One-Year Outcomes after Amulet or Watchman/FLX Device for Percutaneous Left Atrial Appendage Closure:

Pre-Specified Analyses of the SWISS-APERO Randomized Clinical Trial

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Disclosure of Relevant Financial Relationships

I, Roberto Galea, DO NOT have any relevant financial relationships to disclose.

Acknowledgements

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Background and objectives

- Residual LAA patency after LAAC has been associated with higher thromboembolic risk, especially when detected remotely after the procedure.

- Watchman FLX and Amulet devices are the two most frequently used devices for LAAC worldwide and SwissApero Trial is the first randomized comparison between them. The main findings of the study showed a similar LAA sealing performance of the two devices at 45-day CCTA.

- In these pre-specified subanalyses of SwissApero Trial, we compared Watchman FLX and Amulet in terms of LAA patency and DRT at 13-month CCTA, besides clinical outcomes through 13 months.

SWISS-APERO Trial Design

Screening phase

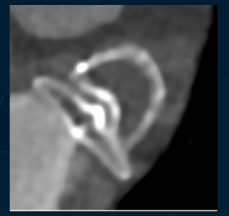
LAAC clinically indicated

Eligibility
- High bleeding risk
- LAA morhology suitable for both devices
- No LAA thrombus

LAAC

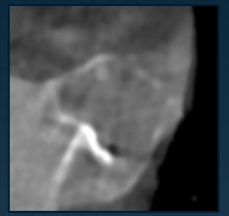
DEVICE RANDOMIZATION

- **Amulet**
- **Watchman FLX**



13-Month fu

Long-term LAA PATENCY



ASA +
Clopidogrel or (N)OAC

(Days after LAAC) 45 ± 7 90 ± 7 395 ± 30

- Medical and drug history assessment
- Laboratory tests
- TEE (optional if intraprocedural TEE)
- CCTA

- Intraprocedural TEE/ICE
- Randomization

- Medical and drug history assessment
- TEE
- CCTA

- Medical and drug history assessment
- CCTA

Pre-specified Analyses

Primary Analyses

Comparison of two study groups in terms of:

- Residual LAA patency and related subtypes at 13-month CCTA
- DRT at 13-month CCTA
- 13-month clinical outcomes
  - All cause or cardiovascular death
  - All stroke, ischemic or haemorrhagic stroke
  - Systemic or Pulmonary embolism
  - Bleeding according to the BARC classification

Both imaging and clinical endpoints were centrally adjudicated

Secondary Analysis

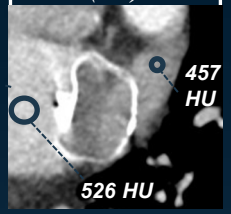
- Comparison of 45-day and 13-month CCTAs with the aim of exploring the evolution of LAA patency and related subtypes during the first year after procedure

LAA Patency subtypes

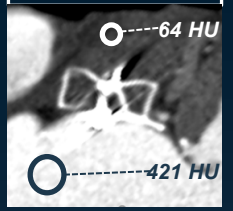
LAA PATENCY DEFINITION:

LAA density ≥ 100 HU and/or LAA density ≥ 25% of that of the LA

PATENT LAA (PA)



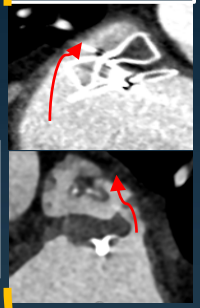
NON PATENT LAA (NPA)



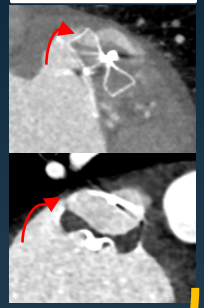
AMULET

WATCHMAN

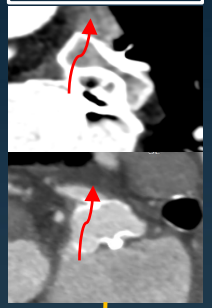
PERIDEVICE



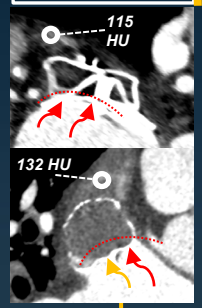
MIXED



INTRADEVICE



PANVL



Underlying Leak Mechanisms

INCOMPLETE SIDE SEALING (GAP LEAKS)

DEVICE PERMEABILITY

UNCLEAR

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LAA Closure performed (n = 423)

Excluded (n=202)

- Enrolled in other cardiovascular device or an investigational drug trial (n=47)
- Patient did not provide consent (n=44)
- Severe chronic kidney insufficiency (n=40)
- Incomplete screening (n=25)
- First operator with limited experience with one of the two LAAC devices (n=18)
- Intra-cardiac thrombus (n=10)
- LAA morphology not suitable for one of the two devices (n=9)
- Other eligibility criteria not met (n=9)

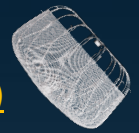
Randomized (n = 221)

Allocated to Amulet (n=111)

- Death (n = 12)
- 13-month CCTA refused (n=11)
- 13-month CCTA not performed for medical reasons (n=1)
- Patient withdrew consent (n = 2)
- Patient was lost to follow-up (n = 1)

Considered for 13-month CCTA analysis (n = 84)

Allocated to **Watchman FLX (n=110)**



From June 2018 until October 2019 only Watchman 2.5 available (n = 25)

- Death (n = 11)
- 13-month CCTA refused (n=11)
- 13-month CCTA not performed for medical reasons (n=6)
- Patient withdrew consent (n = 1)
- Patient was lost to follow-up (n = 1)

Considered for 13-month CCTA analysis (n = 80)

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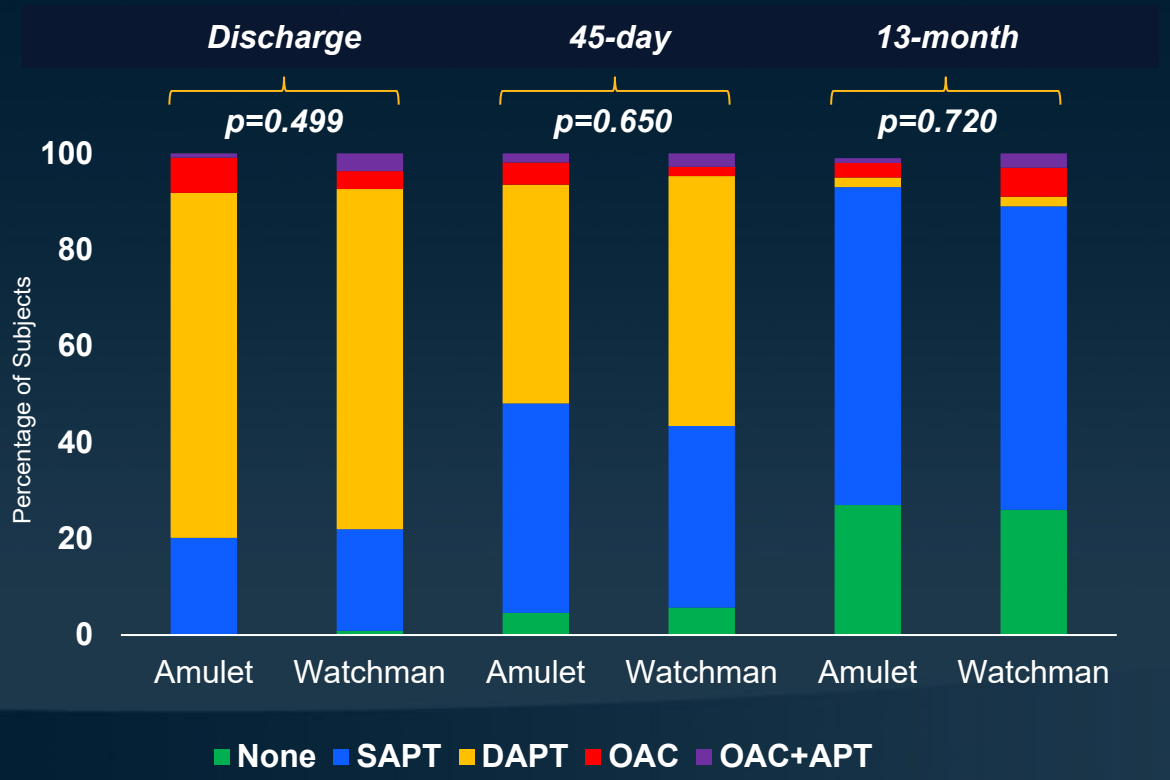
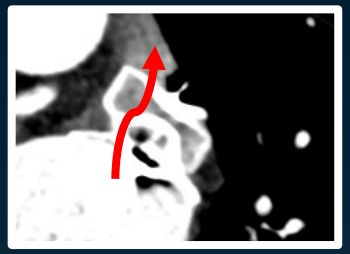
Baseline characteristics and post-LAAC antithrombotic therapy regimen

- *Mean age: 76.9 years*
- *Male: 70.6%*
- *Prior cerebrovascular event: 39.3%*
- *Mean CHA2DS2-VASc score: 4.3*
- *Mean HASBLED score 3.1*
- *Prior relevant bleeding: 87.8%*



Patent Appendage rate at 13-month CCTA

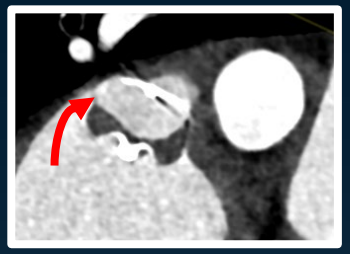


AMULET
53.6%
(n=45/84)

VS.

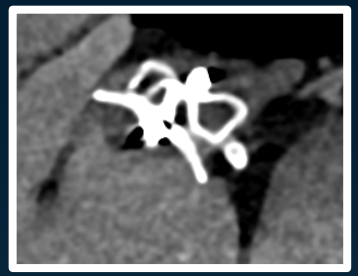
1.10 (0.81-1.48);
P= 0.537

WATCHMAN FLX
48.8%
(n=39/80)



	Amulet N = 84	Watchman/FLX N = 80	Amulet vs Watchman/FLX Risk Ratio (95% CI)	P value
PDL or MIL, no. (%)	24 (28.6%)	22 (27.5%)	1.04 (0.64-1.70)	0.879
IDL, no. (%)	20 (23.8%)	14 (17.5%)	1.36 (0.74-2.51)	0.319
PANVL, no. (%)	6 (7.1%)	10 (12.5%)	0.57 (0.22-1.50)	0.248

Device Related Thrombus rate at 13-month CCTA

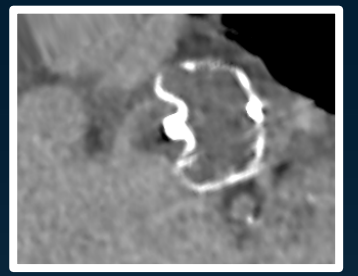


AMULET
1.2%
(n=1/84)

VS.

0.95 (0.06-14.97);
P= 0.972

WATCHMAN FLX
1.3%
(n=1/80)



	Amulet N = 84	Watchman/FLX N = 80	Amulet vs Watchman/FLX Risk Ratio (95% CI)	P value
Definite or possible DRT, no. (%)	2 (2.4%)	3 (3.8%)	0.63 (0.11-3.70)	0.610

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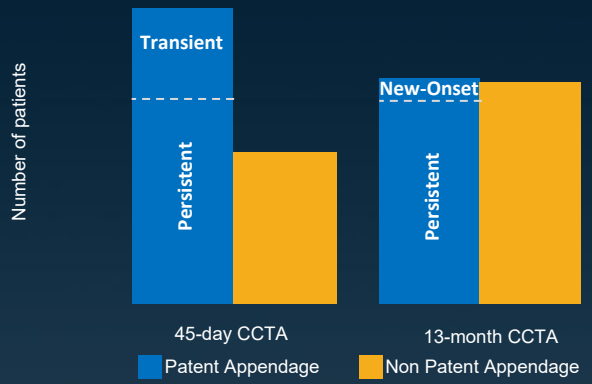
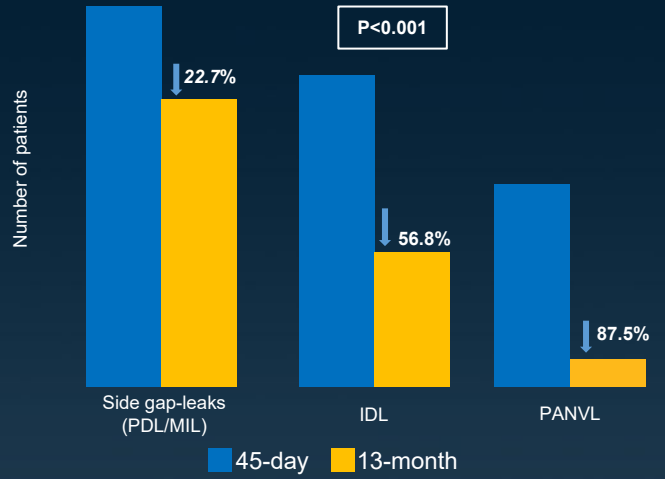
13-Month Clinical Follow-up

	Amulet N = 111	Watchman/FLX N = 110	Amulet vs Watchman/FLX Hazard Ratio (95% CI)	P value
Composite of CV death, stroke or systemic embolism, no. (%)	10 (9.5%)	11 (10.2%)	0.91 (0.39-2.14)	0.829
Death, no. (%)	13 (11.7%)	11 (10.1%)	1.19 (0.53-2.66)	0.671
Cardiovascular death, no. (%)	8 (7.7%)	9 (8.3%)	0.90 (0.35-2.33)	0.823
Stroke, no. (%)	3 (2.7%)	4 (3.7%)	0.75 (0.17-3.35)	0.706
Ischaemic stroke, no. (%)	3 (2.7%)	3 (2.9%)	1.00 (0.20-4.95)	0.999
Haemorrhagic stroke, no. (%)	0 (0.0%)	1 (0.9%)	0.33 (0.01-8.01)	0.498
Systemic or Pulmonary embolism, no. (%)	3 (2.9%)	1 (0.9%)	3.00 (0.31-28.88)	0.341
Systemic embolism, no. (%)	0 (0.0%)	1 (0.9%)	0.33 (0.01-8.01)	0.498
Pulmonary embolism, no. (%)	3 (3.0%)	0 (0.0%)	6.94 (0.36-132.79)	0.247
Any bleeding, no. (%)	45 (40.8%)	34 (31.4%)	1.46 (0.93-2.28)	0.098
Minor bleeding (BARC 1-2), no. (%)	32 (29.4%)	26 (24.3%)	1.31 (0.78-2.20)	0.302
Major bleeding (BARC 3-5), no. (%)	18 (16.5%)	10 (9.3%)	1.84 (0.85-3.99)	0.122

Evolution of Residual LAA Patency During the First 13 Months After LAAC

(analysis including 158 of 221 randomized patients where LAA patency was assessable by both 45-day and 13-month CCTA)





***30.5%* of 45-day PA resolved at 13-months after LAAC**

Only 13.2% of appendages became patent later than 45 days

PDL/MIL was the PA subtype more frequently persistent over the 1st year

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Study Limitations

- Open label study: the two devices can be easily distinguished during CCTA assessment
- Trial not powered to show differences with regard to clinical endpoints
- Minority yet sizable proportion of Watchman/FLX patients received Watchman 2.5
- A relevant percentage of randomized patients died before undergoing 13-month CCTA follow-up, due to the high-risk population included in this study

Conclusions

- Among patients undergoing clinically indicated LAAC and in whom LAA anatomy was deemed suitable for both Amulet and Watchman FLX devices:

  - Rates of PA, its subtypes and DRT at 13-month CCTA were similar between the randomised device groups
  - Rates of clinical outcomes at 13 months did not differ between the study groups.

Two thirds of 45-day PAs and especially those related to side-gap leaks, persisted at 13 months.