Dr Olson's discovery and the meaning of "scientific"

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A few years ago I suggested that the neglect of clinical research in family practice was due to three things: the devaluation of taxonomic research, our lack of awareness of the limitations of randomized controlled trials, and a lack of confidence in our ability to add to medical knowledge.[1,2] Using Ryle's[3] definition of clinical research (observing, recording, classifying, and analyzing), I described how it could be part and parcel of our daily practice, a source of great interest, and a field of research that can be explored only by clinicians who are participant observers. Clinical practice is the heart of our discipline, and if it is not at the centre of our research, how can our discipline survive?

Dr Olson's description of a new treatment for intractable ischemic leg pain **(page 1225)** is a reminder that important discoveries can be made in family practice. Dr Olson's original paper was a retrospective review of patients he had treated with intermittent positive pressure since 1979.[4] A retrospective chart review of one's own patients has some special features. Usually the records have not been kept with research in mind. Only when research is planned in advance will standardized data be available. On the other hand, a physician's personal knowledge of a patient can add richness and depth to that data. The patients studied cannot be a selected sample: they are simply all the patients seen with the condition in question. A physician's involvement in care of a patient adds a risk of bias but also adds depth of knowledge. Thus, for every value reduced, there is value added.

No straight path

When a physician is developing a new idea, or on the trail of a new discovery, each case could add new insight. The path to the discovery, or to the fully formed idea, is not straight. Having a fixed protocol at this stage can be a disadvantage if it makes us blind to an unexpected event. The biologist and Nobel Prize winner P.B. Medawar writes:

> There is a clear distinction between the acts of mind involved in discovery and in proof. The generative or elementary act in discovery is "having an idea" or proposing a hypothesis. Although one can put oneself in the right frame of mind for having ideas, the process is outside logic and cannot be made the subject of logical rules.[5]

Unfortunately, this important distinction has been forgotten. The creative process by which theories are formed and discoveries are made lacks rules and is declared unscientific. Given this prejudice, Fleming's discovery of penicillin might never have been reported.

Temporal correlation

Dr Olson had great difficulty publishing his original discovery. He could not explain the background of his idea, because, as he put it, "it popped out [from my head] like Athena from the head of Zeus." He could not provide biological support because it was unavailable at the time. He tried to measure pain levels, but found that the elderly patients could not understand the rating scale. Quantifying pain is notoriously difficult for the elderly. But for his patients, the pain relief was so immediate and so total as to make measurement superfluous. In a prospective study it would have been possible to measure functional improvement more precisely. But in another respect, his data were more compelling than most "scientific" studies. He was able to follow his patients for long periods, often until death, thus answering the crucial question: "is the effect sustained if treatment is continued"? To have this evidence is rare and precious. Temporal correlation was the invention of Thomas Sydenham (the "English Hippocrates") in the 17th century. It enabled him to endow disease categories, such as

chorea, gout, smallpox, cholera, and measles, with predictive power.

For a century Sydenham's insight was forgotten. Numerous categories of disease were described, but they were without predictive value and therefore clinically useless. It was only in the 19th century—the great days of taxonomic research—that the prognostic categories we use today were described. To this, general practitioners made a significant contribution. Dr Olson was able to follow his patients for years. In this respect his data are stronger than those provided by cohort studies of short duration.

Anecdotes can be scientific

When Dr Olson sought publication, he was told by two journals that his paper was anecdotal. What exactly does this mean? The Oxford dictionary gives two meanings of anecdote: an unpublished narrative and a narrative of interesting or striking incidents. Dr Olson's paper certainly fits this definition. But does this make it unscientific? All scientific papers tell stories. What makes a paper scientific is not its story but whether its story can be tested and verified. Dr Olson's results are eminently amenable to refutation, and his paper is, therefore, scientific.[6] It cries out for further testing, and it would not be difficult to design a method. But unless the paper is published—preferably in a widely read journal—who is going to be aware of Dr Olson's discovery? If Fleming's "anecdote" had not been published, it would never have been seen 10 years later by Florey and Chaim who were eventually able to produce usable penicillin. Failure to publish what appears to be a compelling discovery might also deprive patients of an effective new therapy.

Another journal rejected Dr Olson's paper on the grounds that (according to an expert reviewer) the therapy did not alter the natural history of the disease. Again, what does this mean? When a harmless therapy promises to relieve relentless pain and makes amputation unnecessary, is this not a change in the natural history of the disease? And which is more important: changing the natural history or relieving suffering?

There is little doubt that Dr Olson has made an important discovery that could change the way relentless ischemic leg pain is managed in family practice. The case report from an independent source adds even more evidence for its effectiveness. Some questions remain about its effectiveness for patients with intermittent claudication, who were not followed by Dr Olson, and there is conflicting evidence about its effect on patients with diabetes. The stage is set for a prospective study. With the start that Dr Olson has given us, we could soon have further verification, as well as a taxonomy to tell us who will respond and who will not.

As for the future of clinical research, I fear that nothing will change until we stop passing on to our students what Steven Jay Gould calls a "false stereotype of science."[7] Scientists such as S.J. Gould, Michael Polanyi,[8] and P.B. Medawar[5] have been doing their best to correct our misconceptions—but so far with little success.

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