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Original Article

Left atrial appendage closure (WATCHMAN™) after bleeding complications during oral anticoagulant therapy in high risk patients

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ABSTRACT

Introduction: Therapy with coumarin-derivates in patients with atrial fibrillation is often associated with a high risk of bleeding complications. The LAA-closure with the WATCHMAN™ device provides an alternative to lifetime anticoagulation. We evaluated success rate and safety of WATCHMAN™ implantation in patients with atrial fibrillation and contraindications to oral anticoagulation due to severe bleeding.

Methods: In 26 patients (72 ± 11 years, 8 female) with contraindications to anticoagulation due to severe bleeding (19 patients with gastrointestinal bleeding and 7 patients with hemorrhagic strokes) we performed LAA-closure with the WATCHMAN™ device. After LAA-closure patients received a short time dual antiplatelet therapy with aspirin and clopidogrel (100 mg of aspirin and 75 mg clopidogrel per day) for 6 weeks, followed by a monotherapy with 100 mg of aspirin per day. We screened patients for ischemic or bleeding events and performed a transoesophageal echocardiography at 6 weeks, 6 and 12 months after the implantation of the WATCHMAN™ device.

Results: WATCHMAN™ device was positioned in a total of 25 patients (96%), 1 patient was excluded because of thrombus-detection in LAA. One pericardial effusion (4%) appeared after positioning and was successfully drained. In the follow-up at 6 weeks, 6 and 12 months 2 patients (8%) presented a severe bleeding event 8 weeks and 9 months after LAA-closure (1 patient with a bleeding of oesophageous varices, 1 patient with a bleeding of the hemorhoides). None of the patients got either an ischemic or hemorrhagic stroke or a systemic embolism. Transoesophageal echocardiography demonstrated a correct position of the device in each of the 25 patients, no device-attached thrombus or device embolization.

Conclusion: The closure of the left atrial appendage with a WATCHMAN™ Device and a subsequent treatment with a short time dual antiplatelet therapy in high risk patients after bleeding complications due to oral anticoagulation with coumarin-derivates appears to be a save alternative treatment strategy to long-term oral anticoagulation.

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1. Introduction

Atrial fibrillation is the most common cardiac arrhythmia with an incidence of 2.2 million in US and 6 million in Europe [1] and is associated with high risk of cardiac embolism. Patients with atrial fibrillation are five times more at risk to suffer a stroke than people without atrial fibrillation. Meta-analyses confirmed that cardiac embolism causes upto 25% of all ischemic strokes, and in case of left atrial thrombi in patients with non-valvular atrial fibrillation 90% of those thrombi are found in the left atrial appendage.[2] So far, Warfarin is thought to be the most effective therapy to prevent a stroke.[3] However, treating patients with atrial fibrillation with Warfarin is associated with a relevant risk of bleeding.[4] Alternatively, there is the possibility to percutaneously close the left atrial appendage (LAA-closure) with a WATCHMAN™ device to prevent strokes in patients especially after bleeding complications due to therapy with coumarin-derivates.

In the 4-years-follow-up of the PROTECT AF study, Reddy et al described the mortality effects of LAA-closure versus Warfarin for stroke prophylaxis in atrial fibrillation, and showed a lower risk of all-cause and cardiovascular mortality for the combined effort, and therefore its superiority to Warfarin therapy alone.[5] However, patients treated in the PROTECT AF study also received concomitant Warfarin for 6 weeks after LAA-closure with a WATCHMAN™ device. This study excludes patients with a contraindication for oral anticoagulation. In the ASAP-study Reddy et al used a dual antiplatelet therapy with aspirin and clopidogrel for 6 months after implantation of a WATCHMAN™ device and showed that LAA-closure with the WATCHMAN™ device can be safely performed without Warfarin transition.[6]

Therefore we investigated the rate of major adverse events in patients with severe bleeding under therapy with coumarin-derivates cause of atrial fibrillation after LAA-closure with the WATCHMAN™ device while treating these patients with a dual antiplatelet therapy only for 6 weeks after implantation.

2. Methods

We included 26 patients (8 females and 18 males) aged 72 ± 11 years between 2012 and 2013 with non-valvular atrial fibrillation who presented contraindications to oral anticoagulation due to severe bleeding (TIMI-definition: intracranial bleeding, loss of hemoglobin >5 g/dl or hematocrit >15%; 19 patients with gastrointestinal bleeding and 7 patients with hemorrhagic strokes) with the aim to perform a left atrial appendage closure with a WATCHMAN™ device (Table 1). With continuous transoesophageal echocardiography and fluoroscopic guidance (Fig. 1), WATCHMAN™ implantation was performed as previously described.[7] After LAA-closure patients received a dual antiplatelet therapy with aspirin and clopidogrel (100 mg of aspirin and 75 mg clopidogrel per day) for 6 weeks, followed by a monotherapy with 100 mg of aspirin per day, as the results of four GLP (good laboratory practices) studies indicated the endothelial overgrowth within 45 days[8] and safety of this medical strategy was demonstrated in another clinical trial.[9] Over the next 9 ± 3 months the patients were followed-up regarding complications as severe bleedings or strokes. A case history of the patient with screening for ischemic or bleeding events was noted and a transoesophageal echocardiography was performed 6 weeks, 6 and 12 months after the implantation of the WATCHMAN™ device to assess device position, peri-device LAA flow and device-related thrombi. Informed consent was obtained from all patients. The research protocol was approved by the institutional review board and the study complies with the Declaration of Helsinki.

3. Results

The LAA-closure was successful in a total of 25 patients (96%), one patient was excluded because of thrombus-detection in LAA that prohibited positioning of the WATCHMAN™ device. One pericardial effusion appeared after positioning and releasing the device. The patient was provided with an intermittent draining therapy and was discharged from hospital without any adverse consequences.

In the follow-up at 6 weeks, 6 and 12 months after LAA-closure transoesophageal echocardiography demonstrated a correct position of the device in each of the 25 patients and none of them showed a thrombus formation on the atrial surface of the device or an embolization. Two patients presented a severe bleeding event 8 weeks and 9 months after LAA-closure (Fig. 2) (one patient with a bleeding of oesophageous varices, one patient with a bleeding of the hemorhoides) with successful treatment and continuing therapy with aspirin. None of them got a hemorrhagic stroke. In summary 23 of the 25 of the patients with severe bleeding events in their medical history who underwent LAA-closure with a WATCHMAN device didn't get another major bleeding complication. None of the patients got an ischemic stroke or systemic embolism.

4. Discussion

Atrial fibrillation is the most common arrhythmia and is associated with a high risk of systemic embolism, especially

Table 1 – Baseline characteristics of patients.

Characteristics	N = 26
Age – yr	72 ± 11
Sex – no. (%)	
Male	18 (69.2)
Female	8 (30.8)
Weight – kg	79.3 ± 11.9
Cardiovascular risk factors – no. (%)	
Current smoking	9 (34.6)
Hypertension	18 (69.2)
Diabetes mellitus	8 (30.1)
Hypercholesterolemia	10 (38.5)
Gastrointestinal bleeding (%)	19 (73)
Hemorrhagic stroke (%)	7 (27)
LAA – Thrombus (%)	1 (3.8)