

## Flutamide: Dermatology and respect to evidence and safety

### *Flutamida: a Dermatologia e o respeito às evidências e à segurança*

A clinical case that was carefully studied and presented in this issue under the name of "Flutamide hepatotoxicity in a patient undergoing acne treatment" compels us to go into a series of reflections.

This is about a heated and momentous issue, which not only allows a specific analysis, but can also give way to a transposition to another very frequent situation in today's Dermatology.

Not only the dermatologist, but also the medical class in general, is faced with the dilemma between the merits and risks involved in the prescription of drugs which are not approved by the National Agency for Sanitary Surveillance (Anvisa). It may be pleaded that when we limit ourselves to prescribing only the drugs approved by the official regulatory agencies, we retard, break the evolutionary process of therapeutics. At the same time, for others, such prescriptions would be on the borderline between medical malpractice and anti-ethical attitudes.

In the specific case of flutamide, we have important statements such as that of the Brazilian Center of Drug Information, belonging to the Federal Pharmacy Council: "studies that refer to the use of flutamide do not display sufficiently consistent results to advocate dermatological application. In the opinion of this organ, further study is needed." In several countries, flutamide is registered with the exclusive indication for prostate cancer (USA, France, Italy, Belgium, Canada, Turkey, Argentina, Switzerland). In 1999, the laboratory that is responsible for the product commercialization itself published a letter addressed to health professionals, through the World Health Organization, highlighting the lack of studies in women and opposing the use of the drug in this population, mainly in affections that carry no life-threatening risks.

In Brazil, Anvisa issued a warning in October 2004 recommending caution with the use of flutamide, due to case reports of fulminating hepatitis associated to the use of this drug in women. The agency decided to confirm prostate cancer as the only approved indication and to request notification of suspicion of any adverse reaction, considering the cost/benefit relation totally unfavorable to women.

As said by Dr. Álvaro Atallah, one of the worldwide references in Evidence-Based Medicine, the great majority of drugs ends up receiving approval in studies carried out, even when in large scale, in no more than about 5,000 patients. A single death in this sample can be interpreted as not related to the use of the drug. What can happen when after commercialization this correlation proves itself positive in a population of millions of users? By the way, remember the recent episodes surrounding anti-inflammatory drugs.

Particularly in our midst, a few aggravating issues must be considered, namely:

- lack of proper clinical and laboratorial follow-up by a considerable number of colleagues;
- trivialization and vulgarization of the indications, without due discussion about risks with patients;
- indication, by colleagues of various areas and even by lay people, of the use of the medication;
- inexistence of fulfillment, by drugstores, of the mandatory presentation of medical prescription for the acquisition of drugs, and precarious control by official agencies;
- sale of the product by some pharmacies that do not enforce the obligation to attach the description, specifications and orientation on product use, as well as warnings about possible side effects.

<sup>1</sup>see pages 381-4

We should not forget, either, to consider the existing therapeutic weaponry, alternative to the use of flutamide and which is the safety profile exhibited by each of these drugs.

We must keep on respecting the unstoping

search for the best for our patients, because they are the reason for our being; hence there are no excuses for sacrificing their safety in the quest for efficacy.

*Primo non nocere!*



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