Quantitative Assessment of Acute Regurgitation Following Transcatheter Aortic Valve Replacement: A Multicenter Pooled Analysis of 2,258 Valves

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Running title: Quantitative Regurgitation after TAVR

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Tweet/handle: @R_Modolo; In this study, Modolo et al. performed an independent core lab analysis of PVL after TAVR in a large “real-world” cohort, finding lower regurgitation rate with newer devices.
ABSTRACT

Background: Regurgitation following transcatheter aortic valve replacement (TAVR) impacts all-cause mortality. Thus far, no quantitative comparison of regurgitation amongst multiple commercially available transcatheter heart valves (THV) has been performed.

Objectives: We sought to assess the acute regurgitation following TAVR comparing different implanted THV.

Methods: Aortograms from a multicenter cohort of consecutive 3,976 TAVR were evaluated in this pooled analysis. A total of 2,258 (58.3%) were considered analyzable by an independent academic core lab using videodensitometry. Results of quantitative regurgitation are shown in percentage. Valves evaluated were: Acurate (n=115), Centera (n=11), CoreValve (n=532), Direct Flow Medical (n=21), Evolut Pro (n=95), Evolut R (n=295), Inovare (n=4), Lotus (n=546), Lotus Edge (n=3), Sapien XT (n=239) and Sapien 3 (n=397). For the main analysis only valves with more than 50 procedures (7 types) were used.

Results: Lotus valve had the lowest mean regurgitation (3.5±4.4%), followed by Evolut Pro (7.4±6.5%), Sapien 3 (7.6±7.1%), Evolut R (7.9±7.4%), Sapien XT (8.8±7.5%), Acurate (9.6±9.2%) and CoreValve (13.7±10.7%, ANOVA p-value<0.001). The only valves that statistically differed from all their counterparts were Lotus (as the lowest regurgitation) and CoreValve (the highest). The proportion of patients presenting a moderate or severe regurgitation followed the same ranking order: Lotus (2.2%), Evolut Pro (5.3%), Sapien 3 (8.3%), Evolut R (8.8%), Sapien XT (10.9%), Acurate (11.3%) and CoreValve (30.1%) – chi-square p-value <0.001.

Conclusion: In this pooled analysis stemming from daily clinical practice, the Lotus valve showed to have the best immediate sealing. This analysis reflects the objective evaluation of regurgitation by an academic core lab (non-sponsored) in a real-world cohort of patients using a quantitative technique.

KEY WORDS: transcatheter aortic valve replacement, paravalvular leak, aortic regurgitation.

CONDENSED ABSTRACT

Quantitative assessment of regurgitation after TAVR in a multicenter analysis of different valves. A total of 2,258 were analyzable by a core lab and showed that the amount of regurgitation was lower after Lotus implantation (3.5±4.4%), followed by Evolut-Pro (7.4±6.5%), Sapien-3 (7.6±7.1%), Evolut-R (7.9±7.4%), Sapien XT (8.8±7.5%), Acurate (9.6±9.2%) and CoreValve (13.7±10.7%, ANOVA p-value<0.001). The only valves that statistically differed from all their counterparts were Lotus (as the lowest regurgitation) and CoreValve (the highest).

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation
LV = left ventricle
LVOT = left ventricle outflow tract
LVOT-AR = quantitative regurgitation
PVR = paravalvular regurgitation
ROI = region of interest
TAVR = Transcatheter aortic valve replacement
THV = transcatheter heart valve
INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is proven to be a safe and effective therapy for patients with severe aortic stenosis and has recently expanded its indication to low surgical risk patients (1,2). Currently, an estimated 270,000 patients are potential candidates for TAVR annually in the European Union and Northern-America countries combined (3). Paravalvular regurgitation (PVR) after TAVR is a major predictor of short- and long-term survival (4) and an important factor in composite endpoints in trials comparing TAVR with surgical approach, and TAVR vs. TAVR, such as the SCOPE 1 (5). Thus, PVR should be assessed and properly quantified in the catheterization laboratory. Thus far, echocardiography was considered the gold standard of PVR assessment. However, echocardiographic assessment of regurgitation is semi-quantitative, operator-dependent and not reproducible – even when performed by core laboratories (6). Furthermore, transthoracic echocardiography in a supine patient in the catheterization laboratory may be challenging and sub-optimal. Recently, quantitative assessment of regurgitation with aortogram has emerged and validated in vitro and in vivo with favorable reproducibility and accuracy (4,7-12). In addition, regurgitation assessed with this quantitative assessment immediately after TAVR has shown to have prognostic value (4).

To date little is known about comparative quantitative angiographic assessment of regurgitation in clinical trials comparing transcatheter heart valves (THV) to determine objectively the acute regurgitation after TAVR. Thus, we sought to evaluate aortograms from clinical practice in a large multicenter cohort of TAVR patients in order to determine the sealing features amongst multiple commercially available THV platforms.

METHODS

Study population. The present study is a retrospective analysis of aortograms from a multicenter, multicontinental cohort of consecutive patients that underwent TAVR following
each participating Institution’s Heart Team recommendation. The study complied with the Declaration of Helsinki and Good Clinical Practices and was approved by each Institutions ethical committees. A listing of participating centers, collaborators and periods of inclusion is provided in the Supplemental appendix (Supplementary Table 1).

**Angiographic quantitative assessment of regurgitation.** Quantitative assessment of regurgitation was performed using the videodensitometry technique, described previously (4,7,9,11). This technique relies solely on the aortogram acquired after the transcatheter implantation of the valve. Briefly, the software (CAAS A-valve 2.0.2 – research mode, Pie Medical Imaging, Maastricht, The Netherlands) constructs two time-density curves: in the aortic root (where the contrast is injected), and in the left ventricle outflow tract (LVOT, the obligatory pathway of regurgitation towards the left ventricle). The ratio of the area under these 2 curves (LVOT / aortic root) is the continuous regurgitant fraction, given in percentage, namely LVOT-AR (Figure 1). Only the final aortogram was used for analysis, i.e. if the patient underwent a balloon post-dilatation or repositioning of the device, the aortogram to be assessed was always the final one. Angiographic contrast medium type, volume (mL), and injection rate (mL/s) were left to the discretion of the operators. The analysis was performed by an independent academic core laboratory in Rotterdam, the Netherlands, not financially subsidized by the industry.

**Feasibility of retrospective assessment.** Since the quantitative analysis is based on the density changes over time in the aortic root (reference area) and LVOT (region of interest - ROI), no overlapping of the opacified ROI or reference area with other opacified structures (e.g. descending aorta), encompassed in the 2D angiogram, can occur during the entire acquisition, as it may influence the final result (Figure 2). Thus, due to the retrospective nature of the assessment, without pre-planning of aortogram projection, this overlapping was
frequent, resulting in a moderate feasibility of analysis by the core lab. A list of reasons for the cases assessed as non-analyzable are shown in Figure 3.

**Valve comparison.** The investigators opted to perform the comparison among all THV that had at least a sample size of 50 analyzable, for improved reliability of the findings. Comparison amongst the THV types was performed either with regards to the amount of regurgitation (continuous variable assessment of LVOT-AR) and with regards to the proportion of patients (categorical variable) with that particular THV presenting a moderate or severe regurgitation, with a predetermined threshold criteria of LVOT-AR > 17%, previously identified as moderate/severe regurgitation with respect to echocardiogram (4,9). In addition, it has been shown that the same threshold of regurgitation is an independent predictor of long-term all-cause mortality (4).

**Statistical analysis.** All regurgitation evaluations were performed in the entire population. For the final statistical analysis, Centera (n=11), Direct-Flow-Medical (n=21), Inovare (n=4) and Lotus-Edge (n=3) were excluded for not reaching the determined sample size of 50. The results of regurgitation fraction are shown in mean values and standard deviation of the mean for each valve. Parametric tests for continuous variables were used relying on the concept of central limit theorem (13). Comparison of quantitative regurgitation was performed with one-way ANOVA, and two by two comparisons with post-hoc Bonferroni test. Patients were dichotomized into: none to mild regurgitation (LVOT-AR ≤ 17%) and moderate to severe regurgitation (LVOT-AR>17%). Proportion of patients with LVOT-AR>17% was compared using Chi-square or Fisher’s exact test when appropriate. Stratification of continuous variable regurgitation into categorical variables was performed according to the following predetermined threshold criteria: (i) none or trace regurgitation (LVOT-AR < 6%), (ii) mild (6% ≤ LVOT-AR ≤ 17%) and (iii) moderate or severe (LVOT-AR > 17%) (4,10). A two-sided p-value of 0.05 was considered indicative of statistical
significance. All statistical analyses were performed with SPSS software, version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Quantitative aortogram population. A total of 3,976 aortograms were evaluated by the core lab. Out of those, 2,258 (58.6%) aortograms were analyzable and underwent core lab quantitative assessment of regurgitation. The THV with analyzable angiographies were as follows: Lotus Edge (n=3, 0.1%), Inovare (n=4, 0.2%), Centera (n=11, 0.5%), Direct Flow Medical (n=21, 0.9%), Evolut Pro (n=95, 4.2%), Acurate (n=115, 5.1%), Sapien XT (n=239, 10.6%), Evolut R (n=295, 13.1%), Sapien 3 (n=397, 17.6%), CoreValve (n=532, 23.6%) and Lotus (n=546, 24.2%).

Out of the THV excluded from the main analysis for having a sample size less than 50, the mean values of regurgitation fraction (LVOT-AR) were: Lotus Edge (median, Q1 – Q3; 8.0%, 6.0 – ), Inovare (5.0%, 1.25 – 10.25), Direct Flow Medical (4.0%, 1.5 – 9.0) and Centera (8.0%, 6.0 – 10.0). Among the valves retained in the pooled analysis, Lotus valve had the lowest mean regurgitation (3.5 ± 4.4%), followed by Evolut-Pro (7.4 ± 6.5%), Sapien-3 (7.6 ± 7.1%), Evolut-R (7.9 ± 7.4%), Sapien XT (8.8 ± 7.5%), Acurate (9.6 ± 9.2%) and CoreValve (13.7 ± 10.7%, ANOVA p-value<0.001) – Figure 4. Post-hoc two-by-two testing revealed that Lotus had significantly (p<0.05) lower regurgitation compared with each of the other valves. Similarly, the first generation CoreValve had significantly higher regurgitation compared with each of the counterparts. Apart from CoreValve and Lotus, no other valve differed in the amount of regurgitation from each other.

Moderate or severe regurgitation. The proportion of patients presenting a moderate or severe regurgitation, within each THV group, follows the same ranking order previously described for the continuous variable of regurgitation of the valves. The Lotus valve has the lowest proportion of patients with LVOT-AR > 17% (2.2%), followed by Evolut Pro (5.3%),
DISCUSSION

The main findings of the present study are that:

(i) The Lotus valve has the least amount of regurgitation compared to all the other evaluated valves and is also the valve with the lower proportion of patients with moderate/severe regurgitation categorized by videodensitometry of the angiogram.

(ii) The first generation CoreValve presents the highest regurgitation fraction amongst the evaluated valves.

(iii) The amount of regurgitation amongst all the other evaluated THV (Evoluts R and Pro, Sapien 3, Acurate and Sapien XT) are slightly numerically different, but statistically similar.

(iv) Protocol for aortogram acquisition is required for optimal evaluation of videodensitometry.

To the best of our knowledge, this is the first study to compare the acute regurgitation following TAVR in multiple different available devices, with an objective assessment in a large cohort of consecutive “real-world” patients.

It has been established that regurgitation after TAVR is closely linked to morbidity and all-cause mortality (4,14). Categorizing patients in strata of regurgitation insufficiently discriminate them with regards to clinical outcomes; since even mild paravalvular regurgitation has been associated with poor outcomes and increased mortality (15,16). Thus far, regurgitation assessment in clinical trials of TAVR vs. surgery or TAVR vs. TAVR has relied on qualitative and semi-quantitative evaluation with transthoracic echocardiogram after the procedure – usually at 30 days post-TAVR. Hahn et al. (6) have previously shown that even between core laboratories, reproducibility of this evaluation by echocardiogram is low. The agreement in regurgitation assessment between a consortium of echocardiographic core
laboratory directors and the Placement of Aortic Transcatheter Valves (PARTNER) IIB trial
core laboratory was considered weak (17) (Kappa=0.48 for the 4-class grading of
paravalvular regurgitation and Kappa=0.52 for the 7-class grading) (6).
Videodensitometric analysis of regurgitation is an objective method of evaluation of
regurgitation derived from time-density analysis of the angiography. It has been validated
both in vitro and in vivo, and compared with regards to echocardiogram (both transthoracic
and transesophageal) and cardiac magnetic resonance imaging (4,7-10,12,18). Although the
feasibility of analysis was moderate in the current study, due to the retrospective nature of the
analysis, the multicenter ASSESS-REGURGE study (19) has recently showed that a simple
protocol of image acquisition renders the feasibility of analysis almost perfect (95.5% of
analyzability) (19). Its continuous variable (in percentage of regurgitation) may increase
discrimination of regurgitation even within the same strata of echocardiographic evaluation
(e.g. within none/trace or mild regurgitation) – thus adding diagnostic information at the time
of the procedure. In addition, this method has shown to be highly reproducible, with an inter-
observer correlation coefficient of 0.95 (p<0.0001, Bland-Altman: mean difference±SD:
0.01±0.04, p=0.3261) and intraobserver of 0.97 (p<0.0001, Bland-Altman: mean
difference±SD: 0.01±0.05, p=0.5280) (4). The advent of the minimalist approach for TAVR
and consequent increasingly uncommon use of intraprocedural transoesophageal
echocardiography should not preclude an accurate evaluation of post-implantation
regurgitation. This can be achieved with quantitative analysis of the aortogram using
videodensitometry.

The THV with the lowest regurgitation amount in our analysis was the Lotus valve.
Interestingly, this advantage was seen with the first-generation Lotus which has been
discontinued and was replaced by the Lotus Edge. In our analysis, there were insufficient
Lotus Edge (n=3) cases to include in the primary analysis, but nevertheless, this new THV
appears to have a similar sealing profile (mean regurgitant fraction of 3.3%) to the predicate first generation Lotus (3.5%). Another interesting finding is the comparison among the THV recently approved for low risk patients – The Evolut (R and Pro) and the Sapien 3. Recent clinical trials of these valves reported rates of 3.5% and 0.8% of moderate or severe regurgitation at 30 days with the Evolut and Sapien systems, respectively (1,2). Our findings show higher proportions than those reported: 5.3% and 8.8% of patients with Evolut Pro and R, respectively, and 8.3% of patients with the Sapien 3 valve. One explanation for this consistently higher proportion of patients with greater than mild regurgitation in our study is that we are assessing the immediate regurgitation (within seconds to minutes after implantation), as opposed to EVOLUT Low risk and PARTNER 3 trials that used 30-day echocardiogram (1,2). The sealing feature of the anti-leak skirts of novel devices may take minutes to achieve its complete functionality. Thus, a later stage echocardiogram may assess the regurgitation with a fully operating anti-leak skirt, with consequently a lower amount of regurgitation. Nevertheless, in our study, the amount of regurgitation (as a continuous variable) of the Evolut valves and Sapien 3 are virtually similar (7.35%, 7.58% and 7.86% for Evolut Pro, Sapien 3 and Evolut R, respectively), raising the hypothesis that, with an objective and reproducible assessment, their immediate regurgitation amounts may not differ. The introduction of the anti-leak skirt appeared to have greatly benefited regurgitation in the THV. Our analysis can exemplify the improvement in post-TAVR paravalvular regurgitation caused by introduction and improvement of the skirt. Namely the decrease in regurgitation from CoreValve to Evolut R and Pro is noticeable.

Quantitative assessment of regurgitation with videodensitometry would allow, on one hand, for a better evaluation of the sealing features of the newer devices, especially with the constant development of novel devices and, on the other hand, for assessment of immediate result following future TAVR scenarios: (i) for aortic regurgitation patients, (ii) for novel
bioengineered or biorestorative leaflets and (iii) for bicuspid aortic valve patients. In addition, an analysis independent from the industry is less prone to bias. Collecting post-market data adds real-life data to the data from pivotal trials that include highly selected population.

**Limitations.** Our study presents several limitations that should be acknowledged. First, this is a pooled analysis of real-world patients undergoing TAVR, thus, no randomization was performed for the valve comparison, what may inherently lead to selection bias. Though this is a limitation, it could conversely be perceived as a positive methodological strength, since we relied on post-market clinical practice data form consecutive patients in multiple centers. Second, since this was a retrospective analysis of aortograms, without a proper acquisition protocol, the feasibility of analysis was rendered moderate, and 41% of the aortograms were not analyzable. For prospective analysis we know that a simple protocol for acquisition may render the analyzability almost perfect (95.5% in the multicenter ASSESS-REGURGE Registry)(19). The purpose of the present analysis was to show the different regurgitation patterns amongst the valves. Thus, no information regarding calcification, presence of bicuspid valves, aortic annulus size and shape, THV diameter, technique and depth of implantation were collected (20-22).

**CONCLUSIONS**

The Lotus valve had the lowest amount of acute regurgitation post-TAVR and the first generation CoreValve had the highest. This objective assessment may be of great value for clinical trials of TAVR, comparing different valves, techniques of implantation or clinical scenarios. These results should be confirmed in prospective cohorts randomized patients with head-to-head comparisons.

**PERSPECTIVES**

**WHAT IS KNOWN?**
Aortic regurgitation following TAVR negatively impacts patients’ outcomes. To date little is known about comparative quantitative angiographic assessment of regurgitation in clinical trials comparing THVs to determine objectively the acute regurgitation after TAVR.

**WHAT IS NEW?**
This study evaluated independently and with an objective and validated tool the aortic regurgitation immediately after TAVR, comparing PVL in multiple commercially available valves in daily clinical practice. We found that the Lotus valve was the one with less regurgitation after TAVR in the “real-world”.

**WHAT IS NEXT?**
This technique of analysis could be implemented in future randomized clinical trials comparing different transcatheter aortic valves – and also newly developed devices – to objectively differentiate their sealing features.
REFERENCES


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FIGURE LEGENDS

**Figure 1.** Schematic representation of the quantitative aortogram calculation of regurgitation with videodensitometry. On the left panel we can see the representation of the left ventricle outflow tract as the region of interest in yellow and the aortic root as the reference area in red. On the right panel two time-density curves constructed according to the increase in density (y-axis) for the reference area (red) and the region of interest (yellow). The ratio of the area under both curves represents the result of quantitative regurgitation (LVOT-AR). AUC: area under the curve; ROI: region of interest; LV: left ventricle. Reproduced with permission from Modolo et al. (19)

**Figure 2.** Three-dimensional computed tomography reconstruction of the aorta (ascending and descending – in orange) and the left ventricle outflow tract (purple). In this image we can appreciate the location of the reference area (aortic root) and of the region of interest (LVOT). On the left corner the demonstration of the C-arm position and the angulation and rotation for this image acquisition during angiography. In this particular case there is overlapping of the region of interest with the descending aorta, thus making this projection unfeasible for a proper evaluation of LVOT-AR. LVOT: left ventricle outflow tract; RAO: right anterior oblique; CAUD: caudal; dAo: descending aorta. Modified from Sahyoun presentation in Paris, France, at EuroPCR 2017. Image is a courtesy of Dr. Cherif Sahyoun.

**Figure 3.** Flowchart of core laboratory quantitative assessment of regurgitation in all post-TAVR evaluated angiographies.

**Figure 4.** Comparison of LVOT-AR amongst the most implanted valves in the cohort showing different regurgitation amongst the evaluated valves. Regurgitation after Lotus implantation was significantly lower compared with each other valves and regurgitation following first generation CoreValve implantation was significantly higher compared with
each other valves. Bars are the mean regurgitation values and the error bars are standard errors of the mean.

**Figure 5.** Cumulative frequency curves for the valves divided by the one with least regurgitation (Lotus – green), the one with the highest regurgitation (CoreValve – red) and the other evaluated valves (Evolut R and Pro, Sapien XT and 3 and Acurate – all in blue). The light blue background shows the area above 17% of regurgitation, meaning moderate or severe regurgitation.

**Central Illustration.** Cumulative percentage of the different degrees of post-TAVR aortic regurgitation assessed with quantitative aortogram. Green shows the incidence of none or trace regurgitation, blue shows mild regurgitation and red the moderate or severe aortic regurgitation.
3,976 TAVR cases evaluated

3,873 Aortograms

1,615 non-analyzable:
• 892 overlapping of the descending aorta with ROI
• 219 deep breathing
• 190 overlapping of the descending aorta with reference area
• 36 table motion
• 31 insufficient time of image acquisition
• 11 radiopaque structures in the ROI
• 10 insufficient contrast in the aortic root
• 226 other

103 patients with no final aortogram performed

2,258 Aortograms Analyzed

Feasibility of analysis 58.3%
ANOVA p-value <0.001

* p<0.05 vs. all other valves
⊕ p<0.05 vs. Lotus and Corevalve, p=NS vs. the other valves
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Article entitled: Quantitative assessment of acute regurgitation following transcatheter aortic valve replacement: Multicenter pooled analysis of 2,258 valves

Manuscript number: JINT021620-0340
Corresponding Author: Dr. Serruys
Corresponding author's printed name: Patrick Serruys
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Article entitled: Quantitative assessment of acute regurgitation following transcatheter aortic valve replacement: Multicenter pooled analysis of 2,258 valves

Manuscript number: JINT021620-0340R

Corresponding Author: Dr. Serruys

Corresponding author's printed name: Patrick Serruys

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Manuscript number: JINT021620-0340

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