

Letters to the Editor

[The Editor is not responsible for the views expressed by the correspondents]

Minocycline for Rosacea : Balancing Efficacy with Safety — Advancing Treatment through Innovation and Vigilance

SIR, — Rosacea is a chronic inflammatory skin condition that affects millions of adults worldwide, characterized by erythema, telangiectasia, and inflammatory lesions. Despite its prevalence, effective long-term management remains a challenge due to the complex pathophysiology of the disease. The recent advancements in therapeutic options, particularly the FDA approval of oral minocycline for inflammatory lesions, mark a significant milestone in addressing these challenges. This editorial examines the evolution of minocycline's role in rosacea management, with a focus on its efficacy, safety profile, and the potential for new formulations to improve patient outcomes.

Efficacy of Minocycline in Rosacea :

In 2020, minocycline was approved by the FDA as an oral therapy specifically targeting inflammatory lesions in adult rosacea patients¹. This approval was supported by robust clinical trials demonstrating its efficacy in reducing lesion counts and enhancing patient-reported quality of life metrics. For example, phase III trials showed that low-dose, extended-release minocycline significantly reduced inflammatory lesions as early as four weeks into treatment, with further improvement observed through week 12. Importantly, these results underscore the anti-inflammatory properties of minocycline, which act by modulating key inflammatory pathways implicated in rosacea rather than solely addressing bacterial activity².

Patients receiving minocycline also reported relief from hallmark symptoms of rosacea, such as redness, swelling, and burning sensations. These outcomes emphasize the drug's role as an effective treatment option, particularly for moderate-to-severe cases where topical treatments may fall short. The extended-release formulation not only enhances therapeutic efficacy but also minimizes fluctuations in drug levels, reducing the likelihood of adverse reactions commonly associated with traditional formulations³.

Comparative Efficacy and Emerging Role :

When compared to existing treatments such as topical metronidazole, azelaic acid, and other oral antibiotics like doxycycline, minocycline offers several distinct advantages. Its anti-inflammatory mechanism is more targeted, resulting in broader applicability for patients resistant to other therapies. Furthermore, clinical evidence suggests that minocycline achieves comparable or superior efficacy while offering the convenience of once-daily dosing⁴.

This positions minocycline as an attractive option in the therapeutic arsenal for rosacea, addressing a critical need for treatments that balance efficacy and patient adherence. Notably, the approval of Emrosii (minocycline hydrochloride) in November 2024 as a next-generation extended-release capsule reflects ongoing efforts to refine the drug's safety and tolerability⁵.

Safety Concerns and Drug Monitoring :

Despite its efficacy, the safety profile of minocycline necessitates vigilance, particularly for long-term use. Common Adverse Drug Reactions (ADRs) include gastrointestinal disturbances, dizziness and photosensitivity. Rare but serious effects such as drug-induced lupus, liver toxicity, and skin pigmentation have also been documented⁶.

To mitigate these risks, clinicians must adopt a proactive approach to drug monitoring. Regular assessment of liver and renal function, especially for patients on prolonged therapy, is essential. Moreover, patient education on recognizing early signs of ADRs plays a crucial role in preventing complications. Tailored dosing strategies, such as initiating treatment at lower doses and escalating only as needed, can further enhance safety⁷.

Certain populations, such as individuals with pre-existing liver or renal impairments, pregnant patients, and those taking concurrent hepatotoxic medications, may require additional precautions. Identifying and addressing these risk factors is critical to optimizing therapeutic outcomes while minimizing harm⁸.

Balancing Efficacy and Safety in Clinical Practice :

Effective rosacea management involves striking a balance between maximizing therapeutic benefits and minimizing risks. For clinicians, this requires a nuanced approach that integrates evidence-based protocols with individualized patient care. Factors such as disease severity, patient preferences, and comorbidities must be carefully weighed when selecting minocycline or any other treatment option⁹.

Preventive measures to mitigate ADRs include :

- (1) Regular monitoring of organ function.
- (2) Educating patients on recognizing symptoms like unusual skin discoloration or persistent nausea.
- (3) Considering alternative therapies for high-risk patients.

By fostering open communication and encouraging adherence to monitoring protocols, healthcare providers can enhance the overall safety and efficacy of minocycline therapy.

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Future Directions :

The approval of Emrosi underscores the potential for innovation in minocycline formulations to address unmet needs in rosacea treatment. Future research should prioritize:

(1) Long-term Safety Studies: To better understand the implications of extended minocycline use in diverse patient populations.

(2) Alternative Formulations: Exploring topical or even non-antibiotic derivatives to reduce systemic ADRs.

(3) Mechanistic Insights: Elucidating the anti-inflammatory pathways modulated by minocycline to inform the development of next-generation therapies¹⁰.

As the landscape of rosacea management evolves, ongoing collaboration between clinicians, researchers, and regulatory bodies will be crucial to ensuring that advancements in therapy translate into meaningful improvements in patient care.

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REFERENCES

- 1 Gallo RL, Granstein RD, Kang S, Mannis M, Steinhoff M, Tan J, et al — Rosacea comorbidities and future research: the 2017 update by the National Rosacea Society Expert Committee. *J Am Acad Dermatol* 2018; **78**(1): 167-70. doi:10.1016/j.jaad.2017.08.038.
- 2 Thiboutot D, Gold LS, Kircik L, Cook-Bolden F, Webster GF, Tanghetti E, et al — Efficacy and safety of once-daily oral extended-release minocycline in moderate to severe inflammatory lesions of rosacea: Results from two phase 3 randomized controlled trials. *J Drugs Dermatol* 2017; **16**(6): 605-10.
- 3 Feldman SR, Hino P, Rogers J — Efficacy and safety of oral minocycline for the treatment of inflammatory lesions of rosacea: A systematic review. *Dermatol Ther* 2020; **33**(6): e14100. doi:10.1111/dth.14100.
- 4 Tan J, Almeida L, Bewley A, Kircik L, Alexis A, Stein Gold L, et al — Randomized controlled trial of modified-release minocycline in treatment of rosacea. *J Am Acad Dermatol* 2021; **84**(2): 463-70. doi:10.1016/j.jaad.2020.07.095.
- 5 Stein Gold L, Kircik L, Fowler J, Del Rosso JQ, Webster G — Update on oral minocycline use in dermatology: Focus on rosacea. *Cutis*. 2018; **102**(5): 321-6.
- 6 Del Rosso JQ, Tanghetti E, Webster G, Kircik L, Thiboutot D — Update on the management of rosacea from the American Acne & Rosacea Society (AARS). *J Clin Aesthet Dermatol* 2019; **12**(6): 17-24.
- 7 Yamasaki K, Di Nardo A — The role of the immune system in rosacea. *Semin Cutan Med Surg* 2011; **30**(3): 148-51. doi:10.1016/j.sder.2011.06.006.
- 8 Gallo RL, Nakatsuji T — Microbial symbiosis with the innate immune defense system of the skin. *J Invest Dermatol* 2011; **131**(10): 1974-80. doi:10.1038/jid.2011.182.
- 9 Schaller M, Almeida LM, Bewley A, Cribier B, Dlova NC, Kautz G, et al — Rosacea treatment update: Recommendations from the Global ROSacea Consensus (ROSCO) panel. *J Eur Acad Dermatol Venereol*. 2017;31(3):490-8. doi:10.1111/jdv.13956.
- 10 Feldman SR, Werner CP, Alinia H. Coping with rosacea: An approach to successful management. *Clin Cosmet Investig Dermatol* 2016; **9**: 65-71. doi:10.2147/CCID.S80446.

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