variant angina and normal coronary angiograms. Our results suggest that basal production/release of NO may not be decreased at spastic sites in these patients. We did not investigate the NO-generating capacity or vasomotor responses to vasoconstrictor stimuli at the site of spasm. Therefore, we cannot conclude that the NO-generating capacity is augmented at spastic sites.

Tousoulis et al. proposed an intriguing hypothesis that atherosclerotic human coronary arteries can regenerate basal NO production from an abnormal source, such as the inducible isoform of NO synthase. This hypothesis is based on the fact that patients with variant angina have varying degrees of coronary atherosclerosis and that the inducible NO synthase is found in some human coronary arteries and that with atherosclerotic lesions. It has been demonstrated that total NO-generating capacity is altered during the process of atherosclerosis (1); however, its precise mechanism has not been well understood. There is substantial evidence demonstrating that endothelium-derived NO-related vasodilation is impaired early in atherosclerosis (1). However, the results of recent investigations (2,3) suggest that endothelial constitutive NO synthase messenger RNA and NO protein production are augmented in atherosclerotic vessels. These findings suggest that altered NO-related vasomotion during atherosclerotic process might result from an increased breakdown of NO but is not necessarily related to expression of inducible NO synthase. This hypothesis is based on the fact that patients with variant angina and normal coronary angiograms. Our results suggest that basal production/release of NO may not be decreased at spastic sites in these patients. We did not investigate the NO-generating capacity or vasomotor responses to vasoconstrictor stimuli at the site of spasm. Therefore, we cannot conclude that the NO-generating capacity is augmented at spastic sites.

KENSUKE EGASHIRA, MD
Research Institute of Angiology and Cardiovascular Clinic
Kyushu University School of Medicine
Fukuoka 813-85, Japan

References

Cost Efficacy Modeling of Catheter Reuse for Percutaneous Transluminal Coronary Angioplasty

I wish to comment on the report by Mak et al. (1) and indirectly on the accompanying editorial by Natarajan and Williams (2). Although the report by Mak et al. is well written and discusses an important topic, it seems to me that the authors have made several major assumptions in their cost analysis that have gone unstated and unexamined. In particular, the authors assume that the price, or cost, of balloon catheters is a fixed quantity and would not change if the results of their study were applied widely, even for a subset of patients with stable angina. Would the medical device industry really be able to continue to charge the same price for balloon catheters if the total number sold was reduced by 80% ("best" case)? How can this possibly make economic sense, since presumably the marginal cost for the production and sales of any product is dependent, to some extent, on the volume of sales. The authors might argue that their analysis is one of microeconomics and that the "system" would not be affected if the results of their analysis were applied only on a small scale, to their medical center, say. Yet their motivation is clearly macroeconomic in scope because they claim that "if coronary angioplasty equipment could be reused [based on the results of this and other studies], the total cost could be potentially reduced by more than $1 billion per year in the United States." The systemic implications of this type of inquiry are also implied by the accompanying editorial, which refers to the yearly total charges for angioplasty in the United States of $6 billion.

The reason for this glaring oversight is important is that this report, and others like it, will be used by policymakers interested only in short-term cost reduction and not on the larger question of who should bear the cost of innovation, including innovation that might ultimately (but not necessarily immediately) reduce overall costs and improve care. When policymakers advocate reuse, even in "low risk" settings (or any such "cost reduction"), they are reducing the incentive for entrepreneurs and inventors to develop new technologies that might ultimately improve outcomes. This is not to excuse manufacturers from pricing devices or drugs so as to result in unreasonably high profits, but it needs to be remembered that the costs of developing any new medical technology are large and growing, and industry bears the majority of such costs. Those costs are in turn built into the price of each device sold, and if fewer are sold, either the price must rise concomitantly or innovation will simply not occur.

Another cost not mentioned is that associated with the medicolegal ramifications of reuse. Although reuse of balloon catheters labeled "single-use only" is not a prima facie violation of standard of care, it certainly transfers some of the medicolegal burden to those who willingly violate Food and Drug Administration labeling. Thus, one can reasonably assume that in some percentage of cases where reused catheters cause a complication or additional procedure that might not have occurred with a new catheter, a patient will become a plaintiff with a willing attorney and medical expert willing to say that reuse violates standard of care. Furthermore, in some of those cases the jury will agree with the plaintiff and award damage costs on the order of 10 to 20 times actual costs. If this series of assumptions is entered into the cost-utility model developed by the authors, it might well shift the cost-utility toward single use.

A final issue that was not discussed in the report by Mak et al. relates to the way in which some part of hospital cost savings are implicitly shifted as expenses for physicians, without any clear mechanism for the physicians to recoup those extra expenses. In particular, procedures performed with reusable catheters are likely to take longer (81 vs. 68 min was used in the study by Mak et al.), with much of that extra time requiring exposure of the operator to potentially harmful fluoroscopic radiation. Thus, the hospital saves money on catheters while physician reimbursement per unit time falls (because he or she is not likely to collect more for the same procedure, which takes longer simply because of reuse), and his or her long-term risk of radiation exposure rises. Perhaps when physicians and hospitals are in a true revenue-sharing relationship (such as in a provider-owned health maintenance organization or foundation such as the Cleveland Clinic), this cost shifting is irrelevant, but in most delivery systems and hospitals, both for-profit and not-for-profit, including our own University Medical Center, cost savings by the hospital are not transferred to the physicians, even if they incur additional expenses. This is, of course, an issue that goes well beyond that of balloon catheters and gets into the matter of how willing we should be, as physicians and researchers,
to assist hospitals in their cost-saving measures when such measures are potentially detrimental to our patients and ourselves.

MICHAEL D. LEUK, MD, FACC
University of California, San Francisco
500 Parnassus Avenue
Room MU428, Box 1354
San Francisco, California 94143-1354

References


Reply

We thank Lesh for his comments. Despite the limitations of our study, we believe that our models were instructive in illustrating cost savings associated with reuse of balloon catheters in various scenarios. We agree that the cost of balloon catheters may vary as a function of a new "reuse" era in interventional cardiology. As such, we have constructed a sensitivity analysis based on the different costs of balloon catheters in our report (1) (Fig. 2). As the cost of balloon catheters increases, the potential for savings is also greater. This analysis preempts Lesh’s criticism.

Medicolegal problems may arise after complications from any medical or surgical treatment. Indeed, with regard to reuse of balloon catheters, several other clinical and technical issues require further consideration (2). An important point highlighted by the study by Plante et al. (3) was the possibility of a higher complication rate when reusing catheters. However, a preliminary report from another Canadian study (4) suggested that reuse of balloon catheters was not associated with an increase in complications. Furthermore, a reanalysis of the study by Plante et al. (3), using multivariate logistic regression modeling, also suggested that reuse of balloon catheters was not associated with increased in-hospital complication rates (5). If these results are replicated in other large, randomized trials, then it would indicate that reusing balloon catheters may be as safe as using new ones, provided that the process of cleaning, sterilization, reprocessing and packaging is performed properly. In summary, for reuse to be practiced widely in the United States, there has to be some form of discussion among representatives from policymakers, industry and health care providers.

Koon-Hou MAK, MBBS
ERIC J. TOPOI, MD, FACC
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

References