Call for Data Partners

2025 APAC Studies

Gastrointestinal Risk of GLP-1 Receptor Agonists versus SGLT-2 and DPP-4 Inhibitors in Type 2 Diabetes: A Multi-Database Observational Study

Yongqi Zheng, Department of Epidemiology and Biostatistics, Peking University
Feng Sun, Department of Epidemiology and Biostatistics, Peking University

Study Background

Pharmacologic Approaches to T2DM Treatment

Metformin: foundational glucose-lowering therapy, typically used as first-line agent
GLP-1RAs: recommended as monotherapy or as add-on therapy to agents such as metformin in patients with T2DM and established ASCVD, CKD, or obesity, based on their cardiovascular and renal benefits

Evaluate Gastrointestinal(GI) Risks of GLP-1RAs Using Real-World Evidence: Rationale & Gap

Safety Concern: Delayed gastric emptying → possible gastroparesis, intestinal obstruction

Conflicting Evidence:

- Several large-scale observational studies (e.g., Sodhi et al., Nielsen et al.) have reported significantly increased risks of gastroparesis and intestinal obstruction
- Several studies (e.g., Gao et al., Ueda et al.) found no significant increase in gastrointestinal obstruction
- There have been no RCTs specifically designed to evaluate the gastrointestinal safety outcomes of GLP-1RAs

Need for Real-World Evidence:

- Prior studies limited by insufficient confounder adjustment
- Few multi-database studies on GI safety of GLP-1RAs

SODHI M, et al. Jama, 2023. NIELSEN J, et al. Inflamm Bowel Dis, 2024. GAO Z, et al. Acta Diabetol, 2025. UEDA P, et al. Clin Gastroenterol Hepatol, 2024.

Study Objectives

- Primary objective
  - Compare the risk of gastroparesis in T2DM patients initiating GLP-1RAs versus DPP-4 inhibitors or SGLT-2 inhibitors
  - Compare the risk of intestinal obstruction in T2DM patients initiating GLP-1RAs versus DPP-4 inhibitors or SGLT-2 inhibitors

- Secondary objective
  - Compare the risk of acute pancreatitis and nonalcoholic fatty liver disease (NAFLD) in T2DM patients initiating GLP-1RAs versus DPP-4 inhibitors or SGLT-2 inhibitors, as secondary outcomes to provide a broader assessment of digestive system safety

Study Design

Analytic use case	Type	Structure
Population-level effect estimation	**Comparative effectiveness**	Does exposure to **GLP-1RAs** have a different risk of experiencing **gastroparesis or intestinal obstruction** within **end of continuous observation**, relative to **DPP4-i or SGLT2is** among the population with **type 2 diabetes and history of metformin**?

Population

Inclusion

- Adults (≥18 years) with T2DM
- ≥365 days prior observation
- ≥90 days prior metformin use

Exclusion

- T1DM or secondary diabetes
- Prior exposure to study drugs or anti-diabetic exposure
- No prior insulin use or combo initiation
- History of pancreatitis, digestive system cancer, or abdominal surgery
- Renal dialysis, renal transplantation or end stage renal disease

Target: GLP-1RAs

Comparator: SGLT-2 inhibitors, DPP-4 inhibitors

Outcome:

Primary outcome:

- Gastroparesis
- Intestinal obstruction

Secondary outcome:

- Acute Pancreatitis
- NAFLD

CohortDiagnostics

- URL of CohortDiagnostics package:
  - https://github.com/ohdsi-studies/2025APACStudy-Peking/tree/master/CohortDiagnostics
- For troubleshooting:
  - Open an issue at https://github.com/ohdsi-studies/2025APACStudy-Peking/issues
- Send your results to:
  - Yongqi Zheng zyq4664@pku.edu.cn
  - OHDSI APAC apacsymposium@ohdsi.org
- Join us at our study Teams channel: 2025 APAC Study 2 - Peking

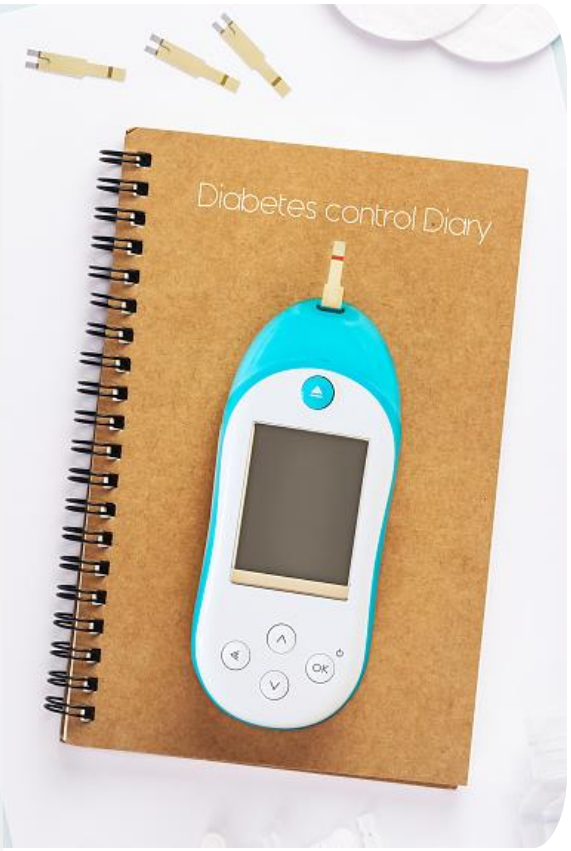
Association Between Fasting Plasma Glucose Levels and Annual Hospitalization Days: A Multicenter Study Using the OHDSI Framework

Ph.D. Jianying Gu, Zhongshan Hospital, Fudan University
Ph.D. Lei Liu, Fudan University

Study Background

Fasting Plasma Glucose Levels

- Abnormal FPG levels relate to metabolic health, diabetes, and increased healthcare resource use.
- High levels can cause disorders, inflammation, and exacerbate chronic diseases, potentially leading to longer hospital stays



OHDSI Framework about FPG: Investigates association between FPG levels and annual hospitalization days using OHDSI framework, to inform glucose management and resource allocation strategies

Study Objectives

Problem statement——Exploring the Relationship FPG Levels and Hospitalization

- Evaluating how glucose abnormalities affect hospitalization days, aiming to quantify their impact on healthcare resources utilization

- Standard multicenter data in OHDSI to understand the relationship between plasma glucose levels and hospitalization days. This uses OHDSI's multicenter data to study how plasma glucose levels relate to the length of hospital stays, identifying trends for better care planning

Study Design

The study population will be defined as:

1. Patients aged ≥18 years, of any gender.
2. A documented fasting plasma glucose (FPG) measurement during inpatient stay, including a valid numerical value and timestamp, expressed in mg/dL or mmol/L, and with FPG ≠ 0.

Patients must also have complete hospitalization records with both admission and discharge dates.

Additionally, patients must also meet one or both of the following criteria:

- Admission to a specified clinical department (specialty).
- More than one hospitalization episode.

Exclusions:

Incomplete hospitalization records or hospitalization dates falling outside the past 5 years.

Preliminary Analysis to Determine Feasibility

	Analytic use case	Type	Structure
1. FPG only	**Clinical characterization**	**Disease Natural History**	Amongst patients **with at least one fasting plasma glucose (FPG) measurement within a fixed continuous observation period starting from the event**, what are the patient's characteristics from their medical history?
2. Glucose measurement in hospital	**Clinical characterization**	**Disease Natural History**	Amongst patients **who experience an inpatient or ER visit accompanied by glucose measurement during the same clinical encounter**, what are the patient's characteristics from their medical history?

CohortDiagnostics

- URL of CohortDiagnostics package:
  - https://github.com/ohdsi-studies/2025APACStudy-Fudan/tree/master/CohortDiagnostics
- For troubleshooting:
  - Open an issue at https://github.com/ohdsi-studies/2025APACStudy-Fudan/issues
- Send your results to:
  - Changran Wang crwang@fudan.edu.cn, Jiaqi Liu liu.jiaqi@zs-hospital.sh.cn
  - OHDSI APAC apacsymposium@ohdsi.org
- Join us at our study Teams channel: 2025 APAC Study 1 - Fudan