Impact of Cardiovascular Medications on Non-Traumatic Amputation Rates in Type 2 Diabetes Mellitus: Insights from a Large-Scale Retrospective Real-World Data Analysis

RWD184

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BACKGROUND AND OBJECTIVES

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by hyperglycemia due to defects in insulin secretion, insulin action, or both. It is a growing global epidemic with an estimated 537 million people living with diabetes worldwide [1].

This study investigated **the impact of cardiovascular medications** on the **incidence of non-traumatic amputation in patients with T2DM.**

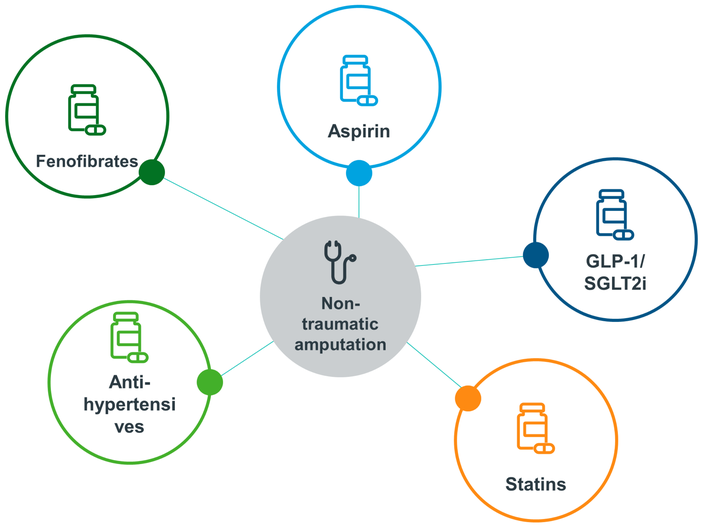

Figure 1. Impact of cardiovascular medications on non-traumatic amputation

METHODOLOGY

T2DM patients over 18 years with at least 365 days prior observation were included. Data from IQVIA™ US and Japan, formatted in the **Observational Medical Outcomes Partnership (OMOP)** common data model, were used. The study period spanned from **January 1, 2015, to December 31, 2022**, and the **time-at-risk was 15 years** from index date.

The analysis focused on patients prescribed statins, fenofibrates, anti-hypertensives, aspirin, and GLP-1/SGLT2 inhibitors, without concurrent use of other study drugs.

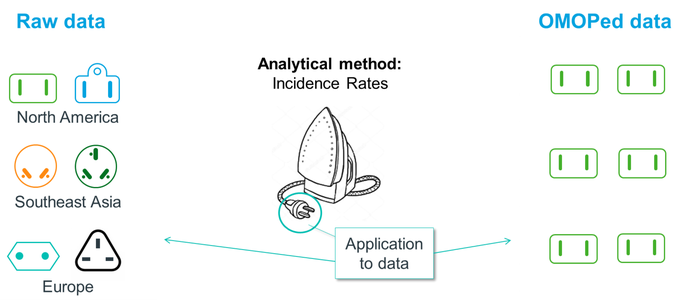

Figure 2. OMOP Common Data Model

The OMOP common data model transforms observational health data into a common format that allows real-world evidence to be generated across multi-country data assets using standardized analytical methods and tools.

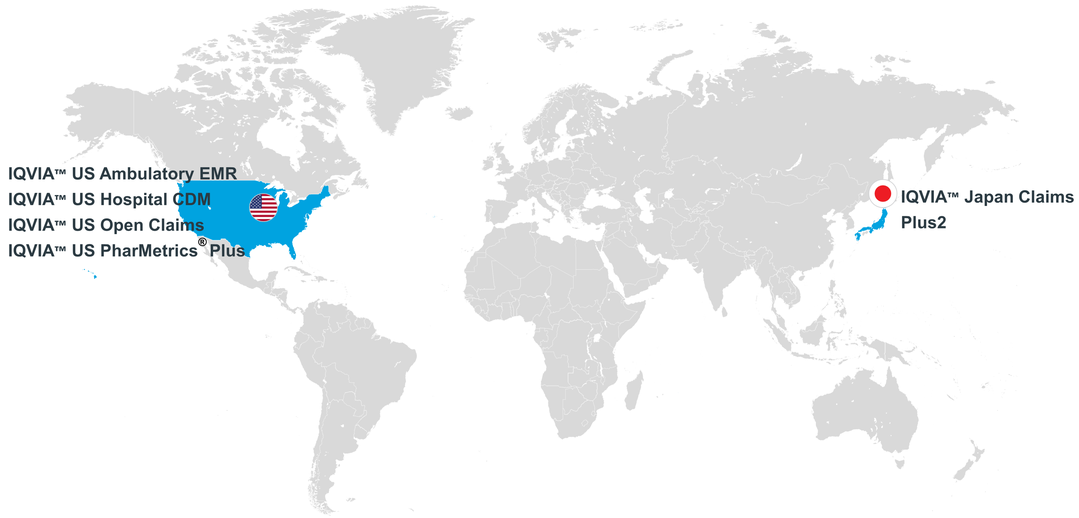

Figure 3. Data assets using large-scale real-world data from 1.2 billion patients

RESULTS IN A NUTSHELL

- The analysis revealed a significant **reduction in incidence rates of non-traumatic amputation** when patients were prescribed to **statins (0.11-2.13) and fenofibrates (0.13-2.78)** compared to the others (0.16-2.16), when considering the time at risk for patients.
- Assessing different types of RWD in the US, our results show that **incidence rates** across all drugs were considerably **higher in Hospital EMRs (0.66-2.78)** compared to the **Claims (0.33-1.29) and Outpatient databases (0.16-0.35)**.

Table 1. Non-traumatic amputation incidence rates per 100k patients

Setting	Data asset	Statins	Fenofibrates	Anti-hypertensives	Aspirin	GLP-1/ SGLT2i
Claims	Japan Claims Plus2	0.11	0.13	0.29	0.91	0.25
	US Open Claims	0.49	0.51	1.28	0.64	0.33
	US PharMetrics® Plus	0.39	0.75	1.29	0.45	0.42
Hospital EMR	US Hospital CDM	2.13	2.78	2.16	0.66	1.49
Outpatient	US Ambulatory EMR	0.20	0.16	0.27	0.35	0.16

CONCLUSIONS, what you want to take away…

- In summary, this study indicates that **statins and fenofibrate** although prescribed for a different diagnosis, they **seem to have a protective effect** on **developing more severe T2DM complications**, such as non-traumatic amputation.
- Continued research, **employing rigorous experimental designs and advanced statistical techniques** like propensity score matching and negative controls, **are needed** for more definitive comparative analysis.
- Additionally, the variance in **incidence rates across different data sources underscores the importance** of considering the **context of real-world healthcare settings** in evaluating drug effectiveness.
- This study underscores **the value of RWD** in enhancing our understanding of the real-world implications of medication use in T2DM management.

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[1] International Diabetes Federation. IDF Diabetes Atlas. 10th ed. Brussels, Belgium: International Diabetes Federation; 2021