Brachytherapy is Better in In-stent Restenosis

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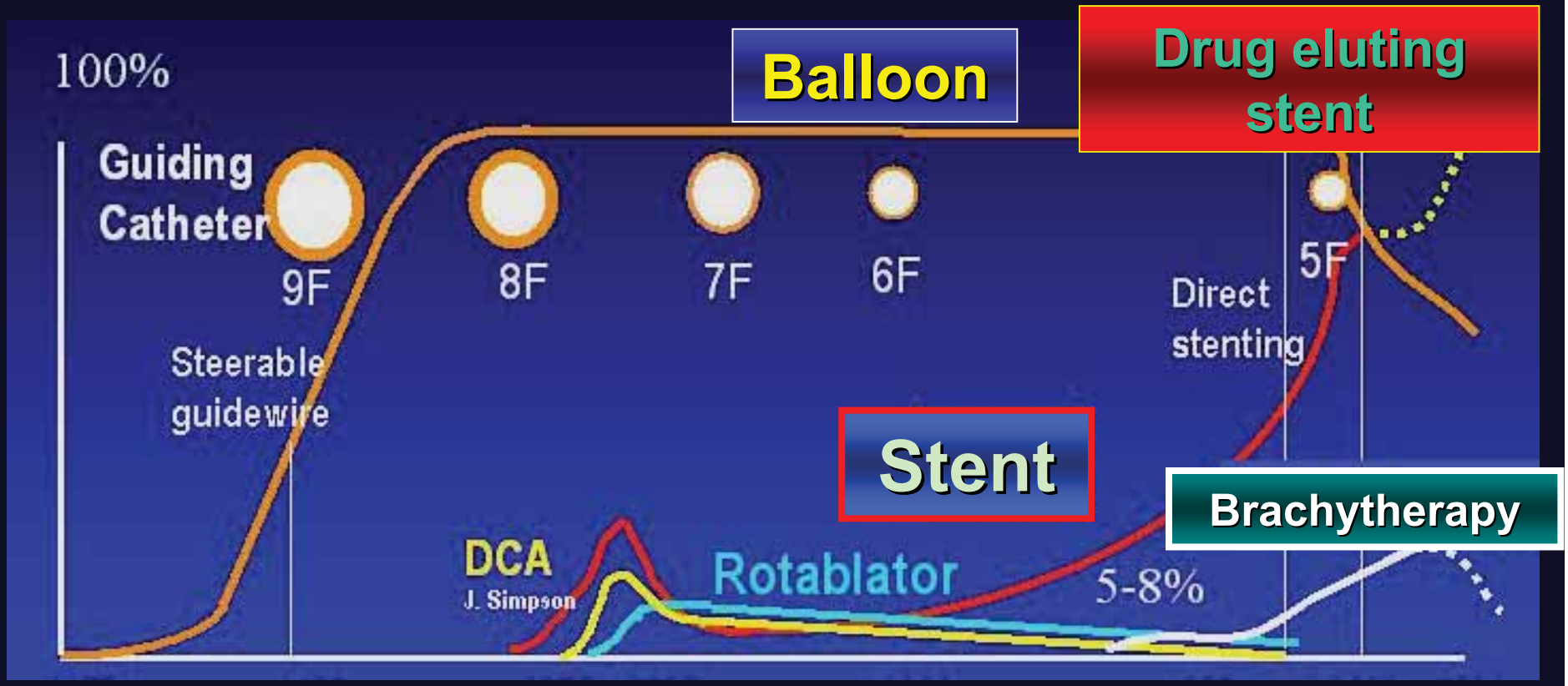
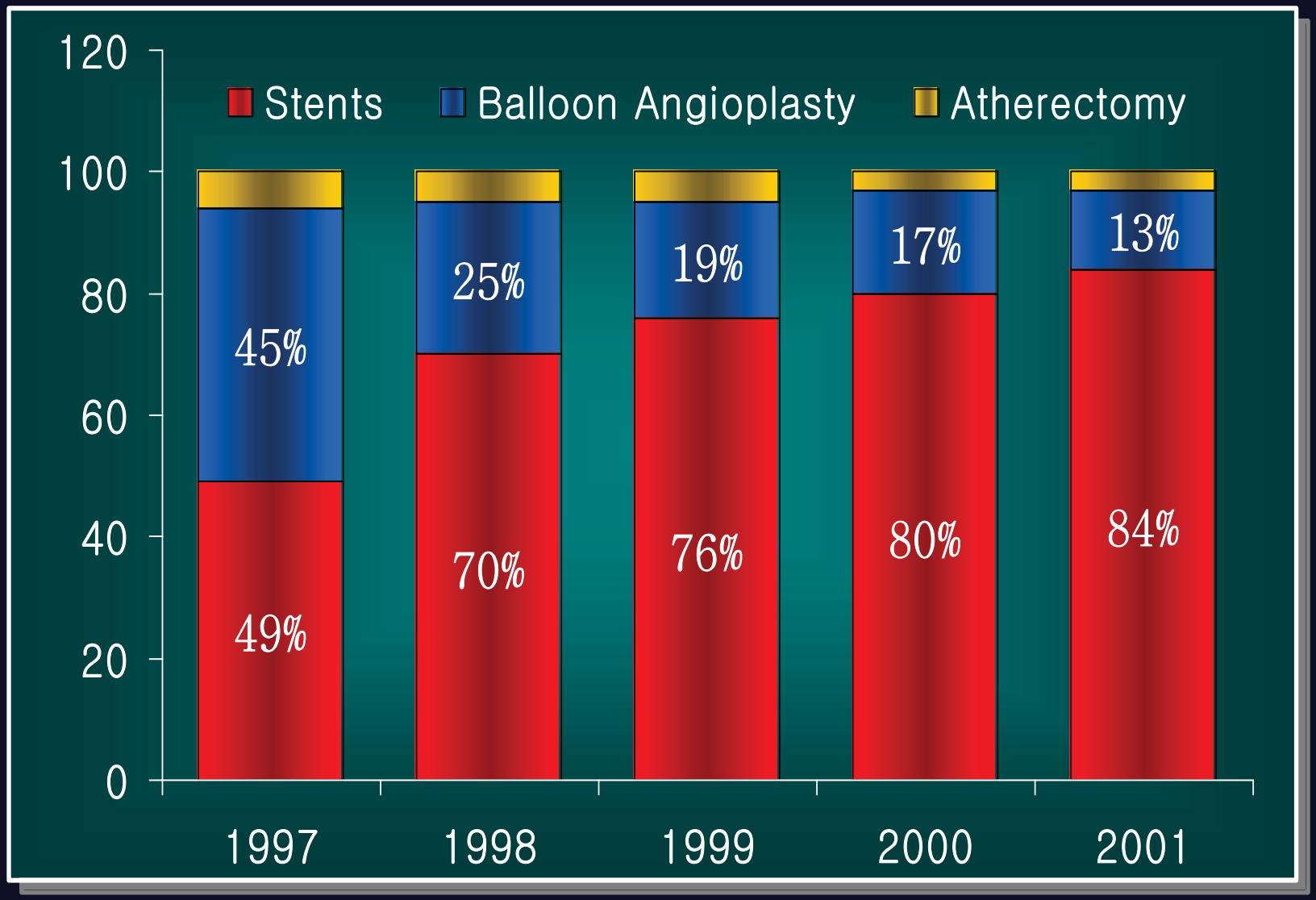
Technical Evolution in Interventional Cardiology



Coronary Intervention



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Current Problem in PCI

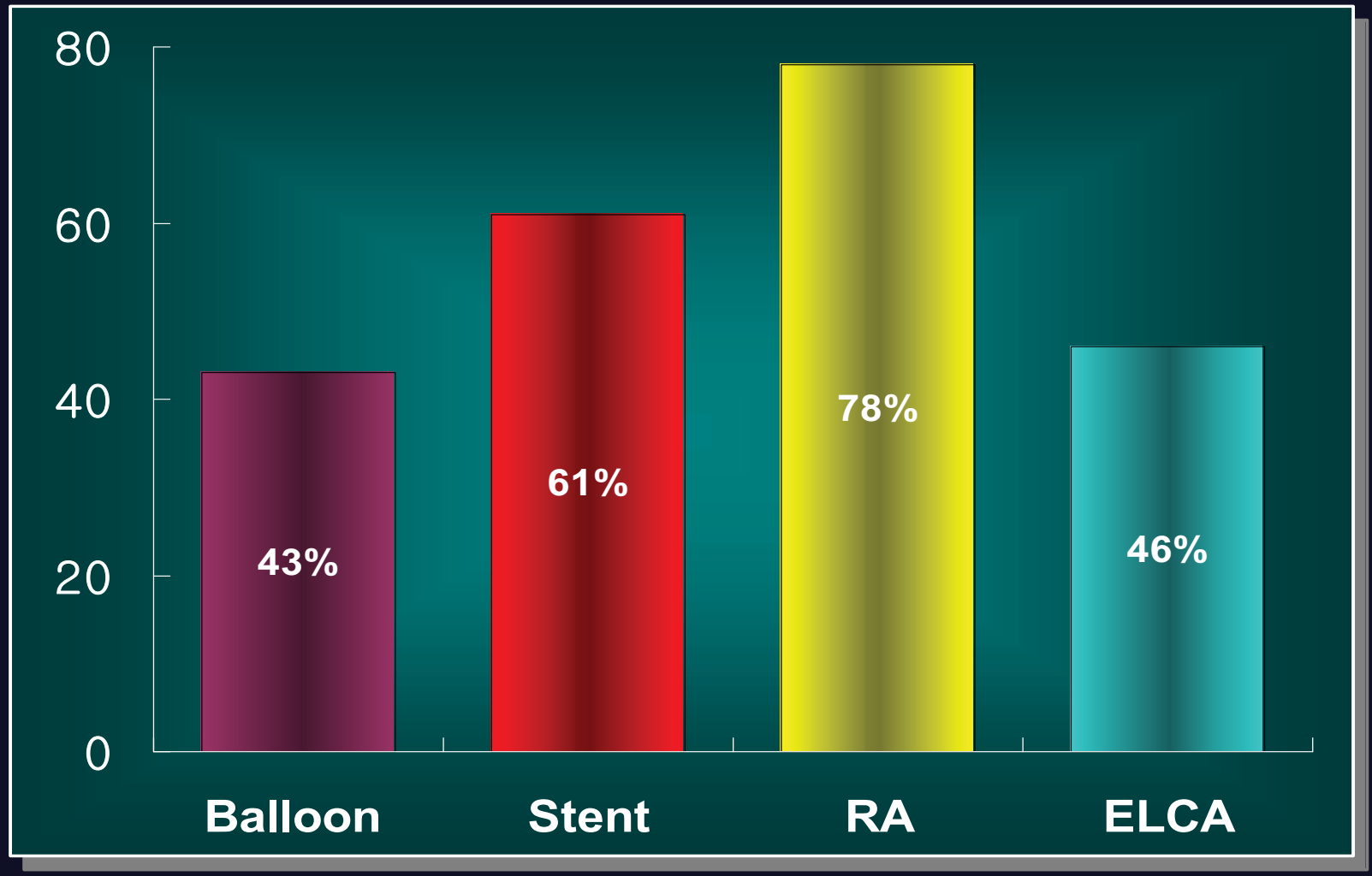
Angioplasties per year **= 1,550,000**
(worldwide)

Stents per year **= 1,200,000**
(worldwide 75%)

Restenosis per year **= 300,000**
(10 ~ 50%)

In Stent Restenosis

All Therapies ***- long lesion -***



Waksman R, et al. ACC 2000

Evidences ….

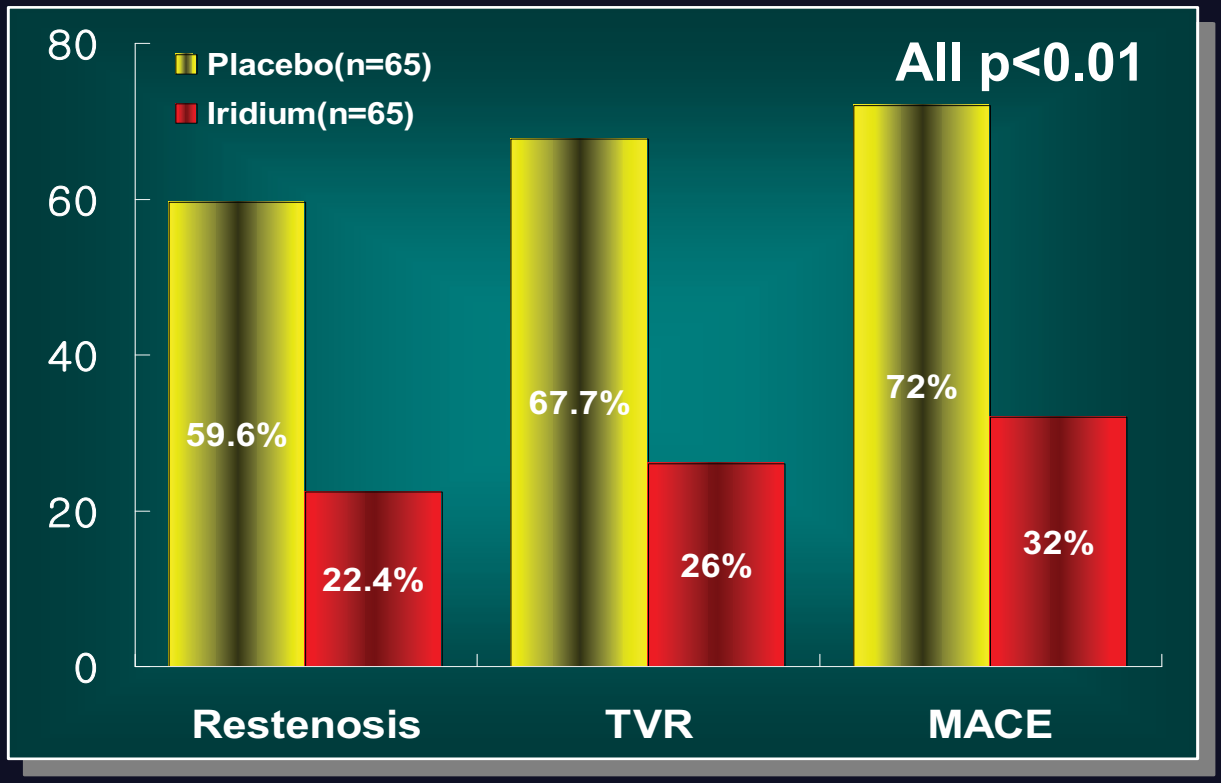
Brachytherapy

Trials ….

Radiation Source	Trial	Patient Number	Lesion Length(mm)	Restenosis Rates(Rx vs. control)
γ (Gamma)				
^{132}Ir wire	**GAMMA-I**	252	< 45 mm	32% vs. 55%
	γ WRIST	130	< 47 mm	22% vs. 60%
	Long WRIST	120	36-80 mm	32% vs. 71%
β (Beta)				
SR^{90}	**START**	485	< 20 mm	29% vs. 45%
^{32}P	**INHIBIT**	332	< 22 mm	19% vs. 50%
^{32}P	**PREVENT**	105	< 15 mm	8% vs. 39%

γ - radiation

WRIST trial

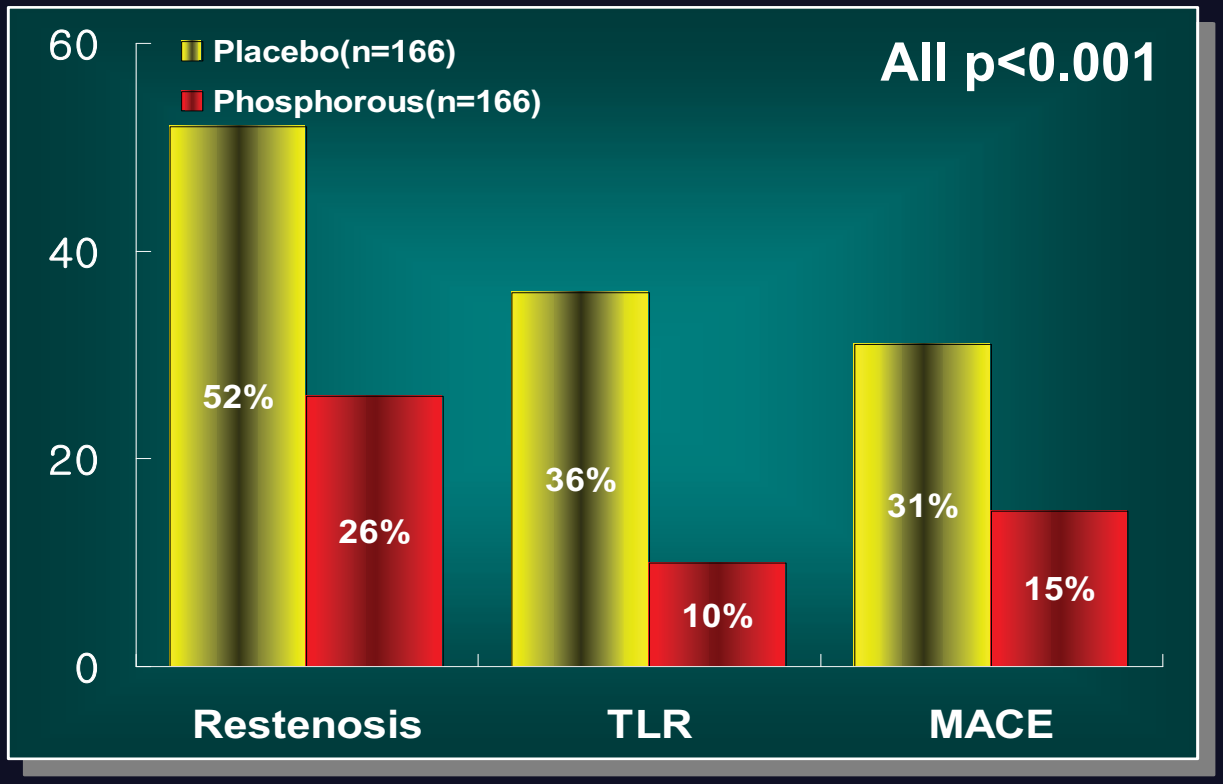


- Randomized, double blinded trial
- Iridium vs. placebo
- Mean vessel size = 2.7 mm
- Mean lesion length = 22 mm

Waksman R, et al. Circulation 2000;101:2165

β - radiation

INHIBIT trial

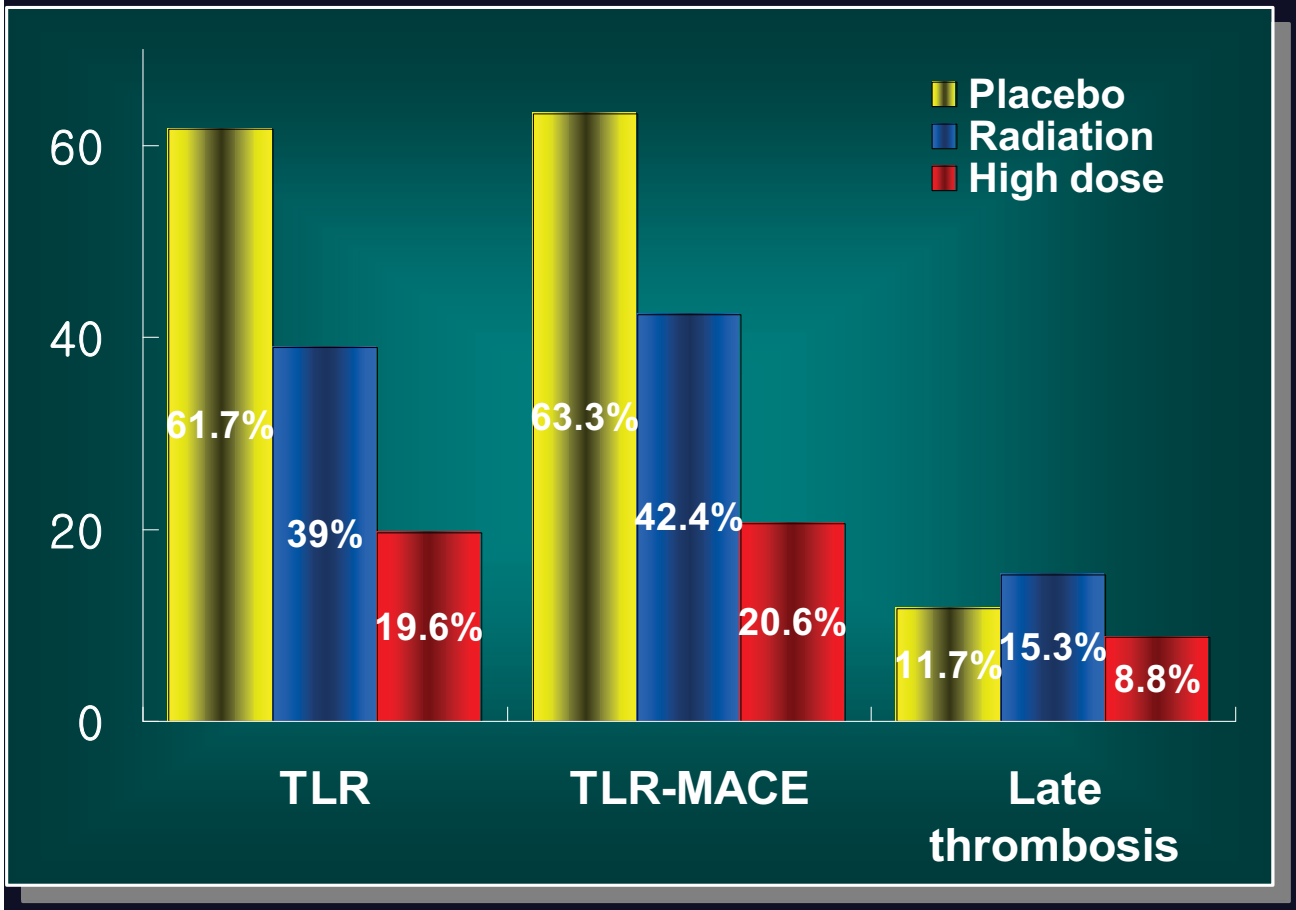


- Randomized, multicenter trial
- ^{32}P vs. placebo
- Mean lesion length = 17 mm
- 9 mo angiographic and clinical follow-up

Waksman R, et al. Lancet 2002;359:551

Brachytherapy – long lesions

Long WRIST

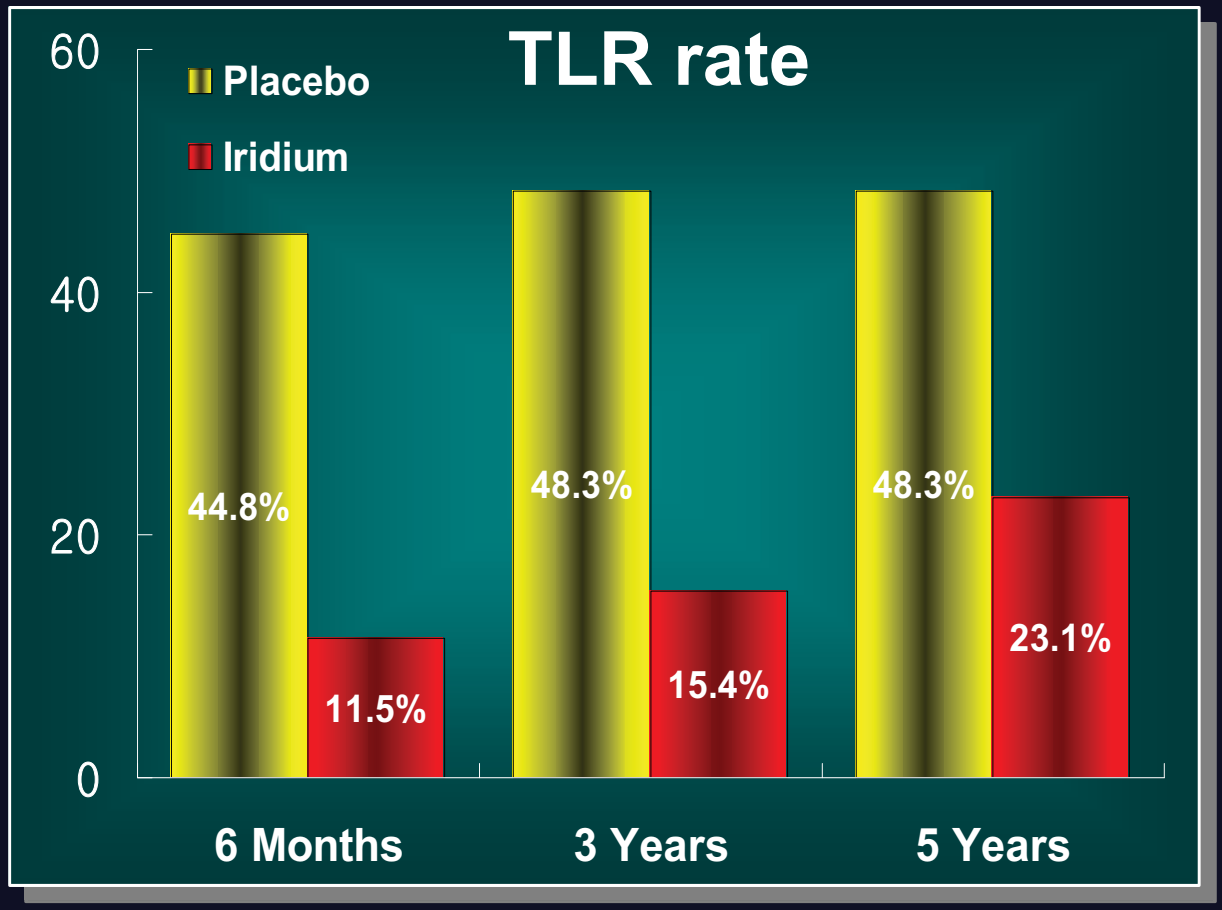


- Randomized trial (n=240)
- Control vs. Low dose vs. High dose group
- Lesion length: 36-80mm
- ^{192}Ir vs. placebo
- 12 mo follow-up

Waksman R, et al. Circulation 2003

Brachytherapy – long term results

SCRIPPS trial – *5 yr results*



- Randomized, double blinded trial(n=55)
- Iridium vs. placebo
- ISR lesion: 62%
- No follow-up loss

Grise MA, et al. Circulation 2002

Drug Eluting Stents

Very little data exist for treating ISR with DES, and the results are conflicting !

Some subgroup still had non-trivial restenosis in SIRIUS trial !

Diameter < 2.5 mm	18.6%
Diabetes	17.6%
Insulin req. DM	35 %

Brachytherapy vs. DES

	Brachytherapy	DES
Long-term data	**Yes !**	Not available
Large trials	**Yes !**	Not available
Very long lesions	**Yes !**	Not available
SVG lesions	**Yes !**	Not available

Problems in Brachytherapy

Still serious ?

Problems in Brachytherapy

- **Devices**
- **Edge restenosis**
- **Stent thrombosis**

Delivery Devices

Complex, difficult to handle, high cost, ….

Rhenium - filled Balloon System

Conventional balloon system

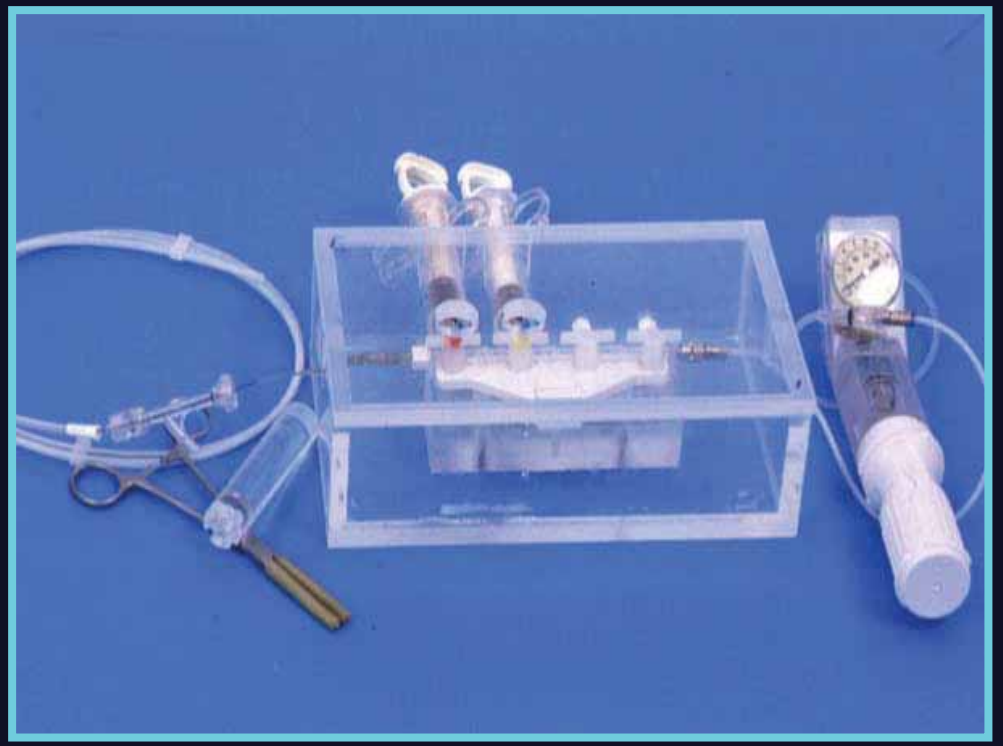
- Simple, inexpensive
- No need of additional system
- Self-centering
- Applicable to various lesions

^{188}Rhenium (Re)

- Easily prepared from

  ^{188}W/^{188}Re generator

- Relatively low cost
- Less radiation hazard



SNUH System

Safety & Feasibility of ^{188}Re-filled Balloon System

- Intracoronary β-irradiation with a liquid 188Re–filled balloon: Six–month results from a clinical safety and feasibility study

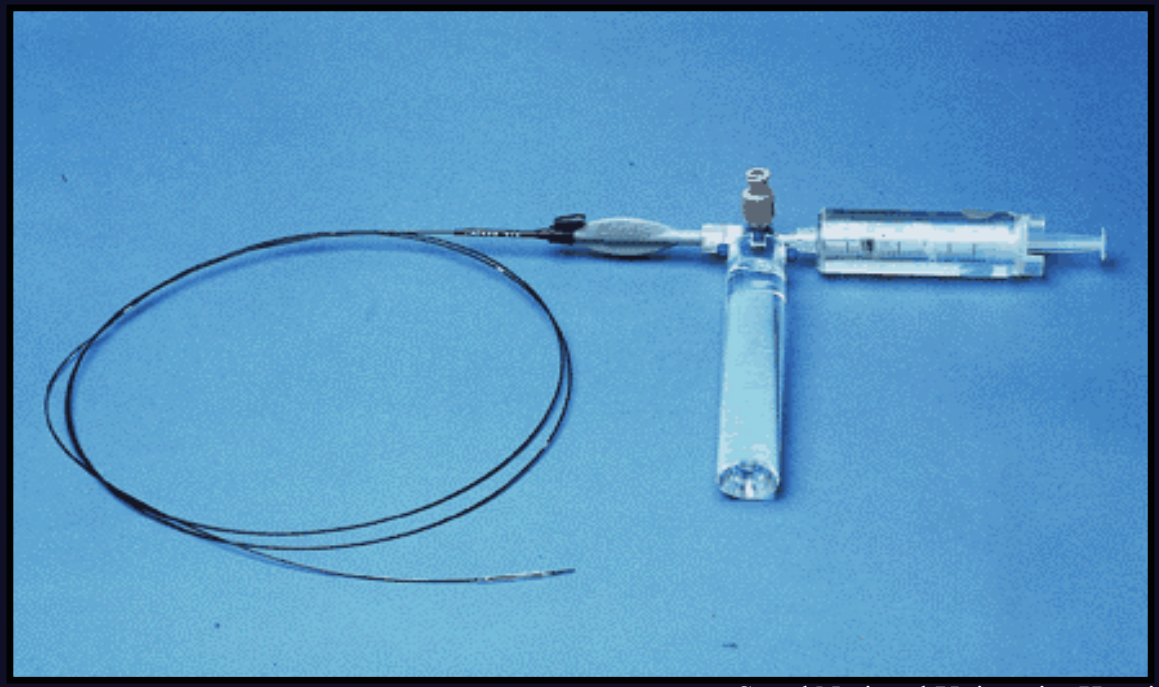
  Hoeher M et al. Circulation 2000

- Treatment of diffuse in-stent restenosis with rotational atherectomy with a rhenium-188-mercaptoacetyltriglycine-filled balloon.

  Park S-W, et al. J Am Coll Cardiol 2001

- Intracoronary β -irradiation with a rhenium-188-filled balloon catheter. A randomized trial in patient with de novo and restenotic lesions.

  Hoeher M et al. Circulation 2003



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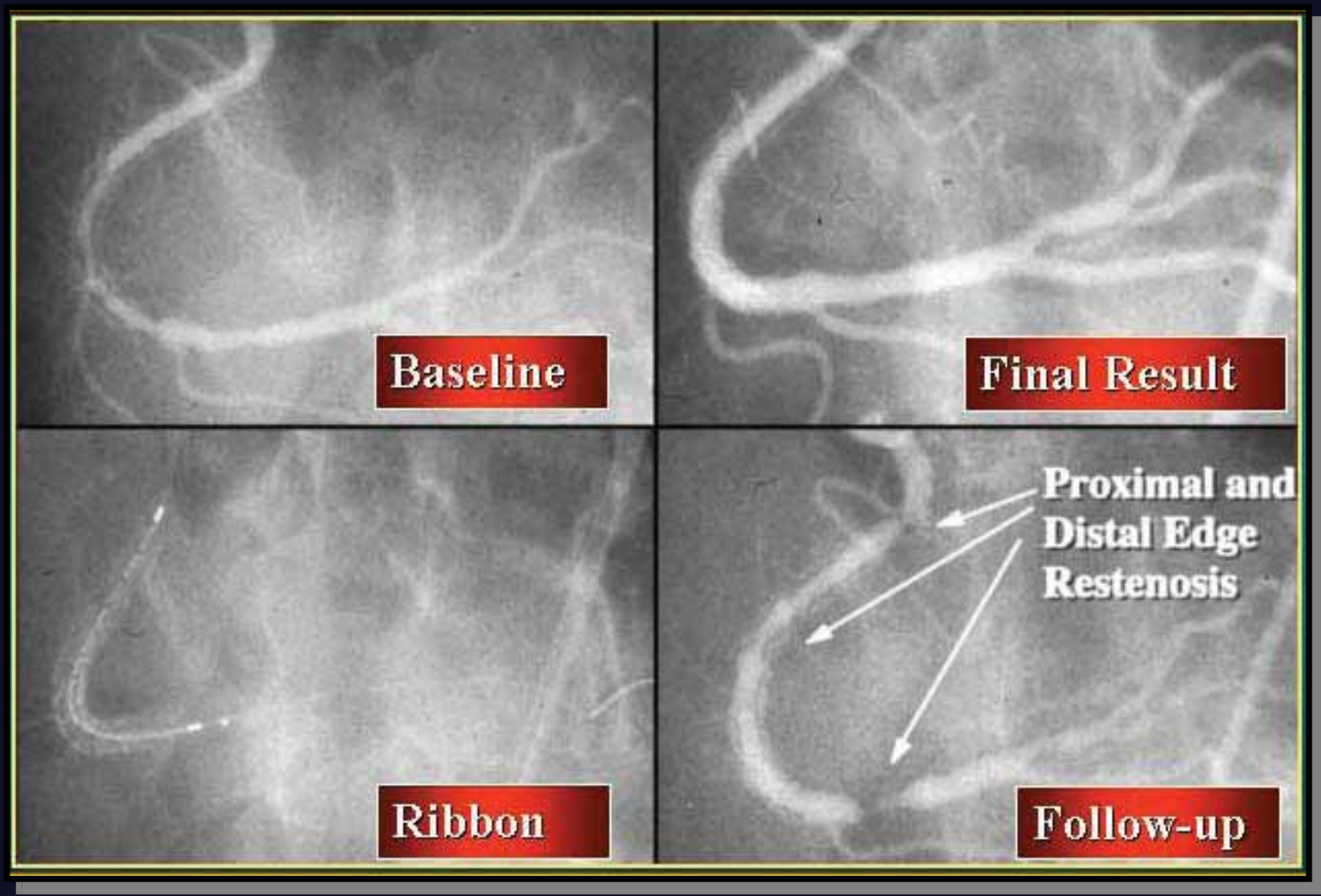
Brachytherapy – *Edge Restenosis*



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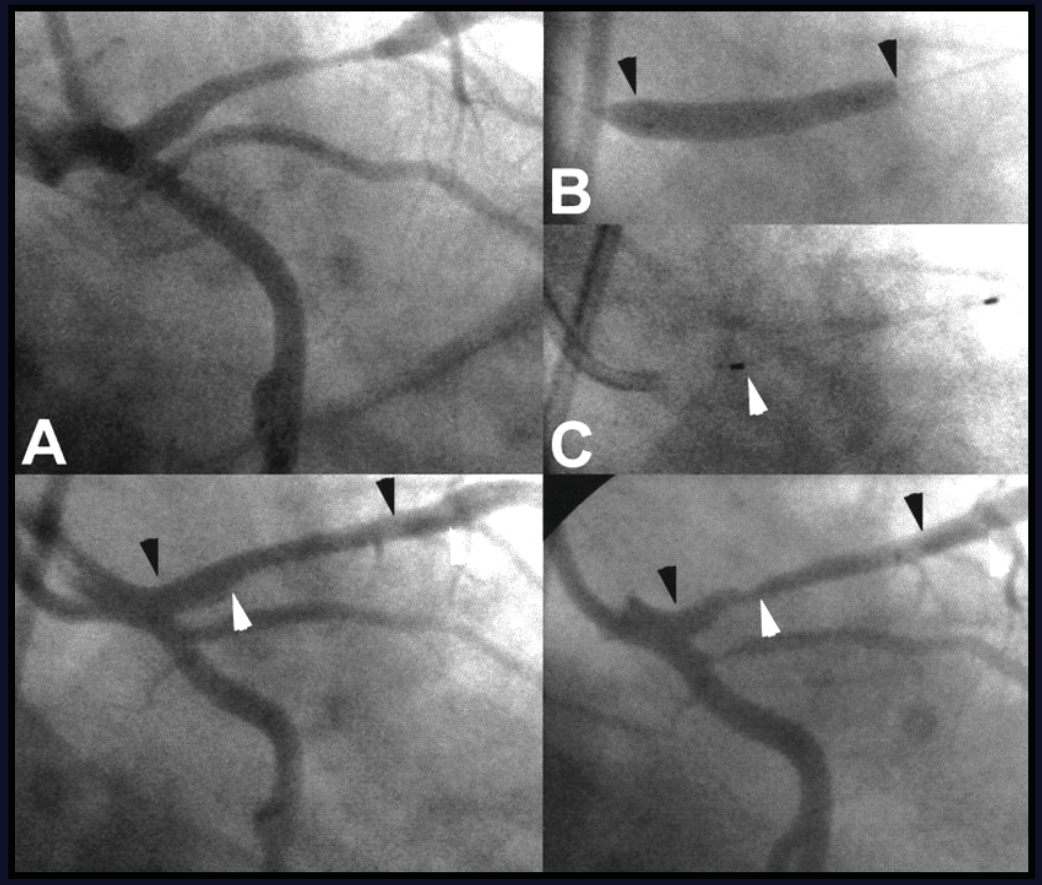
Geographical Miss

Coronary segments that were injured but received low-dose radiation

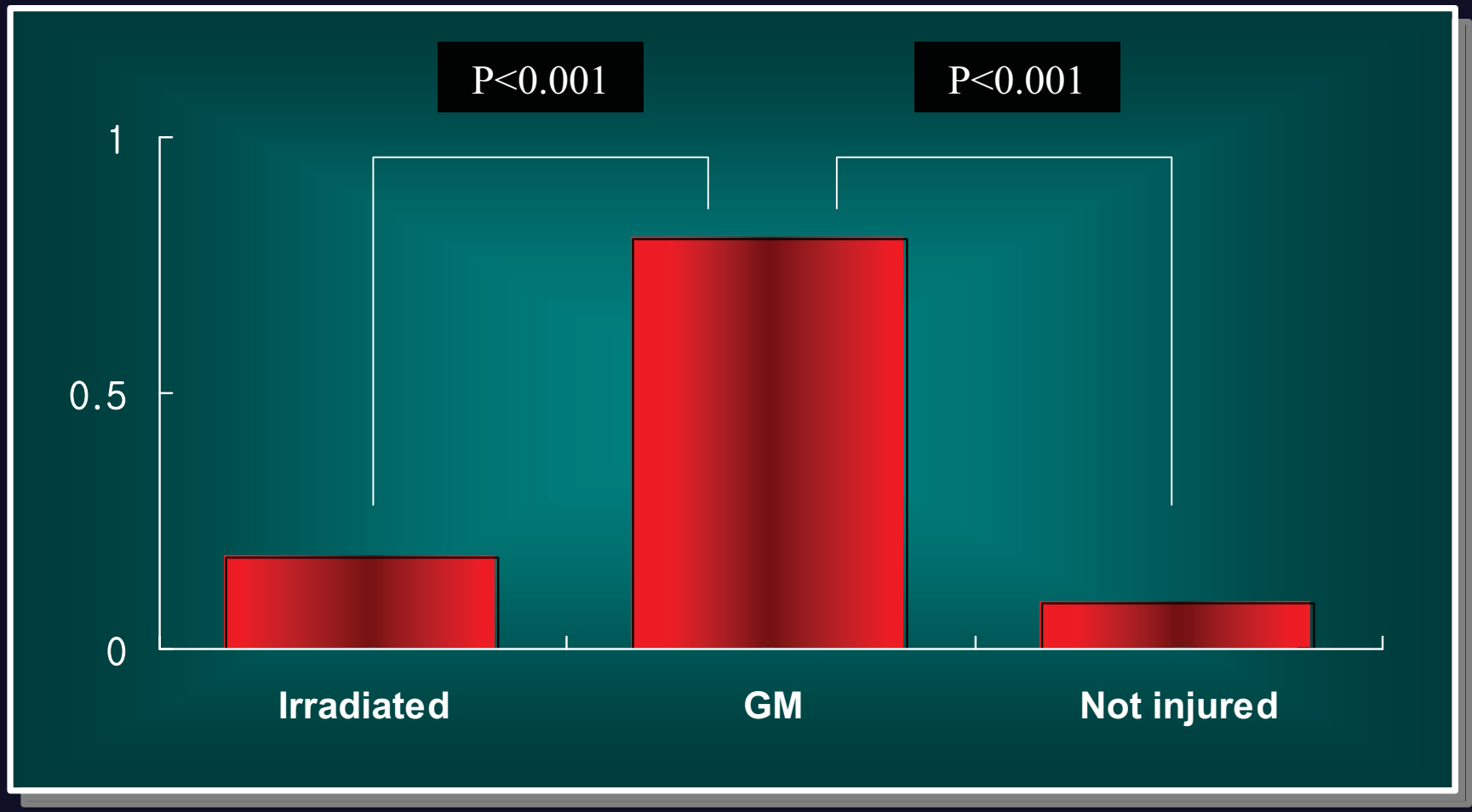
Associated with higher edge restenosis rate



Sabate M, et al Circulation 2000

Geographical Miss

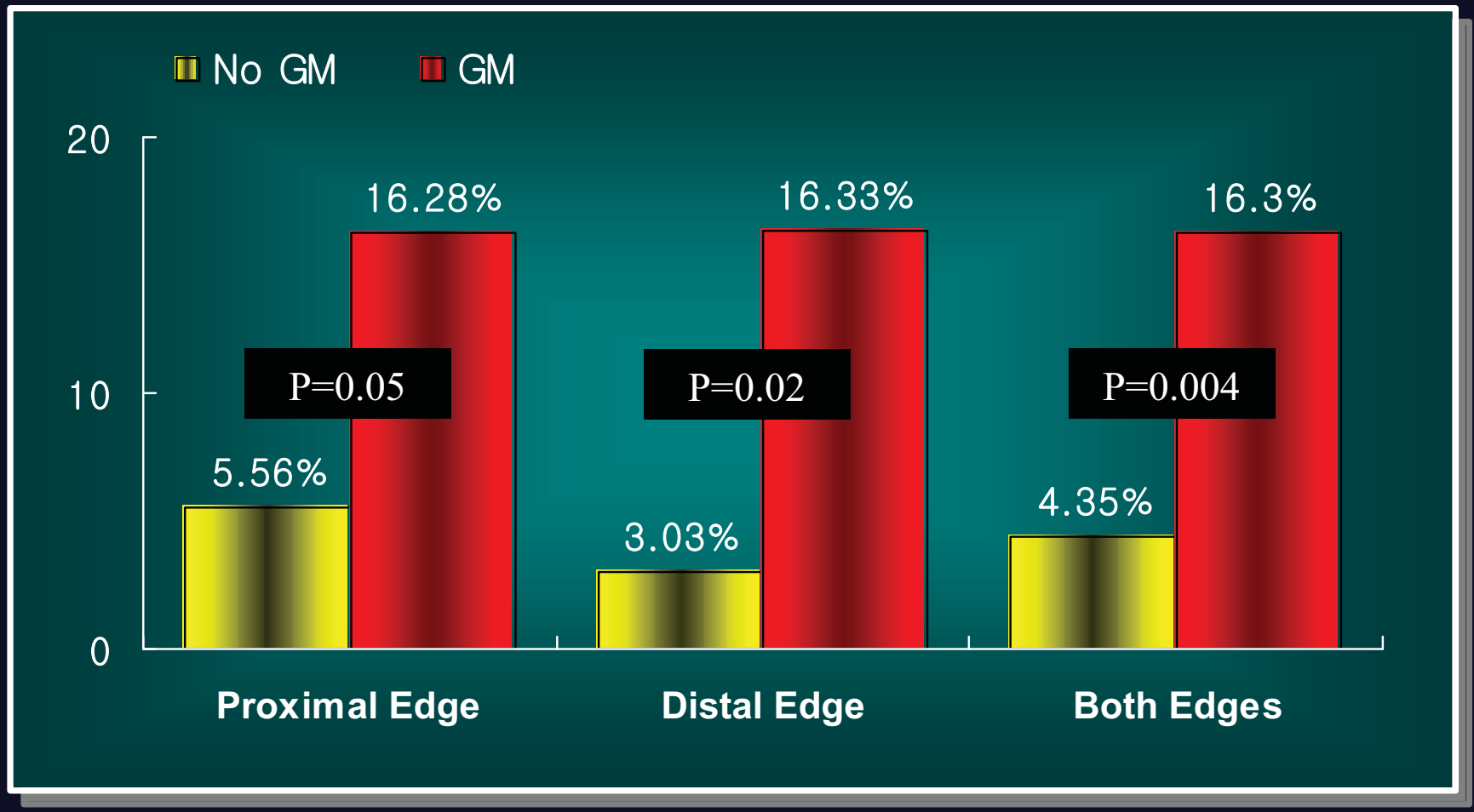
Late loss after irradiation



Sabate M, et al Circulation 2000

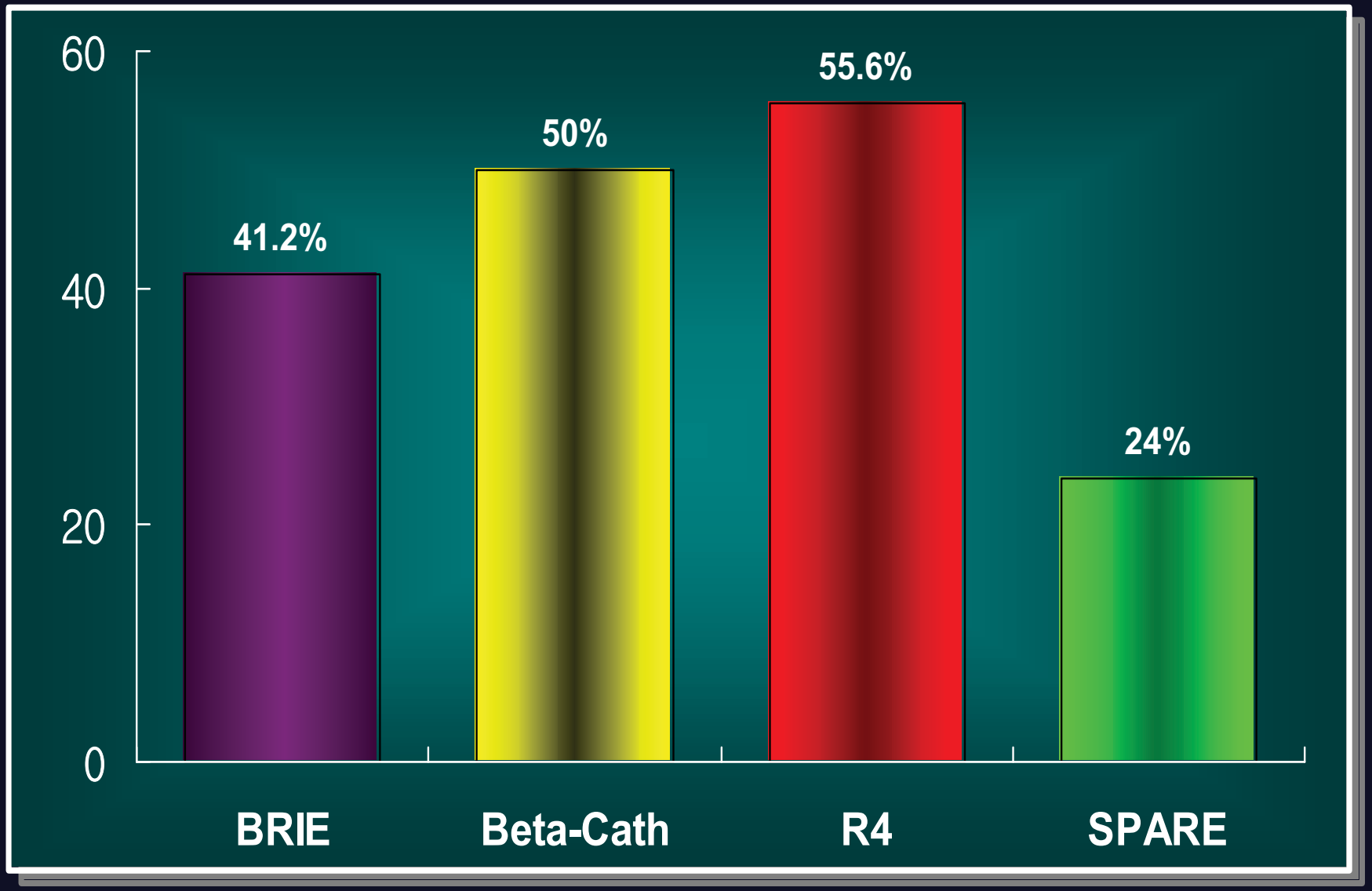
Geographical Miss

Restenosis rate in BRIE trial

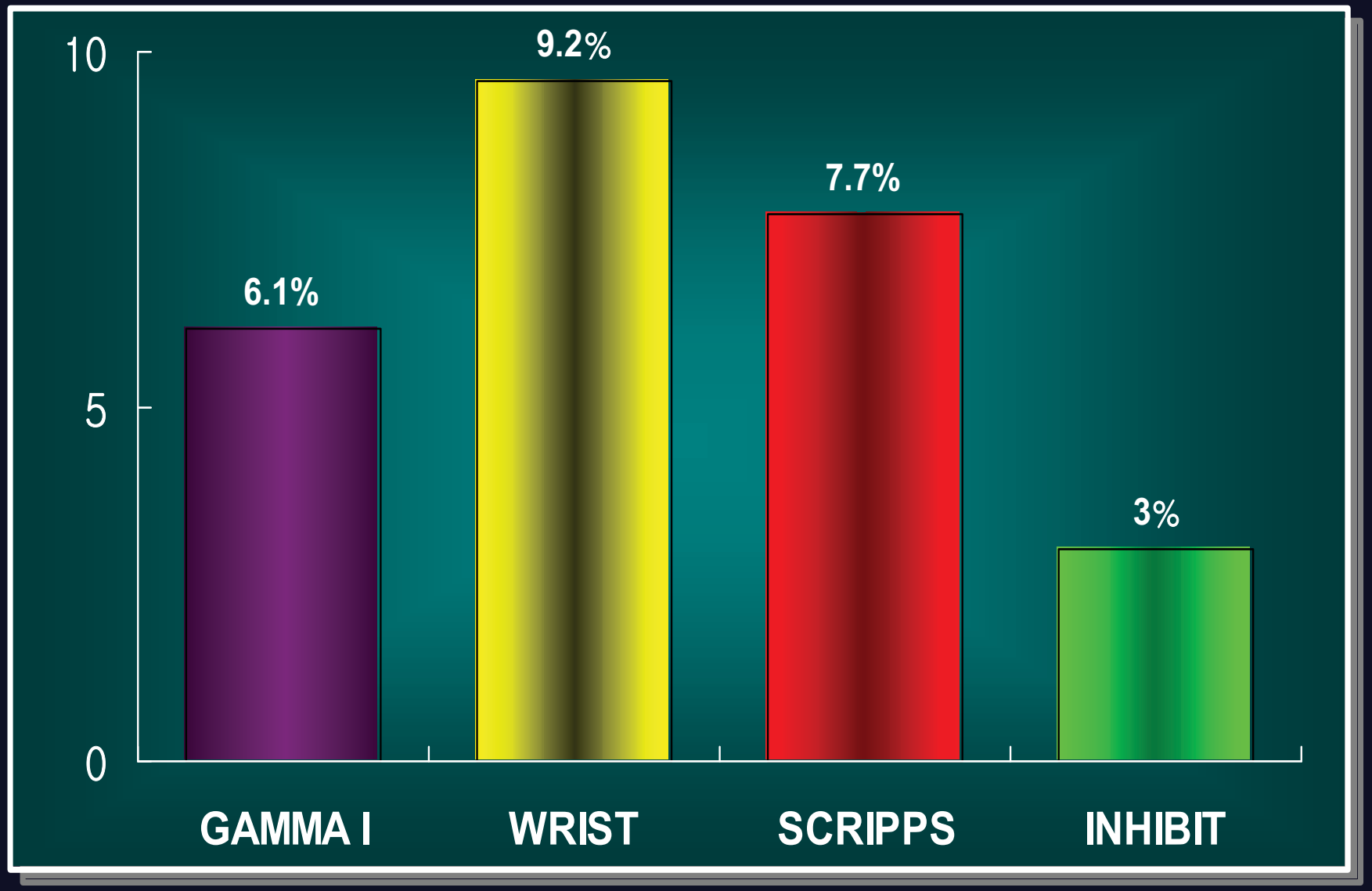


Sianos G, et al JACC 2001

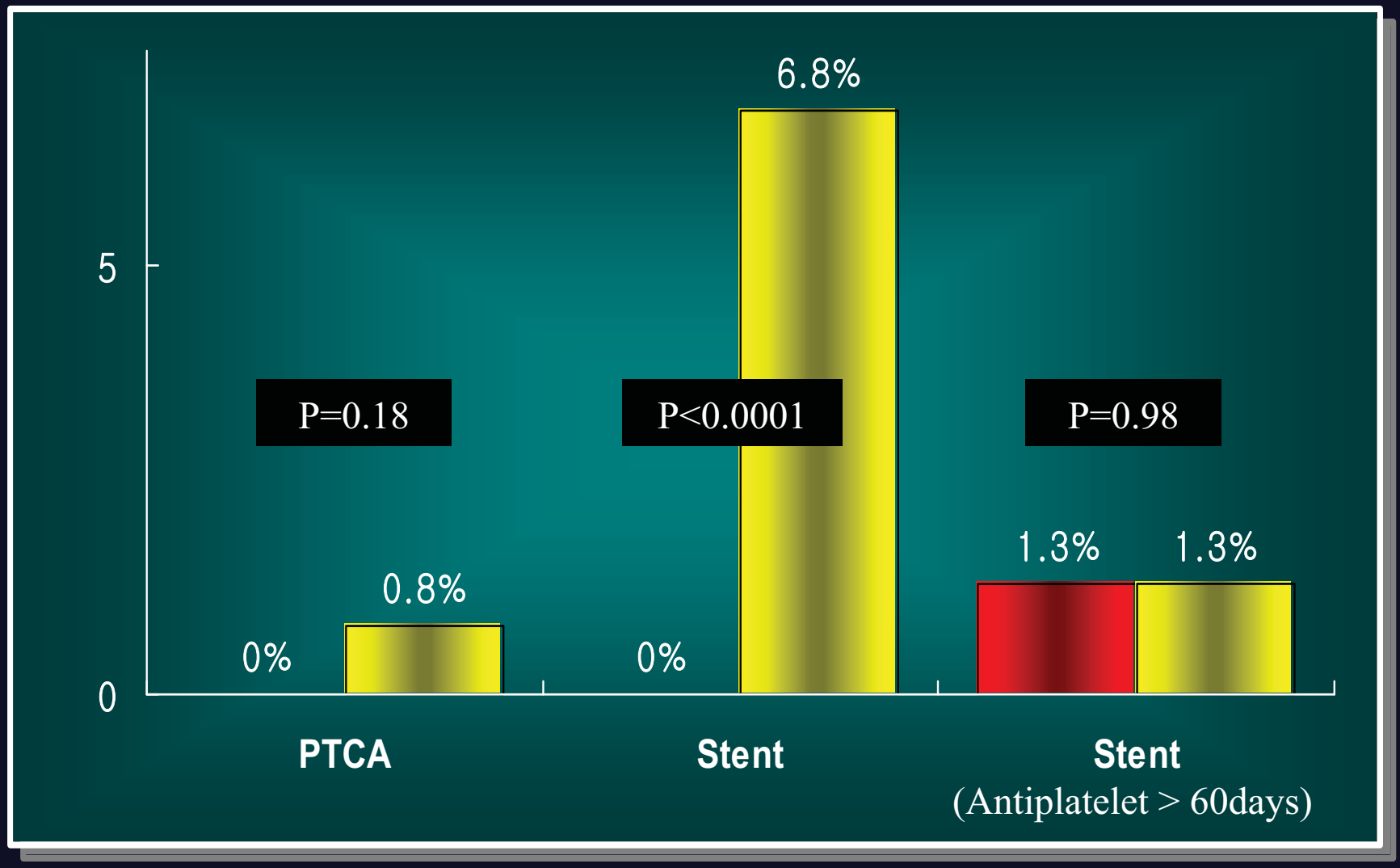
Geographical Miss



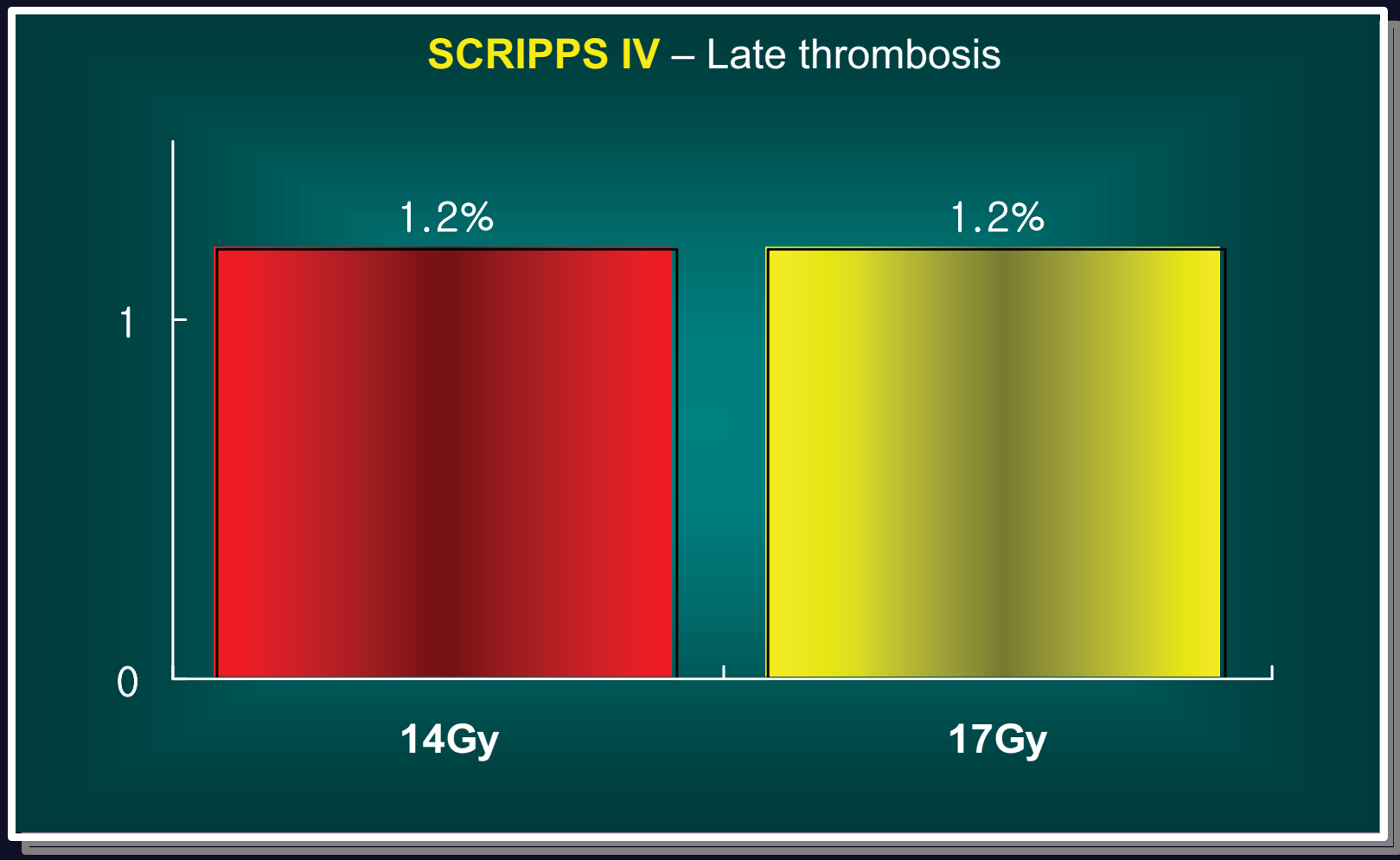
Brachytherapy – *Late total occlusion*



Late total occlusion – Beta-Cath & SCRIPPS IV



Late total occlusion – Beta-Cath & SCRIPPS IV



Summary

- Intracoronary brachytherapy is the only proven modality for the treatment of ISR.
- The problems associated with brachytherapy have been reduced.
- Until now, very little data exist for treating ISR with DES.

Conclusion

Until now, Brachytherapy

is still a standard therapy

for In-stent Restenosis lesions!