



How to bring your crazy idea to first-in-man (FIM) study?

M. Vaturi

Department of Cardiology

Rabin Medical Center

The Need

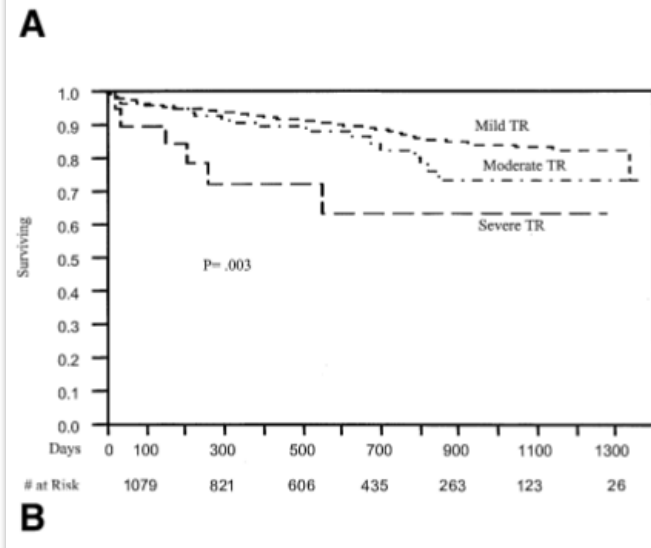
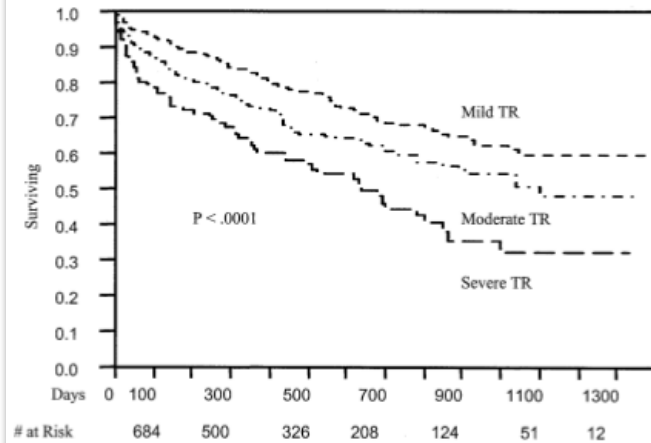
Severe TR is bad news

Journal of the American College of Cardiology
© 2004 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 43, No. 3, 2004
ISSN 0735-1097/04/\$30.00
doi:10.1016/j.jacc.2003.09.036

Impact of Tricuspid Regurgitation on Long-Term Survival

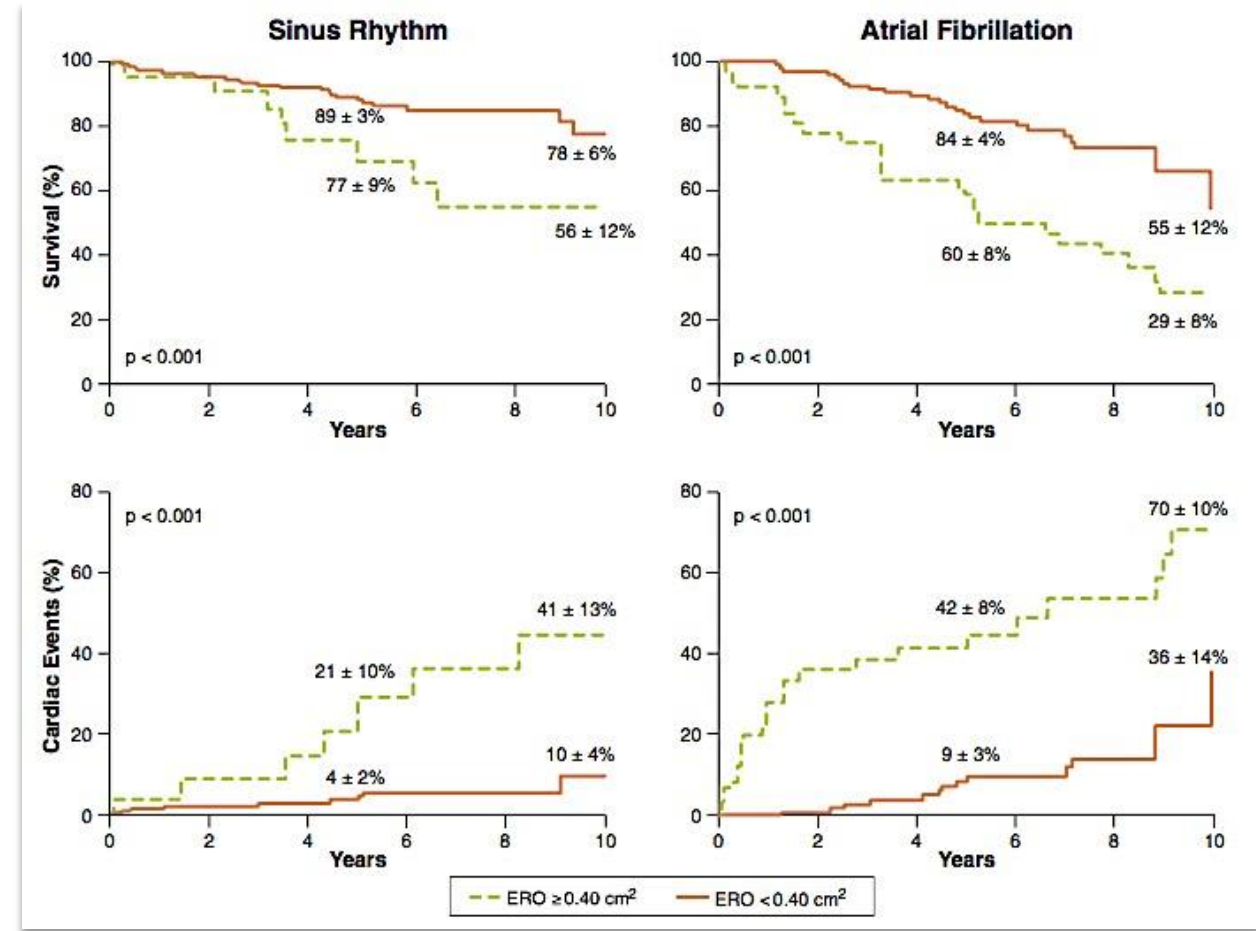
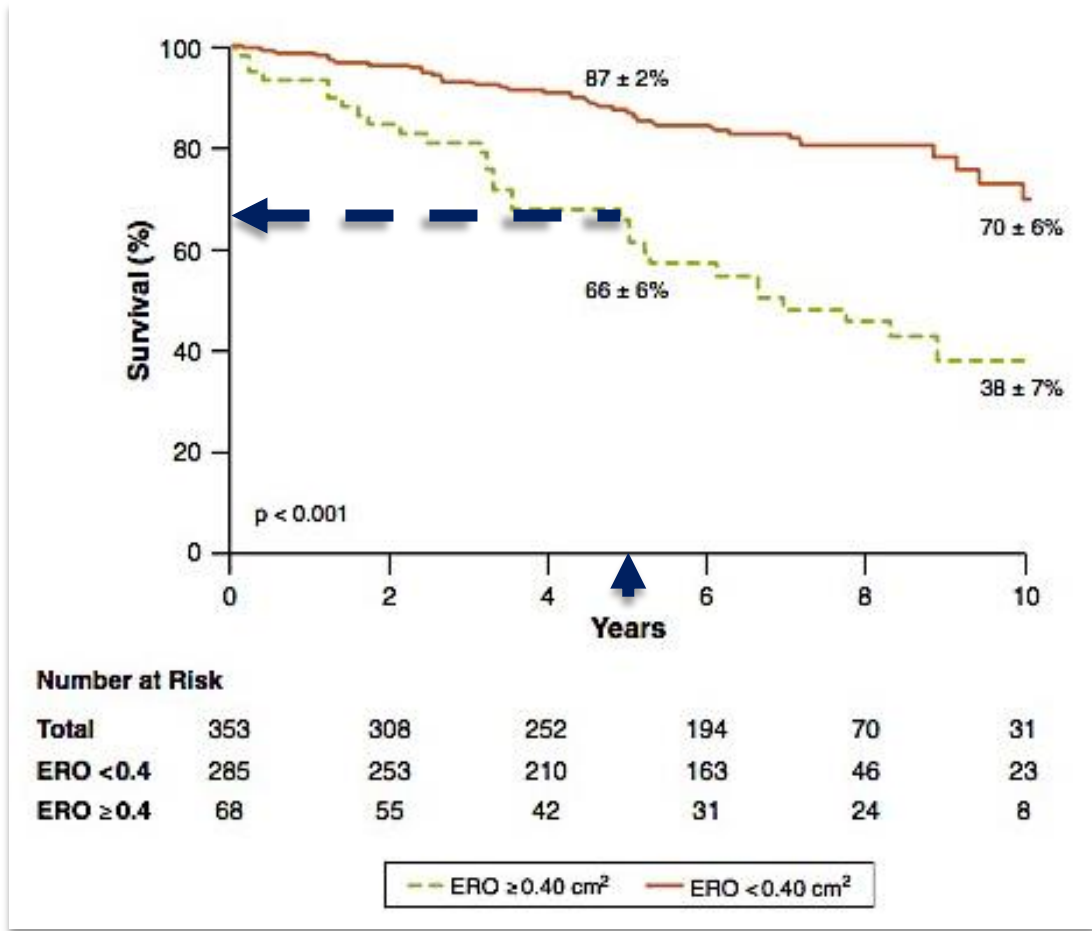
Jayant Nath, MD,* Elyse Foster, MD, FACC,† Paul A. Heidenreich, MD*
Palo Alto and San Francisco, California



Severe TR is associated with a poor prognosis, independent of age, biventricular systolic function, RV size, and inferior vena cava dilation.

The prognostic impact appears even with moderate TR

1 of 3 patients with severe TR is dead by the 1st year, 1 of 2 will die within 5 years !



In 5 years ~35% of the severe TR patients are dead

The Clinical Experience

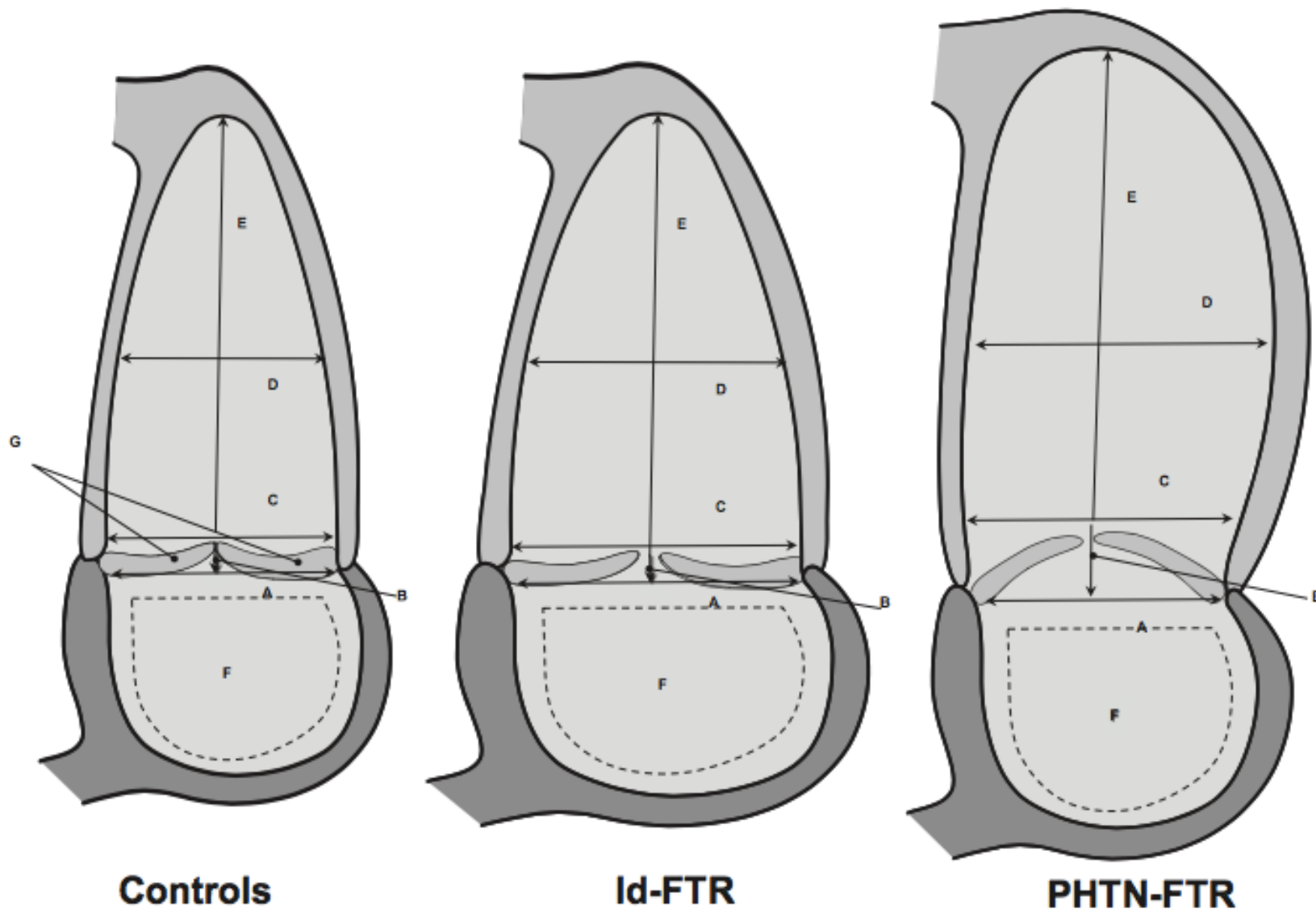
- High-risk profile combined with old age, frequent previous cardiac interventions, many comorbidities, and the consequences of low cardiac output state (CKD, liver congestion, gut congestion).
- Surgical risk for TR intervention exceeds those of AVR and MVR.
- Prolonged recovery after TV surgery.
- Persistent dependence on high-dose diuretics despite TR elimination.
- The medical therapy is useless to **cure** severe TR.
- The right ventricle

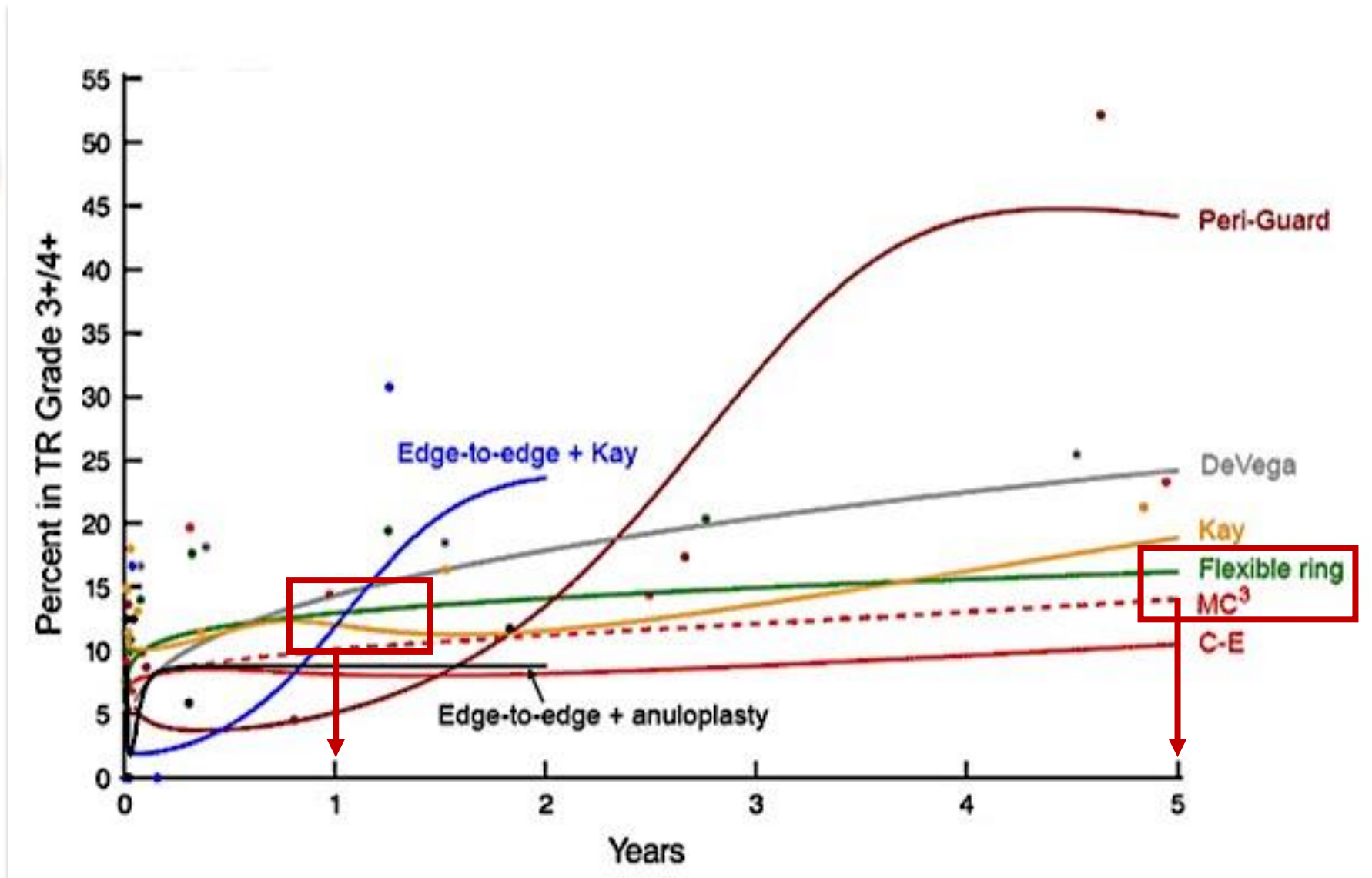
...and there's the V.A.T



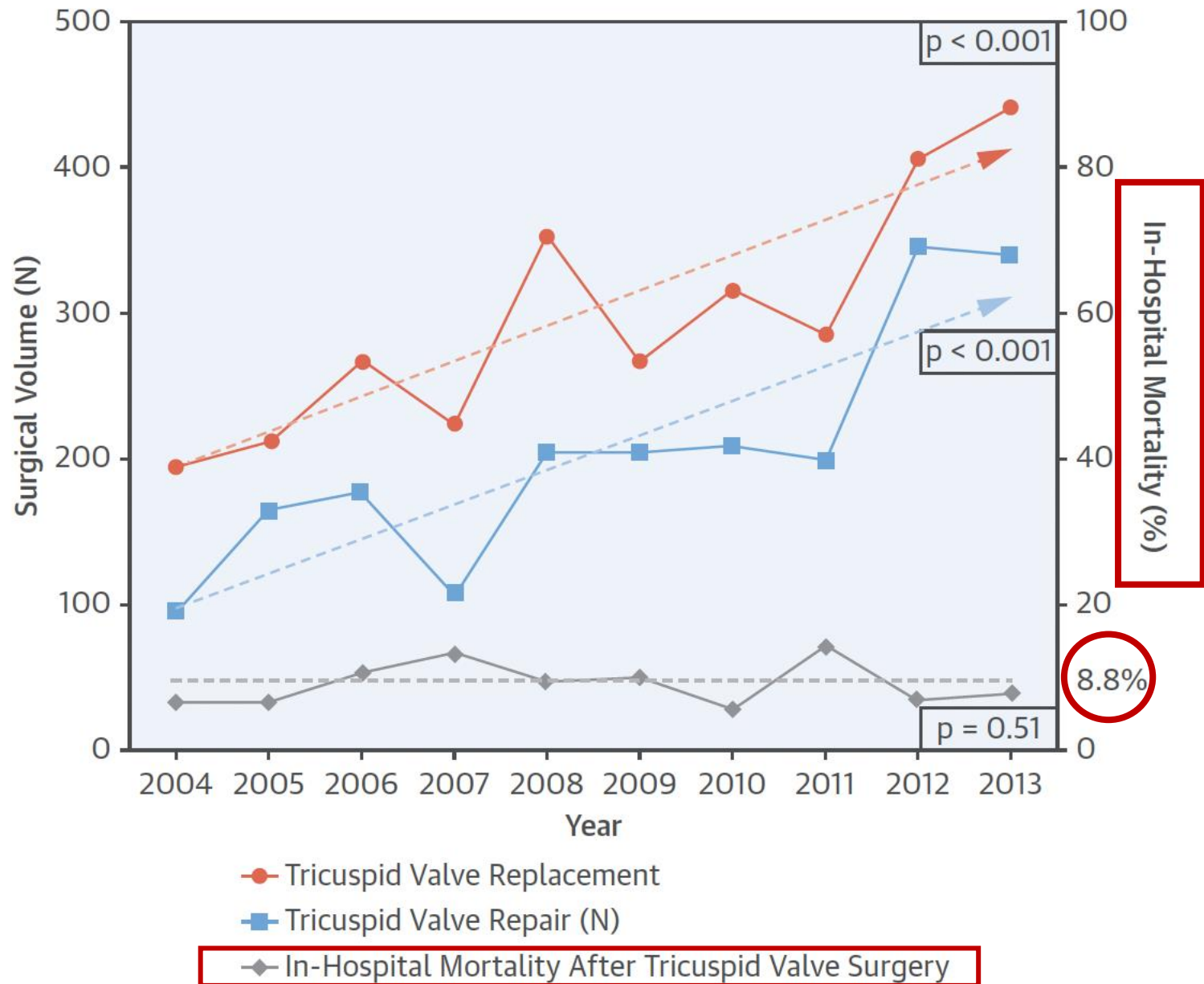
Substantial mileage in the O.R and the valvular clinic

When the Current Solution is not Ideal





The most used TR repair techniques resulted in approximately 15% severe TR (+3\+4 TR) within five years after the surgery



Mortality

TV repair:
5.9%;

TV replacement:
9.1% bioprosthetic valve
13.6% mechanical valve

Outcomes of Isolated Tricuspid Valve Surgery Have Improved in the Modern Era



Mohanad Hamandi, MD, Robert L. Smith, MD, William H. Ryan, MD, Paul A. Grayburn, MD, Anupama Vasudevan, PhD, Timothy J. George, MD, J. Michael DiMaio, MD, Kelley A. Hutcheson, MD, William Brinkman, MD, Molly Szerlip, MD, David O. Moore, MD, and Michael J. Mack, MD

Departments of Cardiovascular Research, Cardiothoracic Surgery, and Cardiology, Baylor Scott & White-The Heart Hospital, Plano, Texas



Outcomes	Overall (N = 95)	Repair (n = 68)	Replacement (n = 27)	p Value
Postoperative stroke	2 (2.1)	1 (1.5)	1 (3.7)	0.49
New requirement for dialysis	5 (5.3)	3 (4.4)	2 (7.4)	0.62
Cardiac tamponade	1 (1.1)	1 (1.5)	0 (0)	1.0
New-onset atrial fibrillation	11 (11.6)	9 (13.2)	2 (7.4)	0.72
New pacemaker	16 (16.8)	8 (11.8)	8 (29.6)	0.06
In-hospital mortality	2 (2.1)	2 (2.9)	0 (0)	1.0
Readmission	9 (9.5)	4 (5.9)	5 (18.5)	0.11
30-day mortality	3 (3.2)	3 (4.4)	0 (0)	0.56
Initial ICU stay (hours)	133.8 ± 200.3	129.8 ± 195.8	143.8 ± 214.9	0.76
Length of stay (days)	11.6 ± 10.6	11.1 ± 9.6	12.8 ± 12.8	0.50

“We believe that our low operative mortality rate is the result of improved patient selection resulting from increasing experience, careful preoperative assessment, and pre-and postprocedural management leading to earlier patient referral.”

The Itch

“There’s a fine line between fishing and just standing on the shore like an idiot”

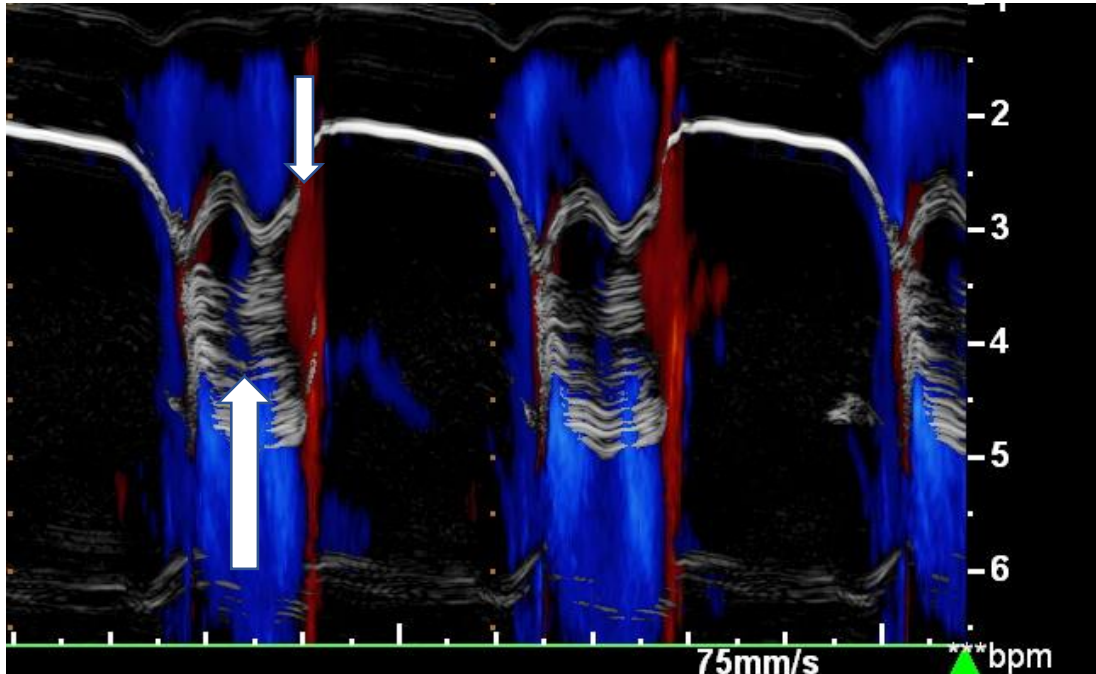
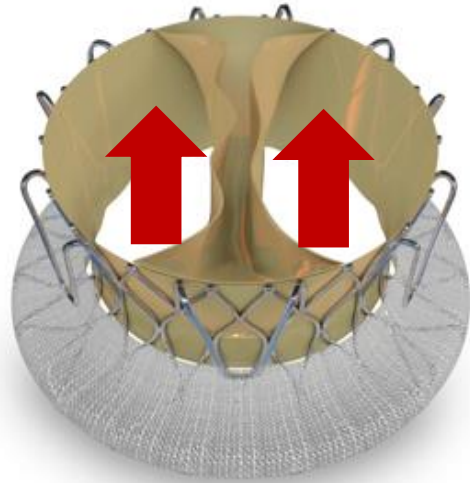
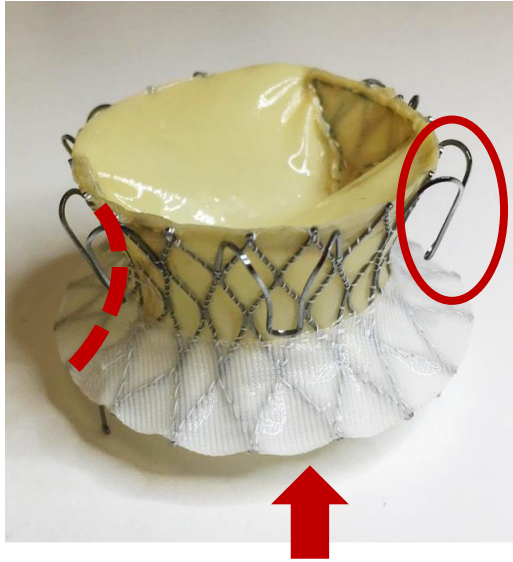
Steven Wright



Transforming
an idea to a
sophisticated
model



Let's pour some innovation into
this valve



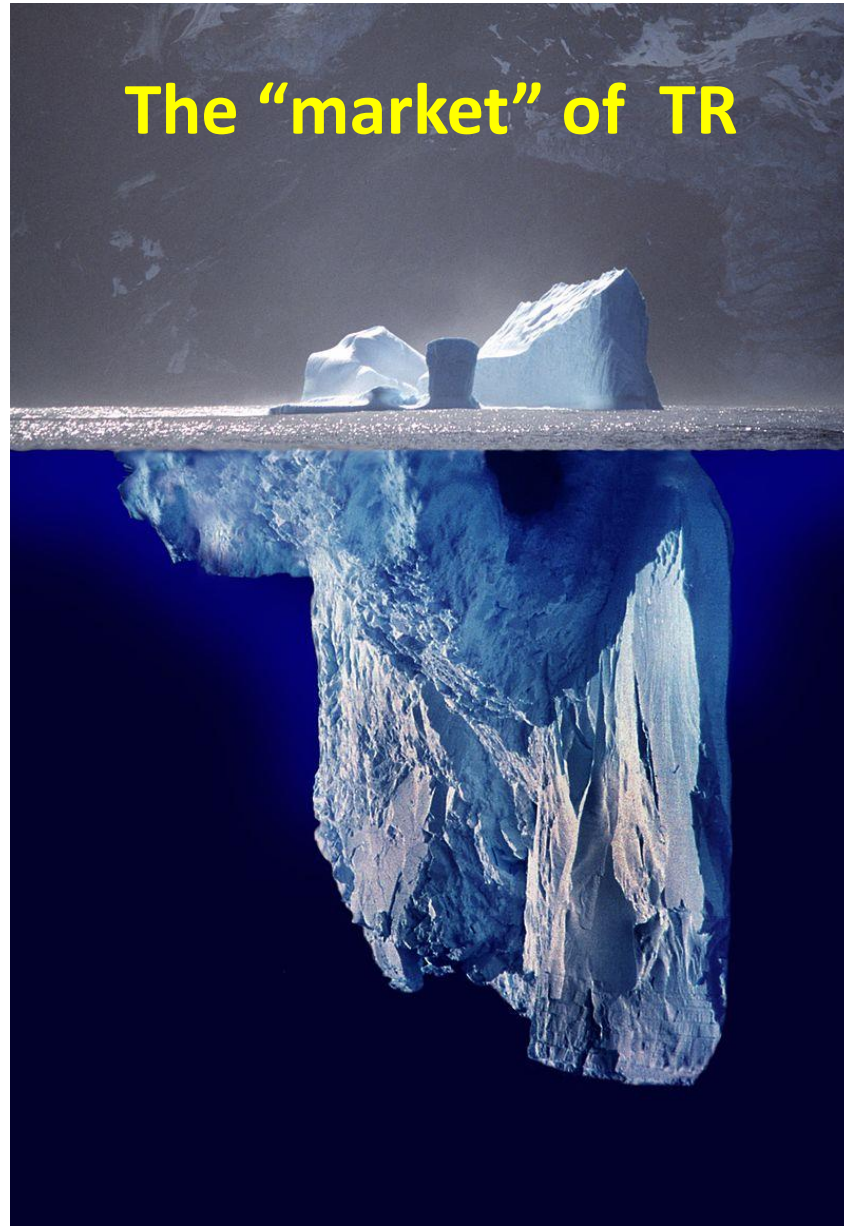
- Anchoring onto a “virtual annulus”
- Avoiding pressure on the adjacent conduction system
- A sizeable effective orifice area
- Something to alleviate the abrupt rise in RV’s afterload immediately upon elimination of severe TR: a parachute-like valve with a closing volume
- A transcatheter valve



The Via Dolorosa to the Pocket



The “market” of TR



Meanwhile

The hard and tedious work in the lab.



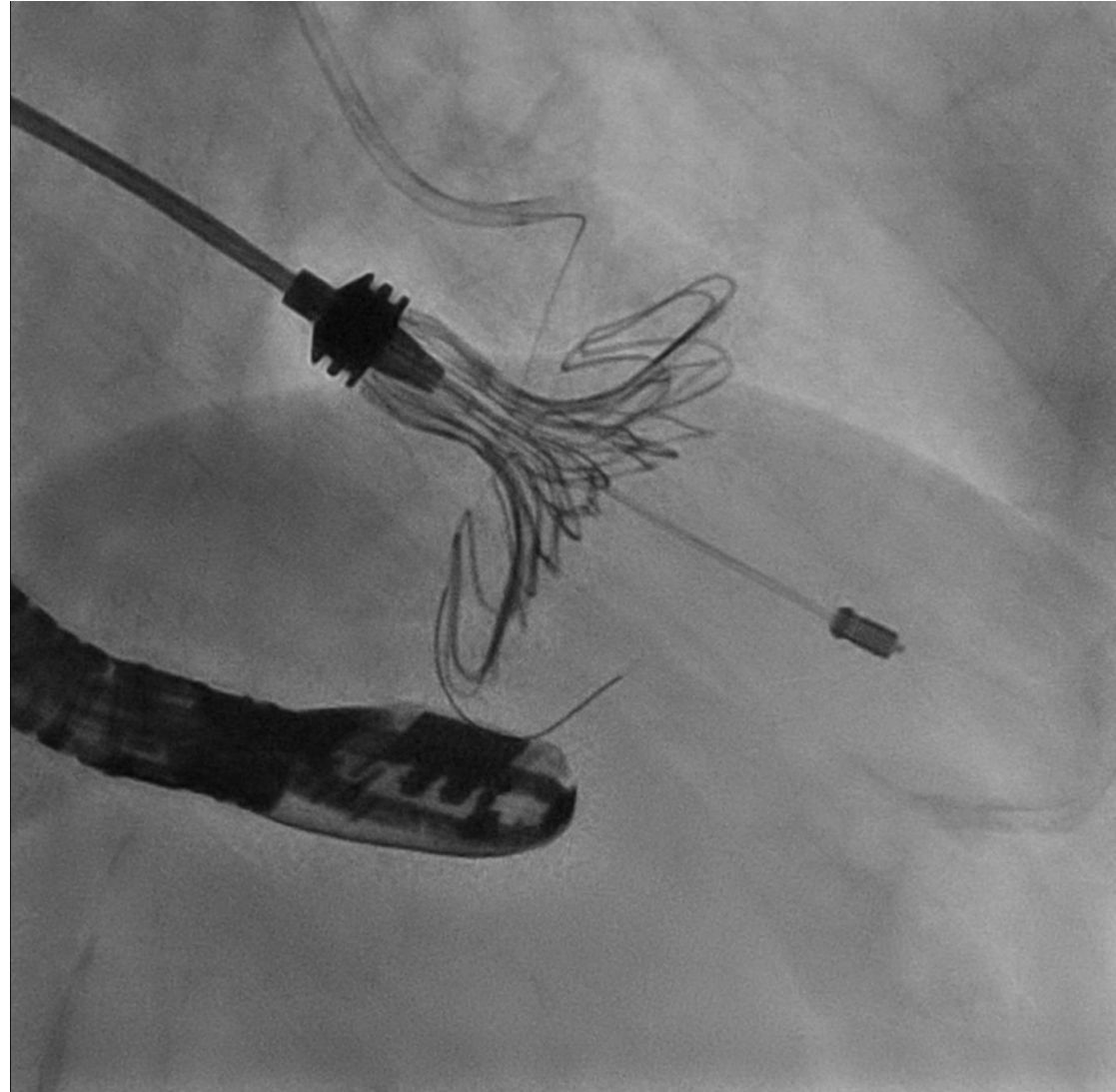
A consorted effort of engineers, technicians, secretaries, CEO...and me.

In Vitro => In Vivo (animals) => FIM

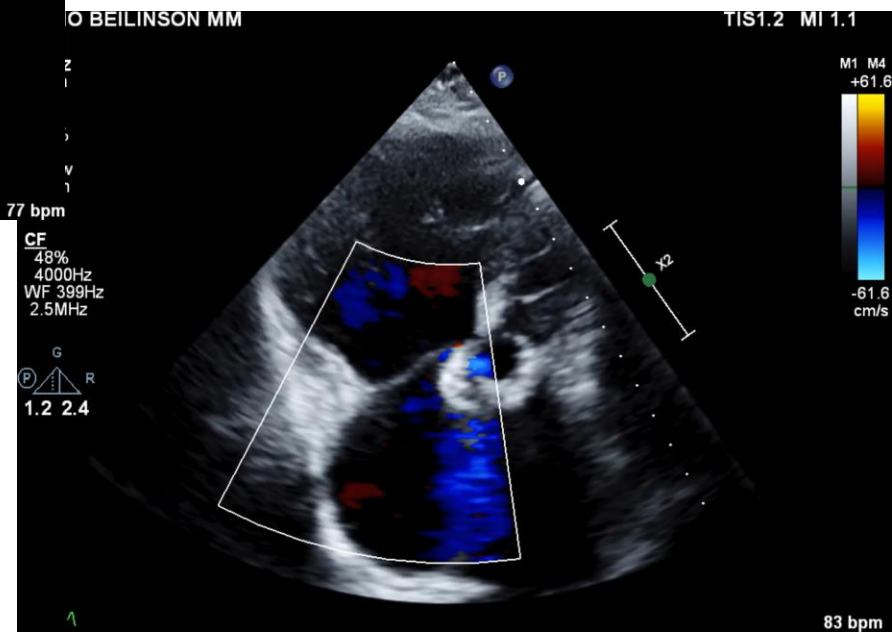
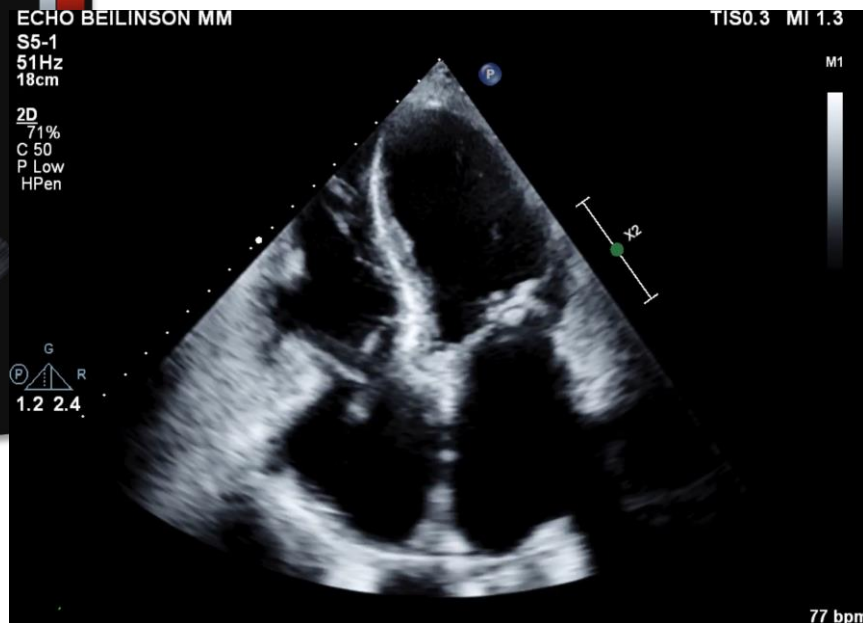
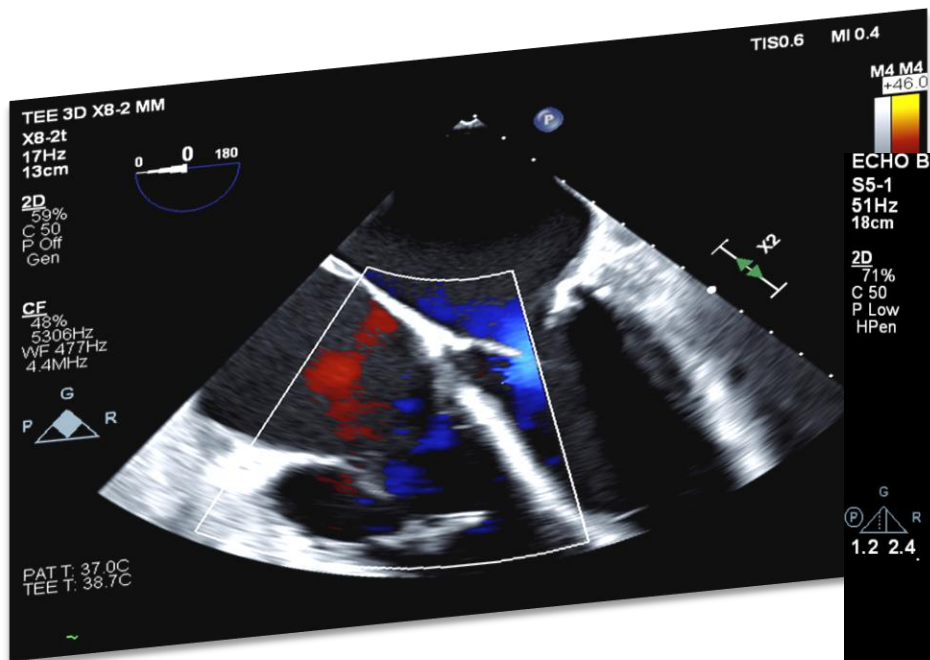
Better have these for ...



...this moment



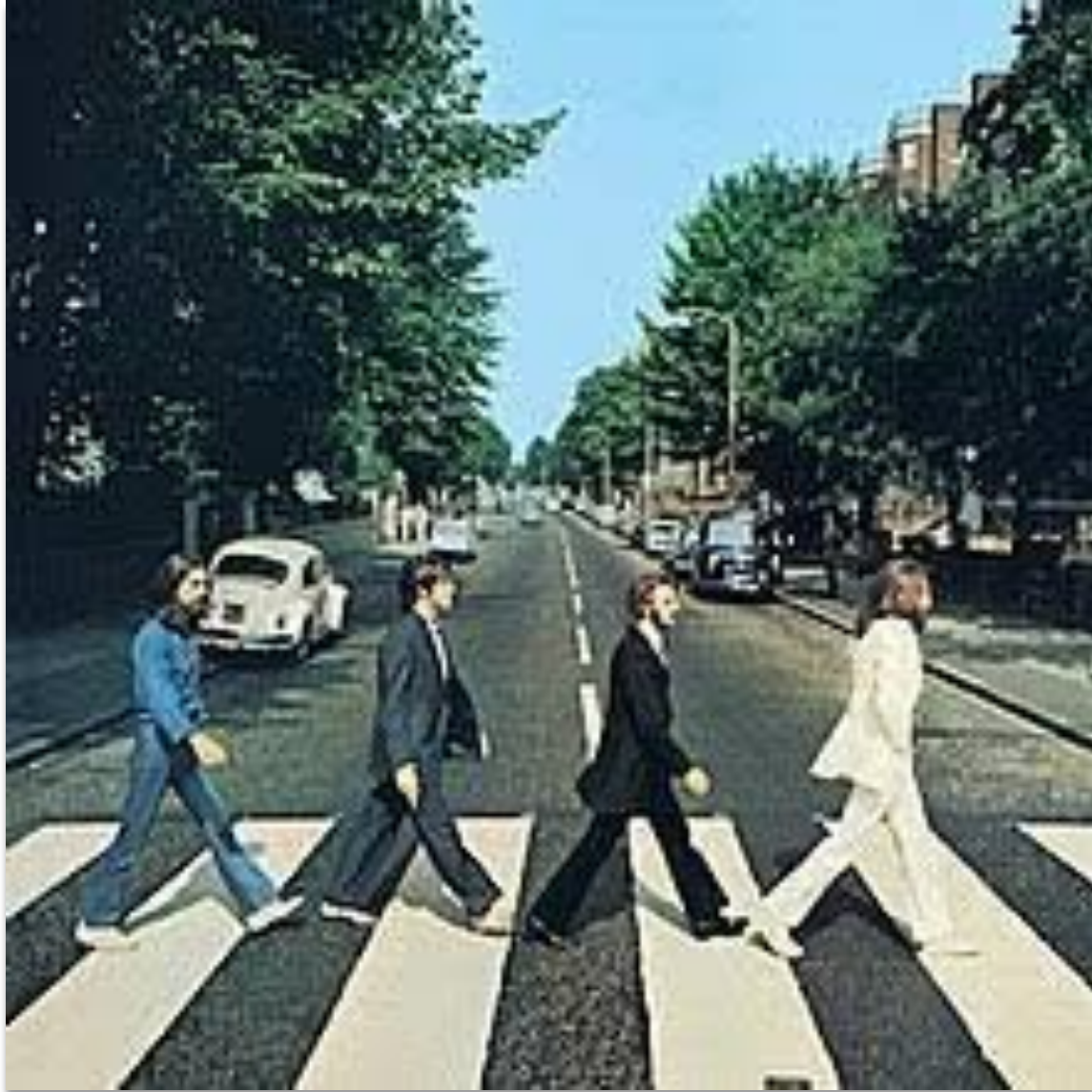
...and this moment



Think Positive,
Be Prepared for Dissapointments



HIGH EXPECTATIONS



VS.

ACHIEVEMENTS *(so far...)*



Who Dares Wins



Thank You for Your Attention