A collection of surgical instruments, including forceps and scissors, are arranged on a brushed metal surface. The instruments are in sharp focus, with some showing signs of use. The background is a soft, out-of-focus light gray.

HOW TO IMPROVE

CABG RESULTS & REDUCE COSTS

Heart disease is the leading cause of death in the United States.

The National Vital Statistic Report on mortality in the United States in 2012, released on Aug. 31, 2015, reveals that diseases of the heart again topped the list of the 15 leading causes of death for that year with 23.6% of the total mortality related to heart conditions. Cancer followed as a close second with 22.9% of all deaths (Fig. 1).¹

Although there are a number of treatment modalities for heart disease—including the advent and widespread use of percutaneous coronary intervention (PCI) with drug eluting stents—coronary artery bypass surgery (CABG) remains the optimal non-emergent treatment of multi-vessel disease in older patients, according to the ASCERT study published in the April 2012 issue of the New England Journal of Medicine.²

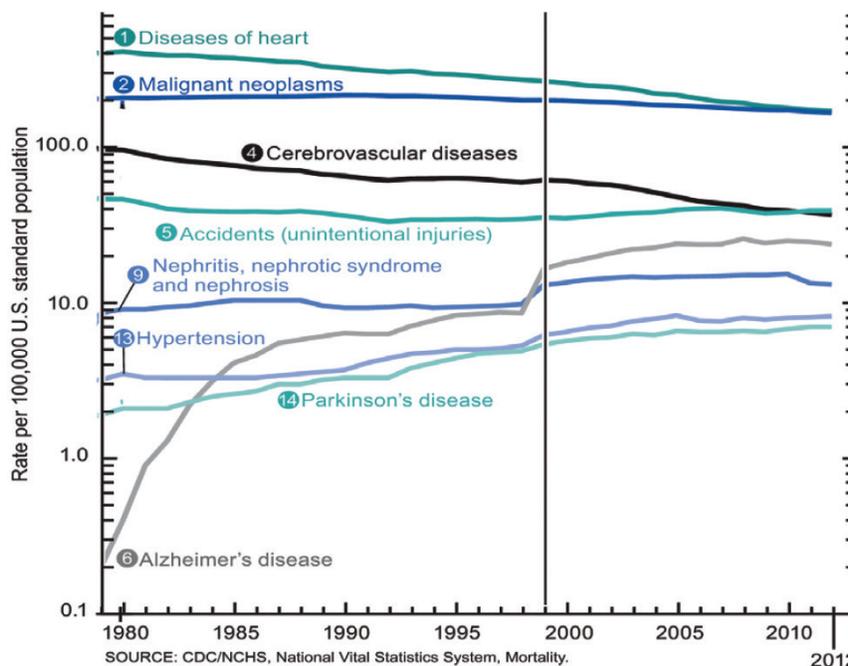
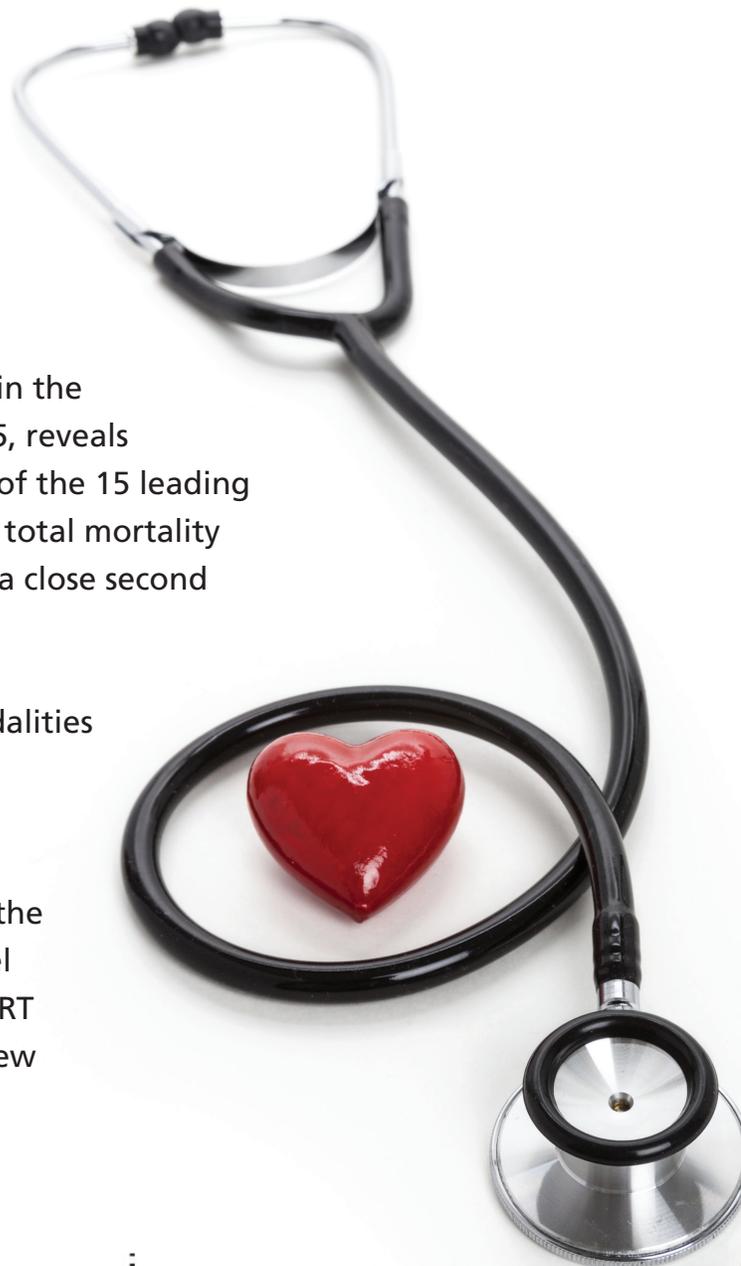


Figure 1 Major causes of mortality in the United States in 2012.



"In summary, the ASCERT study used data from the ACCF PCI database and the STS CABG database, with linkage to CMS claims records, to evaluate the comparative effectiveness of PCI and CABG. We found that among patients older than 65 years of age with multi-vessel coronary artery disease that did not require emergency treatment, there was a long-term survival advantage associated with CABG as compared with PCI."²



CABG is one of the most frequently performed surgeries around the world with more than 200,000 operations performed annually in the United States alone. CABG surgery expends more resources than any other cardiovascular procedure.³⁻⁴ An average CABG surgery in the United States costs more than \$38,000.⁵ As the Affordable Care Act's pay-for performance measures seek to reduce healthcare (Medicare) costs by relating the cost of a procedure to the value received,⁵ any new measure must be scrutinized for its clinical quality (value) and what it costs. Intraoperative blood flow measurement to measure the patency of newly sewn anastomoses during CABG surgery is one such measure.

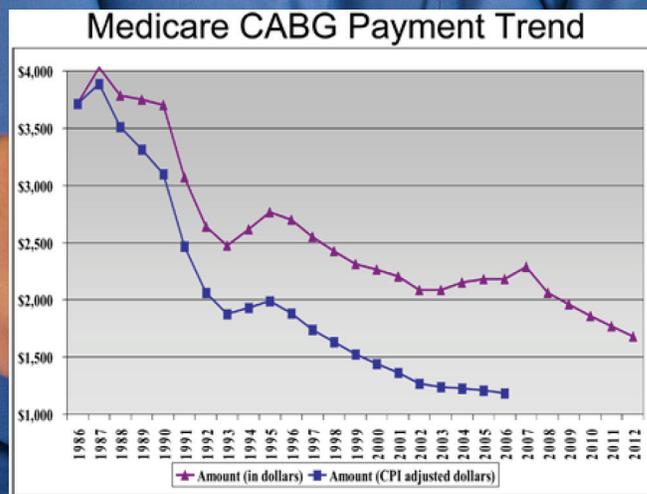
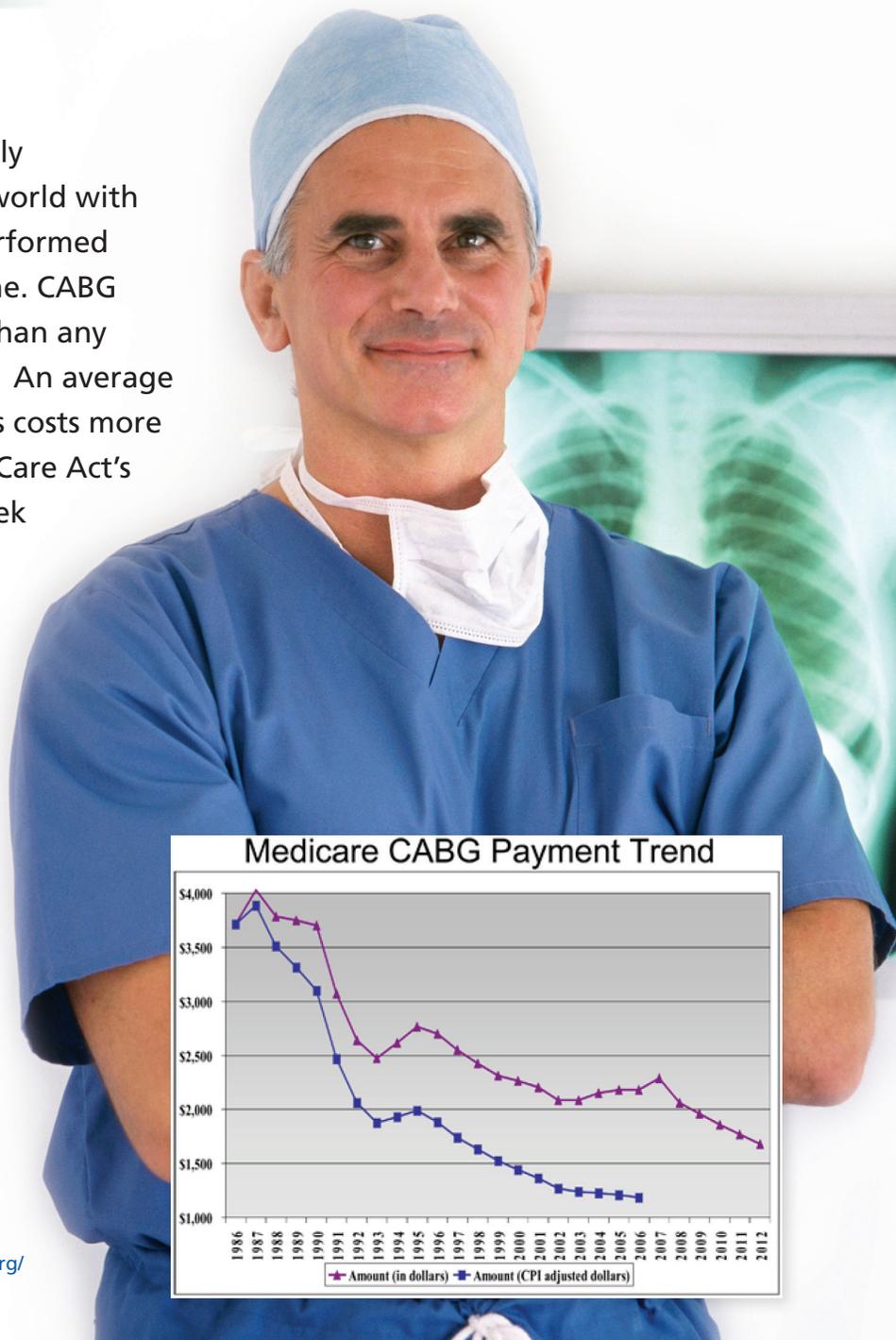


Figure 2

Medicare CABG Payment Trends: <https://www.sts.org/sites/default/files/.../MedicareCABGPayTrend.pdf>

\$ Clinical and Financial Benefits

These clinical benefits of a procedure and its financial cost-effectiveness are two of the major concerns for hospital and surgical administrators. Clinically, administrators are obliged to listen to the needs of surgeons, tempered by an awareness that surgeons bring their own biases to the table based on their training and expertise. Administrators also have to be finely attuned to the cost-effectiveness of introducing any new component into a procedure given the decreasing Medicare Severity-DRG (MS-DRG) Medicare reimbursement for CABG (Fig. 2). It is, therefore, a constant challenge for administrators to consolidate costs while maximizing value. Measuring flow during CABG is one example of a quality measure that meets both criteria.



CLINICAL BENEFIT: CONFIRMATION OF GRAFT PATENCY

As health costs soar and institutional accountability has escalated with publicly reported data scrutinized and used as quality metrics to determine and receive hospital payment, it becomes all the more important to have quality measures in place to assure the best possible outcomes for any surgery. This also applies to CABG surgery where one quality measure, universally accepted in Europe and included in their 2010 European Guidelines for Myocardial Revascularization, is intraoperative graft patency assessment.⁶

In a comprehensive clinical update “Coronary artery bypass grafting: Part 2—Optimizing outcomes and future prospects,” an international group of cardiothoracic surgeons chronicle the suboptimal rate of saphenous vein failure caused by a number of conditions. They report that intraoperative graft assessment has been introduced to evaluate grafts and identify anastomotic problems and limited outflow. Cited are a number of techniques that have been used for intraoperative graft assessment, with transit time flow measurement or intraoperative fluorescence imaging (IFI) named as the most frequently performed.⁷

“Despite issues, the clinical value of TTFM has been demonstrated in studies that found that TTFM predicted graft failure at 3, 6 and/or 12 months post CABG.”⁸⁻¹⁴

“Graft flow measurement, related to graft type, vessel size, degree of stenosis, quality of anastomosis, and outflow area, is useful at the end of surgery. Flow < 20 mL/min and pulsatility index >5 predict technically inadequate grafts, mandating graft revision before leaving the operating theatre.”⁶

Intraoperative flow measurement provides an objective (quantitative) quality assessment of the success of CABG surgery. Whether a CABG is

performed minimally invasively, off-pump, on-pump, or robotically, the end point is the same: to know how much blood flow is going through each newly created anastomosis. While the surgery might appear successful, in spite of an unseen surgical problem, as the patient is wheeled off to recovery and recovers from anesthesia, the longer-term success of that surgery won't be realized for hours or days. Prudence requires immediate physiological measurements to provide confirmation that all the grafts are operational. It takes intraoperative measurement of graft flow before closure to help the surgeon identify the problem source, whether it be physiologic, such as vasospasm, or technical such as kinking of a graft. A two-minute spot check to validate a four-hour surgery provides cost effective long-term outcome optimization.

Clinical Benefit Well-Documented

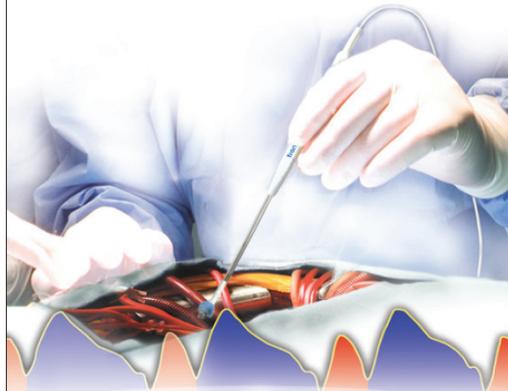
Over 100 publications have documented the benefits of intraoperative measurement of flow with transit time ultrasound. After analyzing 102 studies, Di Giammarco selected 10 that best represented the evidence to answer the clinical question, "If transit-time flow measurement (TTFM) can improve graft patency and clinical outcomes in patients undergoing coronary artery bypass grafting surgery."⁸

The papers considered for the analysis focused attention on three major topics:

- intraoperative graft verification with the aim of improving immediate graft patency
- predictive power of early and midterm graft patency
- clinical outcome.

The author found that the studies demonstrated the usefulness of intraoperative transit time flow measurement as a method to improve intraoperative graft patency and concluded that transit time flow measurements offer a reliable method to verify intraoperative graft patency. Other studies also concluded that intraoperative use of transit time flow measurement could predict early and midterm failure of coronary artery bypass grafts.^{8,10-11}

Flow-based Intraoperative Coronary Artery Bypass Patency Assurance



HIGH STAKES FINANCIAL COST EFFECTIVENESS

Hospital Cost Savings

U.S. healthcare spending accounts for almost 18% (\$3 trillion) of the gross domestic product.⁵ Therefore, it is critical to consider the cost effectiveness and fiscal ramifications of introducing any new measure to a surgical protocol. Flow-based intraoperative graft patency assurance offers clear fiscal benefits. They include the following:

AVOID RE-OPERATION:

Re-ops (or bringbacks) are costly, and frequently are not reimbursed by the patient's insurer. Whenever intraoperative flow measurement alerts the surgeon to a flow-limiting problem that can be corrected immediately during surgery, a possible re-operation is avoided and money is saved by the hospital.

"The intraoperative use of flow measurements provides invaluable information in a timely, accurate, cost-effective manner allowing for the surgical correction of a surgical problem."

B.P. Mindich, MD

AVOID READMISSIONS:

In their continuing effort to improve hospital performance and quality of care, the Centers for Medicare & Medicaid Services (CMS) began examining hospital readmission rates and penalizing hospitals whose readmission rates rose above the national average. The Hospital Readmissions Reduction Program (HRRP), mandated by the Affordable Care Act, Section 3025, was formally instituted on October 1, 2012 for three conditions: heart attack, heart failure and pneumonia. Under the program, the maximum reduction in Medicare payments was 1% in 2013. In 2014, the penalty increased to 2%. Chronic obstructive pulmonary disease (COPD) and total hip and/or knee surgeries were added to the HRRP program in 2015. Also in 2015, the penalty for being above the national average for readmission increased to 3%.

In 2017, 30-day readmissions for post-op CABG patients will also come under the CMS purview. Individual hospital rate for CABG readmissions will be compared to the national 30-day observed unplanned readmission rate or 30-day observed death rate. If a hospital's readmission rate supercedes the national average, the hospital could be penalized up to 3% of their Medicare reimbursement for the procedure.

"As a surgeon you are continually striving to do the best possible operation tailored to the specific findings of a particular patient. You are trying to do the best with what you've got. Consequently, during surgery you are constantly re-assessing its progress to try to give the patient the best long-term result.

Any technology that you can use to provide an intraoperative assessment can be invaluable. Transonic Flow-QC intraoperative blood flow measurement is such a measurement. The measurements may either confirm what appears to be an acceptable surgical result, or it can alert you that there may be potential problems at a time when it can be more easily addressed. The assessment may dictate an immediate major revision or a change in the postoperative treatment such as the addition of long-term anticoagulation.

Transonic Flow-QC provides a measurable improvement in the quality of care you can extend to your patients. With Transonic Flow-QC you can: improve patient outcomes; reduce or delay the need for future interventions and document surgical results."

T. Wolvos, MD, FACS

AVOID LITIGATION:

In our increasingly litigious society, hospitals are ever more aware that juries have become increasingly inclined to award large damages that fault institutions and surgeons who do not take the opportunity to check and document the quality of their surgical repair before the patient is closed. If a graft has failed, it would be reasonable for a lawyer to ask if graft flow had been measured before closing or what the graft flow was before closing. To be able to provide quantitative documentation that graft flows were good upon closure of the patient as evidence of surgical technical success is strong ammunition to support and protect a surgeon in court.

"The primary aim of intraoperative volume flow measurement is to obtain information on the immediate result of the reconstruction where a technical failure may jeopardize an otherwise successful operation."

Lundell A, Bergqvist D, Ann Chir Gynaecol 1992; 81(2):187-191

Hospital's Reputation

PATIENT CARE:

Hospital and surgical care is all about patients. Patients deserve the best, and now will often shop around for hospitals that provide the best care. Hospitals must therefore stay on the forefront of medical innovation and quality assurance to meet their patient/customer demands.

BEST PRACTICES:

In our competitive medical landscape, hospitals need to be able to set themselves apart by instituting and adhering to best practices. Intraoperative flow measurement is one of these best practices.





CONCLUSION

Heart disease continues to be the leading cause of death in the United States and CABG surgery is still considered the preferable treatment for the elderly with multi-vessel coronary artery disease. Yet CABG is the most costly cardiovascular procedure.

Hospital budgets are being squeezed as DRG payments from Medicare are trending downward. Under the Affordable Care Act's pay-for-performance measures, hospital administrators are asked to not only be sensitive to the requests and needs of surgeons, but also to analyze the cost-effectiveness of any new procedure that is initiated. The procedure must have a clear clinical benefit, and must also be affordable.³⁻⁵

The clinical benefits of intraoperative blood flow measurement of coronary artery bypass grafts prior to closure to assess the quality of the anastomosis and the flow are indisputable. Many publications attest to its value in predicting early and midterm patency of the bypass grafts.

The financial benefits are also impressive. By guaranteeing graft patency at the end of CABG surgery, the hospital avoids costly returns to the OR, and protects against 30-day readmissions that are subject to a 3% penalty from Medicare's HRRP program. Flow-based graft patency assurance also provides strong documentation in the event of any adverse litigation.

One cardiothoracic surgeon emphatically stated, "Transit-time flow measurement enables technical problems to be diagnosed accurately, allowing prompt revision of grafts. It should be mandatory in coronary artery bypass grafting to improve surgical outcomes."¹⁴

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Americas

Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY 14850
U.S.A.
Tel: +1 607-257-5300
Fax: +1 607-257-7256
support@transonic.com

Europe

Transonic Europe B.V.
Business Park Stein 205
6181 MB Elsloo
The Netherlands
Tel: +31 43-407-7200
Fax: +31 43-407-7201
europe@transonic.com

Asia/Pacific

Transonic Asia Inc.
6F-3 No 5 Hangsiang Rd
Dayuan, Taoyuan County
33747 Taiwan, R.O.C.
Tel: +886 3399-5806
Fax: +886 3399-5805
support@transonicasia.com

Japan

Transonic Japan Inc.
KS Bldg 201, 735-4 Kita-Akitsu
Tokorozawa Saitama
359-0038 Japan
Tel: +81 4-2946-8541
Fax: +81 4-2946-8542
japan@transonic.com