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EDITORIAL

How evidence-based are industry-sponsored clinical trials?

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Evidence-based medicine is about collating evidence to make correct clinical decisions. However, all types of evidence are not considered to be equal. There is a hierarchy of evidence, ranging from randomized controlled trials (RCT), which are considered as the highest form of evidence to expert opinion.

Recently, the quality of evidence from RCTs, especially industry-sponsored RCTs, has been called into question. Let us examine why even well randomized RCTs with large numbers of participants and clear-cut evidence may not translate to significant clinical results in real life situations.

First, clinical trials recruit carefully chosen study populations, and, therefore, the results may not be generalizable to the typical patient. Clinical trials favour carefully selected, homogenous populations, far removed from the complex mix of clinical practice. Inclusion and exclusion criteria may exclude patients seen in the clinical setting, for example children. RCTs are conducted in ideal settings which may not be replicated in, for example, third world hospitals.

Another way data may be compromised is if the RCT tests the medicine in question against placebo or a comparator that may not be current best treatment. Using an appropriate comparator is vital to the practical usefulness of trial results.

Many RCTs are designed to end once a significant benefit is shown. Limiting outcome measure to short term outcomes may not adequately reflect the use of the drug in real world situations, especially in chronic disease requiring long term treatment. In some cases, drugs shown to be efficacious in an RCT have been withdrawn later due to safety concerns that emerged after use, because most RCTs are not adequately powered to look for harm (safety).

Over-interpretation and spin is often used in reporting RCTs. Post hoc modification of the tools used to measure outcomes, for examples scales or questionnaires, may be used to manipulate results. Subgroup analysis may be done to show beneficial effects. Conclusions may not reflect the data presented in the paper. In addition, non-publication

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of negative findings and duplicate publication of positive results can bias the evidence base. It has been shown that industry-sponsored clinical trial results are more likely than investigator-initiated clinical trials to show beneficial results.

It is useful to be aware of these pitfalls when we read the results of RCTs and systematic reviews.