STEMI-RADIAL

A Prospective Randomized Trial of Radial vs. Femoral Access in Patients with ST-Segment Elevation Myocardial Infarction

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(ClinicalTrials.gov. NCT 00136187)

Disclosure Statement of Financial Interest

I, Ivo Bernat DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

RIVAL *versus* RIFLE-STEACS

Characteristics	RIVAL (STEMI) n=1958	RIFLE-STEACS n=1001
Sites	158	4
Substudy	RIVAL / OASIS 7	no
Primary PCI	74%	92%
Fibrinolytics	12%	7.6%
GPI IIb/IIIa	1/3	2/3
Shock patients	no	yes
Radial experience	variable	large
Cross-over	7.6%	9.6%
IABP	1%	8.0%

Jolly et al. *Lancet* 2011;377:1409-20 Romagnoli et al. *JACC* 2012 online

STEMI-RADIAL - objectives

To compare radial *vs* femoral approach in

primary PCI for patients with STEMI < 12 hours

in very high volume radial centers

> 80% radial primary PCI

STEMI-RADIAL - sample size

- **Superiority of radial approach compared to femoral in terms of major bleeding and access site complication**

- **The trial has 80% power to detect 70% relative reduction in major bleeding and access site complications with radial approach compared to femoral approach with an alpha level of 0.05 assuming a reference rate of 6.5%.**

STEMI-RADIAL end-points

- **Primary**
  - **HORIZONS-AMI bleeding and access site complication ***
- **Secondary**
  - **MACE (death, MI, stroke)**
  - **NACE**
  - crossover
  - angiographic success
  - contrast volume
  - procedural and fluoroscopic times
  - ICU stay

* Hematoma ≥15cm

STEMI-RADIAL - study criteria

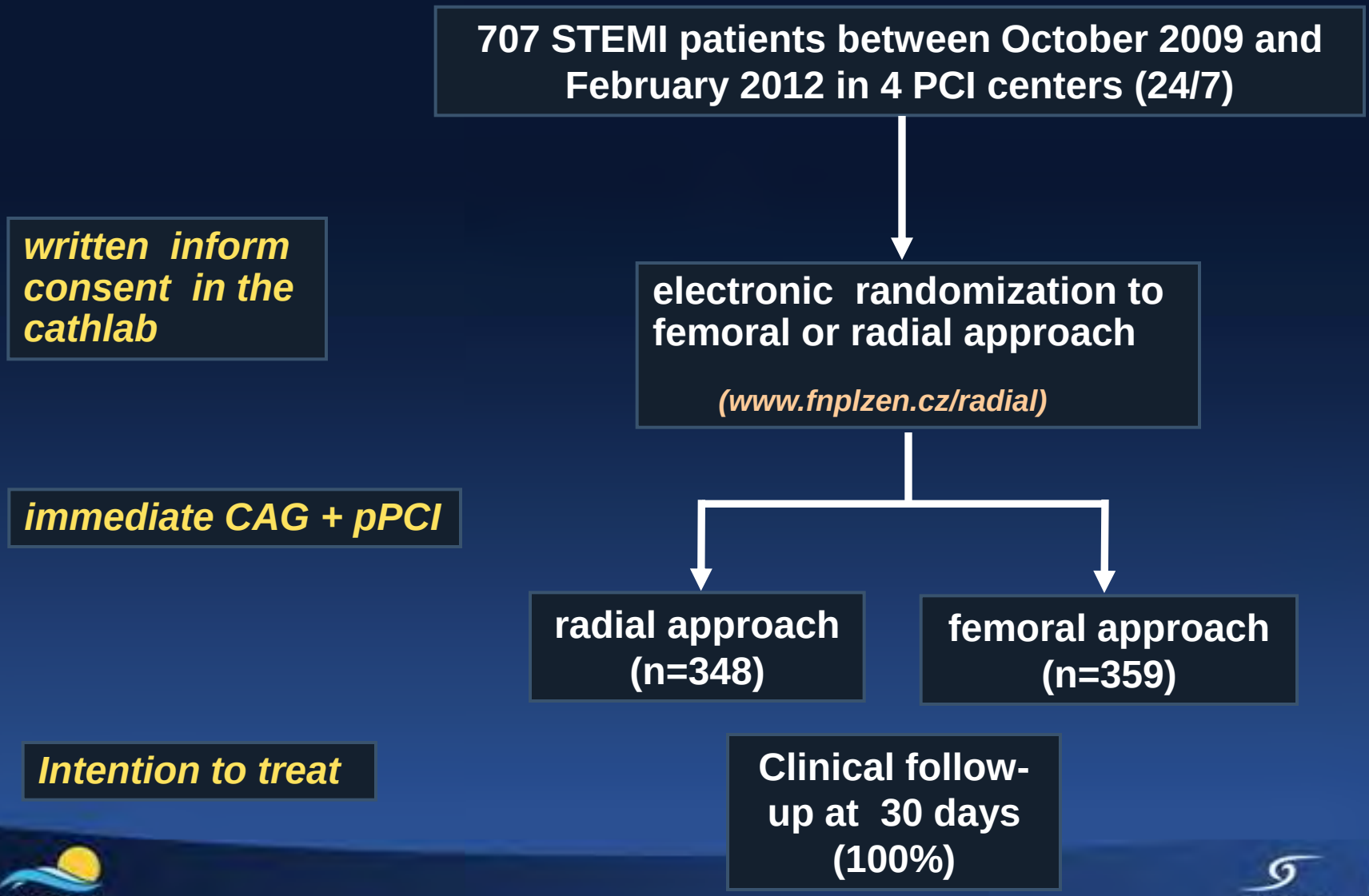
Inclusion criteria:

- age over 18 years
- admission for STEMI <12 hours after onset of symptoms
- ability to sign written informed consent

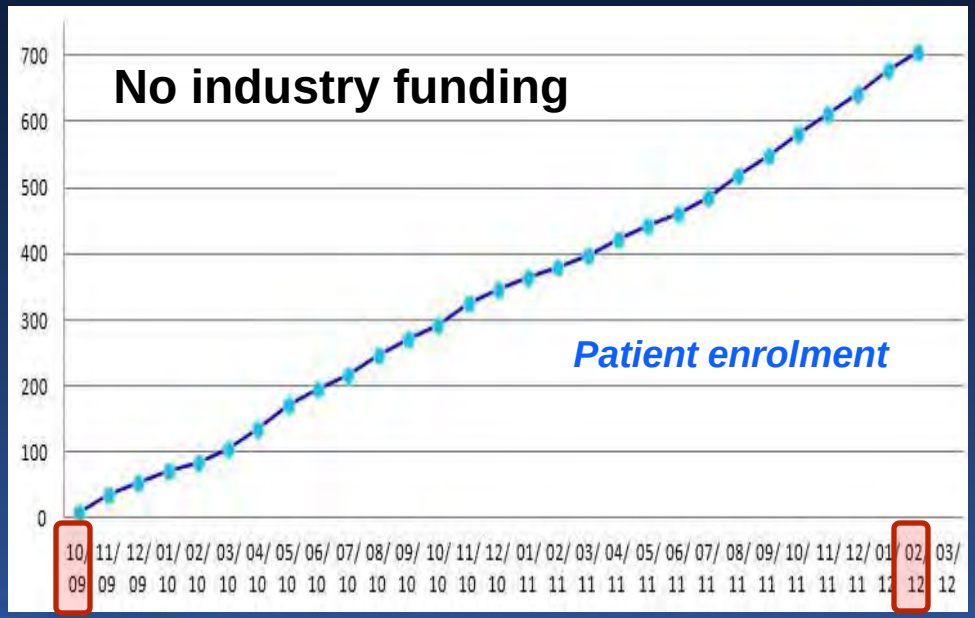
Exclusion criteria :

- Killip IV class or unconsciousness
- Patient refusal
- prior aortobifemoral bypass
- no radial or femoral artery pulse
- participation in another clinical trial
- negative Allen's test or Barbeau test type D
- treatment with oral anticoagulants

STEMI RADIAL - Study design:



Four study centers in the Czech Republic



- *University Hospital Pilsen*
- *Regional Hospital Liberec*
- *University Hospital Hradec Kralove*
- *Na Homolce Hospital Prague*

STEMI RADIAL - baseline characteristics I.

	overall (n=707)	Radial (n=348)	Femoral (n=359)	p value
Age (years)	62±11	62±11	61±11	0.16
Male gender	77%	75%	79%	0.24
Weight (kg)	84±15	85±16	83±14	0.056
Hypertension	61%	65%	57%	0.037
Diabetes	21%	22%	19%	0.27
Smoking	51%	48%	55%	0.06
Stroke	4.4%	4.9%	3.9%	0.58
Dyslipidemia	38%	38%	38%	1.00

STEMI RADIAL - baseline characteristics II.

	overall (n=707)	Radial (n=348)	Femoral (n=359)	p value
Prior MI	10.6%	9.2%	12%	0.27
Prior PCI	7.2%	7.8%	6.7%	0.66
Prior CABG	0.85%	0.9%	0.8%	1.0
Anterior MI	41%	40%	42%	0.7
Inferior MI	47%	47%	47%	0.88
Lateral MI	13%	14%	13%	0.66
Symptoms to balloon (min)	213(155-296)	215(157-301)	210(150-293)	0.28

STEMI RADIAL - procedural characteristics I.

	Radial (n=348)	Femoral (n=359)	p value
Vessel disease			0.93
0	3.7%	3.6%	
1	50%	50%	
2	31%	30%	
3	15%	17%	
Killip class			0.14
I.	85%	90%	
II.	12%	7.8%	
III.	3.4%	2.2%	

	Radial (n=348)	Femoral (n=359)	p value
Initial TIMI			0.55
0	52%	52%	
1	13%	13%	
2	18%	21%	
3	17%	14%	
Sheath			0.20
5 F	25%	27%	
6 F	75%	72%	
7 F	0%	0.8%	

STEMI RADIAL - procedural characteristics II.

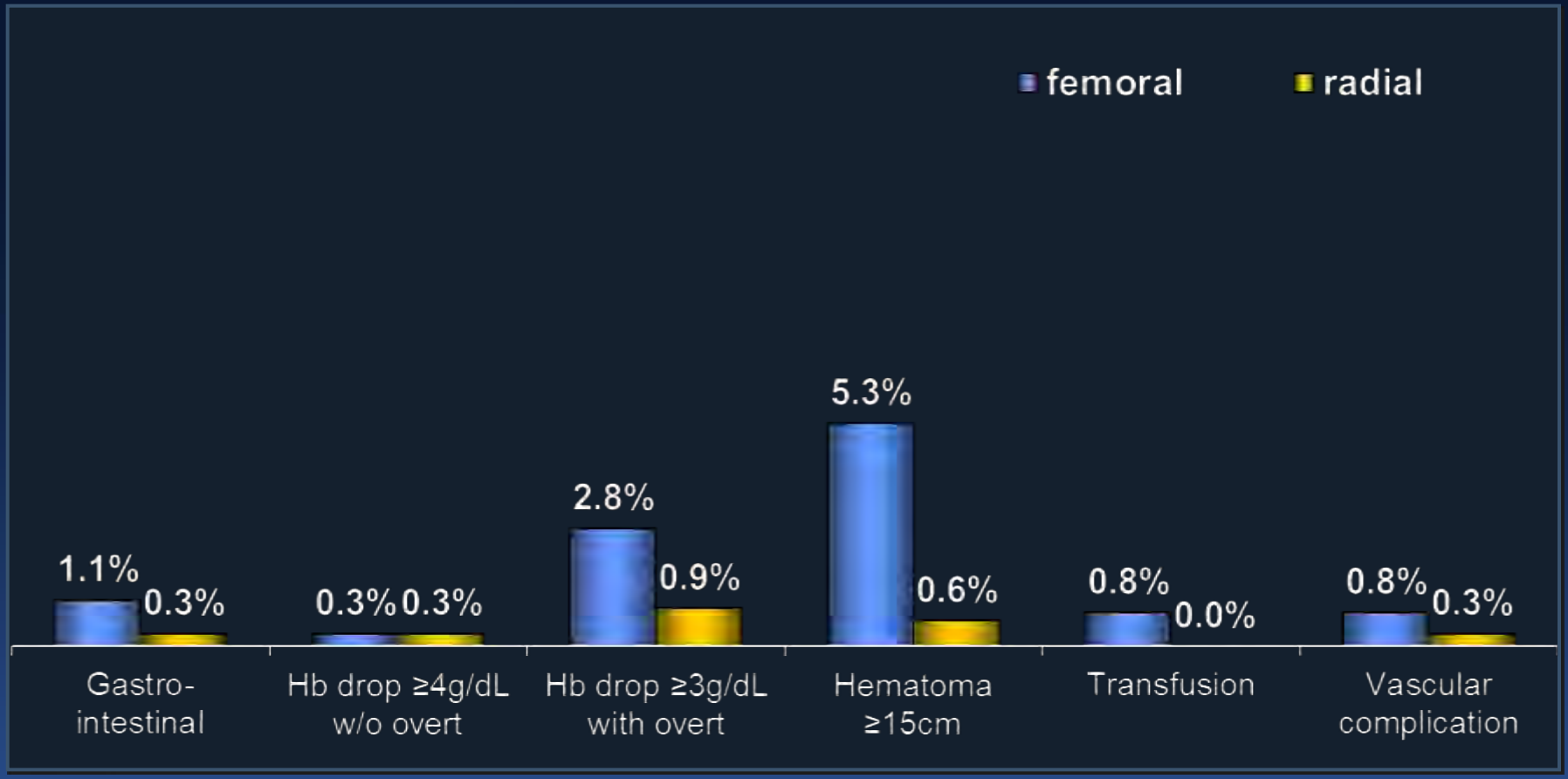
	overall (n=707)	Radial (n=348)	Femoral (n=359)	p value
Crossover	2.1%	3.7%	0.6%	0.003
GPI IIb/IIIa	45%	45%	45%	0.88
Thromboaspiration	28%	26%	30%	0.32
UFH dose (IU/kg)	104±32	103±34	105±31	0.41
ASA	99%	99%	99%	0.68
Clopidogrel	99%	99%	98%	0.51
Procedural time (min)	49±19	49±20	49±18	1.0
Fluoroscopy time (min)	8.0±5.1	7.9±4.7	8.0±5.5	0.76

STEMI RADIAL - procedural characteristics III.

	overall (n=707)	Radial (n=348)	Femoral (n=359)	p value
Angiographic success	91%	91%	91%	0.79
Contrast volume (ml)	176±66	170±71	182±60	0.01
ICU stay (day)	2.8±2.4	2.5±1.7	3.0±2.9	0.0016
Final TIMI				0.62
0	1.3%	1.7%	0.8%	
1	1.0%	1.1%	0.8%	
2	5.5%	4.9%	6.1%	
3	92%	92%	92%	

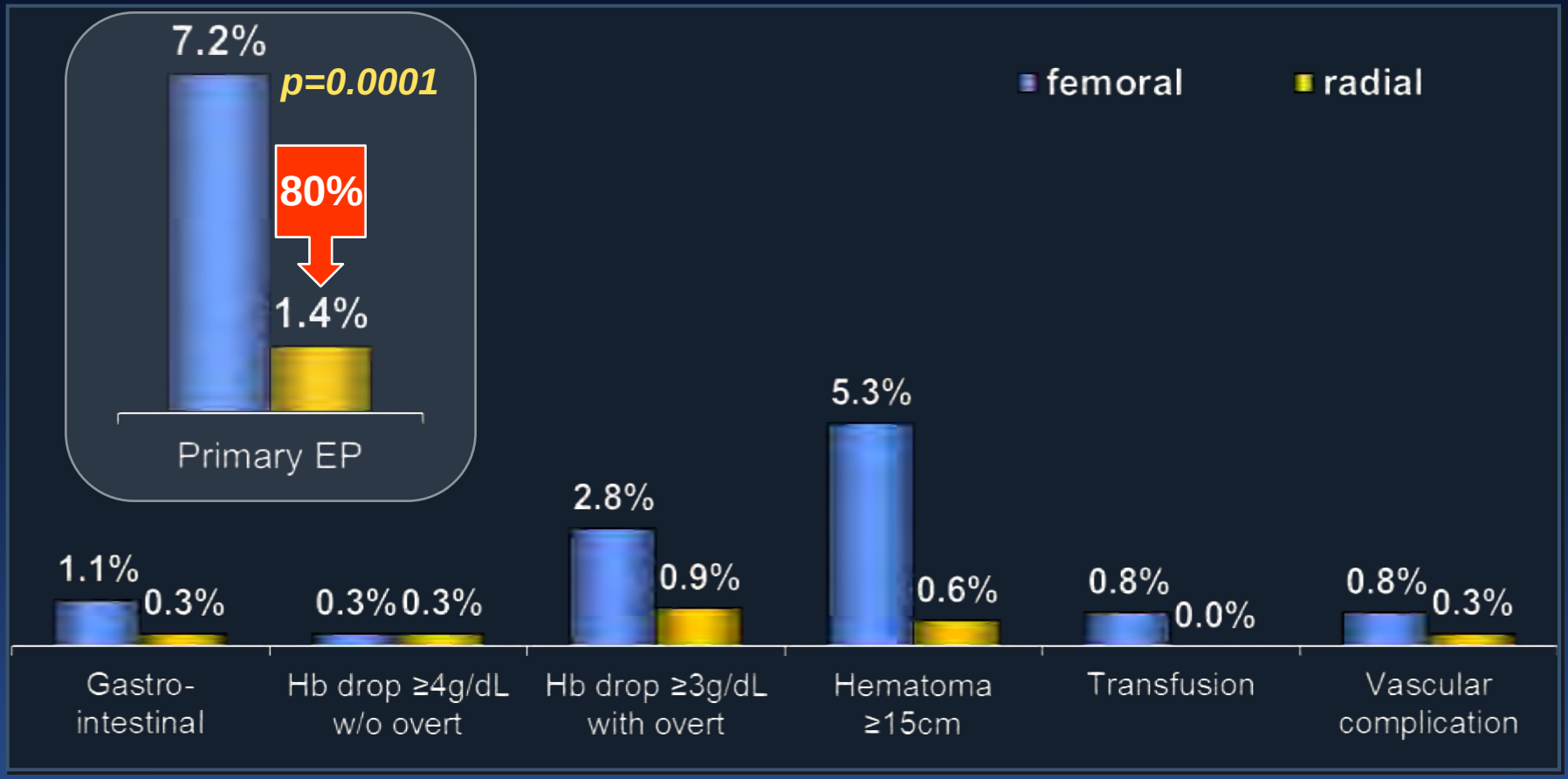
STEMI RADIAL - results

30-day bleeding and access site compl.



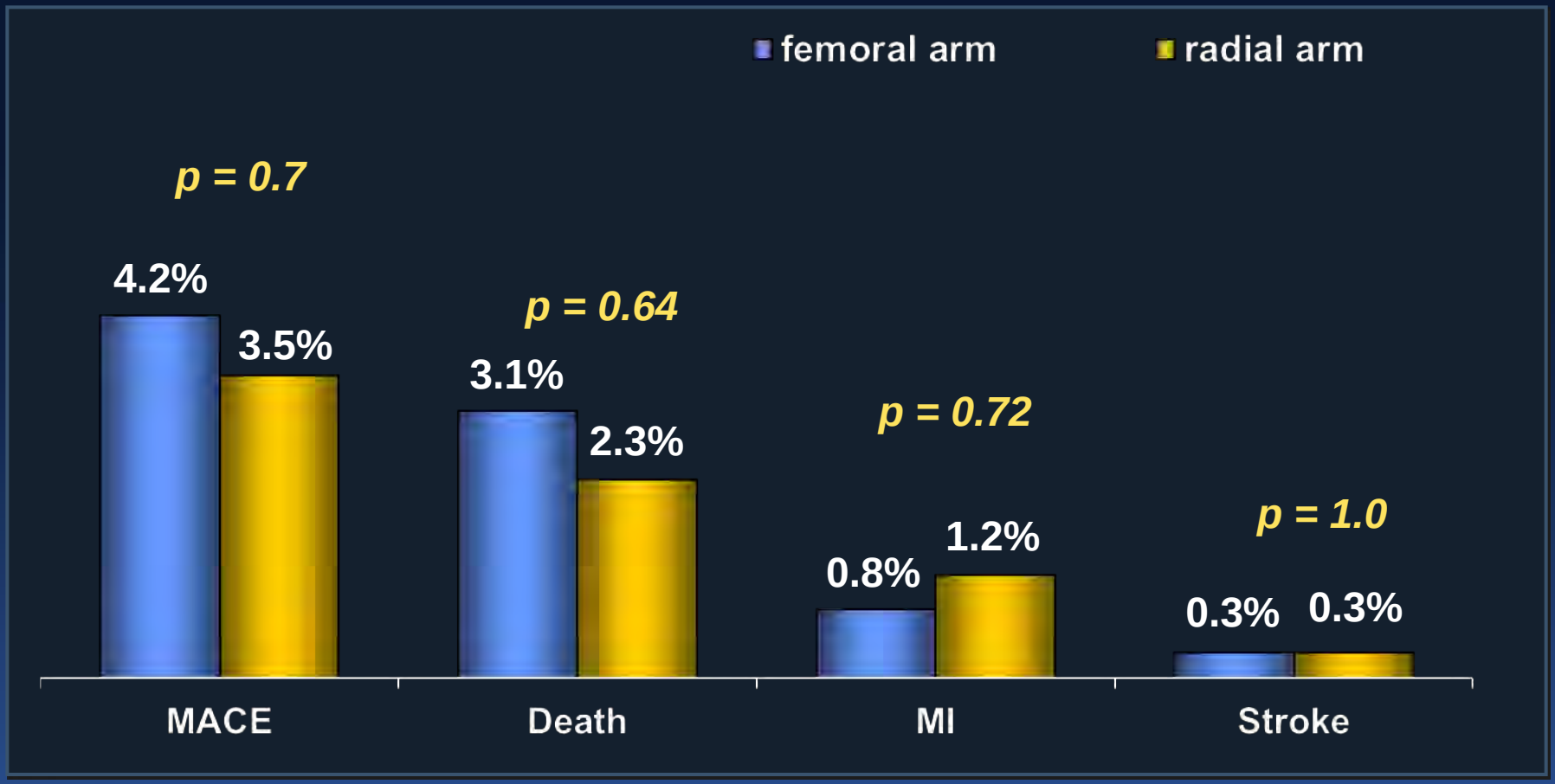
STEMI RADIAL - results

30-day bleeding and access site compl.



STEMI RADIAL - results

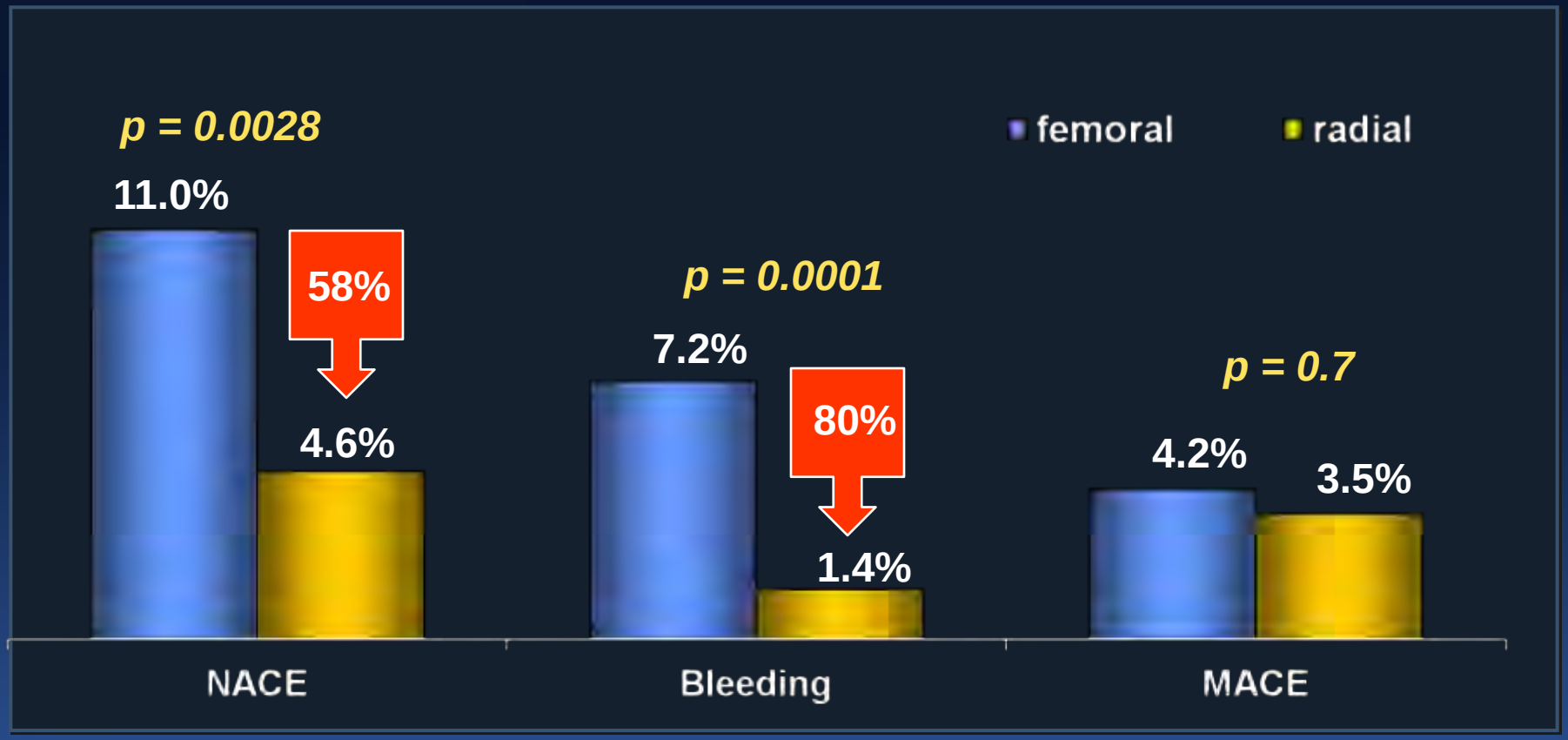
30-day MACE



MACE = composite of death, myocardial infarction and stroke

STEMI RADIAL - results

30-day NACE



Net Adverse Clinical Event (*NACE*) = MACE + major bleeding
MACE = composite of death, myocardial infarction and stroke

Conclusion

- **In patients with STEMI <12 hrs, radial approach was associated with a significant lower incidence of major bleeding and access site complications and a significant better net clinical benefit.**

- **Moreover radial approach reduced significantly ICU stay and contrast volume compared to femoral approach.**

- **Our results support the use of radial approach in primary PCI in high volume centers as a first choice.**

80-year old man from the STEMI-RADIAL trial :

Radial PCI one week after randomization to femoral primary PCI