Research in Neurosurgical Training: Clinical Reviews and Trials

G. M. Teasdale

Department of Neurosurgery, Institute of Neurological Sciences, Southern General Hospital, Glasgow, United Kingdom

Summary

A well prepared intellectual basis is at least as important as a sound technical training for a safe, successful Neurosurgeon. Correct decisions depend as much upon clinical information and experience as upon biomedical theory and an appreciation of the science of real life clinical research is more valuable than experience in laboratory techniques. Understanding of what makes up a good study, providing a reliable basis for clinical practice, is best gained through the training conducting personal research. The training must provide an enquiring, motivating, intellectual environment, as well as disciplined organisation and support. Successful clinical research is difficult and demanding but is one of the clearest testimonies to the quality of both trainer and trainees.

Keywords: Clinical research, clinical trials.

Introduction

Familiarity with clinical reviews and trials is a vital part in the process of life-long learning, and a basis for producing the educated, accomplished, successful Neurosurgeon. We need therefore to consider why such studies are relevant, the roles of different types of study, the factors that promote a successful experience and application and the mechanics and technicalities of performing studies.

The Basis of Neurosurgical Practice

The two vital aspects of Neurosurgery are the making of incisions and the taking of decisions. Training in the craft of surgery focuses on the production of competence in the technical skills required for safe performance of operative procedures. This can be gained through didactic teaching and apprenticeship in the operating theatre but to restrict neurosurgical education to this level is akin to producing a technical tradesman. The Neurosurgeon is elevated to the level of a professional by his responsibility for the posing and, in consultation with the patient, the taking of decisions. Questions such as “is an operation appropriate?” and, if so “what kind of operation, how should it be done, and when?” are at least as crucial in the patient’s welfare as a practical per-operative procedure. Trainee Neurosurgeons need to understand how decisions are made, in particular the origin of the factors they take into consideration and the strength of evidence behind a particular approach or viewpoint.

Much of medical education in this Century has been dominated by the concepts derived from the biological approach to medicine. This reflects the immense advances in understanding the functions of the human body, the nature of disease, and the identification of increasingly specific and fundamental methods by which the body’s mechanisms in both health and disease and now be influenced. Yet such knowledge essentially produces a theory of medical practice, producing the attitude, when considering a patient, that “this form of intervention should work”. Unfortunately, concepts derived from relative purity of experimental biological investigations, whether in the laboratory or the clinic, are an imperfect basis for dealing with the vagaries and variations in both patients and diseases encountered in real clinical practice. The role of the clinical observational research, that is the basis of reviews and trials, is to enable statements such as “this treatment does work or more often that “this treatment is likely to work” and to be able also to put some estimate on such likelihood. To express it in the words of Osler “Medicine is a science of uncertainty and an art of probability”.
What is needed in the case of an individual patient is to know the relative likelihood of a particular course of action producing a certain outcome. Although it is possible, with experience, for the individual surgeon to make an estimate based upon his personal knowledge, such experience can hardly ever be sufficiently extensive, or sufficiently precisely recalled, to form a perfect basis for practice. All too often the antidote to this is dogma. Attitudes illustrated by the saying “I am always certain about the things that are a matter of opinion” (Charlie Brown) or “I am not always right but I am never unsure” (anonymous) are surely incompatible with the faculty for ascertaining the truth that we wish to instil in the future Neurosurgeon.

The Importance of Clinical Studies

Clinical observational studies can be carried out in many ways and at many levels. These range from the report of a single case, of a series of cases – (the basis for so many neurosurgical publications) – to case control series (in which a group characterised by a particular outcome is identified and compared retrospectively in an effort to identify a causal factor) – to cohort studies, in which populations are identified prospectively and studied in parallel or series, a so called “quasi experimental design”, to finally the randomised prospective controlled trial.

Whatever kind of clinical observational studies are carried out, the aspects that are important for the trainee are to gain an understanding of the intellectual processes involved in collection, analysis, and interpretation of clinical observations, in a systematic way. This is essential so the trainee can evaluate evidence and concepts produced from clinical experience and reports because these are the ammunition the trainee needs to enlist the support of art of probability in the battle against uncertainty. This understanding and appreciation can be gained in abstract, and there are an increasing number of publications and courses that provide education in clinical information science. Nevertheless, it is the actual doing of a clinical study that is most likely to focus the trainee’s mind and to promote the awareness and understanding that is desired – provided that the experience is conducted in the appropriate way. Not all such endeavours need progress beyond presentation to a critical, informed local audience but publication of the results should be a target. The process of preparation for publication contains many hurdles from which much can be learnt. It also can provide valuable indicators and information back about the trainee, and also the training environment, and not just about “scientific” quality of mind and intellect, but about aspects of character such as common sense, enterprise, and determination. Not least important is the reality that information unpublished is knowledge lost.

The Design, Conduct, Analysis and Interpretation of Studies

The issues involved in either doing or recognising a good study are many. They include the choice of subjects, the conduct of the study, the intervention to be studied – whether prospectively or retrospectively, the choice of data both about early and the late states, and the principles of analysis and of interpretation. An appreciation of the importance of involving a statistician before the study starts is perhaps one of the most important lessons of the trainee. Statements and conclusions that are not supported by information gained are more often traced to lack of clear concepts and criticism than neglect of statistics. Indeed, lack of statistical rigour is more often shown by an over testing and an over reliance on “significance” testing.

It is unfortunately true that many published reviews and trials contain a range of defects and flaws. In this Neurosurgery is not different from all other branches of clinical medicine and specialist Neurosurgical journals are no different, in principle, from leading international general medical journals! The publication of the “CONSORT” statement by Editors of several international medical journals, containing clear and rigorous standards that must be met, is to be applauded. Editors of Neurosurgical journals should endorse similar high standards in the reporting of reviews and trials, and should promote this through the routine involvement of statisticians in the review process, recognising that this does not necessarily go with a Neurosurgical reviewer’s expertise in clinical and biological matters. Good quality information on clinical studies will clearly be of ever increasing importance with the growing emphasis on “evidence based medicine”. It is statutory that the