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Impact of diabetes education and self-management on the quality of care for people with type 1 diabetes mellitus in the Middle East (the International Diabetes Mellitus Practices Study, IDMPS)

Juan José Gagliardino^{a,*}, Jean-Marc Chantelot^b, Catherine Domenger^b, Ambady Ramachandran^c, Ghaida Kaddaha^d, Jean Claude Mbanya^e, Marina Shestakova^f, Juliana Chan^g, on behalf of the IDMPS Steering Committee

^a CENEXA Center of Experimental and Applied Endocrinology (La Plata National University – La Plata National Scientific and Technical Research Council), La Plata, Argentina

^b Sanofi, Paris, France

^c India Diabetes Research Foundation, Dr. A. Ramachandran's Diabetes Hospitals, Chennai, India

^d Diabetology Unit, Government of Dubai, Dubai Health Authority, Dubai, United Arab Emirates

^e Biotechnology Center, Doctoral School of Life Sciences, Health and Environment, and Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon

^f Endocrinology Research Center, I.M. Sechenov First Moscow State Medical University, Moscow, Russia

^g Department of Medicine and Therapeutics, The Chinese University of Hong Kong, The Prince of Wales Hospital, Shatin, Hong Kong Special Administrative Region

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ABSTRACT

Aims: Self-management (self-monitoring of blood glucose, plus self-adjustment of insulin dose) is important in diabetes care, but its complexity presents a barrier to wider implementation, which hinders attainment and maintenance of glycemic targets. More evidence on self-management is needed to increase its implementation and improve metabolic outcomes.

Methods: Data from 1316 participants with type 1 diabetes mellitus who were enrolled from Middle East countries into the International Diabetes Management Practices Study (IDMPS), a multinational observational survey, were analyzed to assess the impact of education on disease management and outcomes.

Results: A majority (78%) of participants failed to achieve glycemic target ($HbA_{1c} < 7.0\%$ [< 53 mmol/mol]). Participants who had received diabetes education (59%) were more likely to practice self-management than those who had not (odds ratio [OR]: 2.51; 95% confidence interval [CI]: 1.7–3.69; $p < 0.001$), and those who practiced self-management were more likely to attain target HbA_{1c} than those who did not (OR: 1.49; 95% CI: 1.06–2.09; $p = 0.023$).

* Corresponding author at: CENEXA, Center of Experimental and Applied Endocrinology, National Scientific and Technical Research Council, National University of La Plata, Calle 60 y 120, La Plata, Argentina.

E-mail addresses: cenexaar@yahoo.com.ar (J.J. Gagliardino), Jean-Marc.Chantelot@sanofi.com (J.-M. Chantelot), Catherine.Domenger@sanofi.com (C. Domenger), ramachandran@ardiabetes.org (A. Ramachandran), jchan@cuhk.edu.hk (J. Chan).
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Conclusions: These relationships between diabetes education, self-management and glyce- mic control suggest that diabetes education provides knowledge and skills to optimize self- management, favoring HbA_{1c} target attainment. Middle East health authorities should search for ways to facilitate access to diabetes education to optimize treatment outcomes.

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1. Introduction

Poor glyce- mic control of type 1 diabetes mellitus (T1DM) is associated with serious long-term complications that impact negatively on quality of life and increase both direct and indirect costs of the disease [1,2]. Intensive insulin therapy combined with dose adjustments based on self-monitoring blood glucose (SMBG) measurements, facilitates attainment of glycated hemoglobin (HbA_{1c}) target values, decreasing the risk of development and progression of chronic complications [2,3]. However, this degree of control is difficult to attain/ maintain in real-life situations due to barriers such as the complexity and demands of diabetes self-management and the occurrence and fear of hypoglycemia [2,4].

Structured education programs about diabetes self-management can help to overcome these barriers, leading to substantial improvements in glyce- mic control and other diabetes outcomes. In Germany, following a 5-day inpatient diabetes treatment and teaching program (DTTP), HbA_{1c} fell significantly from 8.1% (65 mmol/mol) to 7.3% (56 mmol/ mol) over the subsequent year, with a significant reduction in the number of severe hypoglycemic episodes [5]. Similarly, in the UK, implementation of the Dose Adjustment For Normal Eating (DAFNE) program, improved glyce- mic control and quality of life while reducing 10-year costs by approximately £2200 per patient treated, without increasing the risk of severe hypoglycemia [6,7]. Such treatment programs have also improved outcomes (metabolic control and treatment satisfaction) for patients with moderately controlled T1DM receiving intensive insulin therapy [8]. Furthermore, these programs can also improve emotional outcomes [9].

While results from these European programs show the benefits of education about diabetes self-management, there are limited data on this subject outside the Western world. Since 2005, the International Diabetes Mellitus Prac- tices Study (IDMPS) has been seeking to understand the challenges of managing diabetes in the real world. Data from IDMPS, the largest ever observational study program that describes patient profiles, management and patterns of care across time in developing regions, support the pro- posed benefits of education [10]. Results from IDMPS cohorts in Asia, Latin America and Eastern Europe have been published previously [10–12]. This current manuscript describes results for people with T1DM in the Middle East, a region that has undergone major social and economic changes over the last three decades. Its objective was to investigate potential associations between diabetes educa- tion, self-management and degree of glyce- mic control in people with T1DM.

2. Materials and methods

The design and objectives of the IDMPS study have been described previously [10]. Briefly, IDMPS is an observational, multinational study with the aim of assessing the therapeutic management of people with type 2 diabetes mellitus (T2DM) and T1DM in regular medical practice. Data collected included: glyce- mic control; frequency of HbA_{1c} testing; level of screening for diabetes-related complications; and evalua- tion of insulin dosing regimens used. The study was con- ducted in six waves (Wave 1: 2005; Wave 2: 2006; Wave 3: 2008; Wave 4: 2010; Wave 5: 2011–12; Wave 6: 2013–14), each of which included a cross-sectional survey; data from Waves 2–4 are reported here. Middle East Centers that participated in Waves 2 onwards included Egypt, Iran (Wave 3 only), Lebanon, Saudi Arabia, and the United Arab Emirates.

2.1. Study implementation

The study was coordinated by Sanofi-Diabetes Intercontinen- tal. A steering committee integrated by an international group of diabetologists advised the project team regarding study design and registry structure, monitored study progress, reviewed and validated all study-related documents, and pro- posed decisions regarding protocol amendments, analyses and publications. Ethics approval was obtained from institu- tional review boards in each country and the study was con- ducted in accordance with the Declaration of Helsinki.

2.2. Sample size estimation and selection of centers/physicians

Sample sizes were determined for each country to estimate the primary study endpoint (percentage of people with T2DM treated with insulin), with 20% absolute precision and 95% confidence. The number of centers was determined based on a recruitment target of ten people with T2DM per center. In each country, a leading diabetologist compiled and endorsed the list of investigators, who were then asked to participate. They included endocrinologists, diabetologists, and general practitioners with experience in initiation and titration of insulin therapy [10]. Participating investigators/- centers for each study wave were selected independently, although investigators could participate in more than one wave.

2.3. Participants

Physicians were asked to enroll the first ten people with T2DM and the first five people with T1DM (male or female) aged

≥18 years who attended their clinic over the 2-week recruitment period. People could participate in only one wave. Any patients who were actively participating in another clinical study, or those receiving temporary insulin treatment (e.g. for gestational diabetes or pancreatic cancer) were also excluded. All participants provided written informed consent.

2.4. Data collection and outcome measures

Before each study wave, participating investigators recorded their age, gender, specialty, care setting (hospital, private office), experience in treating people with diabetes, and any participation in diabetes educational programs.

Patient data, collected on case report forms, included: demographics; socio-economic profile (urban vs rural home, education level, health insurance coverage); diabetes medical history, comorbidities and screening frequency for diabetes-related complications; presence of diabetes complications; physical measurements (including height, weight, blood pressure and heart rate); cardiovascular risk factors (including hypertension, lipid profile); glycemic control (including SMBG, HbA_{1c} monitoring frequency and last recorded value); history of hypoglycemia; exercise frequency; current insulin treatment (regimen, dose, insulin type, device); investigator opinion on attainment of targets for glycemic control, blood pressure and lipid status; patient's diabetes education (e.g. membership of support groups, type and modality of education received); and level of follow-up care (number of visits to physician/endocrinologist/diabetologist within previous 3 months).

Glycemic control was defined as HbA_{1c} < 7.0% (<53 mmol/mol). Self-management was defined as SMBG and self-adjustment of insulin dose.

2.5. Statistical analysis

Unless specified, data from all waves were pooled for analysis. All case report forms were transferred from study centers to Mapi, France, for quality control, transcription into electronic format and analysis using SAS (version 9.2; SAS Institute, Cary, NC). For variables with two modalities, Wilcoxon signed-rank (quantitative variables) or Chi-squared (qualitative variables) tests were used; for variables with more than two modalities, Kruskal-Wallis (quantitative variables) or Fisher's exact (qualitative variables) tests were used. Univariate and logistic regression analyses were performed to identify predictive factors for: self-management; patient's diabetes education; glycemic control. For the logistic regression, age was considered in three classes: <40 years old, 40–64 years old and ≥65 years old. Continuous variables included in the model were: total daily insulin dose, time since diagnosis, time on insulin treatment and waist circumference.

All predictors with a *p*-value <0.20 in univariate analysis were included in a logistic regression model. Then, a stepwise procedure was used to select the most relevant model. Starting from a full model with all independent variables selected based on the univariate analysis, all non-significant variables were removed one by one until all parameters reached a level of significance of at least 0.05. Interactions between

independent variables were not considered. Odds ratios were provided with 95% confidence intervals (CIs). In all data analyses, participants with missing data were not considered when reporting proportions of participants in categories described.

3. Results

Clinical and metabolic characteristics of the 1316 participants with T1DM (52% male) recruited by 762 investigators across Waves 2–4 in the Middle East are listed in Table 1. The mean (±SD) age of participants was 32.4 (±12.9) years, and most (85%) were of Oriental/Arab/Persian ethnicity. Most participants (87%) lived in an urban setting, and 47% were educated to university/higher level; 69% were covered by health insurance and 79% had been seen by a GP at least once within the previous 3 months. Basal plus prandial insulin was the most commonly used regimen (51% overall), while 30% of participants used premixed insulin alone.

3.1. Diabetes education

Overall, 59% of participants had received diabetes education. Most participants received diabetes education in an individual rather than group setting. Mean age and disease duration were similar in diabetes-educated and non-educated groups. Basal plus prandial insulin regimen was more common among participants who had received diabetes education (60%) compared with those who had not (39%, *p* < 0.001). The proportion of participants who had received diabetes education was similar whether recruited by a general practitioner (60% had received education) or a diabetes specialist (58%).

3.2. Self-management behaviors

Overall, 75% of participants practiced SMBG but only 54% of participants practiced self-management (i.e. both SMBG and insulin self-adjustment [ISA]). Overall, 16% of participants practiced neither SMBG nor ISA (Table 1). Similarly, self-management was more common among people with university/higher education level than those with primary/secondary education level (62 vs 45%, respectively; *p* < 0.001). Self-management was significantly more common among those who had received diabetes education compared with those who had not (60 vs 41%, respectively; *p* < 0.001). Fig. 1 provides an overview of participant self-management according to diabetes education status, excluding those who reported practicing ISA alone (6% of overall population).

3.3. Associations between glycemic control, diabetes education and self-management

Overall, 22% of participants attained HbA_{1c} target values (HbA_{1c} < 7.0% [<53 mmol/mol]). Target attainment was significantly associated with diabetes education status: 25% of participants who had received diabetes education attained target values, compared with only 19% of those who had not received education (*p* = 0.01, Fig. 2). Conversely, most participants (52%) who did not receive diabetes education

Table 1 – Participant baseline characteristics, overall and according to diabetes education.

	Overall (N = 1316) ^a	Diabetes education status N = 1267 ^b		Significance (test used)
		Educated n = 746 (59%)	Not Educated n = 521 (41%)	
Ethnicity, n (%)				0.365 (C)
Caucasian	76 (6)	51 (7)	24 (5)	
South Asian	73 (6)	45 (6)	27 (5)	
Black	13 (1)	7 (1)	2 (1)	
Oriental, Arab, Persian	1123 (85)	630 (85)	455 (87)	
Other Asian	29 (2)	12 (2)	12 (2)	
Other	2 (<1)	1 (<1)	1 (<1)	
Male, n (%)	678/1295 (52)	378/731 (52)	275/516 (53)	0.581
Mean age, years (SD)	32.4 (12.9)	31.0 (12.1)	34.3 (13.7)	<0.001 (W)
Mean time since diabetes diagnosis, years (SD)	12.4 (9.3)	12.2 (8.9)	12.6 (9.8)	0.926
Mean BMI, kg/m ² (SD)	25.7 (4.9)	25.4 (4.8)	26.0 (5.0)	0.031 (W)
Glycemic control, n (%)				
HbA _{1c} < 7.0% (53 mmol/mol)	248/1109 (22)	165/653 (25)	77/416 (19)	0.010
Insulin regimen, n (%)				<0.001 (C)
Basal alone	133/1275 (10)	42/717 (6)	88/514 (17)	<0.001
Basal+prandial	651/1275 (51)	432/717 (60)	198/514 (39)	<0.001
Others	80/1275 (6)	40/717 (6)	37/514 (7)	0.247
Prandial alone	30/1275 (2)	24/717 (3)	5/514 (1)	0.007
Premix alone	381/1275 (30)	179/717 (25)	186/514 (36)	<0.001
Health insurance, n (%)	896/1299 (69)	542/737 (74)	317/514 (62)	<0.001
Mean number of daily injections according to insulin used (SD)				
Basal alone	1.6 (0.6)	1.5 (0.5)	1.7 (0.7)	0.214 (W)
Basal+prandial	3.9 (0.7)	4.0 (0.7)	3.8 (0.7)	0.007 (W)
Prandial alone	2.6 (0.6)	2.4 (0.5)	3.0 (0.8)	0.174 (W)
Premix alone	2.1 (0.4)	2.0 (0.3)	2.1 (0.4)	0.021 (W)
Diabetes management strategy used, n (%)				<0.001 (C)
SMBG ^c	925/1232 (75)	607/738 (82)	318/494 (64)	<0.001
Self-management (SMBG and ISA)	637/1180 (54)	434/711 (61)	203/469 (43)	<0.001
No self-management	192/1180 (16)	75/711 (11)	117/469 (25)	<0.001

C, Chi-squared test; ISA, insulin self-adjustment; SD, standard deviation; SMBG, self-monitoring of blood glucose; W, Wilcoxon test.

^a Participants with missing data were not considered when reporting proportions of participants in categories listed.

^b Data on diabetes education status were not available for 49 participants.

^c Includes all patients who use these specific self-management practices, but participants may use more than one self-management practice.

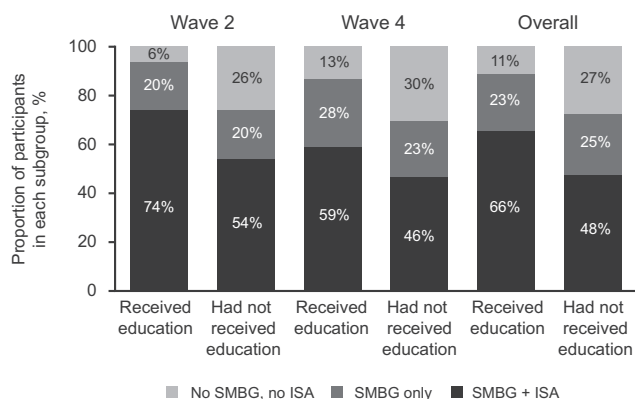


Fig. 1 – Self-management[†] according to diabetes education status[†]. Data for participants who reported practicing ISA alone (6% of overall population) are not presented; [†]Data for Wave 3 are not presented, as this wave included centers in Iran, whereas the participating countries were the same between Waves 2 and 4. ISA, insulin self-adjustment; SMBG, self-monitoring of blood glucose.

had $HbA_{1c} \geq 8.0\%$ (≥ 64 mmol/mol), compared with 42% of those who did receive education ($p = 0.003$).

A similar association was observed between HbA_{1c} levels and self-management: 26% of participants who practiced self-management attained target values and 41% had $HbA_{1c} \geq 8.0\%$ (≥ 64 mmol/mol). In comparison, only 19% of participants who did not practice self-management attained target values ($p = 0.007$) while 51% had $HbA_{1c} \geq 8.0\%$ (≥ 64 mmol/mol) ($p < 0.001$).

ISA was also important for attainment of appropriate control of glucose metabolism: people who practiced SMBG without ISA were no more likely to attain target values than those who practiced neither SMBG nor ISA (21% vs 17%, $p = 0.437$).

The effectiveness of self-management was favorably affected by diabetes education. Among people who practiced self-management, there was a numerical non-significant trend towards higher attainment of HbA_{1c} target value in those who had received diabetes education: 27% of participants who practiced self-management and had received diabetes education attained $HbA_{1c} < 7.0\%$ (< 53 mmol/mol), compared with 23% of

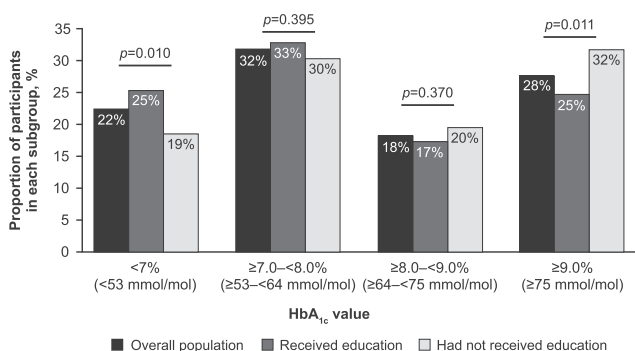


Fig. 2 – HbA_{1c} percentage distribution according to diabetes education status.

participants who practiced self-management, but had not received diabetes education ($p = 0.280$).

3.4. Multivariate analysis

Participants who received diabetes education were 2.5 times more likely to practice self-management compared with those who had not received it (OR: 2.51; 95% CI: 1.7–3.69; $p < 0.001$). Other factors associated with the use of self-management practices included age, time since diagnosis of diabetes, general education level and insulin device (Fig. 3).

Of the factors tested for association with glycemic control (self-management, diabetes education, diabetes complications, insulin regimen, age, BMI, gender, total daily insulin dose, time since diagnosis, glucometer availability), self-management was the only factor that showed a significant association. Participants who practiced self-management were 1.5 times more likely to attain HbA_{1c} target values than those who did not (OR: 1.49; 95% CI: 1.06–2.09; $p = 0.023$).

4. Discussion

These data show significant positive associations between diabetes education, self-management practices (SMBG and ISA) and improved glucose metabolic control: people that had received diabetes education were 2.5 times more likely to perform self-management and those who practiced self-management were 1.5 times more likely to have $HbA_{1c} < 7.0\%$ (< 53 mmol/mol).

The beneficial effect of diabetes education on self-management was not unexpected: SMBG and ISA are complex procedures that can be difficult to perform appropriately for an uneducated patient since having the disease does not automatically give the patient sufficient knowledge on how to control it. Further, these beneficial diabetes self-management and education outcomes are consistent with data reported previously [13–15].

Although the Diabetes Control and Complications Trial (DCCT) outcomes provided strong evidence that strict glycemic control reduces microvascular complications in people with T1DM, the three-fold increase in severe hypoglycemia associated with intensive insulin therapy presented a serious challenge for its implementation in routine care [16]. However, there is increasing evidence that intensive insulin therapy is not necessarily associated with a high risk of severe hypoglycemia [5,17–20]. In fact, implementation of a 5-day structured inpatient training course for intensive insulin therapy (DTTP, developed by a German group), showed sustained improvements in glycemic control after 22 months without increasing the risk of severe hypoglycemia [17]. Similarly, in the DAFNE trial, HbA_{1c} and quality of life were significantly improved after appropriate training, while the incidence of severe hypoglycemia remained unchanged [19]. Although the long-term sustainability of the improvement in glycemic control observed in the DAFNE trial has been challenged, an analysis using the Sheffield Type 1 diabetes mellitus Policy Model showed that DAFNE was cost-effective for the reduction of long-term complications and increasing survival [21,22].

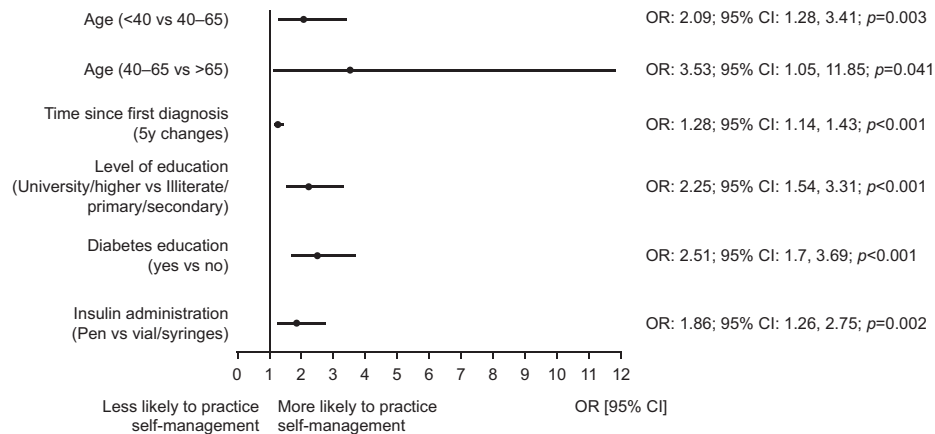


Fig. 3 – Predictive factors for self-management. CI, confidence interval; OR, odds ratio.

In our study, diabetes education, age, diabetes duration, level of general education and type of insulin administration were significant predictors for the practice of self-management. Given the significant positive association observed between self-management and degree of glycemic control, these results suggest that provision of education about self-management to people with T1DM early after diagnosis may help to maximize its beneficial effect on glycometabolic control. Although access to diabetes education, insulin, devices and strips for SMBG could also influence our results, this does not appear to be the case because the majority of participants in diabetes-educated and diabetes-uneducated groups had healthcare coverage.

Unexpectedly, in this Middle East population, approximately 40% of participants had not received diabetes education, regardless of whether they had been recruited by a general practitioner or a diabetes specialist. However, we do not know whether the type and extent of the education programs were alike in both groups. Nevertheless, this suggests a need for an intensive promotion of diabetes education for people with T1DM in the Middle East, even among people already receiving specialist care. It is also important to promote the use of diabetes education programs in primary care settings, as this has been shown to improve the quality of care [23,24].

These data clearly show the beneficial impact of diabetes self-management on attainment of glycemic target, and the positive association between diabetes education and self-management. However, these results should be considered with caution because the data were the product of an observational study, and participating patients were under the care of a selected group of physicians with experience in insulin titration and administration. Therefore, these results may not be representative of all physicians, nor the general population of people with T1DM in this region. Consequently, the true percentage of people with T1DM that have access to diabetes education may differ from that reported here across the Middle East region. Nevertheless, due to the large size of this sample and the standardized method used for data collection, our results provide objective evidence for health authorities and decision makers about the benefits of diabetes education and self-management to improve treatment outcomes. This

assertion is supported by other studies that have shown a similar positive association between self-management and better treatment outcomes [9,25–27].

In summary, our findings show that diabetes education is significantly associated with effective self-management in people with T1DM, which in turn would favor the attainment of HbA_{1c} target. Diabetes education provides the knowledge and skills to optimize self-management, but more importantly, induces a positive attitude towards patients' active participation in the control and treatment of their disease. Thus, Middle East health authorities should invest great efforts to facilitate access to education for people with T1DM, in order to optimize treatment outcomes and prevent the development of chronic complications.

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Disclosures

CD and JMC are employees of Sanofi.

All of the other authors are members of the IDMPs Steering Committee and have received honoraria and traveling sponsorships in relation to the IDMPs. No other potential conflicts of interest relevant to this article were reported.

Author contributions

All authors interpreted the results, revised the manuscript, and approved the final version of the manuscript. JJG is the

guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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