How to overcome difficulties in the evaluation of best possible decision-making in redo-revascularization?

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This editorial refers to 'Predictors of revascularization method and long-term outcome of percutaneous coronary intervention or repeat coronary bypass surgery in patients with multivessel coronary disease and previous coronary bypass surgery'† by S.J. Brener et al., on page 413

The value of studies on coronary artery bypass grafting (CABG) vs. percutaneous coronary intervention (PCI) is predominantly influenced by three important aspects:

(i) Study design and statistical methodology are of crucial importance concerning validity and reliability of the obtained results.

(ii) CABG, PCI, and supportive medical therapy vary by time. The influence of such developments on the outcome is difficult to evaluate because of the limited number of patients and the lack of long-term experience.

(iii) The most intriguing problem in comparing treatment modalities for coronary artery disease (CAD), remains the variety of coronary status and patient characteristics. Neither a straightforward strategy for a precise description of the coronary status nor a sufficient characterization of the patient’s status is currently available.

Only few studies on different methods in the treatment of CAD fulfil the requirements necessary to generate new knowledge. According to the list given here, a most promising approach by Brener et al.,1 concerning the even more complex issue of repeat revascularization after CABG is discussed.

Study design and statistical methods

Randomized studies are called ‘gold standard’ for the development of guidelines. The definition of inclusion criteria and exclusion criteria offers the chance to achieve a ‘homogeneous’ patient group; the random distribution in different treatment arms allows a direct comparison of the results for the randomized group. In CAD, many randomized trials have been performed to compare PCI vs. CABG. Because of the obvious heterogeneity within the large group of CAD patients, the obtained results count only for 2.5–8% of the patients, as only such few patients fit the strict inclusion criteria. In clinical practice, the achieved results of randomized trials in CAD patients cover only a small minority. Nevertheless, the results are often extrapolated to the entire 100% of CAD patients.

More complex statistical methods (such as the parametric, time-adjusted hazard function, or propensity score matched analyses) allow the investigation of total patient cohorts. Although results of such studies are so far not accepted to represent first level of evidence, they are much more helpful for clinical decision-making.2,3

Procedural aspects

Completeness of revascularization

According to various studies, completeness of revascularization represents an important issue in clinical outcome after primary CABG and PCI.4,5 However, the lack of a precise definition and standardized documentation for completeness of revascularization appears as an important limitation for the comparison of different studies on PCI and/or CABG.

Appropriateness of current technology in retrospective studies

Most studies, even randomized trials are criticized being obsolete because of more recent developments in stenting technologies (drug-eluting stents, etc.). However, mid- and long-term results are not available and the present data do not meet scientific proof.6 Whether even the latest version of drug-eluting stents will resolve the remaining problem in the more systemic and not stenosis-related multivessel CAD needs to be evaluated in the coming years.

Similarly, CABG summarizes a variety of different approaches and includes new developments concerning intraoperative management (off-pump CABG, minimally invasive techniques), the use of different graft material and surgical grafting techniques. To obtain a conclusive answer about the most appropriate surgical strategy in the individual patient, further analyses including mid- and long-term outcome are necessary.7

Supportive medical therapy

Brener et al.,1 focus on another important issue in terms of long-term results after revascularization. Anti-platelet and statin therapy has become obviously very effective in the
prediction of early rapid progression of CAD. As the most recent strategies of good clinical practice will be used in both, PCI and CABG patients, the effects of these substances presumably influence the result in the same way.

Comparability of the subsets of patients

The meaning of redo-procedures in terms of risk stratification

Redo-strategies are so far rarely addressed when compared with the large number of still controversially discussed results concerning primary PCI vs. primary CABG in CAD. Currently, 3–7% of the CAD patients in cardiac surgery are undergoing redo-CABG.1

The very distinct differences between the cohorts and the large number of patients with redo-CABG compared with redo-PCI (two-third to one-third) in the study of Brener et al.,1 indicates a slight tendency of CABG being superior to PCI in terms of mid- and long-term survival as the redo-procedure after primary CABG. Patients with more diseased grafts, diabetes, and more jeopardized myocardium tend to undergo redo-CABG rather than PCI. About one-third of the patients undergoing PCI underwent left main stem PCI which means more than the group with identified left main lesions of at least 50%. The increasing aggressiveness concerning left main interventional procedures is a common finding even across European centres. The large number of patients in this group with patent left IMA to the LAD (62%) may be an explanation for this strategy. The higher number of patients with unstable angina in the group of patients with PCI refers to the question of patient selection. Despite the exclusion of patients with acute myocardial infarction, the urgency of procedure is another important variable, to take into account when procedural mortality is compared. The differences between the subsets are expressed by the enormous selectivity of propensity score matching. Hence, clinical decision-making is obviously not performed ‘at random’. This indicates the limited value of randomization for the complex cohort of patients with CAD, especially after primary CABG.

Anatomical appearance

Brener et al.1 stress on the fact, that the intention to perform either CABG or PCI is mainly driven by anatomical considerations. The limited information from even most modern imaging techniques is often either under- or over-estimation of the coronary status, especially in advanced multivessel CAD. The precise description and documentation of coronary status for scientific purposes is rather impossible, seen the wide variety of coronary anatomy including the dominance of left or right coronary artery, appearance of native calcification, linear sclerosis, diffuse or localized stenoses at proximal to distal parts of the coronary vessel and collateralization. In studies on some rough coronary disease patterns, multiple complex lesions turned out to be associated with an ~50% higher risk of major adverse events after PCI.8 Furthermore, in isolated high-grade lesions of the proximal LAD, 4-year results indicate a better clinical outcome (cardiac death, myocardial infarction, stroke, repeat target vessel revascularization, angina pectoris status, need for anti-anginal medication) for patients after off-pump CABG than after PCI.9 Abbott et al.10 found PCI in arteries that supply collaterals to be of higher risk concerning adjusted mortality and myocardial infarction at 1 year after PCI.

Is redo-CABG superior to PCI in patients after CABG?

The present study by Brener et al.1 does not conclusively answer the question in which patient PCI is superior to CABG. There is a trend towards a better functional status and survival for the redo-CABG group. For the most recent patient group, 5-year follow-up is incomplete. In contrast to many non-randomized studies comparing primary PCI vs. CABG, patients in the study of Brener et al.1 undergoing PCI for redo-revascularization were older when compared with the group of patients with redo-CABG. All other factors, such as a higher likelihood of two-vessel disease, unstable angina, a patent left mammary artery to the left anterior descending artery, fewer chronic obstructions, a higher incidence of women, a closer time elapse to first CABG, and a higher ejection fraction are similar to non-randomized comparisons between primary CABG and PCI. More detailed subgroup analyses bear the risk of misconduct by small treatment arms. Therefore, the chosen calculation and presentation of results on patient cohorts can be used as an example and represents an important benchmark for further analyses.

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References