

One might argue that the former monastic, undistracted, self-effacing training lifestyle had some valuable elements that should be preserved to help generate our future leaders and reduce the risk of injury from a motor vehicle crash.

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**THE AUTHORS REPLY:** Although it may be true that participants in our study were not representative of all interns with respect to their interest in or knowledge of the study hypotheses, that would not explain why the interns who participated with Dr. Halpern in our study had more than twice as many motor vehicle crashes after extended shifts ( $\geq 24$  hours) as after nonextended shifts ( $< 24$  hours) when they were compared with themselves. In addition, we designed the study to guard specifically against this type of bias by also gathering data on work hours prospectively, well before data on documented motor vehicle crashes were collected. The monthly rate of motor vehicle crashes increased by 9.1 percent for every extended work shift scheduled per month (i.e., 91 percent on an every-third-night schedule). We think it unlikely that the presumed interests of the participants or the investigators in the outcomes of this research could account for the concordant results from these two different analytic techniques.

Dr. Wallach correctly points out that forcing trainees to live in the hospital where they work would eliminate commuting and thereby reduce their risk of motor vehicle crashes. Not even this draconian policy could bring back the era in which trainees had the opportunity to sleep in the hospital. Our data indicate that the current health care environment of high acuity and often intensive care with shortened lengths of stay would prevent trainees from obtaining the sleep they need even if they were truly “resident” in the hospital.

Although the voluntary taxicab voucher pro-

gram, described by Drs. Borden and Kamp, may reduce the risk of crashes, the limited reported use of taxicab vouchers supports our concern that the residents’ judgment of their impairment is compromised by chronic sleep deprivation.<sup>1</sup> Moreover, as Dr. Hunt points out, taxicab vouchers do not address the risks that extended work shifts pose for patients. Our group has recently shown that interns in critical care units have twice as many attentional failures<sup>2</sup> and make 36 percent more serious medical errors<sup>3</sup> — including 5.6 times as many diagnostic errors — when scheduled to work extended work shifts as compared with shifts of up to 16 hours. Taken together, these three studies indicate that the health and safety of interns and their patients would benefit from the elimination of the marathon, 30-consecutive-hour work shifts that the Accreditation Council for Graduate Medical Education continues to sanction.<sup>4</sup>

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## Coronary Revascularization before Vascular Surgery

**TO THE EDITOR:** McFalls et al. (Dec. 30 issue)<sup>1</sup> report on a randomized trial demonstrating that prophylactic coronary revascularization before vascular surgery is not beneficial. However, methodologic

concerns limit its generalization to high-risk patients, as the authors propose. The guidelines of the American College of Cardiology and the American Heart Association<sup>2</sup> advocate preoperative coronary

angiography before elective vascular surgery for selected patients with known or suspected stable coronary artery disease only after noninvasive testing showing moderate-to-severe inducible ischemia. Patients in the study by McFalls et al. were not selected according to these guidelines. After 91.3 percent of 5859 patients screened were excluded, only 44.3 percent of 510 patients studied had moderate or large defects on perfusion imaging (data on their distribution among groups were not provided). Consequently, only 33.3 percent of patients randomized had triple-vessel disease. In a recent large cohort study, preoperative coronary revascularization in patients undergoing major vascular surgery who had moderate-to-severe ischemia on thallium imaging was associated with improved long-term survival.<sup>3</sup> Of patients treated by revascularization, 75.5 percent had left main coronary artery disease, triple-vessel disease, or both, and 43.2 percent had reduced left ventricular function.<sup>3</sup> The findings of McFalls and colleagues are applicable to patients at low-to-moderate risk, but their study leaves unanswered the more important question of coronary revascularization in high-risk patients as classified according to the American College of Cardiology–American Heart Association guidelines.

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**TO THE EDITOR:** If percutaneous coronary intervention was planned in the Coronary Artery Revascularization Prophylaxis (CARP) trial (as it was in 59 percent of the patients assigned to preoperative coronary-artery revascularization), the trial coordinators expected the vascular operation to be delayed for at least two weeks. However, patients undergoing noncardiac surgery in the first six weeks after successful placement of a coronary stent have

an increased risk of an in-stent coronary-artery thrombus.<sup>1</sup> Stent thrombosis is a serious complication of coronary-stent placement, and most cases of stent thrombosis result in acute myocardial infarction or death.<sup>2,3</sup> Thus, it is generally accepted that elective noncardiac surgery should be delayed at least six weeks after placement of bare-metal stents and up to six months after implantation of drug-eluting stents.<sup>1,4</sup>

Elective vascular surgery early after percutaneous coronary intervention and coronary stenting without a completed course of antiplatelet therapy may have exposed patients who had been randomly assigned to preoperative coronary-artery revascularization to an increased risk of death and myocardial infarction. It also may have masked possible beneficial effects of coronary revascularization in the CARP trial.

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**TO THE EDITOR:** According to one of the American College of Cardiology–American Heart Association guidelines, preoperative coronary intervention before noncardiac surgery “is rarely necessary simply to lower the risk of surgery unless such intervention is indicated irrespective of the preoperative context.”<sup>1</sup> However, portions of the guidelines are inconsistent with this statement. For example, an algorithm recommends noninvasive cardiac testing for patients with certain risk factors (e.g., diabetes and prior myocardial infarction) who will undergo peripheral vascular surgery. Patients with positive noninvasive-test results are generally referred for coronary angiography and — if appropriate — revascularization. Yet many of these patients have no cardiac symptoms and would not

have undergone this sequence outside the preoperative context.

Such patients are similar to many participants in the CARP trial, who derived no benefit from coronary revascularization before peripheral vascular surgery. A coauthor of the accompanying editorial, Dr. Eagle, chaired the committee that issued the guideline; however, the editorial does not directly acknowledge that the CARP results invalidate portions of the guideline.<sup>2</sup> Updated guidelines that reflect the CARP findings are now needed.

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**THE AUTHORS REPLY:** Dr. Brett is concerned about inconsistencies in the American College of Cardiology–American Heart Association guidelines on preoperative cardiac testing and revascularization. In a substudy, we showed that recommendations for preoperative revascularization deviated from those guidelines 40 percent of the time, with a 26 percent chance that opinions were widely disparate.<sup>1</sup> Perhaps the lack of pertinent randomized studies can explain the ambiguity in the guidelines.

Dr. Landesberg and colleagues have provided important information about risk stratification and stress imaging. However, we disagree with their opinion that our patients were at low to moderate risk. Two thirds of the study patients had multivessel coronary artery disease and two thirds of those undergoing stress imaging tests had a high-risk test result indicative of multivessel coronary artery disease. Three fourths of the study patients would have been considered high-risk patients on the basis of either multiple clinical risk factors or high-risk stress imaging.

We also disagree with the implication that study patients were not screened according to acceptable clinical practice. The CARP study was designed in 1993, and enrollment began before the guidelines were developed. At that time, it was acceptable to consider coronary angiography in the absence of stress imaging with three or more Eagle risk factors.<sup>2</sup> The present guidelines state that similar patients are candidates for angiography, even with “equivocal” results on noninvasive tests.<sup>3</sup> We hope

that sufficient information about the study is provided to permit clinicians to estimate the generalizability of our results to their patients and to generate new hypotheses if necessary.

Dr. Auer and colleagues are concerned that the risk of perioperative complications from in-stent thrombus is highest within six weeks after percutaneous coronary intervention, an effect that may have abolished protection after such intervention in our study. The investigators were aware of this risk, and clinical need dictated any decision regarding an earlier vascular operation. Of the 72 patients who underwent surgery within six weeks after percutaneous coronary intervention, 4 died and 1 had a nonfatal myocardial infarction. Two patients with complications underwent percutaneous transluminal coronary angioplasty without stenting, and in three of the four deaths, the cause was noncardiac (sepsis, acute respiratory distress syndrome, and renal failure). The concern about in-stent thrombus is legitimate and underscores our conclusion that revascularization with delays in the required vascular operation is not necessarily in the best interest of these patients.

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**THE EDITORIALISTS REPLY:** Dr. Brett suggests that the results of the CARP trial “invalidate” portions of the American College of Cardiology–American Heart Association guidelines for perioperative evaluation for noncardiac surgery. Although the CARP trial was underpowered to assess the value of revascularization in high-risk patients, we believe that its study design and exclusion criteria do not invalidate but, rather, complement the current guidelines recommending revascularization in patients with high-risk coronary anatomy and in whom the

long-term outcome would probably be improved by coronary-artery bypass grafting.<sup>1</sup> The CARP trial was a study about therapy, rather than screening, and it was screening that permitted the identification of those high-risk patients with left main coronary artery disease, left ventricular dysfunction, or aortic stenosis who would benefit from coronary-artery bypass grafting or valve-replacement surgery and who were excluded from the study. In addition, in the CARP trial there was a nonsignificant trend toward a benefit of revascularization in a small group of patients with multiple risk factors and a large ischemic burden, suggesting that it is perhaps premature to exclude completely a role for revascularization in those high-risk patients. We agree with Dr. Brett that the results of this landmark trial will need to be carefully weighed in the next revision of the guidelines.

Dr. Auer and colleagues raise the issue of the relationship between the duration of antiplatelet therapy and adverse outcomes in patients undergoing stent implantation before noncardiac surgery. We agree with their statement on the generally accepted timing of noncardiac surgery after the implantation of bare-metal stents (six weeks) or drug-eluting stents (up to six months). However, in the CARP study, enrollment was completed in Febru-

ary 2003, before the introduction of drug-eluting stents. In addition, vascular surgery was performed in the revascularization group at a median of 54 days after randomization (interquartile range, 28 to 80 days), and a large proportion of patients were maintained on antiplatelet therapy in the perioperative period, suggesting that the duration of antiplatelet therapy might not have been an important issue.

Dr. Landesberg and colleagues point out that the CARP study is applicable to low-to-moderate-risk patients. We agree with their statement, and we believe that the high mortality rate observed at less than three years of follow-up (23 percent) calls for a series of randomized studies to assess the value of additional therapies and of revascularization in high-risk patients.

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## Long-Term Outcome of Bariatric Surgery

**TO THE EDITOR:** The primary outcome of the Swedish Obese Subjects (SOS) Study, reported by Sjöström et al. (Dec. 23 issue),<sup>1</sup> was mortality, but only secondary outcomes are presented. There is a statement in the report that “the safety monitoring committee found no reason to interrupt the study prematurely because of positive effects or harm.” This report should not have been published without data on the primary outcome. In the absence of a significant effect on the primary outcome, the authors present the attractive changes that occurred in secondary outcomes. Solomon and Dluhy, in the accompanying editorial,<sup>2</sup> emphasize that it “is not known . . . whether . . . benefits [of changes in body weight and so forth] translate into reduced rates of . . . death.” But this is not enough. If the significant changes described are really of benefit, why do they not translate into a reduced death rate? A simple explanation is that these changes are not as good for health as they appear to be. If the out-

come was not changed under the treatment, the most likely explanation is that the treatment is not effective.

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**DR. SJÖSTRÖM REPLIES:** Dr. Vlassov suggests that our article on changes in risk factors 10 years after surgery in the SOS Study should not have been published, since the primary outcome of SOS (i.e., total mortality) was not reported. SOS is a controlled intervention trial that was started in 1987 with plans for continuation until 2020. In addition to the pri-