

## Prescribing and dispensing of isotretinoin: A survey

Sir,

Since the thalidomide disaster in the 1960s, physicians and patients have become aware of the teratogenic effects of drugs used during pregnancy. Isotretinoin is one such teratogenic drug and pregnancies exposed to isotretinoin are at severe risk of serious congenital malformations and have resulted in spontaneous or elective abortions, risk of depression, suicide, and liver damage.<sup>[1]</sup>

Several risk-management strategies like iPLEDGE have been implemented in the US to prevent pregnancy in females during the course of isotretinoin treatment.<sup>[2]</sup> In India, isotretinoin is widely prescribed by the dermatologists as well as general practitioners. Hence, this study was done to find out whether care is taken while prescribing and dispensing teratogenic drugs like isotretinoin by healthcare professionals and pharmacists in one large and small city in Maharashtra. Package inserts of various companies marketing isotretinoin in India were assessed for their completeness of information.

This was a survey-based study carried out during the period from November 2008 to January 2009 in which a survey of physicians and pharmacists and analysis of package inserts were undertaken. Dermatologists and general practitioners were randomly selected by personal contact and were personally interviewed. A questionnaire was also circulated to them from

which they were asked to tick the answer they thought appropriate and were assured anonymity.

The questionnaire was completed by a total of 38 healthcare professionals (28 dermatologists and 10 general practitioners) from two different cities and their response is mentioned in Table 1.

The dispensing practices of pharmacists were assessed by sending ten female dummy patients of childbearing age, 10 married female patients with visible indicators of being married (like wedding chain in the neck) and 10 visibly pregnant women to pharmacies; they asked for isotretinoin without prescription and surprisingly, it was dispensed readily by the pharmacists to all patients without prescription and without giving any instructions about its teratogenic effect.

Package inserts of six different pharmaceutical companies marketing or manufacturing isotretinoin in India was assessed for their contents regarding precautions to be taken while on treatment.

All mention the need for a pregnancy test to be carried out twice before putting a female patient on this medication but the patient information sheet did not mention anything about double contraception i.e. one hormonal and one barrier method to be followed to avoid any remote chances of pregnancy.

Earlier, such studies have been carried out in the developed countries, which showed that prescriptions for teratogenic medicines are given to women of childbearing age without any documentation of contraceptive counselling.<sup>[3]</sup> Such studies are very

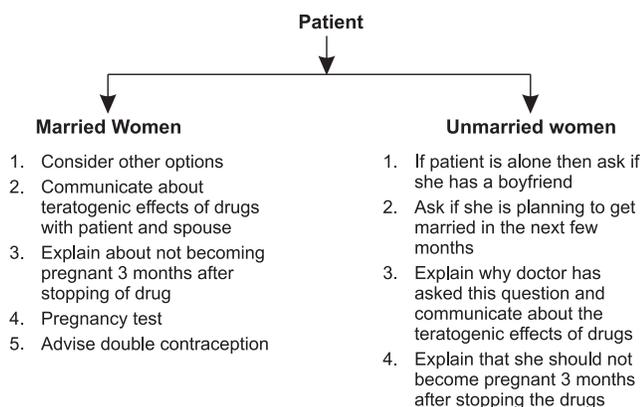
**Table 1: Prescribing practices of dermatologists and general practitioners while prescribing isotretinoin**

	Dermatologists	GP
Total number of healthcare professionals interviewed	28	10
Number of healthcare professionals who prescribe isotretinoin	20	5
Number of healthcare professionals who do complete documentation of pregnancy tests with proper instructions	2	0
Number of healthcare professionals who do initial pregnancy test with instructions but no follow-up with further counselling	15	3
Number of healthcare professionals who don't do pregnancy test, only give instructions	3	2

important to India because we do not have an adequate pharmacovigilance program. It has been observed that prescribing instructions are not followed by most of the prescribers as there is a taboo to carry out pregnancy tests for unmarried women, physicians face a lot of difficulty to convince the families to get their daughter to do a pregnancy test even though it may be for the safe use of the drug.

In conclusion, all these factors put Indian women patients at risk but it is also one of the unavoidable facts that in a high-population country like India implementation of a risk minimization program like iPLEDGE become practically difficult. Thus there is not only a need for education and awareness among patients, prescribers and pharmacists about the potential preventable harm from teratogenic drugs but also a need for development of a simpler and practicable risk minimization method.

So we have come up with some recommendations to implement a simple risk minimization method shown in the chart below. In another article (under publication) detailed instructions to patients and physicians about pregnancy test and contraception are described.



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