

Off-label Use of Percutaneous Pulmonary Valved Stents in the RVOT

*Boshoff D, Cools B., Heying R., Troost E., Budts W., Louw J., Eyskens B., Gewillig M.
University Leuven, Belgium*

Introduction: Percutaneous pulmonary valve implantation is now considered feasible and safe in selected patients with dysfunctional RVOT conduits. The “native” RVOT, smaller conduits (less than 16mm) and the relatively large RVOT with dynamic outflow aneurysms are considered off-label use for percutaneous valve implantation.

Aim of study: To report the safety and feasibility of extended (off-label) application of percutaneous pulmonary valve implantation in patients with RVOT dysfunction.

Design: Retrospective analysis of prospectively collected data.

Setting: Tertiary pediatric and adult congenital heart cardiac centre.

Patients and Methods: Off-label use was defined as valve implantation in patients with a native RVOT (pulmonary valve or patch), RVOT conduits smaller than 16mm or larger than 24mm or the final valve diameter $\geq 110\%$ of the nominal conduit diameter. Successful valve implantation was defined as sufficient relief of RVOT obstruction (if present) and valve competence.

Results: Twenty Melody® valves and 2 Sapien® valves were successfully implanted in 22 patients at a mean age of 17 years (range 6.1 – 80.4years). Pre-stenting was performed in 21 patients 4.8 months (range 0 – 69.2) before valve implantation (14 covered stents; 12 bare stents). In 10 patients valves were implanted in the native RVOT after transannular/infundibular patch (n = 8) or pulmonary valvoplasty (n = 2). Mean diameter of the native RVOT was 18.8mm (range 14 – 24) and mean final valve diameter was 22mm (range 16 – 26). Twelve patients had their valves implanted in existing conduits ranging from 10 to 20mm in size (mean 16mm) with a mean final valve diameter of 20mm (range final size 18 – 22; increase of diameter from nominal 4mm (range 2-6 mm)). The implantations were uneventful and all patients were hemodynamically stable throughout the procedure.

Conclusions: Percutaneous pulmonary valve implantation is safe and feasible even in patients with unfavourable anatomy according to traditional protocol. Creating an adequate “landing zone” by pre-stenting is recommended. Larger studies are needed to identify the “ideal timing” for pre-stenting of the native RVOT.