Melody transcatheter pulmonary valve implantation. Results from the Registry of the Italian Society of Pediatric Cardiology (SICP)

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Introduction
We aimed to analyze current practice in Italy of patients treated by using the Melody Medtronic valve.

Methods
Prospective, observational, multi-centric survey by means of a web-based database.

Results
Six centres participated and 63 patients were included in the registry (49 % female; median age of 24 years (range 11-65 years). Subjects included had a history of a median 3 previous surgeries (range 1-5) and a median of 1 previous cardiac catheterization (median 0-4).
A tronco-conal disease was present in 39 patients, previous Ross operation in 9, other diagnosis in 15. Right ventricular outflow tract was reconstructed with homograft in 33 pts, biological valved conduit in 28 and other types in 5. Indication to valve implantation was pure stenosis in 21 patients (33%), pure regurgitation in 12 (19%), association of stenosis and regurgitation in 30 (48%). In all, except four, a femoral approach was used. Implantation was performed in 61 subjects. Pre-stenting was performed in 85% of cases. Ensemble delivery system was used (18 mm in 31%, 20 mm in 24%, 22 mm in 45%). The system was post-dilated in 63% of the procedures. Median procedure time was 170 minutes (range 85-360). No significant regurgitation was recorded after procedure while the trans-pulmonary gradient reduced significantly. Early complications occurred in 7 subjects (11%). Minor complications occurred in three subjects. One death occurred in the early post-operative period in a severely ill subject. Hospital stay was a median of 5 days (range 3-45 days). At a median follow-up of 30 months (range 12-48 months) three patients died due to underlying disease. Complications occurred in 6 patients: external electric cardioversion due to atrial fibrillation (1 pt), herpes virus encephalitis (1 pt), Melody valve endocarditis needing surgical explantation (2 pts), major fractures of the stent needing a second Melody valve implantation (2 pts). Freedom from valve failure at latest follow-up was 81.4%±9%.

Conclusion
Results of the SICP registry on transcatheter Melody pulmonary valve implantation shows that the procedure is safe and successful. Major concerns are related to the occurrence of stent fracture and bacterial endocarditis. Longer follow-up and larger series are needed.