



*Medical Device Strategic Marketing,
Market Research,
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Technology Prevails! The Long Awaited Transcatheter Aortic Valve Replacement Device

The current average age for US patients diagnosed with severe aortic stenosis is 70 years old¹. Traditional valve replacement is considered a high risk surgery for these elderly patients, especially those with co-morbidities. Due to their condition, a significant percentage of patients diagnosed with moderate or severe valve disease have been denied traditional valve surgery, due to its high operative mortality rate.

Why this is Important

Interventional cardiologists are exceptionally enthusiastic² about the potential of transcatheter aortic valve replacement, and with good reason. The preliminary data on this new device show that the procedure provides a minimally invasive alternative to cardiac valve surgery. Sessions at the 2010 EuroPCR meeting in Paris, France, were standing room only, as crowds of MDs attended to hear presentations on transcatheter aortic heart valve implantation.

The Source Registry

Dr Martyn Thomas, Cardiothoracic Services Director at Guy's & St. Thomas' Hospital in London, presented one-year results³ at EuroPCR from Edwards Lifesciences' SAPIEN SOURCE registry. The SOURCE registry included 1,038 patients (98% follow-up) treated in 32 hospitals and medical centers across Europe. 30 day and 1 year survival rates for this very high risk population are presented in Chart 1⁴.

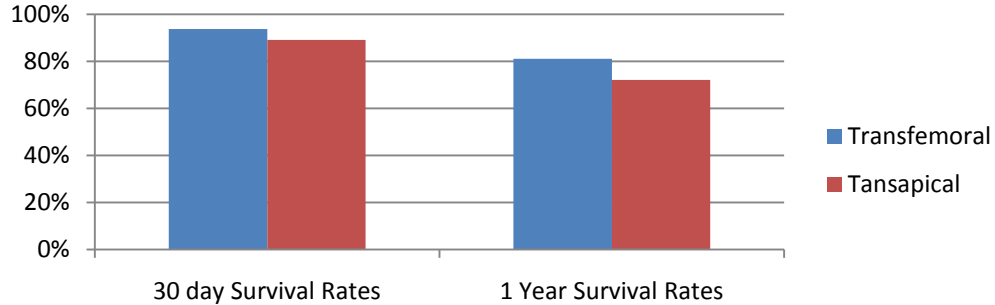
¹ www.cdc.gov

² Tuzcu, E. Murat, et. al, Editorial; "SOURCE" of Enthusiasm for Transcatheter Aortic Valve Implantation, (*Circulation*. 2010;122:8-10.)

³ <http://www.medicaldevicestoday.com/2010/06/euroPCR-highlights-tavi-set-to-continue-rampant-growth.html>

⁴ Thomas, M. et. al. the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry, *Circulation*. 2010;122:62-69.

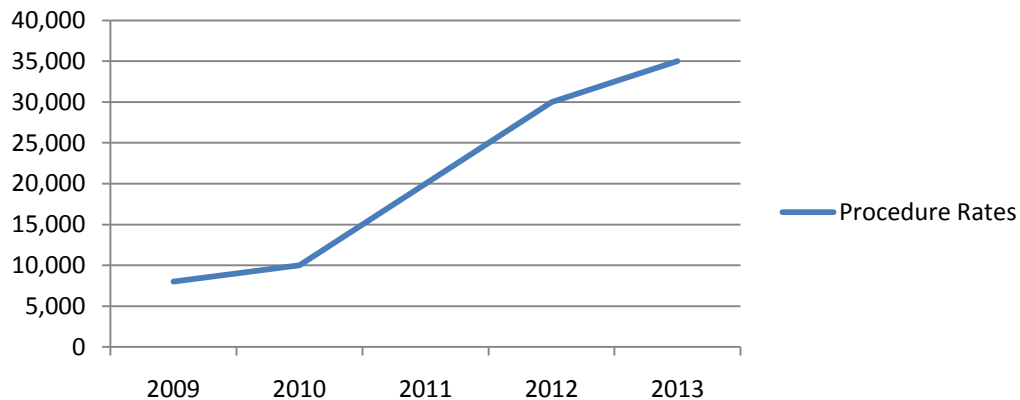
SOURCE Registry: 30 Day Survival Rates for Transfemoral vs. Transapical Patients (n=1038)



The first transcatheter aortic valve replacement was performed in 2002 and since then, the prosthetic heart valve market has evolved at a dramatic pace. This market is extremely competitive with over 100 products in development from more than 25 companies. There are currently two products commercially available internationally, (except in the US), the Edwards SAPIEN; from Edwards Life Sciences and the CoreValve; from Medtronic.

Both products show rapid adoption rates in spite of constrained patient exclusion criteria. The high cost of these devices is especially by European standards. Device costs are reported to range from \$25,000 - \$35,000, as compared to \$2,800 - \$5,600 for traditional aortic valve surgery). Estimated procedure volumes are presented in the Chart 2⁵.

2009-2013 Estimated Transcatheter Valve Replacement Procedure Rates



⁵ Medtech Insight - June, 2010

The global market opportunity⁶ for transcatheter heart valves is estimated at more than 300,000 patients worldwide annually. While transcatheter heart valves are currently indicated only for high-risk patients, it is expected that they will be indicated in the future for lower-risk patients as well.

Technology prevails! Transcatheter valve replacement surgery has been in development for more than 20 years, but finally, the benefit of a minimally invasive approach is showing remarkably improved patient outcomes though faster recovery time and less morbidity and mortality.

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Maria Shepherd has 20 years of leadership experience in medical device/life-science marketing in small startups and top-tier companies. Following a career in senior management positions including Vice President of Marketing for Oridion Medical, Director of Marketing for Philips Medical and Group Marketing Manager at Boston Scientific, she founded Data Decision Group. Data Decision Group provides critical data to support sound decision making. The firm quantitatively and qualitatively sizes opportunities, provides marketing services, evaluates new technologies, and assesses prospective acquisitions. Shepherd has taught marketing and product development courses in the WPI/MassMEDIC Medical Device Certificate and HCMA programs, and can be reached at (617) 548-9892 or at mshepherd@ddecisiongroup.com.

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⁶ Global Cardiovascular Pipeline Landscape, Jan, 2010