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Importance of Contrast Aortography With Lotus Transcatheter Aortic Valve Replacement

A Post Hoc Analysis From the RESPOND Post-Market Study

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ABSTRACT

OBJECTIVES The aim of this post hoc analysis from the RESPOND (Repositionable Lotus Valve System-Post-Market Evaluation of Real World Clinical Outcomes) post-market study was to assess the final implantation depth on the contrast aortogram after Lotus valve (Boston Scientific, Marlborough, Massachusetts) transcatheter aortic valve replacement (TAVR) and to correlate with permanent pacemaker implantation (PPI) and paravalvular leak (PVL).

BACKGROUND Contrast aortography allows for the assessment of implantation depth and PVL during and after TAVR. Previous reports suggested an association between final device position and rates of PPI and PVL.

METHODS The RESPOND study was a prospective, open-label, single-arm study in 41 centers evaluating outcomes after Lotus TAVR in routine clinical practice. Aortograms were collected at the Erasmus Medical Center and analyzed by researchers who were blinded to clinical outcomes. The primary analysis correlated implantation depth with PPI and PVL and required aortograms in a coaxial projection. The relation between implantation depth and need for PPI was assessed by multivariate logistic regression, adjusting for pre-defined confounders. A secondary analysis compared PVL analysis by contrast aortography with transthoracic echocardiography (TTE) performed by the independent core laboratory.

RESULTS A total of 724 angiographic studies were included in this analysis. Mean Lotus implantation depth was 6.67 ± 2.19 mm. The overall PPI rate was 35%. PPI rate was lower with shallow implants (<6.5 mm: 21% vs. ≥6.5 mm: 41%; $p < 0.001$). After adjustment for confounders, implantation depth independently predicted need for PPI (odds ratio per 1-mm increment in depth: 1.200; 95% confidence interval: 1.091 to 1.319; $p = 0.002$). More than trivial PVL was present in 23% by contrast aortography and in 8% by TTE. Implantation depth was not correlated with PVL by contrast aortography or TTE ($p = 0.342$ and $p = 0.149$, respectively). PVL grading by contrast aortography and TTE was concordant in 77%.

CONCLUSIONS In this post hoc analysis of the RESPOND study PPI was highly correlated with implantation depth, whereas PVL was not. Higher Lotus implantation may reduce need for PPI. (J Am Coll Cardiol Intv 2018;11:119–28) © 2018 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

LVOT = left ventricular outflow tract

OR = odds ratio

PPI = permanent pacemaker implantation

PVL = paravalvular leak

RBBB = right bundle branch block

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

TTE = transthoracic echocardiography

Transcatheter aortic valve replacement (TAVR) is recommended for symptomatic severe aortic stenosis in patients at elevated surgical risk (1-7). Multiple transcatheter heart valve (THV) designs are commercially available (8). The Lotus valve (Boston Scientific, Marlborough, Massachusetts) is a mechanically expanding system and includes an adaptive seal. These features make it completely repositionable and retrievable for precise placement as well as minimizing paravalvular leak (PVL) (9,10). The RESPOND (Repositionable Lotus Valve System-Post-Market Evaluation of Real World Clinical Outcomes) study was a prospective post-market study including 1,014 patients from 41 centers and confirmed Lotus valve safety and efficacy with an 2.6% all-cause mortality and 2.2% disabling stroke rate at 30 days with more than mild PVL in 0.3% and permanent pacemaker implantation (PPI) undertaken in 30% of patients (11). TAVR in its current form no longer requires general anesthesia and relies mostly on fluoroscopic guidance. Operators use contrast aortography to determine the implantation depth, device position relative to the coronary ostia, and final PVL assessment. The aim of this post hoc analysis from the RESPOND study was to assess the final implantation depth on the contrast aortogram after Lotus TAVR and to correlate with need for PPI and PVL.

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METHODS

STUDY POPULATION AND DESIGN. The design and outcomes of the RESPOND post-market study (NCT02031302) have been reported elsewhere (11). In brief, 1,014 patients with elevated operative risk were treated with Lotus TAVR and prospectively enrolled. An independent core laboratory (Cardialysis, Rotterdam, the Netherlands) analyzed the transthoracic echocardiography (TTE).

Clinical events were reported through electronic clinical research forms using the latest Valve Academic Research Consortium-2 criteria (12); all events were monitored by a contract research organization, and an external independent medical reviewer adjudicated death and stroke. The final contrast aortograms after implantation of the Lotus valve were collected and transferred to the Erasmus Medical Center for centralized uniform and blinded analysis. All patients provided written informed consent for participation in the RESPOND study. The primary objective of this study was to correlate depth of Lotus implantation with need for PPI and occurrence of more-than-trivial PVL by contrast aortography. A secondary analysis looked at the concordance of PVL grading between contrast aortography and pre-discharge TTE as assessed by the independent core laboratory.

DATA QUALITY. The current analysis used the as-treated population from the RESPOND study (n = 996) and excluded 132 patients with a pacemaker before TAVR. Of the 864 patients without a pacemaker a final contrast aortogram was not acquired in 140 patients, thus 724 cases were available for the final analysis.

For the PVL analysis contrast aortograms were submitted to the following quality check: 1) presence of sufficient contrast volume; 2) pigtail located >2 cm above the aortic annulus; and 3) no wire across the Lotus valve. Of the 724 cases, 36 (5%) did not meet these criteria and were thus removed from the PVL analysis (**Figure 1**).

Previous reports suggested an error in measuring the implantation depth if the aortogram had been obtained in a noncoaxial projection (13). To address this matter, all participating centers were requested to perform a baseline and final aortogram in the same coaxial C-arm projection with the 3 coronary cusps aligned. Ultimately, 506 of 724 (70%) aortograms were acquired using a coaxial projection. Only aortograms in coaxial projection were used for the primary implantation depth analysis.

DATA ANALYSIS. Dedicated trained clinical researchers, who were blinded to clinical and echocardiographic results, analyzed all aortograms. Measurements were performed with Cardiovascular Angiographic Analysis System version 5.11.2 (Pie Medical Imaging, Maastricht, the Netherlands). Core measurements consisted of the final implantation depth at the noncoronary and left coronary

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