Patent Foramen Ovale Closure Is Effective in Divers

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Letters

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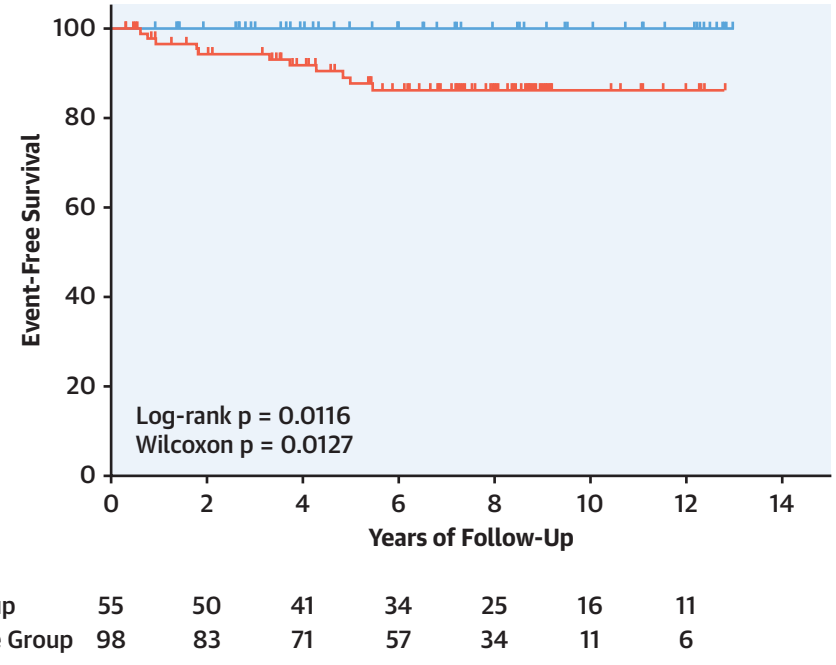
Long-Term Results From the DIVE-PFO Registry

Patent foramen ovale (PFO) is associated with increased risk of decompression sickness (DCS) in divers because of paradoxical embolization of nitrogen bubbles (1). These events can be unpredictable in divers with a PFO (2). Catheter-based PFO closure led to the elimination of arterial emboli after simulated dives (3). However, the evidence of its clinical effectiveness is sparse (4). This study aimed to evaluate the long-term clinical effectiveness of catheter-based PFO closure in the prevention of unprovoked DCS.

A total of 829 consecutive divers were prospectively included in the DIVE-PFO (Decompression Illness Prevention in Divers with a Patent Foramen Ovale) registry between January 2006 and December 2018. The study was approved by the Ethics Committee of University Hospital Motol. Transcranial color-coded sonography (TCCS) was used for the detection and grading of a right-to-left shunt, as previously described (2). Demographic data, diving experience, and details of any DCS were collected by means of questionnaires at enrollment and on a telephone follow-up visit. For divers for whom follow-up was not available, survival was checked in the National Database of Deaths. Transesophageal echocardiography was offered to divers with: 1) DCS history; 2) high-grade shunt on TCCS; or 3) unsuccessful TCCS examination (insufficient bone window). If the result of transesophageal echocardiography was available, the higher grade of the 2 examinations was counted.

The PFO closure procedures were performed in 5 centers. The Amplatzer Septal Occluder (AGA Medical

FIGURE 1 Unprovoked Decompression Sickness Occurrence



Survival free from unprovoked decompression sickness in divers after catheter-based patent foramen ovale closure (closure group) and with a high-grade patent foramen ovale (conservative group).

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Corporation, Golden Valley, Minnesota) was used in 10 (18%) divers, and the Occlutech Figulla PFO Occluder N (Occlutech GmbH, Jena, Germany) was used in 46 (82%). The indication for the procedure was the presence of a grade 3 PFO and either: 1) a history of unprovoked DCS; or 2) diver's preference (not able to adapt to conservative diving recommendations, i.e., professionals). Minor bleeding occurred in 2 divers (3.6%); no other procedure-related complications occurred.

The endpoint of the study was unprovoked DCS (2). Estimates for long-term event-free survival were made by the Kaplan-Meier method, and differences were assessed by the log-rank test and the Gehan-Breslow-Wilcoxon method.

The follow-up was available for 748 (90%) divers, of whom 702 continued diving. Of these, a high-grade PFO was diagnosed in 153 (22%) divers: 55 underwent a catheter-based PFO closure (closure group), and 98 were advised to dive within the limits of recreational diving (conservative group). The mean follow-up time was 7.1 ± 3.8 years and 6.5 ± 3.2 years ($p = 0.339$), numbers of new dives were 30,684 and 25,328 ($p < 0.001$), mean ages were 40.0 ± 7.9 and 37.3 ± 9.8 years ($p = 0.079$), and 78.2% and 79.6% ($p = 0.893$) of divers were male for the closure group and conservative group, respectively. An unprovoked DCS occurred in 11 (11%) divers in the conservative group versus 0 in the closure group ($p = 0.012$) (**Figure 1**).

There is still a large knowledge gap regarding the optimal risk stratification and management strategy in divers with PFO. To date, there are no prospective studies to assess the clinical benefit of PFO closure in divers. The present study is unique in its uniform screening method and prospective participant inclusion. The results are consistent with previous findings that: 1) PFO closure eliminates arterial gas emboli; and 2) PFO is a major risk factor for unprovoked DCS (2,3). PFO closure is a safe procedure with a very low complication rate (5). According to our data, PFO closure is recommended in divers with a high-grade PFO, with a history of unprovoked DCS, or at the diver's preference. Besides protection from DCS, PFO closure also offers the diver lifelong protection from PFO-associated stroke.

This study is subject to inherent limitations, including selection bias. Although this study is, to our knowledge, the largest available, the number of endpoints is still low. The self-reporting of endpoints is another limitation; the majority of cases were not examined by a specialist at the time of the DCS event.

The results of the DIVE-PFO registry demonstrated that catheter-based PFO closure was more effective in DCS prevention than the conservative approach in divers with a high-grade PFO.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC* author instructions page.

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The Need for and Benefits of an International Database for Cardiac Tumors

The report by Sultan et al. (1) is an excellent review that confirms both the rarity and poor long-term prognosis of cardiac tumors. It represents the largest collection of these tumors published to date.

Finally, we have a reasonably large group of patients with the diagnosis of primary cardiac