Case Series

Low Incidence of Pump-Related Infections

in Jarvik 2000 Ventricular Assist Device Recipients with a Subcostal Driveline Exit Site

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Driveline infection has been a persistent problem with mechanical cardiac assist devices. The reported incidence of infection has been low in patients who receive a Jarvik 2000 continuous-flow left ventricular assist device when a skull-pedestal driveline exit site is used. We evaluated whether this is also true when a subcostal driveline exit site is used.

We reviewed baseline demographic variables, postimplantation vital signs, laboratory values, and culture results in patients who underwent Jarvik 2000 implantation at our center from April 2000 through October 2009, including follow-up through June 2014. All patients had a subcostal driveline exit site. We defined device-related infection as a positive blood or wound culture associated with a medical or surgical device intervention. Event and time-to-event rates were calculated.

Eighty-one patients received 89 Jarvik 2000 devices, all as bridges to transplantation. The median support duration was 69 days (interquartile range, 27–153 d; range, 2–2,249 d). Five superficial driveline infections and one incision-site infection occurred (0.002 events per patient-year of support). The median time from pump implantation to onset of driveline infection was 30 days; the incision-related infection occurred at 44 days.

The Jarvik 2000 has a low incidence of infection when implanted with use of a subcostal driveline exit site. The incidence of pump infections is particularly low. Using a subcostal driveline exit site may be as effective in preventing infections as using a skull-pedestal driveline exit site. We detail our findings in this report. ***(Tex Heart Inst J 2019;46(3):179-82)***

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Heart disease is the world's leading overall cause of death.[1] Patients with end-stage heart failure have a dismal prognosis even with optimal medical management.[2] Continuous-flow left ventricular assist devices (LVADs) have provided a meaningful survival benefit to these patients.[3] However, device-related complications remain substantial causes of morbidity and death and hinder wider LVAD use.[4-9] Infections are among the most detrimental.[10-12]

Typical infection sites are the driveline, pump body, pump pocket, and internal blood-contacting surfaces.[12] Effective treatment may involve hospital readmission, antibiotic therapy, and surgical débridement. Severe infection may necessitate device removal, which can be catastrophic, particularly for patients who depend on LVADs as destination therapy.[12] More LVADs are being implanted worldwide, so durable, uncomplicated support is crucial.[3]

Unlike other LVADs, the continuous-flow Jarvik 2000® Ventricular Assist Device (Jarvik Heart, Inc.) has a pump inside the inlet cannula, and it is placed entirely within the left ventricular cavity (Fig. 1).[13] This placement makes a pump pocket unnecessary and minimizes the need for extracardiac hardware, thus decreasing the risk of infectious complications. Furthermore, the Jarvik 2000 can be implanted not just through a median sternotomy, but also through a left anterolateral thoracotomy or

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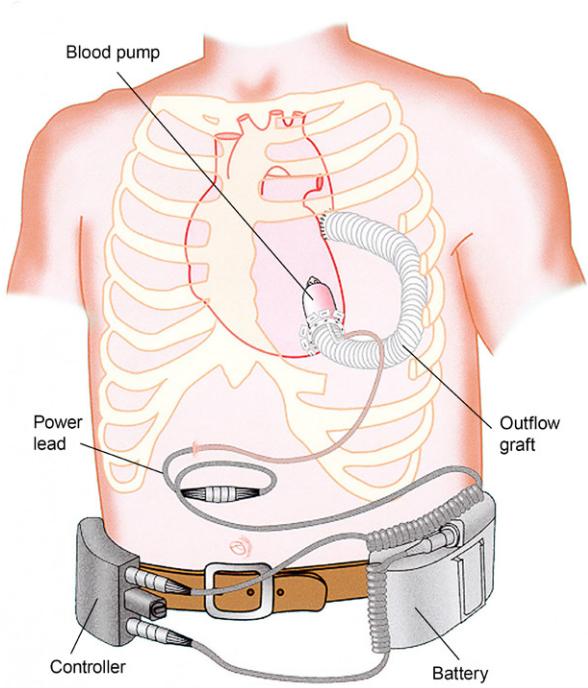

Fig. 1 *The Jarvik 2000 left ventricular assist device.*

Image previously published in Myers TJ, et al. Development of the Jarvik 2000 intraventricular axial-flow left ventricular assist system. J Congest Heart Fail Circ Support 2000;1(3):133-40.[13]

left subcostal incision.[14] These alternative incisions may prevent infections associated with sternal disruption.

Jarvik 2000 drivelines can be placed through a skull-pedestal or subcostal exit site. Infection rates associated with the former have been analyzed. We compared those findings with those in our cohort of Jarvik 2000 recipients, all of whom had a subcostal exit site.

Patients and Methods

Our Institutional Review Board approved this study. We retrospectively reviewed all Jarvik 2000 implantations at our institution from April 2000 (the first-ever clinical use of this device) through October 2009, with patient follow-up complete through June 2014. The patients were part of a bridge-to-transplant clinical trial.[15] From that database, we collected baseline demographic variables, postimplantation vital signs, laboratory values, culture results, and data on medical or surgical interventions. Culture information was obtained from patients' charts. We defined device-related infection (the study's primary endpoint) as a positive blood or wound culture associated with a medical or surgical device intervention. Infections were categorized as superficial driveline, surgical site, or pump infections. We defined pathogens as bacterial or fungal and categorized them by species. We calculated event and time-to-event rates.

Results

During the study period, 81 patients received 89 Jarvik 2000 LVADs. Of these implantations, 75 were primary, 4 replaced a previous pulsatile LVAD, and 2 replaced a HeartMate II™ LVAD (Thoratec, an Abbott company). Eight patients later had their original Jarvik 2000 exchanged for a new one. The median age of the 61 men (75%) and 20 women (25%) at first Jarvik 2000 implantation was 55 years (interquartile range [IQR], 45–63 yr; range, 16–79 yr). The median duration of device support was 69 days (IQR, 27–153 d; range, 2–2,249 d); the cumulative duration was 36 patient-years.

Of the 81 patients, 5 had a total of 6 device-related infections: 5 affected the superficial driveline and one, the subcostal implantation incision site (Table I). Four of the driveline infections occurred in patients whose Jarvik 2000 was a primary implant, and one was in a patient whose device had replaced a HeartMate II. Two of the driveline infections were coagulase-negative *Staphylococcus aureus*, 2 were methicillin-resistant *S. aureus*, and one was vancomycin-resistant *Enterococcus* (Table II). The median time from implantation to driveline infection was 30 days (IQR, 30–94 d; range, 16–198 d). The incision-site infection was *Penicillium*; it occurred at 44 days. The event rate was 0.002 per patient-year of support.

Discussion

During the past decade, continuous-flow LVADs have become increasingly beneficial as therapy for end-stage heart failure. However, long-term support is hindered by device-related complications. Chief among these are infections, which substantially increase the morbidity and mortality rates associated with LVAD implantation. Because advanced heart disease is becoming more prevalent, donor hearts for transplantation are scarce; therefore, the use of mechanical circulatory support for destination therapy continues to expand, which makes minimizing device-related infections an important goal.

In our trial of 81 patients who received Jarvik 2000 support as bridge to transplant, the infection rate was 0.002 events per patient-year, compared with a rate of 0.48 for patients given a HeartMate II in a bridge-to-transplant trial,[16] and 0.27 for patients given a HeartMate II in a destination-therapy trial.[17] Although exact comparisons between the 3 trials cannot be made, the inclusion and exclusion criteria for all of them were similar, and the differences in event rates are notable. Siegenthaler and colleagues[18] also reported a low incidence of device-related infections (0.24/300 d) in pa-

TABLE I. Characteristics of the Patients Who Had Device-Related Infections

Patient No.	Age (yr), Sex	Cardiomyopathy	Infection Site	Infection Onset (d)	Jarvik 2000 Support (d)	Outcome
1	52, F	Nonischemic	Driveline	30	79	Lived 14 yr, then died of metastatic cancer
2	49, M	Nonischemic	Driveline	16	89	Underwent transplantation; lived 9 yr to last follow-up evaluation
3	57, M	Ischemic	Driveline	94	103	Care withdrawn after stroke
4	52, M	Nonischemic	Driveline	198	797	Underwent transplantation; died of allograft rejection at 2.5 yr
5	65, F	Ischemic	Driveline Subcostal surgical incision	30 44	60	Right-sided heart failure; died at 7 yr

F = female; M = male

TABLE II. Device-Related Infections

Culture Site	Organism	WBC Count ($\times 10^9$/L)	Maximum Temperature (°C)	Time to Infection (d)
Superficial driveline	Coagulase-negative *Staphylococcus aureus*	14.6	37.7	16
	Coagulase-negative *S. aureus*	8.7	38.8	94
	MRSA	8.2	35.5	198
	MRSA	8.4	37.3	30
	Vancomycin-resistant *Enterococcus*	14.3	36.4	30
Surgical site	*Penicillium spp*	14.2	38	44

MRSA = methicillin-resistant *Staphylococcus aureus*; WBC = white blood cell

tients who underwent Jarvik 2000 implantation with a skull-pedestal driveline exit site. We tunneled all drivelines to a subcostal exit site and observed a low infection rate.

Advantages of the Jarvik 2000 over other continuous-flow LVADs may contribute to a lower infection rate. Because of its smaller, more flexible driveline, less surgical dissection is needed for placement. Perhaps even more important, its intracardiac location eliminates the need for a pump pocket—infections of which are typically caused by gram-positive *Staphylococci*, the most difficult LVAD-related infection to control.[19] Finally, the intraventricular pump is surrounded by myocardium and blood, minimizing the need for extracardiac hardware and decreasing the risk of surgical contamination.

Our study has limitations. The single-center, retrospective data collection may have resulted in bias. In addition, this patient cohort represents an early Jarvik 2000 experience from a bridge-to-transplant trial, which may not generally apply to other Jarvik 2000 populations.

In conclusion, Jarvik 2000 implantation is associated with a low incidence of device-related infection in general. Moreover, the use of a subcostal driveline exit site, which is faster and less complicated to create than a skull-pedestal site, resulted in a very low rate of infection and may be appropriate for many patients.

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