

SPY Intra-operative Imaging in Coronary Artery Bypass Graft Surgery; Technical and Functional Outcome Quality Improvements in Clinical Practice

“It is not at all surprising that the presence of intra-operative imaging to guide and confirm success at the point of care might be expected to improve the overall quality of outcomes in revascularization procedures as it enables surgeons to perform the best possible procedure for each individual patient.”

T. Bruce Ferguson, MD

Principal Investigator on behalf of the VICTORIA® Registry Investigators

When Novadaq® Technologies introduced SPY® Intra-operative Imaging to Cardiac Surgeons, the company made the extraordinary commitment to sponsor an independent multi-center, post-marketing registry clinical study for the purpose of observing the impact of intra-operative fluorescence angiography during coronary artery bypass graft (CABG) Surgery. The multi-year, multi-center project is being conducted and coordinated by East Carolina University Heart Institute, Brody School of Medicine Division of Cardiovascular Medicine and Clinical Effectiveness under the direction of T. Bruce Ferguson, MD. With the aim to assess the impact of intra-operative technical and functional imaging assessment during CABG surgery on real world highly non-selective every day patient outcomes, the project has enrolled > 300 patients to date.

Pre-operative, operative and 30 day post-operative data, including SPY images and registry case reports from U.S. Centers, are collected by the coordinating investigative team at ECU. Raw imaging data and matched clinical criteria are evaluated in ECU's core lab using sophisticated image analysis tools to assess native and bypass vessel function, pre- and post-operative microvascular perfusion by patient risk profile, operative technique and standardized STS National benchmark criteria.

Clinical Registries represent important evidence-based data in medicine because a Registry provides opportunity to observe patients and treatments in the real world, without the “controls” of a clinical trial. The STS Adult Cardiac Surgery Registry is highly respected because it represents a large body of data about cardiac surgery patients and practice over the past twenty years. The STS National Databases are the cornerstone for cardiac surgery quality management for the more than 900 surgeon practice & hospital cardiac surgery program participants.

About benchmarking trends and the STS National Databases

Since 1990, more than 3 million patient records have been submitted to the STS National Databases resulting in more than 40 publications in a variety of professional journals and textbooks. Recently, the STS National Database served as the basis for a federally funded national quality improvement randomized trial, as well as for research in targeted areas of cardiac surgery. The STS National Cardiac Database is an adjudicated, observational database that serves three principal functions for the cardiac surgical community. 1) it is the data registry for the generation of procedure-based risk models for process and outcomes of care delivery and analysis; 2) it is the data registry for large scale, observational analyses in cardiac surgery; and 3) it is the source of national data against which to benchmark clinical performance.

In addition, the STS Adult Cardiac Surgery Database is used by the medical community, industry and government organizations to assess national trends in practice patterns. STS proprietary risk adjustment algorithms, based upon patient risk factors that are present prior to surgery, allow STS database participants to assess their performance compared to other participants. The process of patient "risk adjustment" allows for comparison of outcomes across centers, and suggests how participants would perform relative to one another if they performed surgery on similar patient populations. This comparison is made by the generation of a widely accepted Observed vs. Expected (O/E) Ratios for outcomes.

Risk adjustment with Observed vs. Expected (O/E) Ratio Comparisons

The O/E Ratio couples the number of observed outcome events in a particular population with relative outcome events that are expected (predicted), based on the participant's case mix and adjusted by the STS risk model. The O/E Ratio is a statistic that allows a participant to gauge whether their observed outcomes were better, the same, or worse than what would be expected given the existing underlying risk factors presenting in their patients. Because the models are re-calibrated for each year included in the report, the O/E Ratio reflects performance relative to the STS national average achieved during that calendar year. This allows participants to benchmark their performance relative to a contemporary standard. The term "benchmark" is used to describe a methodology by which individual experiences can be compared to a recognized standard. In the case of the CABG today, there is no known statistical method of achieving a comparison to the STS National Databases, which is why the O/E ratio has become an accepted method of comparison and reporting of data.

VICTORIA vs. STS Patient Demographics

	STS 2007	STS- Q1-Q3 2008	Isolated CAB from Victoria Registry (285)
Age >=65yrs	52.60%	52.30%	57.89%
HTN	82.70%	83.90%	78.60%
DM	39%	39.20%	40.70%
LM>50%	30.60%	31.10%	38.60%
1 Vessel CAD	4.40%	4.60%	2.46%
2 Vessel CAD	19.20%	20.20%	11.93%
3 Vessel CAD	76%	74.80%	85.61%
EF<40%	16.40%	15.70%	17.54%
MI	46.10%	46.20%	22.11%
Prev Cardiac Surgery-cab/vlv/other cardiac	5.80%	6.00%	4.21%

VICTORIA STS Benchmark Patient Demographics Comparison

Currently there are 327 cases in the VICTORIA Registry, of which 285 are isolated CABG. The table below shows selected risk factors and their relative percent occurrence for isolated CABG patients in the 2007 STS Data, the 2008 STS data (through Q3), and the total Registry isolated CABG population. These data suggest that the VICTORIA patients are older, have less hypertension, are equivalent in terms of diabetes, and have a higher incidence of left main disease than the national benchmark. There is a greater incidence of 3-Vessel CAD, and of patients with EF < 40%. These data are illustrated in FIGURE 1.

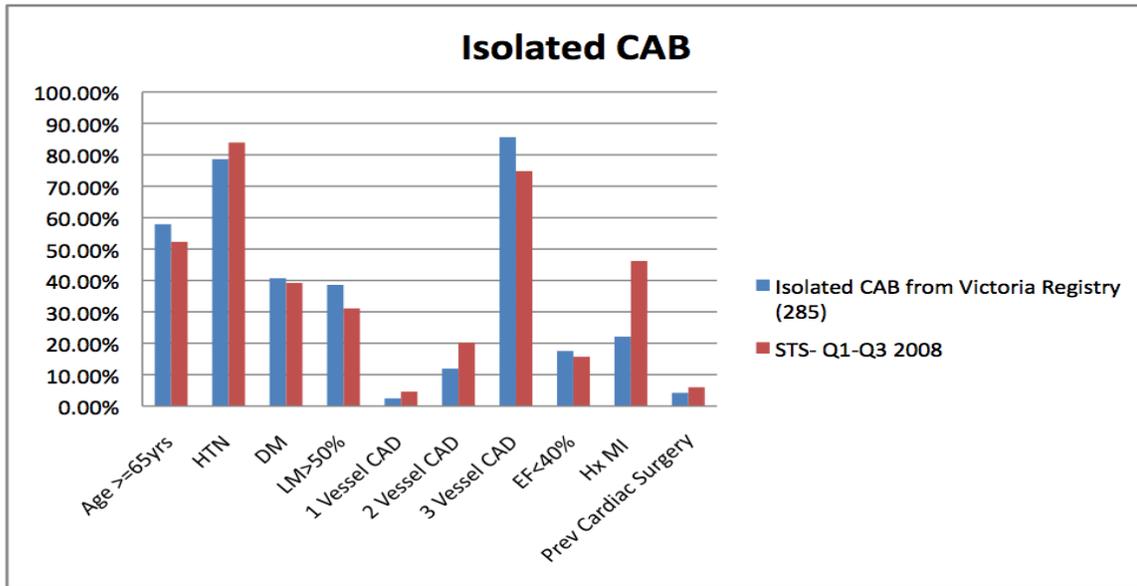


figure 1

Observed vs. Expected Post Operative Complications VICTORIA to STS

In evaluating outcomes, the STS O/E ratio is arbitrarily set at 1. An O/E < 1 for a population suggests that the outcomes are more favorable than expected compared to the overall STS benchmark, while a ratio > 1 suggests less favorable than expected outcomes.

	STS 2007	STS- Q1-Q3 2008	Isolated CAB from Victoria Registry (285)
Re Op OE	1	1	0.59441
Permanent Stroke OE	1	1	0.85772
Renal Failure OE	1	1	0.76498
Prolonged Ventilation OE	1	1	0.79786
Deep Sternal Wound Infx OE	1	1	0
Mortality or Morbidity	1	1	0.86622
Mortality OE	1	1	0.87592
Short Length of Stay OE	1	1	0.96077
Long Length of Stay OE	1	1	0.62838

The major outcomes categories for the STS Database for isolated CABG are: 1) the five morbidity complications of; reoperation for any reason, stroke, renal failure, prolonged ventilation, and deep sternal wound infection; 2) mortality and combined mortality and morbidity; and 3) Length of Stay (LOS) following CABG. A Short LOS > 1 is favorable, while a Long LOS < 1 is favorable. These data are depicted also in Figure 2.

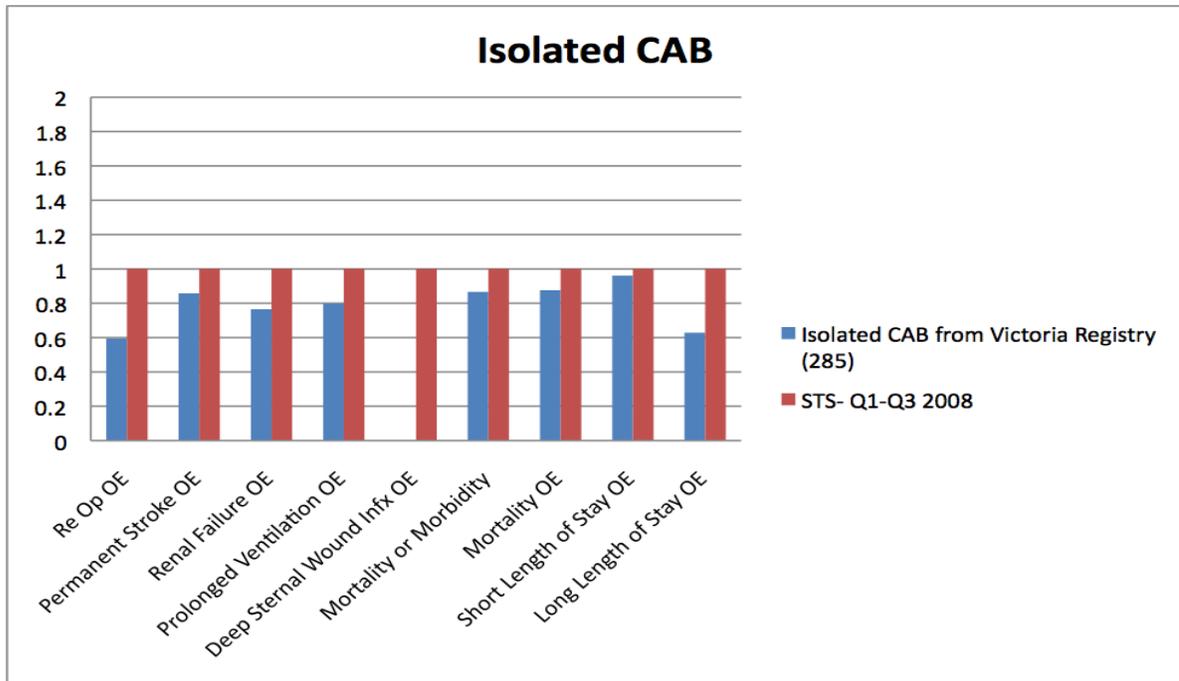


figure 2

Overall, the comparison of outcomes from the Registry population is favorable compared to the national STS benchmarks, both for mortality and morbidity metrics. Short LOS is the only metric that wasn't quite as favorable as the STS value. This may be attributable to the increased age, number of patients with 3-Vessel CAD and a higher number of patients with an EF of <40% in the registry population. However, the long term LOS was favorable in the registry population, which suggests that although sicker, these patients did not suffer prolonged LOS. These results should be interpreted with some caution since no formal comparison of data or outcomes is possible. However, it can be noted that as the number of sites contributing to the Victoria Registry expands and the number of patients enrolled increases, these improved outcomes are a consistent finding when compared to the 2007 and 2008 STS benchmark data. There are several possible explanations for this trend: 1) use of the SPY technology for intra-operative imaging has a potentially beneficial effect on outcomes (potential technology effect); 2) the decision to use the SPY technology for intra-operative imaging to improve outcomes has been made by centers that have care processes in place that result in improved outcomes compared to the STS benchmark (potential center effect); 3) there are other confounding factors, as yet unknown, that are contributing to these results outside of the technology and center effects.

The use of SPY intra-operative imaging to improve the quality of CABG has been shown in the VICTORIA population to have an association with improved outcomes, regardless of the cause. This sustained trend of improved quality is an important finding, one that will be tracked closely as the Registry population continues to grow. In summary, use of the SPY technology in high quality centers is associated with excellent outcomes. The Victoria Registry data will ultimately give important insight into the reason this trend is consistent. In addition, Registry data will give new and important insights into other improvements and refinements that will further optimize surgical revascularization for ischemic heart disease.