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Same-day discharge after elective percutaneous closure of patent foramen ovale

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Abstract

Percutaneous closure of the patent foramen ovale (PFO) is increasingly performed in specific patients with cryptogenic stroke or clinical evidence of a paradoxical embolism. This study was performed to determine the safety of same-day discharge (SDD) following such procedures.

This is a prospective, observational study of patients undergoing elective percutaneous PFO closure in a single tertiary center in Portugal between January 2020 and July 2023. Amplatzer™ devices (St. Jude Medical, St. Paul, MN, USA) and Nobblestich™ EL (HeartStitch, Inc., Fountain Valley, CA, USA) were used. After 6 months, the following events were looked at: post-procedural paroxysmal atrial fibrillation, stroke, unplanned cardiac re-hospitalization, urgent cardiac surgery, major vascular complications, pericardial effusions, device embolization, and death.

We studied 122 consecutive patients (52% female, 68; 48±12 years old) who had elective percutaneous closure with success and no complications. A total of 49 (40%) patients had SDD. Amplatzer™ devices were used more frequently in the SDD group, while Nobblestich™ EL was more common in the overnight group. During the overnight group's follow-up period, there was one non-cardiovascular death; there were no further events.

SDD after elective percutaneous closure of PFO was shown to be a safe and successful patient management method, including Nobblestich™, which we describe for the first time. Our results prove the safety of this SDD strategy. We hypothesize that in the near future, in selected cases, PFO closure might become an ambulatory procedure.

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Introduction

Patent foramen ovale (PFO) is a remnant of normal fetal anatomy that occurs in 25% of adults [1,2], and is infrequently an incidental finding with no clinical implications [3]. However, the existence of PFO has been linked to several clinical disorders, the most common of which are cryptogenic stroke and paradoxical embolism [4,5]. Current guidelines advice PFO closure in certain circumstances [6,7]. PFO closure is often performed percutaneously *via* a venous femoral approach, with a low rate of complications. Depending on the procedure, transoesophageal echocardiographic guidance may be required. Overnight hospitalization has been advised for monitoring potential peri-procedural complications.

As with other elective catheterization laboratory procedures, PFO closure procedures could be performed as a same-day discharge (SDD) procedure [1]. So far, studies have shown no probable periprocedural problems appearing at 24-48 hours that would otherwise warrant overnight hospitalization, but there is a lack of data describing the safety and feasibility of SDD after percutaneous PFO closure [3,8,9]. As a result, we set out to assess the safety of SDD after PFO closure in a single tertiary cardiology department in Portugal.

Materials and Methods

Patients and clinical data

This prospective, observational study was conducted at *Centro Hospitalar Universitário de São João*, Porto, Portugal, between January 2020 and June 2023. Patients submitted to elective PFO closure with acute success and no complications during or immediately after the procedure were included consecutively. Clinical, sociodemographic, and procedural data were collected.

Procedure

All patients fasted from midnight and were admitted on the morning of the procedure. Irrespective of the device, all patients performed antibiotic prophylaxis with endovenous cefoxitin 2 g before the procedure and 1 g every 8 hours during 24 hours if no allergy history; in case of penicillin allergy with a high risk of anaphylaxis clindamycin 900 mg and gentamicin, 5 m/kg were used as a single dose. All PFOs were routinely closed under fluoroscopic guidance and, often, also with trans-esophageal echocardiogram (TOE) guidance. The need for general anesthesia *vs.* standard intravenous sedation was assessed at the time of diagnostic TOE. Femoral venous access was gained using a 7-14 French femoral sheath. Intravenous heparin bolus was administered upon catheter passage into the left atrium. The femoral sheath was removed 4 hours after the procedure. Groin hemostasis was performed with manual and mechanical compression.

Concerning the devices used, Amplatzer™ devices (St. Jude Medical, St. Paul, MN, USA) including Amplatzer™ PFO Occluder, Amplatzer™ Septal Occluder and Amplatzer™ Cribiform Occluder, and Nobblestich™ EL device (HeartStitch, Inc., Fountain Valley, CA, USA) were used.

Regarding antithrombotic therapy, in general, in the case of Amplatzer™ patients had to start (if naïve for antithrombotic therapy) double antiplatelet (DAPT) therapy for 1 month (mostly clopidogrel) and at least 6 months of mono antiplatelet (mostly aspirin); in case of indication for hypocoagulation [either direct oral anticoagulant (DOAC) or vitamin K antagonist (VKA)], aspirin was added for 1 month. When Noblestich™ EL was implanted, aspirin was added for 1 month if naïve for antithrombotic therapy, if already under antithrombotic therapy, it was maintained.

The decision of SDD was operator-based in case the patient fulfilled all safety criteria (Table 1). Before discharge, patients had an electrocardiogram and echocardiogram performed. At discharge, patients were advised to avoid intensive physical activity for 1 month and antibiotic prophylaxis for 6 months before dental procedures was recommended. All patients were followed at 6 months in the outpatient clinic and underwent a TOE and transthoracic echocardiogram with bubble test at this time.

Outcomes and clinical follow-up

Patients were followed for 6 months, and the following complications were looked at: post-procedural paroxysmal atrial fibrillation, stroke, unplanned cardiac re-hospitalization, urgent cardiac surgery, major vascular complications, pericardial effusions, device embolization, and death. Follow-up of all elective PFO closure patients was performed by reviewing the electronic medical records and at the 6-month appointment after the procedure.

Statistical analysis

Categorical variables were summarized using frequencies and percentages, and the Fisher exact test was used to compare groups of patients. Continuous variables were summarized using the mean and standard deviation, or the median and interquartile range (difference between the 75th and 25th percentiles), and compared using the unpaired *t*-test or the Wilcoxon rank-sum test. A two-sided p-value of 0.05 was considered statistically significant. At the time of the last follow-up, patients who did not experience the primary outcome were censored. SPSS 27 was used for statistical analysis (IBM, New York, NY, USA).

Results

Between January 2020 and July 2023, 122 patients had elective percutaneous PFO closure in our center; all procedures were successful, with no complications during or shortly after the treatment, and were all included. The mean age was 48±12 years and 61 (52%) of patients were women. When comparing the overnight and SDD groups, the main cardiovascular risk factors were similar (Table 2). Most cases (115 patients, 95%) were conducted following a cryptogenic cerebrovascular, as shown in Table 2.

Table 1. Criteria for study inclusion (all required).

Criteria
Elective procedure
Any clinical staff acknowledges that the patients is not recommendable for SDD
Adequate family/third person support
Patient accepts to have SDD (shared decision)
4-to-6-hour monitoring after procedure (before discharge)
No complication during or after procedure
No acute decompensation of previous condition (*e.g.,* heart failure; hypertension; asthma)
Same neurological status after procedure
Direct contact if any emergency is known by the patient and family
Patient understands medical therapy and clinical recommendations (including venous access)
Patient has antithrombotic therapy
Patient has a 6-month visit at the outpatient clinic

SDD, same-day discharge.

Overall, Amplatzer™ devices and Nobblestich™ EL were used in 62 (48%) and 68 (52%) of patients, respectively. In terms of discharge protocol, the SDD group had more Amplatzer™ devices implanted, while the overnight group had more Nobblestich™ EL implants [32 (65%) *vs.* 51 (62%) patients; p=0.02]. This difference was reflected in the overnight group's longer fluoroscopy time and use of higher femoral venous access sheaths diameters. The procedure features are summarized in Table 3.

Most patients (58, 89%) with Nobblestich™ EL procedure followed the described antithrombotic protocol; 5 patients performed an Amplazter-like protocol (mono to DAPT or added mono antiplatelet to DOAC for 1 month) and 2 patients changed from DOAC to antiplatelet therapy. Of the 52 patients (91%) treated with an Amplazter device followed the described antithrombotic protocol, 2 patients who were previously on DOAC changed to DAPT (1 month of aspirin), and 2 patients treated with VKA changed to DAPT. Additional details may be found in Figure 1.

During a follow-up of 6 months, one patient died 4 months after the procedure due to a non-cardiovascular cause (infection not related to the procedure). No other event was seen during this period. At the end of the follow-up, cardiac imaging showed an overall success of 76% (63% in the overnight group and 95% in the SDD group).

Discussion

This single-center real-world study of patients presenting for elective percutaneous closure of PFO illustrates that the strategy of SDD is safe.

Our group matched those described in the literature. When compared to patients undergoing other percutaneous treatments, the younger age and lower frequency of conventional cardiovascular risk factors may help to explain the low occurrence of complications.

Only one patient out of a total of 122 demonstrated any of the predetermined outcomes, non-cardiovascular mortality in the overnight group 4 months after the procedure. This reflects the safety of the procedure and follow-up, with no noticeable differences between the overnight and SDD groups. Despite this, the reported complication rate is as low as 1.4%, and the size of our cohort may be not large enough to report such infrequent adverse events difficulties [3].

NoblestichTM EL has been licensed in Europe for PFO closure and cardiovascular suturing since 2018. This unique technology arose as an alternative to nitinol double-disc occluders to minimize the risks associated with these devices, such as arrhythmias, thrombus development, embolization, and erosion. There is still little evidence detailing the efficacy and safety of the NobleStitchTM system; we report the safety of SDD for the first time by enrolling 17 patients in such conditions. Although this approach does not provide the same dramatic effect when embolization occurs, the need for larger venous access sheaths with possible inherent access complications could be a concern. We did not observe in our cohort any difference in vascular complications in the SDD group.

After PFO closure, several complications may arise, and overnight hospitalization has been the preferred way of management, primarily to watch for peri-procedural complications [3]. However, larger follow-up studies make no mention of complications occurring within 24 hours of the treatment [9,10]. These trials reveal no significative potential periprocedural problems appearing at 24-48 hours, which would ordinarily necessitate extensive observation and may warrant overnight hospitalization.

Limitations

Because of the study methodology, sample size, and inherent selection bias, this single-center prospective study has significant limitations and may be incapable of detecting rare periprocedural complications. As this is a single-center study, the generalization of results may be hampered, and larger, multicentric studies are required to corroborate this evidence. Nonetheless, it mirrors real-world experience, which appears to be safe and with positive patient outcomes. Randomized controlled trials are required to evaluate the safety and efficacy of day-case percutaneous PFO closure.

Table 2. Patients' baseline characteristics.

Variables	Total (122)	Overnight (73)	SDD (49)	p
Female, n (%)	61 (52)	37 (51)	24 (49)	0.6
Age at repair, years - mean±SD	48±12	45±12	50±11	0.1
BMI, kg/m^2, median (IQR)	26 (5)	27 (6)	26 (3)	0.8
Smoking, n (%)	16 (13)	7 (9)	9 (18)	0.4
Diabetes mellitus, n (%)	28 (22)	16 (21)	12 (24)	0.5
Dyslipidemia, n (%)	34 (28)	16 (22)	18 (37)	0.8
Hypertension, n (%)	30 (25)	18 (24)	12 (25)	0.5
Previous cryptogenic stroke, n (%)	115 (95)	70 (86)	45 (91)	0.2
Previous paradoxical embolism, n (%)	7 (5)	7 (9)	0 (0)	-

BMI, body mass index; SD, standard deviation; SDD, same-day discharge.

Table 3. Procedure details.

Variables	Total (122)	Overnight (73)	SDD (49)	p
Amplazter™ device, n (%)	57 (46)	25 (34)	32 (65)	0.03
Noblestich™ EL device, n (%)	65 (53)	48 (65)	17 (35)	0.03
Venous access size, Fr - median (IQR)	7 (7)	8 (7)	7 (1)	0.01
Fluroscopy time, min - median (IQR)	10 (11)	12 (11)	5 (9)	0.01

IQR, interquartile range; SDD, same-day discharge.

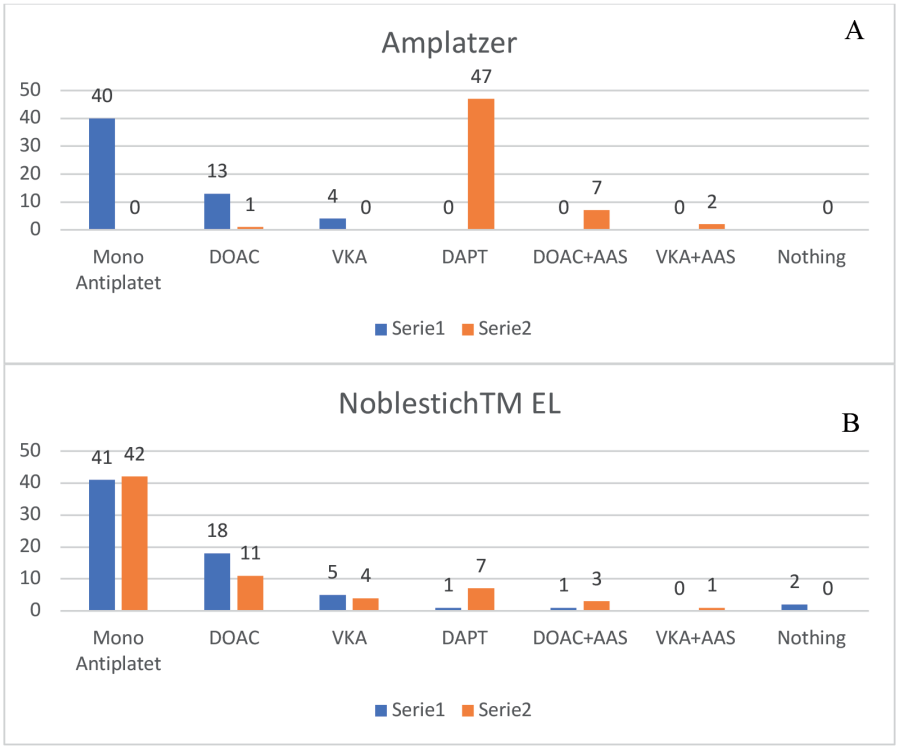

Figure 1. Antithrombotic management before and after Amplatzer (A) and Noblestich (B). Serie 1, before procedure; serie 2, after procedure; blue bar, before closure and orange bar after closure; AAS, aspirin; DAPT, double antiplatelet; DOAC, direct oral anticoagulant; VKA, vitamin K antagonist.

Conclusions

While guidelines are lacking recommendations on SDD, there is some evidence that PFO closure could become a day-case procedure. According to our findings, SDD is safe following percutaneous PFO closure. We hypothesize that in the near future, in selected cases, PFO closure might become an ambulatory procedure. Larger, randomized trials investigating the safety and efficacy of SDD following PFO closure are warranted.

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