Scientific papers: Industrial sessions

Non-comparable biologics vs. originator - the use of non-comparable biologics and biosimilar insulins: What is the current perspective?

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Abstract

Many biosimilar insulins are currently used to treat type 2 diabetes mellitus (T2DM), but it is still unclear if these are equally safe and effective. Bio-similarity must be confirmed through clinical trials, if not, the molecule can be considered non-comparable biologics (NCBs). Clinicians should know that biosimilars are not generics. Risk-benefit analyses and post-marketing safety data are needed to ensure biosimilar safety. They should focus on providing better care for insulin-dependent diabetic patients with lower complication rates and related morbidity. Three varieties of long-acting insulin analog biosimilars are approved. Originator insulins have their own delivery devices (insulin pens) for delivering safe and accurate doses of insulin. Delivery devices of biosimilars remain untested. Despite that additional research on the real-world cost-effectiveness of biosimilar insulins is needed. Currently, available biosimilars offer limited price reductions vs. the originator. In the real-world scenario, using biosimilar insulins solely based on perceived cost savings has not been supported by representatives of healthcare professionals or by people with DMs. Concerns regarding the use of different devices to deliver biosimilar insulins and the prevalence of hypoglycemia need to be resolved with appropriate studies before recommending the use of biosimilar insulins across a wider spectrum of people with T2DM in Southeast Asian countries including Bangladesh. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S26]*

Keywords: Diabetes mellitus, Biosimilar, Insulin, Non-comparable biologics

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Advanced approach on the day-to-day implementation of premix & co-formulation insulin analogs

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Abstract

Guidelines for people with type 2 diabetes (T2DM) who have failed to maintain glycemic control with oral antidiabetic treatments recommend additional treatment options, including starting incretins followed by initiating insulin treatment (with either a basal or a premixed insulin regimen). International guidelines endorsed premix insulin for initiation. The recent consensus report by ADA stated that if HbA1c remains above target; add prandial insulin usually one dose with the largest meal or meal with the greatest post-prandial glucose excursion; prandial insulin can be dosed individually. Also, it recommends considering initiating a self-mixed or premixed insulin regimen. Biphasic insulin aspart 30 (BIAsp30) can be considered a safe and effective option for initiating as well as intensifying insulin therapy for T2DM. BIAsp 30 improves postprandial glycemic control compared with both insulin lispro mix25 and biphasic human insulin 30 among people with T2DM. Insulin degludec/insulin aspart (IDegAsp) is a fixed-ratio co-formulation of insulin degludec (a basal insulin) and insulin aspart (a prandial insulin). People with T2DM, initiating IDegAsp, or switching to it from previous antidiabetic treatment, were associated with improved glycaemic control, lower basal insulin dose (in insulin-experienced participants), and lower rates of hypoglycemia. Early initiation of insulin therapy & intensification are needed to avoid the effects of prolonged glycemic burden and alter the course of disease progression. Hence, Premix/co-formulation insulins are the preferred choice as per country guidelines considering the clinical trial date and real-world evidence. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S27]*

Keywords: Diabetes mellitus, Premix insulin, Insulin aspart, Insulin degludec

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Once-weekly therapeutic options for type 2 diabetes mellitus: Recent updates

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Abstract

The management of type 2 diabetes mellitus (T2DM) has been transformed by the advent of once-weekly therapeutic options, which offer a significant leap in both patient convenience and clinical outcomes. These therapies primarily encompass GLP-1 receptor agonists, dual GIP/GLP-1 receptor agonists, and DPP-4 inhibitors. One of the major advantages of these once-weekly formulations is their ability to enhance patient compliance by reducing the frequency of dosing compared to daily medications. Beyond convenience, the clinical benefits of once-weekly therapies are considerable- meaningful weight loss, cardiovascular benefits, and superior efficacy in both glycemic control. Despite the clear advantages, the adoption of once-weekly therapies is not without challenges. Higher costs, limited availability in certain markets, and potential side effects, such as gastrointestinal discomfort, can be barriers to widespread use. Moreover, the long half-life of these medications may complicate dose adjustments in response to acute changes in blood glucose levels. As clinical evidence continues to support the efficacy and safety of these once-weekly treatments, their role in the management of T2DM is set to expand. Healthcare providers must carefully weigh the benefits against the potential limitations to tailor treatment plans that align with individual patient needs. The rise of these therapies represents a significant step forward in diabetes care.
[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S28]

Keywords: Diabetes mellitus, Glucagon-like peptide 1 receptor agonist, Incretins

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SGLT2 inhibition in focus: The renal and cardiac benefits of empagliflozin

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Abstract

Empagliflozin, a sodium-glucose co-transporter-2 (SGLT2) inhibitor, has emerged as a key therapeutic agent in the management of type 2 diabetes mellitus (T2DM), offering notable benefits beyond glycemic control. It effectively reduces HbA1c while providing long-term cardiovascular and renal protection. DM is associated with significant comorbidities, particularly cardiovascular and renal diseases, which considerably shorten patients' life expectancy. T2DM patients with cardiovascular disease face an additional 12-year reduction in life span. Empagliflozin addresses these challenges by lowering blood glucose levels and offering substantial cardiovascular and renal benefits, as demonstrated in clinical trials like the EMPEROR-Reduced study. Empagliflozin's mechanisms provide a revolutionary approach to diabetic care, reducing cardiovascular mortality and morbidity while extending its use to non-diabetic chronic kidney disease and heart failure. Furthermore, its cost-effectiveness and oral administration make it an appealing option for elderly patients and those for whom insulin therapy is unsuitable. The drug is now endorsed as a first-line therapy for T2DM by leading guidelines such as the European Society of Cardiology (ESC) and the American Diabetes Association (ADA), further supported by recommendations from recent trials. This expanding indication profile highlights Empagliflozin's critical role in addressing the complex needs of diabetic patients. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S29]*

Keywords: SGLT2 inhibitors, Empagliflozin, Diabetes mellitus, Cardiovascular events

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Reviewing Bangladeshi patients for a simplified insulin experience

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Abstract

The number of people with diabetes worldwide is increasing at an alarming rate and is estimated to reach 783 million by 2045. Differences in genetic susceptibility, phenotype and underlying pathophysiology, age of onset, and body mass index (BMI) have been reported between Asians and Caucasians with diabetes. Patients and health care professionals face many potential barriers to insulin initiation and intensification in primary care that can be categorised as low motivation, lack of familiarity or experience, fear of hypoglycaemia, needles, weight gain and time constraints. In Bangladesh, both low & high mix premix is very much essential to maintain patients' good control of blood sugar. Premix analog insulins are mixture of rapid-acting insulin to control blood sugar at meal times and intermediate-acting insulin to control blood glucose all through the day. Lispro Mix 25 insulin with single device provides effective HbA1c reduction up to 1.92% controlling both FPG & PPG which is non inferior to basal bolus therapy. When conventional low mix ratio (e.g. Premix 30/70) is not sufficient to control high PPG due to rich carbohydrate diet in each meal, Lispro mix 50 could be the ideal choice to manage blood glucose & significant reduction of HbA1c upto 1.87%. Lispro Mix insulins provide the simple option to initiate & intensify with same insulin. Three times daily Lispro Mix also have been found to be non-inferior to basal-bolus regimens with similar rates of hypoglycemia. In conclusion, premix insulin regimens like Lispro Mix 25 and Lispro Mix 50 offer a simplified yet effective approach to insulin therapy in the Bangladeshi population. They provide non-inferior glycemic control compared to basal-bolus therapy with a reduced injection burden, while maintaining a strong safety profile regarding hypoglycemia. Given the barriers to insulin initiation and adherence, these options should be considered as a practical solution in resource-limited settings like Bangladesh. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S30]*

Keywords: Premix insulin, insulin Lispro Mix 25, Insulin Lispro Mix 50, Insulin Lispro

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Connecting the power of Dulaglutide: Efficacy, quality & tolerability

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Abstract

Diabetes is a major global health concern, affecting an estimated 537 million individuals worldwide. Several guidelines emphasize the importance of personalized treatment approaches for diabetes management. Dulaglutide (Trulicity), a glucagon-like peptide-1 receptor agonist, is indicated for patients with type 2 diabetes. It has various benefits, including effective glycemic control and notable weight reduction, which is important for managing obesity-related complications in diabetic patients. In all phase 3 clinical trials, the average reduction in HbA1c with once-weekly Dulaglutide was 2%. In addition to glycemic and weight management, Dulaglutide provides cardiovascular and renal benefits. The REWIND trial showed that Dulaglutide reduces the risk of major adverse cardiovascular events (MACE), including heart attack, stroke, and cardiovascular death. The AWARD-7 trial also highlighted Dulaglutide's potential in slowing the progression of renal disease in patients with type 2 diabetes. Emerging evidence suggests that Dulaglutide may also offer benefits in managing Metabolic Dysfunction-Associated Steatohepatitis (MASH), and long-term use may reduce the severity of erectile dysfunction. The AWARD-PEDS clinical trials demonstrated improved glycemic control, with a reduction of up to -0.9% HbA1c at 26 weeks among youths with type 2 diabetes mellitus (10 years and above). Dulaglutide exhibits fewer gastrointestinal adverse events compared to other GLP-1 receptor agonists. The once-weekly dosing regimen and the simple, single-use, pre-filled pen with an automatic needle insertion and retraction system enhance patient convenience and adherence, ultimately improving treatment outcomes. In conclusion, Dulaglutide is a comprehensive therapeutic option for diabetes management, providing glycemic control, weight reduction, cardiovascular and renal protection, and potential benefits in MASH and erectile dysfunction. Its innovative delivery device enhances patient adherence, positioning it as the preferred choice for the management of type 2 diabetes. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S31]*

Keywords: Dulaglutide, GLP-1, DM, Obesity

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Newer anti-obesity medications: A paradigm shift in obesity management?

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Abstract

Pharmacotherapy for obesity is recommended in adults with a BMI of 30 or a BMI over 27 when associated with at least one weight-related comorbidity. Excessive weight gain results from intricate bodily interactions, especially involving the brain's regulation of other organs like the gastrointestinal system, muscles, and adipose tissue. While calorie reduction and increased physical activity can lead to weight loss, the body's compensatory biological mechanisms frequently cause weight regain. Anti-obesity medications (AOMs) are designed to counter these mechanisms, making them an essential tool in weight management. Several FDA-approved AOMs aim to reduce weight and minimize obesity-related complications, particularly cardiovascular events. Evidence increasingly supports their role in reducing obesity-related comorbidities like diabetes and hypertension. Newer AOMs, particularly GLP-1 receptor agonists, have demonstrated significant cardiovascular benefits, with the SELECT study showing a 20% reduction in cardiovascular events with Semaglutide 2.4 mg. These newer treatments, along with others in development, have the potential to transform the management of obesity and its complications. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S32]*

Keywords: Obesity, Anti-obesity medication, GLP-1 receptor agonist

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Role of semaglutide in Bangladesh perspective

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Abstract

Semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, represents a significant advancement in managing type 2 diabetes mellitus (DM) and obesity. In Bangladesh, where the prevalence of DM is on the rise—driven by urbanization, dietary changes, and sedentary lifestyles—semaglutide offers a promising therapeutic option. This abstract examines the role of semaglutide from a Bangladeshi perspective, emphasizing its clinical efficacy in improving glycemic control and promoting weight loss, which are critical for mitigating the long-term complications associated with DM. Despite its benefits, the implementation of semaglutide in Bangladesh faces several challenges. High treatment costs can limit accessibility, especially in a healthcare system where affordability is a significant concern for many patients. Additionally, it needs to enhance healthcare provider training to ensure proper patient selection and management. Furthermore, public awareness and education regarding diabetes management and new treatment options are crucial for fostering acceptance and adherence to therapy. By addressing these barriers through policy interventions, healthcare reforms, and patient education initiatives, Bangladesh could harness the potential of semaglutide to improve health outcomes and reduce the burden of diabetes and obesity. This analysis underscores the importance of a multifaceted approach to integrate semaglutide effectively into the healthcare framework of Bangladesh, ensuring that the benefits of this innovative therapy reach those in need. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S33]*

Keywords: Semaglutide, Glucagon-like peptide 1 receptor agonist, Diabetes mellitus

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Empagliflozin: A game-changer SGLT2 inhibitor for the management of type 2 diabetes mellitus, heart failure, chronic kidney disease, metabolic dysfunction-associated steatotic liver disease

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Abstract

Empagliflozin, a sodium-glucose co-transporter 2 inhibitor (SGLT2i), has revolutionized the management of a wide range of metabolic and cardiovascular diseases. Initially developed to improve glycemic control in patients with type 2 diabetes mellitus (T2DM), its benefits extend far beyond glucose reduction. Clinical trials, such as EMPA-REG OUTCOME, DAPA-HF, and EMPA-KIDNEY, have established its remarkable efficacy in reducing cardiovascular events, including heart failure (HF) hospitalizations, while also offering significant renoprotective effects for those with chronic kidney disease (CKD). Additionally, empagliflozin's anti-inflammatory and antifibrotic properties make it a promising candidate for treating metabolic dysfunction-associated steatohepatitis (MASLD). In this presentation, I will discuss the mechanisms underlying its pleiotropic effects, clinical data from key studies, and practical applications of empagliflozin in managing complex patients with T2DM, HF, CKD, and MASLD. Empagliflozin represents a significant shift towards a more integrated, patient-centered approach to chronic disease management. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S34]*

Keywords: Empagliflozin, SGLT2 inhibitors, Type 2 diabetes mellitus, Heart failure, Chronic kidney disease

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Tirzepatide: A dual incretin analogue for multiple targets

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Abstract

Tirzepatide represents a significant advancement in the treatment of type 2 diabetes mellitus (T2DM) and obesity, addressing two major global health challenges. The efficacy and safety of tirzepatide are demonstrated in the SURPASS and SURMOUNT trials. These studies show that tirzepatide provides superior results in lowering HbA1c levels and achieving significant weight reduction compared to traditional treatments, including other GLP-1 receptor agonists. Additionally, it offers promising cardiovascular benefits, which are critical in managing T2DM. With its convenient once-weekly dosing, tirzepatide offers an integrated approach to managing both diabetes and obesity, conditions that often coexist and exacerbate each other. The safety profile is consistent with other incretin-based therapies, with gastrointestinal side effects being the most commonly reported. In summary, tirzepatide presents a promising dual mechanism for managing glycemic control and obesity, potentially redefining treatment strategies for patients facing these interconnected health challenges. *[J Assoc Clin Endocrinol Diabetol Bangladesh, 2024;3(Suppl 1): S35]*

Keywords: Tirzepatide, Diabetes mellitus, Obesity

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