A factorial randomised controlled trial of decision analysis and an information video plus leaflet for newly diagnosed hypertensive patients

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SUMMARY

Background: *There is a lack of evidence regarding the value of tools designed to aid decision making in patients with newly diagnosed hypertension.*

Aim: *To evaluate two interventions for assisting newly diagnosed hypertensive patients in the decision whether to start drug therapy for reducing blood pressure.*

Design of study: *Factorial randomised controlled trial.*

Setting: *Twenty-one general practices in south-west England, UK.*

Method: *Adults aged 32 to 80 years with newly diagnosed hypertension were randomised to receive either: (a) computerised utility assessment interview with individualised risk assessment and decision analysis; or (b) information video and leaflet about high blood pressure; or (c) both interventions; or (d) neither intervention. Outcome measures were decisional conflict, knowledge, state anxiety, intentions regarding starting treatment, and actual treatment decision.*

Results: *Of 217 patients randomised, 212 (98%) were analysed at the primary follow-up (mean age = 59 years, 49% female). Decision analysis patients had lower decisional conflict than those who did not receive this intervention (27.6 versus 38.9, 95% confidence interval [CI] for adjusted difference = –13.0 to –5.8,* P*<0.001), greater knowledge about hypertension (73% versus 67%, adjusted 95% CI = 2% to 9%,* P *= 0.003) and no evidence of increased state anxiety (34.8 versus 36.8, adjusted 95% CI = –5.6 to 0.1,* P *= 0.055). Video/leaflet patients had lower decisional conflict than corresponding controls (30.3 versus 36.8, adjusted 95% CI = –7.4 to –0.6,* P *= 0.021), greater knowledge (75% versus 65%, adjusted 95% CI = 6% to 13%,* P*<0.001) and no evidence of increased state anxiety (35.7 versus 36.1, adjusted 95% CI = –3.9 to 1.7,* P *= 0.46). There were no differences between either of the interventions and their respective controls in the proportion of patients prescribed antihypertensive medication (67%).*

Conclusions: *This trial demonstrates that, among patients facing a real treatment decision, interventions to inform patients about hypertension and to clarify patients' values concerning outcomes of treatment are effective in reducing decisional conflict and increasing patient knowledge, while not resulting in any increases in state anxiety.*

Keywords: *decision-making tools; patient choice; hypertension; randomised controlled trial.*

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Introduction

THERE is clear evidence that reducing blood pressure reduces cardiovascular risk and that intensive lowering of blood pressure lowers cardiovascular mortality.[1] Explicit estimation of absolute cardiovascular risk is now a central focus of hypertension guideline recommendations,[2-4] encouraging targeted drug treatment for those at higher risk of a cardiovascular event.

A potential criticism of current hypertension guidelines is that they fail to take into account patient preferences for health states that may result from having hypertension; for example, side effects of drug treatment. Evidence in both hypertension[5] and atrial fibrillation[6,7] suggests that incorporating patients' preferences into the decision-making process can have an important influence on treatment recommendations for individual patients. The opportunity to consider individual preferences and risks explicitly may be particularly important in an asymptomatic condition such as hypertension, where drug treatment used to control blood pressure is generally lifelong.

There is evidence that interventions to assist patient decision making improve knowledge about treatment options, make patients more realistic in their expectations, reduce decisional conflict, and increase active involvement in decision making.[8] By explicitly combining patients' values regarding treatment outcomes and individual probability information, decision analysis attempts to provide a rational framework to guide patient decision making.[9] Decision analysis can be considered appropriate whenever there is a trade-off in terms of advantages and disadvantages of at least two competing strategies, a situation that clearly applies to the decision whether or not to start drug therapy to reduce blood pressure. Decision aids for many clinical conditions have been developed and evaluated.[10] The use of individualised decision analysis has been questioned,[11] but as yet there is little empirical evidence of its value as an aid to patient decision making.

The aim of this study was to evaluate, in a factorial randomised controlled trial, whether simple (information video/leaflet) and complex (decision analysis) decision aids for treatment of hypertension were associated with changes in decisional conflict, knowledge, anxiety, treatment intentions, and actual treatment choice in a sample of newly diagnosed hypertensive patients.

HOW THIS FITS IN

What do we know?

Observational studies in hypertension and atrial fibrillation suggest that treatment guidelines based on estimation of absolute cardiovascular risk may not be consistent with individual patient preferences. A systematic review has shown that decision aids for a variety of conditions can assist patient decision making, but we are not aware of any randomised controlled trials of patient decision aids for hypertension.

What does this paper add?

This randomised controlled trial suggests that simple (video/leaflet) and complex (decision analysis) decision aids for patients with newly diagnosed hypertension can reduce decisional conflict and increase patient knowledge, while not resulting in any increases in state anxiety. Not all patients with hypertension may want to be involved in decision making. For those who do, our results suggest that these decision aids can be of real benefit.

Methods

Participants

All 110 general practices in Avon Health Authority in England that use the EMIS and Torex computing systems were invited to participate in the study. Patients were eligible for the study if they were aged 30 to 80 years, not currently taking antihypertensive medication, and had sustained raised blood pressure at a level where their general practitioner (GP) would normally discuss initiation of pharmacological therapy. To maximise generalisability to current primary care practice, no specific thresholds for either blood pressure or absolute cardiovascular risk were given to participating doctors. Exclusion criteria were: severe hypertension requiring immediate treatment (as determined by the GP); secondary hypertension; hypertension associated with pregnancy; inability to understand written and spoken English; and dementia or learning difficulties. GPs were requested to inform eligible patients about the trial and ask them if they would like to be contacted by the research team with further details about the trial. Patients who agreed to being contacted were sent detailed information about the purpose of the trial and the procedures involved, a baseline questionnaire, and a written consent form. GPs were asked to manage patients according to their usual practice, subsequent to receipt of any interventions as part of the trial. Participants were recruited between March 2000 and May 2001. Ethical approval was obtained from the South and West Multi-Centre Research Ethics Committee.

Interventions

Decision analysis is a technique to aid decision making when uncertainty exists over the balance between benefits and risks of treatment.[9,12] The technique employed here was a simple decision tree, constructed to include likely outcomes of treatment options. These outcome health states were rated by patients to give utility values, represented on a quantitative scale between 0 and 1. The decision tree for hypertension used in the present study (Figure 1), sources of probability data, and descriptions of the standard gamble method of assessing patient utilities have been reported previously.[5,13] Patients' utilities were assessed using a computerised self-completed interview (http://osler.wustl.edu/~utiter/index.html) with minimal input from the researcher.[14] Individual absolute cardiovascular risk was calculated[15] and combined with utilities using decision analysis software.[16] The purpose of the decision tree and the individual nature of its components were explained to participants. At the end of the intervention, participants were given a printed sheet detailing their cardiovascular risk factors and summarising the decision analysis; that is, whether the 'optimal' decision determined by maximised expected utility would be to accept or decline pharmacological treatment. Intervention sessions were conducted in either the participant's own home, their health centre or the university department (according to their choice) and lasted approximately one hour. All decision analysis consultations were given by one of the research team (AM).

The information video, *What you really need to know about high blood pressure*, lasts 30 minutes and is one of an 'off-the-shelf' series produced by Videos for Patients.[17] The information booklet was four fact sheets from the British Hypertension Society, covering blood pressure measurement, self-help measures including salt reduction, and antihypertensive drugs (http://www.hyp.ac.uk/bhsinfo/published.htm). Participants who received decision analysis and were then further allocated to receive the video and leaflet were given these immediately after the interview to take home. Participants allocated to receive the video and leaflet only were sent these in the post. Participants were allowed to keep the information video and booklet.

Randomisation

Patients were first allocated to 'decision analysis' or 'no decision analysis', minimising by age and sex, and stratified according to practice. Patients were further randomised to 'video/leaflet' or 'no video/leaflet' using the same procedure. Allocation to video/leaflet for patients who received decision analysis was performed at the end of the interview. The trial is therefore a 2×2 factorial design, with patients allocated to receive neither intervention, one or the other, or both. The allocation schedule was computer-generated by an individual not involved in the study and executed by one of the authors (AM), to whom the allocation was concealed in advance by the nature of the minimisation procedure. Given the nature of the interventions, there was no masking of participants or the researcher administering the interventions (AM). Likewise, blinding was not possible for outcome assessment, as this was conducted principally through self-completion questionnaires.

Primary outcome

The primary outcome was the total score on the Decisional Conflict Scale, a questionnaire measuring the degree of uncertainty about which course of action to take and the main modifiable factors contributing to uncertainty.[18,19] The Decisional Conflict Scale has been used in trials of decision aids for conditions such as prostate and breast cancers, hormone replacement therapy, atrial fibrillation, and ischaemic heart disease.[8] The primary follow-up included the 16-item

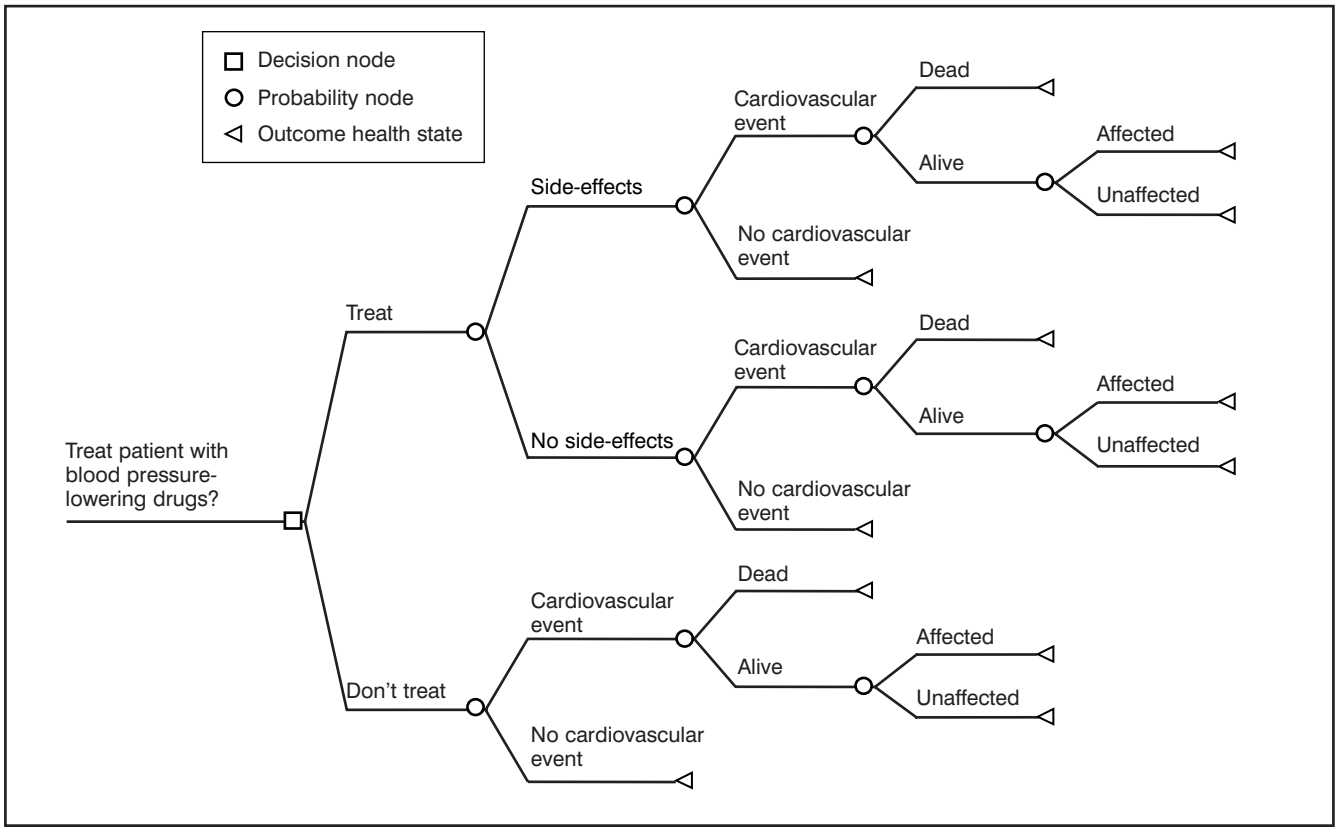

Figure 1. Decision tree for the treatment of high blood pressure. A 'cardiovascular event' was defined as newly diagnosed angina, myocardial infarction, coronary heart disease, stroke, or transient ischaemic attack.

version of this questionnaire, whereas at baseline the 12-item version was applied, omitting items relevant only after making a decision.

Secondary outcomes

The subscales of the Decisional Conflict Scale were designated as secondary outcomes. For the 12-item version, these subscales comprise level of uncertainty and the following three main modifiable factors contributing to uncertainty: feeling uninformed; feeling unclear about values; and feeling unsupported. An additional four-item subscale included in the primary follow-up measures the patient's perception of decision quality after making a choice. Responses to each item are on a five-point Likert scale ranging from 'strongly agree' (1) to 'strongly disagree' (5). Lower scores indicate less conflict about making the decision. For comparison with a systematic review on decision aids that also used the Decisional Conflict Scale,[8] scores were rescaled to range from zero to 100. The four other secondary outcomes were: intentions about starting treatment (yes, no or unsure); state anxiety (possible range of 20 to 80);[20] knowledge about hypertension (percentage of answers correct); actual treatment decision (started drug therapy or not).

Follow-up

The primary follow-up questionnaire was given to participants after receiving the allocated intervention(s) but before returning to their GP to discuss treatment. The secondary follow-up questionnaire was sent out three months after the primary follow-up.

Sample size

Previous intervention studies of a decision aid for hormone replacement therapy in post-menopausal women demonstrated reductions in the rescaled total Decisional Conflict Scale score of 5.0 to 7.5 (equivalent to a difference of 0.33 to 0.5 of a standard deviation).[21,22] To achieve 80% power to detect a standardised difference of 0.4 at the two-sided 5% significance level, a sample size of 198 would be required. One advantage of the factorial design is its efficiency; this sample size relates simultaneously to both interventions. The sample size justification assumes no interaction between the decision analysis and video/information leaflet interventions.

Statistical analysis

Data analysis was performed using Stata Statistical Software, version 7.[23] Baseline comparability of the groups was investigated using descriptive statistics. All analyses comparing the groups at follow-up were conducted on an intention-to-treat basis. To realise the benefit of the factorial design in terms of efficiency, the primary estimate of effectiveness of an intervention should be based on a comparison of all individuals allocated to receive it versus those allocated not to receive it (within each of these two groups, half will have been allocated to receive the other intervention). For example, decision analysis is assessed by comparing the two groups with this intervention (decision analysis only plus both interventions) against the other two groups (video/leaflet only plus control).

Commentary

Decision analysis (DA) refers to the particular technique in which we (a) determine what evidence we need to obtain to decide what to do, by first modelling the scenarios emanating from each of the available options (as opposed to determining what evidence we have and then asking what should we do); (b) distinguish very carefully between evidence on all uncertainties, which must be quantified as probabilities, and evidence on the decision owner's preferences about all possible outcome states, which must be quantified as utilities (or some partially utility-based measure such as the Quality Adjusted Life Year); and (c) integrate these two conceptually distinct types of evidence by some explicit and agreed mathematical procedure (of which maximising expected value of some is one possibility). In its simpler form, the analysis can be visualised as a decision tree, but more complex models require Markov modelling or discrete event simulation. An excellent series of tutorials on DA appeared in *Medical Decision Making* during 1997, but the future lies in doctors tailoring pre-prepared (and probably online) models to each specific patient.[1]

It is important to see that DA can be conceptualised either as a decision aid — an input into some other decision technology, of which 'clinical judgment' and 'evidence-based practice (EBP)' are currently dominant examples — or as a decision technology (DT) in itself, where the recommendation emerging from it is to be interpreted as a 'second' or 'third opinion' (depending on how many have gone before). This latter interpretation is not at all popular with those who have great confidence as well as heavy investment in the existing DTs, nor with most of their clients who have little or no knowledge of the more analytical alternative and a heavy emotional involvement with the deliverers of the present technology.

For whatever reason, attention and evaluation is invariably focused on the flaws and limitations of any particular instantiation of decision analysis, as compared with some *perfect* DT. Using this irrelevant comparator they are, of course, usually many and huge. However, the only relevant comparators are actual instantiations of the alternative DTs of clinical judgment and EBP. The flaws and limitations of these are, unfortunately, also usually many and huge. The only proper and ethical evaluation is therefore, like that demanded with any other technology (for example, drugs) *comparative*, on a 'level playing field' and with an independent judge and jury.

But such a proper comparative evaluation would still miss one key point concerning rights. The way a decision should be made is not a matter of looking at the results for some decisional *consequence*, such as the relative changes in the state of 'decisional conflict' or 'uncertainty' of the decision owner. (Incidentally, the assumption that reductions in these are necessarily a good thing is highly questionable.) It is a matter of deciding whether the *process* of decision making has been undertaken in line with that person's preferences about how to take decisions — what I have called their meta-preferences about analytical mode and professional relationship.[2] The relevant question to ask is: which DT is optimal for a particular decision owner for a particular decision, given their meta-preferences?

Whether or not the average population rating on some decision-related scale is higher or lower for DA than for some other aid is therefore irrelevant to whether or not it should be available, as a right, as an alternative DT. Failing to make it available simply discriminates against those whose meta-preferences favour an explicitly analytical rational choice model in their health care. Such a DA could be undertaken either in collaboration with the doctor, or by the doctor alone at the request of the patient. In other words, the patient should have the right to ask for a (DA-competent and supported) doctor to 'do what a decision analysis for me suggests is best, doctor', rephrasing the traditional request made in the context of the currently dominant DT of experience-based clinical judgment; or to be involved as a partner in this decision analytic process if they wish. The existence of these alternatives makes clear that the current vogue and pressure for 'shared decision making' confuses the question of the desired analytical level of decision making with the desired model of the physician—patient relationship.

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References

1. Pell I, Dowie J, Clarke A, *et al*. Development and preliminary evaluation of a clinical guidance programme for the decision about prophylactic oophorectomy in women undergoing a hysterectomy. *Qual Health Care* 2002; **11:** 32-39.
2. Dowie J. The role of patient's meta-preferences in the design and evaluation of decision support systems. *Health Expect* 2002; **5(1):** 16-27.

Such comparisons are best performed in a multivariable regression model adjusting each intervention for the other one, as well as for the value of the outcome variable at baseline and the minimisation/stratification variables (age, sex and general practice). Depending on the outcome variable, these were either linear or log-linear (multinomial) regression models. Lastly, although the study was not powered to detect interactions between the two interventions, such effects were investigated in secondary analyses.

Results

Participants

Twenty-one general practices agreed to participate in the study. In total, 258 patients were referred (Figure 2). There was no difference between consenting and non-consenting patients in terms of age and sex (data not shown). Baseline characteristics of consenting participants are given in Table 1. The median time taken for receipt of completed primary and secondary follow-up questionnaires was 14 and 117 days after randomisation respectively.

Primary outcome

From the primary comparisons in the relevant regression model, both interventions were successful in reducing patients' total decisional conflict at the primary follow-up, with decision analysis resulting in a greater decrease than the video/leaflet (Table 2).

Secondary outcomes

Decisional conflict subscales. For the decision analysis intervention there was strong evidence of a reduction in three of the five subscales ('uninformed', 'unclear values' and 'unsupported'), marginal evidence for the 'uncertainty' subscale and no evidence of a difference for the 'decision quality' subscale. For the video/leaflet intervention there was no evidence of a difference for these latter two subscales; for the other three the evidence was only clear for the 'uninformed' subscale (Table 3).

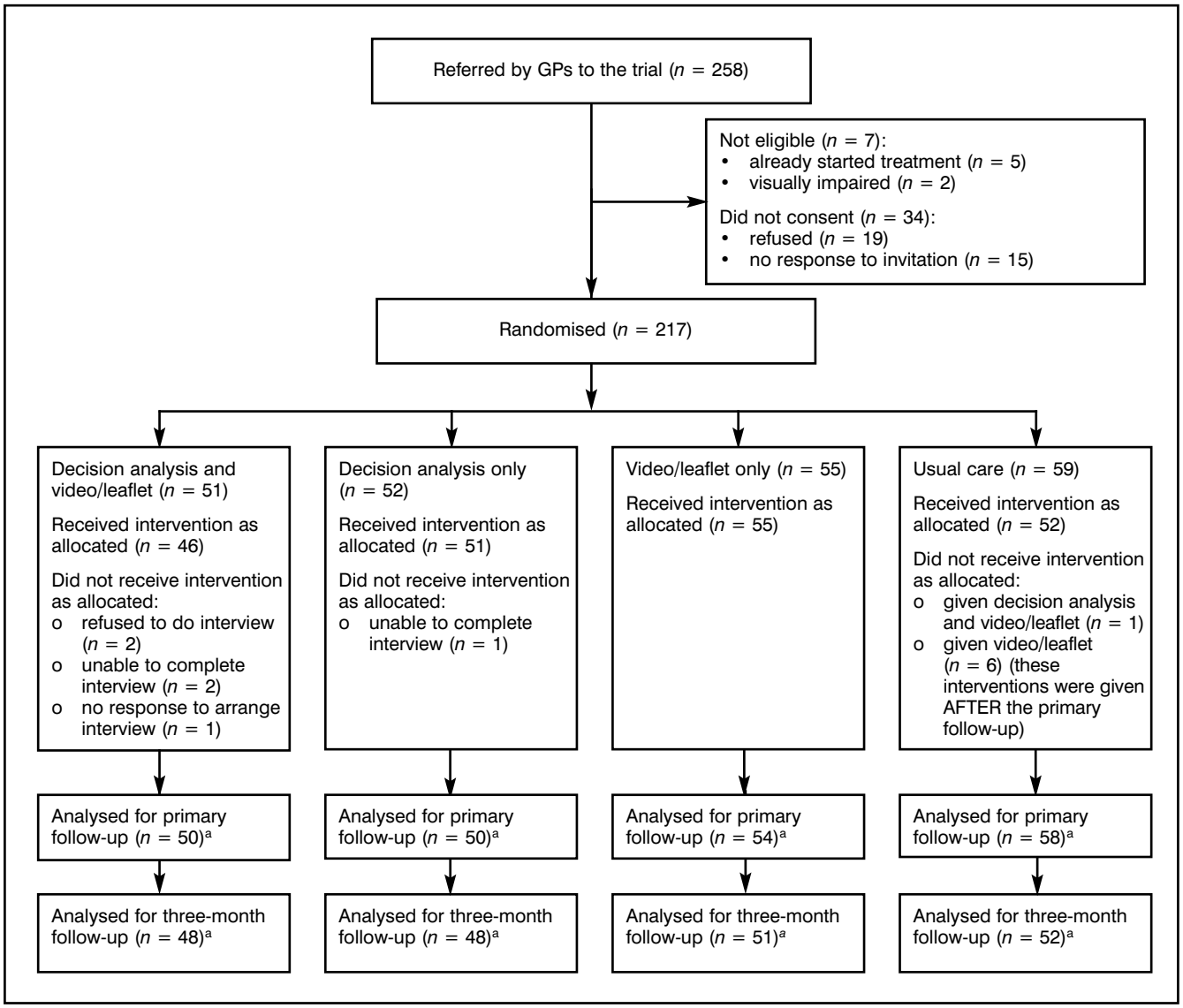

Figure 2. Progress of participants through the trial. [a]For each of the (small numbers) lost to follow-up, no reason was given.

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)
Age in years (mean, SD)	57 (11)	59 (9)	60 (10)	58 (11)
Female (%)	49	46	47	49
Total decisional conflict (mean, SD)	42.5 (18.0)	47.8 (15.8)	48.0 (17.9)	49.9 (19.2)
State anxiety (mean, SD)	40 (12)	37 (11)	37 (13)	38 (13)
Knowledge: % of correct answers (mean, SD)	58 (19)	60 (13)	61 (16)	57 (17)
Intention to start drug therapy (%)				
Yes	48	44	49	42
No	10	12	13	15
Unsure	42	44	38	42

Intention to start treatment and actual prescribing. At the primary follow-up, there was some evidence that decision analysis patients were more likely to state that they did not intend to start drug treatment compared with being unsure (Table 4). Conversely, there was a suggestion that video/leaflet patients were more likely to state that they did intend to start drug treatment. At the three-month follow-up, 133 (67%) partici-

Table 2. Decisional conflict at primary follow-up.

	Decision analysis (n = 100)	No decision analysis (n = 112)	Video/leaflet (n = 104)	No video/leaflet (n = 108)
Total decisional conflict (mean, SD)	27.6 (12.1)	38.9 (18.3)	30.3 (13.4)	36.8 (18.8)
Adjusted difference[a,b] (95% CI)	–9.4 (–13.0 to –5.8)		–4.2 (–7.8 to –0.6)	
P-value	<0.001		0.021	

[a]Adjusted for age, sex, decisional conflict at baseline, factorial design and general practice (all comparisons are for the intervention compared with its respective control). [b]Negative differences represent a favourable outcome for the relevant intervention group.

Table 3. Subscales of decisional conflict at primary follow-up.

	Decision analysis (n = 100)	No decision analysis (n = 112)	Video/leaflet (n = 104)	No video/leaflet (n = 108)
Uncertainty (mean, SD)	37.0 (22.4)	44.3 (24.3)	38.1 (21.9)	43.6 (25.1)
Adjusted difference[a,b] (95% CI)	–5.4 (–10.6 to –0.2)		–2.0 (–7.2 to 3.3)	
Uninformed, mean (SD)	23.7 (11.8)	40.7 (23.1)	27.1 (14.2)	38.0 (24.0)
Adjusted difference[a,b] (95% CI)	–15.7 (-20.2 to –11.2)		–9.2 (–13.7 to –4.8)	
Unclear values, mean (SD)	28.4 (14.7)	43.8 (24.3)	32.2 (17.1)	40.7 (24.8)
Adjusted difference[a,b] (95% CI)	–13.1 (–18.0 to –8.1)		–6.4 (–11.4 to –1.5)	
Unsupported, mean (SD)	24.4 (13.4)	34.8 (18.3)	26.3 (13.0)	33.4 (19.5)
Adjusted difference[a,b] (95% CI)	–8.7 (–12.8 to –4.7)		–5.1 (–9.2 to –1.1)	
Decision quality, mean (SD)	25.4 (13.4)	33.0 (17.2)	28.5 (14.6)	30.3 (17.2)
Adjusted difference[a,b] (95% CI)	–1.7 (–6.0 to 2.5)		–0.2 (–0.4 to 0.01)	

[a]Adjusted for age, sex, subscale score at baseline (where measured), factorial design and general practice (all comparisons are for the intervention compared with its respective control). [b]Negative differences represent a favourable outcome for the relevant intervention group.

Table 4. Intentions to start blood pressure-lowering therapy at primary follow-up and actual treatment prescription at three-month follow-up.

	Decision analysis (n = 100)	No decision analysis (n = 112)	Video/leaflet (n = 104)	No video/leaflet (n = 108)
Intention to start treatment: adjusted risk ratio[a,b] (95% CI):				
Yes versus unsure	1.19 (0.59 to 2.40)		1.80 (0.89 to 3.63)	
No versus unsure	3.15 (0.91 to 10.98)		0.52 (0.15 to 1.77)	
Overall *P*-value (2 df)	0.09		0.17	
Prescription of blood pressure-lowering medication:				
Prescribed treatment	65/96	68/103	68/99	65/100
Adjusted odds ratio[a,c] (95% CI)	1.13 (0.59 to 2.19)		1.12 (0.59 to 2.15)	
P-value	0.71		0.73	

[a]All comparisons are for the intervention compared with its respective control. [b]Adjusted for age, sex, baseline intentions, factorial design and general practice. [c]Adjusted for age, sex, factorial design and general practice. df = degrees of freedom.

pants had been prescribed blood pressure-lowering medication, with no difference between either of the interventions and their respective controls (Table 4). For patients in the decision analysis group, concordance between outcome of the decision analysis and treatment decision was low ($\kappa = -0.06$).

Anxiety. There was a suggestion ($P = 0.055$ in Table 5) that decision analysis might reduce anxiety at the primary follow-up, although the evidence was weak, especially given the number of statistical tests performed and the fact that the differences were diminished at the three-month follow-up (Table 5). There was no evidence of any effect on anxiety for the video/leaflet intervention (Table 5).

Knowledge. Both interventions significantly increased knowledge about hypertension, with the video/leaflet being initially more effective (Table 5). There were small and very similar reductions in knowledge from primary to three-month follow-up for both the decision analysis group and the corresponding control group. There was a decrease in knowledge over this time period for those in the video/leaflet group, and a small increase for the corresponding control group; this difference between groups in changes in knowledge through time was highly statistically significant (Table 5).

Interactions. At the primary follow-up, participants allocated to receive both interventions had the lowest decisional conflict (unadjusted mean = 27.1, compared with 28.2, 33.3, and 44.2 for decision analysis only, video/leaflet only, and control, respectively). Likewise, this group had a high knowledge score (unadjusted mean = 75%, compared with 71%, 75%, and 60% for decision analysis only, video/leaflet only, and control, respectively). Within the regression models there was a significant (antagonistic) interaction between decision analysis and video/leaflet, such that the effect of each intervention was reduced in the presence of the other (interaction

Table 5. Anxiety and knowledge at primary follow-up and change between primary and three-month follow-up.

	Decision analysis	No decision analysis	Video/leaflet	No video/leaflet
Anxiety				
Primary follow-up, mean (SD)	34.8 (10.3)	36.8 (13.8)	35.7 (12.3)	36.1 (12.4)
	n = 87	*n* = 97	*n* = 91	*n* = 93
Adjusted difference[a,b] (95% CI)	–2.8 (–5.6 to 0.1)		–1.1 (–3.9 to 1.7)	
P-value	0.055		0.46	
Change from primary to 3-month follow-up, mean (SD)	–0.3 (10.9)	–2.2 (11.1)	–0.5 (10.7)	–2.0 (11.3)
	n = 77	*n* = 83	*n* = 79	*n* = 81
Adjusted difference[c] (95% CI)	2.4 (–1.2 to 6.0)		1.5 (–2.1 to 5.1)	
P-value	0.19		0.42	
Knowledge				
Primary follow-up, mean (SD)	73 (15)	67 (16)	75 (14)	65 (17)
	n = 100	*n* = 112	*n* = 104	*n* = 108
Adjusted difference[a,d] (95% CI)	5 (2 to 9)		10 (6 to 13)	
P-value	0.003		<0.001	
Change from primary to 3-month follow-up, mean (SD)	–1.9 (10.6)	–1.2 (16.6)	–4.9 (15.0)	1.8 (12.1)
	n = 96	*n* = 103	*n* = 99	*n* = 100
Adjusted difference[c] (95% CI)	–1.2 (–5.1 to 2.7)		–6.6 (–10.5 to –2.7)	
P-value	0.53		0.001	

[a]Adjusted for age, sex, baseline score, factorial design and general practice (comparisons are for the intervention compared with its respective control). [b]Negative differences represent a favourable outcome for the relevant intervention group. [c]Adjusted for age, sex, factorial design and general practice (comparison of changes in outcome measure through time for intervention compared with respective control). [d]Positive differences represent a favourable outcome for the relevant intervention group.

coefficient = 12.5, 95% confidence interval (CI) = 5.4 to 19.5, $P = 0.001$ for decisional conflict, and –9.1, 95% CI = –16.3 to –1.9, $P = 0.013$ for knowledge).

Discussion

Summary of the main findings

This study has demonstrated that both relatively complex (decision analysis) and simple (information video/leaflet) decision aids are effective in reducing decisional conflict among newly diagnosed hypertensive patients. Decision analysis had a greater effect on total decisional conflict than the video/leaflet and this was further reflected in each of the decisional conflict subscales. The antagonistic interaction between the two interventions suggests there may be a ceiling to the amount of information and assistance that patients benefit from, in terms of decisional conflict and knowledge. This should not be interpreted as suggesting that receiving both interventions results in participants receiving confusing and/or conflicting messages, since the group with both interventions had the lowest decisional conflict. Rather, it appears that although overall the video/leaflet intervention led to a reduction in decisional conflict, the benefits of receiving this intervention in addition to the decision analysis were extremely small.

Both interventions had moderate and opposite effects on participants' intentions regarding starting treatment, but neither had any effect on the overall proportion of participants who were actually prescribed medication. This suggests that patients' treatment decisions were subject to various influences, including that of the GP, rather than just the decision aids. This is further supported by the low concordance between the treatment decision and the outcome of the decision analysis. To elicit the various impacts of such factors would require further study, including qualitative research. Both interventions improved patient knowledge about hypertension in the short term, particularly the video/leaflet, but these improvements were not maintained after three months. Neither intervention substantially affected anxiety, especially since any marginal *P*-values should be treated with caution, bearing in mind the number of statistical tests performed for the secondary outcomes.

Comparison with existing literature

We are not aware of any other randomised controlled trials of patient decision aids for hypertension, and believe that our use of decision analysis as a tool to aid individual decision making in this context is unique. Previous research indicates that effect sizes for the outcome of total decisional conflict ranging between 0.43 and 0.82 standard deviations can discriminate between individuals who make a decision and those who delay or are unsure.[18] Observed effect sizes in this study suggest that decision analysis (effect size = 0.57) but not video/leaflet (effect size = 0.25) may have an important role in reducing decisional conflict and helping patients make decisions. Despite reservations about using decision analysis in individual clinical decisions,[11,24] our data demonstrate that decision analysis is a useful decision aid for patients with increased blood pressure facing a treatment decision. Treatment guidelines based on absolute risk stratification represent an improvement on simple blood pressure thresholds.[25] Incorporating patient preferences by means of decision analysis enables treatment decisions to further reflect the 'intensely individual nature of social distress resulting from cardiovascular disease'.[26]

Increases in knowledge in both decision analysis and video/leaflet groups, compared with controls, were smaller than the pooled results of seven trials (pooled difference in favour of decision aids = 19%).[8] Although follow-up knowledge scores in both intervention groups were similar to those achieved by intervention groups in the systematic review,

scores among controls were higher, indicating that participants in our study were quite well informed about their condition. Our finding that neither intervention increased state anxiety, and may even slightly reduce anxiety, was comparable to the pooled results of five studies. In line with a previous review,[27] this suggests that the assertion made by some clinicians that informing patients about risk and uncertainty can be harmful appears not to be true.

Limitations of the study

The main limitation of this study is that the decision analysis intervention took about 45 to 60 minutes to complete, and would therefore be unsuitable for a normal consultation with a GP. However, it is encouraging that the vast majority of participants found the utility assessment interview acceptable and were able to complete it. It is worth noting that more complex techniques, such as Markov modelling, may not necessarily result in qualitatively different outcomes of the decisional analysis.[28] Assistance from the (non-clinical) researcher during the interview was limited to technical queries about using the computer or understanding the standard gamble method of utility assessment. Care was taken to avoid discussing patients' general or specific concerns about taking antihypertensive therapy, but without further research into different methods of delivery it is not possible to completely rule out any unintended effect of simply spending up to an hour with the researcher. The timescale of the trial did not allow for collection of blood pressure and other clinical data. While these are clearly important outcomes, they address a different question to that investigated here, namely, 'do these decision aids help patients in the decision making process?'. With longer-term follow-up, these trial participants provide an excellent opportunity to study the effects of decision aids on persistence with treatment choices and clinical outcomes.

Implications for practice

We would envisage that both types of decision aid could be made available to patients. The video and leaflet may provide enough information to answer many patients' questions. For patients who wish explicit quantification of their preferences and risks, the individual decision analysis could be developed to be entirely self-completed by the patient prior to meeting with their GP to discuss treatment.

Not all patients wish to be actively involved in making decisions about their treatment.[29] For those who do, our results suggest that giving information about their condition, as well as an opportunity to explore their own values regarding various treatment options, can benefit patients facing a real treatment decision.

References

1. Staessen JA, Wang JG, Thijs L. Cardiovascular protection and blood pressure reduction: a meta-analysis. *Lancet* 2001; **358:** 1305-1315.
2. Core Services Committee. *Guidelines for the management of mildly raised blood pressure in New Zealand*. Wellington: Core Services Committee, 1994. URL: www.nzgg.org.nz/library/gl_complete/bloodpressure/team.cfm (Accessed 14 April 2003.)
3. Joint National Committee. *The sixth report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure*. Bethesda, MD: National Institutes of Health, 1997.
4. Working Party of the British Cardiac Society, British Hyperlipidaemia Association and British Hypertension Society. Joint British recommendations on prevention of coronary heart disease in clinical practice. *Heart* 1998; **80 (Suppl. 2):** S1-S29.
5. Montgomery AA, Harding J, Fahey T. Shared decision making in hypertension: the impact of patient preferences on treatment choice. *Fam Pract* 2001; **18:** 309-313.
6. Thomson R, Parkin D, Eccles M, Sudlow M, Robinson A. Decision analysis and guidelines for anticoagulant therapy to prevent stroke in patients with atrial fibrillation. *Lancet* 2000; **355:** 956-962.
7. Protheroe J, Fahey T, Montgomery AA, Peters TJ. The impact of patients' preferences on the treatment of atrial fibrillation: observational study of patient-based decision analysis. *BMJ* 2000; **320:** 1380-1384.
8. O'Connor AM, Stacy D, Rovner D, *et al.* Decision aids for people facing health treatment or screening decisions. In: Cochrane Collaboration. *Cochrane Library*, Issue 4. Oxford: Update Software, 2002.
9. Robinson A, Thomson RG. The potential use of decision analysis to support shared decision making in the face of uncertainty: the example of atrial fibrillation and warfarin anticoagulation. *Qual Health Care* 2000; **9:** 238-244.
10. Edwards A, Elwyn G. The potential benefits of decision aids in clinical medicine. *JAMA* 1999; **282:** 779-780.
11. Elwyn G, Edwards A, Eccles M, Rovner D. Decision analysis in patient care. *Lancet* 2001; **358:** 571-574.
12. Detsky AS, Naglie G, Krahn MD, Naimark D, Redelmeier DA. Primer on medical decision analysis: Part 1—Getting started. *Med Decis Making* 1997; **17:** 125.
13. Sox HC, Blatt MA, Higgins MC, Marton KI. *Medical decision making*. Boston: Butterworth-Heinemann, 1988.
14. Sumner W, Nease R, Littenberg B. U-titer: a utility assessment tool. In: *Proceedings of the Fifteenth Annual Symposium on Computer Applications in Medical Care*. 1991; 701-705,.
15. Anderson KM, Odell PM, Wilson PWF, Kannel WB. Cardiovascular disease risk profiles. *Am Heart J* 1990; **121:** 293-298.
16. TreeAge Software, Inc. *Data 3.5 for Healthcare*. Williamstown, MA. 1998.
17. *What you really need to know about high blood pressure*. London: Videos for Patients, 1996.
18. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995; **15:** 25-30.
19. O'Connor AM. Decisional Conflict Scale. URL: http://www.ohri.ca/programs/clinical_epidemiology/OHDEC/dcs-doc.pdf (Accessed 14 April 2003.)
20. Marteau TM, Bekker H. The development of a six-item short form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). *Br J Clin Psychol* 1992; **31:** 301-306.
21. O'Connor AM, Tugwell P, Wells GA, *et al.* A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns* 1998; **33:** 267-279.
22. O'Connor AM, Tugwell P, Wells GA, *et al.* Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making* 1998; **18:** 295-303.
23. StataCorp. *Stata Statistical Software. (Release 7.0)*. 2001. College Station, TX, Stata Corporation.
24. Naylor CD. Clinical decisions: from art to science and back again. *Lancet* 2001; **358:** 523-524.
25. Jackson R. Which hypertensive patients should be treated? *Lancet* 1994; **343:** 496-497.
26. Swales JD. Treating hypertension. *J Hypertens* 1996; **14:** 813-814.
27. Coulter A. Partnerships with patients: the pros and cons of shared clinical decision-making. *J Health Serv Res Policy* 1997; **2:** 112-121.
28. Moskowitz AJ, Dunn VH, Lau J, Pauker SG. Can hypersimplified decision trees be used instead of Markov models? [Abstract.] *Med Decis Making* 1984; **4:** 530
29. Robinson A, Thomson R. Variability in patient preferences for participating in medical decision making: implication for the use of decision support tools. *Qual Health Care* 2001; **10 (Suppl I):** i34-i38

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