The ROYAL COLLEGE of OPHTHALMOLOGISTS

focus

An occasional update commissioned by the College.
The views expressed are those of the authors.

Evaluation and research of surgical innovations in ophthalmology: a comic opera?

Augusto Azuara-Blanco, PhD, FRCOphth

Clinical Professor of Ophthalmology, Queen's University Belfast

Honorary Consultant Ophthalmologist, Belfast Health and Social Care Trust

Centre for Public Health, ICS-A, Grosvenor Road, Belfast, BT12 6BA

Phone: 028 9097 6350

Email: a.azuara-blanco@qub.ac.uk

https://pure.qub.ac.uk/en/persons/augusto-azuara-blanco

A few weeks ago, *the Lancet* published an editorial entitled: "Surgical research-comic opera no more" referring to the famous quote by Richard Horton from 1996.[1,2] At the end of the last century surgical research was mainly based on case series, and the few existing randomised controlled trials were typically poorly designed.

Over the following decade, collaborative efforts between surgeons and researchers culminated in the IDEAL (Idea/Innovation, Development, Exploration, Assessment, Long-term follow-up) collaboration.[3,4] Recommendations were proposed for the assessment of surgical innovations based on a five-stage description of the surgical development process, (see www.ideal-collaboration.net/). For example, instead of case series studies, surgeons were encouraged to do prospective studies, with openly registered protocols. Randomised comparative trials should be used whenever possible, with collaboration and support of researchers and trial units. Adopted surgical procedures should be monitored with prospective databases to analyse long term outcomes and uncommon adverse events.

The Royal College of Surgeons of England (RCSEng), with support from the National institute for Health Research (NIHR) has developed a network of clinical trial units with expertise in surgical research (named surgical trials centres, SCT), and surgical leads for each subspecialty. There are over 20 subspecialty leads representing all surgical specialties and colleges. These joint efforts have seen an increased research funding for surgical trials, and an improvement in the quality of surgical research and patient outcomes.[5]

The RCSEng has issued guidelines on how novel surgeries should be introduced into clinical practice, eg, promoting the use of the IDEAL Framework that offers a structured approach to surgical innovation, and highlights the importance of proper clinical governance, patient consent processes, ethical considerations, and management of conflicts of interest.[6-8]

Typically, IDEAL stage 1 is prompted by the need for a novel solution to a clinical problem and generates a case report or a short case series. This should include a clear explanation of the technique or equipment, and any adverse events. Based on the outcomes of IDEAL Phase 1, it will be possible to assess whether it is desirable to proceed with further patients.[4]

IDEAL phase 2a results will determine if the technique and outcomes have reached stability and if the approach is ready for evaluation in a prospective, multi-centre cohort study (IDEAL phase 2b). This should include description of the inclusion criteria, surgeon's learning curve, a detailed explanation of the technique, and clinical outcomes and safety. IDEAL phase 2b will inform the feasibility of a RCT.

The goal of IDEAL stage 3 is to compare the efficacy between the conventional and novel surgeries. IDEAL stage 4 focuses on long-term evaluation and monitoring of possible rare adverse events, preferably by using prospective databases and registries.[4] Suggestions about how to support surgical innovations in ophthalmology have been summarised recently.[9] Recently the RCSEng invited the Royal College of Ophthalmologists to join the network of surgeons, researchers, and surgical trial centres to support and promote high quality research in surgical innovations. The RCOphth was keen to join this network but as the proposal did not have any attached funding, the RCOphth had to defer their decision to join until a funding source becomes available. The quality of surgical research in ophthalmology is poor. In a recent systematic review evaluating the quality of recent ophthalmic surgery RCTs (n=52) a description defining the surgeon's experience or level of expertise was reported in 30 RCTs (57%); specification of the number of cases performed in the particular surgical innovation being assessed prior to the trial was reported in 10 RCTs (19%) and quality assurance processes were described in 7 RCTs (13%). Prospective trial registration was recorded in 12 RCTs (23%), retrospective registration in 13 (25%), and there was no registration record in the remaining 28 (53%) studies.[10]

I am afraid surgical research in ophthalmology will continue to sound like comic opera for the foreseeable future.

Pouya Alaghband
Editor, Focus

Visit **www.rcophth.ac.uk/standards-publications-research/focus-articles/** for references relating to this Focus feature