Retrograde Jugular Vein Access From the Inside-Out: A Safer New Paradigm For Obtaining First Attempt Central Venous Access Even in High Risk Patients

Lakshmikumar Pillai, MD., Thomas Lawson, Ph D, Patrick Burt, Anatole Besarab, MD., and Mark H. Wholey, MD
Vascular Access Technologies, Inc. Palo Alto, CA
Henry Ford Hospital, Detroit, Michigan
Pittsburgh Vascular Institute
Disclosures

• Lakshmikumar Pillai MD- Founder, CMO, equity interest
• Thomas Lawson Ph D-none
• Patrick Burt- Founding CEO, equity interest
• Anatole Besarab MD- SAB, equity interest
• Mark H. Wholey MD- SAB, equity interest
CV Access

- Over 5 million procedures performed annually and increasing
- Jugular and Subclavian Vein Access-not PICC’s
- Landmark Technology
- B-Mode Ultrasound Guidance
Successful Right Internal Jugular Vein Cannulation
Complications Of Percutaneous Central Venous Access

- Adjacent Vascular, Pulmonary, Airway and Neural Structures ALWAYS AT RISK of Injury (From Needle, Guidewire, Introducer) Due to Close Proximity and Present Essentially Blind Technique/Technology

![Anatomy of the root of the neck](Fig2)
Some Frequent Complications of Percutaneous Central Venous Access

- Pneumothorax
- Hemothorax
- TENSION Hemo/Pneumothorax-
- Arterial/Venous Injury (carotid/subclavian/aortic arch)-risk for stroke
- Misplacement of Devices
- Cardiac Arrhythmia
- Nerve Injury
- Airway Laceration
- Death
Complications of Percutaneous Central Venous Access

• Can be immediately life threatening or result in serious permanent disability/injury

• Frequently Serious Complications Can Remain Latent and UNRECOGNIZED- Until it is TOO LATE

• Treatment Even if Done Promptly May NOT be Successful or Life Saving
Complications

• 4% overall rate of serious complications
• 200,000 serious injuries/year
• $$ $$
• More than 2 attempts
• Less Experienced Operators
References

• Complications of Central Venous Cannulation
  • RE Kusminsky,
  • JACS 2007: 681-696

• Injuries and Liability Related to Central Vascular Catheters- A Closed Claims Analysis
  • KB Domino, TA Bowdle, KL Posner, PH Spitellie, LA Lee, FW Cheney
  • Anesthesiology 2004: 1411-8
References

• Agency for Health Care Research and Quality
• Evidence Report/Technology Assessment # 43-2001
• A Critical Analysis of Patient Safety Practices
• Chapter 21- Ultrasound Guided Central Vein Catheterization
• JM Rothschild
References

• Avoiding Common Errors in Subclavian Central Venous Catheter Placement
• MJ Kilbourne GV Bochicchio, T Scalea, Y Xiao
• JACS 2008: 104-109
• Simulation Training In Central Venous Catheter Insertion: Improved Performance In Clinical Practice
• LV Evans, KL Dodge, TD Shah, LJ Kaplan, MD Siegel, CL Moore, CJ Hamann, Z Lin, G D’Onofrio
• Academic Medicine, Vol 85, No 9, Sept 2010 pp 1462-1469
High Risk Patients

- Morbid Obesity
- CKD
- Multiple Previous CV Access
- Coagulopathy
- Ventilated Critically Ill
- CV occlusion
“High” Risk Practitioners

- Trainees
- Low Volume Docs
- Docs that do not use image guidance and fluoroscopy
Complications
Tension Left Pneumothorax After Left Subclavian Central Line Placement
“Successful” Right Jugular TCC
Tension Right Hemothorax
Misplaced Left IJ TCC
Tension Left Hemothorax
Ante-Mortem
Pulsatile Expanding Right Supraclavicular Hematoma After “Ultrasound Guided” Central Line Placement – Lacerated Right Subclavian Artery
Active Hemorrhage In Right Subclavian Artery Pseudoaneurysm
Central ‘Venous’ Line in Right Carotid Artery-Day 3 After Embolic Stroke Line Removed In OR-Carotid Repaired
Lacerated Right Subclavian Artery After US “Guided” Swan Placement-Patient Developed Cardiac Arrest Two Days After Line Placed-
Bleeding Right Hemothorax (Ante-mortem)
Conclusion

First Attempt Success Is Critical to Avoiding Complications in CV Access
Introducing

The SAFE CVAD
The SAFE CVAD

**SAFECVAD**

**Step 1:** Insert into the femoral

**Step 2:** Make a simple *inside-out* exit at the jugular or subclavian vein

Guided Path • "Inside-out" Access

Precise Catheter Placement *on First Attempt*
Catheter Tip Design

- .014” Nitinol Stylet
- Nitinol hypotube (distal) pre-set to 90 deg
- SS Tube (proximal) joined to distal Nitinol Tube
- Conical Tip to follow the Guidewire
- 7 Fr (.092”) Catheter w/ RX lumen
- .035” Guidewire
Summary

• Percutaneous access right or left femoral vein with placement of 7F short sheath.
• 0.035 Guidewire Passage to SVC
• Pass 5F Angled Catheter Over Guidewire and Place Wire in Jugular or Subclavian Vein
• Exchange 5F Catheter for SAFE CVAD TM
• Image Guide SAFE CVAD to Anterior Lateral Wall of Central Vein
• Deploy Puncture Wire and Deliver to Skin Surface
• Pass Catheter Into Central Vein
Results

• Sheep model- Gen 3, November 2012
• Jugular and Subclavian Vein Access
• 6/6 insertions and exit
• Trackability
• Positioning
• Torque
• Multiple Exits
• Compression for bleeding
SafeCVAD in-vivo demonstration: Femoral Vein to Internal Jugular Vein (1 entry, 2 exits) Femoral Vein to Subclavian Vein Femoral Artery to Carotid Artery

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Conclusion

- SAFE CVAD=First Attempt CV Access
- Avoids Serious Complications
- Better For Patients
- High Risk Patients
- Short Learning Curve
- Lowers Risk for Trainees and Low Volume Docs
- Reduces Costs