Experience with Low Flow ECCO2R device on a CRRT platform : CO2 removal

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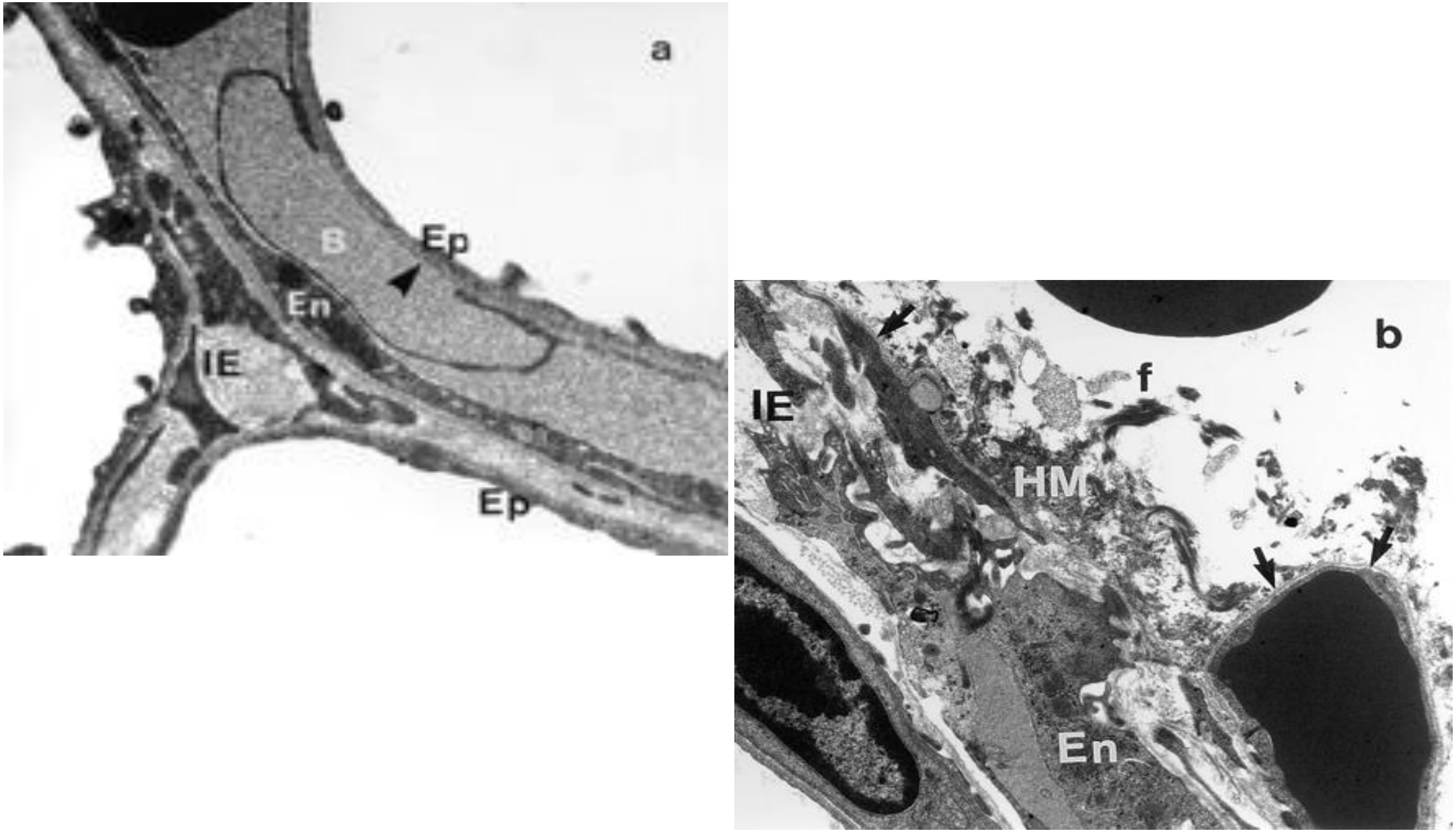
Conflict of interest

- Principal Investigator: EOLIA trial
  - VV ECMO in ARDS
  - NCT01470703
  - Sponsored by MAQUET, Getinge Group
- Received honoraria from
  - MAQUET, XENIOS, GAMBRO/BAXTER, ALUNG

The rationale of ECCO2R…
For ARDS patients…

The goods and the bads of MV in patients with ARDS…

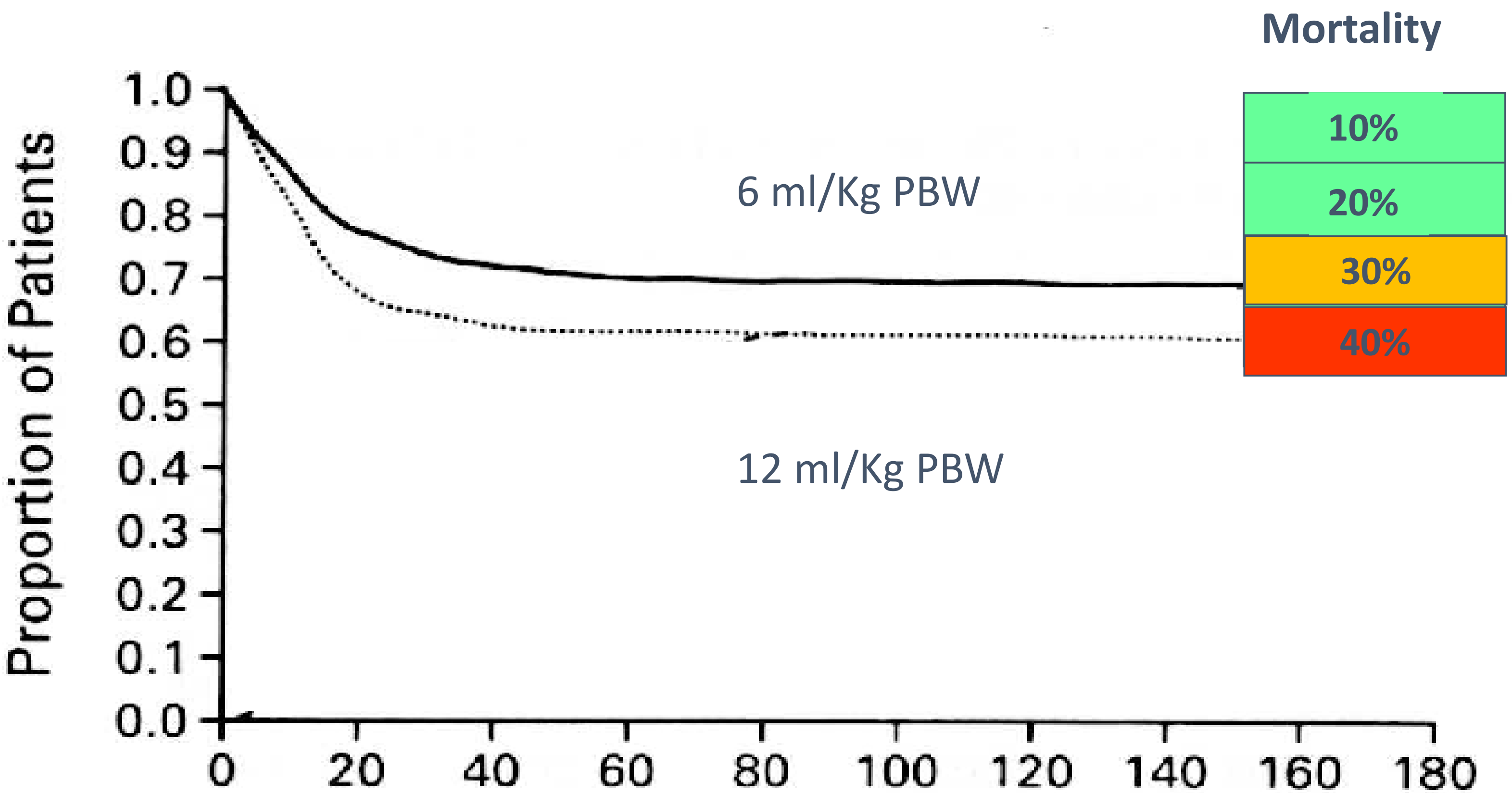
- MV harms the respiratory system
- Ventilator-Induced Lung Injury
  - *Pressure*
  - *Volume*
  - *Respiratory Rate*



Dreyfuss D & Saumon G. AJRCCM 1998; 157: 294-323

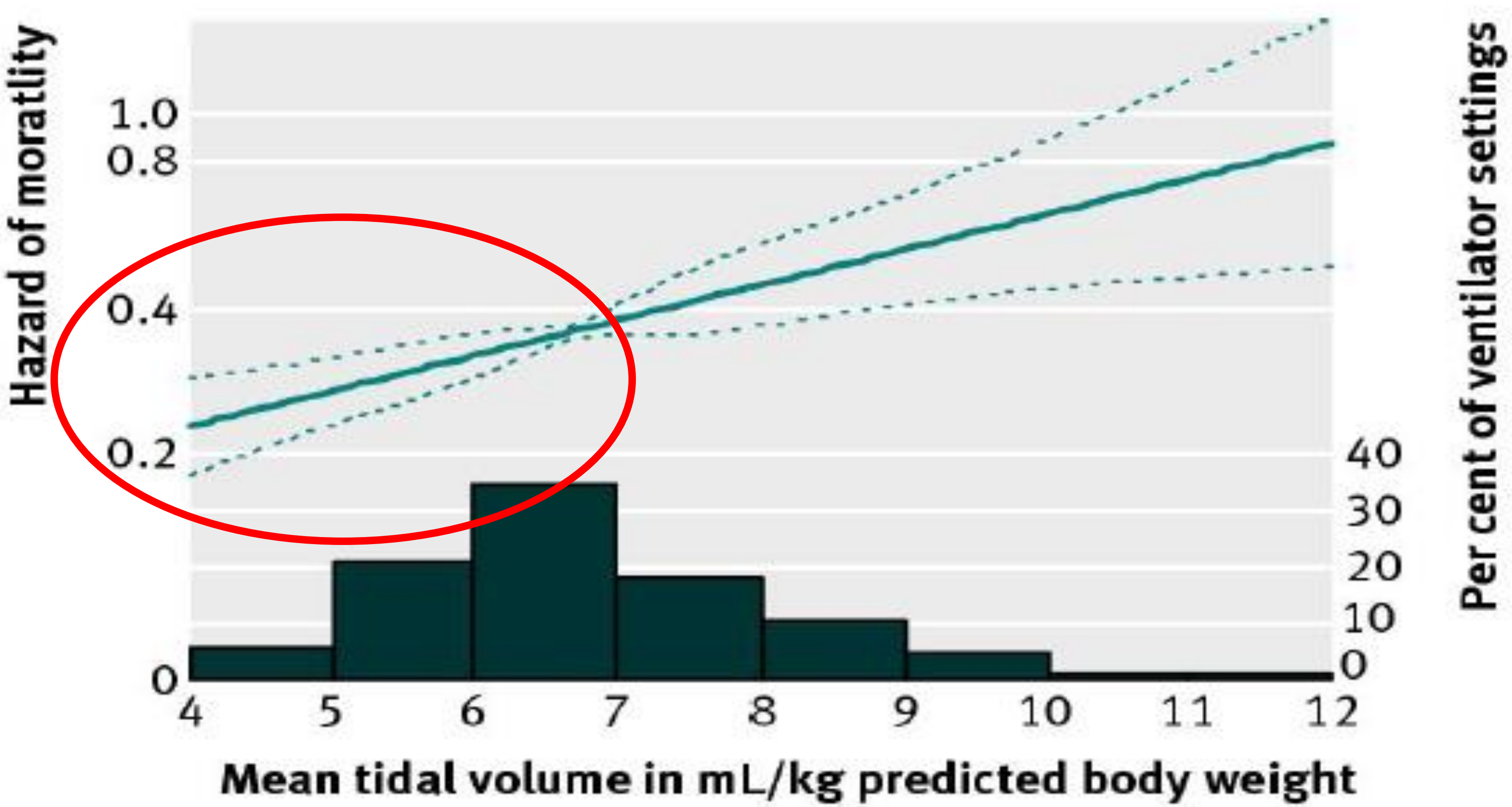
The Acute Respiratory Distress Syndrome Network, ARMA

N Engl J Med 2000; 342:1301-1308



Lung protective mechanical ventilation and two year survival in patients with acute lung injury: prospective cohort study

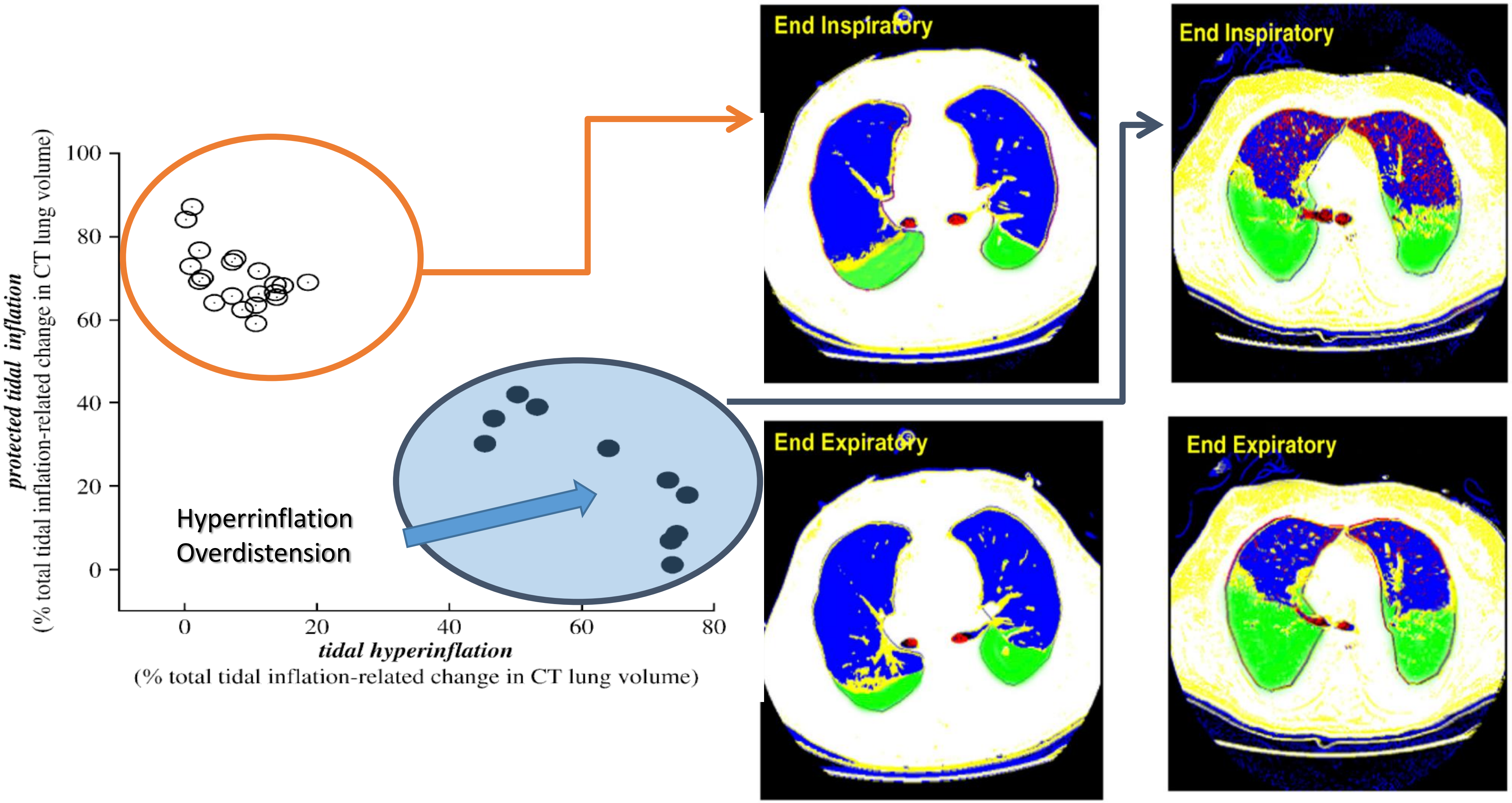
Needham DM et al., BMJ 2012;344:e2124.



Tidal Hyperinflation during Low Tidal Volume Ventilation in Acute Respiratory Distress Syndrome

Pier Paolo Terragni, Giulio Rosboch, Andrea Tealdi, Eleonora Corno, Eleonora Menaldo, Ottavio Davini, Giovanni Gandini, Peter Herrmann, Luciana Mascia, Michel Quintel, Arthur S. Slutsky, Luciano Gattinoni, and V. Marco Ranieri

Am J Respir Crit Care Med 2007;175:160-166.



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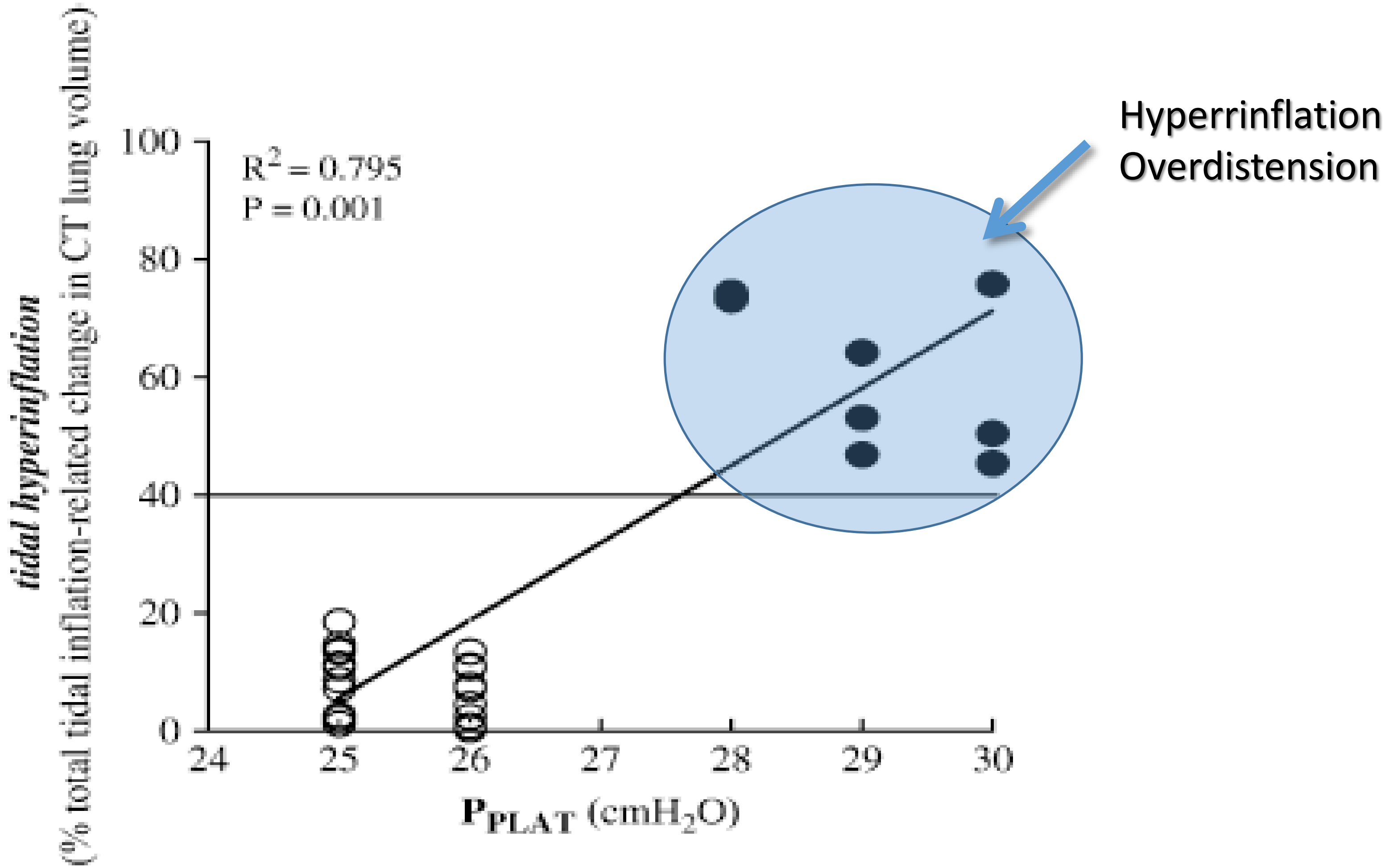
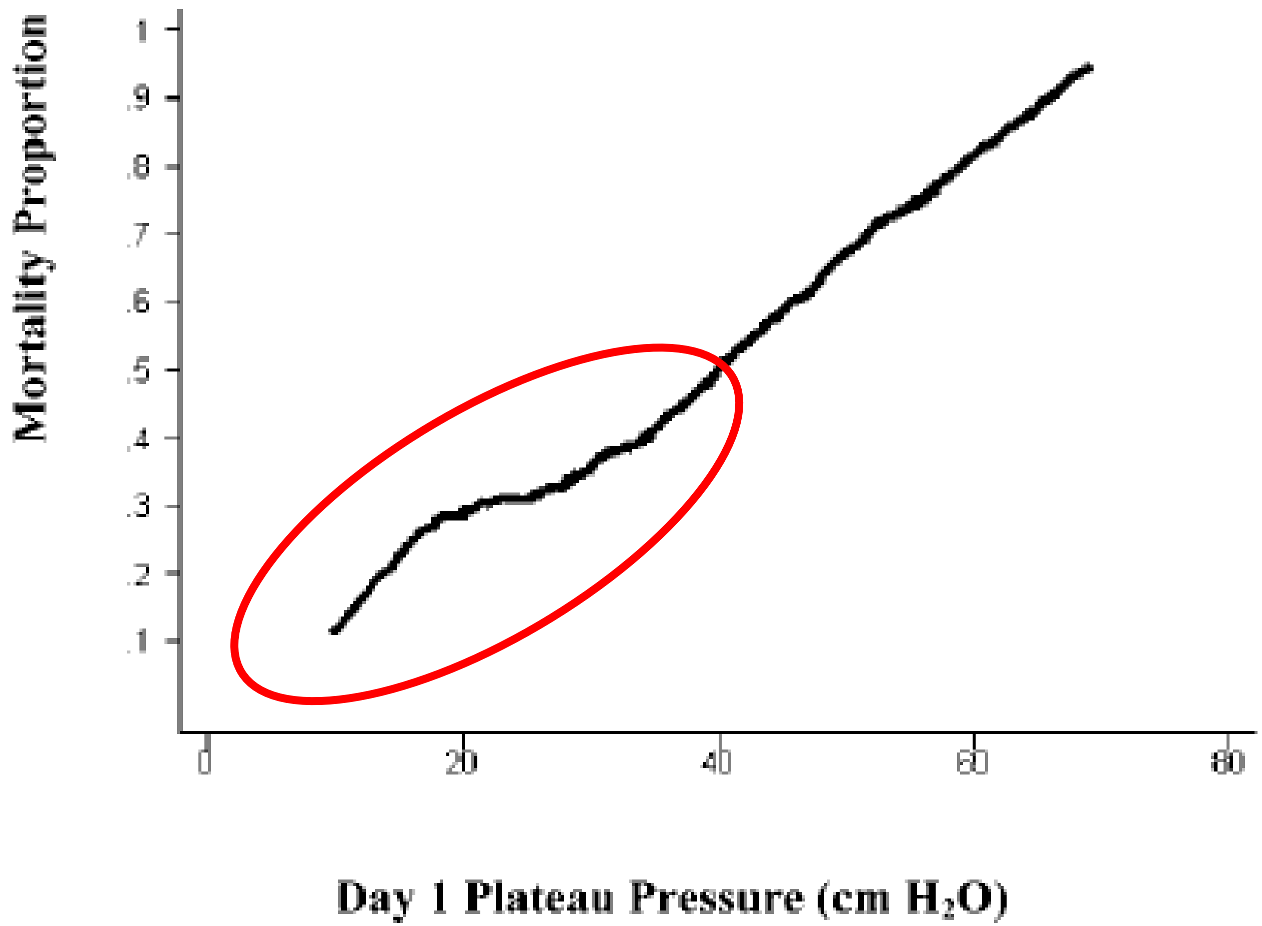


Tidal Volume Reduction in Patients with Acute Lung Injury When Plateau Pressures Are Not High

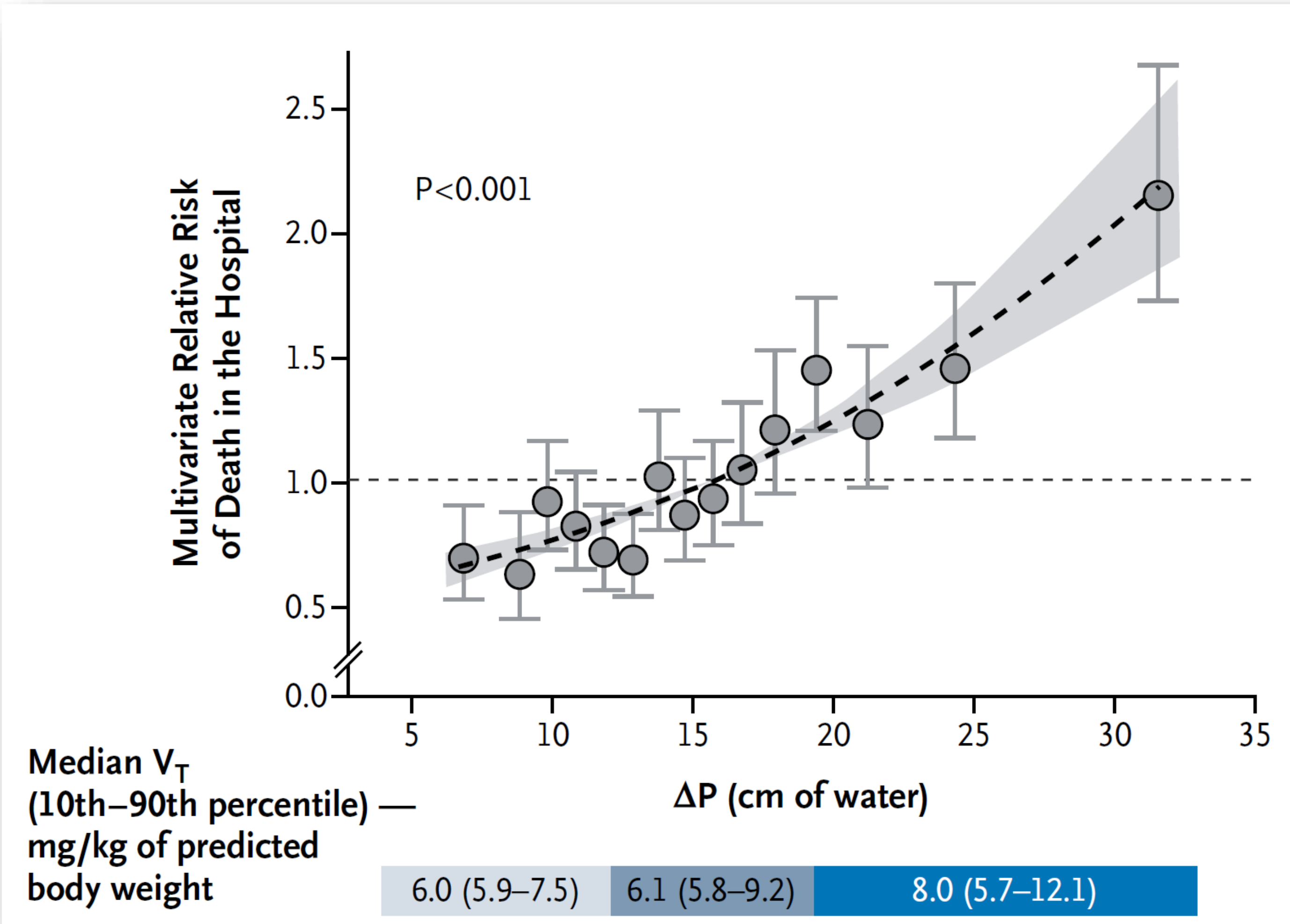
David N. Hager, Jerry A. Krishnan, Douglas L. Hayden, and Roy G. Brower for the ARDS Clinical Trials Network

Am J Respir Crit Care Med Vol 172. pp 1241–1245, 2005



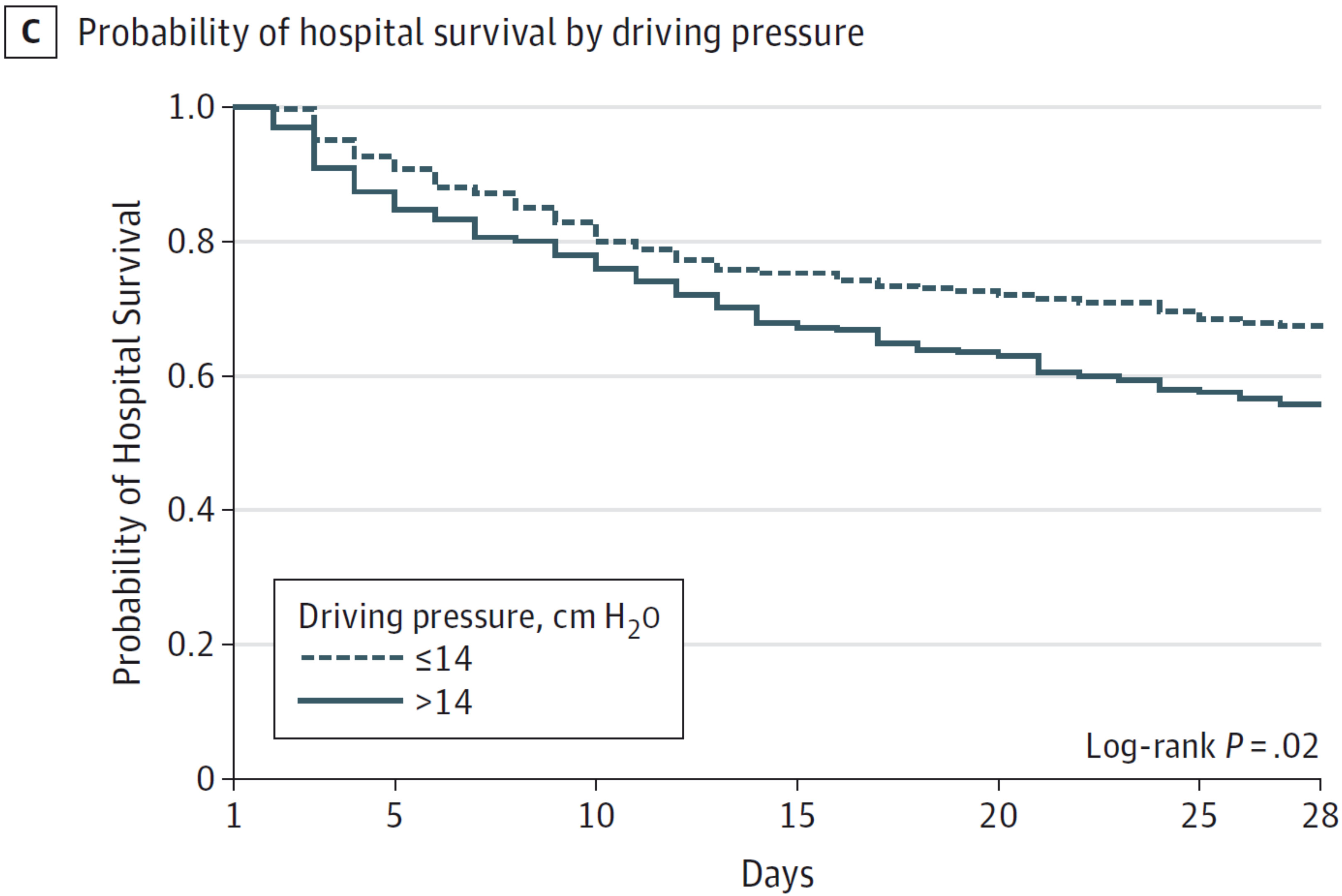
N ENGL J MED 372;8 NEJM.ORG FEBRUARY 19, 2015

Driving Pressure and Survival in the Acute Respiratory Distress Syndrome



Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries

JAMA. 2016;315(8):788-800.



The evolving paradigm…

- ARDSnet strategy might not protect against tidal hyperinflation
  - When Pplat remains >28-30 cm H_2O
- Further decrease of Vt to reduce VILI
  - From 6 to 5, 4 or 3 ml/kg IBW
  - To decrease Pplat <25 cm H_2O
  - With sufficient PEEP to prevent lung derecruitment
  - Resulting in a significant **decrease in ΔP**
- Induced Hypercapnia controlled by $ECCO_2$ removal
  - "CO_2 dialysis"
  - Low-flow devices

The History of CO_2 removal in ARDS …

The History

Gattinoni 1978, BJA

TABLE III. *Comparative technical difficulty of haemodialysis, extracorporeal removal of carbon dioxide and extracorporeal oxygenation*

	Renal haemodialysis	Extracorporeal removal of carbon dioxide	Extracorporeal oxygenation
Extracorporeal blood flow (ml min^{-1})	200–300	500–1000	2000–4000
Blood pumping	optional	optional	required
Haemodynamic changes	small	small	major
Vascular access	A–V shunt or A–V fistula	A–V shunt or A–V fistula or V–V pumping	V–A or V–V
Surgical complexity	simple	simple	complex
Complexity of equipment	moderate	simple	advanced
Requirement for heparin	small	small	large

Low-Frequency Positive-Pressure Ventilation With Extracorporeal CO_2 Removal in Severe Acute Respiratory Failure

Luciano Gattinoni, JAMA 1986;256:881-886

- 43 patients, uncontrolled study
- Low-flow veno-venous CO2 removal device
  - ECCO2-R
- To avoid lung injury from conventional MV, the lungs were kept "at rest"
  - 3-5 breaths/min
  - “Low” peak airway pressure, **35-45 cm H_2O**
- Survival: 21/43 (48.8%) patients
- Lung function improved in 31(72.8%) patients
- Blood loss: 1800±850mL/day…

Randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO2 removal for adult respiratory distress syndrome

Morris, AH, AJRCCM, 94

- Randomized controlled clinical trial
- 40 patients with severe ARDS
- Extracorporeal CO2 removal:
  - ECCO2R
  - Low-flow veno-venous device
- Survival at 30 days not significantly different:
  - 42% in the 19 mechanical ventilation
  - 33% in the 21 ECCO2R patients ($p = 0.8$)
  - All deaths occurred within 30 days of randomization
- Study stopped for futility
- >30% patients with severe hemorrhage

Techniques of the 2000's…

Novalung, ILA pumpless AV shunt

A new pumpless extracorporeal interventional lung assist in critical hypoxemia/hypercapnia*

Thomas Bein, MD; Frank Weber, MD; Alois Philipp, ECCP; Christopher Prasser, MD; Michael Pfeifer, MD; Franz-Xaver Schmid, MD; Bernhard Butz, MD; Dietrich Birnbaum, MD; Kai Taeger, MD; Hans J. Schlitt, MD

Crit Care Med 2006 Vol. 34, No. 5

Objective: Pump-driven extracorporeal gas exchange systems have been advocated in patients suffering from severe acute respiratory distress syndrome who are at risk for life-threatening hypoxemia and/or hypercapnia. This requires extended technical and staff support.

Design: We report retrospectively our experience with a new pumpless extracorporeal interventional lung assist (iLA) establishing an arteriovenous shunt as the driving pressure.

Setting: University hospital.

Patients: Ninety patients with acute respiratory distress syndrome.

Interventions: Interventional lung assist was inserted in 90 patients with acute respiratory distress syndrome.

Measurements and Main Results: Oxygenation improvement, carbon dioxide elimination, hemodynamic variables, and the amount of vasopressor substitution were reported before, 2 hrs after, and 24 hrs after implementation of the system. Interventional lung assist led to an acute and moderate increase in arterial oxygenation (Pa_{O_2}/F_{IO_2} ratio 2 hrs after initiation of iLA [median and interquartile range], 82 mm Hg [64–103]) compared with pre-iLA (58 mm Hg [47–78], $p < .05$). Oxygenation continued to improve for 24 hrs after implementation (101 mm Hg [74–142], $p < .05$). Hypercapnia was promptly and markedly reversed by iLA within 2 hrs (Pa_{CO_2}, 36 mm Hg [30–44]) in comparison with before (60 mm Hg [48–80], $p < .05$], which allowed a less aggressive ventilation. For hemodynamic stability, all patients received continuous norepinephrine infusion. The incidence of complications was 24.4%, mostly due to ischemia in a lower limb. Thirty-seven of 90 patients survived, creating a lower mortality rate than expected from the Sequential Organ Failure Assessment score.

Conclusions: Interventional lung assist might provide a sufficient rescue measure with easy handling properties and low cost in patients with severe acute respiratory distress syndrome and persistent hypoxia/hypercapnia. (Crit Care Med 2006; 34:1372–1377)

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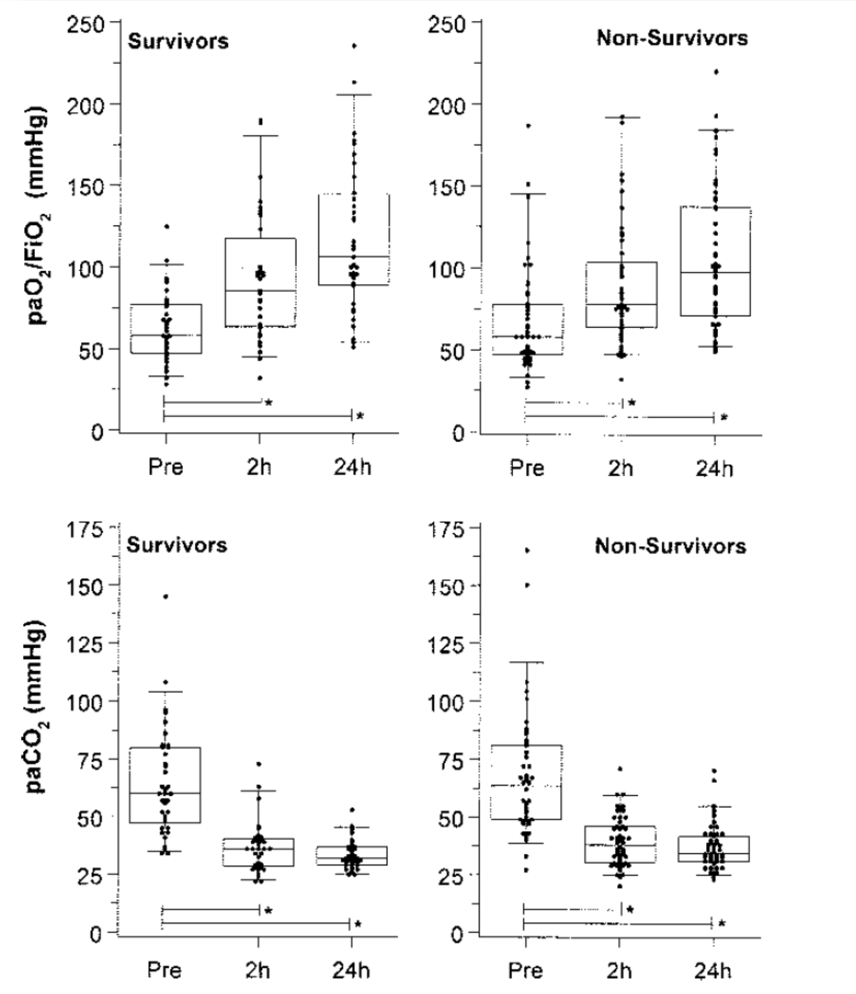

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Crit Care Med 2006 Vol. 34, No. 5

Mortality = 59%

Parameter	Survivors (S)	Nonsurvivors (NS)	All Patients	*p* (S vs. NS)
Patients	37	53	90	
Age, yrs	32 (22–49)	49 (33–60)	44 (26–59)	.009
Female/male ratio	8/29	13/40	21/69	NS
Body mass index	24.1 (22.5–26.6)	27.7 (24.0–30.8)	25.4 (23.4–29.7)	.001
Days on ventilator before ILA	1 (1–8)	4 (1–14)	3 (1–10)	.034
SOFA score	10 (7–11)	11 (8–14)	11 (8–13)	.016
Lung injury score	3.7 (3.3–3.8)	3.5 (3.3–3.8)	3.5 (3.5–3.8)	NS

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Crit Care Med 2006 Vol. 34, No. 5

	Pre	2 Hrs
F_{IO_2}	1.0 (1.0–1.0)	0.9 (0.8–1.0)[a,b]
Minute ventilation, $L \cdot min^{-1}$	13.0 (10.0–16.4)	11.0 (8.0–14.1)[a]
Tidal volume, mL	430 (360–540)	410 (330–480)[a]
Respiratory frequency, breaths/min	27 (21–43)	25 (20–40)
Peak inspiratory pressure, cm H_2O	38 (35–40)	36 (32–39)
PEEP, cm H_2O	15 (12–17)	15 (13–18)

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Crit Care Med 2006 Vol. 34, No. 5

Complication/Side Effect	No. of Patients
Ischemia of a lower limb after cannulation	9
Cannula thrombosis	4
Compartmental syndrome in a lower limb	4
Hematoma/aneurysm at cannulation site	2
Hemolysis	1
Intracerebral hemorrhage	1
Diffuse bleeding/shock syndrome during cannulation	1
All	22 (24.4%)

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Crit Care Med 2006 Vol. 34, No. 5

Complication/Side Effect	No. of Patients
All	22 (24.4%)

25% Incidence of complications and side effects

Limb ischemia due to arterial canulation +++

Need for IV norepinephrine

Intensive Care Med
DOI 10.1007/s00134-012-2787-6

ORIGINAL

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Lower tidal volume strategy ($\approx$3 ml/kg) combined with extracorporeal CO_2 removal versus 'conventional' protective ventilation (6 ml/kg) in severe ARDS

The prospective randomized Xtravent-study

Lower tidal volume strategy (≈ 3 ml/kg) combined with extracorporeal CO_2 removal versus 'conventional' protective ventilation (6 ml/kg) in severe ARDS

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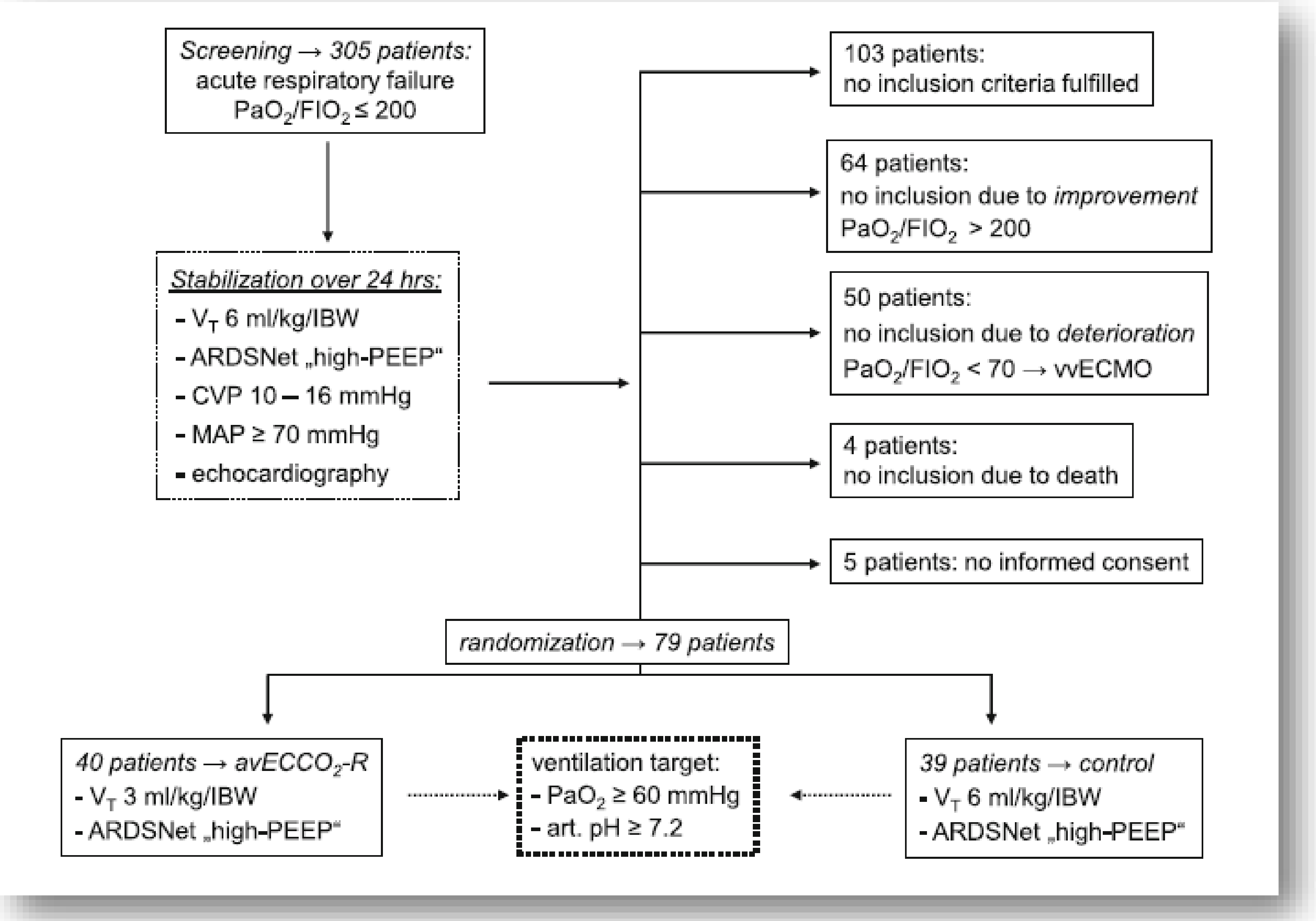

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Anton Goldmann

Intensive Care Med

	All patients		
	$avECCO_2$-R	Control	*p*
Ventilator-free-days-28	10.0 ± 8	9.3 ± 9	0.779
Ventilator-free-days-60	33.2 ± 20	29.2 ± 21	0.469
Non-pulmonary organ failure free days-60	21.0 ± 14	23.9 ± 15	0.447
Lung injury score on day 10	2.2 ± 0.6	2.1 ± 0.5	0.854
Length of stay in hospital (days)	46.7 ± 33	35.1 ± 17	0.113
Length of stay in ICU (days)	31.3 ± 23	22.9 ± 11	0.144
In-hospital mortality	7/40 (17.5 %)	6/39 (15.4 %)	1.000

Lower tidal volume strategy ($\approx$3 ml/kg) combined with extracorporeal CO_2 removal versus 'conventional' protective ventilation (6 ml/kg) in severe ARDS

The prospective randomized Xtravent-study

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Intensive Care Med

	Subgroup: PaO_2/FIO_2 <150		
	$avECCO_2$-R	Control	p
Ventilator-free-days-28	11.3 ± 7.5	5.0 ± 6.3	0.033
Ventilator-free-days-60	40.9 ± 12.8	28.2 ± 16.4	0.033
Non-pulmonary organ failure free days-60	24.1 ± 7.5	29.0 ± 17.7	0.428
Lung injury score on day 10	2.3 ± 0.8	2.2 ± 0.5	0.601
Length of stay in hospital (days)	42.0 ± 16.6	40.3 ± 15.7	0.815
Length of stay in ICU (days)	25.9 ± 13.1	31.0 ± 12.7	0.258
In-hospital mortality	1/21 (4.8 %)	1/10 (10 %)	0.563

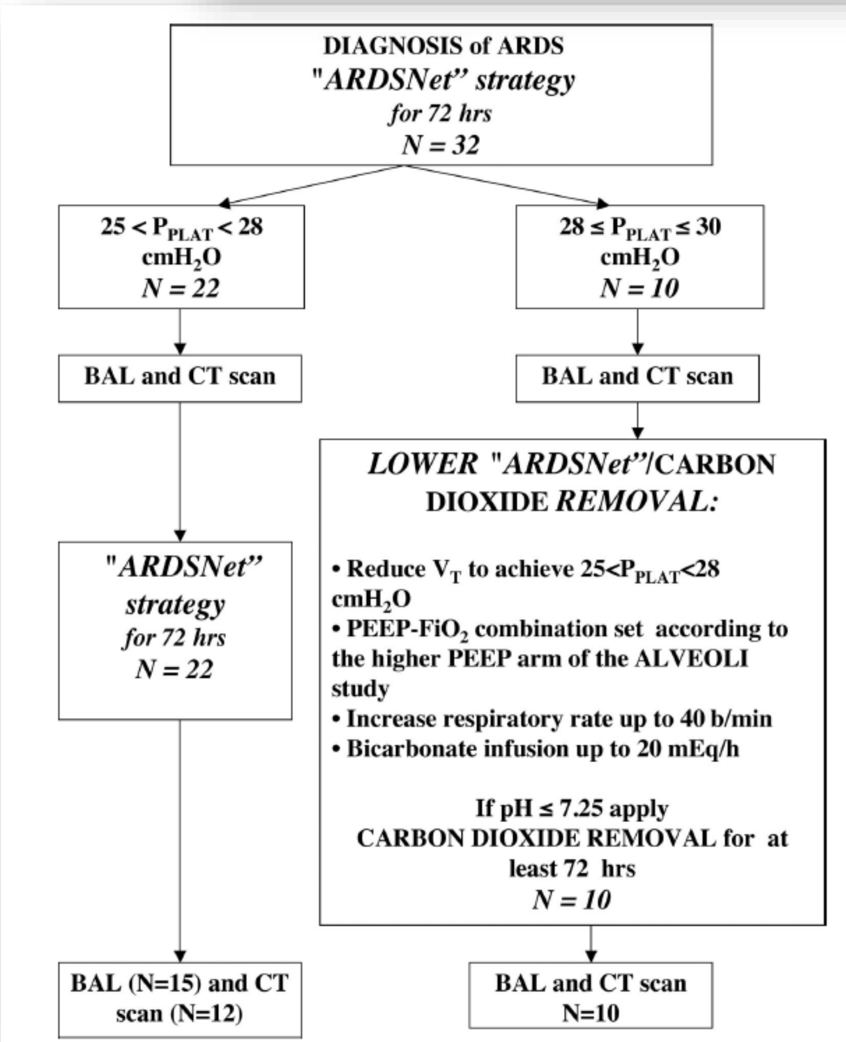
Hemodec DECAP

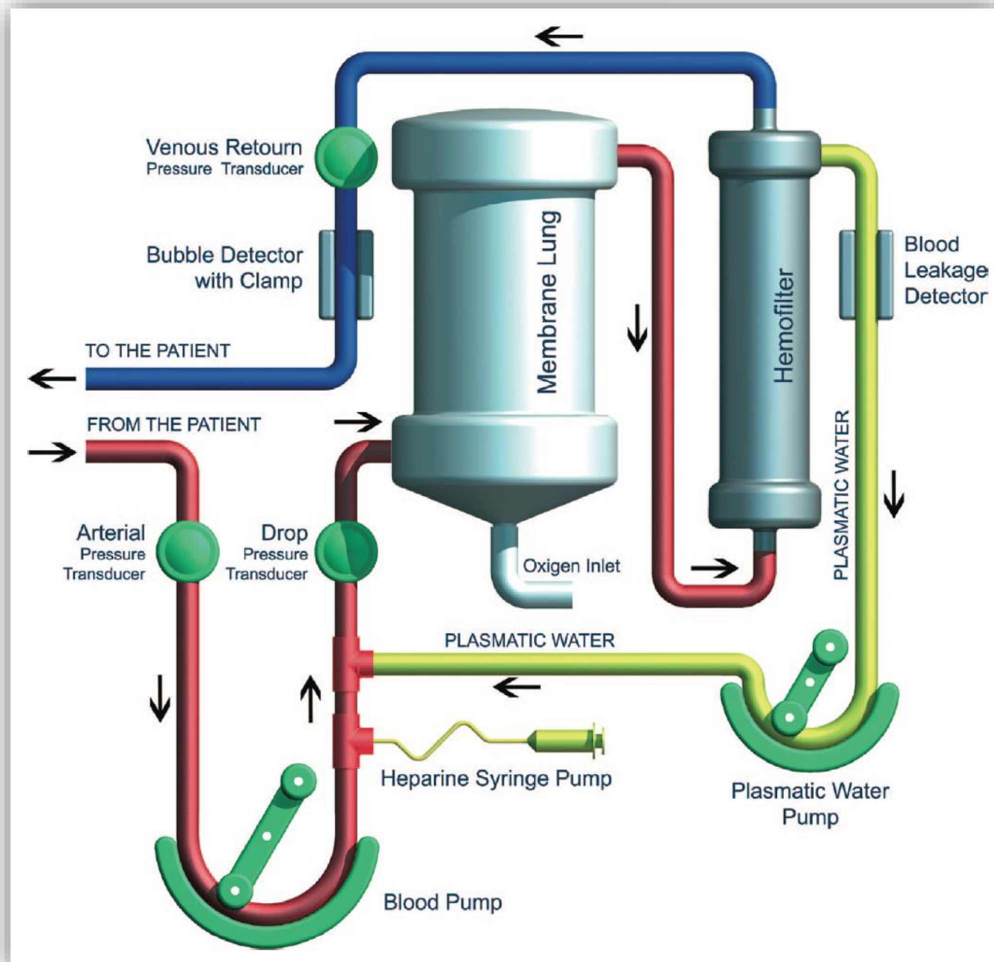
Tidal Volume Lower than 6 ml/kg Enhances Lung Protection

Role of Extracorporeal Carbon Dioxide Removal

Anesthesiology 2009; 111:826–35

Pier Paolo Terragni, M.D., Lorenzo Del Sorbo, M.D.,* Luciana Mascia, M.D., Ph.D.,* Rosario Urbino, M.D.,**
Erica L. Martin, Ph.D., Alberto Birocco, M.D.,† Chiara Faggiano, M.D.,† Michael Quintel, M.D.,‡ Luciano Gattinoni, M.D.,§*
V. Marco Ranieri, M.D.||





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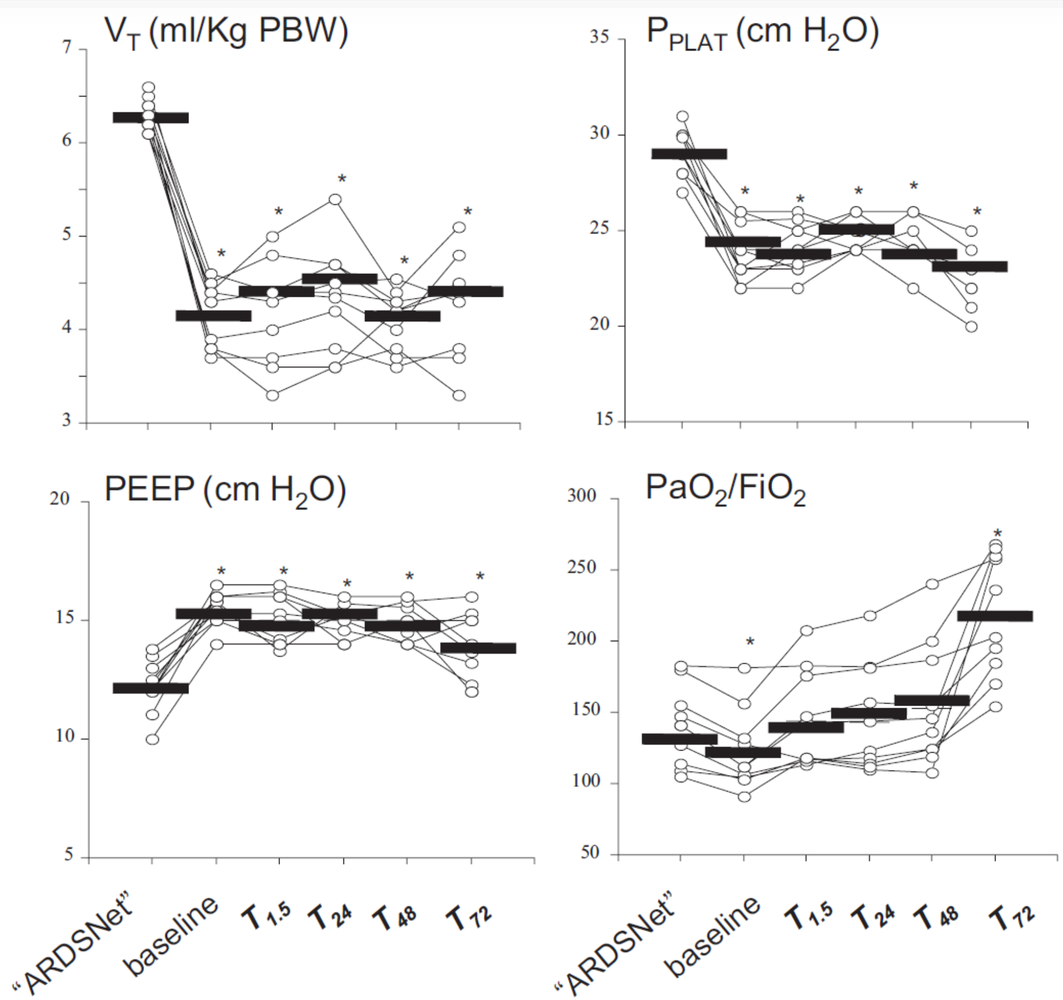

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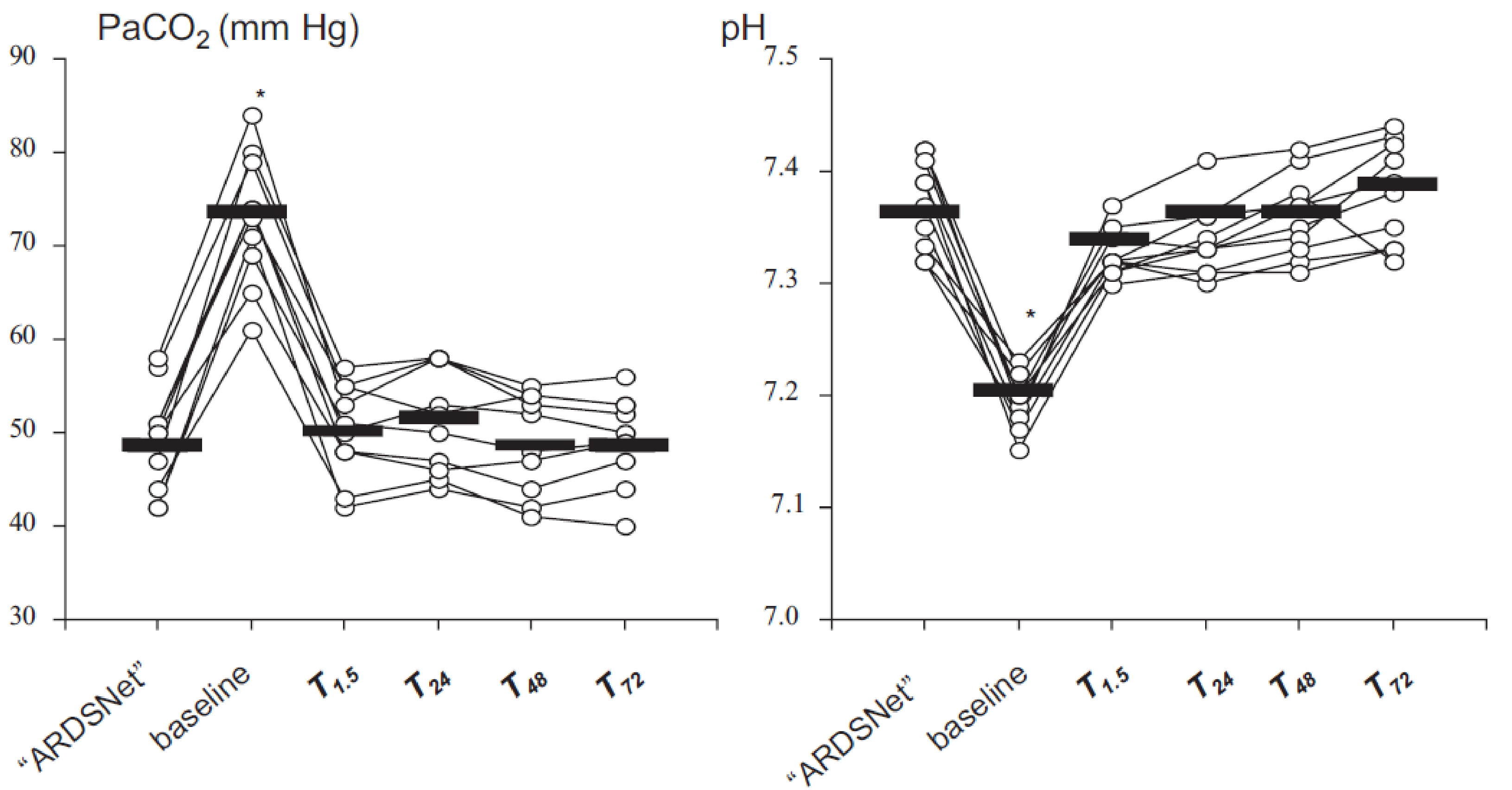

Techniques of the 2010's…

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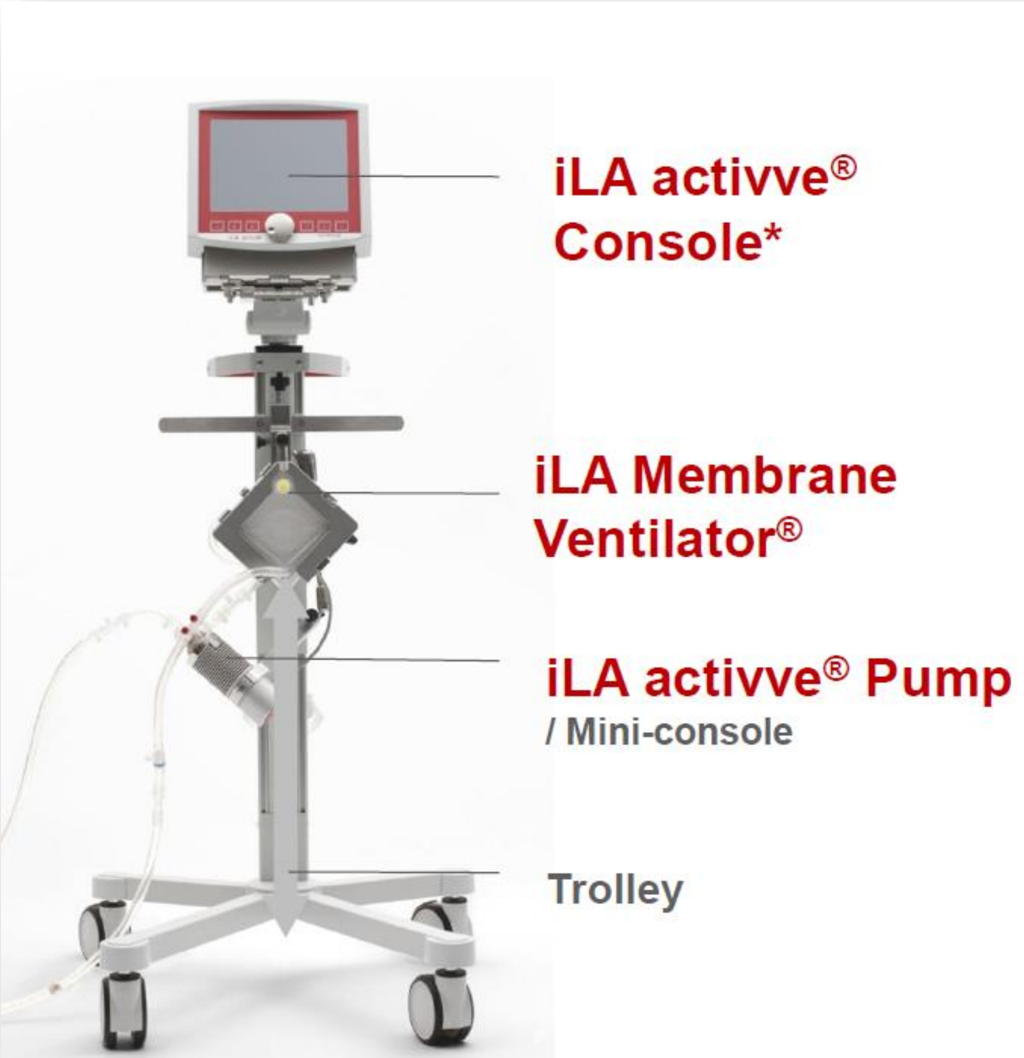

NOVALUNG

Alexander Hermann
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Peter Schellongowski
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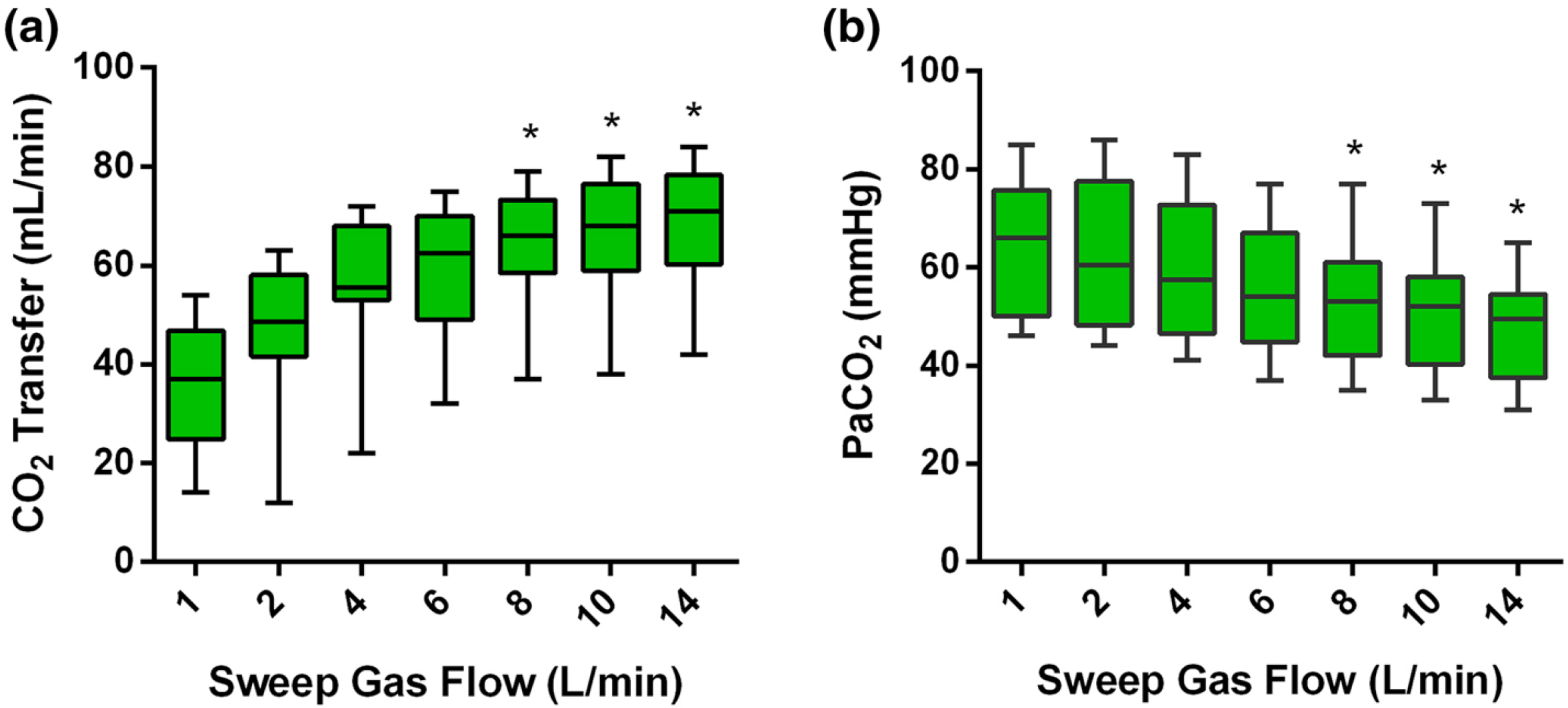
Philipp Wohlfarth
Oliver Robak
Wolfgang R. Sperr
Thomas Staudinger

A novel pump-driven veno-venous gas exchange system during extracorporeal CO_2-removal

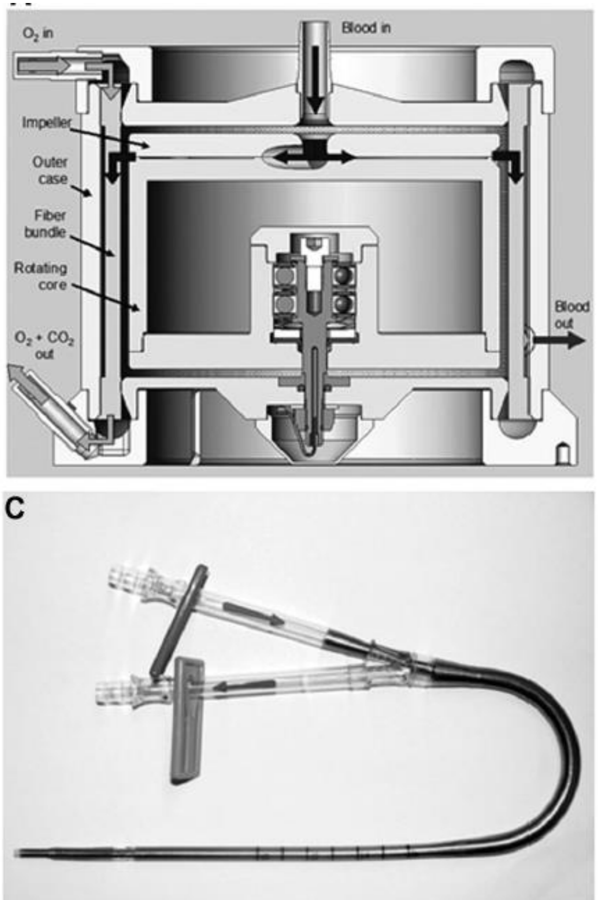
Intensive Care Med (2015) 41:1773–1780



Respiratory dialysis: Reduction in dependence on mechanical ventilation by venovenous extracorporeal CO_2 removal*

Andriy I. Batchinsky, MD; Bryan S. Jordan, RN, MSN; Dara Regn, MD; Corina Necsoiu, MD; William J. Federspiel, PhD; Michael J. Morris, MD; Leopoldo C. Cancio, MD

Crit Care Med 2011; 39:1382–1387



Hemolung, Alung Technologies

Feasibility and safety of low-flow extracorporeal carbon dioxide removal to facilitate ultra-protective ventilation in patients with moderate ARDS

Vito Fanelli[1*], Marco V. Ranieri[2], Jordi Mancebo[3], Onnen Moerer[4], Michael Quintel[4], Scott Morley[5], Indalecio Moran[3], Francisco Parrilla[3], Andrea Costamagna[1], Marco Gaudiosi[1] and Alain Combes[6]

Critical Care (2016) 20:36

Methods: In fifteen patients with moderate ARDS, V_T was reduced from baseline to 4 mL/kg PBW while PEEP was increased to target a plateau pressure – (P_{plat}) between 23 and 25 cmH_2O. Low-flow $ECCO_2R$ was initiated when respiratory acidosis developed (pH < 7.25, $PaCO_2$ > 60 mmHg). Ventilation parameters (V_T, respiratory rate, PEEP), respiratory compliance (C_{RS}), driving pressure ($DeltaP = V_T/C_{RS}$), arterial blood gases, and $ECCO_2R$ system operational characteristics were collected during the period of ultra-protective ventilation. Patients were weaned from $ECCO_2R$ when PaO_2/FiO_2 was higher than 200 and could tolerate conventional ventilation settings. Complications, mortality at day 28, need for prone positioning and extracorporeal membrane oxygenation, and data on weaning from both MV and $ECCO_2R$ were also collected.

Table 2 Time course of ventilation variables during the run-in phase

Variables	Baseline	V_T 5 mL/kg	V_T 4.5 mL/kg	V_T 4 mL/kg
V_T (mL/kg)	6.2 ± 0.7	5.02 ± 0.1*	4.48 ± 0.1*	3.96 ± 0.1*
Respiratory rate (beats/minute)	28 ± 7	29 ± 4	30 ± 4*	30 ± 5*
Positive end-expiratory pressure (cmH_2O)	12 ± 3	13.8 ± 3	13.6 ± 4	13.0 ± 4.0
Plateau pressure (cmH_2O)	27.7 ± 1.6	25.2 ± 1.6*	23.6 ± 1.3*	22.7 ± 1.8*
Patients who reached the pH threshold for $ECCO_2R$, n		0	2	15

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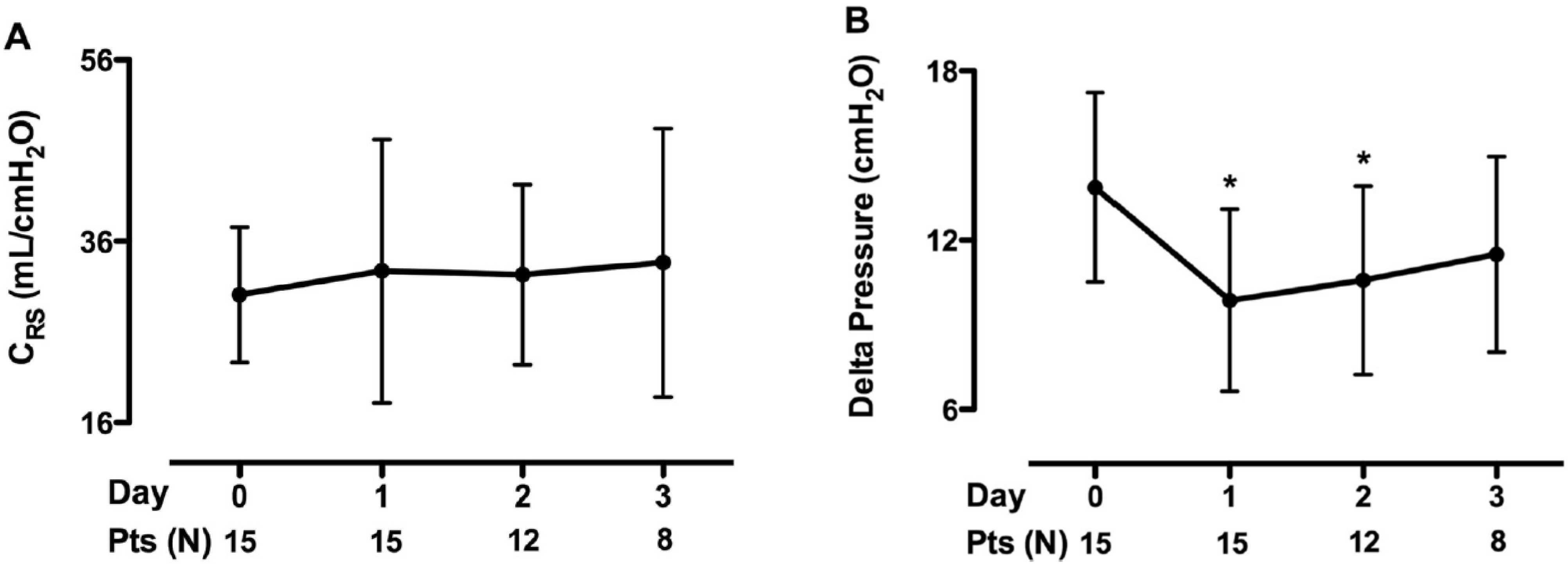

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Critical Care (2016) 20:36

Results: During the 2 h run in phase, V_T reduction from baseline (6.2 mL/kg PBW) to approximately 4 mL/kg PBW caused respiratory acidosis (pH < 7.25) in all fifteen patients. At steady state, $ECCO_2R$ with an average blood flow of 435 mL/min and sweep gas flow of 10 L/min was effective at correcting pH and $PaCO_2$ to within 10 % of baseline values. PEEP values tended to increase at V_T of 4 mL/kg from 12.2 to 14.5 cmH_2O, but this change was not statistically significant. Driving pressure was significantly reduced during the first two days compared to baseline (from 13.9 to 11.6 cmH_2O; $p < 0.05$) and there were no significant differences in the values of respiratory system compliance. Rescue therapies for life threatening hypoxemia such as prone position and ECMO were necessary in four and two patients, respectively. Only two study-related adverse events were observed (intravascular hemolysis and femoral catheter kinking).

Conclusions: The low-flow $ECCO_2R$ system safely facilitates a low volume, low pressure ultra-protective mechanical ventilation strategy in patients with moderate ARDS.

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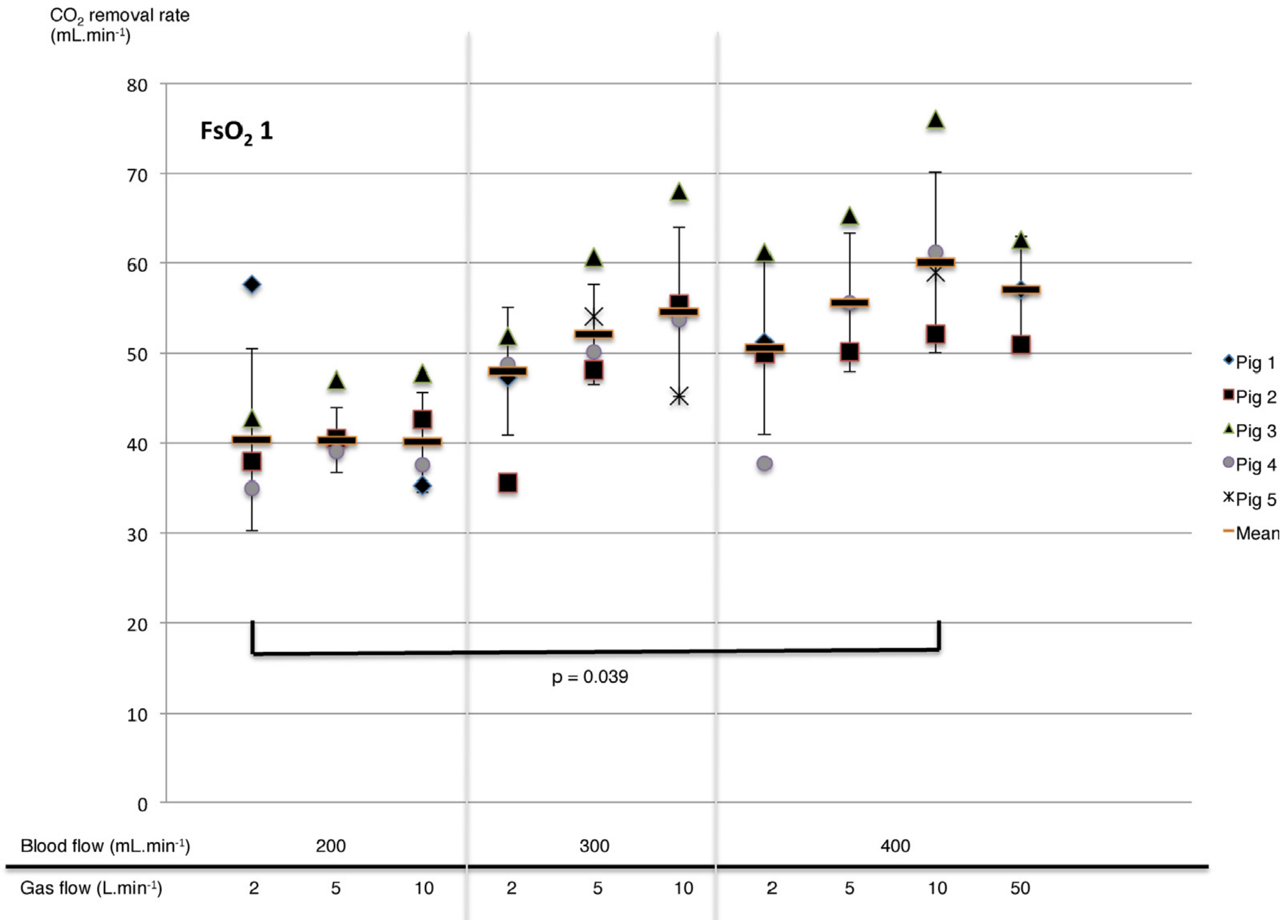
Novel CO_2 removal device driven by a renal-replacement system without hemofilter. A first step experimental validation

Thomas Godet [a], Alain Combes [b], Elie Zogheib [c], Matthieu Jabaudon [a,d], Emmanuel Futier [a,d], Arthur S. Slutsky [e], Jean-Michel Constantin [a,d,*]

Anesth Crit Care Pain Med 2014



ECCO2R set-up on the PrismaFlex Platform

Practical Aspects…

Double lumen catheter insertion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DOUBLE LUMEN CATHETER KIT
1 radiopaque catheter (13F) polyurethane (coated) with curved extension lines and inner dilator
1 introducer needle (17G x 70mm)
1 calibrated guidewire with "J" – tip (.038"/0.97mm x 700mm)
1 vessel dilator (13F x 150mm)
2 luer – lock injection caps
1 wound dressing
REF MC – GDHK – 1315J
150mm
LOT 2014 – 05 – 1437
2014 / 05
2016 / 04
MC – GDHK – 1315J 2014 – 05 – 1437
MC – GDHK – 1315J 2014 – 05 – 1437
MC – GDHK – 1315J 2014 – 05 – 1437
EAN – 14: 07332414087845
GAMBRO.
STERILE EO
0086

Double lumen catheter insertion

Double lumen catheter insertion

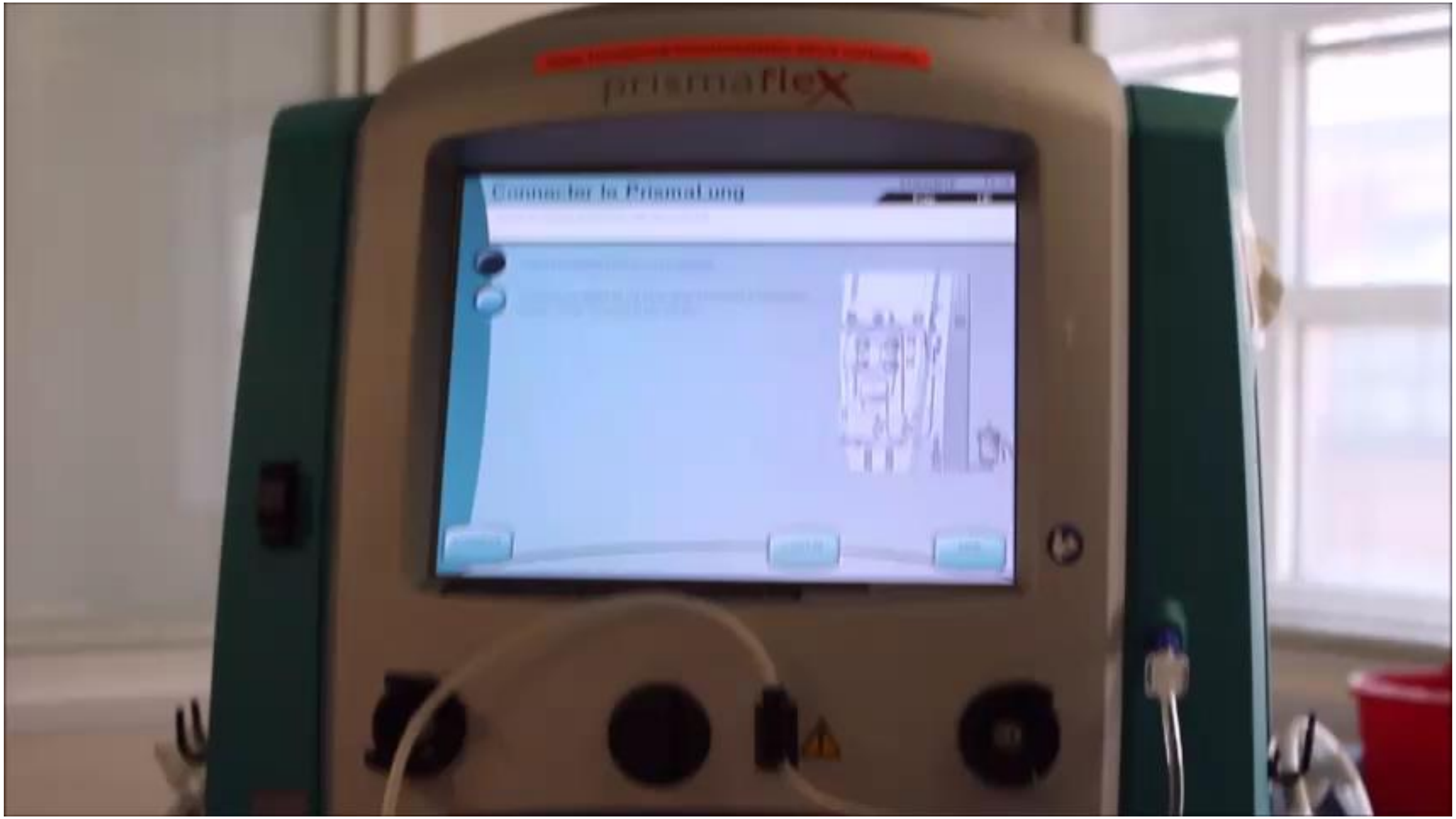
Double lumen catheter insertion

Double lumen catheter insertion

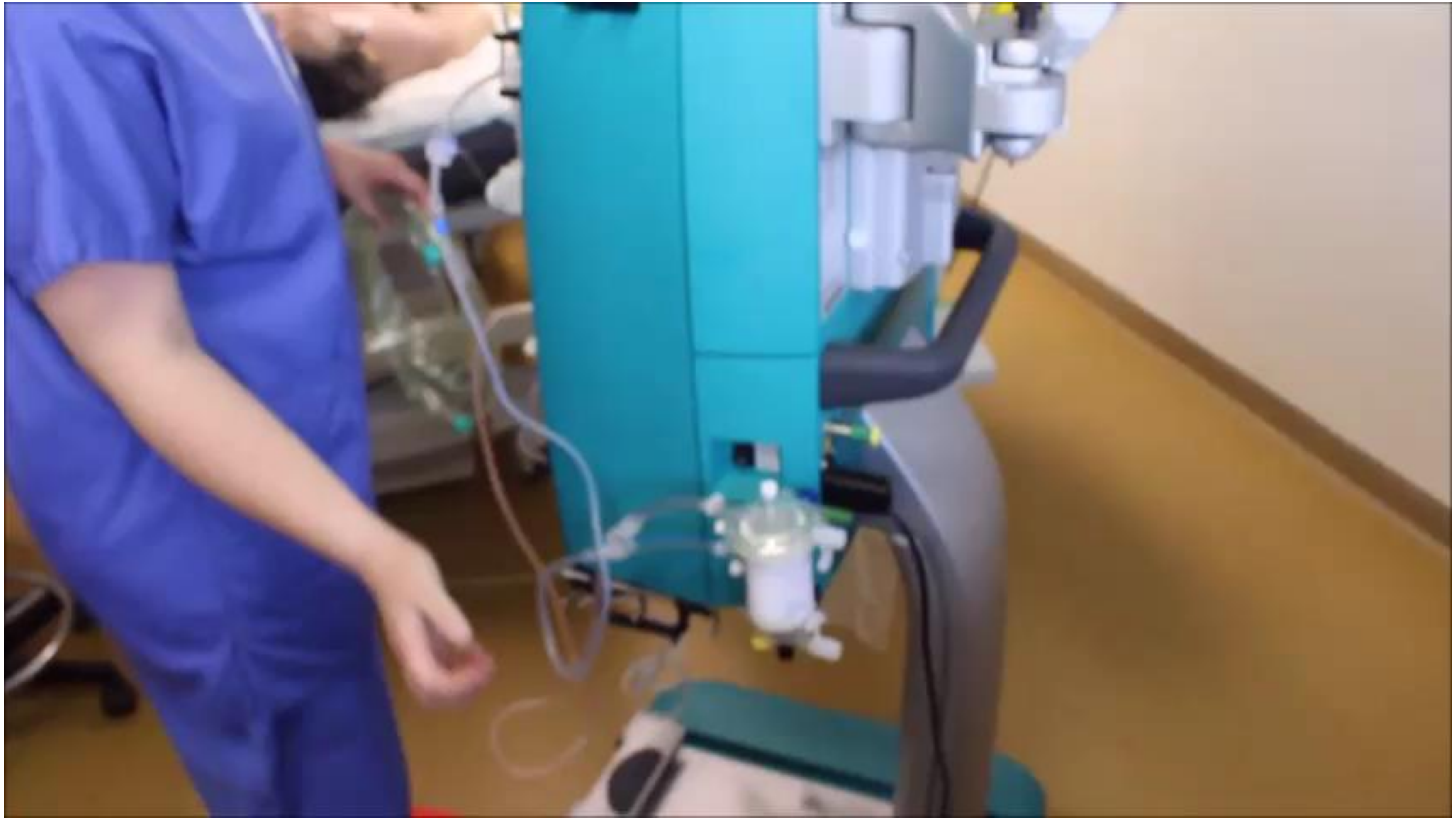
Double lumen catheter insertion

PrismaLung set-up on the PrismaFlex Platform

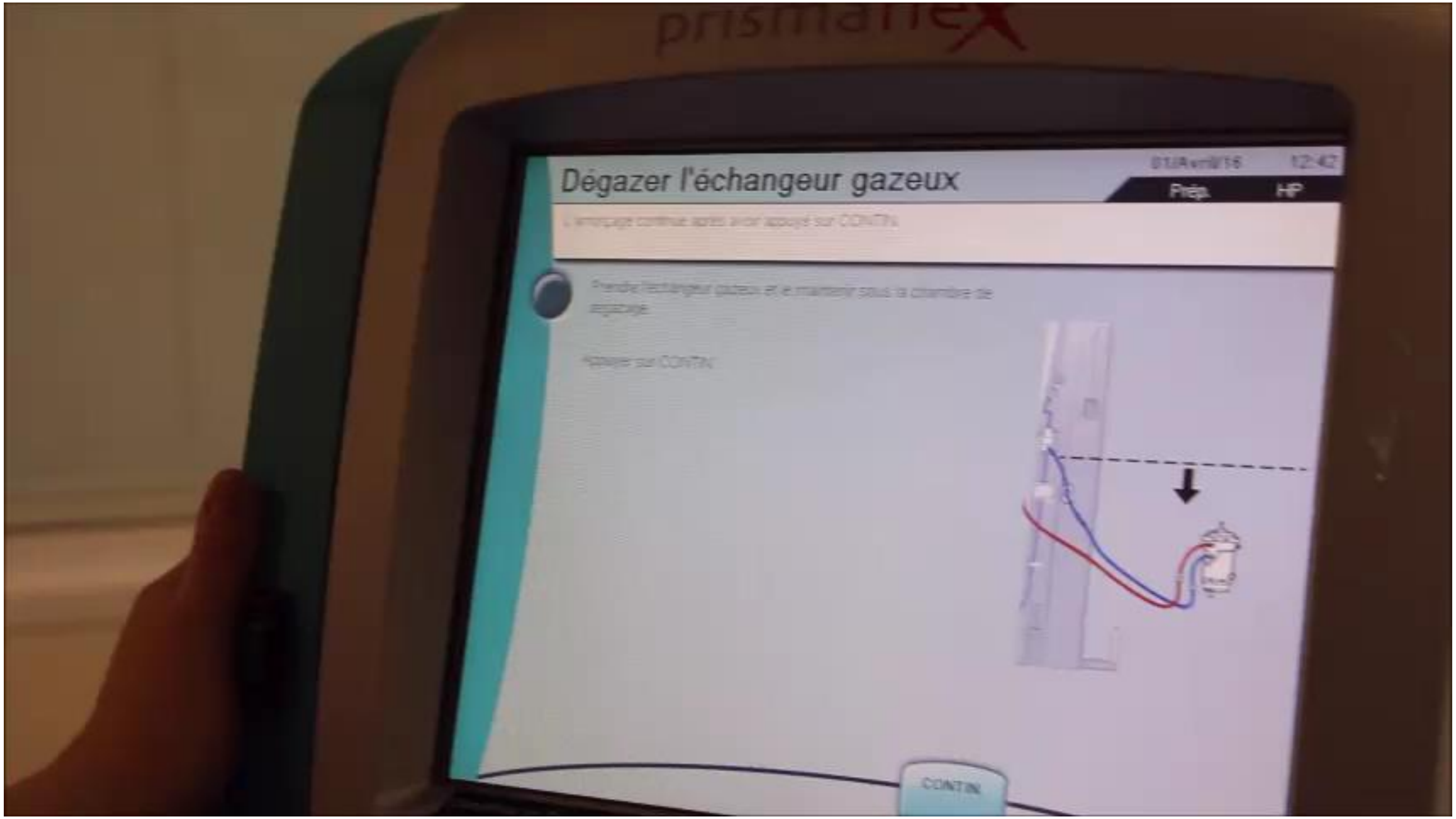
PrismaLung set-up



PrismaLung set-up



PrismaLung set-up



Patient's Connnexion to the PrismaLung device

PrismaLung on-line

Protocol for Ultraprotective MV


10:06:39
VC-VAC
mbar
Débit L/min
mmHg
VT mL
380
1000
FiO₂ Vol%
80
FR /min
28
40
Pcrête mbar
36
50
VM L/min
10,7
Pplat mbar
27
etCO₂ mmHg
Arrêt
PEP mbar
17
Config ...
Alarmes...
Jour/Nuit
Réglages ventilation...
Copie d'écran
Trigger
Tendances/ Données...
Capteurs/ Paramètres...
Journal
Paramétrage système...
SC journal
Capteur CO₂
Procédures spéciales...
Aide...
Nébulisation
Aspiration O₂
Insp. man./ pause
PEPi
Pause exp.
Marche/ Veille...
VC-VAC
80
FiO₂
380
VT
0,81
Ti
28,0
FR
16,0
PEP
50
Débit

Protocol for Ultraprotective MV

- Baseline ventilator settings = EXPRESS protocol
  - V_T = 6 mL/kg
  - PEEP set so that 28 cm $H_2O \leq P_{plat} \leq$ 30 cm H_2O
- 2-hour run-in time (time to setup PRISMALUNG)
  - Single veno-venous dialysis catheter
  - Jugular vein strongly suggested
  - Blood flow set up to 450 mL/min
  - Initially, sweep gas set at 0 L/min
- Anticoagulation with unfractionated heparin
  - Target aPTT of 1.5 – 2.0X baseline
  - A bolus of heparin suggested at the time of cannulation
- NMBA for the first 24 hours

Protocol for Ultraprotective MV

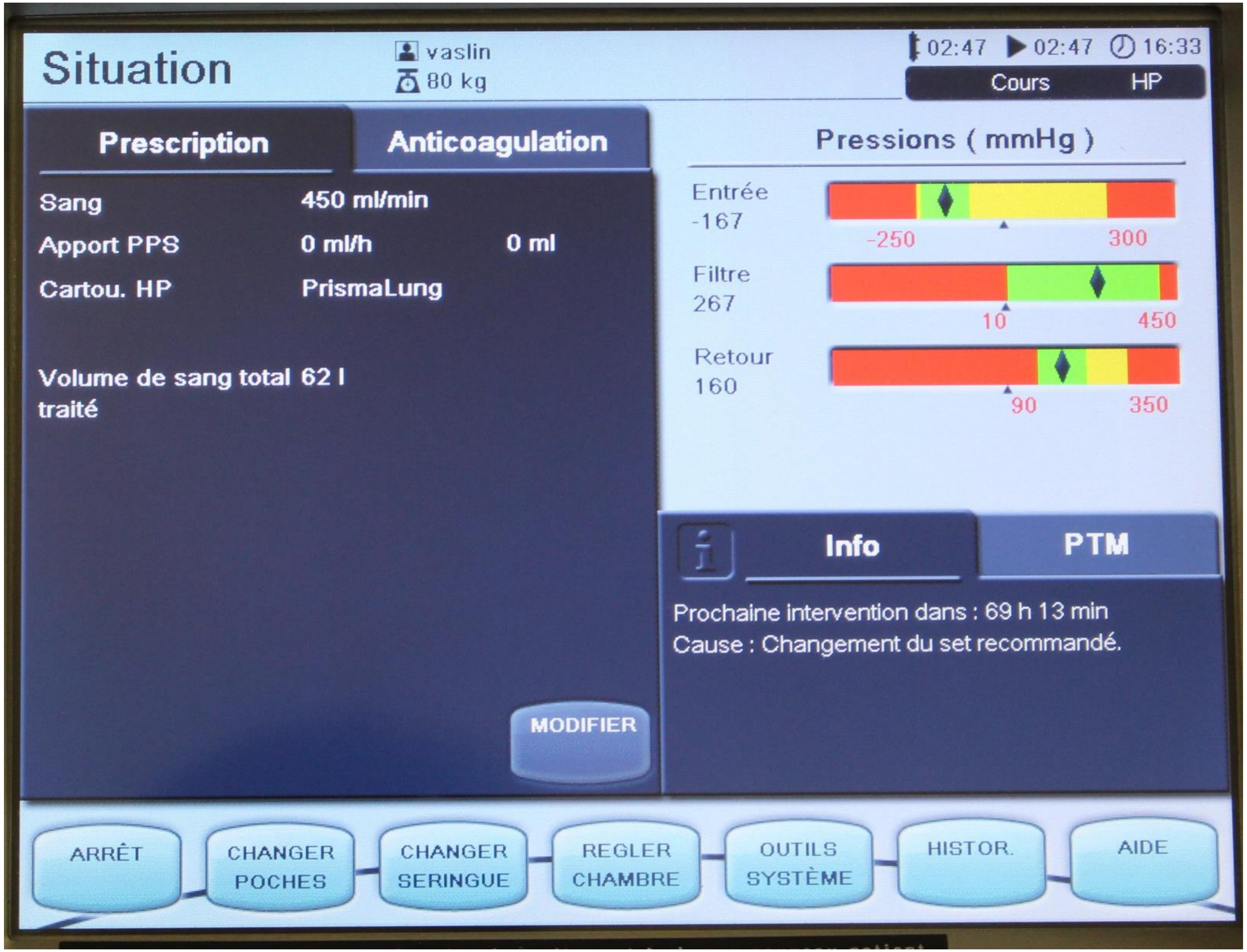
- Intervention
  - V_T gradually reduced to 5 mL/kg
  - Then V_T reduced to 4.5 then 4mL/kg
  - PEEP adjusted to $23 \leq P_{plat} \leq 25$ cm H_2O
  - Blood gases analyzed 20-30 minutes after each V_T reduction
  - Initially, RR kept what it was at baseline
  - Sweep gas set at 10 L/min
  - If $PaCO_2$ remains within the target range, respiratory rate progressively decreased to a minimum of 15/ min
- Objective
  - Maintain $PaCO_2$ to its baseline value ± 20%
  - If $PaCO_2$ in the target range, decrease RR to a minimum of 15/ min
  - If $PaCO_2$ > 75 mmHg and/or pH < 7.2, despite RR of 35/min
    - *Increase V_T to the last previously tolerated V_T*

Protocol for Ultraprotective MV

- $ECCO_2R$ and the "low volume - low pressure" MV strategy will be continued for at least 24 hours
- After 24h
  - if PaO_2/FiO_2 > 200 regardless of PEEP level
  - V_T will be set at 6 ml/kg IPBW
  - PEEP 5-10 cm H_2O
  - RR 20-30 /min
  - FiO_2 40%
  - Gas flow on the $ECCO_2R$ device switched off
  - $ECCO_2R$ device and catheter removed
    - *Minimum of 12 hours of stability under the aforementioned MV settings*

Final Step
Ultraprotective MV settings

Final Step Ultraprotective MV settings



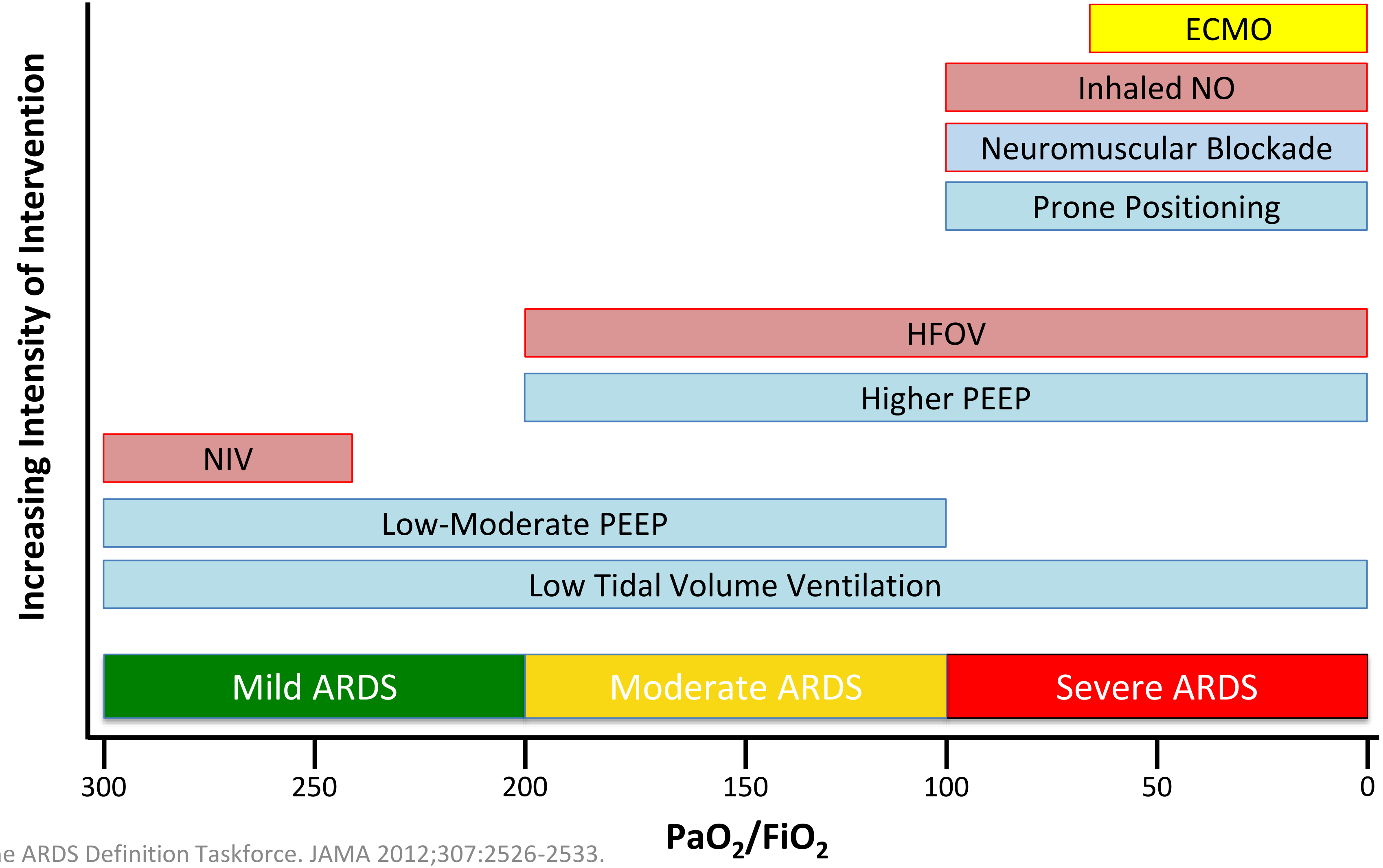
Final Step Ultraprotective MV settings

Ultraprotective MV settings

	6 ml/kg	5 ml/kg	4.5 ml/kg	4.5 ml/kg	4 ml/kg
PrismaL Gas Flow	0	0	0	10	10
Vt	450	380	340	340	300
PEEP	9	10	11	11	12
PPlateau	29	27	25	25	24
Driving Pressure	20	17	14	14	12
RR	24	24	24	24	26
pH	7.43	7.37	7.28	7.36	7.32
PaCO2	40	47	58	47	51
PaO2	72	66	70	69	71

A new paradigm…

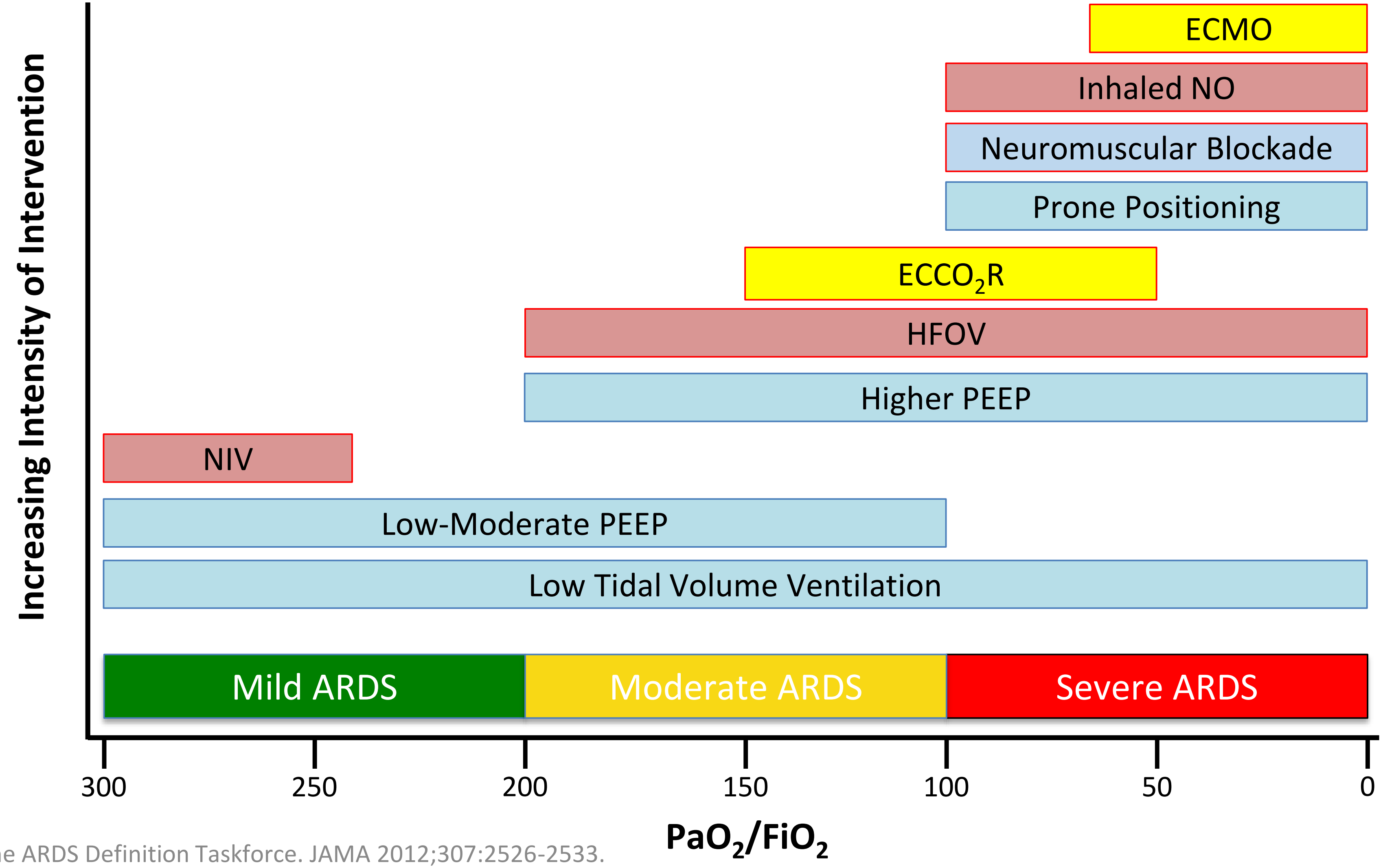
Acute Respiratory Distress Syndrome
The Berlin Definition



The ARDS Definition Taskforce. JAMA 2012;307:2526-2533.

Acute Respiratory Distress Syndrome

The Berlin Definition



The ARDS Definition Taskforce. JAMA 2012;307:2526-2533.

"In God we trust; all others must bring data…"

W. Edwards Deming (1900-1993)

A **S**trategy of **U**ltra**P**rotective lung ventilation With **E**xtracorporeal CO_2 **R**emoval for **N**ew-**O**nset moderate to se**V**ere **A**RDS

The SUPERNOVA trial

INTERNATIONAL ECMO NETWORK
ECMONet

ESICM
EUROPEAN SOCIETY OF INTENSIVE CARE MEDICINE

TRIALS GROUP

Pilot trial, RCT

- PILOT trial
  - Feasibility and safety
  - 100 patients
  - 3 devices (MAQUET, NOVALUNG, ALUNG)
  - Start: October 2015
  - ESICM trial group
- RCT
  - Will randomize up to 1500 patients
  - Adaptive design
  - Protocol will be finalized according to the results of the Pilot trial
  - ESICM trial group

Study objectives

- **ECCO2R**
  - PALP, MAQUET; ILA, NOVALUNG; Hemolung, ALung
- To allow **V_T /Pplat/ΔP reduction**
  - in patients with moderate ARDS
  - P/F: 200-100 mmHg, with PEEP $\geq$ 5 cmH_2O
- This study will assess changes in
  - pH/ PaO_2 / $PaCO_2$, Respiratory Rate and device CO_2 clearance
  - In the first 24 hours of $ECCO_2R$ following V_T and plateau pressure reduction
  - In patients with moderate ARDS
- Safety variables will also be analyzed

Conclusion

- ExtraCorporeal CO_2 Removal
  - "Respiratory dialysis"
  - Not for refractory hypoxemia: VV-ECMO
- Potential for use for moderate to severe ARDS
  - To allow further reduction of Vt/Pplat/ΔP
  - To limit VILI, without major respiratory acidosis
- Before large diffusion, should be (re)tested in large clinical trials…


La Pitié "International Diploma in ECMO
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