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A Study on Efficacy of Intermittent Dose of Oral Isotretinoin in the Management of Acne Vulgaris

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ABSTRACT

Acne vulgaris is a common skin condition affecting adolescents and young adults, often requiring systemic treatment for moderate to severe cases. Oral isotretinoin is a highly effective therapy, traditionally administered daily, but concerns over side effects like dryness and liver toxicity have prompted interest in alternative dosing strategies. Intermittent dosing, where isotretinoin is given at intervals rather than daily, has been proposed as a safer option with similar efficacy. This study aims to assess the efficacy and safety of intermittent oral isotretinoin in the management of acne vulgaris, comparing it to the traditional daily regimen. To evaluate the clinical efficacy of intermittent dose Isotretinoin regimens in acne vulgaris using Global acne grading system (GAGS). A prospective observational study in which 30 patients with acne vulgaris were assessed clinically using Global acne grading system(GAGS). Intermittent dose of Isotretinoin was administered as 0.5 mg/kg/day on alternate days. The Patients were reviewed on a monthly basis and any instances where no additional lesions were observed were documented. We identified 30 patients with Acne vulgaris and were given intermittent dose of isotretinoin. The mean acne scores were compared after completion of treatment, it was observed that, a significant decrease in the mean scores from 119.04±7.07-12.5±1.64 among the patients was seen. This difference was found to be statistically significant. Patient satisfaction levels was about excellent response in 60% of patients. Intermittent isotretinoin dosing a promising alternative to the conventional daily regimen for treating acne, particularly for mild to moderate cases. This approach effectively reduces acne severity while minimizing mucocutaneous side effects. Given its reduced side effect and improved patient adherence, intermittent dosing may be a preferred treatment strategy, especially for those who struggle with the adverse effects of standard isotretinoin therapy.

INTRODUCTION

Acne vulgaris is an inflammatory skin disease that is persistent and affects the hair follicles, caused by excess sebum production, inflammation and microbial colonization[1]. Clinically, pleomorphic lesions such as comedones, papules, pustules, nodules and cysts are indicative of this condition involving, seborrheic regions such as the face, upper chest and back of the trunk. Approximately 20% of adolescents exhibit facial acne scars[2]. A common combination used in systemic therapy for acne is Isotretinoin (13-cis retinoic acid 3) and oral antibiotics[4]. Retinoids have biological effects that are enabled by nuclear receptors, particularly RAR and RXR receptors, which specifically target abnormal follicular proliferation, effectively preventing the development of micro comedones that are the precursors to acne[3]. Retinoids are recommended for initial and ongoing treatment of mild to moderate acne, either alone or in combination with other treatments. When it comes to people with moderate to severe acne that is accompanied by significant physical and psychological scarring, resistance to traditional treatment, frequent relapses and severe nodulocystic acne that is difficult to treat, for such cases oral isotretinoin is recommended,. For most people, the recommended daily dosage of Isotretinoin is between 0.5 and 1.0 mg/kg. Until there is a cumulative impact, the treatment is continued. Excessive Isotretinoin dosages can cause systemic side effects such as headache, musculoskeletal and central nervous system effects and issues with the skin and mucous membranes. Scientists are testing lower doses of Isotretinoin to prevent these side effects. Acne can cause scars, especially if it is left untreated for a long time. Therefore, it is important to treat acne early to prevent scarring. This study aims to evaluate the effectiveness of inter mitten Isotretinoin treatment regimen for acne vulgaris.

MATERIALS AND METHODS

This prospective observational study was conducted at the outpatient department of a tertiary care center and included 30 patients diagnosed with Acne Vulgaris who were selected based on predefined inclusion and exclusion criteria, ensuring a homogenous sample for reliable results, with the study carried out over a period of one and a half years and approved by the relevant ethics committee. Inclusion Criteria includes Patients with failure of first line therapy, Moderate to severe acne frequently relapsing, Moderate acne with imminent scarring, Severe acne with nodules and cysts, Inflammatory acne with scarring. Exclusion Criteria includes Age <12 years, Pregnancy, married females planning for pregnancy, Drug induced acne, Abnormal liver functional tests, H/O Hyperlipidemia, Musculoskeletal deformities. The study procedure consists of following steps: The acne severity is evaluated with the Global Acne Grading System (GAGS)This grading system quantifies lesions such as comedones, papules, pustules and nodules, on various anatomical regions like the forehead, right cheek, left cheek, nose, chin, chest and back. Global Acne Grading System score is the sum of local scores and acne severity was graded as :1-18 Mild, 19-30-Moderate, 31-38-Severe, >39-Very Severe. Intermittent dose of Isotretinoin was administered as 0.5 mg/kg/day on alternate days. The Patients were reviewed on a monthly basis and any instances where no additional lesions were observed were documented. By the completion of the treatment, the level of patient satisfaction was evaluated using a visual analogue scale (VAS) to measure satisfaction. Patients were followed up 6 months after completion of the therapy for Recurrence rates in each group. We conducted an analysis of complications using a questionnaire, physical examination, and laboratory.

Statistical Analysis: Data from the questionnaires was entered in MS Excel spread sheet and was analyzed using SPSS Software version 23. Data is represented in the form of frequencies and percentages with the help of tables, bar diagrams and pie diagrams. Categorical variables are presented in numbers and percentages (%) and continuous variables are presented as mean ±SD and median.

RESULTS AND DISCUSSIONS

The present one and half year prospective observational study was conducted under the Department of Dermatology, Venereology and leprosy in a tertiary care centre from August 2022 to February 2024. Among the 30 patients The mean age in the group was 19.52±3.17 years. Most of the patients were observed to have severe acne was 40% to very severe acne 43.3% and with moderate acne33.3% being found to be not significant ($p>0.05$). The mean acne scores were compared after completion of treatment, it was observed that, a significant decrease in the mean scores from 119.04±7.07-12.5±1.64 among the patients was seen. This difference was found to be statistically significant. Patient satisfaction levels was about excellent response in 60% of patients.

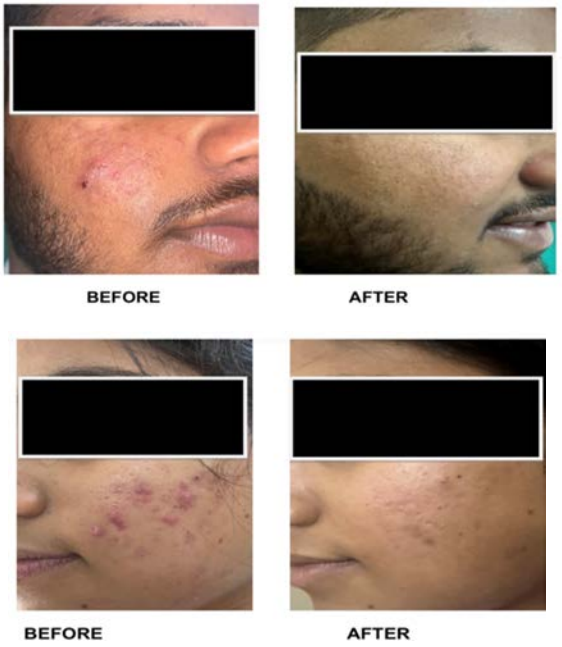

Fig. 1a,1b: Clinical Photographs Before and After Treatment with Intermittent Dose Isotretinoin

Acne Vulgaris is a chronic inflammatory condition affecting the pilosebaceous units, characterized by comedones, papules, pustules, nodules, cysts, abscesses and scarring. It primarily affects the face, upper back, chest and upper arms, typically beginning in adolescence and improving by the mid-thirties. Different types of acne include acne conglobata, a severe nodulocystic form., acne fulminans, which is painful and ulcerating., acne excoriee, caused by obsessive picking and infantile acne, resulting from androgen surges. Drug-induced acne can also occur, especially from anabolic steroids, corticosteroids and other medications. Acne severity is evaluated using the Global Acne Grading System (GAGS), categorizing acne as mild, moderate, severe, or very severe based on lesion type and distribution. Isotretinoin, a systemic retinoid, is most effective for severe acne that doesn't respond to other treatments. It works by reducing sebaceous gland activity and sebum production, with a typical dose range of 0.5-1.0 mg/kg/day. Common side effects include dry lips, dry skin, xerostomia, sun sensitivity and hyper triglyceridemia. Regular monitoring of liver function and lipid profiles is recommended. Before starting isotretinoin therapy, baseline investigations like fasting lipid profiles, liver function tests and blood glucose are required. Periodic checks for cutaneous and ocular changes are also advised. In this study, the mean age of patients was similar across all groups, with a slight male predominance. Most patients had severe to very severe acne, a finding consistent with other studies. The group showed significant improvement in acne severity ($p<0.05$) i.e, (12.5±1.64). Low-dose isotretinoin has been found to be as effective as standard doses for mild to moderate acne, with the added benefit of fewer side effects and lower costs. The current study supports this, with lower doses showing positive outcomes in preventing relapses. Cheilitis was more common in high doses while dry skin was equally prevalent across all doses. Dry mouth and rashes were significantly less frequent in low dose. These findings are consistent with other research suggesting that lower doses and intermittent regimens reduce side effects while maintaining efficacy[5]. Akman *et al.* in their study reported that, acne scores in each group were significantly lower by the completion of treatment and follow-up periods ($P<0.05$). When patients were evaluated separately as moderate (n=31) and severe (n=29), no statistically significant differences were found among the treatment protocols in patients with moderate acne[6]. Agarwal *et al.* found that there was a statistically significant variation in response rates among the various treatment groups in their investigation. Though delayed response in initial therapy (P value <0.05). But after eight weeks of therapy patients began to exhibit noticeable progress. There was a statistically significant reduction in the overall amount of acne throughout follow-up[7-9]. In conclusion, isotretinoin, particularly in lower doses or intermittent regimens, remains an effective treatment for moderate to severe acne, with a favorable side effect profile and reduced cost compared to conventional high-dose regimens[5].

Grading of Acne

Grade	Severity	Clinical findings
I	Mild	Open and closed comedones with few inflammatory papules and pustules
II	Moderate	Papules and pustules, mainly on face
III	Moderately severe	Numerous papules and pustules, and occasional inflamed nodules, also on chest and back
IV	Severe	Many large painful nodules and pustules

CONCLUSION

Intermittent isotretinoin dosing presents a viable and effective alternative to traditional daily dosing for the management of acne vulgaris, particularly in cases of mild to moderate acne. This regimen has demonstrated comparable efficacy in reducing acne severity while significantly minimizing mucocutaneous side effects such as cheilitis, xerosis and xerostomia, which are commonly associated with higher doses. Furthermore, intermittent dosing offers the advantage of being cost-effective, with fewer adverse events reported, making it an attractive option for both patients and clinicians. Although recurrence rates in the intermittent dosing group were slightly higher, this

difference did not reach statistical significance, suggesting that intermittent therapy can still provide durable results. Further longitudinal studies are warranted to better understand its long-term efficacy and potential for relapse prevention, but current evidence supports its role as a safer, more manageable treatment option in dermatological practice.

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