PATIENT SELECTION FOR THE HARMONY TRANSCATHETER PULMONARY VALVE

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Background:

The Harmony TPV (Medtronic Inc, Minneapolis MN) was developed for regurgitant native RVOT self-expanding valve available in 2 sizes (TPV 22 and TPV 25). It was approved in Japan last year through international clinical trial in Japan and US. Because the anatomy of RVOT in this subgroup is highly variable and the device size are limited in only two, careful screening to ensure acceptable device fit is required. The screening of device fit is based on “Fit analysis” system provided by the industry. DICOM data of ECG-gated CT angiogram obtained in systole and diastole are sent online to industry. The data are analyzed focused on measurements of centerline-based perimeter of RVOT at specific regions in both phases corresponding to maximum and minimum. The anatomy of RV, RVOT, MPA, and proximal branch PAs are also evaluated. The patients report card provides not only the decision of device fit, but also recommendations for the optimal device landing zone on 3D virtual implant and appropriate projection angle while device deployment on virtual angiography.

Objectives:

To reevaluate the results of Fit analysis in a single center.

Methods:

Retrospective review of patients report cards of Fit analysis.

Results:

A total of 7 patients are referred to Fit analysis. Six are male. Age at Fit analysis are 16 to 57 years old. The basic diagnoses are TOF in for, PA/VSD in two and one is unknown (probably valvular PS and PDA). The number of previous median sternotomy are one (four patients) or two (three patients). RVEDV index and PR by CMR are 170 (SD 78) ml/m2 and 43 (DS 12) % respectively. One patient has significant left branch PS. One patient is not undergone CMR because of previous ICD implantation for sustained VT. Some patients have additional extra-

cardiac problems including liver cirrhosis, chronic myeloid leukemia, severe scoliosis, depression requiring multiple medication and blood transfusion refusal by Jehovah's Witnesses. They are selected from patients who met general criteria for PV replacement, according to physician's subjective assessment of maximum diameter and length of RVOT which meet the requirements of TPV 22 and 25. Two met criteria for implant of TPV 22 and five met for TPV 25 (two met both). Two did not tolerate both, because of insufficient interference fit to RVOT, which could not be evaluated with the physician's naked eye. Beneficial information for following device implantations were obtained from virtual assessment in patient report card.

Conclusion:

The screening system using Fit analysis is unique and valuable to ensure acceptable device fit to highly variable RVOT.