

# Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

CCL BASED PROCEDURES	FY23	FY24	FY25	YTD DIFF
<b>Diagnostic Catheterization</b>				
288(CIRC DIS EXC AMI, W CATH W MCC	\$14,549	\$15,093	\$15,752	4.4%
287(CIRC DIS EXC AMI, W CATH W/O MCC	\$7,547	\$7,573	\$7,755	2.4%
<b>Coronary Intervention</b>				
321(PCI W/ INTRALUMINAL DEVICE W/MCC OR 4+ ARTERIES	-	\$20,127	\$20,260	0.7%
322(PCI W/ INTRALUMINAL DEVICE W/O MCC	-	\$12,707	\$12,875	0.9%
323(CORONARY INTRAVASCULAR LITHOTRIPSY W/ INTRALUMINAL DEVICE W/	-	\$28,987	\$29,313	4.4%
324(CORONARY INTRAVASCULAR LITHOTRIPSY W/O INTRALUMINAL DEVICE	-	\$20,785	\$22,739	9.4%
325(CORONARY INTRAVASCULAR LITHOTRIPSY W/ INTRALUMINAL DEVICE W/	-	\$18,514	\$20,399	10.0%
250(PCI W/O STENT W MCC	\$16,598	\$16,459	\$16,460	0.0%
251(PCI W/O STENT W/O MCC	\$11,149	\$11,111	\$11,120	0.1%
<b>Peripheral Intervention</b>				
252(OTHER VASC PROCEDURES W MCC	\$22,903	\$23,482	\$24,413	4.0%
253(OTHER VASC PROCEDURES W CC	\$18,342	\$17,862	\$18,169	1.7%
254(OTHER VASC PROCEDURES W/O MCC/MCC	\$12,543	\$12,148	\$12,450	2.5%
278(ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL	-	\$31,230	\$35,606	14.0%
279(ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL	-	\$22,409	\$22,804	1.8%

## REIMBURSEMENT UPDATE CMS 2025 Updates – Inpatient and Outpatient

Jackie Shepard, Business Consultant, Corazon

The Centers for Medicare & Medicaid Services (CMS) recently released its 2025 updates, introducing significant changes to the Medicare payment systems that will impact healthcare providers nationwide. These updates, which include adjustments to the Inpatient Prospective Payment System (IPPS), Outpatient Prospective Payment System (OPPS), Ambulatory Surgery Centers (ASCs), and Physician Fee Schedule (PFS), are designed to address current challenges and trends within the healthcare landscape. As providers navigate these updates, understanding the detailed revisions and their implications will be essential for strategic planning and operational efficiency in the year ahead.

*continued on page 13*

## In This Issue

### Conversations in Cardiology: Avoiding Catastrophe – Managing an Errant Inferior Epigastric Artery Puncture

Morton Kern, MD, with Phillip Mumford, MHA, MBA, BSHA, RCIS; Duane Pinto, MD; Steve Ramee, MD; Ken Rosenfield, MD; Curtiss Stinis, MD; Zoltan Turi, MD

page 6

### Paravalvular Leak in Aortic and Mitral Valve Disease

CLD talks with Nish Patel, MD.

page 21

### What Running a Global Education Platform Has Taught Me

Samantha Proper, MBA, BS, RCIS

page 20

## STRUCTURAL HEART & EP

### Lead Management in Patients With Cardiac Implantable Devices and Tricuspid Regurgitation

CLD talks with Electrophysiologist Mark D. Metz, MD, and Structural Interventionalist Mark J. Ricciardi, MD.

How often do cardiac implantable electronic device (CIED) leads cause significant tricuspid regurgitation (TR) and what are the causes?

Dr. Ricciardi (Structural Interventionalist): While there are cases where the lead can impinge on the valve leaflets and cause tricuspid valve dysfunction, it is not very common. We see many patients in valve clinic with significant TR and a lead in place, where the leads themselves are not causal; they just happen to be present. A review summarizing the frequency of occurrence or worsening of TR following CIED implantation found that its occurrence ranged from 7% to 45% of studied patients.<sup>1</sup>



*continued on page 10*

## MEETING UPDATE

### Fall Meeting Roundup: Highlighted Research From the Latest Interventional Symposia

From the 2024 European Society of Cardiology (ESC), Transcatheter Cardiovascular Therapeutics (TCT), and Vascular Interventional Advances (VIVA) meetings



*continued on page 16*

# Fall Meeting Roundup: Highlighted Research From the Latest Interventional Symposia

Find out what you missed from the 2024 European Society of Cardiology (ESC), Transcatheter Cardiovascular Therapeutics (TCT), and Vascular InterVentional Advances (VIVA) meetings

## TCT: EARLY TAVR in Asymptomatic AS Study Finds Early TAVR Can Be Beneficial for Patients with Asymptomatic Severe Aortic Stenosis

The first powered randomized trial examining early intervention with transcatheter aortic valve replacement (TAVR) in patients with asymptomatic, severe aortic stenosis (AS) found this strategy to be both a safe and effective alternative to clinical surveillance (CS).

Findings were reported at TCT 2024, the annual scientific symposium of the Cardiovascular Research Foundation (CRF). Results were also published simultaneously in the *New England Journal of Medicine*.<sup>1</sup>

For patients with asymptomatic, severe AS and

preserved left ventricular ejection fraction, current guidelines recommend clinical surveillance every six to 12 months. Whether the strategy of early TAVR confers benefits over guideline-indicated clinical surveillance remains to be determined.

From March 2017 through December 2021, 1,578 patients consented for screening at 75 centers in the United States and Canada. A total of 901 patients were randomized to either transfemoral TAVR (n=455) or clinical surveillance (n=446). The mean age was 76 years, 69% were male, the mean Society of Thoracic Surgeons risk score was 1.8%, and 84% of patients were considered low surgical risk per local heart team evaluation. Asymptomatic status was confirmed in more than 90% of patients with a negative

treadmill stress test. In addition, the mean Kansas City Cardiomyopathy Questionnaire score at baseline was 92.7 (excellent status). Baseline echo characteristics were also similar between both groups.

The primary endpoint, the composite of death, stroke, or unplanned cardiovascular hospitalization, was evaluated for superiority in the intent-to-treat population after a minimum follow-up of two years. Early TAVR resulted in a significant reduction of the primary endpoint at two years as well as a median follow-up of 3.8 years, occurring 35.1% in the TAVR group compared with 51.2% in the surveillance group [HR (95% CI): 0.50 (0.40, 0.63),  $P < .001$ ].

The secondary endpoint of favorable health status outcome occurred more frequently in the early TAVR group (86.6%) compared with the surveillance group [68.0%, Abs  $\Delta$ : 18.5% [12.6%, 24.3%],  $P < .001$ ].

Left ventricular and left atrial health at two years was also better for those who underwent early TAVR [48.1% versus 35.9%, Abs  $\Delta$ : 12.2% (4.4%, 19.4%),  $P = .001$ ]. Change in left ventricular ejection fraction from baseline to two years, new onset atrial fibrillation, and death or disabling stroke were similar between the two groups.

By two years, more than 70% of the patients in the clinical surveillance group had aortic valve replacement, with the vast majority becoming symptomatic. The median time to conversion was 11.1 months, with 26% and 47% requiring aortic valve replacement at 6 months and 1 year, respectively. More importantly, ~40% of patients from the clinical surveillance group presented with acute and advanced signs and symptoms, such as NYHA III-IV heart failure, pulmonary edema, or syncope.

“Given the benefits observed and the lack of harm, early TAVR may be preferred to clinical surveillance in patients with asymptomatic severe AS, especially when combined with the challenges of timely symptom recognition and prompt treatment in real-world settings,” said Philippe Généreux, MD, Director of the Structural Heart Program at the Gagnon Cardiovascular Institute at Morristown Medical Center. “Not only is early intervention safe and effective, but it also prevents a decline in quality of life for those who later receive TAVR and could prevent the development of cardiac damage.”

The study was funded by Edwards Lifesciences.

## Reference

1. Généreux P, Schwartz A, Oldemeyer JB, et al; EARLY TAVR Trial Investigators. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. *N Engl J Med*. 2024 Oct 28. doi:10.1056/NEJMoa2405880



## ESC: NSTEMI Treatment in Elderly SENIOR-RITA Trial Investigates Use of Invasive Strategy to Treat Older Patients After a NSTEMI

- In the largest trial to date in this population, the SENIOR-RITA trial showed no significant reduction in the combined risk of cardiovascular death or non-fatal myocardial infarction (MI) with an invasive strategy vs a conservative strategy to treat patients aged  $\geq 75$  years who had a non-ST-elevation MI (NSTEMI).
- A significant reduction in the risk of non-fatal MIs and subsequent revascularization procedures was observed with an invasive vs a conservative strategy.
- These results provide a foundation for older patients with NSTEMI and their clinicians to make an informed decision about whether or not to undergo invasive management.

An invasive strategy versus optimal medical therapy alone after a non-ST-elevation myocardial infarction (NSTEMI) in older adults did not affect the combined risk of cardiovascular death or MI, although non-fatal MIs and subsequent revascularization procedures were reduced.<sup>1</sup>

In higher-risk patients after NSTEMI, guidelines recommend an invasive strategy over medications alone.<sup>2</sup> However, older patients with NSTEMI are less likely to receive guideline-recommended care, including an invasive strategy.<sup>3</sup> This might be due to clinician or patient fear of the risk of procedural complications or futility. Furthermore, older patients are underrepresented in clinical trials of NSTEMI treatment strategies and robust evidence-based recommendations for their care are lacking. Therefore, the care of older adults with NSTEMI is not standardized.

Lead investigator Professor Vijay Kunadian of the Translational and Clinical Research Institute, Newcastle University and Freeman Hospital, Newcastle-Upon-Tyne, UK, explained: “Our hypothesis was that an invasive strategy on top of optimal medical therapy versus a conservative strategy of optimal medical therapy alone would be superior in terms of reducing the combined risk of cardiovascular death or non-fatal MI in patients aged  $\geq 75$  years admitted with a NSTEMI. In a broad inclusive trial population, which represents the older patients we see in our daily clinical practice, we did not see a reduction in the combined risk of cardiovascular death or non-fatal MI, but we did see a reduction in recurrent non-fatal MIs and the need for subsequent revascularization procedures.”

In the open-label SENIOR-RITA trial, patients aged  $\geq 75$  years presenting with type 1 NSTEMI were randomly allocated (1:1) to one of two treatment groups. In the conservative strategy group, patients received ESC Guideline-recommended secondary prevention therapy, including antiplatelet therapy,



statins, angiotensin-converting enzyme inhibitors and beta-blockers.<sup>2</sup> In the invasive strategy group, in addition to these medications, patients had invasive coronary angiography and, if deemed necessary, coronary revascularization (stent or bypass surgery). All patients had formal assessment of frailty, cognition and comorbidity at baseline and follow-up. The primary endpoint was time to cardiovascular death or non-fatal MI. Secondary endpoints included components of the primary endpoint, all-cause death, subsequent coronary revascularization and bleeding complications.

In total, 1,518 patients were recruited from around 48 NHS sites across England and Scotland. The mean overall age was 82.4 years and 72% were aged 80 years or older (the oldest being 103 years old). Almost half were female (45%). Overall, 80% of patients were classified as prefrail or frail, more than 60% had cognitive impairment and the majority had a comorbidity index of  $\geq 5$ , indicating multiple concurrent long-term conditions. Medical therapy was balanced between the two groups. In the invasive group, 90% had the intended angiog-

raphy and 50% had revascularization procedures during hospitalization.

After median follow-up of 4.1 years, there was no difference in the primary endpoint of cardiovascular death or non-fatal MI between the invasive strategy group (25.6%) and the conservative strategy group (26.3%; hazard ratio [HR] 0.94, 95% confidence interval [CI] 0.77–1.14;  $P=.53$ ). This pattern was observed for the different prespecified subgroups (including those who were frail, cognitively impaired or had multiple comorbidities).

No differences were observed for cardiovascular death (15.8% with invasive strategy vs 14.2% with conservative strategy; HR 1.11; 95% CI 0.86–1.44). There was a significant reduction in non-fatal MI, which occurred in 11.7% of patients in the invasive strategy group vs. 15.0% in the conservative strategy group (HR 0.75; 95% CI 0.57–0.99). Patients in the invasive strategy group also required fewer subsequent revascularization procedures than those in the conservative strategy group (3.9% vs 13.7%; HR 0.26; 95% CI 0.17–0.39). There were no observed differences in the other



secondary outcomes, including all-cause death, all MIs combined, stroke, hospitalization for heart failure or any bleeding complications. The rate of procedural complications was less than 1%.

Professor Kunadian concluded: “An invasive strategy did not reduce the primary endpoint (combined risk of cardiovascular death or non-fatal MI), but we did see some benefits. Importantly, the invasive strategy appeared to be safe overall in our older patients. These results are consistent with our recent patient-level meta-analysis,<sup>4</sup> which we are currently updating with data from SENIOR-RITA to further strengthen the evidence base in this understudied population. Including older patients in trials enables us to challenge current practice and highlights that age should not be a barrier to individualized care, including access to angiography and percutaneous coronary intervention.”

## References

1. Kunadian V, Mossop H, Shields C, et al; British Heart Foundation SENIOR-RITA Trial Team and Investigators. Invasive treatment strategy for older patients with myocardial infarction. *N Engl J Med*. 2024 Nov 7;391(18):1673-1684. doi:10.1056/NEJMoa2407791
2. Byrne RA, Rossello X, Coughlan JJ, et al. 2023 ESC Guidelines for the management of acute coronary syndromes. *Eur Heart J*. 2023;44:3720-3826.
3. Zaman MJ, Stirling S, Shepstone L, et al. The association between older age and receipt of care and outcomes in patients with acute coronary syndromes: a cohort study of the Myocardial Ischaemia National Audit Project (MINAP). *Eur Heart J*. 2014;35:1551-1558.
4. Kotanidis CP, Mills GB, Bendz B, et al. Invasive vs. conservative management of older patients with non-ST-elevation acute coronary syndrome: individual patient data meta-analysis. *Eur Heart J*. 2024;45:2052-2062. ■

## VIVA: CLTI and TADV

### Two-Year Outcomes From the PROMISE II Trial of Transcatheter Arterialization of the Deep Veins

Up to 20% of patients with chronic limb-threatening ischemia (CLTI) are not eligible for conventional surgical or endovascular revascularization techniques and have a resultant amputation rate of 50% within 6 months. An alternative option for these no-option patients is transcatheter arterialization of the deep veins (TADV) with the LimFlow System (Inari Medical), the only FDA-approved option. The LimFlow System consists of an integrated system for arteriovenous crossing, atraumatic vein preparation, and flow diversion. Two-year outcomes from the prospective, multicenter, single-arm, PROMISE II trial of the LimFlow System for TADV in no-option patients were presented by Daniel Clair, MD, during the VIVA24 conference.

All patients had Rutherford class 5/6 disease and were confirmed as ineligible for endovascular or surgical interventions by an independent physician review committee. Key exclusion criteria were systemic infection, rapidly deteriorating wounds, or advanced heart failure. Study conduct included an independent clinical events committee to adjudicate safety outcomes and a core laboratory to assess all wound images. Two-year outcomes included limb salvage, survival, amputation-free survival, wound healing, and Rutherford classification.

A total of 105 CLTI patients underwent TADV between 2018 and 2022. At 2 years, the limb salvage rate was 65%. An improvement was seen in Rutherford classification: 65.8% of patients had Rutherford class 4 or below and 54.3% had Rutherford class 0. Wounds were completely healed/healing in 82% of patients at 2 years; the mean wound area was 0.1 cm<sup>2</sup>, and the mean pain score was 1.2 out of 10. When combined with the PROMISE I trial, the 2-year limb salvage rate was 68%, with no differences observed based on age, sex, race, baseline Rutherford classification, diabetes, or dialysis.

The long-term outcomes from the PROMISE II trial represent data from the largest cohort of patients with 2-year data and demonstrate sustained limb salvage and wound healing in no-option CLTI patients. ■

## ESC: Intravascular Imaging With OCT

### OCCUPI Study: Optical Coherence Tomography Outperforms Conventional Angiography for Stent Guidance in Complex Cases

- Optical coherence tomography (OCT) reduced the combined risk of cardiac death, heart attacks, stent thrombosis, and the need for revascularization by 38% compared to conventional angiography at 1 year follow-up.
- Results provide strong support for the superior benefits of OCT guidance over conventional angiography-guided PCI.

Using optimal coherence tomography (OCT) to guide stent implantation during percutaneous coronary intervention (PCI) in patients with complex coronary lesions significantly improves survival and reduces adverse cardiovascular events compared to angiography-guided PCI, the most commonly used method.<sup>1</sup>

“Our results show that the use of OCT guidance improves clinical outcomes and enhances safety and effectiveness of coronary stenting, reducing cardiac death, myocardial infarction, stent thrombosis, and the need for revascularization by 38% in a group of very complex patients, which more reflects contemporary interventional cardiology practice,” said lead investigator Professor Byeong-Keuk Kim from Yonsei University Severance Hospital, Seoul, Korea.

OCT uses light instead of x-ray to create cross-sectional and longitudinal images, which have much higher resolution and are more accurate, and more detailed compared to angiography.

Previous studies have suggested practical benefits for OCT-guided PCI, providing comprehensive information on coronary vessels, plaque, and implanted stents. This latest study follows on findings of the OCTOBER trial, published in 2023, showing that OCT-guided PCI of complex bifurcation lesions is superior to angiography-guided PCI for cardiovascular outcomes at 2 years.<sup>2</sup>

The OCCUPI trial enrolled 1,604 patients (aged 19 or older) from 20 centers in The Republic of Korea with anatomically complex lesions requiring PCI using drug-eluting stents.

Patients were randomized in a 1:1 ratio to undergo either OCT guidance (803 patients) or angiography guidance (801 patients). In total, 1,588 (99%) patients completed the 1-year follow-up.

The primary measure of interest was a composite of cardiac death, myocardial infarction, stent thrombosis, and target-vessel revascularization at 1 year.

At 1-year follow-up, patients who received OCT guidance experienced a 38% reduction in

the combined risk of cardiac death, heart attacks, stent thrombosis, and the need for revascularization compared with angiography guidance (37 patients, 4.6% vs 59 patients, 7.4%, respectively).

Notably, patients who received OCT guidance were 64% less likely to experience a spontaneous myocardial infarction (excluding periprocedural myocardial infarction) or require target-vessel revascularization than those in the angiography-guided group (0.9% vs 2.4% and 1.5% vs 4.1%, respectively).

The study also found that the incidence of contrast-induced nephropathy after PCI was not significantly different between two groups (1.3% vs 0.9%).

“Our findings provide more evidence that OCT guidance of PCI procedures in patients with complex lesions has a greater impact on improving their lives than conventional angiography guidance,” said Professor Kim. “Based on the OCCUPI trial, we now need to establish detailed standards for optimal use of OCT for the improvement of clinical outcomes of PCI in complex cases.”

## References

- Hong SJ, Lee SJ, Lee SH, et al; OCCUPI investigators. Optical coherence tomography-guided versus angiography-guided percutaneous coronary intervention for patients with complex lesions (OCCUPI): an investigator-initiated, multicentre, randomised, open-label, superiority trial in South Korea. *Lancet*. 2024 Sep 14;404(10457):1029-1039. doi:10.1016/S0140-6736(24)01454-5
- Holm NR, Andreassen LN, Neghabat O, et al; OCTOBER Trial Group. OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions. *N Engl J Med*. 2023 Oct 19;389(16):1477-1487. doi:10.1056/NEJMoa2307770

## TCT: Orbital Atherectomy ECLIPSE Trial: Orbital Atherectomy Prior to Coronary Stent Implantation Does Not Lead to Better Outcomes Compared to Conventional Balloon Angioplasty

Results from the large-scale randomized ECLIPSE trial found that a lesion preparation strategy of routine orbital atherectomy had similar outcomes compared with conventional balloon angioplasty prior to implantation of a drug-eluting stent (DES) in severely calcified coronary arteries.

Findings were reported at TCT 2024, the annual scientific symposium of the Cardiovascular Research Foundation (CRF).

Severe coronary artery calcification has been associated with stent underexpansion, procedural complications, and increased rates of early and late adverse clinical events among patients undergoing percutaneous coronary intervention. Coronary atherectomy can ablate and fracture calcium, improving lesion compliance, thus facilitating stent delivery and expansion. To date, no lesion preparation strategy for severely calcified coronary artery lesions has definitively shown

to improve clinical outcomes in an adequately powered randomized trial.

From March 2017 to April 2023, a total of 2,005 patients (2,492 lesions) were enrolled at 104 sites in the United States. The mean patient age was 70 years; 27.0% were female, 44% had diabetes and 24% had chronic kidney disease. By angiographic core laboratory analysis, mean reference vessel diameter was 3.0 mm, mean lesion length was 28.7 mm, and 97.1% of lesions met criteria for severe calcification. A large proportion (62%) of patients underwent intravascular imaging in the trial.

Patients were randomized after successful wire crossing to either the orbital atherectomy strategy (n=1,008) or conventional balloon angioplasty (n=997) prior to second generation drug-eluting stent implantation and optimization. Procedural complications were largely similar between groups.

The primary imaging endpoint consisted of the acute post-PCI minimal stent area at the site of maximum calcification as assessed by optical coherence tomography (OCT) in a pre-specified cohort of 555 subjects enrolled at 39 sites in the United States. Stent areas were not appreciably different between the two groups [ $7.67 \pm 2.27$  for orbital atherectomy vs  $7.42 \pm 2.54$  for balloon angioplasty, 99% CI 0.26 (-0.31, 0.82 mm<sup>2</sup>),  $P=.08$ ].

The primary clinical endpoint of target vessel failure (TVF), defined as the composite of cardiac death, target vessel-related myocardial infarction, or ischemia-driven target vessel revascularization at one year follow-up, occurred in 11.5% in the orbital atherectomy group compared with 10.0% in the traditional balloon angioplasty group [hazard ratio 1.16 (96% CI 0.87, 1.54),  $P=.28$ ]. The two secondary endpoints of procedural success and strategy success without the need for crossover were similar between both groups.

“Compared with conventional balloon angioplasty, the routine use of orbital atherectomy did not reduce minimal stent area or target vessel failure,” said Ajay J. Kirtane, MD, SM, Director of Columbia Interventional Cardiovascular Care at NewYork-Presbyterian/Columbia University Irving Medical Center and Professor of Medicine at the Columbia University Irving Medical Center. “The high use of intravascular imaging within this trial was remarkable and was associated with improved outcomes in both treatment groups. But the take-home message for me is that we showed that adequate stent expansion and low rates of adverse outcomes are achievable with conventional balloon angioplasty if meticulous attention is paid to lesion preparation, further highlighting the importance of randomized trials to inform treatment strategies.”

*The study was funded by Abbott Vascular (formerly Cardiovascular Systems, Inc).* ■

## VIVA: Percutaneous Fem Pop Bypass 36-Month Results of DETOUR2 Study Evaluates Novel Detour System for Fully Percutaneous Femoropopliteal Bypass

Endologix LLC announced the final 36-month results of the DETOUR2 Study. The Detour System enables physicians to percutaneously bypass lesions in the superficial femoral artery by using stents routed through the femoral vein to restore blood flow to the leg. The Detour System is comprised of the Endocross device and Torus stent grafts. The DETOUR2 Study findings show the Detour System to be comparable to open bypass with a synthetic graft. Additionally, the low rates of complications and deep venous thrombosis (DVT) demonstrate the favorable safety profile of this novel technique.

The 36-month results from the study were presented at the Late Breaking Clinical Trial session at VIVA24 by one of the study’s principal investigators, Sean Lyden, MD, Chairman of the Department of Vascular Surgery at Cleveland Clinic.

“These extended results from the DETOUR2 study help continue to demonstrate using the Detour system is comparable to surgical bypass but without requiring general anesthesia, which can come with additional complications and longer length of stay,” said Dr. Lyden.

Matt Thompson, MD, President, and CEO of Endologix, said, “As we move forward, our focus remains on ensuring optimal patient outcomes through rigorous training, ongoing data collection, and the PTAB-1 post-market study to further validate these results in real-world settings.”

The DETOUR2 Study enrolled 202 patients at 32 sites, and 200 patients were treated with the Detour System. The mean lesion length was 32.7 cm, 96% were chronic total occlusions (CTO), and 70% were severely calcified.

The results presented highlight:

- Freedom from clinically driven target lesion revascularization was 66.8% through 3 years.
- Primary patency was 58.2% through 36 months.
- Clinical success, defined as improvement in at least one Rutherford Category at 36 months, was 96.7%.
- The freedom from symptomatic deep vein thrombosis was 95.9% at 36 months.
- The freedom from major lower limb amputation was 98.5% at 36 months.
- Average length of hospital stay was 1.1 days.

*About the Detour System.* Percutaneous trans-femoral arterial bypass (PTAB) with the Detour System offers a novel approach to treating complex peripheral arterial disease, enabling physicians to bypass lesions in the superficial femoral artery, by using stents routed through the femoral vein via a transmural passage, to restore blood flow to the leg. This approach is effective for patients with long lesions (20 cm-46 cm in length), those that have already undergone failed endovascular procedures, or those that may be suboptimal candidates for open surgical bypass. ■