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MINI-FOCUS ISSUE: MECHANICAL CIRCULATORY SUPPORT: OPPORTUNITIES AND CHALLENGES

Identification and Management of Pump Thrombus in the HeartWare Left Ventricular Assist Device System

A Novel Approach Using Log File Analysis

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ABSTRACT

OBJECTIVES The study sought to characterize patterns in the HeartWare (HeartWare Inc., Framingham, Massachusetts) ventricular assist device (HVAD) log files associated with successful medical treatment of device thrombosis.

BACKGROUND Device thrombosis is a serious adverse event for mechanical circulatory support devices and is often preceded by increased power consumption. Log files of the pump power are easily accessible on the bedside monitor of HVAD patients and may allow early diagnosis of device thrombosis. Furthermore, analysis of the log files may be able to predict the success rate of thrombolysis or the need for pump exchange.

METHODS The log files of 15 ADVANCE trial patients (algorithm derivation cohort) with 16 pump thrombus events treated with tissue plasminogen activator (tPA) were assessed for changes in the absolute and rate of increase in power consumption. Successful thrombolysis was defined as a clinical resolution of pump thrombus including normalization of power consumption and improvement in biochemical markers of hemolysis. Significant differences in log file patterns between successful and unsuccessful thrombolysis treatments were verified in 43 patients with 53 pump thrombus events implanted outside of clinical trials (validation cohort).

RESULTS The overall success rate of tPA therapy was 57%. Successful treatments had significantly lower measures of percent of expected power (130.9% vs. 196.1%, $p = 0.016$) and rate of increase in power (0.61 vs. 2.87, $p < 0.0001$). Medical therapy was successful in 77.7% of the algorithm development cohort and 81.3% of the validation cohort when the rate of power increase and percent of expected power values were <1.25% and 200%, respectively.

CONCLUSIONS Log file parameters can potentially predict the likelihood of successful tPA treatments and if validated prospectively, could substantially alter the approach to thrombus management. (J Am Coll Cardiol HF 2015;3:849–56)

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ABBREVIATIONS AND ACRONYMS

BTT = bridge to transplant

CAP = continued access protocol

EPPY = events per patient year

HM II = HeartMate II

HVAD = HeartWare ventricular assist device

tPA = tissue plasminogen activator

VAD = ventricular assist device

Due to the lack of available donors, many patients with advanced heart failure receive mechanical circulatory support devices as a bridge-to-transplant (BTT) therapy (1). Left ventricular assist devices (VADs) have proven to be very effective at improving functional capacity, quality of life, and the survival rates of these patients (2,3). The HeartWare ventricular assist device (HVAD) (HeartWare Inc., Framingham, Massachusetts) is a miniaturized, continuous flow, and centrifugal blood pump that had a survival rate >86% after 1 year in the U.S. BTT trial (4). While continuous flow VADs are becoming more common in the treatment of those with advanced heart failure, there still exist potential risks and complications associated with mechanical circulatory support such as device thrombosis (5–7).

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Pump thrombus is defined as an obstruction that limits blood entering/exiting the pump or otherwise impinges the impeller from properly rotating. However, the location and histology of the clot formation can differ depending on the type of VAD. Globular clot formations have been reported on the inflow bearings and in regions of sharp angulation of the HeartMate II (HM II) inflow/outflow grafts (8,9). In contrast, laminar fibrin formations may develop on the impeller of HVAD pumps if a thrombus event occurs (10). Pump thrombus requiring exchange occurred at a rate of 0.04 events per patient year (EPPY) with a total suspected thrombus rate of 0.08 EPPY in patients implanted with an HVAD from the HeartWare BTT and CAP (Continued Access Protocol) trials (7). Most baseline demographics including mean pump power were not significantly different between patients with and without thrombus events. A multivariate analysis did identify certain risk factors for pump thrombus such as mean arterial pressure >90 mm Hg, aspirin dose ≤81 mg, or international normalized ratio ≤2 (7).

It is well known to clinicians that the presence or ingestion of a thrombus will often lead to a rise in the log file power signal (11,12). As seen in **Figure 1**, occlusion, ingestion, and build-up thrombi have very different effects on the pump power consumption. Further analysis of the log files, beyond measuring an average power, is warranted to determine if there are characteristics in the power signal that could indicate the presence of thrombus. Studies have suggested that recognition of changes in pump power can allow early treatment with thrombolytics to resolve the event (13–15). Improved thrombus detection, prediction of successful management with medical therapy, and thereby avoidance of unnecessary pump exchange surgery would have tremendous clinical value. In the current study, patient log files were analyzed with the goal of developing a tool to aid the diagnosis and management of pump thrombosis.

METHODS

LOG FILE POWER ANALYSIS. The HVAD system has a unique controller log file that records the pump power (mW), rotational impeller speed (rpm), and VAD flow (ml/min) every 15 min (11). The patient's baseline power was calculated by averaging a period of stable behavior prior to the thrombus event. The beginning of the thrombus event was defined as the time when the power had a 3 SD difference from the baseline power for at least 1.5 h. The difference between the time of treatment and beginning of the thrombus event was defined as the "time until treatment."

There were several measures of the power used to assess the thrombus events. The first was the maximum power reached during the thrombus event. The second was the change in power, calculated as the difference between the maximum and baseline power for each patient. The third measure of power accounts for the interpatient variability in pump speed and power and is termed "percent of expected power." An analysis of normal HVAD pump operation parameters showed that there is an "expected value" of power consumption based on the motor speed setting (11). Dividing the maximum power by the expected power for the given motor speed (Equation 1) gives a measure of the difference of the power from normal operating values. This normalization process allows

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