



# Effectiveness of a specialist nurse-led intervention clinic in the management of cardiovascular risk factors in diabetes

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## Introduction

It is well recognised that people with diabetes are at significantly greater risk of developing microvascular complications and cardiovascular (CV) disease.<sup>1,2</sup> Indeed, large-scale epidemiological studies have shown that the risk of CV disease is increased four-fold in patients with type 2 diabetes compared with non-diabetic individuals.<sup>1</sup> Overall, up to 80% of patients with type 2 diabetes die from cardiovascular complications and their average life expectancy is reduced by approximately 10 years.<sup>3</sup>

The increased CV disease risk and mortality in people with diabetes have been extensively investigated; they are associated with a cluster of adverse factors such as hypertension, dyslipidaemia, insulin resistance,

## Abstract

**Aim:** To evaluate the effectiveness of a specialist nurse-led, protocol-driven and doctor-supervised clinic in the management of cardiovascular risk factors, particularly hypertension and hyperlipidaemia.

**Methods:** Patients with type 2 diabetes attending the diabetes specialist service, who had uncontrolled hypertension or hyperlipidaemia, were recruited to participate in the study. Patients were followed in a specialist nurse-led intervention clinic for effective control of blood pressure (BP), lipid profile and other vascular risk factors. Antihypertensive agents and lipid-lowering drugs were sequentially introduced and dose titrated according to protocols. Patients were discharged once target BP (<140/80 mmHg) and/or target lipid profile were achieved.

**Results:** Ninety-four patients were managed in the clinic between April 2003 and March 2004. The mean age of the patients was 62±9 years and their duration of diabetes was 18±14 years. Seventy-seven patients were hypertensive at first visit and antihypertensive agents were initiated or altered, resulting in significant reduction in systolic BP (167±12 versus 132±8 mmHg,  $p<0.001$ ) and diastolic BP (85±9 versus 70±7 mmHg,  $p<0.001$ ). Seventy-two patients (92%) achieved target BP. Patients required two or more antihypertensive agents to achieve targets. Levels in 59 patients treated for hyperlipidaemia and total cholesterol (6.0±1.2 versus 3.9±0.7 mmol/l,  $p<0.001$ ) and triglycerides (4.2±0.8 versus 2.4±1.2 mmol/l,  $p<0.001$ ) significantly improved. Hence, 52 patients (91%) achieved target lipid profile control. Only six patients (10%) required combination drug therapy to achieve target lipid profile. The mean glycosylated haemoglobin (HbA<sub>1c</sub>) level also improved (8.5±1.5 versus 7.4±1.5 %,  $p<0.01$ ) and 45% of patients achieved target glycaemic control (HbA<sub>1c</sub> <7.0%).

**Conclusion:** Specialist nurse-led clinics can be effective in significantly improving BP and lipid profile, and achieving targets, in people with diabetes.

*Eur Diabetes Nursing* 2007; 4(3): 100–105.

## Key words

Nurse-led clinic; hypertension; hyperlipidaemia; cardiovascular risk factors

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Received: 22 February 2007

Accepted in revised form:  
04 June 2007

pro-thrombotic state, central adiposity, endothelial dysfunction and inflammatory state.<sup>4,5</sup> However, it is now well established that both the microvascular and macrovascular complications of diabetes can be reduced by effectively treating the risk factors.<sup>6,7</sup> Thus, the importance of good blood glucose control and identification and management of other CV risk factors is regarded as essential in the management of people with diabetes, as emphasised and recommended in many comprehensive review guidelines.<sup>8–10</sup>

Clinical nurse specialists have taken on increasing responsibilities in chronic disease management, across many disciplines.<sup>11–13</sup> Nurse specialist-led clinics, which are doctor supervised and protocol driven, are being developed in various UK diabetes centres.<sup>14,15</sup> Such clinics improve patient satisfaction, symptom control, data collection and medical and lifestyle components of treatment; they may also result in effective care-plan implementation and reduced hospital admission rates.<sup>11–15</sup>



The present study evaluated the effectiveness of a specialist nurse-led, protocol-driven clinic in the primary prevention of CV risk factors, by optimising the management of hypertension and hyperlipidaemia. Before participating in the study, all patients had received standard care through attending the specialist diabetes centre in a district general hospital.

### Research design and methods

In the diabetes centre of Blackpool Victoria Hospital, a district general hospital, we established a protocol-driven, doctor-supervised, specialist nurse-led intervention clinic. The aim of this clinic was effective control of blood pressure (BP) and hyperlipidaemia in patients with type 2 diabetes. This intervention clinic ran for a one year period from April 2003 to March 2004. Attempts were made to invite all patients with uncontrolled hypertension or hyperlipidaemia to attend for an initial visit during the first nine months of the study. Follow up was encouraged. The frequency of follow-up visits was determined by clinical circumstances, but was usually every three to four weeks.

All study subjects had a prior diagnosis of type 2 diabetes and were receiving shared care from the diabetes centre, or in primary care through a GP. On annual or follow-up review visits in the diabetes centre, patients with uncontrolled hypertension (systolic BP >140 mmHg or/and diastolic BP >80 mmHg), and/or hyperlipidaemia (total cholesterol >4.8 mmol/l, triglycerides >1.7 mmol/l, low-density lipoprotein cholesterol [LDL-C] >3.0 mmol/l and high-density lipoprotein [HDL-C] <1.0 mmol/l) were identified. These patients were referred to the specialist nurse-led clinic for intervention and management of hypertension and/or hyperlipidaemia. A specialist nurse

post was specifically created for this study and was based on the standards for specialist practice identified by the UK Nursing and Midwifery Council.<sup>16</sup> The registered nurse recruited to the post was educated to degree level and had previous experience of diabetes, hypertension and hyperlipidaemia management, patient education and working as an advisor to other health care professionals. Local physicians, clinicians and pharmacists trained the specialist nurse in hypertension and dyslipidaemia management, and guided the nurse in implementing the protocols.

The specialist nurse-led clinic was protocol-driven (Figures 1 and 2). The protocols were used for the management of hypertension, hyperlipidaemia and other uncontrolled risk factors, and were produced in accordance with the published guidelines at that time.<sup>8,10</sup> Protocols were agreed by the local diabetes team and the local drug and therapeutic committee. A uniform therapeutic policy had been adopted in the clinic, based on the stepped care approach as shown in Figures 1 and 2.

At the first clinic visit, patients underwent a 45–60 minute appointment to assess their CV risk factors and to explain the purpose of the study, targets to be achieved during the study, reasons behind these targets and guidelines for the management of CV risk factors. Informed written consent was obtained from all patients. A detailed medical history was not obtained, as all patients were regularly followed in the specialist diabetes clinic; clinical data were already recorded in their medical notes and on an electronic diabetes information system, which were accessible to the specialist nurse. A history was taken, however, with relation to the duration of hypertension and hyperlipidaemia, any previous therapy that had been

used and the reasons for discontinuing such treatment. Current medications were also listed. Detailed physical examinations were not performed, as these were conducted at diabetes clinic reviews and findings were available in patients' medical notes. However, height, body weight and body mass index (BMI) were recorded and BP was accurately assessed. For patients with hypertension, three separate BP measurements were taken at least one minute apart using a standard mercury sphygmomanometer (Maxi-Stabil 3, Speidel & Keller, 72417 Jungingen, Germany). The mean of the second and third readings was recorded as the actual BP, according to British Hypertension Society Guidelines.<sup>18</sup> Diastolic BP was taken as the point of disappearance of sounds (phase V). BP was measured by a single trained specialist nurse in all clinic reviews during this study.

After a minimum eight-hour overnight fast, blood samples were taken to measure lipid profile, liver function and urea, electrolyte and glycosylated haemoglobin (HbA<sub>1c</sub>) values. Fasting blood tests were organised one week before each clinic review, so that the results were usually available at this consultation. Results were discussed with patients and a management plan and targets were agreed. Lifestyle factors likely to be contributing to, or affecting response to hypertension or hyperlipidaemia therapy were discussed. Individualised advice about diet and weight was given, taking account of each patient's personal preferences and dislikes. Moderate regular exercise was recommended in line with UK Health Education Authority guidelines. Smoking was actively discouraged. A patient's willingness to comply with these modifications was also assessed and recorded; patients were encouraged to adopt



behaviour changes by discussing the short- and long-term positive outcomes and also by devising individual patient-centred action plans.

Following the first visit, the specialist nurse reviewed patients every three to four weeks, the duration of each review being 30 minutes. At each review the personal action plan was discussed (including any compliance problems encountered with it), and the specialist nurse took a brief general history relating to CV risk factors and drug treatment. Height, weight and BMI were recorded. BP was also assessed, using the same device and method as on the first visit. If 'white coat' hypertension, labile hypertension or postural hypotension were suspected, 24-hour ambulatory BP monitoring was undertaken.

On each visit, doses of hypertension and hyperlipidaemia medication were titrated according to the patient's treatment response and study protocols (Figures 1 and 2). Dose increments were continued until either target BP or lipid profile was achieved, or the scheduled maximum dose was reached (unless the dose increment caused side effects). If additional medications were required, the specialist nurse discussed the case with the medical team and therapy was initiated when appropriate.

Target BP was <140 mmHg systolic and <80 mmHg diastolic for those with no microalbuminuria or renal impairment. However, for patients with microalbuminuria or renal impairment, the target BP was set at <130/75 mmHg. If target BP was achieved on two consecutive visits, patients would be asked to continue on the same medications and discharged from the nurse-led clinic. Patients who achieved target lipid profile (total cholesterol levels <4.8 mmol/l, triglyceride levels <1.7 mmol/l) were also discharged from the nurse-led clinic.

Each clinic visit concluded with feedback, goal planning and an agreed action plan, which were outlined on a take-home form. Smoking, obesity and other modifiable CV risk factors were routinely assessed at each visit and, if possible, modified with the help of medical staff and paramedical services, such as dietitians.

Following the achievement of the targets for CV risk factors, each patient received an individual management plan before discharge from the specialist-nurse intervention clinic. After discharge, patients attended normal consultations at the routine diabetes clinic in the specialist diabetes centre, or in primary care.

#### *Statistical analysis*

The primary hypothesis was set for the mean systolic and diastolic BP and total cholesterol achieved at the final visit to the specialist nurse-led clinic. Secondary end points were changes in LDL-C, triglyceride, HDL-C and HbA<sub>1c</sub> levels.

All data were entered into a computer database and checked for correct entry. Statistical analysis was performed using SPSS for Windows Version 13.0 (SPSS Inc., Chicago, IL, USA). Data analysis was performed by standard parametric methods. Results are expressed as means  $\pm$ SD unless stated otherwise. Statistical analyses were performed on an intention-to-treat basis. Statistical significance was set at  $p < 0.05$ . Multiple-group comparisons were made by analysis of variance, and two-group comparisons were done with two-tailed Student's paired *t*-tests. Other findings are reported as a matter of observation only.

#### *Biochemical analysis*

Blood samples taken after a minimum eight-hour overnight fast were performed at each clinic visit.

Blood samples for plasma glucose values were collected in a tube containing sodium fluoride (2–3 mg/ml whole blood) and centrifuged to separate the plasma. Plasma glucose was measured automatically using a hexokinase method. Plasma glucose, total cholesterol, triglyceride and HDL-C values were quantified by enzymatic techniques using an Olympus AU2700 general chemistry analysers (Olympus Diagnostics Division, Southall, Middlesex, UK). LDL-C was calculated using Friedewald's formula.<sup>17</sup> HbA<sub>1c</sub> levels were determined using a Tosoh G7 automated glycohaemoglobin analyser (Tosoh Bioscience, Redditch, Worcestershire, UK), using DCCT-aligned calibrants.

#### **Results**

Ninety-six patients were recruited to attend the specialist nurse-led clinic during the study period; 94 patients completed the study and two were withdrawn because of failure to comply with the study protocol. All patients had type 2 diabetes. Characteristics of study completers are shown in Table 1.

The specialist nurse carried out 37 nurse-led clinics during the study period, spending 148 hours running the clinic. On average, each patient was reviewed three times in the nurse-led clinic. Forty-two patients (46%) attended the clinic for the management of both hypertension and hyperlipidaemia, 17 (18%) patients attended for the management of hyperlipidaemia alone and 35 (37%) patients for hypertension alone.

#### *Blood pressure control*

In total, 77 patients were referred for BP control, all of whom had BP above the target level of <140/80 mmHg when referred. By the end of the study period there was a significant improvement in both



systolic and diastolic BP (Table 2) and 72 patients (94%) had achieved target BP. All patients needed two or more antihypertensive agents for BP control; 65 patients (84%) needed three or more agents.

#### Hyperlipidaemia management

Fifty-nine patients were referred for hyperlipidaemia management because unacceptable lipid profiles were identified initially. At the end of the study, lipid profile had significantly improved (Table 2); 52 patients (91%) achieved target lipid profile, with total cholesterol levels <4.8 mmol/l, triglyceride levels <1.7 mmol/l and HDL-cholesterol levels >1.0 mmol/l. Six (10%) patients required a combination of drug therapy (a statin plus a fenofibrate) to achieve recommended lipid profile targets.

#### Secondary outcome measures

The study design permitted the analysis of three predefined variables: improvement in diabetes control, change in body weight and cessation of smoking. HbA<sub>1c</sub> values improved in 82 patients (87%), being significantly lower by the end of the study compared with initial levels (Table 2). However, only 42 patients (45%) achieved target HbA<sub>1c</sub> (<7.0%).

Although 64 (68%) patients lost weight due to lifestyle and dietary modifications applied during the study, the average body weight of patients was not significantly different at the initial and final clinic visits (Table 2). Of the 10 patients who were known smokers at study enrolment, four (40%) had stopped smoking by the end of the study period.

#### Patient contact

In total 303 appointments were made, with 96 new-patient appointments. Only eight appointments

Study participants (n)	96
Study completers (n)	94
Mean age of study completers (years)	62±9
Sex (M:F)	58:36
Duration of diabetes for study completers (years)	18±14
Patients who were reviewed for BP control only (n [%])	35 (37)
Patients who were reviewed for hyperlipidaemia control only (n [%])	17 (18)
Patients who were reviewed for BP and hyperlipidaemia control (n [%])	42 (45)

BP, blood pressure

**Table 1.** Characteristics of patients with type 2 diabetes attending a specialist nurse-led, protocol driven clinic

(3%) were not kept. Patients attended for an average of three visits during the study period. The medical team was consulted on eight occasions for optimal BP control with further drug therapy as stated in the BP protocol (Figure 1). These eight patients received additional antihypertensive treatment following medical review. There were 13 (14%) reported side effects due to drug therapy, none of which required discontinuation of drug therapy, nursing or medical intervention. GPs were routinely informed about clinic review outcomes and any changes in patient medication. There were no queries from GPs concerning medication during the study period.

#### Conclusions

This study demonstrates that nurse-led clinics can effectively improve CV risk factors, hypertension and hyperlipidaemia levels in patients with type 2 diabetes. In the study, 94% of patients achieved target BP control and 91% achieved target lipid profile. Moreover, diabetes control significantly improved and the majority of patients lost weight as a result of appropriate management plans. All drugs used in the study were administered once daily and were well tolerated, with a small number of reported

side effects. Clinic attendance and compliance with drug therapy was constantly monitored. These factors, together with effective education, resulted in good compliance, adherence and reduced polypharmacy.

The role of a specialist nurse in managing hypertension and other CV risk factors in type 2 diabetes has been confirmed by others.<sup>11,18–21</sup> In agreement with our findings, these studies demonstrate that nurse-led clinics can be effective in managing hypertension and hyperlipidaemia, and therefore reduce the CV risk in people with type 2 diabetes. One study<sup>18</sup> was randomised, including a large number of subjects; however in others the patient numbers were similar to our study.<sup>19–21</sup> All studies have revealed the beneficial effects of nurse-led clinics for the management of CV risk factors in type 2 diabetes.<sup>18–21</sup> However, the present study, in contrast with others,<sup>18,19</sup> reported positive findings in a district general hospital. These findings indicate that specialist nurse-led clinics can make a considerable contribution to the quality of diabetes care and control of CV risk factors in an expanding diabetes population. It is encouraging to report that nurse-led clinics can improve vascular risk factors such



	Initial	Final	p-value
Systolic BP (mmHg)	167±12	132±8	<0.001
Diastolic BP (mmHg)	85±9	70±7	<0.001
Total cholesterol (mmol/l)	6.0±1.2	3.9±0.7	<0.001
Triglycerides (mmol/l)	4.2±0.8	2.4±1.2	<0.001
LDL-cholesterol (mmol/l)	3.2±1.0	2.2±0.9	<0.05
HDL-cholesterol (mmol/l)	1.1±0.5	1.2±0.6	NS
HbA <sub>1c</sub> (%)	8.5±1.5	7.4±1.5	<0.01
Body weight (kg)	89±18	87±17	NS

LDL, low-density lipoprotein; HDL, high-density lipoprotein

**Table 2.** Initial and final mean blood pressure (BP), lipid profile, glycosylated haemoglobin (HbA<sub>1c</sub>) and body weight values achieved by patients with type 2 diabetes attending a specialist nurse-led, protocol-driven clinic

as smoking<sup>19</sup> and obesity, along with improving diabetes control. Such clinical practice may yield benefits in years to come, in reducing macrovascular as well as microvascular complications.<sup>6,7</sup>

There is good evidence that systemic target-driven diabetes care and effective management of CV risk factors can reduce the risk of CV complications<sup>6,7,20</sup> and premature death.<sup>20,22</sup> Interventions effective in diabetes include BP lowering,<sup>10</sup> cholesterol reduction<sup>8,9,20</sup> and smoking cessation.<sup>23</sup> Improving these parameters can lead to cost-effective reductions in the development and progression of diabetes-related complications.<sup>24</sup> To implement effective diabetes care with evidence-based targets in growing populations of diabetic patients, there is added pressure on health care professionals and diabetes services. Therefore, to achieve optimal diabetes care, strategies such as nurse-led clinics need to be developed. These strategies should be patient centred, focusing on multifactorial risk reduction, multidisciplinary and multiprofessional. They should also include clear approaches to effective evidence-based treatment regimens for antihypertensive agents, lipid-lowering drugs and antiplatelet treatments.<sup>25</sup>

In accordance with diabetes guidelines<sup>26</sup> and evidence from primary prevention trials<sup>27</sup> that were reported during our study period, the protocols for management of hypertension and hyperlipidaemia that we used require updating. Statin therapy is now recommended for all people with diabetes who are age  $\geq 40$  years, as well as 18–39 year-olds who have at least one additional CV risk factor. Our patients all required a combination of anti-hypertensive agents to achieve recommended BP targets, with two-thirds of patients requiring three or more agents. This combination includes a drug which blocks the renin-angiotensin system (namely, angiotensin-converting enzyme inhibitors or angiotensin-II receptor antagonists), which have the strongest evidence for renal protection in diabetes, compared with other anti-hypertensive agents.<sup>27,28</sup>

Our study demonstrates that significant improvements can be achieved in clinical practice by modifying the way that care is provided. By providing a nurse-led, protocol-driven service one can address a huge unmet need in the diabetes population, in particular with regard to BP, hyperlipidaemia and weight management. The nurse-led clinic can

deliver an integrated approach to ensure (and implement) effective interventions for people with diabetes.

### Acknowledgements

We thank Drs Hayes and MacKay for their support and advice. We are indebted to the patients who participated in this study.

### Conflict of interest statement:

This study was supported by an unrestricted grant from Pfizer UK.

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