

RESPECT Trial

- **Randomized, event-driven, open-label trial with blinded endpoint adjudication**
- **Cryptogenic stroke + PFO, 18-60 years**
- **Patients randomized 1:1 to AMPLATZER PFO Occluder (device) vs. guideline-directed medical management (MM)**
- **980 subjects enrolled from 2003 to 2011**
- **69 sites in U.S. and Canada**

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Company

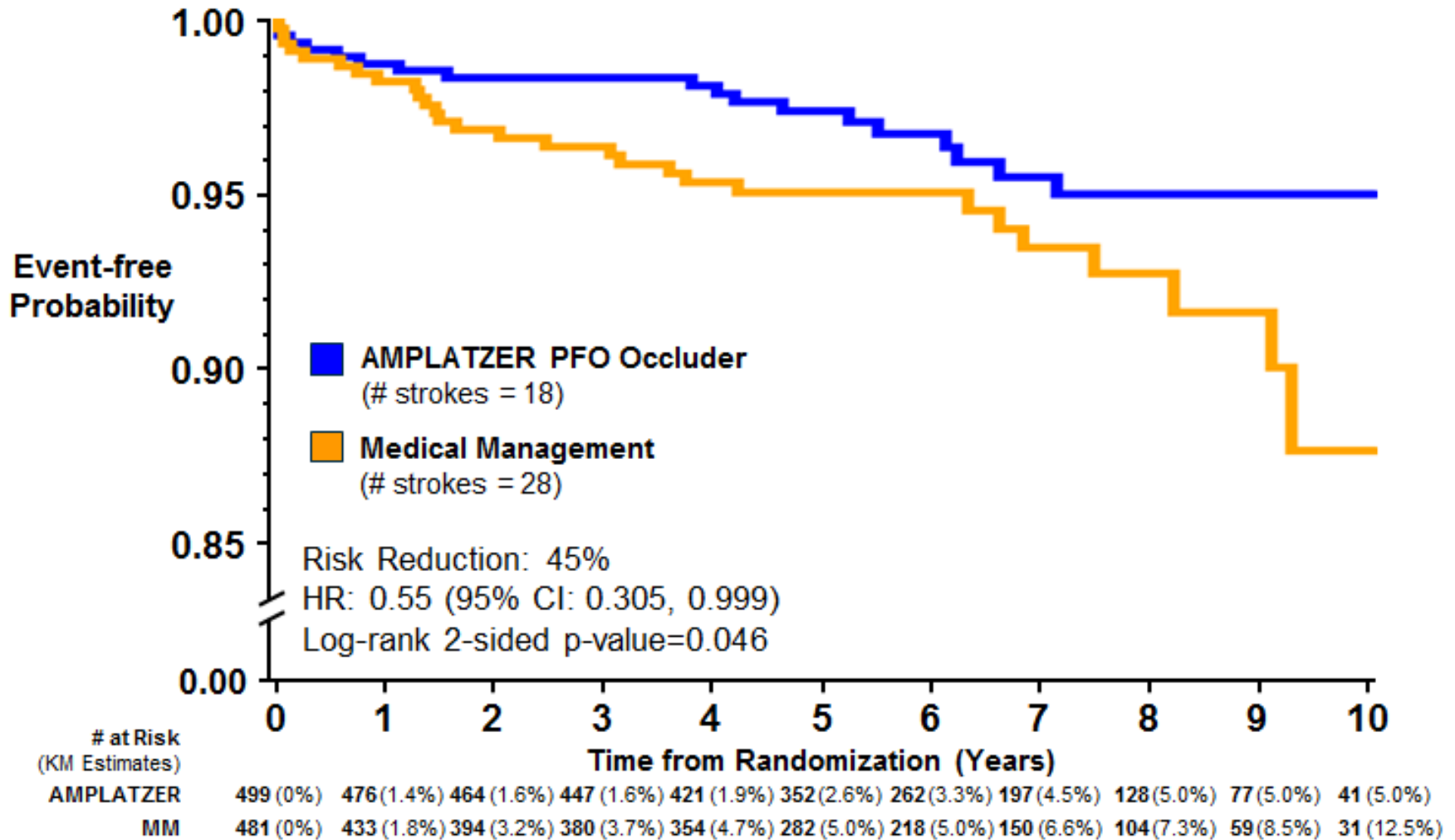
- Grant/Research Support
 - Consulting Fees/Honoraria
 - Major Stock Shareholder/Equity
 - Royalty Income
 - Ownership/Founder
 - Intellectual Property Rights
 - Other Financial Benefit
- Steering Committee, RESPECT Trial, St Jude Medical

Baseline Characteristics Balanced Between Groups

Characteristic	AMPLATZER™ PFO Occluder (N=499)	Medical Management (N=481)
Age (yr), mean ± SD	48 ± 10	46 ± 10
Male	54%	56%
Hypercholesterolemia	39%	41%
Family h/o CAD	33%	33%
Hypertension	32%	32%
COPD	0.8%	1.5%
Congestive heart failure	0.6%	0%
History of DVT	4.0%	3.1%
Atrial septal aneurysm	36%	35%
Substantial shunt	50%	48%

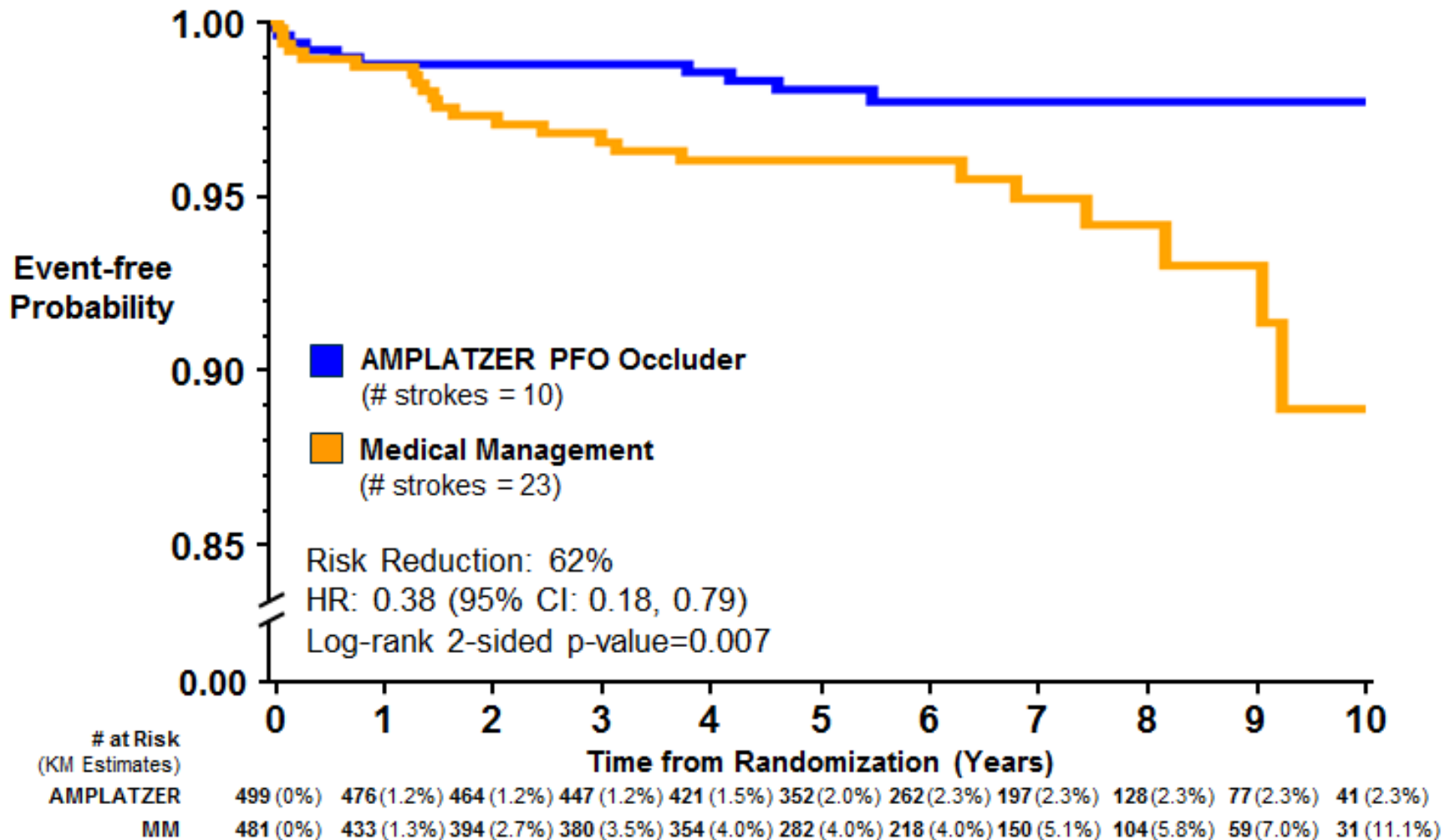
RESPECT Final Results

Freedom from Recurrent Ischemic Stroke (Intention to Treat)



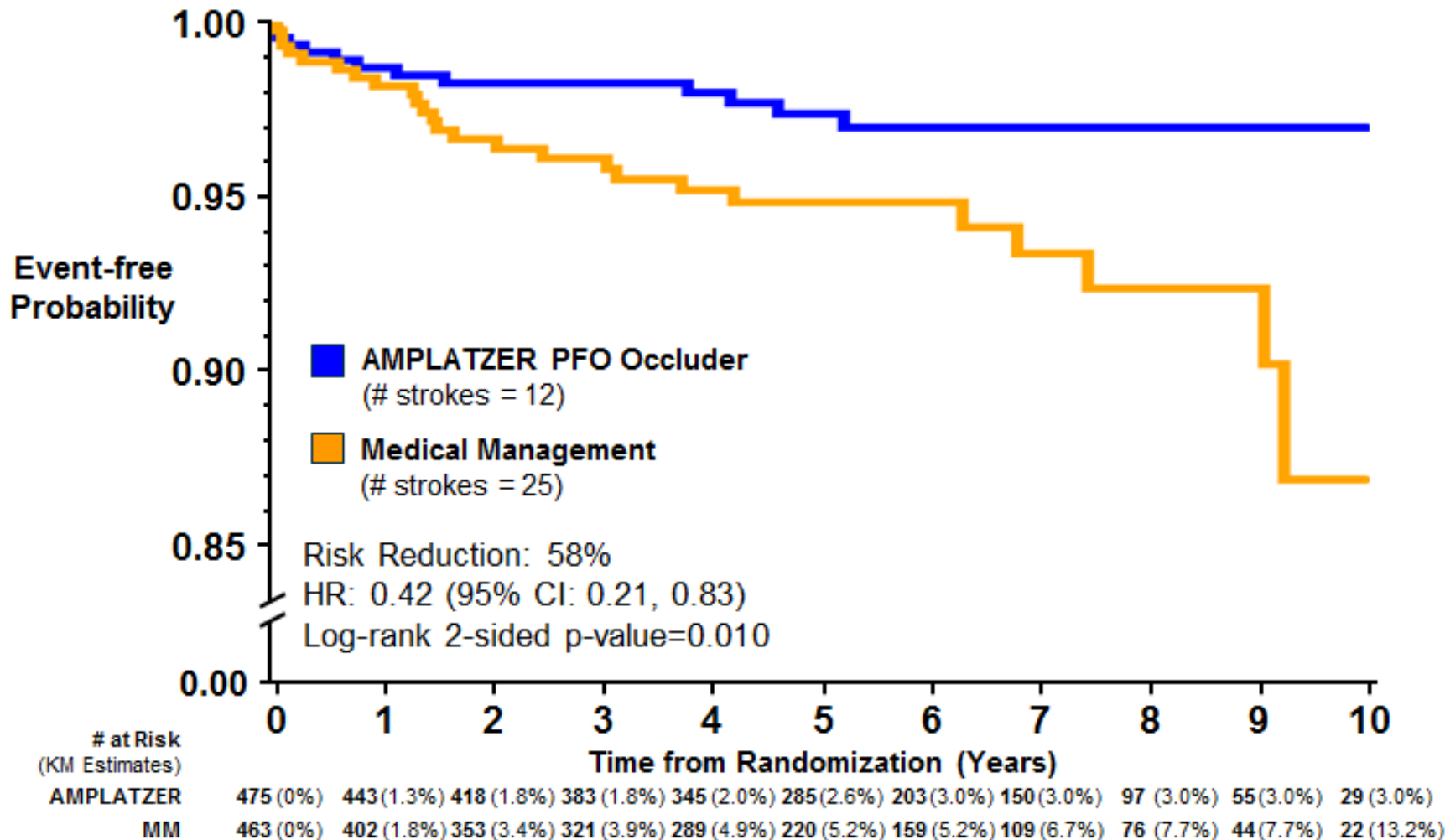
RESPECT Final Results

Freedom from Recurrent Ischemic Stroke of Unknown Mechanism (Intention to Treat)



RESPECT Final Results

*Freedom from Recurrent Ischemic Stroke
(Intention to Treat – Patients censored at age 60 years)*



Interpretation

- **These analyses support the hypothesis that PFO closure is preventing PFO-related recurrent strokes**
- **PFO-closure cannot prevent strokes from non-PFO related causes**

	HR (95% CI)	Risk Reduction	P-value
Ischemic stroke	0.55 (0.305-0.999)	45%	0.046
Stroke without known mechanism	0.38 (0.18-0.79)	62%	0.007
Age-censored analysis (<60y)	0.42 (0.21-0.83)	58%	0.01

Conclusions

- **In the RESPECT trial, PFO closure with the AMPLATZER™ PFO Occluder was more beneficial than medical management alone**
- **Collaboration between a cardiologist and neurologist is important for proper patient selection**
- **For patients with cryptogenic stroke and PFO, closure with the AMPLATZER™ PFO Occluder is an appropriate treatment option that reduces the risk of recurrent stroke**