

Editorial

Medical Science and Bedside Medicine

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Kuwait Medical Journal 2004, 36 (2): 91-92

One would wonder in the beginning as to why the title seems to suggest that the two are different! Common understanding is that medicine is a science and everything that the doctor does on the bedside is evidence-based. That is what the establishment would want to make the common man believe. Where is the reality? Of course, there is good science backing up the discovery of a new interventional tool, a new surgical method or a diagnostic technique, as also in discovering a new molecule of a drug. All these would need investment of large amounts of money in the bargain. From then on, to recover that money, many times over, the industry uses both fair and unfair means. In the case of drugs, after they have gone through the usual laboratory discovery, animal testing and pilot studies on volunteers, the molecule is then let loose on the gullible public through what are called controlled studies. However, most of the newer surgical procedures and investigative tools have never been thus tested before being used on patients. The exciting groundbreaking surgical feats have never been audited. The story of the first heart transplant in South Africa is a shining example.

All those drugs and procedures, tested by the controlled studies, go through peer reviews and invited editorials by the "thought leaders" in the field. Most of the latter, on closer scrutiny, have been connected with the manufacturers or their agents directly or indirectly. Occasionally, someone unconnected might write an adverse remark. "Greater thought leaders" quickly blemish such reports claiming to know everything, based on their long clinical experience. The story of the Oxford study of thromboplastin activator after acute myocardial infarction and the post JNC V dust storm about the report suggesting thiazides as the first drug of choice in the treatment of hypertension are there for everyone to see. Very quickly the report V was replaced by another JNC VI report and thiazides were relegated to the background. Time has shown that both these "experiences" of the wise leaders proved fallacious.

Publication bias is another blow to the truth. Mathew Law "He who hath shall be given" works wonders in this field. The unknown workers in the third world countries rarely get a chance to publish their data, and in the unlikely event of the latter getting published very few people take note of them. Medical wisdom has to come from the horse's mouth. The sad part of the whole business is that no one cares to look the corporate gift horse in the face.

Occasionally, the industry succeeds in taking the watch dog bodies for a ride. Milrinone is the best example. The drug was permitted by the FDA before the first ever human study-PROMISE. Only after a few innocent people lost their lives did the authorities wake up to the reality that milrinone works in two totally different ways in the rat and in man. The drug has since been withdrawn. There have been instances where the whole research project remained unpublished because it did not suit the industry. The 1954 American study of "Diet and Heart" is a good example. This prospective study that looked at the relation between food and heart diseases came to the conclusion, after five years, that the two are not closely connected. Unfortunately, by then millions of dollars of special foods business had come up. The study, if published, would have ruined their business. Despite spending \$100 million of taxpayers' money the results were not published! There are so many skeletons in the cholesterol cupboard also. The letter to the editor of Lancet by Professor Michael Oliver entitled "Consensus or nonsense conference on cholesterol" is a good example. "Female Impotence" and the all powerful "Poly pill" that takes care of all dangerous degenerative diseases are recent examples of this kind of intellectual delusions sold to the medical world as also to the lay people.

The scientific foundation of controlled studies is very, very shaky. Thought to be the last word in drug research, these are being used as the touchstone for drug testing on humans. Two "matched controls" receive the drug and placebo

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for comparison. While the matching uses a few phenotypic features for comparison, time evolution in the human body depends on the total initial state of the organism. That apart changing one or two parameters (like cholesterol or BP) might not hold good as time evolves. The third problem is that the longest duration of any controlled study has been five years. Every single drug that has been thus tested has since been audited in long term clinical audits lasting for three to four decades. Most of the drugs, if not all of them, have acquitted themselves well in these real life situations. Apart from the basic scientific fallacy in the controlled studies described earlier, there are many other major variants between controlled studies and real life bedside situations.

While in every controlled studies all the other parameters are known and only the difference in

the drug and placebo treated group vis-à-vis the clinical outcome is measured, in real life situation many imponderables get into the picture, least of all the patient compliance in society. Even in Western societies drug compliance is very poor. Hardly any patient these days gets a single drug in isolation in practice, the way it was tested in the controlled studies. Many drugs are given together, but there have been no controlled studies that studied drug combinations against placebo combinations. Extrapolation, therefore, of the scientific data to the bedside is totally different and not comparable. One in every four drugs prescribed in the US during the last one year had resulted in serious side effects. Whether the side effects were due to the drug in question or the drug interactions is impossible to know with our present knowledge.