What's New in MCS

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REVIEWS:

1. HAS-BLED and CHA2DS2-VASc Scores as Predictors of Bleeding and Thrombotic Risk After Continuous-Flow Ventricular Assist Device Implantation.
Ryan J. Koene, MD1, Sithu Win, MD, MPH2, Niyada Naksuk, MD2, Sirtaz N. Adatya, MD1, Andrew N. Rosenbaum, MD3, Ranjit John, MD4, Peter M. Eckman, MD1
J Card Fail. 2014 Nov;20(11):800-7.

http://www.ncbi.nlm.nih.gov/pubmed/25152496

HAS-BLED and CHA2DS2-VASc predict bleeding in patients on anticoagulation and thromboembolic (TE) events in patients with atrial fibrillation (AF), respectively. The group from the University of Minnesota hypothesized that these previously validated scores would predict bleeding and TE events in patients supported by left ventricular assist devices (LVADs).They retrospectively calculated baseline HAS-BLED and CHA2DS2-VASc in 173 consecutive patients who underwent HeartMate II (HM2) implantation at their center from 2005 to 2011.

Overall, bleeding was present in 43 of 173 patients (~25%) and TE in 22 patients (~13%) over a 290 patient-year follow up period (median follow up – 1.26 years). Baseline HAS-BLED and CHA2DS2-VASc ≥ 3 were associated with significantly higher risk of bleeding and TE, respectively. Thus, the risk of bleeding in patients with HAS-BLED ≥3 compared to those with a score < 3 were 42 % versus 15% (HR=3.4, p=0.001) while the risk of TE events in patients with CHA2DS2-VASc ≥ 3 compared to those < 3 were 18% versus 4% (HR=4, p=0.025). Cox proportional hazard analysis showed a 59% increase in the risk of future bleeding events for each point increase in the baseline HAS-BLED score (HR=1.59/point increase, p=0.001) and a 29% increase for future TE events for each point increase in baseline CHA2DS2-VASc score (HR=1.29/point increase, p=0.049). Using both scores, they assigned patients to 1 of 4 quadrants to determine the risk for bleeding and TE events. Patients with both scores ≥3 had the highest risk for both bleeding and TE (45% and 20%, respectively) and those with scores < 3 had the lowest risk (13% and 4%, respectively) while those with one score > 3 and one < 3 had intermediate risk.

Analysis.
This study is important since bleeding and pump thrombosis with associated TE events with continuous flow LVADs remain common and carry high morbidity and mortality. The authors

found that HAS-BLED and CHA2DS2-VASc were good predictors for bleeding and TE events in patients supported by HM2 LVADs and suggested that the 2 scores could be used to individualize anticoagulation and antiplatelet therapy.

2. Results With Syncardia Total Artificial Heart Beyond 1 Year.

Torregrossa, Gianluca; Morshuis, Michiel; Varghese, Robin; Hosseinian, Leila; Vida, Vladimiro; Tarzia, Vincenzo; Loforte, Antonio; Duveau, Daniel; Arabia, Francisco; Leprince, Pascal; Kasirajan, Vigneshwa; Beyersdorf, Friedhelm; Musumeci, Francesco; Hetzer, Roland; Krabatsch, Thoamas; Gummert, Jan; Copeland, Jack; Gerosa, Gino
ASAIO J. 2014 Nov-Dec;60(6):626-34.

http://www.ncbi.nlm.nih.gov/pubmed/25158888

The authors reviewed the outcomes of patients supported for more than one year by the SynCardia total artificial heart (TAH). A total of 1,075 patients received the TAH during the study period (from 1989 to December 2011) and 53 patients were supported more than one year. Forty-seven patients from 10 centers worldwide are included in this analysis (6 were excluded). The median support time was 554 days (1.5 years) with a range of 365 – 1,374 days and the cumulative support time was approximately 80 years.

Thirty-four patients (72%) were successfully transplanted, 12 patients (25%) died while on device support and 1 patient (2%) remained supported at the time of their analysis.
Major complications during TAH support were as follows: device failure – 5 patients (10%), systemic infections – 25 patients (53%), driveline infections – 13 patients (27%), thromboembolic events – 9 patients (19%), hemorrhagic events – 7 patients (14%).
The major causes of death were infection and hemorrhagic events while device failure was the leading cause of death in only 2 patients (median time to death was 525 days, range 381 – 971 days).
Although not included in current analysis, the authors also report that, as of December 2013, 1200 patients have been supported with a SynCardia TAH and 82 of them were supported more than one year. Of these 82 patients, 47 patients (57%) underwent transplantation, 15 patients (18%) died and 20 patients are still supported on the device.

Analysis.
This study is very important as it describes the outcomes after long term support with the SynCardia TAH which is the only FDA approved device for total heart replacement.
The authors concluded that the device failure rate during long term support (> one year) was acceptable (4%) and most patients were still likely to survive to transplantation (72% success rate). Infection and hemorrhagic events were the major causes of death. The study excluded patients supported < one year (~99%) which might lead to a selection bias.

3. Bivalirudin for Treatment of LVAD Thrombosis: A Case Series

Sylvia, Lynne M.; Ordway, Linda; Pham, Duc T.; DeNofrio, David; Kiernan,Michael
ASAIO J. 2014 Nov-Dec;60(6):744-7.

http://www.ncbi.nlm.nih.gov/pubmed/25072553

Pump thrombosis in patients with continuous flow (CF) left ventricular assist devices (LVADs) has become more common than initially reported in pivotal clinical trials.

In this small series, the authors described their experience with the use of Bivalirudin as an alternative to heparin for patients with suspected LVAD thrombosis.
Six patients were admitted for a total of 10 hospitalizations for suspected pump thrombosis. All patients were treated with bivalirudin as the initial inpatient strategy instead of heparin. LVAD thrombosis was suspected in the setting of LDH > than 2.5 times the upper limit of normal (or > 550IU/L) in the absence of an alternative etiology, and/or LVAD dysfunction manifested by elevated pump power, new, regular opening of the aortic valve, an/or failure to decompress the left ventricle despite speed increase.

Clinical response to bivalirudin protocol occurred in nine of the ten hospital admissions for suspected pump thrombosis (90%). One treatment with bivalirudin therapy was considered ineffective and changed to a combination of eptifibatide and heparin on hospital day 3. Three of six patients (50%) subsequently received LVAD exchange due to recurrent hemolysis and power spikes at 111, 130 and 259 days following completion of bivalirudin protocol. There were no major bleeding events and one episode of epistaxis that did not require treatment.

Analysis.
The authors concluded that bivalirudin was relatively safe and effective for the medical management of LVAD thrombosis. They point out potential advantages of bivalirudin compared to unfractionated heparin such as the inhibition of both circulating and fibrin-bound thrombin, less immunogenicity, inhibition of platelet adhesion and prior evidence for lower risk of bleeding. The need for frequent monitoring and the cost were the main drawbacks. A study to compare efficacy and cost benefit ratio of bivalirudin and heparin would be useful.

OTHER MCS ARTICLES (November 2014)

I. Circulation Heart Failure.

Clinical Outcomes after Continuous- Flow Left ventricular Assist device: A systematic review.
McIlvennan CK1,Magid KH2, Ambardekar AV2, Thompson JS2, Matlock DD2,Allen LA

This is a comprehensive review of 52 industry sponsored trials, registries as well as multi-center and single center observational studies on outcomes after LVAD implant. Survival and common adverse events such as bleeding, neurological events, infection, device malfunction/pump thrombosis, right heart failure, cardiac arrhythmias are well reviewed**.**

II. ASAIO J

1. Improvement in Glycemic Control After Left Ventricular Assist Device Implantation in Advanced Heart Failure Patients With Diabetes Mellitus
Choudhary, Naila; Chen, Leway; Kotyra, Lisa; Wittlin, Steven D.; Alexis, Jeffrey D.

The authors show in this retrospective study that diabetic patients with severe heart failure have improved glycemic control after LVAD implantation. This confirms findings of a previous smaller study (Uriel et all, Eur J of heart Failure, 2011)

2. Modified HeartMate II Driveline Externalization Technique Significantly Decreases Incidence of Infection and Improves Long-Term Survival
Singh, Ajeet; Russo, Mark J.; Valeroso, Tracy B.; Anderson, Allen S.; Rich, Jonathan D.; Jeevanandam, Valluvan; Akhter, Shahab A.

3. Early Feasibility Testing and Engineering Development of a Sutureless Beating Heart Connector for Left Ventricular Assist Devices. Koenig, Steven C.; Jimenez, Jorge H.; West, Seth D.; Sobieski, Michael A.; Choi, Young; Monreal, Gretel; Giridharan, Guruprasad A.; Soucy, Kevin G.; Slaughter, Mark S

4. Markers of Inflammation in Recipients of Continuous-Flow Left Ventricular Assist Devices. Grosman-Rimon, Liza; McDonald, Michael A.; Jacobs, Ira; Tumiati, Laura C.; Pollock Bar-Ziv, Stacey; Shogilev, Daniel J.; Mociornita, Amelia G.; Ghashghai, Arash; Chruscinski, Andrzej; Cherney, David Z. I.; Rao, Vivek

5. Noncardiac Surgery in Patients on Mechanical Circulatory Support
Taghavi, Sharven; Beyer, Carl; Vora, Halley; Jayarajan, Senthil N.; Toyoda, Yoshiya; Dujon, Jay; Sjoholm,Lars O.; Pathak,Abhijit; Santora,Thomas A.; Goldberg, Amy J.; Rappold,Joseph F.

6. ABO Blood Group Antibody Levels in Infants Exposed to Mechanical Circulatory Support. Guynes, Anthony; Delaney, Meghan; McMullan, David M.; Townsend-McCall, Dee; Kemna, Mariska; Boucek, Robert; Law, Yuk M.

7. Robotic-Assisted Implantation of Ventricular Assist Device After Sternectomy and Pectoralis Muscle Flap. Khalpey, Zain; Sydow, Nicole; Paidy, Samata; Slepian, Marvin J; Friedman, Mark; Cooper, Anthony; Marsh, Katherine M.; Schmitto, Jan D.; Poston, Robert

8. Intracardiac Echocardiography for Diagnosis and Management of Left Ventricular Assist Device Inlet Obstruction. El Banayosy, Aly; Koerner, Michael M.; Brehm, Christoph; Stevenson, Edward R.; Pae, Walter E.; Clemson, Barry; Banchs, Javier; Gonzalez, Mario D.; Shears, Larry; Ghodsizad, Ali

9. Young Woman With Breast Cancer and Cardiotoxicity With Severe Heart Failure Treated With a HeartMate IITM for Nearly 6 Years Before Heart Transplantation
Sundbom, Per; Hedayati, Elham; Peterzén, Bengt; Granfeldt, Hans; Ahn, Henrik; Hubbert, Laila

III. Journal of Cardiac Failure
Case report: Cavitation phenomenon: A Novel Echocardiographic Finding in Pump Thrombosis. Palaniswamy C1, Garg J1, Dutta T1, Shah A2, Gass A1, Lanier GM

IV. European Journal of Heart Failure.
Letter to the editor: Correspondence regarding article published April 2014: Does increased oxygen extraction contribute to the improvement of VO2peak observed in patients who exercise with increased LVAD speed?

V. Journal of the American College of Cardiology – no articles.

VI. Journal of Thoracic and Cardiovascular Surgery – no articles