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Twenty Years of Percutaneous PFO Closure: Long-Term Clinical and Echocardiographic Outcomes

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Introduction: Our experience with percutaneous patent foramen ovale (PFO) closure at MC Medicor began in October 2006, with 487 successful procedures performed over the following 20 years.[1-3] We aimed to evaluate the long-term efficacy and safety of PFO closure, focusing on echocardiographic outcomes and recurrent neurological events.

Patients and Methods: This single-center observational study included 355 consecutive patients who underwent PFO closure following transient ischemic attack (TIA) or cerebrovascular insult (CVI) between 2006 and 2023. Complete closure was defined as the absence of bubbles during the Valsalva maneuver, and functional closure as ≤10 bubbles.

Results: The mean age of our population was 46 years, with most patients (94%) presenting with neurologic symptoms. PFO closure was performed predominantly under conscious sedation (93%). Balloon sizing was performed in 44% of patients, and the Amplatzer PFO occluder was the most frequently implanted device (76%). Device deployment was successful in all but one patient (99.8%). Echocardiographic assessment was available in 306 patients (86%), with examinations immediately after the procedure, at 6 months, and during subsequent follow-up at 1–5 years (median 1.32 years), 5–10 years (median 7.10 years), or beyond 10 years (median 11.64 years). Complete closure increased significantly from 64% immediately after the procedure to 80% at 6 months ($p<0.05$), remaining stable at 77–81% throughout long-term follow-up (NS). Functional closure was achieved in 93% of patients immediately after the procedure and remained consistently high (94–97%) during follow-up. Although immediate complete closure differed between Amplatzer PFO occluders and alternative devices (60% vs. 83%; $p<0.001$), no significant differences were observed thereafter. Among 15 patients with greater than moderate residual shunting, the underlying cause was identified in 73%, including device-related leakage, atrial septal fenestration or defect, and pulmonary arteriovenous malformation. No late device embolization, thrombus formation, or pericardial effusion was detected. Recurrent TIA and CVI rates were 0.11 and 0.06 events per 100 patient-years, respectively. During the study period, the COVID-19 pandemic coincided with an increase in patient referrals to our center. This observation prompted us to investigate the occurrence of PFO-associated stroke during the mass vaccination campaign in Slovenia. The results were described in a separate publication.

Conclusion: Our two decades of experience with echocardiographic follow-up demonstrate that percutaneous PFO closure provides functional closure exceeding 90%, even beyond 10 years, regardless of device type. Recurrent neurological events were rare, and no late device-related complications were detected. These findings support the long-term efficacy and safety of percutaneous PFO closure.

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