



Temporal Trends and Contemporary Use of Insulin Pump Therapy and Glucose Monitoring Among Children, Adolescents, and Adults With Type 1 Diabetes Between 1995 and 2017

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OBJECTIVE

To investigate temporal trends and contemporary use of insulin pump therapy and glucose monitoring in type 1 diabetes.

RESEARCH DESIGN AND METHODS

In a population-based study, we analyzed the use of insulin pump therapy, continuous glucose monitoring (CGM), and self-monitoring of blood glucose (SMBG) from 1995 to 2017 in patients with type 1 diabetes identified from the Diabetes Prospective Follow-up (DPV) database in Germany and Austria. Patients were stratified by age, sex, migration background, and country.

RESULTS

Among 96,547 patients with type 1 diabetes (median age 17.9 years, 53% males), the percentage using insulin pump therapy increased from 1% in 1995 to 53% in 2017, with the highest rates in the youngest patients (92% in preschoolers, 74% in children, 56% in adolescents aged <15 years, 46% in adolescents aged ≥15 years, 37% in adults). The percentage of patients using CGM increased from 3% in 2006 to 38% in 2017, with the highest rates in the youngest patients (58%, 52%, 45%, 33%, and 15% of respective age-groups). Daily SMBG frequencies increased from 1995 to 2016 and decreased afterward, most prominently in the youngest patients. Between 2015 and 2017, pump therapy was more frequently used in female versus male adolescents and adults (all $P < 0.001$), while no sex differences were observed for pump use in children <10 years (all $P = 1.0$) and for CGM use in all age-groups (all $P = 1.0$).

CONCLUSIONS

Since 1995, insulin pump use has continuously increased, and insulin pump therapy is now standard in patients aged <15 years. CGM use sharply rose in recent years, particularly in young children.

Insulin pump therapy offers the potential to improve glycemic control (1,2) and may help to reduce long-term diabetes complications (3,4) as well as the risk of acute complications, such as severe hypoglycemia and diabetic ketoacidosis (2) in patients with type 1 diabetes. Young patients using pump therapy experience a benefit in health-related quality of life (1,5). In recent years, continuous glucose monitoring (CGM) measuring interstitial glucose concentrations to navigate insulin therapy has gained popularity among patients with type 1 diabetes (1,6).

The use of insulin pumps (7) and CGM (8) in type 1 diabetes treatment has been fostered by rapid technological evolution (6,9), efficacy as demonstrated by clinical trials and scientific reports (1,2,6,8,10), cost-effectiveness encouraging reimbursement by health care systems (6,10,11), and acceptance by patients in their daily lives and by health care providers (8,12). The impact of these technologies on routine diabetes care during the past 20 years is, however, not well defined, particularly among patients of different age-groups. The aim of this study was to investigate temporal trends in the use of insulin pump therapy, CGM, and self-monitoring of blood glucose (SMBG) from 1995 to 2017 in children, adolescents, and adults with type 1 diabetes and to compare the contemporary use of insulin pumps, CGM, and SMBG by sex, migration background, and country using a large population-based registry from Germany and Austria.

RESEARCH DESIGN AND METHODS

Study Design

This population-based cohort study analyzed the use of insulin pump therapy and glucose monitoring among patients with type 1 diabetes between 1 January 1995 and 31 December 2017 in Germany and Austria. The percentage of patients using pump therapy, the percentage using CGM, and their mean daily SMBG frequency were longitudinally investigated by calendar year in patients aged 1.5–4.9 years (preschoolers), 5–9.9 years (children), 10–14.9 years (young adolescents), 15–19.9 years (adolescents), and ≥ 20 years (adults). Additionally, in a cross-sectional analysis of the most recent treatment year between 2015 and 2017, the use of pump therapy, CGM, and SMBG frequency were

compared by sex, migration background, and country. Patients included in the study were identified from the Diabetes Prospective Follow-up (DPV) database at Ulm University. As of 31 December 2017, 470 diabetes centers have documented diabetes treatment and outcomes using the DPV Diabetes Documentation System. The analysis of anonymized data was approved by the ethics committee of Ulm University.

Study Population

Patients were eligible for inclusion in the study if they had a clinical diagnosis of type 1 diabetes and were treated with insulin in Germany or Austria. Exclusion criteria were age < 6 months at diagnosis and diabetes duration < 12 months. For each patient, clinical data including age, duration of diabetes, HbA_{1c} level, and BMI (calculated as weight in kilograms divided by the square of height in meters) were aggregated as medians of the most recent treatment year. Insulin treatment regimen was categorized as pump therapy or injection therapy. Migration background was defined as place of birth outside Germany or Austria for the patient or for one or both parents.

Outcomes

The percentage of patients using insulin pump therapy and CGM and the mean daily SMBG frequency were investigated. Pump therapy was defined as continuous subcutaneous insulin infusion documented at least once per year. CGM was defined as the use of either intermittent scanning or real-time glucose monitoring. CGM was analyzed for any use (≥ 1 day/year), for use ≥ 30 days/year, and for use ≥ 100 days/year. Sensor-augmented pump therapy (SAP) was defined as simultaneous use of insulin pump therapy and CGM ≥ 30 days/year. As a subgroup of SAP, low-glucose suspend (LGS) and predictive low-glucose suspend (PLGS) systems were documented. Frequency of SMBG per day was aggregated as the mean from all visits per year. Severe hypoglycemia was defined as requiring assistance from another person to actively administer carbohydrates, glucagon, or intravenous glucose consistent with guidelines from the International Society for Pediatric and Adolescent Diabetes (ISPAD) (13). Hypoglycemic coma was defined as loss of consciousness or occurrence of

seizures according to the ISPAD classification (13).

Statistical Analyses

HbA_{1c} values were mathematically standardized to the Diabetes Control and Complications Trial (DCCT) reference range (4.05–6.05%) using the multiple-of-the-mean transformation method. BMI values were transformed to SD scores on the basis of German reference values by applying the LMS method (14). The Wilcoxon test was used to compare continuous variables. The χ^2 test was used to compare variables with binomial distribution. Adjustment for multiple comparisons was performed according to the Holm-Bonferroni stepdown procedure. $P < 0.05$ (two-sided) was considered statistically significant. All analyses were performed using SAS version 9.4 for Windows software (SAS Institute).

RESULTS

Study Population

A total of 96,547 patients with type 1 diabetes treated in 432 diabetes centers was included in this study. To investigate temporal trends, data from 1,513,196 visits between 1995 and 2017, representing 414,503 patient-years, were analyzed. The median age of the study population was 17.9 years, 53% of patients were males, 33,341 patients were treated with insulin pump therapy, and 63,206 patients were treated with injection therapy (Table 1). CGM was used by 14,419 individuals ≥ 1 day/year, by 10,745 patients ≥ 30 days/year, and by 8,201 ≥ 100 days/year (Table 1). SAP was used by 7,070 patients, including 609 using LGS or PLGS systems.

To compare the contemporary use of diabetes technologies by sex, migration background, and country, 41,597 patients (53% males) were included between 2015 and 2017, of whom 38,324 were treated in Germany and 3,273 were treated in Austria. Of these patients, 7,931 (19%) had a migration background. Median age was 16.4 years (quartiles 12.4; 20.7). Median diabetes duration was 6.8 years (3.5; 12.1). Median HbA_{1c} was 7.7% (7.0; 8.7) (61 mmol/mol [53; 72]). Insulin pump therapy was used in 20,282 patients (49%). CGM ≥ 30 days/year was performed in 10,391 patients (25%) and CGM ≥ 100 days/year in 7,983 (19%). SAP was used in 6,969 patients (17%),

Table 1—Baseline characteristics of the study population during the most recent treatment year between 1995 and 2017

	All patients (<i>n</i> = 96,547)	Insulin pump therapy (<i>n</i> = 33,341)	Insulin injection therapy (<i>n</i> = 63,206)	With CGM (<i>n</i> = 14,419)	Without CGM (<i>n</i> = 82,128)
Age (years)	17.9 (14.8; 34.0)	17.0 (12.5; 21.4)	18.2 (15.9; 41.1)	14.8 (10.8; 18.7)	18.0 (15.7; 36.6)
Age-group (years)					
1.5–4.9	1,059 (1.1)	851 (2.6)	208 (0.3)	456 (3.2)	603 (0.7)
5–9.9	6,771 (7.0)	4,108 (12.3)	2,663 (4.2)	2,465 (17.1)	4,306 (5.2)
10–14.9	17,262 (17.9)	7,565 (22.7)	9,697 (15.3)	4,524 (31.4)	12,738 (15.5)
15–19.9	35,955 (37.2)	11,360 (34.1)	24,595 (38.9)	3,786 (26.3)	32,169 (39.2)
≥20	35,500 (36.8)	9,457 (28.4)	26,043 (41.2)	3,188 (22.1)	32,312 (39.3)
Sex					
Female	45,771 (47.4)	17,658 (53.0)	28,113 (44.5)	6,944 (48.2)	38,827 (47.3)
Male	50,776 (52.6)	15,683 (47.0)	35,093 (55.5)	7,475 (51.8)	43,301 (52.7)
Duration of diabetes (years)	8.0 (4.2; 14.2)	8.1 (4.5; 13.5)	8.0 (4.1; 14.6)	5.9 (3.0; 10.7)	8.4 (4.5; 14.7)
Migration background	12,899 (13.4)	4,751 (14.2)	8,148 (12.9)	2,317 (16.1)	10,582 (12.9)
BMI (kg/m ²)	22.8 (20.0; 25.9)	22.2 (19.0; 25.5)	23.1 (20.5; 26.2)	20.9 (18.0; 24.3)	23.1 (20.5; 26.2)
SD score	0.50 (−0.14; 1.13)	0.50 (−0.12; 1.12)	0.50 (−0.16; 1.14)	0.40 (−0.21; 1.02)	0.52 (−0.13; 1.15)
HbA _{1c}					
%	7.9 (7.0; 9.0)	7.8 (7.1; 8.7)	7.9 (7.0; 9.1)	7.6 (6.9; 8.4)	7.9 (7.0; 9.1)
mmol/mol	63 (53; 75)	62 (54; 72)	63 (53; 76)	60 (52; 68)	63 (53; 76)
Frequency of SMBG per day, mean (SD)	5.1 (2.7)	5.9 (3.2)	4.6 (2.3)	5.8 (3.9)	4.9 (2.4)
CGM use (days/year)					
≥1	14,419 (14.9)	8,187 (24.6)	6,232 (9.9)	14,419 (100)	
≥30	10,745 (11.1)	6,880 (20.6)	3,865 (6.1)	10,745 (74.5)	
≥100	8,201 (8.5)	5,390 (16.2)	2,811 (4.4)	8,201 (56.9)	

Data are median (quartiles) or *n* (%) unless otherwise indicated.

including use of LGS or PLGS systems in 606 (1.5%).

Temporal Trends in the Use of Insulin Pump Therapy and Glucose Monitoring

The percentage of patients using insulin pump therapy increased from 1% in 1995 to 53% in 2017. The increasing use of pumps for insulin delivery became apparent in 1998 for adults and slowed down from 2000 on (Fig. 1A). Pump use increased in adolescents since 2000, and the most rapid increase of pump therapy was observed in the youngest age-groups since 2004 (Fig. 1A). In 2017, insulin pump therapy was used in 92% of preschoolers, 74% of children, 56% of young adolescents, 46% of adolescents, and 37% of adults (Fig. 1A). The percentage of patients with SAP increased from 2% in 2015 to 23% in 2017. In 2017, SAP was conducted in 54% of preschoolers, 40% of children, 27% of young adolescents, 18% of adolescents, and 5% of adults with type 1 diabetes (Fig. 1B).

The percentage of patients using CGM increased from 3% in 2006 to 17% in 2016 and 38% in 2017. Between 2007 and 2015, CGM was predominantly used short term (<30 days/year), mainly

for diagnostic purposes. Approximately 10% of adult patients conducted CGM between 2007 and 2015, and the percentage slowly increased until 2017 (Fig. 1C). The strongest increase of CGM use was seen in the youngest age-groups from 2015 to 2017 (Fig. 1C). In 2017, CGM was performed in 58% of preschoolers, 52% of children, 45% of young adolescents, 33% of adolescents, and 15% of adults (Fig. 1C). In 2017, CGM use ≥100 days/year was conducted in 40% of preschoolers, 40% of children, 33% of young adolescents, 23% of adolescents, and 8% of adults (Fig. 1D). The mean number of SMBG measurements increased from 3.6/day in 1995 to 6.4/day in 2016 and thereafter slightly decreased to 6.1/day in 2017 in the whole population. SMBG frequency increased between 1995 and 2015 most strongly in the youngest age-groups followed by a decrease until 2017, while in adults, a continuous slow increase of SMBG frequency was observed (Fig. 1E).

Temporal Trends of Diabetes-Related Outcomes

From 1995 to 2017, the percentage of patients with HbA_{1c} values >9%

decreased in the entire study population from 27.6% to 16.6% (Fig. 2A). Similarly, the percentage of patients with severe hypoglycemia decreased from 13.3% to 6.0% (Fig. 2B), and the percentage of patients with hypoglycemic coma decreased from 4.4% to 2.1% (Fig. 2C). The decrease in the proportion of patients with poor metabolic control, severe hypoglycemia, and hypoglycemic coma was more prominent in the pump therapy group compared with the injection therapy group (Fig. 2A–C). In 2017, fewer patients using pump therapy than using injection therapy had poor metabolic control (13.6% vs. 20.1%) (Fig. 2A), severe hypoglycemia (5.1% vs. 7.0%) (Fig. 2B), and hypoglycemic coma (1.3% vs. 3.0%) (Fig. 2C).

Sex Differences for Pump Therapy and Glucose Monitoring

During the most recent treatment year between 2015 and 2017, of 19,746 female patients with type 1 diabetes, 53% (*n* = 10,501) used pump therapy, and of 21,851 male patients, 45% (*n* = 9,781) used pump therapy (*P* < 0.001). The sex difference for pump use was significant in adolescents and adults but not in children (Fig. 3A). SAP was performed more

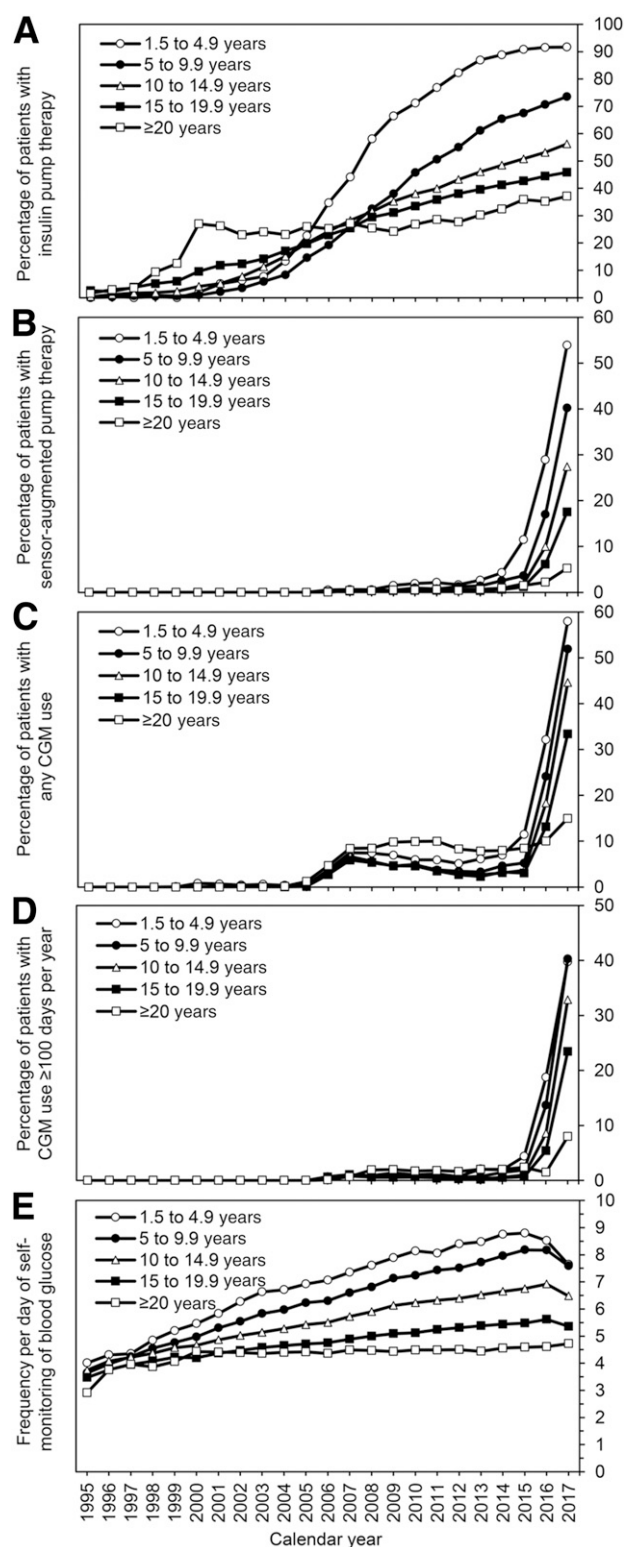


Figure 1—Use of insulin pump therapy, SAP, any CGM, and CGM ≥ 100 days/year and frequency of SMBG by age-group between 1995 and 2017. Shown are the percentages of patients with type 1 diabetes using insulin pump therapy (A), SAP (B), any CGM ≥ 1 day/year (C), and CGM ≥ 100 days/year (D) and the mean frequency of SMBG per day (E) in five different age-groups per calendar year. SAP was defined as insulin pump therapy with simultaneous CGM of ≥ 30 days/year.

frequently in female patients than in male patients (18% and 16%, respectively, $P < 0.001$), particularly in the age-groups

15–19.9 years (14% and 11%, $P < 0.001$) and ≥ 20 years (4% and 2%, $P = 0.002$). Women ≥ 20 years used LGS or PLGS

systems more often than men (1% and 0.3%, respectively, $P = 0.005$).

No sex difference was found for CGM use ≥ 1 day/year (29% in females and 28% in males, $P = 1.0$) and ≥ 30 days/year (25% each, $P = 1.0$) in the whole study population as well as in all age-groups (all $P = 1.0$) (Fig. 3B). Similarly, no sex difference was observed for CGM use ≥ 100 days/year in the entire population (19% each, $P = 1.0$) as well as in all age-groups (all $P = 1.0$). Female patients slightly more often performed SMBG than male patients in the whole population (5.8 and 5.7/day, respectively, $P < 0.001$), which was significant in age-groups 15–19.9 years (5.3 and 5.1/day, $P < 0.001$) and ≥ 20 years (4.6 and 4.5/day, $P < 0.001$) but not in other age-groups (all $P = 1.0$).

Pump Therapy and Glucose Monitoring Among Patients by Migration Background

Patients with a migration background were slightly less frequently treated with insulin pump therapy than patients without a migration background (46% and 49%, respectively, $P < 0.001$), but no significant difference was observed for SAP (16% and 17%, $P = 0.18$) and use of LGS or PLGS systems (1.5% and 1.4%, $P = 1.0$). No difference was observed between patients with and without a migration background for CGM ≥ 1 day/year (27% and 29%, $P = 0.09$) and ≥ 30 days/year (25% each, $P = 1.0$) but for ≥ 100 days/year the proportion was marginally lower (18% and 20%, $P = 0.001$). Mean SMBG frequency was slightly higher in patients with a migration background than in those without a migration background (6.1 and 5.7/day, $P < 0.001$).

Pump Therapy and Glucose Monitoring by Country

Comparing patients aged < 20 years from Austria ($n = 2,202$) and Germany ($n = 28,327$), no differences were observed for the use of pump therapy (54% each), SAP (22% each), CGM ≥ 1 day/year (34% and 35%, respectively), CGM ≥ 30 days/year (32% each), and CGM ≥ 100 days/year (26% and 25%, respectively) (all $P = 1.0$). Mean SMBG frequency was slightly lower in patients treated in Austria than in those treated in Germany (5.7 and 6.1/day, respectively, $P < 0.001$).

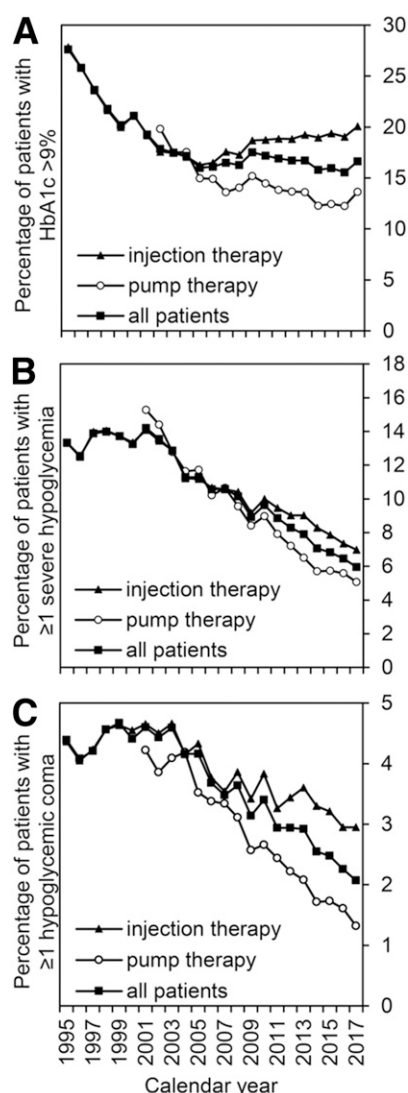


Figure 2—Temporal trends of diabetes-related outcomes in patients using insulin injection therapy and those using insulin pump therapy between 1995 and 2017. Shown are the percentages of patients with type 1 diabetes with HbA_{1c} levels >9% (A), with at least one episode of severe hypoglycemia (B), and with at least one hypoglycemic coma (C) per calendar year.

CONCLUSIONS

To investigate temporal trends and the contemporary use of diabetes technologies among patients with type 1 diabetes, we conducted an observational study in a large population-based cohort of children, adolescents, and adults treated between 1995 and 2017. One major finding is the continuous increase of insulin pump use from 1% in 1995 to 53% in 2017 in the entire cohort. A strong temporal increase of pump use has also been observed in population-based studies from Nordic countries (15,16) and

Canada (17) and in center-based studies from the U.S. (12,18). However, pump use varied considerably between regions (9,19,20) and centers, ranging from 0% to 90% (21). Increasing pump use was associated with improvements in pump technology, including threshold-based insulin suspend since 2009, tubeless pumps since 2010, PLGS since 2015, availability of rapid-acting insulin analogs, and coverage of costs by health care systems (6,7). Of note, the early rise of pump use in adults observed since 1998 in this study preceded the rise in younger patients by several years. This finding may be explained by earlier approval and reimbursement of pump therapy for adult patients followed by approval for adolescents and children later on (1). During the study period, a decrease of severe hypoglycemic events was observed, particularly in pump users, as previously noted during shorter periods in smaller populations (15,16).

Another key finding of this study is the marked age dependency of pump use, with a continuous and strong rise observed in the youngest age-groups since 2004. This observation is supported by center-based studies demonstrating that pump use is less common in older age-groups (18,21), although the rates of pump use considerably differed by age across countries (19). In the T1D Exchange registry, adolescents more frequently used pumps than children aged <6 years (19). The very high percentage of pump users among preschoolers, accounting for 92% in 2017 in the current study, indicates that the youngest patients may particularly benefit from this treatment. In line with data from this study, current ISPAD guidelines consider pump therapy as the preferred mode of insulin delivery for children aged <7 years (22).

In 2017, pump therapy was conducted in the majority of patients with type 1 diabetes aged <15 years, thus constituting the standard of treatment in this population. This finding is in accordance with previous population-based studies from Nordic countries (16,23) and a center-based study from the U.S. (12) reporting pump use in ≥60% of children and adolescents with type 1 diabetes. The standard use of pumps for pediatric patients with diabetes is supported by growing evidence that pump therapy can

be used safely and effectively to assist with achieving targeted glycemic control (1,2). In addition, children with type 1 diabetes and their families reported psychosocial benefits of pump therapy (5) and improved health-related quality of life (1).

More frequent use of pumps in female adolescents in this and other reports (19,24–27) may be related to higher HbA_{1c} than in male adolescents (28,29), being an indication for pump therapy (1,30). Moreover, preprogrammed basal patterns can be used when days of differing insulin sensitivity are predictable during menstruation (1). Pump treatment is beneficial in pregnancy, ideally preconception (1,30). In an analysis of psychological barriers to optimal insulin therapy, female adolescents had more positive coping strategies (31), and women were more self-conscious about how they looked in public when wearing a pump (27,32). The slightly lower pump use among patients with a migration background in this study may be attributable to language or cultural barriers (18,19,26,33).

Since 2006, CGM was used by up to 10% of patients, particularly in preschoolers and adults. This finding is in line with data from the T1D Exchange registry reporting CGM use in 11% of people with type 1 diabetes in 2014 (12). A sharp increase of CGM use was observed since 2015, reaching 38% in 2017 in the entire population. This development is likely related to the approval of intermittent scanning and real-time CGM systems for nonadjunctive use in 2014 and 2015, respectively (1,6), as well as to the coverage of both CGM systems by health insurance since 2016 in Germany. CGM provides more glucose readings along with rate and direction of glucose changes (9), assisting patients to reduce glucose variability and increase time in range (6,8). A strong rise of CGM to >50% in patients aged <10 years was observed in 2017, indicating specific benefits of real-time glucose trends for children and their parents or caregivers (1,22). CGM was more frequently used in patients with pump therapy than in those with injection therapy in this study, although equal benefits have been reported for users of both treatment regimens (1,6,8). The increase of daily SMBG frequencies from 1995 to 2016 in the current study

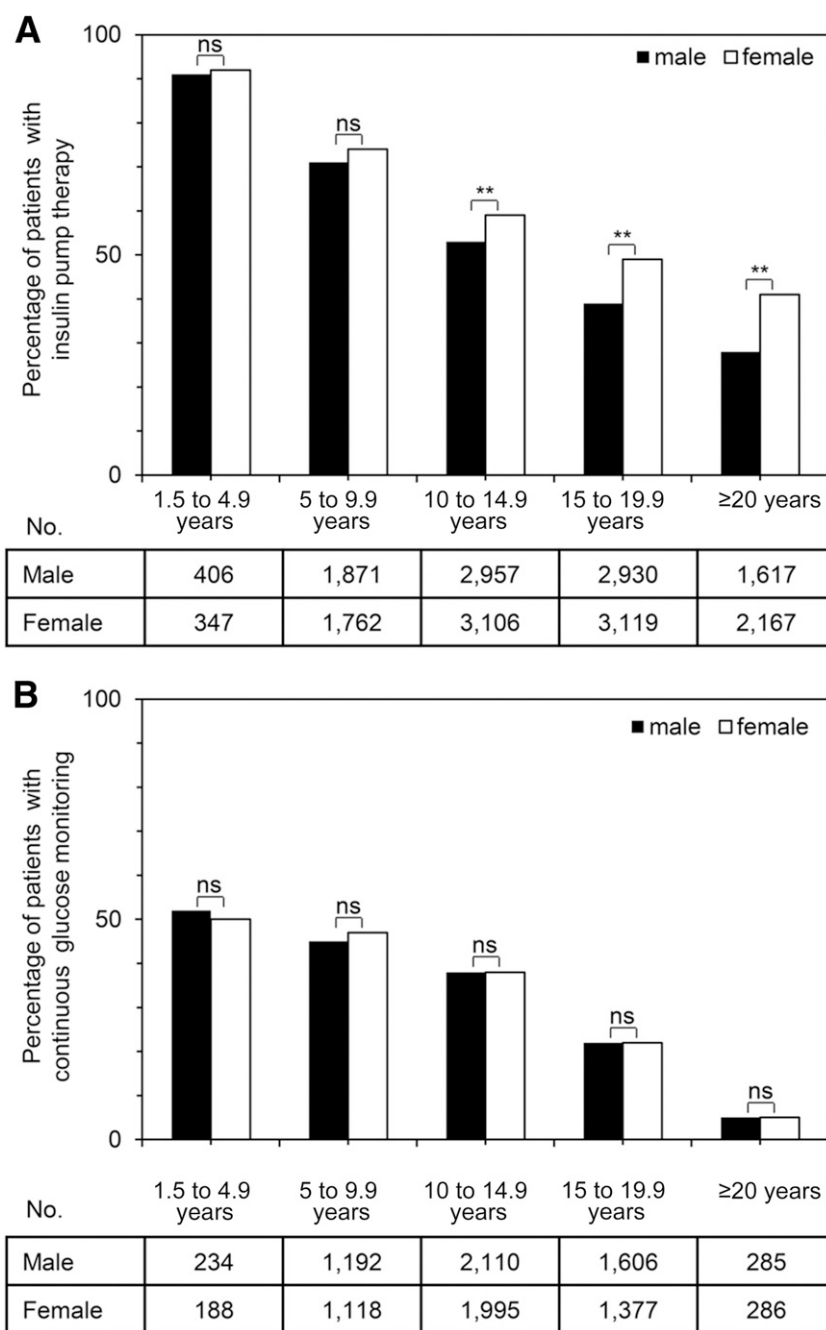


Figure 3—Sex differences for insulin pump therapy and CGM by age-group. Shown are the percentages of male and female patients with type 1 diabetes using insulin pump therapy (A) and CGM ≥ 30 days/year (B) in five different age-groups during their most recent treatment year between 2015 and 2017. ** $P < 0.001$. ns, not significant.

may be linked with increasing pump usage (2) or with lowering targets for HbA_{1c} (34). The moderate decline of mean SMBG frequency from 2016 to 2017, particularly in the youngest age-groups with the highest CGM rates, may result from increasing nonadjunctive CGM use, requiring less routine SMBG measurements (1,6). CGM use was independent of sex, as reported in other cohorts (24,26,27), and equally often

conducted in individuals with and without a migration background, supporting its high acceptance.

Strengths of the current study include its large population-based database with prospective documentation of diabetes treatment and outcome over more than two decades, suitable for analyzing temporal trends as well as contemporary real-life diabetes care. The DPV registry covers an estimated proportion of >90%

of pediatric patients with diabetes, while the nationwide capture rate of adults with type 1 diabetes is lower. We cannot exclude that among adults a higher proportion of patients using pumps and CGM was documented in DPV than patients not using these devices. Another limitation is the definition of age-groups irrespective of pubertal stages, because differences in insulin sensitivity exist between adolescent males and females as determined by body mass effects (35), which may influence diabetes treatment modalities. Socioeconomic status and regional disparities associated with use of insulin pump and CGM technology in recent studies (20,36) were also not considered in this analysis.

The findings of this study may have implications for the future care of patients with type 1 diabetes. Insulin pump therapy is moving toward automated glucose-responsive insulin delivery in closed-loop systems consisting of a pump, a continuous glucose sensor, and algorithms that determine insulin delivery (1,6). The first hybrid closed-loop system was approved by the U.S. Food and Drug Administration in 2016 and entered U.S. clinical practice in 2017 (6). Results of the current study provide further evidence that insulin pump therapy and CGM as core elements of artificial β -cell technology have gained acceptance in routine diabetes care at a population-based level, particularly in young patients. Further research is needed to investigate patient-related and other factors (36) contributing to disparities in insulin pump usage within health care systems.

In conclusion, since 1995, insulin pump usage has continuously increased, and pump therapy is now considered standard of treatment in patients aged <15 years in Germany and Austria, as judged by patients and health care providers and realized by health insurance companies. CGM use sharply rose in recent years, particularly in the youngest patients, and was conducted in 2017 in the majority of patients aged <10 years.

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