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ORIGINAL ARTICLE

Efficacy of Low Dose Oral Isotretinoin on Alternate Day Vs Pulses Regimen for Acne Vulgaris Treatment: RCT

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ABSTRACT

Background: Acne has a worldwide distribution with no specific predilection for any race starting in adolescence and usually resolves by mid-twenties.
Aim: To compare the efficacy of low dose 1mg/kg oral isotretinoin on alternate day versus pulses of oral isotretinoin in the treatment of acne vulgaris.
Study Design: Randomized control trial.
Methodology: All patients (n=254) having severe facial acne vulgaris were included. Patients in group A, was given oral isotretinoin 1mg/kg on alternate day and those in group B, oral isotretinoin 1 mg/kg/day for one week/four weeks. Patients were followed up at 12 weeks to see response of each group. Response was noted in terms of more than 60% improvement in total acne load from baseline. All this information was recorded on Performa. Data was analyzed using SPSS version 26. Results were presented as frequency and percentage. Age was presented as mean± SD.
Results: In group A, total acne load was decreased from a mean of 114.6 to 5.24 with 95.42% response was seen during 24 weeks of treatment .In group B total acne load was decreased from 110.4 to a mean of 22.33 with 79.77% response was seen during 24 weeks of treatment.
Conclusion: It was concluded that treatment received by group A proved to be a better treatment option for acne vulgaris in comparison to treatment received by group B.
Keywords: Isotretinoin, Acne Vulgaris and Treatment Response

INTRODUCTION

Acne is the most common dermal disorder that mainly involves the pilo-sebaceous units.[1-4] It affects men and women about equally.[5] It's a disease of teenage that ends by age of 20–25 years. As a rarity, it persists till fifth decade of life.[6] Its a multifactorial disorder mainly resulting from excess sebum production, skin keratinization, inflammatory processes and genetics as documented previously by many researches[4,5].

Genetics has an influence as shown by an estimate that if both parents are affected then 3 out of 4 children has the chance of acquiring acne and if one parent is affected then 1 out of 4 children has the chance of acquiring acne. However, it may skip generations.[7] One study showed that majority (85%) patients have acne by age of 12 years[8,9]. However, it can occur de novo late (acne tarda) in the third and fourth life decade as shown by literature review[10]. It is not a deadly disease but a social stigma that affects the life of its victim psychosocially as well as emotionally[11].

Acne is a treatable disease with help of agents including creams, ointment, lotions, face washes, soaps, topical agents (Benzyl peroxide, adapalene, isotretinoin) and oral medications (Tetracycline's, azithromycin and OCPs) but its treatment has been revolutionized with the advent of oral retinoids.[12-14] Literature review showed that oral retinoids can be given in every type of acne.[13,14] Due to its increasing prevalence and debilitating effect on the quality of life of the patients, we designed this study.

The objective of the study was to compare the efficacy of low dose 1mg/kg oral isotretinoin on alternate day versus pulses of oral isotretinoin in the treatment of acne vulgaris.

METHODOLOGY

Present study was a randomized control trial. After IRB permissionInformed consent was taken from the patients or guardians prior to enrolling the patients into the study. All patients having severe facial acne vulgaris were included. Patients in group A, was given oral isotretinoin 1mg/kg on alternate day and those in group B, oral isotretinoin 1mg/kg/day for one week/four weeks. Pregnant females as well as patients having hyperlipidemia and diabetes were excluded from study. Patients were followed up at 12 weeks to see response of each group. Response was noted in terms of more than 60% improvement in total acne load from baseline. All this information was recorded on Performa. All this information was recorded on Performa.

Statistical analysis: Data was analyzed by SPSS version 26.0. Mean and SD was calculated for variables such as age, acne load score at presentation, at 12 weeks follow up and 24 weeks at the end of treatment. Gender and efficacy were presented as frequencies and percentages (%). Chi square Test was applied considering P-value< 0.05 as statistically significant.

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RESULTS

Maximum numbers of patients were in the 2nd decade of their lives. Mean age in group-A was 17.86 years± 2.910 SD while in group-B, it was 18.20 years±2.592 SD as shown in table-1.

Table 1: Gender Distribution in Both Groups

Parameters	Group-A	Group-B
Total patients	127	127
Male patients	71 (55.91%)	77 (60.63%)
Female patients	56 (44.10%)	50 (39.37%)
Initial Acne load	114.6	110.4
Mean ± SD (Yrs)	17.86±2.910	18.20±2.592

In (Group A) low dose oral isotretinoin 1mg/kg on alternate day group, the initial acne load was decreased from a mean of 114.6 to 20.55 i.e., an 82.07% improvement was seen during the first 3 months of treatment and to a mean of 3.54 i.e., 95.42% improvement was seen at the end of treatment as shown in table-2.

Table-2: Total acne load at 12 weeks and at 24 weeks of treatment from baseline

Duration	Group-A	Group-B	P-value
Initial score Mean score (Range)	114.6 (32-244)	110.4 (40-228)	<0.5
12 weeks	20.55 (05-25)	43.74 (11-75)	<0.001*
24 weeks	5.24 (0-12)	22.33 (0-43)	<0.001*

*Statistically significant

Improvement in acne score between both groups was noted at an interval of 12 and 24 weeks and was presented as percentage as shown in table-3.

Table-3: Improvement in acne load at 12 weeks and At 24 weeks of Treatment

Duration	Group A	Group B	P-value
12 weeks	82.07%	60.38%	<0.001*
24 weeks	95.42%	79.77%	<0.001*

*Statistically significant

DISCUSSION

Acne is the most common dermal disorder that mainly involves the pilo-sebaceous units. Oral isotretinoins are effective treatment options for inflammatory acne lesions as it inhibits sebaceous gland differentiation and proliferation, reduces sebum production and suppression of inflammatory response[12].

Antibiotic resistance by Propioni-bacterial is an emerging problem. Hence it increases the treatment failure rate among patients especially those who received antibiotics previously.[15] However, its treatment has been revolutionized with the advent of oral retinoids[12,13].

One previous study found that there was a decrease in the total acne loads up to 98.99% (Group A) and 97.69% (Group B) from the baseline ($P < 0.01$).[5] Similarly, In our study, there was a decrease of 95.42% in total acne load hence our results were in the same lines.

Another study showed that daily dose group (A), efficacy was achieved in 90% of patients whereas in alternate dose group, efficacy recorded was in 86.7% of patients (P>0.05) hence concluded that the role of alternate day fixed dose regimen has been shown to be efficious.[16] In our study we compared regimen of 1mg/kg oral isotretinoin on alternate day with pulses 1 mg/kg/day for 1week/4 weeks of oral isotretinoin.

One previous study enrolled 30 patients in each group and this sample size was smaller as compared to our study. They included patients having moderate to severe acne. In our study we enrolled 254 facial acne patients. They assessed their patients at 8 weeks and 16 weeks but our study was continued for 24 weeks and we assessed the patients at 12 weeks and 24 weeks, due to which our results are different from the original study[17].

Our findings suggested that low dose 1mg/kg on alternate day oral isotretinoin was significantly better than pulses 1 mg/kg/day for one week /4 weeks of oral isotretinoin in its treatment. More than 95.42% improvement was seen in group A patients, but only 79.77% in group B.

Limitations: Our study had limitations like financial constraints, lack of resources, genetic workup and short duration of study.

CONCLUSION

It was concluded that treatment received by group-A proved to be a better treatment option for acne vulgaris in comparisn to treatment received by group-B. Hence, in the age range of 14-26 years alternate day 1mg/kg oral isotretinoin is better than pulses 1mg/kg/day for one week/4 weeks in the treatment of severe acne vulgaris.

Authors' Contribution: MD: Conceptualized the study, analyzed the data, and formulated the initial draft, **NN**: Contributed to the proof reading, **SH:** Collected data
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