Three-year follow-up of a factorial randomised controlled trial of two decision aids for newly diagnosed hypertensive patients

Clare L Emmett, Alan A Montgomery, Tim J Peters and Tom Fahey

ABSTRACT

This study is a 3-year follow-up of a factorial randomised controlled trial of two decision aids — decision analysis and information video plus leaflet — for newly diagnosed hypertensive patients. We found no evidence of differences for either of the two decision aids compared with controls for the primary outcome of blood pressure control at follow-up. There were also no differences in any of the secondary outcomes measured — the proportion taking blood pressure lowering drugs, self-reported medication adherence, or consulting behaviour. The randomised controlled trial cohort as a whole, irrespective of randomised group, demonstrated substantial reductions in blood pressure and 10-year cardiovascular risk over the follow-up period.

Keywords

decision aids, follow-up study, hypertension, patient choice, randomised controlled trials.

***CL Emmett**, MSc, research associate; **AA Montgomery**, PhD, senior lecturer in primary care research; **TJ Peters**, PhD, professor of primary care health services research, Academic Unit of Primary Health Care, University of Bristol, Bristol. **T Fahey**, MD, professor of primary care medicine, Tayside Centre for General Practice, University of Dundee, Dundee.*

Address for correspondence

Clare L Emmett, Academic Unit of Primary Health Care, Department of Community Based Medicine, University of Bristol, Cotham House, Cotham Hill, Bristol, BS6 6JL.
E-mail: clare.emmett@bristol.ac.uk

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INTRODUCTION

Decision aids for a wide range of treatment and screening conditions have been found to have beneficial effects in the short-term; such as, reducing decisional conflict, increasing knowledge, making patients more realistic in their expectations and increasing active involvement in decision making.[1] It has been suggested that these effects may translate into long-term benefits, such as, persistence with treatment choice and improved health outcomes. To date, no randomised controlled trials have reported on these longer term outcomes.

We previously conducted a factorial randomised controlled trial of decision analysis and information video plus leaflet interventions to assist newly diagnosed hypertensive patients in deciding whether or not to start drug therapy.[2] Consistent with other studies,[1] the randomised controlled trial demonstrated short-term reductions in decisional conflict and improved knowledge, with no increase in patients' anxiety. The aim of this follow-up study was to investigate the effects of these two decision aids (decision analysis or information video plus leaflet) on participants' blood pressure, 10-year cardiovascular disease risk, persistence with treatment and consulting behaviour, approximately 3 years after entering the original trial.

METHOD

Participants

Between March 2000 and May 2001, 217 newly diagnosed hypertensive patients were recruited from 21 primary care practices in Bristol and the surrounding area. Details of the recruitment procedure, participant characteristics and interventions have been published previously.[2]

Data collection

Blood pressure and other cardiovascular disease risk factors, antihypertensive medication prescription, and consulting data were collected

How this fits in

There is evidence that decision aids provide short-term benefits in the form of lowering decisional conflict and improved knowledge to patients faced with health-related treatment decisions. There is a lack of evidence regarding the effect of decision aids on longer term health outcomes and persistence with treatment choice. In the long-term follow-up of participants in a randomised controlled trial of two decision aids (decision analysis and information video/leaflet) no differences were found compared with control patients in terms of blood pressure control, proportion of patients taking blood pressure drugs or self-reported medication adherence.

from the medical records of trial participants. All practices held computerised records and, where appropriate, paper records were also examined. Up to three blood pressure measurements were collected at the following time intervals: prior to entering the trial; after primary follow-up (14 days after randomisation); and at long-term follow-up (about 3 years). In order to be included, blood pressure measurements had to be taken within 6 months prior to randomisation, 6 months after the primary follow-up and 1 year prior to long-term follow-up for the three time intervals, respectively. For participants with more than one measurement within a time interval the mean was calculated. Pre-randomisation and most recent data for other cardiovascular disease risk factors were collected, including diagnosis of diabetes and left ventricular hypertrophy, smoking status and total and high-density lipoprotein cholesterol. The risk factor data were used to calculate 10-year absolute risk of a cardiovascular event using a Framingham risk equation.[3] Participants with missing cholesterol data were assigned sex and age-matched population values. The class and dose of current antihypertensive medication(s) were collected. All consultations since trial entry where hypertension was entered as a presenting problem or blood pressure was measured were recorded. For each consultation, the healthcare professional seen and the actions taken (such as measuring blood pressure and starting, stopping or changing medication) were recorded.

Current self-reported adherence to medication was assessed by adapting a previously published questionnaire.[4] Participants reported adherence by indicating which of six statements best described their behaviour. These statements describe decreasing levels of adherence, starting with 'I take all of my tablets at the same time of day' and ending with 'I take hardly any of my blood pressure tablets'.

Data analysis

The primary outcomes for the analysis were the mean values of up to three of the most recent systolic and diastolic blood pressures. The trial sample size of 217 allowed detection of a standardised difference of 0.38 (equivalent to about 6 mmHg systolic and 4 mmHg diastolic) with 80% power and two-sided 5% significance level. Multivariable regression was used to make comparisons between groups. Analysis of blood pressure, cardiovascular risk and consulting data was by intention-to-treat; analysis of prescribing data was limited to those on medication. Interactions between the interventions for the primary outcomes were investigated using appropriate terms in the multivariable models. The analyses were carried out using Stata 8.

RESULTS

Follow-up data were collected for 216 of 217 trial participants (one patient had died and their medical records were not available). Baseline characteristics of participants are given in Table 1. Mean length of follow-up was 2.8 years (range = 2.2–3.4 years). There was no evidence of any difference in either systolic or diastolic blood pressure, 10-year cardiovascular disease risk, consulting frequency for hypertension or consultations resulting in management change for either decision analysis or video plus leaflet interventions (Table 2). There was no evidence of any interaction between decision analysis and information video plus leaflet for systolic or diastolic blood pressure. There was no evidence of any difference for either intervention in the proportion of patients prescribed medication at 3 years (82% overall; decision analysis [*n* = 83, 81%] adjusted odds ratio [OR] = 0.93, 95% confidence interval [CI] = 0.46 to 1.86, *P* = 0.85; information video plus leaflet [*n* = 83, 79%] adjusted OR = 0.68, 95% CI = 0.33 to 1.38, *P* = 0.28) or the proportion who reported taking all their medication (91%

Table 1. Baseline characteristics of participants.

	Decision analysis plus video/ leaflet (*n* = 51)	Decision analysis only (*n* = 52)	Video/leaflet only (*n* = 55)	Usual care (*n* = 59)
Mean age in years (SD)	57 (11)	59 (9)	60 (10)	58 (11)
Female (%)	49	46	47	49
Mean systolic blood pressure in mmHg (SD)	170 (14)[a]	167 (11)	166 (14)	169 (13)
Mean diastolic blood pressure in mmHg (SD)	98 (8)[a]	99 (6)	97 (8)	100 (9)
Mean 10-year CVD risk (%)	25(13)[a]	26 (12)	26 (13)	26 (14)

[a]n = *50. SD = standard deviation. CVD = cardiovascular disease.*

overall; decision analysis [*n* = 69, 90%] adjusted OR = 1.56, 95% CI = 0.49 to 4.96, *P* = 0.45; information video plus leaflet [*n* = 64, 94%] adjusted OR = 0.53, 95% CI = 0.15 to 1.84, *P* = 0.32).

We also examined blood pressure and cardiovascular risk data for the trial sample as a whole. There were overall reductions in mean blood pressure from 168/99 mmHg to 148/85 mmHg, and in mean 10-year cardiovascular risk from 26% to 22%, over the follow-up period. Any changes in other cardiovascular risk factors between baseline and follow-up were minor (data not shown); given the increase in mean age, the overall reduction in absolute cardiovascular risk is therefore likely to be due to a reduction in blood pressure.

DISCUSSION

The short-term benefits of two decision aids for newly diagnosed hypertensive patients in terms of reduced decisional conflict and increased knowledge were not accompanied by longer term effects on blood pressure or 10-year cardiovascular disease risk. Nor were there any observed effects on medication prescribing, self-reported adherence, consulting behaviour or management changes. The reductions in blood pressure and cardiovascular risk among the sample as a whole are likely to be due in some part to regression to the mean, a general benefit of taking part in a randomised controlled trial, and a real effect of blood pressure lowering therapy.

Measurements of health status assess only one aspect of improvement on which patients may place importance.[5] It could be argued that despite a lack of evidence for benefits in terms of longer term health outcomes, reducing decisional conflict and increasing knowledge are sufficient benefits in themselves to warrant making these decision aids available to newly diagnosed hypertensive patients who wish to take an active role in the decision-making process. Future studies should continue to investigate whether decision aids impact on longer term health, and also how patients rate any such benefits compared with outcomes such as decision conflict and knowledge.

Table 2. Systolic and diastolic blood pressure and 10-year cardiovascular disease risk at 3-year follow-up.

	Decision analysis (*n* = 87)	No decision analysis (*n* = 101)	Video/ leaflet (*n* = 90)	No video/ leaflet (*n* = 98)
Mean SBP in mmHg (SD)	149 (14)	147 (15)	147 (14)	148 (15)
Adjusted difference[a] (95% CI)	0.94 (-3.2 to 5.1)		-1.45 (-5.5 to 2.6)	
P-value	0.65		0.48	
Mean DBP in mmHg (SD)	85 (8)	85 (10)	85 (9)	86 (10)
Adjusted difference[a] (95% CI)	-0.76 (-3.1 to 1.6)		-0.68 (-3.1 to 1.7)	
P-value	0.53		0.57	
Mean 10-year cardiovascular risk (SD)	22 (11)	23 (12)	22 (12)	22 (11)
Adjusted difference[a] (95% CI)	0.01 (-0.02 to 0.04)		<0.01 (-0.03 to 0.03)	
P-value	0.54		0.94	
Mean consultations per year[b] (SD)	4.5 (2.5)	4.7 (2.1)	4.6 (2.5)	3.1 (2.8)
Adjusted difference[c] (95% CI)	0 (-0.61 to 0.6)		0 (-0.6 to 0.6)	
P-value	0.90		0.98	
Mean consultations in which change to medication was made[d] (SD)	3.1 (3.4)	3.4 (2.9)	3.4 (3.5)	3.4 (3.5)
Adjusted difference[c] (95% CI)	-0.2 (-1.0 to 0.6)		-0.3 (-0.6 to 1.1)	
P-value	0.61		0.51	

[a]Adjusted for factorial design, baseline level, age, sex, practice, length of follow-up and current medication use. [b]Consultations where focus was hypertension or where blood pressure was recorded. [c]Adjusted for factorial design, age, sex and practice. [d]Change to medication defined as alteration to dose, or starting, stopping or swapping any medication. SBP = systolic blood pressure. DBP = diastolic blood pressure. SD = standard deviation.

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Ethics committee
Ethics approval for the study was obtained from the South West Multi Centre Research Ethics Committee (99/6/69)

Competing interests
None

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