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Research Article

Catheter-Based PFO Closure: Safety and Efficacy

Haji-Zeinali AM[1]*, Farhat J[2], Shahrzad M[3] and Zoroufian A[4]

[1]Interventional Cardiology Department, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

[2]General Cardiology Department, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

[3]Cardiovascular Research Department, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

[4]Echocardiography Department, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

***Corresponding author:** Ali Mohammad Haji-Zeinali, Assistant Professor of Cardiology, Tehran Heart Center, North Kargar Street, P.O.Box : 1411713138 Tehran, Iran

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Abstract

Objective: Given the higher risk of thromboembolic events in patients with Patent Foramen Ovale (PFO) as a source of paradoxical emboli, we sought to evaluate the safety and efficacy of PFO device closure in terms of procedure complications and thromboembolic event recurrence.

Methods: Forty-three patients with a prior history of cryptogenic stroke underwent device deployment with fluoroscopy and under the guidance of echocardiography. Two different device types were used: The American Amplatzer in79% patients and The Figulla in the remaining 21%, with the size of devices ranging from18 to35.

Results: The study population consisted of 47% female and 53% male at a mean average age of 42 years. The mean follow-up period was 29 months. The rate of successful closure and no residual shunt during the procedure or immediately afterward was around 95/3%. After 23 months' follow up, the rate of success and residual shunt stood at 83.7% and 16.2%. No mortality, tamponade or perforation was seen after the procedure. Only five patients (11, 63%) experienced recurrence of cerebrovascular events which was not PFO –related in four of them.

Conclusion: PFO device closure can be considered a preferred method over surgery due to its efficacy and lower complication rate.

Keywords: Cryptogenic stroke; PFO; Trans-catheter closure

Introduction

Patent Foramen Ovale (PFO) with overall prevalence of 27-30% is a kind of abnormal communication between atriums [1,2] and is known as a potential source of paradoxical emboli [3-5]. Data suggest 45% PFO prevalence among patients who suffered from cryptogenic stroke [1,6,7] and especially a large size PFO in association with atrial septal aneurysm has potential higher risk of paradoxical emboli [3]. This can be well prevented by timely PFO closure [1,8].

Thromboembolic events also have a high recurrence risk of 3.4% to 3.8% per year in patients with PFO [3]. Advanced Imaging modalities and specialist opinion during the procedure place percutaneous device implication much higher over the surgery [1]. Moreover, fewer adverse outcomes including suboptimal positioning, residual shunts and embolization risk can be seen with the appropriate use of imaging technology in this method [1].

Materials and Methods

Patient population: This retrospective study recruited 46 patients who underwent PFO device closure in Tehran Heart Center between 2005 and 2009. The inclusion criteria were a prior history of cryptogenic stoke as confirmed by neurology consultation and exclusion of hypercoagulability status via appropriate tests. All other cardiac sources for embolus formation were evaluated using echocardiography which yielded negative results but documented PFO. A right to left shunt was diagnosed by contrast echocardiography with saline infusion and the shunt degree was assessed by bubble study. During the procedure, the device type was selected according to the size of the defect. An intra-atrial septal aneurysm was defined as an abnormal movement of the septum in both right and left directions. At the very beginning of the study, two patients were excluded because of concomitant atrial septal defect without a history of a prior stroke and one patient was out of reach. The study continued with the remaining 43 patients.

PFO closure: The patients underwent the procedure without the use of sedation drugs. The Occluder was deployed under fluoroscopy and echocardiography guidance. In regard to medication, ASA (325 mg) and Clopidogrel (75 mg) were prescribed for minimum periods of 6 and 3 months. No heparin or endocarditis prophylaxis was needed. Successful device implantation was immediately assessed through Transesophageal Echocardiography (TEE).

Follow up: Contrast echocardiography was performed for all the patients on day one after the procedure, and they were thereafter advised to refer for follow up visits at month 6 and the year after. On each visit, the patients were evaluated for any procedural complications including residual shunt which was graded according to the number of bubbles passing through the PFO; compressive effect, device deviation, tamponade and perforation. For Thrombo Embolic (TE) recurrence risk evaluation, the patients were investigated regarding cerebrovascular events and if the result was positive, they were referred for neurological consultation and subjected to contrast echocardiography for further evaluation.

This article was written based on the EASE guidelines for authors and translators of scientific articles [9].

Statistics: Descriptive statistics are presented as mean ± standard Deviation (SD) or by absolute frequencies and percentages.

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Results

The study population consisted of 47% female and 53% male at a mean average age of 42 years (ranged:19-60 years). The mean follow up period was 29 months (ranged:6-59 months). Two device types were employed: The American Amplatzer in 79% of patients and The Figulla in the remaining 21%, with the device size ranging from18 to 35.

The PFO defect sizes were categorized into three groups: small (7%), medium (16%) and large (77%). The patients underwent PFO closure due to different cerebral symptoms which are summarized in (Table 1) prior to procedure, major stroke was seen in 12 (28%) and minor stroke in 13 (30.2%) patients. In addition, 19 (44.2%) patients also experienced Transient Ischemic Attack (TIA).

Procedure outcome: The rate of Successful device deployment with no residual shunt was 95/3%, which was confirmed by echocardiography during the procedure or immediately afterward. Residual shunt was only detected in 2 (4.65%) patients (device type was The American Amplatizer, size 25). No in-hospital complication including skin infection or hematoma, were reported.

The successful procedure rate was 97.6% approximately 6 months after the procedure and only one (2.3%) residual shunt was detected at the second follow up visit (device used was The American Amplatizer, size 18). Finally, at the 23months' follow up visit, the rates of success and residual shunt were 83.7% and 16.2%, respectively. The characteristics of the residual shunts of these 7 patients are summarized below:

1. Passage of a few bubbles in 4patients, and the device type was The American Ampletizer: Size 25 (50%), size 18 (25%) and size 30 (25%).

2. Passage of a large number of bubbles in 3 patients and the device type was The Figulla (size 25) and The American Amplatizer (size 18).

Procedure Complications: No mortality, tamponade or perforation was observed after the procedure. Compressive effect was detected only in the first echocardiographic examination of 2 (4.56%) patients (device used was The American Amplatizer, size 35). Device deviation was also reported in 2.32% of the patients in the last follow up visit.

In our series, 5 (11, 6%) patients re-experienced cerebral events; these events were not in consequence of PFO in 4 of these subjects. Cerebral cysts, convulsion, carotid stenosis and ischemia were the probable etiologies in the above mentioned cases. Only one patient had PFO related symptom 7 months later; this patient started experiencing paraplegia which gradually progressed to quadriplegia, dysphasia and deep vein thrombosis. Thrombosis formation in the device site was deemed the probable diagnosis after the exclusion of hypercoagulability status and neurological consultations. It is worthy of note that no residual shunt had been detected in the immediate and follow up echocardiographic examinations of this patient. In the patients who experienced recurrence of the events, hypertension was diagnosed in 2 (40%) patients and inters atrial septum aneurysms in 20%.

Table 1: Cerebrovascular events in patients prior to PFO closure.

Event Type	n	Percent
Visual deficit	8	12
Verbal deficit	9	14
Syncope	4	6
seizure	3	5
Dizziness	2	3
Memory loss	3	5

Discussion

In our study, the rate of successful PFO closure was 95.3% for 46 patients using two different device types. The post-procedural residual shunt rate was estimated to be 4.65%. Moreover, the overall risk of thromboembolic event recurrence at 12 months' follow up was approximately11.63%. The influence of post procedural residual shunt on the recurrence of thromboembolic events is still a matter of controversy. Indeed, whereas some studies have reported lower recurrence risk with the accomplishment of complete closure after device implantation [10,11], spies et al [12] failed to demonstrate the impact of small residual shunts on the recurrence of thromboembolic events.

Such inconsistencies in the results of device closure can also be found elsewhere in the existing literature. Bridges et al [13], reported 36 patients at a mean average of 39 years who underwent closure with The Clamshell Device: the procedure was successful in 28 patients and complete closure was documented via echocardiography. Additionally, during an 8 months follow up period (range:1-24 months), no recurrent cerebrovascular accidents or arterial emboli were observed in any of the study population, with the exception of 4 patients who had experienced some kind of transient focal deficits in the following 5 to 6 months. En de et al [14] utilized the Buttoned Device in 10 patients (mean age=40 years) and achieved success in 9 cases and counter-occluder embolization was the culprit in the failure case, which was subsequently corrected by surgery. In the same study, after one month, residual shunt was detected in only 4 patients and no thromboembolic event recurrence was reported in the next 32 months. In a multicenter study [15], device closure occurred in 46 patients and there was only one case of transient ischemic attack, after 7 months.

The rate of post procedural complications in our study was 4.56% which is comparable to that of the bridges et al study (13), which reported one (2.8%) brachial plexus injury in 36 patients. Sievert et al (15) also experienced such various complications using the ASDOS as device embolization (1%), pericardial effusion (3%), thrombus formation (6%) and infection (2%).

Study Limitations

Our study has different limitations, first and foremost amongst which is its retrospective design inherently suffering from defects in data gathering and referred bias as is the case in other similar case-series (12). Secondly, our sample size was very small and thus not representative of the general population as a whole. Another weak point is that our small sample size and preference for the employment of specific device types precluded us from detecting the probable

effect of any device on the outcome which would have included thromboembolic event recurrence and residual shunt severity. We were, therefore, unable to measure the efficacy of the device type on the success rate. In this study we did not compare the efficacy and safety of PFO closure with those of other treatment modalities such as surgery or medical therapy. Future clinical trials are required to shed sufficient light on this matter.

Conclusion

PFO device closure can be considered a preferred method over surgery due to its efficacy and lower complication rate.

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