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Research paper

Association between statin use and lipid status in quality improvement initiatives: statin use, a potential surrogate?

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ABSTRACT

Objective To test the association between statin use and low-density-lipoprotein (LDL)-cholesterol control in outpatient community practices undergoing quality improvement efforts in diabetes care.
Design A retrospective observational study of primary care practices that underwent efforts at improving the quality of diabetes care. Each practice provided an electronic registry-based monthly report of the percentage of patients with LDL <130 mg/dl (3.4 mmol/l), LDL <100 mg/dl (2.6 mmol/l) and statin use.
Setting Primary care practices in Pennsylvania focused on improving diabetes care by implementing the Chronic Care Model in urban, suburban and rural regions.
Participants Consisted of 109 primary care practices, academic practices and federal health centres. Practices typically saw patients from a mix of government-funded and commercial health plan carriers.
Results There was a positive linear association between documented statin use and the percentage of patients with LDL <130 mg/dl (3.4 mmol/l) and LDL <100 mg/dl (2.6 mmol/l = goal for patients with diabetes). The correlation between statin use and LDL <130 was 0.50 (95% CI 0.41–0.64), and between statin use and the percentage of patients with LDL <100 was 0.47 (95% CI 0.29–0.58). Practices with 5% larger statin use had an expected 1.9% larger percentage of patients with LDL <130 (95% CI 1.4 –2.9%) and an expected 1.7% larger percentage of patients with LDL <100 (95% CI 0.9–2.3%).
Conclusion An association exists between statin use and LDL control in the real world of primary care practices undergoing quality improvement. Additional studies are necessary to ultimately test the validity of statin use as a process measure and/or surrogate for LDL-cholesterol control.

Keywords: chronic care model, dyslipidemia, patient-centred medical home, process measure, quality improvement, statins

How this fits in with quality in primary care

What do we know?
LDL-cholesterol reduction is a cornerstone of clinical care in patient populations with increased cardiovascular risks. It is a commonly used outcome measure and tracked as one of multiple quality of care indicators. Statins have found widespread use and have been demonstrated to be an effective means of lowering LDL-cholesterol in multiple research trials. Many quality improvement initiatives look to utilise process measures as early indicators of potential improvement in clinical outcomes. Evidence, however, is lacking for many process measures since improvements in processes often have limited clinical benefits.

What does this paper add?
Little is known about the effectiveness of statin prescribing as a process measure in the real world of primary care practices striving towards quality improvement. Unlike laboratory values, medication use (specifically the use of statins) is often available in large claims-based databases which makes it an easily accessible process measure. This study demonstrated that, in primary care practices implementing the Chronic Care Model and the Patient Centered Medical Home, a clear positive association exists between statin use/prescribing (as a process measure) and LDL-cholesterol goal attainment. This association supports the continued use of statin prescribing as a valuable quality improvement process indicator and as a possible early surrogate for LDL-cholesterol control.

Introduction

Process measures represent steps in the provision of care that influence important clinical outcomes. The act of documenting and tracking performance measures itself contributes to improvements in clinical care.[1] Based on this premise, many new process measures have evolved in recent years, and providers worldwide are asked to report an increasing number of measures. As a result, the requirements to meet benchmarks and/or goals without appropriate prioritisation are viewed by clinicians as distractors from important activities.[2] Quality of care continues to be a major focus in health systems worldwide, including Australia, New Zealand, the United States and Europe.

A useful process measure is one that increases adherence to recommended practice guidelines and ultimately leads to important clinical benefits and/or improvements in outcome.[2] This, however, is lacking for many process measures since improvements in processes often have limited clinical benefits.[3] Testing the association of a specific process measure with its corresponding clinical outcome is a reasonable early step to establish the validity of the process measure.

Given its high association with cardiovascular events,[4] much attention has been focused on improving dyslipidaemia,[5] including in those with diabetes.[6] As many quality initiatives focus on a number of process and outcome measures, a frequent strategy has been to track the percentage of patients meeting benchmarks for low-density-lipoprotein cholesterol (LDL) levels below 130 (3.4 mmol/l) and/or 100 mg/dl (2.6 mmol/l).[7] At the same time, the tracking of statin use is a relatively simple, transparent process measure since statins achieve potent LDL-cholesterol lowering with established cardiovascular benefits[8,9] and these data may already exist in claims-based databases. However, despite these benefits in large-scale randomised trials, the 'real-world' association between statin use and attainment of LDL-cholesterol goals has not been examined. The objective of this study was to investigate this association and thereby test the validity of tracking statin use as a useful process measure.

Methods

This was a retrospective observational study of a Pennsylvania state-wide implementation of the Chronic Care Model (CCM)[10] and the Patient Centered Medical Home (PCMH)[11] which began in May 2008.[7] The Pennsylvania Chronic Care Initiative (PA-CCI) was aimed at primary care practice redesign with an initial focus on diabetes. A total of 130 Pennsylvania primary care practices, academic centres and federal qualified health centres (government-supported clinics that offer care to underserved populations and individuals who cannot afford insurance), with a variety of geographic locations in urban, suburban and rural areas, participated. A typical practice saw patients from a mix of government and commercial payers. Uniform registry-based monthly self-reporting of diabetes quality measures was required for practice participation. Among other measures, the percentage of patients with LDL-cholesterol levels below 130 ('intermediate LDL control') and 100 mg/dl ('good LDL control') were reported monthly via an electronic registry. LDL control was defined by a numerator consisting of the

number of active diabetes patients (ages 18–75) with a most recent LDL-cholesterol level below 130 and 100 mg/dl, respectively, within the last 365 days of the current reporting period. The denominator of both variables was active diabetes patients (age 18–75). Monthly reporting of statin use was defined as the percentage of active diabetes patients aged 40–75 (with an active statin prescription/count of active diabetes patients aged 40–75). In all cases, practice-level aggregate data and not individual patient data were reported.

Eleven practices (8%) did not collect data for statin use and/or LDL outcomes for any month and were therefore excluded from the analysis (see Figure 1). An additional ten practices were also excluded because these practices had an unrealistic greater than 20% increase or decrease in the percentage of total patients with LDL <130, LDL <100, or statin use in consecutive months, which was likely an early reporting artefact as practices learned to collect these measures. Practices typically needed an initial learning period to establish and maintain accurate registry documentation. Hence, the first three months of reported data were excluded for each practice. The final effective sample size consisted of 109 practices, with eight months of data (the maximum available for most practices at the time of analysis) used for each practice.

To explore the relationship between statin use and LDL-cholesterol outcomes a random month was drawn from each practice. A scatter plot was produced to compare the percentage of patients using statins versus the percentage of patients with LDL <130 (or LDL <100) in this randomly selected data set. Then, a simple linear regression model was fitted and the predicted mean response from the model overlaid in the scatter plot. The process was repeated 1000 times using bootstrapping.[15] Specifically, in each bootstrap sample, practices were sampled with replacement, a random month drawn from each selected practice, and a simple linear regression model fitted. The fitted regression parameters and the correlation coefficient were gathered in each bootstrap sample, and 95% confidence intervals (CIs) were constructed using the BCa method.[16]

Results

The 109 Pennsylvania primary care practices participating in the PA-Chronic Care Initialize (CCI) and included in our analysis collected 787 total months of data. There were a total of 36,440 diabetes patients across these 109 practices. An average of 347 diabetes patients were followed per practice, while in each practice a mean of 64% of patients were on statin therapy. The practices had an average of 66% of patients with LDL <130, and an average of 47% of patients with an LDL <100 (Table 1). Most practices were family medicine (70%) and internal medicine (18%), with federally qualified health centres (government-supported clinics that offer free care to underserved populations and individuals who cannot afford care) and residency training clinics (an integral part of academic and community hospitals) comprising the rest. Most practices consisted of four to ten providers (>50%), while 40% of practices were smaller (one to three providers). Seventy-seven practices (71%) had

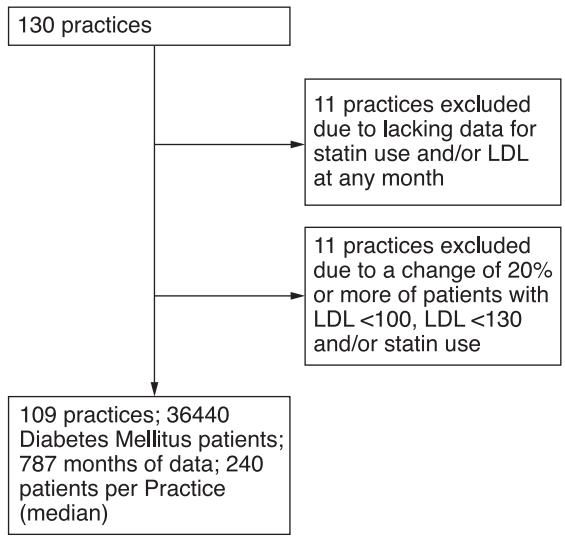

Figure 1 Study flow diagram

Table 1 Summary of the practices used in the analysis

Variable	$n = 109$
Size of practice (number of patients)	
Mean (SD)	347 (306)
Median (range)	262 (20–2236)
Percentage of patients using statins	
Mean (SD)	64% (16%)
Median (range)	64% (23–92%)
Percentage of patients with LDL <130	
Mean (SD)	66% (12%)
Median (range)	67% (15–98%)
Percentage of patients with LDL <100	
Mean (SD)	47% (11%)
Median (range)	48% (14–73%)

the maximum of eight months' data, while 100 practices (92%) had at least five months of data.

Figure 2A shows a scatter plot of the percentage of patients using statins versus the percentage of patients with LDL <130, for a randomly selected month from each practice. The plot indicates a positive linear association: practices with more statin use tended to have a larger percentage of patients with LDL <130. Figure 2B shows the mean response from the simple linear regression model for each of 1000 bootstrap samples. A similar linear relationship was observed in each sample. Based on the bootstrap results, the estimated intercept was 41.9 (95% CI 29.4–49.5) and slope was 0.37 (95% CI 0.27–0.57). Practices with 5% larger statin use had an expected 1.9% larger percentage of patients with LDL <130 (95% CI 1.4–2.9%). The estimated correlation was 0.50 (95% CI 0.41–0.64). Figures 2C and 2D show the same plots for the relationship between statin use and the percentage of patients with LDL <100. Based on the bootstrap results, the estimated intercept was 25.9 (95% CI 13.7–32.8) and slope was 0.33 (95% CI 0.24–0.51). Practices with 5% larger statin use had an expected 1.7% larger percentage of patients with LDL <100 (95% CI 0.9–2.3%). The estimated correlation was 0.47 (95% CI 0.29–0.58).

Discussion

This analysis demonstrated an important and statistically significant association between documented statin use and LDL goal attainment. It implies potential validity for documented statin use as a process measure. This has practical implications, since data on statin use are often available from large claims

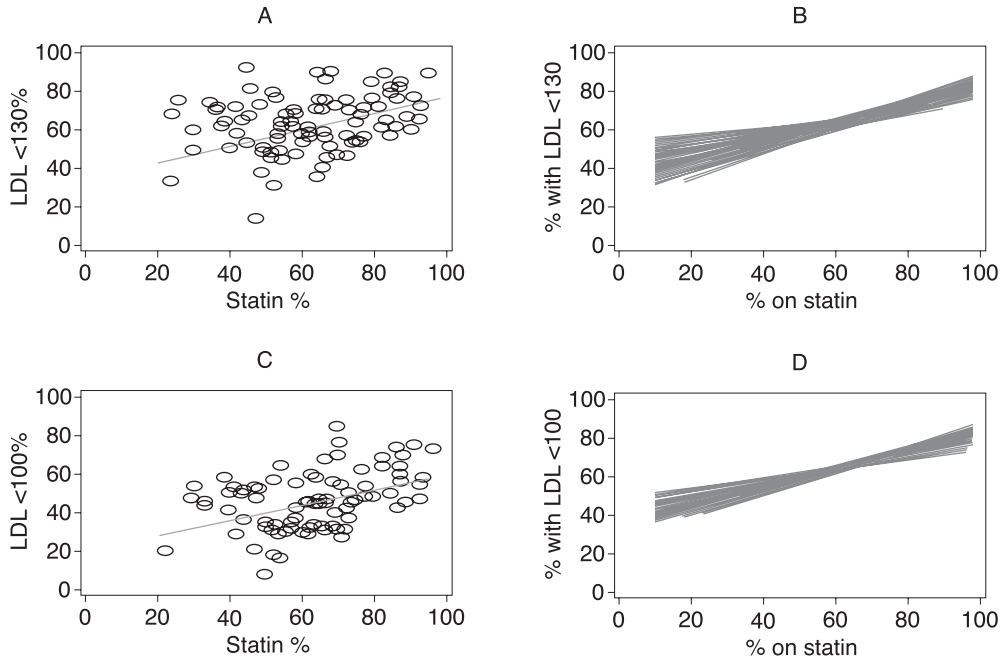

Figure 2 (A) Scatter plot of percentage using statins versus percentage with LDL <130 from a randomly selected month from each practice with mean response from simple linear regression model overlaid; (B) mean response in each of 1,000 bootstrap samples for LDL<130; (C) and (D) are the same plots for LDL<100

databases (e.g. private or government payers often have statin prescription data but not LDL values). In those primary care settings where there is insufficient adherence to evidence-based recommendations in treating diabetic dyslipidaemia,[17] this could be an effective tool to drive broad-scale quality improvement by enhancing adherence to clinical practice guidelines.

While numerous past clinical studies have demonstrated the effectiveness of statins in lowering LDL-cholesterol, they have been performed in clinical research settings designed to assess the efficacy of statin agents on individual participating human subjects.[9] To our best knowledge, however, this is the first study to test the relationship between these two measures in a 'real-life' setting (and at practice level). The participating primary care practices in this analysis are urban, suburban and rural practices, a sample mix representative of most US practice settings. Furthermore, no such analysis of this relationship has been performed among practices undergoing efforts to improve quality in diabetes care.

The healthcare team of each primary care practice attended regular quarterly meetings during which experiences with other practice teams were exchanged and new steps in quality improvement planned. On-site practice coaches helped facilitate the efforts of each practice team at improving the quality of diabetes care. A key hallmark of this commitment to quality improvement was the monthly generation and tracking of diabetes care quality reports by each practice through an electronic database/registry. Typically, besides measures of LDL-cholesterol control and statin prescribing, the reports contained a range of other diabetes care measures such as A1C, blood pressure, foot examinations and urine microalbumin testing. Practices received infrastructure payments to support the costs of quality improvement, and the payments were tied to achieving progressive tiers in the certification as Patient Centered Medical Homes (PCMH).

The PCMH can be regarded as a vehicle to adopt the Chronic Care Model, a widely accepted evidence-based guide to quality improvement efforts in the primary care setting.[12] It holds promise to strengthen primary care in the US and reduce the high expenditures for chronic illness care by improving long-term health outcomes.[11] A critical component of a PCMH is that members of a well-tuned healthcare team work together through effective coordination and communication. The team has a whole-person orientation (patient-centredness) with attention to not only medical aspects of care, but also psychological and social ones. Information technology is an integral part of such an environment and is coupled with a commitment to regular performance review and consistent focus on continuous quality improvement. The performance review typically takes place in the form of regular practice healthcare team meetings during which process and outcome measures are reviewed and further steps planned. The electronic health record which serves as a patient registry enables the preparation of pertinent data necessary for such meetings, leading to effective population-based management within the individual practice.[13] Another proposed component of the PCMH has been a long-term vision for payment reform partly based on a pay-for-performance mode of provider reimbursement.[14]

Upon defining LDL control as a percentage of individuals below the thresholds of 100 and 130 mg/dl, individuals of ages 18–75 years were included. The definition of statin use however included a slightly different age group consisting of individuals aged 40–75 years. This difference in the ages of individuals was not deliberate, but due to the fact that practices reported all the measures as aggregate data and not individual patient data. The inclusion or exclusion of individuals based on age was therefore not possible due to the nature of aggregate data reporting. While this may imply a deficiency in the methodology, the National Health and Nutrition Survey (NHANES), which is representative of the US population, documented that younger adults (age 20–39) with dyslipidaemia are typically not on any cholesterol-lowering medication.[18] It is therefore unlikely that this difference in ages has any significant influence on the results of the analysis.

Measuring various processes in the care of the chronically ill is a common approach to assessing quality in many other conditions, despite a lack of a clear association with relevant outcomes. Examples are stroke care,[20] in which only three out of seven processes were found to have an independent association with an improvement in neurological outcomes. In heart failure, certain process measures (e.g. documenting left ventricular function assessment, smoking cessation advice) had no mortality benefit.[21]

While a correlation is defined as the strength of association between two variables and how closely they are related, it ranges between –1 (perfect negative correlation) and + 1 (perfect positive correlation). Generally, a rule of thumb is that a correlation of 0.50 is 'moderate', but the strength of association is truly dependent on context. A limitation of this retrospective observational study is whether these findings apply to different patient and provider groups. Further studies are needed to determine whether for example type of health system, geographic location or socio-economic status of the community influence this relationship. The question of whether statin use is a good surrogate for LDL-cholesterol therefore remains an open one. Our results are some of the first data that simply support a statistical relationship between statin use and LDL-cholesterol, as evidenced by correlation coefficients of 0.50 and 0.47.

Finally, although these are self-report data from practices, we wish to point out that many quality improvement efforts use self-reporting as a common methodology.

On a final note, an additional argument that supports the tracking of statin prescribing is existing evidence that treating diabetes patients with statins improves health outcomes irrespective of whether LDL-cholesterol targets were reached.[19]

Conclusion

A positive association exists between statin use and LDL-cholesterol use in a real-world setting of practices undergoing diabetes quality improvement efforts. This supports the continued efforts to report statin use as a process measure. Further validation studies are needed to link these types of population measures with decreased mortality in patient populations with increased cardiovascular risk.

REFERENCES

1 Jha AK, Perlin JB, Kizer KW and Dudley RA. Effect of the transformation of the Veterans Affairs Health Care System on the quality of care. *New England Journal of Medicine* 2003;348:2218–27.
2 Werner RM and Asch DA. Clinical concerns about clinical performance measurement. *Annals of Family Medicine* 2007;5:159–63.
3 Werner RM and McNutt R. A new strategy to improve quality: rewarding actions rather than measures. *JAMA* 2009;301:1375–9.
4 Lehto S, Ronnemaa T, Haffner SM, Pyorala K, Kallio V and Laakso M. Dyslipidemia and hyperglycemia predict coronary heart disease events in middle-aged patients with NIDDM. *Diabetes* 1997;46:1354–9.
5 Waters DD, Brotons C, Chiang CW *et al*. Lipid treatment assessment project 2: a multinational survey to evaluate the proportion of patients achieving low-density-lipoprotein cholesterol goals. *Circulation* 2009;120: 28–34.
6 Wouter Jukema J, Chiang CW, Ferrières J *et al*. Lipid goals among patients with diabetes or metabolic syndrome: Lipid Treatment Assessment Project (L-TAP) 2. *Current Medical Research and Opinion* 2589–97.
7 Gabbay RA, Bailit MH, Mauger DT, Wagner EH and Siminerio L. Multipayer patient-centered medical home implementation guided by the chronic care model. *Joint Commission Journal on Quality and Patient Safety* 2011;37:265–73.
8 Law MR, Wald NJ and Rudnicka AR. Quantifying effect of statins on low density lipoprotein cholesterol, ischaemic heart disease, and stroke: systematic review and meta-analysis. *British Medical Journal* 2003;326: 1423.
9 Baigent C, Blackwell L, Emberson J *et al*. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet* 2010;376:1670–81
10 Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J and Bonomi A. Improving chronic illness care: translating evidence into action. *Health Affairs* 2001;20:64.
11 Bojadzievski T and Gabbay RA. Patient-centered medical home and diabetes. *Diabetes Care* 2011;34:1047–53
12 Tsai AC, Morton SC, Mangione CM and Keeler EB. A meta-analysis of interventions to improve care for chronic illnesses. *American Journal of Managed Care* 2005;11:478–88.
13 Khan L, Mincemoyer S and Gabbay RA. Diabetes registries: where are we and where are we headed? *Diabetes Technology and Therapeutics* 2009;11:255–62.
14 Davis K, Schoenbaum SC and Audet AM. A 2020 vision of patient-centered primary care. *Journal of General Internal Medicine* 2005;20:953–7.
15 Efron B. *The Jackknife, the Bootstrap and other Resampling Plans*. Society for Industrial and Applied Mathematics, Philadelphia, PA; 1982
16 Carpenter J and Bithell J. Bootstrap confidence intervals: when, which, what? A practical guide for medical statisticians. *Statistics in Medicine* 2000;19:1141–64.
17 Standards of medical care in diabetes – 2006. *Diabetes Care* 2006;29 Suppl 1:S4–42.
18 Ghandehari H, Kamal-Bahl S and Wong ND. Prevalence and extent of dyslipidemia and recommended lipid levels in US adults with and without cardiovascular comorbidities: the National Health and Nutrition Examination Survey 2003–2004. *Am Heart J* 2008; 156:112–19.
19 Colhoun HM, Betteridge DJ, Durrington PN *et al*. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *Lancet* 2004; 364: 685–96.
20 Bravata DM, Wells CK, Lo AC *et al*. Processes of care associated with acute stroke outcomes. *Archives of Internal Medicine* 2010;170:804–10.
21 Fonarow GC, Abraham WT, Albert NM *et al*. Association between performance measures and clinical outcomes for patients hospitalized with heart failure. *JAMA* 2007;297:61–70.

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