EDITORIAL COMMENT

Guidelines for Surgical Standby for Coronary Angioplasty: Should They be Changed?*

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In this issue of the Journal, Wharton et al. (1) report their experience in performing coronary angioplasty for acute myocardial infarction at two community hospitals, both of which being geographically remote from the nearest cardiovascular surgery facility. Their article re-addresses some fundamental questions about the nature of, and the need for, mandatory cardiovascular surgical standby.

CARDIOVASCULAR SURGICAL STANDBY: WHAT DOES IT MEAN?

Aortocoronary bypass surgery has been an option for treating coronary artery occlusive disease since the late 1960s; in that sense, it has been “standing by” for three decades as a backup for failed cardiologic treatments. In the late 1970s, balloon angioplasty was introduced for treating coronary artery disease. This procedure is performed in a radiology suite (the catheterization laboratory), on an awake patient, in the absence of effective circulatory support. In the early days of coronary angioplasty, catheter devices were far from reliable, entailing a high risk of coronary dissection, plaque disruption, elastic recoil, clot formation and other serious complications. To improve the safety of catheter coronary interventions, the founder of balloon angioplasty, Dr. Andreas Gruntzig, initiated the practice of having a cardiovascular suite and appropriate personnel (including a surgical team) ready and available next to the catheterization laboratory during coronary angioplasty.

In their 1982 guidelines (2), the American Heart Association (AHA) and the American College of Cardiology (ACC) endorsed Gruntzig’s original practice when they recommended that obligatory surgical standby be available for all coronary angioplasty procedures. Even during the early years, however, it became clear to experienced angioplasty operators that active surgical standby was not strictly necessary for most of the patients treated at large, highly experienced cardiovascular centers (3). The literature contains a few reports (reviewed by Wharton et al.), concerning the safety, efficacy and cost-efficiency of performing elective coronary angioplasty in hospitals that lack a cardiovascular surgery department. This practice has never become established, at least in the U.S., and controlled prospective multicenter trials have never been carried out to validate its safety. Currently—mainly because of medical, legal and institutional concerns—the accepted standard is still to perform coronary angioplasty only at institutions that offer cardiovascular surgical services on the same premises. This requirement was reiterated in 1993 by the ACC and AHA guidelines (4). In most U.S. cardiovascular centers, however, it has become common practice to rely on preoperative risk assessment and to institute different degrees of surgical standby (in some cases virtual, in other cases actual), especially in light of cost-efficiency considerations.

Coronary Stenting Reduces the Need for Surgical Standby. Since the introduction and popularization of coronary stenting in the early 1990s, the already weakening case for mandatory surgical standby during coronary angioplasty has become more tenuous. In the first years of experience with fixed-wire balloon catheters, the incidence of urgent coronary bypass surgery ranged from 10% to 25%; by the late 1980s, the incidence had decreased to 2% to 5%, and since 1995, it has been less than 1% (5–7). Now that coronary stents are used in 60% to 80% of coronary angioplasty cases in major interventional cardiology departments worldwide, mandatory surgical standby during coronary angioplasty seems out of touch with reality and is certainly not cost-effective. In fact, active surgical standby implies the actual preparation of a surgical suite and a primed cardiopulmonary bypass pump and circuit as well as the ready availability of anesthesia, perfusion and surgical teams. Even if these services are not used, the cost of preparing and keeping them available ranges from 1,000 to 1,500 U.S. dollars. Interestingly, many U.S. health care providers have followed the example of the federal Health Care Financing Administration (HCFA), which administers Medicare and Medicaid and has introduced fundamental “innovations” in health care. Since 1993, HCFA stopped reimbursing for surgical standby during coronary angioplasty.

Does Angioplasty for Acute Myocardial Infarction Necessitate Surgical Standby? The use of angioplasty as a primary means of urgent revascularization in the treatment of acute myocardial infarction has become a common approach for reasons that have been extensively discussed in the recent literature (5,8,9). In this setting, the cost/benefit ratio for surgical standby is even less favorable than in the setting of elective angioplasty. During the early phase (more

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than 3 h and less than 15 to 30 days) after an acute myocardial infarction, the patient is generally a poor operative candidate and is rarely referred for surgical treatment. At well-equipped centers with experienced angioplasty operators, the probability of successful guidewire passage is about 99% in patients who undergo angioplasty during this phase; moreover, balloon (and better yet, stent) angioplasty is 95% to 99% successful in reducing the degree of stenosis to less than 50%. The no-reflow phenomenon—flow less than Thrombolysis in Myocardial Infarction (TIMI) grade 2 to 3 in the presence of a nonstenotic lesion—is a persistent problem, especially in hearts revascularized more than 3 h after the onset of chest pain, but surgical revascularization, per se, would not favorably affect this phenomenon. Moreover, distal clot embolization, a relatively common although seldom-recognized complication of acute myocardial infarction angioplasty, cannot be treated effectively even with coronary artery bypass surgery. In contrast, balloon counterpulsation or aggressive use of a left ventricular assist device may improve the prognosis for both of these conditions.

In their 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty, the ACC and the AHA recognized the special nature of angioplasty for acute myocardial infarction with respect to the need for surgical standby. According to these guidelines, well-trained operators, in well-equipped laboratories, may perform angioplasty in high-risk cases of acute myocardial infarction even in the absence of active surgical standby, because angioplasty clearly yields better results than intravenous thrombolysis in some subsets of patients.

Since 1993, we have seen the advent of new-generation stents that offer excellent performance in the setting of acute myocardial infarction (5,7); we have also seen the introduction of new anticoagulant regimens, especially those based on the usage of newer antiplatelet agents (10), that offer well-proven efficacy during angioplasty for acute myocardial infarction (11–13). Because of these advances, the general opinion is that mandatory surgical standby during angioplasty for acute myocardial infarction is no longer necessary. However, in this setting, any catheter intervention requires a highly trained team and a broad range of interventional devices, which one would hardly expect to find in hospitals without elective angioplasty and cardiac surgery programs.

**THE EXPERIENCE OF WHARTON AND COLLEAGUES**

Wharton and colleagues (1) used an adapted angioplasty protocol and policy in an atypical situation. Their approach involved routine, systematic, emergency angiography in patients clinically suspected of having an acute myocardial infarction, followed by routine “angioplasty if needed and deemed likely to succeed,” mainly using only balloon catheters; the procedures were carried out at two hospitals, each of which lacked a surgical program and was located 45 to 55 minutes (by ground ambulance) away from the nearest cardiac surgery center. Apparently, both practices (routine emergency angiography and routine angioplasty in a center lacking surgical standby) were prospectively approved as exceptions to accepted guidelines by competent institutional review boards. Did the protocol allow the authors to reach meaningful conclusions about the legitimacy of these treatment modalities? Was the absence of surgical standby relevant to the results of this unusual practice?

This trial should be considered to be only an observational study with positive indications. There is no doubt that even in the absence of surgical standby, highly trained interventional cardiologists working in well-organized and well-equipped catheterization laboratories and relying on the support of competent, dedicated hospital personnel, can obtain results similar to those commonly obtained in centers with cardiac surgery services (which are rarely used in this context anyway). Wharton et al. suggest that multicenter studies be undertaken to prove that emergency angiography and angioplasty can be safely offered universally in hospitals without surgical backup; such studies would seem irrelevant, however, in the United States, where cardiovascular centers with surgical services are available in great numbers and emergency transfer by ambulance or helicopter is possible within a reasonable period. It seems to me that the experience of Wharton and associates reflects a general oversupply and maldistribution of well-trained specialists in the U.S., a trend that promotes neither cost-efficiency, optimal use of resources, nor excellence of service, but only improved distribution.

**CONCLUSIONS**

The important question that remains to be addressed, especially in the light of recent clinical experience with coronary stents and newer anticoagulation protocols, concerns the general need for surgical backup during coronary angioplasty in any center with a well-trained staff. Hasn’t coronary angioplasty finally gained sufficient technological maturity and professional confidence to be self-reliant and free-standing? No physician or medical specialty can claim to be totally self-sufficient, but interventional cardiologists have gained a consistent, dependable proficiency that should enable them to declare their independence from surgery. Once this occurs, surgical standby will be reserved only for exceptional circumstances, although emergency cardiac surgery will remain an option for treating crises that arise in the catheterization laboratory (during either diagnostic or interventional procedures), as well as in the emergency room or any hospital ward. Because many patients may be properly and successfully treated with either angioplasty or coronary bypass surgery, the ultimate choice of treatment should depend on balanced information, open discussion, and the results of prospective randomized, comparative studies. Whether the guidelines for surgical standby during coronary angioplasty are changed or not, continued collaboration
between cardiologists and their surgical colleagues will remain essential for optimal clinical care.

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**REFERENCES**