The Quality of Quality: Is it Time for New Tools?

Running title: Roger; The quality of quality: is it time for new tools?

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Journal Subject Codes: Treatment:[122] Secondary prevention, Etiology:[7] Chronic ischemic heart disease

Key words: Editorial, statin, prevention
Over the past two decades, HMG-CoA reductase inhibitors (“statins”) have taken center stage in the secondary prevention after MI as evidence of their efficacy emerged from clinical trials.\textsuperscript{1-4} Practice guidelines then incorporated the results of clinical trials and since guideline-based care processes were shown to be associated with outcomes,\textsuperscript{5} performance measures became an indicator of the quality of care.\textsuperscript{6} Performance measures track whether or not evidence-based medications are administered after MI. However, they do not assess whether or not the dose was optimal. The dose is an important issue for statins as their efficacy to prevent recurrent MI and death after the initial event has been shown to be greater at higher doses.\textsuperscript{2, 7}

The paper by Arnold et al. in this issue of Circulation\textsuperscript{8} adds more depth to the conversation on quality of care after MI by examining the dose of statins that patients have received after acute MI in an observational study. The authors report on data from the Translational Research Investigating Underlying disparities in acute Myocardial infarction Patients’ Health status (TRIUMPH) study. TRIUMPH is an NHLBI funded prospective registry designed to study the outcomes after MI with a distinct focus on health status outcomes in black and white patients. TRIUMPH collected detailed data on the socioeconomic, clinical, treatment, health status, metabolic, and genetic characteristics of patients with acute MI enrolled in 24 centers across the United States between 2005 and 2008\textsuperscript{9}. The design of the TRIUMPH study included an extensive (5 hours) data collection process and upon study completion, 4340 patients were eligible for analysis. The depth of the data collected in TRIUMPH provides an unprecedented opportunity to gain insights into critical aspects of the presentation, care and outcome of patients with acute MI, and the report in the current issue of Circulation\textsuperscript{8} illustrates such capabilities. The study describes statin initiation, as well as intensification and maximization of dose during MI hospitalization, and reports both patient-level and hospital-level
analyses. Statin initiation among previously untreated patients was high (87%) and uniform across sites. However, among previously treated patients, dose intensification occurred in only 26% of patients with moderate variation across sites, and only 23% of patients were discharged on maximal statin therapy with large differences in practice patterns across sites. While one might argue that outpatient follow-up visits might be the time when dose escalation occurs, a previous report from the same group has documented that, 12 months after the MI, only 26% of eligible patients in TRIUMPH were receiving target doses of statins, indicating that further dose escalation in the outpatient setting is infrequent.10

To interpret these important findings, it is useful to reflect on the selection of patients included in TRIUMPH. During the study period (from 2005 through 2008), 31,567 patients with elevated troponin levels were screened, 6,152 were determined to be eligible, and 4,563 (74%) were enrolled, of which 223 either did not meet inclusion criteria or were from sites excluded due low enrollment. Thus, the final number of patients used in the analysis is 4,340. The case mix of patients in TRIUMPH is noteworthy as patients were on average 59 years old, which is significantly younger than patients screened but not enrolled in TRIUMPH9 and approximately 10 years younger than patients in epidemiology incidence cohorts of acute MI.11,12 Further, in TRIUMPH, the proportion of patients who presented with ST elevation MI is substantially greater than in community cohorts. One may thus conceivably presume that the proportion of patients in whom dose escalation and optimization occurred is higher in TRIUMPH than in routine clinical practice.

These considerations are important to reflect upon within the context of the value of clinical registries as optimal repositories of information on the quality of care.13 Indeed, clinical registries are often envisioned as providing increased generalizability compared to the more
selected randomized control trials, and better reflecting the care delivered in practice. It is critical to underscore, however, that participation in registries is voluntary, such that institutions that elect to participate may differ from those that do not. Similarly, participating institutions may select the patients that they submit to a registry while interpreting the inclusion/exclusion criteria differently. Hence, it should not be assumed a priori that registries provide optimal external validity by design, and examining their design and case mix is crucial to draw proper inference from registry data.

These considerations notwithstanding, the study by Arnold and colleagues has important practice implications. Firstly, these findings raise awareness about the importance of drug escalation, a point critical to treatment effectiveness but that can be overlooked in practice. For example, fifty percent of patients with apparent treatment-resistant hypertension are not prescribed an optimal regimen,14 underscoring the importance of considering drug therapy optimization, including dose and regimen, to appropriately manage hypertension clinically and to understand related population trends.15

Secondly, if we agree that surveillance of drug therapy doses is important, then what are our options for such surveillance activities? As mentioned above, registries are being promoted for the purpose of quality measurement13 and unquestionably offer numerous advantages including sample size and depth of data collection (containing clinical data on risk factors and comorbidities). These characteristics, in turn, afford robust analytical advantages in terms of precision and adjustment strategies over administrative and claims data. Hence, registries have the potential of providing greater insights into clinical decision making and outcomes than claims data. However, as discussed above, while their internal validity is strong, the selection and case mix of registries may hinder the external validity of their data. In other words, if
patients in a given registry are younger and healthier than the overall population affected by the disease under consideration, then the data from the registry do not necessarily apply to all. Electronic medical records (EMR), which implicitly are construed as more generalizable, are an attractive option to monitor drug therapy and its quality. Yet, validation studies suggest that the EMR may not yet be ready for prime time when it comes to quality assessment. However, while cautionary reports on the use of EMR for performance monitoring are surfacing, this is a rapidly evolving field and one can hope that awareness of current shortcomings will lead to addressing them in the near future.

Thirdly, the TRIUMPH data raise the provocative question of the adequacy of current performance measures. Since the dose of a given medication is important for its effectiveness, appropriate dose intensification and escalation indeed reflect the quality of the care that a patient receives. Thus, should performance measures be modified to monitor the dose? Before we can take that leap, several questions should be addressed. Could the current data from TRIUMPH reflect an unintended consequence of existing quality metrics whereby current measures lead practitioners to “check the yes/no box” when it comes to statins without considering the dose? If this were the case, then including the dose in performance metrics could potentially lead to more “playing to the measures” and less than mindful dose escalation in elderly patients where drug side effects and adverse consequences of polypharmacy are critical concerns. Indeed, practice guidelines do not provide an adequate clinical framework to care for the elderly with multimorbidity. In the presence of multiple chronic conditions (the norm in the elderly), treatment plans that follow guidelines are highly complex, thereby creating a risk of errors and leading to polypharmacy with its inherent risk of adverse drug reactions/interactions. Hence, while performance measures have been essential to improving the quality of care, there is an
inherent tension between performance measures and holistic care, and the inadequacy of current, largely process-based systems for the growing elderly population is increasingly recognized.\textsuperscript{20} The optimal treatment should address the target disease while considering the whole individual, with the goal of preserving or even enhancing quality of life. The dose of a given medication, while important, is only one facet of complex care processes. Thus, work on quality measures includes the important task to execute: track the use of effective drug treatment, including dose, while integrating measures of multimorbidity and quality of life. This is clearly a tall order of business and much remains to be done. The present paper commendably challenges us to move forward in this direction.

\textbf{Conflict of Interest Disclosures:} None.

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Circulation, published online February 4, 2014;

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

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World Wide Web at:
http://circ.ahajournals.org/content/early/2014/02/04/CIRCULATIONAHA.114.008390

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