Use of a Novel Pneumatic Compression Device to Improve Fistula Maturation

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Tej M. Singh, MD, MBA
Vascular and Endovascular Surgeon
El Camino Hospital
Mountain View, CA

Disclosure

Intellectual Property on Apparatus for Fistula Maturation
Hemodialysis Vein Preparation with Compression (Fist Assist)

ESRD Background

600K hemodialysis patients with End Stage renal disease (ESRD)

100K new patients yearly start hemodialysis

In 2012, ESRD Beneficiaries Comprised 1.1% of the Medicare Population:

6.3% of total Medicare spending, totaling over $34.3 billion

AV Fistula

Fistulae are preferred for hemodialysis: Fistula First initiative

Primary failure rate: 20-60%, Mean maturation time: 4-9 months,
Average Re-interventions: 2-3 and Thrombosis 17-25%

The Problem

• AVF: Attempted in 62% of hemodialysis access cases
  – Small veins, patency, development concerns

• Over 80% of patient’s start hemodialysis with a catheter
  – Prolonged catheter use is a problem and has complications

Limiting AVF Use: Maturation Delays and Resultant Costs

The Financial Problem

Significant Health Care Costs for Fistula Maturation and Delay
Leads to Further Clinical Issues

• Balloon maturation/interventional costs rising
• Prolonged catheters: readmissions, infections, and central stenosis
• Placement new access cost $34 million per year; yearly maintenance and
care of access may exceed $2.5 billion per year

Need to Develop a Non-invasive, Cost-effective Way to Help Fistulae Mature

The crux of renal failure patients/costs worldwide
Vascular Hemodynamic Research

Vein Maturation Hemodynamics

- Increased blood velocity in a low resistance circuit
- Pressure and flow changes: deformation and dilation
- Shear and distention pressure present
- Veins may continue to dilate with initial pressure and shear, intermittent compression role?

Basic Research on Vein Maturation: Compression and Exercise

- Beninson et al: Use of intermittent pneumatic compression in hemodialysis. 1974
- Chleboun et al: Intermittent pneumatic compression effects on eccentric exercise induced swelling, stiffness, and strength loss. 1995
- Leaf et al: Exercise increases the size of forearm veins in patients with chronic renal failure. 2003
- Rus et al: Effect of local physical training on the forearm arteries and veins in patients with end stage renal disease. 2003
- Rus et al: Effect of intermittent compression of upper arm veins on forearm vessels in patients with end stage renal disease. 2005

IP Position

- Vein Dilation IP
  - Issued: July 31, 2012

Fist Assist Device: Single Balloon Intermittent Compression on Fistula

- Apply device each day for 3 hours while at dialysis (9 total hours per week)
- Intermittent compression on the fistula 10 cm proximal to AVF
- Pre-determined intermittent pressure applied
- 1, 3 and 6 month time period

Trial: Clinical Feasibility/Safety

1. Patient can apply
2. Ease of use
3. High patient compliance
4. Comfortable
5. Maintains fistula flow: adding a pressure dimension
6. Increases patient awareness to fistula
**Study Site**

MS Ramaiah Medical College Hospitals and Research Center, Bangalore, India

- Large Dialysis Center
- Data collection and discussion biweekly
- Complete IRB approved study

**Clinical Application**

**Fist Assist**

**Data: n=12 Patients**

- Adverse effects
  - Thrombosis rate
  - Device failure
- Vein diameter measurements at baseline and 1 month
- 1 and 3 month completion data: Clinical outcomes
- Patient satisfaction with device, compliance and comfort

**Vein Size (mm) at 1 Month**

**3 Month Fist Assist Data**

Continued Enlargement of Proximal vein

**Value Proposition**

- Improving the percent of fistulae that are mature at dialysis from 16% to 50% could save CMS...

$500 million dollars per year

Developing a Non-invasive, Cost-effective Method to Dilate AVF Could Help:

- improve patient outcomes
- improve dialysis quality
- decrease costs for dialysis care
CMS Innovations: The Future

Creation of 13 ESCOs: Medicare is Financial Engine for payment for Seamless Care Organizations

Designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with ESRD.

CMS will partner with health care providers and suppliers to test the effectiveness of a new payment and service delivery model in providing beneficiaries with patient-centered, high-quality care.

Fistula maturation identified

Source: Centers for Medicare & Medicaid Services

Conclusions

1. Non-invasive, pneumatic fistula maturation is new opportunity
2. Could potentially save money and improve quality
3. Demonstrate clinical benefits: decrease catheters and improve fistula
4. Quality and Cost savings

Clinical Efficacy Study: 2016

50 Patient Fistula Study

- 50 with Fist Assist and 20 as device controls
- Blinded study to outcomes
- 1 and 3 month follow-up
- 5-6 hour application daily by patient/7 days a week
- End points: Vein maturation, total catheter time, and vein complications with dialysis.
  - Fistula complications after dialysis start (extravasation and thrombosis) to be collected

- Results in 2016...Stay tuned