

Efficacy of Generic vs. branded Isotretinoin for Acne treatment: a case report

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ABSTRACT

Acne vulgaris can have significant psychological effects and leave extreme skin scarring on the patient. Also, this condition can cause discomfort, disfigurement of the skin, emotional stress, anxiety, and embarrassment. Acne can be treated using either systemic or topical therapies. The effectiveness of oral isotretinoin in acne vulgaris has been well established. The recommended daily prescription varies from 0.5 to 1 mg/kg. The therapy should be maintained for several months to reach cumulative doses of 120-150 mg/kg in maximum. Nevertheless, numerous side effects are identified with its use, some of which can lead to very devastating consequences. Some patients may develop serious early flaring of AV with various deep inflammatory papules and nodules. In other cases, patients may experience a lot of intolerability of dose-related side effects, including xerophthalmia, xerosis, myalgia, and cheilitis. Based on this information, the current paper sought to present a case report of a patient with acne vulgaris and their response to isotretinoin of different generics. The patient did not experience improvements in their acne condition while on generic medications. In line with the reviewed literature, generic medications are linked with comparable effectiveness with their brand counterparts, but bioequivalence tests should be questioned.

Keywords: Acne, Branded, Efficacy, Generic, Isotretinoin, Retinoid

Introduction

Acne vulgaris AV is a prevalent chronic inflammatory condition that affects the skin's pilosebaceous units. The disorder is found in about 80 percent of young adults. It can have significant psychological effects and can leave extreme skin scarring on the patient. Specifically, acne can result in the following negative effects on young adolescents - discomfort, disfigurement of the skin, emotional stress, anxiety, and embarrassment. Some of the factors that may occasion or increase the severity of acne include genetics, youth stress, the male sex, smoking, and comedogenic medications [1, 2]. Additionally, there exists a

considerable body of literature suggesting the combined effect of genetic influence and comedogenic hormones on acne lesions [3, 4].

Acne treatment options may constitute either systemic or topical therapies. Topical therapies come in handy when dealing with mild and moderate acne. These therapies can be used independently or in combination with other treatment approaches. Examples of key topical therapies include benzoyl peroxide, topical retinoids, and topical antibiotics. Benzoyl peroxide is a broad-spectrum topical therapy whose effectiveness is guided by its oxidizing activity. It is available in various formulations – washes, creams, lotions, and gels. Retinoids target the microcomedo-precursor lesion of acne and are mostly prescribed as the first-line therapy, independently or in combination. Topical antibiotics prevent the growth of *P. acne* and reduce the occurrence of inflammation. Additional topical agents that could be used include combination therapy, salicylic acid, azelaic acid, lactic acid/ lactate lotion, tea tree oil, picolinic acid gel, and dapsone gel. Systemic therapies include antibacterial, hormonal, and retinoids. Systemic antibiotics are prescribed in mostly moderate-to-severe

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inflammatory acne, and the most common first choice options include tetracyclines and derivatives. Hormonal therapy may be required in female patients experiencing serious seborrhea and works to avert the effects of androgens on sebaceous glands and follicular keratinocytes. Currently, old and new topical and systemic agents are available to treat acne, which can at times confuse dermatologists. During the treatment process, the patient's progress is documented and as the clinical condition advances, the regimen may be modified [5, 6].

A series of recent studies have identified isotretinoin therapy as a successful treatment for AV. Approved by the United States Food and Drug Administration in 1982, isotretinoin acts as a non-aromatic retinoid. Since its introduction in the market, oral isotretinoin has demonstrated its effectiveness in the treatment of severe and recalcitrant cases of inflammatory acne. Millions of patients, including a subclass of children, have undergone treatment with isotretinoin. Clinical studies and worldwide experience have shown that isotretinoin provides total or nearly complete remission of acne, with long-lasting therapeutic benefits after completion. The most important bit is that isotretinoin remains as the only therapy for acne that can induce remission upon completion of an adequate course of therapy. Lengthy remissions happen with reasonable certainty among most of the patients. Due to the many people with severe and recalcitrant acne who have been treated worldwide, various publications have dealt with the need for retreatment of acne with isotretinoin [7].

The recommended daily prescription varies from 0.5 to 1 mg/kg. The therapy should be maintained for several months to reach cumulative doses of 120-150 mg/kg in maximum. Additionally, researchers recommend the use of isotretinoin therapy for acne cases that are intractable to conventional therapy with a topical retinoid, benzoyl peroxide (BPO) as well as oral antibiotic therapy. Prescribing guidelines also require those female patients of childbearing potential experiencing severe nodular acne use an oral contraceptive or any other form of highly effective contraceptive before taking on isotretinoin therapy [8].

A recent evidence-based update reviewed approaches to managing AV. The researchers identified oral isotretinoin monotherapy as the gold-standard treatment for severe acne. These findings were reached after a review of various RCTs comparing oral isotretinoin monotherapy to several alternatives in the treatment of moderate to severe acne. Using isotretinoin intermittently together with other topical treatments for severe acne did not confer any clear benefit compared to relying on a standard course of oral isotretinoin. The implication from this study is that isotretinoin monotherapy is the treatment of choice among acne patients [9].

Some authors have presented the dosing requirements of oral isotretinoin, reported data on factors that could lead to relapse after oral isotretinoin therapy, and the possible effect of co-administering the therapy with food. The study recommends an optimal initial daily dose of oral isotretinoin of 0.5mg/kg/day, with the potential of increasing it to 1mg/kg/day within 4 to 8 weeks if the patient does not report any serious clinical events.

Past research recommends such a dosage considering that some patients could develop acute early flaring of AV with various deep inflammatory papules and nodules. Besides, others could experience a lot of intolerance of dose-related side effects, including xerosis, xerophthalmia, myalgia, and cheilitis. Certain modes of the drug are responsible for causing sustained remission. For instance, isotretinoin activates a dose-dependent reduction in the size and cross-sectional area of sebaceous glands, which is believed to be a key mode of action of oral isotretinoin in AV treatment. Recently, isotretinoin has been found to cause a longstanding effect on monocyte expression of Toll-like receptor-2 (TLR-2), an outcome that correlates with extended remission after therapy cessation. Isotretinoin also acts by inhibiting comedogenesis. An analysis of different scenarios in oral isotretinoin prescribing patterns, dispensing and administration of medication, and eating habits among adolescents, most studies suggest the use of oral isotretinoin without food [10].

Many side effects, some of which may lead to very devastating results, are known by their use. Some patients may develop serious early flaring of AV with various deep inflammatory papules and nodules. In other cases, patients may experience a lot of intolerance of dose-related side effects, including xerophthalmia, xerosis, myalgia, and cheilitis. The frequency of isotretinoin-related side effects were tested in a recent study among different groups in a multicenter and controlled study. The first group had 66 patients with moderate to severe cases and received isotretinoin for the first 10 days of every month for 6 months. The second group received isotretinoin every day in the first month and the first 10 days of every month for 5 months afterward. The last group received isotretinoin every day for 6 months. In all three groups, patients received a dosage of 0.5 mg/kg each day and were followed-up for 12 months. The rate of recurrence and severity of side effects affiliated with isotretinoin was found to be lower in the 1st and 2nd groups compared to the 3rd. These findings imply that intermittent administration of isotretinoin could be an effective alternative treatment, more so in moderate acne [11, 12].

This paper aims to document the efficacy and typical side effects of isotretinoin therapy between different generics for the treatment of acne in one patient.

Case report

The case of 16 years old female presenting with a moderate type of AV. The patient tried over the counter and various other prescribed medications of either topical or oral regimens with no improvement for one year. On the 17th of September 2020, her doctor prescribed the local brand of isotretinoin 40 mg per day (1 mg/kg/day). For 64 days, the acne did not improve, and the patient noticed the deterioration of the acne appearance. The patient reported none of the typical side effects of isotretinoin. After filling the prescription with the genuine brand isotretinoin, the patient started to notice dryness after 3 days of use. After 45 days of use, the acne went from moderate to mild. The patient reported her concern to the doctor "I read

a lot of posts on social media of patients experiencing a similar problem – delay in experiencing the positive results.”

Results and Discussion

Acne is an upsetting and at times painful problem that affects many teenagers worldwide. The presented case demonstrates the use of generic vs. brand name isotretinoin to treat moderate AV. In this study, generic isotretinoin was found to be less effective compared to brand name varieties and resulted in increased severity of side effects. Treating the patient with the genuine brand isotretinoin resulted in significant reductions in acne scores within a short period. The patient tolerated the new prescription well with limited side effects reported. Consistent with the reviewed results, generic medications are associated with comparable effectiveness with brand medication but could also lead to adverse effects [13]. For instance, the patient in the case report did not experience improvements in their acne condition while on generic medications. Additionally, the study shows significant differences between generic and brand name isotretinoin regarding the time taken to experience a positive outcome. These results, in general, are consistent with previous studies that confirm the effectiveness of brand isotretinoin when administered under the right schedule [11, 12]. The outcome of the case can help encourage educational interventions focused on reviewing the effectiveness of generic medications in managing conditions, such as AV.

Conclusion

In this report, we present a case of a 16-year-old female patient with a moderate type of AV. The case report emphasizes the different responses, effectiveness, side effects between two generics of different companies of isotretinoin for the treatment of acne. While the standard daily dose of isotretinoin is the same, it is clear that bioequivalence is not at least for this one patient experience. Additional well-designed studies are needed to explore the bioequivalences between different generics of isotretinoin.

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Ethics statement: None

References

1. Allam AT, Amer SM. Prevalence and factors influencing self-medication in Medina Al-Munawara, Saudi Arabia. *Arch Pharma Pract.* 2020;11(4):43-54.
2. Algahtani FD. Healthy Lifestyle among Ha'il University Students, Saudi Arabia. *Int J Pharm Res Allied Sci.* 2020;9(1):160-7.
3. Fox L, Csongradi C, Aucamp M, du Plessis J, Gerber M. Treatment Modalities for Acne. *Molecules.* 2016;21(8):1063. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6273829/>
4. Olutunmbi Y, Paley K, English JC. Adolescent Female Acne: Etiology and Management. *J Pediatr Adolesc Gynecol.* 2008;21(4):171-6.
5. Rathi SK. Acne Vulgaris Treatment: The Current Scenario. *Indian J Dermatol.* 2011;56(1):7-13.
6. Gold LS, Baldwin HE, Lin T. Management of Severe Acne Vulgaris With Topical Therapy. *J Drugs Dermatol.* 2017;16(11):1134-8.
7. Leyden JJ, Del Rosso JQ, Baum EW. The Use of Isotretinoin in the Treatment of Acne Vulgaris. *J Clin Aesthet Dermatol.* 2014;7(2 Suppl): S3-21.
8. Zaenglein AL, Thiboutot DM. Expert Committee Recommendations for Acne Management. *Pediatrics.* 2006;118(3):1188-99.
9. Ingram JR, Grindlay DJC, Williams HC. Management of Acne Vulgaris: An Evidence-based Update. *Clin Exp Dermatol.* 2010;35(4):351-4.
10. Del Rosso JQ. Face to Face with Oral Isotretinoin: A Closer Look at the Spectrum of Therapeutic Outcomes and Why Some Patients Need Repeated Courses. *J Clin Aesthet Dermatol.* 2012;5(11):17-24.
11. Akman A, Durusoy C, Senturk M, Koc CK, Soyurk D, Alpsoy E. Treatment of Acne with Intermittent and Conventional Isotretinoin: A Randomized, Controlled Multicenter Study. *Arch Dermatol Res.* 2007;299(10):467-73.
12. Alsaleh N, Alshammari E. Intermittent dosing of isotretinoin. *Int J Pharm Res.* 2021;13(1):3506-8.
13. Alsaleh N, Alsharif A, Alshammari E. Do generic medicines compromise quality? *Int J Pharm Res.* 2021;13(1):919-23.