



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

## Horizon Scanning Technology Prioritising Summary

# Botox<sup>®</sup> injections combined with surgery for migraine treatment

April 2004



**ASERNIP/S**

**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**NAME OF TECHNOLOGY:**

Botox® (*C. botulinum* type A toxin) injections combined with surgery.

**PURPOSE & TARGET GROUP:**

This procedure is beneficial for people who have migraine headaches, particularly for those who do not respond to conventional drug treatment.

**STAGE OF DEVELOPMENT (IN AUSTRALIA):**

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

**INTERNATIONAL UTILISATION:**

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
USA	✓		

**IMPACT SUMMARY****Background:**

After receiving Botox® injections for cosmetic purposes, many patients have reported migraine relief. This is thought to be due to release of muscle tension and reduction in pain perception.<sup>1</sup>

A new treatment for migraine headaches has been developed that combines Botox® with surgery. Botox® is injected into specific muscles associated with migraine headaches (e.g. in the forehead, face or back of the neck) to temporarily paralyse them. Patients who have complete elimination of migraine headaches for >6 weeks or >50% reduction in symptoms are then considered for surgery to remove the involved muscles.

**Clinical need and burden of disease:**

Migraines have been identified as one of the world's top 20 causes of disability, affecting the individual, the family and community. More than 10% of the Australian population have migraine-related headaches. People who get migraines experience reductions in social activity and work capacity. The annual cost of migraine to the community, considering loss of productivity, work absence and cost of medical services, has been estimated at about AUS \$1 billion per annum.<sup>2</sup>

### **Estimated speed and geographic and practitioner use patterns of diffusion in the health system:**

A plastic surgeon, Dr Guyuron, developed this procedure in the United States about four years ago. His study group is half way through a five year trial on 100 patients in the United States.<sup>3</sup>

### **Existing comparators:**

- pain relief drugs (e.g. aspirin or paracetamol)
- anti-sickness medication
- drugs that affect levels of serotonin
- hormone therapy for women
- stress management strategies.

### **Estimated cost impact:**

The cost of Botox® is related to the amount of toxin used and the number of muscles injected.<sup>4</sup> In the United States, Botox® can cost from US \$10 – \$30 per injection.<sup>5</sup> The removal of only the corrugator supercilii muscles would typically cost between US\$6 000 and \$8 000<sup>6</sup>; however, other muscles may also need to be removed.

### **Efficacy and safety issues:**

Short-term safety and efficacy data exist from two case series. A small study by Guyuron *et al.* 2002 found that 24/29 (82.8%) reported a positive response from Botox® and out of the 22 who underwent surgery, 21 reported complete elimination or a significant improvement in migraine headaches. No major negative side effects were noted a year postoperation. No wound infections were reported.<sup>3</sup>

Preliminary results from a current trial of 100 patients show that approximately 90% report complete relief or >50% reduction in severity and number of migraine attacks.<sup>7</sup>

### **Adverse events:**

- two patients reported transient unilateral upper eyelid ptosis, lasting up to three weeks following Botox® injections
- during surgery, three patients bled excessively
- postoperatively, all patients experienced some numbness in the temple area lasting one to six months<sup>3</sup>

Adverse reactions from Botox® generally occur within the first week<sup>8</sup> and include redness, bruising, bleeding, temporary local pain and some weakness in surrounding muscle tissue due to the spread of toxin.<sup>9</sup>

### **Ethical issues:**

Not applicable.

### **Cultural or religious considerations:**

Not applicable.

### Other issues:

The Australian Therapeutic Goods Association (TGA) has approved the use of Botox® for cosmetic purposes and to treat various nerve disorders, but not for the treatment of migraines.<sup>10</sup> Currently, surgery for the relief of migraine headaches is not available in Australia.

### Conclusion:

Limited evidence exists on the safety and efficacy of the combined procedure of Botox® injections with surgery for the treatment of migraine headaches. The recent RCT and case series follow-up suggests an excellent safety and efficacy profile for Botox® injections combined with surgery in the treatment of migraines. However, the procedure still remains experimental in nature, and long-term safety and efficacy data from multiple randomised controlled trials continues to be lacking.

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#### **SEARCH CRITERIA:**

A search of MEDLINE, PubMed, Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register International, Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in October 2003.

Search terms used were 'botulinum toxin and surgery and migraine', 'botox and migraine and surgery' and 'botul\$ and migraine and surg\$'.