

Bandolier

Evidence-based healthcare

What do we think?
What do we know?
What can we prove?

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The 6th Bandolier Conference: Stroke – what to do second. Optimising secondary prevention and follow-up care

Introduction

In the early days of the NHS research and development programme in the former Oxford Region, someone commented at a meeting that only seven things in medicine were 'known' to work. That seemed improbable, and some bright spark piped up that thiopentone was known to work as an induction agent for anaesthesia – inject enough and anyone can be made to go to sleep. OK, so seven things are known to work, plus thiopentone. The game then continued with plaster casts for broken bones, and so on.

Thus *Bandolier* was born, as a list of bullet points of those things 'known' to work, or not to work, in medicine. And where do you put bullets? In a bandolier. Hence the name.

But more than five years and 62 issues of *Bandolier* later, one of the themes that has to be explored is that of the complex intervention – the 'overall package of care' that can make such a difference in quality in healthcare. Stroke is one of those complex areas – especially what to do to maximise quality of life for survivors of a stroke. This conference continued a theme of stroke in *Bandolier*. Stroke occupied a major portion of the third issue, and we have returned to it on other occasions when evidence became available.

In this *Bandolier* conference on secondary prevention of stroke we tried to bring together the most up-to-date evidence from both primary and secondary care.

In the morning sessions there was discussion of pharmacological interventions and the current evidence base from meta-analyses and trials was presented. The problem of translating this evidence of 'best practice' into everyday practice was examined in the light of data showing that even simple, cheap interventions (such as aspirin therapy) are not being universally implemented. The options for secondary prevention were reviewed realistically from both a public health perspective and a health economics perspective. An innovative scheme that aims to systematically improve standards of patient care in East Kent was presented as an example of how secondary prevention can be improved in practice.

The afternoon sessions focused on the work of the multi-disciplinary teams that provide stroke rehabilitation, both in a hospital-based setting and in the community. The role of the voluntary sector in helping stroke survivors and their families and carers was also considered ■

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Evidence from antithrombotics trials

Colin Baigent *BM BCh MA MSc MRC Scientist, Clinical Trial Service Unit and Epidemiological Studies Unit, University of Oxford, Radcliffe Infirmary, Oxford*

This presentation summarised the latest randomised evidence relating to antithrombotic therapy for the treatment and secondary prevention of stroke. The data presented were taken from the systematic overview conducted by the Antithrombotic Trialists' Collaboration, which has not yet been published.

In order not to compromise the future publication of this overview, the data have not been included in these conference proceedings ■

Perspectives from primary care

Nick Hicks *FRCP MRCGP FSPHM Consultant Public Health Physician, Oxfordshire Health Authority*

This presentation illustrated the challenges faced in primary care with regard to implementing secondary prevention interventions, and challenged the delegates with a hypothetical case that showed the current lack of consensus on treatment. Evidence was presented which suggested that in practice even simple, cheap interventions, such as aspirin therapy, are by no means universally applied.

The current evidence in secondary prevention is impressive and it is natural to be excited by it. It gives us a very good guide as to what ought to be happening to people, and tells us that we have a huge opportunity for preventing important morbidity and mortality. However, it also adds to the list of interventions that we know we ought to be able to provide.

Providing an excellent health service is not just about doing the esoteric right thing occasionally, but, just as importantly, it is about doing the simple things right all of the time.

In the NHS we often talk about centres of excellence, and that is a phrase which is usually applied to teaching hospitals. However, excellent care can be provided both in primary care and secondary care, and in any institution large or small. All these institutions should be striving to be centres of excellence.

Standards of care

There is considerable potential for improving quality of care. The evidence suggests that Oxfordshire, which has some of the lowest rates of CHD in the country and has worked particularly hard at secondary prevention, still has plenty of scope for improvement.

Standards in Oxfordshire

Aspirin

The most recent data about coronary heart disease in Oxfordshire are derived from the 1998 audit by the local Primary Care Medical Audit Group. They received data from 28 practices; these are practices that are likely to have better than average results as they are the enthusiasts who volunteered to participate in the audit.

The audit looked at patients with a clear diagnosis of coronary heart disease. For each practice, it determined the percentage of these patients who have a record of whether they are receiving aspirin therapy or not. (It doesn't mean that the patients are not taking aspirin if they are not included, but it does mean that the practices haven't got a record.)

In a handful of practices the percentage of patients who have a record of whether they are taking aspirin is in the high 90s or even 100%; however, other practices have recorded this information for less than 10% of their patients with established disease.

Statins

The data on statins for the same group of patients show a similar picture. Among patients whose cholesterol has been documented as being over 5.5 mmol/l, in some practices only around 5% are not on a lipid-lowering drug. However, there are other practices where most patients with established heart disease and high cholesterol levels are not on a lipid-lowering drug.

A national perspective

It is very easy to criticise, yet, as a whole, the results in Oxfordshire are better than in most parts of the country if you judge them by mortality figures. Despite this, the incidence of simple-to-apply, effective treatments remains, on average, at around 50–60% of what it could be.

This is an example from primary care. Similar gaps between research and practice can also be found in hospital practice. The general point applies to the delivery of healthcare in the NHS as a whole.

Case study

The hypothetical case study was set on a late Friday afternoon and involved a 69-year-old man in atrial fibrillation who had suffered a transient ischaemic attack (TIA) the day before. The delegates were asked to consider what interventions they would consider.

The results from the floor showed substantial disagreement about the action that should be taken, illustrating the difficulties inherent in applying the results of trials to individual cases. There was consensus on aspirin therapy, but opinion was divided on issues such as warfarinisation and whether to refer the patient to hospital for admission.

Conclusions

Currently clinicians are set up to fail when they are expected to deliver the impossible. This is due to a number of factors. In primary care, doctors have an increasing workload and are expected to undertake increasingly complex and important

tasks. They have been bombarded with treatment guidelines and there is new evidence, and new treatments, emerging all the time. The system is generally reactive rather than proactive; it is unsystematic, disorganised and confused. As we have seen, standards of care vary enormously, even within localities.

We need to change so that primary care is set up to succeed. There needs to be systematic identification, investigation, treatment, follow-up and audit of disease areas. Clear guidance that is backed up with external support is essential. Solutions need to be practical and focus on achieving excellence in providing simple, effective interventions.

Practices also need help to become computerised and make better use of information technology. This will help to give GPs the confidence to achieve excellent levels of care that are applied systematically to the whole population ■

PRICCE and the secondary care interface

Tony Snell *MB ChB DRCOG MRCP Medical Director, East Kent Health Authority*

This presentation reviewed East Kent Health Authority's PRiMary Care Clinical Effectiveness (PRICCE) scheme as a model for systematically improving standards and equality of care. The scheme aims to provide effective healthcare with an emphasis on prevention. Achieving value for money, not cost savings, is the intention.

The PRICCE scheme was developed to help GPs and their teams implement evidence-based systems of care to improve patients' quality of life and reduce the number of incidents which might lead to hospital treatment, or worse.

The ideas behind PRICCE

As a concept, preventive medicine is blindingly simple. For example, if you give patients with angina aspirin you can prevent a large number of heart attacks. But the implementation of a major system of preventive medicine is challenging in its complexity and scale.

The idea of getting clinicians to administer guidelines just wasn't working. We realised that GPs needed support to achieve improved standards.

The aim is to deliver health gains in East Kent for a relatively modest investment.

Concerns

As might be expected, the scheme was not universally welcomed. Some consultants contested that more could be done to improve quality of life by simply increasing the number of hip replacements, eye operations, and so on.

Many GPs also reacted with concern and apprehension when the scheme was proposed. Some felt it was a direct interference with clinical practice; others thought that the money was derisory, there were those who didn't agree with the clinical evidence, and many felt they could never achieve the required standards.

How PRICCE works

The scheme sets targets for 13 therapeutic areas: asthma, diabetes, angina, hypertension, heart failure, high cholesterol, the use of anticoagulants and aspirin in heart disease, treatment of myocardial infarction, dyspepsia, epilepsy, leg ulcers, depression and urinary tract infections in children. It is up to the GPs involved to decide how to achieve the targets; however, if they do not reach these standards then they lose funding from the scheme.

The authority has ploughed a considerable sum of money into the scheme, more than £300,000 in the first year. It's a bold, some might say courageous, investment in a programme where, although some benefits are seen in the short to medium term, others materialise only in the long term.

Practices are given £3,000 per participating full-time equivalent doctor a year, and given the number of diseases they have to cover, that's not much. They can spend the money however they choose – on extra staff, IT equipment, audit, or whatever they need.

Remarkably, 102 doctors signed up for the first year of the scheme, which ends in April, and 82 more have indicated that they want to join in the next wave.

Key to the implementation of the scheme are accurate and detailed computerised databases. Setting these up has generated an immense workload for most of the practices taking part. But the exercise has proved invaluable in discovering patients who were slipping through the net in terms of interventions that could have significant health benefits.

Benefits of the scheme

The scheme is already showing results. Nine months from its inception, many of the 102 doctors taking part in the scheme claim that it is saving lives and improving the way in which they manage patients.

The scheme has also improved the relationship between primary and secondary care by increasing the number of appropriate referrals and so on. It has promoted dialogue between GPs and secondary care specialists; for example, GPs are now talking to cardiologists about the treatment and management of heart attack patients.

Despite aiming for equality of care, this scheme initially focuses on encouraging the leading edge rather than bringing the trailing edge up to scratch. Doctors who are already doing well are being helped to do even better.

The autonomy of doctors is preserved by the scheme – there are no rigid protocols. How each practice achieves the required targets is up to them. The scheme also encourages practices to work as a team. Instead of doctors operating in isolation as individuals, they are now better integrated into multidisciplinary teams that include the administrative staff. This means that the whole team is being motivated to achieve real benefits for patients.

The future

This scheme is particularly relevant bearing in mind the introduction of clinical governance. It means that East Kent Health Authority is up to speed on key areas such as cardiovascular disease, diabetes and depression. Soon East Kent will have 60% or more of its GPs involved, and if they all deliver this standard of care then it will set a framework for other doctors to move in the same direction. This is also significant as

regards the legal precedent that says that if the majority of doctors are doing something, then you should be doing it too.

The signs of clinical outcomes are emerging. Most GPs have achieved the required standards in all but diabetes, which is a complicated area. This advance is saving lives and improving quality of care ■

The clinician in a clinical trial setting – ESPS-2

Charles Forbes MD FRCP Professor of Medicine, Ninewells Hospital, University of Dundee

This presentation dealt with the organisation of the second European Stroke Prevention Study (ESPS-2), from the planning stages in 1988, through setting up the various committees and agreeing the trial protocol, to recruiting the centres.

Stroke remains a major problem for all western countries and especially for their healthcare systems. Just over 100,000 new strokes occur each year in the UK with probably 25,000–30,000 recurrences of stroke. This leaves about 500,000 people who have survived a stroke or transient ischaemic attack (TIA) within the community at any one time and it is the cost of managing these people that creates a major financial burden. This cost is estimated conservatively at 1990 figures to be about £1.4 billion. In addition, there are 7.7 million working days lost in people under the age of 65 who have sustained a stroke. The bed usage for stroke patients in the NHS is about 13% of all clinical beds.

ESPS-2: study design

The philosophy of the study was agreed by an independent steering committee, which included representatives of various other committees but which had the overall responsibility for the study. The protocol was devised by a small group who had experience both in stroke management and in clinical trials. They would ultimately be responsible for publishing the results. An independent ethics committee was set up to look at the protocol and also to answer ethical questions as they arose during the course of the study.

The Mortality and Morbidity Assessment Group was set up under the Chairmanship of Professor Pathy, and had a remit to look at the inclusion criteria and to ensure that people who were admitted to the study fulfilled these criteria. Also they had a remit to look at the events and to ensure that the classification of the event was correct. Randomisation was done through EORTC (European Organisation for Randomised Trials in Cancer). In addition, a Samples Supply Centre was created to ensure the logical and accurate distribution of trial material. An independent statistical centre, under the direction of Professor Philip Smets of the University of Brussels, was responsible for data entry and eventually analysis.

The inclusion criteria were clinically stable adult patients with recent TIA or ischaemic stroke. Preferably, the patients had received a CT scan to rule out cerebral haemorrhage. Patients with cerebral haemorrhage or tumour, with a history of peptic ulceration, with hypersensitivity to aspirin, with

concomitant disease (or pregnancy), who were on concomitant therapy, or who had had recent neurovascular surgery, were excluded.

The trial was set up as a multicentre trial, placebo-controlled, double-blind with a factorial element for analysis. There were four treatment groups and a two-year follow-up. The treatment groups were: low-dose aspirin; sustained-release dipyridamole; a combination of low-dose aspirin plus sustained-release dipyridamole; and placebo. The ethical committee approved the use of a placebo in this study as there was no consensus as to the optimum standard treatment at this time.

The dose of aspirin used in the trial was determined from a study of the minimum dose of aspirin that was effective in the inhibition of cyclo-oxygenase in the platelets of human volunteers. In an attempt to reduce the drop-out rate seen in other studies due to aspirin-related side-effects, this minimum dose was recommended. Dipyridamole was used in a new sustained release formulation that gave 12 hours of action and avoided the very large peak plasma levels that had been usual with standard formulations.

The dose of aspirin was therefore set at 50 mg per day and dipyridamole at 400 mg per day in a divided dose. The end-point definitions used were similar to those in ESPS-1: all-cause death; sudden death; stroke; fatal stroke; fatal myocardial infarction (MI). Fifty-nine centres were recruited in 13 European countries and eventually 6,602 patients were made available for analysis, all of them having been followed for two years.

Analysis of the study population showed that the groups were well matched in terms of baseline characteristics including: age, sex, qualifying events, concomitant disease and risk factors. One centre was found to have adopted unacceptable clinical practice and, accordingly, the steering committee decided that this centre should be excluded and all 452 randomisations were taken out. This centre was further investigated and legal action was instituted.

Results

The analysis of the ESPS-2 study has already been published. It shows conclusively that 400 mg sustained-release dipyridamole is as effective as 50 mg of aspirin in secondary prevention. This is the first time in clinical trials that this result has been proven.

In addition, the study has shown that the combination of low-dose aspirin plus sustained-release dipyridamole is significantly better than either therapy on its own – it is probably twice as good in the prevention of fatal and non-fatal stroke and TIA ■

A view from the National Prescribing Centre

Martin Duerden MRCP Dip Ther DFPHM Medical Director, National Prescribing Centre

This presentation considered the problems of translating the evidence base of 'best practice' in secondary stroke prevention into widespread actual practice in

primary care, and raised concern that there is a shortfall in implementing best practice even with widely accepted and cheap interventions such as aspirin.

Optimising stroke prevention in practice

In order to attempt to optimise current practice, the first step is to produce a health needs assessment of the burden of stroke on the community and on the NHS. Second, we need to evaluate the available study evidence and consider what interventions will be feasible in day-to-day practice. We then have to look at how effective we are at implementing these interventions in practice.

Compliance is obviously an issue here – we can prescribe the best treatments but if patients are not taking them then this will not be translated into clinical gain. For example, in hypertension therapy there is some evidence that about 50% of patients stop taking their therapy within about six months.

The issues surrounding the treatment options

If you consider a treatment such as alteplase, which has to be given in acute stroke within a few hours, it is one thing to look at all the good evidence showing how it might work and what benefits it might bring, but if you don't have the service provision to deliver those benefits, there is not much point in carrying it forward. The concept of 'time is brain', and the idea of getting patients into hospital as fast as possible after a stroke, is not something that the NHS has traditionally done, and services would need to be reconfigured to enable this process.

In the large-scale CAPRIE study¹ there was good evidence that both aspirin and clopidogrel reduced further event rate (stroke, MI or vascular death as a composite measure). Clopidogrel was statistically significantly more effective than aspirin. However, when you work out the number needed to treat (NNT) you encounter the problem of converting statistical significance into clinical significance – the NNT to prevent further events with clopidogrel rather than aspirin is around 200 over one year. On this evidence you really couldn't argue that clopidogrel should be adopted as a superior drug for secondary prevention.

How well is 'best practice' being implemented in practice?

Despite the lack of direct evidence that hypertension control prevents secondary stroke, we would be very foolish not to manage high blood pressure in stroke victims. Observational analysis from within the UK TIA aspirin trial suggested that for every 10 mmHg decrease in systolic blood pressure and every 5 mmHg decrease in diastolic blood pressure there was about a 30% decrease in stroke events.²

With this in mind we need to look at how good we are at managing high blood pressure in those who have had a TIA or stroke. In 1995 the Prescribing Research Unit at Liverpool University looked at 76 practices chosen at random in the Merseyside region in a very large audit.³ They found that only 81% of over-65s had had their blood pressure recorded in the previous five years. Of those who were deemed to have controlled hypertension, using 160/90 mmHg or below as the threshold, only 64% were receiving therapy, and only 54% were 'controlled'. Even more worryingly, the researchers

found that if they categorised those with a blood pressure of less than 160/90 mmHg as being controlled, then this figure dropped to 37%. The reason for this finding is digit preference – essentially there were only about three or four different blood pressure levels recorded and this suggests that GPs must round readings up or down to the nearest 10. Current advice is to record to within 2 mmHg.

In 1996 the Liverpool Aspirin Project⁴ did a very large audit of high-risk patients (those who had had a stroke or a myocardial infarction, and those who had vascular disease or angina).

The audit showed that approximately 29% of the high-risk patients who were eligible for aspirin (and in whom it was not contraindicated) were not receiving it. This is in keeping with findings from several other audits but can be difficult to interpret because of use of over-the-counter aspirin. However, this situation may have improved because between 1992 and 1998 there was a three-fold increase in prescribing aspirin 75 mg (from one million prescriptions per year to three million prescriptions a year from PPA data).

Another area of concern that is suggested by further analysis of these data is that the incidence of aspirin prescribing does not correlate with the index of deprivation or need – aspirin has been prescribed most in the areas where death from cardiovascular disease is lowest.

A 1996 survey of 640 GPs in the Manchester area⁵ revealed a lot of vagueness about how GPs should be managing TIAs and minor ischaemic strokes. GPs were sent questionnaires about how they manage stroke. Twenty-four percent of the responding GPs would not arrange further investigations in these patients. The survey also revealed large variations in GPs' thresholds for instituting hypertension treatment – from 135 to 200 mmHg systolic and from 90 to 110 mmHg diastolic.

Summary

A systematised, coherent approach to secondary prevention of stroke should help to address these areas of concern, such as diagnostic and treatment shortfalls, in this very high-risk area. This is necessary alongside evaluation of effective interventions. It is hoped that NICE will provide structure and support to such a process ■

References

1. CAPRIE Steering Committee. *Lancet* 1996; 348: 1329–1339.
2. Rodgers *et al.* *BMJ* 1996; 313: 147.
3. Cranney M, Barton B, Walley T. *Br J Gen Pract* 1998; 48: 1146–1150.
4. Wilcox D, Forrest D, Webster J. The Liverpool Aspirin Project. February 1997. Liverpool Health Authority and Primary Care Audit Group.
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Option appraisals

Dr Tom Dent MRCP MFPHM Consultant in Public Health Medicine, North and Mid Hampshire Health Authority, Basingstoke

This presentation discussed different methods of secondary prevention from a public health perspective:

- Modification of risk factors for cerebrovascular disease.
- Antiplatelet medication.
- Anticoagulants.
- Surgery.

Risk factor modification

Hypertension is definitely a clear and important risk factor for recurrent stroke, and there is a *prima facie* case for lowering blood pressure in stroke survivors. However, definite trial evidence of benefit is not yet available.

There are a number of other risk factors that have been shown to be associated with increased risk of recurrent disease, or first-ever cerebrovascular disease, but we don't have good trial intervention evidence to prove that they should be corrected. However, advising patients to reduce their salt intake, to moderate their alcohol consumption and to take regular exercise is unlikely to be harmful and likely to do some good in those who have proven cerebrovascular disease.

Despite several systematic reviews trying to explore the connection between raised blood cholesterol levels and the risk of stroke, it hasn't been conclusively shown that if you have a high blood cholesterol level you are at increased risk of cerebrovascular disease. However, in trials that used statins to reduce blood cholesterol there has been shown to be a reduced incidence of stroke. In secondary prevention trials, the number needed to treat (NNT) is somewhat high (71), but there are several additional benefits from the use of statins in high-risk patients.

Antiplatelet drugs

Aspirin is very clearly effective, massively cost-effective and substantially under-prescribed and under-used. From a public health point of view, the main emphasis should be on promoting the more extensive use of aspirin in patients who have the appropriate risk factors or clinical history.

The debate about which antiplatelet agent to use in patients who don't tolerate aspirin, or in whom aspirin doesn't seem to work, involves interesting, scientifically controversial issues; however, they are not issues of paramount public health concern.

The key issue of concern in secondary prevention is that we are not doing as well as we should be doing in promoting the use of aspirin. There is a great deal more work to be done, and that should be the main focus in the promotion of evidence-based practice and the promotion of secondary prevention of cerebrovascular disease.

Anticoagulants

There is no evidence that warfarinising patients in sinus rhythm who have had a TIA or stroke is beneficial, and there are obvious risks and costs in warfarinising elderly patients. Such patients should not therefore be prescribed warfarin for secondary prevention.

The trial evidence for anticoagulating patients in atrial fibrillation who have had a stroke or a TIA is very strong; the NNT is very low, many would argue, to prevent a serious vascular event. However, in practice, all kinds of obstacles lie in the path of the successful and safe warfarinisation of an elderly patient.

Some people have speculated that if you take into account the reduced benefit because of difficulties with warfarin control you may be looking at an NNT of about 100 for warfarinisation of these patients – bearing in mind that the NNT to bring about the harmful side-effect of a major haemorrhage may be as low as 50 for warfarinisation.

Surgery

Patients who have a degree of carotid stenosis have been shown in a couple of good trials to benefit from carotid endarterectomy. Two trials, one European, one North American, have been put together in the Cochrane Library to come up with the NNT of about 10 to prevent death or second non-fatal stroke in patients who meet the eligibility criteria.

The tendency has been to concentrate on testing for, and undertaking carotid endarterectomy on patients who have had, a TIA because the evidence seems to indicate that the benefit is greater there; however, less than 20% of strokes are preceded by a TIA. You also need very rapid referral pathways, which are difficult to organise and routinely achieve in practice, because the risk of stroke is highest directly after the TIA.

The population that can benefit is small and therefore the actual impact on stroke prevention is small.

Potential population impacts of various secondary prevention methods

- If aspirin is used in every patient after a TIA who could tolerate it then you might prevent about 3% of all the strokes which occur in the population in question.
- Effective treatment of hypertension after a TIA might achieve about a 2% prevention of stroke.
- Even if you got it absolutely right with carotid endarterectomy – referring possible candidates as quickly as possible, operating appropriately and minimising the risk of stroke and death as a result of the surgery – even under those optimal conditions, you would still prevent less than 1% of all the strokes which occurred.

Conclusions

- We need to be more aware – both professionals and members of the public – of the symptoms of minor stroke and TIA. If this occurs, people will be more likely to consult their GP for these symptoms and, when they do, they are more likely to be investigated and treated appropriately.
- There is a clear, definite, important role for aspirin, and we are not making the most of such an effective and cheap drug.
- There is a possible role for warfarin, but there are problems.
- There is a small role for carotid endarterectomy; however, it may be very difficult in practice to realise all the benefits from this procedure ■

Economic appraisals

Ceri Phillips BSc(Econ) MSc(Econ) PhD Health Economist, University of Wales, Swansea

This speaker presented a health economic analysis of various pharmacological interventions – aspirin, aspirin plus modified-release dipyridamole, simvastatin – in the secondary prevention of stroke.

A term that is often used in economics is efficiency. Unfortunately this term is often misused and has become associated with cost savings. Judging efficiency actually means looking at the relationship between the resources that we put in and what we actually get for the money. We are not

necessarily talking about the cheapest option, or about the intervention which will save us the most money – we are concerned with trying to get the most out of the resources we have available.

The intention of an economic analysis of secondary stroke prevention is to determine how much it is reasonable to invest in prevention to avoid incurring additional costs in terms of treatment and after-care. We have to determine what it is going to cost to treat a person who has a stroke; this gives us a figure that it is cost-effective to spend on stroke prevention. In the following analysis we are only looking at the financial implications of stroke, rather than the quality of life implications that obviously would strengthen the case even more for secondary prevention.

Comparative cost-effectiveness of interventions

The evidence for the effectiveness of preventive treatments came from *Bandolier* No 38.¹ For three interventions (aspirin, a combination of aspirin plus modified-release (MR) dipyridamole, and simvastatin) we looked at the number needed to treat (NNT) to prevent one stroke. Simvastatin didn't really come into it in economic terms for secondary stroke prevention (NNT 65 over 5.4 years, 95% confidence interval (CI) NNT 38–224).

Aspirin had a NNT of 37 over 2 years (95% CI 20–319) and it is cheap – it is very effective. The cost of aspirin plus dipyridamole is much higher but there is an improvement in effect, with an NNT of 18 over 2 years (95% CI 13–29).

Costs of preventive treatment

Having discounted simvastatin for secondary prevention, we translated the figures for aspirin alone and for the combination of aspirin and MR dipyridamole into a cohort of 100 patients. With aspirin, just less than three patients would be prevented from having a stroke, and the cost of this intervention would be £4,028. The cost of aspirin plus dipyridamole would be £23,400 and more than five patients would be prevented from having a stroke. The combination treatment is much more expensive; however, three additional strokes would be prevented at a cost of £19,372.

Costs of stroke treatment

We then need to look at the costs of treating a stroke. Unfortunately the literature is very poor in this area. There were several estimates – lifetime costs of around £46,000; two-year costs of around £6,600; an annual cost of £13,000 – it depends on the perspective. Bear in mind that there are also financial and quality of life costs to the patient and their family and carers, which we haven't included in this analysis.

The basic question is, therefore, is it 'worth' spending an additional £19,372 to prevent two or three strokes per hundred patients treated? If the cost of treating those patients is between £6,457 and £9,686, then the answer is yes.

Unfortunately the brunt of the costs will come out of primary care drug budgets, and the majority of savings will probably be made by social services, not the health service at all. However, this analysis concerns the overall resource allocation issue, rather than individual budgets. It is up to the various budget holders to debate the issues.

Sensitivity analysis

All good economic evaluations require a sensitivity analysis. We considered the implications in terms of the threshold for various values of NNT for the combination treatment and the difference in the number of strokes that would be prevented. Then we also related that to the various costs of treating a stroke. If the cost of treating a stroke is ≤£3,500, then it is not beneficial to commit the resources to the more expensive strategy. As the cost of stroke treatment gets up to realistic proportions, then even at relatively small differences in terms of effectiveness, the benefits begin to emerge. The break-even stroke treatment costs for the two extremes of confidence interval with combination treatment are: £3,798 with an NNT of 13; and £24,215 with an NNT of 29.

Summary

In summary, if the cost of treating a stroke is more than the additional cost of treatment to prevent a stroke, then it is worthwhile committing the resources to prevention. The economic analysis suggests that even though the combination of aspirin plus dipyridamole is more expensive than aspirin alone, the increased effectiveness of the combination treatment means that it is likely to be cost-effective ■

Reference

1. *Bandolier* 1997; 38: 3.

The contribution of stroke units

Helen Rodgers *MB ChB FRCP Senior Lecturer in Stroke Medicine, University of Newcastle-upon-Tyne, on behalf of the Stroke Unit Trialists' Collaboration*

This presentation examined the evidence base for hospital-based stroke units. There is ongoing debate as to whether or not patients with acute stroke should be admitted to hospital. The issues involved are similar to those relating to admission or community care following acute myocardial infarction nearly 30 years ago.

There have been no randomised, controlled trials comparing hospital with community care. Such a study was attempted in Bristol in the early 1980s but it was unsuccessful because a large proportion of those randomised to community care were subsequently admitted to hospital. Current evidence from a large population-based stroke register in the north east of England suggests that 80% of stroke patients are currently admitted to hospital.

Although stroke is a very common condition, a GP will only see five to six new cases per year and diagnosing stroke can be difficult. Excluding conditions which mimic stroke can take time and expertise. Audits of inpatient care have repeatedly shown that 30% of patients diagnosed with stroke upon admission are subsequently found to have another medical problem, highlighting the need for detailed assessment of these patients.

Ongoing research suggests that acute treatments for stroke will need to be given within a few hours following stroke and

will require a prior CT head scan, again emphasising the need for inpatient facilities.

The benefits of dedicated units

Perhaps the most important reason for admitting stroke patients to hospital is the proven benefit of stroke unit care. It is a remarkable finding that the reorganisation of services for stroke patients can lead to such a significant improvement in patient outcome.

In terms of numbers needed to treat (NNTs) we need to treat 25 patients on a stroke unit instead of a general medical ward to prevent one death. The NNT to ensure that one extra patient returns home independently is 20.¹

The evidence of the effectiveness of stroke units was obtained by a detailed systematic review of all of the randomised controlled trials comparing outcomes of care on stroke units and general medical wards.^{2,3} The outcomes of 3,249 patients recruited from studies in the UK, Scandinavia, USA and Australia were included. Treatment on a stroke unit compared with a general medical ward reduces chances of death by 19% (odds ratio (OR) 0.81, 95% confidence intervals (CI) 0.68–0.96).¹

The reduction in mortality is not associated with an increased level of disability in survivors. Stroke units were associated with improved outcome in terms of death or dependence (OR 0.71, 95% CI 0.60–0.84).^{1,2}

What the systematic review does not tell us is which features of stroke unit care lead to improved outcome. Structured interviews with trial coordinators identified organised multi-disciplinary care provided by staff with an interest and expertise in stroke care, particularly nursing staff, as fundamental to stroke unit care. Stroke units also provided training and education for staff, patients and carers.³

Who benefits?

Sub-group analysis found that all stroke patients benefited from stroke units regardless of age, gender or stroke severity.³ Therefore there is no justification for selecting or rejecting patients on the basis of age or stroke severity. If a stroke unit is unable to care for all stroke patients within a hospital, it is important to ensure that patients treated on other wards are not disadvantaged.

The systematic review included different models of stroke unit care. Although there was no direct comparison of types of stroke units, those which care exclusively for stroke patients demonstrated a similar degree of treatment effect to a mixed assessment/rehabilitation unit which cared for patients with other conditions in addition to stroke.

There is insufficient data to assess the efficacy of mobile stroke teams. Stroke rehabilitation units which admitted patients early (within seven days of having a stroke) had a similar size of treatment effect to those that admitted patients after seven days. The benefits of an acute intensive care model of stroke unit without organised rehabilitation services have not been demonstrated.

Maximising the benefits of stroke unit care

It is essential that future service developments – for example, facilitated discharge – should be evaluated using a stroke unit that can demonstrate high standards of care and similar out-

comes to published data to provide a gold standard. Quality of care can be measured using the Royal College of Physicians of London Sentinel Audit.

Although many hospitals have developed an organised stroke service, stroke units are still not available to all patients within the UK. A national survey of stroke services undertaken as part of the Stroke Association Centenary celebration will identify the availability of stroke unit care.⁴

Once a person has had a stroke, a stroke unit is the most effective way of reducing death and disability, and access to this evidence-based service should be available to all ■

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Rehabilitation in the community

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This presentation considered the role of community-based rehabilitation in stroke.

The NHS Executive's *Rehabilitation: A Guide*¹ states that rehabilitation should aim to assess individuals from a multi-disciplinary viewpoint in the context of their personal lifestyle, social roles and responsibilities; it should consider self-care, productivity and leisure; it should look at client priorities rather than service priorities; and it should be concerned with negotiating and agreeing objectives, involving carers in that discussion, and therefore (it is to be hoped) minimising the need for formal and informal carers as a result. These objectives are all complementary to rehabilitation at home.

The evidence for community rehabilitation

It is well established that stroke care should be provided by specialist multidisciplinary teams to reduce mortality and morbidity. The most striking point about the evidence base for specialist multidisciplinary community rehabilitation is that there is such a small body of research in the field.²

A review of the evidence conducted by Lafferty² suggested that this is worrying, considering the number of teams that are being set up in the community. This is not to say that community rehabilitation is not effective but that there is very little randomised, controlled research work to support the practice.

A study by Dr Rudd from St Thomas's Hospital has shown that community rehabilitation did produce significant reductions in hospital stay, had no adverse effects on outcome at one year and had no adverse effects on caregiver strain.³ Interestingly, satisfaction with their inpatient stay was greater

in the group discharged earlier from hospital, and dissatisfaction increased as patients stayed longer.

To try to address the evidence shortfall, the Stroke Association is currently looking at the work of five community teams, including Merton and Sutton, to determine whether it is useful for stroke patients to receive rehabilitation at home, and to identify best practice.

The benefits of community-based care

- The home is usually a more pleasant environment for clients as they feel comfortable and confident there. Those patients with cognitive problems re-learn things more easily in a familiar environment.
- It can help reduce carer stress as carers are more involved in what is going on and understand better what is happening. They also avoid the difficulties of having to keep travelling to hospital and therefore feel more in control of the rehabilitation process.
- The goals can be more meaningful: going to the local shop, getting around a client's own house, learning to walk on carpet and so on.
- Longer sessions can be provided.
- The process can be more client-centred and client-controlled.
- Home care can be cost-saving compared with extended hospital stays. It also frees up inpatient beds.
- The home setting is more conducive to identifying and ameliorating handicap.

Problems of community-based care

- There has to be an adequate care package available, otherwise rehabilitation will be difficult.
- Having someone who is quite dependent at home can in some cases increase carer stress.
- The home may not always be conducive to rehabilitation – for example, too much clutter, or no rails on the stairs.
- The patient has to be medically stable.
- Specialist equipment, or intensive interventions, may not be available, or practical, for a home environment – for example, a standing frame. There is very little rehabilitation, however, that cannot be provided at home.
- There are cost issues with regard to travel time.
- The therapist may feel isolated and so needs to be well trained and confident; therefore, more junior staff cannot be employed in the community.

The Merton and Sutton Community Stroke Rehabilitation Team

The team includes a specialist nurse who coordinates the scheme, physiotherapists, occupational therapists, a speech and language therapist and two therapy assistants. The aim is to provide multidisciplinary neurological rehabilitation to clients in their own homes or residential nursing homes. The work is goal-oriented and treatment continues for as long as the team can set achievable and realistic goals with the patient.

The team provides advice on secondary prevention and education on the causes of stroke. We offer lifestyle counselling and look at reducing risk factors such as smoking and obesity. We endeavour to make sure that coexisting conditions are being managed, such as hypertension and diabetes.

Conclusions

Multidisciplinary teams are well recognised as the best providers of stroke care, but some areas don't have this luxury. Primary healthcare teams, therefore, can play an important part in coordinating provision of care. For example, the practice nurse could provide lifestyle counselling, check blood pressure levels and so on, and put people in contact with support groups and counselling services in the area.

We need more research about community rehabilitation and its uses. To facilitate this process, teams should be using similar outcome measures so that work can be compared more easily across service boundaries.

The views of both patients and carers can, and should, be obtained to complement other forms of evidence in developing clinical guidelines as patients' and carers' priorities may differ from those of professionals.

To smooth the transition between hospital and home, trained link nurses in hospitals help create a 'care pathway' for patients who have suffered a stroke or TIA.

Finally, as a sad reflection of the current situation regarding after-care for stroke patients, a recent report on stroke after-care from the Intercollegiate Stroke Group commissioned to contribute to National Clinical Guidelines, revealed that people felt poorly treated in hospital settings.⁴ As professionals, we have to continue to be concerned with showing stroke patients courtesy and respect in whatever setting we work ■

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The role of the Stroke Association

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The Stroke Association is celebrating its centenary year this year, and this presentation reviewed the work that the charity is doing for people who have suffered a stroke, their families and carers.

Each year 100,000 people in England and Wales have a first stroke and about 10,000 of these people are under the age of retirement. Of course that is a loss to the workforce. There are more than 60,000 deaths due to stroke each year. Around one-third of people who have a stroke die within a year, a third are left with serious disabilities and the remainder make a good recovery. The annual cost of stroke to the NHS is estimated at more than £2 billion. The Stroke Association estimates that by the year 2023 this figure will have gone up in real terms by 30%.

These statistics are obviously important to the Stroke Association because it is these statistics that enable it to plan strategically and do the work that it does.

The work of the Stroke Association

In the field of stroke the voluntary sector as a whole attempts to provide general support in hospital and at home. The Stroke Association is probably the biggest charity working with stroke in England and Wales.

The basic areas the association is involved in are:

- Supporting research (25% of expenditure).
- Providing community services (22% of expenditure).
- Providing patient education, especially in relation to secondary prevention.
- Improving standards of care through the training and education of service providers.
- Lobbying.

The association is tending to spend a little bit more than it can actually afford. So for 1996/97 it actually spent £8.3 million (on an income of £7.9 million) and the following year £10.6 million (on an income of £9.6 million).

Research

This is a very important area of the association's activity. It awards grants to people to undertake projects; £1.6 million each year is spent in this way. People are invited to bid for proactive programme grants that are awarded for up to ten years to undertake research in areas such as prevention, ethnic minority issues and so on. There is about £500,000 committed for the next five years for programme research.

The association provides bursaries to support a nominated nurse or therapist in a stroke-related project, at cost of about £20,000 for up to two years. It also provides clinical fellowships to departments to support trainee doctors through stroke-related projects in their elected area. The association spends anything up to £25,000 a year per fellowship on that.

Major projects include the chair in stroke medicine in Nottingham, held by Professor Philip Bath, that costs about £230,000 per year. The charity has also established a Stroke Association Therapy Research Unit in Salford to train therapists in research techniques – £100,000 for five years has gone towards that.

Community services

There are three main services that the Stroke Association provides for stroke survivors in the community. These include information and education services, dysphasia support services and family support services.

Information and education services

The association has a telephone advisory line that anybody – whether they are a professional, a stroke survivor, a carer or whatever – can ring and ask for information on stroke.

Local Stroke Association Information and Education Services are a very important part of the work that the association does in the community, not only for stroke survivors, but also for professionals who have a particular interest in stroke.

Dysphasia support

There are now more than 4,000 volunteers working in dysphasia support for the Stroke Association. They work with people who have speech and communication difficulties as a result of stroke. The association works very closely with speech and language therapists in providing this service. Patients start off their therapy in the hospital setting and when they are discharged the volunteers take over, working under the supervision of speech and language therapists.

The dysphasia service is provided under a contractual arrangement with local purchasing authorities, so most of the money to provide this service comes from the NHS.

Family support

This service is currently being evaluated in three places: Oxford, Hastings and Nottingham. Many people who have directly benefited from this service have praised the service, and a number of clinicians have felt happy with it, but of course the association still has to scientifically evaluate the service. The association needs to be sure that what it is doing is effective, and this is the purpose of the evaluations that are currently taking place.

Between April 1996 and March 1997 each Family Support Organiser has been able to help an average of 205 families. The average cost to the NHS for family help was £50.21, which was undoubtedly cost-effective.

The association has just under £200,000 a year for which stroke survivors can apply for welfare grants. Maybe they need to have a raised chair, or a new cooker and so on, any small items that social services no longer provide these days for whatever reason.

To summarise, the four planks of the Stroke Association's activities are caring for today, researching for tomorrow, campaigning for improvement in stroke care and attempting to influence change ■

Poster presentation

Welsh National Demonstration Project for Implementing Clinical Effectiveness (NDPCE) in acute stroke (North Wales)

The Welsh NDPCEs, on five topics including acute stroke, were commissioned in response to the realisation that, despite the success of publications and services such as *Bandolier* in bringing the evidence to clinicians, practice was still not changing. The Welsh Clinical Effectiveness Support Unit developed a change management model, and a list of 'deliverables' to guide the projects and enable progress to be charted and lessons shared.

The remit was to complete implementation of effective healthcare within two years, across three acute trusts and four acute hospital sites in North Wales. The total budget was £75,000. The project started in April 1996 and was complete by March 1998, and the six-month prospective re-audit of each site has now been completed. The baseline audit assessed 100 moderate to severe cases at each of the four sites for the period October 1995 to March 1996. Standards of 100% were agreed for each criterion, and detailed evidence-based exceptions were identified for each. The audit tool was based on the 1994 RCP Stroke Audit package, with significant additions to address multidisciplinary work.

As there were no specialist acute stroke services in North Wales, the baseline audit showed performance below 25% for three of the sites on many of the 150 criteria. One trust had a clinician with an interest in stroke, who ran a rehabilitation facility, which led to higher standards at the acute site.

The re-audit has significantly raised compliance at each site, with mean compliance now above 80% for many of the previ-

ously low performing criteria. The clinical view throughout the project has been that its success has depended on:

- Strong willingness on the part of most clinicians to improve practice.
- Tight project management throughout the period.
- Working across three trusts and four sites, which allowed exchange of better practice and an element of competition.
- Early involvement of all major stakeholders, which allowed professions to start understanding each others' roles and responsibilities.
- Intense education programme on the evidence base, with the added purpose of building local consensus.
- In-ward multi-professional education on new processes and structures.
- Emphasis on respect and support throughout.
- Early realisation that there was significant duplication, for example in assessment, both between and within professions
- The low numbers needed to treat (NNTs) in the evidence base, coupled with a fast-growing realisation of how poor interdisciplinary coordination was contributing to high stroke mortality rates in Wales

As a result of the project, one DGH has developed an acute stroke team to capture all stroke admissions. Another is developing an acute site six-bed acute stroke facility to complement its off-site acute rehabilitation facility. The third DGH has established an acute stroke unit. Each has developed multidisciplinary care plans, and established integrated case notes and other measures to allow easy access to other professionals' assessment results. In addition, rates for 1997 suggest an improvement in mortality in line with the NNTs.

Lessons from the Welsh Clinical Effectiveness National Demonstration Projects can be viewed on:
<http://137.6.37.254/NDPCE.HTM> ■

Next Bandolier Conference

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