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OIRPOSDRU REGIUNEA CENTRU

UNIVERSITATEA DE MEDICINĂ ŞI
FARMACIE "CAROL DAVILA"
BUCUREŞTI

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

Data: **12-11-2015**

MODUL TEORETIC

ECMO program

Imputernicit: Prof. Dr. Tammam Youssef

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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

ECMO 3.0

NEW TRAINING PROCESS

ECMO program: really mandatory?

The Annals of Thoracic Surgery
Volume 95, Issue 3, March 2013, Pages 901–906

Original article

Simulation-Based Postcardiotomy Extracorporeal Membrane Oxygenation Crisis Training for Thoracic Surgery Residents

Presented at the Forty-eighth Annual Meeting of The Society of Thoracic Surgeons, Fort Lauderdale, FL, Jan 28-Feb 1, 2012.

Harold M. Burkhart, MD[a], Jeffrey B. Riley, CCP[b], James J. Lynch, MD[c], Rakesh M. Suri, MD[a], Kevin L. Greason, MD[a], Lyle D. Joyce, MD[a], Gregory A. Nuttall, MD[c], John Stulak, MD[a], Hartzell V. Schaff, MD[a], Joseph A. Dearani, MD[a]

[a] Division of Cardiovascular Surgery, Mayo Clinic and Foundation, Rochester, Minnesota

[b] Department of Cardiovascular Perfusion, Mayo Clinic and Foundation, Rochester, Minnesota

[c] Department of Anesthesiology, Mayo Clinic and Foundation, Rochester, Minnesota

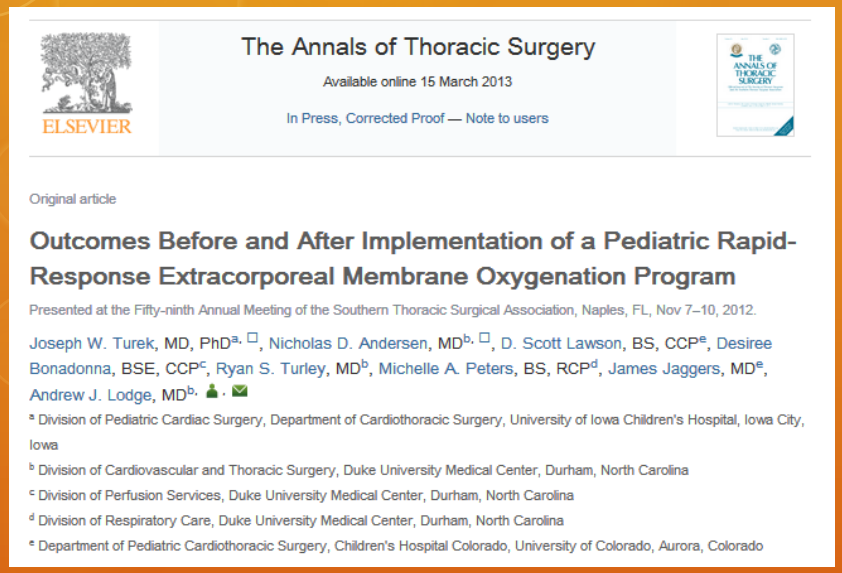
- **MAYO Clinic and Foundation, Rochester, Minnesota**

- 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 Annals of Thoracic Surgery

Available online 15 March 2013

In Press, Corrected Proof — Note to users

Original article

Outcomes Before and After Implementation of a Pediatric Rapid-Response Extracorporeal Membrane Oxygenation Program

Presented at the Fifty-ninth Annual Meeting of the Southern Thoracic Surgical Association, Naples, FL, Nov 7–10, 2012.

Joseph W. Turek, MD, PhD[a], Nicholas D. Andersen, MD[b], D. Scott Lawson, BS, CCP[e], Desiree Bonadonna, BSE, CCP[c], Ryan S. Turley, MD[b], Michelle A. Peters, BS, RCP[d], James Jaggers, MD[e], Andrew J. Lodge, MD[b]

[a] Division of Pediatric Cardiac Surgery, Department of Cardiothoracic Surgery, University of Iowa Children's Hospital, Iowa City, Iowa

[b] Division of Cardiovascular and Thoracic Surgery, Duke University Medical Center, Durham, North Carolina

[c] Division of Perfusion Services, Duke University Medical Center, Durham, North Carolina

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[e] Department of Pediatric Cardiothoracic Surgery, Children's Hospital Colorado, University of Colorado, Aurora, Colorado

- 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

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*

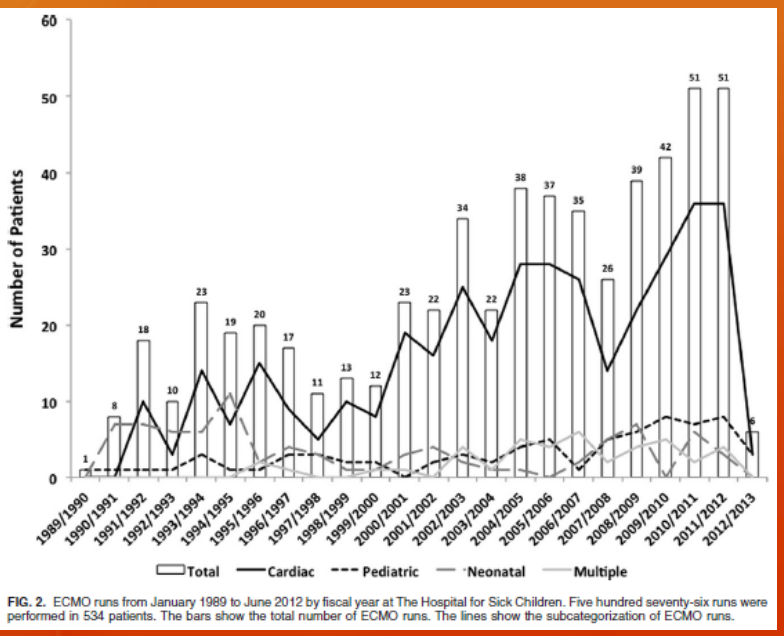

FIG. 2. ECMO runs from January 1989 to June 2012 by fiscal year at The Hospital for Sick Children. Five hundred seventy-six runs were performed in 534 patients. The bars show the total number of ECMO runs. The lines show the subcategorization of ECMO runs.

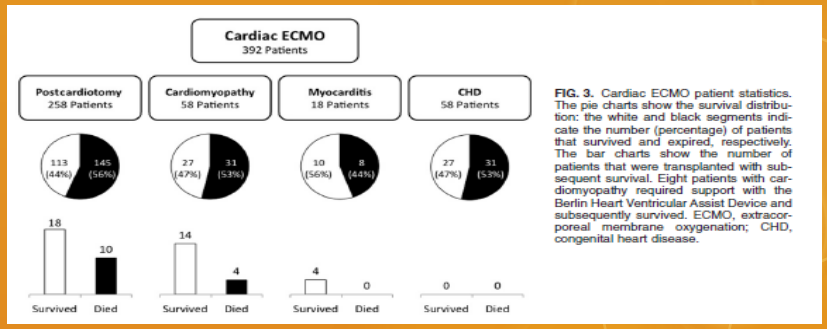

FIG. 3. Cardiac ECMO patient statistics. The pie charts show the survival distribution: the white and black segments indicate the number (percentage) of patients that survived and expired, respectively. The bar charts show the number of patients that were transplanted with subsequent survival. Eight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

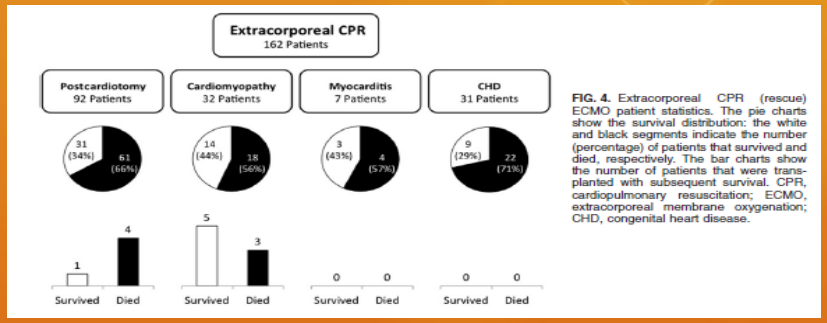

FIG. 4. Extracorporeal CPR (rescue) ECMO patient statistics. The pie charts show the survival distribution: the white and black segments indicate the number (percentage) of patients that survived and died, respectively. The bar charts show the number of patients that were transplanted with subsequent 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 normaly involved in routinarly 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 NON 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 US)

- 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 efficiency evaluation

1. Formal meetings of key ECMO team members occurs on a routine basis to review
    1. 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.