Beneficial effects on body weight of group vs individual care in adults with type 1 diabetes on advanced technologies

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Abstract
Rationale and aims: Outpatient group visits in diabetes care have several potential advantages and can be simplified by the new technologies. The aim of this study was to assess feasibility and effectiveness of group visits vs individual visits in adults with type 1 diabetes on insulin pump therapy (continuous subcutaneous insulin infusion, CSII) and continuous glucose monitoring (CGM).

Methods: Outpatient setting for group visits (2-hour duration, quarterly, 6-8 patients) was the projection on giant screen of each patient's CGM and insulin pump data, with interactive discussion moderated by a diabetologist. Anthropometric measures and glycemic control (HbA1c) were assessed before and after a mean observation period of 4.4 ± 1.2 years (mean ± standard deviation, M ± SD) in CSII patients followed by group visits (GROUP) or individual visits (INDIVIDUAL) between 2013 and 2019.

Results: At the beginning of the observation, GROUP and INDIVIDUAL cohorts were strictly matched for gender (M/F = 37/35 and 37/35), age, diabetes duration, body mass index (BMI), CSII duration, and HbA1c level. HbA1c levels did not change significantly between beginning and end of observation in either cohort (GROUP 7.54 ± 0.80% and 7.60 ± 0.79%, P = .585; INDIVIDUAL 7.73 ± 1.27% and 7.60 ± 1.08%, P = .281) (time*visit effect P = .232, two-way repeated measures analysis of variance [ANOVA]). Body weight remained unchanged in the GROUP cohort (73.2 ± 14.0 vs 73.8 ± 14.8 kg, P = .361), while it increased in the INDIVIDUAL cohort (73.2 ± 14.0 vs 73.8 ± 14.8 kg, P = .361), while it increased in the INDIVIDUAL cohort (70.3 ± 13.5 vs 73.0 ± 13.7 kg, P < 0.001) (time*visit effect P = .009).

Conclusions: Group care is feasible in adult patients with type 1 diabetes using new technologies. Group visits can be beneficial in inducing lifestyle changes, as indicated by the favorable effects observed on body weight trend.
1 | INTRODUCTION

A better glyco-metabolic control leads to a lower risk of chronic complications in patients with type 1 diabetes mellitus (T1DM). However, insulin dependence, together with multimorbidity, makes diabetes management complex because of the need to achieve adequate control of blood glucose and other risk factors while preserving an acceptable quality of life for the patient. To reduce the risk of invalidating complications and rationalize health expenditure through more modern and effective treatments, developing self-management remains a key strategy. In addition, insulin pump therapy and continuous glucose monitoring (CGM) have proven to be valuable aids, showing advantages in terms of glycemic compensation, risk of hypoglycemia, and quality of life.

A critical component of diabetes care is patient education. Current evidence suggests that diabetes education has an overall beneficial impact on health and psychosocial outcomes. Patients with diabetes require both the knowledge and skills to manage their disease, which results in more informed choices and beneficial behavioral changes.

A useful tool for patient education is group care. Group care can significantly affect acceptance of the disease, self-management, and compliance compared to educational therapy provided during traditional visits. The benefits of group visits compared to individual visits are substantially due to help from peers, that is, sharing the experiences of other patients who have managed or are managing the same condition. Group care has proven to be a useful model in the management of type 2 diabetes.

The role of group visits in adult patients with T1D has not been defined. A recent analysis assessing whether—based on the group care models existing in the literature—group visits may or may not work for young patients with diabetes, identified four general principles that can be applied in different contexts to support the involvement in group visits: (a) emphasize self-management as practical knowledge, (b) develop a sense of affinity between patients, (c) provide safe and adequate care, and (d) balance individual and group needs. Conducting group visits can be simplified by the new technologies that allow data sharing and patient interaction by analyzing the graphs of CGM and insulin therapy by continuous subcutaneous insulin infusion (CSII).

Group care has been practiced for several years in our Diabetes Center in place of the classic individual visits in patients with T1DM on insulin pump therapy. This study reports a 6-year experience, through an observational retrospective analysis of the effects of this therapeutic approach on some metabolic parameters (glycated hemoglobin, body weight). The effects of group care were compared with those observed in T1DM patients referring to the same diabetes center and with similar general and clinical characteristics but followed with individual visit.

2 | RESEARCH DESIGN AND METHODS

2.1 | Study subjects

The GROUP cohort comprises T1DM patients (n = 72) who participated in at least five group visits between 2013 and 2019 at the outpatient clinic of the Diabetes Unit of the Federico II University Hospital, Naples. On the basis of the clinical characteristics of this cohort (age, sex, duration of diabetes, duration of pump therapy, body mass index [BMI], and glycosylated hemoglobin), 72 additional T1DM subjects were selected among patients on CSII followed by traditional individual visits (INDIVIDUAL cohort) by the same diabetes Unit and team. As shown in Table 1, at the beginning of the observation period, the clinical variables were similar in the two cohorts. Age of the patients varied from 23 to 77 years, BMI from 18.0 to 39.8 kg/m², duration of diabetes from 2 to 61 years, use of pump from 1 to 32 years, and HbA1c from 5.2% to 12.2%.

Patients signed an informed consent for the treatment of their data. Since only aggregate metrics derived from the electronic health record were utilized, no institutional ethical committee review was required for this research.

| General characteristics of the patients followed by group visits (GROUP) or individual visits (INDIVIDUAL) at the beginning of the observation period |
|-------------------------------|------------------|------------------|
| Number (M/F)                  | 37/35            | 37/35            |
| Age (years)                   | 44.4 ± 11.1      | 44.2 ± 12.6      |
| Body weight (kg)              | 73.2 ± 14.0      | 70.3 ± 13.5      |
| Height (cm)                   | 169 ± 9          | 166 ± 10         |
| Body mass index (kg/m²)       | 25.5 ± 3.5       | 25.3 ± 4.0       |
| Diabetes duration (years)     | 21.3 ± 9.4       | 23.4 ± 11.4      |
| CSII duration (years)         | 5.7 ± 4.8        | 6.0 ± 3.6        |
| HbA1c (%)                     | 7.54 ± 0.80      | 7.73 ± 1.27      |
| HbA1c (mmol/mol)              | 59 ± 6           | 61 ± 8           |

Note: Data are mean ± SD. No significant differences between the two groups.

Abbreviation: CSII, continuous subcutaneous insulin infusion.
2.2 | Group visit methodology

From 2013 to 2019, nine groups were formed in our Diabetes Center, each consisting of 7 to 10 patients. Each group was homogeneous for type of diabetes, insulin pump treatment, and use of continuous blood glucose monitoring, while being generally heterogeneous for age, sex, duration of diabetes, age at onset of the disease, and degree of glyco-metabolic compensation. Patients who practiced group visits signed an informed consent for sharing and processing their personal data.

Generally, group visits were carried out in the afternoon, on a bi-quarterly basis, and lasting 2 hours. To strengthen compliance and therapeutic adherence, patients were sent a reminder of the date of the meeting by instant messaging (WhatsApp). Using a messaging system makes the communication between clinicians and patients more efficient not only for the organization of group visits—remembering the blood chemistry analyses to be carried out and the possible need to download the data at home (reports of CGM and insulin therapy)—but also for communications among patients and between doctors and patients. The data are recorded online on the various cloud platforms (Carelink, Diasend, Accuchek, Dexcom, Eversense), which reduces the actual time of the visit.

In the first 30 minutes of the visit, the anthropometric parameters are recorded, and, when necessary, the data of the continuous glucose monitoring and insulin therapy with the insulin pump are downloaded. During the next 90 minutes, the group visit takes place led by a diabetologist experienced in this therapeutic approach. The data downloaded are projected on a large screen in a dedicated room to be visible to all members of the group (Figure 1). In turn, patients comment on their graphs in relation to the performance of their daily activities also following the clinical advice. This provides a clear picture of eating habits, lifestyle, management of hyper- and hypoglycemia and the use of trend arrows for continuous monitoring of blood glucose. In a wider perspective, this allows each member of the group to learn from the experiences of the others.

The doctor who carries out the group visits mediates the time reserved for each patient in order to administer what is a real educational therapy adapted to the patient himself and the other participants. Each session ends with indications on any therapeutic changes and information on the next appointment and, if necessary, booking individual visits with possible scheduling of the screening of complications.

2.3 | Study data collection

The data used in this study were collected from both hardcopy and electronic medical records (Smart Digital Clinic) where the values of blood tests, therapies, anthropometrics, and the screening data of chronic complications of diabetes are recorded. For this retrospective analysis, each patient’s baseline data correspond to the beginning of their participation to group visits. For the control group, data correspond to an observation period equivalent to that of cases.

2.4 | Measurements

Body weight was measured using a weighing scale with an accuracy of 0.1 kg. Height was measured with a stadiometer with barefoot patients. BMI was calculated as the ratio between weight (kg) and height (m$^2$). HbA1c was measured by high-performance liquid chromatography.

2.5 | Statistical analysis

Results are expressed as mean ± standard deviation (SD), unless otherwise stated. The differences between baseline characteristics of the participants in the two groups were analyzed by t-test for independent samples. Changes vs baseline over follow-up were evaluated by two-way repeated-measures ANOVA, where start and end of the study observation period were included as levels of the within-subject factor time (Start and End), and GROUP and INDIVIDUAL cohorts were included as levels of the between-subject factor visit (group or individual). A P value <.05 was considered statistically significant. The statistical analysis was carried out with the SPSS program for Windows (SPSS/PC version 25. Chicago, Illinois, USA).

3 | RESULTS

At the start of the study, the GROUP and INDIVIDUAL cohorts were strictly matched by gender (M/F = 37/35 and 37/35), age (44.4 ± 11.1 and 44.2 ± 12.6 years), duration of diabetes (21.3 ± 9.4 and 23.4 ± 11.4 years), BMI (25.5 ± 3.5 and 25.3 ± 4.0 kg/m$^2$), time on insulin pump (5.7 ± 4.8 and 6.0 ± 3.6 years), and HbA1c levels (7.54 ± 0.8% and 7.73 ± 1.27%) (P > .05 for all variables) (Table 1).

The mean duration of the study observation period was 4.4 ± 1.2 years in the GROUP cohort and 4.3 ± 1.2 years in the INDIVIDUAL cohort (P = .585).
3.1 | Blood glucose control

As shown in Figure 2, blood glucose control evaluated by glycated hemoglobin did not vary significantly between the start and end of the observation period in either the GROUP (7.54 ± 0.80% vs 7.60 ± 0.79%, \( P = .585 \)) or the INDIVIDUAL cohort (7.73 ± 1.27% vs 7.60 ± 1.08%, \( P = .281 \)) (time*visit effect \( P = .232 \), two-way repeated measures ANOVA). To evaluate whether HbA1c levels had changed differently according to baseline blood glucose control, each cohort was divided into tertiles based on the baseline HbA1c values of the participants. In the first tertile (baseline HbA1c \( \leq 7.2\% \)), the final HbA1c was significantly higher than at the start in both the GROUP cohort (6.68 ± 0.40% vs 7.09 ± 0.83%, \( P = .019 \)) and the INDIVIDUAL cohort (6.63 ± 0.52% vs 6.96 ± 0.90%, \( P = .063 \)) (time*visit effect, \( P = .765 \)). In the second tertile (baseline HbA1c \( \geq 7.3\% \) and \( \leq 7.8\% \)), there were no significant changes in HbA1c in either the GROUP cohort (7.53 ± 0.17% vs 7.69 ± 0.64%, \( P = .257 \)) or the INDIVIDUAL cohort (7.53 ± 0.16% vs 7.50 ± 0.68%, \( P = .836 \)) (time*visit effect, \( P = .349 \)). In the third tertile (baseline HbA1c \( \geq 7.9\% \)), HbA1c decreased significantly at the final observation in both the GROUP cohort (8.39 ± 0.54% vs 7.98 ± 0.63%, \( P = .010 \)) and the INDIVIDUAL one (9.12 ± 1.13% vs 8.38 ± 1.08%; \( P = .008 \)) (time*visit effect, \( P = .258 \)).

3.2 | Body weight

The absolute changes in body weight compared to the beginning of the observation period over the 6 years of the study are shown in Figure 3. The GROUP cohort as a whole did not show an increase in body weight over time (73.2 ± 14.8 vs 73.8 ± 14.0 kg, \( P = .361 \)) while for the INDIVIDUAL cohort, there was an average increase of about 0.5 kg/year.
(70.3 ± 13.5 vs 73.0 ± 13.7 kg, P < .001) with a statistically significant difference between changes in the two groups, time*visit effect P = .009). To evaluate whether body weight had changed differently according to baseline overweight status, participants in each cohort were divided into overweight/obese (BMI ≥ 25 kg/m²) or normal weight (BMI < 25 kg/m²). In the GROUP cohort, weight remained stable in both the 39 patients with BMI ≥ 25 kg/m² (80.9 ± 12.0 vs 81.6 ± 12.3 kg, P = .457) and the 33 patients with BMI < 25 kg/m² (64.2 ± 10.5 vs 64.5 ± 12.1 kg, P = .550). In the INDIVIDUAL cohort, weight remained stable in the 31 patients with BMI ≥ 25 kg/m² (80.5 ± 12.1 vs 81.8 ± 12.6 kg, P = .159), while it increased significantly in the 41 patients with BMI < 25 kg/m² (62.5 ± 8.6 vs 66.3 ± 10.4 kg, P < .001), with a statistically significant difference between changes in the two groups, time*visit effect P < .001).

4 | CONCLUSIONS

This study shows that diabetes care through group visits is feasible in patients with T1DM treated with new technologies; the long adherence to group visits—many patients being followed for a fairly long period (6 years), indicates their willingness to maintain this modality of care.

As for the efficacy of group visits in terms of blood glucose control, patients followed by group visits and those followed by individual visits showed the same changes in blood glucose control. In both cohorts, HbA1c significantly decreased in patients who initially had a worse glycemic compensation, while it increased in patients who initially had an already low baseline HbA1c, probably due to the correction of their high rate of hypoglycemia events.

An important finding of this retrospective analysis concerns the changes in body weight. In line with the increase observed in an observational study with an even longer duration,13 in this study, weight increased by about 0.5 kg per year in patients followed by individual visits. In contrast, weight remained stable in patients followed by group visits. This interesting result was probably due to the greater efficacy of the educational therapy received during group visits in inducing changes in the patients’ lifestyles. This beneficial effect may have relevant clinical implications, considering that obesity is becoming an increasing clinical problem also in patients with T1DM. The analysis of US records shows a prevalence of overweight of 22.9% and obesity of 13.1% in patients suffering from T1DM.14 The problem of obesity in patients with T1DM is even more relevant considering the evidence that people with T1DM, when obese, are more likely to have other cardiovascular risk factors, such as high blood pressure and dyslipidemia—factors related to the development of metabolic syndrome and cardiovascular events.15,16

Group visits are an alternative way of organizing health care, and this might require various operational and administrative resources: adequate space for group visits, interpersonal skills, software and hardware tools suitable for shared presentation, and investment of time to get to know the patients and bring them together in groups. However, it remains essential that the patient’s individual needs be promptly recognized by the doctor to provide the possibility of individual visits.

On the other hand, this approach can be amply repaid by potential positive impact not only on anthropometric parameters and cardiovascular risk but, notably, on the perceived burden of the disease. This probably derives from sharing and overcoming fears and becoming more confident and autonomous in managing the condition/disease. Each patient can act as a model prompting group mates to experience and adopt his/her positive behaviors.

Technologies have proven useful in facilitating group visits and in managing CGM and insulin data directly in real time during the visits. As patients get familiar with analyzing glucose and insulin reports, it becomes easier to recognize patterns and issues that are of common shared interest for all group participants. The use of instant messaging is also useful, making it easier to organize this type of health care and improve the relationships among patients. Advantages in terms of utilization of health care resources should also be considered, including the allocation of appointments with 2-hour slots for 6 to 8 patients, which is less than the sum of individual visits needed for caring these complex, technology-driven patients.

This study has strengths and limitations. One limitation is certainly its nonrandomized retrospective design, although this was counterbalanced by the selection of a control cohort (INDIVIDUAL) closely comparable to that of the GROUP. This was able to minimize the selection bias potentially present in longitudinal retrospective studies, due to initial differences between the two cohorts for factors that may influence the parameters assessed. To this regard, a strength of this study is that the two cohorts were attending the same diabetes center and, therefore, did not differ for professional team and clinical approach to care of diabetes and its associated metabolic conditions. A limitation is that changes in blood glucose control were only evaluated by HbA1c levels. It was not possible to also provide information based on CGM metrics since baseline CGM data were not available for most participants.

In conclusion, the results of this study indicate that group visits can be a therapeutic strategy in caring for patients with type 1 diabetes, in particular those who use new technologies that greatly simplify this type of visit. Using group visits can be advantageous in inducing lifestyle changes, as indicated by the favorable effects observed on body weight trends, which constitute a threatening factor for these patients.

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CONFLICT OF INTEREST

The authors report no conflicts of interest in this work.
TRANSPARENCY STATEMENT
Giovanni Annuzzi affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Giovanni Annuzzi had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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