



The Society for Cardiovascular Angiography and Interventions

SCAI President's Page

ASSESS before ASCERT

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The interventional cardiology community has worked diligently for over 30 years to establish the importance of analyzing patient outcomes and quality of patient care. The first national data registry for catheterization laboratory procedures was started by SCAI in the 1980s. Early PCI results were tracked by the NHBLI registries. Separate from these, over twenty years of randomized clinical trials (RCT) have provided specific insights into multiple patient care issues ranging from drug therapy to coronary revascularization strategies. These clinical studies have been designed to answer specific questions in order to guide specific therapy. In contrast to RCTs, registries record the outcomes of the physician/patient's choice of therapy after it has been made. Physician assessment of the patient in conjunction with patient choice has always driven patient care. However, this assessment and the subsequent therapeutic choices may in itself alter outcomes.

We are currently fortunate in this country to have two well-established data registries acting independently in their specific fields. The National Cardiovascular Data Registry (NCDR) has over 10.5 million PCI patient records while the Society of Thoracic Surgery Database (STS-DB) has over 4.5 million records. These databases are designed for benchmarking data from institution to institution to identify outliers so that appropriate quality improvement alterations can be implemented. Though often classified as providing “real-world type patients,” these databases by definition enter all patients without the specific pre-established entry criteria that would be required for a RCT.

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Significant challenges arise when one database is compared to another in the form of an observational study where investigators have no control over treatment assignment. Therefore, large differences in observed covariates for the two groups may exist with the potential for significant bias in the estimates of treatment effects. In other words, you are comparing apples to oranges when asking which fruit makes the better pie; the differences may be too great for proper comparison.

In the NHLBI-funded ASCERT study, short-term clinical information was extracted from the ACC and STS databases in over 186,000 patients between 2002 and 2007 for isolated coronary artery bypass surgery (CABG) or percutaneous coronary intervention (PCI). These data were then linked to the administrative data registries for the Centers for Medicare and Medicaid Services (CMS) in order to analyze long-term mortality, re-hospitalization, and resource utilization outcomes. Multiple substudy analyses are planned, including, but not limited to, an angiographic subset to assess the SYNTAX scoring system, a cost-effectiveness analysis, a quality of life analysis, and specific patient subgroup analyses. All of these analyses are proposed with the assertion that, "Net benefit methods (will be) used that will incorporate the propensity for one therapy over another."

Compared to RCTs, data registries have the advantage of large patient populations, breadth of experience across large numbers of hospitals and physicians, and immunity to the perception of bias resulting from investigators' financial ties. The analysis and interpretation of registry data to evaluate outcomes are complicated because patient and physician choice are not documented. Additionally, a full understanding of study design and analysis requires an assessment of data quality. This requires specific definition of how missing data are handled as well as verification of accuracy and validity, as is done in a RCT. Bias in specific therapeutic choices is not overcome by the sheer number of records entered. Finally, it should be remembered, registries are designed for provider feedback: to developers, study sponsors, and end users. The ultimate goal is

improving patient outcomes specific to the registry, not in comparison to other registries.

Over 15 years of RCTs have compared PCI and CABG. The recent SYNTAX study established a scoring system to assist in the decision process, among many other notable accomplishments. Regrettably, trials are often completed after new therapies have been introduced, outdating the trial results. The ASCERT study provides data from two large registries conducted in the drug-eluting stent (DES) era. Both registries are designed to enter data specific to their own individual area, PCI or CABG, but not for comparison. ASCERT identifies outcomes for patients selected for one treatment or another in the real world, with very limited information about all the factors used in the selection process. Especially missing are the elements of patient and physician choice. Without that information, a valid comparison of PCI to CABG is impossible no matter how good the statistical manipulations. RCTs are the most rigorous way of determining whether a cause-effect relationship exists between treatment and outcomes through random allocation, blinded providers, rigorous attempts for parity in the groups, specific hypothesis prior to study onset, and analysis based upon the initial hypothesis/endpoint definition. Though challenges are present with RCTs, the end result allows one to identify the best apple pie from other apple pies.

As we move forward, the presentation of the full ASCERT study will occur in comprehensive and repetitive detail. "Trialists" will pontificate over the significance of the propensity score and inverse probability weighting as it applies to observational database studies. Headlines may continue to inappropriately compare CABG and PCI. However, it is clear from the non-randomized physician/patient care choice-driven study design, that comparing two separate databases should not permit one group to declare superiority. However, in our role as clinicians, the key to quality care is the patient. We must continue to assess each patient with all the available clinical information and literature and not "assert" one specific treatment plan but rather "assess" so as to assure the best quality care for the one patient each time.