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Control/Tracking Number: A-24-2431-EASD
Activity: Abstract
Current Date/Time: 4/3/2024 7:45:21 AM

A multicenter, randomized controlled trial in individuals with type 2 diabetes mellitus to evaluate the efficacy of imeglimin on time in range

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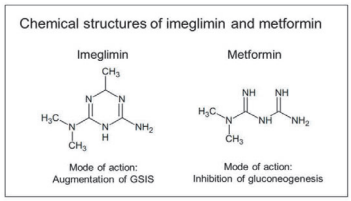
Abstract:
Background and aims: Imeglimin, an anti-diabetic drug recently launched in Japan, shares structural similarity with metformin (Figure). Despite this similarity, imeglimin is thought to lower glycemia by enhancing glucose-stimulated insulin secretion (GSIS), a mechanism distinct from that of metformin. Drugs augmenting GSIS generally reduce postprandial hyperglycemia, thereby improving glycemic fluctuation. However, the effects of imeglimin on these parameters have not yet been tested. Thus, we examined the impact of imeglimin on glycemic fluctuation and compared it with the effects of metformin.
Materials and methods: We recruited individuals aged 20 to 75 years with type 2 diabetes (T2D) who were not treated with insulin, glucagon-like peptide 1 receptor agonists, or two or more anti-diabetic drugs. Sixty individuals were randomly assigned to receive imeglimin or metformin (1:1 ratio) and underwent continuous glucose monitoring (CGM) at 0-2 weeks, 6-8 weeks, and 16-18 weeks post-randomization. The primary outcome was the effect of imeglimin on time in range (TIR), with secondary outcomes including glycemic fluctuation, insulin secretion and sensitivity, reactive oxygen species production, lipid metabolism, and body mass of the imeglimin and metformin groups. This paper presents the primary outcome, while the secondary outcomes will be shown elsewhere.
Results: The median age of the 30 individuals assigned to the imeglimin group was 62.5 years, and 66.7% were male. At baseline, the imeglimin group had a median HbA1c value of 6.9% (interquartile range [IQR], 6.7-7.1), a median diabetes duration of 5.1 years (IQR, 2.3-6.2), and 53.3% were concurrently receiving dipeptidyl peptidase-4 inhibitors. The imeglimin group exhibited a mean TIR of 77.10% (SD, 21.91) at 0-2 weeks, 85.81% (15.90) at 6-8 weeks, and 86.48% (16.05) at 16-18 weeks, with significant changes observed from 0-2 weeks to 6-8 weeks (mean change, 8.49% [SD, 11.79]; p = 0.0007) and to 16-18 weeks (mean change, 10.49% [14.23]; p = 0.0005).
Conclusion: Administering imeglimin to individuals with T2D exhibiting good TIRs and HbA1c values improved the TIR by more than 10 percentage points within 16 weeks, suggesting the efficacy of the drug in reducing glycemic variability. Further evaluation with other indices and comparative assessments with metformin will contribute to a better understanding of the properties of this newly lunched drug.



Author Disclosure Information:

M. Ueda: Grants; Noster Incorporated, Boehringer Ingelheim Japan, Incorporated, Eli Lilly Japan K.K., Sumitomo Pharma Company, Limited, Teijin Pharma Limited, Novo Nordisk Pharma Limited, Kowa Company, Limited, Novo Nordisk Pharma Limited, Takeda Pharmaceutical Company Limited. Lecture/other fees; Sumitomo Pharma Company, Limited, Abbott Japan Company, Limited, Boehringer Ingelheim Japan, Incorporated, Novo Nordisk Pharma Limited.
Keyword (Complete): 39 Oral therapies: metformin, sensitizers and other non-secretagogues
Study information (Complete):
***Human studies**: Yes
***Animal Studies**: No

Clinical Trial Registration Number (Complete):
: Yes
: jRCTs051220061

Grant Acknowledgement (Complete):
Please select Yes or No: No

Status: Complete

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