ABSTRACT

The Relevance of Clinical Pharmacology Studies of Basal Insulins to Primary Care

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Pharmacokinetic (PK) and pharmacodynamic (PD) properties of drugs form the basis for the development of drugs used in everyday clinical practice, such as commonly used insulin products. PK measures the concentration of a drug in the body, and reflects the rates and amounts absorbed and processed. PD is the biologic effect of a drug in the body, including the time-course of when the biologic effect starts, peaks, and ends. While the determination of PK/PD parameters is important and foundational for the development of different insulin products, studies are often complex and can be difficult to translate into real-world clinical practice. In this roundtable, the speakers discuss PK/PD concepts, focusing on the differentiation of basal insulin analogs and their use in individualized diabetes therapy.

First, the speakers discuss the euglycemic glucose clamp methodology—the standard technique for evaluating PK/PD of insulin—including how it is performed, what parameters it measures (and how they can be interpreted), and its limitations.

Next, the speakers discuss how PK/PD impacts drug development, with particular focus on PK/PD studies used in the development of the second-generation basal insulin analogs insulin glargine 300 U/mL (Gla-300) and insulin degludec.

Finally, the speakers discuss how PK/PD data translate into clinical practice, including the relationship between PK/PD and drug efficacy and safety, and how it influences dosing strategies, hypoglycemia risk, and patient education. Further, the speakers discuss how the PK/PD profile of basal insulins can inform primary care providers when selecting appropriate individualized therapy for patients.