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Effect of Catheter-Based Patent Foramen Ovale Closure on the Occurrence of Arterial Bubbles in Scuba Divers

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Objectives This study sought to evaluate the effect of catheter-based patent foramen ovale (PFO) closure on the occurrence of arterial bubbles after simulated dives.

Background PFO is a risk factor of decompression sickness in divers due to paradoxical embolization of bubbles. To date, the effectiveness of catheter-based PFO closure in the reduction of arterial bubbles has not been demonstrated.

Methods A total of 47 divers (age 35.4 ± 8.6 years, 81% men) with a PFO (PFO group) or treated with a catheter-based PFO closure (closure group) were enrolled in this case-controlled observational trial. All divers were examined after a simulated dive in a hyperbaric chamber: 34 divers (19 in the PFO group, 15 in the closure group) performed a dive to 18 m for 80 min, and 13 divers (8 in the PFO group, 5 in the closure group) performed a dive to 50 m for 20 min. Within 60 min after surfacing, the presence of venous and arterial bubbles was assessed by transthoracic echocardiography and transcranial color-coded sonography, respectively.

Results After the 18-m dive, venous bubbles were detected in 74% of divers in the PFO group versus 80% in the closure group ($p = 1.0$), and arterial bubbles were detected in 32% versus 0%, respectively ($p = 0.02$). After the 50-m dive, venous bubbles were detected in 88% versus 100%, respectively ($p = 1.0$), and arterial bubbles were detected in 88% versus 0%, respectively ($p < 0.01$).

Conclusions No difference was observed in the occurrence of venous bubbles between the PFO and closure groups, but the catheter-based PFO closure led to complete elimination of arterial bubbles after simulated dives. (Nitrogen Bubble Detection After Simulated Dives in Divers With PFO and After PFO Closure; NCT01854281) (J Am Coll Cardiol Intv 2014;7:403–8) © 2014 by the American College of Cardiology Foundation

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Scuba (self-contained underwater breathing apparatus) diving is a popular sport that attracts millions of participants worldwide (1). The general risk of death or major injury during scuba diving is small (<0.001% per dive) (2). However, some risk associated with decompression sickness (DCS) still exists.

DCS is caused by nitrogen bubble formation in hypersaturated tissues during the diver's ascent (3). These bubbles either cause local tissue damage or embolize through venous blood (3). Small quantities of venous gas bubbles are believed to be common after most scuba diving (4,5).

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Although most divers remain asymptomatic, symptoms may occur with high bubble load (pulmonary gas embolism) or may be due to paradoxical embolism (arterialization of bubbles) in a diver with a transient right-to-left shunt. The connection between a patent foramen ovale (PFO) and DCS was first described in the 1980s (6,7). Since then, a high prevalence of PFO has been repeatedly reported in divers with the neurological or cutaneous form of DCS (8,9). Multiple brain lesions have also been suggested as possible chronic sequelae of repeated exposure to asymptomatic arterial embolisms (10). The high prevalence of PFO in the general population (11) raises concern among divers and involved medical professionals.

Abbreviations and Acronyms

DCS = decompression sickness

PFO = patent foramen ovale

TCCS = transcranial color-coded sonography

TTE = transthoracic echocardiography

It has been suggested that catheter-based PFO closure might prevent the arterialization of bubbles and reduce the risk of DCS (12–14). The effect of PFO closure to prevent paradoxical embolization of injected bubbles has previously been demonstrated (15). However, there are currently limited clinical data supporting the effectiveness of PFO closure in divers (12,13) and no data confirming its effect on post-dive reduction of arterial gas emboli. The aim of this study was to test the effect of catheter-based PFO closure on the occurrence of arterial bubbles after simulated dives.

Methods

Patients. A total of 183 consecutive divers were screened for PFO at our center. Transcranial color-coded sonography (TCCS) was used for screening, and the diagnosis of PFO was confirmed by transesophageal echocardiography. The right-to-left shunt was graded by means of TCCS according to the International Consensus Criteria (16): grade 1, 1 to 10 bubbles; grade 2, >10 bubbles but no curtain (uncountable number of bubbles); grade 3, curtain. Significant PFO (grade 3) was found in 47 divers. Twenty divers (age 38.8 ± 9.5 years, 80% men) with a history of unprovoked DCS underwent catheter-based PFO closure (closure group). The other 27 divers (age 33.0 ± 6.6 years, 81% men) were either asymptomatic or did not agree with PFO closure, or their PFO closure had not been performed prior to study onset (PFO group). A total of 136 divers (age 33.6 ± 8.3 years, 85% men) that did not have a grade 3 PFO were not included in the study. In this group, 118 tested negative for PFO, 13 had a grade 1 PFO, 5 had grade 2 PFO, mean body mass index was 25.9 ± 3.1 kg/m^2, mean number of logged dives was 225 ± 479, and mean number of logged decompression dives was 47 ± 136. A history of DCS was reported in 11 (8%) of the 136 divers.

Inclusion criteria for the closure group were as follows: age ≥19 years; a PFO that had been occluded by a catheter-based procedure; and a signed informed consent form. Inclusion criteria for the PFO group were: age ≥19 years; a previously diagnosed grade 3 PFO according to the International Consensus Criteria (16); and a signed informed consent form. Exclusion criteria for both groups were: another dive performed in the preceding 24 h and disagreement to being included in the study. The study was approved by the local ethics committee and all study subjects gave written informed consent to participate in the study.

Procedures. The PFO closure procedures were performed in a single center (with the exception of 2 divers) between February 1, 2006, and April 30, 2013. The Amplatzer septal occluder (AGA Medical Corporation, Golden Valley, Minnesota) was used in 5 (25%) divers. In the remaining 15 (75%) cases, the Occlutech Figulla PFO Occluder N (Occlutech GmbH, Jena, Germany) was used. The procedure was performed as previously described (17). In all divers, the indication for the procedure was a history of unprovoked DCS (i.e., without violation of decompression regimen) and the presence of a grade 3 PFO according to the International Consensus Criteria (16). There were no major complications, and bleeding at the puncture site with no need of intervention occurred in 1 (5%) patient.

Simulated dives. To test the effect of catheter-based PFO closure on the reduction of arterial bubbles, decompression dives according to the U.S. Navy Air Decompression Procedure 1996 (18) were used. This decompression procedure was previously reported to generate significant amounts of venous and arterial bubbles but no acute DCS symptoms (5,19). Two dive profiles were used. The divers chose 1 of the 2 simulated dives that best corresponded to their usual diving practice. Thirty-four divers performed a dive to 18 m with a bottom time of 80 min (dive A). The descent and ascent rate was equivalent to 9 m/min; the decompression stop was performed at 3 m for 7 min. Thirteen divers performed a dive to 50 m with a bottom time of 20 min (dive B). The descent and ascent rate was 9 m/min; decompression stops were performed at 6 m for 4 min and at 3 m for 15 min.