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Trelagliptin Path: From regulatory setbacks in the west to approval in India

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Abstract

Diabetes mellitus represents a substantial socioeconomic burden and has a profound effect on daily living and productivity. Dipeptidyl peptidase-4 (DPP-4) inhibitors are frequently employed in the management of type 2 diabetes, where maintaining long-term glycemic control is vital to prevent or delay macrovascular and microvascular complications. Medication adherence is a crucial element of effective type 2 diabetes management, and minimizing dosing frequency can alleviate the treatment burden and improve patient adherence. The once-weekly administration of trelagliptin, a DPP-4 inhibitor, offers a promising therapeutic strategy, as reduced dosing schedules are often preferred by patients and clinicians. Therefore, trelagliptin can provide new avenues and research areas for the future. This article aims to review the trelagliptin as a once weekly treatment option in patient of type 2 diabetes mellitus However, more research, including clinical trials, should be done to further evaluate this.

Keywords: Trelagliptin; Dipeptidyl Peptidase-4 (DPP-4) Inhibitors; Diabetes Mellitus; Hyperglycemia; CDSCO

1. Introduction

Diabetes mellitus is a significant world health problem.[1] According to the 9th edition of the International Diabetes Federation (IDF) Diabetes Report, diabetes has the highest age-standardized prevalence of diabetes in 2019 and expected to rise by 2045. Diabetes mellitus contributes to 1 in every 9 deaths among individuals who are aged between 20 to 79 years. The increasing prevalence of type 2 diabetes mellitus contributed by various factors. It includes sedentary lifestyle habits, obesity, epigenetic factors, inadequate access to proper healthcare and many behavioural and environmental risk factors.[2] It affects people of all age groups and belonging to all demographic and socio-economic background nearly in all the countries of world. Diabetes mellitus follows iceberg phenomenon. This phenomenon explains that number of documented cases denotes only just a small portion of a disease or health condition is visible or diagnosed, while a much larger, undetected portion remains hidden below the surface.[3] It is similar to how most of an iceberg is hidden underwater which signifies unidentified cases.

Diabetes mellitus is characterised by heterogeneous metabolic disorder i.e. associated with wide ranging pathogenic mechanism that leads to chronic hyperglycaemia. It is caused by either a disturbed insulin secretion or a disturbed insulin effect.[4] Prolonged hyperglycaemic state leads to various signs and symptoms which are discussed later and triggers various complications throughout the body. Complications associated can be microvascular or macrovascular which can severely reduce patients' life quality and life expectancy.[5] The main sign and symptoms includes hyperglycaemia, polyuria (increase urination), polyphagia (increase hunger), polydipsia (increase thirst), sometimes weight loss, limb pains, impaired vision, constipation.[6] Diabetes mellitus is mainly divided into two types. Type 1 Diabetes mellitus also called as insulin dependent diabetes mellitus (IDDM) or juvenile onset diabetes. The basic mechanism underlying is autoimmune β-cell dysfunction and depletion leading to insulin deficiency. More than 90% insulin producing cells of the pancreas are permanently destroyed. Etiological factors associated are environmental or

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infectious agents, genetic alterations and generally non obese patients.[7] Type -II diabetes mellitus also called as non-insulin dependent diabetes mellitus (NIDDM) or adult-onset diabetes. The basic mechanism states that the body develops resistance to the effects of insulin. Due to resistance, there is not enough insulin to meet the body's needs i.e. low amounts of insulin production from pancreatic β-cells and peripheral insulin resistance. Etiological factors associated are obesity, sedentary lifestyle, family history, age and metabolic syndrome.[8] There is progressive loss of renal function in diabetic patients who are obese and leads to chronic kidney disease (CKD) and stage wise alternation. Some studies suggest renoprotective effects via various mechanism of GLP-1 receptor agonists.[9] Decreased visual acuity and blindness due to diabetic retinopathy in which GLP-1 agonist seems to prevent this by reversing and preventing early changes.[10]

Various drugs with various mechanism of action are available and some are under trials. The treatment is challenging in patients of diabetes mellitus, because no permanent cure is available because of many shortcomings some of which are suboptimal glycaemic control, adherence to medication is not probable. Broad category of anti-diabetic drugs includes: biguanides (e.g. metformin) reduce liver gluconeogenesis, insulin secretagogues (e.g. sulfonylureas) leads to insulin secretion by stimulating pancreas, insulin sensitizers (e.g. thiazolidinediones) improves peripheral tissues insulin sensitivity, insulin or its analogues in which insulin is given exogenously as recombinant insulin.[11] After food intake secretion of hormones takes place in moments, named Incretin. Incretins secreted from intestine which leads to postprandial glucose stabilization due to pancreatic β-cells stimulation.[12] Incretins reduce glucagon concentrations, improve insulin sensitivity, decreased free fatty acid concentrations and protects cardiovascular system.[13] Glucagon-like peptide-1 (GLP-1) and Glucose-dependent insulinotropic polypeptide (GIP) are the incretins. If diabetic subjects has to be given GlP-1 by intravenously it will promotes insulin secretion and suppresses glucagon release., reduces food intake, delays gastric emptying, fasting and postprandial insulin secretion normalization.[14]

1.1. Glucagon-like peptide-1 (GLP-1)

GLP-1 doesn't last long in the bloodstream. Its duration is less than 2 minutes because it gets broken down by DPP-IV and many other enzymes. To keep it active longer and support insulin release, incretin-based therapies use either DPP-IV inhibitors or modified GLP-1 receptor agonists. Some well-known DPP-IV inhibitors include sitagliptin, saxagliptin, alogliptin, vildagliptin, and linagliptin. These drugs are generally safe with only a few side effects. Interestingly, DPP-IV, also called T-cell activation antigen CD26, is one of the main enzymes responsible for breaking down GLP-1.[15]

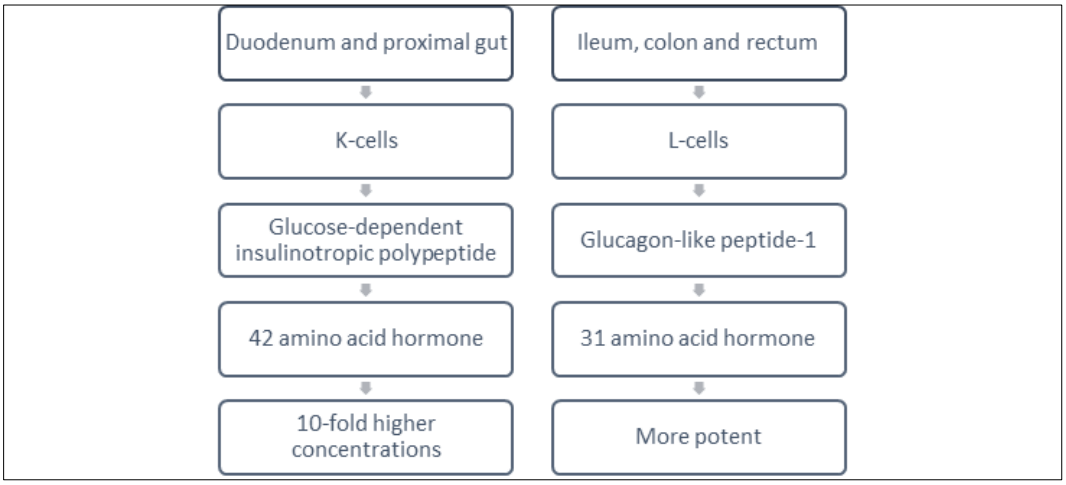

Figure 1 GLP-1 and GIP secretion process

1.2. Dipeptidyl peptidase-4 (DPP-4) inhibitors

Dipeptidyl peptidase-4 (DPP-4) serves multiple physiological roles. It includes proteolytic activity in conjunction with adenosine deaminase (ADA), extracellular matrix interactions, coreceptor-mediated viral entry, and intracellular signalling influencing cell proliferation and migration. The therapeutic inhibition of DPP-4 is a promising approach for metabolic disorders. DPP-4 is responsible for degrading incretin hormones GLP-1 and GIP whose plasma concentrations are lower in fasting states and rise after meals.[16] By blocking DPP-4 inhibitors prolong active GLP-1 availability, thereby enhancing glucose-dependent insulin secretion and suppressing glucagon release.[17] These effects contribute to glycaemic control without hypoglycaemia risk.[18] Furthermore, DPP-4 inhibitors are weight-neutral, well tolerated, and offer prolonged efficacy compared to conventional antidiabetic treatments.[19]

Sitagliptin was discovered as the first DPP-4 inhibitor. It was approved in Japan in December 2009, which was followed by alogliptin in April 2010. Unlike the earlier DPP-4 inhibitors that needed to be taken daily, trelagliptin, introduced in Japan in 2015, is a once-weekly.[20] Trelagliptin sold under the brand name Zafatek® by Takeda Pharmaceutical Company. Chemically, trelagliptin is defined as 2-[[6-[(3R)-3-aminopiperidin-1-yl]-3-methyl-2,4-dioxopyrimidin-1-yl]methyl]-4-fluorobenzonitrile; butane dioic acid, with a molecular formula of $C_{22}H_{26}FN_5O_6$ and a molecular weight of 475.5 g/mol.[21]As a recently developed DPP-4 inhibitor, trelagliptin offers the advantage of once-weekly dosing while maintaining sustained efficacy in type 2 diabetic patients. Kinetic evaluations have characterized it as a reversible inhibitor that competes with the substrate and exhibits slow-binding kinetics, exhibiting a dissociation half-life of 30 minutes. Additionally, X-ray diffraction analysis has revealed that trelagliptin forms a non-covalent interaction with the DPP-4 enzyme.[22] Trelagliptin sustains its DPP-4 inhibitory activity for up to 168 hours post-dose. As a weekly therapy, it maintains efficacy and safety while reducing dosing frequency. This reduction in medication burden may alleviate psychological stress promote adherence, and enhance overall patient satisfaction with treatment.[23]

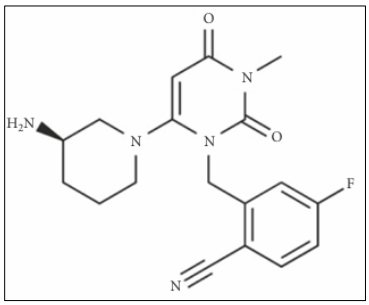

Figure 2 Chemical structure of trelagliptin[24]

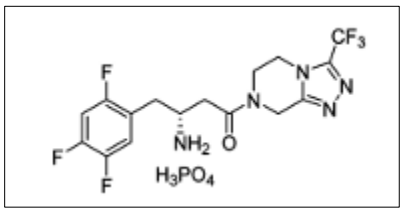

Figure 3 Chemical structure of sitagliptin[25]

Trelagliptin regulates the PI3K/Akt/GLUT4 insulin signalling pathway to improve insulin resistance and has been observed to restore cognitive deficits in diabetic rats, particularly in spatial learning and memory. Additional findings indicate that it suppresses inflammation by downregulating IL-1β, TNF-α, IL-6, NF-κB, and the p-IKKα/IKKα ratio. Furthermore, it prevents neuronal atrophy, enhances synaptic plasticity and aids in dendritic spine recovery. There is facilitation of the PI3K/Akt/GSK-3β pathway during this process further highlights its therapeutic potential for cognitive impairment.[26] By blocking DPP4, trelagliptin helps maintain higher levels of active GLP-1 and GIP in the blood. These hormones boost Insulin release induced by glucose. and in the case of GLP-1, helps lower glucagon levels making trelagliptin effective for diabetes treatment. Additionally, DPP4 inhibitors may protect beta-cells by lengthening their telomeres. Activation of the GLP-1 receptor further supports beta-cell health by enhancing their function, encouraging growth and reducing cell death. These benefits may continue to build over long-term trelagliptin use.[27]

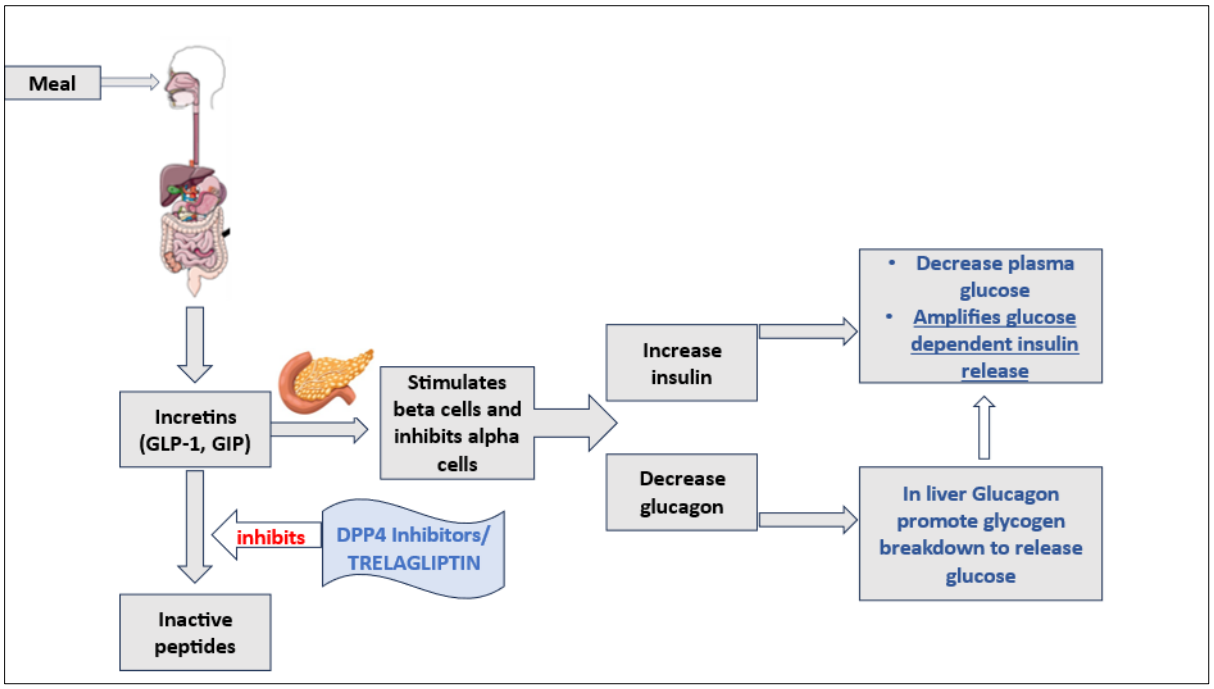

Figure 4 Mechanism of action of dpp4 inhibitors

Trelagliptin undergoes primary metabolism via the CYP2D6 enzyme leading to the formation of M-1, its sole active metabolite, while CYP3A4 contributes minimally to the generation of other metabolites. Despite its activity, M-1 constitutes less than 1% of the total drug concentration in plasma. Trelagliptin has an extended terminal half-life of 54 hours and is predominantly excreted through the renal pathway with a cumulative urinary excretion rate of a pproximately 76.6% in humans.[28]

Table 1 Comparative evaluation of Trelagliptin with other drugs

Comparison group and clinical trials	Study design	Objectives	Population	Intervention	Conclusion
Trelagliptin monotherapy or combination with an existing oral antidiabetic drug[29] ClinicalTrials.gov NCT01431807	A 52-week open-label, phase 3 study	long-term safety and efficacy of Trelagliptin 100 mg	680 patients with type 2 diabetes mellitus	Trelagliptin monotherapy or combination with a sulfonylurea, a glinide, an a-glucosidase inhibitor, a biguanide or a thiazolidinedione	Decrease in change in HbA1c and FPG, and was well tolerated showing no major safety issues[29]
Trelagliptin vs sitagliptin[30] ClinicalTrials.gov NCT01751360	A 15 weeks open-label, phase 3 exploratory study	Efficacy and safety of trelagliptin 100 mg vs sitagliptin 50 mg	14 patients with type 2 diabetes mellitus	Trelagliptin 100 mg vs sitagliptin 50 mg	No major changes in the other efficacy parameters, such as HbA1c and FPG and showed favourable safety and tolerability profiles[30]
Trelagliptin vs Omarigliptin[31]	3 months study	Efficacy and Patient Satisfaction	80 Japanese Patients with Type 2 Diabetes	Trelagliptin 100 mg or Omarigliptin 25 mg alone or in combination with	weekly DPP-4Is (trelagliptin)was effective and safe and affected the

Trial Approval No. 720902, 720903).				other oral hypoglycaemic agents, insulin, or GLP-1 receptor agonists	patient satisfaction[31]
Trelagliptin as add on therapy to insulin [32] Clinical trials. gov NCT02324569; JAPIC JapicCTI-142734)	Phase IV, multicentre, 12-week, randomized, double-blind, placebo-controlled study, followed by a 40-week open-label extended treatment period	Safety and efficacy of trelagliptin 100 mg QW as an add-on therapy to insulin	539 patients who signed informed consent, 240 were randomized to receive treatment	8 to 40 units of insulin per day were randomized to receive, with insulin, Trelagliptin 100mg or placebo for a 12-week double-blind phase	Trelagliptin is efficacious and well-tolerated as both a long-term mono- and combination therapy could be a potential therapeutic option[32]
Trelagliptin with alogliptin [33] ClinicalTrials.gov, number NCT01632007	24 weeks Randomised, double-blind, active-controlled, parallel-group, phase 3, non-inferiority study	Efficacy and safety	357 patients enrolled; 243 patients were included in the analysis	Trelagliptin (100 mg) once per week, alogliptin (25 mg) once per day or placebo	Trelagliptin showed similar efficacy and safety to alogliptin once daily in Japanese patients with type 2 diabetes[33]
Trelagliptin Versus Daily Dipeptidyl Peptidase-4 Inhibitor[34] ClinicalTrials.gov (NCT03 014479) and JAPIC (JapicCTI-173482).	12 weeks Randomized Multicentred open-label, parallel-group, phase IV study	Evaluation of Quality of Life and Treatment Satisfaction	218 patients of Type 2 Diabetes mellitus	Trelagliptin 100 mg once weekly or once or twice daily DPP-4 inhibitor	Trelagliptin resulted in a numerically, but not statistically, greater improvement in QOL and treatment satisfaction versus daily DPP-4 inhibitors[34]

In March 2014, Takeda sought approval for trelagliptin in Japan as a treatment for T2DM. The Japanese Ministry of Health, Labour and Welfare (MHLW) granted approval in March 2015, based on positive findings from phase III clinical trials. While the drug had completed phase II trials in other regions, Takeda discontinued its development in the USA and EU in October 2014, citing the financial implications of pursuing regulatory approval.[35]

Approved dosage strengths in the form of tablets were 25, 50 and 100 mg. Trelagliptin was approved by the Central Drugs Standard Control Organization (CDSCO) in India on 26 December 2024.[36]

2. Conclusion

Trelagliptin is a novel DPP-4 inhibitor designed for once-weekly administration, demonstrating sustained efficacy in patients with type 2 diabetes mellitus. Sustained glycaemic control is essential for delaying or preventing macrovascular and microvascular complications and their impact on patients' health and quality of life. Dipeptidyl peptidase-4 inhibitors, a newer class of oral antidiabetic drugs, provide prolonged glycaemic control compared to conventional treatments. These agents are gaining prominence in type 2 diabetes mellitus treatment strategies. Their mechanism involves inhibiting DPP-4, thereby increasing levels of endogenous glucagon-like peptide-1 (GLP-1) and other hormones. Once-weekly oral trelagliptin reduces HbA1c (glycated haemoglobin) and FPG (fasting plasma glucose) levels over the long term and is generally well tolerated, with no major safety issues, in patients with type 2 diabetes

who are not well controlled by diet, exercise, or other oral diabetes medications. Since no other long-acting oral diabetes drugs are available, trelagliptin provides a valuable treatment option, especially as patients tend to prefer regimens with fewer doses, which can improve adherence. Unlike the earlier DPP-4 inhibitors that needed to be taken daily, trelagliptin, introduced in Japan in 2015, is a once-weekly. The drug approval was given by the Japanese Ministry of Health, Labour and Welfare (MHLW) in March 2015. Trelagliptin underwent phase II trials outside of Japan, but Takeda decided to halt its development in the USA and EU in October 2014, after evaluating the expenses involved in securing approval in these regions. Approved dosage strengths were 25, 50 and 100 mg tablets. Trelagliptin was approved by the Central Drugs Standard Control Organization (CDSCO) in India on 26 December 2024. However, more research including clinical trials and post marketing surveillance are required to investigate the therapeutic safety and efficacy in a larger number of patients is necessary.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest

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