An audit of persistent foramen ovale closure in 105 divers

Alex Pearman, Luc Bugeja, Martin Nelson, Gergely V Szantho and Mark S Turner

Abstract

(Pearman A, Bugeja L, Nelson M, Szantho GV, Turner MS. An audit of persistent foramen ovale closure in 105 divers. *Diving and Hyperbaric Medicine*. 2015 June;45(2):94-97.)

Introduction: Right-to-left shunt across a persistent foramen ovale (PFO) has been associated with cutaneous, neurological and vestibular decompression illness (DCI). Percutaneous closure of a PFO has been used to reduce the risk of DCI. There are no randomised controlled trial data to support PFO closure for the prevention of decompression illness (DCI), so the need for audit data on the safety and efficacy of this technique has been recognised by the National Institute of Health and Clinical Excellence in the UK.

Method: Retrospective audit of all transcatheter PFO closures to reduce the risk of DCI performed by a single cardiologist with an interest in diving medicine.

Results: A total of 105 eligible divers undergoing 107 procedures was identified. There was a low rate of procedural complications; a rate lower than a recent randomised trial of PFO closure for stroke. Atrial fibrillation required treatment in two patients. One patient with a previously repaired mitral valve had a stroke that was thought to be unrelated to the PFO closure. Sixteen divers had minor post-procedure symptoms not requiring any treatment. Two divers required a second procedure because of residual shunt; both subsequently returned to unrestricted diving. Eighty-one of 95 divers in whom follow-up bubble contrast echocardiography was available returned to unrestricted diving.

Conclusions: The PFO closure procedure appeared to be safe and was associated with the majority of divers being able to successfully return to unrestricted diving.

Key words

Patent foramen ovale (PFO); persistent foramen ovale; echocardiography; right-to-left shunt; transcatheter closure; clinical audit

Introduction

The association between right-to-left shunts across a persistent foramen ovale (PFO), and some types of decompression illness (DCI) was first described in 1989.[1] Subsequent studies have added further supportive evidence of this link, such that closing a PFO to prevent DCI has become widely accepted in the diving community.[2–6] Whilst a randomised controlled trial has not been undertaken, the observational evidence on transcatheter closure of PFO is highly supportive of the technique and the proposed mechanism is biologically plausible. As there appears to be excess risk of diving without additional restriction of nitrogen load for those with a large right-to-left shunt, one would question whether a randomized trial of diving with or without PFO closure is ethical.

PFO closure appears safe; however, potentially important complications can occur.[7] The National Institute for Health and Clinical Excellence (NICE) has reported on PFO closure for preventing paradoxical embolus in divers and one of their recommendations is that audits should be undertaken, hence this report.[8] An issue with PFO closure for divers is the potential for residual leaks across the septum. We have reported previously that residual right-to-left shunts can be seen on bubble contrast echocardiography, and these are of particular relevance to divers.[9] In order to follow the recommendations of NICE and to help to inform divers considering PFO closure to prevent DCI, we audited the practice of one cardiologist (MST) at the Bristol Heart Institute, Spire Hospital, Bristol and the Manor Hospital, Oxford.

The aims of the study were to confirm the safety of our management of PFOs among divers and to satisfy the recommendation of the NICE guidelines (Table 1). Four specific objectives were assessed:

- To demonstrate the efficacy of PFO closure;
- To identify complications that have arisen as a result of the procedure;
- To identify the likelihood of being able to return to diving;
- To better inform divers who have a PFO and are considering a closure procedure.

Table 1
Audit standards used in this study

Criteria	Source	Target
Complications		
Serious procedural and device	RESPECT[10]	< 4%
General procedural and device	NICE guidelines[8]	<10%
Successful implantation	NICE guidelines	100%
Reduction in shunt at follow up (minor or no shunt)	Previous studies[9]	>80%
Unrestricted return to diving	NICE guidelines	>80%

Methods

This audit was approved and registered by the University Hospitals Bristol NHS Foundation Trust Audit Department (audit number 3820). The audit standards that were used are listed in Table 1. A retrospective audit of the Bristol Heart Institute cardiology databases was used to identify all patients who had had percutaneous PFO closure between 28 February 2005 and 10 May 2014. As this showed PFO closures for all indications, the patients presenting with DCI had to be identified.

The audit also included patients who were found to have a large right-to-left shunt without DCI but who were offered closure owing to their desire to dive in an unrestricted way. Patients who had the procedure undertaken privately were also included. Two patients were excluded as they had their original procedures performed at different centres and were referred to the Bristol Heart Institute for a second opinion. Other sources of information used included the patients' clinical notes, a congenital heart disease database, a private patient database and the PACS imaging database. The data were transferred to an Excel spreadsheet for analysis.

As the evidence in the NICE guidelines on the expected rates of complications is limited, the decision was made to benchmark against the RESPECT study,[7] which looked at PFO closure after cryptogenic stroke in 980 patients and included 460 PFO closure procedures. It is recognized that this represents a population who have had stroke or transient ischaemic attack rather than DCI; however, the RESPECT study patients were screened for vascular disease or other embolic causes for stroke. Thus, the RESPECT study population did not have overt vascular disease or atrial fibrillation, so may not be so different to a population of divers as might first be considered and represents the largest group of patients described in the medical literature who have undergone PFO closure and the device used was the most prevalent in our patients.

Follow-up bubble contrast echocardiography was usually performed at six months after the procedure. The size of shunt is defined as the largest number of bubbles seen in a single still frame of the bubble contrast echo imaging. Shunts less than 15 bubbles in a single frame have not been associated with DCI, so are considered safe for unrestricted diving. Those with residual leaks of greater than 15 bubbles at six months had a repeat bubble contrast echo usually at one year after the procedure. A negative bubble contrast echo also excludes a pulmonary shunt, which could theoretically be unmasked after closure of a PFO-related shunt.

Results

A group of 105 divers was identified, two of whom had two procedures. One patient who did not have a device implanted because the PFO was too small to justify occlusion was excluded from the analysis, leaving 106 procedures in 104 divers. Sixty-seven were male and 37 female, with a mean age at procedure of 40.8 (range 16–63) years. The balloon size showed a mean diameter of 6.95 mm. The average balloon size in the 16 patients whose pre-procedural shunt was not reported is 6.21 mm, confirming that these patients also had a reasonably sized PFO. The median procedure time was 27 (range 17–130) minutes and median screening time 5 (range 2–17) minutes. All patients had either a transoesophageal echo or intracardiac echocardiographic guidance.

Table 2
Symptoms and signs of decompression illness in order of frequency of presentation in 105 divers presenting for persistant foramen ovale closure procedures

Presenting complaint	Number of divers
Cutaneous	33
Neurological	23
Inner ear	15
Multiple complaints	8
Joint pain only	2
No DCI	16
Not reported	8

DECOMPRESSION ILLNESS

Cutaneous DCI was the most common presentation of DCI followed by neurological and inner-ear symptoms and signs. Presentations are summarised in Table 2. The 16 patients who did not present with DCI wished to continue diving after having been recognised as having a PFO.

PROCEDURES AND COMPLICATIONS

The devices implanted were 89 Amplatzer™ (StJude Medical, USA), seven Gore Septal Occluder™ (Gore Medical, USA), six Premere™ (St Jude Medical, USA), three Helex™ (Gore Medical, USA) and one Starflex™ (NMT Medical, USA). All 106 procedures were considered to have been successful at the time. Major complications occurred in three patients (< 3%), all of which were also reported in the RESPECT study, and three (< 3%) displayed minor complications during the procedure. Sixteen other patients reported a range of minor symptoms. These were not discussed in the RESPECT study nor in the NICE guidelines, and most research does not classify these symptoms as complications. Table 3 lists all the complications that arose.

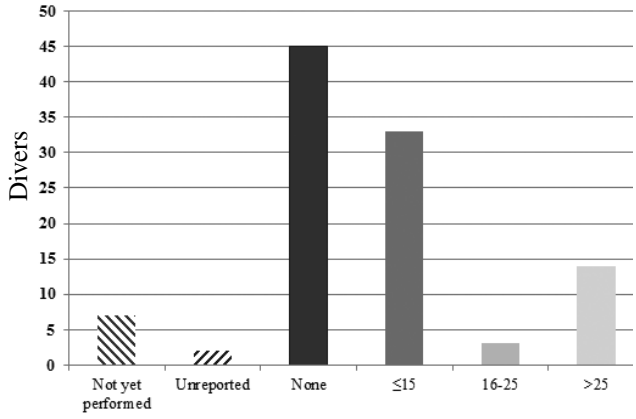
RESIDUAL SHUNT

Post-procedural shunt is displayed in Figure 1. Ninety-eight bubble contrast echocardiography follow-up results were available at the time of writing. No shunt was found after 45 procedures and mild shunt (< 15 bubbles) after

Table 3
Complications documented in individuals who underwent transcutaneous closure of an atrial septal defect

Complication	Occurrence	Number of patients	Treatment
Major			
Atrial fibrillation	> 6 month follow up	1	Ablation
Atrial flutter	6 weeks post procedure	1	Cardioversion
Stroke	> 6 month follow up	1	N/A
Minor			
Transient inferior ST segment elevation	Procedure	1	None
Retroperitoneal haematoma	Procedure	1	None
Vagal symptoms	Procedure	1	Atropine
Other symptoms			
Palpitations	≤ 6 months post procedure	10	None
Chest pain	6 week follow up	3	None
Chest pain and palpitations	6 week follow up	2	None
Nausea and dizziness	6 week follow up	1	None

Figure 1
Post-procedural shunt present at 6 month follow up on bubble contrast echocardiography



33 procedures. Thus 78/98 (80%) were considered fit for unrestricted diving. All patients who received an occluder had reduced shunts compared to pre-procedure but the shunt reduction standard we applied was rigorous.

RETURN TO DIVING

Eighty-one of the 98 divers followed up at the time of writing were cleared to resume unrestricted diving, as the additional three patients had shunts between 15 and 25 bubbles, present only on vigorous Valsalva release. A further 14 were given restrictions on their diving depths and were offered further follow-ups to monitor whether the endothelialisation had progressed and that the shunt had regressed. Two patients who were initially advised to restrict their diving had a repeat procedure which then allowed them to recommence unrestricted diving. An Amplatzer Vascular Plug 4™ (St Jude Medical, USA) was used to occlude the residual shunt in both cases. All divers with residual shunts were advised to minimise lifting and straining for an hour after surfacing, as well as being advised to manage their inert gas load.

MIGRAINE

Thirty-eight of 78 patients, in whom it was recorded, suffered pre-procedural migraine. At follow up, only seven of 45 patients, in whom this was documented, had suffered post-procedural migraine.

Discussion

We have confirmed that closure of an atrial septal defect in a group of divers is safe and effective, achieving our audit standards, and allowing a high proportion of divers to return to diving. The one most serious adverse event (stroke) appears to have been due to a pre-existing mitral valve repair, with implanted prosthetic valve ring and other material in the heart (which would have excluded the patient from the RESPECT trial against which we have benchmarked), or atrial fibrillation. The mitral valve repair had been undertaken using a minimally invasive surgical technique in another hospital (the PFO was not identified at the time). Following the stroke, the patient was assessed in a different hospital independently as he lived in another part of the UK. It was concluded that there was no complication of the PFO device closure itself and we had previously assessed the PFO as being completely closed. Whilst it is possible that the PFO procedure could have increased the chance of atrial fibrillation (AF), previous mitral valve surgery is a potent cause of this arrhythmia.

One episode of DCI occurred in the one diver who had problems with atrial fibrillation, and required a pulmonary vein isolation/AF ablation, which included two punctures in the atrial septum. The recurrent DCI occurred two months after the ablation and after the data collection for this study was completed. The onset of symptoms was soon after

surfacing. He had previously had normal lung function tests and a normal thoracic CT scan to exclude bullae, but it remains possible that he suffered pulmonary barotrauma or that the defects created in the atrial septum for the ablation had not closed at the time of the recurrent DCI. The diver had not followed our usual protocol of having repeat bubble contrast echocardiography after puncture of the atrial septum.

The majority of procedures over the time period audited used the Amplatzer device, primarily because our previous study showed a better closure rate with this device, rather than the Gore Helex device. However, recently the Gore Septal Occluder has been used for some patients as our anecdotal experience is that this device has a good occlusion rate as well.

Whilst some patients have residual shunt at 6 months after the procedure, progressive closure of the PFO is frequently observed.[10] In this audit, a few patients who still had a residual shunt at 6 months returned to unrestricted diving after subsequent bubble contrast echo or repeat procedures. Divers should be aware that, despite complete closure of a PFO, it is still possible to suffer DCI that is not PFO-related. One diver with a residual bubble leak of > 25 (that he was aware of) had an episode of itching suggestive of cutaneous DCI during a deep trimix dive, but treated it himself with an enriched oxygen mixture and so no formal diagnosis was made. He has not had any further episodes and his residual leak has since diminished to around 25 bubbles.

The observed reduction in the recorded prevalence of migraine after PFO closure is in keeping with previous observational studies.[11]

The patients in this audit were highly selected. A careful history was taken and any patients with early onset of DCI were assessed for causes of pulmonary barotrauma and, during the time of this audit, several patients were identified as having bullae on CT scans and did not progress to PFO closure. Only patients with a bubble contrast echo suggesting a moderate or large shunt were offered PFO closure.

Conclusions

In this population of divers, treated with PFO closure after careful assessment by a cardiologist with an interest in diving medicine, PFO closure was associated with a low complication rate and a high rate of return to unrestricted diving.

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Conflicts of interest

MT acts as a consultant and proctor for St Jude Medical, Medtronic and Edwards Lifesciences, as a consultant and lecturer for Gore Medical and performs PFO closures on private patients.

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Alex Pearman[1], Luc Bugeja[2], Martin Nelson[2], Gergely V Szantho[2], Mark S Turner[2]
[1] Medical School, University of Bristol, Bristol, UK
[2] Bristol Heart Institute, Bristol Royal Infirmary, Bristol, UK

Address for correspondence:
Mark S Turner
Level 7 Bristol Heart Institute
Bristol Royal Infirmary
Marlborough Street
Bristol BS2 8HW, UK
E-mail: *<markturner3@nhs.net>*