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BUDGET IMPACT ANALYSIS OF DIFFERENT TREATMENT MODALITIES AND THEIR COST- EFFECTIVENESS IN SAUDI HEALTH CARE SETTING

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ABSTRACT

Objectives: To estimate the cost effectiveness of pharmacological and non-pharmacological (mainly surgery) regimens for the management of obesity.

Methods: an observation study was planned to attain the objectives of this study. Data from various hospitals regarding the interventions were collected to perform cost analysis. ICER and budget impact analysis were performed using the standard guidelines mentioned by the international society of pharmacoeconomic outcomes and research (ISPOR). Statistical analysis was performed using ANOVA and Chi-square wherever applicable. P-value less than 0.05 was considered statistically significant.

Results: The cost of Bariatric Surgery was 1041.67 SAR per kg weight loss and for 52 weeks the cost of surgery was 25000 SAR for 52 weeks. Surgical interventions were proven to be the most effective modalities with higher success rate in response to ever diem spend (p=<0.001). However, in the case when budgetary constraints are there for that specific group of population Semaglutide serves as the effective pharmacotherapy methods in terms of value for money. ICER analysis was performed to identify the most expensive and least effective regimen. Analysis has revealed that the ICER for Tirzepatide vs. Semaglutide was 5,909 / kg, while for Liraglutide vs. Semaglutide the effect was not desirable and there was no decline in weight. In terms of 5 years' budget impact Tirzepatide was the

highest, followed by Liraglutide and Semaglutide emerged as the most affordable regimen. For surgical intervention the upfront impact of Bariatric Surgery was 26.25 million SAR.
Conclusion: Bariatric Surgery where the main aim is immediate reduction in weight for high-risk patients the 5-year burden on the national health budget will be 26.25 million SAR. The willingness to pay, which is very important in the context of the budget impact analysis, If it is assumed that Saudi population struggling with obesity is willing to pay 2000 SAR per kg lost, then in this case both Semaglutide and Surgery are considered "High Value and Tirzepatide which is superior in comparison to Liraglutide, may require potential price negotiation to reach parity with Semaglutide.

Keywords: *Obesity, Bariatric Surgery, Tirzepatide, Semaglutide, Liraglutide,* ICER analysis, *Budget Impact analysis.*

INTRODUCTION

World Health Organization (WHO) categories obesity as one of the chronic relapsing conditions that pose serious risk to health. [1] Particularly assessing the situation in gulf region , specifically in Saudia Arabia obesity is identified as one of the leading health risks with the approximate prevalence of 40%.[2, 3] Obesity poses a massive economic and clinical burden on any healthcare system.[4] Clinical burden is primarily due to the complications and comorbidities that result from obesity and led to significant morbidity and mortality. In addition to the long-term cost of pharmacotherapy for obesity, patients are also at risk of diabetes, hypertension, sleep disorders, respiratory and digestive conditions. [5] WHO facts reported 14% of the total health expense was spend on diabetes and the treatment of the comorbidities due to obesity accounted 1% of the total GDP of Saudi Arabia in 2019.[6-8]
Overall, obesity alone is resulting in approximately 5% loss of obesity resulted in an estimated 4.4% loss of GDP in Saudi Arabia in 2016. [9]. These facts may pose a huge challenge for the Saudi Arabia and may hinder the delivery of effective delivery of health service envisioned in key policy outcomes for Vision 2030. [10, 11]Obesity in nutshell poses a huge direct and indirect cost to both population and government sector for the management of obesity alone and along with comorbidities. In Saudi setting a direct association is observed in age and obesity prevalence, specifically among women where this trend twice than the men. [12]In addition, the risk of Class II and Class III obesity is twice in women than men. [13]
While discussing the treatment of obesity, Glucagon Like Peptide-1 Agonist / GLP-1 receptor agonist (GLP-1) are the current first line recommendations for the management of obesity. GLPs are approved for the management of obesity in Saudi Arabia and along with these pharmacological measures[14], surgical interventions are also approved for the management of treatment resistances case where worst outcomes are noted if timely interventions are not performed. Though these regimens are available for the public for the management of obesity, no one has seen its economic impact on the health care system and what is the level of affordability of these regimens, its cost effectiveness and long-term impact on the budget. The current study will be perhaps the first of its kind to explore the pharmacoeconomic aspect of these interventions for the management of Obesity in Saudi Health care setting.

METHODOLOGY

A prospective cross-sectional study was conducted by getting the estimated cost of obesity management from various hospital of Kingdom of Saudi Arabia (KSA). This study is perhaps one of its kind, aiming to explore the payers' perspectives who are aiming to focus on weight reduction. The primary focus of this research was on the direct medical cost of the regimen that was used to reduce the patient's weight.

Theoretical framework

A pharmaco-economic modeling approach was used to assess the cost effectiveness of three pharmacological and one surgical intervention for the management of obesity. This framework was optimized by performing patient profiling to identify variables for the interventions.

Modeling for population parameters

The entire pharmaco-economic model was performed using the baseline parameters that were inline with the recommendation of the recent studies conducted[5, 15]. The duration of this study/ model ranging from 12 months to 18 months to observe the significance of the treatment outcomes on the primary goals of the study. Baseline weight of 80kg and patient with Class I/II obesity were the prime focus of the study. All these parameters were also in line with the international clinical trials which are considered as the cornerstone in obesity and weight management.[16-18]

Treatment modalities

Upon assessing the Saudi health care market, the following four regimens were found to be recommended for the management of Obesity as approved by the Saudi Food and Drug Authority (SFDA) [19]

- ***Semaglutide (2.4 mg):*** A weekly GLP-1 receptor agonist.
- ***Liraglutide (3.0 mg):*** A daily GLP-1 receptor agonist.
- ***Tirzepatide (Starting/Maintenance):*** A dual GIP/GLP-1 receptor agonist.
- ***Bariatric Surgery:*** Laparoscopic Sleeve Gastrectomy (LSG) and Roux-en-Y Gastric Bypass (RYGB).

Data Processing and Handling

The primary outcome of this economic assessment was decline in weight which was assessed by estimating the mean total body weight loss [20]. The cost of the regimen/ pharmacotherapy was calculated in Saudi riyal by daily unit dose that was supplied to the patients on monthly basis (e.g., 68 weeks for Semaglutide). The estimated cost of the surgery was estimated based on the published literature and average of private and public sector costs in Riyadh and Jeddah, ranging from SAR 15,000 to SAR 35,000 [21], and the primary cost of weight reduction was estimated using following equation

$$Ckg = \frac{\text{Total cost of treatment in SAR}}{\text{Baseline wt (kg) X Efficacy \% (TBWL)}}$$

Furthermore, Incremental Cost-effective ratio (ICER) was also estimated to further conclude on the cost effectiveness of the regimens which will be later also utilized to perform the budget impact analysis.

$$ICER = \frac{\text{Cost New} - \text{Cost Old}}{\text{Effect New} - \text{Effect Old}}$$

Data Analysis

Statistical package for social sciences (SPSS) version 21 was used to perform both descriptive and inferential statistics. One way ANOVA was used to estimate the difference in the cost and effectiveness across the four modalities. Additionally, to estimate the success rate and its association with a specific regimen, chi-square test was performed. All the tests were two tailed and level of significance was set to be at <0.005. Budget impact analysis was performed keeping in view all the recommendations of International Society for Pharmacoeconomic Outcomes Research (ISPOR). [22]

RESULTS

Results have shown that that the % TBWL seemed to be higher in surgical interventions than the enteral and parenteral regimens. The cost of Bariatric Surgery was 1041.67 SAR per kg which when optimized keeping in view the total weight loss makes it the most economical regimen regardless of the overall cost of surgery which was 25000 SAR for 52 weeks. In addition, the second most effective regimen was found to be Tirzepatide with % efficacy of 10% loss of weight in comparison to the base line weight of the patients. Details about the regimen, overall cost and duration of therapy are shown in Table 1

Table 1: Pharmaco-economic outcome and its comparison with Clinical Outcomes

Intervention	Baseline Weight (kg)	Efficacy (% TBWL)	Absolute Loss (kg)	Duration (Weeks)	Total Cost (SAR)	Cost per kg (SAR)	f	p
Semaglutide	80.0	7.9%	6.32	68	6,470	1,023.73	42.2	<0.001
Liraglutide	80.0	5.3%	4.24	56	12,423	2,929.95		
Tirzepatide	80.0	10.0%	8.00	52	16,398	2,049.75		
Bariatric Surgery	80.0	30.0%	24.00	52	25,000	1,041.67		

Further analysis was undertaken to estimate the association of the modality's vs weight loss. It was seen that surgical interventions were proven to be the most effective modalities with higher success rate in response to ever diem spend (p=<0.001). However, in the case when budgetary constraints are there for that specific group of population Semaglutide serves as the effective pharmacotherapy methods in terms of value for money. Thus, posing an idea to the stakeholders to optimize healthcare funding and place a larger share for Semaglutide/Tirzepatide compared to the least cost-effective regimens like Liraglutide. Details are described in Table 2

Table 2: Significant Modalities for the Management of Obesity

Modality	Observed Success (≥5%)	Expected Success	Residual	p-value
Semaglutide	24	24.25	-0.25	0.007
Liraglutide	16	24.25	-8.25	>0.05
Tirzepatide	27	24.25	+2.75	>0.05
Bariatric Surgery	30	24.25	+5.75	>0.05

ICER estimation for treatment modalities

ICER analysis was performed to identify the most expensive and least effective regimen. Analysis has revealed that the ICER for **Tirzepatide vs. Semaglutide** was 5,909 / kg, while for **Liraglutide vs. Semaglutide** the effect was not desirable and no decline in weight was observed in this case **Liraglutide** found to be the most expensive and least effective regimen. Though the direct cost of surgery was found to be the highest, it remained the most cost-effective modality for the management of obesity among patients. Details are shown in Table 3

Table 3: Incremental Cost-effective ratio (ICER) for the intervention use for the management of Obesity in Saudi Arabia

Comparison	Cost	Effect	ICER / kg in SAR	Interpretation
Tirzepatide vs. Semaglutide	SAR 9,928	1.68 kg	5,909 / kg	Moderately high cost for marginal gain

Liraglutide vs. Semaglutide	SAR 5,953	-2.08 kg	Dominated	Inefficient (Higher cost, lower effect)
Surgery vs. Semaglutide	SAR 18,530	17.68 kg	1,048 / kg	Highly Cost-Effective

Budget impact analysis

Keeping in view of the ICER, budget impact analysis was performed for next 5 years. It was revealed that the yearly cost for Semaglutide will be 6.47 million SAR, which is cheapest among all the three pharmacotherapy options in terms of annual financial burden. While in terms of 5 years budget impact Tirzepatide was the highest, followed by Liraglutide and Semaglutide emerged as the most affordable regimen. For surgical intervention the upfront impact of Bariatric Surgery was 26.25 million SAR. Details are shown in Table 4.

Table 4: Projection for the 5yrs Budget Impact for 1000 patients

Intervention	Year 1 Cost (SAR)	Years 2–5 (Maint.)	Total 5-Year Impact	System Cost Rank
Semaglutide	6.47 Million	3.23 Million*	**9.70 Million**	1 (Most Affordable)
Liraglutide	12.42 Million	6.21 Million	**18.63 Million**	3
Tirzepatide	16.39 Million	8.19 Million	**24.58 Million**	4 (Highest Impact)
Bariatric Surgery	25.00 Million	1.25 Million**	**26.25 Million**	5 (High Upfront)

Discussion

Obesity is one of the main health challenges to the Saudi population.[23, 24] Healthcare coverage and equality in treatment acess and affordability are some challenges that may hinder the fair acess and delivery of quality care to the residents. This research is unique in many ways; this is perhaps the first exploratory research to look in to cost effectiveness of the available therapies. Secondly, this research is first of its kind that is exploring the budget impact analysis using ICER so that the Saudi health care authorities can better justify the budget allocation for the modalities for the management of obesity.

This analysis has revealed that among the non-invasive options Semaglutide dominates Liraglutide as the incremental reduction in the base line body weight was 2.08 kg which has resulted in reduction of cost by 5953.00 SAR. [25, 26] It is debated and supported by the literature that weekly GLP-1 is remarkable breakthrough and its availability for the Saudi population shall be economically rationale. Especially in the case of Liraglutide, which is found to be least effective if compared to spending on its purchase therefore a fraction of these funds can prioritize in Saudi health care setting.[6, 8, 27-29]

Budget impact analysis revealed that in the Saudi context Tirzepatide displayed at highest 5-year budget impact relative to Semaglutide. These findings may be contradictory to other studies reporting tirzepatide superiority on the clinical effect. [30] However, this study is primality concluding this based on the ICER and clinical effect of Tirzepatide among the group of patients without comorbidities. Though for this study extension data is lacking to draw a more solid conclusion. Nevertheless, these results open a new direction for new cost effectiveness study to prove the benefit of Tirzepatide compared to Semaglutide.

Another important aspect is the financial impact of surgical interventions among the selected group of patients who are willing to pay for it. It is observed that upfront capital investment for surgical interventions was about 25 million for a 5-year budget impact. However, upon completion of this procedure there is a maintenance cost which is due to the continuous pharmacotherapy to keep the weight managed in the desired threshold. In addition, surgical interventions are proven to be more cost effective for younger patients with Class III obesity or those with higher cardiovascular or

metabolic complications.[31, 32] In this specific case surgical intervention results in immediate clinical benefit i.e. by reducing morbidity / mortality and long-term cost saving for the additional pharmacotherapy.[32] It is important and timely to discuss the burden of obesity and its associated complication in Saudi Arabia. Timely national level interventions under the leadership of Ministry of Health (MOH) are need of hour so that Saudi vision 2030 can be implemented where cost effectiveness of the therapeutic interventions is one of the main aspects in the optimizing health care services in the kingdom.[21, 33]

Conclusion

This economic model further magnifies the cost effectiveness related metric of regimens used in the management of obesity. As unit cost is often a deceiving tool, therefore assessing and ensuring the spending based on the real effect is the prime tool for ensuring an outcome-based decision for the finances allocated by the stakeholders. There are few recommendations from this analysis for the policy makers ; one Liraglutide may be a least cost-effective regimen in Saudi setting when compared to Semaglutide. Switching the spending to Semaglutide is timely move to implement so that cost effective spending can be ensured where Semaglutide reduces the budget by SAR 5,953 for every patient with a clinical reduction of weight of 2 kg. Secondly Semaglutide remained to be the cost-effective non-invasive procedure with an ICER of 1048 SAR/kg relative to surgical intervention, however when patients need surgical intervention i.e. Bariatric Surgery where the main aim is immediate reduction in weight for high-risk patients the 5-year burden on the national health budget will be 26.25 million SAR. Thirdly the most important aspect this analysis has revealed is the willingness to pay, which is very important in the context of the budget impact analysis. If it is assumed that Saudi population struggling with obesity is willing to pay 2000 SAR per kg lost, then in this case both Semaglutide and Surgery are considered "High Value and Tirzepatide which is superior in comparison to Liraglutide, may require potential price negotiation to reach parity with Semaglutide

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