EDITORIAL

The 2018 ESC/EACTS guidelines for myocardial revascularization: a poisoned chalice? A mandatory major revision is now on the way

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The "clinical guidelines" entail all available information at the time of writing, concerning a given specific topic. This document can be used in order to make easier, the decision-making process regarding a given patient having a specific pathological condition. This is an extremely demanding process by several multidisciplinary teams working on different areas step by step, looking for the highest quality standards. This is the final aim for the clinical guidelines and is the true standardization of the decision-making process, as far as possible. Theoretically, the more we follow these guidelines, the more we can avert any large errors. We should recognize all involved, for the tremendous effort which has been put into this guidance.

Nevertheless, when it comes to pass in the real world by taking some clinical decisions, this is a totally different kettle of fish. Several deeply unsettling situations and misleading, confusing facts come to light. Why? There is not a simple compelling answer for such a complex situation. On one hand, the available data do not match with the real data and facts coming from a particular working group, Society or Association, other than Europe, US or Canada. On the other hand, there is an ever-growing concern about the external validity or the cleanness of the trials design. At this point, the problem has escalated to such a great magnitude, that the 2018 ESC/EACTS guidelines for myocardial revascularization have had to be revisited once again [1].

The scandal with the Excel trial has been the tip of the iceberg. Recent findings have shown that there have been a large number of misleading and confusing facts around the Excel trial. The fact of changing the myocardial infarction definition from the 3rd UDMI for the SCAI definition once the trial was running forward, including (for the first time in this kind of trials, as a part of the primary composite endpoint) the peri-procedural MI (contrarily to what the authors in the NOBLE trial did), withdrawing the item repeat revascularization as a part of the primary composite endpoint, while adding the same into the secondary composite endpoint [2, 3, 4]. All of them are just some examples of the arbitrariness that we can find, when these trials are not analyzed in depth. Unfortunately, regarding the chapter of the left main coronary stenosis in the guidelines, the main support derives from the four A-lister trials, viz, Syntax, Precombat, Noble and Excel. Of course, from these facts, it cannot be longer maintained that these guidelines are strongly supported by reliable, hard data and information. The results from the 10-years Syntax trial concerning exclusively the "death for all causes", is another case for incomplete information released [5]. Taking for granted all these data, it does not pull the plow at all. It is more than evident that an external analysis by an independent committee is highly recommended, perhaps, just perhaps, for every single one of these aforementioned trials.

Assuming the guidelines are ready to be applied to the real-world, it begs the question about how feasible the functionality is in our special context. It is worthy to emphasize the fact, that the guidelines recommend the construction of databases by each specific Society or Association, so we can get a general overview about how possible it is the guidelines can be put into practice [1]. This is a well-known fact, that a big deal of decisions are made taking in mind the results reported for CABG or PCI in these big trials. As a way of example, the operative mortality for CABG, briefly speaking for stable angina, must be somewhere around less than 3%, as well as for PCI. This gold standard is so difficult to target in many parts of the planet, with results much higher, as a result of so many special and sui-generis situations. This is in such a way that, the vast majority of times, we are not playing by the same rules when considering CABG as a IA recommendation, while the surgical staff is reporting an operative mortality much higher than 3%, and PCI having less than 3% in the same classification.

In order to get a more realistic overview for each specific surgical group, or even each individual cardiac surgeon, I have previously proposed the calculation of the RAMR (risk-ad-

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justed mortality ratio). In this way, we can get a closer realistic sight about the operative mortality in real-life, adjusted specifically for any surgeon or surgical group [6]. Finally, the current situation leaves plenty to be desired. The Excel trial scandal could have been the late nail in the coffin, all of which has ended up with a lack of credibility.

The item of conflict of interests is another point of great concern in the construction of clinical guidelines [1]. It has been identified that at least one third of the authors and co-authors have some conflict of interest strongly linked to commercial interests related to the manufacture of stents [4,7]. In turn, in December 2019 the EACTS withdrew its support for the LMCS chapter into the 2018 ESC/EACTS guidelines for myocardial revascularization [7]. Finally, in October 2020, the ESC/EACTS announced the guidelines are to be revisited all over again [8].

We have to learn from this experience as producing wrong guidelines based on trials without transparency harms patients. In fact, we must highlight, in particular, the great sense of responsibility with which EACTS has acted in this regard seeking excellence, demanding transparency in the whole process at all times.

There is a considerable task of work to be done. However, when there is a lack or shortage of clarity, this is the way all things end up at the end of the day, as a blurry remnant in the mind, with no more substance than the aftertaste of candy floss.

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