Anticipating the Impact of 2019 Guidelines: Use of SGLT2i and GLP–1 RA in Patients with Diabetes and Cardiovascular Disease

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Together2Goal
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National Diabetes Campaign

Study Objective: Characterize clinical inertia associated with the adoption of new antidiabetic therapies in the treatment of patients with diabetes and cardiovascular disease (CVD) using a large, clinical database

Background

- Patients with type 2 diabetes (T2DM) are at twice the risk of cardiovascular disease (CVD) morbidity and mortality; more than 70% of T2DM patients will die of CVD.[1]
- DM is associated with $37.3 billion in CVD-related care and 16% of CVD deaths.[2]
- From 2005 to 2013, FDA approved DPP-4i, GLP-1 RA, and SGLT2i for the treatment of T2DM.
- In 12/2008, FDA mandated long-term cardiovascular outcomes trials (CVOTs) for approval of new drugs.[3]
- CVOTs for these 3 classes have demonstrated mixed results: from neutral to positive CVD benefit for select drugs within GLP-1 RA & SGLT2i classes.[3,4]
- Discussion of CVD-beneficial CVOTs began appearing in clinical guidelines in early 2016;5 by 2019, ADA and EASD guidelines had codified findings into treatment pathways for people with T2DM & CVD (see figure 1).[4,6]

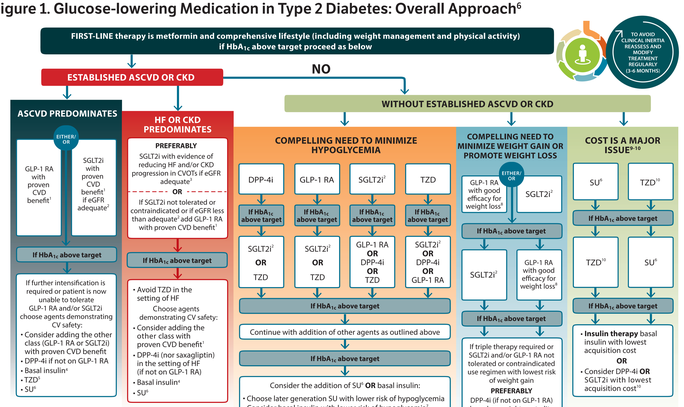
Methods

Study Design: Retrospective descriptive analysis in clinical, EHR database

Population Studied: 2.6 million patients aged 18–75 receiving care 2012–2018 in primary care, endocrinology, cardiology, or nephrology (≥ 2 ambulatory visits in 18 months) in 20 health systems.

Methodology: *Uptake of Therapies:* Three cohorts of ~350,000 patients with T2DM observed for existing or new Rx of novel antidiabetic agents, i.e., GLP-1 RA, SGLT2i, DPP-4i, during three 36-month periods ending Q1 of 2016, 2017, and 2018. *Clinical Inertia:* Three cohorts of ~8,500 patients withT2DM and HbA1c > 8 (1st 6-mos. each period) observed for same Rx during three 12-mo. periods ending as above. Baseline Rx identified in prior 2 years. Patients stratified by presence of CVD in both analyses.

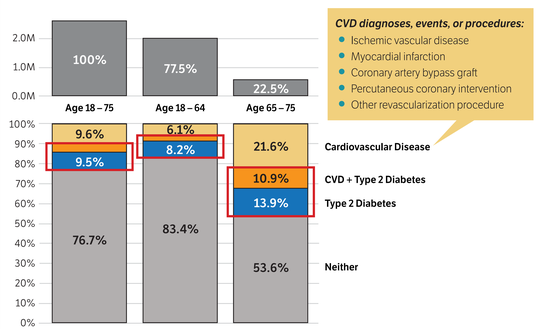
Figure 1. Glucose-lowering Medication in Type 2 Diabetes: Overall Approach[6]



Diabetes and CVD Prevalence

- 2.6 million patients, across 20 AMGA member health systems participating in Together2Goal® (T2G), AMGA's national campaign to improve care for patients with T2DM (April 1, 2017 to March 31, 2018).
- 13.7% with T2DM, 13.8% with CVD, and 4.2% with both T2DM and CVD.

Figure 2. T2G Patients with T2DM and CVD, by Age Group



About AMGA

AMGA is a nonprofit trade association representing 440 multispecialty medical groups and integrated delivery systems with a total of 175,000 full-time equivalent physicians. As AMGA's distinguished data and analytics collaborator, Optum® facilitates shared learning among AMGA members using an Optum population health and risk analytics solution. The Optum dataset includes clinical data from AMGA members' EHRs, mapped and normalized to enable apples-to-apples comparisons. The common data repository, which pools longitudinal EHR data from 54 health care organizations includes records for approximately 79 million patients.

- About 15% of AMGA member organizations, representing 25% of the total patients seen by AMGA member organizations, use Optum population health analytics.
- Benchmarking against other high performing organizations identifies best practices, which are translated to other AMGA member organizations.

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References

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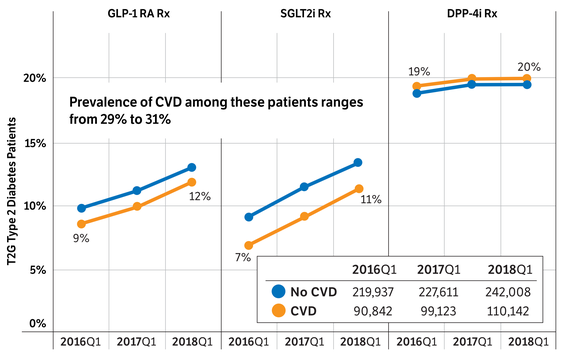
6. Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2018;41:2669–2701

Uptake of New Therapies

(Among All T2DM Patients)

- ~65% of all patients with T2DM were prescribed a combination of ≥ 2 medications.
- GLP-1 RA and SGLT2i prescriptions have increased from 2016–2018 (4 and 3%, respectively) but remain low among patients with T2DM: 12 and 13%, respectively (vs. 20% of patients with Rx for DPP-4i).
- Patients with T2DM and established CVD were less likely than those without CVD to have an Rx for GLP-1 RA or SGLT2i (p < 0.001).

Figure 3. T2DM patients with RX for GLP-1 RA, SGLT2i, or DPP-4i by CVD status



Recommendations

Guideline Adherence: Update care paths to reflect new guidelines and educate prescribers; use clinical decision support in the EHR; align formularies; employ shared decision-making tools to establish predominance of CVD with patients; and address potential cost/access barriers.

Positive Deviants: Identify "positive deviants" or early adopters of guidelines; learn from their successes and disseminate through in-person and virtual education and training.

Care Teams: Employ multi-disciplinary teams, including pharmacists to deploy guidelines and support use of best practices.

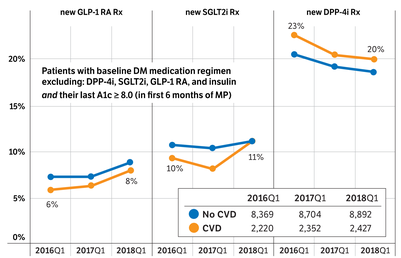
Implications

- Findings indicate a need to track treatment and prescribing among appropriate patient populations, paying attention to inertial behaviors at the system, provider, and patient levels and their underlying causes, e.g., cost, side effects, formularies, etc.
- Prescribing patterns will require substantial change to conform to current ADA Standards of Care.

Clinical Inertia in the Adoption of New Guidelines

(Among T2DM Patients Indicated (A1c ≥ 8.0) for Intensification)

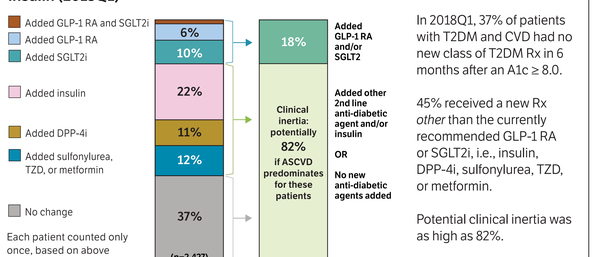
Figure 4. Proportion of patients with new Rx for GPL-1 RA, SGLT2i or DPP-4i by CVD status (in each of three T2G measurement periods)



New GLP-1 RA and SGLT2i prescriptions increased 2.5 and 1.9%; new DPP-4i decreased 2.7%.

Patients with T2DM and CVD were *more likely* than those without CVD to have *any* medication added to their regimen (p<0.001) (data not shown), but *no more likely* to have a *GLP-1 RA or SGLT2i* added to their medication regimen (p=0.30).

Figure 5. Potential clinical inertia among patients with T2DM and CVD, with A1c ≥ 8.0 and a baseline medication regimen excluding: DPP-4i, SGLT2i, GLP-1 RA, and insulin (2018Q1)



In 2018Q1, 37% of patients with T2DM and CVD had no new class of T2DM Rx in 6 months after an A1c ≥ 8.0.

45% received a new Rx *other* than the currently recommended GLP-1 RA or SGLT2i, i.e., insulin, DPP-4i, sulfonylurea, TZD, or metformin.

Potential clinical inertia was as high as 82%.

Conclusions

- Inertial behaviors associated with the introduction of novel antidiabetic drugs was observed in the general uptake of new therapies, the initial reaction to research, and the publication of new treatment guidelines.
- Prescribing of GLP-1 RAs and SGLT2is (as of early 2018) fell short of current expectations for recommended treatment for patients with both T2DM and CVD.
- Quality of care gaps in the treatment of patients with T2DM and CVD are evident.