Compliance with guidelines for disease management in diabetes: results from the SwissDiab Registry

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ABSTRACT

Objective Tight glycemic control and aggressive treatment of additional cardiovascular risk factors can substantially reduce risk of diabetes-related complications. In 2013, the Swiss Society of Endocrinology and Diabetology (SSED) established national criteria on good disease management in diabetes, but little is known about compliance in clinical care. Here we assessed to what extent patients from two tertiary care centers in the German-speaking part of Switzerland enrolled in the Swiss Diabetes (SwissDiab) Registry adhere to the SSED criteria.

Research design and methods SwissDiab is a prospective observational cohort study of patients regularly treated at Swiss tertiary diabetes centers. Data were collected through standardized annual health examinations. Baseline participant descriptive statistics, stratified by diabetes mellitus type 1 (DM1) and type 2 (DM2), were compared with SSED targets for glycemic control, blood pressure, blood lipids, weight maintenance, and ophthalmic examination.

Results By the end of 2016, 604 participants with DM1 (40%) and DM2 (60%) had data available for analyses, 36% and 29% women, respectively. At baseline, all the SSED targets were met with two exceptions: a glycated hemoglobin A1c value <7% was measured in 32% of participants with DM1 (SSED target: ≥80%) and 47% and 56% of overweight or obese participants with DM1 and DM2, respectively, received nutritional counseling in the previous year (SSED target: ≥40%).

Conclusions The SSED targets for good disease management in diabetes were achieved in the majority of participants at the time of enrollment, but results also highlight areas where disease management can be improved, particularly the role of nutrition counseling.

INTRODUCTION

Tight glycemic control and aggressive treatment of additional cardiovascular risk factors have shown to reduce both microvascular and macrovascular complications of diabetes.1–4 This has led to treatment standards targeting both therapeutic and process of care parameters. Benefits from adherence to such guidelines have been shown in several studies, including better glycemic control, lower risk of long-term morbidity and mortality, improved quality of life, and lower healthcare costs.5–8 However, studies have also shown great disparities between guideline objectives and actual standard of care.6 9 10

Data on the current standard of diabetes care in Switzerland are scarce. To fill this gap, two tertiary diabetes care centers in the German-speaking part of Switzerland (St. Gallen and Bern) initiated the Swiss Diabetes (SwissDiab) Registry in 2008, a national multicenter project with the aim to prospectively collect data regarding diabetes management and prevalence and incidence of diabetes-related complications. The first patients were enrolled in 2010. Participants undergo an extensive annual health examination according to a standardized protocol. In 2013, the Swiss Society of Endocrinology and Diabetology (SSED) established national target criteria for good disease management in diabetes. The target criteria are based on the Diabetes Recognition Program established by the American Diabetes Association.
RESEARCH DESIGN AND METHODS

Study participants
SwissDiab is an ongoing prospective observational cohort study enrolling patients with diabetes regularly seen and treated at Swiss tertiary diabetes care centers. Eligible are patients ≥18 years of age, regardless of diabetes type (gestational diabetes excluded), duration, or treatment. Patients with a life expectancy <1 year due to severe comorbidity (eg, end-stage cancer) or unable to comply with the study protocol (eg, due to mental disorder or drug abuse) are excluded at the discretion of the attending physician. Diabetes is defined according to ADA (glycated hemoglobin A1c (HbA1c) ≥6.5% (≥48 mmol/mol) or fasting plasma glucose ≥7 mmol/L or random plasma glucose ≥11.1 mmol/L plus typical symptoms or 2-hour plasma glucose ≥11.1 mmol/L following a 75 g oral glucose tolerance test). Patients under treatment with ≥2 oral hypoglycemic agents and/or insulin in the absence of a clinical diagnosis (as defined above) are also included. Diabetes type is diagnosed clinically in most cases, supported by autoantibody status where appropriate.

The present study includes data from the two initial centers in the German-speaking part of Switzerland, the Division of Diabetes, Endocrinology, Nutritional Medicine, and Metabolism, Inselspital Bern, University Hospital, Bern, and the Division of Endocrinology and Diabetes at the Cantonal Hospital of St. Gallen. All participants provided written informed consent.

Research design and methods
Patient-related data were collected through a standardized annual health examination, comprising the following domains.

Diabetes-specific medical history
Information relevant to the care and management of diabetes (eg, diabetes type, date of diagnosis, family history, treatment history (including drug class and dosages), hypoglycemic events, and diabetes-related complications) was obtained from the patient history, supplemented by information retrieved from other sources like patient records where appropriate.

Clinical and anthropometric measurements
Clinical examinations were conducted by trained medical staff experienced in epidemiological and clinical studies. Weight (to the nearest 0.1 kg) was measured with participants wearing light clothes and no shoes. Height (to the nearest 0.5 cm) was measured using a wall-mounted stadiometer. Body mass index (BMI) was calculated as weight (kg) divided by height (m) squared. Waist circumference was measured at the widest point using a non-stretchable tape. At baseline, systolic blood pressure (SBP) and diastolic blood pressure (DBP) was measured once on each arm following a 5 min rest with the participant in a seated position. The mean of the two measurements was used.

Biochemistry
Participants arrived at the study center following an overnight fast (≥7.5 hours), having been instructed to take their antihypertensive medication as prescribed. Fasted blood was drawn from the antecubital vein and further processed. HbA1c was determined using a Diabetes Control and Complications Trial (DCCT)/UK Prospective Diabetes Study (UKPDS) traceable assay. Serum total, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) cholesterol, and triglycerides were measured according to routine methods at the laboratory medicine at each center. Aliquots of serum and whole blood were stored at −80°C.

Criteria for good disease management in diabetes
The SSED criteria for good disease management in diabetes define treatment targets in eight domains to guide diabetes-specific standard of care in Switzerland. The current analysis focused on a subset of criteria related to clinical and biochemical targets, and frequencies of nutrition counseling and ophthalmic examination. The remaining treatment objectives were excluded from the analysis as they were either part of the SwissDiab annual health examination (ie, foot exam, and screening for neuropathy and nephropathy) and thus performed in all participants or information was not collected (eg, physical activity counseling if BMI ≥25 kg/m², and smoking cessation counseling in active smokers). Specifically, compliance with the treatment targets in the following five domains was assessed:

1. HbA1c:
   - ≥9.0% (75 mmol/mol) in <15% of patients
   - ≤8.0% (64 mmol/mol) in ≥60% of patients
   - ≤7.0% (53 mmol/mol) in ≥80% of patients
2. BP ≥140/90 mm Hg in <35% of patients
3. LDL-cholesterol levels in patients <75 years of age:
   - ≥3.37 mmol/L in <37% of patients
   - <2.6 mmol/L in ≥36% of patients
4. Annual nutrition counseling in ≥80% of patients with a BMI ≥25 kg/m²
5. Annual standard ophthalmic examination in ≥60% of patients

The current analysis was based on data collected during the baseline annual health examination. Data
from both study centers were pooled and analyses were stratified by diabetes mellitus type 1 (DM1) and type 2 (DM2). In secondary analyses, further stratification was done by time since diagnosis (≤5 years or >5 years) to explore whether diabetes duration influences treatment outcomes. Descriptive statistics were computed as medians and IQR for continuous variables and percentages for dichotomous variables. Between-group differences were determined using two-sided Wilcoxon rank-sum test for continuous variables and \( \chi^2 \) test for categorical variables. All analyses were performed using SAS V.9.3 (SAS Institute).

RESULTS

Baseline participant characteristics

By 31 December 2016 data for 674 SwissDiab participants were available for analysis, 55% (n=371) of them recruited in St. Gallen and 45% (n=303) in Bern, constituting 248 cases (37%) of DM1, 375 cases (55%) of DM2, and 51 cases (8%) of rarer forms of diabetes (eg, monogenic and drug-induced diabetes). The latter group was excluded from the analysis. Participants lacking HbA1c (2%) or with implausible data (BMI <15 or >90 kg/m\(^2\) (1%)) were excluded, leaving 239 participants with DM1 and 365 participants with DM2 eligible for analysis. Baseline descriptive characteristics of the 604 SwissDiab participants included in the analysis are shown in table 1.

Compliance with SSED criteria for good disease management of diabetes

Table 2 shows the proportion of SwissDiab participants fulfilling the criteria for good glycemic and BP control established by the SSED.\(^13\) The proportion of participants with an HbA1c≥9%, and an HbA1c<8% comply with the SSED targets (<15% and ≥60%, respectively), regardless of diabetes type and with no statistically significant difference between the DM1 and DM2 group. The SSED target of an HbA1c<7% in ≥40% of patients was only achieved in the group with DM2. The proportion of participants with high BP (≥140/90 mm Hg) was within the SSED target (<35%) in both the DM1 and DM2 groups.

As shown in table 3, although the SSED targets for LDL-cholesterol levels in patients <75 years of age were achieved in both the DM1 and DM2 groups, the proportion tended to be greater in the DM2 group.

Regardless of diabetes type, the majority of participants underwent at least one ophthalmic examination during the year prior to the baseline SwissDiab examination.
The SSED target of \(\geq 80\%\) was achieved in both the DM1 (88.4%, \(n=206\), data missing in six participants) and DM2 groups (90.4%, \(n=328\), data missing in two participants), with no statistically significant difference between the groups (P-difference=0.45).

Of the 109 participants with DM1 and a BMI\(\geq 25\) kg/m\(^2\), information on nutrition counseling was available in 104 participants. Of these, 47.1% (\(n=49\)) received nutrition counseling in the previous year. In the DM2 group, 93.4% (\(n=311\)) were overweight or obese, and 56.1% (\(n=184\)) received nutrition counseling in the previous year (information missing in 13 overweight or obese participants). Neither group thus achieved the SSED target of \(\geq 80\%\).

### Stratification based on time since diagnosis

The 39 participants diagnosed with DM1 \(\leq 5\) years ago (information missing for one participant) were younger at the time of diagnosis compared with the 199 participants diagnosed \(>5\) years ago (36.0 years (27.0–49.0) vs 16.0 years (11.0–31.0), P-difference <0.0001) with a lower average Hba1c (7.0% (6.3–7.8) vs 7.4% (6.9–8.0), P-difference=0.04). Compared with the 282 participants diagnosed with DM2 \(>5\) years ago (information missing for three participants), the 80 participants diagnosed with DM2 \(\leq 5\) years ago were younger (56.5 years (49.9–63.2) vs 63.9 years (56.6–70.1), P-difference <0.0001) and achieved their diagnosis at an older age (53.0 years (46.5–60.5) vs 47.0 years (41.0–54.0), P-difference <0.0001). The latter group had a lower average Hba1c (6.6% (6.1–7.3) vs 7.3% (6.7–8.0), P-difference <0.0001) and higher total cholesterol (4.5 mmol/L (4.0–5.4) vs 4.0 mmol/L (3.5–4.7), P-difference <0.0001) and LDL-cholesterol (2.7 mmol/L (2.1–3.3) vs 2.3 mmol/L (1.8–2.7), P-difference <0.0001) levels. The complete set of participant characteristics stratified by diabetes type and time since diagnosis are available in online supplementary table 1.

Both groups fulfilled the SSED criterion of an Hba1c<7%, achieving the SSED target of \(\geq 40\%\). Among the 199 participants diagnosed with DM1 \(\leq 5\) years ago, 48.7% (\(n=57\)) fulfilled the SSED criterion.

Among the 282 participants diagnosed with DM2 \(>5\) years ago, 38.3% (\(n=108\)) fulfilled the SSED criterion.

### Table 2

| SSED Criterion | SSED target (%) | DM1 (\(n=239\)) | DM2 (\(n=365\)) | P-diff |
|----------------|-----------------|-----------------|-----------------|------|
| Hba1c<9% (75 mmol/mol) | <15 | \(n=20\), 8% | \(n=28\), 8% | 0.76 |
| Hba1c<8% (64 mmol/mol) | \(\geq 60\) | \(n=179\), 75% | \(n=281\), 77% | 0.56 |
| Hba1c<7% (53 mmol/mol) | \(\geq 40\) | \(n=76\), 32% | \(n=159\), 44% | 0.004 |
| BP\(\geq 140/90\) mm Hg | <35 | \(n=7^*\), 3% | \(n=281\), 8% | 0.02 |

Group estimates that meet the SSED targets are highlighted in bold. Between-group differences determined with the \(\chi^2\) test.

*Information missing in three participants.
†Information missing in two participants.

DM1, diabetes mellitus type 1; DM2, diabetes mellitus type 2; Hba1c, glycated hemoglobin A1c.

### Table 3

| LDL-cholesterol | SSED target (%) | DM1 (\(n=235^*\)) | DM2 (\(n=336^\dagger\)) | P-diff |
|-----------------|-----------------|-----------------|-----------------|------|
| \(\geq 3.37\) mmol/L | <37 | \(n=43\), 18% | \(n=43\), 13% | 0.07 |
| <2.6 mmol/L | \(\geq 36\) | \(n=112\), 48% | \(n=198\), 59% | 0.008 |

Group estimates that meet the SSED target criteria are highlighted in bold. Between-group differences determined with the \(\chi^2\) test.

*One participant excluded due to missing LDL-cholesterol data.
†Two participants excluded due to missing LDL-cholesterol data.

DM1, diabetes mellitus type 1; DM2, diabetes mellitus type 2.
result was obtained for the SSED target of an LDL-cholesterol level of <2.6 mmol/L in ≥36% of patients, with 42.3% (n=33) fulfilling the criterion in the group diagnosed with DM2 ≤5 years ago and 64.1% (n=164) fulfilling the criterion in the group diagnosed with DM2 >5 years ago (Pdifference=0.0006). No statistically significant differences in the LDL-cholesterol targets were observed in participants diagnoses with DM1 ≤5 years or >5 years ago.

The complete set of results stratified by diabetes type and time since diabetes diagnosis are available in online supplementary tables 2-3.

CONCLUSIONS

Here we analyzed baseline data of 604 SwissDiab participants with DM1 and DM2 with respect to compliance with a subset of SSED national guidelines for good diabetes management (eg, implementation of new technologies, flexible insulin therapy, and diabetes education). Comparing data of all patients with DM2 with the aim to compare prevalence of vascular disease in the general population, but decreased during the last two decades, indicating improved treatment strategies.

In 2011, Gerber et al published a study on 1121 patients with DM2 treated by general practitioners in the four linguistic regions (German, French, Italian, and Romansh) of Switzerland. The mean HbA1c level was 6.9±1.0% in the German-speaking region compared with 7.3±1.1% (median 7.1% [6.6–7.9]) in SwissDiab. Furthermore, mean BMI (29.5±5.4 kg/m²) as well as BP (SBP, 138.2±16.4 mm Hg; DBP, 81.1±10.4 mm Hg) tended to be lower in the study by Gerber et al compared with the SwissDiab study (BMI, mean=32.8±6.2 kg/m², median=32.1 kg/m² [28.4–36.5]; SBP, mean=138.7±16.6 mm Hg, median=138.0 mm Hg [127.0–149.5]; DBP, mean=77.4±10.0 mm Hg, median=77.5 mm Hg [72.0–83.5]), suggesting that the metabolic profile of participants in the former study was better, which is not surprising given the different clinical settings in which the participants of the two studies were recruited. Mean age at diagnosis of DM2 in SwissDiab was 48.3±10.4 years (median 48.0 years [42.0–56.0]), and the mean age at start of therapy in the study by Gerber et al was 60.9±11.2 years. Given that antidiabetic treatment is generally initiated within 1 year of diagnosis, this might indicate an earlier onset and a more advanced and progressive course of disease in the SwissDiab participants, which would be in line with the tertiary care setting in which participants were recruited. It is also possible that variations in diabetes therapy contribute to the differences; however, data on medication are not yet available in SwissDiab.

In 2013, Burgmann et al published a retrospective study comparing data of all patients with DM2 admitted to the general clinic of medicine at the Hospital Centre Biel in 2009 to the treatment recommendations published by the SSED the same year. Mean age was higher compared with the SwissDiab participants (74.2±10.8 years vs 61.3±10.4 years, median=62.1 years [54.7–68.8]) as was the mean HbA1c (7.7±1.7% vs 7.3±1.1%; median=7.1% [6.6–7.9]). The authors concluded that metabolic control was suboptimal in the majority of patients with DM2 and implementations of treatment guidelines by general practitioners as well as hospitals need to be improved. However, the results may rather reflect a greater disease burden of hospitalized patients with DM2, and as such, may not reflect a general failure to adhere to treatment guidelines. Burgmann et al do not provide detailed information on disease burden or the reason behind hospitalization but 44% of patients with DM2 presented with an HbA1c level ≤7%, which is similar to the proportion seen in the tertiary setting of SwissDiab. Furthermore, 20% had an HbA1c>8.5% (11% in SwissDiab), supporting the assumption that glycemic control in individuals with DM2 and need of hospitalization tends to be worse compared with patients in outpatient clinics.
In 2014, Zuercher et al published baseline data from the CoDiab-VD Study, a population-based cohort of participants with diabetes recruited in the French speaking canton of Vaud. Of the 519 participants, 67% were diagnosed with DM2. Mean age and diabetes duration were similar to that observed in SwissDiab. Self-reported HbA1c was available in 177 participants (34%) with unspecified diabetes type and was similar to baseline HbA1c in the SwissDiab DM1 and DM2 groups (7.3% (95% CI 7.1 to 7.5) vs 7.5% (95% CI 7.3 to 7.6) and 7.3% (95% CI 7.2 to 7.4), respectively). The recruitment strategy via community pharmacies (participation rate ≤50%) has the potential to capture a more health-conscious fraction of the target population. Further assuming that HbA1c-aware participants are more health-conscious and therefore better controlled, the HbA1c level is likely to be an underestimation of the population average. General practitioners might measure HbA1c less frequently in patients with milder forms of diabetes, for example, those treated only with oral antidiabetic medication (51% in CoDiab-VD), or might communicate good HbA1c levels less actively as they may not have an immediate therapeutic consequence. With the limited information provided, it is difficult to draw any conclusions regarding differences in disease severity between the two studies.

The SSED targets for LDL-cholesterol were met in both SwissDiab and the inpatients with DM2 in Burgmann et al. Lack of information in the study by Gerber et al and in CoDiab-VD precludes comparisons with these study populations. That LDL-cholesterol was better controlled in the DM2 compared with the DM1 group is to be expected as cardiovascular risk is higher in DM2 compared with DM1 in the absence of secondary complications. Therefore, one can assume that the proportion of participants on statins was higher in the DM2 group. Higher mean total and LDL-cholesterol levels in participants diagnosed with DM2 ≤5 years ago were unexpected. Given the better glycemic control in this group, one possible explanation is that healthcare professionals in charge are less stringently targeting lipids. Suboptimal adherence to prescribed lipid-lowering medications might also be an explanation. However, information on medication is not yet available for analysis in SwissDiab.

Out of 511 participants in CoDiab-VD, 58% attended an ophthalmic examination during the previous year, whereas the SSED target of ≥80% was achieved in SwissDiab. How representative these results are to the primary care setting is unclear. It is possible that patients with more severe diabetes, as often is the case in tertiary care settings, are more carefully screened.

The SSED criterion regarding weight maintenance addresses the importance of raising patient awareness of the central role of weight and diet for good diabetes management through annual discussions with the healthcare provider. In CoDiab-VD, written or verbal diet recommendations were received by 49% of the participants. Distinction between DM1 and DM2, or based on BMI category was not provided, preventing direct comparisons with SwissDiab, where 47% and 56% of overweight/obese participants with DM1 and DM2, respectively, received nutrition counseling. Irrespective, this area of diabetes care and management can clearly be improved. The primary focus of the SSED criteria is the primary care setting, where fostering of healthy lifestyle choices likely has the potential to substantially reduce the risk of future need of tertiary care, improve quality of life and reduce the burden on healthcare systems. Future studies assessing compliance in the primary care setting are therefore warranted.

Applying diabetes care targets primarily aimed at the primary care setting to tertiary care could be considered too stringent as the patient group of the latter likely includes patients with a more advanced and progressive course of disease where, for example, glycemic control is likely harder to achieve. On the other hand, benefits of intensive multifactorial therapy in reducing microvascular and/or macrovascular complications have been shown, and might thus be beneficial to the high-risk patient group with diabetes treated in tertiary care. As this study illustrates, it is possible to adhere to the majority of the SSED targets in this high-risk patient group. However, although shown to be beneficial, intensive therapy including tight glycemic control has also been associated with increased mortality in high-risk individuals with DM2, emphasizing that on the individual level, treatment goals should always be based on patient-specific characteristics, including risk of hypoglycemia, diabetes duration, life expectancy, comorbidities, and other relevant factors. Longitudinal studies of the SwissDiab participants will be able to assess whether adherence to the SSED targets influences incidence of diabetes-related complications and comorbidities in this patient group.

The main limitation is that the study is based on two out of the six largest tertiary diabetes care centers in the German-speaking part of Switzerland. Although similar hospital standards and access to care are expected, the generalizability of the results to tertiary care in the German-speaking part and Switzerland as a whole is unclear. To what extent the enrolled patients are representative of the patient group at large at the two centers is also not known, but currently under investigation. A further limitation is that not all of the SSED criteria could be assessed due to lack of information on physical activity and smoking cessation counseling, and the inability to provide meaningful data on the performance of nephropathy screenings and foot exams that would be representative of the general clinical practice at the tertiary care centers involved, as these two exams are integral parts of the annual SwissDiab examination.

As patients treated at tertiary care centers are more likely to present with advanced disease stages and diabetes-related complications, the study population represents a patient group that generally requires a large proportion of healthcare resources. It is thus important to obtain information on the status of quality of care.

Epidemiology/Health Services Research

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and treatment in this patient group. Next to CoDiab-VD, SwissDiab is the largest observational study in Switzerland including patients with DM1 and DM2. The longitudinal setting and standardized annual examinations gain advantage over the CoDiab-VD Study, which is based largely on self-report. SwissDiab is thus a resource that has the potential to provide comprehensive and significant information on diabetes care in Switzerland. This will be of vital importance for decision makers in politics and the health sector in view of rising patient numbers and limited financial resources. As additional study centers are recruited, including the other language regions, SwissDiab will continue to give an even more complete picture on the quality of diabetes care and patient outcomes in Switzerland in the future.

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