

Correspondance

Drawing policy conclusions from uncontrolled studies

Studying a population of adults seen in clinic for biliary colic, Boris Sobolev and associates¹ documented an association between longer waiting times and admissions for emergency cholecystectomy.

However, because the patients were not randomly assigned to the waiting list, readers should entertain the possibility that the findings were driven by an association with a so-called "third variable." For example, the patients who ended up on the waiting list might have been sicker. If so, the observed association between waiting times and emergency admissions was actually driven by an unobserved association between health status and emergency admissions. Sobolev and associates¹ acknowledge the possibility of confounding by patient morbidity, and they do attempt rudimentary adjustment for other potential confounding variables. However, even if they had had access to better data on patients' health status, the criticism of potential confounding would remain.

Prior studies, none of which were cited by Sobolev and associates,¹ have addressed this problem by means of

econometric methodology.²⁻⁴ Hamilton and colleagues² used an estimation strategy that accounted for unmeasured health differences and found no effect of waiting times on death rates for patients waiting for hip fracture surgery. Subsequent comparisons of patients with hip fracture in the United States and Canada^{3,4} arrived at a similar conclusion.

Policy-makers seeking to draw conclusions from the findings of Sobolev and associates¹ would be well advised to consider these more sophisticated econometric analyses in their deliberations.

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[Three of the authors respond:]

Appropriate access time for surgery is often determined on the basis of expert opinion. However, in our study,¹ we used surgery records to assess the risk of undergoing emergency surgery in relation to the duration of the wait for elective cholecystectomy. Given the magnitude of the effect that we observed,¹ we assumed that there might be policy implications.

Alexander Tsai brings attention to articles that might be relevant in other circumstances, but for the purposes of our research,¹ it is difficult to see how results concerning length of stay and death after hip fracture surgery could help the reader to better interpret our findings on the risk of emergency admission while awaiting elective cholecystectomy.

Tsai suggests that "the patients who ended up on the waiting list might have been sicker." In our study¹ we assessed the frequency of emergency surgery after registration on the waiting list. Patients who underwent emergency surgery without placement on the list might have been less or more sick, but they were not included in the study. For patients on the list, coexisting illnesses might indeed have caused addi-

tional delay in surgery. However, whether biliary complications, such as acute cholecystitis, obstructive jaundice, cholangitis or pancreatitis, occur more frequently in patients with comorbid conditions is unclear.

There is no doubt that risk selection (the process whereby the makeup of a population changes over time through removal of subjects at higher risk) may bias the observed risk, because of unobserved heterogeneity.² For instance, when the risk of symptoms worsening is constant over the duration of the wait, risk estimates without adjustment for heterogeneity of individual patients will probably underestimate the true risk associated with longer waiting time, and the risk associated with longer relative to shorter waits may also be underestimated. Therefore, our message to health policy-makers should be that the risk of emergency surgery while waiting for elective cholecystectomy increased by a factor of almost 3 after 20 weeks on the waiting list, and that this is perhaps an underestimate.

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How to improve organ donation rates

In Canada, the primary postmortem source of transplantable organs is patients whose deaths have been determined on the basis of brain death criteria (heart-beating donors). Greg Knoll and John Mahoney¹ suggest that patients who die after cardiac arrest (non-

heart-beating donors [NHBDs]) should also be considered as a source of transplantable organs.

Fundamental changes to organ donation in Canada would seem most appropriate if all other conventional approaches related to brain death donation had already been optimally explored. For example, the Collège des médecins du Québec reviewed all deaths in Quebec for the year 2000² and found that, of all patients who appeared brain dead on the basis of the chart review, 23% had not been identified as potential organ donors at the time. Furthermore, for patients with a diagnosis of brain death, 24% of the families were not approached for consent to donation.

Acknowledging variability in the recognition, diagnosis and documentation of brain death, the Canadian Council for Donation and Transplantation (CCDT), which provides advice to various levels of government, sponsored a national forum on the subject in April 2003.³ The forum's multidisciplinary participants developed standards to address the optimal management of severely brain injured patients who may experience brain death, including the option of organ donation as a part of standard end-of-life care.

In its position paper,⁴ the Canadian Critical Care Society (CCCS) has called for a moratorium on NHBD protocols without prior national discussions. The CCDT is preparing to initiate such a national discussion, with input and recommendations from representatives of the relevant health care professions and society as a whole. Planning for this initiative is scheduled for 2004.

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Greg Knoll and John Mahoney¹ correctly point out that the use of NHBDs could increase the number of cadaver organs available for transplantation in Canada. This possibility is under consideration in Quebec, and the Canadian Council for Donation and Transplantation will discuss the topic in an upcoming forum.

However, the use of NHBDs is fraught with ethical and logistic problems, and the addition of this type of donor to the existing pool will not be sufficient to meet the increasing need. In contrast, there is definitely room for better identification of brain-dead donors, as underlined in a recent study by the Collège des médecins du Québec.² In response to that study, the Quebec government is now funding a network of in-house organ donor coordinators, whose role is to help identify potential donors and to support both families and medical personnel throughout the organ donation process.

Living related and unrelated kidney donors are also underused in Canada.