

Weight Change and Dose Adjustment in Isotretinoin Therapy: A Retrospective Study

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ABSTRACT

Isotretinoin is used to treat severe nodulocystic acne. Cumulative doses of 120 to 150 mg/kg have been shown to limit adverse events while maximizing efficacy. Also proven safe, doses of 220 mg/kg and higher may be necessary to achieve optimal clinical results. The current standard of care uses the patient's starting weight to determine goal dosing. This study seeks to identify specific patient groups among adolescents who are likely to experience a significant change in weight necessitating an adjustment to isotretinoin dosage over time. A retrospective cohort study was conducted on adolescent patients who received isotretinoin therapy at Augusta University between 2015 and 2020. A total of 57 patients were analyzed in subgroups of age, gender, and duration of therapy. Results demonstrated that despite a statistically significant weight change among the stratified treatment duration groups, the differences did not prove to be clinically impactful and do not support changing the current standard of care.

J Drugs Dermatol. 2025;24(6):639-640. doi:10.36849/JDD.8949

INTRODUCTION

Isotretinoin has been used to treat severe acne vulgaris since the early 1980s. Initial studies demonstrated acne improvement with dosing regimens of 0.1, 0.5, or 1.0 mg/kg daily.^{1,2} A decade later, cumulative doses of 120 to 150 mg/kg were shown to limit recurrence and adverse events while maximizing efficacy.³ Subsequently, doses of 220mg/kg and greater have also been proven safe in patients demonstrating limited initial response to therapy and have resulted in significantly decreased risk of relapse.⁴ Current standard of care uses the patient's starting weight to determine the cumulative dose, but does not consider the impact of weight change during treatment. For most maturing adolescents, weight change during the treatment period is expected. This study seeks to identify specific patient groups more likely to experience significant changes in weight necessitating adjustments to a target cumulative dose.

MATERIALS AND METHODS

A retrospective cohort study was conducted on patients with acne who were registered in the iPLEDGE database by Augusta University physicians between January 1, 2015, and December 31, 2020. Inclusion criteria included ages 13 to 21 years with documented pre- and post-therapy weights. Patients were stratified by age, sex, and treatment duration in months. Fifty-seven patients were identified; however, 1 outlier with

substantial weight loss was excluded (Table 1). Average weight changes with standard deviations were calculated. One-way analysis of variance (ANOVA), unpaired t-test, and Kruskal-Wallis Test were used to determine the significance of weight change within each stratified group.

TABLE 1.

Patient Demographics by Age, Sex, and Treatment Duration on Isotretinoin

Demographics	Number of Participants (%)
Overall	56
Sex	
Male	50 (89.29)
Female	6 (10.71)
Age	
13-15 years old	23 (41.07)
16-18 years old	26 (46.43)
19-21 years old	7 (12.5)
Treatment Duration	
1-5 months	20 (35.71)
6-10 months	29 (51.79)
11-15 months	7 (12.5)

TABLE 2.

Comparison of Mean Weight Change Among Patient Stratification Groups: Age, Sex, and Treatment Duration While on Isotretinoin				
		Mean weight change in kg (SD)		P-value(s)
Sex	--	Male	Female	--
		+0.78kg (0.64kg)	+0.77kg (0.64kg)	0.9897
Age	13 – 15 years	16 – 18 years	19 – 21 years	--
	+0.94kg (1.2kg)	+0.66kg (1.55kg)	+0.69kg (1.89kg)	0.7946
Treatment Duration	1-5 months	6-10 months	11-15 months	--
	+0.25kg (1.34 kg)	+1.05 kg (1.42 kg)	+1.40kg (2.00kg)	*0.01298† **0.6135 ***0.02564†

SD, Standard deviation

† Statistical significance $P < 0.05$

*Compares weight change over 1-5 months of therapy vs 6-10 months of therapy across all age groups

**Compares weight change over 6-10 months of therapy vs 11-15 months of therapy across all age groups

***Compares weight change over 1-5 months of therapy vs 11-15 months of therapy across all age groups

RESULTS

The duration of isotretinoin therapy varied from 1 to 15 months: 35.71% were treated for 1 to 5 months, 51.79% were treated for 6 to 10 months, and 12.5% were treated for 11 to 15 months. The overall mean weight change was +0.78 kg ($SD = 1.9$ kg). Among males and females, the mean weight changes were +0.78 kg ($SD = 0.64$ kg) and +0.77 kg ($SD = 0.64$ kg), respectively. The mean weight changes in the 13-15, 16-18, and 19-21 age groups were +0.94 kg ($SD = 1.2$ kg), +0.66 kg ($SD = 1.55$ kg), and +0.69 kg ($SD = 1.89$ kg). No statistical difference was found between males and females ($P = 0.9897$; 95% CI [-2.793, 2.757]) or between the age groups $P = 0.7946$ (Table 2). The mean weight changes for 1 to 5 months, 6 to 10 months, and 11 to 15 months were +0.25kg ($SD = 1.34$ kg), +1.05 kg ($SD = 1.42$ kg), and +1.40 kg ($SD = 2.00$ kg). Statistically significant differences in weight were observed when comparing: 1 to 5 months vs 6 to 10 months duration ($P = 0.01298$), and 1 to 5 months vs 11 to 15 months duration ($P = 0.0265$).

The patients treated 11 to 15 months had the highest average weight change of 1.40 kg, which would not extend therapy more than 5 days using a dosing scale of 120 to 150 mg/kg and 8 days using 220 mg/kg. Despite observing a statistically significant weight change among the stratified treatment duration groups, these differences are not clinically impactful and do not support changing the current standard of care.

DISCUSSION

This study was limited by its small sample size and unequal distribution of patients within stratified groups. Also, the study design did not account for biopsychosocial or medical factors that contribute to weight change while on isotretinoin.⁵ This investigation demonstrated that pediatric patients on isotretinoin therapy are unlikely to have a clinically significant weight change, regardless of age, sex, or duration of therapy, that would alter the cumulative goal dose range or duration of therapy. While utilizing starting weight remains a useful clinical

tool to determine treatment goals, it does not establish a strict cut-off for treatment. Management of isotretinoin is best based on individual response to therapy.

DISCLOSURES

The authors have no conflicts of interest to disclose.

ACKNOWLEDGMENT

Thank you to Dr Hanwen Huang from the Department of Biostatistics and Data at the Medical College of Georgia for assisting with the statistical analysis of this data.

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