SUMMARY - Up to the present there is controversy about blood-glucose self-monitoring in type 2 diabetes. In 842 insulin-treated type 2 diabetic patients (age 60.1 ± 10.9, diabetes duration since diagnosis 12.6 ± 7.6 years, relative HbA1c 1.83 ± 0.39 % [relative HbA1c = HbA1c/mean normal, HPLC Diamat]) a cross-sectional study was conducted to assess blood-glucose self-monitoring and interactions with quality of diabetes care.

There was a negative correlation ($r = -0.17$, $p < 0.001$) between the frequency of blood-glucose self-tests/week and HbA1c. Performing multivariate analysis the most important parameters associated with HbA1c (R-square = 0.25) were: The frequency of blood-glucose self-tests/week ($c = 0.005$, $p < 0.001$), the insulin-dosage/kg body weight ($c = 0.001$, $p = 0.0032$) and the participation in a 5-day structured treatment and teaching programme for patients with conventional insulin therapy (5-TTP, $c = 0.085$, $p < 0.0001$). Other factors investigated in the model (age, diabetes duration, number of insulin injections/day, sex) showed no associations. Performing a sub-group analysis in patients older than 60 years ($n = 396$) parameters associated with HbA1c (R-square = 0.10) were: The frequency of blood-glucose self-tests/week ($c = -0.016$, $p = 0.0032$) too. In an further sub-group analysis patients ($n = 249$) were investigated who have not participated in a 5-TTP. In this cohort there were no correlations and no associations between the frequency of blood-glucose self-monitoring and HbA1c. Then, an intervention was started: 33 out of the 249 patients participated in a 5-TTP. At the time of re-examination 1 year after participation in the 5-TTP, the relative HbA1c decreased from 1.84 ± 0.38 % to 1.61 ± 0.30 % ($p = 0.007$) and there was a strong association between the frequency of blood-glucose self-tests/week and HbA1c ($c = -0.016$, $p = 0.0052$, R-square = 0.23).

Daily blood-glucose self-monitoring was statistically associated with better quality of metabolic control. Participation in a 5-TTP and regularly blood-glucose self-monitoring is mandatory for all insulin-treated patients with type 2 diabetes mellitus.

Key-words: Type 2 diabetes mellitus, blood-glucose self-monitoring, structured treatment and teaching programme, conventional insulin therapy, hypoglycaemia.

RÉSUMÉ - Autosurveillance glycémique des diabétiques de type 2 insulinothérapie.

La controverse persiste quand à la place de l’auto-surveillance glycémique (ASG) dans le diabète de type 2. Chez 842 diabétiques de type 2 insulinothérapie (âge 60 ± 10,9, durée de diabète 12,6 ± 7,6 années depuis le diagnostic, HbA1c relative +1,83 ± 0,39 % [soit: vs références normales par HPLC Diamat]) une étude transversale a été menée pour investi- guer l’ASG et ses interactions avec la qualité de prise en charge du diabète dans cette population. Il existe une corrélation négative entre la fréquence des auto-contrôles et l’HbA1c ($r = -0,017$, $p < 0,001$). L’analyse multivariée montre que les principaux paramètres associés à l’HbA1c (R-square = 0,10) sont: la fréquence hebdomadaire des auto-contrôles glycémiques ($c = -0,005$, $p < 0,001$), la dose d’insuline/kg de poids corporel, et la participation à un programme spécifique d’éducation diabétique de 5 jours (5-TTP, $c = 0,085$, $p < 0,0001$). D’autres facteurs testés dans le modèle (âge, nombre d’insulinodose/jour, sexe) ne montrent pas d’association. Dans un sous-groupe de patients de 60 ans ou plus ($n = 396$) les paramètres associés à l’HbA1c sont la participation au 5-TTP ($c = 0,09$, $p = 0,0002$) et la fréquence de l’ASG/semaine ($c = -0,006$, $p = 0,0018$). Dans un autre sous-groupe ($n = 249$) de patients n’ayant pas participé au 5-TTP il n’est retrouvé aucune corrélation entre la fréquence de l’ASG et l’HbA1c. Puis 33 de ces 249 patients participèrent à ce pro- gramme d’enseignement (5-TTP). Un an plus tard leur HbA1c relative fut réduite de +1,84 ± 0,38 % à +1,61 ± 0,30 % ($p = 0,007$) et il existait alors une forte association entre la fréquence de l’ASG/semaine et l’HbA1c ($c = -0,016$, $p = 0,0032$, R-square = 0,25). L’ASG quotidienne était stabi- quement corrélée avec un meilleur contrôle métabolique. Nous concluons que la participation à un programme éducatif sur 5 jours (5- PTT) et l’ASG régulière sont à recommander à l’ensemble des diabéti- ques de type 2 insulinothérapies.

Mots-clés : Diabète type 2, auto-surveillance glycémique, programme structuré d’éducation diabétique, insulinothérapie conventionnelle, hypoglycémies.
For type 1 diabetes mellitus the results of the Diabetes Control and Complications Trial (DCCT) [1, 2] as well as those of the Stockholm studies [3, 4, 5] and numerous other trials [6-10] have clearly demonstrated, that intensive insulin therapy (ICT) with the result of near normoglycaemia could retard the onset and the progression of diabetes long-term complications. The findings of Abraira et al. [11] and Ohkubo et al. [12] show similar results for type 2 diabetic patients. Hence, the goal of treatment in younger, not multimorbide patients with type 2 diabetes should be an HbA1c below 7.0 % [13-16].

Although there are only very few, controversy and mostly anecdotal data about the efficacy of blood-glucose self-monitoring in patients with type 2 diabetes [17-21] self-testing is widely recommended [13, 14, 22]. On the background of this lack of data or confusing findings of previous studies it was the aim of the current cross-sectional survey with an intervention group to conduct an audit of the home monitoring practice of the patients studied. Moreover, patients’ understanding of the results of their tests and possible interactions with quality of diabetes control should be assessed.

**PATIENTS AND METHODS**

**Study design** – In a cross-sectional study a total of 842 patients with insulin treated type 2 diabetes mellitus, diagnosed according to the criteria of “The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus” [23], was examined. At the time of examination all the patients had insulin treatment for at least 12 months. Among the patients studied there were 90 % of all insulin-treated type 2 diabetic patients aged 16 to 60 years and living in the city of Jena, Thuringia, Germany (100 242 inhabitants) [24, 25] and all patients consecutively attended our hospital clinic and the out-patient department of our centre between March, 1991 and October, 1997. Additionally 91 patients were studied, successively treated at the district hospitals of Rudolstadt and Apolda, Thuringia, Germany, between October, 1990 and December, 1991.

**Quality of diabetes care** – To assess quality of diabetes care the following investigations were performed: The glycosylated haemoglobin A1 (HbA1c) was measured centrally in the Department of Clinical Chemistry at our university (HPLC, Diamat®), normal range: 4.1-5.2 % in 1990-1994, 4.4-5.9 % since 1994). The normal range of each method was assessed measuring 100 healthy subjects. For comparison of the two HbA1c methods values were normed on the mean normal value (original HbA1c value divided by the mean normal of each method), a procedure which guarantees good reliability as shown in the German “Working Group for Structured Diabetes Therapy” [26].

In all the patients the frequencies of blood- and urine-glucose self-monitoring were assessed with an standardised questionnaire. Then, the frequencies given by the patients were controlled by comparison with patient’s log books. Furthermore, patients’ understanding of the results of their tests was studied by checking the log books and the assessment of the frequencies of insulin-dose self-adjustments.

Height and body weight were assessed with the patients wearing light clothing and without shoes.

The characteristics of the patients are shown in Table I.

**Structured treatment and teaching programme** – The 33 patients out of the intervention group took part in a structured treatment and teaching programme for patients with type 2 diabetes mellitus and insulin therapy according to Berger et al. [27] performed in 5 days during hospitalisation. The patients were taught by persons who had completed a national postgraduate course for diabetes educators conducted by the German Diabetes Association. The curriculum of the teaching sessions consisted in the following areas of education: preprandial blood-glucose self-monitoring, insulin administration, insulin-dose self-adjustment, identification of carbohydrate-containing food, estimation of amounts of carbohydrates, symptoms, treatment and prevention of hypoglycaemia, foot care, sick day rules and complications of diabetes.

**Statistical analysis** – Statistical analysis was performed using SPSS® (Statistical Package for Social Science). All data are presented as mean ± standard deviation (SD) or, if the data showed no normal distribution, as median and range. For comparisons the

| Table I. Characteristics of the total of 842 patients studied (*relative HbA1c = HbA1c/mean normal, **median). |
|---------------------------------|-------|-------|----------|
| **Age (years)**                 | 60.1  | 10.9  | 20-87    |
| **Diabetes duration (years)**   | 12.6  | 7.6   | 1-57     |
| **Body-mass Index (kg/m²)**     | 28.6  | 5.1   | 15.4-51.1|
| **Relative HbA1c**              | 1.83  | 0.39  | 0.8-3.6  |
| **Injections (n)/day**          | 2.4   | 1.1   | 1-7      |
| **Insulin dosage (IU)/kg bd wt**| 0.52  | 0.46  | 0.03-1.18|
| **Blood-glucose self-tests**    | 3**   | -     | 0-49     |
| **Urine-glucose self-tests**    | 0**   | -     | 0-40     |

[Mean SD Range]

Student’s t-test, chi-square test and Wilcoxon’s rank sum test were used. Significance was defined at the 0.05 level.

RESULTS

In the total population of 842 insulin-treated type 2 diabetic patients there were negative correlations between the frequency of blood-glucose self-tests and HbA1c (r = -0.17, p < 0.001) and age (r = -0.16, p < 0.001) and a positive correlation between the frequency of blood-glucose self-tests and the frequency of insulin-dose self-adjustments of the patients (r = 0.42, p < 0.001).

Performing multivariate analysis – there were associations between HbA1c (R-square = 0.10) and

1. the frequency of blood-glucose self-tests/week (c = -0.005, p = 0.0004),
2. insulin dosage/kg body weight (c = 0.001, p = 0.0032),
3. the previous participation in a structured 5-day treatment and teaching programme for patients with type 2 diabetes and insulin therapy according to Berger et al. [27] (c = 0.085, p < 0.0001),
4. the number of insulin-dose self-adjustments/week (c = -0.015, p = 0.0002),
5. the body-mass index (c = 0.008, p = 0.0012) and
6. the number of urine-glucose self-tests/week (c = -0.009, p = 0.0044).

There were no associations between HbA1c and age, diabetes duration, the number of insulin injections/day or the sex of the patients.

Frequency of blood-glucose self-monitoring – Out of the total group, 340 patients performed at least one blood-glucose self-test (median 20 blood-glucose self-tests/day, range 7-49) per day. The other 502 patients performed less blood-glucose self-tests (median 0, range 0-6) per day. Patients who performed regularly blood-glucose self-tests were younger, had a higher body-mass index, more insulin-injections/day, more insulin-dose self-adjustments/day and a better HbA1c (Table II).

Sub-group analyses –

• Patients older than 60 years

A cohort of 396 patients of the total of 842 patients were older than 60 years. The characteristics of these patients are shown in Table III. Studying this cohort in the multivariate analysis the following parameters showed significant associations with the HbA1c (R-square = 0.16):

1) insulin-dosage/kg body weight (c = 0.004, p = 0.0002),
2) the previous participation in a structured 5-day treatment and teaching programme for patients with type 2 diabetes and insulin therapy according to Berger et al. [27] (c = 0.09, p = 0.002), and
3) the frequency of blood-glucose self-monitoring (c = 0.006, p = 0.0018) and
4) patients’ body-mass index (c = 0.01, p = 0.0012).

The characteristics of the patients are shown in Table III. Studying this cohort in the multivariate analysis the following parameters showed significant associations with the HbA1c (R-square = 0.16):

1) insulin-dosage/kg body weight (c = 0.004, p = 0.0002),
2) the previous participation in a structured 5-day treatment and teaching programme for patients with type 2 diabetes and insulin therapy according to Berger et al. [27] (c = 0.09, p = 0.002), and
3) the frequency of blood-glucose self-monitoring (c = 0.006, p = 0.0018) and
4) patients’ body-mass index (c = 0.01, p = 0.0012).

Table II. Comparison of patients who performed 7 or more blood-glucose self-tests/week (Group A) with patients who performed less (Group B) (*relative HbA1c = HbA1c/mean normal, **median).

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients (n)</td>
<td>340</td>
<td></td>
<td>502</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>58.7 ± 11.2</td>
<td>20-87</td>
<td>61.0 ± 10.6</td>
<td>24-84</td>
<td>0.002</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>12.1 ± 7.0</td>
<td>1-40</td>
<td>12.9 ± 7.9</td>
<td>1-57</td>
<td>0.09</td>
</tr>
<tr>
<td>Body-mass Index (kg/m²)</td>
<td>29.2 ± 5.1</td>
<td>15.4-51.1</td>
<td>28.2 ± 5.1</td>
<td>16.4-48.7</td>
<td>0.006</td>
</tr>
<tr>
<td>Relative HbA1c*</td>
<td>1.76 ± 0.39</td>
<td>0.80-3.30</td>
<td>1.89 ± 0.38</td>
<td>0.94-3.60</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Insulin injections/day</td>
<td>2.8 ± 1.2</td>
<td>1-7</td>
<td>2.2 ± 0.9</td>
<td>1-6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Insulin dose (IU)/kg bd wt</td>
<td>0.52 ± 0.28</td>
<td>0.03-1.75</td>
<td>0.52 ± 0.55</td>
<td>0.04-11.8</td>
<td>0.89</td>
</tr>
<tr>
<td>Insulin-dose self-adjustments/week</td>
<td>0**</td>
<td>0-28</td>
<td>0**</td>
<td>0-10</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Blood-glucose self-tests (n)/week</td>
<td>20**</td>
<td>7-49</td>
<td>0**</td>
<td>0-6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Urine-glucose self-tests (n)/week</td>
<td>0**</td>
<td>0-40</td>
<td>0**</td>
<td>0-21</td>
<td>0.001</td>
</tr>
</tbody>
</table>
The other factors investigated in the model (age, diabetes duration, the frequency of insulin-dose self-adjustments/week, the number of insulin injections/day, the frequency of urine-glucose self-monitoring/week and sex of the patients) showed no significant associations with the HbA1c-values.

Patients who not participated in a structured treatment and teaching programme

This cohort consisted of a total of 249 patients. Table IV shows the characteristics of this group of patients. In this cohort in the multivariate analysis model the only factor associated with HbA1c was the patients’ body-mass index (R-Square = 0.03, c = 0.013, p = 0.005). No associations were found between HbA1c and the frequency of blood- or urine-glucose self-monitoring/week, age, diabetes duration, the frequency of insulin-dose self-adjustments/week, the number of insulin injections/day and the sex of the patients.

Based on these results and the obvious lack of efficacy of blood-glucose self-monitoring in uneducated patients, data of another intervention trial [28] were re-analysed in respect of self-testing: Here, 33 patients took part in a 5-day structured treatment and teaching programme for patients with type 2 diabetes mellitus and conventional insulin therapy according to Berger et al. [27]. On year after participation in the structured treatment and teaching programme all the patients were re-examined [28]. The results of the baseline and the re-examination are shown in Table V.

Multivariate analysis – The only parameter associated with HbA1c at the baseline examination was the diabetes duration (R-square = 0.15, c = -0.02, p = 0.015). At the time of re-examination it was the frequency of blood-glucose self-monitoring (R-square = 0.25, c = -0.016, p = 0.0032). The other parameters investigated in the models (the frequency of urine-glucose self-monitoring/week, age, the frequency of insulin-dose self-adjustments/week, the number of insulin injections/day and the sex of the patients) showed no associations with HbA1c.

**DISCUSSION**

Although for patients with type 2 diabetes mellitus self-testing is widely recommended [13, 14, 22], there is great controversy about its importance. Mostly, papers concerning this topic are reviews, publications based on personal experiences or anecdotal data [17-21, 29]. Faas et al. [29], performing a meta-analysis of 11 studies on patients with type 2 diabetes published during the years 1976 to 1996, concluded that the efficacy of blood-glucose self-monitoring is questionable and should be tested in controlled trials.

On this background of contradictory results the present cross-sectional and intervention study clearly emphasises blood-glucose self-monitoring in insulin-treated type 2 diabetic patients. Patients who performed regularly blood-glucose self-tests had better quality of diabetes care with lower HbA1c-values. Moreover, these positive results were not only found in the total group of patients, but also in the group of patients older than 60 years. However, the effect of blood-glucose self-monitoring was only overt, if patients took part in a structured treatment and teaching programme for patients with type 2 diabetes mellitus and conventional insulin therapy according to Berger et al. [27].

An other conclusion derived from our study concerns the frequency of blood-glucose self-
monitoring: The data give evidence for performing at least one blood-glucose self-test/day. Additionally the study indicated that approximately 40% of the patients attending our diabetes centre were performing blood-glucose self-monitoring. Comparing this data with the results of the investigation of a selection-free population of insulin-treated type 2 diabetic patients [24] in which 87% of the patients performed regular blood-glucose self-tests (in the mean 17.2 ± 9.8 tests/week), the present findings probably reflects a negative selection bias. A lot of patients attending our centre are “problem”-patients with bad blood glucose control or diabetes acute and long-term complications. This bias does not reduce the value of our findings, but it gives evidence for a strong positive effect also in such patients.

However, in both studies, the present trial and the population-based survey [24] the number of patients performing blood-glucose self-monitoring are nearly a twofold or more higher than the number reported from the U.S. population [30]. Like in the American statistic we also found a stepwise increase in the odds of testing with an increasing number of insulin injections per day. But, much more interesting: Patients with a higher frequency of blood-glucose self-monitoring and better HbA1c performed more insulin-dose self-adjustments/week. This leads to an additional underlining of the efficacy of blood-glucose self-testing: Based on the self-assessed blood-glucose values patients can change their insulin dose with the possibility of correction of high or low blood sugar levels. On this background the importance of participation of all patients in structured treatment and teaching programmes is evident. Insulin-dose self-adjustment is one of the main areas of education [27]. Here patients were thought to correct high blood sugar levels by the injection of 10% more insulin or to react to low blood-glucose values with the reduction of insulin or with additional eating of carbohydrate containing food. Probably, like in patients with type 1 diabetes mellitus, this regimen leads not only to an improvement in the quality of diabetes control [26, 31-35], but also to a reduction of the fear of severe hypoglycaemia [28].

Another reason for the importance of patient education and its interaction with quality of diabetes care and the frequency of blood-glucose self-monitoring is the quality of blood-glucose self-tests. As it has been shown in many trials, it is possible to have excellent results in measuring blood-glucose either with visual tests [36, 37] or by using reflectance meters [38, 39, 40]. But in both procedures it is important for the patients to be able to handle correctly with their strips or reflectance meters [18]. The correct handling of blood-glucose self-testing materials is also an area of patient education. Here, in the structured treatment and teaching course [27], the patients measure their blood sugar values mostly more than three times per day and compare their results with an exact laboratory method. They can discuss difficulties in the handling procedure and bad results with the physician or the diabetes educator.

In conclusion in the present cross-sectional and intervention study with a total of 842 insulin-treated type 2 diabetic patients daily blood-glucose self-monitoring (at least 1 test per day) was statistically associated with a better quality of metabolic control. The benefit was not only overt in younger patients but also in patients older than 60 years.

Although the intervention-group out of 33 patients was relatively small and we had failed to design a control group, with these patients we were able to show, that blood-glucose self-monitoring is only beneficial after participation in a structured treatment and

<table>
<thead>
<tr>
<th>Table V. Characteristics of the patients out of the intervention group at baseline and at the time of re-examination (1 year after participation in a 5-day structured treatment and teaching programme according to Berger et al. [27]. *relative HbA1c = HbA1c/mean normal, **median).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
</tr>
<tr>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
</tr>
<tr>
<td>Body-mass Index (kg/m²)</td>
</tr>
<tr>
<td>Relative HbA1c*</td>
</tr>
<tr>
<td>Insulin dose (IU)/kg bd wt</td>
</tr>
<tr>
<td>Blood-glucose self-tests (n)/week</td>
</tr>
<tr>
<td>Urine-glucose self-tests (n)/week</td>
</tr>
</tbody>
</table>
teaching programme. It is not enough for the patients to measure their blood-glucose values, but it is also important to perform insulin-dose self-adjustments or to document the measurements in a diabetes log-book. In the latter case, the physician will be able to draw the conclusions and to discuss blood-glucose values and the correct reactions with the patients.

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**Symposium:**

Belgian Working Group Angiology “Controversies in Diabetic Vascular Disease”.

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