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ORIGINAL ARTICLES

Self-Measurement of Blood Glucose in Patients with Type 2 Diabetes: A Health Economic Assessment

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Abstract

Background:
The clinical role and the potential benefit of self-measurement of blood glucose (SMBG) for patients with type 2 diabetes are still under discussion. Even less information is available on the cost-effectiveness of performing SMBG by this patient group. The goal of this study was to establish cost-effectiveness ratios of performing SMBG by patients afflicted by this disease.

Methods:
We assessed the benefit and cost-effectiveness of SMBG in type 2 diabetes from a third-party payer perspective based on results of both a large epidemiologic cohort study reflecting the reality of care, and a Markov model calculation.

Results:
Analysis of cohort study data revealed that total costs cumulated over the observation period of 8 years were lower in the SMBG group than in the non-SMBG group according to savings of € 1'714 [oral antidiabetic drugs (OAD) only] and € 13'815 (OAD + insulin) per patient. Several scenarios were considered in the model-based calculation. The cost-effectiveness ratio varied from € 20'768/life year gained to domination of SMBG use compared to nonusers in OAD treated patients and from € 59'057/life year gained to domination of SMBG use compared to nonusers in OAD + insulin treated patients.

Conclusion:
Results indicate that SMBG in type 2 diabetes offers an excellent opportunity to get a high investment–outcome ratio in the treatment of this pandemic disease.

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Abbreviations: (AMI) acute myocardial infarction, (CE) cost-effectiveness, (FBG) fasting blood glucose, (LYG) life year gained, (OAD) oral antidiabetic drugs, (SMBG) self-measurement of blood glucose

Keywords: CEA, costs, cost-effectiveness, diabetes mellitus type 2, self-measurement of blood glucose, SMBG

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Background

The clinical benefit of self-measurement of blood glucose (SMBG) is widely accepted for type 1 diabetes. The benefit in type 2 diabetes is still under discussion,[1,2] although a growing body of evidence resulting from several meta-analyses shows that SMBG could also induce a positive effect on metabolic control in these patients, independent from the type of antidiabetic treatment [oral antidiabetic drugs (OAD) only or in combination with insulin].[3–5] Common points to most of the underlying studies on the benefit of SMBG in type 2 diabetes are first their small size with limited statistical power. Second, they analyze only the impact of SMBG on a surrogate parameter (HbA1c) in the short term. Third, some of these studies are not randomized.

In a large, retrospective epidemiological cohort study with over 3000 patients, Martin and co-workers[6] showed that performing SMBG had a positive impact on morbidity and mortality in patients with type 2 diabetes. These positive findings are supported by other observational studies,[7,8] but contradictory results have also been published.[9]

Diabetes is a worldwide pandemic disease with growing incidence and prevalence worldwide.[10] Nevertheless, controversy remains about the significance of rising prevalence rates and the financial impact on the respective health care systems. However, published literature so far has been limited to some cost-of-illness studies,[11–15] and only very few publications have analyzed the cost-effectiveness (CE) of SMBG in type 2 diabetes.[16,17] With one exception,[18] budget impact analyses for third-party payers are lacking completely.

This analysis assessed the benefit and cost-effectiveness of SMBG in type 2 diabetes from a third-party payer perspective based on results of both a large epidemiologic cohort study reflecting the reality of care, and a Markov model calculation.

Methods

ROSSO was a longitudinal retrospective epidemiological cohort study performed in 2003 and 2004 across 192 German practices, including a total of 3268 type 2 diabetic patients diagnosed between 1995 and 1999. Physician records were mined for demographic and clinical data [body weight, blood pressure, blood glucose, blood glucose control, blood lipids, treatments, operative procedures, nonfatal events (myocardial infarction, stroke, foot amputation, loss of vision, and renal failure requiring dialysis), and overall mortality] yearly from diagnosis to the year of withdrawal or study cutoff (2003). The mean follow-up was 6.5 years. More details are published elsewhere.[6]

The primary aim was to determine the influence of SMBG on diabetic morbidity and mortality for at least 1 year, described quantitatively by corresponding hazard functions. The use of SMBG may depend on individual conditions (age, concomitant disease, blood glucose control, diabetes treatment) that influence morbidity and mortality independently, thus potentially biasing direct comparison of hazard functions between SMBG users and nonusers. Hazards were therefore adjusted to similar conditions for both groups using Cox regression based on the proportional hazard rate model in the original study.

In the absence of appropriate regression models for deriving unbiased comparisons of direct costs between SMBG users and nonusers, modified matched pair analysis was used. Total cohort data were stratified into subgroups according to age (≤55, 55–60, 60–65, 65–70, >70 years), gender (male, female), smoker (smoker, nonsmoker, ex-smoker), and fasting blood glucose (FBG) at diagnosis (<7.2, 7.2–9.4, >9.4 mmol/liter). Subgroups were built up by combining classes of the four stratifying variables. Equal numbers of SMBG users and nonusers were randomized to each subgroup from the total cohort. (SMBG users were defined as those with performance of SMBG at a minimum of 1 year prior to an event.) Thus if a subgroup had fewer SMBG users than nonusers, the same number of nonusers was selected randomly from the subgroup, whereas if nonusers were fewer, the same number of users was selected randomly. This approach generated a random sample with 813 SMBG users and 813 nonusers similar in age, gender, smoking habits, and baseline FBG (**Tables 1a** and **1b**) for cost comparison purposes (**Tables 2** and **3**). Costs were updated to 2005 from the year of occurrence or diagnosis of diabetes, applying annual inflation rates corresponding to the general price development of health care in Germany. The observed resource utilizations for complications, medications, health care services, and monitoring were allocated to the corresponding unit costs on the one hand for "OAD only" and on the other hand to "OAD + insulin" treated patients ("matched pairs analysis").

Table 1a.
Baseline Demographics and Smoking Status [*n* (%)]

		SMBG before nonfatal event		Group total
		Yes	No	
Gender	Male	417 (51)	417 (51)	834 (51)
	Female	396 (49)	396 (49)	792 (49)
Group total		813 (100)	813 (100)	1626 (100)
Smoking status	Smoker	175 (22)	175 (22)	350 (22)
	Nonsmoker	551 (68)	540 (66)	1091 (67)
	Ex-smoker	87 (11)	98 (12)	185 (11)
Group total		813 (100)	813 (100)	1626 (100)

Table 1b.
Baseline Clinical Parameters

	SMBG before nonfatal event			
	Yes		No	
	Mean ± SD	Evaluable (*n*)	Mean ± SD	Evaluable (*n*)
Age (years)	61.3 ± 9.2	813	61.7 ± 9.5	813
Body mass index (kg/m²)	29.8 ± 4.9	696	29.9 ± 5.2	649
Blood pressure (mm Hg) Systolic Diastolic	148 ± 21.2 87 ± 11.7	731 731	149 ± 18.8 86 ± 10.3	698 698
Total cholesterol (mmol/liter)	6.0 ± 1.3	630	6.2 ± 1.3	634
Triglycerides (mmol/liter)	2.6 ± 2.0	506	2.7 ± 1.9	512
High-density lipoprotein cholesterol (mmol/liter)	1.3 ± 0.7	253	1.2 ± 0.4	279
Low-density lipoprotein cholesterol (mmol/liter)	3.8 ± 1.2	200	3.8 ± 1.2	215
HbA1c (%)	7.9 ± 2.3	427	7.4 ± 1.8	369
Fasting plasma glucose (mmol/liter)	9.4 ± 4.1	813	9.27 ± 3.5	813
Serum creatinine (µmol/liter)	86.6 ± 23.9	596	83.1 ± 18.6	617

Additionally, we undertook a second cost-effectiveness analysis of SMBG using a validated Markov state model of diabetes published previously[19] to assess the clinical impact and related cost when SMBG was performed by noninsulin ("OAD only") and insulin-requiring patients ("OAD + insulin") within the German health care system

Table 1c.
Parameters Applied in Model Simulation for OAD Only Treated and OAD + Insulin Treated Patients

Parameter	OAD only	OAD + insulin
Age (years)	61	62
Male (%)	51	51
Smoker (%)	22	22
Systolic blood pressure (mm Hg)	149	150
Total cholesterol (mg/dl)	235	248
High-density lipoprotein cholesterol (mg/dl)	46	46
Triglycerides (mg/dl)	233	265
History of AMI (%) Stroke (%) Amputation (%) Hemodialysis (%)	 3 3 0 0	 4 3 1 2

("model analysis"). The conservative assumption was that the benefit of SMBG is limited to improved blood glucose levels reflected by an HbA1c reduction of 0.42% in "OAD only" treated patients as reported in the meta-analysis of Sarol and co-workers[4] or a reduction of 0.6% in insulin treated type 2 diabetes patients reported in Karter *et al.*[7] (scenario 1). In a second scenario we assumed beyond this improved glycemic control an additional improvement of blood pressure and lipid levels by 5% (scenario 2), 10% (scenario 3), and 15% (scenario 4) of the baseline values. Details of the different scenarios are given in **Tables 4** and **5**. Baseline characteristics of the simulation cohort were set according to the "OAD only" and "OAD + insulin" cohort in the ROSSO study (**Table 1c**). The simulation time was set to 8 years or death of the cohort member. Costs were calculated with the same German cost data set as in the matched pairs analysis (**Table 2**). In line with guidelines for Germany, costs and life expectancy were discounted 5% annually.[20] The impact of different discount rates on costs and life expectancy was investigated in sensitivity analysis (range of 0 and 5%).

Because of the fact that the outcomes of our simulation model were limited to the most common diabetes-related complications, acute myocardial infarction (AMI), stroke, coronary heart disease, amputation, end-stage renal disease, blindness, and hypoglycemic events, not all types of cost parameters assessed in the matched pair analysis could be considered in the Markov model analysis. The cost parameters taken into consideration in the simulation model are marked in **Table 2**.

Table 2.
Cost of Diabetes-Related Complications and Follow-Up Costs [a]

Complication	Costs (€) in year of event (adapted to 2005)	Costs (€) in year after event (adapted to 2005)	Source
Coronary heart disease	3184	3184	28
Heart failure	5684	4372	29
Myocardial infarction	16767 [b]	1253 [b]	30
Stroke	20811 [b]	6501 [b]	31
			32
Peripheral arterial occlusive disease	4211	4211	33
Bypass surgery	11412	—	FPK, F23Z
Angiography	2336	—	FPK, F49B
Dilatations	11015	—	[c]
Carotid surgery	5451	—	FPK F38Z
Feet ulceration	990	990	34
Feet amputation	23704 [b]	3476 [b]	35
			36
Blindness	11218 [b]	5092 [b]	37
Cataract surgery	755	—	FPK C64Z
Laser coagulation of the retina	3729 [b]	—	36
Dialysis	60836 [b]	60836 [b]	38
Depression	2868	2868	39
Hypoglycemia	385 [b]	—	38 [c]
Polyneuropathy	304	304	40

[a] Prices in the reference year have been converted from DM in € at a rate of 0.5113 where appropriate. FPK, German flat case rate catalogue 2005, followed by coding for the intervention.
[b] Cost parameters taken into consideration in the simulation model.
[c] Internal data.

Table 3.
Cost of Diabetes Diabetes-Related Resource Use [a]

	Resources	Costs (€) in the first year (adapted to 2005)	Costs (€) in the following year (adapted to 2005)
OAD only	SMBG user		
	- Physician consultation/referral to specialist	460	460
	- Antidiabetic treatment	212	212
	- Monitoring	33	33
	Non-SMBG user		
	- Physician consultation/referral to specialist	438	438
	- Antidiabetic treatment	212	212
OAD + insulin	SMBG user		
	- Physician consultation/referral to specialist	568	568
	- Antidiabetic treatment	499	499
	- Monitoring	50	50
	Non-SMBG user		
	- Physician consultation/referral to specialist	524	524
	- Antidiabetic treatment	485	485

[a] Prices in the reference year have been converted from DM in € at a rate of 0.5113 where appropriate. Sources are Refs. 41 and 42.

Results

Matched Pairs Analysis

Our analysis of ROSSO data revealed that total costs cumulated over the observation period of 8 years were lower in the SMBG group than in the non-SMBG group according to savings of € 1'714 (OAD only) and € 13'815 (OAD + insulin) per patient (see **Figure 1**).

In the "OAD only" cohort, mean costs per patient of initial complications (e.g., first acute myocardial infarction) and surgical interventions (e.g., amputation) were € 1'073 (nonsignificant) lower in SMBG users, whereas in the "OAD + insulin" cohort they were € 4'527 (significant, $p < 0.05$) lower in SMBG users.

The same trends were observed in the follow-up costs of diabetic complications, with savings of € 1'058 and € 10'149 among SMBG users treated with OAD only and OAD + insulin, respectively.

Consultation costs in the "OAD only" cohort were € 171 higher in SMBG users than in nonusers. In the "OAD + insulin" cohort, consultation costs were € 349 higher in SMBG users.

Annual antidiabetic medication costs in the OAD only cohort were equal in SMBG users and nonusers. In the "OAD + insulin" cohort, medication costs were € 111 higher among SMBG users.

Table 4.
Costs, Life Expectancy, and CE Ratios over the 8-Year Simulation Period Comparing SMBG and Non-SMBG Use in OAD Only Treated Patients[a]

	Scenario	1	2	3	4
	Without SMBG	With SMBG (-0.4% HbA1c)	With SMBG (-0.4% HbA1c and reduction of SBP, -7 mm Hg; TG, -11 mg/dl; and TC, -12 mg/dl; increase of HDL by 2.3 mg/dl vs baseline)	With SMBG (-0.4% HbA1c and reduction of SBP, -14 mm Hg; TG, -22 mg/dl; and TC, -24 mg/dl; increase of HDL by 4.6 mg/dl vs baseline)	With SMBG (-0.4% HbA1c and reduction of SBP, -21 mm Hg; TG, -33 mg/dl; and TC, - 36 mg/dl; increase of HDL by 6.9 mg/dl vs baseline)
Cumulated cost over a 8-year period (€; undiscounted)	13'673	13'859	13'345	12'847	12'371
Incremental cost (€; undiscounted)	—	186	-328	-826	-1'302
Life expectancy (years; undiscounted)	7.15	7.16	7.21	7.25	7.30
Incremental life expectancy (years; undiscounted)	—	0.01	0.06	0.12	0.14
Cost per life year gained (€/LYG; discounted with 5%)[b]	—	20'768	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]
Cost per life year gained (€/LYG; discounted with 3%)[b]	—	19'619	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]
Cost per life year gained (€/LYG; undiscounted)[b]	—	17'997	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]

[a] TG, triglycerides; TC, total cholesterol; HDL, high-density lipoprotein; SBP, systolic blood pressure.
[b] € per one additional year of life.
[c] Reduced cost with higher life expectancy.

Table 5.
Costs, Life Expectancy, and CE Ratios over the 8-Year Simulation Period Comparing SMBG and Non-SMBG Use in OAD + Insulin Treated Patients[a]

	Scenario	1	2	3	4
	Without SMBG	Use of SMBG (-0.6% HbA1c)	With SMBG (-0.6% HbA1c and reduction of SBP, -7.5 mm Hg; TG, –13 mg/dl; and TC, –12.5 mg/dl; increase of HDL by 2.2 mg/dl vs baseline)	With SMBG (-0.6% HbA1c and reduction of SBP, -15 mm Hg; TG, -26 mg/dl; and TC, -25 mg/dl; increase of HDL by 4.5 mg/dl vs baseline)	With SMBG (-0.6% HbA1c and reduction of SBP, -22 mm Hg; TG, -40 mg/dl; and TC, -37 mg/dl; increase of HDL by 6.2 mg/dl vs baseline)
Cumulated cost over a 8-year period (€; undiscounted)	27'970	28'749	28'353	27'953	27'585
Incremental cost (€; undiscounted)	—	779	383	-17	-385
Life expectancy (years; undiscounted)	6.91	6.92	6.97	7.01	7.06
Incremental life expectancy (years; undiscounted)	—	0.01	0.06	0.10	0.15
Cost per life year gained (€/LYG; discounted with 5%)[b]	—	59'057	7365	57	SMBG dominates non-SMBG[c]
Cost per life year gained (€/LYG; discounted with 3%)[b]	—	56'559	6980	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]
Cost per life year gained (€/LYG; undiscounted)[b]	—	53'000	6438	SMBG dominates non-SMBG[c]	SMBG dominates non-SMBG[c]

[a] TG, triglycerides; TC, total cholesterol; HDL, high-density lipoprotein; SBP, systolic blood pressure.
[b] € per one additional year of life.
[c] Reduced cost with higher life expectancy.

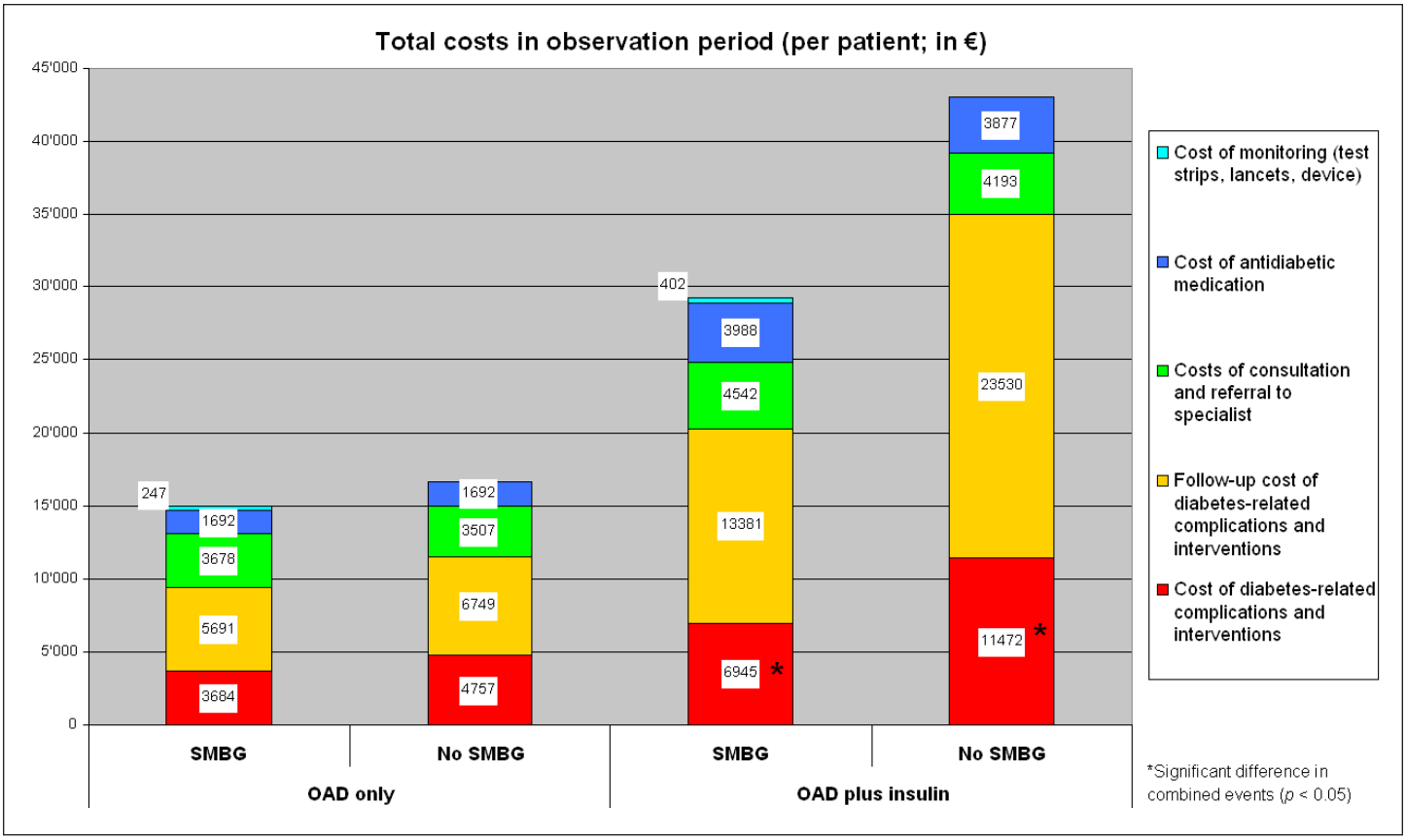

Figure 1. Overview of cost components in the matched pairs analysis derived from the ROSSO study comparing use and nonuse of SMBG in different treatments (OAD only, OAD + insulin).

The analysis also emphasized that the major cost drivers, with at least 60% of the total costs, are complication and follow-up costs (**Figures 2a** and **2b**), whereas SMBG-related costs represented less than 3% of the total costs for both medications (OAD only and OAD + insulin).

Model Analysis

Patients with OAD treatment. Considering only a limited improvement of HbA1c by 0.4% due to SMBG in OAD only treated patients (scenario 1), analysis showed a total cost saving in favor of the non-SMBG group of € 186 per patient and a gain in life expectancy of 0.01 years over a simulation period of 8 years. In contrast, an additional improvement of the clinical parameters as in scenarios 2, 3, and 4 resulted in total cost savings in SMBG users compared to nonusers of € 328, € 826, and € 1'302, respectively. Subsequently, the life expectancy increased by 0.06, 0.1, and 0.14 years, respectively.

In scenario 1 the cost-effectiveness ratio amounted to € 20'768/life year gained (LYG), whereas in scenarios 2, 3, and 4 performing SMBG dominated the nonuse of SMBG.

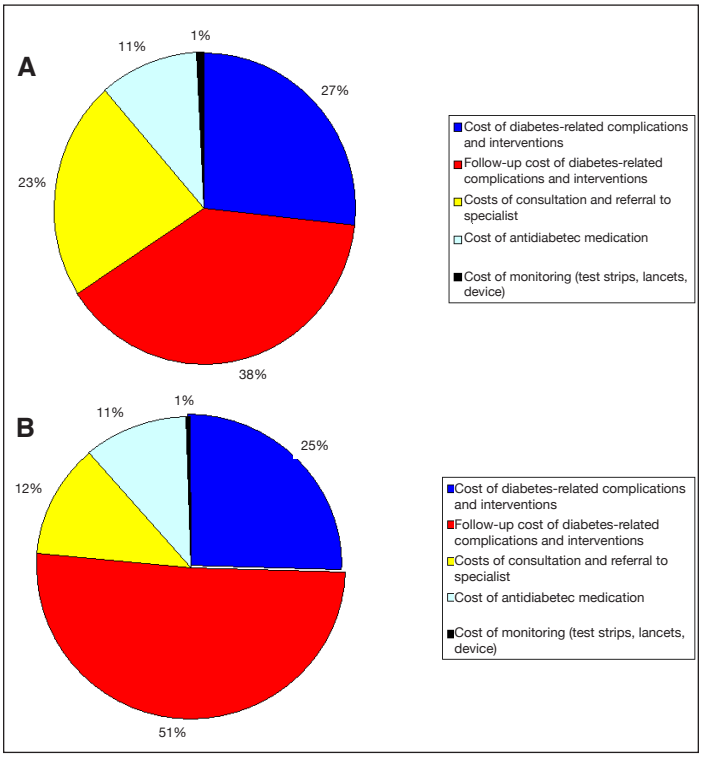

Figure 2. Cost shares (%) in patients with OAD only (**A**) and in patients with OAD + insulin (**B**).

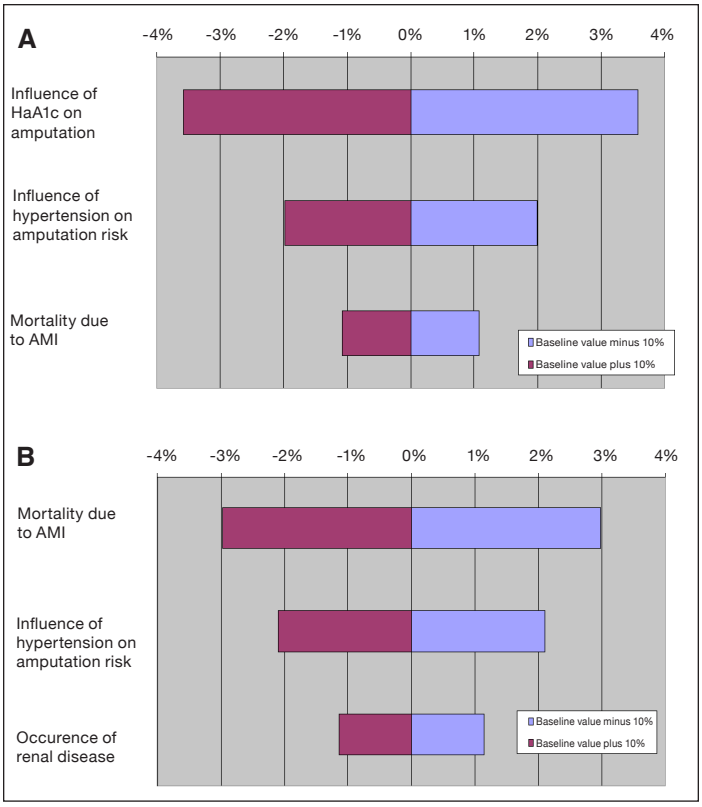

Figure 3. (**A**) Sensitivity analysis in OAD only treated patients: Model parameters with the highest impact on CLYG outcome considering SMBG vs non-SMBG. (**B**) Sensitivity analysis in OAD + insulin treated patients: Model parameters with the highest impact on CLYG outcome.

Patients with OAD + insulin treatment. In OAD + insulin treated patients, assuming a HbA1c improvement of 0.6% (scenario 1) in SMBG users versus nonusers, additional total costs of € 779 and a gain in life expectancy of 0.01 years over the 8-year simulation period occurred. Scenario 2 revealed additional costs of € 383 per patient with SMBG use, and in scenarios 2 and 3, the use of SMBG reduced the total cost by € 17 and € 385, respectively. The gain in life expectancy in scenarios 2, 3, and 4 was 0.06, 0.1, and 0.15 years, respectively.

Under these assumptions the cost-effectiveness ratios in scenarios 1, 2, and 3 were € 59'057, € 7'365, and € 57/LYG. In Scenario 4, SMBG was dominant compared to non-SMBG.

The application of different discount rates of 3 and 0% per annum reduced the CE ratio in the "OAD only" cohort by 5 and 13% compared to baseline analysis (**Table 4**). In the "OAD + insulin" cohort, CE ratios were decreased by 4 and 10% (**Table 5**). A sensitivity analysis (see **Figures 3a** and **3b**) revealed that complications with a major influence on the outcome were amputation and AMI.

Discussion

The analysis presented here is the first detailed assessment of cost-effectiveness of SMBG in patients with type 2 diabetes mellitus based on results of a clinical trial that reflects the reality of care in diabetes treatment.[6] Because the adjustment of individual conditions that may have an influence on the use of SMBG was carried out by Cox regression based on the proportional hazard rate model in the original study, the described outcomes are unlikely to be biased. This proceeding was impossible for this economic analysis because of the lack of appropriate regression models for cost data. Therefore, we chose a modified matched pairs analysis that considered the most important influencing factors (i.e., age, gender, smoking status, fasting blood glucose). The addition of further stratification criteria would have reduced the number of matched pairs to such a small number that results of the analysis would no longer be meaningful. Even the present economic analysis of the ROSSO study was hampered by the fact that only a few patients did not perform SMBG under a combined (OAD + insulin) therapy, thus reducing the number of possible matched pairs to 813. This may explain why savings for the SMBG group, which was treated by OAD only, failed to be statistically significant.

To compensate for this shortcoming and to take into account existing criticism of the underlying study,[21,22] we also carried out a model-based simulation analysis according to well-established and accepted principles and guidelines.[23–25]

Results of Markov simulation indicate that SMBG is indeed cost-effective in patients with type 2 diabetes and represents a good value for money or even cost savings. Scenario 1 represents a very conservative assessment by assuming that SMBG has only an impact on HbA1c. Subsequently, costs for physician visits and antidiabetic treatment were higher in the SMBG user group compared to nonuser groups. Our results of scenario 1 are in line with Palmer and colleagues,[17] who analyzed the cost-effectiveness of SMBG in a United Kingdom setting.

One should keep in mind that SMBG is a diagnostic procedure, which, by definition, can never have an intrinsic effect like a pharmaceutical treatment. It needs the ability to interpret correctly what is displayed on the device and to translate it to an appropriate and sustained action or handling to get a beneficial outcome. In the case of patients treated with oral antidiabetic drugs, this is not necessarily limited to a change in oral therapy or to the addition of short-acting insulin. A lifestyle change

may have an even more important effect than enhanced pharmaceutical treatment.

However, in some cases, health care professionals and/or patients apparently fail to convert the results of self-measurement to a more efficient therapeutic regimen or to changes in healthy behavior. Various circumstances may be responsible, such as health care system shortcomings, physician–patient relationship, ethnicity, socioeconomic status, illiteracy, or other factors extremely difficult to assess in retrospective studies. These factors may also explain the conflicting results of observational studies in this field.

To reflect on the idea that the performance of SMBG should be interpreted more as a proxy for higher awareness of the disease and possible changes in lifestyle, we assessed the potential benefit of SMBG in four different scenarios, covering different levels of additional clinical effects of SMBG beyond optimization of blood glucose levels.

We would like to point out that our model-based calculation represents a very conservative approach, as we limited the simulation time to 8 years to allow comparability to the matched pairs analysis of ROSSO data. This is quite an unusual approach for model-based analyses in diabetes. Because it is well known that diabetes-related complications occur mainly at a later stage of the disease, this approach may severely underestimate the potential benefit of SMBG.

Furthermore, we assessed only the direct costs. However, it is well known that diabetes in a later stage could be a disabling disease (e.g., amputation, loss of vision) and therefore be a major cost-driving factor for indirect costs (e.g., loss of workforce, disability).

Our economic assessment of cost-effectiveness has a clear third-party payer, the German perspective. Transferability of health economic analyses from one health care system to another can be problematic, but is feasible.[26,27] Therefore, data should be interpreted with caution before applying our results to other countries.

In summary, results indicate that SMBG in type 2 diabetes offers an excellent opportunity to get a high investment–outcome ratio in the treatment of this pandemic disease.

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