Cardiovascular Trends 2011: Nursing and Cath Lab Symposia

Access Issues and Bleeding Complications

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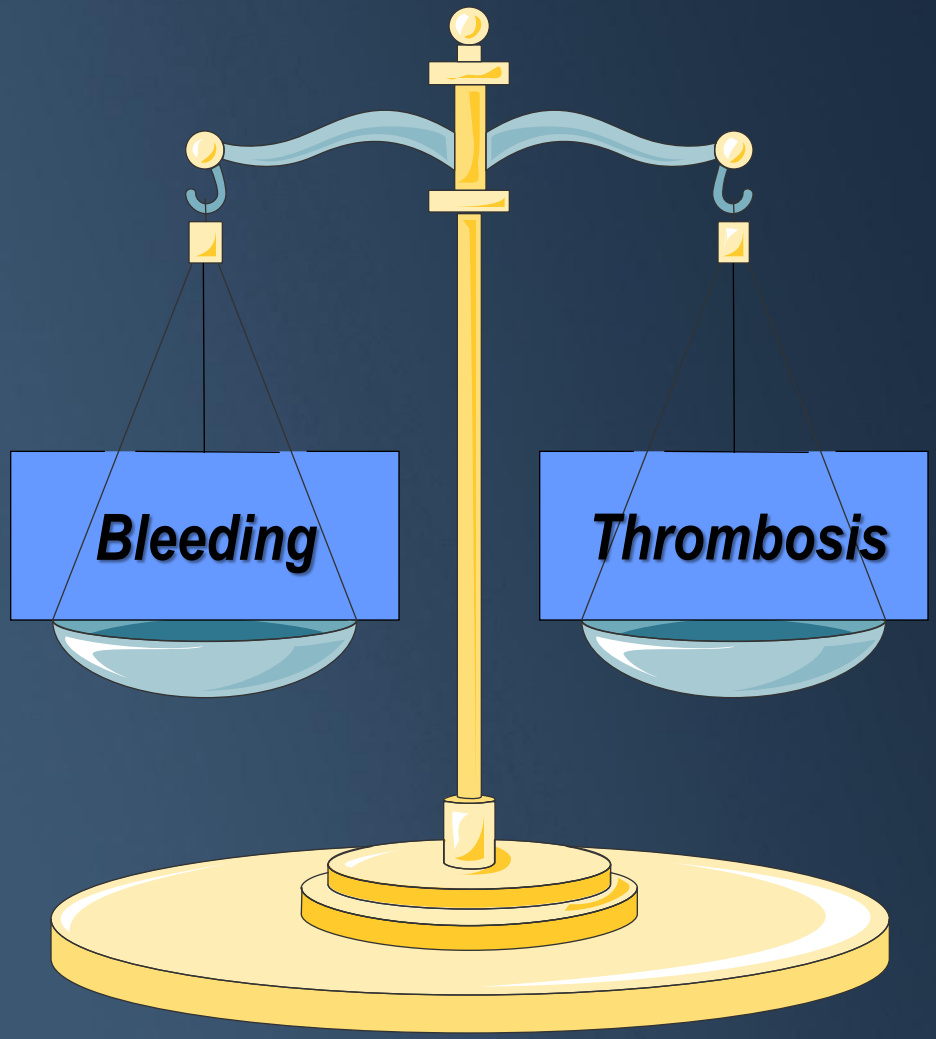
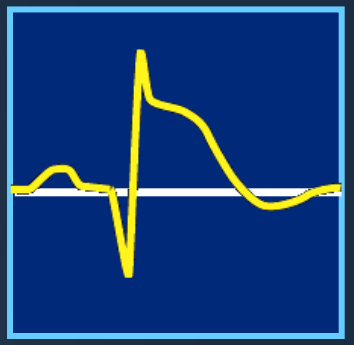
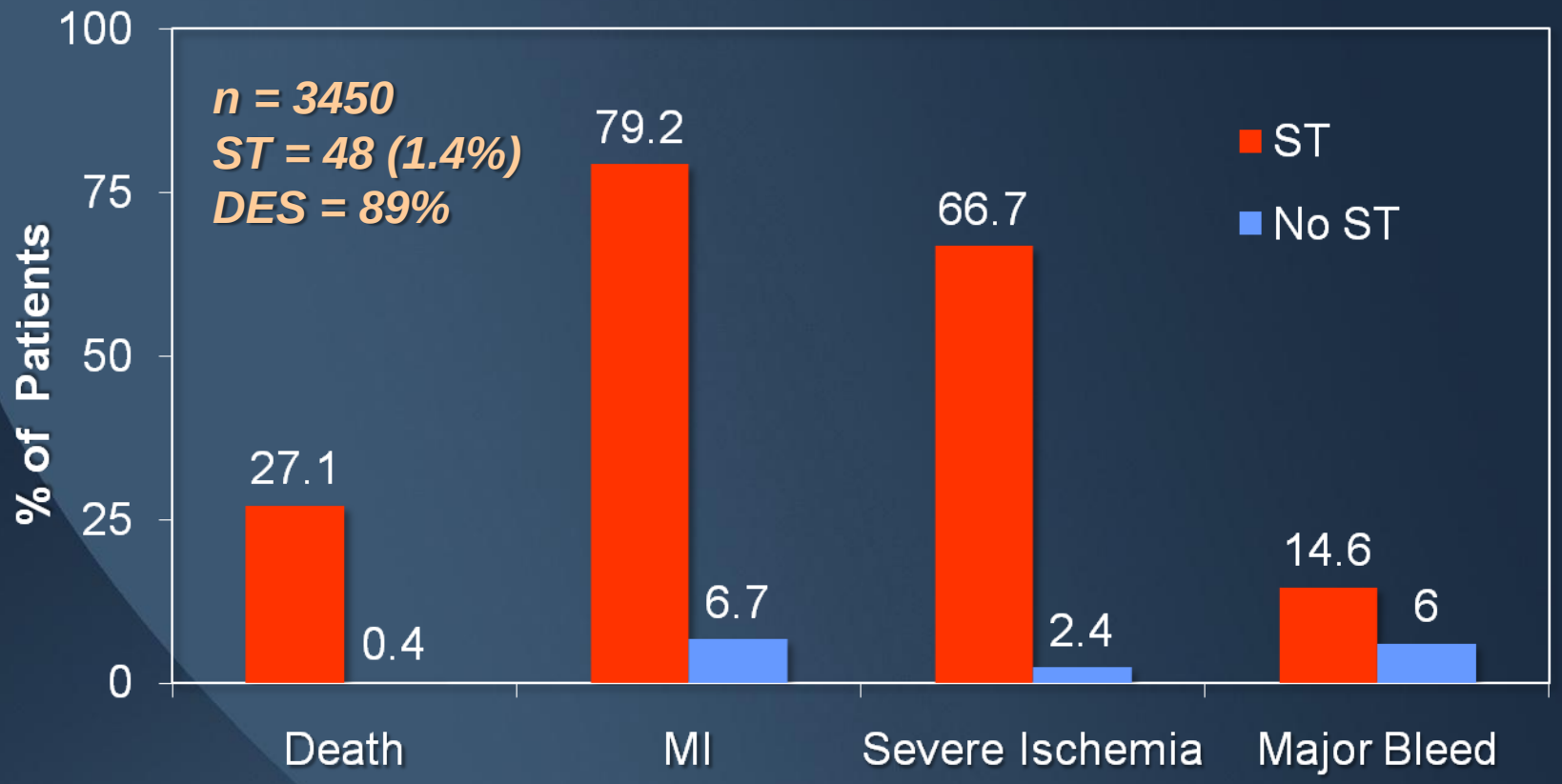
of MEDICINE


Bleeding
Thrombosis



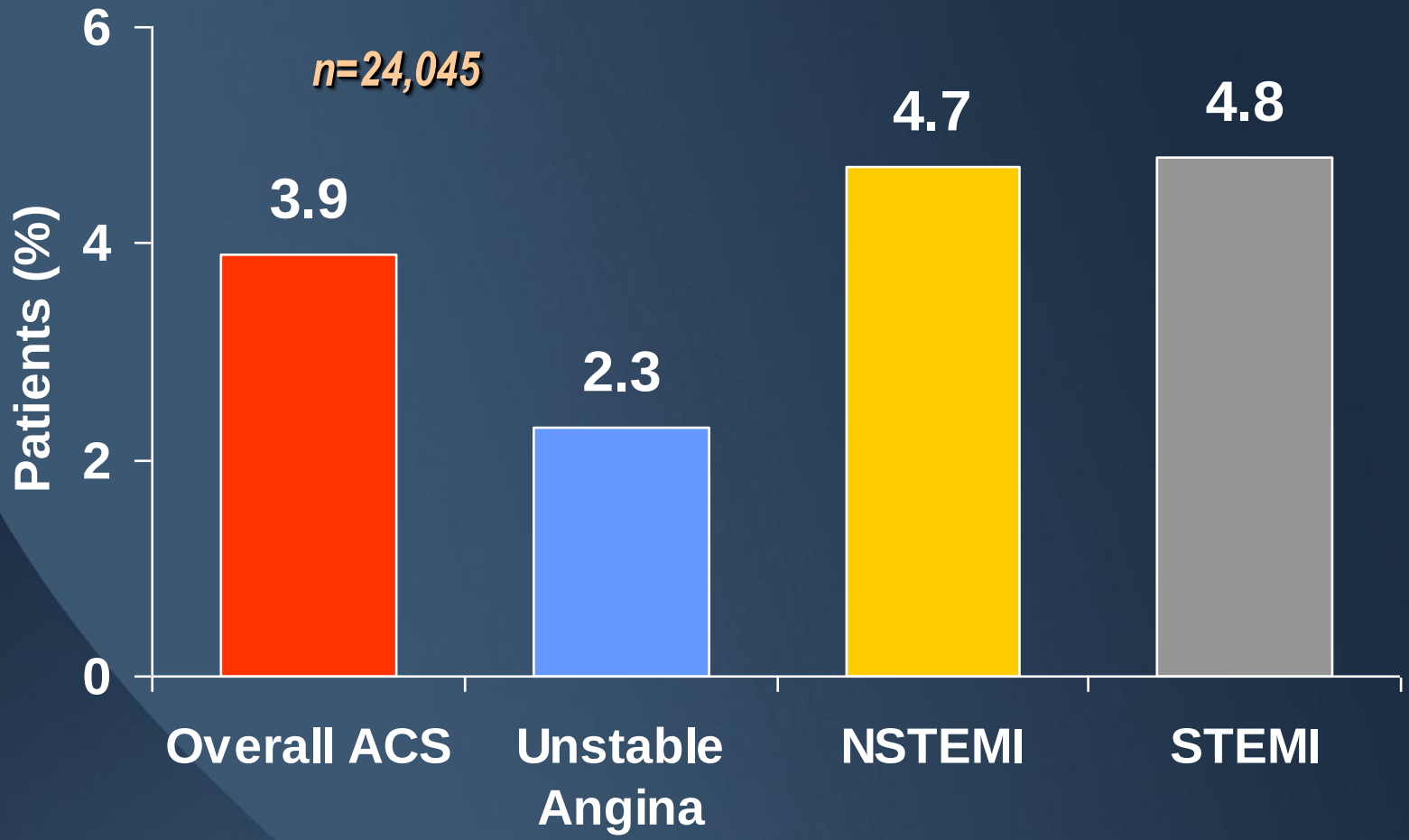
The Consequences of Thrombosis

Definite/Probable ST in Acuity (30 days)



Aoki J et al. Circulation 2009; 119:687-698

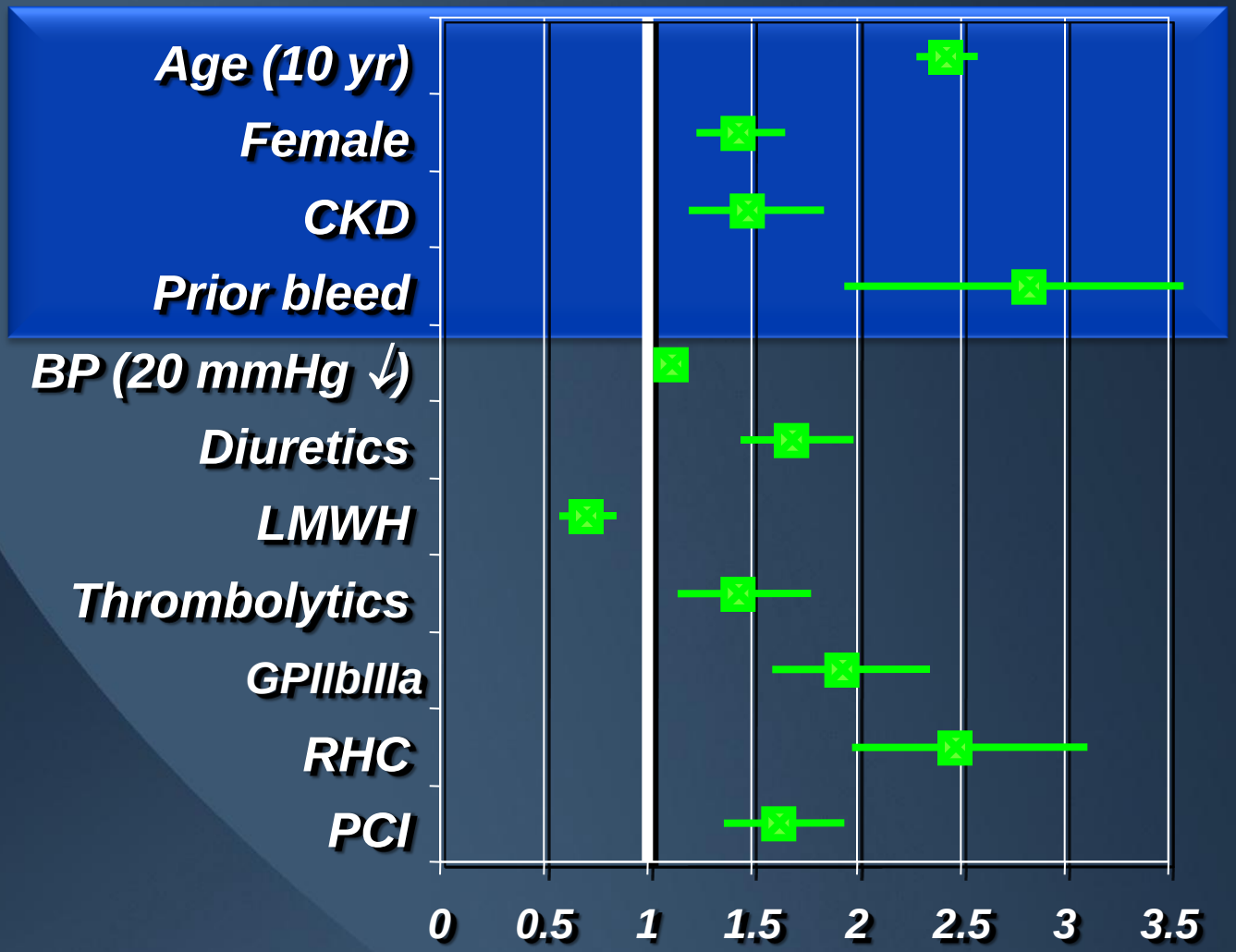
Rates of Major Bleeding



- *Life-threatening with transfusion ≥2 units*
- *Life-threatening with decrease in HCT ≥10%*
- *Resulting in death*
- *Hemorrhagic, subdural hematoma*

Moscucci M et al. Eur Heart J 2003;24:1815-23

Factors Associated with Major Bleeding in ACS patients



C-statistic=0.75

Moscucci M et al. Eur Heart J 2003;24:1815-23

Risk Factors for Bleeding in PCI

Risk Factors For Bleeding in ACS Patients

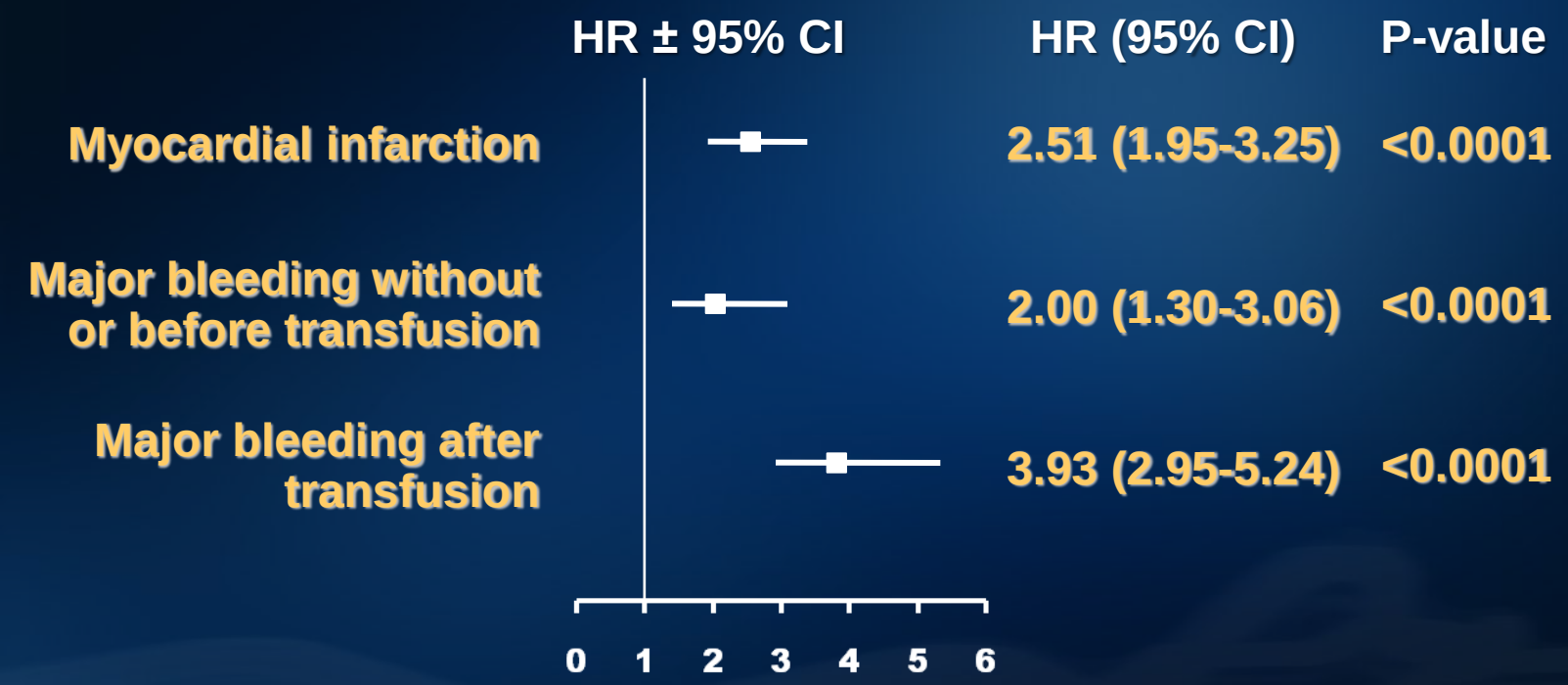
Patient related	Procedure related	Treatment related
➢Female gender ➢Older ➢Hypertension ➢Obesity ➢Low weight ➢Renal failure ➢Low platelet count, pre-existing anemia ➢Medical history (GI disease)	➢Puncture site (femoral vs radial) ➢Level of puncture (femoral) ➢Larger arterial sheath ➢Prolonged sheath time ➢IABP placement ➢Concomitant venous sheath ➢Need for repeat intervention	➢Excess anticoagulation ➢Type of anticoagulation (antiXa, direct thrombin inhibtor or LMWH and UFH) ➢GP IIb/IIIa inhibitors ➢Thrombolytics

Hamon M. et al. EuroIntervention2007, www.angiosoft.net

ACUITY: Influence of Major Bleeding and MI in the First 30 Days on Risk of Death Over 1 Year

Of 13,819 enrolled pts, 524 (3.8%) died within 1 year

Cox model adjusted for 36 baseline predictors, with MI and major bleeding (non-CABG) as time-updated covariates



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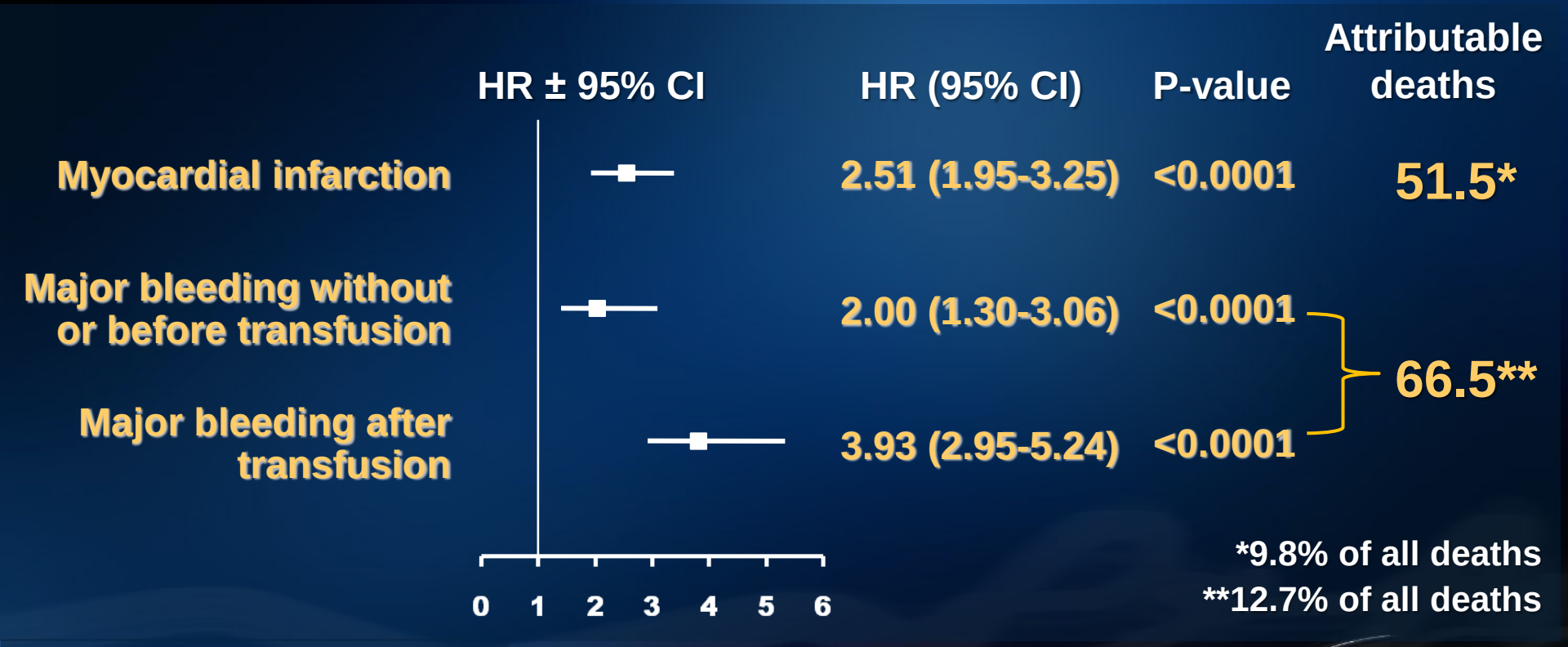


*9.8% of all deaths

**12.7% of all deaths

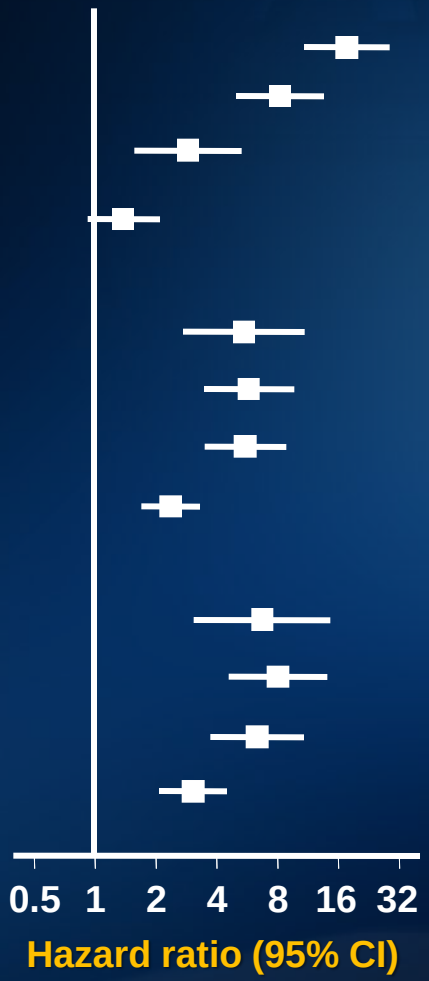
Attributable deaths = N deaths among pts with the time updated event (attribute) X (adj. HR – 1)/adj. HR

Mehran RM et al. EHJ 2009;30:1457-66

ACUITY

Influence of MI, Major Bleed and Transfusion in the First 30 Days on the Risk of Death Over 1 Year

		HR (95% CI)	P-value	Attributable deaths
MI	Day 0-1	17.6 (10.8 to 28.7)	<0.001	21
	Days 2-7	8.2 (5.0 to 13.6)	<0.001	19
	Days 8-30	2.9 (1.6 to 5.3)	0.001	12
	Days 31+	1.4 (0.9 to 2.1)	0.12	25
Major bleed (non CABG)	Day 0-1	5.5 (2.7 to 11.0)	<0.001	9
	Days 2-7	5.8 (3.5 to 9.7)	<0.001	18
	Days 8-30	5.6 (3.5 to 8.8)	<0.001	24
	Days 31+	2.4 (1.7 to 3.3)	<0.001	42
Transfusion	Day 0-1	6.7 (3.1 to 14.7)	<0.001	7
	Days 2-7	8.1 (4.6 to 14.1)	<0.001	15
	Days 8-30	6.4 (3.7 to 10.9)	<0.001	17
	Days 31+	3.1 (2.1 to 4.5)	<0.001	31



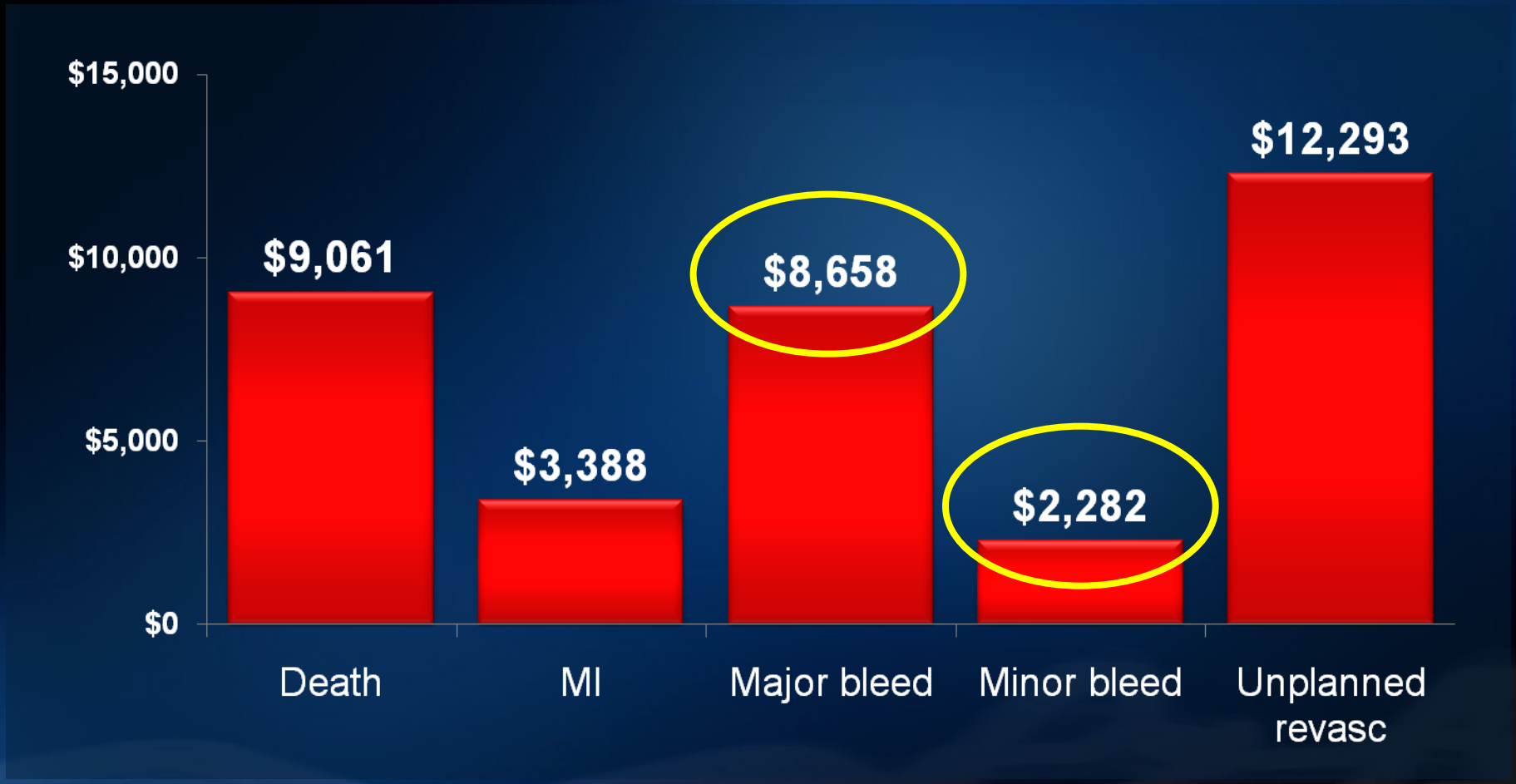
Attributable deaths = N deaths among pts with the time updated event (attribute) X (adj. HR – 1)/adj. HR

Mehran RM et al. EHJ 2009;30:1457-66

ACUITY

ACUITY

Costs of In-hospital Complications

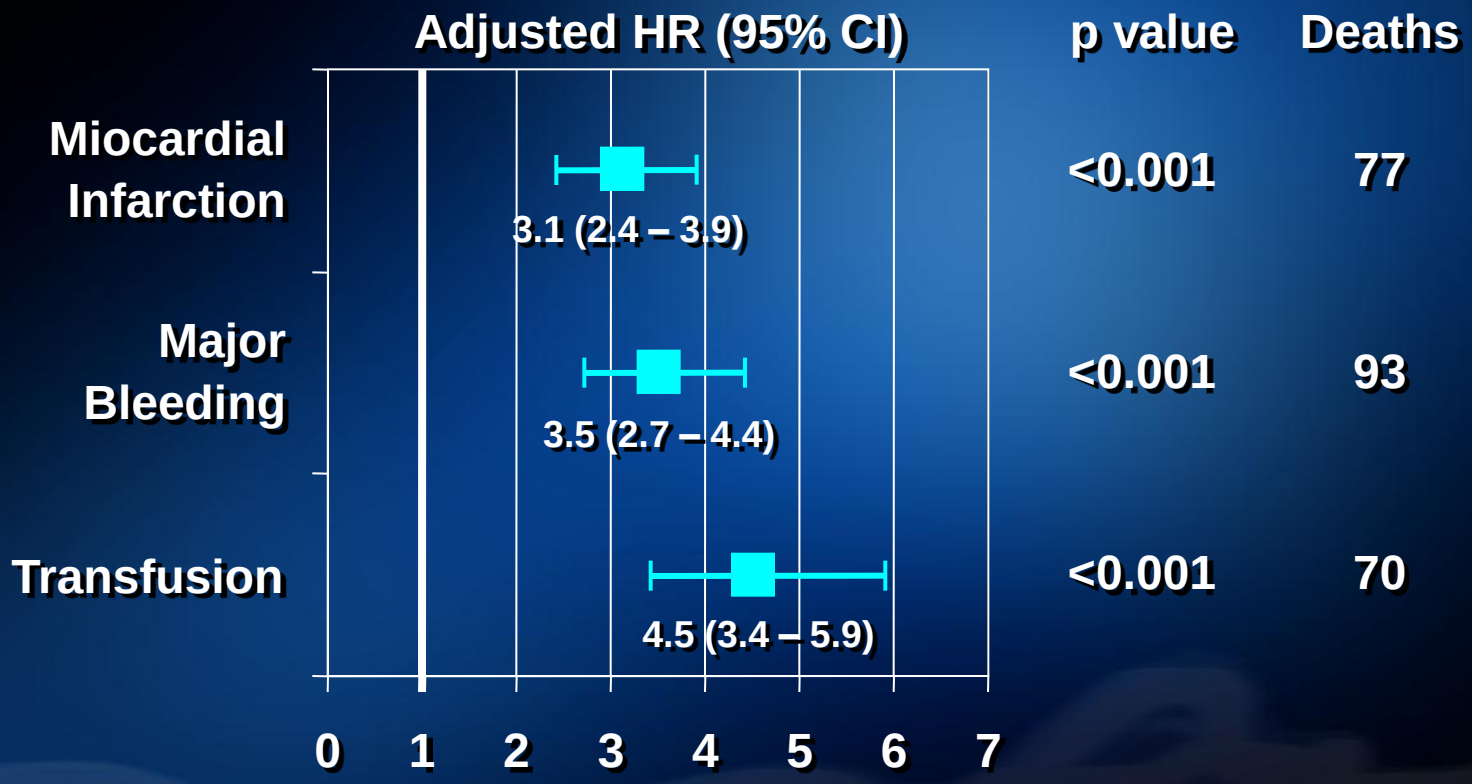


Pinto DS et al. JACC 2008;52;1758-1768

ACUITY

Influence of Major Bleeding and MI in the First 30 Days on Risk of Death Over 1 Year

Cox model adjusted for baseline predictors, with non-CABG major bleeding and MI as time-updated covariates

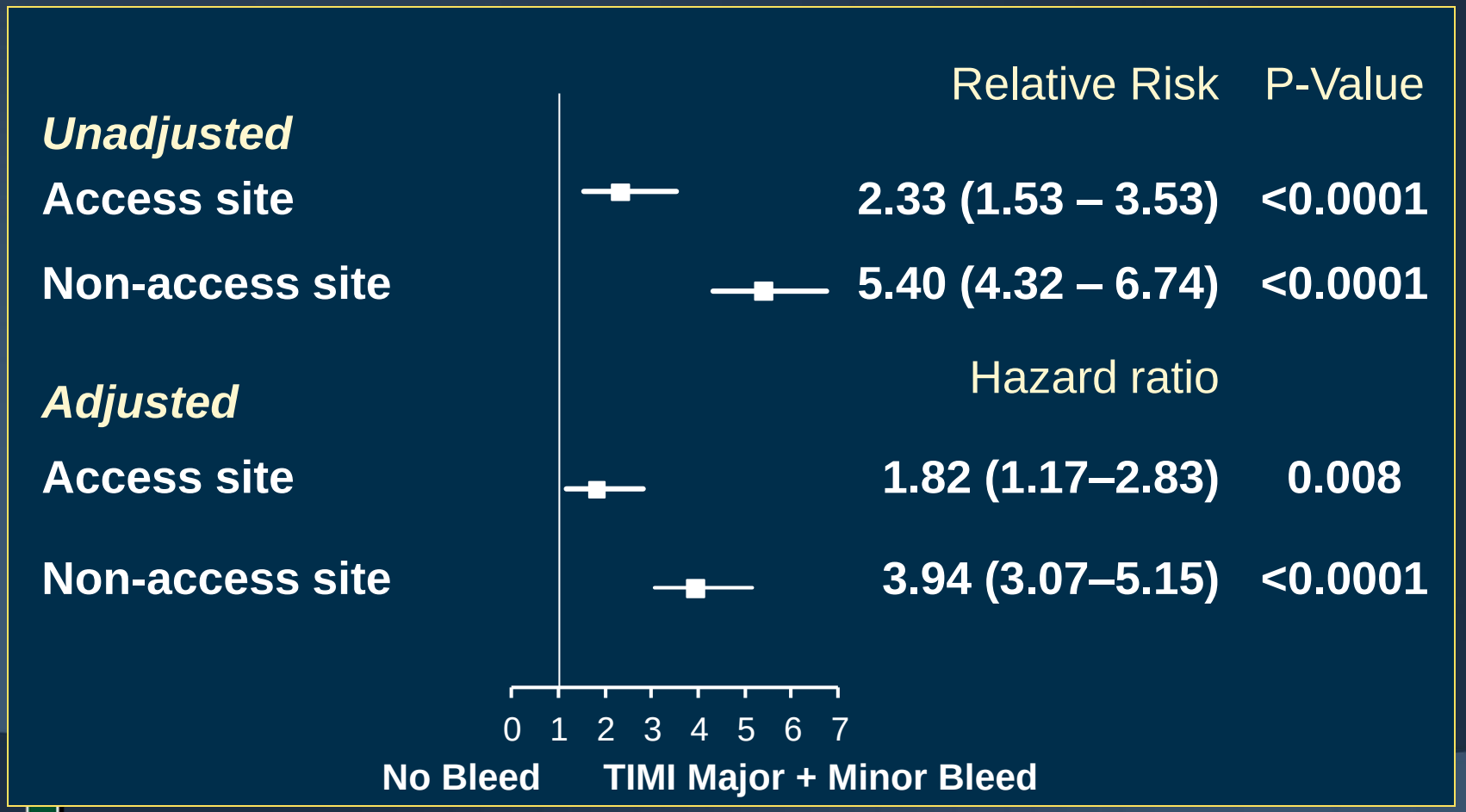


Mehran R et al. Eur Heart J 2009;30:1457-66

ACUITY

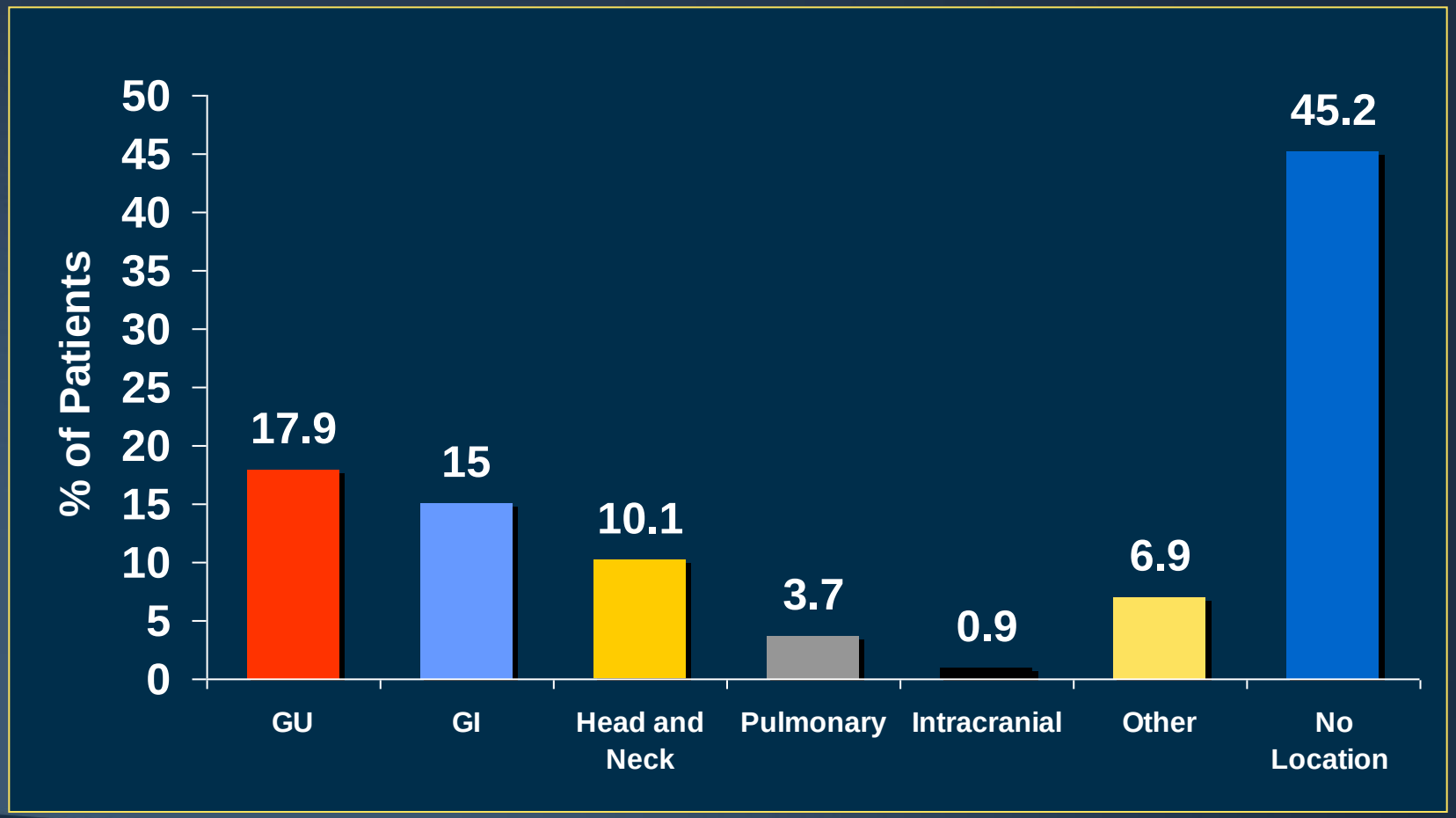
Risk for 1 year mortality

- Combined REPLACE-2, ACUITY, HORIZONS-AMI (n=17,393)
- 1-year mortality risk of *non-access* site bleeding vs *access* site = HR 2.27 (95%CI 1.42-3.64), p=0.0007



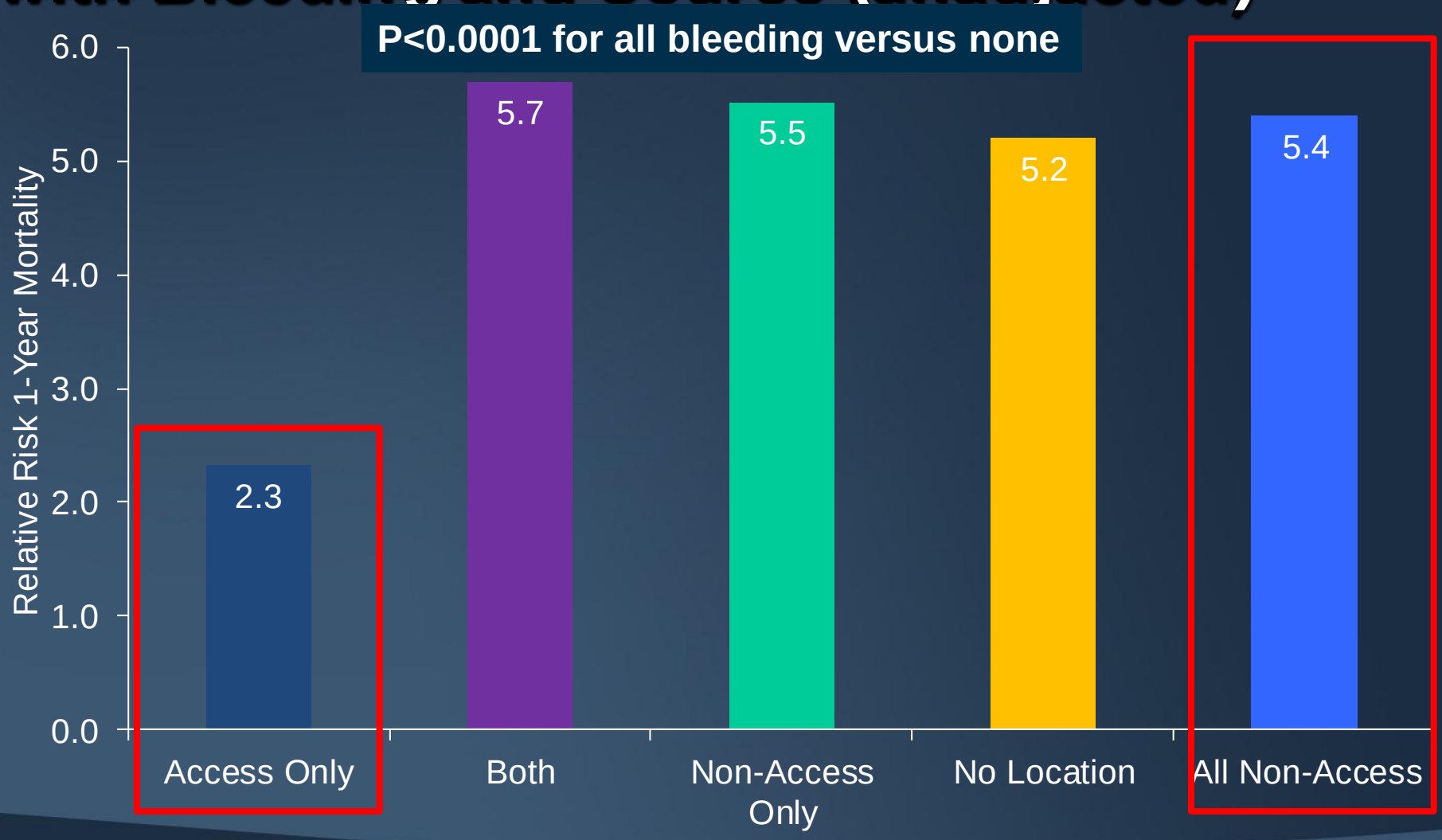
Verheugt *JACC Cardio Interv* 2011;4:191-7:

Incidence and source of bleeding excluding access site



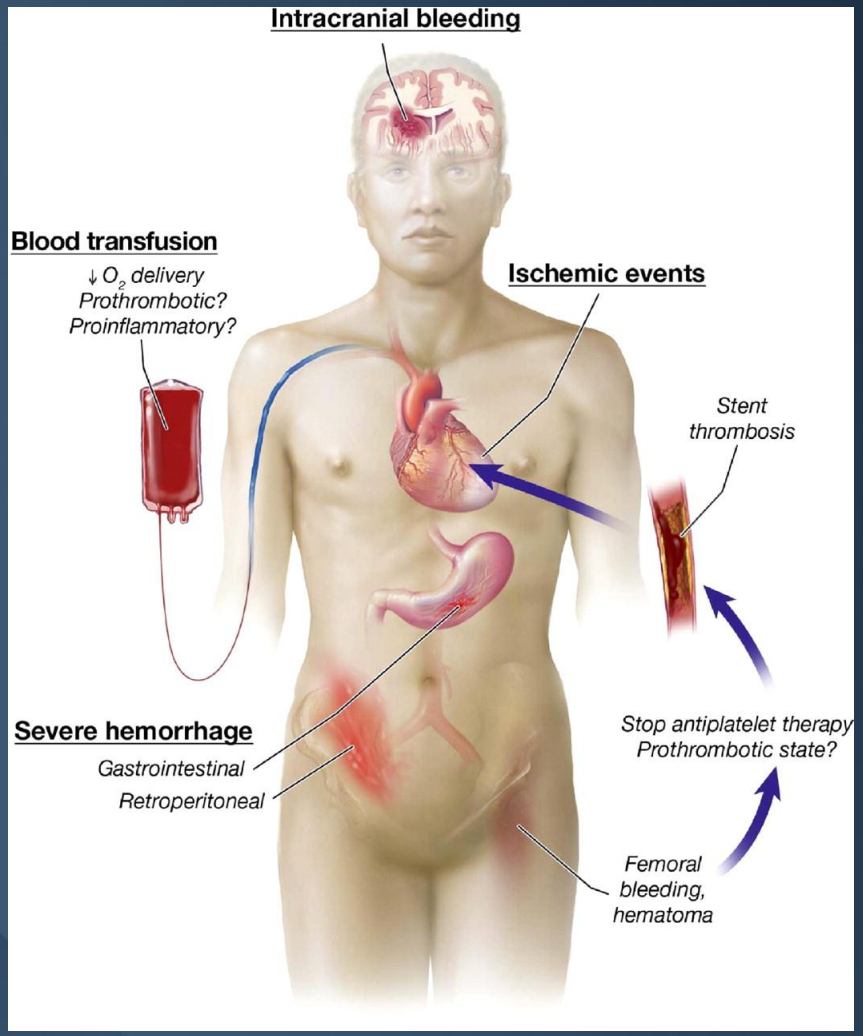
Verheugt *JACC Cardio Interv* 2011;4:191-7:

Relative Risk of 1-year Mortality Associated with Bleeding and Source (unadjusted)



Verheugt *JACC Cardio Interv* 2011;4:191-7:

Mechanisms Linking Bleeding With Increased Mortality

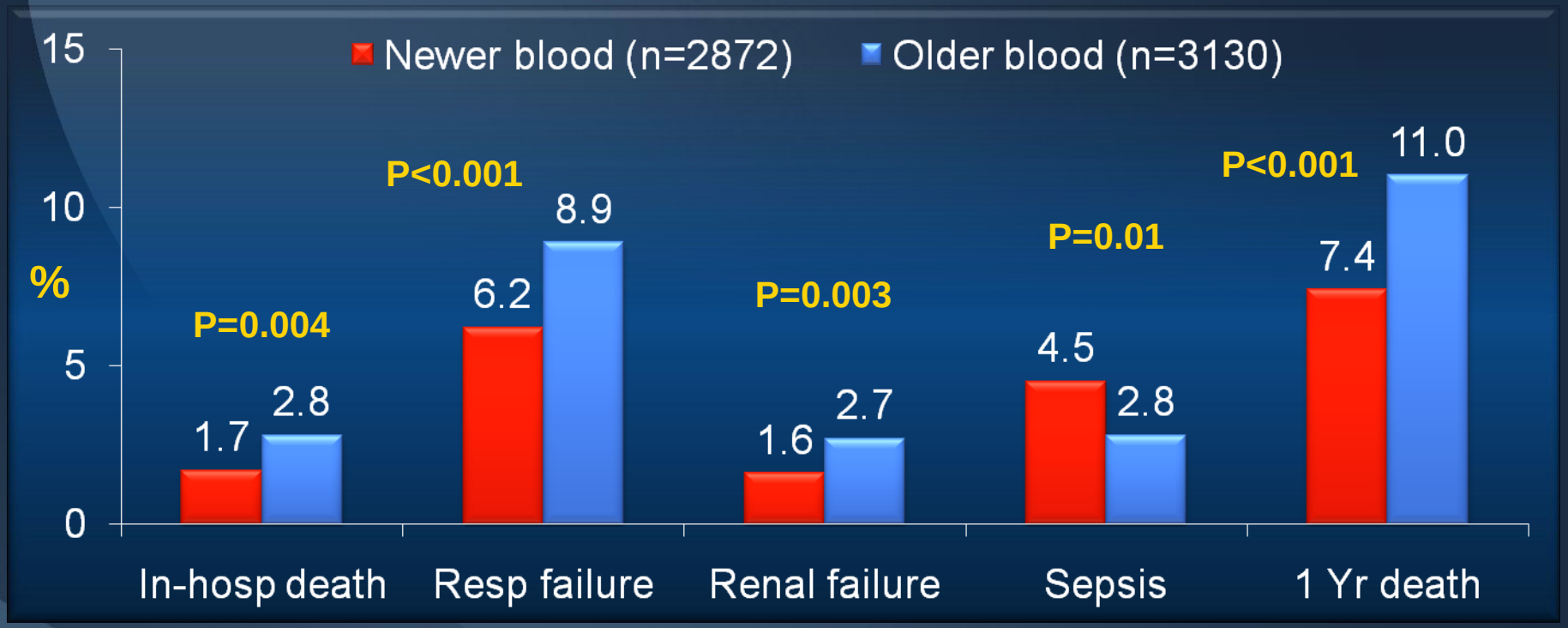


Doyle, B. J. et al. J Am Coll Cardiol 2009;53:2019-2027

Impact of the Age of PRBC Transfusion After Cardiac Surgery on Outcomes

Cleveland Clinic, June 30, 1998 – January 30, 2006

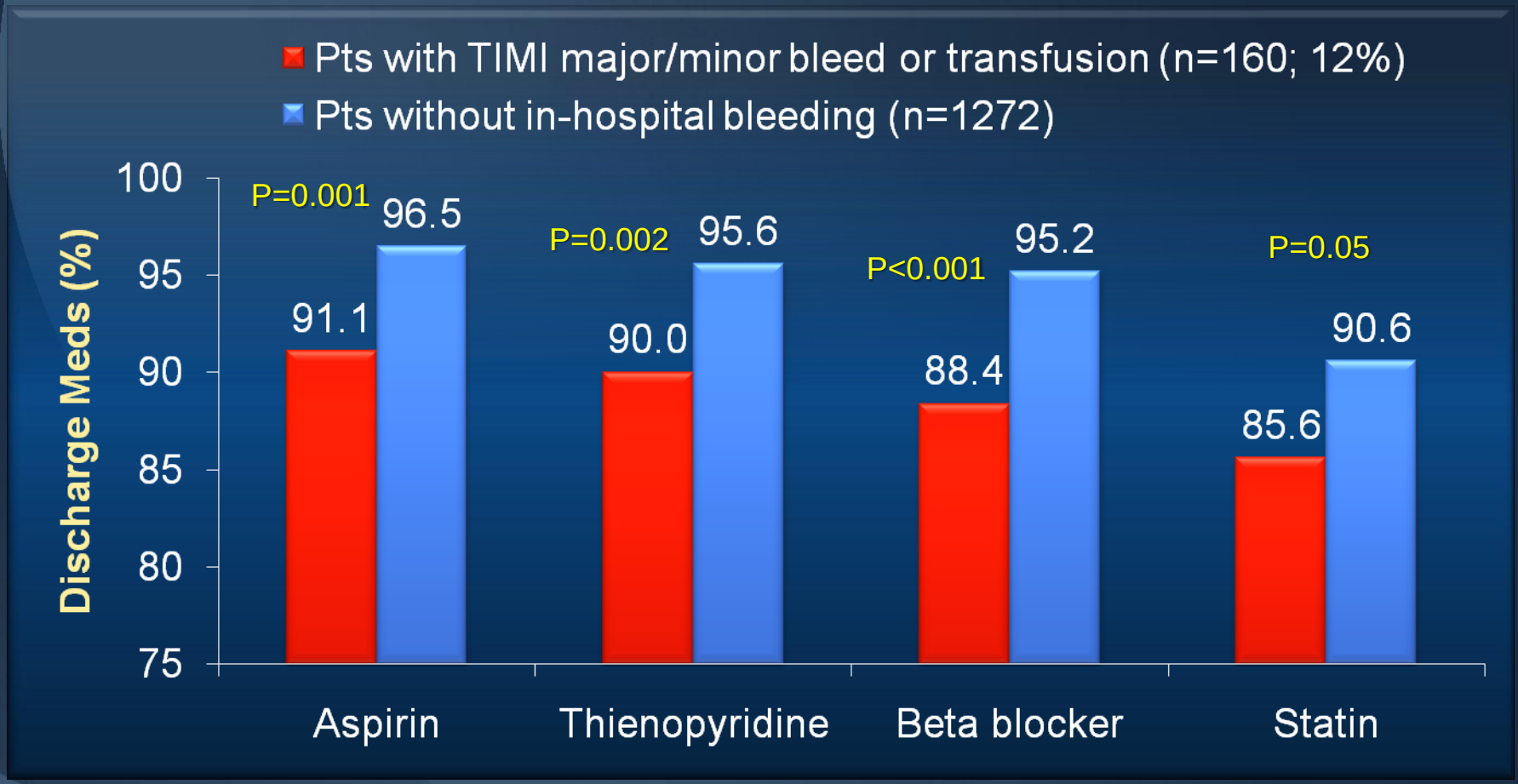
2,872 pts transfused with 8,872 U of blood stored ≤14 days (mean 11d; "newer blood") and 3,130 pts transfused with 10,782 U stored 15 days – 42 days (mean 20d; "older blood")



Koch CG et al. NEJM 2008;358:1229-1239

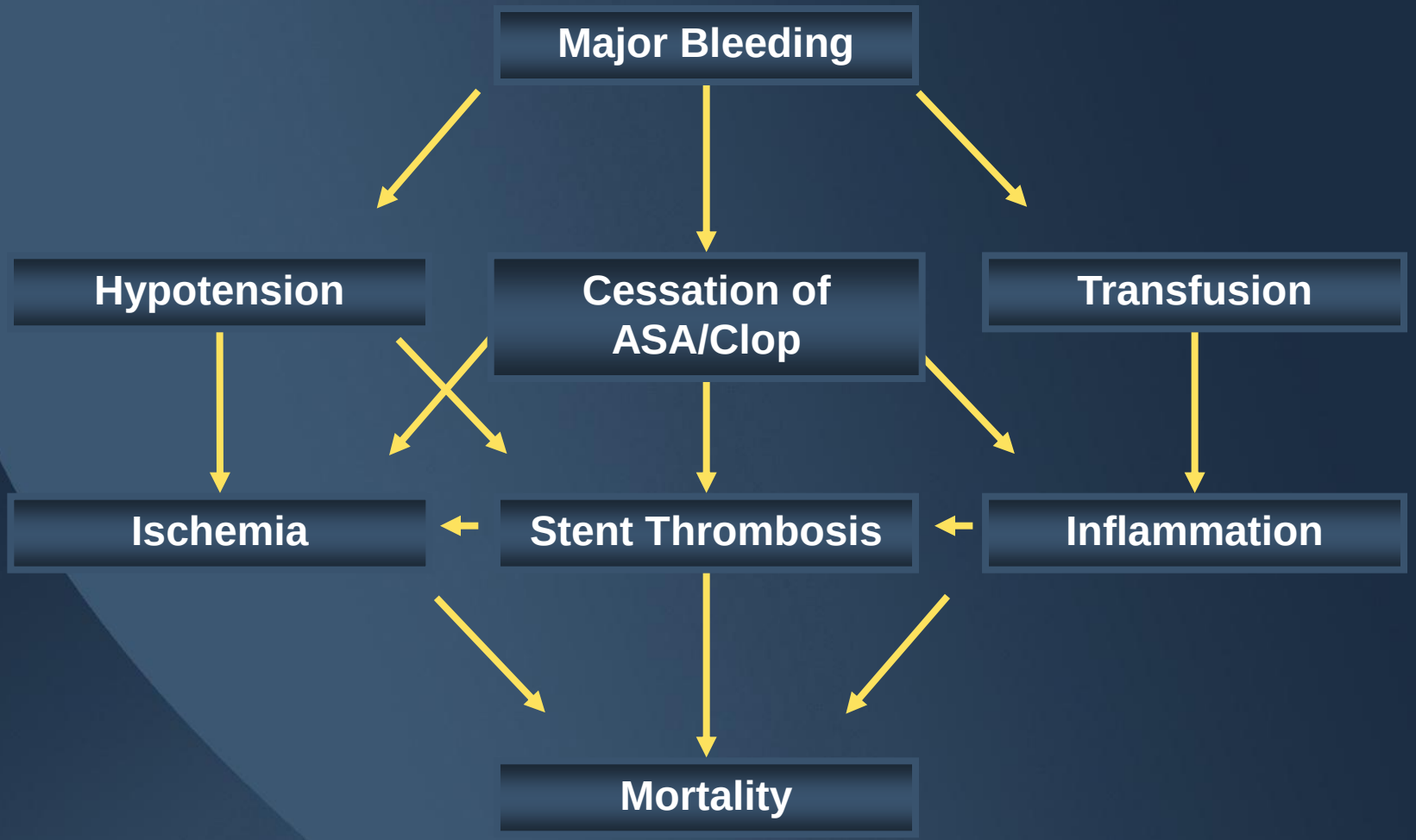
Discharge Medication Use in Patients who Bleed: PREMIER Registry (STEMI)

1433 STEMI pts treated with primary stenting



Wang TY et. al. Circulation 2008;118:2139-2145

Bleeding and Mortality



Bhatt DL. In Braunwald EB, Harrison's Online. 2005.

Reducing Bleeding Risk

Reducing Bleeding Risk: Preventive Actions

Patient level	Procedural level	Treatment level
• **Patient information (coughing, heavy lifting to be avoided after femoral puncture)** • **Nurse training for early recognition of retroperitoneal hemorrhage** • **Blood pressure control**	• **Perfect puncture site** • **Angiographic control before closure device use** • **Different access sites for staged procedures** • **Decrease size of arterial sheath** • Alternative access site (Radial)	• **ACT during procedures for heparin monitoring** • **Discontinuation of antithrombin after uncomplicated PCI** • **Anticoagulants (Bivalirudin, Fondaparinux)**

Hamon M. et al. EuroIntervention2007, www.angiosoft.net

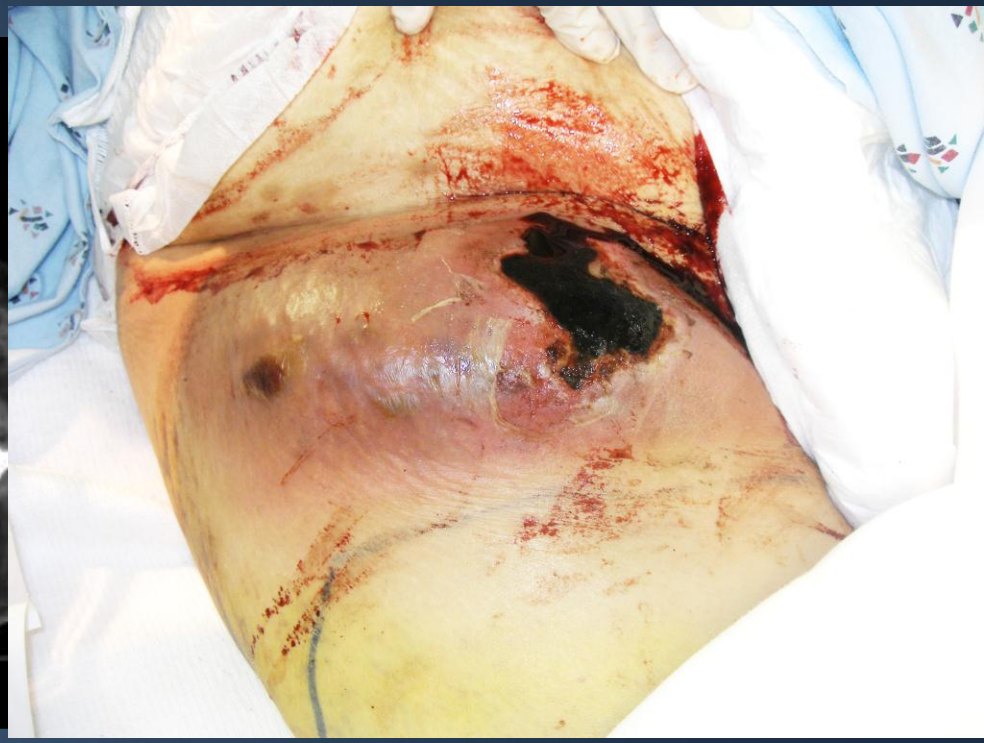
Transfemoral Advantages

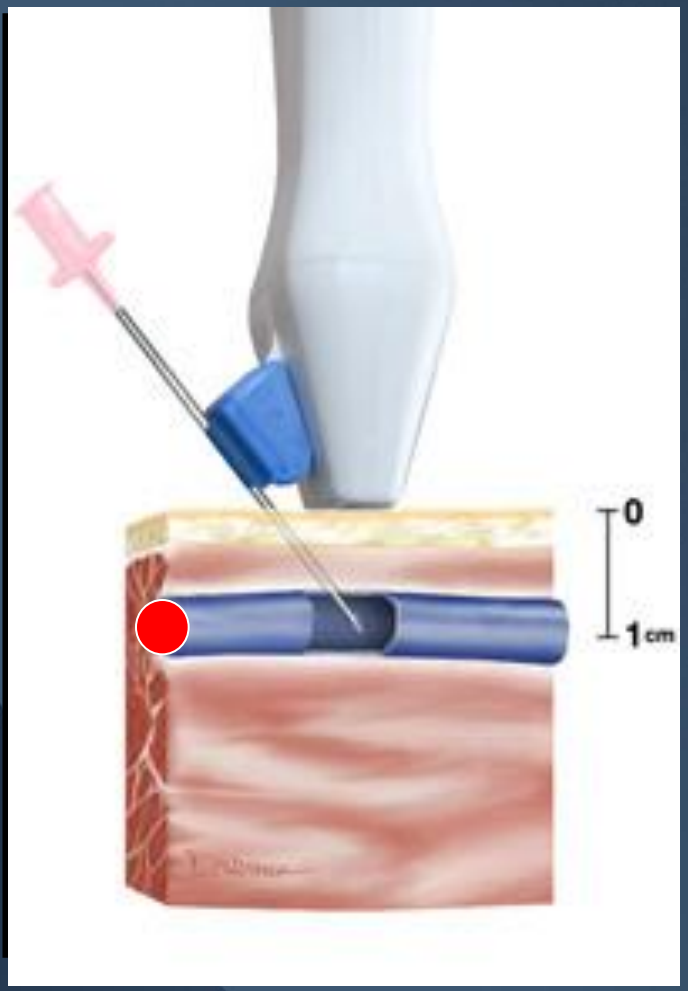
- Long history and technically easy to perform
- Facilitates the use of larger catheters
- Early sheath removal with using closure devices

Transfemoral Disadvantages

- Prolonged bedrest (usually about 4 hrs)
- Associated with more back pain, urinary retention, and neuropathy
- Bleeding (including retroperitoneal hemorrhage)
- Increased incidence of other vascular complications
- Vascular closure devices allows earlier ambulation but do not decrease vascular complications

Vascular Access

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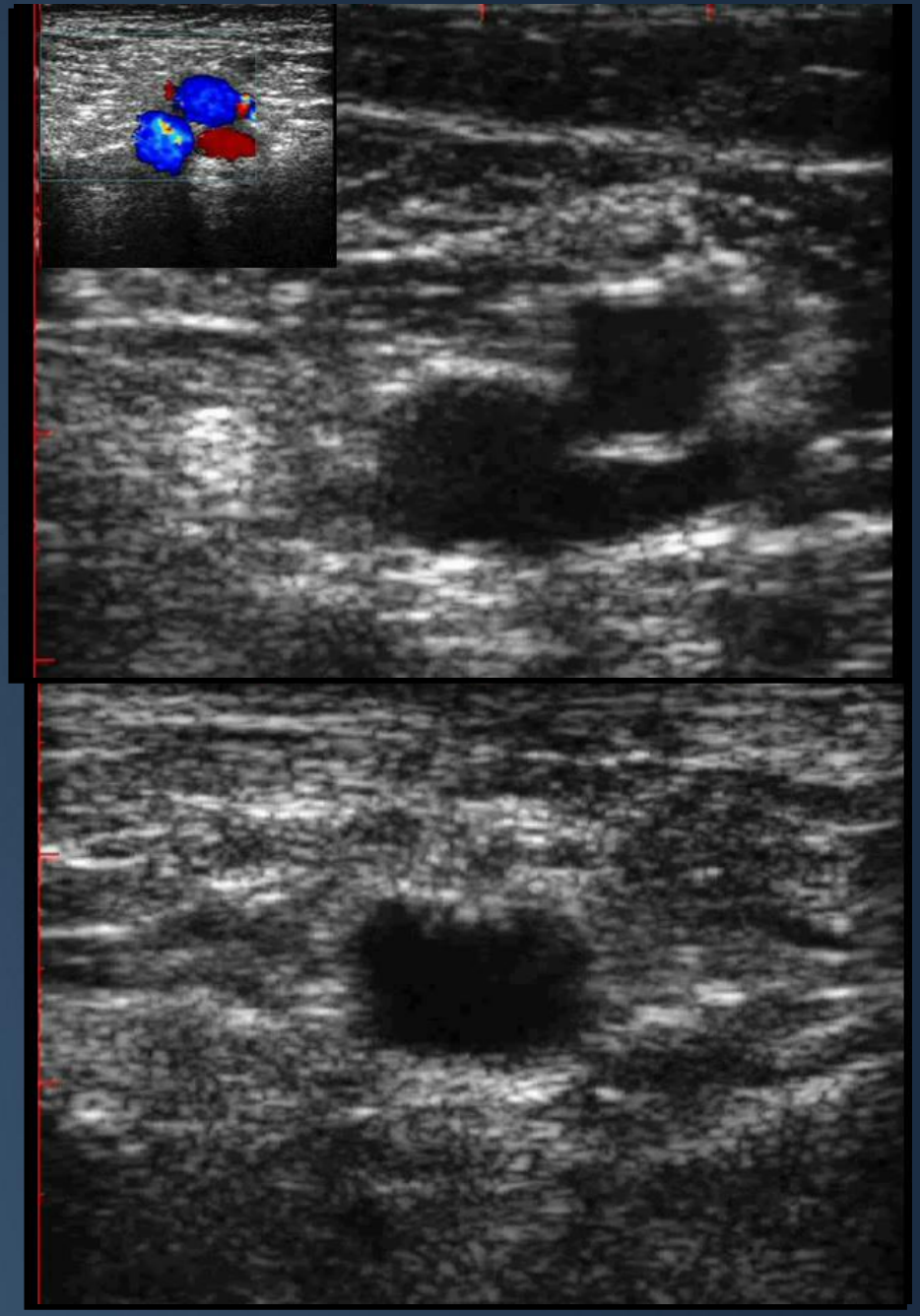
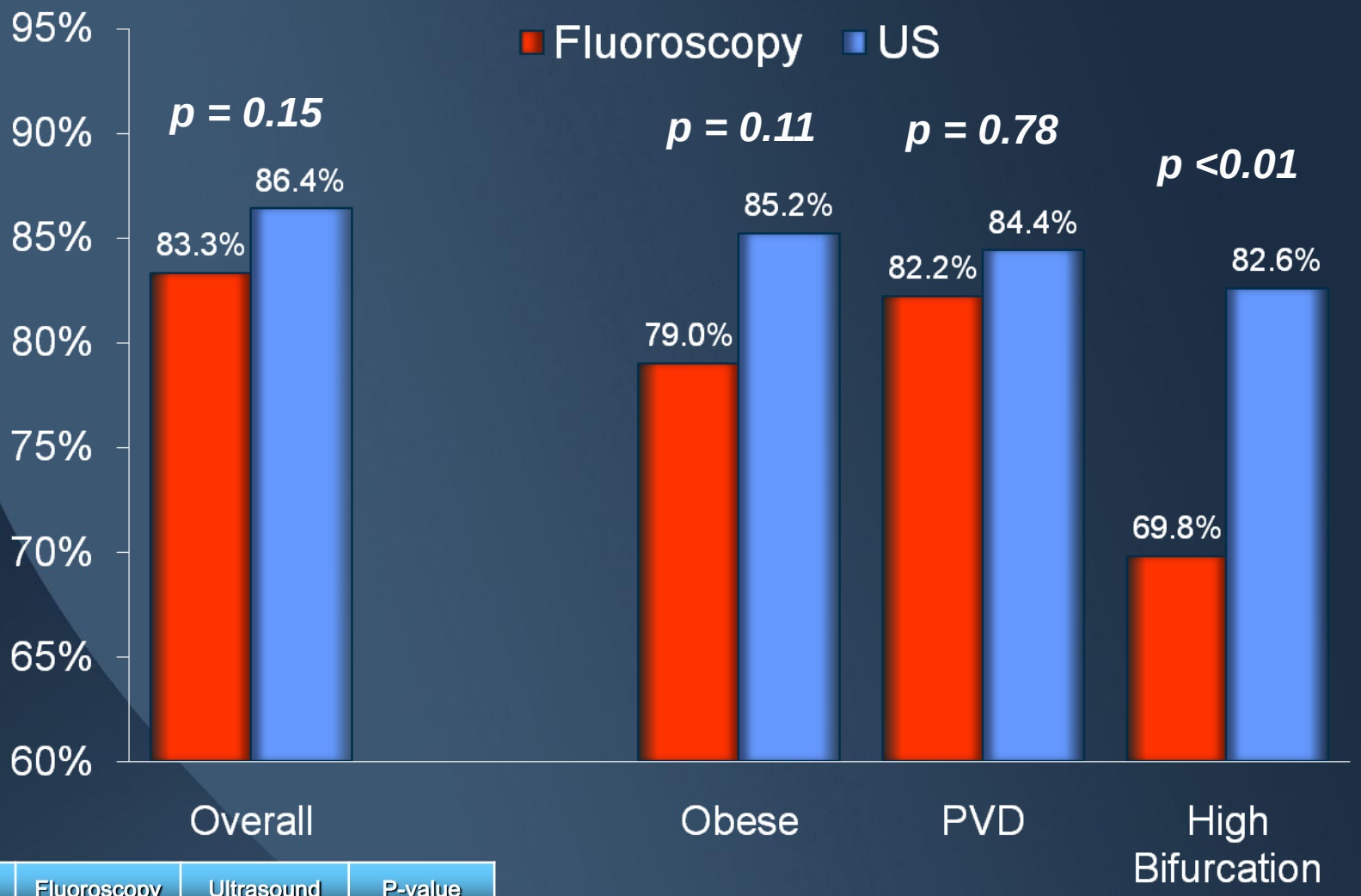
1 cm



FAUST Trial: CFA Cannulation Success



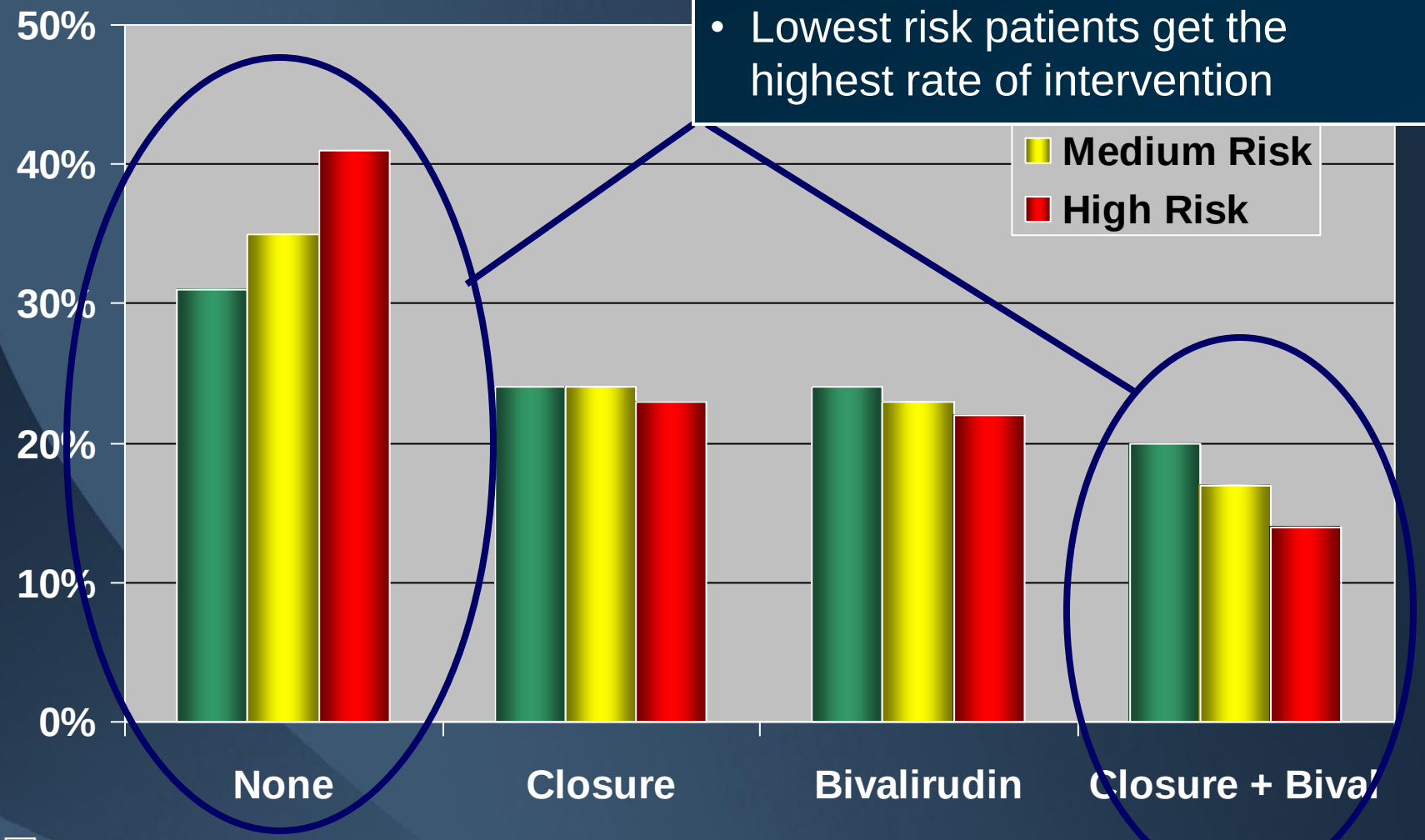
	Fluoroscopy	Ultrasound	P-value
High stick	24 (4.9)	33 (6.6)	0.25
CFA	408 (83.3)	431 (86.4)	0.15
Low stick	58 (11.8)	35 (7.0)	<0.01

Seto A et al. JACC Intv. 2010;3;751-758

Bleeding Avoidance Rx

Risk-Treatment Paradox

- Highest risk patients get the lowest rate of intervention
- Lowest risk patients get the highest rate of intervention



N=1,522,935

Marso et al. *JAMA* 2010; 303: 2156-2164

Bleeding in PCI patients

- **Analysis of 10,974 "real world" patients at 3 centers**

TIMI Major	588 (5.4%)
–Hemorrhagic strokes	15
–Gastrointestinal	63
–Retroperitoneal	30
–Hematoma	370
TIMI minor	1394 (12.7%)
–Gastrointestinal	88
–Retroperitoneal	11
–Hematoma	823
Transfusion	(5.4%)
None	8992 (81.9%)

68%

60%

"Radial Opportunity"

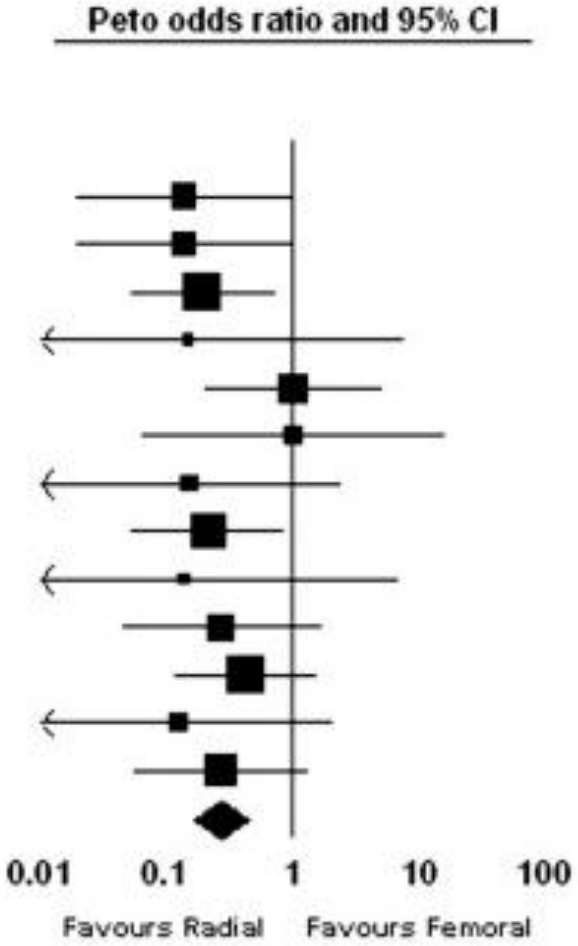
Kinnaird et al. Am J Cardiol 2003

Radial vs. Femoral Meta-Analysis

Major Bleeding

23 Trials, n=7,020 – 1980 to 2008

Study name	Radial	Femoral	Peto odds ratio
ACCESS	0 / 300	4 / 300	0.13
Achenbach	0 / 152	4 / 155	0.14
Bodi	3 / 666	7 / 332	0.19
BRAFE	0 / 50	1 / 55	0.15
FARMI	3 / 57	3 / 57	1.00
Gorge	1 / 214	1 / 216	1.01
Mann 1998	0 / 68	2 / 77	0.15
OCTOPLUS	1 / 192	7 / 185	0.21
OUTCLAS	0 / 322	1 / 322	0.14
RADIAL AMI	1 / 25	4 / 25	0.27
RADIAMI	3 / 50	7 / 50	0.41
TEMPURA	0 / 77	2 / 72	0.12
Vazquez-Rodriguez	1 / 217	5 / 222	0.27
	13 / 2390	48 / 2068	0.27



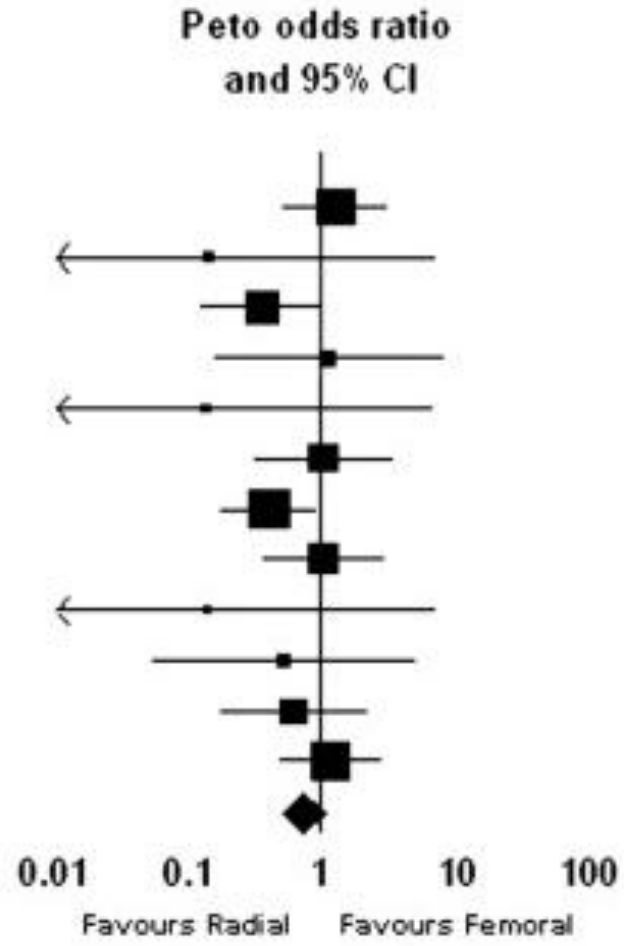
OR 0.27 (95% CI 0.16, 0.45) $P < .001$

Fatal, ICH, or ≥3 g/dL hgb drop, or transfusion, or requiring surgery

Jolly SS et al. Am Heart J 2009;157:132-40

Radial vs. Femoral Meta-Analysis
Death, MI, or Stroke

Study name	Radial	Femoral	Peto odds ratio
ACCESS	11 / 300	9 / 300	1.23
Achenbach	0 / 152	1 / 155	0.14
Bodi	7 / 666	9 / 332	0.35
BRAFE	2 / 50	2 / 55	1.10
Cooper	0 / 101	1 / 99	0.13
FARMI	6 / 57	6 / 57	1.00
OCTOPLUS	7 / 192	17 / 185	0.40
OUTCLAS**	7 / 322	7 / 322	1.00
RADIAL AMI	0 / 25	1 / 25	0.14
RADIAMI	1 / 50	2 / 50	0.51
TEMPURA*	4 / 77	6 / 72	0.61
Vazquez-Rodriguez	11 / 217	10 / 222	1.13
	56 / 2209	71 / 1874	0.71



OR 0.71 (95% CI 0.49, 1.01) $P = .058$

23 Trials, n=7,020 – 1980 to 2008

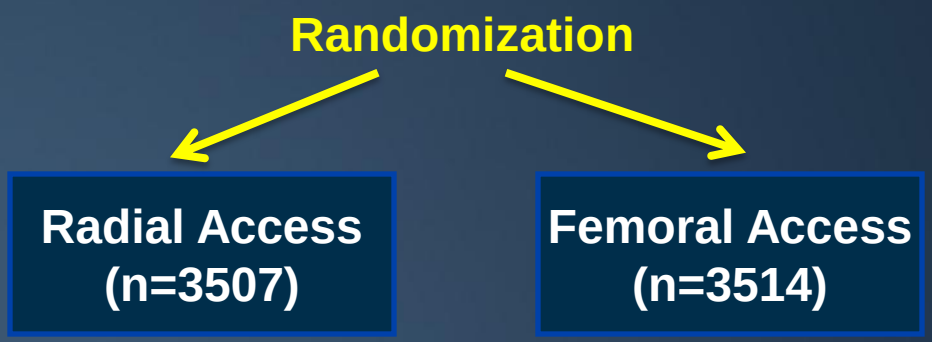
Jolly SS et al. Am Heart J 2009;157:132-40

RIVAL Study Design

NSTE-ACS and STEMI (n=7021)

Key Inclusion:

- Intact dual circulation of hand required
- Interventionalist experienced with both (minimum 50 radial procedures in last year)



Blinded Adjudication of Outcomes

Primary Outcome: Death, MI, stroke or non-CABG-related Major Bleeding at 30 days

Jolly SS et al. Am Heart J. 2011;161:254-60.

Primary and Secondary Outcomes

	Radial (n=3507) %	Femoral (n=3514) %	HR	95% CI	P
Primary Outcome					
Death, MI, Stroke, Non-CABG Major Bleed	3.7	4.0	0.92	0.72-1.17	0.50
Secondary Outcomes					
Death, MI, Stroke	3.2	3.2	0.98	0.77-1.28	0.90
Non-CABG Major Bleeding	0.7	0.9	0.73	0.43-1.23	0.23

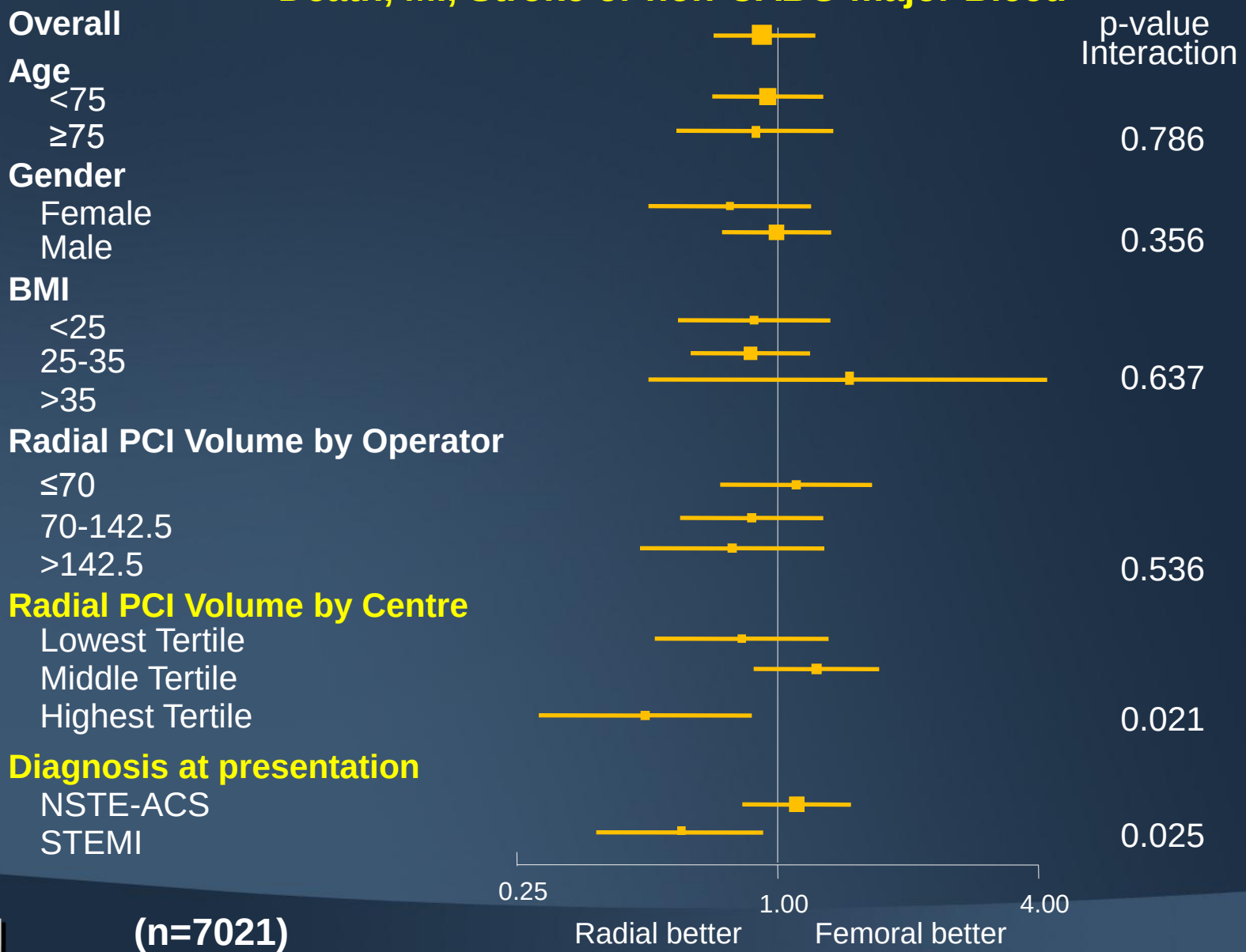
Other Outcomes

	Radial (n=3507) %	Femoral (n=3514) %	HR	95% CI	P
Major Vascular Access Site Complications	1.4	3.7	0.37	0.27-0.52	<0.0001
Other Definitions of Major Bleeding					
TIMI Non-CABG Major Bleeding	0.5	0.5	1.00	0.53-1.89	1.00
ACUITY Non-CABG Major Bleeding*	1.9	4.5	0.43	0.32-0.57	<0.0001

* Post Hoc analysis

RIVAL Subgroups: Primary Outcome

Death, MI, Stroke or non-CABG major Bleed



(n=7021)

Jolly et al. Lancet 2011

Economics of Radial Access

- **Vascular complication**
  - Prolonged hospital stay (~ 3 days)
  - Incremental cost: $6,400
- **Bleeding complication (Incremental cost)**
  - GUSTO IIb
    - **Mild/severe bleed** **$3,770**
    - **Transfusion** **$2,080**
  - REPLACE-2
    - **Major bleed** **$6,300**
- **Diagnostic Cath**
  - Saves $290 per case
    - **Driven by lower nursing utilization and pharmacy costs**
- **Nursing Workload**
  - Femoral: 174 [134–218] min
  - Radial: 86 [58–126] min, (p <0.001)

Kugelmass AD et al. Am J Cardiol 2006;97:322-7
Rao SV et al. Am Heart J 2008;155:369-74
Cohen DJ, et al. J Am Coll Cardiol 2004;44:1792-800
Cooper CJ et al. Am Heart J 1999;138:430-6
Amoroso G et al. Eur J Cardiovasc Nurs 2005;4:234-41

Why Radial? The Disadvantages

- **Catheter manipulation needed for coronary cannulation**
- **Learning curve ~ 100 cases**
- **Failure to reach the ascending aorta**
  - Vascular anomalies
  - Elderly hypertensive patients may have increased tortuosity of the radial and subclavian arteries
- **Limited compatibility with larger (>2.0mm) Rotablator burrs or other large devices**

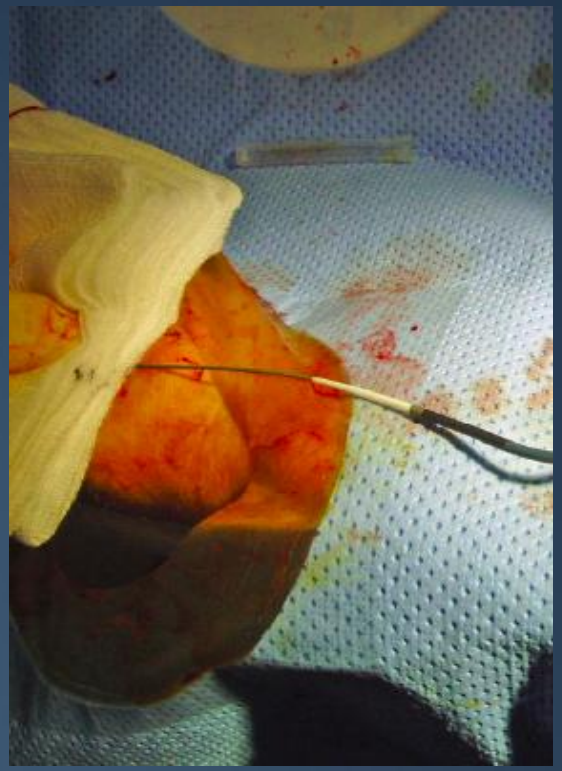
Learning Curve

	<80 Patients	>80 Patients
Access failure	14%	2%
Sheath insertion time	10.2 ± 7.6 min	2.8 ± 2.5 min
Procedure time	25.7 ± 12.9 min	17.4 ± 4.7 min

Spaulding et al. Cathet Cardiovasc Diagn 39:365-70, 1996

New Guiding Catheter Technologies

7.5 Fr Sheathless Hydrophilic Guiding Catheter
Smaller outer diameter than 6Fr sheath



Catheter external diameter: 2.49mm
6F Sheath external diameter: 2.62 mm

Mamas MA et al, CCI 2008;72:357–364

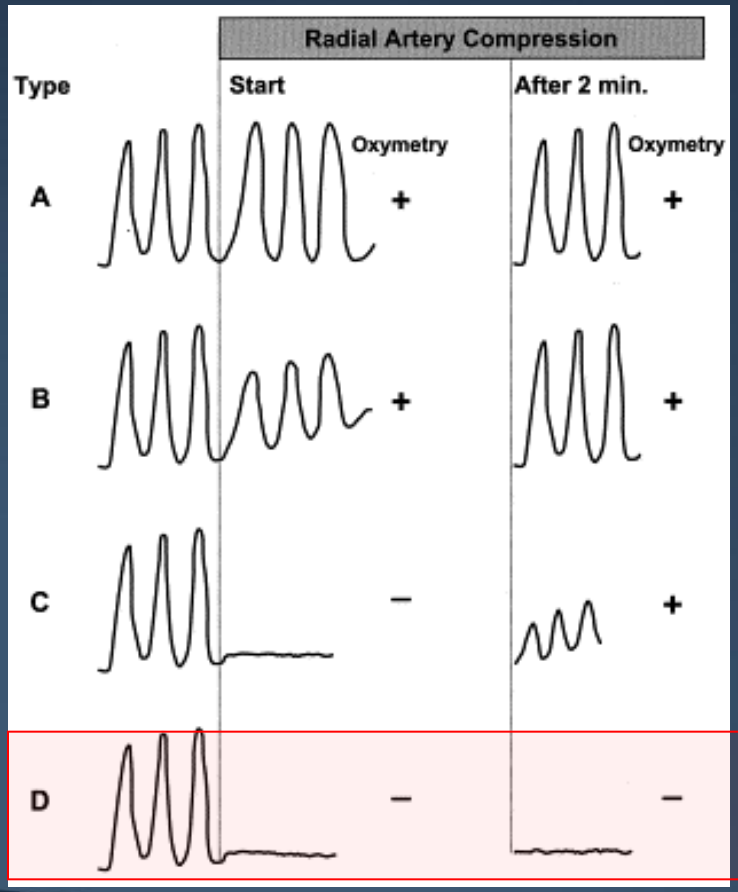
Contraindications?

- **Abnormal Allen test????**
  - However, it is now questioned by some operators
    - **No reports of hand ischemia/necrosis in more than 20 years**
    - **Most reports from critical care and anesthesiology literature**
    - **Harvesting radial arteries for CABG is safe**
- **Need for right heart catheterization is not an excuse for not using the radial approach**
  - RHC can be performed via the antecubital vein (using a 5F 110 cm balloon-tipped catheter)
- **Raynaud's Syndrome, Dialysis**

Oxymetry + Plethysmography

Oxymetry + Plethysmography

The clamp sensor is applied to the thumb



No damping of pulse tracing immediately after radial artery compression	15%
Damping of pulse tracing	75%
Loss of pulse tracing followed by recovery of pulse tracing within 2 minutes	5%
Loss of pulse tracing without recovery within 2 minutes.	5%

Barbeau et al. Am Heart J 2004;147:489–93

Rules
Radial is Different than Femoral

- **Precise puncture & never push (finesse over muscle)**
- **Prophylactic antispasm medication is needed**
  - Verapamil 3 mg
- **Anticoagulate to prevent (reduce) thrombosis**
  - Heparin 5000 U (80 U/Kg in lighter patients)
- **Hold on to hard won territory (exchange wire or jet-catheter exchange technique)**
- **Find a catheter series that works for you (practice makes perfect)**
- **Remove the sheath at the end of the case**

Cath Lab Digest
www.cathlabdigest.com
A Product, News and Clinical Update for the Cardiac Catheterization Laboratory Specialist

Transradial Access at the University of Miami

Cath Lab Digest talks with Mauricio G. Cohen, MD, FACC, Director of the Cardiac Catheterization Laboratory, Joey Collazo, RCIS, Chief Technologist, Cardiac Cath Lab, and Kymberlee Manni, RCIS, PhD, Associate Vice President Cardiovascular Service Line Administrator University of Miami Hospital, the flagship facility of UHealth – University of Miami Health System, Miami, Florida

Dr. Cohen, medical director of the cardiac cath lab, Anne Lee, director of the cardiac cath lab, and Joey Collazo, chief technologist.

Dr. Mauricio Cohen has been performing transradial access procedures for approximately 5 years. After joining the University of Miami Hospital cath lab in January of 2009 as director, he instituted a transradial program.

What's your sense of how transradial access is utilized in Argentina?

I believe it is used slightly more than in the U.S., but not quite as much as in high-use countries like France, Canada, Spain or Sweden.

How often do you use transradial

include the presence of an occluded radial artery, usually secondary to a previous procedure; lack of radial pulse; hemodialysis with an arteriovenous (AV) fistula in the forearm, and an abnormal Allen's test. It is worth

if we are unsuccessful, we will use a femoral approach.

How often do you find that you are converting to femoral access after beginning with a radial approach?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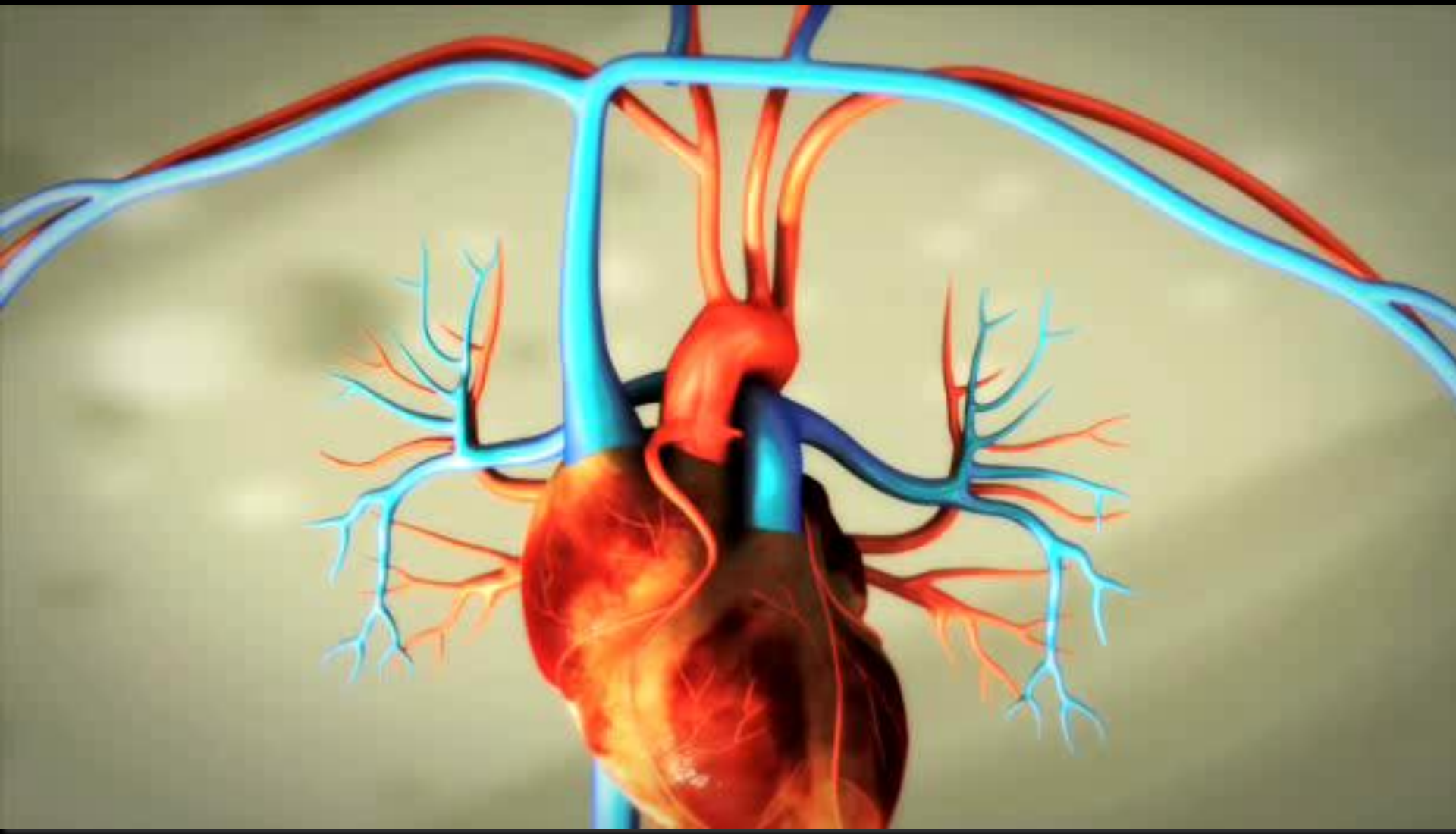
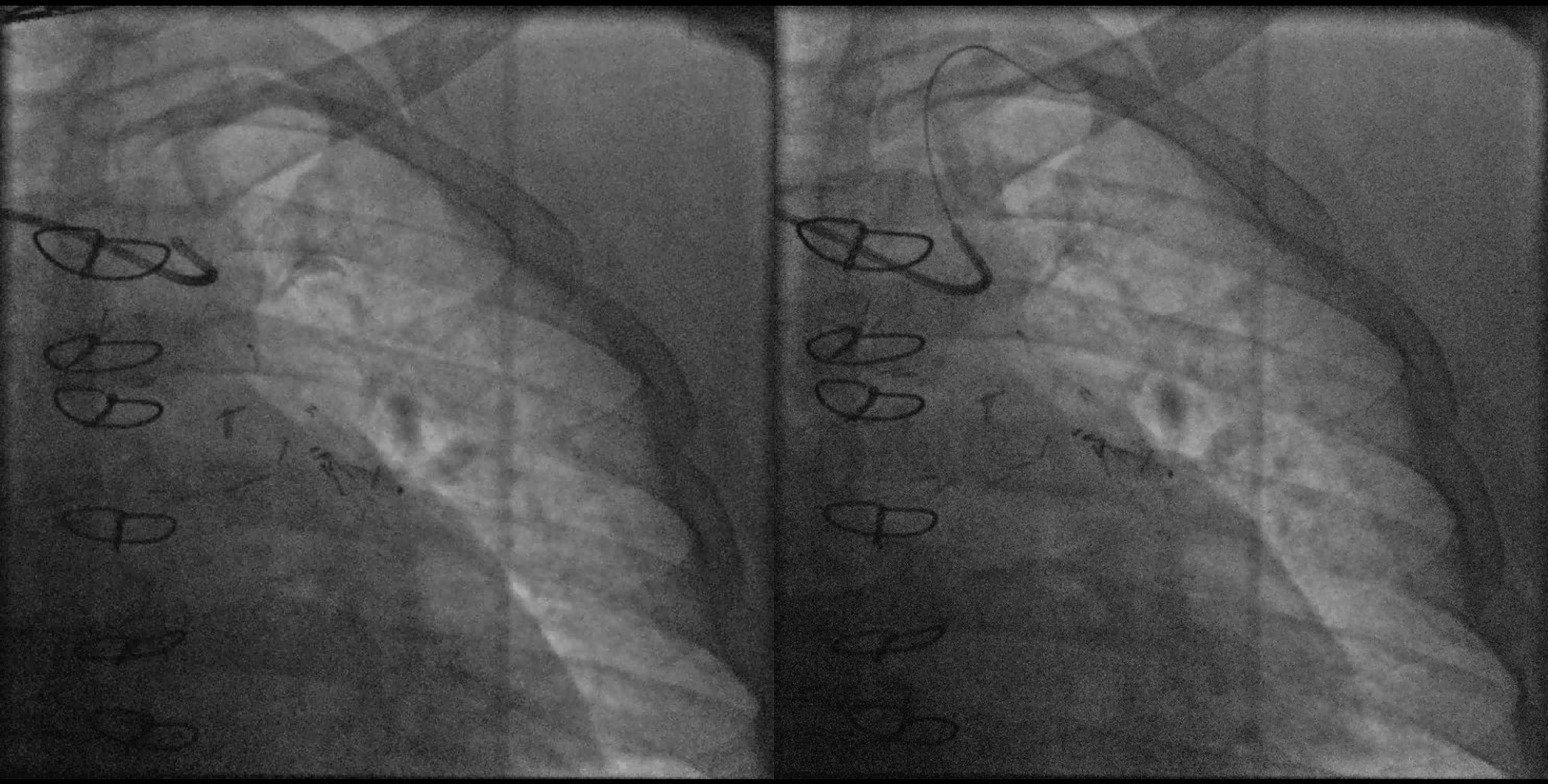


Challenges: Double Mammary Case



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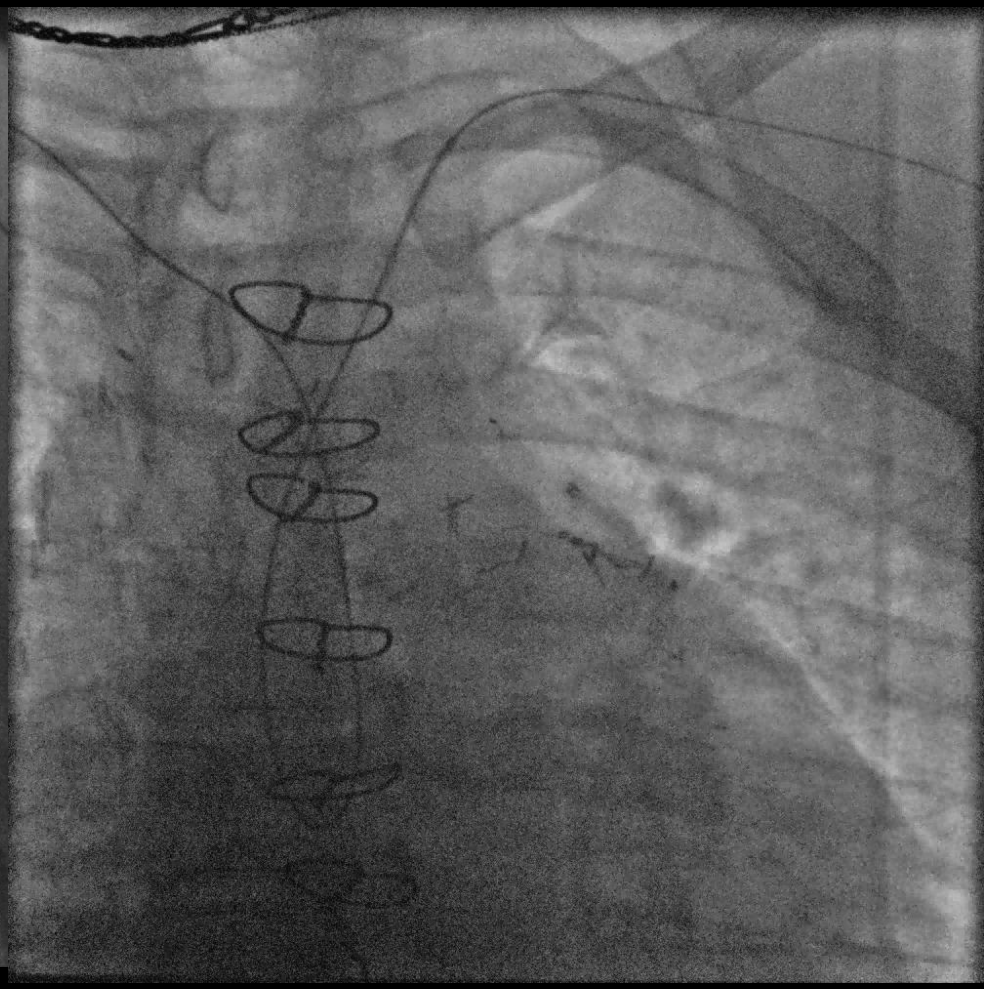

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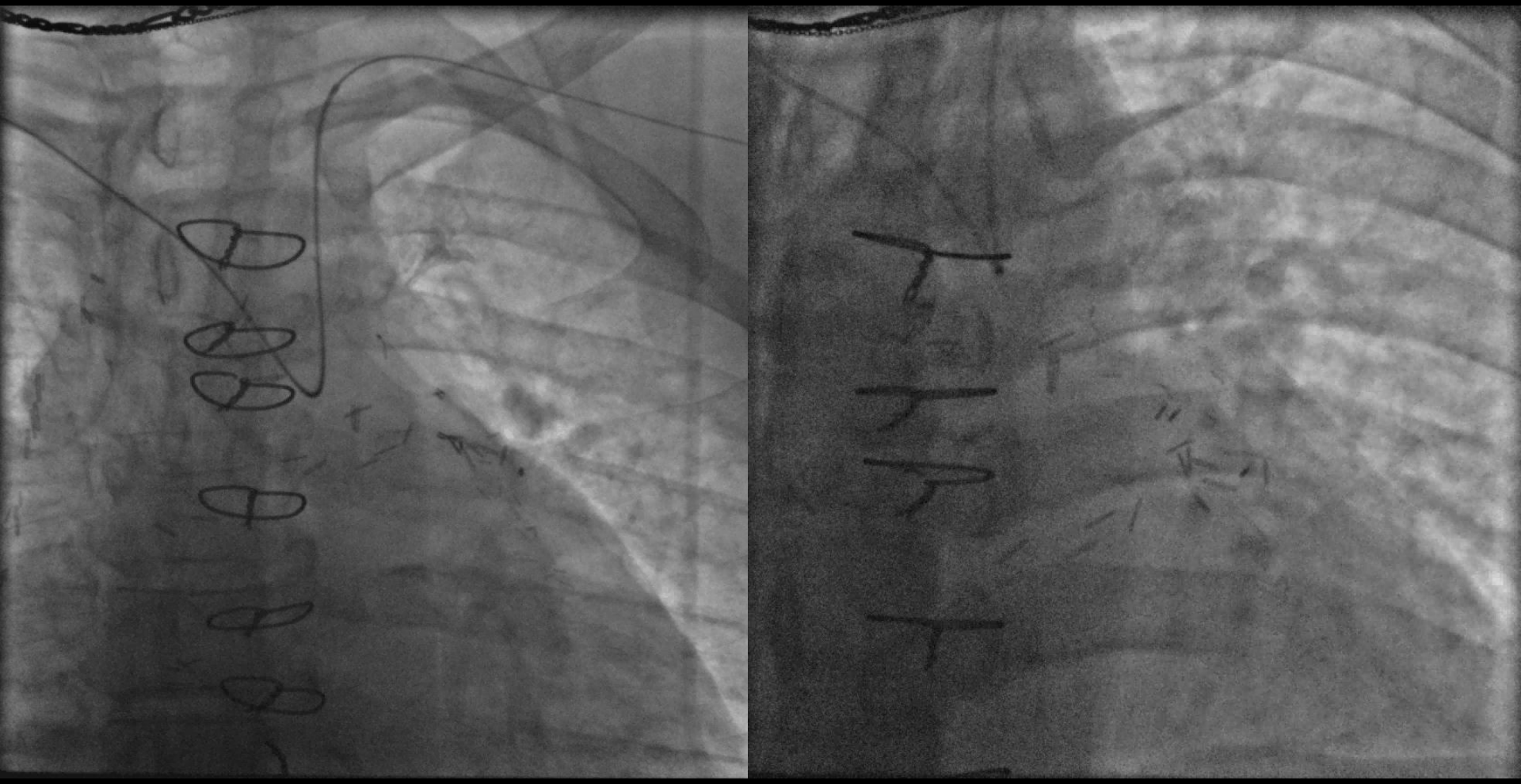

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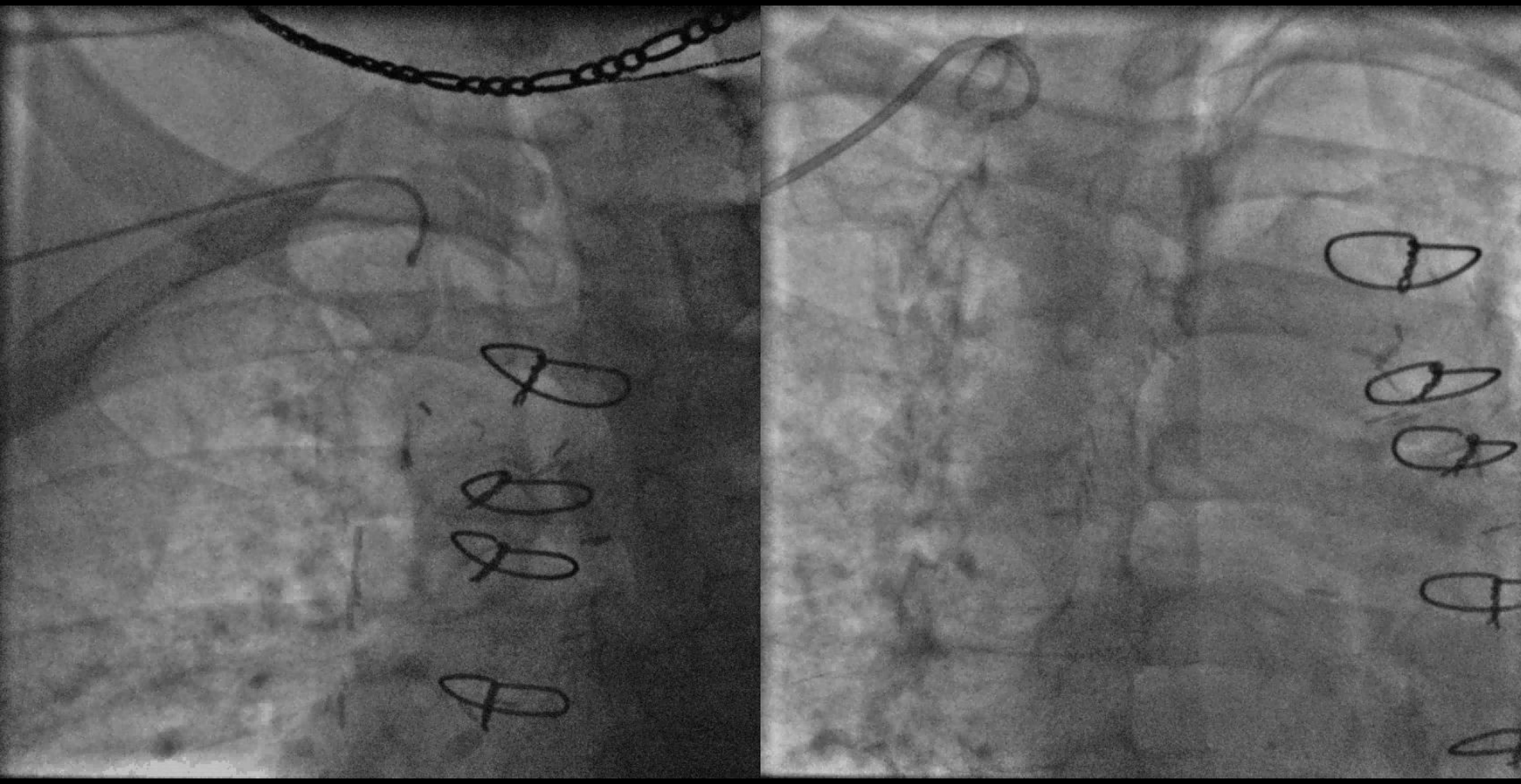


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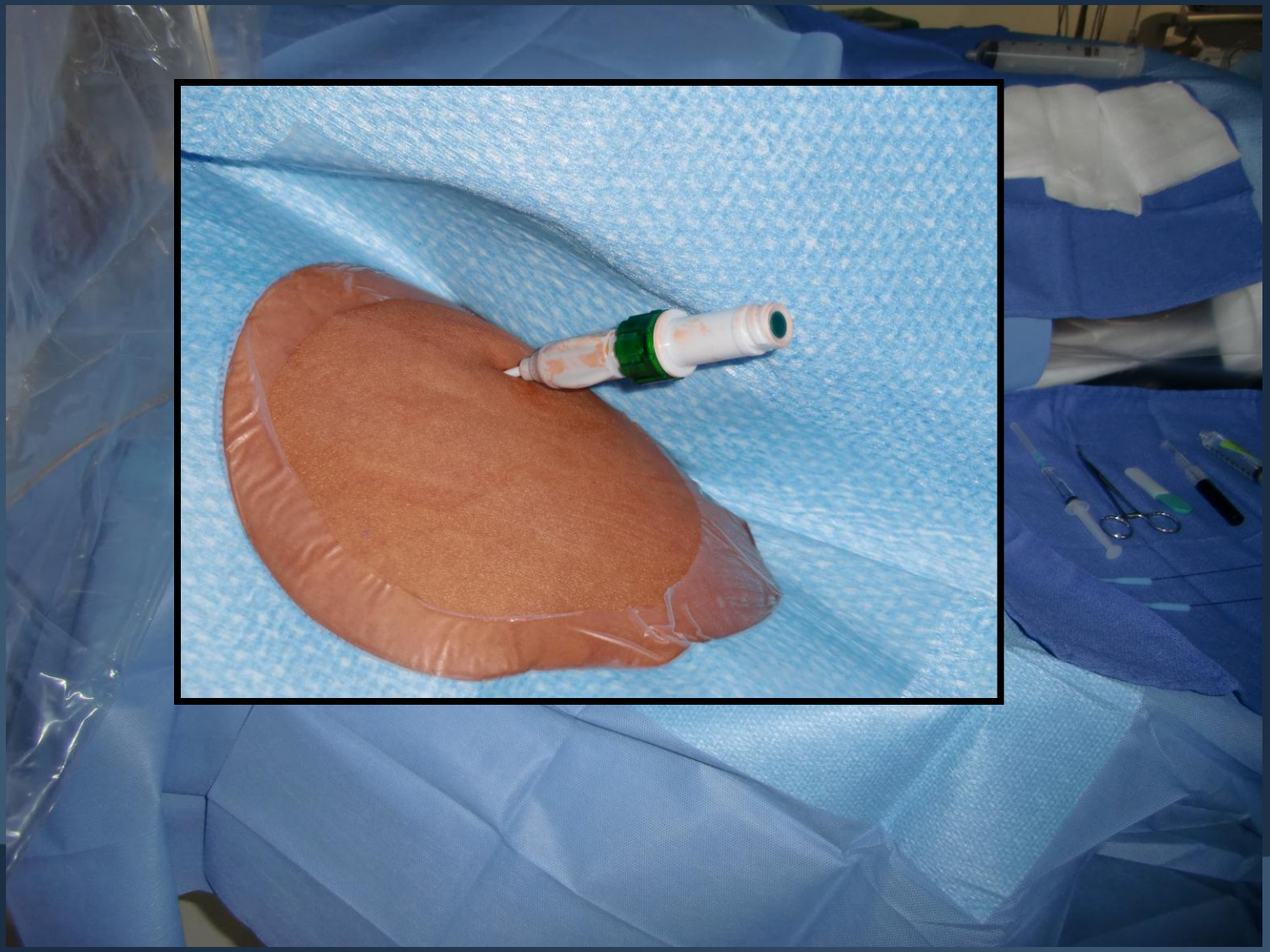
Right Heart Catheterization via Antecubital Vein



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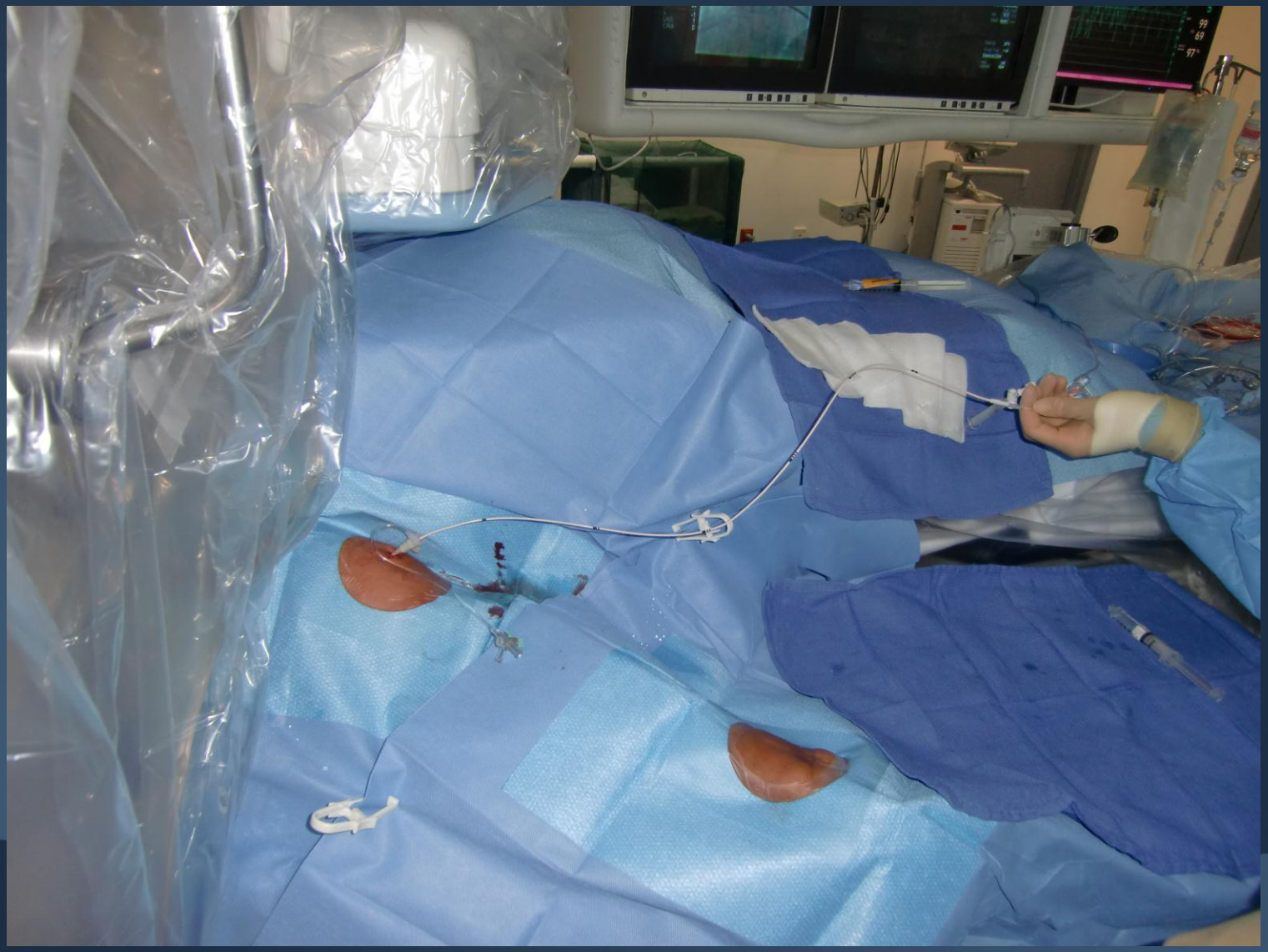

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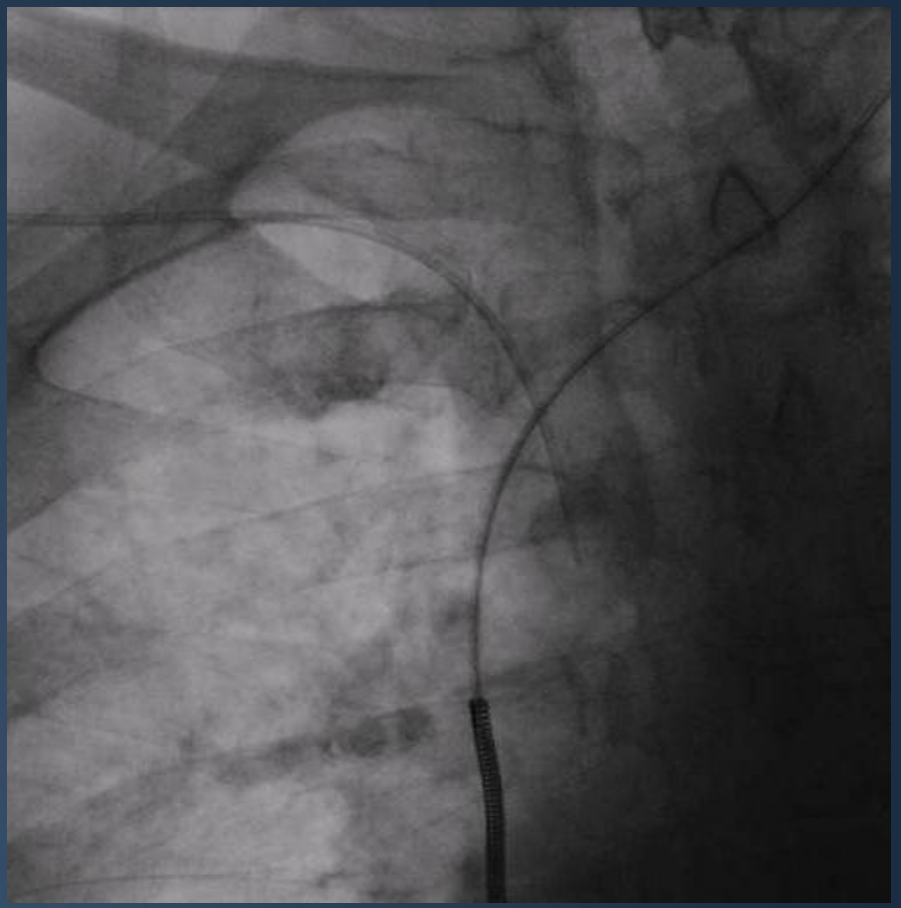

Conclusion

- **Bleeding is associated with worse outcomes**
  - Optimization of femoral access
  - Transradial access
- **Choice of anticoagulant**
  - Improve balance between bleeding and ischemia