The significance of evidence-based ophthalmology in clinical practice: why bother?

PRACTICING eye care and thinking about evidence is a paradigm shift. We were taught traditionally that A causes B and that C is the treatment for E. No questions were asked—there was no uncertainty. It was probably different in the days when José Rizal studied ophthalmology because then they knew so much less and minds had to be kept open to force progress. Since then, much has been discovered and certainty has become the preferred approach—it’s simpler to be sure about things but, in the end, less interesting. With an evidence-based approach, every “certainty” is questioned, every assertion challenged. And because of this, medicine is becoming interesting again. We move from learning facts by rote to understanding uncertainty and being able to estimate its dimensions.

Relative risks or odds ratios with confidence limits estimate the extent to which the risk or probability of an outcome might be modified by an intervention or exposure. This is a more sophisticated approach to the simple dichotomous concept, perhaps inevitably preferred by surgeons, that a treatment will work or not as the case may be. Naturally, surgeons prefer a high benefit to risk ratio; a high probability of a positive outcome to justify submitting the patient to the knife. Physicians are more used to relatively small risk modifications in their interventions and perhaps this is why evidence-based medicine is so called and that evidence-based surgery is a less widespread phenomenon.

Ophthalmologists are fortunate to practice both medicine and surgery in “general practice,” though many of us are becoming superspecialized to the extent that some of us are now only performing one operation. Cataract surgery dominates our practice and we are fortunate to have such an excellent intervention where the benefits are large and the risks are small. We still need to quantify those risks and evidence to inform patients about the likelihood of an adverse outcome. These risks—especially rare but serious adverse events—cannot be well quantified from randomized, controlled trials and better data are provided from large and representative outcome studies (sometimes termed phase 4 “open-label” studies).

Changes in practice are generally justified by the provision of good evidence that the new treatment is better. This has not always been the case in eye care. Phacoemulsification was implemented across the world without a single RCT justifying the change in practice. The desire to be modern and the perhaps obvious advantage of a small incision not needing sutures were sufficient to justify the change. But what about the cost?

Ultimately, a trial was carried out in the UK and the cost issue in particular was addressed. In the context of publicly funded practice in the affluent
western world, cost benefit could be demonstrated on the basis of a reduced requirement for outpatient follow-up. But what about poorer countries where the cost of "disposable" consumables might be a problem? This has been addressed by a series of excellent trials from Pune, India comparing traditional extracapsular surgery (ECCE) to small-incision sutureless cataract surgery (SISCS) and SISCS to Phaco. SISCS is as cheap as ECCE and has outcomes nearly as excellent as those of phaco.2,3,4

Surgical trials can be problematic when skills must be acquired in a new technique before optimum outcomes can be achieved—the learning curve. Sometimes it might be difficult for the same surgeon to be equally skilled in both techniques. In the Moorfields trial, the trialists admitted to having to relearn their ECCE skills in order to take part in the study.

An alternative trial design is to randomize participants to surgery performed by experts in the specific technique under comparisons so that the learning curve is avoided and optimum surgical skill is employed in all arms of comparison.3 ECCE in skilled hands probably achieves equally excellent outcomes but requires refinement in section design and suturing technique. In fact, there are numerous variables at play in determining the excellence of outcome, and these are not just about surgical technique. There are many questions about calculating intraocular-lens power and selecting the most suitable lens material and shape and the way the lens is introduced into the eye.

Abandoning the ECCE technique has meant that certain skills, such as suturing a corneal or limbal wound, have been lost to the trainee. It is hard to measure the impact of such a development, but it is clearly not desirable when the ability—necessary to manage the closure of corneal perforations and to convert when small incision surgery has failed—is lost.

The assumption that phaco was a doubtless benefit is even less clear when we realize that our younger surgeons have become dependent on high technology and expensive consumables. We should realize that equal to the challenge we face in finding better treatments for common blinding diseases is that of simply delivering a basic standard of care equitably to those less advantaged in the world where, of course, there is the greatest need. I believe this is a much greater challenge than pushing forward the frontiers of technology—minimal gains for greater cost in richer countries when major gains for much less cost can be made in poorer ones.

We need to reflect carefully and employ the highest standards of evidence-based methodology when we make major decisions about changes in our practice. When a new product is being heavily marketed, it becomes even more important that at least some intelligent eye surgeons ask questions about evidence and cost benefit and effectiveness. Otherwise, scarce resources can easily be wasted on the latest modern technology that turns out to provide minimal additional clinical benefit at huge additional cost.

In Britain, the National Institute of Clinical Excellence (NICE) has been established to make evidence-based decisions about providing new treatments in the National Health Service. They have considered the provision of Photodynamic Therapy for the treatment of neovascular age-related macular degeneration.6 Their review refers to our Cochrane Review, a recently updated version of which appears in this issue. We could not conclude benefit, and in particular, cost benefit could not be demonstrated from the existing evidence. There were doubts about the validity of the subgroup analyses and we concluded that more evidence was needed. A particular concern is the opportunity cost of such new treatment when it has already been demonstrated in the UK that services for the provision of simple low-vision aids and rehabilitation for the visually impaired are unevenly and inequitably distributed across the country.

The Philippine Academy of Ophthalmology is well ahead of the field in considering the importance of evidence in determining practice. Their last meeting was dominated by an EBM theme and numerous trainees are now engaged in the conduct of systematic reviews for the Cochrane Collaboration. It is essential that this culture grows for the scientific and equitable development of eye care and for the prevention of blindness throughout the world.

References