Concomitant atrial fibrillation ablation and left atrial appendage occlusion using Amplatzer devices – a single centre experience


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Summary

In selected patients with atrial fibrillation (AF), left atrial appendage (LAA) occlusion is a valuable alternative to oral anticoagulation (OAC). The combination of LAA occlusion and AF ablation during the same procedure may be useful in selected patients. At our centre, the combined procedure has routinely been performed using Amplatzer devices (Abbott, Plymouth, MN, USA) with local anaesthesia and conscious sedation, and without periprocedural transoesophageal echocardiography (TOE) guidance. Outcome data of this approach have not been reported. Data for all patients who underwent AF ablation and LAA occlusion during the same procedure at our centre were retrospectively assessed. The combined procedure was performed in 26 patients (18 males, age 67 ± 9 years, CHADS2–VASc score 2.3 ± 1.3) between 2002 and 2014. Non-dedicated devices (Amplatzer Septal Occluders) were used in 3 patients (11%), and dedicated devices in 23 patients (89%). 18 were Amplatzer Cardiac Plugs and 5 were Amplatzer Amulets. The device was successfully implanted in 25 patients (96%). In total, nine device-related complications occurred in seven patients (27%), including bleeding from the femoral access site in four and device embolisation in two patients – in one patient combined with an ischaemic stroke. Tamponade necessitating drainage and transient ST-segment elevation were seen in one patient each. After a mean follow-up time of 36 ± 33 months, 12 patients (46%) had recurrence of atrial arrhythmias. There was no device embolisation, stroke or other thromboembolic event during follow-up. One patient died 10 years after the procedure from congestive heart failure. LAA occlusion using Amplatzer devices combined with AF ablation during the same procedure, under local anaesthesia and conscious sedation and without periprocedural TOE, seems feasible and effective regarding stroke prevention and safety in the long term but is associated with a high periprocedural complication rate.

Keywords: catheter ablation, atrial fibrillation, left atrial appendage occlusion, stroke prevention

Introduction

Atrial fibrillation (AF) is the most frequent arrhythmia in the elderly and associated with an overall annual stroke risk of 5%, increasing up to 15% in high-risk patients [1, 2]. The left atrial appendage (LAA) is the assumed source of thrombi in more than 90% of patients with nonvalvular AF [3]. Percutaneous LAA occlusion has demonstrated safety and efficacy in long-term stroke prevention and has emerged as an alternative to oral anticoagulation (OAC) [4–8]. Radiofrequency ablation for paroxysmal and persistent AF is an effective treatment option for symptomatic patients [9–12]. The combination of AF ablation and LAA occlusion during the same procedure in the sense of a one-stop-shop procedure, not only addressing symptoms (radiofrequency ablation) but also obviating the need for long-term OAC (LAA occlusion), appears attractive for patients and cost saving.

Multiple studies have evaluated feasibility and safety of the combined procedure [13–17]. The Watchman device (Boston Scientific, Natick, MS, USA) was mainly used in previous studies and procedures were usually performed in separate procedures, with periprocedural transoesophageal echocardiography (TOE) guidance, and under general anaesthesia. The present study describes our long-term experience of AF ablation and LAA occlusion during the same procedure using Amplatzer devices (Abbott, Plymouth, MN, USA)
implanted under local anaesthesia and conscious sedation without periprocedural TOE guidance.

Methods

Patient selection
Since 2001, data on all AF ablation procedures performed at our centre have been prospectively collected in a database. For this study, data from all patients who underwent AF ablation and percutaneous LAA occlusion during the same procedure were retrospectively analysed. All interventions were performed under local anaesthesia and conscious sedation using fentanyl and midazolam or propofol, with the exception of one patient, who preferred general anaesthesia. Datasets were completed from a centralised database containing records of all patients treated at our centre. Written informed consent for the procedure and data collection were obtained from all participants. The study was approved by the local ethics committee (ID: 2016-01574).

AF ablation
Preprocedural TOE was performed to visualise LAA anatomy and to exclude left atrial thrombus. Radiofrequency AF ablation was performed as described elsewhere [12]. Conventional fluoroscopy guided by a circumferential mapping catheter (Lasso, Biosense-Webster Inc., Diamond Bar, CA, USA) was used in 12 cases. Since 2013, a three-dimensional mapping system has been systematically used (Carto3, Biosense-Webster Inc.). Before 2005, only electrically active veins were isolated. Since then, the endpoint for the ablation procedure has been complete electrical isolation of all pulmonary veins. Adjunctive ablation was performed at the discretion of the operator.

LAA occlusion
Immediately after completion of AF ablation, LAA occlusion was performed under fluoroscopic guidance only, as described elsewhere [18, 19]. Briefly, contrast injections in different projections were used to visualise LAA size and anatomy without TOE guidance. The device was delivered to the LAA via a dedicated transseptal sheath (Amplatzer TorqVue, Abbott, Plymouth, MN, USA) and stable device position was confirmed by contrast injections and a tug test before device release (fig. 1). The day after the procedure, transthoracic echocardiography (TTE) was performed to assess for device position and pericardial effusion.

Follow-up
TOE was performed during follow-up at 4 to 6 months in order to evaluate device position, thrombus formation on the device and significant residual flow in the LAA (defined as a jet around the device of >5mm). If no significant residual flow was present, OAC was discontinued. Seven-day ECGs were routinely recorded at 3, 6, and 12 months after the procedure and on a yearly basis thereafter. Freedom from atrial arrhythmia was assessed after a blanking period of 3 months. Recurrence was defined as AF, atrial flutter, or atrial tachycardia lasting ≥30 seconds documented on long-term or 12-lead ECG, irrespective of symptoms. All patients or, in the case of death, their relatives and family doctors, were contacted and bleeding events, neurological events, recurrence of AF, and deaths were recorded.

Statistical analysis
Continuous variables are provided as mean ± SD (standard deviation) or median and IQR (interquartile range). Percentages are used to report categorical variables. Values were compared using Student’s T-test or a chi-square test, as appropriate. A two-tailed p-value <0.05 was considered statistically significant. Statistical analysis was performed using SPSS software (IBM SPSS Statistics, Version 21).

Results
Concomitant pulmonary vein isolation and LAA occlusion during the same procedure were performed in 26 patients (age 67 ± 9 years, 69% males) between November 2002 and June 2014. Patient characteristics are summarised in table 1. Structural heart disease was present in 19 patients (73%). AF was persistent in 10 patients (39%) with a mean AF duration of 13 ± 9 months. Mean CHA2DS2-VASc score was 2.3 ± 1.3. Before the procedure, 22 patients (85%) were on OAC. The remaining four patients (15%) were not on OAC, despite given indications.

The device was successfully implanted in 25 patients (96%). Stable device position was confirmed by TTE the day after the procedure in all these patients. In the first three patients treated before 2008, non-dedicated LAA occlusion devices were used (off-label use of Amplatzer Septal Occluders). All non-dedicated devices were implanted successfully and without any complications. After 2008, the dedicated Amplatzer Cardiac Plugs and Amplatzer Amulets were used exclusively.
In seven patients (27%), four of them being women, a procedure-related complication occurred as summarised in table 2. One patient with a dedicated device experienced device embolisation to the left ventricular outflow tract in combination with an ischaemic stroke and bleeding from the femoral access site. The patient underwent surgical extraction of the embolised device and the LAA was left open. This was the only case with unsuccessful device implantation. The other embolised dedicated device could be retrieved percutaneously from the right iliac bifurcation artery by using a snare catheter. In the same procedure, a new device was placed to occlude the LAA. One patient developed tamponade due to LAA perforation. The patient recovered uneventfully after pericardiocentesis.

Nineteen patients (73%) were discharged the day after the procedure. The median duration of the hospitalisation was 1.0 (1–1.8) nights. A longer hospitalisation of 12 and 16 nights, respectively, was necessary in two patients because of adverse events. The remaining five patients were discharged two or three nights after the procedure.

Three patients (12%) needed to be re-hospitalised after discharge owing to bleeding from the femoral access site that required surgery.

In the same time period, 1248 AF ablation procedures (without LAA occlusion) were performed at our centre. Table 2 compares procedural characteristics and complications between the combined procedures and AF ablation only procedures.

Follow-up TOE data were available from 23 patients (89%). Examinations have been performed 19 ± 11 weeks after the procedure. No device thrombi were detected. Complete sealing of the LAA was confirmed in 19 patients (74%). In three patients (12%) minimal residual flow (<5mm) was detected. In one patient, LAA had been left open after surgical extraction of the embolised device.

During a mean follow-up time of 36 ± 33 months (range 3–121 months), 12 patients (46%) had recurrence of atrial arrhythmias. Repeat left atrial ablations were performed in three patients without any problem despite the LAA occlusion and six patients underwent pacemaker implantation and atrioventricular node ablation.

In 25 patients, OAC was stopped 3 ± 1 months after the procedure. In three patients, OAC was restarted later by the referring physician for unknown reasons. OAC was never stopped in the patient in whom LAA was left open after device embolisation. No strokes, other thromboembolic events or device embolisations occurred during follow-up. One patient developed gastrointestinal bleeding after colonoscopy, 26 months after the procedure. One patient died 10 years after the procedure from longstanding congestive heart failure. Follow-up results are summarised in table 3.

**Discussion**

The study describes a single centre experience combining AF ablation and LAA occlusion using Amplatzer devices, performed in the same procedure without periprocedural

**Table 1: Baseline characteristics (n = 26).**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>67.3 ± 9</td>
</tr>
<tr>
<td>Male gender</td>
<td>18 (69)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.9 ± 4.8</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>19 (73)</td>
</tr>
<tr>
<td>Hypertensive</td>
<td>15 (58)</td>
</tr>
<tr>
<td>Ischaemic</td>
<td>8 (31)</td>
</tr>
<tr>
<td>Valvular</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Tachycardiomyopathy</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Congenital</td>
<td>1 (4)</td>
</tr>
<tr>
<td>LVEF</td>
<td>60 ± 6</td>
</tr>
<tr>
<td>LA size (PLAX, mm)</td>
<td>44 ± 7</td>
</tr>
<tr>
<td>LAA orifice diameter (mm)</td>
<td>19 ± 5</td>
</tr>
<tr>
<td>Persistent AF</td>
<td>10 (39)</td>
</tr>
<tr>
<td>Any previous AF ablation</td>
<td>8 (31)</td>
</tr>
<tr>
<td>CHA2DS2-VASc score</td>
<td>2.3 ± 1.3</td>
</tr>
<tr>
<td>HAS-BLED score</td>
<td>2.3 ± 0.9</td>
</tr>
<tr>
<td>Pre-procedural anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Coumadin</td>
<td>13 (50)</td>
</tr>
<tr>
<td>NOACs</td>
<td>7 (27)</td>
</tr>
<tr>
<td>LMWH</td>
<td>2 (8)</td>
</tr>
<tr>
<td>No anticoagulation</td>
<td>4 (15)</td>
</tr>
<tr>
<td>Therapy with amiodarone</td>
<td>13 (50)</td>
</tr>
<tr>
<td>Indication for LAA closure</td>
<td></td>
</tr>
<tr>
<td>History of prior bleeding</td>
<td>5 (19)</td>
</tr>
<tr>
<td>Labile INR</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Ischaemic stroke on OAC</td>
<td>1 (4)</td>
</tr>
<tr>
<td>OAC intolerance</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Patient preference</td>
<td>16 (61)</td>
</tr>
</tbody>
</table>

AF: atrial fibrillation; BMI: body mass index; INR: international normalised ratio; LA: left atrium; LAA: left atrial appendage; LWMH: low molecular weight heparin; LVEF: left ventricular ejection fraction; NOAC: non-vitamin K dependent oral anticoagulant; OAC: oral anticoagulation; PLAX: parasternal long axis All values are provided as mean ± SD or n (%).
TOE guidance or general anaesthesia (with the exception of one patient who requested general anaesthesia).

Based on single-centre observational series and expert consensus, the European Heart Rhythm Association / European Association of Percutaneous Cardiovascular Interventions document on catheter-based LAA occlusion suggests that selected patients with significant risks for thromboembolic events, and strict or relative contraindications to OAC undergoing AF ablation may be acceptable candidates for the combined procedure [20, 21]. Provided that the patient has an indication for both procedures, the simultaneous combination is cost efficient, patient-friendly, and avoids the need for a repeated transseptal puncture with its associated risks.

To the best of our knowledge, four single-centre [13–16] and one multicentre series [17] on combined procedures, including 35, 98, 45, 30 and 139 patients, have been published. In the series by Calvo and coworkers [13], Amplatzer devices were used in 18% of cases. In all other studies the Watchman device was used exclusively. In all series, the procedures were performed under general anaesthesia, with TOE guidance. In summary, the results of these studies suggest that the combined approach is feasible for selected patients [22]. In these series, device-related adverse events were reported in up to 8.6% of patients and included tamponade, transient ST-segment elevation, groin haematoma, and device embolisation.

We performed AF ablation and LAA occlusion in the same procedure in 26 patients. The LAA could be occluded with Amplatzer devices successfully in 96% with good long-term results and no stroke or device embolisation during follow-up.

However, we observed a disproportionally high rate of procedural device-related complications, affecting 27% of pa-

### Table 2: Procedural details.

<table>
<thead>
<tr>
<th></th>
<th>AF ablation and LAA occlusion combined (n = 26)</th>
<th>AF ablation only (n = 1248)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total procedure time (min)</td>
<td>208 ± 78</td>
<td>185 ± 82</td>
<td>0.11</td>
</tr>
<tr>
<td>Total fluoroscopy time (min)</td>
<td>58 ± 37</td>
<td>57 ± 31</td>
<td>0.3</td>
</tr>
<tr>
<td>Total radiation dose (cGy × cm²)</td>
<td>423 ± 350</td>
<td>344 ± 314</td>
<td>0.93</td>
</tr>
<tr>
<td>Total RF time (min)</td>
<td>46 ± 21</td>
<td>42 ± 24</td>
<td>0.3</td>
</tr>
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</table>

**LAA occlusion**
- Successful occlusion: 25 (96)
- Devices used:
  - Amplatzer Septal Occluder: 3 (11)
  - Amplatzer Cardiac Plug: 19 (73)
  - Amplatzer Amulet: 5 (19)

**Procedure-related complications**
- Patients with any complication: 7 (27)
- Relevant bleeding from the femoral access site: 4 (15)
- Transient ST segment elevation: 1 (4) vs 1 (<0.01)
- Tamponade necessitating drainage: 1 (4)
- Device embolisation: 2 (8)
- Iatrogenic stroke / TIA: 1 (4)
- Atrial-oesophageal fistula: 5 (19)
- Catheter entrapment (requiring surgery): 1 (4)

### Table 3: Follow-up results (n = 26).

<table>
<thead>
<tr>
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<th>36 ± 33</th>
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<tbody>
<tr>
<td>Time to last follow up (months)</td>
<td>23 (88)</td>
</tr>
<tr>
<td>Follow-up TOE available</td>
<td>19 (83)</td>
</tr>
<tr>
<td>Complete sealing of LAA</td>
<td>0</td>
</tr>
<tr>
<td>Device related thrombi</td>
<td>3 (13)</td>
</tr>
<tr>
<td>LAA open (left open)</td>
<td>1 (4)</td>
</tr>
</tbody>
</table>

**Oral anticoagulation**
- OAC stopped: 25 (96)
- Time to OAC stop (months): 3 ± 1
- OAC restarted later: 3 (12)
- OAC never stopped: 1 (4)

**Events during follow up**
- Ischaemic stroke / TIA: 0
- Device embolisation: 0
- Gastrointestinal bleeding (after colonoscopy): 1 (4)
- Death: 1 (4)

**Recurrent of atrial arrhythmias**
- Afibrillation: 12 (46)
patients. In the same time period, the total complication rate during AF ablation procedures at our centre was 3%. The most frequent complication from AF ablation and LAA occlusion in the same procedure, affecting four patients (15%), was the development of relevant bleeding from the femoral access site. According to the Bleeding Academic Research Consortium (BARC) classification, three patients developed type 3 bleeding and one patient type 2 bleeding. All these patients were under uninterrupted OAC. Previous reports on solitary LAA occlusion from our centre found femoral access complications in 2.6% [18]. The additional sheath change after having applied therapeutic doses of heparin for AF ablation may increase the risk of access complications. One of these patients had an additional large bore arterial vessel puncture in order to extract an embolised device.

Device embolisation occurred in two patients (7.6%), both with dedicated devices. Our previous isolated LAA closure experience showed device embolisation in only 3.9% patients [19]. The above mentioned series with Watchman devices showed device embolisation in 0 to 3.3%. Oedema formation caused by the preceding ablation may lead to an underestimation of the LAA size, which might explain embolisation of an undersized device. In one patient, embolisation was associated with an ischaemic stroke after reversion of anticoagulation. Pericardial effusion and tamponade owing to LAA perforation, which occurred in one patient (4%), is a complication that has been reported in up to 8% in other series. Transient ST-elevation during the LAA occlusion, as seen in one patient, was probably caused by air embolism and was described in 2% in one earlier study [14].

Total procedure time (208 ± 78 min) and total fluoroscopy time (58 ± 37 min) in this series were higher than reported in other studies on combined procedures. This may be because 12 of 26 procedures were performed conventionally without the use of a 3D mapping systems. Overall, 46% of all patients had recurrence of atrial arrhythmias after the index procedure. Notably, the procedures were performed between 2002 and 2014 and results may not be comparable to outcomes achieved with today’s technique and technology. In addition, 39% of the population included had persistent AF with a mean AF duration of more than one year and 73% of patients had structural heart disease. Therefore, and considering the limited number of patients included, our results may not provide reliable evidence on the influence of combining AF ablation with LAA occlusion on the effectiveness of the ablation procedure.

Even though the procedure seemed to be effective and safe in the long term, the combined approach was no longer used by the electrophysiologists of the team after the described series. AF ablation and LAA occlusion at our centre are currently performed in separate procedures with deep sedation and TOE guidance for LAA occlusion. Modified implantation techniques in combination with improved device design may lead to better results. LAA occlusion using TOE is currently the standard technique worldwide. Further research is needed to compare LAA occlusion with and without TOE.

The main limitation of this study is the limited number of patients. Secondly, the procedures have been performed over a period of 12 years. During this period, ablation approaches and LAA occlusion technologies have improved and experience has accrued. This limits direct comparability. Thirdly, follow-up TOE was routinely scheduled or recommended, but time to TOE differed widely and follow-up TOE data were not available for three patients. Fourthly, in three patients OAC was restarted during follow-up at the discretion of the referring physician. This may have led to an overestimation of the efficacy of the Amplatzer device. Finally, because of the small study sample, the number of thromboembolic events to be expected is low. The absence of thromboembolic events in the presented series cannot prove the efficacy of LAA occlusion.

Conclusions

Our data suggest that LAA occlusion using Amplatzer devices in combination with catheter ablation for AF using a simplified approach without general anaesthesia and without periprocedural TOE guidance is feasible, and effective regarding stroke prevention and safety in long-term, but associated with a disproportionately high complication rate. Moreover, even though the combined intervention may be convenient for the patient, current reimbursement schemes may represent an argument against combined interventions.

Disclosure statement

Bernhard Meier received speaker and proctor fees from Abbott. Stephan Winneldecker reports research and educational grants to the institution from Abbott, Amgen, BMS, Bayer, Boston Scientific, Biotronik, Cardinal Health, CardioValve, CSL Behring, Daiichi Sankyo, Edwards Lifesciences, Johnson&Johnson, Medtronic, Querbet, Polares, Sanofi, Terumo, Sinomed. Stephan Winneldecker serves as unpaid member of the steering/executive group of trials funded by Abbott, Abiomed, Amgen, BMS, Boston Scientific, Biotronik, CardioValve, Edwards Lifesciences, MedAlliance, Medtronic, Polares, Sinomed, V-Wave and Xelis, but has not received personal payments by any pharmaceutical company or device manufacturer. He is also member of the steering/executive committee group of several investigated-initiated trials that receive funding by industry without impact on his personal remuneration. Hildegard Tanner received educational grant from Biosense Webster, travel grant from Abbott. There are no other conflicts of interest.

References


