EDITORIAL

Poor Routine Healthcare System Data Quality is a Major Obstacle to Clinical and Epidemiological Surgical Research in Developing Countries

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Accurate, routine healthcare system data potentially begets valuable research if imagination, creativity, integrity and expertise are applied. Nonexistent, poorly recorded and inaccurate data foretell missed opportunities to answer critical research questions regarding clinical epidemiology of disease, treatment effectiveness and quality of care, and worse, generate misleading findings and conclusions that could jeopardize the well-being of patients if used to guide practice (1).

Although these truisms apply to retrospective observational clinical research in general, they are of special importance for the surgical research enterprise, in which retrospective analysis of prospectively collected data often provides the highest level of evidence practicable. Attempts have been made to quantify the percentage of surgical practice guided by the highest levels of evidence (well conducted randomized controlled trials (RCTs) and meta-analyses/systematic reviews of RCTs) (2), but such estimates are likely to be imprecise, given the complexity and multi-component nature of the specialty, with its preoperative, operative and postoperative elements. Notwithstanding, it has been estimated in one study, admittedly dated, that only 24% of procedures performed in surgery are based on RCT evidence (3). Even where RCTs are performed in surgery, design flaws have been reportedly identified in 56% (4). This has the potential to seriously mislead, since so much weight is accorded RCT evidence.

Why are RCTs not more commonly performed in Surgical Research?

RCTs serve a very specific and narrow purpose in medical research, namely, to determine the true comparative effectiveness of two or more interventions when doubt exists about which is the better or best option. There are several reasons why RCTs may not be necessary, possible, or constitute the best methodology for supporting evidence-based practice in surgery:

1. When an intervention has a dramatic, curative effect and there are no other treatment options (5). This category is becoming smaller as technology advances. For example, endovascular aneurysm repair is now an acceptable alternative to open aneurysmorrhaphy whereas just a relatively few years ago the latter was the only option.
2. Equipoise between treatment options cannot be established (4). Equipoise describes a condition in which there is doubt that either contending treatment option is superior or inferior to the other. For an RCT to be ethical, equipoise must be objectively established on the basis of existing data. Prospective participant surgeons and patients must also be convinced that equipoise exists between contending treatments, otherwise they will not be willing to participate in a RCT, thereby compromising the randomization process (4).
3. Placebo controlled RCTs are difficult in surgery, because equipoise still needs to be established between the tested intervention and no intervention, and sham surgery is unethical (5).
4. Blinding of participant surgeons and patients is usually impossible, thereby decreasing the bias-reducing effect of this procedure (5). Blinding independent assessors of study outcomes should be instituted whenever possible in surgical RCTs.
5. Standardization of procedures is difficult but critical, as different surgeons tend to practice small variations that may affect outcomes (5). The position of participating surgeons on their learning curve for the intervention must be determined and compensations made for this bias in the analysis (4).
6. Similar compensations must be made for variability in the severity of cases and other factors such as physiological status, that affect outcomes.
7. RCTs are expensive and require special expertise that may not be available in resource-constrained countries.

The Importance of Observational Study Designs, particularly Cohort Studies, as evidence in surgical practice

Well conducted cohort studies constitute the level of evidence below single RCTs (2). This versatile

observational study design is well suited to clinical and epidemiological surgical research, from incidence and outcome studies to survival analysis and comparative research, a much broader repertoire than that of RCTs and the source of cumulative evidence required to establish equipoise between treatments. In addition, cohort studies may be retrospective or prospective or both.

The first of the main weaknesses of comparative cohort studies is that they are subject to error from bias and confounding by known and unknown variables. The effect of known confounders may be interrogated using multivariable regression but accounting for unknown confounders requires randomization. However, a relatively recent statistical technique known as propensity score matching offers the prospects of approaching the effect of randomization. Several encouraging studies have demonstrated no difference between the estimates from RCTs and those derived from using propensity score matching to analyze the same data (6, 7).

A second is the high cost and long time required for completion of prospective cohort studies, both of which could be abrogated if retrospective analysis can be achieved with the same degree of reliability. But is that possible?

The great weakness of retrospective cohort studies is unreliability of the quality of the data. In some, mostly developed countries, this problem has been addressed through continuous, prospective collection and integration of structured, digitized, routine and non-routine (e.g., registry) health systems data. This provides a vast, reliable database for retrospective analysis. Too often results of such studies are inappropriately extrapolated to our populations in developing countries because there are no local statistics.

Improving Routine Data Quality in Developing Countries to drive reliable local research

Following are recommendation for improving routine health systems data collection in developing countries:

1. Transitioning from handwritten, paper- to digital-based recording systems. Handwriting is often undecipherable and paper-based systems subject to data loss from misplaced files and deterioration of the medium; records have to be searched manually to find relevant data. Digital-based systems are searchable electronically and can be backed-up and maintained/renewed indefinitely.
2. Transitioning from narrative- to predominantly structured, synoptic-based reporting of health system encounters with patients and population. Purely narrative-based reporting of patient encounters is notorious for missing important observations, the remedy being data capture via structured forms with limited narrative input.
3. Expansion of the range of variables currently recorded, such as structured data describing surgical operations and patient characteristics, like height and weight.
4. Enable direct input into the database by clinicians and clinical support staff from point-of-care encounters.
5. Upgrade skills, training and remuneration of Health Data Management staff.
6. Establishment of registries for recording of non-routine health systems data. Well run routine data collection systems provide seed information necessary to populate disease-based (e.g., cancer, trauma) or quality control registries. Registries, like routine databases, constitute a rich source of data for surgical research but require additional health system funding and dedicated staff.

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