

Use of the MemoSorb bioresorbable PFO device in an 11-year-old diver with phospholamban mutation and family hypertrophic cardiomyopathy

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Case Report

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Abstract

We report biodegradable device implantation for primary prevention in an asymptomatic 11-year-old boy with a patent foramen ovale, normal biventricular function and phospholamban mutation, conferring an elevated future risk of hypertrophic cardiomyopathy. He was a keen diver, with ambitions to be a marine biologist. Following multidisciplinary discussion, closure of the defect was agreed, using a bioresorbable device to optimize future transseptal intervention for potential cardiomyopathy. A 34 mm Memosorb® PFO Occluder (Lepu medical Technology, Beijing, China) was positioned, complicated by complete atrioventricular block, regressing to first degree after removing the device. A 28mm device was then successfully implanted. Intermittent 2nd degree atrioventricular block occurred post-procedurally, treated with steroids, with normal holter ECG few weeks later. Bubble test echocardiography was negative after 6 months. The patient was allowed to dive again. The Memosorb® biodegradable device can be implanted in selected cases. More studies are needed to confirm safety and efficacy.

Introduction

Transcatheter closure of patent foramen ovale (PFO) is mostly performed as secondary prevention of a recurrent cryptogenic ischemic stroke/transient ischaemic attack, presumably due to paradoxical embolism in patients between 18- and 60-year-old. It is also recommended in platypnea-orthodeoxia syndrome and sometimes considered for migraine headaches and decompression sickness (DCS), often on a case-by-case basis [1]. Especially in divers with DCS, the clinical evidence and efficacy of PFO closure is sparse. Consequently, PFO closure in divers is only considered as secondary prevention, in selected cases. Finally, PFO closure is rarely performed in pediatric patients, although it seems to be safe and effective for the same conditions as in adult patients [2].

Nitinol occluder devices are the standard of care for PFO closure. However, they carry potential complications due to their metallic component, including erosion, thrombosis, infection, and allergies. Additionally, any future transcatheter access to the left atrium is more difficult. A recent multi-center study demonstrated that the bioresorbable Memosorb® (Lepu medical Technology, Beijing, China) device is non-inferior to metallic occluders in patients with PFO, potentially decreasing the above-mentioned complications [3].

We report the implantation of a biodegradable device as primary prevention in an 11-year-old boy with the unusual association of a PFO with family hypertrophic cardiomyopathy due to phospholamban mutation.

Case presentation

An 11-year-old boy was diagnosed with a PFO (versus small secundum atrial septal defect, Fig. 1A) during a systematic echocardiogram, for cardiomyopathy screening, in the setting of family hypertrophic cardiomyopathy due to phospholamban mutation. The patient was heterozygous for a pathogenic familial phospholamban variant, that was also found in his mother and maternal grandmother, with his

maternal grandmother having a confirmed clinical diagnosis of hypertrophic obstructive cardiomyopathy. He was asymptomatic with normal biventricular morphology and function by echocardiography, despite carrying the mutation. Nevertheless, he was felt to be at high-risk of developing hypertrophic cardiomyopathy in the future. He was also a keen diver with ambitions to be a marine biologist. Due to the PFO, deep diving became contraindicated. Following discussion in multidisciplinary meeting, his case was accepted for transcatheter closure of the defect, as primary prevention. Additionally, it was agreed to use a bioresorbable device, in case transseptal intervention would be indicated if he develops cardiomyopathy in the future.

The procedure was performed under fluoroscopy, transesophageal and transthoracic echocardiographic guidance (Figs. 1B-1C). A 7Fr short sheath was inserted in the right femoral vein, later upsized to 14Fr. Right heart catheter showed normal pulmonary artery pressure (mean, 13mmHg). The PFO was crossed and measured at 3.5x1.7mm by echocardiography. The PFO tunnel measured 8.5mm in length. A 34mm Memosorb® PFO Occluder device (Lepu medical Technology, Beijing, China) was initially implanted. However, it appeared oversized with protrusion toward the mitral valve. Additionally, the patient went into complete AV block, regressing to first degree AV block after pulling out the device. A 28mm device was subsequently implanted and successfully released, with a good result. Although the patient was in sinus rhythm at the end of the case, he later experienced transient 1st and intermittent 2nd degree atrioventricular (AV) block (Fig. 1D). Oral steroids were administered, and he reverted to sinus rhythm after a couple of days. He was subsequently discharged home.

Subsequent follow up transthoracic echocardiograms confirmed good position of the device (Fig. 1E). A 7-day holter ECG showed normal sinus rhythm throughout, with normal PR interval. Subsequent bubble study after 6 months follow-up was negative (Fig. 1F). The patient was then allowed to restart diving, with a plan to redo bubble test echocardiography one and 2 years post implantation to confirm the absence of residual shunt after full biodegradation of the device.

Discussion

To our knowledge, this represents the first reported successful implantation of a bioresorbable PFO device in a pediatric patient as primary prevention for decompression illness. We fully recognize that this is an off-label indication. In a similar setting, any adult patient would certainly not undergo PFO closure. However, our pediatric patient was fully engaged and committed to becoming a diver in his future professional life. The reason for closing the PFO was not only medical. There was full consensus of the multidisciplinary meeting to proceed with this. After discussing risks and benefits with the patient and his family, we also clarified that there was no scientific evidence that he would benefit from PFO closure with a bioresorbable device. Subsequently, the UK Medicines and Healthcare products and Regulatory Agency allowed us to use the non-CE mark MemoSorb biodegradable device for this case. Finally, funding of the device was approved by the departmental Clinical Director and hospital clinical governance group.

The biodegradable MemoSorb has the potential to avoid some of the complications associated with nitinol-based device closure. It is made from biomedical polymers, including polydioxanone (often used in dissolving stitches) and a membrane of Poly-L-lactic acid. The device seals the defect, promotes endothelialization, and gradually degrades to leave native functional tissue. Two recent multicenter randomized studies in China showed non-inferiority of the Memosorb® bioresorbable device (Lepu medical Technology, Beijing, China) for PFO and secundum ASD closure and has been shown to take 12–24 months to fully dissolve. There have been no reports of device migration, infection, allergy or erosion and preliminary studies indicate a reduction in mid-term progression of mitral valve regurgitation and arrhythmia as secondary complications [3, 4]. In our patient, the specific indication to use a biodegradable device was not only to avoid the above-mentioned complications, but also to allow any future transseptal device (ie atrial flow regulator) that could be useful if he later develops heart failure in the setting of cardiomyopathy [5].

In our case, the initial choice of the device was too large, resulting in complete AV block. However, this was quickly solved through selection of a smaller device, highlighting the importance of having a wide range of sizes available during the procedure to accommodate for different PFO sizes and morphologies. Oversizing the device triggered post procedural conduction disturbance, which quickly resolved under oral steroid therapy, highlighting the risk for secondary conduction disturbances even with the use of a bioresorbable device. The patient received 6 months of aspirin, like patients with a nitinol-based device. Echocardiographic follow-up showed an excellent result, with a negative bubble test after 6 months. However, we plan to perform another bubble test in 18–24 months after full device resorption to confirm the absence of residual shunt.

In divers, a PFO is linked to a higher frequency of DCS, including neurological DCS, inner ear DCS, and cutis marmorata. This occurs when nitrogen bubble formation within supersaturated tissues during decompression reach the venous circulation and are shunted through a PFO, becoming arterialized, where they may produce symptoms of DCS if they obstruct arterial blood flow [6]. Divers with PFO have two and a half times greater overall risk of DCS than divers without a PFO and four times greater risk of neurological DCS. However, the absolute incidence of neurological DCS remains small, estimated at 4.7 DCS cases per 10,000 dives [7]. Routine screening for PFO in divers is therefore not recommended, except where there is history of more than one episode of DCS with cerebral, spinal, vestibulocochlear or cutaneous manifestations. It is stressed, however, that closing a PFO after an episode of DCS does not provide full certitude that DCS will not occur again, due to other potential mechanisms of DCS occurring, for example, through intrapulmonary shunts [6, 7]. Options for divers who have tested positive for a PFO include stopping diving altogether, diving more conservatively (which may limit diving activity to a non or limited-occupational context) and PFO closure. Following closure of a PFO and before returning to diving, the diver requires a repeat bubble contrast echocardiogram demonstrating shunt closure, a minimum of three months after the closure, which was performed in our case. Diving should not be resumed until satisfactory closure of the PFO is confirmed, and the diver has ceased potent antiplatelet medication, although aspirin is acceptable [7]. One multicenter study found that PFO closure is recommended in large PFO, a history of unprovoked DCS or at the diver's preference, although there

remains an inherent lack of evidence for PFO closure in divers overall. However, it is also recognized that besides DCS, successful PFO closure offers lifelong protection against PFO-associated stroke [8]. In our case, the decision to close the PFO was not only based on the risk of DCS, but also on the very rare association with phospholamban mutation and the risk of future hypertrophic cardiomyopathy. In addition to allowing any potential future interatrial septal intervention, the use of a biodegradable device would potentially minimize some of the complications associated with metallic devices, including infection, allergy, arrhythmia and erosion.

Although there are no current reports of device embolization with this bioresorbable device, this remains a core concern. Due to the lack of radio-opaque material, locating and retrieving an embolized device would present a distinct challenge. The need for high quality echocardiographic guidance in the correct placement of bioresorbable devices cannot be overstated. In our patient, it was decided to fully optimize imaging guidance with the combined use of fluoroscopy, transesophageal and trans-thoracic echocardiography.

In conclusion, although more studies are needed, especially to confirm mid and long-term safety and efficacy of the Memosorb ® biodegradable device, this case highlights that it can be successfully implanted in selected cases, when there is potential benefit as compared to metallic devices.

Declarations

Author Contributions: All authors contributed to the conception, drafting, and critical revision of this manuscript, and approved the final version for submission.

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Funding Statement:

This case report received no external funding; the cost of the MemoSorb device was approved and covered by the Trust.

Ethics Statement:

This case report was conducted in accordance with institutional ethical guidelines; formal institutional review board approval is not required for single-patient case reports at our institution.

Consent for Publication:

Written informed consent for publication of this case report and accompanying clinical images was obtained from the patient's parent/legal guardian.

Disclosure Statement:

Alain Fraisse is consultant and proctor for Occlutech Inc, Meril, Acrostak UK, Venus Medtech and Abbott Inc. Carles Bautista-Rodriguez is consultant and proctor for Occlutech Inc and Abbott Inc Other authors have no conflict of interest.

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Figures

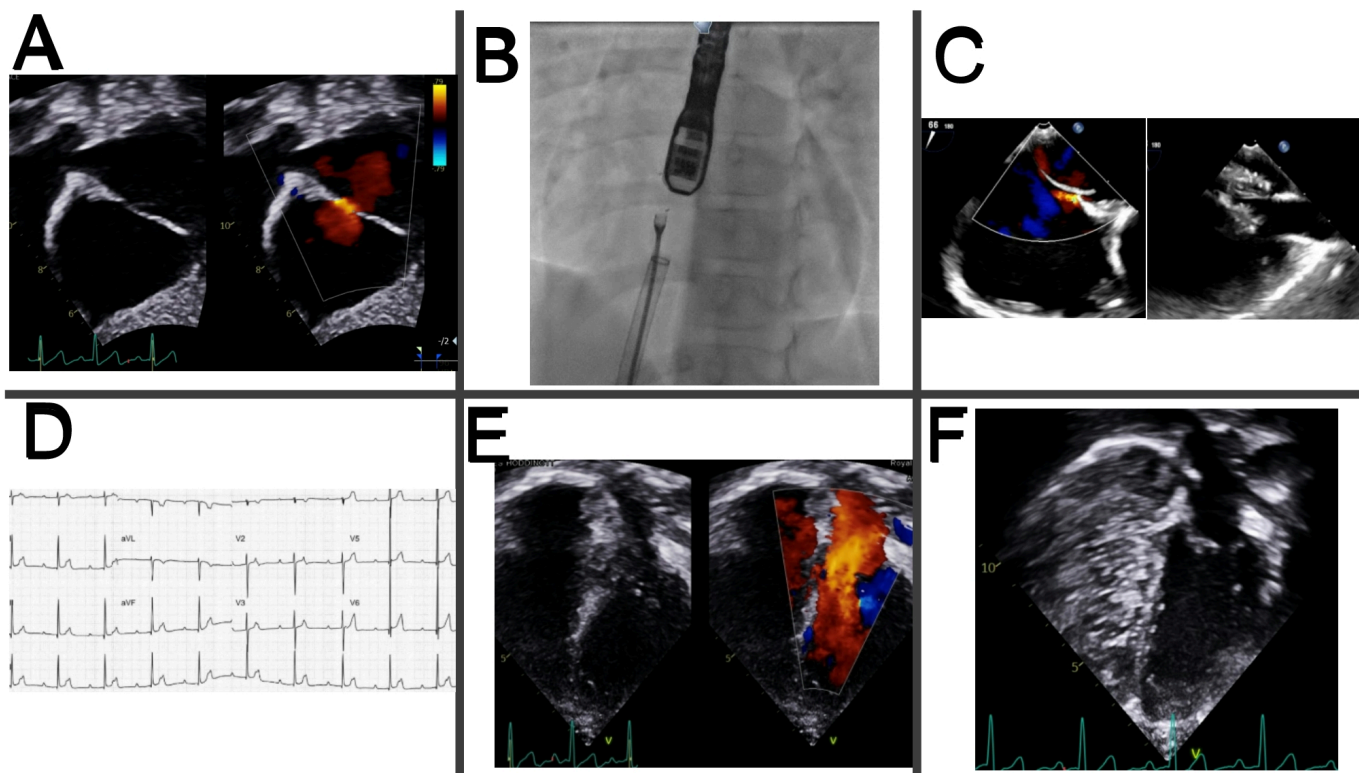


Figure 1

A) transthoracic echocardiography showing a small secundum atrial septal defect versus patent foramen ovale in sub-costal view. B) fluoroscopic guidance during device implantation, with limited interest as only the delivery system and the markers on the device can be seen C) 2D transesophageal echocardiogram showing the patent foramen ovale before (Left) and after (Right) implantation of the device. D), 12-lead ECG showing second-degree AV block post-procedurally. E) 2D Transthoracic Echo with colour Doppler flow showing the device in-situ with no residual shunt and F) Negative Bubble study test at 6 months post device closure.