(e) ISSN Online: 2321-9599

(p) ISSN Print: 2348-6805

# ORIGINAL ARTICLE

## Prospective Assessment of the Efficacy of Low-Dose Isotretinoin in Moderate Acne Vulgaris

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***ABSTRACT:***

**Background:** Acne vulgaris is a chronic inflammatory disorder commonly affecting adolescents and young adults, often leading to significant psychosocial distress and permanent scarring. While conventional-dose isotretinoin is highly effective, its dose-dependent adverse effects may limit use in patients with moderate disease. Low-dose isotretinoin has emerged as a promising alternative with comparable efficacy and improved tolerability. This study prospectively evaluates the clinical effectiveness and safety of low-dose isotretinoin in patients with moderate acne vulgaris treated at a tertiary care hospital. **Aim:** To assess the efficacy, safety, and patient satisfaction associated with low-dose isotretinoin therapy in moderate acne vulgaris. **Material and Methods:** This prospective study included 88 patients aged 12–35 years with clinically diagnosed moderate acne. All participants received low-dose isotretinoin at 0.25–0.30 mg/kg/day. Baseline demographic data, total lesion counts, inflammatory and non-inflammatory lesion counts, and Global Acne Grading System (GAGS) scores were recorded. Clinical assessments were repeated at predefined intervals using standardized evaluations. The primary outcome was percentage reduction in total lesion count, while secondary outcomes included changes in inflammatory and non-inflammatory lesions, GAGS scores, Physician Global Assessment (PGA) grades, patient satisfaction, and adverse effects. Data were analyzed using SPSS version 26.0, with $p < 0.05$ considered statistically significant. **Results:** Low-dose isotretinoin produced a significant reduction in acne severity. Total lesion count decreased by 70.60%, inflammatory lesions by 69.37%, non-inflammatory lesions by 71.89%, and GAGS scores by 61.97% (all $p < 0.001$). PGA results showed that 46.59% of patients achieved an excellent response and 32.95% a good response. High satisfaction scores were reported by 43.18% of patients, while 34.09% were satisfied. Adverse effects were generally mild, with dry lips (54.55%) and dry skin (40.91%) being the most common. No severe side effects or treatment discontinuations occurred. **Conclusion:** Low-dose isotretinoin is an effective, safe, and well-tolerated treatment for moderate acne vulgaris, providing substantial clinical improvement and high patient satisfaction with minimal adverse effects. It represents a practical therapeutic option in tertiary care settings.

**Keywords:** Acne vulgaris, Isotretinoin, Low-dose therapy, GAGS score, Clinical efficacy

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**This article may be cited as:** Kaur P. Prospective Assessment of the Efficacy of Low-Dose Isotretinoin in Moderate Acne Vulgaris. J Adv Med Dent Scie Res 2017;5(10):142-147.

## INTRODUCTION

Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous unit and remains one of the most common dermatological conditions worldwide. It affects an estimated 9.4% of the global population, ranking among the leading skin diseases in terms of prevalence and disability burden, particularly in adolescents and young adults.[1,2] The persistence of acne into adulthood, especially among women, has further shifted its perception from a self-limited adolescent problem to a long-lasting condition with substantial psychosocial and economic implications. Visible facial lesions, post-inflammatory hyperpigmentation, and scarring are frequently associated with low self-esteem, social withdrawal, anxiety, and depression, underscoring the need for effective and durable therapeutic strategies that not only clear lesions but also prevent long-term sequelae.[1–3]The pathogenesis of acne vulgaris is multifactorial, involving increased sebum production, altered follicular keratinization, colonization by *Cutibacterium acnes* (formerly *Propionibacterium acnes*), and complex inflammatory and neuroendocrine pathways.[3] These mechanisms are further modulated by genetic predisposition, hormonal influences, diet, environmental factors, and skin microbiome alterations. Contemporary reviews highlight that inflammation is present from the earliest stages of comedone formation, and that pathways involving sebocyte activity, innate immunity, and the skin barrier interact in a self-perpetuating cycle.[3] This evolving understanding supports the use of agents that act on multiple pathogenic steps simultaneously, such as oral isotretinoin, particularly for patients at risk of scarring or with disease resistant to conventional therapies.Clinically, acne ranges from mild comedonal disease to moderate inflammatory papulopustular acne and severe nodulocystic or conglobate forms. Moderate acne represents a pivotal stage: although not as dramatic as severe nodular disease, it is often widespread, persistent, and associated with early scarring and significant psychosocial distress. Epidemiological data show that adolescents and young adults are disproportionately affected, with acne consistently among the top dermatologic causes of years lived with disability in individuals aged 10–24 years.[2,3] In many low- and middle-income settings, patients with moderate acne

frequently present to tertiary care centers only after prolonged, unsuccessful use of over-the-counter preparations or long courses of antibiotics, increasing both the risk of scarring and the burden of antimicrobial resistance.Current management of acne vulgaris follows a stepwise approach, including topical agents (retinoids, benzoyl peroxide, antibiotics), systemic antibiotics, hormonal therapies in women, light-based modalities, and oral isotretinoin.[4] Recent evidence-based guidelines emphasize combination topical regimens targeting multiple pathogenic mechanisms, restriction of systemic antibiotics to the shortest effective duration, and early use of oral isotretinoin in severe, scarring, or treatment-resistant disease.[4] However, a substantial proportion of patients with moderate acne experience incomplete response or early relapse with topical therapy and systemic antibiotics. In this context, oral isotretinoin offers a unique ability to induce long-term remission by reducing sebaceous gland size and activity, normalizing follicular keratinization, and exerting anti-inflammatory and anti-microbial effects.[5]Traditional isotretinoin regimens (0.5–1.0 mg/kg/day, cumulative dose 120–150 mg/kg) are highly effective but frequently limited by mucocutaneous adverse effects, laboratory abnormalities, strict teratogenic precautions, and cost, which can compromise adherence and lead to early discontinuation.[5,7] Systematic reviews of different isotretinoin doses and regimens show that while conventional doses may provide slightly lower relapse rates in severe acne, they are also associated with a higher incidence and severity of dose-dependent adverse effects.[5,7] These safety concerns are particularly relevant in moderate acne, where the risk–benefit threshold for aggressive dosing may differ from that of severe nodulocystic disease.Emerging evidence suggests that low-dose isotretinoin regimens can achieve comparable clearance rates to standard doses in patients with mild to moderate acne, but with improved tolerability and patient satisfaction.[5,6] Continuous low-dose regimens—typically ranging from 0.1 to 0.3 mg/kg/day—have been associated with substantial reductions in lesion counts and GAGS scores, while significantly decreasing mucocutaneous side effects and laboratory abnormalities.[5,6] A systematic review of randomized controlled comparative studies concluded that low-dose regimens demonstrated similar efficacy to conventional dosing across different acne severities, with fewer adverse events and better compliance, and identified continuous low-dose isotretinoin as the preferred regimen among low-dose strategies.[6] Although relapse rates may be slightly higher with some low-dose protocols, careful patient selection, appropriate treatment duration, and adequate cumulative dosing can mitigate this risk.[5,6]

## MATERIAL AND METHODS

This prospective study was conducted in the Department of Dermatology of a tertiary care hospital and included a total of 88 patients diagnosed clinically with moderate acne vulgaris. Patients were enrolled consecutively based on predefined eligibility criteria. Individuals aged 12–35 years with moderate acne—classified according to the Global Acne Grading System (GAGS)—were included after obtaining informed written consent. Exclusion criteria were severe or nodulocystic acne, pregnancy or lactation, hypersensitivity to retinoids, hepatic dysfunction, hyperlipidemia, concurrent use of systemic acne therapies, or any dermatological disorder that could interfere with outcomes. Basic demographic information including age, gender, occupation, family history of acne, cosmetic use, and aggravating factors was recorded at baseline.

All enrolled patients received oral low-dose isotretinoin at 0.25–0.30 mg/kg/day as a single daily dose with food. Patients were evaluated at baseline and at predefined follow-up visits by the same dermatologist to ensure assessment uniformity. Clinical parameters recorded included total acne lesion count, inflammatory lesion count, non-inflammatory lesion count, and GAGS score. Standardized digital photographs under uniform lighting were taken at each visit. Treatment-related tolerability was evaluated by monitoring mucocutaneous adverse effects, musculoskeletal complaints, and other systemic symptoms, which were documented using a structured checklist.

Baseline laboratory investigations included complete blood count, liver function tests, renal function profile, and lipid panel. These tests were repeated periodically to detect any treatment-related abnormalities. Female patients of reproductive age underwent a urine pregnancy test before initiating therapy and were counseled regarding contraceptive precautions. Compliance to therapy was assessed through patient interviews and pill counts during follow-up.

The primary efficacy outcome was the percentage reduction in total acne lesion count from baseline to the final follow-up visit. Secondary outcomes included reduction in inflammatory and non-inflammatory lesions, change in GAGS scores, overall clinical improvement assessed using a 5-point physician’s global assessment scale, and patient satisfaction graded on a validated Likert scale. Safety outcomes comprised the frequency and severity of adverse effects.

All collected data were entered into a statistical database and analyzed using SPSS version 26.0. Quantitative variables such as lesion counts and GAGS scores were expressed as mean ± standard deviation, while categorical variables such as gender and adverse effects were summarized as frequencies and percentages. Pre- and post-treatment comparisons were performed using paired t-tests for continuous

variables and chi-square tests for categorical outcomes. A *p*-value of <0.05 was considered statistically significant. Appropriate data validation procedures were undertaken to ensure accuracy and completeness of all entries prior to final analysis.

## RESULTS

The baseline demographic characteristics of the 88 patients enrolled in the study are summarized in Table 1. The majority of patients were between 19–25 years of age, accounting for 46.59%, followed closely by adolescents aged 12–18 years comprising 38.64% of the study population. Only a smaller proportion, 14.77%, belonged to the older age group of 26–35 years. A slightly higher representation of males (55.68%) was observed compared to females (44.32%). A positive family history of acne was present in 36.36% of participants, indicating a considerable genetic predisposition within the cohort. Cosmetic use, a known exacerbating factor for acne, was reported by 31.82% of the patients, while the remaining 68.18% did not report any cosmetic exposure. These baseline characteristics reflect a typical distribution seen in moderate acne cases presenting to dermatology clinics.

Table 2 presents the comparative evaluation of acne severity before and after low-dose isotretinoin therapy. There was a marked and statistically significant improvement across all clinical parameters. The mean total lesion count reduced from 62.45 ± 8.72 at baseline to 18.36 ± 6.41 at the end of treatment, reflecting a 70.60% reduction ($p< 0.001$). Inflammatory lesions showed a decrease of 69.37%, declining from a baseline mean of 32.17 ± 6.58 to 9.85 ± 4.12 after treatment. Non-inflammatory lesions exhibited the greatest improvement, with a 71.89% reduction from 30.28 ± 5.44 to 8.51 ± 3.97. The Global Acne Grading System (GAGS) score showed a significant decline of 61.97%, demonstrating a consistent improvement in overall acne severity. All reductions were highly significant ($p< 0.001$), confirming the efficacy of low-dose isotretinoin in managing moderate acne vulgaris.

The Physician Global Assessment (Table 3) further supported the clinical effectiveness of treatment. Nearly half of the patients (46.59%) achieved an excellent response, defined as >75% improvement in lesion counts. Additionally, 32.95% of participants demonstrated a good response with 51–75% improvement. A moderate response (26–50% improvement) was seen in 14.77% of subjects, while only 5.68% experienced a mild response. Importantly, no patient fell into the "no response" category, indicating that all participants derived some degree of clinical benefit from low-dose isotretinoin therapy. This distribution highlights the strong therapeutic potential of isotretinoin even at lower doses.

Table 4 summarizes patient satisfaction based on the Likert scale. A substantial proportion of patients expressed positive feedback regarding the treatment outcome. A total of 43.18% rated themselves as highly satisfied, while another 34.09% reported being satisfied with their improvement. Neutral responses were recorded in 13.64% of patients, suggesting they perceived moderate benefit but expected greater improvement. Only a small percentage reported dissatisfaction, with 6.82% marking themselves as dissatisfied and 2.27% as highly dissatisfied. The predominance of positive satisfaction scores indicates that clinical improvements translated into subjective patient satisfaction and enhanced quality of life.

Table 5 describes the adverse effects observed during therapy. The most frequently reported side effect was dry lips (cheilitis), affecting 54.55% of patients, which is consistent with the known mucocutaneous effects of isotretinoin. Dry skin was the second most common adverse effect, reported by 40.91% of patients. Less common side effects included epistaxis (11.36%), headache (7.95%), and myalgia (4.55%). Importantly, 21.59% of patients did not experience any adverse effects during treatment. Statistical comparison of adverse effects between male and female patients revealed no significant gender-related differences, with all *p*-values > 0.05. Overall, the adverse effects were mild, manageable, and did not necessitate treatment discontinuation in any patient, indicating that low-dose isotretinoin was well tolerated.

**Table 1: Baseline Demographic Characteristics of Patients (n = 88)**

| Variable | Category | Frequency (n) | Percentage (%) |
|---|---|---|---|
| **Age Group (years)** | 12–18 | 34 | 38.64% |
| | 19–25 | 41 | 46.59% |
| | 26–35 | 13 | 14.77% |
| **Gender** | Male | 49 | 55.68% |
| | Female | 39 | 44.32% |
| **Family History of Acne** | Present | 32 | 36.36% |
| | Absent | 56 | 63.64% |
| **Cosmetic Use** | Yes | 28 | 31.82% |
| | No | 60 | 68.18% |

**Table 2: Comparison of Acne Lesion Counts Before and After Treatment**

| Parameter | Baseline Mean ± SD | Final Mean ± SD | Mean Reduction (%) | p-value |
|---|---|---|---|---|
| **Total Lesion Count** | 62.45 ± 8.72 | 18.36 ± 6.41 | 70.60% | <0.001* |
| **Inflammatory Lesions** | 32.17 ± 6.58 | 9.85 ± 4.12 | 69.37% | <0.001* |
| **Non-Inflammatory Lesions** | 30.28 ± 5.44 | 8.51 ± 3.97 | 71.89% | <0.001* |
| **GAGS Score** | 22.14 ± 3.87 | 8.42 ± 2.75 | 61.97% | <0.001* |

*Paired t-test used.

**Table 3: Physician Global Assessment (PGA) of Improvement**

| Improvement Grade | Definition | Frequency (n) | Percentage (%) |
|---|---|---|---|
| **Excellent Response** | >75% improvement | 41 | 46.59% |
| **Good Response** | 51–75% | 29 | 32.95% |
| **Moderate Response** | 26–50% | 13 | 14.77% |
| **Mild Response** | <25% | 5 | 5.68% |
| **No Response** | 0% | 0 | 0.00% |

**Table 4: Patient Satisfaction Level (Likert Scale)**

| Satisfaction Score | Interpretation | Frequency (n) | Percentage (%) |
|---|---|---|---|
| **5** | Highly Satisfied | 38 | 43.18% |
| **4** | Satisfied | 30 | 34.09% |
| **3** | Neutral | 12 | 13.64% |
| **2** | Dissatisfied | 6 | 6.82% |
| **1** | Highly Dissatisfied | 2 | 2.27% |

**Table 5: Adverse Effects Observed During Treatment**

| Adverse Effect | Frequency (n) | Percentage (%) | p-value (Male vs Female)* |
|---|---|---|---|
| **Dry Lips (Cheilitis)** | 48 | 54.55% | 0.214 |
| **Dry Skin** | 36 | 40.91% | 0.337 |
| **Epistaxis** | 10 | 11.36% | 0.562 |
| **Headache** | 7 | 7.95% | 0.441 |
| **Myalgia** | 4 | 4.55% | 0.628 |
| **No Adverse Effects** | 19 | 21.59% | – |

## DISCUSSION

The present study provides further support for the role of low-dose isotretinoin as an effective and well-tolerated option for moderate acne vulgaris. The age distribution in our cohort, with 85.23% of patients between 12–25 years and a slight male predominance (55.68%), aligns with the known epidemiology of acne as a disease mainly affecting adolescents and young adults. Bhate and Williams reported that moderate-to-severe acne affects around 20% of young people and frequently persists into the 20s and 30s, with a strong influence of genetic factors and family history on disease severity.[8] The 36.36% rate of positive family history in our study is compatible with their estimate of high heritability of acne and the tendency toward more severe disease in those with affected relatives, supporting the representativeness of our sample for typical moderate acne populations.

In terms of primary efficacy outcomes, low-dose isotretinoin at 0.25–0.30 mg/kg/day led to a 70.60% reduction in total lesion counts, with inflammatory and non-inflammatory lesions decreasing by 69.37% and 71.89%, respectively, and GAGS scores improving by 61.97%. These findings are comparable to those of Amichai et al., who used low-dose isotretinoin (either fixed 20 mg/day or approximately 0.3–0.4 mg/kg/day) and reported "good" or "excellent" clinical responses in over 90% of patients, with response rates of about 94–95% in their low-dose groups.[9] The magnitude of improvement in our study—particularly the >70% reduction in comedonal and inflammatory lesions—supports the concept that low-dose regimens can achieve efficacy similar to higher conventional doses while potentially limiting dose-dependent toxicity.

The distribution of physician-assessed global response in our cohort further emphasizes the strong clinical activity of low-dose isotretinoin. We observed an excellent response (>75% improvement) in 46.59% and a good response (51–75% improvement) in 32.95% of patients, meaning that 79.54% achieved at least a good response. Only 5.68% had a mild response, and no patient had "no response." These results compare favorably with the prospective open-label Iraqi series by Kubaisi et al., where a fixed 20 mg/day (approximately low-dose) regimen for moderate papulopustular acne achieved complete improvement in 93.5% of patients after four months, with only 6.5% showing relapse during subsequent follow-up.[10] The slightly lower proportion of

"excellent" responses in our series may be related to differences in baseline severity grading, outcome definitions, or treatment duration, but overall both studies support a high likelihood of substantial improvement with low-dose isotretinoin in moderate acne.

Our GAGS-based outcomes and lesion count reductions are also in line with randomized comparative evidence evaluating different isotretinoin regimens. Lee et al. randomized 60 patients with moderate acne to conventional dosing (0.5–0.7 mg/kg/day), low-dose continuous therapy (0.25–0.4 mg/kg/day), or intermittent therapy and found that conventional and low-dose continuous regimens achieved similar clinical efficacy, while intermittent therapy was somewhat less effective.[11] Their study showed that low-dose regimens could match standard-dose treatment in terms of GAGS improvement but with fewer side effects and higher patient satisfaction scores. Our observed ~70% reduction in lesion counts and ~62% reduction in GAGS thus sits comfortably within the efficacy range reported for low-dose arms in that trial, suggesting that our dosing strategy is consistent with the best-performing regimens in randomized data.

Although our study was not designed to evaluate long-term relapse, the robust initial responses observed are relevant to the growing literature on low-cumulative-dose isotretinoin protocols. Borghi et al. treated 150 patients with mild-to-moderate acne using an "isotretinoin-sparing" approach: treatment was continued until complete clearance and then for one additional month, resulting in a mean cumulative dose of 80.92 mg/kg; over a two-year follow-up (with topical adapalene maintenance for one year), only 9.35% of the 139 patients who completed the study experienced relapse.[12] The substantial lesion and GAGS reductions in our cohort suggest that a similar low-cumulative-dose strategy (if followed to clearance and short extension) may be adequate to provide durable remission in many moderate acne patients, challenging the dogma that a cumulative dose of 120–150 mg/kg is obligatory in less severe disease.

Patient-reported outcomes in our series also support the clinical value of low-dose isotretinoin. A combined 77.27% of patients were either "highly satisfied" or "satisfied" with treatment on the Likert scale, while only 9.09% reported dissatisfaction (scores 1–2). These high satisfaction rates are comparable to those observed in randomized comparisons of dosing schemes. In the trial by El-Sherif et al., daily low-dose isotretinoin (20 mg/day) and an intermittent low-dose regimen produced excellent or good clinical responses in the majority of patients with moderate acne, and the low-dose daily regimen was associated with favorable tolerability and overall patient acceptance.[13] While that study used categorical clinical response rather than a specific satisfaction scale, the high proportion of excellent/good responses parallels the 77.27% satisfied or highly satisfied patients in our study, indicating that the objective clinical benefit of low-dose therapy translates into meaningful subjective improvement.

The safety profile in our cohort was favorable and consistent with known mucocutaneous adverse effects of isotretinoin, though with somewhat lower frequencies than many conventional-dose series. Dry lips (cheilitis) occurred in 54.55% and dry skin in 40.91% of patients, while epistaxis, headache, and myalgia were less common (11.36%, 7.95%, and 4.55%, respectively). Notably, 21.59% of patients reported no adverse effects, and no clinically significant laboratory abnormalities or treatment discontinuations were documented. In the low-dose 20 mg/day study by Kubaisi et al., mild cheilitis was reported in 100% of patients, xerosis in 66.5%, and epistaxis in 13%, with no biochemical derangements detected, again highlighting that low-dose regimens predominantly produce manageable mucocutaneous toxicity without serious systemic events.[10] Our somewhat lower rates of cheilitis and xerosis may reflect the slightly lower mg/kg dose range (0.25–0.30 mg/kg/day), differences in climate or skin type, or stricter use of emollients, but overall confirm that low-dose isotretinoin is generally well tolerated.

Finally, the high level of patient satisfaction in our study likely reflects not only lesion clearance but also improvement in psychosocial burden, which is well documented in isotretinoin literature. Marron et al. evaluated 346 patients with moderate acne treated to a cumulative dose of 120 mg/kg and demonstrated significant reductions in clinical severity, Dermatology Life Quality Index scores, and Hospital Anxiety and Depression Scale anxiety and depression scores after 30 weeks, with a mean patient satisfaction of 84.4% regarding symptom improvement.[14] In our cohort, 77.27% of patients were satisfied or highly satisfied despite using a lower daily dose regimen, suggesting that even low-dose isotretinoin can provide substantial psychosocial benefit similar to that achieved with conventional cumulative dosing, while maintaining an acceptable safety profile.

Overall, by demonstrating approximately 70% reduction in lesion counts, high rates of excellent/good physician-assessed response, predominance of positive satisfaction scores, and only mild, manageable adverse effects, this prospective study supports low-dose isotretinoin (0.25–0.30 mg/kg/day) as an efficacious and well-tolerated option for moderate acne vulgaris in a tertiary-care setting, in line with and complementary to the existing body of evidence on low-dose and low-cumulative isotretinoin regimens. Low-dose strategies may provide a pragmatic balance between efficacy, tolerability, cost, and long-term remission for appropriately selected patients.

## CONCLUSION

The present study demonstrates that low-dose isotretinoin (0.25–0.30 mg/kg/day) is a highly effective and well-tolerated therapeutic option for moderate acne vulgaris, achieving more than 70% reduction in lesion counts and significant improvement in GAGS scores. Most patients experienced excellent or good clinical responses, accompanied by high satisfaction levels and minimal adverse effects. The favorable safety profile supports its suitability for earlier use in moderate disease. Overall, low-dose isotretinoin offers a balanced approach that maximizes efficacy while minimizing dose-related toxicity, providing a reliable treatment strategy in tertiary care settings.

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