Diagnosis of Device Thrombosis

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Trends in Patient Profiles, LVAD Volumes and Management Strategies

Secular Trends

Implant Year

- 2008
- 2009
- 2010
- 2011
- 2012
- 2013

FDA approves HMII for BTT

FDA approves HMII for DT

INTERMACS Profile 1/2 (%)

Destination Therapy (%)

LVAD volume Trend (n)

Cumulative LVADs Implanted

0
2,000
4,000
6,000
8,000
10,000

GI bleeding and vWF deficiency
Low reported thromboembolic events
Relaxed anticoagulation targets
Reduced emphasis on post-op bridging
Aortic valve pathology emerges
Lower pump speed for AV opening

Spike in HeartMate II Thrombosis

Adapted from Mehra et al, J Heart Lung Transplant 2014;33:1-11
Definition of Pump Thrombosis

- Development of clot within the flow path of any the pump components:
  - Inflow cannula
  - Pump housing / rotor
  - Outflow graft

- Thrombus may originate in the pump, or
  - from the left atrium or ventricle, or
  - from right sided chambers and travel through a septal defect
- And lodge in any, or all, of the pump components
LVAD Thrombosis

Inflow Cannula

Rotor

Outflow Cannula
Diagnosis of Pump Thrombosis May be Elusive

- echo
- CTA
- cardiac catheterization
- VADoscopy
- direct examination intraoperatively

Algorithm for the Diagnosis of Suspected LVAD Thrombosis

1. **Power Elevations**
   - Early or Late?
     - Early
       - Consider Echocardiogram +/- Speed Changes
     - Late
       - LV Unloading?
         - Yes
           - Close Follow-up
**Diagnosis of VAD Thrombosis - 2018**

Clinical Suspicion of VAD Thrombosis (At least one of the following):
- Signs of Symptoms Suggestive of VAD thrombosis
- Evidence of hemolysis
- Change in pump parameters

- **Check LDH**
  - Normal
  - >3X Upper Normal Limit
    - Admit to Hospital
      - Consider intravenous anticoagulation
    - Assess other causes of HF or change in pump parameters

*Adapted from Rame and Birati, J Am Coll Cardiol HF 2015;3 (11); 857-858*
The Relationship Between Hemolysis and VAD Thrombosis

Thrombus Formation
- Hemolysis, but No Hemodynamic Compromise

Incomplete Thrombosis
- Hemolysis, with Abnormal Pump Function

Complete Thrombosis
- Pump Stop With Cardiogenic Shock

Elevated LDH Levels Within 3 Months After HM II Implantation

LDH and Serum Free Hb as Markers of Device Thrombosis

Shah et al, J Heart and Lung Transplant 2014;33;102-104
**Diagnosis of VAD Thrombosis - 2018**

Clinical Suspicion of VAD Thrombosis (At least one of the following):
- Signs of Symptoms Suggestive of VAD thrombosis
- Evidence of hemolysis
- Change in pump parameters

Check LDH

- Normal: Assess other causes of HF or change in pump parameters
- >3X Upper Normal Limit: Admit to Hospital, Consider intravenous anticoagulation

Hemodynamically Stable?

- Yes: HM II
  - Diagnosis: **Echo Ramp study**
    - Higher peak power
    - Consider CT angio
    - Consider RHC
  - HVAD
- No: Consider Pump Exchange or OHT
Echocardiography for Device Thrombosis

Increased LV size by LVIDd after LVAD thrombosis

**Echocardiography Ramp Test - Diagnosis of Device Thrombosis**

*Increased AV Opening Time by M-mode*

Echocardiography Ramp Test - Diagnosis of Device Thrombosis

Low Velocity Inflow Cannula Peak velocity

Echocardiography Ramp Test - Diagnosis of Device Thrombosis

Abnormal Inflow Cannula Colorflow

Development of a Novel Echocardiography Ramp Test for Speed Optimization and Diagnosis of Device Thrombosis in Continuous-Flow Left Ventricular Assist Devices

The Columbia Ramp Study

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Normal vs Device Thrombosis RAMP Echo Study

Uriel et al, J Am Coll Cardiol 2012;60:1764-75
## Ramp Echo Study - Normal vs Device Thrombosis

| Table 2: Baseline Characteristics and Results: Device Thrombosis Patients (n = 8) Versus No Thrombosis Patients (n = 29) Versus All Patients (n = 39) |
|-----------------|-----------------|-----------------|-----------------|
|                 | Confirmed Thrombosis Patients (n = 8) | No Thrombosis Patients (n = 29) | p Value | All Patients (n = 39*) |
| Age, yrs        | 53 ± 20          | 59 ± 14          | 0.47          | 57 ± 14          |
| Male            | 5 (62)           | 26 (90)          | 0.10          | 33 (85)          |
| Race            | 2 (25) AA, 6 (75) other | 3 (12) AA, 22 (88) other | 1.0          | 6 (15) AA, 33 (85) other |
| Heart failure etiology, dilated cardiomyopathy | 4 (50) | 12 (48) | 0.70 | 20 (51) |
| Hypertension    | 3 (38)           | 7 (28)           | 1.0           | 13 (33)          |
| Diabetes mellitus | 3 (38)           | 7 (28)           | 0.66          | 14 (36)          |
| Former smoker   | 5 (62)           | 14 (56)          | 0.70          | 21 (54)          |
| IVS, cm         | 1.0 ± 0.2        | 1.1 ± 0.2        | 0.06          | 21 (54)          |
| LVAD surgery combined with | | | | |
| Mitral valve repair | 1 (13) | 7 (28) | 0.65 | 9 (23) |
| AV repair/closure | 0 (0)            | 7 (28)           | 0.16          | 8 (21)          |
| Tricuspid valve repair | 1 (13) | 2 (8)   | 1.0          | 4 (10)          |
| PFO closure     | 1 (13)           | —                | 0.24          | 1 (3)           |
| Ramp test results | | | | |
| LVEDD slope     | −0.08 ± 0.04     | −0.29 ± 0.11     | <0.001        | N/A             |
| PI slope        | −0.16 ± 0.04     | −0.46 ± 0.20     | <0.001        | N/A             |
| Power slope     | 0.74 ± 0.15      | 0.62 ± 0.17      | 0.03          | N/A             |
| Speed for complete AV closure | 11,100 ± 1,146  | 9,124 ± 1,222   | <0.001        | N/A             |
| LDH value       | 1,737 ± 684      | 454 ± 263        | <0.001        | N/A             |
| Low haptoglobin | <7               | N/A              | N/A           | N/A             |
| High plasma-free hemoglobin | 19.1 ± 14.0     | N/A              | N/A           | N/A             |
| Length of follow-up, post-ramp test, days | 171 ± 111 | 148 ± 89 | 0.6 | N/A |

Uriel et al, J Am Coll Cardiol 2012;60:1764-75
Ramp Echo Study - Normal vs. Device Thrombosis

No patient with VAD Thrombosis had a LVEDD Slope <- 0.16

Best LDH Cutoff >1103 (5X ULM)

Uriel et al, J Am Coll Cardiol 2012;60:1764-75
Using RAMP Echo Studies to Predict VAD Thrombosis

Suspected Device Malfunction
LDH Elevation, Power Spikes

Check for Hemolysis: LDH, Plasma Free Hemoglobin
Check Anticoagulation: INR, PTT

LVEDD Slope > -0.16
Device Thrombosis is Likely

LVEDD Slope < -0.16
No Device Thrombosis or Malfunction

Adapted from Uriel et al, J Am Coll Cardiol:60;1764-75
Diagnosis of VAD Thrombosis - 2018

Clinical Suspicion of VAD Thrombosis (At least one of the following):
- Signs of Symptoms Suggestive of VAD thrombosis
- Evidence of hemolysis
- Change in pump parameters

Check LDH

Assess other causes of HF or change in pump parameters

>2.5X Upper Normal Limit

Admit to Hospital
Consider intravenous anticoagulation

Consider Pump Exchange or OHT

Hemodynamically Stable?

Yes

HVAD

No

HM II

Diagnosis:
- Echo Ramp study
- Higher peak power
- Consider CT angio
- Consider RHC

Adapted from Rame and Birati, J Am Coll Cardiol HF 2015;3 (11); 857-858
Computed Tomography Angiography (CTA)

• Helpful in diagnosing mechanical issues predisposing to pump thrombosis

• Important positive findings include:
  - Left ventricular thrombus
  - Dilated left ventricle
  - Cannula malposition toward any of the left ventricular walls
  - Outflow graft thrombus, kinking or twisting
  - Lack of opacification of the outflow graft
Computed Tomography Angiography (CTA)

Misdirection of the apical cannula toward the interventricular septum

Milano et al, J Heart Lung Transplant 2011;30:838–40
Computed Tomography Angiography (CTA)

Mural thrombus in the proximal LVAD outflow cannula

Krishnan et al, J Cardiovasc Comp Tomography 2014;8:473-474
**Diagnosis of VAD Thrombosis - 2018**

Clinical Suspicion of VAD Thrombosis (At least one of the following):
- Signs of Symptoms Suggestive of VAD thrombosis
- Evidence of hemolysis
- Change in pump parameters

- Check LDH
  - Normal
  - >3X Upper Normal Limit

  - Admit to Hospital
    - Consider intravenous anticoagulation

Hemodynamically Stable?

- Yes
  - Diagnosis:
    - Log file analysis
    - Higher peak power
    - Consider CT angio
    - Consider RHC

- No
  - Consider Pump Exchange or OHT

HM II

- Diagnosis:
  - Echo Ramp study
  - Higher peak power
  - Consider CT angio
  - Consider RHC

HVAD

- Diagnosis:
  - Log file analysis
  - Higher peak power
  - Consider CT angio
  - Consider RHC

Adapted from Rame and Birati, *J Am Coll Cardiol HF* 2015;3 (11); 857-858
RAMP Echo Slope Does Not Diagnosis HVAD Thrombosis

Uriel et al, J Cardiac Fail 2015;21;785-791
HVAD Log File Analysis to Diagnosis Thrombosis

Najjar et al, J Heart Lung Transplant 2014;33:23–34
HVAD Log File Analysis to Diagnosis Thrombosis

Najjar et al, J Heart Lung Transplant 2014;33:23–34
Diagnosis of VAD Thrombosis - 2018

Clinical Suspicion of VAD Thrombosis (At least one of the following):
- Signs of Symptoms Suggestive of VAD thrombosis
- Evidence of hemolysis
- Change in pump parameters

Check LDH

- Normal
  - Assess other causes of HF or change in pump parameters
- >3X Upper Normal Limit
  - Admit to Hospital
  - Consider intravenous anticoagulation

Hemodynamically Stable?

- No
  - Consider Pump Exchange or OHT
- Yes
  - Consider HM II
    - Diagnosis:
      - Echo Ramp study
      - Increased peak power
      - Consider CT angio
      - Consider RHC
  - Consider HVAD
    - Diagnosis:
      - Log file analysis
      - Consider CT angio
      - Consider RHC

Adapted from Rame and Birati, J Am Coll Cardiol HF 2015;3 (11); 857-858