

Principled Versus Statistical Thinking in Diagnosis and Treatment of Stroke

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Opinion statement

Medical science is now synonymous with probability-based statistics. Statistics deals with a group; it does not need probability theory. Probability theory is consistent with the worldview that the universe is infinite, bounded, random, and governed by chance. Its logic is binary, its geometry is Cartesian, its rules offer a scientific method by which hypotheses may be tested. Clinical trials and even hypothesis testing at the bedside have nestled into the probability foundation. As a result, scientific “evidence” now appears only through the lens of probability theory. Because there is no definitive truth in the worldview of probability theory, the truth of evidence lies in probabilities only. The probabilistic view of science has a firm impact on the practice of medicine and implications for medical–legal decisions.

Introduction

The evidence in “evidence-based medicine” might be based on scientific principles and not exclusively on probability-based statistics. Although probability-based statistics has a role in the evidence structure of clinical epidemiology, it need not dominate the evidence structure of medical practice. The hard-won principles of pathophysiology developed by clinical medicine and laboratory research constitute the core principles of medical evidence. Probability-based statistics now masquerades as the foundation of medical research, but clinical decisions are made with regard to the individual patient, who is a unique microcosm of

physiologic, genetic, and biochemical processes [1•]. Evidence-based medicine must be liberated from bondage to probability-based statistics, which is founded on the notion of chance and random processes, and instead become established on the determinate processes of molecular biology, based on the universal principles of biological science. The current bondage of evidence-based medicine to probability-based statistics has led to a mindset on the part of the physician that leads to the misapplication of statistics to the diagnosis and treatment of the individual patient and to the definition of *standard of care*.

Diagnosis and treatment of stroke

- The diagnosis and treatment of stroke traditionally have been based on the principles of pathophysiology, biology, histology, anatomy, neuropharmacology, and individual patient context. Medical education requires a foundation in these basic sciences, because the physician's perception regarding the disease process unfolding before him/her depends on the individual features of that one patient he/she is engaging. Principles of these basic disciplines apply to the clinical behavior of the patient's disease and healing process. The changing state of the patient demands active monitoring and an adaptive response from the physician; it is a dynamic process of interaction. Probability-based evidence-based medicine demands the physician's detachment from the dynamic principles of the disease and healing process, and thus from the individual patient, because the physician is required to apply statistical findings from population-based clinical trials to the diagnosis and treatment of each patient with stroke.

Diagnosis by probabilities and statistics

- When a physician is faced with a patient in the throes of an acute stroke, the situation is dynamic. The principles of Virchow's triad suggest a continuum of vascular integrity. Currently, there is a classification of stroke diagnosis that conforms to the binary logic of probability, requiring a rounding off of diagnosis to the ischemic or the hemorrhagic type in order to generalize the situation to facts that can be applied to any group of stroke patients.
- These generalized categories of patients are the object of large clinical trials. It is at the bedside where evidence-based medicine founded on these trials is now practiced. To apply any "scientific" (statistical probability) result from these trials, the physician must round the patient off, regardless of his/her specifics, to one of the categories.
- The most common questions asked of any treatment choice or diagnosis in this context are, What is the most common thing that could be wrong with the patient? and In how many patients does this or that treatment work? The answers to these questions become the diagnosis and treatment choices.
- The science of clinical trials is based on probability theory. Clinical guidelines for evidence-based medicine require the physician to reason from a probability standpoint. The intended result is a statistical approach to medicine.
- When a physician is faced with a patient, he/she has the notion that the patient has a diagnosis of x with probability 0.3 (for example), a

number pulled from a large clinical trial. Because of this probability-based approach to diagnosis, the physician imagines 10 hypothetical patients in front of him/her, one of whom is the indicated real patient. Thus, he/she says that given the probability of diagnosis x , seven of the hypothetical patients in our example do not have x and three must have x . He/she considers it his/her duty to guess or bet which one of the hypothetical patients matches the real patient. The guess is a conclusion based on what most patients must have according to the probabilities. Taking a bet or chance on being right is justified because of the basic belief in a random universe in which truth is not based on principle but on statistical probability.

- The clinical consequence of betting on the match between the patient and the known statistics, once this matching occurs, is that the tendency to go further with diagnostic testing to refute or confirm the diagnosis or to search for other diagnoses becomes more difficult to justify because the “scientific” basis for all medical decisions is the known probabilities. Thus, the probability-based mindset of the physician who must practice probability-based evidence-based medicine turns the one-on-one patient–physician interface into an imaginary, but false, statistical situation.
- The application of statistics to the individual, unique patient becomes necessary only because of and through probability theory.

Diagnosis by principle

- If one abandons the requirement of probabilities, then it is not necessary to apply statistics to the clinical encounter. The physician is free to think about the clinical situation in terms of principles of basic science, physiology, biology, chemistry, pharmacology, anatomy, and pathology.
- The principles of these basic sciences are the cornerstones of diagnosis and treatment of the individual patient. Each physician has his/her perception of their dynamic in any single patient. Because their interaction is ever changing, the physician perceives new interactions and can discover what is specific and special to that patient. No probabilities are necessary, because each process can be measured as a clinical impression, by constant monitoring, and by laboratory results. The bedside question is, What is the process, disease dynamic, and specifics that apply to this patient? Although each of these elements applies to any patient to a certain degree, any individual patient has the opportunity to have his/her unique clinical situation properly diagnosed and appropriately treated [2••].

A clinical/legal example

- A patient presents with uncontrollable hypertension. The previously reported incidence of an unusual cause, pheochromocytoma, is a

small percentage. The statistical mindset bases this patient's diagnosis on prior probabilities that the patient has pheochromocytoma. This leads to a tendency not to test for this condition, as the probability is less than 0.5. Medical-legally, when considered more probable than not—that is, there is a 51% percent chance the patient does not have pheochromocytoma—the physician who does *not* test for this condition is off the hook. He/she is off the hook because he/she has practiced “science”-based medicine of probability-based statistical medicine, “evidence”-based medicine based on probabilities.

- Probability theory reinforces the physician's tendency to think in terms of legal liability and to use the legal formula “more likely than not” or 51% probability regarding the correctness of his/her judgment rather than asking what is actually wrong with this patient and applying physiologic principles. Probability-based thinking also leads to the excessive ordering of unnecessary tests rather than ordering the correct tests required by physiology-based thinking. The decision not to order frivolous tests is based on the confidence that comes with physiology-based thinking. Intimate knowledge of neuroanatomy and neurophysiology is the only source of confidence that can safeguard the neurologist against the urge to order frivolous tests but also gives him/her the confidence to request tests that may be relatively arcane and experimental when necessary. The solution to the malpractice crisis lies in emphasizing physiology-based thinking at both the medical and legal levels of understanding and freeing both areas from relying on the 18th century mathematical model of probability-based statistics.

Summary

- The requirement of evidence-based medicine to apply probabilities to the individual patient leads necessarily to underdiagnosis, undertreatment, and missed diagnoses. The word *evidence* implies truth, but once the false image of a statistical situation is applied to an individual clinical situation, truth has been abandoned. Independent, knowledgeable, principled diagnosis and treatment are required for each patient because the physician's expertise and the patient's specific disease state are what bring that patient to that physician in a unique, historical moment. That historical moment is not the same as any other.

Disclosure

No potential conflicts of interest relevant to this article were reported.

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References and Recommended Reading

Papers of particular interest, published recently, have been highlighted as:

- Of importance
- Of major importance

1. • Kent D, Hayward R: **When averages hide individual differences in clinical trials.** *Am Sci* 2007, 95:60–68.

This article takes another look at the problem of applying statistics at the bedside.

2. •• Helgason CM, Jobe TH: **Measurable prediction for the single patient and the results of large double blind randomized clinical trials.** *Plos One* 2008, 3:e1909.

This article shows how an individual can be the subject of measured clinical outcome.