Development of a Mechanical Cardiac Support Program

Successes, Challenges & Patient Management

What you will learn

• VADS what are they and where are they going?
• Kaiser Permanente and VADS
• Kaiser NW experience
• NW status report
• Lessons learned and where to next

Mission Statement

The Kaiser Permanente Advanced Heart Failure Team is dedicated to improving the lives of its members with end-stage heart failure while improving quality of life through access to, and management of, advanced heart failure therapies including optimizing medicinal management, device therapies including mechanical circulatory support, and heart transplantation.

Ventricular Assist Device

• VAD: a mechanical circulatory device that is used to partially or completely replace the function of a failing heart
• Goal of device: to direct blood away from the failing ventricle (Left and/or Right) and provide flow to the circulation (Systemic and/or Pulmonary)
• Uses: Bridge to decision/ recovery, Bridge to transplant, Destination therapy, Bridge to candidacy,

Improving Technology

VADS FDA Approval

BT & DT

BT only

DT: clinical trial
HeartMate II
- A surgically implanted, continuous-flow device
- Percutaneous driveline
- Electrically powered
  - Batteries & line power
- Fixed speed operating mode
- Home discharge

Source: Thoratec Corp, Pleasanton, CA

Improving Technology and Growth
- Since 2010 40% of implants are designated DT
- Implanted in 38 countries
- Since 2008 >13,000 implanted worldwide
- 7,254 pts on device in the U.S.
- 121 pts on device >5 yrs
- 1,995 new implants in 2012
- 145 active implant sites in U.S.
- Age range 10-91 yrs old

Source: Thoratec Corp, Pleasanton, CA

INTERMACS
Interagency Registry for Mechanically Assisted Circulatory Support
Registry providing data to demonstrate continued device outcomes, appropriate risk stratification, and patient selection.
- 6885 patients implanted (6-23-06 to 6-23-12)
  - 145 participating hospitals
  - 114 centers approved for DT
  - 72 pediatric pts, 9 isolated RVAD

Source: Interagency Registry for Mechanically Assisted Circulatory Support

Kaiser Permanente NW
- >100 VAD patients in Oregon.
- 80 in Portland metro area
- 3 implant centers: OHSU, PSVMC, and KSMC
- 4 Rescue devices since 2010
- 2 Percutaneous devices
- Kaiser VAD patients:10
- Total LVAD Implants for BT & DT since 2009 :21

Source: Kaiser Permanente NW

The Team
- Kathy Crispell MD: Heart Failure Cardiologist
- Timothy Jacobson MD: Heart Failure Cardiologist
- Yong Shin MD: Cardiac Surgeon
- Siobhan Gray MD
- Patricia Prevosto MSN: Dept Administrator
- Barbara Mckenna RN, CNS: VAD Program Manager
- Pamela Montes RN: VAD Coordinator
- Keith Stockbauer RN: Transplant Coordinator
- Kristen Perry, PAC: Cardiology
- Patty Salvey-Sunde LCSW
- Susan Porter NP: EP

Source: Kaiser Permanente NW
Questions we asked ourselves

1. Do we have systems in place to support this?
2. Does our program have a clear vision—one we can articulate to all the stakeholders?
3. Does financial viability exist?
4. Are we prepared to share our results internally as well as publicly?
5. Do we have an organizational culture that welcomes change?
6. Are we going to rock the boat?
7. Does the hospital support us, can we support the hospital?

Planning and Developing

Identification of all stakeholders
Staged and controlled implementation
Presentations to ROQG
Development of a shared care contact with OHSU
VAD Oversight Committee
VAD Internalization Committee
Contracting and product sourcing

Getting to Go-Live

Phase 1: Clinic
- Began 10/2010
- Shared care developed
- Contracts with vendor for clinic equipment
- Clinic training and set up
- 1st patient seen 4/2011

Phase 2: Hospital
- From the doorway in ED readiness
- Inpatient care
- Care protocols and policies
- ED5 training
- Community awareness
- Go-live 9/2011

Phase 3: Implant
- CVOR, ICU, PCU readiness
- Blood bank and lab readiness
- Anesthesia staff
- Contracts, equipment purchasing and management
- Go-live April 2012
VAD Strategic Planning Committee

<table>
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<tr>
<th>Care Team</th>
<th>Support services</th>
<th>Patient care</th>
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</thead>
<tbody>
<tr>
<td>HF Cardiologists</td>
<td>Department Administrator</td>
<td>CVOR, Perfusion, Anesthesia</td>
</tr>
<tr>
<td>Cardiac surgeon</td>
<td>Membership services, billing, coding, finance</td>
<td>CVICU/CVPCU, Critical care medicine, Hospitalists</td>
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<tr>
<td>VAD Coordinators</td>
<td>Product sourcing, contracts, MSD, Biomed compliance, legal, ethics, accreditation regulatory</td>
<td>RT/P/T/OT</td>
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<td>Social services</td>
<td>Quality and Research</td>
<td>Care coordination</td>
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<tr>
<td>Palliative care</td>
<td>Data and IT management, Health connect</td>
<td>Dietary</td>
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<tr>
<td>Transplant coordinator</td>
<td>ACC clinic, Thoracic clinical support team</td>
<td>Chaplain services</td>
</tr>
</tbody>
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Education and Training

**Off site:**
Surgical implant training, patient management, users meeting, financial summits

**On site:**
CVOR, anesthesia, perfusion, nursing staff, PT/OT, RT, dietary, pharmacy, care coordination, Critical Care Medicine, Hospitalist staff, all ancillary services

**Community:**
Home health, cardiac rehab, nursing schools, chamber of commerce, EMS, fire dept

INTERMACS

- Protocol development and IRB approval
- INTERMACS fee
- Application for approval as a implanting center
- INTERMACS training
- Transfer of existing patients from OHSU

A Patients Pathway to a VAD

- Seen by Advanced Heart Failure MD
- Case is discussed in HF weekly meeting
- EP referral if needed for BiV/ICD placement
- Completion of all pre-op testing and labs
  - i.e. RHC, ECHO, PFT, Vasc US, CT
- Evaluation by VAD Coordinators, social services, palliative care
- Patient seen by surgeon
- Cath conference presentation
- Selection committee approval
- Case scheduled within 14 days

Selection Committee Process

- All primary team members attend and have input
- Review of pt history and team member evaluations:
  - medical, psych-social, financial
- Standard documentation template in HC
- Decision must be unanimous

Implant and Hospital Management

- Admitted night before surgery to CVPCU
- All pre-op education and tests completed
- ICU post op: usual LOS 5 days
- Extubated and out of bed: post-op day 1
- Pt and family education
- LOS post-implant: 12-14 days
- Home with 24/7 caregiver for 4 weeks
Long Term Management

- Clinic visit Q wk X 4, then Q 2 wks X 4, then monthly
- Anticoagulation by ACC clinic
- Labs weekly → biweekly
- Full device interrogation, driveline assessment, and education with clinic appointment
- Ongoing equipment maintenance
- INTERMACS reporting
- Social support

Foundations for Success

Foundations is a benchmarking program that utilizes best practices, published articles, and INTERMACS as a foundation to establish:

- a viable MCS program culture
- improve sustainability
- allow for comparison against national standards

Foundations for Success

Quality  | Finance  | Resource  | Service & growth

Where Are We Today?

- Implants: 3
- Average LOS post-implant: 13 days
- Total patients on support: 10
- HF/VAD clinic: every Friday and prn
- Order sets, policies & protocols for all aspects of care

Where Are We Today?

Kaiser and Community-wide Support Group
- Improved pt/family satisfaction
- EMS/VAD consortium
- VAD Disaster Response Plan
- City-wide VAD coordinator consortium
- Shared care for BT pts

All Kaiser VAD pt Re-Admissions

- Driveline infection: 1
- Arrhythmias: 1
- Pneumonia: 2
- CHF management: 1
- Planned procedures: 2
Challenges

- Patient selection
- Low volume
- TJC certification readiness
- Increasing awareness among primary care providers
- Staff competency and education
- Maintaining a healthy partnership with our transplant center
- Maintaining patient independence and well-being

Opportunities For Improvement

- Understand cost, reimbursement and members benefits
- Community education and outreach
- Clear understanding and identification of appropriate pts for this device
- VAD clinic growth
- Early identification and referral to AdvHF team
- Coordination of care, need to reengage the primary care provider

Money!

Do we really know how much we spend?

Using spreadsheets, 4 financial analysts, fingers, toes and an abacus we determined the following...

- On average billed charge for outside KP implant: $350,000+
- On average cost of implant at KP: $133,000+

Is it all about cost savings?

Lessons Learned

- There can never be too much information shared.
- Expect the unexpected, be prepared to be shocked, scared and above all resourceful.
- Expect ongoing learning and aha moments.
- We gave them this device to improve their quality of life, let them live it.
- We need to rely on our internal systems to work.
- Expect to say no, expect to be told no.
- Expect ongoing learning and aha moments.
- Resource utilization and cost.
- Balance underutilization with hyper vigilance.

Where to Next?

- Thoratec Connect
- TJC certification
- Perform BT implants
- Develop a national Kaiser model for Advanced Heart Failure management and MCS therapy for use by other Kaiser regions
- Be recognized as a leader in the US for device therapy

Thank You
References

• INTERMACS. Available from http://www.uab.edu/intermacs