

Patent Foramen Ovale Closure: Time to Rethink?

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BACKGROUND

Ischemic strokes are a common cause of considerable morbidity and mortality. However, despite exhaustive investigations, the etiology behind a considerable proportion of these strokes remains uncertain and therefore many strokes are termed “cryptogenic”. Since the prevalence of Patent Foramen Ovale (PFO) is much higher in patients with cryptogenic strokes than the general population, it is logical to hypothesize that the closure of PFO will result in reduced incidence of recurrent strokes in patients. However, prior trials have failed to demonstrate any discernible clinical benefit of transcatheter closure compared to medical management.

WHAT DO THE NEW STUDIES ADD?

New England Journal of Medicine recently published 2 new randomized controlled trials (REDUCE and CLOSE) and the long-term outcomes of a third clinical trial (RESPECT) [1-3]. The publication of these trials is likely to reignite the debate of the clinical benefit obtained with transcatheter PFO closure.

The RESPECT trial is a long-term follow-up of the initial RESPECT study that failed to demonstrate the reduced risk of stroke with PFO closure [3]. This trial tracked 980 patients for a median duration of 5.8 years and found that the recurrent ischemic stroke event rate was significantly lower with PFO closure than with medical therapy alone ($p=0.046$).

The REDUCE clinical trial had strict inclusion criteria where transesophageal echocardiography was used to characterize the shunt size (with 1 to 5 microbubbles seen in the left atrium in three phases of cardiac cycle deemed as small, 6 to 25 as moderate and greater than 25 as large) [1]. The majority (81%) of the 664 patients had moderate or large shunts. Again, the risk of ischemic stroke was significantly lower in the PFO closure group than in the medical therapy group ($p=0.002$).

Finally, the CLOSE trial followed 663 patients with a history of ischemic stroke and presence of a large inter-atrial shunt or an atrial aneurysm for a median of 5.3 years [2]. Once again, the closure was linked with significantly reduced risk of recurrent ischemic stroke ($p=0.001$).

In terms of the adverse events, the risk of supraventricular arrhythmias was significantly higher in the intervention group than the control group in these trials.

WHAT IS THE WAY FORWARD?

It is important for clinicians to understand the limitations of the current evidence. New studies are likely positive because of the strict patient inclusion criteria. For instance, 78 years old male presenting with a lacunar stroke in the context of the prolonged history of uncontrolled hypertension is unlikely to benefit from a PFO closure, even if a PFO is found on an echocardiogram. On the other hand, a younger patient presenting with ischemic stroke may be a better candidate if the cause remains elusive despite exhaustive investigations and an echocardiogram reveals a large PFO.

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