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Original article

# Glycaemic control in insulin deficient patients using different insulin delivery and glucose sensoring devices: Cross-sectional real-life study

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ABSTRACT

*Aims:* To assess glycaemic control in ≥15-year-old patients with type 1 diabetes treated in Tampere University Hospital in a real-life cross-sectional registry study.
*Methods:* Glycaemic control was assessed with HbA1c, time in range (TIR) and the incidence of acute complications. The effect of age, BMI, gender, duration of diabetes, daily insulin dose, and device group on the glycaemic control was studied.
*Results:* The study included 1,132 patients. Eighty-four percent of the patients had TIR≤70%. Two percent of patients had an episode of diabetic ketoacidosis and 0,2% had severe hypoglycemia within the last 12 months. Intermittently scanned CGM (IsCGM) with MDI was used in 59%, continuous subcutaneous insulin infusion (CSII) with glucose sensor in 15%, and sensor-augmented/hybrid closed-loop pump (SAP/HCL) in 9% of the patients. In the logistic regression analysis, TIR≤70% was associated with young age group (OR 2.70; 95% CI 1.43−5.09) and daily insulin dose per weight (OR 6.66; 95% CI 3.53−12.57). CSII with glucose sensor and IsCGM with MDI were associated with poor glycaemic control compared to SAP/HCL.
*Conclusion:* There is room for improvement in the glycaemic control in our area although serious acute complications are rare. Closed insulin pump system was more effective than open system.


## Introduction

Good glycaemic control requires optimal use of glucose monitoring systems and insulin delivery systems in patients with diabetes mellitus. The currently available glucose measurement methods (continuous glucose monitoring (CGM), intermittently scanned CGM (IsCGM) and self-measurement of blood glucose (SMBG) using finger-stick blood samples) are combined with the means of insulin delivery systems (multiple daily injections (MDI), continuous subcutaneous insulin infusion (CSII), sensor-augmented pump (SAP), hybrid closed loop (HCL), or advanced hybrid closed loop (AHCL)). [1,2] While SMBG shows only current blood glucose concentration and no indication of the rate of changes, CGM and IsCGM capture continuous measurements of glucose and show glucose variations including hypoglycaemic and hyperglycaemic events [3]. Glycaemic control can be measured by glycated haemoglobin (HbA1c), which reflects two- to three-month average of blood glucose concentrations. However, it does not reflect short-term variations in blood glucose, unlike the desired range-related variables, i.e., time in range (TIR), time below range (TBR), time above range (TAR), and the coefficient of variation of glucose (CV) comparing fluctuations and capturing all glucose levels for the given time frame. [4–6]

Several studies have shown that intensive insulin therapy and good glycaemic control decrease the risk of long-term complications, thereby decreasing mortality [1,7-10]. Even though the mortality rate from diabetes has declined in recent years [11], estimated life expectancy for patients with type 1 diabetes is still lower than for those without diabetes [12,13]. This suggests that the treatment is not yet optimal. The prevalence of diabetes is expected to increase in the future [14] and the incidence of type 1 diabetes (T1D) in Finland is one of the world's highest [15]. Since devices cause additional costs [16], we need information on the effectiveness of treatment modalities, which factors predict poor glycaemic control, and whether glucose control is affected by optimal patient selection, treatment modality and device training, and the patient's ability to utilize the device.

The aim of this study was to assess the glycaemic control with HbA1c values, glucose determination derived values (TIR, TBR, TAR, CV, and mean glucose) and to determine the incidence of severe hypoglycaemia and ketoacidosis over the last 12 months in patients

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with T1D and different glucose determination and treatment modalities. Furthermore, we aimed to study factors associated with inadequate glycaemic control.

## Methods

This cross-sectional study is based on the patient database of Tampere University Hospital (Tays) and assesses the quality of care of patients with T1D treated at the Tays endocrinology outpatient clinic. All patients from January 2019 to May 2020 with T1D and age above 15 years treated at Tays were included. In Tays, youth transit to same clinic with adults at the age of 15 years, although they are seen more frequently than adults during the transition period.

The baseline data were collected through the hospital endocrine medical record system called Endo. The data included age, sex, body mass index (BMI), hypertension, dyslipidaemia, atherosclerosis, duration of diabetes, ketoacidosis leading to hospitalization and severe hypoglycaemia occurring within the preceding 12 months. Severe hypoglycaemia was defined as hypoglycaemia requiring medical assistance. Diabetic ketoacidosis was defined as hospitalization with elevated serum ketones and decreased blood pH (< 7.3) or bicarbonate concentration (< 15 mmol/l). [4]. Cardiac disease, nephro-, retino- and neuropathy were not included or studied as factors explaining glucose control as they represent chronic complications.

Current glucose measurement method (SMBG, CGM or IsCGM), current insulin delivery system (MDI, CSII or SAP/HCL), and current insulin doses were collected. The devices in our unit during the study period were chosen according to current or previous competitive bidding or their use was initiated previously in other hospitals. Glucose sensors were Dexcom G6, Eversense and Freestyle Libre 1 and 2. Pumps were AccuChek Insight and Spirit Combo, Minimed 670G, 640G and earlier Minimed series (Veo), Omnipod and YpsoPump. The first AHCL systems were introduced into our unit in February 2021 and thus there were no data in this study on AHCL.

From the latest visit, mean glucose, standard deviation of glucose, CV, TIR (3.9–10.0 mmol/l), TBR (< 3.9 mmol/l), TAR (> 10.0 mmol/l), blood glucose testing or intermittent scanning times per day, total daily insulin dose, basal insulin dose per day and bolus insulin dose per day during the past two weeks were collected. The parameters were collected into Endo from digital systems provided by the pump and sensor manufacturers or an aggregate system (Diasend). If the patient was using self-monitoring of blood glucose and blood glucose testing frequency was less than four times per day, the glucose averages and TIR were not considered. In addition, latest HbA1c was collected. HbA1c values were reported as IFCC units (mmol/mol).

The ethics committee of the Pirkanmaa Hospital District approved the study protocol (study number R20084R). The study was a retrospective registry study and thus patients' consent was not required. The Declaration of Helsinki was complied with throughout the study.

### *Statistical analysis*

Statistical analyses were performed with IBM SPSS Statistics for Windows, version 26.0 (IBM Corp. Released 2016 Armonk, NY, USA). The numerical data are expressed as median (Md; min, max). Qualitative variables are presented as numeric and percentage values. Unpaired t-test was used to compare the mean values between the patient groups. To compare medians of variables between groups, Mann-Whitney U test and Kruskal-Wallis test were used. Differences between the study groups were analysed using $\chi^2$ or Fisher's exact test for categorical variables. A p-value of < 0.05 was considered statistically significant.

Glycaemic control was assessed according to incidence of acute complications (severe hypoglycaemia and ketoacidosis), HbA1c values and average glucose sensing values. The analyses were stratified by age and by group of glucose determination and treatment modality (later referred to as device group). The analyses by age used the following groups: age from 15 to 24 years, 25 to 49 years, 50 to 64 years, and age over 65 years. There were six device groups [SMBG + MDI, SMBG + CSII, IsCGM + MDI, CGM + MDI, glucose sensor (IsCGM or CGM) + CSII, and SAP/HCL]. For statistical analysis, HbA1c was divided into two different classes (< 53 mmol/mol and ≥ 53 mmol/mol).

The outcome was described as poor glycaemic control, which was defined in first analysis as time in range ≤ 70%, and in second analysis as HbA1c ≥ 53 mmol/mol. First, univariate models for each exposure were created separately, with odds ratios (ORs) and 95% confidence intervals (95% CIs). Further, a multivariable logistic regression model was used where exposures were estimated simultaneously. The model was adjusted with age groups, BMI, gender, duration of diabetes, daily insulin dose per weight, and device groups.

## Results

A total of 1,132 patients ≥ 15 years of age with T1D were treated in Tays and recorded in the Endo system from January 2019 to May 2020. Table. 1 presents the baseline characteristics of the study cohort. A total of 54% of the study population were males and the

**Table 1**
Descriptive factors and treatment results for all patients.

| N | n / median<br>1132 | % / min, max |
|---|---|---|
| Age, years | 37 | 15, 86 |
| Duration of diabetes, years | 17 | 0, 66 |
| Gender | | |
| Male | 608 | 54 |
| Female | 524 | 46 |
| BMI, kg/m2 | 25.5 | 14.9, 60.4 |
| Smoking | 172 | 15 |
| HbA1c, mmol/mol | 65 | 30, 141 |
| HbA1c classification | | |
| < 53 mmol/mol | 166 | 15 |
| Mean glucose, mmol/l | 10.0 | 5.1, 23.2 |
| Standard deviation of glucose | 3.7 | 0.3, 9.9 |
| Coefficient of variation of glucose, CV | 36 | 4, 67 |
| Time in range, TIR, % | 48 | 0, 98 |
| TIR ≥ 70% | 176 | 16 |
| Time below range (TBR), % | 3 | 0, 35 |
| TBR ≤ 4%, | 320 | 28 |
| Time above range (TAR), % | 47 | 0, 100 |
| TAR ≥ 25% | 831 | 73 |
| TBR ≤ 4% and TIR ≥ 70% | 87 | 8 |
| Ketoacidosis | 20 | 2 |
| Severe hypoglycaemia | 2 | 0.2 |
| Blood glucose testing times per day | 7 | 0, 63 |
| Daily insulin, units/kg/day | 50 | 3, 500 |
| Basal insulin per day, % | 49 | 0, 100 |
| Bolus insulin per day, % | 51 | 0, 100 |
| Device group | | |
| SMBG[1] + MDI[2] | 143 | 13 |
| SMBG + CSII[3] | 12 | 1 |
| IsCGM[4] + MDI | 665 | 59 |
| CGM[5] + MDI | 37 | 3 |
| Glucose sensor[6] and CSII | 170 | 15 |
| SAP[7]/HCL[8] | 105 | 9 |
| Hypertension | 304 | 27 |
| Dyslipidaemia | 275 | 24 |
| Atherosclerosis | 40 | 4 |
| Sleep apnoea | 57 | 5 |

1 SMBG self-monitoring of blood glucose.
2 MDI multiple daily injections.
3 CSII continuous subcutaneous insulin infusion.
4 IsCGM intermittent scanning continuous glucose monitoring.
5 CGM continuous glucose monitoring.
6 Glucose sensor, IsCGM or CGM.
7 SAP sensor-augmented pump.
8 HCL hybrid closed loop.

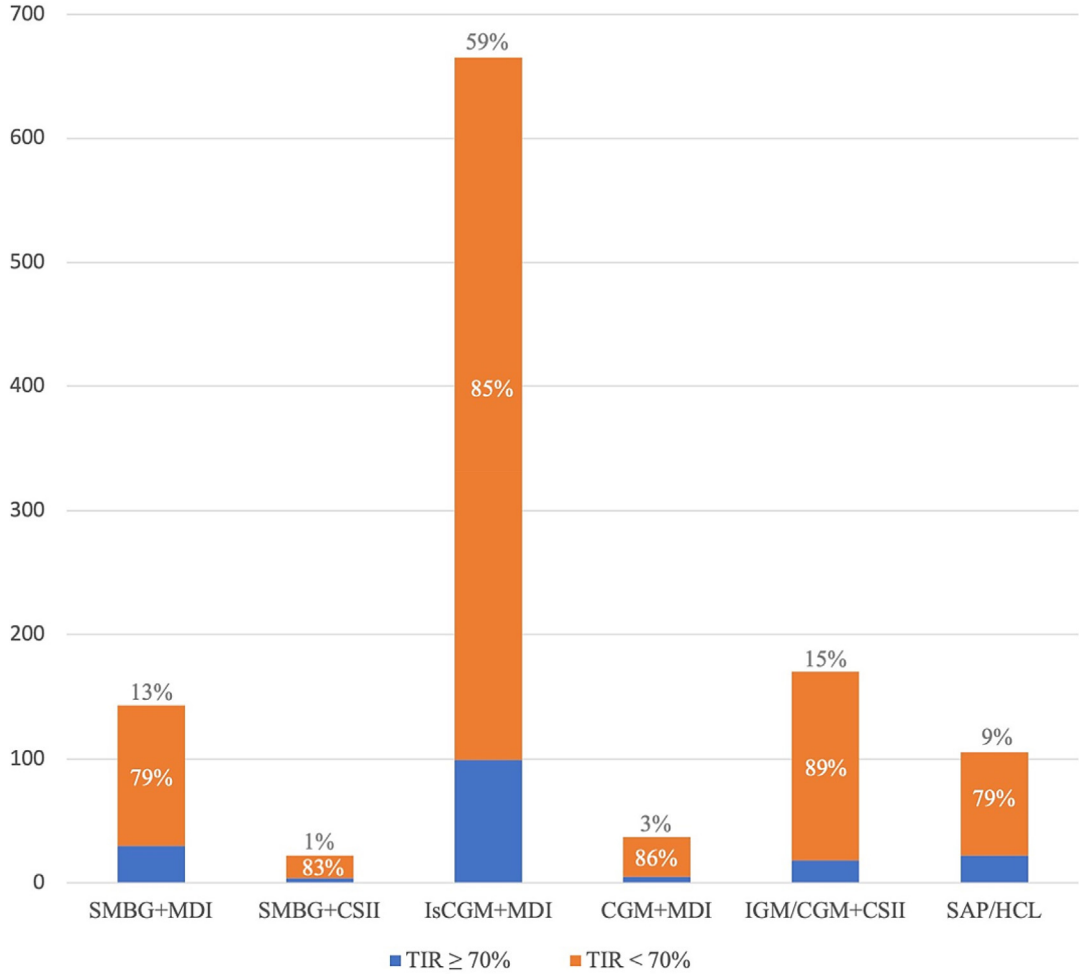


**Fig. 1.** Distribution of device groups among patients and the portion of patients who don't meet the treatment goal. In total, 956 (84%) patients had TIR ≤ 70%.

median age was 37 years. In total, 275 (24%) patients had dyslipidaemia, 304 (27%) patients had hypertension and 40 (4%) patients had atherosclerosis. The median duration of diabetes was 17 years (min 0, max 66) years. Of the 1,132 patients, SMBG + MDI was used by 143 (13%) and SMBG + CSII by 12 (1%) patients. Moreover, 665 (59%) had IsCGM + MDI, 37 (3%) had CGM + MDI, 170 (15%) were using glucose sensor (IsCGM or CGM) with CSII, and a total of 105 (9 %) were using SAP or HCL (Fig. 1). Median HbA1c was 65 mmol/mol, 934 (83%) patients had HbA1c over 53 mmol/mol, and 956 (84%) had TIR ≤ 70%. Only 87 (8%) patients had both TIR ≥ 70% and TBR ≤ 4%. Overall, 20 (2%) patients had an episode of diabetic ketoacidosis and 2 (0.2%) patients had severe hypoglycaemia within the last 12 months.

When comparing treatment results by age group (Table. 2), all outcome measurements for blood glucose improved as age increased. Patients aged over 65 years spent more time in range, had lower mean blood glucose, lower TAR, and lower CV than patients in the age group 15−24 years ($p < 0.001$). The age group 15−24 years had higher HbA1c values than any other age groups ($p < 0.001$). Older patients had statistically significantly more insulin boluses per day than the youngest patients. The incidence of severe hypoglycaemia was low in all age groups. Diabetic ketoacidosis only occurred in patients aged under 50 years and especially in the age group 15 −24 years ($p < 0.001$).

The treatment results by device groups are shown in Table. 3. The best glycaemic control according to HbA1c values, mean blood glucose, CV and TIR was in the group with SAP/HCL, who also had the longest duration of diabetes and one of the highest age. Patients using glucose sensor + CSII had the widest glucose variation (CV) and the lowest TIR. Patients using SAP/HCL had statistically significantly lower HbA1c than those using MDI + SMBG ($p = 0.039$), those using glucose sensor + CSII ($p = 0.004$), and those using IsCGM + MDI ($p < 0.001$).

In the multivariable logistic regression model adjusted with age groups, BMI, gender, duration of diabetes, daily insulin dose per weight and device group, the ORs and 95% CIs for poor glycaemic control assessed according to TIR ≤ 70% are shown in Table. 4. The data was found in 1022 (90%) patients. Poor glycaemic control was explained independently by age group. Compared to the age group of those over 65 years, all the other age groups had higher risk for having TIR ≤ 70%. Another independent risk factor for TIR ≤ 70% was high daily insulin dose per weight. Furthermore, IsCGM + MDI, CGM + MDI, and glucose sensor + CSII were independently associated with poor glycaemic control compared to SAP/HCL. Young age and high daily insulin dose per weight were associated with poor glycaemic control even when only the three most common device groups (IsCGM + MDI, glucose sensor and CSII, and SAP/HCL) were considered in the multivariable analysis. When poor glycaemic control was assessed according to HbA1c ≥ 53 mmol/mol, poor glycaemic control was associated with female gender, insulin dose, and glucose sensor + CSII. The data about HbA1c was found in 1100 (97%) patients. Furthermore, when poor glycaemic control was assessed according to HbA1c ≥ 64 mmol/mol, the results were decidedly similar as when poor glycaemic control was assessed according to TIR ≤ 70% (data not shown).

**Table 2**
Treatment results by age groups.

| | Age group | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 15 24 | | 25–49 | | 50–64 | | 65 | | |
| | n/Md | %/min, max | n/Md | %/min, max | n/Md | %/min, max | n/Md | %/min, max | *p*-value |
| n (%) | 374 | 33 | 418 | 37 | 232 | 20 | 108 | 10 | |
| HbA1c, mmol/mol | 72 | 33, 141 | 64 | 30, 137 | 63 | 34, 127 | 60 | 38, 116 | 0.001 |
| HbA1c classification | | | | | | | | | 0.001 |
| 53 mmol/mol | 29 | 8 | 68 | 16 | 39 | 17 | 30 | 28 | |
| Mean glucose, mmol/l | 11.2 | 5.6, 23.2 | 9.9 | 5.9, 18.9 | 9.5 | 6.0, 16.9 | 9.1 | 5.1, 19.3 | 0.001 |
| Standard deviation of glucose | 4.4 | 1.6, 9.9 | 3.6 | 0.3, 7.0 | 3.3 | 1.6, 7.9 | 3.0 | 1.3, 6.5 | 0.001 |
| Coefficient of variation of glucose, CV | 39 | 10, 67 | 34 | 3, 59 | 35 | 18, 53 | 33 | 14, 58 | 0.001 |
| Time in range, TIR, % | 40 | 0, 93 | 51 | 3, 98 | 54 | 2, 97 | 61 | 0, 98 | 0.001 |
| TIR 70% | 26 | 7 | 67 | 16 | 50 | 22 | 33 | 31 | |
| Time below range (TBR), % | 3 | 0, 35 | 2 | 0, 23 | 3 | 0, 22 | 2 | 0, 27 | 0.026 |
| TBR 4% | 212 | 57 | 262 | 63 | 146 | 63 | 72 | 67 | |
| Time above range (TAR), % | 56 | 3, 100 | 45 | 0, 97 | 41 | 2, 98 | 34 | 1, 100 | 0.001 |
| TAR 25% | 307 | 82 | 310 | 74 | 164 | 70 | 65 | 60 | |
| TBR 4% and TIR 70% | 11 | 3 | 37 | 9 | 22 | 9 | 17 | 16 | 0.001 |
| Blood glucose testing times per day | 5 | 0, 56 | 8 | 1, 38 | 8 | 1, 63 | 11 | 2, 41 | 0.001 |
| Daily insulin, units/kg/day | 58 | 4, 246 | 48 | 3, 200 | 44 | 7, 500 | 40 | 12, 204 | 0.001 |
| Basal insulin per day, % | 50 | 0, 100 | 50 | 0, 100 | 48 | 17, 100 | 46 | 22, 86 | 0.024 |
| Bolus insulin per day, % | 50 | 0, 100 | 50 | 0, 100 | 52 | 0, 83 | 54 | 14, 78 | 0.007 |
| Ketoacidosis | 17 | 5 | 3 | 0.7 | 0 | | 0 | | 0.001 |
| Severe hypoglycaemia | 1 | 0.3 | 1 | 0.2 | 0 | | 0 | | 0.001 |

## Discussion

In this real-life, cross-sectional study we described and compared the characteristics and differences between groups on the basis of the glucose determination and insulin treatment methods in patients with DM1 treated in Tampere University Hospital, Finland. Our study shows that good glycaemic control is associated with high age, low daily insulin dose per weight and device group, in which case the best glycaemic control was in the group with SAP/HCL.

Poor glycaemic control according to TIR ≤ 70% was more common in younger patients. Similar results have been reported previously, when the relationship between age and glycaemic control has been assessed [16–22]. As young age is an independent risk factor for poor treatment results, health care efforts should focus more on young patients with poor glycaemic balance and help them achieve optimal glycaemic levels. Optimal treatment achieved at a young age would reduce the incidence of long-term complications which, in turn, would reduce the medical costs and improve estimated life expectancy. Meanwhile, the focus for elderly patients should be on early detection and effective treatment of complications and comorbidities.

Patients with SAP/HCL had markedly better glycaemic control compared to the other patients after adjusting for confounding factors. Even though it is possible that SAP/HCL-therapy might have been chosen for those with already better glycaemic balance and for patients well versed in the treatment of diabetes, not all SAP users took full advantage of the sensoring feature of the device, because there were 14 (13%) patients using IsCGM alongside SAP. This emphasizes the importance of training and choosing the right device for the patient so that everyone could benefit from all the features of the device. If another device has to be introduced alongside the former device, it might affect the cost-effectiveness of the treatment.

In accordance with our results, an earlier study found in one-year follow-up that both SAP and CGM were superior treatment modalities to SMBG with CSII, and to SMGB with MDI [23]. In contrast, a recent systematic review suggests that there is no statistically significant difference between HbA1c values in patients using any type of diabetes monitoring system. However, the most notable changes in glycaemic balance were in patients using CGM. [24] A few studies have compared CGM to IsCGM and found that CGM has more beneficial impact on hypoglycaemia and treatment results [25,26]. In our study CGM seems to be numerically, but not statistically more effective treatment than IsCGM according to HbA1c, TIR and the incidence of acute complications. However, there were very few patients with standalone CGM, and the majority of patients were using IsCGM in our study cohort, hence there was inadequate statistical power.

Combining an insulin pump with a glucose sensor as a non-integrated open system did not seem an effective treatment in our study. This is consistent with the recent study that compared the economic value of a combination of CSII and CGM, and found that, in addition to impairing glycaemic control, the combination also impaired quality of life and increased costs when compared to patients using CGM with MDI [27]. One of the issues with standalone insulin pumps may be in usability since the users need to handle separate devices when adjusting insulin and administering boluses and they may not see the sensor graph and the insulin data simultaneously when analysing them.

A combination of a glucose sensor and an insulin pump as a non-integrated open system may increase the costs but does not affect the treatment results – the same results could be achieved with modern insulins and sensors. Instead, SAP or HCL provides better glycaemic control. Future prospective studies are needed to study whether it is possible to achieve an equally good glycaemic balance as with SAP or with HCL, if the patient successfully masters self-monitoring of blood glucose and multiple daily insulin injection treatment.

Total daily insulin dose per weight was a significant explanatory factor for poor glycaemic control. Greater exogenous insulin needs could be associated with less residual insulin secretion as well as with diminished physical activity and increased hormonal factors, dietary carbohydrates, and insulin resistance. In our study, total daily insulin was the greatest in the youngest age group (15 - 24 years) and diminished, consistently, towards the oldest group, but it did not differ among user groups. BMI and duration of diabetes did not affect glycaemic control in our multivariable analyses, although they are considered clinically important in achieving a good glycaemic balance.

**Table 3**
Treatment results by device groups.

| | SMBG + MDI | | SMBG + CSII | | IsCGM + MDI | | CGM + MDI | | Glucose sensor + CSII | | SAP/ HCL | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/ Md | %/min, max | n/ Md | %/min, max | n/ Md | %/min, max | n/ Md | %/min, max | n/ Md | %/min, max | n/ Md | %/min, max | *p*-value |
| *n* (%) | 143 | 13 | 12 | 1 | 665 | 59 | 37 | 3 | 170 | 15 | 105 | 9 | |
| Age, years | 37 | 16, 86 | 19 | 15, 74 | 39 | 15, 86 | 33 | 16, 68 | 26 | 15, 78 | 39 | 15, 78 | 0.001 |
| Duration of diabetes, years | 14 | 0, 61 | 13 | 5, 49 | 16 | 0, 66 | 21 | 4, 58 | 16 | 2, 63 | 25 | 3, 62 | 0.001 |
| BMI, kg/m$^2$ | 25.7 | 17.4, 45.0 | 21.9 | 19.1, 27.2 | 25.6 | 16.0, 60.4 | 23.6 | 18.9, 33.5 | 25.6 | 14.9, 48.3 | 25.6 | 16.1, 43.29 | 0.003 |
| HbA1c, mmol/mol | 65 | 34, 130 | 65 | 33, 91 | 66 | 30, 141 | 62 | 41, 105 | 66 | 38, 130 | 59 | 33, 110 | 0.001 |
| HbA1c classification | | | | | | | | | | | | | 0.041 |
| 53 mmol/mol | 23 | 16 | 4 | 33 | 89 | 13 | 7 | 19 | 19 | 11 | 24 | 23 | |
| Mean glucose, mmol/l | 10.2 | 6.2, 20.1 | 10.1 | 5.6, 16.1 | 10.1 | 5.4, 23.2 | 10.0 | 7.0, 18.9 | 10.2 | 5.1, 22.4 | 9.3 | 6.0, 15.1 | 0.013 |
| Standard deviation of glucose | 3.8 | 1.3, 7.4 | 3.8 | 2.0, 6.4 | 3.8 | 1.5, 9.9 | 3.2 | 2.1, 5.2 | 3.9 | 2.0, 7.7 | 3.0 | 0.3, 6.3 | 0.001 |
| Coefficient of variation of glucose, CV | 36 | 10, 67 | 37 | 26, 50 | 36 | 14, 63 | 33 | 21, 43 | 38 | 23, 58 | 32 | 3, 50 | 0.001 |
| Time in range, TIR, % | 49 | 9, 98 | 53 | 14, 82 | 47 | 0, 97 | 52 | 3, 88 | 47 | 5, 88 | 58 | 3, 92 | 0.008 |
| TIR 70% | 30 | 21 | 2 | 17 | 99 | 15 | 5 | 14 | 18 | 11 | 22 | 21 | |
| Time below range (TBR), % | 3 | 0, 33 | 6 | 0, 21 | 3 | 0, 28 | 1 | 0, 14 | 3 | 0, 35 | 2 | 0, 22 | 0.001 |
| TBR 4% | 76 | 53 | 4 | 33 | 425 | 64 | 31 | 84 | 97 | 57 | 59 | 56 | |
| Time above range (TAR), % | 47 | 1, 90 | 41 | 5, 86 | 48 | 2, 100 | 46 | 8, 97 | 48 | 0, 95 | 38 | 1, 97 | 0.026 |
| TAR 25% | 86 | 60 | 5 | 42 | 553 | 83 | 28 | 76 | 140 | 82 | 53 | 50 | |
| TBR 4% and TIR 70% | 8 | 6 | 1 | 8 | 49 | 7 | 4 | 11 | 10 | 6 | 15 | 14 | |
| Blood glucose testing times per day | 6 | 0, 63 | 6 | 2, 26 | 8 | 0, 56 | 17 | 3, 27 | 8 | 1, 32 | 4 | 2, 18 | 0.001 |
| Daily insulin, units/kg/day | 50 | 4, 246 | 48 | 28, 75 | 52 | 3, 500 | 50 | 11, 124 | 45 | 18, 130 | 49 | 15, 141 | 0.063 |
| Basal insulin per day, % | 52 | 0, 100 | 46 | 28, 75 | 47 | 0, 100 | 46 | 0, 80 | 50 | 0, 90 | 50 | 0, 74 | 0.005 |
| Bolus insulin per day, % | 48 | 0, 100 | 50 | 0, 63 | 51 | 0, 86 | 54 | 0, 83 | 50 | 0, 74 | 50 | 0, 74 | 0.015 |
| Ketoacidosis | 2 | 1 | 0 | | 14 | 2 | 0 | | 3 | 2 | 1 | 1 | 0.153 |
| Severe hypoglycaemia | 0 | | 0 | | 2 | 0.3 | 0 | | 0 | | 0 | | 0.056 |

**Table 4**
Explanatory factors for poor glycaemic control (time in range (TIR) under 70%) by odds ratio (OR) and 95% confidence interval (95% CI). The data was found in 1022 (90%) patients.

| | Odds ratio for TIR ≤ 70% | | | | | |
|---|---|---|---|---|---|---|
| | Univariate analysis | | | Multivariable analysis | | |
| | Odds ratio | (95% CI) | *p*-value | Odds ratio | (95% CI) | *p*-value |
| Age group | | | | | | |
| Age 15–24 | 3.46 | (2.17–5.52) | < 0.001 | 2.70 | (1.43–5.09) | 0.002 |
| Age 25–49 | 2.16 | (1.39–3.36) | 0.001 | 2.27 | (1.35–3.81) | 0.002 |
| Age 50–64 | 1.84 | (1.14–2.96) | 0.013 | 1.82 | (1.08–3.05) | 0.025 |
| Age over 65 | 1 | | | 1 | | |
| BMI | 1.00 | (0.97–1.02) | 0.732 | 0.99 | (0.96–1.02) | 0.673 |
| Gender | | | | | | |
| Male | 0.93 | (0.71–1.22) | 0.610 | 0.82 | (0.60–1.10) | 0.187 |
| Female | 1 | | | 1 | | |
| Duration of diabetes | 0.99 | (0.98–1.00) | 0.080 | 1.01 | (1.00–1.02) | 0.174 |
| Daily insulin dose per weight | 7.90 | (4.49–13.89) | < 0.001 | 6.66 | (3.53–12.57) | < 0.001 |
| Device group | | | | | | |
| SMBG + MDI | 1.40 | (0.81–2.32) | 0.196 | 1.40 | (0.81–2.41) | 0.230 |
| SMBG + CSII | 0.98 | (0.30–3.24) | 0.975 | 0.89 | (0.25–3.19) | 0.854 |
| IsCGM + MDI | 4.16 | (2.71–6.38) | < 0.001 | 4.53 | (2.87–7.16) | < 0.001 |
| CGM + MDI | 3.56 | (1.49–8.50) | 0.004 | 3.12 | (1.27–7.68) | 0.013 |
| Glucose sensor and CSII | 5.43 | (3.08–9.57) | < 0.001 | 5.65 | (3.15–10.12) | < 0.001 |
| SAP/HCL | 1 | | | 1 | | |

Our study has several limitations. Firstly, the cross-sectional nature of the study excludes the possibility of long-term follow-up. Secondly, the device groups were not studied prospectively or randomized and thus direct conclusions about the differences between groups cannot be drawn. Finally, the study population does not fully correspond to the average Finnish people with diabetes, because, besides average patients, our cohort consists of more complex patients such as recently diagnosed, young, other than local residents using a device and adult patients with comorbidities, which affects the treatment outcomes. However, one of the key strengths of this study is its real-life patient cohort. Although the study was a retrospective registry study, there was only little missing data because the data was collected by a standardized method in our quality registry, and this improved the quality of the data. There are only a few real-life studies comparing different glucose determination methods with treatment modalities in patients with diabetes, hence our study gives a good view of how the selection and utilization of devices is reflected in the treatment results.

In conclusion, in patients with T1D there is still a lot to improve in the glycaemic control in our hospital district, especially in young patients. Glucose determination method and treatment modality affect glycaemic control as an independent risk factor in addition to age. Attention should therefore be paid to selection criteria, training, utilization, usability of devices and quality of life.

## Author Agreement Statement

We the undersigned declare that this manuscript is original, has not been published before and is not currently being considered for publication elsewhere.

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## Disclosure statement

The authors have nothing to disclose.

## Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.deman.2022.100072.

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