Correspondence

Unanswered questions on the safety of MDT-U*

Ajit Barve[1]

DOI: http://dx.doi.org/10.1590/abd1806-4841.20198564

Dear Editor,

After reading the article "Clinical trial for uniform multidrug therapy for leprosy patients in Brazil (U-MDT/CT-BR): adverse effects approach"[1] in your esteemed journal, I had several questions - skin pigmentation (21.7%) and xerosis (16.9%) were the most frequent complaints among 753 patients.[1] Comments - Pigmentation and xerosis are due to clofazimine, and not to either dapsone or rifampicin. In a patient proven to be paucibacillary by lesion counting and BI, and treated with the six-month World Health Organization (WHO) paucibacillary regime of dapsone and rifampicin, the question of clofazimine-induced pigmentation or xerosis does not arise, and hence when such a patient is treated with MDT-U, the patient is definitely exposed to additional risk of clofazimine-induced pigmentation and possibly a risk of non-compliance. The said study[1] does not address the issue. Since 1982, millions of patients have been treated and cured with MDT, and reports of adverse effects (AE) have been quite low when compared to the benefits for patients and leprosy control programs.[2] The study in question states that 24 patients (3.2%) stopped dapsone because of AE and received an alternative treatment; 16 (66.7%) had anemia, three patients of this group had leukopenia, and two developed mild increase in their aminotransferase levels. Three patients (12.5%) developed erythroderma secondary to dapsone, and all these patients had mild anemia. Methemoglobinemia was diagnosed in one patient. Other reasons for MDT interruption were urticaria, headache, and psychiatric disorders. Sulfone syndrome (dapsone-induced hypersensitivity syndrome) was seen in one patient.[1] The key unanswered question remains: when during the course of therapy did these adverse events necessitating cessation of therapy occur? MDT-U consists of six months of dapsone, rifampicin, and clofazimine. Are six months not more than enough to develop serious dermatological adverse effects such as sulfone syndrome (which usually develops within two to seven weeks) or drug-induced erythroderma? During the first three months of therapy, the risk of agranulocytosis and sulfone syndrome is the highest.[3,4] Do the authors wish to say that a six-month course gives the patient statistically significant protection against adverse events? (That dapsone would cause a drop in hemoglobin in all patients is well-known.) The article has a lot of focus on anemia, yet glucose-6-phosphate dehydrogenase (pre-treatment status or deficiency) is not even mentioned. However, I agree with the authors that monthly monitoring enables early detection of AE, facilitating prompt interventions.[1] ❑

REFERENCES

1. Cruz RCS, Bührer-Sékula S, Penna GO, Moraes MEA, Gonçalves HS, Stefani MMA, et al. Clinical trial for uniform multidrug therapy for leprosy patients in Brazil (U-MDT/CT-BR): adverse effects approach. An Bras Dermatol. 2018;93:377-84.
2. Sansarricq H. Multidrug therapy against leprosy: development and implementation over the past 25 years. Geneva: World Health Organization; 2004.
3. Hall RP. Dapsone. In: Wolverton SE, editor. Comprehensive dermatologic drug therapy. Philadelphia: W.B Saunders Company; 2001. p. 230-50.
4. Wolverton SE, Remlinger K. Suggested guidelines for patient monitoring: hepatic and hematologic toxicity attributable to systemic dermatologic drugs. Dermatol Clin. 2007;25:195-205.

Received 24 June 2018.
Accepted 2 April 2019.
* Study conducted at the Dermatology Department, Navi Mumbai Municipal Corporation, Navi Mumbai, India.
Financial support: None.
Conflict of interest: None.

[1] Dermatology Department, Navi Mumbai Municipal Corporation, Navi Mumbai, India.

Mailing Address:
Ajit Barve
E-mail: dermajit@gmail.com

AUTHORS' CONTRIBUTIONS

Ajit Barve 0000-0002-9705-1220
Approval of the final version of the manuscript; elaboration and writing of the manuscript.

How to cite this article: *Barve A. Unanswered questions on the safety of MDT-U. An Bras Dermatol. 2019;94*(4):499.