TRI in STEMI
What is the equipoise in 2012?

Christopher T. Pyne M.D.
Lahey Clinic
Burlington, Massachusetts

(No Disclosures)

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Some things we think we know in primary PCI for STEMI.

(What works well) :

- Various pharmacologic strategies and PCI will reduce mortality in STEMI.
- Major Bleeding (Access or non-Access site) is associated with worse outcomes in STEMI.
- Primary PCI via the transradial approach can reduce mortality in STEMI – Likely by reducing access site bleeding.

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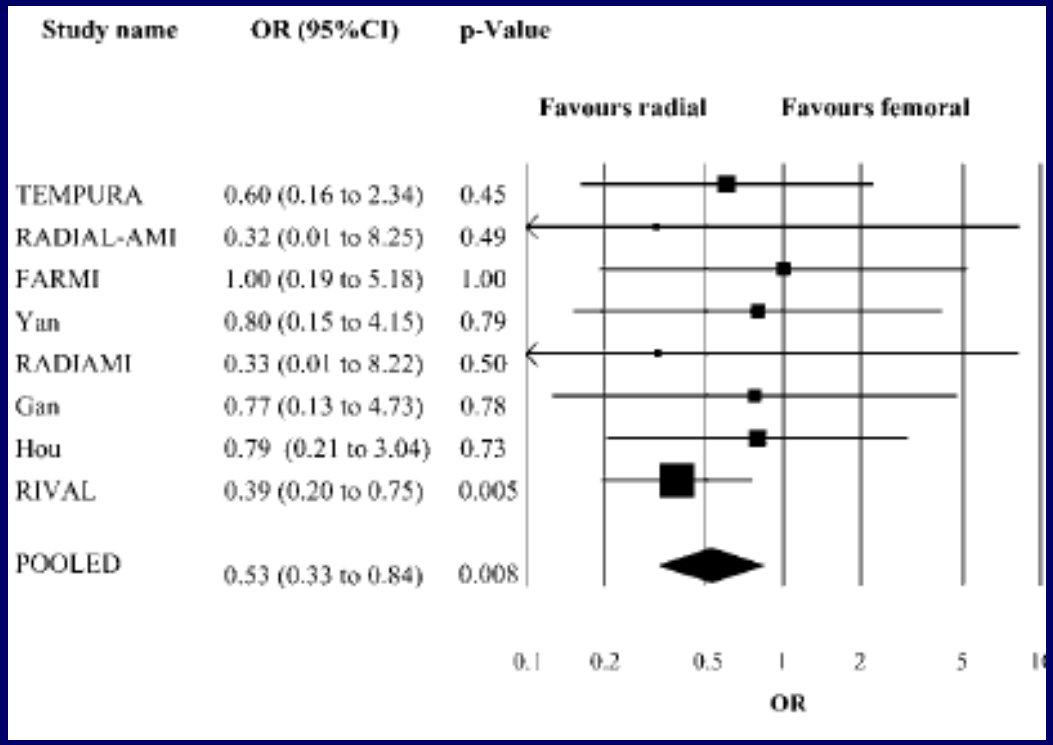
Mortality in published RCT for TRI vs. TFA in STEMI:



- *Most RCT small – unable to show mortality improvement.*
- *Most show significant reduction in access site complications.*
- *RIVAL with reduction in mortality without reducing major bleeding.*

9 RCTs: 2997 total patients (RIVAL:1958)
TRA mortality OR: .53 (.33 to .84 *p* = .008)

Mamas, Nolan et al: HEART 2012:98:303

Large RCT TF vs. TR in STEMI:

	N	DTB	Radial Failure	Shock?	Anticoag / Antiplatelet	Access Complications	Mortality
RIVAL	**1958**	**NR**	**5.3%**	**No .9% IABP**	**ASA Plavix LMWH: 51% Bival: 2.2% GPI: 31%**	**R:1.3% F:3.5%**	**R1.3% F:3.2%**
RIFLE STEACH	**1001**	**NR**	**4.7%**	**Yes 7.6% IABP**	**Bival.:7.6% GPI:67.4%**	**R:2.6% F:6.8%**	**R: 5.2% F: 9.2%**

Both trials with low Bivalirudin use and varied GPI use.
*Large percentages of bleeds (approximately 50%) **not** access site related*

Jolly S: LANCET: April 2011
Romagnoli: TCT OCT 2011

What is missing:

- What do radial access failures mean for outcomes?
- Comparative D2B data missing
  - *Single center registries encouraging*
- Impact of direct thrombin inhibitors on radial – femoral mortality.
- Reducing non-access site bleeding in TRI STEMI.
  - *Newer agents to reduce this?*
  - *Is non-access site bleeding a marker for sick patients ?*
- Impact of new anti-platelet agents on TRI STEMI mortality rates.
- What to do with shock patients?

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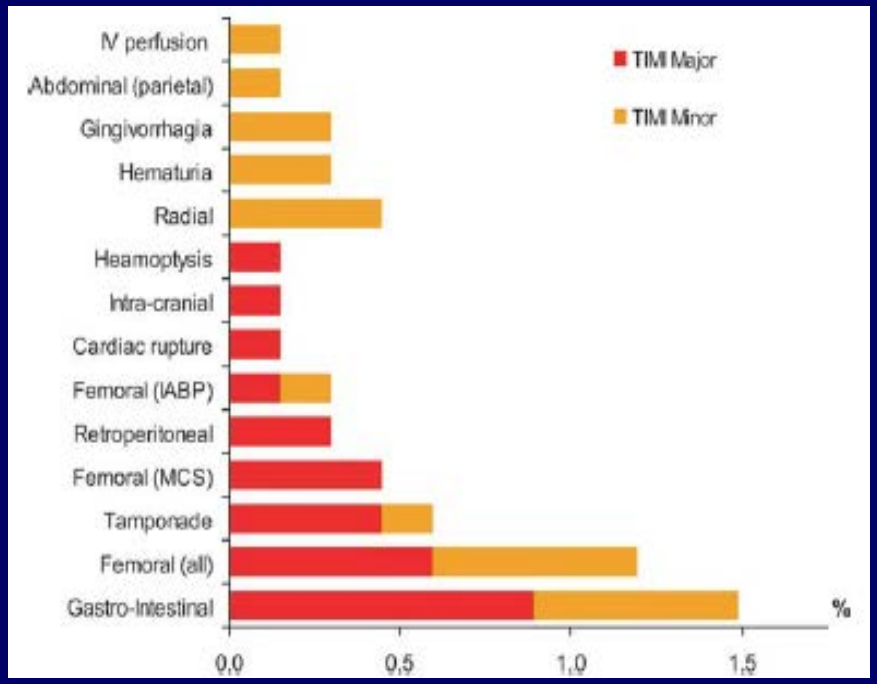
Etiologies of TIMI Major (2.5%) and Minor (5.7%) bleeding in 676 STEMI patients in a “Radial Center”:



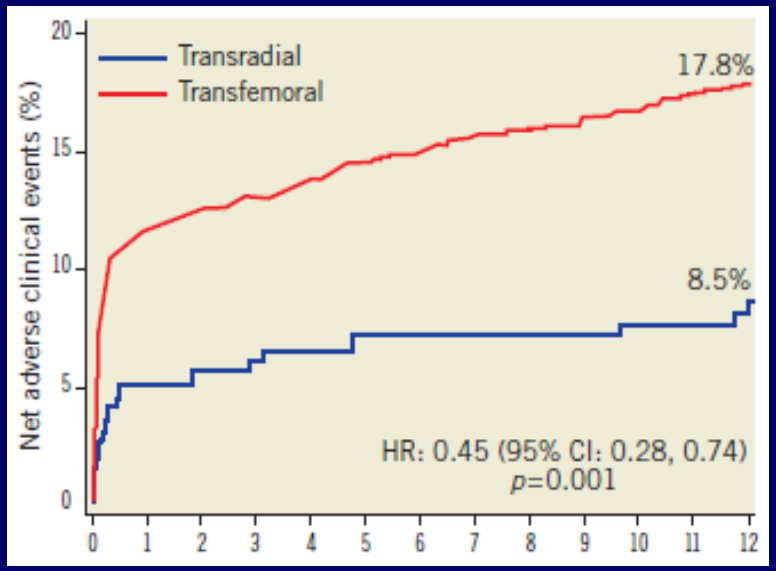
	OR	*P*
Age (10yrs)	**1.5**	**.012**
Ionotrops.	**2.46**	**.053**
Circulatory Support	**3.87**	**.008**
Respiratory Support	**2.97**	**.036**

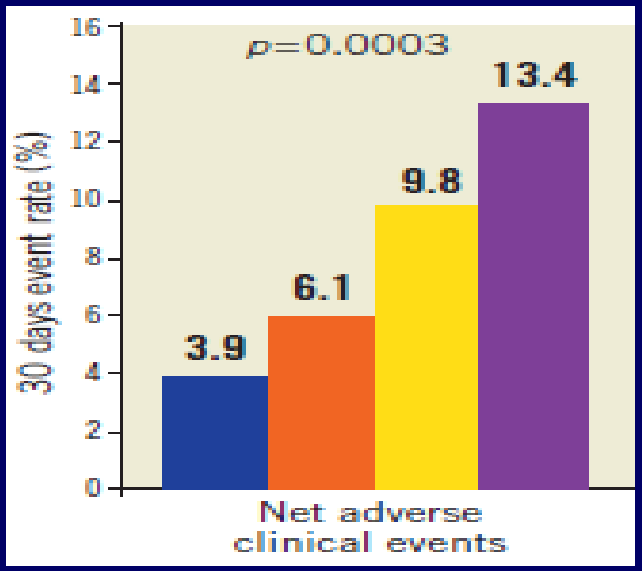
GI sites and femoral access for support leading cause of bleeding in TRA STEMI

88% of patients treated with TRI
78% Abciximab
7% IABP

Barthelemy, Montalescot et al: CCI 79:104 2012

STEMI with Bivalirudin and TRI:





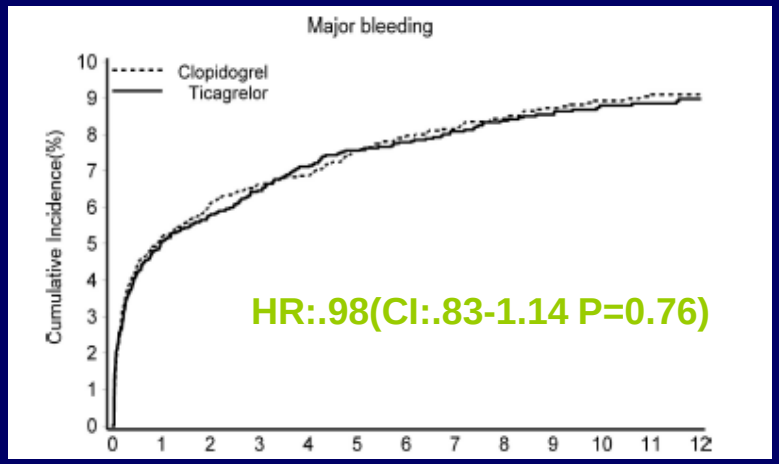
- *6 % of HORIZONS-AMI done via TRI / 1% Killip 4*
- *GPI use not uniform in all arms.*
- *TRI D2B times 11 minutes slower*
- *30 day and 1 year composite reduction in death or re-infarction*

Generoux, Mehran et al: EuroIntervention 2011;7:905-916

Impact of P2Y12 antagonist on bleeding in STEMI:

Ticagrelor

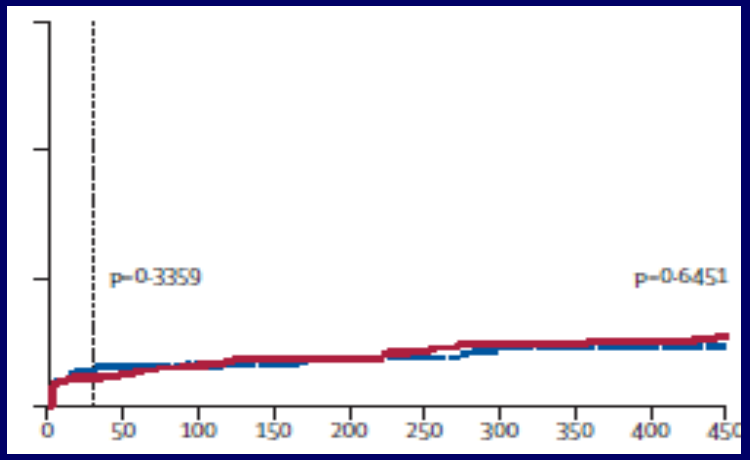
Circulation:2010:122:2131



Major Bleeding in PLATO – STEMI
(.87 HR for primary endpoint p=.07)

Prasugrel

Lancet: 373; Feb. 2009



Major Bleeding in TRITON – TIMI38
(.68 HR for primary endpoint p=.0017)

- *9% of Triton patients treated with TRI*
- *PLATO access sites not reported*
- *Impact of TRI with new agents given no increase in major bleeding?*

Shock and STEMI:

- Where do Shock patients fit in?
  - *Are failure rates higher?*
  - *Does IABP use negate the access site protection of TRI*
  - *Do hemo-dynamics predict outcome more than access?*
- *Has selection bias towards the femoral for shock favored the radial approach?*

Bell CCI:2011

Ongoing questions (Equipoise 2012)

- Do TRI access failures and resultant D2B delays negate the positive impact of bleeding reduction with the approach?
  - What level of operator experience is needed for TRI?
- Will optimizing medical therapies for both TRI and TFA in STEMI change the equation?
  - *Reducing access and non-access site bleeding with bivalirudin*
  - *Improving long term results with optimal DAPT*

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Ongoing questions (Equipoise 2012)

- Do operator selection bias make meaningful RCT difficult?
  - *Technically challenging patients not randomized despite the highest likely gain.*
- Should shock be studied in a TRI-TFA trial?
  - *Do presenting hemo-dynamics outweigh access bleed differences?*

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