More than 4 years have elapsed since the publication of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial, which led to rampant speculation regarding its potential impact on clinical practice. As memories of the heated rhetoric that punctuated that debate fade, we are now in a position to look back with calmer heads and use observational data to see whether COURAGE was indeed associated with changes in the use of percutaneous coronary intervention (PCI). Given the importance of the issue (>600,000 patients underwent PCI in 2007), assessing the impact of COURAGE is an important test of the ability of these observational data resources to measure not only the presence of evidence-associated changes in practice, but also the pace and magnitude of those changes.

COURAGE and Overall PCI Volumes

Perhaps the most straightforward approach to assess the effect COURAGE on practice is to determine whether there was a temporally associated change in the overall use of PCI. In a recent issue of Circulation: Cardiovascular Quality and Outcomes, Riley et al. reported, using Medicare claims data, a 12.5% reduction in the use of PCI from 2004 through 2009, with most of the decline occurring in 2007. Although that drop may seem relatively modest, it occurred after a period of unprecedented growth in PCI during the preceding decade. It is tempting to attribute the observed decline to changes in the management of stable coronary artery disease (CAD), but this study left open the question of whether at least some of the reduction in PCI volumes could be a consequence of other factors. Foremost among these other factors were concerns regarding late thrombosis of drug-eluting stents (DES) that was initially brought to attention at the European Society of Cardiology Conference in September 2006 (6 months before the presentation of COURAGE). In addition, there have been reports of a concomitant decline in the incidence of myocardial infarction, which also could result in fewer PCI procedures. Finally, less clinical restenosis with DES also likely contributed to the decline in overall PCI volume. Given the myriad of factors influencing overall PCI use, determining the impact attributable to adoption of the evidence provided by the COURAGE trial is challenging.

PCI for Stable Angina: A Smaller Piece of the Pie?

To better assess the impact of COURAGE on the use of PCI, ideally one would focus on the subset of patients with stable CAD—the clinical setting for COURAGE. Clinical registries are better suited than administrative data for making this distinction, given their richer clinical detail and explicit quantification of procedural indications. A “stable proportions” approach has been applied to registry data to assess trends in the proportion of PCI procedures performed for stable indications. The implicit assumption is that the strengths of the indications and contraindications for PCI for unstable presentations provide a constant denominator so that the changes in the numerator (ie, patients with stable disease) can readily influence this ratio and reflect changes in the treatment patterns of stable CAD.

In this issue of Circulation: Cardiovascular Quality and Outcomes, investigators from the Northern New England (NNE) PCI Registry used the stable proportions approach to document for the first time in a large population a reduction in the use of PCI for stable angina that was temporally associated with the presentation of COURAGE. Using data on 26,388 procedures, the investigators reported a 26% relative decline in the proportion of PCI procedures performed for stable angina from the first quarter of 2006 to June 2009 along with a 16% relative decline in overall use of PCI. These findings provide empirical data supporting the adoption of the evidence provided by COURAGE into routine clinical practice, an important insight given the growing demand for comparative effectiveness studies and the hopes for them to be translated into clinical practice.

Limitations of Registry Data

Although the authors have made an important contribution, there are several potential limitations to their analysis. As the authors state, information on baseline optimal medical therapy is lacking in the NNE PCI Registry as well as information on trends in referral for diagnostic angiography. Therefore, they could not assess the extent to which patients underwent PCI for stable symptoms refractory to medical therapy or distinguish whether the decline in PCI for stable angina was...
a consequence of fewer patients being sent for diagnostic angiography or fewer patients being treated with initial PCI after diagnostic angiography (the latter being the algorithm tested in COURAGE). The authors also point out that declines in PCI for stable angina began before the publication of COURAGE but after DES safety concerns arose. Ascribing the relative impacts of these 2 considerations to changes in practice is not possible using NNE or other registry data. There are additional limitations to consider. Whereas clinical registries are superior to administrative data in that information on procedural indications usually is available, the categorization of indications often is imperfect given pragmatic considerations. Although the authors used the coding of stable angina as the indication for PCI to define their study populations, many patients with stable CAD, in fact, are not classified as having stable angina in procedural registries. Ideally, observational studies of practice patterns would prospectively collect more detailed health status (symptoms, function, and quality of life) information from patients themselves.

Another limitation relevant to registry data is the assumption that the pool of eligible stable patients has remained constant. More than 1 decade since enrollment in COURAGE commenced, patients with less-complex disease may be managed medically, whereas the population appropriate for PCI shifts into an anatomic realm once exclusively the domain of coronary artery bypass grafting. Although this is a “limitation” of the present study, both a shift in the pool of stable patients considered eligible for PCI and the aforementioned declines in unstable disease would be expected to attenuate the effect the investigators observed. If the authors were able to adjust for either or both of these considerations, it is likely that an even stronger impact would have been apparent. These limitations notwithstanding, the current study is an important contribution, and the authors should be commended accordingly.

Measuring the Pace of Adopting Evidence Into Practice
Registries are especially valuable in that they provide a broad view of clinical practice as a function of time. If one accepts that the temporal association between COURAGE and a decline in PCI for stable angina implies some degree of causation, then perhaps the most encouraging aspect of the present study is the demonstration of a relatively expeditious translation of evidence into practice—far more rapid than the 17-year average adoption rate cited in the seminal 2001 Institute of Medicine Crossing the Quality Chasm. What are the factors responsible for this pace of adoption, and is this emblematic of a new paradigm of rapidly incorporating evidence-based medicine into routine care? Although concerns regarding the safety of DES were largely ameliorated, the well-publicized and quickly disseminated initial concerns coupled with doubt regarding indications for PCI in stable CAD likely exerted a synergistic effect in promoting a relatively quick and persistent change in both patient and physician behavior. Moreover, it is possible that COURAGE provided a better foundation on which physicians could share the benefits and risks of PCI with patients and, thereby, inspired greater shared medical decision-making.

Looking Beyond NNE
Do these results from NNE reflect national practice patterns? Because it captures data on more than three quarters of PCI procedures performed nationally, the American College of Cardiology National Cardiovascular Data Registry (NCDR) is an ideal resource for answering this question. Without accounting for changes in participation in the NCDR and assuming asymptomatic presentations to be clinically stable, there has been a 13% relative decline in the proportion of PCI procedures performed for stable as opposed to unstable clinical indications from 2006 to 2010. Without accounting for changes in participation in the NCDR and assuming asymptomatic presentations to be clinically stable, there has been a 13% relative decline in the proportion of PCI procedures performed for stable indications from 2006 to 2010 (National Cardiovascular Disease Registry Cath PCI Registry, with permission). We look forward to more detailed analyses from the NCDR that would potentially extend these insights from NNE. Equally important will be elucidating other changes in practice in the evaluation of stable angina that may be associated with the reduction in PCI for stable CAD. Although it is convenient to vilify interventional cardiologists performing ad hoc PCI on inadequately medically treated patients, both patients and physicians typically arrive in that situation as a consequence of prior procedures. Given concerns expressed about missing more severe CAD (eg, left main disease) if diagnostic angiography is omitted in the assessment of stable symptoms (and conversely given the implicit hazards of revascularization procedures), the potential impact of the reduction in PCI for stable CAD on other cardiovascular outcomes also is of central importance and will require population-based approaches. Finally, although the present study is an encouraging demonstration of a rapid translation of evidence into practice, gauging whether the magnitude of the changes now apparent in practice has been appropriate or sufficient will be another important challenge and will require linking the observed changes in practice to changes in patients’ survival and health status outcomes.

Conclusions
The present study from the NNE Cardiovascular Disease Study Group provides important empirical data regarding the impact of COURAGE. Their findings of reduced overall PCI volume, with a more significant reduction in the use of PCI as treatment of stable angina, support that evidence from clinical trials is affecting practice. Although there is still an appropriate role for PCI in the treatment of CAD, even stable CAD, we as interventional and noninterventional cardiologists alike should welcome further studies clarifying which patients benefit most from our treatments and embrace opportunities to see the impact of our efforts translated into practice. Thoughtful studies from registries, like the present one from NNE, will be useful means toward that end.
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References


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