

The impact of previous diabetes education level on the control of cardiovascular risk factors in type 2 diabetic patients at the start of the North Catalonia Diabetes Study

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Abstract

The aim of this study was to evaluate the effect of different levels of previously received diabetes education on metabolic control, cardiovascular disease (CVD) with many CVD risk factors (CVRF), components of metabolic syndrome (MS) and the 10-year coronary heart disease (CHD) risk at the start of the North Catalonia Diabetes study (NCDS) in the Primary Care Setting. A multi-center cross-sectional descriptive study was performed in a random sample of 302 type 2 diabetes (T2DM) patients from the cohort of the NCDS. Diabetes education was classified as specialized or non-specialized. Diabetic metabolic control, CVD, CVRF, MS components and CHD risk were evaluated. A total of 79.8% patients did not receive specialized education and 20.0% were given specialist diabetes education. All T2DM patients were also controlled by general physicians and primary health care nurses. 44.4% of patients showed optimal metabolic control (HbA1c < 7.1%). Three or more CVRF were observed in 91.3% of patients, mean CHD was 10.0% and MS was present in 68.8% of T2DM patients. The initial evaluation showed a decrease in HbA1c with a better metabolic control ($p < 0.05$) in the group that received previous specialized education. The number of components of the MS decreased significantly ($p < 0.05-0.001$) and cardiovascular risk control improved ($p < 0.01$) in this group. The study showed poorer metabolic control and higher prevalence of CVRF in patients without specialized diabetes education. Our results suggest that higher levels of diabetes education may play a major role in reducing cardiovascular risk in T2DM patients. (Int J Diabetes Metab 14: 61-67, 2006)

Key words: diabetes, cardiovascular risk factors, metabolic syndrome, diabetes nurse specialist, health education.

Introduction

Diabetes is associated with long-term complications that increase the morbidity and mortality of the disease. The prevention of these complications requires a multidisciplinary approach, which can be achieved, in part, in the Primary Care setting.¹

The DCCT trial² in type 1 diabetes mellitus and the UKPD trial³ in type 2 diabetes mellitus (T2DM) suggested that the genesis of diabetes complications is not only related to glycaemic control but also to cardiovascular risk factors (CVRF), such as blood pressure (BP) and lipid control.

Cardiovascular disease (CVD) is the cause of approximately 70% of deaths in patients with diabetes;⁴ however, the main interest of diabetes education (DE) for many years has been to improve metabolic control. Training in the prevention of CVD is presently considered as important as metabolic control.^{5,6}

T2DM has been considered by the American Heart Association⁷ as a CVD and it implies a cardiovascular risk equivalent to that in patients who have had previous cardiovascular events.⁸ Association of T2DM with another risk factor emphasizes a comprehensive management that should include optimal metabolic control of diabetes and

secondary prevention of CVRF³, such as control of high BP (HBP), lipid profile and components of the metabolic syndrome (MS).^{7,9}

There is a considerable controversy concerning findings relating to nursing intervention in T2DM patients. Several studies¹⁰ have reported minimal results after DE from non-specialized nurses,¹⁰⁻¹³ while others have found a positive effect of DE from specialized nurses on metabolic and CVRF.^{12,14-20}

Furthermore, several authors consider that the impact of specialized nursing interventions in education could be similar to those of general practitioners in the control of diabetic populations at a PC level.¹⁷

DE is an essential and effective tool for clinical management of diseases as evidenced in a large number of studies evaluating the relationships between education and improved medical outcomes.^{14,20-22} Most such studies have evaluated the relationship between educational interventions and the metabolic control of glycaemia.^{11,12,17,18,20,23,24} Several studies have also evaluated the effect of DE intervention on BP, weight and dyslipidemia control^{10,13} and they have investigated the effect of different DE levels on CVRF^{20,25} in T2DM patients.

Despite its potential impact and strong evidence base, DE gives little attention to the reduction of cardiovascular risk.²⁶ The number of nursing interventions in the

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management of CVD risk factors in diabetes is few²⁷ and particularly sparse in Spain where no literature is available. Nevertheless, the role of nursing DE and/or a direct-nurse role in CVRF^{19,20} and/or metabolic MS have not been studied in depth in T2DM.

The aim of this study was to evaluate the relationship between previously received DE by different categories of nurses on the outcomes of metabolic control of diabetes, CVRF, MS components and the 10-year CHD risk in a PC setting before starting the North Catalonia Diabetes Study (NCDS). The study of the relationship between previous DE and CVRF and their control was the main objective of the study within the NCDS.

Research Design and Methods

A multi-centre cross-sectional descriptive study was carried out from November 2001 to January 2003 in seven PC Centers in La Garrotxa, Ripollès and Pla de l'Estany (Girona), North Catalonia, Spain. The area has a population of 92,912 inhabitants.

An initial random sample of 400 patients (aged 30 to 69 years) was selected from among our T2DM population. The size of the sample was set at 282 subjects, based on a study of diabetic polyneuropathy^{28,29} (prevalence: 30%, precision: 5%; C.I: 95%; statistical power: 80%) and then extended to 400 as a precaution against possible losses. 302 patients (75.5%) fulfilled the inclusion criteria. No differences were observed between the T2DM sample and the general population concerning sex and age (C.I: 95%).

Selection criteria

T2DM patients were diagnosed according to the WHO guidelines. *Exclusion criteria* were neuropathies of other aetiology, alcohol consumption of more than 60 g/day in women and more than 80 g/day in men, previous foot ulcers or refused consent.

Data collection

Fourteen family physicians and eighteen nurses collected clinical information through interviews with patients, clinical examinations, medical records and administrative data during three visits. All researchers received a special training of twenty hours.

Previous diabetes education was classified at the start of the NCDS when patients were included for evaluation. The previously received health education was classified into two categories: 1) non-specialized when education was performed by general physicians and nurses without specific training in diabetes and 2) specialized when performed by a nurse who had participated in a specific training program in diabetes education.

Patients were classified as having specialized DE (specialized group) when they received a minimum of one year or six sessions of programmed specialized DE and as having non-specialized education (non-specialized group) when they received regular health education in a PC setting. The specialized DE was given by a diabetes specialist nurse accredited by the Certificate Program of 300 hours, as part

of the European Nurses Diabetes Collaborative University Project (ENDCUP) of the Federation of European Nurses for Diabetes (FEND) and the Autonomous University of Barcelona. Structured DE represented a minimum of 6 diabetic controls every year. The first intervention was 45 min and successive control was 30 min. Only one specialized nurse worked in one area.

Non-specialized DE was given by primary care nurses and general practitioners and performed by institutional guidelines without a structured program. The mean number of follow-up visits in this group was 4 times per year.

The level of DE was evaluated before the educational intervention of the present study. A simple test with 16 questions was used before the start of NCDS (about type of diabetes, diabetes control, complications, diet, exercise and therapy) in order to evaluate the level of DE.

Patients were non-randomized in two groups for DE, because this was questioned by the Ethics Committee. Patients received the same education when they were included in NCDS.

Clinical and metabolic data.

The degree of metabolic control was defined by HbA1c levels. An HbA1c <7% was considered to be good metabolic control in accordance with the American Diabetes Association criteria.³⁰

The distribution of different T2DM therapies was: diet alone, 24.8%; oral hypoglycaemic agents alone or combined with metformin, 43.6%; metformin alone, 11.8%; insulin alone or combined, 18.9% and others 0.90%.

The 10-year estimate risk (Framingham Point Scores) for coronary heart disease (CHD) was calculated according to the ATP III criteria.³¹

Other CVRF were also studied including diabetes, dyslipidemia, arterial hypertension, smoking, age, sex, obesity and familial cardiovascular disease.

BP was measured by electronic tensiometer (Omron HEM 711), clinically validated and with the patients in resting position for 30 minutes prior to the measurement. BP over $\geq 140/90$ mm/Hg or taking antihypertensive medication was considered as having HBP.

Dyslipidemia was established according to criteria applicable to a population receiving pharmacological treatment or presenting one or more of the following analytical values (mg/dl): triglycerides ≥ 150 , cholesterol ≥ 240 , LDL cholesterol ≥ 160 , HDL cholesterol <35 men or <45 women.

Weight and height and Body Mass Index (BMI) were measured. Waist circumference was measured by soft tape midway between the lowest rib and iliac crest with the patient in standing position.

MS was established on the basis of the NCEP ATP III criteria.³¹

Table 1: Anthropomorphic, clinical characteristics and biochemical variables of study population

| | Mean \pm SD | Men | Women | Significance |
|----------------------------------|---------------------|---------------------|--------------------|--------------|
| Age (yrs) | 59.63 \pm 7.87 | 58.58 \pm 8.54 | 61.02 \pm 6.40 | p = 0.005 |
| Duration of T2DM (yrs) | 8.58 \pm 7.00 | 7.68 \pm 6.14 | 10.09 \pm 8.09 | p = 0.007 |
| Height (cm) | 162.84 \pm 8.88 | 167.58 \pm 6.86 | 155.39 \pm 6.21 | p < 0.001 |
| Weight (kg) | 79.60 \pm 13.66 | 82.75 \pm 13.91 | 74.92 \pm 11.93 | p < 0.001 |
| BMI | 30.01 \pm 4.70 | 29.45 \pm 4.44 | 31.02 \pm 5.01 | p = 0.005 |
| Waist circ (cm) | 101.65 \pm 11.44 | 102.28 \pm 11.39 | 100.76 \pm 11.71 | p = 0.267 |
| Systolic blood pressure (mm/Hg) | 143.68 \pm 19.70 | 141.45 \pm 18.09 | 146.79 \pm 21.70 | p = 0.029 |
| Diastolic blood pressure (mm/Hg) | 82.07 \pm 10.50 | 81.93 \pm 10.55 | 82.27 \pm 10.53 | p = 0.788 |
| HbA1c (%) | 7.00 \pm 1.44 | 7.06 \pm 1.50 | 6.88 \pm 1.35 | p = 0.297 |
| Basal glycaemia (md/dL) | 153.66 \pm 50.76 | 156.42 \pm 51.76 | 148.17 \pm 48.59 | p = 0.170 |
| Cholesterol (mg/dL) | 209.39 \pm 41.13 | 207.03 \pm 41.35 | 213.49 \pm 40.96 | p = 0.188 |
| Cholesterol HDL (mg/dL) | 54.00 \pm 12.91 | 51.77 \pm 13.56 | 57.81 \pm 10.86 | p < 0.001 |
| Cholesterol LDL (mg/dL) | 126.24 \pm 34.84 | 124.21 \pm 33.81 | 129.71 \pm 36.01 | p = 0.192 |
| Triglycerides (mg/dL) | 153.17 \pm 126.53 | 164.15 \pm 149.27 | 146.76 \pm 76.48 | p = 0.028 |
| Microalbuminuria (mg/L) | 36.13 \pm 98.48 | 35.59 \pm 109.14 | 36.27 \pm 79.50 | p = 0.951 |
| Creatinine (mg/dL) | 1.05 \pm 0.58 | 1.12 \pm 0.68 | 0.94 \pm 0.36 | p = 0.008 |

Sex: Men: 61,4%; Women: 38,6%. Caucasian 100%

Significance: Men vs. Women

Nicotine (smokers: any cigarette/day) and alcohol (g/day) habits were also analyzed.

Biochemical parameters

Blood tests were taken after 10 hours fasting (including no coffee or smoking) and with the patients in resting position for 30 minutes prior to sampling.

HbA1c levels (liquid chromatography technique, Menarini), basal glycaemia (mg/dl) (glucose-oxidase), creatinine (mg/dl) (Jaffe method), total cholesterol (mg/dl) (enzymatic method), HDL cholesterol (mg/dl) (enzymatic method after VLDL & LDL precipitation), LDL cholesterol (mg/dl) (by Friedewald's formula), triglycerides (mg/dl) (enzymatic hydrolysis and glycerol measurement), and microalbuminuria (mg/l) (immunoturbimetry method, specific antibody linked to solid phase) were analyzed in the clinical laboratory ICS (Girona).

Ethical considerations: All participants signed informed consent to participate and the study was approved by the PC Ethics Committee, J. Gol i Gurina Foundation.

Statistical analysis.

Data were analyzed by the SPSS 11.5 for windows statistical package (SPSS Inc. Chicago).

Qualitative variables are expressed as sample size (number of cases) and percentage (%), and quantitative variables are expressed as mean and standard deviation.

The relationship between two qualitative variables was assessed using the Chi square (X^2) test with continuity checking or Fisher exact test whenever necessary.

The degree of metabolic control, presence or absence of CVD and MS, CHD at 10 years risk, prevalence of CVRF (obesity, hypertension, family CVD antecedents, age, sex and nicotine habits), and the MS components (abdominal obesity, high triglycerides, low HDL cholesterol, BP), were

considered dependent variables. Significance level was 5% ($\alpha=0.05$). All tests were two-sided.

Results

Characteristics of T2DM patients are shown in Tables 1 and 2. The female group showed higher age ($p = 0.005$), onset of diabetes ($p = 0.007$), BMI ($p = 0.005$), and systolic blood pressure ($p = 0.029$) than the male group. Nevertheless triglycerides ($p = 0.028$) and creatinine plasma levels were higher and HDL lower in the male group (Table 1).

DE level is shown in Table 3. There were no differences between the groups regarding gender, age and years since diagnosis of T2DM. The correct answers in the simple test of DE manifested significant difference between patients in specialized and non-specialized groups (14.7 ± 2.1 vs. 4.8 ± 2.3 ; $p < 0.001$).

HbA1c <7% was defined as a sign of good control and was observed in 56.95% ($n = 172$) of patients and only 23.75% of patients had HbA1c values >8% ($n = 71$). Patients with specialized DE presented lower HbA1c values than non-specialized group ($p = 0.047$) (Table 3).

CVD prevalence was observed in 22% of patients ($n = 66$), with a higher average for men ($p < 0.001$) than women. Peripheral ischemia was seen in 4.6% of patients ($n = 14$). Cardiovascular disease prevalence was similar in the two groups of diabetes education.

Familial CVD (Table 2) were observed in 114 patients (38.1%). No differences for gender and DE level were observed

The 10-year CHD risk estimate mean (Framingham point scores) was 10.0% for the total group (C.I: 9.17-10.86) and was significantly higher in men than in women ($p < 0.001$).

Table 2: Prevalence of Cardiovascular risk factors (CVRF) characteristics

| <i>CVRF</i> | (%) | men | Women | Significance |
|--|-----------------------------|---------------|---------------|---------------------|
| High blood pressure | 74.50% (69.56-79.45) | 69.35% | 79.13% | p = 0.056 |
| Dyslipidemia | 56.67% (51.03-62.31) | 58.38% | 53.91% | p = 0.450 |
| Obesity (BMI \geq 30 kg/m ²) | 45.70% (40.05-51.35) | 39.25% | 56.03% | p = 0.004 |
| Smokers | 14.98% (10.97-19.00) | 24.19% | 0.00% | p < 0.001 |
| Sex (% of men) | 61.56% (56.09-67.04) | | | |
| Age (men \geq 45; women \geq 55) | 86.32% (56.09-61.99) | 90.86% | 78.45% | p = 0.005 |
| Familial CVD | 38.13% (32.59-43.66) | 34.97% | 43.10% | p = 0.163 |
| M. Syndrome Prevalence | 68.23% (62.92-73.54) | 58.38% | 84.21% | p < 0.000 |
| MS components | | | | |
| Abdominal Obesity | 60.91% (55.42-66.40) | 44.09% | 87.07% | p < 0.000 |
| HBP | 80.33% (71.20-83.39) | 77.30% | 85.22% | p = 0.082 |
| High Triglycerides | 35.33%(29.89-40.77) | 38.92% | 29.57% | p = 0.095 |
| Low HDL | 19.00% (15.54-23.46) | 15.68% | 24.35% | p = 0.074 |
| Three or more CVRF | 91.13% (87.85-94.40) | 91.11% | 91.15% | p = 0.991 |

Data are % and Confidence Interval

Significance: Men vs. Women

Table 3: Relationship between biochemical characteristics, cardiovascular disease and risk factors (CVRF) and received diabetes education level

| | Type of Diabetes Education | | p |
|-----------------------------|--|--------------------------------|-------|
| | non-specialized (n = 241; 79.8%) | specialized (n = 61; 20.2%) | |
| Age | 57.71 \pm 6.8.17 | 59.45 \pm 7.3 | 0.051 |
| Fasting glucose(mg/dL) | 155.59 \pm 51.86 | 144.11 \pm 44.81 | 0.114 |
| HbA1c (%) | 7.08 \pm 1.47 † | 6.66 \pm 1.3 | 0.047 |
| CVD prevalence | 23.43% (18.02-28.84) | 16.39% (6.83-25.95) | 0.205 |
| Periph. Vasc. Disease (%) | 5.39 (2.52-8.27) | 1.64 (-1.64-4.92) | 0.089 |
| CHD risk at 10 years | 10.57 \pm 7.59 ‡ | 7.63 \pm 9.41 | 0.006 |
| Number of CV R. Factors | 4.67 \pm 1.27 ‡ | 4.13 \pm 1.27 | 0.003 |
| Systolic BP (mmHg) | 145.12 \pm 20.24 ‡ | 136.86 \pm 15.71 | 0.004 |
| Diastolic BP(mmHg) | 82.73 \pm 10.16 † | 79.35 \pm 10.46 | 0.027 |
| Triglycerides (mg/dL) | 158.56 \pm 132.56 | 131.52 \pm 100.6 | 0.138 |
| Cholesterol (mg/dL) | 210.71 \pm 41.06 | 204.82 \pm 42.02 | 0.320 |
| HDL-c (mg/dl) | 53.34 \pm 12.79 † | 57.00 \pm 13.09 | 0.048 |
| LDL (mg/dL) | 127.05 \pm 35.06 | 123.49 \pm 33.50 | 0.479 |
| BMI (kg/m2) | 30.45 \pm 4.69 † | 28.48 \pm 4.55 | 0.004 |
| Obesity (BMI \geq 30) (%) | 48.96 (42.51-55.41) † | 32.79 (20.79-55.63) | 0.023 |
| W. Circumference(cm) | 102.93 \pm 11.4 † | 96.81 \pm 10.75 | 0.000 |
| Abdominal Obesity (%) | 63.49 (57.28-69.70) † | 49.18 (36.28-62.08) | 0.049 |
| MS presence (%) | 73.22 (67.48-78.96) ‡ | 48.33 (35.32-61.34) | 0.001 |

Bold data indicate significant differences between non-specialized vs. specialized education.Data are means \pm Standard Deviation, or % and Confidence Interval.

CHD risk was lower in patients who received specialized DE than in patients with non-specialized (Table 3).

Prevalence of CVRF was expressed in table 2. Simultaneous presence of 3 or more cardiovascular risk factors was observed in 267 patients, without significant difference for gender (Table 2). The number of CVRF in patients observed in the specialized DE group was lower than in the non-specialized group (Table 3).

HBP was observed in 225 patients without significant differences between men and women (Table 2). Optimal BP

(<130/80 mm/Hg) was observed only in 16.67% of patients (n = 50) and inadequate in 83.33% (n = 250). Patients who received previous specialized DE presented lower systolic and diastolic BP values than the non-specialized group (Table 3).

Dyslipidemia was observed in 170 patients (Table 2). No differences were observed between specialized DE vs non-specialized group (Table 3).

Obesity (BMI \geq 30) was observed in 45.7% (n = 138) (Table 2). Patients with specialized DE presented lower prevalence

of obesity than the non-specialized group ($p=0.023$) (Table 3).

MS prevalence was observed 204 patients. It was significantly higher among women than men (Table 2) and was related to age ($p = 0.023$; OR: 1.036). Patients with specialized DE presented lower prevalence of MS (Table 3). and lower number of metabolic syndrome components ($p = 0.004$) than in non specialized group. Abdominal obesity (waist circumference) was higher in group of non-specialized DE. Lower HDL-c values were also observed among non-specialized group (Table 3).

15.0% of patients in the cohort were active smokers (Table 2) and 41.7% (128 patients) consumed alcohol regularly. There were no differences between the two groups of educational level.

Discussion

In our study, about 57% of patients showed adequate metabolic control with HbA1c levels of $<7\%$ and only 24% manifested HbA1c over 8%. However, a high average of the T2DM group showed 3 or more CVRF, with a moderate CHD risk level. Moderate CHD risk and insufficient control of the majority of cardiovascular risk factors were similar to findings in other studies in Spain^{32,33} showing that the objectives of secondary prevention have not been reached.

In our population three or more components of the MS were observed in a significant proportion of patients and the most prevalent component was HBP (80.5 %). HBP was a common feature in our population study group and its control was not adequate in a very high number of patients. Several studies have confirmed that adequate BP control can prevent cardiovascular disease in patients with diabetes and the evidence from major clinical trials indicates that HBP is a continuous risk factor for CV events in patients with diabetes.³

Lipid control was inadequate in a high number of patients. An adequate lipid profile, with LDL below 100 mg/dl and control of MS components is crucial for secondary prevention of cardiovascular disease.

The significantly higher proportion of patients with BMI >30 and abdominal obesity may have contributed to the HBP measurements in our sample. Obesity was observed in a high percentage of patients.

We have evaluated the relationship between previous DE performed by a specialist nurse in diabetes and outcomes of metabolic control, CVRF, MS components and the 10-year CHD risk. In spite of the fact that all patients were also controlled by their general physician and PC nurse, a significant relationship was observed between specialized DE and better control of BP, lipid profile, cardiovascular risk and other components of MS (Table 3). Like other authors, we have observed some relationship between specialized DE and optimal metabolic control^{11,12,17,18,20,23,24} adequate BP, correct weight and dyslipidemia control^{10,13} and the MS components.^{20,25}

T2DM is a chronic disease with constantly growing prevalence³⁴ and thus constitutes a global public health problem. CVD morbidity and mortality are high and social and economics costs are increasing annually³⁵⁻³⁷. Reduction of CVD events in people with diabetes is possible by an aggressive treatment³⁷. The ultimate goal for DE includes optimal metabolic control (correct blood glucose, plasma lipids and BP) and control of vascular risk factors. Unfortunately, DE gives little attention to the reduction of cardiovascular risk.²⁶ Our results suggest that specialized DE in a T2DM population could help to decrease the prevalence of cardiovascular risk factors.

A significant proportion of patients with BMI >30 and abdominal obesity were observed in the non-specialized DE group. It seems highly improbable that six sessions or one year of specialized DE could make such a difference in BMI and abdominal obesity between the two groups, given that practitioners have been struggling for years trying to encourage people with diabetes to alter their lifestyles and the impact is so far often minimal.

We have not observed any descriptive studies, controlled clinical trials or randomised controlled trials, on the impact of the specialized DE on metabolic control, CVRF, MS components and the CHD risk in a PC setting. Only a few studies have been conducted in control-randomized interventions of DE^{6,12,38,39} in CVRF. Our study did not pretend to demonstrate the cause-effect relation between specialized DE and CVRF. It was a descriptive evaluation of patient's DE at the start of NCDS and related to different components of CVRF and MS.

T2DM is a complex illness that requires specific knowledge for its management, many factors could be important in the control of CVRF, such as changes in style of life, hours of diabetic control and compliance. Well-informed patients appear to be more motivated to reach target values and prevent the main risk factors.⁴⁰

The real effect of DE on CVRF has to be evaluated in random sample groups of T2DM. The positive results from our study should be confirmed in our prospective study of NCDS.

In conclusion, the high prevalence of cardiovascular risk factors and MS observed in our population calls for more aggressive interventional changes of lifestyle and adequate secondary prevention. Despite the observational character of our study, it suggests that higher levels of DE may play a major role in reducing cardiovascular risk in T2DM patients.

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