

ULTRA

*Unprotected Left Main Trunk Angioplasty
(ULTRA) Registry in Japan*

*Update in ULTRA Registry
--- Is it still risky? ---*

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Unprotected Left Main Trunk Angioplasty

ULTIMA Registry

(Unprotected Left Main Trunk Intervention Multi-center Assessment)

1994-1996, from 25 centers

- ✓ *1st multi-center registry for unprotected LM angioplasty*
- ✓ *1st Report (Ellis SG et al, Circulation 96: 3867-3872, 1997)*
 - 107 pts: 91 pts electively or 16 pts as acute MI*
 - stents(50%), DCA(24%) & POBA(20%)*
 - In-hospital death: Acute MI (n=16) 69%*
 - Elective/CABG candidate (n=68) 5.9%*
 - Elective/not CABG candidate (n=23) 30.4%*
 - Cardiac death within 6 mos after PCI: 10.6%*

Unprotected Left Main Trunk Angioplasty

ULTIMA Registry (1st Report)

(Unprotected Left Main Trunk Intervention Multi-center Assessment)

1994-1996, from 25 centers

- ✓ *Initial results for selected pts appear promising,*
- ✓ *LM angioplasty should not be considered an alternative to CABG, until early cardiac death after discharge can be minimized.*
- ✓ *F/u angiogram 6 to 8 wks after PCI is advisable.*

Unprotected Left Main Trunk Angioplasty

ULTIMA Registry (Final Report)

(Unprotected Left Main Trunk Intervention Multi-center Assessment)

1993-1998, from 25 centers

- ✓ *Tan WA, et. Circulation 104:1609-14, 2001*
- ✓ *279 pts: 46% inoperable or at high surgical risk
stents(69%), DCA(17%) & POBA(15%)
In-hospital death: 13.7%*
- ✓ *32% pts <65yrs with LVEF>30% and without shock:
no in-hospital death and 3.4% 1-y-mortality*

ULTIMA Registry (Final Report)

(Unprotected Left Main Trunk Intervention Multi-center Assessment)

1993-1998, from 25 centers n=279 pts

Correlates of All-cause Mortality (In-hospital and during F/U)

<i>Event</i>	<i>% of Study Population</i>	<i>Hazard Ratio</i>	<i>95% CI</i>	<i>p</i>
<i>LVEF(<30%)</i>	14.3	4.21	2.27-7.81	0.001
<i>MR grades 3 or 4</i>	4.1	3.66	1.61-8.30	0.001
<i>Cardiogenic shock</i>	13.7	3.56	1.73-7.34	0.001
<i>Cr > 2 mg/dl</i>	5.8	3.10	1.30-7.39	0.001
<i>Severe lesion calc.</i>	8.9	2.32	1.13-4.76	0.022

Tan WA, et. Circulation 104:1609-14, 2001

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ULTIMA Registry (Final Report)

(Unprotected Left Main Trunk Intervention Multi-center Assessment)

1993-1998, from 25 centers n=279

In conclusion,

- ✓ ***LMT PCI may be an alternative to CABG for a select population proportion of elective pts,***
- ✓ ***may also be appropriate for highly symptomatic inoperable pts.***
- ✓ ***Meticulous follow-up of hospital survivor is required.***

Tan WA, et. *Circulation* 104:1609-14, 2001

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Results and Long-term Predictors of Adverse Clinical Events after Elective PCI on ULMTD

(Takagi T, et al. Circulation 106:698-702, 2002)

- ✓ ***67 pts in Centro Cuore Columbus, 1993-2001***
*Stents (n=39) , DCA/Stent (n=13), Rotastent (n=12),
DCA alone (n=3)*
- ✓ ***3-y Mortality: 9%***
- ✓ ***Restenosis: 31.4%, TVR 23.9%***
- ✓ ***Independent covariate of cardiac death: preserved LV function***
- ✓ ***The most important predictors of favorable follow-up:
Ref. vessel size and LV function***

***Elective ULMT angioplasty has good long-term results
in pts with low surgical risk and large reference vessel size.***

Elective Stenting of Unprotected LM Coronary Artery Stenosis

***-- Effect of Debulking before Stenting and IVUS Guidance—
(Park SJ, et al. J Am Coll Cardiol 38:1054-60, 2001)***

- ✓ ***127 pts with ULMD and normal LV function***
 - IVUS guide (n=77) vs. Angio. guide (n=50)*
 - debulking+stent (n=40) vs. stenting alone (n=87)*
- ✓ *Larger lumen in IVUS guide*
- ✓ *Lower restenosis in debulking+stent (8.3% vs.25%)*
- ✓ ***2-y Mortality: 3%***

***Stenting for ULMTD might be favorable long-term results
in selected pts and debulking before stenting seems to be
effective in reducing the restenosis.***

ULTRA

*Unprotected Left main TRunk Angioplasty
(ULTRA) Registry in Japan*

ULTRA I Registry: 7 centers

ULTRA II Registry: 12 centers



Purpose

We evaluated the immediate and long-term outcomes of consecutive patients undergoing unprotected left main coronary artery angioplasty, considered unsuitable for coronary artery bypass graft surgery or who desired angioplasty, in a multicenter registry.

Methods

- *Emergent and elective angioplasty for unprotected left main trunk disease (LMD)*
- *Registration:*
 - ULTRA I: Jan. 1, 1996 ~ Dec.31, 2000*
 - ULTRA II: Jan. 1, 2001 ~ Until DES approval*
- *Study Design: Multicenter prospective study*

ULTRA

The ULTRA I Study

The Unprotected Left main TRunk Angioplasty Study *Investigators*

Hideo Nishikawa, Kazuki Nakajima; Yamada Red Cross Hospital
Hideo Tamai, Kunihiro Kosuga; Shiga Medical Center for Adults
Tohru Kobayashi, Etsuo Tsuchikane; Osaka Medical Center for Cancer
and Cardiovascular Diseases
Osamu Katoh; Kyoto Katsura Hospital
Yoshiaki Yokoi; Kishiwada Tokusyukai Hospital
Kinzo Ueda; Takeda Hospital
Takahiko Suzuki, Mariko Ehara; Toyohashi Heart Center

Inclusion Criteria

- *De novo unprotected left main trunk disease*
- *Left main stenosis > 50%*
- *Need for revascularization*
- *The absence of patent bypass graft
to the left coronary artery*

Exclusion Criteria

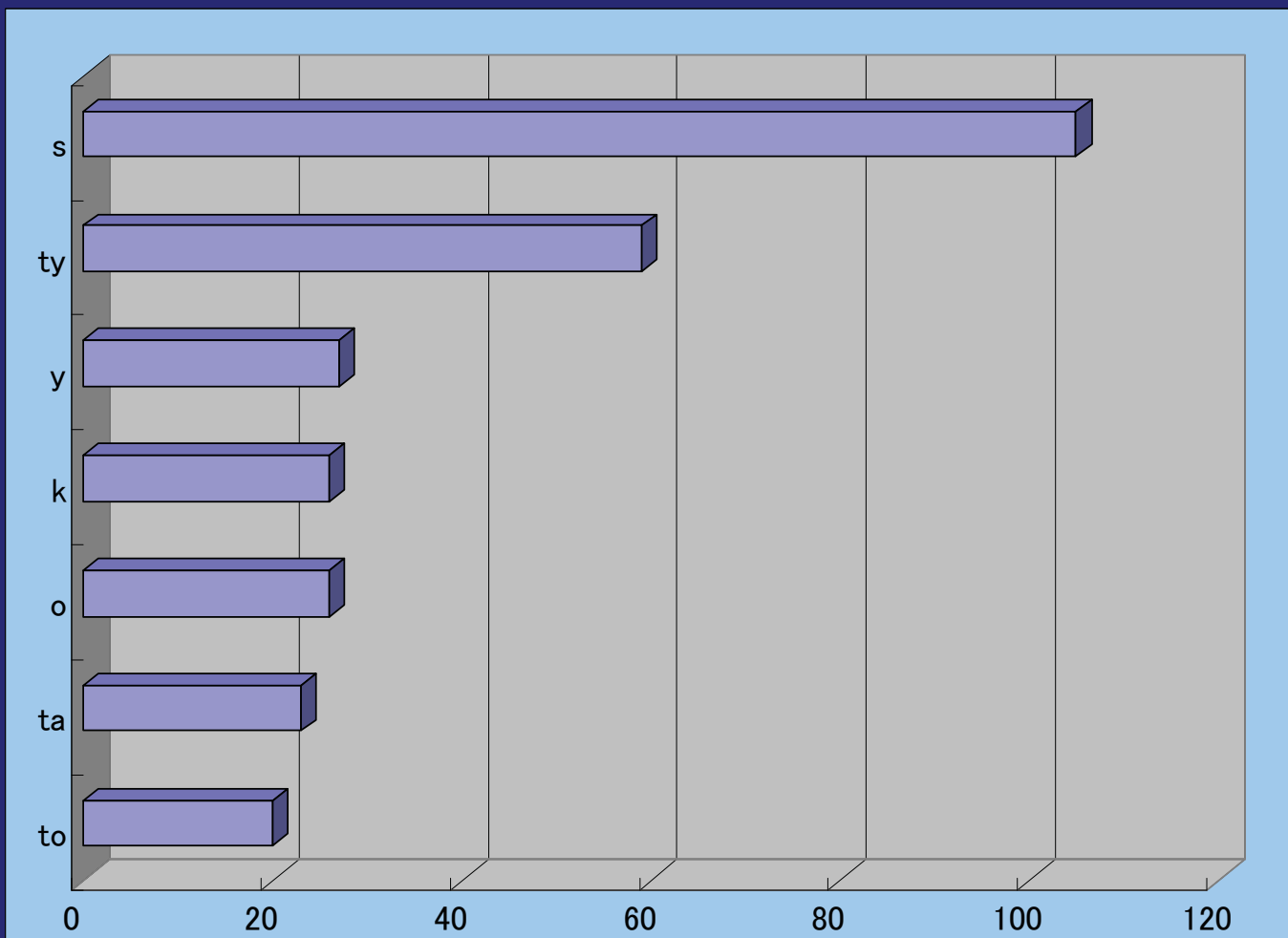
- *Catheter-induced left main stenosis*
- *The presence of good collateral flow from the right coronary artery*



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The ULTRA I Study

Patients registered: n=284



1996.1-2000.12

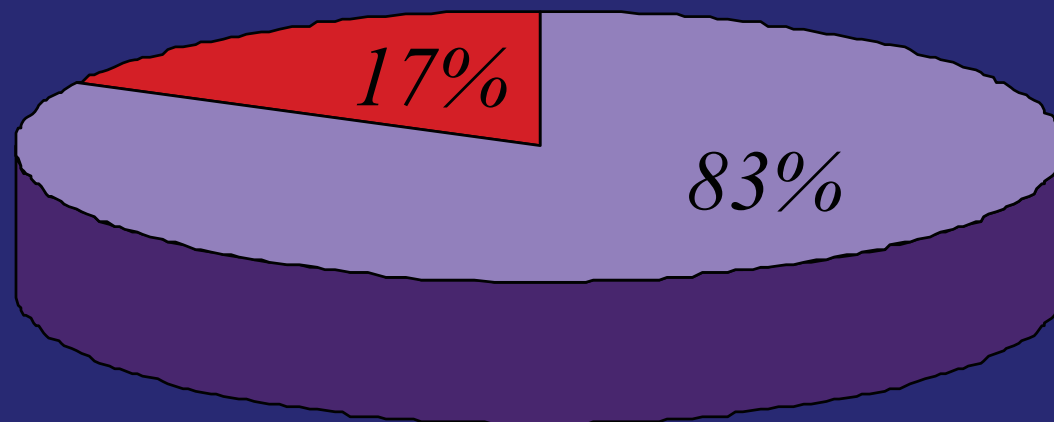
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Patients registered: n=284

1996.1-2000.12

AMI 50



Non-AMI 234

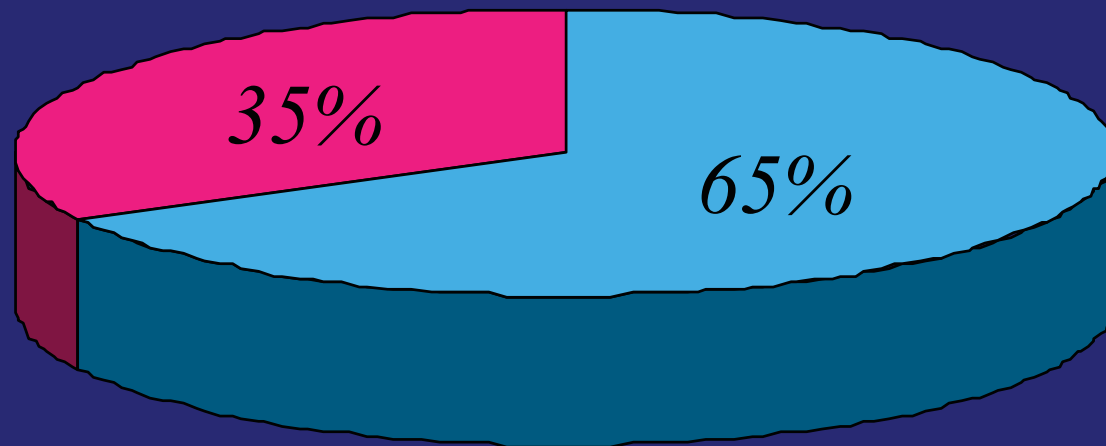
AMI: related to LM lesion

ULTRA

Patients registered: n=284

1996.1-2000.12

Emergent 101

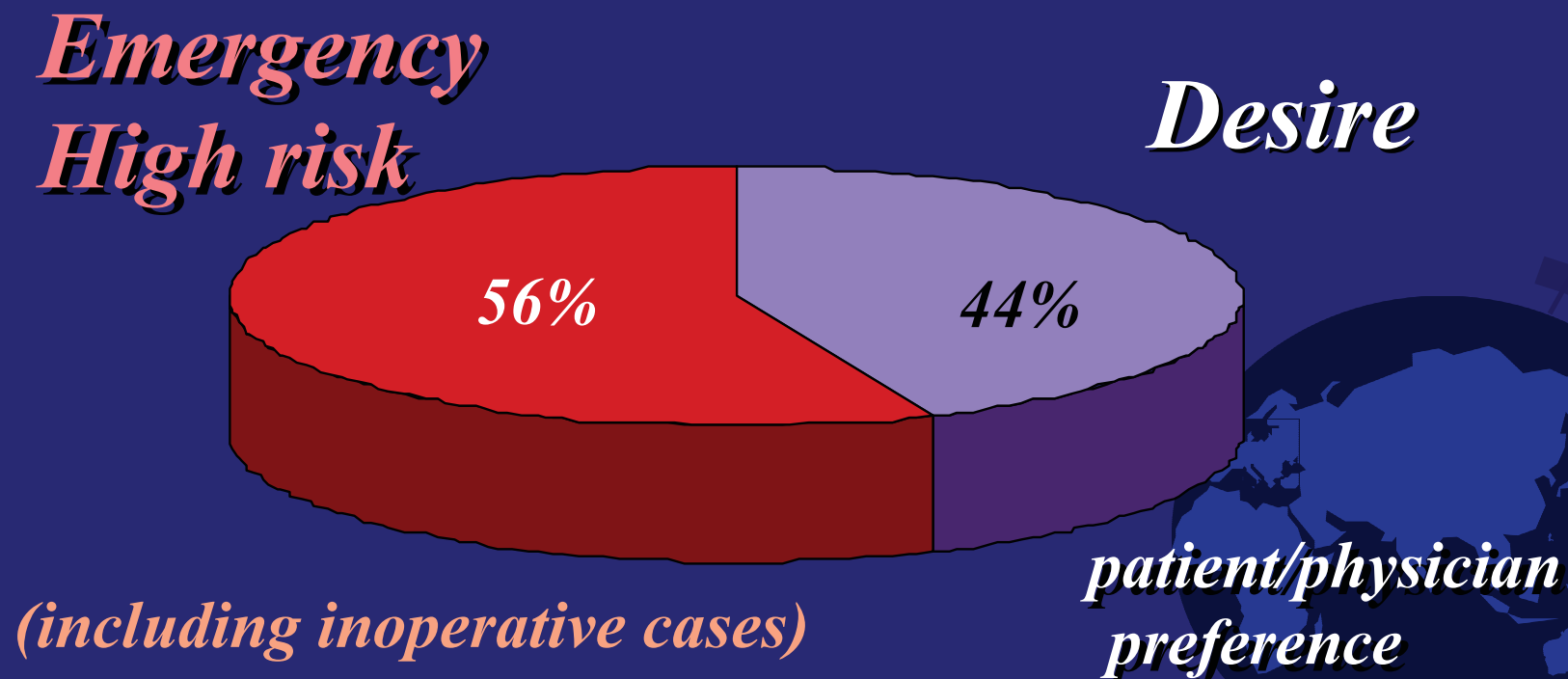


elective 183



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Reason for Catheter Intervention



Clinical Characteristics (1)

n=284

<i>Age (yr)</i>	<i>68 ± 10</i>
<i>Male gender (%)</i>	<i>79</i>
<i>Acute myocardial infarction (%)</i>	<i>17</i>
<i>Recent myocardial infarction (<2wks)(%)</i>	<i>11</i>
<i>Stable angina (%)</i>	<i>33</i>
<i>Unstable angina (%)</i>	<i>27</i>
<i>Prior myocardial infarction (%)</i>	<i>37</i>
<i>Prior CABG (%)</i>	<i>7</i>



Clinical Characteristics (2)

n=284

LVEF (%)

52 ± 17

Coronary Risk Factors;

Diabetes mellitus (%)

36

Current smoker (%)

37

Hypercholesterolemia (%)

39

Hypertension (%)

54

Obesity (%)

11



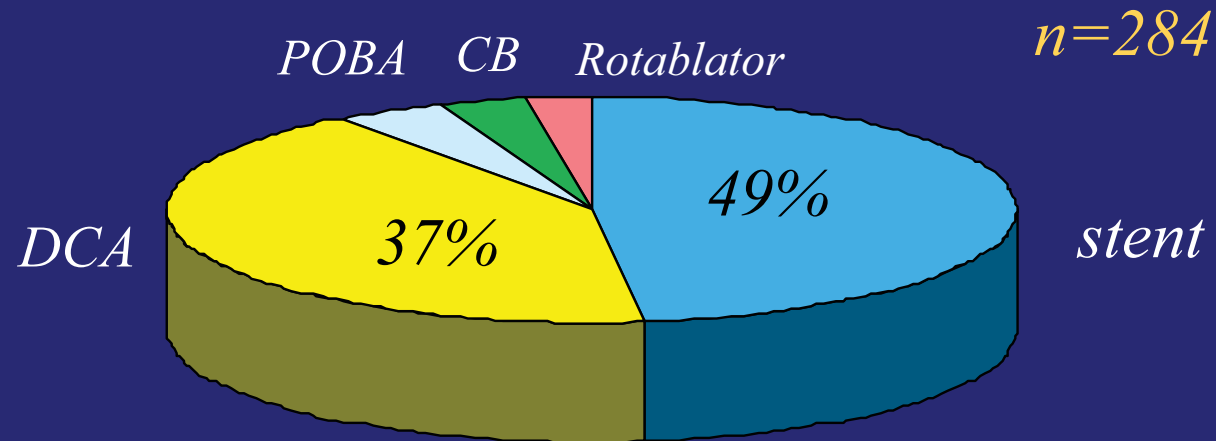
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Angiographic Characteristics

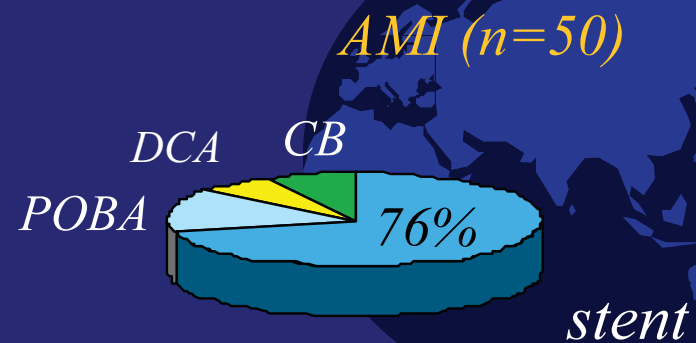
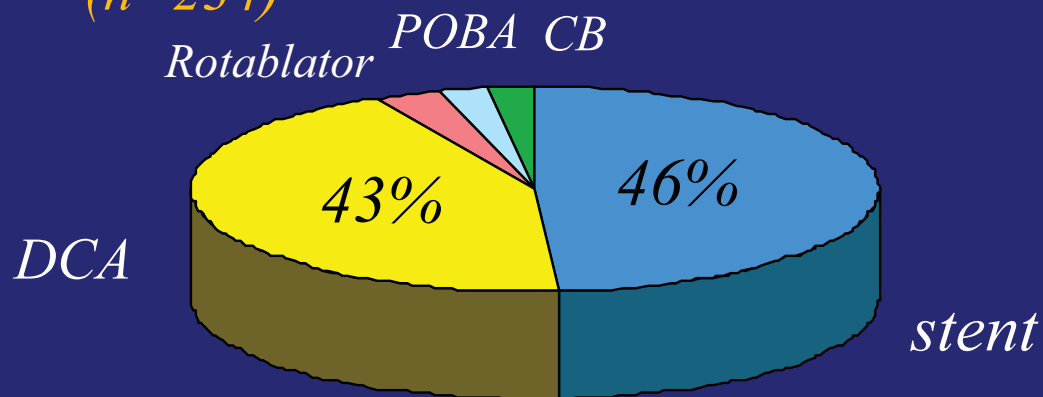
<i>Lesion length (mm)</i>	8.1 ± 4.9
<i>Lesion location (%)</i>	
<i>Ostial</i>	31
<i>Midshaft</i>	35
<i>Distal</i>	59
<i>LVEF</i>	0.49 ± 0.20
<i>No. of diseased vessels except LMD (%)</i>	
<i>Zero / One / Two / Three</i>	7 / 31 / 39 / 23
<i>Reference diameter (mm)</i>	3.3 ± 0.6
<i>Percent stenosis (%)</i>	65 ± 15

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Final Procedure



*non-AMI
(n=234)*



Procedural Characteristics

Type of stent (%)

P-S stent

29

ML stent

21

gfx/s670 stent

18

NIR stent

15

Wiktor stent

12

GR stent

5

IABP (%)

57

PCPS (%)

8



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Angiographic Results

Reference diameter (mm)

Pre

3.3 ± 0.6

Post

3.7 ± 0.6

Diameter stenosis (%)

Pre

64.7 ± 14.2

Post

12.5 ± 12.6

Follow-up

30.6 ± 16.7

Minimal lumen diameter (mm)

Pre

1.2 ± 0.5

Post

3.1 ± 0.6

Follow-up

2.6 ± 0.7

Maximal balloon inflation pressure (atm)

13.0 ± 2.4

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Initial Results in Patients with AMI

n=50

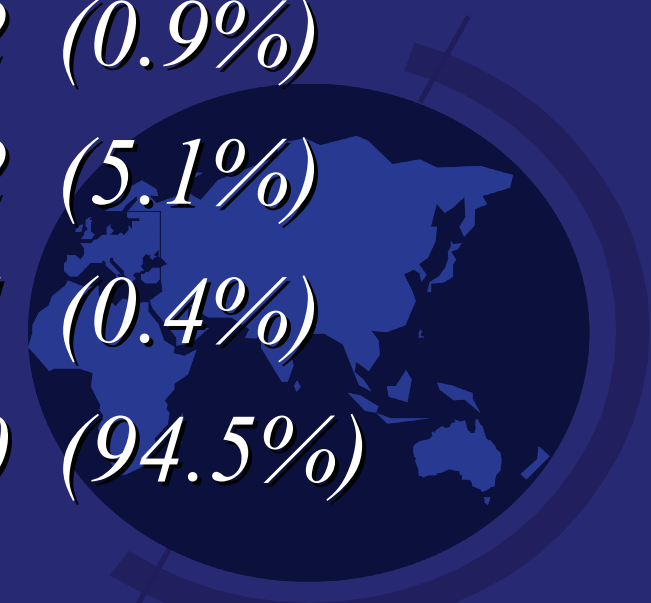
<i>Procedural success (%)</i>	<i>49 / 50 (98%)</i>
<i>In-hospital death</i>	<i>17 / 50 (34%)</i>
<i>Emergency CABG</i>	<i>2 / 50 (4%)</i>
<i>Elective CABG</i>	<i>3 / 50 (6%)</i>
<i>Clinical success</i>	<i>32 / 50 (64%)</i>

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Initial Results in Patients without AMI

n=234

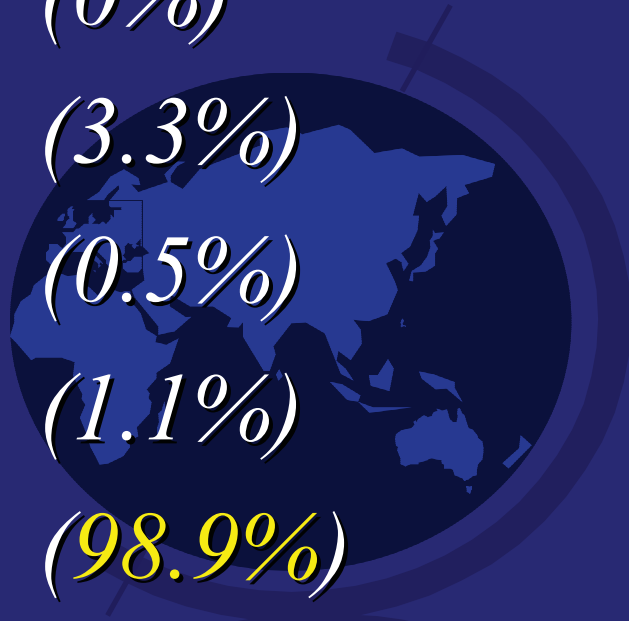
<i>Procedural success</i>	<i>233 (99.6%)</i>
<i>In-hospital death</i>	<i>11 (4.7%)</i>
<i>Q-MI</i>	<i>2 (0.9%)</i>
<i>nonQ-MI</i>	<i>12 (5.1%)</i>
<i>Emergency CABG</i>	<i>1 (0.4%)</i>
<i>Clinical success</i>	<i>220 (94.5%)</i>



Initial Results in Elective Cases

n=183

<i>Procedural success</i>	<i>182 (99.5%)</i>
<i>In-hospital death</i>	<i>1 (0.5%)</i>
<i>Q-MI</i>	<i>0 (0%)</i>
<i>nonQ-MI</i>	<i>6 (3.3%)</i>
<i>Emergency CABG</i>	<i>1 (0.5%)</i>
<i>CVA</i>	<i>2 (1.1%)</i>
<i>Clinical success</i>	<i>181 (98.9%)</i>



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Late Outcomes

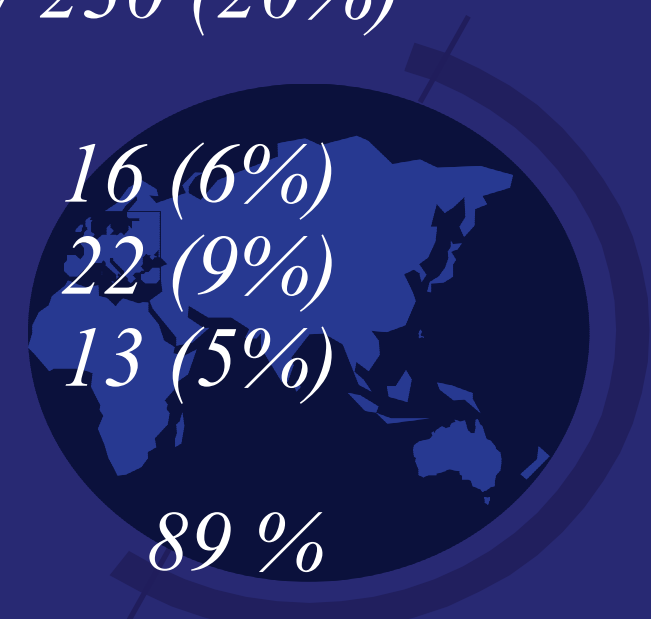
n=247

Follow-up (months) *29.8 ± 10.9*
Clinical follow-up rate (>1yr) *97 %*

Restenosis *51 / 230 (22%)*
TLR *47 / 230 (20%)*

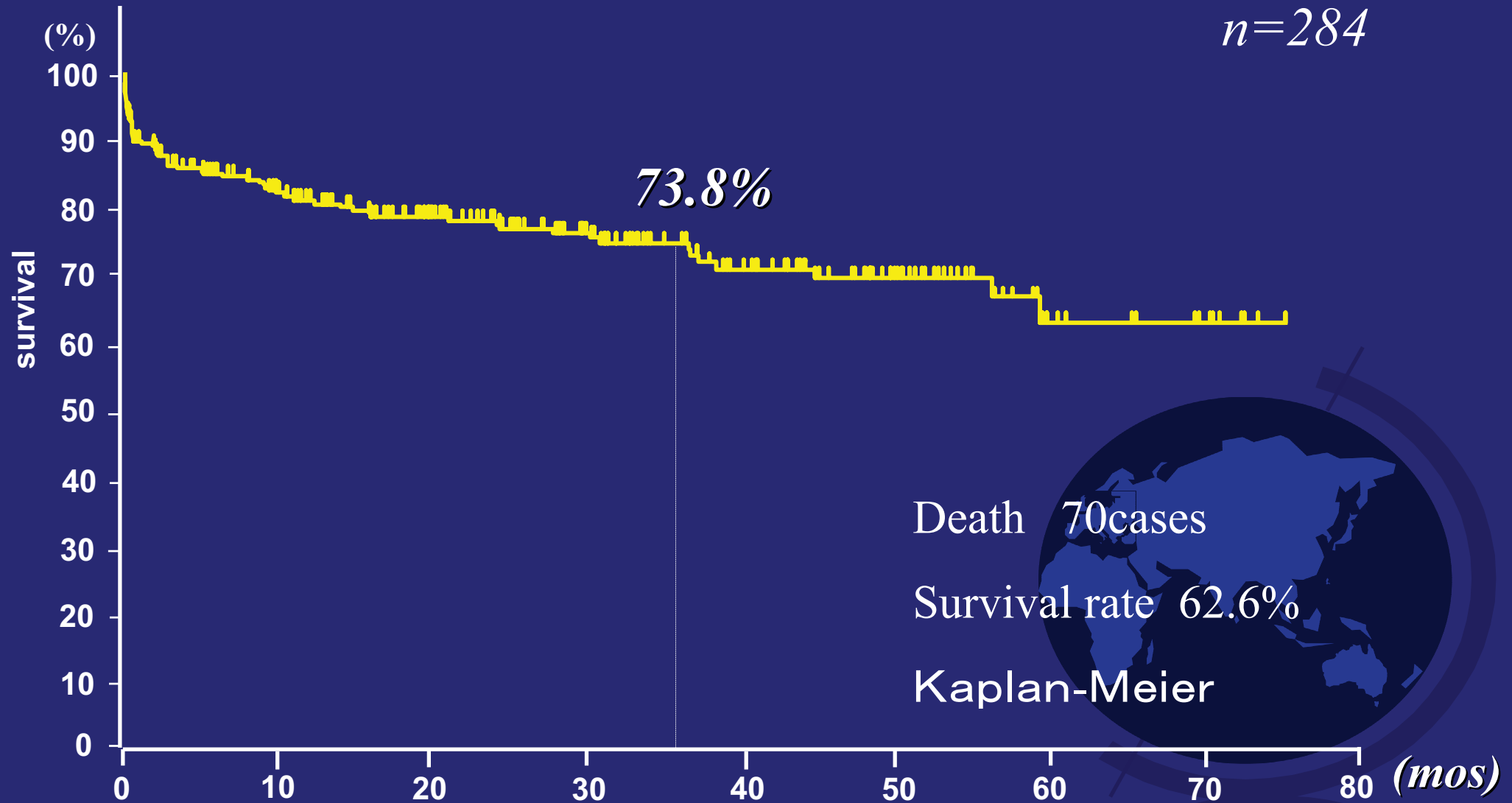
Cardiac Death *16 (6%)*
MI *22 (9%)*
CABG *13 (5%)*

1-Y-Event (MACE) free survival *89 %*



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Overall Cumulative Survival Curve

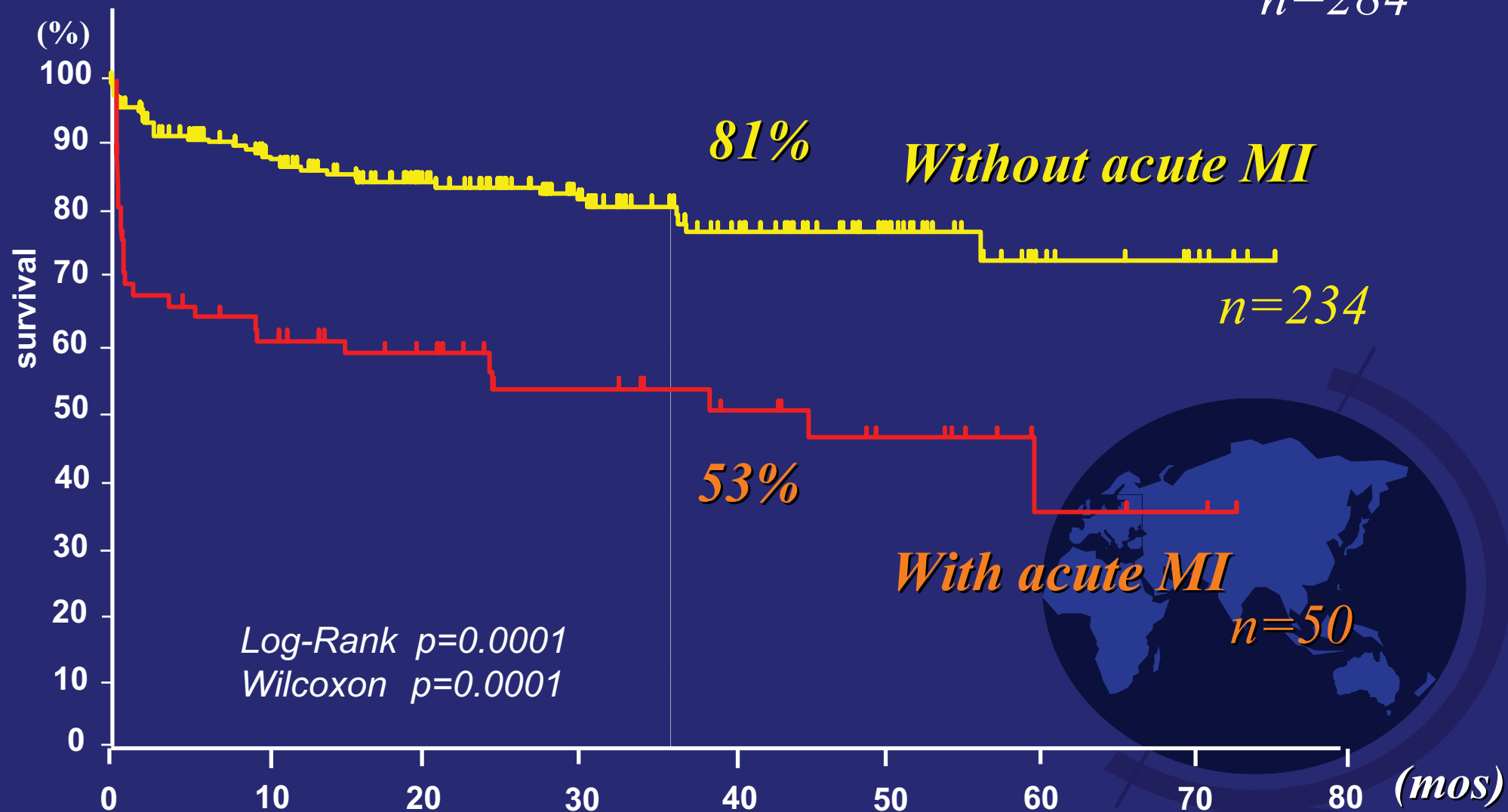


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Cumulative Survival Curve

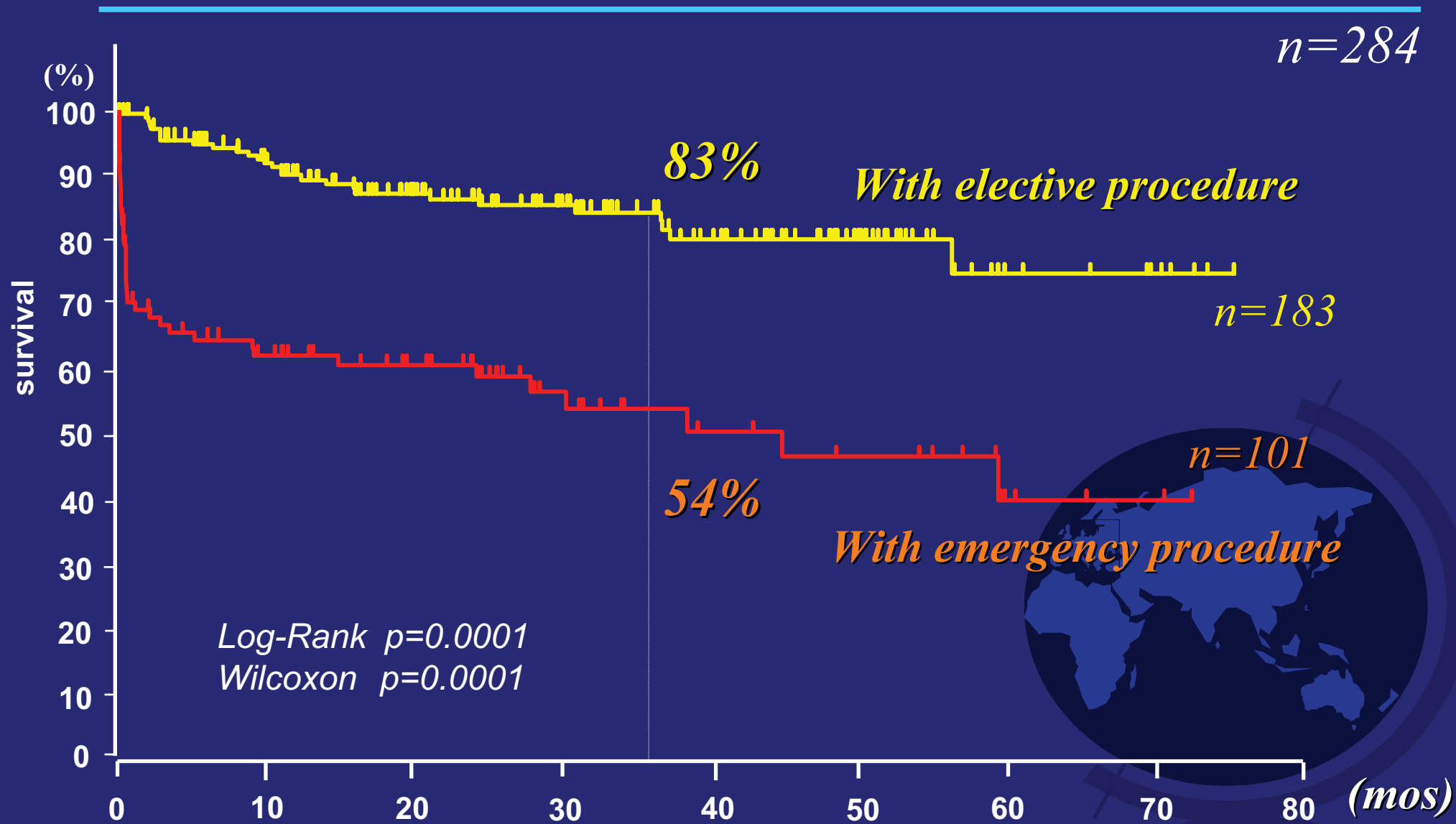
$n=284$



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Cumulative Survival Curve



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Contemporary surgical outcomes

***Spectrum of surgical risk for LM stenoses:
Benchmark for potentially competing PCI***

(Ellis SG, et al. Am Heart J 135: 335-8, 1998)

- ✓ ***Cleveland Clinic Foundation, 1990-1995***
- ✓ ***Overall In-hospital Mortality: 2.3% (for 1585 pts)***
Correlates: Renal insuff., Age & CHF(class 3or4)

- ✓ ***Overall 3-y Mortality: 15.6%***
Correlates: Age, Renal insuf., COPD

Group I: 4.5%

Group II: 6.5%

Group III: 20.0%

Group IV: 39.8% (high risk)

0.5%~4.7%

17~19%

<46%

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ULTRA

The ULTRA II Study

The Unprotected Left main TRunk Angioplasty Study

Investigators

Hideo Nishikawa;

Hideo Tamai, Kunihiko Kosuga;

Tohru Kobayashi, Etsuo Tsuchikane;

Osamu Katoh;

Yoshiaki Yokoi;

Kinzo Ueda;

Yasushi Asakura;

Kenshi Fujii;

Haruo Hirayama;

Hiroataka Oda;

Akitsugu Oida;

Takahiko Suzuki, Mariko Ehara;

Yamada Red Cross Hospital

Shiga Medical Center for Adults

*Osaka Medical Center for Cancer
and Cardiovascular Diseases*

Kyoto Katsura Hospital

Kishiwada Tokusyukai Hospital

Takeda Hospital

Keio University Hospital

Sakurabashi Watanabe Hospital

Nagoya Daini Red Cross Hospital

Niigata City General Hospital

Dokkyo University Hospital

Toyohashi Heart Center

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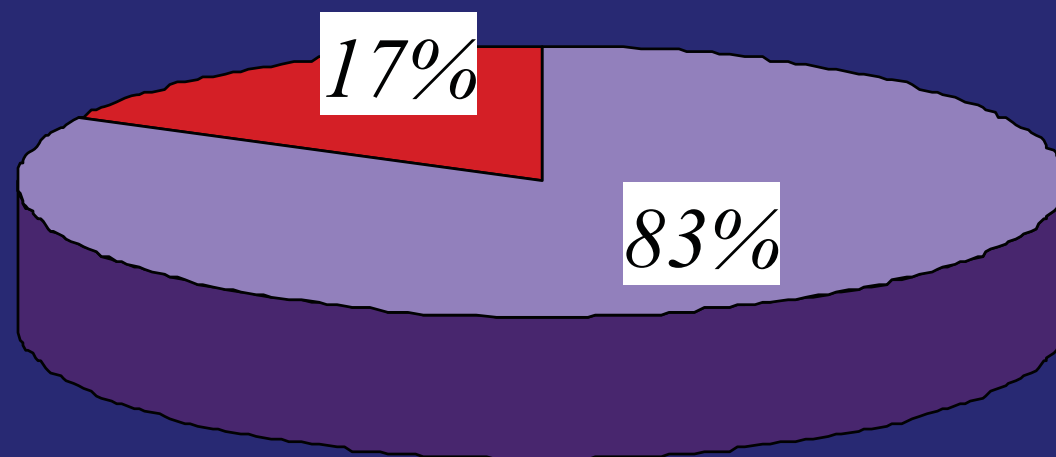
ULTRA

ULTRA II

Patients registered: n=178

2001.1-2003.9

AMI 31



Non-AMI 147

AMI: related to LM lesion



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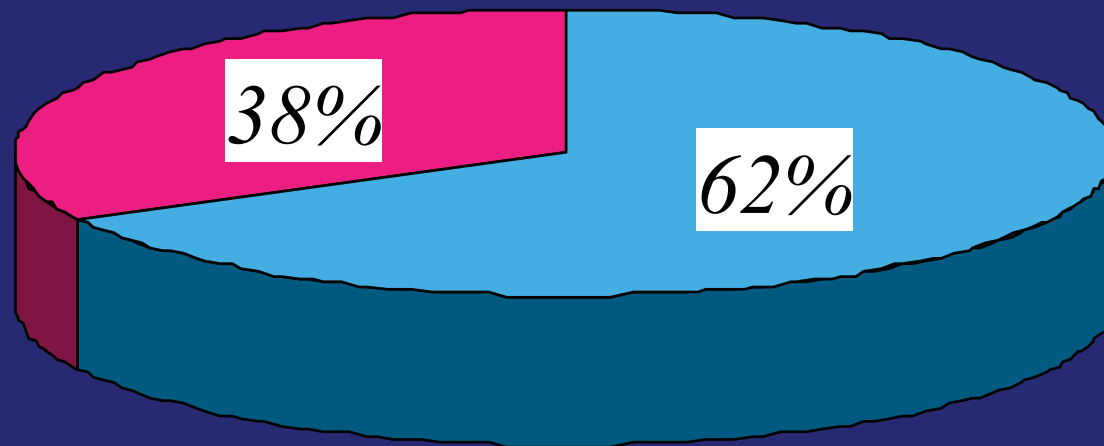
ULTRA

ULTRA II

Patients registered: n=178

2001.1-2003.9

Emergent 67



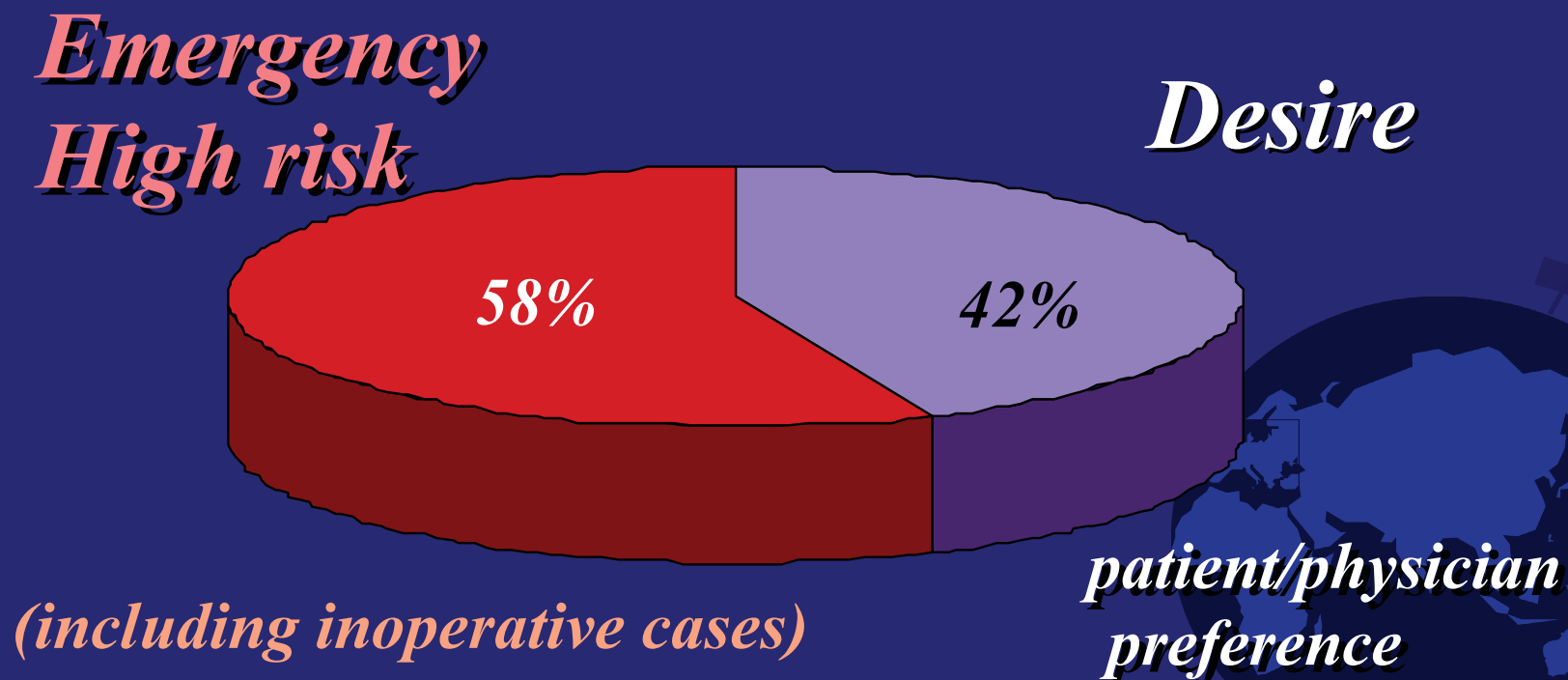
elective 111



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Reason for Catheter Intervention


2001.1-2003.9



Clinical Characteristics (1)

n=178

<i>Age (yr)</i>	<i>69 ± 11</i>
<i>Male gender (%)</i>	<i>78</i>
<i>Acute myocardial infarction (%)</i>	<i>17</i>
<i>Recent myocardial infarction (<2wks)(%)</i>	<i>10</i>
<i>Stable angina (%)</i>	<i>34</i>
<i>Unstable angina (%)</i>	<i>27</i>
<i>Prior myocardial infarction (%)</i>	<i>34</i>
<i>Prior CABG (%)</i>	<i>8</i>



ULTRA

ULTRA II

Clinical Characteristics (2)

n=178

LVEF (%)

51 ± 18

Coronary Risk Factors;

Diabetes mellitus (%)

38

Current smoker (%)

34

Hypercholesterolemia (%)

38

Hypertension (%)

55


Obesity (%)

13



Angiographic Characteristics

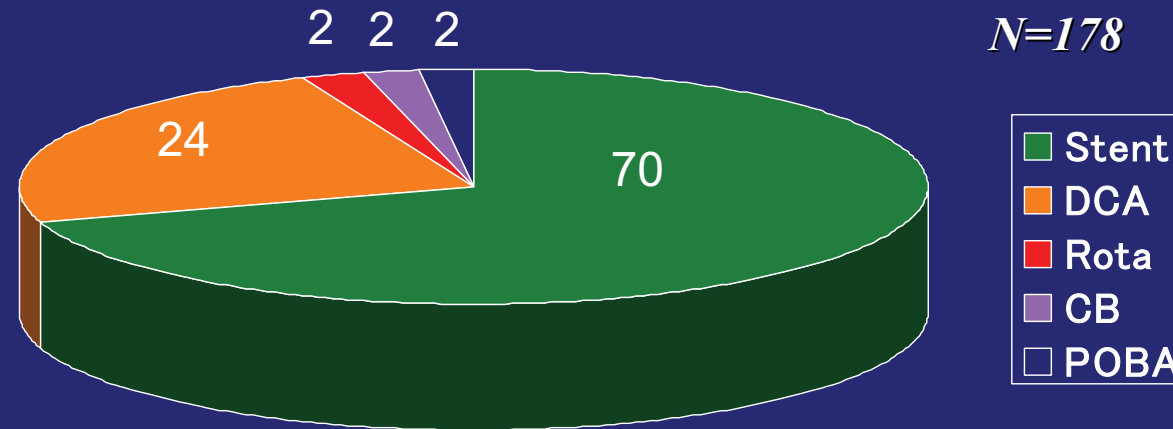
<i>Lesion length (mm)</i>	8.4 ± 4.6
<i>Lesion location (%)</i>	
<i>Ostial</i>	30
<i>Midshaft</i>	36
<i>Distal</i>	60
<i>LVEF</i>	0.48 ± 0.21
<i>No. of diseased vessels except LMD (%)</i>	
<i>Zero / One / Two / Three</i>	6 / 32 / 39 / 23
<i>Reference diameter (mm)</i>	3.5 ± 0.7
<i>Percent stenosis (%)</i>	66 ± 14



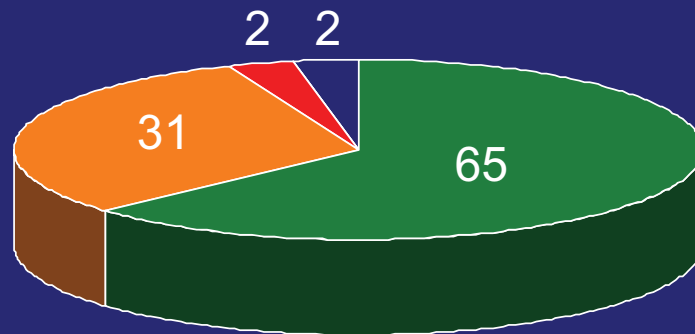
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Final Procedure

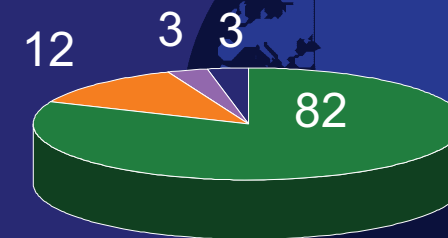
ULTRA II



Non-AMI (n=147)



AMI (n=31)



Procedural Characteristics

Type of stent (%)

ML stent

37

Bx stent

32

gfx/s670 stent

18

NIR stent

13

IABP (%)

56

PCPS (%)

8



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Angiographic Results

ULTRA II

Reference diameter (mm)

Pre

3.5 ± 0.7

Post

3.8 ± 0.6

Diameter stenosis (%)

Pre

65.7 ± 14.1

Post

11.1 ± 12.1

Follow-up

29.1 ± 16.0

Minimal lumen diameter (mm)

Pre

1.2 ± 0.5

Post

3.2 ± 0.6

Follow-up

2.7 ± 0.7

Maximal balloon inflation pressure (atm)

14.7 ± 2.9

Initial Results in Patients with AMI

n=50

<i>Procedural success (%)</i>	<i>31 / 31 (100%)</i>
<i>In-hospital death</i>	<i>11 / 31 (35%)</i>
<i>Emergency CABG</i>	<i>2 / 31 (6%)</i>
<i>Elective CABG</i>	<i>2 / 31 (6%)</i>
<i>Clinical success</i>	<i>19 / 31 (61%)</i>



Initial Results in Patients without AMI

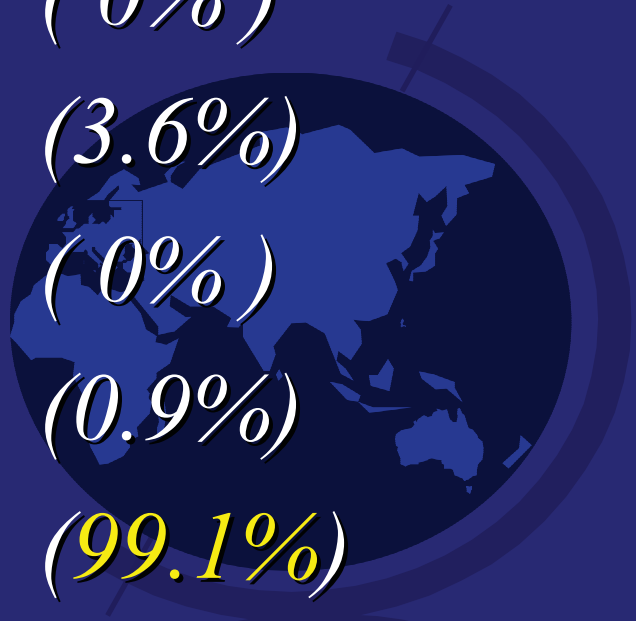
n=147

<i>Procedural success</i>	146 (99.3%)
<i>In-hospital death</i>	5 (3.4%)
<i>Q-MI</i>	1 (0.7%)
<i>nonQ-MI</i>	8 (4.6%)
<i>Emergency CABG</i>	1 (0.7%)
<i>Clinical success</i>	140 (95.2%)

Initial Results in Elective Cases

n=111

<i>Procedural success</i>	<i>110 (99.1%)</i>
<i>In-hospital death</i>	<i>0 (0%)</i>
<i>Q-MI</i>	<i>0 (0%)</i>
<i>nonQ-MI</i>	<i>4 (3.6%)</i>
<i>Emergency CABG</i>	<i>0 (0%)</i>
<i>CVA</i>	<i>1 (0.9%)</i>
<i>Clinical success</i>	<i>110 (99.1%)</i>



Conclusion

Catheter interventions for selected and elective patients with unprotected LMD could be accomplished safely and effectively with new devices in this registry. The benefit of angioplasty for patients with acute MI was, however, undetermined.

Mid to long term follow-up results are favorable in patients with elective angioplasty for unprotected LMD.

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Unprotected Left Main Trunk Angioplasty

--- Is it still risky? ---



It is safe with new devices.

However, we need a large-scale, randomized study.



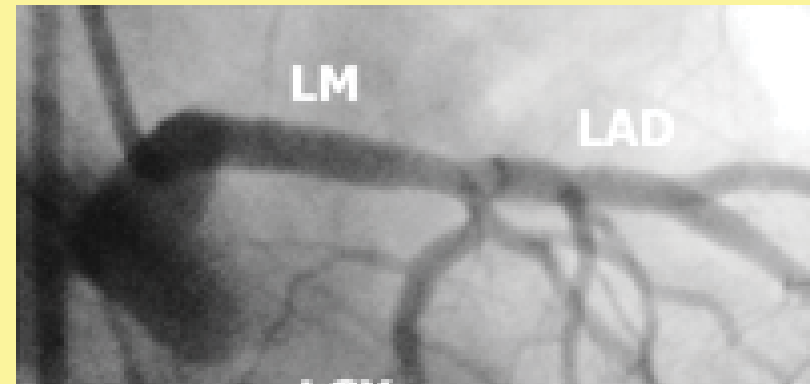
Left Main Rapamycin-Coated Stent

*Nieman K, et al. Circulation 105: e130, 2002
(the Netherlands)*

Case 47y/o male
a history of recurrent PCI
Rapamycin-coated stent
(Bx Velocity 4.0x18mm)

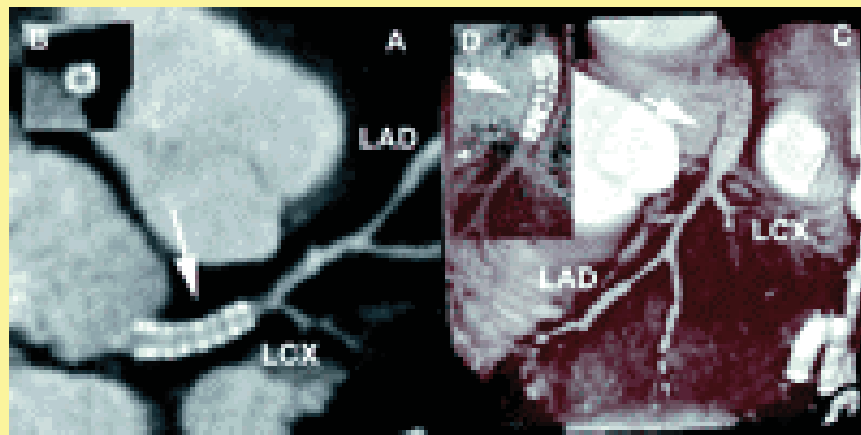
At 6-mo f/u:
no symptoms
no intimal hyperplasia

Conventional angiogram

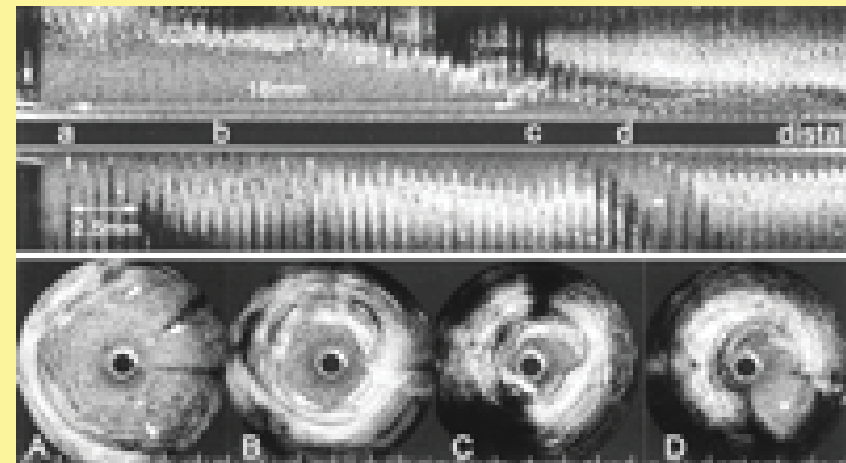


Drug eluting stent is not available in Japan!

Multislice spiral CT



Intravascular ultrasound



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Unprotected Left Main Trunk Angioplasty

- *PCI for LMD might be superior to CABG in drug eluting stent era.*
- *We have to do a large-scale, randomized study after the approval.*



Surgeons for CABG



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END

Thank you for your attention.



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