



AMERICAN SOCIETY OF EXTRACORPOREAL TECHNOLOGY

2209 DICKENS ROAD RICHMOND, VA 23230-2005
GOVERNMENT AFFAIRS 301-588-2822
BALOBBY@VERIZON.NET

Position Statement On Portable and Percutaneous Extracorporeal and Mechanical Circulatory Support Devices

Mechanical Circulatory Support Committee

Chair: Mark Lucas, CCP

Co-Chair: James Reagor, CCP, LP

Tom Rusk, CCP

Gary Grist, CCP

Ron Matheis, CCP

Preamble

Portable extracorporeal cardiopulmonary life support (ECLS) devices are increasingly gaining the attention of mainstream medicine. On the surface such attention could only be expected to benefit patients with occurrences of acute respiratory failure or acute myocardial infarction. As perfusionists, we know the advantages and disadvantages of these devices, which we operate routinely to rescue patients who may otherwise decompensate and die before the proper treatment can be effected. Device manufacturers realize the untapped markets for these advanced products and pursue bringing mechanical circulatory support (MCS) devices to the mainstream.

There is a great risk that the future operators of these devices may not include perfusionists and will not have the background or experience to safely manage these devices and patients. The recent introduction of percutaneous mechanical circulatory support devices to cardiac cath labs have shown the direction that these newer generation of portable ECLS devices will most likely take.

Heart disease remains the leading cause of death in the United States with lung disease the third leading cause. Consider that mortality caused by acute cardiogenic shock is estimated at 50-70% even with current therapeutic paradigms including inotropes and IABPs. While some heart failure and respiratory failure patients are treated with immediate transplants, the limited availability of donor organs often requires MCS devices as a bridge to transplant, bridge to decision or as destination therapy. The use of Extracorporeal membrane oxygenation (ECMO), has developed into a specialized, multidisciplinary effort with steadily improving results for respiratory failure. Perhaps wider availability of cardiopulmonary rescue devices would decrease patient morbidity and mortality. But also, perhaps not; if the device operator is insufficiently prepared to manage acutely ill patients supported on the device or to be able to respond to device emergencies that could be disastrous.

Over the past several years, the MCS Committee has been working to provide resources for MCS knowledge and create standards and guidelines for training and competency in current and emerging circulatory assist technologies. As part of these efforts, the committee has evaluated publicly available information on the newer generation of devices and has determined that a qualified perfusionist should be involved directly, as a primary consultant or in a supervisory capacity in the operation of all such devices to provide the highest degree of patient safety. Perfusion practice has more than fifty years of knowledge and experience in extracorporeal support and a proven record of safety .

AmSECT Recommendation

The American Society of Extracorporeal Technology (AmSECT) is the world's largest professional society of cardiovascular perfusionists. AmSECT seeks to foster improved care, safety and outcomes for patients supported with extracorporeal devices. Perfusionists are the only medical professionals whose scope of practice expressly includes the utilization of extracorporeal devices to support patients in a variety of clinical circumstances. Perfusionists are qualified through CAAHEP-accredited educational programs and certified by the American Board of Cardiovascular Perfusion.

It is the AmSECT position that optimal patient care and safety must not be compromised. Mechanical Circulatory Support (MCS) devices which are a variation on or are substantially equivalent to current systems operated by perfusionists are beginning to be utilized by other health care providers. AmSECT has charged its Mechanical Circulatory Support Committee with providing knowledge, guidance and insight into MCS devices. The MCS Committee continues to evaluate the available information regarding the current and pending generation of devices.

The Mechanical Circulatory Support Committee believes that the safe and effective operation of these life-sustaining systems requires that a qualified perfusionist directly participate in or supervise their use. The introduction of such life support devices into the clinical setting without the involvement of a properly trained cardiovascular perfusionist will jeopardize safety and subject patients to substantial and unnecessary risk of injury.

AmSECT strongly recommends that a perfusionist qualified by formal education and possessing clinical expertise be utilized directly or in a supervisory capacity throughout the implementation, operation and management of all mechanical circulatory support systems.