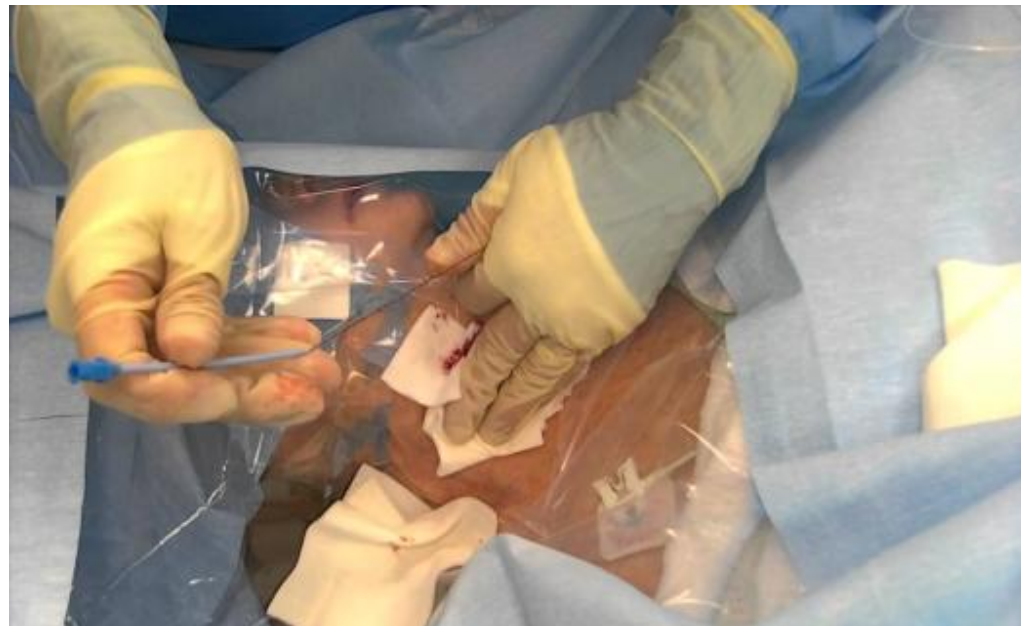


Catheter Related Insertion Complications: Cost and Incidence

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Disclosure

The speaker's presentation today is on behalf of Bard Access Systems. Any discussion regarding Bard products during the presentation today is limited to information that is consistent with Bard labeling. Please consult Bard product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

Results presented may not be predictive for all institutions or patients.

Kathy Kokotis is an employee of Bard Access Systems and holds C.R. Bard Stock and well as Johnson and Johnson Medical Stock.

What are the complications?

**Instructions for Use provide
some information**



Power Injectable PICC Line

The potential exists for serious complications including the following:

Air Embolism	Endocarditis	Myocardial Erosion
Bleeding	Exit Site Infection	Perforation of Vessels or Viscus
Brachial Plexus Injury Cardiac Arrhythmia	Extravasation	Phlebitis
Cardiac Tamponade	Fibrin Sheath Formation	Spontaneous Catheter Tip Malposition or Retraction
Catheter Erosion Through the Skin	Hematoma Heparin induced thrombocytopenia	Thromboembolism
Catheter Embolism	Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement ¹ , positioning ¹ , flushing ² of catheter or cleaning of catheter exit site ³	Venous Thrombosis
Catheter Occlusion	Intolerance Reaction to Implanted Device	Vessel Erosion
Catheter Related Sepsis	Laceration of Vessels or Viscus	Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

Power Injectable CVC

Possible Complications (but not limited to):

Pleural injury

Mediastinal injury

Air Embolism

Nerve injury

Catheter Embolism

Thoracic duct laceration

Bleeding / hemorrhage

Occlusion

Bacteremia

Septicemia

Hematoma

Inadvertent arterial puncture

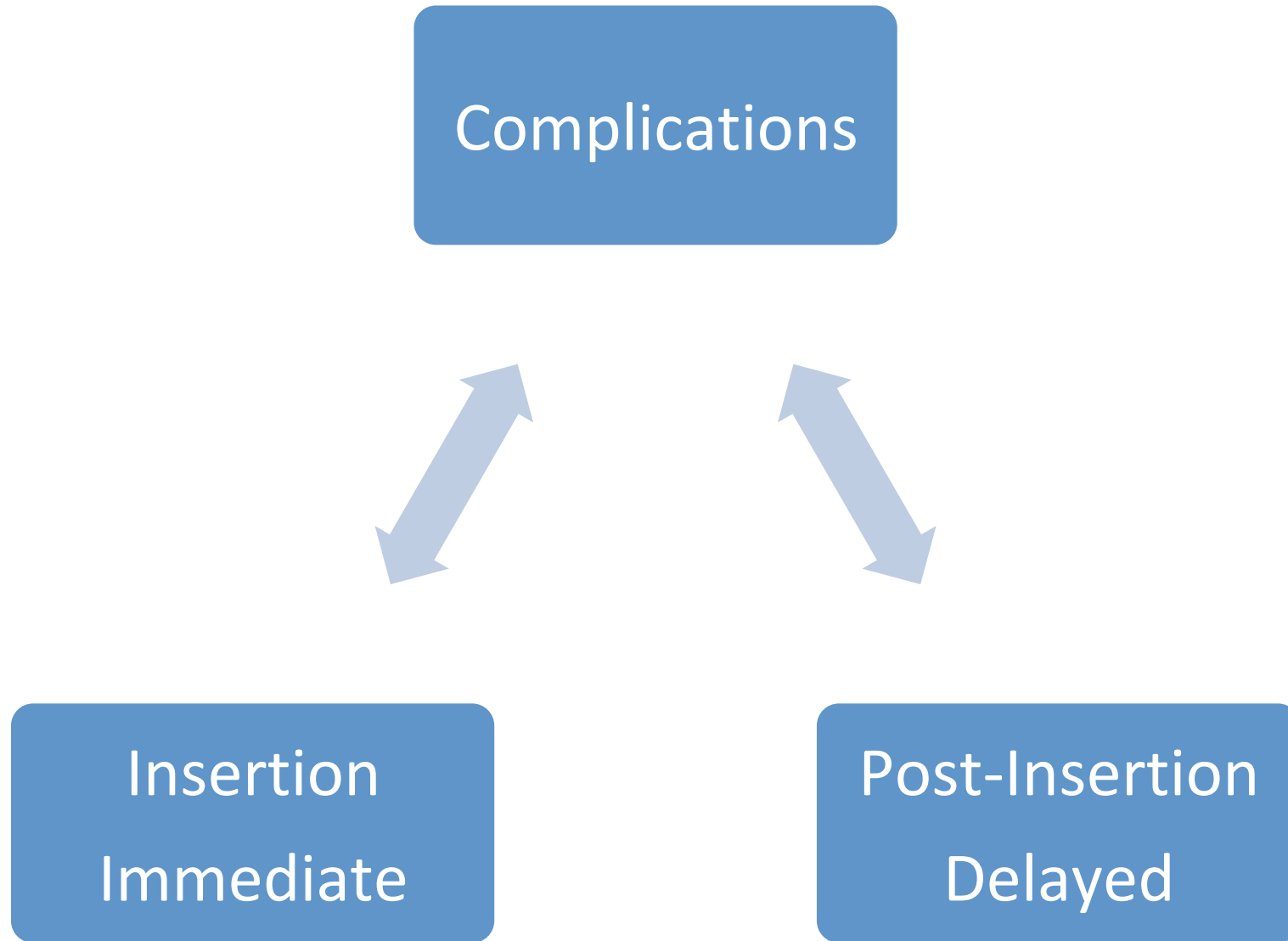
Fibrin Sheath Formation

Exit Site Infection

Vessel erosion

Catheter tip malposition

Changes in Practice



CVC Placement: Arterial Injury

(Rates in reported series by Bowdle)

Inadvertent arterial puncture

- Small needle (18 G) or smaller
- 4.2% - 9.3% in reported series
- Small needle puncture appears to be harmless in the vast majority of cases
- Most of small needle punctures go unrecognized

Inadvertent arterial placement

- 0.1% - 1.0% in reported series
- Large bore >7 Fr. Catheter into an artery
- May result in hemorrhage, pseudoaneurysm, stroke, or death

Prevention of Arterial Cannulations

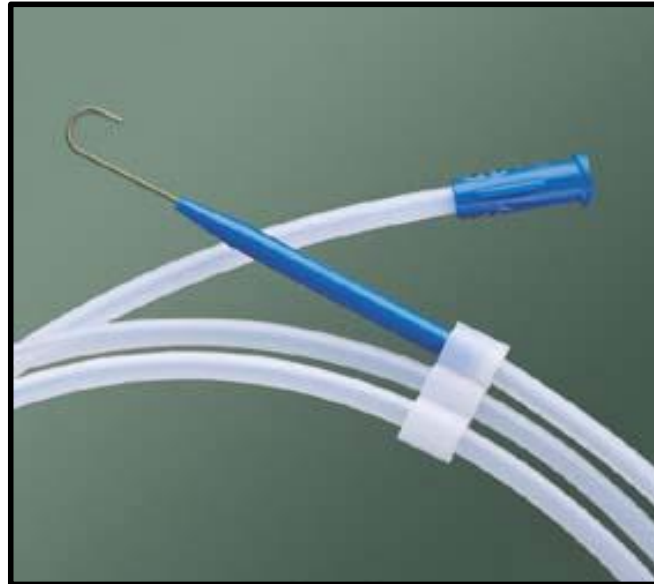
Author	Year	Number CVCs	Arterial Punctures	Arterial Cannulations
Jobes	1983	1,284	(4.0%) 51	(0.8%) 10
Ezaru	2009	511	(5.5%) 28	(0.8%) 4
Oliver	1997	1,172	(9.3%) 105	(0%) 0

Complications of Arterial Injury: Bowdle (2014)

- Out of 11,870 attempted IJ placements there were 20 inadvertent arterial cannulations
- Incidence 0.17%
- The “pull-and-pressure” technique was applied in 19/20 patients
 - 6 patients suffered complications and 2 died
- Direct surgical repair may be the treatment of choice for inadvertent catheterization of subclavian and jugular with catheter >7 Fr.

Complication

Loss of Guidewire



Retained Guidewire Events:

Retained Guidewire Events

Why do they occur?

Cited by Williams and not definitive

Rationale by reviewing managers	Percentage
Staff inexperience	24%
Distractions, interruptions, emergent	10%
Equipment malfunction	10%
Staff inattention	7%
Inadequate supervision	5%
Poor communication between providers	5%
Uncooperative and agitated patient's	Noted

Corrective actions (Williams 2014)

- Education & training
- Discussion with MD
- Revision of P&P
- Referral to medical leadership
- Manufacturer investigation

Alternative wire designs suggested by Williams:

1. Bendable proximal end?
2. Lightweight retention device attaches proximal to the end
3. Brightly colored proximal wire tip
4. Checklist of components (needles & wires)
5. Reminder in kit to remove the wire (sticker over the securement device needle or needle free)

Potential Arterial Puncture

PICC

- Brachial artery

CICC

SCV & IJ

- Subclavian artery
- Rare Pulmonary artery
- Carotid artery

FICC

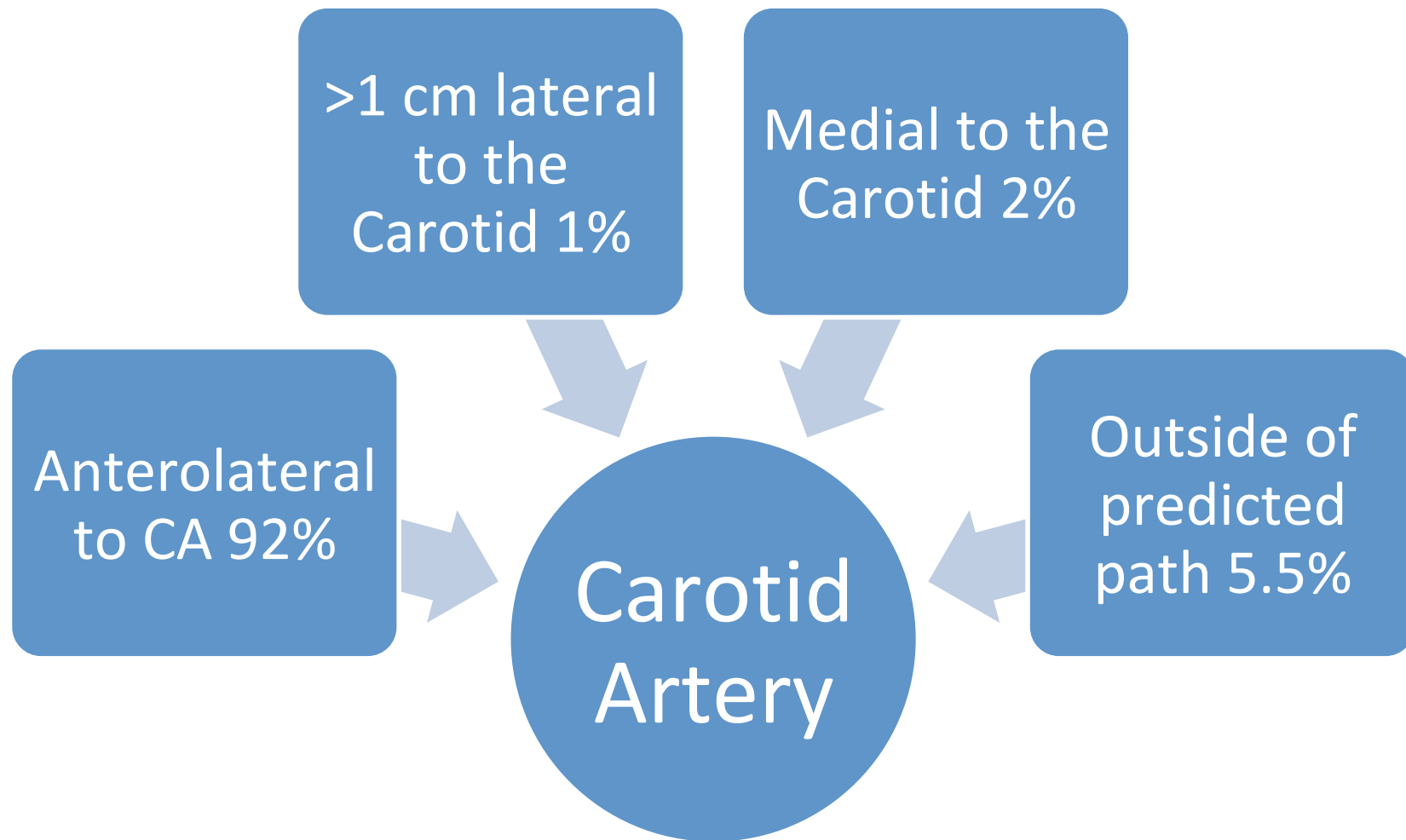
- Femoral artery

Landmark (Blind) Technique

- Arterial puncture rate
- Internal Jugular
 - 6.3%-9.4%
- Subclavian Vein
 - 3.1%-4.9%
- Femoral Vein
 - 9.0%-15.0%



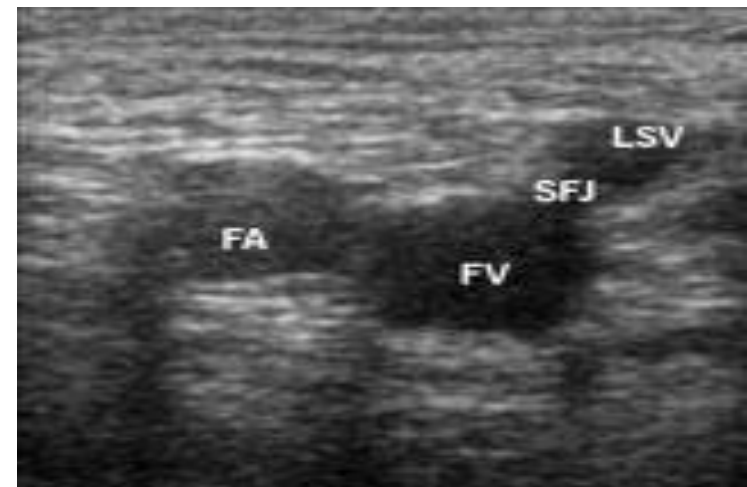
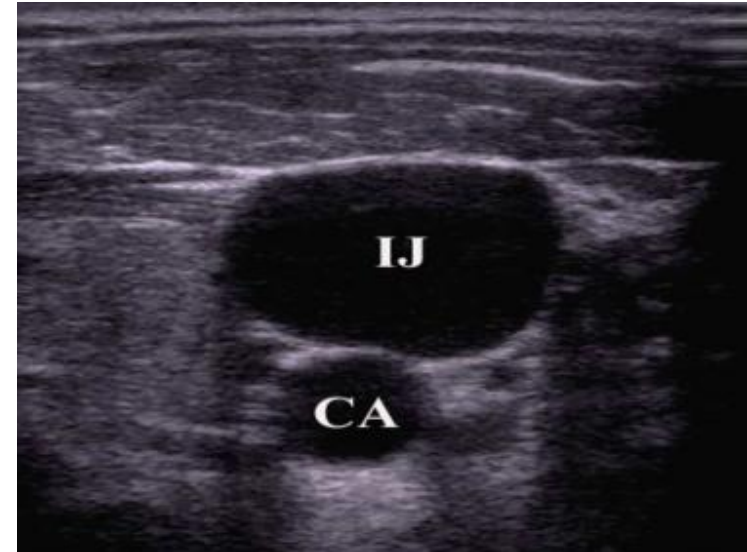
Landmark (Blind) Technique II



Troianos C (2011) J AM Soc Echocardiogr 24 (12): 1291-1318

Potential Arterial Puncture Rate: Ultrasound Guidance (IJ)

- Success rate of cannulation
 - 96% to 100%
- First attempt success rate
 - 54% to 73%
- Decreased needle advances
 - 2.8 attempts to 1.4 attempts
- Time to cannulation
 - 117 seconds to 61 seconds
- Arterial puncture rate
 - 8.43% to 1.39%

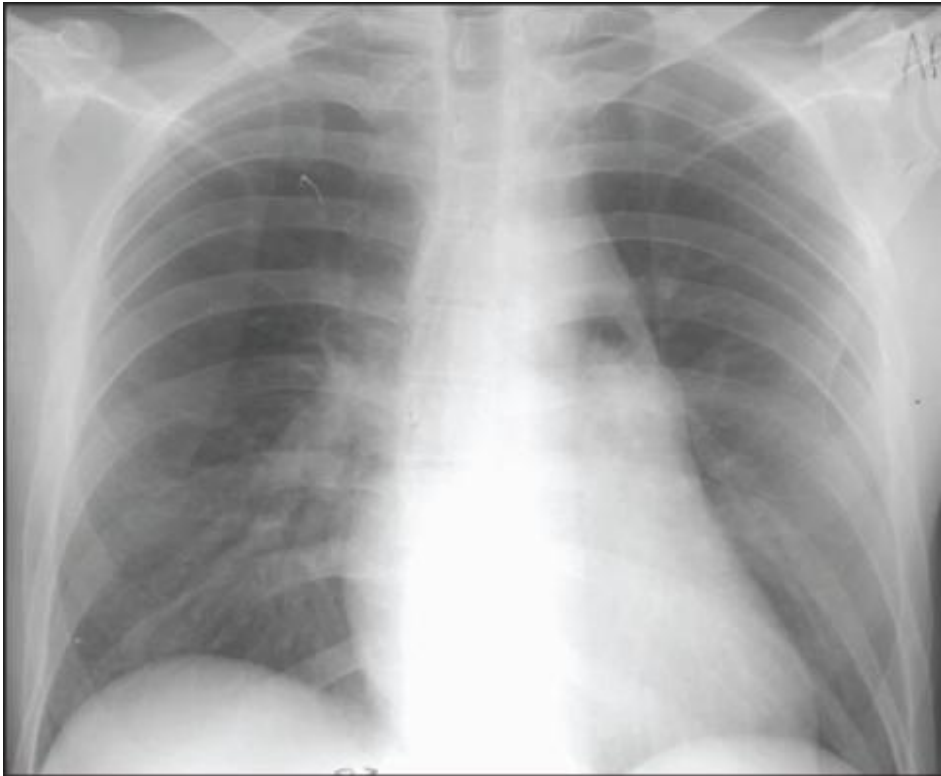


Arterial Puncture Can Happen with Ultrasound (IJ)

- Misalignment between needle and imaging screen
- Through and through technique of the vein into the posteriorly positioned artery
- Misidentification of the vessel
- Arterial pulsatility may be an issue with cardiopulmonary bypass, nonpulsatile ventricular circulatory assistance, and cardiac or circulatory arrest
- IJ-CA overlap may increase the possibility of arterial puncture
- Ultrasound vein diameter <7mm has been associated with decreased cannulation success
- Junior operators 4.2%

Vascular Air Embolism: CVC Placement

Rare but potentially fatal event



Large air embolism due to left subclavian central line placement with air evident in the main pulmonary artery

Estimated 0.2 to 1% patients central line insertion¹

Air embolism is a risk during insertion and removal despite optimal positioning (1) in 772 placements out of 11,000 CVC placements²

Rates reported case series varies from 1 in 47 to 1 in 3,000 placed CVC's²

True incidence is unknown¹

¹Gordy S. (Jan-Mar 2013) Int J Crit Illn Inj Sci 3(1) 73-76 ²McCarthy CJ (Nov. 2016) J Clin Med 5(11) 93 7-20

Vascular Air Embolism

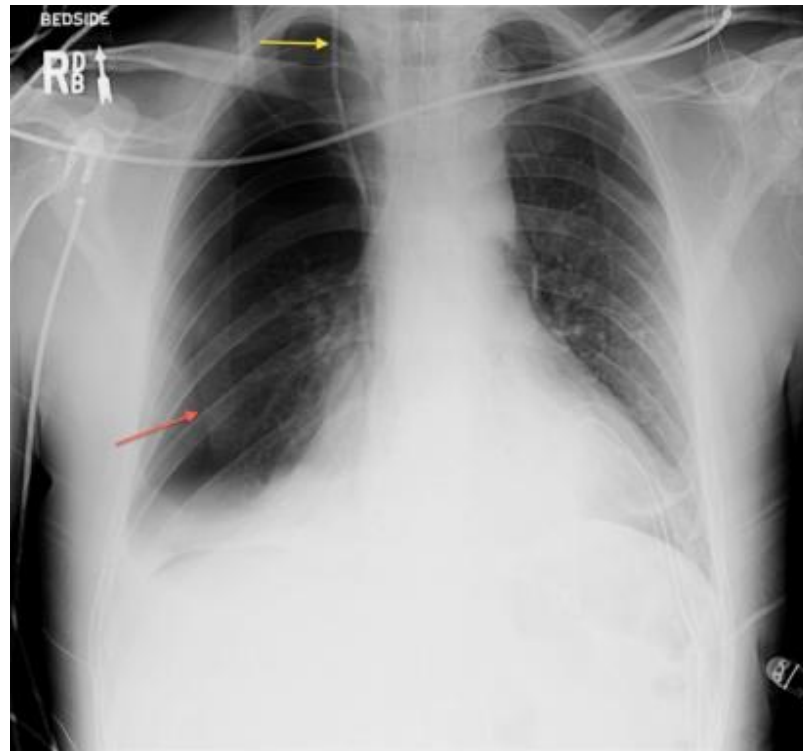
- Patients may be asymptomatic or have complete cardiovascular collapse¹
- Lethal dose for humans in theory: 3-5 ml/kg 300-500 ml of gas introduced at rate of 100 ml/sec¹
- Rate of accumulation and patient position contribute to lethality¹
- Infusion rates of >1.5 ml/kg/min bradycardia and cardiovascular decompression¹
- 14 gauge needle can transmit 100 cc air/s²
- 15 Fr. (5mm) peel-away sheath 300 cc in 0.5 s (dialysis tunneled catheter placement²
- Trendelenburg and hydration in hypovolemic patients for insertion²
- Trendelenburg and supine for removal (Valsalva /active expiration) and supine (30) min after removal²

¹Gordy S. (Jan-Mar 2013) Int J Crit Illn Inj Sci 3(1) 73-76

²McCarthy CJ (Nov. 2016) J Clin Med 5(11) 93 7-20

Iatrogenic Pneumothorax:

One of the most Frequent Complications (Tsotsolis 2015)



Post right internal Jugular central line

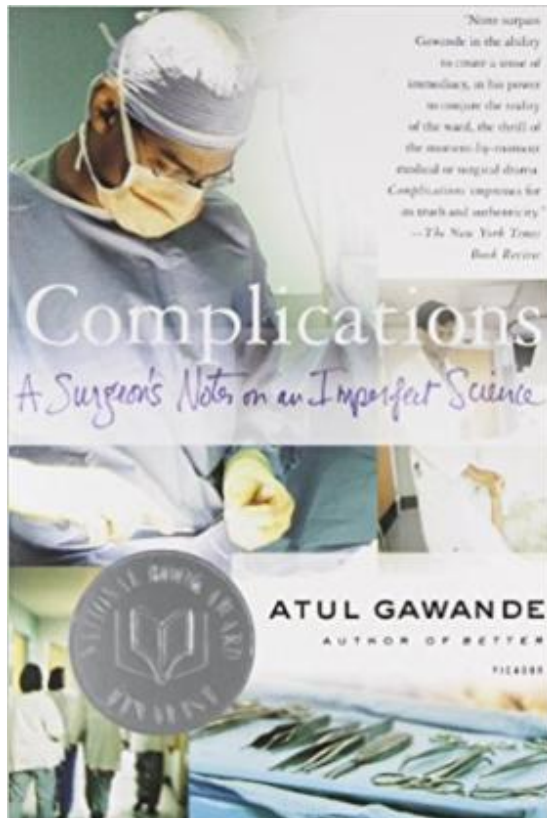
Tsotsolis N. Annals of Translational Medicine (2015) 3(3):40

Mechanical Complication Rate According to the Sites of Central Vascular Access

Tsotsolis N. Annals of Translational Medicine (2015) 3(3):40

Complications: A Surgeon's Notes on an Imperfect Science

Atul Gawande on placing a central line



The Learning Curve

Central Venous Cannulation

(Internal jugular, Subclavian, Femoral Veins)

- The incidence of mechanical complications has been shown to increase in the following types of patients:
 - Obesity, cachexia
 - Distorted tortuous or thrombosed vascular anatomy
 - Congenital anomalies such as persistent left superior vena cava
 - Compromised procedural settings (mechanical ventilation or emergency)
 - Presence of co-morbidity (coagulopathy, emphysema)
 - Less experienced operator

Competency: Placement

Lack of scientific literature to specifically delineate the number of procedures

Author / Year	Number of Procedure	Comments
Guideline American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists (2011)	10 under supervision Ultrasound guided CICC	A portion in simulation lab

A physician who has performed 50 or more catheterizations is half as likely to result in a mechanical complication as insertion by a physician who has performed < 50

Reported that (1) attempt of catheterization the complication rate is 4.3% which rises to 24% in patients who undergo more than two attempts

Troianos C (2011) J AM Soc Echocardiogr 24 (12): 1291-1318
Tsotsolis N. Annals of Translational Medicine (2015) 3(3):40

Surgical Trainee: Complication Rate Study

Hameeteman M (2010) J Vas Access 11 (4): 288-292

Complication of Central Vein Cannulation

Cited by Tsotsolis (2015)

Placement
Arterial puncture
Hematoma
Hemothorax
Pneumothorax
Arterial-venous fistula
Nerve injury
Thoracic duct injury (left side only)
Intraluminal dissection
Puncture of the Aorta

Tsotsolis N. Annals of Translational Medicine (2015) 3(3):40

Patients who may have the Potential for Complications on Insertion

- CVC
 - Obese patients
 - Arterial puncture
 - Pneumothorax
 - Hemostasis disorders
 - Uncooperative patients
 - Unconscious patients
 - Hypovolemic patients
 - Critically ill patients
- PICC
 - Risk for ipsilateral lymphedema
 - Risk for arterio-venous fistula patients who have had multiple catheter insertions

Central Line Complication Summary

Complication	NEVER Event (IPPS HAC reportable) ¹	PPC Code ²	Estimated HAC Cost ²	Incidence Rate (per SIR Central Venous Access CPG) ³	
				PICC Lines	Subclavian & Jugular Lines
CLABSI*	X	54	\$12,455	1%	1% - 3%
Air Embolism	X	48	\$9,350	Not Listed	1%
Pneumothorax	X	49	\$4,136	0%	1% - 3%
Thrombosis		16	\$8,607	3%	4%
Hemothorax		8	\$5,165	0%	1%
Perforation		42	\$3,215	Not Listed	0.5% - 1%
Hematoma		64	\$712	1%	1% - 3%
Wound Dehiscence		64	\$712	1%	1%
Phlebitis		64	\$712	4%	Not Listed
Arterial Injury		64	\$712	0.5%	Not Listed

*Procedure induced sepsis

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Key CVAD Patient Considerations

- ☐ Status of bleeding
- ☐ Status of ability to cooperate
- ☐ Status of position for insertion and removal
- ☐ Status of neck and chest
- ☐ Status of breathing
- ☐ Status of hemodynamics
- ☐ Risk of infection with placement site

Increased Insertion Complications

- Less experienced operators
- Challenging patient anatomy
 - Obesity
 - Cachexia
 - Distorted, tortuous or thrombosed anatomy
 - Congenital anomalies i.e. persistent left superior vena cava
- Compromised procedural settings
 - Mechanical ventilation
 - Emergency
- Presence of co-morbidity
 - Coagulopathy
 - Emphysema

Body mass index $>30 \text{ kg/m}^2$
resulted in a cannulation failure
rate of 20.1% for attempted
Subclavian vein cannulation

Troianos C (2011) J AM Soc Echocardiogr 24 (12): 1291-1318

Patient Coagulation Considerations

...and damaging the vein or artery

Procedures with Low Risk of Bleeding, Easily Detected and Controllable (Category 1)

Applicable Vascular Procedures

Dialysis access intervention
Central line removal
PICC line placement

PICC- small vein, small catheter

CICC- large vein, large catheter

Procedures with Moderate Risk of Bleeding (Category 2)

Applicable Vascular Procedures

Tunneled central venous catheter
Subcutaneous port procedure

Management related to line placement⁹

- Platelet count: $< 50 \times 10^9 /L$
- International normalized ratio (INR): > 2.0

- Platelet count: $< 50 \times 10^9 /L$
- International normalized ratio (INR): < 1.5

Who is the Patient?



Key Patient Considerations

Pulmonary Status

- CHF, COPD
- Emphysema
- Lung surgeries
- Asthma
- Pneumonia
- Pneumothorax

Coagulopathy Status

- $PLT \leq 50 \times 10^9 /L$
- $INR \geq 1.5$
- $aPTT \geq 20 \text{ s}$
- Anticoagulants
- Clotting disorder
- Past history thrombosis

Mechanical Status

Placement concerns

- Cervical Collars
- Halo
- Pacemaker Wires
- Positive pressure ventilation
- Vena cava filters

Patient Status

Device Type Considerations

- Trendelenburg position contraindicated
- Confusion/Dementia
- Hypovolemia
- Local infection site
- Lymph node dissection / lymphedema
- Obesity / Cachexia
- Contralateral pneumothorax
- Hemothorax
- Oral Candida / Nasal MRSA
- Need for arterio-venous fistula
- Persistent left Superior Vena Cava
- Previous catheterizations
- Radiotherapy in anatomic region of interest
- Operative history (Thoracic)
- Clavicular fracture
- Sternotomy
- Severe hypoxemia

Summary

- Patient assessment is critical to safe practice
 - Evaluation tool
- Competency and experience may decrease complications
 - Standardized training programs (i.e. evidence based consensus document)
- Severity of complications may effect cost of care
- Although some insertion complications are rare they have high rates of mortality and morbidity
- Design changes and practice changes have and will continue to improve safety
- Device selection is critical (PICC vs CICC vs FICC)
- Evaluate the specific patient risk to each type of VAD

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Questions

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