The article, "Recently Approved Systemic Therapies for Acne Vulgaris and Rosacea" (*Cutis*. 2007;80:113-120), provided an incorrect heading. Consequently, the entire page 118 is reprinted below in its corrected form. *Cutis*® makes every possible effort to ensure accuracy in its articles and apologizes for the mistake.

The efficacy profile of ER minocycline tablets was shown in data collected during the phase 2 dose-finding study and 2 phase 3 pivotal trials, all of which used similar protocol designs (randomized, multicenter, double-blind, placebo-controlled, prospective trials) and subject populations.[34,35] All subjects (N=1038) included in the pooled analysis demonstrated moderate or severe acne vulgaris and were treated for 12 weeks with ER minocycline 1 mg/kg or placebo once daily.[35] In all 3 studies, the nominal and percentage reduction in inflammatory lesions was greater in subjects treated with active drug compared with placebo. At week 12, the mean nominal reduction in inflammatory lesions was 17.3 and 12.6 and the mean percentage change was 45.5% and 32.4% in subjects treated with ER minocycline 1 mg/kg once daily and placebo, respectively. These differences were statistically significant ($P<.001$).[35]

What is the overall safety profile of minocycline extended-release tablets?

As with the discussion of efficacy above, the safety analysis of ER minocycline 1 mg/kg once daily versus placebo was pooled from the similarly performed phase 2 dose-finding study and pivotal phase 3 trials completed over 12 weeks.[35] Adverse events were similar in type and frequency between subjects who were actively treated (n=674) and placebo treated (n=364), with most adverse events graded as mild in severity. The most commonly noted adverse events were cephalalgia, nausea, fatigue, dizziness, diarrhea, and pruritus. In all 3 trials, no cases of cutaneous dyschromia or hyperpigmentation were observed.[35]

The study protocols defined acute vestibular adverse events as vertigo, dizziness, tinnitus, nausea, and vomiting.[34,35] Most vestibular adverse events occurred within the first 5 days of therapy in all 3 studies. Pooled analysis of the 3 trials demonstrated that acute vestibular adverse events occurred in 7.9% to 16.4% of subjects treated with placebo and 9.0% to 10.5% of subjects treated with ER minocycline 1 mg/kg once daily.[35]

Laboratory evaluations, including complete blood cell counts, serum chemistry panels, and urinalysis, were performed as part of the safety evaluation, with no clinically important abnormalities observed based on comparisons with baseline indices.[35] Importantly, no treatment-associated effects on liver panel or thyroid panel parameters were observed. One subject in each phase 3 trial developed weak antinuclear antibody positivity. In one case, the subject also experienced flulike symptoms, and in the other case, the subject was asymptomatic, with antinuclear antibody positivity noted during follow-up after completion of treatment with ER minocycline.[35]

COMMENT

This article discusses 2 new formulations, anti-inflammatory dose doxycycline capsules, which are FDA-approved for the treatment of inflammatory rosacea, and ER minocycline tablets, which are FDA-approved for the treatment of inflammatory acne vulgaris. Both of these tetracycline derivatives have been available collectively for approximately 7 decades. What are the similarities and differences between these agents?

These agents are similar in that they represent the first systemic agents that are FDA-approved for their respective disease state indications (with the exception of oral isotretinoin, which is approved for the treatment of severe recalcitrant nodular acne) based on phase 3 clinical trials. These large-scale trials were performed based on FDA-approved protocols that were randomized, multicenter, double-blind, placebo-controlled, prospective studies that were adequately powered for statistical analysis using recognized methodologies.

Another similarity between these agents is that their formulations are uniquely designed and are not bioequivalent with other doxycycline or minocycline formulations. More importantly, the pharmacokinetic properties of both anti-inflammatory dose doxycycline and ER minocycline have been correlated with clinically relevant properties based on the available studies reviewed in this article. In the case of anti-inflammatory dose doxycycline, the CR formulation administered once daily provides anti-inflammatory activity proven to be effective for inflammatory rosacea without emergence of antibiotic-resistant bacterial strains and with an apparent reduction in the potential for adverse reactions such as gastrointestinal tract upset, photosensitivity, and vaginal candidiasis. ER minocycline allows for effective treatment of inflammatory acne vulgaris using a weight-based dosing regimen (1 mg/kg once daily) that decreases both the potential for acute vestibular adverse reactions and cumulative drug exposure with time. Therefore, these agents should not be substituted with other generic or brand-name formulations of doxycycline or minocycline.

Anti-inflammatory dose doxycycline and ER minocycline differ in several ways. First, the former is FDA-approved for inflammatory rosacea and the latter is approved for inflammatory acne vulgaris. Second, anti-inflammatory dose doxycycline is not an antibiotic and ER minocycline does exhibit antibiotic activity. This is an important differentiation