OUTCOMES OF PERCUTANEOUS PFO CLOSURE: SINGLE CENTRE EXPERIENCE

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Background and objective:

Patent foramen ovale closure aims to reduce recurrent stroke risk in a specific group of patients. On the other hand, absolute risk reduction with PFO closure compared to antiplatelet treatment is still under investigation due to procedural complication risks. The objective of this trial is to report short and long-term results of PFO closure in our center.

Method:

In this prospective observational clinical trial, 369 patients who had undergone PFO closure between 2006 to 2021 were enrolled. Patients had been followed for at least three months. Preprocedural characteristics, procedural outcomes, postprocedural antiplatelet treatment, and major adverse events, including all-cause mortality, and stroke, were recorded.

Results:

In our study group (mean age 43.7±11.12), 217 (58.8%) of them were female, the most common comorbidity was hypertension (in 87 pts, 23.6%), atrial fibrillation was present in 9 patients (2.4%), and 46 pts (12.5%) had migraine. The median rope score of patients was 6 (2-9). The percutaneous PFO closure was performed without complications in 352 patients (95.4%). Pericardial effusion, access-related bleeding, dislocation, and supraventricular arrhythmia were observed in 5, 9,1, and 2 patients, respectively. Pericardiocentesis, urgent surgery, and blood transfusion were not needed in any patient. The device migrated after releasing in one patient, and it was collected with a snare catheter. The transseptal atrial septal puncture was required in 15 (4.1%) patients. 327 patients (88.6%) used DAPT, and 42 patients (11.4%) used SAPT (ASA or clopidogrel) or oral anticoagulant after procedure. The median follow-up duration was 12.7 months (3-147 months). Mortality was not observed in the study group, but 18 patients (5.7%) presented with recurrent stroke during follow-up. Clinically disabling stroke was present in 3 patients (0.81%). Device malposition or thrombus formation on the closure device were not observed at the third-month transthoracic echocardiography.

Conclusion:

PFO closure is a safe, feasible, and effective therapeutic option for thromboembolic risk reduction in selected patients. Procedure-related complication risk and postprocedural recurrent stroke are low. Further randomized controlled trials and cost-effectivity analysis are needed to understand the absolute outcomes of the procedure.

Table 1. Baseline Characteristics	
Age	43.7±11.12
Female	217 (58.8%)
Hypertension	87 (23.6%)
T2DM	30 (8.1%)
KAH	13 (3.5%)
AF	9 (2.4%)
Migrane	46 (12.5%)
LVEF	63.8±4.15%
ROPE Score	6 (2-9)
Follow-up Duration (Month)	12.7 (3-147)

Table 2. Procedural and Follow-up Outcomes	
DAPT	327 (88.6%)
SAPT	33 (8.9%)
OAC	9 (2.4%)
Device Size	
• **18 mm**	34 (9.2%)
• **25 mm**	283 (76.7%)
• **28 mm**	18 (4.9%)
• **30 mm**	34 (9.2%)
Procedural Success	369 (100%)
Transseptal Puncture	15 (4.1%)
Complication	17 (4.6%)
Pericardial effusion	5 (1.4%)
Access-related bleeding	9 (2.4%)
Supraventricular arrhythmia	2 (0.5%)
Dislocation	1 (0.3%)
Mortality	0 (0%)
Recurrent Stroke	3 (0.8%)