ALL THAT IS MEASURED MAY NOT HELP

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The paper by Lane and associates in this issue (page 442) raises significant concerns about the premise upon which a registry is based. Any registry or depository of information regarding patient care or outcomes is only as good as the data collected and the inclusiveness of that data related to the population under study. The authors make the point that much of the data pertaining to the study of head-injured patients is missing, and the consequences of this missing data are acknowledged in the discussion. The reviewers of the paper were divided as to the value of publishing the paper in view of the incomplete data sets; however, it was felt that publication of this study would be an important starting point for a discussion regarding evidence-based treatment protocols.

The questions raised by the authors' interpretation of the data in this paper are important. It is inappropriate, in my opinion, to dismiss randomized controlled trials as too expensive; the data they present clearly indicates the need for a randomized controlled trial regarding the effectiveness of intracranial pressure monitoring in the head-injured patient. If significant resources are being expended based on the clinical results of intracranial pressure monitoring and yet the use of this technology is variable across Level I trauma centres, then the need for a trial is clinically evident. The cost of those resources used already in intracranial pressure monitoring would justify the costs of a study to determine the effectiveness of this technique.

Arguments with regard to cost and to patient outcomes have been used to discourage clinical trials in a number of interventions; however, well-structured randomized clinical trials of other interventions either surgical or pharmaceutical have demonstrated clear evidence of the value of specific treatments.

The use of intracranial pressure monitoring is controversial in the neurosurgical literature; Lane and associates suggested that improved survival associated with the use of intracranial pressure monitoring is in itself justification for its continued use. However, the alternate hypothesis must also be discussed: Is it possible that survival is worse than death? Is survival in a vegetative state a satisfactory outcome? The variability in the neurosurgical literature with regard to the use of intracranial pressure monitoring may well be based upon individual decisions by surgeons examining their results and concluding that a survivor's quality of life would not justify the intervention.

The role of randomized clinical trials in the trauma population is often difficult — the patients themselves are frequently incapable of giving consent, and their relatives or guardians are reluctant to make decisions that may be inadequate or even harmful to the patient. The development of clinical trials in trauma patients should not include physicians alone but other health professionals and even members of the public for a frank discussion regarding the selection of appropriate outcome measures in order to judge the success or failure of an intervention. This is particularly so in the severely brain injured or the severely traumatized patient. It is not enough to accept the status quo based on data collected in a prospective database; rather this information should be used to plan an appropriate randomized clinical trial of currently recommended intervention. Every registry has a role in outcome research since it indicates the size of the problem; unfortunately it does not always provide enough data to solve the problem that is being studied. The need for well-designed clinical trials has never been greater. Several surgical organizations in Canada are involved in randomized clinical trials, and head injury management should be added to the list of such trials that need to be initiated. ■

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