Management of Uncontrolled Hypertension in a Nurse-Led Clinic Compared With Conventional Care for Patients with Type 2 Diabetes

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OBJECTIVE — To compare the effectiveness of a nurse-led hypertension clinic with conventional community care in general practice in the management of uncontrolled hypertension in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We studied 120 men and women outpatient attendees (61% non-Caucasian) with type 2 diabetes and a seated blood pressure (BP) ≥140/80 mmHg. All patients were being treated for hypertension, and 71% had increased urinary albumin excretion (UAE). Patients were allocated to either a nurse-led hypertension clinic or conventional primary care. The primary outcome measure was a change in systolic BP. Secondary outcome measures were total cholesterol, HDL cholesterol, total triglycerides, HbA_{1c}, UAE, serum creatinine, and changes in absolute stroke and coronary heart disease (CHD) risk scores.

RESULTS — The mean (95% CI) difference in the decrement of systolic BP was 12.6 mmHg (5.9–19.3) ($P = 0.000$) in favor of the nurse-led group, whose patients were three times more likely to a reach target systolic BP <140 mmHg compared with conventional care ($P = 0.003$). A significant fall in 10-year CHD ($P = 0.004$) and stroke risk ($P = 0.000$) scores occurred only in the nurse-led group. There were no significant differences in the reduction of diastolic BP or any of the other secondary outcome measures at 6 months.

CONCLUSIONS — Compared with conventional care, a nurse-led hypertension clinic is a more effective intervention for patients with type 2 diabetes and uncontrolled hypertension. A target systolic BP <140 mmHg is more readily achieved and may be associated with significant reductions in 10-year cardiovascular disease risk scores.

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Hypertension is a major and modifiable risk factor for cardiovascular disease that frequently coexists with diabetes (1). A progressive rise in blood pressure (BP) is also a promoter of renal dysfunction and the development of end-stage renal failure (2). The presence of proteinuria and hypertension also increases the risk of premature death from cardiovascular disease eightfold compared with unaffected patients (3,4). A large evidence base of randomized controlled trials have demonstrated that treating hypertension reduces morbidity and mortality from hypertension-related diseases (5,6). More recently, the use of antihypertensive agents that interrupt the renin-angiotensin system has been shown to be an effective strategy to retard the progression of nephropathy and reduce cardiovascular events in people with diabetes (7–9). Throughout the western world, expert committees on hypertension recommend that treatment to lower BP is warranted in patients with diabetes who have a systolic BP ≥140 mmHg (10,11). Currently, hypertension is poorly managed. The Health of England Survey (12) suggests that <30% of affected patients receiving treatment have attained target BP. Furthermore, it has been suggested that with current models of care, the attainment of these stringent BP targets for patients with diabetes may not be attainable in the majority of cases (13). These observations imply that alternatives to conventional care for patients with hypertension and diabetes are required.

Nurse-led clinics (NLCs) can improve care outcomes in some chronic circulatory diseases (14,15). It is unknown whether the intensification of BP management by this approach is more effective than conventional care. Therefore, we studied the effect of a hypertension NLC versus conventional care on lowering BP in diabetic patients with uncontrolled hypertension at high risk of cardiovascular disease. Moreover, we determined what effect this intervention had on absolute coronary heart disease (CHD) and stroke risk scores.

RESEARCH DESIGN AND METHODS

— The study was organized from Whittington Hospital, which serves an inner-city community of 154,000 adults in North Islington, London. Adult patients with type 2 diabetes and uncontrolled hypertension (BP >140/80 mmHg) were referred to the outpatient NLC from the hospital diabetes clinic. Between June 2000 and June 2001, investigators referred 120 patients.

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Abbreviations: BP, blood pressure; CHD, coronary heart disease; CPC, conventional primary care; NLC, nurse-led clinic; UAE, urinary albumin excretion; UAER, UAE rate.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

All patients previously diagnosed as hypertensive and in receipt of BP-lowering treatment, without any serious or life-threatening comorbid conditions requiring intensive management, were eligible for the study. Patients were considered to have renal complications if they had a history of a persistently elevated urinary albumin excretion rate (UAER) (>30 mg/day) and/or elevated serum creatinine. A BP target <140/80 mmHg was set for patients without renal complications and <120/70 mmHg for patients with renal complications.

Treatment allocation

Each of the three investigators independently assessed and randomly referred eligible patients from their clinics. Patients were then allocated to conventional primary care (CPC) or the nurse-led hypertension clinic group on an alternate basis. This scheme prevented individual physicians from predicting the treatment patients would receive, thereby eliminating referral bias and generating equally sized groups.

Baseline clinical and biochemical measurements

At the first (baseline) visit to the hypertension nurse, principal diagnoses were listed along with allergies, current treatment, smoking history, and weekly alcohol consumption. Recreational exercise was graded as low (on feet for less than half a day), medium (on feet for most of the day or regular exercise), or high (regular vigorous exercise). Anthropometric measurements and demographic data (age, duration of diabetes, sex, and racial origin) were also collected.

BP was measured using a validated oscillometric digital monitor (OMRON 705HEM CP; OMRON Healthcare, West Sussex, U.K.) according to British Hypertension Society guidelines. Patients were rested (seated for 5 min). BP was measured in both arms; if no significant difference was found, the left arm was used in future measurements. Measurements were carried out twice with a 2-min rest between each. The second reading was recorded and used for treatment decisions. Absolute 10-year CHD and stroke risk scores were calculated according to the Framingham equation (16).

A 24-h urine collection was made for the measurement of UAER by immunoturbidimetry. In a subset of patients in the NLC ($n = 47$) and CPC ($n = 29$) groups urinary sodium excretion was also determined. Fasting serum total cholesterol, HDL cholesterol, and total triglyceride concentrations were determined by enzymatic methods. Serum creatinine was analyzed by a rate-reaction method. HbA_{1c} was measured by high-pressure liquid chromatography (HA 8121 Biomen; Berkshire, U.K.).

Follow-up protocol

Patients in the NLC group were seen monthly for 3 months and then every 6 weeks for 3 months. At each visit BP was measured and compliance with the recommended antihypertensive drug regimens was reviewed. These recommendations were guidelines of pharmacological and nonpharmacological management of hypertension, agreed upon by primary care and hospital-based physicians and were in line with those of the National Institutes of Clinical Excellence in the U.K. (10). These guidelines were presented and disseminated to all physicians in the district before the study commenced. A treatment algorithm was not used.

The hypertension nurse emphasized the need for tight BP control, gave nonpharmacological advice for healthy living, and (if necessary) discussed problems regarding side effects of existing antihypertensive treatment. Comorbid conditions were not addressed. The nurse also initiated treatment changes, and new prescriptions were provided by attending physicians. A treatment change was recorded as having occurred if existing drugs were titrated or if a new drug was added on at least one occasion.

A letter stating the measured BP, target BP, and recommendations for treatment according to the common guidelines were sent to the practitioners of patients in the CPC group. At the end of the 6-month follow-up period, patients in the NLC and CPC groups were reviewed by the nurse, and the baseline clinical and biochemical measurements were repeated. The study was approved by the ethics committee of Whittington Hospital.

Statistics

Continuous data were analyzed with parametric or nonparametric tests according to their distribution and categorical data with χ^2 test using SPSS version 10.1 for Windows (Chicago, IL). Skewed data were log transformed before analyses. Multivariable analyses were carried out with the primary end point, with absolute BP or change in BP after follow-up as the dependent variable. For our predefined hypothesis, we calculated that in order to demonstrate a difference of 10 mmHg in systolic BP between the NLC and CPC groups with 80% power at a significance level of $P < 0.05$, a total of 60 patients needed to be studied in each group. Analysis was on an intention-to-treat basis. Data are presented as means ± SD unless otherwise stated.

RESULTS — The baseline clinical data showed that both groups were well matched (Table 1). Antihypertensive treatment regimens consisted of combinations of either ACE inhibtors, angiotensin II receptor blockers, β-blockers, calcium channel blockers, thiazide diuretics, α-blockers, or the centrally acting agents methyl dopa and moxonidine. Regimens were composed of a median of two agents per patient and based on agents that interrupted the renin-angiotensin system in >80% of each group. The proportion of patients in the NLC and CPC groups using ACE inhibitors (61.7 vs. 55.0; $P = 0.41$) or angiotensin II receptor blocking agents (21.7 vs. 30.7%; $P = 0.58$) was similar.

The study was completed by 56 (93%) and 59 (98%) patients in the CPC and NLC groups, respectively. Three patients failed to attend the final visit, and one patient died in the CPC group. One patient from the NLC group refused to continue in the study. After 6 months of follow-up, the proportion of the NLC cohort in which a treatment change took place was higher (88 vs. 15%; $P = 0.000$) and reflected the significant changes in the proportion who received new prescriptions for calcium channel blockers (20.3 vs. 5.4%; $P = 0.01$) and thiazide diuretics (30.5 vs. 3.6%; $P = 0.000$), and the median number of agents per patient, which increased to three, compared with the CPC group remained unchanged from baseline at two ($P = 0.016$).

Systolic and diastolic BP fell within both groups after 6 months. The magnitude of the fall in diastolic BP was similar, but that of systolic BP was significantly greater in the NLC than in the CPC group (Fig. 1). Final systolic BP was significantly higher but diastolic BPs were similar in the CPC and NLC groups (151.0 [21.9]

Table 1—*Baseline demographic and clinical data of patients with type 2 diabetes and uncontrolled hypertension allocated to CPC or NLC*

	CPC	NLC	*P*
n	60	60	
Sex (m:f)	42:18	34:26	0.13
Age (years)	62.4 ± 9.1	58.1 ± 13.8	0.95
Diabetes duration (years)	14.2 ± 8.6	14.6 ± 7.5	0.78
Race			0.43
Caucasian	21	26	
Indo-Asian	10	8	
African-Caribbean	27	26	
Far-East Asian	2	0	
Renal complications			0.16
No	14	21	
Yes	46	39	
Smoking history			0.56
Yes	8	11	
No	44	44	
Ex	8	5	
Alcohol			0.70
None	32	33	
Moderate	24	25	
High	4	2	
Exercise			0.86
Low	21	21	
Medium	26	32	
High	7	7	
BMI (kg/m^2)	29.0 ± 6.4	31.2 ± 6.0	0.06
Systolic BP (mmHg)	157.6 ± 22.8	160.7 ± 23.0	0.46
Diastolic BP (mmHg)	86.9 ± 11.6	87.7 ± 9.8	0.70
Pulse pressure (mmHg)	70.7 ± 20.0	73.1 ± 20.4	0.53
10-year CHD risk (%)	15.1 ± 7.6	18.8 ± 9.5	0.08
10-year stroke risk (%)	9.7 ± 7.4	11.5 ± 8.2	0.24

Data are means ± SD and *n*.

vs. 141.1 [19.3] mmHg, $P = 0.02$, and 82.2 [12.4] vs. 79.9 [10.6] mmHg, $P = 0.28$). Target systolic and diastolic BP were achieved in 38% ($n = 20$) vs. 12% ($n = 6$) and 50% ($n = 30$) vs. 36% ($n = 22$) of the NLC compared with the CPC group after 6 months ($P = 0.003$ and $P = 0.26$, respectively).

There were no changes in the CHD and stroke risk scores in the CPC group. However, there were significant falls in both scores in the NLC group after 6 months (Fig. 2). There were no changes from baseline values in any of the biochemical secondary outcome measures at 6 months in either group (Table 2). Multivariable analysis was performed with the change in systolic BP from baseline as the dependent variable and age, sex, racial group, duration of diabetes, baseline HbA_{1c}, baseline systolic BP, baseline total cholesterol, smoking history, alcohol intake, and group (NLC or CPC) allocation as independent variables. In the final model, all of the variables were excluded apart from baseline systolic BP and group allocation (Table 3).

CONCLUSIONS — We have shown that a nurse-led approach to the management of uncontrolled hypertension in patients with type 2 diabetes is highly effective. Achievement of target systolic BP was more than threefold greater than conventional care. In addition, within 6 months of this intervention there was a significant lowering of 10-year CHD and stroke risk.

Both groups in this study were well matched at baseline. There were no differences in any of the variables that might be related to the sustained elevation of BP. We did not find any differences in changes in lifestyle measures or surrogate markers of dietary changes (sodium excretion and body weight) that might have contributed to these results. Moreover, none of the biochemical secondary outcome measures were altered by the intervention. This intervention focused on intensifying antihypertensive treatment. The hypertension nurses and the primary care physicians used the same guidelines, which were based on the evidence used and recommended by the National Institutes of Clinical Excellence in the U.K. (10). The majority of patients were already in receipt of agents that interrupt the renin-angiotensin system, which are considered first-line treatment of increased albuminuria that coexists with hypertension (17). The treatment changes mainly involved adding thiazide diuretics and calcium channel blockers, which are efficacious in combination with ACE inhibitors in lowering BP (18,19).

A challenge for health care providers is translating research findings into clinical practice. Patients in research settings on several drugs for hypertension can achieve high compliance, effective BP lowering, and low drop-out rates during the life of the studies (18,19). In our study, one of the patients in the NLC group was lost to follow-up, whereas 5% of the CPC group failed to attend the 6-month visit. Reanalysis of the data with only the patients who completed the study had no effect on the size of the differences in the primary outcome measures (data not shown).

The focus on hypertension and its management by the hypertension nurse provides much of the organizational similarities in research settings. Organizational factors are considered by some to be more important than guidelines in contributing to poor levels of BP control in patients with diabetes (20). Lowering BP in hypertensive patients and improving the quality of life of patients with heart failure has been shown to be more effective in community NLCs than in hospital-based services (14,15,21). Together, these data support our observations that a nurse-led approach per se is an effective strategy in the intensification of BP management for patients with type 2 diabetes.

The reinforcement of patient education positively affects BP control and possibly contributed to our findings (22). However, we did not formally assess patient education. Neither can we exclude an improvement in compliance with

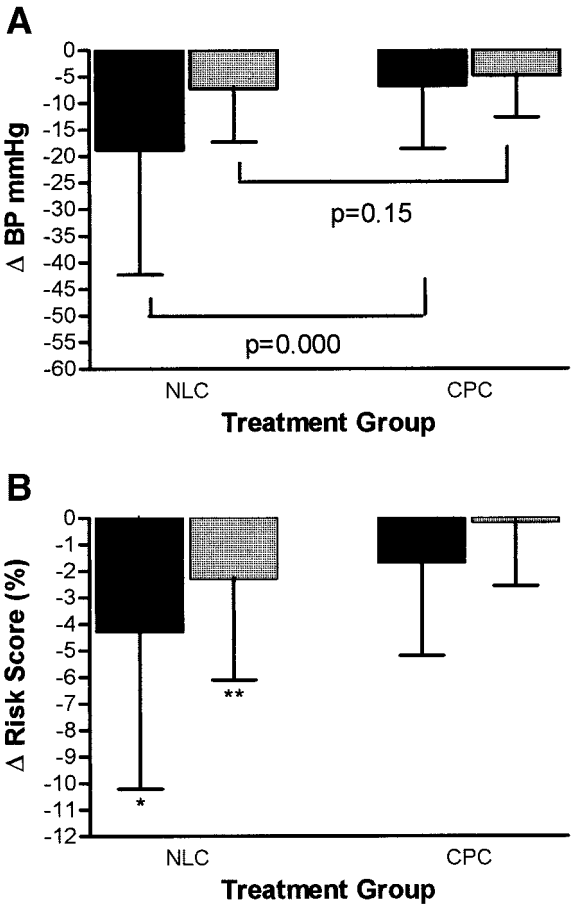

Figure 1—A: *Mean (95% CI) fall in systolic (■) and diastolic BP (■) in patients allocated to CPC and NLC after 6 months of follow-up.* B: *Mean (95% CI) fall in 10-year stroke risk (■) and CHD risk (■) in patients allocated to CPC and NLC after 6 months of follow-up. Differences in stroke* and CHD** risk from baseline were significant at* P = *0.0000 and 0.004, respectively.*

Table 3—*Stepwise multivariable analysis with change in systolic BP after 6 months as the dependent variable*

	β	*t*	*P*
Baseline systolic BP	0.585	6.381	0.000
Treatment allocation group	0.248	2.880	0.000

treatment as a factor in the improved outcome. In a recent report (23) of patients with resistant hypertension, a lack of compliance with medication was not shown to be the cause of failure to reach target BP. Improved access to monitoring and pharmacological intervention facilitated by the hypertension nurse appears to be central to the outcome of this study. The greater reduction in BP in the patients allocated to nurse-led care was related to the greater frequency of changes in treatment. The guidelines were effective as BP was significantly lowered in both the conventional and nurse-led groups. Our observations are consistent with a previous study (24) that suggests that failure to change treatment, despite frequent monitoring of BP, is an important factor in the poor management of hypertension in specialist clinics (24). The patients in the nurse-led groups were nearly six times more likely to have their treatment regimen adjusted compared with those in conventional care. Therefore, we consider rigorous application of the guidelines in the context of nurse-led management to be the key to greater improvement.

The majority of our patients were at high risk of premature death due to cardiovascular disease in the presence of increased albuminuria. Tight BP control has been recommended for patients with type 2 diabetes and renal involvement. A target of <135/75 mmHg is recommended by the National Institutes of Clinical Excellence (17). Moreover, data from the Modification of Diet in Renal Disease Study Group suggest an even lower target BP of <120/70 mmHg to limit progressive renal disease (25). In our study, the level of albuminuria was unaffected by BP lowering. This is consistent with studies showing low rates of resolution of microalbuminuria and suggests that strategies in addition to BP lowering are required to prevent the progression of nephropathy (8).

Our findings are relevant to the delivery of care in relation to the National Service Framework requirements for diabetes and cardiovascular disease in the U.K. Our model may be generally applicable and enhanced if algorithms are developed for nurse specialist/practitioners

Table 2—*Biochemical data at baseline and at 6-month follow-up for patients with type 2 diabetes and uncontrolled hypertension managed in a NLC and in CPC*

	NLC		CPC	
	Baseline	6 months	Baseline	6 months
Total cholesterol (mmol/l)	4.9 (1.0)	4.8 (0.9)	4.8 (1.0)	4.7 (0.8)
HDL cholesterol (mmol/l)	1.4 (0.4)	1.3 (0.3)*	1.4 (0.4)	1.4 (0.5)
Triglycerides (mmol/l)	2.5 (1.9)	2.4 (1.7)	2.5 (2.6)	2.3 (1.4)
HbA_{1c} (%)	8.2 (1.8)	8.2 (1.4)	7.9 (1.7)	7.9 (1.9)
UAE (mg/24 h)	33.0 (14.3–136.3)	39.2 (16.0–200.0)	55.0 (18.4–151.4)	30.5 (14.5–147.2)
Urine sodium (mmol/day)	182.5 (67.7)	178.7 (103.1)	172.8 (88.1)	177.3 (87.7)
Serum creatinine (μmol/l)	113.4 (39.5)	117.6 (40.2)	120.2 (38.8)	114.7 (37.2)

Data are median (interquartile range) for UAE values. *HDL cholesterol lower at 6 months, $P = 0.02$.

with appropriate prescribing authority. Tight control of BP for patients with newly diagnosed type 2 diabetes is cost effective (26). The cost-benefit of our approach for patients at higher risk of cardiovascular disease needs to be explored and the sustainability of the effect confirmed. Further, longer-term studies using this approach for specialist care for patients with diabetes are now required.

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