ETHICS and CARDIOVASCULAR DISEASE

Kenneth Rosenfield, MD, MHCDS
Section Head, Vascular Medicine and Intervention
Division of Cardiology
Mass General Hospital
Kenneth Rosenfield, MD, MHCDS
Conflicts of Interest

- **Consultant/Advisor**
  - Abbott Vascular
  - AccelMed
  - Capture Vascular
  - Cardinal Health
  - Contego
  - Cook Medical
  - CRUZAR Systems
  - Endospan
  - EXIMO
  - HCRI
  - InspireMD
  - Medicines Company
  - MD Insider
  - Micell
  - Shockwave
  - Silk Road Medical
  - Surmodics
  - Valcare

- **Equity**
  - Access Closure
  - CardioMEMs
  - Contego
  - Icon
  - Janacare
  - Medical Simulation
  - MD Insider
  - Micell
  - PQ Bypass
  - Primacea
  - Sapient LLC
  - Shockwave
  - Vortex

- **Research or Fellowship Support**
  - Abbott Vascular
  - Atrium
  - NIH
  - Lutonix-Bard

- **Board Member**
  - VIVA Physicians (Not For Profit 501(c) 3 Organization)
    - [www.vivapvd.com](http://www.vivapvd.com)
The Central Role of Ethics

• Basis for everything we do in Medicine
• Reflected in Hippocratic Oath
• At the core of…
  – Appropriateness
  – Fairness
  – Transparency
  – Informed consent
  – Accountability
  – Quality improvement
  – Patient-centered decision-making
Case #1

Ken Rosenfield
Rahul Sakhuja
Clinical Presentation –

Telephone call from ED MD at community hospital

- “I have a 46 y.o. female bus driver who was at the high school when she went down with cardiac arrest. Had CPR by the school nurse and another bystander. Shocked 3x in schoolyard, 5x in ambulance, and then 11x in ED at community hosp → unsuccessful and remained in refractory VFib; Continuous CPR the entire time.

Before 21st shock, MD states: “we’ll give her one more, then call it”

- 21st DCCV → sinus tachy. EKG now shows anterior STEMI…will you take her?

- Summary:
  - Comatose, intubated; BP 112/55; HR 95, on pressors, amio
  - 59 minutes of continuous CPR, 21 shocks
Backdrop

- MA is a public reporting state
- Mortality (all cause)
  - Tracked for each operator
  - High mortality operators subject to “outlier review”, which can affect licensure if discover inappropriate care or poor technique
  - Mortality publicly reported (by institution not by operator)
Question: Would You...

A – Transfer to CCU and observe neuro status, treating MI conservatively for now?

B – Transfer urgently to cath lab and look for culprit vessel to PCI (with or without CT scan)?

C – Transfer to cath lab and perform dx angio for risk stratification, but specifically avoid PCI?

D – Wait for family to consent?
Influence on Decision-making

• Would you select differently if…
  – You are not in a public reporting state?
  – Your mortality this year is already high c/t peers at your hospital?
  – Your hospital underwent external peer review for high mortality two years earlier → exonerated, but all operators put on notice and instructed to “be cautious” in decision-making
  – Patient is 76, not 56 y.o.

Etc., etc., etc…. 
Occluded Left Anterior Descending artery (LAD)

- What now???
PCI: Aspiration and balloon dilation
Stent in LAD
Course

- Urgent transport (same as any STEMI who is awake)
- PCI without delay
- Neuro eval: non-responsive but moving some extremities → “too awake for cooling”
- CK Rise but rhythm and hemodynamics stable
- Awoke two days later and back to normal MS @ four days
Text 11/27/14:

As I get ready to be with my family today, there is not a day that goes by I don’t think about how thankful I am to be here. Thank you for all the amazing time and work you put into me to save my life.

HAPPY THANKSGIVING  Dr. R
What next???

Kenneth Rosenfield
Bharat Samy
Patient Presentation

- 48 F with DM2, HTN, and obesity (BMI 37) presented to OSH with N/V x 5 days and SOB x 1d
- WBC 23, bicarb 15, glucose 538
- EKG: Inferolat STE; Anterior STD
- Tn-T 11, CKMB 22
- Echo: EF 15%; diffuse severe hypo/akinesia; LV dilated w/thrombus
- Decision at OSH not to cath given delayed presentation and concern for sepsis and DKA
- Started on ASA, clopidogrel, and heparin
OSH Transfer

- Acute decompensation day 2 $\rightarrow$ SBP 80, HR 115, RR 30s
- Decision to transfer to MGH; accepted by cath lab access nurse
- En route, SBP to 60s with progressive respiratory distress
- Intubated $\rightarrow$ norepinephrine and dopamine
- On arrival to cath lab, in profound cardiogenic shock; Labs sent stat
Transfer EKG (on cath lab table)

Not a whole lot of voltage.....
Ethical Decision-Making

Question: Would You...

A – Take off table, tx to CCU and treating MI conservatively for now?
B – Cath and look for culprit vessel to PCI?
C – Perform dx angio for risk stratification, but specifically avoid PCI?
Angiography
Cath lab - IABP placed
Ethical decision-making...

- Continued decompensation on cath table despite IABP $\rightarrow$ further escalation of pressors
- Emergency “PCI council” discussion with CCU attending, CT surgery, other interventionalists
- Alternatives:
  - Conservative (CMO) $\rightarrow$ certain demise
  - Hemodynamic support (Impella…but fem artery small for Impella, ECMO with distal fem line)
  - Salvage intervention
Ethical Decision-Making

Question: Would You...

A – PCI (LAD, RCA, or Both)?
B – Conservative Rx: Leave in IABP and send to CCU?
C – Add additional support…IMPELLA or ECMO?
Ethical Decision-Making

Question: Would You…

A – PCI (LAD, RCA, or Both)?

B – Conservative Rx: Leave in IABP and send to CCU?

C – Add additional support…IMPELLA or ECMO?
Decision making

- Decision to proceed with salvage intervention

Implications...

- Likelihood of survival?
- Mortality statistics (hosp and provider)?
- Public reporting?
- Resource utilization?
- “Stopping point” if does not respond?
Salvage PCI – “give her every chance we can”

• **During PCI** → Admission labs returned
  – Chem: **bicarbonate 7**, Cr 0.7
  – CBC: WBC 20, Hct 39, Plt 530
  – ABG: **7.15/32/88**
  – Cardiac markers: TnT 5, CKMB 49, BNP 10458

• Challenging technically
  – Temp Pacer
  – Wiring PDA/PLV
  – Thrombectomy/balloon → slow flow/no flow
  – Stenting of PDA/PLV/distal RCA

• Continued deterioration, with BP 80→70→60
Intervention – 2.5 hours
Ethical Decision-Making
Question: Would You…

A – Abandon efforts and inform family “not able to save her”?

B – Add additional support…ECMO, Impella?
• Family consultation → Decision to ECMO in cath lab…”either heart will partially recover or may ‘become’ transplant candidate (with weight loss, etc.)”

• VA ECMO with
  - 19F arterial cannula in left femoral artery
  - 5F antegrade arterial cannula in left SFA
  - 25F venous cannula in right common femoral vein
What next?

- Despite ECMO, continues to be in shock/extremis
- Surgeon requests “open LAD if you can… maybe she has some viable myocardium there”
Hospital day 3…back to cath lab

LAD occlusion crossed and
Stented with 2 overlapping BMS
Hospital course

• No change, Continued shock
• Bleeding from ECMO cannulation sites requiring repair in the OR x 2
• Developed ventricular arrhythmias that become refractory

What next??
Hospital course

- Hospital day…
  18: HeartMate-2 placed
  19: LLE ALI; treated conservatively
  26: Tamponade; pericardial window
  30: Tracheostomy
Day 30: Return to cath lab

...large thrombus protruding from LM origin...treated medically
Ethical Decision-Making

Question: Would You…

A – Abandon efforts and inform family “not able to save her”?

B – Continue support…hope for transplant possibility?
Hospital course continued

- Hospital day…

**33:** RLE ALI; thrombectomy of EIA and PFA; endarterectomy/patch angioplasty of SFA

- Multiple subsequent groin complications (bleeding, tissue necrosis) requiring repair / debridement / fasciotomies / wound vacs

**75:** RLE AKA for non-salvageable limb after unsuccessful attempt at percutaneous revascularization
Terminal event

- **Hospital day 85**
  - Acute L MCA infarct involving L posterior frontal lobe and insula
  - R posterior parietal periventricular white matter new hypodensity suggestive of central embolic source
  - Comfort measures instituted
  - Expired hospital day 86
Ethical considerations for this case

• When to apply major expensive therapies
• When to withhold
• When to stop after applying therapies
• Implications for resource utilization that “drains” and siphons away from other important needs

Aftermath of this case
• Criteria developed for ECMO
• Functioning of the council

Should there be Societal Guidelines?
Four Principles of Biomedical Ethics

• Autonomy - patient has the right to refuse or accept treatment.

• Beneficence - physician should act in the best interest of the patient.

• Non-malificience - "first, do no harm"
  – Be aware of the doctrine of double effect, where a treatment intended for good unintentionally causes harm.

• Justice - distribution of scarce health resources, and decision of who gets what treatment (fairness and equality)
Ethical decision-making in CV care

• To practice it well requires serious commitment, dedication, extra time and effort

• Patient/family comprehension is critical
  – Importance of decision aids and educational materials to make issues understandable
  – Use of other personnel who can relate to patient and family and are trusted
Ethical decision-making in CV care

- Multidisciplinary approach/involvement of knowledgeable peers
  - Help to “step back” and “look at big picture”

- Systems must exist
  - Facilitate/optimize patient and family-centered decisions

- Decisions should never be influenced by ego, bravado, or fear of personal consequences of failure
  - …it should be about the patient
“All patients need emotional support, which means we have to give of ourselves to them.”

“Compassion is having the ability to feel something of the patient's predicament and to assure the patient he or she will not be abandoned.”

- Edmund Pellegrino MD
Case #3

Ken Rosenfield
Bharat Samy
History of Present Illness

• 68F h/o CAD, PAD, CKD presented to MGH 4/12 am with chest pain and nausea

• Woke up from sleep at 6 am with symptoms, arrived at ED 8:45 am
Past Medical History

- CAD (cath 2011 for HFpEF: occluded LAD with collaterals Rt → Lt)
- CKD (baseline Cr ~ 2.5 - 2.7)
- PAD (Lt CEA, Rt renal artery stent)
- HFpEF
- HTN
- HL
Physical Exam

- T 97.2, P 67, BP 130/80, RR 20, O2 100% 4L NC
- Heart: RRR, nl S1/S2, no m/r/g
- Lungs: Clear
- Ext: WWP, no edema
- Neuro: AOx3

- ED course: HR to 40s, BP to 70 → Norepinephrine gtt
Labs

- Na 144, K 4.4, Cl 109, HCO3 25, BUN 46, **Cr 2.7**, Gluc 116

- WBC 10, Hct 30, Plt 255
- INR 1.1
- TnT 0.78
ECG 4/12 AM – Hosp Day 1
Ethical Decision-making

Would you:

- Perform PCI?
  - RCA alone?
  - LAD alone?
  - Both RCA and LAD?

- Place Mechanical Support?
  - Before or after PCI?
  - IABP?
  - Impella?
Cardiac cath: Hosp Day 1

• Chronic LAD occlusion with Rt \(\rightarrow\) Lt collaterals
• Mid RCA: 80-90% thrombotic lesion
  – Thrombectomy, IC Abciximab (5 cc)
  – 3.0 x 32 DES, post-dilated to 3.5
• Clopidogrel 600 mg
• Low-dose Norepinephrine, off following arrival in CCU
6 hrs post-PCI

- Recurrent chest pain, nausea, SBP 80-90s
- Not responsive to nitrates
- Eptifibatide started given concern large thrombotic burden at time of cath
- Clopidogrel switched to Ticagrelor
- Norepinephrine restarted
- Omeprazole increased to bid dosing
- Symptoms and ECG changes resolved overnight
ECG 4/12 post-cath
ECG: 6 hrs post-PCI
2 Days Post-PCI

- Coffee-ground emesis and melena (Hct down to 20)

*Additional hx not known prior to cath:*

- Prior endoscopy 8 mos ago c/w HSV esophagitis, gastric erosions, and colitis
  - ASA 81 stopped, started on PPI
  - Hct remained stable high 20s
  - Repeat endoscopy 3 months ago: mild esophagitis, diffuse mild gastritis with bleeding
2 Days Post-PCI

- Transfused 10 units pRBCs
- Intubated for endoscopy
  - Patient initially expressed desire not to be intubated but agrees as part of GI workup
- EGD
  - Normal esophagus, duodenum
  - No definite ulcer or bleeding vessel
  - Diffuse erythematous mucosa with oozing in pre-pylorus -> region coagulated
- IR consulted, NO further intervention given absence of precise source
ECG PM day 2
Hospital Course

• Days 3 & 4
  – Remains intubated for airway protection
  – Hct stable high 20s without further transfusion
  – Acute on chronic oliguric renal failure
  – Worsening hypoxia

• Day 5
  – Significant family conflict
    “…She would not have wanted to remain intubated.”
  – Patient made CMO by family: extubated
    → Morphine gtt
  – Expired @ 4 am
Lessons in Ethical Decision-making?

- Did we do the right thing to do initial PCI?
- Should she have had mechanical support, despite severe PAD and CKD?
- Should we not have intubated her?
- What is role of patient and family discussion in advance of decisions? After decisions?
- What about decisions to withdraw support?...how “binding” is the commitment to proceed? (e.g. “in for a penny, in for a pound?”) Should support be withdrawn if there is still significant chance of recovery? Can we predict what patient will be like after recovery?
Lessons in Ethical Decision-making?

- Did we do the right thing to do initial PCI?
- What is role of patient and family discussion in decisions?
- What about decisions to withdraw support?...how “binding” is the commitment to proceed? (e.g. “in for a penny, in for a pound?”) Should support be withdrawn if there is still significant chance of recovery? Can we predict what patient will be like after recovery?
Four Principles of Biomedical Ethics

- **Autonomy** - the patient has the right to refuse or accept treatment.
- **Beneficence** - a physician should act in the best interest of the patient.
- **Non-maleficence** - "first, do no harm"
  - Be aware of the doctrine of *double effect*, where a treatment intended for good unintentionally causes harm.
  - This doctrine helps you make difficult decisions about whether actions with double effects can be undertaken.
- **Justice** - the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality)
Ethical decision-making in CV care

- To really practice it well requires serious commitment, dedication, time and extra energy

- Systems must exist to facilitate/optimize patient and family-centered decisions

- Patient/family comprehension is critical...decision aids and educational materials targeted to make issues understandable can help, as can other personnel who can relate to patient and family and are trusted

- Multidisciplinary approach – and involvement of knowledgeable peers who have ability to “step back” and “look at the big picture” – can be crucial

- It should not be about ego, bravado, or fear of personal consequences of failure...it should be about the patient
“All patients need emotional support, which means we have to give of ourselves to them.”

“Compassion is having the ability to feel something of the patient's predicament and to assure the patient he or she will not be abandoned.”

- Edmund Pellegrino MD