

The Healthcare Marketplace
Professor: Stephen T. Parente

Market Research

Cardiac Surgery Market at a Glance

Introduction

Cardiac surgery covers surgery on the heart and/or great vessels performed by a cardiac surgeon. Frequently, it is done to treat complications of ischemic heart disease (for example, coronary artery bypass grafting), correct congenital heart disease, or treat valvular heart disease created by various causes including endocarditis. It also includes heart transplantation¹. The cardiac surgery market includes heart valves, oxygenation systems, blood pumps, biocompatible surfaces, custom perfusion systems, cardioplegia delivery systems, auto-transfusion systems, and heart stabilization devices².

This market is poised for strong growth, as the number of potential patients' increases and due to lack of competitive alternatives. This paper will detail the market size, technology improvement, the main stakeholders and layout the risks and outlook in this market.

Market size

Each year, cardiovascular disease causes almost 20,000 deaths in the United States, and more than half a million Americans undergo heart surgery to treat the symptoms of heart disease. The potential worldwide market reaches 533,000 operations a year³. The analysis from Frost & Sullivan (www.medicaldevices.frost.com) on U.S. Cardiac Surgery Markets reveals that this market generated revenues worth \$806.3 million in 2002 and is expected to reach \$893.2 million in 2009. Another market research provided the similar result: in 2004, the cardiac surgery market was valued at US\$290 million. The US emerging cardiac surgery devices market is expected to drive the total market to over \$500 million

¹ <http://en.wikipedia.org/>

² www.medtronic.com

³ <http://www.stanfordalumni.org/news/magazine/>

in sales by 2009⁴. With the high margin, this market remains lucrative to big players such as Medtronic, Boston Scientific Guidant as well as start-ups.

Technology Improvement

Material innovation

The heart valves market is expected to continue shifting from mechanical valves to tissue valves; however, none of them replies to patients' long term replacement requirement.

In response to end-user demand for a durable replacement of diseased heart valves, researchers have been working on a prototype of longer-lasting polymer valve that combines high amounts of silicone with polyurethane. While prosthetic valves can be outgrown, tissue valves are prone to wear and calcification. The new polymer valve will blend the advantages of both mechanical and tissue valves to be more robust and prevent blood clots. It is expected to be available commercially in three to five years.

Procedure innovation

The minimally invasive operation procedure is the trend in heart surgery. The new approach has galvanized doctors, patients, insurance providers and investors because it avoids the big, traumatic neck-to-navel incision called a median sternotomy, shortens the patient's hospital stay and gets him back to work sooner.

First performed on April 1, 1995, the procedure was invented by Wes Sterman and John Stevens, medical school classmates at Stanford. Instead of sawing a patient's breastbone in half and ratcheting it apart with big steel retractors, the surgeon performs a single-

⁴ <http://www.researchandmarkets.com/>

coronary-artery bypass operation through a 3-inch incision just below the patient's left chest. In four days, the patient could be resting at home on the way to full recovery⁵.

Another recent procedure is called coronary artery bypass grafting, or CABG. This enabled doctors to reroute multiple arteries – not just those at the front of the heart – while still eliminating the expense and potential complications of the heart-lung machine. These surgeries are performed to bypass the blocked artery to keep the blood flowing smoothly. The physician adoption rate for beating heart continues to rise due to the effective clinical results. It is estimated nearly 370,000 CABG surgeries in 2003⁶. Clinical studies emphasizing beating heart CABG surgery's efficacy and its cost-effectiveness are encouraging more surgeons to switch to this procedure. It has a great advantage over traditional cardiopulmonary bypass surgeries that carry the inherent risks of renal insufficiency, pulmonary insufficiency, and immunosuppression, especially in aged patients. Beating heart CABG not only reduces the chances of stroke and need for blood transfusions considerably but also entails a very short post-operative hospital stay. Other significant benefits include less blood loss, decreased systemic inflammatory response, and fewer arrhythmia and neurological post-operative complications. The market is expected to expand significantly as new heart stabilization devices are introduced and more surgeons learn the beating heart technique.

Other minimally invasive cardiovascular devices such as catheter-based treatment also enable grafting of stents to let blood pass through, taking pressure off the weak aorta. Such surgeries minimize complications since they can be performed without making a large breastbone incision. Further studies are being conducted on endovascular valve

⁵ <http://www.stanfordalumni.org/news/magazine/1998/mayjun/articles/>

⁶ <http://www.hospitalnetwork.com/content/news/>

procedures in the United States and Europe since these have immense potential to drive growth of heart valves.

Major Stakeholders

Payers

Cardiac surgery has developed over the past four decades in the United States as an important component of the entire health care industry. It is apparent that cardiac surgery is transitioning from its emerging or rapid growth phase to that of a mature industry. This transition, when combined with the environment in all of health care, has caused payers to reassess the value of cardiac surgical services and they have been targeted as overvalued and consuming a disproportionate share of health care resources. The insurance provider adapts actively the technology change when assessing the procedure. The example of Cardiac Surgery reimbursement updated by the center for Medicare and Medicaid Service (CMS) is shown in Appendix I. CMS has raised slightly the reimbursement for most of the procedures, however, a substantial change in the way cardiac surgery is practiced and reimbursed would occur in the future.

Surgeons

New ways of treating heart disease have changed that outlook: Cardiac surgeons are having a tougher time finding work. The use of artery-opening stents has helped lead to a sharp drop in the number of patients having cardiac bypass surgery and contributed to a tight job market for cardiac surgeons and falling interest in the specialty by medical school graduates. A survey of 88 cardiothoracic residents finishing their training found that 12% received no job offers in 2004, according to a 2006 article in the *Annals of Thoracic Surgery*. At the same time, the number of applicants choosing to pursue one of

the 140 training spots each year has also declined. In 2005, there were only 104 applicants filling 100 of the 139 available spots, according to the article. Cardiac surgery residents spend an average 10 years after medical school pursuing training for the specialized field, whose practitioners earn a median income of \$419,980⁷. The graduating residents, whose average age in the survey was nearly 36, spent five to seven years in general surgery residency and two to three to become cardiothoracic surgeons.

Since many older surgeons will soon be retired and as baby boomers enter their prime heart disease years, how to keep balance the supply and demand of Cardiac surgeons would be a challenge, especially considering the long training cycle.

Risks

Aged patients

Nationwide, cardiac surgery is being performed more frequently in patients aged 65 years and older⁸. The elder the patients, the riskier the operations. According to a research report (Appendix II), the 30-day mortality rate for patients aged 65 to 75 years was 3.4% (12 of 351 patients), versus 13.5% (14 of 104) for patients aged 80+ ($p = 0.0004$), which ranged from 2% (1 of 50) in nonemergent coronary artery bypass grafting to 75% (3 of 4) in double valve procedures. Complications occurring more frequently in octogenarians were severe low output state, reintubation, and atrial fibrillation⁹.

Neurological damage

A major concern with cardiac surgery is the incidence of neurological damage. Stroke occurs in 2-3% of all people undergoing cardiac surgery, and is higher in patients at risk for stroke. A more subtle constellation of neurocognitive deficits attributed to

⁷ www.salary.com

⁸ <http://ats.ctsnetjournals.org/cgi/content/abstract/71/2/591>

⁹ Ann Thorac Surg 2001;71:591-596© 2001 The Society of Thoracic Surgeons

cardiopulmonary bypass is known as post-perfusion syndrome (sometimes called 'pumphead'). The symptoms of post-perfusion syndrome were initially felt to be permanent, but were shown to be transient with no permanent neurological impairment¹⁰.

Future outlook

In future, the market growth will be driven by the minimally invasive alternatives and improvement in technological device design.

Using conservative assumptions, a 1 percent difference in mortality rates could lead to 2,000 excess deaths a year if the wrong procedure prevails¹¹. Though the investors are hyperbolic about minimally invasive alternatives, the surgeons move slowly to switch to the new procedure. It would take time to turn around 30 years of established cardiac surgery procedures and practices. How to convince average cardiac surgeons to embrace alternative techniques is a challenge for medical device innovators.

¹⁰ <http://en.wikipedia.org/>

¹¹ http://www.stanfordalumni.org/news/magazine/1998/mayjun/articles/doctors_of_invention.html

Appendix I Cardiac Surgery Reimbursement

Source: http://www.guidant.com/reimbursement/cs_codes/

On August 1, 2006, the Centers for Medicare and Medicaid Services (CMS) released the final update to the 2007 fiscal year Inpatient Prospective Payment System (2007 FY IPPS). The changes that affect Cardiac Surgery (CS) are detailed below. The changes are effective October 1, 2006 - September 30, 2007.

| DRG | Procedure | FY07 [†] vs. FY06 ^{††} | Base DRG Reimbursement ^{†††} |
|-----|--|---|--|
| 104 | Cardiac Valve Procedures and Other Major Cardiothoracic Procedures with Cardiac Catheterization | 3.7% | \$43,922 |
| 105 | Cardiac Valve Procedures and Other Major Cardiothoracic Procedures without Cardiac Catheterization | 3.5% | \$32,104 |
| 106 | Coronary Bypass with PTCA | -1.3% | \$35,778 |
| 108 | Other Cardiothoracic Procedures | 0.8% | \$30,528 |
| 547 | Coronary Bypass with Cardiac Catheterization with MCV Diagnosis | 2.0% | \$32,554 |
| 548 | Coronary Bypass with Cardiac Catheterization without MCV Diagnosis | 1.3% | \$24,639 |
| 549 | Coronary Bypass without Cardiac Catheterization with MCV Diagnosis | 1.5% | \$26,656 |
| 550 | Coronary Bypass without Cardiac Catheterization without MCV Diagnosis | 2.3% | \$19,062 |

DRG = Diagnosis Related Group

MCV = Major Cardiovascular Condition

Patients with MCV are determined by the conditions and related ICD-9-CM diagnosis codes specified by Medicare. For a list of these MCV diagnosis codes, please refer to pages 47477-47478 of the 2006 FY IPPS Final Rule published on the CMS website, or download the MCV Diagnosis Codes [here](#).

[†] CMS Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates Final Rule, document CMS-1488-F published in the Federal Register dated August 18, 2006, on display August 1, 2006

^{††} CMS Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates Final Rule, document CMS-1500-F on display at the Federal Register August 12, 2005

††† Many factors, such as geographic location, wages and teaching institutions, all contribute to payment rates for hospitals. DRG rates vary dramatically throughout the country and will be different for every hospital. Hospitals should always check internally or with their fiscal intermediary to get actual payment rates and to confirm appropriate billing for the procedure performed.

Appendix II Cardiac surgery in the octogenarian: evaluation of risk, cost, and outcome

By G. James Avery, II, MD^a, S. Jill Ley, RN^a, J. Donald Hill, MD^a, James J. Hershon, MD^a, Stuart E. Dick, MPH^b

^a Department of Cardiac Surgery, Clinical Resource Management, California Pacific Medical Center, San Francisco, California, USA

^b Department of The Research Institute, California Pacific Medical Center, San Francisco, California, USA

Source: *Ann Thorac Surg* 2001;71:591-596 © 2001 The Society of Thoracic Surgeons

Accepted for publication May 11, 2000.

Address reprint requests to Dr Avery, 2100 Webster St, Suite 320, San Francisco, CA 94115
e-mail: leyj@sutterhealth.org

Methods: One hundred four octogenarians undergoing a variety of heart–lung procedures were prospectively studied between 1995 and 1998 for comparison with similar patients aged 65 to 75 years (n = 351).

Results: Octogenarians were more likely to be of female gender, and be nondiabetic than the younger group. The 30-day mortality rate for patients aged 65 to 75 years was 3.4% (12 of 351 patients), versus 13.5% (14 of 104) for patients aged 80+ ($p = 0.0004$), which ranged from 2% (1 of 50) in nonemergent coronary artery bypass grafting to 75% (3 of 4) in double valve procedures. Complications occurring more frequently in octogenarians were severe low output state, reintubation, and atrial fibrillation. Elders experienced a longer intensive care (69.2 versus 43.3 hours, $p = 0.002$) and postoperative stay (10.09 versus 7.45 days, $p = 0.001$), and were discharged to a skilled nursing facility more often than younger patients (47% versus 21.1%, $p = 0.0001$). Total direct costs were \$4,818 higher in the octogenarian group ($p = 0.0007$).

Conclusions: Although emergency operations and complex procedures carried high risks for the octogenarian, the majority of these patients can be offered operation with short-term morbidity, mortality, and resource use that only modestly exceeds that of younger patients.

References:

<http://en.wikipedia.org/>

<http://www.stanfordalumni.org/news/magazine/>

<http://www.researchandmarkets.com/>

<http://www.stanfordalumni.org/news/magazine/>

<http://www.hospitalnetwork.com/content/news/>

www.salary.com

<http://ats.ctsnetjournals.org/cgi/content/abstract/71/2/591>

Ann Thorac Surg 2001;71:591-596© 2001 The Society of Thoracic Surgeons

http://www.stanfordalumni.org/news/magazine/1998/mayjun/articles/doctors_of_invention.html

<http://www.guidant.com/>

<http://www.medtronic.com/>

<http://www.heartvalvechoice.com/>

Magazine “Drug discovery and development”, issue December 2006

Magazine “Health Affaires”, issue Jan/Feb. 2007, Volume 26, Number 1