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Interrelations between Self Measurement of Blood – Glucose (SMBG), Therapy, Metabolic Disorder and Non-Fatal or Fatal Events in Diabetes Type II Patients

Results of the Longitudinal Cohort Study ROSSO

gmds Leipzig 2006
September 11.-14. 2006
Retro-lective Study “Self-monitoring of Blood Glucose (SMBG) and Outcome in Patients with Type 2 Diabetes”

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Martin et al.: Self-monitoring of blood glucose in type 2 diabetes and long term outcome: an epidemiological cohort study
• **Study aims:**
   The study was designed to investigate the impact of SMBG on diabetes-related morbidity and all-cause mortality in patients with type 2 diabetes.

• **Study type:**
   Retrospective, longitudinal, multicenter cohort study with data acquisition from medical records in the centers.

• **Inclusion criteria:**
   Patients with diagnosis of type 2 diabetes between January 1, 1995 and December 31, 1999, age greater than 45 years at time of diagnosis and at least one year follow up.
Results:

3268 Patients from 192 centers were included

SMBG means ‘begin of SMBG before onset of a non fatal event’

• SMBG: 1479 patients (45%), no SMBG: 1789 patients (55%)
  64 patients with SMBG after onset of a non fatal event are included in the ‘no SMBG’ group.

• Follow up time: mean: 6.51 years
  SMBG 6.69 years
  no SMBG 6.35 years

• Begin SMBG (mean): 2.46 years after diagnosis
• Duration SMBG (mean): 4.26 years
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Patients with SMBG in the years after diagnosis
Begin and duration of SMBG

% patients with SMBG

Year after diagnosis

Mean duration of SMBG (years)

Begin SMBG (year after diagnosis)
## Baseline data:

<table>
<thead>
<tr>
<th>Data at diagnosis</th>
<th>SMBG</th>
<th>no SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>treated by general practitioner *</td>
<td>70%</td>
<td>75%</td>
</tr>
<tr>
<td>sex (male/female) *</td>
<td>53/47%</td>
<td>46/54%</td>
</tr>
<tr>
<td>legislative health insurance *</td>
<td>95%</td>
<td>97%</td>
</tr>
<tr>
<td>retired *</td>
<td>49%</td>
<td>60%</td>
</tr>
<tr>
<td>coronary heart diseases in anamnesis</td>
<td>21%</td>
<td>24%</td>
</tr>
<tr>
<td>myocardial infarction in anamnesis</td>
<td>4.1%</td>
<td>3.9%</td>
</tr>
<tr>
<td>stroke in anamnesis</td>
<td>3.0%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

* significant for $p=0.001$
Baseline data:

<table>
<thead>
<tr>
<th>Means of:</th>
<th>SMBG</th>
<th>no SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) *</td>
<td>60.5</td>
<td>64.0</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.9</td>
<td>29.8</td>
</tr>
<tr>
<td>Blood pressure systolic (mmHg)</td>
<td>148</td>
<td>150</td>
</tr>
<tr>
<td>Blood pressure diastolic (mmHg)</td>
<td>87</td>
<td>87</td>
</tr>
<tr>
<td>HbA1c adjusted to 6.1% (%) *</td>
<td>8.14</td>
<td>7.23</td>
</tr>
<tr>
<td>Fasting blood glucose (mmol/l) *</td>
<td>10.05</td>
<td>8.66</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>6.09</td>
<td>6.12</td>
</tr>
<tr>
<td>Triglycerides (mmol/l) *</td>
<td>2.86</td>
<td>2.45</td>
</tr>
</tbody>
</table>

* significant at p=0.001
Diabetes therapy in follow up

<table>
<thead>
<tr>
<th>Diet:</th>
<th>SMBG</th>
<th>no SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1415 (96%)</td>
<td>1687 (94%)</td>
</tr>
</tbody>
</table>

Medications before non-fatal event:

<table>
<thead>
<tr>
<th>Total</th>
<th>SMBG</th>
<th>no SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>No medication</td>
<td>603</td>
<td>66 (11%)</td>
</tr>
<tr>
<td>only Insulin</td>
<td>103</td>
<td>96 (93%)</td>
</tr>
<tr>
<td>only OAD</td>
<td>1912</td>
<td>742 (39%)</td>
</tr>
<tr>
<td>OAD+INS</td>
<td>650</td>
<td>575 (88%)</td>
</tr>
</tbody>
</table>

Mean begin of therapy (years after diagnosis)

<table>
<thead>
<tr>
<th>SMBG</th>
<th>no SMBG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin (only Insulin)</td>
<td>0.76</td>
</tr>
<tr>
<td>(OAD+INS)</td>
<td>3.52</td>
</tr>
<tr>
<td>OAD (only OAD)</td>
<td>1.34</td>
</tr>
<tr>
<td>(OAD+INS)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Begin SMBG before insulin 3% OAD 13%
Begin SMBG with insulin 90% OAD 36%
Begin SMBG after insulin 3% OAD 51%
(Patients treated only with insulin or OAD)
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Development of HbA1c and fasting blood glucose
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Mean HbA1c and fasting blood glucose before and after begin of SMBG

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Fasting blood glucose before and after begin of SMBG in treatment groups

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No medication

Insulin

OAD

OAD + Insulin
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HbA1c and fasting blood glucose before and after begin of SMBG by frequency of SMBG (<30 or >=30 measurements per month)
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Mean % change of HbA1c and fasting blood glucose after maximum
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Non fatal events after diagnosis

- Myocardial Infarction
- Stroke
- Foot-Amputation
- Blindness
- Dialysis

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Non fatal events
Myocardial infarction, stroke,
Foot-amputation, blindness,
Dialysis dependency

SMBG: 107 pts 7.2%
no SMBG: 186 pts 10.4%

Odds ratio: \(0.67\) (95% CI: 0.52-0.86)
Mean survival time:
SMBG: 8.63 yrs, no SMBG: 8.36 yrs

Hazard Ratio:
\(0.63\) (95% CI: 0.50-0.80)
Hazard Ratio adjusted:
\(0.68\) (95% CI: 0.51-0.91)
Fatal event (death)

SMBG 41 pts 2.7%
no SMBG 79 pts 4.6%

Odds ratio: 0.62 (95% CI: 0.42-0.91)

Mean survival time:
SMBG: 8.87 yrs, no SMBG: 8.75 yrs

Hazard Ratio:
0.52 (95% CI: 0.36-0.76)

Hazard Ratio adjusted:
0.49 (95% CI: 0.31-0.78)
Non fatal or fatal events:

SMBG: 144 pts 9.7%
no SMBG: 254 pts 14.2%

Odds ratio: **0.65** (95%CI: **0.53-0.81**)

Mean survival:
SMBG: **8.51** yrs, no SMBG: **8.15** yrs

Hazard Ratio:
**0.62** (95%CI: **0.50-0.76**)

Hazard Ratio adjusted:
**0.61** (95%CI: **0.50-0.76**)

Event-free survival time (years after diagnosis)
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Events in subgroups:
Type of praxis and employment

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Events in subgroups:
Smoker status and age groups
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Events in subgroups:
Blood glucose at diagnosis and diabetes therapy
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Coefficients B and 95%CI
of Cox regression with time dependent covariates:
T_SMBG, T_Insulin, T_OAD, Interaction T_SMBG*INS
Conclusions

• **Representativity**
  The centers and patients represent well the praxis of diabetes type 2 treatment in Germany. The number of included patients (3268) and the follow up time (mean 6.5 years) is high enough to allow valid conclusions.

• **Characterization of patients with SMBG**
  Patients who practise SMBG are younger, have more often private insurance and higher blood glucose and triglycerides levels at diagnosis. 93% insulin treated and 39% OAD treated patients perform SMBG. Begin of SMBG is highly associated with an increase of blood glucose to maximum and dropped down significantly after it.

• **Control of diabetes**
  Patients with SMBG show a higher reduction of blood glucose and HbA1c after maximum.

• **Outcome**
  Patients with SMBG have less and later non fatal or fatal endpoints (odds ratio 0.65, adjusted hazard ratio 0.62). The effect is independent of baseline conditions like age, socio-economic factors and disease status at diagnosis. Cox regression with time dependent SMBG and treatments shows a significant hazard reduction by SMBG and increase for insulin treatment. The hazard with insulin is significantly reduced by SMBG (interaction).