Use of ICD for Primary Prevention of Sudden Cardiac Death:

Results from the Improve SCA Clinical Study

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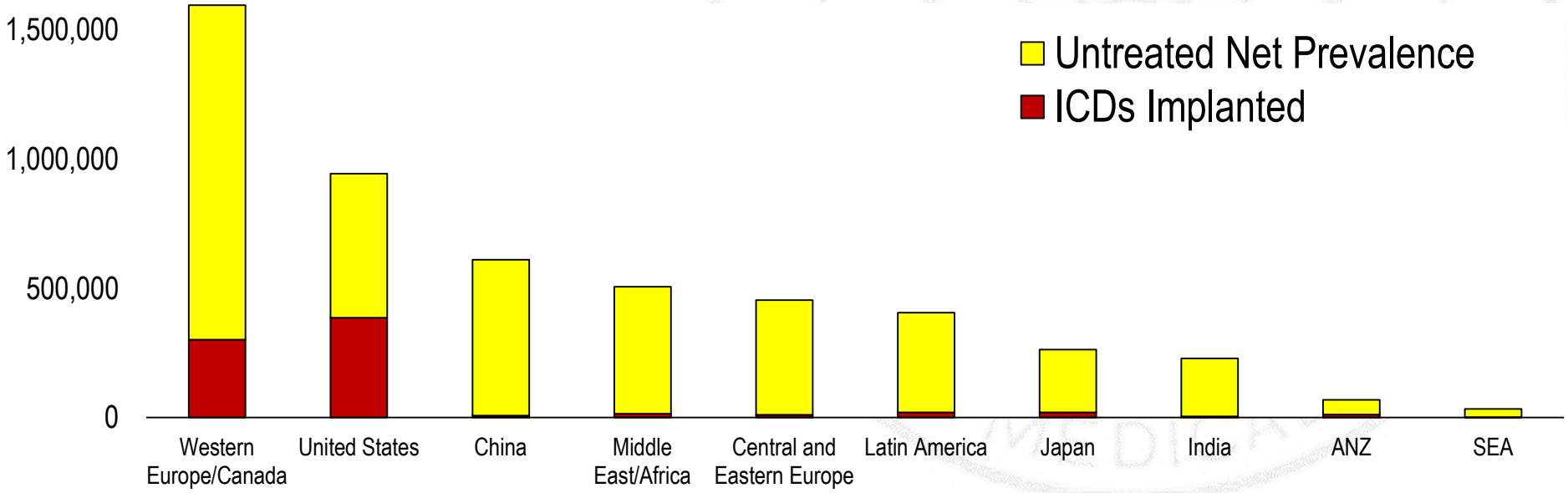
Background

- ICD has been proven to **reduce mortality in primary prevention**
- ICDs are ***underutilized globally***
- Asia, South America, Eastern Europe, and Africa have been **under-represented** in large ICD trials



Background

ICD implantation for the prevention of SCD

PRIMARY PREVENTION	SECONDARY PREVENTION
At risk for, but not yet had an episode of sustained VT, VF or resuscitated cardiac arrest	Cardiac arrest survivor or sustained VT

Background

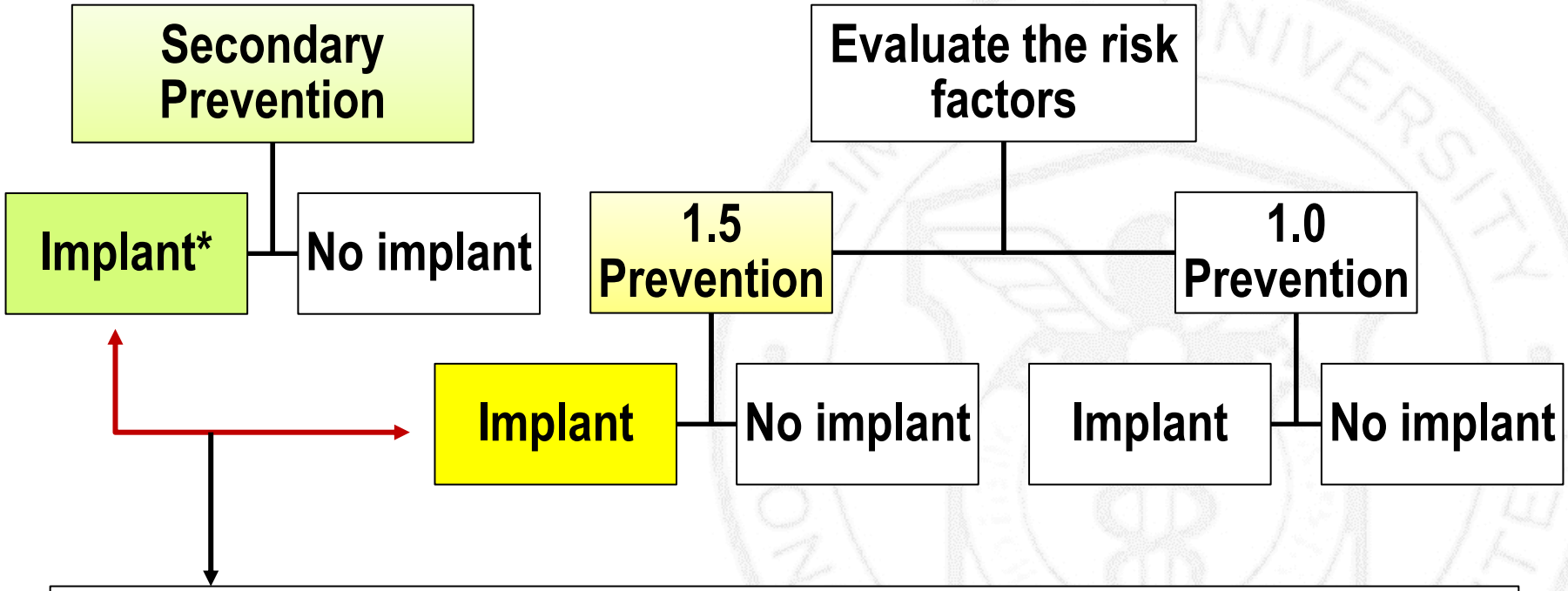
- **High risk factors among Primary Prevention population**
  - ✓ Near syncope/syncope
  - ✓ LV EF < 25%
  - ✓ NSVT: ≥ 3 consecutive PVCs, > 100 BPM, & < 30 sec
  - ✓ Frequent PVCs: > 10 PVCs/1 hour

≥ 1 high risk factors → **Categorized as 1.5 Prevention group**

Hypothesis

- **1.5 Prevention patients** are at a ***similar risk of life-threatening ventricular arrhythmias*** when compared with **2ndary Prevention patients** and would receive the **same benefit from an ICD or CRT-D implant**

Objectives

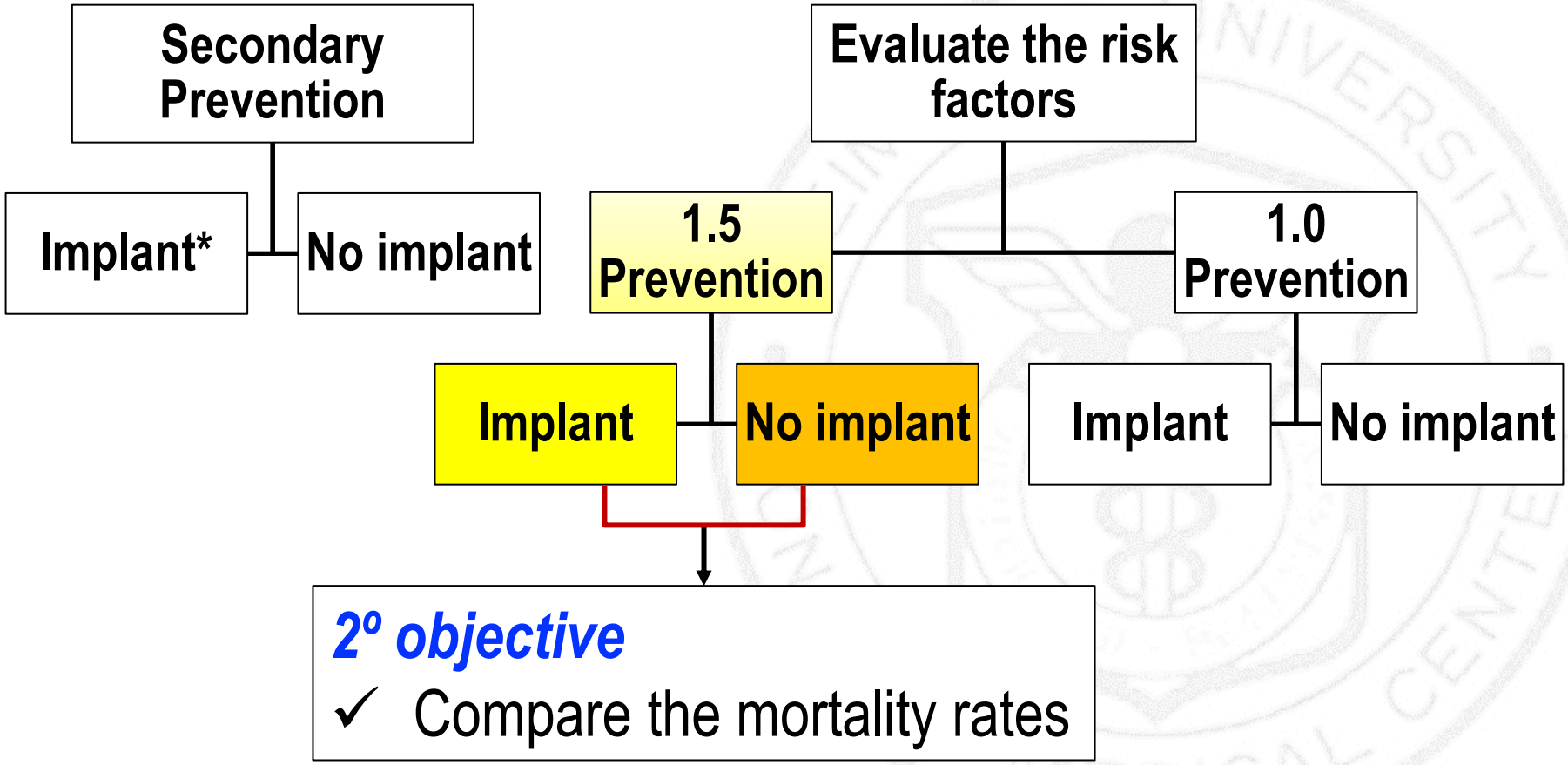


1º objective

✓ Compare appropriate VT/VF therapy rates (shock & ATP)

**Decision was made by patients*

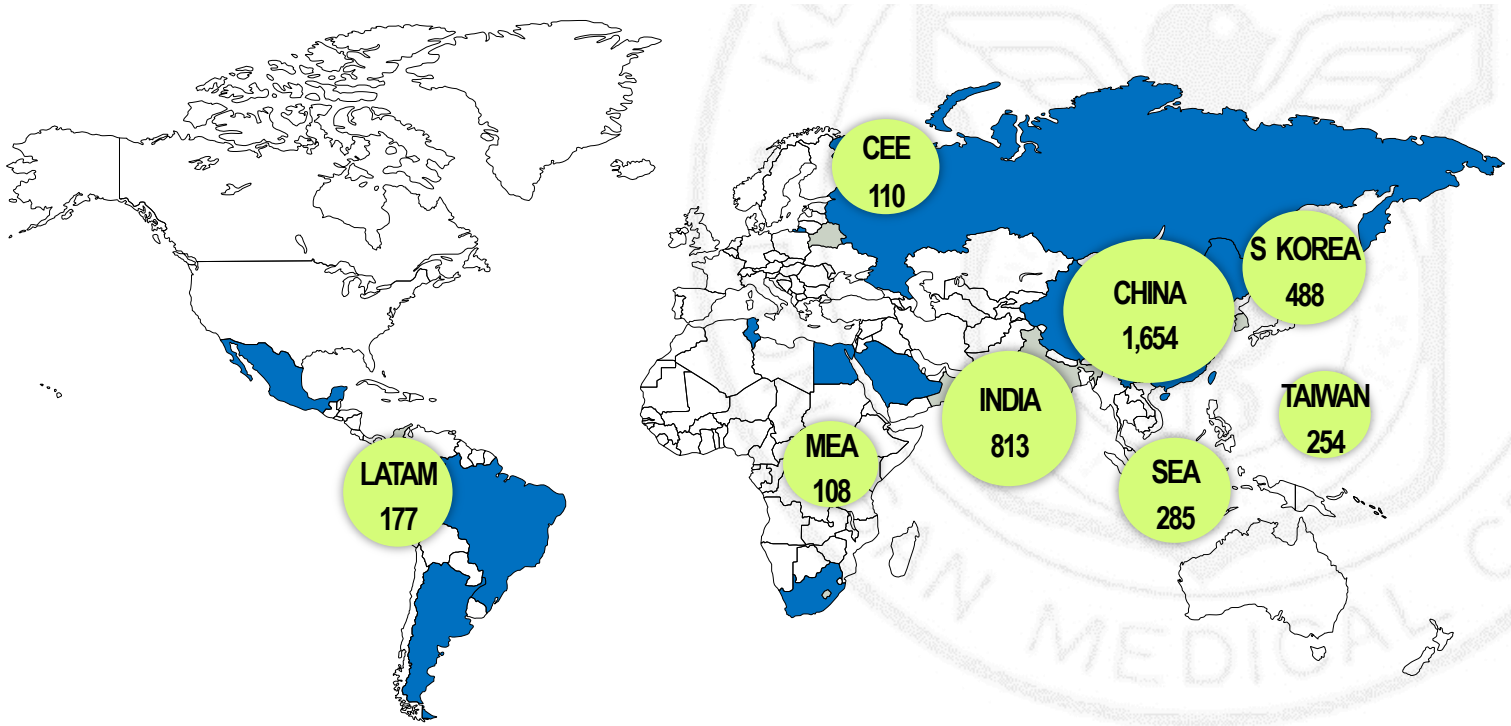
Objectives



*Decision was made by patients

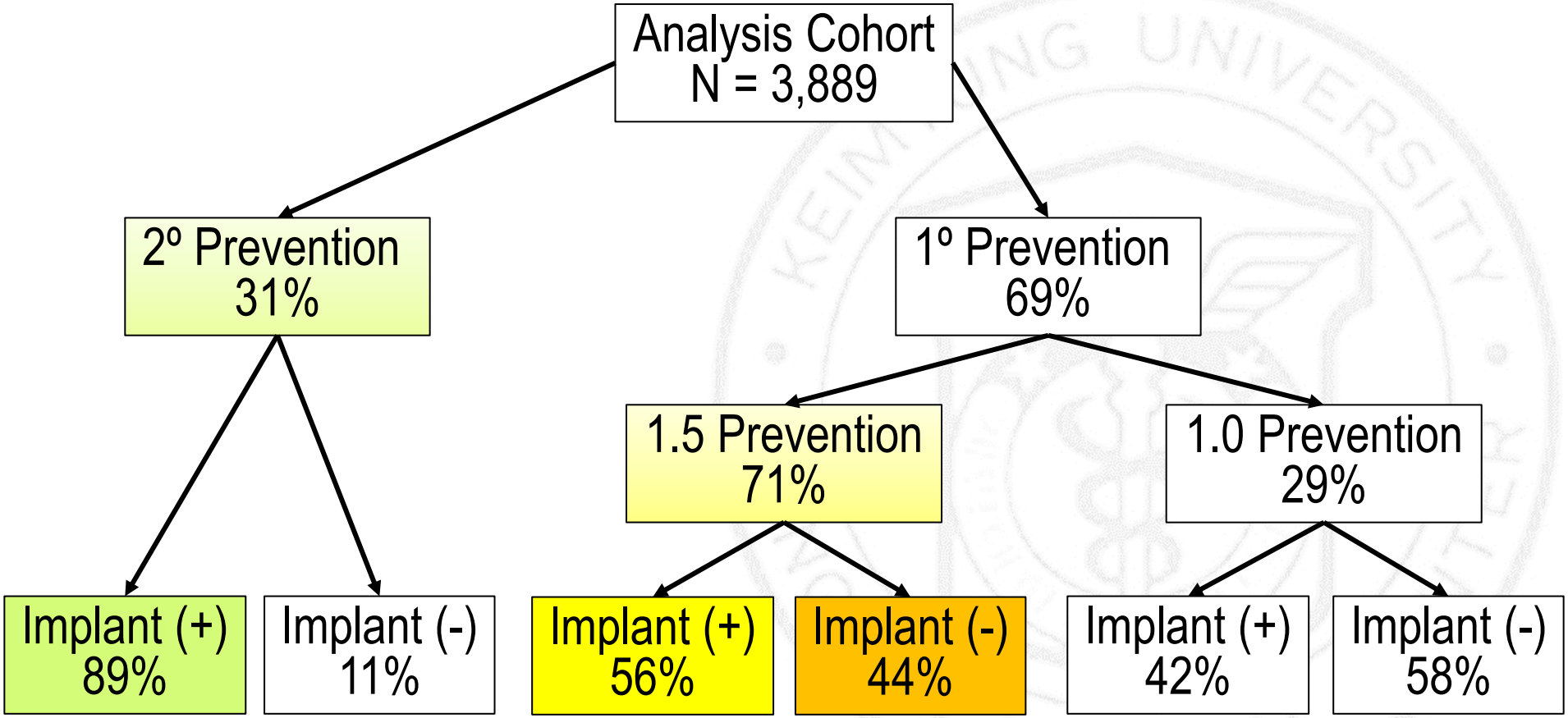
Methods

- Non-randomized prospective observational study
- March 2014 – July 2017: Final visit - Aug. 2018
- **3,889 patients**; 17 countries; 84 sites
- Mean FU duration: 21.0 ± 10.8 months (0 – 51 months)



ClinicalTrials.gov: NCT02099721

Patients Distribution



Results

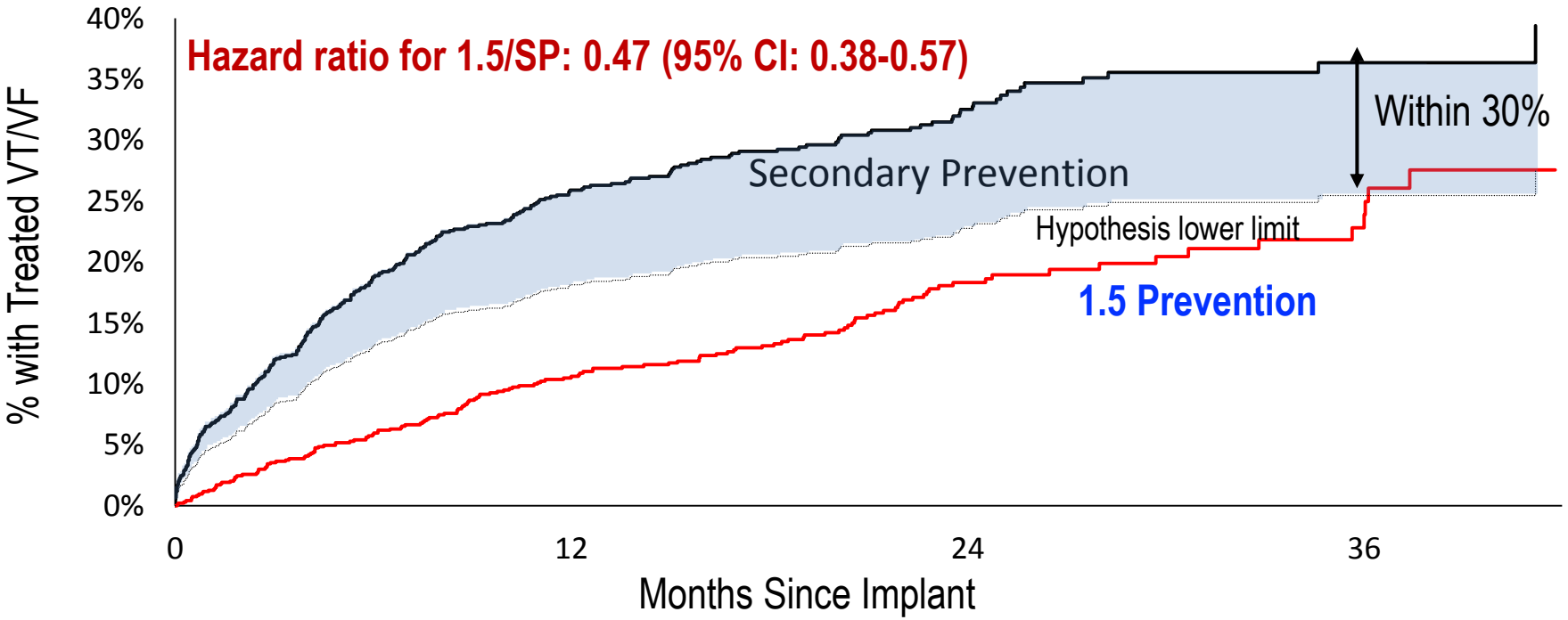
Baseline Characteristics of 1º objective population

	2º Prevention Implanted (n = 1,066)	1.5 Prevention Implanted (n = 1,068)	P-value*
Age (years) (mean ± SD)	57.1 ± 14.3	**61.1 ± 11.7**	<0.0001
Gender, male (%)	76.2	76.3	0.94
QRS Duration (ms) (mean ± SD)	115 ± 33	**132 ± 36**	<0.0001
Ischemic CM (%)	21.9	20.4	0.41
LBBB (%)	6.8	**29.5**	<0.0001
NYHA III (%)	25.9	59.1	<0.0001
Diabetes (%)	21.2	28.9	<0.0001
CRT-D (%)	11.5	47.9	<0.0001
LVEF (%) (mean ± SD)	43 ± 16	**25 ± 6**	<0.0001
LVEF < 25% (%)	10.5	46.0	<0.0001

*two-sample t-test or chi-square test

Results

1º objective: Time to first VT/VF therapy (shock & ATP)

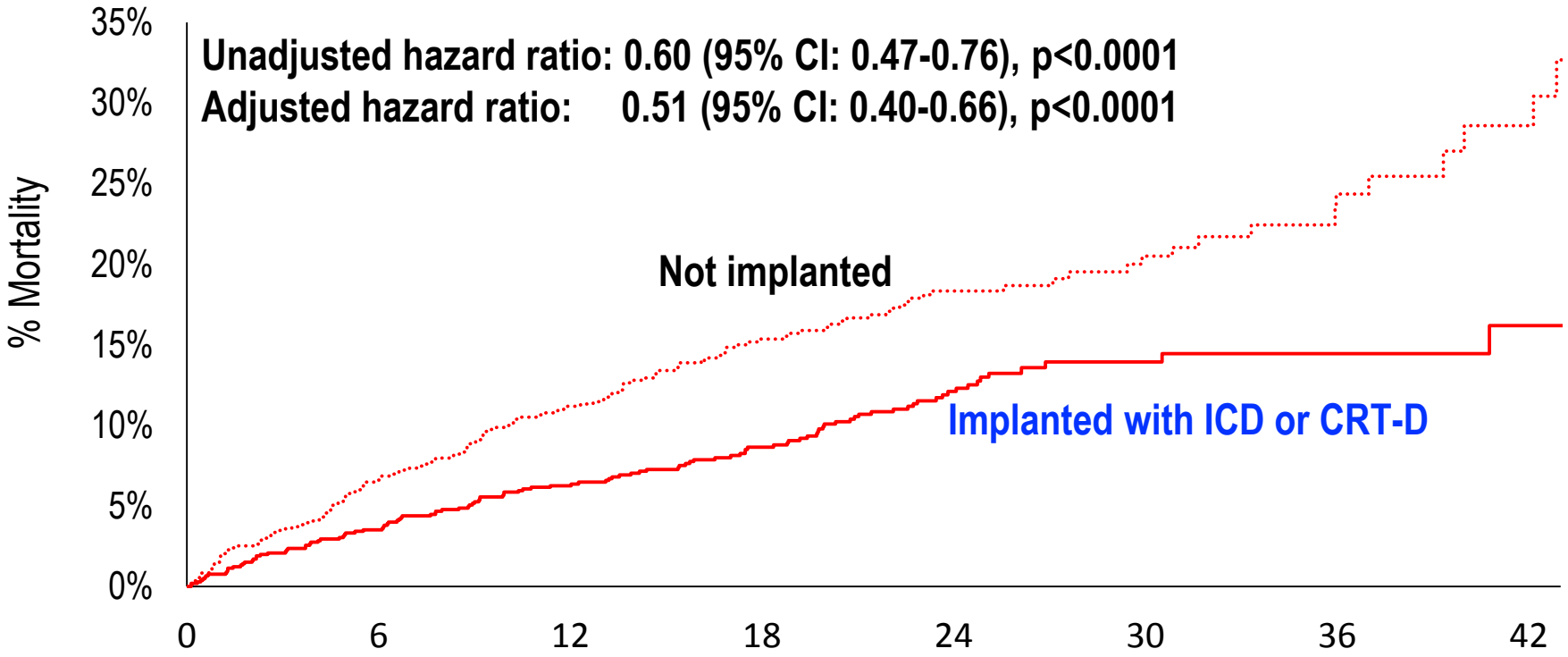


Number@Risk

2º	1,053	565	252	67
1.5	1,068	682	296	72

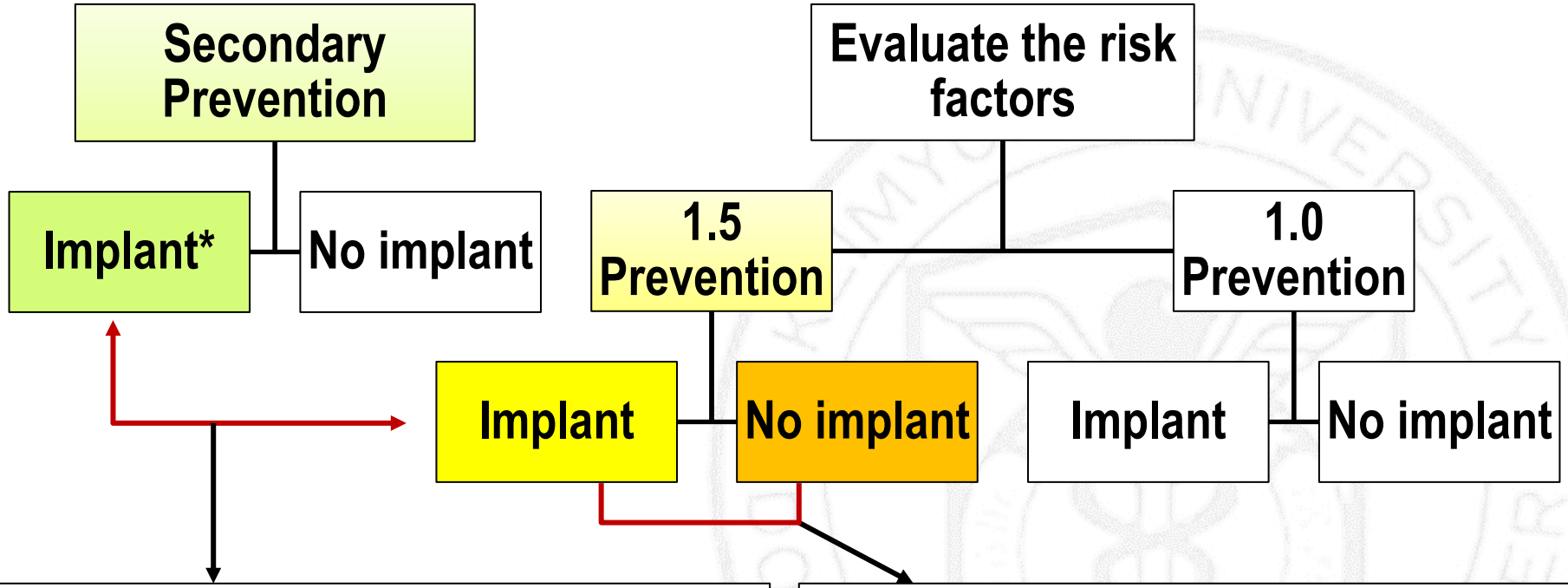
Results

2º objective: Mortality rates



Number@Risk				
Implant (-)	845	649	325	78
Implant (+)	1,068	879	438	94

Results overview



1º objective

Incidence of **first treated VT/VF** in the **1.5 prevention group** ***was lower than 2º prevention group***

2º objective

After adjusting for covariates, the **ICD implant** ***reduced the risk of mortality by 49% (p<0.0001)***

Conclusion

- **Incidence of first treated VT/VF** in the 1.5 prevention group was ***lower than secondary prevention***
- 1.5 prevention patients with ICD had a ***49% relative risk reduction in mortality*** compared to those without an ICD implant
- These data **confirm the mortality benefits of ICD** therapy in primary prevention ***in the under-represented population of the world*** and align with past randomized trials

Thank You for Your Attention !