IACTS position statement on “2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization”: section 7.1—a consensus document

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Abstract

American College of Cardiology (ACC), American Heart Association (AHA) and Society for Cardiovascular Angiography and Interventions (SCAI) recently released the Clinical Practice Guidelines for myocardial revascularization [1]. The guidelines were the felt need of the fraternity and this single all-encompassing document, relegating the previous six guidelines on the subject to archives, is indeed welcome. However, the downgrading of coronary artery bypass surgery for stable multivessel coronary artery disease and its bracketing with percutaneous coronary interventions has caused a lot of anguish in the surgical fraternity. This document presents the official viewpoint of the Indian Association of Cardiovascular and Thoracic Surgeons on the matter.

Keywords 2021 ACC/AHA guideline on coronary artery revascularisation · Clinical practice guidelines · Myocardial revascularisation · Stable ischemic heart disease · CABG · STS/AATS/LACES/EACTS/ESC/IACTS

The Indian Association of Cardiovascular and Thoracic Surgeons (IACTS) appreciates the herculean task that the guideline writing committee has undertaken to compile this well-presented document with a focus on clinical decision-making with a patient-centric attitude. The avant-garde call to equitable healthcare is notable. In a developing country like India, the healthcare disparities due to gender, economics, geographies, beliefs, and cultures can be multifarious and hence the sensitization to these issues is very topical and timely. Hope the regulatory and governmental authorities globally would take note and be

suitably egged on to take appropriate and swift actions to address them. The standalone modular “knowledge chunk” presentation with hyperlinked references too is a welcome change and makes it for an easy reading and cross-referencing. All this sure must have taken a huge effort—kudos to all involved.

We also acknowledge the advances in pharmacotherapy, from antianginals to disease-modifying drugs, and appreciate medical treatment being given its rightful place in the management of coronary atherosclerosis in the current guidelines. Just when the audience should stand suitably sensitized to the utility and validity of guideline-directed medical treatment (GDMT) in the overall management of coronary artery disease (CAD), *pari-passu*, they must also realize that the quality of coronary artery bypass graft (CABG) surgery has also improved over the last 2 decades. There is universal adoption of at least one internal mammary artery (IMA) use, besides increasing traction to multiple arterial grafts. Myocardial protection techniques too have evolved, and the use of off-pump and an-aortic techniques reduce the incidence of stroke. Therefore, the entire fraternity of IACTS laments that this elevation of the medical therapy has come at the cost of a well-researched and time-tested modality of treatment in the form of CABG surgery. We strongly believe that the two, viz. medical treatment and CABG, could have blossomed together in the guidelines to the ultimate benefit of the patients and the society.

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However, the guidelines have done a great disservice to the surgical fraternity while formalizing the management options in stable ischemic heart disease (SIHD). The guidelines have awarded a class IIb B-R recommendation (a downgrade from class I) to CABG in SIHD for patients with triple vessel CAD with normal left ventricular (LV) function, irrespective of the proximal left anterior descending (LAD) artery involvement, and for standalone significant proximal LAD stenosis [1]. The current guideline also downgrades CABG from class I to from class IIa in stable 3-vessel disease with LV ejection fraction (LVEF) 35 to 50% (mild to moderate LV dysfunction). These recommendations are at odds with 2018 ESC/EACTS (European Society of Cardiology/European Association of Cardiothoracic Surgery) Guidelines on myocardial revascularization [2], which accord a class I recommendation to CABG for 3 vessel CAD, and 1 or 2 vessel CAD with proximal LAD stenosis. This drew a sharp reaction from EACTS, “Chapter 7.1 arbitrarily downgraded coronary artery bypass grafting..... EACTS does not support the conclusions of Chapter 7.1.....” [3]. The Society of Thoracic Surgery (STS) and the American Association of Thoracic Surgery (AATS) too did not endorse the guidelines and have represented against them [4]. The Latin-American Association of Cardiac and Endovascular Surgery (LACES) has also written an open letter opposing these guidelines [5].

This beckons a fundamental question—is the evidence to downgrade the recommendations for CABG in multivessel and proximal LAD in stable CAD robust enough? To address the matter, IACTS constituted a committee of this authorship, and to democratize our response, we sought views from the entire membership of IACTS, through an electronic note. The consensus thus built is being presented in this “Position Statement” document.

We feel the guideline writing committee, hereinafter referred to as “authors” for brevity, made serious fundamental and pithy errors on 3 fronts:

- i. Over-reliance on ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) Trial [6];
- ii. Equating and clubbing CABG and Percutaneous Coronary Intervention (PCI) under “Revascularization”; and
- iii. Unqualified generic use of the term “Multivessel CAD.”

Grant us to dig deep and delve into each.

Is ISCHEMIA trial the “Holy Grail”?

Using the ISCHEMIA trial to provide an evidence base for a cohort of triple vessel CAD and proximal LAD lesions was, from the outset, fraught with risks, since only 39.6% of the

trial patients had triple-vessel disease and only 36% had proximal LAD lesions [6]. The ISCHEMIA trial, launched in 2012, was structured to assess the efficacy of the “initial” approach (Conservative versus Intervention) for the management of CAD. It had a host of issues with its conduct—reduction of sample size from 8000 to 5179 leading to reduction of the power of the study; lower event rates than expected; enrolment of patients with less than moderate ischemia (14%); etc. Moreover, 6 years into the trial in 2018, the primary end-points were reconstituted to include resuscitated cardiac arrest, hospitalization for unstable angina, and hospitalization for heart failure, and there was no sensitivity analysis for completeness and type of revascularization. Further, it was neither designed, nor powered, to determine whether CABG improved survival. The authors also ran the risk of learning excessively from a non-blinded trial. Forty percent of the enrolled patients were not randomized at all, and there was a significant cross-over between the two groups. More patients in the conservative group received invasive therapy, than in the invasive group who received CABG as the preferred revascularization strategy. Not to be missed, despite all the touted benefits of GDMT, only 40% of patients achieved pre-specified target goals with medical therapy. Another confounder, the limited median follow-up of 3.2 years, can at best be labeled short-term. The benefits of CABG become evident in the longer term as shown in the EXCEL (XIENCE versus Coronary Artery Bypass Surgery for effectiveness of Left Main Revascularisation) [7], NOBLE (Nordic–Baltic–British Left Main Revascularisation Study) [8], and FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) follow-on [9] trials and the survival curve diverges in favor of CABG only beyond 5 years [10]. Even in the Surgical Treatment for Ischemic Heart Failure (STICH) trial, the apparent equivalence of the medical and surgical arms at 5 years yielded to the increased efficacy of the CABG arm at 10 years [11]. In the ISCHEMIA trial, the time to event curves for the primary end-point for the treatment arms crossed even earlier at 2 years, and continue to diverge in favor of the revascularization arm at 3.2 years [6]. Notwithstanding the supra, the pre-eminence given to the trial in the index guidelines was not entirely unexpected, as this was the only randomized controlled trial (RCT) in this domain between 2018 and 2021.

In a trial with more than 40% diabetics with multivessel CAD, CABG was grossly under-utilized—only 26% of all revascularizations [6]. “The impact of CABG on survival cannot be ascertained from trials in which the majority of revascularization procedures performed were PCI and not CABG, such as ISCHEMIA” [4]. Given the incontrovertible evidence favoring CABG in diabetics in the likes of FREEDOM [9] and SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) trials [12],

which are too fundamental to our practice to be ignored, overdependence on short-term data of ISCHEMIA trial, with a limited perspective, was rather injudicious and resulted in the presumptuous and far-reaching conclusions of downgrading coronary revascularization, especially CABG, for survival benefits. It would have been both prudent and sagacious of the authors to have waited for the results of the CABG sub-group analysis of the ISCHEMIA trial, which is yet to be published, before reaching this conclusion.

Moving askew from the ISCHEMIA trial, rather flummoxing, a meta-analysis by Windecker et al. quoted in support of the downgrade actually supports the role of CABG in SIHD. This included 93,553 randomized patients with 262,090 patient-years of follow-up in 100 trials, and showed that compared to a strategy of initial medical treatment, CABG reduced all-cause mortality by 20% (rate ratio 0.80, 95% credibility interval 0.70 to 0.91) and had an even greater protective effect against myocardial infarction (MI) (rate ratio—0.79; credibility interval—0.63 to 0.99). In verbatim, the study unequivocally concluded, “Among patients with stable coronary artery disease, coronary artery bypass grafting reduces the risk of death, myocardial infarction, and subsequent revascularization compared with medical treatment” [13].

Several RCTs comparing GDMT with revascularization, and used as evidence base for supporting the downgrade, like Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) [14], Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) [15], and Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 (FAME-2) [16] trials had several limitations. They enrolled patients with only mild amount of inducible ischemia and were therefore not in the mold of an archetypical surgical patient. In addition, the trials were not blind, and the patients were enrolled only after the results of coronary angiography were known. This raised the possibility that SIHD patients with more extensive and severe disease may have been excluded from trial participation due to selection bias. Notwithstanding the limitations, the BARI 2D trial [15] did not find any difference in the PCI stratum as compared to optimum medical treatment (OMT) in all-cause death, cardiac death, or MI. In contrast, prompt CABG with an OMT was superior to OMT alone in patients with more severe and extensive CAD to prevent non-procedural MIs that are associated with increased cardiac mortality risk, thereby providing a survival advantage to CABG over OMT. However, the guidelines do not seem to consider that the objective of “revascularization” is not mere “survival,” but “event-free survival,” which should be the overarching guiding principle for evaluating any form of therapy. Undisputable increased repeat revascularization with PCI, and its consequences on both physical and financial health of an individual, can thus not be brushed under the carpet.

Even downgrading of CABG in moderate LV dysfunction from class I to class IIa is inexplicable. Indeed, most of the evidence of improved survival for CABG with LV dysfunction comes from earlier studies like coronary artery surgery study (CASS) [17], and Veterans Administration Coronary Artery Bypass Surgery Cooperative study (VACOOP) [18]. But is there any current evidence to the contrary? In the absence of new evidence showing lack of survival advantage for CABG in multivessel disease with moderate LV dysfunction, the reason for the downgrade of CABG was unclear, and probably unfair.

Lastly, if penchant for new evidence was the overarching guiding principle of the guidelines, then the “newest of the new” data came just last month, presumably after the guidelines had been framed. This meta-analysis of 25 trials involving 19,806 patients provided 4 important conclusions—firstly, elective coronary “revascularization” reduced cardiac mortality compared with medical therapy alone (relative risk (RR) 0.79 (0.67–0.93), $p < 0.01$); secondly, it reduced spontaneous MIs (RR 0.74 (0.64–0.86), $p < 0.01$); thirdly, the survival benefit increased over time (RR per 4-year follow-up: 0.81 (0.69–0.96), $p=0.008$); and lastly, the cardiac survival benefit with revascularization was more pronounced in studies with multivessel disease ($p=0.004$) [19]. Would then the ACC/AHA issue an update, revising its guidelines, and be guided by its own avowed principle, “To ensure that guideline recommendations remain current, new data will be reviewed on an ongoing basis by the writing committee and staff. Going forward, targeted sections or knowledge chunks will be revised dynamically after publication and timely peer review of potentially practice-changing science” [6]?

Can “revascularization” be used as a surrogate for “CABG”?

The accumulated wisdom over the years, scientifically documented and peer reviewed [10, 20–24], was unceremoniously dismissed as outdated and antiquated under the euphemism of being “>20 to 40 years ago” and pitted against “new evidence” from the ISCHEMIA trial [6] and a few other studies [19, 25–28]. However, the downgrade seems to be supported not so much by “new evidence,” but by a facetious “new definition” for “revascularization,” that included both CABG and PCI [6, 13, 25–27].

PCI and CABG have been erroneously used as equivalent and inter-changeable methods of coronary revascularization, even though they are fundamentally distinct in their premise and logical basis and the ways they address flow restitution in the compromised coronary circulation and have vastly different long-term outcomes. Even ratiocination dictates that just when PCI treats only the flow-limiting lesion, CABG creates a surgical collateral distal to the entire atherosclerosis-prone

proximal segment of the coronary tree, thereby according protection from future coronary events, as most infarcts are generated by non-flow-limiting lesions. Putting them together as “revascularization” is as unscientific, as putting apples and oranges together and outlandishly creating “Apps-oranges”!

Placing PCI at par with CABG is in contradiction to the evidence emanating from more robust studies like the SYNTAX trial (40% higher mortality in triple-vessel disease with PCI compared to CABG and superiority of latter over PCI in decreasing re-interventions and post-procedural MIs) [12] and FAME-3 (Fractional Flow Reserve versus Angiography for Multivessel Evaluation-3) trial, where 50% better freedom from death, MI, repeat revascularization, or stroke (hazard ratio, 1.5; 95% confidence interval, 1.1 to 2.2) was observed in the patients randomized to CABG versus Fractional Flow Reserve (FFR) guided PCI [29]. Similar sentiments were echoed in the EXCEL trial [7] and well espoused in the STS retort to the ACC/AHA guidelines, “If CABG did not improve survival over Medical Treatment (MT), how would one explain the survival benefits of CABG over PCI in the EXCEL trial, without suggesting that PCI causes harm compared to MT?” [4].

The authors have not quoted a single adequately powered randomized study that has compared CABG alone, and not CABG and PCI bundled together, with standalone medical management, with a sufficiently long follow-up. The meta-analysis by Bangalore et al., which has been used as a supportive document, included 14 RCTs with 14,877 patients, with a mean follow-up of 4.5 years. However, 5 of those 14 studies did not have a single patient undergoing CABG and the number of patients in the revascularization arm who got a CABG was 16.2%. Besides, the study concluded that “revascularization” led to reduced risk of nonprocedural MI and the authors recommended a longer follow-up of trials to assess if this led to improved long-term survival [25]. Keeping in tango with the same ethos of clubbing PCI and CABG, guidelines have cited another recent meta-analysis by Laukkanen et al., consisting of 12 RCTs comparing “revascularization” with medical management alone, albeit 9 of them not recruiting a single patient undergoing CABG! Lest this gets missed, it has to be re-iterated that 75% of the studies included in this meta-analysis did not include patients undergoing CABG, yet the authors provide this as evidence to downgrade the recommendation for CABG. In the remaining 3 trials (Medicine, Angioplasty, or Surgery Study—MASS II, BARI 2D, and ISCHEMIA), the percentage of patients undergoing CABG in the “revascularization” arm ranged between 26 and 33%. Overall, in the revascularization arm, only 15% of patients underwent CABG. Hence, this meta-analysis was essentially a comparison of PCI plus medical therapy versus medical therapy [27]. Despite running the risk of sounding repetitive, it has to be highlighted that yet another meta-analysis

quoted by the authors provides the same picture—4 out of 7 RCTs did not have a single patient undergoing CABG [26]. Thus, with only a minority of patients receiving CABG, and the majority getting PCI, it is only logical to conclude that the primary driver for outcomes in the revascularization group was PCI.

In fact, there are internal contradictions in the index document in what it professes and what it preaches. Under “Top Ten Take Home Messages,” the 4th message reads, “Updated evidence from contemporary trials supplement older evidence with regard to mortality benefit of revascularization in patients with stable ischemic heart disease, normal left ventricular ejection fraction, and triple-vessel coronary artery disease. Surgical revascularization may be reasonable to improve survival. A survival benefit with percutaneous revascularization is uncertain.....” [1]. This flies in the face of logic used for downgrading CABG and bracketing it with PCI. If there is a “mortality benefit” of revascularization, and the survival benefit of PCI (one of the 2 components of revascularization) is uncertain, gumption dictates that “survival benefit” of CABG (the other component) has to be certain—Q.E.D. (Quod Erat Demonstrandum).

Using “revascularization” as an overarching term for both procedures is scientifically inaccurate and can be considered to be erroneous at best, and misleading and irresponsible at worst. CABG should not be construed as a mere technique of “coronary revascularization,” in the same sense as PCI, but is in fact a technique of “myocardial protection,” thereby providing a mechanistic basis for improved survival with CABG [30]. Moreover, use of left IMA, in addition to superior patency, is associated with a lesser degree of downstream distal vessel disease progression as compared with PCI. This results in the increased event-free long-term survival in patients treated with CABG as compared to those treated with PCI in complex multivessel CAD [31–33]. No wonder then, 77% of trials suggest a better survival with CABG compared with PCI [30].

Multivessel CAD versus amount of myocardium in jeopardy

Using the generic term “multivessel disease” muddies the waters further, as a juxta-left main proximal LAD, circumflex and an ostial right coronary artery (RCA) “multivessel disease” is an altogether different ball game from a triple-vessel disease with distal involvement of the coronary tree, after major branches have taken off. We do agree that in the latter group, class IIb indication for survival for CABG may have been justified, but certainly not when proximal segments of the coronary tree are involved. Therefore, the amount of myocardium in jeopardy should have been factored in decision-making in patients with SIHD with multivessel CAD. Even though the myocardial jeopardy scores may be cumbersome

to calculate for a practicing cardiac surgeon, at least a sense should have been provided of a large amount of myocardium in jeopardy getting survival benefit with CABG and should have been awarded a class I recommendation.

Proximal LAD

Proximal LAD, through its subservience of a large amount of myocardium, has always held a prima-donna presence in weightage for decision-making for myocardial revascularization, almost at par with left main lesions. It was therefore not without a reason that CABG was awarded a class I recommendation in 2-vessel disease with proximal LAD stenosis of >70% in the earlier guidelines. In single-vessel disease with proximal LAD stenosis, the indication was class IIa, which got upgraded to class I if extensive ischemia was documented [34]. This recommendation was supported by subsequent updates in 2004 and 2011 [35, 36]. These recommendations were also upheld in the 2012 guidelines that were written specifically for the “Diagnosis and Management of Patients with Stable Ischemic Heart Disease” and re-affirmed in the 2014 focused update [37, 38]. In the 2017 update, while CABG remained a class I recommendation for 2-vessel disease with proximal LAD lesions, the single-vessel disease was reclassified differently. Proximal LAD lesion was clubbed with proximal circumflex lesions and depending on the outcomes of stress-testing, a complex algorithm was provided to choose between PCI and CABG [39]. However, the 2014 ESC/EACTS guidelines awarded an unequivocal class I recommendation to CABG in patients with proximal LAD lesions greater than 50%, irrespective of the number of vessels involved, and upheld this recommendation in 2018, based on evidence suggesting prognostic benefit [40, 41]. Notwithstanding the above, the 2021 ACC/AHA/SCAI guidelines have downgraded the recommendation for CABG in proximal LAD lesions with normal LV function from class I to class IIb [1].

To overturn the strong evidence-based recommendations made over the last 2 decades, by several independent committees that examined the role of CABG in proximal LAD lesions, one would expect some overwhelming evidence to the contrary. However, what has been provided can be summed up as questionable and irrelevant, to the least. The only study in the last 10 years, the ISCHEMIA trial [6], should never have been used as an evidence base for proximal LAD lesions, because 63.8% (2 out of 3 patients) in the study did not have a proximal LAD lesion. Almost one in four (23.5%) patients did not even have an LAD lesion! Moreover, myocardial revascularization was achieved using PCI in as many as 74.2% of the patients in the invasive arm. These facts, only become apparent on scouring the supplementary files and disqualify the ISCHEMIA trial as an evidence base for CABG in proximal LAD lesions.

On the flip side, current guidelines have, for reasons inexplicable, chosen to ignore some of the most compelling data that exists in the literature regarding the role of CABG in proximal LAD lesions. In a patient-level robust meta-analysis of RCTs, Yusuf et al. demonstrated improved survival of CABG in not only multivessel CAD, but also in those with single- or double-vessel CAD involving significant proximal LAD stenosis [10]. In the Duke single-center study, 18,481 patients with significant CAD (>75% stenosis) underwent PCI, CABG, or medical management alone. Revascularization with PCI or CABG provided a significant survival advantage compared with medical management alone, even in single-vessel disease. Moreover, CABG was found to have better survival compared to PCI in patients with high severity of CAD [22]. Another study that reviewed the New York registry data concluded that in patients with proximal LAD stenosis of at least 70%, survival with CABG was superior to PCI, irrespective of the number of coronary vessels diseased [42]. The downgrade even flies in the face of their averment in Section 7.1.8—“A clinical principle from several studies is that the more myocardium is at risk, the greater is the survival advantage of revascularization over medical therapy,.....” [1], and proximal LAD certainly subtends to a critical mass of myocardium. Therefore, the downgrading of class of recommendation for CABG in the presence of proximal LAD lesions is not based on any credible evidence. We rest our case to the readers’ wisdom.

Some musings—multidisciplinary heart-team!

In the right ethos of the oft used terms in the index guideline—“collaborative,” “multidisciplinary heart-team,” “patient-centered care,” and “shared decision-making” [1]; equitable representation of surgeons, and for that matter, all the stakeholders, was of paramount importance to democratize the guidelines for wider acceptability, adoption, and compliance. This in quintessence seems to be conspicuous by its absence (24 cardiologists versus 9 surgeons in the drafting committee!). The AATS and STS were each allowed only one representative, with all other surgeons on the writing committee chosen by ACC/AHA. “It is unfathomable that guidelines on subjects key to the Heart Team, would include only one side of the Heart Team” [3]. This is likely to be detrimental to the health of the society, and the interests of the medical profession, alike.

Are these down-gradations only “framing issues,” as suggested by Kirtane and Grubb in their editorial in AHA’s official publication—*Circulation* [43]—for they are only for “survival” and CABG still is a class I recommendation for refractory symptoms and class IIa for improving outcomes? Even if we grant this flawed reasoning its unreasonable due, is not the messaging likely to be misconstrued by those not willing to read between the lines? Objective of “practice guidelines” should be to provide a direct construct, and not a convoluted

one. However, we endorse editorialists plea, “.....couching of specific recommendations based upon technical competence might have been more appropriate..... one solution for future refinement would be to add contingencies to specific recommendations such as ‘if performed by an experienced operator/surgeon’.....” [43].

Giving credence to the foregoing logic and hard science, the entire fraternity of the IACTS agrees to disagree on the hasty recommendations made by the framers of the 2021 ACC/AHA/SCAI Guidelines for Coronary Revascularization and take a strong exception to the skewed scientific evidence base used, the conclusions reached and the headlines generated. As a corollary, in all earnestness, we urge the ACC, AHA, and SCAI to revisit the sections of concern and it will be in the propriety of “Scientific behavior” to address the anomalies and amend the erratic sections of the impugned guidelines suitably, so that right practice prevails.

Until the matters are resolved, we exhort the clinicians, surgeons, and physicians alike, to use their clinical acumen and wisdom in the best interests of the patients they serve.

Conclusions

Hard evidence to downgrade the recommendation for CABG in the setting of SIHD, with multivessel disease or proximal LAD stenosis, with normal LV function is lacking, or is at best tenuous and obfuscated due to clubbing with PCI. Section 7.1 of the guidelines is likely to muddy the waters and confuse the readership, rather than enlighten and guide them. The downgrading of CABG, and placing PCI at the same class of recommendation, does not meet our interpretation of evidence and may lead to the disservice of our patient population. We earnestly beseech ACC, AHA, and SCAI to brood and cogitate over contentious issues and work towards resolving them amicably and swiftly.

May good sense prevail!

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Declarations

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