

## Letter to the Editor

### Editöre Mektup

#### Which is the best evidence for a cardiac surgeon: controlled randomized trial or database analysis?

*Bir kalp cerrahisi için en iyi bilimsel kanıt hangisidir: Kontrollü randomize çalışma mı, yoksa veritabanı analizi mi?*

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A randomized controlled trial (RCT) is basically an experiment in which investigators randomly assign eligible subjects into groups to receive or not receive one or more interventions that are being compared. Randomized controlled trials are known to be the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome and for assessing the cost-effectiveness of a treatment.<sup>[1]</sup> The 'consolidated standards of reporting trials' (CONSORT) statement was released in 1996 to improve the quality of reports of RCTs<sup>[2]</sup> and prominent medical associations and journals have endorsed it. It is a research tool consisting of a checklist and flow diagram for 21 different items (methods, objective, outcome, sample size, blinding, etc.) regarding the structure of an RCT. These 21 items are the essentials of an RCT to obtain an honest and scientific answer to a specific question.

We mainly encounter studies of small samples with mostly composite and surrogate outcomes in RCTs in the cardiac literature. They also have inadequate blinding in most cases. It is obvious that randomization, blinding, and standardization of the intervention are not easy in surgical procedures, but still these trials will be poorly reported by CONSORT standards and it is not possible to accept a generalized scientific cause-effect relation with these studies.

In a study of Anyanwu and Treasure, 119 RCTs from the most prominent cardiothoracic journals were exam-

ined in one-year period.<sup>[3]</sup> The median trial size was 50 patients, 45% of the trials included less than 20 patients, and the mean number of CONSORT criteria that were fulfilled was only eight. They concluded that many RCTs in surgery, on the grounds of their design, sample size, and insufficient power, were incapable of answering the questions that were addressed. Any cardiac surgeon would possibly agree on that the situation would not differ in examination of any other journal in cardiac surgery. In another report of the same authors, 169 articles (of which 29 were RCT only) were examined and the mortality reported was found to be unrealistic when compared with the national registries that reflected the 'real world'.<sup>[4]</sup> The common idea of both articles is that more realistic results can be derived from large databases, especially if you are dealing with cardiac surgery.

There are many large regional, national or international databases still running in different fields in cardiac surgery. The results derived from the analyses of these databases are highly respected and routes the attempts for improving the quality of health care.

In conclusion, we have to develop and improve national databases in all specific subgroups of cardiovascular surgical fields, integrate them with the international databases and construct risk models. On the other hand, the editors should encourage the authors to improve the quality of RCTs. We must keep in mind that RCTs may not apply to all surgical questions but sufficient answers can be derived from large database analyses and this may be more reliable and safe in routing our clinical practice. We do not randomize or exclude our patients in the real world, do we?

### REFERENCES

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