PRO: Preoperative Coronary Revascularization in High-Risk Patients Undergoing Vascular Surgery

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Dr. Kertai has done an excellent job in the core review[1] in distilling the essence from the complex and multifaceted literature on preoperative coronary revascularization. However, under the surface, a titanic debate takes place on some major issues: Does any randomized controlled trial (RCT) always provide better evidence than any observational study? Can two recent RCTs completely overturn the data accumulated by a number of previous observational studies? Was the methodology used to generate the data adequately convincing? First some basic facts that must be acknowledged in the discussion:

1. Vascular surgery patients have high prevalence of significant coronary artery disease (CAD) of which 18% have severe triple vessel disease (TVD) and 4% left main disease (LMD),[2] who are the target of any possible coronary revascularization.
2. Patients with peripheral vascular disease have a 6–15-fold higher long-term mortality from CAD than patients without peripheral vascular disease.[3]
3. Patients with TVD or LMD have worse long-term survival than those with only single or double-vessel CAD. This is not only true for patients with unstable but also for patients with stable CAD[4] and more so for patients with coexisting reduced left ventricular function.
4. Coronary revascularization by coronary artery bypass graft (CABG) improves long-term survival and event-free survival in patients with multi-vessel (TVD and/or LMD) CAD, especially if left ventricular function is impaired.[5,6,7,8] This has never been proven though for percutaneous coronary intervention (PCI) with or without stenting, although several studies have reported comparable long-term results for PCI and CABG. Recently the COURAGE study found no survival benefit with PCI over optimal medical therapy;[9] however, this RCT has been criticized regarding patient selection bias (less than 10% of the patients evaluated were included), PCI methodology and incomplete revascularization in most patients (59%), weakening its conclusions.[10,11]
5. Large areas of moderate-to-severe ischemia on noninvasive radionuclide imaging of the heart predict long-term outcome even better than the number of diseased vessels on coronary angiography.[12] Similar or even better results have been obtained for dobutamine stress echocardiography.[13]
6. Although no RCT was designed to compare survival with revascularization versus medical therapy in patients with ischemia on myocardial perfusion scans, a large scale observational study (10,627 consecutive patients)[14] demonstrated a better survival with revascularization over medical therapy when moderate-to-severe ischemia (>20%) was present on myocardial perfusion scan, especially in high-risk patients (elderly, women, diabetics) (Fig. 1).

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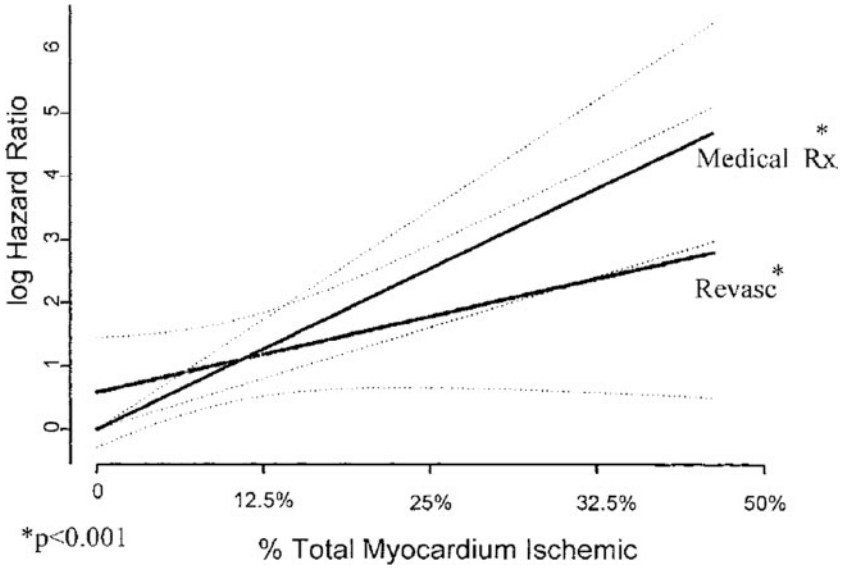

Figure 1. Log Hazard ratio for revascularization (Revasc) versus medical therapy (Medical Rx) as a function of % myocardium ischemic Based on final Cox proportional hazards model. (Adopted with permission from Circulation 2003;107;2900–7).

LIMITATIONS OF RCTs

There is an abundance of literature discussing the pros and cons of RCTs versus observational studies.[15,16,17] All agree that RCT is the best study design for investigating primary treatment effects in large phase III pharmaceutical trials in compliant populations. However, observational studies are not only more feasible but may actually give more accurate results than RCTs when a clinical dilemma is seeking an answer where there is no one clear-cut solution but rather it strongly depends on various complex patients' features and on overall clinical judgment. Although the impact of allocation biases, spurious observations, and missing covariates cannot be ignored, patients in observational studies better represent those seen in real clinical practice. A RCT provides optimal results when the clinicians providing a new drug or treatment are blinded (preferably, double-blinded) and impartial to its effect. A RCT loses its effectiveness when the physicians enrolling patients are biased as to the potential benefits or harms of the investigated treatment, simply because of their often justifiable reluctance to randomize patients who they believed may either benefit or be harmed by the treatment (or its prevention). Typical to such RCTs is that too few screened patients, those who are not likely to be affected by the randomization, are finally randomized. This obviously raises a fundamental issue of selection bias, and seriously calls into question the validity and generalizeability of such RCTs. Also, typically, these RCTs are likely to find lack of treatment effect on patient outcomes, since most patients who could have benefited or been harmed by the treatment were excluded. Two RCTs opposing preoperative coronary revascularization in candidates for vascular surgery have been recently published.[18,19] However, these RCTs suffer from many of the above-mentioned limitations.

LIMITATIONS OF THE CARP TRIAL[17]

The CARP trial aimed to challenge the long debated concept that preoperative coronary revascularization in high-risk vascular surgery patients improves long-term outcome. While this is a worthy and justifiable goal, it must be judged also by the means used to achieve it.

1. The trial screened 5859 vascular surgery patients from 18 Veterans Adminstration hospitals in the United States, each center using different methods for screening patients (Eagle's criteria/Revised Cardiac Risk Index, with or without noninvasive testing). There was no unified method for screening patients' preoperative risk, neither were the American Heart Association/American College of Cardiology guidelines systematically implemented which recommend noninvasive testing before coronary angiography in patients with moderate clinical predictors.
2. Vascular surgery patients typically have low functional capacity and asymptomatic CAD, which is difficult to evaluate with noninvasive testing. Preoperative nuclear stress testing was performed in only 62% of randomized CARP patients, and only 44% of randomized patients had moderate-large ischemia on nuclear imaging.
3. As a result, only 32% of randomized patients had TVD or 2.9% of all 5859 screened patients. This proportion is in marked contrast to the expected 18% of patients with TVD according to the data obtained from Hertzer et al.'s study using systematic coronary angiography in 1000 vascular surgery patients. Thus, the majority of patients with TVD in the CARP trial – those most likely to benefit from revascularization – were either not identified by the screening process or excluded because of the clinicians' judgment that they should not be randomized. The other 68% of

randomized patients with single or double-vessel disease were unlikely to have a survival benefit from coronary revascularization.

4. Although the CARP study did not find differences in postoperative myocardial infarction (MI) with or without preoperative revascularization, it did find (in one of its sub-studies)[20] that the more complete the preoperative coronary revascularization, particularly with CABG, the less were postoperative MIs. However, the same authors previously reported that postoperative MI after elective vascular surgery is associated with worse long-term survival.[21] Thus, based on CARP's own data, complete preoperative revascularization in the right patients prevented postoperative MI, and therefore improved long-term survival.

LIMITATIONS OF THE DECREASE-V TRIAL[18]

In theory, the DECREASE-V trial could have filled the gap that the CARP study created by aiming to randomize the very high-risk patients with significant inducible ischemia on noninvasive preoperative testing who are most likely to benefit from coronary revascularization. However, several issues in the methodology and results make this study unrealistic and cast serious doubt on its generalizeability:

1. "Of 430 high-risk patients, 101 (23%) showed extensive ischemia and were randomly assigned to revascularization (n = 49) or no revascularization." Apparently, all 49 patients with extensive ischemia on preoperative testing eventually underwent coronary revascularization. However, this is not compatible with real life as we know it. Up to 1/3 of vascular surgery patients with severe ischemia on noninvasive testing may not be suitable for revascularization, based on their coronary anatomy. Problems such as poor run-off, multiple small vessel CAD mainly in diabetics, chronic total obstructions not suitable for PCI in patients who are too sick for CABG, etc. may render them unsuitable for revascularization. The DECREASE-V trial "forced" all 49 patients with severe ischemia on noninvasive testing to undergo coronary revascularization, with no exclusions. The only clinical judgment applied was if it would be by PCI or CABG. This may explain the extremely high morbidity in the revascularization arm (two patients had ruptured aortic aneurysm before the vascular surgery) and the lack of postoperative benefit.
2. Patients in the revascularization arm had extremely high 30-day mortality after vascular surgery, twice as high as the control arm (22% vs. 11%). This is in contrast to multiple studies which report reduced mortality and MI after vascular surgery in patients who had prior successful coronary revascularization, particularly with CABG.[22,23] No explanation was given to the markedly high postoperative mortality despite successful and complete revascularization (in 86% of patients). Perhaps the "catastrophic" incidence of postoperative complications was because double antiplatelet therapy was not discontinued in patients who had surgery shortly after PCI,[24] but this is not reported.
3. Postoperative MI rate was also extremely high in both groups (35% and 31%) and all were Q-wave infarctions.[25] This is in contrast to multiple studies in vascular surgery patients, which showed that postoperative Q-wave MI is rare whereas close to 100% are non-Q-wave infarctions. In a study that monitored hundreds of vascular surgery patients with continuous on-line 12-lead electrocardiogram perioperatively, none of the patients had Q-wave MI.[26]
4. The same group that published the DECREASE-V trial has reported that prophylactic perioperative beta-blockage does not prevent postoperative cardiac events in patients with extensive myocardial ischemia on preoperative testing, similar to those randomized in the DECREASE-V trial.[27]

POSTOPERATIVE MI: UNSTABLE PLAQUE OR UNSTABLE PATIENT?

One of the main arguments of those opposed to preoperative coronary revascularization is that revascularization to arteries with stable coronary lesions is futile because it does not prevent postoperative MI allegedly caused by plaque rupture of relatively non-occluding (<70% stenosis) but unstable coronary plaques. We will not elaborate much on this issue here. However, after years that we have been preaching for the concept that prolonged, stress-induced ST-depression-type ischemia is a distinct and common mechanism for MI, particularly in the postoperative period,[28] it has recently been accepted by the widest community of cardiologists. A new "Universal classification of MI" has been presented in the European Society of Cardiologists congress (2007) as a consensus document by the European Society of Cardiologists, American College of Cardiologists, American Heart Association and World Heart Federation (in press). This new universal classification includes 5 types of MI: Type I is spontaneous MI related to an acute coronary event (plaque rupture, fissuring or erosion); Type II is MI secondary to prolonged oxygen supply-demand imbalance (anemia, hypotension etc.); Types III to IV are sudden cardiac death, post-PCI and post CABG, respectively. The purpose of coronary revascularization in major vascular surgery patients with typically long-standing and stable CAD is to prevent type-II MI, both perioperatively and in the long-term. Although beta-blockers may help prevent some of

these perioperative events, they are not yet a substitute for coronary revascularization in patients with severe CAD.

PREOPERATIVE CORONARY REVASCULARIZATION AS A CLINICAL DILEMMA

RCTs treat scientific questions as if they have only one possible answer – yes or no – given that all confounding factors are controlled. However, in reality, complex clinical issues may have more than one answer and a careful clinical judgment must be made for each individual patient with his/her special complex combination of predictors and demographic features. When the clinical judgment itself is evaluated, rather than the quality of a specific medication or therapy, there is probably no better alternative but to refer to observational cohort studies. Such is the case when coronary revascularization is considered in patients with complex preoperative clinical features, different results on preoperative cardiac stress testing and multiple possible combinations of coronary anatomy findings. Our recent findings[29] show that intermediate-risk vascular surgery patients, those with 2–3 risk predictors of the Long-Term Survival Score (LTSS), were most likely to benefit from preoperative coronary revascularization. In contrast, low-risk patients, those with low LTSS 0–1 had good long-term survival that was not significantly affected by the revascularization. Similarly, high-risk patients (LTSS $\geq$4) had poor early and long-tern survival after vascular surgery that was also not significantly affected by coronary revascularization, even if severe ischemia on noninvasive testing was found and treated. This result could only be obtained by a cohort study that included all consecutive patients undergoing vascular surgery, without the unavoidable exclusions curtailing RCTs.

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CON: Preoperative Coronary Revascularization in High-Risk Patients Undergoing Vascular Surgery

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Practicing anesthesiologists are frequently confronted with the difficult task of risk-stratifying patients just before a high-risk noncardiac operation. Overall, elective surgical procedures in a population of general medical patients without cardiac symptoms carry a very low risk of perioperative cardiac complications and, therefore, probably need no adjunctive testing.[1] As discussed in the comprehensive review by Kertai,[2] however, patients undergoing vascular surgery have a frequent prevalence of atherosclerotic heart disease and coupled with the complex hemodynamic stresses associated with aortic and arterial procedures, require special attention in the preoperative period. Coronary artery disease remains the major cause of death after any vascular operation and, therefore, consideration for preoperative coronary artery revascularization has been a justifiable endeavor.

PREOPERATIVE CORONARY ARTERY REVASCULARIZATION AND LONG-TERM OUTCOMES

Kertai's review focused on three studies that address the potential role of preoperative coronary artery revascularization in patients undergoing elective vascular surgery. The Coronary Artery Revascularization Prophylaxis (CARP) trial was the first multicenter, randomized study to test the hypothesis that coronary artery revascularization before major elective vascular surgery improves outcome in patients with documented coronary artery disease that is amenable to revascularization with either percutaneous coronary intervention or bypass surgery. Long-term survival was the primary end-point of the study and, at a median of 2.7 yr after randomization, was 78% in patients assigned to preoperative revascularization and 77% in patients assigned to conservative treatment (Relative Risk, 0.98; 95% Confidence Interval, 0.70–1.37; $P = 0.92$).[3] By study design, those individuals who were selected for preoperative coronary angiography demonstrated increased clinical risk factors, either because of multiple intermediate risk variables or myocardial ischemia on a preoperative stress imaging test.[4] Although a preoperative stress imaging test was not a prerequisite for enrollment into the study, 74% of the randomized cohort would have been deemed high clinical risk by the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines, either because of the presence of multiple intermediate clinical risk variables or a high-risk stress-imaging test.[5] Therefore, the CARP study results should be considered generalizeable to the vast majority of patients who have documented coronary artery disease and have been scheduled for elective vascular surgery. As one might expect, a strategy of preoperative coronary artery revascularization was not associated with a successful outcome in all end-point measures. Twice as many people failed to return for their needed vascular operation and, of those who did return, the delay from

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randomization to surgery was three times longer compared with the conservatively treated group (median of 54 days versus 18 days). Coupled with the increased expenditures associated with revascularization therapies and the lack of efficacy in either the short-term or long-term, widespread identification and treatment of fixed obstructive coronary artery disease in patients scheduled for elective vascular surgery is hardly an encouraging strategy. An additional consideration is that drug-eluting stents were not used during the CARP enrollment period yet have rapidly gained acceptance as the device of choice within most catheter laboratories. Accordingly, the associated delays in the present era are likely to be much greater than estimated from the CARP trial, with the uncertain risks of nonfatal myocardial infarctions after stopping antiplatelet drugs in the perioperative period. In the final interpretation of the CARP trial, it is imperative to understand that β-blockers were used in >85% of the randomized cohort before and after vascular surgery and highlight the evidence that conservative therapy with this class of drugs is more than just a placebo effect.[6,7]

Although the CARP trial supports a conservative approach in patients scheduled for elective vascular surgery, the trial was not designed to assess the optimal screening test for all patients with increased risk who are being considered for noncardiac operations. To address the utility of screening before elective surgery, the second article discussed in Kertai's review comes from Landesberg et al. who compiled an elegant review of their own institutional experience on preoperative stress thallium testing as a means of prognosticating long-term postoperative outcomes. Among patients with a high-risk preoperative thallium result, individuals who had successful coronary artery revascularization had an improved 3-yr survival after vascular surgery, compared with individuals of equivalent intermediate clinical risk scores who were not selected to undergo revascularization.[8] The authors have suggested that the prevalence of multivessel disease was higher in their cohort compared with the CARP trial and speculate that the improved outcomes with preoperative revascularization reflect differences in anatomical risk. In defense of this position, by study design, patients with an unprotected left main stenosis ≥50% were excluded from randomization into the CARP trial.[4] Although this could explain some differences between studies, a severe left main stenosis was identified in only 48 of 1048 (4.6%) patients screened for the CARP trial[9] which is not sufficient to account for the larger outcome differences between studies.

An alternative interpretation of the observed survival benefit with preoperative coronary artery revascularization after high-risk thallium tests is the potential selection bias that may occur with retrospective analyses. A comparison between those patients who were selected for preoperative revascularization and who returned for the vascular operation may result in the "survival of the fittest," when compared with those patients who were not selected for either coronary angiography or revascularization and proceeded directly to vascular surgery. Within the CARP registry, 1525 (34.5%) of 4414 screened patients were excluded from the randomization process by design, because of the presence of one or more severe comorbid conditions or an urgent vascular operation.[10] These individuals had a frequent prevalence of clinical cardiac risk variables and a long-term risk of death that was 2.5 times higher than low-risk registry patients, yet they were not considered suitable candidates for preoperative coronary angiography and complex revascularization therapies. It is conceivable that these patients could have had high-risk preoperative thallium test results, yet inconceivable that they should have been exposed to excess cardiac procedures prior to surgery, considering their associated noncardiac conditions. Although Landesberg et al. have provided important prognostic information about postoperative outcomes in patients with high-risk thallium tests, until recently, it remained a testable hypothesis that preoperative revascularization improves outcomes in this highest risk cohort.

To address the optimal treatment in the highest risk group of patients being considered for vascular surgery, the final study discussed in the review was the Decrease V pilot study from Erasmus Medical Center in Rotterdam. The investigators in this trial enrolled patients with a high-risk stress imaging test before vascular surgery and randomized them to a strategy of preoperative revascularization or no revascularization prior to the scheduled vascular surgery.[11] The prevalence of advanced coronary artery disease including three-vessel disease and unprotected left main disease was high and, therefore, addressed the potential limitations of a lower risk group of patients within the CARP trial. The results showed that, at 1 yr after surgery, the composite end-point of death and nonfatal myocardial infarction was not different between groups and provide complementary evidence that a strategy of preoperative revascularization before elective vascular surgery does not improve long-term outcomes.

TRANSLATING RANDOMIZED TRIALS INTO COMMON PRACTICE

Based on the ACC/AHA Guidelines, major risk variables should be identified before any elective noncardiac operation and these include unstable coronary syndromes, decompensated congestive heart failure, a severe valvular abnormality and life threatening arrhythmias.[5] Patients with these risks were never included in the major randomized trials and their outcomes after noncardiac surgery were likely influenced by the unstable cardiac status. Among the vast majority of patients who do not have evidence of

unstable cardiac signs or symptoms, however, we have come closer to accepting the concept that widespread screening with preoperative cardiac imaging tests will likely delay treatment of the primary vascular condition, without assurance of any improved outcome measure. It is time for clinicians to shift the emphasis from indiscriminate "pre-ops" with widespread cardiac imaging to adoption of evidence-based therapies including β-blockers, statins and antiplatelet drugs that preserve survival and quality of life while conserving valuable medical resources.

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