

EDITORIAL

Resheathing and Repositioning During Transcatheter Aortic Valve Implantation

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The Evolut platform (Medtronic, Minneapolis, MN) and the Portico (Abbott, Abbott Park, IL) are self-expanding transcatheter heart valves (THVs) designed with recapturable and repositionable capabilities to achieve optimal device deployment during transcatheter aortic valve implantation (TAVI). Importantly, the recapture/resheathing capability incorporated in the Evolut THV platform has led to improving device success and lowering procedural mortality and the need for permanent pacemaker implantation (PPI), as well as the degree of paravalvular regurgitation, in comparison with its processor, the classic CoreValve (Medtronic) THV.^{1,2}

See Article by Bernardi et al.

The reported rates of recapture/resheathing for THV repositioning ranges from 25% to 35% with Evolut R/PRO³⁻⁵ and 33% to 44% with Portico⁶⁻⁸ devices. Because of extended maneuvers at the level of the aortic valvar complex, there have been procedural-safety concerns in light of the potential risks for aortic valve-tissue embolization should resheathing and repositioning be required.⁹

Kefer et al¹⁰ initially investigated the impact of multiple resheathing on procedural and clinical outcomes, and the authors reported the need for overall resheathing in 22.9% of the self-expanding cases. Although the THV was recaptured once in 15.9% of cases, multiple resheathing was needed in 8.8% of patients (twice in 6.5% and 4 times in 0.6%). Full resheathing was required

in 10% of cases, whereas partial was required in 12.9% of implants. The outcomes were similar among patients undergoing multiple versus single recapture and those requiring partial versus full recapture.

In this issue of the *Journal of the American Heart Association (JAHA)*, Bernardi and colleagues¹¹ report the results of a retrospective observational study assessing the impact of recapturing/resheathing (partial or full attempt) for THV repositioning during TAVI with the Evolut R (n=720, 70.2%), Evolut PRO (n=117, 11.4%), and Portico (n=189, 18.4%) THVs between June 2014 and May 2020. Of 1023 participants, 336 (32.7%) required 1 resheathing and 95 (9.3%) required multiple (≥ 2) resheathing, with a median of 2 attempts per patient (interquartile range, 2–3; range, 2–6).

The present study agrees with the findings of Kefer et al¹⁰ reporting the need for multiple resheathing in roughly 9% of the cases, but also expands the previous knowledge by adding more granularity to help elucidate potential underlying issues behind the multiple resheathing matter. The authors found that resheathing and repositioning were mostly required with the use of the Portico THV. Conscious sedation was less frequently used among individuals who needed multiple resheathing, and this group also required more balloon pre- and postdilation, as compared with the no-resheathing and single-resheathing counterparts. The presence of moderate/severe aortic regurgitation at baseline (odds ratio, 2.33; 95% CI, 1.4–3.87) and the use of the Portico THV (odds ratio, 2.81; 95% CI, 1.68–4.7) were identified as independent factors associated with the need for multiple resheathing.¹¹

Key Words: Editorials ■ aortic valve ■ aortic valve stenosis ■ transcatheter aortic valve replacement ■ self-expanding ■ resheathing

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Device success rate was lower among patients with multiple resheathing, although similar with single resheathing as compared with no resheathing (80% versus 89.8% versus 89.9%, respectively; $P=0.01$), and this was mostly driven by the need for a second valve and THV embolization. No differences were observed in terms of procedural death, life-threatening bleeding, stroke, acute kidney injury (AKI), or the need for PPI. Moderate/severe aortic regurgitation at baseline (odds ratio, 0.47; 95% CI, 0.3–0.76; $P=0.002$) and multiple resheathing (odds ratio, 0.42; 95% CI, 0.23–0.74; $P=0.003$) were factors independently associated with lower device success rate, and these estimates remain unchanged after a sensitivity analysis excluding individuals who underwent TAVI with the Portico THV.¹¹

At 30 days, there was a similar rate of all-cause death, stroke, and other safety outcomes among the groups; however, multiple resheathing was associated with increased 1-year mortality in comparison with no resheathing and single resheathing groups (18.8% versus 10.5% versus 8.0%, respectively, $P=0.014$). Chronic obstructive pulmonary disease (hazard ratio, 1.74; 95% CI, 1.11–2.73; $P=0.03$), multiple resheathing (hazard ratio, 2.06; 95% CI, 1.18–3.6; $P=0.01$), and lower center volume (<25 self-expanding cases; hazard ratio, 1.89; 95% CI, 1.06–3.36; $P=0.03$) were the factors independently associated with cumulative mortality.¹¹

CLINICAL INSIGHTS BEHIND DIFFERENCES IN OUTCOMES WITH RESHEATHING DURING TAVI

The authors show that outcomes between no resheathing versus single resheathing are essentially similar; and, interestingly, the 1-year survival analyses favor, numerically, the single resheathing group, and this finding was consistent with and without Portico patients. Therefore, the fact that individuals requiring multiple resheathing experienced worse 1-year outcomes should be interpreted with caution, and the rationale behind this finding deserves further elaboration. Although several variables were used for the adjustment in the multivariable analysis, because of the retrospective nature of these type of studies, there is certainly a sizable amount of heterogeneity in the accuracy of data collection; hence, residual confounders cannot be excluded. As a matter of the fact, if a study computes and thus analyzes resheathing as a binary variable (Table) instead of categorical, such as the present article including a considerable number of procedures in which multiple resheathing were performed, they would have been pooled as a single resheathing. Even underreporting or misreporting would classify patients from multiple resheathing to single resheathing.

Considering that patients needing multiple resheathing underwent TAVI more often under general anesthesia

may let us infer, as acknowledged by the authors, that this subset of patients may have presented with a higher-risk clinical, anatomical, or hemodynamic profile, regardless of similar baseline STS (Society of Thoracic Surgeons) score, for which the heart team decided to offer general anesthesia, although anesthesia teams (center specific) preferences cannot be excluded either. In this regard, the use of transesophageal echocardiography guidance during THV positioning¹² may also have added a source of unmeasured confounding bias.

TECHNICAL AND MECHANISTIC DETERMINANTS INFLUENCING OUTCOMES

Bernardi and colleagues¹¹ showed that those who needed a single resheathing have nearly similar acute/periprocedural and intermediate-term outcomes; indeed, these patients showed numerically better cumulative survival than no resheathing. Notably, the authors make a provocative comment and take-home message stating that “it may be reasonable for the operators to consider changing the strategy/approach or type/size of the valve before final release in cases where multiple resheathing is needed.” However, because of its nonrandomized design, the actual or potential causal associations between multiple resheathing, a procedure-related issue, and subsequent increased hazard for 1-year mortality with multiple resheathing will remain unknown, simply because the study was underpowered to detect a hypothetical treatment effect size for this matter.

The authors also highlight the importance of the operator’s/center’s experience and showed no interaction between self-expanding THV center caseload and multiple resheathing with respect to device success and 1-year mortality. What remains difficult to explain is that individuals who underwent TAVI in centers performing <25 self-expanding cases per year had a 1.9-fold hazard of death at 1-year. As discussed above, a potential explanation would be that multiple resheathing could be a surrogate of higher-risk profile that, coupled with low volume/experience, turned to worse (1.6-fold odds) device success rates, with the inherent procedure-related complications, ultimately impacting on mortality at 1 year.

A trend analysis based on the number of times that resheathing was required would have helped determine if there was a time-dependent effect on learning curve. In this regard, Kefer et al¹⁰ showed that resheathing was more frequently required during the first half of Evolut R implants (30% versus 14%, $P=0.04$) but was equally required for the first and second half of Portico implants (12% versus 40%, $P=0.11$), though the latter is certainly subject to a small sample size.

The results of the present article are informative from the clinical and mechanistic perspectives, making us

revisit several aspects to bear in mind during our TAVI sessions and while using THVs with resheathing technology. Among others, special attention has to be paid to the angulation, dimension, and calcification of the aortic root, the type of guidewire as the default for self-expanding cases (stiffer support, preshaped guidewires), tracking the device toward the outer curvature aiming at the posterior aspect of the aortic root, performing ventricular pacing at 120 to 140 bpm (also known as "control pacing", often used for the cusp-overlap technique or to override ventricular wire-induced ectopy) during THV positioning and deployment to obtain device stability, and, importantly, to help mitigate the instability caused by moderate/severe aortic regurgitation that is often encountered, and confirmed by this study, in cases where multiple resheathing is required.

POTENTIAL COLLATERAL DAMAGE WITH RESHEATHING AND REPOSITIONING

It is expected that TAVI requiring multiple resheathing and repositioning would entail prolonged manipulations at the level of the aortic valvar complex, hereby

increasing the risk for debris embolization, but also interactions with the conduction system as well as the need for more contrast dye and subsequent risk of AKI.

The authors report a higher incidence of new-onset left bundle branch block among patients with multiple resheathing, although the need for new PPI was similar. From the anatomical and mechanistic perspectives,¹³ this finding makes lot of sense and is in line with the FORWARD Study (CoreValve Evolut R FORWARD Study),³ which showed a deeper final implant depth at the left coronary cusp (LCC) in the repositioned group, although this was not statistically significant.³ This was further confirmed in a recent post hoc analysis pooling the SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial continued access study and the Evolut Low Risk Trial, showing lower implant depth at the noncoronary cusp (data for Evolut Low Risk Trial patients only) of 4.1 ± 2.1 mm versus 3.6 ± 2.0 ($P=0.005$ and trend toward $P=0.05$), and lower implant depth at the LCC level, although rates of new PPI at 30 days and 1 year were similar.⁵ Interestingly, Kefer and colleagues¹⁰ reported higher rates of new PPI with resheathing (26%) versus no resheathing (16%), although they were not statistically different, again, likely because of a small sample size.

Table. Studies Reporting Data on Transcatheter Heart Valves Resheathing for Valve Repositioning

Author/study, year	Patients, n	Type of valve	% of resheathing	Summary of findings
Grube et al, 2017, FORWARD Study ³	1038	Evolut R	25.8%	<ul style="list-style-type: none"> >1 valve implanted was needed in 1.9% of resheathing/recapturing vs 0.7% ($P=0.08$) among those that did not. There were no differences in all-cause mortality (1.9% vs 1.8%, $P=0.96$) and all stroke (2.7% vs 2.9%, $P=0.83$) between cases using resheathing/recapturing capabilities and those that did not.
Seeger et al, 2019 ⁹	200	Evolut, R/ Evolut, PRO/ Lotus	11.5%	<ul style="list-style-type: none"> Periprocedural clinical stroke rate was not different between groups (2.8% in the 177 patients without repositioning vs 0% in the 23 patients with repositioning, $P=0.41$). Contrast amount of 85 ± 35 mL without vs 139 ± 181 mL with repositioning ($P<0.01$). Renal failure 1.7% without vs with repositioning 8.7% ($P=0.04$).
Attizzani et al, 2020, Evolut Low Risk and SURTAVI trials (pooled) ⁵	946	Evolut R/Evolut PRO	33.6%	<ul style="list-style-type: none"> There were no differences in death (0.3% vs 0.3%; $P=0.99$) or disabling stroke (0.3% vs 0.5%; $P=0.71$) at 30 d or 1 y (1.9% vs 2.9%; $P=0.44$ and 0.8% vs 0.9%; $P=0.79$, respectively) with repositioning vs no repositioning. 30-d nondisabling stroke (3.9% vs 2.0%, respectively; $P=0.09$). 30-d pacemaker implantation rate was similar between groups (19.1% repositioned group vs 16.3% nonrepositioned group, $P=0.26$). Acute kidney injury was higher in the repositioned group (2.2% vs 0.5%, $P=0.01$). Coronary obstruction was higher in the repositioned group (1.6% vs 0.2%, $P=0.01$). Moderate or severe PVL at 1 y was similar between groups (4.6% repositioned group vs 4.1% nonrepositioned group, $P=0.83$).
Kefer et al, 2020 ¹⁰	170	Evolut, R/ Portico	Overall=23%, Evolut R=24%, Portico=26%	<ul style="list-style-type: none"> Multiple (≥ 2 attempts) resheathing 22.9%. Device success and in-hospital death was not different between groups ($P=0.93$ and $P=0.67$, respectively). New pacemaker implantation was needed in 26% with resheathing and 16% without resheathing ($P=0.23$). Stroke rate was 2% with resheathing and 0.7% without resheathing ($P=0.18$). Overall and event-free survival was similar between groups at 1, 2, and 5 y.

FORWARD indicates CoreValve Evolut R FORWARD Study; PVL, paravalvular leak; and SURTAVI, Surgical Replacement and Transcatheter Aortic Valve Implantation.

In terms of stroke, it is important to highlight that 4 studies,^{5,9–11} including Bernardi et al, show comparable rates of stroke with repositioning and no repositioning. However, Attizzani and colleagues,⁵ in a substantially larger study, showed almost double incidence of non-disabling stroke with resheathing (3.9% versus 2.0%, $P=0.09$), yet the overall stroke rate remained similar compared with no resheathing.

Attizzani et al⁵ also reported a more prolonged time with the delivery catheter in the body (18.5±19.0 versus 15.6±17.4 minutes, $P=0.02$), whereas times in the procedure room were similar. One may argue about the clinical impact of 3 more minutes if this would lead to achieving an optimal implant. Nonetheless, the authors also found that coronary obstruction occurred more often in the repositioned group (1.6% versus 0.2%, $P=0.01$).⁵

Seeger et al⁹ and Kefer et al¹⁰ showed a higher amount of contrast dye with repositioning (139±181 versus 85±35 mL, $P<0.01$ and 243±93 versus 217±93 mL, $P=0.009$, respectively); however, ambiguous results with regard to the occurrence of AKI should be mentioned. While Seeger et al⁹ and Attizzani et al⁵ found higher incidence of AKI with resheathing/repositioning (8.7% versus 1.7%, $P=0.04$ and 2.2% versus 0.5%, $P=0.01$, respectively), the studies by Kefer et al and Bernardi et al show comparable results.^{10,11} These findings are relevant based upon the well-known deleterious impact of AKI on follow-up outcomes.¹⁴ A summary of the studies reporting data on THV resheathing for valve repositioning is presented in the Table.

In summary, Bernardi et al's¹¹ work highlight that there are specific THV-type mechanistics coupled with clinical and anatomical features that play a role in terms of THV system stability during valve positioning, translating into the need for resheathing and repositioning to achieve optimal results. This article shed further light on to the importance of the operator's experience with different THVs as well as clinical factors that are neither related to the procedure nor type of THV, but will, undoubtedly, impact on intermediate and long-term outcomes. The major uncertainty that still remains, perhaps the most relevant, is the lack of a preprocedural prediction model to help identify patients who would require resheathing or repositioning during TAVI. So, to resheath, or not to resheath during TAVI? Sure, but with finesse.

ARTICLE INFORMATION

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