Antithrombotic Therapy Following LAA Occlusion

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EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion – an update

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Original Scheme of Antithrombotic Treatment for Watchman (Protect AF)

- All patients were eligible to take OACs
- Procedure on full heparinization
- ASA +Warfarin to INR 2-3 for 6 weeks
- 6 weeks - TEE -> 6 m ASA + Clopidogrel
- 6 m and on - ASA only

Original Antithrombotic Therapy for ACP

- Extrapolated from ASD/ PFO devices
- Included ASA indefinitely and clopidogrel for variable amount of time (1-3 m)

New Strategies

- DAPT for variable amount of time
- SAPT
- No antithrombotic Rx
- NOACS

DAPT in LAA Occlusion

- ASAP study : ASA indefinitely and Clopidogrel for 6 months . Stroke rate similar to Protect AF 1.5- 2.3%, device thrombus 4% , similar to Protect AF
- Ewolution registry : 59% DAPT (1.4% stroke, but device thrombus more common with DAPT than with OAC)
- ACP registry – majority on DAPT (1% stroke)
- Amulet registry – 54% on DAPT (1.4% stroke)
- In the French registry (Fauchier et al) DAPT had the lowest rate of device thrombus .

Bleeding Risk on DAPT

- DAPT Similar risk to OAC ? (Active w trial)
- Ewolution 1 year DAPT bleeding rate 2.1% vs expected 5.4 on VKA as per HAS BLED
- ASAP 1 y bleeding 4.7%

Short-Term Antiplatelet Versus Anticoagulant Therapy After Left Atrial Appendage Occlusion

A Systematic Review and Meta-Analysis

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- N = 12326 pts in 83 studies comparing APT to OAC in Watchman or ACP/Amulet
- Follow up 13.7m ± 11m
- Similar results included:
  - Any stroke (1-1.7%)
  - Major bleeding (3-4%)
  - DRT (2-3%)
  - Mortality (2-6%)

DAPT following LAAC

- Most real-life patients do not receive OAC
- DAPT is as effective and safe as OAC in both devices
- DAPT is the new standard of care for both types of devices
- Information is scarce regarding the needed duration of DAPT before switching to SAPT

Single Antiplatelet Therapy

- Used in 23% of Amulet registry and in 7% of Ewolution registry and in 34% of the French registry
- In the French registry SAPT was associated with a higher rate of device-related thrombi
- No clear association with thrombi in Ewolution and in Amulet registries
- Small series did not find higher rates of thrombi / embolic complications on SAPT (Rodriguez 2016, Korsholm 2017)

Transcatheter left atrial appendage occlusion in patients with atrial fibrillation and a high bleeding risk using aspirin alone for post-implant antithrombotic therapy

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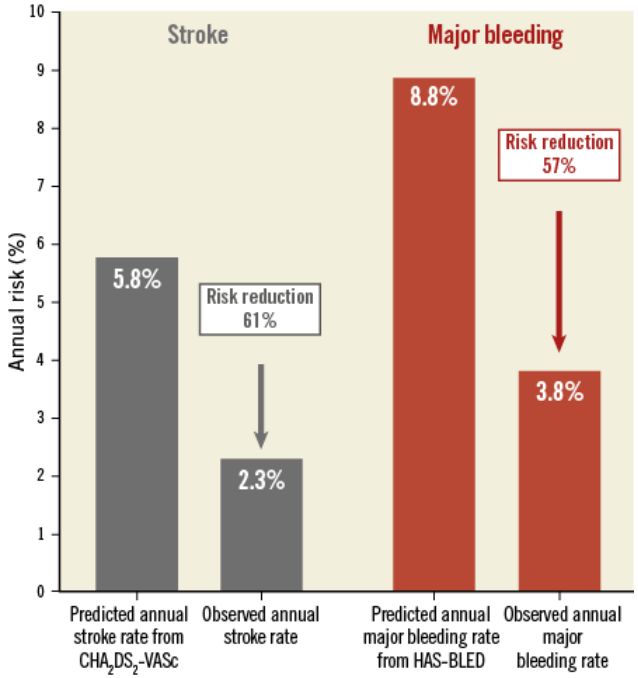

EuroIntervention 2017;12:2075-2082

Transcatheter left atrial appendage occlusion in patients with atrial fibrillation and a high bleeding risk using aspirin alone for post-implant antithrombotic therapy

Left atrial appendage occlusion versus standard medical care in patients with atrial fibrillation and intracerebral haemorrhage: a propensity score-matched follow-up study

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- 150 pts in Nordic area received LAAC following ICH
- 50% of patients received SAPT, mostly ASA only
- Compared to a propensity matched group , there was > 80% reduction in major events

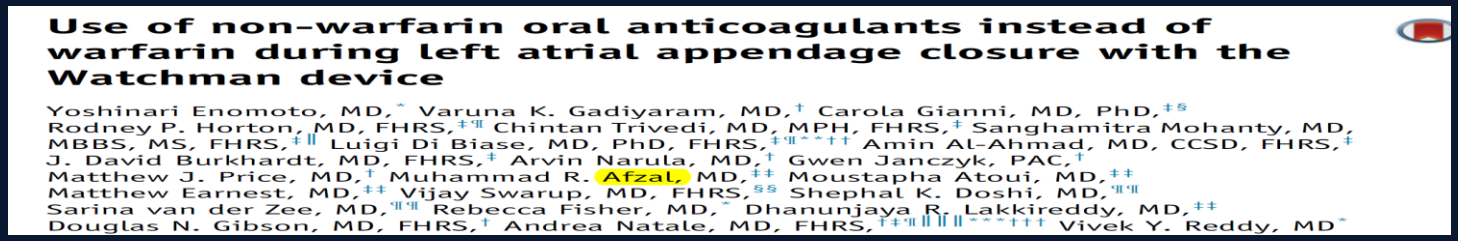
SAPT for LAAO

- Safe and effective alternative to traditional treatment
- May be associated with somewhat increased tendency to device thrombus
- Should be reserved to patients at high risk for bleeding

No anti thrombotic treatment

- 6% of Ewolution pts
- 2% of Amulet registry
- 8% of French registry

- Insufficient information on results
- Consensus committee recommended at least 2-4 weeks of at least SAPT



Use of non-warfarin oral anticoagulants instead of warfarin during left atrial appendage closure with the Watchman device

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- 214 pts on NOACS following Watchman implantation
- Compared to 212 pts on Warfarin following Watchman
- Similar rate of embolic events and bleeding events
- It is conceivable that DOACS may have the same advantages over VKA as in the general AF population

EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion – an update

Table 18 (part 1). Antithrombotic therapy before and after LAAO

Clinical situation and therapeutic concept	Consensus statement	Symbol	References
Acetylsalicylic acid 75-325 mg/day for the procedure and then continued long term (load 300-500 mg prior to procedure if not previously on acetylsalicylic acid)	"Should do this"		108,114,140,173
Anticoagulation, using unfractionated heparin, is recommended during the implantation procedure prior to or immediately after TSP, aiming for an activated clotting time of >250 s	"Should do this"		106,165
After WATCHMAN implantation, warfarin (INR 2-3) should be given for 45 days, followed by clopidogrel for 6 months after the procedure in low bleeding risk group of patients, while in high bleeding risk group OAC should not be applied	"Should do this"		106,108
NOAC is a possible alternative to warfarin after WATCHMAN implantation	"May do this"		157,166–168
After WATCHMAN implantation in patients not suitable for oral anticoagulation, DAPT including clopidogrel 75 mg/day for 1 to 6 months after the procedure (load 300-600 mg prior to procedure if not previously on clopidogrel)	"May do this"		106,108,174
After AMPLATZER Cardiac Plug or Amulet implantation, DAPT including clopidogrel 75 mg/ day for 1 to 6 months after the procedure (load 300-600 mg prior to procedure if not previously on clopidogrel)	"May do this"		115,173
Other options that may be considered on a case-by-case basis include a single antiplatelet therapy (acetylsalicylic acid or clopidogrel) for short periods of time, as long as approved by a team consensus	"May do this"		175

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Table 18 (part 2). Antithrombotic therapy during and after LAAO

Device/patient	Heparin (ACT ≥250)	Low-molecular-weight heparin	Acetylsalicylic acid	OAC	Clopidogrel	Comments
WATCHMAN / low bleeding risk	Prior to or immediately after TSP	Post-procedure till INR ≥2 for warfarin	Load 300-500 mg prior to procedure if not on acetylsalicylic acid, continue 75-325 mg/day indefinitely	Start warfarin after procedure INR 2–3 till 45 days or continue till adequate occlusiona by TOE. NOAC are possible alternatives	Start 75 mg/day when (N)OAC stopped, continue till 6 months after the procedure	Some centres do not withhold (N)OAC at the time of procedure (no data to support or deny this approach)
WATCHMAN / high bleeding risk	Prior to or immediately after TSP	None	Load 300-500 mg prior to procedure if not on acetylsalicylic acid, continue 75-325 mg/day indefinitely	None	Load 300-600 mg prior to procedure if not on clopidogrel, continue 75 mg/day 1-6 months while ensuring adequate occlusion and no device- related thrombusa	Clopidogrel often given for shorter time in very high-risk situations, clopidogrel may replace long-term acetylsalicylic acid if better tolerated
ACP / Amulet	Prior to or immediately after TSP	None	Load 300-500 mg prior to procedure if not on acetylsalicylic acid, continue 75-325 mg/day indefinitely	None	Load 300-600 mg prior to procedure if not on clopidogrel, continue 75 mg/day 1-6 months while ensuring adequate occlusion and no device- related thrombusa	Clopidogrel often given for shorter time in very high-risk situations, clopidogrel may replace long-term acetylsalicylic acid if better tolerated

[a]Less than 5 mm leak. ACP, AMPLATZER Cardiac Plug; ACT, activated clotting time; DAPT, dual antiplatelet therapy; INR, international normalised ratio; OAC, oral anticoagulation; (N)OACs, (non-vitamin K dependent) oral anticogulants; TOE, transoesophageal echocardiography; TSP, transseptal puncture.

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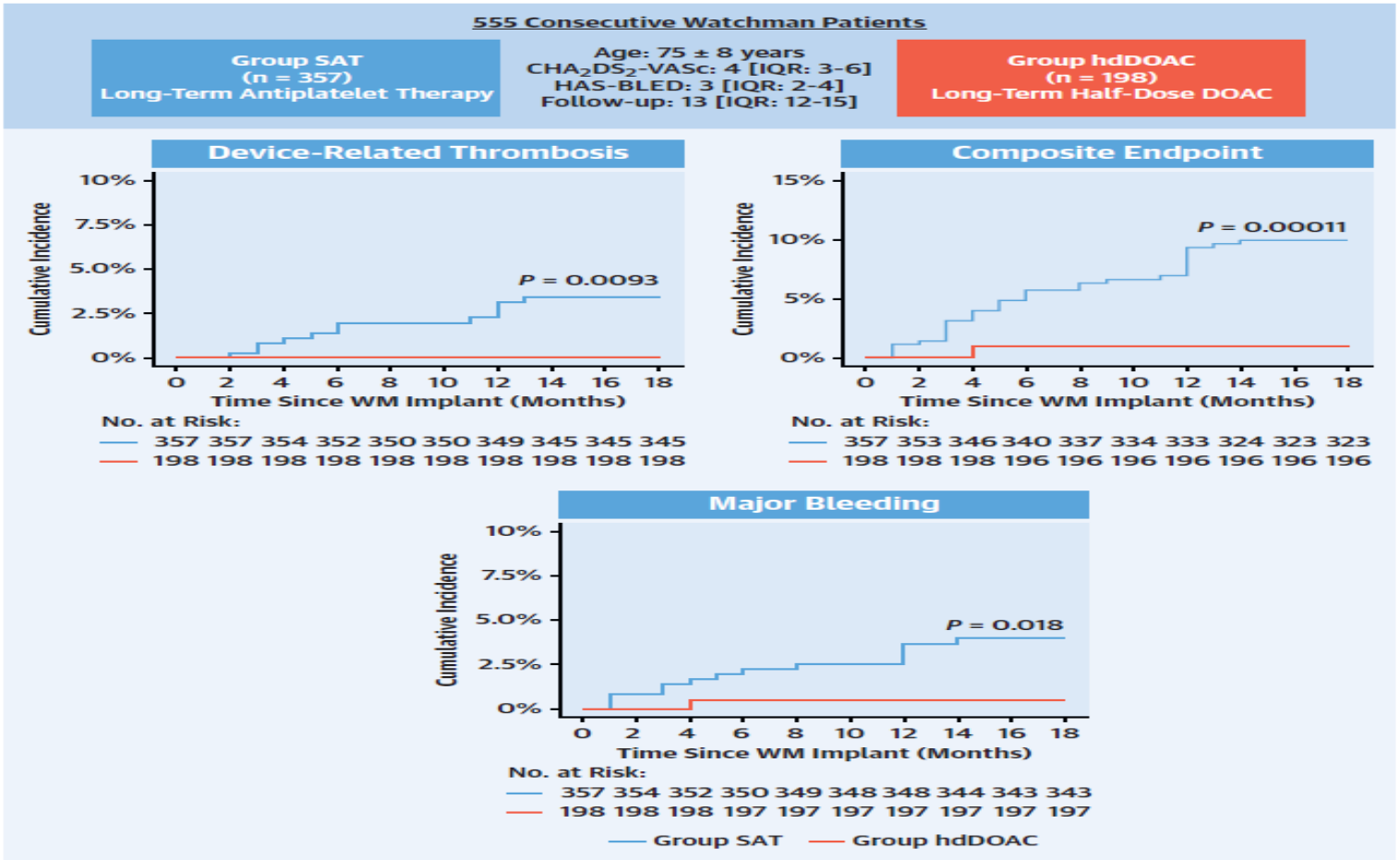
STRUCTURAL

Half-Dose Direct Oral Anticoagulation Versus Standard Antithrombotic Therapy After Left Atrial Appendage Occlusion

Domenico G. Della Rocca, MD,[a] Michele Magnocavallo, MD,[a,b] Luigi Di Biase, MD, PhD,[a,c,d]

CENTRAL ILLUSTRATION Patient Characteristics, Study Groups, and Kaplan-Meier Survival Curves for DRT, Major Bleeding, and the Composite Endpoint of DRT, TE, and Major Bleeding Events



Della Rocca, D.G. et al. J Am Coll Cardiol Intv. 2021;14(21):2353–2364.

Conclusions

- DAPT followed by Aspirin is becoming the new standard of care following LAAC
- In high risk populations SAPT may be used with slight increase in thrombus on device
- There is little data to support no antithrombotic therapy in very high risk situations
- NOACS are often being used in lieu of VKAs
- Half dose DOACS seem to be promising

Thrombus on Device

Lempereur Cath CV Int 2017 , n = 82

- Incidence up to 4% in most series
- Usually diagnosed on routine TEE after 6-12 months
- Partial association with weaker anticoagulation (SAPT)
- The majority are asymptomatic
- Higher incidene of clinical stroke (Up to 7 % of DRTs ?)
- Treatment (average duration 45d):
  - OAC or IV heparin or LMWH if on APT
  - Intensified anticoagulation if already on OAC
- 95% complete resolution with treatment (100% with LMWH)

TABLE II. Potential Risk Factors for Device-Related Thrombosis

Characteristics	Risk factors
Patient characteristics	High $CHADS_2$ score [8]
	High CHA_2DS_2-VASc score [8]
	High platelet count [8]
	Early discontinuation of antithrombotic medication [9, 29]
	Poor treatment compliance or under-target INR [12, [27, 30]]
Echocardiogram findings	Low ejection fraction [[8], [24]]
	Spontaneous echo or dense smoke in LA [4, 13, 24, 27, 31]
	Markedly enlarged LA [24, 31]
Procedure results	Deep implantation [32]
	Incomplete LAA occlusion [33]
	Poor inferior disc-apposition (ACP) [34]
Device	Thrombus on screw, on connector pin or at fabric insert site [7, 23, 30, 35]

LA: left atrium; LAA: left atrial appendage.

Leaking LAA following Closure

- Relatively common finding (up to 40%)
- Most of the information on outcome comes from surgical literature where leaks were associated with adverse outcomes
- The 3- 5 mm cutoff comes from surgical studies

Residual leaks following percutaneous left atrial appendage occlusion: assessment and management implications

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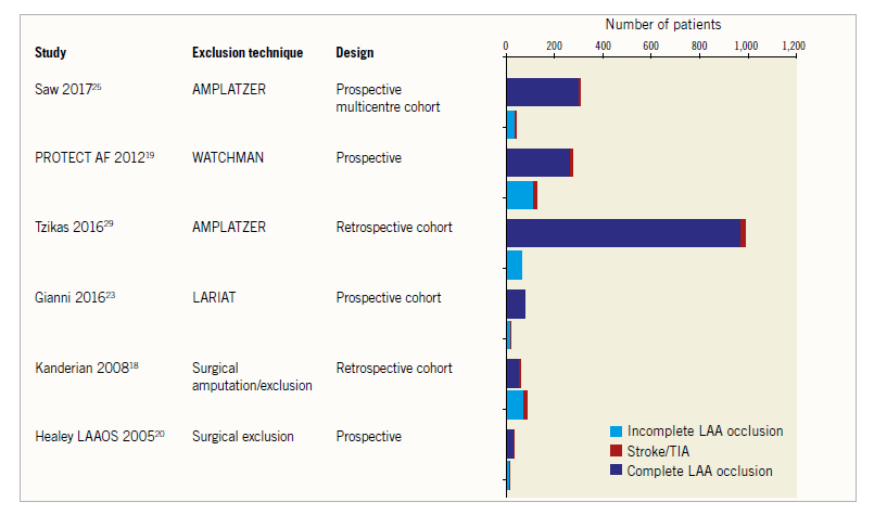

Incidence 15-40%
Rare > 5 mm

Conclusions :

- **Leaks < 5 mm – follow up**
- **Leaks > 5 mm:**
  - **Continued OAC?APT?**
  - **Leak closure ?**

Temporal changes and clinical significance of peridevice leak following left atrial appendage occlusion with Amplatzer devices

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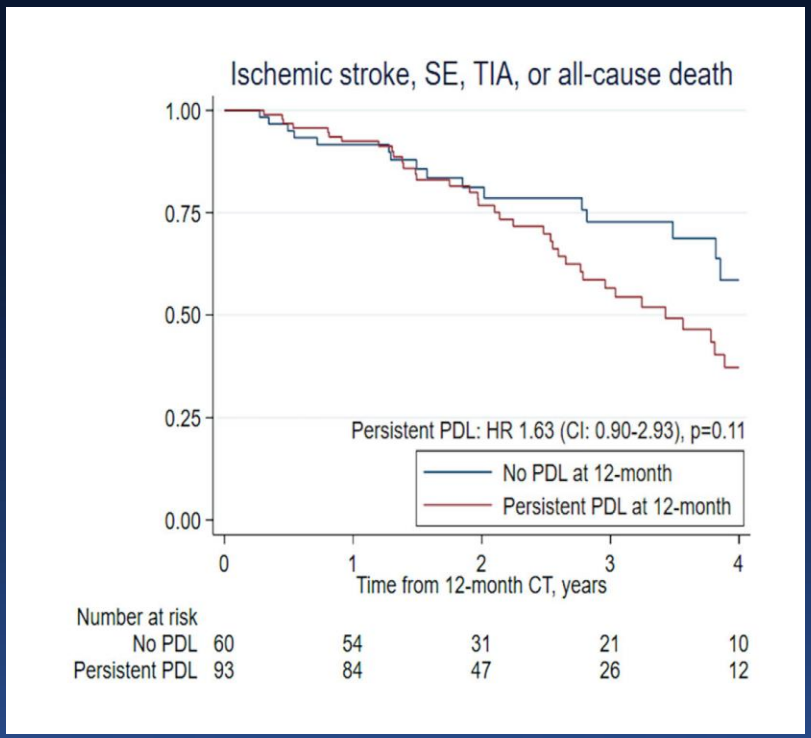
- Single center experience with ACP (n=153)
- 2 and 12 m CT
- 3 y follow up
- Contrast patency : 66% (2m) 47% (6m), mostly at the disc level
- HR = 1.63 for outcomes (NS)



Leak closure following left atrial appendage exclusion procedures: A multicenter registry

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- Four center registry of 72 pts undergoing percutaneous closure of leaks (53 Watchman , 19 surgical)
- Used Amplatz vascular plug (13) , duct occluder (18) and coils (40)
- 94% procedural success
- 2-pericardial effusion , 1 stroke

Radiofrequency Energy Applications Targeting Significant Residual Leaks After Watchman Implantation

A Prospective, Multicenter Experience

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- N= 43 WM cases with peridevice leaks >4mm
- 19/43 were performed during the initial implantation
- Average 18 applications
- Immediate result – negligible leak
- Follow up TEE – 53% complete sealing , the rest with negligible leak

Thank You !

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