Using Freestyle Libre CGM With GLP-1 Treatment is a Cost-Effective Combination for People Living With Type 2 Diabetes

Eugene E Wright[1], Eden Miller[2], Anila Bindal[3], Yeesha Poon[3]

[1]South Piedmont Area Health Education Center, Charlotte, North Carolina, USA; [2]Diabetes and Obesity Care LLC, Bend, Oregon, USA; [3]Abbott Diabetes Care, Alameda, California, USA

Introduction

- For people living with type 2 diabetes mellitus (T2DM), optimal glycemic control is important to help reduce disease burden and complications[1]
- FreeStyle Libre (FSL) is a factory-calibrated flash continuous glucose monitoring (CGM) system which allows patients to regularly monitor glucose fluctuations and trends[2]
  - In clinical trials and real-world data studies, patients using FSL saw improved glucose control[3–6]
  - Guidelines in the USA currently recommend the use of FSL or other CGM devices for people living with diabetes who are using insulin[7,8] or have a history of problematic hypoglycemia[7,9]
- For people living with T2DM who have HbA1c levels above their target, US guidelines recommend consideration of the use of a glucagon-like peptide 1 receptor agonist (GLP-1)[10]
  - Clinical trials have found some injectable GLP-1 treatments to have similar or better efficacy, compared with basal insulin, in lowering glucose levels,[11] with a lower risk of hypoglycemia[12]
- A recent US real-world study, conducted using a linked database of electronic health records and claims, found statistically significant improvements in HbA1c levels with combination use of GLP-1 plus FSL, compared with GLP-1 alone, with benefits seen for patients using intensive insulin and for those using non-intensive or no insulin[13]
- This analysis was conducted to investigate whether the addition of FSL to GLP-1 therapy is cost effective

Objectives

- To assess the cost effectiveness from a US payer perspective of GLP-1 plus FSL, compared with GLP-1 alone, in people living with T2DM

Materials and methods

Microsimulation model

- The DEDUCE model (DEtermination of Diabetes Utilities, Costs, and Effects) is a validated, patient-level microsimulation model[14]
  - DEDUCE assigns costs and utilities according to the acute diabetic events (ADEs; diabetic ketoacidosis [DKA] and severe and non-severe hypoglycemic events [SHE and NSHE, respectively]) and complications experienced by each simulated patient
  - The incidence and history of complications are updated each 1-year cycle
  - Diabetes complications are modeled using the RECODe risk engine, which is based on data from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) randomized controlled trial (RCT)[15]

Analysis overview

- The DEDUCE model was run using Microsoft Excel for 10,000 patients over a lifetime horizon (80 years)
- Outcomes were assessed as quality-adjusted life years (QALYs), with costs (in 2023 $) and utilities discounted at 3%

Model inputs and assumptions

- Target population
  - Patient characteristics (**Table 1**) were based on the US real-world study of GLP-1 and FSL use,[13] or on the ACCORD RCT[15,16]
  - The analysis was carried out both for the entire real-world study cohort and for the subgroup of patients not using intensive insulin (73% of the total)
- Treatment effects and complications
  - The effect of FSL on HbA1c levels was taken from the US real-world study[13] and applied as a one-time, persistent reduction (**Table 2**)
  - Compared with GLP-1 alone, use of FSL was associated with a 44% reduction in SHEs and a 29% reduction in NSHEs, based on French and US real-world data, respectively[17,18]
  - In addition, DKA was reduced by 75%[17]
- Costs
  - The costs associated with GLP-1 and FSL were calculated using US wholesale acquisition cost data (**Table 2**)
  - Costs associated with ADEs and diabetes complications were taken from a US claims database study and the US National Inpatient Sample database[19,20]
    - NSHEs were assumed to have no associated costs
- Utility values
  - A baseline health utility of 0.8 and disutility values associated with complications and SHEs were taken from an analysis of the ACCORD RCT (**Table 2**)[21]
    - Disutility values were applied per event for ADEs and annually for complications
  - A utility increment of 0.03 was applied to patients using FSL, based on the benefit of avoiding fingerstick tests as estimated in a UK time trade-off study[22]

Results

Base-case results

- The base-case incremental cost-effectiveness ratio (ICER) for GLP-1 plus FSL versus GLP-1 alone in the overall cohort was $78,550/QALY (**Table 3**)
  - Total costs over the lifetime horizon were $21,094 higher with GLP-1 plus FSL than with GLP-1 alone ($515,483 vs. $494,389)
  - The addition of FSL to GLP-1 was associated with a gain of 0.27 additional QALYs (13.74 vs.13.47)

Table 1. Patient characteristics

Patient Characteristics	Value	Source
Demographics		
Age (years)	53.5 (11.6)	US real-world study[13]
Gender (% female)	42.2%	
Race		
African American	17%	US real-world study[13]
Hispanic	12%	
Non-Hispanic White/other	71%	
Insulin use		
Intensive insulin	27%	US real-world study[13]
Basal Insulin	25%	
No Insulin	48%	
Baseline risk factors		
Baseline HbA1c (%)	10.2% (1.7%)	US real-world study[13]
SBP (mmHg)	136.5 (17.1)	ACCORD 2010[16]
Total cholesterol (mg/dL)	183.20 (41.7)	
HDL cholesterol (mg/dL)	41.8 (11.60)	
Serum creatinine (mg/dL)	0.9 (0.2)	
Urine albumin:creatinine ratio	99.20 (359.40)	
% current smokers	12.0%	
% with CVD	35.7%	
Medication use		
Blood pressure	84.2%	Basu 2017 (RECODe)[15]
Statins	64.0%	
Oral antidiabetics	83.0%	
Anticoagulants	3.0%	

Data are mean (SD) or percentage of patients
CVD, cardiovascular disease; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; SBP, systolic blood pressure; SD, standard deviation

- Similar results were seen in the non-intensive insulin subgroup, with an ICER of $81,349/QALY (**Table 3**)
  - Total costs were $20,626 higher with GLP-1 plus FSL than with GLP-1 alone ($513,906 vs. $493,280)
  - The addition of FSL to GLP-1 was associated with a gain of 0.25 additional QALYs (13.75 vs.13.50)

Table 2. Model inputs

Input	GLP-1 plus FSL	GLP-1 alone	Source
One-time absolute reduction in HbA1c			
Overall cohort	2.43%	2.06%	US real-world study[13]
Non-intensive or no insulin	2.47%	2.13%	
Hypoglycemic events			
SHE (annual probability)	0.41%	0.73%	Guerci 2023[17]
NSHE (events per year)	16.50[a]	23.31	Bergenstal 2021;[18] Edridge 2015[23]
DKA			
DKA (annual probability)	0.34%	1.37%	Guerci 2023[17]
DKA mortality (probability per event)	4.7%		Sagy 2021[24]
Intervention costs			
GLP-1 cost	$932.84	$934.42	US wholesale acquisition cost[b]
FreeStyle Libre 2	$140.01	–	
Total monthly cost	$1072.86	$934.42	Calculated
ADE costs			
SHE, per event	$10,927		Yang 2020[19]
DKA, per event	$27,839		Desai 2018[20]
Costs for complications, year 1 (subsequent years)			
Blindness	$15,231 ($15,231)		Yang 2020[19]
Congestive heart failure	$36,571 ($8,278)		
Myocardial infarction	$53,038 ($10,047)		
Renal failure	$110,446 ($110,446)		
Stroke	$27,872 ($5,543)		
General utilities			
Baseline health utility	0.8		Shao 2019[21]
Fingerstick disutility	0.03		Matza 2017[22]
ADE disutilities			
SHE, per event	0.036		Shao 2019[21]
NSHE, per event	0.00163		Bilir 2018[25]
DKA, per event	0.0091		Jorissen 2022[26]
Disutilities for complications, year 1 (subsequent years)			
Blindness	0.057 (0.057)		Shao 2019[21]
Congestive heart failure	0.089 (0.041)		
Myocardial infarction	0.042 (0.011)		
Renal failure	0.024 (0.024)		
Stroke	0.204 (0.101)		

[a]Calculated by applying the 29.2% reduction in non-severe hypoglycemic events seen in Bergenstal 2021[18] to the SMBG rate
[b]Weighted average of GLP-1 agents used by patients in US real-world study[13]
ADE, acute diabetic event; DKA, diabetic ketoacidosis; FSL, FreeStyle Libre system; GLP-1, glucagon-like peptide 1 receptor agonist; HbA1c, glycated hemoglobin; NSHE, non-severe hypoglycemic event; SHE, severe hypoglycemic event

Table 3. Cost-effectiveness results

	GLP-1 plus FSL	GLP-1 alone	Incremental
Overall cohort			
Costs	$515,483	$494,389	$21,094
QALYs	13.742	13.473	0.269
ICER (Cost/QALY)		**$78,550**	
Non-intensive insulin subgroup			
Costs	$513,906	$493,280	$20,626
QALYs	13.754	13.500	0.254
ICER (Cost/QALY)		**$81,349**	

FSL, FreeStyle Libre system; GLP-1, glucagon-like peptide 1 receptor agonist; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year

Discussion

- This economic evaluation demonstrated that, based on the US willingness-to-pay threshold of $100,000/QALY, GLP-1 plus FSL is cost effective compared with GLP-1 alone
- The individual benefits of GLP-1 and FSL for people living with T2DM are well established, with extensive evidence available from clinical trials and real-world studies
  - This analysis was based on a recent US real-world study that found use of FSL to improve HbA1c levels for patients using GLP-1 therapies, with or without intensive insulin
  - The results of this analysis demonstrate that FSL use is beneficial and cost effective for all patients using GLP-1 therapies, including those not using intensive insulin
- A limitation of this analysis is that the costs of blood glucose monitoring, which is likely to be conducted by a proportion of patients using GLP-1 therapies, could not be included; these costs could potentially be reduced by the use of FSL
  - In addition, it was necessary to assume that NSHEs have no associated costs
  - Together, these limitations mean that the ICER for GLP-1 plus FSL versus GLP-1 alone may be conservative

Conclusion

- From a US payer perspective, FSL can be considered to be a cost-effective addition to GLP-1 for the treatment of T2DM

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