Successes and Lessons from the CHSS & STS Databases

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CHSS & STS

Polar opposites, therefore interesting

CHSS
  • Focus on efficacy from beginning to end of life & everything in between

STS
  • Focus on short-term surgical safety

Both
  • Improve outcomes
Congenital Heart Surgeons Society (CHSS) Data Center
Small N & Complexity
Rare Disease

Small N problem!

• Single institution may not see enough cases to learn how to best treat patients

Consequences

• Expert-driven vs. data-driven management
• Strong-but-wrong management
• Long-term benefit uncertain
Kirklin / Blackstone Proposal

Objectives

• To assemble a multi-institutional inception cohort of neonates with transposition of the great arteries

• To compare survival of 2-week-old neonates presenting with all forms of TGA, managed in different ways, and followed for life
CHSS Challenge

Rationale

• Collectively generate new knowledge impossible without sufficient N

Why TGA?

• Which switch?
• Consensus: a unique opportunity
• Not ready to randomize
PAIVS: Initial Strategy

Survival

- Tricuspid Valve
- Shunt Alone
- RV Outflow Proc. + Shunt
- RV Outflow Proc. - Shunt
CHSS Mode of Operation

No CRFs

- When knowledge is so incomplete that there is no consensus on what variables are important to collect
- When it is critically important to generate data-driven hypotheses

Solution

- Go to the charts!
- Over and over again
CHSS as Model

Centers

• Across North & South American continents

Nature of studies

• A few rare lesions
• Time zero at or near birth
• Capture all management strategies: none, medical, interventional, surgical

Emphasis

• Long-range outcomes appropriateness
Lessons Learned

Since fall, 1984

• Need important problem people care about

• Need medical records when you don’t know *a priori* what is important

• Need life-long follow-up for lesions that seem “fixed” but not cured
Society of Thoracic Surgeons (STS) National Databases
STS vs. CHSS

Purpose

- Risk-adjusted estimates of institutional performance, initially of CABG

Data elements

- Based on decades-long experience and analyses

High-volume, single entity

- Amenable to large data analytics
Mission Creep

Number of data elements

- Escalating far beyond what are needed for risk-adjusted estimates of adverse events
- Now envisioned as a research database
And it Multiplies

Now

- Multiple cardiology and cardiothoracic databases
- Mostly housed at DCRI
- Getting into the business of Phase IV trials
- Linkages with multiple registries (including CHSS)
What Sustains It?

Threat

• Today, $20M is at risk at Cleveland Clinic for non-participation in STS and other cardiovascular registries
• For some, required for CMS payment
• Required for ranking
CHSS vs. STS

Both

• Sustained by institutional “dues”

Differences

• CHSS has no “stick”
• Once near 100% capture, now about 33%, though a random sample
• PHN: Provided NIH support & money talks!
## At What Cost?

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Christmas Tree Effect

Proliferation of variables

• About 30 variables for models of mortality and multiple morbidities in routine cardiac surgery

• Currently hundreds collected!

FDA mandates?

• We are dealing with a device trial that has an 800-page CRF

• FDA requires a miniscule fraction!
Lessons Learned

There is a difference

- Academic vs. quality assurance

There is a cost

- Borne by institutions as added cost of business

Coercion is effective

In theory

- Standardized variables should be gatherable automatically
Parked Slides
1-week mortality worse with unbalanced ventricles

![Graph showing ventricular area ratio with LV and RV labels. The graph illustrates a curve that increases with ventricular area ratio, indicating higher mortality with unbalanced ventricles.]
Institution Code

(*Out of 53 Total Institutions)

Legend

- IAA
- PA/IVS
- TGA

Rank #2 for 3 lesion sets

Rank #7 for 2 lesion sets

Rank #2 for 3 lesion sets