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Echocardiographic Parameters of Right Ventricular Size and Function Associated With Right Heart Failure After Durable Left Ventricular Assist Device Implantation—A Systematic Review and Meta-Analysis

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ABSTRACT

Background: Late-onset Right Ventricular (RV) failure is an established complication of Durable Left-Ventricular Assist Device (D-LVAD) implantation. Transthoracic echocardiography (TTE) remains the primary imaging modality for serial monitoring in this population, but its interpretation remains challenging due to device-related changes in RV size and function and a lack of guidelines addressing this impact. This study aims to examine the diagnostic and prognostic utility of TTE parameters of RV size and function in the detection of late-onset RV failure post-implantation.

Methods and Results: A systematic literature search of medical databases was performed to identify all relevant studies assessing TTE parameters in adult patients with D-LVADs (January 2003–August 2023; English only). Of the 350 studies identified, nine studies with a pooled cohort of 627 patients and three studies with a pooled cohort of 175 patients (40 Cases and 135 controls) were meta-analyzed across a range of structural and functional TTE parameters. Compared to World Alliance Societies of Echocardiography (WASE) reference values, this population had dilated RV size (as quantified by RVEDD) and reduced systolic function (as quantified by TAPSE, RVFAC, and RVEF). TAPSE was positively associated with the non-RVF group, while RVEDD was negatively associated with the non-RVF group.

Conclusions: Based on the available studies, there was baseline RV dilatation and reduced systolic function in patients with D-LVADs. Additionally, TAPSE and RVEDD demonstrated a statistically significant association with the development of RVF post-implantation, indicating a potential role as prognostic markers. Further studies should also be conducted to establish post-implantation TTE reference values.

1 | Introduction

There is an increasing prevalence of end-stage left ventricular (LV) failure worldwide often requiring advanced therapies and/or heart transplantation. Wait times for heart transplantation differ greatly between countries, with medians ranging from 2 months to 2 years [1, 2]. Long wait times coupled with high symptom burden have necessitated the use of mechanical circulatory support as a bridge to cardiac transplantation or as destination therapy in patients who do not qualify for heart transplantation. The use of D-LVADs in isolated end-stage LV failure as a bridge-to-transplantation or destination therapy has prolonged the survival of patients with end-stage heart failure but necessitates regular monitoring for the development of late-onset RVF. Late-onset RVF is characterized by the development of right-sided dysfunction requiring mechanical support or resumption of inotropes, vasopressors, or intravenous diuretics at least 30 days post-implantation. Approximately 10%–40% of D-LVAD recipients have been reported to eventually develop late-onset RVF, an established complication requiring early detection for active intervention [3]. RVF after D-LVAD implantation has been associated with the development of multiple organ failure, worse long-term survival, and a lower functional status.

Echocardiography remains the primary imaging modality for routine assessment in this cohort of patients due to its accessibility, low cost, and the inherent MRI-incompatibility of many D-LVADs. Despite its widespread use, echocardiography currently has a minimal role in the 2023 INTERMACS guidelines [4] for the monitoring and diagnosis of RVF in patients outside the peri-operative period. Current guidelines recommend hemodynamic assessment via right heart catheterization as the gold standard for assessing pressures; repeated and routine invasive assessments are impractical in this largely outpatient population.

The two most prominent barriers to the utilization of echocardiography in patients with D-LVADs are (a) the lack of data and consensus on baseline RV function in patients with D-LVADs and (b) technical difficulty in interpreting traditional echocardiographic parameters due to alterations in RV geometry and function secondary to LV unloading from implanted D-LVADs. Without a baseline TTE reference, it is difficult to accurately characterize if RVF exists with only one specific data point during the first follow-up appointment post-implantation. Furthermore, research in patients with D-LVADs have predominantly focused on identifying parameters that would predict RVF in patients that have yet to be implanted with a D-LVAD. Comparatively few studies have characterized baseline RV function post-implantation and the prognostic value of these parameters in the development of RVF. This study thus aims to:

1. Establish baseline values of right heart size and function following implantation of a D-LVAD and to compare these to established normal values.
2. Assess the prognostic value of echocardiographic measures of RV size and function associated with the development of RVF post D-LVAD-implantation.

2 | Methods

2.1 | Search Strategy and Selection Criteria

This study was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) 2020 statement and registered online with the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42024525332). Medical databases including PubMed, Ovid Medline, EMBASE, Web of Science, Cochrane Central Register of Controlled Trials, Scopus, Proquest, and Science Direct were searched using both free-text and Medical Subject Heading terms (Table S1) for adult human studies in the English language that reported TTE parameters for right heart size and function in patients with a D-LVAD. A gray literature search was also performed. Two investigators (J.C.K.C. and J.L.C.) independently screened records retrieved by title and abstract. Covidence (Veritas Health Innovation, Melbourne, Australia) was used to facilitate the screening process, and a full text review was carried out independently by the authors. After each stage, discrepancies were discussed and resolved after concurrent review of the full text.

2.2 | Inclusion Criteria

Studies selected were published in the English language from January 2003 to August 2023 and featured TTE data on human adults with D-LVADs. To be included, studies also had to report the number of participants, mean and standard deviation of each selected TTE parameter of RV size and function. Additionally, studies that were included in the RVF versus non-RVF (NRVF) segment had to specify time of follow up, criteria used to diagnose RVF and number of participants within each arm.

2.3 | Exclusion Criteria

Studies were excluded if they were (a) only in abstract form, (b) did not report means and standard deviations, or (c) had missing data.

2.4 | Data Extraction

A template comprising publication details, study design, participant characteristics and outcomes was used by two investigators (J.C.K.C. and J.L.C.) for data extraction (Table 1). Discrepancies at any stage of selection were arbitrated by the senior author (T.C.T.) if discussion between all three reviewers failed to achieve a consensus.

2.5 | Statistical Analysis

To address the first aim, baseline TTE values of RV size and function were compared against normal values from the WASE study [5]. To address the second aim, data was extracted for individual parameters corresponding to RV function TAPSE, RV fractional area change (RVFAC), RV end diastolic diameter (RVEDD), RV global longitudinal strain (RVGLS), and RV free

TABLE 1 | Characteristics of included studies.

	Author	Year	Study design	D-LVAD	Patients	RVEDD (mm)	TAPSE (mm)	RVFAC	RVEF
Baseline parameters	Demirozu et al.	2016	Case series	HA	9	N/A	13 ± 2	35 ± 11	N/A
	Kukucka et al.	2011	RCT	DH, HM, IN, VA	23*	44 ± 2	11.8 ± 0.6	28.9 ± 2.0	39 ± 2
	Lam et al.	2009	Case series	HM	21	38 ± 8	14 ± 6	42 ± 10	N/A
	Mezzani et al.	2018	Case series	HM, HW	25*	N/A	13 ± 2	N/A	N/A
	Morgan et al.	2013	Case series	HM	105	N/A	20 ± 5	N/A	40.4 ± 6.2
	Mulzner et al.	2022	Cohort	HM, HW	219	41.4 ± 6.84	14.0 ± 3.6	N/A	N/A
	Ozturk et al.	2013	Cohort	HW	15*	N/A	11.7 ± 1.9	N/A	44.7 ± 6.1
	Schreiber et al.	2021	Cohort	HM	135	47.5 ± 7.2	14.7 ± 3.7	N/A	N/A
	William et al.	2020	Cohort	HM, HW, VA	75	45 ± 8	11 ± 4	N/A	N/A
	Author	**Year**	**Study design**	**D-LVAD**	**Patients**	**TAPSE (NRVF)**	**TAPSE (RVF)**	**RVEDD (NRVF)**	**RVEDD (RVF)**
NRVF vs. RVF	Cameli et al.	2013	Cohort	JA	10	14.5 ± 2.6	14.5 ± 2.4	42.6 ± 6.6	44.1 ± 7.5
	Kato et al.	2013	Cohort	Unspecified	68	18 ± 5	15 ± 5	38.6 ± 4.4	40.0 ± 4.4
	Ruiz-Cano et al.	2021	Cohort	HW, HM	97	14.67 ± 3.77	10.33 ± 2.49	38.67 ± 6.03	45.67 ± 11.63

Abbreviations: DH, DuraHeart; HA, heart assist; HM, HeartMate; HW, HeartWare; IN, incor; JA, Jarvik; VA, VentraAssist.

wall strain (RVFWS) were compared between those who developed RVF and those who did not (NRVF). Only parameters with data from 3 or more studies were meta-analyzed. Articles were required to report on a quantitative estimation including mean, confidence intervals (CI), and standard deviation. 95% confidence intervals (CIs) were calculated for all indices with p value < 0.05 being considered statistically significant. Heterogeneity within the pooled studies was tested using the I^2 statistic and deemed significant if ≥50%. All statistical analysis was performed using the Metan package included in the STATA version 16.1 statistical software.

2.6 | Risk of Bias

Two authors (J.C.K.C. and J.L.C.) adjudicated the risk of bias using the Joanna Briggs Institute Tool (JBI) to increase methodological rigor, evaluating for potential bias and threats to validity. Individual studies were critically appraised using the JBI checklist to determine methodological quality and extent to which it addressed the possibility of bias in its design, conduct, and analysis (Figure 1). Publication bias was assessed by visual analysis of funnel plots and using Egger methods (Figure S1) [6, 7].

3 | Results

The approach utilized in this study is summarized in the attached PRISMA diagram (Figure 2). The combined search of Embase, Medline, Cochrane, Web of Science, and gray literature yielded 350 unique papers. Two hundred sixty-six papers were excluded during the abstract screening phase and 69 papers were excluded after full text review.

Nine studies were found to have sufficient detail to address the first aim of establishing baseline values of RV size and function following D-LVAD implantation. These studies were predominantly retrospective cohort studies that had varying endpoints but published relevant baseline TTE values post-implantation. Except for the study by Kukucka and colleagues 2011, all studies reported TTE data at the first follow up session post-implantation of the LVAD device, that is, 1 month (n = 1), 6 months (n = 5), or 12 months (n = 2). Tricuspid annular plane systolic excursion (TAPSE), RV Fractional Area Change (RVFAC), RV End-Diastolic Diameter (RVEDD), and RV Ejection Fraction (RVEF) were five parameters that were consistently reported in at least two papers and thus represent the focus of this study. Patients with implanted D-LVADs were found to have a lower TAPSE (SMD −2.07; 95% CI −2.53, −1.61; p = 0.00), RVFAC (SMD −1.91; 95% CI −3.80, −0.02; p = 0.05), and RVEF (SMD −2.47; 95% CI −3.00, −1.94; p = 0.00) alongside an increased RVEDD (SMD +2.83; 95% CI 2.32, 3.33; p = 0.00) when compared to normal controls from the WASE RV study [5]. SMD of TAPSE in patients with D-LVADs was calculated in a pooled cohort of 627 patients from nine studies with reported means ranging from 11 to 20 mm compared to the WASE reference range of 22 ± 4 mm. SMD of RVFAC in patients with D-LVADs was calculated in a pooled cohort of 53 patients from three studies with reported means ranging from 28.9% to 42% compared to WASE reference range of 43% ± 4%. SMD of RVEF in patients with D-LVADs was calculated in a pooled cohort of 143 patients from three studies with reported means ranging from

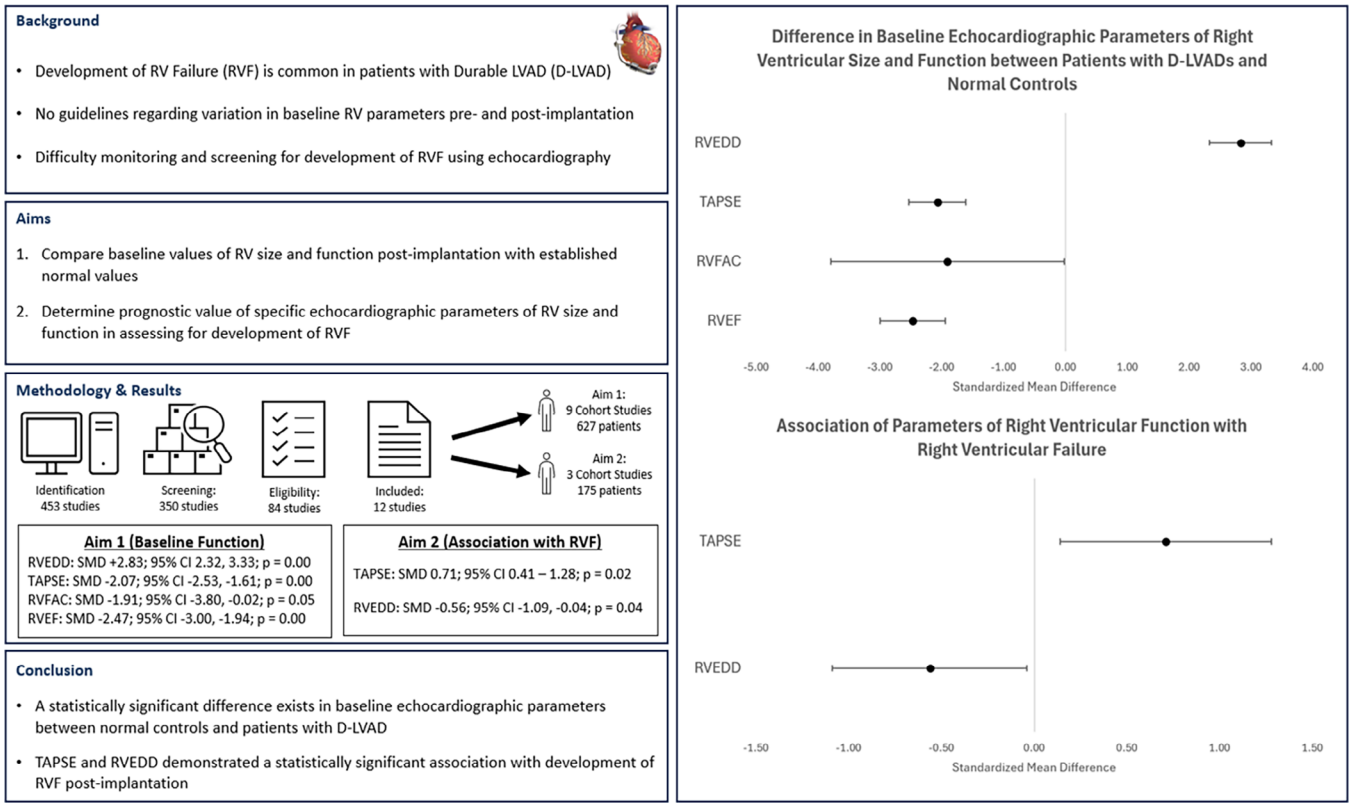

FIGURE 1 | Graphical abstract of study.

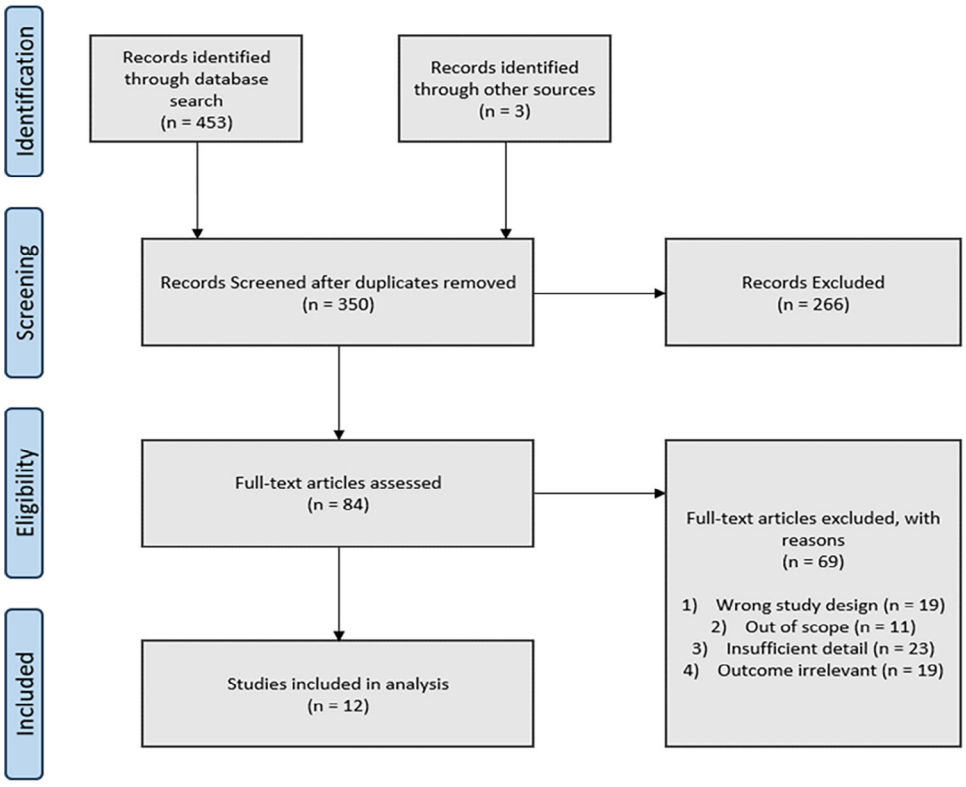

FIGURE 2 | PRISMA flow diagram outlining the identification, screening, and inclusion of studies.

39% to 44.7% compared to the WASE reference range of 56% ± 6%. SMD of RVEDD in patients with D-LVADs was calculated in a pooled cohort of 473 patients from five studies with reported means ranging from 38 to 47.5 mm compared to WASE reference range of 26 ± 6 mm.

Three retrospective cohort studies with a pooled cohort of 175 patients met the selection criteria for the second aim of determining the association between echocardiographic measurements of RV size and function with the development of RVF post-implantation. Compared to patients with D-LVADs that developed NRVF, patients with RVF had lower TAPSE (SMD 0.71; 95% CI 0.41–1.28; $p = 0.02$) and higher RVEDD (SMD −0.56; 95% CI −1.09, −0.04; $p = 0.04$). SMD for TAPSE in the pooled cohort of 135 patients from three studies had reported means in the NRVF group ranging from 14.5 to 18 mm and in the RVF group ranging from 10.3 to 15 mm. SMD for RVEDD in the pooled cohort of 135 patients from three studies with reported means in the NRVF group ranging from 38.6 to 42.6 mm and reported means in the RVF group ranging from 40 to 45.67 mm. RVFAC, RV Global Longitudinal Strain (RVGLS), and RV Free Wall Strain (RV FWS) were only featured in two studies and were unable to be meta-analyzed but were consistently lower in patients who developed RVF compared to those who did not.

4 | Discussion

Our results indicate that patients with D-LVADs have significantly reduced baseline RV function relative to that of the normal population. This observed decrease in RV function is likely multifactorial, but D-LVADs are hypothesized to contribute by unloading the LV, which results in both morphological and functional changes in the RV due to interventricular dependence [8–10]. Reduced Inter-ventricular septum (IVS) activity has been demonstrated to account for a substantial proportion of RV systolic function and would result in decreased RV output [11–13].

Visual estimation of RV function remains the most common method of assessing RV function despite its suboptimal nature, with studies demonstrating a strong correlation between accuracy and user experience [14–16]. The changes in RV morphology in this cohort highlight the importance of using formal quantification for purposes of serial monitoring given significant inter- and intra-observer variability. This is particularly pertinent in the cohort of patients receiving a D-LVAD because of the high prevalence of RV dilatation or dysfunction with end-stage LV. RV chamber quantification before and after implantation thus represents an objective method of tracking changes in RV function over time. In this subset of patients, the degree of RV dysfunction or change in echocardiographic parameters over time will likely be more useful in informing management than a simple assessment of the presence or absence of RVF. This further highlights the necessity of reporting objective parameters of baseline RV function prior to and post-implantation in all patients.

While the recently updated 2023 INTERMACS guidelines do encourage quantitative assessment prior to implantation and at regular intervals post-implantation, it does not specify which parameters to use. A consensus on what qualifies as a "standard" quantitative assessment is not available and presently subjective due to the lack of studies comparing and/or validating each parameter at detecting RVF post-implantation. Our systematic review of available literature clearly highlights the need for further research in this area considering the lack of studies formally reporting echocardiographic measures of RV size and function alongside the lack of consistency between studies that do so. Furthermore, the association between specific echocardiographic measures of RV size and function with the development of RVF post-implantation were also limited. Of the three papers addressing the second aim of this study, only the measures of TAPSE and RVEDD had sufficient overlap between the three studies to allow for meta-analysis.

4.1 | Right Ventricular End Diastolic Diameter

RVEDD represents an echocardiographic parameter used in the quantification of RV size that has been shown to be a marker of poor prognosis but is infrequently used due to its variability and reliance on probe positioning [17]. The results from the meta-analysis addressing the first aim (Figure 3) demonstrated a statistically significant difference in RVEDD (SMD 2.83, $p < 0.01$) in patients with a D-LVAD compared to that of the reference WASE population. Inter-user variability was a potential confounder for this result and could have negatively impacted the sensitivity of this parameter, given the limited sample size. However, these limitations should not preclude the use of RVEDD in patients with D-LVAD.

The meta-analyzed studies (Figure 3) also demonstrated a significant negative association between higher RVEDD and the NRVF arm (SMD −0.56; 95% CI −1.09, −0.04; $p = 0.04$) suggesting that patients who do not develop RVF are those who do not have significant dilatation and remodeling of the RV. It is well established that dilatation is often the first indicator of ventricular remodeling from increased pulmonary vascular resistance and has been discussed in the American Society of Echocardiography guidelines [18]. RVEDD thus warrants further study as a parameter for quantifying changes in RV size within this population.

4.2 | Tricuspid Annular Plane Systolic Excursion

After visual estimation, TAPSE is the second most prevalent method of assessing RV function due to its ease of acquisition and clinician familiarity. In the normal population, TAPSE represents an objective assessment of RV longitudinal shortening and has a strong correlation with RV systolic function when validated by cardiac MRI or radionucleotide angiography [19–21]. Our results (Figure 4) demonstrated that there was a statistically significant difference (SMD: −2.07, $p < 0.01$) in TAPSE between patients with implanted D-LVADs when compared with the normal WASE population. A potential confounder would be the presence of pre-existing RV dysfunction prior to D-LVAD implantation from LVF. However, reported mean values for TAPSE within the included studies clearly demonstrate that even patients who did not meet INTERMACS hemodynamic cutoffs for RVF still had TAPSE scores below WASE cutoffs for RV dysfunction (<17 mm). This would detract from the likelihood that pre-existing RV dysfunction was the sole reason for the difference seen between groups.

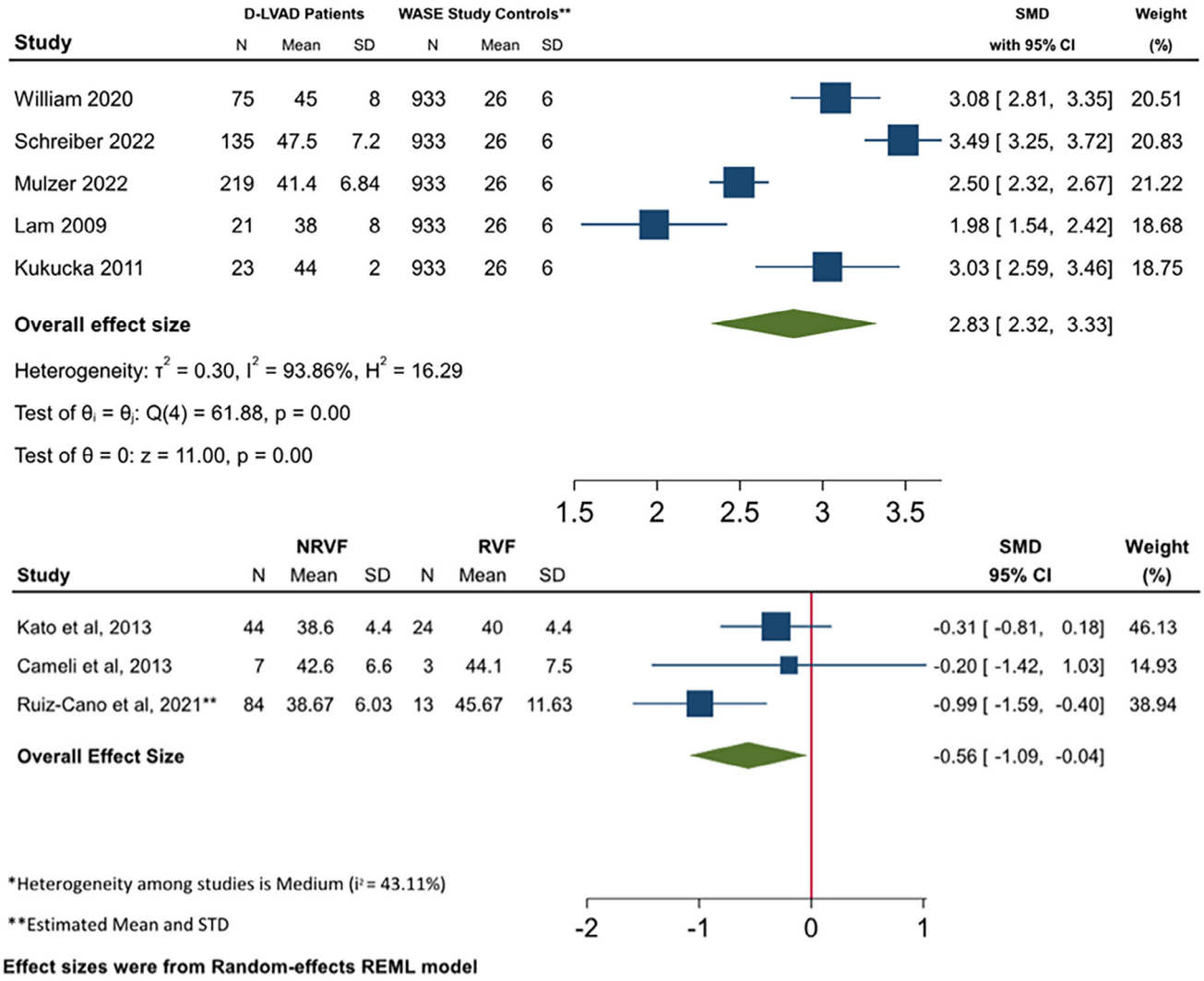

FIGURE 3 | Forest plot for RVEDD in patients with a D-LVAD versus WASE normal controls (top) and NRVF versus RVF (bottom).

Our results also demonstrated that TAPSE could still be used to prognosticate the development of RVF, despite a significant difference at baseline levels following implantation of the device between the normal population and that of D-LVAD patients. There was a statistically significant association (SMD 0.71; 95% CI 0.41–1.28; $p = 0.02$) between lower TAPSE and RVF after implantation (Figure 4). While this result likely represents a true difference in the populations, it should be noted that alterations in RV morphology could potentially impact the ability of TAPSE to accurately predict RV systolic function. In a normal RV, the three primary contributing mechanisms to pump function are longitudinal shortening, radial movement of RV free wall, and bulging of the IVS into the RV from LV systole [22]. The reduced RV function seen in D-LVADs is postulated to be due to decreased IVS movement, resulting in decreased shortening in the anteroposterior direction [23, 24]. Given that TAPSE is a measurement of longitudinal shortening of the RV, it is mechanistically less likely to be impacted by alterations in IVS activity from D-LVAD-induced LV unloading. As with all other 2-dimensional parameters of RV function, however, TAPSE may still be an overly simplistic measurement of a geometrically complex shape. Despite its apparent shortcomings, its popularity and results across the meta-analyzed studies demonstrate promise as a reliable indicator for monitoring of RVF after D-LVAD implantation.

4.3 | Right Ventricular Fractional Area Change

RVFAC is another validated 2D parameter used to quantify RV systolic function by determining the degree of change in RV area between diastole and systole. While not as commonly used as TAPSE, it has demonstrated good correlation with advanced imaging in studies and is included in chamber quantification guidelines from international societies and in some systematic reviews [25, 26].

A statistically significant difference (SMD –1.91, $p = 0.05$) was noted between patients with a D-LVAD and the reference WASE population (Figure 5), but there was insufficient data to conduct a meta-analysis regarding its prognostic value for predicting the development of RVF post-implantation. Of the two studies examining the relationship between RVFAC and the development of RVF post D-LVAD implantation, both did demonstrate a

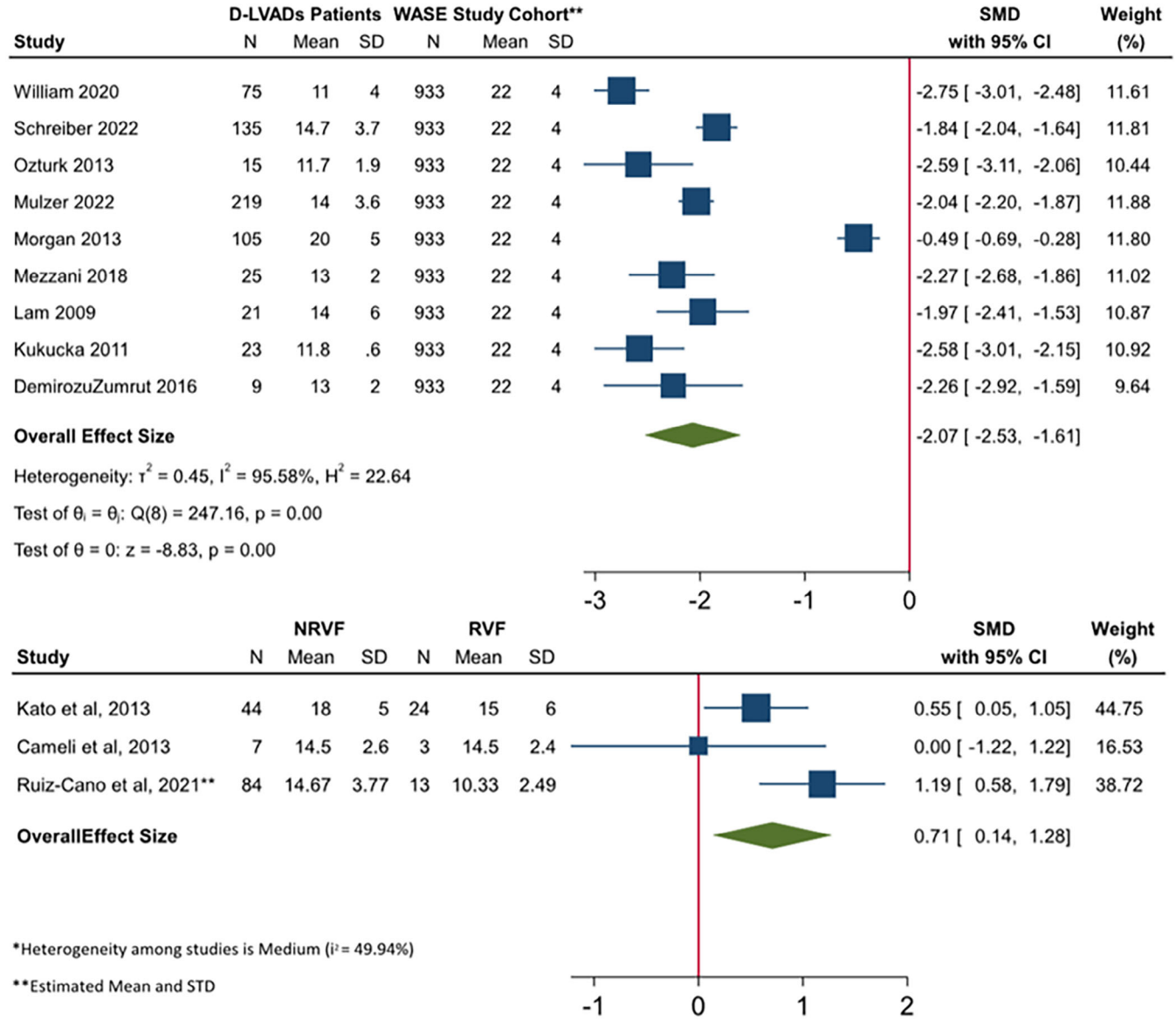

FIGURE 4 | Forest plot for TAPSE in patients with a D-LVAD versus WASE controls (top) and NRVF versus RVF (bottom).

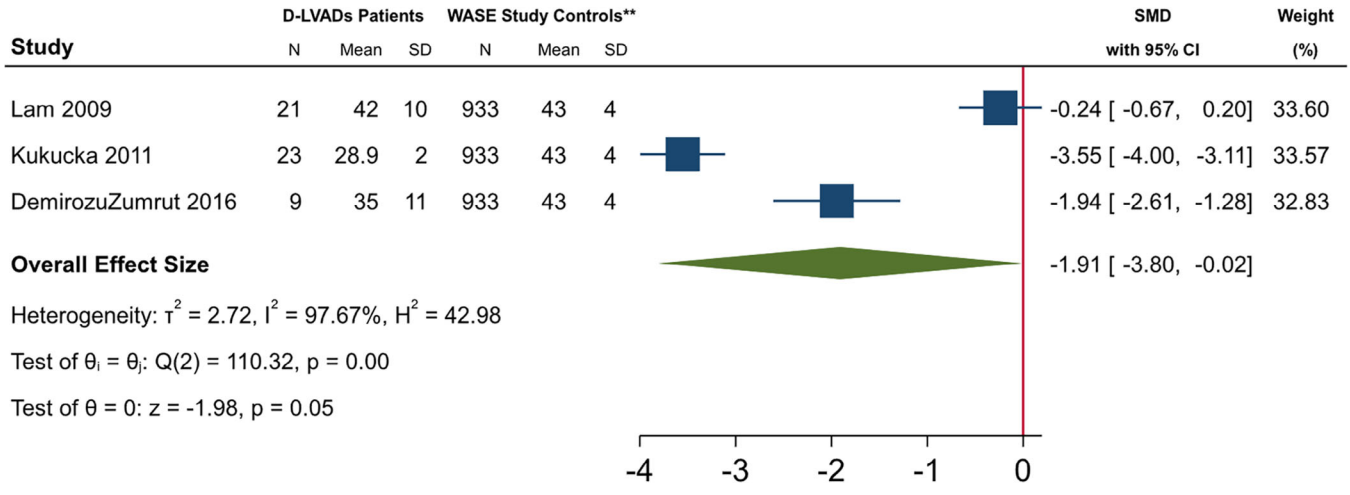

FIGURE 5 | Forest plot for RVFAC in patients with a D-LVAD versus WASE normal controls.

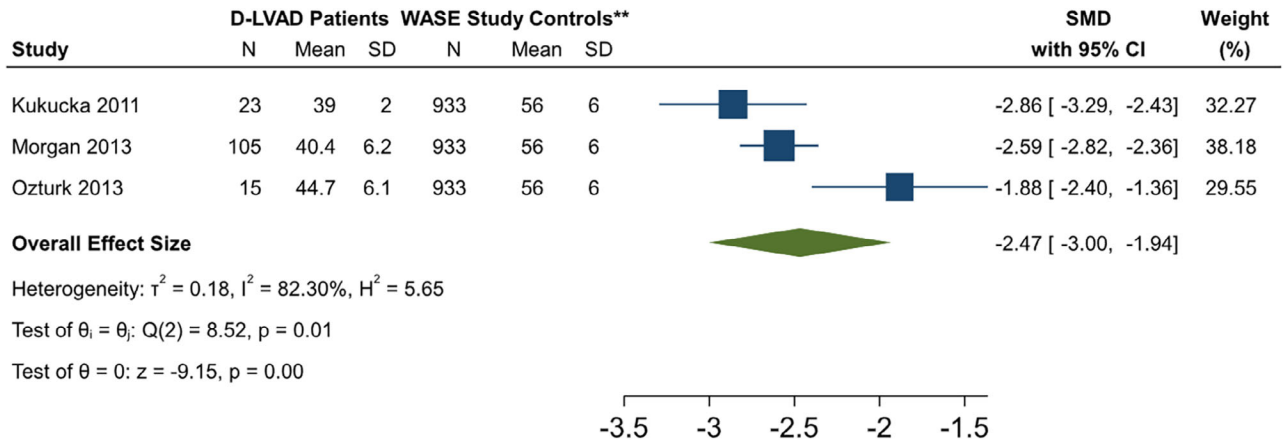

FIGURE 6 | Forest plot for RVEF in patients with a D-LVAD versus WASE normal controls.

statistically significant association between a markedly lower RVFAC at baseline in patients who subsequently developed RVF. This suggests that RVFAC could have prognostic value in identifying patients at risk of developing RVF post-implantation. There are also inherent challenges associated with measuring post-implantation RVFAC relating to the difficulty in delineating the endocardial border due to variations in morphology from the implanted D-LVAD device. It is, however, clear that further studies examining the utility of RVFAC in this population are needed, and current cut-offs may need to be redefined.

4.4 | Right Ventricular Ejection Fraction

Due to the complexity of RV geometry, traditional methods of calculating EF for the LV (e.g., Simpson's biplane) cannot readily be applied to the RV due to its incongruous shape [27]. 3D RVEF measurement is proposed to better account for the complex geometry of the RV compared to 2D RVEF and is more likely to be able to account for changes to RV morphology from D-LVAD implantation. Furthermore, validation studies of 3D RVEF performed in the normal population have demonstrated a strong correlation between 3D RVEF by echocardiography and Cardiac MRI-derived RVEF [28, 29]. Our systemic search only identified three studies that reported measurements of RVEF post-implantation of a D-LVAD; the lack of data may be reflective of its limited availability and lack of widespread use in the clinical setting. Unfortunately, none of the included studies provided details regarding how RVEF was measured but had mean values that were consistently below the WASE cut-off for normal RV function (RVEF 56%). It is assumed that the reported RVEF were 3D RVEF measurements, although we cannot definitively exclude visual estimation of RVEF. Meta-analysis of the results from the three studies demonstrated a statistically significant difference (SMD −2.47, $p = 0.01$) in patients with D-LVADs relative to that of the reference WASE population (Figure 6).

4.5 | Limitations

The primary limitation of this meta-analysis was the low number of studies available (despite a comprehensive search strategy), which could have potentially led to higher heterogeneity. This was due in part to multiple incomplete abstract-only papers, alongside the inherently limited number of D-LVADs implanted globally. The range of different D-LVAD models in the market and within the included studies (Table 1) also limits the generalizability of this data. However, given the scarcity of clinical data and the limited number of LVADs implanted globally, it was impractical to limit data to each model type at the time of writing. All included D-LVAD models were, however, of the continuous-flow variety. Additionally, the establishment of a control group for baseline RV function in patients with end-stage LVF was difficult because of large variations in the degree of co-existing RV dysfunction. The heterogeneity of this population further underscores the importance of formal quantification of baseline RV size and function to better enable track trends in RV function. Last, apart from one study that controlled for gender, all others featured predominantly male samples, and it remains difficult to predict the impact gender may play due to the lack of data.

4.6 | Clinical Significance

The focus of echocardiographic research in D-LVADs has historically revolved around identification of specific echocardiographic markers predictive of RV failure prior to D-LVAD implantation. While important, results from such studies are not relevant to patients who have already been implanted with D-LVADs and require ongoing monitoring. Compared to prior studies, this meta-analysis is unique because it attempts to highlight the differences in baseline function at the first follow-up between this unique cohort of patients and the average population. At present, there is a gap in the literature on how to best monitor RV function post-implantation with echocardiography and consequently, current guidelines do not include what is otherwise an invaluable tool in the assessment of the RV.

5 | Conclusion

Our results demonstrate that current reference standards for baseline RV function should not be applied to patients with D-LVADs, and further research is required to determine what constitutes normal RV function post-implantation. This is important as studies have demonstrated recovery in RV function with

D-LVAD implantation over time, which could have implications for the diagnosis of RVF [30]. In the interim, echocardiography should be performed prior to implantation, after implantation, and during each follow-up to better quantify the effects D-LVADs have on each patient's RV size and function.

Based on the available studies, TAPSE and RVEDD demonstrated a statistically significant association with the development of RVF post-implantation. While recent studies allude to the importance of strain and 3D echocardiography in the diagnosis of RVF post-implantation, there is insufficient data in this population to conduct a meta-analysis. Our study highlighted the need for further research on the value and utility of standard measures of RV function as potential prognostic markers in this population.

Future studies in the D-LVAD population should focus on determining quantification ranges for normal RV function at baseline alongside the identification of specific parameters for the echocardiographic diagnosis of RVF.

Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.