Evaluating the Budget Impact of the Co-Existence of Oral and Injectable Forms of Semaglutide in the Saudi Public Healthcare System

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Introduction

KSA is recognized as one of the countries with high prevalence of diabetes globally, and it is projected to become one of the top five countries with the highest prevalence of T2D by 2030.[1] In 2014, the prevalence of diabetes in KSA was 13.4%, affecting 1,745,532 individuals, and it was expected that by 2021, KSA will have 4.3 million adults with diabetes, resulting in a national prevalence rate of 18.7%. T2DM is associated with various complications including CVD, nephropathy, neuropathy, retinopathy, and peripheral vascular disease.[2]

An observational retrospective study emphasized the substantial economic burden faced by T2DM patients with comorbidities such as CVD and renal complications.[3] ADA/EASD consensus statements indicated that semaglutide is recommended as a first-line GLP-1 RA with a significant impact on reducing the risk of MACE, including non-fatal stroke, in high-risk patients with T2DM.[2] For people with T2DM who are uncontrolled on metformin and living with obesity, the SNDC Guidelines recommended a GLP-1 RA or SGLT-2i for their good effect on weight loss.[4]

In response to the challenges hindering glycemic control among T2D patients in KSA, oral semaglutide has emerged as a promising intervention. Recognized through a recent US FDA label update as a first-line therapy for adults with T2DM, oral semaglutide offers a more convenient prescription and adherence option, potentially tackling the barriers physicians and patients face.[5] The Saudi Scientific Diabetes Society, in collaboration with 400 physicians in KSA, published a consensus document pointing out that the availability of oral forms of GLP-1 RA medications could overcome therapeutic inertia caused by fear of injections, allowing for timely usage of this medication.[6]

The objective is to determine the financial impact of introducing oral semaglutide as a treatment option for people with T2DM, specifically from a Saudi public payer perspective. Given the growing interest among healthcare professionals in GLP-1, it would be valuable to the national payers to evaluate the budget implications of including the oral semaglutide in the formulary for the patients who are more compliant with oral medications while keeping the injectable form to the patients with established CVD.

Methodology

The budget impact analysis included patients with T2DM who have not achieved their HbA1c targets with metformin. A patient-centric approach to treatment selection was recommended, taking into account comorbidities such as cardiovascular complications and obesity.[4]

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 (aged 45-69), with a BMI of 32-35 with public coverage and uncontrolled on Metformin.

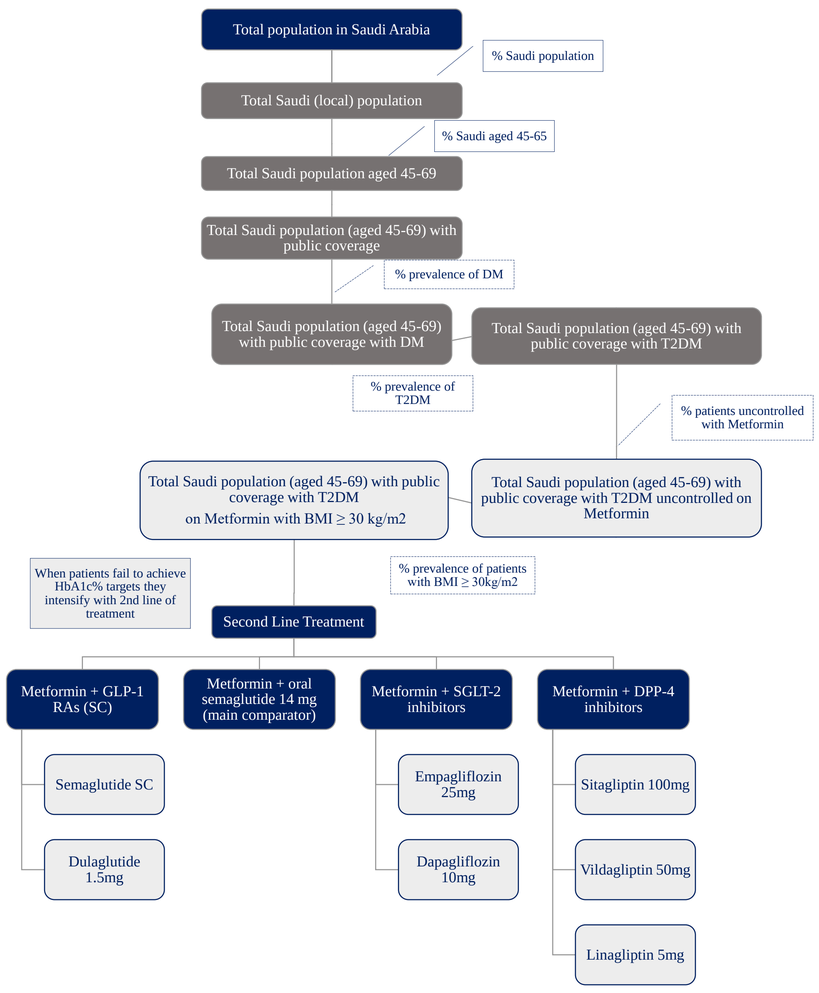


Figure: 1 Flow diagram of literature search.

Comparators

The primary comparator was the newly introduced oral semaglutide 14mg in addition to the injectable form of the same molecule against dulaglutide 1.5 mg in addition to the injectable form of semaglutide. Dulaglutide 1.5 mg was included in the evaluation as it was one of the well-established GLP-1 options. SGLT 2i and DPP-4i were included in the model, since the diffusion of the oral semaglutide might introduce an attrition impact on the other oral diabetes medication; therefore, it was necessary to take this into consideration. SGLT 2i; and DPP-4i were adopted in the model using a weighted average approach based on the molecules' market share in the public sector derived from the IQVIA market intelligence reports.[7]

Market mix

The market mix scenarios were considered with and without the inclusion of oral semaglutide 14mg over a five-year time horizon. The model assumed that injectable semaglutide would be available in both scenarios and compared the inclusion of oral semaglutide with dulaglutide 1.5 mg with market percentages determined through IQVIA market intelligence reports.[7] (Table 1)

Current scenario (without oral semaglutide 14mg)					
	2023	**2024**	**2025**	**2026**	**2027**
Injectable Semaglutide	39%	39%	38%	37%	35%
Dulaglutide 1.5 mg	15%	22%	27%	28%	30%
SGLT 2i	12%	13%	14%	14%	15%
DPP-4i	34%	26%	21%	21%	20%
	100%	**100%**	**100%**	**100%**	**100%**
New Scenario (with oral semaglutide 14mg)					
	2023	**2024**	**2025**	**2026**	**2027**
Semaglutide (Both forms)	54%	63%	68%	68%	70%
Dulaglutide 1.5 mg	0%	0%	0%	0%	0%
SGLT 2i	12%	13%	13%	14%	14%
DPP-4i	34%	24%	19%	18%	16%
	100%	**100%**	**100%**	**100%**	**100%**

Table 4: Market Mix
GLP-1 RA – glucagon-like peptide-1 receptor agonist; SGLT 2i - sodium-glucose transport protein 2 inhibitor; DPP-4i - dipeptidyl peptidase 4 inhibitor; mg – milligram

Input parameters

The budget impact analysis included the direct medical costs from the perspective of the KSA public health payer e.g., medications, hospitalizations, outpatient visits, and lab tests. Medications acquisition costs have been derived from NUPCO website.[8]
The model was designed to incorporate different health outcomes to produce the budget impact results, e.g., cardiovascular risk reduction, proportion of patients achieving HbA1c% target, savings incurred due to weight loss, and its impact on health outcomes and risk reduction related to CKD, HF, hypertension and dyslipidemia.[9] Diabetes management costs and costs related to T2DM comorbidities were also considered and inflated to the current value using the latest consumer price indices (CPI).[10]

Sensitivity Analyses

Probabilistic sensitivity analyses were conducted by attributing different distribution options of Beta, Normal, Lognormal, or Gamma distributions to each input parameter in the series. We ran the model for 1000 iterations to assess the robustness of the BIM and determined the probability of budget inflation greater than 5, 10, and 15% and the probability of budget savings greater than 5, 10, and 15%.

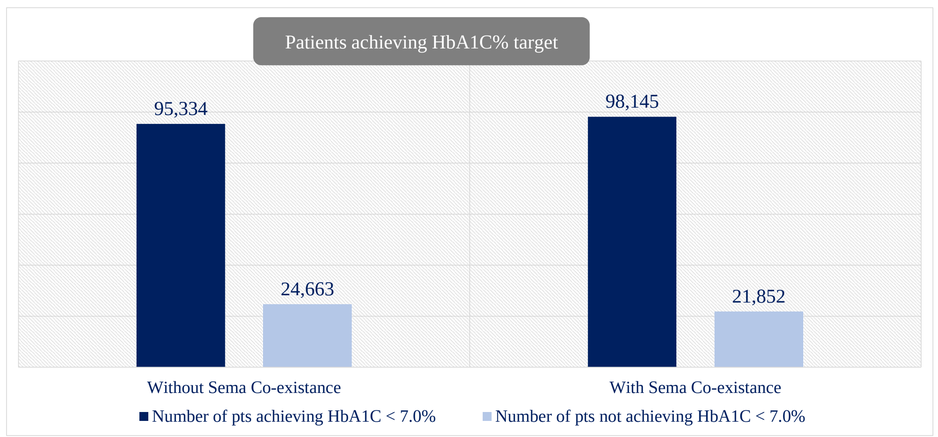
Results

The addition of oral semaglutide increased medication costs, while decreasing diabetes management costs and CV complication costs, and providing weight loss savings. Over the five-year time horizon, the cumulative cost differential compared with the scenario of adding dulaglutide to the injectable form of semaglutide was 4.86 million USD (1.5%) budget savings.

Medication costs increased by 5.66 million USD due to the higher acquisition cost for oral semaglutide compared with dulaglutide, while diabetes management costs decreased by 1.98 million USD due to the higher proportion of patients achieving the HbA1c% target compared with dulaglutide, SGLT-2i, and DPP-4i, CV complications costs decreased by 6.6 million USD, and by the introduction of oral semaglutide to the public sector, 7.24 million USD has been saved due to the superior mean weight loss.

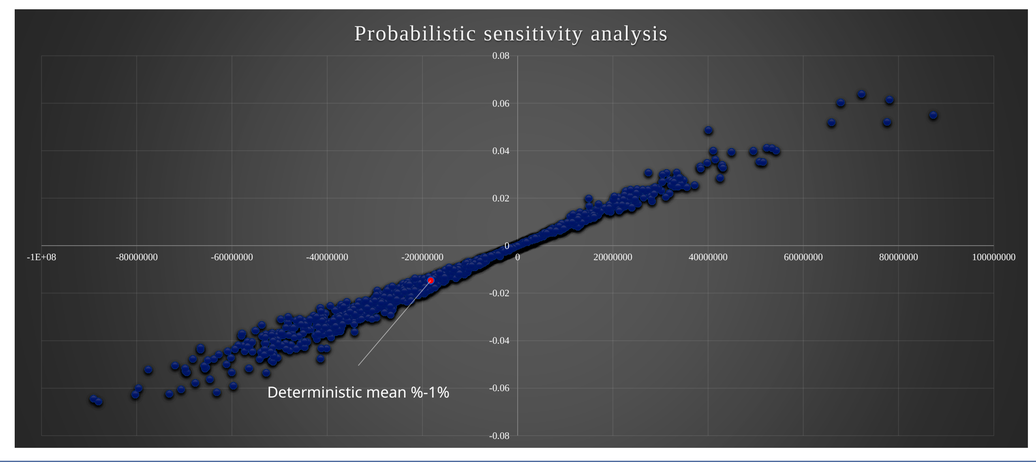
	Medication costs	Diabetes management costs	SHE costs	CV. Complications costs	Weight loss savings	Total costs
Current scenario (without Sema Co-existence)	$319,956,519	$523,817,253	$1,151,840	$436,058,959	$36,500,432	$1,244,484,139
New Scenario (with Sema Co-existence)	$341,245,086	$516,346,928	$1,228,451	$411,157,274	$43,749,929	$1,226,227,810
Difference (value)	$21,288,567	-$7,470,324	$76,611	-$24,901,686	$7,249,497	-$18,256,329
Difference (%)	**7%**	**-1%**	**7%**	**-6%**	**20%**	**-1%**

The impact of diffusion of the oral semaglutide on the health outcomes was conspicuous, with an increase in the number of patients achieving HbA1C% target by 2,811 patients, reduction in the number of CV death cases, and non-fatal stroke.



Probabilistic sensitivity analysis (PSA)

PSA considered 101 input parameters including prevalence data, prices, and health outcomes. Furthermore, PSA demonstrated that the semaglutide co-existence scenario was budget-saving in 72.3% of the sensitivity analysis iterations endorsing the outcome of the model that there is a high probability that the co-existence of both forms of semaglutide may be attributed to a budget-saving impact on the healthcare system budget.



Discussion

The results of the study showed that, the increase in medication costs would be offset by a reduction in DM management costs, CV complications costs, and savings realized through weight loss. This is important for decision-making and healthcare budget planning in KSA, as it helps understand the cost implications of this new therapeutic option for people with T2DM. The model also found positive health outcomes for patients with T2DM, including improved HbA1c results, and weight loss benefits, based on randomized controlled trials. This new intervention could address challenges among the growing T2DM population in KSA without overwhelming the healthcare budget.

The strengths of this budget impact analysis include a comprehensive sensitivity analysis that enhances confidence in the presented probabilities. Key opinion leaders were involved in populating the model with input costs due to the lack of specific information and the complexity of care required.

Scarcity of KSA-specific data e.g., baseline risks and epidemiological data was one of the limitations, which is a challenge faced in previous economic analyses of health technologies.[11] Furthermore, the health outcomes associated with all the comparators regarding cardiovascular complications have been derived from different literature.

Conclusion

The model indicated with high confidence that the co-existence of both forms of semaglutide (oral and injectable) as a second-line treatment after metformin is budget-saving for the public pharmaceutical formulary of KSA. The price difference between oral semaglutide and other comparators (dulaglutide, SGLT-2i, and DPP-4i) is offset by positive health outcomes including more patients in KSA achieving HbA1c targets, fewer CV events, and impactful weight-loss cost savings.

References