Safety and Efficacy of Single Versus Dual Antiplatelet Therapy After Left Atrial Appendage Occlusion

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The optimal antiplatelet strategy after left atrial appendage (LAA) occlusion able to protect from device-related thrombosis, paying the lowest price in terms of bleeding increase, is unclear. In a real-world, observational study we performed a head-to-head comparison of single versus dual antiplatelet therapy (SAPT vs DAPT) in patients who underwent LAA occlusion. We included 610 consecutive patients, stratified according to the type of post-procedural antiplatelet therapy (280 on SAPT and 330 on DAPT). Primary outcome measure was the incidence of the net composite end point including Bleeding Academic Research Consortium classification 3-5 bleeding, major adverse cardiovascular events or device-related thrombosis at 1-year follow-up. The use of SAPT compared with DAPT was associated with similar incidence of the primary net composite end point (9.3% vs 12.7% p = 0.22), with an adjusted hazard ratio (HR) of 0.69, 95% confidence interval 0.41 to 1.15; p = 0.15) at multivariate analysis. However, SAPT significantly reduced Bleeding Academic Research Consortium classification 3-5 bleeding (2.9% vs 6.7%, p = 0.038; adjusted HR 0.37, 0.16 to 0.88; p = 0.024). The occurrence of ischemic events (major adverse cardiovascular events or device-related thrombosis) was not significantly different between the 2treatment strategies (7.8% vs 7.4%; adjusted HR 1.34, 0.70 to 2.55; p = 0.38). In patients who underwent LAA occlusion, post-procedural use of SAPT instead of DAPT was associated with reduction of bleeding complications, with no significant increase in the risk of thrombotic events. These hypothesis-generating findings should be confirmed in a specific, randomized study. **(Am J Cardiol 2020;134:83−90)**

Left atrial appendage (LAA) occlusion is an effective percutaneous intervention able to protect from atrial fibrillation-related thromboembolic events; it is intended for patients in whom long-term oral anticoagulation is deemed highly risky or contraindicated.[1,2] No specific recommendations are provided by current guidelines about post-procedural antiplatelet therapy and it is matter of debate.[1,2] There is only a consensus statement supporting the use of dual antiplatelet therapy (DAPT) with aspirin plus clopidogrel up to 6 months in patients not suitable for oral anticoagulant treatment who underwent LAA occlusion.[3] However, available data on the topic essentially refer to observational (and often retrospective), nonrandomized studies,[4−9] without direct comparison between different antiplatelet strategies. Accordingly, given the paucity of robust data, the type and duration of post-procedural antiplatelet therapy are variable and often guided by the patient convincement of the treating physicians. Notably, patients receiving LAA occlusion are generally older and have multiple co-morbidities, in whom the risk of bleeding events is a major concern and a multidrug antithrombotic therapy can further contribute to such risk. Conversely, doubts on the efficacy of an approach with single antiplatelet therapy (SAPT) to prevent postimplantation thrombotic events might exist. Thus, to add more evidence on the topic we addressed in a real-world, multicenter, retrospective study the issue of whether SAPT warrants similar protection from device-related thrombosis and ischemic events than DAPT, with decreased bleeding risk.

Methods

Consecutive patients who underwent successful percutaneous LAA occlusion in 9 high-volume Italian centers and receiving SAPT or DAPT after the intervention were enrolled. The centers involved in the registry represent high volume catheterization laboratories connected during scientific partnerships. The indication for percutaneous LAA occlusion followed current European guidelines,[1] that is, a previous major bleeding event with or without oral

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See page 89 for disclosure information.

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anticoagulant therapy, contraindication or noncompliance to long-term anticoagulant therapy. The only exclusion criterion for the study was the use of oral anticoagulant treatment, even temporary, immediately after the procedure; however, as in the involved centers LAA occlusion is essentially reserved to patients with contraindication to anticoagulant therapy, the previously mentioned exclusion criterion applied to a small number of patients (n = 42). For the inclusion in the study there was no restriction regarding patient's risk profile, type of implanted device and type of SAPT or DAPT. The type of post-implantation antiplatelet regimen (SAPT or DAPT) was chosen by each operator in accordance with his/her practice patterns and perceived ischemic and bleeding patient's risk. Interventions were performed according to local standard practice. One investigator at each center collected information related to hospital stay from the medical records and data from the office visits; these visits followed usual practice in the involved centers, but were generally done between 1 and 3 months after the procedure and at 6- and 12-month follow-up. All patients who underwent transesophageal echocardiography between 1 and 3 months after the procedure to detect device-related thrombosis. A second investigator at each center confirmed the adverse events adjudication; he/she was not blinded to treatment allocation. Discrepancies for the event adjudication were resolved by consensus. All outcome data were confirmed by source documentation. All data provided by each interventional center were anonymized and centrally collected. Both in-hospital and events occurring from discharge up to 1-year follow-up were considered for the study end points. Institutional Review Board approval was not required because the study was retrospective, did not use biologic material and did not involve the collection, use, or transmittal of patient identifiable data.

Primary outcome measure was the net composite end point of Bleeding Academic Research Consortium (BARC) classification 3-5 bleeding,[10] major adverse cardiovascular events (MACE, including cardiovascular death, ischemic stroke and systemic embolic event) or device-related thrombosis from the time of the procedure to 1 year. The following bleeding events are comprised in the BARC classification 3-5: overt bleeding with hemoglobin decrease ≥3 g/dl; any transfusion with overt bleeding; cardiac tamponade; bleeding requiring surgical intervention; bleeding requiring intravenous vasoactive agents; intracranial hemorrhage; intraocular bleed compromising vision; coronary bypass-related bleeding within 48 hours; fatal bleeding. Secondary end point was the comparison in the 2 groups (SAPT vs DAPT) of the patient components of the primary net composite end point.

Categorical variables are expressed as number (percentage). Proportions were compared by Fisher's exact test when the expected frequency was <5, otherwise the chi square test (Yates' corrected) was applied. Continuous variables are indicated as mean ± standard deviation and were compared by *t* test for normally distributed values (as assessed by Kolmogorov-Smirnov test). Time-to-event analysis by Kaplan-Meier estimator was performed for the crude incidence of the end points. Hazard Ratios (HR) with 95% confidence intervals (CIs) were obtained from Cox proportional hazard model with multivariate analysis. Univariate analysis was performed for the following potential confounders: type of post-procedural antiplatelet treatment (SAPT vs DAPT), age, gender, body mass index, type of atrial fibrillation, systemic hypertension, diabetes mellitus, congestive heart failure, previous myocardial infarction, previous stroke, concomitant peripheral artery disease, chronic renal failure, left atrial enlargement, left ventricular ejection fraction, previous major bleeding, CHA_2DS_2-VASc score, HAS-BLED score, type of implanted device, and device size. All variables with p values <0.2 were then included in the multivariate model.

Further, propensity score analysis was performed to minimize selection biases associated with SAPT and DAPT groups. For each patient, a propensity score for the treatment group was calculated by logistic regression analysis of CHA_2DS_2-VASc and HAS-BLED scores, age, and gender. The 257 propensity score−matched cases (SAPT vs DAPT) were then evaluated by univariate analysis. Balancing between the 2 groups was checked by standardized mean differences (SMD).[11] All calculations were performed by the SPSS 23.0 software and p values <0.05 (2-tailed) were considered significant.

Results

A total of 610 patients who underwent successful percutaneous LAA occlusion were included in the analysis, 280 of whom treated with SAPT and 330 with DAPT after the intervention. Table 1 indicates main clinical and procedural features in the 2 groups. Patients on SAPT tended to be older and had a significantly higher prevalence of paroxysmal atrial fibrillation, hypertension, peripheral artery disease, chronic renal failure, and previous stroke. CHA_2DS_2-VASc and HAS-BLED scores were significantly higher in the SAPT group. Prevalence of previous myocardial infarction was more elevated in the DAPT group. Amplatzer Cardiac Plug/Amulet device (Abbott Vascular, Santa Clara, California) was prevalent in patients receiving SAPT, whereas the use of DAPT was more frequent after Watchman implantation (Boston Scientific, Marlborough, Massachusetts). All procedures were successful (as judged by the operators), without failure of disc apposition or residual leak >3 mm. The large majority of patients on SAPT received low-dose aspirin (95%), with the remaining being given clopidogrel as antiplatelet agent. SAPT was generally continued up to 1-year follow-up. DAPT was low-dose aspirin plus clopidogrel (75 mg daily) in all patients. Mean DAPT duration after the procedure was 3.6 ± 3.3 months, with aspirin generally being continued alone when DAPT was stopped.

SAPT strategy was similar to DAPT for the incidence of the primary net composite end point including BARC classification 3-5 bleeding, MACE or device-related thrombosis at 1 year: 9.3% vs 12.7%, p = 0.22 (Figure 1). The crude rates of the patient components of the primary net composite end point are reported in Table 2**.** BARC 3-5 bleeding was significantly lower with SAPT compared with DAPT use (2.9% vs 6.7%; p = 0.038), whereas the occurrence of ischemic events (MACE or device-related thrombosis) was similar (7.8% vs 7.4%; p = 0.33). Specifically, the incidence of MACE was 7.9% vs 6.4% (p = 0.53) and of device-

Table 1
Main baseline characteristics in the overall population, stratified by SAPT and DAPT

Variable	SAPT (n = 280)	DAPT (n = 330)	p Value
Age (years)	76.0 ± 6.8	74.9 ± 8.5	0.08
Women	124 (44%))	147 (45%)	0.98
Body mass index (kg/m^2)	26.8 ± 4.3	26.6 ± 4.3	0.57
Type of atrial fibrillation			0.032
Paroxysmal	117 (42%)	109 (33%)	
Persistent/permanent	163 (58%)	221 (67%)	
Systemic hypertension	255 (91%)	267 (81%)	0.001
Diabetes mellitus	83 (30%)	96 (29%)	0.95
Congestive heart failure	53 (19%)	69 (21%)	0.61
Previous myocardial infarction	36 (13%)	97 (29%)	0.001
Previous stroke	109 (39%)	93 (28%)	0.006
Peripheral artery disease	119 (43%)	102 (31%)	0.004
Previous major bleeding	158 (56%)	182 (55%)	0.81
Chronic renal failure*	157 (56%)	130 (39%)	0.001
Left ventricular ejection fraction (%)	55.2 ± 8.6	54.2 ± 11.1	0.11
Left atrial enlargement	252 (90%)	283 (86%)	0.14
CHA_2DS_2-VASc score	4.28 ± 1.46 median 4 (IQR 3−5)	3.94 ± 1.42 median 4 (IQR 3−5)	0.004
HAS-BLED score	3.42 ± 0.87 median 3 (IQR 3−4)	3.25 ± 1.08 median 3 (IQR 2.25−4)	0.03
Implanted device			0.001
Amplatzer cardiac plug/amulet	216 (77%)	204 (62%)	
Watchman/other devices	64 (23%)	126 (38%)	
Device size (mm)	24.4 ± 3.8	23.9 ± 3.8	0.11

DAPT = Dual antiplatelet therapy; IQR = Interquartile range; SAPT = Single antiplatelet therapy.
Data are expressed as n (%) or mean±standard deviation (median and IQR are also reported for CHA_2DS_2-VASc score and HAS-BLED score).
* Estimated glomerular filtration rate <60 ml/min/1.73 m^2.

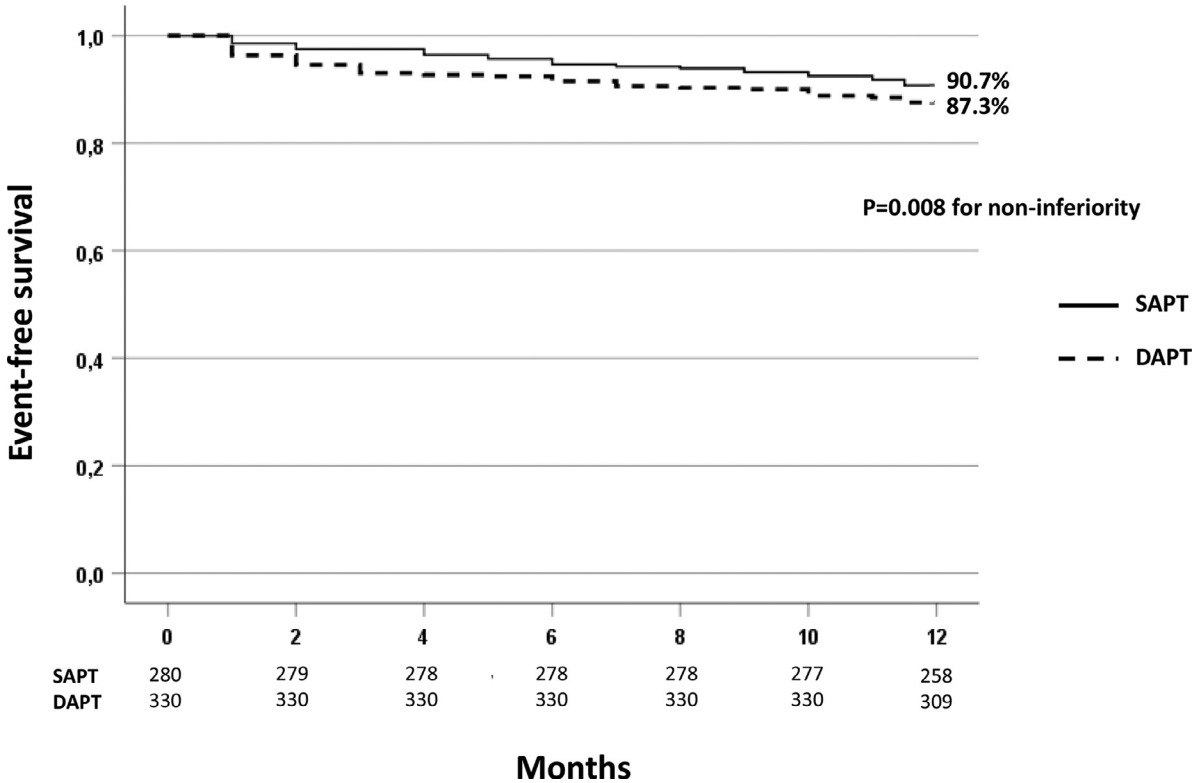

Figure 1. Kaplan-Meier curves of SAPT versus DAPT for the cumulative incidence at 1 year of the primary net composite end point, including BARC classification 3 to 5 bleeding, MACE or device-related thrombosis in the overall population. BARC = Bleeding Academic Research Consortium; DAPT = Dual antiplatelet therapy; MACE = Major adverse cardiovascular events (including cardiovascular death, ischemic stroke or systemic embolic event); SAPT = Single antiplatelet therapy.

Table 2
Number of patients (%) with events at 1 year for the primary net composite end point and its patient, multiple components

Variable	SAPT (n = 280)	DAPT (n = 330)	p Value (for superiority)
Primary net composite end point	26 (9.3%)	42 (12.7%)	0.22
BARC classification 3−5 bleeding	8 (2.9%)	22 (6.7%)	0.038
MACE	22 (7.8%)	25 (7.4%)	0.88
Cardiovascular death	17 (6%)	18 (5.5%)	
Ischemic stroke or systemic embolism	5 (1.8%)	7 (2.1%)	
Device-related thrombosis*	4 (0.7%)	3 (0.9%)	0.38

BARC = Bleeding Academic Research Consortium; DAPT = Dual antiplatelet therapy; MACE = Major adverse cardiovascular events; SAPT = Single antiplatelet therapy.
* Demonstrated after a stroke event in 2 patients (1 patient on SAPT and 1 on DAPT).

related thrombosis was 0.7% vs 0.9% (p = 0.98). Post-procedural pericardial tamponade developed in 0.36% of patients of the SAPT group and 0.30% of the DAPT group, with all events occurring within 48 hours from the procedure. In patients on DAPT, the occurrence of BARC 3-5 bleeding was numerically, but not significantly, lower in those receiving such antiplatelet strategy for ≤3 months (n = 98) compared with >3 months (n = 232): 6.1% vs 6.9%, p = 0.51, respectively.

In patients on SAPT having a BARC 3-5 bleeding (n = 8), the site of bleeding was gastro-intestinal in 4 (50%), pericardial in 2 (25%), and urinary in 2 (25%). In patients on DAPT with a BARC 3-5 bleeding (n = 22), the site of bleeding was gastro-intestinal in 45%, pericardial in 22%, urinary in 18%, intracranial in 5%, retroperitoneal in 5%, and unknown in 5%. All patients with device-related thrombosis were treated with low-molecular weight heparin for at least 1 month and were included in the analysis. Each center included at least 45 patients, there were irrelevant differences in the numbers of patients enrolled at each institution and there was no significant interaction in the study end points based on the implanting center (data not shown, due to the very low number of patients and events in each stratum).

Multivariate analysis by Cox proportional hazard model showed that the use of SAPT compared with DAPT after LAA occlusion was associated with a significant reduction of BARC 3-5 bleeding (HR 0.37, 0.16 to 0.88; p = 0.024), without increase in MACE or device-related thrombosis (HR 1.34, 0.70 to 2.55; p = 0.38) (Figure 2). The net composite end point including BARC 3-5 bleeding, MACE or device-related thrombosis was not significantly different (HR 0.69, 95% CI 0.41 to 1.15; p = 0.15).

We then performed a propensity score analysis, where patients receiving SAPT or DAPT, matched for age, gender, CHA_2DS_2-VASc, and HAS-BLED scores, were considered (overall 514 patients, 257 in both groups). Table 3 reports main baseline characteristics in the 2 groups. The HAS-BLED score was 3.36 ± 0.87 in patients on SAPT and 3.33 ± 1.10 in those on DAPT (p = 0.73), whereas the CHA_2DS_2-VASc score was 4.18 ± 1.47 and 4.21 ± 1.30, respectively (p = 0.81). Groups were well matched for the large majority of variables; only the prevalence of previous myocardial infarction was lower (SMD = 0.33) and the

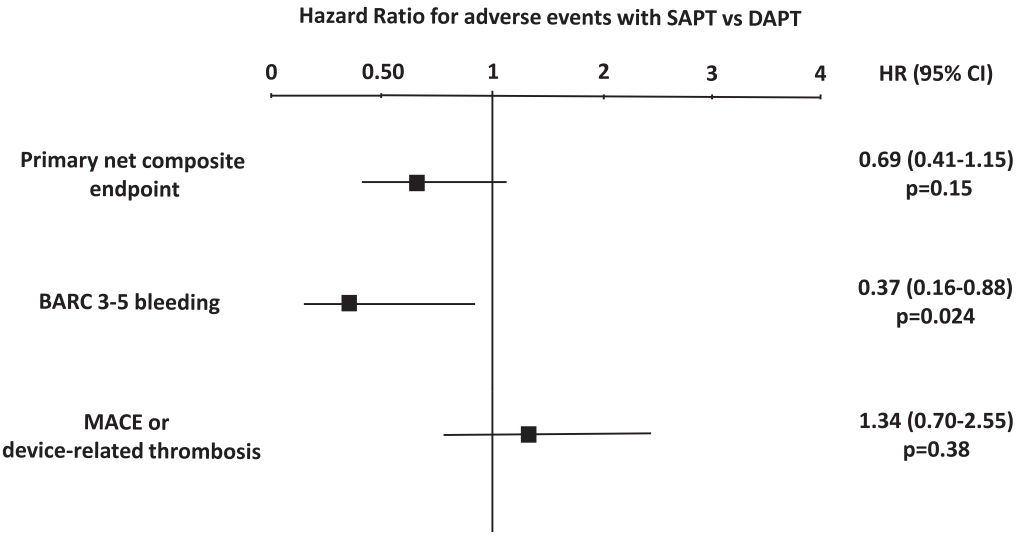

Figure 2. Multivariate analysis for adverse events with SAPT versus DAPT. BARC = Bleeding Academic Research Consortium; DAPT = Dual antiplatelet therapy; MACE = Major adverse cardiovascular events (including cardiovascular death, ischemic stroke or systemic embolic event); SAPT = Single antiplatelet therapy.

Table 3
Main baseline characteristics in the propensity score matching population, stratified by SAPT, and DAPT

Variable	SAPT (n = 257)	DAPT (n = 257)	p Value	SMD
Age (years)	76.1 ± 6.6	75.1 ± 8.5	0.10	0.11
Women	117 (46%)	124 (48%)	0.60	0.04
Body mass index (kg/m^2)	27.0 ± 4.4	26.5 ± 4.5	0.61	0.10
Type of atrial fibrillation			0.97	0.008
Paroxysmal	98 (38%)	99 (39%)		
Persistent/permanent	159 (62%)	158 (61%)		
CHA_2DS_2-VASc score	4.18 ± 1.47	4.21 ± 1.30	0.81	0.02
HAS-BLED score	3.36 ± 0.87	3.33 ± 1.10	0.73	0.03
Systemic hypertension	218 (85%)	209 (81%)	0.35	0.09
Diabetes mellitus	81 (32%)	78 (30%)	0.85	0.02
Congestive heart failure	50 (20%)	44 (17%)	0.57	0.07
Previous myocardial infarction	32 (13%)	65 (25%)	0.001	0.33
Previous stroke	86 (34%)	90 (35%)	0.78	0.02
Peripheral artery disease	101 (39%)	94 (37%)	0.59	0.07
Previous major bleeding	143 (56%)	143 (56%)	1.0	0.00
Chronic renal failure*	140 (55%)	108 (42%)	0.001	0.26
Left ventricular ejection fraction (%)	54.7 ± 9.2	54.0 ± 10.8	0.29	0.07
Implanted device			0.09	0.14
Amplatzer cardiac plug /amulet	195 (76%)	177 (69%)		
Watchman/other devices	62 (24%)	80 (31%)		

DAPT = Dual antiplatelet therapy; SAPT = Single antiplatelet therapy; SMD = Standardized Mean Differences.
Data are expressed as n (%) or mean ± standard deviation.
* Estimated glomerular filtration rate <60 ml/min/1.73 m^2.

prevalence of chronic renal failure was higher (SMD = 0.16) in the SAPT group. A nonsignificant, numerically lower incidence of the primary net composite end point was observed with SAPT compared withwith DAPT (9.0% vs 13.9%; p = 0.09) (Figure 3). SAPT use was associated with a significant reduction in BARC 3-5 bleeding (2.3% vs 7.0%; p = 0.02). The incidence of MACE or device-related thrombosis was similar in the 2 treatment strategies (7.8% vs 7.4%; p = 0.99). Similar results were observed for the exploratory thrombotic outcome measure including ischemic stroke, systemic embolic event or device-related thrombosis (3.1% vs 3.1%; p = 0.98).

Discussion

In this retrospective, real-world study we found that in patients who underwent percutaneous LAA occlusion the postprocedural use of SAPT compared with DAPT is associated with reduction of bleeding complications, with no signal of increased risk of ischemic and thromboembolic events.

Experimental studies indicated that the endothelization of the implanted device in patients who underwent percutaneous LAA occlusion may require up to 90 days.[12] Although in the early phases of introduction of percutaneous LAA occlusion patients were given oral anticoagulant therapy to enhance device endothelization, DAPT is an effective antithrombotic strategy to prevent device-related thrombosis until the device endothelization is completed. However, the occurrence of hemorrhagic complications after the intervention may impact on patient's morbidity and mortality. As the hemorrhagic risk is also a function of the number of antithrombotic agents given, the DAPT-related bleeding risk in patients who underwent LAA occlusion, characterized by an elevated propensity to hemorrhagic events, has clinical relevance.[13] A safer approach may be the use of SAPT instead of DAPT after the intervention.[14] Single-center, observational data showed that a strategy with SAPT (essentially aspirin, without P2Y12 inhibitor) was associated with a low risk of device-related thrombosis (1.9% at a median follow-up of 2.3 years), a 61% risk reduction of stroke compared with the predicted rate based on the correspondent CHA_2DS_2-VASc score and a 57% risk reduction of major bleeding compared with the predicted rate based on the correspondent HAS-BLED score.[15] Moreover, a recent investigation reported similar post-procedural levels of markers of platelet activation in patients receiving SAPT or DAPT.[16] However, a retrospective evidence suggested that SAPT might be inadequate to prevent thrombotic complications after LAA occlusion[17]; in fact, in this study the prevalence of SAPT use was higher in patients with device-related thrombosis (42%) compared with those without (29%). Notably, the risk of device-related thrombosis in patients who underwent LAA occlusion is even higher because of older age and elevated prevalence of "prothrombotic" conditions, such as diabetes mellitus, chronic renal failure, and a previous cardiovascular event.[18] Device-related thrombosis is associated with increased risk of ischemic stroke or transient ischemic attack.[14,17] Thus, concerns on either the bleeding risk related to DAPT and the ischemic protection with SAPT exist. To date, no data on a direct comparison between these 2 antiplatelet approaches in patients receiving percutaneous LAA occlusion are available; therefore, more evidence on the topic should be welcome.

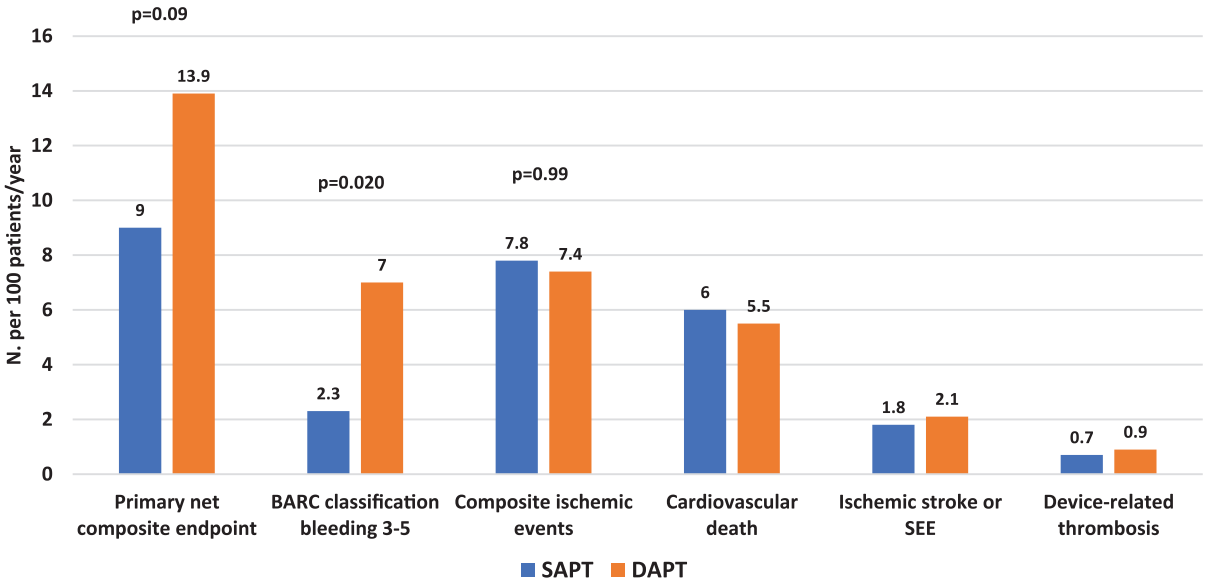

Figure 3. Incidence of the net composite end point and its patient components with SAPT versus DAPT in the propensity score matching population. BARC = Bleeding Academic Research Consortium; DAPT = Dual antiplatelet therapy; SAPT = Single antiplatelet therapy; SEE = Systemic embolic event.

We performed a multicenter, retrospective, head-to-head evaluation of SAPT vs DAPT in a large population, considering as end points both ischemic and bleeding events. In our investigation SAPT was essentially represented by aspirin; it was given throughout 1-year follow-up. Patients on DAPT received aspirin plus clopidogrel for a mean of 3.6 months after the intervention and continued aspirin alone thereafter. Both unadjusted and adjusted analysis showed that SAPT use was associated with significant reduction in bleeding complications, without evidence of increase in ischemic events (MACE or device-related thrombosis). Indeed, the adjusted 95% CI for the net composite end point (HR 0.69, 95% CI 0.41 to 1.15) suggests that it is unlikely that a SAPT strategy may result in a clinically relevant increase of net clinical damage. As expected, patients who were given SAPT had a higher bleeding risk profile, as expressed by a higher HAS-BLED score. Nevertheless, the occurrence of the safety end point including BARC 3-5 bleeding was significantly lower in the SAPT arm; this was confirmed either at propensity score analysis, where there was a 68% relative reduction of BARC 3-5 bleeding in the SAPT group, and at multivariate analysis, where the use of SAPT was independently associated with lower incidence of hemorrhagic complications. Importantly, the rates of ischemic cardiovascular events and device-related thrombosis were similar in the 2 arms, without any signal of increased risk in patients on SAPT, despite their higher risk profile. Again, this was confirmed either at multivariate and propensity score analysis; notably, in the latter analysis the incidence of the exploratory thrombotic outcome measure, including ischemic stroke, systemic embolic event or device-related thrombosis, was equal in the 2 groups.

In light of the study limitations, our results should be considered as hypothesis-generating. Our investigation reported a relatively low incidence of periprocedural pericardial tamponade. These results reflect contemporary practice in high-volume centers. Thus, the findings of this study should not be extrapolated to low-volume centers. Data were adjusted by multivariate and propensity score analysis, but residual confounding cannot be excluded; nevertheless, an estimation of the impact of a potential unmeasured confounder on the outcome measures suggests that it is unlikely such a confounder alone could have driven the results. Moreover, bias in patient enrollment and treatment decision cannot be excluded, although recruitment of consecutive patients at each center was mandatory. No specific information on adherence and persistence to antiplatelet treatment was available, although all patients who underwent the 3 scheduled follow-up visits within 1 year; here the compliance was assessed and no patient reported premature permanent discontinuation of the antiplatelet therapy. Event adjudication was locally performed by confirmation of a second investigator, but no external, independent adjudication of adverse events, including device-related thrombosis, was used for the outcome measures; this may carry a further risk of bias, as well as the lack of a specific assessment of stroke and systemic embolic events by neurologists and radiologists in the context of a prespecified protocol. However, follow-up events were confirmed by source documentation. All patients who underwent a single trans-esophageal echocardiography 1 to 3 months after the procedure, but this evaluation was not performed following a specific, fixed timing, and a prespecified design. The overall occurrence of device-related thrombosis was low (0.8%) compared with previous observational and randomized studies (3% to 4%);[5,19] this can be due to the lack of a systematic transesophageal evaluation, but may also reflect the heterogeneous timing of postprocedural transesophageal echocardiography, as usually occurs in observational registries.[14] Thus, we cannot exclude a different incidence in the 2 groups of asymptomatic, undetected, device-related thrombosis; however, even if present, this did not translate into different rates of clinically relevant, thromboembolic events. Our study is underpowered to evaluate the efficacy and safety of SAPT versus DAPT in relation to various types of device, as well as in specific subgroups of different

bleeding and thromboembolic risk profiles. Accordingly, suggestions in this scenario are speculative and data on different devices were considered together in the analysis, without comparison between different devices. The reasons for the prevalent use of SAPT in patients receiving the Amplatzer Cardiac Plug/Amulet device and of DAPT in those who underwent Watchman deployment are unclear, but might be related to the higher risk profile of SAPT patients. However, multivariate analysis was adjusted also for the type of device and confirmed all findings of the unadjusted analyses.

In conclusion, this observational study suggests that after LAA occlusion a strategy with SAPT is safer than DAPT, with significant lower bleeding, and apparently provides similar protection from thrombotic events. In the background of no specific guideline recommendations, this analysis can add evidence to practice patterns concerning antiplatelet approaches following LAA occlusion. Our investigation is hypothesis-generating and, as it may be underpowered for the evaluation of the efficacy of SAPT, merits confirmation. The ongoing randomized STROKE-CLOSE study (ClinicalTrials.gov identifier: NCT02830152), performed on patients with previous intracranial hemorrhage receiving aspirin alone or standard medical therapy after LAA occlusion with the Amulet device, will provide indirect insights on postimplant use of SAPT. However, our study may represent the basis for a randomized, head-to-head study evaluating the clinical outcome, especially related to thrombotic events, with the use of SAPT versus DAPT in this setting of noncoronary percutaneous interventions.

Author contributions

Dr. G. Patti designed the study. Dr. A. Sticchi and Dr. G. Verolino performed data collection. Analysis and interpretation of the results was done by Dr. V. Pasceri, A. Sticchi and G. Patti. The study was drafted by Dr. G. Patti. Critical revision of the study for important intellectual content was done by all authors.

Disclosure

GP: speaker/consultant/advisory board for Amgen, Sanofi, Bayer, Boehringer-Ingelheim, BMS-Pfizer, Daiichi Sankyo, Astra Zeneca, Sigma-Tau, Malesci, PIAM and MSD. AS, GV, VP, VV, MDB, MV, DS, EB, PM, PG, VR, GA, AMo, GB, AL, FG, MC, GPU, AC: no disclosure. GC: Proctor for Boston Scientific and Abbott Vascular. AR: speaker/consultant for Abbott, Boston Scientific, Biotronik. AMa: institutional grant from Boston Scientific. PAP: proctor for Cardia and Boston Scientific. The authors declare that they have no known competing financial interests or personal relations that could have appeared to influence the work reported in this study.

Appendix

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