An Observation Study Evaluating the Efficacy and Tolerability of Tazarotene 0.05% and 0.1% Gels, as Monotherapy and in Combination with Adjunctive Therapies, in Stable Plaque Psoriasis

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Introduction

The use of tazarotene gel in the treatment of plaque psoriasis has been evaluated extensively under clinical trial conditions, both as monotherapy[1,2] and in combination with a topical corticosteroid[3,4] or UVB phototherapy.[5] Because study protocols of clinical trials necessarily impose certain restrictions on treatment regimens, such as prohibiting the use of certain medications concomitantly, study treatments may not always accurately reflect everyday clinical prescribing decisions. To address this issue, a large-scale observation study has been performed in which investigators were afforded greater flexibility, in terms of permitted concomitant medications and the timing of patient evaluation visits, than is often possible within the confines of a clinical trial.

Objective

To confirm previous reports, both anecdotal and published,[3] which suggest that the adjunctive use of an emollient and/or a mid- or high-potency corticosteroid helps to optimize the efficacy and tolerability of tazarotene treatment.

Methods

Study design

- Multicenter, open-label study.
- Maximum of 5 patients enrolled per study site (to ensure inclusion of a broad cross-section of patients).

Inclusion criteria

- Stable plaque psoriasis on up to 20% of body surface area.

Exclusion criteria

- Women who were pregnant, nursing, or planning a pregnancy during the course of the study.
- Women unwilling to use reliable contraception.

Treatment regimen

- Tazarotene 0.05% or 0.1% gel once daily for up to 12 weeks, either as monotherapy or in combination with other psoriasis therapies.

Efficacy evaluations

- Patients were assessed clinically at Visit 1 (baseline), Visit 2 (at a mean of 4 weeks), and Visit 3 (at a mean of 10 weeks).
- The overall severity of the psoriasis, and the degree of plaque elevation and scaling, were graded as severe, moderate, mild, trace, or none. A 1-grade improvement was from severe to moderate, moderate to mild, mild to trace, or trace to none. A 2-grade improvement was from severe to mild, moderate to trace, or mild to none.

Results

A total of 1,314 patients were enrolled by 285 physicians.

Efficacy

Tazarotene monotherapy versus tazarotene plus emollient

Use of an emollient* in conjunction with tazarotene increased the percentage of patients achieving an improvement in plaque elevation of 1 grade or more by Visit 3—from 40% with tazarotene alone to 60% with tazarotene plus emollient (Figure 1).

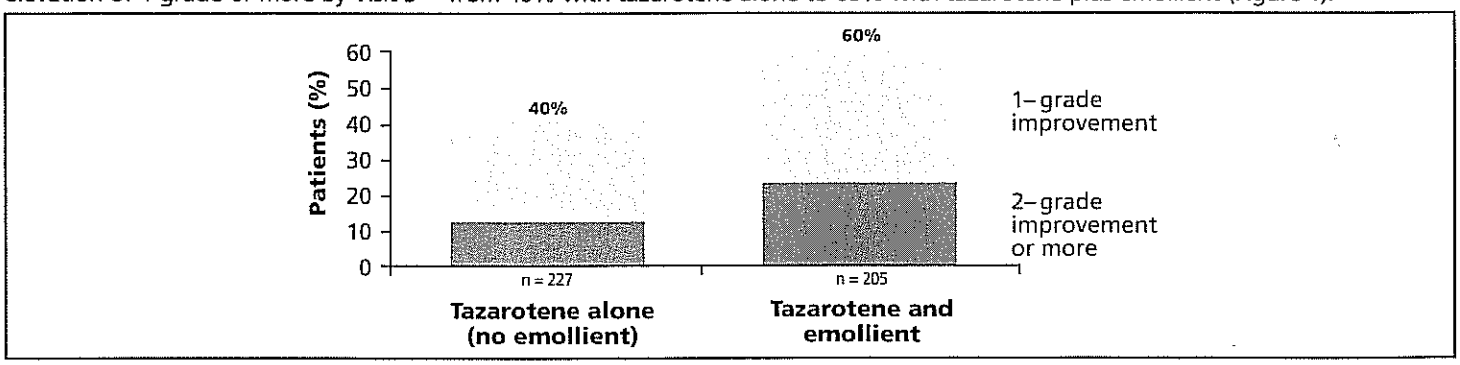

Figure 1. Percentage of patients who achieved at least a 1-grade improvement in the degree of plaque elevation at Visit 3 with tazarotene treatment, with and without adjunctive use of an emollient. (A 1-grade improvement is from severe to moderate, moderate to mild, mild to trace, or trace to none. A 2-grade improvement is from severe to mild, moderate to trace, or mild to none.)

Tazarotene monotherapy versus tazarotene plus corticosteroid

Use of either a mid- or high-potency corticosteroid[1] or a superpotent corticosteroid[1] in conjunction with tazarotene increased the percentage of patients achieving improvements of 1 grade or more in the overall severity of psoriasis, degree of plaque elevation, and degree of scaling (Figure 2).

For all three of these parameters, efficacy at the end of treatment was optimal in the patients treated with a mid- or high-potency corticosteroid in conjunction with tazarotene.

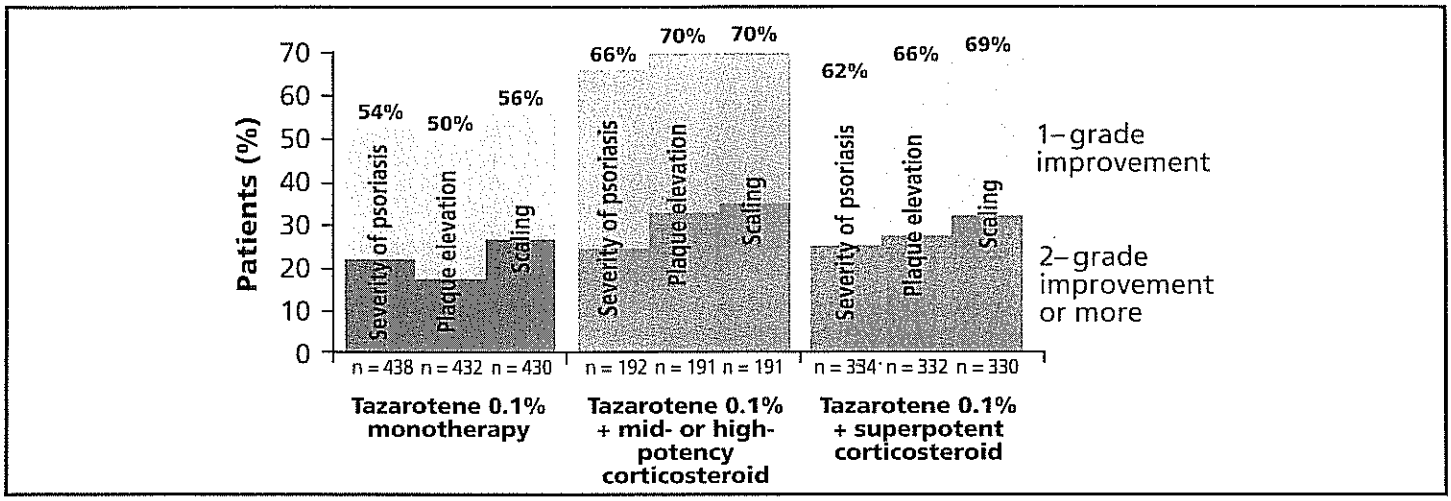

Figure 2. Percentage of patients who achieved at least a 1-grade improvement in the severity of psoriasis, plaque elevation, and scaling at Visit 3 with tazarotene treatment, with and without adjunctive use of a topical corticosteroid. (A 1-grade improvement is from severe to moderate, moderate to mild, mild to trace, or trace to none. A 2-grade improvement is from severe to mild, moderate to trace, or mild to none.)

Tazarotene plus steroid in patients switched from calcipotriene with or without a steroid

A total of 166 patients had been treated with calcipotriene with or without a steroid immediately before the start of this study and were switched to treatment with tazarotene plus steroid on the first day of this study. In this subset of switched patients, substantial additional improvements in efficacy were obtained (beyond any obtained with calcipotriene ± steroid treatment). Additional improvements of 1 grade or more in the severity of plaque psoriasis, plaque elevation, and scaling were achieved by 71%, 73%, and 75% of these patients by Visit 3, respectively (Figure 3). Additional mean percentage reductions in the severity of plaque psoriasis, plaque elevation, and scaling were 35%, 41%, and 44% by Visit 3, respectively.

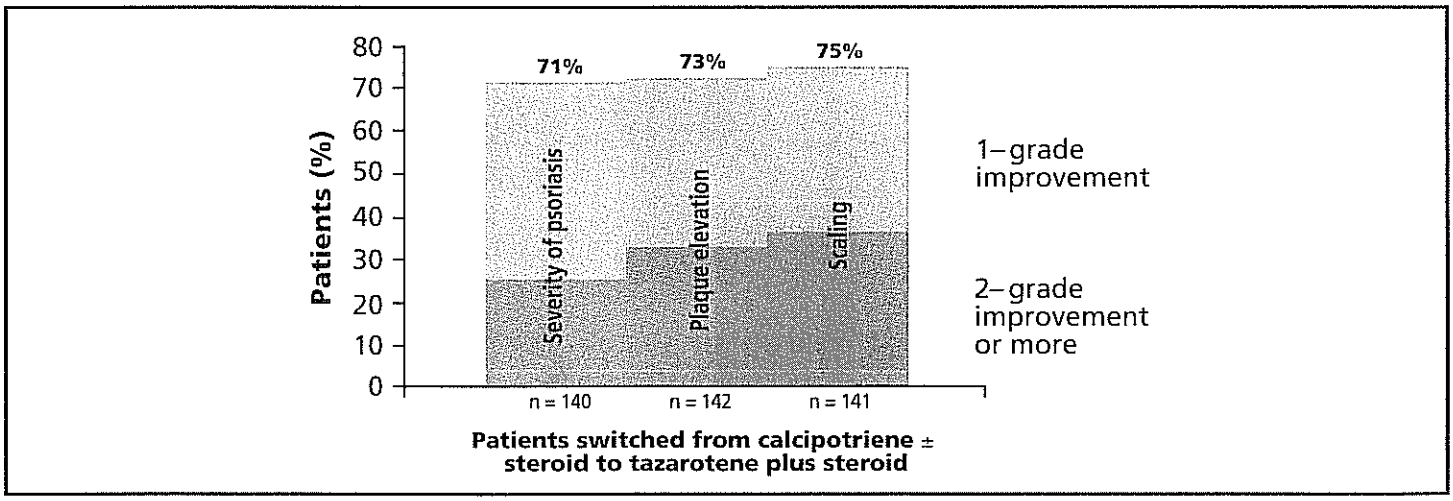

Figure 3. Percentage of patients switched from treatment with calcipotriene ± steroid who achieved at least a 1-grade improvement in the severity of psoriasis, plaque elevation, and scaling at Visit 3 with tazarotene plus steroid treatment. (A 1-grade improvement is from severe to moderate, moderate to mild, mild to trace, or trace to none. A 2-grade improvement is from severe to mild, moderate to trace, or mild to none.)

Tolerability and safety

The incidence of adverse events declined between Visits 2 and 3, suggesting that the tolerability of tazarotene therapy improved with continued treatment (Figure 4).

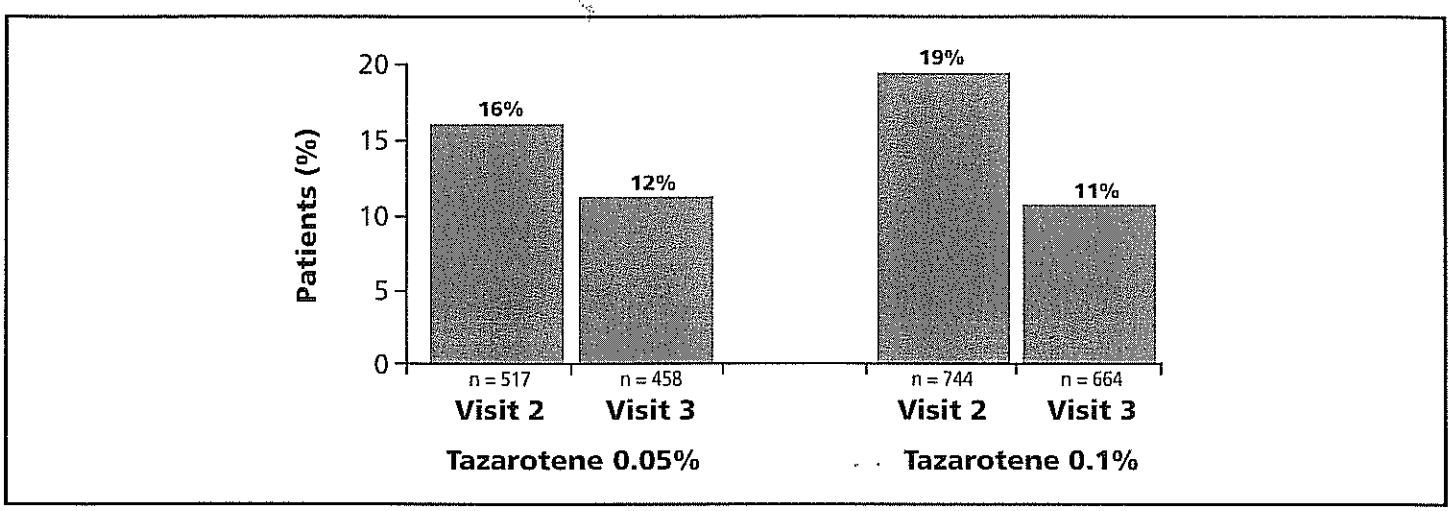

Figure 4. Incidence of adverse events during treatment with tazarotene 0.05% and 0.1% gels.

The use of a mid- or high-potency corticosteroid, or a superpotent corticosteroid, in conjunction with tazarotene reduced the incidence of adverse events at Visit 2 compared with tazarotene monotherapy (Figure 5), showing that such steroids can offer improved tolerability in the early weeks of treatment with tazarotene when adverse effects are most common.

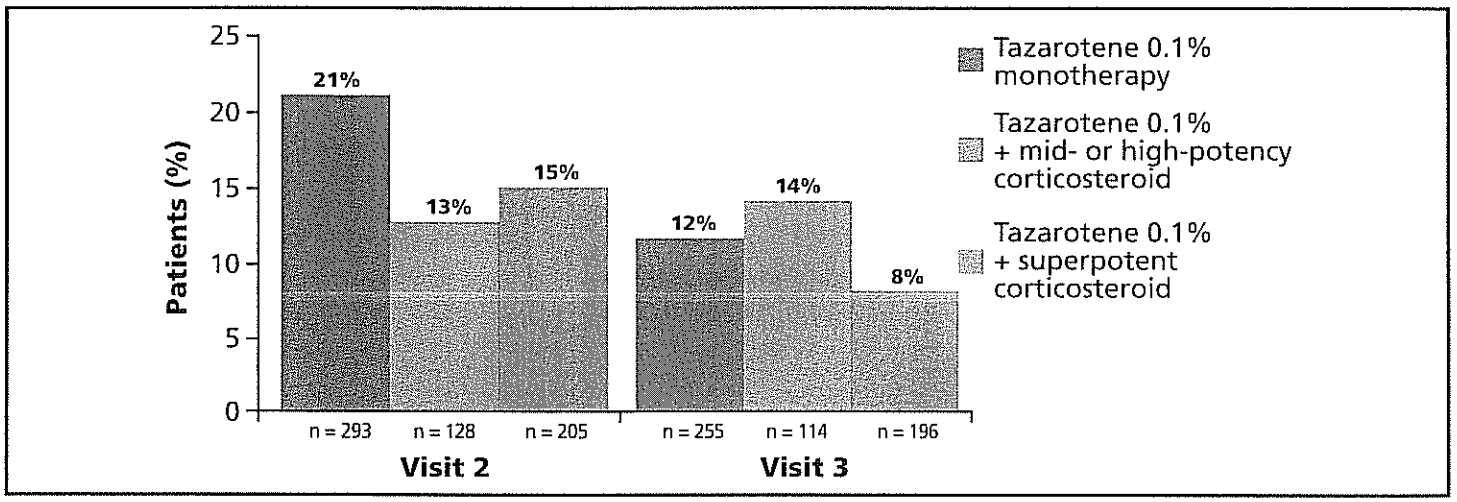

Figure 5. Incidence of adverse events during tazarotene treatment, with and without the adjunctive use of a topical corticosteroid.

Patient satisfaction

The percentage of patients who were satisfied with their current treatment regimen doubled from 27% at baseline (pre-tazarotene treatment) to 54% at Visit 2, and further increased to 60% at Visit 3 (Figure 6). In the subset of patients switched from calcipotriene ± steroid to tazarotene plus steroid treatment, the percentage of satisfied patients increased even more dramatically, from 28% at baseline to 67% at Visit 2, and 73% at Visit 3.

The use of an emollient and/or a topical corticosteroid had a direct impact on patients' likelihood of using tazarotene again in the future. Overall, a total of 70% of patients who had used an emollient indicated that they would use tazarotene again, compared with 57% of patients who had not used an emollient. Similarly, 77% of patients who had used a corticosteroid indicated that they would use tazarotene again, compared with 63% of patients who had not used a corticosteroid.

Overall, 74% of patients treated with tazarotene gel rated tazarotene as at least as effective as other topical antipsoriatic medications they had previously tried (54% rated tazarotene as more effective, 21% rated tazarotene as equally effective). In the subset of patients switched from calcipotriene ± steroid treatment, 89% of patients rated tazarotene plus steroid treatment as at least as effective as other topical antipsoriatic medications they had previously tried (69% rated tazarotene plus steroid as more effective, 20% as equally effective).

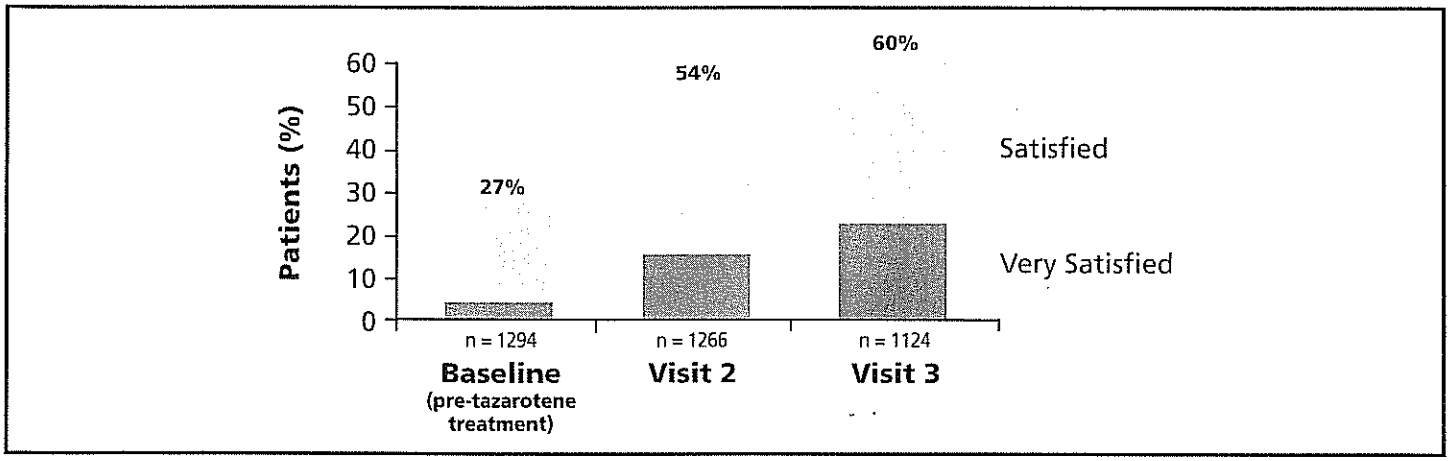

Figure 6. Percentage of patients satisfied with their current treatment regimen, both before and during tazarotene treatment. Patients were asked to rate their level of satisfaction as one of the following: very satisfied, satisfied, indifferent, dissatisfied, very dissatisfied.

Conclusions

Tazarotene is effective and well tolerated in the treatment of plaque psoriasis. The adjunctive use of an emollient and/or a mid-, high- or super-potent corticosteroid enhances the efficacy of tazarotene treatment and increases the percentage of patients likely to use tazarotene again in the future. Adjunctive use of such corticosteroids also reduces the incidence of adverse events during the first 2-4 weeks of treatment when adverse events are most common. Substantial improvements in the severity of psoriasis, plaque elevation, and scaling are achieved in patients switched from treatment with calcipotriene ± steroid, to treatment with tazarotene plus steroid.

Comparable improvements in efficacy were achieved whether tazarotene was used in conjunction with a superpotent corticosteroid or in conjunction with a mid- or high-potency corticosteroid. The risk/benefit ratio of tazarotene treatment is therefore optimal with the adjunctive use of a mid- or high-potency steroid.

References

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Acknowledgements

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*The most commonly used emollients were Eucerin®, Cetaphil®, and Lac-Hydrin®.
†The most commonly used mid- or high-potency steroids were triamcinolone, fluocinonide, and mometasone furoate.
‡The most commonly used superpotent steroids were clobetasol propionate, augmented betamethasone dipropionate, and halobetasol propionate.