

Phacoemulsification vs Small-Incision Manual Cataract Surgery: An Expert Trial

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IN THIS ISSUE, RESULTS FROM A RANDOMIZED, CONTROLLED TRIAL (RCT) are published in which two techniques for cataract extraction are compared.¹ The question of whether manual sutureless small-incision extracapsular cataract surgery (SICS) is as effective and safe as phacoemulsification is addressed.

This may seem to be a fruitless enquiry because it is assumed by most that phacoemulsification is the gold standard for treatment of cataract worldwide. Remarkably, this standard was established without a single RCT comparing the new technique to established extracapsular surgery being published. When publication was sought for a British Medical Research Council (MRC) trial comparing phacoemulsification to extracapsular extraction, peer reviewers initially recommended rejection because they regarded the case already made that phacoemulsification was safer and more effective. But it was, in fact, an important trial (and the study was eventually published) because it showed that despite the additional costs associated with the technology, phacoemulsification resulted in longer-term savings as a result of more rapid rehabilitation and fewer postoperative visits.²

But this was only relevant to affluent health systems. For poorer countries, the capital and consumable costs of phacoemulsification remain a major issue. Cost is one of the most important barriers to cataract surgery, and it is in the poorer parts of the world where the huge backlog of avoidable cataract blindness exists. Pioneers of cataract techniques in India and Nepal soon found a way of reducing the incision size and eliminating the need for sutures in manual or nonmechanized techniques. This constituted the specific disadvantage of the traditional extracapsular technique: the need to have the sutures removed at three months, and the degree of postoperative astigmatism. Variations of the small-incision manual technique have rapidly developed, and last year, the first trials comparing phacoemulsification with SICS and SICS with extracapsular surgery were published.³⁻⁵ These trials as-

essed visual outcome, vision-related quality of life, and cost. SICS was found to be almost as good as phacoemulsification.

A problem with trials in which the same surgeon is randomized to both techniques under investigation is that the surgeons involved may not be equally skilled in both techniques. It makes it possible for experts who disagree with a trial's findings to implicate the surgical skill of the trial surgeons. It is not the technique that is at fault, but the fact that the surgeons involved may have perfected one technique over another. In the British MRC trial, the surgeons involved had already converted to phacoemulsification and had effectively to relearn extracapsular extraction. In Pune in Maharashtra, India, were the surgeons equally proficient in both phacoemulsification and SICS techniques?

This problem is addressed by a design recommended in a *British Medical Journal* article published in 1998 but not much cited (as yet) in ophthalmology.⁶ The design is called "expertise-based trial design." Patients are randomized to an expert in either surgical technique so that the relative effectiveness of each technique in expert hands can be compared—a neat design that avoids a learning curve for either technique. This design is used in the trial described in this issue.

Other aspects of this trial are perhaps less expert. The random allocation method was not properly concealed. The patient or the trialist could influence the choice of a black or white ball if the significance of the color was known. A ball could be selected or rejected at will, with the next patient being allocated the alternate option. Switching the sequence could have manipulated allocation and allowed selection bias. We are not given sufficient information to judge whether sufficient steps were taken to achieve allocation concealment. Concealed allocation means that there is no way either the participant or trialist could predict or manipulate the random allocation process. Although there is no reason to suspect that selection bias might have occurred, external users of evidence apply independent quality criteria for inclusion in systematic reviews. Allocation concealment is a critical quality issue in RCTs.⁷ However, trials where allocation concealment has failed tend to overestimate effect size, and here the findings were more equivalent.

See accompanying Article on page 32.

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Trials of equivalence are also a problem. To confidently assert that one treatment is as good as another makes enormous demands on sample size. To detect small differences, a huge sample size is required. In this study, there was no up-front sample size calculation. The size of the trial was presumably determined by the number of participants who could be recruited within a fixed time frame. Study power is definitely an issue when no difference is found in primary outcome measures. What sort of difference could have been detected in a study of this size?

But the trial was essentially pragmatic—the best that could be achieved under the circumstances. Its findings are undoubtedly valuable, and the study is an important contribution to the growing number of RCTs addressing the most cost-effective means of dealing with cataracts in different circumstances, and in particular, in poor parts of the world with excess cataract blindness. Riaz and associates⁸ have recently updated a Cochrane systematic review on this question with several new and important studies—which, when next updated, should include this trial. A problem in conducting this update was that different outcomes at different time points are reported, which makes useful meta-analysis impossible. We should expect researchers in the field to agree on some standard outcome measures, both for trials and for audit.

The assumption that phacoemulsification is the gold standard should always have been questioned, and there are much firmer grounds for doing so now. The issue of capsule opacification is crucial, and in this study, it may well be explained by intraocular lens fixation. In-the-bag placement of an intraocular lens with a small-incision manual technique may reduce the capsule opacification risk but lengthen the duration of the procedure. It is to the authors' credit that this important issue is addressed: it is a critical question in the debate on which technique to use in high-volume, low-cost cataract surgery programs. The question remains whether the phacoemulsification group will have a capsule opacification rate that catches up over time. We should hope, if not expect, that such an attempt will be made at longer-term follow-up in this trial, at three and, if possible, five years. Although this will not be easy in Nepal, longer-term follow-up has been achieved in other trials there.⁹

This trial reflects a growing awareness in our profession that high-quality evidence is essential to make important

decisions about surgical technique. Trials in surgery are not always easy, but the expert design in this study is a good example of one way to overcome problems in design.

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