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Day-Case Patent Foramen Ovale Closure Under Transthoracic Echocardiography and Fluoroscopic Guidance: A Safe and Cost-Effective Approach as Compared to Conventional Hospitalization

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Abstract

Background: Transcatheter Patent Foramen Ovale (PFO) is recommended as a therapy in secondary prevention of cryptogenic stroke. The aim of this study was to report one-year French single-center experience in PFO closure under sole Transthoracic Echocardiography (TTE) and fluoroscopy guidance performed as a day-case procedure versus a 3-day hospitalization.

Methods: In 2018, all consecutive patients undergoing PFO closure for stroke were retrospectively included: 108 patients as a day-case procedure (group 1) versus 20 patients performed under a 3-day hospitalization (group 2). A comparison was performed between Occlutech and Amplatzer PFO devices and the impact on hospitalization costs was studied.

Results: Occluders included Occlutech (n=81), Amplatzer (n=43), Lifetech (n=2) and PFM (n=2) PFO devices. Implantation succeeded in all. In-group 1, hospital discharge was delayed in only 3 cases. At one-month, 5 patients had Atrial Fibrillation (AF) and 91 patients (84%) had no residual shunt. In-group 2, hospital discharge was delayed in 4 patients. At one month, 1 patient had AF and no shunt was observed in 80%. In the comparative study, no significant statistical difference could be observed between Amplatzer and Occlutech devices. The one-day strategy leaded to a positive balance of 1825 euros per procedure in 2018, with a difference of 3785 euros with group 2.

Conclusion: Our experience suggests that day-case PFO closure under fluoroscopy and TTE guidance is safe and effective in the majority of patients leading to a cost reduction and no increased risk of embolization.

Keywords: Patent Foramen ovale; Stroke; Occlutech device; Amplatzer device; Transthoracic echocardiography

Introduction

Transcatheter Patent Foramen Ovale (PFO) occlusion is a well-established procedure that could be proposed as a first-line therapy for patients who suffered from Cryptogenic Ischemic Stroke (CIS) according to different randomized trials published recently [1-3]. The number of PFO closure has therefore significantly raised. The main purpose of this study was to report one-year and single-center experience of transcatheter PFO occlusion performed as a day-case procedure, under sole Transthoracic Echocardiography (TTE) and fluoroscopic guidance, versus a 3-day hospitalization with its effect on hospitalization costs. A comparison between the two most employed devices, Figulla Flex II and PFO Amplatzer occluders, was also carried out.

Methods

Study population

From January to December 2018, 128 consecutive patients who suffered from a CIS underwent transcatheter PFO closure in a tertiary center. Among these patients, 108 patients were scheduled for day-case procedure and defined as group 1. The twenty other patients (defined as group 2) had PFO closure during a 3-day hospitalization which was the conventional strategy before the study period: 12 of them has PFO closure under local anesthesia and TTE, similarly as in group 1, and 8 others under general anesthesia with Transesophageal Echocardiography (TOE) guidance. Indications for this approach in group 2 were: patient single (n=5) with no supervision by a family member after discharge, association of a large Atrial Septal Aneurysm (ASA) to the PFO (n=3), multiperforated ASA (n=3), associated congenital heart disease (n=2), long distance home from the hospital (n=1), Willebrand disease (n=1), patient preference (n=3) and others (n=2). In all cases, neurologists performed the initial screening to confirm the CIS and the indication for PFO closure. All patients had undergone TOE prior to the intervention for usual diagnosis of PFO and ASA and 24 hour-Holter monitoring. Nitinol devices employed were: Figulla Flex II devices (Occlutech GmnH, Iena, Germany) (n=81), Amplatzer devices (Amplatzer, Abbott Vascular, USA) (n=43), CeraFlex PFO Occluder (Lifetech Scientific, Shenzhen,

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Table 1: Patient data (Group 1 and 2).

Group 1	
Patients	N=108
Sex Ratio	51 Females/57 Males
Age	48.4 years (SD 13.7 years)
	Median 48.7 years
Weight	77kg (SD 16kg)
	Median 76kg
Height	172cm (SD 9cm)
	Median 172cm
Group 2	
Patients	N=20
Sex Ratio	9 females/11 males
Age	51 years (SD 16 years)
	Median 51.9 years
Weight	75kg (SD 18kg)
	Median 73kg
Height	170cm (SD 12cm)
	Median 168cm

Mean ± Standard Deviation.

China) (n=2) and Nit-occlud PFO device (PFM medical, Köln, Germany) (n=2). Patient data are listed in Table 1 and 2.

Procedure

Before the procedure, all patients provided written informed consent. Under local anesthesia, the occluder was placed from femoral venous access under fluoroscopic and transthoracic TTE guidance alone with no angiography to cross the septum and no balloon sizing of the defect [4]. All patients received intravenously a bolus of heparin (80-100 IU/kg). Choice of the device was made at the discretion of the operator after reviewing pre-operative TOE images and according to device availability. Use of symmetric device was preferred for patients combining PFO and large ASA. The device position was controlled by TTE before and just after release. The patient was then transferred to the day-case unit with ECG monitoring for 3-5 hours. A chest X ray was performed before discharge and patient left the hospital under dual antiplatelet therapy (75mg aspirin plus 75mg clopidogrel per day for 3 months) [1]. For patients with a 3-day hospitalization, the same procedure was realized with hospital discharge on the day following the implantation, and for those requiring TOE, a similar technique was performed but under general anesthesia. In both groups, a control TTE was planned one month later with saline contrast injection at rest and during Valsalva maneuver. This was repeated 6 months later in case of persistent shunt. During follow-up, patients were assessed by the neurologist/cardiologist but also underwent structured telephone interviews addressing recurrent embolic events, device-related problems and health status.

Table 2: Neurologic event distribution and device choice in both groups.

Device	N	Initial Event	Lesion	Occluder
Group 1				
Occlutech	67	65 strokes 2 TIAs	PFO+ASA: n=65 PFO: n=2	27/30mm device: n=40 33mm uniform device: n=23 28.5mm uniform device: n=2 31/35mm device: n=1 23/25mm device: n=1
Amplatzer	37	37 strokes	PFO+ASA: n=36 PFO: n=1	35mm cribriform device: n=28 25/35mm device: n=9
Lifetech	2	1 stroke 1 TIA	PFO+ASA: n=2	25mm device: n=1 35mm device: n=1
PFM	2	2 strokes	PFO+ASA: n=2	30mm Nit occlud device: n=2
Group 2				
Occlutech	14	13 strokes 1 TIA	PFO+ASA: n=13 PFO: n=1	33mm uniform device: n=8 27/30mm device: n=4 24mm uniform device: n=1 40mm uniform device: n=1
Amplatzer	6	6 strokes	PFO+ASA: n=6	35mm cribriform device: n=6

ASA: atrial septal aneurysm; PFO: patent foramen ovale; TIA: transient ischemic attack.

Hospitalization costs

In France, each French citizen has a unique health care number assigned to every individual at birth. The cost of a transcatheter PFO closure is determined by its quotation according to the GHM (Groupe Homogène de Malades/Homogeneous group of patients): item for PFO closure (GHM 05K221) determined by the "Assurance Maladie" (French National Health Service). The cost equals the amount perceived by the institution minus the cost for hospitalization. The cost of the occluder is not included in the previous GHM because the device is a reimbursable product. Before 2018, all patients who underwent PFO closure were hospitalized in our institution 3 days: from the day before to the day following the procedure. In 2018, day-case PFO closure program was started using the same devices and a similar procedure in the catheterization laboratory.

Statistical analysis

All distributions were tested for normality using Shapiro-Wilks normality test. Data are shown as mean (standard deviation) if case of normality, median (interquartile range) otherwise. For categorical data, comparisons between groups were computed using Pearson's Chi-squared test with Yates' continuity correction, or Fisher exact test for small groups. For continuous data, an unpaired t-test was used in case of normality; a Wilcox-Mann-Whitney test was used otherwise. Alpha risk was set at 5%; Beta risk was set at 20%.

Results

Results in Group I

Early results: Device implantation succeeded in all patients with the 4 different devices. Ten patients (7 patients with Occlutech and 3 with Amplatzer device) presented gas embolism with transient ST-segment elevation during implantation. All 10 patients recovered without cardiac consequences or brain damage confirmed by neurological examination after the event. For these patients, a selective coronarography was performed during the same procedure showing no coronary artery obstruction. Same-day discharge occurred in all but 3: discharge was delayed because of a femoral fistula successfully treated with compression (day 5), a small pericardial effusion treated by colchicine alone (day 2), and an Atrial Fibrillation (AF) resolvable under oral medication (day 3). At last, another patient (Amplatzer group) with history of epilepsy had seizure during implantation, which spontaneously resolved.

One-month follow-up: At one month, 7 patients complained from chest discomfort (including the one in the Amplatzer group

Table 3: One-month follow-up data for Group 1.

	Occlutech (n=67)	Amplatzer (n=37)	Lifetech (n=2)	PFM (n=2)
Chest Discomfort	5	1	/	1
Palpitations	6	3	/	/
AF	3	2	/	/
No Shunt	60	28	1	2
Residual Shunt	6*	9**	1***	/
Loss of follow-up	1	/	/	/

*Five of them had no shunt at the 6-month control, and another one did not come to the further control echocardiography; **Five of them had not shunt at the 6-month control, another 3 had no shunt at the one-year control, and finally one had a persistent shunt at the one-year and half control; ***This patient had no shunt at the 6-month control.

due to pericardial effusion successfully treated by colchicine). Nine patients reported palpitations and 4 others experienced AF within two weeks after implantation, requiring beta-blocker and anticoagulation. All of them fully recovered sinus rhythm at the one month-control with no need for cardioversion. All patients but one had echocardiography to assess residual shunt (Table 3). Ninety-one patients had no residual shunt (84%).

Results in Group 2

Implantation succeeded in all patients. No complications occurred except one gas embolism with transient ST deviation during implantation of an Amplatzer device. All patients but 4 were discharged on day 3: one on day 5 because of a groin hematoma not requiring surgery nor transfusion, one on day 4 because of the Willebrand disease, and 2 for miscellaneous reasons unrelated to the procedure. During the first month after implantation, 3 patients complained from palpitations, one had atrial flutter resolving under beta-blockers (Occlutech device). At the one-month follow-up TTE, 16 patients had no shunt, 3 patients a tiny persistent shunt with Occlutech device, and one with Amplatzer device was lost of follow-up. For the 3 patients with residual shunt, 2 of them had no shunt at 12-month control and the remaining had no further echo control.

Late follow-up: At their last follow-up clinic review or phone consultation (529 days; IQR = 232 days), no patient had experienced any recurrent transient ischemic attack (TIA)/CIS in the entire study population.

Comparison between Occlutech and Amplatzer devices: A comparison between Occlutech and Amplatzer devices is presented in Table 4. Patients were older in the Amplatzer group but no significant difference was noticed for weight and height. During implantation, there was a tendency for shorter fluoroscopy time with Amplatzer device but no significant difference about radiation dose between Amplatzer and Occlutech devices was observed. At last, no significant difference could be noticed concerning the occurrence of transient myocardial ischemia (p=1), persistence of residual shunt at one-month TTE control (p=0.21), and occurrence of AF (p=1) between these 2 devices.

Cost effectiveness: The cost of this procedure related to GHM 05K221 (closure of inter-atrial shunt by percutaneous approach) was 2949 euros in 2018 perceived by the hospital finance department without taking the cost of the hospital stay into account. This latter

Table 4: Comparison between Occlutech and Amplatzer PFO devices at implantation in both groups.

	Occlutech	Amplatzer	p
Age (years)[α]	46 (SD 19)	52.6 (SD 15)	0.009
Weight (kg)[α]	77 (SD 16)	76.3 (SD 18)	0.82
Time of fluoroscopy[α] (minutes)	3.96 (SD 2.37)	3.25 (SD 1.54)	0.044
Radiation dose[β] ($Gycm^2$)	Median 5 (IQR 6)	Median 5 (IQR 5)	0.93

α: Mean ± Standard Deviation; β: Median (Interquartile Range).

for our institution was 1478.42 euros per day for hospitalization in conventional unit and 649.56 euros for hospitalization in a day-case unit, on which is added the mean cost per procedure of 474.32 euros in our catheterization laboratory. The 3-day strategy of group 2 resulted in a deficit of - 1960 euros per patient, including the cost of the GHM minus the cost of 3 days of hospitalization in conventional unit plus the cost of procedure in catheterization laboratory. On the opposite, the day-case procedure of group 1 resulted in a positive balance of 1825 euros per patient and per procedure, including the cost of the GHM minus the cost of hospitalization in day-case unit and the cost of procedure as above. This resulted in a difference of 3785 euros per procedure and per patient between the 2 strategies for 2018 in our institution, clearly in favor of the day-case procedure.

Discussion

Our study shows that day-case PFO closure under TTE is feasible in the majority of the patients with appropriate image quality [5]. In fact, day-case interventions are becoming more common and increasingly seen as the standard of care, even though they are not mentioned in the current guidelines. Here, some may argue about the necessity of additive imaging modalities, Intra Cardiac Echocardiography (ICE) or TOE, because of specific atrial septal anatomy [4,6]. It seems that this choice may be based on center's practice [7,8]. It is of interest to notice that need for additive ICE has been reported in 25% of the procedures in Toronto but a decline in its use has also been mentioned to 5% more recently, which is very similar to the use of TOE in 6% of our population [6]. Moreover, day-case PFO closure is safe and effective with no increased risks for the patients such as arrhythmias, vascular lesion, neurologic complication or device embolization. It has several advantages: shorter hospital stay, better patient's comfort, and lower cost as discussed below. Same-day discharge was also performed by different teams [4-6]. In the large cohort from Toronto including 467 patients, it was achievable in 97.2% of patients [6]. Some may also worry about the risk of device embolization and the need for an early follow-up imaging to detect this (chest X ray or echocardiography the day after implantation). We did not observe any embolization but this point could be easily assessed by TTE performed one or 2 days after implantation by a local cardiologist close to the patient's home.

PFO closure drawbacks

PFO closure carries few drawbacks. One is the persistence of shunt on follow-up control with the potential risk for recurrent thromboembolic events [9]. In the present study, a residual shunt was observed in 16% of patients at one month, which is very similar to other publications [4,10,11]. In fact, residual shunt requiring another procedure is very rare, around 0.4% [2] as the majority of the persistent shunts will disappear with time. However, the best way as well as the appropriate timing for shunt detection remains debatable.

Another matter of concern is transient myocardial ischemia during device placement, also reported by others [1,9]. Most of them were not associated with any hemodynamical compromise and lasted few seconds. This clearly emphasizes the need for systematic attention to eliminate bubbles within the system and during all steps of the procedure. Arrhythmia is another complication and not rare after closure. In few patients, these palpitations were related to AF/flutter that were not noticed before PFO closure despite systematic realization of ECG Holter monitoring. In fact, the AF detection may be correlated to the duration of the ECG monitoring. Longer monitoring ideally for at least 72 H should be recommended. The incidence of AF/Flutter, 4.6% in our population, has been reported between 0.4-6.6% [1-4,6,7,9,11-18]. Trabattoni has mentioned more supraventricular arrhythmias with Amplatzer versus Figulla but difference was not significant concerning paroxysmal AF [16], as similarly noted in the present study. In the same way, Tsivgoulis has reported lower risk of new-onset AF with Amplatzer and Gore devices compared to Starflex [17]. However, all patients were in sinus rhythm at one month control in our experience and it has also been reported no recurrence of AF during a median follow-up of 4.4 years after device implantation [1].

Comparison between Amplatzer and Occlutech PFO devices

A comparison was done between the 2 most employed nitinol PFO devices: Occlutech and Amplatzer (Table 4). Both occluders achieved good results in terms of procedural success with a low rate of complication and a high rate of full occlusion. In fact, no inferiority of Occlutech devices compared to the Amplatzer devices could be established, as already noted [5,9,13,16]. Both devices are effective and safe for transcatheter PFO occlusion. In fact, these results are not surprising because both Figulla and Amplatzer devices share many similarities. They are both designed as self-expandable, double-disc structure made of nitinol with very similar disc sizes and waist lengths. The notable difference is the coating of the Figulla nitinol wire mesh by titanium oxide that may decrease dissolution of nickel ion, accelerate endothelial growth and minimize risk of thrombus formation. In the same way, no significant difference in results could be observed between Amplatzer and Lifetch PFO devices [19]. Further experience will be necessary to draw more definite conclusion concerning all types of devices employed here.

Cost reduction

At last, we have clearly shown a cost reduction of the day-case procedure in comparison to the classic approach with 3-day hospitalization and this strategy is effective if no complication occurs as observed in the majority of patients. In our practice, all patients were aware before catheterization of the possibility of prolonged hospitalization if any complication occurred. Moreover, most of patients appreciated not to stay overnight in the hospital. However, there are different limitations to the one-day strategy as noticed in about one sixth of the patients. First, day-case procedure is not suitable for those who are living alone or far away from the hospital. Second, for more complex anatomy according to our pre-selection, there is a need for a better imaging system during device release such as TOE or ICE than the classic TTE [6]. These imaging modalities have also been proposed in anatomical difficulties such as persistent Eustachian valve, long PFO tunnel, ASA with excessive mobility, hypertrophy of the interatrial septum [5,6,12,13]. However, these 2 imaging methods present also risks such as need for general anesthesia with prolonged procedure recovery times with TOE guidance or additional vascular puncture and significant cost for ICE. The results of our study showed that PFO closure under fluoroscopy and TTE guidance is easier, convenient and less invasive when compared to other strategies involving either TOE or ICE guidance [5,12] and probably applicable in many centers around the world .

Limitations

This study has several limitations. First, it is an observational, retrospective, single center study with lack of randomization for patient selection and device implantation. Second, the sample size is relatively limited. Third, absence of prolonged Holter monitoring before and after implantation may have underestimated the rate of AF/flutter. Fourth, assessment of residual shunt by TTE instead of TOE with contrast study and provocative maneuvers may also underestimate the rate of shunt. Fifth, parts of the costs (conventional, day-case unit) are specific to our institution/country and vary among each National Health Service according to reimbursement modalities. Finally, all patients were referred to our tertiary center for PFO occlusion creating a possible selection bias.

Conclusion

Day-case transcatheter PFO closure using TTE and fluoroscopy guidance is safe, simple, effective with a low rate of complications, and applicable in more than 80% of patients. The one-day strategy generates a positive balance of 1825 euros in 2018 for our center much more cost-effective than the previous conventional organization with 3-day hospitalization. Moreover, this approach is safe in terms of success of implantation, with few complications, either with Occlutech or Amplatzer PFO devices. Day-case procedures are well suited for most PFO closures, and guidelines are needed to improve the initial screening of patients for this procedure.

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