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Immediate and short-term outcome of the Gore Septal Occluder® (GSO) in patent foramen ovale and atrial septal defect closure – Early clinical experience

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Background:
A new GORE® septal occluder (GSO) was granted CE mark in Europe in June 2011 for the treatment of patent foramen ovale (PFO) and atrial septal defect (ASD). Major changes have been made to the device and delivery system compared to the HELEX® device. The new delivery system has simplified the implantation procedure and the retrievability of the device after deployment if needed. The design of GSO has improved the device apposition ability and tissue response whilst keeping its atraumatic design, low septal profile with minimal septal distortion and long-term biocompatibility. We report the immediate and short-term outcome of patients treated with the device.
Methods:
Consecutive patients treated with GSO for PFO or ASD were evaluated within six months following their procedures.
Results:
Ten patients (6 women) with a mean age 53 ± 10 (range 40 – 67) years were reviewed 76 ± 30 (range 45 – 120) days following their procedure. Nine patients had PFO closure due to at least one episode of paradoxical cerebral or peripheral arterial embolism and one patient had ASD closure.
All the procedures were performed under local anaesthetic using intracardiac echocardiograhic and fluoroscopic guidance. All the devices were successfully deployed upon the first attempt without the need for retrieval. There was no device embolisation or vascular complications. Only one patient had minor residual shunt on agitated saline contrast and valsalva manoeuvre immediately after the procedure.
During follow-up, one patient had developed paroxysmal atrial fibrillation. Two patients reported transient or intermittent palpitation without any arrhythmia documented. In all the patients, there was no evidence of thrombosis associated with the device and no residual shunt was noted on echocardiogram with agitated saline contrast and valsalva manoeuvre. There was also no evidence of wire fracture in the five patients who had follow-up fluoroscopy examination.
Conclusion:
In a small number of predominantly patients with PFO, our initial experience indicates that GSO is associated with an excellent immediate and early complete closure rate without associated device thrombosis or wire fracture. Larger and longer-term study is needed to determine its efficacy and durability.