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Research Article

Effective Assessment of Diabetes Control Using Personal Glucometers (CONTOURLINK, Bayer, Germany; CALLA, Wellion, Austria; LINUS, Agamatrix, USA)

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Aim of this trial was to assess (1) the accuracy and precision of electrochemistry-based glucometers CONTOURLINK, CALLA, and LINUS and (2) the diabetes control using Ambulatory Glycaemic Profiles (AGP) as markers of therapeutic effectiveness. Glucometers and COBAS INTEGRA 400 Plus analyzer were used by one laboratory professional to estimate P-glucose (PG) in 112 out-patients. There were 112 sets of 12 PG estimations analyzed. In each set, means of 3 capillary PG estimations on 3 respective glucometers and on INTEGRA analyzer were calculated. The statistical program SPSS, v. 15, was applied. The mean INTEGRA PG values ranged from 2.7 to 25.3 mmol/L. There were strong correlations between mean PG on INTEGRA versus CONTOURLINK, versus CALLA, and versus LINUS; PG deviations from INTEGRA were mostly within the range ±15%. Wilcoxon Signed Rank Test revealed differences between CONTOURLINK-INTEGRA and LINUS-INTEGRA; CALLA-INTEGRA showed no difference. SD INTEGRA = 0.061 mmol/L, SD CONTOURLINK/SD CALLA/SD LINUS were 0.256/0.290/0.286 mmol/L. All patients were trained to perform defined 10-point PG profiles to adapt food, exercise, and insulin doses. The PG differences between all tested glucometers and reference values were in borderline of ISO 15197 but worthy of consideration. AGP are helpful markers of diabetes control.

1. Introduction

Fasting and postprandial plasma glucose concentrations (PG) are principal diagnostic markers of diabetes mellitus. Physiological development of PG in the course of day and night is a prerequisite for the optimum physical and intellectual working capacity and prevention of diabetes complications. Therefore, the diabetes treatment is targeting on recovery of glucose homeostasis. Haemoglobin A1c brings information on long-lasting diabetes control. However, in daily life, a simple marker enabling undelayed assessment of various external factors and therapeutic outcomes is needed; ambulatory glycaemic profiles (AGP) with timing and quantity of food, exercise, and insulin dosage are known to be helpful to assess the diabetes control and the effects of various therapeutic and interfering factors [1–3].

Since the discovery of insulin by Paulescu in 1921 [4] and after its purification and introduction to human medicine by Banting, Best, Collip, and Mc Leod in 1922 [5], the needs of comfortable estimation of PG concentration are continuously growing [6, 7]. In 1974, the first glucometer (Ames) was introduced into clinical practice. To date, self-monitoring by means of various glucometer-strips systems is widely applied [8–11]. Diabetes management in many centres has been based on conventional self-monitoring of plasma glucose concentration (SMPG) for several years [12–16] or even on

continuous glucose monitoring (CGM) [17–20] resulting in a downward trend in all diabetes complications, especially in individuals with type 1 diabetes [8–10].

At present, the quality of a glucometer-strips system is usually assessed considering the international standard ISO 15197 (*In vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*) [21, 22].

Accuracy and precision of a glucometer-strips system were evaluated in several studies using different methods [21–25]. Within the course of 15 years, we have tested the glucometer systems Card (Medisense), Optium (Abbott), Advance (Hypoguard, GB) [26–28], and LINUS (Agamatrix, USA) [29] at our diabetes centre considering their accuracy when used in real life.

The purpose of the present trial was to assess the accuracy and precision of the electrochemistry-based glucometers CONTOURLINK, Bayer, Germany, using FAD glucose dehydrogenase strips, and CALLA, Welion, Austria, as well as LINUS, Agamatrix, USA, both using glucose oxidase strips. The previous tests performed with these glucometers by manufacturers under strictly standardized laboratory conditions and, in part, independently, also in our clinical department, resulted in acceptable results [30, 31]. We also paid attention to the assessment of diabetes control in real life using glucometer CALLA for ambulatory glycaemic profiles (AGP) as markers of therapeutic effectiveness.

2. Materials and Methods

The study was carried out in accordance with the Helsinki Declaration in adult persons attending medical checkups, who gave their consent to capillary blood collection. There were no exclusion criteria. Concomitant diseases and additional medication were not considered.

In the course of six consecutive weeks, 9 glucometers (3 CONTOURLINK, 3 CALLA Light, and 3 LINUS) were used by one laboratory professional to estimate PG in 112 outpatients (Figure 1). Within 2 following minutes 200 μL of blood from the same fingerprick was also collected in a heparinized tube with fluoride lithium (Figure 2) and centrifuged to estimate the PG 3 times on the analyzer COBAS INTEGRA 400 PLUS using hexokinase reference method. Samples with traces of hemolysis were not processed.

In each type of glucometer one lot of test strips was used for all tests in 112 tested individuals. The calibration of the analyzer COBAS INTEGRA was performed every day. The conditions in the laboratory were standardized (temperature 20–24°C, usual humidity and light conditions).

3. Results

3.1. Accuracy and Precision of Glucometers. There were 112 sets of 12 PG estimations analyzed. In each set, individual means of 3 PG estimations on 3 glucometers CONTOURLINK (one estimation on each of them), on 3 glucometers CALLA, and on 3 glucometers LINUS and results of 3 estimations of each specimen on INTEGRA analyzer were calculated.

Figure 1: PG estimation on glucometers CONTOURLINK, CALLA, and LINUS. The test sequence has always started on CONTOURLINK 1 to 3, then CALLA 1 to 3, and finally LINUS 1 to 3 which lasted up to 1 minute and was followed by collection of blood to a sample tube (see Figure 2).

Figure 2: Capillary blood collection in a heparinized tube with fluoride for PG estimation on laboratory analyser COBAS INTEGRA. This procedure lasted up to 2 minutes and was followed by centrifugation.

The mean INTEGRA PG values ranged from 2.7 to 25.3 mmol/l.

There were strong correlations (Spearman) between mean PG estimations on INTEGRA versus CONTOURLINK ($r = 0.988$), on INTEGRA versus CALLA ($r = 0.982$), and on INTEGRA versus LINUS ($r = 0.990$).

Deviations of mean PG on glucometers from mean PG on INTEGRA were mostly within the range ±15%. The percentage of sample deviations from INTEGRA within the range ±15% was as follows:

(i) glucometer CONTOURLINK 94.6% of 112 pairs (Figure 3),

(ii) glucometer CALLA 93.8% of 112 pairs (Figure 4),

(iii) glucometer LINUS 97.3% of 112 pairs (Figure 5).

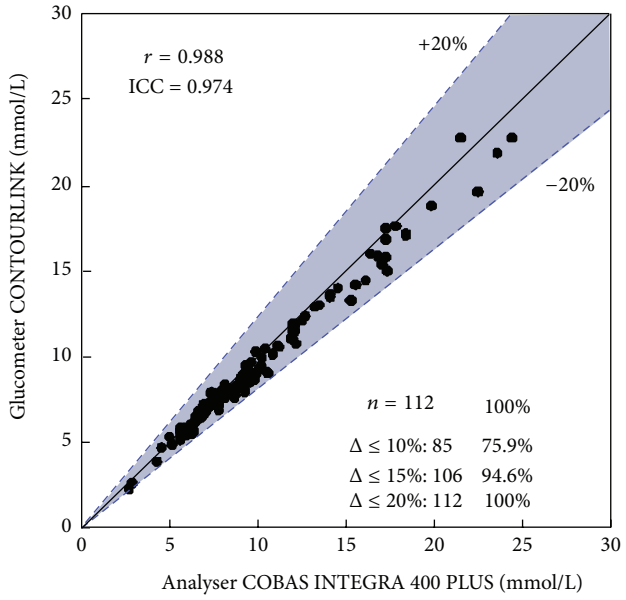


Figure 3: Error-Grid diagram of CONTOURLINK versus INTEGRA.

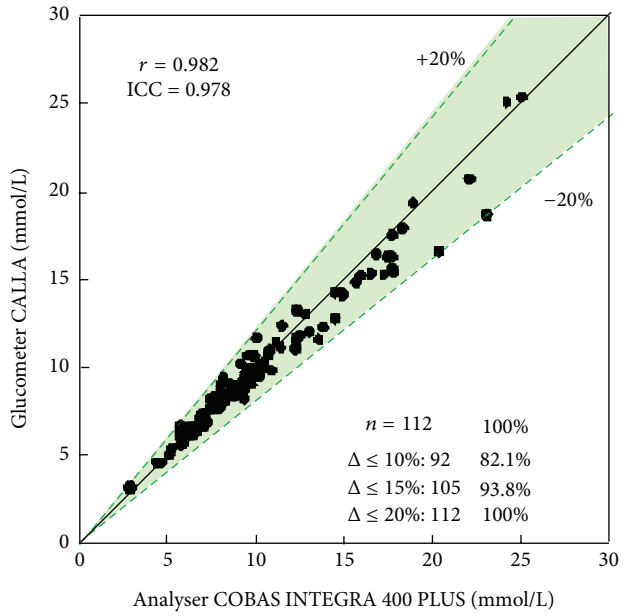


Figure 4: Error-Grid diagram of CALLA versus INTEGRA.

3.2. Statistical Analysis. The statistical program SPSS, v. 15, SPSS Inc., Chicago, IL, USA, was applied to assess the results. $P < 0.05$ was considered significant.

The accuracy of glucometers was assessed by comparison of differences between individual glucometers and reference values on the analyzer COBAS INTEGRA (Figure 6).

Wilcoxon Signed Rank Test with Bonferroni correction revealed differences between mean PG on CONTOURLINK versus INTEGRA ($P < 0.0001$) and LINUS versus INTEGRA ($P < 0.0001$).

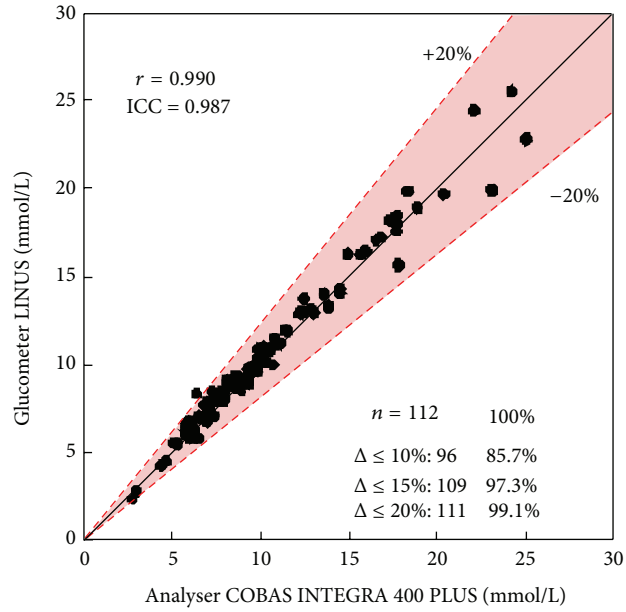


Figure 5: Error-Grid diagram of LINUS versus INTEGRA.

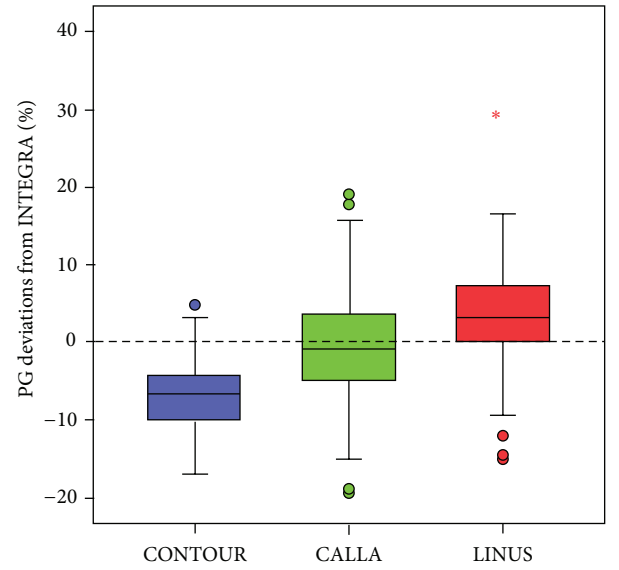


Figure 6: Box graph: relative PG deviations (glucometers versus INTEGRA) $N = 112$, median, lower, and upper quartils.

There was no significant difference between mean PG values on glucometer CALLA versus INTEGRA ($P = 0.419$).

The variability (precision) of PG estimations was assessed by mean standard deviation calculated from 112 individual means of 3 estimations on INTEGRA and in each set of respective glucometers:

(i) SD INTEGRA = 0.061 mmol/L,

(ii) SD CONTOURLINK = 0.256 mmol/L,

(iii) SD CALLA = 0.290 mmol/L,

(iv) SD LINUS = 0.264 mmol/L.

University Hospital Olomouc, 2nd Department of Medicine						
Name	Patient no. 1					
Diagnosis	Diabetes mellitus type 1					
Meal	Breakfast	2nd breakfast	Lunch	Snack	Dinner 1	Dinner 2
Time	6:30	9:30	12:30	15:00	18:00	22:00
Food	Bread, butter, ham, tea		Vegetable soup, potatoes, fried fish	Fruits	Bread, cheese, fruits	Bread, milk

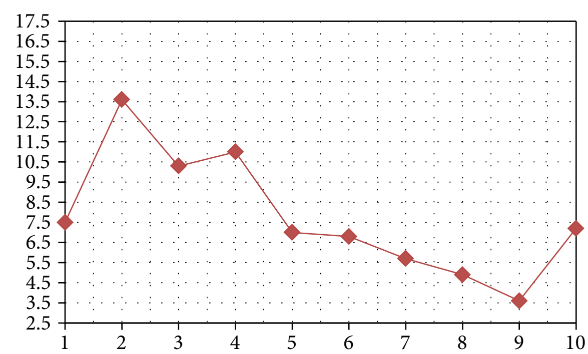
Insulin								
Time	6:00	9:00	12:00	15:00	17:30	22:00	BR/d	Sum
Dose (IU)	5	3	5	3	4	2	20.2	42.2

Sample	1	2	3	4	5	6	7	8	9	10
Time	6:00	9:00	12:00	15:00	17:30	20:30	22:00	0:30	2:30	6:00

Start date 4/3/2012 | End date 4/4/2012

Kind of insulin
Novorapid
Means of application
Insulin pump
Glucometer
CALLA, Wellion
Drugs

Glycaemia (mmol/L)



	1	2	3	4	5	6	7	8	9	10
Glycaemia	7.5	13.6	10.3	11	7	6.8	5.7	4.9	3.6	7.2

What do you need?			
Date of visit	4/4/2012	Time	
Body mass (kg)	72	Heart rate	68
Body height (cm)	185	BP (mmHg)	130/80
Present complaints			
Recommendation	Reduce basal rate between 21:00 and 5:00		

Figure 7: Ambulatory glycaemic profile. Man with type 1 diabetes on an insulin pump. Near-hypoglycaemia at 2.30 a.m. and hyperglycaemia in the morning hours. Form filled by the patient.

3.3. Assessment of Diabetes Control in Real Life Using Glucometer CALLA for Ambulatory Glycaemic Profiles (AGP) as Markers of Therapeutic Effectiveness. Having found the acceptable accuracy and precision in all three types of tested glucometers, we have recommended the glucometer CALLA to all persons with diabetes on insulin and on oral antidiabetic drugs as well as on diet only. All individuals have been encouraged to estimate at least one complete AGP including the data on food consumption, insulin dosage, and other relevant factors and to bring it to each medical checkup. Based on the general condition and considering both the HbA1c and AGP and additional laboratory parameters the recent therapeutic outcomes were assessed.

Example 1. 50-year-old man with type 1 diabetes treated by means of an insulin pump has experienced frequent morning hyperglycaemias. HbA1c was 55 mmol/mol. AGP revealed nocturnal near-hypoglycaemia (Figure 7). The AGP improvement (Figure 8) is deemed to result from the reduction of the basal rate between 9 p.m. and 5 a.m. (Figure 9).

Example 2. 60-year-old woman with type 2 diabetes, hyperlipoproteinemia, hypertension, and obesity treated with metformin 1700 mg/d. No complaints. HbA1c was 75 mmol/L. AGP revealed hyperglycaemia particularly in the morning hours (Figure 10). Four months later, the AGP improvement is deemed to result from the increased metformin dose from 1700 to 3000 mg/d. HbA1c was 50 mmol/mol (Figure 11).

University Hospital Olomouc, 2nd Department of Medicine																							
Name	Patient no. 1																						
Diagnosis	Diabetes mellitus type 1																						
Meal	Breakfast		2nd breakfast		Lunch		Snack		Dinner 1		Dinner 2												
Time	6:30		9:30		12:30		15:00		18:00		22:00												
Food	Bread, cheese, vegetable, tea		Vegetable		Rice, beef, fruits		White bread		Porridge, fruits		Bread												
Insulin	Time	6:00		9:00		12:00		15:00		17:30		22:00		BR/d		Sum							
	Dose (IU)	5		2		5		3		4		2		19.2		40.2							
Glycaemia (mmol/L)	Sample	1	2	3	4	5	6	7	8	9	10	Kind of insulin											
	Time	6:00	9:00	12:00	15:00	17:30	20:30	22:00	0:30	2:30	6:00	Novorapid											
	Start date 4/12/2012								End date 4/13/2012			Means of application											
												Insulin pump											
												Glucometer											
												CALLA, Wellion											
												Drugs											
	1	2	3	4	5	6	7	8	9	10													
Glycaemia	6.0	9.8	8	10.7	8.5	8.1	6.6	6.9	5.8	7.2													
What do you need?																							
Date of visit				4/13/2012				Time															
Body mass (kg)				72				Heart rate			66												
Body height (cm)				185				BP (mmHg)			130/70												
Present complaints																							
Recommendation	Intensive self-monitoring																						

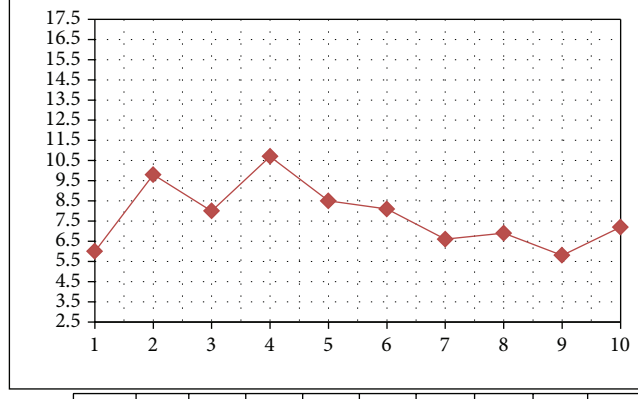


Figure 8: Improved AGP after reduction of the basal rate between midnight and 5.00 a.m. Form filled by the patient.

4. Discussion

This study focuses (1) on the accuracy and precision of three different types of electrochemistry-based glucometers (CONTOURLINK, CALLA, and LINUS) and (2) on the assessment of diabetes control using ambulatory glycaemic profiles (AGP) as markers of therapeutic effectiveness. The glucometers are produced by different companies and available on the market. All investigations were carried out in an out-patient department under conditions of everyday's practice and under supervision of one specialist.

ISO 15197:2003 [21] demands that all glucometers for SMPG adhere to the following guidelines: ≥95% of blood glucose (BG) results should fall within ±15 mg/dL (0.83 mmol/L) of the reference method at BG concentrations <75 mg/dL (4.2 mmol/L) and within ±20% at BG concentrations ≥75 mg/dL (4.2 mmol/L).

ISO 15197:2013 is a tighter standard applicable to manufacturers, regulatory authorities, and conformity assessment bodies. It specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples and are intended for self-measurement by lay persons for management of diabetes mellitus. The new ISO 15197:2013 differs from the previous 2003 version in the following points: increased accuracy for glucometer systems, in particular for glucose values greater than 75 mg/dL (4.2 mmol/L). Manufacturers of glucometer systems must ensure that their technology enables accuracy to improve from ±20% to ±15%. The new version accounts for 99% of results, as opposed to 95% for the

University Hospital Olomouc, 2nd Department of Medicine

Basal rates overview							
Name		Patient no. 1		Diagnosis	Diabetes mellitus type 1		
Type of insulin pump		Paradigm Veo 554		Pump start	3/20/2012		
Basal rates							
Date	4/3/2012	4/7/2012					
0-1 h	0.6	0.5					
1-2 h	0.8	0.6					
2-3 h	0.8	0.7					
3-4 h	0.9	0.8					
4-5 h	1.0	0.9					
5-6 h	1.0	1.0					
6-7 h	1.1	1.1					
7-8 h	1.1	1.1					
8-9 h	0.9	0.9					
9-10 h	0.8	0.8					
10-11 h	0.7	0.7					
11-12 h	0.6	0.6					
12-13 h	0.7	0.7					
13-14 h	0.8	0.8					
14-15 h	0.9	0.9					
15-16 h	1.0	1.0					
16-17 h	1.1	1.1					
17-18 h	1.0	1.0					
18-19 h	0.9	0.9					
19-20 h	0.8	0.8					
20-21 h	0.7	0.7					
21-22 h	0.7	0.6					
22-23 h	0.7	0.5					
23-24 h	0.6	0.5					
Sum	**20.2**	**19.2**					

Boluses (IU) to be adjusted to actual situation							
Breakfast	5	5					
2nd breakfast	3	2					
Lunch	5	5					
Snack	3	3					
Dinner 1	4	4					
Dinner 2	2	2					
Sum	**22.0**	**21.0**					

Figure 9: Basal rates in man on an insulin pump (see Figures 7 and 8 to assess the possible outcomes of basal rate adaptation). Form filled by physician.

previous one. For the first time, the standard provides formal acceptance criteria for accuracy as regards testing by patients and assessment of interferents (including hematocrit).

Project leader for ISO 15197, Dr. Alan Cariski, comments: "More accurate glucose measurements will help patients to better regulate their diabetes, through more informed treatment decisions that may affect, for example, dietary intake and medication dose, especially insulin."

Our "real life results" for all three glucometers (CONTOURLINK, CALLA, and LINUS) described in this study are in accordance with the present international standard ISO 15197:2003 [21]. However, the distribution of reference values between hypoglycaemic, euglycaemic, and hyperglycaemic range is the weak point of our trial.

Considering the recent ISO 15197:2013 [22], which should become mandatory in the year 2015, our results may be assessed as borderline. It is necessary to mention that the number of pairs (glucometer system versus reference method) was 112 only (i.e., lower than the demanded number of 200 pairs) leaving less than 99% of the results obtained from individual glucometers within the range ±15% from the reference values measured on COBAS INTEGRA 400 PLUS analyzer.

SMPG is clearly associated with improved HbA1C concentrations in persons with type 1 diabetes and insulin-treated type 2 diabetes. Persons with diabetes who are not treated with insulin may also benefit from SMPG; however, the discussion on this topic is still ongoing. This may be caused by the rising cost [9].

Both these international standards are suggested for *in vitro* testing of glucometer-strips systems. Considering the accuracy and precision *in real life testing*, our results may be undoubtedly influenced by many interfering factors (e.g., differences in haemoglobin concentration, different temperature, the blood transferred on strips step by step directly from the fingerprick without previous homogenization, etc.). We have not paid adequate attention to all

University Hospital Olomouc, 2nd Department of Medicine	
Name	Patient no. 2
Diagnosis	Diabetes mellitus type 2

Meal	Breakfast	2nd breakfast	Lunch	Snack	Dinner 1	Dinner 2
Time	6:30	9:30	12:30	15:00	18:00	22:00
Food	White bread, butter, ham, coffee with milk	Vegetable	Bouillon, potatoes, chicken, vegetable	Apple	Bread, cheese, vegetable	

Insulin								
Time	6:00	9:00	12:00	15:00	17:30	22:00	BR/d	Sum
Dose (IU)	—	—	—	—	—	—	0	0

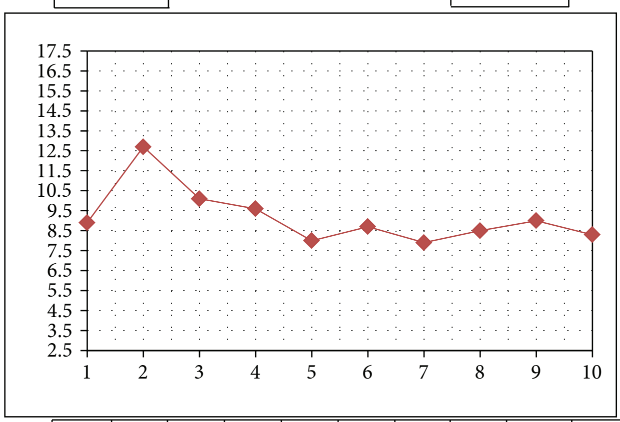
Sample	1	2	3	4	5	6	7	8	9	10
Time	6:00	9:00	12:00	15:00	17:30	20:30	22:00	0:30	2:30	6:00

Start date 5/9/2012

End date 5/10/2012

Kind of insulin
—
Means of application
—
Glucometer
CALLA, Wellion
Drugs
Metformin 850 mg 1-0-1
Sortis 20 mg 0-0-1
Prestarium Neo 1-0-0

Glycaemia (mmol/L)



	1	2	3	4	5	6	7	8	9	10
Glycaemia	8.9	12.7	10.1	9.6	8	8.7	7.9	8.5	9	8.3

What do you need?			
Date of visit	5/10/2012	Time	
Body mass (kg)	96	Heart rate	70
Body height (cm)	179	BP (mmHg)	140/90
Present complaints			
Recommendation	Increase metformin		

Figure 10: 60-year-old woman with type 2 diabetes treated with metformin 1700 mg/d. AGP show hyperglycaemia. Form filled by the patient.

potentially interfering factors. In addition, it was hardly possible to carry out such a large number of investigations in a short period of time demanded by exact scheme of the international standard. Despite these facts, the tested glucometers brought helpful results and supported decisions dealing with adaptations of diabetes therapy, particularly when applied for the investigation of ambulatory glycaemic profiles.

In our centre, the ten-point ambulatory glycaemic profiles are performed as a substantial part of regular diabetes check-ups. The persons with diabetes (PWDs) are trained in AGP including corrections of timing of fingerpricks, meals, and insulin application exceeding ±15 min of the times printed on the AGP sheet. On the evaluation of an AGP the following is especially recommended.

(i) To compare the fasting PG values at 6,00 h at the beginning and at the end of the AGP to assess the stability of diabetes control.

(ii) To pay attention to the evolution of PG between midnight and 6,00 h a.m.; the increase ≥1.0 mmol/L indicates a dawn phenomenon.

(iii) To explain the postprandial PG variations over the day.

(iv) To identify hypoglycaemias.

(v) To discuss all items dealing with insulin dosage, meals, and exercise

(vi) To suggest adaptations.

University Hospital Olomouc, 2nd Department of Medicine	
Name	Patient no. 2
Diagnosis	Diabetes mellitus type 2

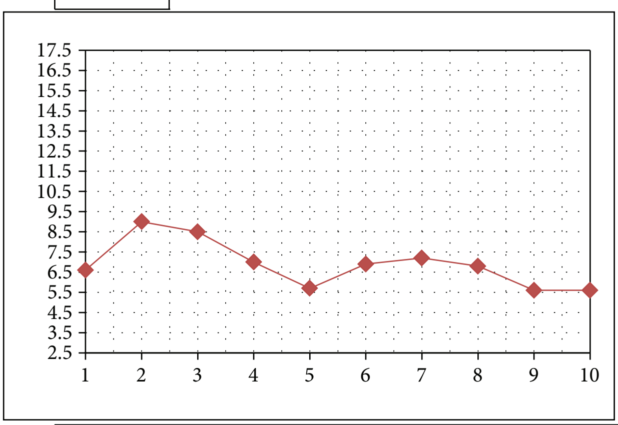
Meal	Breakfast	2nd breakfast	Lunch	Snack	Dinner 1	Dinner 2
Time	6:30	9:30	12:30	15:00	18:00	22:00
Food	White bread, natural yogurt, tea	Bread, butter	Mushroom soup, pasta, chicken		Bread, ham, tea	

Insulin									
Time	6:00	9:00	12:00	15:00	17:30	22:00	BR/d	Sum	
Dose (IU)	—	—	—	—	—	—	0	0	

Sample	1	2	3	4	5	6	7	8	9	10	Kind of insulin
Time	6:00	9:00	12:00	15:00	17:30	20:30	22:00	0:30	2:30	6:00	—

Start Date	End date
9/1/2012	9/2/2012

Means of application
—
Glucometer
CALLA, Wellion
Drugs
Metformin 1000 mg 1-1-1
Sortis 20 mg 0-0-1
Prestarium Neo 1-0-0



	1	2	3	4	5	6	7	8	9	10
Glycaemia	6.6	9	8.5	7	5.7	6.9	7.2	6.8	5.6	5.6

What do you need?			
Date of visit	9/2/2012	Time	
Body mass (kg)	96	Heart rate	70
Body height (cm)	179	BP (mmHg)	140/90
Present complaints			
Recommendation	Self-monitoring		

Figure 11: Improvement of the AGP (Figure 10) is likely due to increasing metformin dose to 3000 mg/d. Form filled by the patient.

The variability (precision) of PG estimations was assessed by mean standard deviation calculated from 112 individual means of 3 estimations on CONTOURLINK (0.256 mmol/L), on CALLA (0.290 mmol/L), and on LINUS (0.264 mmol/L) which is four to five times more than mean standard deviation on COBAS INTEGRA (0.061 mmol/L). That means that a difference of PG values in AGP need not be always related to a real change of PG concentration but may be due to the lower precision of glucometer. For example, the "decrease" of PG reading from 11 mmol/L at 12,00 h to 9 mmol/L at 15,00 h may be due to the variability of the glucometer-strips system when the reference value at 12,00 h and 15,00 h remains always 10,0 mmol/L but the glucometer reading at 12,0 h was 10 mmol/L − 10% and 10 mmol/L + 10% at 15,0 h.

The frequency of a single PG estimation and/or AGP's is often discussed considering patient's comfort, costs, and metabolic outcomes. However, there are still many patients who are making self-monitoring in order to fulfill the physicians recommendation only, without any active approach to correction of glycaemia.

From the point of view of practice, the monitoring and self-monitoring of glycaemia make sense if they results in active treatment adaptation in order to improve the metabolic control.

To date, researchers pay attention to standardization of glucose estimation [32, 33], to standardization of SMBG, and to ambulatory glycaemic profiles. Some papers keep using the abbreviation SMBG even though several glucometer systems are estimating the glucose concentration in plasma and the abbreviation SMPG appears to be more appropriate.

Many papers deal with the continuous glucose monitoring [34–45].

The present situation is characterized in the papers of Thorpe and Bergenstal.

Thorpe [23] tried to assess the quality of publications evaluating the accuracy of blood glucose monitoring systems. Many studies determine the performance of blood glucose monitoring (BG) systems. Correct evaluation is, however, complex, and apparent contradiction of results creates confusion. This study aimed to provide an overview of frequently made errors and to develop easy-to-use checklists to verify the quality of such studies. Building on the work from Mahoney and Ellison [42] and subsequent reevaluation, study designs of accuracy studies were assessed, and best practice and internationally accepted norms were determined. Key issues were collated, and two simplified checklists were developed, one for the assessment of analytical accuracy studies and a second for guidance with studies assessing the influence of interferences. The checklists have been used in a feasibility study with 20 representative studies selected from a literature search between 2007 and 2012. This check revealed that limitations in the designs and methods of studies assessing the performance of BG systems are common. The use of the accuracy checklist with the 20 representative studies showed that only 20% were in agreement with most of the issues deemed important and that 40% showed clear nonconcordance with ISO 15197. The use of the interference checklist showed that only 50% of the publications were in good agreement with the quality checks. In agreement with previous studies, which concluded that many evaluations are performed poorly and present questionable conclusions, the use of these checklists demonstrated that few publications adhered to international guidelines and recommendations. Taking this into consideration, it becomes obvious that the publications must be examined in more detail to establish their quality and the validity of conclusions drawn.

Bergenstal and others [8] reported on the expert panel of diabetes specialists in Tampa, FL, March 28-29, 2012. The purpose of the meeting was to develop recommendations for standardization of analysis and presentation of glucose monitoring data, with the initial focus on data derived from CGM systems. The panel acknowledged that self-monitoring of blood glucose (SMBG) was currently the predominate mode of glucose monitoring in diabetes and that additional conferences were needed to address the issues particularly relevant to reporting and analysis of SMBG data, even though there is considerable overlap between SMBG and CGM standardization.

There were important conclusions from this meeting. Despite advances in insulin preparations, insulin delivery devices, and glucose monitoring technology, glycemic control in many individuals with type 1 diabetes remains suboptimal. Use of the HbA1c value as a primary (or sole) measure of glycemic status, underutilization of SMBG and CGM data, and lack of easy and standardized glucose data collection, analysis, visualization, and guided clinical decision making are, clearly, key contributors to poor glycemic control within this population.

The IDC will continue to develop, test, and assist with implementation of the AGP "Dashboard" as the standard reporting system for CGM and, ultimately, data from SMBG. Through standardization of clinical terms and key metrics, with glucose data visualized in an easily interpreted format, the AGP "Dashboard" has the opportunity to benefit clinicians, patients, payers, and regulators through improved patient care, better understanding and utilization of glucose data in clinical practice, and greater ability to evaluate and improve clinical performance. Standardized reporting also has potential to benefit clinical research by enabling investigators and regulators to agree on standardized benchmarks that define improvement in glycemic control and a reduction in hypoglycemia, hyperglycemia, and glucose variability. This will allow for new drugs, new devices, and new team-based approaches to diabetes management to be evaluated more effectively.

Standardizing glucose reporting and analysis, with tools such as AGP, may be one step toward optimizing clinical decision making in diabetes. Although CGM has been shown to be valuable in several clinical settings, continued research is needed to define which individuals with type 1 or type 2 diabetes will benefit most from either real-time use of CGM or retrospective analysis of intermittent use of CGM.

Hence, from the practical point of view and considering various interfering factors, we believe that in one diabetes centre one type of glucometer system should be recommended for all individuals with diabetes. The AGP belong to important markers of therapeutic effectiveness. Appropriate timing and frequency of ambulatory glycaemic profiles are advisable.

Glucometer systems CONTOURLINK, CALLA, and LINUS appear to be acceptable means for routine AGP self-monitoring and clinical use. Nevertheless, the differences in PG-readings between individual types of glucometers should be considered both in clinical studies and diabetes care. Self-monitoring of glycaemia makes sense if it results in active adaptation of therapy in order to improve the metabolic control.

Conflict of Interests

The authors declare that they have no conflict of interests

Dedication

This paper is dedicated to the memory of Professor Dr. med. Michael Berger, June 2, 1944–August 18, 2002, Department of Endocrinology and Metabolic Diseases, Heinrich Heine Universität, Düsseldorf, Germany, for his enthusiastic approach to diabetes education, self-monitoring, and evidence-based medicine.

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