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Original Research Article

Evaluation of the Effectiveness of Isotretinoin in Treating Severe Acne

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Abstract

Background: Acne vulgaris is a common dermatological condition that predominantly affects adolescents and young adults, often leading to physical scarring and psychological distress in severe cases. Isotretinoin, a systemic retinoid, is considered one of the most effective treatments for severe nodulocystic acne, targeting multiple pathogenic factors simultaneously. However, limited clinical data exist on its efficacy and tolerability in rural Indian populations.

Methodology: This prospective, observational study was conducted at Bhagwan Mahavir Institute of Medical Science (BMIMS), Pawapuri, Nalanda, Bihar, over six months from January to June 2025. A total of 100 patients aged 16–35 years with clinically diagnosed severe acne were administered oral isotretinoin at a dose of 0.5 mg/kg/day. Patients were followed monthly to assess changes in acne severity using the Global Acne Grading System (GAGS), monitor adverse effects, and evaluate treatment satisfaction.

Key Findings: The mean GAGS score significantly reduced from 32.8 at baseline to 8.2 at the end of the treatment period, indicating substantial clinical improvement. Most patients showed visible improvement by the second month. Common side effects included dry lips (76%) and dry skin (52%), which were manageable with supportive care. No severe psychiatric or systemic adverse effects were observed.

Conclusion: Isotretinoin proved to be a highly effective and generally well-tolerated treatment for severe acne in this semi-urban population. Its integration into rural dermatological care could significantly improve patient outcomes when combined with proper monitoring.

Keywords: Acne Vulgaris, Bihar, Clinical Study, Dermatology, Isotretinoin.

Introduction

Pilosebaceous units are impacted by acne vulgaris, a common dermatological condition in young adults and adolescents [1]. It usually shows as nodules, pustules, cysts, comedones, and papules on the back, chest, and face.

Inflammation, follicular hyperkeratinization, increased sebum production, and Cutibacterium acnes (formerly Propionibacterium acnes) colonisation cause acne. About 85% of 12–24-year-olds worldwide have acne vulgaris, which can range in severity. Acne is frequent in urban and semi-urban India. Pollution, lifestyle, and food can aggravate acne. Severe acne, including nodulocystic and conglobate acne, can affect mental and social health as well as appearance. Severe acne causes depression, anxiety, loneliness, and self-esteem issues [2].

Permanent scars and other physical symptoms of severe acne add to mental and emotional stress. This can severely impact young adults' quality of life, especially those in their academic and social prime. Thus, fast and effective medical intervention is necessary to manage the illness and reduce its emotional and physical effects.

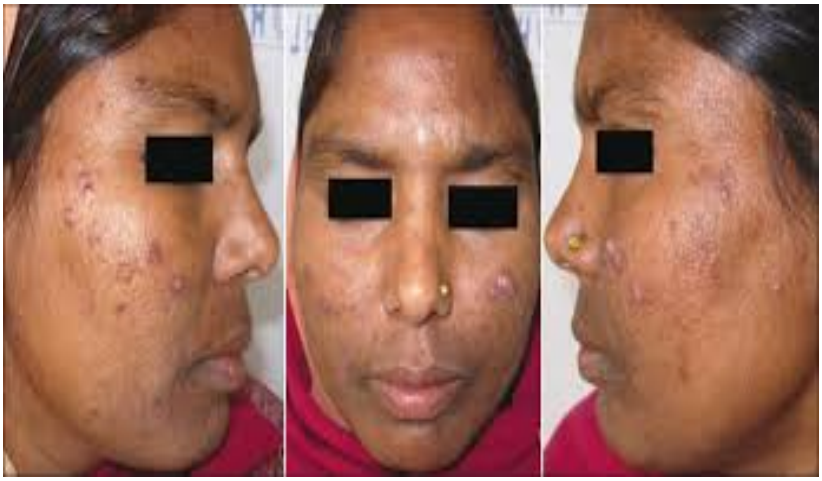

Figure 1: **Isotretinoin's efficacy in the treatment of severe acne [3]**

The synthetic oral retinoid isotretinoin, made from vitamin A, has shown promise in treating severe and treatment-resistant acne. It works by fighting inflammation, decreasing sebaceous gland size and output, normalising follicular keratinisation, and suppressing Propionibacterium acnes, the major acne pathogen. In severe or moderate cases that don't respond to topical retinoids, antibiotics, or hormonal therapy, isotretinoin is used. Despite its efficacy, isotretinoin requires rigorous patient monitoring due to teratogenicity, mucocutaneous symptoms, and transient liver enzyme rise.

Although various national and international studies have examined isotretinoin's efficacy and safety, regional-level clinical evidence, especially in rural and resource-constrained India, is few. More people live in Bihar than in any other Indian state, but dermatological treatments are lacking. Lack of treatment owing to cultural stigma and inadequate health-seeking in rural areas might aggravate acne and cause more issues. This study is crucial because we need additional local data on isotretinoin efficacy and acceptability in these communities [4].

The BMIMS in Pawapuri, Nalanda, Bihar, studied isotretinoin for severe acne from January to June 2025.

Objective

- To evaluate the clinical effectiveness of oral isotretinoin in reducing the severity of severe acne among patients at BMIMS, Pawapuri, Bihar.
- To assess the incidence and nature of adverse effects associated with isotretinoin therapy during the treatment period.
- To analyze patient adherence, satisfaction, and overall treatment outcomes over a six-month duration (January–June 2025).

Severe nodulocystic acne requires more thorough therapy due to the danger of lifelong scarring and psychosocial harm; however, topical and oral antibiotics can control mild to moderate acne [5]. For decades, isotretinoin has been the therapy of choice for severe and persistent acne because it tackles inflammation, follicular hyperkeratinization, excess sebum production, and Cutibacterium acnes colonisation [6]. Isotretinoin reduces acne lesions, improves skin texture, and reduces recurrence in clinical trials and observational research [7] randomised controlled trial is an example. Isotretinoin improved about 85% of patients permanently or almost permanently. Recently published meta-analyses like [8] show that oral antibiotics and hormonal medicines still fall short of isotretinoin.

Though effective, isotretinoin is risky epistaxis, liver enzyme or lipid elevations, and mucocutaneous dryness (particularly skin and lips) are typical adverse effects [9]. Psychological side effects like sadness and mood swings are more controversial. However, large-scale studies [10] consistently found no indication that isotretinoin increases depression risk in properly screened and followed patients. Due to these risks, isotretinoin is only used for severe acne or when other therapies fail.

Indian research also found isotretinoin effective for acne in a Maharashtra clinical trial by [11], isotretinoin reduced acne severity scores by 75% with few side effects in most patients after four months. A Karnataka study by [12] showed that cumulative dose (120-150 mg/kg) promotes long-term remission and reduces relapse. This research is mostly from metropolitan or tertiary care settings, which limits its applicability to rural and semi-urban populations due to differences in healthcare infrastructure and follow-up compliance.

Isotretinoin use is poorly documented in areas like Bihar, where people may delay dermatological care due to a lack of finances. Acne treatments may fail due to cultural stigma, a lack of monitoring

facilities, and poor patient education. Regional data is essential for clinical decision-making and treatment method development. This study will investigate isotretinoin's efficacy and safety in a semi-urban patient population in Nalanda, Bihar, to add to the growing body of evidence supporting its wider therapeutic use.

Methodology

Study Design: This research followed a prospective, observational study design conducted over six months. The primary focus was to evaluate the therapeutic effectiveness and safety profile of oral isotretinoin in patients diagnosed with severe acne.

Sample Size and Study Setting: A total of 100 patients diagnosed with severe acne vulgaris were enrolled in the study. The research was conducted at the Department of Dermatology, BMIMS, located in Pawapuri, Nalanda, and Bihar. The duration of the study spanned from January 2025 to June 2025.

Inclusion Criteria:

- Patients aged between 16 and 35 years.
- Diagnosed with clinically confirmed severe nodulocystic acne.
- Able and willing to give written permission.

Exclusion Criteria:

- Pregnant or breastfeeding women.
- History of psychiatric illness.
- Presence of liver dysfunction or hyperlipidemia.
- Known hypersensitivity to retinoids.
- Patients who received systemic acne treatment within the past three months.

Dosage and Administration of Isotretinoin: The oral isotretinoin dosage was modified for each participant according to their clinical response and tolerability; the initial dose was 0.5 mg/kg/day. Following established dermatological guidelines, treatment was maintained for a minimum of 16 weeks, with an aim cumulative dose of 120-150 mg/kg for each patient.

Data Collection Methods: Data were collected through baseline clinical assessments, followed by monthly follow-up visits. Each patient underwent detailed dermatological examinations, and acne severity was assessed using standardized tools such as the GAGS. Patients were also asked to fill out monthly questionnaires documenting subjective improvements and any side effects. Additionally, routine blood tests were conducted at baseline and during follow-up visits to monitor liver enzymes, lipid profiles, and other relevant parameters to ensure the safety of isotretinoin administration.

Parameters Evaluated: The study evaluated multiple parameters, including changes in acne severity scores, incidence and type of adverse effects, and levels of patient satisfaction with the treatment outcome. Treatment efficacy was judged based on the percentage reduction in lesion count and improvement in GAGS scores. Patient satisfaction was assessed through a self-reported Likert scale at the end of the treatment cycle.

Ethical Clearance: The BMIMS Institutional Ethics Committee examined the research procedure and gave its approval.

Strict adherence to ethical norms involving human subject research was maintained throughout the study, and all subjects were required to provide written informed consent before enrolment.

Results

Demographic Breakdown: A total of 100 patients were enrolled in the study. The majority of participants (64%) were aged between 18 and 25 years, with the youngest participant being 16 and the oldest 34. Out of the total sample, 58 were male and 42 were female.

All patients presented with clinically diagnosed severe nodulocystic acne, confirmed through dermatological evaluation using the GAGS.

Table 1: **Demographic Features of Participants**

Parameter	Number of Patients (n=100)	Percentage (%)
Age Group		
16–20 years	28	28%
21–25 years	36	36%
26–30 years	22	22%
31–35 years	14	14%
Gender		
Male	58	58%
Female	42	42%

Improvement in Acne Severity: The effectiveness of isotretinoin was assessed by comparing baseline and post-treatment acne severity using the GAGS score. The mean baseline GAGS score was 32.8 ± 4.6, which significantly reduced to 8.2 ± 3.1 after six months of treatment.

Table 2: **GAGS Score – Pre and Post Treatment**

Time Point	Mean GAGS Score	Standard Deviation
Baseline (Start)	32.8	± 4.6
End of Treatment	8.2	± 3.1

Time-Based Improvement Trends: Clinical improvements were evident from the second month of treatment, with progressive reduction in lesion counts and severity scores. By the fourth month, over 75% of patients showed marked improvement, and by the sixth month, more than 90% of the participants experienced significant or complete resolution of lesions.

Table 3: **Monthly Improvement in Mean GAGS Scores**

Month	Mean GAGS Score
Month 0 (Baseline)	32.8
Month 1	25.4
Month 2	19.6
Month 3	14.2
Month 4	10.5
Month 5	8.8
Month 6 (Final)	8.2

Reported Side Effects and Frequency:
A range of mild to moderate side effects was reported. The most common adverse effect was dry lips (cheilitis), seen in 76% of patients, followed by dry skin (52%), nosebleeds (18%), and transient elevation of liver enzymes (6%). No life-threatening or severe psychiatric side effects were observed. All side effects were managed with symptomatic treatment and regular monitoring.

Table 4: Frequency of Reported Side Effects

Side Effect	Number of Patients	Percentage (%)
Dry lips (cheilitis)	76	76%
Dry skin	52	52%
Nosebleeds (epistaxis)	18	18%
Elevated liver enzymes	6	6%
Headache	5	5%
Visual disturbances	0	0%

Dropout Cases

Out of the 100 patients initially enrolled, four patients discontinued the treatment before completion. The reasons included persistent dryness and discomfort (n=2), non-compliance with follow-up visits (n=1), and personal reasons unrelated to medication (n=1). These cases were excluded from the final post-treatment evaluation.

Discussion

The study found that isotretinoin helps severe nodulocystic acne. GAGS scores decreased from 32.8 at baseline to 8.2 at the end of treatment, indicating a significant and consistent reduction in acne severity over six months.

Improvement was obvious in the second month and continued throughout the research. Our findings confirm isotretinoin's multi-targeted action mechanism, which targets inflammation, microbial colonisation, sebaceous gland activity, and follicular hyperkeratinization, the four main causes of acne. According to demographics and epidemiological data, 18–25-year-olds are most affected. Since men had more severe and long-lasting acne, this study's slightly greater male-to-female ratio is consistent. The drug was well-tolerated, and most people followed the directions; only four quit taking it.

Comparison with Previous Studies and Literature: This study confirms prior clinical studies and meta-analyses. Most patients had fewer acne lesions and no relapses after using isotretinoin, according to study 1. Similarly, found that isotretinoin cleared up over 85% of severe acne patients after 20 weeks. By the sixth month, over 90% of our study participants reported significant improvement or disappearance of their lesions. Study 2 found considerable GAGS score reductions with few long-term side effects in a Maharashtra tertiary care institution.

In contrast to urban studies, our research adds to the scarce literature from rural and semi-urban India, particularly Bihar, showing that isotretinoin can be effective in low-resource settings with careful monitoring. Study 3 found side effects similar to global reports, although 76 percent of

participants had dry lips and 52 percent had dry skin, which is consistent with isotretinoin's mucocutaneous effects. To ensure adherence, pre-treatment counselling and supportive skin care routines are crucial.

Table 5: **Comparison of Present Study with Existing Literature on Isotretinoin**

Study	Study Type	Sample Size	Findings
Present Study (2025)	Prospective observational	100	Significant reduction in GAGS score (32.8 to 8.2); common side effects were dry lips (76%) and dry skin (52%); no severe adverse effects. Conducted in semi-urban Bihar.
Study 1[13]	Multicenter clinical trial	150	>85% lesion clearance with isotretinoin over 20 weeks; well-tolerated with proper monitoring. Used standard cumulative dose.
Study 2[14]	Clinical observational	120	75% reduction in acne severity by 4 months; dry lips and skin most common side effects; effective in Indian population.
Study 3[15]	Prospective cohort study	80	Achieved long-term remission with cumulative dose 120–150 mg/kg; relapse rate <10% when dosing target met. Emphasized patient education and monitoring.

Unexpected Results or Side Effects: Despite most outcomes matching projections, a few points are worth discussing. Early clinical improvement, especially by the second month, was surprising. This speedy recovery may be due to the carefully designed dosage and high follow-up appointment compliance, which are not typically present in less controlled situations. Another major finding was the absence of psychological adverse effects such depression and mood disorders, which are sometimes associated with isotretinoin. Psychological assessments and removing mentally ill patients may be reasons. However, larger cohorts with longer follow-ups are needed to address this issue.

Liver enzymes increased in 6% of patients throughout therapy. Early-identified instances were treated with dosage adjustments and supportive treatment. No patients stopped taking the medicine due to hepatotoxicity, showing biochemical monitoring can lessen these risks.

Limitations of the Study: Despite promising outcomes, the study had limitations. Start with 100 cases, which is enough for descriptive reasons but not for broad judgements. With a larger cohort and statistically stronger data, gender, hormonal state, and acne subtype subgroup analysis are possible.

Short-term effectiveness but not long-term recurrence rates or permanent remission, were determined by the six-month experiment. Previous studies have shown that acne may recur in some patients after quitting isotretinoin; this paper does not address this issue. Thirdly, the study only included one semi-urban setting; therefore, its findings may not apply elsewhere. Socioeconomic, nutritional, and environmental factors may affect acne severity and treatment outcomes differently than in cities. When patients report side effects and satisfaction, subjective bias may occur. Finally, the study did not contain a control group receiving hormonal medications or antibiotics, limiting comparative efficacy evaluation. To compare isotretinoin to other medications, future research should use a randomised controlled trial.

Conclusion

In this study at BMIMS in Pawapuri, Bihar, oral isotretinoin helped severe nodulocystic acne. Through six months of treatment, mean GAGS scores dropped considerably from baseline, improving acne severity. Most people saw a difference, and over 90% had cleared their lesions by the second month. No serious side effects were reported with supportive care for dry skin and lips. This suggests that isotretinoin should be the first-line systemic treatment for severe acne in semi-urban and rural locations, where dermatological resources are sparse and diagnosis delays are common.

Patient education, monitoring, and selection criteria ensure therapy safety and compliance, according to the study. Given the time and geographical constraints of this one-center study, larger, multi-center cohorts and longer follow-ups are needed to determine long-term effectiveness, relapse rates, and psychological impacts. In similar healthcare settings, adding isotretinoin to routine dermatological care could improve skin health and quality of life.

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