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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

**Retroolective Study “Self-monitoring  
of Blood Glucose (SMBG) and  
Outcome in Patients  
with Type 2 Diabetes”**

# RoSSO

Martin et al.: Self-monitoring of blood glucose in type 2 diabetes and long term outcome: an epidemiological cohort study

Diabetologia (2006) 49: 271-278

# RoSSO

- **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.

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## Results:

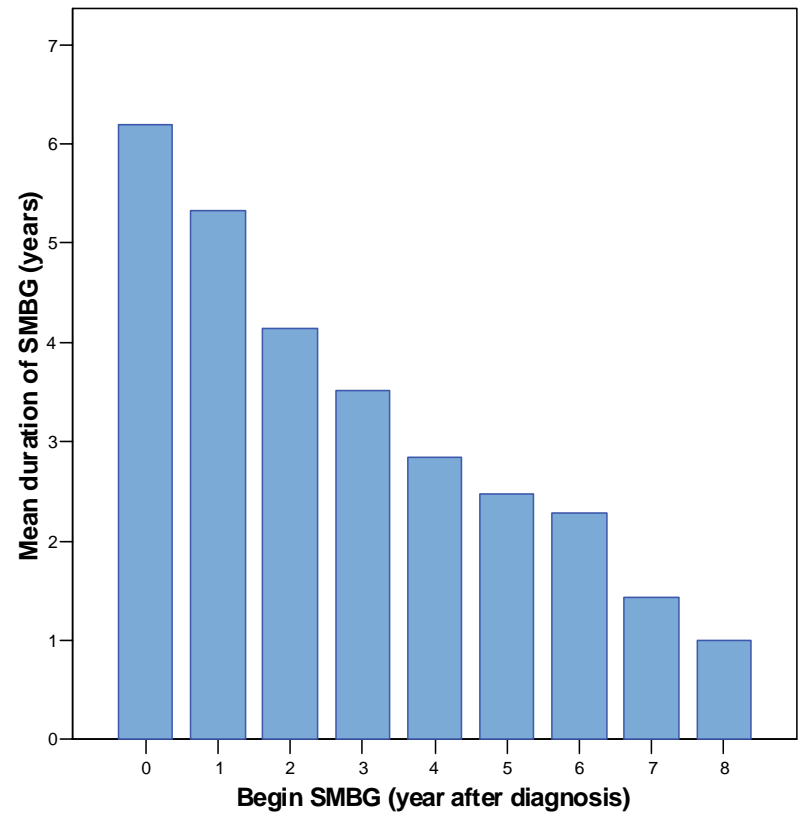
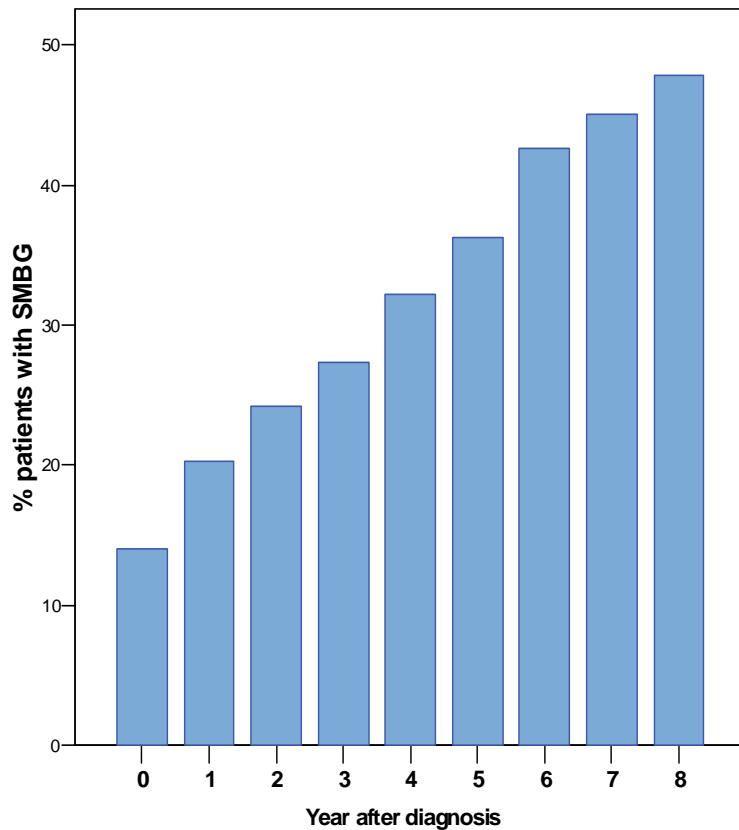
**3268** Patients from **192** centers were included

*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



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## Baseline data:

Data at diagnosis	SMBG	no SMBG
treated by general practitioner *	<b>70%</b>	<b>75%</b>
sex (male/female) *	<b>53/47%</b>	<b>46/54%</b>
legislative health insurance *	<b>95%</b>	<b>97%</b>
retired *	<b>49%</b>	<b>60%</b>
coronary heart diseases in anamnesis	<b>21%</b>	<b>24%</b>
myocardial infarction in anamnesis	<b>4.1%</b>	<b>3.9%</b>
stroke in anamnesis	<b>3.0%</b>	<b>3.2%</b>
<b>* significant for <math>p=0.001</math></b>		

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## Baseline data:

Means of:	SMBG	no SMBG
Age (years) *	<b>60.5</b>	<b>64.0</b>
BMI (kg/m <sup>2</sup> )	29.9	29.8
Blood pressure systolic (mmHg)	148	150
Blood pressure diastolic (mmHg)	87	87
HbA1c adjusted to 6.1% (%) *	<b>8.14</b>	<b>7.23</b>
Fasting blood glucose (mmol/l) *	<b>10.05</b>	<b>8.66</b>
Total cholesterol (mmol/l)	6.09	6.12
Triglycerides (mmol/l) *	<b>2.86</b>	<b>2.45</b>
<b>* significant at p=0.001</b>		

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## Diabetes therapy in follow up

Diet: **SMBG** 1415 (96%) **no SMBG** 1687 (94%)

Medications before non-fatal event:

	<b>Total</b>	<b>SMBG</b>	<b>no SMBG</b>
No medication	<b>603</b>	<b>66 (11%)</b>	<b>537 (89%)</b>
only Insulin	<b>103</b>	<b>96 (93%)</b>	<b>7 ( 7%)</b>
only OAD	<b>1912</b>	<b>742 (39%)</b>	<b>1170 (61%)</b>
OAD+INS	<b>650</b>	<b>575 (88%)</b>	<b>75 (12%)</b>

Mean begin of therapy (years after diagnosis)

	<b>SMBG</b>	<b>no SMBG</b>
Insulin (only Insulin)	<b>0.76</b>	<b>0.57</b>
(OAD+INS)	<b>3.52</b>	<b>3.13</b>
OAD (only OAD)	<b>1.34</b>	<b>1.49</b>
(OAD+INS)	<b>0.71</b>	<b>0.80</b>

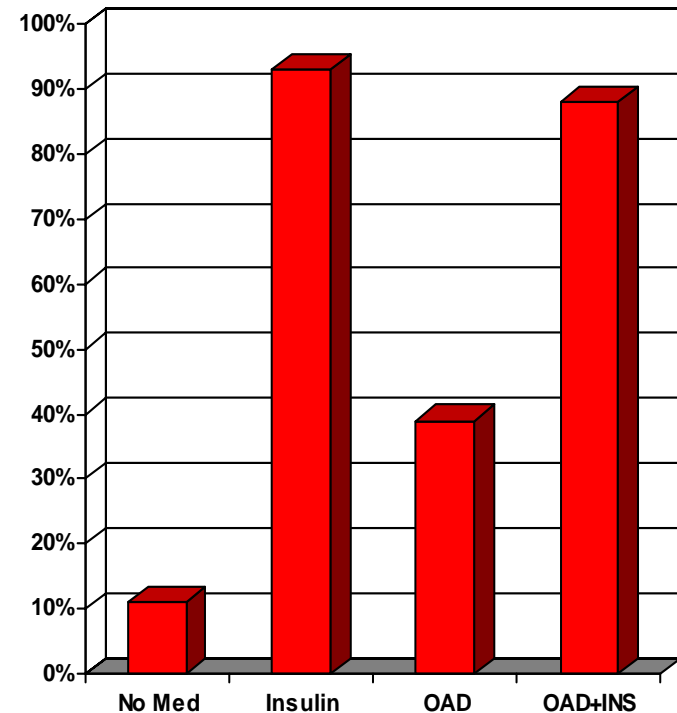
Begin SMBG before insulin **3%** OAD **13%**

Begin SMBG with insulin **90%** OAD **36%**

Begin SMBG after insulin **3%** OAD **51%**

(Patients treated only with insulin or OAD)

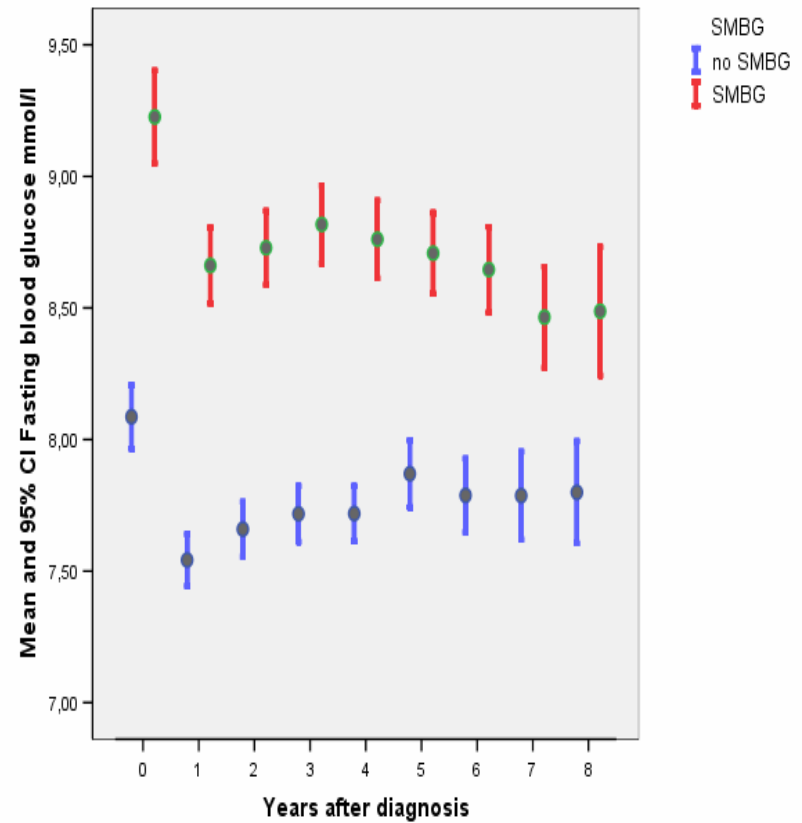
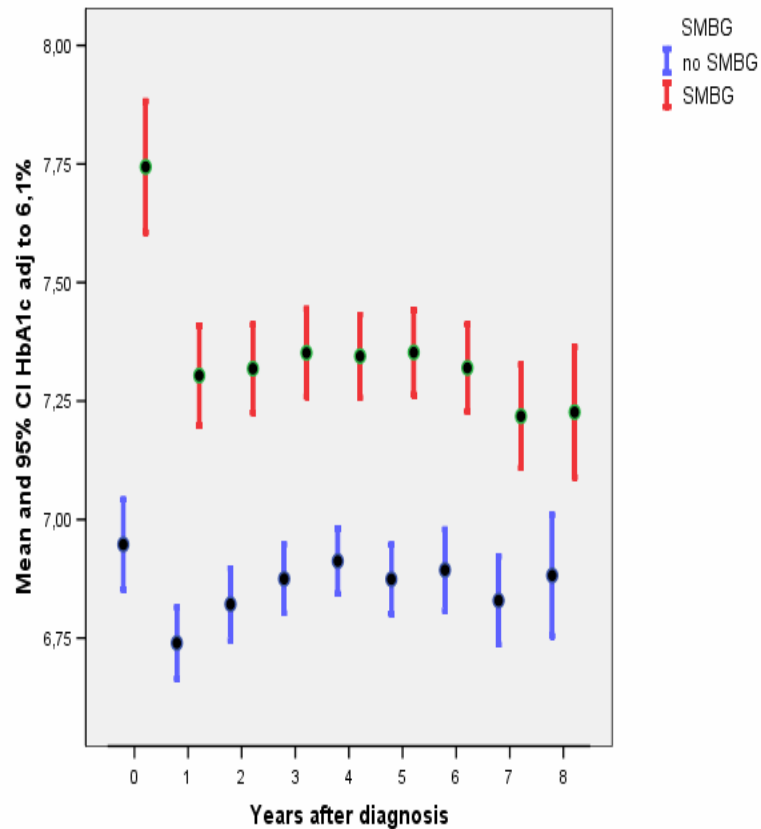
**% SMBG in treatment groups**





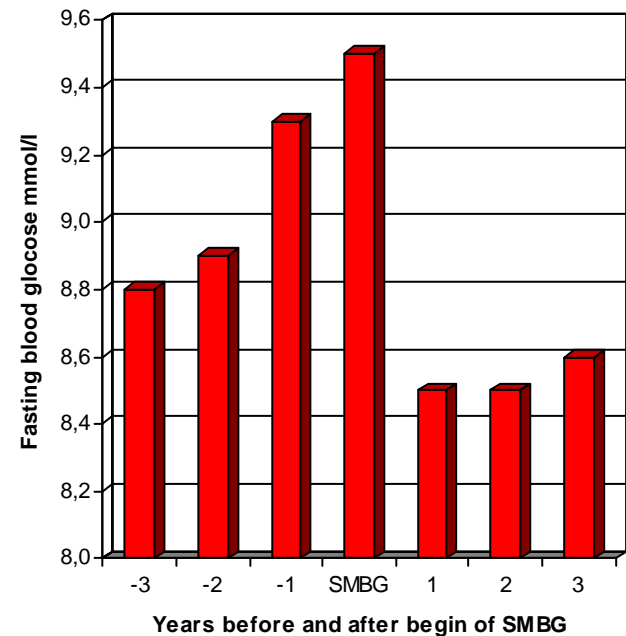
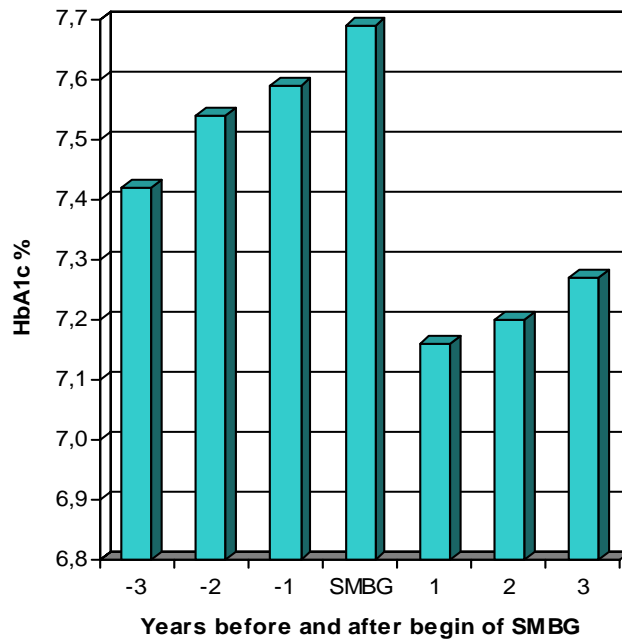
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## Development of HbA1c and fasting blood glucose



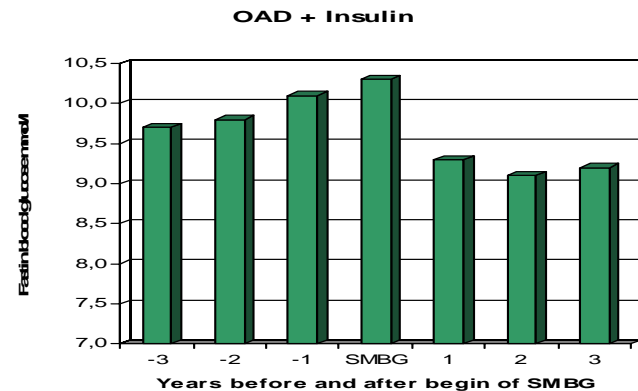
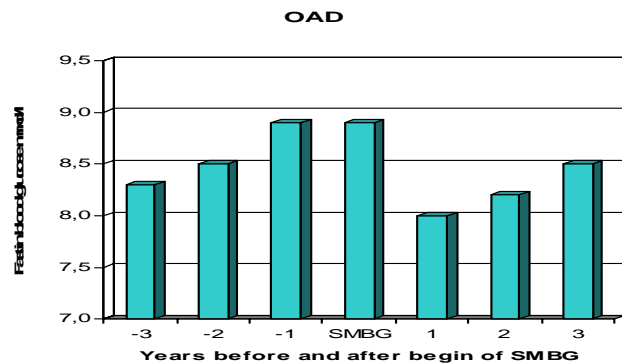
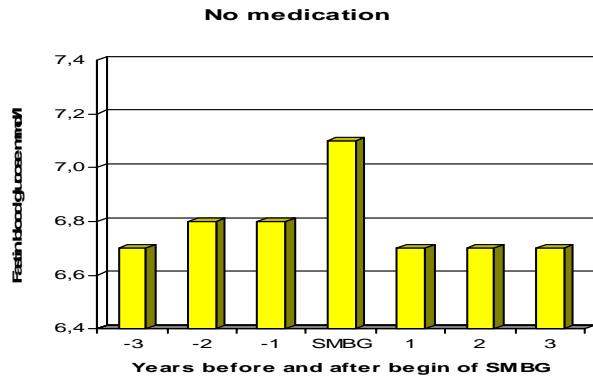
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Mean HbA1c and fasting blood glucose  
before and after begin of SMBG



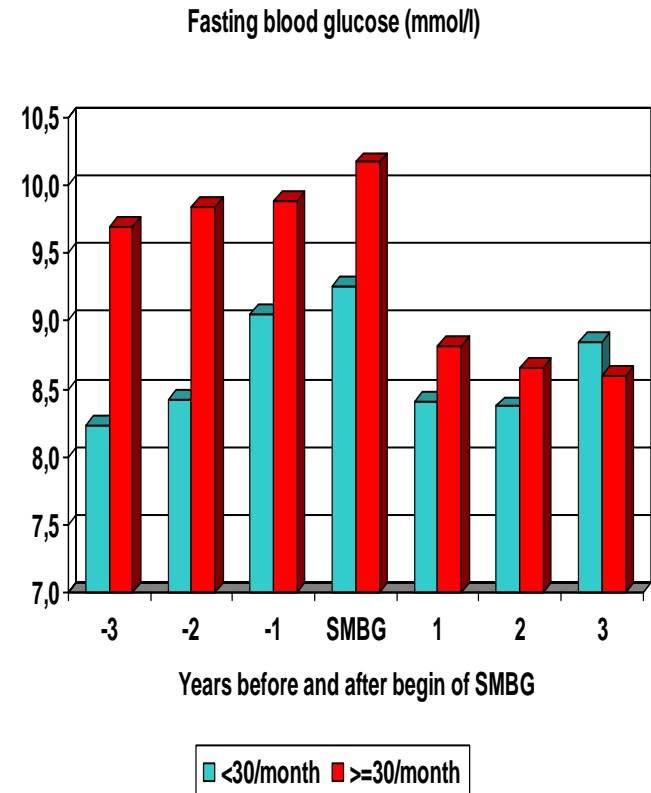
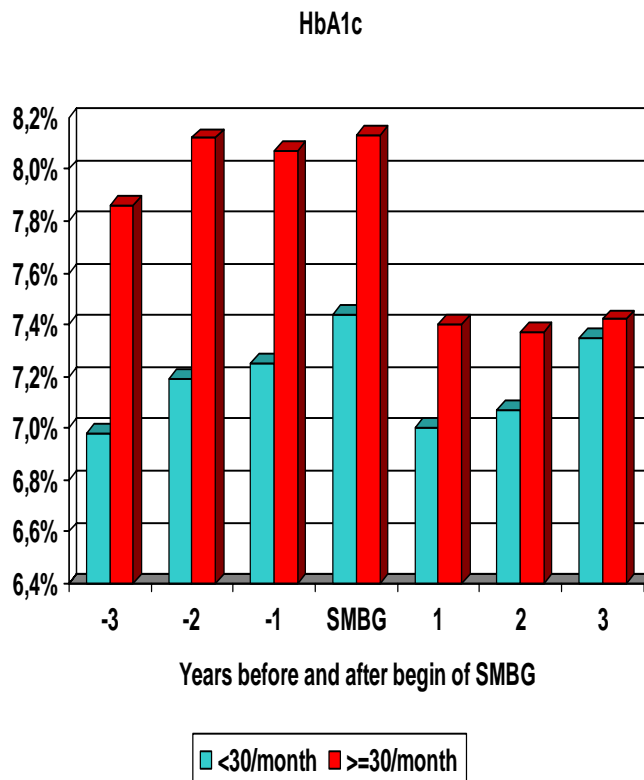
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## Fasting blood glucose before and after begin of SMBG in treatment groups



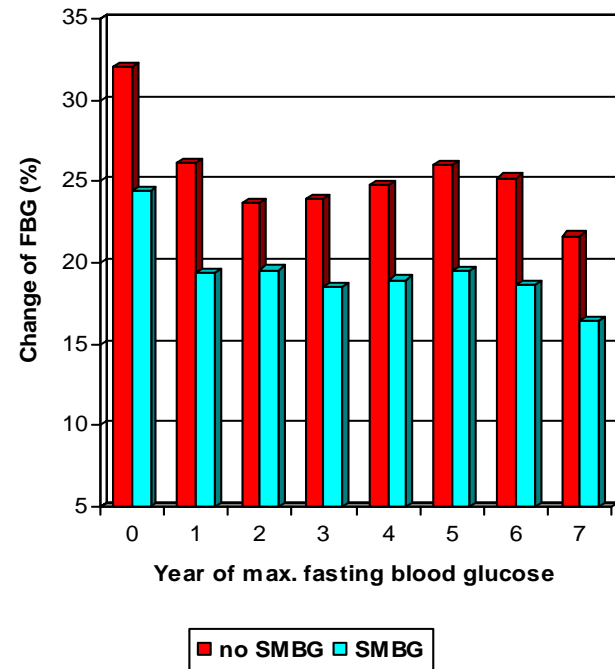
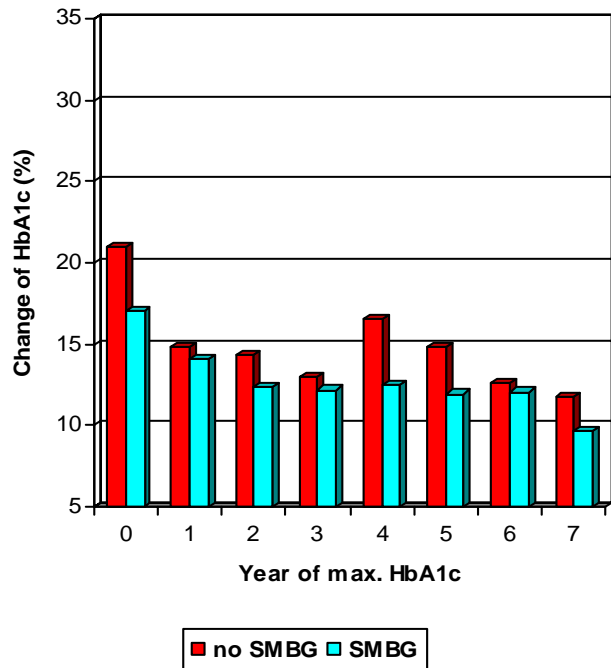
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HbA1c and fasting blood glucose before and after begin of SMBG by frequency of SMBG (<30 or >=30 measurements per month)



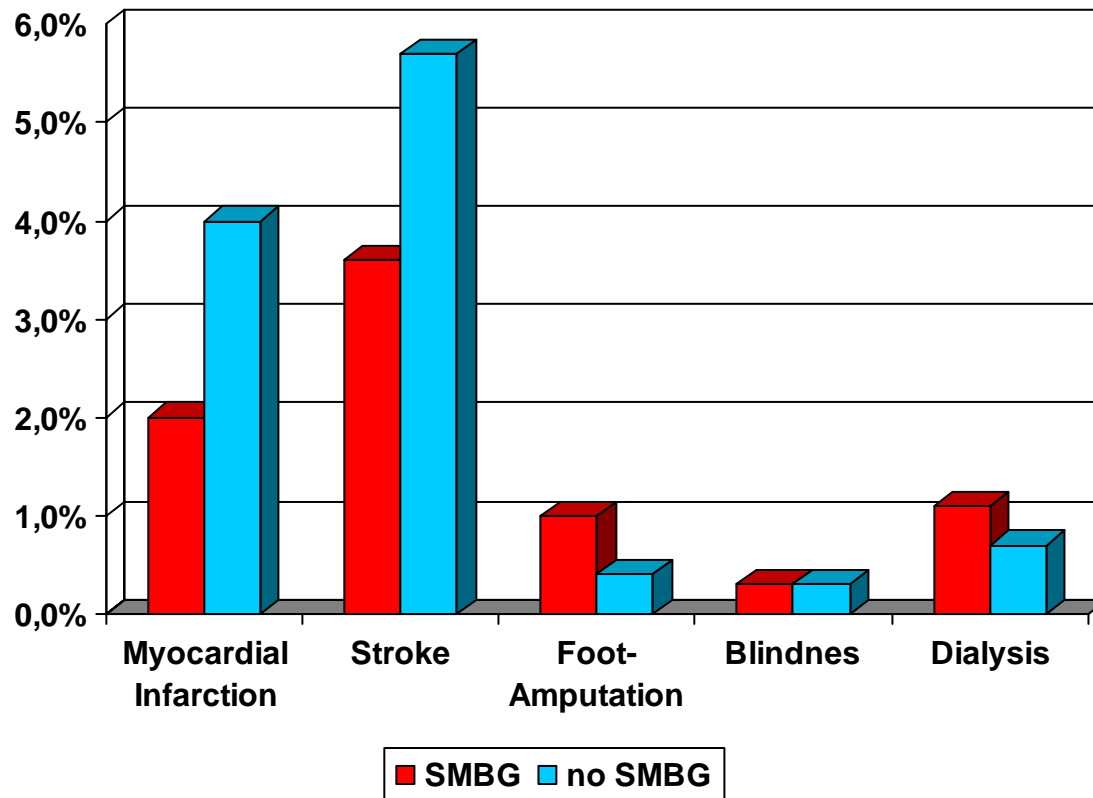
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Mean % change of HbA1c and fasting blood glucose after maximum



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## Non fatal events after diagnosis



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## Non fatal events

Myocardial infarction, stroke,  
Foot-amputation, blindness,  
Dialysis dependency

SMBG	107 pts	<b>7.2%</b>
no SMBG	186 pts	<b>10.4%</b>

Odds ratio: **0.67** (95%CI:**0.52-0.86**)

Mean survival time:

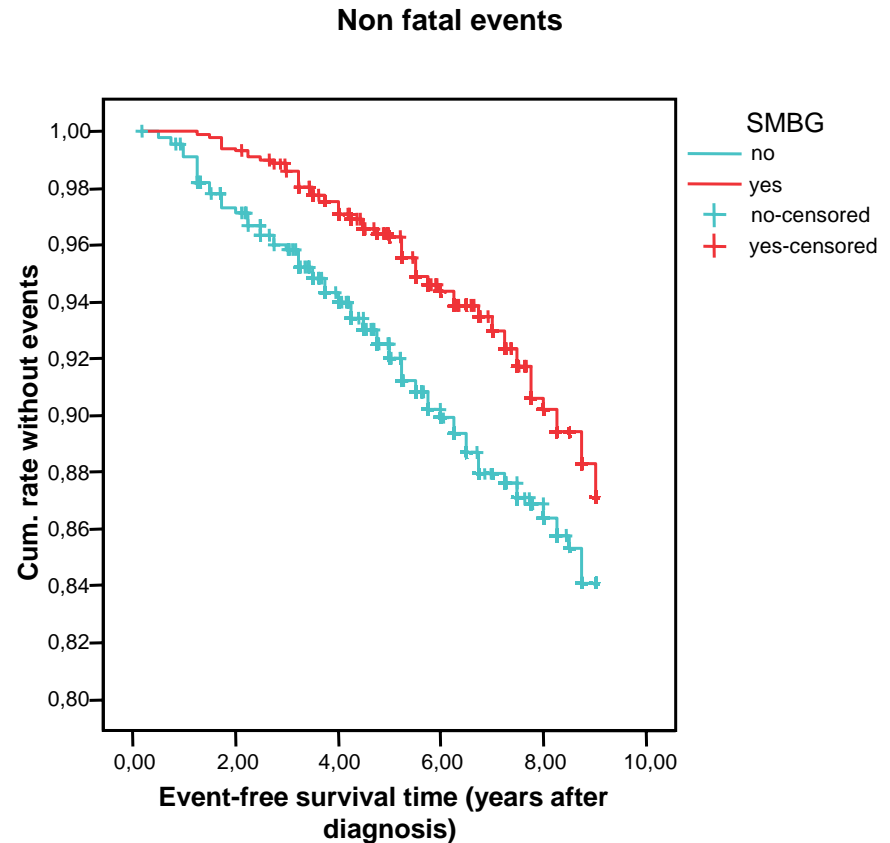
SMBG: **8.63** yrs, no SMBG: **8.36** yrs

Hazard Ratio:

**0.63** (95%CI:**0.50-0.80**)

Hazard Ratio adjusted:

**0.68** (95%CI:**0.51-0.91**)



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## 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:

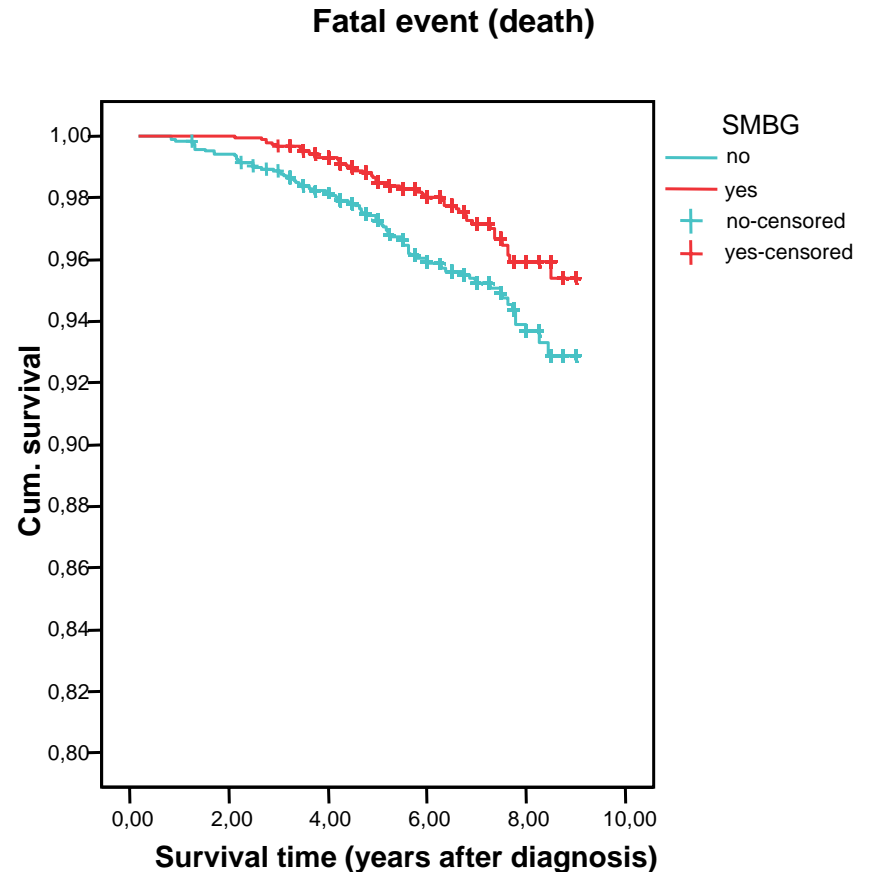
SMBG: **8.87** yrs, no SMBG: **8.75** yrs

Hazard Ratio:

**0.52** (95%CI:**0.36-0.76**)

Hazard Ratio adjusted:

**0.49** (95%CI:**0.31-0.78**)





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## 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

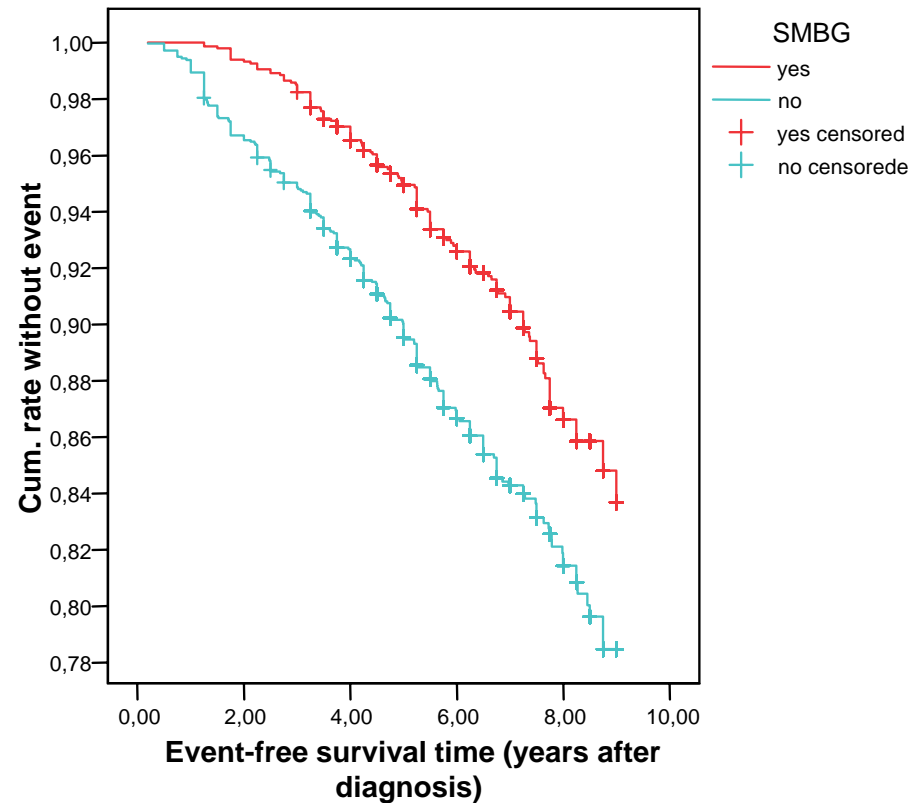
Hazard Ratio:

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

Hazard Ratio adjusted:

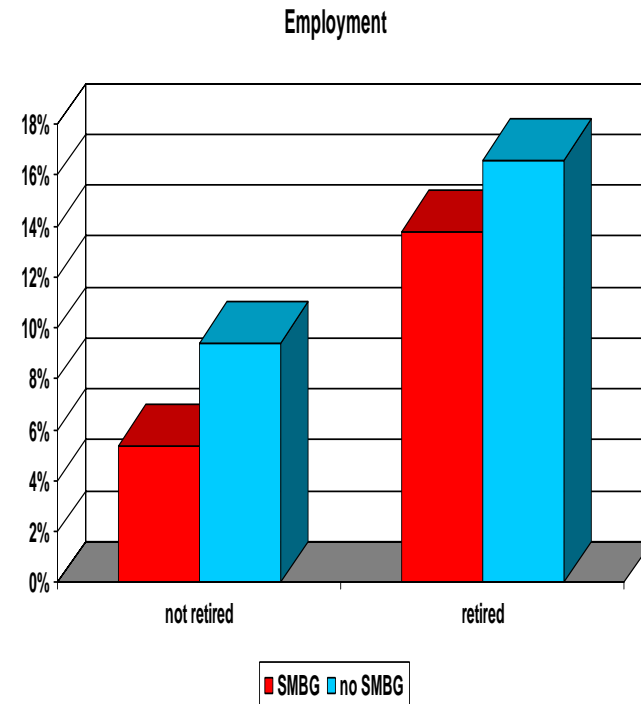
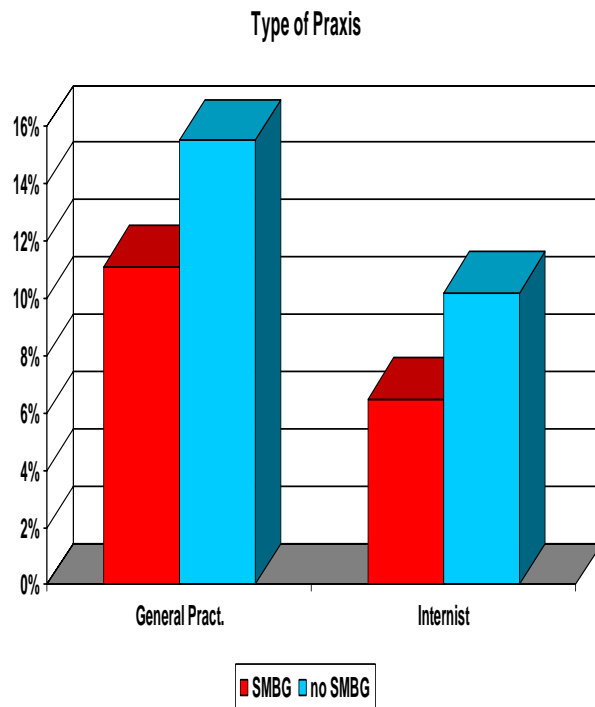
**0.61** (95%CI:0.50-0.76)

Non fatal or fatal events



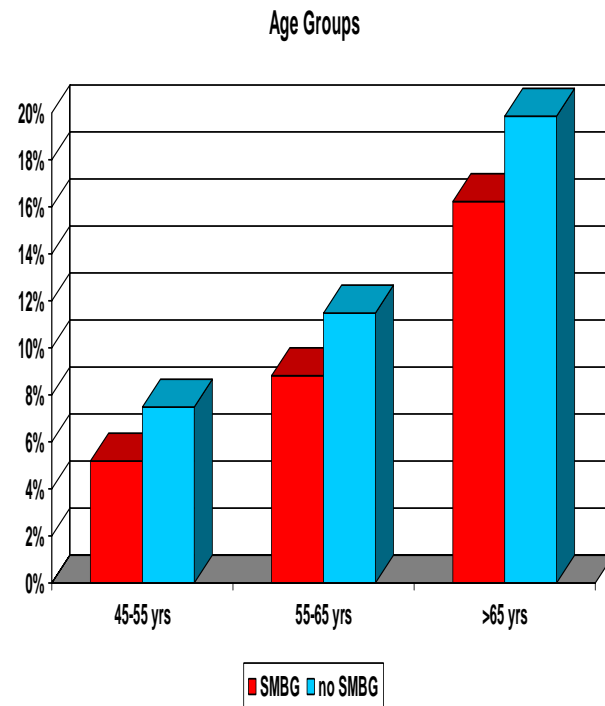
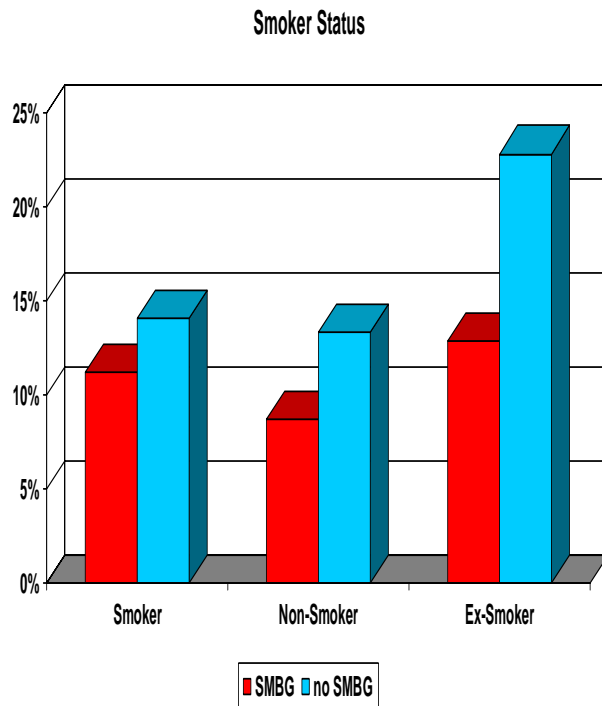
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## Events in subgroups: Type of praxis and employment



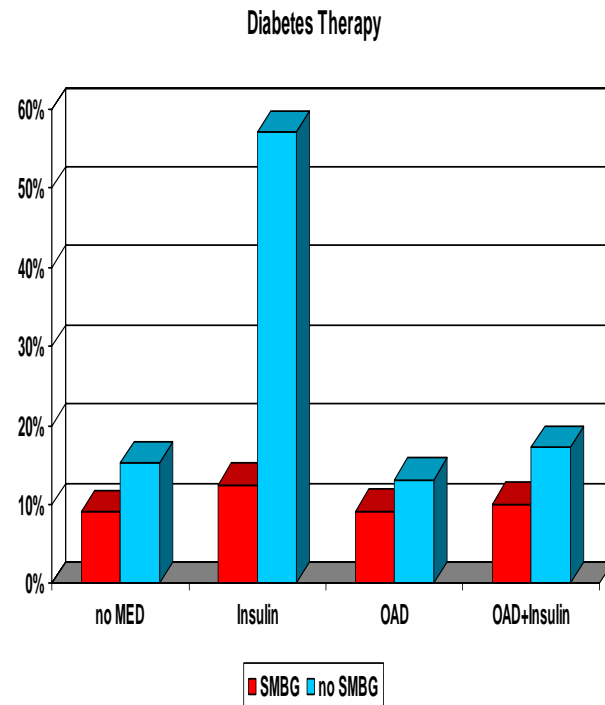
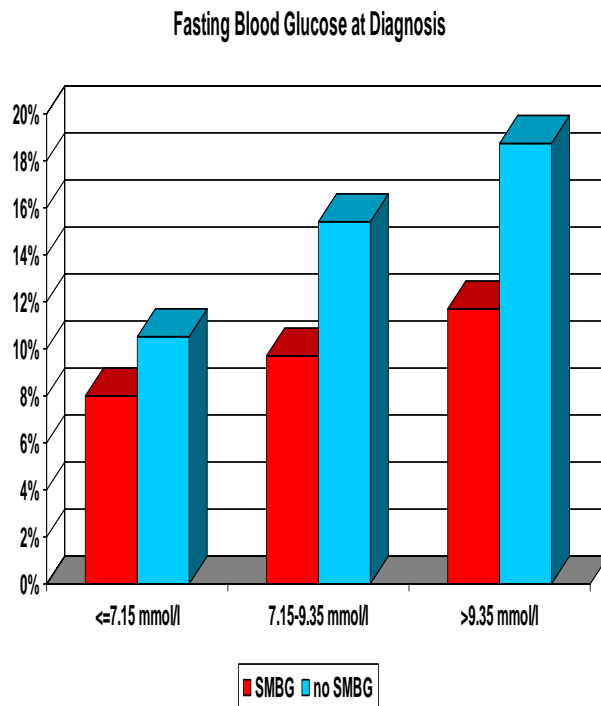
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## Events in subgroups: Smoker status and age groups



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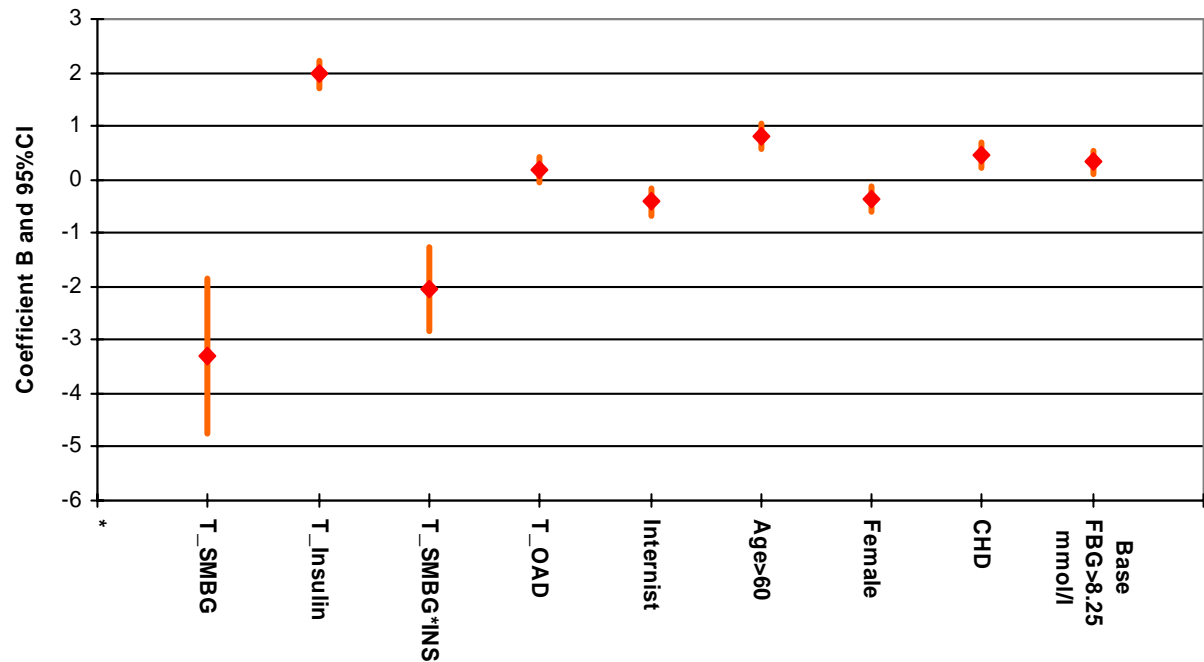
## Events in subgroups: Blood glucose at diagnosis and diabetes therapy



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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).