The impact of stroke nurse specialist input on risk factor modification: a randomised controlled trial

SIR—Interventions with an educational or counselling component have been reported to be effective in a variety of patient groups to encourage smoking cessation [1], lower blood pressure (BP) [2, 3], achieve modest reductions in cholesterol [4], and promote weight loss [5]. Evaluation of the impact of education on physical outcomes is lacking in stroke disease, despite evidence that inadequate provision of information may adversely affect compliance with secondary prevention and psychosocial outcomes [6].

We describe a single-blind randomised controlled trial of health education and counselling for patients with stroke or transient ischaemic attack (TIA), and its effects on risk factors, satisfaction, mood and perceived health status.

Methods

We recruited ambulant patients identified from a TIA clinic or a geriatric medical day hospital (where patients discharged with a diagnosis of stroke were attending for ongoing rehabilitation), in a UK teaching hospital.

Patients were eligible for inclusion if they had a clinical diagnosis of stroke, TIA or amaurosis fugax commencing in the previous 3 months. They had to have one or more of the following risk factors: high BP, a history of current smoking, high cholesterol and/or diabetes (regardless of their risk factor control). Patients with cognitive impairment (defined as an AMT <5 on screening) were excluded from involvement [7].

After collecting baseline data, and written consent, eligible patients were randomly allocated to treatment or control groups using a computer-generated random sequence concealed in sequentially numbered opaque sealed envelopes.

Patients randomised to the control group received usual care, which included generic risk factor advice from medical staff as well as the Stroke Nurse Specialist (SNS), given within the outpatient context. This service was standard to the control group and the intervention group prior to enrolment within the study. Following enrolment, control patients were discharged back to the care of their general practitioner and had no further input from the SNS.

Treatment group patients were offered additional input from the SNS, who reviewed them at monthly intervals for approximately 3 months. These reviews were conducted within the hospital premises as an outpatient consultation. Patients were interviewed and given individual advice on lifestyle changes, the importance of medication compliance and its relevance to secondary prevention. Issues of lifestyle including diet, exercise or increased activity, and interaction with medical services were discussed in depth and tailored to the patient's circumstances and functional abilities. All verbal information was backed up by written information that was selected by the SNS as relevant to the individual patient. Personalised patient-held records were also given to patients, detailing their risk factors, and the recommended risk factor targets. This record was updated at each visit, and was considered a key part of the intervention. The SNS did not attempt to contact the patient's general practitioner (GP) or hospital specialist in order to influence prescribing. Where a risk factor (e.g. BP) was deemed to be at unacceptable levels, patients were encouraged to consult their GPs with that information. Additional open questions gave patients the opportunity to bring up other subjects as the patient felt appropriate. The average consultation length was approximately 30 minutes.

GPs of both treatment and control group patients were informed of the study by letter, and of the form of intervention. At the end of the study, a letter summarising the patient's risk factors as well as our recommended risk factor targets was sent to the GPs of all the patients (treatment and control groups).

Outcomes were recorded at 5 months by an independent blinded assessor. The primary outcome of interest was the proportion of patients whose risk factors were 'on target', defined as the number of patients whose major modifiable risk factors were within the recommended treatment range according to the contemporary national and local treatment guidelines including BP (<140/85 mmHg), reported cigarette consumption (complete cessation), random blood glucose (<8.0 mmol/l) and HbA1c (<7.5%), and total cholesterol (<5.0 mmol/l). Secondary outcome measures included survival, the EuroQol perceived health status [8], Geriatric Depression Score [9] and a stroke services satisfaction questionnaire [10].

Power calculations were based on a case note survey of 51 consecutive patients attending the TIA clinic. The average number of risk factors per patient was 2.9 and only 20% had achieved complete risk factor control by the time of discharge. Eighty-nine patients per group would be needed to show an increase in the proportion of patients whose risk factors were 'on target' from 25 to 50%.

Local ethical approval was obtained for the study.

Data were entered by the principal investigator and analysed on an intention-to-treat basis using SPSS version 10.0.

Results

From an initial screening of 1,804 patients, 205 patients were recruited at their concluding visit to the stroke clinic or geriatric medical day hospital. Three patients were entered twice in error, each time to the treatment group. These subjects were analysed on their initial data only and subsequent data were excluded from the analysis. One patient in the control group was later found to be ineligible based on information unavailable at the time of enrolment. This patient has been included on an intention-to-treat basis. For additional information please see Appendix 1 in the supplementary data on the journal website (www.ageing.oupjournals.org). Baseline characteristics demonstrate the similarity of the two groups at randomisation (Table 1).

The main results are summarised in Table 2. Initial (planned) analysis of individual risk factors appeared to demonstrate a statistically significant reduction in systolic BP in the treatment group compared to the control group. In view of baseline differences in BP between the two groups, we performed analysis using a general linear model

Table 1. Summary of baseline characteristics

		Intervention group $n=100$ (%)	Control $n=105$ (%)	P value
Age		64.3 (62.4–66.1)	65.8 (64.0–67.5)	0.25
Sex (male)		54 (54%)	52 (50%)	0.68
Diagnosis				
TIA		29 (29%)	27 (26%)	0.18
Stroke		61 (61%)	68 (65%)	0.18
Multi-infarct disease		2 (2%)	4 (4%)	0.16
Amaurosis fugax		4 (4%)	4 (4%)	0.21
Transient global amnesia		2 (2%)	0 (0%)	0.13
Retinal artery occlusion (embolic)		2 (2%)	2 (2%)	0.36
Modifiable risk factors				
Smoker		36 (36%)	42 (40%)	0.55
Number of cigarettes per day		13 (9.4–16.7)	13 (9.7–16.3)	0.99
Hypertensive		66 (66%)	77 (73%)	0.26
Systolic BP (mmHg)		156.2 (150.7–161.7)	151.1 (145.6–156.6)	0.19
Diastolic BP (mmHg)		83.4 (79.7–87.1)	80.0 (76.8–83.2)	0.18
Diabetic		25 (25%)	26 (25%)	0.97
Random blood glucose (mmol/l)		10.73 (8.63–12.83)	9.94 (8.26–11.62)	0.57
HbA1C (%)		7.54 (6.47–8.61)	7.89 (7.26–8.52)	0.58
Hypercholesterolaemia		79 (79%)	79 (75%)	0.52
Total cholesterol (mmol/l)		5.8 (5.49–6.11)	5.7 (5.46–5.94)	0.66
Other risk factors				
Previous TIA		18 (18%)	11 (11%)	0.12
Previous stroke		12 (12%)	23 (22%)	0.06
Atrial fibrillation		2 (2%)	4 (4%)	0.45
Number of modifiable risk factors	1	22 (22%)	26 (25%)	0.64
	2	49 (49%)	42 (40%)	0.20
	3	29 (29%)	34 (32%)	0.60
	4	0 (0%)	3 (3%)	0.09

Data are presented as the mean (95% confidence intervals) or number (%).
Comparisons are made using the chi-squared test or Mann–Whitney U test.

(Ancova) to adjust for baseline BP. This suggested the result could not be fully explained by regression to the mean. However, repeating the analysis with adjustment for baseline BP indicated that the difference between groups in systolic BP drop was less marked (−7.8 mmHg, 95% CI −13.1 to −2.6 versus −2.2 mmHg, CI −7.1 to 2.7, $P=0.126$).

Changes in diastolic BP, reported smoking number, cholesterol, random blood glucose and HbA1c did not reach statistical significance.

There was no significant difference between the groups on the EuroQol or Geriatric Depression Score.

On the stroke service satisfaction questionnaire there were some significant differences between the groups. Patients in the treatment group were more likely to express satisfaction that they had been able to talk to someone ($P=0.027$), and that they knew who to contact if they needed to ($P=0.034$). They also expressed greater satisfaction with the information they had received, both about the causes of stroke ($P=0.022$) and about their risk factors ($P=0.010$). For additional information please see Appendix 2 in the supplementary data.

Discussion

It appears that nurse specialist-led education with tailored risk factor advice and patient-held documentation was well tolerated. However, the intervention did not result in significant improvements in risk factor control. This may reflect underpowering of the trial as the risk factor control in the control group was better than anticipated from pilot studies and in comparison to other trial evidence [11–13]. The lack of statistical significance for the reduction in systolic BP when adjusted for baseline BP is likely to represent underpowering.

Patients in the intervention group were statistically more likely to express satisfaction that they had been able to talk to someone about the problems they were having and that they knew who to contact should they have further problems relating to their stroke or TIA. Intervention group patients were also more satisfied with the amount of information they received, and expressed satisfaction that they felt they had someone they could contact with regard to their stroke disease.

Key points

- This stroke nurse specialist advice and counselling improved patients' satisfaction that they were able to talk to a member of staff and knew who to contact if they had a problem.
- Patients were more satisfied that they had received adequate information about their risk factors and the nature and causes of their disease.
- This intervention did not change overall risk factor control, but may be effective in lowering systolic BP.

Table 2. Summary of results

Outcome	Intervention group $n = 94$	Control $n = 98$	P value
'All relevant risk factors controlled'	45 (46.4%)	41 (41.7%)	0.34
Individual risk factors			
Hypertension			
Change in systolic BP (mmHg)	−9.3 (−15.0 to −3.5)	−1.0 (−6.3 to 4.3)	0.039
Change in diastolic BP (mmHg)	−2.1 (−5.7 to 1.5)	−1.2 (−4.5 to 4.5)	0.71
Smoking			
Change in number of cigarettes per day	−1.6 (−5.1 to 1.8)	−0.4 (−3.7 to 2.8)	0.61
Diabetes			
Change in random blood glucose (mmol/l)	0.92 (−1.39 to 3.23)	0.89 (−2.09 to 3.87)	0.99
Change in HbA1C (%)	−0.25 (−0.57 to 0.08)	−0.78 (−1.50 to 0.05)	0.20
Hypercholesterolaemia			
Total cholesterol (mmol/l)	−0.96 (−1.20 to 0.71)	−0.87 (−1.14 to 0.61)	0.63
Quality of life (EuroQol)			
Percentage with a deterioration in QOL[a] (score increase of ≥1)			
Mobility	11 (12%)	17 (17%)	0.27
Self-care	8 (9%)	16 (16%)	0.10
Usual activities	14 (15%)	22 (22%)	0.18
Pain	18 (19%)	25 (26%)	0.29
Anxiety and depression	17 (18%)	25 (26%)	0.21
Percentage change (visual analogue scale)[b]	3.5 (−0.9 to 7.9)	1 (−3.3 to 5.3)	0.43
Geriatric Depression Score[c]	4.3 (3.6–4.9)	5.1 (4.4–5.7)	0.11

[a]Positive scores indicate worse functioning.
[b]Positive scores for change in visual analogue scale indicate improvement.
[c]Positive scores indicate worse function.
Data are presented as the mean (95% confidence intervals) or number (%).
Comparisons are made using the chi-squared test or Mann–Whitney U test.

Acknowledgements

G.E. was responsible for the study design, patient recruitment, data entry and analysis and writing. J.R. reviewed patients in the intervention and control groups. C.M. provided clinical supervision and advice. P.L. provided advice on trial design, data analysis and writing. We would like to thank the patients who participated in this study for their co-operation.

Funding

This study was funded by a grant from the Chief Scientists Office, Scotland. We would also like to thank Boehringer Ingelheim who contributed towards the printing of the individualised patient records. G.E., J.R. and C.M. have received reimbursement for attendance at educational meetings from Boehringer Ingelheim. P.L. has received similar expenses from Boehringer Ingelheim, Sanofi and Pfizer.

Graham Ellis[1]*, Jan Rodger[2], Christine McAlpine[3], Peter Langhorne[1]
[1]*Academic Section of Geriatric Medicine, 3rd Floor, Centre Block, Glasgow Royal Infirmary, Glasgow G4 0SF, UK*
Fax: (+44) 0141 211 4944
Email: g.ellis@clinmed.gla.ac.uk
[2]*Geriatric Day Hospital, Stobhill Hospital, 133 Balornock Road, Glasgow G21 3UW, UK*
[3]*Medicine for the Elderly, Stobhill Hospital, 133 Balornock Road, Glasgow G21 3UW, UK*
**To whom correspondence should be addressed*

1. Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. In The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
2. Ebrahim S, Davey Smith G. Lowering blood pressure: a systematic review of sustained effects of non-pharmacological interventions. J Public Health 1998; 2: 441–8.
3. He J, Whelton PK, Appel LJ, Charleston J, Klag MJ. Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. Hypertension 2000; 35: 544–9.
4. Hooper L, Summerbell CD, Higgins JPT *et al.* Dietary fat intake and prevention of cardiovascular disease: systematic review. BMJ 2001; 322: 757–63.
5. Anderson RE, Wadden TA, Barlett SJ, Babette Z, Verde TJ, Franckowiak SC. Effects of lifestyle activity vs structured aerobic exercise in obese women: a randomised trial. JAMA 1999; 281: 335–40.
6. O'Mahoney PG, Rodgers H, Thomson RG, Dobson R, James OFW. Satisfaction with information and advice received by stroke patients. Clinical Rehabil 1997; 11: 68–72.
7. Hodkinson HM. Evaluation of a mental test score for assessment of mental impairment in the elderly. Age Ageing 1972; 1: 233–8.
8. The EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 1990; 16: 199–208.
9. Sheikh JI, Yesavage JA. Geriatric Depression Scale (GDS): Recent evidence and development of a shorter version. Clinical

Gerontology : a Guide to Assessment and Intervention 165–173. NY: The Haworth Press, 1986.
10. Pound P, Gompertz P, Ebrahim S. Patients' satisfaction with stroke services. Clinical Rehabil 1994; 8: 7–17.
11. Dennis M, O'Rourke S, Slattery J, Staniforth T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial. BMJ 1997; 314: 1071.
12. Redfern J, McKevitt C, Dundas R, Rudd AG, Wolfe CDA. Behavioural risk factor prevalence and lifestyle change after stroke: a prospective study. Stroke 2000; 31: 1877–81.
13. Lenore J, Babikain VL, Allen NC, Winter MR. Risk factor modification in stroke prevention: the experience of a stroke clinic. Stroke 1999; 30: 16–20.

doi:10.1093/ageing/afi075

Non-valvular atrial fibrillation and cognitive function—baseline results of a longitudinal cohort study

SIR—Risk factors for cerebrovascular disease increase the risk of dementia and cognitive decline [1]. Non-valvular atrial fibrillation (NVAF) is an established risk factor for thromboembolism and stroke [2], which is significantly reduced by antithrombotic therapy [3]. Small cross-sectional studies report associations between NVAF, silent cerebral infarction and cognitive impairment [4–10], but there has been no longitudinal work in this area except for one small, highly selective comparison of cognition before and after coronary artery bypass grafting [11]. Given the high prevalence of NVAF in older people [12], we wished to determine whether NVAF is a preventable cause for cognitive decline in a prospective, longitudinal, community-based cohort study. Here we report baseline data comparing detailed neuropsychological testing of NVAF patients and controls, and assessing the effect of antithrombotic therapy.

Methods

Participants in NVAF and controls in sinus rhythm, recruited from general practice and aged over 60 years, underwent a home visit composed of a validated battery of neuropsychological tests [13]: a health questionnaire; a health status questionnaire (the SF-36 [14]); a physical examination; an ECG and blood tests. Cases and controls were analysed as subgroups according to antithrombotic therapy (aspirin/warfarin/neither).

Neuropsychological tests

The neuropsychological test battery included measures of selective/divided/sustained attention, short- and long-term verbal and non-verbal memory, information processing and premorbid intelligence.

Confounding factors

We incorporated all key confounders (age, duration of atrial fibrillation, coronary heart disease, diabetes, hypertension, cholesterol, health status (SF-36), congestive heart failure and education) into a multivariate model (Analysis of Covariance, ANCOVA) as covariates and found almost no effect of confounders on the neuropsychological tests, with only age showing borderline significance. Extensive additional analysis demonstrated no effect of confounders on the relationship between NVAF and cognitive function, regardless of use of antithrombotic therapy. Therefore we adjusted for age only.

Please see Appendices 1, 2 and 3 in the supplementary data on the journal website (www.ageing.oupjournals.org) for more details of methods, analyses, confounders and neuropsychological tests.

Results

After baseline interview, 362 participants were included (Table 1). There was no evidence of significant response bias, and cases and controls were comparable in most respects. Please see Appendix 4 in the supplementary data for full details of recruitment, response bias and characteristics of the cohort.

Baseline cognitive function tests (Table 2)

There were no significant differences ($P > 0.05$) in the means of the neuropsychological tests between cases and controls for the majority of sub-tests after adjustment for age, except for one item, 'time taken to perform the telephone task', where cases performed less well ($P = 0.003$ adjusted for age).

Subgroup analysis

Cases and controls were analysed as subgroups and the means of the test scores compared (cases on aspirin ($n = 62$), warfarin ($n = 80$) or neither ($n = 32$), and controls on aspirin ($n = 52$) or neither ($n = 136$)). The small sample size in cases who were in the 'neither warfarin nor aspirin' subgroup limits the interpretation of the results for this subgroup.

Initially significant differences between subgroups for the variables logical memory delayed, Rey figure copy, PASAT-4 seconds, telephone task number and digit span, were no longer significant when age was used as a covariate, with the exception of 'telephone task time taken' with aspirin cases performing significantly worse (118.43 seconds) than aspirin controls (90.25 seconds, $P = 0.004$).

Discussion

This is the largest cross-sectional study comparing cognitive function in older people with NVAF to those in sinus rhythm and adds considerably to previous cross-sectional data.

Context of existing research

The results presented here contrast with the findings of previous research addressing the association between NVAF and cognitive decline, including our pilot study in the North of England [13], as we found no difference at baseline between patients with NVAF and controls. Furthermore, there was no clear difference between patients on different forms of antithrombotic therapy.