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ORIGINAL INVESTIGATIONS

National Trends in the Utilization of Short-Term Mechanical Circulatory Support

Incidence, Outcomes, and Cost Analysis

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ABSTRACT

BACKGROUND The number of alternatives to intra-aortic balloon counterpulsation in the treatment of anticipated and established acute circulatory failure is growing. Despite the clinical importance and significant cost of short-term mechanical circulatory support (MCS) devices, the state of their present use has not been analyzed on a national scale.

OBJECTIVES The purpose of this study was to characterize the demographics, treatment practices, survival rates, and cost of short-term MCS.

METHODS In this serial cross-sectional study, we analyzed all adult patients receiving short-term MCS in the United States from 2004 to 2011 by using the Nationwide Inpatient Sample from the Healthcare Cost and Utilization Project.

RESULTS From 2007 to 2011, use of percutaneous devices for short-term MCS increased by 1,511% compared with a 101% increase in nonpercutaneous devices. Mortality rates declined over this period (p for trend = 0.027) from 41.1% in 2004 to 2007 to 33.4% in 2008 to 2011. A similar trend was observed for the subset of patients with cardiogenic shock, decreasing from 51.6% to 43.1% (p for trend = 0.012). Hospital costs also declined over this period (p for trend = 0.011). Multivariable analysis revealed balloon pumps (odds ratio [OR]: 2.00; 95% confidence interval [CI]: 1.58 to 2.52), coagulopathy (OR: 2.35; 95% CI: 1.88 to 2.94), and cardiopulmonary resuscitation (OR: 3.50; 95% CI: 2.20 to 5.57) before short-term MCS were among the most significant predictors of mortality.

CONCLUSIONS Use of short-term MCS in the United States has increased rapidly, whereas rates of in-hospital mortality have decreased. These changes have taken place in the context of declining hospital costs associated with short-term MCS. (J Am Coll Cardiol 2014;64:1407–15) © 2014 by the American College of Cardiology Foundation.

Acute circulatory collapse is a broad term referring to failure of the pumping mechanism of the heart and an inability to maintain adequate organ perfusion. The most common situation in which it is encountered is cardiogenic shock. However, similar circulatory collapse can be anticipated during procedures that may compromise hemodynamic stability, including high-risk percutaneous coronary intervention (PCI), ablation for arrhythmias, and transcatheter valvular interventions.

Historically, institution of short-term mechanical circulatory support (MCS) was largely reserved for patients exhibiting significant circulatory compromise requiring cardiac output augmentation, with a

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ABBREVIATIONS AND ACRONYMS

AMI = acute myocardial infarction

CAD = coronary artery disease and other heart disease

CCS = Clinical Classification Software

CHF = congestive heart failure

ECMO = extracorporeal membrane oxygenation

HCUP = Healthcare Cost and Utilization Project

HVD = heart valve disorder

IABP = intra-aortic balloon pump

LVAD = left ventricular assist device

MCS = mechanical circulatory support

PCI = percutaneous coronary intervention

PCPS = percutaneous cardiopulmonary support

bias toward supporting patients perceived as eligible for transplant or left ventricular assist device (LVAD) implantation (either bridge or destination therapy). More recently, the availability of rapidly deployable percutaneous MCS has led to a paradigm shift in the field that is characterized by growing use of these devices in an anticipatory or prophylactic fashion that was previously uncommon. Although the intra-aortic balloon pump (IABP) is not a true circulatory support device because it does not contribute directly to cardiac output, it was the only rapidly deployable support device available for decades. Reliable circulatory devices including the Thoratec PVAD (Thoratec Corporation, Pleasanton, California), AB5000 and BVS 5000 (both Abiomed, Inc., Danvers, Massachusetts), and various centrifugal pumps usually require a median sternotomy. Venoarterial extracorporeal membrane oxygenation (ECMO) delivered through peripheral cannulation with a centrifugal pump driver is another option but has always been reserved for emergency near-arrest situations. The morbidity and mortality associated with these devices are significant and restricted their use to potential transplant candidates.

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The Impella 2.5 (Abiomed, Inc., Danvers, Massachusetts) and TandemHeart (CardiacAssist, Inc., Pittsburgh, Pennsylvania) are percutaneous MCS devices that can be deployed in the catheterization laboratory. The CentriMag (Thoratec Corporation, Pleasanton, California) and the Impella 5.0/CP have greatly increased ease of cannulation and device placement. These developments, among others, have theoretically made possible early deployment of short-term MCS before the downward spiral and inflammatory cascade associated with circulatory collapse can develop. Irrespective of surgical or percutaneous deployment, all temporary MCS devices share similar functional characteristics in terms of augmentation of cardiac output in liters per minute.

In U.S. and European guidelines for acute heart failure, the mainstays of therapy remain intravascular volume control, inotropes, and IABP (1,2). The combination of revascularization, antithrombotic therapy, and intensive care management has only modestly affected the mortality of cardiogenic shock in the last decade (3,4). Despite a paucity of randomized trials, recent guidelines have recommended the use of short-term MCS for profound hemodynamic compromise (1,5); these recommendations reflect the growing impact of short-term MCS on clinical practice and the lack of viable alternatives.

Unlike the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) and Extracorporeal Life Support Organization (ELSO) registries, which track outcomes and adverse events in patients receiving long-term MCS and ECMO, no such registry exists for short-term MCS. To begin addressing the existing deficit of information on patients receiving short-term MCS, we examined national trends in utilization.

METHODS

DATA SOURCE. The Nationwide Inpatient Sample, Healthcare Cost and Utilization Project (HCUP), under the auspices of the Agency for Healthcare Research and Quality (6), is the largest database of all-payer inpatient hospital stays in the United States. It approximates a 20% stratified sample of all nonfederal hospitals. All discharges from sampled hospitals are included, thus enabling the generation of national estimates. This study was deemed exempt by Yale University's Institutional Review Board.

INCLUSION CRITERIA. We included all adults ≥18 years old who were receiving short-term MCS between 2004 and 2011. Short-term MCS was defined by the International Classification of Diseases-ninth revision-Clinical Modification (ICD-9-CM) codes for percutaneous (37.68) or nonpercutaneous (37.60, 37.62, and 37.65) MCS in any procedure position (Online Figure 1). Nonpercutaneous devices included the Thoratec PVAD, AB5000, BVS 5000, and CentriMag. Percutaneous devices included the TandemHeart and Impella devices. IABP (37.61), ECMO (39.65), and percutaneous cardiopulmonary support (PCPS) (39.66) were excluded from our definition of short-term MCS. Permanent devices (37.52 and 37.66) included the HeartMate XVE and HeartMate II (Thoratec Corporation). Earlier years were not analyzed because ICD-9-CM codes do not distinguish short-term from permanent MCS devices before 2004.

DEMOGRAPHICS. Elixhauser comorbidities were generated from ICD-9-CM diagnosis codes using the HCUP Comorbidity Software (7). The sum of comorbidities for each record was reclassified as 0, 1, 2, or ≥3. Comorbidities present in ≥5% of all patients were reported.

HOSPITAL COURSE. We defined the indication for a hospital stay as the diagnosis listed in the primary position and categorized each using HCUP Clinical Classification Software (CCS). Level 3 CCS diagnoses constituting ≥5% of all indications for hospital stays