Distal Filter Protection Versus Conventional Treatment during PCI in Patients with Attenuated Plaque Identified by IVUS

VAcuuM asPIration thrombus Removal (VAMPIRE) 3 trial

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For the VAMPIRE 3 Investigators

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

| Affiliation/Financial Relationship	Company
Grant/Research Support	None
Consulting Fees/Honoraria	Nipro and Boston Scientific
Major Stock Shareholder/Equity	None
Royalty Income	None
Ownership/Founder	None
Intellectual Property Rights	None
Other Financial Benefit	None

Disclosure Statement of Financial Interest

I, (Kiyoshi Hibi) 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.

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Background
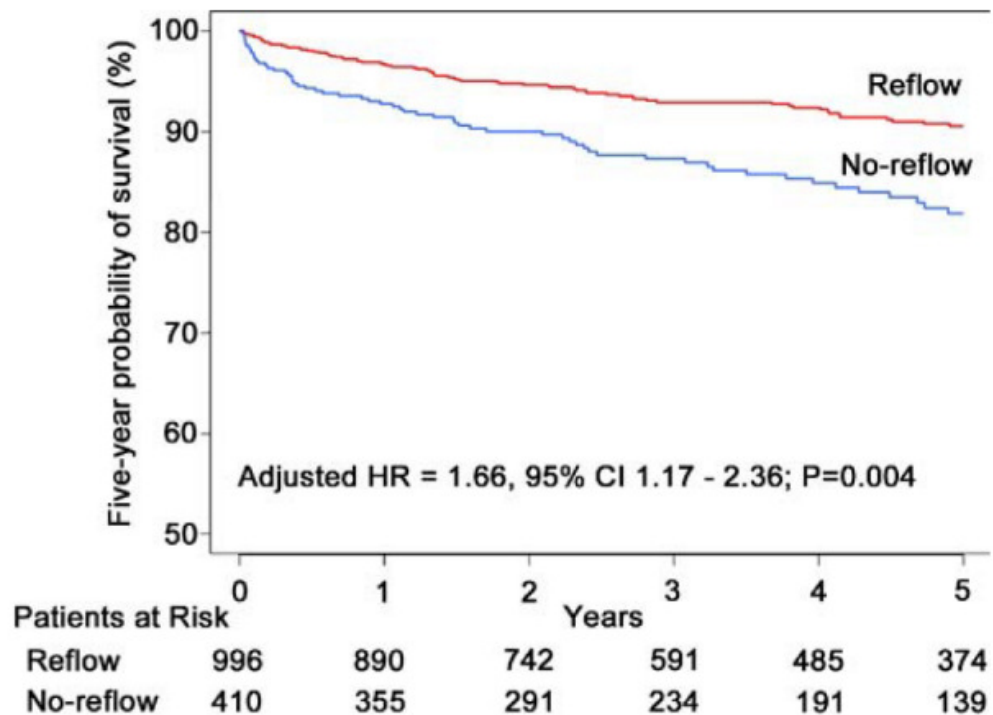## *"Routine" use of distal protection device and infarct size*
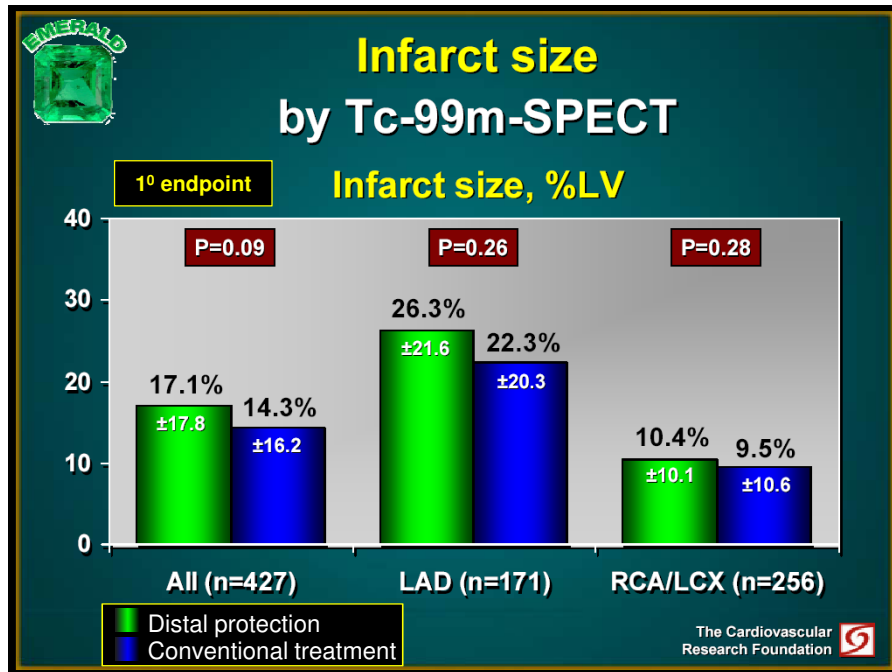
Stone et al. *JAMA.* 2005;293:1063-72
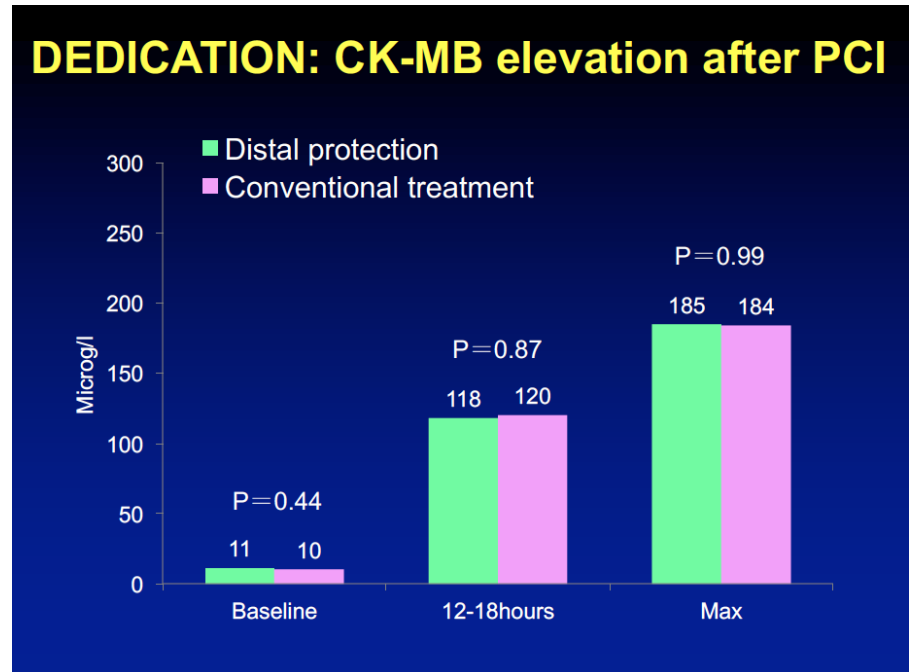
Kelbæk et al. *J Am Coll Cardiol. 2008;51:899-905*

Background
No-reflow phenomenon and 5y mortality

Reflow group : N=996
No-reflow group: N=410

Adjusted HR = 1.66, 95% CI 1.17 - 2.36; P=0.004

Patients at Risk	0	1	2	3	4	5
Reflow	996	890	742	591	485	374
No-reflow	410	355	291	234	191	139

Background
Attenuated plaque length and no-reflow phenomenon

Endo, Hibi et al. *JACC Cardiovasc Interv.* 2010;3:540-9
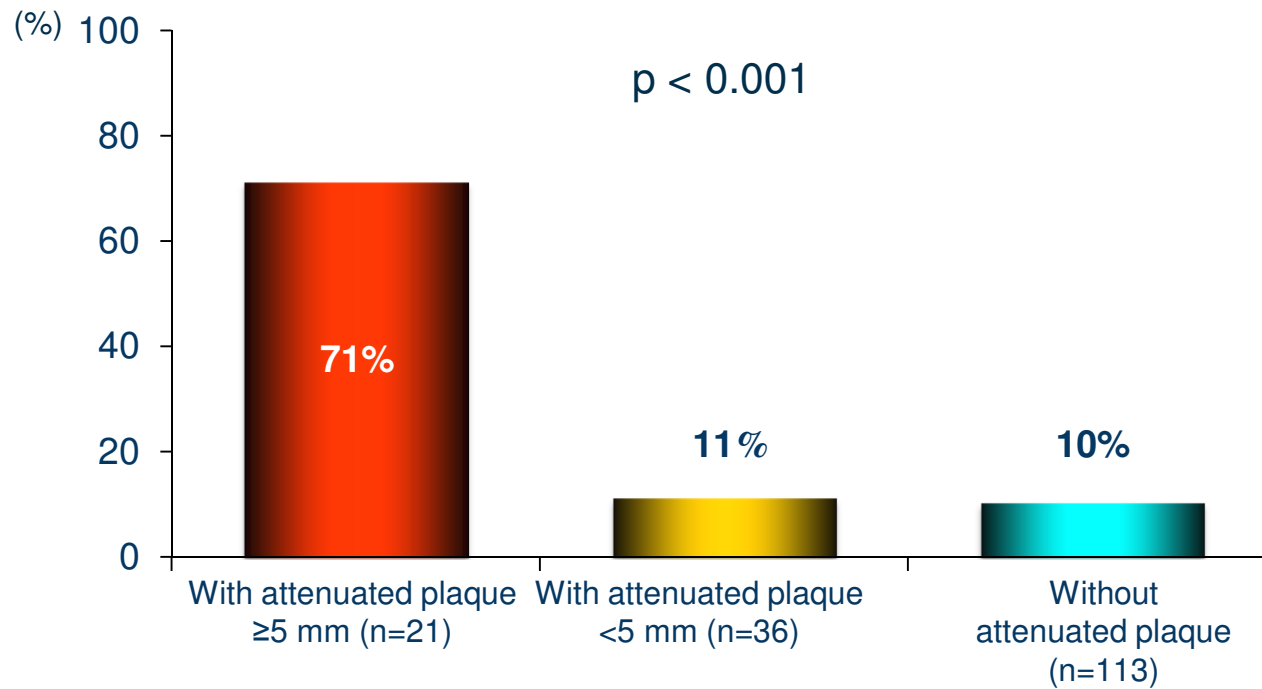
Design

DESIGN
Randomized, open-label, multi-center study of distal protection or conventional treatment

OBJECTIVE
To test the hypothesis that the selective use of distal filter protection might decrease the incidence of no-reflow phenomenon after PCI in ACS patients with attenuated plaque ≥5mm

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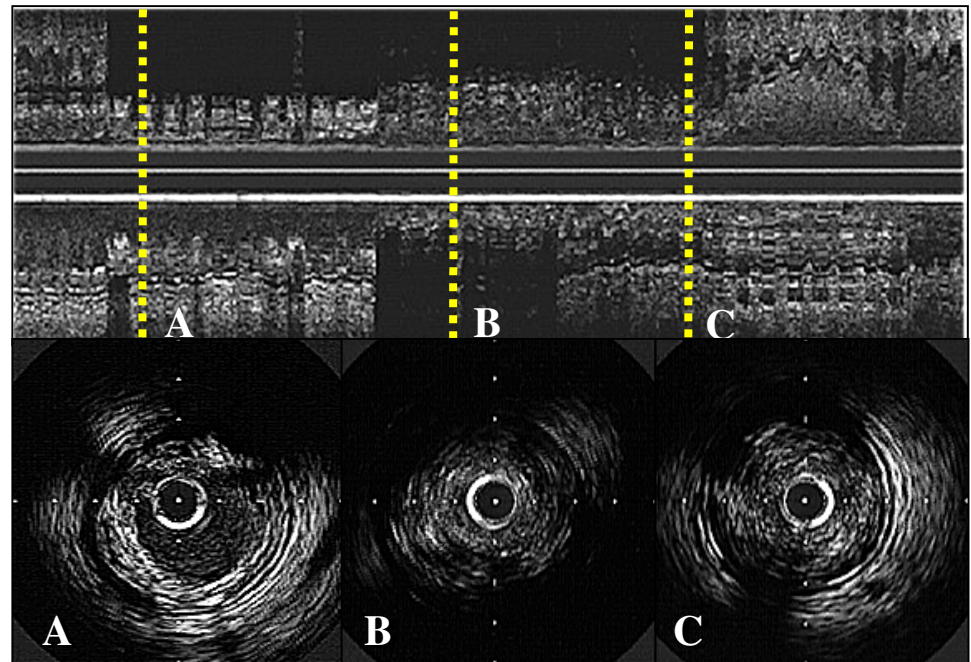
Study Subjects

Inclusion criteria
- **Patients with STEMI/non-STEMI within 2 months from symptom onset or with unstable angina for which PCI was indicated**
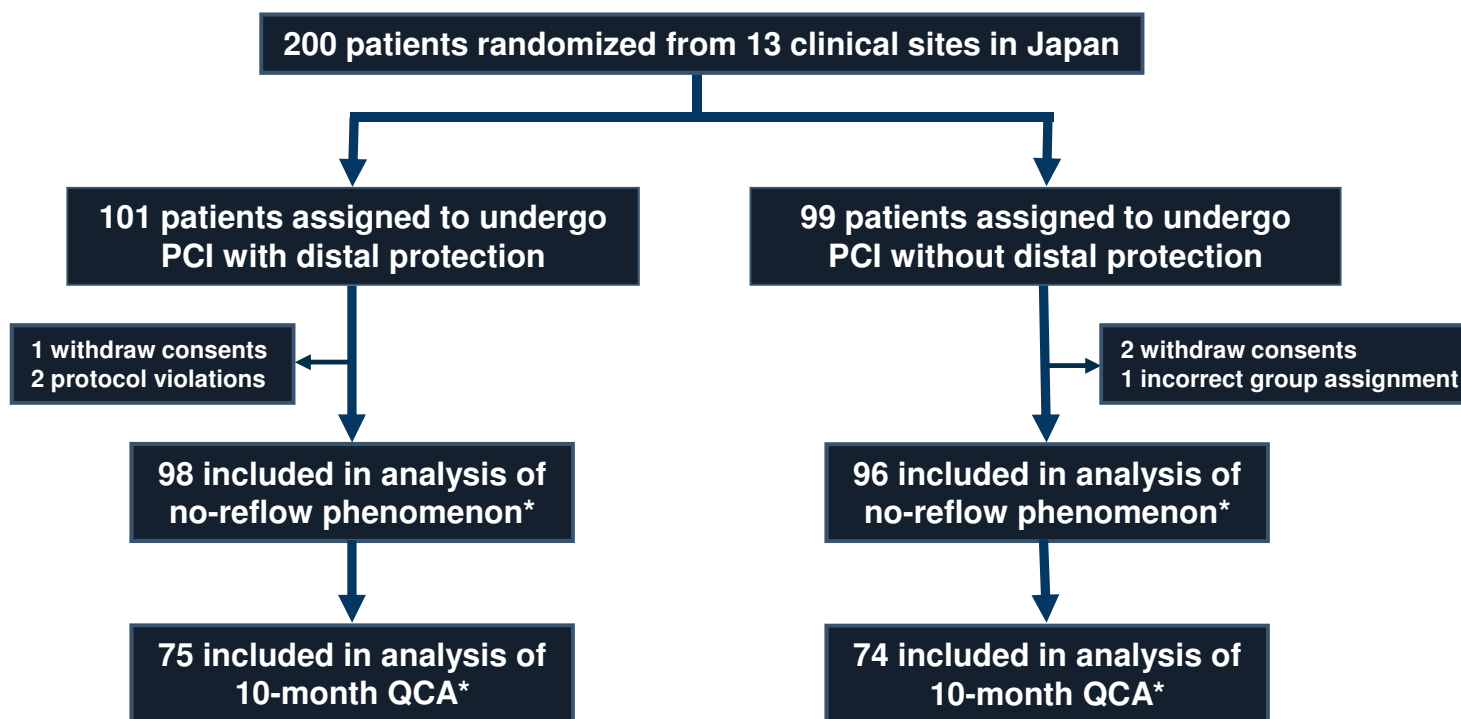- **Vessel diameter between 2.5 and 5 mm**

Exclusion criteria
- **Cardiogenic shock or cardiac arrest**
- **Hemodialysis or renal insufficiency (serum creatinine >1.5 mg/dL)**
- **Left main trunk or saphenous vein graft lesions**
- **In-stent restenosis lesions**
- **Balloon dilatation was necessary before IVUS interrogation**

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IVUS Eligibility Criteria

- **Attenuated plaque with a longitudinal length of ≥5 mm by 40MHz IVUS before PCI**

- **Attenuated plaque was defined as IVUS images with backward signal attenuation of ≥180° behind plaque without dense calcium**
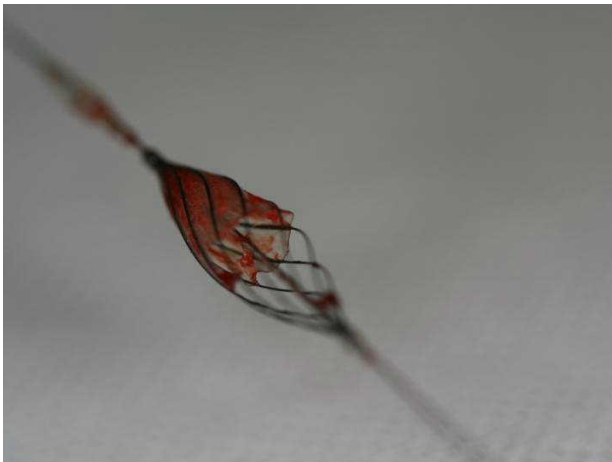

Endo, Hibi et al. *JACC Cardiovasc Interv.* 2010;3:540-9

Sample Org Chart

200 patients randomized from 13 clinical sites in Japan

101 patients assigned to undergo PCI with distal protection

99 patients assigned to undergo PCI without distal protection

**1 withdraw consents
2 protocol violations**

**2 withdraw consents
1 incorrect group assignment**

98 included in analysis of no-reflow phenomenon*

96 included in analysis of no-reflow phenomenon*

75 included in analysis of 10-month QCA*

74 included in analysis of 10-month QCA*

Procedures

**Distal filter protection system
3.5 mm or 5 mm in diameter**

Filtrap™, Nipro, Tokyo, Japan

✓ **Balloon dilatation with balloon diameter ≤2 mm was allowed if filter device could not cross the lesion**

✓ **In the distal protection group, aspiration immediately after stent implantation (before any angiography if possible) was strongly encouraged**

✓ **Sufficient leaking of blood from the guiding catheter was encouraged to prevent the injection of embolic debris dropped off from the balloon catheter in the guiding catheter**

Study Endpoints

Primary endpoints

- **Incidence of no-reflow phenomenon during PCI**

Secondary endpoints

- **Post-procedural TIMI flow**

- **Corrected TIMI frame count**

- **Creatine kinase (CK) or CK-MB elevation 6 to 24 hours after PCI**

- **Rate of major adverse cardiac events occurring before discharge**

Baseline Clinical Characteristics of the Patients

	Distal Protection n = 98	Conventional Treatment n = 96	P Value
Age, yrs	66.8 (11.4)	68.0(11.9)	0.49
Male (%)	81 (82.7)	72 (75.0)	0.19
Diagnosis (%)			0.84
STEMI	59 (60.2)	60 (62.5)	
NSTEMI	28 (28.6)	24 (25.0)	
UAP	11 (11. 2)	12 (12.5)	
Diabetes mellitus (%)	30 (30.6)	32 (33.3)	0.68
Hypertension (%)	63 (64.3)	57 (59.4)	0.48
Hypercholesterolemia (%)	63 (64.3)	57 (59.4)	0.48
Current smoker (%)	40 (40.8)	44 (45.4)	0.48

Baseline Angiographic Characteristics of Patients

	Distal Protection n = 98	Conventional Treatment n = 96	P Value
Culprit artery (%)			0.36
RCA	47 (48.0)	52 (54.2)	
LAD	38 (38.8)	37 (38.5)	
LCX	13 (13.3)	7 (7.3)	
Reference vessel diameter, mm (SD)	3.1 (0.5)	3.0 (0.6)	0.27
Visible thrombus (%)	79 (80.6)	72 (75.0)	0.35

*Analyzed by an independent core laboratory (Cardiocore, Tokyo, Japan)

Procedural Results

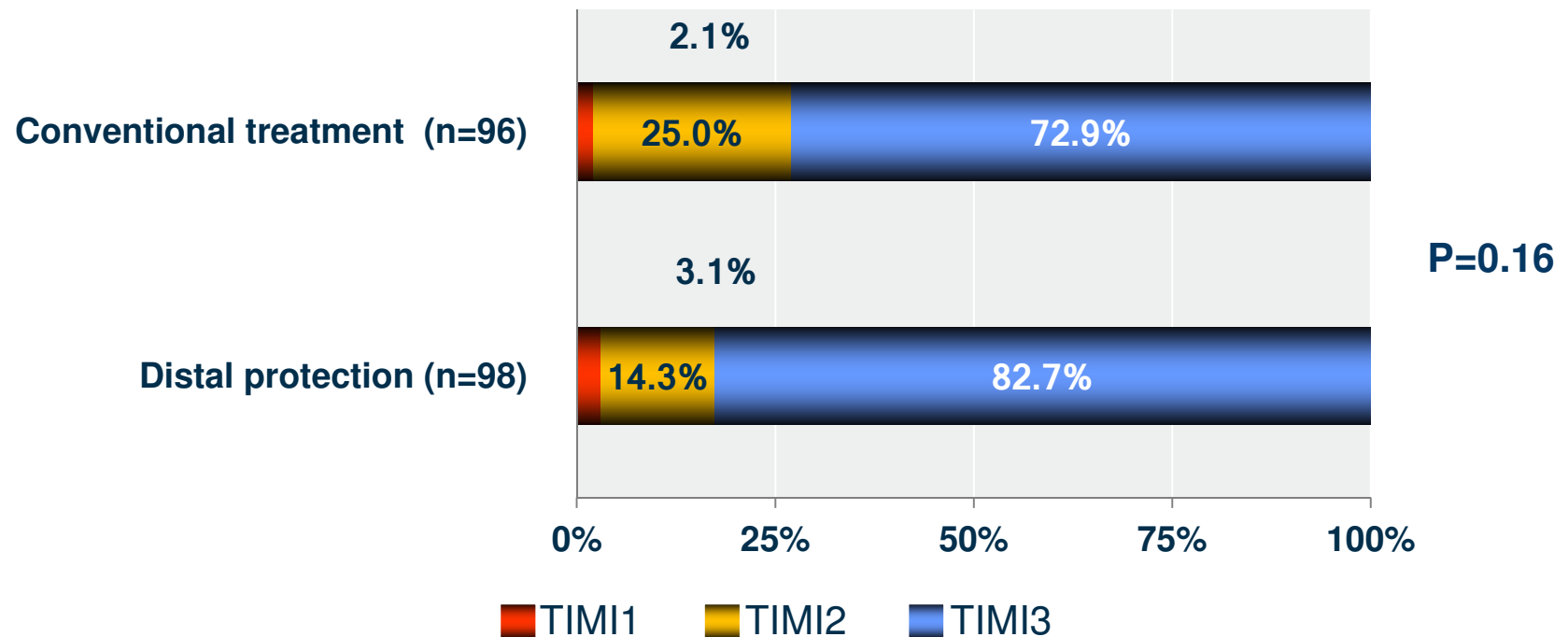|	Distal Protection n = 98	Conventional Treatment n = 96	P Value
Aspiration performed (%)	87 (89)	65 (68)	0.0004
Filter wire success (%)	96 (98)	0 (0)	
Procedural success (%)	93 (95)	93 (97)	0.72
≥2 stents implanted (%)	11 (11)	16 (17)	0.27
Drug-eluting stent (%)	73 (75)	77 (81)	0.33
Stented length (median, IQR), mm	23 (18-30)	24 (18-33)	0.29
Fluoroscopy time (median, IQR), min	26.2 (19-38)	24 (17-31)	0.0498
Contrast volume, ml (SD)	155 (57)	150 (48)	0.56
Distal emboli (%)	14 (14)	16 (17)	0.65

Primary endpoint; Incidence of no-reflow phenomenon

No-reflow phenomenon

(%)

P=0.0261

26.5

41.7

Distal protection
(n=98)

CTFC

P=0.0003

23.0

30.5

Distal protection
(n=93)

Conventional
Treatment
(n=88)

Analyzed by an independent core laboratory (Cardiocore, Tokyo, Japan)

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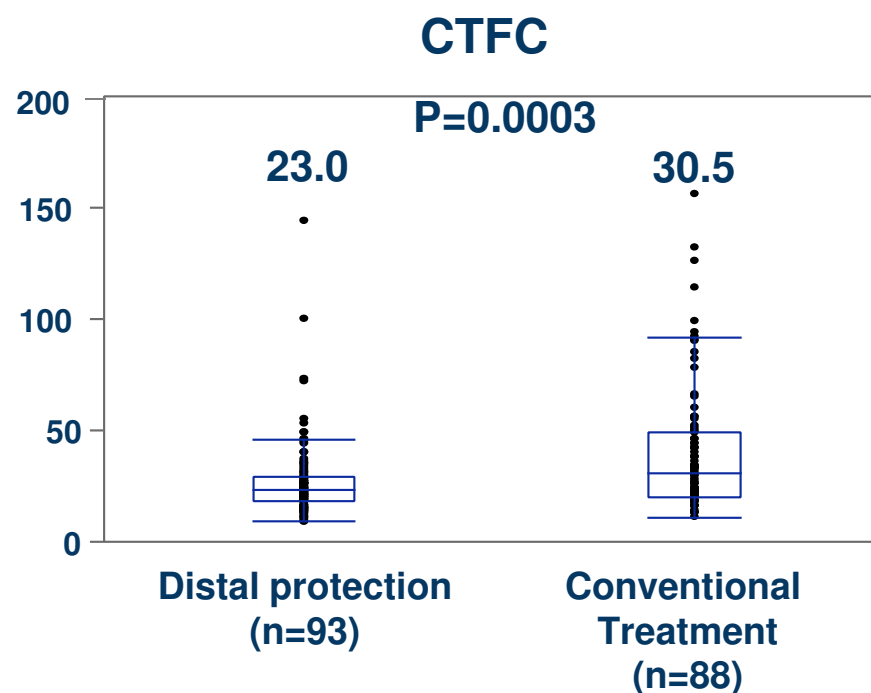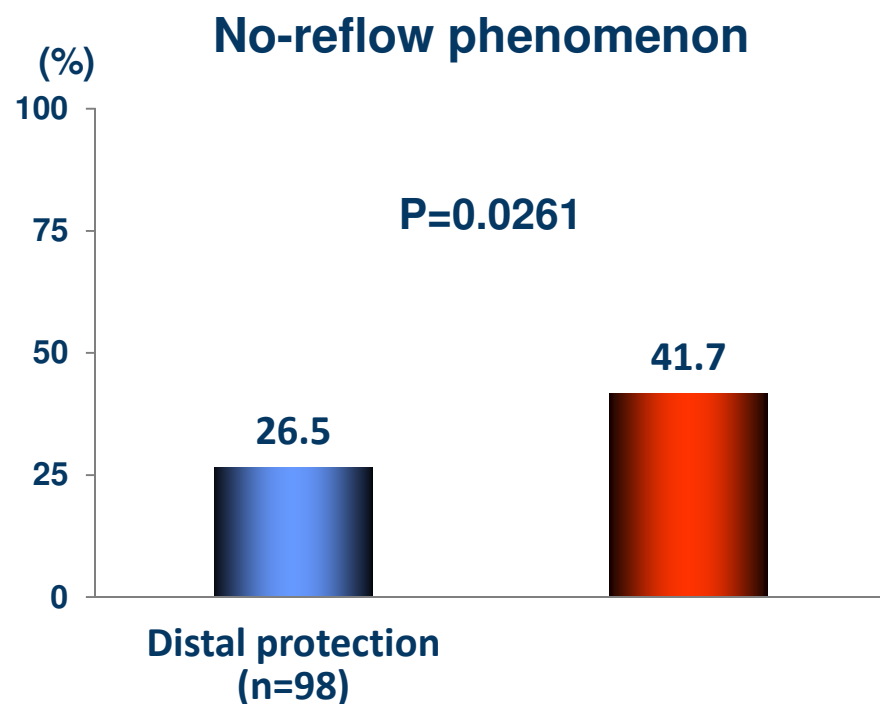
Subgroup analysis for primary endpoint

	OR	95% CI		P value
<70	0.48	0.26	0.87	0.02
≥70	0.53	0.29	0.97	0.04
Male	0.47	0.26	0.85	0.01
Female	0.52	0.26	1.03	0.06
With DM	0.34	0.19	0.64	0.00
Without DM	0.60	0.33	1.10	0.10
With Statin Pretreatment	0.29	0.15	0.54	0.00
Without Statin Pretreatment	0.65	0.36	1.18	0.16
Visible Thrombus	0.41	0.23	0.74	<0.01
Non Visible Thrombus	0.94	0.44	2.01	0.87
Vd ≤3mm	0.50	0.26	0.93	0.03
Vd > 3mm	0.48	0.27	0.87	0.02
LAD	0.66	0.36	1.22	0.18
LCX/RCA	0.43	0.24	0.79	0.01
TIMI 0-1	0.31	0.17	0.56	<0.01
TIMI 2-3	0.82	0.40	1.68	0.59

0.1   0.2   0.5   1   2   5   10

Favours distal protection   **Favours conventional therapy**
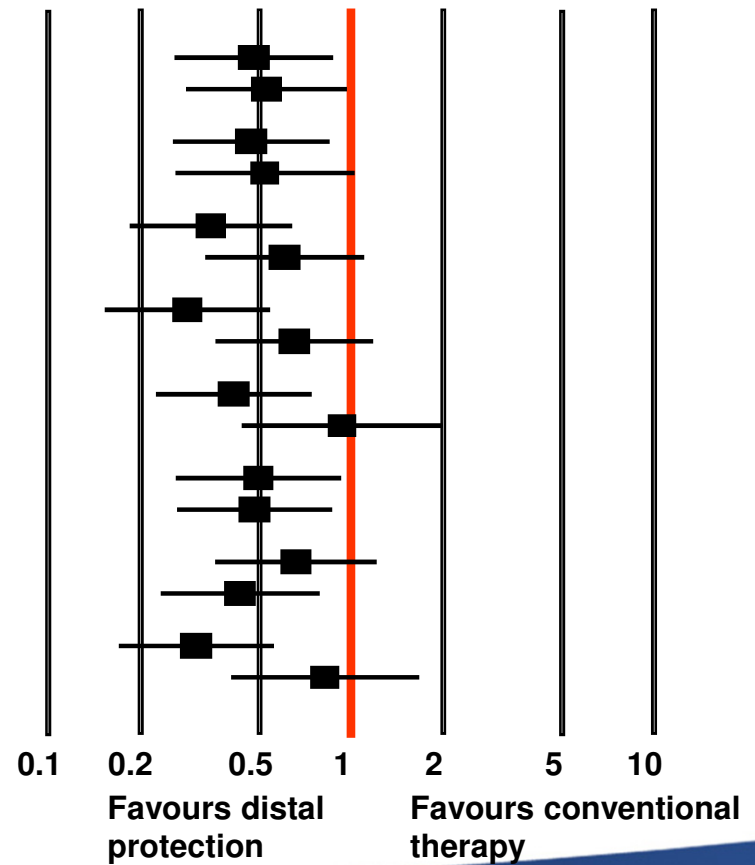
Secondary endpoint; TIMI flow

P=0.16

Legend: TIMI1, TIMI2, TIMI3

Conventional treatment (n=96): 2.1%, 25.0%, 72.9%

Distal protection (n=98): 3.1%, 14.3%, 82.7%
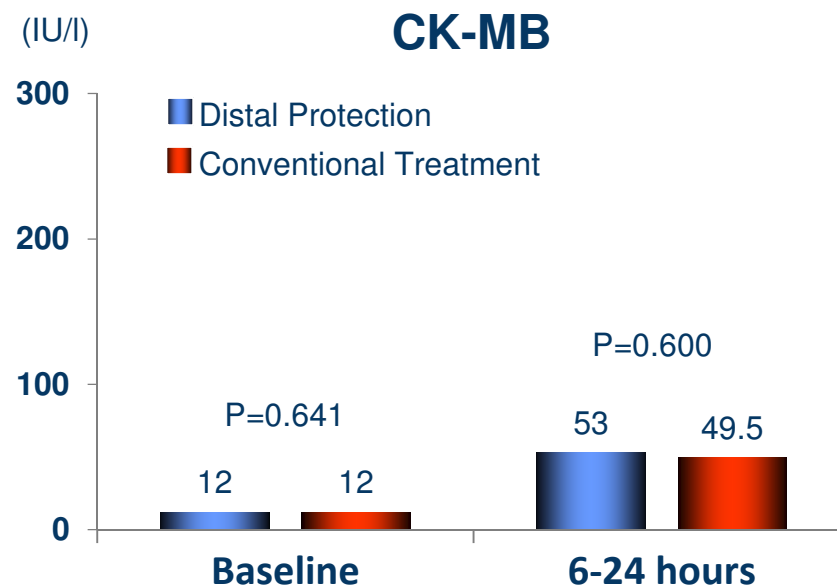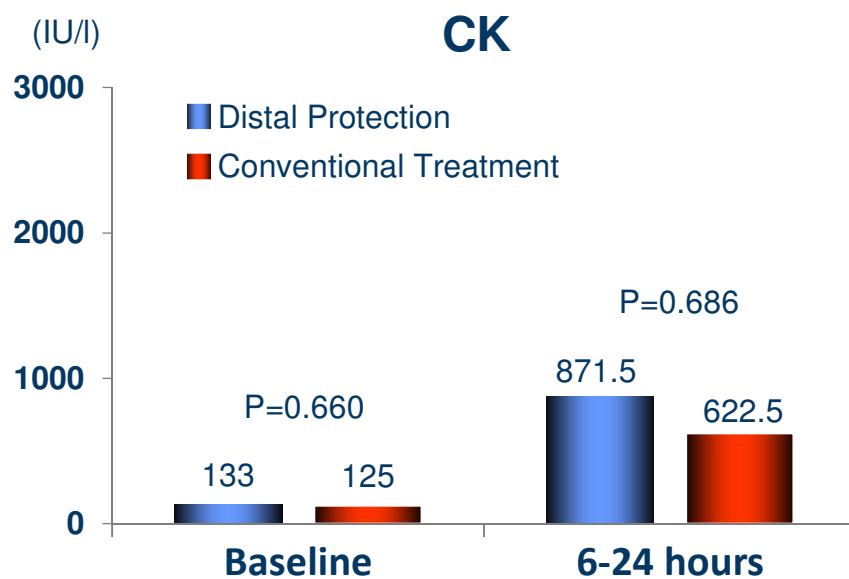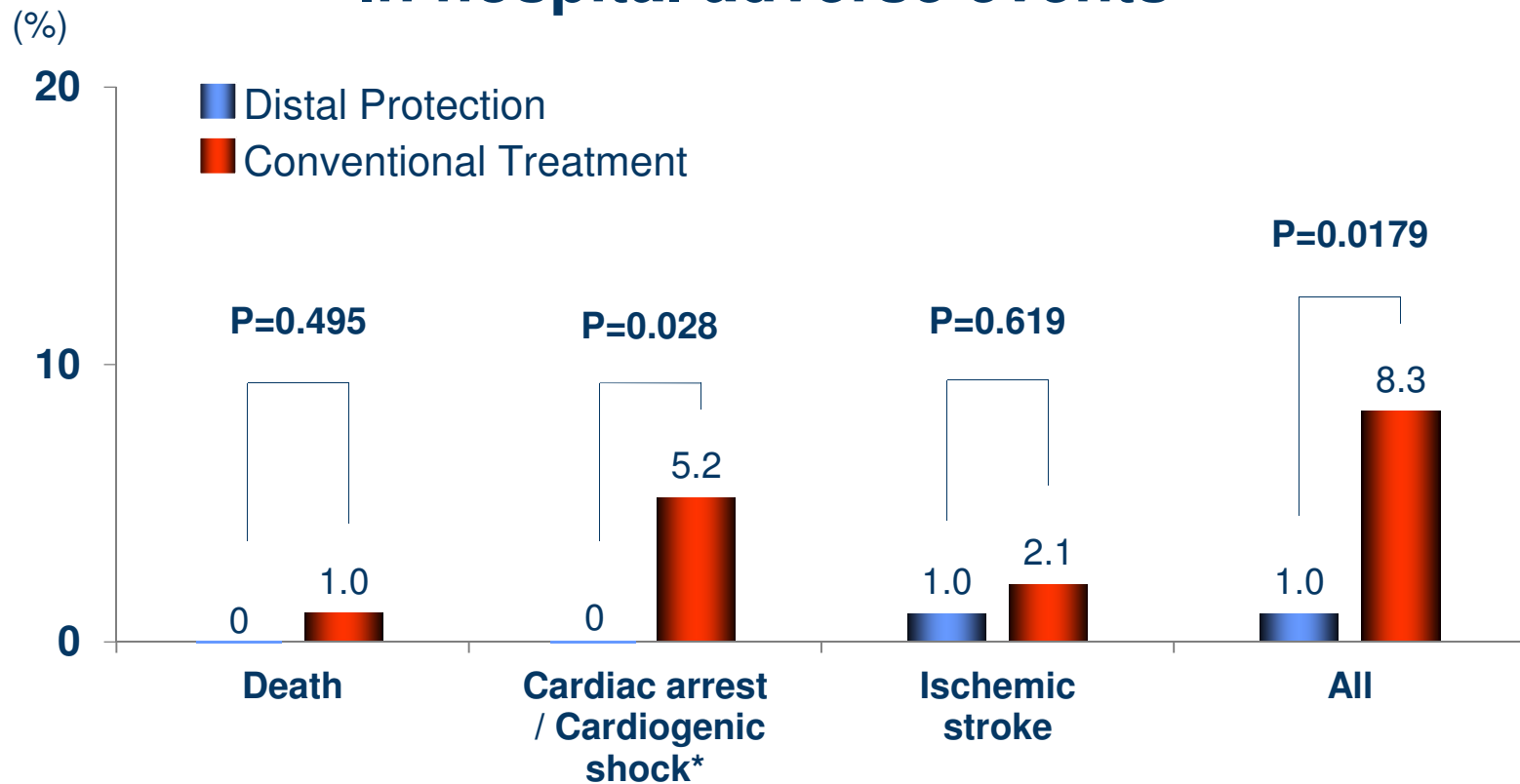
Patients with cardiac arrest/cardiogenic shock

Age	Sex	Diagnosis	*Attenuated plaque length	Event	Treatment	Max CK
38	M	STEMI	9 mm	VF	Defibrillation	8285 IU/L
59	F	STEMI	10 mm	VF	Defibrillation	3410 IU/L
71	M	STEMI	12 mm	VT	Defibrillation ECMO	618 IU/L
56	M	STEMI	24 mm	Cardiac arrest	Defibrillation ECMO IABP	12996 IU/L
84	M	NSTEMI	31 mm	Cardiac arrest	CPR, IABP	2293 IU/L

10-month follow up QCA (n=149)

% diameter stenosis

(%)

P=0.86

28.2 — Distal protection (n=75)

25.5 — Conventional Treatment (n=74)

Late loss

P=0.083

0.26 — Distal protection (n=75)

0.09 — Conventional Treatment (n=74)

Restenosis rete

(%)

P=0.116

8.0 — Distal protection (n=75)

1.4 — Conventional Treatment (n=74)

Analyzed by an independent core laboratory (Cardiocore, Tokyo, Japan)

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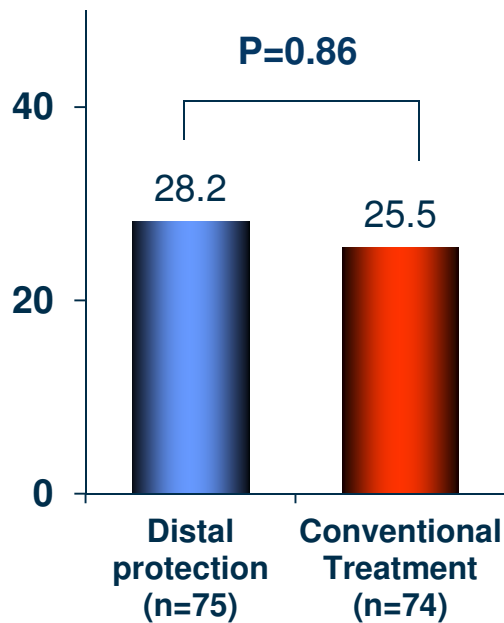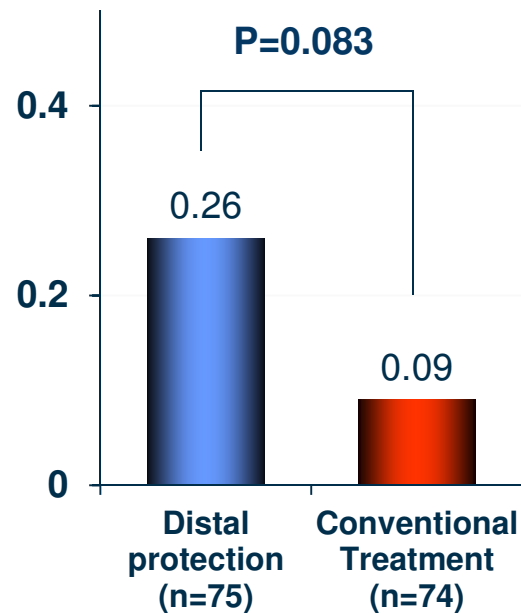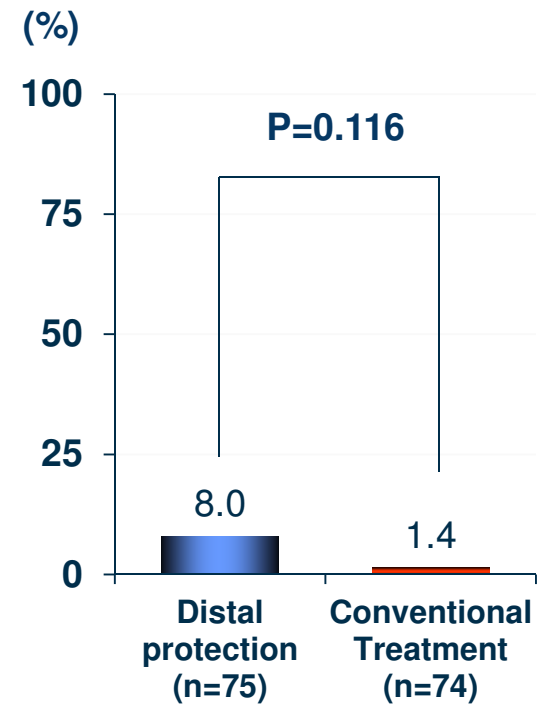
Conclusions

The use of distal embolic protection applied with a filter device decreased the incidence of no-reflow phenomenon and was associated with fewer serious adverse cardiac events after revascularization than conventional PCI in ACS patients with attenuated plaque ≥5 mm in length.