032	1.059	0.73	0.588	0.495	0.001	0.001
D9	0.235	0.427	0.176	0.383	0.059	0.237	0.001	0.001
D10	2.118	1.085	1.294	0.753	0.706	0.458	0.001	0.001

The CADI scores showed a significant decrease indicating and improvement in QoL at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 5 domains - C1, C2, C3, C4, C5 [Table 3].

The quality of life as assessed by DLQI scores showed a significant decrease indicating an improvement in the QoL at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 10 domains - D1, D2, D3, D4, D5, D6, D7, D8, D9, D10 [Table 4].

## DISCUSSION

Up to 85% of teenagers have been observed to be suffering from acne. Such individuals suffer from mental health issues, such as depression, anxiety, low self-esteem, feeling of social solace, and high levels of social anxiety. In such individual QoL tends to decline with severity of disease.<sup>[7]</sup> The best-known treatment for acne is isotretinoin, an oral synthetic

retinoid. Since its introduction to the market in 1982, numerous negative psychological consequences, such as sadness and suicidal thoughts, were linked to use of isotretinoin.<sup>[8]</sup> Studies, however, were unable to provide solid evidence linking isotretinoin therapy to depression or suicide. Previous studies have correlated the isotretinoin treatment with the improvements in anxiety, sadness, and QoL in acne patients. The aim of present study is to assess the effect of isotretinoin on quality of life in patients with acne vulgaris over the follow up of 6 months.

In present study, the age of patients ranged from 15 to 31 years with a mean age of 21.41±4.39 years. Our study comprised of 70.59% females and 29.41% males. The acne severity based on the GAGS showed a significant improvement at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline. The CADI scores showed a significant improvement at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 5 domains - C1, C2, C3, C4, C5. The QoL as assessed by DLQI scores showed a significant

improvement at 3 months and at 6 months after therapy with isotretinoin on comparison to baseline in all 10 domains - D1, D2, D3, D4, D5, D6, D7, D8, D9, D10. In our study, the DLQI had a mean score of  $13.2 \pm 3.7$  at baseline and this score was  $4.2 \pm 2.4$  at the end of follow up indicating a significant decrease in the adverse effect and improvement in the QoL.

Kamyak et al. compared anxiety, depression, and QoL in individuals with acne treated with topical treatments against isotretinoin, and their findings were comparable to present study. 87 acne patients were divided into the study group (n = 37) receiving isotretinoin treatment, and the control group (n = 41) receiving topical treatment. By end of the second month, QoL was impaired in the topical therapy group with a greater extent as compared to the isotretinoin group. By the end of the fourth month, the isotretinoin group showed significant improvement as compared to the topical therapy in terms of QoL and all psychological test scores.<sup>[9]</sup> Yesilova et al. carried out a prospective trial to examine isotretinoin effect on QoL and social anxiety in cases of acne vulgaris. According to the GAGS score, the study group acne severity ranged from 10 to 32, with a mean value of  $20.1 \pm 7.1$ . At the end of isotretinoin treatment, the mean scores on the SF-36, LSAS, and GAGS were significantly higher than baseline.<sup>[10]</sup>

Akyazı et al. analyzed the QoL in acne treatment. When the study group DLQI score was compared to the control group, it was shown that there was a significant difference ( $8.74 \pm 5.07$  versus  $2.21 \pm 2.44$ ).<sup>[11]</sup> Fakour et al. analyze the impact of isotretinoin on depression and QoL in a cohort of patients receiving isotretinoin therapy. QoL of life found to be improved after the course of treatment.<sup>[12]</sup> Rademaker et al. carried out a randomized double-blind study to evaluate the effectiveness of 5 mg/day isotretinoin for adult acne. Following 16 weeks of isotretinoin versus placebo, there were highly significant reduction in the number of acne lesions were reported.<sup>[13]</sup> Newton et al. research on the efficacy of acne treatment also produced findings that were comparable to our study. After therapy, the clinical acne grade was significantly improved. Additionally, at 4 or 12 months, there were notable improvements in the GHQ-28, DLQI, self-esteem, and all five SF-36 aspects that were compromised at baseline.<sup>[14]</sup>

Ibrahim et al., conducted a study to compare the effectiveness of normal higher-dose isotretinoin (0.5 mg/kg/day) as monotherapy for the treatment of acne vulgaris with the combination of low-dose isotretinoin (0.25 mg/kg/day). After three and six months, both groups demonstrated a significant improvement over baseline in all evaluated parameters.<sup>[15]</sup> McGrath et al. carried out a prospective study to examine the impact of isotretinoin on depression and QoL. The isotretinoin group experienced a higher improvement in social QoL. Significant increases in physical, psychological, and social quality of life were

observed in patients at end of follow up as compared to baseline depression levels.<sup>[16]</sup>

The primary limitations of the study that there is no control group and it was limited to participants from a single hospital. A further study with a control group could offer further context for understanding our results. It would not be ethical, nevertheless, to deny patients any care during the trial. The outcomes, though, have been methodically contrasted with those of previous research. The small sample size of this investigation was another drawback.

## CONCLUSION

Isotretinoin is one of the treatment modalities for acne with good effectivity and has been used as standard acne management in many countries due to its mechanism of actions that affect the entire acne pathogenesis. Considering the various side effects of isotretinoin ranging from mild to severe, its use requires adequate clinical assessment and monitoring by a dermatologist. Because acne affects both physical and mental well-being, it has a significant impact on overall health of the patients. QoL of patients appears to significantly improve after receiving successful therapy with oral isotretinoin. But there are drawbacks to oral isotretinoin therapy as well. Because it might cause teratogenicity, women who are fertile should use it with extreme caution. Before starting oral isotretinoin therapy, patients must also undergo laboratory testing. The relationship between acne, isotretinoin, quality of life, and psychosocial impact needs further investigation.

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