Respiratory Management is Evolving (London Seminar)
Doubletree Hilton West End, London, UK
December 6, 2022, 13:30–14:00 HH

# Would You Consider Automated Ventilation?

## automated ventilation—is it about patients, or about something else?

Courtesy by Marcus Schultz

# Disclosures

- Xenios/Fresenius, Germany
- Roche Diagnostics, Netherlands
- Ferring Pharmaceuticals, Denmark
- Exvastat, UK
- Hamilton Medical AG, Switzerland

Courtesy by Marcus Schultz

# Agenda

- why
- safety
- effectiveness
- efficiency
- future

Courtesy by Marcus Schultz

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- why
- safety
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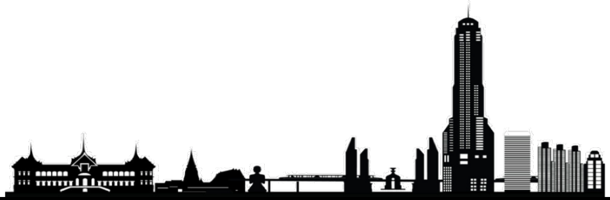
superiority & safety

↓

non–inferiority & easiness

Courtesy by Marcus Schultz





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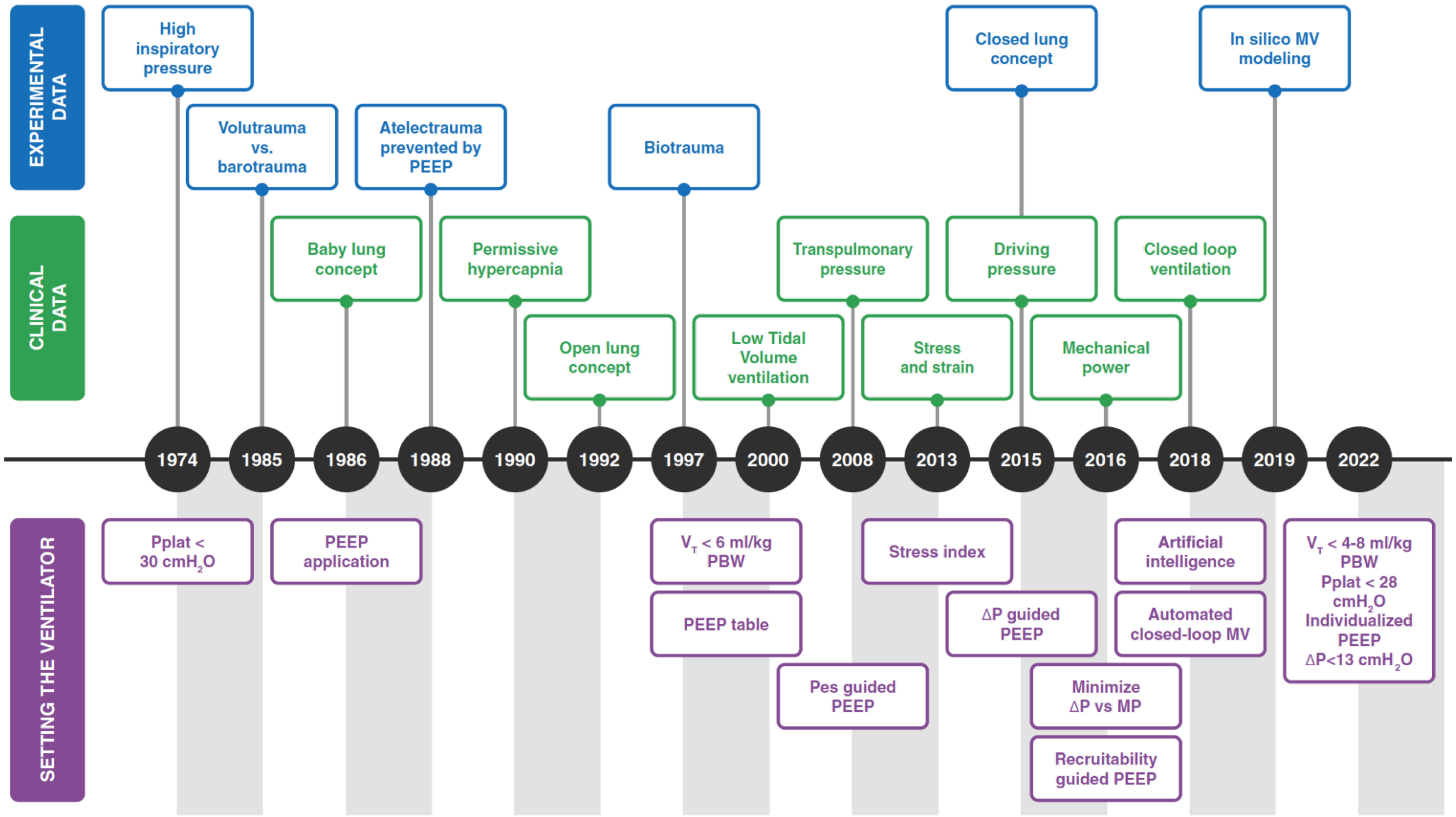
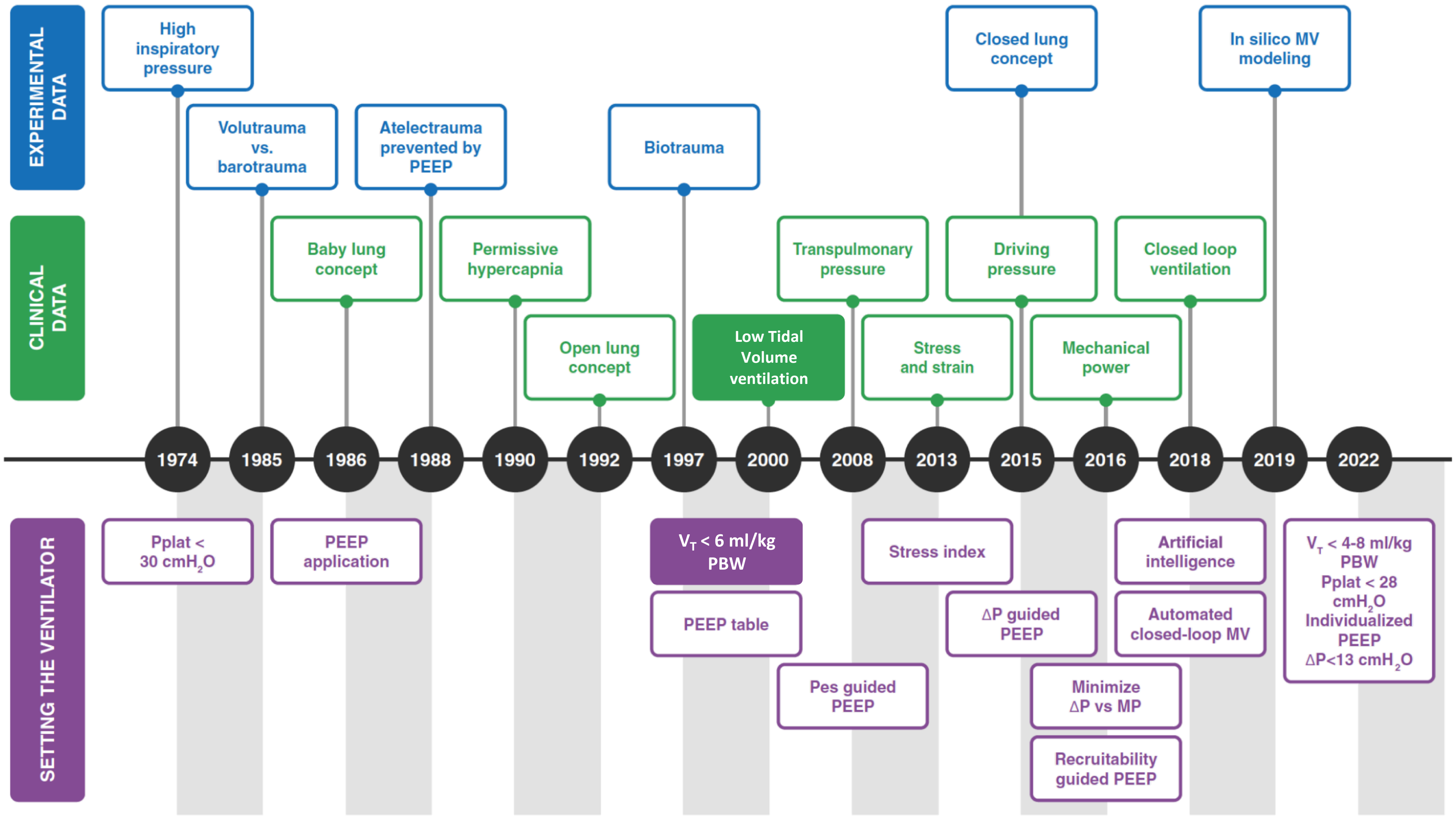



**Fig. 1** Contributions over time to the knowledge of how to apply protective ventilation

Juffermans N *Intensive Care Med* 2022; **48**:1629

Courtesy by Marcus Schultz

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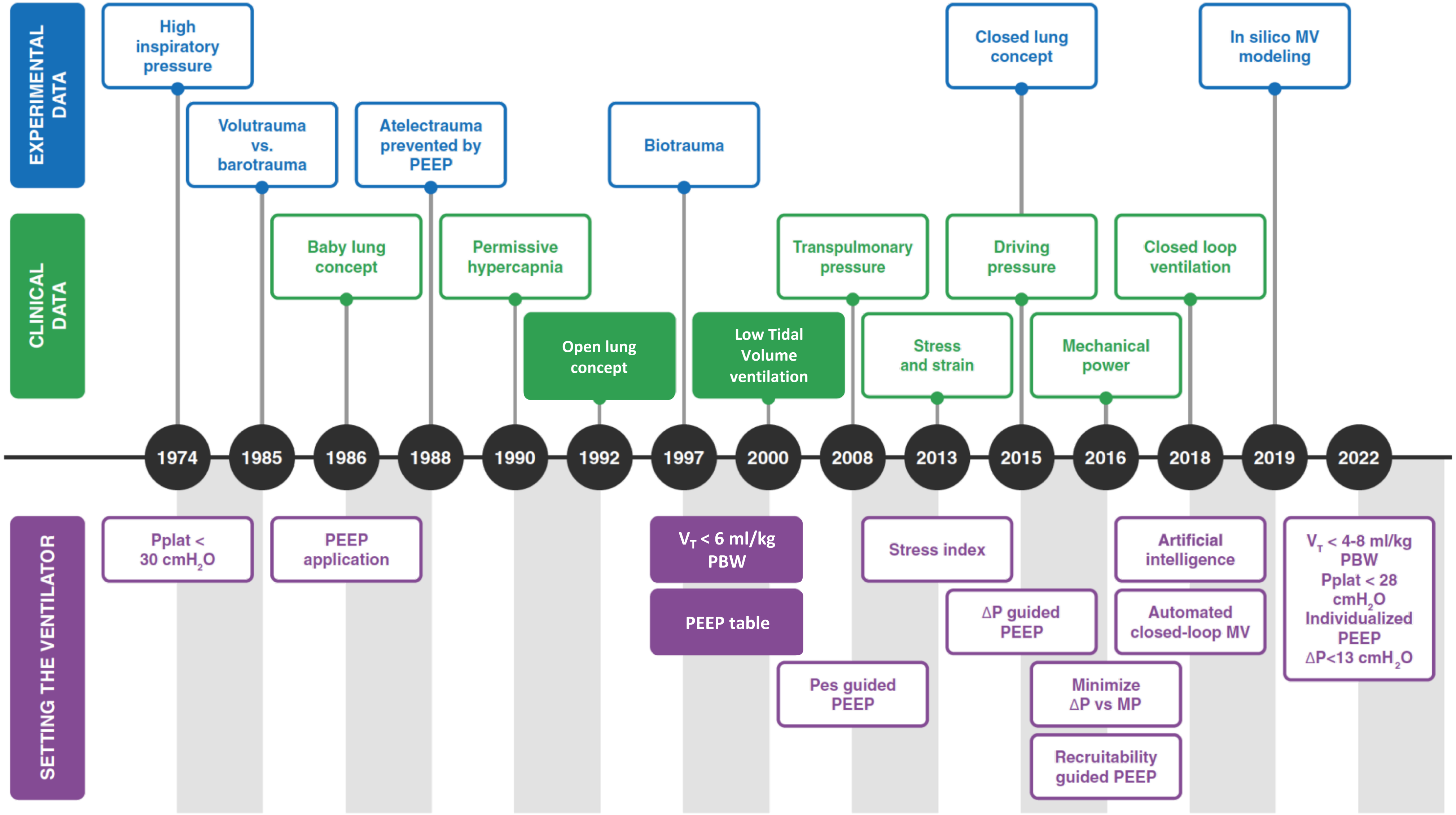


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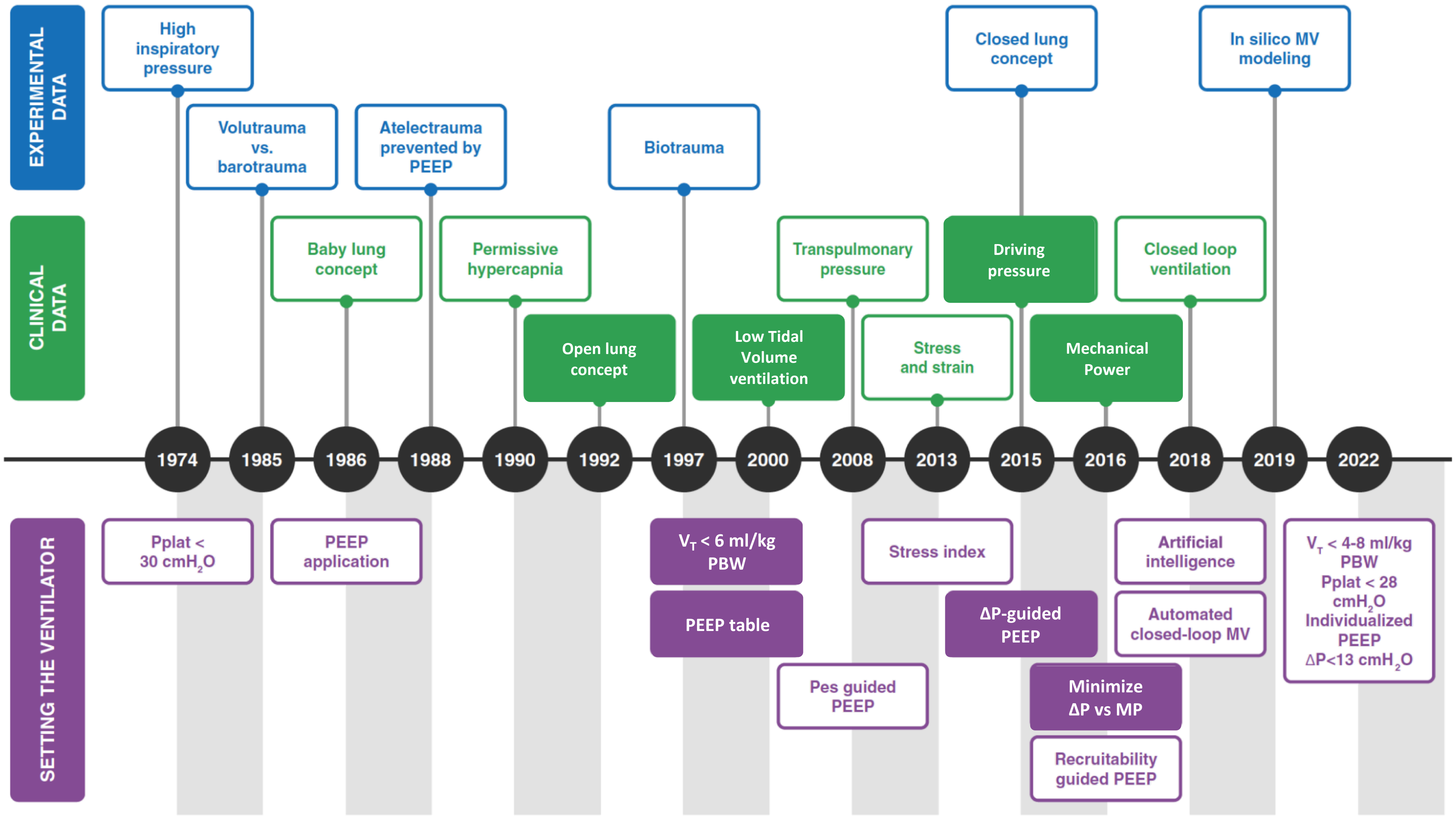


**Fig. 1** Contributions over time to the knowledge of how to apply protective ventilation

Juffermans N *Intensive Care Med* 2022; **48**:1629

The NEW ENGLAND JOURNAL of MEDICINE

**QUESTION** Does the use of a lower tidal volume ($V_T$) with mechanical ventilation affect important clinical outcomes in ARDS patients?

**CONCLUSION** Ventilation with a lower $V_T$ than is traditionally used results in decreased mortality and increases the number of days without ventilator use.

## POPULATION

**344** Women **516** Men

Patients with ARDS

Mean Age: **52** years

## LOCATION

**ICUs** in the USA

## VENTILATION STRATEGIES

**861** patients with mild, moderate or severe ARDS

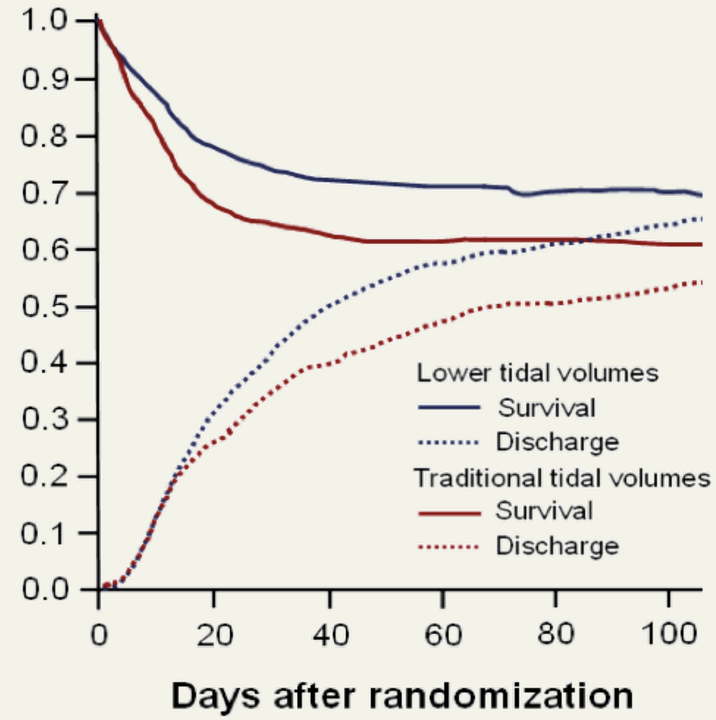
**432** patients
**lower $V_T$**
**(6 ml/kg)**
**[~ 400 to 500 ml]**

**429** patients
**traditional $V_T$**
**(12 ml/kg)**
**[~1000 to 1200 ml]**

## (PRIMARY) OUTCOME

Hospital mortality and duration of invasive ventilation

## FINDINGS




ARDS Network investigators. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. [*New Eng J Med* 2000; **342**:1301 doi: 10.1056/NEJM200005043421801]

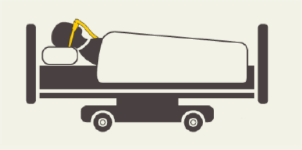
courtesy by Marcus Schultz

THE LANCET
Respiratory Medicine

**QUESTION** How was ventilation managed and what were the outcomes in invasively ventilated patients with COVID–19 in the Netherlands during the first months of the outbreak?

**CONCLUSION** Lung–protective ventilation with low $V_T$ and low ΔP was broadly applied and prone positioning was often used; applied PEEP varied widely, despite an invariably low respiratory system compliance.

## POPULATION



**320** Women **802** Men

Consecutive invasive ventilated patients in the first month of the national outbreak

Median Age: **67** years

## LOCATION

**22** ICUs
in the Netherlands

## TYPE OF VENTILATORY SUPPORT

individual patient data from
**1122** patients

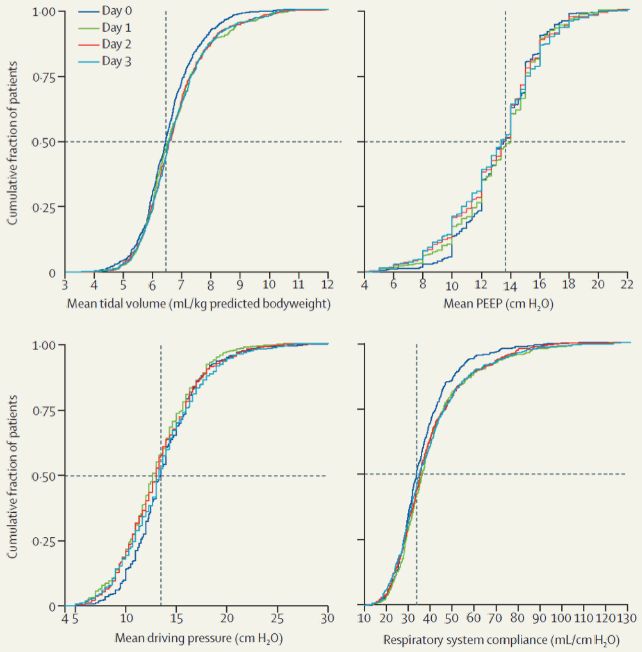
**1022**
**(invasively) ventilated**

**0**
**not ventilated**

## (PRIMARY) OUTCOME

a combination of $V_T$, PEEP, $C_{RS}$ and ΔP over the first 4 calendar days of ventilation; adjunctive treatments; VFD–28, LOS and mortality

## FINDINGS




$V_T$ had an independent association with mortality (OR, 1.28 [1.00–1.64]; *P*=.049)

The PRoVENT–COVID investigators. Ventilation management and clinical outcomes in invasively ventilated patients with COVID–19: a national, multicenter, observational cohort study. [Lancet Resp Med 2021; 9:132; doi:10.1016/S2213-2600(20)30459-8; Epub 2020 Oct 23]

courtesy by Marcus Schultz

BJA

**QUESTION** Is there heterogeneity in treatment effects in patients enrolled in the ART, using a machine learning approach?

**CONCLUSION** Recruitment maneuvers and titrated PEEP may be harmful in ARDS patients with pneumonia or requiring vasopressor support. Driving pressure appears to modulate the association between the ART study intervention, etiology of ARDS, and mortality.

## POPULATION

**379** Women **631** Men

consecutive patients with moderate to severe ARDS

Mean Age: **51** years

## LOCATION

**120** ICUs
from **9** countries

## VENTILATION STRATEGIES

**1010** patients with moderate or severe ARDS

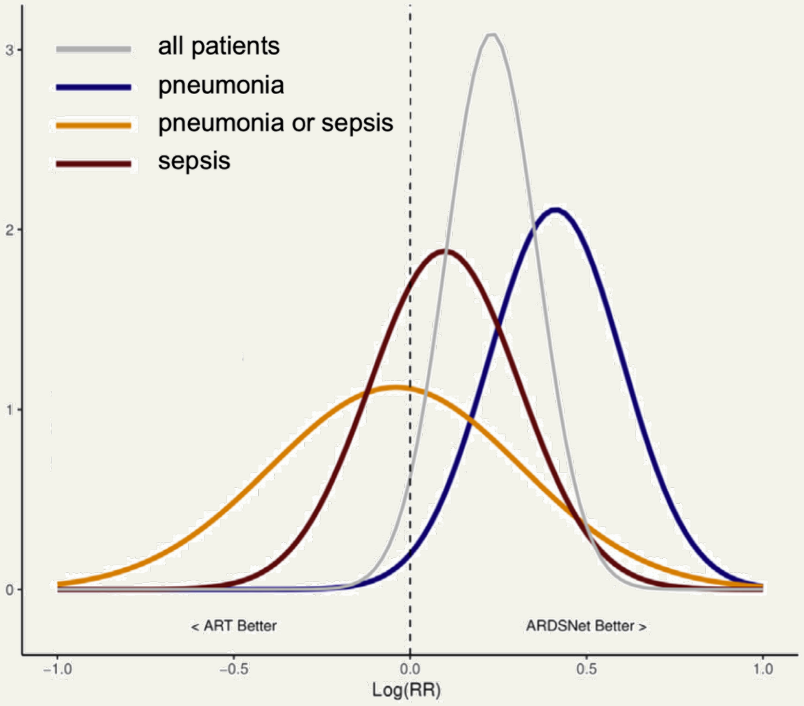
**501** patients
**titrated (high) PEEP**
**[>15 cm $H_2O$] with RM**

**509** patients
**standard (low) PEEP**
**[< 12 cm $H_2O$] without RM**

## OUTCOME OF THE BAYESIAN ANALYSIS

28–day mortality

## FINDINGS




Zampieri F for the ART Investigators. Heterogeneous effects of alveolar recruitment in acute respiratory distress syndrome: a machine learning reanalysis of the Alveolar Recruitment for Acute Respiratory Distress Syndrome Trial [*BJA* 2019; **123**:88; 10.1016/j.bja.2019.02.026]

courtesy by Marcus Schultz

THE LANCET
Respiratory Medicine



**QUESTION** Does a mechanical ventilation strategy that is personalized to individual patients' lung morphology improve the survival of patients with ARDS when compared with standard of care?

**CONCLUSION** Personalization of ventilation decreased mortality in patients with ARDS [in the posthoc analysis]; a ventilator strategy misaligned with lung morphology substantially increases mortality.

## POPULATION

**114** Women **286** Men

patients with ARDS for less than 12 hours

Median Age: **62** years

## LOCATION

**20** ICUs in France

## INTERVENTION

**400** patients with moderate to severe ARDS

**204**
**standard care**
$V_T$ 6 ml/kg PBW
low PEEP

**196**
**personalized care**

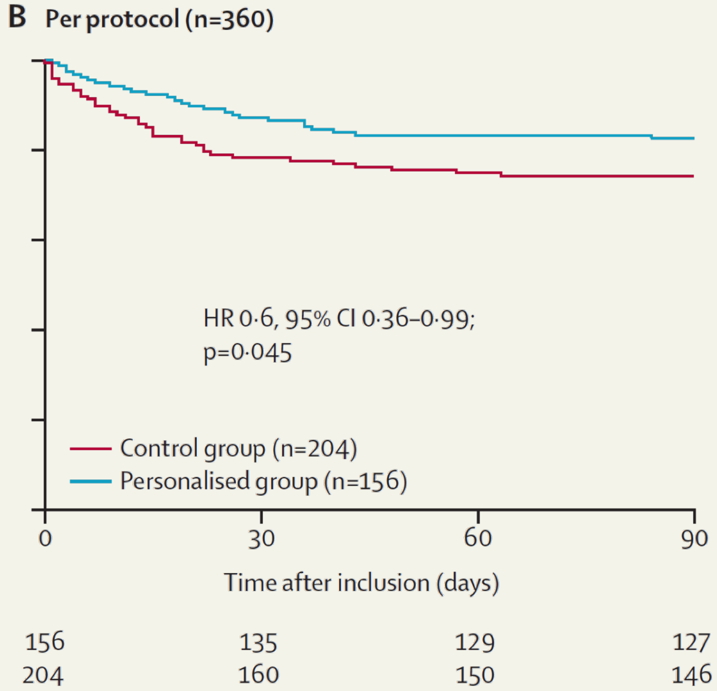
**non–focal**
$V_T$ 6 ml/kg PBW
high PEEP
with RM

**focal**
$V_T$ 8 ml/kg PBW
low PEEP and
prone positioning

## (PRIMARY) OUTCOME

mortality at day 90; ventilator–free days, ARDS resolution; LOS in ICU; barotrauma

## FINDINGS




LIVE–investigators. Personalized mechanical ventilation tailored to lung morphology versus low PEEP for patients with ARDS in France: a multicenter, single–blind, randomized clinical trial. [*Lancet Respir Med* 2019; **7**:870; doi:10.1016/S2213-2600(19)30138-9. Epub 2019 Aug 6]

THE LANCET
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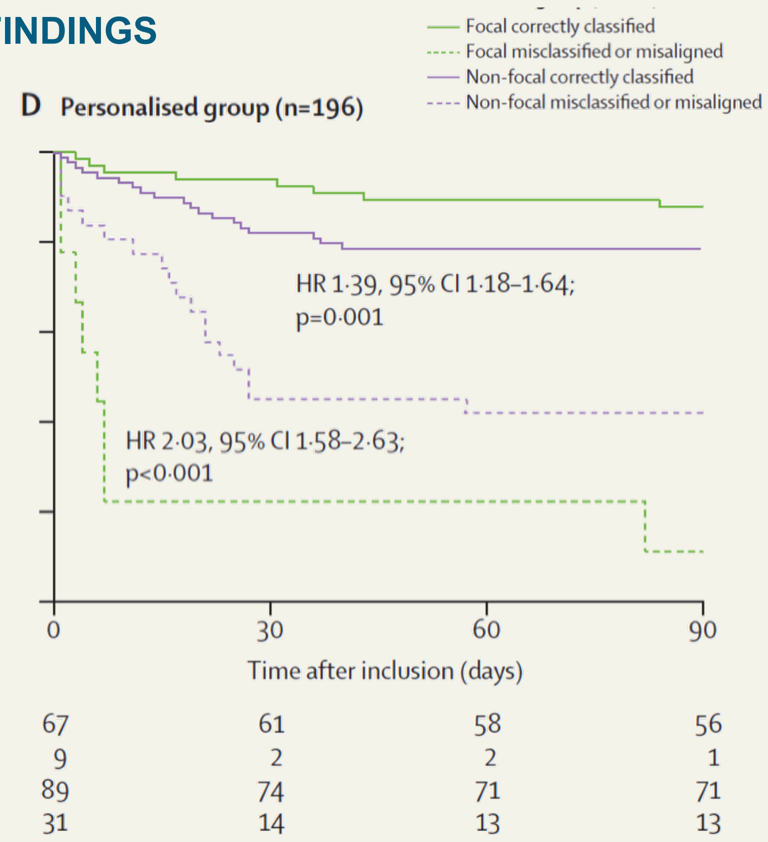


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The NEW ENGLAND JOURNAL of MEDICINE

**QUESTION** Is ΔP an index more strongly associated with survival than $V_T$ or PEEP in patients who are not actively breathing?

**CONCLUSION** ΔP is the ventilation variable that best stratified risk; decreases in ΔP owing to changes in ventilator settings may be strongly associated with increased survival.

## POPULATION

**~40%** Women **~60%** Men

patients with ARDS included in RCTs

Mean Age: from **34** to **60** years

## SOURCE

**9** trials worldwide

## METHODS

multilevel mediation analysis of individual patient data from **3562** patients

**prediction model**
**univariate**
**multivariate**

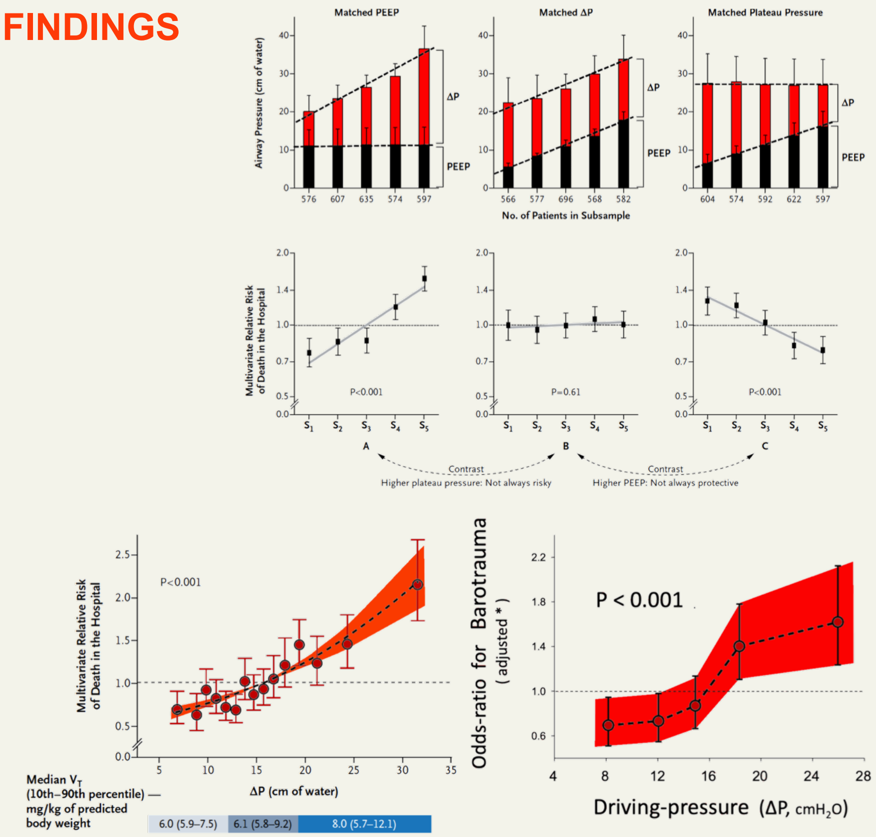
**mediation analysis**

**risk priority**
**of ΔP, $V_T$ and PEEP**

## (PRIMARY) OUTCOME

60–day mortality

## FINDINGS




Amato M. Driving Pressure and Survival in the Acute Respiratory Distress Syndrome. [*New Eng J Med* 2015; **372**:747; doi:10.1056/NEJMsa1410639]

courtesy by Marcus Schultz

THE LANCET
Respiratory Medicine

**QUESTION** What is the association between exposure to different intensities of mechanical ventilation over time and intensive care unit (ICU) mortality in patients with acute respiratory failure?

**CONCLUSION** Cumulative exposure to higher intensities of mechanical ventilation was harmful, even for short durations.

## POPULATION

**5141** Women **8267** Men

patients receiving ventilation for 4 hours or more

Median Age: **62** years

## LOCATION

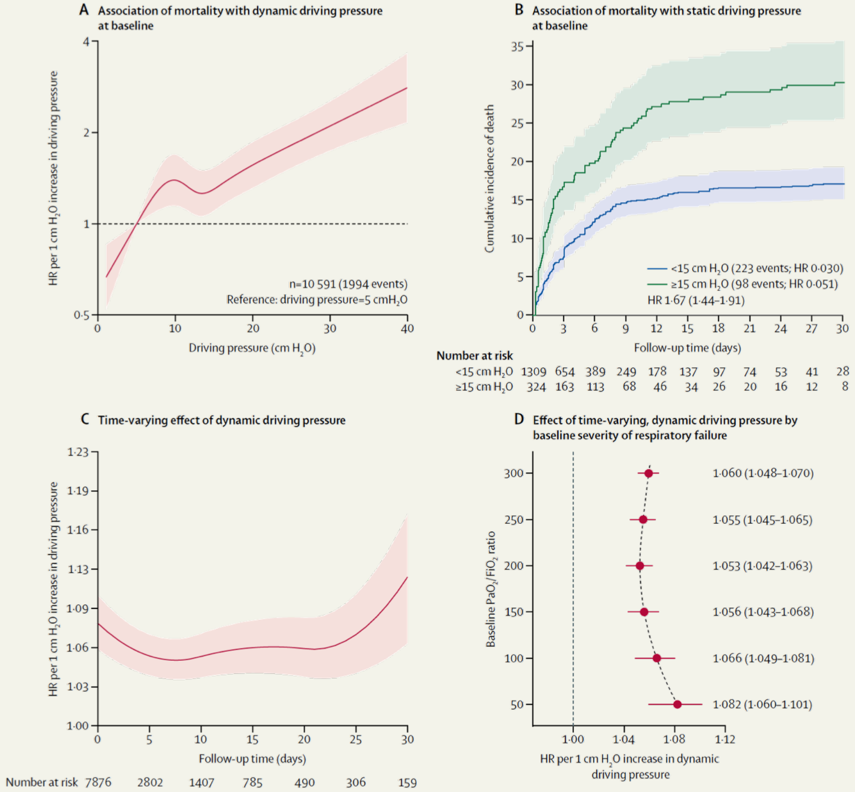
**9** ICUs in Toronto, Canada

## FINDINGS

| | Exposure to high driving pressure | | Exposure to high mechanical power | |
|---|---|---|---|---|
| | HR estimate (95% CrI) | p value | HR estimate (95% CrI) | p value |
| **Baseline variables** | | | | |
| $PaO_2/FiO_2$, mm Hg | 0·945 (0·896–0·994) | 0·026 | 0·977 (0·930–1·031) | 0·38 |
| Age, years | 1·108 (1·048–1·160) | <0·0001 | 1·128 (1·080–1·182) | <0·0001 |
| APACHE III score | 1·602 (1·526–1·680) | <0·0001 | 1·591 (1·524–1·669) | <0·0001 |
| APACHE pH | 0·832 (0·809–0·859) | <0·0001 | 0·840 (0·820–0·864) | <0·0001 |
| **Time-varying variables** | | | | |
| Days with driving pressure ≥15 cm $H_2O$ | 1·049 (1·023–1·076) | <0·0001 | .. | .. |
| Days with mechanical power ≥17 J/min | .. | .. | 1·069 (1·047–1·092) | <0·0001 |

1622 (20·6%) of 7876 patients died; 64 281 daily observations were recorded. HRs were the adjusted HRs associated with a 1-SD increment in the given variable. Values higher than 1 indicate increased mortality. The values used for SDs were as follows: $PaO_2/FiO_2$ ratio 119; pH 0·11; age 17 years; and APACHE III score 29. The effects of the number of days with either driving pressure greater than or equal to 15 cm $H_2O$ or mechanical power greater than or equal to 17 J/min were estimated using Quasi-Poisson models in the joint model analyses. HR=hazard ratio. CrI=credible interval. $PaO_2$=partial pressure of oxygen. $FiO_2$=fraction of inspired oxygen. APACHE=Acute Physiology and Chronic Health Evaluation.

*Table 3:* **Cumulative effect on HRs of exposure to high intensities of mechanical ventilation for 7876 patients with available data**




Urner M. Time-varying intensity of mechanical ventilation and mortality in patients with acute respiratory failure: a registry-based, prospective cohort study. [*Lancet Resp Med* 2020; **8**:905; doi: 10.1016/S2213-2600(20)30325-8]

courtesy by Marcus Schultz

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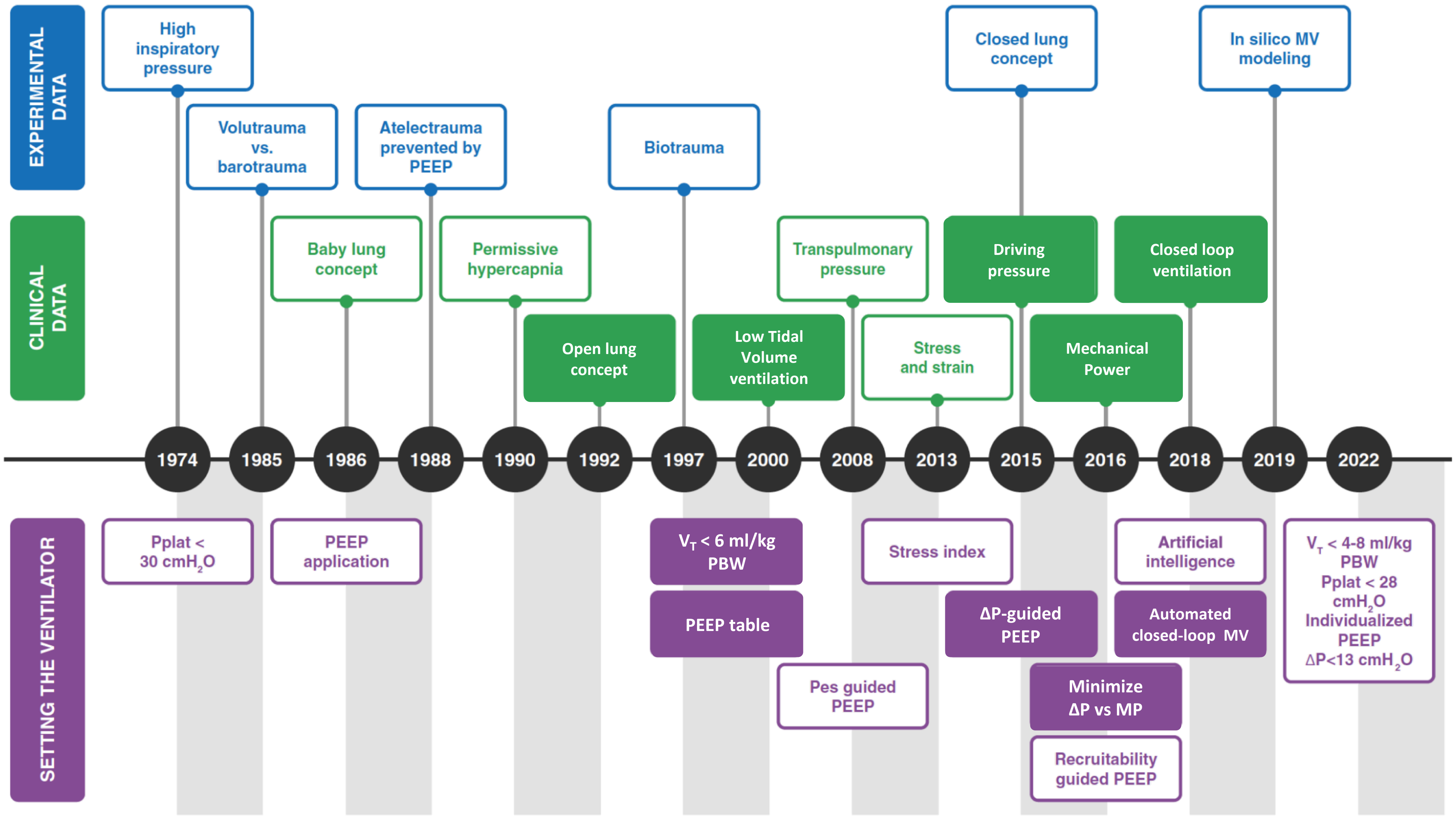


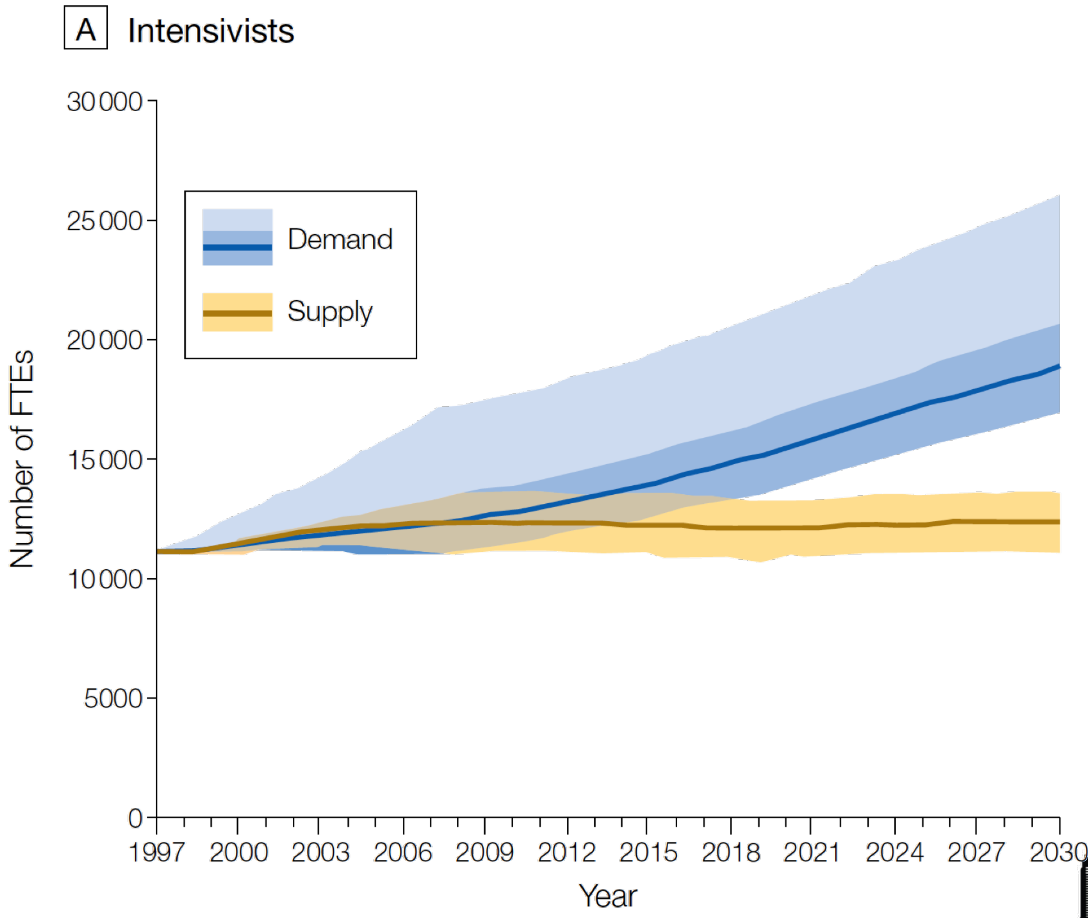

**Fig. 1** Contributions over time to the knowledge of how to apply protective ventilation

Juffermans N *Intensive Care Med 2022; in press*

Courtesy by Marcus Schultz

# Healthcare Workers

- gaps between supply and demands

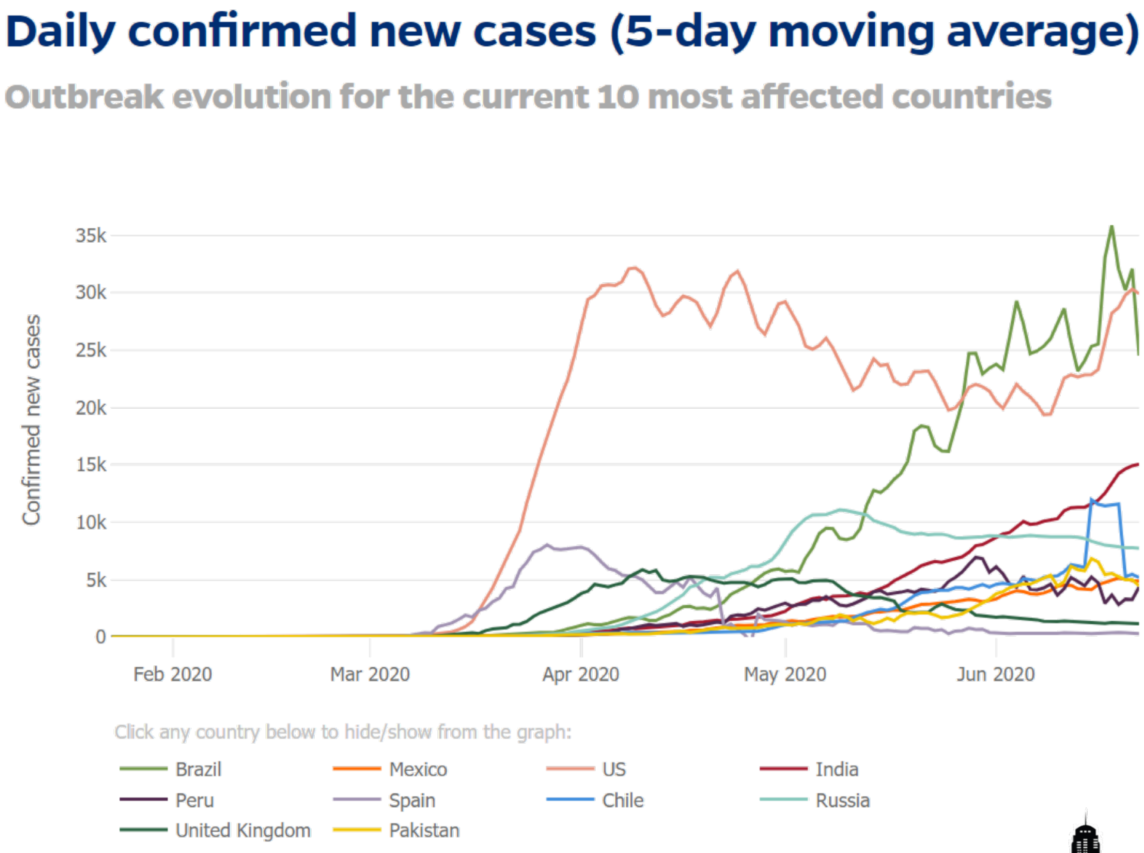



Angus D. *JAMA* **2000**; 284:2762

Courtesy by Marcus Schultz

# Healthcare Workers

- gaps between supply and demands

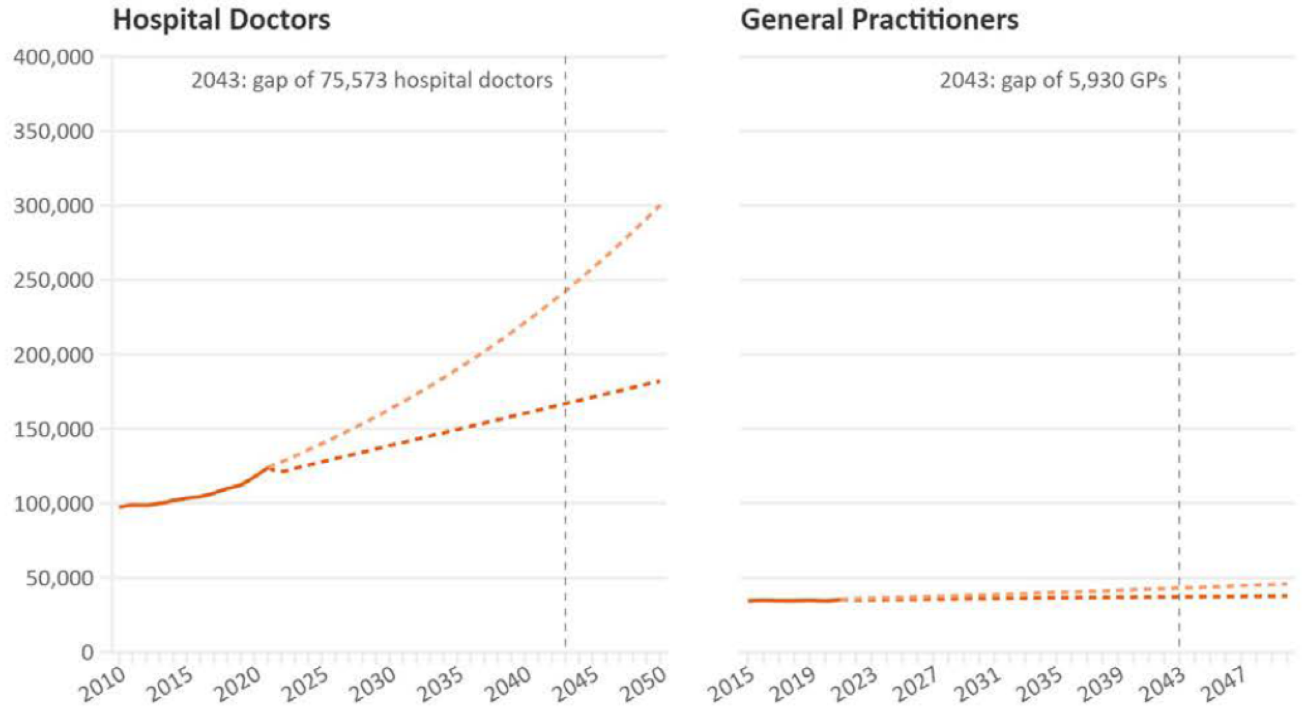



Johns Hopkins University

Courtesy by Marcus Schultz

# Healthcare Workers

- gaps between supply and demands




**Potential gap between supply and demand of NHS doctors (FTE)**

Gap between **projected trend growth** and **required growth** to meet expected growth in activity level

BMA 20210134

quarantine

Courtesy by Marcus Schultz

communication


Courtesy by Marcus Schultz

# oxygen shortages

Courtesy by Marcus Schultz

A History of

# Automated Ventilation

**Despite years of research in mechanical ventilation many settings remained to be set by hand**

**Here is when the ventilators became smarter**


**PAV+**
monitors flow and volume
inspiratory assist in proportion to patient's effort
1 — **1992** — PAV+

**ASV**
automated selection of $V_T$ and RR
according to the least WOB (Otis)
2 — **1998**

**NAVA**
monitors diaphragm activity
inspiratory assist in proportion to diaphragm activity
3 — **2002**

**SmartCare**
automated weaning mode
monitors $V_T$, RR, and $etCO_2$
reduction of PS and performs SBT
4 — **2006**

**INTELLiVENT–ASV**
automated selection of $V_T$ and RR
according to the least WOB (Otis) and FOB (Mead)
monitors $V_T$, RR, $etCO_2$ and $SpO_2$
automated titrations of AMV, PEEP and $FiO_2$
reduction of AMV via reduction of PS, performs SBT
5 — **2016**

Buiteman–Kruizinga L *Intensive Care Med* 2022; **48**:943

Buiteman–Kruizinga L *Clin Crit Care* 2022; *submitted*

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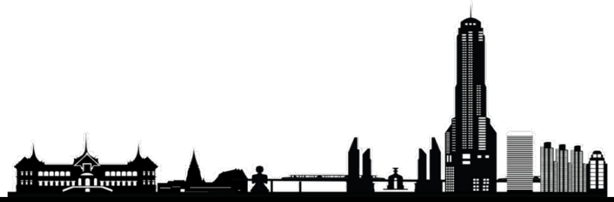
Courtesy by Marcus Schultz

# Safety

- derangement requiring immediate intervention
- (severe) adverse events
- unsafe ‘ventilation ranges’

Courtesy by Marcus Schultz





# Safety

- derangement requiring immediate intervention
- (severe) adverse events
- unsafe ‘ventilation ranges’

Courtesy by Marcus Schultz

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**Table 3.** Safety of INTELLiVENT–ASV.

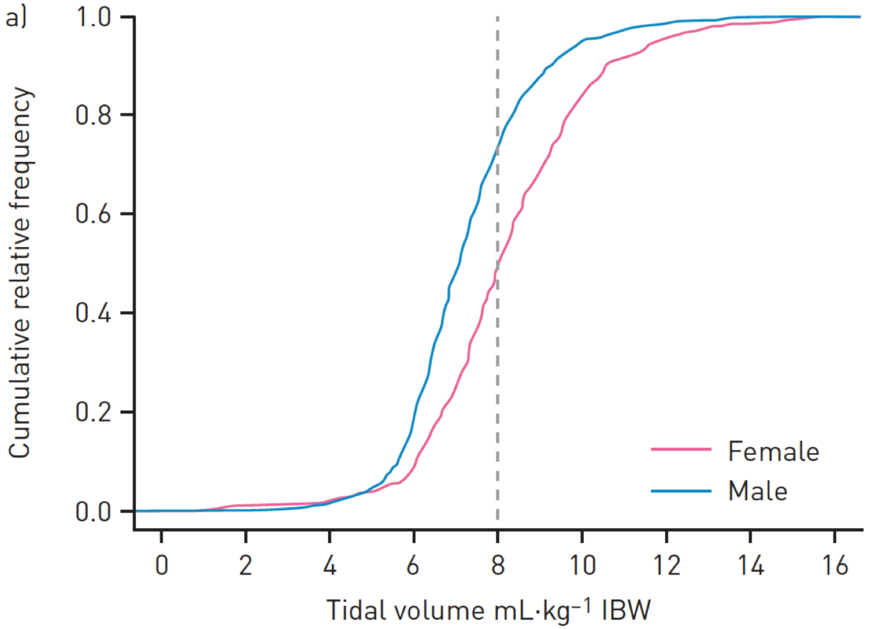
| Author | Ref. | Ventilation parameter | Not acceptable range | Time within not acceptable range (min) | Time within not acceptable range (%) | Incidence of episodes of derangements (n/%) |
|---|---|---|---|---|---|---|
| Lellouche *et al.* (2013) | 43 | $V_T$ (ml/kg PBW) | > 12 | 1 ± 4 vs 15 ± 38* | 0.5 vs 7.3* | - |
| | | $etCO_2$ (mmHg) | < 25 or ≥ 51 | | | |
| | | Plateau pressure ($cmH_20$) | > 35 | | | |
| | | $SpO_2$ (%) | < 85 | | | |
| Bialais *et al.* (2016) | 46 | $V_T$ (ml/kg PBW) | < 3 or > 12[a,b,c] | - | 1.3 (0.1–8.0) vs 0.8 (1.1–4.3) | - |
| | | RR (breath/min) | < 10 or > 30[a] <10 or > 35[b,c] | - | 0.9 (1.4–8.5) vs 1.7 (2.7–14.1) | - |
| | | $P_{max}$ ($cmH_20$) | > 30[a,b,c] | - | 6.4 (13.3–31.6) vs 0.0 (7.1–30.4)** | - |
| | | $SpO_2$ (%) | < 90[a,b] < 83[c] | - | 0.5 (0.6–3.0) vs 0.7 (1.4–6.1) | - |
| | | $etCO_2$ (mmHg) | > 55[a] < 26 or > 43[b] < 30 or > 65[c] | - | 0.0 (0.1–2.3) vs 0.1 (1.6–15.8) | - |
| Fot *et al.* (2017) | 47 | $V_T$ (ml/kg PBW) | < 6 | - | - | 3/17 vs 11/55 |
| | | | > 10 | - | - | 1/6 vs 5/25 |
| | | $etCO_2$ (mmHg) | < 25 | - | - | 5/28 vs 7/35 |
| | | | > 45 | - | - | 6/33 vs 9/45 |
| | | RR (breath/min) | > 30 | - | - | 3/17 vs 7/35 |
| | | $SpO_2$ (%) | < 90 | - | - | 0 vs 2/10 |
| Chelly *et al.* (2020) | 50 | $SpO_2$ (%) | < 90 | 5 ± 12 vs 6 ± 11* | - | 30/11 vs 50/19* |
| | | | < 85 | 2 ± 6 vs 3 ± 8* | - | 69/26 vs 92/35* |
| De Bie *et al.* (2020) | 51 | $V_T$ (ml/kg PBW) | > 12 | - | 1.5 ± 4.7 vs 3.6 ± 8.1* | 23,710/4.7 vs 38,929/7.3**[d] |
| | | $P_{max}$ ($cmH_20$) | ≥ 36 | | | |
| | | $etCO_2$ (mmHg) | < 25 or ≥ 51 | | | |
| | | $SpO_2$ (%) | < 85 | | | |

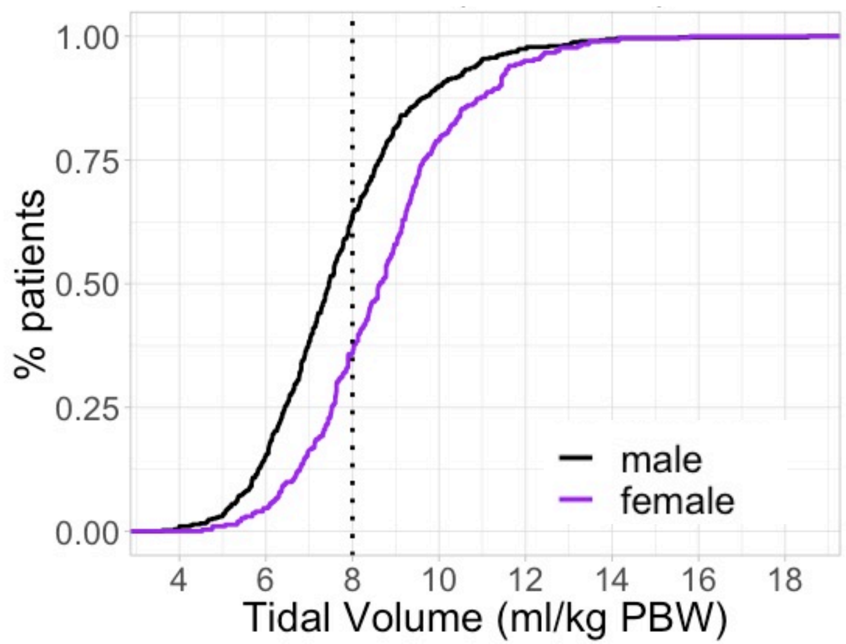
Botta M *Exp Rev Resp Med* 2021; **15**:1403

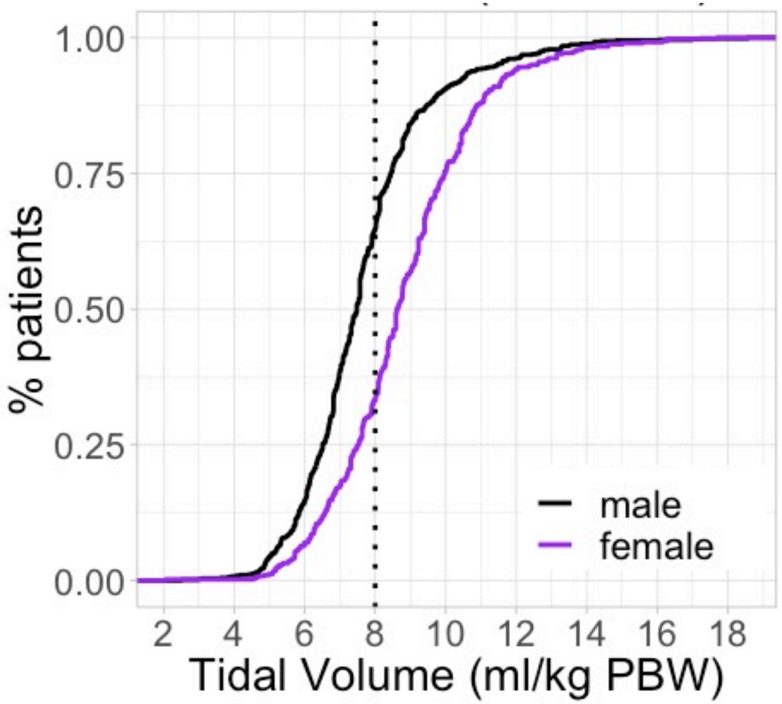
courtesy by Marcus Schultz

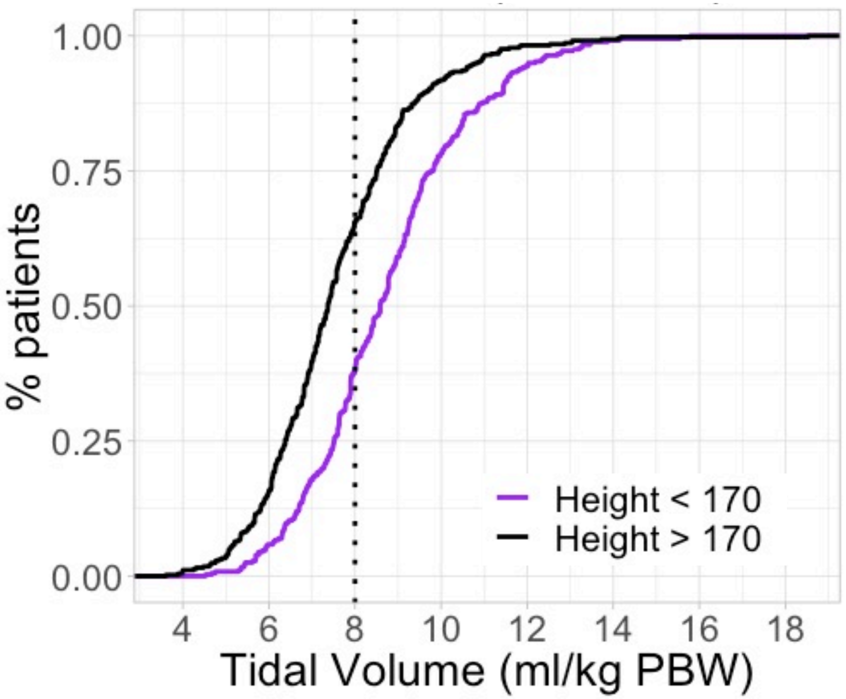
McNicholas B *Eur Resp J* 2019; **54**: 1900609

Serpa Neto A *Lancet RM* 2016; **4**:882



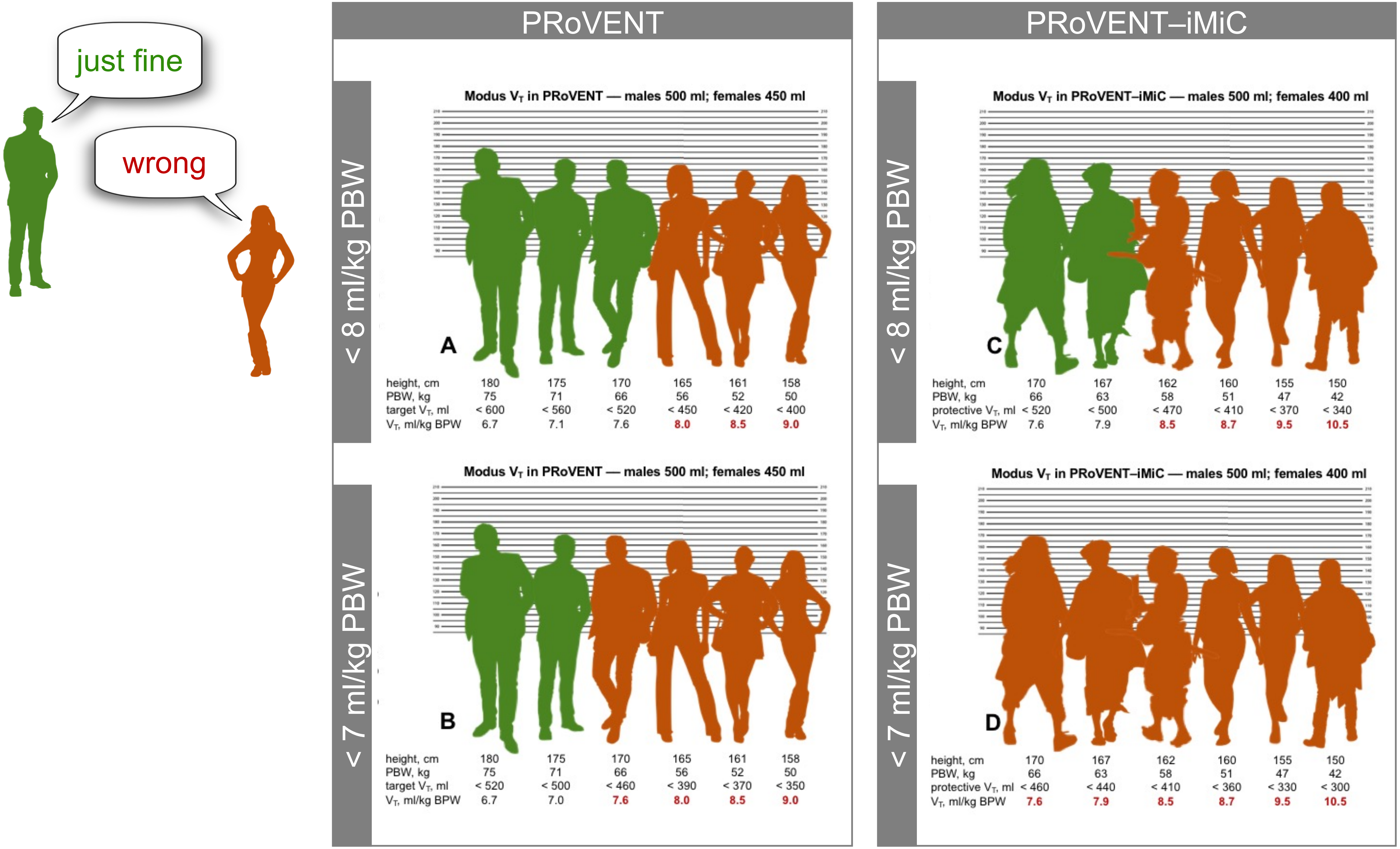




Pisani L *Lancet RM* 2017; **10**:e227

courtesy by Marcus Schultz




Schultz M *Eur Resp J* 2019; **54**:1901588

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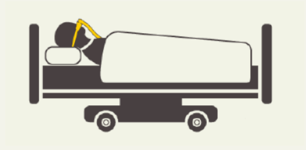
Courtesy by Marcus Schultz

BJA British Journal of Anaesthesia

**QUESTION** In patients receiving post–operative ventilation after cardiac surgery, does INTELLiVENT–ASV improve the quality of breathing compared with conventional ventilation?

**CONCLUSION** Fully automated ventilation in patients after cardiac surgery optimized lung–protective ventilation during postoperative ventilation, with fewer episodes of severe hypoxaemia and an accelerated resumption of spontaneous breathing.

## POPULATION



**67** Women **153** Men

patients after uncomplicated cardiac surgery

Median Age: **62–76** years

## LOCATION

**1** ICU in the Netherlands

## INTERVENTION

**220** patients after surgery

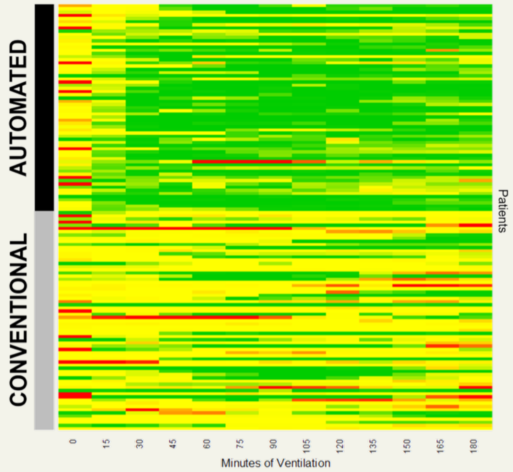
**111** conventional ventilation

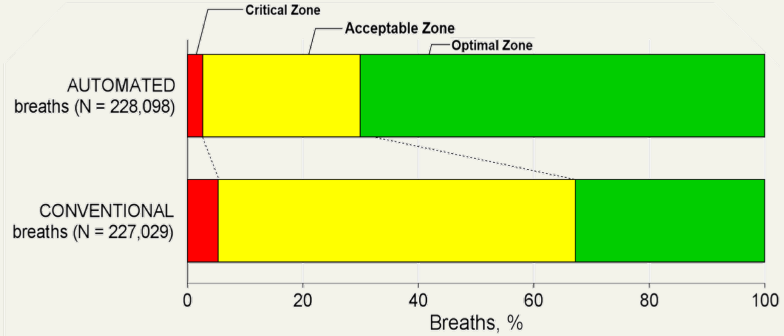
**109** automated ventilation

## (PRIMARY) OUTCOME

proportion of breath within predefined optimal, acceptable, and critical ranges ($V_T$, Pmax, $SpO_2$ and $etCO_2$); severe hypoxaemia ($SpO_2$ <85%) and resumption of spontaneous breathing

## FINDINGS




POSITiVE–investigators. Fully automated postoperative ventilation in cardiac surgery patients: a randomized clinical trial. [*BJA* 2021; **125**:739; doi: 10.1016/j.bja.2020.06.037]

courtesy by Marcus Schultz

Critical Care Explorations
Society of Critical Care Medicine
The Intensive Care Professionals

**QUESTION** Is the amount of mechanical power of ventilation (MP) under adaptive support ventilation (ASV) different from that under nonautomated pressure–controlled ventilation?

**CONCLUSION** This study suggests ASV may have benefits compared with pressure–controlled ventilation with respect to the MP transferred from the ventilator to the respiratory system in passive invasively ventilated critically ill patients.

## POPULATION

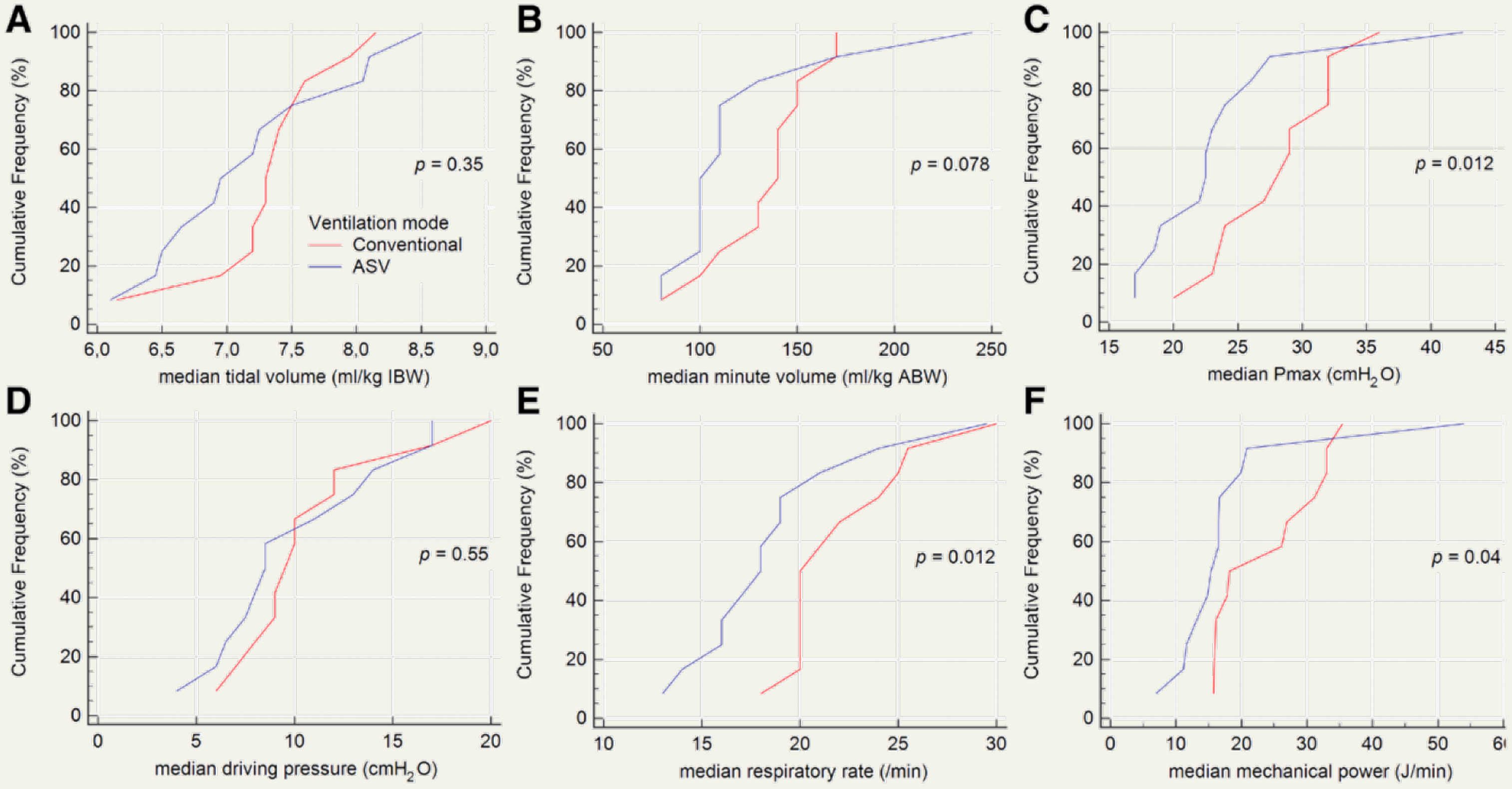
**7** Women **15** Men

patients expected to nee invasive ventilation for the next 24 hours

Median Age: **67** years

## LOCATION

**1** ICUs in The Netherlands




Buiteman–Kruizinga L. Comparison of Mechanical Power During Adaptive Support Ventilation Versus Nonautomated Pressure–Controlled Ventilation—A Pilot Study. [*Crit Care Explorations* 2021; **3**:e0335. doi: 10.1097/CCE.0000000000000335]

courtesy by Marcus Schultz

Journal of
*Clinical Medicine*

**QUESTION** In COVID–19 patients with ARDS, does INTELLiVENT–ASV reduce the driving pressure and mechanical power of ventilation compared with conventional ventilation?

**CONCLUSION** INTELLiVENT–ASV reduces the intensity of ventilation in COVID–19 patients with ARDS.

## POPULATION

**12** Women **39** Men

COVID–19 with moderate to severe ARDS

Median Age: **63** years

## LOCATION

**2** ICUs in the Netherlands

## INTERVENTION

**51** patients intubated in the ICU for acute hypoxemia

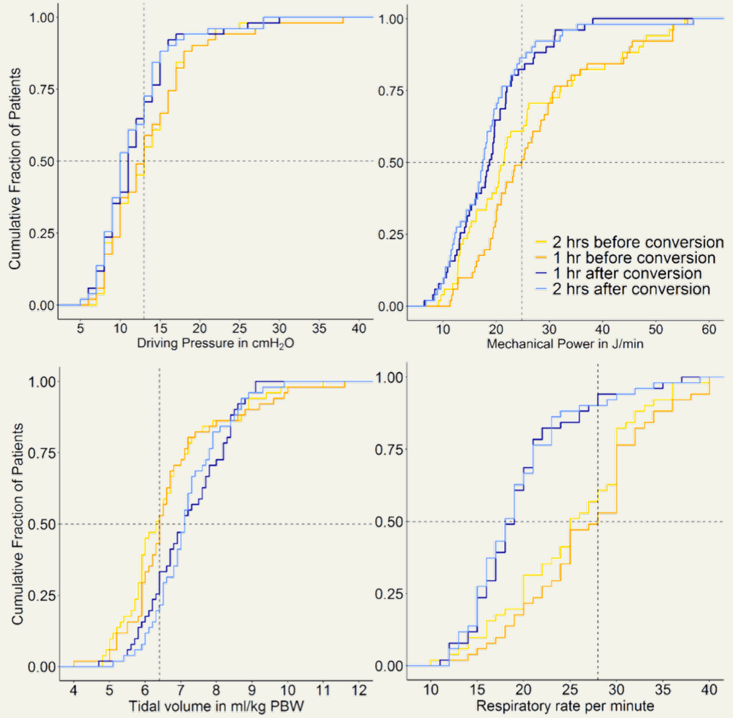
**conventional ventilation** → **automated ventilation**

*crossover*

## (PRIMARY) OUTCOME

ΔP and MP before and after converting from conventional ventilation to INTELLiVENT–ASV

## FINDINGS




Buiteman–Kruizinga L. Effect of INTELLiVENT-ASV versus Conventional Ventilation on Ventilation Intensity in Patients with COVID-19 ARDS—An Observational Study. [*J Clin Med* 2021; 10:5409]

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Journal of
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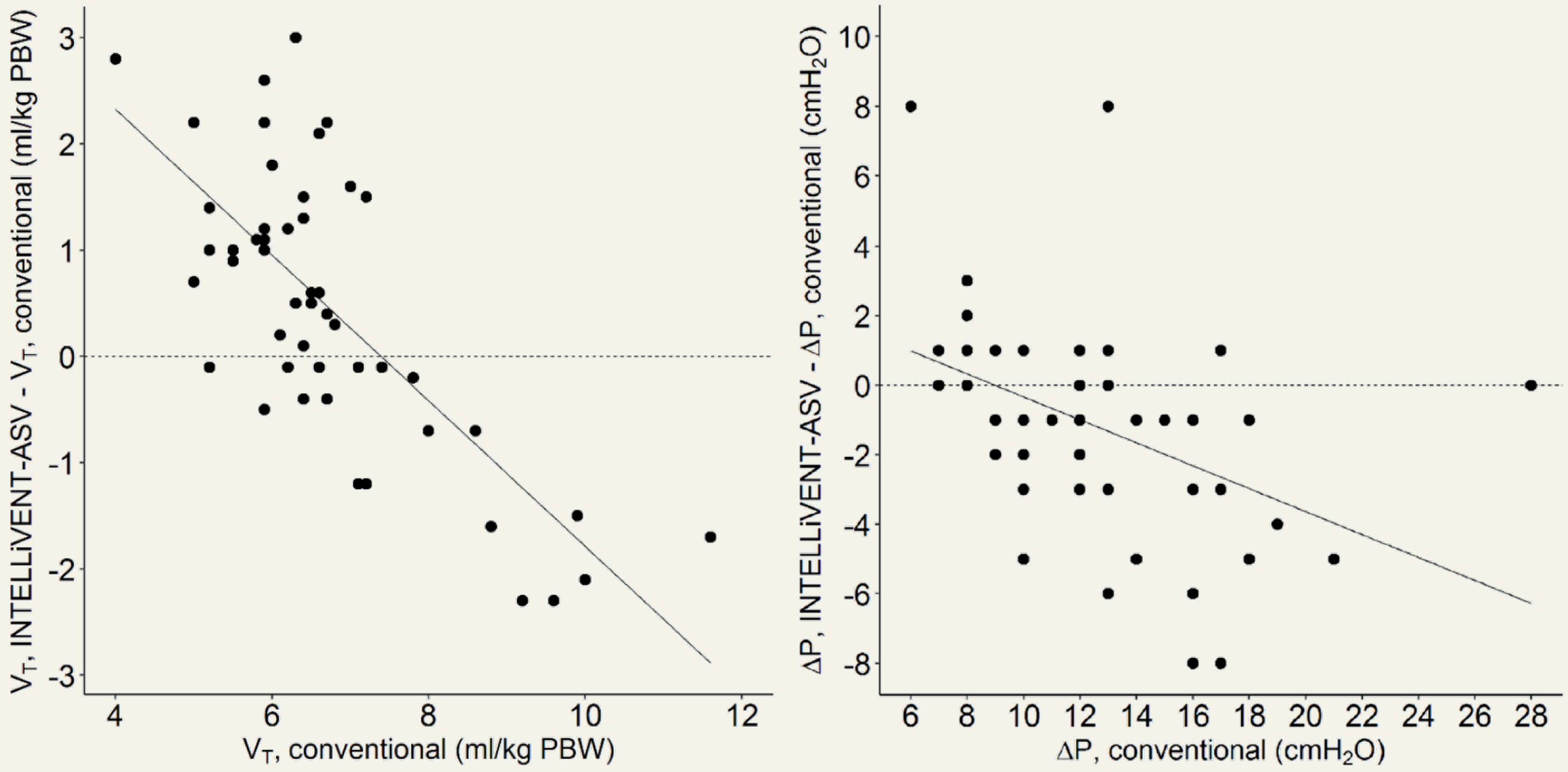



Buiteman–Kruizinga L. Effect of INTELLiVENT-ASV versus Conventional Ventilation on Ventilation Intensity in Patients with COVID-19 ARDS—An Observational Study. [*J Clin Med* 2021; 10:5409]

courtesy by Marcus Schultz

frontiers | Frontiers in Medicine

**QUESTION** What is the effect of automated closed–loop oxygen control, compared to automated ventilation with manual oxygen titrations, on time spent in predefined pulse oximetry ($SpO_2$) zones in pediatric critically ill patients?

**CONCLUSION** In this randomized crossover trial in pediatric critically ill patients under invasive ventilation with ASV, the percentage of time spent within in optimal $SpO_2$ zones increased with the use of closed–loop oxygen control.

## POPULATION

**37** Pediatric Patients

children with or without ARDS under invasive ventilation

Median Age: **1** year

## LOCATION

**1** ICU in Turkey

## INTERVENTION

37 patients under ASV for acute hypoxemia

↓

**2 hours manual or automated $FiO_2$ control**

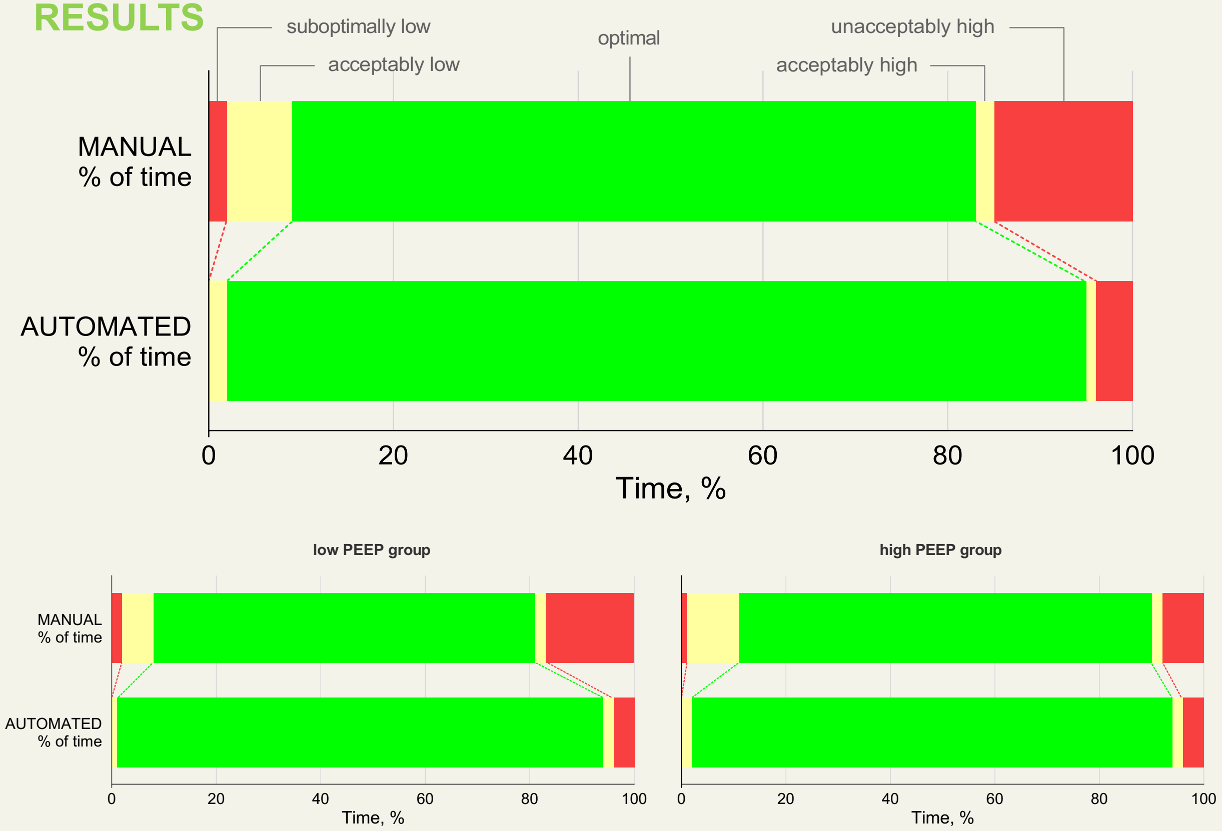
↓ *crossover*

**2 hours automated or manual $FiO_2$ control**

## (PRIMARY) OUTCOME

$FiO_2$ settings and $SpO_2$ readings

## RESULTS




Soydan E & Ceylan G. Automated Closed–loop $FiO_2$ Titration Increases the Percentage of Time spent in Optimal Zones of Oxygen Saturation in Pediatric Patients—a randomized crossover clinical trial [Frontiers Med 2022; 9:969218; doi: 10.3389/fmed.2022.969218]

CRITICAL CARE

**QUESTION** What is the efficacy of a closed–loop oxygen control in critically ill patients with moderate to severe acute hypoxemic respiratory failure (AHRF) treated with high flow nasal oxygen (HFNO).

**CONCLUSION** Closed–loop oxygen control improves oxygen administration in patients with moderate-to-severe AHRF treated with HFNO, increasing the percentage of time in the optimal oxygenation range and decreasing the workload of healthcare personnel.

## POPULATION

**45** patients under HFNO

patients with moderate to severe ARF, including patients with COVID–19

Median Age: **49** year

## LOCATION

**1** ICU in Spain

## INTERVENTION

45 patients under HFNO

**4 hours manual or automated $FiO_2$ control**

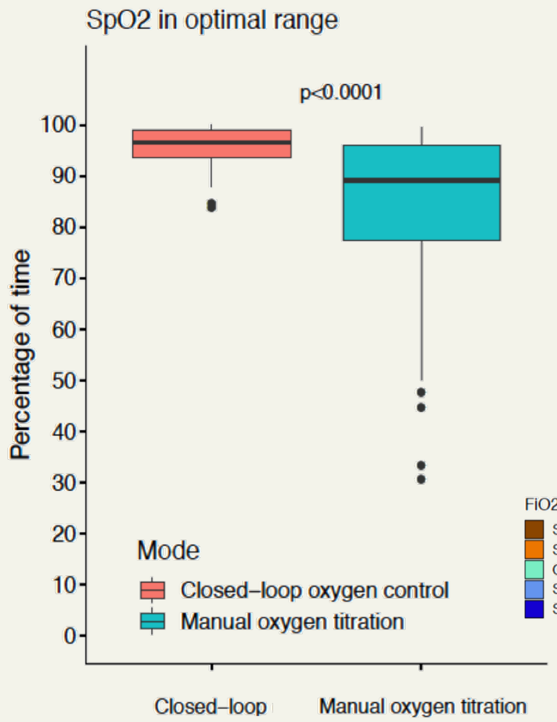
*crossover*

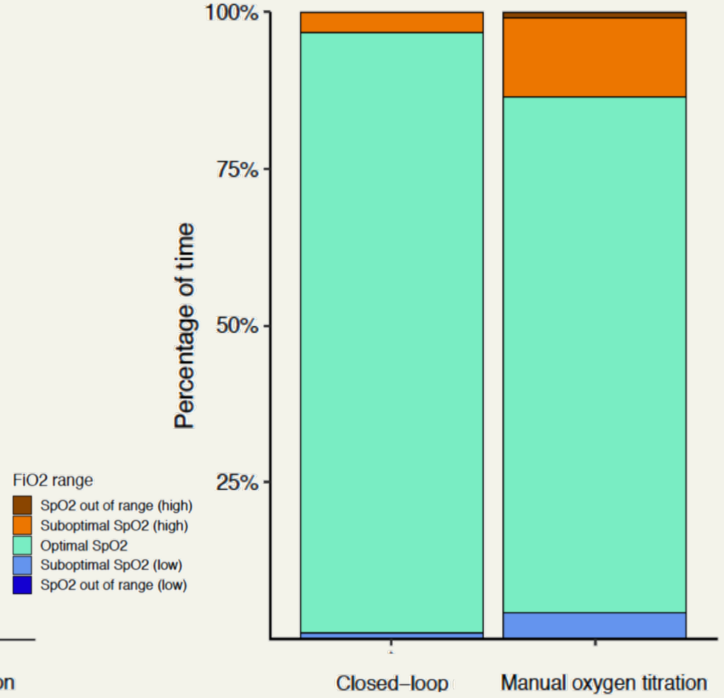
**4 hours automated or manual $FiO_2$ control**

## (PRIMARY) OUTCOME

percentage of time spent in the individualized optimal $SpO_2$ ranges

## RESULTS




Roca O. Closed–loop oxygen control improves oxygen therapy in acute hypoxemic respiratory failure patients under high flow nasal oxygen (HILOOP): a randomized cross-over study. [*Crit Care* 2022; **26**:108; doi10.1186/s13054-022-03970-w]

courtesy by Marcus Schultz

frontiers | Frontiers in Medicine

**QUESTION** What is the effect of HFNO with closed–loop control of the fraction of inspired oxygen ($FiO_2$), compared to HFNO with manual titrations of the $FiO_2$, on time spent in predefined pulse oximetry ($SpO_2$) zones in pediatric critically ill patients?

**CONCLUSION** In this randomized crossover trial in pediatric critically ill patients under HFNO, the percentage of time spent within in optimal $SpO_2$ zones increased with the use of closed–loop $FiO_2$ control.

## POPULATION

**23** Pediatric Patients

children with acute hypoxemic respiratory failure under HFNO

Median Age: **1** year

## LOCATION

**3** ICUs in Turkey

## INTERVENTION

**23** patients under HFNO for acute hypoxemia

**manual or automated $FiO_2$ control**

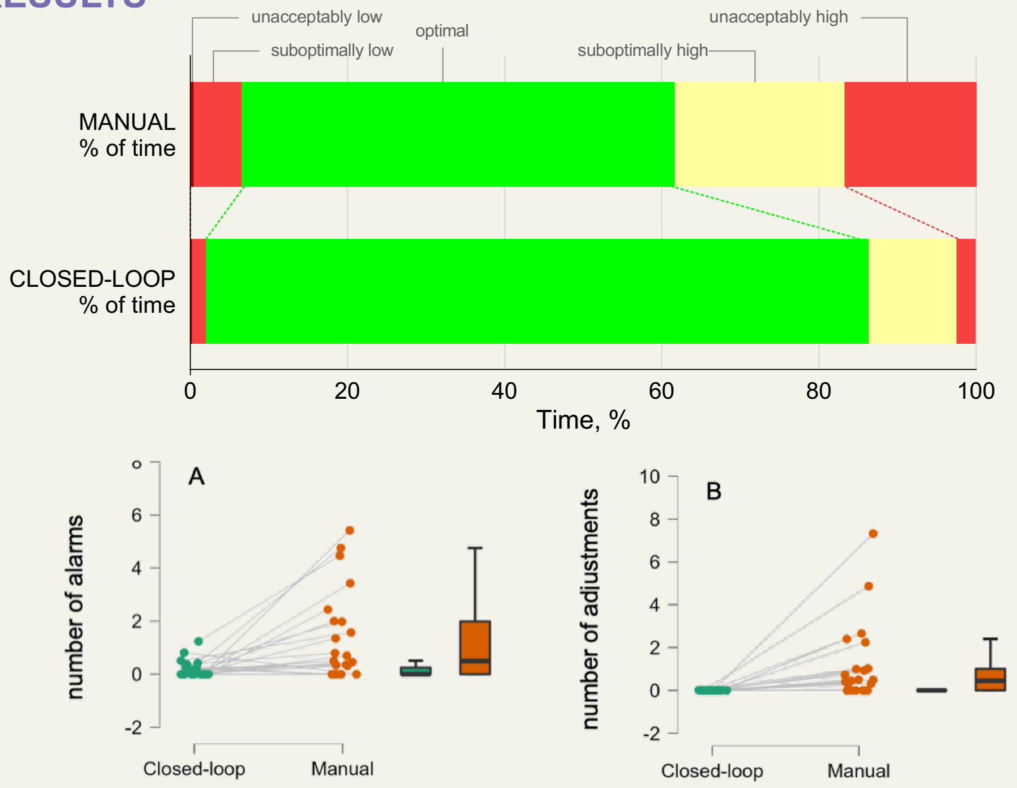
*crossover*

**automated or manual $FiO_2$ control**

## (PRIMARY) OUTCOME

$FiO_2$ settings and $SpO_2$ readings; alarms and manual adjustments

## RESULTS



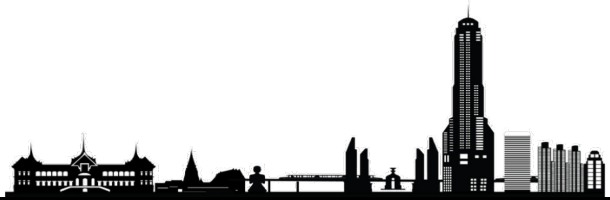

Sandal O. Closed–loop Oxygen Control Improves Oxygenation in Pediatric Patients Under High–flow Oxygen Therapy – a randomized crossover study. [Frontiers Med 2022; *in press*]

courtesy by Marcus Schultz

# Agenda

- why
- safety
- effectiveness
- efficiency
- future

Courtesy by Marcus Schultz



# Agenda

- why
- safety
- effectiveness
- efficiency
- future

Courtesy by Marcus Schultz

# Challenges

- reduction in workloads?
  - what is workload
  - how to measure workload
  - cost–effectiveness?
  - translation in better … what?

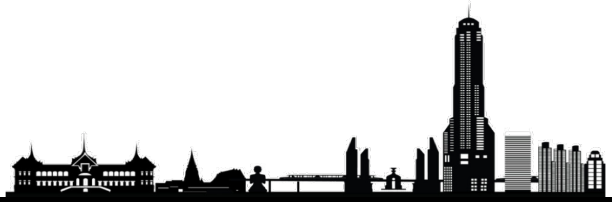
Courtesy by Marcus Schultz

# Future

- benefits of automated ventilation are ‘safety’ and ‘effectiveness’
- automated ventilation is non–inferior to conventional ventilation with regard to outcomes
- workloads, workloads, workloads, workloads, workloads, workloads, workloads, workloads, workloads
- scarcities, scarcities, scarcities, scarcities, scarcities, scarcities, scarcities, scarcities

Courtesy by Marcus Schultz





# Take Home Messages

- do no longer expect studies about superiority with respect to mortality
- expect studies about workloads & scarcities

Courtesy by Marcus Schultz