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GORE® SEPTAL OCCLUDER: early clinical results.

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Background: Transcatheter closure of patent foramen ovale (PFO) is a widespread procedure. However the “quest” for the ideal device is still ongoing. Here we present the procedural and early results of transcatheter closure of PFO with the GORE® Septal Occluder.

Methods: Four Italian centers participated in a multicentric registry and collected data from 25 patients undergoing PFO closure by using GSO device. Indication for closure was previous stroke in 15 and previous TIA in 10 subjects.

Results: The procedure was successful in all of the patients. The procedure was performed with local anaesthesia, fluoroscopic and intracardiac echocardiographic imaging in 12 subjects while it was performed under general anaesthesia, fluoroscopic and trans-esophageal echocardiographic imaging in 13 subjects. Twenty-three patients received a 25 mm device while 2 received a 30 mm device. Procedure and fluoroscopy times were 47 ± 12 and 6 ± 2 minutes, respectively. Residual shunting at procedure was absent in all subjects when performed at the basal status while a mild shunt was present in 3 subjects at Valsalva Manoeuvre. Two subjects (8%) experienced vascular complications. At one month follow-up one subject experienced atrial fibrillation. All subjects showed a well positioned device with no signs of complications. No neurological recurrences occurred. No significant residual shunting was found.

Conclusion: GORE® Septal Occluder in our experience is an easy, safe and effective device in closing PFO.