

**Comprehensive assessment of outcome in percutaneous device closure of congenital isolated ventricular septal defects in > 400 cases: A single center retrospective database study.**

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**Introduction:** Percutaneous device closure of a ventricular septal defect (VSD) is an alternative to surgical treatment in selected cases. Ductal occluders are other alternatives used in our institute to close VSD, which are cost effective and seemed safer. In order to identify suitable cases and reduce failure and complication rates of percutaneous VSD closure, we aimed to 1) study causes of device failure in percutaneous VSD closure and 2) compare outcomes with different VSD types and devices in a high-volume single centre.

**Methods:** Retrospective data of elective percutaneous VSD closure of isolated congenital VSDs in the 2003-2017 period was analyzed. Outcome was assessed using echocardiography, electrocardiography, and catheterization data. Echocardiography and electrocardiography were performed before procedure, immediately after procedure and during follow up period. Any complications and reinterventions were noted. Logistic regression analyses were used to assess effects of age, VSD type, device type and device size.

**Results:** During the study period, percutaneous VSD closure was attempted in 412 patients. In n=363 patients VSD closure was successful, in n=30 device implantation failed, and in n=19 the procedure was abandoned because angiographically the VSD seemed unsuitable for device closure.

Median(range) age and body surface area were 6.6 years [4.1-10.9] and 0.7 m<sup>2</sup> [0.5-1.0] respectively. Device failure was not associated with manufacturer (p=0.09) nor was there a significant difference in failure rate between muscular and ductal devices (p=0.33). Device failure was not associated with age (p=0.08), type of VSD (p=0.5), device type (p=0.2), or device size p=0.1. We observed very low incidence of complete atrioventricular block (0.3%), severe aortic regurgitation (0.3%), and severe tricuspid regurgitation (0.3%).

**Conclusion:** In our high-volume centre, failure of percutaneous VSD closure occurred in <10% of patients. Because device type is not related to failure rate, it is justified to use the financially beneficial ductal devices in VSD position. Considering the absence of age related risk of device failure or complications, it does not seem necessary to postpone percutaneous VSD closure in symptomatic moderate shunts in younger children.