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SGS: a structured treatment and teaching programme for older patients with diabetes mellitus—a prospective randomised controlled multi-centre trial

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Abstract

Objectives: evaluation of the effectiveness of a new structured diabetes teaching and treatment programme (DTTP) with specific didactical approaches and topics for geriatric patients with diabetes mellitus.
Design: a prospective randomised controlled multi-centre trial.
Setting and participants: a total of 155 geriatric patients were randomly admitted to either the new DTTP SGS ($n = 83$) or the standard DTTP ($n = 72$) for insulin-treated patients with type 2 diabetes mellitus (HbA1c 8.0 ± 1.4%, age 76.2 ± 6.3 years).
Measurements: biometrical data, metabolic control, acute complications, diabetes knowledge, self-management.
Results: SGS participants showed improved levels of HbA1c 6 months after the DTTP, and less acute complications than the standard group ($P<0.009$). Both groups demonstrated a good capacity for diabetes self-management and improvement in diabetes knowledge after the DTTP ($P<0.01$).
Conclusion: the new SGS diabetes education programme, focusing on the learning capabilities and the particular needs of older persons, is effective in improving metabolic control and in maintaining auto-sufficiency in geriatric patients with diabetes mellitus.

Keywords: *diabetes mellitus type 2, patient education, treatment and teaching programme, insulin therapy, randomised controlled trial, elderly*

Introduction

Although patient education has become an integral part of all diabetes therapy programmes, the elderly are often not able to competently follow the variety of topics comprising the standard treatment and teaching programmes for insulin-treated patients with type 2 diabetes mellitus (T2DM), due to neuropsychological and physical deficits [1–3]. To balance clinical recommendations [3, 4] and the needs of older adults with diabetes, a working group of the German Diabetes Association

has developed a structured diabetes treatment and teaching programme (DTTP) specialised for older adults with T2DM called SGS (Strukturierte Geriatrische Schulung, structured geriatric DTTP). In comparison to a standard education programme [5, 6] for patients with T2DM on insulin therapy, which has been well validated in inpatient and outpatient cohorts in Germany [7], the new SGS programme focuses particularly on individual therapeutic goals and maintenance of autonomy. The aim of the present study was to evaluate the effectiveness of the SGS DTTP for insulin-treated older patients with diabetes mellitus, in a prospective, randomised and controlled multi-centre trial.

The SGS DTTP for elderly patients with diabetes

The SGS comprises seven educational classes of 45 min duration. In contrast, the standard DTTP of Berger *et al.* [5] for insulin therapy takes a period of 5 days with 20 h of training. The SGS DTTP focuses less on theoretical knowledge (pathophysiology, insulin dose adoption, or assessment of carbohydrate intake) but allows a more intensive training of practical capabilities such as insulin injection, self-monitoring and management of hypoglycaemia. The new SGS programme takes into account the changes in learning habits of older people (reduced short-term memory, slowed informational processing). The programme is adapted to the demands of older people, for example by giving instruction more slowly and loudly, avoiding technical terms or giving more intensive practice and using defined numbers of repetitions. Educational materials such as patient books and flipcharts with an adequate type size are provided. In the SGS DTTP, a smaller class size of four to six patients is used, whereas the standard DTTP allows up to 10 people to participate in the education classes.

Methods

Inclusion and exclusion criteria

A total of 196 patients with insulin-treated T2DM were screened for study participation from May 2004 until May 2005. Inclusion criteria were insulin-treated diabetes mellitus, at least one geriatric syndrome (such as incontinence, reduced mobility requiring the use of assistive devices, a history of falls during the previous 2 years or cognitive dysfunction), multi-morbidity (more than two chronic diseases besides T2DM) and age >65 years. Exclusion criteria were stroke or myocardial infarction within 2 weeks prior to enrolment as well as a Mini-Mental State Examination (MMSE) below 18 points implying moderate cognitive dysfunction. Of the 196 screened patients, 41 were excluded from statistical analysis (dropouts) because of missing data sets ($n = 22$) or their not finishing the DTTP ($n = 17$). One patient dropped out because of sufficient metabolic control on oral antidiabetic drug therapy.

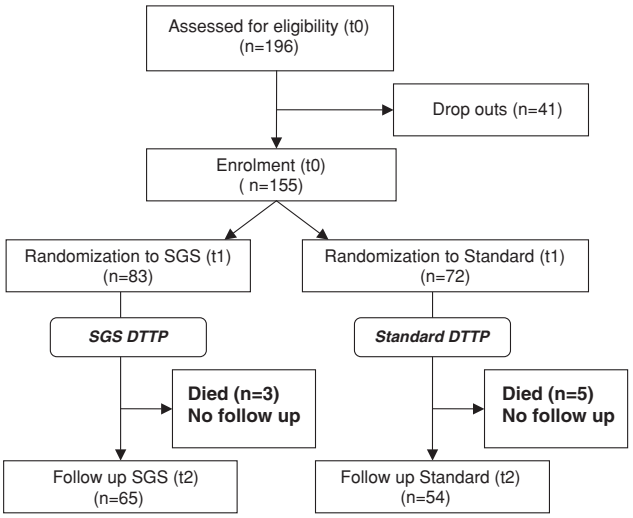

Figure 1. Patient flow.

Sample size and randomisation

According to the sample size calculation for an α set at 0.05 and a power at $1-\beta = 0.8$, a total sample size of 102 in each group will be needed.

Randomisation: a total of 155 patients were admitted to one of 18 study centres in Germany, and sent randomly in groups of four to six people to either the new SGS DTTP or the standard DTTP for insulin-treated patients with T2DM following Berger *et al.* [5]. Randomisation was performed centrally by one study investigator. Randomisation lists were used throughout. The study investigator received a fax of the planned education group (with the study codes, age and sex of the patients) and randomised the group according to the randomisation protocol. Nine of the 18 study centres were outpatient diabetes clinics recruiting 105 study participants (67.7%). Ten inpatient diabetes departments recruited 50 study participants (32.3%). Eighty-three of the 155 patients who were eligible for statistical analysis were randomly sent to the new SGS DTTP, and 72 were placed in the standard programme (patient flow, see Figure 1). Due to delayed patient recruitment, dropout rate and limited financial resources, the study had to be stopped after the inclusion of 155 patients.

The ethics committee approved the study in 2003. The study is registered at Clinical Trials.gov (NCT00391040). All patients gave written informed consent.

The primary outcome measures were improvement of metabolic control and self-management skills. Secondary outcomes were incidence of acute complications, diabetes knowledge and treatment satisfaction.

Measurements

Before (t0), immediately after (t1) and 6 months after the DTTP (t2), outcome quality was measured using standardised methods:

Table 1. Patient characteristics at baseline visit: full sample ($n = 155$) and completers ($n = 119$)

	Full sample			
	Full sample	SGS	Standard	*P*-value
Number of patients	155	83	72	–
Mean HbA1c% ± SD	8.0 ± 1.4	8.3 ± 1.5	7.6 ± 1.3	0.003
Mean age (years) ± SD	76.2 ± 6.3	75.3 ± 6.2	77.3 ± 6.1	0.75
Median diabetes duration (years) (Range)	12.5 (0–56.5)	12.5 (0–56.5)	14.5 (0.3–42.5)	0.12
Mean score MMSE ± SD	26.0 ± 3.1	26.2 ± 2.8	25.8 ± 3.3	0.41
Mean score AKT ± SD	50.9 ± 6.4	51.1 ± 4.8	50.7 ± 8.0	0.72
Female, *n* (%)	103 (66.5)	58 (69.9)	45 (62.5)	0.33
	Completers			
	Completers	SGS	Standard	*P*-value
Number of patients	119	65	54	–
Mean HbA1c% ± SD	8.0 ± 1.4	8.3 ± 1.5	7.7 ± 1.3	0.02
Mean age (years)	75.9 ± 6.4	74.6 ± 6.1	77.5 ± 6.3	0.79
Median diabetes duration (years) (range)	13.7 (0.03–48.5)	12.5 (0.03–48.5)	15.1 (0.3–42.5)	0.09
Mean score MMSE ± SD	25.9 ± 3.2	26.3 ± 2.9	25.5 ± 3.5	0.22
Mean score AKT ± SD	50.7 ± 6.5	51.1 ± 4.7	50.1 ± 8.1	0.51

There was a significant difference SGS versus standard group ($P<0.05$) in HbA1c and body mass index (BMI).

Quality of metabolic control (HbA1c, HPLC Diamat®, Munich, normal range: 4.4–6.3%) was measured by the Institute of Clinical Chemistry, University of Jena, Germany. Additionally, we assessed diabetes duration, duration of insulin therapy, insulin dose and medication.

Treatment satisfaction and diabetes knowledge were assessed using standardised questionnaires [5, 8, 9]. To assess patient skill in diabetes self-management (correct insulin injection, self-monitoring), a detailed standardised handling test (maximum score 23 points [10]) was performed. This test was only performed on patients who injected insulin themselves. All of these 110 participants completed the handling tests immediately after the structured education (t1).

A neuropsychological examination was performed to assess cognitive function including the MMSE [11], and the age concentration test AKT [12]. The MMSE score of 24–30 points reflects no cognitive dysfunction, 18–23 points mild cognitive impairment and below 18 points moderate-to-severe cognitive impairment. The AKT is a validated German symbol test for cognitive function developed for older people using a sum score (maximum 55 points).

Diabetes treatment: at enrolment, 10 (6.7%) patients started on insulin therapy, 107 (70.8%) patients were already on insulin therapy and 34 were on insulin and oral antidiabetic drug therapy (22.5%). There were no significant differences in treatment strategies comparing SGS and standard group participants prior to the DTTP. The mean insulin dose was 42 IU (insulin units)/day (6–140). A total of 77 (49.7%) patients had already participated in a structured DTTP before [22 patients (14.2%) in a DTTP without insulin therapy, 54 patients (34.8%) in a DTTP for insulin-treated patients, no data regarding the type of DTTP given for one patient]. Patient characteristics are shown in Table 1. The mean age of the 155 enrolled patients was 76.2 ± 6.3 years showing a mean HbA1c level of 8.0 ± 1.4% and a median diabetes duration of 12.5 (0–56.5) years.

Comorbidity and acute complications such as symptomatic/severe hypoglycaemia or coma were assessed by patient self-report and medical records. Peripheral polyneuropathy was examined according to Young *et al.* [13], nephropathy according to creatinine clearance [14] and retinopathy according to the ETDRS criteria [15]. Forty-nine per cent of the 155 patients had at least one late complication (retinopathy, nephropathy or peripheral foot ulceration). Retinopathy was present in 12.3% of the patients, peripheral polyneuropathy in 34.8% and nephropathy in 16.1%. Of the 155 patients, 69.2% had at least one geriatric syndrome such as urinary incontinence, cognitive decline, reduced mobility or a history of falls in the past 2 years. The remaining 21.9% suffered from two geriatric syndromes and 8.9% from three or more geriatric syndromes. The most common geriatric syndrome was urinary incontinence in 73.3% of the patients. Coronary heart disease was present in 37.7% of the patients, previous stroke in 15.1% and arterial hypertension in 74.1%. At enrolment, patients were asked a screening question for depression [16]. Thirty-one patients (20%) reported feelings of sadness and depression.

Statistical analysis

Statistical analysis was performed with the software SPSS® (Statistical Package for Social Science, SPSS, Chicago, IL, USA). Normally distributed values were registered as mean ± standard deviation, not normally distributed values as median and range. Comparisons were evaluated with chi-square tests. Student's *t*-test and Wilcoxon tests were used to compare the mean. The significance was set at $P<0.05$. Two-sided testing was used throughout. Associations were evaluated using Pearson's correlations for normally distributed values. Exploratory multiple regression analysis was performed.

Table 2. Results of patients completing the follow-up visit 6 months after participation in the DTTP

	SGS	Standard	*P*-value (SGS vs. standard group)
Number of patients	65	54	–
Diabetes knowledge and results in handling test			
Diabetes knowledge, points ± SD, t0	7.4 ± 2.3	6.8 ± 2.8	0.22
Diabetes knowledge, points ± SD, t1	8.7 ± 2.6	8.7 ± 2.7	0.93
Diabetes knowledge, points ± SD, t2	8.4 ± 2.3	8.3 ± 2.6	0.85
P-value t1 versus t0	0.004	<0.001	–
P-value t2 versus t1	0.011	0.001	–
Handling test, points ± SD, t1	16.7 ± 3.8	15.5 ± 4.6	0.89
Handling test, points ± SD, t2	16.6 ± 3.9	15.4 ± 5.0	0.21
Δ points in the handling test ± SD	0.1 ± 4.6	0.7 ± 6.0	0.61
P-value t2 versus t1	0.93	0.49	–
Metabolic control			
Mean HbA1c% ± SD, t1	8.3 ± 1.5	7.7 ± 1.3	0.02
Mean HbA1c% ± SD, t2	7.7 ± 1.5	7.6 ± 1.5	0.85
P-value t2 versus t1	0.01	0.97	–
Δ mean HbA1c%	0.5 ± 1.5	0.01 ± 1.5	0.08
Treatment satisfaction			
Median treatment satisfaction, points (range), t0	28 (6–38)	28 (13–36)	0.81
Median treatment satisfaction, points (range), t2	31 (13–36)	31 (14–36)	0.97
Hyperglycaemia-related self-reported burdens, points (range), t0	3 (0–6)	3 (0–6)	0.49
Hyperglycaemia-related self-reported burdens, points [range], t2	3 (0–6)	2 (0–6)	0.01
Incidences of acute complications			
Symptomatic hypoglycaemia, events/patient/year, t0	0.63	0.79	0.44
Symptomatic hypoglycaemia, events/patient/year, t2	0.47	0.92	0.009
Severe hypoglycaemia, t0	0.13	0	0.13
Severe hypoglycaemia, t2	0.06	0	0.50
Foot ulceration, t0	0.09	0	0.25
Foot ulceration, t2	0.03	0.15	0.17

Results

One hundred nineteen of 155 patients (78%) were re-examined 6 months after the DTTP (mean 0.64± 0.28 years). Eight patients died during follow-up visits (three out of SGS, five out of the standard group; causes of death in three cases: heart failure, stroke and myocardial infarction; in five cases cause of death was unknown, mean HbA1c at enrolment 7.1 ± 1.0%). Patient characteristics at follow-up (t2) are presented in Table 1.

Primary outcomes

Although on average the SGS participants began the programme with slightly higher HbA1c values (SGS vs. standard group: 8.3 ± 1.5% vs. 7.7 ± 1.3%) due to group randomisation, the HbA1c decrease was significant after SGS education (t1 vs. t2: 8.3 ± 1.5% vs. 7.7 ± 1.5%, $P = 0.01$), while standard group participants maintained their baseline level (7.7 ± 1.3 vs. 7.6 ± 1.5, n.s., Table 2).

Skills in diabetes self-management were similar in both groups (handling test SGS vs. standard: 16.6 ± 3.9 points vs. 15.4 ± 5.0 points, n.s.). The handling test was performed only on patients independent of third-party assistance regarding their insulin therapy. The total number of patients who were able to inject insulin by themselves was higher after the SGS DTTP (SGS vs. standard: 88.2% vs. 75.8%). Six months after teaching, there were still more patients from the SGS group able to perform precise insulin injection (SGS vs. standard: 83.1% vs. 72.2%). In both groups together, 90% of the elderly patients were able to perform correct insulin injection and 85% correct self-monitoring of blood glucose. A total of 96.4% of the patients knew the correct timing and area of insulin application after the structured DTTP, but only 63% of the geriatric patients were able to remember the name and type of their insulin.

Secondary outcomes

Diabetes knowledge increased significantly in both groups after the DTTP (SGS t0 vs. t1: 7.4 ± 2.3 points vs. 8.7 ± 2.6 points, $P = 0.004$; standard t0 vs. t1: 6.8 ± 2.8 vs. 8.7 ± 2.7 points, $P = 0.001$. Six months after the structured DTTP (t2), a slight decrease in diabetes knowledge in both groups was measured, but compared to baseline knowledge, was still at a significantly higher level (SGS t0 vs. t2: 7.4 ± 2.3 points vs. 8.4 ± 2.3 points, $P = 0.011$; standard: 6.8 ± 2.8 points vs. 8.3 ± 2.6 points, $P = 0.001$). Overall treatment satisfaction was equal in both groups at the t0 and t2 visits [SGS vs. standard t0: 28 (6–38) points vs. 28 (13–36) points, n.s.; t2: 31 (13–36) points vs. 31 (14–36) points, n.s.]. However, patients who participated in the SGS DTTP reported a significantly lower number of problems due to

hyperglycaemia 6 months after the DTTP [SGS vs. standard t2: 3 (0–6) points vs. 2 (0–6) points, $P = 0.01$].

Acute complications

The number of incidences of symptomatic hypoglycaemia was significantly lower in the SGS group (SGS vs. standard group t2: 0.47 events/patient/year vs. 0.92 events/patient/year, $P = 0.009$). The numbers of incidences of severe hypoglycaemia (need of i.v. glucose or i.m. glucagon injection) and incidences of foot ulceration were comparable in both groups. There were no cases of coma during the study period.

Correlation analysis

There was a significant negative correlation of skills in diabetes self-management with age ($r = -0.21$; $P = 0.02$), number of geriatric syndromes ($r = -0.26$; $P = 0.005$) and points in AKT ($r = 0.20$; $P = 0.04$). There was a correlation of the performance in diabetes knowledge test ($r = 0.19$; $P = 0.03$) with the performance in the MMSE and with diabetes duration ($r = 0.19$; $P = 0.04$), but not with age. In multivariate analysis, the points in the MMSE prior to the DTTP ($P = 0.02$) and the absence of geriatric syndromes ($P = 0.009$) were associated with better diabetes self-management skills after the DTTP (other factors included in the model: age, AKT score).

Discussion

This study demonstrates that the new SGS DTTP promotes a significant HbA1c decrease, reduces incidence of acute complications, improves diabetes knowledge and enhances diabetes self-management skills.

Although the study was performed as a randomised trial, there are limitations due to differences in HbA1c levels at enrolment. The randomisation of study participants was performed using group randomisation lists. HbA1c was measured in one central laboratory at the University of Jena to avoid bias. As other variables were well randomised, we suggest that the reason for the differences in HbA1c is the small sample size. According to the sample size calculation, 102 patients per group should have been randomised to obtain a significant HbA1c decrease, but due to limited financial resources and difficulties in recruitment of older geriatric patients facing multi-morbidity, the study had to be stopped before. In our opinion, both groups tend to stay close to the target levels and differences in baseline HbA1c should not strongly affect the study results. The adjustment of HbA1c reduction for baseline HbA1c in this study cohort was not indicated due to its small variance.

Both training groups had a favourable effect on diabetes knowledge. The present study demonstrates that patient-oriented education is suitable to enhance diabetes self-management skills in the older patients. Moreover, the SGS DTTP needs fewer resources (e.g. time expense). Its didactic particularities reduce common barriers for the diabetes education of older patients.

Prevention of frailty, cognitive decline or immobility not only reduces the need for care by the elderly, but increases quality of life as well—and clearly promotes motivation for better diabetes control [17–19]. Furthermore, epidemiological data indicate that serious quality issues in the treatment of elderly people with diabetes will indeed challenge health care providers in the near future, because of the increasing life expectancy and incidence of diabetes in older age [20, 21].

The participation in structured education programmes is associated with improvement in quality of life in elderly patients with T2DM [22]. Elderly diabetic patients showed a slight but not significant increase in treatment satisfaction in both groups, but SGS participants showed less personal anxiety due to hyperglycaemia even though they showed higher HbA1c levels at enrolment. One conclusion of this study is that geriatric patients with diabetes, even with mild cognitive impairment and depression, can benefit from a DTTP concerning objective outcomes as well as self-reported measures, as shown by the reduction of fear of hypoglycaemia.

There is increasing evidence that patient-oriented education is beneficial with regard to quality criteria and patient outcomes [1, 23, 24]. Patient education enables patients with diabetes to perform treatment strategies on their own authority [22, 25]. Several studies have found that younger patients with diabetes who have participated in a structured DTTP perform more accurate blood–glucose self-monitoring, show improved diabetes knowledge, improved metabolic control and increased diabetes-related quality of life and suffer fewer acute complications [1, 3, 26].

The innovative training programme SGS addresses a current and rapidly growing problem, and fills an existing gap centring on the geriatric patient with diabetes.

Although the average diabetes duration in this study was nearly 14 years, only half of the participants had previously participated in any structured diabetes training programme. The barriers to health care are still more for geriatric patients. Increasingly, patients with diabetes live to an advanced age accompanied by a variety of impairments and geriatric syndromes [17–19] as well as multi-morbidity. Besides the prevention of catabolic symptoms or acute complications, the new DTTP SGS embraces a practical approach focusing on the maintenance of autonomy and definition of individual therapeutic goals to assure well-being of the older patients concerning also the interaction between diabetes and geriatric syndromes [4, 20].

The SGS is a new approach to education of the geriatric patient, focusing on resources, accepting deficits and lowering barriers to participation in modern treatment strategies for elderly patients.

Key points

- The SGS programme is a new structured DTTP for geriatric patients with diabetes mellitus considering the limited resources and learning capabilities of older people.

- The SGS programme focuses on the maintenance of autonomy of older people and is effective in transferring both diabetes knowledge and diabetes management to geriatric patients. Its effectiveness has been proven within the present randomised controlled trial.

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Conflicts of interest

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Prevalence of flexible bronchoscopic removal of foreign bodies in the advanced elderly

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Abstract

Objectives: to define the likelihood and establish the overall safety and effectiveness of flexible bronchoscopy in the removal of foreign bodies in the advanced elderly compared to those younger.
Design: a retrospective case–control analysis.
Setting: tertiary care academic hospital.
Population: 7,089 adults (age >18 years), including 949 (15%) advanced elderly (age >75 years), who underwent flexible bronchoscopy between January 1995 and June 2007.
Measurements: in those patients with foreign body aspiration (FBA) ($n = 20$), a comparison of multiple clinical characteristics based on defined age groups (group 1, age <75 years and group 2, age >75 years) was performed.
Results: FBA requiring bronchoscopic removal was greater than three and a half times more likely in patients aged >75 years compared to those younger (OR 3.78, CI 1.4–10: $P < 0.05$). Flexible bronchoscopy was 87.5% effective in the removal of foreign bodies in the advanced elderly and associated with no increase in adverse events.
Conclusion: bronchoscopic removal of foreign bodies is more likely in the advanced elderly when compared to those younger. This implies that this population may be most at risk. Flexible bronchoscopy is a safe and effective initial diagnostic and therapeutic approach in this age group.

Keywords: *foreign body aspiration, elderly, advanced elderly, flexible bronchoscopy*

Introduction

Foreign body aspiration (FBA), defined as the introduction of a large particulate material into the tracheobronchial tree, is a rare event that increases with age [1–4]. Despite this age association, the risk of FBA in older adults remains poorly defined. The presence of cerebrovascular disease, heart