Interventional Market Assessment

A summary of the 8th Morgan Stanley Interventional Cardiology Conference provides insight into the trends that will be affecting endovascular care for the next several years.

BY THE *ENDOVASCULAR TODAY* STAFF

On February 24, 2005, Glenn Reicin, Managing Director, Hospital Supplies and Medical Technology, Morgan Stanley (New York, NY) and his team conducted their 8th Annual Interventional Cardiology Conference, which provided assessments from leading interventional specialists regarding the future for carotid artery stenting, abdominal and thoracic endografts, coronary stent platforms, as well as a look into those technologies that may revolutionize interventional treatments in the next 5 years. The expert panel consisted of Martin Leon, MD, Director of the Center for Interventional Vascular Therapy at Columbia University Medical Center, New York, New York; Takao Ohki, MD, Chief of Vascular and Endovascular Surgery at Montefiore Medical Center, New York, New York; Elazer Edelman, MD, Director of the Harvard-MIT Biomedical Engineering Center, Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology at MIT, Cambridge, Massachusetts; and Campbell Rogers, MD, Director of the Cardiac Catheterization Laboratory at Brigham & Women's Hospital, Boston, Massachusetts.

Dr. Leon provided a review of the present state of the interventional cardiology market and also shared a glimpse into newer emerging technologies for the future. Dr. Ohki discussed carotid stenting, embolic protection, and endovascular grafts. Dr. Edelman offered scientific research and clinical issues impacting the drug-eluting stent market today. Dr. Rogers spoke about optimizing new stent designs and also provided a preview of the American College of Cardiology (ACC) Conference.

CAROTID ARTERY STENTING

Morgan Stanley predicts that the carotid artery stent market will accelerate rapidly since the FDA approval of the Guidant (Indianapolis, IN) carotid artery stent in August of 2004. The panel thought this assessment may be too optimistic in light of the recent draft decision by the Centers for Medicare and Medicaid Services (CMS) limiting reimbursement to severely symptomatic patients. Dr. Ohki did express optimism regarding the CREST study (NINDS, NIH) and the ACT I trial (Abbott Labs, Abbott Park, IL), both of which include asymptomatic patients. The analysts anticipate that Cordis Endovascular (a Johnson & Johnson company, Miami, FL) and Boston Scientific Corporation (Natick, MA) will both gain FDA approval of their device platforms in the second quarter of 2005, with Abbott and Medtronic, Incorporated (Santa Rosa, CA) to gain FDA approval in the second half of the year, and ev3 (Plymouth, MN) to gain approval in 2006. The worldwide carotid artery stenting market was $60 million in 2004, and is expected to reach near $600 million by 2008, assuming CMS expands its reimbursement policy pending more data.

AORTIC ANEURYSMS

The aortic aneurysm market was $330 million in 2004, and the analysts believe that the market is expected to experience a growth rate in the low double digits, with Dr. Ohki offering a more optimistic assessment. The biggest factors for growth are the expected FDA approval of thoracic aneurysm endografts, clinical benefits of AAA stent grafts, and the pending SAAAVE legislation designed to provide reimbursement for AAA screening. (See related article on page 71). Dr. Ohki pointed to data presented in 2004 from the randomized prospective study EVAR 1 and the DREAM trial (Dutch). Both studies demonstrated a dramatic reduction in 30-day mortality, hospital stay, and length of operation. In addition, increasing public awareness of AAA stent grafts should help support penetration of this device in the future. Dr. Ohki pointed out that approximately 200,000 patients are diagnosed with an AAA annually in the US, even with little screening. With the advent of newer imaging technologies, such as ultrasound and CT (computed tomography) imaging, AAA stent graft penetration should accelerate.

Several competitors are trying to gain a footprint in the AAA area including Cordis Endovascular (Fortron, US/OUS launch 1Q 2007/3Q 2006) and Boston Scientific (Trivascular, US launch 4Q 2007). W. L. Gore & Associates (Flagstaff, AZ) will likely obtain FDA approval of its thoracic aneurysm device in the next month. Dr. Ohki estimates that this market may include approximately 22,000 procedures, representing a $220 million to $250 million opportunity. Medtronic and Cook (Bloomington, IN) are also in clinical studies in this market, and Medtronic could have its thoracic aortic device on the market as early as late 2005.

DRUG-ELUTING STENTS

The analysts believe the drug-eluting stent market is maturing, leading to a slowdown in the $8.75 billion interventional cardiology market. The ACC meeting in March is expected to provide interesting data regarding comparisons between the Cordis Cypher and the Boston Scientific Taxus drug-eluting stents. Full coverage of these study results will be provided in the April issue of *Endovascular Today* and in our biweekly eNewsletter.

TOP DEVICES IN THE PIPELINE

Dr. Leon provided his assessment of several of the top interventional cardiology devices in the pipeline and the analysts highlighted these three as the ones to watch:

Micro and Nanotechnology

The analysts believe this is an area that will represent a strong opportunity in the future. In particular, they believe there is a high probability that nanotechnology will be an effective tool for patients to monitor AAA stent grafts, with Remon Medical (Caesaria Industrial Park, Israel) and CardioMEMS (Atlanta, GA) as the leaders in this emerging market.

Percutaneous Heart Valves

Both percutaneous mitral valve repair and aortic valve replacement are promising technologies. Of the two technologies, valve repair will probably materialize sooner. Currently, there are several companies vying for this opportunity, including Edwards Lifesciences (Irvine, CA), Viacor (Wilmington, MA), and CoreValve (Irvine, CA).

Interventional Treatment of Congestive Heart Failure

The analysts believe that one of the most significant opportunities going forward is the potential for interventional devices in the treatment of congestive heart failure (CHF). Dr. Leon views biventricular pacing devices and implantable cardioverter defibrillators as the "tip of the iceberg" when it comes to treating CHF. Two potential device CHF therapies that appear to have significant market potential are: (1) Cardiac Contractility Modulation (Impulse Dynamics, Netherlands Antilles), which is an electrical stimulation device used to relieve symptoms of CHF, and (2) an Interventional Intravascular Defibrillator (IID being developed by Interventional Rhythm Management, Research Triangle Park, NC). IID is a downsized defibrillator that can be implanted in 10 minutes by an interventional cardiologist.

ENDOVASCULAR THERAPY ASSESSMENT

The analysts believe that endovascular therapies are still in their infancy, with the primary candidates for growth being carotid artery stenting, AAA endografts, thoracic endografts, renal stenting, and venous disease treatments. The panelists were "cautious" about the prospects for peripheral drug-eluting stents, which have not performed well in clinical studies to date.

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