OHTAC Recommendation

Deep Brain Stimulation in Parkinson's Disease and Other Movement Disorders

March 2, 2005

OHTAC Ontario Health Technology Advisory Committee

Ontario

Deep Brain Stimulation

The Ontario Health Technology Advisory Committee (OHTAC) met on March 2, 2005 and reviewed the evidence on the effectiveness of deep brain stimulation (DBS) in Parkinson's Disease and other movement disorders.

Deep brain stimulation is a surgical procedure indicated in patients with movement disorders that are no longer adequately controlled with drug therapy. These movement disorders include conditions such as Parkinson's Disease, Essential Tremor, and Primary Dystonia. Deep brain stimulation is considered a symptom therapy, and while its mechanism of action is not clear, it has been considered, thus far, as an adjunct to drug therapy.

The DBS system is a pacemaker-like device with three implantable components. These are the lead (inserted into specific target sites of the brain), the extension (which connects the lead to the neurostimulator), and the neurostimulator (which includes the battery and electronic circuitry that produces the electric impulses). Following the surgery, the device is programmed by the physician, and the patient is supplied with a hand-held component with which they can regulate the stimulation, within parameters pre-set by their physician.

DBS can be a bilateral (on both sides of the brain) or unilateral (one side of the brain) procedure, based on the laterality of symptoms. For example, as Parkinson's Disease affects both sides of the body in more advanced disease, these patients will likely have a bilateral procedure.

Deep Brain Stimulation

The MAS review included an evaluation of the evidence for the three above-mentioned conditions. A summary of the findings is as follows:

- Level 1b evidence that bilateral deep brain stimulation is effective in the short-term control of advanced Parkinsonian symptoms, and level 3a evidence that the effect is sustained for at least 5 years.

- Level 3a evidence that deep brain stimulation is effective in the control of tremor in patients with Essential Tremor and tremor-predominant Parkinson's Disease. The longest duration of follow-up was 6 years.

- Level 3a evidence that bilateral deep brain stimulation is effective in the control of symptoms of Primary Dystonia for a duration of at least 1 year.

Further evaluation included the review of data on possible complications associated with the device, procedure, or both. Expert consultation suggests that the complication rate associated with DBS may be as high as 8% (for severe outcomes), but as low as 4% when the procedure is conducted in a multi-disciplinary expert centre.

These procedures are highly specialized and require the efforts of a multi-disciplinary team. Therefore, it is imperative that DBS be restricted to facilities that can provide the level of medical and technologic expertise required for these procedures.

It is estimated by Ontario neurosurgeons that currently three of the approximately 60 neurosurgeons in Ontario have the expertise to conduct such surgeries. As the actual diffusion rate for Ontario is not known, it is imperative that diffusion of DBS be monitored, with adjustments to be made with increases in human resource capacity. Assuming the need for approximately 200 procedures per year for Ontario, the estimated costs (hospital and device costs minus cost avoidance) for these procedures would be in the range of $3.8 to 4.6 million.

In making their recommendation, OHTAC members considered the evidence of effectiveness and possible complications of this set of procedures. Based on their review of the evidence, OHTAC recommends the following:

> that access to the set of procedures for deep brain stimulation be increased in Ontario for persons with movement disorders refractory to treatment, and that the procedures be considered in the context of centers which offer multi-disciplinary expertise and under guidelines for patient selection.

Deep brain stimulation is a set of procedures that require the careful selection of patients eligible for this surgery. This selection must be made in consultation with several experts, which may include a neurosurgeon, neurologist, neurophysiologist, psychologist or psychiatrist, and other specialty areas in cases of underlying conditions.