Quality of life in type 2 diabetes patients under intensive multitherapy

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Abstract

Aim. – To assess the impact of an intensive multitherapy (IMT) on perceived quality of life (QOL), attitudes, knowledge and diabetes self-management in patients with poorly controlled type 2 diabetes.

Methods. – A 12-month randomized trial was conducted in 72 patients with type 2 diabetes, HbA\textsubscript{1c} ≥ 8%, blood pressure (BP) > 130/80 mmHg and dyslipidemia. Subjects were assigned to the IMT or control group, each \( n = 36 \). IMT consisted in monthly visits including clinical and biochemical assessment, education sessions on diet, physical exercise, medical management of diabetes and associated diseases and adjustments in medication. Control patients were under the care of their physicians. We developed and validated a diabetes-specific questionnaire assessing QOL, attitudes, knowledge, diabetes self-management and socio-demographic data for this study. Outcomes were measured at 0, 6 and 12 months.

Results. – Subjects were 54.8 ± 8.1 years old (duration of diabetes: 10.3 ± 7.2 years). At baseline, questionnaires showed no difference in QOL between groups. At 12 months, QOL improved significantly in the IMT group when compared to controls (+13.2 ± 10.3/+5.6 ± 13.2%, \( p = 0.003 \)), particularly with respect to the satisfaction scale (+25.3 ± 13.9/+5.4 ± 21.7%, \( p < 0.001 \)). QOL was not affected by complications or hypoglycaemic episodes. QOL scores improved in IMT subjects who began insulin therapy during the trial. Attitude scores, in the high normal range at baseline, did not change. Knowledge (+18.2 ± 26.3/+8.9 ± 30.4%, \( p = 0.047 \)) and diabetes self-management (+22.6 ± 35.3/+6.8 ± 20.1%, \( p < 0.001 \)) improved.

Conclusions. – In poorly controlled subjects, QOL improved statistically despite the inherent constraints imposed by IMT.

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Résumé

Qualité de vie des diabétiques de type 2 sous traitement intensif multifactoriel.

Objectif. – Évaluer, chez des patients diabétiques (type 2) mal contrôlés, l’impact d’un traitement intensif multifactoriel sur la qualité de vie, les attitudes, les connaissances et la prise en charge du traitement.

Méthodes. – Une étude randomisée de 12 mois a été effectuée chez 72 sujets diabétiques de type 2 (HbA\textsubscript{1c} ≥ 8%, pression artérielle ≥ 130/80 mmHg et dyslipidémie). Un questionnaire spécifique a été développé et validé pour analyser (à 0, 6 et 12 mois) les quatre sphères citées ci-dessus ainsi que les variables sociodémographiques des participants. Les 36 sujets du groupe traitement intensif multifactoriel devaient suivre un régime et un programme d’exercices physiques ; ils étaient vus tous les mois (prises de sang, éducation portant sur le régime, l’exercice physique, la gestion du diabète et des maladies associées, ajustements et/ou augmentation de médications). Les patients du groupe témoin bénéficiaient du suivi habituel, avec bilan biologique à 0, 6 et 12 mois.

Résultats. – Au début de l’étude, les patients étaient âgés de 54,8 ± 8,1 ans (durée du diabète : 10,3 ± 7,2 ans) et il n’y avait aucune différence entre les groupes. À 12 mois, la qualité de vie s’est améliorée dans le groupe traitement intensif multifactoriel comparativement au groupe témoin (+13,2 ± 10,3/+5,6 ± 13,2 %, \( p = 0,003 \)), en particulier pour l’échelle de satisfaction (+25,3 ± 13,9/+5,4 ± 21,7 %, \( p < 0,001 \)). Ces résultats ont été retrouvés chez les participants qui ont débuté l’insuline durant l’étude. La qualité de vie n’a pas été affectée par les complications ni les hypoglycémies. Le score des attitudes, élevé au début de l’étude, est resté stable. Les connaissances (+18,2 ± 26,3/+8,9 ± 30,4 %, \( p = 0,047 \)) et la prise en charge du traitement (+22,6 ± 35,3/+6,8 ± 20,1 %, \( p < 0,001 \)) ont progressé.

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Conclusion. – Chez les diabétiques de type 2 mal contrôlés, le traitement intensif multifactoriel améliore la qualité de vie malgré les contraintes inhérentes au traitement.

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Keywords: Type 2 diabetes; Quality of life; Intensive multitherapy

Mots clés : Diabète de type 2 ; Qualité de vie ; Traitement intensif multifactoriel

1. Introduction

Glycaemic control [1] as well as reducing blood pressure (BP) [2] and lipoprotein concentrations [3] are three major therapeutic objectives for prevention of target organ damage and other complications arising from diabetes. Studies have shown that a comprehensive and aggressive management approach is effective in decreasing the rate of progression of cardiovascular complications [1,4]. Intensive multitherapy (IMT), requiring substantial patient self-participation, is often necessary and therefore currently recommended [5,6]. Accordingly, patients must deal with diabetes and associated diseases, making countless decisions in an effort to approximate the non-diabetic metabolic state on a day-to-day basis [7]. Importantly, the heavy psychosocial burden of living with diabetes can affect self-care behavior and quality of life (QOL) [8,9] as well as the long-term risk of developing complications. Surprisingly, the perceived impact of a rigorous IMT on QOL has never been thoroughly explored in patients with poorly controlled type 2 diabetes.

We hypothesized that in patients with poorly controlled type 2 diabetes, a 12-month IMT program could improve QOL despite the constraints of the intervention. To address this question in a French-speaking population, a 5-section diabetes-specific questionnaire assessing QOL, attitudes, knowledge, diabetes self-management and socio-demographic data was developed and validated. The trial was conducted in subjects presenting without stringent complications, although at very high risk for microvascular and macrovascular events, [3,10,11] in order to assess the effects and feasibility of an IMT program in a subset of the vast population of patients with poorly controlled type 2 diabetes commonly treated by family practitioners and endocrinologists.

2. Methods

2.1. General design of the study

The design of this 12-month randomized controlled trial was reported in detail previously [12]. Briefly, sedentary patients aged 30-70 yrs with poorly controlled type 2 diabetes (HbA1c ≥ 8%), high BP and dyslipidemia were randomized to the IMT group or the control group (conventional treatment by physician). Therapeutic goals were HbA1c < 7%, BP < 130/80 mmHg, LDL-C < 2.5 mmol/l, ratio cholesterol/HDL < 4.0 and triglycerides < 1.5 mmol/l [5].

The components of intensive multitherapy were: 1) monthly visits including individual and group education on diet, physical exercise, medical management of diabetes, hypertension and dyslipidemia, in addition to measurement of clinical and biochemical variables; 2) between visits, patients were asked to monitor their blood glucose at least twice daily, to go through their home-based physical exercise routine using provided stationary bicycle, elastic exercise band and Polar heart rate monitor (Polar Electro Inc, Woodbury, NY), and to follow diet recommendations; 3) patients received 2 inter-visit phone calls for therapy adjustments, motivational support and feedback information on tests results; 4) three months into the study, when intervention focused on lifestyle habits, pharmacological therapy was introduced or increased as needed [12]. Following optimization of treatment with oral hypoglycaemic agents (OHA), bedtime NPH insulin was introduced if HbA1c remained ≥ 7%. Thereafter, as in subjects already taking insulin, the type of insulin, number of injections and dosages were adjusted. To control high BP, ACE inhibitors were used as first line therapy, with other hypotensive agents added as needed. Statins and/or fibrates were prescribed to control lipid abnormalities. In all cases, optimal dosages and number of pills were given with the full consent of subjects.

Subjects in the control group remained under care of their primary care physician and/or endocrinologist. For ethical considerations, they were given general health and diabetes advice at each of the three outcome measurement visits (0, 6 and 12 months).

Following each visit, clinical (weight, BMI, BP) and all biochemical results were communicated over the telephone to patients from both groups and mailed with recommended guidelines [5] to their physicians. Moreover, a summary of all prior results were handed over to each participant during their subsequent visit.

The study protocol was duly approved by the institutional ethics review board at the Centre Hospitalier Universitaire de Sherbrooke. All subjects gave written informed consent in accordance with applicable laws and regulations, prior to participation in the study.

2.2. Data collection

Because a suitable instrument validated in French was not available at the time this study was designed, a French language 5-section diabetes-specific questionnaire assessing per-
ceived QOL, attitudes, knowledge and diabetes self-management was developed from a combination of well-recognized diabetes-specific instruments and thereafter validated. Original instruments were adapted to Québec’s cultural environment by a committee of experts including 3 nurses, 2 dieticians, 1 psychologist and 3 endocrinologists, all qualified as diabetes educators. Recommendations took into account clinical experience, patient interviews and data from the literature pertaining to the typical concerns of diabetics and the problems impacting their daily life. French translation and validation of the new instrument were performed specifically for this study. Standard forward/backward translation techniques were used to ensure conceptual equivalence [13,14].

1) The QOL section was adapted from the Diabetes Quality of Life (DQOL) questionnaire [15]. This tool was previously adapted in French by Renard [16]. The DQOL is short, easily administered [15,17] and suitable for people with type 2 diabetes [18]. The QOL section consisted of 46 items divided into three sub-sections: patient satisfaction, diabetes impact and diabetes-related worries including anticipated effects of diabetes and social worries. Answers were given on a 5-point Likert scale rated from 1 (very satisfied, no impact, no worry) to 5 (very dissatisfied, very impacted, very worried).

2) The ATT34 questionnaire [19] was used to assess emotional adjustment and attitude of subjects towards their illness including perceived levels of stress, adaptation, guilt, alienation, illness conviction and tolerance (34 items). Subjects rated their agreement or disagreement with each item on a 5-point Likert scale ranging from ‘I disagree completely’ to ‘I agree completely’, with some items with reverse score.

3) The Diabetes Knowledge (DKN) scale [20] was used to assess knowledge in basic physiology of diabetes and insulin action, hypoglycemia, food groups and diabetes management during intercurrent illness. Twenty-two multiple choice questions were retained and only one exact answer per question was allowed, marked as 1 or 0.

4) Finally, since no suitable measure of diabetes self-management was available, a new, self-management section was developed. This tool was based on various expert recommendations [21–23] and comprised 42 multiple choice questions grouped under five sub-sections: diet and weight control, glucose self-testing, compliance to medication (diet, OHA, insulin), lifestyle habits (exercise, smoking, alcohol), and prevention of complications with a particular focus on foot care. Only one exact answer per question was allowed, marked as 1 or 0.

5) Data from the socio-demographic section, reporting on variables influencing outcomes [24–26], are given in Table 1.

The experimental version of the instrument was first tested in an initial set of 10 subjects with type 2 diabetes to assess whether questions were clear and without ambiguity. Then a test-retest (1-month interval) was performed in another group of 36 subjects with type 2 diabetes (19 females), aged 61 ± 9.2 years, duration of diabetes 7.9 ± 6 years, prescribed diet (n = 8), OHA (n = 18), insulin (n = 5), OHA+insulin (n = 5), in order to evaluate reliability and construct validity of the final French version. Content validity of the questionnaire was assessed by a technique combining the Delphi method [27] and nominal groups. Temporal stability of the QOL scale was excellent as shown by an intra-class correlation coefficient of 0.90 (0.81–0.95) [ICC (95% confidence interval)] [28]. Test-retest reliability of each section ranged from very good to excellent [satisfaction: 0.81 (0.66–0.90), impact: 0.86 (0.74–0.93), worries: 0.86 (0.74–0.93), attitudes: 0.75 (0.56–0.86), knowledge: 0.83 (0.69–0.91) and self-management: 0.83 (0.69–0.91)]. Internal consistency was excellent with a Cronbach’s α value of 0.85 for the questionnaire as a whole, and values of 0.82, 0.84, 0.76, 0.77 and 0.85 for satisfaction, impact, worries, attitudes and knowledge subscales, respectively [29].

In conclusion, this questionnaire provides a specific, reliable and valid measure of QOL and related variables in patients with type 2 diabetes, regardless of treatment regimen. To our knowledge, this is the first French language diabetes-specific instrument assessing QOL, attitudes, knowledge and self-management. The questionnaire is available free of charge for academic use, all rights are otherwise reserved. The instrument

Table 1. Clinical and socio-demographic characteristics of patients

<table>
<thead>
<tr>
<th></th>
<th>IMTG (n = 36)</th>
<th>CG (n = 36)</th>
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</thead>
<tbody>
<tr>
<td>Age (yrs)*</td>
<td>53.7 ± 7.5</td>
<td>55.9 ± 8.6</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>27/9</td>
<td>22/14</td>
</tr>
<tr>
<td>Duration of diabetes (yrs)*</td>
<td>10.6 ± 6.7</td>
<td>10.0 ± 7.3</td>
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<tr>
<td>Smoking (n)</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Complications

- Non-proliferative retinopathy 6 3
- Microalbuminuria† 9 5
- Erectile dysfunction 4 2
- Neuropathy† 6 5
- Myocardial infarction§ 2 6
- Stroke 1 1

Total: 28 22

Marital status

- Married 29 27
- Single, widow, separated, divorced 7 9

Employment

- Full- or part-time employed 19 15
- Unemployed 2 3
- Retired 8 12
- Others (at home, disabled) 7 6

Education

- 1-12th grade 21 25
- Specialized course, collegiate, university 15 11

IMTG: intensive multitherapy group; CG: Control group. *Mean ± SD; †30-299 mg/L; §more than 1 year ago.
was self-administered at times 0, 6 and 12 months of our study [12].

2.3. Statistical analysis

Scores of QOL, knowledge and diabetes self-management were arithmetically transformed to a 100-point scale, with 100 reflecting the highest possible score (5 – score × 25), as recommended [17,18]. Accordingly, a high transformed score indicates a positive performance, e.g. a low degree of dissatisfaction, impact or worry, or a high degree of compliance. For attitudes, a score of 34 to 79 reflects a negative and pessimistic attitude, a score of 80 to 125 a positive and optimistic attitude [19].

The similarity of baseline group characteristics was tested using unpaired t-test, Chi² or Fisher’s exact test where appropriate. Associations of demographic, clinical or treatment regimen variables with QOL were tested in all study subjects over the course of the study using Pearson’s correlation and ANOVA with Scheffe’s post hoc test. The groups were compared with respect to change over time in QOL, attitudes, knowledge and self-management using the repeated measures analysis of covariance with baseline values as covariates. All comparisons between treatment and control groups were performed on the basis of “intention to treat”. p values were computed for two-tailed tests at an α level = 0.05. Statistical analysis was performed using SPSS software version 10.0.5 (SPSS INC., Chicago, IL).

3. Results

3.1. At baseline

There was no significant difference between groups (each n = 36) with respect to age, gender, duration of diabetes, lifestyle habits and arrangements, education or occupation (Table 1). Prevalence of minor complications [12] was equally distributed in both groups. QOL, attitude, knowledge and self-management scores did not differ between IMT and control groups (Table 2). As reported elsewhere [12], only 3 subjects (2 in the intervention group and 1 in the control group) were lost to follow-up during the intervention period. Most of the subjects (IMT group: 24, Control group: 31, P = ns) participated in a 4-day education program in the year prior to their entry into the study and 70% (n = 25 in both groups) were under the care of endocrinologists in addition to their general practitioner.

Cross-sectional analyses including all subjects showed that neither duration of diabetes, complications, living alone nor education level were associated with QOL or attitude scores. However, QOL score was correlated with attitude score in each group (IMT: r = 0.646, P < 0.001, Control: r = 0.654, P < 0.001). HbA1c was not correlated with QOL. Subjects treated with insulin had lower QOL scores (64.3 ± 13.1 vs. 70.5 ± 10.0, P = 0.02), were more ‘impacted’ (69.1 ± 14.0 vs. 76.8 ± 12.0, P = 0.02) and more ‘worried’ (68.2 ± 15.8 vs. 76.3 ± 14.7, P = 0.03). Since a higher score indicates a more positive performance, impact of diabetes was lower in men compared to women (76 ± 14 vs. 70 ± 10, P = 0.04) and they showed lower scores for self-management (58.2 ± 9.4 vs. 65.3 ± 8.9, P = 0.003), self-glucose testing (50.0 ± 22.5 vs. 62.3 ± 19.2, P = 0.03) and prevention of complications (41.9 ± 18.5 vs. 62.3 ± 20.6, P < 0.001) scales. Subjects aged 50-yrs or more (n = 53, e.g. 74% of our population) demonstrated better QOL (70.0 ± 12.1 vs. 63.5 ± 8.0, P = 0.03), satisfaction (61.8 ± 14.3 vs. 48.4 ± 8.7, P < 0.001), attitudes (115.6 ± 14.0 vs. 105.6 ± 15.2, P = 0.01) and self-management scores (62.1 ± 9.4 vs. 55.8 ± 9.8, P = 0.02) compared to younger subjects (all P < 0.05). Subjects (n = 36) with one or more complications had better scores on self-management (63.0 ± 11.0 vs. 58.1 ± 8.0, P = 0.04) and prevention of complications scales (54.0 ± 21.0 vs. 42.5 ± 20.2, P = 0.003).

Table 2

<table>
<thead>
<tr>
<th>QOL, attitudes, knowledge and diabetes self-management over the course of the study (0, 6 and 12 months)</th>
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<tr>
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<tr>
<td>IMTG (n = 34)</td>
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<tr>
<td>Quality of life**</td>
</tr>
<tr>
<td>Satisfaction</td>
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<tr>
<td>Impact</td>
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<tr>
<td>Diabetes-related worry</td>
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<td>Attitudes*</td>
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<td>Knowledge*</td>
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<td>Diabetes self-managementa</td>
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<td>Diet and weight control</td>
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<td>Glucose self-testing</td>
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<td>Medication</td>
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<td>Lifestyle habits</td>
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<tr>
<td>Prevention</td>
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</table>

** Mean ± SD.

b P < 0.05 within group.

c P < 0.001 within group.

d Change over time between groups. For QOL, knowledge and diabetes self-management, score ranges from 0 to 100. Higher score reflects positive performance.
Higher education was associated with better knowledge (73.4 ± 11.8 vs. 57.0 ± 20.8, \( P < 0.001 \)).

At baseline, no difference was observed between the two groups (IMT/Control) for clinical or biochemical data (HbA1c 9.1 ± 1.0/9.3 ± 1.0%, systolic BP 144 ± 21/143 ± 17 mmHg, diastolic BP 85 ± 11/86 ± 10 mmHg, LDL-C 3.2 ± 1/3.0 ± 1.2 mmol/l, ratio cholesterol/HDL 6.4 ± 2.2/6.0 ± 2 and triglyceride 3.1 ± 3.1/3.6 ± 2.4 mmol/l) and therapies [12].

Normal values in our laboratory are: HbA1c: 4–6\%,

LDL-C: 2.0–3.4 mmol/l, and triglyceride: 0.6–2.3 mmol/l.

### 3.2. Effect of IMT

Over the course of the study, QOL improved significantly in both groups, but improvement was significantly greater in the IMT compared to the control group (13.2 ± 10.3 vs. 5.6 ± 13.2\%, \( P = 0.003 \), Table 2). Although the 3 subscale scores (satisfaction, impact and worry) improved over time, only changes in satisfaction subscale were statistically significant (25.3 ± 13.9 vs. 5.4 ± 21.7\%, \( P < 0.001 \)). Interestingly, 10 IMT subjects who started insulin therapy during the study showed improvement in QOL (+8.2 ± 8.0\%, \( P = 0.012 \)) and satisfaction (+14.4 ± 11.2\%, \( P = 0.005 \)). Improvement of HbA1c was not correlated with QOL at the end of the study, whether within each group or within the cohort as a whole. The number of patients (n = 15) who had at least one minor episode of hypoglycaemia and the frequency of hypoglycaemic events/patient/month (IMT: 1.7, control: 1.9) were similar in both groups. QOL was not associated with hypoglycaemia at 0, 6 or 12 months. Relationship between variables of QOL (patient satisfaction, diabetes impact and diabetes-related worries), attitudes, knowledge, variables related to diabetes self-management (diet and weight control, glucose self-testing, compliance to medication, lifestyle habits and prevention of complications and foot care) and HbA1c were examined. We found no significant correlation for the difference of change in QOL at 12 months in both groups.

Attitude scores were in the ‘high normal’ range at baseline in both groups and did not change significantly over the course of the study. However, at 12 months, a positive relationship between QOL and attitude was observed in both groups (IMT: \( r = 0.72, P < 0.001 \), control: \( r = 0.59, P < 0.001 \)). Furthermore, changes in QOL from baseline to 12 months were correlated with attitudes (\( r = 0.35, P = 0.004 \)) when all subjects were included in the analysis.

Knowledge scores increased in both groups, in particular in IMT patients (Table 2).

Diabetes self-management improved in the IMT group, but not in controls, mainly owing to the upgrading of scores on 3 sub-sections: glucose self-testing, prevention of complications and, to a lesser extent, lifestyle habits (Table 2).

Clinical and biochemical variables were reported previously [12]. While weight remained stable, at 12 months, changes (IMT group/Control group) were significant \( (P < 0.05) \) for HbA1c \(-1.6 ± 1.1/–0.7 ± 1.3\%\), systolic BP \(-14 ± 19/–2 ± 17 \text{ mmHg}\), ratio cholesterol/HDL \(-1.6 ± 1.8/–0.2 ± 1.5\) and triglyceride \(-1.0 ± 2/–0.05 ± 2 \text{ mmol/l}\).

### 4. Discussion

This prospective study showed that quality of life improved significantly in subjects with poorly controlled type 2 diabetes receiving intensive multitherapy, despite the constraints of such an intervention on sedentary subjects.

Our results differ from others’ reporting that intensive therapies had no or little detrimental effect on QOL [9,17]. The clinical significance of our statistical data could be debated; lack of strong published data precludes a clear interpretation in this regard. Nevertheless, significant improvement in satisfaction, low rate of withdrawals and compliance to all facets of the study (visits, biochemical tests, diet and physical exercise) [12], all point to acceptance and feasibility of the proposed IMT program. In addition, contrary to other studies [17], volunteers were not carefully selected for their level of motivation. Subjects included in this study were similar to the majority of day-to-day clinical practice patients followed by general practitioners and endocrinologists. They were obese, sedentary, hypertensive, dyslipidemic and had inadequate control of their diabetes. They were not highly educated and came from various social classes. Accordingly, the external validity of the present study is considered as good, suggesting that IMT may be proposed without undue concern as to adverse effects on QOL. This is of particular relevance in view of alarming data published recently with respect to the worsening of glycaemic control in the US diabetic population between 1988 and 2000 [30]. In summary, our data suggest that IMT is acceptable and does not entail quality of life deterioration.

Small changes in QOL and satisfaction scales observed in the control group may be explained by the fact that control subjects may have received better than usual conventional treatment. Indeed, controls benefited from general health and diabetes advice from the team at each visit and were informed of clinical and biochemical results, over the phone, within the week following each visit. Moreover, physicians received clinical and biochemical evaluations of their patients on a regular basis. Therefore, this difference in care may have influenced overall perceptions of subjects.

Improvement in QOL was not related with attitude or knowledge. The stability observed over the course of the study with regard to impact, diabetes-related worry and attitude scores was unexpected. Different interpretations may explain, at least in part, those results. Firstly, at baseline, scores indicated very little diabetes-related impact or worry in our study subjects [15] and the attitude score reflected a high normal attitude about diabetes. Such positive dispositions at baseline did not entail quality of life deterioration.

Secondly, the study was conceivably too short in duration. It is recognized that changes in attitude occur over long periods of time [19,32]. Nevertheless, a change in QOL was positively associated with attitude when all sub-

jects were included in the analyses, confirming that attitude does play a role in QOL, as well as other unmeasured variables such as personality traits [19,33], coping skills [33] and motivation [34].

There is ongoing debate as to the relationship between glycaemic control and QOL. Some reports have shown a parallel between these variables while others have not [9,35,36]. Our data demonstrated an absence of effect of glycaemic control on QOL. This may be related to the use of a questionnaire specific to diabetes. A generic QOL tool would contain measures of little relevance for individuals with diabetes and would omit several critical aspects of a diabetic’s day-to-day life, such as self-monitoring of blood glucose, dietary restrictions, insulin injections or hypoglycaemia [7]. Our highly specific questionnaire takes into account these QOL issues.

Complications [8,9] and their severity [18] have previously been associated with worsened QOL. By contrast, our results did not show any of these correlations, in accordance with other reports [9,35,36]. The main reason is likely due to our study’s exclusion criteria: our subjects had only mild complications as we endeavored to recruit subjects representative of the typical population of patients with type 2 diabetes.

Insulin therapy is usually associated with a greater negative impact on QOL than other therapies [8,18]. Such an impact may be related to the higher prevalence of co-morbidities and complications observed in insulin-treated patients rather than to the type of medication per se [18]. However, other studies contradict these conclusions [35,36]. In our study, subjects taking insulin at baseline had indeed a worse QOL than subjects taking OHA only. However, those who started insulin therapy during the study reported an improvement in QOL, suggesting that subjects were receptive to motivational support and education, two essential components of diabetes care [37].

The improvement in diabetes self-management is certainly one key to improving the quality of diabetes control. Subjects were informed and invited to adapt lifestyle and to control medications. They may have used this empowerment as indicated by the results in glucose self-testing, lifestyle habits and prevention scores.

The role of the clinical team members (2 endocrinologists, 1 nurse, 1 dietician, 1 fitness trainer and study coordinator), their availability and motivation may have promoted a sense of well-being secondary to the high level of support, as in the DCCT [17]. This is illustrated by the rapid deterioration of clinical outcomes following the discontinuation of this trial: within 6 months after the end of the intervention, in which subjects resumed ‘normal care’, weight, HbA1c and systolic BP increased significantly [12]. Decreased physical activity is a probable explanation as suggested by negative correlations between time devoted to exercise and weight or systolic BP [12]. Such patients may require a less intensive “maintenance” intervention to promote behavioral changes over time. Our results may also depend on the number of team-subject interactions, i.e. monthly visits and multiple telephone calls. To our knowledge, the impact of the frequency of these contacts has not been studied in depth. However, given the burden of diabetes, the cost efficiency of such possible management should be explored. Finally, aside from the role of the team, improvement in clinical and biochemical parameters and low incidence of severe hypoglycaemia could partly explain the QOL findings, as previously argued [9].

In summary, intensive management may be recommended in patients with poorly controlled type 2 diabetes, as shown by the QOL and satisfaction scores in our study. Patients are able to cope with the intensity of multitherapy, in spite of the inherent constraints of such multifaceted interventions.

Acknowledgements

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References