Defining the Potential "Real-world" Impact of the EMPA-REG OUTCOME Trial on Improving Cardiovascular Outcomes: Observations from the Diabetes Collaborative Registry®

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BACKGROUND

- The EMPA-REG OUTCOME trial demonstrated beneficial cardiovascular (CV) effects of empagliflozin, a sodium-glucose co-transporter 2 inhibitor (SGLT2i) in patients with type 2 diabetes (T2D) and established CV disease.
- We estimated the current use and potential impact of empagliflozin, as well as any SGLT2i, in patients enrolled in the Diabetes Collaborative Registry® (DCR).
- DCR was formed to understand the quality of diabetes care across the primary and specialty care continuum.

METHODS

- DCR is comprised of primary care, endocrinology, and multispecialty practices in the United States.
  - Due to an established IT integration, cardiology sites predominated the initial data sample (>90% of sites).
- Study Population: 1,029.807 patients across 374 US practices
  - Excluded patients with type I diabetes (n=45,620) and those without documented HbA1c data (n=635,607).
- We assessed the percentage of patients in DCR who would have met main eligibility requirements for EMPA-REG OUTCOME trial
  - Age ≥18 years
  - T2D
  - HbA1c 7-10%
  - Established CV disease (prior MI, CAD, coronary revascularization, or peripheral artery disease).
- We compared patients who were vs. were not treated with SGLT2i.
- We then estimated the number of events potentially avoided among the eligible patients using the published absolute risk reductions (both overall and per 100-patient years).
- The benefits observed with empagliflozin in EMPA-REG OUTCOME trial were assumed to be a class effect for all SGLT2i medications.
- The more recent visit for each patient was used for analysis.

FIGURE: Eligibility for EMPA-REG OUTCOME in DCR and Use of SLGT2i

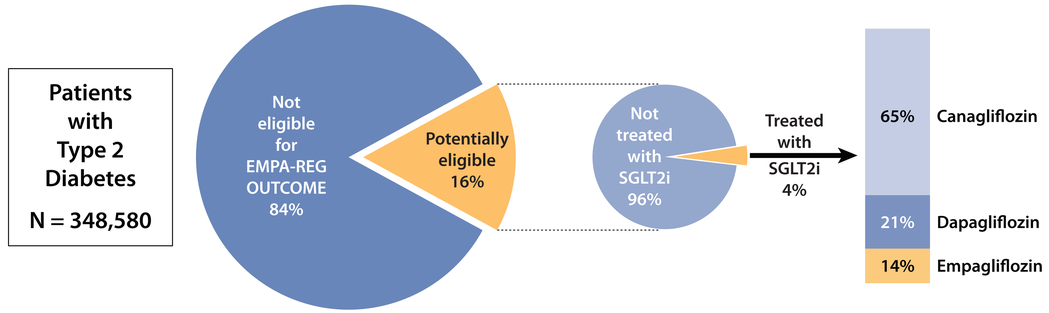

TABLE 1: Patient Factors

	SGLT2i n=2422	No SGLT2i n=52,990	p-value
Age	63.7 y	70.2 y	<0.001
Male Sex	67%	61%	<0.001
White Race	87%	86%	0.592
Body Mass Index	33.5 kg/m^2	32.3 kg/m^2	<0.001
HbA1c	8.1%	8.1%	0.03
Hypertension	89%	90%	0.278
Systolic Blood Pressure	127 mmHg	130 mmHg	<0.001
Diastolic Blood Pressure	74 mmHg	72 mmHg	<0.001
Dyslipidemia	94%	91%	<0.001
Coronary Artery Disease	83%	89%	<0.001
Prior Myocardial Infarction	20%	23%	0.004
Prior Coronary Artery Bypass Graft	18%	22%	<0.001
Heart Failure	22%	35%	<0.001
Peripheral Artery Disease	29%	31%	0.011
Prior Stroke	24%	18%	<0.001
Prior Transient Ischemic Attack	8%	8%	0.819
Atrial Fibrillation	15%	26%	<0.001
Chronic Kidney Disease	9%	16%	<0.001

TABLE 2: Possible Events Avoided

	Event Rate (total)		Event Rate (annualized)		Potential Events Avoided	
	Rate in Drug	Rate in Placebo	Rate in Drug	Rate in Placebo	Total (3.1 y)	Per Year
All Cause Death	5.7%	8.3%	1.94%	2.86%	1441	510
CV Death	3.7%	5.9%	1.24%	2.02%	1219	432
CHF Hospitalization	2.7%	4.1%	0.94%	1.45%	776	283

CONCLUSIONS

- In a large US-based outpatient registry of DM patients across the spectrum of primary and specialty care, we found that ~1 in 6 outpatients with T2D met the main eligibility criteria for EMPA-REG OUTCOME.
- SGLT2i therapy is rarely used and tends to be prescribed in lower risk patients (younger, better kidney function, less heart failure).
- Expanded and better targeted use of SGLT2i's (if the benefit is found to be a class effect) in eligible patients, particularly those at highest risk for adverse CV outcomes, could significantly reduce CV morbidity/mortality.

DISCLOSURES

- This research was supported by the American College of Cardiology Foundation. Additional organizations partner with ACCF on the Diabetes Collaborative Registry. The views expressed in this abstract represent those of the author(s), and do not necessarily represent the official views of the ACCF or its partnering organizations.
- For more information go to www.thediabetesregistry.org
- The registry is sponsored by AstraZeneca (Founding Sponsor) and Boehringer Ingelheim Pharmaceuticals, Inc.