Best of TCT 2002

Highlights of the Transcatheter Cardiovascular Therapeutics Annual Meeting, September 24–28, 2002 Washington, DC

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The Transcatheter Cardiovascular Therapeutics Annual Meeting 2002 (TCT 2002), held in Washington, DC, and directed by Drs. Martin Leon and Gregg Stone, lived up to its reputation as the premier international interventional cardiology meeting. Presentations included pivotal clinical trial results from PRAGUE-2, RESCUT, TAXUS, SIRIUS, and MAGIC, among others, that will impact the way we practice today, as well as a look into the future, with presentations focusing on genomics, cardiovascular imaging, and myogenesis.

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RESCUT: Restenosis Cutting Balloon Evaluation

Several retrospective studies and two small, randomized, pilot trials have reported a lower incidence of recurrent in-stent restenosis in lesions treated with cutting balloon angioplasty compared with standard balloon angioplasty. To determine whether these results could be corroborated in a larger, prospective, randomized trial, 428 patients undergoing treatment of in-stent restenosis at 23 sites in Europe were evaluated. The primary end point of the trial was angiographic restenosis at 7 months following the procedure. Although the first episode of restenosis was present in the majority of patients, focal as well as multifocal and diffuse lesions were included. The average stent length was approximately 18 mm, reference diameter was 2.5–2.6 mm, and lesion length was less than 20 mm in 86.7% and 83.6% of cutting and standard balloon groups, respectively. As expected, baseline demographics were similar between groups, except for a higher prevalence of prior coronary artery bypass surgery in the cutting balloon group compared with the standard balloon group (12% vs 6%; $P < .05$). There was no difference in the incidence of recurrent in-stent restenosis between groups (in the 82% of patients undergoing angiographic follow-up), nor in the

incidence of major adverse cardiac events. Of note was that the amount of balloon slippage was significantly less (6.5% vs 25.1%; $P < .01$) and the balloon length significantly shorter (11.3 mm vs 18.3 mm; $P < .01$) in the cutting and standard balloon groups, respectively. It was concluded that use of both the cutting and standard balloon for the treatment of in-stent restenosis is safe and that use of the cutting balloon results in less slippage and need for fewer balloons.

Discussion

Despite the initial enthusiasm for use of the cutting balloon for the treatment of in-stent restenosis, this study suggests that, for patients with in-stent restenosis of small vessels, use of the cutting balloon does not reduce recurrent in-stent restenosis or major adverse cardiac events. The convenience of reduced slippage provided by the cutting balloon in this setting will be weighed against the increased cost associated with its use.

PRAGUE-2

Evidence continues to accumulate suggesting that, for patients with acute myocardial infarction, primary percutaneous coronary intervention (PCI) is associated with improved clinical outcomes compared with fibrinolytic therapy. However, widespread use of primary PCI is limited by the lack of cardiac catheterization laboratories in the majority of community hospitals. Whether it is beneficial to transfer patients to hospitals capable of performing primary PCI rather than opting for on-site fibrinolytic therapy remains unclear. Accordingly, the Primary Angioplasty in Acute Myocardial Infarction Patients from General Community Hospitals Transported to PTCA Units Versus Emergency Thrombolysis (PRAGUE)-2 study was conducted in the Czech Republic after the first PRAGUE study demonstrated that the transfer of such patients from community hospitals to a tertiary PCI center was feasible and safe.

The authors concluded that hospital transfer for primary PCI for patients with acute myocardial infarction is associated with improved outcomes at 30 days compared with on-site fibrinolysis administration.

In this second study, 850 patients with acute myocardial infarction presented at a community hospital without a catheterization laboratory within 12 hours of symptom onset. Subjects were randomized to receive either immediate fibrinolysis or transport to a PCI center. The 421 patients randomized to fibrinolytic therapy received 1.5 million units of streptokinase in the community hospital, whereas the 429 patients who were randomized to primary PCI received heparin, 200 U/kg, and were transported (initiated within 30 minutes) to the nearest PCI center. The primary end point of the study was mortality at 30 days.

As expected, baseline characteristics, including age, sex, and comorbid disease, were similar between groups. Assuming that fibrinolysis occurs 60 minutes following administration of streptokinase, reperfusion occurred, on average, 245 minutes from symptom onset in the fibrinolytic therapy group and 277 minutes from symptom onset in the primary PCI group.

Results of the intention-to-treat analysis revealed a mortality rate at day 30 of 10% in the fibrinolysis group and 6.8% in the primary PCI group ($P = .12$). Furthermore, 30-day mortality in patients treated within three hours of the onset of symptoms was virtually the same in both groups. However, for patients who received treatment 3–12 hours from the onset of symptoms, primary PCI was associated with a significant survival advantage compared with fibrinolysis (6% vs 15.3%; $P < .002$).

In addition, a secondary combined end point of death, reinfarction, and stroke within 30 days was also significantly lower in the primary PCI group compared with the fibrinolysis group (8.4% vs 15.2%). Analyzed according to treatment received, mortality was significantly lower in the primary PCI group than in the fibrinolysis group (6% vs 10.4%; $P < .05$). The authors concluded that hospital transfer for primary PCI for patients with acute myocardial infarction is associated with improved outcomes at 30 days compared with on-site fibrinolysis administration.

Discussion

In the wake of continuing enthusiasm for primary PCI as the reperfusion strategy of choice in patients with acute myocardial infarction, this study is particularly timely and significant. The study is strengthened by its multicenter, randomized design, its thoughtful approach to a critically important and practical question, and its careful consideration of time lapse from symptom onset to reperfusion when comparing strategies and treatment centers. It is noteworthy that primary PCI, when compared with fibrinolysis, has not yet been shown to reduce mortality; the difference in outcomes between primary PCI and fibrinolysis groups, in other studies, has largely been driven by a decrease in the incidence of recurrent myocardial infarction in the PCI group.

It is not yet clear whether primary PCI for patients presenting to PCI centers is superior to primary PCI for patients transferred from referral hospitals to PCI centers. If so, community hospitals (without a high PCI volume) may be obliged to offer this reperfusion strategy.

Finally, the question of whether primary PCI performed at a community hospital without on-site surgery or an elective PCI program is equally effective as primary PCI performed at a PCI center has yet to be answered. Notwithstanding, this study adds additional credence to the hypothesis that primary PCI is associated with improved outcomes compared with fibrinolysis, even if reperfusion is delayed for an additional 30 minutes.

[Alice K. Jacobs, MD, FACC, FAHA]

SIRIUS

A U.S. multicenter, randomized, double-blind study of the sirolimus-eluting stent in de novo native coronary lesions (SIRIUS) was presented by Jeff Moses, MD, for the SIRIUS investigators. The purpose of the trial was to assess the safety and effectiveness of the sirolimus-eluting Bx Velocity stent in reducing target vessel failure in de novo native coronary artery lesions compared with the uncoated Bx Velocity stent. The primary end point of this trial was target vessel failure (TVF), defined as the composite of cardiac death, myocardial infarction (MI), or target vessel revascularization (TVR) at 9 months postprocedure. A variety of prespecified secondary end points were also established, including target lesion revascularization (TLR) and TVR, angiographic in-stent and in-segment binary restenosis at 8 months, and an intravascular ultrasound (IVUS) study of in-stent neointimal volume and volumetric plaque volume at 8 months.

Approximately 1101 patients were randomized between the two groups, with an 8-month angiographic follow-up of 85% and clinical follow-up at 9 months of 96%. There was a mean of 1.4 stents used per patient, with a mean reference diameter of 2.8 mm. The primary end point of TVF was reached in 8.6% of patients randomized to sirolimus (S) and 21.0% of those in the control (C) group ($P < .001$). The incidence of major adverse cardiac events (MACE) at 9 months was 7.1% in the S group and 18.9% in the C arm ($P < .001$). There were no significant differences in the incidence of death or MI, with a significant benefit in TLR in the S group. In-segment late loss was 0.24 mm in the S group and 0.81 in the C group ($P < .001$), and loss index was 0.15 and 0.54, respectively ($P < .001$). In-segment restenosis was 8.9% in the S group, most of which occurred in the proximal and distal stent margin; a 36.3% restenosis rate occurred in the C group ($P < .001$), with most of the restenosis occurring within the stent. There was a relationship between tertiles of vessel diameter and in-segment restenosis in both the S and C arms, with a 1.9% and 30.2% incidence, respectively, in the largest tertile group (mean, 3.3 mm) and 18.6% and 42.9%, respectively, in the smallest tertile (mean, 2.3 mm). The incidence of stent thrombosis was not significantly different between the S and C groups, (0.4% and 0.8%, respectively). There was no difference at 8-month angiographic follow-up in the incidence of perforation, embolization, or aneurysm formation.

There is no doubt that the results of SIRIUS, which demonstrate a significant reduction in restenosis in this "real-world" population of patients, reinforce previous clinical trial experience showing a restenosis benefit with sirolimus.

TAXUS II

The TAXUS trial was an international (non-U.S.), randomized, double-blind trial of paclitaxel (1 μg/mm^2) on the NIRx stent in de novo lesions in vessels with reference diameters of 3.0–3.5 mm and lesion length of 12 mm or less. This represented a population at relatively low risk for restenosis. The primary end point of this trial was percentage in-stent net volume obstruction at 6-month intravascular ultrasound. Dr. Antonio Columbo presented the study results.

Percentage in-stent net volume was reduced by over 60% (23.17% vs 7.85%; $P < .0001$) in the paclitaxel group compared with the control group. One-day stent thrombosis occurred in 1% of the paclitaxel arm versus 0% of the control group (P = NS). There was no difference in 30-day MACE. Six-month TLR occurred in 12.0% of patients in the control arm and 4.6% of the paclitaxel arm ($P = .043$). Late loss (0.31 vs 0.79 mm; $P < .001$) and loss index (0.53 vs 0.22; $P < .0001$) within the stented segment were superior in the TAXUS arm. The types of patients treated and lesions instrumented in TAXUS II (reference vessel diameter of 2.8 mm and lesion length of 10.5 mm) resemble those studied in the Randomized Study with the Sirolimus-Eluting Bx Velocity Balloon Expandable Stent (RAVEL) trial (mean lesion length of 9.6 mm and vessel diameter of 2.6 mm), in which the late loss was −0.01 mm compared with the late loss of 0.31 mm in TAXUS II.

Multi-Link Vision Registry

Data on the newest generation of stent technology, which uses a cobalt chromium alloy, were presented at TCT 2002. This device, Vision, has a multicellular design

with reduced strut thickness, which is believed to provide enhanced deliverability, scaffolding, and visibility while maintaining a restenosis rate similar to the Multi-Link. This was a prospective, open-label, multicenter, global registry enrolling 265 patients with de novo coronary lesions in vessels 3.0–4.0 mm in diameter and 25 mm or less in length. The lesions approached in the registry were relatively complex, with 40% classified as B2/C by ACC/AHA lesion class. The 30-day and 180-day MACE rates, defined as death, MI, or TVR, were 1.9% and 6.2%, respectively. Low rates of 180-day TVR (5.1%) and binary restenosis (15.7%) were observed.

The primary end point of the SIRIUS trial was target vessel failure.

CREDO Trial

The objective of the Clopidogrel for Reduction of Events During Observation (CREDO) trial was to compare the efficacy of a 300 mg clopidogrel loading dose given 3–24 hours preceding a PCI with a 75 mg dose of clopidogrel given at the time of the procedure on a background of aspirin with or without the planned use of a GP IIb/IIIa inhibitor. The primary end point was the composite of death, MI, or urgent TVR at 28 days. There was no significant difference in the primary end point between the pretreatment and no-pretreatment arms (6.8% vs 8.3%; $P = .23$). In patients receiving the loading dose less than 6 hours before the procedure, there was a trend toward a higher MACE rate, with patients loaded from 6–24 hours before the procedure having a reduction in event rates. There was no significant difference in major or procedure-related bleeding events between the pretreatment and no-pretreatment groups. There was no difference in the major bleeding rates in either arm when a GP IIb/IIIa inhibitor was used.

It seems that between 6 and 24 hours of pretreatment with clopidogrel is needed in order to realize a reduction in PCI-related events. Without this strategy of loading approximating the robust reduction in 1-month event rates observed with the use of GP IIb/IIIa inhibitors (51% reduction with abciximab in the Evaluation of Platelet IIb/IIIa Inhibitor for Stenting [EPISTENT] trial and 35% reduction in the Enhanced Suppression of the Platelet Receptor IIb/IIIa with Eptifibatide Therapy [ESPRIT] trial), it will be difficult to recommend a pretreatment protocol on the background of aspirin therapy as the "poor man's ReoPro."

Paclitaxel stabilizes microtubules and inhibits cell processes that require microtubule turnover.

ACE Trial

The Abciximab Carbostent Evaluation (ACE) trial was a multicenter, multinational, randomized trial including patients with acute MI treated by primary PCI who were randomly assigned to receive abciximab therapy with stent or stent alone. Unlike the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial, there was no restriction based on age, sex, clinical status, or high-risk coronary anatomy. The primary end point was 1-month MACE. Greater than 50% resolution of ST segment elevation occurred in 85% of patients in the abciximab group and only 68% of control patients ($P < .001$), with less creatinine kinase (CK) release in the abciximab group, consistent with more rapid reperfusion. No differences were observed for hemorrhagic adverse events. One-month MACE by multivariate analysis was related to the presence of cardiogenic shock, multivessel disease, and age, with a strong protective effect exerted by the use of abciximab.

These trial data reinforce the positive protective effects of GP IIb/IIIa inhibition, particularly with abciximab, in patients with acute MI undergoing stent implantation. The improved rate of ST segment resolution and smaller CK release are consistent with abciximab's ability not only to enhance vessel patency but also to improve perfusion in this patient population.

Renal Insufficiency and Coronary Artery Disease/Radiocontrast Nephropathy

Several sessions dealt with the relationship of renal insufficiency and cardiovascular disease. It seems evident that progressive loss of renal function translates into an increase in cardiovascular events, with a stronger relationship seen between renal function and cardiac death

Table 1
Effects of Hormone Replacement Therapy

Event	Cr Cl >70 mL/min	Cr Cl 50-69 mL/min	Cr Cl 30-49 mL/min	Cr CL <30 mL/min	Dialysis
In-hospital death	0.5%	0.7%	2.3%	7.1%	6.0%
1-year death cum	2.1%	4.2%	10.0%	25.3%	24.4%
Any MI 1-year cum	8.4%	10.3%	13.0%	14.5%	17.8%
In-hospital ARF	0.1%	0.3%	2.0%	6.5%	—

Cr Cl, creatinine clearance; MI, myocardial infarction; ARF, acute renal failure.
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than between left ventricular dysfunction and cardiac death. This relationship seems to become clinically significant at levels of creatinine clearance as low as 60 mL/min. Calculating creatinine clearance using the Cockroft-Gault formula, [(140-age) x weight (kg)/72 x serum creatinine (mg/dL)] x 0.85 (for women) is a much better estimate of renal function than is serum creatinine.

In Table 1, it is clear that a strong inverse relationship between in-hospital mortality, 1-year cumulative mortality, 1-year rate of myocardial infarction, and renal function exists in patients undergoing PCI. In a typical community cardiac catheterization laboratory, an "average" patient has an estimated creatinine clearance of 40–50 mL/min. Chronic renal insufficiency is associated with a proatherogenic metabolic syndrome of hypertriglyceridemia, hyperhomocystinemia, hyperinsulinemia, and low HDL cholesterol.

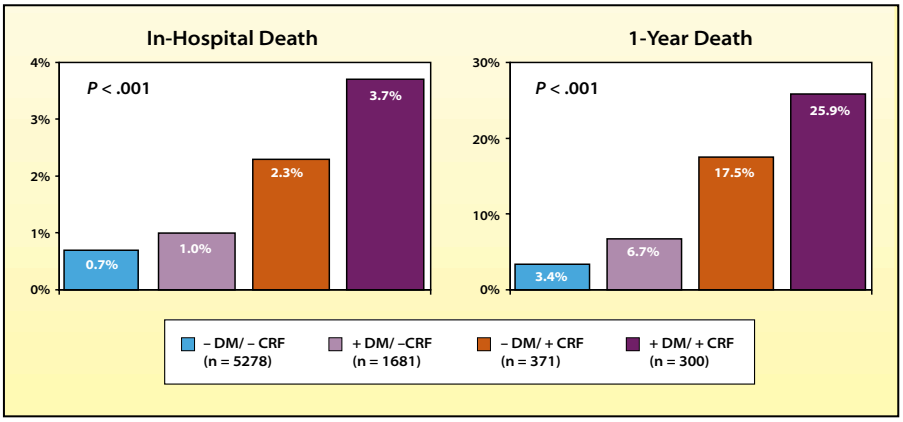
The importance of radiocontrast nephropathy (RCN) as an important cause of in-hospital acute renal insufficiency was underscored. Patients at risk for RCN include those with underlying chronic renal insufficiency (creatinine clearance < 50 mL/min) and/or proteinuria, particularly associated with diabetes. The implications of developing RCN are profound, with impressive increases in both short- and long-term mortality (Figure 1).

A discussion of potential prevention strategies took place at TCT 2002, along with a review of the data evaluating the efficacy of saline, mannitol, furosemide, aminophylline, low-dose dopamine, N-acetyl cysteine, and fenoldopam. Based on a review of clinical trial data, it was clear that mannitol and furosemide increased the risk of RCN, whereas aminophylline and low-dose dopamine did no better than hydration. Once RCN occurred, low-dose dopamine led to worsening renal function.

The data on N-acetyl cysteine (NAC) were evaluated, including data from three recently reported clinical trials.[1] Two trials have found lack of efficacy of NAC[1,2] and two trials have shown limited efficacy.[3,4] The consensus of the panel was that at the present time, based on the accumulation of clinical data, it would be unreasonable to rely solely on NAC to prevent RCN.

The role of fenoldopam as a renal protective agent was also discussed. Fenoldopam was found in a canine model and in multiple prospective clinical experiences to prevent RCN and, in a recently published randomized clinical trial, to prevent an increase in serum creatinine following contrast exposure (Figure 2). Fenoldopam is unique as a selective agonist of the renal DA_1 receptor that works by preventing contrast-induced reductions in renal blood flow and renal ischemia without inducing significant hypotension in normotensive patients.

Figure 1. *Prognosis post-percutaneous coronary intervention (PCI) in patients with chronic renal failure. 7445 consecutive patients followed for 1 year after PCI. A direct relationship exists between renal dysfunction and mortality following PCIs. DM, diabetes mellitus; CRF, chronic renal failure. Reprinted with permission from the American College of Cardiology Foundation* Journal of the American College of Cardiology*, 2000, Vol. 36, 1542–1548.*[6]



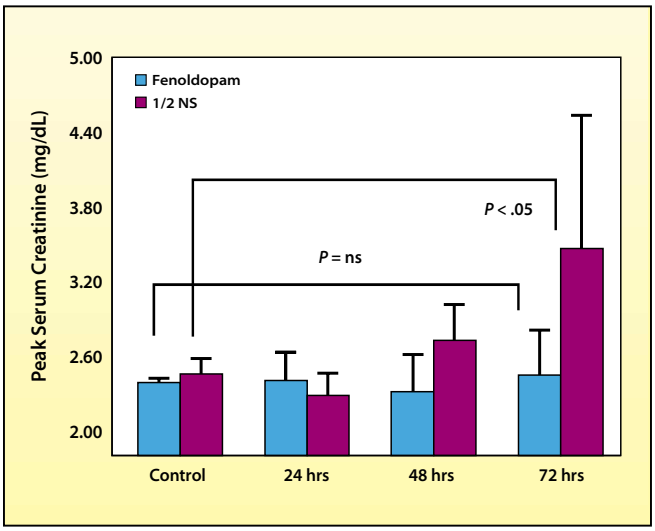


Figure 2. *Fenoldopam mesylate reduces peak serum creatinine 72 hours post-contrast. 1/2 NS, normal saline solution; ns, not significant. Data from Tumlin et al.*[7]

Data were also presented underscoring the renal protection provided by fenoldopam in patients undergoing coronary artery bypass surgery as well as in those undergoing other major surgeries, including abdominal aortic aneurysm repair, vascular reconstruction, trauma, orthopedic reconstruction, and abdominal surgery. Fenoldopam is indicated for the treatment of severe hypertension. In contradistinction to other intravenous agents, such as nitroprusside, esmolol, and intravenous angiotensin-converting enzyme inhibitors, fenoldopam enhances renal perfusion while achieving needed blood pressure reduction.

[Norman E. Lepor, MD, FACC, FAHA]

Myogenesis

This year, debate continued to simmer as to whether myogenesis will soon be a reality in clinical practice. On one hand, ongoing clinical trials seem to imply that human applications are around the corner; on the other hand, words of caution are circulating among the experts. What is the current state of knowledge of these potentially revolutionary applications? We will examine a few of these trials in this review. Because not all numbers have been verified independently, the patient populations in each study are estimates.

Clinical Trials

The Bioheart technology utilizes skeletal myoblasts to improve left ventricular (LV) function. Cells are harvested from the patient's own skeletal muscle and grown in a specialized tissue-culture laboratory. Once these cells have matured to supply enough myoblasts (700–1200 million cells), they are injected into the myocardium either surgically or percutaneously using a special injection catheter.

Cells are harvested from the patient's own skeletal muscle and grown in a specialized tissue-culture laboratory.

Dr. Philippe Menasche was the first to perform the surgical procedure as an adjunct at the time of a coronary artery bypass graft (CABG). Ten patients with heart failure after MI received 700–1200 million cells and showed 11 months improvement of 1 symptomatic class; ejection fraction (EF) improved from 0.27 to 0.32. Two sudden deaths were most likely due to ventricular arrhythmias. Subsequently, 4 patients developed ventricular tachycardia (VT) at 8–24 days and required the placement of an internal cardiac defibrillator (ICD). This study was not controlled; thus, it is unclear whether the observed improvements were due to the CABG or the injected cells. The likely explanation for the ventricular arrhythmias is the inability of the skeletal myoblasts to communicate with the rest of the myocardium due to the lack of connexon (gap junctions).

The Polish group lead by Dr. Siminick also reported the results of 10 patients treated with skeletal myoblasts who showed significant EF improvement of 0.05 to 0.15; 2 patients also developed VT and were treated with amiodarone.

Two studies are ongoing or planned for the near future. The Magnesium in Coronaries (MAGIC) trial is a 50-patient adjunct to the CABG patient study with a 15-patient Phase 1 component. Safety and clinical events will be measured in 3 cohorts receiving 25 million, 75 million, and 224 million cells, respectively. All patients will receive an ICD. The Myogenesis Heart Efficiency and Regeneration Trial (MYOHEART) will study the percutaneous approach in 2003.

Dr. Nabil Dib presented experience with the technology of Diacrin Corporation. Two patient populations are being studied; one clinical trial is examining the treatment of patients with skeletal myoblasts at the time they receive a left ventricular assist device (LVAD), and the other study is administering treatment as patients undergo CABG. The LVAD is implanted as a bridge to cardiac

transplantation; 300 million cells are implanted along with the LVAD. After the patient is transplanted with a new heart, the old heart can be examined histologically to determine the efficiency of cell transplantation. Preliminary results from one heart showed that cells had survived and new blood vessel formation was stimulated.

The clinical trial involving CABG patients is a 12-patient dose-escalation trial, with safety being evaluated at doses ranging from 10–300 million cells.

Questions for Study

The ability to create functional tissue is one of the holy grails of medicine. If new myocardium can indeed be generated from a patient's own muscles (or bone marrow), this will clearly be a major breakthrough in the treatment of cardiomyopathy of any etiology. But many questions remain unanswered. Studies are needed to establish the relative efficiency of surgical and percutaneous transplantation methods; the percentage of the cells injected that actually implant and survive; whether the cells connect to the surrounding myocardium in a functional manner (mechanically and electrically); how the cells will function if they are surrounded by scar tissue; whether new blood supply to the new tissue is critical; and whether these transplant techniques will impart clinical benefits. With time and effort, it is hoped that we will find the answers to these questions. ■

[Alan C. Yeung, MD]

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Main Points

- The RESCUT trial failed to show an advantage in the use of cutting balloon technology versus standard balloon angioplasty for the treatment of in-stent restenosis.
- PRAGUE-2 further demonstrated the association of favorable outcomes with percutaneous coronary intervention versus fibrinolytic therapy for patients with acute myocardial infarction, even if therapy is delayed by up to 30 minutes due to the need for patient transfer to a surgical facility.
- The SIRIUS study of the Bx Velocity sirolimus-eluting stent in de novo native coronary lesions showed a significant reduction in restenosis in a "real-world" population of patients.
- The newest generation of stent technology, using a cobalt chromium alloy, has a multicellular design with reduced strut thickness to provide enhanced deliverability, scaffolding, and visibility; low restenosis rates were observed despite evaluation in a higher-risk lesion set.
- The Abciximab Carbostent Evaluation (ACE) trial data reinforce the positive protective effects of GP IIb/IIIa inhibition, particularly with abciximab, in patients with acute myocardial infarction undergoing stent implantation.
- The Bioheart technology uses cells harvested from the patient's own skeletal muscle, grown in a laboratory, and injected into the myocardium either surgically or percutaneously to stimulate coronary myogenesis.
- Preliminary results from a study of hearts treated with skeletal myoblasts and later replaced in heart transplants showed that cells had survived and new blood vessel formation had been stimulated.