Antileprosy Drugs, Pregnancy and Fetal Outcome

TO THE EDITOR:

In 1982, a World Health Organization (WHO) Study Group devised and recommended multidrug therapy (WHO/MDT) with pulsed doses of rifampin and clofazimine in addition to dapsone for leprosy. There is a lot of controversy regarding the use of these drugs in pregnancy due to the lack of controlled studies. Most of the studies have advocated the use of dapsone and clofazimine ([2, 3, 5, 6]) in pregnancy without serious side effects, including teratogenicity. However, congenital malformations have been reported in 2 out of 56 newborns of leprosy patients treated with dapsone in another study ([4]). The status of rifampin is still more controversial. Experimental studies in mice and rats have shown it to produce spina bifida and cleft palate in doses above 150 mg/kg ([8]). Another report describes 9 malformations in 204 human full-term pregnancies ([7]). In contrast, a surveillance study of Michigan (U.S.A.) Medicaid recipients has shown no major birth defects in 20 newborns exposed to rifampin in the first trimester ([1]). Presently, clofazimine and rifampin are classified in category C: according to their fetal risk as defined by risk factors used by the U.S. Food and Drug Administration (Federal Register 1980; 44:374, 34–67) ([1]).

We have retrospectively studied 5500 leprosy patients over a 19-year period who included 13 female patients (age group 18–30 years) of different subtypes (TT = 1, BT = 3, BL = 6, LL = 3) who had taken these drugs out of ignorance during pregnancy. All of these patients received 100 mg dapsone daily with 600 mg rifampin once monthly. Further, two patients received clofazimine and two patients took intermittent prednisolone throughout their pregnancies. All of these patients had full-term normal deliveries, including twins in one case.

Although our study is an uncontrolled study, it still shows that these drugs can be safely used in pregnancy.

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