it will be necessary in the future to study the possible role of the mechanisms of neurogenic regulation of vascular tone and of hormonal and metabolic processes, which we did not evaluate in our study.

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doi:10.1016/j.jacc.2006.04.050

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Hubris Versus Evidence

Yang et al. (1) from the Mayo Clinic have made a valuable contribution to the growing evidence supporting the current safety of percutaneous coronary intervention (PCI). Unfortunately, in the accompanying editorial, Bittl (2) digresses from this evidence to attribute “hubris” (arrogance resulting from excessive pride) to those who support PCI at qualified hospitals with off-site surgical backup.

Abundant recent data demonstrate the safety of PCI at qualified hospitals with off-site surgical backup (3,4), which neither Bittl (2) nor the PCI guidelines evaluate. This steadily growing practice is supported by many thought-leaders with no perceived hubris (cited elsewhere [4]), including Singh, the senior author of the present report (5), by the guidelines of five other countries, and (tacitly) by the European Society of Cardiology (6). The only negative study cited by the guidelines is based on claims-coding Medicare data and pertains only to “non-primary/rescue” PCI at ultra-low volume sites (<50 Medicare PCI/yr) (7).

The speculation that emergency surgery after PCI would be more frequent at non-“premier” centers neglects the available data and is based on theoretical arguments. The notion that most hospitals cannot replicate the outcomes at the Mayo Clinic is unfounded. In fact, the Mayo Clinic itself supports PCI at off-site hospitals; these have had no surgical emergencies in 1,700 procedures (5). It should be recognized that satellite hospitals are inherently motivated to use the most careful case-selection (5) and generally do not perform the most complex procedures nor use higher-risk equipment. A fundamental paradox is built into the PCI guidelines themselves, in that they accept off-site backup only for primary PCI but not for nonemergent PCI despite their advocacy of higher procedural volumes to improve quality.

The assertion that the surgeon’s presence in the catheterization laboratory after a complication somehow lessens the patient’s risk compared to a direct telephone conversation between colleagues is only theoretical and ignores the reality that even on-site PCI complications may occur when the surgeon is occupied in the operating room, is in an off-site office, or is at home during off-hours.

Indeed, the very intensity of this debate over surgical backup, replete with inappropriate rhetoric, might suggest that there are other agendas being raised by this question that have little to do with the published data.

In this era when the importance of evidence-based medicine is universally recognized, proffering speculation as established conclusions while ignoring considerable data could itself be considered a form of “academic hubris.” The advantages of increased access, increased procedural volumes, and the resultant shorter door-to-balloon times that are documented for PCI at nonsurgical hospitals (8) may far outweigh any proposed disadvantages of offering both primary and nonemergent PCI with off-site backup.

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doi:10.1016/j.jacc.2006.04.049

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I am grateful to Dr. Wharton for his interest in the editorial (1) about the declining need for emergency bypass surgery for failed percutaneous coronary interventions (PCIs) at the Mayo Clinic (2).

The Mayo report (2) and the current PCI guidelines raise the issue of what constitutes adequate evidence to perform elective PCIs in community hospitals without on-site bypass surgery. Although Wharton et al. (3) showed that direct PCI is superior to fibrinolytic therapy for ST-segment elevation myocardial infarction in a broad range of hospital settings, this level of evidence is currently lacking for elective PCIs without on-site bypass surgery in the U.S. The Mayo report (2) does not prove that it is safe to perform elective PCIs without on-site surgery in Exeter, New Hampshire, or anywhere else.

The assessment of elective PCIs without on-site bypass surgery underway in some states (4) is a step in the right direction. However, choosing the right metrics is challenging. An observational matched cohort analysis constitutes a good start, but results from a single pair of closely linked hospitals within one health care delivery system are not broadly generalizable (5), and statistical tests for non-inferiority require larger comparison groups.

The motivation to perform an elective PCI without on-site bypass surgery needs clarification. “During its ~28-year-history, elective PCI has never been shown to extend life or prevent death” (4). The recent proliferation of cardiac procedures in North America has not been explained by an increased prevalence of disease but has generated serious questions about the value to individual patients and society (6). Costs will increase further in the absence of safeguards to limit the inevitable expansion in the number of hospitals performing PCIs.

Finally, the term “hubris” in the editorial (1) has rankled some readers. The medical meaning, based on the classical character flaw of arrogantly flaunting natural law and suffering tragic consequences, connotes more than the dictionary definition. Even the most gifted physicians can be humbled by unforeseeable twists and turns in the response to treatment. But I digress.

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doi:10.1016/j.jacc.2006.04.048

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doi:10.1016/j.jacc.2006.04.047