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# Isotretinoin dosing in acne vulgaris: consensus or conviction?

Wojciech Modzelewski<sup>1\*</sup>, Danuta Borowska<sup>2</sup>

## ABSTRACT

Isotretinoin (13-cis-retinoic acid) was approved in 1982 by the U.S. Food and Drug Administration (FDA) for the treatment of nodulocystic acne. Currently, it is also used in the management of other dermatological conditions; however, its optimal dosing remains a subject of ongoing debate. An increasing body of research supports the superiority of low daily doses of isotretinoin compared to the originally approved higher doses. Low-dose regimens demonstrate comparable short-term efficacy—i.e., throughout treatment—while offering better tolerability and a lower incidence of adverse effects. Nevertheless, the persistence of acne remission after treatment—reflecting long-term efficacy—remains a topic of debate. Traditionally, reaching a cumulative dose of 120–150 mg/kg of body weight has been regarded as the key factor in achieving sustained remission. Recent studies, however, suggest that using low-dose oral isotretinoin until the acne is completely cleared, and then continuing treatment for another 2–3 months, can achieve similar effectiveness while causing significantly fewer side effects.

**Keywords:** acne vulgaris, isotretinoin, treatment, dosage

## 1. INTRODUCTION

Acne vulgaris is the most common dermatological condition during adolescence; however, its prevalence among older individuals is increasing. The primary etiological factors include increased sebum production under the influence of androgens, abnormal keratinization of the sebaceous duct resulting in sebum retention within the hair follicle, colonization of deeper follicular layers by the anaerobic bacterium *Cutibacterium acnes*, and the development of inflammation around the pilosebaceous unit.

For mild to moderate acne, first-line treatments typically include topical retinoids, benzoyl peroxide, and topical antibiotics. In cases of severe acne, a high risk of scarring, or insufficient response to topical therapy, oral isotretinoin is often prescribed. Isotretinoin is a first-generation retinoid that functions as a prodrug—its biological activity is mediated by its metabolites. Its high therapeutic efficacy is attributed to several mechanisms, including the: suppression of sebaceous gland activity, inhibition of bacterial proliferation, normalization of keratinization, and reduction of inflammation (Oge et al., 2019).

Over the course of more than four decades of clinical use, numerous studies have evaluated the efficacy of oral isotretinoin during treatment, the risk of relapse,

and the incidence of adverse effects. Most authors agree that low, standard, and high daily doses are all effective in treating acne (Costa et al., 2018).

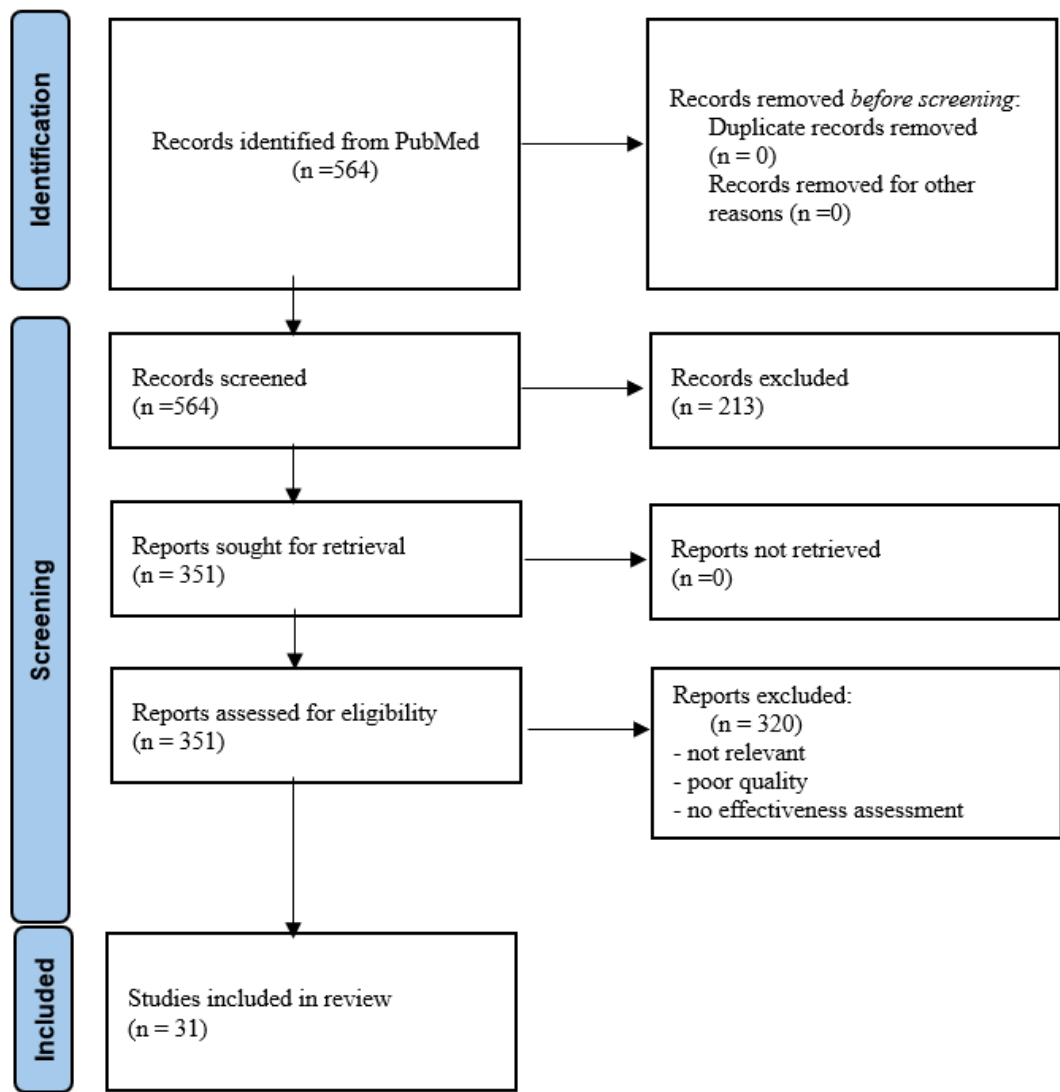


Figure 1: PRISMA diagram showing the article selection process.

2. REVIEW METHODS

This paper analyzes the literature from PubMed covering the years 1983–2022, using the keywords "isotretinoin," "acne vulgaris," "treatment," and "dosage." The inclusion criteria were based on the relevance to the topic and the presence of specific keywords. Publications outside the specified date range were excluded. Only articles written in English were analyzed. In total, 31 articles were included in our review (Figure 1).

3. RESULTS & DISCUSSION

Isotretinoin, which has been used in clinical practice for over 40 years, remains an essential medication in dermatology. Its therapeutic effectiveness, however, relies heavily on patients’ adherence to the prescribed treatment regimen (Table 1). If adverse effects— even the fear of them —discourage patients from continuing therapy, a critical opportunity for achieving significant clinical improvement and preventing irreversible consequences of acne, such as scarring, may be lost. Existing studies confirm that the use of low-dose oral isotretinoin in acne treatment provides short-term efficacy comparable to that of standard doses, while being associated with a lower

incidence of adverse events. In the authors' view, low daily doses of isotretinoin are fully adequate for the majority of patients, supporting better treatment adherence and greater satisfaction with both the therapeutic process and its outcomes.

**Table 1.** Characteristics of published studies evaluating isotretinoin use in acne

Investigators	Study design	Participants	Main findings
(Strauss et al., 1984)	Multicenter, dose–response clinical trial	150 patients with acne	Compared isotretinoin at 0.1, 0.5, and 1 mg/kg/day. All effective, but higher relapse with lowest dose.
(Shalita et al., 1983)	Clinical review	Not applicable	Summarized early isotretinoin experience; confirmed efficacy but emphasized monitoring for side effects.
(Harms et al., 1986)	Long-term follow-up study	89 patients with cystic acne	Relapse after isotretinoin was age-related, more frequent in younger patients.
(Harms, 1993)	Review article	Not applicable	Ten years' experience confirmed efficacy but highlighted relapse and safety concerns.
(Lehucher-Ceyrac et al., 1999)	Prospective cohort study	237 patients with acne	Identified predictors of treatment failure: male sex, severe baseline acne, lower cumulative doses.
(Layton et al., 1993)	Observational study, 10-year follow-up	Not specified	Confirmed isotretinoin as effective and safe long-term treatment with durable remission.
(Amichai et al., 2006)	Prospective study, low-dose regimen	638 patients with moderate acne	Low-dose isotretinoin (0.3–0.4 mg/kg/day) effective; relapse 3.9% at 4 years.
(Sardana & Garg, 2010)	Prospective trial	Not specified	Low-dose isotretinoin effective and well tolerated; viable alternative to conventional regimens.
(Agarwal et al., 2011)	Randomized comparative trial	120 patients	Different regimens all effective; intermittent dosing had higher relapse risk.
(Lee et al., 2011)	Randomized controlled trial	60 patients	Conventional, low-dose, and intermittent isotretinoin similarly effective; intermittent less durable.
(Boyraz & Mustak, 2013)	Comparative study	60 patients	Intermittent and continuous low-dose regimens had comparable efficacy; continuous more consistent.
(Cyrulnik et al., 2012)	High-dose treatment study	80 patients	High-dose isotretinoin improved outcomes and quality of life with acceptable safety.
(Blasiak et al., 2013)	Retrospective study	180 patients	High-dose isotretinoin reduced relapse and retreat rates; adverse effects manageable.
(Rademaker, 2013)	Review article	Not applicable	Reviewed 30 years of isotretinoin; dosing and relapse depend on cumulative exposure.

(Rao et al., 2014)	Prospective trial	50 patients	Low-dose isotretinoin effective and safe in moderate to severe acne.
(Rasi et al., 2014)	Prospective study	146 patients	Fixed 20 mg/day isotretinoin effective and safe for scar-prone acne.
(Zaenglein et al., 2016)	Guidelines of care	Not applicable	Comprehensive guidelines for acne management, isotretinoin central in severe cases.
(Faghihi et al., 2017)	Randomized trial	60 patients	Low dose (0.25 mg/kg/day) vs conventional (0.5 mg/kg/day): similar efficacy (95.4% vs 97% clearance).
(Tan et al., 2016)	Systemic review	Not applicable	Evaluated remission with cumulative dosing 120–150 mg/kg; supported as effective threshold.
(Rademaker, 2016)	Review article	1453 patients	Discussed cumulative dosing; higher total doses associated with lower relapse risk.
(Leyden et al., 2014)	Review article	Not applicable	Clinical considerations in isotretinoin therapy; emphasized individualized dosing.
(Oge et al., 2019)	Clinical review	Not applicable	Diagnosis and treatment update for acne vulgaris including isotretinoin.
(Abdelmaksoud et al., 2020)	Review article	Not applicable	Comprehensive review of low-dose isotretinoin; effective and safe across studies.
(Sadeghzadeh-Bazargan et al., 2020)	Systematic review	Not applicable	Reviewed low-dose isotretinoin: indication, dosage, regimen, efficacy, safety, satisfaction, follow-up.
(Al Muqarrab & Almohssen, 2022)	Systematic review & meta-analysis	Not applicable	Low-dose isotretinoin effective in adults with favorable safety profile.
(Costa et al., 2018)	Cochrane systematic review	3836 patients	Systematic review on oral isotretinoin for acne; confirmed efficacy but emphasized monitoring.
(Thiboutot et al., 2018)	International consensus guidelines	Not applicable	Global Alliance consensus on acne management; isotretinoin essential for severe acne.
(Landis, 2020)	Review article	Not applicable	Updated recommendations for isotretinoin dosing, safety, compliance, and outcomes.
(Ahmad, 2015)	Comparative study	58 patients	Once vs twice daily dosing: both effective; side effects and lab changes comparable.
(Fallah & Rademaker, 2021)	Review article	Not applicable	Practical prescribing guidance for isotretinoin in acne vulgaris.
(Fallah & Rademaker, 2022)	Review article	Not applicable	Update on adverse effects and lab monitoring during isotretinoin therapy.

### Early Use of Isotretinoin

From 1983 to 2000, multiple studies investigated the efficacy and safety of isotretinoin in acne treatment. These studies showed similar efficacy between three dosing regimens (0.1, 0.5, and 1 mg/kg/day); however, significant differences emerged in relapse rates, which were markedly higher with the lowest dose (Strauss et al., 1984). Doses below 1 mg/kg/day were avoided because of the increased risk of recurrence. A daily dose of 1 mg/kg/day was recommended, or 0.5 mg/kg/day in cases of adverse effects (Shalita et al., 1983).

Initially, no association was found between cumulative dose and acne recurrence (Harms et al., 1986). However, subsequent studies indicated that the best long-term results were achieved with cumulative doses in the range of 100–150 mg/kg. No additional benefit was observed with cumulative doses exceeding 150 mg/kg (Harms, 1993). Researchers held differing views on the importance of relapse in relation to total cumulative dosing. Some suggested that treatment length should be based on the daily dose and the pace of clinical improvement. Factors linked to a higher risk of relapse included younger age and more severe acne, while neither daily nor cumulative dose appeared to predict outcomes (Lehucher-Ceyrac et al., 1999).

Other studies, however, reported that patients who reached a cumulative dose >120 mg/kg experienced fewer relapses than those who received lower total doses (Layton et al., 1993). These researchers proposed that reduced daily doses might remain effective if the treatment period is prolonged to reach the advised cumulative dose. During the period from 1983 to 2000, low-dose regimens were shown to be as effective as standard dosing. However, due to inconsistent findings regarding relapse, standard dosing—aiming to reach a cumulative total of 120–150 mg/kg—was more commonly adopted in clinical practice.

#### Comparable Efficacy of Low and Standard Doses

Since the year 2000, a growing number of publications have highlighted the effectiveness of low-dose regimens (e.g., 20 mg/day) in the treatment of acne (Rao et al., 2014; Rasi et al., 2014). Several studies have demonstrated the advantages of using lower doses (0.3–0.4 mg/kg/day) over standard regimens, citing comparable therapeutic efficacy along with a reduced risk of adverse effects (Amichai et al., 2006; Sardana et al., 2010; Agarwal et al., 2011; Lee et al., 2011).

Therapeutic equivalence has also been observed between doses of 0.5 mg/kg/day and 0.25 mg/kg/day (Faghihi et al., 2017). It has been reported that administering isotretinoin at a dose of 1 mg/kg/day for mild to moderate acne is inappropriate, as it exposes patients to an increased risk of side effects (Sardana et al., 2010). Moreover, achieving a cumulative dose of 120–150 mg/kg may not be necessary to cure moderate acne (Boyras et al., 2013). An article summarising experiences with isotretinoin treatment was published in 2013 (Rademaker, 2013).

The author recommended continuing oral isotretinoin until the acne had cleared entirely, followed by a maintenance phase lasting another 3–4 months. The typical dose was 10–20 mg per day, with treatment lasting from 3 to 12 months depending on how severe the acne was and the individual patient's needs. Lower doses enabled the avoidance of most adverse effects associated with standard isotretinoin dosing, including acne flare-ups and excessive scarring.

Conversely, regimens involving doses above 1 mg/kg/day were rarely used. While they offered similar cure rates to standard regimens, they were associated with significantly higher rates of adverse effects (Cyrulnik et al., 2012; Blasiak et al., 2013). The 2016 guidelines recommended a standard dosing regimen of 0.5–1.0 mg/kg/day, aiming for a cumulative dose of 120–150 mg/kg in patients with severe acne. For patients with moderate acne, a low-dose regimen of 0.25–0.4 mg/kg/day was suggested. The recommended duration of therapy was 15–20 weeks. In very severe cases, low doses were also advised, with the optional addition of oral corticosteroids when necessary. Intermittent (non-continuous) dosing was deemed ineffective and associated with a higher risk of acne relapse (Zaenglein et al., 2016).

### The Significance of the Cumulative Total Dose

The effectiveness of acne remission has also been evaluated in relation to achieving a cumulative total dose of 120–150 mg/kg. Evidence suggests that the required cumulative dose of isotretinoin tends to be lower for the treatment of mild to moderate acne and higher for severe cases (Tan et al., 2016).

Researchers have also investigated the impact of both daily and cumulative dosing on acne relapse. It was concluded that neither the daily dose nor the cumulative dose significantly influences relapse rates—provided that treatment is continued for at least two months after the complete resolution of acne lesions (Rademaker, 2016).

### Short-Term vs. Long-Term Efficacy

Short-term success is defined as acne resolution following a single course of isotretinoin therapy. According to researchers, short-term outcomes do not depend on the daily dosage of the drug. No significant differences in treatment efficacy were observed among doses of 0.1, 0.5, and 1 mg/kg/day over a 20-week treatment period (Leyden et al., 2014).

Long-term success is defined as the absence of acne relapse after completing therapy. This outcome is believed to depend on reaching a specific cumulative dose during the initial course. A cumulative dose of 120–150 mg/kg is generally recommended to maintain lasting results and reduce the risk of recurrence. The authors propose initiating therapy with a standard dose of 0.5 mg/kg/day for the first 4 weeks, followed by an increase to 1 mg/kg/day (administered BID—twice daily) through the end of the fifth month. If adverse effects become intolerable, lower doses may be used, provided that the target cumulative dose is ultimately achieved.

In studies involving patients treated exclusively with isotretinoin and followed for three years, researchers found that the risk of acne relapse was eight times higher in patients who received a total dose of <100 mg/kg compared to those who received >100 mg/kg.

Additionally, relapse occurred in 92% of patients whose total dose was <90 mg/kg, whereas only 40–50% of those who received >110 mg/kg experienced recurrence.

### Findings from Studies Published After 2018

Recommendations for initiating therapy at 0.25–0.4 mg/kg/day in cases of moderate acne, and 0.5 mg/kg/day in severe cases, have been reaffirmed. For patients with severe acne, gradual dose escalation up to 1 mg/kg/day, along with achieving a cumulative dose of 120–150 mg/kg, has been advised to reduce the risk of relapse (Oge et al., 2019). However, some authors have noted that individualized dose adjustment based on patient-specific needs—even when resulting in a cumulative dose below the recommended threshold—does not increase the risk of relapse or adverse events, including hepatotoxicity (Abdelmaksoud et al., 2020).

The benefits of low-dose regimens (0.1–0.3 mg/kg/day) in reducing side effects have also been confirmed. For example, while up to 98% of patients receiving 1 mg/kg/day reported adverse events, this proportion dropped to only 50% among those treated with less than 0.25 mg/kg/day (Sadeghzadeh-Bazargan et al., 2020). Nevertheless, some researchers maintain that standard-dose isotretinoin may be more effective than low-dose regimens in preventing relapse in adults with mild to moderate acne (Al Muqarrab et al., 2022). A Cochrane review involving 3,836 patients concluded that further studies are needed to assess optimal oral isotretinoin dosing across different severities of acne (Costa et al., 2018).

The 2018 publication *Practical Management of Acne for Clinicians* summarized current dosing recommendations for isotretinoin (Thiboutot et al., 2018). One key guideline proposed maintaining therapy throughout the treatment period and continuing for one additional month after complete clearance. The authors stressed that existing data do not yet allow for a precise definition of the dose needed to sustain remission. Risk factors for relapse include younger age, truncal acne, pronounced seborrhea, and a positive family history. It was also noted that the risk of acne flare—observed in up to 15% of patients following initiation of isotretinoin—can be minimized by starting treatment at a low dose.

Interestingly, two seemingly opposing therapeutic strategies—targeting a cumulative dose of 120–150 mg/kg versus continuing treatment until full clearance plus an additional month—often yield similar clinical outcomes over time (Landis, 2020). Patients with treatment-resistant acne may still require higher cumulative doses. No statistically significant difference in treatment efficacy has been found between once-daily and twice-daily isotretinoin dosing (Ahmad, 2015).

The interpretation of cumulative dosing has also evolved. Rather than rigid adherence to a numerical threshold, therapy is now increasingly guided by achieving complete clinical resolution, followed by a continuation period of 2–3 months. This strategy reduces the risk of dose-dependent adverse effects. The traditional regimen of 0.5–1.0 mg/kg/day administered over a fixed period (typically 20 weeks) is now regarded as outdated. Similar clinical outcomes can be achieved with low-dose therapy—even without reaching the cumulative threshold—while significantly lowering the risk of side effects (Fallah and Rademaker, 2021).

The most common adverse effect during isotretinoin treatment remains cheilitis, the severity of which is dose-dependent. Although isotretinoin is associated with a broad spectrum of potential adverse effects, low-dose treatment regimens substantially reduce their frequency, including the risk of acne flare, which is regarded as one of the most serious complications of therapy (Fallah and Rademaker, 2022).



#### 4. CONCLUSION

Nearly 40 years of clinical experience with isotretinoin support the conclusion that low-dose oral isotretinoin regimens in the treatment of acne offer short-term efficacy comparable to standard dosing, while being associated with a lower risk of adverse effects. However, long-term effectiveness remains a subject of ongoing debate and requires further research. At present, achieving a cumulative dose of 120–150 mg/kg is a commonly accepted and effective strategy for maintaining remission. Nevertheless, an equally effective approach involves administering low doses until complete clinical clearance is achieved, followed by an additional 1–3 months of maintenance therapy to consolidate the therapeutic outcome.

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#### Author contributions

Wojciech Modzelewski - Literature review and writing a scientific paper

Danuta Borowska - Literature review and modification of scientific work

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#### Ethical approval

Not applicable.

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#### Conflict of interest

The authors declare that there is no conflict of interest.

#### Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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