Rivastigmine licensed for dementia in Parkinson's

Robert Meadowcroft considers the implications of a licence extension for a dementia drug for use in Parkinson's, and how NICE might respond

here are approximately 120 000 people with Parkinson's disease in the UK, and at any one time, up to 40% of these patients will suffer from varying levels of dementia. The symptoms of dementia in Parkinson's disease vary and often fluctuate, so that the person may seem better or worse at different times. Parkinson's dementia is marked by forgetfulness, slowness of thought processes, lethargy and loss of 'executive functions' such as decision-making, planning, reasoning, and coping with novelty. Some people become obsessional, and may also experience loss of emotional control with sudden outbursts of anger or distress. Non-motor features such as sleep disturbances occur frequently, and visual hallucinations may also occur.

Blow

The onset of dementia symptoms is often an additional blow to the families of a loved one with Parkinson's disease. It is a significant problem for patients and their families, and can affect their ability to cope at home. It is often the development of dementia and other cognitive difficulties that leads to admission into a care home.

The *Just Invisible* report (2005), based on a Parkinson's Disease Society survey of Parkinson's patients and carers, examined the impact of, and issues around, the more advanced stages of Parkinson's disease. This survey revealed how the physical aspects of advanced Parkinson's disease, the emotional strain it produces, and, in some cases, the cognitive changes and mental health difficulties, combine to isolate the person, and to a larger extent, their carer.

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Treatment options

Until recently, there has been a lack of a licensed treatment option for dementia symptoms associated with Parkinson's disease. Nevertheless, some specialists have, in practice, been prescribing acetylcholinesterase inhibitors, a class of drugs used in the treatment of Alzheimer's disease, to manage the symptoms of Parkinson's disease dementia. Many have reported that selected patients have responded very well to these treatments.

CLINICIANS ON THE
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DEVELOPMENT GROUP
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WITH PARKINSON'S
DISEASE DEMENTIA

Rivastigmine, an acetylcholinesterase inhibitor, recently became the first and only medicine approved in Europe for the treatment of mild-to-moderately severe dementia associated with idiopathic Parkinson's disease. Its approval was based on the outcome of an international 24week, randomized, multicentre doubleblind, placebo-controlled study, known as the EXPRESS study, involving 541 patients (Emre et al, 2004). The results showed significantly positive outcomes for rivastigmine in all primary and secondary endpoints. This means that rivastigmine is effective on a wide range of symptoms of Parkinson's disease dementia and that the benefits were maintained over 48 weeks.

While the results from the clinical trial were promising, it should be observed that, in practice, clinicians report variable responses, with some patients responding better than others. One of the challenges for the future is to identify which patients might benefit most.

The Parkinson's Disease Society welcomes therapies such as rivastigmine, which give new hope to families caring for a loved one with dementia and may improve the quality of life of the whole family.

Specialist involvement

Treating the dementia symptoms associated with Parkinson's disease is a specialist area and requires a team with expertise in treating both Parkinson's disease and dementia.

Rivastigmine should be initiated and supervised by a physician experienced in the diagnosis and treatment of Alzheimer's disease or Parkinson's disease dementia. Although some nurses working in neurology will have the necessary prescribing powers and experience to initiate rivastigmine treatment, it is likely that the majority may not wish to on their own; they may prefer to recommend rather than prescribe treatment.

It is important not to underestimate the important role neuroscience nurses, in particular, Parkinson's disease nurse specialists, play in the management of Parkinson's disease dementia. It is often these nurses who identify the onset of dementia when reviewing a patient's Parkinson's symptoms. It therefore follows that these nurses play an important role in ensuring that the patients receive the specialist help they need, by referring them to the more specialist care of an old-age psychiatrist, geriatrician or a neurologist.

NICE's position

Now that an acetylcholinesterase inhibitor has been approved for clinical use in

Parkinson's disease dementia, it is necessary to ask what the National Institute for Health and Clinical Excellence (NICE) thinks about their use.

WE EXPECT A CAUTIOUS RECOMMENDATION FROM NICE FOR THEIR USE AND FOR THE NEED FOR REGULAR REVIEWS

The NICE guidelines for the diagnosis and management of Parkinson's disease are due to be published later this June, following publication of a draft in January (NICE, 2006). As the Parkinson's Disease Society representative on the Guideline Development Group, I have studied, with other members of the group, all areas involved in the diagnosis and management of Parkinson's. The Guideline Development Group examined the evidence for whether acetylcholinesterase inhibitors are effective cognitive enhancement therapies in

Parkinson's disease, and clinicians discussed their experiences in practice.

Clinicians on the Guideline Development Group considered acetylcholinesterase inhibitors to be useful agents commonly used in clinical practice and that they should be available for patients with Parkinson's disease dementia. Until the final guidelines are published, we will not know for certain what recommendation will be given by NICE. We expect a cautious recommendation from NICE for their use and for the need for regular reviews of these agents to be highlighted, as not all patients respond. NICE may also recommend that further research should be undertaken to help identify which patients are most likely to respond positively to drug therapy.

Welcome step

If such a recommendation is received, this will be a very welcome step forward for patients and their carers who are living with the burden of Parkinson's disease dementia every day.

Table 1. Resources

Parkinson's Disease Society

215 Vauxhall Bridge Road, London SW1V 1EJ

Tel: 020 7931 8080

E-mail: enquiries@parkinsons.org.uk

Helpline (freephone) 0808 800 0303 (Monday to Friday 9.30 am to 5.30 pm)

Just Invisible report

For a summary of the report please contact the Policy and Campaigns team on 020 7963 9307 or email campaigns@parkinsons.org.uk

Emre M, Aarsland D, Albanese A, Byrne EJ, Deuschl G, De Deyn PP, Durif F et al (2004) Rivastigmine for the dementia associated with Parkinson's disease patients: A randomized double-blind, placebo-controlled study. N Eng J Med **351**: 29-38

National Institute for Health and Clinical Excellence (2006) Parkinson's disease: Diagnosis and management in primary and secondary care. NICE guideline. Second draft for consultation, January 2006. www.nice.org.uk/page.aspx?o=289461 (accessed 6 June 2006)

Parkinson's Disease Society (2005) Just Invisible. PDS, London

USEFUL NEUROSCIENCE WEBSITES

Compiled by Belinda Crawford, Clinical Nurse Leader, Neuro Critical Care, National Hospital for Neurology and Neurosurgery, UCLH NHS Trust

http://www.trauma.org/resus/neuromoulage/index.html

Trauma site with an excellent neurology moulage on a head-injury scenario. Can you save your patient from secondary damage?

http://www.smartgroups.com/groups/Neurosciences

A multiprofessional web forum. Learn from the experience of members by asking for help with projects, setting up new services, or creating new posts. You can advertise study days, post a vote or access the 80-plus linked neurology websites. To access files posted on site and to receive mail you need to subscribe

http://www.brainandspine.co.uk

Great resource for patient information booklets on assorted brain and spine conditions, e.g. brain tumours, epilepsy, subarachnoid haemorrhage, head injury and angiogram

http://www.neuroguide.com

Neurosciences on the internet - search neurology journals, images, databases and A-Z of diseases

http://www.wfnn.nu/links.htm

World Federation of Neuroscience Nurses (WFNN) site. Details of the WFNN conferences. Links to neuroscience nursing organizations, journals and other neurology sites

http://www.bann.org.uk

British Association of Neuroscience Nurses (BANN) site. Find out about the work of BANN, join the organization, access information on benchmarking, national neurology conference details.

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http://www.SBNS.org

Society of British Neurological Surgeons

http://www.theabn.org

The Association of British Neurologists

http://www.neurologicalalliance.org.uk

Access information on a variety of charities involved in supporting patients with neurological disorders. Also download or order the excellent 'Getting the best from Neurological Services' - this booklet contains details of most neurology charities and provides patients/ relatives questions to ask their healthcare professionals

http://www.neuropat.dote.hu/

Excellent site on neuroanatomy, pathology and neuroradiology with great image banks, quizzes and links to resources on neurological observation and neuromuscular diseases

http://www2.braintrauma.org/

Excellent site on management and research into traumatic brain injury (TBI). Includes extensive clinical guidelines on TBI

http://www.criticalcareinfo.co.uk

Produced by the London Standing Conference for Nurses, critical care branch. If you work in a neurological critical care setting then use this site to develop a custom-made information pack for your relatives

http://www.adventuresinneuroscience.com

DVD-based neuroanatomy course that runs for about 2.5 hours and addresses many pathologies and assessment