JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 13, 2016

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.04.019

Predictors of Early (1-Week) Outcomes Following Left Atrial Appendage Closure With Amplatzer Devices

Konstantinos C. Koskinas, MD, MSc,[a] Samera Shakir, MD,[a] Máté Fankhauser, MS,[a] Fabian Nietlispach, MD,[b] Adrian Attinger-Toller, MD,[b] Aris Moschovitis, MD,[a] Peter Wenaweser, MD,[a] Thomas Pilgrim, MD,[a] Stefan Stortecky, MD,[a] Fabien Praz, MD,[a] Lorenz Räber, MD,[a] Stephan Windecker, MD,[a] Bernhard Meier, MD,[a] Steffen Gloekler, MD[a]

ABSTRACT

OBJECTIVES The aim of this study was to assess predictors of adverse 1-week outcomes and determine the effect of left atrial appendage (LAA) morphology following LAA closure (LAAC) with Amplatzer devices.

BACKGROUND Percutaneous LAAC is a valuable treatment option for stroke prevention in patients with atrial fibrillation. Determinants of procedural safety events with Amplatzer occluders are not well established, and the possibly interrelating effect of LAA anatomy is unknown.

METHODS Between 2009 and 2014, 500 consecutive patients with atrial fibrillation ineligible or at high risk for oral anticoagulation underwent LAAC using Amplatzer devices. Procedure- and device-related major adverse events (MAEs) were defined as the composite of death, stroke, major or life-threatening bleeding, serious pericardial effusion, device embolization, major access-site vascular complication, or need for cardiovascular surgery within 7 days following the intervention.

RESULTS Patients (mean age 73.9 ± 10.1 years) were treated with Amplatzer Cardiac Plug (n = 408 [82%]) or Amulet (n = 92 [18%]) devices. Early procedural success was 97.8%, and MAEs occurred in 29 patients (5.8%). Independent predictors of MAEs included device repositioning (odds ratio: 9.13; 95% confidence interval: 2.85 to 33.54; $p < 0.001$) and left ventricular ejection fraction <30% (odds ratio: 4.08; 95% confidence interval: 1.49 to 11.20; $p = 0.006$), with no effect of device type or size. Angiographic LAA morphology, characterized as cauliflower (33%), cactus (32%), windsock (20%), or chicken wing (15%), was not associated with procedural success ($p = 0.51$) or the occurrence of MAEs ($p = 0.78$).

CONCLUSIONS In this nonrandomized study, procedural success of LAAC using Amplatzer devices was high. MAEs within 7 days were predicted by patient- and procedure-related factors. Although LAA morphology displayed substantial heterogeneity, outcomes were comparable across the spectrum of LAA anatomies. (J Am Coll Cardiol Intv 2016;9:1374–83)

Although oral anticoagulation (OAC) is currently the standard treatment for stroke prevention in patients with atrial fibrillation (AF), OAC is frequently contraindicated or insufficiently controlled (1), it entails an inherent bleeding risk (2), and it is discontinued in up to 50% of patients within 3 years of treatment initiation (3). Because >90% of cardiac thrombi form in the left

From [a]Cardiology, Cardiovascular Department, University Hospital of Bern, Bern, Switzerland; and [b]Cardiology, University Hospital of Zurich, Zurich, Switzerland. Prof. Meier is a consultant to and has received grants to the institution from St. Jude Medical. Prof. Windecker has received grants to the institution from Abbott, Biotronik, Boston Scientific, Medtronic, Edwards Lifesciences, and St Jude Medical. Dr. Nietlispach is a consultant to St. Jude Medical, Edwards Lifesciences, Direct Flow Medical, and Medtronic. Dr. Gloekler has received a grant from the Swiss Heart Foundation. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Koskinas and Shakir contributed equally to this work.

Manuscript received December 7, 2015; revised manuscript received March 15, 2016, accepted April 19, 2016.

atrial appendage (LAA) in patients with nonvalvular AF (4), catheter-based LAA closure (LAAC) has emerged as a valuable nonpharmacological treatment alternative and is advocated as a potential therapeutic option in current guidelines (5).

Randomized trials established the superiority of LAAC with the Watchman device (Boston Scientific, Natick, Massachusetts) over warfarin for long-term stroke prevention and reduction of mortality (6). Previous studies with Amplatzer LAA occluders (St. Jude Medical, St. Paul, Minnesota) (7-11) showed the feasibility of the intervention but were limited by small sample sizes, assessed patients treated with dedicated or nondedicated devices (10), and included centers with variable operator experience (11)—factors known to affect LAAC outcomes (12). Although some concerns have been expressed regarding the rate of early safety events following LAAC procedures, little is known about patient-, device-, and procedure-related predictors of periprocedural complications of LAAC. Moreover, whether procedural outcomes with Amplatzer devices may be influenced by LAA morphology remains unknown despite the fact that LAA structure is highly heterogeneous, affects the propensity to thrombotic complications in patients with AF (13,14), and modifies device healing responses upon LAAC in pre-clinical models (15).

SEE PAGE 1384

The purposes of this observational study were to determine predictors of early (1-week) outcomes of LAAC using Amplatzer devices and to investigate the association of LAA morphology with procedural performance and early safety events. We therefore analyzed a sizable cohort of consecutively enrolled patients undergoing LAAC with dedicated Amplatzer devices at 2 high-volume centers.

METHODS

PATIENT POPULATION. All consecutive patients who were scheduled for LAAC between 2009 and 2014 at 2 Swiss centers, the Bern and Zurich University hospitals, were enrolled in this prospective observational registry. In line with current recommendations (5,16), we included a wide range of patients with AF with moderate to high thromboembolic risk who had absolute or relative contraindications to OAC, were deemed by their physicians to be at high risk for long-term OAC treatment (including indication for triple antithrombotic therapy in view of the necessity of dual-antiplatelet therapy, e.g., because of previous or planned percutaneous coronary interventions [PCI]), or preferred an alternative to OAC. The study was approved by the local ethics committees.

LAAC PROCEDURES. Device characteristics and procedural aspects were previously described in detail (16,17). Procedures were performed by experienced operators mostly under fluoroscopic guidance using dedicated Amplatzer devices (first-generation Amplatzer Cardiac Plug [ACP] and second-generation Amulet). LAAC was performed either alone, possibly combined with diagnostic coronary angiography ("lone LAAC"), or in combination with concomitant procedures, including PCI, closure of patent foramen ovale (PFO) or atrial septal defect, transcatheter

ABBREVIATIONS AND ACRONYMS

ACP = Amplatzer Cardiac Plug
AF = atrial fibrillation
LAA = left atrial appendage
LAAC = left atrial appendage closure
LVEF = left ventricular ejection fraction
MAE = major adverse event(s)
OAC = oral anticoagulation
PCI = percutaneous coronary intervention
PFO = patent foramen ovale

TABLE 1 Baseline Patient Characteristics

	All Patients	No MAEs (n = 471)	MAEs (n = 29)	p Value
Demographics				
Age (yrs)	73.9 ± 10.1	73.8 ± 10.2	74.6 ± 7.4	0.69
Female	152 (30.4)	141 (29.9)	11 (37.9)	0.36
Body mass index (kg/m^2)	27.5 ± 8.8	27.5 ± 8.9	27.7 ± 6.2	0.89
Cardiac risk factors				
Diabetes mellitus	116 (23.2)	108 (22.9)	8 (27.6)	0.56
Arterial hypertension	441 (88.2)	414 (87.9)	27 (93.1)	0.40
Coronary artery disease	305 (61)	288 (61.1)	17 (58.6)	0.79
Previous PCI/CABG	291 (58.2)	275 (58.4)	16 (55.2)	0.73
Previous myocardial infarction	116/467 (24.8)	110/440 (25)	6/27 (22.2)	0.75
History of systemic embolization	137 (27.4)	129 (27.4)	8 (27.6)	0.98
Previous stroke	151 (30.1)	143 (30.4)	8 (27.6)	0.75
Ischemic stroke	116 (23.2)	109 (23.1)	7 (24.1)	0.90
eGFR (ml/min/1.73 m^2)	69.6 ± 33.1	69.8 ± 33.2	68.2 ± 31.1	0.80
eGFR <60 ml/min/1.73m^2	217 (43.4)	201 (42.7)	16 (55.2)	0.19
Atrial fibrillation				
Permanent/persistent	223 (44.6)	207 (43.9)	16 (55.2)	0.24
Paroxysmal	253 (50.6)	240 (50.9)	13 (44.8)	0.52
LVEF (%)	54.9 ± 11.5	55.3 ± 11.3	49.7 ± 14	0.01
LVEF ≤30%	35 (7)	28 (5.9)	7 (24.1)	<0.001
HAS-BLED score	2.95 ± 1.12	2.94 ± 1.13	3.03 ± 0.82	0.69
HAS-BLED score ≥3	334 (66.8)	313 (66.4)	21 (72.4)	0.29
$CHADS_2$ score	2.57 ± 1.31	2.57 ± 1.32	2.65 ± 1.23	0.73
$CHADS_2$ score ≥3	251 (50.2)	236 (50.1)	15 (51.7)	0.87
CHA_2DS_2-VASc score	4.33 ± 1.66	4.32 ± 1.67	4.55 ± 1.48	0.47
Baseline medications				
Oral anticoagulation	278 (55.6)	257 (54.5)	21 (72.4)	0.06
Warfarin	233 (46.6)	215 (45.6)	18 (62.1)	0.09
NOAC	45 (9.0)	42 (8.9)	3 (10.3)	0.54
Acetylsalicylic acid	299 (59.8)	278 (59)	21 (72.4)	0.17
$P2Y_{12}$ inhibitor	116 (23.2)	108 (22.9)	8 (27.6)	0.63
Dual-antiplatelet therapy	97 (19.4)	89 (18.9)	8 (27.6)	0.26

Values are mean ± SD or n (%).

CABG = coronary artery bypass grafting; eGFR = estimated glomerular filtration rate; LVEF = left ventricular ejection fraction; MAE = major adverse event(s); NOAC = non-vitamin K oral anticoagulant; PCI = percutaneous coronary intervention.