

'Evidence' based medicine: the need for a close look at the evidence.

Yash Lokhandwala

The present pathetic state

Ad-hocism is rife in the medical profession in India. We seem to keep abreast of current medical knowledge from the information received from medical representatives and from industry-sponsored conferences. There is no programme for continuing medical education worth its name. Very few doctors take the effort to regularly read textbooks and indexed medical journals. Obviously, medical representatives do the job of selling their products by the 'Convince, corrupt and cancel' methodology.

With the stiff competition and ever-burgeoning drug companies with their myriad tongue-twisting drug-combinations, the market is flooded with thousands of formulations, most of them irrational. Also, with more and more specialists and super-specialists crowding each other out in the cities, the general practitioners, too are often bereft of sufficient patients. We have the situation wherein many doctors and pharmaceutical companies vie for the restricted pool of patients who can afford to buy drugs and undergo multiple tests (At present 99% of people in India cannot afford secondary and tertiary level private health care and flock to public hospitals for major illness. It is predicted that this situation will prevail in the year 2020, when an already strained public hospital infra-structure will be woefully inadequate for the hugely expanded demand).

People are living longer

Modern medicine has developed more rapidly in the last century than in the previous accumulated history of mankind. Diagnostic and therapeutic modalities have evolved at a breathtaking pace. Technological advances have, in the last two decades, allowed us to probe and intervene in remote, previously inaccessible regions of the human body.

Demographic statistics show that people are living longer in most parts of the world than they did forty years ago. The quality of life for patients with some crippling diseases has undergone a sea change with the advent of transplant operations. Discoveries such as penicillin, insulin and heparin and their more recent equivalents have made a big difference in man's ability to combat disease.

On the other hand, we find that there are people, such as in

the Caucasian countries and in parts of India, who live long, healthy lives without recourse to modern medicine. A few years ago, during a visit to the Narmada valley, I was surprised to find that people were locally self-sufficient in food, eating what they grew and plucked. They did not feel the need for additional medical facilities. The populace was healthy and lived fairly long. Before the Sardar Sarovar project, the land was fertile, the air unpolluted, clean water aplenty and greenery all around.

Causes of longevity

If we go deeper into the mechanisms of longevity, we come across some thought-provoking revelations. In individual cases, the 'miracles' of modern medicine have been life-saving. The average life-span in the developed countries is now close to eighty years, while it was only around forty-five years in these very countries early this century. Analysis reveals that most of this increase in longevity has been due to:

- fewer wars;
- a more equitable distribution of wealth and economic progress, leading to alleviation of poverty and less malnutrition;
- improved hygiene and
- vaccines.

All the other revolutionary medical discoveries put together have made only a minor contribution towards the increase in longevity.

A typical example is that of rheumatic fever. This scourge, which leads to crippling heart disease in children and adolescents, continues unabated in India. In most developed countries, this disease, which was rampant till a few decades ago, has now disappeared. Penicillin was a major landmark in the secondary prophylaxis against rheumatic heart disease. What really helped in removing the scourge was the eradication of poverty, leading to better nutrition, less overcrowding and improved hygiene. This led to less streptococcal infections and an enhanced immunity in combating them. The high-tech heart operations and balloon valvotomies are a poor third in fighting the problem, since they are palliative measures for advanced disease. Some well-meaning but misguided scientists continue to labor to find a vaccine against rheumatic fever, while the 'vaccine' is well known - eliminate poverty!

Need for careful analysis of 'hard' evidence

If we are to employ any therapy, it must be based on hard evidence that it works. A lot of medical practice in bygone years was empirical, and it was not rare for the 'cure' to be worse than the disease.

In the current era of a profusion of medical literature, communication revolution, randomised trials and frequent conferences, one would expect that doctors were much better informed about current data and concepts. But the newer, aggressive, market-oriented world has also brought along with it the hard-sell approach, wherein economic pressures and considerations are often paramount in the making of clinical decisions.

Speakers at some of the conferences are in fact selected by 'the industry rather than by medical bodies. Thus those who give maximum business, rather than those with genuine scientific work, are often invited to deliver lectures.

Even being abreast with current medical literature is not a safeguard against irrational practice. It is not sufficient to read. One must also be able to differentiate between grain and chaff and filter out dubious material. Improperly planned studies, falsification of data, variable patient populations, inappropriate statistical methods and bias due to **funding by industry** lead to inconsistent, even contradictory results about any treatment modality.

As one studies published matter with a discriminating eye, it soon becomes obvious that one can find evidence to support almost any therapy. One can selectively quote literature to justify using a particular drug. There are numerous such examples, but let me use the example of ischemic heart disease. For patients with stable angina pectoris and after myocardial infarction, aspirin and **beta**-blockers along with nitrates when needed, have been shown to prolong life. These three drugs suffice for a majority of these patients. When one goes through medical prescriptions for such patients, it is common to see that they have been advised to take five or even ten different medications! At best many of these superfluous drugs would be harmless if taken alone; but few prescribing doctors are conversant with the drug interactions that take place when so many medications are administered. During preclinical testing of any drug it is never given as part of such a 'masala' and hence we have no data on what happens with this 'khhichdi'.

One of the techniques to bamboozle an audience into using a particular form of treatment is by the misuse of statistics. Let me illustrate this. One of the important issues facing physicians today is whether we can prolong the lives of patients with ischemic heart disease. Various therapeutic modalities like bypass surgery, angioplasty, cholesterol lowering drugs, free-radical scavengers are being used with this hope. Till date, most of these attempts have not succeeded in proving that they prolong life. Where they do, it is in highly selected subgroups of patients. And yet, our

'messiahs', tout such regimens such that we wonder how humans ever survived without them in the **past!**

These 'messiahs' find it useful to lump together the 'end-points' of a trial of any of these modalities. They lump together death and other, much less catastrophic, events like recurrent angina or enzyme elevation. They then compare, let us say, a cholesterol lowering drug with a placebo in a large number of patients and follow them up for a few years. They are not deterred when they find that even with the placebo, patients live equally long. They are cheered by noting that, statistically, more patients in the placebo group developed angina during follow up. So they lump together death with recurrent angina and prove that the drug was beneficial in reducing the composite end point.

An even more blatant method is to misrepresent data to make an insignificant change look dramatic. Take for instance two sets of a thousand patients each, treated for a serious illness with a drug and a placebo to see if the drug saved lives. In the group given the placebo, six patients died. In the group given the drug, 3 patients died. By applying analytical statistical techniques, this difference was not found significant and deemed due to chance. While promoting the drug, however, it is driven home that it reduced mortality by **50%! Few doctors look at data critically.**

The tragedy is that even in our medical colleges, we are not trained to probe and analyse. Dissent is discouraged. Intelligent students enter medical college to be churned out as memorizing robots.

Is there any scope for optimism? When we are mass-producing unquestioning zombies in our medical colleges, it may be asking too much for them to be critical in analysing the 'evidence'.

Suggested reading

1. Rainer TH, Robertson TE: Adrenaline, cardiac arrest and evidence based medicine. *Journal of Accident and Emergency Medicine* 1996;13:234-7.
2. Nee PA: Thrombolysis after acute myocardial infarction. *Journal of Accident and Emergency Medicine* 1997;14:2-9.
3. Liefke E, Nieschlag E. Male infertility treatment in the light of evidence-based medicine. *Andrologica Supplement* 1996; 1:23-30.
4. Sandifer QD, Lo SV, Crompton PG: Evaluation of a journal club as a forum to practise critical appraisal skills. *Journal of the Royal College of Physicians of London* 1996;30:520-522.
5. Cooper AB, Doig GS, Sibbald WJ: Pulmonary artery catheters in the critically ill. An overview using the methodology of evidence-based medicine. *Critical Care Clinics* 1996; 12:777-794.
6. MacAuley D: The integration of evidence based medicine and personal care in family practice. *Irish Journal of Medical Science* 1996;165:289-91.
7. Hamilton J: Training for skills. *Medical Education* 1995;29 Suppl 1:83-7.
8. Rosenberg WM, Sackett DL: On the need for evidence-based medicine. *Therapie* 1996;51:2 12-7.
9. Tonelli MR, Benditt JO, Albert RK: Clinical experimentation. Lessons from lung volume reduction surgery. *Chest* 1996; 110:230-8.
10. Rosenberg W, Donald A: Evidence based medicine: an approach to clinical problem-solving. *BMJ* 1995;3 10: 1122-6.