Impact of preoperative versus postoperative dialysis on left ventricular assist device outcomes: An analysis from the Society of Thoracic Surgeons Interagency Registry for Mechanically Assisted Circulatory Support database

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ABSTRACT

Objective: Chronic kidney disease and renal failure are common in patients being considered for left ventricular assist device support. We sought to evaluate the outcomes of patients undergoing left ventricular assist device implantation with preoperative dialysis and those with new-onset postoperative renal failure requiring dialysis.

Methods: All patients (n = 14,090) undergoing primary left ventricular assist device implantation who were listed in the Intagency Registry for Mechanically Assisted Circulatory Support database (2014-2019) were evaluated. Landmark analysis then stratified patients alive at 1 month by preoperative dialysis and at 1 month postoperatively, preoperative dialysis only, postoperative dialysis only, and no dialysis.

Results: Of 14,090 patients undergoing left ventricular assist device implantation, patients on dialysis (400%, 3%) preoperatively had significantly higher mortality at 1 month (18% vs 6%, P < .0001). However, of patients on preoperative dialysis, 131 (32.8%) no longer required dialysis at 1 month postoperatively and had long-term survival similar to patients who never required dialysis (no dialysis vs recovered, P = .13). Long-term survival was significantly worse in patients with persistent dialysis and new dialysis at 1 month postoperatively (P < .0001). Time to first stroke, major nondevice infection, any bleeding event, and gastrointestinal bleeding were all worse in patients on preoperative or postoperative dialysis (all P < .0001). Device infection, malfunction, or thrombosis was not associated with dialysis status (P > .05). Negative predictors of recovery include biventricular assist device (odds ratio, 0.20) and inotropes 1 week postimplant (odds ratio, 0.19).

Conclusions: Preoperative renal failure is associated with 3 times higher mortality and worse morbidity in patients receiving a left ventricular assist device. However, one-third of patients with preoperative dialysis will recover renal function postimplant with similar long-term survival and quality of life as those without dialysis. (JTCVS Open 2022;9:122-43)
Left ventricular assist devices (LVADs) have been shown to prolong survival and improve quality of life for appropriately selected patients with advanced heart failure.1,2 Over the past 20 years, developments in LVAD technology have been correlated with improved patient outcomes and more widespread use of the therapy. However, determining which patients will ultimately benefit from the use of an LVAD remains complicated because patients with medically refractory heart disease are a heterogeneous group and often have other comorbidities.

Kidney disease is often associated with heart disease and can be directly linked as in cardiorenal syndrome or can exist as 2 separate entities. The prevalence of heart failure is approximately 40% among patients with end-stage renal disease (ESRD), with more than one-third (37%) dying of complications related to heart failure.3 Few studies have evaluated outcomes among LVAD recipients with kidney disease, and these have largely focused on patients with earlier stages of kidney disease not receiving dialysis and those receiving acute dialysis for acute kidney injury, rather than those with ESRD.4,5 Some groups argue that diminished renal function is a strong predictor of adverse outcomes after LVAD implantation and should be viewed as a contraindication to this therapy.7 Others argue that LVAD implantation improves renal function and can be performed with reasonable outcomes in this patient subset; therefore, preoperative renal dysfunction should not be an exclusion criterion for LVADs.8

In light of recent conflicting data, the purpose of this study was to assess the impact of preoperative ESRD and new postoperative dialysis on patient outcomes after LVAD placement in the Society of Thoracic Surgeons (STS) National Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database.5 Specifically, we sought to evaluate the association between preoperative dialysis and survival, complications, and quality of life after LVAD implant. We evaluated major adverse events, survival, and patient-reported quality of life with the hypothesis that patients on dialysis undergoing LVAD implantation would have worse outcomes and those who develop renal failure requiring dialysis after LVAD implantation will have poor long-term survival. Secondary objectives included identification of predictors of renal recovery in patients on dialysis before LVAD implant. Finally, subgroup analysis evaluated the association between outcomes and patient acuity by preoperative dialysis.

**MATERIALS AND METHODS**

**Patient Data**

All adult patients (aged >18 years; n = 14,325) undergoing first durable continuous-flow mechanical circulatory support device implant in the STS INTERMACS database between June 2, 2014, and June 30, 2019, were included in the analysis with follow-up through December 31, 2019. Patients receiving total artificial heart and primary isolated right ventricular devices were excluded (Figure E1). Standard STS INTERMACS definitions were used, and longitudinal data were assessed according to customary STS INTERMACS practices. Patients were stratified by preoperative dialysis (n = 400) or no preoperative dialysis (n = 13,925). Landmark analysis then stratified patients alive at 1 month by preoperative dialysis and at 1 month postoperatively (n = 186, persistent dialysis), preoperative dialysis only (n = 131, recovered), postoperative dialysis only (n = 819, new dialysis), and no dialysis (n = 11,047, no dialysis). Recovered was defined as no dialysis preoperatively and no dialysis at 1-month follow-up. Given the deidentified nature of this national database study, it was exempt from review by the University of Virginia Health Sciences Institutional Review Board with waiver of consent.

**Statistical Analysis**

Categorical variables are presented as counts and percentages, and continuous variables are shown as mean ± standard deviation or median (25th, 75th percentiles) based on normality. Baseline characteristics and short-term outcomes were assessed by univariate analysis. The Student t test or Mann–Whitney U test was used for continuous variables, and the chi-square test was used for categorical variables; when appropriate, Tukey’s post hoc correction for multiple comparisons was used. Kaplan–Meier survival estimates were calculated, censoring patients at the time of transplantation, device exchange, or explant for recovery. Time to event analysis was performed with standard INTERMACS methodology using Kaplan–Meier censoring for transplant, device exchange, explant, or death. For all time-varying analyses, differences for specific subsets of data were compared with the use of log-rank testing. A logistic regression was fit in the cohort of all patients on preoperative dialysis for the outcome of “no dialysis” at 1 month after implant. Forward stepwise selection was used for all preoperative and 1-week follow-up variables with less than 20% missing. Model fit and performance were assessed with c-statistic. The patients self-reported if they would undergo LVAD placement again, and these data were presented. All analysis was performed using SAS Version 9.4 (SAS Institute).

**RESULTS**

**Patient Characteristics and Competing Risks**

After applying exclusion criteria, a final population of 14,090 patients undergoing LVAD implantation were included for analysis (Figure E1). A total of 400 (3%) of these patients were on dialysis preoperatively. Patients on dialysis were younger (55 vs 57 years P = .001), with lower rates of bridge to transplant already listed status (18.3% vs 23.1%, P = .02) and significantly higher rates of INTERMACS profile level 1 (49% vs 16%, P < .0001, Table 1). Patients on preoperative dialysis were also significantly

**Abbreviations and Acronyms**

| Abbreviation | Description |
|--------------|-------------|
| BIVAD | biventricular assist device |
| CI | confidence interval |
| ESRD | end-stage renal disease |
| INTERMACS | interagency registry for mechanically assisted circulatory support |
| LVAD | left ventricular assist device |
| OR | odds ratio |
| STS | Society of Thoracic Surgeons |
TABLE 1. Baseline characteristics

| Preimplant characteristics | No predialysis (n = 13,690) | Predialysis (n = 400) | P value |
|----------------------------|----------------------------|----------------------|---------|
| Alcohol abuse              | 1029 (7.5%)                 | 30 (7.5%)            | .99     |
| Aortic regurgitation (moderate/severe) | 521 (4.4%)                 | 12 (3.8%)            | .61     |
| Ascites preimplant         | 436 (4.7%)                  | 26 (9.5%)            | .0002   |
| Blood type O               | 6443 (47.4%)                | 178 (44.9%)          | .33     |
| Cancer                     | 646 (4.7%)                  | 22 (5.5%)            | .47     |
| College                    | 5022 (49.9%)                | 150 (53.6%)          | .22     |
| Current smoker             | 739 (5.4%)                  | 26 (6.5%)            | .34     |
| Drug abuse                 | 1208 (8.8%)                 | 30 (7.5%)            | .36     |
| Bridge to transplant: listed | 3164 (23.1%)                | 73 (18.3%)           | .02     |
| Bridge to transplant: likely to be listed | 1746 (12.8%)             | 37 (9.3%)            | .04     |
| Bridge to transplant: moderately likely to be listed | 1146 (8.4%)       | 44 (11.0%)           | .06     |
| Bridge to transplant: unlikely to be listed | 350 (2.6%)               | 12 (3.0%)            | .58     |
| Destination therapy        | 7170 (52.4%)                | 224 (62.9%)          | <.0001  |
| Failure to wean            | 173 (1.3%)                  | 7 (1.8%)             | .39     |
| History of hepatitis       | 167 (1.2%)                  | 4 (1.0%)             | .69     |
| History of CABG            | 2388 (17.4%)                | 72 (18.0%)           | .77     |
| History of valve surgery   | 908 (6.6%)                  | 31 (7.8%)            | .38     |
| ICD                        | 10,669 (78.4%)              | 248 (62.9%)          | <.0001  |
| INTERMACS Patient Profile Level 1 | 2172 (15.9%)             | 196 (49.0%)          | <.0001  |
| INTERMACS Patient Profile Level 2 | 4731 (34.6%)             | 150 (37.5%)          | .22     |
| INTERMACS Patient Profile Level 3 | 5010 (36.6%)             | 40 (10.0%)           | <.0001  |
| INTERMACS Patient Profile Level 4 | 1496 (10.9%)             | 10 (2.5%)            | <.0001  |
| INTERMACS Patient Profile Level 5 | 187 (1.4%)                | 2 (0.5%)             | .14     |
| INTERMACS Patient Profile Level 6 | 69 (0.5%)                 | 1 (0.3%)             | .48     |
| INTERMACS Patient Profile Level 7 | 25 (0.2%)                 | 1 (0.3%)             | .76     |
| Inotropes                  | 11,556 (84.7%)             | 368 (92.2%)          | <.0001  |
| ECMO                       | 398 (2.9%)                  | 53 (13.3%)           | <.0001  |
| IABP                       | 2380 (17.4%)                | 87 (21.8%)           | .02     |
| Ventilator                 | 599 (4.4%)                  | 68 (17.0%)           | <.0001  |
| LVEF (<20 severe)          | 9180 (70.0%)                | 258 (68.3%)          | .45     |
| Male                       | 10,630 (77.8%)              | 334 (83.5%)          | .01     |
| Married                    | 8115 (60.6%)                | 251 (64.0%)          | .17     |
| Mitral regurgitation (moderate/severe) | 7342 (57.4%)              | 211 (59.8%)          | .38     |
| NYHA = 4                   | 11,155 (84.1%)             | 364 (95.3%)          | <.0001  |
| Peripheral vascular disease | 558 (4.1%)                 | 23 (5.8%)            | .1      |
| Race: White                | 8810 (64.4%)                | 242 (60.5%)          | .11     |
| RV dysfunction (severe)     | 1664 (14.8%)                | 75 (23.4%)           | <.0001  |
| Severe diabetes*           | 1254 (9.2%)                 | 52 (13.0%)           | .01     |
| Temporary cardiac support  | 3740 (32.1%)                | 255 (66.9%)          | <.0001  |
| Tricuspid regurgitation (moderate/severe) | 5341 (42.0%)             | 177 (49.9%)          | .0033   |
| Age (yrs)                  | 56.9 ± 13.0 (n = 13,690)   | 54.8 ± 12.7 (n = 400) | .0011   |
| Albumin (g/dL)             | 3.43 ± 0.6 (n = 13,037)    | 3.07 ± 0.6 (n = 388) | <.0001  |
| Total bilirubin (mg/dL)    | 1.30 ± 1.6 (n = 13,169)    | 2.72 ± 4.5 (n = 391) | <.0001  |
| BMI (kg/m²)                | 28.63 ± 7.4 (n = 13,635)   | 28.89 ± 7.3 (n = 399) | .49     |

(Continued)
TABLE 1. Continued

| Preimplant characteristics | No predialysis (n = 13,690) | Predialysis (n = 400) | P value |
|----------------------------|----------------------------|----------------------|---------|
| BNP (pg/mL)                | 1213.27 ± 1116.4 (n = 6059) | 1638.28 ± 1273.8 (n = 196) | <.0001 |
| BSA (m²)                   | 2.07 ± 0.3 (n = 13,635)     | 2.10 ± 0.3 (n = 399)     | .11     |
| BUN (mg/dL)                | 28.82 ± 16.8 (n = 13,672)   | 34.51 ± 22.1 (n = 399)   | <.0001 |
| Cholesterol                | 128.73 ± 42.4 (n = 8319)    | 108.44 ± 35.5 (n = 241)  | <.0001 |
| Cardiac index (L/min per m²)| 2.14 ± 0.8 (n = 11,670)     | 2.42 ± 1.1 (n = 287)     | <.0001 |
| Creatinine (mg/dL)         | 1.37 ± 0.6 (n = 13,671)     | 2.25 ± 1.7 (n = 399)     | <.0001 |
| Diastolic blood pressure (mm Hg) | 66.09 ± 11.5 (n = 13,454) | 63.21 ± 12.1 (n = 388)   | <.0001 |
| Hemoglobin (mg/dL)         | 11.22 ± 2.2 (n = 13,654)    | 9.11 ± 1.7 (n = 400)     | <.0001 |
| Heart rate (bpm)           | 89.78 ± 17.6 (n = 13,636)   | 95.07 ± 18.0 (n = 398)   | <.0001 |
| INR (international units)  | 1.29 ± 0.5 (n = 13,179)     | 1.42 ± 0.6 (n = 392)     | .0001   |
| LDH                        | 355.76 ± 339.9 (n = 8793)   | 720.69 ± 1445.6 (n = 304) | <.0001 |
| LVEDD (cm)                 | 6.81 ± 1.1 (n = 11,022)     | 6.45 ± 1.1 (n = 293)     | <.0001 |
| Platelet (K/µL)            | 198.11 ± 78.8 (n = 13,643)  | 141.39 ± 78.8 (n = 399)  | <.0001 |
| Pre albumin (mg/dL)        | 18.77 ± 7.3 (n = 7589)      | 14.85 ± 6.8 (n = 256)    | <.0001 |
| Pulmonary diastolic pressure (mm Hg) | 24.89 ± 8.9 (n = 12,182) | 25.81 ± 8.7 (n = 323)   | .07     |
| Pulmonary systolic pressure (mm Hg) | 49.61 ± 14.9 (n = 12,246) | 50.17 ± 15.3 (n = 326)  | .5      |
| Pulmonary wedge pressure (mm Hg) | 25.01 ± 9.4 (n = 10,104)  | 27.51 ± 9.2 (n = 212)    | .0001   |
| Pulmonary vascular resistance (PVR) using cardiac output (wood units) | 4.22 ± 1.4 (n = 11,643) | 4.84 ± 1.6 (n = 285)     | <.0001 |
| RA pressure (mm Hg)        | 12.51 ± 8.1 (n = 9438)      | 16.91 ± 9.4 (n = 195)    | <.0001 |
| AST (µL)                   | 49.08 ± 165.4 (n = 13,192)  | 119.21 ± 538.2 (n = 392) | .01     |
| ALT (µL)                   | 57.70 ± 158.6 (n = 13,174)  | 138.06 ± 464.7 (n = 390) | .0007   |
| Sodium (mmol/L)            | 135.09 ± 4.8 (n = 13,671)   | 135.23 ± 4.9 (n = 399)   | .56     |
| Systolic blood pressure (mm Hg) | 106.55 ± 16.2 (n = 13,484) | 100.59 ± 16.3 (n = 392)  | <.0001 |
| WBC (K/µL)                 | 8.59 ± 3.9 (n = 13,651)     | 11.52 ± 5.8 (n = 399)    | <.0001 |

CAIG, Coronary artery bypass grafting; ICD, implantable cardioverter defibrillator; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; BMI, body mass index; BNP, brain natriuretic peptide; BSA, body surface area; BUN, blood urea nitrogen; INR, international normalized ratio; LDH, lactate dehydrogenase; LVEDD, left ventricular end-diastolic diameter; RA, right atrium; AST, aspartate aminotransferase; ALT, alanine aminotransferase; RV, right ventricle; WBC, white blood cell. *Severe diabetes defined as hemoglobin A1c greater than 8 mg/dL or associated with diabetic nephropathy, vasculopathy, or oculopathy.

more likely to be on temporary circulatory support (66.9% vs 32.1%, P < .0001) including extracorporeal membrane oxygenation (13.3% vs 2.9%, P < .0001), intra-aortic balloon pump (21.8% vs 17.4%, P = .02), and isotropes (92.2% vs 84.7%, P < .0001). Additionally, patients on dialysis had more preoperative right ventricular dysfunction (23.4% vs 14.8% severe, P < .0001) and pulmonary vascular resistance (4.84 vs 4.22 Wood units, P < .0001), and higher brain natriuretic peptide (1638 vs 1213 pg/mL, P < .0001) and total bilirubin (2.72 vs 1.30 mg/dL, P < .0001). Overall markers of acuity were worse in the preoperative dialysis group, including hemoglobin level (9.1 vs 11.2, P < .0001), platelets (141 vs 198, P < .0001), albumin (3.1 vs 3.4, P < .0001), and ascites (9.5% vs 4.7%, P = .0002).

Competing risk of death, transplant, and recovery were assessed for the no preoperative dialysis group (Figure 1, A) and the preoperative dialysis group (Figure 2, B). There were lower rates of transplantation (18% vs 25%, P < .0001) and higher mortality (45% vs 24%, P < .0001) over the first 24 months for patients on preoperative dialysis.

Time to Adverse Events and Patient-Reported Quality of Life

The time to first stroke, including hemorrhagic, ischemic, or transient ischemic attack, was worse in the patients with preoperative dialysis (P < .0001, Figure 2, A). The time to first major nondevice infection was significantly worse for the preoperative dialysis group (P < .0001, Figure 2, B). When assessing time to first major bleeding event, the preoperative dialysis group performed worse (P < .0001, Figure 2, C). Additionally, time to first major gastrointestinal bleeding event was worse in the preoperative dialysis group (P < .0001, Figure 2, D). When assessing time to first adverse device-related event, we saw no statistical association for major pump-related infection (Figure 3, A, P = .99). The time to first major nonthrombotic device malfunction was not statistically associated with preoperative dialysis.
status (Figure 3, B, $P = .34$). Finally, time to first device thrombosis did not statistically differ between groups (Figure 3, C, $P = .06$).

Patient-reported outcomes were assessed in the STS INTERMACS database and compared by preoperative dialysis status. Responses to the question “Knowing what you
FIGURE 2. Time to major adverse event by preoperative dialysis. A. Time to first CVA by preimplant dialysis status: censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B. Time to first major infection by preimplant dialysis status: censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. C. Time to first bleeding episode by preimplant dialysis status: censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. D. Time to first gastrointestinal bleeding by preimplant dialysis status: censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. CVA, Cerebrovascular accident; GI, gastrointestinal.
know now would you still have undergone ventricular assist device support?” demonstrated no difference by preoperative dialysis (all $P > .05$, Figure E2, A). A majority of patients in both groups at all time points answered positively that they would undergo LVAD implantation again. Response rates for patient-reported outcomes were between 38% and 54% over the first 12 months.

Landmark Analysis and Predictors of Renal Recovery

Subgroup analysis landmark on survival at 30 days demonstrated patients on preoperative dialysis; 131 (32.8%) no longer required dialysis at 1 month postoperatively, and this subset had similar long-term survival to patients who never required dialysis (no dialysis vs recovered,
Long-term survival was significantly worse in patients with persistent dialysis and new dialysis at 1 month postoperatively ($P < .0001$, Figure 4).

Two logistic regressions were fit to identify independent predictors of renal recovery, with the first only including preoperative factors and the second including preoperative...
and 1-week postoperative variables. A total of 131 patients no longer required dialysis at 1 month for the model. In the preoperatively only model, several independent predictors were identified with higher preoperative sodium (odds ratio [OR], 0.93; 95% confidence interval [CI], 0.89-0.98), creatinine (OR, 0.47; 95% CI, 0.35-0.63), and white blood cell count (OR, 0.93; 95% CI, 0.88-0.98) were associated with lower rates of recovery. However, higher blood urea nitrogen (OR, 1.02; 95% CI, 1.01-1.03) was associated with higher rates of renal recovery (Table 2).

In a model including preoperative and 1-week postoperative variables, preimplant dialysis within 48 hours (OR, 0.52; 95% CI, 0.29-0.93), previous cardiac surgery (OR, 0.53; 95% CI, 0.30-0.94), biventricular assist device (BIVAD) implant (OR, 0.20; 95% CI, 0.08-0.53), and higher preoperative sodium (OR, 0.93; 95% CI, 0.88-0.98) and creatinine (OR, 0.67; 95% CI, 0.49-0.90) were independently associated with a lower chance of recovery. One-week postimplant variables independently associated with renal recovery included higher blood urea nitrogen (OR, 1.04; 95% CI, 1.03-1.06), whereas higher creatinine (OR, 0.43; 95% CI, 0.27-0.67), albumin (OR, 0.33; 95% CI, 0.19-0.58), and white blood cell count (OR, 0.90; 95% CI, 0.86-0.95) were associated with lower renal recovery (Table 3). Finally, the strongest negative predictor of renal recovery was requirement of inotropic support 1 week after implant (OR, 0.19; 95% CI, 0.08-0.48).

Subgroup Analysis by Acuity

To account for the disproportional number of high-acuity patients in the preoperative dialysis group, we performed a subgroup analysis stratified by INTERMACS level (1-2 and 3-7). All-cause survival was significantly higher in patients not requiring preoperative dialysis regardless of INTERMACS level (Figure 5, A and B). When looking at time to adverse event, contrary to the primary analysis, cerebrovascular accident was significantly worse in patients on preoperative dialysis in the INTERMACS 1-2 subgroups with no statistical difference in the INTERMACS 3-7 subgroup (Figure E3). However, the remainder of the subgroup time to adverse event analysis was similar to the primary analysis with patients on preoperative dialysis having significantly worse time to event for major infection (Figure E4), major bleed (Figure E5), and gastrointestinal bleed (Figure E6) in both the high-acuity (INTERMACS 1-2) and lower-acuity (INTERMACS 3-7) groups. Likewise, the device-related time to adverse events did not differ by dialysis status for pump-related infection (Figure E7) or device malfunction (Figure E8) in the INTERMACS 1-2 or INTERMACS 3-7 cohorts. However, freedom from device thrombus was significantly worse for patients on preoperative dialysis in the INTERMACS 1-2 cohort but not in the INTERMACS 3-7 cohort (Figure E9).
DISCUSSION

This study demonstrates that a minority of patients undergoing LVAD implantation in the STS INTERMACS database required preoperative dialysis. These patients had significantly higher acuity and worse baseline right heart function. As hypothesized, patients requiring preoperative dialysis before LVAD implantation had significantly higher mortality with worse long-term survival and freedom from adverse events. However, there was a subset of patients who recovered renal function and had similar long-term outcomes similar to patients not on dialysis preoperatively. We identify several preoperative and 1-week postoperative predictors of renal recovery, with BIV AD implant and remaining on inotropes at 1 week being the strongest predictors of no renal recovery. The subgroup analysis demonstrated similar findings when accounting for acuity by analyzing INTERMACS 1-2 and INTERMACS 3-7 patients separately (Figure 6).

FIGURE 4. The 1-month landmark survival for persistent dialysis (blue), preoperative dialysis that recovered (red), new postoperative dialysis (green), and no preoperative or postoperative dialysis (yellow). Number at risk listed across the bottom. Log-rank comparison of each group listed in the right top corner.

TABLE 2. Predictors of renal recovery in patients on preimplant dialysis including preimplant risk factors

| Predictor                     | Odds ratio | 95\% CI | \( P \) value |
|-------------------------------|------------|---------|---------------|
| Preimplant sodium (mmol/L)    | 0.93       | 0.89-0.98 | .01           |
| Preimplant BUN (mg/dL)        | 1.02       | 1.01-1.03 | .006          |
| Preimplant creatinine (mg/dL) | 0.47       | 0.35-0.63 | <.0001        |
| Preimplant WBC (\( \times 10^9 \)L) | 0.93   | 0.88-0.98 | .005          |

CI, Confidence interval; BUN, blood urea nitrogen; WBC, white blood cell.
These data support the hypothesis that preoperative dialysis before LVAD implantation is a major risk factor for death and adverse events. A recent study by Bansal and colleagues also examined this question using Medicare claims data 2003-2013 and demonstrated a median survival of 16 days with 51.6% of patients with ESRD dying during the index hospitalization for LVAD implantation. A more recent study by Kilic and colleagues reports outcomes of 18 patients requiring preoperative dialysis with a 1-year survival of 55%. However, the contemporary data in the present study are more encouraging with a 55% 2-year survival. In addition to improved patient selection and expanded device options, the experience in providing multidisciplinary care for these complex patients has improved over time. Despite these advancements, it is still appropriate to consider dialysis dependence a major risk for patients undergoing consideration for LVAD implant, and we would highlight the importance of etiology of renal dysfunction in patient selection. Mohamedali and colleagues further highlighted the relationship between preoperative renal dysfunction (glomerular filtration rate ≤60) and postimplant survival, which was strongly associated with recovery of renal function postoperatively.

These data demonstrate that preoperative dialysis was associated with postimplant complications including stroke, infection, and bleeding but not device-specific complications. These findings are important when considering LVAD implantation in patients on dialysis because the inherent risks can be overcome if the patient has renal recovery with no persistent risk from the device. However, if patients do not recover renal function, the early morbidity will contribute significantly to early mortality. These issues further highlight the importance of defining etiology of preoperative renal dysfunction to determine the likelihood of renal recovery after LVAD implantation. Despite the associations between postoperative dialysis and mortality, an overwhelming majority of patients said they would undergo LVAD implantation again given their experience.

We identify a subset of patients on preoperative dialysis (32.8%) who recover renal function after LVAD implant. This cohort of patients did very well long term and had equivalent outcomes to those who do not require dialysis preoperatively or postoperatively. The single-center study by Kilic and colleagues showed similar findings examining patients with preoperative renal dysfunction or dialysis. In their series of 273 patients undergoing LVAD implant, they demonstrate that approximately 50% of patients with preoperative renal dysfunction ultimately recover renal function by 1 year. Another series by Franz and colleagues reports 50% renal recovery or progression to heart/kidney transplant in 11 patients requiring maintenance hemodialysis after LVAD implant. The present study goes one step further to identify predictors of renal recovery for preoperative patient selection with negative predictors including BIVAD implants, prior cardiac surgery, and higher sodium or creatinine. We also include 1-week postimplant characteristics for the purpose of patient counseling and decision making for postimplant. Most important, we demonstrate that patients still requiring inotropes 1 week postimplant are more than 5 times less likely to have renal recovery by 1 month postimplant (OR, 0.19).

Several studies have evaluated the incidence and impact of postoperative renal failure after LVAD implant. The present data from the STS INTERMACS database demonstrate a 6.9% rate of new postoperative renal failure, with these patients having the lowest survival, which was comparable to patients with preoperative and persistent dialysis. These data are further supported by the study from Seese and colleagues identifying 2 pathways to multisystem organ failure after LVAD implantation, with postoperative renal failure highlighting the early-death cluster pathway. According to the authors, the early-death pathway was characterized by renal failure-to-respiratory failure-to-death with a median survival of less than 1 month. Additionally, data from Walther and colleagues highlight the significant association between new-onset renal dysfunction and hospital readmission after LVAD implant. Given the high morbidity and mortality associated with postoperative renal failure, a clinical risk prediction tool would be beneficial for patient selection. Current data support preoperative renal function as one of the strongest predictors of postoperative renal failure, with other predictors likely similar to those used in survival models given the strong association between renal failure and death.

### Study Limitations

The limitations of this study include the retrospective nature precluding demonstration of causality. Additionally,
we do not have specific data on the nature of preoperative dialysis including chronicity, frequency, or duration. Furthermore, we are unable to control for clinical decision making pertaining to device implantation or management of renal failure. Finally, the patient-reported outcomes represent data available for a minority of patients in each group and may be biased toward patients with optimal outcomes.20,21
CONCLUSIONS

Preoperative renal failure is associated with 3 times higher mortality and worse freedom from adverse events for patients receiving LVADs. However, a subset of patients (32.8%) will recover renal function postimplant and experience long-term survival and quality of life similar to those without dialysis. However, patients undergoing BIVAD and requiring inotropes at 1 week postimplant are significantly less likely to have renal recovery. Patient selection in the presence of dialysis dependence should focus on identifying these patients who have the greatest potential for renal recovery or successful bridge to heart/kidney transplant to benefit from LVAD implantation.

Conflict of Interest Statement

Dr Yarboro is proctor and consultant for Medtronic. Dr Yount is a proctor and consultant for Edwards Life Science. Dr Kirklin is Director of the Data Center for STS INTERMACS and receives partial salary support paid to his institution. Dr Ailawadi is a consultant for Abbott, Edwards, Medtronic, Anteris, Attricure, and Gore. All other authors reported no conflicts of interest.

The Journal policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.
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References

1. Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009;361:2241-51.

2. Rose EA, Gelijns AC, Moskowitz AJ, Heitjan DF, Stevenson LW, Dembinsky W, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med*. 2001;345:1435-43.

3. Patel AM, Adegbeye GA, Ahmed I, Mitter N, Rame JE, Rudnick MR. Renal failure in patients with left ventricular assist devices. *Clin J Am Soc Nephrol*. 2013;8:484-96.

4. Raichlin E, Babiha B, Lowes BD, Zolty R, Lyden ER, Vongooru HR, et al. Outcomes in patients with severe preexisting renal dysfunction after continuous-flow left ventricular assist device implantation. *ASAIO J*. 2016;62:261-7.

5. Kirklin JK, Naftel DC, Kormos RL, Pagani FD, Myers SL, Stevenson LW, et al. Quantifying the effect of cardiorenal syndrome on mortality after left ventricular assist device implant. *J Heart Lung Transplant*. 2013;32:1205-13.

6. Topkara VK, Dang NC, Barili F, Cheema FH, Martens TP, George I, et al. Predictors and outcomes of continuous veno-venous hemodialysis use after implantation of a left ventricular assist device. *J Heart Lung Transplant*. 2006;25:404-8.

7. Bansal N, Harlpern SM, Katz R, Hall YN, Kurella Tamura M, Kreuter W, et al. Outcomes associated with left ventricular assist device recipients with and without end-stage renal disease. *JAMA Intern Med*. 2018;178:204-9.

8. Kilic A, Chen CW, Gaffey AC, Wald JW, Acker MA, Altieri P. Preoperative renal dysfunction does not affect outcomes of left ventricular assist device implantation. *J Thorac Cardiovasc Surg*. 2018;156:1093-101.e1.

9. Teuteberg JJ, Cleveland JC Jr, Cowger J, Higgins RS, Goldstein DJ, Keebler M, et al. The Society of Thoracic Surgeons Intermacs 2019 annual report: the changing landscape of devices and indications. *Ann Thorac Surg*. 2020;109:649-60.

10. Sosa Barrios H, Palmer A, Khan T, Baner T, Duncan N. Successful long-term intermittent hemodialysis in a patient with left ventricular assist device. *Clin Nephrol*. 2014;82:407-10.

11. Roeher B, Vest AR, Weiner DE. Left ventricular assist devices, kidney disease, and dialysis. *Am J Kidney Dis*. 2018;71:257-66.

12. Ajmal MS, Parikh UM, Lamba H, Walther C. Chronic kidney disease and acute kidney injury outcomes post left ventricular assist device implant. *Curr Rev*. 2020;12:e7725.

13. Mohamedali B, Bhat G. The influence of pre-left ventricular assist device (LVAD) implantation glomerular filtration rate on long-term LVAD outcomes. *Heart Lung Circ.* 2017;26:1216-23.

14. Franz DD, Hussein WF, Abra G, Diskin CD, Duggal V, Teuteberg JJ, et al. Outcomes among patients with left ventricular assist devices receiving maintenance outpatient hemodialysis: a case series. *Am J Kidney Dis*. 2021;77:226-34.

15. Muslem R, Caliskan K, Akin S, Sharma K, Giotra NA, Constantinescu AA, et al. Acute kidney injury and 1-year mortality after left ventricular assist device implantation. *J Heart Lung Transplant*. 2018;37:116-23.

16. Seese L, Movahedi F, Anstaki J, Kilic A, Padman R, Zhang Y, et al. Delineating pathways to death by multisystem organ failure in patients with a left ventricular assist device. *Ann Thorac Surg*. 2021;111:881-8.

17. Walther CP, Winkelmaier WC, Deswal A, Niu J, Navaneethan SD. Readmissions after acute kidney injury during left ventricular assist device implantation hospitalization. *Am J Nephrol*. 2020;51:172-81.

18. Kanswar MK, Lohmueller LC, Kormos RL, Teuteberg JJ, Rogers JG, Lindenfield J, et al. A Bayesian model to predict survival after left ventricular assist device implantation. *JACC Heart Fail*. 2018;6:771-9.

19. Harmon DM, Tecson KM, Lima B, Collier JG, Shailkh AF, Still S, et al. Outcomes of moderate-to-severe acute kidney injury following left ventricular assist device implantation. *Cardiovasc Med*. 2019;9:100-7.

20. Gupta BP, Grady KL, Fendler T, Jones PG, Spertus JA. Variation of quality of life data collection across INTERMACS sites. *J Card Fail*. 2016;22:323-37.

21. Grady KL, Jones PG, Cristian-Andrei A, Naftel DC, Myers S, Dew MA, et al. Causes and consequences of missing health-related quality of life assessments in patients who undergo mechanical circulatory support implantation: insights from INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support). *Circ Cardiovasc Qual Outcomes*. 2017;10:e003268.

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FIGURE E1. Consort diagram of the study population and 30-day outcomes for each group. VAD, Ventricular assist device; TAH, total artificial heart; RVAD, right ventricular assist device; LVAD, left ventricular assist device.

FIGURE E2. Patient-reported response to the question “Knowing what you know now would you get a VAD?” for preoperative dialysis (red) and no preoperative dialysis (blue) at 3, 6, and 12 months with response rate. VAD, Ventricular assist device.
FIGURE E3. Time to first CVA by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first CVA by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first CVA by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. CVA, Cerebrovascular accident.
FIGURE E4. Time to first major infection by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first major infection by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first Major Infection by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom.
FIGURE E5. Time to first bleeding episode by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first bleeding episode by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first Bleeding episode by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom.
**FIGURE E6.** Time to first GI bleeding by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first GI bleeding by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first GI bleeding by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. GI, Gastrointestinal.
FIGURE E7. Time to first pump-related infection by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first pump-related infection by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first pump-related infection by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom.
FIGURE E8. Time to first device malfunction (not thrombus) by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first device malfunction (not thrombus) by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first device malfunction (not thrombus) by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom.
FIGURE E9. Time to first thrombus event by preimplant dialysis groups. A, INTERMACS Profile 1-2 time to first thrombus event by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom. B, INTERMACS Profile 3-7 time to first thrombus event by preimplant dialysis status. Censored at transplant, cessation of support, or study close. Bands represent 70% CIs. Number at risk listed across the bottom.