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# Research Update for Nurses

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15<sup>th</sup> Annual Cardiovascular Nursing Conference  
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# SPHC Research Coordinators

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To demonstrate the benefits of research,  
let us introduce you to....

- Age 50
- Sedentary Lifestyle
- Hyperlipidemia
- Obesity
- Smoker
- Positive Family History  
for Heart Disease



## Bennie has an MI.

- He is taken to the Cath Lab and a stent is placed in his LAD.
- He needs an anti-platelet drug.
- His doctor prescribes Effient.



# JUMBO Study TIMI-26

(2004)

- Can we improve on Plavix?
  - CS-747: greater inhibition of platelet aggregation
  - Objective: Evaluate safety of various doses
  - 51 patients consented at United Hospital
  - Results: No significant difference
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# TRITON TIMI-38

(2005-2007)

- Phase 3 study with 14,000 patients
- Objective: Is CS-747 (prasugrel) superior to Plavix?
- 10 patients consented at St. Joe's
- Results: Significantly reduction in ischemic events
- But... Also a significant increase in bleeding

# FDA Approval

- July 2009: FDA approves prasugrel (Effient)
  - Indicated to reduce rate of thrombotic CV events in ACS pts managed with PCI
  - Lower doses for patients who weigh <132 lbs
  - Boxed warning alerting to bleeding risks
  - Not recommended in pts  $\geq 75$  yrs, pts with history of TIA or stroke
- On formulary at United & St. Joe's

# Bennie develops Atrial Fibrillation.

- He needs long-term anticoagulation.
- He enrolls in a clinical trial that is comparing warfarin to dabigatran.



Bennie Fitz

*Pradaxa*<sup>®</sup>  
dabigatran etexilate

A red graphic element consisting of a curved line that starts from the bottom right, loops around to the top right, and then curves back down to the bottom right, ending in a small red circle.

*Transforming anticoagulation*

# Dabigatran Characteristics

- Coumadin competitor
- Direct thrombin inhibitor
- Peaks 2-3 hrs after PO dose
- Terminal half-life is 12-17 hrs
- Steady-state reached within 2-3 days

# Dabigatran Characteristics

- Given BID
- Excreted via kidneys (80%) & bile
- Dialyzable
- Contraindicated in pts with  $< 30\text{mL/min}$  CrCl
- 75% of drug excreted w/in 24 hrs of last dose

# RE-LY Clinical Trial

(2008)

- Study compared warfarin and dabigatran in patients with atrial fibrillation.
- Patients randomized in a 1:1 ratio
- 5 subjects enrolled at SPHC
- Results:
  - Similar decrease in stroke and systemic embolism at 110mg BID
  - Significant decrease in stroke and systemic embolism at 150mg BID
  - 20% reduction in major bleeding rates
  - No hepatotoxicity
- Pending FDA approval

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## Need to Know

- No vitamin K restrictions
  - Anticoagulant effect not routinely monitored
  - Interpret aPTT or TT with caution
  - No specific antidote
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# Procedure Preparation

- **Cardioversion:** continue medication
- **Revascularization:** measure ACT & administer heparin as needed
- **CABG:** delay 12 hrs after last dose if possible
- **Elective Surgery:** stop 24 hours prior (2 doses)

# Elective Surgery

Renal Function (CrCl, mL/min)	High Risk	Standard Risk
$\geq 50$ to 80	2 to 3 days	24 hrs prior
$\geq 30$ to $< 50$	4 days	at least 2 days
$< 30$	$> 5$ days	2 to 5 days

# Bennie wants to take fewer meds.

- He enrolls in a trial of an occlusion device as an alternative to long-term anticoagulation.



Bennie Fitz

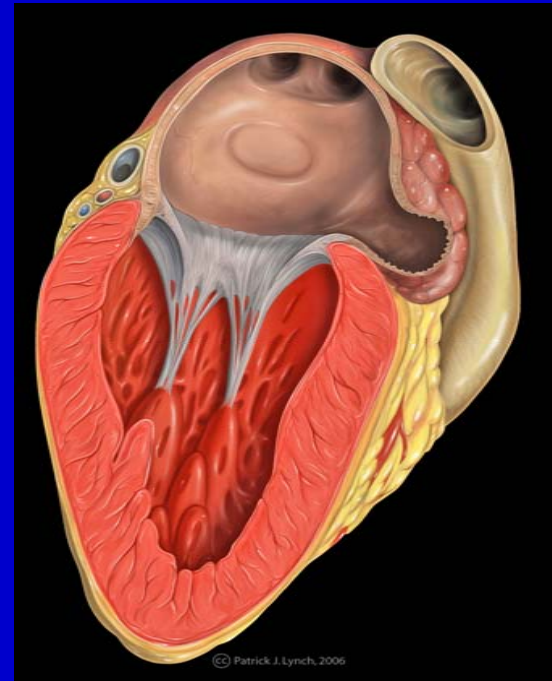
# PROTECT-AF Trial

(current)

- Study compared a medical device to long-term coumadin therapy in patients with non-valvular atrial fibrillation
- Patients randomized to device in 2:1 ratio
- 11 patients enrolled at SPHC with device implant at United Hospital
- Patients followed for occurrence of thrombotic stroke, CV death, and systemic embolism

# Thrombus Formation

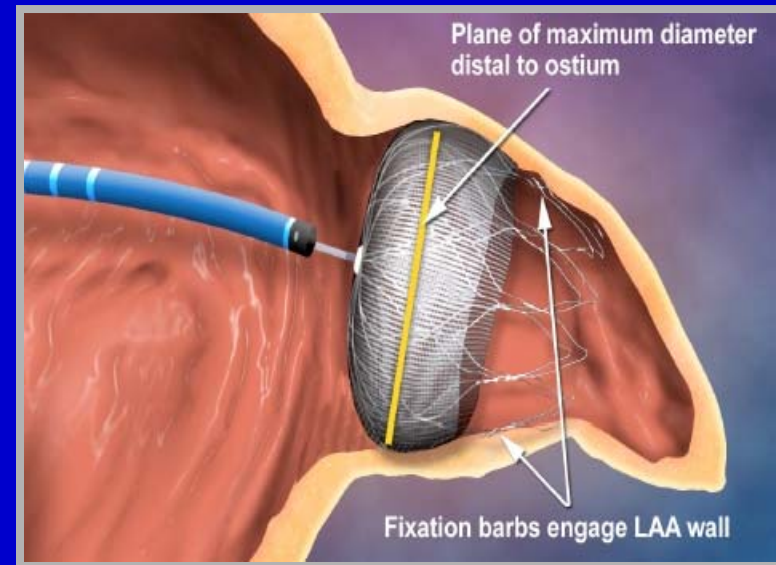
- 90% of the clots that embolize form in the left atrial appendage (LAA).
- A device that occludes the LAA could prevent the migration of these clots.



# WATCHMAN Occlusion Device



- Nitinol frame with permeable polyester fabric
- Delivered to the left atrium percutaneously on a delivery catheter
- Placed distal to ostium of LAA
- Placement confirmed via serial TEEs



# Results of the Study

- 87% of patients were able to discontinue coumadin by day 45.
- Incidence of stroke, cardiovascular death and systemic embolization was 32% lower in the device group.
- There were more procedure-related complications in device group, primarily pericardial effusion.
- FDA Circulatory System Devices Panel recommended conditional approval.
- Awaiting final FDA approval

# Bennie develops Heart Failure.

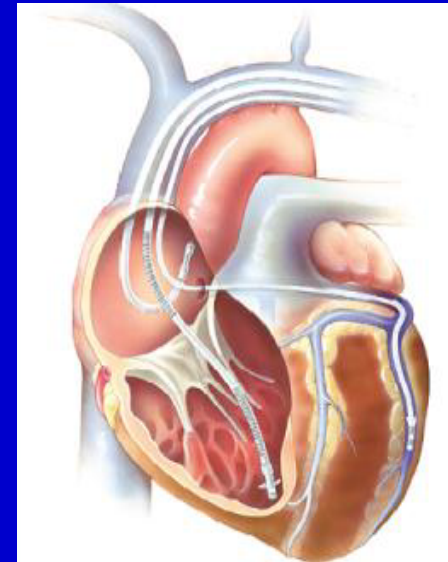
- Large left ventricle with:
  - LV Ejection Fraction 30%
  - QRS duration 160ms
- NYHA Functional Class III
- He fits the criteria to receive a CRT-D device.



Bennie Fitz

# Cardiac Resynchronization Therapy

- Biventricular stimulation “synchronizes” septal and left ventricular free wall activation to improve LV function.
- CRT-P devices have pacing function only.
- CRT-D devices have pacing function and defibrillator for life-threatening arrhythmias.

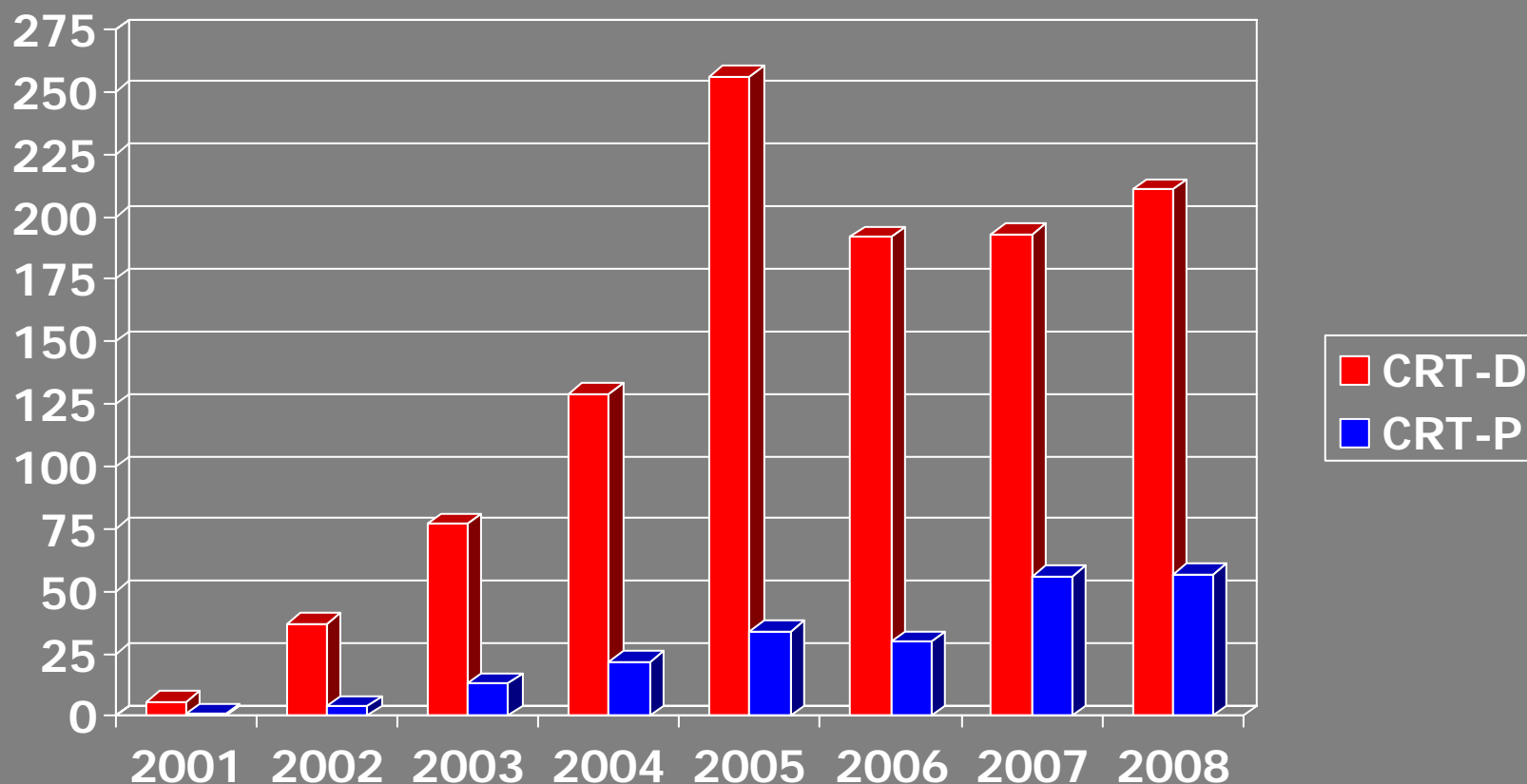


# COMPANION Clinical Trial

(2004)

- Comparison of medical therapy, pacing, and defibrillation in Heart Failure patients
  - SPHC had 22 patients in the trial.
  - CRT reduced hospitalizations and symptoms, and improved exercise tolerance and quality of life for **NYHA Class III and IV patients**.
  - When the defibrillator function was included, mortality was reduced by 36%.
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# CRT Implants at St. Paul Heart Clinic



The incidence of Hospitalization and Death with SPHC patients is even lower than the results reported in the COMPANION Trial.

# MADIT-CRT Clinical Trial

(2009)

- Comparison of CRT and ICD-only therapy in minimally symptomatic cardiac patients
  - CRT reduced hospitalizations, improved ejection fractions, and prevented or slowed the progression of heart failure in **NYHA Class I and II patients.**
  - Likely to influence future standard of care
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## Current Research at SPHC

- Intracoronary infusion of autologous stem cells to improve LV function post-MI
- New medication designed to elevate HDL levels in post-ACS patients
- Studies exploring the optimal duration of dual anti-platelet therapy following stent implant
- Studies evaluating new devices for the treatment of heart failure and/or arrhythmias

## What you can do...

- Be aware of patients like Bennie who are involved in an active research study.
- Call a SPHC Research Nurse if you have questions or referrals.



Bennie Fitz