Real World Clinical Outcomes Among Exenatide Once-Weekly Initiators Compared to Matched Initiators of Basal Insulin

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Introduction

- Exenatide once-weekly (EQW) is a glucagon-like peptide-1 receptor agonist treatment for patients with type-2 diabetes (T2D)
- EQW is an alternative to basal insulin (BI) when considering a first injectable therapy for a patient
- EQW may have advantages over BI, such as reducing insulin resistance, weight loss, limiting hypoglycemia risk, and improving blood pressure and lipid profiles.
- The degree to which these advantages of EQW improve outcomes in customary clinical care is unknown

Objectives

To quantify the effectiveness and tolerability of EQW initiation relative to initiation of BI among T2D patients initiating first injectable treatment.

Data Source

Humedica Research Database: An integrated electronic health record (EHR) database, including records from over 195 hospitals. The database represents a geographically diverse US population, over 25,000 physicians and over 25 million patients

Methods

Study Design and Population

- This retrospective cohort study used EHR data from July 2011 through March 2015 and identified injectable-naïve T2D patients who initiated either EQW or BI between January 2012 and January 2015
- EQW and BI initiations were identified from patients' prescribed medications

Patient Eligibility

- No prior injectable T2D treatment
- 6-months of care observed in the EHR prior to initiation
- A T2D diagnosis in the prior 6-months
- No T1D or gestational diabetes diagnosis within the prior 6-months

Propensity Matching

- EQW initiators were matched 1:2 to BI initiators by estimated propensity score using multivariable logistic regression and greedy matching
- Covariates used in propensity score modeling included demographics, clinical observations, laboratory values, site of care, comorbidities, and empirically identified indicators of drug classes, diagnoses, and procedures

Outcomes

- HbA1c and weight were evaluated for completeness, multiply-imputed, and reported in 3-month intervals up to 1-year following initiation
- Hypoglycemia was identified from diagnostic codes as well as through natural language processing of free text clinical notes

Analysis

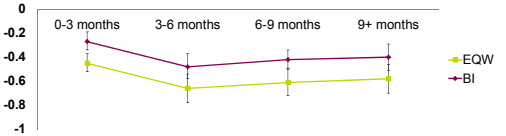
- Change in HbA1c and body weight were calculated as the difference between values observed in follow-up intervals from baseline
- For hypoglycemia, number and frequency of events during follow-up was reported. Incidence rates of hypoglycemia (and 95% CI) were reported using person-time censored at first event during follow-up. Cohorts were compared using a relative rate (RR) estimate and its 95% CI

Results

Table 1. Comparison of Baseline Characteristics between Propensity Score Matched Cohorts of Exenatide Once-Weekly and Basal Insulin Initiators

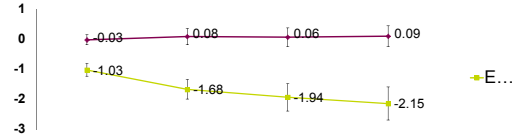
Baseline Characteristic		EQW (n=1,005) N (%)	BI (n=1,944) N (%)
Age Group (years)			
	18-34	40 (4.0)	94 (4.8)
	35-44	124 (12.3)	225 (11.6)
	45-54	289 (28.8)	548 (28.2)
	55-64	320 (31.8)	633 (32.6)
	65-74	197 (19.6)	378 (19.4)
	75+	35 (3.5)	66 (3.4)
Gender			
	Male	489 (48.7)	938 (48.3)
	Female	516 (51.3)	1006 (51.7)
Body Mass Index (kg/m^2)			
	Underweight or Normal weight (<24)	13 (1.3)	36 (1.9)
	Overweight (25-29)	130 (12.9)	290 (14.9)
	Obese (30-39)	522 (51.9)	1028 (52.9)
	Morbidly obese (>=40)	340 (33.8)	590 (30.3)
Hemoglobin A1c (%)			
	≤7.0%	260 (25.9)	485 (24.9)
	7.1-9.0%	463 (46.1)	880 (45.3)
	> 9.0%	282 (28.1)	579 (29.8)
Hypoglycemia Present		44 (4.4)	91 (4.7)

Figure 1. Change in HbA1c% from Baseline



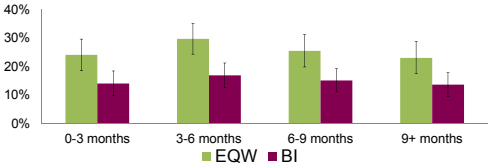
- For both EQW and BI, change from baseline was most notable 3-6 months after initiation
- Baseline values of HbA1c were 8.16% for EQW and 8.35% for BI; one year values were 7.61% and 7.93%, respectively

Figure 2. Change in Weight (kg) from Baseline



- Patients initiating EQW lost an average of 2.15 kg in the one year following initiation
- On average, patients in the BI group did not lose any weight in the one year following initiation

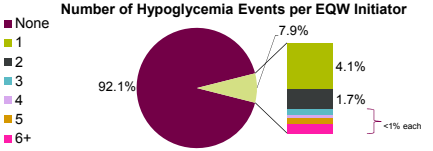
Figure 3. Percent of Patients with HbA1c ≤ 7% and Any Weight Loss



- In each quarter of follow-up, relative to patients in the BI cohort, patients in the EQW cohort were more likely to have both an HbA1c ≤ 7% and weight loss.

Figure 4. Occurrence of Hypoglycemia during Follow-up

Number of Hypoglycemia Events per EQW Initiator



Number of Hypoglycemia Events per BI Initiator

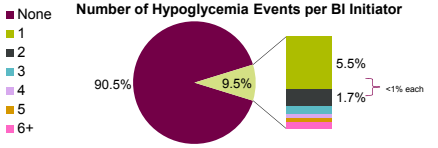


Table 2. Incidence of Hypoglycemia in Propensity Score Matched Cohorts of EQW and BI

	EQW (N=1,005)	BI (N=1,944)
Hypoglycemia Incidence		
Number of Incident Events	79 (7.9%)	185 (9.5%)
Person-Years of Follow-up Censored at First Event	1,607	3,099
Incidence Rate per 1,000 person years (95% CI)	49.15 (38.91 - 61.25)	59.69 (51.40 - 68.94)
Rate Ratio (95% CI)	0.82 (0.63 - 1.07)	1.00 (--)

Conclusions

- EQW offers a clinical advantage compared to BI with respect to likelihood of achieving both glycemic control and weight loss.
- The advantages of EQW relative to BI were apparent in each quarter of the first year after initiation.

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