Background

Clinical application of ventricular assist device (VAD) in Japan began in 1980 and 1343 cases were reported to the Japanese Association for Artificial Ventricular Assist Systems, up to September 2011. Of those, 610 received various types of VAD (extracorporeal, n=460; implantable, n=150) as a bridge to transplantation. The mean support time was 383 days and 137 cases later underwent transplantation. Establishment of a database of mechanical circulatory support device (MCSD) cases is needed for development and promotion of clinical applications of new devices. For this purpose, INTERMACS was organized in USA and began data collection in 2006.

Methods

Japanese government has launched a Japanese database - Japanese registry for Mechanically Assisted Circulatory Support (J-MACS) - as an enterprise based on the Pharmaceuticals and Medical Devices Agency (PMDA) interim plan. The framework was constructed from discussion with 7 academic societies, participating hospitals (6 at start), manufactures (4 at start), and PMDA. All patients who receive a durable VAS, approved in Japan, are included. J-MACS is a prospective registry and post-marketing observational research systems designed to collect clinical data, including from follow-up examinations. All data are entered using the J-MACS web-based data entry system. Membership in J-MACS is one of the essential conditions for authorization of hospitals to use an implantable left VAD under national medical insurance coverage.

Framework of J-MACS

- Participating institutions
- Pharmaceutics and Medical Devices Agency
- Data Center (DC)
- VAD companies
- Administrative Office
- Support Organization
- Steering Committee (SC)
- Operating Committee (OC)
- Auditing Organization
- Observational Study Monitoring Board (OSMAB)
- Adverse Event and Adjudication committee
- Study Entity

Participating sites

- Tohoku U
- Tokyo U
- Tokyo Women’s Medical U
- National Cerebral & Cardiovascular Center
- Osaka U
- Kyoto U
- Hokkaido U
- Shiga Medical U
- International Medical Center Tokyo Medical and Dental University
- Hirosaki University
- Gunma Prefectural Cardiovascular Center
- Saitama Watanabe Hospital
- Saitama Medical U
- International Medical Center
- Patients who receive a durable VAS (Ventricular Assist Systems) which is approved.
- Kyushu U
- Tohoku U
- Sakurabashi Watanabe Hospital
- Gunma Prefectural Cardiovascular Center
- Tokyo Medical and Dental University
- Post implant follow up data will be collected at 1 week, 1 month, 3 months, 6 months and every December, 2011.

Results

Table 1: Demographics for patients (gender)  
Table 2: Demographics for patients (age)  

Figure 1: Device types (June, 2010 - December, 2011)  
Figure 2: The number of enrollment from June, 2010 to December, 2011.  
Figure 3: InterMACS level at primary LVAD (Implantable:51, Extracorporeal:29)  
Figure 4: Kaplan-Meier survival after MCSD  
Figure 5: Kaplan-Meier survival after MCSD, stratified by device types

Conclusion

J-MACS will be useful for improving clinical assessment, management, treatment, and development of new technologies for MCSD. The data are expected to be beneficial for assuring patient safety, when developing new devices by clarifying the risks and benefits, with the resulting data assessments useful for implementation of appropriate safety measures.