In this article the authors present the results of treatment of 21 treatment-naïve MS patients and 2 NMO patients with mitoxantrone in a prospective non-blinded study without a placebo group.[11] Although not a Class I study, the information presented is unique in the Indian MS population. Compared to the patients’ baseline status, there was significant reduction in annualized relapse rates and EDSS progression for up to two and one-half years after completion of therapy. Adverse events were noted, but manageable. No life-threatening side effects occurred in this small population.

The results are not really unexpected. Mitoxantrone is an efficacious drug for the treatment of MS, probably more effective than interferons and glatiramer acetate (GA), although large direct comparison studies are lacking. It is generally conceded that the earlier treatment is started in a population of MS patients, the better the clinical and MRI outcome over several years and perhaps longer. A few small studies have shown or suggested significant benefit in patients treated with mitoxantrone induction therapy, followed by standard disease modifying therapy with an interferon or GA.
Yet the treatment of MS with mitoxantrone early in the course of the disease is not routinely undertaken, and in fact, it is discouraged by many MS specialists. The reason, of course, is the risk of adverse events, including permanent cardiac damage resulting in congestive heart failure and leukemia. For example, a recent study of 2854 mitoxantrone-treated MS patients showed the risk of leukemia was 0.74% (about 1 in 135). As a result of these risks and others, mitoxantrone is generally used, if at all, in patients exhibiting breakthrough exacerbations or secondary progression of their MS, often after multiple drug failures.

So why do this study in treatment-naïve patients? The authors were treating an indigent multiple sclerosis population, without insurance and unable to afford expensive medications. In their opinion it was considered reasonable to offer a more dangerous, but much less expensive, medication to these patients. The patients understood the potential risks, as well as the potential benefits, of mitoxantrone. As a result, a number of patients received treatment for their MS that they could not have obtained otherwise.

This study highlights the ethical dilemmas in treating patients around the world. Is it best to treat patients with a less expensive, but riskier, medication, rather than not treat them at all? This question can be asked for many diseases and the dilemma undoubtedly will be the subject of discussion in many years.

In the meantime, individual physicians need to treat individual patients on a daily basis. If both the physician and patient understand the benefits and risks of medication, as well as the financial issues, should treatment be denied if the safer, but less effective drug, is not affordable? Furthermore, should patients be allowed to choose a more effective, but riskier drug, even if affordability is not an issue?

This article and this review will not answer the questions posed, but should encourage both physicians and patients to participate in an unbiased, open and properly educated discussions about their disease and their medications.

Address for correspondence:
Dr. David W. Brandes,
Hope MS Center, 10810 Parkside Dr., Knoxville, TN 37934, USA
E-mail: dwbnorth@sbcglobal.net

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