

Appraising Therapies

By Ashton Embry

There is certainly no shortage of proposed therapies for helping a person with MS control the progression of their disease. Most persons with MS are naturally very interested in hearing about as many therapeutic options as possible because right now there is no obvious therapy which will, beyond a reasonable doubt, stop MS in its tracks or even slow it significantly. With each new therapy option comes the big question “Should I give it a try or not”. In this column I will try to provide some advice on how to best answer this critical question.

Because MS can cause a great deal of damage in the central nervous system, it is important to do everything reasonably possible to ensure MS does not result in serious disabilities over the long run. We often look to physicians to prescribe an appropriate therapy to take care of a specific medical problem (e.g. an antibiotic in the case of a bacterial infection). Doctors like to use what they call “evidence-based” medicine to prescribe the appropriate therapy for a given ailment. Evidence-based medicine simply means that the recommended therapies are based on reliable scientific evidence.

To conventional medicine, “evidence” usually means the results of acceptable clinical trials (e.g. randomized, blinded trials with a large sample size) and other scientific evidence is rarely considered in decision making. This attitude can be seen in the oft quoted book “Therapeutic Claims in Multiple Sclerosis” published by the International Federation of Multiple Sclerosis Societies. Any proposed therapy for which there are no supporting clinical trial results is summarily dismissed. Such an approach to evidence-based medicine ensures that only patented drugs manufactured by pharmaceutical companies can be considered as a suitable therapy. Thus don’t expect a neurologist to recommend anything but a drug therapy. Such a narrow approach is not the best for appraising a variety of proposed therapies for MS and selecting those that might be of benefit.

First of all other scientific evidence such as epidemiological and animal experimental data can be very useful for reaching a solid decision about a therapy. Furthermore, other factors must be taken into account when evaluating the proposed therapy. These other factors include the financial cost of the therapy, its safety and its ease of use. Clearly, if a proposed therapy is low cost, safe and easy to use, one would not require much scientific evidence before giving it a try. It all comes down to a benefit/risk/hassle/finance analysis. If risk and hassle are very low and costs are reasonable then one has very little to lose and perhaps much to gain by using such a therapy regardless of the availability of much reliable science.

When it comes to a drug, there is no doubt that very reliable, clinical trial data are needed before such a therapy can be recommended. Drugs are very powerful chemicals and thus carry a high risk that negative side effects will outweigh and positive effects. Death can be one of the negative side effects as shown by the Tysabri trials of a few years ago. The currently recommended drugs, with the exception of Tysabri, have reliable clinical trial data which indicate they are reasonably safe and that there is a chance they will slow disease progression over the long term. This chance of some success tends to offset their high cost and unpleasant side effects.

Tysabri, despite the fact that it has been approved, is still under cloud of doubt regarding safety. A recent study showed extremely low T helper immune cells in the CNS of those using Tysabri. Notably, the counts were equivalent to those found in AIDS patients who do suffer from

uncontrollable brain infections because of low T cell counts. In AIDS it is the virus that is responsible for such low numbers but with Tysabri it is the drug itself, which is causing such an alarming effect. Clearly more scientific evidence is needed before one could feel comfortable about using Tysabri.

A proposed nutritional therapy such as the “Best-Bet Diet” is safe, costs little and has potential positive side effects of better general health. However, it does represent a fair amount of hassle due to the drastic dietary changes required. In a case like this, one would want a reasonable amount of scientific evidence but, unlike for a drug, clinical trial data would not be essential due to the complete safety of the therapy. Importantly, a lot of diverse scientific evidence has been compiled to support use of the various aspects of the BBD and thus persons with MS would be wise to seriously contemplate its use.

Perhaps the hardest therapies to evaluate are those with no clinical trial data, have no solid scientific rationale, are quite expensive and/or are possibly harmful. A classic case of such a therapy is the use of “goat serum” which is also known as Aimspro. To me such a therapy is best avoided until a reasonable amount of scientific data are available regarding its safety and its effectiveness for MS. An additional factor worth looking at with such a therapy is the type of individual(s) promoting it. Are they health care professionals or are they businessmen looking to earn lots of money? A recent newspaper article revealed that the principal businessman behind Aimspro has a “spotty” track record when it comes to business (one or more bankruptcies) and that Aimspro is his first foray into health care. These are red flags which are additional reasons to avoid such a therapy until some proper scientific evidence is available. Notably, it is important to give “anecdotal accounts of success” little weight unless you are very familiar with the cases. It seems every therapy under the sun, no matter how implausible, always has lots of anecdotal accounts which attest to its great value.

In my next column I’ll be showing an example of an appraisal of a proposed therapy which was first recommended over 50 years ago and is now part of the BBD. This is the avoidance of specific food proteins such as gluten and dairy.