Title: Evaluating the benefit of Primary Prevention ICD therapy in Ischemic and Non-ischemic Cardiomyopathy patients from Asia, South America, Eastern Europe, and Africa: Sub-Analysis from the Improve SCA Clinical Study

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Background:

Despite the burden of sudden cardiac death worldwide, implantable cardioverter defibrillators (ICDs) are underutilized, especially in Asia, Latin America, Eastern Europe, the Middle East, and Africa. The Improve SCA study demonstrated that primary prevention (PP) patients (pts) in these regions benefit from an ICD/CRT-D. One of the main study objectives was to determine whether there was a reduction in all-cause mortality among PP ICD recipients with one of the following risk criteria: syncope, NSVT, PVCs>10/h, LVEF<25%; all PP study patients with one or more of these criteria were categorized as 1.5PP pts.

Objective:

The purpose of this sub-analysis was to evaluate the mortality benefit between implanted and non-implanted ischemic cardiomyopathy (ICM) and non-ischemic cardiomyopathy (NICM) pts categorized as 1.5PP.

Methods:

Improve SCA was a prospective, non-randomized, non-blinded multicenter study that enrolled pts from regions where ICD utilization is low: Asia, South America, Eastern Europe, the Middle East, and Africa. Implanted and non-implanted pts were followed for ≥1yr. Cox proportional hazards methods were used, adjusting for factors affecting mortality risk.

Results:

There were 1,361 1.5PP NICM pts, 790 (58.0%) of whom received devices; there were 387 1.5PP ICM pts, 218 (56.3%) of whom received devices. Overall, there was a statistically significant 51% relative risk reduction in all-cause mortality among 1.5PP NICM pts. The
mortality rate at 2 years for 1.5 PP NICM pts with or without an ICD/CRT-D was 11.7% and 19.4%, respectively. This equates to an NNT of 12.9. This mortality benefit was also observed in 1.5PP ICM pts, with a 48% reduction in all-cause mortality among pts that received an ICD/CRT-D (Figure). The mortality rate at 2 years for 1.5 PP ICM pts with or without a device was 15.0% and 19.0%, respectively. This equates to an NNT of 24.9.

**Conclusion:**

In this large prospective evaluation of PP ICD pts, a 51% reduction in all-cause mortality was observed in 1.5PP NICM pts and 48% reduction in all-cause mortality was observed in 1.5PP ICM pts, which demonstrates a clear benefit to implanting ICDs in primary prevention pts with ischemic/non-ischemic cardiomyopathy categorized as 1.5PP.