EVALUACIÓN COMPARATIVA DE COSTES DE UNA NUEVA TECNOLOGÍA PARA LA MONITORIZACIÓN "FLASH" DE LA GLUCOSA EN PACIENTES CON DIABETES TIPO 1 EN ESPAÑA

York Zöllner PhD[1], Katharina Kolbe[2], Hipólito González MD[3], Javier García Valero[3], Magnus Stüve[3], Aesha Khan-Mirón[4]

1 Hamburg University of Applied Sciences (HAW), Germany 2 Econ-Epi, Germany. 3 Johnson & Johnson Diabetes Care Companies. 4 Universidad Pública de Navarra, Spain

Speaker´s Conflict of Interest:

Dr. Hipólito González is employee of Johnson & Johnson Diabetes Care Companies

Glucose Monitoring

Self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM) are two techniques that patients with diabetes can use at home to help them maintain blood glucose within a safe range

SMBG

Provides an instantaneous reading of current blood glucose levels at single points in time

CGM

- Displays the current blood glucose level as well as the direction and rate of change.
- Uses alarms and alerts to inform patients when blood glucose is exceeding or falling below specified thresholds.

Glucose Monitoring

CHARACTERISTIC	SMBG	FGM	CGM
Glucose Compartment	Capillary blood	Interstitial Fluid	Interstitial Fluid
Sensor under skin	No	Yes	Yes
Finger Prick required	Yes	Yes, in various situations	Yes, to calibrate and in various situations
Type	Episodic testing.	On-demand scanning.	Real Time results.
Viewing results	Results displayed in meter	Results displayed in reader	Results displayed in device
Automatic Alarms	No	No	Yes

… under the following circumstances, use a blood glucose meter

- ✓ During times of rapidly changing glucose levels
- ✓ To confirm hypoglycemia
- ✓ If symptoms do not match the system readings

Glucose Monitoring

Self-monitoring of blood glucose **(SMBG) is the standard of care** for patients with diabetes treated with multiple daily insulin injections[1]

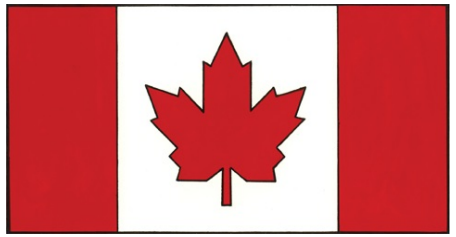
SMBG in the management of diabetes **plays a key role** in many large-scale outcome studies, acting as an **important contributor to results**. **SMBG has many proven benefits**, such as aiding the achievement of HbA1c targets minimizing glucose variability and helping to predict severe hypoglycemia[2]

1- Ish-Shalom, M. et al. Improvement in glucose control in difficult-to-control patients with diabetes using a novel flash glucose monitoring device. Journal of Diabetes Science and Technology. 2016, Vol. 10(6) 1412–1413

2- Schnell, O. et al Self-monitoring of blood glucose: A pre-requisite for diabetes management in outcome trials. Journal of Diabetes Science and Technology. 2014, Vol. 8(3) 609–614

Flash Glucose Monitoring

FGM has been approved by EU, Canadian and US regulators

	2014 Aproved for adults 2016 Aproved for 4 -17 years 2017 Aproved for pregant women	14 days	Finger Prick in various situations
	2017 Aproved for adults only, with at least 2 years of experience in Diabetes Self-Management	14 days	Finger Prick in various situations
	2017 Aproved for adults only	10 days	Use non-adjuvant 12 hours warm up Post approval study required

Flash Glucose Monitoring

Clinical Randomized Controlled Trials

- ✓ BolinderJ, et al. Novel glucose-sensing technology and hypoglycemia in type 1 diabetes: amulticentre, non-masked, randomized controlled trial. The Lancet 2016;388(10057): 2254-2263

- ✓ Haak T, et al. Flash glucose-sensing techology as a replacement for bloode glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. Dabetes Ther 2016;8(1):55-73.

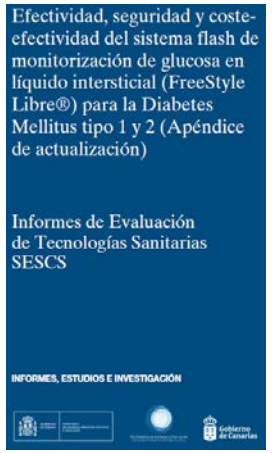
Accuracy

- ✓ Bailey et al. The performanceand usability of a factory-calibrated flash glucose monitoring system. Diabetes Technology and Therapeutics 2015;17(11):787-794

- ✓ Edge J, et al. An alternative sensor/based method for glucose monitoring in children and young people with diabetes. Arch Dis Child 2017;0:1-7.

Flash Glucose Monitoring

Health Technology Assestments



Canarian HTA
2016 - 2017

Recommendations

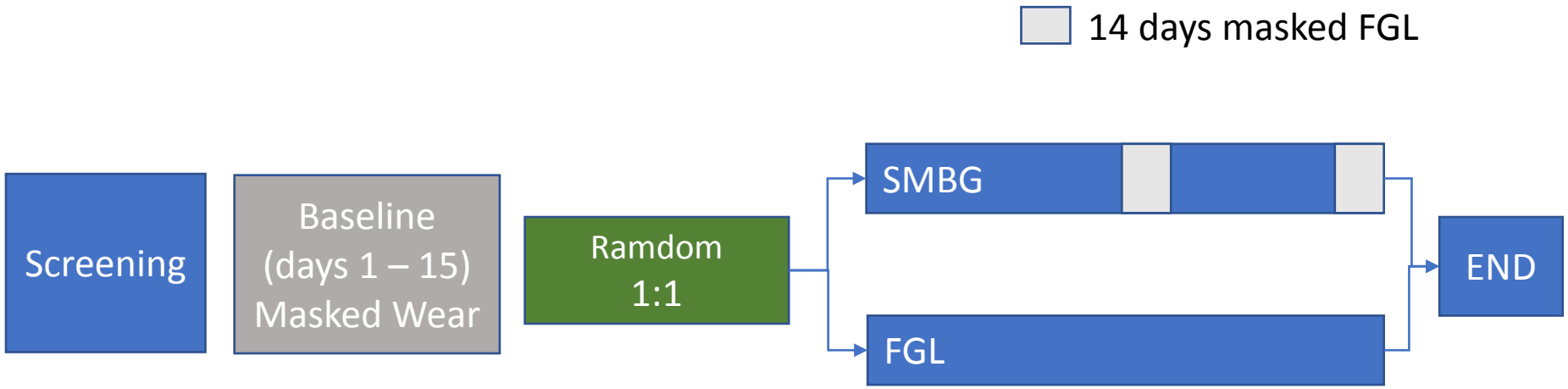
- A conditional recommendation is made in favor of the FreeStyle Libre® System for adult patients with DM1 with controlled HbA1c levels (<7.5%), and with a previous good adherence to self-monitoring blood glucose.

Norwegian HTA
2017

Overall FreeStyle Libre does not seem to provide a higher efficacy or fewer adverse events or increased quality of life measures for insulin treated patiens than other SMBG devices, thus it makes difficult to support the lower costs associated with FreeStyle Libre.

Impact Clinical Trial

Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomized controlled trial.
Authors: Jan Bolinder, Ramiro Antuna, Petronella Geelhoed-Duijvestijn, Jens Kröger, Raimund Weitgasser.
The Lancet, Volume 388, Issue 10057, 5–11 November 2016, Pages 2254-2263



Break-even Analysis

Costs Technology A = Costs Technology B

- ✓ Our model only reflects an economic perspective
- ✓ Socio-economics or adherence data have not being asssesed.
- ✓ Size of target population has been difficult to asses
- ✓ FGM readings requires finger pricking validation under some circunstances so **cannot be a replacement for SMBG.**

Break-even Analysis

	Incidence of High/Low Readings (1 per every X scans)	5	**Size of Target Population**	254.000

	Cost Elements		**Unit Price (€)**	**Useful Life (Days)**
Flash Monitoring	Scanning cost elements	FGM device	59,9	720
		FGM Sensor	59,9	14
	Finger pricking cost elements	Abbott Strip	0,2817	Single Use
		Lancing Device	0	360
		Lancets	0	Single Use
		Control Solution	5	30
Self Monitoring	SMBG Meter		0	320
	Strips		0,2817	Single Use
	Lancing Device		0	360
	Lancets		0	Single Use
	Control Solution		0	30

Break-even Point

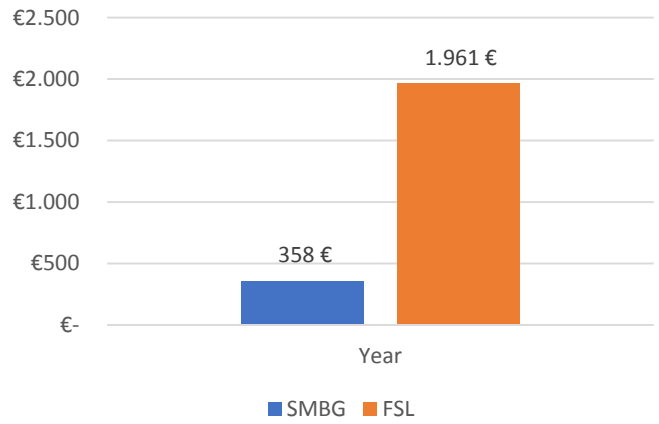
Daily testing frequency	Daily Cost/person FGM(€)	Daily Cost/person SMBG (€)	Daily Cost Difference between FGM and SMBG (€)	Annualized Cost Difference between FGM and SMBG/ Population (€)
1	4,58	0,28	4,30	393.472.953
2	4,64	0,56	4,08	372.866.035
3	4,70	0,85	3,85	352.259.116
4	4,75	1,13	3,63	331.652.198
5	4,81	1,41	3,40	311.045.279
6	4,87	1,69	3,18	290.438.361
7	4,92	1,97	2,95	269.831.443
8	4,98	2,25	2,73	249.224.524
9	5,04	2,54	2,50	228.617.606
10	5,09	2,82	2,27	208.010.687
11	5,15	3,10	2,05	187.403.769
12	5,20	3,38	1,82	166.796.851
13	5,26	3,66	1,60	146.189.932
14	5,32	3,94	1,37	125.583.014
15	5,37	4,23	1,15	104.976.095
16	5,43	4,51	0,92	84.369.177
17	5,49	4,79	0,70	63.762.259
18	5,54	5,07	0,47	43.155.340
19	5,60	5,35	0,25	22.548.422
20	5,66	5,63	0,02	1.941.503

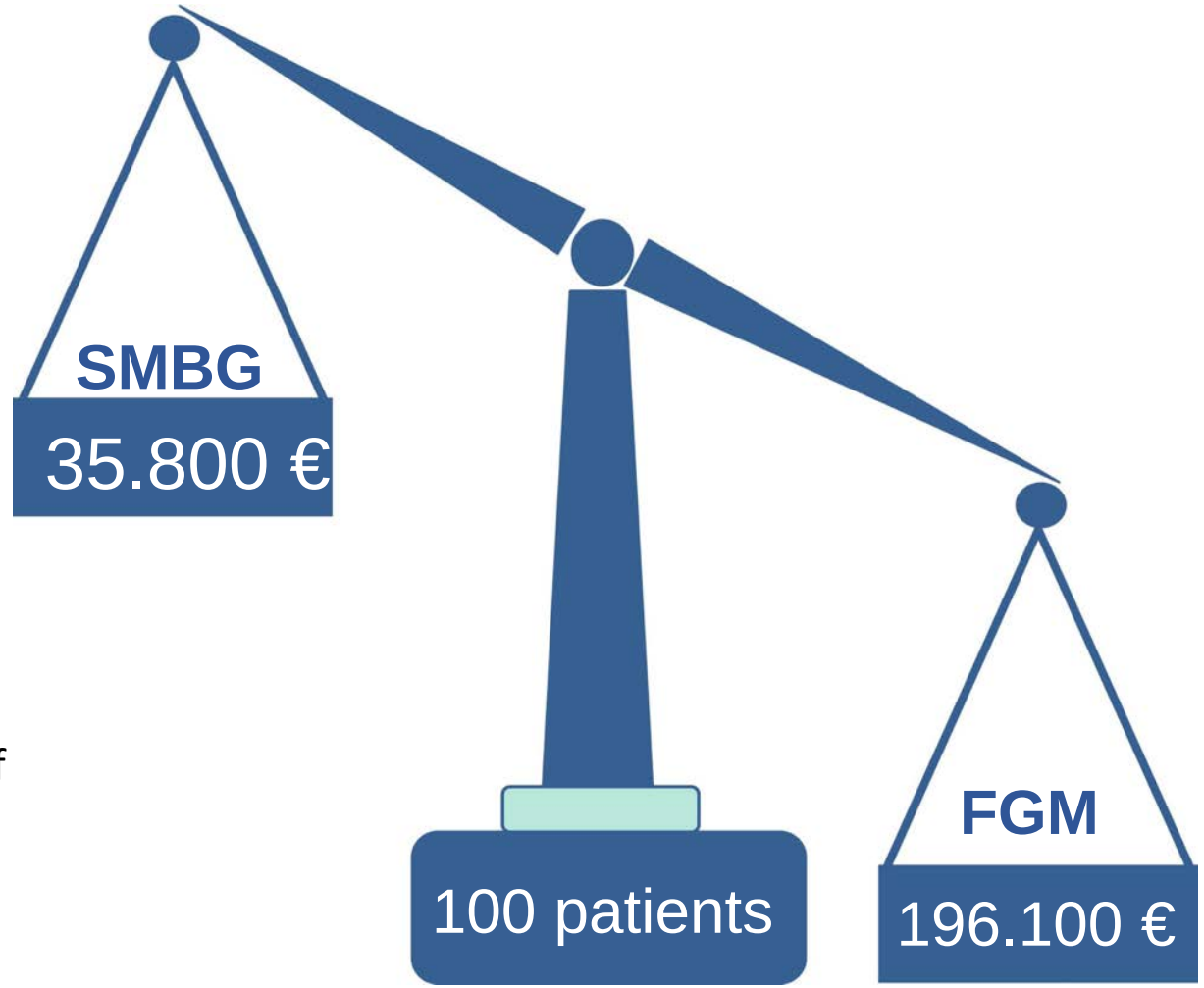
Results

"Break-even point" in different scenarios			
	SMBG: n strips/day		
	3,5	6	8
Day additional cost FGM vs SMBG	3,57 €	3,01 €	2,56 €
The cost of 1 FGM patient would equal the cost of …. SMBG patients	5,5	2,9	2,2
Annual budget of SMBG will be spent in … days if it would be destinated to FGM	67	115	153
N Patients with FGM(%target population) that SMBG budget can assume	18%	31%	42%

Results

Spain SMBG average test: 3,5[1]



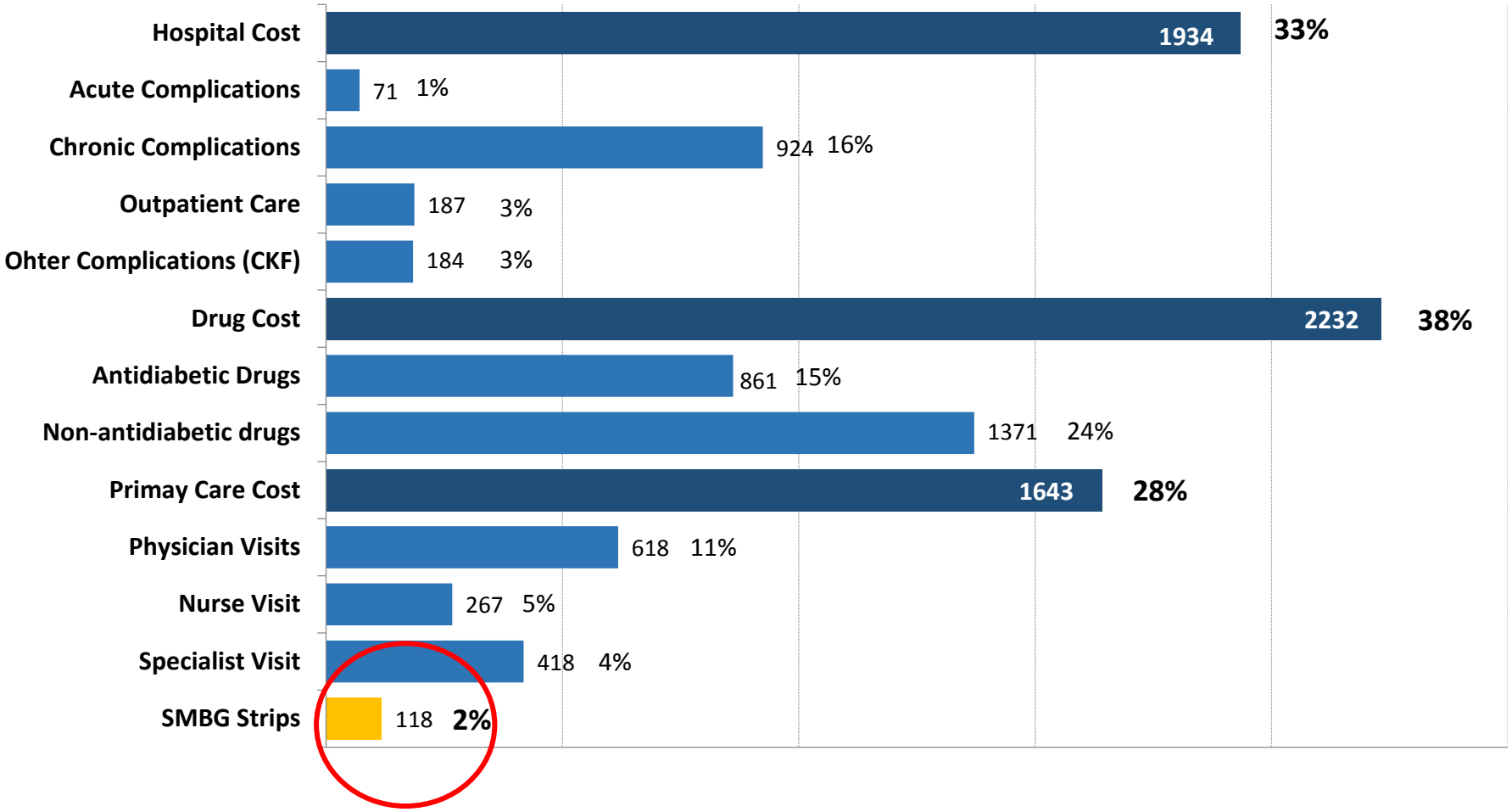


The cost of 1 patient with FGM would equal the cost of

5,5 patients with SMBG

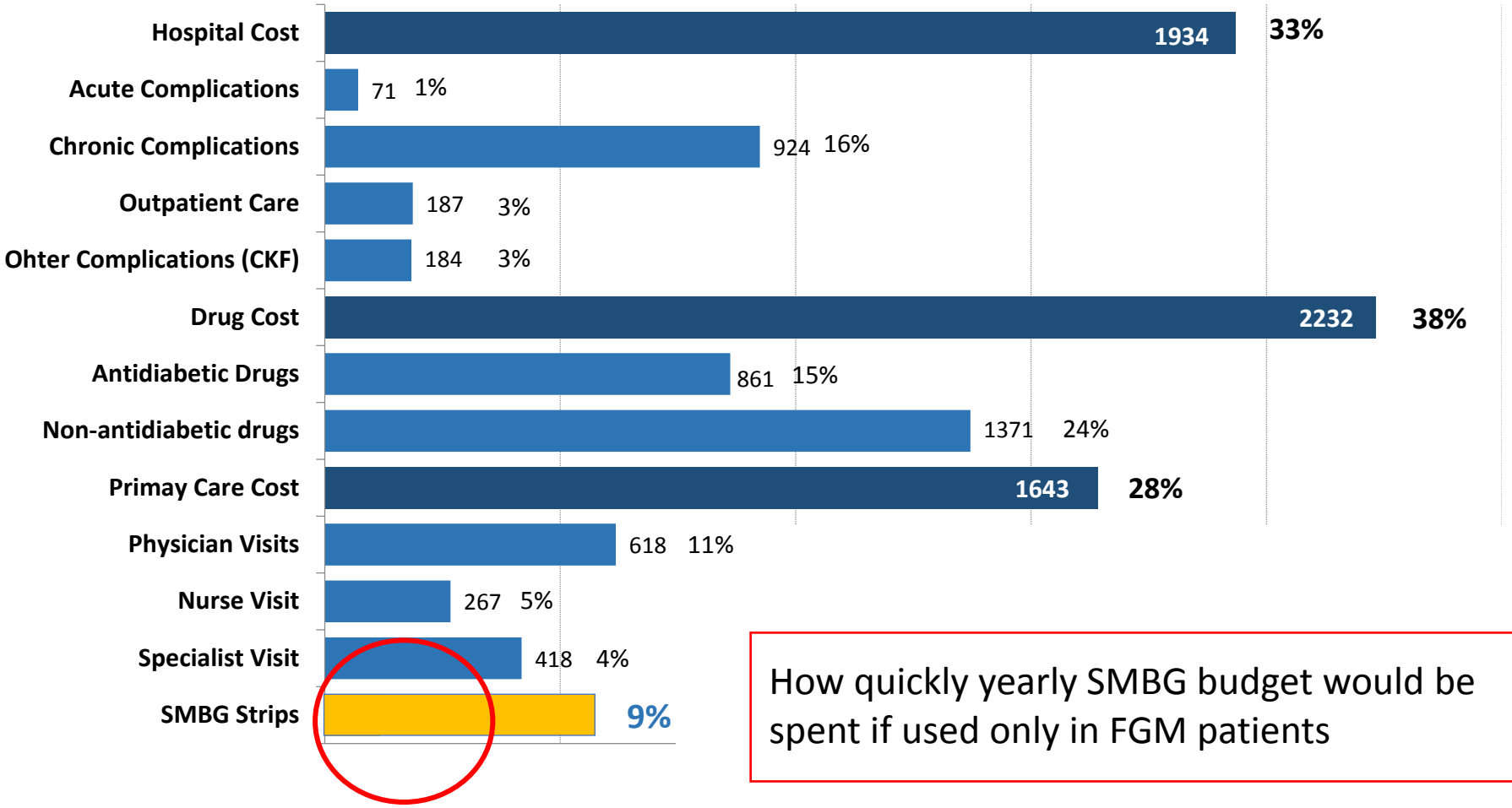
1- Torre M. Recomendaciones 2012 de la Sociedad Española de Diabetes sobre la utilización de tiras reactivas para la medición de la glucemia capilar en personas con diabetes. *Av Diabetol*. 2012; 28(1): 3-9

Results



Crespo C. et al. Costes directos de la diabetes mellitus y de sus complicaciones en España (Estudio SECCAID). Av Diabetol 2013. 29(6): 182-189

Results



How quickly yearly SMBG budget would be spent if used only in FGM patients **67** days

Crespo C. et al. Costes directos de la diabetes mellitus y de sus complicaciones en España (Estudio SECCAID). Av Diabetol 2013. 29(6): 182-189

Conclussions

Our study complements IMPACT clinical trial:

- ✓ A reduction in time spent in hipoglicemia was observed, but not reduction in the number of events and therefore not reducing clinical resources use.
- ✓ HbA1c (secondary endpoint) was not significative compared to SMBG
- ✓ Impact Study could not show a clinical superiority compared to SMBG.
- ✓ FGM despite of marketing claims it is **still requiring finger pricks**
- ✓ Reimbursement decissions have not considered HTA conditional recommenations

From our study we can asume that SMBG is still the gold standar and have important economic advantages versus FGM

Thanks!

Selection Criteria

1. 18 years or older who had been diagnosed with type 1 diabetes for 5 years or longer.

2. had been on their current insulin regimen for at least 3 months before study entry.

3. had a screening HbA1c concentration of 58 mmol/mol (7.5%) or lower.

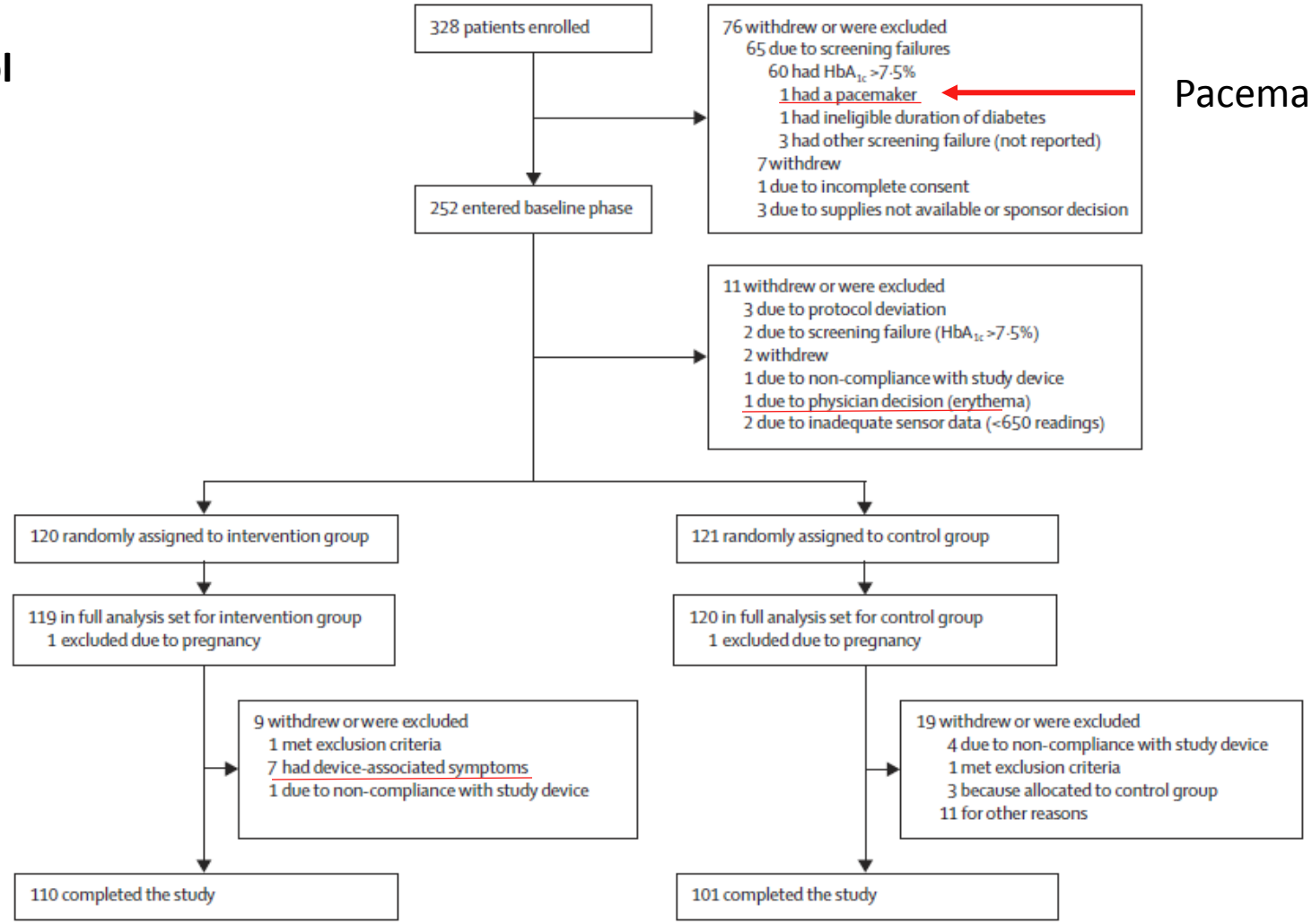
4. reported self-monitoring of blood glucose levels on a regular basis (equivalent to ≥3 times a day) for 2 months or more before study entry.

5. were considered by the investigator to be technically capable of using the flash sensor-based glucose monitoring system.

Exclusion Criteria

1. Patients were currently diagnosed with hypoglycaemia unawareness.
2. had diabetic ketoacidosis or myocardial infarction in the preceding 6 months.
3. had known allergy to medical-grade adhesives.
4. had used continuous glucose monitoring within the preceding 4 months.
5. were currently using sensor-augmented pump therapy.
6. were pregnant or were planning pregnancy; or were receiving oral steroid therapy for any disorders.

Protocol



Pacemaker

Results – Primary Enpoint

Time spent in hypoglycaemia (<3.9 mmol/L [<70 mg/dL]) for the 14 days preceding the end of the 6-month study period (days 194–208).

Grupo	ncia
FSL	oras
SMBG	001

Time in hypoglycaemia (<3·9 mmol/L) changed from 3·38 h/day to 2·03 h/day in the intervention group (baseline adjusted mean change −1·39), and from 3·44 h/day to 3·27 h/day in the control group (baseline adjusted mean change −0·14). The adjusted between-group difference of −1·24 (SE 0·239 h/day) was highly significant (p<0·0001), equating to a 38% reduction in time in hypoglycaemia in the intervention group compared with the control group (figure 2; table 2).

Results – Primary Enpoint

Time spent in hypoglycaemia (<3.9 mmol/L [<70 mg/dL]) for the 14 days preceding the end of the 6-month study period (days 194–208).

Grupo	Baseline	14 días finales	Media Ajustada	Diferencia
FSL	202,8 min	121,8 min	-83,4 min	74,4 min
SMBG	206,4 min	196,2 min	-8,4min	P<0,0001

38% reducción

A lo largo del día

Results – Primary Enpoint

Time spent in hypoglycaemia (<3.9 mmol/L [<70 mg/dL]) for the 14 days preceding the end of the 6-month study period (days 194–208).

Grupo <45 años	Baseline	14 días finales	Diferencia	Diferencia Ajustada
FSL	3,51 h	2,11 h	-1,4 h	-0,61 h
SMBG	3,95 h	2,95 h	-1 h	P= 0,0372

24 minutos

Grupo >45 años	Baseline	14 días finales	Diferencia	Diferencia Ajustada
FSL	3,23 h	1,94 h	-1,29	-1,87 h
SMBG	2,93 h	3,6 h	+,0,67	P<0,001

117,6 minutos

Results – Secondary Enpoint

Frequency (media (Desv std))	SMBG	
	Baseline	Final
FSL	5,5 (SD 2,0)	0,5 (0,7)
SMBG	5,8 (1,7)	5,6 (2,2)
Frecuencia Scans		15,1 (SD 6,9)
Uso del dispositivo		92,8% (7.7)

The device has been used under off label recommendations

HbA1C: No differences.