

Ventricular assist device implantation in the elderly

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Background: Dramatic advances in ventricular assist device (VAD) design and patient management have made mechanical circulatory support an attractive therapeutic option for the growing pool of elderly heart failure patients.

Methods: A literature review of all relevant studies was performed. No time or language restrictions were imposed, and references of the selected studies were checked for additional relevant citations.

Results: In concordance with the universal trend in mechanical circulatory support, continuous flow devices appear to have particular benefits in the elderly. In addition, the literature suggests that early intervention before the development of cardiogenic shock, important in all patients, is particularly paramount in older patients.

Conclusions: The ongoing refinement of patient selection, surgical technique, and post-operative care will continue to improve surgical outcomes, and absolute age may become a less pivotal criterion for mechanical circulatory support. However, clear guidelines for the use of mechanical circulatory support in the elderly remain undefined.

Keywords: Ventricular assist device (VAD); elderly; heart failure; mechanical circulatory support



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Introduction

Since the dawn of the modern era of cardiac surgery and the first clinical use of cardiopulmonary bypass in 1953, the indications and applications for mechanical circulatory support have grown tremendously. The 1960s yielded the first successful pneumatic left ventricular assist device (LVAD), implanted by Dr. DeBakey, as well as the first human heart transplant. Shortly thereafter, mechanical circulatory support was being utilized not only to facilitate recovery in patients suffering from post-cardiotomy shock but to potentially bridge them to transplantation. The high mortality of early cardiac transplantation and the severe limitations of the first generation extracorporeal LVADs led the National Institutes of Health and pioneering researchers of the 1970s and 1980s to redouble efforts to develop durable implantable assist devices intended

for use in chronic heart failure (1). Decades of hard work and radical innovation to pump design resulted in the landmark REMATCH trial in 2001, which demonstrated the superiority of mechanical circulatory support to optimal medical management for transplant ineligible patients with chronic heart failure, and led to FDA approval of the pulsatile HM XVE for permanent destination therapy in 2003 (2). While ultimately supplanted by continuous flow devices, this study permanently unchained mechanical circulatory support from transplant eligibility and has resulted in a sizable and growing population of patients receiving lifetime LVAD support. It also brought into question the validity of using the age of 70, the arbitrary threshold at which most transplant centers will no longer consider a patient eligible for transplant, as a contraindication to mechanical circulatory support.

According to the most recent American Heart

Association update, an estimated 5.1 million American adults have heart failure. Their projections show that the prevalence will increase by 46% from 2012 to 2030, resulting in greater than eight million Americans suffering from heart failure and a steep increase in the incidence with each decade of life beyond 65 years (3). With its widespread acceptance as a destination therapy, coupled with dramatic advances in device design and patient management, mechanical circulatory support provides an attractive therapeutic option for an ever expanding pool of elderly heart failure patients. However, clear guidelines for the use of mechanical circulatory support in the elderly have yet to be delineated and justification for the use of continuous flow devices in older patients will depend upon whether it provides superior, cost-effective outcomes compared to optimal medical therapy.

Outcomes

Much of the early data on mechanical circulatory support in elderly patients are small-sample, single-center, retrospective analyses that may not be immediately translatable to the modern era of circulatory support, due to their wide use of pulsatile VADs and multiple outdated platforms. Despite these methodological issues, it has been demonstrated that implantation of non-pulsatile systems results in a significantly higher survival rate in elderly patients when compared to pulsatile systems (4). Furthermore, patients over the age of 65 years who are implanted with contemporary continuous flow LVADs can achieve excellent long term survival, compared to predicted medical survival (5).

In recent years, an effort has been made to undertake more population-based analyses to better understand both the outcomes of mechanical circulatory support in patients of advanced age, as well as identify unique predictors of morbidity and mortality. Utilizing the Healthcare Cost and Utilization Project-Nationwide Inpatient Sample (HCUP-NIS) registry, the largest all-payer database in the United States with over 1,000 participating hospitals, Kilic *et al.* (6) analyzed a total of 2,787 patients aged 60-69 years and 1,472 patients aged ≥ 70 years who underwent VAD implantation between 2003 and 2008. They found that unadjusted mortality rates were comparable between elderly and control patients (aged 60-69 years) in both primary support (35.7% *vs.* 32.1%, $P=0.61$) and post-cardiotomy support (58.1% *vs.* 56.1%, $P=0.70$). Also, in risk-adjusted multivariable logistic regression analysis, age >70 years did not exert an independent effect on inpatient mortality, which may be

partially explained by choosing a somewhat older subset of patients as a control group.

In a retrospective analysis of all patients in the INTERMACS national registry that underwent implantation of a continuous flow LVAD from June 2006 to April 2012 (greater than 5,000 patients), Atluri *et al.* (7), utilizing Cox proportional hazard multivariable analysis, found that age greater than 70 was an independent risk factor for death. However, it was noted that, while slightly less than the control group, patients aged 70 years or greater had excellent overall survival (75% at one year, 63% at two years, 54% at three years). This data was congruent with the most recent and fifth INTERMACS annual report, which states that current survival for all patients (greater than 95% of whom received continuous flow devices) is approximately 80% at one year and 70% at two years. They also found that older age is a risk factor for early mortality, although the actuarial survival of patients aged older than 70 years is only modestly inferior to that of patients older than approximately 50 years. Older age also proved to be a marker for increased fragility in patient tolerance for other important risk factors. This was demonstrated by the interaction between age and INTERMACS level, which revealed reduced tolerance in the elderly when LVAD implantation occurred during acute cardiac decompensation (8).

Discussion

To date, there seems to be several overarching themes that can be extrapolated from the data on mechanical circulatory support in the elderly. In keeping with the universal trend, continuous flow devices appear to have particular benefit in this population. Also, it has been shown that early intervention before the development of cardiogenic shock, important in all patients, is particularly paramount in older age patients (9). Additionally, while it seems clear that age is an independent predictor of increased mortality, the overall survival in elderly patients undergoing mechanical circulatory support is quite good. This is especially true when juxtaposed with medical therapy. The next step will be to parse this population further and discover which patient variables predict poor outcomes, as well as to better delineate the concept of frailty, which encompasses a vulnerability to stress and adverse outcomes. Frailty in elderly mechanical circulatory support patients is associated with an increased risk of death and may represent a significant patient selection consideration. However, no universal definition exists (10). Going forward, rigorous preoperative assessment must

not focus solely on physiologic parameters and successful, discerning patient selection in the elective setting will include routine assessment of gait, functional status and cognition, degree of caregiver support, and advance care planning (11). There is much reason for optimism regarding mechanical circulatory support in patients of advanced age. The ongoing refinement of device design, patient selection, surgical technique, and post-operative care will continue to improve outcomes. Furthermore, as the indications and contraindications for the use of mechanical circulatory support in the elderly become more clearly defined, absolute age, while simple to quantify, may become a less pivotal criteria not only for assist devices, but also for transplant.

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