

A high Risk Patients Cohort, Age over 70 and 80 Years in the Worldwide e-HEALING Registry.

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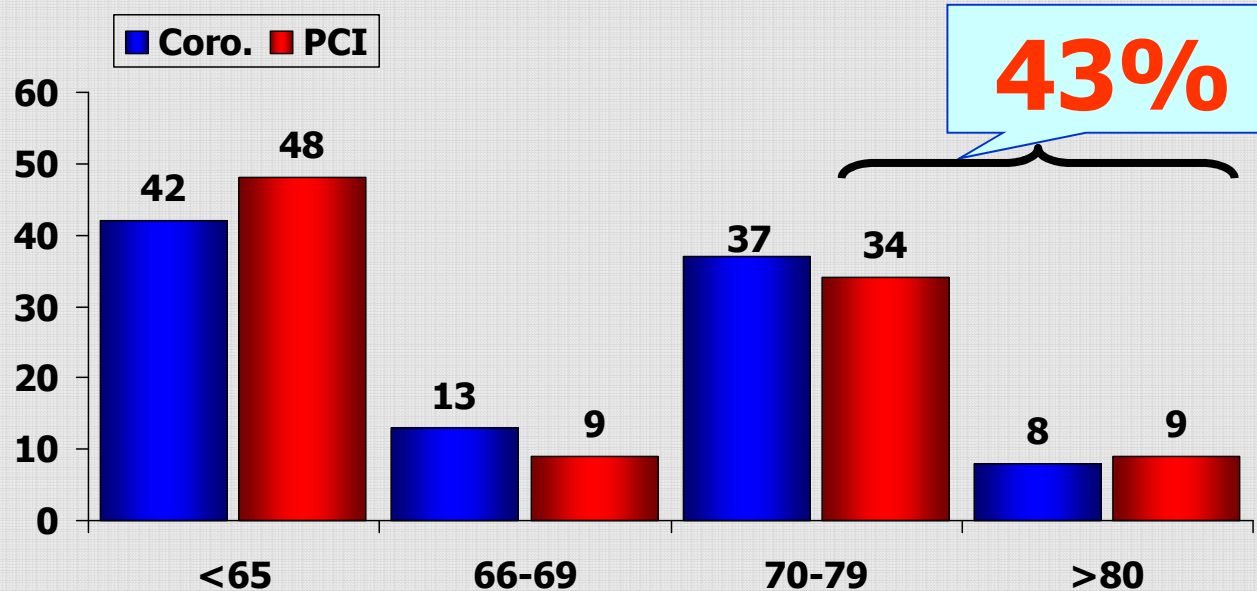
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Age Related Inequities

- Elderly patients represent an important proportion of total patients undergoing PCI Procedures.



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Elderly Co-morbidities

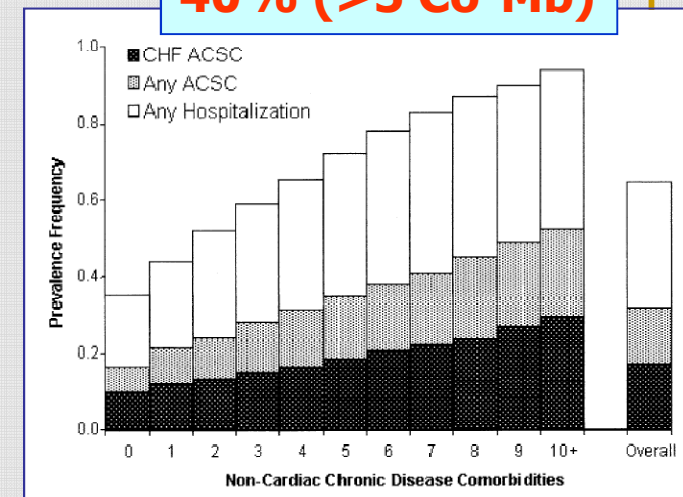
■ High rate of Cardiovascular Co-M.

- Prior MI (42-49%)
- Prior CABG/PCI (18-20%)
- Prior CHF (10-12%)
- Prior TIA/Stroke (7-10%)
- Peripheral Vascular Disease (13-21%)
- HBP (39-59%)
- Diabetes (19-31%)

■ Frequent Non-Vascular Co-M.

- COPD (7-26%)
- Ulcer/Liver disease (6-7%)
- Chronic Renal Insufficiency (10-11%)
- Anemia (15-50%)

40% (>5 Co-Mb)



Dahlström et al. EHJ 2005; 7: 309-316
Braunstein et al. JACC 2003; 42: 1226-1233.

Elderly Co-morbidities

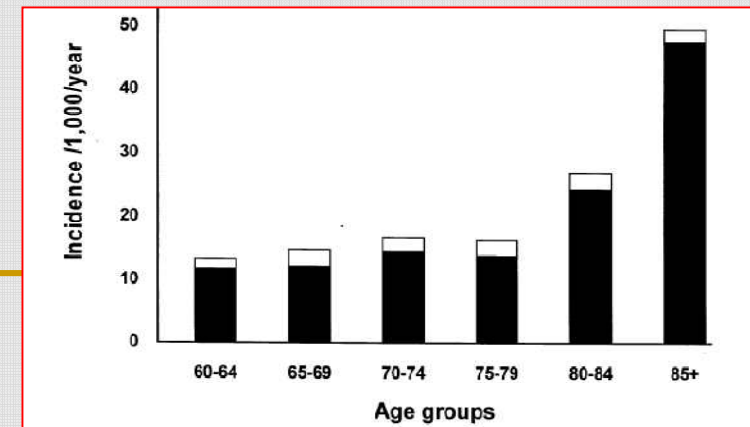
■ Plurimedication

- Aspirin (87%) / Coumarins (15%)
- B-blocker (84%)
- ACE inhibitors (89%)
- Insulin (13%)

**Drug Interactions /
Low Drug Compliance**

■ Frequent Need of Non-Cardiovascular Interventions

- Hip Fracture



Johansen et al.
Arch. Gerontol Geriatrics 1999; 29: 215-221.



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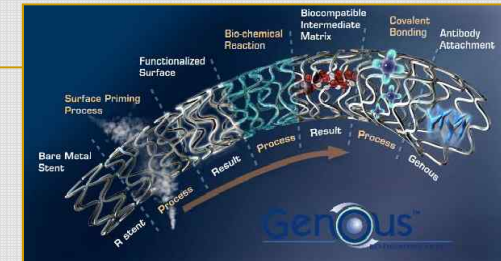
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DES Implantation Consequences in the Elderly

- *DES Uncertainties*
 - *Sub-acute/Late Thrombosis*
- *Long-Term Antiplatelet Therapy*
 - *Efficacy ~ Resistance/Length of Therapy?*
- *Age Concerns*
 - *Co-morbidities*
 - *Drug Interactions /Low Drug Compliance*
 - *Frequent Need of Non-Cardiovascular Interventions*
 - *Need to suppress AP Treatment*



Safety Concern with DES Use in the Elderly



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e-HEALING Registry: Objectives

- Collect post marketing data on patients:
 - Receiving at least one Genous Bio-engineered R stent
 - With "On Label" indication
 - With recommended one month of DAPT post stenting
- Assess clinical outcomes and safety of these patients out to 12 months post procedure
- Identify any potential unanticipated adverse device-related effects that may not have been noted prior to market approval
- Collect data on procedural practices and demographic characteristics and to determine how these variables affect clinical outcomes.



e-HEALING: Methods

- e-HEALING Registry: 4.996 Patients included
 - 1.567 Patients (2.169 lesions) were over 70 years old (31,2%).
- Criteria for Inclusion:
 - At least one coronary artery lesion suitable for stenting.
 - A 2,5-4,0mm diameter Genous R stent TM stent of lengths 9 to 33mm.
- Recommended 1 month of dual antiplatelet therapy after PCI.
- Clinical follow-up was at 1, 6 and 12 months.
- MACEs (Major Adverse Cardiac Event): defined as cardiac death, myocardial infarction (MI) or clinically driven target lesion revascularization (TLR), were adjudicated by an independent committee.



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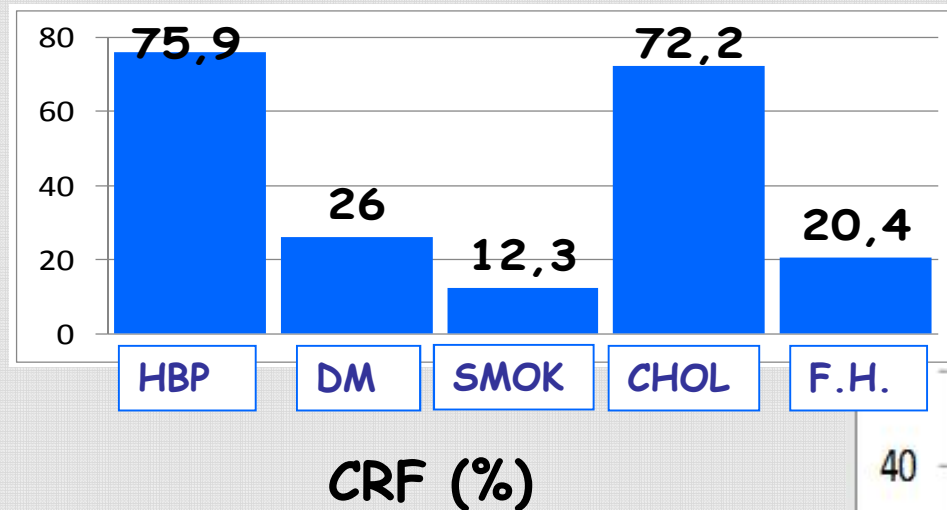
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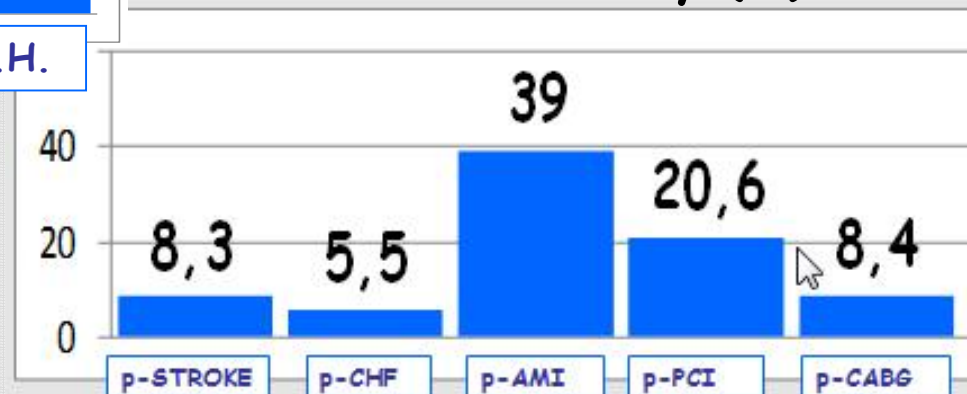
e-HEALING: Methods

Baseline Data (#:1.567 P. over 70 years) - 2.169 Lesions

- Mean age: 75 years old (Min. 72 - Max. 93)
- Male: 1.063 (67,8 %) / Female: 504 (32,2%)



Prior CV History (%)



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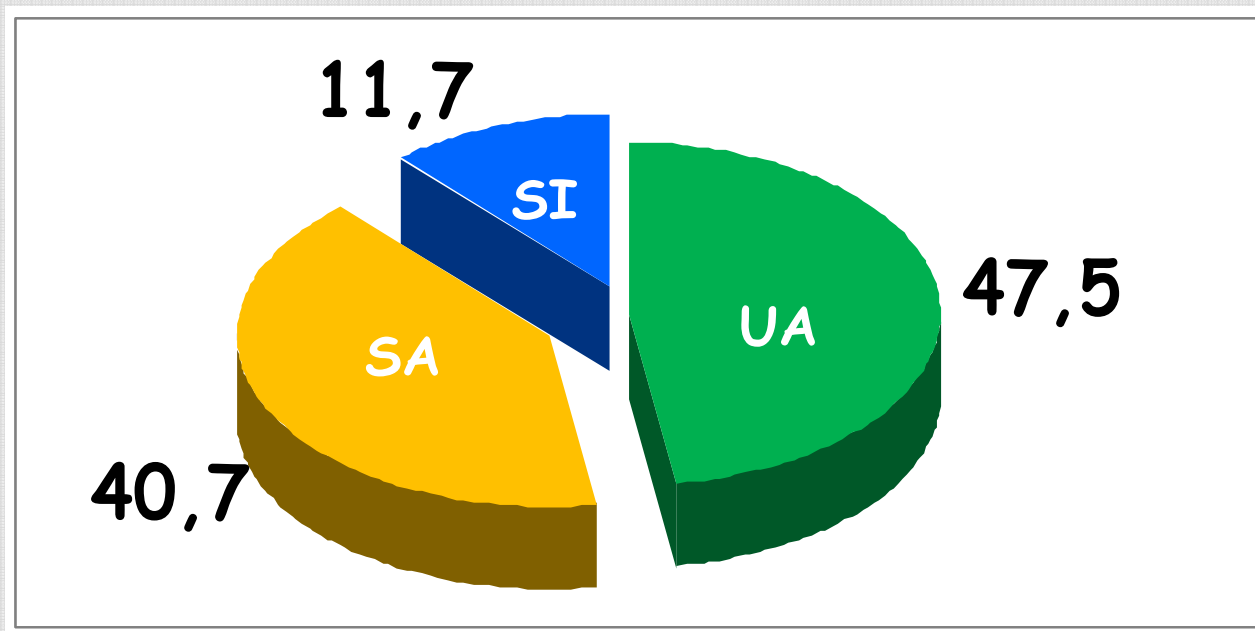
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e-HEALING: Methods

Ischemic Status at Screening

- #: 1.567 patients (%)

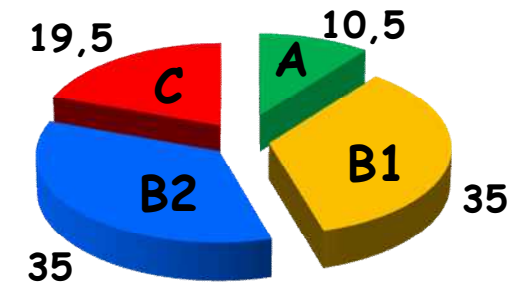


e-HEALING: Results

Baseline Data (#:1,567 P. over 70 years)

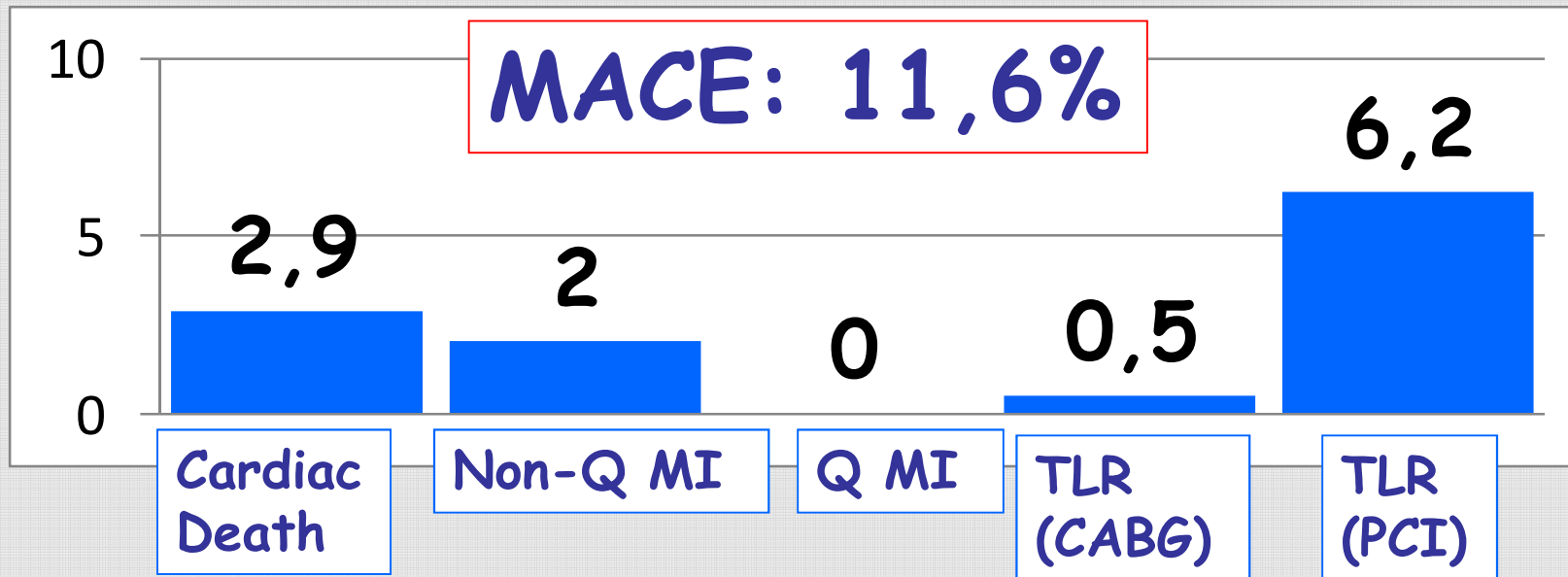
# Lesions	2.169
Direct stenting	33,9%
Mean Lesion Length	16,2±8,3
RVD (mm)	3,0±0,4
% Diameter Stenosis pre-PCI	85,0±11,8
Lesions Characteristics De Novo / Restenotic Lesions at Bifurcation	97,4% / 2,6% 10,9%
# Lesions / Patient	1,1±0,6
Stent / Lesion (Mean ± SD)	1,4±0,5

**AHA lesions classification
(#: 2.169 Lesions) (%)**



e-HEALING: Results

12 months Events * (%)



12 months Event Free 88,4%

* MACE per patient Non Hierarchical (cardiac death, MI, TLR)



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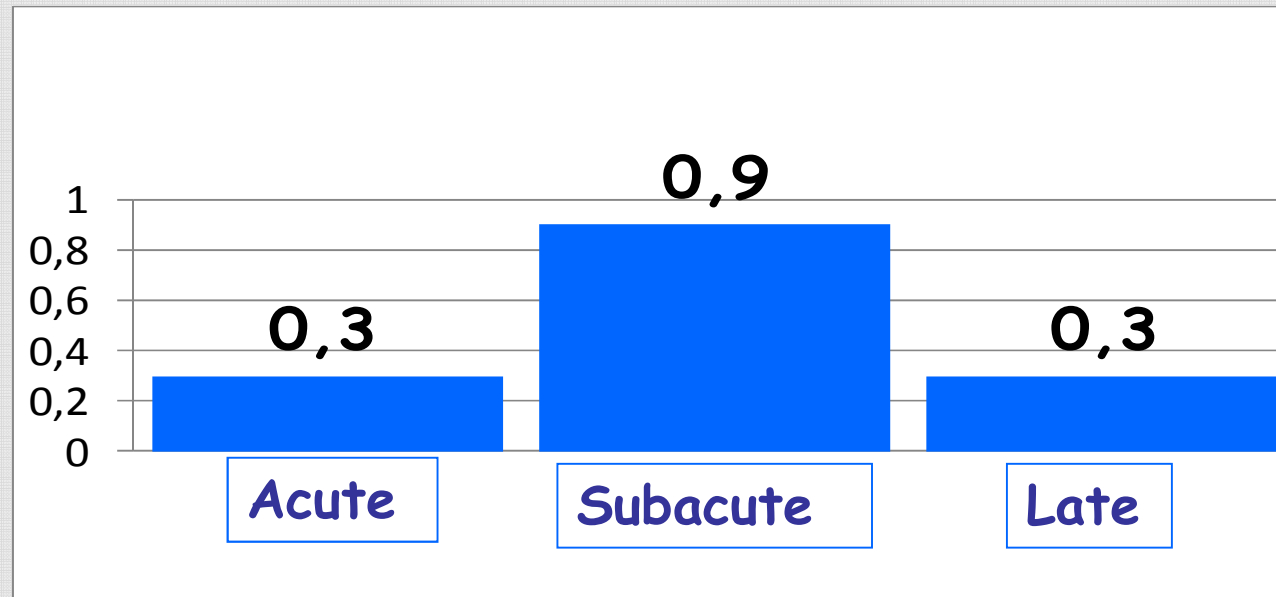
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e-HEALING: Results

1 year Follow-up Events

Stent Thrombosis as per ARC definition
(definite + probable) (1.5%)



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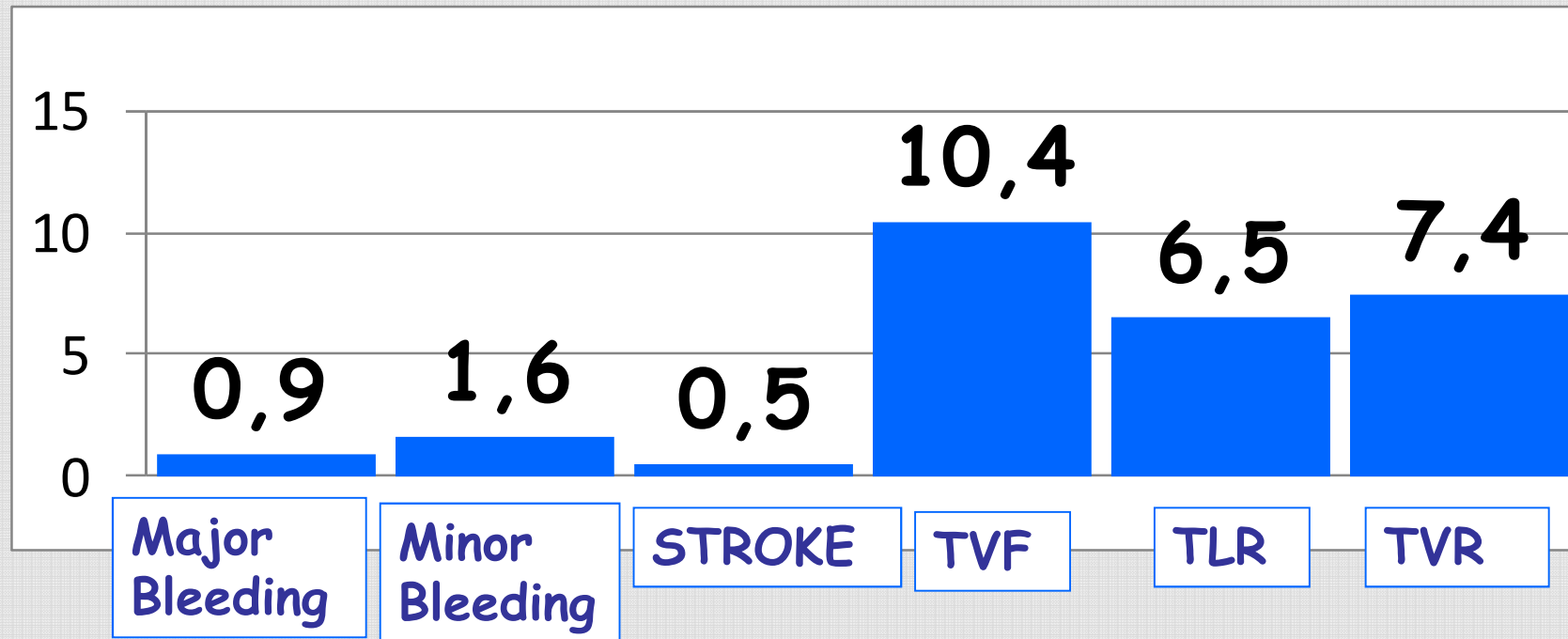
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e-HEALING: Results

1 year Follow-up Events (Others) (%)



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SENIOR e-HEALING: Conclusions

- Patients over 70 years old treated with the Bio-engineered Genous EPC stent have excellent one-year clinical outcome despite an associated unfavorable baseline clinical and anatomical risk profile (MACE) (cardiac death + MI + TLR) of 11,6%
- These results compared favorably with most registries of DES published.

