ORIGINAL RESEARCH

Improvement of HbA$_{1c}$ and stable weight loss 2 years after an outpatient treatment and teaching program for patients with type 2 diabetes without insulin therapy based on urine glucose self-monitoring

Nicolle Müller[1]
Daniela Stengel[2]
Christof Kloos[1]
Michael Ristow[2]
Gunter Wolf[1]
Ulrich A Müller[1]

[1]University Hospital of Jena, Department of Internal Medicine III, Jena, Germany; [2]Friedrich-Schiller-University Jena, Institute of Nutrition, Department of Human Nutrition, Jena, Germany

Correspondence: Nicolle Müller
University Hospital Jena, Department of Internal Medicine III, Bachstr 18, D 07743 Jena, Germany
Tel +49 3641 934840
Fax +49 3641 933009
Email nicolle.mueller@med.uni-jena.de

Objective: Long-term outcomes after participation in a structured diabetes treatment and teaching program (DTTP) for patients with diabetes without insulin use, primarily based upon postprandial urine glucose self-monitoring (UGSM).

Methods: A total of 126 patients took part in the DTTP in a university outpatient department in 2004–2005. We re-evaluated 119 (94.4%) at baseline and at 6 months, 12 months, and 24 months. Hemoglobin A$_{1c}$ (HbA$_{1c}$) was DCCT adjusted.

Results: HbA$_{1c}$ decreased significantly 6 months after education from 7.33% ($\pm$1.59%) to 6.89% ($\pm$0.98%; $P = 0.001$ versus baseline) and was maintained for up to 12 months (7.02% $\pm$ 1.07%; $P = 0.017$ versus baseline) as well as up to 24 months (6.96% $\pm$ 1.06%; $P = 0.005$ versus baseline). Weight decreased from 92.5 kg at baseline to 90.3 kg at 24 months ($P = 0.014$). A total of 36.5% of patients not on insulin therapy preferred UGSM, whereas 23.5% preferred blood glucose monitoring, at 24 months. Glucose control was similar in both groups at 24 months (HbA$_{1c}$ UGSM 7.03 versus blood glucose monitoring 6.97%; $P = 0.807$).

Conclusion: Participation in the DTTP resulted in long-term behavior modification. HbA$_{1c}$ of patients without insulin met the target 24 months after the DTTP, irrespective of the type of glucose self-monitoring.

Keywords: diabetes mellitus type 2, treatment and teaching program, patient education, HbA$_{1c}$, body weight

Introduction

Type 2 diabetes mellitus affects about 5% of the German population.[1] Eighty percent of patients with type 2 diabetes are treated with diet or oral antiglycemic drugs (OADs).[2] For successful treatment of patients with diabetes, we have different therapy options, such as modification of eating behavior and physical exercise, OADs, and insulin. A necessary prerequisite of successful treatment is the active involvement of the patients in their treatment. Continuous adjustment of nutrition, exercise, and medication according to the patient's insulin secretion and/or insulin resistance is necessary for the treatment of diabetes mellitus. Therefore, diabetes education is crucial, whatever therapeutic option is chosen.

Diabetes education contributes to better metabolic control or to preservation of good control.[3,4] However, some reviews on the effectiveness of education in type 2 diabetes

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have also reported positive effects on patient knowledge, self-care behavior, and psychological outcomes.[5–7] The duration of effective diabetes education programs is controversial. The trials evaluating the majority of these treatment and teaching programs have only a relatively short follow-up period of 6–12 months.[3,4,8] Another controversial topic is whether blood glucose self-monitoring (BGSM) has advantages over urine glucose self-monitoring (UGSM) in patients not requiring insulin therapy.[9–12]

A structured diabetes treatment and teaching program (DTTP) for patients with type 2 diabetes not on insulin therapy was implemented in the German health care system several years ago. This program comprised four sessions of 90 minutes each. It is primarily based upon postprandial UGSM. The first evaluation of this DTTP in Germany with a follow-up of 12 months was published 20 years ago.[3] Another evaluation from Austria published in 1995 had a follow-up of 6 months.[4]

However, longer follow-up periods have hitherto not been studied. We evaluated outcomes 24 months after participation in this DTTP.

Patients and methods

A total of 126 patients with type 2 diabetes mellitus not requiring insulin therapy took part in the DTTP in 2004–2005 in the outpatient department for endocrinology and metabolic diseases of the university hospital in Jena, Germany. All patients with newly diagnosed type 2 diabetes or problems with metabolic control were enrolled in the DTTP. Medication, type and frequency of self-monitoring, severe hypoglycemia, hemoglobin A_{1c} (HbA$_{1c}$), weight, and blood pressure were recorded before the DTTP and then at every visit, usually quarterly. We re-evaluated complete data sets from 119 patients. Data were obtained from the electronic patient record EMIL® (v4.3.9.79; Marburg, Germany) were collected from general practitioners' files. Data are described at baseline (before DTTP) and at 6 months, 12 months, and 24 months after participation in the DTTP. HbA$_{1c}$ was adjusted to DCCT standards with an evaluated standardization procedure using local reference ranges.[13]

Diabetes treatment and teaching program

The DTTP consists of four sessions once a week of 90–120 minutes, including interactive training. The topics of the DTTP are basic information about diabetes, postprandial self-monitoring of urine glucose, physiology and pathophysiology, hypocaloric nutrition, withdrawal of insulinotropic oral agents when unnecessary, foot care, hypoglycemia, and exercise (for details, see Table 1). Patients were trained to achieve glucose-free urine

Table 1 Structured treatment and teaching program

Education unit	Information topic
Unit 1	What is diabetes?
	Postprandial urine glucose self-monitoring
	Hypoglycemia
Unit 2	Pathophysiology of diabetes
	Oral hypoglycemic agents
	Nonpharmacological therapy
	Calorie-defined diet
	Lifestyle changes
Unit 3	Diabetic neuropathy
	Foot care
	Physical activity
Unit 4	Sick-day rules
	Smoking
	Check-up for late complications

2 hours postprandially and to tailor the type and amount of their food accordingly. If postprandial glucosuria-free tests correlated with the desired level of metabolic control, this inexpensive testing was considered to be sufficient. The main teaching part of the DTTP was performed by diabetes educators (ie, nurses and dieticians with special postgraduate training).

Outcomes

Primary outcomes are changes in HbA$_{1c}$, weight, and OADs 24 months after training in the DTTP. A secondary outcome is the difference in HbA$_{1c}$ between self-monitoring of urine glucose and blood glucose.

Statistical analysis

Statistical analysis was performed with SPSS 14.0 (SPSS, Inc, Chicago, IL). Normally distributed values were registered as mean ± standard deviation and non-normally distributed values as median and range. Differences were statistically evaluated by t-test, Mann-Whitney U Test, or χ^2 test. A P-value of <0.05 was considered to be statistically significant.

Results

From the initial 126 trained patients we were able to re-evaluate 119 (94%) after 24 months. At baseline, age was 61.5 years (±10.29 years), time since diagnosis of diabetes was 5.57 years (±6.53 years), body weight was 89.89 kg (±15.88 kg), body mass index was 32.23 kg/m^2 (±5.74 kg/m^2), and blood pressure was 159/88 mmHg (±24.69/±12.18 mmHg). Of the patients, 39.4% (n = 47) were newly diagnosed with type 2 diabetes, and 59.7% (n = 71) were still cared for in the university outpatient department.

HbA$_{1c}$ decreased significantly 6 months after education from 7.33% (±1.59%) to 6.89% (±0.98%; $P = 0.001$

Table 2 HbA$_{1c}$ and body weight according to diabetes therapy used at 24 months

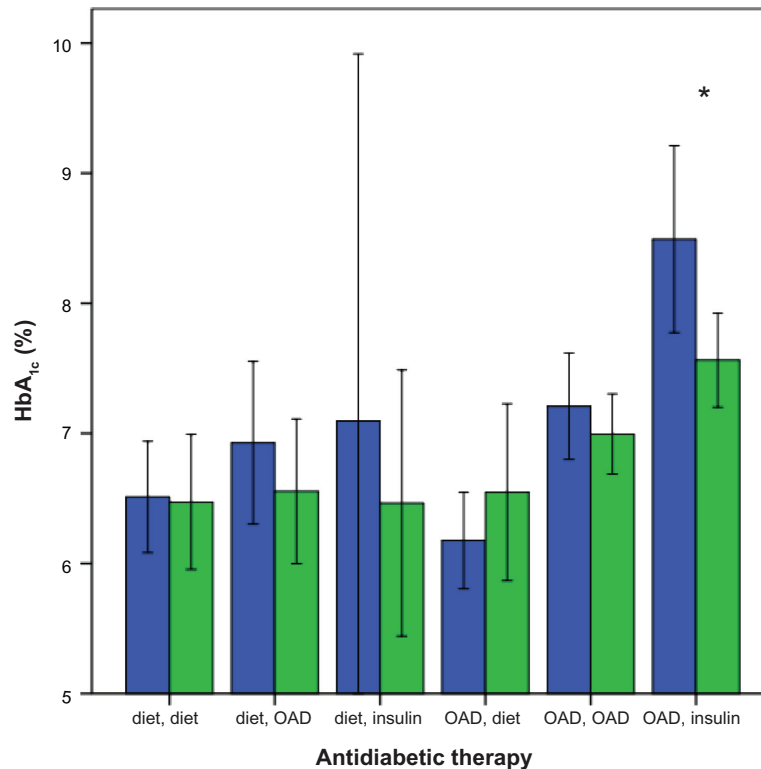| Antidiabetic therapy at 24 months	HbA$_{1c}$ (%)			Body weight (kg)		
	Baseline	**24 months**	***P*-value**	**Baseline**	**24 months**	***P*-value**
All patients	7.33	6.96	0.001	89.9	88.5	0.001
No drug (19.3%)	6.42	6.49	NS	92.5	90.3*	0.014
OAD (52.1%)	7.14	6.88	NS	87.4	85.1*	0.001
Insulin (28.6%)	8.33	7.43*	0.01	92.7	93.7	0.088

Abbreviations: HbA$_{1c}$, hemoglobin A$_{1c}$; NS, not significant; OAD, oral antiglycemic drug.

versus baseline) and was maintained for up to 12 months (7.02 ± 1.07%; $P = 0.017$ versus baseline), as well as up to 24 months (6.96 ± 1.06%; $P = 0.005$ versus baseline). Patients still attending our university outpatient department had a higher baseline HbA$_{1c}$ than patients of general practitioners (7.61% versus 6.94%; $P = 0.024$) and also a higher HbA$_{1c}$ 12 months (7.23% versus 6.69%; $P = 0.008$) and 24 months after education (7.18% versus 6.65%; $P = 0.007$). HbA$_{1c}$ decreased in both groups, but the change was significant only in patients cared for at the university hospital ($P = 0.027$). At baseline, 49.6% of patients had an HbA$_{1c}$ of ≤ 7% and 10.1% > 9%. Twelve months after participation in the DTTP, the number of patients with an HbA$_{1c}$ ≤ 7% increased to 60.0% ($P = 0.001$), whereas the number with an HbA$_{1c}$ > 9% decreased to 3.5% ($P = 0.069$). These results were maintained after 24 months, with 58.8%

having an HbA$_{1c}$ ≤ 7% and 5% > 9% ($P = 0.112$ versus baseline). Body weight decreased significantly from 89.9 kg at baseline to 87.8 kg after 6 months ($P = 0.001$), increased to 88.9 kg at 12 months ($P = 0.001$ versus baseline), and was 88.5 kg 24 months later (–1.4 kg compared with baseline; $P = 0.001$). Blood pressure decreased from 159/87 mmHg to 140/81 mmHg ($P = 0.001$) 24 months after participation in the DTTP.

Antidiabetic medication

Changes in HbA$_{1c}$ and body weight are shown in Table 2, changes in HbA$_{1c}$ according to diabetes therapy at baseline and at 24 months are shown in Figure 1, and changes in body weight according to therapy are depicted in Figure 2. At baseline, 31.1% of the patients were not on antidiabetic medication (HbA$_{1c}$ 6.75%), and 68.9% were on OADs (HbA$_{1c}$

Figure 1 Changes in HbA$_{1c}$ at 24 months according to antidiabetic therapy used at baseline (blue bars) and 24 months (green bars).
Note: *$P < 0.05$.
Abbreviations: HbA$_{1c}$, hemoglobin A$_{1c}$; OAD, oral antiglycemic drug.
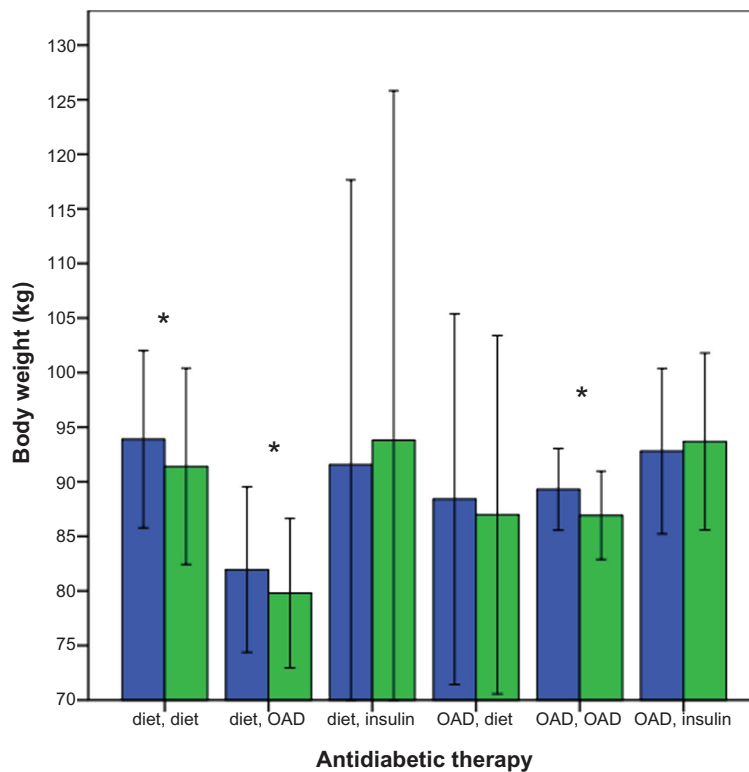
Figure 2 Changes in body weight at 24 months according to antidiabetic therapy used at baseline (blue bars) and 24 months (green bars).
Note: *P < 0.05.
Abbreviation: OAD, oral antiglycemic drug.

7.60%). Twenty-four months after the DTTP, 19.3% were still not on antidiabetic medication. The baseline HbA$_{1c}$ of this subgroup was 6.42% and remained constant (6.49% at 24 months; not significant). The body weight of this group decreased significantly from 92.5 kg at baseline to 90.3 kg at 24 months ($P = 0.014$).

The HbA$_{1c}$ values of patients taking OADs at 24 months (52.1%) decreased slightly (7.14% at baseline; 6.88% at 24 months; not significant), whereas body weight decreased significantly from 87.4 kg at baseline to 85.1 kg at 24 months ($P = 0.001$).

HbA$_{1c}$ of patients with insulin treatment at 24 months (28.6%) decreased significantly from 8.33% at baseline to 7.43% ($P = 0.011$), but body weight increased from 92.7 kg to 93.7 kg ($P = 0.088$). Patients attending the university

outpatient department were more often on insulin therapy at 24 months than patients in the care of a general practitioner (43.7% versus 6.3%, $P = 0.001$).
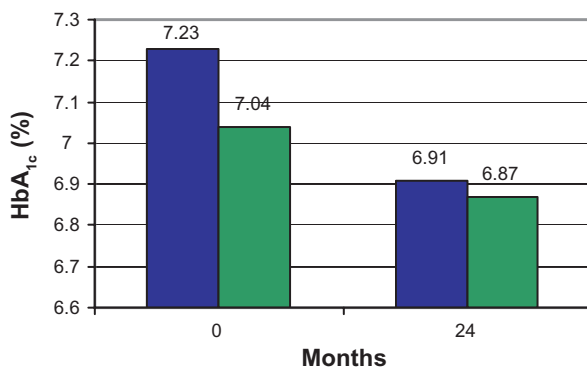
Self-monitoring

The methods of self-monitoring according to diabetes therapy are shown in Table 3. Only 53.8% of the patients performed self-monitoring at baseline, compared with 75.6% at 24 months. UGSM was performed at baseline by 31.1% and at 24 months by 26.1%. BGSM was performed at baseline by 18.5% and at 24 months by 44.5%. Both methods, UGSM and BGSM, were used at baseline by 4.2% and at 24 months by 5.0%. Of those patients not on insulin therapy at 24 months, more preferred UGSM (36.5% versus 23.5%, $P = 0.048$).

Table 3 Methods of self-monitoring (percent patients) according to antidiabetic therapy used

Antidiabetic therapy at 24 months	No self-monitoring		Urine glucose		Blood glucose	
	Baseline	2 years	Baseline	2 years	Baseline	2 years
All patients	46.2	24.4	31.1	26.1	18.5	44.5
No drug	67.6	52.2	16.2	43.5	10.8	4.3
OAD	36.6	27.4	37.8	33.9	22.0	30.6
Insulin				2.9		97.1

Abbreviation: OAD, oral antiglycemic drug.

Figure 3 Hemoglobin A$_{1c}$(HbA$_{1c}$) according to the method of self-monitoring used at baseline and 24 months after participation in the diabetes treatment and teaching program (urine glucose self-monitoring [blue bars]; blood glucose self-monitoring [green bars]).

There were differences concerning the self-monitoring method applied between those patients who were exclusively treated by a general practitioner and those who also attended the university outpatient department. All patients treated in the university outpatient department used one kind of self monitoring (UGSM or BGSM), but only 39.6% of patients treated by their general practitioner performed self monitoring (P = 0.001). At 24 months, most patients not requiring insulin therapy and treated in the university outpatient department performed UGSM (UGSM 65%; BGSM 22.5%). This compares with those patients who were treated by their general practitioner with most of them performing BGSM (UGSM 11.1%; BGSM 24.4%). Comparing the HbA$_{1c}$ of those patients not requiring insulin therapy applying UGSM or BGSM, no difference was found either at baseline (7.23% versus 7.04%; P = 0.597) or at 24 months (6.91% versus 6.87%; P = 0.855; Figure 3).

Discussion and conclusion

The first evaluation of DTTP for patients with type 2 diabetes not requiring insulin therapy was published in 1988.[3] The program was primarily developed for general practitioners to improve care for diabetic patients. We studied the long-term effects of this program. The follow-up of the first evaluation was 12 months. Patients had a significant reduction in bodyweight of 2 kg and the already good HbA$_{1c}$ at study entry did not deteriorate in spite of 30% less OADs used and none of the patients switching to insulin. The following evaluations of this DTTP in Austria and Latin America showed reductions in HbA$_{1c}$ ranging from 0.4% to 1.1% after a follow-up of 6–12 months,[4,16–18] and a body weight reduction of 2.5 kg. These favorable results are also shown in our study but with a considerably longer follow-up of 24 months. The recently published DESMOND (Diabetes Education

and Self Management for Ongoing and Newly Diagnosed) study in the UK evaluated the effectiveness of another group education program in people with newly diagnosed type 2 diabetes mellitus[19] and found that 12 months after education there was a greater weight reduction for those patients than for patients in the control group (−2.98 kg versus −1.86 kg), without there being a difference in HbA$_{1c}$.

It is well known that a reduction in body weight reduces insulin resistance in patients with type 2 diabetes, which results in better metabolic control.[3,8,14,18] In contrast to these results, patients in the UK Prospective Diabetes Study assigned to diet therapy only had weight gain and the worst HbA$_{1c}$. The different results might be caused by the DTTP initiating behavior modification by the participating patients and the possibility of continuous feedback by self-monitoring. A further reason for encouraging results is the absence of a diet plan in the curriculum used in our study. Except for drinks with sugar and instant food, all nutrients are allowed. Type and amount of food corresponds to the endogenous insulin present and to the person's individual insulin resistance if postprandial urine glucose tests are negative.

Lifestyle interventions are effective, particularly in obese type 2 diabetes patients, but, in the long term, insulin treatment will become necessary in many people with type 2 diabetes.[15] After 24 months, 29% of our patients were on insulin therapy. Initially, these patients had the worst baseline HbA$_{1c}$ but the greatest improvement in metabolic control. Before starting insulin therapy these patients took part in another DTTP conceived for patients with insulin therapy. All those patients switched to insulin after the first evaluation of this program after 12 months.[3] In the evaluation from Pieber et al,[4] no patient was on insulin therapy 6 months after education. However, the HbA$_{1c}$ value 6 months after education was 8.11% and considerably higher than in the study presented.

Not surprisingly, patients on insulin therapy gained weight, as was reported in other studies starting with insulin treatment.[15] However, weight gain was only 1 kg after 2 years.

The number of sessions recommended in DTTPs is debatable. The outcome of the DTTP with only four sessions is not worse compared with a program with eight or twelve sessions.[8] This program decreased HbA$_{1c}$ from 8.1% to 7.4% and weight from 87.8 kg to 85.3 kg. The highest decrease of HbA$_{1c}$ was in patients on insulin, so the significant total HbA1c reduction mainly derives from the reduction in HbA$_{1c}$ of patients on insulin therapy. It was not the target of the DTTP to reduce the good HbA1c, which was already at baseline in

the target. The aim for these patients was to maintain good HbA$_{1c}$ for longer, and this aim was achieved.

It is likely that it is not the number of sessions that is important but the delivery of the program by the team who is responsible for the permanent care of the patient. This is usually the family physician or general practitioner.

In the DTTP presented and evaluated, all patients not requiring insulin therapy are trained to perform postprandial urine tests for glucose. If postprandial urine is glucose free and matches the desired level of metabolic control after 3–6 months, this inexpensive testing is considered to be sufficient. Nevertheless, some subgroups may require BGSM (eg, patients with elevated or reduced renal threshold for glucose). Whether BGSM has any advantages in patients not requiring insulin therapy treatment has been repeatedly evaluated and discussed. In a retrospective study from Germany, Martin et al[10] showed a decreased diabetes-related morbidity and all-cause mortality in type 2 diabetes patients who received a prescription of BGSM material in spite of higher HbA$_{1c}$, compared with those not using BGSM, and this association was also present in a subgroup of patients not receiving insulin therapy. In the Fremantle study from Australia, Davis et al[11] did not find any difference in HbA$_{1c}$ in BGSM users or nonusers, but BGSM was associated with a 79% increased risk of cardiovascular mortality in patients not treated with insulin.[20] In addition, a large survey from Austria and Germany did not show any association between HbA$_{1c}$ and the frequency of BGSM in type 2 diabetic patients not requiring insulin therapy.[21] In the randomized controlled trials by Miles et al[9] and the recently published DESMOND study, BGSM was not superior to UGSM in respect of no self-control in patients with newly diagnosed type 2 diabetes.[12] The results of our study support those findings that UGSM is not inferior to BGSM in well-trained patients, considering that most patients not requiring insulin therapy performed UGSM and that no difference in HbA$_{1c}$ after 2 years was found.

The strongest limitation of our study is the lack of a control group. For ethical reasons, it is not possible to refuse patients participation in the DTTP over 2 years. Furthermore, there are already controlled trials that have shown the effectiveness of the DTTP but over a shorter period.[3,4] Another limitation is the possibility of a negative selection of patients, because we are a specialist university outpatient department. However, the good HbA$_{1c}$ of the patients is contradicted.

In summary, the results of our study showed that a treatment and teaching program consisting of four sessions once a week effectively reduces HbA$_{1c}$ and weight over 2 years, irrespective of the method of self-monitoring applied.

Conclusion

Weight decreased significantly in patients with and without OADs. HbA$_{1c}$ of patients without OADs still met the target after 24 months. In patients on OADs, HbA$_{1c}$ fell 0.26% below the initial level. Twenty-nine percent of patients were on insulin therapy 24 months after the DTTP. Glucose control (HbA$_{1c}$) was similar with UGSM (7.03%) and BGSM (6.97%; $P = 0.807$) at 24 months. These findings suggest that postprandial urine testing is effective, as well as blood glucose control. More research is required to assess whether there is a difference in effectiveness between these types of self-monitoring. Patient education should be an integral part of the diabetes treatment, and all patients should have the opportunity to participate in the DTTP.

Acknowledgments

Disclosure

The authors declare no conflicts of interest in this work.

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