



No Role for Thalidomide in Leprosy

During the mid-1960s, the drug thalidomide was reintroduced as treatment for a complication of leprosy called *Erythema nodosum leprosum* (ENL). Although the evidence was not fully established, very soon the drug was heralded as the drug of choice for the management of ENL reactions in leprosy.

Thalidomide's effectiveness in minimizing the symptoms of ENL was mainly due to its antipyretic action. Its effectiveness to control neuritis, the major cause of permanent disabilities in leprosy, was limited. Several controlled studies done in the 1970s demonstrated that prednisolone was more effective in controlling ENL and associated neuritis. In addition, it was demonstrated that clofazimine, an anti-leprosy drug introduced on a small scale in the early 1960s, had anti-inflammatory action.

Subsequent studies have shown that clofazimine is the drug of choice for the management of chronic, recurrent ENL reactions, as it has both anti-reaction and anti-leprosy effects. Moreover, while almost all patients given thalidomide relapsed after discontinuation of the drug, none of the patients treated with clofazimine for ENL reactions relapsed.

The drug clofazimine is now a component of the multidrug therapy (MDT), introduced by WHO in 1981 as the standard treatment for leprosy, and which is now available from WHO free of cost to all patients in endemic countries. The presence of clofazimine in the combination has significantly reduced the frequency and severity of ENL reactions worldwide.

Today ENL reaction is a rare complication, limited to a small proportion of multibacillary patients. Most of the ENL reactions are mild in nature and do not require any specific treatment except some analgesic/antipyretics. In those patients suffering from ENL associated with neuritis, the drug of choice is prednisolone. For chronic recurrent reactions, the drug of choice is clofazimine.



The Return of Thalidomide

The drug was reintroduced in some countries for the management of ENL reactions in leprosy. The tragedy returned with it. Today, a new group of victims are suffering in many countries, particularly in Brazil, which also continues to manufacture and export thalidomide on a large scale. The drug is used for a number of off-label indications with limited and often ineffective control.

In addition, there is some evidence that second generation babies are being born to victims of thalidomide with similar deformities. In Brazil, which has more than 1000 registered thalidomide victims, the last officially known case was born in 1995. In

addition, there are at least ten second-generation deformed babies born to these victims in the last few years.

Misuse of Leprosy as an Entry-Point

Very often, leprosy is being used as an entry point to reintroduce thalidomide (USA, Europe, India). This is not justified, as leprosy does not need thalidomide. Too often, once introduced the drug is used for a multitude of conditions with very little or no control. This is evident by the fact that millions of treatments are being prescribed annually and almost all of it is for non-leprosy conditions.

The drug thalidomide is associated with a human tragedy and is banned in almost all countries in the world. Using the name of leprosy and misusing the appeal of human suffering to introduce this drug in the market will be a tragedy. The medical community which supports the use of thalidomide for other life-threatening conditions can make their own case for the drug. **Leprosy does not need thalidomide.**

Source: WHO Leprosy Team, World Health Organization, Geneva.