

INVITED COMMENTARY

## DOA: A New Paradigm of the Level of Proof or a Simple Complementary Tool?

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At present, the methodologies applied in clinical research are based on therapeutic trials carried out for diagnostic, therapeutic, or prognostic purposes. Indeed, randomised trials and meta-analyses of randomised trials are the foundation of evidence based medicine.

However, in a given population, observations in everyday practice may differ, and most of the time RCTs ignore sub-groups that are rarely identified or poorly represented (elderly people, pregnant women). Moreover, in RCTs, statistical significance is not always predictive of a practice and a holistic patient centered approach has been gaining increased acceptance, thereby avoiding marginalisation of a specific effect, especially concerning polyopathologies and comorbidities.

The discord outcome analysis (DOA) described by Kalodiki et al.<sup>1</sup> in this issue of the journal is a benchmarking technique, primarily a Venn diagram,<sup>2</sup> that can complement standard statistics. In this respect, the idea of conditional probabilities is of undeniable interest.

For the record, the set theoretic representation attributed to John Venn<sup>2</sup> was inspired well before by the work of Euler. It provides a visual proposition for abstract data structures.

This method is based on visual representation of sets and their intersections. One set characterises one variable and their intersections the overlapping variables of another set. This technique has some limitations insofar as it is appropriate for only two or three sets. Furthermore, in the context of clinical research it gives no information on set size or cardinality.

The authors have reported 24% of discord outcomes in the EVLA group and 41% in the UGFS group. In other words, improvement in one domain is countered by deterioration in another.

Strictly speaking, DOA is not a method in its own right but rather, as stated in the article, “a reporting standard for comparative analyses”: a count. Considering the way it is applied by the authors, the reader will find it interesting to note that the DOA determines patterns and trends of improvement or deterioration by comparing the change in post-treatment score with regard to the pre-treatment score on the basis of defined criteria (AVVQ, VCSS, VFI).

Although the paper published by Kalodiki et al.<sup>1</sup> presents some reading difficulties for a vascular surgeon, implementation of this new technique may improve decision making processes and contribute to a rethinking of our paradigm for randomised studies.<sup>3</sup> The informational input of Venn diagrams should consequently be considered as a complementary tool to be interpreted with caution and within a clearly identified statistical methodology. At present, whether DOA will lead to a better understanding of RCTs remains uncertain, as does the role it will ultimately assume as a reporting standard for comparative analyses.

### REFERENCES

- 1 Kalodiki E, Azzam M, Schnatterbeck P, Geroulakos P, Lattimer CR. The discord outcome analysis (DOA) as a reporting standard at 3 months and 5 years in randomized varicose vein treatment trials. *Eur J Vasc Endovasc Surg* 2019;57:267–74.
- 2 Venn J. On the diagrammatic and mechanical representation of propositions and reasonings. *Phil Mag Ser 5* 1880;9:59. Retrieved October 12 2018 from <https://www.tandfonline.com/doi/abs/10.1080/14786448008626877>.
- 3 Maisonneuve H, Babany G. Real-world data and clinical research: the complement data from randomized trials. *La Presse Médicale* 2015;44:586–9.

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