



Real-World Outcomes of Complex PCI in a Large-Scale Multicenter International Study: Insights from 2001 Patients

By Pr. Mamas Mamas



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Potential conflicts of interest

Speaker's name: Professor Mamas A. Mamas

- ☐ I do not have any potential conflict of interest to report
- ☐ I have the following potential conflicts of interest to report:

Why this study?

Complex PCI: a multidimensional challenge of lesion complexities and patient factors.

≈ **30%** of all PCI are Complex.



Complex PCI are at high risk of ischemic and bleeding events.



...But complexity goes beyond the lesion - patient risk matters too.



± **45%** of your patients are at high bleeding risk

NAGOMI COMPLEX study

Ultimaster Nagomi
Stentless, stenting coronary stent system



To evaluate the safety and performance of the Ultimaster Nagomi™ stent and offer real-world insights into complex patient populations.

Why this study?

 A European Prospective Study of a Sirolimus-Eluting Stent in Routine Clinical Practice

Enrollment
completed

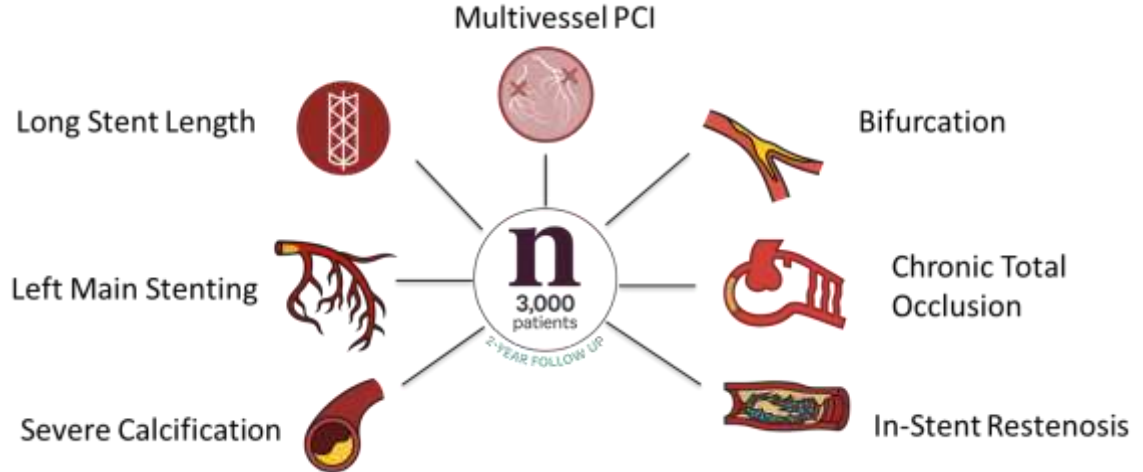
13 countries
52 sites

3000 Complex PCI
patients recruited

Ultimaster Nagomi
Sirolimus-eluting coronary stent system

Primary endpoint: TLF at one year

NAGOMI COMPLEX study



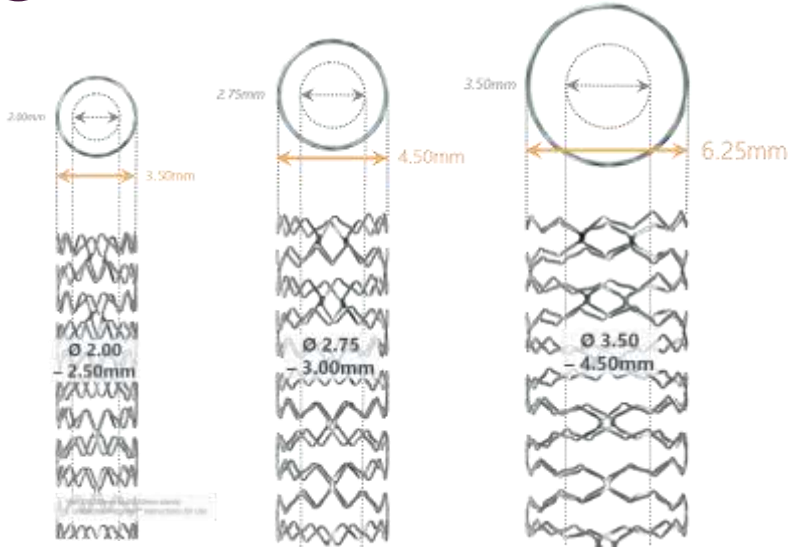
Dedicated focus on subgroups of particular interest: **High-bleeding risk patients**

Why this study?



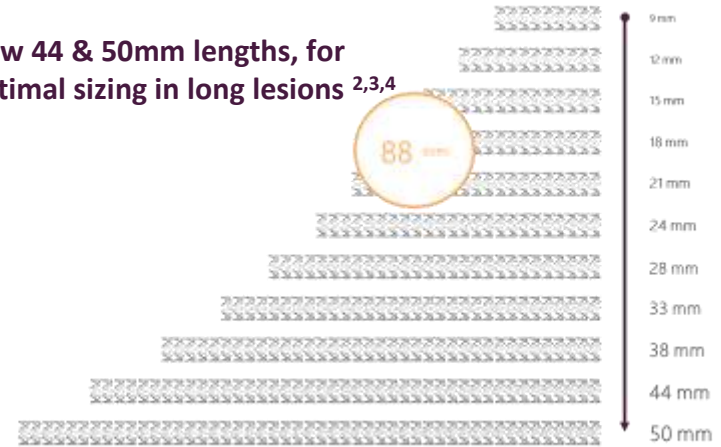
Ultimaster Nagomi™: A Stent Optimized for Complex PCI

- Stent design allows good overexpansion capacities ¹

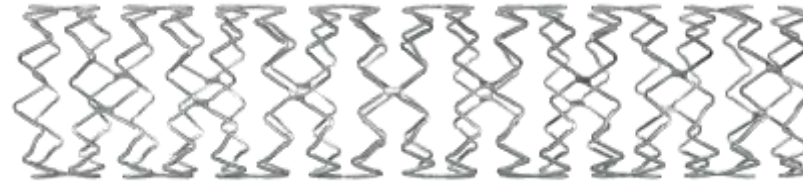


Designed to support left main stenting and complex bifurcation interventions.

- New 44 & 50mm lengths, for optimal sizing in long lesions ^{2,3,4}



- Open-cell, 2-link design, for flexible stent platforms ^{2,3,5,6}

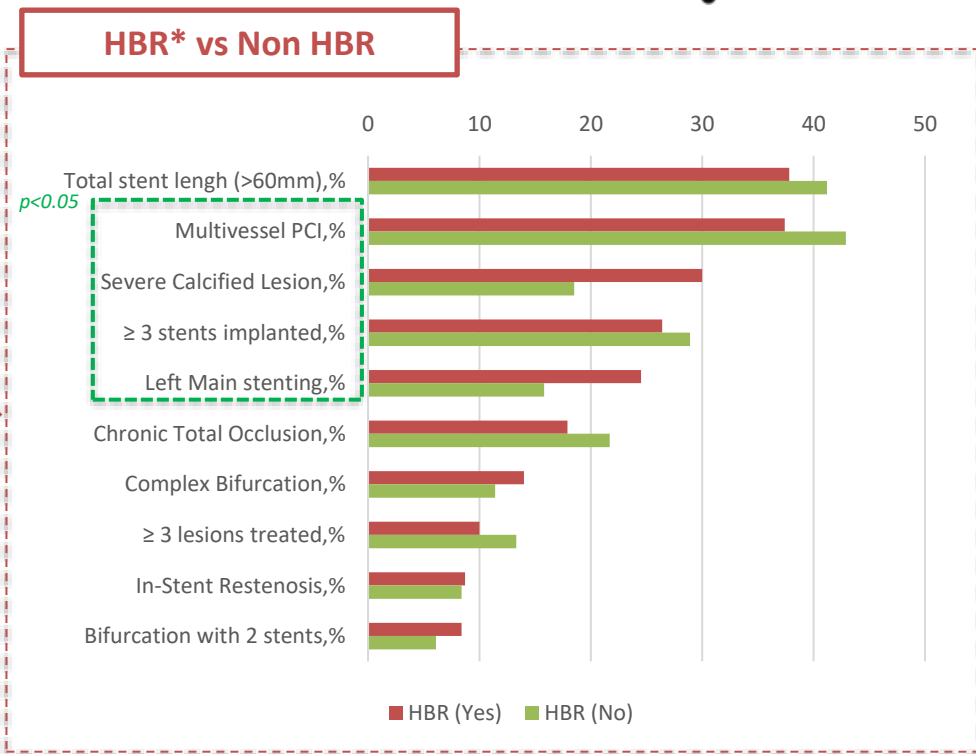
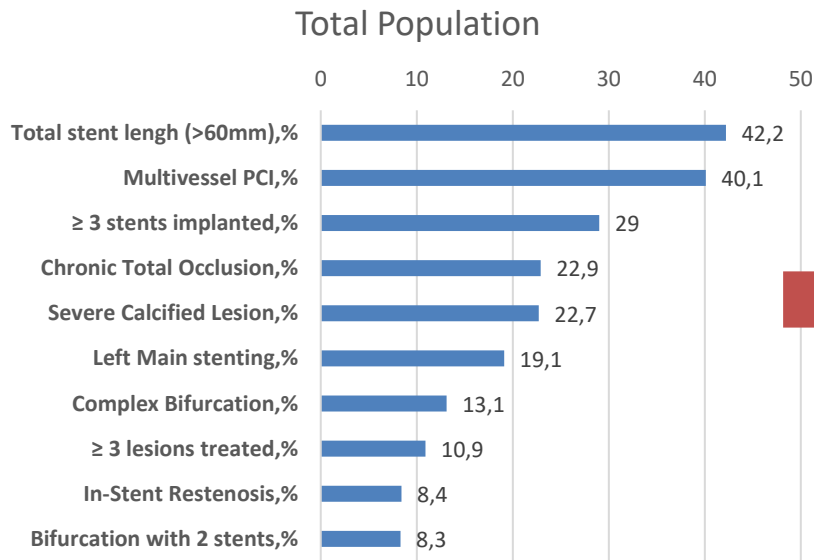


What are the essential results?



Complex PCI criteria distribution

These findings are based on preliminary data - extracted February 28, 2025



44.9% (759/1692)

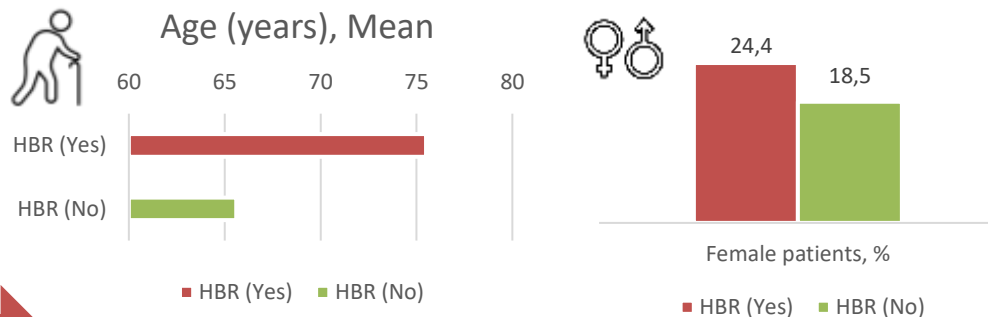
What are the essential results?

Baseline clinical presentation

Patient characteristics	Total Population
Age (years), Mean±SD	69.2±10.38
Female patients, %	20.6
Age ≥75, %	34.5
HBR patients, %	44.9
Diabetes, %	28.0
Previous PCI, %	36.3
Previous MI, %	29.7
Present with ACS, %	28.8

HBR* vs Non HBR

$p < 0.05$



HBR patient profiles less favorable:

- More diabetes, hypertension;
- Higher creatinine levels;
- More Atrial Fibrillation, prior MI, prior PCI;
- Higher COPD, PAD.

**following ARC-HBR score

What are the essential results?



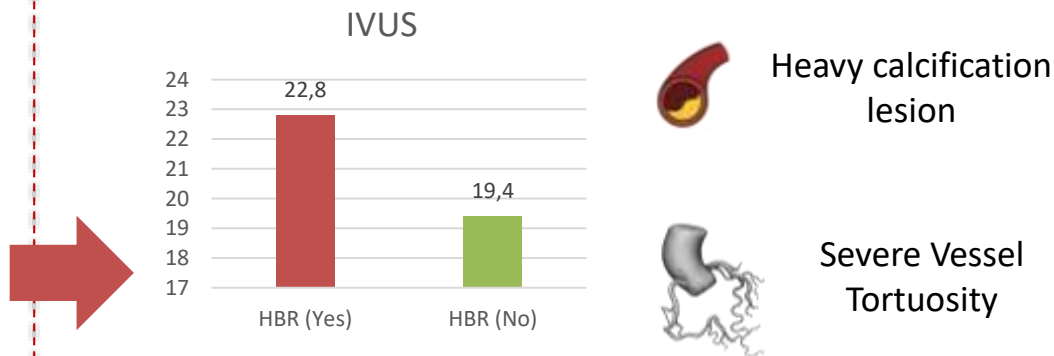
Lesion & procedural characteristics

Lesion/procedure characteristics	Total Population
Radial access, %	90.7
Num of lesions identified, Mean±SD	1.9±1.02
Num of lesions treated, Mean±SD	1.6±0.75
Num of stents/subj, Mean±SD	2.1±1.03
Num of stents/lesion, Mean±SD	1.4±0.68
Stent length, Mean±SD	27.7±11.30
Imaging used (IVUS/OFDI/OCT), % per lesion	27.9

HBR** vs Non HBR

$p<0.05$

Significantly higher for HBR:



Total number of Ultimaster Nagomi™ implanted: **4332**

**following ARC-HBR score

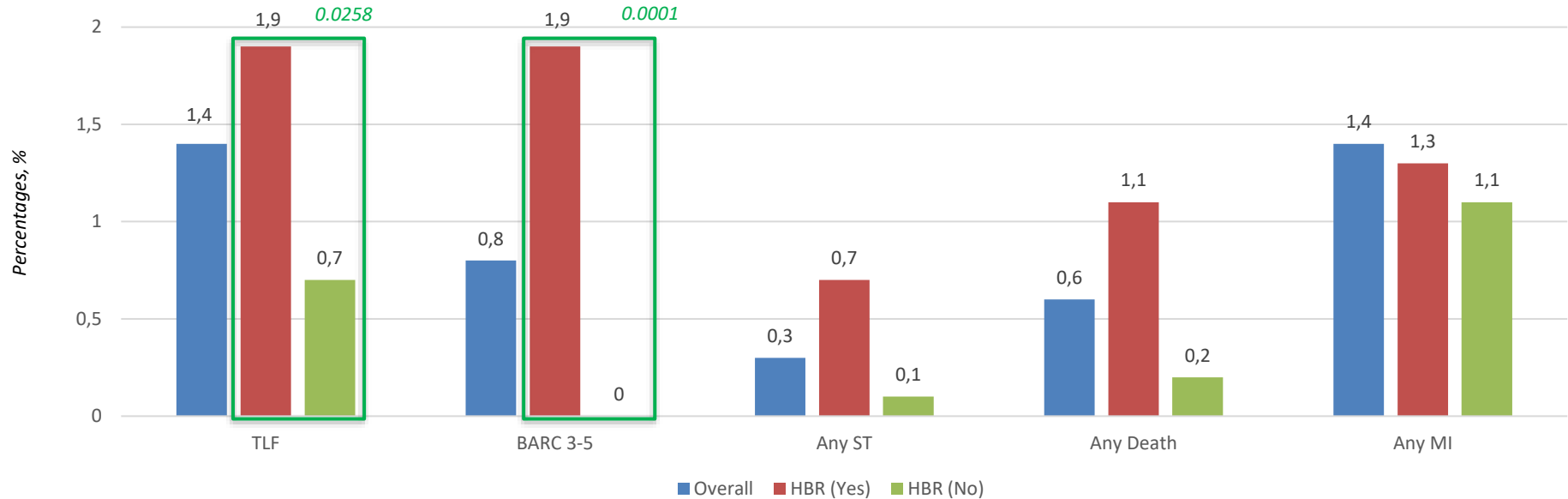
What are the essential results?



Clinical Outcomes - Incidence rates at 30 days



44.9% (759/1692)



CONCLUSION & PERSPECTIVES

1

The Ultimaster Nagomi™ is a stent optimized for **high-risk PCI profiles**, including complex lesions and patient conditions.

2

44.9% of patients were classified as **having a high bleeding risk** (ARC-HBR), with notable differences in patient profiles and lesion characteristics within the population.

3

The stent demonstrated **excellent short-term clinical outcomes** in this complex cohort, with a 30-day **TLF rate of 1.4%** and **stent thrombosis rate of 0.3%**.



Primary endpoint results expected in 2026

(1-year TLF in 3,000 complex PCI patients)



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