Teronac and Teratogenicity

Sir,

I wish to bring to the attention of practising doctors the inadvertent use of anorectic therapy in pregnancy. In the recent past, I had 2 patients who had been on Teronac, an anorectic agent, and who were exposed to it for a period of approximately 1 month before their pregnancies were confirmed. Both of them, after counselling, decided to continue with their pregnancies which ended in the happy event of both mothers delivering full term healthy babies. However, advising these mothers on the dangers of the drug, especially when it is stated that it is not recommended during pregnancy, can pose a difficult problem to the practitioner. There is no world literature on the subject of teratogenicity.

Mazindol, the active ingredient of Teronac, has been studied in reproduction experiments in rats and rabbits. An increase in neonatal mortality and a possible increased incidence of rib abnormalities in rats were observed at relatively high doses. It was concluded that these findings were not relevant to man.

Until September 1990, by spontaneous reporting, the Drug Monitoring Centre of Sandoz Pharma Ltd in Basle, Switzerland, had received information on a total of 20 patients who took Teronac for obesity inadvertently during the first trimester of pregnancy. Two pregnancies resulted in spontaneous abortions (one fetus with unspecified abnormalities). Another pregnancy was terminated because of a depressive reaction in the mother. Four babies were delivered prematurely, of which one was a male baby with multiple malformations involving the genitalia, limbs, heart, lungs and kidneys who subsequently died. Thirteen babies were born at term and were healthy.

While only one unfavourable pregnancy outcome was noted in the 20 patients, we cannot take it for granted that these form of therapies are safe in pregnancy, especially when there is no hard data in the literature. Thus, as practising physicians, the onus is on us to inform patients that anorectic therapy is not recommended during pregnancy. Women in the reproductive age group on this form of therapy should be advised to practise some form of contraception.

Acknowledgement

I would like to express my thanks to Sandoz Pharmaceuticals (Malaysia) Sdn Bhd for providing me with the necessary data.

S.P. Rachagan
Faculty of Medicine, University of Malaya, Kuala Lumpur