Resolute PAS

- **CONDITION:** Coronary artery disease
- **PI:** Yale Wang, MD
- **CONTACT INFO:** Rose Peterson | Rose.Peterson@allina.com | 612-863-6051
- **DESCRIPTION:** A study to assess the continued safety and efficacy of the Resolute Onyx stent for the treatment of lesions in coronary arteries amenable to treatment with the Resolute Onyx 2.0 mm – 5.0 mm stent. The purpose of the study is to observe the continued performance of the Resolute Onyx Zotarolimus-Eluting Stent System in a real-world population.
- **CRITERIA LIST/ QUALIFICATIONS:**
  - Symptomatic coronary artery disease including subjects with chronic stable angina, silent ischemia, and acute coronary syndromes including non-ST elevation and ST-elevation myocardial infarction
  - Subject is an acceptable candidate for treatment with a drug-eluting stent in accordance with the applicable guidelines on percutaneous coronary interventions, manufacturer’s Instructions for Use, and the Declaration of Helsinki.
  - Key exclusion criteria: unprotected left main disease; subjects with planned PCI of three vessel disease
- **SPONSOR:** Medtronic
N=1
Musings on an Anecdotal Experience

John S. Zakaib, MD
Minneapolis Heart Institute
October 30, 2017

How it works:

• Medical Knowledge
  – what we know or think we know
  – what we haven’t realized is wrong yet
  – we drown in it in Medical School

• Medical Training
  – what we do
  – how and why we do what we do
  – we glean it in Training Programs

• Medical Judgement
  – how we know whether to intervene
  – how we decide what to offer
  – we develop it in Practice
Note to self...

Good Judgement comes from Experience

Experience Comes from Bad Judgement

Anecdotes in Medicine

• We gain our experience of the practice of medicine in increments of “one patient at a time”
• Each individual interaction hones our acumen and tempers our exuberance for offering therapy a little bit
• Anecdotes are the universal unit of tangential knowledge
• Anecdotes provide focus – they are relevant and entertaining but not central to our understanding
• Evidence comes from average outcomes in large groups
• Care is what providers offer individual patients
• Anecdotes come from real human interactions
Why am I here?

- Dr. Sharkey asked me to be here at 6:30am
- There is no place I would rather be?
- You gotta be someplace
- I am the New Guy

- I survived

Life Stories

- St. Christopher’s School, Richmond 1975-1988
- The University of Virginia 1988-1992
- The Medical College of Virginia 1995-2003
- Chief Resident, 2002-2003
- The Cleveland Clinic Foundation 2003-2008
- Chief Fellow, CCF, 2004-2008

- I had no inkling that I wouldn’t continue to achieve at a high level and have a long and predictably successful life and career
Note to self...
If you write your life story in advance...
use a pencil.

An Anecdote
The Odessey of cardiac testing

- EKG - Normal
- Transthoracic Echocardiogram - ????
- Cardiac CT scan - ?Fluid in Transverse Sinus?
- Cardiac MRI scan – Solid Tumor
- Cardiac PET/CT scan - Low grade Malignancy?
- Cardiac Catheterization
  - feeder vessels LMT
  - contrast in the core of the tumor

As is common in anecdotes, the pictures show the pathology, but they don’t tell the whole story
Angiography

The Odessey: Cardiac testing

- EKG - Normal
- Transthoracic Echocardiogram - ???
- Cardiac CT scan - ?Fluid in Transverse Sinus?
- Cardiac MRI scan – Solid Tumor
- Cardiac PET/CT scan - Low grade Malignancy?
- Cardiac Catheterization
  - feeder vessels from the LMT
  - contrast in the core of the tumor
- Pulmonary Angiogram – No PA feeders
- Transesophageal Echocardiogram
Note to self...

If you are planning to gag someone with a TEE probe, put holes in their femoral artery and vein AFTER, not BEFORE...

The Stages (of Grief)

*On Death and Dying*, Elizabeth Kubler-Ross, 1969

- **Denial** – A defense against the reality
- **Anger** – Why is this happening to me?
- **Bargaining** – Dialogue with a higher power or an internal monologue? “If only...”
- **Depression** – Presumption of the worst
- **Acceptance** – The peace of inevitability
The Stages (of Grief)
On Death and Dying, Elizabeth Kubler-Ross, 1969

• Denial – A defense against the reality
• Anger – Why is this happening to me?
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• Depression – Presumption of the worst
• Acceptance – The peace of inevitability

• Robert Kastenbaum, MD, editor of International Journal of Aging and Human Development:
  – There is no empirical evidence for the existence of stages of grief
  – There is no evidence that people progress through these stages

October 19th, 2004

• Awaken and shower with surgical scrub
• 1mg Ativan just to get out of the house
• Pre-Op unit 7AM
• To OR 8AM
Hopeful in the pre-operative suite
October 19th, 2004

- Awaken and shower with surgical scrub
- 1mg Ativan (just to get out of the house)
- Pre-Op unit 7AM
- To OR 8AM...
- Extubated in the OR around noon
- “It was benign...”
- 4PM visitors in ICU, Chest tube drainage clear
- 8PM hypotension, IV Fluids, pressors

October 20th, 2004

- Midnight: refractory hypotension and tachycardia
  (6L IVF, 3 pressors infusing)
- Profound fatigue, lethargy, burning pain
- Echo reveals RV beating empty
- Chest tube suddenly drains thousands of mL blood
- Rapid Transfusion, Transition to OR, Sense of Futility
- 23rd Psalm
- The mask...
Recovery

- ICU care
- Tubes and drains
- Dyspnea
- Pain
- Solitude
- Loneliness
- Fear
Recovery

- Walking, Breathing
- Coughing, Sitting up
- Hurting
- Anger
- Anguish
- Exhaustion
- Insomnia
- Hope

The emotional response to illness

- A pervasive change in outlook
- Evolution of emotions and feelings
- Lots of questioning and revisiting of events
- Recovery... Now what?
- Starting anew – how life changes
- Life is precious... and fragile...
- Amazingly, newfound insight and renewal leads to a quest for normalcy and the ease of the mundane tasks of life
Aftermath...

• Scars fade but they are never gone
• The pane between sympathy and empathy is thin
• The best intentioned intervention is fraught with risk of mayhem
• I strive to do my best for each person each day
• I hope to try again tomorrow
• Life stories are retrospective case reports where N=1, but their anecdotal lessons guide us – we should share them!