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ORIGINAL ARTICLE

Prognostic impact of remote dielectric sensing value following TAVR

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Abstract
Remote dielectric sensing (ReDS) system non-invasively quantifies pulmonary congestion. Re-admission following trans-catheter aortic valve replacement (TAVR) remains an unsolved matter. Residual pulmonary congestion is a strong risk factor of worse clinical outcomes in patients with heart failure. ReDS system may have a prognostic impact in patients undergoing TAVR. Patients who received TAVR and ReDS measurements during index hospitalization between 2021 and 2022 were included. The prognostic impact of ReDS value on the composite endpoint of death or re-admission following index discharge was investigated. Totally, 42 patients (median 84 years, 14 men) were included. Median ReDS value at index discharge was 27% (24%, 30%) and 10 patients had ReDS values > 30%. During a median of 316 (282, 354) days following index discharge, a higher ReDS value at baseline was independently associated with the incidence of composite endpoint with an adjusted hazard ratio of 1.32 (95% confidence interval between 1.10 and 1.58) with a calculated cutoff of 30%, which significantly stratified the cumulative incidence of the composite endpoint (78% in the high ReDS group [$N = 10$] and 36% in the normal ReDS group [$N = 32$], $p = 0.002$). ReDS technology may be a promising tool to predict future clinical outcomes following TAVR by quantifying residual pulmonary congestion. The clinical implication of ReDS-guided aggressive intervention following TAVR remains the next concern.

Keywords Heart failure · Hemodynamics · Congestion · Aortic valve disease

Background

Given the recent innovation of trans-catheter aortic valve replacement (TAVR), symptomatic severe aortic stenosis can be treatable even in elderly patients with multiple comorbidities [1]. The indication of TAVR has expanded from high-surgical risk cohorts to intermediate or low-surgical risk cohorts given accumulating favorable clinical studies involving these cohorts [2]. Thus, the number of TAVR is increasing all over the world including Japan. Nevertheless, the incidence of readmission following TAVR have not yet been satisfactory low [3].

One of the unmet needs for clinical management following TAVR is residual congestion [4, 5]. A persistently elevated afterload due to severe aortic stenosis and concentric hypertrophy cause pulmonary congestion, which sometimes persists even following TAVR [4]. Even mild pulmonary congestion without any symptoms seems to have considerable negative impacts. In general, residual pulmonary congestion, even though it is trivial, is associated with mortality and morbidity among those with heart failure [6]. In addition, among the elderly patients with heart failure, pulmonary congestion might impair patients' exercise capacity, decrease patients' quality of life, progress frailty and sarcopenia, causing a variety of clinical events including falling and pneumonia [7, 8]. These multiple comorbidities-related readmissions, in addition to heart failure readmission, are the target that we should approach in patients receiving TAVR so far.

However, there have been no established methodologies to accurately quantify the degree of pulmonary congestion. Physical examination, which is a traditional and practical methodology to assess pulmonary congestion, is not necessarily accurate and reliable [9]. Chest X-ray is one of the most practical and less invasive tool to assess pulmonary congestion, but this is semi-quantitative and requires expert technique to be appropriately assessed.

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Remote dielectric sensing (ReDS) system is a recently introduced non-invasive tool to quantify the degree of pulmonary congestion with accumulating validation studies (Fig. 1) [10, 11]. ReDS system displays within a minute the ReDS value, a representative of lung fluid amount as a percentage. The use of ReDS system in daily clinical practice has been increasing to assess and manage pulmonary congestion, particularly in patients with congestive heart failure. However, applicability of ReDS system to those with other etiologies is restricted thus far.

Given all together, the ReDS system might be a promising tool to assess residual pulmonary congestion and predict various clinical outcomes following TAVR, particularly comorbidity-related readmissions. We in this study investigated for the first time the prognostic impact of ReDS value, which was measured following TAVR among the elderly cohort with severe aortic stenosis.

Methods

Patient selection

Consecutive patients who admitted to our institute to receive TAVR were prospectively listed for our prospective registry database. Patients who received TAVR and could be discharged alive at our institute between 2021 and 2022 were considered to be included in this retrospective study. Patients received ReDS measurement before index discharge as detailed below. Patients with obvious pulmonary diseases, including lung cancer, pneumonia, and chronic obstructive pulmonary disease, were excluded, although such patients rarely receive TAVR in general. Patients with inappropriate physics to obtain appropriate ReDS values, including extremely small body size and skeletal malformation, did not receive ReDS measurements and were excluded. Patients who died during index hospitalization did not receive ReDS measurements and were not included. Written informed consents were obtained from all participants on admission. The institutional review board approved the study protocol.

Fig. 1 ReDS system. Patients are instructed to sit on the chair. They wear the sensors for 1 min under natural breathing. The ReDS values, representative of lung fluid amounts as a percentage of fluid among the whole lung, are displayed on the monitor screen. Lung fluid amount can be estimated non-invasively without any expert technique

TAVR procedure

The elderly patients with symptomatic severe aortic stenosis with aortic valve peak velocity > 4.0 m/sec were considered to receive TAVR. Low-flow low gradient aortic stenosis, another potential indication of TAVR, was defined by inotropes-loading echocardiography. The indication for TAVR was determined based on the clinical consensus of a multi-disciplinary team that included cardiac surgeons, interventional cardiologists, anaesthesiologists, and imaging specialists. Patients received TAVR using Edward Sapien 3 Transcatheter Heart Valve (Edwards Lifesciences, Irvine, California, USA) or Medtronic Evolute PRO + Revolving System (Medtronic, Minneapolis, Minnesota, USA) via trans-femoral approach or alternative approach under the general or local anesthesia. Following the procedure, all patients received guideline-directed standard medical therapy according to the standard manner.

ReDS measurement

ReDS value was measured during index hospitalization before index discharge according to the standard manner as detailed previously [12]. ReDS system is a non-invasive electromagnetic energy-based technology to quantify lung fluid levels within a minute and displays the percentage of lung fluid amount (Fig. 1). ReDS system received FDA and CE approval for monitoring of lung fluid amount and it is available in other territories across the world as well. In Japan, ReDS system has been clinically available from 2022 in the same manner to other countries and gradually utilized in daily clinical practice.

Patients were instructed to sit under natural breathing for 45 s, during which ReDS values were measured. Manufacture-recommended normal rage of ReDS values is between 20% and 35%, although this range has not been clinically validated [10]. ReDS values were measured by non-attending clinicians and the values were completely blinded to the attending cardiologist. Thus, the values were not referenced to the clinical management. The clinicians assessed and managed pulmonary congestion without ReDS values by referencing conventional modalities, such as chest X-ray.

Clinical variables

Conventional data collection included baseline characteristics, post-TAVR laboratory data, post-TAVR echocardiographic data, and clinical outcomes in terms of mortality and all-cause re-hospitalization following index discharge (day 0). Heart failure readmissions were also censored. All patients were followed in our institute or affiliated institutes by board-certified cardiologists.

Statistical analysis

Continuous variables were presented as median (IQR) and compared between the two groups using Mann–Whitney *U* test. All continuous variables were assumed as non-parametric irrespective of their distributions given moderate sized sample size. Categorical variables were presented as number of cases (percentage of the total) and compared between the two groups using Fisher's exact test. A value of two-tailed $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS Statistics 22 (SPSS Inc, Armonk, IL, USA).

The independent variable was defined as ReDS value at index discharge. The primary outcome was defined as a composite of all-cause death and all re-admission following index discharge (day 0). Cox proportional hazard ratio regression analyses were performed to investigate the impact of ReDS value on the primary outcome. The impact of ReDS value was adjusted for pre-specified potential confounders of pulmonary congestion, including age, plasma B-type natriuretic peptide, glomerular filtration rate, and diuretics use. A receiver operating characteristics analysis was performed to calculate a cutoff of ReDS value to predict the primary outcome. Kaplan–Meier curves for the cumulative incidence of the primary endpoint were compared between the groups stratified by the calculated cutoff of ReDS value.

Results

Baseline characteristics

A total of 46 patients who received TAVR at our institute were considered to be included. Of them, deceased patients, one patients with obvious lung diseases, and three patients without ReDS measurements were excluded. Finally, 42 patients were included (Table 1). All included patients received successful TAVR and ReDS measurements before index discharge. All included patients were discharged alive. All patients did not have clinically obvious congestive symptom at index discharge.

Median age was 84 (81, 87) years and 14 (33%) were men. Median STS score was 4.4 (3.9, 4.9). Following TAVR, median plasma B-type natriuretic peptide level was 94 (56, 253) pg/mL and median left ventricular ejection fraction was 63% (57%, 70%). Almost half of the patients (40%) received diuretics. Beta-blockers were prescribed in 67% patients, renin–angiotensin system inhibitors were prescribed in 74% patients, and mineralocorticoid receptor antagonists were prescribed in 40% patients.

ReDS values at index discharge

ReDS value, which was measured at index discharge as independent variables, was distributed widely with a median value of 27% (24%, 30%) (Fig. 2). The patients' cohort was divided into two groups at a statistically calculated cutoff of ReDS value 30%. Ten patients had ReDS values > 30%. There were no statistically significant differences in baseline characteristics between the high ReDS value group and low ReDS value group, except for a higher prevalence of coronary artery disease in the high ReDS group (Table 1).

ReDS value and post-procedure complications

Post-procedure complications are listed in Table 2. The incidences of post-procedure complication were not significantly different between the patients with high ReDS and those with normal ReDS, which were stratified by the below-detailed cutoff: ReDS 30% ($p > 0.05$ for all).

Prognostic impact of ReDS value

During a median of 316 (282, 354) days following index discharge, 11 patients encountered the primary endpoint: death or readmissions (3 patients died [stroke, pulmonary embolism, and unknown origin] and 11 patients had readmissions [including ileus, limb ischemia, falling, heart failure, and pneumonia]).

ReDS value that was measured at index discharge was associated with the primary endpoint with an unadjusted hazard ratio of 1.25 (95% confidence interval 1.06–1.46, $p = 0.006$). ReDS value was independently associated with the primary endpoint with a hazard ratio of 1.32 (95% confidence interval 1.10–1.58, $p = 0.002$), which was adjusted for 4 potential confounders (Table 3). The prognostic impact of ReDS value on heart failure recurrence did not reach a statistical level (hazard ratio 1.37, 95% confidence interval 0.92–2.02, $p = 0.12$).

A cutoff of ReDS value to best stratify the primary endpoint was statistically calculated as 30% with 0.55 of sensitivity and 0.87 of specificity (area under the curve 0.81; 95% confidence interval 0.67–0.94) (Fig. 3). This finding is a rationale why we used ReDS value of 30% as a cutoff to stratify patients' cohort into two groups. Ten patients had ReDS value > 30% at index discharge. They had a

Table 1 Baseline characteristics (post-TAVR clinical variables)

	Total ($N=42$)	High ReDS ($N=10$)	Normal ReDS ($N=32$)	p value
Demographics				
Age, years	84 (81, 87)	84 (79, 86)	84 (82, 89)	0.33
Men	14 (33%)	6 (60%)	22 (69%)	0.44
Body surface area, m^2	1.4 (1.3, 1.5)	1.5 (1.3, 1.6)	1.4 (1.3, 1.5)	0.74
Systolic blood pressure, mmHg	116 (105, 126)	114 (107, 118)	117 (105, 128)	0.49
Pulse rate, bpm	68 (63, 77)	69 (62, 74)	68 (63, 78)	0.83
STS score	4.4 (3.9, 4.9)	4.7 (4.2, 4.9)	4.2 (3.8, 4.9)	0.18
Implanted valve				
SAPIEN3	26 (62%)	7 (70%)	19 (59%)	0.55
Evolut PRO +	16 (38%)	3 (30%)	13 (41%)	0.55
Comorbidity				
Hypertension	31 (74%)	7 (70%)	24 (75%)	0.52
Dyslipidemia	22 (52%)	3 (30%)	19 (59%)	0.10
Diabetes mellitus	13 (31%)	4 (40%)	9 (28%)	0.37
Coronary artery disease	11 (26%)	6 (60%)	5 (16%)	0.011*
History of heart failure	11 (26%)	3 (30%)	8 (25%)	0.52
History of stroke	4 (10%)	1 (10%)	3 (9%)	0.68
Atrial fibrillation	7 (17%)	3 (30%)	4 (13%)	0.20
Peripheral artery disease	4 (10%)	2 (20%)	2 (6%)	0.24
Chronic obstructive pulmonary disease	0	0	0	–
Laboratory data				
Hemoglobin, g/dL	10.6 (9.8, 11.2)	10.5 (9.6, 11.8)	10.6 (9.8, 11.1)	0.81
Serum albumin, g/dL	3.2 (3.0, 3.5)	3.3 (2.9, 3.4)	3.2 (3.0, 3.5)	0.87
Serum sodium, mEq/L	139 (137, 140)	138 (135, 140)	139 (138, 140)	0.41
Serum potassium, mEq/L	4.2 (3.9, 4.4)	4.0 (3.7, 4.3)	4.2 (4.0, 4.5)	0.21
Serum total bilirubin, mg/dL	0.6 (0.4, 0.7)	0.6 (0.4, 0.7)	0.6 (0.4, 0.7)	0.74
eGFR, mL/min/1.73m^2	47 (32, 58)	47 (24, 60)	47 (34, 57)	0.97
Plasma BNP, pg/mL	94 (56, 253)	68 (49, 235)	102 (56, 268)	0.46
Echocardiography				
Aortic valve area, cm^2	1.4 (1.2, 1.6)	1.3 (1.1, 1.6)	1.4 (1.2, 1.6)	0.70
LVDD, mm	43 (40, 47)	45 (42, 54)	43 (40, 46)	0.20
LVEF, %	63 (57, 70)	64 (60, 73)	63 (56, 69)	0.31
Medication				
Diuretics	17 (40%)	3 (30%)	14 (44%)	0.35
Beta-blocker	28 (67%)	9 (90%)	19 (59%)	0.075
RAS inhibitor	31 (74%)	9 (90%)	22 (69%)	0.18
Mineralocorticoid receptor antagonist	17 (40%)	6 (60%)	11 (34%)	0.14
Statin	23 (55%)	6 (60%)	17 (53%)	0.50

ReDS remote dielectric sensing, *STS* society of thoracic surgeons, *eGFR* estimated glomerular filtration rate, *BNP* B-type natriuretic peptide, *LVDD* left ventricular end-diastolic diameter, *LVEF* left ventricular ejection fraction, *RAS* renin–angiotensin system. Continuous variables are stated as median (IQR) and compared between the two groups using Mann–Whitney *U* test. Categorical variables are stated as number (percentage of total) and compared between the two groups using Fischer's exact test

*$p<0.05$

significantly higher cumulative incidence of the primary endpoint (78% versus 36%, $p=0.002$; Fig. 4). Plasma B-type natriuretic peptide levels trended to be higher in patients with high ReDS value compared with those with normal ReDS value at 6-month follow-up (114 [45, 293] pg/mL versus 54 [37, 214] pg/mL, $p=0.068$).

Discussion

In this study, we investigated the prognostic impact of ReDS value, which was measured blindly for the attending clinicians and assessed retrospectively at index discharge following TAVR, on the composite endpoint consisting of death

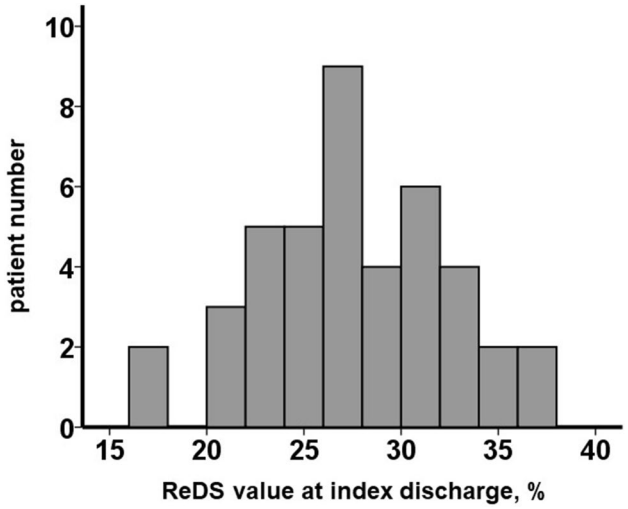

Fig. 2 Distribution of baseline ReDS value at index discharge. Baseline ReDS values were distributed widely between 17% and 37% with a median value of 27% (24%, 30%). A manufacture-recommended normal range of ReDS value is between 20% and 35% (<25% is considered to be hypovolemia and 30–35% is considered to have mid pulmonary congestion)

Table 2 Post-procedural complication

Complications	High ReDS ($N=10$)	Normal ReDS ($N=32$)	p value
Pacemaker implantation	0 (0%)	1 (3%)	0.57
Cardiac tamponade	0 (0%)	0 (0%)	–
Stroke	0 (0%)	0 (0%)	–
Moderate or greater peri-valvular leak	0 (0%)	0 (0%)	–
Vascular complication	0 (0%)	0 (0%)	–
Systemic infection	0 (0%)	2 (6%)	0.42
New atrial fibrillation	0 (0%)	1 (3%)	0.57
New complete left bundle branch block	0 (0%)	3 (9%)	0.32

Variables are stated as number (percentage of total) and compared between the two groups using Fischer's exact test

*$p<0.05$

and all-cause readmissions. ReDS value at index discharge was distributed widely with a median value of 27%. ReDS value was independently associated with the primary composite endpoint during the observational period following index discharge with a cutoff of 30%.

ReDS system and pulmonary congestion

ReDS value had a moderate correlation with the lung fluid amount estimated using high-resolution computed tomography, which requires expert software and cannot apply to

Table 3 Prognostic impact of clinical variables including ReDS value on the primary endpoint

Variables	Hazard ratio	95% confidence interval	p value
ReDS value, %	1.32	1.10–1.58	0.002*
Age, years	1.01	0.90–1.13	0.89
eGFR, mL/min/1.73m^2	0.98	0.95–1.01	0.22
Plasma BNP, pg/mL	1.01	1.00–1.02	0.17
Diuretics use	1.79	0.37–8.66	0.47

ReDS remote dielectric sensing, *eGFR* estimated glomerular filtration rate, *BNP* B-type natriuretic peptide

*$p<0.05$ by Cox proportional hazard ratio regression analysis wit forced method

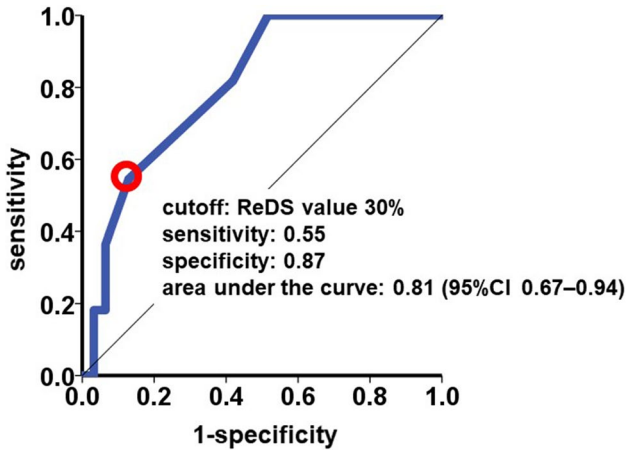

Fig. 3 Cutoff of ReDS value for the primary endpoint. *CI* confidence interval. The cutoff was statistically calculated as ReDS value of 30% to achieve maximum sensitivity and specificity

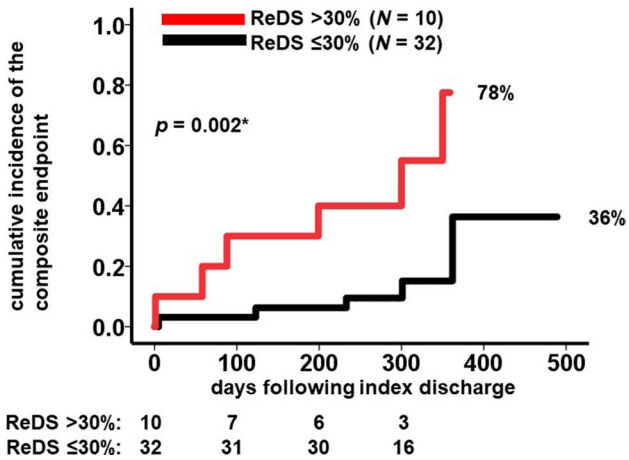

Fig. 4 Cumulative incidence of the primary endpoint stratified by ReDS value. Patients with ReDS value > 30% ($N=10$) had significantly higher cumulative incidence of the primary endpoint consisting of death and all-cause readmission compared with those with ReDS value ≤ 30% ($N=32$). *$p<0.05$ by log-rank test

general institutes [13, 14]. ReDS value had a mild correlation with pulmonary artery wedge pressure, which was measured invasively and also does not apply to all TAVR candidates [15, 16]. The correlation between ReDS value and pulmonary artery wedge pressure is relatively weaker probably due to the difference between tissue congestion (measured by ReDS system) and intra-vascular pressure (measured by right heart catheterization).

Other modalities including lung ultrasound and chest X-ray are semi-quantitative or qualitative. They have a moderate correlation with ReDS values in patients with severe pulmonary congestion (i.e., ReDS value > 35%) but cannot stratify mild-degree pulmonary congestion among patients with less congestion [17, 18]. Thus, ReDS technology has an advantage over conventional modalities given that it is accurate and easy to perform without any expert technique.

One of the limitations of ReDS system is that this modality cannot distinguish the etiologies, such as pulmonary pneumonia and lung cancer from pulmonary congestion. Patients with inappropriate physics to wear the device, such as those with extremely small physics, are also not applicable to this technology.

Pulmonary congestion following TAVR

Pulmonary congestion following TAVR is common due to persistently incremental afterload on left ventricle [19]. An incremental pulmonary artery wedge pressure following TAVR is associated with recurrent heart failure [4]. Here, we should understand the difference between pressure and volume. Incremental intra-cardiac pressure does not necessarily represent the existence of lung fluid overload. Furthermore, we cannot recommend mandatory right heart catheterization following TAVR for all candidates.

Systemic congestion, which is estimated by fibrosis-4 score, is also associated with worse clinical outcomes following TAVR [20]. Here, we should understand the difference between pulmonary congestion and systemic congestion. The distribution type of congestion in each organ varies in each patient. For example, some patients have pulmonary congestion alone. Others have both pulmonary congestion and systemic congestion.

In this study, a higher baseline ReDS value was associated with incremental mortality and all-cause readmission following TAVR. Interestingly, even mild congestion (i.e., ReDS value between 30% and 35% according to the previous finding that ReDS value of 28% was approximately equivalent to pulmonary artery wedge pressure of 15 mmHg) had a negative prognostic impact [15]. It might be challenging to distinguish such mild pulmonary congestion without ReDS measurements. Again, invasive modalities such as right heart catheterization cannot be applied for all TAVR candidates.

Uniquely, not heart failure recurrence but all-cause readmission was affected by the baseline ReDS value. The incidence of decompensated heart failure accompanying obvious volume overload might not be so high in this cohort. Instead, mild pulmonary congestion would decrease patients' quality of life and impair exercise capacity, causing frailty and sarcopenia-related non-cardiac events including falling and pneumonia [8]. We might attempt to increase the dose of diuretics to manage pulmonary congestion. Such an attempt sometimes causes hypovolemia, chronic kidney disease, and stimulation of renin–angiotensin system, followed by the incremental incidence of cardiovascular disease. [21]

Clinical implication of our findings

Given its high specificity, we should pay special attention for those with high ReDS value at index discharge following TAVR. Such patients are at high risk of mortality and all-cause readmissions despite successful TAVR procedures, even if they are asymptomatic without any congestive symptoms. Therapeutic and prophylactic strategy for such patients remains the next concern. Adjustment of diuretics by referencing the ReDS values might ameliorate pulmonary congestion and improve clinical outcomes, although further studies are warranted to validate the clinical implication of ReDS-guided diuretics adjustment. We should avoid extensive up-titration of diuretics, which rather cause diuretics-related adverse events including hypotension and acute kidney injury particularly for those with multiple comorbidities.

Limitations

Several potential limitations should be declared. Given that ReDS technology has become clinically available recently [11], the sample size is small. ReDS technology has a potential to quantify the lung fluid amount non-invasively but accurately under natural breathing [22], whereas it has not yet been sufficiently validated in a variety of clinical scenario. This is a proof-of-concept and further larger-scale multi-institutional studies are warranted to validate our findings. The incidence of heart failure readmission was low and the prognostic impact of ReDS value did not reach statistical significance. Larger-scale studies might be required to demonstrate its prognostic impact on heart failure recurrence.

We selected beforehand several potential confounders of pulmonary congestion for the adjustment in the time-to-event analyses. However, any other uninvestigated confounders might have existed. ReDS values cannot be measured in patients with inappropriate physics, such as very small body size [10]. The validity of ReDS values in patients with obvious pulmonary diseases is unclear. We excluded such patients in this study. This is an observational study and the detailed causality between the ReDS value and clinical

outcome remains uncertain. We measured ReDS values only one time and their trends following index discharge remain unknown. We included current standard TAVR candidates with high age and multiple comorbidities. Pulmonary congestion might not be associated with frailty and sarcopenia-related clinical events for other unique cohorts (for example, younger cohort).

The ReDS value was completely blinded to the attending clinicians given the lack of any validated cutoff of ReDS values that indicated significant pulmonary congestion. In this study, we measured ReDS values just for the research purpose. The implication of ReDS-guided aggressive intervention in this cohort remains the next concern. The cost-effectiveness also remains the next concern that should be investigated. The cost of this device is approximately $40,000, whereas ReDS-guided management might decrease the incidence of readmission and reduce the total medical cost.

Conclusions

ReDS technology might be a promising non-invasive tool to predict future death and readmission following TAVR by quantifying residual pulmonary congestion. Even a mild pulmonary congestion might be associated with adverse clinical outcomes following TAVR. The clinical implication of ReDS-guided aggressive intervention following TAVR remains the next concern.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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