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How the Interventionalists Can Improve the Outcomes of Coronary Artery Bypass Grafting

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ABSTRACT

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Introduction

The field of coronary revascularization has advanced considerably over the last 2 decades, principally driven by randomized trials comparing the outcomes of percutaneous coronary intervention (PCI) to coronary artery bypass grafting (CABG), Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) trial [1], Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) trial [2], Evaluation of XIENCE versus Coronary Artery Bypass Graft Surgery for Effectiveness of Left Main Revascularizaton (EXCEL) Trial [3], International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) Trial [4] and follow-up studies, among others. In patients with diabetes and those with high SYNTAX coronary complexity scores, CABG confers better long-term outcomes with reduced mortality, lower rate of spontaneous myocardial infarction (MI) and lower rates of repeat revascularization at the cost of being more invasive with a higher risk of stroke than PCI[1,5]. Within the PCI realm, unblinded trials have shown PCI reduces angina compared to medical therapy [6-8] and also compared to a placebo sham procedure on a background of no or little anti anginal therapy with objective evidence of ischemia. In terms of outcomes, PCI is mostly equivalent to medical therapy in sub-groups with low angina burden and low coronary disease severity [6], while documentation of a mortality benefit with PCI alone has been elusive [4]. Within the CABG realm, multiple arterial CABG confers an additional mortality benefit compared to conventional CABG utilizing LIMA and venous conduits in appropriate patients[9-11]. Females have worse outcomes after CABG compared to males[12]. Invasiveness remains a necessary consequence.

Correctly applying these results to individual patients is very challenging but has been definitely helped by the Heart Team approach. To further pursue this agenda, this paper makes the case for multi-disciplinary pre and/or intra-operative physiological characterization of epicardial coronary disease and myocardial perfusion to develop patient-focused precision management of coronary revascularization.

Coronary Physiology Guided PCI Is Established

The purpose of revacularization is to improve the supply of blood to the heart such that it can meet demand. Anatomic stenosis severity is only a reliable surrogate for flow limitation in stable ischemic heart disease under conditions of increased demand when the stenosis severity is truly critical (85% or more). The Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) trial randomized patients with≥1 vessel having a 50% or greater stenosis to either angiography guided PCI or fractional flow reserve (FFR) guided PCI. Physiology guided PCI resulted in improved outcomes to 2 years[13], similar clinical outcomes at 5 years[14], with fewer unnecessary stents implanted than the angiography guided group. In acute coronary syndromes, unstable angina, and non-ST elevation myocardial infarction (NSTEMI), physiology guided PCI also results in fewer unnecessary stents implanted than an angiography guided approach[15,16].

The link between cardiac catheterization laboratory physiologic indices of flow limitation, abnormal perfusion on noninvasive imaging studies and subsequent improvement in myocardial perfusion after relief of the stenosis with PCI and documented normalization of the physiologic indices post-PCI has been firmly established [17-19].

Thus, in the realm of PCI, there is a strong evidence base to support physiology guided PCI.

Use of Coronary Physiology to Guide CABG Is Not Established

This is in contrast to CABG, which is performed solely anatomy guided, using a 70% cut off for the main coronary vessels and 50% for left main stem stenoses. Studies on so called 'FFR guided CABG' have focused on using FFR to reduce graft occlusion, which is an elusive clinical outcome. The paper by Botman et al showed 8.9 % of grafts to functionally significant vessels were occluded at 1 year after CABG compared to 21.4 % of grafts to functionally non flow limiting vessels[20]. Most subsequent studies and randomized trials have failed to show a notable impact on graft patency rates by using FFR to determine whether a vessel should be bypassed [21-23].

Which raises the question of why the clinical outcome for FFR-guided PCI and FFR-guided CABG should be different in the first place. Unfortunately, there is a lack of data linking preoperative coronary physiologic indices (FFR, instantaneous wave free ratio (iFR) etc) to perfusion change plus the more complex physiologic state of CABG has limited the usefulness and utilization of FFR in guiding coronary graft strategy. Therefore, we propose that the correct clinical outcome for coronary physiology applied to CABG is the same as it is for PCI: the improvement in myocardial perfusion, in this case after the stenosis is grafted. This approach can directly impact the strategy and technical execution of CABG in the following ways.

Use of Coronary Physiology for Arterial Conduit Selection

A more careful examination of the Botman paper however shows the majority of the occluded conduits to functionally non flow limiting target coronary vessels were non internal mammary arterial conduits. This strongly suggested that the degree of flow limitation present in the target vessel will impact arterial conduits differently to venous conduits. This was confirmed in the prospective randomized single blind IMPAG trial which specifically investigated the influence of preoperative FFR on arterial conduits in the setting of exclusively multiple arterial conduit CABG. The trial found that only 3% of arterial conduits to vessels with FFR≤0.78 were occluded[24].

Despite these compelling data, the take up of physiology guided conduit selection has been limited. To an extent this reflects inertia due to the fact that the anatomy guided model yields excellent long-term outcomes and multiple arterial grafting, which is technically more challenging, remains confined to a minority of surgeons, even though the evidence it confers a further mortality benefit evident 10 years and onwards after surgery is strong.

Use of Coronary Physiology to Optimize Completeness of Revascularization

Observational data shows that patients who do not have an important severely diseased epicardial vessel revascularized at CABG or PCI have worse outcomes [25-29]. The greater comorbidities, prevalence of diabetes and heart failure could confound these findings. Patients in the SYNTAX trial who had incomplete revascularization during either CABG or PCI had worse long-term outcomes [30]. Comparing the revascularization modalities, in the SYNTAX trial, CABG has been shown to have a lower rate of anatomically judged complete revascularization than PCI. In a separate analysis of the trial data, anatomically incomplete revaascularization by PCI was associated with adverse events but not CABG [31]. Overall, this means on average, CABG will increase the perfusion to the heart to a greater degree than PCI, likely one of the factors that leads to this therapy's mortality benefit. An analysis of the ISCHEMIA trial based on coronary artery disease and ischemia severity however showed the severity of ischemia was not associated with increased all-cause mortality; increasing severity of coronary artery disease was associated with death (HR, 2.72 [95% CI, 1.06-6.98]) and myocardial infarction (HR, 3.78 [95% CI, 1.63-8.78]) for the most versus least severe CAD subgroup). The types of tests used to detect inducible myocardial ischemia were mainly nuclear stress tests, stress echocardiography and treadmill ECG. No patients had PET assessment of both regional ischemia or whole myocardial blood flow coronary flow reserve and less than 6% had cardiac MRI, both being more sensitive and specific than standard tests for assessing myocardial perfusion. In the most severe CAD subgroup (n=659), the 4-year rate of cardiovascular death or MI was lower in the invasive strategy group than the conservative group (difference, 6.3% [95% CI, 0.2%-12.4%]), but 4-year all-cause mortality was similar. When the trials outcomes were analyzed according to revascularization modality most early events were peri-procedural MI of questionable clinical significance. Although the authors did not formally compare the outcomes between PCI and CABG due to significant differences in extent of coronary disease, both modalities were associated with a lower rate of myocardial infarction and cardiac death than the conservative arm [32]. Importantly, the burden of angina in the ISCHEMIA trial was low. Thus, the applicability of the trial results to patients with higher degrees of angina burden and high tertile SYNTAX scores or patients with diabetes with 3 vessel disease is debatable.

The complete revascularization data would suggest that the current approach to CABG approach is optimal. However, vein graft failure is associated with increased rates of repeat revascularization but with no impact on death or spontaneous MI [33]. Asymptomatic vein graft failure, a subset of this`, may have no significant clinical impact. A retrospective observational study of saphenous vein grafting use in CABG from 2001-2015 from the Medicare database found no association between the frequency with which surgeons used SVG's per case and long-term survival suggesting a conservative approach to use of this conduit was justified [34]. These data suggest too many bypass grafts are likely used than are needed to achieve this optimal myocardial perfusion.

To date, with the solely anatomy guided approach to CABG, there has been no other way to determine which conduits should be applied to which non-LAD vessels. What has been missing is direct evidence linking the preoperative functional severity of the target epicardial coronary vessel and the acute perfusion response to grafting.

New Data Linking Coronary Stenosis Severity and Acute Perfusion Response to Grafting

Early indication that anatomical stenosis severity did not reliably predict if there was an increase in perfusion after coronary artery bypass grafting came from observational work using near infra-red fluorescence imaging during CABG. Near-infrared fluorescence (NIRF) angiography is used in multiple surgical specialties to document graft integrity and tissue perfusion [35]. In consecutive, mainly off-pump CABG, NIRF imaging was used to assess graft integrity angiographically and also assess the acute net change in regional myocardial perfusion after the graft was created using proprietary software. Ferguson et al found in angiographically widely patent anastomoses that 40/165 (24%) of LIMA grafts to LAD vessels with > 70% stenoses did not exhibit an acute increase in regional myocardial perfusion (RMP-QC) suggesting that anatomical epicardial coronary stenosis severity cannot be the only determinant of flow limitation to the myocardium it subtends[36]. In addition, this study documented the extensive collateralization present to account for these findings. This study logically led to the prospective single center interventional cardiology-cardiac surgery collaborative PERSEUS Pilot Study.

Published in December 2022, we prospectively studied patients that underwent routine care coronary angiography either for stable angina or stable NSTEMI who were to be referred for CABG[37]. All non-critical (<85%) intermediate severity coronary vessels were interrogated by pressure wire, with core lab FFR and iFR measured. Anatomic stenosis severity of the intermediate lesions was assessed by core lab QCA (quantitative coronary angiography). At CABG near-infrared fluorescence imaging was used to assess anastomotic integrity and quantified the relative change (post- vs pregrafting, termed RMP-QC, Regional Myocardial Perfusion-Quantified Change) in the grafted vessel's perfusion territory. RMP-QC was determined blinded and offline using proprietary software. 48 patients were recruited with a final study population with paired coronary angiography and NIRF data available in 41 patients and 75 grafted vessels, 62 intermediate severity vessels and 13 critically stenosed vessels. Scatter plots were constructed for RMP-QC versus quantitative coronary angiography and RMP-QC versus FFR/iFR and analyzed. FFR/iFR values of 0.50/0.59 were assigned to vessels too critically diseased (≥85%) to interrogate with pressure wire. (Figure 1A-C scatter plots from PERSEUS)

FIGURE 1. A, Scatter plot of individual paired quantitative coronary angiography (QCA) and regional myocardial perfusion quantified change (RMP-QC) observations. B, Scatter plot of individual paired fractional flow reserve (FFR) and RMP-QC observations. C, Scatter plot of individual paired instantaneous wave-free ratio (iFR), RMP-QC observations. EQRT, exact quadrant randomization test vertical/horizontal quadrant plot reference lines at QCA 70%, FFR 0.80, or iFR 0.89/RMP-QC 1.10.

Reprinted from JTCVS Open, Buch AN, Alwair H, Cook CM, Petraco R, Efird JT, Gregory CP, Chagarlamudi AK, Davies JE, van de Hoef TP, Ferguson Jr TB,12,158-76, 2022. Immediate impact of coronary artery bypass graft surgery on regional myocardial perfusion: Results from the Collaborative Pilot Study to Determine the Correlation Between Intraoperative Observations Using Spy Near-Infrared Imaging and Cardiac Catheterization Laboratory Physiological Assessment of Lesion Severity, 158-76, Copyright 2022, with permission from Elsevier, permission conveyed through Copyright Clearance Center, Inc

Figure 1A

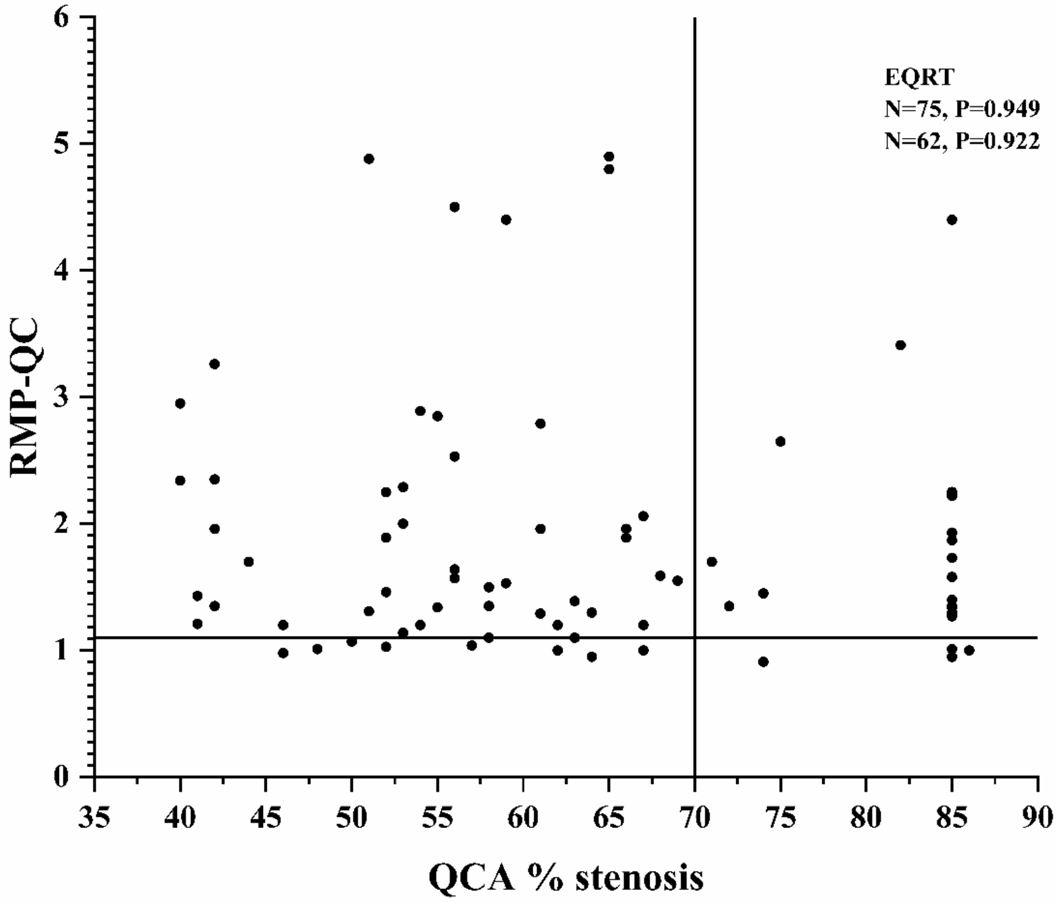


Figure 1B

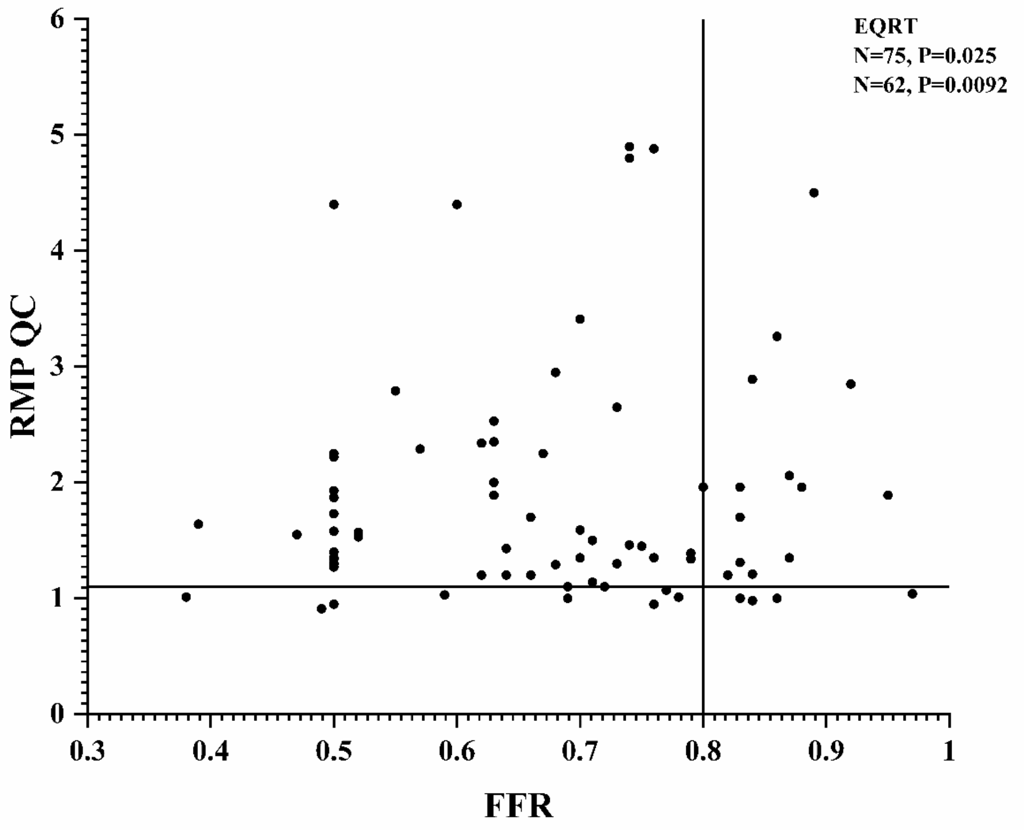
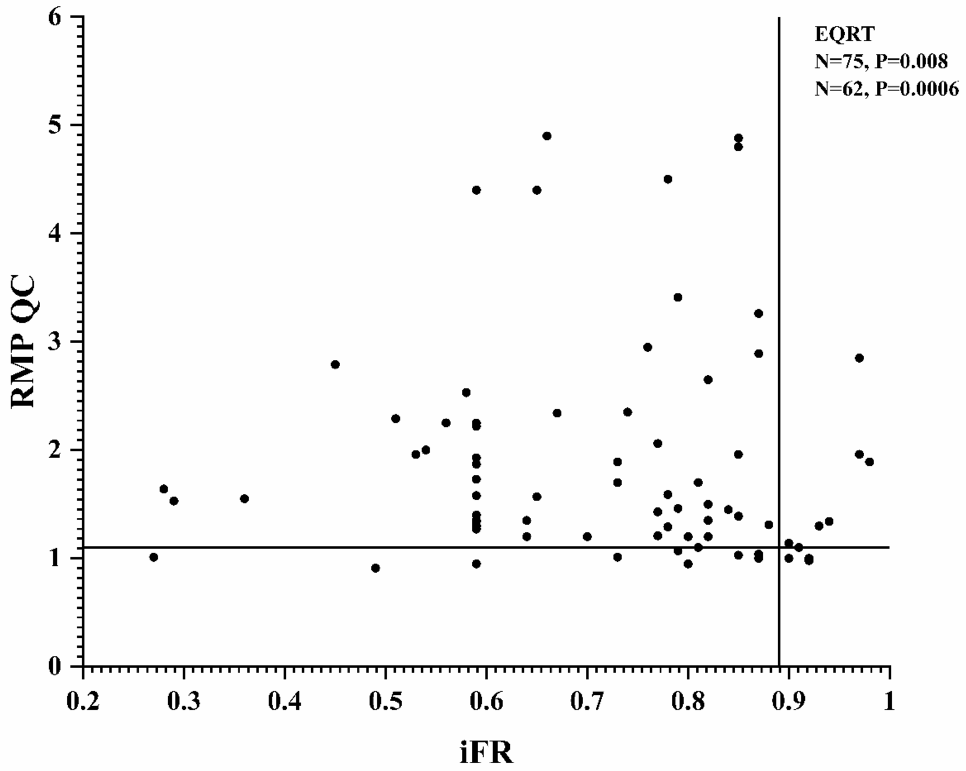


Figure 1C



There was no association between angiographic coronary artery stenosis severity and acute perfusion change after grafting for all vessels (P=.949) or intermediate severity vessels with core lab QCA only (P=.922). In contrast there was a significant nonrandom association between RMP-QC and FFR (P=.025, all vessels, excluding assigned FFR, P=.0092), as well as RMP-QC and iFR (P=.008, all vessels, excluding assigned iFR, P=.0006). Cubic spline analysis showed no significant linear relationship for FFR or iFR. Therefore, the association between FFR/iFR and RMP-QC was complex and nonlinear.

Not published in the original paper were observations where for example in the context of both the left anterior descending artery and diagonal vessels being functionally severely flow limiting, after the left internal mammary (LIMA) had been applied to the LAD with a documented significant increase in RMP-QC to the LAD territory, the subsequent graft to the diagonal graft did not result in an increase in perfusion to its territory. We hypothesize the increased perfusion via the LIMA also provided sufficient blood to the diagonal territory via collaterals. These observations suggest diagonal graft may not have been required, an example of a graft that asymptomatically later occludes with no adverse impact on hard outcomes.

Implications for Future CABG strategies and proposed New Personalized Coronary Revascularization Paradigm

The PERSESUS Pilot study data lends further support for the use of preoperative cath lab physiologic indices to guide conduit selection as per the IMPAG trial. It also more directly supports the self-evident purpose of CABG - to increase perfusion to areas of the heart that are under perfused to a maximal extent. The standard of care for CABG still remains a median sternotomy approach with revascularization based on angiographic anatomic stenosis severity to determine graft placement and type of conduit. We propose that using physiologic techniques not just on an individual graft basis but on the revascularization strategy as a whole could allow more appropriate conduits and fewer total bypasses on average than are currently performed with no diminution in clinical outcomes. For example, once the left internal mammary has been anastomosed to an unequivocally severely diseased LAD and other critical vessels have had their conduits placed, intra operative imaging could be used to determine the requirement for further grafts. Preoperative physiology would help optimize the use of arterial conduits thus potentially improving long term clinical outcomes. Intra operative physiologic imaging at the time of surgery could refine the preoperative provisional grafting strategy.

Using physiology as well as anatomy would also provide a more scientific framework for hybrid revascularization once the LAD has been grafted with a LIMA. For example, preoperative FFR/iFR could identify non-LAD vessels that may benefit form an arterial conduit. The others could be treated with PCI. Thus, with this provisional preoperative plan, at the time of surgery it is possible the non-LAD vessel to which the arterial conduit would have been applied is not anatomically suitable. In that case, PCI or venous grafting could be opted for. After CABG, any non-LAD vessels which the preoperative heart team had decided would be treated with PCI, would have these vessels stented after CABG. During the surgery, there may be vessels where preoperative physiology is unavailable e.g. a marginal or diagonal branch. Real time interoperative perfusion imaging could be performed after the other grafts have been created to help determine whether these vessels need a graft. Excellent perfusion to the relevant territory and no graft may be applied. With an equivocal result, many surgeons may opt to graft the vessel. In this way, pre and possibly intra operative physiology could help provide a scientific basis for hybrid coronary revascularization.

These hypotheses and treatment strategies need to be rigorously tested initially with larger multi center observational intraoperative imaging data sets followed by adequately powered clinical trials.

Conclusion

In conclusion, CABG regardless as to how it is performed has no significant further possible innovations in grafting strategy if anatomical stenosis severity is the only factor that is considered. This approach, to be clear, with advances in cardiothoracic anesthesia, has yielded excellent clinical outcomes. The patient population is however ageing, the prevalence of diabetes is at epidemic levels. Physiologic information can help refine and simplify invasive treatments to allow similar hard ischemic outcomes with potentially fewer wound complications, shorter lengths of stay. Finally, this approach combined with minimally invasive surgical techniques may broaden the population that could benefit from multiple arterial CABG.

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