Long Term Outcomes in HeartMate II Patients Managed With Vitamin K Antagonists Without Antiplatelet Therapy - Results of the EU-TRACE Study

Purpose: TRACE (Study of Reduced Anti-Coagulation/Anti-platelet Therapy in Patients with the HeartMate II LVAS) was initiated in the US and Europe.

Methods: The TRACE-US enrolled HMII outpatients who at enrollment or as of Jan 1, 2011 were on a reduced anti-thrombotic (RT) regimen: warfarin only (RT-w), aspirin only (RT-a), or no anticoagulant or antiplatelet therapy (RT-n). The indication for RT, subsequent anti-thrombotic changes, as well as any bleeding, stroke, or pump thrombosis after RT were documented. Patients were prospectively followed for up to 24 months post-enrollment. 100 outpatients on RT were enrolled in the TRACE-US Study from 9 sites. In this report we present adverse events at 2 years post RT initiation. Freedom from ischemic stroke, hemorrhagic stroke, and pump thrombosis at two years were 93±3%, 96±3%, and 93±3%, respectively.

Conclusion: This preliminary analysis of the TRACE study suggests that patients may be safely managed on a single vitamin K antagonist (AVK) with a target INR greater than 2.0, without anti-platelet therapy. Further prospective studies are needed to confirm if these results are applicable to a larger patient population.

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Chronic Management With Reduced Anti-Thrombotic Therapy in HeartMate II Patients With Persistent Bleeding - Results From the US-TRACE Study

Purpose: Persistent bleeding in LVAD patients often requires a reduction in standard anti-thrombotic therapies of warfarin plus aspirin. To assess the long term safety of such approaches, TRACE (STudy of Reduced Anti-Coagulation/Anti-platelet Therapy in Patients with the HeartMate II LVAS) was initiated in the US and Europe.

Methods: The TRACE-US enrolled HMII outpatients who at enrollment or as of Jan 1, 2011 were on a reduced anti-thrombotic (RT) regimen: warfarin only (RT-w), aspirin only (RT-a), or no anticoagulant or antiplatelet therapy (RT-n). The indication for RT, subsequent anti-thrombotic changes, as well as any bleeding, stroke, or pump thrombosis after RT were documented. Patients were prospectively followed for up to 24 months post-enrollment. 100 outpatients on RT were enrolled in the TRACE-US Study from 9 sites. In this report we present adverse events in patients on RT for 2 years.

Results: As of September 2014, 75 patients had been on RT for at least 24 months (n=58) or reached an outcome (n=17). The median age was 65 years (36-80), 87% were male, 64% had ischemic etiology and 71% were DT. The primary reason for RT (79% of pts) was to control bleeding (GI or epistaxis). RT-w, RTa, and RT-n, were used in 33%, 29%, and 37% of the patients. At enrollment the median INR of the RT-w group was 2.1 (IQR 1.7-2.5). The primary reason for RT (79% of pts) was to control bleeding (GI or epistaxis). RT-w, RTa, and RT-n, were used in 33%, 29%, and 37% of the patients. At enrollment the median INR of the RT-w group was 2.1 (IQR 1.7-2.5). The median INR at follow-up was 2.31 [range: 0.73-5.2] which was higher than the median INRs of patients in the HMII clinical trial (median of 2.0). Only 4% of the INR measurements were below 1.5. Median LDH was 365 U/L [range: 66-3020]. At 2 years post initiation of RT therapy, freedom from bleeding, hemorrhagic stroke, ischemic stroke and pump thrombosis were respectively 86±5%, 96±3%, 93±3%, and 93±3%.

Conclusion: This preliminary analysis of the TRACE study suggests that patients may be safely managed on a single vitamin K antagonist (AVK) with a target INR greater than 2.0, without anti-platelet therapy. Further prospective studies are needed to confirm if these results are applicable to a larger patient population.