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Review Article

Biosimilar insulin glargine: a solution for affordable and equitable diabetes care

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ABSTRACT

Over past decades, insulin therapy has been a cornerstone in reshaping diabetes care from a chronically morbid disease into a manageable condition. Despite availability of multiple pharmacological therapies, diabetes patients still suffer from optimum glycaemic control especially fasting hyperglycaemia which further increase the risk of developing vascular complications. Basal insulin is a choice of medication when patients require fasting blood glucose control to achieve desired glycaemic goal. With such crucial need of basal insulin therapy for controlling fasting hyperglycaemia, it remains inaccessible for majority of patients in need. This challenge is more prevalent in low- and middle-income countries where need for insulin is rising as prevalence of diabetes increases. Biosimilar insulin has arisen as an important strategy to bridge this gap. This review addresses the outline of evolution of basal insulin therapy, especially biosimilar insulin glargine as a solution to overcome fasting hyperglycaemia. One such illustration is of biosimilar insulin glargine (BASALOG®, BIOCON) for which evidence from global clinical trials and real-world studies has demonstrated its safety, efficacy and immunogenicity comparable to the reference insulin glargine available. This has further led to the approval for biosimilar insulin glargine overseas including interchangeability designation by USFDA. Further this review underlines the Indian perspective regarding biosimilar insulin glargine affordability and adoption with emphasis on patient education, cold-chain management to increase access and real-world data generation. Collectively, biosimilar insulin glargine offers a scalable and sustainable model which has potential to expand access of basal insulin therapy to patients who are in need.

Keywords: Diabetes mellitus, Biosimilar insulin glargine, Affordability, Accessibility

INTRODUCTION

The management of diabetes stands as one of the most remarkable success stories in medicine, especially with the centennial anniversary of insulin's discovery.[1] With the advent of insulin in 1921, diabetes ceased to be a terminal illness, becoming a chronic, controllable illness, and saving the lives of millions of people worldwide. Glycaemic control and quality of life in people with diabetes have been optimized over the decades through constant innovation, starting with animal extracts, recombinant human insulin, and long-acting analogues.[2] Despite such scientific progress, insulin remains unaffordable and inaccessible.[3] The existing international insulin markets have various structural impediments that restrict fair accessibility. The overall cost of insulin

remains high, which places a significant burden on the healthcare system and patients ability to purchase the treatment.[4] The concentration of supply among many multinational manufacturers leads to a lack of competition, making the market vulnerable to fluctuations in price and supply. Moreover, insufficient uptake of biosimilar insulins, despite its strong evidence of safety and efficacy, has been witnessed in most regions. These obstacles continue to widen the accessibility that persists even hundred years after the discovery of insulin. In this context, biosimilar insulin is an important innovation that should be included.[5] Biosimilars have the potential to expand treatment options for patients who were previously inaccessible. Their rise is not solely about scientific advancements but also about the change in the approach to the innovation of pharmaceuticals towards a more equitable and fair paradigm, where affordability and accessibility are part and parcel of improvement.[6] An example of such an innovation is biosimilar insulin glargine (BASALOG®, BIOCON), which has been developed because of strong local biotechnological capabilities which matches globally accepted regulatory standards. Its course reflects how the innovation of emerging markets can be used to address the long-existing disparities in the provision of vital biologic treatment.[7] This review outlines the development, clinical outcomes and adoption of biosimilar insulin glargine, as a scalable framework for equitable and affordable insulin access.

EVOLUTION OF BASAL INSULIN THERAPY

Brief historical overview

Over the years, the therapeutic environment of diabetes care has changed tremendously compared to the first clinical application of insulin in 19228. Initial preparations based on animal pancreatic extracts were lifesaving but were constrained by the short-term duration of action and intermittent absorption patterns. Injections are frequently necessary, with patients needing multiple injections every day and having high glycemic variability and risk of hypoglycaemia.[9] In the middle of the 20th century, there were progressive improvements, such as Neutral Protamine Hagedorn (NPH) insulin and lente preparations, that provided intermediate-acting profiles but were still unable to provide physiologically like basal insulin secretion.[10] A breakthrough came with the invention of recombinant DNA technology in the 1980s, which led to the replacement of extraction-based insulin with biosynthetic human insulin, which was better in terms of purity, reproducibility, and immunogenicity. However, human insulin cannot completely mimic the constant basal release of insulin by the body, especially in the fasting state or overnight. These clinical constraints have led to the creation of basal insulin analogs, which are engineered molecules that offer smoother, longer, and more predictable glucose control.[10,11]

Design logic behind insulin glargine and its advantages

The first long-acting analog specifically intended to provide a 24-hour insulin profile with a peakless profile was insulin glargine, which was launched at the turn of the 21st century. The replacement of glycine at A21 and the introduction of two arginine amino acids at B31 and B32, which are structural changes at the A and B chains, altered the isoelectric point of the molecule, making it less soluble at physiological pH (Figure1). When glargine is subcutaneously injected, it is deposited in the subdermal tissue and is released gradually and continuously into the circulation.

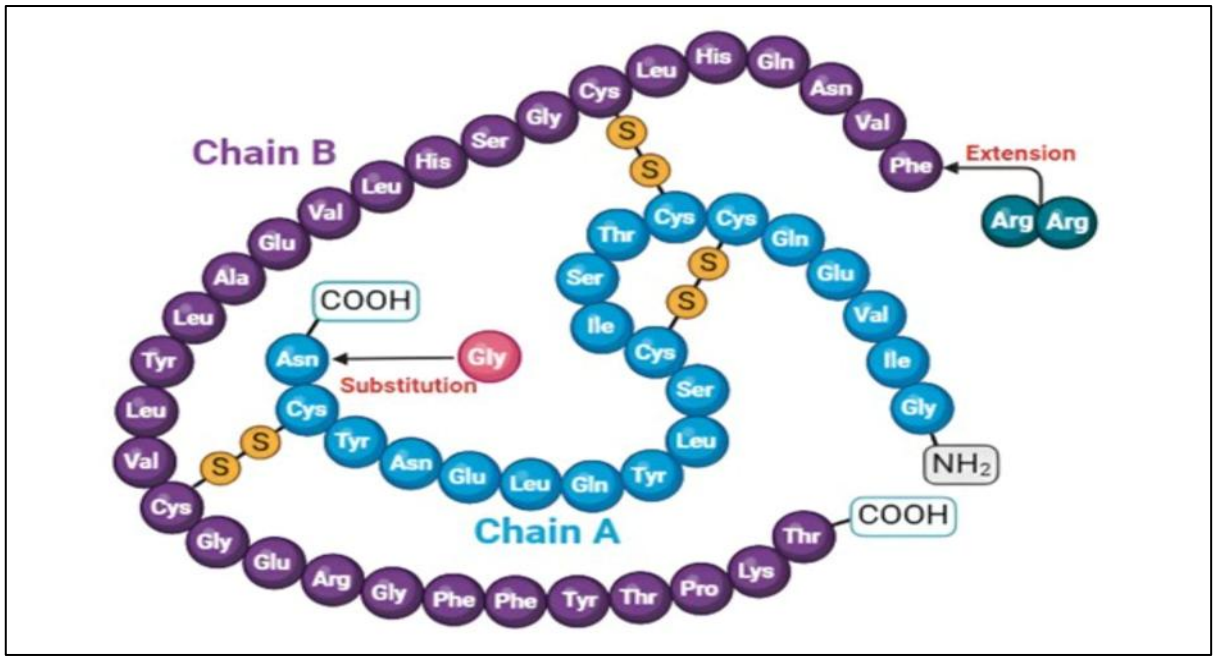

Figure 1: Structure of insulin glargine.

The design is an innovation that minimizes plasma insulin concentration peaks and troughs, which reduces nocturnal hypoglycaemia and enhances fasting glucose stability over NPH and previous versions. As proven by clinical research, glargine was more predictable, with less day-to-day variability and more patient satisfaction, which was a new standard of basal insulin therapy.[12,13]

From molecular optimization to patient-centric delivery

Further advancements in basal insulin treatment have gone beyond molecular refinement to include patient-based innovations. Increased usability, adherence, and accuracy in self-administration have been made possible by the integration of prefilled insulin pens, enhanced injection devices and digitized monitoring of dosages. Development of glargine U300 and degludec, which last longer and are more stable, are more accommodating to patients in terms of flexibility and decreased injection burden. This change represents a much broader transition in diabetes management and provides a holistic and patient-centric approach to treatment.[14,15]

Lead-in: biosimilars as the next evolutionary step

With patents on originator basal insulin analogs expiring, biosimilar insulins especially insulin glargine were the next logical innovation in this innovation continuum.[16] Biosimilar insulin glargine can be used to increase access, affordability, and supply diversity and reduce costs without negatively impacting quality by copying the proven safety and efficacy properties of reference analog insulin using advanced biotechnological techniques.[17,18]

This development aligns scientific progress with social responsibility, positioning biosimilars as both a technological and humanitarian advancement in basal insulin therapy. Here, biosimilar insulin glargine is representative of the fact that the century-old history of insulin development, starting with animal extracts and now moving to the field of molecularly modified analogs, has entered the realm of an inclusive biopharmaceutical innovation.[19]

BIOSIMILAR INSULIN GLARGINE: SCIENCE, REGULATION AND EQUIVALENCE

Differentiation between biosimilar drugs vs generic drugs

The production of biosimilar insulins is a clear difference in the scientific and regulatory paradigms in contrast with usual generic drugs. Generic drugs are small molecules that are chemically identical to their reference products and can be easily synthesized using traditional methods.

They are normally found to be similar based on bioavailability studies, which show the same pharmacokinetic profiles.[20] In comparison, biosimilars consist of large complex protein molecules that are synthesized in living systems as recombinant cell lines. Due to the natural variation in the biological production mechanisms, it is not scientifically possible to produce an exact molecular copy of the reference biologic. Rather, bio-similar drugs are created in a step-by-step process that focuses on attaining a high degree of similarity in structure, functioning and clinical efficacy. Such complexity gives rise to a much broader comparability framework used in generics.[21]

The expression of bio similarity depends on the totality-of-evidence method, which brings together layers of analytical, preclinical, and clinical analyses. Analytical characterization is its base which ascertains that the biosimilar and its reference product have similar primary, secondary and tertiary structures, and similar glycosylation patterns and biological functions.[22,23] Receptor binding, potency and in vitro or in vivo pharmacodynamics are then measured using preclinical tests. After achieving analytical similarity, clinical studies are conducted to compare pharmacokinetics, pharmacodynamics, efficacy, safety, and immunogenicity.[24]

Regulatory frameworks across regions

Regulatory authorities worldwide have increasingly aligned their strategies regarding the approval of biosimilars, which still have region-specific demands. Embracing analytical comparability and gradual production of evidence, the European Medicines Agency (EMA) was the first regulatory authority to develop a biosimilar regulatory pathway.

US Food and Drug Administration (FDA) later developed its structure based on the Biologics Price Competition and Innovation Act, which concentrates on proving biosimilarity and, in certain cases, providing interchangeability designation.[25] The Indian regulatory body Central drugs standard control organisation (CDSCO) and Department of biotechnology (DBT) came together and created the “Guidelines on similar biologics,” which outlined the regulatory pathway for biosimilar approvals by emphasizing comparability studies to demonstrate similarity to the reference biologics. This has further helped enhance the accessibility of biosimilar medications for patients.[26]

Basalog® approval journey

An example of such a rigorous scientific and regulatory route is of biosimilar insulin glargine (BASALOG®, BIOCON).[27] Biosimilar insulin glargine is a developed product of recombinant DNA technology and it has undergone comprehensive phase of analytical, clinical comparability tests and regulatory approval in India.[22]

Its success provided a base for further international expansion and approvals in European union through EMA and in Japan through Pharmaceutical and medical devices

agency (PMDA). Further, journey culminated in USFDA approval of insulin glargine-yfgn, which also includes designation as the first interchangeable biosimilar insulin glargine. These achievements collectively underscore the ability of emerging market innovations to address the most challenging international regulatory requirements.[28-31]

Interchangeability as a trust-building mechanism

One of the most important features of biosimilar uptake is interchangeability, a regulatory term used to imply that a biosimilar can be used in lieu of its reference product without the intervention of the prescribing physician. Interchangeability bridges the difference between regulatory approval and clinical confidence for clinicians, pharmacists, and patients, building trust in biosimilar products.

In this regard, interchangeability can be both a regulatory milestone and a tool to develop long-term confidence in biosimilar insulin as a part of contemporary diabetes treatment.[32]

CLINICAL AND REAL-WORLD EVIDENCE

Overview of global clinical trials

The clinical development of biosimilar insulin glargine has undergone stringent clinical and regulatory principles. A global PK/PD study demonstrated a superimposable Pharmacodynamic Glucose infusion rate (PD-GIR) profile, and the bioequivalence of biosimilar insulin glargine was further strengthened by PK and PD endpoints with the reference product.[33] INSTRIDE 1 and 2 which are phase 3 clinical trials that provides evidence of safety and efficacy of biosimilar insulin glargine in type 1 diabetes and type 2 diabetes, respectively by revealing no statistically significant difference of HbA1c reduction, incidence of nocturnal hypoglycemia, reduction of fasting plasma glucose, safety and immunogenicity between biosimilar insulin glargine and reference insulin glargine.[34-37] Similar robust evidence of biosimilarity between biosimilar and reference insulin glargine in patients with type 1 diabetes was proven by the INSTRIDE 3 switch study38 (Figure 2).

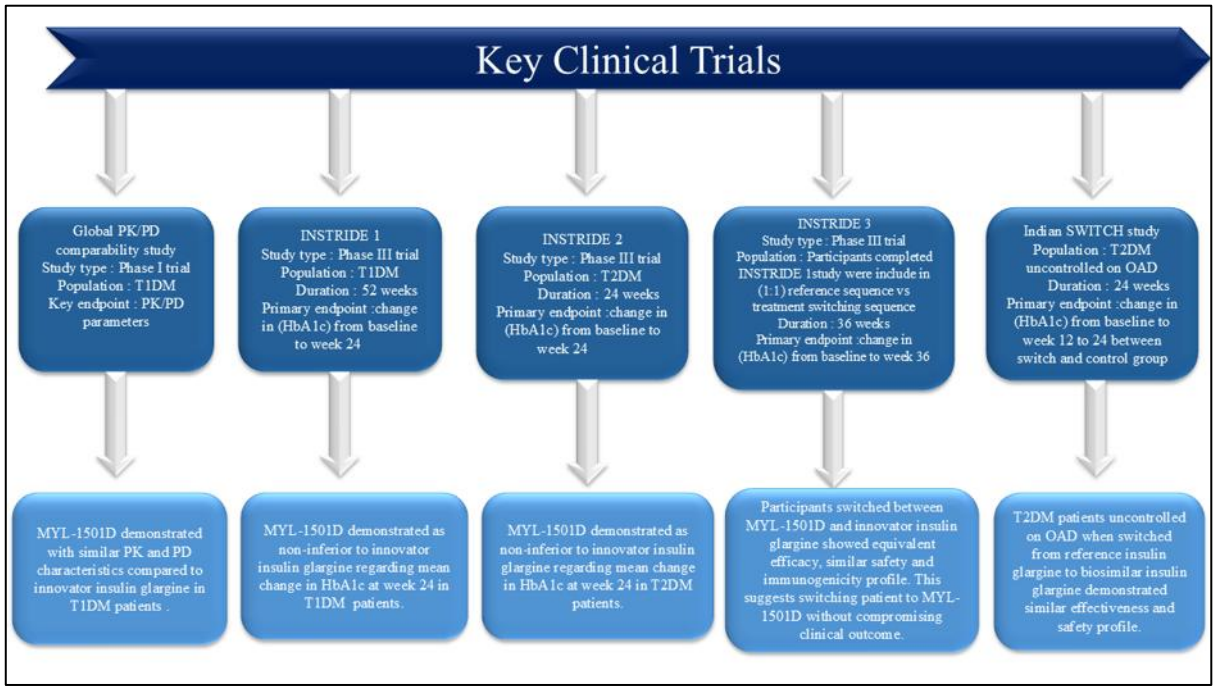

Figure 2: Key clinical trials of biosimilar insulin glargine (data summarized form global PK/PD comparability study INSTRIDE 1 study, INSTRIDE 2 study, INSTRIDE 3 and Indian switch study).[33,35,36,38,39]

Safety, efficacy and immunogenicity

The safety profiles of biosimilar insulin glargine closely mirror those of the reference product. Both had similar nocturnal and overall hyperglycaemia control with comparable injection-site reactions. Immunogenicity, a central concern for all biologic therapies, has been extensively evaluated. Overall, the proportion of patients who developed anti-insulin antibodies following treatment with biosimilar insulin glargine was low, transient and clinically insignificant. No meaningful differences were observed in antibody titers or their impact on glycemic control, insulin dose, or adverse events. Overall, the findings from the evidence support the immunological similarity and comparable clinical safety of biosimilar insulin glargine with the reference.[40]

Indian experience of biosimilar insulin glargine

In India, Biosimilar insulin glargine (BASALOG®, BIOCON) has already developed a great body of clinical and real-world evidence since its approval. Real-world

evidence of switching from reference insulin to biosimilar insulin glargine further supports robust evidence on biosimilarity with no statistically significant change in HbA1c levels for patients with type 2 diabetes in the parallel design Indian switch study.[39]

ECONOMIC AND ACCESS PERSPECTIVES

Global insulin pricing and the affordability crisis

A century after the discovery of insulin, its affordability remains a characteristic issue in the medical management of diabetes worldwide. Insulin is included in the World Health Organization Model List of Essential Medicines, but it is unaffordable to a significant number of patients in low-and middle-income countries and is becoming unaffordable to many in high-income environments.[41,42] There are a small number of multinational manufacturers who control the global insulin market, which lacks price competition and highlights a continuous concentration of supply. This form of oligopoly has resulted in significant price disparities among regions and patients in poorer countries tend to pay a large percentage of their earnings to sustain their life.[43] Individual patients are not the only ones who bear the economic burden. The financial pressure on health systems is increasing due to the rising prevalence of diabetes and the increased need for insulin every year. These structural imbalances have led to what is commonly termed an insulin affordability crisis, in which innovation in therapy has surpassed innovation in access.[44]

Biosimilars as catalysts for affordability and expanded coverage

In this aspect, biosimilar insulins have appeared as a tool for cost management and market diversification. Through established reference product technology and shorter regulatory approval processes, biosimilars can penetrate markets at reduced development and manufacturing expenses compared to the originators.[45] This cost advantage may be converted to significant price cuts, thus reducing the treatment spending of patients.[46] In addition, competition would lead to supply security and reduce the threat of supply shortages and counteract the effects of international prices. In this regard, the utilization of biosimilars is not only a business phenomenon but also a health systems reform initiative that promotes equity and sustainability of diabetes care.[47]

Biosimilar insulin glargine affordability and adoption – Indian scenario

The case of insulin glargine (BASALOG®, BIOCON) in India is an example of the potential of local biopharmaceutical development, which has contributed to transforming insulin accessibility and affordability economics.[48] Further to streamline adoption of biosimilar insulin glargine use on the bigger scale few initiatives should be incorporated effectively. There should be clear communication regarding clinical safety, efficacy and interchangeability of biosimilar insulin glargine to build trust amongst physician and avoid to misconception regarding product.[34] Also, there should be structured patient education programme on correct use for insulin pen and injection technique which can directly improve patient adherence to biosimilar insulin therapy.[49] Apart from this, extensive field presence of potential pharmaceutical companies which can effectively manage cold-chain as well as robust patient care initiatives will further enhance use of biosimilar insulin glargine into rural and semi-urban regions, where insulin access has traditionally been limited.[50] These initiatives enable broader accessibility to biosimilar insulin glargine in India.

CONCLUSION

A century after discovery of insulin which is considered as a major therapeutic advance in the treatment of diabetes mellitus, faces the persistence challenges of accessibility and affordability. Biosimilar insulin glargine emerges as a potential solution to overcome this challenge with robust evidence of efficacy, safety and immunogenicity. Furthermore, for the wider adoption of biosimilar insulin glargine, physician confidence, patient education programme and effective supply management plays crucial role to bridge insulin access gaps especially in resource limited settings. This ultimately results in making biosimilar insulin more sustainable and equitable therapy in current scenario.

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