Association Between Statin Therapy and CV Disease: Results from a Large US Health Research Network

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BACKGROUND

A recent secondary analysis of clinical trial data showed older patients taking statins for primary prevention of dyslipidemia received no benefit from the medication when compared to patients not on statins[1].

The aim of this analysis was to replicate these findings in a large federated health network in the US.

METHOD

The TriNetX network captures electronic medical record data from 11 healthcare organizations, representing 2 million patients aged 65 and older.

- Inclusion criteria: US patients aged 65 to 90 in 2013 with at least one medication code in 2013.
- Exclusion criteria: Secondary prevention criteria (cardiovascular (CV) disease, diabetes, or peripheral arterial disease) prior to index event.
- Index event: First statin code (exposed) or first medication code (unexposed) between 2013 and 2014.
- Outcome: First CV event after the index event, defined by ICD-9/10 codes for heart failure, ischemic cardiac events, or stroke

Baseline mean and frequency values, stratified by statin use, are presented in Table 1 and Figure 1.

Figure 2 shows a Kaplan Meier curve, stratified by statin use.

Unadjusted logistic and Cox models were used to estimate the odds and hazard ratios, respectively, for the association between statin use and cardiovascular events.

Age, sex, race, hypertension, CKD and smoking status were included in adjusted logistic and Cox models. IPTW were calculated using the same variables listed above to conduct a weighted Cox proportional hazards model.

RESULTS

- Statin users had a higher prevalence of dyslipidemia, but were similar in regards to other comorbidities and demographics.
- 541 statin and 24,295 non-statin users had a CV event during follow-up.
- Unadjusted survival curves were similar over the 3+ years of follow-up.
- Crude and adjusted logistic regression models who showed statin users had a small increased risk of CV events.
- Adjusted and IPTW Cox proportional hazards models showed a small decreased risk of CV events.

CONCLUSIONS

Results from logistic regression models, controlling for baseline characteristics, show a small increased risk of CV events among statin users. Results such as these have raised question about the efficacy and safety of statins in primary prevention patients. However, a more robust analysis using a weighted Cox model shows a protective effect between statin use and CV events. These findings suggest published literature may overestimate the risk of statins[1]. Further analysis will address additional limitations, such as competing risks and censoring, that were not taken into account in the current analysis.

Table 1. Sample Characteristics at Baseline

	Statin users (n=3,643)	Non-statin users (n=172,892)
Mean age (sd)	74 (7)	75 (8)
Mean duration of follow-up (sd)	134 days (187)	104 days (170)
Mean HbA1c* (sd)	6.1 (1.2)	5.8 (0.9)
Mean LDL cholesterol* (sd)	105.7 (60.6)	113.6 (37.1)
Mean BMI* (sd)	29.0 (0.3)	28.0 (6.2)

*only includes patients with results of measure or lab

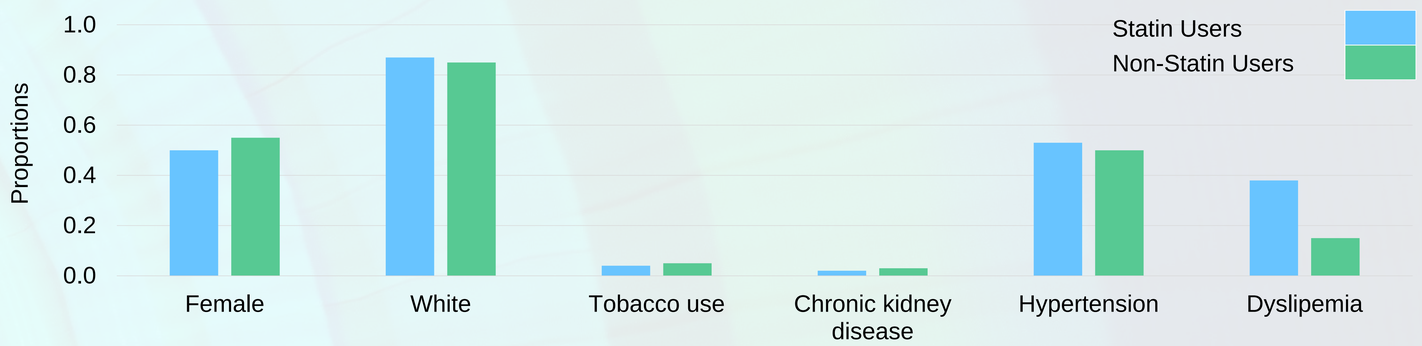
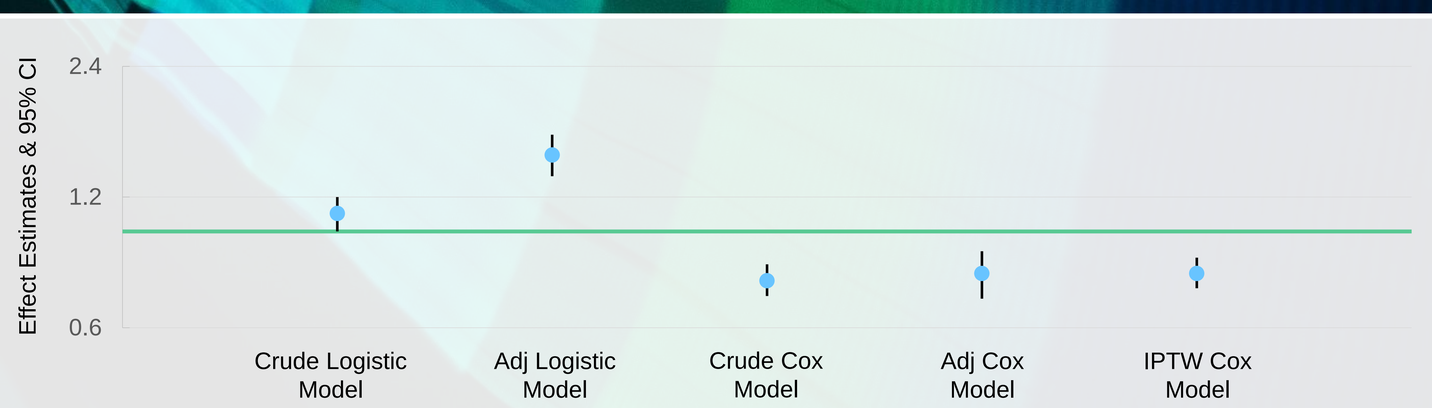


Figure 1. Characteristics at Baseline

Figure 2. Kaplan-Meier Survival Curves



Note: Each model compares statin users to non-statin users. Adjusted models control for age, sex, race, CKD, hypertension, smoking.

Figure 3. Results from Logistic & Cox Proportional Hazards Models

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1. Huesch MD. Association of Baseline Statin Use Among Older Adults Without Clinical Cardiovascular Disease in the SPRINT Trial. JAMA Intern Med. 2018;178(4):560-561.