A randomized controlled trial of an information booklet for hypertensive patients in general practice

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SUMMARY. A randomized controlled trial of an information and medical record booklet designed to improve patient understanding and participation in the management of hypertension was conducted in six inner London general practices. After one year there were no significant differences between the group who had received the booklets and the control group in mean systolic or diastolic blood pressure, but the study group scored significantly higher on knowledge about hypertension and its management. However, the difference between the two groups was small, possibly because both groups started with a high level of understanding about hypertension and its management. In addition, the mean diastolic blood pressure in the control group showed that the treatment provided was already satisfactory, and that there was little need for improvement. Nevertheless, the information booklet evaluated in this study provides health professionals with a highly acceptable method of informing the patient about hypertension and its management and could be used both in hospital and general practice.

Introduction

THE management of chronic conditions such as diabetes, asthma and hypertension depends on patients keeping to complicated regimens of treatment over long periods and it has been argued that patients should be involved in decisions about their own health care.[1-6] Such involvement depends on patients understanding the natural history of the condition, the way in which management alters it and their role in the management programme.

Booklets have been widely used to provide information about health matters and have been shown to be potent influences in modifying health behaviour.[7-9] A booklet to provide information for hypertensive patients was written by the Department of General Practice of the United Medical and Dental Schools of Guy's and St Thomas's Hospitals, assisted by the health education unit of the West Lambeth Health Authority. It contained information on the natural history of the condition and the different forms of treatment available. It also provided an opportunity for the general practitioner and patient to set the objectives of management together and to share the information on how well these objectives had been attained. The booklet was tested for acceptability and comprehensibility using a small sample of hypertensive patients registered with a practice not involved in the main evaluation study, and minor amendments were made before the final edition was printed.

This paper describes a study to examine the acceptability of the booklet and to describe its pattern of use by hypertensive patients in general practice. A randomized controlled trial was used to test the effect of the booklet on patients' knowledge about the natural history of hypertension and on management as indicated by their blood pressure.

Method

Six group general practices in south London were recruited for the study; only two had chronic disease registers. To identify hypertensive patients photocopies of prescriptions dispensed to patients in the participating practices by the most commonly used pharmacies were provided by special arrangement with the Prescription Pricing Authority. These were reviewed for antihypertensive drugs by a research assistant over a three-month period before the start of the study. The age of the hypertensive patients was determined from their medical records and those outside the age range 35–64 years were excluded. The patient's sex and the date and value of their last recorded blood pressure were then extracted.

A sample of 552 patients was the target — two groups of 276 each — in order to detect with 90% probability at the 5% level of significance a true difference in mean diastolic pressure between the study and control groups of at least 3 mmHg, allowing for a 25% migration rate and a 75% response in the remainder.

Randomization to study and control groups was carried out separately for each practice, thus stratifying the total sample by one possible confounding variable — variation in the management of hypertension between practices. The sample was also stratified according to age (above and below 55 years), sex and last recorded diastolic blood pressure.

Booklets were then mailed to each patient in the study group with an accompanying letter from his or her own general practitioner. One year later all the patients in both groups were visited at home by a trained field worker, who was blind to the patient's group. At interview, information about educational attainment, racial group and occupational status was obtained. A single measurement of the subject's blood pressure was then made with a Hawksley random zero sphygmomanometer (diastolic phase 5). The patients were asked whether or not they had received the booklet and if so how useful it had been. They were also asked to complete a questionnaire measuring their understanding about hypertension and its management. The questionnaire was developed specifically for this study and consisted of a series of contradictory statements about the aetiology, effects and management of hypertension to which patients were asked to respond true, false or do not know. A score of 2 was given for each correct answer, 1 for not known, and 0 for each incorrect answer. Scores for paired contradictory statements were averaged and these were added together to form a total score for each patient.

Each practice was enrolled into the study sequentially to allow a single field worker to carry out all the blood pressure recordings and interviews. In the two practices with chronic disease

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registers those patients on the registers who were not identified by prescription review were also enrolled in the study as a separate group.

Results

Six hundred hypertensive patients in the age range 35–64 years were identified. Thirty five patients were excluded, chiefly owing to serious physical or psychiatric ill health, and the 565 patients eligible for study were randomized into study and control groups. At the time of despatch of the medical record booklets, a further 10 patients from one practice were excluded, mainly because of recent ill health or adverse family events. During the study year nine patients died. No contact could be established with 66 patients who had either moved or were temporarily unavailable at their present address, 11 patients from one practice were considered unsuitable for interview because of recent illness of the patient or his/her immediate family and 55 patients refused to be interviewed. Thus, 414 patients provided complete data for analysis.

The characteristics of the study and control groups were very similar with respect to age, sex, diastolic blood pressure prior to the start of the study, racial origin, social class and educational status. Almost two-thirds of the sample were aged 55–64 years, and there were more women (59%) than men (41%). The sample showed characteristic features of an inner city population — 71% were or had been in manual occupations, only 6% had received any full-time education after the age of 16 years, and 27% were non-Caucasians. In the six months prior to the study blood pressure had been recorded for 313 patients (76%) of whom 147 (47%) had diastolic blood pressures of at least 95 mmHg.

Outcome measures

The mean levels of blood pressure and understanding about hypertension and its management for the study and control groups are shown in Table 1. The values are shown adjusted for the stratifying variables of age, sex, practice and blood pressure prior to the study.

Those whose diastolic blood pressure in the six months before the start of the study was above 95 mmHg had a significantly higher diastolic pressure at the end of the study than those with lower initial diastolic blood pressures ($P<0.001$). Men had significantly higher diastolic blood pressures than women ($P<0.01$), and those over the age of 55 years had higher systolic and diastolic blood pressures than younger patients ($P<0.02$). There was no significant difference between the study and control group with respect to systolic or diastolic blood pressures, before or after adjustment for these stratifying variables (Table 1).

Caucasians and those in non-manual occupations scored significantly higher on the questionnaire than non-Caucasians and those in manual occupations, independently of whether or not they were in the study or control group ($P<0.001$). Patients who had been educated beyond the age of 16 years and those with a university education had significantly higher 'knowledge scores' than those who only had primary school education ($P<0.05$). There was a significant trend showing increasing knowledge scores with increasing levels of education ($P<0.05$). The study group had a mean adjusted score of 25.95 on the knowledge questionnaire, significantly higher ($P<0.001$) than that of the control group (25.08). The maximum attainable score was 34. There were no significant differences in knowledge scores between men and women, according to the number of years the patient had been diagnosed hypertensive or according to the practice where the patient was registered.

The only pair of contradictory questions to show a significant difference between study and control groups concerned whether only a qualified nurse or doctor can measure blood pressure ($P<0.001$). These questions were answered correctly by 42% of the study group and 15% of the control group. When the responses to these questions were omitted from the total score, there was no significant difference between the two groups.

In the two practices with chronic disease registers 143 of the 191 hypertensive patients (75%) on the registers were identified by prescription review. The remaining 48 patients were enrolled in the study and 45 provided complete data. This group did not differ significantly in mean blood pressure levels or knowledge score from those identified by prescription review.

Table 1. Outcome measures for study and control groups before and after adjustment for stratifying variables.

	Mean (SE)	
	Study group ($n=204$)	Control group ($n=210$)
Systolic blood pressure (mmHg)		
Unadjusted	147.3 (1.3)	146.4 (1.3)
Adjusted[a]	149.8 (2.6)	149.2 (2.6)
Diastolic blood pressure (mmHg)		
Unadjusted	91.2 (0.8)	90.4 (0.8)
Adjusted[b]	95.3 (1.7)	94.9 (1.7)
Knowledge scores		
Unadjusted	26.03 (0.18)	25.15 (0.17)***
Adjusted[c]	25.95 (0.21)	25.08 (0.21)***

***$P<0.001$, t-test. SE = standard error. n = total number in group. [a]For men aged 35–54 years, registered with group practice 1, whose initial systolic blood pressure was 150 mmHg. [b]For men aged 35–54 years, registered with group practice 1, whose initial diastolic blood pressure was 95 mmHg. [c]For Caucasians in manual occupations who completed their education by age 16 years.

Use of the booklet

Of the 204 patients interviewed in the study group 175 recalled receiving the booklet a year prior to the interview and the overwhelming majority of these (164, 94%) liked the booklet, while only six did not. Five patients had not read the booklet or felt unable to comment on it. Only seven patients felt anxious about some aspect of the booklet — three were concerned about the advice to stop smoking, three about the advice on weight reduction and one patient was unable to be specific.

Ninety seven patients (55%) had read the booklet at home when it first arrived, but had not referred to it since, 29 (17%) had lost the booklet at some time during the study year and there was no response from eight patients. The remaining 41 patients (23%) were still using or referring to the booklet at home, with varying degrees of frequency, a year after it had been received. The interviewer asked to see the booklet, and 81 patients (46%) were able to produce it. Of these booklets 65 were used or well-used, while the remaining 16 appeared to be unused.

The booklet contained pages for the doctor or patient to record measurements of blood pressure, weight, symptoms experienced and tablets prescribed. Of the 175 patients who recalled receiving the booklets, only 16 (9%) had written in it. Seventeen patients (10%) had been asked by their doctor to produce the booklet and 58 (33%) had produced it spontaneously for the doctor to use. Fifty one booklets (29%) contained written entries of blood pressure. The booklet told patients how to buy their own sphygmomanometers to measure their own blood pressure, and four patients had done so.

Discussion

The purpose of the booklet was to provide information about hypertension and its management in an acceptable way and to promote greater involvement and participation in the management of hypertension. This study has shown that the booklet was highly acceptable to those hypertensive patients who received it, with only seven of the 175 patients expressing some anxieties about its content. Over one fifth of the patients were still using the booklet regularly one year after it was distributed and one third of the patients produced the booklet spontaneously so that their doctor could make entries. Only 10% of patients were asked by their general practitioner for their booklet because the doctors were unaware which of their hypertensive patients had been sent booklets.

One year after the booklet had been mailed to the study group, there was no significant difference in the mean blood pressure of those who were provided with the booklets and those who were not. The significant difference between the two groups in understanding about hypertension was accounted for by a higher proportion of those in the study group recognizing that blood pressure measurements could be carried out by a non-professional.

There are a number of possible reasons for the lack of effect of the booklet on hypertensive patients. First, in the sample of patients studied 76% had had their blood pressure recorded in the six months before the start of the study. The overall level of blood pressure control was satisfactory in both study and control groups, which suggests that the standard of care of the participating general practitioners allowed little room for improvement.

Secondly, despite the poor educational attainment and the racial mix of the group, which may result in language difficulties, the overall knowledge about hypertension and its management was satisfactory, again allowing little room for improvement. However, a significantly higher proportion of those in the study group recognized that blood pressure measurements could be carried out by a non-professional. This suggests that the booklet did have some effect on those who received it, changing their attitudes and allowing them to become more involved in self-management.

One possible explanation for the satisfactory level of blood pressure control and understanding about hypertension and its management could have been the identification of the sample by prescriptions dispensed, favouring those patients who attend their general practitioners regularly for treatment. However, the group of patients on the chronic disease registers who were not identified by prescription review did not differ significantly from those identified by prescription review with respect to mean blood pressure levels or knowledge score. This suggests identifying patients by prescription review did not bias the selection of the study sample towards a particularly compliant group of hypertensive patients.

In conclusion, the booklet evaluated in this study seems to be an acceptable method of providing hypertensive patients with information about the condition. There is some evidence that those patients who received the booklet might be prepared to become more involved in the management of their condition. The study also revealed the high standard of care provided for hypertensive patients receiving regular treatment in the participating practices.

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