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Original Research Article

To compare the safety of Low-dose Isotretinoin with High dose Isotretinoin in patients with moderate and severe acne.

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Abstract:

Background & Method: The aim of the study is to compare the efficacy of isotretinoin at low dose (0.20 to 0.45mg/kg) vs high dose (0.50 to 0.75mg/kg) at 4, 8, 12 and 16 weeks. In this prospective, comparable study, 100 patients having moderate to severe acne vulgaris were selected after taking an informed written consent using purposive sampling technique. The patients' records were studied to compile the diagnostic and clinical data including age, sex, site of acne, duration and severity of acne, indications for isotretinoin therapy.

Result: 29 cases with nodulocystic acne had high dose of isotretinoin, 10 cases with low dose isotretinoin were resistant to treatment. 10 cases of relapse had high dose treatment. 11 cases and 10 cases had resistance to treatment. significant association was found. 3 cases with high dose of isotretinoin treatment had previous treatment on isotretinoin. While 4 cases with low dose isotretinoin treatment had previous treatment of isotretinoin.

Conclusion: In this prospective, comparable study, 100 patients having moderate to severe acne vulgaris were selected after taking an informed written consent using purposive sampling technique. The patients' records were studied to compile the diagnostic and clinical data including age, sex, site of acne, duration and severity of acne, indications for isotretinoin therapy.

Keywords: efficacy, isotretinoin, high dose & safety.

Study Designed: Comparative Study.

1. Introduction

Acne is a chronic inflammatory disease of the pilosebaceous unit almost everyone develops some acne during adolescence but the range of clinical expression is enormous. It varies from the transient presence of few comedones and papules to a severe disabling and debilitating condition marked by persistent deep papules, nodules and cysts[1].

It has been shown that even clinically mild to moderate acne can be associated with higher rates of depression and suicidal thoughts among adolescents than other chronic and disfiguring skin diseases. Acne is a common skin disease that affects 85% of adolescents at

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some time during their lives[2]. Acne affects the areas of skin with densest population of sebaceous follicles which are the face area, the upper part of the chest area and the back area[3]. The prevalence and severity of acne on the face, chest and back areas is reported to be 92%, 45% and 61% respectively[4].

AV present with pleomorphic skin lesions from mild comedones to disfiguring nodulocystic variant, micro-comedones are the primary lesions of acne which are not even visible by naked eyes. This requires special attention for the development of treatment. They represent the central precursor lesions which evolve into either non-inflammatory comedones or inflammatory, papules and pustules[5].

Retinoids were first observed to be extremely effective in curing acne in 1962. Nowadays, retinoids are most commonly used in the treatment of acne vulgaris. They are derivatives of vitamin A and produce its sebo-suppresive effects by inducing apoptosis in sebocytes through retinoic acid receptors[6&7].

2. Material & Method

Patients attending Dermatology, Venereology and Leprosy OPD in People's College of Medical Sciences and Research Center, Bhopal having severe to moderate acne vulgaris.

In this prospective, comparable study, 100 patients having moderate to severe acne vulgaris were selected after taking an informed written consent using purposive sampling technique. The patients' records were studied to compile the diagnostic and clinical data including age, sex, site of acne, duration and severity of acne, indications for isotretinoin therapy etc.

- **INCLUSION CRITERIA**

i) Patients diagnosed with moderate to severe type of acne vulgaris (including Comedones, Pustules, Nodules, Cysts).
ii) Patients who were willing to participate in the study.
iii) Patients aged >12 years.

- **EXCLUSION CRITERIA**

i) Patients who didn't gave their consent for the study or didn't show willingness for follow up.
ii) Patients aged < 12 years.
iii) Mild Acne vulgaris with GAGS score of < 16 or where systemic therapy was not needed.
iv) Pregnant and lactating females.
v) Patients with hyperlipidemia/hepatic dysfunction (elevated AST/ALT).
vi) Female Patient who is planning to conceive in next 4 month.

3. Results

Table 1: Distribution of age according to treatment groups

Age	High dose	High dose	Low dose	Low dose
	(N)	(%)	(N)	(%)
Less than or equal to 20	31	62.00%	22	44.00%

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21 to 30	**15**	**30.00%**	**28**	**56.00%**
31 to 40	**4**	**8.00%**	**0**	**0.00%**
Age	**Chi-square**	**9.459**	**P value**	**0.009**

In the present study 31 cases on high dose were of age group less than or equal to 20. Fifteen cases with high dose were of 21 to 30 years. While 28 cases with age group 21 to 30 years received low dose isotretinoin. 22 cases of low dose were less than or equal to 20 years.

Table 2: Mean between age groups of both doses

		Mean	**Std. Deviation**	**t**	**P value**
Low dose	**Age**	**21.22**	**4.196**	**0.528**	**0.6**
High dose	**Age**	**20.76**	**5.755**		

In the present study, Mean age of cases who received low dose isotretinoin was 21.22 years. While mean age of cases who received high dose isotretinoin was 20.76 years.

Table 3: Distribution of groups according to indication of treatment

Indication for treatment	**High dose (N)**	**High dose (%)**	**Low dose (N)**	**Low dose (%)**
Nodulocystic acne	**29**	**58.00%**	**24**	**48.00%**
Relapse	**10**	**20.00%**	**16**	**32.00%**
Resistant to treatment	**11**	**22.00%**	**10**	**20.00%**
Indication for treatment	**Chi-Square Test**	**1.904**	**P value**	**0.386**

In the present study, 29 cases with nodulocystic acne had high dose of isotretinoin, 10 cases with low dose isotretinoin were resistant to treatment. 10 cases of relapse had high dose treatment. 11 cases and 10 cases had resistance to treatment.

Table 4: Site of acne with dose of isotretinoin

Site of acne	**High dose (N)**	**High dose (%)**	**Low dose (N)**	**Low dose (%)**
Truncal	**00**	**0.00%**	**02**	**4.00%**
Facial	**44**	**88.00%**	**40**	**80.00%**

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Both	**06**	**12.00%**	**08**	**16.00%**
Site of acne	**Chi-square**	**2.476**	**P value**	**0.29**

In this present study 44 cases with high dose had facial acne. 8 cases with low dose isotretinoin had both types of acne. 40 cases of low dose had facial lesion. Face was found to be most common site to be involved in AV. There was no association found with site and dose of treatment.

Table 5: Distribution of previous treatment with doses of isotretinoin

Previous treatment	High dose (N)	High dose (%)	Low dose (N)	Low dose (%)
Antibiotics	**02**	**4.00%**	**00**	**0.00%**
Antibiotics+Topical therapy	**12**	**24.00%**	**08**	**16.00%**
Isotretinoin	**03**	**6.00%**	**04**	**8.00%**
Isotretinoin+Topical therapy	**00**	**0.00%**	**02**	**4.00%**
Topical therapy	**18**	**36.00%**	**14**	**28.00%**
No previous treatment	**15**	**30.00%**	**22**	**44.00%**
Previous treatment	**Chi-square**	**6.767**	**P value**	**0.239**

In the present study significant association was found. 3 cases with high dose of isotretinoin treatment had previous treatment on isotretinoin. While 4 cases with low dose isotretinoin treatment had previous treatment of isotretinoin.

4. Discussion

Acne vulgaris is one of the most common skin disorders, according to the systematic analysis for the Global Burden of Disease study indicated that acne was the eighth most prevalent disease globally in 2010[8]. Isotretinoin is First generation retinoid which most commonly used in acne patient. This study was done to compare the effect and safety of low-dose isotretinoin with high dose in patients with moderate and severe acne.

A total of 118 patients were enrolled out of which 18 patients dropped out during the course of study. Therefore, the study was conducted on 100 patients of AV presenting at Department of Dermatology, People's Hospital Bhopal with the aim to assess and compare the efficacy and safety of isotretinoin at low dose (0.20 to 0.45mg/kg) vs high dose (0.50 to 0.75mg/kg). While using this treatment protocol the incidence of side-effects was monitored. It has been

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debated whether isotretinoin should be reserved for severe nodulocystic acne only or it can be used for mild and moderate acne also. In the present study 2 different dosage of oral isotretinoin have been used and compared[9&10].
Many papers have demonstrated that acne presentation is influenced by demographic factors. The onset of acne typically correlates with the onset of puberty, when sebum production increases. As such, the prevalence of acne increases with increasing age, showing highest incidence in teenagers and a relatively low incidence in pre-pubertal children. After reaching the late teenage years or young adulthood, acne prevalence rates follow a decreasing trend with increasing age[11].

5. Conclusion

In this prospective, comparable study, 100 patients having moderate to severe acne vulgaris were selected after taking an informed written consent using purposive sampling technique. The patients' records were studied to compile the diagnostic and clinical data including age, sex, site of acne, duration and severity of acne, indications for isotretinoin therapy etc.

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