

# Comparison of the CardioWest Total Artificial Heart, the Novacor Left Ventricular Assist System and the Thoratec Ventricular Assist System in Bridge to Transplantation

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**Background.** Device selection has historically been supported by minimal comparative data. Since 1994, we have implanted 43 patients with the CardioWest Total Artificial Heart (CW), 23 with the Novacor Left Ventricular Assist System (N), and 26 with the Thoratec Ventricular Assist System (T). This experience provides a basis for our device selection criteria.

**Methods.** We reviewed retrospectively the results for survival, stroke, and infection in the CW, N, and T groups. Statistical methods included the Student's *t*-test,  $\chi^2$  analysis, and Kaplan-Meier actuarial survival curves.

**Results.** The T group patients were younger and smaller sized than the CW or N group. The CW group had the highest mean central venous pressure (CVP) and lowest mean cardiac index. Survival to transplantation

was 75% for CW, 57% for N, and 38% for T. Multiple organ failure postimplant caused most deaths in the CW and T groups. Right heart failure and stroke caused most N deaths. Linearized stroke rates (event/patient-month) were 0.03 for CW, 0.28 for N, and 0.08 for T. Serious infections were found in 20% of CW, 30% of N, and 8% of T patients, but linearized rates showed little difference and death from infection was rare.

**Conclusions.** The N device should be used in "stable" patients with body surface area (BSA) greater than 1.7 m<sup>2</sup> and with minimal right heart failure. Unstable patients with biventricular failure should receive a CW if the BSA is greater than 1.7 m<sup>2</sup> or a T if they are smaller.

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The choice of a device in bridge to transplantation may be lifesaving. Unfortunately, little information is available comparing different types of devices [1, 2], and often the choice depends on institutional device availability, experience, and physician comfort and bias [3]. There are several retrospective single-device studies that have indirectly shed light on this question by identifying risk factors from the use of various devices [4].

Since 1985, we have had experience with mechanical circulatory support of 209 patients with seven types of cardiac assist devices. Included among these are 142 long-term support devices used for bridge to transplantation (Table 1).

We have accumulated 11 patient-years of experience with total artificial hearts and 12 patient-years with ventricular assist devices. Over the past 2 years, the average waiting time on device support has been 117 days for the CardioWest (CW) [Tucson, AZ] total artificial heart, 128 days for the Novacor (N) [Oakland, CA] left

ventricular assist system, and 40 days for the Thoratec (T) [Pleasanton, CA] ventricular assist system.

We started our bridge-to-transplant experience in March 1985 with a total artificial heart [5], followed by Novacor in 1989 and Thoratec in 1995. Thus, we have had to choose among CW, N, and T, for several years [6-9].

From this experience, we have developed a systematic approach to device selection in deteriorating potential cardiac recipients. This is based upon our perception of differences among the devices in efficacy and safety related to patient size, degree and presentation of cardiac insufficiency, and device capability. In this report, we summarize our data on survival, thromboembolism, and infection in the CW, N, and T groups and explain our rationale for device selection in bridge to transplantation.

## Material and Methods

We have retrospectively analyzed data from patients in whom the intention was to perform a cardiac transplant. Nearly all had been completely evaluated and accepted for cardiac transplantation [10, 11]. All were implanted with devices on at least a semiurgent basis. Most had inotrope-dependent heart failure with progressive failure to respond. The standard criteria for device implantation

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Table 1. Bridge to Transplant, University of Arizona Experience

	Patients	Patient-Years
Total artificial heart (Phoenix, Symbion, CardioWest)	55	11.0
Novacor	37	6.4
Thoratec (21 BVAD, 9 LVAD)	31	4.2
Berlin VAD	1	0.3
Symbion VAD (13 BVAD, 5 LVAD)	18	1.4
Total	142	23.3

BVAD = biventricular assist device; LVAD = left ventricular assist device; VAD = ventricular assist device.

for biventricular devices were: cardiac index less than 2.0 L/min/m<sup>2</sup>, central venous pressure (CVP) ≥ 16 mm Hg, and high dose of inotropes (minimum of two); most had decreasing renal function in spite of renal dose dopamine and diuretics, and often we observed declining state of consciousness. For the N left ventricular assist system, we attempted to avoid patients with CVP greater than 16 or any other sign of right heart failure and those who rapidly deteriorated, failed to wean from cardiopulmonary bypass, or had sudden cardiac arrest.

Student's *t* tests were used to compare means for preimplant variables. We examined survival to implantation and survival to discharge using  $\chi^2$  analysis to compare the results with the three devices with a significance level of 0.05. When  $\chi^2$  testing was significant, *z* tests for comparing two proportions were used to determine which proportions significantly differed. Multiple comparisons were adjusted using Bonferroni's correction. We also examined Kaplan-Meier actuarial survival curves for survival to explantation and to discharge. Survival was evaluated for all bridge-to-transplant patients from January 1, 1994, to July 1, 2000.

Thromboembolism and infections were evaluated retrospectively from September 30, 1994, to April 2000. The start date was chosen to coincide with the implementation of our current anticoagulation protocol [12].

## Results

Patient profiles are shown in Table 2. There were a higher percentage of females in the T group. And they were significantly younger than N, but not CW. Also, N patients were significantly older than CW. T patients were significantly smaller than CW and N, whereas CW and N patients were not different in size. Preimplant CVP was higher in the CW group than either the N or T group. The preimplant CI was lower in the CW group than in the T group, but not significantly lower than the N group with the numerical data. However, in 4 of the CW patients, hemodynamics were not entered because the patients presented with failure to wean or cardiac arrest, thus making the CW group distinctly sicker hemodynamically than the N group. Of interest was that 12 of 18 strokes in the N group occurred in 4 females with an average weight of 62 kg and BSA of 1.63 m<sup>2</sup>.

Table 2. Patient Preimplant Profiles

	CardioWest	Novacor	Thoratec
Number of patients	43	23	26
Female, %	23	26	38
Age, years ± SD	50 ± 11 <sup>a</sup> (18-64)	55.7 ± 7.6 <sup>ac</sup> (35-65)	43 ± 18 <sup>c</sup> (7-66)
Weight, kg ± SD	83.4 ± 18.4 <sup>b</sup> (62-112)	80.8 ± 15.9 <sup>c</sup> (52-101)	68.6 ± 18 <sup>bc</sup> (17-110)
BSA, m <sup>2</sup> ± SD	2.03 ± 0.16 <sup>b</sup>	1.96 ± 0.19 <sup>c</sup>	1.76 ± 0.27 <sup>bc</sup>
CVP, mm Hg ± SD	20 ± 8 <sup>a,b</sup>	14 ± 6 <sup>a</sup>	15 ± 7 <sup>b</sup>
CI, L/min/m <sup>2</sup> ± SD	1.9 ± 0.2 <sup>b</sup>	2.1 ± 0.6	2.3 ± 0.8 <sup>b</sup>
Creatinine, mg/dL	1.4	1.4	1.3
BUN, mg/dL	33	28	28
Bilirubin, mg/dL	1.9	2	2

Means are shown for each group.

<sup>a</sup>*p* < 0.05 for CW vs N; <sup>b</sup>*p* < 0.05 for CW vs T; <sup>c</sup>*p* < 0.05 for N vs T.

BSA = body surface area; CI = cardiac index; CVP = central venous pressure.

Survival was evaluated in 43 CW, 23 N, and 26 T patients. Percent survivals to explant were: 75% for CW, 57% for N, and 38% for T (Table 3). By  $\chi^2$  analysis, there was a significant association between device type and survival to explant (*p* = 0.012). By *z* test for comparing proportions, CW versus N and N versus T were not significantly different, but CW versus T was significant at *p* = 0.003. Further analysis of the T data revealed a 25% survival to explant in the 8 patients with initial left ventricular assist device (LVAD) implantation (1 of 3 patients converted from LVAD to biventricular assist device [BVAD] survived) and a 50% survival to explant of the 18 BVAD implants. Survival from implant to discharge posttransplant was 59% for CW, 56% for N, and 33% for T (Table 3). This was nearly significant by  $\chi^2$  analysis (*p* = 0.72), and the CW versus T *z* analysis approached significance (*p* = 0.035), whereas other comparisons did not. Actuarial survival to explant was significantly better for CW and N than for T (CW vs T, *p* < 0.01; N vs T, *p* < 0.05). Actuarial survival from implant to discharge was also better for CW and N than for T (CW vs T, *p* < 0.01; N vs T, *p* < 0.05) (Figs 1 and 2). Not shown in the figures are the curves comparing T

Table 3. Bridge to Transplantation Results

	CardioWest	Novacor	Thoratec	Total
Number of patients	43	23	26	92
Number currently on device support	3	0	0	3
Mean days of device support	84	86	45	73
Deaths	10	10	16	36
Percent surviving to transplantation	75%	57%	38%	60%
Percent surviving to discharge	59%	56%	33%	52%

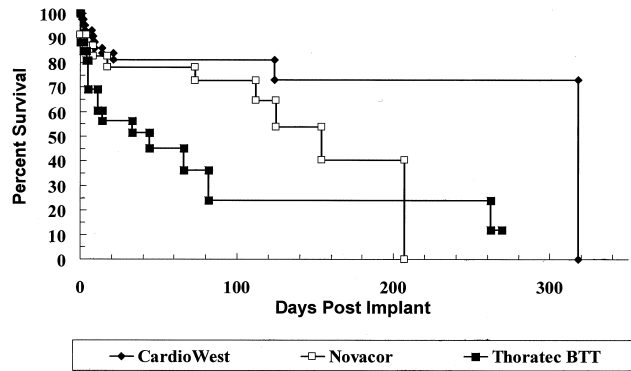


Fig 1. Actuarial survival from implantation to explantation. CW and N were better than T at  $p < 0.05$ . (BTT = Bridge to transplant.)

with initial LVAD and T with initial BVAD where there was no significant difference.

Causes of death were predominated by multiple organ failure, right heart failure, sepsis, and stroke, and were distinctive for each device (Table 4). In the CW group, five deaths from multiple organ failure were in the first 3 postimplant days, one death from sepsis was related to mediastinal infection from a coronary artery bypass graft (CABG) 3 days previously, and one related to poor general condition of the patient. The device malfunction was a diaphragm rupture at 145 days of support, apparently a unique event because none other has ever been reported with this device. Also of note were two cases of a central venous catheter entrapment of the prosthetic tricuspid valve of the right ventricle causing device shutdown and death. In the N group, there were four deaths attributed primarily to right heart failure and three to stroke. All 6 of these patients had other associated morbidity. In the T group, 18 were BVADs only, 5 started as LVADs and converted to BVADs, and 3 were LVADs for the entire implant period. Survivors in the T group included 8 of 18 (44%) of the BVAD-only group that survived, 1 of 3 (33%) of the BVADs that were converted from LVADs, and 1 of 5 (20%) of the LVADs.

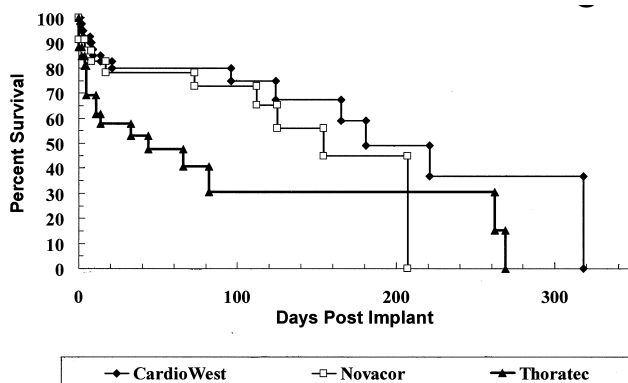


Fig 2. Actuarial survival from implantation to posttransplant hospital discharge. CW and N were better than T at  $p < 0.05$ .

Table 4. Causes of Death

Cause of Death	CardioWest	Novacor	Thoratec	Total
Multiple organ failure	5	0	7	12
Right heart failure	0	4	5	9
Sepsis	2	2	1	5
Stroke	0	3	2	5
Device malfunction	1	0	0	1
Catheter entrapment	2	0	0	2
Respiratory failure	0	0	1	1
Total	10	10	16	36

Multiple organ failure and right heart failure (low output or high CVP on device support) were the major causes of death. The considerable number of multiple organ failure deaths attests to the “end-stage” condition of many of the patients in this group. Four of the five right heart failure deaths were in patients that began with an LVAD. Two were converted to T BVADs and two were not. In the other right heart failure death, the patient was in heart failure with a BVAD. Throughout his 7-month implant, he had ascites, hepatomegaly, dependent edema, and high CVP. He was a large man (90 kg) who seemed to have inadequate pump flows.

Table 5 summarizes the experience with strokes and transient ischemic attacks (TIAs). We found a clustering of strokes in the Novacor group that appeared to relate to gender: 12 of the 18 strokes were in the 4 female stroke patients. Similarities they shared were lower outputs and smaller stature. For this reason, we looked at the experience with and without (N\*) these female patients. Strokes were seen in 8% of the CW group, 32% of the N patients, 21% of the N\* patients, and 12% of the T patients. Linearized stroke rates revealed the N rate to be three times higher than the T group and seven times higher than the CW group. The CW group, with a rate of 0.03 strokes/patient month, was also nearly three times lower than the T stroke rate. TIAs were seen in 8% of the CW group, 34% of the N group, 21% of the N\* group, and 4% of the T group. Linearized TIA rates were fairly similar for CW (0.05) and T (0.08), but two to four times higher for the N groups.

As in any sick hospital population, there were many infections, but most were of no consequence (Table 6). We have shown only the “serious” infections defined as culture-positive blood, mediastinum, or Novacor pocket. The mediastinal infections for both the CW and T groups were incidental findings and not clinically apparent even at the time of explant. None of the 3 CW patients died. The T patient died of multiple organ failure, not from infection. Other causes of death in this group included: for CW, sepsis related to a CABG operation 4 days before implantation, and for N, Candida sepsis with stroke (1), pocket infections with strokes (2). There was no significant association between device type and infection incidence by  $\chi^2$  analysis.

Table 5. Neurologic Events

	CardioWest	Novacor	Novacor <sup>a</sup>	Thoratec
Number of patients from Sept 1994 to Apr 2000	40	23	19	26
Total number of patients with strokes/ number of patients	3/40 (8%)	8/23 (32%)	4/19 (21%)	3/26 (12%)
Total number of strokes	3	18	6	3
Patient days/patient years accumulated	3,050 days (8.38 years)	1,976 days (5.4 years)	1,413 days (3.88 years)	1,168 days (3.2 years)
Linearized rate: strokes/patient year	0.36	3.3	1.5	0.94
Linearized rate: strokes/patient month	0.03	0.28	0.13	0.08
Total number of patients with TIAs/ number of patients	3/40 (8%)	3/23 (34%)	4/19 (21%)	1/26 (4%)
Total number of TIAs	5	13	7	3
Linearized rate: TIAs/patient year	0.58	2.4	1.8	0.94
Linearized rate: TIAs/patient month	0.05	0.20	0.15	0.08

<sup>a</sup> Novacor refers to the N group minus 4 females with strokes.

TIAs = transient ischemic attacks.

### Comment

The results of this study must to some extent reflect institutional biases in patient referral patterns, patient selection for implantation, timing of implantation, and device selection. Clearly, these are very sick patients, with 1 of 3 dying from multiple organ failure and an additional 1 of 4 (all from the N and T groups) dying of right heart failure. The T survival rate of 38% is lower than that reported by others [1, 2] (72% and 61%). The N survival to transplant was at 57%, equal to the "noncore" survival (n = 27) and 20% lower than the "core" (n = 129) of 77% reported by the company from their US trial [13]. And the 75% survival for the CW group was nearly 20% below that reported from the national trial (93% survival to explant, n = 27) [14], and closer to the international results (69% survival to explant, n = 114) [15] and to our previous institutional experience (83% survival to explant, n = 24) [16]. Patient selection for the CW from 1993 to 1996 in 14 patients was more stringent than for the subsequent 29. Only patients who were reasonable candidates for transplantation were included in the initial 14. For the subsequent 29, selection criteria included failure to wean, cardiac arrest, and patients who might become reasonable transplant candidates, but were not at the time of implantation. Patient selection for the N has eliminated candidates with right heart failure since 1994. From 1991 until the end of 1993, when we had N as our

only mechanical support device, our experience using N for "all comers" was not good. Since 1995, we have used the T as a device for smaller patients and often as a "last resort." Timing is always individualized. We have not hesitated to use the CW and T for patients that require emergent support (failure to wean, cardiac arrest, rapid deterioration), but we have avoided this type of patient in the N group. The survival for the CW group was significantly better than for the T group. It was also better than the N group, but for that difference to be significant, we would need approximately six times as many patients in each group. Patients in all three groups became better transplant candidates on device support. The CW patients were extubated at 3 ± 3 days, discharged from the intensive care unit in 11 ± 8 days, and able to gain weight and attend cardiac rehabilitation daily.

Besides having demonstrated a mortally ill population influencing survival, we have in previous presentations [17, 18] looked at predictors of survival in most of the same patients analyzing a large list of preimplant variables with univariate and multivariate stepwise logistic regression analysis. We found that multivariate predictors of poor outcome for CW and T were the same: prothrombin time more than 15 seconds ( $p = 0.025$ ) and cardiac surgery preceding the implantation by 7 days or less ( $p = 0.003$ ). For N, multivariate analysis predictors of poor outcome were CVP more than 20 mm Hg ( $p =$

Table 6. Serious Infections

	CardioWest	Novacor	Thoratec
Positive blood cultures	4 ( <i>Staph epi</i> 3, <i>S aureus</i> 1)	3 (group D strep 2, candida 1)	1 ( <i>S aureus</i> 1)
Positive mediastinal cultures	3 ( <i>S epi</i> 2, bipolaris)	0	1 (anerobes)
Positive Novacor pocket cultures		6 (group D strep 1, <i>S epi</i> 3, bipolaris 1, klebsiella 1)	
Number of seriously infected patients	8/41 (20%)	7/23 (30%)	2/26 (8%)
Deaths in infected patients	1	3	1
Strokes in infected patients	0	4	1



0.05), serum creatinine more than 2 mg/dL ( $p = 0.04$ ), and APACHE II score of more than 28 ( $p = 0.001$ ). We also found that a positive predictor of survival for all devices was a cardiac index during the first 24 postimplant hours of 2.5 L/min/m<sup>2</sup> or more. From these analyses, sicker patients with right ventricular failure and renal impairment are best treated with biventricular support. Further, if the CI does not reach 2.5 L/min/m<sup>2</sup> in the first 24 hours postimplantation, a second intervention such as repositioning the device or cannulas or adding an RVAD may be warranted.

The data on strokes and infections also help in discriminating among the three devices studied. Stroke incidences in this study were 8% for CW, 34% for N, 21% for the N\* group after censoring the 4 small females with clusters of strokes, and 12% for T.  $\chi^2$  analysis of CW versus N\* versus T revealed no significant association between device type and stroke ( $p = 0.126$ ). In the two other studies comparing different devices in bridge to transplantation [1, 2], the cerebral embolism incidence was 22% and 24% for T, 39% for N, and 16% in both studies for HeartMate. Our results for CW and T compare favorably, and for N are similar to previous reports. The linearized stroke rates per patient month were 0.03 for CW, 0.13 for the "low-risk" N group, and 0.08 for the T group. This supports the concepts of prolonged device support with reasonable thromboembolism rates and of the monitoring and anticoagulation protocol that was uniform throughout this study [12].

Obviously, the increased stroke incidence with N is of concern. If the trend we have observed continued, we would have a significant difference with about four times as many patients in each group with an 80% power. Fortunately, we have seen no strokes or TIAs in the last 364 patient-days with the N since making two changes in our protocol with that device. First, because of the clustering of strokes in small female recipients, we have increased our lower limit for size with the N from greater than 1.5 m<sup>2</sup>, the recommended cutoff, to greater than 1.7 m<sup>2</sup>. We believe that flows in the range of 6 or more L/min tend to prevent stasis and embolism in that device. Our observation has been that smaller patients tend to have lower flows. Second, it is well established that infection stimulates hypercoagulability. We have found this to be particularly true in device patients. As can be seen in this study, the incidence of serious infection for N patients was 30%. Most of these (86%) were "pocket infections." Because of that, we have abandoned the abdominal wall pocket technique, and in the past year adopted a "walled-off" intraabdominal technique (technique suggested by T. Icenogle, MD). We use a perforated Gore-Tex abdominal wall patch material to create an intraabdominal space next to the diaphragm that excludes the abdominal contents. Not only is this large and easy to use, but because of the patch perforations, the device space may be "protected" from infection. Thus far, we have seen no infections and no strokes with this new technique in 4 patients.

The incidences of infection of 20% for CW, 30% for N, and 8% for T are similar to those previously reported. The

apparent advantage of T seems to be lost because linearized infection rates per patient year are 0.93 for CW, 1.29 for N, and 0.65 for T. The T duration of implant of about one-half the time for the other devices may have some impact on these numbers. As has been previously observed [19], patients with mechanical device support commonly have infections, but rarely die from infection. We found mortality from infection to be 2% for CW, 13% for N, and 4% for T.

Before discussing our approach in device selection for bridge to transplantation, there are some important technical and surgical differences among these devices that may be of considerable importance. Manufacturers' published maximal flows attainable under optimal filling are CW, 8 to 9 L/min; N, 7 to 8 L/min; and T, 5 L/min. These flow characteristics are explained by the anatomy of the devices. The inflow diameters for the devices are CW, 27-mm; N, 22-mm; and T, 10-mm atrial or 12-mm apical inflow conduit. The approximate total lengths of blood flow pathway for one ventricle are CW, 21 cm; N, 70 cm; and T, 93 cm with apical inflow, 101 cm with atrial. We know that patients have better survival with a postimplant CI of 2.5 or more L/min/m<sup>2</sup>; therefore, the typical 2-m<sup>2</sup> patient needs a 5 L/min flow. Larger and sicker patients may need more. Thoratec BVAD support, as we noted, may not eradicate congestive failure in large patients. Patients receiving LVADs may have difficulty if the native right ventricle fails.

Our device selection protocol is based primarily upon patient size, hemodynamic stability, and clinical assessment of right heart failure. Specific inclusion and exclusion criteria are shown in Table 7. We do not believe all potential bridge-to-heart transplant patients could or should be automatically treated with an LVAD.

In patients who are hemodynamically unstable or

Table 7. Device Selection Criteria for Bridge to Transplantation: CW Versus N Versus T

Indications	CardioWest	Novacor	Thoratec
Unstable, rapid decline <sup>a</sup>	X		X
Failure to wean from bypass	X		X
Cardiac arrest	X		X
Right heart failure <sup>c</sup>	X		X
Pulmonary edema	X		X
CVP > 16	X		X
Creatinine > 2 mg/dL	X		X
Aortic valve prosthesis, rejected heart transplant, stone heart, postinfarct VSD	X		
Gradual decline, <sup>b</sup> no right heart or renal failure <sup>d</sup>	X	X	X
Patient size BSA > 1.7 m <sup>2</sup>	X	X	
Patient size BSA ≤ 1.7 m <sup>2</sup>			X

<sup>a</sup> Hemodynamic deterioration over 48 hours or less. <sup>b</sup> Hemodynamic deterioration over 2 days or more. <sup>c</sup> CVP > 16. <sup>d</sup> Creatinine > 2 mg/dL.

BSA = body surface area; CVP = central venous pressure; VSD = ventricular septal defect.

deteriorating rapidly, or have clinical right heart failure who are large ( $BSA > 1.7 \text{ m}^2$ ), we use the CW. If they are small ( $BSA \leq 1.7 \text{ m}^2$ ), we use the T. If they are slowly deteriorating on inotropic support and have no clinical right heart failure and have reasonable renal function and are large ( $BSA > 1.7 \text{ m}^2$ ), we use N. If they are similarly stable and smaller, we use T.

Given our current understanding of the three devices in this study and the variety of presentations of mortally ill patients, it is clear that device selection for transplantation should not be automatic. Each type of device discussed has advantages and disadvantages, including many that have not been mentioned in this study. The primary priority should be patient survival with the lowest mortality and morbidity possible. All other considerations are secondary.

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