THE AMULET STUDY: A Multicenter, Prospective Registry of the Amulet Left Atrial Appendage Closure Device for Stroke Prevention in Patients with Atrial Fibrillation

David Hildick-Smith, John Camm, Hans-Christoph Diener, Ulf Landmesser, Vincent Paul, Boris Schmidt, Magnus Settergren, Emmanuel Teiger, Claudio Tondo

On behalf of Amulet Observational Study Investigators

Disclosure Statement of Financial Interest

I, David Hildick-Smith, have Advisory with St Jude Medical

Study Design and Flowchart

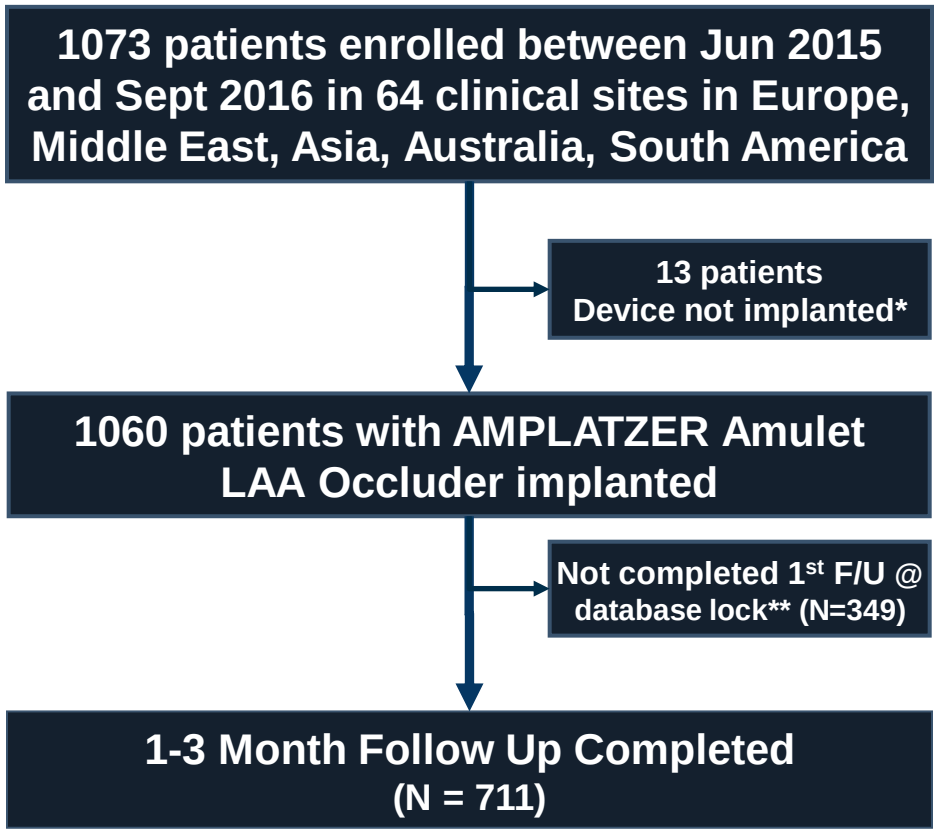
Design

- **DESIGN:**

  Prospective, multicenter, international observational study of the AMPLATZER™ Amulet™ LAA occluder. Follow-up visits: 1-3, 6, 12 and 24 months post implant.

- **OBJECTIVES:**
  - **Assess acute serious adverse events** (0 - 7 days post procedure)
  - **Assess late serious adverse events** (> 7 days post-procedure through 2 years)
  - **Report ischemic stroke, systemic embolism and cardiovascular death** (through 2 years)
  - **Report bleeding events** (through 2 years)

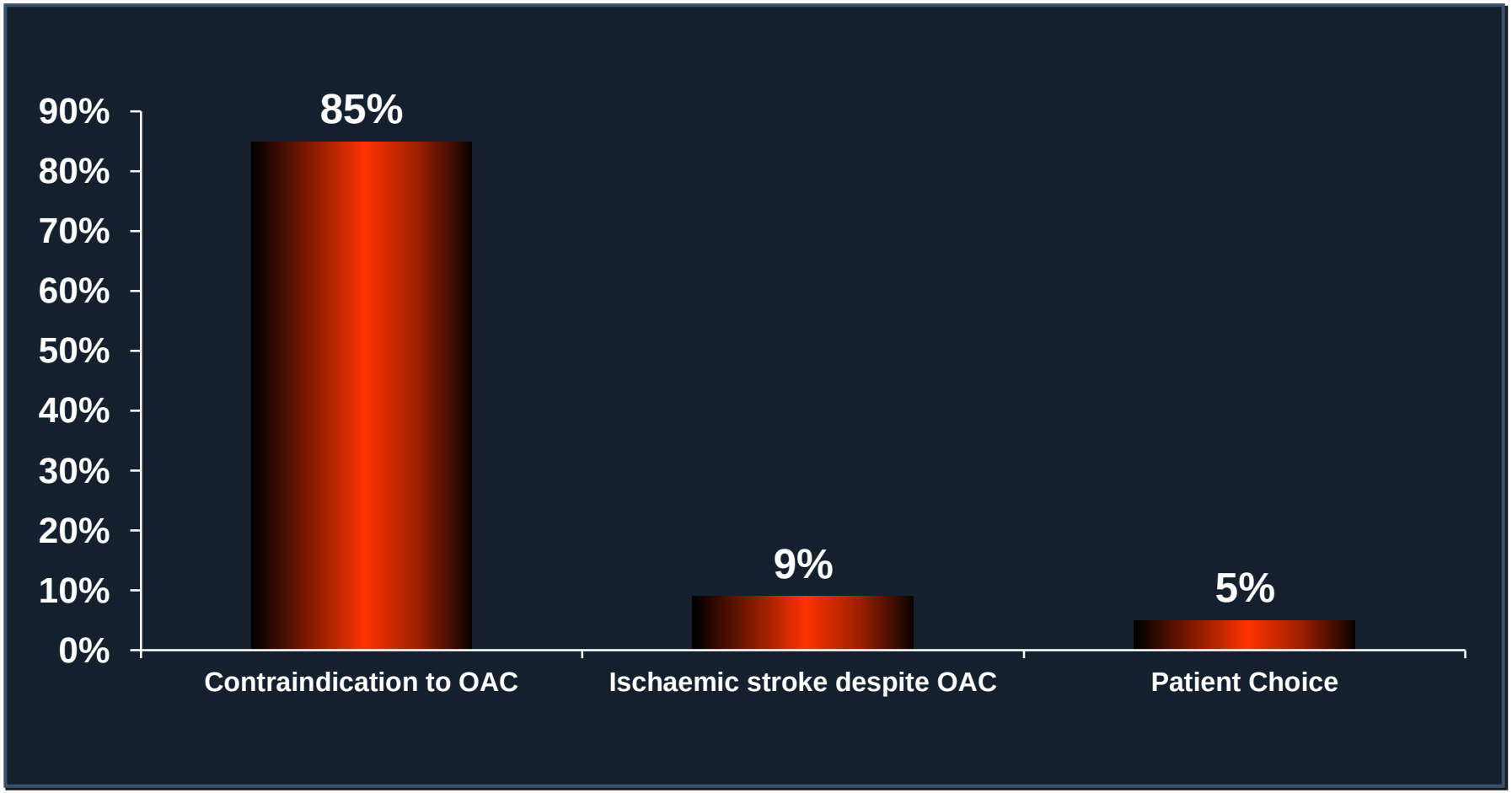
- **PRINCIPAL INVESTIGATOR**
  David Hildick-Smith, Brighton, UK



* Device Not Implanted	N
Evidence of intracardiac thrombus in LA	7
Anatomical/Sizing Considerations	6

** Database lock: October 3, 2016

Results: Indication for Procedure



Implant Success

Implant	No.	%
Implant Success Defined as successful implantation of the Amulet device in the LAA.	**1060/1073**	**98.8%**

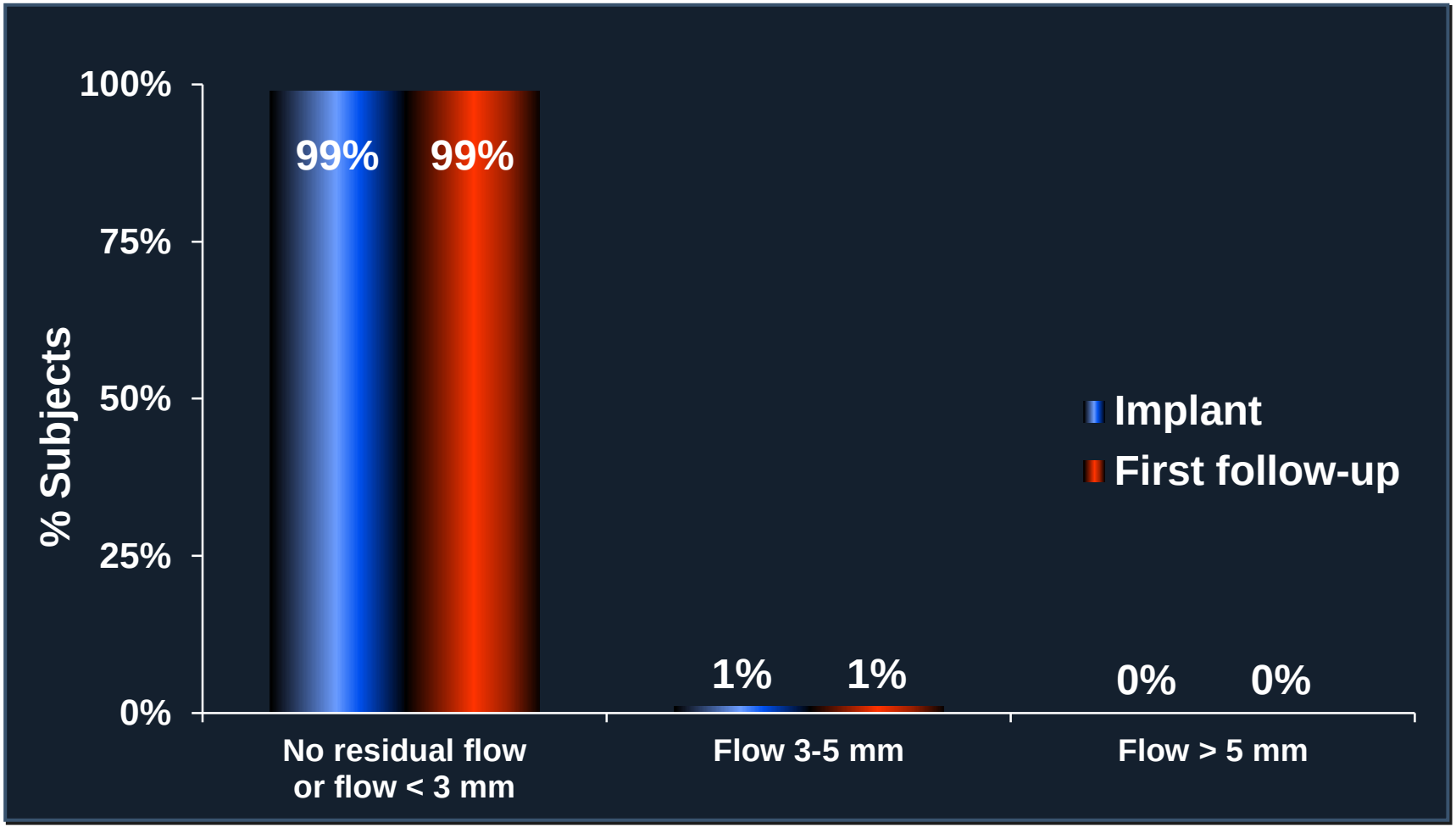
Major Adverse Events

Device/Procedure Related MAE	No.	%
Death	3	0.3%
Related to Cardiac Perforation	*1*	*0.1%*
Related to Myocardial Infarction	*1*	*0.1%*
Related to Cardiorespiratory Arrest	*1*	*0.1%*
Stroke	3	0.3%
Pericardial Effusion	5	0.5%
Resulted in Pericardiocentesis	*4*	*0.4%*
Resulted in Surgical Intervention	*1*	*0.1%*
Embolization	1	0.1%
Bleeding	10	0.9%
Other	7	0.7%
TOTAL	**29**	**2.7%**

Antiplatelet and Anticoagulant therapy
(1-3 months F/U)

	Baseline N = 1073	Discharge N = 1058	1-3 Month F/U N = 719
None	40.6%	14.7%	6.5%
Single Antiplatelet	20.5%	23.8%	31.3%
Dual Antiplatelet	14.4%	41.8%	45.6%
(N)OAC only	15.8%	7.3%	4.7%
(N)OAC plus Single Antiplatelet	1.5%	1.9%	1.3%
Triple Therapy	0.7%	2.2%	2.4%

TEE verified LAA Closure Rate



Independent Echo Core lab utilized for analysis

Comparison to Other Studies

	ACP Registry[1]	Watchman EWOLUTION[2]	Amulet (Current Study)
Implant Success	97.3%	98.5%	98.8%
LAA Closure Rate (1-3 months) ≤ 5 mm	98.1%	99.3%	100.0%
Device or Procedure-Related Complications	5.0%	2.7%	2.7%
Early Mortality	0.8% (30-day)	0.7% (30-day)	0.3% (7-day)

[1] Tzikas et al. *EuroIntervention.* 2015;10

[3] Boersma et al. *Eur Heart J*. 2016 Aug;37(31):2465-74.

Conclusions

- The Amulet device has very high technical implant success rates
- Implantation is associated with low rates of peri-procedural and early adverse events
- AMPLATZER Amulet demonstrated high closure rates
- Antiplatelet therapy is appears to be a reasonable treatment strategy post-implantation in the short-term
- Additional long-term data will be collected to confirm these promising early findings