Clinimetrics in Stroke Research

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WHAT distinguishes clinical medicine from biomedicine? Most physicians would probably agree that in their daily clinical work they rely not only on biomedical but also on humane qualities. Many patients express a concern that the humanistic aspects of medicine are overshadowed by mechanistic ideas, which they feel have come to dominate much of the medical community. At the same time, there is little doubt among physicians and laymen that the contributions of biomedicine to medical care have been most impressive and fruitful. To phrase it in biological terms, clinical medicine and biomedicine do not act as competitive inhibitors; instead, they exert synergistic effects.

Why is it that biomedicine has come to dominate clinical medicine? Even if medical care is influenced by a great number of external factors, scientific development is unquestionably a major determinant. In the scientific sphere, the proliferation and quality of biomedicine has been so overwhelming that it has ruled much of the recent development of clinical medicine.

A Common Language in Clinical Science

A major reason for poor recognition of the nonbiomedical aspect of clinical medicine as a science is that its methodology is often perceived as inferior to that of biomedicine — and probably rightly so. A few drops of cerebrospinal fluid (CSF) obtained from the stroke patient can easily be defined in biochemical terms. The technical machinery and universally accepted conventions provide ample quality as well as quantity in the measurements, and we have a common biochemical language.

When we then interview the same patient and he expresses pain, anxiety, distress, joy or sorrow, has difficulties in speech, and presents with hemiparetic symptoms, our means to convert such information into a generally accepted scientific language are very limited. Yet, these qualities are of major concern to the patient and his family, and they are therefore of crucial clinical importance. Neither this nor the CSF analyses should be neglected in good clinical stroke research.

In a series of articles, Feinstein has discussed the need for clinical medicine to create a scientific methodology of its own that extends beyond the limitations of biomedicine. Today, biometrics, psychometrics, econometrics, and many other metrics (even cliometrics after Clio, the muse of history!) are established as scholarly domains. Is it not time for clinical research to form a similar scientific basis? Feinstein asks. He proposes that the new basic methodology be termed clinimetrics. Clinimetrics could apply to some of the methods used in present-day stroke research. The most obvious examples are the neurological assessments used in different therapeutic and other follow-up studies. Do these assessments meet the standards of high-quality clinimetrics? Are there generally accepted methods, procedures, and taxonomies? Do they fulfill the fundamental criterion of scientific measurements, consistency? Are the method errors sufficiently characterized? These and other questions need to be answered before we can evaluate whether or not the neurological measurements used today in stroke research are good enough as clinimetry.

Clinimetrics in Articles Published in Stroke

To illustrate this point, I reviewed clinical articles published in Stroke in 1984 and 1985. Only articles with some clinical assessment (as opposed to chemical and radiological measurements) were included, and case reports were not considered. The first characteristic I looked for was conformity — was there any general agreement between the authors on which methods to use when assessing neurologic conditions, activities of daily living (ADL), and mental performance in stroke patients? As seen in Table 1, only very brief verbal accounts of neurologic assessments were made in nearly half of the articles. In works where neurologic rating scales were employed, 16 different scales were used. Of these, 10 were newly developed, sometimes modified from previously published scoring systems. In the 6 instances where the authors had applied scoring systems that had been used by previous investigators, 6 different systems were employed. Thus, no single neurologic scale or structured description was applied more than once in the 28 publications. Conformity and standardization seem to be very remote.

Validity in New Scoring Systems

The rationale for using a new rating scale is often that it is developed to meet the specific requirements of that particular study. Prognostication quo ad vitam may be the prime interest in one study and neurologic outcome of survivors in another. This would very likely lead to differences in the items included in scorings, and their relative weights would perhaps also differ. Similarly, as pointed out by Spence and Donner, some of the factors determining short-term survival (such as deviation conjugée and level of consciousness) are less relevant during long-term neurologic follow-up.

Using this kind of reasoning, a new scoring system could be more valid than any of the previous ones, i.e., actually measuring what it purports to measure in a better way. If and how a new neurologic scoring sys-
Requirements of Clinical Measurements

The present situation represents a "bewildering confusion of our times" (Matthew Arnold). It must be recognized that, even in biometrics, today's conformity is the result of agreements on taxonomy and standards. All such agreements are based on compromises. The different scales used today have so many basic elements in common that it should not take any giant leaps to reach agreement. A "standard" neurologic scoring system that is generally acceptable would create a basis for a common language spoken in the entire community of clinical stroke investigators. It is obvious that, for special purposes, optional additions could be made.

To be credible and universally acceptable, such a standard neurologic scoring system would have to meet some basic clinimetric requirements, the most important being consistency. Is the same observer able to repeat the results when reexamining the same patient? Can another observer reproduce the same results? If so, the data are no longer "soft." Instead, they have the basic ingredients of "hardness." In none of the articles reviewed was intra- or interobserver variability reported (much to my embarrassment, this includes articles that I have coauthored). In many instances, clinical descriptions were so laconic that they would in themselves refute any attempts at estimating consistency and variability. Even in controlled therapeutic trials, the clinical course was categorized as improved-stable-worsened-death, and no delineations were given. It is interesting to note that, at the same time, the importance of consistency is well recognized in another developing area of stroke research that has a more biomedical dimension: ultrasonography of precerebral and cerebral vessels. Detailed data on the reproducibility of carotid artery Doppler measurements were recently published in Stroke.

Once consistency has been attained, standardization by consensus is the next step. As Feinstein discusses, present-day "hard" measurements are all based on such consensual agreements of authorities. To take an example from the stroke sphere, consensus on international taxonomy and standards was reached very soon after the computed tomography (CT) scan became available. There are now many sophisticated statistical methods available to help transform basic information into salient variables, arrange these variables in principal axes, and then combine them into a focal index in which the ultimate result is expressed. Any scoring system must be tested for validity, including its value as a prognostic index.

It may seem that all of this is a very cumbersome process and that clinically sound ad hoc scoring systems, as used now by stroke investigators, should be just as useful. Reasoning so, we clinicians tend to disregard all the intricacies involved in biometric developments. The standardization of electrocardiographic recordings and interpretations, for instance, has been a tremendous undertaking, and yet few would today question its value in medical care and research. To establish itself as a scientific domain of excellence, clinical medicine must go through a corresponding laborious process.

ADL Performance and Psychological Variables

Whereas clinimetric quality is questionable in neurologic assessments, the situation is perhaps somewhat better in other sectors of stroke research. For assessment of ADL performance, some validated rating scales used widely in rehabilitation medicine are available. But, as shown in Table 1, these were not very often used in articles published in the 1984-85 issues of Stroke. Both Katz's and Barthel's indices could be said to be established scales for primary ADL in patients with cerebrovascular disorders. Still, it would be desirable to have more information on their reliability in different clinical settings. Are these indices consistent in the acute as in the late phase of stroke, in elderly as well as young stroke patients, in subjects who have cognitive impairments as well as in those who don't? For detailed information, more elaborate rating systems that include secondary ADL items and are validated, such as the Fugl-Meyer inventory, could be added.

It seems that, in general, the measurement of psychological variables in stroke patients follows basic scientific principles. Several well-established psychometric scales have been validated for use in stroke patients, and these have, without exception, been applied in the 3 articles dealing with cognitive and psychological measurements presented in Stroke in the last two years. But even here, data on intra- and interobserver variability and on consistency of data in different categories of stroke patients have not been presented. Sometimes, this makes it unnecessarily difficult for the reader to estimate how meaningful the reported differences in scorings really are. Furthermore, it is striking that also in communications with well-validated psychometric methods, accounts of neurologic status and clinical course in the same patients are presented in primitive terms hardly meeting even modest clinimetric requirements.
Concluding Remarks

It may be argued that clinimetrics, such as the use of scoring systems to assess clinical qualities in a stroke patient, is just an expression of reductionism and positivism and that hermeneutically directed studies would be more relevant to express the "real" situation of the patient. It seems to me, however, that there is a very long way for hermeneutics to go to establish its role in clinical research. Awaiting the possible results of such a development, it appears that clinimetrics, as discussed here, is probably the most feasible way to achieve scientific quality and self-respect in clinical medicine today.

It is beyond the scope of this paper to give a detailed description of what a neurologic scoring system that is universally acceptable would include. The aim of the article has rather been to identify and discuss some of the many methodologic problems involved in clinical cerebrovascular research. Stroke care and research, so multifaceted, are domains where improved clinimetrics would probably be a major scientific and humane achievement.

References


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