

Sami T. AZAR, Line P. MALHA, Mira S. ZANTOUT, Mohammed NAJA, Fariha YOUNES, Marie-Therese SAWAYA\*

Azar ST, Malha LP, Zantout MS, Naja M, Younes F, Sawaya MT. Management and control of patients with type 2 diabetes mellitus in Lebanon : Results from the International Diabetes Management Practices Study (IDMPS). J Med Liban 2013 ; 61 (3) : 127-131.

**ABSTRACT • BACKGROUND :** The IDMPS is a study to identify changes in diabetes treatment practice in several developing countries. This paper focuses on diabetes management and compliance with guidelines in a Middle Eastern country like Lebanon.

**METHODS :** The cross-sectional data from the 2006 wave of two weeks duration on the Lebanese population along with the longitudinal data of a 9-month follow-up study were collected.

**RESULTS :** A large proportion of Lebanese patients were not adequately controlled or followed up. A slight proportion was managed by diet and exercise alone while most patients were on two or more oral anti-hyperglycemics. Metformin was the most common monotherapy followed by sulfonylureas. 22.6% of Lebanese patients were on insulin, most commonly basal insulin alone followed by premix insulin alone. Blood glucose self-monitoring was more frequently done by insulinized patients and was associated with better glycemic control. Glycemic control was reached in 29.6% of type 2 patients (HbA1c < 7%) with poorest outcome for patients on insulin and was more frequently achieved in patients who had more frequent monitoring of HbA1c levels.

**CONCLUSION :** For a proper assessment of diabetic control, maintaining adherence to international guidelines needs to be evaluated. Promoting patient education, improving physician knowledge with better implementation of guidelines is recommended.

Keywords : type 2 diabetes, management, glycemic control, HbA1c, Lebanon

#### INTRODUCTION

Diabetes is a disease that causes severe morbidity, decreased quality of life and premature mortality. The prevalence of diabetes in Lebanon is 7.8% for the population aged 20-79 years. The prevalence of diabetes worldwide,

\*Department of Internal Medicine, Division of Endocrinology, American University of Beirut Medical Center, Beirut, Lebanon.

Correspondence: Sami T. Azar, M.D.

e-mail: [sazar@aub.edu.lb](mailto:sazar@aub.edu.lb)

Fax: +961 1 365 189

Azar ST, Malha LP, Zantout MS, Naja M, Younes F, Sawaya MT. Prise en charge et contrôle des patients atteints du diabète sucré de type 2 au Liban : Résultats de l'International Diabetes Management Practices Study (IDMPS). J Med Liban 2013 ; 61 (3) : 127-131.

**RÉSUMÉ • CONTEXTE :** L'IDMPS est une étude visant à identifier les différentes conduites thérapeutiques du diabète dans plusieurs pays en voie de développement. Cet article présente la prise en charge du diabète et la conformité avec les recommandations dans un pays du Moyen-Orient comme le Liban.

**MÉTHODES :** Étude des données transversales sur la population libanaise recueillies au cours de deux semaines en 2006 ainsi que les données longitudinales sur 9 mois de suivi.

**RÉSULTATS :** Une grande partie des patients libanais n'était pas bien contrôlée ou suivie. Une minorité a été traitée par diète et exercice alors que la plupart des patients étaient sous deux ou plusieurs hypoglycémifiants oraux. La metformine étant la plus utilisée en monothérapie, suivie par les sulfonylurées. 22,6% des patients libanais étaient sous insulinothérapie, l'insuline basale étant la formule la plus utilisée suivie par l'insuline mixte. L'auto-surveillance glycémique était plus pratiquée par les patients insulino-dépendants et était associée à un meilleur contrôle glycémique. Le contrôle glycémique a été atteint chez 29,6% des patients diabétiques type 2, en particulier chez les patients ayant un suivi régulier de l'hémoglobine glyquée. Ceux sous insulinothérapie avaient les résultats les plus médiocres.

**CONCLUSION :** Pour une évaluation pertinente du contrôle du diabète, la conformité aux recommandations doit être évaluée. Promouvoir l'éducation des patients et améliorer les connaissances du médecin avec un meilleur suivi des directives sont recommandés.

Mots-clés : diabète de type 2, prise en charge, contrôle glycémique, HbA1c, Liban

and in developing countries in specific, is expected to dramatically increase by the year 2030 [1]. Akel *et al.*, in a study published in 1999 involving 204 patients with diabetes, reported that HbA1c was assessed in only 40% of the patients recruited. Controlled disease (HbA1c < 7%) was in only 28.4% of the patients and 38.3% patients had an HbA1c  $\geq$  8.5%. In 57.9% of these patients, plasma glucose level was found to be > 160 mg/dl [2].

Another study conducted in Denmark in 2007 showed that patients of Lebanese descent are prone to be on oral anti-hyperglycemics and to have worse diabetes control

as compared to Danes [3]. Among the several factors that could account for this observation, genetic predisposition and culture-related lifestyle have been mentioned. Increasing awareness on the management of diabetes should be followed by proper documentation of medical information and better implementation of the international guidelines and standard procedures, such as the American Diabetes Association/European Association for the Study of Diabetes (ADA/EASD). Hirbli *et al.* reported that six months after starting a “diabetes initiative” in Lebanon, there was an improvement in recording the parameters of diabetes control including lifestyle, medical condition and blood tests [4].

In this paper, data from the International Diabetes Management Practices Study (IDMPS) were retrieved in order to primarily assess the therapeutic management and control of type 2 diabetes mellitus in the current medical practice in the Lebanese population. Secondary end points included management of type 1 diabetes patients, insulin therapy, follow-up of patients and proportion of patients under the HbA1c threshold compared to international guidelines, ADA and EASD.

#### STUDY DESIGN

The IDMPS is an international, multicenter, observational study of patients with type 1 and type 2 diabetes. The study consists of five waves conducted as one wave per year, consisting of two parts, a cross sectional and a longitudinal study. For the current 2006 cross sectional wave, a random sample of physicians from the participating countries recruited the first 10 patients with type 2 diabetes and the first 5 patients with type 1 diabetes during a 2-week time frame. Patients less than 18 years of age were excluded from the study. Other criteria for exclusion were current participation in another clinical study, participation in a previous IDMPS wave and current temporary insulin treatment. The study mainly concentrated on diabetes practices and evaluated the degree of compliance with guidelines in non-Western countries in Asia, Eastern Europe, Latin America, Africa and the Middle East [5]. A paper has been recently published by Chan *et al.* on predictive factors of glycemia control based on results from the IDMPS study [6].

#### METHODS

The data used in this paper has been collected during the 2006 wave and involves the cross-sectional data of 2 weeks duration and the longitudinal data of a 9-month follow-up collected in Lebanon.

Registries of the IDMPS included both type 1 and type 2 diabetic patients. Informed consent was obtained from all participating patients. Ethics committee’s approval was obtained from participating centers where such committees are in place.

Statistical analysis was retrieved, with permission, from the original analysis for the IDMPS second wave which

was conducted by Mapi-Naxis in Lyon, France, using SAS version 8.02 (SAS Institute Inc., Cary, NC, USA).

#### Statistical analysis

Mean and standard deviation (SD) was used to summarize numeric variables such as age, body mass index (BMI), duration of the disease and total daily insulin dose while percentages were used for summarizing categorical variables such as type of diabetes, type of treatment, self-monitoring, and reaching blood pressure target (systolic < 130 mmHg and diastolic < 80 mmHg); reaching LDL target (< 100 mg/dl); reaching HbA1c target (< 7%); reaching fasting blood glucose target ( $\leq$  100 mg/dl). Similarly, the data based on physicians’ opinions about glycemic control were summarized using frequency distributions. Concordance between glycemic control based on the value of HbA1c and that based on the physicians’ opinion were assessed using the kappa statistic and McNemar’s test. The t-test was used to compare months since most recent HbA1c value between those who achieved glycemic control and those who did not. A *p*-value of .05 or less was considered statistically significant. The sample size was determined to give an absolute precision of 20% and a confidence interval of 95%.

#### RESULTS

A total of 15,016 patients with type 2 diabetes were recruited to the second wave of the IDMPS; 1630 patients were recruited in Lebanon with 1571 patients included in the intention-to-treat analysis. The sample consisted of 286 patients with type 1 diabetes and 1285 patients with type 2 diabetes. Recruitment was carried out in 128 sites by a total of 115 physicians. The mean age of recruited Lebanese patients was  $59.94 \pm 11.51$  years and the mean duration of disease since diagnosis was  $8.73 \pm 7.49$  years. Most patients with type 1 diabetes were under the age of 40 years (73%) while the majority of patients with type 2 diabetes were between 40 and 65 years old (61.3%). Mean BMI was 24.6 kg/m<sup>2</sup> for type 1 diabetes patients while it was 29.04 kg/m<sup>2</sup> in type 2 diabetes patients. 26.2% of patients did not benefit from any kind of insurance (neither public nor private). This paper will elaborate on the findings for only the type 2 diabetes patients in Lebanon.

#### Type of treatment regimen used in Type 2 patients in the Lebanese population

Diet and exercise was the treatment of choice for 4% of the patients, 73.3% were on oral glucose lowering drug (OGLD) alone and 22.7% on insulin therapy, alone or in combination with OGLD.

The most commonly prescribed OGLD regimen consisted of a combination of metformin and sulphonylureas, with or without the addition of other drugs (55.4% of patients on OGLD). Metformin or sulphonylurea monotherapy was the treatment in 15.7% and 13.3% of the patients on OGLD respectively (Fig. 1a, 1b).

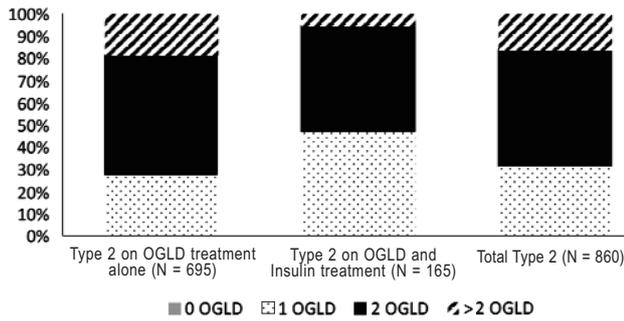


FIGURE 1a

Detailed one glucose lowering drug/OGLD management for type 2 diabetic patients by number of OGLD used.

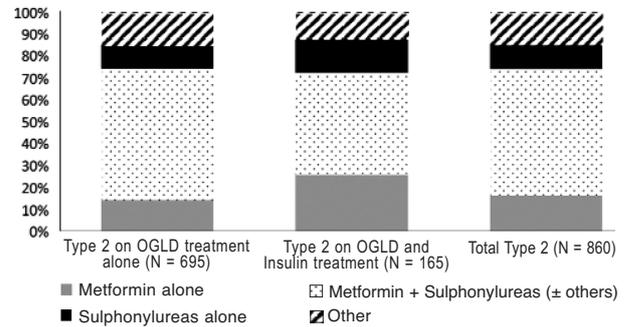


FIGURE 1b

Detailed one glucose lowering drug/OGLD management for type 2 diabetic patients by class of OGLD used

### Insulin therapy regimen and follow-up

Insulinized patients were on insulin therapy for  $3.65 \pm 4.97$  years. Of these patients, 61.2% were on basal insulin, 9.3% were on basal plus prandial and 27.1% on premixed insulin. The mean total daily insulin dose was  $38.26 \pm 23.43$  U. A majority of patients self-administered their insulin (61.9%) and 46.1% self-adjust their insulin dose. Patients on insulin therapy, with or without OGLD, had been diagnosed with diabetes for  $14.62 \pm 8.46$  years versus  $7.36 \pm 6.20$  years for patients on OGLD alone.

### Blood glucose monitoring & HbA1c levels in Lebanese patients with Type 2 diabetes

Patients on insulin more consistently self-monitored their blood glucose either fasting or postprandial (77.6%) as compared to patients on OGLD alone (50.6%). A small proportion of patients recorded their blood glucose more than 30 times a month thus making an average of more than once daily. The proportion of patients who monitored their fasting blood glucose (FBG) was higher than those who monitored postprandial glucose levels (PPG); 71.0% of patients, including 52.3% of insulin users, did not

self-monitor PPG. HbA1c measurements were available for 95.1% of the patients with at least one measurement in the previous year for 98% of these patients, with a mean of  $2.24 \pm 1.27$  measurements per year.

### HbA1c, fasting blood glucose and diabetes control

Diabetes control, defined as HbA1c < 7% was achieved by 29.6% of the recruited patients, with 41.1% patients having an HbA1c > 8%. Comparing modalities of treatment, 16.7% of patients on insulin, with or without OGLD, achieved an HbA1c < 7% versus 33.5% of patients on OGLD alone.

When assessing glycemic control based on physician's opinion, 39% of patients with type 2 were considered as controlled. Patients on OGLD alone were more controlled (42.4%) than patients on insulin treatment ± OGLD (30.7%) or lifestyle modification (31.4%). Concordance between physician's opinion and HbA1c value was assessed using Mc Nemar's test ( $\kappa = 0.55$ ) and Bowker's test of symmetry ( $p < 0.0001$ ). The inter-rater variability was moderate. Reasons for not achieving glycemic target were reported and charted in Figure 2. Self-monitoring

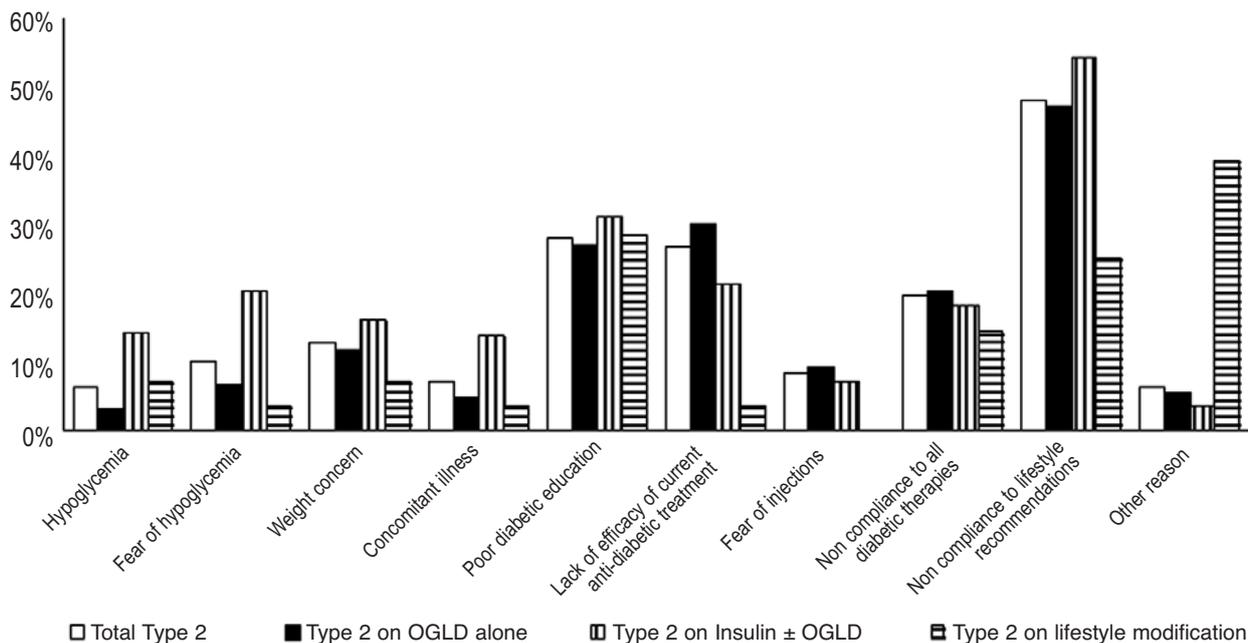


FIGURE 2. Reasons for not reaching glycemic target presented as proportion of patients in non exclusive categories for type 2 diabetic patients.

of plasma glucose (FBG or PPG) was associated with better HbA1c outcomes. Significance was only reached for patients on OGLD alone ( $p = 0.006$ ). The frequency of FBG measurement however was not associated with patient being considered at glycemic target ( $p = 0.257$ ).

Availability of HbA1c value was not correlated with better control of fasting glycemia. On the contrary, 71.7% of patients without an HbA1c level had an elevated FBG > 100 mg as opposed to 93.7% for patients with an available HbA1c level. An available HbA1c level was associated with reaching glycemic target as determined by the treating physician. Patients who achieved glycemic control had more frequent HbA1c measurements and significantly more recent HbA1c values than those not at target ( $1.88 \pm 3.12$  vs  $2.88 \pm 5.79$  months;  $p < 0.001$ ). Diabetes management was evaluated through the three main targets: LDL < 100 mg/dl, BP < 130/80 mmHg and HbA1c < 7%. Only 2.7% of type 2 patients were found to have all three controlled (Figure 3).

### DISCUSSION

This study identified inadequate glycemic control linked to type 2 diabetes in 15,016 patients recruited in Asia, Latin America, Africa and the Middle East. Similar to international observations, the management of type 2 diabetes in Lebanon was more targeted toward pharmacologic treatment than proactive measures [6]. Oral anti-hyperglycemic treatment involved 2 or more drugs. In monotherapy, metformin was the most commonly used agent. Inclusion of metformin in the treatment regimen would offer a protective effect in terms of related morbidity and mortality [8]. International guidelines advise using metformin as a first line agent and to add a sulphonylurea or basal insulin if monotherapy fails [8-9].

Results show that 22.6% of patients with type 2 diabetes were on insulin therapy, which is a low proportion internationally [6-7]. As expected from international guidelines, the main type of insulin used with OGLD in type 2 diabetics is basal insulin. Education of patients with diabetes on insulin therapy is a necessary step for disease

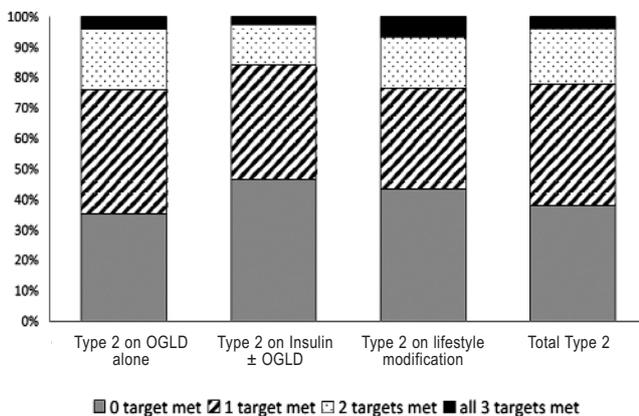


FIGURE 3

Number of target(s) met per patient subpopulation

control. Patients should be empowered, as recommended by several international guidelines, to perform their own injections and adjust their insulin dose according to glycemic level. Insulin titration is at the center of effective insulin treatment and should therefore be reinforced. For adequate insulin titration, patients first need to be compliant to glucose self-monitoring. Although the study showed that patients on insulin had more frequent monitoring, the mean is 17 measurements per month which is insufficient to establish careful monitoring required for safe insulin titration. The importance of PPG in addition to FBG monitoring and control should be stressed upon and highlighted to the patients. Self-monitoring rates in Lebanon were shown to be above the international rate of 32% [6].

Internationally, glycemic control is achieved for 20-40% [6] of patients with type 2 diabetes. In Lebanon, 29.6% of the patients achieved the recommended target of HbA1c < 7%.

Patients at target had a more regular and frequent HbA1c monitoring regimen than patients who were not controlled. In the IDMPS sample, similarly to previous studies [2], only 30% of type 2 diabetics have reached the target HbA1c and were thus considered to have adequate glycemic control. From the collected HbA1c values, patients taking insulin were less controlled than patients on OGLD alone, with a majority of the insulinized patients with HbA1c > 8%. The lack of control of insulinized patients may be attributed to the delay in initiating insulin therapy. Patients initiating insulin therapy had been diagnosed with diabetes for more than 14 years, treated with lifestyle intervention, one and two or more OGLD and then started on insulin. Another reason might be inadequate titration of insulin therapy by the physician and/or the patient. Current ADA/EASD guidelines recommend initiation of basal insulin therapy as a second step option for patients failing metformin therapy. For patients on OGLD with or without insulin therapy, control was noted to be worse in patients who do not self-monitor their glucose levels. Reasons for not reaching glycemic target included non compliance to lifestyle modification (48.2%), followed by poor diabetic education in 28% of patients. Lack of efficacy of current treatment was one of the reasons for not reaching target in 26.8% of the patients. Other reasons impairing disease control were fear, non compliance and suboptimal education. The IDMPS portrays the importance of patient empowerment with regards to education about the disease, complications, management and control. The three main targets for diabetes control were not reached in most of type 2 patients (97.3%). This finding should alarm physicians to monitor blood pressure and lipid profile in addition to HbA1c as a mandatory part of their routine diabetic care.

### CONCLUSION

Despite presence of international guidelines and recommendations for the treatment of diabetes, and abundance

of treatment options, the majority of the diabetes patients in Lebanon remain with an uncontrolled disease. Tight control of diabetes would reduce the overall morbidity and mortality for Type 2 diabetics [10-11]. Improving education and promotion of a healthy lifestyle can help patients achieve a better control of their disease. Education about insulin, its role in the management of diabetes in a timely manner and titration would aid both the physician and the patient to achieve better results. Self-monitoring of blood glucose at home is an essential element of the treatment for insulinized patients. Awareness on the disease and its proper management should be an integrated, continuous process involving the patient, physician and educators, for a better outcome of the patient.

#### ACKNOWLEDGEMENTS

This study was supported by Sanofi-Aventis. We would like to thank them for the help, support and providing the data needed for this publication.

CONFLICT OF INTEREST: Sami Azar is on the advisory board for Sanofi-Aventis. Mohammed Naja, Marie-Therese Sawaya, Fariha Younes are employed by Sanofi-Aventis.

#### REFERENCES

1. <http://www.diabetesatlas.org/map>
2. Akel M, Hamadeh G. Quality of diabetes care in a university health center in Lebanon. *International Journal for Quality in Health Care* 1999; 11 (6): 517-21.
3. Kristensen JK, Bak JF, Wittrup I et al. Diabetes prevalence and quality of diabetes care among Lebanese or Turkish immigrants compared to a native Danish population. *Primary Care Diabetes* 2007; 1: 159-65.
4. Hirbli KI, Jambeine MA, Slim HB et al. Prevalence of diabetes in Greater Beirut. *Diabetes Care* 2005, 28 (5): 1262.
5. Gagliardino JJ. Results on the International Diabetes Management Practices Study (IDMPS), year 2: Compliance with the International Guidelines of the Management of Patients with Type 2 Diabetes. Amsterdam: EASD Conference Abstract, 2007.
6. Chan JCN, Gagliardino JJ, Bail SH et al. Multifaceted determinants for achieving glycemic control: the International Diabetes Management Practice Study (IDMPS). *Diabetes Care* 2009; 32: 227-33.
7. Ringborg A, Cropet C, Jonsson B et al. Resource use associated with type 2 diabetes in Asia, Latin America, the Middle East and Africa: results from the International Diabetes Management Practices Study (IDMPS). *International Journal of Clinical Practice* 2009; 63 (7): 997-1007.
8. American Diabetes Association. Implications of the United Kingdom Prospective Diabetes Study. *Diabetes Care* 2003; 26: S28-S32.
9. Nathan DM, Buse JB, Davidson MB et al. Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy: A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2009; 32 (1): 193-203.
10. The DCCT Research Group, Bethesda, Maryland. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. *New England Journal of Medicine* 1993; 329: 977-86.
11. UK Prospective Diabetes Study (UKPDS) group. Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications with subjects with type 2 diabetes (UKPDS 33). *The Lancet* 1998; 352: 837-53.