Assignment of patients to clindamycin/benzoyl peroxide or vehicle was by randomization. No patients discontinued treatment because of adverse events.

The percentage of patients achieving ≥50% improvement in papule plus pustule count was significantly greater with tazarotene plus clindamycin/benzoyl peroxide than with tazarotene alone at week 4 (Figure 4B). The median percentage reduction in papules and pustules was significantly superior with the combination regimen compared with tazarotene alone at week 4 (Figure 6).

The percentage of patients achieving ≥70% improvement in open plus closed comedos at week 4 and ≥80% improvement at week 12 was significantly greater with tazarotene plus clindamycin/benzoyl peroxide than with tazarotene alone. The combination regimen also offers comparable or superior efficacy to tazarotene monotherapy in the treatment of acne vulgaris.

The median percentage improvement in facial redness/erythema was significantly greater with tazarotene plus clindamycin/benzoyl peroxide than with tazarotene alone at week 4 (Figure 5; Table 1). The combination regimen also offers significantly superior reduction in inflammatory and non-inflammatory acne. Furthermore, it may be possible to enhance its phototoxicity (as compared with tazarotene alone).

Methods

Study design

• Multicenter, double-blind, randomized, parallel group

Inclusion criteria

• At least 12 years of age

• Stable residence to severe facial inflammatory acne vulgaris:
  - 15-49% papules plus pustules
  - 50-74% comedones

• No prior treatment with benzoyl peroxide

• Patients had a mean age of 20 years and were predominantly female (85% and >60% respectively), though not specifically in combination with each other.

Withdrawal criteria

• 2 weeks for topical acne medications
• 30 days for systemic antibiotics and investigational drug

• >12 weeks for hydroxyurea

• No other topical treatments

Treatment regimen

• All patients were instructed to apply the following treatments to their face for 12 weeks:
  - Tazarotene 0.1% twice daily
  - Clindamycin/benzoyl peroxide 1%/5%

• Patients were instructed to wash their face with a non-soap cleanser and patting dry with a soft towel.

• At the end of the study period, patients were instructed to discontinue all topical acne treatments and were subsequently followed for a period of 4 weeks to assess the effect of discontinuing treatment on acne activity.

Efficacy

Tazarotene plus clindamycin/benzoyl peroxide resulted in a significantly greater improvement in open plus closed comedos compared with tazarotene alone from week 0 to week 6 (Figure 1A). The median percentage reduction in papules and pustules was significantly greater with the combination regimen compared with tazarotene alone (Figure 6).

Overall impression

The combination regimen was noted to be safe and well-tolerated, with no significant differences in the incidence of any treatment-related adverse events.

Conclusions

Tazarotene cream plus clindamycin/benzoyl peroxide gel offers significantly greater efficacy than tazarotene alone. The combination regimen also offers comparable or superior efficacy to tazarotene monotherapy in the treatment of acne vulgaris.

References


