Editorial

Controlled Trials of Cardiac Surgery
Responsibility of Journal Editors and Reviewers

In theory, reviewers of scientific papers impose standards for acceptance based on the aim of all scientists—to report a true result. For therapeutic trials a true result depends on appropriate design, i.e. the results should reveal real treatment effects by measures which minimize biases in selecting patients and administering therapy. Acceptance of the results for publication implies merit, and without publication it is very difficult to establish a new treatment in practice. Medical journals thus become the filter through which appropriately studied modalities can go on to application but through which inappropriately studied modalities should not be able to pass. While this has been increasingly true for medicinal agents it has not been the case for new surgical procedures and new applications of established procedures. Most journal reviewers, abstract referees for scientific meetings and hospital research committees maintain high standards for the design of medical therapeutic trials. Yet they do not impose equal standards for surgical trials. This is not because such trials cannot be done.

It has been shown that prospective, controlled trials of surgical therapy, including random allocation of patients, are quite feasible though perhaps more complicated to perform than comparably designed trials of nonsurgical therapy. Relatively few, however, have been done, and these have followed rather than preceded the widespread introduction of new operations. Yet, to establish as early as possible (a) that a treatment is truly effective and (b) exactly for whom it is indicated, the same principles must apply to all therapies. Unless this is recognized, uncertainty will continue to provoke controversies like the protracted arguments over appropriate operations for common diseases like peptic ulcer, breast carcinoma and coronary artery obstruction. The years consumed and the heat generated by disputants whose skill and intellect are undoubted, testify to the persistent problem of getting valid evidence—to the detriment of our patients. We believe that this is the result of the absence of appropriate standards of proof for new surgical treatments and new applications of existing surgical treatments.

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There is no scientific or humanistic reason why standards for acceptance should not be equal for all treatments. On the contrary, science and ethics demand our best efforts for equal standards. Moreover, there is every reason for their application from the very first clinical trial of each treatment. It is true that reduction of operative mortality improves with experience, yet proof of current benefit to patients necessarily applies to current experience. Our point is related to the quality of such proof.

We believe that the publication "filter" is the place to maintain equally high standards for all treatments. We request the editors and reviewers of the Japanese Heart Journal to consider an explicit policy of equal standards for therapeutic trials of all therapies.

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