

## INVITED PERSPECTIVE

# STS/AATS-Endorsed Rebuttal to 2023 ACC/AHA Chronic Coronary Disease Guideline: A Missed Opportunity to Present Accurate and Comprehensive Revascularization Recommendations

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The recently published 2023 American College of Cardiology (ACC)/American Heart Association (AHA) Chronic Coronary Disease (CCD) Guideline<sup>1</sup> incorporates salient sections on many aspects of coronary artery disease (CAD). However, it falls short in addressing a number of important issues on coronary revascularization.<sup>1</sup>

We had hoped that the 2023 CCD Guideline would resolve the controversial recommendations plaguing the 2021 ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) Guideline for Coronary Artery Revascularization.<sup>2-7</sup> Unfortunately, this did not happen. Instead, it made recommendations on revascularization that, in our view, represent inexact and flawed adaptations of the 2021 Revascularization Guideline.

Not addressed by the 2023 CCD Guideline are the survival recommendations for coronary artery bypass grafting (CABG) vs medical therapy (MT) in patients with 3-vessel CAD and an ejection fraction (EF) >0.35.<sup>1</sup> The 2021 ACC/AHA/SCAI Guideline downgraded CABG from class I to class IIa in patients with moderate left ventricular dysfunction and to class IIb in patients with normal left ventricular function. These downgrades

are not based on randomized data or robust scientific facts and resulted in international criticism and disapproval.<sup>3-7</sup>

Recent publications have demonstrated a survival benefit for patients randomized to CABG over MT.<sup>3,8</sup> In addition, CABG has a significant survival advantage over percutaneous coronary intervention (PCI) in patients with complex 3-vessel CAD<sup>9,10</sup> regardless of left ventricular function. Both the 2021 and 2023 Guidelines recommend CABG over PCI.<sup>1,2</sup> Therefore, if CABG is better than PCI in prolonging survival, how can it be of questionable effectiveness (class IIb) compared with MT without implying that PCI is harmful? Such contradictions are a departure from the accuracy and clarity that are important pillars of the Institute of Medicine's *Guidelines We Can Trust*.<sup>12</sup>

In the synthesis of evidence for the 2021 Guideline, the Writing Committee gave more weight to some studies than others and made other studies irrelevant based on the date of publication.<sup>3-6</sup> In addition, several of the recommendations were in contradiction with the supporting evidence.<sup>4</sup>

A glaring misrepresentation in the 2021 and 2023 Guidelines is the misconception that in the

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International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) study, patients were randomized to either CABG or MT.<sup>13</sup> Not a single patient was randomized to CABG or MT in that study; specifically, patients were randomized to an initial invasive versus an initial conservative therapy. The randomization in ISCHEMIA, therefore, occurred upstream of the performance of coronary angiography, and consequently, all comparisons between revascularized and nonrevascularized patients are observational and strongly prone to confounding by indication. This represents a form of selection bias by which therapies are allocated (often appropriately) according to disease severity and prognosis.<sup>14</sup> The observation that patients who received CABG in the ISCHEMIA study fared as well as those with lesser angiographically severe CAD who did not receive it supports that the effects of CABG are both risk-neutralizing and natural-history altering; however, as pointed out, this correlation in the ISCHEMIA study remains entirely observational.

Another important tenet of evidence appraisal when comparing therapies is to evaluate how similar the study population is to the patient population who routinely receive the therapy being examined. The ISCHEMIA study patient population is not representative of patients who receive CABG today. Based on a recent Society of Thoracic Surgeons Adult Cardiac Surgery Database publication, a contemporary CABG population<sup>15</sup> includes patients who are more likely to be diabetic and 2 to 4 times more likely to have peripheral/cerebrovascular disease or heart failure than patients in the ISCHEMIA study.<sup>15</sup> In addition, only 36.2% of patients in the ISCHEMIA study had  $\geq 50\%$  proximal left anterior descending (LAD) lesions.<sup>15</sup> Despite this, the ISCHEMIA study was considered a cornerstone of the evidence by which the 2021 Guideline Writing Committee chose to downgrade CABG. Significant weighting of ISCHEMIA replaced meaningful, direct, and relevant evidence with extrapolated, indirect, and inappropriately applied information.<sup>16</sup> The 2023 CCD Guideline continued this misinterpretation of the ISCHEMIA study in formulating its recommendations and, by failing to adhere to the study's intended scope, overstretching its applicability.

MT for CAD has improved significantly over time. Still, initial MT should be distinguished from lifetime MT without intervention as evidenced by the significant crossover rate (21% over 3.2 years) in the ISCHEMIA study. A recommendation of initial conservative management with close follow-up of ISCHEMIA-like patients, after the exclusion of significant left main stenosis using computed

tomography and before coronary angiography (as per the ISCHEMIA study protocol), would have been appropriate and reflective of available evidence. Instead, the 2021 Guideline extrapolated observational findings from patients with relatively favorable cardiovascular risk profiles (who typically would not be immediately referred for CABG) to inform decision making and erroneously weakened the CABG recommendations.

Questions regarding the accuracy of ISCHEMIA publications have also surfaced. Close evaluation of the data in an ISCHEMIA substudy investigating the impact of CAD severity on outcomes identified errors that required 2 separate, published corrections.<sup>17</sup> These corrections did not address all discrepancies, including lingering questions about the exact number of patients with prior CABG. Notably, the only surgeon serving on the ISCHEMIA Steering Committee also resigned amid concern that the data sets were inaccurate.<sup>4</sup>

Other misconstrued evidence that strongly shaped both the 2021 and 2023 Guidelines was a meta-analysis of 14 randomized trials, including the ISCHEMIA study, that compared initial MT vs routine revascularization in patients with stable CAD.<sup>18</sup> Half of the trials did not include a CABG arm, and overall, only 16% of the revascularization procedures were CABG. Despite being different revascularization modalities with different indications and outcomes, CABG and PCI were lumped together and compared with MT.<sup>18</sup> In addition, very few patients in this meta-analysis satisfied the Guideline definition of significant ( $\geq 70\%$  stenosis) 3-vessel CAD.<sup>9</sup> Altogether, the evidence provided by this meta-analysis should not have rationally informed the CABG recommendations.

Rather, the 2023 CCD Guideline should have corrected course by focusing on what is best supported by medical evidence. It should have outlined the limitations associated with the published evidence, including a relative lack of recent studies directly comparing CABG and MT. In addition, it should have considered the consistent evidence demonstrating a survival advantage for CABG over PCI in patients with 3-vessel CAD, providing strong indirect support that CABG also provides a survival advantage over MT. By ignoring this, the Guideline committee indirectly stated that PCI brings worse survival than MT, which no prior trial or study has ever indicated.

The ACC/AHA Guideline methodology manual stipulates that in case of a conflict, disease-based guidelines take precedence over procedure-based guidelines.<sup>19</sup> However, in this instance, the opposite occurred. Strict instructions to avoid any contradiction or even minor revisions to the 2021 Guideline for Coronary Artery Revascularization resulted in the 2023 CCD Guideline

defaulting to recommendations that perpetuated an inaccurate assessment of the role of CABG in patients with multivessel CAD in both survival and major adverse cardiovascular events. **Omitting some of the contested CABG recommendations in the 2023 CCD Guideline served no useful purpose and retained major gaps and unanswered questions.**

**The potential harm to patients associated with weakening CABG recommendations cannot be ignored. Death and adverse cardiovascular events are well documented in patients awaiting CABG.<sup>20</sup> In addition, there is increased operative risk associated with urgent or emergency (vs elective) CABG and with diminished left ventricular EF (vs normal EF),<sup>21</sup> which can both arise from delaying surgical revascularization.<sup>20</sup> On the other hand, the safety of elective modern-day CABG is remarkable. The 30-day mortality of CABG in the Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) 3 Trial was 0.3%—identical to that of PCI.<sup>22</sup>**

The 2 surgeons representing the American Association for Thoracic Surgery (AATS) and The Society of Thoracic Surgeons (STS) on the 2023 ACC/AHA CCD Guideline Writing Committee gave considerable time

and effort to writing their assigned sections, completing their numerous reviews, and participating in weekly committee calls. They also submitted repeated proposals to reexamine the 2021 Revascularization Guideline recommendations and recalibrate them in accordance with the best available evidence. Unfortunately, these proposals were disregarded. **Therefore, given the inability to register their significant concerns, and after thorough consultation, these 2 surgeons made the difficult decision to withdraw from the 2023 ACC/AHA CCD Guideline Writing Committee.**

To many in the national and international cardiovascular community, the 2023 ACC/AHA CCD Guideline had represented an opportunity to better align recommendations with the evidence for the benefit of patients with CAD. We believe that this can still be achieved. However, this will require a process that is fair, transparent, evidence based, and unbiased.

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