Get With the Guidelines: A New Chapter?

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For more than 25 years, the American College of Cardiology (ACC) and the American Heart Association (AHA) have collaborated on clinical practice guidelines in an effort to improve the quality of care in this country. Studies in the early 1990s showed that the medical therapy recommended by the guidelines was frequently not followed. Both organizations initiated programs to improve the implementation of guidelines, which focused on medical therapy in patients with known coronary artery disease, acute coronary syndromes, and congestive heart failure. However, there have been relatively little data regarding the implementation of guidelines, which focused on medical therapy in patients with known coronary artery disease, acute coronary syndromes, and congestive heart failure. Therefore, there have been relatively little data regarding the implementation of guideline recommendations for revascularization.1

In this issue of Circulation, Hannan et al2 have completed an important study on that subject. Using the resources of the New York State Cardiac Diagnostic Catheterization database, the authors examined the recommendations for revascularization made by the catheterization laboratory cardiologist in 10,333 patients for whom that physician was the final source of the recommendation. Their findings suggest that 94% of patients for whom percutaneous coronary intervention (PCI) was indicated by the guidelines were recommended for PCI, and that 93% of patients for whom either bypass surgery (CABG) or PCI was indicated by the guidelines were recommended for PCI. A more controversial finding from this study relates to patients for whom the ACC/AHA guidelines indicated CABG, inasmuch as only 53% of these patients were recommended for CABG by the catheterization laboratory cardiologist, and 34% of these patients were recommended for PCI. Of patients for whom neither CABG nor PCI was indicated by the guidelines, 6% were recommended for CABG, and 21% were recommended for PCI.

Before we accept or interpret these findings, we must carefully review the authors’ methodology and the fundamental general limitations of guidelines. As the authors indicate, it is not easy to apply clinical practice guidelines to medical databases, and it is even more difficult when more than 1 guideline, with potentially subtle differences in wording and patient descriptions, are involved. To facilitate application of the ACC/AHA guidelines for CABG and PCI, the authors constructed three separate complex flow diagrams (Figures 1 to 3) for patients with mild (Class I–II) or no angina, Class III stable angina, or unstable angina/non–ST-elevation myocardial infarction. Although I recurring criticism of clinical practice guidelines is that they are “too complicated,” my experience with several ACC/AHA guidelines has convinced me that it is extraordinarily difficult to summarize the complex process of clinical decision making in a simple flow diagram. I suspect that the construction of Figures 1 to 3 was a very difficult task, and I commend the authors for their effort.

How well did the authors do? Their Figure 2 attempts to summarize the Class I and Class Ia recommendations for PCI and CABG for patients with Class III stable angina. Although this flow diagram does generally well, there are some potential problems. Consider a patient with Class III angina, two-vessel disease with a normal ejection fraction, proximal LAD stenosis without left main stenosis or its equivalent, whose anatomy is not suitable for PCI, and has moderate but not extensive ischemia. CABG is a Class I indication in the guidelines for such a patient, but the authors’ Figure 2 seems to suggest that neither CABG nor PCI is indicated. Thus, Figure 2 seems to incorrectly assign some patients with Class I guideline indications for CABG to the “neither CABG nor PCI” category.

As acknowledged by the authors, another limitation of their study is the absence of any details of medical therapy in the database. Many of the recommendations in the PCI and CABG guidelines specifically assume prior medical therapy. Experienced clinicians will make different recommendations for revascularization to patients who have not yet received any medical therapy and are referred for coronary angiography to resolve some uncertainty regarding their findings on noninvasive testing, compared to patients with classic symptoms, and definite ischemia on noninvasive testing, who are already taking maximal medical therapy.

Finally, as also acknowledged by the authors, guidelines are just that—guidelines. They are meant to provide clinicians with the best summary of evidence-based therapy and expert opinion. However, they are not intended to replace patient-centered decision making by experienced clinicians.

Despite these limitations, several of which are inevitable in any registry study, the data of Hannan et al provide important insights into whether contemporary clinical practice follows the ACC/AHA guidelines for revascularization, and an opportunity to examine potential overuse, underuse, and misuse of both PCI and CABG.

Do these data demonstrate overuse? Of potential concern are the 27% of patients recommended for either procedure in the “neither CABG nor PCI” category and the number of patients recommended for either procedure when the other was indicated by the guidelines. For example, 455 patients were recommended for PCI although the ACC/AHA indication was for CABG, and 261 patients were recommended for

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PCI when “neither CABG or PCI” was indicated. However, these 716 patients represented only 9% of the total of 7,984 patients recommended for PCI. Similarly, for CABG, 124 patients were recommended for CABG although the ACC/AHA guidelines indicated PCI, and an additional 70 patients were recommended for CABG when “neither CABG nor PCI” was indicated. Somewhat surprisingly, these 194 patients represented 20% of all the patients recommended for CABG. However, given the fundamental limitations of guidelines, the apparent error in Figure 2 and recognition that the “neither CABG nor PCI” category included patients with Class IIb recommendations (“may be considered”) for PCI and/or CABG, I do not think the data suggest overuse.

Do the data suggest underuse? Probably not. Although 12% of the patients indicated for CABG by the ACC/AHA guidelines were recommended for medical treatment, and 4% of those indicated for PCI were recommended for medical treatment, both of these relatively low percentages potentially reflect patient preferences and the fundamental limitation of guidelines in an increasingly elderly population with multiple comorbidities. However, as the authors correctly indicate, a definitive answer to this question would require data regarding the patients who did not undergo coronary angiography.

Do these data suggest misuse? This important issue is emphasized by the authors. Approximately one third of the patients indicated for CABG were recommended for PCI, and this percentage varied from 17% in hospitals without PCI or cardiac surgery capabilities to 43% in those hospitals with these capabilities. (The apparent error in Figure 2 might have caused an underestimate of the magnitude of this problem.) What are the potential explanations of these findings?

First, these findings might simply reflect the underlying limitations of the study that have been already outlined. In particular, patients with diabetes and suspected multivessel disease who were informed of the guideline recommendations before catheterization might have expressed a clear preference for PCI.

However, these findings might also reflect a lack of acceptance of the guidelines by the catheterizing cardiologist, for particular patient subgroups, such as diabetic patients with multivessel disease. After publication of the BARI trial,3 many interventionalists continued to perform PCI in diabetic patients with multivessel disease.4 The data of Hannan et al were acquired before publication of a systematic evidence review that reported no advantage of CABG over PCI in diabetic patients with multivessel disease.4 However, the most recent analysis of the pooled randomized trial data on an individual patient basis has confirmed a consistent benefit for CABG in such patients, supporting the ACC/AHA guideline recommendations.5

Moreover, physicians who are trained to do certain procedures will naturally tend to do them. This is not unique to coronary intervention. Echocardiographers refer more patients for echocardiography, and nuclear cardiologists refer more patients for single photon emission computed tomography. There is a natural human tendency for us to believe in what we do.

Another potential explanation for these data are that they represent the “supply-sensitive care” described by researchers at Dartmouth.6 When medical facilities (in this case, PCI facilities) are available, they are utilized more often.

A final potential explanation, and in my view the most concerning, is that these recommendations for PCI in patients indicated for CABG reflect a “grow the business” and “make it up on volume” mentality in response to declining reimbursement rates.2 I believe that this attitude accounts for at least some of the dramatic growth in imaging over the past decade. The current reimbursement system favors tests and procedures. There are compelling financial incentives for cardiologists performing intervention to do more procedures, even when the patient might be better treated with CABG. Until there is significant reform of the medical payment system, which is part of the current healthcare reform debate, we will not know the true magnitude of this effect.

Can these findings from New York State be extrapolated to the rest of the country? Only to some areas. There are widespread regional variations in medical expense, which have been the subject of many previous studies. “Researchers have reported that, after controlling for local practice costs, health status, and demographics, between one-half and three-fourths of total variation in spending remains unaccounted.”7

Utilization rates vary widely across the country and likely contribute to these differences in cost. Figure 1 shows Medicare PCI rates in different hospital referral regions (healthcare markets) in the United States for 2005, during the study by Hannan et al9 The rates of PCI in different healthcare markets in New York State vary from a low of 6.2 per 1,000 Medicare beneficiaries in Binghamton to a high of 13.0 in Manhattan—a greater than twofold difference. The New York State rates are generally comparable to the rates in Rochester, Minnesota (9.7), or Cleveland, Ohio (13.1), where the Mayo Clinic and the Cleveland Clinic, respectively, dominate cardiovascular practice. However, the highest PCI rate in New York State is lower than the rate in 69 other healthcare markets (23% of the nation’s 305 markets), and only one third of the nation’s highest rate of 39 in Elyria, Ohio (which is not shown on Figure 1 to avoid compression of the other points).
There is similar variability for CABG (Figure 2). The rates for New York State are almost all below the national average of 4.5 and are similar to the rates for Rochester and Cleveland. The highest rate for CABG in New York State (4.6 of 1,000 Medicare beneficiaries in Syracuse) is less than one half the rate of 9.8 in McAllen, Texas—the well-publicized, second most expensive healthcare market in the country. These data from New York State may therefore offer insight into current clinical practice in those regions with comparable utilization of PCI and CABG, but they should not be extrapolated to the multiple regions with higher rates.

Should surgical consultation be encouraged, as suggested by the authors? For patients for whom ad hoc PCI remains the best option, particularly those with refractory unstable angina, the risk of delay to permit such a consultation does not seem justified. However, there are many other patients with stable symptoms for whom issues of contrast load, and the need for further discussion with the patient, dictate that PCI is best performed on a different day. In such patients, surgical consultation should be considered but not mandated.

These data should concern the general cardiology community, particularly interventional cardiologists. We must carefully consider whether “supply-sensitive care,” a “grow the business” mentality, and self-interest are unfortunately influencing our clinical judgment. The profession needs to critique and improve itself to avoid the arbitrary imposition and burden of either mandatory precertification requirements or postprocedure review, which will interfere with patient-centered care and the doctor–patient relationship. The pace of current clinical practice and the increasing use of ad-hoc PCI make this difficult. Both the SCAI and the ACC/AHA guidelines have indicated that ad hoc PCI should not be the standard strategy for all patients. Another study from the New York State database showed that the priority of intervention was elective in 48% of the patients undergoing ad hoc PCI. For patients in such stable condition, we should consider less ad hoc PCI.

Additional studies of this important issue are clearly warranted. Hannan et al are to be congratulated for this groundbreaking effort. In the meantime, we must carefully examine our own recommendations on a daily basis.

In our current seriously flawed healthcare system, with its perverse economic incentives, this is a major challenge.

Disclosures
None.

References

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