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Open Access Research Article

Efficacy and Safety of Low-Dose Isotretinoin in the Treatment of Acne Vulgaris: A Prospective study

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Abstract:

Background: Conventional isotretinoin dosing (0.5–1.0 mg/kg/day) for acne vulgaris achieves high efficacy, but is limited by significant adverse effects. Low-dose regimens (≤ 0.5 mg/kg/day) may offer an improved therapeutic ratio.
Objectives: To evaluate the efficacy, safety, and relapse outcomes of a flexible low-dose isotretinoin protocol in Iraqi adolescents and young adults.
Methods: A prospective single-arm study involving 72 patients aged 14–25 years) with mild-to-severe acne vulgaris received isotretinoin 0.1–0.5 mg/kg/day for 16–20 weeks. The study was conducted at the Dermatology Outpatient Clinic of Al-Diwaniyah Teaching Hospital, Iraq, between January 2023 and December 2024. The clinical response was assessed using the Investigator's Global Assessment. Safety was monitored via adverse events and laboratory tests for liver function and lipid profile. The patients were followed for 6–12 months for relapse assessment. Data were analyzed using the SPSS software and presented using descriptive statistics.
Results: Treatment success was achieved in 88.9% (64/72) of the patients. Adverse events were mild including cheilitis (97.2%), xerosis (4.2%), myalgia (2.8%), dry eyes (4.2%), and transient headache (2.8%). No mood alterations or severe skin reactions occurred. No significant laboratory abnormalities were noted. During follow-up, 27.8% (20/72) relapsed; all completed a second identical low-dose course.
Conclusion: Low-dose isotretinoin demonstrates high efficacy and safety. Even as relapse rates are higher than with conventional dosing, the good tolerability supports its use as a first-line strategy, with re-treatment being a viable option.

Keywords: Acne vulgaris; cumulative dose; isotretinoin; low-dose therapy; relapse.

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Introduction

Acne vulgaris is a chronic inflammatory dermatosis affecting approximately 85% of adolescents and young adults globally, with profound psychosocial and quality-of-life implications (1,2). Its pathogenesis is multifactorial, involving increased sebum production, follicular hyperkeratinization, cutibacterium acne colonization, and inflammation (3). Oral isotretinoin (13-cis-retinoic acid) remains the most effective treatment for moderate-to-severe or refractory acne, due to its unique ability to target all major pathogenic pathways (4,5).

The conventional dosing paradigm, established in the early 1980s, recommended 0.5–1.0 mg/kg/day, for over 4–6 months, to achieve a cumulative dose of 120–150 mg/kg, aiming to maximize long-term remission and minimize relapse (6,7). However, this high-dose approach was consistently associated with dose-dependent adverse effects, including nearly universal mucocutaneous side effects (e.g., cheilitis, xerosis), musculoskeletal symptoms, and laboratory abnormalities, such as, hypertriglyceridemia and elevated transaminases (8,9). These effects often reduced treatment adherence and impaired the quality of life during therapy (10).

In recent years, low-dose isotretinoin (LDI) regimens (≤ 0.5 mg/kg/day) have gained attention as a strategy to mitigate toxicity while preserving clinical efficacy (11,12). Studies from Asian and European populations report favorable efficacy with significantly improved tolerability and a reduced incidence of laboratory disturbances (13,14). Although a few Iraqi studies have explored isotretinoin for acne treatment, with mostly utilized fixed doses (10–20 mg/day) without weight-based adjustments (15,16,17). In contrast, the present study applies a flexible, weight-adjusted regimen (0.1–0.5 mg/kg/day), representing one of the systematic applications of LDI in the Iraqi population with a duration of 16-20 weeks. This approach aims to reduce adverse effects while preserving clinical efficacy, consistent with the findings of the Asian and European cohorts (18,19).

The aim of the current study is to evaluate the clinical efficacy, biochemical safety, and relapse outcomes of a flexible, response-guided, low-dose isotretinoin protocol, in a cohort of Iraqi adolescents and young adults with acne vulgaris.

Methods

Study Design: This prospective, single-arm study was conducted at the Dermatology Outpatient Clinic of Al-Diwaniyah Teaching Hospital, Iraq, between January 2023 and December 2024. The study involved 72 patients, who met the inclusion criteria set for the study.

Inclusion Criteria: Age 14–25 years; clinical diagnosis of acne vulgaris graded as mild, moderate, or severe (Investigator's Global Assessment [IGA] 2–4); involvement of face, trunk, or both; and inadequate response to conventional topical therapies. Female participants of childbearing potential were advised to have two effective contraceptives (combined oral contraceptives, progestogen-only pills, intrauterine device, or barrier methods) for at least one month before, during, and one month after isotretinoin therapy. Pregnancy tests were performed before treatment initiation and monthly thereafter.

Exclusion Criteria: Previous isotretinoin therapy; pregnancy, lactation, or inadequate contraception; hepatic or renal impairment; psychiatric disorders; and hypersensitivity to isotretinoin.

All patients received oral isotretinoin. The regimen was flexible with monthly dose adjustments within the range of 0.1–0.5 mg/kg/day, based on clinical response and tolerability. The duration of treatment course was 16–20 weeks.

Regarding the cumulative dose, there was no pre-determined target (e.g., 120 mg/kg). Treatment was guided by clinical clearance. Also, patients were permitted to use non-medicated moisturizers and lip balm as needed.

Assessments and Outcome Measures

Clinical Efficacy: Patients were evaluated monthly. The primary efficacy endpoint was the proportion of patients achieving treatment success, defined as IGA score 0 (clear) or 1 (almost clear) at the end of treatment (16–20 weeks) (19).

Safety Monitoring: All adverse events (AEs) were recorded and graded as mild, moderate, or severe. Laboratory safety assessments — including liver function tests (total serum bilirubin, ALT, AST, alkaline phosphatase) and total lipid profile (cholesterol, triglycerides, HDL, LDL, VLD) — were performed at baseline and at the end of treatment.

Follow-up and Relapse Assessment: After completion of the treatment, the patients were scheduled for follow-up visits at 3, 6, and 12 months. They were instructed to return if they noticed significant recurrence. Relapse was clinically defined as recurrence of inflammatory lesions (comedones, papules, pustules, or nodules) sufficient to warrant medical re-intervention, resulting in an IGA score of ≥ 2.

Statistical Analysis: Data were analyzed using SPSS software (Version 26.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were applied, with continuous variables presented as mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Given the single-arm design without a comparator group, inferential statistical tests were not used for primary outcome evaluation. However, inferential statistics were applied selectively for exploratory

subgroup analyses (e.g., Chi-square test, independent t-test, and Pearson correlation) to assess potential associations, differences and correlations between variables. Sample size was not pre-determined a priori. The sample of 72 patients was based on feasibility over the 24-month study period. This sample size is comparable to previously published prospective studies on low-dose isotretinoin, such as Li et al. (2024) [20], which included 76 patients, and Van et al. (2019) [11], which included 68 patients.

Ethical Approval This : study was approved by the Scientific Research Ethics Committee of the College of Medicine, University of Al-Qadisiyah, Iraq (Approval No. 98, dated August 13, 2023). The research was conducted in accordance with the ethical principles of the Declaration of Helsinki (1964) and its subsequent amendments. Written informed consent was obtained from all participants (or from parents i.e. legal guardians for patients aged 14-17 years) prior to enrollment. Confidentiality and anonymity were ensured, and participants were free to withdraw at any time. No interventions beyond routine clinical practice were performed.

Results

Patient Demographics and Baseline Characteristics: As shown in Table 1, all 72 enrolled patients completed the treatment. The cohort had a mean age of 19.40± 3.10 years, with a male predominance (58.3%, n = 42). The baseline acne severity was mild in 26.4% (n = 19), moderate in 43.1% (n = 31), and severe in 30.6% (n = 22). Acne distribution was facial only in 55.6% (n = 40), facial and truncal in 34.7% (n = 25), and truncal only in 9.7% (n = 7). The mean daily dose of oral isotretinoin was 0.32 ± 0.11mg/kg/day, over a mean treatment period of 18.10± 1.80 weeks, resulting in a mean cumulative dose of 98.50 ± 22.30 mg/kg.

Clinical Efficacy: At the end of treatment (16–20 weeks), 88.9% of the patients (64/72) achieved treatment success (IGA 0 or 1), (Figure 1). The remaining 11.1% (8/72) reached mild disease state (IGA 2). No poor response was observed.

Safety and Tolerability: As shown in Table (2), all reported adverse effects were mild (Grade 1). The incidence of adverse effects was as follows: Cheilitis 97.2% (70/72), xerosis 4.2% (3/72), myalgia 2.8% (2/72), dry eyes 4.2% (3/72), and transient headaches 2.8% (2/72). No mood alterations, severe skin reactions, or treatment discontinuations were recorded.

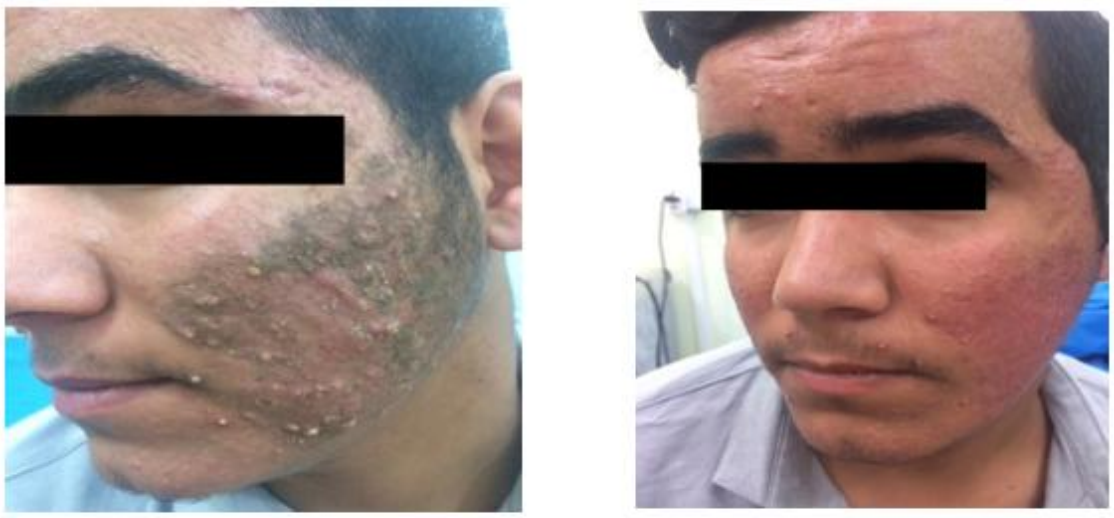
Laboratory Safety: No significant abnormalities were seen in laboratory safety parameters (LFTs or lipid profile) requiring intervention. All post-treatment values remained within normal limits. No significant changes were observed in laboratory safety parameters between baseline and the end of treatment, indicating a favorable biochemical safety profile.

follow-up and Relapse Outcomes: All patients entered follow-up (mean duration: 9.20 ± 2.10 months). During this period, 27.8% (20/72) experienced clinical relapse (median time: 5.5 months, range 3–10 months). All 20 relapsed patients were recommended to have a second identical low-dose course, reporting good efficacy and minimal side effects.

Table 1: Table 1: Baseline and treatment characteristics of the study cohort (N = 72)

Characteristic	Category	Value
Age (year), Mean ± SD		19.4 ± 3.10
Gender, n (%)	Male	42 (58.3%)
	Female	30 (41.7%)
Baseline IGA, n (%)	Mild (Grade 2)	19 (26.4%)
	Moderate (Grade 3)	31 (43.0%)
	Severe (Grade 4)	22 (30.6%)
Acne Distribution, n (%)	Face Only	40 (55.6%)
	Face & Trunk	25 (34.7%)
	Trunk Only	7 (9.7%)
Mean Daily Dose (mg/kg/day), Mean ± SD		0.3 ± 0.11
Cumulative Dose (mg/kg), Mean ± SD		98.5 ± 22.30

SD: Standard deviation. **IGA**: Investigator global assessment



A B

Figure (1). (A) Before isotretinoin treatment. (B) Almost clear (Grade 1) improvement at the end of the treatment course

Table 2: Incidence and Severity of Adverse Events During Treatment

Adverse Event	Incidence - n (%)	Severity	Management
Cheilitis	70 (97.2%)	Mild	Lip balm
Xerosis	3 (4.2%)	Mild	Emollients
Myalgia/Arthralgia	2 (2.8%)	Mild	Activity modification
Dry Eyes	3 (4.2%)	Mild	Artificial tears
Headache	2 (2.8%)	Mild, Transient	Spontaneous resolution

Subgroup and Correlational Analysis: No significant association was found between baseline acne severity and treatment success (X^2 = 2.34, *P* = 0.31). The mean daily dose was slightly lower in patients who later relapsed compared to those who remained in remission (0.29 ± 0.09 vs. 0.34 ± 0.12 mg/kg/day, respectively; *P* = 0.08, independent t-test). The cumulative dose showed a weak positive correlation with treatment success (Pearson's r = 0.21, *P* = 0.07).

Table 3: Comparison of IGA Scores Before and After Treatment

IGA Grade	Before Treatment n (%)	After Treatment n (%)
0 (Clear)	0 (0%)	40 (55.6%)
1 (Almost clear)	0 (0%)	24 (33.3%)
2 (Mild)	19 (26.4%)	8 (11.1%)
3 (Moderate)	31 (43.0%)	0 (0%)
4 (Severe)	22 (30.6%)	0 (0%)
Success rate (IGA 0–1)	0%	88.9%

Table 4: Statistical Correlations and Comparisons

Analysis	Variable 1	Variable 2	Test Value	P value
Chi-square	Baseline severity	Treatment success	χ^2 = 2.34	0.31
t-test	Daily dose (relapse vs. no relapse)	Relapse status	t = 1.78	0.08
Pearson correlation	Cumulative dose	Treatment success	r = 0.21	0.07

Discussion

This study demonstrated that in an adolescent / young adult Iraqi population, a flexible, low-dose isotretinoin regimen (0.1–0.5 mg/kg/day) is effective and safe for treating acne vulgaris. Our findings aligned with and extended the growing body of international literature advocating for a shift away from the rigid, high-cumulative-dose protocols for all patients (21-23), as well as recent Iraqi reports supporting the efficacy of low-dose approaches (24). The treatment success rate of 88.9% is comparable to rates reported in other standard-dose studies (6,25), indicating that significant clinical clearance can be achieved with lower daily and cumulative exposures. This is particularly relevant for patients with moderate acne, who constituted the largest subgroup in the current study and showed significant outcomes. This suggests that LDI may be suitable for this severity category.

The most notable finding is the exemplary safety profile. The complete absence of clinically significant laboratory abnormalities contrasts sharply with the well-documented 20%–45% incidence of hypertriglyceridemia and transaminitis, associated with conventional dosing (8,26). This underscores the profound dose-dependency of isotretinoin's metabolic effects and suggests that LDI regimens can markedly reduce this risk (27). The adverse event profile was dominated by mild, mucocutaneous effects, with no treatment discontinuations. This perfect adherence is a critical factor for real-world effectiveness and is rarely achieved with standard dosing due to its higher toxicity burden (10).

The principal trade-off observed was a relapse rate of 27.8%, which is higher than the <10%–20% often reported with cumulative doses of ≥120 mg/kg [6,28]. However, our study provides a crucial, patient-centered perspective on managing this trade-off. The 100% re-treatment acceptance rate among relapsed patients is a significant and novel outcome. It suggests that the positive initial experience — characterized by high efficacy and minimal discomfort — fostered significant patient trust and satisfaction. Consequently, patients viewed relapse not as a therapeutic failure, but as a manageable event with a known, tolerable solution (13). This "treat-and-re-treat-as-needed" paradigm, using a gentle regimen, may be preferable for many patients and parents over a single, more aggressive course that carries a higher short-term morbidity burden. This approach aligns with modern principles of personalized medicine and shared decision-making in dermatology (29).

In this study, a weight-based, low-dose isotretinoin, appeared to be effective and generally well-tolerated among the study group. This differs from the previous local reports that mainly used fixed daily doses (15-17), and therefore, add to the Iraqi experience of flexible dosing. Our observations are broadly consistent with findings from Asian and European studies that also suggest improved tolerability with low-dose regimens (18,19).

Although subgroup analysis did not identify statistically significant predictors of response or relapse—likely due to the modest sample size—the observed trends (lower daily dose in relapsed patients, r=0.21 for cumulative dose-success correlation) suggest that dose-dependent effects warrant further investigation in larger studies. The Chi-square analysis revealed no significant association between baseline acne severity and treatment success, suggesting that LDI is equally effective across all severity grades. The trend toward lower daily doses in patients who later relapsed did not reach statistical significance, which may reflect the limited sample size rather than a true absence of effect. The weak positive correlation between cumulative dose and treatment success further supports the dose-dependent nature of isotretinoin efficacy, although larger studies are needed to confirm this relationship.

Limitations

The present study has several limitations. The single-arm design without a comparator group precludes direct comparative efficacy conclusions. The relatively modest sample size and single-center setting may limit generalizability. In addition, the follow-up period may not capture very late relapses beyond 12 months, and the clinical definition of relapse may introduce subjectivity.

Conclusions

A flexible low-dose isotretinoin regimen represents an effective and safe therapeutic strategy for acne vulgaris. It achieves excellent clearance rates with markedly superior tolerability and biochemical safety compared to conventional dosing. Although associated with a higher relapse rate, its excellent side-effect profile ensures perfect compliance and makes re-treatment a highly accepted and effective management pathway. This approach should be considered a valuable first-line option, particularly for patients with moderate-to-severe acne, who prioritize tolerability and quality of life during treatment.

Authors' declaration:

We confirm that all the Figures and Tables in the manuscript belong to the current study. Besides, the Figures and images, which do not belong to the current study, have been given permission for re-publication attached to the manuscript. Authors sign on ethical consideration’s Approval-Ethical Clearance: The project was approved by the local ethical committee in (College of Medicine, University of AL-Qadisiyah) according to the code number (98) on (13/ 08/ 2023).

Conflict of Interest: Dr. Mohammed AH Jbarah is an Editor member of the journal but did not participate in the peer review process other than as an author
The authors declare that there is no conflict of interest regarding the publication of this paper.

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Data availability: Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' contributions:
Study conception & design: (Usama A. Althuwayni, Mohammed A-H Jabarah). Literature search: (Usama A. Althuwayni, Mohammed A-H Jabarah). Data acquisition: (Usama A. Althuwayni). Data analysis & interpretation: (Mohammed A-H Jabarah). Manuscript preparation: (Mohammed A-H Jabarah). Manuscript editing & review: (Usama A. Althuwayni, Mohammed A-H Jabarah).

AI Declaration: No artificial intelligence tools were used in the design, analysis, or writing of this manuscript.

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فعالية وسلامة الإيزوتريتينوين بجرعات منخفضة في علاج حب الشباب الشائع: دراسة مستقبلية أحادية الذراع

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الخلاصة

الخلفية: يؤدي استخدام إيزوتريتينوين بالجرعات التقليدية (0.5–1.0 ملغ/كغ/يوم) لعلاج حب الشباب البسيط إلى فعالية عالية ولكنه محدود بتأثيرات جانبية كبيرة. قد توفر الجرعات المنخفضة (≤0.5 ملغ/كغ/يوم) نسبة علاج أفضل.

الهدف: تقييم فعالية وسلامة ونتائج الانتكاس لبروتوكول إيزوتريتينوين منخفض الجرعة ومرن لدى المراهقين والشباب العراقيين.

الطرق: أُجريت دراسة مستقبليةاحادية الذراع شملت 72 مريضاً تتراوح أعمارهم بين 14–25 سنة يعانون من حب الشباب البسيط إلى الشديد، وتلقوا إيزوتريتينوين بجرعة 0.1–0.5 ملغ/كغ/يوم لمدة 16–20 أسبوعًا. أُجريت الدراسة في عيادة الأمراض الجلدية بمستشفى الديوانية التعليمي، العراق، بين يناير 2023 وديسمبر 2024. تم تقييم الاستجابة السريرية باستخدام التقييم العالمي للمحقق. تمت مراقبة السلامة عبر الأحداث الضارة والفحوصات المخبرية لوظائف الكبد وملف الدهون. تمت متابعة المرضى لمدة 6–12 شهرًا. تم عرض النتائج باستخدام الإحصاءات الوصفية.

النتائج: تم تحقيق نجاح العلاج في 88.9٪ (72/64) من المرضى. كانت الأحداث الضارة خفيفة تشمل التهاب الشفاه (97.2٪)، جفاف الجلد (4.2٪)، ألم العضلات (2.8٪)، جفاف العيون (4.2٪)، وصداع عابر (2.8٪). لم تحدث تغييرات في المزاج أو تفاعلات جلدية شديدة. لم تُلاحظ أي شذوذات مخبرية ذات دلالة سريرية. خلال المتابعة، حدث انتكاس لدى 27.8٪ (72/20)؛ وأكمل جميعهم بنجاح دورة ثانية منخفضة الجرعة مماثلة.

الاستنتاج: يُظهر الإيزوتريتينوين منخفض الجرعة فعالية عالية وسلامة استثنائية. على الرغم من أن معدلات الانتكاس أعلى مقارنة بالجرعات التقليدية، إلا أن التحمل الممتاز يدعم استخدامه كاستراتيجية أولية، مع إمكانية إعادة العلاج كخيار قابل للتطبيق.

الكلمات المفتاحية: حب الشباب البسيط؛ الجرعة التراكمية؛ الإيزوتريتينوين؛ العلاج منخفض الجرعة؛ الانتكاس.