LETTERS TO THE EDITOR

Angioplasty for Acute Myocardial Infarction in Community Hospital Without Surgical Back-Up: Response to Wharton and Angelini

Publications “Should Guidelines Be Changed?: Not Whether but When”

Guidelines evolve in response to rigorously acquired evidence-based data. Thus, the validity of any guideline to describe a current standard of care is dependent on the robustness of the database from which it is derived. The recent publication by Wharton et al. (1) and the accompanying editorial comment by Angelini (2) may be the bell weather for a new guideline for the treatment of acute myocardial infarction (MI) with coronary angioplasty in community centers without on-site surgical back-up. The series of patients with evolving MI who underwent emergency coronary angiography with or without percutaneous coronary intervention (PCI) reported by Wharton et al. (1) represent a successful experience from a single, prospective clinical approach. However, in considering new guidelines for the treatment of patients with acute MI, one must recognize that this isolated experience represents neither a randomized clinical trial nor a prospective parallel comparison of outcomes, achieved at facilities without cardiothoracic surgical backup.

Before attempting to extrapolate such findings (1) to clinical practice, several concerns merit discussion. As Wharton et al. (1) note, clinicians will need “standards for the performance of primary angioplasty for operators, laboratories and institutions.” Although the “operators” in this report (1) are “experienced interventionalists who regularly perform elective intervention at a tertiary surgical center,” defining yearly volume, credentialing the operators, and quantifying a satisfactory cumulative experience are all critical to the process. Operators and credentialing committees should remember that 72% of all interventional procedures performed in the U.S. were done by operators who performed ≤50 interventions yearly (3). Recent data suggest that optimal outcomes (lowest incidence of death and/or urgent revascularization) are achieved with individual operator volumes exceeding 75 to 150 procedures yearly (4–6). This “practice makes perfect” concept (7) has gained broad support (8,9). It should be no surprise that the ACC/AHA Task Force Committee has adhered to the recommendation for performance of ≥75 interventional procedures yearly to maintain competency (10). Extrapolation of results from studies without such data may be misleading.

We agree with Wharton et al. (1) that there is a need to establish “a nursing and technical catheterization laboratory staff (that must be) experienced in handling acutely ill patients and comfortable with interventional equipment.” The care of an acutely ill patient with an evolving MI undergoing coronary angioplasty oftentimes involves handling multiple IV drips, the placement of an intra-aortic balloon pump, managing ventricular ectopy, and intubation and ventilation. This requires an extremely experienced support team (in addition to an experienced interventionalist), which is less likely to be available in a hospital performing only primary angioplasty procedures. As with operator experience, recent data link institutional volume with procedural outcomes (4,11,12), such that optimal procedural outcomes are achieved with institutional volumes exceeding 600 interventional procedures yearly (6), a volume unlikely to be achieved in hospitals performing only primary coronary angioplasty. The qualifications and quality of the technical staff in low volume institutions should be carefully examined.

Although it is true, as Dr. Angelini indicates, that “coronary stents are used in 60% to 80% of coronary angioplasty cases in major interventional cardiology departments worldwide . . . surgical standby during coronary angioplasty seems out of touch with reality and is certainly not cost effective,” the nature of surgical standby has clearly changed. Whether surgery is on-site or 30 min away, the central issue is whether hospitals without on-site surgery will perform too few interventional procedures to ensure optimal outcomes. More importantly, the availability of on-site surgical standby is a surrogate for institutional volume and, to a large extent, program quality. Similarly, merely equipping a laboratory with stents does not negate the impact of operator quality, case volume, or credentialing. It is noteworthy that a recent multivariable analysis identified low operator volumes as an independent hazard for adverse clinical outcomes following elective coronary stent deployment (12).

Guidelines generally do not address logistics. Wharton et al. (1) remind us that the catheterization laboratory must be “well-equipped with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump support, and a broad array of interventional equipment.” The cost of maintaining a 24-h on-call team and a well-equipped laboratory in a facility that performs only 50 to 100 procedures per year may be prohibitive. Furthermore, recent data (13–15) suggest complementary benefit is derived from stents and abciximab as adjunctive therapy during PCI for evolving MI. The cost consequences of these recent valuable technologies must also be considered.

Operators and community hospitals should be concerned about the management of the few patients requiring emergency surgery. Although formalized protocols for “immediate efficient transfer of patients to the nearest cardiac surgical facility” are recommended (1), details of such a protocol are not provided. In the MITI Registry (16), patients undergoing primary angioplasty at facilities without on-site surgery were less likely to receive bypass surgery. The impact of this strategy on patient outcome is unclear. Unequivocal guidelines for patients from mobile labs and the status of ambulance availability for stable and unstable patients, as well as criteria for having a physician in attendance during transfer, need to be established. Time limits for availability of transport and access to a tertiary center should be prespecified and followed.

Perhaps acute invasive interventions in diagnostic laboratories without an on-site surgery will be superseded by recent advances in pharmacotherapy with combination reduced dose fibrinolytic and platelet GP IIb/IIIa therapy (17), making observations such as those by Wharton et al. (1) obsolete (18). For example, the restitution of normal, TIMI grade 3 flow in more than 70% of patients within 60 min of instituting such combination therapy (17,19) might be preferable in some community hospitals to invasive reperfusion at an average of 94 min between hospital arrival and first coronary angiogram (or 109 min until first balloon catheter inflation noted in Wharton’s community hospital experience). Cost efficacy of these disparate community hospital-based approaches to acute infarct reperfusion deserves further study.
To date, large-scale community experience (MITI, NRMI) has not reproduced the results of the randomized trials such that mortality is similar between patients receiving thrombolytic therapy and primary angioplasty. Furthermore, it is unclear how fast reperfusion can be achieved in these settings. In NRMI-2, the median “door to balloon” time for thrombolytic eligible patients was 111 min. Only 10% of the patients were treated within 1 h and approximately 60% between 1 and 3 h after hospital arrival (20).

The availability of catheterization laboratories is also a concern. Although the majority of the Medicare population lives within 50 to 100 miles of a catheterization laboratory, not all laboratories have angioplasty capabilities. Extending primary angioplasty to diagnostic laboratories and withdrawing the need for on-site surgery for elective angioplasty will promote low volume situations. Based upon the paucity of data suggesting that primary angioplasty in the community is superior to thrombolytic therapy in terms of mortality and that volume and outcome are not as closely related in the setting of primary angioplasty, it is not yet time to change a public policy that will affect millions of people and cost billions of dollars.

In the context of the above-noted concerns, the report by Wharton et al. (1) on primary angioplasty for evolving MI in community hospitals without cardiac surgical backup is provocative. However, in extrapolating this innovative approach to a broadly applicable standard of care, we strongly urge caution. We commend these operators for achieving competitive outcomes compared with both historical and current tertiary medical center results. We believe the answer to Dr. Angelini’s question, “Guidelines . . . Should they be changed?” is not “whether” but “when.” Any substantive change in the present guidelines must be “evidenced based” and in the context of rigorously acquired and analyzed data. As such, the AHA/ACC PTCA guidelines undergoing updating should provide current and valid recommendations that are readily applicable to the broad scope of clinical practice by interventional cardiologists.

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