Clinical guidelines -what's up and what's new?

Jon Henrik Laake

SSAI Clinical Practice Committee and Rikshospitalet – Oslo University Hospital



The Scandinavian Society of Anaesthesiology and Intensive Care Medicine







Elegance based



VIEWPOINT

Specialty Society Clinical Practice Guidelines Time for Evolution or Revolution?

- "Most specialty societies cannot afford the financial expense to replicate the ACC/AHA or American Cancer Society experience, and the need for a more economic and streamlined process with a succinct work product suggests another pathway is clearly called for. That pathway is likely to be successful through partnerships with other organizations that have expertise in implementation science, multistakeholder perspectives, and transparency regarding COIs."
- "the Clinical Practice Guideline development process should continue to be led by specialty societies <u>but</u> with a new model that integrates other stakeholders, including patients"



Fed Walling

" There was never a lack of good ideas!"

Fred Walberg 1921-2005

Severe ARDS

Berlin definition: p/f ratio < 13.3 with PEEP > 5 cm H2O

Pathophysiology

- Oxygenation failure
- Ventilation failure
- Inflammation
- Coagulopathy
- Pulmonary oedema
- V/Q disturbances
- Pulmonary hypertension
- Extrapulmonary organ failure

- Therapy ?

Baby lung



Gattinoni et al.



Normal Rat Lungs and Rat Lungs after Receiving High-Pressure Mechanical Ventilation at a Peak Airway Pressure of 45 cm of Water.

Dreyfuss D, Saumon G. Ventilator-induced lung injury: lessons from experimental studies. Am J Respir Crit Care Med 1998;157:294-323.

The New England Journal of Medicine

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VENTILATION WITH LOWER TIDAL VOLUMES AS COMPARED WITH TRADITIONAL TIDAL VOLUMES FOR ACUTE LUNG INJURY AND THE ACUTE RESPIRATORY DISTRESS SYNDROME

THE ACUTE RESPIRATORY DISTRESS SYNDROME NETWORK*







" In my experience..."



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The Scandinavian Soc Knusende krit	ikk mot Global Views on Mora	Protocolized versus n	board: SSAI Intensive	board: SSAI Intensive	Speak softly, and carr +
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SSAI Organization	The Scandinavian Society of Anae and Intensive Care Medicine Acta Education	esthesiology Guidelines	Research	Search	Search
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A Study or Subgrou ABIOS 2014 SAFE 2004	Albumin Crystalloid Risk Rate p Events Total Events Total Weight M-H, Fixed 365 888 389 893 64.4% 0.94 (0.1) 185 603 217 615 35.6% 0.87 (0.2)	atio Risk Ratio I, 95% Cl M-H, Fixed, 95% Cl 85, 1.05] 74, 1.02]		The mission of SSAI is to p safe, modern and effective patients. In SSAI the five Nordic nati shared values and preferen	promote e care for our ions with nces, work
New guidel	550 606 P=0.69, df=1 (P=0.41); P=0% pt Z=189 (P=0.60) ines from the SSAL	0.01 0.1 1 Favours albumin Favours of) 100 rystalloid	together to harmonize the five national societies, base Nordic ambitions and expe health care and our specia	work of the ed on high ectations in Ities.
study or Subgrou published by th	p Events Total Events Total Weight M-H, Fixed	1. 95% CI M-H, Fixed, 95% CI 97, 1. 36]			Read more
developed usir	g GRADE methodology	96, 1.27]			
Total events Heterogeneity: Cr Test for overall eff	335 306 #= 0.56, df = 1 (P = 0.45); I* = 0% ect. Z = 1.43 (P = 0.15)	0.01 0.1 1 Favours albumin Favours	0 100 rystalloid	Newsletter	
and Supplie Day. Supporting to	The world sepsis day call for action!	y September 13th	2015 – a	Sign up for our newsletter an email when there is imp from SSAI.	and receive portant news

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Quicklinks

MaimöM 6-8 Sept

esicm.org is safe and can be used as usual

September 1, 2015

follow the webinar September 13th!

August 25, 2015

Today (26/8-15), ESICM provided proof that the issue of potential cyber attack of the provider of the website is solved. You can therefore use esicm.org as usual and especially the registration site for the congress! Message to the Norwegian healthcare authorities is sent and hopefully access to esicm.org from...

The non-profit organization Global sepsis alliance (an alliance of several other

non-profit organizations like WFSICCM) announces a call for action to raise public and professional awareness of sepsis and to increase survival. Please find more information here. You can sign the world sepsis declaration and

Read more

Read more



Scandinavian clinical practice guideline on choice of fluid in resuscitation of critically ill patients with acute circulatory failure

A. Perner¹, E. Junttila², M. Haney³, K. Hreinsson⁴, R. Kvåle⁵, P. O. Vandvik⁶ and M. H. Møller¹

¹Department of Intensive Care, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark
 ²Department of Anaesthesiology, Division of Intensive Care, Oulu University Hospital and Department of Anaesthesiology, Tampere University Hospital, Tampere, Finland
 ³Anaesthesiology and Intensive Care Medicine, Umeå University, Umeå, Sweden
 ⁴Department of Anaesthesiology and Intensive Care Medicine, Landspitali University Hospital, Reykjavik, Iceland
 ⁵Department of Intensive Care, Haukeland University Hospital, Bergen, Norway

⁶Department of Medicine, Innlandet Hospital Trust-Division Gjøvik, Norway and Norwegian Knowledge Centre for the Health Services, Oslo, Norway

REVIEW ARTICLE

Scandinavian clinical practice guideline on mechanical ventilation in adults with the acute respiratory distress syndrome

J. Claesson¹, M. Freundlich², I. Gunnarsson³, J. H. Laake⁴, P. O. Vandvik^{5,6}, T. Varpula⁷ and T. A. Aasmundstad⁴

¹Department of Intensive Care, Surgical Division, Umeå University Hospital, Umeå, Sweden

²Clinic for Anaesthesiology, Aalborg University Hospital, Aalborg, Denmark

³Department of Anaesthesiology and Intensive Care Medicine, Landspitali University Hospital, Reykjavik, Iceland

⁴Department of Anaesthesiology, Division of Critical Care, Oslo University Hospital, Oslo, Norway

⁵Department of Medicine, Innlandet Hospital Trust-Division Gjøvik, Gjøvik, Norway

⁶Norwegian Knowledge Centre for the Health Services, Oslo, Norway

⁷Department of Intensive Care Medicine, Helsinki University Hospital, Helsinki, Finland



The Grading of Recommendations Assessment, Development and Evaluation



G Guyatt, McMaster, Canada



PO Vandvik, UiO

		gradeworkinggroup.org	(†
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	GRADE working group	SSAI The Scandinavian Society of Anaesthesiology and	d Intensive Care Medicine
GRADE wor	king group		
Home Introduction To	olbox Publications Member login Links Contact		
Organizations			GRADE
Learn more			
FAQ	Organizations that have endorsed or that	are using GRADE*	
Organizations	Some organizations in their onthusiasm to use GRADE have m	adified the GRADE approach. We recommend against such modifications h	because the elements of the
Downloads	GRADE process are interlinked, because modifications may con	nfuse some evidence and guideline users, and because such changes com	promise the goal of a single system
About us	with which clinicians, policy-makers and patients can become fa	amiliar.	
	World Health Organization	World Health Organization - International	Example
	ENDOCRINE SOCIETY*	Endocrine Society - USA	Example
	AMERICAN COLLEGE OF CHEST PHYSICIANS	American College of Chest Physicians - USA	Example
	UpToDate.	UpToDate - Putting Clinical Information Into Practice - US	SA UTD GRADE tutorial
	Agenzia Sanitaria Regionale	Agenzia sanitaria regionale, Bologna - Italia	
	Ontario Health Quality Ontario	Health Quality Ontario, Ontario - Canada	Example
	Surviving Sepsis	Surviving Sepsis - International	

The guideline process in GRADE

P – Population/Problem	Mechanically ventilated adults with ARDS
I – Intervention C – Comparator	, Pressure and Volume limitation (PVL) Conventional ventilation
O – Outcome (s)	Mortality, Ventilator(-free) days, LOS, O2-efficiency, Barotrauma
Evidence •Importance •Effect size •Bias •Inconsistency •Imprecision •Indirectness	Study or SubgroupProtective ventilation EventsControl FotalRisk Ratio WeightRisk Ratio M-H, Fixed, 95% CIRisk Ratio M-H, Fixed, 95% CIStewart 19983060286010.0% $1.07 [0.74, 1.55]$ 1998Brochard et al 1998275822587.8% $1.23 [0.80, 1.89]$ 1998Amato et al 199811291724 6.6% $0.54 [0.31, 0.91]$ 1998Brower 199913261226 4.3% $1.08 [0.62, 1.91]$ 1999ARDS network 2000133452170429 62.0% $0.74 [0.62, 0.89]$ 2000Villar et al 200617502545 9.4% $0.61 [0.38, 0.98]$ 2000Total (95% CI)675642100.0% $0.80 [0.70, 0.92]$ $0.1 + 0.5 + 2 + 510$ Total events231274Heterogeneity: Chi² = 11.38, df = 5 (P = 0.04); I² = 56% 7.4% 100.0% $0.80 [0.70, 0.92]$ Test for overall effect: Z = 3.16 (P = 0.002) 7.4% 7.4% 7.4%
Quality of evidence	High, <u>Moderate</u> , Low, Very Low
Benefits vs risks	"Large effect on mortality vs low risk of barotrauma, LOS etc"
Values and preferences	"Reserved for patients with reasonable life prognosis"
Strength of recommendation	Strong OR Weak

ONLINE FIRST

Acute Respiratory Distress Syndrome The Berlin Definition

ARDS is characterized by the following four criteria:

•Lung injury of acute onset, within 1 week of an apparent clinical insult and with progression of respiratory symptoms

- •Bilateral opacities on chest imaging not explained by other pulmonal pathology (e.g. pleural effusions, lung collapse, or nodules)
- •Respiratory failure not explained by heart failure or volume overload
- •Decreased arterial PO2/FiO2 ratio:
 - mild ARDS: ratio is 201 300 mmHg (≤ 39.9 kPa)
 - moderate ARDS: 101 200 mmHg (≤ 26.6 kPa)
 - severe ARDS: \leq 100 mmHg (\leq 13.3 kPa)

(a minimum PEEP of 5 cmH2O is required; it may be delivered noninvasively with CPAP to diagnose mild ARDS).

ARDS Definition Task Force, Ranieri VM, Rubenfeld GD, Thompson BT, Ferguson ND, Caldwell E, Fan E, Camporota L, Slutsky AS. Acute respiratory distress syndrome: the Berlin Definition. JAMA, June 20, 2012—Vol 307, No. 23 pages 2526–33.

Scandinavian clinical practice guideline on mechanical ventilation in adults with the acute respiratory distress syndrome

Jonas Claesson, Morten Freundlich, Ivar Gunnarsson, Jon Henrik Laake, Per Olav Vandvik, Tero Varpula, Tor Aksel Aasmundstad

Informal clinical question		PICO Question		
-	Population (P)	Intervention (I)	Comparator (C)	Outcomes (O)
 Should pressure and volume limitation (PVL) be used in patients with ARDS? Should small tidal volumes always be used in ARDS? Should plateau pressure always be kept low? (i.e. < 31 cm H2O) 	Mechanically ventilated adults with acute respiratory distress syndrome (ARDS)	 Pressure and volume limitation (PVL) Small tidal volumes (5-8 mL/kg) Plateau pressure < 31 cm H2O 	 Conventional ventilation* Large tidal volumes (10-12 mL/kg) Plateau pressure => 31 cm H2O 	 Mortality 28/30 days 60-180 days ICU Hospital Duration of study
2. Should PEEP be set to a high or low level?		High PEEP • > 5 cm H2O	Low PEEP • <= 5 cm H2O	Oxygenation efficiency
3. Should mechanical ventilation be spontaneous or controlled?		Ventilator modes that allow spontaneous breathing	Fully controlled ventilation	Barotrauma
4. Should mechanical ventilation be pressure		Pressure controlled ventilation	Volume controlled ventilation	LOS in ICU
controlled or volume controlled?				Ventilator free days
5. Should patients be ventilated in the prone position?		Prone ventilation during => 50 % of each ICU-day	Ventilation in the supine position only	Days of
6. Should lung recruitment manoeuvres be utilised in ARDS?		Lung recruitment manoeuvres	No lung recruitment manoeuvres	ventilation
7. Should high frequency oscillatory ventilation (HFOV) be used in ARDS?		HFOV	Conventional mechanical ventilation	Use of rescue therapies

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McMaster Allhalashibliotakat na	Historikk						
PLUS gir deg fri tilgang til denne tjenesten	Mechanical ventilation AND ARDS Søk						
Utvalgte nye studier	Current PLUS Database: Lege C Avansert sok						
otvargte nye studier							
	Oppslagsverk ★★★★★						
	Mechanical ventilation of adults in acute respiratory distress syndrome						
A	Mechanical ventilation of adults in the emergency department						
•	More Results						
	Best Practice						
65 model explained	Assessment of respiratory alkalosis						
Criteria for articles in PLUS	Assessment of respiratory acidosis						
	More Results						
■ Oppslagsverk ★★★★★	Oppsummerte oversikter ****						
Up ToDate Best Practice	ACP Journal Club (selected via PLUS)						
	Review: Lower rather than higher tidal volume benefits ventilated patients without ARDS						
■ Oppsummerte oversikter ★★★★	DARE						
ACP Journal Club (via PLUS) DARE	Pressure-controlled versus volume-controlled ventilation for acute respiratory failure due to acute lung injury (ALI) or acute respiratory distress syndrome (ARDS)						
	Neuromuscular blocking agents for patients with acute respiratory distress syndrome						
Systematiske oversikter ***** PLUS Syntheses	More Results						
	Systematiske oversikter ****						
Oppsummerte enkeltstudier *****	PLUS Syntheses						
	Corticosteroid Therapy for Patients Hospitalized With Community-Acquired Pneumonia: A Systematic Review and						
Enkeltstudier ****	Meta-analysis.(Systematic Review)						
PLUS Studies	High-frequency ventilation does not provide mortality benefit in comparison with conventional lung-protective ventila in acute respiratory distress syndrome: a meta-analysis of the randomized controlled trials. (Systematic Review)	tion					
	More Results						
PubMed Clinical Queries	Oppsummerte Enkeltstudier ★★★★★	_					
PubMed							
	ACP Journal Club (selected via PLUS)						
	Prone positioning for 16 h/d reduced mortality more than supine positioning in early severe ARDS						
	46 hours of cisatracurium reduced 90-day mortality in patients with early, severe ARDS						
	More Results						
	Enkeitstudier (pre-appraised by these criteria) *****						
	PLUS Studies						
	The Adult Calfactant in Acute Respiratory Distress Syndrome Trial.(Original Study)						

Forest plot of comparison: High PEEP vs Low PEEP, outcome: Hospital mortality [death before discharge].



Forest plot of comparison: High PEEP vs Low PEEP, outcome: Oxygenation efficiency [PO2/FiO2].

	Expe	rimental		Control			Mean Difference			Mean Difference	
Study or Subgroup	Mean [PaO2/FiO2]	SD [PaO2/FiO2]	Total	Mean [PaO2/FiO2]	SD [PaO2/FiO2]	Total	Weight	IV, Fixed, 95% CI [PaO2/FiO2]	Year	IV, Fixed, 95% C	I [PaO2/FiO2]
Brower 2004	220	89	244	168	66	230	16.7%	52.00 [37.95, 66.05]	2004		
Villar et al 2006	139	43	50	124	54	45	8.4%	15.00 [-4.77, 34.77]	2006	-	
Meade et al 2008	187	69	464	149	61	498	48.4%	38.00 [29.75, 46.25]	2008		-#-
Mercat et al 2008	218	97	378	150	69	371	22.7%	68.00 [55.96, 80.04]	2008		
Huh 2009	161	65	30	137	48	27	3.8%	24.00 [-5.48, 53.48]	2009		
Total (95% CI)			1166			1171	100.0%	44.69 [38.95, 50.43]			•
Heterogeneity: Chi ² = 28	8.52, df = 4 (P < 0.0000	1); l² = 86%								-100 -50 () 50 100
Test for overall effect: Z	= 15.26 (P < 0.00001)									Favours low PEEP	Favours high PEEP

Downgrading

- Bias
- Inconsistency
- Imprecision
- Indirectness

- Benefits vs harms
- Values and preferences



"Inconsistency" - Corticosteroids vs placebo; Outcome: Hospital- or 60-day mortality



Test for subgroup differences: $Chi^2 = 3.14$, df = 1 (P = 0.08), l² = 68.1%

"Inconsistency" - Corticosteroids vs placebo; Outcome: Infectious complications



Test for subgroup differences: $Chi^2 = 8.92$, df = 1 (P = 0.003), I² = 88.8%

"Imprecision" - Beta-agonists vs placebo; Outcome: Mortality at end of follow-up for each trial



"Indirectness"

-Looking for data on children; all studies are with adults

-Your patients are "medical" ARDS-patients; studies included large numbers of trauma patients

-Published studies are from US and south Europe; how to interpret these in a Nordic context?

-No hard end-points, only surrogates; e.g. oxygenation; your interest is survival

"Benefits vs harms"

Nitric oxide vs placebo; Outcome: p/f ratio



Nitric oxide vs placebo; Outcome: Acute kidney injury

	NO		Contr	ol		Risk Ratio		Risk Ratio)	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl		M-H, Random, 95	5% CI	
Dellinger 1998	20	120	7	57	29.6%	1.36 [0.61, 3.02]				
Lundin 1999	28	93	12	87	51.1%	2.18 [1.19, 4.02]			-	
Taylor 2004	10	192	6	193	19.3%	1.68 [0.62, 4.52]			•	
Total (95% CI)		405		337	100.0%	1.80 [1.17, 2.79]				
Total events	58		25							
Heterogeneity: Tau ² = 0	.00; Chi² =	= 0.88, c	lf = 2 (P =	0.64); I	² = 0%					
Test for overall effect: Z	= 2.65 (P	= 0.008	3)				0.1 0.2	Favours NO Fav	Z ours control	5 10

"Values and Preferences"

- •Reasonable expectancy of survival with acceptable quality of life?
- •Age?
- •Cause and Co-morbidity?
- •Low income societies?
- •Cultural and religious context (e.g. Blood transfusion)

Intervention	Recommendation	QoE	Outcome	Comment
Pressure and volume limitation (PVL)	Strong	Moderate	Death 🕹	
PEEP > 5 cm	Weak	Low	O2 ↑ LOS ↑	
FiO2	None	Absent		No trials
Spontaneous breathing modes	None	Absent		No trials
Pressure vs volume control	Weak	Very low		Irrelevant with modern ventilators
Prone positioning	Weak	Very low	O2 ↑ Death ♥	Inconsistent results
Recruitment manoeuvres	Weak	Very low	02 🛧	Rescue therapy
HFOV	Strong	High	LOS 🛧 Death 🛧	PVL better

QoE = Quality of evidence LOS = length of stay O2 = oxygenation

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Scandinavian clinical practice ge v0.0 DRAFT	uideline on mechanical ventilation in adults	s with the acute respiratory distress syndror	r Home Settings Feedbac	ck Help Account L	
Sections Activity Messages	References Evidence	Recommendations	Search fo	or recommendations	Search
Add New Section	¹ About and background			Background Text	Add Recommendation
About and background	2 Lung protective ventilati	on		Background Text	Add Recommendation
Lung protective ventilation	Pressure- and volume limitation				0
Oxygenation	Strong recommendation				Options
Noninvasive ventilation	We recommend use of pressure lim	nitation (plateau pressure < 31 cm H2O) an	d small tidal volumes (5-8 mL/kg p	redicted body weight)	in patients with 🖉
Ventilator mode +	ARDS (strong recommendation, mo	oderate quality evidence).			
Prone ventilation	PEEP				0
Recruitment manoeuvres	Weak recommendation				Options
High frequency oscillatory ventilation	We suggest using positive end-exp with respiratory failure (weak recom	iratory pressure (PEEP) to improve oxygen mendation, low quality evidence).	ation and to prevent atelectasis in	all mechanically ventila	ated patients 🧷
Discussion					
Conclusion	3 Oxygenation			Background Text	Add Recommendation
Pooled together-sections	Practice statement				Options
	No recommendation (no relevant st	tudies)			0
	4 Noninvasive ventilation			Background Text	Add Recommendation
	Practice statement				Options
	No recommendation (no relevant st	tudies)			0





Regional Communities / G-I-N Nordic

About G-I-N Nordic Members & Governance Discussion Board

G-I-N Nordic

G-I-N Nordic is a regional group, formally established in 2013 to address the needs and provide collaboration opportunities among our members in the Nordic countries.



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Sep 24	4, 2015	Б	ecutiv	e					
Sep 25	Sep 25, 2015 Conference Committee								

Vasoactive agents in circulatory failure
Drugs and fluids in ARDS
Emergency anaesthesia
Prehospital airway management
Neuraxial blockade in disturbed haemostasis
Acute pain



Thank you!

Jon Henrik Laake

SSAI Clinical Practice Committee and Rikshospitalet – Oslo University Hospital



The Scandinavian Society of Anaesthesiology and Intensive Care Medicine