OHTAC Recommendation

Updated Health Technology Policy Assessment (HTPA) on Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease

April 18, 2006

OHTAC Ontario Health Technology Advisory Committee

Ontario

Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease

On April 18, 2006, the Ontario Health Technology Advisory Committee (OHTAC) reviewed the updated HTPA on artificial disc replacement for degenerative disc disease completed by the Medical Advisory Secretariat (MAS). This letter reports on the findings of the updated review and the subsequent OHTAC recommendations regarding the use of artificial disc replacement technology in Ontario.

Background

On March 24, 2004, OHTAC reviewed the initial MAS HTPA on artificial disc replacement (ADR) technology for degenerative disc disease and concluded that evidence of improved patient outcomes after ADR was insufficient to warrant wide spread adoption of the technology but that additional evidence from randomized controlled trials was expected within 12-24 months. OHTAC recommended that ADR technology be reviewed by MAS and reconsidered by the committee when additional evidence on improved outcomes became available. In accordance with that recommendation MAS has now completed an updated HTPA on the technology.

Degenerative disc disease (DDD) is the deterioration of the intervertebral disc(s) causing pain and disability. Surgery may be required to treat DDD if non surgical treatments are ineffective. Spinal fusion is the standard surgical treatment. Spinal fusion prevents the spine from moving and because of this may promote further degeneration of the spinal structures (bones and discs). However, ADR allows the spine to retain movement which may prevent further degeneration.

Ontario completes an estimated 3,000 spinal fusion surgeries annually. Approximately 5% of these may be eligible for ADR. The average cost of an artificial disc device is approximately $6,763.

OHTAC Findings

Data from 2 studies that compared people having lumbar ADR to those having lumbar spinal fusion for DDD provided moderate quality evidence that lumbar ADR was no worse than lumbar spinal fusion in terms of the surgical success and failure rates 2 years after surgery. A MAS Bayesian statistical analysis determined that when compared with lumbar spinal fusion lumbar ADR was successful 79% more often. Additionally, it was found that patient satisfaction and quality of life physical outcome

scores were statistically significantly better 2 years after lumbar ADR surgery compared with scores after lumbar spinal fusion. Finally, the duration of hospital stay after ADR surgery was statistically significantly less compared with that after lumbar spinal fusion. There was also a trend for measures of disability and pain to be better 2 years after ADR surgery compared to lumbar spinal fusion but these results were not statistically significant. Likewise, there was a trend for fewer neurological complications to occur during the first 2 years after lumbar ADR compared with lumbar spinal fusion but this difference was also not statistically significant.

Data from observational studies provided very low quality evidence of the long-term rate (> 2 years after surgery) of major complications (re-operation for any reason, or device removal, revision or failure). One study of 100 people having lumbar ADR surgery determined that 11 years after surgery 2/100 (2%) people had degeneration in the spinal structures around the artificial disc implant. Degeneration of surrounding spinal structures has been estimated to occur at a rate of 3%/year and up to 80%/8 years (clinical expert estimate) with spinal fusion.

Currently there is no comparative research evaluating the effectiveness of cervical ADR. Because of this there was very low quality evidence to support the effectiveness of cervical ADR and to quantify the short or long-term rate of major complications. Comparative evidence from a Food and Drug Administrative (FDA) randomized controlled trial is expected to become available within the next 12 months.

The incremental cost associated with lumbar ADR compared to spinal fusion was approximately $4,060 per case. An economic evaluation of cervical ADR was not completed because of the paucity of evidence supporting effectiveness of the procedure at this time.

Based on moderate quality evidence of effectiveness, the benefits of lumbar ADR appear to outweigh those of spinal fusion and the risks of the procedure 2 years after treatment. However, there is uncertainty in the estimates of benefits and risks beyond 2 years.

Ontario Perspective

Currently there are 14 surgeons among 6 hospitals who are trained to implant artificial discs. Clinical experts have cited an insufficient amount of operating room time, operating room nurses and anesthetists as barriers to diffusion for this technology. There is a disparity among hospital facilities regarding funding of the device with some facilities funding it from the hospital's global budget while others do

not. Indications for ADR have expanded beyond those stated in clinical trials as surgeons become more experienced with the surgical procedure.

OHTAC Recommendations

- OHTAC recommends the adoption of lumbar ADR according to well defined patient eligibility criteria to be determined by a panel of Ontario experts using the eligibility criteria from the randomized controlled trials reported in the HTPA as a starting point.

- Because data on major complications beyond 2 years after treatment is lacking, a patient registry should be developed to track long-term complications of lumbar ADR.

- Because of the uncertainty in the estimates of benefits, risks and burdens associated with cervical ADR, OHTAC does not recommend the use of cervical ADR to treat DDD over the use of other alternatives such as spinal fusion at this time.