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Efficacy of Mechanical Circulatory Support Devices for Termination of Drug – Refractory Sustained Ventricular Tachycardia

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Abstract

Management of patients with sustained ventricular tachycardia or ventricular fibrillation (VT/VF) refractory to maximal medical therapy poses a challenging clinical situation because remaining options are limited. Mechanical circulatory support devices such as intra-aortic balloon pumps (IABP) and left ventricular assist devices (LVAD) have been used in this setting not only to provide hemodynamic stability, but also for arrhythmia management. However, data to support their placement in this clinical situation is limited. We conducted a retrospective observational study investigating the efficacy of mechanical circulatory assist devices to terminate drug refractory sustained VT/VF. We identified 17 patients (76% male; age 65.2 ± 10.4 years; LVEF (%) 31 ± 20) with sustained VT/VF who required IABP or LVAD placement for this purpose. Sustained VT/VF patients on maximal doses of intravenous amiodarone were categorized based on a "positive response" to device placement, which was defined as termination of VT/VF within 24 hours with no recurrences. Four patients (24%) had a positive response to device placement. In-hospital survival was 100% (4/4) for responders and 31% (4/13) for nonresponders (p = 0.015). Non-responders were more likely to have an elevated creatinine (mg/dL) (2.02 ± 0.92 vs 1.12 ± 0.40; p = 0.03) and a prior history of sustained VT/VF (p = 0.012). Other comparison points including age, sex, left ventricular ejection fraction, presence of coronary artery disease, and history of myocardial infarction were not different between responders and non-responders. In conclusion, the findings suggest that placement of circulatory assist devices for sustained VT/VF refractory to medical treatment has a beneficial effect to terminate VT/VF but its efficacy may be limited to patients with no prior history of sustained VT/VF and no renal insufficiency.

Introduction

Sustained ventricular tachycardia (VT) refractory to maximal medical treatment ("electrical storm") remains a rare, but challenging clinical scenario with high mortality. Management of the patients with refractory VT is not well established because there are limited options when an underlying correctable etiology is not identified and pharmacologic and cardiac pacing strategies fail. Mechanical circulatory support devices such as intra-aortic balloon pumps (IABP) and left ventricular assist devices (LVAD) have been used in this setting to provide hemodynamic stability presumably by unloading the left ventricle and possibly augmenting coronary blood flow [1-4].

Although data to support the use of circulatory support devices in patients with refractory ventricular arrhythmias is limited, employment of these devices are viewed by some as a readily available means (especially IABPs) to attempt to suppress ventricular arrhythmias and achieve hemodynamic stability [5-9]. However, the efficacy of this modality in suppressing drug - refractory sustained VT has not been well established. The aim of this study was to determine the efficacy of mechanical circulatory assist devices to terminate drug - refractory sustained VT and to characterize which patients might benefit from their placement.

Methods

This was a retrospective observational case series. The study was approved by the institutional review board for medical research. Patients admitted to the coronary intensive care unit at our institution with a diagnosis of ventricular arrhythmias (ventricular tachycardia or ventricular fibrillation, VF) and placement of intra-aortic balloon pump (IABP) or left ventricular assist device (LVAD) for control of VT/VF from January 2004 to May 2010 were selected for analysis. The study population consisted of 17 consecutive patients with documented sustained ventricular tachycardia refractory to anti-arrhythmic therapy (maximal doses of intravenous amiodarone with or without other concomitant antiarhythmic agents) in whom mechanical circulatory assist devices were placed for the purpose of controlling the VT. Sustained ventricular tachycardia was defined as VT lasting at least 30 s or VT (or VF, ventricular fibrillation) requiring electrical cardioversion because of hemodynamic instability. Drug refractory VT was defined as recurrent sustained VT despite maximal doses of intravenous amiodarone with or without other anti-arrhythmic agents. A "positive response" to device placement was defined as termination of sustained VT within 24 hours with no subsequent recurrences. Clinical characteristics including age, gender, pre-existing cardiac conditions, history of ventricular arrhythmia, left ventricular ejection fraction, type/duration of ventricular assist device used, laboratory and mortality data were collected.

Results are presented as mean ± standard deviation. Comparison of the groups using appropriate statistical analysis was performed using SPSS (version 18.0). Logistic regression analysis was performed to ascertain which clinical variables were independently associated with a positive response to device placement. Chi-Square was utilized for discrete categorical variables and independent sample t-test was applied for continuous variables. Levene's test was employed to test the

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assumption of equal variances amongst the samples. A p value <0.05 was considered statistically significant.

Results

Seventeen patients (13/17 male, 76%) fulfilled criteria for drug refractory sustained VT on chart review. One patient (1/17) had concomitant recurrent sustained VT and episodes of VF. All but one patient received IABP; the remaining patient received an LVAD (HeartMate II, Thoratec Corporation, Pleasanton, CA). All patients continued to receive anti-arrhythmic therapy (amiodarone with or without other anti-arrhythmic agents) while on mechanical circulatory support. The clinical characteristics of the study population are listed in (Table 1).

Outcome

There were no observed immediate direct complications from either mechanical support device implantation. Fourteen of the 17 patients (82%) had a history of coronary artery disease and a prior myocardial infarction whereas 3/17 (18%) had a non-ischemic cardiomyopathy. All patients with known coronary artery disease underwent emergent coronary angiography; 5 underwent immediate percutaneous angioplasty deemed appropriate for significant coronary stenosis and 1 underwent emergent coronary artery bypass surgery.

Four of the 17 total patients (24%) had complete resolution of sustained VT/VF within 24 hours of device placement with no subsequent recurrences. Only 3 of the 6 patients (50%) who underwent emergent revascularization had termination of the arrhythmia. All 4 patients who responded survived the hospitalization (in-hospital survival 100%). In contrast, non-responders (4/13) had a 31% in-hospital survival (p = 0.015, Table 2). The 4 non-responder patients who survived hospitalization had eventual control of the ventricular arrhythmia during the hospitalization but the arrhythmia was not controlled within the 24 hour window of device placement.

Age	65.2 ± 10.4
Male	13/17 (76%)
History of MI	14/17 (82%)
History of VT/VF	9/17 (53%)
Family history of SCD	5/17 (30%)
Ejection fraction	30.7 ± 20.0
IV antiarrythmic	17/17 (100%)
CAD	14/17 (82%)
Cr (mg/dL)	1.6 ± 0.8
Baseline QTc (msec)	480 ± 49.9
Ventilator	13/17 (76%)
IABP	16/17 (94%)
LVAD (Heart Mate II)	1/17 (6%)

VT: ventricular tachycardia; VF: ventricular fibrillation; SCD: sudden Cardiac death; IV: intravenous; CAD: coronary artery disease; Cr: serum creatinine; IABP: intraaortic balloon pump; LVAD: left ventricular assist device

Table 1: Clinical Characteristics.

	Responders (n=4)	Non-Responders (n=13)	p-Value
Age	60 ± 8	67 ± 10	NS
Male	3/4 (75%)	9/13 (69.2%)	NS
History of MI	3/4 (75%)	11/13 (84.6%)	NS
History of VT/VF	1/4 (25%)	6/13 (46.2%)	0.012*
Family History of SCD	0/4 (0%)	5/13 (38.5%)	0.053
Ejection Fraction	34 ± 18	30 ± 16	NS
CAD	3/4 (75%)	11/13 (84.6%)	NS
Cr (mg/dL)	1.12 ± 0.40	2.02 ± 0.92	0.03*

SCD, sudden cardiac death; NS, Not statistically significant; *Statistcally significant

Table 2: Responders vs Non-responders.

Comparison analysis

Groups were compared based on resolution of sustained VT within 24 hours. Clinical characteristics were similar between the two groups with exception of creatinine. The non-responder patient group had a higher mean serum creatinine than the positive responder group (2.02 ± 0.92 v 1.12 ± 0.40; p=0.034) at time of device placement. There was an observed trend towards having a positive family history of sudden cardiac death in predicting death; however, this did not meet statistical significance (p=0.053). Notably, 46% of non-responder patients had a prior history of ventricular arrhythmia which contrasts with 25% of patients for which placement of IABP was successful (p = 0.012). All other comparison points including age, sex, history of myocardial infarction (MI), ejection fraction, or presence of coronary artery disease were not significantly different (Table 2). Logistic regression analysis did not identify any clinical variable that was independently associated with a positive response to device placement.

Discussion

Patients with sustained ventricular arrhythmias refractory to standard therapies represent a highly morbid patient population. Cardiac assist devices may provide an alternative mechanical modality to aid in stabilization of these patients and terminate the malignant arrhythmia. Most reports supporting the use of these devices in this setting have been single case studies [6-9], One report indicated little arrhythmia control with device placement [10]. The largest study to support a beneficial effect was by Fotopoulos et al. [11] who reported that 18 of 21 patients with drug refractory VT in whom IABPs were placed for suppression of ventricular arrhythmias had termination of the arrhythmia within 35 to 85 minutes of placement. The results of our study are somewhat at variance with that study. Our study also demonstrated a modest beneficial effect of circulatory support device placement in some patients but the 24% positive response rate contrasts with the 86% rate reported in their study and termination of the VT was not as immediate and definitive. The criterion in our study for sustained VT was at least 30 s and successful termination required no recurrences in the subsequent hospital stay. It is of course possible that placement of IABPs in the 4 patients in our study who survived the hospitalization but whose sustained VT episodes were not terminated within the 24 hour cut-off period was responsible or at least contributed to the eventual control of the VT. However, with the necessary and numerous interventions and medical adjustments often undertaken simultaneously in critically ill patients, it would be difficult if not impossible to discern which factor(s) was primarily responsible for termination of the VT. It could be argued that the criteria we defined as a "positive response" to device placement were too stringent and arbitrary. Nevertheless, we believe they are reasonable and appropriate and take into account the possibility that other factors and treatments (eg., emergency percutaneous coronary angioplasty) undertaken contemporaneously in these critically ill patients in an ICU setting also played a role to control the malignant arrhythmia. It is likely that study entrance criteria, differences in patient populations, and disease severity might account for the disparity between our study and that of Fotopoulos et al. [11]. Indeed, we found that patients with

no prior history of sustained VT and who had normal renal function had a higher likelihood of a positive response to device placement, suggesting that disease severity did play a role in whether or not the VT was successfully terminated with device placement.

The mechanism of termination of the arrhythmia by device placement is most likely attributed to reduction of left ventricular wall stress as a consequence of afterload reduction [12]. Augmentation of coronary blood flow and attendant relief of myocardial ischemia might also be a factor but the incidence of coronary artery disease of the group with a positive response was the same as that of the non-responders, and there was no clear benefit of revascularization in the appropriate patients for termination of the VT.

Conclusion

The results of our study do support a role for placement of mechanical circulatory support devices in patients with drug-refractory VT, but the modest beneficial effect may be limited to patients with no prior history of sustained VT and normal renal function. Patients whose VT/VF was terminated within 24 hrs of device placement had 100% in-hospital survival. Future controlled, randomized and prospective studies are needed to answer the question whether mechanical unloading of the heart alone can terminate drug-refractory malignant ventricular arrhythmias.

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