Drugs for dementia: the first year

An audit of prescribing practice

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SUMMARY
In March 1998 the Department of Health and Social Services issued prescribing guidelines for the use of drugs for dementia. A criterion based audit of 202 consecutive cases was undertaken over one year which showed that the prescribing guidelines in general were being followed. A small number of patients, 3, were prescribed the drugs outside the guidelines and most failures, 10, were due to poor recording of data in the clinical record. Despite the recommendation of the DHSS no agreed shared care protocols have been implemented but this does not seem to have affected access to these drugs.

As a result of this audit changes have been made with regard to documentation of patient assessments and suggestions made to review Clinical Resource Efficiency Support Team (CREST) guidelines.

INTRODUCTION
Dementia is an organic syndrome characterised by a progressive decline in intellect, behaviour and personality in which there is no clouding of consciousness. It is estimated that 3.2% of people aged 70 - 79 and 10.8% of those aged 80 - 89 years have dementia of the Alzheimer's type (DAT).1 The condition is usually irreversible and until recently there have been no drugs developed which have had a significant effect on any of the aspects of the condition. In DAT, loss of cholinergic neurones in the nucleus basalis and loss of choline acetyl transferase in the hippocampus and neocortex are the main pathological and biochemical changes.2,3,4 Research into drugs for DAT has mainly been directed at combating this cholinergic deficit by reducing its breakdown through inhibiting acetylcholinesterase. By the end of 1994 several double blind clinical trials suggested that tacrine, a centrally active non-competitive reversible acetylcholinesterase inhibitor, when prescribed for DAT may improve cognitive impairment.5,6,7,8 In 1996 evidence was published showing improvement in cognition with donepezil hydrochloride, a piperidine based cholinesterase inhibitor.9,10 In April 1997, both tacrine and donepezil were licensed for use in DAT. In March 1998, regional guidelines for the use of Drugs for Dementia (DFD) were published by the Clinical Resource Efficiency Support Team (CREST) on behalf of the Department of Health and Social Services (DHSS), Northern Ireland.11

The Antrim/Ballymena Psychiatry of Old Age (POA) team uses a multidisciplinary consultant led approach in which social workers, community psychiatric nurses and doctors have a role in the assessment and management of patients. The team, in anticipation of the CREST guidelines of which they had prior knowledge through one of the authors (SAC) extended its service in January 1998 to provide a “Memory Clinic” to which General Practitioners (GP) could refer patients over 65 for assessment of early cognitive impairment. Although suitability for DFD was a prime consideration, it was intended that any patient could be assessed whatever the cause of their impairment. Assessment could be undertaken

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by any team member and protocols were established for data collection, cognitive assessment, prescribing and review which were necessary to ensure adherence to the CREST guidelines. All patients were seen by the consultant at the first appointment to verify the accuracy of data collected and establish the diagnosis. It was required that for all referrals to the memory clinic a physical examination and necessary investigations (e.g. ECG, FBP, U&E etc.) would be performed by the referring GP.

After the first year of DFD use it was decided to perform a criterion based audit of the prescribing practice of the Antrim/Ballymena POA team. The audit objectives were to see if all patients with DFD had been assessed for DFD, if drugs were prescribed in accordance with CREST guidelines and to identify any failures, why they occurred and how they could be overcome. The opportunity was taken to establish a database for future audit and research on this patient population.

METHODS

All patients seen by the Antrim/Ballymena POA team in the period January 1 1998 to December 31 1998 were identified using the hospital patient administration system and the patient record retrieved for audit. The inclusion criteria for audit were that DFD were recommended or prescribed during the audit period or that the patient had a diagnosis of DAT or any variant either in words or using the ICD.10 codes F00.0, F00. 1, F00.2 and F00.9 (pre-senile, late onset, mixed and unspecified Alzheimer's disease respectively).

There were no exclusion criteria.

Patient's notes that satisfied the inclusion criteria were audited. The audit criteria were based on the regional guidelines issued by CREST in March 1998. These, in essence, recommended that a diagnosis using ICD. 10 criteria for DAT should be made by a specialist (in old age psychiatry, elderly care medicine or neurology), and that the disease should be mild to moderate as measured by a Mini Mental State Examination (MMSE) score of 10 to 26.12 There should also be a shared care arrangement in which the GP would prescribe as advised by the specialist and monitor side effects, and the specialist would keep the patient under review to assess ongoing need for treatment. However, despite attempts to initiate formal shared care agreements locally no agreement has been reached. At present the authors of this paper are not aware of any shared care agreement being implemented anywhere in Northern Ireland so it was decided to acknowledge that all cases would be an audit failure as regards this criterion.

Demographic details, diagnosis, assessment, follow up arrangements and whether or not DFD were recommended or prescribed were recorded from the notes. Reasons for not starting or for discontinuation of DFD were also recorded.

An audit success was that any patient diagnosed with DAT was assessed for suitability for DFD and any patient with mild to moderate DAT (MMSE 10 to 26) was recommended for DFD with follow up by the specialist according to the CREST guidelines.

Audit failures were those patients who received DFD without a diagnosis of DAT, who were not assessed in accordance with the CREST guidelines or if the CREST guidelines were satisfied but the patient was not considered for DFD.

RESULTS

There were 509 patients seen during the year and it was possible to obtain the notes of 505. The inclusion criteria for audit were satisfied in 202 cases. The results of the audit are summarised in the Table.

199 of the audited patient notes contained a diagnosis of DAT, the remaining three cases having a diagnosis of multi-infarct dementia (2) and organic amnesia (1). All three patients had been prescribed DFD.

In the 199 DAT cases, 100 patients were recommended for DFD. Of these 98 satisfied the audit criteria and two did not, having a MMSE <10. These two had been started on DFD for management of severe behaviour disturbance that had failed to respond to all conventional treatments. In all but four cases DFD were initiated by the POA team, the others being started by a GP, a neurologist, a geriatrician and a cardiologist.

In 14 patients DFD were discontinued because of continued cognitive decline (1), deteriorating mental state i.e. irritability, aggression, delusions and agitation (7), bradycardia (1), gastrointestinal (GI) side effects i.e. nausea or diarrhoea (4) and one patient because of a cerebrovascular accident. Of the 99 DAT patients not on DFD 50 had a MMSE < 10, 19 had no MMSE recorded and 30
TABLE
Summary of audit results

| Audit failures | 7  | CREST criteria met but DFD not offered |
|----------------|----|----------------------------------------|
| 18             | 5  | no MMSE recorded                        |
|                | 3  | diagnosis other than DAT but offered DFD|
|                | 2  | MMSE less than 10 but offered DFD       |
|                | 1  | wrong diagnosis                         |

| Audit successes | 98 | CREST criteria met; DFD offered and used|
|-----------------|----|----------------------------------------|
| 184             | 50 | CREST criteria failed and refused DFD   |
|                 | 22 | CREST criteria met, DFD offered but not used|
|                 | 14 | MMSE impossible to record (documented)  |

had a MMSE score of 10-26. In the 19 cases where no MMSE were recorded 11 were too mentally impaired to test, one patient was too physically ill and two patients refused testing: they were considered valid exceptions. In five cases no reason was given for a MMSE not being recorded.

Of the 30 DAT patients who had an MMSE of 10-26, five patients had deteriorated cognitively after initial assessment which had taken place several months before the memory clinic started and when reassessed during the audit period had dropped below the lower limit of 10 on the MMSE. Three had become physically ill and two patients had died. Although DFD had been recommended by the POA team three patients refused or were non-compliant with treatment. Three further patients did not receive DFD despite specialist recommendation because either the GP refused to prescribe or the family refused to dispense. In another four cases investigation results were pending before DFD recommendation. DFD were not recommended in two patients due to cardiovascular conduction defects. These 22 were considered valid exceptions. In seven cases no reason was given for non-prescription of DFD and one patient was wrongly diagnosed.

Nearly all the patients had been prescribed donepezil as rivastigmine, another acetylcholinesterase inhibitor, was only licensed for use in May 1998, halfway through the audit period.

Follow-up of the 100 patients commenced on DFD occurred in 99 cases; the remaining patient moved away from the area and had been referred to another POA consultant.

In summary, there were 148 audit successes, 18 audit failures and 36 valid exceptions.

DISCUSSION
Although CREST guidelines suggest that various specialists may recommend treatment with DFD the burden is falling particularly on consultants in POA both in Northern Ireland and Great Britain.13 In this study DFD were initiated by doctors other than old age psychiatrists in only four of the 100 cases. If a consultant in another specialty recommends and a GP initiates treatment, patients usually will be referred to POA teams for follow up, assessment of psychiatric or behavioural problems or for access to domiciliary services. So although DFD may be initiated outside POA teams at some point most patients will become known to the local team. It is probable therefore that most people residing in Antrim and Ballymena who received DFD during 1998 were seen by this POA service. The outcome of this prescribing audit is probably a fair reflection of what is actually happening to the total population receiving DFD and lessons learned can be applied to any specialist prescribing DFD.

Most patients diagnosed with DAT were assessed for DFD, and if prescribed, the CREST guidelines
were generally adhered to and follow-up was universal. However, there were 18 audit failures, a rate of 9%. In three of these patients there was a failure in prescribing i.e. DFD were prescribed for a diagnosis other than DAT. A specialist not recommended by CREST prescribed for one patient with multi-infarct dementia and a neurologist and a psychiatrist prescribed for organic amnesia and multi-infarct dementia respectively.

In 13 patients there was a failure in the POA team’s assessment. No MMSE had been recorded in five cases; in seven cases, although the patients met the CREST guidelines, DFD were not considered and no reason given. One patient had been wrongly diagnosed. The patients in these 13 cases had not been assessed in the memory clinic but rather on domiciliary visits or in other psychiatric clinics. It is possible that patients were referred for other reasons e.g. depression or behaviour disturbance and priority given to this and the possibility of treatment of dementia overlooked.

In the two cases of DFD use in DAT with a MMSE less than 10 the indication was for treatment of severe behaviour disturbance which had not responded to conventional treatments i.e. neuroleptics, antidepressives and anticonvulsants. There is evidence that DFD can improve the behaviour disturbances associated with DAT \(^{14,15}\) and in these cases families were involved in the decision to use DFD and were aware of the licence restrictions. There was a dramatic improvement in one patient who was able to return to her previous home having been considered for an on-going care hospital bed prior to prescription of DFD.

A small number of patients (3) who agreed to the use of DFD were refused the drugs by the family or the patient’s GP. These patients had expressed clear views about treatment and the team felt that the patients’ views were valid and competent. Subsequent family discussions and letters to the GPs involved did not change the situation. This is a worrying aspect of service delivery and one that is impossible for the specialist to deal with as family, on whom the patient depends, refuse to fill prescriptions or administer the drugs. Although not a concern of this audit it is an ethical and practical problem which specialists need to be aware of and which requires further debate.

The failure of any grouping to produce a shared care agreement needs to be considered. Although no agreements exist, in reality GPs and specialists are working together to provide a service. If no difficulties are being experienced perhaps there is no need to provide such agreements and the CREST guidelines should therefore be reviewed. CREST should also consider including in the guidelines indications for DFD use in severe behaviour disturbance when conventional treatment measures have failed.

As most audit failures occurred during the assessment process protocols should ensure that anyone with a diagnosis of dementia has a recorded MMSE, that the type of dementia is specified and that a statement is recorded for those with DAT as to whether or not they are suitable for DFD.

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