LVAD Complications - Understanding Risks and Rewards in the Context of Appropriate Use Benchmarks

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University of California San Francisco

CUTTING EDGE of TRANSPLANTATION

TRANSPLANT SUMMIT 2018
Breaking Through Regulatory Barriers to Unleash Transplant Innovation

FEBRUARY 8–10, 2018
ARIZONA BILTMORE • PHOENIX, AZ
Disclosure

Related to the presentation: Abbott (consultant), Medtronic (consultant), NHLBI (research grants).
Survival in Advanced Heart Failure: A Decade of Progress (COMPANION)

67 yo, EF 22%, 250 m, class III

Survival in Advanced Heart Failure: A Decade of Progress (ENDURANCE)


66 yo, EF 17%, 100 m, class III/IV, 70% inotropes
Current Estimate of Stage D Patients

280 million US adults

~ 2% with HF => ~ 6.5 million

55% with EF > 40%
~ 3.6 million

45% with EF < 40%
~ 2.9 million

EF < 25%, NYHA IIIB/ IV, < 80 yrs.
~ 100,000 pts.

35% NYHA class I
35% NYHA class II
20% NYHA class IIIA
5% NYHA class IIIB
5% NYHA class IV

VADs as BTT/ DT

Current Estimate of VAD Implants

7 ways the iPhone has gotten worse

By Kara Alaimo

Updated 10:09 AM ET, Thu June 29, 2017

10 Horrific Deaths Caused By Cell Phones

ELLiot ROSENHAUS MARCH 25, 2016

We love our smartphones. They’re everything to us—our GPS, our video gaming device, our way to connect with the world socially, and lastly, a way to occasionally communicate when necessary. Many of us will quickly experience a panic attack if we realize that we left home without our digital companion.

Few of us would ever think that the very thing we love so much could one day lead to our death. In fact, more people are now killed in selfie-related deaths than shark attacks! Below are 10 of the most bizarre ways that people have died due to their favorite electronic devices.
Survival

2-year 70%

Adverse Events
- GI bleeding (25-35%)
- Pump thrombosis leading to replacement (10%)
- Stroke (10-15%)
- Driveline infections (15-20%)
- Hospitalizations (80-90%)

High event rate @ 2 years

Quality of Life
- Improved significantly

Readmissions After LVAD Implant

- Overall readmission rate: $1.64 \pm 1.97$ per patient year
- Highest in the first 6 months ($2.0 \pm 2.3$ per patient year)

Readmissions Relate to Survival

Who’s Benchmarking LVAD Therapy?

If the device seems effective and does not kill lots of people, we’ll approve it.
If FDA approved it and it can help old people, we’ll pay for it.
We’ll record data, create graphs, allow you to guess how good/bad you are.
We’ll pay for this for some of our members if it seems cost effective.
We’ll make you standardize everything, audit yourself to improve, give you...
Benchmarking: a standard or point of reference against which things may be compared or assessed

- What are acceptable AE rates to benchmark against?
- Should we demand/wait the perfect LVAD that has no AEs?
- Can we use existing technology to lower AEs/?
- Who should keep track, incentivize/coerce (and how) centers to lower AEs?
How Should LVAD Benchmarking Work?

We will mandate long term (5 yrs) real world data (post-approval registry), we can withdraw approval if AEs are high

We will mandate real world data (QOL PROs, cost effectiveness data) and pay (MIPS) accordingly

We’ll help (share best practices), hold you accountable (public data)

We’ll make data available in real time, actionable (comparisons across centers)

We’ll restrict therapy to CoEs (not just saying it, but actually redirect our members to CoEs and support it $$)
Using Technology to Decrease AEs@ UCSF

Remote Monitoring and Outcomes in Pacemaker and Defibrillator Patients

Big Data Saving Lives?*

James V. Freeman, MD, MPH, MS,† Leslie Saxon, MD‡
Using Technology to Decrease AEs@ UCSF

Can we apply remote monitoring concepts to LVADs?

<table>
<thead>
<tr>
<th>Preventing</th>
<th>Monitoring</th>
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<td>• Bleeding (GI and others)</td>
<td>-&gt; INR</td>
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<td>• Stroke</td>
<td>-&gt; INR, BP</td>
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<td>• Pump thrombosis</td>
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<td>• Heart failure</td>
<td>-&gt; VAD, BP, Weight</td>
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<tr>
<td>• Arrhythmias</td>
<td>-&gt; ICD</td>
</tr>
<tr>
<td>• Infections (DL)</td>
<td>-&gt; DL Pictures</td>
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</table>
Using Technology to Decrease AEs@ UCSF

• Since 2015 all LVAD pts are discharged with Alere VAD Watch or ActiCare home monitoring system
  • Scale, Roche INR, Terumo or A&D BP Cuff or Doppler ICD remote to UCSF
  • Direct download to EPIC
  • Smartphone on all patients -> DL pictures to EPIC
• Weight/ VAD parameters input daily (90% compliance)
• BP checked daily (SBP 90-100; MAP 70-85)
• INR Mon/ Thu if stable (2-2.5), more often if not (enoxaparin 40 mg QD if INR < 2)
• Labs on demand (Quest/ LabCorp) -> download to EPIC
Using Technology to Decrease AEs@ UCSF

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<td>12 L/min</td>
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LVAD Patient Report | Profile | Med List
Using Technology to Decrease AEs@ UCSF

Patient Lists

LVAD Active

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LVAD Patient Report

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<td>10.6 L/min</td>
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Using Technology to Decrease AEs@ UCSF

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### LVAD Patient Report

**Last 3 WBC Values**
- 1/21/2018 1/23/2018 2/2/2018
- 4:57 PM 12:12 PM 1:27 PM
- WBC 7.22 5.4 5.6

**Last 3 Hemoglobin Values**
- 1/21/2018 1/23/2018 2/2/2018
- 4:57 PM 12:12 PM 1:27 PM
- HGB 13.8 13.1 (L) 12.7 (L)

**Last 3 INR Values**
- 2/6/2018 2/7/2018 2/7/2018
- 3:55 PM
- INR 4.8 2.5 ✔ 2.1 (H) □

**Last 3 Lactate Dehydrogenase Values**
- 1/23/2018 2/2/2018 2/7/2018
- 12:12 PM 3:55 PM
- LDH 204 217 213

**Last 3 Plasma Free Hemoglobin Values**
- 1/15/2018 1/17/2018 1/17/2018
- 9:06 AM 7:38 AM 5:29 AM
- PHGBS <8 <8 <8

**Last 3 BNP Values**
- 8/11/2017 1/13/2018 1/13/2018
- 1:12 PM 6:08 AM 2:05 PM
- BNP 173 (H) 306 (H) 251 (H)

**Last 3 Creatinine Values**
- 1/21/2018 1/23/2018 2/2/2018
- 5:29 AM 12:12 PM 1:27 PM
- CREAT 1.19 1.50 (H) □ 1.23 □

**Last 3 Potassium Values**
- 1/21/2018 1/23/2018 2/2/2018
- 4:48 PM 12:12 PM 1:27 PM
- K 4.0 4.7 4.3
Using Technology to Decrease AEs@ UCSF
Using Technology to Decrease AEs at UCSF

- 150 IT hours (~$20,000) from UCSF -> 3 months implement
- Partnered with vendors (Alere, ActiCare)

- LVAD RN time spent per patient per day ~ 7 min

- Time in therapeutic range: INR (82%), BP (85%)
- 22% reduction in all cause readmissions
- 39% reduction in VAD related readmissions (GI bleed, pump thrombosis, stroke, arrhythmias, heart failure, DL infections)
- 21% reduction in GI bleed
- 54% reduction in stroke/pump thrombosis
- All pump thrombosis episodes (n=15 over 2 years) treated medically (both HM2 and HVAD), no pump exchange
Using Technology to Decrease AEs@ UCSF

**EARLY (<92 days post implant)
(per 100 person-month)**

**LATE (92 days ~ <24 mths post implant)
(per 100 person-month)**

- **Bleeding**: UCSF 1.5%, INTERMACS 3.7%
- **Device Malfunction**: UCSF 0.9%, INTERMACS 1.5%
- **Infection**: UCSF 2.0%, INTERMACS 3.6%
- **Stroke**: UCSF 1.1%, INTERMACS 1.2%
- **Renal Dysfunction**: UCSF 0.3%, INTERMACS 0.3%
- **Rehospitalization**: UCSF 5.2%, INTERMACS 16.1%

UCSF: January 2012 ~ November 27, 2017
INTERMACS: June 23, 2006 - June 30, 2017
LVAD Complications: Understanding Risks, Rewards and Benchmarking

- MCS community needs to agree on acceptable AE rates over time (5 yrs+), QOL (PROs) and how to monitor them
- LVAD programs need to work with Industry, FDA, CMS, TJC, INTERMACS, Private payers on establishing benchmarks and being held accountable for them (including limiting the number of programs that offer LVADs)
- Until Elon Musk invents the perfect pump that has no thrombosis, no stroke, no GI bleeding and without driveline and is powered indefinitely by a low energy battery we **should use existing technology to improve AEs NOW**