

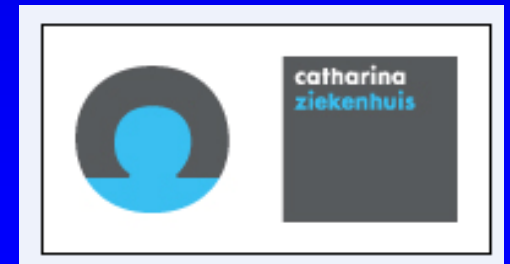
Imaging & Physiology Summit

RCT to Compare Maximum Hyperemic Effect of Single i.v. Bolus Regadenoson to Central venous Infusion of Adenosine

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Background

- *Maximum coronary hyperemia* is mandatory for correct decision making with respect to revascularization in the catheterization laboratory
- *(Central venous) Adenosine* is the present gold standard to induce maximum coronary hyperemia
 - Reliable, safe, well investigated & reproducible
 - In some centres, the non-trivial preparation, high price and need for central venous access may be a barrier
- *Regadenoson* is a selective A_{2A} receptor agonist
 - Single bolus, non-weight based injection
 - Only limited data available with respect to efficacy, reproducibility, safety and ways of administration

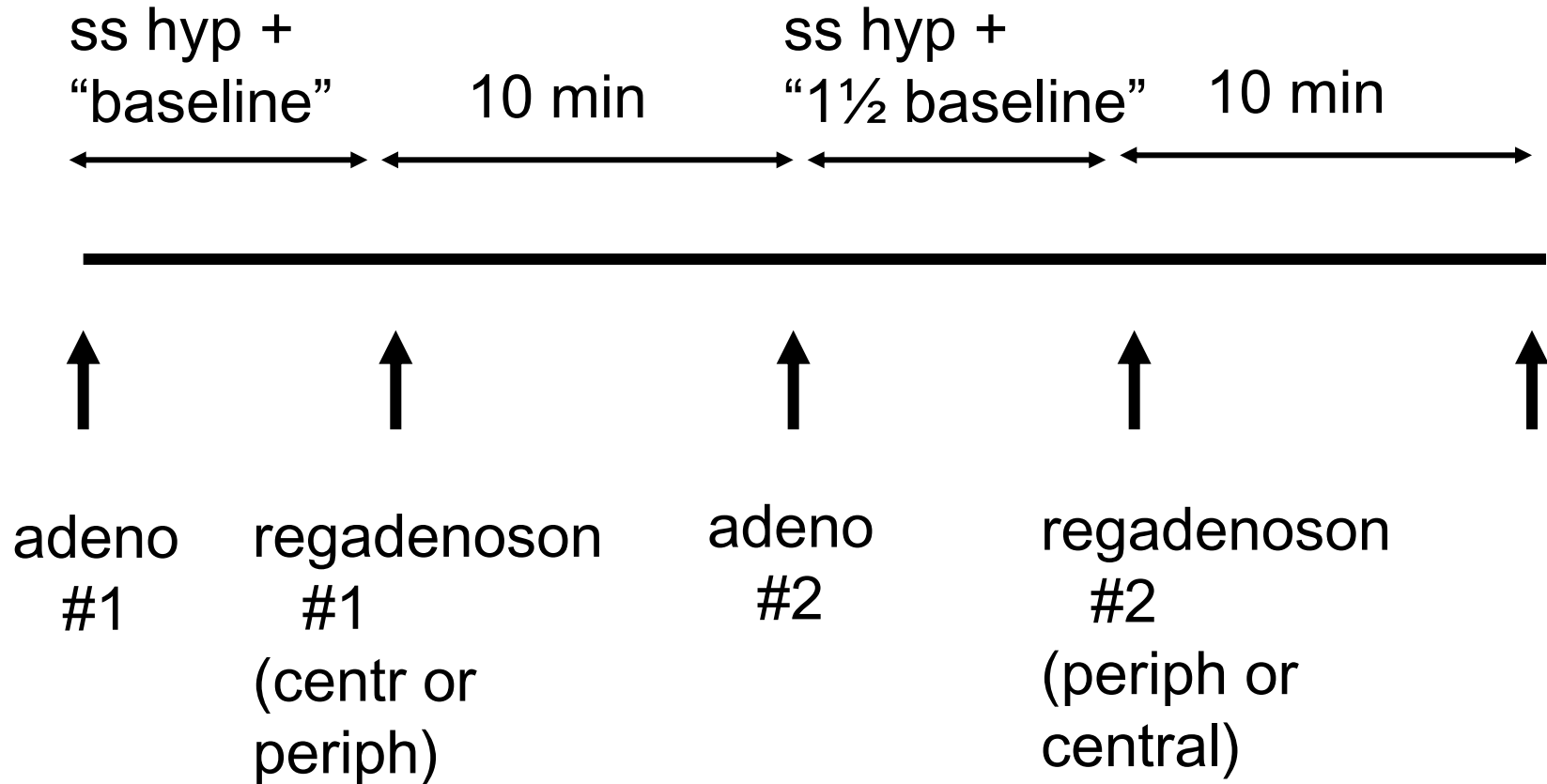
Aims of this Study

- To investigate if the hyperemic effect of *single bolus regadenoson injection* is equal to the present gold standard (i.e. *central venous adenosine infusion*)
- To determine *time intervals* to onset of maximum hyperemia and the *duration of steady state hyperemia* after single bolus regadenoson injection
- To compare *central venous versus peripheral venous* single bolus administration of regadenoson
- To investigate *side-effects* as well as *safety of repeated regadenoson injections*

Population & Methods

- *100 patients* scheduled for measurement of FFR (diagnostic and/or interventional procedures)
- Pa measured by guiding catheter
- Pd measured by 0.014 PressureWire (St. Jude Medical)
- Central venous line for *adenosine infusion* (140 $\mu\text{g}/\text{kg}/\text{min}$) or central venous regadenoson injection (single bolus 400 μg)
- Peripheral venous access for peripheral venous *regadenoson* injection (single bolus of 400 μg)
- Randomization with respect to regadenoson
 - central / central (N=25)*
 - peripheral / central (N=25)*
 - central / peripheral (N=25)*
 - peripheral / peripheral (N=25)*

Adenosine (central venous infusion) vs single bolus of Regadenoson for maximum hyperemia (N=100)

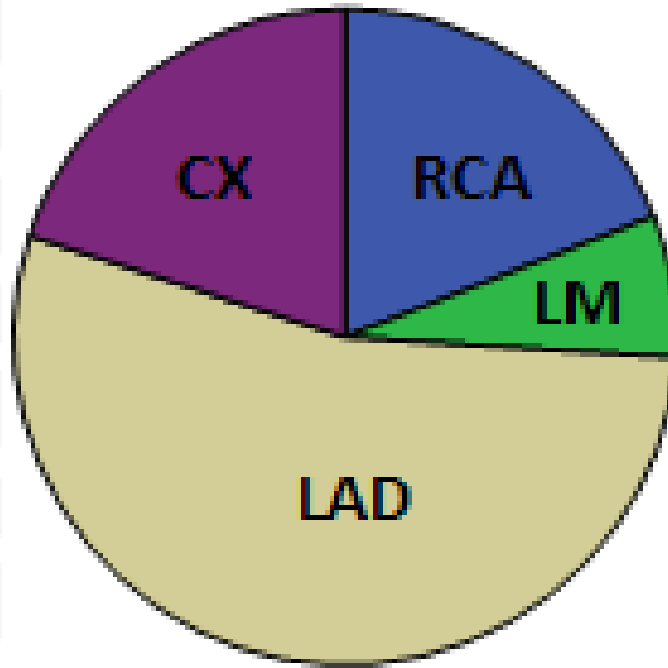


randomization with respect to regadenoson: *central/central (N=25)*
peripheral/central(N=25)
central/peripheral (N=25)
peripheral/peripheral (N=25)

Baseline Characteristics

<i>Characteristics</i>	<i>Number/Percentage</i>
Male/female	75 / 25
Age (years)	66 ± 8
Study coronary artery	
– LM	7
– LAD	54
– CX	20
– RCA	19
Diameter (mm)	3.2 ± 0.6
Stenosis percentage	
– 30-50%	35
– 50-70%	38
– 70-90%	21
– >90%	6
Fractional Flow Reserve	0.75 ± 0.10
Interventional procedure	54

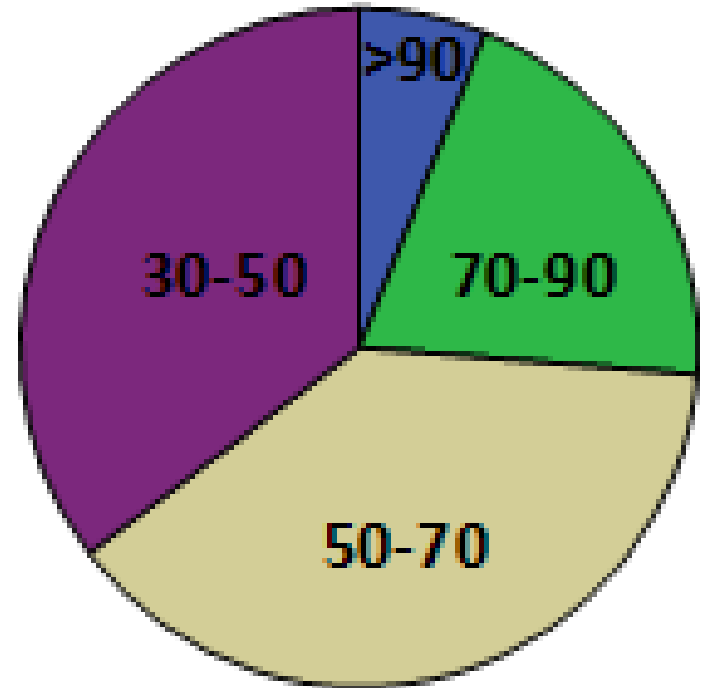
distribution of coronary artery



N= 100

LM: 7
LAD: 54
LCX: 20
RCA: 19

stenosis percentage



N= 100

0-50 % : 35
50-70 % : 38
70-90 % : 21
> 90 % : 6

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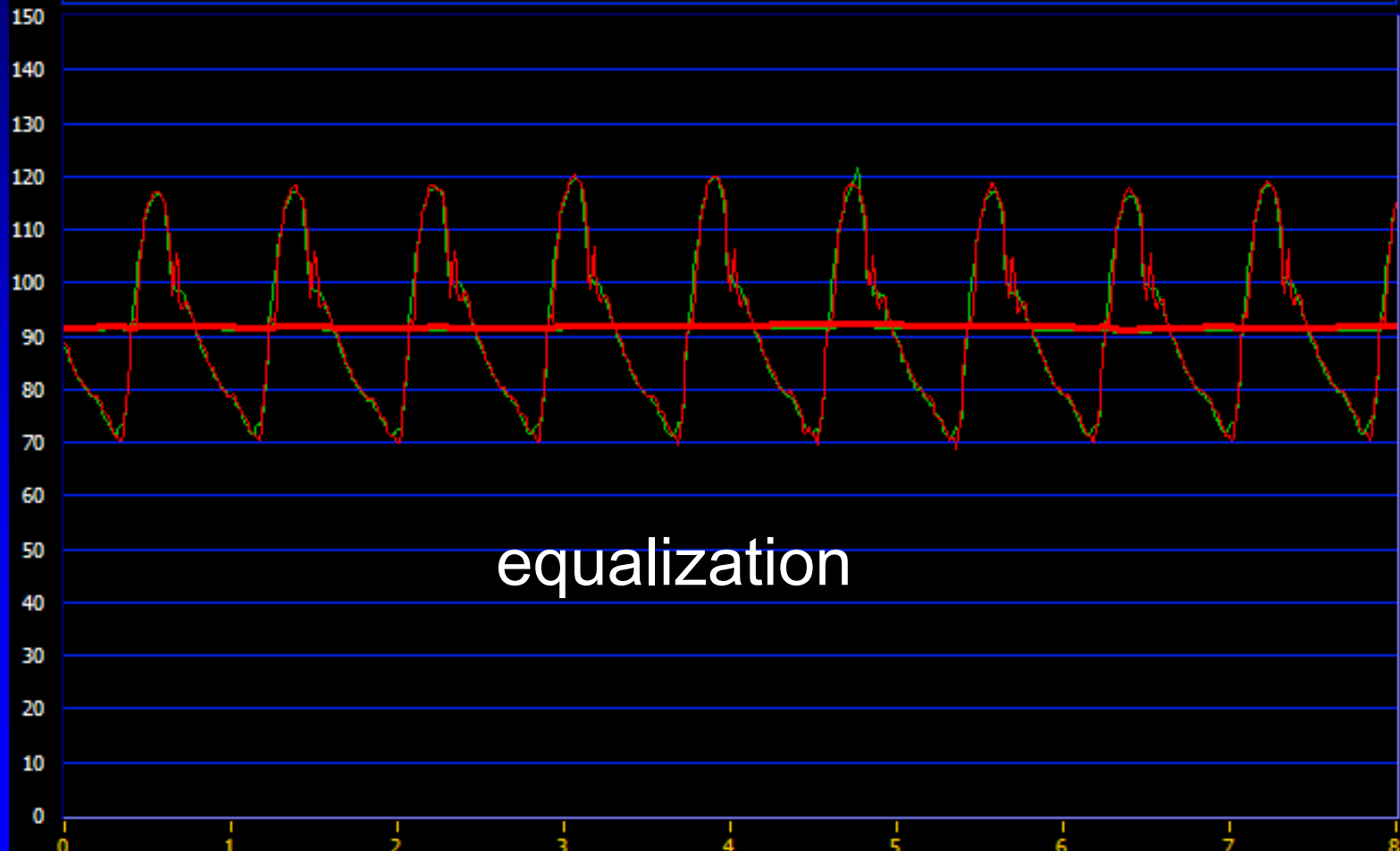
- REGADENOSON_081_ ▼
- REGADENOSON_034_ ▼

D:\Mijn documenten\radi_download\REGADENOSON_081_Peters

PATIENT ID	DATE	TIME	VESSEL	PROCEDURE	ACTION	TYPE	SIZE
REGADENOSON_081_	2013-08-05	13:41:09				FFR	586Kb
REGADENOSON_081_	2013-08-05	13:29:55				FFR	114Kb
REGADENOSON_081_	2013-08-05	13:22:41				FFR	9Kb

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REGADENOSON_081_I 2013-08-05 13:22:41



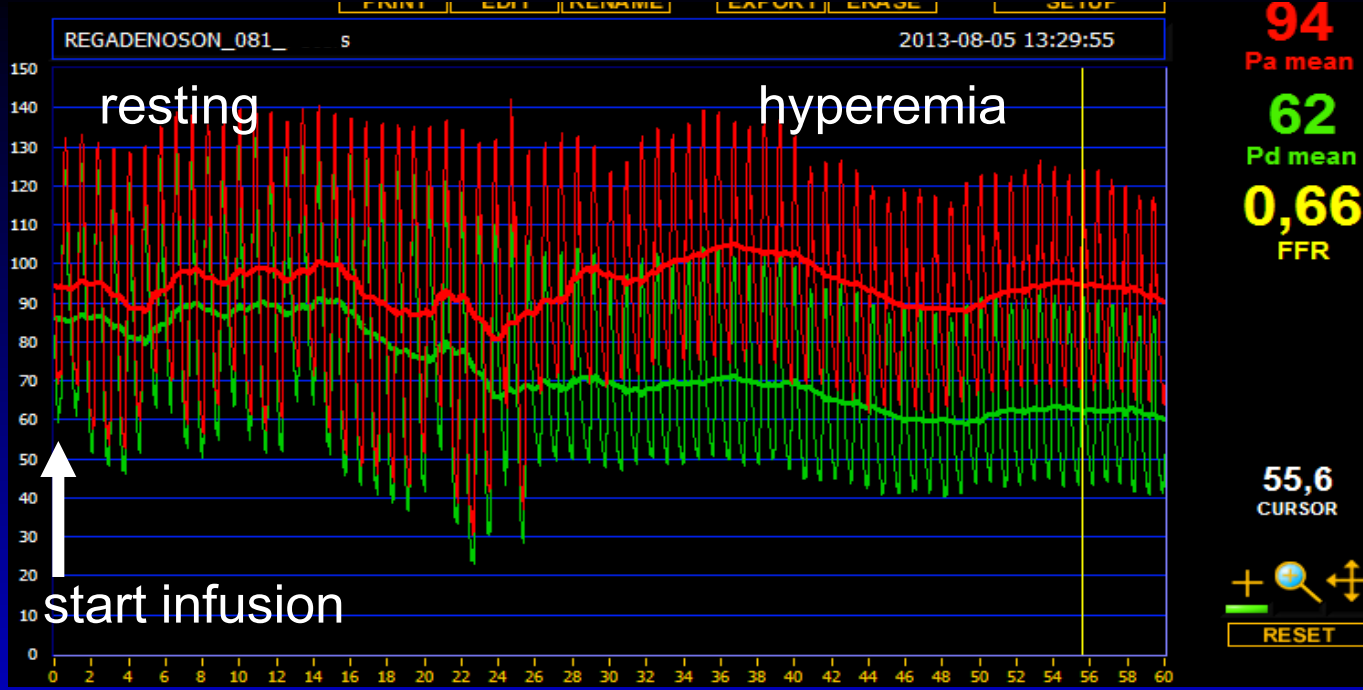
92
Pa mean

92
Pd mean

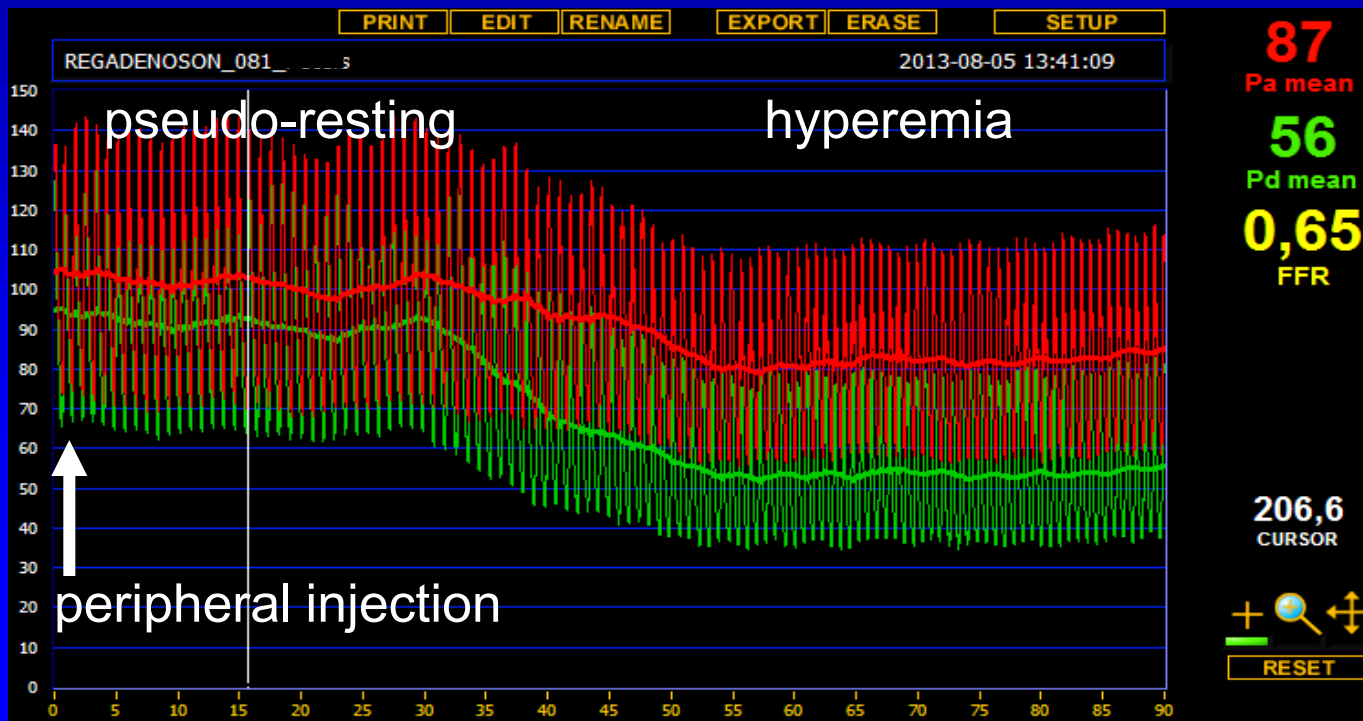
1,00
FFR

8,2
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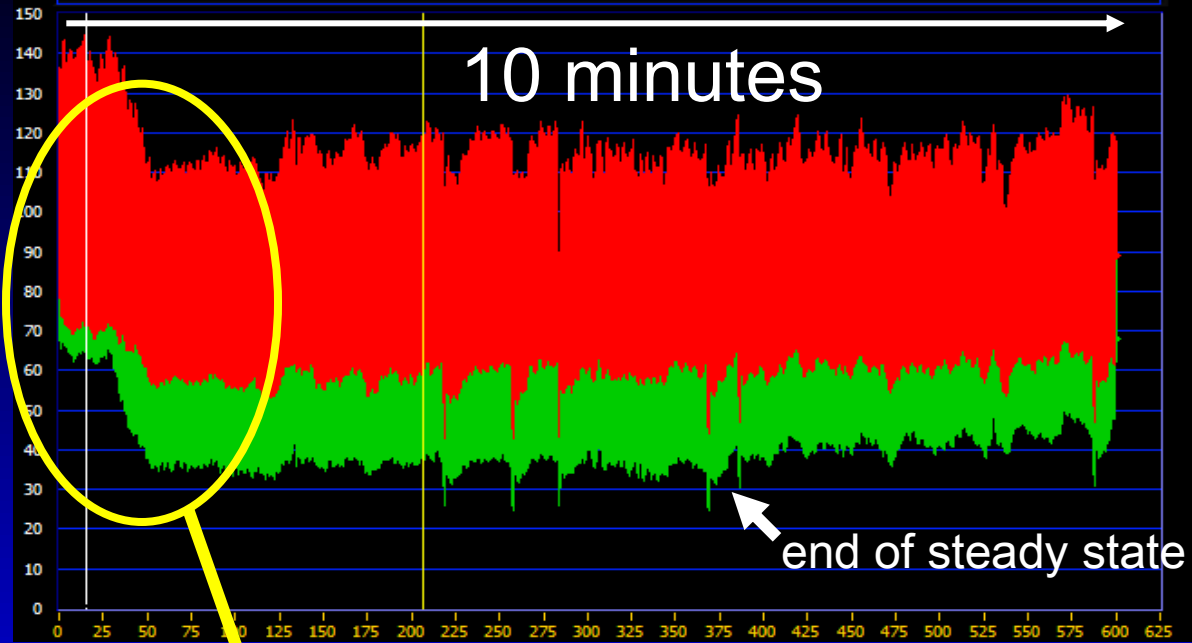
central
venous
adenosine
Infusion
140 $\mu\text{g}/\text{kg}/\text{min}$



Single bolus
Peripheral
Injection of
400 μg of
regadenoson

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REGADENOSON_081_Peters 2013-08-05 13:41:09



87
Pa mean

56
Pd mean

0,65
FFR

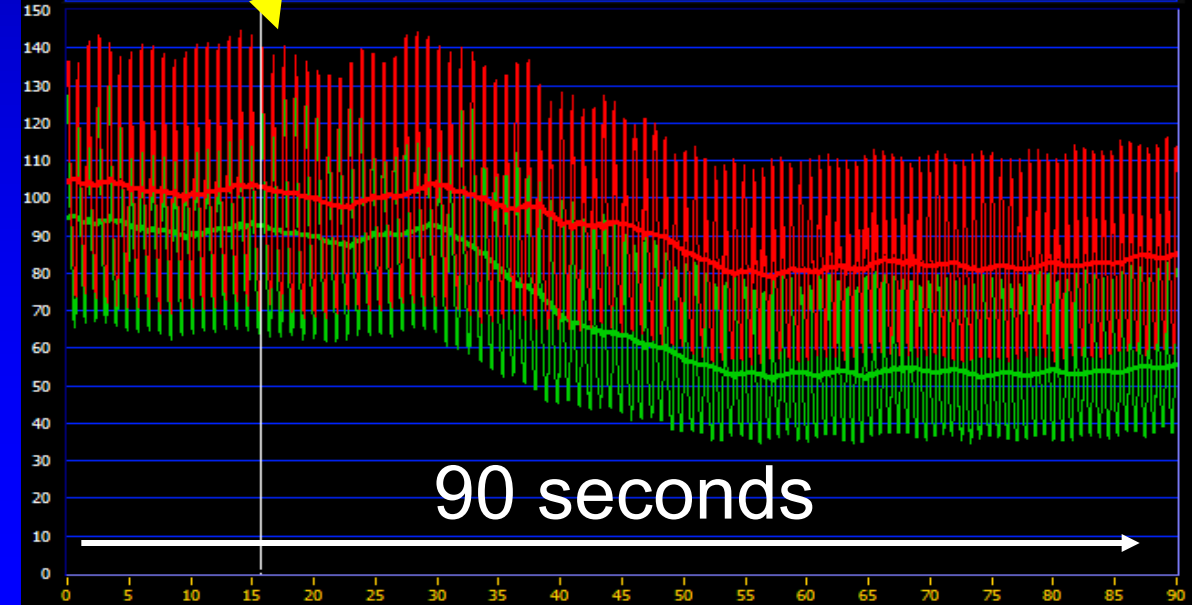
206,6
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+ [magnifying glass] [crosshair]
RESET

peripheral
single bolus
injection of
400 µg of
regadenoson

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REGADENOSON_081_Peters 2013-08-05 13:41:09



87
Pa mean

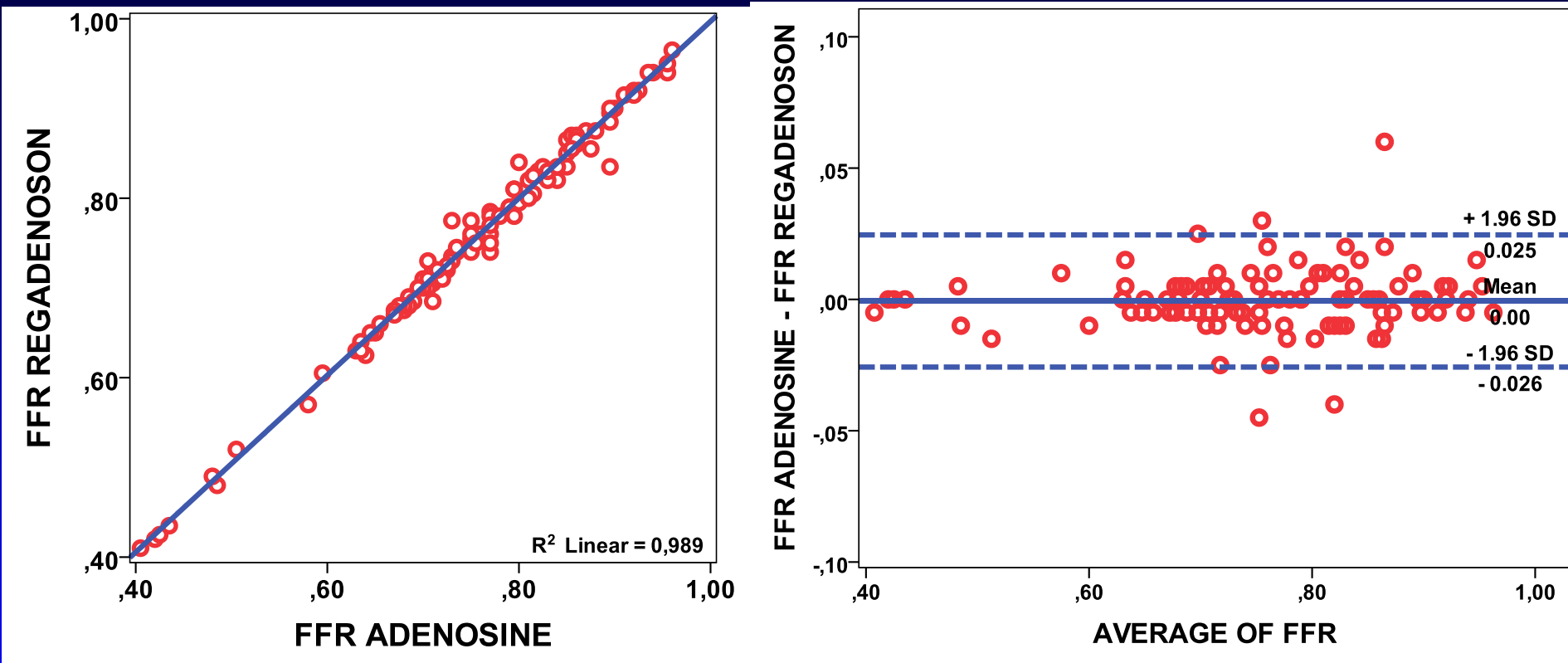
56
Pd mean

0,65
FFR

206,6
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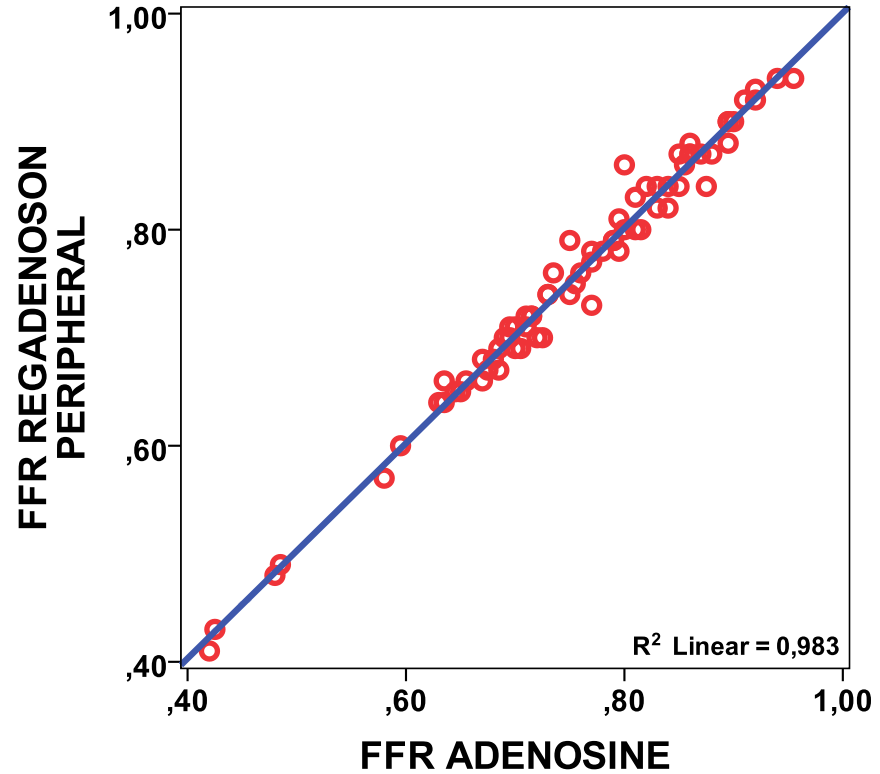
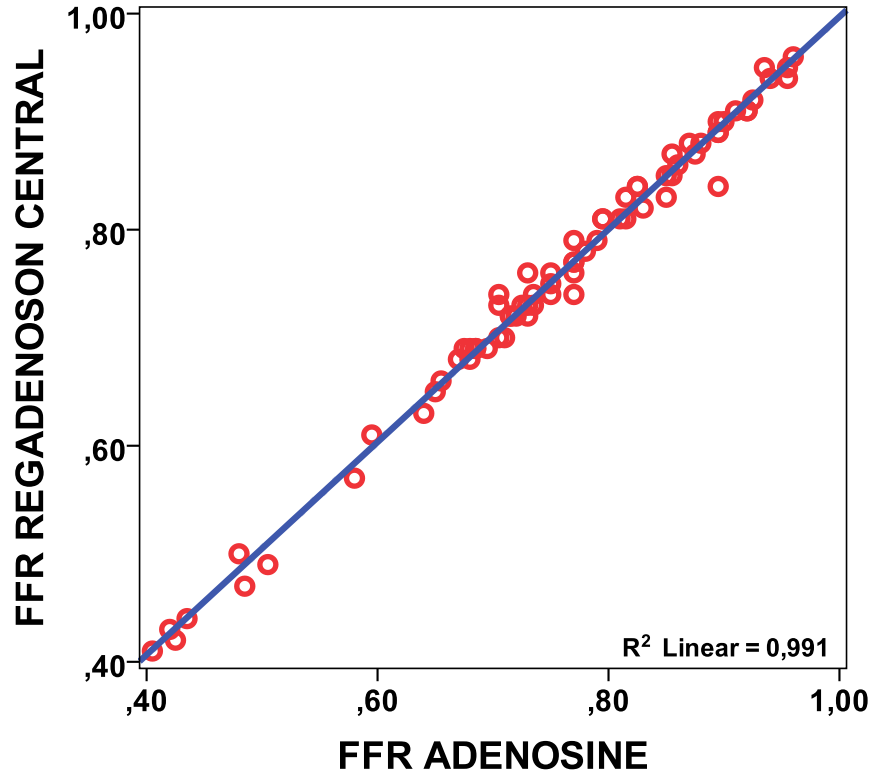
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Regadenoson vs Adenosine (N=100)



- Mean Difference 0.00 ± 0.01
- In only 3 patients difference > 0.02
- No patient in whom decision changed

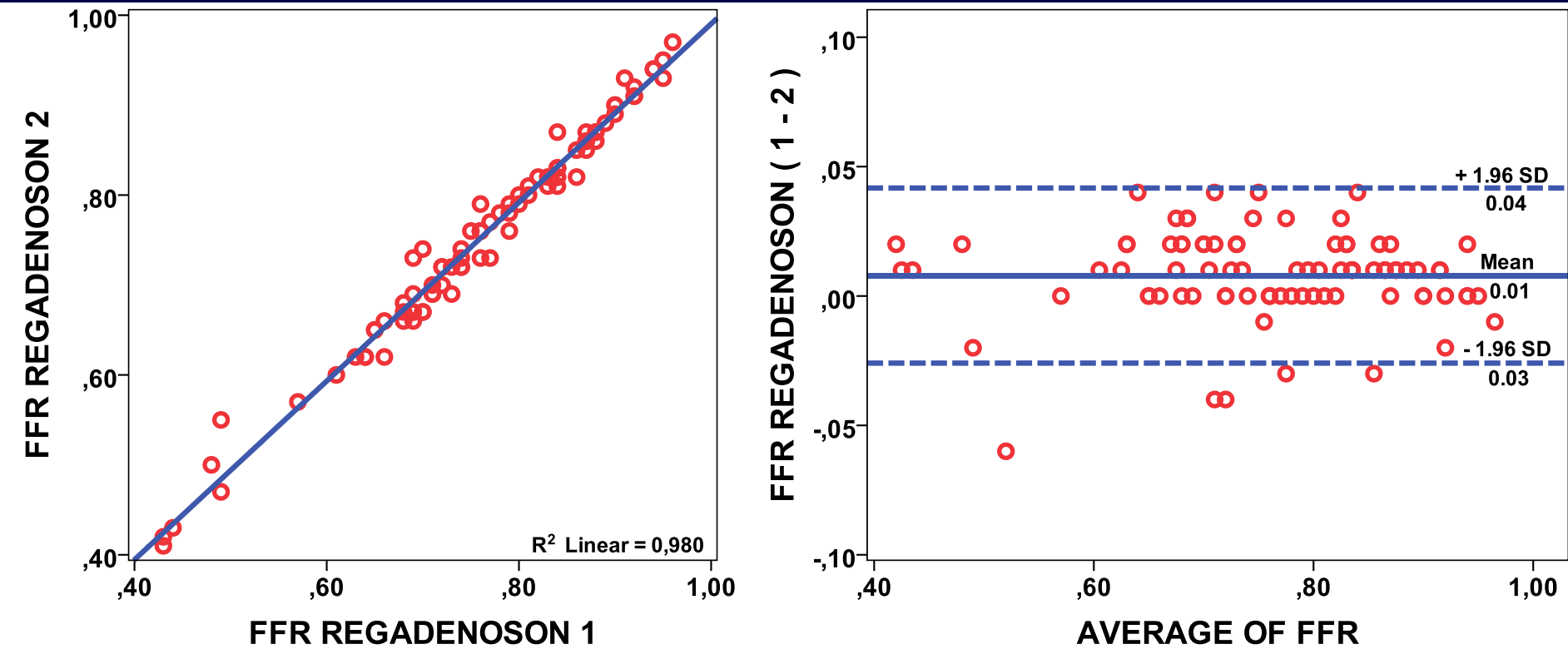
Central & Peripheral Regadenoson



- Mean Difference $0,00 \pm 0,01$

- Mean Difference $0,00 \pm 0,02$

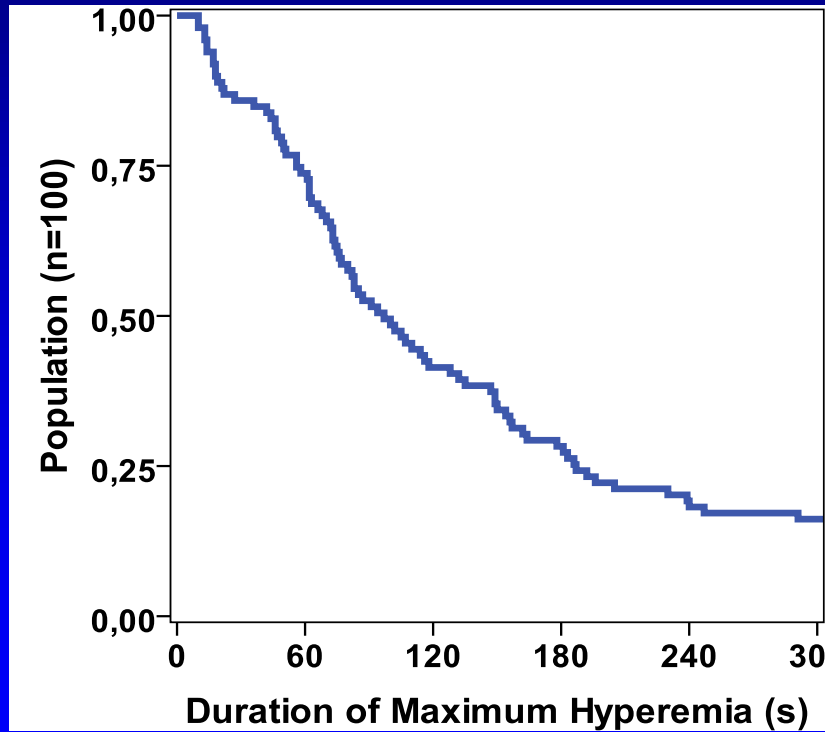
Reproducibility of Regadenoson (N=87)



- Mean Difference 0.01 ± 0.02

Duration of Maximum Hyperemia

- In *all* patients, steady state maximum hyperemia was achieved with adenosine and maintained during infusion
- For regadenoson, the hyperemic plateau after single injection ranged from 10 sec – 10 minutes.



Duration of hyperemia

> 30 sec	86%
> 1 min	74%
> 3 min	35%

Safety & Side Effects

- No noticeable side effects were seen with both drugs, except for the well-known chest pain
 - Severity rating 6/10 for adenosine and 4/10 for regadenoson
- In 6 patients, short innocent transient AV-conduction disturbances occurred without necessity to interrupt administration
 - Five times with adenosine only, once with both drugs
- Not any problem occurred with repeated regadenoson injections
- Hemodynamic response to regadenoson was similar to adenosine

Conclusions (1)

- Regadenoson, as a single bolus injection of 400 μg , is an excellent alternative for central venous adenosine infusion to induce maximum hyperemia
 - Rapid onset (< 30 sec) but variable duration
 - No difference between central and peripheral regadenoson
- Useful in many patients with single-vessel disease or focal two-vessel disease
- In complex cases where extensive pressure-pullback recordings are necessary (with more prolonged hyperemia), central venous adenosine remains the drug of choice

Conclusions (2)

- Repeated injections of regadenoson can be performed and are safe
- No noticeable side effects of regadenoson or adenosine, except the harmless chest discomfort
- Finally, steady state hyperemia was achieved in all patients in this study with central venous adenosine, which confirms the role of this drug as gold standard