Editor's preface

Français à la page suivante

For over a decade the randomized clinical trial has been touted as the supreme study design for the evaluation of the efficacy of interventions. Grant organizations fund them, medical journals publish their findings, and increasingly physicians apply their results in clinical practice. However, there are certain questions that randomized trials cannot answer. It is not always clear that treatments shown to have efficacy in the highly selected patients and highly controlled environments of randomized trials are effective and safe in the real world, where pregnancy, old age, comorbidity and noncompliance live. In short, sometimes we need to move beyond randomized trials.

In their population-based study of double- and triple-drug antiretroviral regimens in HIV-positive patients, Robert Hogg and colleagues do just that (page 659). Using an administrative database in British Columbia, they performed an intention-to-treat analysis involving 500 men and women with HIV infection to determine differences in survival and progression to AIDS between patients receiving 2 antiretroviral drugs (ERA-II group) and those receiving 3 drugs (ERA-III group). They found that the likelihood of death at 12 months was more than 3 times higher and the likelihood of progression to AIDS or death at 12 months more than 2 times higher in the ERA-II group than in the ERA-III group, even after adjustment for prognostic variables. The authors describe the results as reassuring, since the magnitude of benefit is likely an underestimate and is comparable to that found in randomized trials. In an accompanying editorial, Peggy Millson and Anita Rachlis commend the authors for their important study, emphasizing the provider, patient and coverage factors that only population-based studies of "community effectiveness," not clinical trials, can address (page 669).

Although randomized trials are the gold standard for evaluating treatment efficacy, a single small trial is often not enough. There is strength in numbers, particularly when drug safety is at issue. In an effort to evaluate the efficacy and safety of benzodiazepines in the treatment of acute alcohol withdrawal, Anne Holbrook and colleagues performed a meta-analysis of 11 randomized trials, representing a total of 1286 patients (page 649). Benzodiazepines were found to be superior to placebo in terms of clinical benefit, with no significant differences in adverse events or dropout rates between benzodiazepines and alternative drugs. In a companion review, the authors outline the diagnosis and management of acute alcohol withdrawal (page 675).

Just as care must be taken in extrapolating the results of a randomized clinical trial to patients outside the target population, it is often difficult to apply the results of health care research in one health care system to another. Studies in the mixed public–private health care system of the US have shown that institutions with higher numbers of pancreatic resections for neoplasm have lower mortality rates associated with the procedure. In their retrospective analysis of 842 such resections in 68 centres in Ontario, Marko Simunovic and colleagues ask whether the same volume–outcome relation holds true for a publicly financed health care system (page 643). Their answer is Yes, but Wexler underlines some of the important methodologic difficulties involved in attributing outcome to volume alone (page 671).