Using administrative data to assess health care outcomes

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In the United States, Canada, and Europe, many large administrative databases have been developed by governments and private insurers responsible for funding health care, enabling them to monitor the use of health services and pay providers for their care. These databases commonly record hospitalizations and ambulatory visits for individual patients, and they often list specific diagnoses and procedures. Because these databases are maintained primarily for financial and administrative purposes, they are audited to ensure their accuracy for making payments and allocating resources, but not necessarily for clinical veracity. With steady increases in computing power over the past two decades, administrative databases have become much more accessible to health services researchers, and they are now tapped regularly to study the processes and outcomes of health care.

In this issue, Lewsey and colleagues analyse the outcomes of percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) surgery in Scotland using one type of administrative data — hospital discharge records — and they compare these findings to those of randomized controlled trials on the same topic. Such non-randomized analyses of community practice are characterized as effectiveness studies to assess outcomes across a wide range of patients and healthcare providers. In contrast, randomized controlled trials are described as efficacy studies for determining the value of interventions in carefully controlled circumstances. Relative to population-based effectiveness studies, randomized controlled trials often have the limitation of studying more narrowly defined groups of patients and providers. However, randomized controlled trials have the inherent strength of balancing patients’ measured — and unmeasured — characteristics between different treatment groups. Careful randomization greatly reduces the risk of selection bias, by which differences in outcomes can arise from disparities in patients’ underlying characteristics rather than true effects of treatment.

Lewsey and colleagues venture to describe their study as a 'pseudo-randomized controlled trial', and their title queries whether health service data can ‘complement and enhance’ randomized controlled trials comparing coronary angioplasty and bypass grafting. They conclude that the rates of cardiac death and non-fatal myocardial infarction in community practice were not significantly different 1 year after PTCA or CABG surgery, consistent with a meta-analysis that summarized eight randomized trials comparing these procedures. However, of the three largest randomized trials in the meta-analysis, only the Randomised Intervention Treatment of Angina (RITA) trial enrolled a population that appeared clinically comparable to the observational cohort of Lewsey et al.. The two other large trials excluded patients with single-vessel disease and enrolled patients who were older and more often diabetic than the Scottish population studied by Lewsey and colleagues.

How can practising physicians evaluate the methods and findings of effectiveness studies that use administrative data to address clinical questions? Many of the principles that readers would use to evaluate a randomized trial can also be applied to a study based on administrative data:

- Is the research question clinically important?
- Is the study population clearly defined and of sufficient size for statistical comparisons?
- Are the subjects’ clinical characteristics specified with adequate detail and accuracy?
- Are the outcomes valid and fully ascertained?
- Are the analytic methods appropriate?

The report of Lewsey et al. clearly addresses an important research question. The relative merits of PTCA and CABG surgery have been the subject of numerous randomized trials and intense debate, with substantial consequences for patients with coronary artery disease. Comparing the relative outcomes of these procedures in community practice with those of randomized trials could be very useful information for practicing physicians who treat patients with coronary artery disease.

This study also has the strength of identifying all patients who underwent PTCA or CABG surgery in Scotland over a 7-year time period. By linking patients’ coronary procedures to their subsequent hospital admissions and death records across the Scottish healthcare system, the investigators could identify the relevant outcomes of non-fatal myocardial infarction and cardiac death even when these events occurred outside of the original hospital. Thus, the findings, if valid, would probably be generalizable to other areas of the United Kingdom and other countries with access to coronary revascularization procedures of similar quality.

Nonetheless, this report has fundamental limitations arising from the lack of clinically detailed
information about the patients in the study — a typical problem for studies of outcomes based on administrative data[7–9]. As a result of these limitations, readers must exercise substantial caution in interpreting the results of this study. The findings may be accurate, but the methods are not definitive.

As the authors note, they had no information about the severity of patients’ symptoms before revascularization, and they also lacked information about patients’ left ventricular function — two of the most critical factors for determining the appropriateness of PTCA or CABG surgery. This study did not validate the extent of subjects’ coronary artery disease or their subsequent clinical outcomes of cardiac death and non-fatal myocardial infarction. Such validation of administrative data can be performed through blinded reviews of a random sample of angiographic reports and clinically detailed case summaries. This study was also constrained by the limited length of time (1 year) that patients were followed for cardiac death and non-fatal myocardial infarction and the absence of data on patients’ cardiac symptoms and functional status after PTCA or CABG surgery. In a comparable population, the RITA trial demonstrated that rates of cardiac death and non-fatal myocardial infarction were similar for randomized patients who received either of these procedures, but CABG surgery was more effective in relieving symptoms of angina[4,10].

Lewsey et al. acknowledged some evidence of selection bias in physicians’ choice of PTCA or CABG surgery for individual patients in their cohort, but their clinical data and statistical techniques were inadequate to control for this type of bias. They also did not analyze a specific subgroup, diabetic patients with multivessel disease, that had significantly higher mortality with PTCA than CABG surgery in the Bypass Angioplasty Revascularization Investigation (BARI) trial[11]. Because randomized trials often have insufficient numbers of patients for subgroup analyses, such analyses represent one way in which observational studies could plausibly augment existing randomized trials and guide the direction of future ones.

Rather than relying on sketchy administrative data to draw inferences about complex clinical outcomes, health services researchers and policy-makers can work to create clinically detailed databases that foster more rigorous comparisons of treatments in community practice. The efforts of physicians, hospitals, and public officials in New York State exemplify the value of such databases for PTCA and CABG surgery. Although these databases required substantial effort and cooperation to implement, they have provided a much richer resource than traditional administrative data for studying outcomes and improving care[12,13]. The Cooperative Cardiovascular Project in the United States Medicare program has also demonstrated how clinically detailed health services data can be used to evaluate and improve the quality of cardiac care[14].

Future studies can build on the work of Lewsey and colleagues by applying more advanced methods to the analysis of health services data. Simple logistic regression models are often insufficient to control for selection bias when comparing the outcomes of non-randomized treatments. Two statistical techniques emerging in health services research — propensity scores and instrumental variables — hold promise to reduce the impact of selection bias in observational studies and provide more accurate estimates of treatment effects[15,16].

Returning to the question posed by Lewsey et al. in the title of their article, health services data should not be expected to enhance randomized controlled trials or produce pseudo-randomized controlled trials, but they can certainly complement randomized controlled trials in many situations. If health services data are bolstered with complete and accurate clinical information and rigorous statistical techniques, these data can provide reasonable estimates of treatment effects in community practice. They can also be used to assess how practicing physicians apply the findings of randomized controlled trials in their care of patients. By coupling the lessons of well designed randomized controlled trials and observational studies, researchers and clinicians will have a better chance of achieving their mutual goal of improving patients’ outcomes.

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References
Acute myocardial infarction: new protagonists and new challenges

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Since the observation that acute myocardial infarction is associated with coronary artery occlusion, various mechanical and pharmacological approaches have been developed to restore vessel patency, assuming that vessel recanalization would result in myocardial reperfusion. Several options are now available to recanalize an occluded coronary artery, including thrombolytic agents, percutaneous coronary angioplasty, and cardiac surgery. Large scale clinical studies have demonstrated the efficacy of these strategies and have concluded that early vessel recanalization significantly reduces in-hospital mortality. So, early vessel recanalization is the primary goal of therapy in acute myocardial infarction.

Unfortunately, it has emerged that re-establishing vessel patency does not necessarily result in effective myocardial reperfusion\textsuperscript{[11]}. In experimental animals it has long been known that reperfusion of ischaemic myocardium, while preventing or reducing necrosis, is associated with detrimental morphological and functional changes known as reperfusion injury. Several mechanisms contribute to reperfusion injury, including oxygen free radical production, neutrophil activation, cellular and interstitial oedema. Myocardium still viable at the end of the ischaemic period may therefore lose viability as a consequence of reperfusion\textsuperscript{[11]}.

Today these events are no longer confined to the experimental laboratory, but are part of our clinical routine. Although a clear distinction in man between reperfusion injury and ischaemic damage is difficult, we do face prolonged post-ischaemic depression of ventricular function, the so-called ‘stunned myocardium’ as well as progressive increase in microcirculatory resistance to flow, the so-called ‘no-reflow phenomenon’.

Both adverse events have been repeatedly reported after successful coronary revascularization by thrombolysis or primary PTCA. In prospective studies, evidence of impaired myocardial perfusion after a successful PTCA has been found in one third of the patients and was consistently associated with adverse prognosis\textsuperscript{[3]}. And few experiences are as frustrating for the interventional cardiologist as rushing an acute patient to the cath lab to successfully dilate the occluded vessel, only to see, a few minutes later, the flow progressively slowing down, the ST segment rising again, and re-exacerbation of chest pain.

So far, the attention of investigators and clinicians has been focused on ‘myocardial ischaemia’. Morphological, metabolic, and mechanical reactions of myocardial cells to ischaemia have been explored in depth and treatments have been proposed based on these observations. It is becoming increasingly clear that this approach is no longer adequate and may

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