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BMJ

Antidepressants and chronic pain

Effective analgesia in neuropathic pain and other syndromes

See p 827

Antidepressants are used widely to treat symptoms other than depression, many of which fit into a general category of pain. They include neuropathic pain (postherpetic neuralgia, diabetic neuropathy (p 827)[1]), irritable bowel syndrome, temporomandibular joint dysfunction, atypical facial pain, and fibromyalgia. In Britain no antidepressant is licensed for these indications. Do they work?

There is strong evidence from systematic reviews of randomised trials that tricyclic antidepressants are effective treatments for several of these conditions.[2-4] For established postherpetic neuralgia, tricyclic antidepressants seem to be the only drugs of proved benefit,[4] and the number needed to treat to achieve at least 50% pain relief after three to six weeks compared with placebo was 2.3 (95% confidence interval 1.7 to 3.3).[2] This means that two patients in five will achieve this (high) level of relief who would not have done so with placebo. Numbers needed to treat of two to three compare well with the most effective analgesics in acute pain, and with anticonvulsants in neuropathic pain.[5]

Figure 1 shows results from individual randomised trials of diabetic neuropathy and postherpetic neuralgia, each point representing one randomised trial.[2] All the points fall in the upper segment, showing treatment to be better than placebo. Overall, about 50-90% of patients can expect to achieve at least 50% pain relief with antidepressants, while others will achieve a lower level of relief that may still be worth while for them.

Antidepressants also work in other neuropathic pain syndromes. In 13 randomised studies of diabetic neuropathy the number needed to treat to achieve at least 50% pain relief was 3.0 (2.4 to 4), and in two studies of atypical facial pain it was 2.8 (2.0 to 4.7). The estimated number needed to treat from one study of pain after stroke was 1.7.[3]

The analgesic effects of antidepressants differ in several ways from classic descriptions of their action on depression itself. Amitriptyline, for example, has proved analgesic efficacy with a median preferred dose of 75 mg (with a clear dose response[6]) in a range of 25-150 mg daily. This range is lower than traditional doses for depression of 150-300 mg. The speed of onset of effect is much faster (one to seven days) than that reported in depression, and the analgesic effect is distinct from any effect on mood.[7]

The commonest adverse effects are drowsiness and dry mouth, which occur in one in three cases. About one in 30 patients has to stop taking the drug because of intolerable or unmanageable side effects. The profile of adverse effects is the same as when the drugs are used to treat depression.

Antidepressants have two roles in managing chronic pain. The primary role is when pain relief with conventional analgesics (from aspirin or paracetamol through to morphine) is inadequate or when pain relief is combined with intolerable or unmanageable adverse effects. The failure of conventional analgesics should justify a therapeutic trial of antidepressants, particularly if the pain is neuropathic (pain in a numb area). There used to be a dogma that the character of the neuropathic pain was predictive of response, so that burning pain should be treated with antidepressants and shooting pain with anticonvulsants. Max showed that this was wrong; in his study both burning and shooting pain responded to tricyclic antidepressants.[7]

A secondary role of antidepressants in treating chronic pain is their use in addition to conventional analgesics. This can be particularly effective in patients with cancer who have pain in multiple sites, some nociceptive and some neuropathic. Improved sleep is a huge bonus.

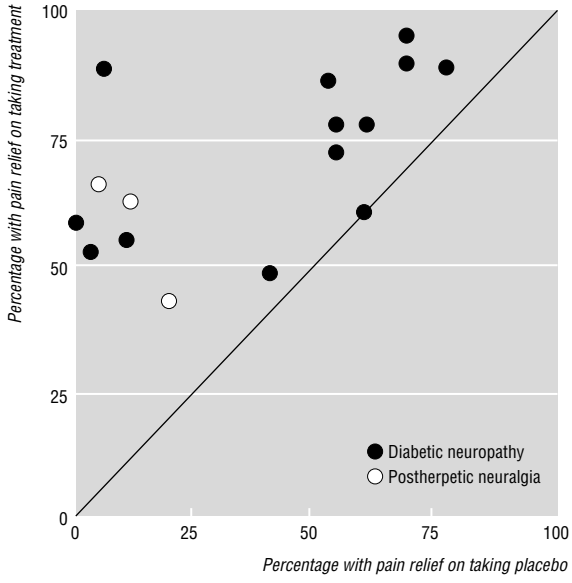

Fig 1 L'Abbé plot for trials of antidepressants in diabetic neuropathy and postherpetic neuralgia, showing percentage of patients achieving at least 50% pain relief when taking antidepressants versus placebo[1]

So which antidepressant should be chosen and at what dose? Tricyclic antidepressants have proved efficacy in chronic pain, but there is little evidence that one drug is better than another, though some patients troubled by adverse effects may benefit from changing drug. The common first choice is amitriptyline, with a starting dose of 25 mg (10 mg in frail patients) to be taken as a single night time dose one hour before lights out. We advise patients to increase the dose by 25 mg at weekly intervals until they either achieve pain relief or adverse effects become problematic. The maximum dose is 150 mg. Patients are warned to expect a dry mouth and drowsiness, which is why they should take the drug at night. If they are still drowsy first thing in the morning they should take the drug earlier in the evening.

There is no evidence that the newer antidepressants have greater analgesic effect than tricyclic drugs. The number needed to treat to achieve at least 50% pain relief was five for paroxetine and 15.3 for fluoxetine, while mianserin showed no difference from placebo.[1] There is still insufficient evidence from trials to be sure about this. The lower incidence of adverse effects for selective serotonin reuptake inhibitors (fluoxetine and paroxetine) than with tricyclic drugs may make them worth trying for those patients who cannot take tricyclics because of adverse effects.

One obvious question is what happens in the long term. Most evidence of efficacy comes from short term trials (lasting weeks to months), and, although many patients continue to achieve pain relief with antidepressants for months to years, this is not true for everybody. Another puzzle is how antidepressants work as analgesics. The standard (but not compelling) explanation is that they act on descending tracts from the brain via noradrenaline and serotonin systems to modulate signalling of pain in the spinal cord. This sounds, and is, an unsatisfactory explanation. But in the meantime it is clear that antidepressants have an important role to play in relieving chronic pain.

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Breast cancer screening in women aged under 50

Slower and smaller benefits, and more frequent adverse effects

Although there is a reasonably strong consensus that screening for breast cancer saves lives among women aged 50-69, debate is fierce about the effect in women aged 40-49. The debate is particularly strong in North America. The American Cancer Society, American Medical Association, and American College of Radiology recommend that screening should begin at age 40, while the United States Preventive Services Task Force, American College of Physicians, and Canadian Task Force on the Periodic Health Examination recommend starting at age 50. In 1993 the United States National Cancer Institute stepped back from its recommendation to begin at age 40 after reviewing the most up to date data from the seven randomised trials conducted in Edinburgh, Sweden, the United States, and Canada. The report of the institute's international workshop concluded: "For (women aged 40-49 years) it is clear that in the first five to seven years after study entry, there is no reduction in mortality from breast cancer that can be attributed to screening. There is an uncertain, and if present, marginal reduction in mortality at about 10-12 years. Only one study (Health Insurance Plan) provides information on long term effects beyond 12 years, and more information is needed."[1]

In January, with four more years of follow up from these trials available, the National Institutes of Health convened a consensus development conference on breast cancer screening in women aged 40-49. After reviewing the literature and hearing presentations from 32 experts, the independent panel concluded that "at the present time, the available data do not warrant a single recommendation for mammography for all women in their forties. Each woman should decide for herself whether to undergo mammography. Given both the importance and complexity of the issues involved in assessing the evidence, a woman should have access to the best possible information in an understandable and usable form."[2]

The dilemma for women in their 40s is that randomised trials of breast cancer screening have, on the one hand, found slower and smaller benefits and, on the other, found more frequent adverse effects than in older women. A meta-analysis found that, whereas mortality from breast cancer decreased among older women by about a third within seven years of study entry, mortality in screened and control groups among younger women was almost identical throughout the first seven years.[3] Recently, a repeat meta-analysis, with 10-15 years of follow up data, found a 15% reduction

in mortality among younger women invited for screening (ratio = 0.85, 95% confidence interval 0.71 to 1.01).[4]

Why the slow and small benefit? At the consensus conference, Tabar presented data suggesting that some cancers in younger women spread faster and argued that younger women must be screened yearly for optimal effect. Others have pointed out that all trial analyses are done according to age at entry, not age at diagnosis.[5] Because the incidence of breast cancer increases with age and because women age during a trial, it has been suggested that some of the delayed benefit of screening is due to cancers detected through screening when women reach their 50s and menopause. Three trials reviewed at the conference found that about a third of cancers among women in their 40s were detected after the women turned 50. The NHS breast screening programme now under way in Britain[6] avoids this "age-creep" problem by entering women at ages 40 and 41 and screening for five years, thus ensuring that all cancers are detected during the 40s.

Important adverse effects reviewed at the conference included false negative and false positive mammograms and possible overdiagnosis because of ductal carcinoma in situ. All these problems were more frequent in younger women: screening misses up to a quarter of cancers in younger women (compared with a tenth in older women), and the false positive rate is higher in younger women, leading to more benign biopsies, increased costs,[7] and greater anxiety.[8] The percentage of mammograms read as abnormal (and the resultant percentage of false positive mammograms) varies by country. In the United States, about 11% of mammograms are read as abnormal,[9] compared with fewer than 5% in the Edinburgh and Swedish trials.[1] Proponents of screening suggest that technical improvements in mammography should mitigate the problems of false negative and false positive results. Again, the ongoing British trial will help determine if this is so.

Ductal carcinoma in situ is a more difficult problem because it is not clear how often it progresses to invasive cancer. In one study ductal carcinoma in situ accounted for 43% of cancers detected by mammography in women in their 40s.[10] It may be that detection of ductal carcinoma in situ has led to overdiagnosis and is at least partly responsible for the increased incidence of breast cancer.[11]

There are few places in the developed world where a large scale trial could still be carried out to sort out these questions about breast cancer screening. As time goes on and questions remain about the usefulness of screening women in their 40s for breast cancer, the wisdom of the organisers of the British trial becomes increasingly apparent.

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Interdepartmental peer review

Allows exchange of ideas about clinical practice and organisation

Peer review in clinical medicine is concerned with maintaining and enhancing the quality of health care. It does this through formal external assessment by peers of the structures, processes, and outcomes of health care for which standards are known or accepted. It is distinct from appraisal, a confidential process in which individuals' professional and performance development and job progress are reviewed against agreed objectives at regular intervals by an educational supervisor or clinical manager. It is usually applied to specific aspects of care or outcomes of a service but is equally applicable to an entire service or department. Several specialties are now introducing interdepartmental reviews, enabling doctors to share and exchange ideas on best clinical and organisational practice.

The British Thoracic Society introduced a system of voluntary interdepartmental review in 1992.[1] This focuses on the organisational aspects of service provision and training, using the review as a forum for the exchange of ideas and experiences in subjects of particular interest or concern. The system grew out of a pilot scheme between units in East Anglia and Yorkshire[2] and encompasses many features of the organisational audit of the King's Fund in London.

Units are visited by two reviewers from different regions, at least one of whom comes from a hospital of similar size. Before the review, basic data are collected

on a detailed questionnaire. These include the population served; staffing levels; workload; inpatient, outpatient, and investigative facilities; provision for particular patient groups; and provision for training. This prepares the unit for the depth of the review and ensures that no time is wasted on collecting data when it could more profitably be spent focusing on particular subjects of interest or need and exchanging ideas.

The brief for reviewers is to assess the overall running of the unit during a two day visit, using published criteria where appropriate,[3-14] and to produce a detailed confidential report. The report highlights strengths (to enhance local morale) and notes any perceived weaknesses, including a list of recommendations for change. That nearly a third of chest physicians in Britain volunteered for the 1992 reviews, and over 140 (again, about a third) have volunteered for the 1997 reviews, suggests that the scheme fulfils a need and is popular.

In 1992 the reviewers made 155 key recommendations for change in 21 units and drew attention to a further 165 adverse factors, of which 72% did not require substantial additional resources for implementation. Predictably, many of these were already appreciated by the reviewed units, but unanticipated recommendations were made in about half the reviews. Highlighting excellence in the reports undoubtedly boosted local morale.

Schemes such as this must be judged on results. Half of the key recommendations for change had been achieved or were imminent one year later, but, perhaps more importantly, 82% of the participants thought that they had gained new ideas during the reviews. All but two of the 86 participants found the exercise helpful and rewarding.

The organisation of healthcare delivery is a neglected area, and clinical practice is continuously evolving with the introduction of new treatments and new management strategies. This form of peer review offers a way of helping clinicians respond and contribute to these changes. In Britain it has the support of the Royal College of Physicians and the Department of Health. Other specialties, including cardiology, are developing similar schemes. With increasing demands for accountability in the NHS, periodic peer review of departments may become mandatory, and experience from voluntary schemes should help ensure that mandatory schemes are both effective and acceptable.

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Disease modifying drugs in rheumatoid arthritis

Encouraging signs but effects not proved

Despite extensive research rheumatoid arthritis continues to cause suffering, disability, economic loss, and premature death. New approaches to treatment include immunotherapy, targeting cell surface structures, cell functions, cytokines, and adhesion molecules known to have a role in the inflammatory reaction.[1] However, the clinical controversy is whether to treat every patient soon after onset with disease modifying drugs. These include antimalarials, sulphasalazine, D-penicillamine, oral and parenteral gold, and methotrexate.

Recent support for early aggressive treatment has come from an open randomised study of very early cases from several centres in the Netherlands. The investigators compared treatment with several disease modifying drugs and with non-steroidal anti-inflammatory drugs. The results after one year showed that the patients given disease modifying drugs had lower sedimentation rates and had also done better on most clinical measures of disease activity. However, no difference was observed in the radiological measures of progression of the disease.[2]

The Dutch authors are to be congratulated on their successful organisation of collaboration between academic centres and doctors in routine clinical practice, and their results left no doubt that the patients

who completed a year on disease modifying drugs had a better immediate quality of life than those taking only non-steroidal drugs. But this study did not answer the crucial question: should all patients with very early rheumatoid arthritis be treated with disease modifying drugs? In a recent prospective cohort study of patients with early rheumatoid arthritis, treatment with disease modifying drugs was started only if the disease was not controlled by non-steroidal drugs or non-pharmacological means. After five years the radiological assessment of joint damage showed markedly greater progression in the patients not given disease modifying drugs. These patients made up around 10% of the total cohort and 25% of those in whom erosions were present within two years of the onset of the disease.[3] This suggests that rheumatologists are able to select patients who seem to be in need of more aggressive treatment using clinical judgment and simple laboratory measures.

When early aggressive treatment is thought appropriate, choices have to be made from among the disease modifying drugs. The research reports are not much help. Early use of specific disease modifying drugs has in some controlled studies been shown to retard but not halt radiographic progression. One much cited Dutch study concluded that sulphasalazine might be better than hydroxychloroquine after three years.[4] Auranofin was found superior to placebo after two and five years in a Scandinavian multicentre study.[5] Methotrexate was found to be slightly better than auranofin in a 36 week randomised trial assessing radiographic progression.[6] Cyclosporin was compared with placebo and claimed to halt progression in patients with "less early" disease, but on radiographic assessment the groups were not equal at the start.[7] Clearly more controlled long term studies of this nature are needed.

One possible confounder in such studies based on radiographic assessment of progression of the disease is concomitant administration of low doses of corticosteroids. The first modern study investigating the effect of adding prednisolone to treatment with disease modifying drugs in patients with early rheumatoid arthritis indicated that it might retard radiographic progression but not progression of symptoms or disability after two years.[8] Two other aspects of early treatment with disease modifying drugs need to be included in any assessment. The treatment requires close monitoring, and the patients must be made aware of the potential toxic effects. These factors may have a negative impact on their quality of life, marking them as "patients" to a greater extent than simpler treatments. The final negative feature of early aggressive treatment is its cost.

The questions posed here represent a major challenge for clinical rheumatologists. As they try to answer them they will need to coordinate their efforts in planning relevant interventional studies and organising early referral to specialist centres. General practitioners and general physicians will need to be motivated to support these efforts. The hope must be that further research has the potential to change rheumatoid arthritis into a controllable if not curable disease.[9]

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Setting the agenda for health after the election

The BMA's challenge

As we approach the general election the opinion polls place health issues near the top of the public's agenda. Last week the BMA council issued its challenge to all the political parties (see box). This challenge needs to be placed in the context of the past few turbulent years. Three years ago the BMA supported my seven point plan to reform the reforms of 1991. What is the interim verdict?

Firstly, I called for everyone to face the facts, inviting the government to acknowledge that its "huge national experiment" had failed and inviting the profession to recognise that it had not always been as imaginative or adaptable to change as it might have been. Politicians and public were challenged to admit that they had not matched expectations with resources. Greater realism now exists about the damaging irrelevance of market ideology to health care, with its bureaucracy and its inequities. Additional resources have been budgeted, although with an assumption of "efficiency savings," which are increasingly impossible

BMA's challenge to all parties

(1) To promote the health of the nation through action involving all relevant government departments, local government, health authorities, and voluntary organisations
(2) To support doctors and other health professionals in articulating targets and taking action, for example:
• To help people disadvantaged by physical, mental, or social problems
• To reduce the level of health and environmental hazards of tobacco
• To deal with problems affecting the health of young people
• To influence the development of environmental, housing, and transport policies
(3) To allocate resources on the basis of assessed need and the quality of the outcome of care to ensure equity of access and treatment for all patients
(4) To enunciate a clear evidence based strategy for the balanced development of primary and secondary health care, together with community care
(5) To recognise the need for coherent and consistent policies on the development, welfare, and use of the skills of staff in the service
(6) To fund the NHS unambiguously and explicity from public funds with due allowance for service inflation and no assumption of efficiency savings.

to realise without jeopardising patient care. The medical profession has reaffirmed its commitment to promote and deliver the highest possible quality of care.[1]

Secondly, I called for a restoration of the consensus over aims and objectives which are explicit in the Health of the Nation policy, based on equity, an intersectoral approach, community and patient participation, priority for disease prevention and health promotion, the appropriate use of advanced technology and expensive therapeutics, and international cooperation. The NHS was designed not as a narrow disease treatment system but as a comprehensive vehicle for promoting the nation's health in conjunction with other government departments and voluntary agencies.

The contemporary scene is mixed. Progress has been made in raising immunisation rates, screening for cancer of the breast and uterus, reducing fatalities from road accidents, and containing the epidemic of HIV and AIDS. But young people—girls in particular—are smoking more than ever, suicide rates in young men are a major concern, and obesity is a growing problem. A more encouraging feature is the commitment by the government[2] and political parties in general to the principles of equity, relevance, and quality in health care. The development of primary health care is currently the subject of legislation and must be matched by a coherent strategy for the hospital service and community care.

Thirdly, I urged the importance of assessing needs rather than demands, and outcomes rather than outputs. There was nothing new in this. A government working paper envisaged "a gradual introduction of a population approach to health needs assessment." [3] Sadly, commissioning of care continues to be based largely on secondhand information of limited relevance to local needs. While the efficiency index has proved to be flawed, progress has been made in devising mechanisms to evaluate the outcomes of care, and medical audit is established, although its potential remains to be exploited. The imperative of evidence based medicine is now holy writ, 25 years after Archie Cochrane's assertion that "there is a whole rational health service to gain."[4] The position of public health physicians, who are the key to this work, is critical and in many places parlous. With few exceptions, they remain trapped within the purchasing process, unable to fulfil their crucial functions fully.

My fourth point concerned the need for society to determine its priorities and allocate resources accordingly. Debate about priorities continues, with tortured issues of rationing generating fitful heat and little light.

Fifthly, I called for the reform of purchasing to include locality planning and rolling contracts based on quality, safety, and choice with a commitment to education, training, and research. Locality planning is winning support—although it is bedevilled by uncertainty about the future of fundholding; and the need for longer term contracts is generally acknowledged. An imaginative research and development strategy is in place, and the role of postgraduate medical deans has been enhanced.

The sixth point concerned the corresponding need to reform the provider side of the purchaser-provider split. Trusts have been forced to compete for survival by offering every major service, thereby duplicating specialist services for a defined population. Indeed, they were enjoined not to "collude." Sensible rationalisation is now beginning to happen, though the public remains to be educated. Local pay determination has been discredited by its disastrous imposition on nurses. The medical input to management through clinical and medical directors has fostered a palpable improvement in relations between medical and other managers.

My seventh point was a call for purchasers and providers to join forces in strategic planning. This is an aspiration whose time has come, and both authorities and trusts are now beginning to talk of joint planning.

Given some progress so far, the BMA's new six point challenge emphasises where we need still more effort. We have thrown down the gauntlet. Who will pick it up?

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Correction

Dietary treatment of active Crohn's disease

An error occurred in this article by Wight and Scott (15 February, pp 454-5). The first author's name should have been Nick Wight (not Nick Wright).