

Primary care

Randomised equivalence trial comparing three and six months of follow up of patients with hypertension by family practitioners

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Abstract

Objective To compare blood pressure control, satisfaction, and adherence to drug treatment in patients with treated hypertension followed up by their family physicians either every three months or every six months for three years.

Design Randomised equivalence clinical trial.

Settings 50 family practices in south eastern Ontario, Canada.

Participants 609 patients aged 30-74 years with essential hypertension receiving drug treatment whose hypertension had been controlled for at least three months before entry into the study.

Results 302 patients were randomly assigned to follow up every three months and 307 to follow up every six months. Baseline variables in the two groups were similar. As expected, patients in the six month group had significantly fewer visits, but patients in both groups visited their doctor more frequently than their assigned interval. Mean blood pressure was similar in the groups, as was control of hypertension. Patient satisfaction and adherence to treatment were similar in the groups. About 20% of patients in each group had blood pressures that were out of control during the study.

Conclusions Follow up of patients with treated essential hypertension every six months is equivalent to follow up every three months. Patient satisfaction and adherence to treatment are the same for these follow up intervals. As about 20% of patients' hypertension was out of control at any time during the study in both groups, the frequency of follow up may not be the most important factor in the control of patients' hypertension by family practitioners.

Introduction

One of the achievements of contemporary health care is the decrease in morbidity and mortality through the control of chronic cardiovascular conditions such as hypertension. The mortality from cardiovascular disease has fallen by a third over the past 25 years, and although the reasons for this have not been clearly established, control of hypertension may be a central reason.¹ However, control of blood pressure by patients

and their doctors is still far from ideal. The Canada heart health survey found that only about 13% of Canadians with hypertension were adequately controlled.² This result was even lower than the 25% found in a US study.³ After initial diagnosis and treatment of chronic diseases such as hypertension, most people need lifelong medical care and follow up, and their doctors must decide how often to follow up for blood pressure control and monitoring of treatment.

Currently, the suggested interval for follow up of hypertension is 3-6 months.⁴ The British Hypertension Society says that follow up depends on the severity of hypertension, variability of blood pressure, complexity of treatment regimen, patient's compliance with treatment, and the need for non-pharmacological advice. After blood pressure is controlled, follow up every three months should be adequate and the interval should generally not exceed six months.⁵ The 1999 Canadian consensus guidelines recommend similar intervals.⁶ All of these recommendations are based on level 3 evidence.

We undertook a pragmatic randomised equivalence trial comparing three month and six month follow up of patients whose essential hypertension had been treated and controlled for at least three months before entry into the study.

Methods

Study population

One hundred and thirty family doctors in the region of Kingston, Ontario, were asked to participate in the study; 50 agreed and enrolled their patients. Patients were eligible for the study if they were between the ages of 30 and 74, had a diagnosis of essential hypertension, were taking at least one antihypertensive drug, and had controlled blood pressure for at least three months before entry. Control meant blood pressure was <140/90 mm Hg in patients aged 40 or less, <150/95 in patients aged 41-59, and <160/95 in patients aged 60 or more. Since the study was initiated



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the targets for blood pressure control have changed, and the analysis is based on the current recommended blood pressure threshold of < 140/90 for all ages. The exclusion criteria were pregnancy, inability to give informed consent, hypertension follow up by a specialist, and that in the opinion of the family doctor the patient could not be randomised to the six month group because of other medical problems requiring more frequent follow up.

Follow up groups

Patients were randomised to three month or six month follow up groups. Patients were asked to return to their family doctor for follow up of their blood pressure every three or six months, depending on group assignment. The doctor saw the patient earlier if the blood pressure was out of control, if other medical reasons dictated a more frequent follow up, or if there had been a change of drug. Once blood pressure was again controlled, the patient returned to the assigned visit frequency. Patients were free to visit the doctor at any time.

Follow up and outcome assessment

The main outcomes were blood pressure measurements in the doctor's premises and in patients' homes by the research nurse, patient satisfaction, and adherence to medication.

We assessed systolic and diastolic blood pressure as continuous variables; whether the target of < 140/90 had been achieved was assessed as a dichotomous variable. We also asked the doctor whether the patient's blood pressure was in control. Patient satisfaction was assessed with a validated questionnaire.^{7,8} Adherence was assessed by pill count at the nurse's visit at entry, at 18 and 36 months, and by questionnaire. If patients had consumed $\geq 80\%$ of their pills, we considered them adherent.

Sample size and data analysis

We based the sample size calculation on significance testing to establish equivalence between the follow up groups with the hypothesis that the true difference in blood pressure control between groups was < 10%. An $\alpha = 0.05$ and $\beta = 0.20$ were used. This resulted in a sample size requirement of 296 patients per group.

In our intention to treat analysis we compared blood pressure, patient satisfaction, and adherence to assess equivalence between the two groups. We applied generalised estimating equations to take into account the dependence of patients' blood pressure measurements obtained from the same doctor's practice. We constructed 90% confidence intervals for adjusted mean differences, and inferred equivalence when the confidence interval fell within the equivalence margins. The equivalence margin for both systolic and diastolic blood pressure was ± 5 mm, and for patient satisfaction and adherence it was $\pm 10\%$.

Results

Six hundred and nine patients (302 in the three month group and 307 in the six month group) were enrolled between November 1997 and July 2002 and were followed over an average of 33.6 months.

Baseline variables were similar in the groups (table 1). However, the three month group contained more patients with diabetes.

Table 1 Comparison of baseline variables at entry between groups. Values are numbers (percentages) of patients unless indicated otherwise

Variable	3 month group (n=302)	6 month group (n=307)
Mean (SD) age (years)	55.6 (9.9)	56.1 (9.6)
Sex:		
Female	166 (55)	161 (52)
Male	136 (45)	146 (48)
Mean (SD) blood pressure at entry (mm Hg)	141.6 (16.7)/84.5 (9.7)	143.3 (16.9)/84.3 (8.9)
Duration of hypertension (years):		
<1	26 (8.6)	30 (9.8)
1-5	130 (43)	121 (39.4)
6-10	63 (20.9)	63 (20.5)
>10	83 (27.5)	93 (30.3)
Organ damage	39 (12.9)	42 (13.7)
Retinopathy	7 (2.3)	5 (1.6)
Left ventricular hypertrophy	23 (7.6)	25 (8.1)
Transient ischaemic attacks or stroke	12 (4.0)	9 (2.9)
Comorbidity:		
Heart disease	59 (19.5)	59 (19.2)
Diabetes	26 (8.6)	15 (4.9)
Mean (SD) number of drugs taken for blood pressure	1.4 (0.6)	1.4 (0.6)

The six month group had more unscheduled visits for measuring blood pressure and more visits unrelated to blood pressure, although the difference between groups was not significant (8.68 *v* 7.95, $P = 0.23$). The six month group had significantly fewer visits to the doctor over the three years (mean 16.2 (SD 8.5) visits in six month group *v* 18.8 (8.1) in three month group, $P < 0.0001$). The mean time between visits was 2.16 (2.25) months for the six month group and 1.89 (1.61) months for the three month group.

Control of hypertension

At 0, 12, 24, and 36 months mean blood pressures measured by doctors during a consultation were equivalent between groups (table 2). The mean blood pressure measurements taken at patients' homes by nurses were similar to the doctors' measurements but were consistently lower in years 2 and 3 (see bmj.com). There was a trend to lower blood pressure readings in both groups after three years for both the doctors' and nurses' measurements.

Table 3 shows the percentage of patients whose blood pressure was out of control as judged by their doctor over the course of the study. Although we pro-

Table 2 Mean (SE) numbers of systolic and diastolic blood pressure measurements (mm Hg) in patients with hypertension by family doctors

Time (months)	No of patients	Blood pressure		Difference	Equivalence 90% CI*
		3 month group	6 month group		
Systolic blood pressure					
0	605	140.62 (1.15)	141.16 (1.10)	-0.53 (1.18)	-2.48 to 1.42
12	503	139.82 (1.16)	139.87 (1.08)	-0.05 (1.21)	-2.04 to 1.94
18	494	138.58 (0.95)	139.32 (1.13)	-0.74 (1.09)	-2.54 to 1.05
24	486	140.34 (1.25)	141.51 (1.06)	-1.17 (1.49)	-3.61 to 1.27
36	386	137.55 (1.36)	138.52 (1.12)	-0.98 (1.54)	-3.50 to 1.55
Diastolic blood pressure					
0	605	84.89 (0.56)	83.69 (0.61)	1.21 (0.55)	0.30 to 2.11
12	503	83.55 (0.74)	83.53 (0.61)	0.01 (0.78)	-1.21 to 1.29
18	494	83.55 (0.60)	82.83 (0.70)	0.71 (0.59)	-0.26 to 1.68
24	486	83.48 (0.74)	83.71 (0.63)	-0.22 (0.83)	-1.59 to 1.14
36	386	82.29 (0.66)	81.18 (0.79)	1.11 (0.81)	-0.21 to 2.44

*If the 90% CI falls entirely within the equivalence range (± 5 mm Hg), the groups are considered equivalent.

Table 3 Number (percentage) of patients whose blood pressure was out of control as judged by doctor

Time (months)	3 month group	6 month group
12	63/302 (21)	52/300 (17)
24	59/299 (20)	67/291 (23)
36	50/275 (18)	41/260 (16)

vided doctors with guidelines for levels of blood pressure that should be considered out of control, we asked them to use their own judgment.

Satisfaction with medical care

All of the factors measured for patient satisfaction were equivalent in the two groups, as was patients' satisfaction with the care of their blood pressure by their doctor (see bmj.com). More patients in the six month group thought that the doctor did not take their blood pressure problem seriously enough towards the end of the study.

Adherence to treatment

Adherence to treatment was equivalent between groups. However, we found that pill counts in this pragmatic trial were unreliable.

Discussion

The findings of this study suggest that six monthly follow up is sufficient for patients with controlled hypertension. In three years of follow up of patients with hypertension, we found that blood pressure control, patient satisfaction, and adherence to treatment were equivalent in patients assigned to follow up at three month and six month intervals.

Patients in both groups visited their doctor more frequently than their assigned follow up times, but the six month group had fewer visits to the doctor overall. Patients in this group had more visits unrelated to hypertension, which suggests that patients given longer intervals between regular appointments see their doctor between these appointments for other reasons. We do not know if these other issues would have been dealt with at the regular hypertension visit if shorter intervals had been used.

As the study included patients from 50 family doctors in Canada who practise in a variety of rural and

urban settings, its findings can be generalised to most family practice settings in North America and Britain.

We found a high rate of inadequately controlled blood pressure in patients in both groups. The higher mean blood pressure at entry and the level of control may result from the higher acceptable targets for blood pressure in older recommendations for control of blood pressure, which were used initially. It may also explain why blood pressure in both groups fell during the 36 months of follow up. Determining the reasons for this fall was not part of this study, but the results suggest that frequency of follow up is not as important in blood pressure control as has been thought. The quality of the doctor-patient encounter, the doctor's awareness of guidelines, clinical inertia,⁹ and the view of "treating the patient rather than treating the number" may all contribute to the large numbers of known hypertensive patients whose blood pressure is out of control.

The following family practitioners participated in the study: M Bala, W Beck, P Bell, S Blanchard and E Nancekievill, D Briggs, H Bright, M Browne, N Burget, G Burke, B. Campbell-Unger, T Clarke, I Crawford, L Dempsey, P Farmer, M K Gazendam, J Griffiths, B Hart, J Henstock, S Hinton, N Hobbs, P Johannsson, B Kain, P Kenny, D Koval, C Lawlor, R Lees, S M Lim, K Lockington, D MacLean, D Marcassa, M McCall, V Mohr, J Molson, A Newman, C Newton, P O'Donnell, B Parker, G Patey, C Pettis, D Pinkerton, J Raleigh, C Rice, T Richards, S Sangster-Gibson, K Schultz, J Sloan, L Stewart, T Touzel, S Verma, R Wilson, and D Wyatt.

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What is already known about this topic

Recommendations of current hypertension guidelines from Canada, Britain, and the United States for the follow up of patients with stable hypertension are based on expert opinion or usual practice

The decision about the frequency of follow up of a chronic disease such as hypertension has important implications for hypertension control by family doctors and the cost of care

What this study adds

Follow up of patients with treated hypertension every six months is equivalent to every three months for mean blood pressure, blood pressure control, patient satisfaction, and adherence to hypertensive drugs

Blood pressure of 20% of patients was out of control when assessed at yearly intervals over three years in both groups

Endpiece

Life according to Wilde

The old believe everything; the middle aged suspect everything; the young know everything.

Oscar Wilde (1854-1900)

Fred Charatan, retired geriatric physician, Florida