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Rotational Atherectomy for In-Stent Restenosis

ABSTRACT & COMMENTARY

Synopsis: *In symptomatic patients with in-stent restenosis, rotational atherectomy is a safe and feasible technique and has a low "re-restenosis" rate relative to balloon angioplasty.*

Source: Sharma SK, et al. *J Am Coll Cardiol* 1998;32:1358-1365.

New stents with improved stent technology have made it easier to go where no stent has gone before. Unfortunately, both the increasing use of stents, in general, and the ability to stent previously unstenable lesions has led to an increase in the prevalence of in-stent restenosis (ISR). Since ISR is secondary to neointimal proliferation, debulking intimal hyperplasia prior to balloon angioplasty is an appealing approach to this problem. Sharma and associates sought to evaluate the clinical safety and long-term results of rotational atherectomy for the treatment of in-stent restenosis. One hundred consecutive patients with symptomatic first-time ISR underwent rotational atherectomy. All had stents of at least 3.0 mm deployed with high-pressure inflations. Restenosis was defined as a greater than 50% diameter stenosis within or at the edge of a stented lesion that presented at greater than eight weeks after initial stent placement. Early ISR presented within 90 days. Intravascular ultrasound was used to evaluate the mechanism of lumen enlargement in the first 15 cases and in the last 30 cases.

Procedural success (angiographic residual stenosis of less than 30%) was achieved in all patients. The short-term composite end points of death, bypass surgery, or Q-wave infarction during the hospital stay did not occur in any patients. Follow-up was a minimum of nine months post-atherectomy with a mean of 13 ± 5 months. Five patients had an uncomplicated non-Q-wave infarction with re-restenosis. Recurrent ISR occurred in 28/100 patients or 28% of the patients at a mean of 102 ± 52 days. Of these 28, two were treated medically and the other 26 underwent percutaneous (20) or surgical (6) revascularization. Thus, in a patient population already known to be at high risk for re-restenosis, Sharma et al were able to achieve a long-term restenosis rate of 28% with rotational atherectomy, which is lower than historical controls using balloon angioplasty alone.

INSIDE

COMMENT BY MICHAEL H. CRAWFORD, MD

The treatment of ISR has become an increasingly common challenge. The physiology of ISR is neointimal proliferation, not stent recoil. This neointimal proliferation is generally diffuse but may be focal or at the stent edges. The plaque/tissue burden may favor the approach of removing or "debulking" the lesion and then performing balloon angioplasty to further improve the lumen within the stent.

The technique most commonly used for debulking is rotational atherectomy. The debulking may prove superior over simply compressing the plaque with balloon angioplasty. Sharma et al were able to safely and effectively treat 100 patients who returned with ISR. The nine-month follow-up identified only 28% of patients with restenosis. This is a remarkably low rate considering the proven propensity of these patients for restenosis.

There has yet to be a large randomized trial comparing treatment strategies for ISR; however, a multicenter registry in Europe—the BARASTER registry—has shown rotational atherectomy plus balloon angioplasty to be far superior to rotational atherectomy alone. Some recently published small series with ISR report restenosis rates of 20%. However, this group of patients appeared to have predominantly focal restenosis. Sharma et al's group of patients had predominantly diffuse restenosis and, thus, had a much greater plaque burden.

Laser and radiation are also promising techniques in the treatment of ISR; however, these are not widely available technologies.

The strategy of using intravascular ultrasound to identify a large plaque burden vs. an underdeployed or undersized stent provides additional insight into the mechanism of restenosis. This information may then direct us to "debulk" using rotational atherectomy with balloon angioplasty vs. balloon angioplasty alone in an undersized, underdeployed stent.

This series of patients treated by Sharma et al provides a ray of hope in an otherwise daunting area. Rotational atherectomy was used safely and effectively in this patient group. Thus, the use of rotational atherectomy may prove an invaluable asset in those patients with ISR. ❖

Which is most correct concerning in-stent restenosis?

a. Almost all are due to thrombosis.
b. The majority are due to poor stent deployment.
c. The mechanism is neointimal hyperplasia.
d. New lipid-rich plaque formation is causative.

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More Good News About Beta Blockers for Heart Failure

ABSTRACT & COMMENTARY

Synopsis: *Nonselective beta blockers may be better than beta-one selective agents, although the results of this trial indicate that predominant beta-one selectivity also infers treatment benefit.*

Source: CIBIS-II Investigators and Committees. *Lancet* 1999;353:9-13.

Cibis-ii, the second cardiac insufficiency bisoprolol Study, is the largest published trial supporting a robust benefit of beta blockers in patients with advanced heart failure. The study cohort consisted of 2647 patients from 18 countries in Western and Eastern Europe who had class III or IV heart failure and an ejection fraction of less than 35%, all on an ACE inhibitor and diuretic, who were randomized to bisoprolol or placebo. All patients were symptomatic from chronic heart failure. Active coronary artery disease or uncontrolled hypertension were among the exclusion criteria. There was no run-in period. All subjects were on a diuretic and an ACE inhibitor. Patients were started on bisoprolol 1.25 mg; the dose was increased incrementally to a target of 10 mg daily. The trial primary end point was all-cause mortality. Multiple secondary end points were assessed, including hospital admissions, cardiovas-

cular mortality, and a combined end point of death and hospital admission. Sudden death was carefully defined.

The following results occurred. The study was stopped prematurely because of a significantly lower all-cause mortality in the bisoprolol cohort ($P < 0.0001$), 11.8% bisoprolol vs. 17.3% placebo (risk reduction, 34%). The mean follow-up was only 1.3 years. Bisoprolol patients also had significantly fewer hospitalizations and fewer cardiovascular deaths. Withdrawal from therapy was equal (15%) in beta blockers and placebo patients. No differences in outcome were noted between ischemic and cardiomyopathic heart failure. Sudden death was 42% less with bisoprolol ($P = 0.001$); admissions for ventricular arrythmias were less with bisoprolol.

The CIBIS investigators conclude that bisoprolol is effective in advanced heart failure, and they point out that the existing database supporting beta blocker therapy is quite robust. The carvedilol trials, MERIT-HF, and the CIBIS-II are convincing about the efficacy of these agents. An antiarrhythmic effect of bisoprolol was suggested by the large decrease in sudden death as well as lower rates of ventricular tachycardia or fibrillation. LV function was not measured at follow-up, but in the initial CIBIS study, a better prognosis was concordant with improved Left ventricular (LV) ejection fraction. Finally, the CIBIS investigators discuss the view of many experts that nonselective beta blockers may be better than beta-one selective agents, although the strongly positive results of this trial as well as the recent MERIT-HF study (metoprolol), clearly indicate that predominant beta-one selectivity also infers substantial treatment benefit in heart failure.

COMMENT BY JONATHAN ABRAMS, MD

I agree with the CIBIS investigators that "the addition of a beta-blocker to standard therapy can be recommended in appropriate stable ambulatory patients who have heart failure caused by impaired LV systolic function." As of this writing, it is uncertain as to whether one agent is better than another; carvedilol is an alpha and beta nonselective drug with vasodilating and antioxidant properties; metoprolol is beta-one selective, as is bisoprolol. Ongoing comparative trials, such as COMET, may or may not show important differences among these agents. In my view, the beta blocker story parallels the early years of ACE inhibitors for heart failure, when "only specialists" used these agents. Widespread therapy for CHF with beta blockers is not yet a reality; this approach will involve a major change in current clinical practice. Americans tend to underuse beta blockers post-myocardial infarction, and their use in heart failure appears to be limited, although perhaps growing. This CIBIS II study provides considerable reassurance and "proof of principle" that beta adrenergic antagonism is beneficial in heart failure, improving both morbidity and mortality. ❖

The bisoprolol heart failure study of class III/IV patients showed:

a. reduced all-cause mortality on the beta blocker.
b. fewer cardiovascular deaths on the beta blocker.
c. fewer sudden deaths on the beta blocker.
d. All of the above

Angiographic and Intravascular Ultrasound Predictors of In-Stent Restenosis

ABSTRACT & COMMENTARY

Synopsis: *Intravascular ultrasound guidance may optimize stent deployment and ultimately decrease in-stent restenosis rates.*

Source: Kasaoka S, et al. *J Am Coll Cardiol* 1998; 32:1630-1635.

Intracoronary stents have been shown to reduce restenosis compared with balloon angioplasty. However, in-stent restenosis (ISR) continues to be an important clinical problem. The ability to predict restenosis and subsequently alter procedural decisionmaking would provide invaluable information. Thus, Kasaoka and associates sought to determine predictors of ISR from a high-volume, single-center practice. Between April 1993 and March 1997, 1706 consecutive patients with 2343 lesions were treated with a variety of intracoronary stents, predominantly Palmaz-Shatz (46%). Angiographic follow-up was requested in all patients within six months. Those patients with angiographic follow-up comprised the patient study group. Clinical, angiographic, and intravascular ultrasound (IVUS) variables were analyzed to determine predictors of ISR. All stents were deployed with standard high-pressure balloon inflations to achieve angiographically optimal results. IVUS was performed in 79% of patients. ISR was angiographically documented in 24% of the patients.

The restenosis group had a higher incidence of hyperlipidemia, diabetes, and previous bypass surgery. Additionally, they had more complex lesion morphology with more type C lesions and dissections and more frequently required multiple stents and a

longer total stent length. Angiographic predictors of ISR included a longer lesion length, a smaller final minimal luminal diameter (MLD), and a higher percent diameter stenosis. IVUS indicators of a higher restenosis recurrence include a smaller final stent lumen cross-sectional area. In those patients who had IVUS guidance to optimize stent deployment, additional balloon inflations were performed and more stents placed. These lesions had a significantly larger final MLD, a smaller final diameter stenosis, and a greater acute gain. More important, the lesions with IVUS guidance had a statistically significant lower restenosis rate (24% vs 29%; P = 0.03). Kasaoka et al conclude that using IVUS guidance to achieve the optimal stent lumen and minimizing total stent length may reduce ISR.

COMMENT BY MICHAEL H. CRAWFORD, MD

Intracoronary stents have become common in therapy for coronary artery disease. Advances in stent technology have facilitated ever more challenging stent procedures to be performed. With this has come the problem of ISR, which poses a significant challenge as we have yet to discover a good solution. In various series looking at ISR, "re-restenosis" occurs anywhere from 20-80% of the time. Thus, the onus is on us to identify methods of optimizing stent deployment and to predict which stent results may pose a greater risk of restenosis. This information could provide valuable guidance in angioplasty technique and modality selection.

The total stent length and the number of stents used were significant variables by univariate analysis, and total stent length was the strongest predictor of restenosis in the multivariate analysis. These results suggest that an optimal result should be achieved using a minimum amount of metal and perhaps tolerating moderate downstream disease and small, non-flow-limiting dissections. This also raises the issue of focal stenting in a diffusely diseased vessel. Further study of these issues is warranted. However, it has become clear that, if possible, the use of long or multiple stents should be kept to a minimum.

Those patients who had stents placed with IVUS guidance had a significantly decreased (20%) incidence of restenosis. In patients who have been identified to be at high risk for restenosis—diabetics, hyperlipidemics—post-CABG, the use of IVUS may markedly improve the stent result and thereby decrease restenosis. Judicious use of IVUS may have a positive effect on immediate results and long-term clinical outcome, which would more than compensate for the additional cost and time involved. Finally, patient selection for stenting must be revisited. Perhaps other modalities besides stenting should be first considered and applied knowing this may provide the eventual use of a stent in the event of restenosis.

This is an exciting paper that addresses the ongoing dilemma of restenosis. The ability to predict those patients at risk for restenosis may provide the avenue by which to alter and enhance our current techniques. ❖

Predictors of in-stent restenosis in optimally deployed stents include:

a. final lumen size.
b. total length of stents used.
c. number of stents used.
d. b & c.

Cholesterol and Stroke

ABSTRACT & COMMENTARY

Synopsis: *Pravastatin reduced strokes/TIAs in postmyocardial infarction patients with average cholesterol levels despite concomitant use of antiplatelet agents by most of the patients.*

Source: Plehn JF, et al. *Circulation* 1999;99:216-223.

The relationship between cholesterol levels and stroke is controversial. The Cholesterol and Recurrent Events (CARE) trial is the first secondary prevention trial of "statins" after myocardial infarction that included stroke as a secondary end point. The 4159 patients in this study had average cholesterol levels (mean 209 mg/dL) and LDL levels (139 mg/dL). The primary end point of reduction in cardiac events was reduced 24% in the pravastatin vs. placebo patients. Also, strokes were reduced 32%. The patients were well matched and antiplatelet drug use was 85% in each group. Pravastatin lowered cholesterol 20%, LDL 32%, and triglycerides 14%; HDL was raised 5%. Strokes or TIAs occurred in 92 patients on pravastatin and 124 on placebo—a 27% reduction. There was no increase in intracerebral hemorrhage on pravastatin and no difference in fatal strokes (6 total). Subgroup analysis showed equally beneficial effects for groups based on age, sex, hypertension, smoking, left ventricular ejection fraction, and baseline lipid levels. Plehn and colleagues conclude that pravastatin reduced strokes/TIAs in postmyocardial infarction patients with average cholesterol levels despite concomitant use of antiplatelet agents by most of the patients.

COMMENT BY MICHAEL H. CRAWFORD, MD

Stroke following myocardial infarction is mainly cardioembolic in the early recovery phase (< 3 months) but is more ischemic later due to the relationship between coronary and cerebrovascular disease. The CARE patients were randomized from three to 20 months (mean 10) postinfarction and only 15% of the strokes were considered embolic. However, the benefit was observed in all types of strokes. The reduction in stroke/TIA rates paralleled the reduction in coronary events, but the point where the event curves separated between the groups was different: 3.5 years for stroke and about 1.5 years for coronary events. Similar results were seen with the 4S secondary prevention study, with a 30% stroke reduction starting after three years. Although the percent reduction is impressive, the P value was not robust at 0.02, but considering that 85% of patients were on antiplatelet drugs, the results are noteworthy.

The mechanism of pravastatin's benefit is unknown, but a relationship was noted with serum LDL levels; the higher the level, the more the benefit. Stroke reduction was a nonsignificant 14%, with LDL less than 125 mg/dL and 54% with LDL more than 150 mg/dL ($P < 0.001$). However, in the West of Scotland primary prevention trial of patients with similar lipid levels, but no prior myocardial infarction, stroke reduction was an insignificant 11% despite similar reductions in cholesterol on pravastatin treatment. Thus, the mechanism of stroke reduction may involve effects of the statins beyond lipid lowering. Also, the West of Scotland study suggests that the results of this trial in postmyocardial infarction patients may not be transferable to patients with less disease. Whatever the mechanism, it appears that stroke reduction should be another expected benefit of lowering LDL cholesterol in postmyocardial infarction patients with LDL more than 130 mg/dL. ❖

Which is most correct concerning stroke postmyocardial infarction?

a. Almost all are cardioembolic.
b. They are independent of cholesterol levels.
c. Beta blockers reduce their incidence.
d. Statin therapy reduces their incidence.

Surgical Decisions in Mitral Regurgitation

ABSTRACT & COMMENTARY

Synopsis: *Patients with severe mitral regurgitation and class III/IV symptoms have higher mortality independent of other baseline characteristics.*

Source: Tribouilloy CM, et al. *Circulation* 1999; 99:400-405.

Despite compelling evidence that surgery should be considered in asymptomatic patients with severe mitral regurgitation who meet certain clinical criteria (i.e., left ventricular ejection fraction < 60%), clinicians find this a tough sell. Thus, Tribouilloy and associates from the Mayo Clinic evaluated 478 consecutive patients who underwent operations for severe mitral regurgitation between 1984 and 1991. Patients with associated mitral stenosis and those with mitral regurgitation due to ischemic or cardiomyopathic disease were excluded. Patients with concomitant coronary disease were not excluded. Of the 478 patients, 379 had mitral valve prolapse, 39 had rheumatic disease, 39 had endocarditis, and 21 had miscellaneous symptoms. The New York Heart Association functional class was I/II in 199 and III/IV in 279 prior to surgery. Valve replacement was performed in 155 patients, repair in 323, and concomitant coronary bypass in 130 (27%). Post-operative long-term survival was higher at 10 years in class I/II vs. the III/IV patients (76% vs 48%; $P < 0.001$); part of this difference was due to a lower perioperative mortality (0.5% vs 5.4%; $P < 0.003$). Compared to age- and sex-matched actuarial data, class I/II patients had a survival rate equal to expected, whereas class III/IV had a survival rate only 74% of expected. Other predictors of survival in the multivariate model were age, atrial fibrillation, valve repair, ejection fraction, and coronary artery disease. However, the survival difference between functional classes persisted in all these subgroups. Tribouilloy et al conclude that patients with severe mitral regurgitation and class III/IV symptoms have excess mortality independent of other baseline characteristics. Thus, surgery should be considered before this level of symptoms develops.

COMMENT BY MICHAEL H. CRAWFORD, MD

Since a randomized clinical trial of class I/II patients with severe mitral regurgitation (randomized to surgery or medical follow-up) will never be done, this type of observational study will be our best effort to answer the question of who to send to surgery. Also, since there is no known effective medical therapy, surgery is our only option; but surgery includes repair, which, in the appropriate candidates, can be done with little or no excess mortality. Unfortunately, only about 80% of patients referred for repair actually get it; the others get prosthetic valves, which, in the mitral position, usually require anticoagulation. Previous studies have shown that preoperative ejection fraction, coronary artery disease, atrial fibrillation, large left atrium, pulmonary hypertension,

and left ventricular end-systolic volume are predictive of postoperative outcome. Thus, the clinical decisions in this study were done with this knowledge. However, previous trials have not carefully evaluated the role of symptoms in decision-making, which makes this study valuable.

The message of this study is that in the current milieu, symptom status is the strongest independent predictor of postoperative survival. To say that it is stronger than other characteristics of the patients assumes that all factors were distributed equally and did not affect the clinician's decisions. We know this is not the case since knowledge of previous trial results was present and there were baseline differences between the two symptom class groups in age, atrial fibrillation, and the number repaired vs. replaced. Also, it is assumed that symptom history was not a major factor in the decision for surgery. This is more tenable since there are few prior data to support its role; yet, it is hard to ignore symptom status and, consequently, it may have influenced decision-making. Despite these limitations, it appears that surgery should be considered in severe mitral regurgitation in class I/II patients.

The recently published ACC/AHA guidelines (*J Am Coll Cardiol* 1998;32:1486-1588) address this issue and consider all symptomatic patients (NYHA Class II-IV) with severe mitral regurgitation Class I surgical candidates. Asymptomatic patients (NYHA Class I) are only considered Class II surgical candidates (data less firm) if they have atrial fibrillation, pulmonary hypertension, left ventricular dysfunction (EF < 60%), or in whom repair is highly likely. It is not possible for these guidelines to have influenced decisions in this trial, but the data they were based upon could have. The only real difference is the more firm recommendation for surgery in the asymptomatic (Class I) patient based upon the Mayo experience. When they separated the Class I and II patients, Class I patients had a slightly higher survival than Class II patients, but the difference did not reach statistical significance. Part of this may be the difficulty in distinguishing Class I from II status in patients with a chronic illness.

One factor that helps propel the notion of operating in Class I/II patients is the low operative mortality in this study—0.6% for repair, 0% if younger than age 75, and 0% if no bypass surgery. If the patient was older than age 75 or had class III/IV symptoms increased their operative mortality to 2.5-3.6%. Also, repair, which was accomplished in 84% of those operated since 1988, is associated with a 25% increase in 10-year survival vs. replacement. Thus, many patients have benefited from improved surgical techniques.

Tribouilloy et al suggest that surgery should be strongly recommended in symptom class I/II patients with mitral regurgitation if: 1) severe mitral regurgitation is well documented; 2) the mitral regurgitation is not due to ischemia or cardiomyopathy; 3) the likelihood of valve repair is high; and 4) the operative risk is low. If these criteria are not met, other factors, such as left ventricular function, pulmonary pressure, etc., should be taken into consideration per the ACC/AHA guidelines. ❖

Good outcomes following surgery in severe mitral regurgitation occur when:

a. ischemic heart disease is the etiology.
b. class I/II symptoms are present.
c. class III/IV symptoms are present.
d. mechanical prostheses are used.

More from Framingham

ABSTRACT & COMMENTARY

Synopsis: *The new Framingham analysis provides a model to assess the cumulative and lifetime risk of developing coronary heart disease for men and women.*

Source: Lloyd-Jones DM, et al. *Lancet* 1999;353:89-92.

A novel approach to understanding the risk of developing coronary heart disease (CHD) has been proposed by the Framingham Heart Study, which has continued for 50 years. The present Framingham program has created a model to assess the cumulative and lifetime risk of developing CHD for men and women. This approach uses the Framingham database, derived from the original cohort of 5200 (free from heart disease and enrolled in 1948), as well as another 5100 offspring enrolled in 1971. A total of 7732 participants, aged 40-94 years, without a history of coronary disease, were included in the analysis. All deaths were coded for six mutually exclusive causes, including CHD, stroke, and cancer. In addition, CHD events were categorized. Careful statistical analysis was used to calculate the lifetime risk of development of CHD. Follow-up was concluded in 1996, the year of the first CHD event, death, or age 95. A total of 10,000 person years were accumulated during follow-up; 1057 subjects developed CHD and another 1312 died from noncoronary causes. The main analysis is as follows: the risks of developing CHD for the entire cohort was age-dependent for both men and women. (*See Table*.) Thus, for individuals at age 40, there is a 50% lifetime risk of CHD for men and 32% for women. As the cohorts continued to be free from CHD, the lifetime risk for a first event decreases. At age 70, the lifetime CHD risk is still as high as 1 in 3 for men and 1 in 4 for women.

Men demonstrated a higher short-term risk of CHD as well as a higher lifetime risk than women at all ages. The risk curves for individuals older than 60 rise steeply in men and women. This lifetime risk approach has been used for breast cancer and several other diseases. This analysis did not directly evaluate significant CHD risk factors, such as hypertension or hypercholesterolemia; including these would clearly result in worse CHD risk prediction than the average subject. Lloyd-Jones and colleagues conclude that this new Framingham analysis "provides a rationale for screening and treatment of hypertension and hypocholesterolemia in older and younger patients."

COMMENT BY JONATHAN ABRAMS, MD

These data should be instructive for physicians and patients. The steep rise in the risk curves graphically demonstrates the burden of vascular disease with age; the good news is that as one lives longer without having a coronary event, the remaining lifetime risk for developing overt CHD is less than at an earlier age. Adding CHD risk factors to these curves (or the absence of CHD risk) can clarify what one's future likelihood is for CHD when counseling a patient or embarking upon prevention programs. One main limitation of the Framingham data, as pointed out by Lloyd-Jones et al and an accompanying editorial, is the uniform ethnic identity of the Framingham population, which is predominantly white from a single town, with presumably common genetic and environmental factors operating. Thus, extrapolation of these findings to other populations may be problematic. Furthermore, new therapies for CHD could alter these estimates. Nevertheless, I believe this is a useful construct that should help all those interested in assessment of CHD risk. ❖

Analysis of the Framingham study concerning risk of developing coronary disease has shown:

a. a strong relationship to age.
b. short-term risk at any age is higher for men.
c. lifetime risk is higher in men.
d. All of the above

Table

Lifetime Cumulative Risk of Developing CHD

Age	Men	Women
40	49%	32%
50	50%	31%
60	43%	29%
70	35%	24%

Use of an Extended Monitoring Strategy in Patients with Problematic Syncope

ABSTRACT & COMMENTARY

Synopsis: *Prolonged monitoring using an implantable loop recorder is an effective means for evaluating patients with recurrent symptoms.*

Source: Krahn AD, et al., for the Reveal Investigators. *Circulation* 1999;99:406-410.

Krahn and colleagues report on the use of implantable loop recorders in 85 patients with recurrent syncope. Patients with recurrent syncope were eligible for inclusion in the trial. All had undergone at least one 24-hour period of conventional ECG monitoring. Head-up tilt studies, electrophysiologic studies, and external loop recordings had been performed in 49%, 43%, and 24% of the patients, respectively. The implantable loop recorder used in this study (Reveal, Medtronic) is a 61 × 19 × 8-mm recording device with two sensing bipoles. The device can store 21 minutes of uncompressed ECG signals or 42 minutes of compressed signals in 1,3 divided parts. The data are stored in a circular buffer that can be frozen with a handheld activator provided to the patient. The data obtained from symptomatic episodes of syncope or pre-

syncope can then be downloaded on a standard pacemaker programmer. The device is implanted in a procedure analogous to a pacemaker implantation, usually in a left infraclavicular subcutaneous pocket.

The patients enrolled were 59 ± 18 years of age and 62% had structural heart disease. They had experienced 5.1 ± 5.5 episodes of syncope within the prior year. Symptoms had been present for more than two years in 71% of the patients. During 10.5 ± 4 months of follow-up, symptoms recurred in 58 of 85 patients. The median time to recurrence was 51 days. Adequate data that allowed evaluation of symptoms and rhythm were obtained during 128 episodes of syncope or presyncope in 50 patients. On 24 occasions in 14 patients, the patient failed to appropriately activate ECG storage. Arrhythmias were recorded in 21 of 50 (42%) patients with symptoms and an adequate recording. Of this, 18 had bradycardia and three had a tachycardia. The remaining 29 patients in this group had sinus rhythm documented at the time of recurrence. Episodes of syncope were more likely to be associated with an arrhythmia (70%) than episodes of presyncope (24%). Complications associated with the device included two local infections, one erosion plus infection, and one pocket revision due to pain at the initial implant site. Krahn et al conclude that prolonged monitoring using an implantable loop recorder is an effective means for evaluating patients with recurrent symptoms.

COMMENT BY JOHN DiMARCO, MD, PhD

Patients with recurrent syncope are difficult to manage since the cause of their symptoms often remains obscure. By definition, episodes of syncope are transient and the patient usually has a stable rhythm and blood pressure when he presents for evaluation. Standard ambulatory ECG monitoring is of limited value unless the patient has frequent episodes. Available patient activated external loop recorders require rapid activation due to limited memory and are inconvenient for the patient to wear or carry. Tilt table studies or electrophysiologic studies are provocative tests that have frequent false-negative and false-positive results.

In this study, implantation of a small subcutaneous recorder allowed symptom-rhythm correlation in about 60% of a group of patients with recurrent syncope. It is interesting to note that sinus rhythm was the most common rhythm documented. Unfortunately, the device does not monitor blood pressure so episodes of severe hypotension without arrhythmia were not excluded. However, even in these cases, the devices provided reliable information to exclude arrhythmias and prevented fruitless therapeutic trials to treat possible brady- or tachyarrhythmias.

We can expect to see further advances in these devices. The model used in this study is easy to implant, produces no unsightly scar or bulge, and can be easily removed. Algorithms to automatically activate recording in response to high- or low-rate episodes would eliminate the absolute need for patient activation even though the latter feature would not store episodes where the rhythm remained stable.

The data presented here suggest that implantable loop recorders should become an important part of the diagnostic approach to patients with recurrent, unexplained syncope. Patients at high risk for a life-threatening arrhythmia that is usually reproducible at electrophysiologic study should still undergo that procedure first. Neurocardiac syncope is usually diagnosed on clinical grounds and tilt table studies used, when necessary, to support that impression. In other patients, the implantable loop recorder will be an attractive diagnostic option. The major limiting factors with these devices will be their cost and the need for an invasive procedure. ❖

Which of the following is correct concerning monitoring in recurrent syncope?

a. Almost all have tachyarrhythmias.
b. The majority are nonarrhythmic.
c. Bradyarrhythmias are rare.
d. Ventricular tachycardia explains most episodes.