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LITERATURE REVIEW: Cost-Effective Analysis of Sitagliptin for the Treatment of Diabetes Mellitus Type 2

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Abstract: Diabetes mellitus (DM) is a chronic disease characterized by increased glucose levels in the blood. The prevalence of type 2 DM is currently increasing. In pharmacological treatment, metformin is the first-line oral therapy for most patients with type 2 diabetes. Therapy with targeted incretin has been shown to stimulate glucose-dependent insulin secretion, reduce glucagon secretion, improve beta cell function, slow gastric emptying, increase satiety, reduce appetite, and provide general benefits beyond the pancreas. Search for scientific articles by utilizing internet searches through Google Scholar and PubMed. Using keywords related to "Cost Effective Analysis", "Diabetes Mellitus type 2", "Sitagliptin" with the Boolean operator "AND". Sitagliptin is less cost-effective when compared to liraglutide. Sitagliptin is the first agent of the DPP-4 inhibitor with other substances following soon after. The evaluation shows that the prevention of complications in patients with type 2 diabetes and cardiovascular disease (CVD) in the SGLT2 inhibitor group is more recommended, namely empagliflozin as the second line compared to sitagliptin.

Keywords: Cost effective analysis, Diabetes Mellitus, Sitagliptin

INTRODUCTION

Diabetes mellitus (DM) is a chronic disease characterized by increased glucose levels in blood. The prevalence of DM type 2 is currently increasing. Based data from the International Diabetes Federation (IDF), the number of diabetics in the world in 2021 will reach 537 million. This figure is predicted to continue to increase to 643 million in 2030 and 783 million in 2045. According to the IDF, Indonesia ranks fifth globally in terms of the highest number of diabetes sufferers, with 19.5 million in 2021, and is predicted to reach 28.6 million in 2045 (IDF, 2021)

In recent years, type 2 DM has resulted in significant expenditures in health system budgets. In 2013, DM type 2 was responsible for approximately 4.6 million deaths and placed a financial strain of around $500 billion on global healthcare systems. The most representative share of the costs caused by this disease are hospitalization costs, medications, and medical supplies, representing 50% and 12% of expenses, respectively. In addition to the cost of treatment, data shows that 11% of the cost of treatment for type 2 DM patients is used for the treatment of disease complications (Cazarim et al., 2017a). This complication is closely related to hyperglycemia due to insulin resistance in peripheral tissues, insulin deficiency due to insufficient pancreas to excrete, and hepatic glucose that comes out excessively, if not controlled, it can result in microvascular or macrovascular complications (Garber, 2010)

Treatment that is started early on can postpone the development of problems. Both pharmaceutical and non-pharmacological treatments are used to treat diabetes mellitus. For the majority of individuals with DM type 2 undergoing pharmaceutical treatment, metformin is the initial oral medicine recommended. However,

most patients need extra therapy to maintain glycemic control since the condition is progressive and causes a gradual reduction in beta cell function. Often used second-line oral antidiabetic medications are thiazolidinediones and sulfonylureas. Although this treatment is beneficial in establishing glycemic control, it raises the risk of hypoglycemia episodes, weight gain, and cardiovascular problems (Pérez et al., 2015a).

Blood glucose regulation is currently being studied using a variety of innovative therapies that specifically target the hormone incretin (Drucker & Nauck, 2006). In addition to promoting glucose-dependent insulin secretion, targeted incretin therapy has been shown to enhance beta cell function, reduce glucagon release, increase satiety, reduce appetite, and slow stomach emptying. Dipeptidyl peptidase-4 (DPP-4) inhibitors, such as saxagliptin and sitagliptin, prevent the DPP-4 enzyme from deactivating incretin hormones. GLP-1 receptor agonists, on the other side, simulate the effects of endogenous GLP-1. These two types of incretin medications have been developed. GLP-1 receptor agonists are linked with weight reduction, whereas DPP-4 inhibitors are only associated with preventing weight gain (Pérez et al., 2015b)

METHODS

Search for scientific articles by utilizing internet searches through Google Scholar and PubMed. Using keywords related to "Cost Effective Analysis", "Diabetes Mellitus type 2", "Sitagliptin" with Boolean operator "AND". Articles were identified through a database of 41 articles from PubMed with a research period of 2004-2024 and 16,100 articles from Google Scholar in the research period of 2004-2024. Data processing based on predetermined inclusion criteria, namely a research topic related to the Cost-effective analysis of Sitagliptin in Diabetes Mellitus type 2 by writing articles in Indonesian and English. Based on the inclusion criteria, 12 articles were obtained that had the most relevant topics. The results of the literature review are then explained in Table 1.

RESULT AND DISCUSSION

Based on a review of 12 articles, sitagliptin is less *cost-effective* when compared to liraglutide. Liraglutide is a drug with a class of GLP-1 agonists and glucose-dependent insulinotropic polypeptides (GIPs), both of which are incretin hormones inactivated by dipeptidyl peptidase-4 (DPP-4), stimulating insulin secretion after oral glucose administration through the effects of incretin. GLP-1 receptor agonists can decrease the apoptosis of pancreatic β cells while increasing their proliferation.

A class I oral antidiabetic medication called sitagliptin is being used more often to treat DM type 2. It was the first DPP-4 inhibitor medicine to be released in 2006, and other drugs were soon to follow. The drugs sitagliptin, linagliptin, vildagliptin, saxagliptin, and alogliptin are the most commonly used ones. DPP-4 inhibitors are included in numerous national and international guidelines for DM type 2 management. The DPP-4 inhibitor class is indicated for usage in patients whose metformin monotherapy is not providing satisfactory control. Patients on this combination of treatment can safely use a number of fixed-dose combinations of DPP-4 inhibitors and metformin, particularly when lowering the daily pill dose (Gallwitz, 2019)

Previous studies have tested the drug as an add-on drug after the use of metformin has not produced a therapeutic effect. Extended use of once-daily doses of 1.2 mg and 1.8 mg of liraglutide demonstrated enhanced improvements in life expectancy and quality-adjusted life expectancy, along with a decrease in the occurrence of diabetes-related complications compared to daily doses of sitagliptin 100 mg or exenatide 10 µg administered twice daily. (Tzanetakos et al., 2014c) .However, when compared with the glp-1 agonist group, sitagliptin is easier to use because it is taken orally. Currently, the dosage form is combined with metformin.

Based on the study, it is advised that individuals with DM type 2 and cardiovascular disease (CVD) take empagliflozin as their second line of treatment instead of sitagliptin to prevent complications. In the total T2D population, the second-line empagliflozin versus sitagliptin incremental cost-effectiveness ratio (ICER) was $6967/QALY. Comparing empagliflozin to sitagliptin, individuals with CVD experienced an 11% decrease in mortality and a longer CVD-free life of 0.07 years. Patients with first CVD benefited more from

empagliflozin at a higher cost than those without; as a result, their ICER was $3589/QALY as opposed to $12,577/QALY (Reifsnider et al., 2021b).

Table 1. The Results Of The Analysis In 12 Scientific Articles

Author & year	Method	Sample	Result
(Tzanetakos et al., 2014a)	The method used is a prospective cohort with initial data being a randomized clinical trial	1860 Study Group which is for patients who are already using metformin and liraglutide monotherapy and sitagliptin are used as adjunct therapy.	Liraglutide with sitagliptin comparison. Liraglutide was better, increasing life expectancy by an average of 0.13 years (SD 0.23) and 0.19 QALY (0.16) in quality-adjusted life expectancy. It also showed a positive correlation with Additionally, liraglutide has a reduced incidence of long-term side effects, such as amputation, myocardial infarction, and stroke (17.16%, 8.79%, and 10.06%, compared to 17.83%, 9.24%, and 10.54%, respectively, for sitagliptin). The cost of drug acquisition, which accounts for Liraglutide (38.13%) and Sitagliptin (30.60%) of the total cost, respectively, is the largest component of the lifetime direct cost for the liraglutide and sitagliptin treatment groups. The cost of treating ulcers, amputations, and neuropathy, which includes Liraglutide (16.86%) and Sitagliptin (19.42%), is the second largest. In light of the previously stated health effects and expenses, an ICER of €15,101 per QALY obtained is estimated for liraglutide.
(Vidal et al., 2020)	The method used was a double randomized test for 56 weeks by comparing semaglutide 0.5 mg and 1 mg with sitagliptin 100 mg	Samples taken based on clinical trials, in patients with DM type 2 who are not controlled with the use of metformin, pioglitazone, rosiglitazone, or a combination of metformin and pioglitazone or metformin and rosiglitazone as many as 1225	Semaglutide 1 mg had results with comparable or lower control costs compared to sitagliptin considering the effects of hypoglycemia and weight loss along with glycemic control. Semaglutide 0.5 mg has a lower cost of control considering the HbA1c reduction endpoint ≥ 1.0% with a weight loss ≥ 5.0%.
(Brown et al., 2014)	Comparison of insulin glargine and sitagliptin using a randomized trial with an open trial. .	Patients with DM type 2 aged 35 to 70 years, with an average duration of 4.5 years, and HbA1c levels between 7% and 11%, comprised the sample used in the EASIE experiment. Some respondents in this publication reported experiencing diabetes-related complications such as myocardial infarction, angina, coronary artery disease, heart failure, stroke, transient ischemic attack, peripheral vascular disease, diabetic	With a $1434 cost savings and a quality-adjusted life year (QALY) of 0.08 years per patient over a 50-year period, insulin glargine is more economical than sitagliptin. When compared to sitagliptin, insulin glargine produces a higher reduction in HbA1c and may lead to a reduction in problems connected to diabetes. Diabetes-related problems may take longer to manifest when taking insulin glargine. The quality of life (15,006 vs 14,830) and life expectancy (19,784 years vs 19,567 years) increased as a result

		neuropathy, nephropathy, and retinopathy.	of delaying these problems. Additionally, insulin glargine reduced costs by 1% for consequences related to cardiovascular disease, 5% for complications related to kidneys, 3% for difficulties related to neuropathy, and 2% for complications associated to retinopathy. However, insulin glargine is more expensive per patient to treat hypoglycemia due to higher levels of the condition; sitagliptin costs $17 per patient, but insulin glargine costs $50.
(Cazarim et al., 2017b)	The retrospective study with the collection of data originated from the legalization of the health sector in the city of Divinópolis, in the state of Minas Gerais (MG), Brazil in 2013. Effectiveness.	29 T2DM patients that received at least one DPP-4 Inhibitor medication from PHS through legal actions between January and December 2013.	Abdominal pain is the most cost-effective adverse medication reaction associated with the use of dpp-4 inhibitors; it is projected to cost US$ 731.84 and may arise during sitagliptin and vildagliptin treatment. Sitagliptin, on the other hand, has the lowest cost per patient/year when taking into account the entire cost of treating all potential ADRs of each class of dpp-4 inhibitors, with an estimated cost of US$ 1,142.16. With a CER of US$ 1,497.01, sitagliptin in combination with metformin is the DPP-4 inhibitor with the best ratio when considering the drug's cost-effectiveness. At US$ 4,566.91, or three times more than the gliptin with the lowest CER (sitagliptin plus metformin), linagliptin is the gliptin with the greatest CER. The best dpp-4 inhibitor for reducing A1c is sitagliptin in combination with metformin; this is crucial for managing DM type 2 and reducing chronic consequences.
(Reifsnider et al., 2021a)	Individual simulation models were used to project lifelong diabetes-related complications. The UKPDS-OM2 equation was employed for patients without cardiovascular disease (CVD), while the EMPA-REG OUTCOME equation was utilized for those with CVD.	A group of 5000 patients who shared the same basic individual characteristics.	In the whole population with DM type 2, the incremental cost-effectiveness ratio (ICER) of empagliflozin as a second-line therapy compared to sitagliptin was $6,967 every quality-adjusted life year (QALY). Compared to sitagliptin, empagliflozin has been related to an 11% decrease in cardiovascular mortality among individuals with CVD and a longer duration of CVD-free survival (0.07 years). Empagliflozin showed higher costs but more benefits to patients with first CVD than to those without; the ICER is $3,589/QALY for the former group and $12,577/QALY

			for the latter. Empagliflozin, thus, is cost-effective than sitagliptin (up to a $50,000/QALY threshold in the US) when used as a second-line treatment for individuals with DM type 2 after metformin monotherapy of the presence of cardiovascular disease.
(Neslusan et al., 2015)	Cohort prospective	The entire population totaled 1284 and the Latin American sample of 240 was divided into three groups using canagliflozin 300mg, canagliflozin 100mg and sitagliptin 100mg added to metformin.	Canagliflozin at dosages of 300 mg and 100 mg over a 20-year period generated an additional benefit of 0.16 and 0.06 years of quality-adjusted life (QALY) in comparison to 100 mg of sitagliptin. Comparing canagliflozin 300 mg and 100 mg to sitagliptin 100 mg, the average cost differences were 1797 Mexican pesos (US$134) and 7262 Mexican pesos (US$540), consequently The resulting outcome was a cost per QALY gained of US$9,590 (or 11,210 Mexican pesos) and US$834, and 128,883 Mexican pesos. These two cost-effectiveness ratios are less than what Mexico considers to be cost-effective. Sensitivity analysis adds further weight to the main result that, in Mexico, canagliflozin is cost-effective than sitagliptin.
(Tzanetakos et al., 2014b)	The method used was a prospective cohort for 5 years	Based on clinical trial data, 1000 non-identical patients were obtained	Liraglutide increased quality-adjusted mean life expectancy by 0.13 years (SD 0.23) and 0.19 QALYs (0.16) in comparison to sitagliptin. It also showed a positive correlation with higher lifetime health expenditure (€2797 [SD 1468]). Furthermore, compared to sitagliptin (17.83%, 9.24%, and 10.54%), liraglutide users had a decreased incidence of long-term problems such myocardial infarction, stroke, and amputation (17.16%, 8.79%, and 10.06%). The cost of purchasing medications is known as the "direct lifetime cost," of which sitagliptin and liraglutide account for 38.13% and 30.60% of the overall cost, respectively. The second-largest component of the cost is made up of unpaid bills for neuropathy, ulcers, and amputations (16.86%) and 19.42%, respectively. Liraglutide is expected to have an ICER of €15101 per QALY based on the health outcomes and expenses described above. With a willingness threshold of €30,000 per QALY achieved, the probability

			of liraglutide 1.2 mg being a financially advantageous therapeutic choice is greater than 70% (72.5%).
(Langer et al., 2013)	52-week randomized and controlled trial	665 samples with adults with DM type 2 who failed with metformin monotherapy. Randomized will be grouped by receiving additional therapy of liraglutide 1.2 mg, liraglutide 1.8 mg, or sitagliptin 100 mg daily, in addition to metformin.	Overall pharmacy expenses, including syringe costs, are greater for patients using liraglutide compared to those using sitagliptin. The cost per patient achieving an HbA1c level below 7% was lowest among those receiving liraglutide 1.2 mg ($7,993) and highest among those receiving sitagliptin ($11,570). When considering the average cost per patient achieving the HbA1c target without experiencing hypoglycemia or weight gain (cost of control), the use of liraglutide was significantly less expensive compared to sitagliptin. The annual average control cost was $10,335 for liraglutide 1.2 mg and $11,755 for liraglutide 1.8 mg versus $16,858 for sitagliptin.
(Martín et al., 2020)	Prospective cohorts	The sample was 1225 and divided into 3 groups, namely semaglutide 0.5 mg, semaglutide 1 mg and sitagliptin 100 mg	Compared to sitagliptin, semaglutide once weekly of 0.5 mg and 1 mg was associated with an increase in life expectancy of 0.17 and 0.24 years and quality-adjusted life expectancy of 0.16 and 0.23 QALYs, respectively. Avoidable complications result in semaglutide 0.5 mg and 1 mg once a week which is cost-effective compared to 100 mg sitagliptin from a healthcare payer's point of view.
(Mezquita Raya et al., 2013)	Randomized controlled trials	The study included individuals aged 18-80 years diagnosed with DM type 2 mellitus who had poorly controlled blood sugar levels (HbA1c between 7.5% and 10.0%) despite taking metformin (at least 1,500 mg daily for at least 3 months). 225 patients were randomly allocated to receive either 1.2 mg of liraglutide administered subcutaneously once daily and 219 patients receive 100 mg of sitagliptin taken orally once daily at various locations across Europe and North America.	Comparing liraglitide to sitagliptin, there was a lower increase in life expectancy (14.05 against 13.91 years) and quality-adjusted life expectancy (QALYs) [9.04 versus 8.87 QALYs]. Better glycemic management contributed to a reduction in the incidence of diabetes-related complications, such as renal disease, cardiovascular disease, and diabetic foot and ocular problems, which in turn improved clinical outcomes. Compared to sitagliptin, ligarglutide resulted in an increased cost-effectiveness ratio of EUR 13,266 per QALY due to an increase in direct costs of EUR 2,297.
(Gu et al., 2024)	56-week randomized, double-blind, and double-blinded trials	A randomization process was used to assign sixty-eight patients with DM type 2, whose	Patients in the semaglutide group (0.5 mg and 1 mg once a week) projected decreased rates of most

		average age was 53.1 years, and who were not receiving enough metformin control, to receive either 100 mg of sitagliptin or 0.5 mg of semaglutide once weekly. Years of life (QALYs) and quality-adjusted costs (QALYs) are estimated with a 5% discount rate from the viewpoint of the healthcare system. To evaluate for uncertainty, three types of sensitivity analyses were conducted: probabilistic, scenario, and univariate.	vascular problems, death, and hypoglycemia, as well as a lower overall cost when compared to the sitagliptin group, based on their lifetime forecasts. Semaglutide 0.5 mg once weekly resulted in a slight gain in quality-adjusted life years (QALYs) of 0.08 and a lower cost of $5173 for individual patients when compared to sitagliptin; semaglutide 1 mg once weekly resulted in an additional QALY benefit of 0.12 and a lower cost of $7142, in addition to metformin. Consequently, semaglutide at both doses once a week is thought to be superior to sitagliptin in terms of QALY benefits at a lower cost.
(Eliasson et al., 2022)	Prospective cohorts	At the start of the simulation, patients who did not have their condition managed with metformin or metformin ± sulfonylurea began a new treatment regimen. This treatment involved either oral semaglutide (with a dosage increased to 14 mg once daily) or empagliflozin (25 mg once daily) as outlined in PIONEER 2, or a gradual increase in dosage (starting at 100 mg once daily) of oral semaglutide or sitagliptin as described	Comparing oral semaglutide to sitagliptin (SEK1,405,789 vs. 1,377,381) and empagliflozin (Swedish Krona [SEK] 1,245,570 vs. 1,210,172), the total lifetime cost is higher due to the higher treatment costs. When comparing with empagliflozin and sitagliptin, oral semaglutide has shown a higher incremental cost-effectiveness ratio (ICER) of SEK239,001 per quality-adjusted life year (QALY) and SEK120,848 per QALY, respectively, from the payer's viewpoint. From a societal perspective, the ICER was lower at SEK191,721 per QALY compared to empagliflozin and SEK95,234 per QALY compared to sitagliptin.

CONCLUSION

Sitagliptin which is a dpp 4 inhibitor is not more cost effective compared to the glp-1 agonist and sglt-2 inhibitors in the treatment of diabetes and in preventing complications. However, sitagliptin is an oral therapy that can be used together with metformin to treat uncontrolled DM type 2 when using metformin monotherapy.

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