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Title: The Use of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) to Generate Objective Performance Criteria (OPCs) for Use in MCSD Trials

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Purpose: For some investigational devices, the FDA has allowed the approval process to include single arm clinical studies where the control group has been replaced by expected standard results known as objective performance criteria (OPCs). OPCs are derived from summarizing the major endpoints in published studies with well defined patient (pt) populations and definitions of events of similar devices. INTERMACS provides a unique opportunity to generate OPCs for mechanical circulatory support devices (MCSDs) based on actual clinical results.

Methods and Materials: INTERMACS is a national registry that attempts to enroll all pts with durable FDA-approved MCSDs. It collects detailed, audited data and adjudicated well-defined major endpoints. An initial assessment of INTERMACS to develop OPCs was performed by employing competing outcomes methodology, which estimates the time-related probability of the terminal events (death, transplant, recovery). Both linearized and time-varying rates have been produced for major morbid events.

Results: From June 2006 to Aug. 2007, 261 MCSD pts were entered into INTERMACS. The implants included 196 pts with LVADS, and 51 with Bi-VADs. The initial device strategy includes 46 destination therapy (DT) and 198 bridge to transplant (BTT) pts. The table contains results that could provide the basis for data-derived OPCs.

Conclusions: INTERMACS can provide OPCs for a variety of events and pt subgroups. These OPCs can also be risk adjusted according to the pt mix in a device trial. Although INTERMACS is a young registry, the opportunity exists for new device trials to use registry information to design efficient trials with objective comparisons.

Proportion of Patients	BTT				DT	
	LVAD (n=144)		Bi-VAD (n=43)		LVAD (n=43)	
	1 mo	6 mo	1 mo	6 mo	1 mo	6 mo
Death	9%	17%	19%	29%	7%	30%
Transplant	11%	35%	17%	44%	0%	8%
Recovery	0%	4%	3%	6%	0%	2%
Alive (with device)	80%	44%	61%	21%	93%	60%
Total	100%	100%	100%	100%	100%	100%

	BTT & DT: LVAD (n=187)	
	1 mo (% pts)	2-12 mo (events/100 mo)
Bleeding	24%	4.5
Infection	21%	11.5
Neuro dysfunction	12%	1.7