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Spanish Registry of percutaneous VSD closure with NitOcclud® Le VSD-Coil device: lessons learned after the first hundred implants

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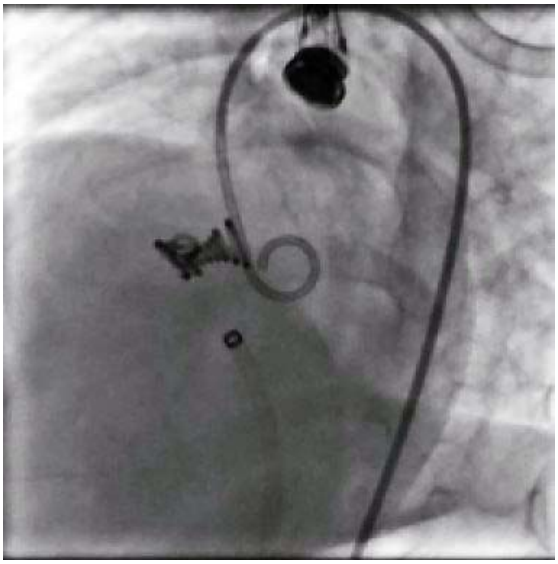

Introduction: The NitOcclud Le VSD Coil was specifically designed for transcatheter occlusion of VSDs and became available for this purpose in August 2010. Our objective is to compile the Spanish experience and present the midterm results of this technique.

Methods: Spanish multicentric observational study, which retrospectively recruited all patients (any age) with VSD (any location or nature) who underwent percutaneous NitOcclud occlusion of their defect, using an intention-to-treat analysis, until May 2018.

Results: 105 attempts were made to implant at least NitOcclud® in a total of 104 patients, whose procedures were performed in 9 institutions (representing more than 96% of the national experience). The median (range) of age and weight was 8.6 years (0.4-68) and 25 kg (5.8-97) respectively. Ten patients were <9Kg. The VSD was an isolated defect in 88 of the cases. The classification by its septal location was: 86 perimembranous (69 with aneurysm), 5 muscular, 4 Gerbode and 10 related to a surgical patch.The mean fluoroscopy time was 37 '. The implant was successful in 96 of the 105 procedures and its (range) follow-up time was 1.8 years (0-4.5). Of these, 4 had to be explanted due to severe haemolysis (n = 2), embolization (n = 1) or transient complete AV block+ significant residual shunt (n = 1). In the others (n = 92), the procedure was safe, without major complications, and the initial percentage of complete occlusion of the defect without residual shunt or in a minimum degree was 71% (68/96) (complete occlusion= 32, trivial shunt= 36) and final percentage of 90% (83/92) (complete occlusion= 62, trivial shunt= 21). Four patients required a second procedure for residual shunt occlusion with additional devices. There were no deaths and the percentage of total hemolysis was 4.7% (2 of them with spontaneous resolution).

Conclusions: The NitOcclud® device can be used successfully for a wide variety of selected patients with VSD. We have not found permanent changes in AV conduction. Patients with residual shunt should be periodically checked to rule out the occurrence of clinically significant haemolysis and delaying the start on aspirin after discharge is our recommendation.