The prohibition of thalidomide for the erythema nodosum leprosum

Hansen. Int, 25121: 113-114, 2000

Editorial

The thalidomide, alfa-N-ftalimido-glurarimide is derived from the glutamic acid that was synthesized in 1954 in Germany. In 1956 it was introduced in several countries as a hypnotic and sedative anti-emetic drug during the first trimester of pregnancy. In 1960, McBride and Lenz reported the association between the use of thalidomide by pregnant women and congenital malformations, including focomielia. That is why the drug was immediately withdrawn from the market but it left about 12 thousand children with severe deformities'.

In 1965, Sheskin[10] in Israel verified that patients with type II leprosy reactions, to whom thalidomide had been given as a sedative, improved markedly from these reactional manifestations. Since then, it became the drug of choice for most of the cases of erythema nodosum leprosum (ENL). Later, the thalidomide has shown to be useful for other morbid conditions such as lupus erythematosus, graft versus host disease, aphthous stomatitis, Behçet's disease, prurigo nodularis, actinic prurigo, sarcoidosis, rheumatoid arthritis, Langheran's cells histiocytosis, lymphocytic infiltration of the skin Jessner-Kanof), uremic pruritus, pyoderma gangrenosum, erythema multiforme, human immunodeficiency virus infection, and still other conditions such as WeberChristian panniculitis, ulcerative colitis, post-herpetic neuralgia, aids associated painful proctitis, eruptive acute pustular psoriasis, bullous pemphigoid and cicatricial pemphigoid[1,2,3,4,5,6,8,9,11,12].

In spite of its efficacy for all the mentioned diseases, the use of thalidomide has been restricted to a few countries.

Some years ago, the American FDA allowed the use of thalidomide for leprosy and aids in the treatment of aphthous stomatitis[7].

In our country, the 354/97 government regulation allows this drug to be used for type II leprosy reaction (erythema nodosum leprosum), in the idiopathic aphthous ulcers of aids patients, and in chronic degenerative diseases like lupus erythematosus and graft versus host disease. However, our Health Department prohibits the use of it by women in reproductive age, consisting from menarche to menopause.

The type II leprosy reaction may occur at any age, but the young women with this type of reaction can not benefit from the use of this medication, and they have to go through costicosteroid treatment and its side effects, that are not a few. The lesions of the ENL frequently relapse and can ulcerate affecting the appearance of patients, especially when located on the face.

The women in reproductive age then have as their only choice prednisone (corticosteroid distributed for free by the Health Department. They end up having the reactions controlled but remain for a long time with generalized edema, including on the face ("moon face") and with a large number of striae besides the risk of other manifestations,

These girls, with this type of reaction, would be astonished if they knew there is another drug, as teratogenic as thalidomide, the isotretinoin, that is utilized with some freedom by millions of young girls with acne of puberty, in several countries, including Brazil where it was properly approved by the Health Department.

It would be interesting to remember here there was a time everybody believed that the use of clofazimine in the OMS recommended treatment scheme for leprosy wouldn't be accepted by the patients because of the darkening of the skin it caused. As time passed, however, it was verified that the health workers thought so, not the patients.

In this respect there is a curious case. A medical doctor diagnosed leprosy in an individual and prescribed him the treatment omitting the clofazimine because he thought the patient wouldn't tolerate it. By the time the patient found out the drug was very important for his cure, he had no doubt, he sued the doctor.

This doesn't happen very often because leprosy occurs in a great number of uneducated, humble people who passively accept the treatment prescribed to them.

Our Constitution says that every citizen has the right to health. That can be interpreted as every citizen, when sick, has the right to access the medication which will make him recover. It is therefore hard to understand why a part of the diseased population, may be the minority, is totally denied the access to a medication proved to be efficacious on improvement of their clinical status.

As mentioned earlier, the alterations the ENL can

cause in the appearance of patients are sometimes very severe. When lesions ulcerate they leave scars that disfigure the person in such a way that it looks like the person has been burned. When that happens with young women, the hurt it causes to their personality is much worse than the disease itself and the stigma all together. Then, marriages break apart, dreams of a future marriage end, and these cutaneous deformitíes also difficult the relationship of patients with their familíes and the community, they impair their participatíon on social gatherings, school and any place where they will have to face people. All of that many times could be avoided by the use of the "damned drug".

That is why it seems like these patients can and must demand the use of this medication if they need to. Of course, they or their guardians should take responsibility over its use, like they do with the young girls who take isotretinoin for acne treatment.

When thalidomide was found to have teratogenic effect, in the early sixties, associations were created to defend the right of victims, the children who were born with malformations. Today, other associations may be created, also demanding lots of money, but this time to protect the victims from the prohibitíon of thalidomide.

The Health Institutions had better watch out!

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