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Original article

# Patients' education, and its impact on care outcomes, resource consumption and working conditions: Data from the International Diabetes Management Practices Study (IDMPS)

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#### Abstract

Aim. - To evaluate the impact of diabetes education provided to patients with type 2 diabetes mellitus (T2DM) in non-controlled studies ("real-world conditions") on quality of care, resource consumption and conditions of employment.

*Methods.* – This cross-sectional study and longitudinal follow-up describe the data (demographic and socioeconomic profiles, clinical characteristics, treatment of hyperglycaemia and associated cardiovascular risk factors, resource consumption) collected during the second phase (2006) of the International Diabetes Management Practices Study (IDMPS). Patients received diabetes education directly from the practice nurse, dietitian or educator, or were referred to *ad hoc* group-education programmes; all programmes emphasized healthy lifestyle changes, self-care and active participation in disease control and treatment. Educated vs non-educated T2DM patients (n = 5692 in each group), paired by age, gender and diabetes duration, were randomly recruited for the IDMPS by participating primary-care physicians from 27 countries in Eastern Europe, Asia, Latin America and Africa. Outcome measures included clinical (body weight, height, waist circumference, blood pressure, foot evaluation), metabolic (HbA<sub>1c</sub> levels, blood lipid profile) and biochemical control measures. Treatment goals were defined according to American Diabetes Association guidelines.

*Results.* – T2DM patients' education significantly improved the percentage of patients achieving target values set by international guidelines. Educated patients increased their insulin use and self-care performance, had a lower rate of chronic complications and a modest increase in cost of care, and probably higher salaries and slightly better productivity.

Conclusion. - Diabetes education is an efficient tool for improving care outcomes without having a major impact on healthcare costs.

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Keywords: Diabetes; Education; Developing countries; Costs

#### Résumé

Éducation des diabétiques de type 2 : impact sur les soins, la consommation des ressources et les conditions de travail. Données de l'International Diabetes Management Practices Study (IDMPS).

*Objectif.* – Évaluer l'impact de l'éducation prodiguée aux patients atteints de diabète de type 2 à partir de l'étude observationnelle (dans les conditions réelles de suivi des patients) de la qualité des soins et de leurs coûts, exprimés en dépenses de soins et en journées de travail perdues.

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J.J. Gagliardino et al. / Diabetes & Metabolism 38 (2012) 128-134

*Méthodes.* – Étude transversale et longitudinale ayant pour but de recueillir des données des patients concernant leur profil socioéconomique, le traitement du diabète et de ses complications et les coûts. Cette étude appartient à la seconde vague de l'International Diabetes Management Practices Study (IDMPS) (2006). Les patients ont reçu des informations relatives au diabète d'une infirmière, d'un diététicien, d'un éducateur spécialisé ou grâce à un programme d'éducation spécifique. Chaque programme mettait l'accent sur les modifications hygiéno-diététiques et la prise en charge active de la maladie et de son traitement par le patient lui-même. Les diabétiques de type 2 qui avaient reçu on non cette éducation (n = 592 dans chaque groupe) étaient appariés selon l'âge, le sexe, et la durée de diabète. Les patients avaient été recrutés par randomisation par les médecins traitants de 27 pays de l'Europe de l'Est, de l'Asie, de l'Amérique Latine et d'Afrique. Les données recueillies étaient cliniques (poids, taille, périmètre adominal, pression artérielle, examen des pieds), métabolique (HbA<sub>1c</sub>, profil lipidique) et biologiques. Les objectifs de traitement étaient ceux définis par les recommendations de l'American Diabetes Association.

*Résultats.* – L'éducation diabétique apportée aux diabétiques de type 2 augmente significativement le pourcentage de patients atteignant les objectifs de traitement définis par les recommandations internationales. Les patients qui avaient reçu une éducation diabétologique utilisaient davantage l'insuline et se prenaient mieux en charge. Ils présentaient un plus faible pourcentage de complications chroniques. Une augmentation modérée des coûts de traitement fut notée, associée probablement à des salaires plus élevés et à une productivité légèrement plus élevée.

Conclusion. - L'éducation diabétique est efficace et améliore le devenir des patients sans élévation importante des coûts de traitement.

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Mots clés : Diabète ; Éducation ; Pays en voie de développement ; Coût

# 1. Introduction

Type 2 diabetes mellitus (T2DM) affects a large percentage of the adult population worlwide, and is responsible for the use of a large part of health-service resources, mostly due to the presence of its macrovascular complications [1–3]. The disease is also associated with increased morbidity and premature death from cardiovascular disease, conditions that have a negative impact on quality of life and individual productivity [4,5].

Although such costs may still be affordable in developed countries, this is not the case in many developing countries and, in the near future, they may become unaffordable even in the developed countries. However, the evidence suggests that this scenario may be mitigated by implementing aggressive and effective preventative strategies, such as improving the quality of care [6,7]. In this context, the active participation of patients in disease control and treatment after patients' empowerment for successful self-management may play a key role in optimizing metabolic and risk factor control, and quality of life [8-11]. Although patients' education may be pivotal in encouraging and supporting patients to assume such an active responsibility [12,13], in many places, patients do not have easy access to diabetes education programmes. The traditional medical model in which patients are merely passive recipients of care only partly explains the situation [14].

Educational programmes developed worldwide [15–18] have shown that a firm theoretical basis and the use of cognitive reframing are associated with improved outcomes [19,20]. In this regard, the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) study recently reported that a structured group-education programme for patients with newly diagnosed T2DM led to greater improvements in weight loss and smoking cessation, as well as more positive beliefs about illness, with no differences in levels of glycated haemoglobin (HbA<sub>1c</sub>) up to 12 months after diagnosis [21]. However, many people still claim that the evidence available for the effectiveness of any educational approach in patients with T2DM is scanty [10,22,23]. They also argue that most of the published data come from controlled research studies implemented in comparatively small populations or patient cohorts, and that there is little or no data for T2DM patients' education outcomes in "real-world conditions" worldwide.

In response to this criticism, we have evaluated the impact of diabetes education in non-controlled studies on quality of care, resource consumption and employment conditions. The data obtained revealed significant improvement in care indicators in a large population of such educated patients with T2DM recruited from different countries in Africa, Asia, Eastern Europe, the Middle East and Latin America, with care-indicator values close to the treatment goals recommended in the European Association for the Study of Diabetes/Amerian Diabetes Association (EASD/ADA) guidelines [24].

# 2. Methods

# 2.1. Participants

Participants in the International Diabetes Management Practices Study (IDMPS) were recruited from 27 countries in Eastern Europe, Asia, Latin America and Africa during November and December of 2006 (Table 1). Physicians were requested to enroll the first ten patients with T2DM and the first five patients with type 1 diabetes (T1DM) visiting their offices during the 2-week recruitment period. Details of the criteria used for patients' and physicians' selection have been reported elsewhere [25]. For the present study, data from 11,384 patients with T2DM were

Table 1

Characteristics of the paired sample of patients.

	Received diabetes education		P value
	No	Yes	
Number of participants	5692	5692	
Age (years; mean $\pm$ SD)	$57.7 \pm 11.1$	$57.7 \pm 11.1$	0.947 <sup>a</sup>
Gender (female)	53.1%	53.1%	1.000 <sup>b</sup>
Time since diagnosis (years)	$8.0\pm7.0$	$8.1\pm7.0$	0.810 <sup>a</sup>

<sup>a</sup> Wilcoxon test.

<sup>b</sup> Chi-square test.

used; within this population, those patients who had received diabetes education, albeit with different teaching characteristics and degrees of intensity ("educated" patients), and those who had not ("non-educated" patients) were identified. Thereafter, the patients in both groups were paired by age, gender and diabetes duration, with 5692 patients finally allocated to each group.

#### 2.2. Procedures

The IDMPS is an ongoing 5-year study with five phases. Each phase consists of a cross-sectional period lasting 2 weeks in each study centre, followed by a 9-month longitudinal followup period [25]. The present study is based on the data recorded during the cross-sectional study of the second phase (2006); thus, the practices included here represent the wide spectrum of routine care currently available in the participating countries.

During the cross-sectional period, physicians collected information on the patients' demographic and socioeconomic profiles, relevant medical history (chronic complications, associated cardiovascular risk factors and co-morbidity factors), previous and current treatments for hyperglycaemia and its associated cardiovascular risk factors, disease-related education, and employment conditions and performance.

#### 2.3. Outcome measures

Clinical data (body weight, height, waist circumference, blood pressure, foot evaluation) were collected at practice visits. Metabolic control measures included  $HbA_{1c}$  levels and blood lipid profiles [total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C) and triglycerides]. Blood samples were collected and assayed locally, applying the same methodology in all participating countries to maximize data robustness and to allow regional comparisons.

Treatment goals were defined according to ADA guidelines [HbA<sub>1c</sub> <7%, blood pressure (BP) < 130/80 mmHg, LDL-C < 100 mg/dL] [24].

#### 2.4. Educational strategies

The participating centres offered various diabetes-education strategies: face-to-face consultation with a practice nurse, dietitian or educator (67%); referral to an *ad hoc* structured group-education programme with different degrees of complexity and numbers of interactive sessions (22%); or both (11%). All strategies placed strong emphasis on healthy lifestyle changes (meal-planning and regular bouts of physical activity), self-care and active patient participation in disease control and treatment. Educational contents included general concepts of T2DM, effect of obesity on insulin demand and benefits of weight loss, performance of self-monitoring of blood glucose (SMBG) and clinical self-monitoring, physiological changes in serum glucose levels and symptoms of hypo-/hyperglycaemia. The minimum frequency of clinical control and laboratory tests necessary for good diabetes care was also included. The IDMPS study protocol was approved by the appropriate regulatory and ethics committees in all of the participating countries and centres. Accordingly, all participants provided written informed consent before entering the study. Implementation was developed under the guidance of a steering committee that also proposed the statistical analyses, and reviewed and validated the registry data [25].

The study was coordinated by Sanofi-Aventis Intercontinental (Sanofi-Aventis Group). In each participating country, the study was monitored by Sanofi-Aventis staff, who assisted the local coordinators and investigators in collecting data through a study case-report form.

#### 2.5. Statistical analysis

Data were analyzed using Wilcoxon's and Chi-square tests for continuous and categorical variables, respectively.

# 3. Results

There were no significant differences between the educated and non-educated groups in terms of age, gender and diabetes duration, due to the pairing process used to select the patients included in the two arms of the study (Table 1). However, the percentage of illiterate individuals was significantly higher among the educated vs non-educated patients (9.9% vs 8.3%, respectively) and, in the latter group, the percentage of patients with higher/university-level education was higher (27.8% vs 25.1% in the educated group). No significant differences were recorded between groups as regards current or previous smoking habits.

Mean body mass index (BMI) and waist circumference values were significantly lower among educated patients (Table 2). In addition, the percentage of those with BMIs within the normal range was also significantly higher in this group, whereas the opposite situation was observed in patients who were overweight/obese.

No significant differences were recorded between groups in either systolic blood pressure (SBP) absolute values or percentage of patients with values within treatment goals (<130 mmHg); conversely, the mean value and percentage of patients with normal diastolic BP (DBP) values were significantly lower and higher, respectively, in the educated group (Table 2). Similarly, the percentage of people with SBP and DBP at target values was significantly higher in the educated group.

In addition, performance of  $HbA_{1c}$  control was significantly higher among the educated patients, who had significantly lower mean and median values, and a higher percentage of patients with values less than 7% (Table 2).

Serum lipid profiles (total cholesterol, LDL-C and triglycerides) showed significantly lower mean values in the educated arm. The percentage of patients with serum LDL-C and triglyceride levels within the normal range was also significantly higher in this group. On the other hand, comparable HDL-C levels were measured in both groups of patients.

As for chronic complications, no significant differences between groups were recorded in the percentage of those with

#### J.J. Gagliardino et al. / Diabetes & Metabolism 38 (2012) 128-134

#### Table 2

Patients' clinical and metabolic indicators and chronic complications.

	Received diabetes educat	tion	<i>P</i> value
	No	Yes	
Number of participants	5692	5692	
BMI (kg/m <sup>2</sup> )	$28.5 \pm 5.2$	$28.2 \pm 5.2$	< 0.001 <sup>a</sup>
≤ 18.5	0.7%	0.8%	
> 18.5–25	24.4%	28.3%	
> 25-30	41.8%	39.5%	
> 30–35	22.4%	21.4%	
> 35	10.8%	9.9%	
Waist circumference (cm)	$97.7 \pm 13.6$	$96.3 \pm 13.8$	< 0.001 <sup>a</sup>
SBP	$133 \pm 18$	$133\pm18$	NS
DBP	$80.1\pm10.2$	$79.5 \pm 10.4$	< 0.001 <sup>a</sup>
< 80 mmHg	32.3%	36.5%	< 0.001 <sup>b</sup>
SBP < 130 mmHg and DBP < 80 mmHg	20.8%	23.7%	< 0.001 <sup>b</sup>
HbA <sub>1c</sub> measurements in the past year:			
0	2.9%	2.6%	
1	37.4%	33.5%	
2	29.2%	27.4%	
3	17.1%	18.7%	< 0.001 <sup>a</sup>
4	10.3%	13.5%	
Mean $\pm$ SD	$2.1 \pm 1.4$	$2.24 \pm 1.41$	
Value of last HbA1c measurement	$7.9 \pm 1.9$	$7.8 \pm 1.9$	0.009 <sup>a</sup>
Median	8	7	
Q1–Q3	7–9	7–9	0.009 <sup>a</sup>
$HbA_{1c} < 7\%$	35.8%	38.1%	0.032 <sup>b</sup>
$HbA_{1c} > 8\%$	37.3%	34.6%	0.028 <sup>b</sup>
Total cholesterol (mg/dL)	$198.3\pm53.4$	$194.4 \pm 54.3$	< 0.001 <sup>a</sup>
LDL-C (mg/dL)	$134.9 \pm 145.1$	$125.9 \pm 125.7$	< 0.001 <sup>a</sup>
< 100 mg/dL	33.0%	39.5%	< 0.001 <sup>b</sup>
Triglycerides (mg/dL)	$184.7 \pm 150.7$	$179.6 \pm 159.2$	< 0.001 <sup>a</sup>
< 150 mg/dL	49.0%	52.7%	< 0.001 <sup>b</sup>
Foot ulcer Patients screened and with complications within the last 12 months	3.5%	2.4%	0.026 <sup>b</sup>
Peripheral vascular disease Patients screened and with complications within the last 12 months	5.7%	4.2%	0.002 <sup>b</sup>

Data are presented as means  $\pm$  SD unless otherwise stated; BMI: body mass index; DBP: diastolic blood pressure; SBP: systolic blood pressure; LDL-C: low-density lipoprotein cholesterol.

<sup>a</sup> Differences between groups were measured using Wilcoxon tests for continuous and categorical variables, respectively.

<sup>b</sup> Differences between groups were measured using Chi-square tests for continuous and categorical variables, respectively.

angina, acute myocardial infarction/acute coronary syndrome, heart failure or stroke. However, significantly lower percentages of proteinuria (13.3% vs 16.7%; P < 0.001), foot ulcer (2.4% vs 3.5%; P < 0.026) and peripheral vascular disease (4.2% vs 5.7%; P < 0.002) were recorded in the educated group.

Resource consumption is summarized in Table 3. In the group of educated patients, the annual number of visits to specialists (21% higher; P < 0.001), the percentage of those treated with insulin (40% higher; P < 0.001), and the average performance of fasting (3% higher; P < 0.001) and postprandial (52% higher; P < 0.001) SMBG were all significantly increased. Indeed, differences in SMBG performance were even larger when the highest monthly frequencies were considered. As regards employment and performance at work, the percentage of people with full-time jobs was higher in the educated than in the non-educated group (35.0 vs 34.2%; P > 0.002by Chi-square test). Also, although not significantly different, annual absenteeism figures were 15% higher among noneducated than educated patients ( $6.24 \pm 31.45$  vs  $5.41 \pm 23.91$ days/year, respectively; P < 0.12 by Chi-square test).

# 4. Discussion

Our present data show that most of the clinical and biochemical indicators measured in T2DM patients receiving different kinds of diabetes education decreased significantly.

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#### 132

#### J.J. Gagliardino et al. / Diabetes & Metabolism 38 (2012) 128-134

## Table 3

Patients' resource use, diabetes treatment and self-monitoring of blood glucose (SMBG).

	Received diabetes education		P value
	No	Yes	
Number of participants	5692	5692	
Visits to specialist Annual resource use per patient	$5.91 \pm 5.49$	$7.18\pm7.00$	< 0.001 <sup>a</sup>
Visits to diabetes educator Annual resource use per patient	$0.00 \pm 0.00$	$2.91 \pm 4.32$	< 0.001 <sup>a</sup>
Type of diabetes treatment			< 0.001 <sup>b</sup>
OGLD treatment alone <sup>c</sup>	70.3%	61.6%	
Insulin treatment (with/without OGLD) <sup>c</sup>	25.0%	34.9%	
Diet and exercise alone	4.7%	3.5%	
SMBG (FBG or PPG; yes)	39.6%	51.4%	
Frequency of self-monitoring of FBG/month Frequency/month (classes)	$12.06 \pm 12.65$	$12.41 \pm 12.64$	0.013 <sup>a</sup>
1–5 times/month	41.5%	36.8%	
6–10 times/month	22.7%	25.3%	
11–15 times/month	13.0%	13.7%	0.011 <sup>b</sup>
16–30 times/month	19.6%	21.5%	
> 30 times a month	3.2%	2.6%	
Does the patient self-monitor PPG using glucometer? Yes	24.7%	37.5%	
Frequency of self-monitoring of PPG/month	$8.99 \pm 10.60$	$9.76 \pm 10.98$	<0.001 <sup>a</sup>

Data are presented as means ± SD unless otherwise stated; OGLD: oral glucose-lowering drug; FBG: fasting blood glucose; PPG: postprandial glucose.

<sup>a</sup> Differences between groups were measured by Wilcoxon tests for continuous and categorical variables, respectively.

<sup>b</sup> Differences between groups were measured by Chi-square tests for continuous and categorical variables, respectively.

<sup>c</sup> Associated with diet and exercise prescription.

The frequency of  $HbA_{1c}$  measurements and the percentage of patients with  $HbA_{1c}$  levels at target values, according to international guidelines, were significantly higher in the educated group, with a median concentration at 1 point below target. According to the United Kingdom Prospective Diabetes Study (UKPDS) and Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified-Release Controlled Evaluation (ADVANCE) Trial results, such a decrease in HbA<sub>1c</sub> values would, in turn, reduce the risk of developing microangiopathic complications by about 25% [26,27].

Similarly, markers of the other cardiovascular risk factors measured – namely, BMI (obesity), and BP and lipid profiles – were also lower in the educated group. Although of small magnitude, these changes were statistically significant and within the range reported in controlled diabetes-education studies [15,18–20,28]. Based on data reported in the literature, such lower values can decrease the risk of cardiovascular disease:

• Albu et al. [29] reported that, in cross-sectional analyses, both BMI and waist circumference were independently associated with increased atherothrombotic risk in centrally obese cohorts, such as the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) patients, with T2DM and coronary artery disease;

- a reduction in BP decreases microvascular and macrovascular events [30];
- both the Helsinki Heart Study and the Scandinavian Simvastatin Survival Study (4S) [31,32] showed that high HDL-C and low LDL-C levels effectively contribute to the prevention of coronary heart disease;
- the Steno-2 trial, which simultaneously lowered HbA<sub>1c</sub>, BP and lipids in patients with T2DM, demonstrated relevant longterm reductions in cardiovascular disease and mortality [33].

Regarding the type of treatment, our records showed a greater percentage of insulin use as well as a higher percentage and frequency of SMBG in the educated patients. Also, despite the greater use of insulin, it is worth mentioning that their BMI was lower than in the non-educated group, thereby indicating that hormone administration did not induce body weight increases as it normally would. Taken altogether, these differences indicate greater active involvement of educated patients in the control and treatment of their disease, as well as better compliance with prescribed treatments (including meal-planning) and improved performance of self-care.

As previously shown [26,30,33–35] and, thus, consequently expected, such better profiles of control indicators were accompanied by significantly lower rates of foot ulcers and peripheral

vascular disease. Evidently, the above-mentioned characteristics also impacted favourably on the chances of educated patients to earn higher salaries: a significantly larger percentage with full-time jobs, and a slightly – although not significantly – lower rate of absenteeism from work were recorded in this group. These data agree with the previous results showing how poor disease control and the development of chronic complications had negative impacts on workers' productivity [5].

On the other hand, resource consumption was significantly higher in educated patients; the annual number of visits to specialists was 21% higher, as was insulin use (40%), and performance of fasting (30%) and postprandial (9%) SMBG. However, the increased cost of care represented by such consumption was not estimated in monetary values in our study. As the educated group also had lower rates of chronic complications-the main engine driving the costs of care up [2,3,36,4] – we assume that this would soon be of benefit to healthcare providers due to lower costs of care for these patients in the near future. This beneficial situation could, in addition, affect the families of educated patients, as they are more likely to earn higher incomes (full-time jobs) and spend less out-of-pocket money for disease treatment. It should be borne in mind, however, that the development and progression of chronic complications are also affected by other factors, such as general education and socioeconomic levels.

Quality of life was not assessed in the IDMPS; however, based on other studies reporting that education improves quality of life [16,21,37], similar results would be expected among our educated patients.

The limitations and difficulties of carrying out pragmatic interventional trials in a primary-care setting are well recognized [38,39]; consequently, our conclusions are subject to a number of constraints. One concerns the nature of the present study, which was observational rather than a randomized controlled trial. The latter trials are considered superior to observational studies because they eliminate selection bias and reduce confounding factors [40]. However, from the point of view of generalizability, data from observational studies are usually applicable to much wider populations and are often even population-based [41]. Nevertheless, in the present case, such generalizability is limited by the fact that the data recorded in different countries are not necessarily representative, one reason why the findings need to be applied with caution.

Other limitations are the heterogeneity of the educational procedures used, the differences in accessibility to education and care, the differences in healthcare settings and the different cultural predispositions in each participating country. In fact, our study included a wide variety of methodologies and interventional durations compared with the standardized educational programmes. This could represent a serious challenge, as a positive effect on metabolic control strongly correlates with patients' motivation, number of training sessions, and quality of the relationship between the patient and caregiver/instructor [42]. However, it could be argued that, even though our patients did not receive identical multidimensional therapeutic education, the education that was received was sufficient to attain HbA<sub>1c</sub> levels comparable to those recorded in well-controlled studies [42]. For this reason, the differences found in our present study

might have been of even greater magnitude if standardized procedures had been implemented. Also, given our sample size (the largest so far reported) and the paired comparison performed, all of the above-mentioned limitations might be mitigated, if not removed completely, thus lending additional support to the favourable impact of patients' education on diabetes care outcomes.

# 5. Conclusion

In brief, the IDMPS data demonstrate that, in T2DM patients, diabetes-related education involving different characteristics and degrees of intensity, and implemented worldwide in a large population at the primary-care level, significantly increased the percentages of patients achieving target values as set by the international guidelines. Among educated patients, the rate of chronic complications was lower while insulin use and self-care performance were higher, resulting in a relatively modest increase in costs of care in this group. These results should help healthcare providers and policy makers to arrive at the decision to include diabetes education as an efficient and routine therapeutic tool within the strategies used to control and treat patients with diabetes.

#### Disclosure of interest

The IDMPS is an epidemiological survey entirely funded by Sanofi-Aventis. J.-M. C. is an employee of Sanofi-Aventis, a sponsor of the IDMPS. All the other authors are members of the IDMPS steering committee, and have received honoraria and traveling sponsorships related to the IDMPS.

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J.J. Gagliardino et al. / Diabetes & Metabolism 38 (2012) 128-134

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134