Clinical Epidemiology, Clinical Care, and the Public’s Health

Clinical epidemiology is the “science of making predictions about individual patients...using strong scientific methods” to “obtain the kind of information clinicians need to make good decisions in the care of patients.” Although randomized clinical trials are cited routinely as the highest form of clinical epidemiology, recent interest has focused on the ability of observational methods to yield valuable insights into the nature and effect of treatments of common and serious diseases that represent major threats to the public’s health.

Many observational treatment studies attempt to answer the same type of questions as randomized trials: Does a treatment work and is it safe? It is remarkable how often observational studies and randomized trials yield similar results. Even when seeming contradictions exist, for example with the effect of hormone replacement therapy on cardiovascular risk in postmenopausal women, a careful look shows that when appropriate methods are used and confounding variables are properly measured, the contradictions may disappear. A different type of observational treatment study goes a step further. Investigators accept that trial data are true and therefore worthy of widespread acceptance in clinical practice. Now the question is: Are effective treatments actually being used? Rather than asking about the effectiveness of care, clinical epidemiologists are instead asking about the quality of care.

In the current issue of the Mayo Clinic Proceedings, Perschbacher et al report on the use of accepted evidence-based therapies for acute myocardial infarction in Olmsted County, Minnesota, between 1979 and 1998. They focused on 4 therapies for which there is now indisputable randomized trial evidence of benefit, at least among important subsets of patients with myocardial infarction. For all 4 therapies, namely reperfusion therapy or revascularization, aspirin, angiotensin-converting enzyme (ACE) inhibitors, and β-blockers, use has increased substantially. Nonetheless, even after accounting for numerous possible confounding variables, the authors found that elderly patients were less likely to be treated with β-blockers and that reperfusion therapy or revascularization was less likely to be administered for women and elderly patients. The implications of these findings are clear and important: Despite many journal publications reporting on treatment effects and despite countless meetings, symposia, lectures, grand rounds, published guidelines, and even industry marketing, many patients with acute myocardial infarction are not receiving the best-quality care.

Measuring quality of clinical care with epidemiological methods presents numerous challenges. Both patient populations and treatment options are rapidly moving targets, particularly in this era of an aging population and exploding biotechnology. As shown by Perschbacher et al, patients with myocardial infarction in the 1990s were different from their counterparts in the 1970s. They were older, more often women, less likely to have ST-segment elevation on presenting electrocardiography, and more likely to have important comorbidities including hypertension and diabetes. Also, treatments for myocardial infarction have changed dramatically. The role of reperfusion was firmly established only in the mid-1980s, and the preferred treatment has moved from thrombolysis with anticoagulants to stenting with aggressive platelet antagonism. Similarly, in the 1980s and 1990s, ACE inhibitors were shown to have value for patients with reduced ejection fraction; more recently, it has been suggested that ACE inhibitors may benefit patients with coronary disease irrespective of left ventricular function. Because of changing patient populations and treatments, measurement of the appropriateness of care is, at least to some degree, inherently limited.

Despite these concerns, numerous authors, including Perschbacher et al, have shown consistently that many patients with acute myocardial infarction do not receive appropriate evidence-based care. Even if we do not know the exact severity of the problem, clearly there is a pressing need to develop methods for systematically improving the quality of clinical care that the public should expect. Of note, a recent report indicated that the “best” cardiovascular centers, as reported by U.S. News & World Report, were also...
those that more often used aspirin and β-blockers, 2 of the treatments Perschbacher et al examined in their Olmsted County patients.12

Despite much interest in clinical efficacy and quality, it is unknown which methods optimally improve quality of cardiovascular clinical care. Using qualitative methods, Bradley et al13 found that hospitals that successfully increased β-blocker use after myocardial infarction reported quality improvement efforts that included shared goals, solid administrative support, physician champions, and credible data feedback. A coordinated effort of multiple institutions and groups in southern Michigan led to the Guidelines Applied in Practice (GAP) initiative, which included multiple interventions such as presentations, guideline-based tools, identification and encouragement of opinion leaders, and frequent data measurements with feedback.14 In their pilot initiative, the GAP group, using a controlled but nonrandomized design, found modest but real improvements in smoking cessation counseling and use of β-blockers and aspirin.15 A similar approach adopted from industry is Continuous Quality Improvement, in which processes and outcomes are measured repeatedly before and after implementation of test interventions.15 In a large randomized trial, Continuous Quality Improvement was found to increase the use of β-blockers and internal mammary artery grafts among patients undergoing coronary artery bypass surgery, particularly in medical centers that had low utilization initially.15

Interest in measuring and improving quality of cardiovascular care is also intense outside of the clinical community. Of particular concern to many is the development of “scorecard” or “report card” medicine, in which outcomes, rather than processes, are publicly reported on the Internet or in print media and presented as credible evidence of quality of care.16 Some reporting mechanisms are based on clinical data that are carefully obtained with conscientious efforts to adjust for differences in case mix.16 These data may be used to advantage for assessment of cardiac surgery outcomes, although it has been argued that apparent quality improvements were due to worried physicians shying away from higher-risk patients.17 Other reporting mechanisms use administrative data and propriety models for publicly grading hospitals.18 Although these reports, in aggregate, may correctly predict outcomes as a function of which hospital patients receive care, on an individual hospital basis there may be substantial error.18 Still other reports focus on volume, arguing that high-volume institutions almost by definition will provide high-quality care; careful examination of this presumption has questioned the strength of the volume-quality link.19

Perschbacher et al make it clear that clinical epidemiology has more to offer than assessments of treatment efficacy and safety. By showing that despite improvements many patients with acute myocardial infarction are receiving suboptimal care, these investigators highlight the importance of frequently measuring and attempting to improve the delivery of evidence-based treatments. Only in this way will the tremendous advances we have seen in biomedical science translate into real improvements in clinical care and the public’s health.

Michael S. Lauer, MD
Department of Cardiovascular Medicine
Cleveland Clinic Lerner College of Medicine
of the Case Western Reserve University
Cleveland, Ohio