

Commentary

Celebrating a prospective randomised control trial

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I am writing this commentary on April 1, which is called April Fool's Day in the United States. Historically it is a day for pranks being played on persons, in print, and now even online.^[1-4]

If I were to state that the preceding article was of a higher evidence-based medicine quality than the latest article on the subject to appear in the Journal of Hand Surgery, you would think that I was pulling an April Fool's prank on you.

It is no prank. It is the truth. Published ahead of print and available online at the Journal of Hand Surgery, although not yet indexed in PubMed, is a retrospective study from the Harvard Medical School/Massachusetts General Hospital.^[5]

The importance of this study in the Indian Journal of Plastic Surgery cannot be sufficiently underscored. Why?

Not only is it a higher quality study than the one from the Massachusetts General Hospital, but I also discovered, by using the PubMed database, that this is the first randomised controlled blinded trial to be published in this journal.

What is most impressive is that the authors began this study almost ten years ago, before the concept of evidence-based medicine became au courant among our confreres.

One could quibble with some aspects of the methodology,

for example, allocating alternating patients to the control and treatment arms, was pseudo-randomisation.^[6] In 2012, random number generators are freely available on the internet. Nevertheless, the points worth noting about this study are:

1. That the authors sought to answer a meaningful clinical question rather than continue to employ the dogma that they had learned from their professors
2. That the authors proceeded in an ethical manner by obtaining approval from their institutional ethics committee
3. That the authors clearly described the informed consent that they obtained from their patients
4. That the results were measured by an independent therapist who was blinded to the treatment arms

The ethical standards that the authors maintained were those included in the Declaration of Helsinki. The only ethical requirement that the authors did not fulfil, which the IJPS and the Declaration of Helsinki now require is that all prospective trials be registered in a publicly accessible database before the first patient is enrolled.^[7] The trial registration is free.

With the wealth of patients needing treatment for their hand problems, Indian plastic surgeons have a golden opportunity to not only help their patients, but also to answer important clinical questions with high quality, ethical, prospective, blinded randomised controlled trials.^[8]

These authors have been Indian pioneers. Other should follow in their footsteps.

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