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ORIGINAL ARTICLE

The second official report from Japanese registry for mechanical assisted circulatory support (J-MACS): first results of bridge to bridge strategy

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Abstract

Background The Japanese registry for mechanical assisted circulatory support (J-MACS) is a prospective registry to collect all data of implantable left ventricular assist device (LVAD) (and part of paracorporeal VAD) established in 2010. The first analytical report was published in 2017. The organization running J-MACS was used to be the pharmaceuticals and medical devices agency (PMDA), but has been changed to the council for clinical use of ventricular assist device related academic societies in 2017.

Methods Since 2018, we changed the analytical methods as follows: first, we eliminated paracorporeal VAD from the analysis. Second, we included not only primary implantation but bridge to bridge (BTB) implantation of LVAD. Third, we added the analyses of adverse events that were not included in the previous analysis.

Results As of Oct 2018, 711 primary LVAD implants and 168 BTB implants were enrolled. Survival rate of primary LVAD was 93% at 360 days and 91% at 720 days, and that of BTB was 86% at 360 days and 82% at 720 days.

Conclusion We first reported the results of BTB in the second official report of J-MACS. The prognosis after LVAD implantation has been kept good in Japanese circumstances.

Keywords Ventricular assist device · Implantable · Paracorporeal · Heart failure · Heart transplantation

Introduction

Like interagency registry of mechanically assisted circulatory support (INTERMACS) in North America or the European registry for patients with mechanical circulatory support (EUROMACS), the Japanese registry for mechanical assisted circulatory support (J-MACS) is a prospective registry for implantable left ventricular assist device (LVAD). These registries have now merged as the international society for heart and lung transplantation (ISHLT) mechanically assisted circulatory support (IMACS) since 2016. J-MACS was established in 2010, and the first analytical report of J-MACS appeared in 2017 [1], and the details of organizing system for J-MACS were described in it.

In 2017, the organization of J-MACS has been changed to the council for clinical use of ventricular assist device related academic societies that consists of members elected from ten societies. Analyzed J-MACS data have been uploaded on the biannual basis on the home page of the Japanese Association for Thoracic Surgery (https://www.jpats.org/) since Oct 2018. Similar to INTERMACS [2] and IMACS [3], we have decided to publish annual report of J-MACS, and this is the second official report of J-MACS, which includes data as of Oct 30, 2018. The cut-off date for data collection of this report was Dec 31, 2018.

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Methods

We have changed the analytical methods for J-MACS data. First, we eliminated paracorporeal VAD data from the analysis. The second alteration is to add the data of bridge to bridge (BTB) implants in the new analysis. BTB means conversion from paracorporeal VAD (or centrifugal pumps for extracorporeal circulation) to implantable LVAD. Bridging from percutaneous VAD (IMPELLA, Abiomed, Danvers, MA, USA) or percutaneous/central extracorporeal membrane oxygenation (ECMO) are included in primary LVAD group. BTB neither includes bridging from implantable LVAD, i.e. pump exchange. J-MACS used to assign a different number for the exchanged pump, which was necessary to track each pump performance in view of post-marketing surveillance. However, to focus patients' prognosis after LVAD implantation, data of 2 (or more) pumps in a single patient are merged when overall survival (including stratification by age) is analyzed. In other words, overall survival curve is not censored at the time of pump exchange. We still censor at the time of transplantation, pump removal including exchange, and the last observation when comparing between primary LVAD and BTB or stratifying by J-MACS profile levels in primary LVAD group. We need primary LVAD data censored as such to compare INTERMACS or previous J-MACS data that were all from primary LVAD. Definition of profile has yet to be discussed in detail among BTB cases, and we did not include stratified data by preoperative profiles from BTB patients in this study. The third alteration is to draw Kaplan–Meier curves for specific adverse events. Previously, J-MACS only reported the incidence rate of adverse events [1]. However, the timing of first occurrence of adverse events may also be important to prevent them. Recent INTERMACS analyses also reported Kaplan–Meier curves for specific adverse events [2]. Kaplan–Meier curves for adverse events are censored at the time of first occurrence of the events in addition to at the time of transplantation, pump removal including exchange, and the last observation. With a limited space for publication, many of the analyses for adverse events appear as supplementary figures.

For comparison between primary LVAD and BT groups, unpaired *t* test was used for numerical data, and Chi-square test or Fisher's exact test was used for categorical data. Kaplan–Meier curves were compared with log-rank test.

Results

Device types

The implantable VADs included in this report were EVEHEART (Sun Medical, Nagano, Japan), DuraHeart (Terumo, Tokyo, Japan), HeartMate II (Thoratec, Pleasanton, CA, USA, now merged to Abbott, Abbott park, IL, USA), and Jarvik 2000 (Jarvik, New York, NY, USA) (supplementary table 1). HVAD (Medtronic, Mineapolis, MN, USA) and HeartMate 3 (Abbott, Abbott park, IL, USA) were also approved in Dec 2018 and Apr 2019 respectively, but this report did not include any of them. We excluded paracorporeal Nipro VAD (Nipro, Osaka, Japan) from this report, but otherwise the same as the first report [1].

Patient population

Patient inclusion criteria for J-MACS are previously described [1]. From Apr 1, 2011 to Oct 30, 2018, 1130 implants from 49 participating hospitals were enrolled. Among them, we analyzed 879 patients after the exclusion of paracoporeal VAD cases (139), pump exchange cases (105), insufficient data cases (7). As described above, data from pump exchange cases were merged to the first pump data if data were available (101 cases). As a result, we analyzed 711 primary LVAD and 168 BTB cases. The implant number of primary LVAD and BTB is shown in Fig. 1. Recent annual implants were about 150.

Male gender accounted for 74% of the patients (Table 1). Most of patients ranged from 30 to 59 years old. The most common etiology was dilated cardiomyopathy. Almost all strategy for implantable LVAD was bridge to transplant (BTT), with 70% already listed on the Japan organ transplant network as a candidate for heart transplant (Table 1). Since 2015, in-house approval for heart transplant was introduced in three high volume centers (National Cerebral and Cardiovascular Center, Osaka University, University of Tokyo), and it consisted of 15%.

There were significant differences between primary LVAD and BTB groups in age, etiology of heart failure, time since first diagnosis of heart failure, cardiac resynchronization therapy, and history of blood transfusion (Table 1, supplementary Table 2).

Survival

Actuarial survival rate, determined by the Kaplan–Meier method, for the entire cohort was 92% at 360 days and 88% at 720 days after implantation (Fig. 2a). As described, in this overall survival analysis, patients were censored at the time of transplantation, device explanation because of recovery, or at the time of the last observation, but not at the time of pump exchange. Survival rate censored as the previous analysis (including pump exchange) of primary LVAD was 93% at 360 days and 91% at 720 days, and that

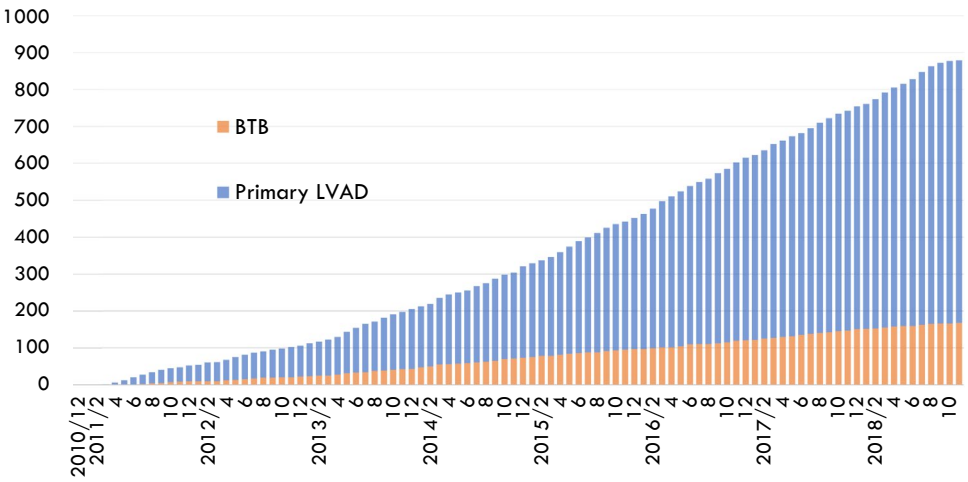


Fig. 1 Accumulated number of implants in J-MACS. After exclusion of paracoporeal VAD (139), pump exchange cases (105), insufficient data cases (7), 879 patients' data were analyzed. Among them, 711 were primary LVAD and 168 were BTB

of BTB was 86% at 360 days and 82% at 720 days (Fig. 2b). As observed, BTB had significantly worse survival rate than primary LVAD ($P = 0.0499$ by log-rank test). When stratified by J-MACS profile among primary LVAD patients, most of patients had profile 2 (45%) or profile 3 (44%). Small number of patients were assigned to profile 1 (5%) or profile 4–7 (5%). Survival rate at 360 days was 88% for level 1, 93% for level 2, and 94% for level 3. Patients at level 1 had significantly poor outcome compared with those at level 2 or 3 ($P = 0.0067$ by log-rank test, Fig. 2c).

Competing outcomes

The likelihood to undergo heart transplant was very low within 1 year after VAD implantation, but gradually increased after 2 years (Fig. 2d). Approximately 1340 days after implantation, one-third of them received heart transplant while one-third of them were still on LVAD. At this point, the two curves crossed. Over the 5 year period, total death rate was about 17%, and pump exchange occurred 16% of patients. LVAD removal by recovery was extremely rare (less than 4%).

Cause of death

The causes of death are listed in Table 2. Neurologic events and infection were the two major causes leading to death in implantable LVAD patients.

Adverse events

After LVAD implantation, one of the remaining issues was high rate of re-hospitalization as shown in Fig. 3a. Many of the re-hospitalizations were due to adverse events described below. Among them, pump exchange was sometimes necessary mainly because of device malfunction and pump pocket infection. Pump exchange rate was about 5% at 360 days as shown in Fig. 3b.

As shown in Fig. 3c, Japanese LVAD patients had markedly lower incidence of pump thrombosis (only 3% at 360 days). In contrast, device malfunction other than pump thrombosis was relatively frequent (approximately 20–25% occurrence rate at 360 days) (Fig. 3d), primarily due to malfunction of controller or cool seal unit, or driveline damage.

The most frequent adverse event was driveline infection in J-MACS (Fig. 3e). Driveline infection rate was about 25–30% at 360 days, and no significant differences between primary LVAD and BTB. In extreme cases, driveline infection ended up to pump pocket infection, but the incidence was rare (Fig. 3f). BTB cases had a higher incidence of pump pocket infection than primary LVAD.

Stroke (Fig. 3g) was one of the critical adverse events after LVAD implantation. Unfortunately, we did not have the severity score of stroke (modified Rankin scale) in J-MACS, and we could only report the whole incidence of stroke in this paper. The rate of stroke was about 25% at 360 days, and no differences between primary LVAD and BTB.

According to INTERMACS, gastrointestinal bleeding was known to be popular after continuous flow LVAD implantation, but Japanese LVAD patients had extremely lower incidence of gastrointestinal bleeding (less than 5% at 360 days) (Fig. 3h).

Since LVAD should only support left ventricle, right heart failure sometimes becomes a concern after implantation. As shown in Fig. 3i, small number of patients developed right heart failure, but the number was gradually increased year by year.

Arrhythmias were also a problem after LVAD implantation, and ventricular arrhythmias requiring cardioversion was the mainstay of them. The rate of developing arrhythmias requiring cardioversion was less than 10% at 360 days, but time-dependent increases in the number of incidence

Table 1 Patients' demographics, profiles, and device strategies

Number of cases (%)	Total ($N=879$)	Primary LVAD ($N=711$)	BTB ($N=168$)	P value
Gender				0.24
Male	654 (74)	535 (75)	119 (7)	
Female	225 (26)	176 (25)	49 (29)	
Age range (years)				0.11
Under 10	1 (0)	1 (0)	0 (0)	
10–19	49 (6)	36 (5)	13 (8)	
20–29	92 (10)	69 (10)	23 (14)	
30–39	174 (20)	135 (19)	39 (23)	
40–49	233 (27)	189 (27)	44 (26)	
50–59	230 (26)	194 (27)	36 (21)	
60–69	99 (11)	86 (12)	13 (8)	
70–79	1 (0)	1 (0)	0 (0)	
Etiology for heart failure				< 0.001
CHD	16 (2)	16 (2)	0 (0)	
CAD	101 (11)	61 (9)	40 (24)	
HCM (include DHCM)	98 (11)	88 (12)	10 (6)	
VHD	5 (1)	3 (0)	2 (1)	
DCM	576 (66)	482 (68)	94 (56)	
RCM	4 (0)	4 (1)	0 (0)	
Others	79 (9)	57 (8)	22 (13)	
Mean ± SD	Total ($N=879$)	Primary LVAD ($N=711$)	BTB ($N=168$)	
Age (years)	43.5 ± 13.2	44.2 ± 13.1	40.6 ± 13.3	0.0015
Height (cm)	166.9 ± 8.7	166.9 ± 8.9	166.9 ± 8.2	1.000
Body weight (kg)	57.4 ± 11.6	57.6 ± 11.5	56.4 ± 12.0	0.228
BMI (kg/m^2)	20.5 ± 3.3	20.6 ± 3.3	20.1 ± 3.5	0.081
BSA (m^2)	1.64 ± 0.18	1.64 ± 0.18	1.62 ± 0.19	0.200
Number of case (%)	Total ($N=879$)	Primary LVAD ($N=711$)	BTB ($N=168$)	P value
Device strategy				0.087
BTT, listed	614 (70)	502 (71)	112 (67)	
BTT, applied	128 (15)	108 (15)	20 (12)	
BTT, in-house approval	134 (15)	98 (14)	36 (21)	
Long-term support w/o transplant	3 (0)	3 (0)	0 (0)	

CHD congenital heart disease, *CAD* coronary artery disease, *(D)HCM* (dilated) hypertrophic cardiomyopathy, *VHD* valvular heart disease, *DCM* dilated cardiomyopathy, *RCM* restrictive cardiomyopathy, *BMI* body mass index, *BSA* body surface area, *BTT* bridge to transplant

were observed (Fig. 3j). Although insignificant, there might be a trend to be higher incidence of critical arrhythmias in primary LVAD than BTB.

Discussion

This is the second official report of J-MACS, in which we have focused on patients' demographics, device type, survival, competing outcomes and adverse events.

In this report, we eliminated paracorporeal VAD data from the analysis. J-MACS used to include data of paracorporeal VAD as a reference to compare with implantable LVAD, but the enrollment of paracorporeal VAD has never been mandatory, and the selection bias of paracorporeal VAD data cannot be ignored. In fact, the survival rate of paracorporeal VAD in the first report was 84% at 360 days and 84% at 720 days [1], which was too good for this type of device considering the previous reports of Nipro VAD [4–6] and the data might not reflect real world clinics.

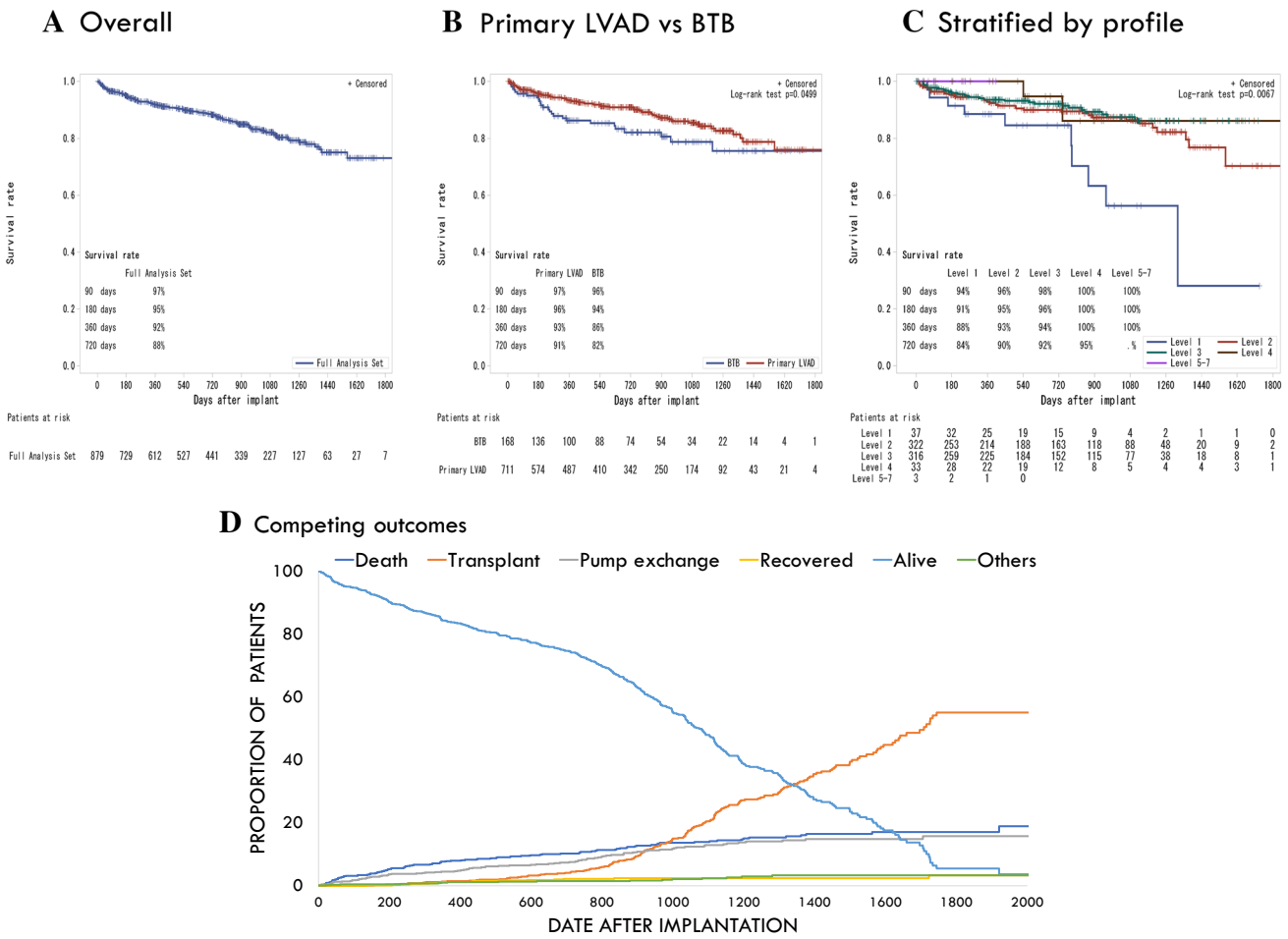


Fig. 2 Survival curves and competing outcomes. **a** Actuarial survival for entire population censored at the time of transplantation, device explantation because of recovery or at time of the last observation, but not at the time of pump exchange. **b** Actuarial survival for primary LVAD and BTB population censored at the time of transplantation, device explanation including pump exchange or at time of the last observation. **c** Actuarial survival stratified by J-MACS profile levels censored at the time of transplantation, device explanation including pump exchange or at time of the last observation among primary LVAD patients. **d** Analysis of competing outcomes after the implantation of LVAD. *Death* died with device, *recovered* device removal after recovery, *alive* device in place. At all points in time, the sum of the probabilities of each outcome event totaled 100%

Table 2 Primary cause of death

Number of case (%)	Total ($N=101$)	Primary LVAD ($N=73$)	BTB ($N=28$)	P value
Device malfunction	6 (6)	4 (5)	2 (7)	0.75
Infection	20 (20)	14 (19)	6 (21)	0.80
Neurologic event	44 (44)	28 (38)	16 (57)	0.088
Right heart failure	5 (5)	3 (4)	2 (7)	0.53
Bleeding	4 (4)	3 (4)	1 (4)	0.90
Multi-organ failure	5 (5)	4 (5)	1 (4)	0.69
Others	14 (14)	14 (15)	0 (0)	0.013

The survival rate of primary LVAD was kept in good figures as observed in the first report (93% at 360 days, 90% at 720 days) [1]. As our patients were mostly assigned as BTT, we need to compare our data with the same population in INTERMACS. The most recent INTERMACS data as of the end of 2017, which did not include HeartMate 3 but

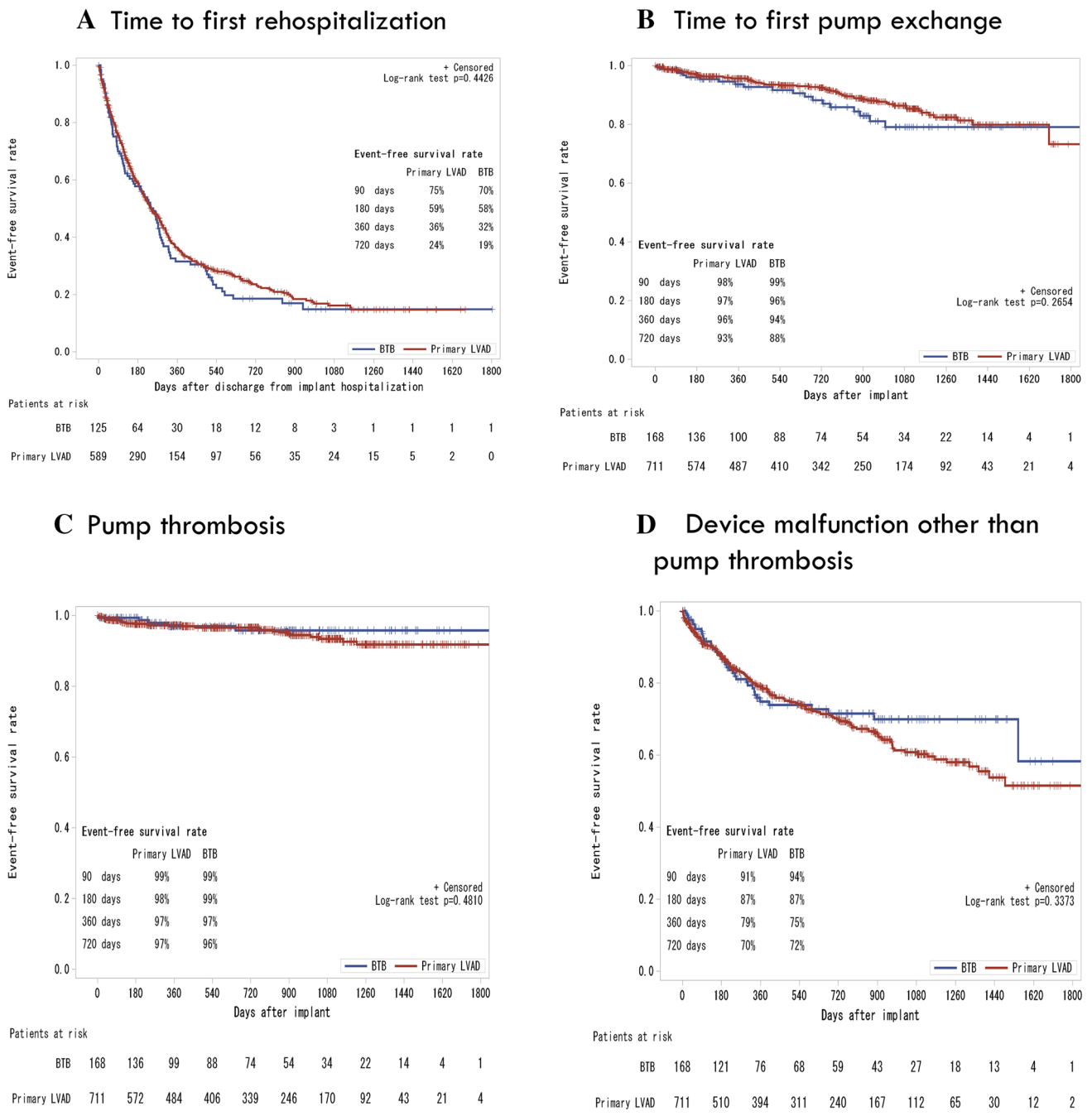


Fig. 3 Adverse events. Time to first occurrence of adverse events are shown. **a** re-hospitalization; **b** pump exchange; **c** pump thrombosis; **d** device malfunction other than pump thrombosis; **e** driveline infection; **f** pump pocket infection; **g** stroke; **h** gastrointestinal bleeding; **i** right heart failure; **j** arrhythmia requiring cardioversion

HVAD, showed that BTT listed patients with primary LVAD implantation had 88% at 12 months and 80% at 24 months [2]. According to the competing analysis, the timing of two lines crossing (i.e. "transplant" and "alive") was more than 1300 days in this report which was less than 1000 days in the first one [1]. The results may suggest longer waiting period for heart transplant in these years. In fact, the average waiting period before heart transplant was reported to be longer year by year mostly because of increased number of newly listed patients [7]. This phenomenon was not a good trend for waiting patients, but the increased number of wait-listed patients was on the other hand due to the good survival rate of implantable LVAD in Japan.

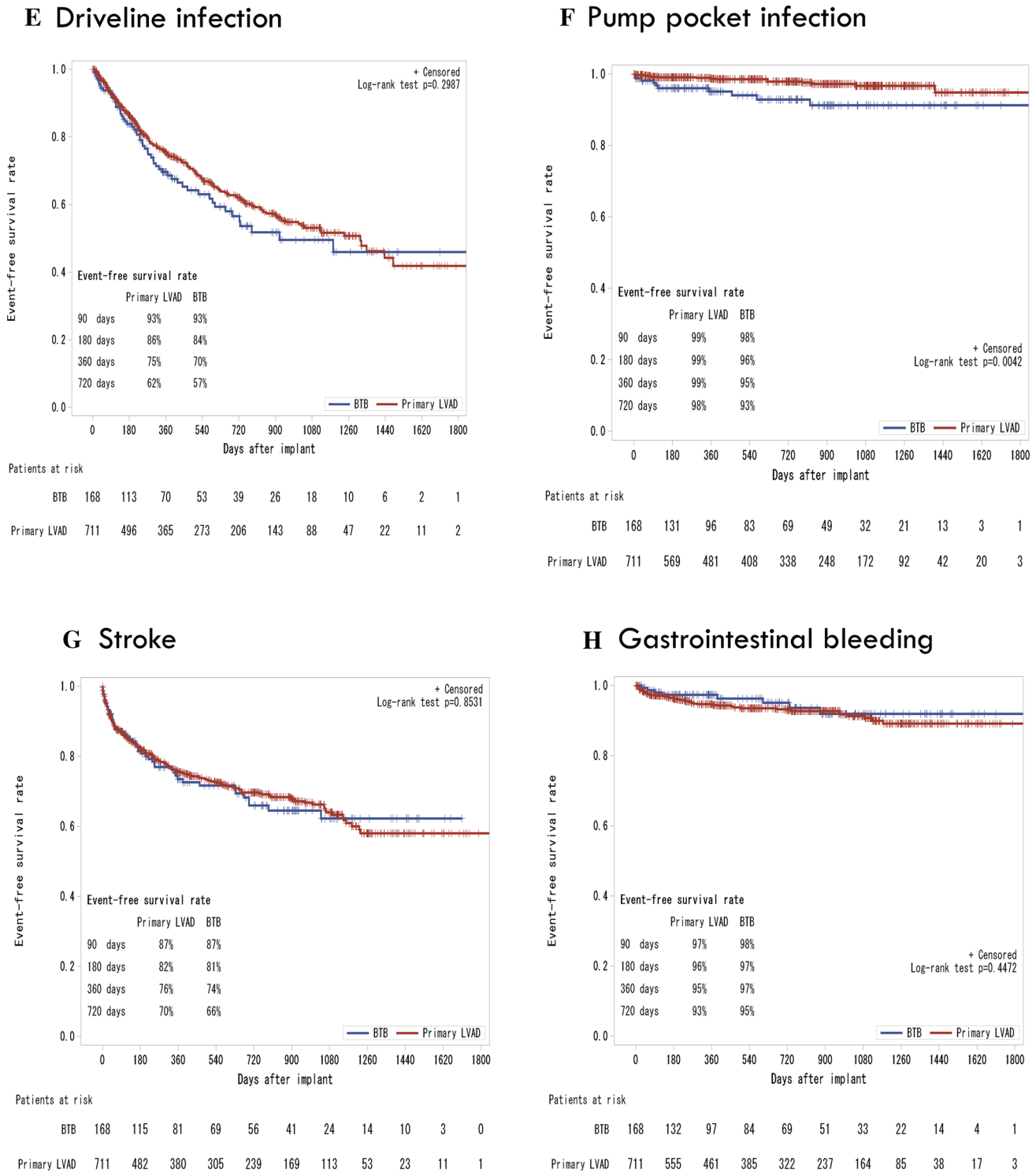
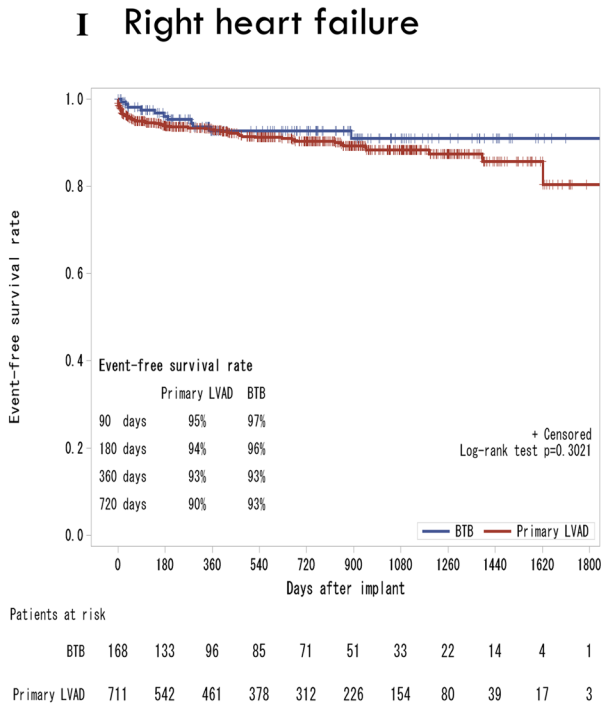


Fig. 3 (continued)

We added the data of BTB in the new analysis. BTB means conversion from paracorporeal VAD to implantable LVAD. As INTERMACS has only reported primary implantation of LVAD, J-MACS used to do so. However, more than 150 of BTB cases have been enrolled in J-MACS, and the number is still increasing in the recent days. The trend may be attributable to the reimbursement policy for implantable LVAD in Japan. If a patient has end-organ dysfunction which does not allow immediate heart transplant listing, many physicians try



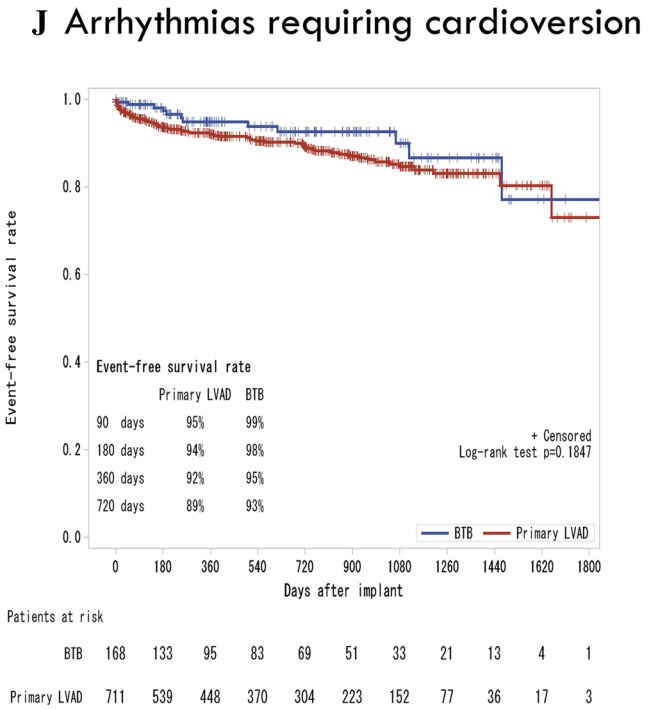


Fig. 3 (continued)

to reverse end-organ damage by medical treatment but often in fail. In that situation, paracorporeal VAD (or a centrifugal pump for extracorporeal circulation as an alternate) has been used as a device for bridging to candidacy. After a couple of months, the patient may recover from end-organ dysfunction, being eligible for heart transplant listing, and eventually paracorporeal VAD is converted to implantable LVAD. This scenario was supported by the first report [1], in which the competing analysis of paracorporeal VAD showed that the line of "withdraw" and "on-going" crossed at approximately 100 days. The line of "withdraw" did not mean complete withdrawn from LVAD but bridging to implantable LVAD in most cases. Therefore, it is important to analyze BTB data that are quite unique to J-MACS at least until bridge to candidacy is approved for implantable LVAD in Japan. Apparently, BTB patients had a worse prognosis than primary LVAD patients. BTB data were not reported systematically, and we believe that this is the first nationwide data for BTB. According to the patients' background, BTB group had more prevalence of ischemic etiology, shorter duration of heart failure, less chance for cardiac resynchronization therapy, and higher rate of blood transfusion. These characteristics fit to the above typical scenario for BTB. Rapidly deteriorating hemodynamics often accompanied by acute myocardial infarction necessitates temporary mechanical support that requires blood transfusion at the time of operation.

The primary cause of death after LVAD implantation was neurologic events in both this study and the recent report from INTERMACS [2], but the incidence rate was quite different. Almost half of the death was due to neurologic events in J-MACS, suggesting that more serious stroke (probably hemorrhagic one) was likely to happen in Japanese LVAD patients.

Re-hospitalization rates were relatively lower in J-MACS (64% at 360 days) than the most recent data from INTERMACS [2] (77% at 12 months), but both were still high and not likely to decrease over the time [8]. Combined pump-related infection (driveline and pump pocket infection) was almost identical between J-MACS (25% at 360 days) and INTERMACS [2] (25% at 12 months), but stroke was more frequent in J-MACS (24% at 360 days) than INTERMACS [2] (13% at 12 months for axial pump [HeartMate II]). Considering that stroke is the main cause of death in Japanese patients, effective strategies for decreasing stroke events must be explored anytime soon. Pump thrombosis was rare in Japanese LVAD patients compared with the HeartMate II arm of MOMEMTUM 3 study (12% at 12 months) [9]. Gastrointestinal bleeding was also rare in J-MACS than reported in INTERMACS [2] (20–25% at 12 months).

Limitations

We acknowledge several limitations of this report. First, not all data of J-MACS are available in this periodical report. Therefore, we need additional analyses to determine the more detailed characteristics of BT patients or the risk factors for the worse outcome of BTB. Second, we are not able to analyze which factors are attributable to the better outcome of J-MACS compared with other countries' data. I-MACS may be able to provide such comparison. Third, this report does not provide who will be a good candidate for destination therapy bridged from paracorporeal VAD. One Japanese report [10] found that several predictors for worse outcome or insufficient recovery of end-organ function during paracorporeal VAD support, i.e. not an ideal candidate for destination therapy. However, we have to need larger and more detailed data on this issue, and it will be a next concern.

Conclusions

The second official J-MACS report showed the results of BTB patients for the first time. It also revealed that good survival rate of primary LVAD patients maintained. The re-hospitalization rate was still high, and detailed analyses for each adverse event will help to lessen them.

Compliance with ethical standards

Conflict of interest GM received research grant from Terumo and Century Medical. Other authors have no conflict of interest.

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