

# Evidence-based medicine (EBM) vs. personalized medicine in stroke victims. EBM should be the basis for high quality care.

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The way doctors manage patients – and management is here used in the sense of diagnosing, treating and following up patients - is a central issue for modern health systems.

In fact, when one looks at the new tendencies for health care policies - quality assurance systems, patient-centred care, rational practice implementation and outcome based financing (to name just a few) – the central role of the quality of care is obvious. And quality of care means above all clinical care, done by physicians.

The central issue is then: which is the best information source for clinical care, science or experience?

The classic definition of Evidence-Based Medicine (EBM) is from Dr. David Sackett (1996):  
...“the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

EBM is the integration of three factors into the decision making process for patient care (Sackett D, 2002): research evidence (found in clinically relevant studies conducted using sound methodology), clinical expertise (clinician’s cumulated experience) and patient values (personal preferences and unique concerns and expectations).

The practical steps of EBM include: 1) assess the patient, 2) ask the clinical question, 3) acquire the evidence, 4) critically appraise the evidence, 5) apply the results to the patient and 6) self-evaluate one’s practice.

Despite the impressive foundations EBM has constructed to use research into practice, some clinicians still debate the role of clinical experience of the individual doctor as opposed to scientific data from high quality clinical studies in taking care of patients.

Certainly, clinical experience is crucial for the quality of clinical care if for no other reason because it captures a reality that science hardly can. For example, the average elderly patient usually presents with three or four diseases and a couple of extra risk factors, and these type of patients is seldom studied in clinical research. The patients usually included in clinical study's samples are very homogeneous, possessing mostly the same level of baseline risk (or in subgroups well defined), have much less co-morbidities and therefore are less representative of the group of daily patients needing care.

On the other hand, clinical experience alone is absolutely insufficient to give patients a high quality of care. One has to stay abreast of the scientific evolution of one's field of clinical practice, so that patients have the full benefit of innovation of care happening every day. As a well-known saying goes: "...If the clinician does not continually learn the scientific basis of his/her trade, after a while the patient is not consulting with a doctor but with a museum..."

The problem of combining one's expertise with clinical data is not very problematic if these two types of knowledge are more or less overlapping. The problems arise when they are opposite. For example, for decades patients with serious head trauma (GCS <14) were treated with steroids to diminish cerebral edema (an intervention never tested in a proper fashion). The study CRASH (*Lancet* 2004; 364: 1321–28) showed that, when compared with placebo, there was no significant reduction in mortality with the use of methylprednisolone in the 2 weeks after head injury (21.1% vs 17.9%; relative risk 1.18 [95% CI 1.09–1.27]; p=0.0001). However, the risk of death at 6 months of follow-up (*Lancet* 2005; 365: 1957–59) was clearly higher in the corticosteroid group than in the placebo group (25.7% vs 22.3%, relative risk 1.15, 95% CI 1.07–1.24; p=0.0001), as was the risk of death or severe disability (38.1% vs 36.3% dead or severely disabled; 1.05, 0.99–1.10; p=0.079). This is an example in which clinical impressions were invalidated by sound scientific data originating in high quality studies. Confronted with these results, the clinician must decide the appropriate course for the individual patient, always justifying his/her specific choices.

Concerning the scientific basis for medical decision support, two concepts are important (Horton R, 2007):

1. How good are the data in terms inherent quality? This is reliability.
2. How appropriate are those data to the individual patient's problem? This relevance.

If doctors want to use scientific data to manage patients, reliability and relevance are the most important questions to consider.

What about patients with stroke?

Given the fact that there is a lot of studies on stroke (a quick search of Medline looking for papers with the word "stroke" in the title gives back almost 70,000 articles...), the question should be how to select the reliable and relevant studies to support medical decision making in stroke patients.

Specifically concerning therapy, we need to select clinical trials that are useful to guide us through interventions on stroke victims by providing data that correctly assesses the effects of treatments on major morbidity as well as mortality, on subgroups of patients presenting with different baseline risks. This is due to the well-known fact that some treatments for chronic diseases can produce large benefits but, given the fact that stroke is a heterogeneous

condition (similar patients have different prognosis), the selection of individualized therapy should be based on clear and reproducible data.

The scientific basis of clinical practice demands that, once the best evidence is selected, every study should be appraised in terms of its internal validity (how rigorous is the design of the study to answer the clinical question it posed), the importance of its results (clinical, not statistical significance) and its external validity (the degree of generalizability of its results). For example, to minimise biases and random errors in clinical trials one should guarantee proper randomization, intention-to-treat analysis, rigorous blinding and accounting of patients (to name only a few factors).

Clinicians are used to treat individual patients and therefore may feel that clinical trials do not give individual information for optimal care. However, clinicians that feel this way should bear in mind that all the diagnostic or therapeutic techniques available for them were developed in groups of patients similar to the ones they wish to manage, as one of the reasons to do these type of studies is that the individual variability of prognostic factors can only be identified through sufficiently large randomized groups of patients compared among them.

Concerning therapy for acute stroke, the external validity of clinical trials results is paramount, since it allows using the data generated in these studies. But its limitations should also be understood: among the most important are the setting of the trial, the specific characteristics of trial patients, outcome measures, difference between trial protocols and clinical practice and the difference in the rate of adverse effects of treatment. Once careful analysis is done, the practitioner can then apply (or not) the interventions provided by the studies.