CABG versus PCI—‘evidence’ and ‘practice’ not the flip side!

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Almost a year of hard work, half perspiration and the rest inspiration of the Guest Editor, Prof. David Taggart and here we are with the special issue on ‘Surgical Myocardial Revascularisation’. This issue was mooted as coronary artery bypass grafting (CABG) surgery has not been given a fair deal and the volumes have been dwindling. Newer techniques and advances are not being highlighted and not adequate stress has been paid on total arterial revascularisation (TAR). More literature on CABG seems to have emanated from cardiology journals than surgical. No wonder then, that it is more often than not skewed, if not blatantly biased. Whenever percutaneous coronary intervention (PCI) is compared with CABG, it is the best of stents, in the best of hands, in high-volume centres, under the rigours of a trial setting, versus, by default, a ‘run of the mill’ left internal mammary artery-left anterior descending (LIMA-LAD) and balance saphenous vein revascularisation, which we all know is an archaic sub-optimum surgery. PCI should be compared to TAR, and the latter should in fact become a quality metrics for myocardial revascularisation. Further, the trial should not be abbreviated, but allowed to run through a period sufficient to allow events, which should be cardio-specific and meaningful such as survival, to unfold. Therefore, even guidelines, which are based on these trials, do not guide us, and though they may look balanced in ‘letter’, but certainly are not well intended in ‘spirit’. This featured issue thus attempts to present what an ideal CABG operation should and could be, if we stuck to the right tenets and principles of surgical myocardial revascularisation. That is the only way, of leading from the front, that the lost glory of CABG can be restored, and PCI challenged, and if not stopped, at least fathomed in its tracks. PCI certainly has a salutary complementary role to CABG, and that is where it should be, in the pecking order of myocardial revascularisation.

I am reminded of an anecdote recounted by late Dewang Mehta, the debonair chief of the National Association of Software and Service Companies, NASSCOM, in a personal interlude. A school inspector asked a class II student, ‘How much do 2 and 2 add up to’? Pat came the reply—‘Four Sir’. The same question to a college mathematics professor, and he took his calculator out and then gave the answer—‘Four Sir’, but when addressed to a statistician, the answer was—‘How much do you want it to be Sir’! And it is not through any act of jugglery or maveric mysticism, but sheerly through well-established scientific norms of ‘Grouping’ that a desired result can be obtained. I recall Dewang almost 30 years after his untimely death, reading an editorial in the European Journal of Cardiothoracic Surgery by Freemantle et al. on ‘Pooling and Sub-grouping of Dataa call to circumspection’ [1]. In the current era of evidence-based medicine, evidence can be generated, and in fact manufactured, on demand, by manipulation of data in such a way that just as it can be justified on scientific and technical grounds; it is diligently and deliberately laid out and analysed in a manner to produce a desired result. It is no brainer; the result is what suits the sponsor of the trial or the corporate world. Generically speaking, tongue in cheek, PCI versus CABG trials reek of this aberration.

The way the problem is addressed or the scientific enquiry framed, by design or default, may influence the end results. The researcher may pose only such questions which are likely to give the results that suit them. A prime example is the study by Windecker et al., comprising of trials of PCI or CABG [2]. They included 93,553 patients from 100 randomised controlled trials (RCTs) in a network meta-analysis which compared PCI with alternative forms of therapies. ‘Curiously, despite the choice of treatment to be most likely between two interventional strategies, the authors chose to describe the differences between intervention and medical therapy and did not report the difference between PCI and CABG’ [1].

Coronary artery disease (CAD), in any health care disposition the world over, enjoys the status of cash cow and no therapy has undergone such extensive scientific scrutiny as

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the one for CAD, be it PCI or CABG surgery. Unfortunately, most PCI trials have a limited follow-up and inform decision-making based on early- and mid-term outcomes only. Further, as pointed out in the study by Freemantle et al. [1], most if not all, RCTs, comparing PCI with CABG that have shown non-inferiority of PCI, have looked at composite end-points and that too by pooling in data from multiple trials. Individual patient data is either not available, or even when available is not analysed. It therefore becomes pertinent, and in fact paramount, to note that a landmark study, an individual patient-level meta-analysis [3] of 11 trials including 11,518 patients comparing PCI with CABG, has clearly shown that PCI was associated with 20% higher mortality (95% CI 6–37%; $p = 0.004$). This practice informing information unfortunately is unlikely to be reflected in ‘Practice Guidelines’.

This thus behooves us to reconsider as to how we write our guidelines and the metrics on which our recommendations are based. In fact, instead of composite primary end-points of death/MI/CVA/re-hospitalisation, one should exclusively look at cardiovascular death, where it has been conclusively shown that PCI has a higher cardiovascular mortality than CABG across the entire spectrum of Syntax Scores and that CABG should be the gold standard [4].

A perpetual tricky issue, a keen reader of any scientific literature must grapple with is, whether it is a true or a chance occurrence? The outcomes defined should be such that they occur in a sufficient number to offset the ‘chance effect’ and the test for interaction, a statistical tool to differentiate between true and chance occurrence of an event in a sub-group, should be reported for each trial and should be sufficiently powered to lend authenticity. However, ‘within individual trials, such interaction tests are notoriously under powered’ [1]. Quoting the famous study of Richard Peto et al., Freemantle et al. [1] very succinctly surmise, ‘In that classic analysis, Peto et al. noted that patients with a star sign of Gemini or Libra appeared to experience increased mortality when taking Aspirin, but that a strong benefit was associated with Aspirin for other star signs. Certainly, no body believes that star sign affects the action of Aspirin, and the test for interaction was non-significant, but this example provides a timely reminder that we must combine statistical rigour not only with biological plausibility but also with prospective definition of end-points to separate true sub-group effects from the chance phenomenon’.

Is Syntax Score the holy grail?

Based on the Syntax Trial, a score was formulated with a lot of fanfare, but with very tenuous data supporting its use. Syntax Score became a sine qua non of decision-making between PCI

and CABG, with high Syntax Scores going in for CABG and lower ones for PCI. However, the study by Head et al. [3] found no significant interaction between the Syntax Scores and the end-point of mortality. In fact, no single trial in world literature has used Syntax Score as a prospectively declared primary or secondary outcome [1]. Therefore, it is subjudice whether Syntax Score should guide us in decision-making and should not all patients with multi vessel disease and left main stenosis, with huge amount of myocardium in jeopardy, be subjected preferably to CABG over PCI? Besides coronary anatomy, associated comorbidities like diabetes mellitus, nephropathy, left ventricular dysfunction, hypothyroidism and rheumatoid arthritis too should tilt the balance towards CABG, as also exemplified by the Syntax Score II and Clinical/Functional Syntax Scores.

All available guidelines accord I (B) level of recommendation to the Heart-Team concept. However, how should certain imponderables which actually define the Heart-Team, such as the experience and competence level of an individual surgeon, institutional facilities available, patient preferences, economic considerations and patient’s psychological makeup, be measured and accounted? These are elements of decision-making which generally do not get factored into any level of analysis, no matter the degree of diligence or sincerity, with which the analysis is carried out.

Is it end of the tunnel for CABG?

A doomsday thought that seems to be haunting the trainees and our junior colleagues. Those sounding the death knell for CABG alone seem to be living in a fool’s paradise. Fizzle out and go out into oblivion shall CABG, but not alone! It is the entire spectrum of myocardial revascularisation—be it CABG or PCI, that will fade, when a totally correctable metabolic, cellular or genetic basis to CAD is discovered, and make the posterity marvel at our repose to such sub-optimum responses to this malady, When? May be 20 ... 3050 yearsbut happen it shall.

Until we bid adieu to CAD, and I hope and pray it is sooner than later, we have to make the best of what we have. However, one thing for sure, one cannot implement medicine based just on the trials and guidelines—the so-called evidence-based medicine. One can at best be guided and informed by the guidelines, but the final decision obviously has to be borne out of a combination of the ‘Head’ and the ‘Heart’, a kind of holistic solution to a problem presented to an individual clinician. These decisions have to be organic, with the patient and the treating doctor amalgamating into one integral being or a unit, and every decision must, by default, beget a question—what if it were me?

Food for thought and happy browsing!

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