Clinical Trials in Surgery

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A randomized clinical trial (RCT) is a type of experimental study where participants are randomly assigned to separate groups that compare different treatments (1). RCTs are considered the goal standard in evaluating the efficacy and effectiveness of treatment interventions because the potential for selection bias is avoided through randomization of the study participants (2).

The history of experimental studies is as old as humanity itself. One of the earliest references to a trial in the bible is in the book of Daniel where young men were allocated to two different diets with baseline and follow-up measurements taken (3). In modern times, records of experiments conducted in medicine were fundamentally flawed due to a lack of an appropriate control group. This was exemplified by two different experiments on small pox by Lady Mary Wortley Montagu and Edward Jenner (4). One of the earliest records of a properly conducted trial with an appropriate control may be found in Lind's experiment on the management of scurvy where he had six groups of patients who received similar diets but differed in what was thought to be different remedies for the disease (5). The placebo effect was famously brought to the attention of clinicians by James Haygarth who proved that the metallic tractors being advocated for the management of furuncles through their 'animal magnetism' were nothing more than an expensive sham as wooden tractors worked just as well (6). In surgery, many practices that were institutionalized, had no foundation in science and have been discarded with the emergence of evidence against them (7).

Although RCTs have been widely accepted as the gold standard in evaluating medical therapies, there are lesser reports for surgical procedures (8). Challenges faced when designing surgical RCTs include standardization of the surgical procedure, timing of surgical trials, difficulties with blinding of subjects and investigators, ethics of surgical trials, and patient and surgeon acceptance of surgical trials (8-10). In medical trials for instance, the dosage for a drug can be standardized, and compliance can be measured. In surgical trials, however, standardization of a procedure may be difficult because surgeons vary in their experience with, and their ability to perform, a surgical technique. In addition, there may be individual preferences when performing the procedure. In order to ensure uniformity in the surgical intervention, there is need for consensus among the participating surgeons on how to perform the procedure and limiting participation to experience surgeons only. In a recent study by Gatura et al where they sought to determine if feracrylum would reduce the rate of seroma formation, the issue of standardization comes to play as the surgeries had to be conducted by different surgeons of varying skill levels (11). This study is however very useful to the breast surgeon in the ongoing search for an agent to reduce seroma formation. The outcome of seroma can also be said to have been subjective as there is no objective measure for collection of the seroma. While in medical studies; sample size calculation will ensure that one ends up with a well powered study; this may not always be possible in the surgical field. A study on malignant pleural effusion published in this issue highlights the difficulties in getting adequate patient numbers for certain clinical conditions (12). This study however highlights that cost effective and readily available remedies can be offered to patients with this terminal ailment to improve the quality of life.

Further, most surgical interventions are multidisciplinary, involving care by different health professionals and other adjunctive treatment in addition to the surgical intervention. Each of these components may be difficult to standardize, and may influence the treatment effect. It may therefore be difficult to accurately determine whether the treatment effect

was purely a result of the surgical intervention or the intervention plus the adjunctive treatment. It is therefore important to report all components related to the procedure namely pre-operative care, intra-operative care, and post-operative care.

Despite these challenges, surgeons should not shy away from designing and conducting clinical trials as this will further the progress of science and make patient care more objective. In certain cases, clinical trials can be used to cement established practices in other regions of the world that may not be readily accepted in one's local situation. A study on oro-tracheal intubation in patients who may have cervical spine immobilization indicates that trauma teams should be prepared with other adjuncts to ensure airway placements as the risk of failed intubation is high (13).

Overall, clinical trials are the way to provide evidence for best management of surgical patients and the surgeon has a calling to aspire to participate in the production of this evidence.

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