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# Impact of Intensive Therapy With Continuous Subcutaneous Insulin Infusion on Quality of Life in Patients With Type 1 Diabetes

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The purpose of this research was to study the effects of treatment with continuous subcutaneous insulin infusion (CSII) on quality of life in patients with type 1 diabetes. A quasi-experimental pretest-posttest design was used. Thirty-seven patients were evaluated before and after receiving treatment. The Diabetes Quality of Life Questionnaire, Beck Depression Inventory-II, State-Trait Anxiety Inventory, and Multidimensional Health Locus of Control Scale were applied. Patients treated with CSII reported a significant improvement in their quality of life (better total quality of life, higher diabetes life satisfaction, and less social and vocational concerns) when compared with patients with Multiple Daily Injections. Although some limitations are described, the results of this study show some evidence of positive effect of pump therapy in patients with poor glycemic control prior to pump start.

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## Introduction

At present, long-term management of diabetes continues to be a challenge for the patient, his family, and the healthcare team. Tight glycemic control is critical in the treatment of diabetes and its benefits are well known. The "*Diabetes Control and Complications Trial*" (The Diabetes Control and Complications Trial Research Group, 1993), conducted from 1983 to 1993, highlighted that intensive therapies lead to better glycemic control than conventional treatments, more effectively delaying the development and progression of microvascular complications (retinopathy, nephropathy, and polyneuropathy). However, these patients presented a higher risk (two to threefold greater) of severe episodes of hypoglycemia.

Following this trial, many studies have been carried out comparing metabolic results and potential risks between continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI). The published results show that CSII is associated with significant improvement in glycemic control with respect to treatment with MDI (Bell & Ovalle, 2000; Bode, Steed, & Davidson, 1996; Colquitt, Green, Sidhu, Hartwell, & Waugh, 2004; Hoogma et al., 2006; Pickup, Mattock, & Kerry, 2002; Retnakaran et al., 2004; Weissberg-Benchell, Antisdel-Lomaglio, & Seshadri, 2003). With regard to potential complications (hypoglycemia, ketoacidosis, poor functioning, and local infection), the results of these studies both indicate that CSII therapy decreases the frequency of severe episodes of hypoglycemia in adults, adolescents, and children (Bode et al., 1996; Boland, Grey, Oesterle, Fredrickson, & Tamborlane, 1999; Chantelau, Schiffers, Schutze, & Hansen, 1997; Haakens et al., 1990; Hoogma et al., 2006; McMahon et al., 2005), and that there is no association with an increase in episodes of ketoacidosis (Bode et al.; Boland et al.; Chantelau et al.; Colquitt et al., 2004; The Diabetes Control and Complications Trial Research Group, 1995; Haakens et al.; Hoogma et al.; McMahon et al.; Pickup et al., 2002; Retnakaran et al., 2004; Weissberg-Benchell et al., 2003). Furthermore, thanks to technological advances in these insulin infusion systems, episodes of device failure and catheter occlusion, as well as secondary infections of the insertion site, decreased significantly (Weissberg-Benchell et al.).

On the other hand, it must be kept in mind that, although intensive treatment regimens like MDI and CSII have experienced great advances from a technological standpoint and have increased life expectancy in people with diabetes, the requirements in self-care have also increased. These greater demands pose a challenge for all professionals involved in the treatment of diabetes (Schiffrin, Desrosiers, Mofflatt, & Belmonte, 1983) which is to be able to meet the specific medical needs of the patient with diabetes without any detrimental effect on the patient's quality of life. In this context, we must consider the concept of "quality

of life" defined by the World Health Organization (The World Health Organization Quality of Life Group, 1994) as *the perception of physical health, psychological state, level of independence, social relationships, personal beliefs and relationship to salient features of the environment* (Schalock & Verdugo, 2003). The construct "health-related quality of life" (HRQL) is derived from this concept. Some authors have defined HRQL as *the different life issues of a person that are affected by changes in the health state* (Schalock & Verdugo) or as *the impact of disease and treatment on physical, emotional and social well-being* (Cella et al., 1999).

This theoretical impulse within the framework of quality of life has influenced investigators in the field of diabetes who are not satisfied with simply measuring the indices of glycosilated hemoglobin (HbA1c) as the therapeutic target, broadening their interests to include the evaluation of the perception of the individual regarding his/her disease, its consequences and treatment as a key element in understanding and comprehensively measuring therapeutic objectives (Mora et al., 2005). Thus, in the 1990s, the need to develop instruments to measure HRQL emerged (The World Health Organization Quality of Life Group, 1994).

In this way, the Diabetes Control and Complications Trial (DCCT) study (The Diabetes Control and Complications Trial Research Group, 1993) was a pioneer in evaluating quality of life in patients with diabetes treated with conventional treatments and intensive therapy utilizing the *Diabetes Quality of Life* (DQOL). Although no significant differences in quality of life between the two groups (conventional and intensive therapies) were found in this study, the DCCT findings caused an important change in diabetes research. Since then, an improvement in quality of life came to be considered as one of the principal goals of diabetes treatment and its measurement a clear objective in the evaluation of treatments (Mora et al., 2005).

Therefore, this study marked a milestone in the field of diabetes intervention and became the starting point for subsequent research attempting to analyze whether intensive treatment with CSII improves quality of life in patients with type 1 diabetes mellitus. To date, research on this subject has produced the following results: patients treated with CSII present improvement in quality of life (Kamoi, Miyakoshi, & Maruyama, 2004; Linkeschova, Raoul, Bott, Berger, & Spraul, 2002), and specifically, greater leisure time flexibility and less worry about the future and dietary restrictions (Bott, Muhlhauser, Overmann, & Berger, 1998), less interference with daily activities, less worry about diabetes and social burden, as well as greater treatment satisfaction and psychological well-being, both in patients with type 1 and type 2 diabetes (Peyrot & Rubin, 2005), in adults (Bruttomesso et al., 2002; Hoogma et al., 2006; Rodrigues, Reid, Ismail, & Amiel, 2005), as well as in children and adolescents (Fox, Buckloh, Smith, Wysocki, & Mauras, 2005; Litton et al., 2002; Mednick, Cogen, & Streisand, 2004; Weissberg-Benchell et al., 2003).

Nonetheless, several authors did not find improved quality of life in patients treated with CSII, in either adults (Chantelau et al., 1997; Hoogma et al., 2004; Tsui, Barnie, Ross, Parkes, & Zinman, 2001), or in children and adolescents (O'Neil, Jonnalagadda, Hopkins, & Kicklighter, 2005; Pickup et al., 2002; Valenzuela et al., 2006; Weintrob et al., 2003; Wilson et al., 2005).

In keeping with the suggestions of some authors (Barnard, Lloyd, & Skinner, 2007; Weissberg-Benchell et al., 2003), further investigation in this subject is needed as, although there is heightened interest in the repercussions of CSII treatment on psychosocial response, fewer studies exist on this topic than on metabolic results. Thus, despite the fact that quality of life in patients with type 1 diabetes mellitus improves with good metabolic control (Delamater et al., 2001; Guttmann-Bauman, Flaherty, Strugger, & McEvoy, 1998), there is scarce investigation in this area.

The aim of this research, which contributes new empirical evidence, is to study the effects of CSII treatment on quality of life in adult patients with type 1 diabetes. Considering the scientific literature, we put forth the following hypothesis: "*patients with type 1 diabetes mellitus treated with CSII will have better quality of life than those treated with MDI.*"

## Method

A quasi-experimental pretest-posttest design with a study group (CSII) and a nonequivalent control group of patients with type 1 diabetes mellitus in intensive treatment with MDI was used in this work. In conducting this study, the recommendations of the *Helsinki Declaration of the World Medical Association* (1964–2008) were followed. The study received a positive report from the Hospital Ethics Committee.

### *Study Sample*

Respondents were from an initial pool of 91 patients treated with MDI who had been invited to take part in a study evaluating quality of life in patients with type 1 diabetes. Seventy-eight (86%) patients (39 men and 39 women) agreed to take part and were screened to establish their health status. Their ages ranged from 16 to 60 years ($M = 30.53$, $SD = 1.08$). No significant differences were found between the patients who originally agreed to participate and those who refused to take part in the study ($p > .05$).

The study group (Group 1) consisted of 33 patients with type 1 diabetes (13 men and 20 women), seen in the Diabetes Unit of the Endocrinology Department of Carlos Haya Regional University Hospital of Malaga (south of Spain) in order to receive intensive treatment with CSII. These patients were selected for transition to the pump according to indications of the *Andalusian Health Service*

published in the *Official Bulletin of the "Junta de Andalucía*" (BOJA.RSC 566/03). The control group (Group 2) consisted of 45 patients with type 1 diabetes (26 men and 19 women) seen in the Diabetes Unit of the Carlos Haya Regional University Hospital for monitoring of their disease through scheduled appointments and under treatment with MDI in whom treatment with CSII was not indicated. Patients in both groups participated voluntarily in the current study after receiving detailed information regarding the nature of the research and signing an informed consent. The inclusion criteria were the following: patients with type 1 diabetes in intensive multidose treatment with more than 2 years evolution, over age 14, and a C peptide less than .5 ng/mL. Exclusion criteria were: patients with type 2 diabetes, type 1 diabetes in conventional treatment (one or two injections/day), and incapacitating psychological disorders. Once included in the study, the installation and use of the insulin pump was explained to patients in Group 1 in detail.

Group 1 patients had an average age of 31.09 years ($SD = 11.16$). These patients had an HbA1c of 8.62 ($SD = 1.73$) and a mean of .72 ($SD = 1.12$) severe hypoglycemias (last 6 months). The duration of diabetes was 14.82 years ($SD = 7.35$). Five patients had retinopathy and one had polyneuropathy.

Group 2 patients had an average age of 30.11 years ($SD = 10.33$). These patients had an HbA1c of 7.17 ($SD = 1.08$) and a mean of 1.32 ($SD = .47$) severe hypoglycemias (last 6 months). The duration of diabetes was 10.60 years ($SD = 8.11$). One patient had nephropathy and another polyneuropathy. The demographic characteristics of both patient groups are shown in Table 1.

### *Instruments*

Patients from both groups were interviewed regarding socio-demographic variables (age, education level, occupation, etc.). Subsequently, quality of life was evaluated using the DCCT Research Group DQOL questionnaire (The Diabetes Control and Complications Trial Research Group, 1988) adapted to the Spanish population (Millán, Reviriego, & del Campo, 2002). This tool specifically assesses quality of life in people with diabetes. It is composed of 43 items distributed in four dimensions: "Diabetes Life Satisfaction" (15 items), "Diabetes Impact" (17 items), "Social/vocational concerns" (7 items), and "Worry about long-term complications of diabetes" (4 items). Each item has five Likert-type response options ranked on a scale of 1 to 5. In the satisfaction subscale, the answers to each item range from "very satisfied" (1 point) to "not at all satisfied" (5 points). In the other three subscales, the answers range from "never" (1 point) to "always" (5 points). A total rating and a rating by subscale may be obtained. Additionally, it must be kept in mind that a *lower score implies better quality of life*. It is designed to be self-administered. The reliability and validity data of the questionnaire given by the authors are adequate. In our study, we found, as did the

Table 1

*Demographic Characteristics of Group 1 and Group 2*

| | Group 1 (CSII) | | Group 2 (MDI) | |
|---|---|---|---|---|
| | *n* | % | *n* | % |
| Occupation | | | | |
| Employed | 19 | 57.6 | 25 | 55.6 |
| Unemployed | 3 | 9.1 | 3 | 6.7 |
| Retired | 0 | 0 | 2 | 4.4 |
| Sick leave | 0 | 0 | 1 | 2.2 |
| Homemaker | 3 | 9.1 | 4 | 8.9 |
| Student | 8 | 24.2 | 10 | 22.2 |
| Marital status | | | | |
| Single | 17 | 51.5 | 23 | 51.1 |
| Married | 11 | 33.3 | 19 | 42.2 |
| Separated | 2 | 6.1 | 1 | 2.2 |
| Divorced | 1 | 3.0 | 0 | 0 |
| Widowed | 1 | 3.0 | 1 | 2.2 |
| Unmarried couple | 1 | 3.0 | 1 | 2.2 |
| Level of education | | | | |
| Basic reading and writing | 0 | 0 | 4 | 9.1 |
| Primary school studies | 11 | 33.3 | 22 | 50.0 |
| High school studies | 8 | 24.2 | 10 | 22.7 |
| Vocational training | 1 | 3.0 | 3 | 6.8 |
| Bachelor's degree | 5 | 15.2 | 2 | 4.5 |
| Master's degree | 8 | 24.2 | 3 | 6.8 |

CSII = continuous subcutaneous insulin infusion; MDI = multiple daily injections.

authors of the original scale, adequate internal consistency (DQOL-Diabetes Life Satisfaction, $\alpha = .68$; DQOL-Diabetes Impact $\alpha = .87$; DQOL-Social-vocational concerns $\alpha = .70$; DQOL-Worry about long-term complications of diabetes $\alpha = .60$; DQOL-Total, $\alpha = .89$).

In addition to quality of life, a baseline and 6-month evaluation of depression, anxiety, and locus of control was included:

- Beck Depression Inventory (BDI)-II: The Spanish version of the BDI—Second Edition (Sanz, García-Vera, Espinosa, Fortín, & Vázquez, 2005) assesses the intensity of depressive symptoms provided by an individual. The instrument is self-administered and consists of 21 items, each with four statements describing the spectrum of severity of symptomatic and behavioral categories evaluated. Scores for each item are assigned a value from 0 to 3 according to the statement that best describes how the patient felt over the past week. A value of 0 indicates absence of depressive symptoms, while a value of 3 describes maximum severity of symptoms. The original instrument and its adaptations to Spanish have shown adequate validity and reliability for use in clinical practice and research (Ramos, 1986; Torres, Hernández, & Ortega, 1991). The BDI has proved to be an effective instrument for depression in people with diabetes and other chronic diseases (Lustman, Griffith, & Clouse, 1997).
- State-Trait Anxiety Inventory (STAI): The Spanish version of the STAI (Seisdedos, 1988) measures state and trait anxiety and consists of 40 items: the first 20 are designed to detect symptoms of anxiety as a transient reaction (state anxiety subscale, STAI-E) and the following 20 look for the presence of persistent features of anxiety (trait anxiety subscale, STAI-R). Items of the STAI-E are answered on a Likert scale ranging from 0 (nothing) to 3 (much), and items of the STAI-R are answered on a Likert scale ranging from 0 (almost never) to 3 (almost always). The STAI has good discriminative validity and internal consistency.
- Multidimensional Health Locus of Control (MHLC): The Spanish version of the MHLC Scale (Chorot & Navas, 1995) assesses where the person places the locus of control (LOC) for their health. This self-report measure is composed of 18 items, of which 6 items measure an internal LOC, and 12 items evaluate an external LOC. The internal LOC is related to the belief that one can overcome the health obstacle or at least control it. On the other hand, the external LOC is related to the belief that control of health and coping with negative events are dependent on external variables such as luck, healthcare team, medication, etc. Items are answered on a Likert scale ranging from 1 (completely disagree) to 6 (fully agree). The authors of the instrument report reliability and validity appropriate for use in clinical practice and research (Wallston & Strudler, 1981).

### *Procedure*

In the study group (Group 1), the baseline evaluation of quality of life was carried out before the patients began intensive treatment with CSII. After baseline evaluation, the patients in the study group received CSII treatment. After 6

months of treatment, these patients were reevaluated following the same protocol as in the baseline evaluation. For the evaluation of Group 2, the same procedure as described for the study group was used, although in this case the patients did not change treatment after basal evaluation.

In Group 2, multiple doses of insulin with mixtures of NPH insulin (slow-acting) and rapid-acting insulin analogs (Humalog, Eli Lilly Inc., Indianapolis, IN, USA) were administered. In Group 1, three models of insulin pumps were used (Spirit [F. Hoffmann-La Roche Ltd., Basel, Switzerland], Paradigm [Medtronic Minimed Inc., Minneapolis, MN, USA], and Animas 1200 [Animas Corp., West Chester, PA, USA]) with rapid-acting insulin analogs (Humalog).

To carry out the statistical analyses, version 16 of the SPSS statistical program for Windows (SPSS Inc., Chicago, IL) was used. The confidence level was 95%.

To test the hypothesis of our study, an analysis of covariance was performed to evaluate the effects (posttest) of the treatments (CSII/MDI) on quality of life, taking into account the influence of the initial state of the patients (pretest) as covariate.

In order to analyze whether there were differences between the groups, the following tests were used. Quantitative variables: Student's *t* test, Mann–Whitney *U*-test, Wilcoxon signed-rank test. Qualitative variables: $\chi^2$ test.

## Results

After 6 months of treatment, 10 patients from Group 1 (CSII) and 31 patients from Group 2 dropped out of the study. No significant differences were found at baseline in Group 1 (CSII), between the patients who completed the full 6 months of treatment, and those who abandoned treatment before completing the 6-month evaluation.

Significant differences were found in Group 2 (MDI): the participants who dropped out of the study had higher scores on anxiety, $z = -2.524$, $p < .05$; and quality of life (social concern subscale, $z = -2.480$, $p < .05$) than those who remained (Table 2). On the other hand, significant differences were found between the two study groups at baseline (Table 3). Patients in Group 1 (CSII) had higher levels of HbA1c, $t(45.574) = 3.401$, $p = .001$; more years with diabetes, $t(76) = 2.359$, $p = .021$; lower external locus of control, $t(74) = -2.072$, $p = .042$; worse quality of life, $t(65) = 2.161$, $p = .034$; and dissatisfaction with treatment, $t(66) = 2.551$, $p = .013$; than patients in group 2. Gender differences were also observed (Table 4). Women had higher scores on depression, $t(73) = -2.032$, $p = .046$, and anxiety, $t(72) = -3.264$, $p = .002$; worse quality of life (subscale of worry about long-term), $t(76) = -2.482$, $p = .015$; and more years with diabetes than men. However, gender differences were not found between the two groups ($\chi^2 = 2.574$; $p = .109$).

Table 2

*Characteristics of the Participants Who Drop Out/Continue the Study in Group 2 (MDI)*

| | Mean rank | $p^a$ |
|---|---|---|
| STAI: State Anxiety | | **.020** |
| Patients who continued | 23.79 | |
| Patients who drop out | 14.25 | |
| STAI: Trait Anxiety | | .338 |
| Patients who continued | 22.23 | |
| Patients who drop out | 18.35 | |
| BDI: Total Score | | .313 |
| Patients who continued | 23.28 | |
| Patients who drop out | 19.04 | |
| DQOL[b]: Diabetes Life Satisfaction | | .839 |
| Patients who continued | 18.24 | |
| Patients who drop out | 19.09 | |
| DQOL[b]: Diabetes Impact | | .170 |
| Patients who continued | 23.17 | |
| Patients who drop out | 17.33 | |
| DQOL[b]: Social and vocational concerns | | **.013** |
| Patients who continued | 26.24 | |
| Patients who drop out | 15.82 | |
| DQOL[b]: Worry about long-term complications of diabetes | | .087 |
| Patients who continued | 25.24 | |
| Patients who drop out | 18.04 | |
| DQOL[b]: Total score | | .287 |
| Patients who continued | 19.18 | |
| Patients who drop out | 15.05 | |
| MHLC: *Internal* | | .362 |
| Patients who continued | 21.30 | |
| Patients who drop out | 25.07 | |
| MHLC: *External* | | .688 |
| Patients who continued | 22.57 | |
| Patients who drop out | 20.82 | |

[a]Mann–Whitney's U test.
[b]A lower score implies better quality of life.
BDI = Beck Depression Inventory; DQOL = Diabetes Quality of Life; MDI = multiple daily injections; MHLC = Multidimensional Health Locus of Control; STAI = State-Trait Anxiety Inventory. Significant scores are in bold.

Table 3

*Characteristics of the Participants in Group 1 and Group 2 at Baseline*

| | Mean | *SD* | *p*[a] |
|---|---|---|---|
| Years with diabetes | | | .021 |
| Group 1 (CSII) | 14.82 | 7.35 | |
| Group 2 (MDI) | 10.60 | 8.11 | |
| HbA1c | | | .001 |
| Group 1 (CSII) | 8.62 | 1.85 | |
| Group 2 (MDI) | 7.17 | 1.08 | |
| DQOL[b]: Total score | | | .034 |
| Group 1 (CSII) | 93.34 | 19.94 | |
| Group 2 (MDI) | 81.85 | 23.23 | |
| DQOL[b]: Satisfaction subscale | | | .013 |
| Group 1 (CSII) | 35.59 | 7.13 | |
| Group 2 (MDI) | 30.27 | 9.67 | |
| External locus of control | | | .042 |
| Group 1 (CSII) | 32.24 | 7.84 | |
| Group 2 (MDI) | 36.09 | 8.17 | |

[a]Student's *t* test.
[b]A lower score implies better quality of life.
CSII = continuous subcutaneous insulin infusion; DQOL = Diabetes Quality of Life; MDI = multiple daily injections.

Significant differences were observed after 6 months of treatment (Table 5). Group 1 showed an improvement in the quality of life of the patients, $z = -2.353$, $p = .019$. While in patients in Group 2, no significant differences were found.

As the previous status of the patients could have influenced the results, a covariance analysis was performed to compare the effects of treatment on the *quality of life* of patients in the posttest in the study group (Group 1) with the control group (Group 2), with the results obtained in the pretest (previous status) taken as the covariate. As seen in Table 6, there was a notable decrease[1] in the

[1]It must be kept in mind that a *lower score implies better quality of life*.

Table 4

*Characteristics of the Participants: Gender Differences*

| | Mean | *SD* | *p*[a] |
|---|---|---|---|
| Years with diabetes | | | .023 |
| Woman | 14.44 | 8.84 | |
| Man | 10.33 | 6.61 | |
| BDI-II | | | .046 |
| Woman | 8.91 | 8.01 | |
| Man | 5.56 | 6.22 | |
| DQOL[b]: Worry about long-term | | | .015 |
| Woman | 9.71 | 2.87 | |
| Man | 8.02 | 3.14 | |
| STAI: State Anxiety | | | .002 |
| Woman | 20.66 | 9.25 | |
| Man | 13.55 | 9.47 | |

[a]Student's *t* test.
[b]A lower score implies better quality of life.
BDI = Beck Depression Inventory; DQOL = Diabetes Quality of Life; STAI = State-Trait Anxiety Inventory.

scores of the subjects belonging to Group 1 in relation to Group 2 in the variable quality of life, $F(1.29) = 4.769$, $p = .039$. However, the effect produced by the previous state of the patients was statistically significant, $F(1.29) = 11.261$, $p = .003$. Therefore, the effects that intensive treatment with CSII have on quality of life in patients with type 1 diabetes are because of both the treatment and the state of the patient before the intensive treatment, the latter having a larger effect size (.311). The model explains 42.5% of the variance observed.

There was also a significant decrease in the scores of the subjects in Group 1 compared with those in Group 2 in the DQOL *satisfaction* subscale, $F(1.31) = 4.356$, $p = .046$. The effects of the previous state of the patients were significant, $F(1.31) = 11.654$, $p = .002$. Thus, the effects that treatment with CSII have on the satisfaction of patients with type 1 diabetes are due as much to the treatment as to the patients' previous state, the latter having a larger effect size (.301). The variance observed (36.7%) is explained by the model.

Table 5

*Effects of Treatment in Quality of Life of Patients (Group 1 and Group 2)*

| | Mean rank (DQOL[a]) | $p$[b] |
|---|---|---|
| Group 1 (CSII) | | .019 |
| Baseline | 12.92 | |
| After 6 months | 6.00 | |
| Group 2 (MDI) | | .310 |
| Baseline | 5.00 | |
| After 6 months | 2.67 | |

[a]A lower score implies better quality of life.
[b]Wilcoxon's test.
CSII = continuous subcutaneous insulin infusion; DQOL = Diabetes Quality of Life; MDI = multiple daily injections.

Regarding the subscale *social and vocational concerns* (DQOL), there was a significant decrease in the scores of the subjects in Group 1 as compared with those in Group 2, $F(1.36) = 7.233$, $p = .011$. The effects of previous state were also significant, $F(1.36) = 12.751$, $p = .001$. Therefore, the effects that treatment with CSII produced on the subscale social and vocational concerns of patients with type 1 diabetes are because of the action of treatment as well as to the patients' state before treatment, the latter having a larger effect size (.28). Of the variance observed, 29.3% is explained by the model.

CSII treatment did not have statistically significant effects on the subscales *impact*, $F(1.33) = 3.484$, $p = .072$; and *worries about future effects of diabetes,* $F(1,37) = 2.147$, $p = .152$. But the effect of the previous state of the patients showed statistical significance, $F(1,33) = 43.281$, $p = .000$; and $F(1,37) = 18.849$, $p = .000$, respectively.

Because of significant differences between groups at baseline, the results fail to verify the hypothesis. While there was an improvement in the quality of life and, specifically, in the satisfaction of the patients and their social concerns, it cannot be said that this improvement was due solely to treatment with CSII, because it must be kept in mind that these effects are because of the type of treatment as well as to the previous state of the patient. This was a limitation of this study as was the high dropout rate.

Table 6

*Effects of Treatment in Quality of Life Controlling the Previous State of Patients*

| | Group 1 (CSII) | | Group 2 (MDI) | | |
|---|---|---|---|---|---|
| | Mean | *SD* | Mean | *SD* | *p* |
| Total quality of life (DQOL) | | | | | |
| Pretest[a] | 93.34 | 19.94 | 81.85 | 23.23 | .003 |
| Posttest[b] | 78.33 | 15.19 | 68.45 | 16.90 | .039 |
| Satisfaction | | | | | |
| Pretest[a] | 35.59 | 7.13 | 30.27 | 9.67 | .002 |
| Posttest[b] | 29.33 | 8.00 | 28.91 | 10.38 | .046 |
| Impact | | | | | |
| Pretest[a] | 35.30 | 9.73 | 31.26 | 9.13 | .000 |
| Posttest[b] | 30.22 | 7.52 | 27.46 | 8.88 | .072 |
| Social concern | | | | | |
| Pretest[a] | 13.42 | 5.00 | 12.60 | 5.05 | .001 |
| Posttest[b] | 10.77 | 2.63 | 10.57 | 3.54 | .011 |
| Worry about long term | | | | | |
| Pretest[a] | 9.00 | 2.75 | 8.77 | 3.37 | .000 |
| Posttest[b] | 7.78 | 2.10 | 7.21 | 2.32 | .152 |

*Note*. A lower score implies better quality of life.
[a]Group 1: $n = 33$; Group 2: $n = 45$.
[b]Group 1: $n = 23$; Group 2: $n = 14$.
CSII = continuous subcutaneous insulin infusion; DQOL = Diabetes Quality of Life; MDI = multiple daily injections.

## Conclusions

There was an improvement in the scores of Group 1 subjects as compared with Group 2 subjects in the quality of life variable. However, the effect produced by the previous state of the patients was statistically significant. As shown in Table 4, the patients in the study group began with a poorer quality of life than the patients in the control group. In spite of this, CSII treatment had significant effects, producing a greater decrease in DQOL scores than in the group treated

with MDI. So, indeed, an intensive treatment with CSII has significant effects on the quality of life of patients with type 1 diabetes, improving their general quality of life (total DQOL scale). In these patients, we observed higher diabetes life satisfaction and less social and vocational concerns (DQOL subscales). Therefore, like other authors (Bott et al., 1998; Bruttomesso et al., 2002; Hoogma et al., 2006; Kamoi et al., 2004; Linkeschova et al., 2002; Peyrot & Rubin, 2005; Rodrigues et al., 2005), we found that the quality of life of patients with type 1 diabetes mellitus improved after CSII treatment. The improvement in quality of life (total score), observed in our study group, is based on a better approval of the treatment and less concern about social and vocational issues. In addition, although the patients treated with CSII began with a poorer quality of life, both general (total DQOL score) and specific (DQOL subscales), than the patients treated with MDI, the quality of life of these patients improved more than that of the control group (MDI); thus, they benefited more from the treatment.

In summary, according to our data, the patients with type 1 diabetes who most benefit from therapy with CSII are those who previously had a high level of diabetes life dissatisfaction and worry about the repercussions of their diabetes on social–vocational issues, as it could be said that those aspects have a detrimental effect on the patients' perception of their quality of life.

This would require further investigation beyond these limitations. Therefore, we consider replicating the study controlling for these biases: homogeneous group and dropout rate. Even though the results are limited, we were able to show some valid conclusions covered in the following arguments.

First, although there was a high dropout rate, no significant differences were found in Group 1 (CSII) between participants and those refusing to take part in any of the available measures.

Second, it was known that the patients in Group 1 (CSII) would have worse glycemic control and quality of life at baseline, because these patients were selected for transition to the pump according to indications of the *Andalusian Health Service* published in the *Official Bulletin of the "Junta de Andalucía"* (BOJA.RSC 566/03). One of the main criteria for selecting patients is poor glycemic control. Therefore, it is not surprising to find that these patients are those with worse glycemic control and, hence, poor quality of life. The participants in this study were chosen by the Endocrinology Department for treatment with CSII based on the above criteria. Because randomizing the groups would have caused some patients in need of CSII to be placed in the control group, randomization was prohibited by the Ethics Committee. Consequently, treatment was in response to the clinical needs of the Endocrinology Department.

Third, participants in Group 2 (MDI) who dropped out of the study had higher scores on anxiety and social concern than those who remained (Table 2). However, Group 2 patients showed more satisfaction with treatment than Group 1 patients (Table 3). Indeed, the perception of quality of life in Group 2 (MDI)

patients was greater than in Group 1 (CSII) patients. Additionally, Group 2 patients had higher scores on the external locus of control variable than those in Group 1 (Table 3). Accordingly, the attributional style of these patients shows the following characteristics: belief that control of health and coping with negative events are dependent on external variables such as luck, healthcare team, medication, etc. Thus, patients in Group 2 were initially satisfied with the treatment received and furthermore their attributional style (external LOC) does not appear to motivate them to take charge of their health but rather, "leave control of the disease in the hands of others" which does not favor self-management of the disease. From this it seems evident that Group 2 patients were not motivated to continue the study.

Fourth, the dropout rate in Group 1 was lower. Perhaps because they were more motivated to improve their health (higher levels of HbA1c, more years with diabetes, lower external locus of control, worse quality of life, and dissatisfaction with treatment).

In summary, the results from this study show evidence of a positive effect of pump therapy in patients with poor glycemic control prior to pump start. Nonetheless, the existence of baseline differences between the two groups studied, a high percentage of dropouts, especially in Group 2, and a small sample size, must be taken into account.

Future research topics include a lengthier longitudinal study (at least 2 years) with a larger sample of patients. Data from the present study have made us aware of the possible biases that could occur, which suggest that special attention must be paid to the sample selection process. A recent study found that certain personality characteristics might also produce bias in patients with diabetes who receive treatment with CSII (Anarte et al., 2009). Recommendations made by the authors of this study will therefore be taken into account. We will also consider the possibility of carrying out a randomized study, based on recommendations from our hospital ethics committee.

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