Case Report

New PFO Device for Closure of Patent Foramen Ovale in Patients Who had a History of Cryptogenic Stroke; a Report of 14 Cases

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Objective: *The Cocoon PFO Occluder is a device for percutaneous closure of inter-atrial communications. Its self-centering characteristics make it attractive for closure of patent foramen ovales (PFOs) with or without atrial septal aneurysms. The goal of this study is to report the immediate and follow-up results of the first 14 patients in implanted with the Cocoon PFO Occluder.*

Material and Method: *This is a retrospective report of immediate and short-term clinical and echocardiographic outcome of patients who underwent transcatheter closure of PFO because of paradoxical embolism. Procedural success was defined as successful deployment of the device and effective occlusion (no, or trivial, shunt after device placement). All patients had a transesophageal echocardiography (TEE) with saline contrast injection at baseline and clinical follow-up at 6 months.*

Results: *Between September 2012 and March 2014, 14 patients had successfully undergone transcatheter closure of PFO using Cocoon® device. During follow-up none of the patients had a recurrence of stroke after device closure. No residual shunt was observed in any patients at follow-up.*

Conclusion: *Transcatheter closure of PFO with the Cocoon PFO device is safe and effective and can be used for preventing recurrent strokes in patients who present with cryptogenic stroke and PFO.*

Keywords: *Patent foramen ovale, Closure device, Cryptogenic stroke*

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Patent foramen ovale (PFO) is a commonly associated finding in patients presented with cryptogenic stroke[1-3]. Pathogenesis of stroke may be caused by the paradoxical emboli from right atrium to left atrium crossing the PFO. Percutaneous transcatheter closure of PFO with device seems to prevent recurrent strokes in previous studies. This is the first report in Thailand using new Cocoon PFO closure device® (Vascular Innovations, Thailand) to close PFO in patients who presented with cryptogenic stroke. The device is made from braided nitinol wires and then coated with platinum using nanofusion technology. The device is then filled with polypropylene fabric to assist thrombogenicity (Fig. 1).

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Material and Method

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Fig. 1 Cocoon PFO device.

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Results

The patient population of 14 who had transcatheter PFO closure included 7 male and 7 female. The average patient age was 53 years. All patients had history of transient ischemic attack (TIA) or embolic stroke. Ten of them had repeated TIA or stroke by clinical or imaging, which demonstrated multiple brain lesion abnormality. One had embolic stroke along with a submassive pulmonary embolism. Table 1 demonstrates the characteristics of the patients. All patients underwent transesophageal echocardiography (TEE) evaluation at baseline and at 6 months follow-up. Patients' evaluations varied but included the following: neurological examination, 12-lead ECG, 24- and 48-hour Holter monitoring, 2D echocardiography with micro bubble test with the Valsalva maneuver, TEE and standard blood tests.

The PFO was closed using the Cocoon PFO Occluder. A Cocoon sizing balloon catheter was advanced to the PFO, and stretched balloon sizing of the PFO was performed by fluoroscopy and TEE. A Cocoon PFO Occluder device diameter was chosen by using PFO stretch diameter plus 14 and, advanced through the Cocoon sheath, then deployed under fluoroscopy and TEE guidance. Good placement of the device was verified by TEE and by the presence of none or minimal shunt after deployment by color flow Doppler (Fig. 2 and 3).

Patients were followed clinically and echocardiography at 24 hours, 1 month and 6 months after device implantation. Residual shunt was determined by 2D echocardiography and color flow Doppler. Two patients showed trivial shunt at day 1, which was completely closed at 1-month follow-up. None of the patients had a recurrent stroke at 6 months follow-up. Two initial patients were followed-up at 19 months and did not have any recurrent stroke.

Discussion

In non-randomized controlled trial for PFO closure after cryptogenic stroke demonstrated the reduction or recurrent stroke rate when compared with medications alone[4-6]. However, the CLOSURE I trial[7] did not demonstrate the benefit of PFO closure using

Table 1. Patient characteristics for patent foramen ovale (PFO) closure

No.	Gender	Age	History of stroke or TIA	Repeated stroke or TIA	Present of septal aneurysm	Positive contrast echo at rest	Positive contrast echo on Valsava	PFO size (mm)	PFO after balloon sizing (mm)	Device Size (mm)
1	F	32	Yes	No	n/a	Yes		n/a	5.7	18/18
2	F	44	Yes	No	Yes	Yes		2.5	6.3	18/18
3	M	66	Yes	Yes	Yes	Yes		2	3.2	25/18
4	M	28	Yes	No	n/a	Yes		n/a	6.2	25/18
5	F	45	Yes	Yes	Yes	Yes		2	3.1	25/18
6	F	58	Yes	Yes	Yes	Yes		5.9	10.2	25/18
7	M	25	Yes	No	Yes	Yes		n/a	14	35/25
8	F	36	Yes	Yes	No	Yes		2.7	n/a	25/18
9	F	73	Yes	Yes	Yes	Yes		2.5	11	35/25
10	M	55	Yes	Yes	Yes	Yes		3	4.5	25/18
11	F	85	Yes	Yes	Yes	Yes		2.7	13	30/30
12	M	58	Yes	Yes	Yes	No	Yes	3.5	7	18/18
13	M	57	Yes	Yes	No	Yes		2	n/a	18/18
14	M	68	Yes	Yes	Yes	Yes		3	6	35/25

F = female; M = male; TIA = transient ischemic attack; n/a = not available

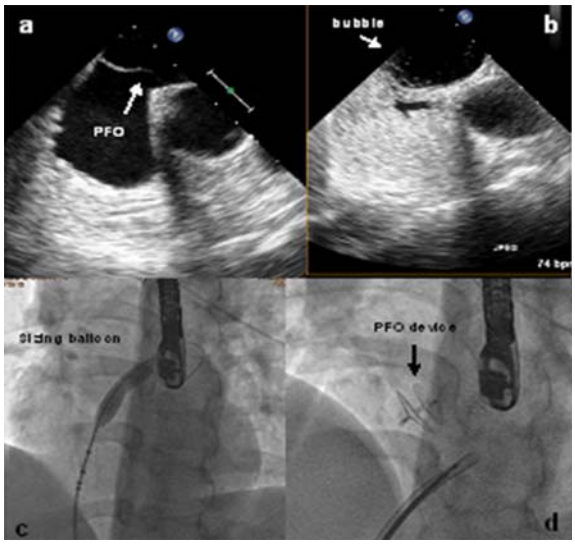

Fig. 2 A) demonstrate patent foramen ovale (PFO) by transesophageal echocardiography (arrow). B) agitated saline injection filled in right atrial and demonstrated into left atrium (arrow). C) sizing balloon was used to evaluate the PFO tunnel. D) PFO device after detach from cable.

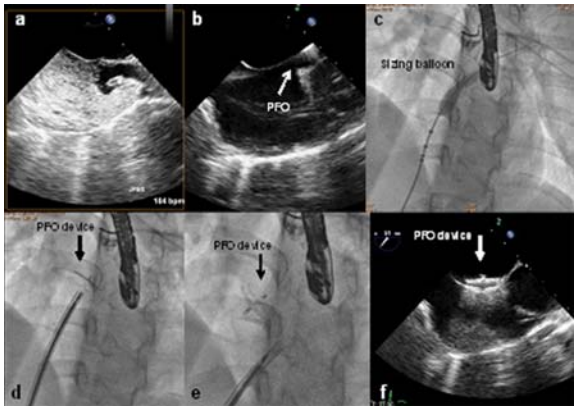

Fig. 3 A) small patent foramen ovale was detected during agitated saline injection. B) when catheter crossed the PFO and demonstrated the tunnel (arrow). C) sizing balloon showing the PFO tunnel. D and E) PFO device (arrow) position. F) PFO device after implantation as demonstrated by TEE.

Starflex device®. Many questions arose from this trial such as if the device itself was too bulgy and high thrombogenicity. The high-risk patients of developing venous thrombosis were excluded. This group of patients was supposed to receive the highest benefit from device closure. The cardiac arrhythmia and other complications during implantation were exceptional high. Finally, the follow-up was too short to determine the outcomes. The RESPECT trial[8] using St. Jude PFO device®, showed 50.8% relative risk reduction of developing recurrent fatal and nonfatal strokes in the device group (*p*-value = 0.0825, CI = 0.217-1.114) when compared with medically treated groups according to the intention to treatment analysis. However, 3 patients in the device group developed strokes before receiving PFO closure. When analyzed as treated cohort, the relative risk reduction was up to 72.7% (*p*-value = 0.007, CI = 0.100-0.747).

In the present cases, it is quite difficult to explain the cause of stroke from atherosclerosis, so closure PFO with device to prevent recurrent stroke is reasonable. The authors use the new design device with smaller left atrial disc to close PFO instead of an atrial septal occluder device. Consequently, thrombus formation in the left atrium and atrial arrhythmia, depending on the device, may be less.

Conclusion

Cocoon PFO device can be used to close PFO defect with right to left shunt for preventing recurrent strokes in patients who present with cryptogenic stroke and PFO. Less metal and a smaller LA disc is the benefit of new device to prevent high thrombogenicity and atrial arrhythmia.

Potential conflicts of interest

None.

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การปิด patent foramen ovale ด้วยอุปกรณ์ชนิดใหม่ในผู้ป่วยที่มีภาวะสมองขาดเลือดโดยไม่ทราบสาเหตุ: รายงานผู้ป่วย 14 ราย

สุพจน์ ศรีมหาโชตะ, นครินทร์ ศันสนยุทธ, วรฤทธิ์ เลิศสุวรรณเสรี, จิราณัติ ชลธีศุภชัย, พรเทพ เลิศทรัพย์เจริญ

วัตถุประสงค์: *Cocoon PFO Occluder เป็นอุปกรณ์ที่สำหรับใช้ปิดผนังหัวใจห้องบนที่เชื่อมต่อกันโดยผ่านสายสวนตัวอุปกรณ์ที่เป็น self-centering ซึ่งเหมาะสมกับการปิด patent foramen ovale (PFO) โดยจะมีหรือไม่มี atrial septal aneurysm จุดประสงค์ของการศึกษานี้เพื่อดูผลการรักษาทันทีและติดตามระยะสั้นในผู้ป่วย 14 ราย ที่ได้รับการรักษาการปิด PFO ด้วย Cocoon® PFO Occluder*

วัสดุและวิธีการ: *เป็นการศึกษาย้อนหลังเพื่อดูผลการรักษาทันทีหลังการปิด PFO ผ่านสายสวนและติดตามผลระยะสั้นในผู้ป่วยที่มีภาวะ paradoxical embolism ความสำเร็จของการทำหัตถการ หมายถึงการสามารถปล่อยอุปกรณ์และปิด PFO สำเร็จ (ไม่พบการรั่วหรืออาจจะมีการรั่วเพียงเล็กน้อย) ผู้ป่วยได้รับการทำคลื่นเสียงสะท้อนหัวใจผ่านทางหลอดอาหาร (TEE) ร่วมกับฉีดน้ำเกลือก่อนปิดและติดตามอาการที่ 6 เดือน*

ผลการศึกษา: *ระหว่างเดือนกันยายน พ.ศ. 2555 ถึงเดือนมีนาคม พ.ศ. 2557 ผู้ป่วยจำนวน 14 รายประสพความสำเร็จในการรักษาการปิด PFO โดยใช้ Cocoon® PFO Occluder ระหว่างการติดตามผู้ป่วยไม่พบการเกิดภาวะสมองขาดเลือดซ้ำ และไม่พบการไหลของเลือดผิดปกติอีก*

สรุป: *การปิด PFO โดยใช้ Cocoon® PFO Occluder ผ่านสายสวนสามารถทำได้ด้วยความปลอดภัยและมีประสิทธิภาพในการใช้ป้องการเกิดซ้ำของภาวะสมองขาดเลือดชนิดที่ไม่ทราบสาเหตุและตรวจพบ PFO*