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Instrumente Structurale
2007-2013



GUVERNUL ROMÂNIEI
MINISTERUL MUNCII, FAMILIEI,
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ȘI PERSOANELOR VÂRSTNICE
OIRPOSDRU REGIUNEA CENTRU



UNIVERSITATEA DE MEDICINĂ ȘI
FARMACIE "CAROL DAVILA"
BUCUREȘTI

AD-COR Program inovativ de formare in domeniul cardiologiei pediatrice POSDRU/179/3.2/S/152012

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MODUL TEORETIC

ECMO PROGRAM IN 2015

Imputernicit: Prof. Dr. Tammam Youssef

**Activitate prestata de I.R.C.C.S. POLICLINICO SAN DONATO – MILANO, ITALIA
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Acest material a fost documentat/ validat/ prezentat la sesiunile de formare în cadrul proiectului „AD-COR Program inovativ de formare în domeniul cardiologiei pediatrice” - POSDRU/179/3.2/S/152012, proiect cofinanțat din Fondul Social Operațional Sectorial Dezvoltarea Resurselor Umane 2007-2013.

Beneficiar: Universitatea de Medicină și Farmacie „Carol Davila” București

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ECMO PROGRAM IN 2015:

Bucharest 10/2015

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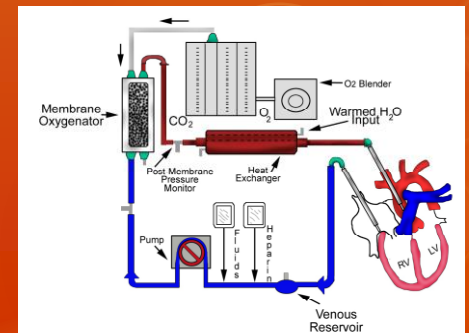
ECMO: ExtraCorporeal Membrane Oxygenation definitions

“Cardiopulmonary bypass circuit for temporary life support”

- for patients with potentially reversible cardiac and/or respiratory failure
- when no other form of treatment has been or is likely to be successful.

ECMO IS NOT A THERAPY: **IS A “BRIDGE” TO DECISION**

- allows to “buy time”
 - for recovery from lung or cardiac disease
 - To optimize medical/surgical options



WHEN ECMO IS USEFUL?

Indications

○ Cardiac Failure



<u>Post-cardiotomy</u>	• when unable to get pt off cardiopulmonary bypass following cardiac surgery
<u>Post-heart transplant</u>	• usually due to primary graft failure
<u>Severe cardiac failure due to almost any other cause</u>	• Decompensated cardiomyopathy • Myocarditis • Acute coronary syndrome with cardiogenic shock • Profound cardiac depression due to drug overdose or sepsis • Peri-partum cardiomyopathy

○ Respiratory Failure



NEONATES	• Persistent Pulmonary Hypertension • Meconium Aspiration Syndrome • Respiratory Distress Syndrome • Congenital Diaphragmatic Hernia (CHD)
PEDS and CHILDRENS	• Sepsis/pneumonia • ARDS Aspiration pneumonia
ADULTS	• Pulmonary embolism • Adult respiratory distress syndrome (ARDS) • Pneumonia • Trauma • Primary graft failure following lung transplantation.

AND WHEN IT IS NOT?

Contraindications

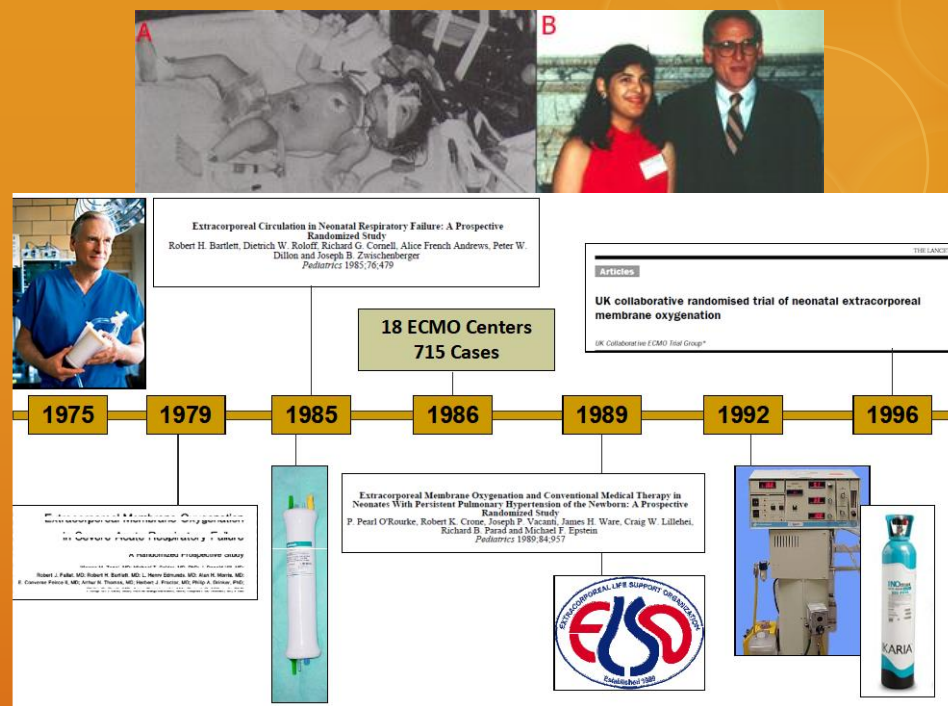
- considerations must be weighed before planning an ECMO implant:
 - ACUTE ORGAN (heart and/or lungs) FAILURE irreversible (A)
 - Chronic end stage organ failure (kidney, liver, metabolic syndrome) (A)
 - Lethal congenital anomalies (A)
 - Gestational age < 34 weeks (R)
 - NO other option after ECMO (BRIDGE TO BRIDGE/TX)? (A)
 - PRE-ECMO clinical consideration:
 - Active (disseminated) malignancy (A)
 - Contraindications to anticoagulation therapies (A)
 - Known severe brain injury (Severe irreversible brain damage, Grade III or IV Intra Ventricular Hemorrhage) (A)
 - Graft vs. host disease (post organ transplantation) (A)
 - Unwitnessed cardiac arrest or cardiac arrest of prolonged duration without effective CPR (ET CO₂ < 18) (A)

AND WHEN IT IS NOT?

Contraindications

- Technical contraindications
 - aortic disease (dissection, coartaction, severe vasculopathy) (A)
 - AOV regurgitation (blood “goes back” in to the left ventricle impairing heart recovery) (A)
 - Mechanical prosthetic valve (valve thrombosis, aortic root thrombosis despite aggressive anticoagulation therapy) (A/R)
 - weight in neonates less than 1.6 kg (vessels cannulation) (A)
- **Advanced age and palliated CHD questionable contraindication (R). Evaluation on:**
 - **QOL pre-acute events**
 - **Life expectancy**

ECMO: a story of fluctuating fortune...



- first used successfully for neonates with respiratory failure in 1975.
- In '70 mainly as respiratory support; most cases were neonates and peds.
- In mid '80 ECMO lost its appeal:

In cardiac-circulatory support because

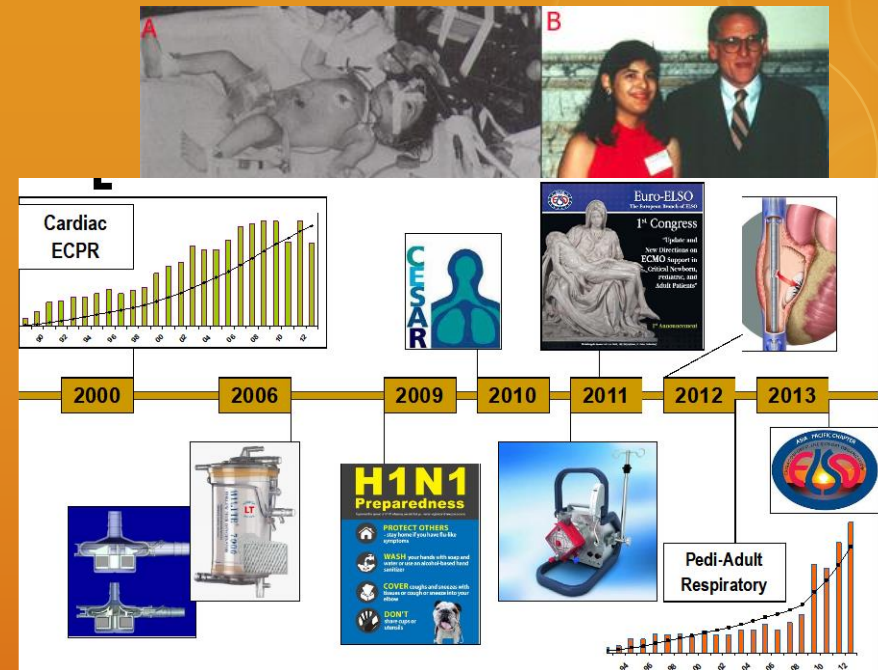
- NO CLEAR INDICATION AND CONTRAINDICATION, NO CLEAR TIMING
- Mainly used in Transplant Center (difficulties in transportation) or exclusively as a bridge to recover end-stage Pts
- unsatisfactory survival rates in HF

In respiratory support because

- Conventional treatment in ARDS improved (HFOV, NO, new ventilatory setting)



ECMO: a story of fluctuating fortune...



- In mid 2000 ECMO got a new lighting era, particularly as cardio-circulatory support in HEART FAILURE.
- Pediatric and adult patients started to be successfully treated in increasing numbers.
- In the US, have been estimated approximately 2800 newborns/Yr could benefit from ECMO (one of every 1309 live births).
- 2009 "suine Flu": Healthcare systems provided this life-saving technology to some awarded Centers in treatment of respiratory disease.

WHAT MOVE TO THIS NEW SCENARIO?

○ NEW DEVICES



○ NEW PROTOCOLS

- Optimized timing, defined indications and contraindication,
- Improve implant strategy
- New coagulation management and point of care

○ NEW TRAINING PROCESS

- ECMO CENTER
- ECMO UNIT
- ECMO TEAM
- ECMO SPECIALIST



The background is a solid orange gradient, transitioning from a lighter shade at the top to a darker shade at the bottom. Scattered across the background are numerous thin, white, semi-transparent circles of varying sizes, some overlapping each other.

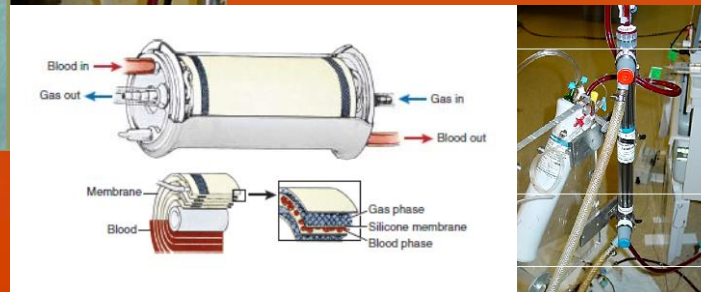
ECMO

NEW DEVICES

THE OLD'S ONES???

SILICONE MEMBRANE OXYGENATORS:

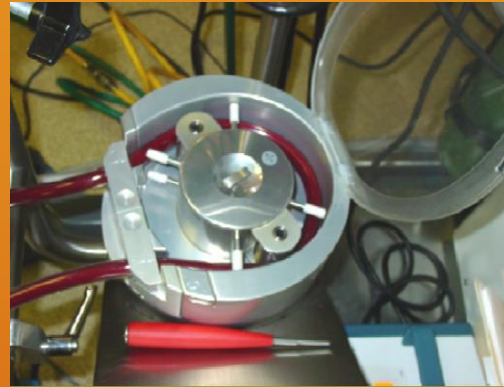
- High flow resistance (high shear stress and blood tissue damage)
 - Hemolysis
 - Coagulation disorders (PLTs depletion)
- external heat exchanger (high priming volume)
- Difficult to de-air (CO_2 insufflation to wash-out nitrogen)



ANACHRONISTIC...OR NOT?

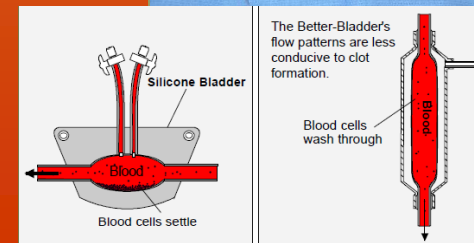
ROLLER PUMPS

- Compression & displacement
- Inactive drainage
- Raceway durability
- Occlusion

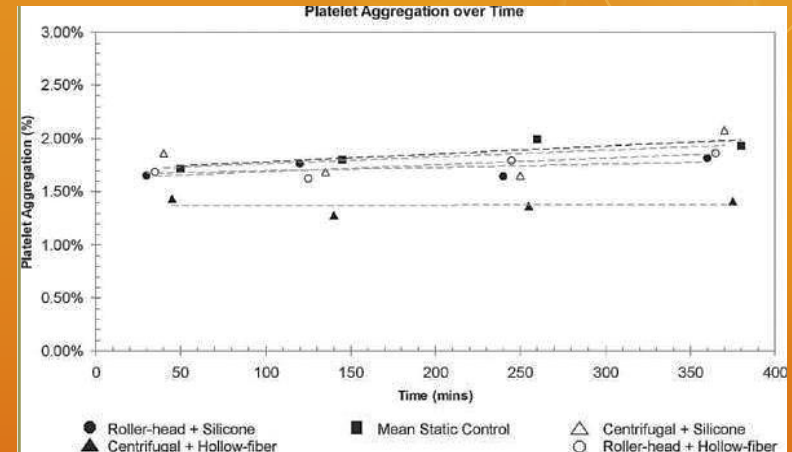
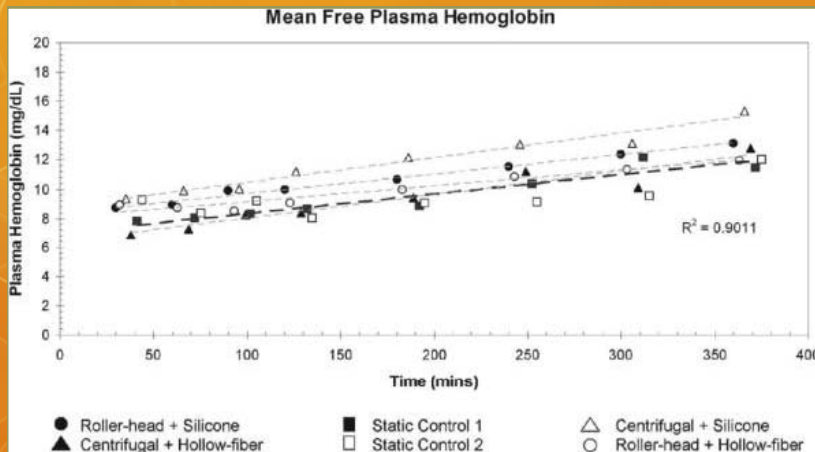


DRAINAGE RESERVOIR (BLADDER)

- Mechanical switch vs. pressure
- Communicates with pump
- Safeguard against cavitation



Nothing good, but...what's worst?



Centrifugal

Smaller circuit volume
No raceway
More compact
Active drainage
Hemolysis
Preload / Afterload sensitive

Roller

- Large circuit volume
- Raceway durability
- Drainage reservoir needed
- Hemolysis

- **Silicone oxygenator, rather than pump type, seems to be associated to**
 - **increased hemolytic damage**
 - **Induced platelet adhesion and aggregation**

Meyer, A. et al. Hemolytic and thrombocytopenic characteristics of extracorporeal membrane oxygenation systems at simulated flow rate for neonates. *Pediatr Crit Care* 2012;13,4: e255.

New devices

Artificial
Organs



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Pediatric and Neonatal Extracorporeal Life Support Technology Component Utilization: Are US Clinicians Implementing New Technology?

*Deborah Reed-Thurston, †Feng Qiu, †Akif Ündar, *Kim Kopenhaver Haidet,
and *Jeffrey Shenberger

**Department of Pediatrics, Division of Newborn Medicine; and †Department of Pediatrics, Surgery and Bioengineering,
Penn State Hershey Pediatric Cardiovascular Research Center, Penn State Hershey College of Medicine, Penn State Hershey
Children's Hospital, Hershey, PA, USA*

- 125 US ECLS centers identified by ELSO in November 2010.
 - 42% of 95 respondent changed their oxygenator of choice in the past 3 years,
 - 30% both the oxygenator and pump.
 - 46% of respondents cited "clinical preference/experience" as primary reason.
 - others "FDA approval" or "research results."
- Unclear whether these changes were made by clinical evidence of patient benefit or simply due to current trends.

New devices

Technology provides new generation ECMO Systems:

- customized and pre-assembled
- Easy to set and prime
- High performance gas ex-change
- Optimized fluido-dynamics profile
 - Low emolitic pump (centrifugal devices, MAGLEV or ceramic single bearing technology)
 - Low trans-membrane gradient oxygenators
- Smaller and lighter (mobile devices with AMBULANCE and AVIO-TRANSPORTATION CERTIFICATION)
- Up to 30 days certification (upon Company policy)



New ECMO system: what is made of?

○ HARDWARE all-in-one

- Console-pump drive
- Heat-exchanger
- Gas line
- On-line parameters (perfusion and ventilation adequacy)



○ DISPOSABLE all-in-one

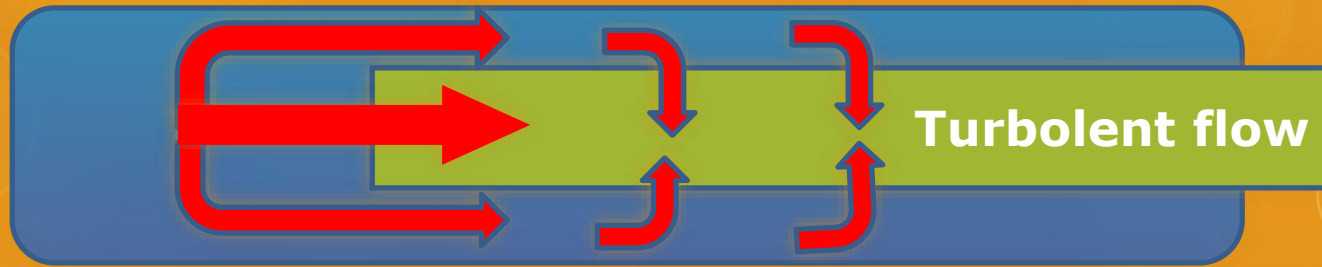
- Pumps
 - centrifugal
- Oxygenators
 - PMP
- Tubes
 - coated
- Cannulas
 - Hi-flow, small size



**Cannula: chose
the right size...**



Size matters...

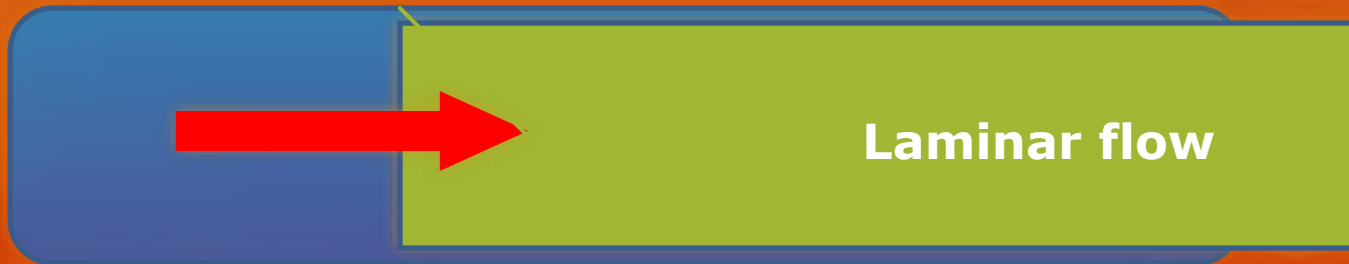


Poiseuille's Law

Flow $\propto \frac{\text{Radius}^4 \times \text{Pressure}}{\text{Length}}$

In other words **short** and **fat** is best

...but wall thickness too!!!



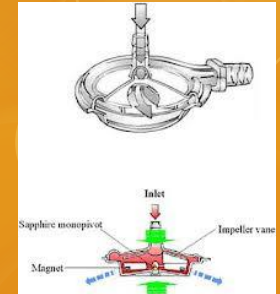
Cannula Design

- Integrated connectors
- Side holes
 - Number
 - Size
 - Configuration
 - VA vrs VV
- Coating
- certification

Mandatory feature in ECMO equipment:

- LOW shear stress/HI washout Centrifugal pump

- Magnetical Levitation
- Single ceramic/rubin bearing
- Low hemolytic rate, low thrombogenicity



- poly-4-methyl-1-pentene diffusion plasma-tight membrane

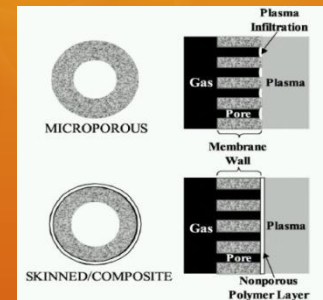
- Same advantages as the hollow-fiber design
- thin nonporous polymer layer protecting the polymethylpentene fibers.



Polymethylpentene
"plasma-tight" fiber



Polypropylene
"standard" fiber



- (2-ethylhexyl) phthalate (DEHP) free.

- added to PVC tubing providing durability or flexibility;
- The US FDA and Health Canada recommend limiting DEHP exposure in patient populations such as the male prepubescent and neonate (**INCREASED RISK OF HORMONAL DISORDERS**)

- Heparin-bonded (Bioline) or bio-mimetic (phosphorilcoline, PHISIO) TIP TO TIP coating

- Reduced hemostatic disorders intrinsic pathway dependent
- Inhibits platelets adhesion/aggregation
- Reduce SIRS

ECMO TRANSPORTATION: THE «HUB&SPOKE» PROGRAMM

New ECMO system allows transportation

- In-hospital (Cath lab, CT-scan,...)
- Inter-hospital
 - SPOKE to HUB
 - HUB to HUB (VAD/transplantation)

TRANSPORTATION PROGRAM:

- Small, light hand devices
- Certified for avio-transportation
- Long term internal accumulators



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ECMO

NEW PROTOCOLS

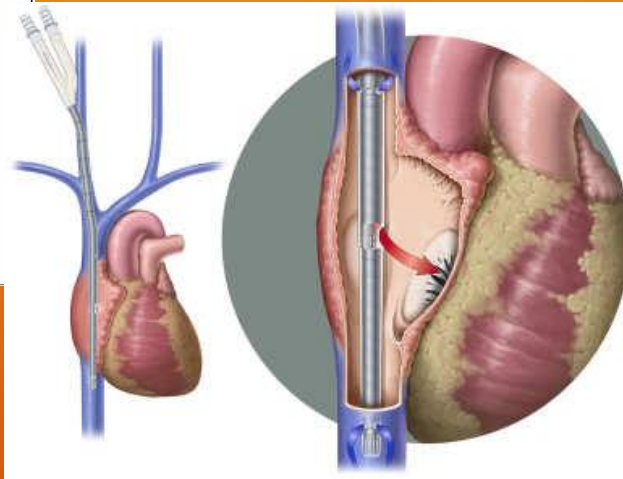
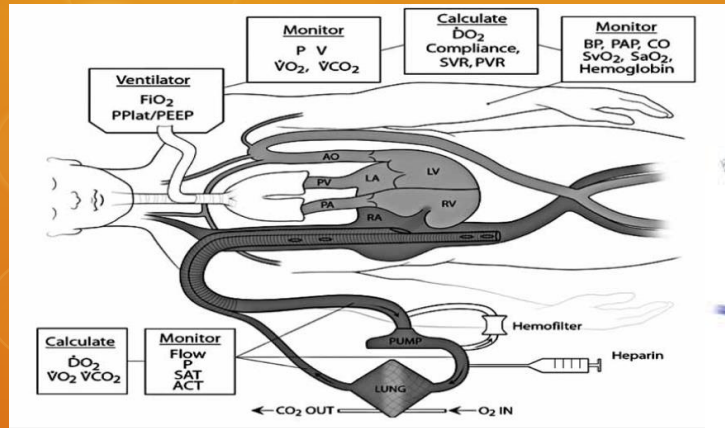
IMPLANT STRATEGY AND CANNULATION principles

- Depending on the purpose, ECMO can be initiated in a “Veno-Venous” or a “Veno-Arterial” mode:
 - **Veno-venous:** RESPIRATORY ECMO SUPPORT
 - **Veno-arterial:** CIRCULATORY ECMO SUPPORT and RESPIRATORY ECMO SUPPORT
- Depending on the cannulation site, ECMO can be initiated in a CENTRAL or a PERIPHERAL fashion
- According to ongoing clinical modification, ECMO can
 - be converted each other
 - upgrade to new ***“hybrid configuration”***

Mode	Drainage	Reinfusion
VA	Venous	Arterial
VVA	Venous-Venous	Arterial
VV	Venous	Venous
VVV	Venous-Venous	Venous
VVDL	Venous-Venous Dual-lumen	
Bi-caval	Venous-Venous Dual-lumen Bi-Caval	

○ Veno-Venous (VV) configuration is namely a **respiratory support**:

- Provides oxygenation and CO₂ removal
- NO CIRCULATORY SUPPORT



- Blood being drained from venous system and returned to venous system.
- Achieved by peripheral cannulation
 - Fem-Fem
 - Fem-Jug
 - J-J via double lumen cannula

V-V ECMO

ADVANTAGES

- Eliminates potential for ischemic lung injury
- No manipulation or ligation of carotid artery in neonates/pediatrics
- Preserves cardiac pulsatility
- Emboli will travel to pulmonary rather than central or cerebral circulation
- Possible decreased risk of cerebral reperfusion injury

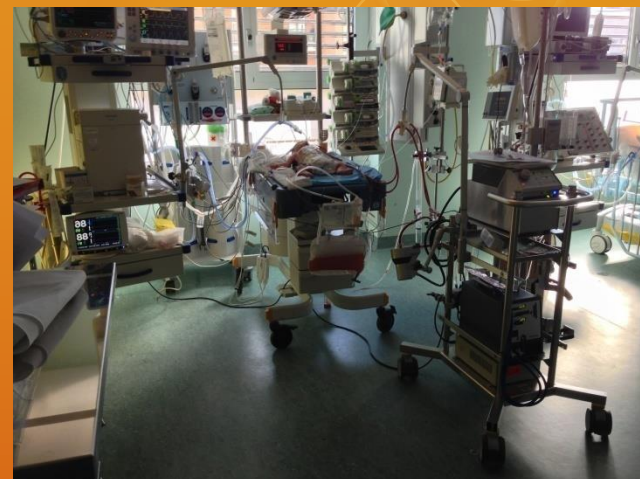
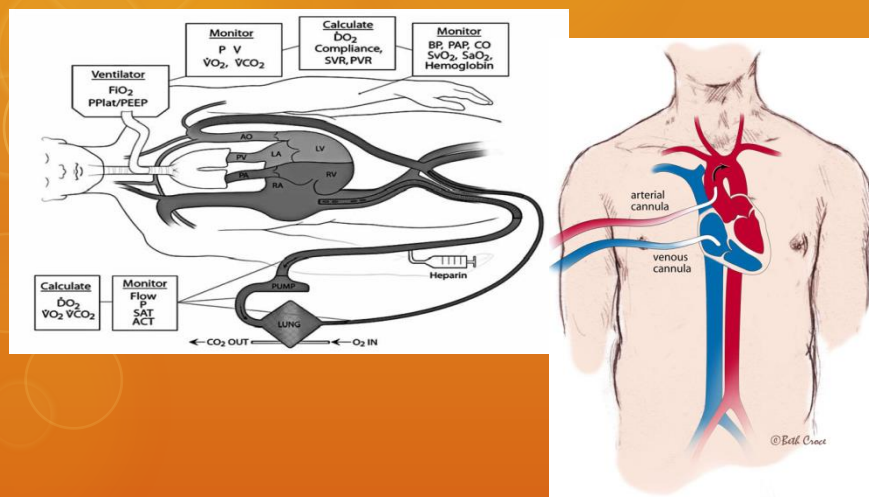
DISADVANTAGES

- No circulatory support
- Maximum oxygen delivery may not be adequate for demand
- Recirculation
- Flow dependent on venous drainage

V-V ECMO: RECIRCULATION

- Blood coming from ECMO is drained back to ECMO before been returned to patient
 - Average 30% recirculation with V-V ECMO
 - SaO_2 low as 80-85%
- Clinical signs:
 - decrease in arterial saturation
 - increase pre-membrane saturation
- Factors that increase recirculation:
 - Small distance between drainage and return cannula
 - Axial rotation in DLC ("Coanda effects")
 - Excessive suction in hypovolemic patient
 - Increased cardiac output (INCREASED FLOW "ESCAPING" to the lungs)

○ Veno-arterial (VA) configuration could be either a **respiratory** as a **cardio-circulatory support**



- Blood being drained from the venous system and returned to the arterial system.
- Achieved by either peripheral or central cannulation
 - RA-Ao
 - Fem V-Fem A/Axil A (distal limb perfusion)
 - Jug V-Carot A (in neonates up to 5kg)
- Left cavity vented to improve recovery

V-A ECMO

ADVANTAGES

- Full cardiopulmonary support
- Myocardial rest by unloading the left ventricle
- Improve systolic and diastolic pressure
- Improve end organ and coronary perfusion

DISADVANTAGES

- Myocardial stun
- Lose cardiac pulsatility
- Increased afterload → LV failure → increased LA pressure → pulmonary edema
- Atrial septostomy to off-load the left heart

HOW TO SITE CANNULAS

CENTRAL

- **Surgical, open technique**

PERIPHERAL

- **Percutaneous (Seldinger technique)**
 - **IV catheters first, verify position**
 - **Largest possible cannula, over heavy wire**
- **Semi-Seldinger**
 - **Expose vessel, place wire under direct vision (for infant double lumen)**
- **Cut down**
 - **Direct exposure, distal ligation, cannulation, distal perfusion or collaterals**

Anatomic Location

- What access sites are available?
 - Echo/ultrasound pre-cannulation
- Neck
- Groin
- Central
- Subclavian
- Axillary

CANNULATION SITE

○ CENTRAL CANNULATION

- No cannula sizing problems
- Antegrade arterial flow

- RIGHT ATRIUM
- ASCENDING AORTA
 - Direct for very short term
 - Side vascular graft
- LEFT ATRIUM/VENTRICLE
 - Left side unloading



- Main complications
 - BLEEDING
 - INFECTION

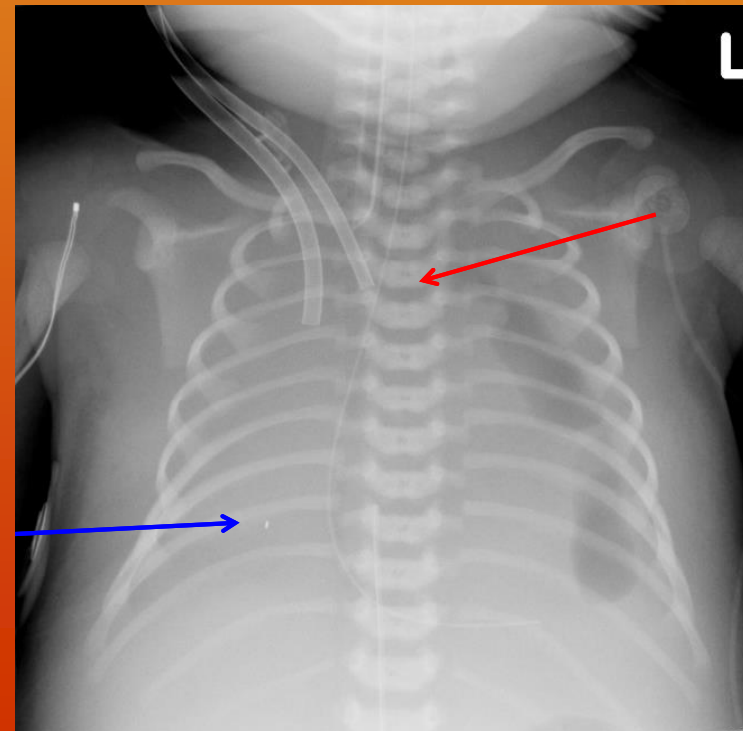
V-A ECMO: is it in the right place?

Echo confirmation

- Arterial cannula should be in aortic arch/RCCA junction
- Venous cannula in right atrium



Chest X-ray confirmation



(if possible) KEEP THE THE CHEST CLOSE...

• **TRANSTHORACIC APPROACH**

- Usually after cardiac surgery
- Full ECMO support
- Dedicated cannulas
- Re-sternotomy to remove cannulas



• **ADVANTAGES**

- **LESS BLEEDING:**
 - Less surgical trauma
 - Less Tissue Factor pathway
 - Less Fibrinolytic response
- **LESS INFECTION RATE**
- **ADVANCED REHABILITATION**
 - Weaning from mechanical ventilation
 - Feeding
 - Rehabilitation

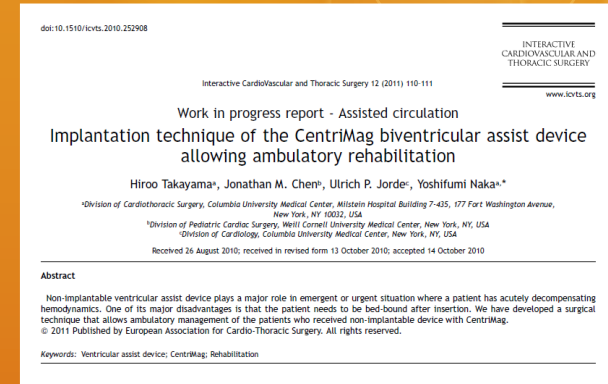
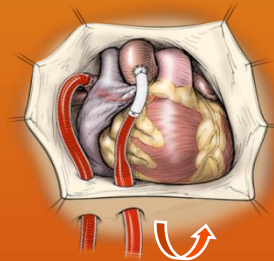


Fig. 1. A patient ambulating with CentriMag BiVAD. BiVAD, biventricular assist device.

PERIPHERAL CANNULATION

○ **WIDELY USED (now)**

○ Ideal for

- short term support
- Emergency (neck, femoral vessel)

○ **ADVANTAGES:**

- Percutaneous approach with Seldinger technique (adults): RAPID TIME
- Awake/Spontaneous breathing patients
- No need to open/re-open the chest
- Easy transportation



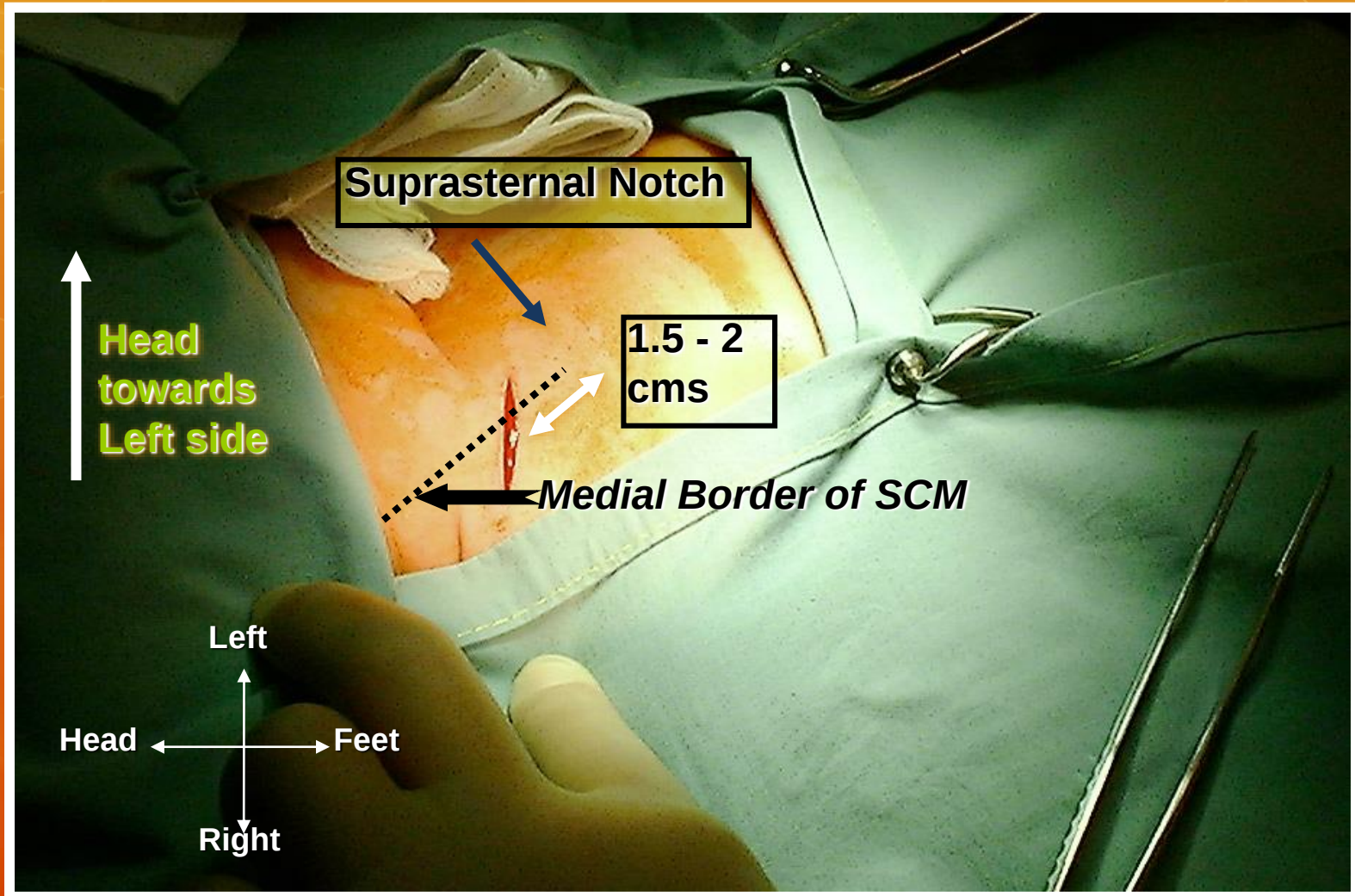
Small size cannula

- Jugular vein (15 F)
- Femoral vein (19-21 F)
- Femoral artery (15-17 F)
- Carotid artery (newborns)
- Axillary artery

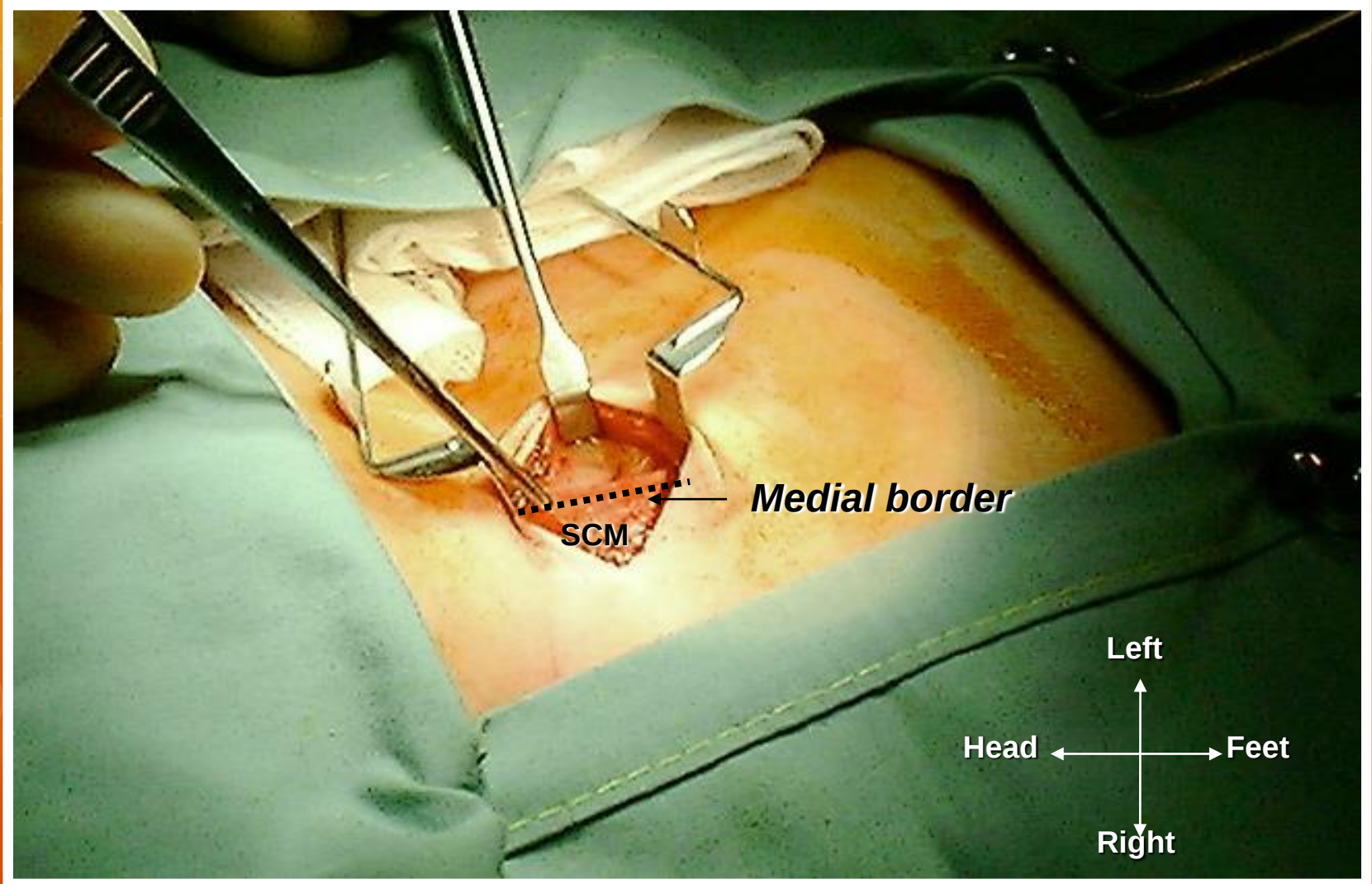
Pediatric VA Cannulation

- R IJ and R carotid artery in children < 10-15kg
- Stroke rate increased in pediatric population with carotid artery cannulation
- Femoral artery and R internal jugular vein for children >15kg
- Reperfusion cannula in lower extremity to prevent ischemia
- Femoral artery & vein + R IJ reinfusion (VA-V) if cerebral hypoxia
- Central cannulation

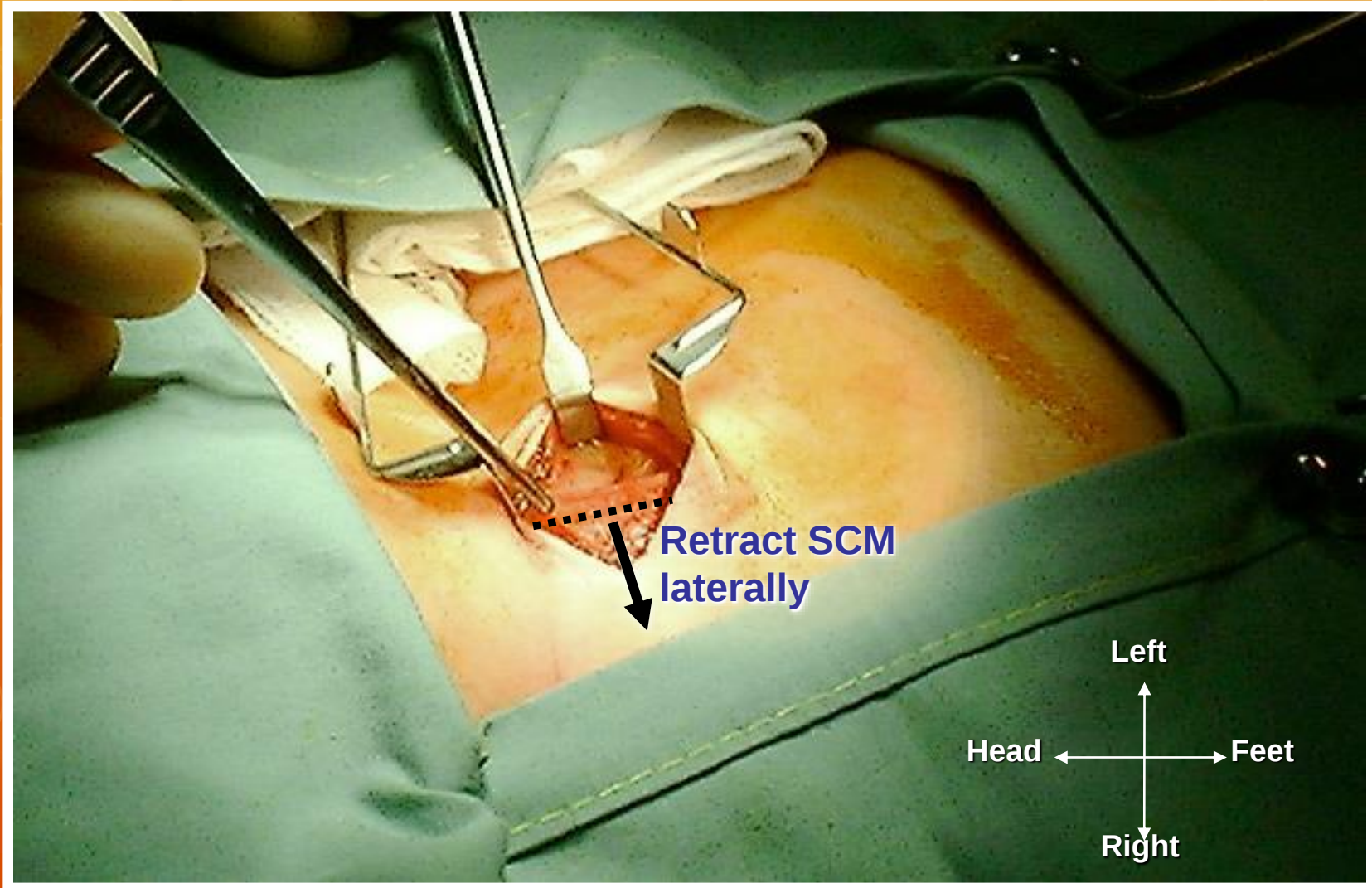
Neck Incision



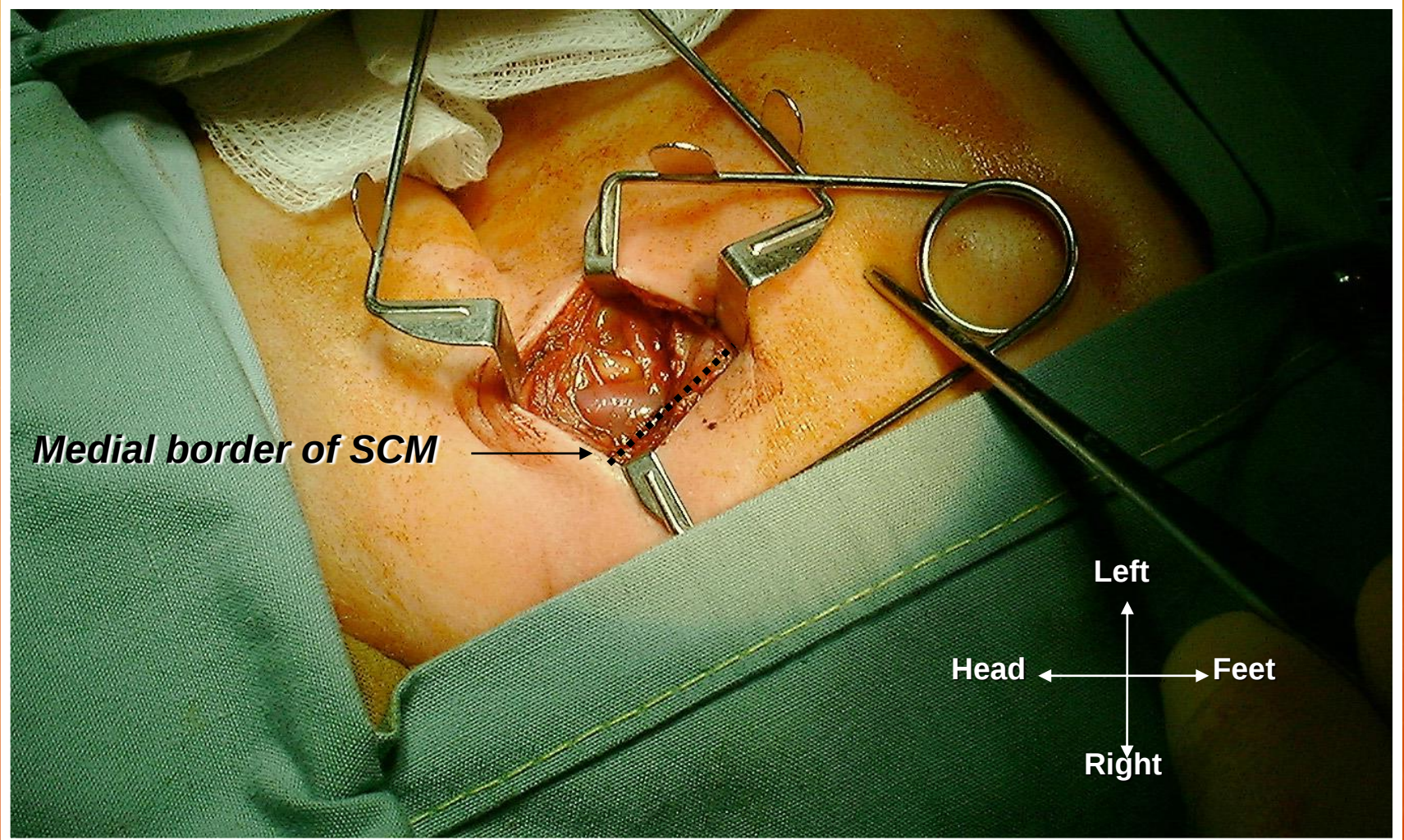
Exposure



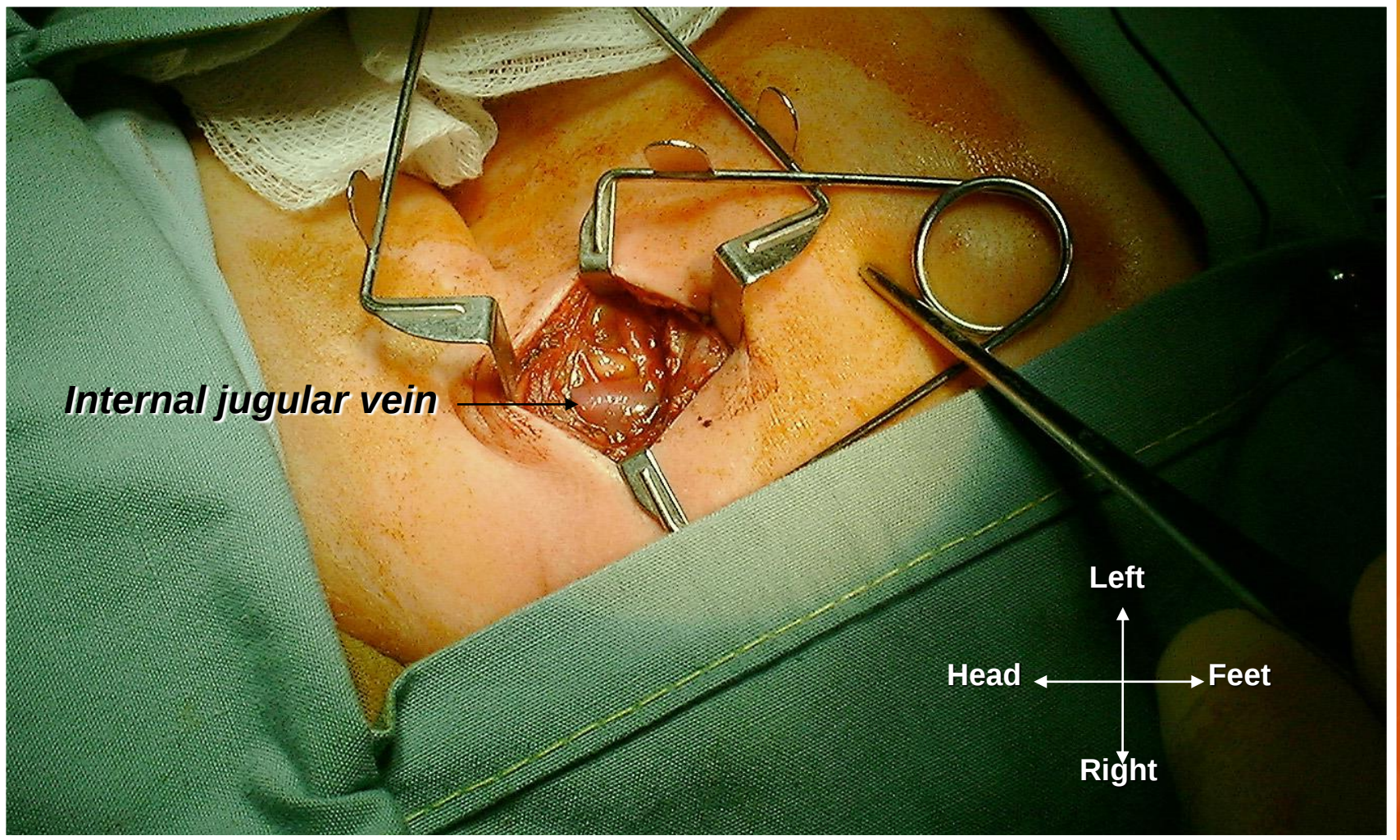
Exposure



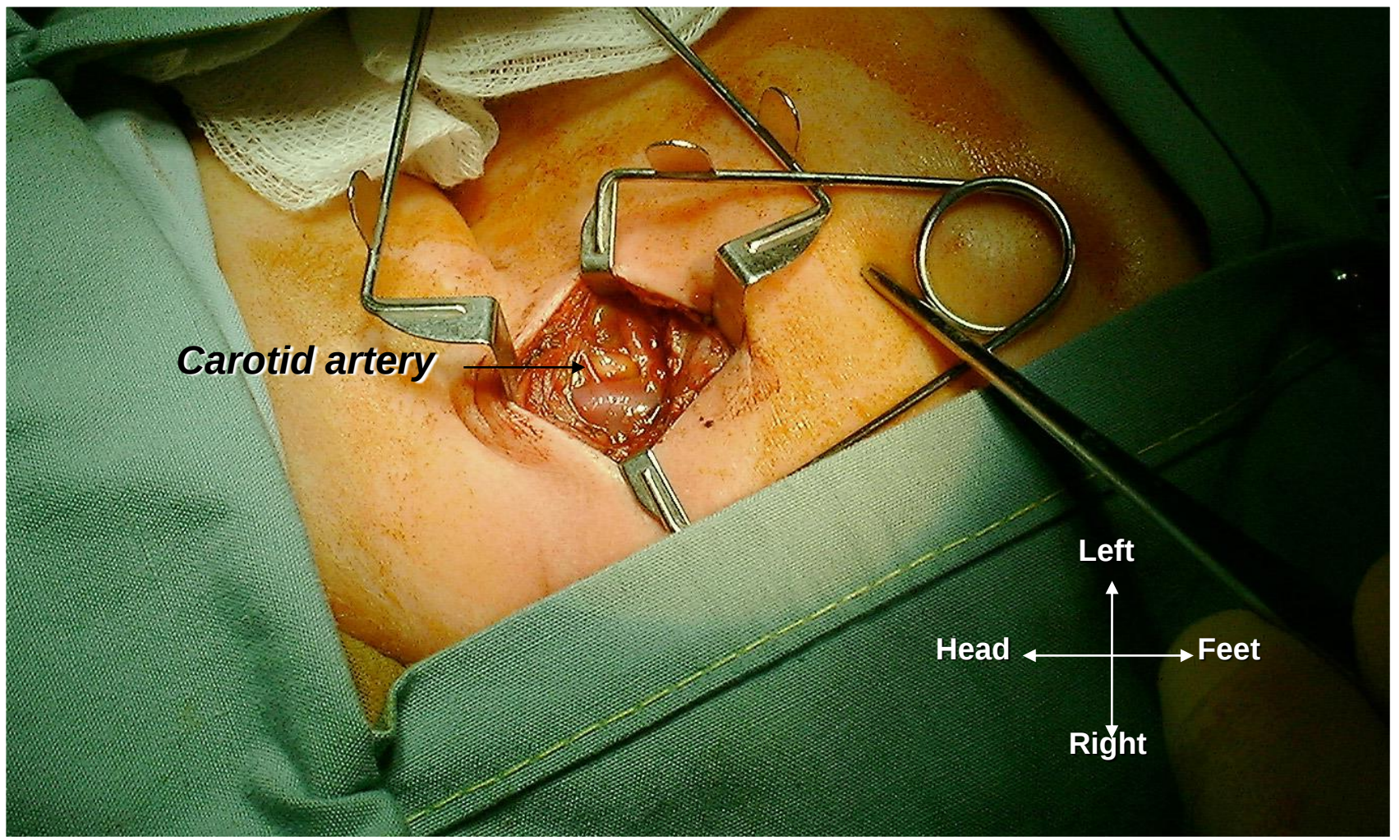
Carotid Sheath



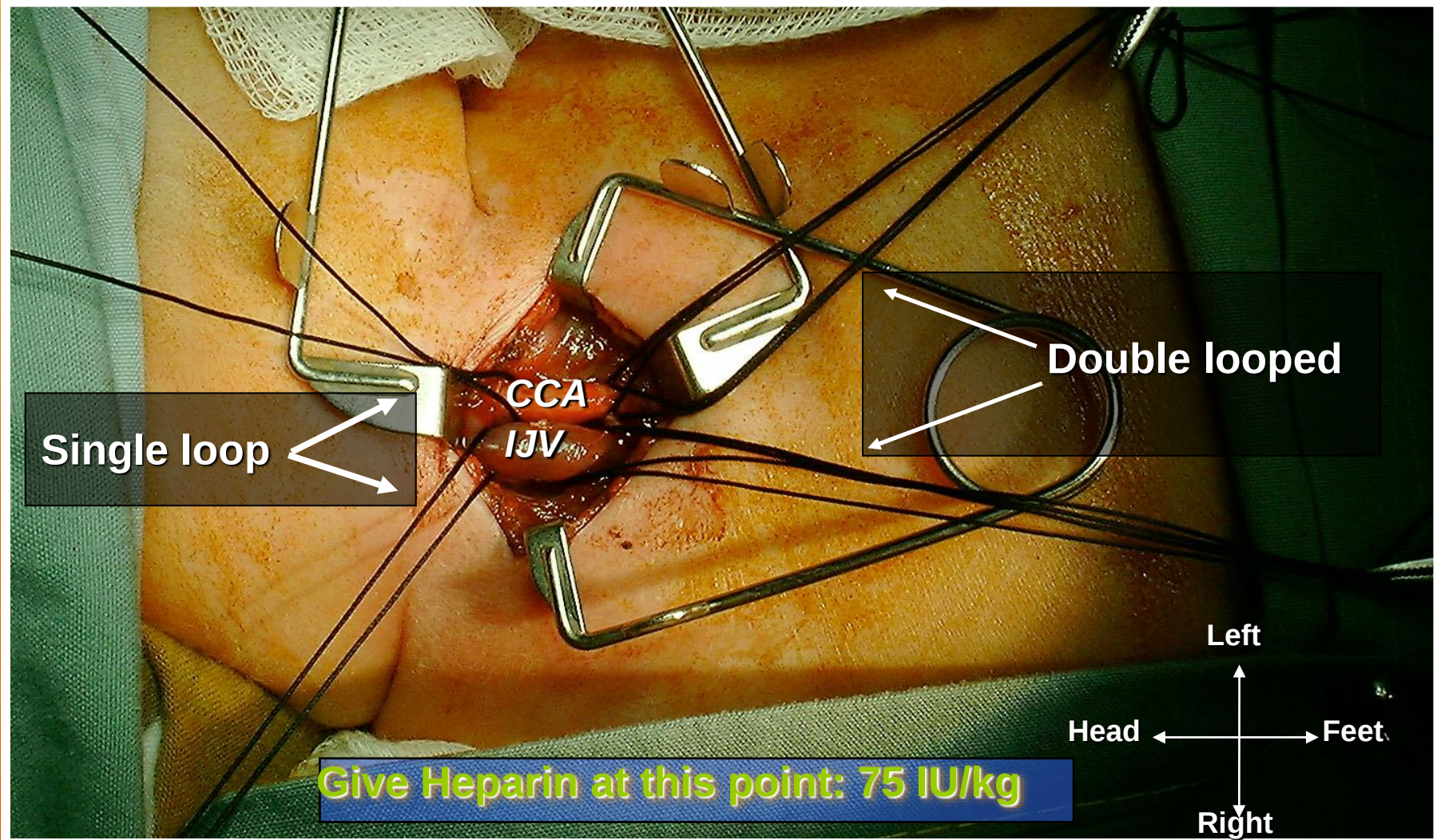
Carotid Sheath



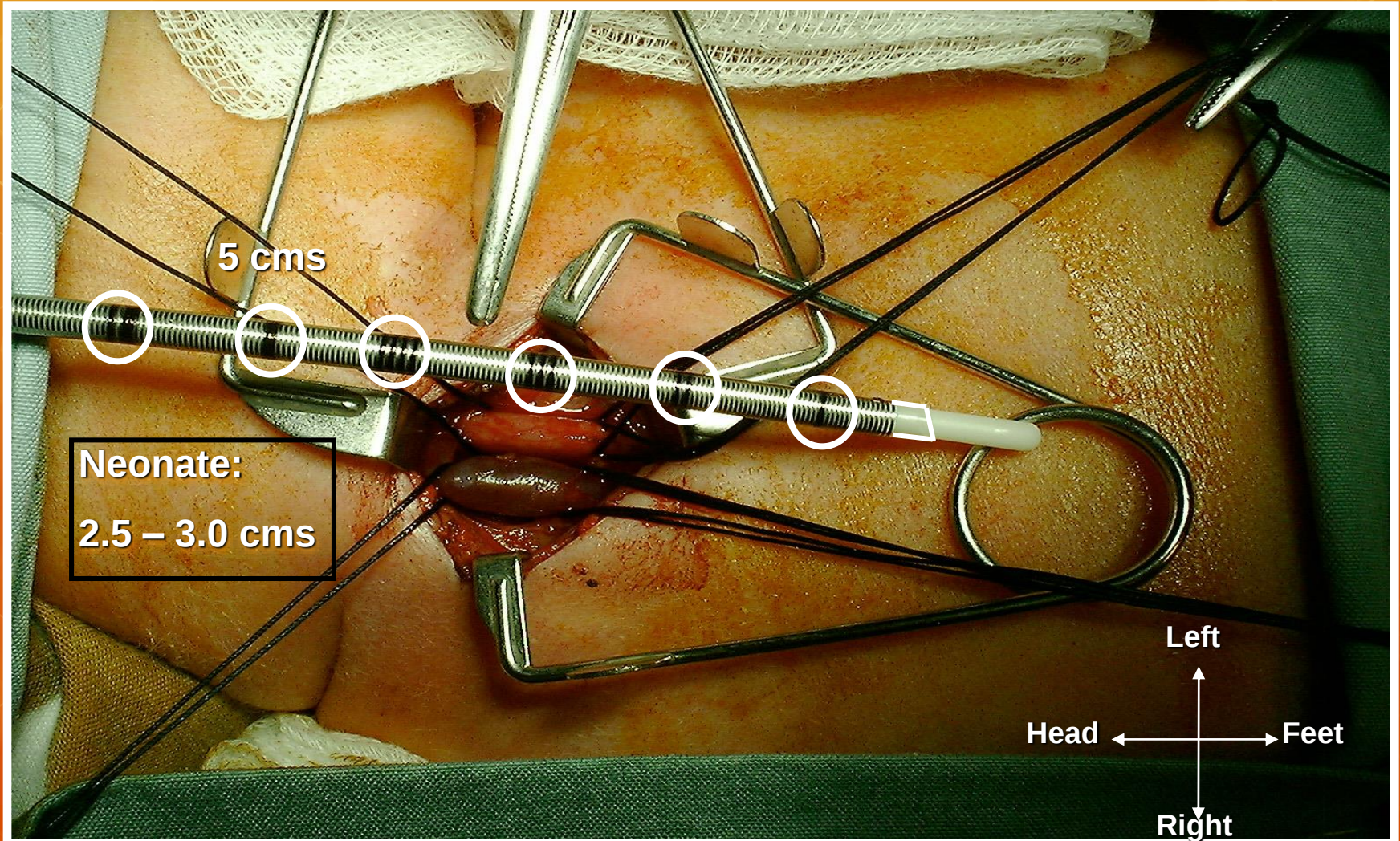
Carotid Sheath



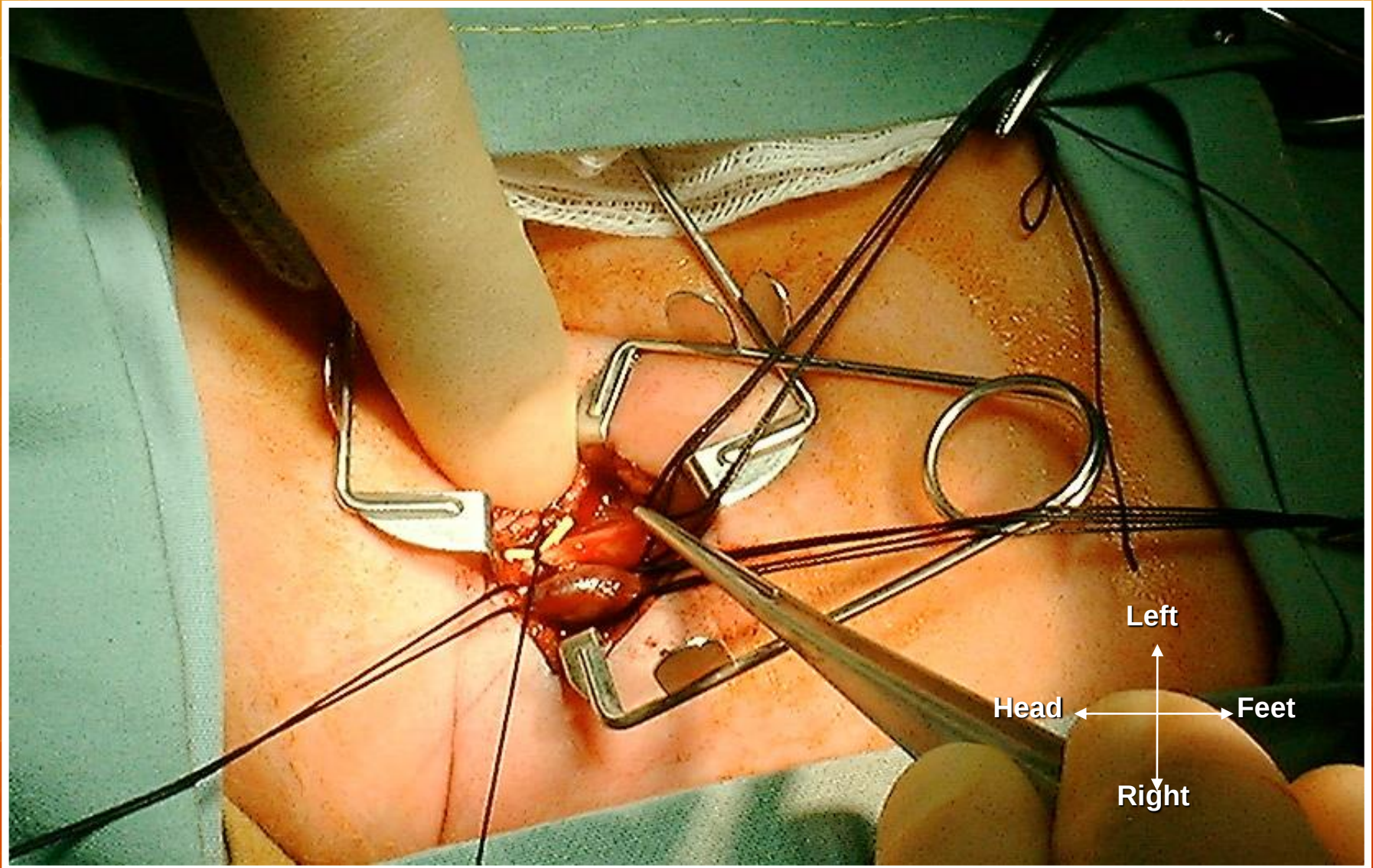
Encircling of the Vessels



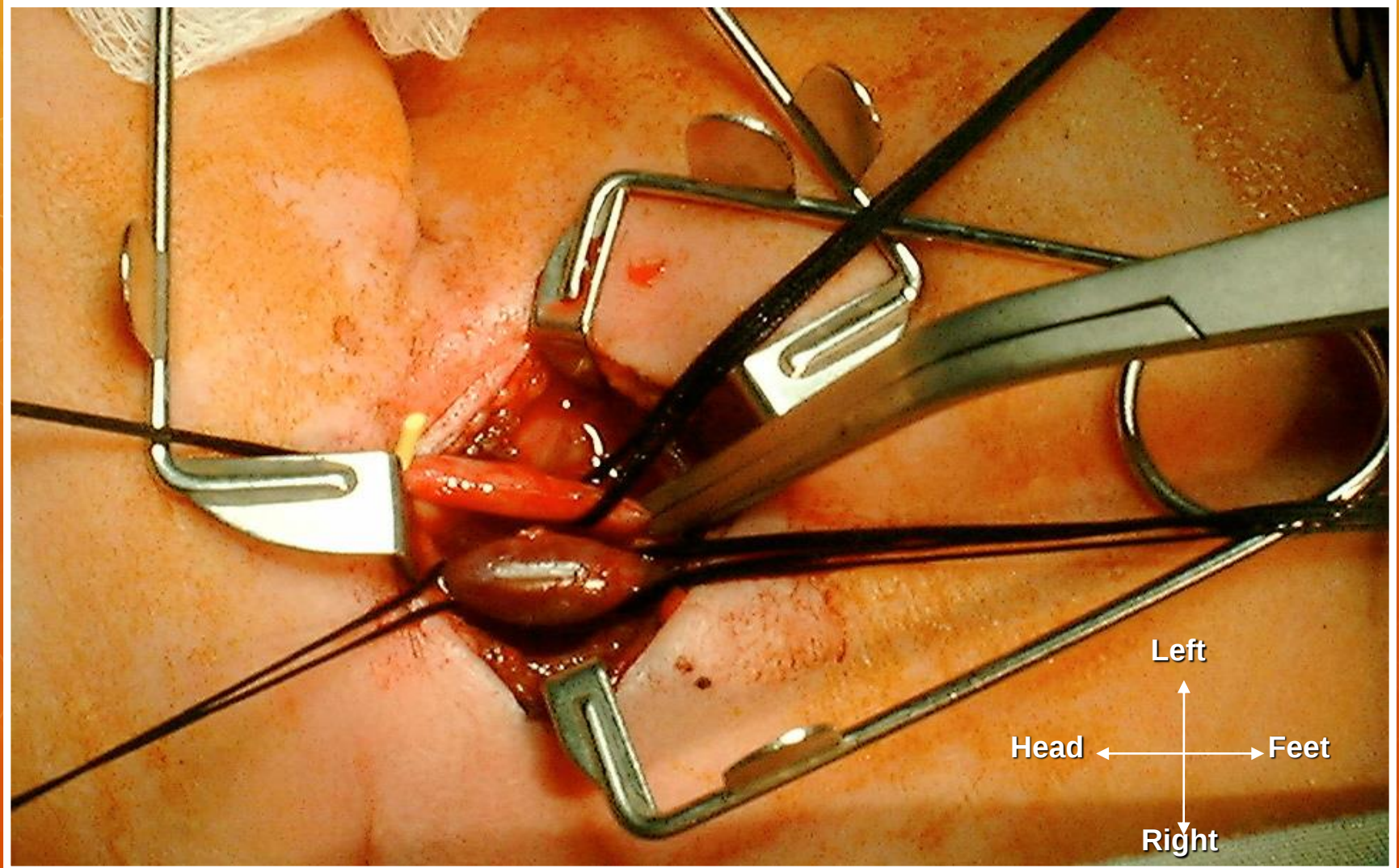
Arterial Cannula Sizing



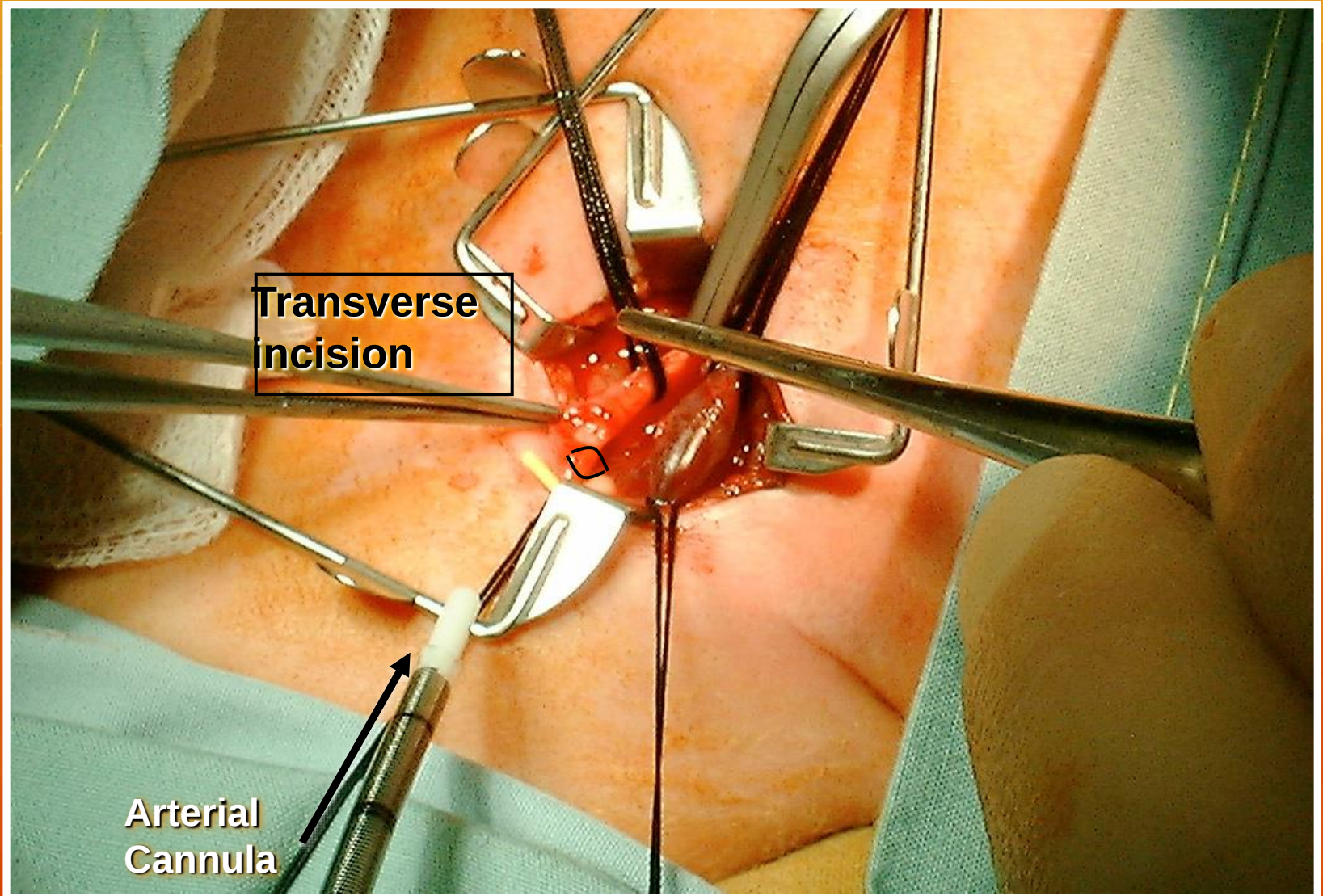
Distal Ligation of the Carotid



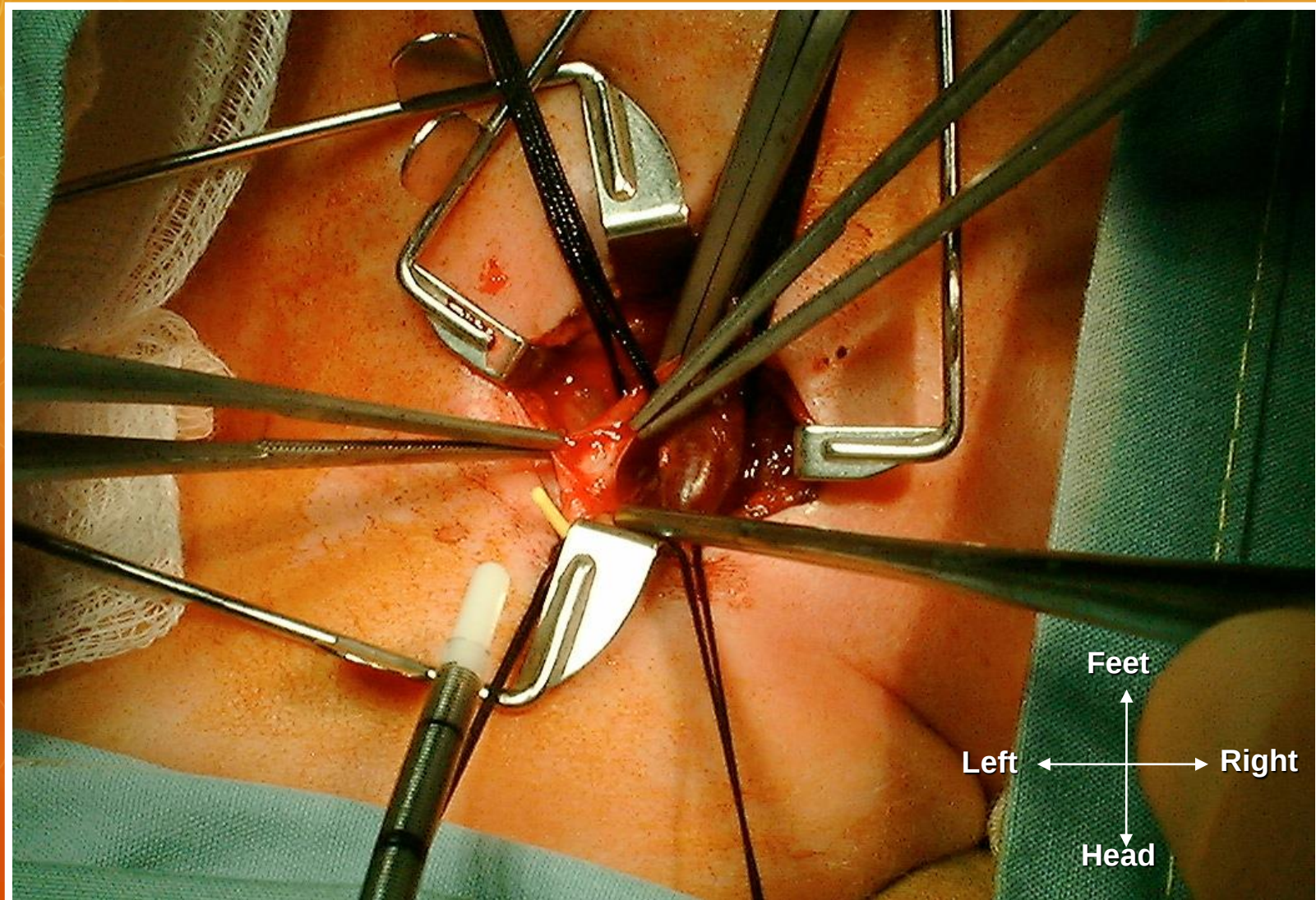
Cross-Clamping the Carotid



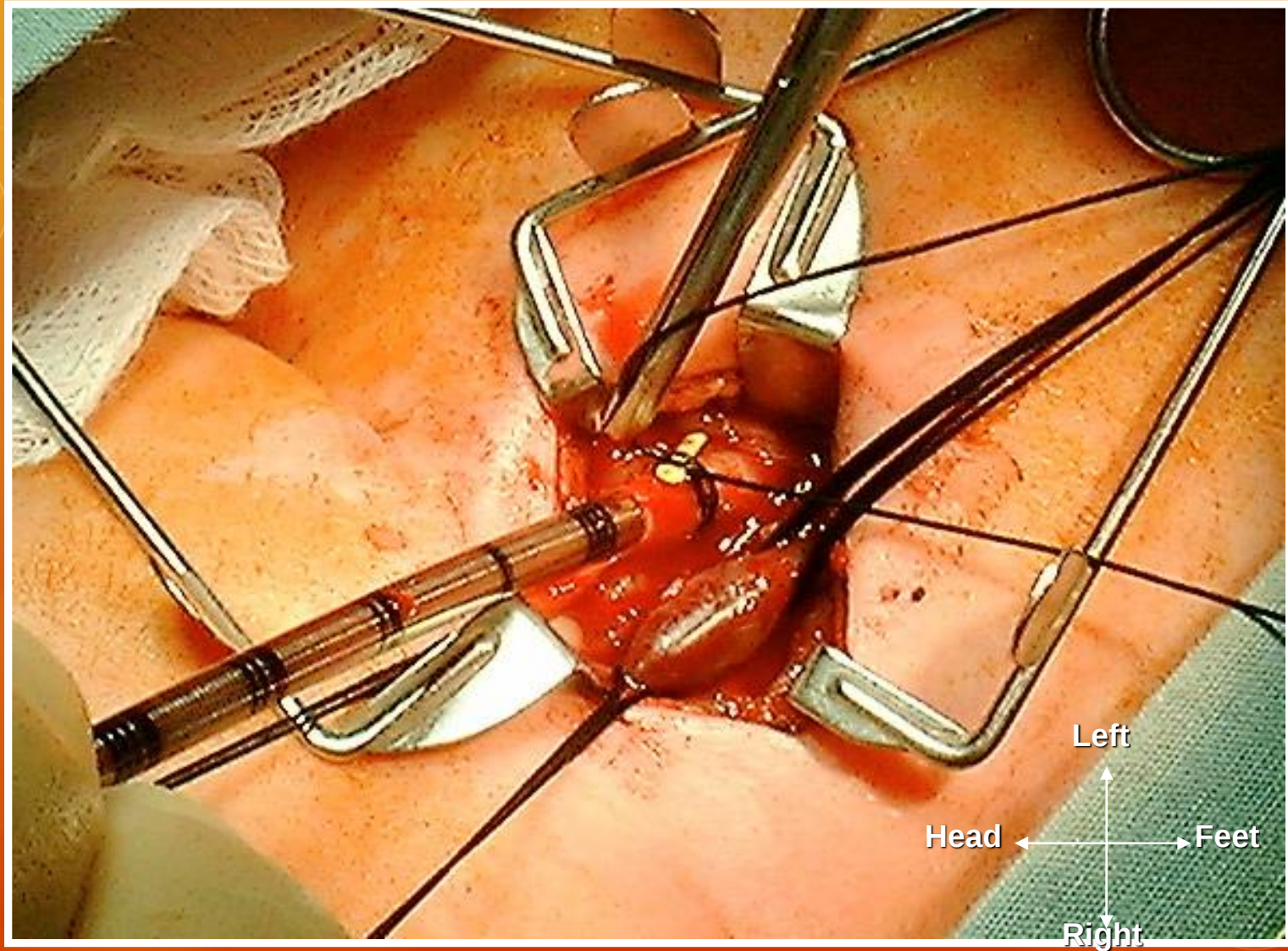
Carotid Arteriotomy



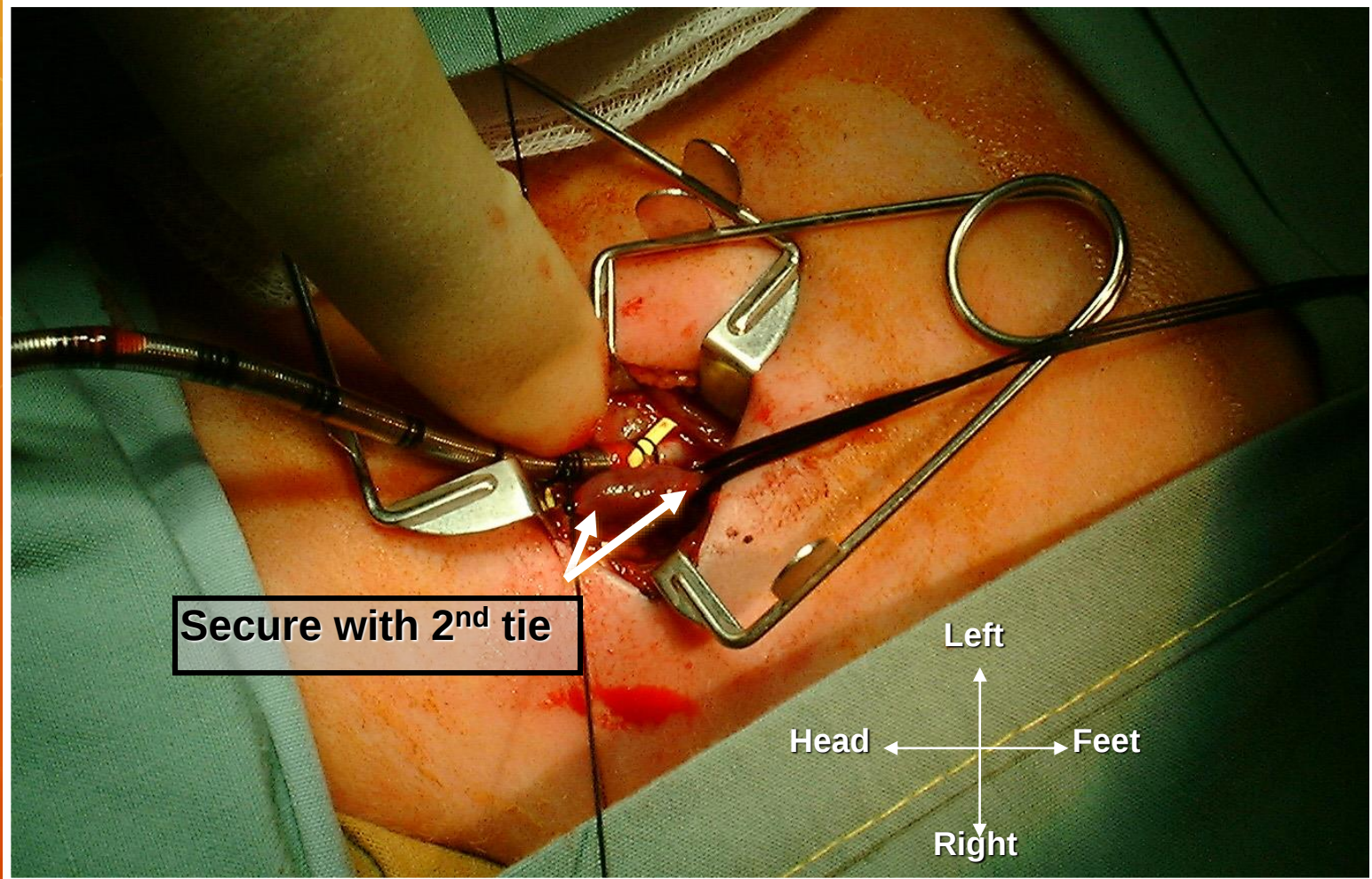
Arterial Cannulation



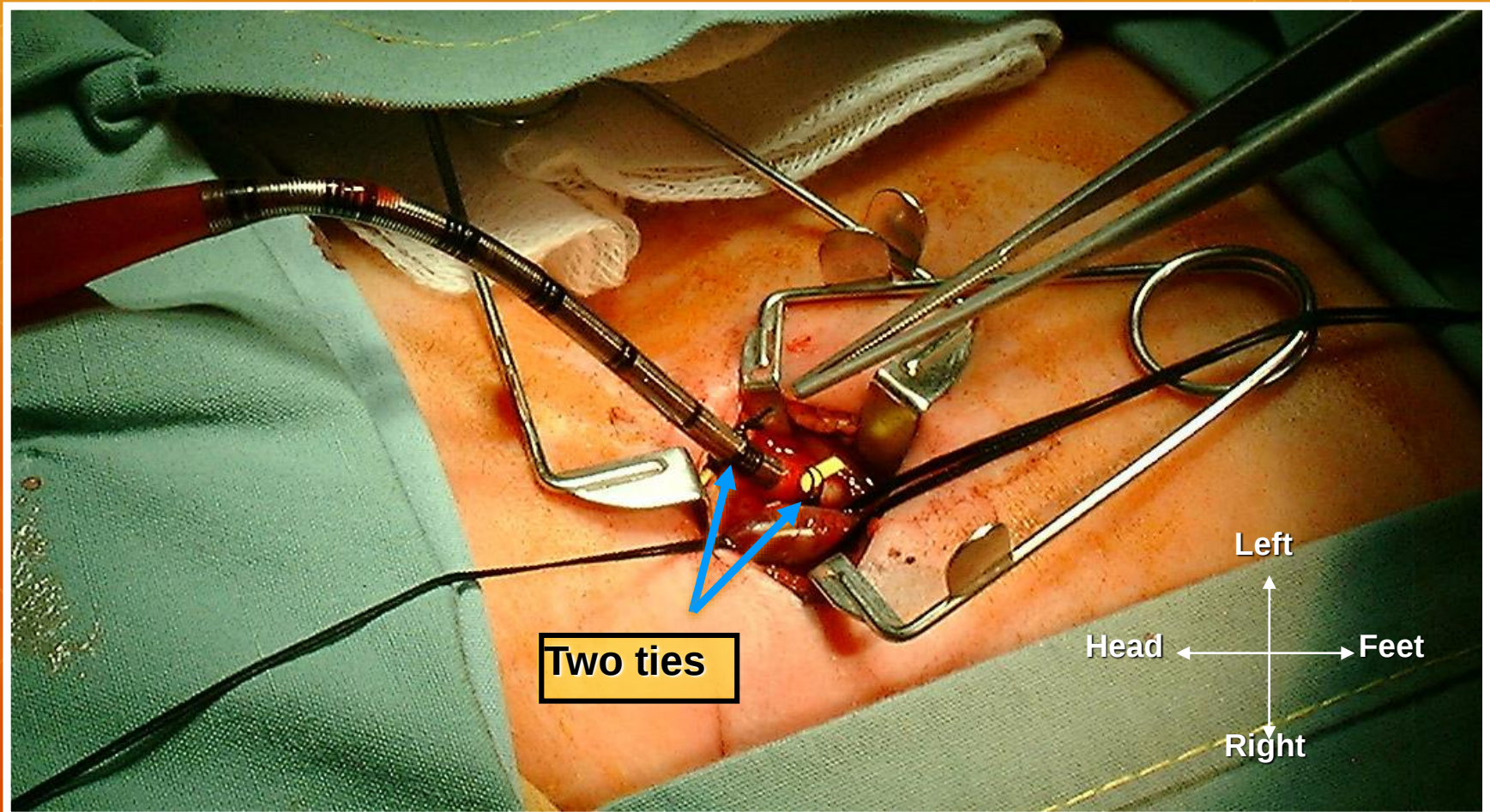
Securing the Cannula



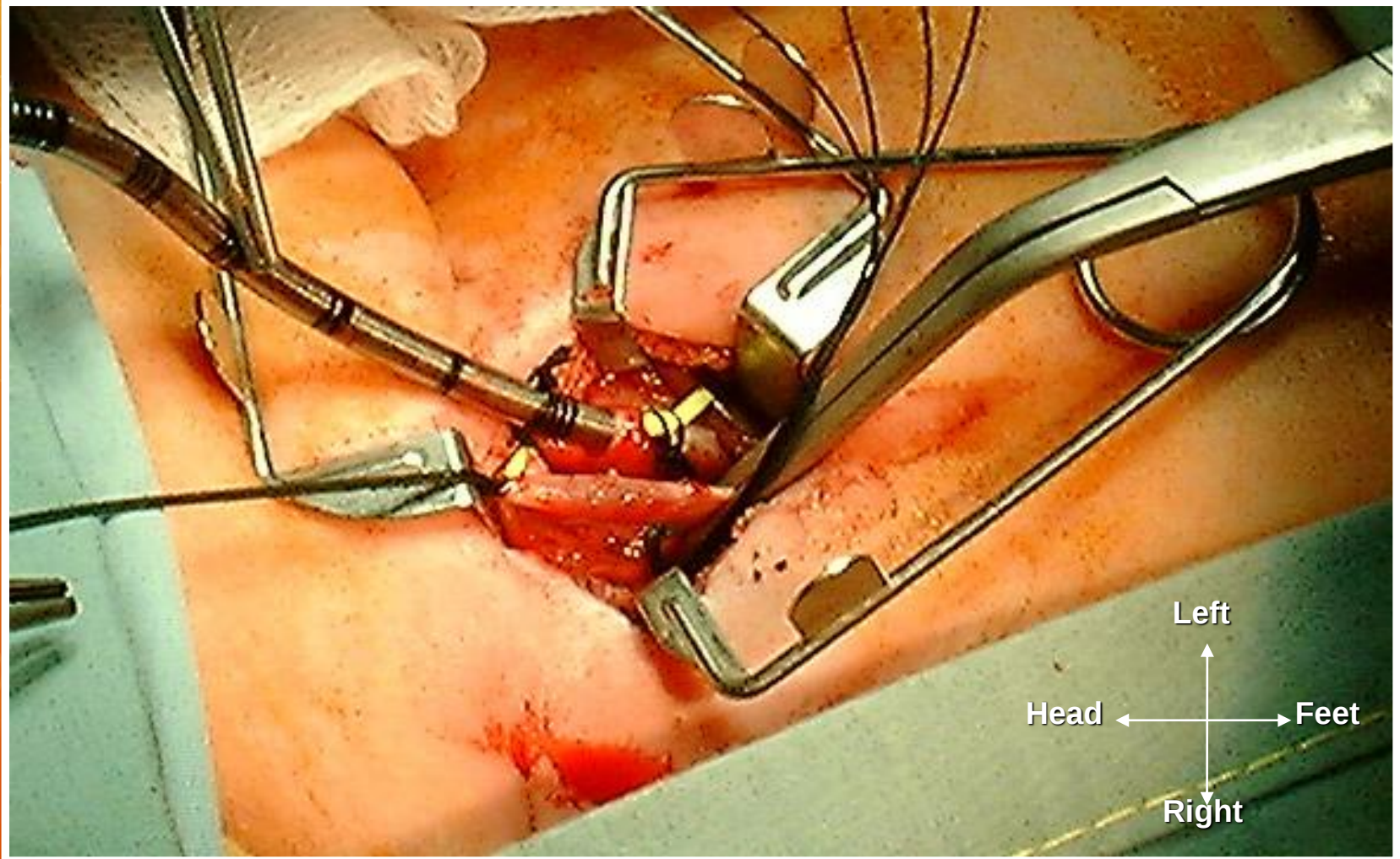
Securing the Cannula Distally



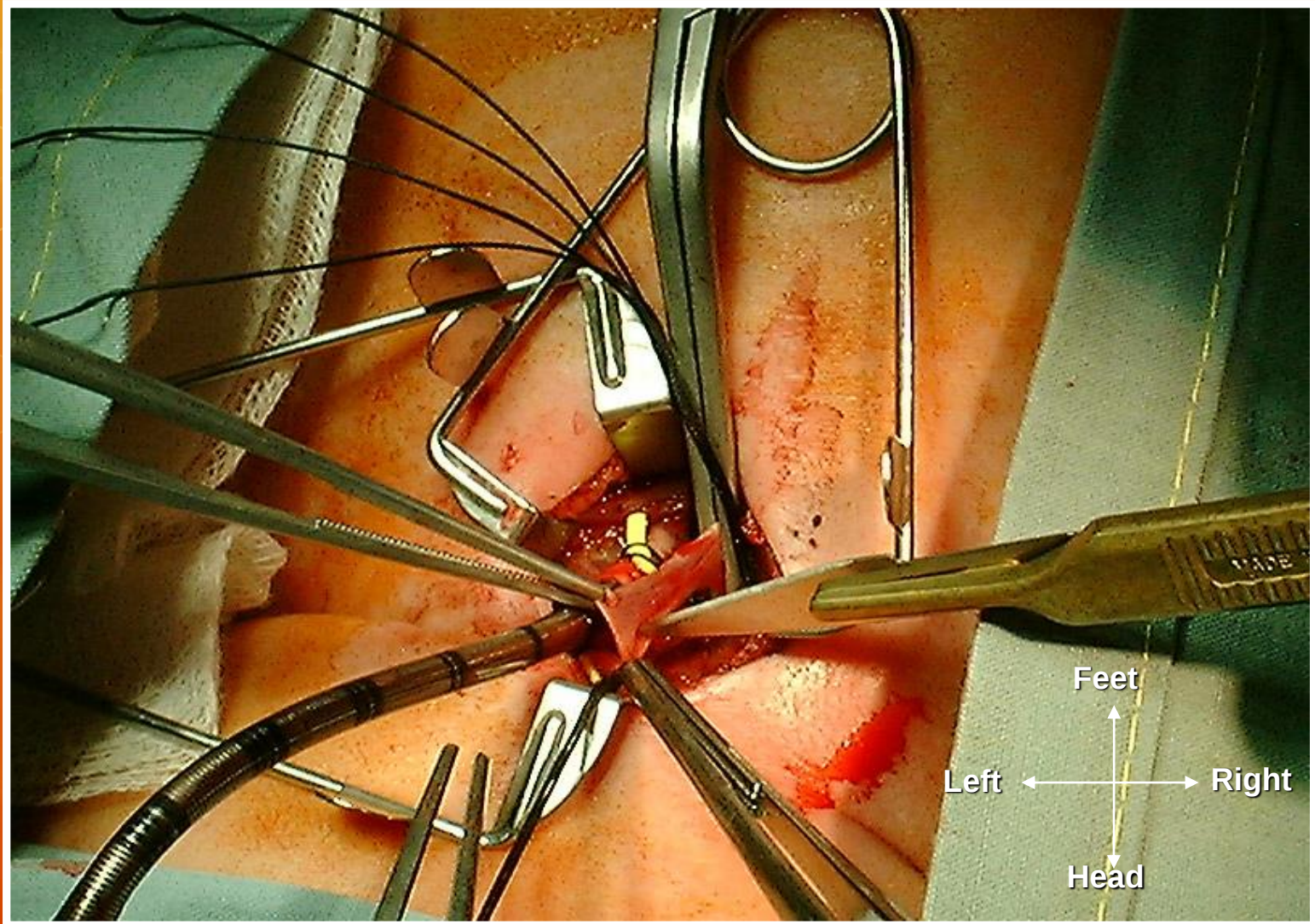
The Secured Arterial Cannula



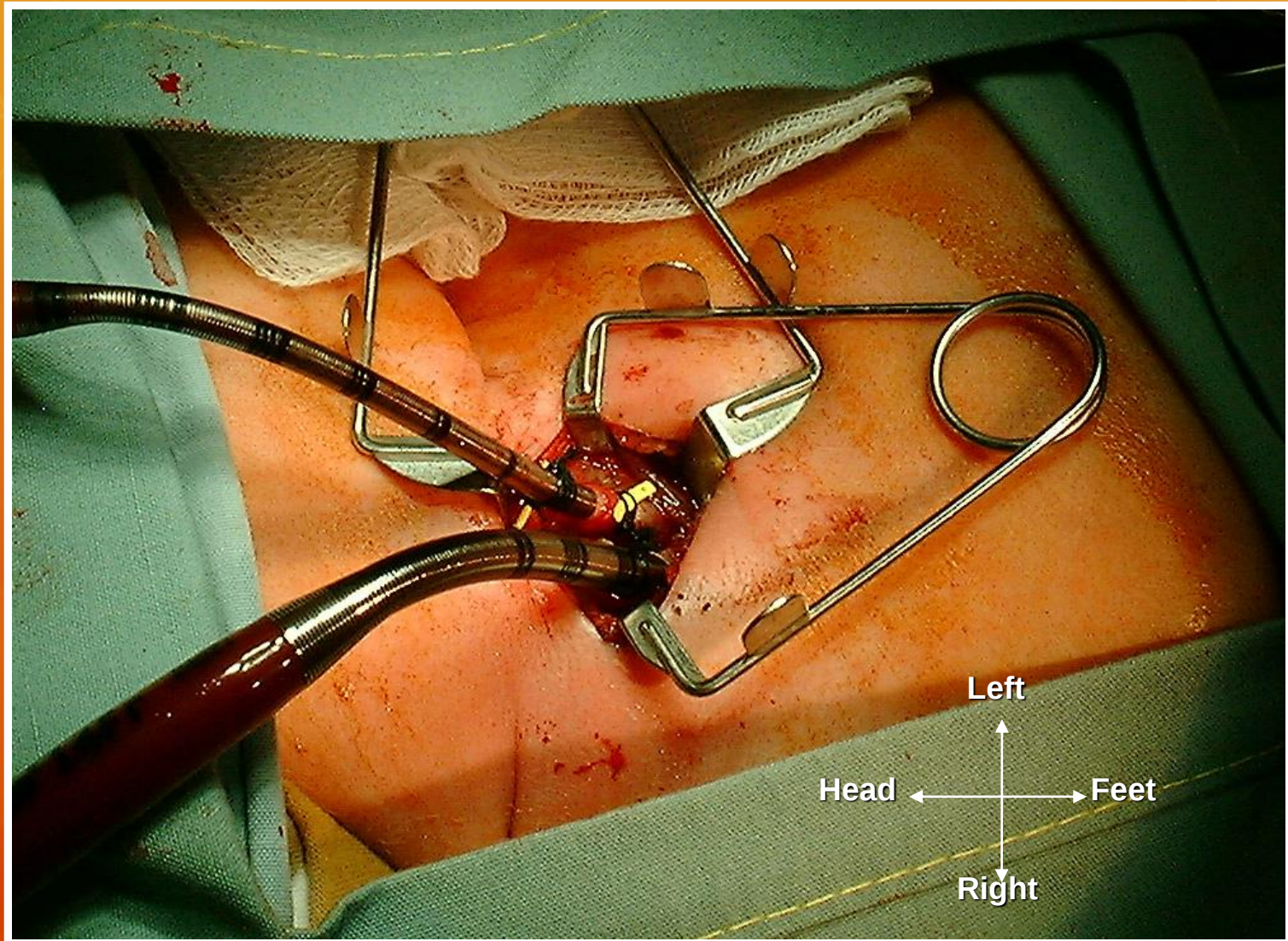
Venous Cross Clamp



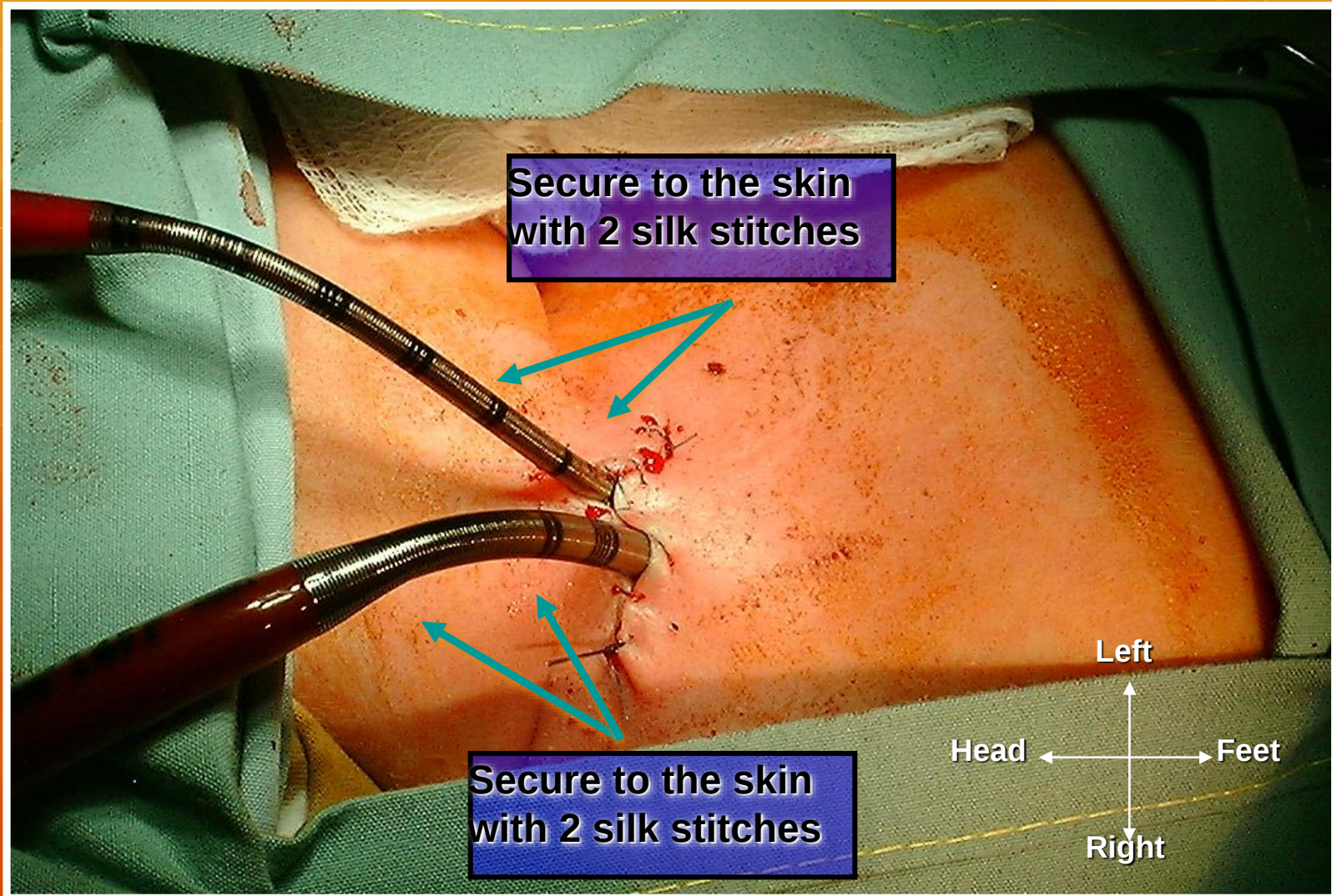
Jugular Venotomy



Venous Line Secured



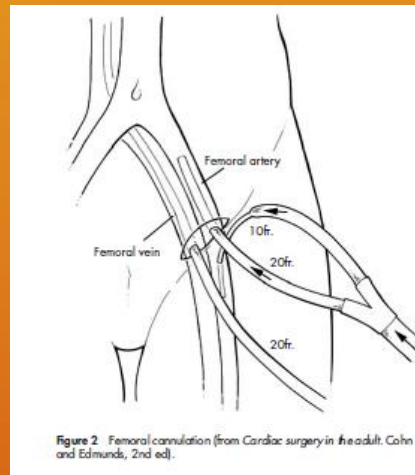
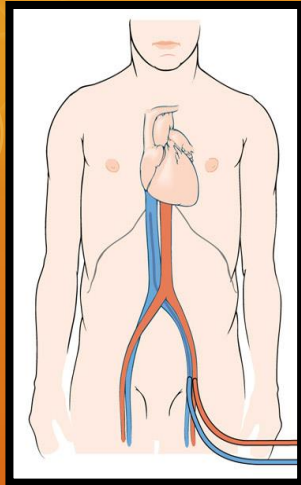
Skin Closure



Baby on VA ECMO

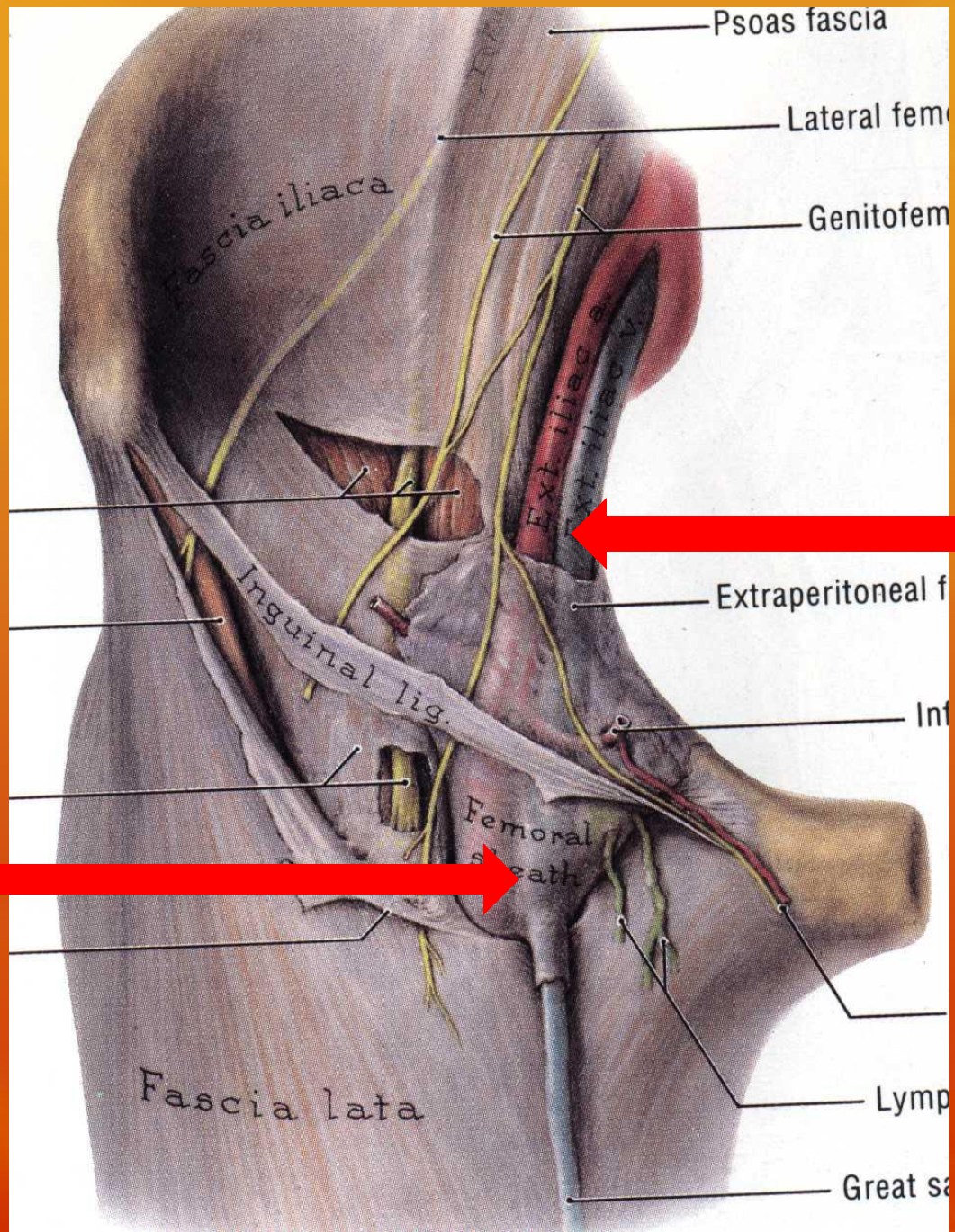


V-A ECMO Femoral cannulation



- >15kg
 - Percutaneous (seldinger/semi-seldinger)
 - Open cut down technique
- Ideal positioning
 - venous cannula at level of diaphragm
 - Arterial cannula below renal artery



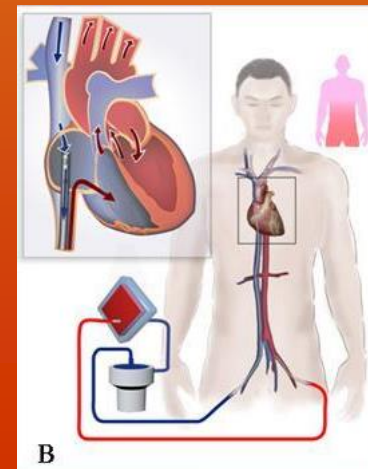
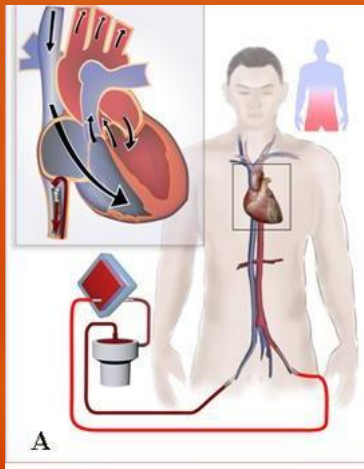


Not Here

Puncture
here

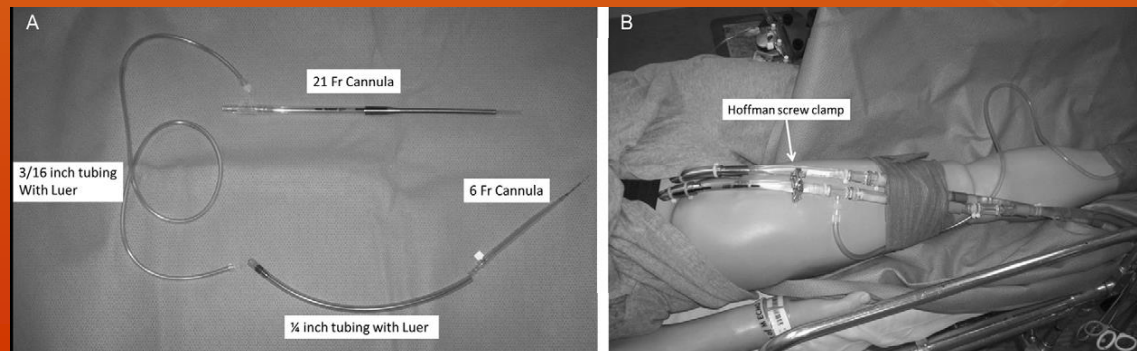
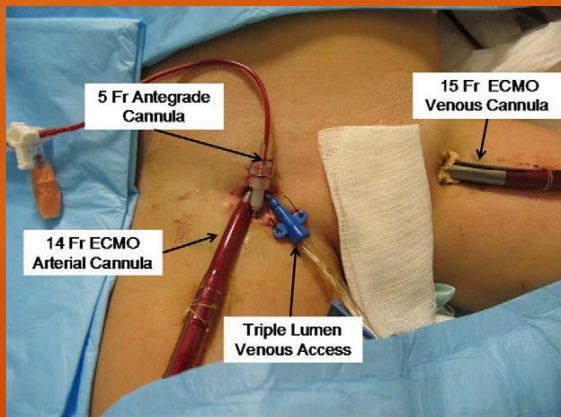
V-A ECMO Femoral cannulation

- Effective for cardiac failure
- Ineffective for respiratory failure
 - Fails to perfuse aortic arch if LV is ejecting
 - Poorly oxygenated blood delivered to brain and coronaries (Arlequin Syndrome)
- **VA-V ECMO**
 - **Addition of arterialized IJ cannula improved oxygenation to coronaries and brain**



Arterial reperfusion cannula in leg to avoid limb ischemia

- Limb ischemia rate 20-50% with femoral artery cannulation
- Options for reperfusion cannula
 - Antegrade cannulation of superficial femoral artery
 - Common femoral artery cannulated in retrograde direction
 - Ipsilateral posterior tibial artery cannulation



NIRS to prevent lower limb ischemia

Artif Organs, 2012 Aug;36(8):659-67. doi: 10.1111/j.1525-1594.2012.01496.x. Epub 2012 Jul 23.

Cerebral and lower limb near-infrared spectroscopy in adults on extracorporeal membrane oxygenation.

Wong JK, Smith TN, Pflieger HT, Hirose H, Cavarocchi NC.

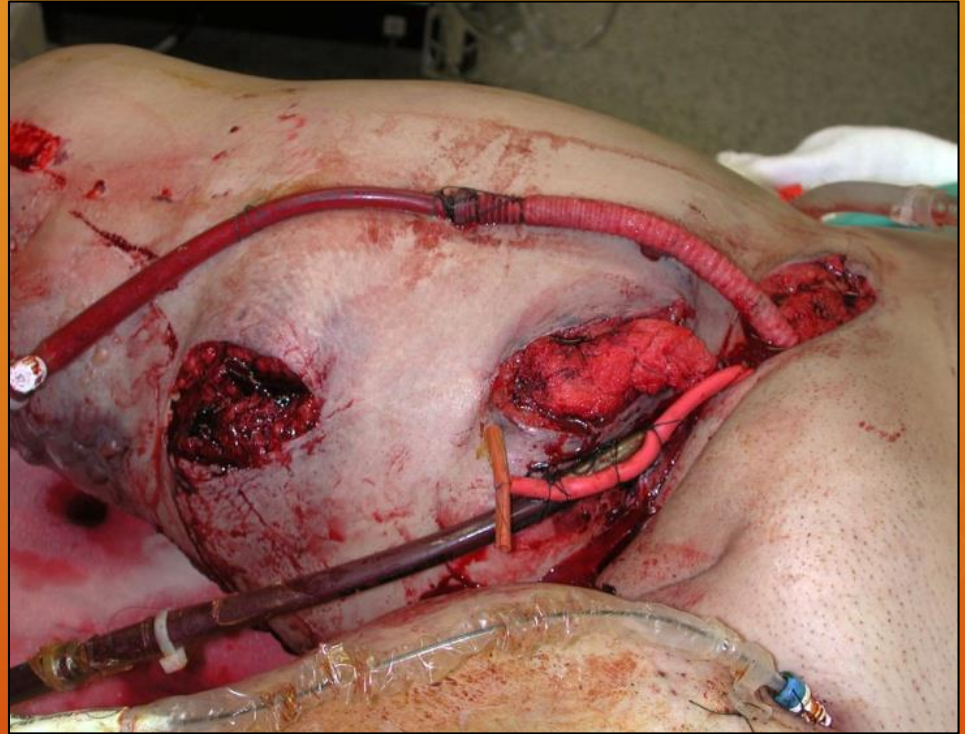
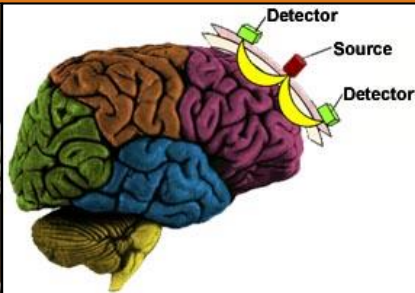
Department of Surgery, Division of Cardiothoracic Surgery and Critical Care, Thomas Jefferson University Hospital, 1025 Walnut Street, Philadelphia, PA 19107, USA.

Abstract

Percutaneous femoral venoarterial (VA) or jugular venovenous (VV) extracorporeal membrane oxygenation (ECMO) can result in delivery of hypoxic blood to the brain, coronaries, and upper extremities. Additionally, VA-ECMO by percutaneous femoral artery cannulation may compromise perfusion to the lower limbs. Use of near-infrared spectroscopy (NIRS) detects regional ischemia and warns of impending hypoxic damage. We report the first known series with standardized monitoring of this parameter in adults on ECMO. This is an institutional review board-approved single institution retrospective review of patients with NIRS monitoring on ECMO from July 2010 until June 2011. Patients were analyzed for drops in NIRS tracings below 40 or >25% from baseline. VA-ECMO and VV-ECMO were initiated by percutaneous cannulation of the femoral vessels and the internal jugular vein, respectively. Sensors were placed on the patients' foreheads and on the lower limbs. NIRS tracings were recorded, analyzed, and correlated with clinical events. Twenty patients were analyzed (median age: 47.5 years): 17 patients were placed on VA-ECMO, and three patients on VV-ECMO. The median duration on ECMO was 7 days (range 2-26). One hundred percent of patients had a significant drop in bilateral cerebral oximetry tracings resulting in hemodynamic interventions, which involved increasing pressure, oxygenation, and/or ECMO flow. In 16 patients (80%), these interventions corrected the underlying ischemia. Four patients (20%) required further diagnostic intervention for persistent decreased bilateral and/or unilateral cerebral oximetry tracings, and were found to have a cerebrovascular accident (CVA). Six (30%) patients had persistent unilateral lower limb oximetry events, which resolved upon placement or replacement of a distal perfusion cannula. No patient was found to have either lower limb ischemia or a CVA with normal NIRS tracings. Use of NIRS with ECMO is important in detecting ischemic cerebral and peripheral vascular events. This allows for potential correction of the underlying process, thus preventing permanent ischemic damage.

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PMID: 22817780 [PubMed - in process]



- Patients analyzed for drop in NIRS tracings below 40 or < 25% from baseline
- 30% persistent unilateral lower limb oximetry events

No lower limb ischemia with normal NIRS tracings

Posterior tibial artery approach



Central VS. peripheral cannulation

The Thoracic and
Cardiovascular Surgeon



Thieme

Thorac Cardiovasc Surg, 2010 Dec;58(8):459-62. Epub 2010 Nov 25.

Peripheral versus central cannulation for extracorporeal membrane oxygenation: a comparison of limb ischemia and transfusion requirements.

Kanji HD, Schulze CJ, Oreopoulos A, Lehr EJ, Wang W, MacArthur RM.

Division of Cardiac Surgery, University of Alberta, Edmonton, Canada. hdkanji@gmail.com

Abstract

BACKGROUND: Extracorporeal membrane oxygenation (ECMO) can be instituted centrally, through the right atrium and ascending aorta, or peripherally, most commonly using the femoral artery and vein. We sought to investigate the impact of the mode of cannulation on the incidence of limb ischemia, perfusion and overall morbidity.

METHODS: A retrospective analysis of 50 consecutive patients over 5 years who underwent ECMO by central or peripheral cannulation was performed.

RESULTS: There was no difference in the incidence of limb ischemia and end-organ perfusion when peripheral and central cannulation cohorts were compared. Central cannulation was associated with a higher incidence of bleeding from the cannulation site (64% vs. 18%, $P = 0.002$), blood product utilization and reoperation (66% vs. 14%, $P < 0.0001$). 30-day mortality was similar in both cohorts (46% peripheral, 50% central, $P = 0.8$).

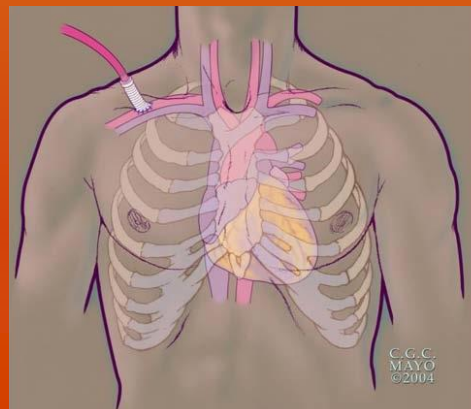
CONCLUSION: Our results suggest that there is comparable tissue perfusion and limb ischemia with both cannulation techniques. Central cannulation is associated with a higher incidence of bleeding, higher transfusion rates, a greater need for reoperation and greater resource utilization. Therefore, peripheral cannulation is safe and may be advantageous in certain clinical scenarios.

© Georg Thieme Verlag KG Stuttgart · New York.

- **No difference in incidence of limb ischemia**
- Central cannulation associated higher incidence of
 - **bleeding from cannulation site** (64% vs 18%, $p=0.02$)
 - **transfusion and reoperation** (66% vs 14%, $p<0.0001$)
- 30-day mortality similar

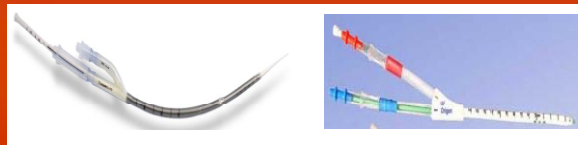
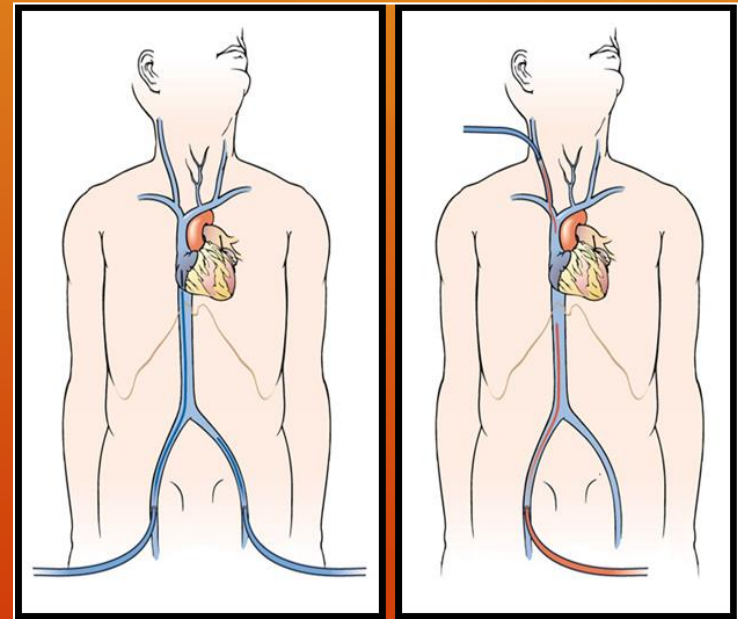
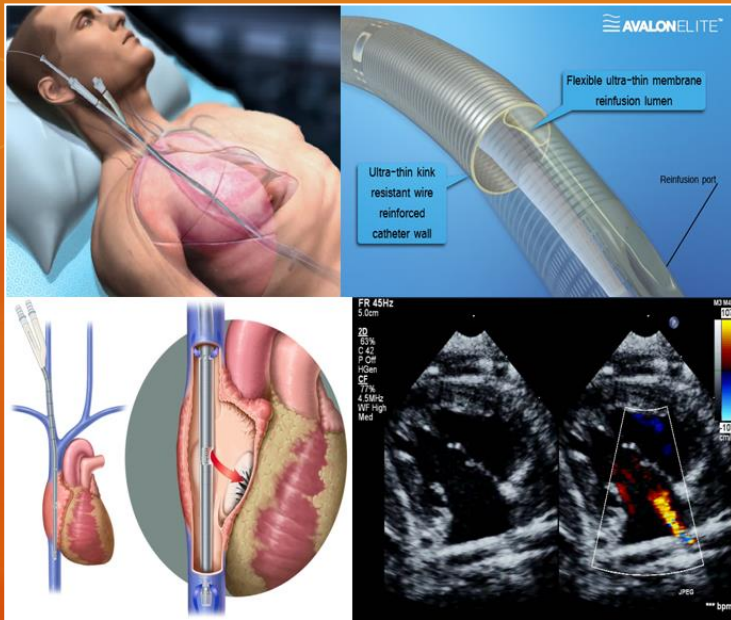
Subclavian Artery Cannulation

- Alternative site for those with peripheral vascular disease, pelvic trauma, promote ambulation
- Side graft cannulation to avoid arm ischemia
- Complications: hematoma, infection, arm swelling



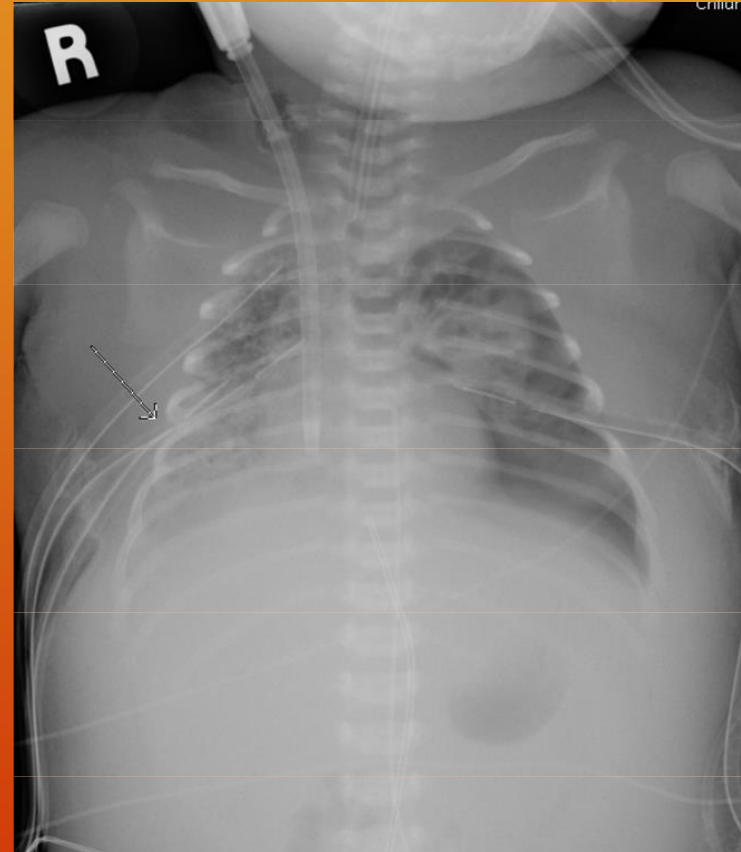
V-V ECMO CANNULATION

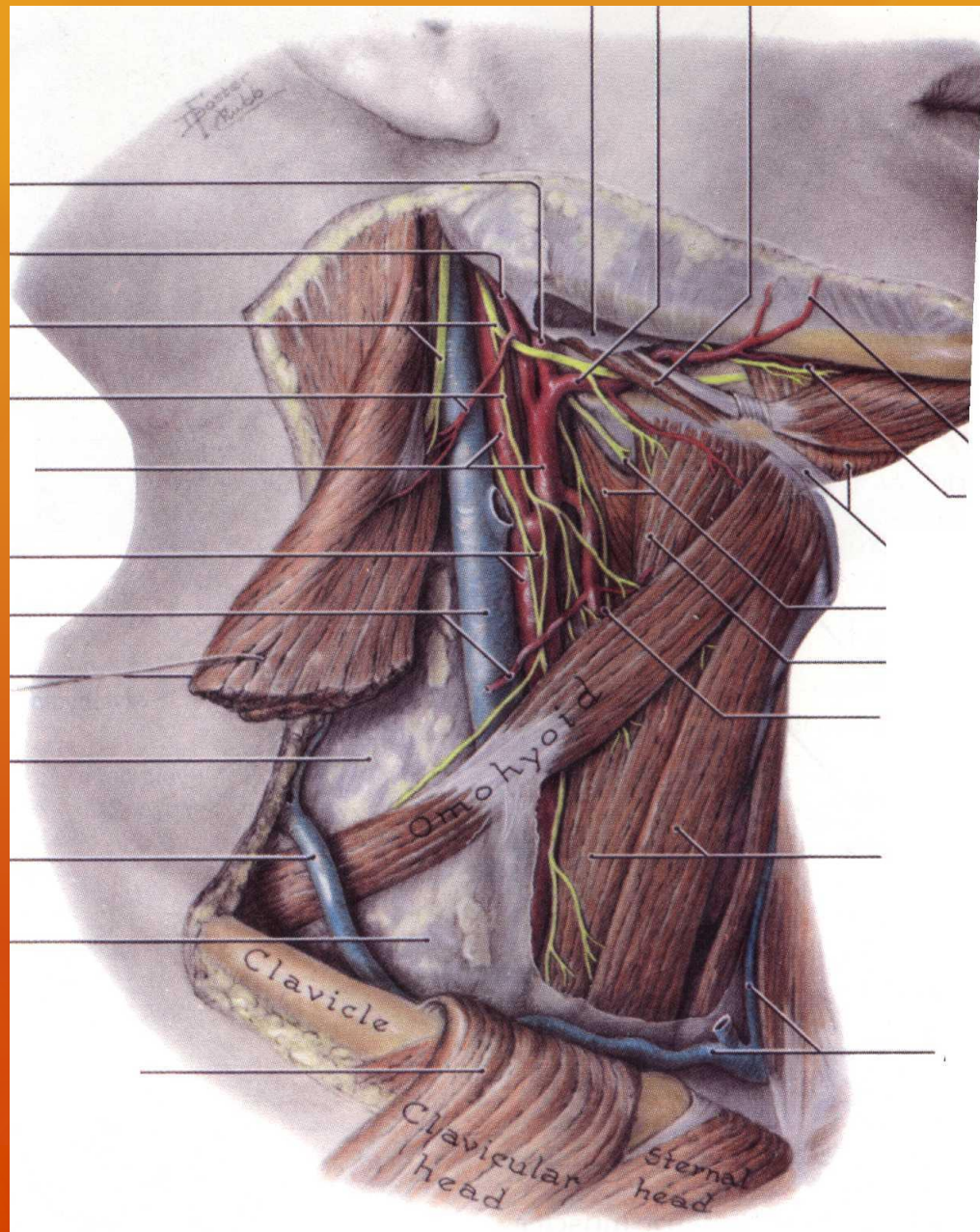
- Consider for all children who do not have cardiac disease or refractory pulmonary hypertension
- Wire reinforced & non-wire reinforced double lumen cannulae



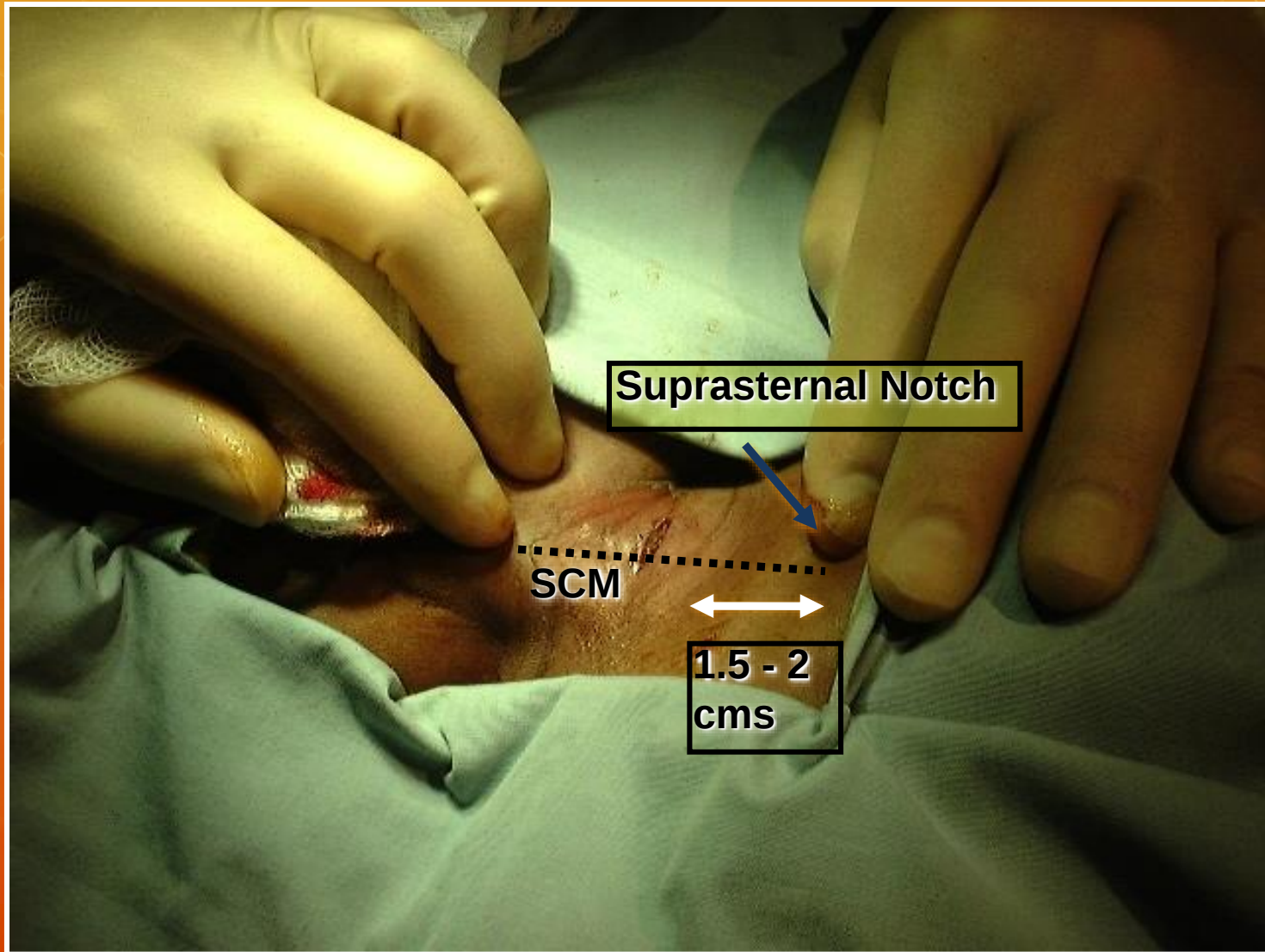
NEONATE V-V CANNULATION

- Double lumen cannula in RIJ
- Femoral vein too small to accommodate cannula
- Non-wire Reinforced DLC
 - Outflow jet directed towards tricuspid valve to reduce recirculation
 - Arterial side up (red lumen) to help direct oxygenated blood towards tricuspid
 - 1cm above diaphragm on CXR





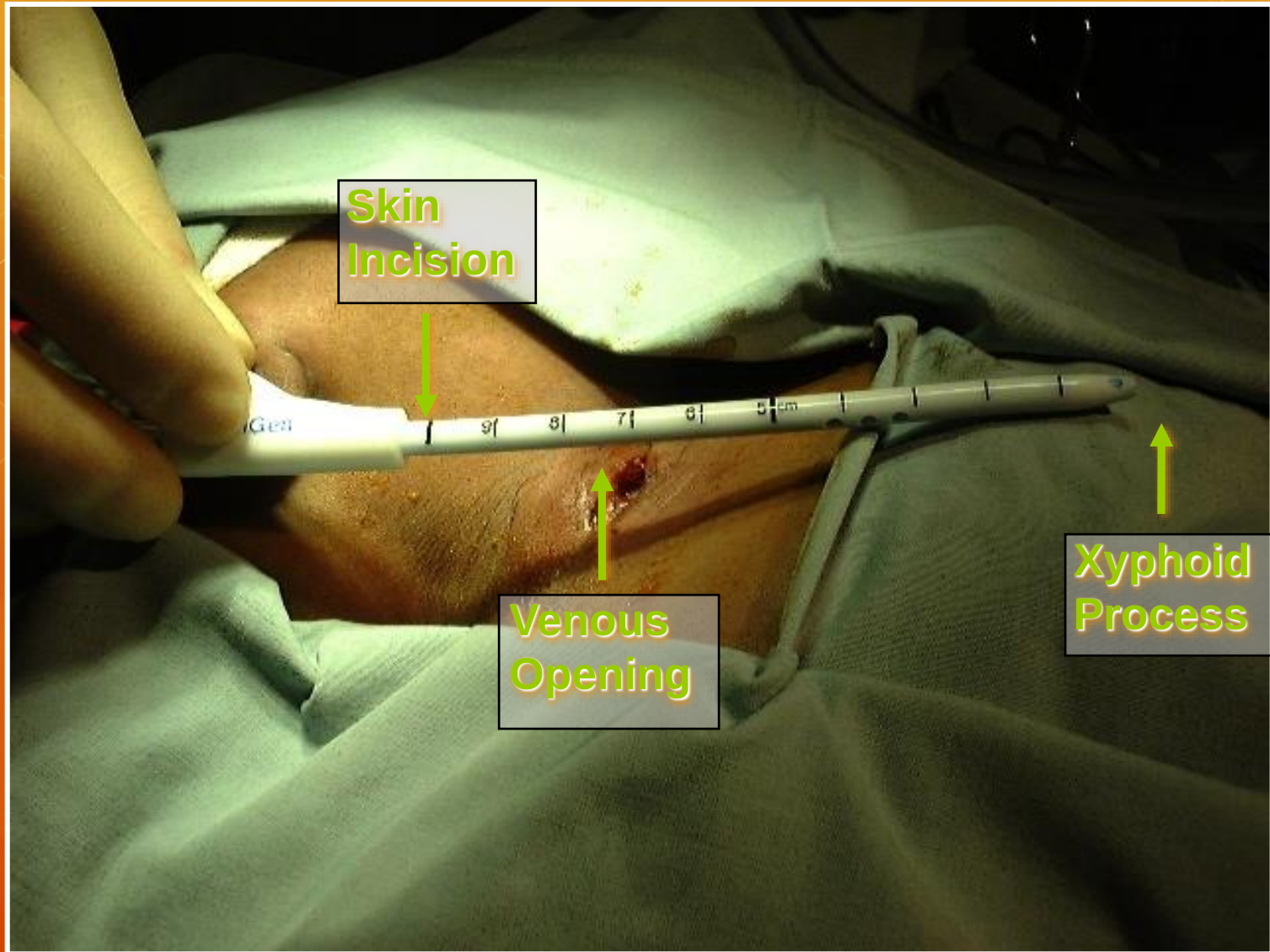
V-V Neck Cannulation



Expose internal jugular vein



Measure length VV cannula

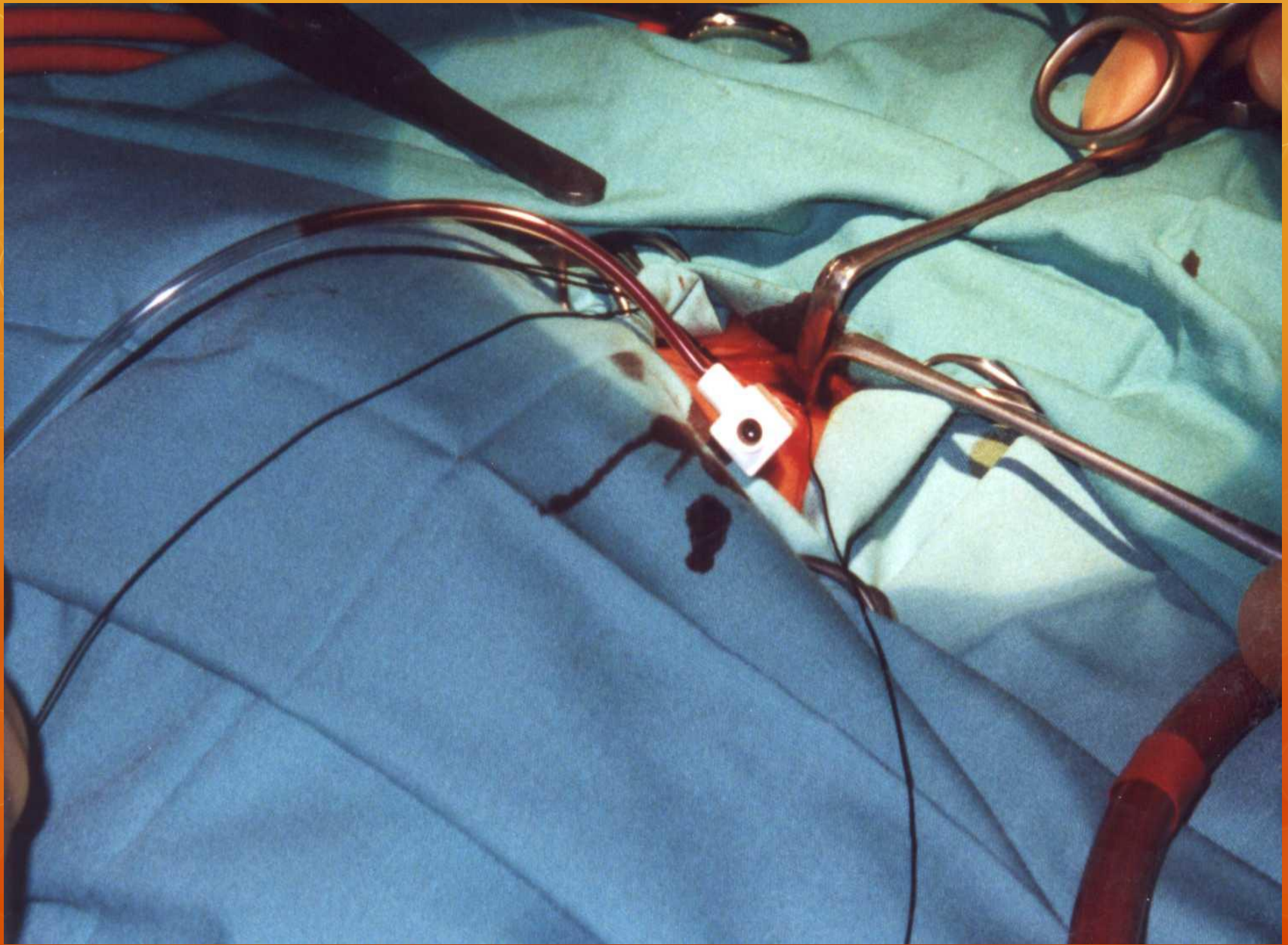


Make puncture incision for cannula

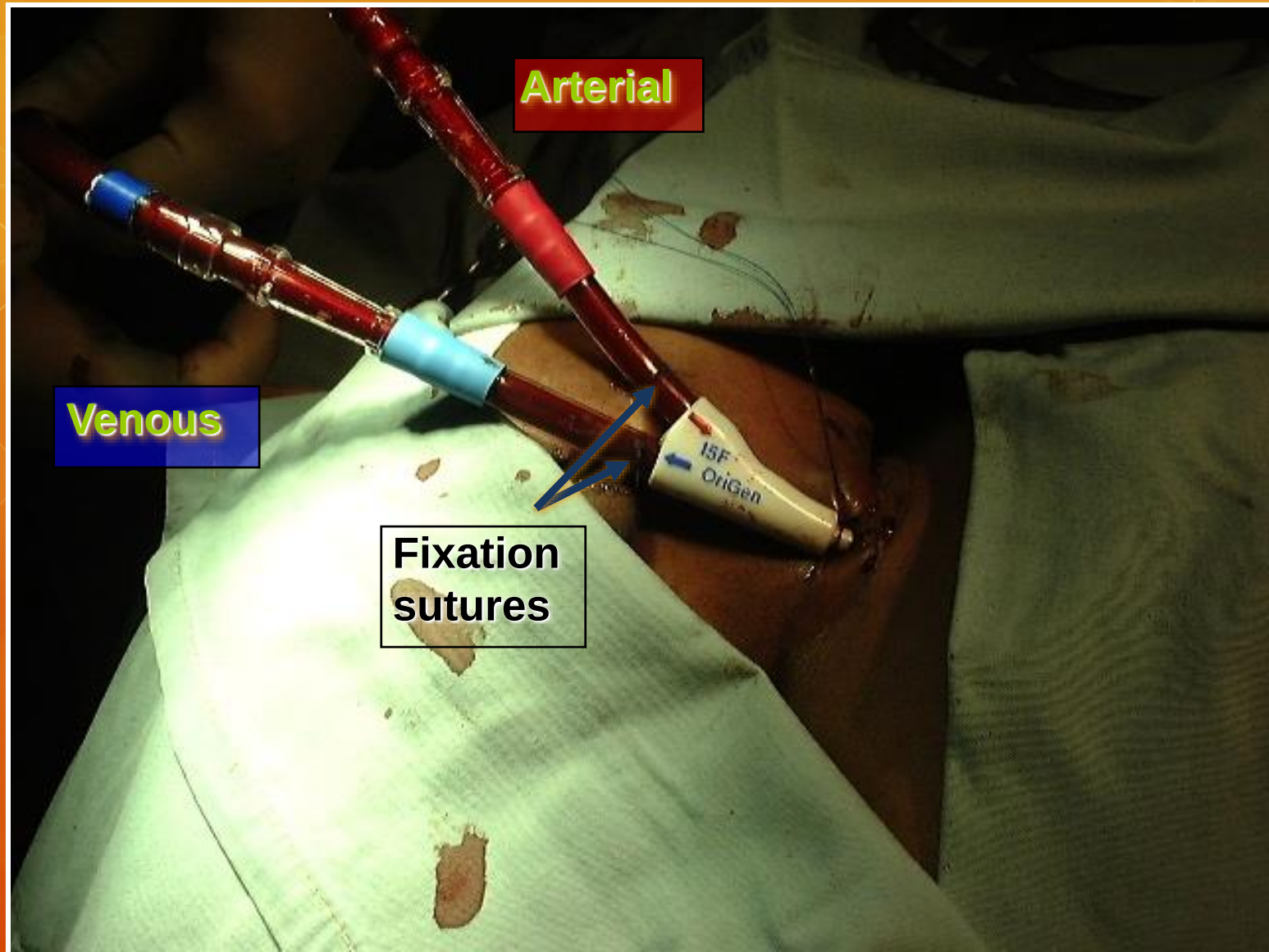


Insert 20 G pink cannula & guide wire

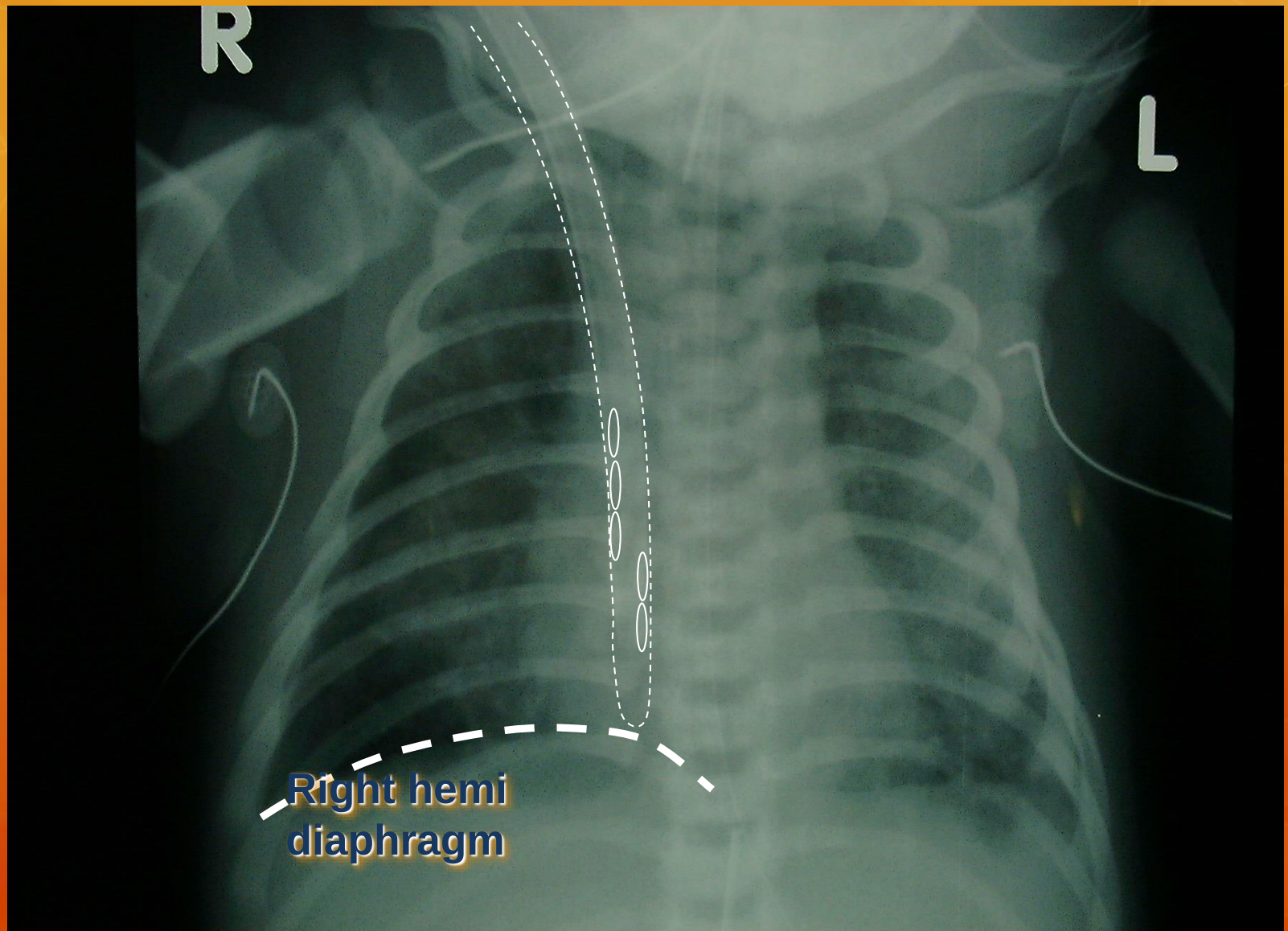








Adequate Cannulae Position - Patient on V-V ECMO



PEDIATRIC V-V CANNULATION

- Double lumen cannula in RIJ preferred
- ■ Alternative femoral vein drainage and R IJ reinfusion



Wire Reinforced Double Lumen VV Cannula

- IJ cannulation
- Should place with image guidance
 - Echocardiogram
 - Fluoroscopy
 - CXR confirmation
- Why place under image guidance?
- Reports of cardiac tamponade & atrial perforation
 - Possibly secondary to cannula characteristics and need for precise location in IVC



ADVANTAGES OF DL VV CANNULA



Unloading in Cardiac ECMO

- Venting catheter
 - Need for separate flow measurement (clamp)
 - High (increasing ?) recirculation fraction
- Rashkind/surgical atrioseptectomy
- IABP
- Impella
 - Technical feasible
 - Case report
- Apical – aorta in LVAD



ANTICOAGULATION AND BEDSIDE POINT OF CARE

- In postcardiotomy: started when no more bleeding from drainage tubes
 - HEPARIN 10-20 U.I./kg/h if no adequate washout of heart cavities
 - AT3 supplementation
 - BIVALIRUDIN 0.3-0.5 MG/KG/HR in all other cases
 - Aspirin 2-5 mg/kg/die
- Coagulation parameters strictly monitored
 - PTT (>65), PT (INR <2.5), Plt's counts (<80000) every 6hr
 - TEG (R >12)/ROTEM (mainly INTEM and FIBTEM) every 8hr

THE ECMO PARADIGM: how, when, why, where (to do...)



•...and not:

- Indication
- Contraindication
- Ethical issue (withdrawal)

•BRIDGE TO DECISION...

- RECOVERY
- OTHER BRIDGE
- TRANSPLANTATION

WHEN

WHY

HOW

WHERE

- Technology
- Implantation procedure
- Coagulation management
- Ventilatory settings

- In-hospital setting
 - ICU
 - OR
 - CATH LAB
 - ER
- «HUB-SPOKE» program

DECISION MAKING PROCESS

- «**how to do**» probably represent the heaviest acknowledgment

BUT...

- «**when and why**» major discriminant in successful outcome:
 - Not all candidates are good candidates,
 - Therapeutic window lies between correct timing (but not prophylactic) and elective weaning (before complication onset)
 - Sometimes weaning means “withdrawal”...(ethical, legal,...)

ECMO OUTCOME IN ELSO REGISTRY

(1989-2010)

	Total	Surv ECLS	Surv to DC
<i>Neonatal</i>			
Respiratory	23 558	19 964 (85%)	17 720 (75%)
Cardiac	3 909	2 338 (60%)	1 515 (39%)
ECPR	537	340 (63%)	203 (38%)
<i>Pediatric</i>			
Respiratory	4 376	2 831 (65%)	2 431 (56%)
Cardiac	4 776	2 995 (63%)	2 250 (47%)
ECPR	1 003	528 (53%)	387 (39%)
<i>Adult</i>			
Respiratory	1 860	1 140 (61%)	968 (52%)
Cardiac	1 131	541 (48%)	379 (34%)
ECPR	408	147 (36%)	109 (27%)
Total	41 558	30 824 (74%)	25 962 (62%)

RCT's in respiratory ECMO

Health Technol Assess. 2010 Jul;14(35):1-46. doi: 10.3310/hta14350.

Randomised controlled trial and parallel economic evaluation of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR).

Peek GJ, Elbourne D, Mugford M, Tiruvoipati R, Wilson A, Allen E, Clemens F, Firmin R, Hardy P, Hibbert C, Jones N, Killer H, Thalanany M, Truesdale A.

Department of Cardiothoracic Surgery, Glenfield Hospital, Leicester, UK.

Abstract

OBJECTIVES: To determine the comparative effectiveness and cost-effectiveness of conventional ventilatory support versus extracorporeal membrane oxygenation (ECMO) for severe adult respiratory failure.

DESIGN: A multicentre, randomised controlled trial with two arms.

SETTING: The ECMO centre at Glenfield Hospital, Leicester, and approved conventional treatment centres and referring hospitals throughout the UK.

PARTICIPANTS: Patients aged 18-65 years with severe, but potentially reversible, respiratory failure, defined as a Murray lung injury score $> = 3.0$, or uncompensated hypercapnoea with a pH < 7.20 despite optimal conventional treatment.

INTERVENTIONS: Participants were randomised to conventional management (CM) or to consideration of ECMO.

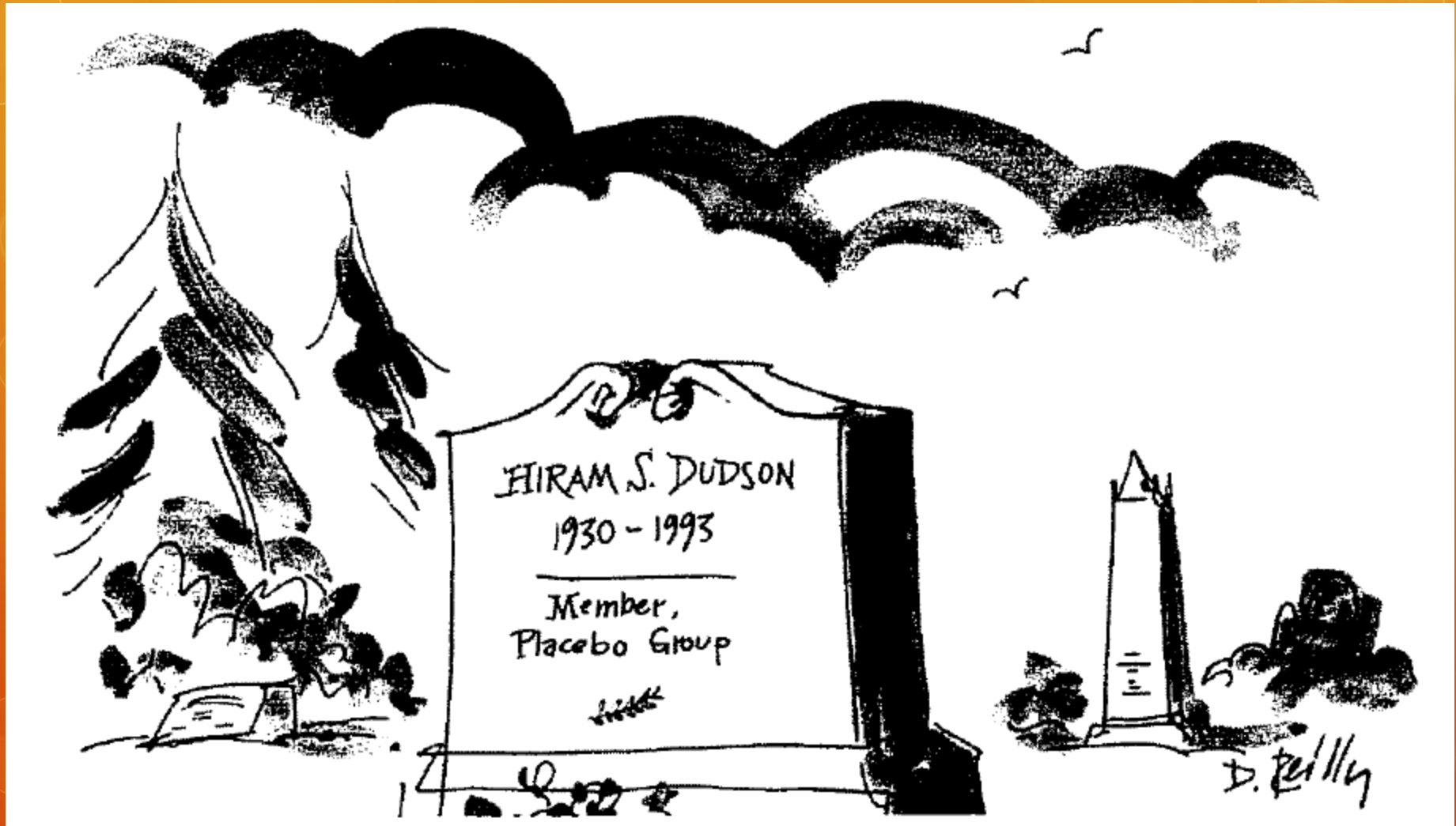
MAIN OUTCOME MEASURES: The primary outcome measure was death or severe disability at 6 months. Secondary outcomes included a range of hospital indices: duration of ventilation, use of high frequency/oscillation/jet ventilation, use of nitric oxide, prone positioning, use of steroids, length of intensive care unit stay, and length of hospital stay - and (for ECMO patients only) mode (venovenous/veno-arterial), duration of ECMO, blood flow and sweep flow.

RESULTS: A total of 180 patients (90 in each arm) were randomised from 68 centres. Three patients in the conventional arm did not give permission to be followed up. Of the 90 patients randomised to the ECMO arm, 68 received that treatment. ECMO was not given to three patients who died prior to transfer, two who died in transit, 16 who improved with conventional treatment given by the ECMO team and one who required amputation and could not therefore be heparinised. Ninety patients entered the CM (control) arm, three patients later withdrew and refused follow-up (meaning that they were alive), leaving 87 patients for whom primary outcome measures were available. CM consisted of any treatment deemed appropriate by the patient's intensivist with the exception of extracorporeal gas exchange. No CM patients received ECMO, although one received a form of experimental extracorporeal arteriovenous carbon dioxide removal support (a clear protocol violation). Fewer patients in the ECMO arm than in the CM arm had died or were severely disabled 6 months after randomisation, [33/90 (36.7%) versus 46/87 (52.9%) respectively]. This equated to one extra survivor for every six patients treated. Only one patient (in the CM arm) was known to be severely disabled at 6 months. Patients allocated to ECMO incurred average total costs of 73,979 pounds compared with 33,435 pounds for those undergoing CM (UK prices, 2005). A lifetime model predicted the cost per quality-adjusted life-year (QALY) of ECMO to be 19,252 pounds (95% confidence interval 7622 pounds to 59,200 pounds) at a discount rate of 3.5%. Lifetime QALYs gained were 10.75 for the ECMO group compared with 7.31 for the conventional group. Costs to patients and their relatives, including out of pocket and time costs, were higher for patients allocated to ECMO.

CONCLUSIONS: Compared with CM, transferring adult patients with severe but potentially reversible respiratory failure to a single centre specialising in the treatment of severe respiratory failure for consideration of ECMO significantly increased survival without severe disability. Use of ECMO in this way is likely to be cost-effective when compared with other technologies currently competing for health resources.

TRIAL REGISTRATION: Current Controlled Trials ISRCTN47279827.

No large RCT's in cardiac ECMO



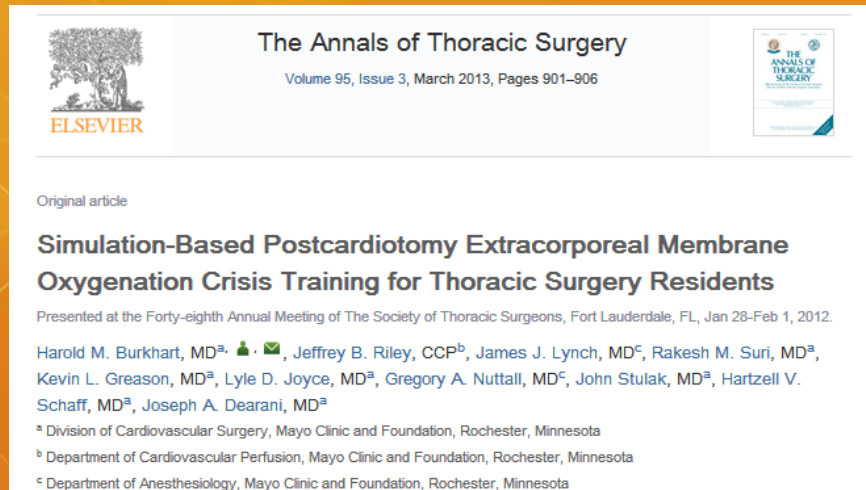
No one happy to be volunteers in the control group!!!

ECMO

NEW TRAINING PROCESS



ECMO program: really mandatory?



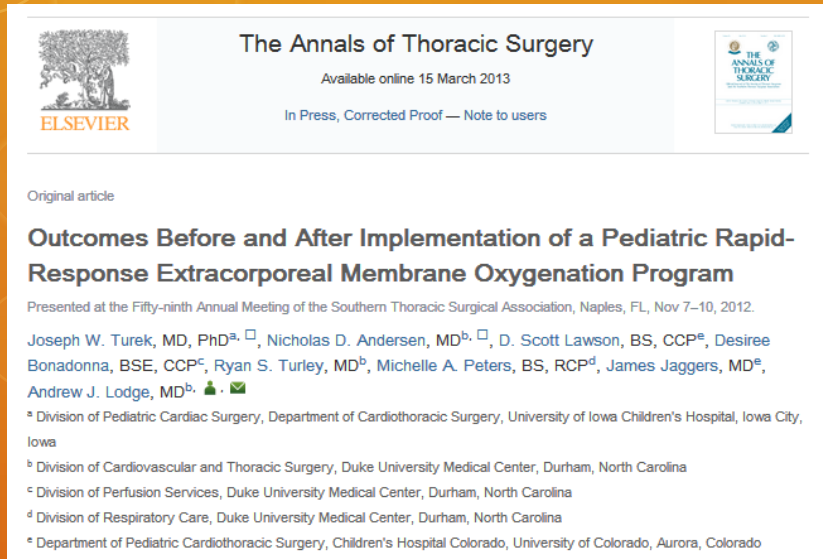
○ MAYO Clinic and Foundation, Rochester, Minnesota

○ They concluded:

*"...We developed a **simulation-based postcardiotomy ECMO training program** that resulted in improved ECMO confidence in thoracic surgery residents.*

Crisis management in a simulated environment enabled residents to acquire technical and behavioral skills that are important in managing critical ECMO-related problems."

ECMO program: really mandatory?



- The peak performance of the ECMO team was assessed by measuring ECMO initiation times for the ECPR patient subgroup.
- shift toward more ECPR initiations achieved in less than 40 minutes (24% pre-RR-ECMO versus 43% RR-ECMO; $p = 0.25$)
- fewer requiring more than 60 minutes (47% pre-RR-ECMO versus 21% RR-ECMO; $p = 0.14$)
- After multivariable risk adjustment, RR-ECMO was associated with a 52% reduction in neurologic complications for all patients (adjusted odds ratio, 0.48; 95% confidence interval, 0.23 to 0.98; $p = 0.04$)
- risk of in-hospital death remained unchanged (adjusted odds ratio, 0.99; 95% confidence interval, 0.50 to 1.99; $p = 0.99$).

○ They concluded:

“Implementation of a **pediatric RR-ECMO program** for veno-arterial ECMO initiation was associated with reduced neurologic complications but not improved survival during the first 3 years of program implementation...

...development of a coordinated system for rapid ECMO deployment may benefit both ECPR and non-ECPR patients, but further efforts are required to improve survival.”

ECMO program: really mandatory?

Artificial Organs

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Evolution of Technology, Establishment of Program, and Clinical Outcomes in Pediatric Extracorporeal Membrane Oxygenation: The “SickKids” Experience

*§Yasuhiro Kotani, *§Osami Honjo, †§Lisa Davey, *§Devin Chetan,
‡Anne-Marie Guerguerian, and †§Colleen Gruenwald

Divisions of *Cardiovascular Surgery, †Cardiovascular Perfusion, ‡Critical Care Medicine, and §The Labatt Family Heart Centre, The Hospital for Sick Children, University of Toronto, Toronto, Ontario, Canada

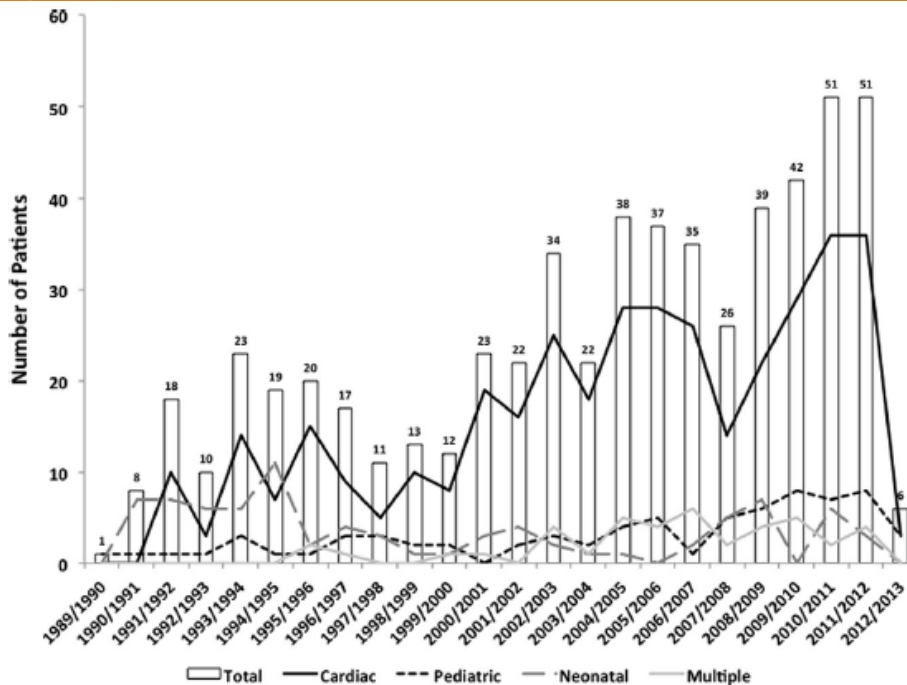


FIG. 2. ECMO runs from January 1989 to June 2012 by fiscal year at The Hospital for Sick Children. Five hundred seventy-six runs were performed in 534 patients. The bars show the total number of ECMO runs. The lines show the subcategorization of ECMO runs.

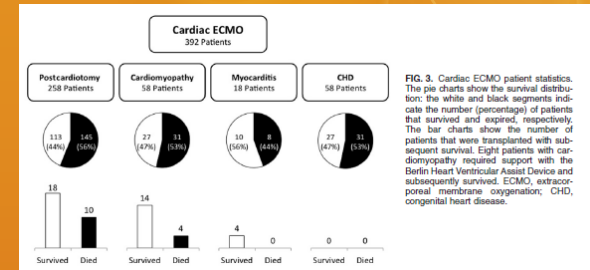


FIG. 3. Cardiac ECMO patient statistics. The pie charts show the survival distribution: the white and black segments indicate the number (percentage) of patients that survived and expired, respectively. The bar charts show the number of patients that were transplanted with subsequent survival. Eight patients with cardiomyopathy required support with the Berlin Heart Ventricular Assist Device and subsequently survived. ECMO, extracorporeal membrane oxygenation; CHD, congenital heart disease.

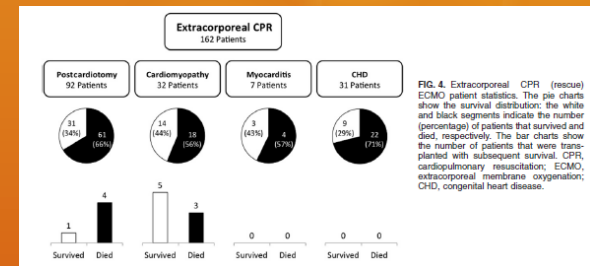


FIG. 4. Extracorporeal CPR (rescue) ECMO patient statistics. The pie charts show the survival distribution: the white and black segments indicate the number (percentage) of patients that survived and died, respectively. The bar charts show the number of patients that were transplanted with subsequent survival. CPR, cardiopulmonary resuscitation; ECMO, extracorporeal membrane oxygenation; CHD, congenital heart disease.

TABLE 1. ECLS/AT leadership committee

ECLS/AT medical director, PICU (cochair)
Perfusion/ECLS/AT director (cochair)
ECLS/AT coordinator
ECLS/AT clinician educator
VAD program medical director, CCCU
Cardiovascular surgeon
PICU senior manager
CCCU senior manager
Respiratory therapy director
ECLS/AT ECMO specialist (1-RRT and 1-RN)
Biomedical engineer specialized in ECLS
Additional resources will be invited as required (i.e., pharmacy, social work)

ECLS, extracorporeal life support; PICU, pediatric intensive care unit; AT, advanced technologies; VAD, ventricular assist device; CCCU, cardiac critical care unit; RRT, registered respiratory therapist; RN, registered nurse.

TABLE 2. Complications during extracorporeal membrane oxygenation

	Cardiac	Pediatric	Neonatal	Total
Mechanical	85 (4.94%)	39 (11.34%)	34 (6.54%)	158 (6.11%)
Hemorrhagic	150 (13.95%)	35 (16.28%)	38 (11.69%)	223 (13.81%)
Neurologic	39 (3.63%)	13 (6.05%)	13 (4.00%)	65 (4.02%)
Renal	106 (9.86%)	26 (12.09%)	39 (12.00%)	171 (10.59%)
Cardiovascular	136 (7.03%)	24 (6.20%)	18 (3.08%)	178 (6.12%)
Pulmonary	24 (5.58%)	15 (17.44%)	6 (4.62%)	45 (6.97%)
Infectious	16 (7.44%)	13 (6.98%)	3 (4.62%)	22 (6.81%)
Metabolic	32 (2.98%)	10 (4.65%)	7 (2.15%)	49 (3.03%)

Cardiac: all patients who had cardiac support. Pediatric: children (>1 month old) who had support for any issues other than heart disease. Neonatal: neonates (<1 month) who had support for any issues other than heart disease.

Once you decide for a Program, who should refer to?

Who is "*the Gold Standard*"?



ELSO Guidelines for ECMO Specialist

Provides centers with physical and personnel attributes needed to safely provide ECMO

ELSO Guidelines for ECMO Centers

valuable information for new and experienced ECMO centers regarding the training and continuing education of the bedside ECMO specialist

These Guidelines refer to the US experience and may differ from each one own country:

It is assumed that each ECMO center must develop their institution specific guidelines and policies.

ECMO CENTERS

- A. Located in tertiary hospitals with a tertiary level Intensive Care Unit (Neonatal, Pediatric and/or Adult).
- B. Located in geographic area that can support a minimum of 6 ECMO patients per center per year.

**fewer than 6 cases/Y strongly associated
with loss/lack of clinical expertise**

**take into account when developing a new
program!!!**

- C. actively involved in ELSO and the ELSO Registry.

ECMO CENTER: General Structure

- ECMO UNIT (full and exclusively dedicated)

Or

- ECMO TEAM (staff normally involved in routinely ICU/OR activity, with special education and high expertized/experienced in ECMO procedures)?

- consider

1. Volume of treated patients
2. Width of reference area
3. Administration policy

ECMO CENTER: staffing issue

ECMO PROGRAM Director

1. assuring specialist training and performance,
2. directing quality improvement meetings and projects,
3. assuring submission to ELSO,
4. credentialing of other physicians who care for ECMO patients or who manage the ECMO circuit.

ECMO coordinator

1. supervision and training of technical staff,
2. maintenance of equipment,
3. collection of patient data.

ECMO Team should have

- quality assurance procedures for annual ECMO evaluation internally.
- Formal Policy and Procedures outlining
 - the indications and contraindications,
 - clinical management,
 - maintenance of equipment,
 - termination of ECMO therapy,
 - follow-up of the ECMO patient
- Simulation lab for training and continuing medical education should be available

Staffing Issues: educational background

- The ECMO medical director should be a board certified
 - Neonatologist,
 - critical-care specialist,
 - pediatric, cardiovascular, thoracic surgeon with specific training and experience in ECMO support.

- The ECMO coordinator may be an
 - experienced neonatal, pediatric, or adult intensive care registered nurse,
 - registered respiratory therapist with a strong ICU background (minimum of 1 year of ICU experience),
 - a certified clinical perfusionist with ECMO experience.

Staffing Issues: educational background

The ECMO Specialist

- strong intensive care background (at least 1 year of NICU, PICU, MICU, CCU)
- attained one of the following:
 - school of nursing by the Board of Nursing for that state;
 - school of respiratory therapy and be recognized as a Registered Respiratory Therapist (RRT) by the National Board of Respiratory Care (NBRC).
 - school of perfusion and national certification through the American Board of Cardiovascular Perfusion (ABCP).
 - Physicians trained in ECMO who have successfully completed institutional training requirements for the clinical specialists.
 - Other medical personnel such as biomedical engineers or technicians who received specific ECMO training and have practiced as an ECMO specialist (equivalent training approved specifically as an ECMO specialist by the medical director)

Staffing Issues

- An ECMO-trained physician will provide 24-hour on-call coverage for the ECMO patient.
- An ECMO specialist should provide 1:1 or 1:2 care throughout the course of ECMO.
- In clinical settings where the ECMO patient is primarily managed by the ICU nurse (**the single care giver model**)
 - specifically trained in ECMO patient and circuit management.
 - approved by the program director.

Staffing Issues

- Physicians or other medical personnel:
 - Pediatric/adult cardiology
 - Pediatric/adult cardiovascular surgery
 - Pediatric/general surgery
 - Cardiovascular perfusion
 - Pediatric/adult anesthesiology
 - Pediatric/adult neurosurgery
 - Pediatric/general radiology
 - Genetics
- Biomedical engineer
- Respiratory therapists experienced in intensive care (in USA)

- The following consultants should be available as needed.
 - Pediatric/adult neurology
 - Pediatric/adult nephrology
 - Occupational/physical therapist
 - Developmental/rehabilitation specialist
- A fully trained and equipped transport team should be available 24 hours a day.
- a well-defined developmental follow-up program for the ECMO patient

Physical Facilities and Equipment

ECMO should be located inside the ICU:

- 2 full loaded ECMO system (one wet)
- A point of care anticoagulation lab (ACT, TEG, ROTEM or other bedside equipment)

○ readily available close to the ECMO location:

- Backup components of the ECMO system and supplies for all circuit components.
- Adequate lighting to support surgical interventions.
- Surgical instrument set for revision of cannulae or exploration for bleeding complications.

Physical Facilities and Equipment

- The following support facilities with staff should be available on a 24-hour basis.
 - a. A blood gas/blood chemistry and hematologic testing lab
 - c. Blood bank
 - d. X-Ray, CT-scan and Cath-lab support
 - e. Cardiovascular OR facilities with St-by CPB availability

Program Evaluation

1. Formal meetings of key ECMO team members occurs on a routine basis
 1. to review cases,
 2. equipment needs,
 3. administrative needs.

Minutes to these meetings should be available for review.

2. A prompt review of any major complication or death
 - ECMO team members
 - Morbidity and Mortality committee in the hospital.
3. Formal clinical-pathological case reviews with a multi-disciplinary approach should be regularly conducted.
4. An Annual Data Report, utilizing the center's collated data or data submitted to the ELSO Registry, should be available for quality assurance review.

"ELSO GUIDELINES FOR TRAINING AND CONTINUING EDUCATION OF ECMO SPECIALISTS"

- Developed by ELSO
 - reference for current and future ECMO centers.
 - guideline for designing training and education programs for ECMO specialists.
- each ECMO center must develop institution specific guidelines and policies for training ECMO Specialists.

TRAINING PROGRAMS:

- **New ECMO programs:** centers which have not treated patients;
- **Experienced ECMO programs:** centers which have been in ongoing operation and are training new ECMO specialists.

TRAINING OUTLINE: NEW ECMO PROGRAM

A. Didactic Course:

- Between 24 to 36 hours will be required to cover the following material.
- Case presentations are encouraged.
- Topics should include the following

- ***Introduction to ECMO***
- ***Physiology of the diseases treated with ECMO***
- ***Pre ECMO Procedures***
- ***Criteria and contraindications for ECMO***
- ***Physiology of coagulation***
- ***ECMO equipment***
- ***Physiology of Venoarterial and Venovenous ECMO***
- ***Daily Patient and Circuit management on ECMO***

- ***Emergencies and complications during ECMO***
- ***Management of complex ECMO cases***
- ***Weaning from ECMO (techniques and complications)***
- ***Decannulation procedures***
- ***Post ECMO complications***
- ***Short and long-term developmental outcome of ECMO patients***
- ***Ethical and social issues***

TRAINING OUTLINE: NEW ECMO PROGRAM

B. Water-drills: small sessions for individual “hands-on” experience.

- circuit emergencies and the appropriate intervention.
- describe and conceptually demonstrate how to change the major equipment.
- able to change less complicated components of the circuit (raceway, pigtails, and checking pump head occlusion on ECMO) in a pre-established period of time.

C. Animal Laboratory Sessions:

- As bedside training sessions are not possible in a new ECMO center, more extensive laboratory training is required compared to an experienced center.

TRAINING OUTLINE: NEW ECMO PROGRAM

- **Basic Session should include** a discussion and demonstration of the equipment including:
 - Review of Circuit configuration and function
 - Access and sample ports to the circuit
 - “The basic circuit check”
 - Basic troubleshooting
 - Pigtail and stopcock changes
- • **Emergency Session, should include** training in the management of:
 - Raceway ruptures
 - Heat exchanger, bladder, membrane lung changes (assist with procedure only)
 - Venous/arterial air
 - Pump head occlusion checks
 - Power failure
 - Inadvertent decannulation

TRAINING OUTLINE: EXPERIENCED CENTER

A. Didactic Sessions - as above

B. Water-drills - as above

C. Animal Sessions: not required for experienced centers, but useful.

D. Bedside Training:

- 16-32 hours in 8 or 12-hour shifts.
- The preceptor should be an experienced specialist.

EVALUATION AND INSTITUTIONAL CERTIFICATION

ECMO specialist should meet:

- A. Written Evaluation:** skills and competence during ECMO training course (attendance, water-drills, animal lab sessions and examinations).
- B. Written/Oral Exam:** didactic and laboratory sessions.
- C. Institutional Certification:** granted after successful completion of the ECMO training course and successfully passing the oral and/or written exam.

CONTINUING EDUCATION

A. Formal team meetings:

- Case reviews
- Updates on ECMO therapy
- Quality assurance review
- Review of ECMO policy and procedures
- Administrative information
- Frequency based on Team size and the volume of ECMO. Attendance monitored.

○ Water-drills:

- held periodically throughout the year (every six months is recommended as a minimum)
- interval should be based on volume of ECMO

B. Annual examination

C. Minimum number of hours of pump time:

- minimum amount of pump time to maintain competency.
- Re-training should be undertaken if this standard is not met.

So, to sum up...

- Extra Corporeal Membrane Oxygenation
 - Provides cardiopulmonary support in adults and peds as a BRIDGE TO DECISION
 - Its usage has been improved, particularly as circulatory support in heart failure (chronic and acute, ECPR)
 - Technology, protocols and procedures lead to plan easier, longer, better outcome and less morbidity ECMO
 - Results, even partially unsatisfactory and controversial, suggest it's the right way for a population of patient that conversely would has not any other option...

THANK YOU