Quality of service provision for anticoagulation in atrial fibrillation

Bridges from evidence to practice are fragile

EDITOR,—C M Sudlow and colleagues are right to raise doubts about the applicability of the evidence regarding anticoagulation for atrial fibrillation to current situations in both primary and secondary care.¹ This debate takes place, however, in a wider context: there are further barriers to the implementation of research findings that need to be addressed. Clinical situations are complex, and even if all the relevant resources were in place for widespread anticoagulant treatment how likely is it that such treatment would become routine rather than the domain simply of enthusiasts? Three such barriers are as follows.

Firstly, clinicians are concerned that studies select patients too carefully, thus maximising both the effects of the clinical risk and responsiveness to the intervention.² This bias may be addressed by selecting and monitoring "real life" patients as carefully as is done in the trials.¹ But a second barrier to implementation of the results can be envisaged: if one uses the criteria for entry to the anticoagulation trials as the basis for deciding who should receive treatment then 60-97% of patients would be ineligible.¹ If, for example, only 1 in 10 qualifies according to these criteria then a practitioner may find the time burdens of assessment excessive in relation to the clinical activity implemented. This may discourage attempts to be certain that every patient who could benefit receives the treatment.²

Thirdly, the way in which the results of trials are conveyed to clinicians may influence practice: do they provide enough predictive information on which to base a decision about treatment? Does the presentation of percentages, relative risks, annual event rates, or numbers needed to treat influence acceptance by clinicians, for whom (along with patients) the information was designed to be useful? Translation of the language of research into that of the consultation may require a change from the current numerical presentation to a more narrative approach, taking account of psychological and contextual considerations.³

These factors require recognition and further study if we are to improve the way in which research findings are implemented. Practitioners are of necessity accustomed to making decisions in situations of uncertainty. Thus the shift from the current experiential and qualitative modes of practice to a quantitative or evidence based mode is likely to be slow. Given the complexity of clinical situations that arise for the same disorder, it will be a long time before we generate the answers to most of the questions that confront practitioners to enable them to make this shift. Bridges from evidence to clinical practice are bound to be fragile for the foreseeable future.² The research questions themselves may have to be radically revised to focus on the problems that confront practitioners rather than those that are apparent to researchers or resource managers.

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Letters will be edited and may be shortened.

- 1 Sudlow CM, Rodgers H, Kenny RA, Thomson RG, Sweeney KG, Pereira Gray DJ, *et al.* Service provision and use of anticoagulants in atrial fibrillation. *BMJ* 1995;311:558-61. (26 August.)
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Many patients are ineligible

EDITOR,—I share C M Sudlow and colleagues' concern over whether evidence from studies of the prevention of stroke in patients with atrial fibrillation applies to clinical practice because of the highly selected nature of the patients in randomised trials.¹ Compliance and safety may be different when anticoagulants are used in clinical practice rather than in the carefully selected, well motivated, and closely monitored participants in studies, and patients in clinical practice may have different risks of thromboembolism and bleeding. In a recent survey of patients with atrial fibrillation, for example, the monitoring interval was less frequent, the international normalised ratio less commonly within the target therapeutic range, and the prevalence of concurrent illness higher than was the case in patients in clinical trials.² The concerns about translating the results of clinical trials to clinical practice do not mean, however, that we should neglect to give anti-thrombotic drugs, including warfarin, to suitable patients with atrial fibrillation.

Sudlow and colleagues suggest that further

information is required on the prevalence of atrial fibrillation in Britain, the prevalence of and contraindications to anticoagulant treatment, and the factors that influence doctors' decisions in treating atrial fibrillation. In prospective surveys of acute medical admissions to a Scottish district general hospital³ and a hospital in the centre of Birmingham serving a multiracial population,⁴ colleagues and I found atrial fibrillation in 3-6% of patients. Importantly, however, we noted suboptimal use of standard clinical investigations and of antithrombotic treatment for patients with atrial fibrillation despite clinical risk factors for thromboembolism (hypertension, heart failure, previous thromboembolism) being present.^{3,4}

In our survey in Birmingham, among the 61 patients newly diagnosed as having atrial fibrillation who were discharged from hospital only 15 were prescribed warfarin and 19 aspirin (the latter predominantly for concomitant vascular disease). Among the whole group (n=185) contraindications to warfarin were as follows: a history of gastrointestinal bleeding or peptic ulcer in 32, recent stroke in 18, "age" in 32, dementia or lack of comprehension in six, and chronic renal failure in two.

Atrial fibrillation is a common arrhythmia with various aetiologies, clinical presentations, and therapeutic options. Colleagues and I conducted a questionnaire survey of 214 consultant physicians in England, Wales, and Scotland and found considerable variation in the management of atrial fibrillation, with more cardiologists than non-cardiologists considering cardioversion and thromboprophylaxis with anticoagulants.⁵ Reassuringly, decisions about anticoagulant treatment were usually related to the perceived relative risk of thromboembolism versus haemorrhage in each of the case management scenarios described in our questionnaire.⁵

The continuing debate over the use of anticoagulant treatment in atrial fibrillation and the results of our questionnaire survey strongly suggest that guidelines on the clinical management of this common arrhythmia are required.

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Patients and doctors play it safe

EDITOR,—C M Sudlow and colleagues draw attention to the need for the planned provision of facilities to monitor the increasing number of patients to be treated,¹ in line with current recommendations.² We wish to make several suggestions in the light of a recent audit of a cardiac anticoagulation clinic that we undertook recently.

A random sample of 151 patients (83 female) was given a questionnaire, and the current international normalised ratio was noted in addition. The mean (SD) age was 63.7 (10.7) years (range 24-93). Most of the patients (126) had a cardiac diagnosis (valve replacement, valvular disease, etc), while the rest had deep venous thrombosis and pulmonary embolism.

Strength of warfarin tablets—Warfarin tablets are available in three strengths (1, 3, and 5 mg). Only seven patients used the 5 mg tablet. Since only five patients were taking 9 mg or more daily, we suggest that all patients could be simply and perhaps more safely treated with the 1 and 3 mg tablets only. We suggest that the 5 mg tablet be abandoned.

Playing safe and computerisation—With increasing numbers of patients being treated, computerisation of the dose is being considered. The official target for the international normalised ratio was 2.0-3.0. Our results showed a peak in the lower half of the target zone, presumably because the doctors were playing safe: the ratio was 1.0-1.4 in 11 patients, 1.5-1.9 in 37, 2.0-2.4 in 45, 2.5-2.9 in 38, 3.0-3.4 in 16, 3.5-3.9 in three, and 4.0-4.4 in one. The low incidence of side effects (only one patient required admission to hospital) reflects this caution. A transfer to computerised control, aiming for the middle of the official target zone, would shift the distribution to the right, possibly increasing the rate of complications.

Communication with patients—Patients were aware of their dose of warfarin ($n=148$), knew the reason for taking it (143), and were meticulous in their compliance (149 took it at same time each day, and 138 knew not to take a double dose to compensate for forgetting a dose). Ninety five, however, did not know the desirable international normalised ratio, and only three knew that the abbreviation INR stood for international normalised ratio. With patients being encouraged to have more involvement in their treatment, it is important for them to have a better of understanding of the goals of treatment and the terms used to monitor it.

The information was collected by Miss Belinda Teh as part of a master's degree in medical science; the study was approved by the faculty of medicine's research ethics committee.

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Difficulties of routine treatment are exaggerated

EDITOR—C M Sudlow and colleagues, and K G Sweeney and colleagues' commentary on their article, exaggerate the difficulties in acting on the research evidence on the use of anticoagulants in atrial fibrillation.¹ They point to the risk of bleeding, the need for data on prevalence, and patients' preferences as areas of uncertainty.

Much of the evidence on the incidence of bleeding as a side effect of anticoagulant treatment derives from data recorded in the 1980s and earlier, since when the technology of monitoring has improved. Nevertheless, bleeds are a reason to consider stopping treatment, on the grounds that patients' quality of life may be adversely affected by continued anticoagulation.² Fortunately, results from controlled trials have been corroborated by experience of anticoagulant treatment in clinical practice from a large health maintenance organisation in Boston. Treatment of 65% of those with atrial fibrillation was achieved in a population with higher levels of comorbidity than those seen in trials. The incidence of strokes and major and minor bleeds (14% annually in the latter case) was similar in practice to that in the treatment arms of the trials.³

Using data on prevalence from the Framingham study, I have estimated the number of strokes occurring in people with atrial fibrillation in Northamptonshire. At 18% of all first strokes, my estimate agrees closely with figures in community studies of stroke (17% in the Oxfordshire community stroke project), suggesting that the prevalence of atrial fibrillation in Northamptonshire is similar to that in the Framingham study.

If we accept the results of meta-analysis of the controlled trials a further 52 strokes would be avoided annually in Northamptonshire district if 65% of patients aged 65 to 84 were treated instead of current levels of coverage (estimated in an audit as 7.5%). This would mean 1900 more people taking warfarin. Five additional episodes of major bleeding would be expected. Additional monitoring costs would not exceed £90 000 and drug costs £20 000. Overall, treating 40 people at a cost of under £2400 would avert one outcome event. Even if start up and diagnostic costs doubled this figure the treatment would remain worth while. With a 14% annual drop out rate, fewer people would be treated but the cost of avoiding a stroke would remain the same (unpublished MSc thesis).

We know who will benefit and by how much—current evidence suggests all those over 65 with atrial fibrillation and those under 65 with any of three additional risk factors (previous transient ischaemic attack or stroke, diabetes, and hypertension). We know roughly how many will benefit. We know roughly how much such treatment will cost the health service. It has been shown to work elsewhere. Given this knowledge, it is hard to agree that the need for more research is greater than the need for action. As for patients' autonomy, how is this served if we do not offer the choice?

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Cardioversion should be attempted

EDITOR—C M Sudlow and colleagues introduce the concept of packages of care in atrial fibrillation.¹ Full packages of care for patients with atrial fibrillation will involve much more than the provision of anticoagulant treatment. Atrial fibrillation causes not only an increased risk of embolism but also important symptoms in itself, especially when the ventricular rate is poorly controlled, and it is an inefficient cardiac rhythm. The aim of treatment should therefore be not only to minimise the risk of embolism but also to achieve good control of the ventricular rate and to restore sinus rhythm when possible. Cardioversion to sinus rhythm improves functional capacity² and, if maintained, removes the need for long term anticoagulant treatment.

Attempted direct current cardioversion of atrial fibrillation inevitably necessitates referral to secondary care, and patients need anticoagulant treatment before the attempt. This includes young

patients with "lone" atrial fibrillation, in whom cardioversion is most likely to be successful. Even if sinus rhythm is not restored, anticoagulants may be stopped later in such patients. Nevertheless, this shows that good management of atrial fibrillation has considerable cost implications, and packages of care are likely to include use of secondary care facilities as well as echocardiography and anticoagulant treatment.

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In Finland anticoagulant treatment is monitored by general practitioners

EDITOR—C M Sudlow and colleagues emphasise the importance of an understanding of "the whole package of care" when new research evidence concerning the effect of anticoagulant treatment in preventing strokes in patients with atrial fibrillation is applied to everyday work.¹ In their commentary on the article K G Sweeney and colleagues are worried about complications of the treatment and about underanticoagulation.²

In Finland anticoagulant treatment is monitored by general practitioners in primary health care. In some cases they also start the treatment. The country thus has a system that Sweeney *et al* and Pell *et al* might view as ideal.³

In 1992 we carried out a study of the prevalence of anticoagulant treatment in Finland. We also recorded the main and secondary indications for anticoagulant treatment and the most recent measurement of the prothrombin time. Among the total population of 182 091 patients in eight ordinary health centres we found (from laboratory records) that 1255 (0.69%) were receiving anticoagulant treatment. Altogether 590 of these patients—0.32% of the total population—had atrial fibrillation as the main or a secondary indication. The prevalence of patients with atrial fibrillation who were receiving anticoagulant treatment was 0.9% (169/17 793) among people aged 60-69, 1.8% (123/6654) among those aged 70-74, and 1.4% (32/2314) among those aged over 85. As the prevalence of atrial fibrillation in Finland is 3.4%, 6.1%, and 18.0% in these age groups, respectively,⁴ we can estimate that about one third of patients with atrial fibrillation receive anticoagulant treatment.

The most recent prothrombin time was available for 589 patients with atrial fibrillation who had been treated for more than one month. Values were within the recommended range in 497, below the lower limit of the range in nine, and above the upper limit of the range in 74. The distribution of values was the same in all age groups.

Follow up data at one year were available on 1131 patients from seven health centres. Altogether 522 had atrial fibrillation, of whom 414 were still receiving treatment; only 13 had stopped the treatment because of complications. Sixteen patients with atrial fibrillation had developed bleeding that necessitated admission to hospital, while 38 had developed minor bleeding (for example, epistaxis). One of the 522 patients had died of subarachnoid bleeding possibly connected with the treatment, and four had died of a thromboembolism that had not been prevented.

Our data reflect the ordinary "package of care" in eight health centres in Finland. The prevalence of anticoagulant treatment and the proportion of patients receiving such treatment because of atrial fibrillation seem to be high compared