Budget Impact Analysis of IDegAsp for the Management of Type 2 Diabetes in Saudi Arabia

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Introduction

Due to the progressive nature of type 2 diabetes (T2D), patients often require treatment intensification to maintain good glycemic control, which can eventually lead to insulin therapy.[1] Premixed insulin can be a convenient alternative to basal-bolus therapy, as it can control both fasting and post-prandial glucose with fewer injections.

Insulin degludec/insulin aspart (IDegAsp) is the first soluble co-formulation of a basal and rapid-acting analog in a single injection. IDeg has a long duration of action, with a longer half-life, and less within-patient variability compared to insulin glargine U100.[2,3] IDegAsp co-formulation also eliminates the risk of incomplete mixing. Which can cause hypoglycemia as it doesn't need to be resuspended.[4]

To ensure the best use of healthcare resources, the decision to prescribe a specific product relies on both clinical and economic evidence. Thus, it is crucial to examine the financial impact of the new interventions for diabetes. Traditionally, budget impact analyses of diabetes interventions have been performed by estimating the long-term clinical consequences based on variations in HbA1c levels.

However, adhering to the guidelines issued by the US Food and Drug Administration, it is recommended that new insulins be compared with a standard insulin rather than a placebo or non-insulin agent. This comparison allows for the evaluation of safety endpoints such as hypoglycemia, and insulin dosage.[5,6]

Objective

To evaluate the budget impact of replacing BIAsp30 (Biphasic insulin aspart 30/70) with IDegAsp in the management of T2D from a Saudi Arabia public payer perspective using a short-term budget impact model.

Methodology

A Microsoft Excel-based budget impact model was developed from a Saudi public payer perspective to estimate the expected costs to be incurred by the payer before and after the replacement of BIAsp30 (Biphasic insulin aspart 30/70) with IDegAsp for 53,717 Saudi patients with T2DM over 5 years. Time horizon.

Target population

The affected patient population was derived from the total population size of Saudi Arabia, based on epidemiological data. The model targeted a population with public coverage and uncontrolled on basal insulin.

To estimate the budget impact of replacing BIAsp30 with IDegAsp, two market scenarios were compared.

- In scenario 1, patients received only BIAsp30 for the entire 5-year period.
- In scenario 2, patients received both BIAsp30 and IDegAsp, according to projected market shares and uptake.

Current market shares were based on different market estimates for BIAsp30, and a 20% annual market uptake for IDegAsp was assumed starting with a market share of 30% in the current year.

Current scenario (without IDegAsp)					
	2023	**2024**	**2025**	**2026**	**2027**
IDegAsp	0%	0%	0%	0%	0%
BIAsp30	100%	100%	100%	100%	100%
	100%	**100%**	**100%**	**100%**	**100%**
New Scenario (with IDegAsp)					
	2023	**2024**	**2025**	**2026**	**2027**
IDegAsp	30%	50%	70%	90%	100%
BIAsp30	70%	50%	30%	10%	0%
	100%	**100%**	**100%**	**100%**	**100%**

Table 1: Market Mix
IDegAsp – Insulin degludec / insulin Aspart co formulation
BIAsp30 – Biphasic insulin aspart

Health outcomes

The model included daytime non-sever hypoglycemia, severe hypoglycemia, and average insulin dose per day (IU) as main cost offsets. The rate of hypoglycemia was calculated by multiplying the baseline risk of each type of hypoglycemia by the hazard ratio attributed to both comparators.
The hypoglycemia hazard ratios associated with the two comparators were derived from a meta-analysis that included two randomized controlled trials with similar designs, where the patients administered both IDegAsp and BIAsp 30 twice daily, with breakfast and their main evening meal.[7]

Direct medical costs

Treatment costs include insulin acquisition, self-monitoring blood glucose (SMBG), and needles. Severe and non-severe symptomatic hypoglycemia episodes have also been identified based on expert opinion and correlated with additional SMBG costs per hypoglycemia episode.

Deterministic sensitivity analysis (DSA)

DSA has been conducted to test the robustness of the result by varying all the inputs by + and – 20% to estimate the input parameters that highly impact the results of the model.

The model calculated the impact on the budget in 2023 Saudi Riyals (SAR) and converted to United States Dollars (USD) with a conversion rate of (1.00 SAR = 0.27 USD).

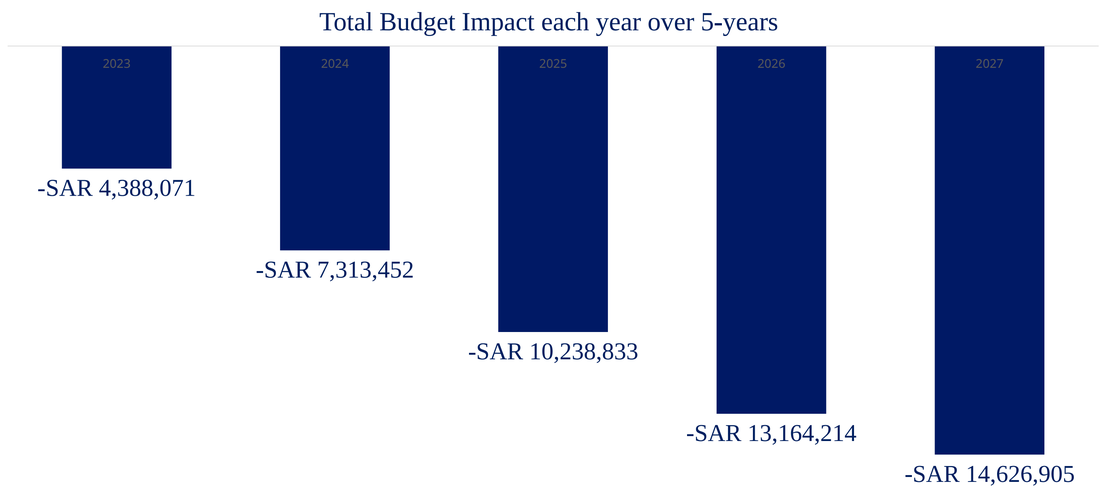
Results

The total cumulative cost for 53,717 T2DM Saudi patients before and after replacing BIAsp30 with IDegAsp was estimated at 497.7 million USD and 484.4 million USD, respectively, over the five years.

The total costs for patients who received IDegAsp decreased by 1.16, 1.94, 2,72, 3.50, and 3.89 million USD in years 1-5, respectively, resulting in a cumulative decrease of 13.25 million USD.

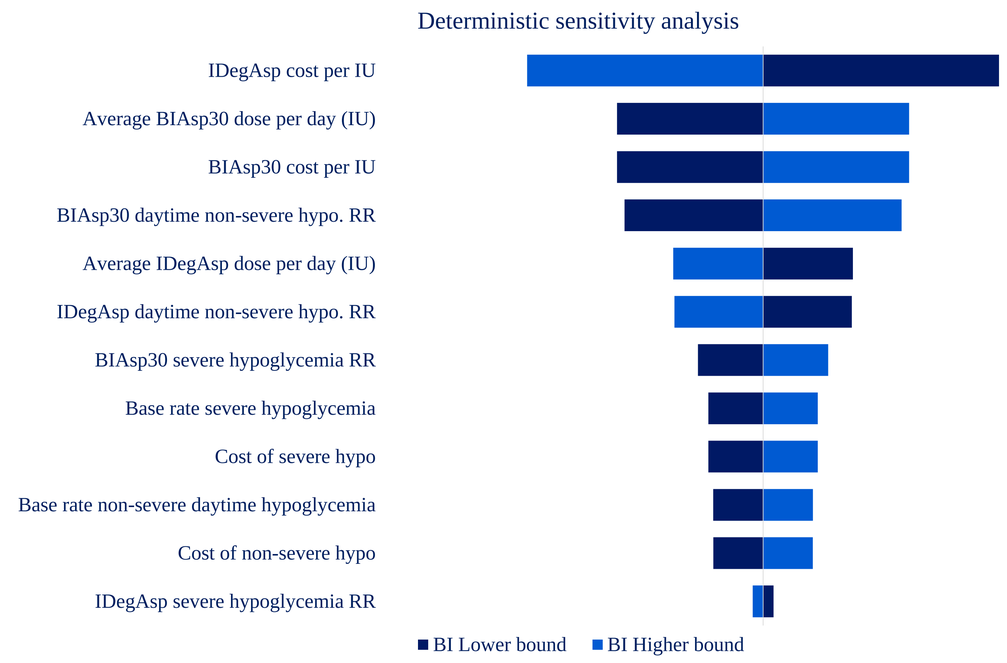
	Non-severe hypo costs	Severe hypo costs	Insulin costs	Needle costs	SMBG costs	Total costs
Current scenario (without IDegAsp)	USD 183,259,824	USD 86,151,052	USD 193,168,182	USD 13,035,318	USD 22,420,746	USD 498,035,123
New Scenario (with IDegAsp)	USD 138,397,819	USD 36,941,571	USD 273,977,942	USD 13,035,318	USD 22,420,746	USD 484,773,396
Difference (value)	-USD 44,862,005	-USD 49,209,481	USD 80,809,759	USD 0	USD 0	-USD 13,261,727
Difference (%)	-24%	-57%	42%	0%	0%	-3%

Over the 5 years, the cumulative insulin acquisition cost has increased the impact by 81.02 million USD. The decrease in the cumulative costs of non-severe hypoglycemia (44.85 million USD) and severe hypoglycemia (49.19 million USD) outweighed the increase in insulin acquisition costs, which reduced the overall impact.



Deterministic sensitivity analysis (DSA)

DSA demonstrated that the model is highly sensitive to the acquisition cost, average dose per day (IU), and non-severe hypoglycemia.



Discussion

Hypoglycemia bears both clinical and economic burdens on patients as well as the health system. The utilization of insulin analogs that feature a lower risk of hypoglycemia can improve the patient's quality of life and save healthcare systems significant expenditures.

IDegAsp insulin reduces the risk of hypoglycemia, resulting in budget savings for public Saudi payers. Hypoglycemia and its associated costs may justify the price difference between the two comparators.

The input parameters significantly influence all modeling approaches. In this particular model, only parameter estimates that demonstrated a statistically significant distinction between the treatment groups were used. It was assumed that all other differences arose from random variations. The model also assumed that patients would continue treatment with IDegAsp and BIAsp 30 for the entire 5-year duration without switching to another insulin regimen.[8]

Similar to most models, the cost data for hypoglycemia were collected from various publicly available sources and expert opinions were utilized to address the data gaps. However, these sources may use different methods to measure parameters and might not accurately reflect the economic impact of hypoglycemia. It is important to note that the estimations did not consider out-of-pocket expenses or lost work productivity, suggesting that the actual costs of hypoglycemia could potentially be higher.[8]

Conclusion

The utilization of IDegAsp over 5 years provided cost-savings of around SAR 50 million (USD $13 million), it was mainly driven by the reduction of hypoglycemia events for patients using IDegAsp compared to BIAsp30, and subsequently, the cost of the management and/or the monitoring of hypoglycemia.

References