Clinical and Economic Value of Flash Glucose Monitoring Systems in the Management of People with Type 2 Diabetes Mellitus on Basal Insulin and Poor Glycemic Control

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Introduction

- FreeStyle Libre® systems (FSLs) are convenient and effective glucose monitoring devices for type 2 diabetes (T2D) population treated with basal insulin[1].
- In Spain, FSLs could produce cost-savings in several populations[2,3], including those poorly controlled subjects with T2D on basal insulin[4]. However, the relation between costs and health outcomes remains unclear.

Objective

This cost-utility analysis compared FSLs with self-monitoring of blood glucose (SMBG) in poorly controlled (HbA1c > 8% [64 mmol/mol]) people with T2D on basal insulin in Spain.

Methods

- The DEDUCE model[5] was used to estimate costs (€, 2024) and quality-adjusted life years (QALYs) over the patient's lifetime horizon (50 years), considering the perspective of the Spanish National Health System (SNHS). All model inputs were validated by a national multidisciplinary group of experts.
- The model generated a hypothetical cohort of 10,000 subjects with poor glycemic control (HbA1c>8%) receiving basal insulin, as the only insulin treatment, according to baseline clinical and sociodemographic characteristics (Table 1)[6-11].

Table 1. Baseline characteristics of the hypothetical cohort.

Baseline characteristics	Value
Age (years) [mean (SD)] [6]	62.9 (12.8)
Women [%] [6]	41.0
HbA1c (%) [mean (SD)] [7]	9.2 (1.0)
SBP (mmHg) [mean (SD)] [6]	139.9 (28.4)
HDL-Cho (mg/dL) [mean (SD)] [6]	46.8 (9.6)
Total-Cho (mg/dL) [mean (SD)] [6]	201.8 (41.2)
Serum creatinine (mg/dL) [mean (SD)] [8]	0.86 (0.2)
UACR (mg/g) [mean (SD)] [9]	99.2 (359.4)

Baseline characteristics	Value
Active smokers [%] [6]	27.8
People with CVD [%] [9]	35.6
Treat. with statins [%] [6]	36.6
Treat. with anti-hypertensives [%] [6]	44.3
Treat. with anticoagulants [%] [8]	39.5
Treat. with oral antidiabetics [%] [10]	84.4
Baseline utility value [11]	0.784

Cho: Cholesterol; CVD: Cardiovascular Disease; HbA1c: Hemoglobin A1c; HDL: High-Density Lipoprotein; SBP: Systolic Blood Pressure; SD: Standard Deviation; UACR: Urinary Albumin-Creatinine Ratio.

- The annual incidence, costs and disutility values associated with both acute and chronic diabetic complications were obtained from the scientific literature (Table 2)[11-26]. The RECODe motor[14] was used to model the occurrence of chronic diabetic complications according to population's characteristics.
- FSLs were associated with a reduction of 1.1% in HbA1c levels[7], 58% hypoglycemias[1] and 68% diabetic ketoacidosis[1], based on real-world evidence studies.

Table 2. Model inputs: Probabilities of health events, costs and disutility values.

Health events	Probability (event/person-year)	Cost per event [€, 2024] First year	Cost per event [€, 2024] Subsequent years	Disutility value
Non-SHE	100% (17,02) [12]	€3.81 [15,16,A]		-0.0016 [24]
SHE	8.9% (2.5) [12]	€1,003.59 [17-20,B]		-0.0470 [25]
DKA	0.25% (1.0) [13]	€2,455.18 [13,18,C]		-0.0470 [25]
AMI	RECODe [14]	€30,168.50 [21]	€1,214.44 [21]	-0.0550 [11]
CHF	RECODe [14]	€6,327.90 [22]	€1,481.65 [22]	-0.1080 [11]
Stroke	RECODe [14]	€7,635.68 [23]	€3,101.09 [23]	-0.1640 [11]
Blindness	RECODe [14]	€2,863.20 [11]	€2,863.20 [11]	-0.0740 [11]
Renal failure	RECODe [14]	€3,946.55 [21]	€41,592.79 [21]	-0.2040 [11]
Finger stick	–	–	–	-0.0300 [26]

AMI: Acute Myocardial Infarction; CHF: Congestive Heart Failure; DKA: Diabetic Ketoacidosis; SHE: Severe Hypoglycemic Event.

[A] Weighted average of non-SHE managed by a specialist (21.9%[15]; €17.40[16]) and self-managed by the subject (complementary: 78.1%; €0.00).

[B] Weighted average of SHE requiring hospital assistance (26.1%[17]; with hospital admission [21.7%[17]; €4,389.19[18]]; without hospital admission [complementary: 78.3%; €2,071.09[19]]) and not requiring hospital assistance (complementary: 73.9%, €448.91[20]).

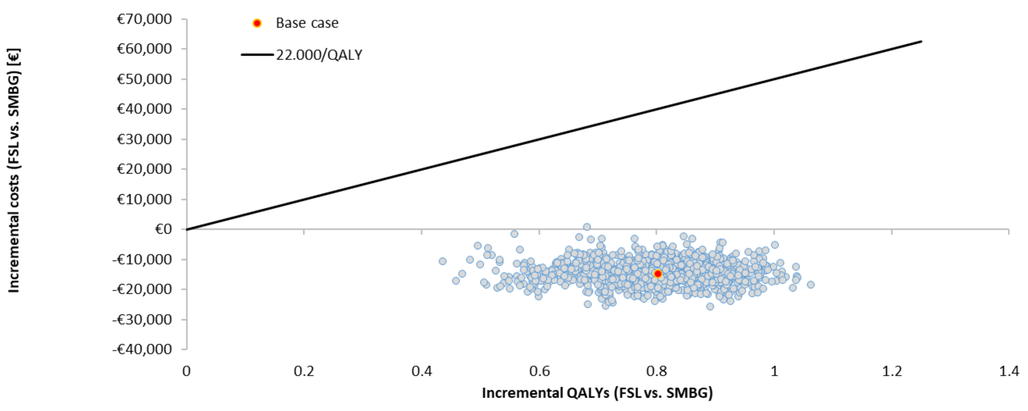
[C] Weighted average of DKA requiring hospital assistance (87.1%[13]; €2,818.81[18]) and not requiring hospital assistance (complementary: 12.9%; €0.00).

- Based on the Spanish clinical recommendations[27], SMBG required a daily consumption of 2.5 reactive strips (€0.55/unit[28]; VAT included) and 2.5 lancets (€0.14/unit[28]; VAT included). FSLs were associated with a consumption of 26 sensors per year (€3.00/sensor-day, VAT included) and with a reduction of 83% in the use of strips and lancets[1].
- According to the Spanish guidelines for economic evaluations[29], an annual discount rate of 3.0% was applied to both costs and health outcomes.
- The robustness of the model and results was assessed by conducting a probabilistic sensitivity analysis (PSA) consisting of 1,000 second order Monte Carlo simulations.

Results

- Compared with SMBG, FSLs decreased the 50-year cumulative incidence of renal failure (10.4% vs 11.6%), blindness (18.2% vs 19.7%), acute myocardial infarction (36.7% vs 39.6%), stroke (11.9% vs 15.1%) and congestive heart failure (25.3% vs 27.8%).
- FSLs in comparison to SMBG, delayed the onset of chronic diabetic complications (measured as mean number of years until the occurrence of the first event) such as renal failure (13.03 vs 12.49 years), blindness (14.82 vs 14.34 years), acute myocardial infarction (13.78 vs 12.90 years), stroke (15.41 vs 14.45 years) and congestive heart failure (15.43 vs 14.55 years).
- Per subject lifetime, FSLs implied 0.80 additional QALYs and reduced total costs by €14,797 vs. SMBG (Table 3). Thus, FSLs represent a dominant alternative vs. SMBG.
- The PSA revealed that all Monte Carlo simulations were dominant or cost-effective when considering a willingness-to-pay threshold of €22,000/QALY[30] (Figure 1).

Figure 1. PSA results: Scatterplot of 1,000 second order Monte Carlo simulations.



FSLs: FreeStyle Libre systems; PSA: Probabilistic Sensitivity Analysis; QALY: Quality-Adjusted Life Year; SMBG: Self-Monitoring of Blood Glucose.

Table 3. Results of the CEA (per subject-lifetime).

Baseline characteristics	FSLs	SMBG	FSLs vs. SMBG
Total QALYs	9.98	9.18	+ 0.80
Total costs	€60,196	€74,992	- €14,797
Glucose monitoring-related costs	€17,037	€8,580	+ €8,458
Chronic diabetic complications	€28,983	€32,940	- €3,958
AMI	€4,680	€5,183	- €502
CHF	€3,998	€4,253	- €254
Stroke	€13,674	€15,516	- €1,843
Blindness	€3,062	€3,992	- €930
Renal failure	€3,569	€3,997	- €429
Acute events	€14,176	€33,472	- €19,296
Non-SHE	€370	€841	- €471
SHE	€13,779	€32,548	- €18,769
DKA	€27	€83	- €56
ICER (FSLs vs. SMBG) [€/QALY]	FSLs dominant (better health outcomes & cost-savings)		

AMI: Acute Myocardial Infarction; CEA: Cost-Effectiveness Analysis; CHF: Congestive Heart Failure; DKA: Diabetic Ketoacidosis; FSLs: FreeStyle Libre systems; ICER: Incremental Cost-Effectiveness Ratio; QALY: Quality-Adjusted Life Year; SHE: Severe Hypoglycemic Event; SMBG: Self-Monitoring of Blood Glucose.

Conclusions

FSLs represent a cost-effective option vs. SMBG that diminish the incidence of acute and chronic diabetic complications, improve quality of life for poorly controlled (HbA1c > 8%) people with T2D on basal insulin, and provide cost-savings for the SNHS.

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