The BASE-ACS Trial

A Randomized Comparison of a TITAN-2 BAS with XIENCE-V-EES Stent in Acute Coronary Syndrome

18 months Follow-up results

Pasi Karjalainen, MD, PhD, adjunct Professor

on behalf of the Investigators

Heart Center, Satakunta Central Hospital,

PORI, Finland

AsiaPCR 2012 12-Jan-2012

asia PCR Singapore Live

Potential conflicts of interest

Speaker's name: Pasi P Karjalainen

☐ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☒ **I do not have any potential conflict of interest**

asia PCR Singapore Live BASE-ACS

Patients presenting with Acute Coronary Syndrome (ACS)

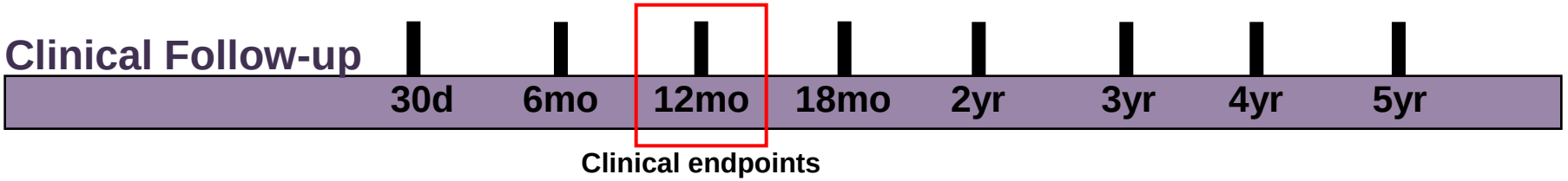
N = 827
14 International Sites
Randomisation 1:1

TITAN-2® stent

Titanium-Nitride-Oxide Coated Bio-Active Stent (BAS)
417 Patients

XIENCE-V™/PROMUS™ stent

Everolimus-Eluting Stent (EES)
410 Patients



Primary Endpoint: MACE (MI, TLR and Cardiac Death) at 12 months

Secondary Endpoints: All Cause Death; Cardiac Death/Non-Fatal MI, Stent Thrombosis

Investigators: P Karjalainen (Finland), Principal Investigator (PI)
A Ylitalo (Finland), co-PI
O Hess (Switzerland), co-PI
KEJ Airaksinen (Finland), co-PI
M Niemelä (Finland), co-PI

asia PCR Singapore Live

Clinical Sites

BASE-ACS

Investigators	Hospital	Patients
P Karjalainen, A Ylitalo, J Mikkelsson	Satakunta Central Hospital, Pori, Finland	270
M Niemelä, K Kervinen, H Romppanen	Oulu University Hospital, Oulu, Finland	151
F Rivero, J Salamanca	Hospital Universitario de la Princesa, Madrid, Spain	69
J Airaksinen, M Pietilä	Turku University Hospital,Turku, Finland	60
J Sia	Kokkola Central Hospital, Kokkola, Finland	49
J Lalmand, A Aminian, D Dolatabadi, P Lefebvre	C.H.U. de Charleroi, Charleroi, Belgium	46
O Hess, B Meier	Bern University Hospital, Bern, Switzerland	36
B De Bruyne, W Wijns	Cardiovascular Center Aalst, Aalst, Belgium	32
M Carlier, S Fasseaux, C Mortier, Y Dascotte	Grand Hôpital de Charleroi, Charleroi, Belgium	26
A deBelder	Royal Sussex County Hospital, Brighton, UK	25
J R López-Minguez, J M Nogales Asensio	Infanta Cristina University Hospital, Badajoz, Spain	20
M Laine	Helsinki University Hospital, Helsinki, Finland	19
P Tedjokusumo, A F Yahya,C Ahmad,J W Marta	Dr. Hasan Sadikin Hospital, Bandung, Indonesia	19
K Nyman	Jyväskylä Central Hospital, Jyväskylä, Finland	5

PCR National Heart Centre Singapore SingHealth Asian Pacific Society of Interventional Cardiology

asia PCR Singapore Live

BASE-ACS: Devices

	Titanium-Nitride-Oxide coated Bio-Active-Stent (Titan-2® BAS)	Everolimus-Eluting Stent (Xience-V™ /Promus™ EES)
Stent Platform	Stainless Steel BMS Helicoidal Design Strut Thickness 91 µm	Cobalt Alloy BMS Slotted Tube Strut Thickness 81 µm
Drug	---	Everolimus
Drug Density	---	1.0 µg/mm^2
Coating	Titanium-Nitride-Oxide (TiNoX)	---
Polymer	---	Fluoropolymer Polyvinylidene fluoride
Manufacturer	Hexacath, France	Abbott vascular

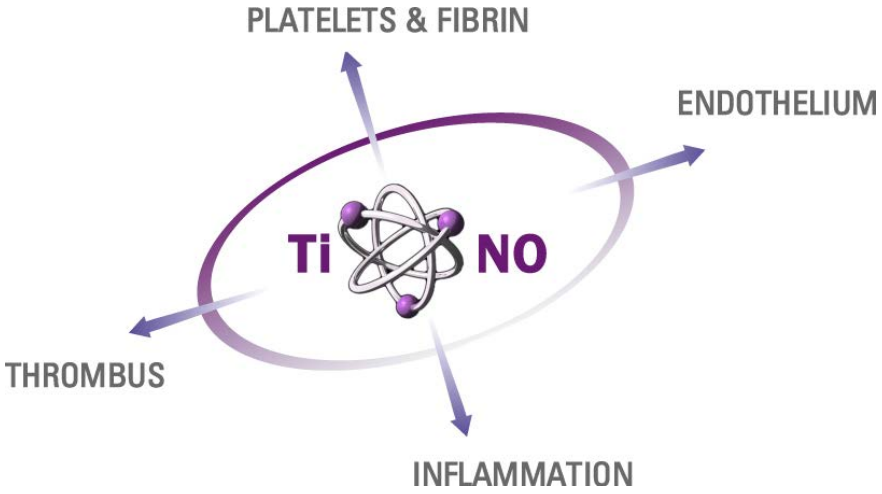
Titanium-Nitride-Oxide coated BAS

What is known from the literature?

HELISTENT TiTAN2

BIO ACTIVE STENT

B.A.S Hexacath, France

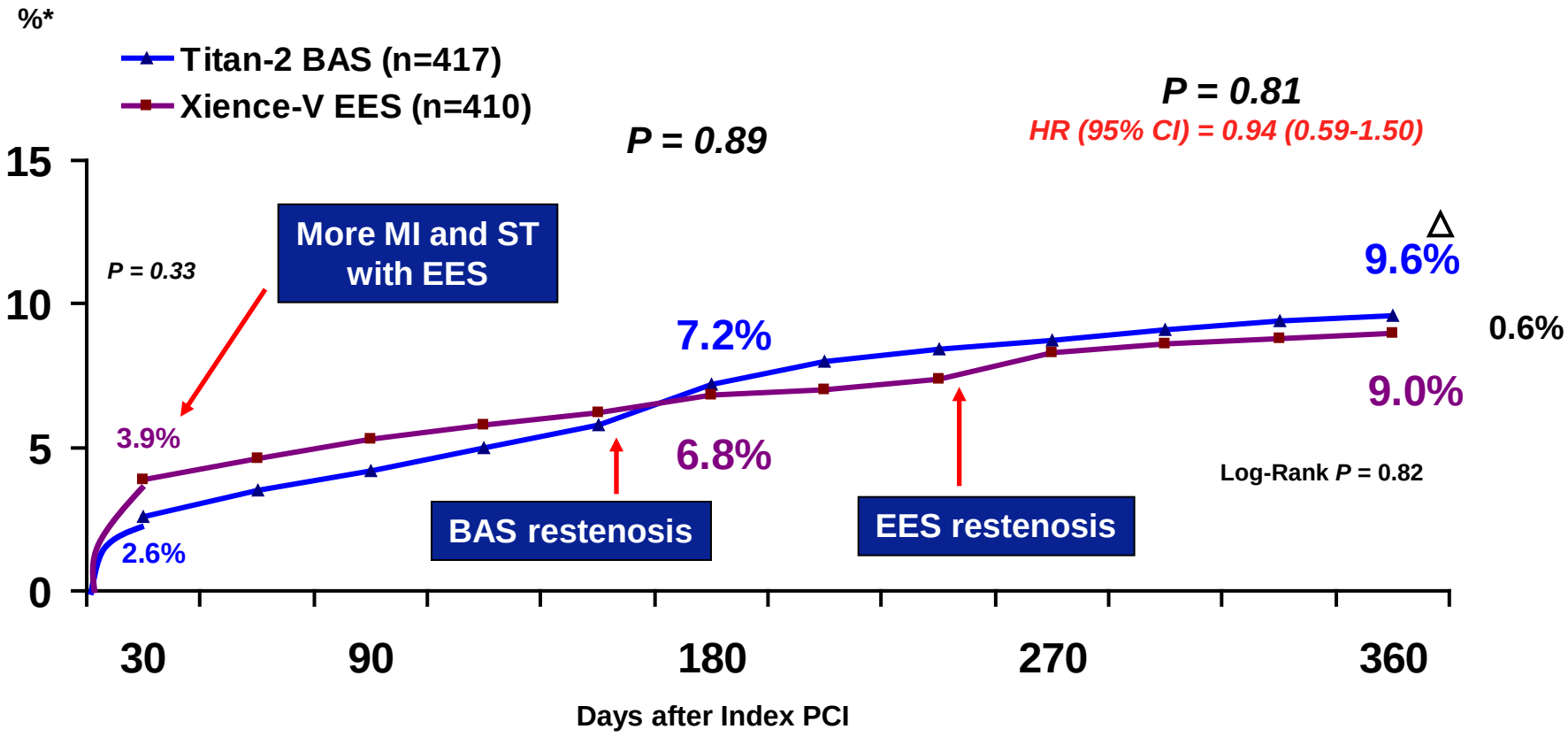


- Inhibits Platelet Aggregation
- Minimizes Fibrin Growth
- Minimizes Thrombus Formation
- Reduce Inflammation
- Promotes Endothelial Healing

BASE-ACS: Background

MACE at 12 months

(late breaking clinical trial; EuroPCR2011)



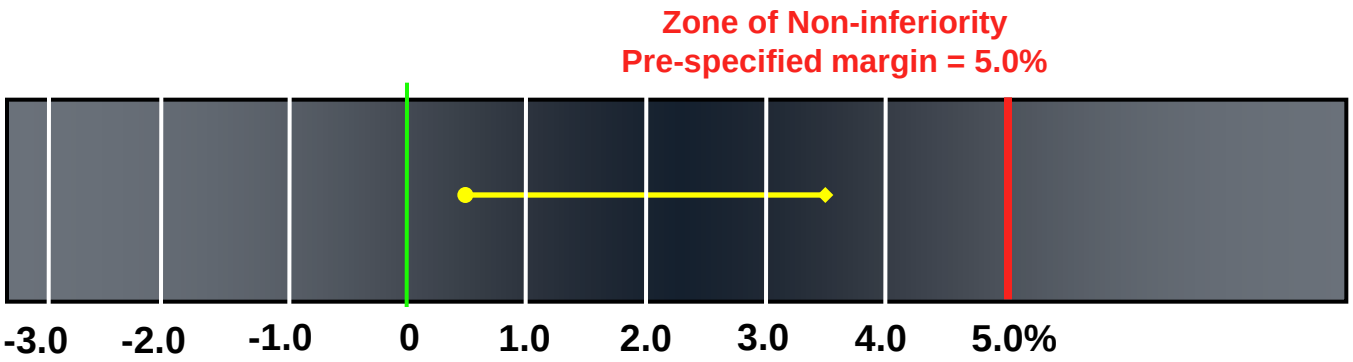
* Cumulative incidence of events (%)

Primary Endpoint

MACE at 12 Months

Titan-2 BAS (n=427)	Xience-V EES (n=410)	Difference : 0.6% (Upper 1-sided 95% CI)	*P* Value (Noni-nferiority)
9.6%	9.0%	0.6% + 95% CI = 3.5%	0.001

Primary Non-Inferiority Endpoint Met



BASE-ACS 18 months FU

Background

- **Premature discontinuation of thienopyridine therapy is recently recognized as the most important predisposing factor for late and very late ST following DES implantation.**

BASE-ACS trial

- **Clopidogrel treatment beyond 12 months was discouraged**

  ➔ Duration of DAPT was 8.7 (BAS) and 10.2 (EES) months

- **We sought to examine whether clopidogrel diacontinuation will predispose late thrombotic events?**

asia PCR Singapore Live

BASE-ACS

Patient Eligibility

Inclusion Criteria:

- Written informed consent
- Age > 18 years
- Patient with acute coronary syndrome (ACS) requiring PCI
- ACS:
  - Unstable angina
  - Non-ST-elevation myocardial infarction
  - ST-elevation myocardial infarction

Exclusion Criteria:

- Prior PCI on target vessel (ISR)
- Unprotected LM disease
- Aorto-ostial lesion
- Contraindication to:
  - aspirin, heparins, clopidogrel
- Life expectancy < 12 months
- Stent length needed > 28 mm

asia PCR Singapore Live

BASE-ACS trial

Stent Thrombosis

Academic Research Consortium (ARC) definition:

(Circulation 2007;115:2344-51)

Definite:

- Acute coronary syndrome and angiographic (or autopsy) confirmation of stent thrombosis

Probable:

- Any unexplained death within the first 30 days
- Target vessel related acute MI

Possible:

- Any unexplained death from 30 days after PCI

asia PCR Singapore Live

Baseline Demographics

	Titan-2 BAS (n=417)	Xience-V EES (n=410)	*P* value
Age (years)	63 ± 12	63 ± 12	0.93
Male	76.0%	76.1%	0.94
Diabetes	15.6%	18.3%	0.31
- Insulin treated	4.6%	4.1%	0.87
Hyperlipidemia	45.8%	48.0%	0.53
Hypertension	48.2%	51.7%	0.33
Current smoker	34.5%	32.7%	0.61
Prior myocardial infarction	13.4%	9.8%	0.10
Prior PCI	9.6%	10.5%	0.73
Prior CABG	4.8%	4.1%	0.74
NSTEMI	49.4%	45.6%	0.30
STEMI	38.8%	38.8%	1.0

asia PCR Singapore Live

Procedural Characteristics

	Titan-2 BAS (n=417pts) (n=480 lesions)	Xience-V EES (n=410pts) (n=484 lesions)	*P value*
Stents per culprit lesion	1.15 ± 0.38	1.14 ± 0.36	0.64
- Stent diameter (mm)	3.15 ± 0.44	3.15 ± 0.45	0.97
- Stent length (mm)	18.0 ± 5.2	18.5 ± 5.6	0.18
- Total stent length per lesion (mm)	20.8 ± 9.4	20.6 ± 8.2	0.70
Thrombus aspiration	19.7%	17.6%	0.48
Post-Dilatation	42.2%	43.9	0.67
Stent failure	0%	1.0%	0.03
Procedural success	99.8%	99.8%	0.99

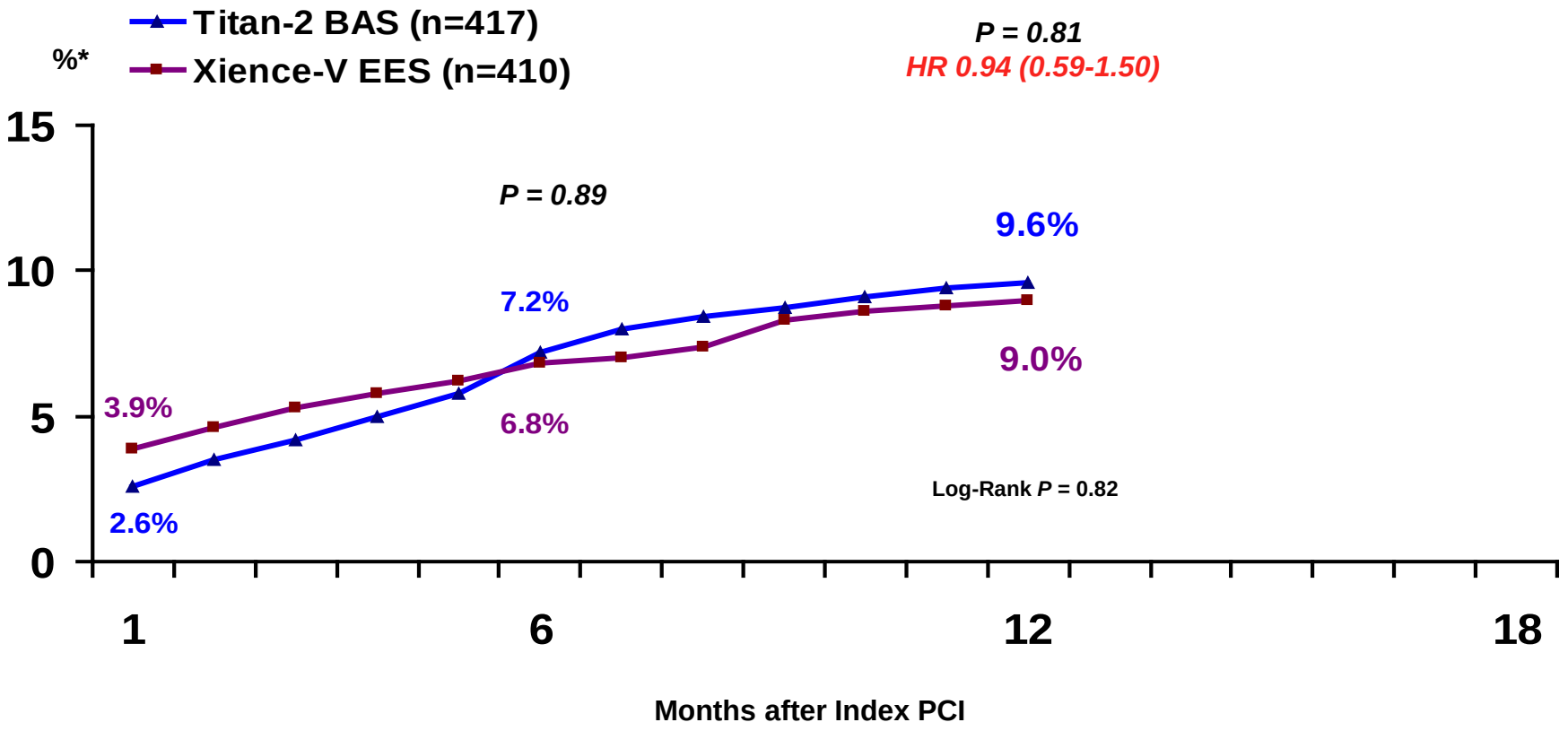
asia PCR Singapore Live

Antiplatelet Agent Utilization

	Titan-2 BAS (n=417)	Xience-V EES (n=410)	*P* value
Aspirin			
- At 6 months	99.8%	99.5%	NS
- At 12 months	99.5%	99.3%	NS
- At 18 months	99.3%	99.1%	NS
Clopidogrel			
- At 6 months	89.7%	99.3%	< 0.001
- At 12 months	51.3%	68.3%	< 0.001
- At 18 months	2.2%	2.7%	NS
Mean duration of Clopidogrel (months)	8.7 ± 3.6	10.2 ± 3.0	< 0.001

BASE-ACS

MACE

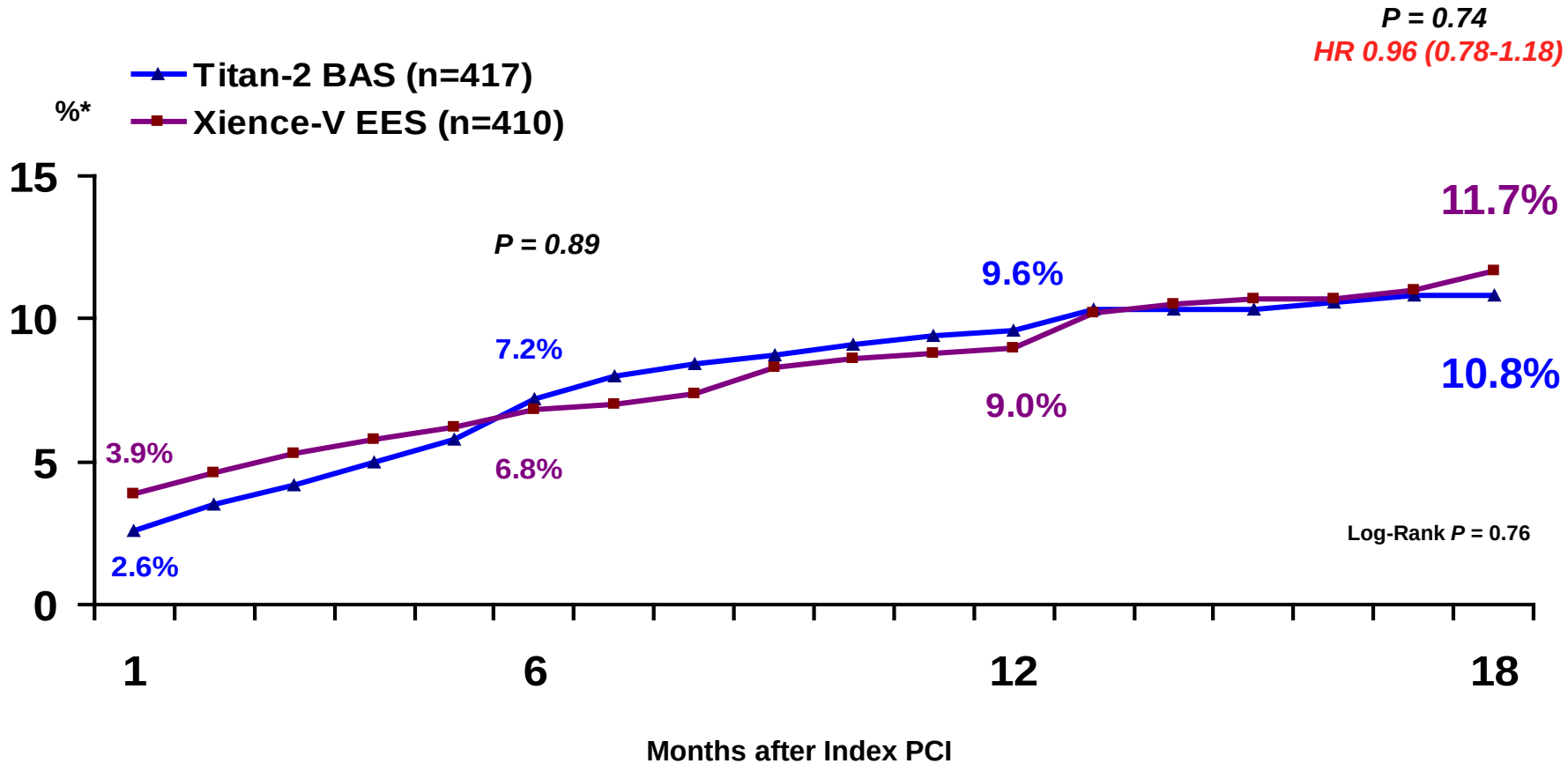


* Cumulative incidence of events (%)

asia PCR Singapore Live

BASE-ACS

MACE

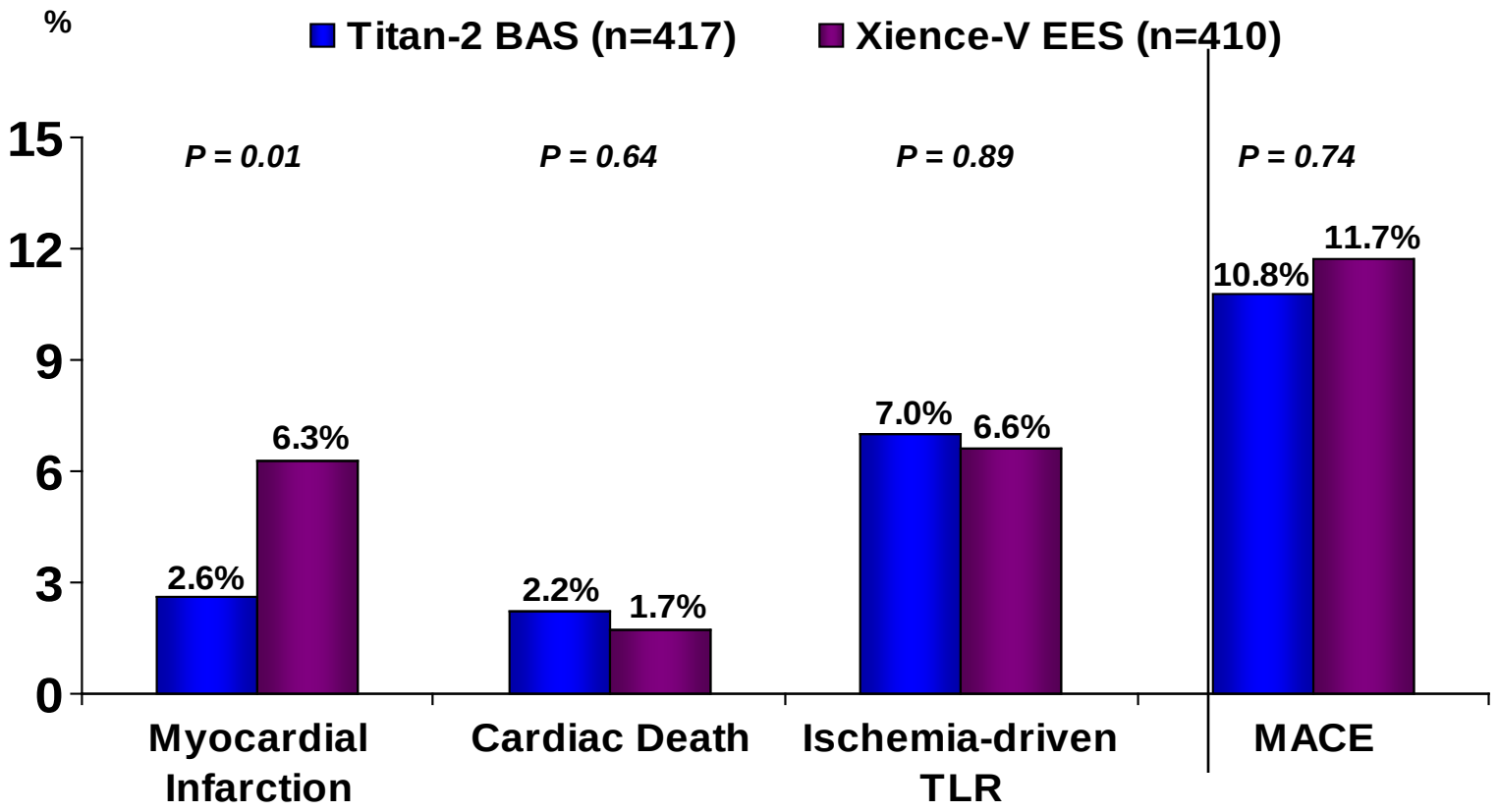


* Cumulative incidence of events (%)

PCR National Heart Centre Singapore SingHealth Asian Pacific Society of Interventional Cardiology

MACE Components

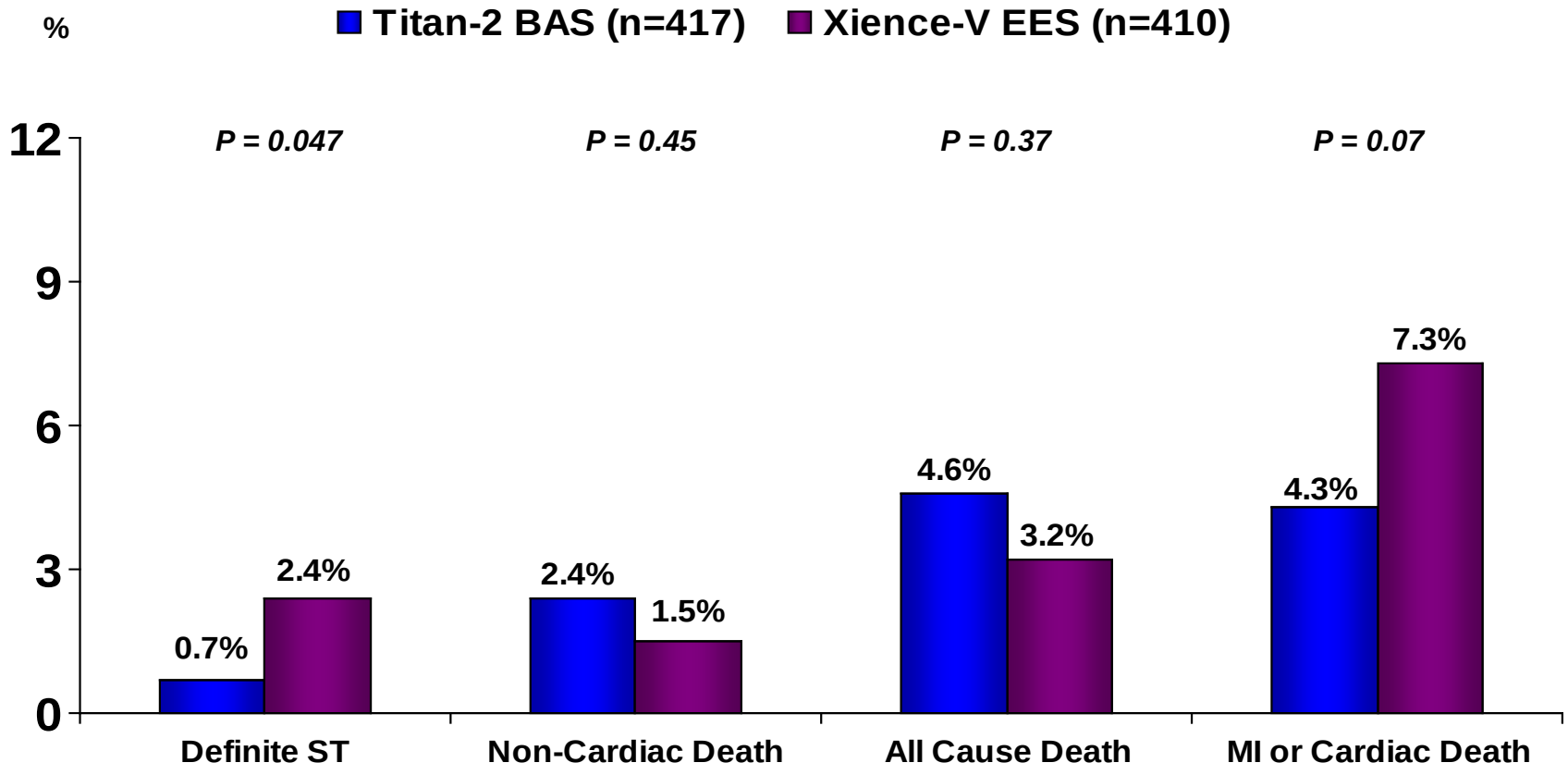
18 months Follow-up



TLR = Target Lesion Revascularization

Secondary Endpoints

18 months Follow-up



ST = Stent Thrombosis
MI = Myocardial Infarction

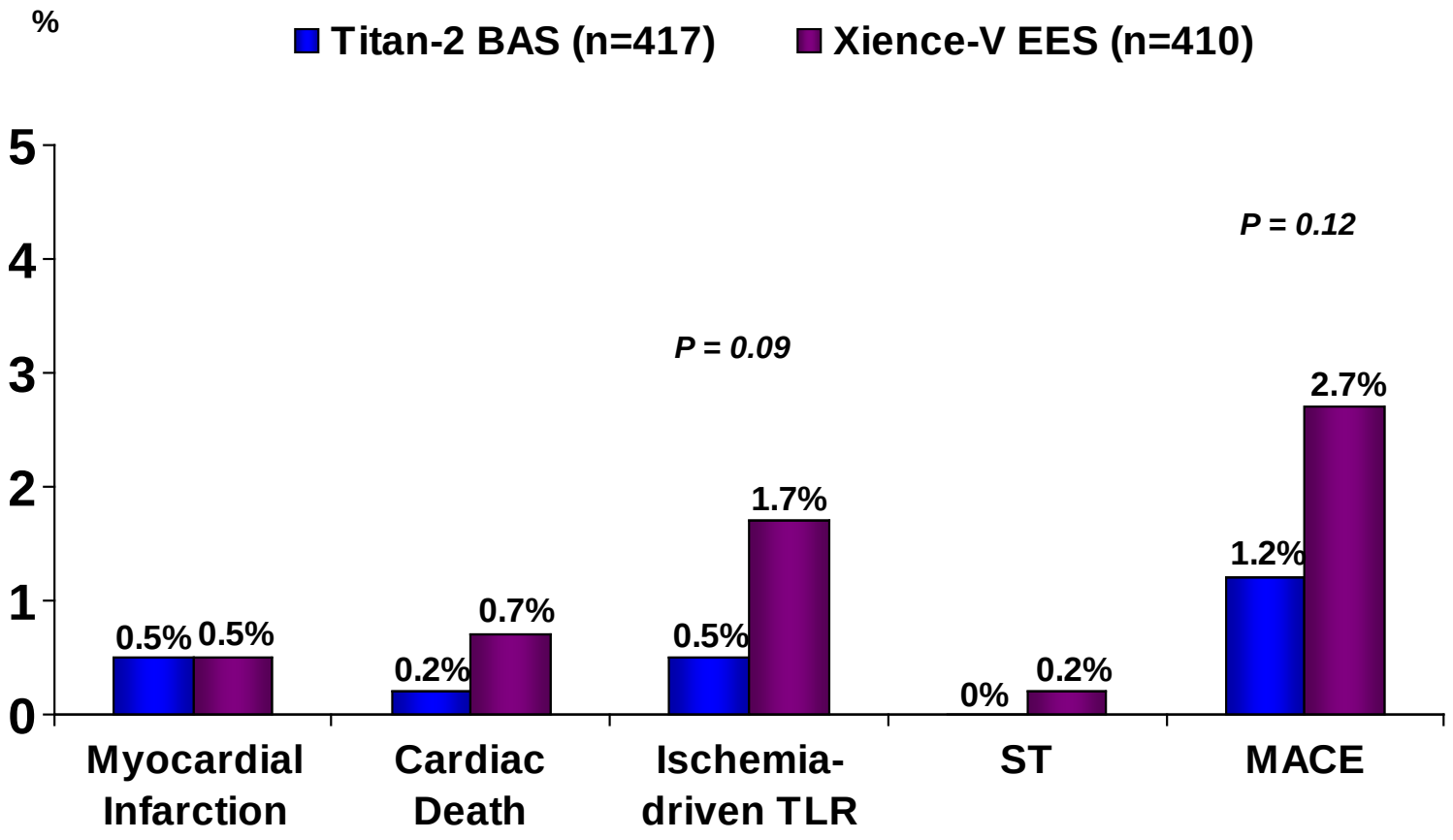
BASE-ACS

asia PCR Singapore Live

ARC Stent Thrombosis

	Titan-2 BAS (n=417) n (%)	Xience-V EES (n=410) n (%)	*P Value*
Definite ST			
Acute/Subacute (<30 days)	3 (0.7)	7 (1.7)	0.19
Late (30-360 days)	0 (0)	2 (0.5)	0.15
Very Late (>360 days)	0 (0)	1 (0.2)	0.31
All ST	3 (0.7)	10 (2.4)	0.047
Definite or Probable ST			
Subacute (< 30 days)	5 (1.2)	8 (2.0)	0.39
Late (30-360 days)	0 (0)	3 (0.7)	0.08
Very Late (>360 days)	0 (0)	4 (1.0)	0.04
All ST	5 (1.2)	15 (3.7)	0.021

Events Between 12-18 months FU

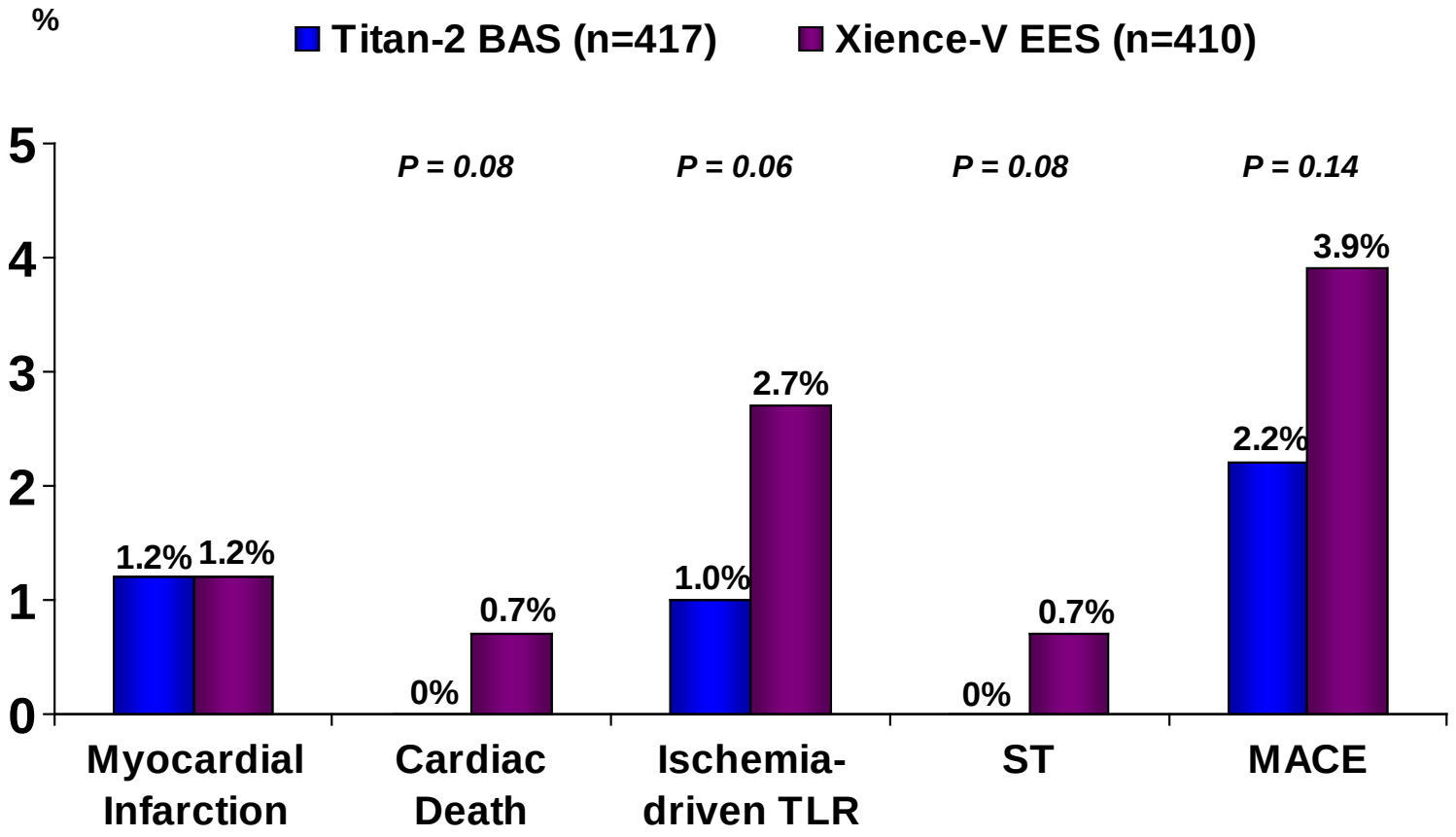


TLR = Target Lesion Revascularization
ST = Definite Stent Thrombosis

BASE-ACS

MACE Components

After Clopidogrel Discontinuation



FU = 6-12 months

BASE-ACS

BASE-ACS 18 months FU

Conclusions

- **TITAN-2 BAS and XIENCE-V EES were associated with a comparable frequency of efficacy adverse events (TLR) in patients presenting with acute coronary syndrome (ACS)**
- **However, the rate of MI and ST tended to be higher in the EES group**
- **The present study suggest that a stent coated with Titanium-Nitride-Oxide (TITAN-2 BAS) represents a safe and effective alternative to Xience-V EES in ACS patients**

asia PCR Singapore Live

BASE-ACS

'Thank You – Kiitos'

Investigators	Hospital
P Karjalainen, A Ylitalo, J Mikkelsson, Minna Ampio	Satakunta Central Hospital, Pori, Finland
M Niemelä, K Kervinen, H Romppanen, Eija Niemelä	Oulu University Hospital, Oulu, Finland
F Rivero, J Salamanca	Hospital Universitario de la Princesa, Madrid, Spain
J Airaksinen, M Pietilä, Tuija Vasankari	Turku University Hospital,Turku, Finland
J Sia	Kokkola Central Hospital, Kokkola, Finland
J Lalmand, A Aminian, D Dolatabadi, P Lefebvre, V Piamonte	C.H.U. de Charleroi, Charleroi, Belgium
O Hess, B Meier, C SchoenenbergerWeber	Bern University Hospital, Bern, Switzerland
B De Bruyne, W Wijns, An Roets	Cardiovascular Center Aalst, Aalst, Belgium
M Carlier, S Fasseaux, C Mortier, Y Dascotte, A. Jourdan	Grand Hôpital de Charleroi, Charleroi, Belgium
A deBelder, Nina Cooter	Royal Sussex County Hospital, Brighton, UK
J R López-Minguez, J M Nogales Asensio	Infanta Cristina University Hospital, Badajoz, Spain
M Laine	Helsinki University Hospital, Helsinki, Finland
P Tedjokusumo, A F Yahya,C Ahmad,J W Marta	Dr. Hasan Sadikin Hospital, Bandung, Indonesia
K Nyman	Jyväskylä Central Hospital, Jyväskylä, Finland