INTELLIVENT-ASV

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Closed loop ventilation mode in Intensive Care Unit: a randomized controlled clinical trial comparing the numbers of manual ventilator setting changes

Arnal JM, Garnero A, Novotni D, Corno G, Donati SY, Demory D, Quintana G, Ducros L, Laubscher T, Durand-Gasselin J

Minerva Anestesiologica 2018 January;84(1):58-67

PMID 28679200, http://www.ncbi.nlm.nih.gov/pubmed/28679200

Design	Randomized controlled study; INTELLiVENT-ASV versus conventional modes (VAC + PSV)
Patients	60 ICU patients with an expected duration of mechanical ventilation of at least 48 hours
Objectives	Compare the number of manual ventilator setting changes, the number of arterial blood gas analyses, the sedation dose and the user acceptance
Main Results	The number of manual ventilator setting changes per 24h per subject was lower in INTELLiVENT-ASV when compared to the conventional ventilation group (5 [4-7] versus 10 [7-17]; p<0.001). The number of arterial blood gas analyses and the sedation doses were not significantly different between the groups. Nurses and physicians reported that INTELLiVENT-ASV was significantly easier to use than conventional ventilation.
Conclusion	INTELLIVENT-ASV reduces the number of manual ventilator setting changes with the same number of arterial blood gas analyses and sedation dose, and is easier to use for the caregivers when compared to conventional ventilation modes

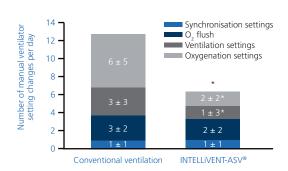


Figure 1: Number of manual ventilator setting changes and total number of ventilator setting changes per day, according to study group

Automated weaning from mechanical ventilation after off-pump coronary artery bypass grafting

Fot EV, Izotova NN, Yudina AS, Smetkin AA, Kuzkov VV, Kirov MY.

Front Med (Lausanne). 2017 Mar 21;4:31

PMID 28377920, http://www.ncbi.nlm.nih.gov/pubmed/28377920

Design	Randomized controlled study; INTELLiVENT-ASV with Quick Wean function versus
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protocolized weaning (SIMV + PSV)

Patients 40 patients after off-pump coronary artery bypass grafting

Objectives Compare duration of mechanical ventilation and assess safety

Main Results INTELLIVENT-ASV required a change in settings in 2 patients vs. 7 (5-9) adjustments per

patient in the protocolized weaning group. Incidence and duration of unacceptable ventilation were reduced in the INTELLiVENT-ASV group. The FiO2 during spontaneous breathing trials was significantly lower in the INTELLiVENT-ASV group: 30 (30-35) vs. 40 (40-45)% in the protocolized weaning group. The time until tracheal extubation did not differ between the INTELLiVENT-ASV and the protocolized weaning groups: 193 (115-309) and 107 (158-352) minutes, respectively.

and 197 (158-253) minutes, respectively.

Conclusion INTELLIVENT-ASV provides postoperative ventilation in a more protective way, reduces the

workload on medical staff, and does not prolong the duration of weaning

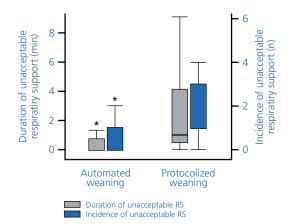


Figure 2: Incidence and duration of unacceptable ventilation were reduced in the INTELLIVENT-ASV group

Closed-loop ventilation mode (IntelliVent-ASV) in intensive care unit: a randomized trial of ventilation delivered

Bialais E, Wittebole X, Vignaux L, Roeseler J, Wysocki M, Meyer J, Reychler G, Novotni D, Sottiaux T, Laterre PF, Hantson P

Minerva Anestesiol. 2016 Jun;82(6):657-68

PMID 26957117, http://www.ncbi.nlm.nih.gov/pubmed/26957117

Design	Randomized controlled study, INTELLiVENT-ASV versus VPC and PSV
Patients	80 ICU patients ventilated for at least 48 h
Objectives	Compare safety, efficacy, and workload
Main Results	Ventilation parameters were similar in both groups except for PEEP (7 ± 4 cmH2O vs. 6 ± 3 cmH2O with INTELLiVENT-ASV and conventional ventilation, respectively, p = 0.028) and PetCO2 (36 ± 7 mmHg with INTELLiVENT-ASV vs. 40 ± 8 mmHg with conventional ventilation, p = 0.041). Safety was similar for INTELLiVENT-ASV and conventional ventilation for all parameters with the exception of Pmax. Efficacy was comparable for the two ventilation strategies for all parameters except SpO2 and Vt, which were more often optimal with INTELLiVENT-ASV (p = 0.005, p = 0.016, respectively). INTELLiVENT-ASV required fewer manual adjustments than conventional ventilation (p < 0.001) for a higher total number of adjustments (p < 0.001).
Conclusion	INTELLIVENT-ASV required fewer manual adjustments than conventional ventilation while delivering safe and effective ventilation

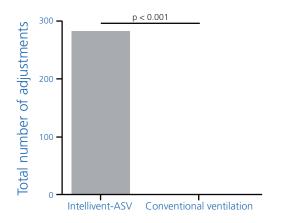


Figure 3: Total number of adjustments including automatic adjustments is higher with INTELLiVENT-ASV

Evaluation of fully automated ventilation: a randomized controlled study in post-cardiac surgery patients

Lellouche F, Bouchard PA, Simard S, L'Her E, Wysocki M

Intensive Care Med. 2013 Mar;39(3):463-71

PMID 23338569, http://www.ncbi.nlm.nih.gov/pubmed/23338569

Design	Randomized controlled study, INTELLiVENT-ASV versus VC + PSV
Patients	60 post-cardiac surgery patients
Objectives	Measure the duration of ventilation within a "not acceptable" range of tidal volumes
Main Results	The percentage of time within the predefined zones of optimal, acceptable, and not acceptable ventilation were 12%, 81%, and 7% with PV; and 89.5%, 10%, and 0.5% with INTELLIVENT-ASV (p < 0.001). 148 interventions during PV and 5 interventions with INTELLIVENT-ASV (p < 0.001).
Conclusion	INTELLIVENT-ASV was safe, reduced the number of interventions, and provided more time in the optimal zone and less time in the not-acceptable zone, in hemodynamically stable patients after cardiac surgery

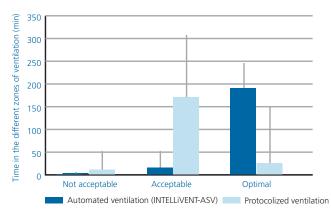


Figure 4: INTELLIVENT-ASV delivered more optimal ventilation than protocolized ventilation. Prococolized ventilation delivered acceptable ventilation.

A prospective comparison of the efficacy and safety of fully closed-loop control ventilation (Intellivent-ASV) with conventional ASV and SIMV modes

Abutbul A, Sviri S, Zbedat W, Linton DM, van Heerden PV S Afr J Crit Care. 2014 Aug;30(1):28-32

Design	Prospective crossover study
Patients	20 ICU patients ventilated at least 24h
Objectives	Compares the efficacy of INTELLiVENT-ASV, ASV, and SIMV on ventilation and oxygenation parameters, blood gases, and hemodynamic status
Main Results	INTELLiVENT-ASV automatically selected higher PEEP (7.6 \pm 5 cmH2O) than the physician in ASV (5.1 \pm 2 cmH2O) and SIMV (5.2 \pm 2cm H2O), lower FiO2 (35 \pm 70 %) than ASV (41 \pm 60%) and SIMV (41 \pm 60%). There was no difference in RR, Vt , MV, Pinsp, PO2, and hemodynamic status. In ASV, PCO2 levels were lower than in INTELLiVENT-ASV and SIMV.
Conclusion	INTELLIVENT-ASV provides better oxygenation efficiency than ASV and SIMV
Comment	Same PO2 with lower FiO2 implies better ventilation/perfusion ratio due to higher PEEP, without hemodynamic consequences

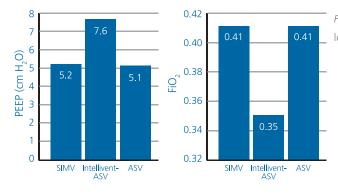


Figure 5: INTELLIVENT-ASV automatically selected higher PEEP and lower FiO2 than physicians in ASV and SIMV

Fully automated closed-loop ventilation is safe and effective in post-cardiac surgery patients

Beijers AJ, Roos AN, Bindels AJ

Intensive Care Med. 2014 May;40(5):752-3

PMID 24577110, http://www.ncbi.nlm.nih.gov/pubmed/24577110

Design	Prospective comparative non inferiority pilot study
Patients	128 low risk post cardiac surgery patients
Objectives	Compare safety and efficacy between INTELLiVENT-ASV, ASV, and conventional ventilation (PCV and PS)
Main Results	No ventilation-related safety issues. The number of interactions was lower in the INTELLIVENT-ASV group compared to the other groups. Duration of mechanical ventilation, reintubations, and desaturations were not different.
Conclusion	INTELLIVENT-ASV was safe and efficient in post cardiac surgery and required less interactions than conventional modes.

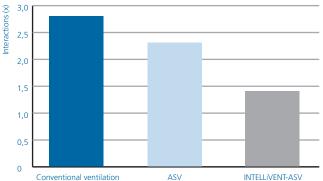


Figure 6: INTELLIVENT-ASV needed fewer manual settings than either ASV or conventional ventilation

Prospective randomized crossover study of a new closed-loop control system versus pressure support during weaning from mechanical ventilation

Clavieras N, Wysocki M, Coisel Y, Galia F, Conseil M, Chanques G, Jung B, Arnal JM, Matecki S, Molinari N, Jaber S

Anesthesiology. 2013 Sep;119(3):631-41

PMID 23619172 , http://www.ncbi.nlm.nih.gov/pubmed/23619172

Design	Prospective, randomized, single-blind crossover study. Two periods of 24 h, randomly PSV or INTELLiVENT-ASV
Patients	14 patients during the weaning phase
Objectives	Evaluate oxygenation and variability in the ventilatory parameters
Main Results	The PaO2/ FiO2 ratio improved significantly from 245 \pm 75 at baseline to 294 \pm 123 after 24 h of INTELLiVENT-ASV. The coefficient of variation of inspiratory pressure and positive end-expiratory pressure were significantly higher with INTELLiVENT-ASV, 16 [11-21] and 15 [7-23]%, compared with 6 [5-7] and 7 [5-10]% in PSV. Inspiratory pressure, positive end-expiratory pressure, and FiO2 changes were adjusted significantly more often with INTELLiVENT-ASV compared with PSV.
Conclusion	INTELLiVENT-ASV improved oxygenation with more variability than PSV, mainly in Pinsp, PEEP, and FiO2

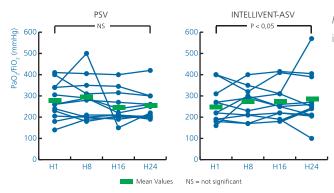


Figure 7: INTELLIVENT-ASV improved oxygenation in actively breathing ICU patients.

Feasibility study on full closed-loop control ventilation (INTELLiVENT-ASV) in ICU patients with acute respiratory failure: a prospective observational comparative study

Arnal JM, Garnero A, Novotni D, Demory D, Ducros L, Berric A, Donati SY, Corno G, Jaber S, Durand-Gasselin J Crit Care. 2013 Sep 11;17(5):R196

PMID 24025234, http://www.ncbi.nlm.nih.gov/pubmed/24025234

Design	Prospective observational comparative feasability study
Patients	100 unselected ICU patients
Objectives	Compare oxygenation and ventilation settings automatically selected by INTELLiVENT-ASV in 3 lung conditions: normal lungs, ARDS, and COPD, in passive and active patients
Main Results	No safety issues. Fully automated ventilation was used for 95% of the total ventilation time. In passive patients, Vt was significantly different between normal lung, ARDS, and COPD patients, 8.1 (7.3-8.9) ml/kg PBW; 7.5 (6.9-7.9) ml/kg PBW; 9.9 (8.3-11.1) ml/kg PBW, respectively. In passive ARDS patients, FiO2 and PEEP were statistically higher than passive normal lung (35 (33-47)% versus 30 (30-31)%, and 11 (8-13) cmH2O versus 5 (5-6) cmH2O, respectively. The ventilation controller was deactivated in 2 patients for 1 day (increased CO2 gradient). PEEP and FiO2 controllers were deactivated for 1 day in 7 patients because of poor SpO2 quality (5 shocks, 1 therapeutic hypothermia, 1 severe chronic arterial disease). The PEEP controller was deactivated in 3 patients (1 COPD, 1 pneumothorax, and 1 ARDS). The FiO2 controller was deactivated in one COPD patient (hyperoxia).
Conclusion	INTELLIVENT-ASV was safely used in unselected ventilated ICU patients. Automatically

selected oxygenation and ventilation settings were different according to the lung condition.

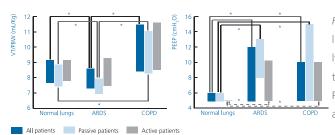


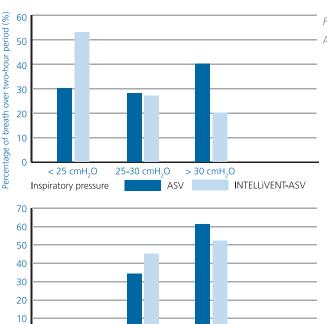
Figure 8: The ventilation parameter Vt was different according to lung condition in the passive patient subgroup. It was not significantly different in the active patient subgroup, as ventilation drive controlled volume and the respiratory rate. The oxygenation parameter PEEP was different according to lung condition in all patients (active and passive).

Safety and efficacy of a fully closed-loop control ventilation (INTELLiVENT-ASV) in sedated ICU patients with acute respiratory failure: a prospective randomized crossover study

Arnal JM, Wysocki M, Novotni D, Demory D, Lopez R, Donati S, Granier I, Corno G, Durand-Gasselin J Intensive Care Med. 2012 May;38(5):781-7

PMID 22460854, http://www.ncbi.nlm.nih.gov/pubmed/22460854

Design	Prospective randomized crossover comparative study. Two periods of 2 h randomly ASV or INTELLiVENT-ASV
Patients	50 sedated ICU patients with ARDS
Objectives	Assess the safety and efficacy of INTELLiVENT-ASV in passive patients
Main Results	No safety issue. MV and Vt decreased from 7.6 (6.5-9.5) to 6.8 (6.0-8.0) I/min and from 8.3 (7.8-9.0) to 8.1 (7.7-8.6) mI/kg PBW during INTELLiVENT-ASV as compared to ASV. Pplat and FiO2 decreased from 24 (20-29) to 20 (19-25) cmH2O and from 40 (30-50) to 30 (30-39)% during INTELLiVENT-ASV as compared to ASV. RR, Pinsp, and PEEP decreased during INTELLiVENT-ASV as compared to ASV. Respiratory mechanics and blood gases were not different except for PaCO2, which was higher during INTELLiVENT-ASV.
Conclusion	INTELLiVENT-ASV was safe in passive patients with acute respiratory failure



6-8 mL/Kg

8-10 mL/Kg

10-12 mL/Kg

INTELLIVENT-ASV

 $\textit{Figure 9:} \ \ \textbf{INTELLIVENT-ASV} \ \ \text{decreased Pinsp and Vt compared with ASV}$

< 6 mL/Kg

Tidal volume

A rational framework for selecting modes of ventilation

Mireles-Cabodevila E, Hatipo⊠lu U, Chatburn RL

Respir Care. 2013 Feb;58(2):348-66 Erratum in Respir Care. 2013 Apr;58(4):e51

PMID 22710796, http://www.ncbi.nlm.nih.gov/pubmed/22710796

Design	Review
Patients	All ICU patients
Objectives	Describe and compare ventilatory modes
Main Results	INTELLIVENT-ASV is PC-IMV(OI,OI) [order- family(genus, species)]: pressure control, intermittent mandatory ventilation, optimal intelligence for the primary and secondary breaths targeting schemes.
Conclusion	INTELLIVENT-ASV is first among all modes in terms of safety (ventilation and oxygenation optimization), comfort, and weaning

Adaptive support ventilation with and without end-tidal CO2 closed loop control versus conventional ventilation

Sulemanji DS, Marchese A, Wysocki M, Kacmarek RM

Intensive Care Med. 2013 Apr;39(4):703-10

PMID 23151992, http://www.ncbi.nlm.nih.gov/pubmed/23151992

Design	Comparative Simulation study
Patients	Lungs model
Objectives	Compare PC, VC, ASV and ASV with ventilation controller in 4 clinical scenarios : Normal lung, COPD, ARDS and brain injury; with 2 points of interest : capnia and Pplat
Main Results	Ventilation parameters in normal lungs, brain injury, and COPD were similar for all modes. In ARDS, capnia was higher in ASV with the ventilation controller than in other modes, Pplat in ASV and ASV with ventilation controller were lower than in VC.
Conclusion	PC, VC, ASV, and ASV with ventilation controller performed similarly in most cases. In ARDS patients, ASV with ventilation controller delivered safer ventilation.

A pilot prospective study on closed loop controlled ventilation and oxygenation in ventilated children during the weaning phase.

Jouvet P, Eddington A, Payen V, Bordessoule A, Emeriaud G, Gasco RL, Wysocki M Crit Care. 2012 May 16;16(3):R85

PMID 22591622, http://www.ncbi.nlm.nih.gov/pubmed/22591622

Design	Prospective observational safety study 5 periods : PSV, ASV, ASV with ventilation controller, INTELLIVENT-ASV, PSV.
Patients	15 childrens, more than 7 Kg during the weaning phase
Objectives	Assess the safety by the percentage of time in normal ventilation
Main Results	No adverse events. Vt, RR, Pinsp, and MV were equivalent for all modalities. The percentage of time in normal ventilation were equivalent for all modalities. The PEEP controller needs further investigation.
Conclusion	ASV with ventilation controller and INTELLiVENT-ASV were safe and kept children under normal ventilation most of the time
Comment	The large ranges of normal ventilation in pediatric patients were probably responsible for the similarity between the groups.

Additional files

Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and acute respiratory distress syndrome

The Acute Respiratory Distress Syndrome Network

N Engl J Med. 2000 May 4;342(18):1301-8

PMID 10793162, http://www.ncbi.nlm.nih.gov/pubmed/10793162

Design	Multicenter randomized controlled study lower Vt (6 ml/Kg) et Pplat (30 cmH2O) versus traditionnal Vt (12 mL/Kg) et Pplat (50 cmH2O)
Patients	861 patients with ARDS
Objectives	Compare protective ventilation and traditional ventilation on clinical outcomes
Main Results	Mortality was lower in the lower Vt group than in the group treated with traditional tidal volumes (31.0 % vs. 39.8 %), and the number of days without ventilator during the first 28 days was greater in this group (12 \pm 11 vs. 10 \pm 11)
Conclusion	The "ARDSNet table" supports the way in which the oxygenation controller increases PEEP and FiO2

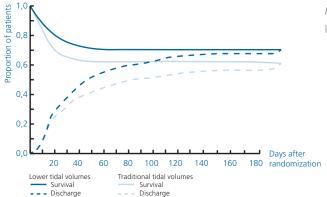


Figure 10: Probability of survival and of discharge were higher in the lower Vt group than in the traditional Vt group.

Higher versus lower positive end-expiratory pressures in patients with acute respiratory distress syndrome

Brower RG, Lanken PN, MacIntyre N, Matthay MA, Morris A, Ancukiewicz M, Schoenfeld D, Thompson BT; National Heart, Lung, and Blood Institute ARDS Clinical Trials Network

N Engl J Med. 2004 Jul 22;351(4):327-36

PMID 15269312, http://www.ncbi.nlm.nih.gov/pubmed/15269312

Design	Randomized controlled study lower versus higher PEEP levels, according to different tables of predetermined combinations of PEEP and FiO2
Patients	549 patients with ARDS
Objectives	Compare the effects of higher and lower PEEP levels on clinical outcomes
Main Results	PEEP was 8 cmH2O in the lower-PEEP group and 13 cmH2O in the higher-PEEP group. Hospital deaths were 24.9% and 27.5%, respectively. From day 1 to day 28, breathing was unassisted for a mean of 14.5 \pm 10.4 days in the lower-PEEP group and 13.8 \pm 10.6 days in the higher-PEEP group.
Conclusion	This study supports the high PEEP-FiO2 table used by the oxygenation controller for decreasing treatment
Comment	PEEP was not set according to recruitability. However, a high PEEP in patients with low potential of recruitability has a negative effect, and low PEEP in patients with high potential of recruitability is harmful.

Conservative oxygen therapy in mechanically ventilated patients: a pilot before-and-after trial

Suzuki S, Eastwood GM, Glassford NJ, Peck L, Young H, Garcia-Alvarez M, Schneider AG, Bellomo R Crit Care Med. 2014 Jun;42(6):1414-22

PMID 24561566, http://www.ncbi.nlm.nih.gov/pubmed/24561566

Design	Before-After study
Patients	108 ICU patients ventilated for more than 48h
Objectives	Compare 2 oxygenation goals: prescribed by clinician and SpO2 = 90-92%
Main Results	During period with "SpO2 = 90-92%", the SpO2, PaO2, and FiO2 were lower than during "prescribed goal" (95.5%, 83 torr and, 0.27 versus 98.4%, 107 torr, and 0.40, respectively). "SpO2 = 90-92%", decreased the total amount of oxygen delivered by two thirds (16 L vs 5 L; p < 0.001). The PaO2/FIO2 ratio was similar during the 2 periods. There were no difference in biochemical or clinical outcomes
Conclusion	Oxygenation goal "SpO2 = $90-92\%$ " in mechanically ventilated ICU patients was feasible and safe, and decrease the oxygen consumption.

Optimal duration of a sustained inflation recruitment maneuver in ARDS patients

Arnal JM, Paquet J, Wysocki M, Demory D, Donati S, Granier I, Corno G, Durand-Gasselin J Intensive Care Med. 2011 Oct;37(10):1588-94

Intensive Care Med. 2011 Oct,57(10).1566-94

PMID 21858522, http://www.ncbi.nlm.nih.gov/pubmed/21858522

Design	Prospective study
Patients	50 patients with ARDS
Objectives	Measure the dynamics of recruitment and the hemodynamic status during a sustained inflation recruitment maneuver
Main Results	Time constant was 2.3 \pm 1.3 s = most of recruitment occured in the first 10 s. Hemodynamic status was maintained for 10 s then decreased significantly.
Conclusion	In early-onset ARDS patients, a sustained inflation RM for 10 s was sufficient and safe. Supports the method used for automatic recruitment maneuver

Higher vs lower positive end-expiratory pressure in patients with acute lung injury and acute respiratory distress syndrome: systematic review and meta-analysis

Briel M, Meade M, Mercat A, Brower RG, Talmor D, Walter SD, Slutsky AS, Pullenayegum E, Zhou Q, Cook D, Brochard L, Richard JC, Lamontagne F, BhatnagarN, Stewart TE, Guyatt G JAMA. 2010 Mar 3;303(9):865-73

PMID 20197533, http://www.ncbi.nlm.nih.gov/pubmed/20197533

Design	Meta-Analysis
Patients	2299 patients with ARDS 3 trials
Objectives	Evaluate the association of higher vs lower PEEP with patient outcomes
Main Results	Mortality was 32.9% in patients assigned to the higher PEEP group and 35.2% in the lower PEEP group (adjusted relative risk = 0.94; 95% confidence interval [CI], 0.86-1.04)
Conclusion	Higher levels of PEEP were associated with improved survival in ARDS patients. This open-lung concept supports the way in which the oxygenation controller decreases PEEP and FiO2

BTS guideline for emergency oxygen use in adult patients

O'Driscoll BR, Howard LS, Davison AG; British Thoracic Society

Thorax. 2008 Oct;63 Suppl 6:vi1-68

PMID 18838559, http://www.ncbi.nlm.nih.gov/pubmed/18838559

Design	Guidelines
Patients	Critically ill patients
Objectives	Summarize the oxygen prescription
Conclusion	Target saturation 94-98% Except for patients with chronic hypercapnia 88-92% Supports the SpO2 target used by the oxygenation controller

Low mortality rate in adult respiratory distress syndrome using low-volume, pressurelimited ventilation with permissive hypercapnia: a prospective study

Hickling KG, Walsh J, Henderson S, Jackson R

Crit Care Med. 1994 Oct;22(10):1568-78

PMID 7924367, http://www.ncbi.nlm.nih.gov/pubmed/7924367

Design	Prospective descriptive study of ventilation management with limitation of peak inspiratory
	pressure and the use of low tidal volumes
Patients	53 severe ARDS patients
Objectives	Evaluate the outcomes in patients with severe adult respiratory distress syndrome who are managed with reduction of regional lung overdistention and permissive hypercapnia
Main Results	The mean maximum PaCO2 was 66.5 mmHg (range 38 to 158 mmHg) and the mean arterial pH was 7.23 (range 6.79 to 7.45). The hospital mortality rate was significantly lower than that predicted by the APACHE II scores (26.4% vs. 53.3%, p = .004), even after correcting the latter for the effect of hypercapnic acidosis (26.4% vs. 51.1%). Mortality increased with the number of organ failures: 43% in patients with \geq 4 failures, 20.5% with \leq 3 failures, and 6.6% with only respiratory failure.
Conclusion	Supports the permissive hypercapnia concept used by the ventilation controller when Pinsp is above 25 cmH2O

Bench-to-bedside review: hypercapnic acidosis in lung injury: from 'permissive' to 'therapeutic'

Ijland MM, Heunks LM, van der Hoeven JG Crit Care. 2010;14(6):237 PMID 21067531, http://www.ncbi.nlm.nih.gov/pubmed/21067531

Design	Review
Conclusion	Explains the physiopathology and benefits of permissive hypercapnia

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The work of breathing

OTIS AB

Physiol Rev. 1954 Jul;34(3):449-58

PMID 13185751, http://www.ncbi.nlm.nih.gov/pubmed/13185751

Design	Physiological study
Conclusion	Supports the ASV principle of selecting a Vt-RR combination according to the least work of breathing principle