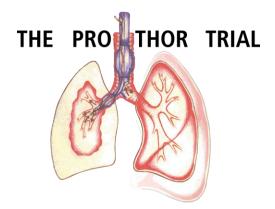
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Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

Patient Serial Number	center patient
Local investigator 1 (intraoperative)	
Local investigator 2 (postoperative)	

Principal Investigator: Mert Sentürk, Department of Anesthesiology and Reanimation, Istanbul University, Turkey

Contact: Thomas Kiss, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, Germany; thomas.kiss@uniklinikum-dresden.de

# **PREOPERATIVE ASSESSMENT**

Case ID			
	center	patient	

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Case ID			
	center	patient	

### 0. General comments

For all scores, definitions and abbreviations refer to the appendix at the end of the document. The use of neuromuscular monitoring during general anaesthesia is strongly recommended. A standardized CPAP device with pressure limitation up to 20 cmH<sub>2</sub>O is necessary for the study. All calculations are based on measured bodyweight, except for tidal volume, which is based on ideal bodyweight (IBW).

## 1. Inclusion Criteria

patient scheduled for open thoracic or video-assisted thoracoscopic surgery under general anesthesia requiring OLV	yes	no
$BMI < 35 \text{ kg/m}^2$		
age ≥ 18 years		
expected duration of surgery > 60 min		
most of ventilation time during surgery expected to be in OLV		
planned lung separation with double lumen tube (DLT, not for study purpose only)		

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	center	patient	

# 2. Exclusion Criteria

COPD GOLD Grade III and IV, lung fibrosis, docu	mented	bullae, severe emphysema,	yes □	no
pneumothorax uncontrolled asthma				
Heart failure NYHA Grade 3 and 4, Coronary Heart Dise	ase CC	S Grade 3 and 4		
previous lung surgery				
documented pulmonary arterial hypertension >25mmH		P at roct or > 10 mmHa syst		
(estimated by ultrasound)	-			
documented or suspected neuromuscular disease muscular dystrophies, others)	(thymom	na, myasthenia, myopathies,		
planned mechanical ventilation after surgery				
bilateral procedures				
lung separation with other method than DLT (e.g. difficu	lt airway	r, tracheostomy)		
surgery in prone position				
persistent hemodynamic instability, intractable shock				
intracranial injury or tumor				
enrollment in other interventional study or refusal of info				
pregnancy (excluded by anamnesis and/or laboratory and				
esophagectomy, pleural surgery only, sympathectomy mediastinal surgery only, lung transplantation				
presence of one of the adverse events, listed as postop (aspiration, moderate respiratory failure, severe resp infection, atelectasis, cardiopulmonary edema, pleura embolism, purulent pleuritis, lung hemorrhage)	biratory	failure, infiltrates, pulmonary		
documented preoperative hypercapnia > 45mmHg (6kP	a)			
Patient included in the study?				
Patient details				
Written informed consent yes no	Date ir	nformed consent signed dd	/ mm	/ уууу
Age [yrs]	Gende	r male	fem	ale
Height [cm]	Weigh	t [kg]		
Investigator Signature		Case Report For	m PROT	HOR study



## **3. ARISCAT Score**

		Ро	ints	Point	S	Points
Age [years]	≤ 50		51-80	3	> 80	16
Preoperative SpO <sub>2</sub> [%] 10 min in room air, supine position, upper body elevated 30-45°	≥ 96		) 91-95	8	≤ 90	24
Respiratory Infection (last month)	No		) Yes	17		
Preoperative Anemia (Hb ≤ 6,2 mmol/l or ≤10 g/dl)	No		) Yes	11		
Emergency procedure	No		) Yes	8		
Surgical Incision	peripheral		) upper abdominal	15	thoracic	24
Planned duration of surgery [hr]	<2		) > 2-3	16	> 3	23
Total Risk Score			+		+	=

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Case ID	_	
	center	patient

# 4 History of previous disease

ASA Score [1-5]				
Cumulated Ambulation Score	e [0-6]:			
Metabolic equivalents	<4	≥4		
Heart failure	yes	no 🗌	if yes	NYHA Score [1-4]:
Coronary heart disease	yes	no 🗌	if yes	CCS Score [0-4]:
Atrial flutter / fibrillation	yes	no 🗌	if yes	acute(duration <4 weeks) paroxysmal chronic
Obstructive sleep apnea	yes	no	if yes	Apnea/Hypopnea Index [events/hr]:
			if no	STOP-Bang Score [0-8]:
COPD	yes	no 🗌	if yes	steroids use yes no no
				inhalation therapy yes no
Respiratory infection within last month	yes	no 🗌	if yes	upper lower respiratory infection
Smoking status	never	former (	cessation >3m	onths) current
Use of noninvasive ventilatory support	yes	no 🗌	if yes	
				duration [hrs/day]: intensity [pressure level]:
Active cancer	yes	no 🗌	if yes	cancer type:
				actual cancer classification: TNM
Diabetes mellitus	yes	no 🗌	if yes	dietary oral medication insulin
Arterial hypertension	yes	no		
Gastroesophageal reflux	yes	no	if yes	events ≥1/day ≥1/week ≥1/month
Alcohol status (past 2 weeks)	0-2 drinks/	day 🗌	>2 drinks/day	
Use of antibiotics (last 3 months)	yes	no 🗌	if yes	indication: drug name:
Use of statins	yes	no	if yes	drug name: dose [mg/day]:
Use of aspirin	yes	no	if yes	dose [mg/day]:

Case ID		
	center patient	

# **5 Actual organ function**

SpO <sub>2</sub> supine position, upper body elevated 30-45°, 10 min in room air possible?	yes	no 🗌	if yes	SpO <sub>2</sub> [%]:
			if no	SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%]:
RR [/min]				
HR [/min]				ABP mean [mmHg]
Temperature [°C]				tympanic axillar inguinal oral rectal
				other if other specify:
Airway secretion	yes	no 🗌	if yes	purulent/yellow colour not purulent
VAS dyspnea [1-10cm]				VAS thoracic rest pain [1-10cm]
				VAS coughing pain [1-10cm]

# 6 Non-mandatory measurements

			Laboratory tests		
Chest X-ray obtained	yes	no 🗌	Hb	mmol/I	g/dl
if yes			WBC	GPt/L	
Infiltrates (any side)	yes	no 🗌	Hematocrit	%	
pleural effusion (any side)	yes	no 🗌	Creatinine	µmol/l	mg/dl
			BUN	mmol/l	mg/dl
Atelectasis (any side)	yes	no	Platelets	GPt/L	
Pneumothorax (any side)	yes	no	PT	sec	INR
cardiopulmonary edema (any side)	yes	no	PTT	sec	
			ALT	µmol/s*l	U/L
			AST	µmol/s*l	U/L
			Bilirubin	µmol/l	mg/dl
			CRP c-reactive protein	mg/l	
			Procalcitonin	ng/ml	

Case ID		
	center patient	

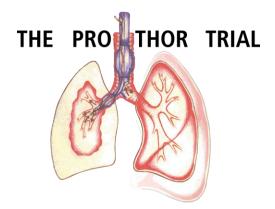
**1** Preoperative Visit

# 7 Preoperative lung variables

pO2 (arterial partial pressure of oxygen) [mmHg/kPa]:	capillary arterial
pCO2 (arterial partial pressure of carbon dioxide) [mmHg/kP	a]: capillary arterial
pH (рН value) :	
FVC (forced vital capacity) [Liters] :	
FEV1 (Forced expiratory volume at 1 second) [Liters] :	
FEV <sub>1</sub> /FVC (Tiffeneau) [%] :	
TLC (Total lung capacity) [Liters]:	
DLCO (Diffusing capacity for carbon monoxide)	[mmol/min/kPa]
VO <sub>2</sub> max (maximal oxygen consumption) [ml/kg/min]	
Predicted postoperative respiratory function	predicted postoperative (ppo) FVC predicted postoperative (ppo) FEV1 predicted postoperative (ppo) DLCO

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# **INTRAOPERATIVE ASSESSMENT**

#### **2** Intraoperative Visit

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# 1 Randomization

Randomization

Low PEEP without RM

High PEEP with RM

# 2 Anaesthetic Overview

Duration of anesthesia [min] from intubation to extubation (or exit from OR if on mechanical ventilation)	
Duration of OLV [min]	
Duration of TLV [min]	
Total Blood loss [ml]	Fotal Urine output [ml]
Side of OLV	
Side of surgery	
Method of OLV double lumen tube double lumen tube	ter, specify:
double lumen tube(embedded camera)	
Confirmation of OLV fiberoptic bronchoscopy embedd	ed camera, specify:
Antibiotics yes no if yes, specify drug nat	me: prophylaxis therapy
Regional anesthesia yes no if yes	epidural paravertebral
	other , specify:
Use of NIV during induction yes no if yes	
Patient's position during induction angle of upper body elev	vation 0-15° 15-30° 30-45° >45°
Temperature [°C] at end of surgery	ympanic axillar inguinal oral rectal
0	ther if other specify:
Neuromuscular function yes no if yes	Residual curarization at yes no no Extubation (TOF < 90%)
Curarization antagonized? yes no if yes	
	other , specify:

**2** Intraoperative Visit

# **3 Surgical overview**

Duration of surgery [min] from incision to closure
Priority of surgery elective urgent emergency
Surgical wound       clean       clean-contaminated       contaminated       dirty
Surgical procedure thoracoscopic open conversion from open to thoracoscopic
Type of resection (multiple answers are possible): pneumonectomy D lobectomy D
wedge resection Sleeve lobectomy segment resection
pleurectomy other , specify:
Patient's position during surgery     supine     lateral     prone       other     ,specify:
estimated amount of resection: $0-10\% \square \le 20\% \square \le 30\% \square \le 40\% \square$
(as a percentage of one lung)
≤50%
≤90% □ 90-100%(e.g pneumonectomy) □

**2** Intraoperative Visit

		cumulative dose			cumulative dose
Analgetics	Alfentanyl	yes	Anesthetics	Dexmedetomidine	yes
[mg]	Fentanyl	yes	[mg]	Etomidate	yes
	Lidocaine	yes		Midazolam	yes
	Morphine	yes		Propofol	yes
	Procaine	yes		Thiopental	yes
	Remifentanil	yes		other	yes
	Sufentanil	yes		other	yes
	Ketamine	yes		other	yes
	other	yes		other	yes
	other	yes	Muscle	Atracurium	yes
	other	yes	Relaxants	Cis-Atracurium	yes
	other	yes	[mg]	Mivacurium	yes
Vapors		mean targeted MAC		Pancuronium	yes
[vol%*min]	Desflurane	yes		Rocuronium	yes
	Enflurane	yes		Succinylcholine	yes
	Halothane	yes		Vecuronium	yes
	Isoflurane	yes		other	yes
	Sevoflurane	yes		other	yes
	other	yes			

# 4 Anesthesia Drugs

2 Intraoperative Visit

# 5 Fluids

		cumulative dose	,	cumulative dose
Artificial	HES	yes	Crystalloids [ml]	yes
Colloids	Gelatine	yes	Albumin (any concentration)[ml]	yes
[ml]	Dextran	yes	other, specify:	yes
	other, specify:	yes		
	Dobutamine	yes		
Vaso-	Ephedrine	yes		
active	Epinephrine	yes		
Drugs	Norepinephrine	yes		
[mg]	Phenylephrine	yes		
	other	yes 🔲		
	other	yes		
	other:	yes		

# **6** Transfusion

\_

Transfusion from anesthesia induction until end of anesthesia (or leaving OR if on mechanical ventilation)

		cumulative dose(ml)			cumulative dose(ml)
Packed red blood cells	yes 🗌		Plasma	yes	
Autologous blood transfusion	yes 🗌		Platelets	yes	

# 7 Protocol adherence

1)	Hypotension (BPsys < 90mmHg) unresponsive to fluids and/or vasoactive drugs (give details	yes
2)	below) New arrhythmias unresponsive to intervention (according to ACLS-Guidelines) (give details below)	yes
3)	Need for a dosage of vasoactive drugs at the tolerance limit of the treating physician (give details below)	yes
4)	Need for massive transfusion ( 4 units of PRBC in 4 hours) (give details below)	yes
5)	Life-threatening surgical complication (injury to the hemodynamic and respiratory system and brain, including major bleeding, tension pneumothorax, intracranial injury) (give details below)	yes
6)	Hypoxemia rescue other than prescribed was necessary due to prolonged SpO2<90% (give details below)	yes
7)	Hypercapnia rescue other than prescribed was necessary due to respiratory acidosis $pH$ <7.20 (give details below)	yes
8)	Deviation from prescribed PEEP(give details below)	yes
9)	Deviation from tidal volume(give details below)	yes
10]	Other reason, specify: (give details below)	yes
Any de protoc	eviation from the yes no if yes, specify:	

Could the protocol be	ves 🗖	no 🗖	
continued?			

2 Intraoperative Visit

Any adverse events	yes	no	if yes specify	according to table	
Event (details, including trea	tment)	Severe AE	Causality	Severity	Outcome
		yes	unrelated possible probable unassessable	mild moderate unassessable	resolved - no sequelae
		yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
		yes	unrelated possible probable unassessable	mild moderate unassessable	resolved - no sequelae

# 8 Adverse events (AE) / severe adverse events (SAE)

**2** Intraoperative Visit

# 9 Mechanical ventilation protocol

Patient's height [cm]	Measured bodyweight [kg]
Ideal bodyweight(IBW) [kg] M: 50+0.91*(height-152.4), F: 45.5+0.91*(height-152.4)	

#### TWO LUNG VENTILATION

Modus	Volume controlled ventilation
FiO <sub>2</sub>	≥40%, adjust to maintain SpO <sub>2</sub> ≥90%
I:E ratio	Range from 1:1 to 1:2
RR	adjust to normocapnia (ETCO <sub>2</sub> 35-45mmHg or 4,6-6kPa)
PEEP	according to randomization with suspected intrinsic-PEEP, resp. rate or I:E ratio change allowed acc. to physician
Inspiratory $V_T$	7 ml/kg ideal bodyweight =ml

#### ONE LUNG VENTILATION

Modus	Volume controlled ventilation
FiO <sub>2</sub>	≥40%, adjust to maintain SpO₂ ≥90%
I:E ratio	Range from 1:1 to 1:2 (change to 1:1 if If $P_{peak} > 40$ cm $H_2O$ , or $P_{plat} > 30$ cm $H_2O$ )
RR	adjust to normocapnia (ETCO <sub>2</sub> 35-45mmHg or 4,6-6kPa)
PEEP	according to randomization with suspected intrinsic-PEEP, resp. rate or I:E ratio change allowed acc. to physician
Inspiratory $V_{T}$	5 ml/kg ideal body weight (change to 4ml/kg if Ppeak > 40 cm H2O, or Pplat $>$ 30 cmH <sub>2</sub> O)

### 9.1 Recruitment maneuver

Recruitment maneuver of the ventilated lung(s) – HIGH PEEP GROUP	<ol> <li>Increase FIO<sub>2</sub> to 1.0</li> <li>Set peak inspiratory pressure limit to 45 cmH<sub>2</sub>O</li> <li>Set respiratory rate to 6 breaths/min</li> <li>Set inspiratory to expiratory ratio (I:E) to 1:1</li> <li>Increase VT in steps of around 2 mL/kg until plateau pressure reaches 30 to 40 cmH<sub>2</sub>O</li> <li>If the maximum VT allowed by the anesthesia ventilator is achieved and the plateau pressure is lower than 30 cmH<sub>2</sub>O, increase the PEEP as needed, but maximum 20 cmH<sub>2</sub>O</li> <li>Allow three breaths while maintaining plateau pressure of 30 to 40 cmH<sub>2</sub>O</li> </ol>
	<ul> <li>8. Set VT, PEEP, respiratory rate, and I:E back to pre-recruitment values</li> <li>RM will be performed <ul> <li>after bronchoscopy,</li> <li>at begin of OLV,</li> <li>every one hour during OLV,</li> <li>at the end of OLV, and</li> <li>at end of surgery in supine position</li> <li>following each disconnection from the mechanical ventilator.</li> </ul> </li> </ul>

Recruitment maneuver of the non-ventilated lung – BOTH GROUPS	<ul> <li>A recruitment maneuver of the non-ventilated lung may be necessary in both groups due to different reasons:</li> <li>a) detection of air leaks by request of surgeons;</li> <li>b) as part of a rescue strategy due to hypoxemia;</li> <li>c) before switching from OLV to TLV to re-expand the collapsed lung.</li> </ul>
	<ol> <li>Keep the non-ventilated under visual inspection</li> <li>Connect the CPAP device with adequate oxygen flow /FiO2 1,0) to the non-ventilated lung</li> <li>Set CPAP to 10 cmH2O during 20 seconds</li> <li>Set CPAP to 15 cmH2O during 20 seconds</li> <li>Set CPAP to 20 cmH2O during 20 seconds</li> <li>Set CPAP to 20 cmH2O during 20 seconds</li> <li>If performed as part of a rescue therapy, reduce CPAP to 10 cmH2O and then 5 cmH2O, otherwise disconnect the CPAP device.</li> </ol>

### 9.2 Hypoxemia rescue therapy

If hypoxemia, defined as **SpO2 < 90%** for **> 1 min**, occurs, rescue is performed.

Hypoxemia Rescue – HIGH PEEP GROUP - before and after one-lung ventilation	1. 2. 3. 4.	Apply "recruitment maneuver of the ventilated lung(s)" Increase PEEP to 12 cmH2O and apply "recruitment maneuver of the ventilated lung(s)" Increase FIO2 in steps of 0.1 until 1.0 Consider stepwise decrease of PEEP of the ventilated lung down to 8 cmH2O
--	----------------------	---

Hypoxemia Rescue - LOW PEEP GROUP - before and after one-lung ventilation	<ol> <li>Increase FIO2 in steps of 0.1 until 1.0</li> <li>Apply "recruitment maneuver of the ventilated lung(s)"</li> <li>Increase PEEP to 6 cmH2O</li> <li>Apply "recruitment maneuver of the ventilated lung(s)"</li> <li>Increase PEEP to 7 cmH2O</li> <li>Apply "recruitment maneuver of the ventilated lung(s)"</li> </ol>
---	---

Hypoxemia Rescue - HIGH PEEP GROUP - during one-lung ventilation	<ol> <li>Apply "recruitment maneuver of the ventilated lung(s)"</li> <li>Increase PEEP to 12 cmH2O and apply "recruitment maneuver of the ventilated lung(s)"</li> <li>Increase FIO2 in steps of 0.1 up to 1.0</li> <li>Apply oxygen to the non-ventilated lung, consider CPAP therapy (recruitment maneuver of the non-ventilated lung) up to a pressure of 20 cmH2O or selective oxygen insufflation via fiberscope</li> <li>Consider stepwise decrease of PEEP of the ventilated lung down to 8 cmH2O</li> <li>Consider surgical intervention (e.g. clamping of pulmonary artery)</li> <li>Consider administration of inhalative nitric oxide or prostacyclin, or intravenous almitrin</li> <li>Switch to TLV</li> </ol>
---	---

	1.	Increase FIO2 in steps of 0.1 up to 1.0
	2.	Apply oxygen to the non-ventilated lung, consider CPAP therapy (recruitment
		maneuver of the non-ventilated lung) up to a pressure of 20 cmH2O or selective
		oxygen insufflation via fiberscope
Hypoxemia Rescue	3.	Apply "recruitment maneuver of the ventilated lung(s)"
-LOW PEEP	4.	Increase PEEP to 6 cmH2O
GROUP - during	5.	Apply "recruitment maneuver of the ventilated lung(s)"
one-lung ventilation	6.	Increase PEEP to 7 cmH2O
	7.	Apply "recruitment maneuver of the ventilated lung(s)"
	8.	Consider surgical intervention (clamping of pulmonary artery)
	9.	Consider administration of inhalative nitric oxide or prostacyclin, or intravenous almitrin
	10.	Switch to TLV

### 9.3 Hypercapnia Rescue therapy

Hypercapnia Rescue – BOTH GROUPS - during one-lung ventilation	<ul> <li>PaCO2 &gt; 60 mmHg with respiratory acidosis (pHarterial &lt; 7.20)</li> <li>1. Increase the respiratory rate (maximum 30/min, while avoiding "intrinsic-PEEP")</li> <li>2. Increase VT in steps up to 7 mL/kg</li> <li>3. Switch to TLV</li> </ul>
---	--

#### **2** Intraoperative Visit

### **10 Intraoperative variables: documentation of routine measurements** (in chronological order)

Record variables within 5 min after anesthesia induction, 5 minutes before OLV, hourly thereafter, at end of surgery

In case of several changing episodes of TLV and OLV record first episode of OLV after start of surgery and last episode of OLV before end of surgery

	Induction	after start of surgery,	10 min after OLV	1 hour after OLV	2 hour after OLV	3 hour after OLV	4 hour after OLV	5 hour after OLV	6 hour after OLV	end of surgery
		prior to OLV								with TLV in supine pos.
Time [hh:mm]		e.g. 14:20								
TLV/OLV		e.g. TLV								
Ppeak [cmH2O]		e.g. 28								
Pplat [cmH2O]		e.g. 26								
PEEP [cmH2O]		e.g. 10								
VT insp [ml]		e.g. 420								
RR [/min]		e.g. 16								
I:E [x:x]		e.g. 1:1,3								
FiO2 [%]		e.g. 80								
SpO2 [%]		e.g. 93								
etCO2 [mmHg/kPa]		e.g. 5,3 kPa								
MAP [mmHg]		e.g. 82								
HR [bpm]		e.g. 77								
paO2[mmHg/kPa]		e.g. 90 mmHg								
paCO2[mmHg/kPa]		e.g. 4,6 kPa								
рН		e.g. 7,33								
Hematocrit[%]		e.g. 33								

### 2 Intraoperative Visit

continued	Induction	after start of surgery, prior to OLV	10 min after OLV	1 hour after OLV	2 hour after OLV	3 hour after OLV	4 hour after OLV	5 hour after OLV	6 hour after OLV	end of surgery with TLV
New hypotension	if sudden BPsys o	drop > 20% or equiv	alent increase of c	atecholamine dose						
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
New bradycardia	if sudden HR dro	p > 20%								
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
New hypoxemia	SpO <sub>2</sub> < 90% for >	> 1 minute				-	-			
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
Disconnection from the ventilator	Disconnection of	f the ventilated lung	or bronchoscopy							
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
Hypoxemia rescue maneuver	if SpO <sub>2</sub> $\leq$ 90% for	<pre>&gt; 1 minute</pre>								
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
Hypercapnia rescue maneuver	PaCO <sub>2</sub> > 60 mm⊦	$H_{arterial} < 7.2$	20							
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
Other event, specify:						-	-			
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
iNO/Prostacyclin/selective fiberoscope insufflation, specify:	use of inhalative	nitrous oxygen, pro	ostacyclin therapy	or selective oxygen	ation through fibe	roscopy				
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no
CPAP non ventilated lung	use of CPAP for t	the surgical/non-ver	ntilated lung neces	sary						
	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no	yes/no

**2** Intraoperative Visit

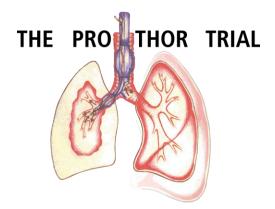
# 11 intraoperative variables: Documentation of Recruitment maneuver (in chronological order)

Routine/Rescue	e.g. Routine	e.g. Routine	e.g. Rescue				
Indication for RM(tick one)							
bronchoscopy/disconnection							
after begin of OLV							
every one hour during OLV							
at the end of OLV							
at end of surgery(supine)							
Time [hh:mm]	e.g. 14:15						
Ppeak [cmH2O]		e.g. 30					
Pplat [cmH2O]		e.g. 28					
PEEP [cmH2O]		e.g. 10					
VT insp [ml]		e.g. 480					
RR [/min]		e.g. 16					
I:E [x:x]		e.g. 1:1,3					
FiO2 [%]		e.g. 80					
SpO2 [%]		e.g. 95					
MAP [mmHg]		e.g. 72					
HR [bpm]		e.g. 83					
Adverse Events							
New hypotension	e.g. no						
New bradycardia	e.g. no						
New hypoxemia	e.g. no		e.g. yes				
Other event, specify:	e.g. no						

Record values when reaching target pressure  $P_{\text{plat}}\,30\text{-}40\text{cm}H_2\text{O}$ 

2 Intraoperative Visit

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Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

Patient Serial Number	center patient
Local investigator 1 (intraoperative)	
Local investigator 2 (postoperative)	

Principal Investigator: Mert Sentürk, Department of Anesthesiology and Reanimation, Istanbul University, Turkey

Contact: Thomas Kiss, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, Germany; thomas.kiss@uniklinikum-dresden.de

# **POSTOPERATIVE ASSESSMENT**

Day 1

### **3** Postoperative Visit

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**3** Postoperative Visit

#### **POSTOPERATIVE DAY 1**

(report events within first 24hrs after end of anesthesia/exit of OR if on mech. vent.)

# **1** Recovery

Lost to follow up	yes 🔲	no 🔲	if yes	discharged death consent withdrawal death to the rest of the rest			
Continuation of MV directly after surgery	yes	no 🗌	if yes	indication: duration [hrs]			
Indication hypothermia \Box bleeding 🗖 cardiovascular 🗖 respiratory failure							
other, specify:							
New requirement of NIV	yes	no 📃	if yes	CPAP NPPV duration [hrs]			
				maximum intensity [pressure level]:			
			indication	standard of care resp. failure			
			Indication	other, specify:			
New requirement of invasive MV	yes	no 🔲	if yes	duration [hrs]			
			indication	re-surgery resp. failure other , specify:			
unplanned ICU admission	yes	no 🗌	if yes	indication:			
Physiotherapy	yes	no 🗌					
Breathing exercises	yes	no 🗌	if yes	incentive spirometry yes no			
Cumulated Ambulation Sco	re [0-6]:						
Impairment of wound healing	yes	no 🗌	if yes	superficial deep			
Surgical wound infection	yes	no 🗌	if yes	superficial deep			
			if yes	abscess empyema phlegmon			
Antibiotics yes	no 🗌	if yes, spe	ecify drug nan	ne: prophylaxis therapy			
PONV	yes	no 🗌					
Return of bowel function	yes	no 🗌					

**3** Postoperative Visit

### 2 Fluids on day 1

#### first 24hrs after end of anesthesia (exit of OR if on mech. vent.) cumulative dose cumulative dose Artificial HES yes Crystalloids [ml] yes Colloids Gelatine Albumin (any concentration)[ml] yes yes other, specify: [ml] Dextran yes yes other, specify: yes Dobutamine yes Vaso-Ephedrine yes active Epinephrine yes Drugs Norepinephrine yes Phenylephrine [mg] yes [ other yes [ other yes other: yes

# 3 Transfusion on day 1

first 24hrs after	r end of anesthesia (exit of OR if on	mech. vent.)		
	cumulative dose(ml)			cumulative dose(ml)
Packed red blood cells	yes	Plasma	yes	
Autologous blood transfusion	yes	Platelets	yes	

#### **3** Postoperative Visit

# 4 Actual organ function

SpO <sub>2</sub> supine position, upper body elevated 30-45°, 10 min in room air possible?	yes	no 🗌	if yes	SpO <sub>2</sub> [%]:
			if no	SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%]:
RR [/min]				
HR [/min]				ABP mean [mmHg]
Temperature [°C]				tympanic axillar inguinal oral rectal
				other if other specify:
Airway secretion	yes	no 🗌	if yes	purulent/yellow colour not purulent
VAS dyspnea [1-10cm]				VAS thoracic rest pain [1-10cm]
				VAS coughing pain [1-10cm]

# Non-mandatory measurements

			Laboratory tests		
Chest X-ray obtained	yes	no 🔲	Hb	mmol/I	g/dl
if yes			WBC	GPt/L	
Infiltrates (any side)	yes	no 📃	Hematocrit	%	
pleural effusion (any side)	yes	no 📃	Creatinine	µmol/l	mg/dl
			BUN	mmol/l	mg/dl
Atelectasis (any side)	yes	no 📃	Platelets	GPt/L	
Pneumothorax (any side)	yes	no 📃	PT	sec	IN
cardiopulmonary edema (any side)	yes	no 📃	PTT	sec	
			ALT	µmol/s*l	U/L
			AST	µmol/s*l	U/L
			Bilirubin	µmol/I	mg/dl
			CRP c-reactive protein	mg/l	
			Procalcitonin	ng/ml	

**3** Postoperative Visit

6 Pulmonary complications

Aspiration pneumonitis resp. failure after inhalation of gastric contents left right both cannot be differentiated	yes no
Severe respiratory failure need for non-invasive or invasive mechanical ventilation due to poor oxygenation	yes no
Moderate respiratory failure SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen > 2l/min	yes no
ARDS according to Berlin definition yes no	if yes mild moderate severe
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions left right both cannot be differentiated	yes no
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area left right both cannot be differentiated	yes no
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray, not explained by poor cardiac function left right both cannot be differentiated	yes no
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray, not explained by the preoperative patient condition alone left right both cannot be differentiated	yes no
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging left right both cannot be differentiated for this study, pneumothorax at the operated side will not be considered as a PPC; please mark anyway	yes no
Pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs left right both cannot be differentiated	yes no
Prolonged air leakage Air leak requiring at least 7 days of postoperative chest tube drainage left right both cannot be differentiated	yes no
Purulent pleuritis Receiving antibiotics for a suspected infection, as far as not explained by the preoperative patient condition alone left i right both cannot be differentiated	yes no
Pulmonary Embolism As documented by pulmonary arteriogram or autopsy, or supported by a ventilation/perfusion radioisotope scans, or documented by echocardiography and receiving specific therapy	yes no

3	Posto	perative	Visit

Lung haemorrhage Bleeding through the chest tubes requiring reoperation, or three or more red blood cell packs	yes	no 🔲
Extended PPCs:		
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes	no 🗌
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen $\leq$ 2l/min	yes 🗌	no

**3** Postoperative Visit

# 7 Extrapulmonary complications

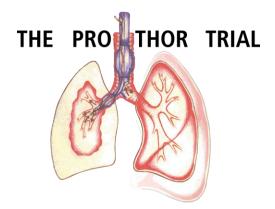
SIRS ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µI	yes	no	
Sepsis SIRS in response to a confirmed infective process	yes	no	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes	no	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes	no	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes	no	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes	no	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes	no	
Acute renal failure Risk: Crea increased 1.5 times baseline or GFR decrease > 25% or urine output < 0.5 ml/kg/h within			
Injury: Crea increased 2 times baseline or GFR decrease > 50% or urine output < 0.5 ml/kg/h within Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis) yes no if yes R I F		nuria for 12	? hrs
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)		nuria for 12	? hrs
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)         yes       no         if yes       R         Disseminated intravascular coagulation	24 hr or ar		? hrs
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)         yes       no       if yes       R       I       F         Disseminated intravascular coagulation according to DIC score > 5       Stroke       I       I       F	24 hr or ar	 ] no	? hrs
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)         yes       no       if yes       R       I       F         Disseminated intravascular coagulation according to DIC score > 5       Stroke       Stroke         New clinical signs of stroke lasting > 24h + corresponding findings in radiologic imaging       Hepatic failure         bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0       Gastrointestinal failure	24 hr or ar	no [	2 hrs
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)         yes       no       if yes       R       I       F         Disseminated intravascular coagulation according to DIC score > 5       Stroke         New clinical signs of stroke lasting > 24h + corresponding findings in radiologic imaging         Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	24 hr or ar		

**3** Postoperative Visit

Any adverse events yes	no 📃	if yes specify a	ccording to table:	
Event (details, including treatment)	Severe AE	Causality	Severity	Outcome
	yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes 🔲 no 🗌	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae

# 8 Adverse events (AE) / severe adverse events (SAE)

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Case Report Form version 1.5

Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

Patient Serial Number	center patient
Local investigator 1 (intraoperative)	
Local investigator 2 (postoperative)	

Principal Investigator: Mert Sentürk, Department of Anesthesiology and Reanimation, Istanbul University, Turkey

Contact: Thomas Kiss, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, Germany; thomas.kiss@uniklinikum-dresden.de

# **POSTOPERATIVE ASSESSMENT**

# Day 2-5

## **3** Postoperative Visit

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**3** Postoperative Visit

POS	STOPER	ATIVE [	DAY
2 🗌	з 🗆	4	5

### (report events within 24 hour period if not stated otherwise)

# **1** Recovery

Lost to follow up	yes	no 📃	if yes	discharged death consent withdrawal death other , specify:
New requirement of NIV	yes	no 🗌	if yes	CPAP NPPV duration [hrs]
				maximum intensity [pressure level]:
			in dia atia a	standard of care resp. failure
			indication	other, specify:
New requirement of invasive MV	yes	no 🗌	if yes	duration [hrs]
			indication	re-surgery resp. failure resp. failure , specify:
unplanned ICU admission	yes	no 🗌	if yes	indication:
Physiotherapy	yes	no 📃		
Breathing exercises	yes	no 🗌	if yes	incentive spirometry yes no
Cumulated Ambulation Sco	re [0-6]:			
Impairment of wound healing	yes	no 🗌	if yes	superficial deep
Surgical wound infection	yes	no 🗌	if yes	superficial deep
			if yes	abscess empyema phlegmon
Antibiotics yes	no 🗌	if yes, spe	ecify drug nan	ne: prophylaxis therapy
PONV	yes	no 🗌		
Return of bowel function	yes	no 🗌		

**3** Postoperative Visit

# 2 Actual organ function

SpO <sub>2</sub> supine position, upper body elevated 30-45°, 10 min in room air possible?	yes	no 🗌	if yes	SpO <sub>2</sub> [%]:
			if no	$SpO_{2}[\%]$ : and $FiO_{2}[\%]$ :
RR [/min]				
HR [/min]				ABP mean [mmHg]
Temperature [°C]				tympanic axillar inguinal oral rectal
				other if other specify:
Airway secretion	yes	no 🗌	if yes	purulent/yellow colour not purulent
VAS dyspnea [1-10cm]				VAS thoracic rest pain [1-10cm]
				VAS coughing pain [1-10cm]

# 3 Non-mandatory measurements

			Laboratory tests		
Chest X-ray obtained	yes	no 🔲	Hb	mmol/I	g/dl
if yes			WBC	GPt/L	
Infiltrates (any side)	yes	no 📃	Hematocrit	%	
pleural effusion (any side)	yes	no 📃	Creatinine	µmol/l	mg/dl
			BUN	mmol/l	mg/dl
Atelectasis (any side)	yes	no 🔲	Platelets	GPt/L	
Pneumothorax (any side)	yes	no 🔲	PT	sec	IN
cardiopulmonary edema (any side)	yes	no 🔲	PTT	Sec	
			ALT	µmol/s*l	U/L
			AST	µmol/s*l	U/L
			Bilirubin	µmol/l	mg/dl
			CRP c-reactive protein	mg/l	
			Procalcitonin	ng/ml	

**3** Postoperative Visit

4 Pulmonary complications

Aspiration pneumonitis resp. failure after inhalation of gastric contents left  right  both  cannot be differentiated	yes no
Severe respiratory failure need for non-invasive or invasive mechanical ventilation due to poor oxygenation	yes no
Moderate respiratory failure SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen > 2l/min	yes no
ARDS according to Berlin definition yes no	if yes mild moderate severe
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions left right both cannot be differentiated	yes no
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area left  right  both  cannot be differentiated	yes no
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray, not explained by poor cardiac function left right both cannot be differentiated	yes no
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray, not explained by the preoperative patient condition alone left right both cannot be differentiated	yes no
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging left right both cannot be differentiated for this study, pneumothorax at the operated side will not be considered as a PPC; please mark anyway	yes no
Pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs left i right both cannot be differentiated	yes no
Prolonged air leakage Air leak requiring at least 7 days of postoperative chest tube drainage left i right i both cannot be differentiated	yes no
Purulent pleuritis Receiving antibiotics for a suspected infection, as far as not explained by the preoperative patient condition alone left right both cannot be differentiated	yes no
Pulmonary Embolism As documented by pulmonary arteriogram or autopsy, or supported by a ventilation/perfusion radioisotope scans, or documented by echocardiography and receiving specific therapy	yes no

3	Posto	perative	Visit

Lung haemorrhage Bleeding through the chest tubes requiring reoperation, or three or more red blood cell packs left right both cannot be differentiated	yes	no 🔲
Extended PPCs:		
Bronchospasm newly expiratory wheezing treated with bronchodilators	yes	no 🔄
Mild respiratory failure SpO₂<90% or PaO₂<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min	yes	no 🔲

**3** Postoperative Visit

# **5 Extrapulmonary complications**

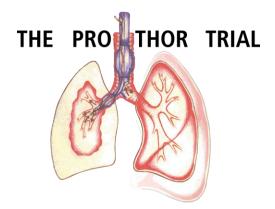
SIRS ≥2 findings: Temp < 36 <sup>o</sup> C or > 38 <sup>o</sup> C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µI	yes		no 🗌	
Sepsis SIRS in response to a confirmed infective process	yes		no 🔲	
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes		no 🗌	
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes		no	
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes		no 🔲	
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes		no	
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes		no 🗌	
Acute renal failure Risk: Crea increased 1.5 times baseline or GFR decrease > 25% or urine output < 0.5 ml/kg/h within	6 hr			
Injury: Crea increased 2 times baseline or GFR decrease > 50% or urine output < 0.5 ml/kg/h within 1 Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2 Loss: complete loss of kidney function > 4 weeks(requiring dialysis) yes no if yes R I F		anuria	for 12 hrs	
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2 Loss: complete loss of kidney function > 4 weeks(requiring dialysis)		anuria -	for 12 hrs	
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2 Loss: complete loss of kidney function > 4 weeks(requiring dialysis)         yes       no       if yes       R       I       F         Disseminated intravascular coagulation	24 hr or	anuria	_	
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2	24 hr or	anuria	no	
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2	24 hr or L yes	anuria		
Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within 2	24 hr or ves [ yes ] yes ]		no  no	]

**3** Postoperative Visit

Any adverse events yes	no 🗌	if yes specify a	ccording to table:	
Event (details, including treatment)	Severe AE	Causality	Severity	Outcome
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae

# 6 Adverse events (AE) / severe adverse events (SAE)

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Case Report Form version 1.5

Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

Patient Serial Number	center patient
Local investigator 1 (intraoperative)	
Local investigator 2 (postoperative)	

Principal Investigator: Mert Sentürk, Department of Anesthesiology and Reanimation, Istanbul University, Turkey

Contact: Thomas Kiss, Department of Anesthesiology and Intensive Care Medicine, University of Dresden, Germany; thomas.kiss@uniklinikum-dresden.de

# **POSTOPERATIVE ASSESSMENT**

**Discharge and Followup** 

## **3** Postoperative Visit

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**3** Postoperative Visit

### DISCHARGE

(report events within last visit to discharge from hospital)

# 1 Discharge

Lost to follow up	yes	no 🗌	if yes	reason
Death	yes	no 🗖		
Date of discharge/death	/	/ 20		Postop day of discharge/death [1-90] (day of discharge/death since randomisation)
Discharge destination:		Home	Other	hospital/Care Death

# 2 Recovery

Now requirement of NIV	yes 🗖	no 🗖	if yes	
New requirement of NIV			li yes	other specify:
				maximum intensity [pressure level]:
				standard of care resp. failure
			indication	other, specify:
New requirement of invasive MV	yes	no 🗌	if yes	duration [hrs]
			indication	re-surgery resp. failure other , specify:
unplanned ICU admission	yes	no 🗌	if yes	indication:
Cumulated Ambulation Sco	re [0-6]:			
Impairment of wound healing	yes	no 🗌	if yes	superficial deep
Surgical wound infection	yes	no 🗌	if yes	superficial deep
			if yes	abscess empyema phlegmon
Antibiotics yes	no 📃	if yes, spe	ecify drug nan	ne: prophylaxis therapy

**3** Postoperative Visit

# 2 Actual organ function

SpO <sub>2</sub> supine position, upper body elevated 30-45°, 10 min in room air possible?	yes	no 🗌	if yes	SpO <sub>2</sub> [%]:
			if no	SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%]:
RR [/min]				
HR [/min]				ABP mean [mmHg]
Temperature [°C]				tympanic axillar inguinal oral rectal
				other if other specify:
Airway secretion	yes	no 🗌	if yes	purulent/yellow colour not purulent
VAS dyspnea [1-10cm]				VAS thoracic rest pain [1-10cm]
				VAS coughing pain [1-10cm]

# 3 Non-mandatory measurements

			Laboratory tests		
Chest X-ray obtained	yes	no 🔲	Hb	mmol/I	g/dl
if yes			WBC	GPt/L	
Infiltrates (any side)	yes	no 📃	Hematocrit	%	
pleural effusion (any side)	yes	no 📃	Creatinine	µmol/l	mg/dl
			BUN	mmol/l	mg/dl
Atelectasis (any side)	yes	no 🔲	Platelets	GPt/L	
Pneumothorax (any side)	yes	no 🔲	PT	sec	IN
cardiopulmonary edema (any side)	yes	no 🔲	PTT	Sec	
			ALT	µmol/s*l	U/L
			AST	µmol/s*l	U/L
			Bilirubin	µmol/l	mg/dl
			CRP c-reactive protein	mg/l	
			Procalcitonin	ng/ml	

**3** Postoperative Visit

4 Pulmonary complications

Aspiration pneumonitis resp. failure after inhalation of gastric contents left  right  both  cannot be differentiated	yes no
Severe respiratory failure need for non-invasive or invasive mechanical ventilation due to poor oxygenation	yes no
Moderate respiratory failure SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen > 2l/min	yes no
ARDS according to Berlin definition yes no	if yes mild moderate severe
Pulmonary infection new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions left i right both cannot be differentiated	yes no
Atelectasis lung opacification with shift of surrounding tissue/ organ towards the affected area left I right both cannot be differentiated	yes no
Cardiopulmonary edema clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray, not explained by poor cardiac function left i right i both cannot be differentiated	yes no
Pleural effusion blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray, not explained by the preoperative patient condition alone left right both cannot be differentiated	yes 🔲 no 🛄
Pneumothorax free air in the pleural space on chest X-ray/ ultrasonic imaging left right both cannot be differentiated for this study, pneumothorax at the operated side will not be considered as a PPC; please mark anyway	yes no
Pulmonary infiltrates monolateral/ bilateral infiltrates without other clinical signs left right both cannot be differentiated	yes no
Prolonged air leakage Air leak requiring at least 7 days of postoperative chest tube drainage left right both cannot be differentiated	yes no
Purulent pleuritis Receiving antibiotics for a suspected infection, as far as not explained by the preoperative patient condition alone left i right both cannot be differentiated	yes no
Pulmonary Embolism As documented by pulmonary arteriogram or autopsy, or supported by a ventilation/perfusion radioisotope scans, or documented by echocardiography and receiving specific therapy	yes no

		<b>3</b> Postoperative Visit
Lung haemorrhage Bleeding through the chest tubes requiring reoperation, or three or more red blood cell packs	yes 🗖	no 🗖
left 🔲 right 🔲 both 🔲 cannot be differentiated 🗔		

### **Extended PPCs:**

Bronchospasm newly expiratory wheezing treated with bronchodilators	yes no
Mild respiratory failure SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen $\leq$ 2l/min	yes no

**3** Postoperative Visit

# **5 Extrapulmonary complications**

SIRS ≥2 findings: Temp < 36 <sup>o</sup> C or > 38 <sup>o</sup> C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl	yes		no 🗌
Sepsis SIRS in response to a confirmed infective process	yes		no 🔲
Severe Sepsis Sepsis with organ dysfunction, hypoperfusion or hypotension	yes		no 🔲
Septic shock Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation	yes		no 🔲
Extrapulmonary infection wound infection + any other (extrapulmonary) infection	yes		no 🗌
Coma Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives	yes		no 🗌
Acute myocardial infarction rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death	yes		no 🗌
Acute renal failure Risk: Crea increased 1.5 times baseline or GFR decrease > 25% or urine output < 0.5 ml/kg/h within Injury: Crea increased 2 times baseline or GFR decrease > 50% or urine output < 0.5 ml/kg/h within Failure: Crea increase 3 times baseline or GFR decrease > 75% or urine output < 0.3 ml/kg/h within Loss: complete loss of kidney function > 4 weeks(requiring dialysis)	12 hr	r anuria	a for 12 hrs
	Π ι		
	yes		no 🔲
yes no if yes R I F Disseminated intravascular coagulation	yes ves		no
yes no if yes R I F Disseminated intravascular coagulation according to DIC score > 5 Stroke			
yes no if yes R I F Disseminated intravascular coagulation according to DIC score > 5 Stroke New clinical signs of stroke lasting > 24h + corresponding findings in radiologic imaging Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0 Gastrointestinal failure	yes		no
yes no if yes R I F Disseminated intravascular coagulation according to DIC score > 5 Stroke New clinical signs of stroke lasting > 24h + corresponding findings in radiologic imaging Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0	yes yes		

**3** Postoperative Visit

Any adverse events yes	no 🗌	if yes specify a	ccording to table:	
Event (details, including treatment)	Severe AE	Causality	Severity	Outcome
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae

# 6 Adverse events (AE) / severe adverse events (SAE)

**3** Postoperative Visit

#### FOLLOWUP

## (report events within DISCHARGE to DAY-28 and 90 after randomisation)

# 7 Followup

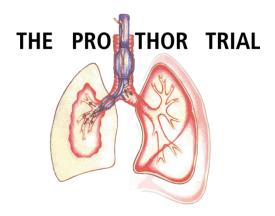
Lost to follow up	yes	no 🗌	if yes	reason
Death	yes	no 🗖		
Date of discharge/death	/	/ 20		Postop day of discharge/death [1-90] (day of discharge/death since randomisation)
Discharge destination:		Home 🗖	Other	hospital/Care Death
Alive hospital free days at d (the number of alive hospital-free as 28 minus the number of days since randomisation (including day due to any reason). All patients wh follow-up will be counted as having	e days will to or part-days i vs of hospital to die before	n a hospital readmission the day 28		
Alive or dead at day 90 afte	r study inc	lusion		Alive/dead

**3** Postoperative Visit

Any adverse events yes	no 📃	if yes specify a	ccording to table:	
Event (details, including treatment)	Severe AE	Causality	Severity	Outcome
	yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae
	yes 🔲 no 🔲	unrelated possible probable unassessable	mild moderate severe unassessable	resolved - no sequelae

# 8 Adverse events (AE) / severe adverse events (SAE)

The PROTHOR Randomized Controlled Trial Appendix



Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

# APPENDIX DEFINITIONS AND SCORES

### **DEFINITIONS and SCORES**

NPPV	Noninvasive Positive-Pressure Ventilation
CPAP	Continuous Positive Airway Pressure
NIV	Noninvasive ventilation
BUN	Blood urea nitrogen
ALT	alanine aminotransferase, serum glutamic-pyruvic transaminase (SGPT)
AST	aspartate aminotransferase, serum glutamic-oxaloacetic transaminase (SGOT)
Hb	Hemoglobin
WBC	White blood cell count
PTT	Partial Thromboplatin time
INR	International normalized ratio
PT	Prothombin time (acc. To "Quick")

**CCS Score :** Canadian Cardiovascular Society Grading System score for describing and categorising effort-related angina pectoris.

### Class I

Angina with strenuous, rapid, or prolonged exertion (Ordinary physical activity such as climbing stairs does not provoke angina.)

### Class II

Slight limitation of ordinary activity (Angina occurs with postprandial, uphill, or rapid walking; when walking more than 2 blocks of level ground or climbing more than one flight of stairs; during emotional stress; or in the early hours after awakening)

### Class III

Symptoms with everyday living activities, ie. moderate limitation. Marked limitation of ordinary activity (Angina occurs with walking 1-2 blocks or climbing a flight of stairs at a normal pace.)

### Class IV

Inability to perform any activity without angina or angina at rest, ie. severe limitation

### NYHA Score : New York Heart Association Functional Classification

### Class I:

Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. no shortness of breath when walking, climbing stairs etc.

#### Class II:

Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. **Class III:** 

Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.

#### Class IV:

Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

### **COPD GOLD Classification**

Stage I	FEV1/FVC<0.70	FEV1≥ 80% normal
Stage II	FEV1/FVC<0.70	FEV1 50-79% normal
Stage III	FEV1/FVC<0.70	FEV1 30-49% normal
Stage IV	FEV1/FVC<0.70	FEV1 <30% normal, or <50% normal with chronic respiratory failure present (usually, this means requiring long-term oxygen therapy)

#### **STOP-BANG Score**

Total score	Yes to questions		
8. Gender	Male?	yes	no 🗌
7. Neck circumference	Neck circumference >40 cm?	yes	no 🗌
6. Age:	Age over 50 years old?	yes	no 🗌
5. BMI	BMI more than 35 kg m <sup>-2</sup> ?	yes	no 🗌
4. Blood pressure	Do you have or are you being treated for high blood pressure?	yes	no 🗌
3. Observed	Has anyone observed you stop breathing during your sleep?		no 🔲
2. Tired	Do you often feel tired, fatigued, or sleepy during daytime?	yes	no 🗌
1. Snoring	Do you snore loudly (loud enough to be heard through closed doors)?	yes	no 🗌

#### **Cumulated Ambulation Score (CAS)**

The patient is assessed on the following functions:

	Able to perform function independently	Only able to perform function with assistance from one or two people	Unable to perform function despite assistance from two people
Transfer from supine-to-sitting-to- supine	2	1	0
Transfer from sitting-to-standing-to- sitting (from armchair)	2	1	0
Walking (with appropriate walking aid)	2	1	0

Total Score [Sum of all values on a given day]: \_\_\_\_\_

Method	O <sub>2</sub> flow (I/min)	Estimated FiO <sub>2</sub> (%)
Nasal cannula	1	24
	2	28
	3	32
	4	35
	5	40
	6	44
Nasopharyngeal catheter	4	40
	5	50
	6	60
Face mask	5	40
	6-7	50
	7-8	60
Face mask with reservoir	6	60
	7	70
	8	80
	9	90
	10	95

### Converting oxygen therapy from $O_2$ to $FiO_2$

### Surgical wound classification

Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
Dirty	Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

### Priority of surgery

Elective	Surgery that is scheduled in advance because it does not involve a medical emergency		
Urgent	Surgery required within < 48 hrs		
Emergency	Non-elective surgery performed when the patient's life or well-being is in direct jeopardy		

#### All variables of the algorithm

### Prediction of postoperative values of FEV1, FVC

The predicted values of FEV1, FVC can be obtained by consideration of the lung volume removed at surgery. For lobectomy, the simple calculation uses the number of bronchopulmonary segments removed compared with the total number (19) in both lungs. For right upper lobectomy (3 segments) in a patient with a preoperative FEV1 of 1.6 liter which is 80% of predicted normal, the ppo-FEV will be  $1.6 \times 16/19 = 1.35$  liter, and the ppo-FEV1% will be 80%  $\times 16/19 = 67\%$ .

## **DEFINITIONS** of pulmonary post–operative complications

• Aspiration pneumonitis:

Defined as respiratory failure after the inhalation of regurgitated gastric contents

• Moderate respiratory failure:

SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen > 2l/min

• Severe respiratory failure:

need for non-invasive or invasive mechanical ventilation due to poor oxygenation

ARDS:

Mild, moderate or severe according to the Berlin definition:

Time	Within one week of a known clinical insult, or new/worsening respiratory symptoms			
Chest imaging*	Bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules			
Origin of edema	Respiratory failure not fully explained by cardiac failure or fluid overload; need objective assessment to exclude hydrostatic edema if no risk factor present (e.g., echocardiography)			
	Mild	Moderate	Severe	
Oxygenation**	$200 < PaO_2 / FiO_2 < 300$	100 < PaO <sub>2</sub> / FiO <sub>2</sub> < 200	$PaO_2/FiO_2 \le 100$	
	PEEP or CPAP $\geq$ 5 cmH <sub>2</sub> O***	PEEP ≥ 5 cmH₂O	PEEP ≥ 5 cmH₂O	

ARDS: acute respiratory distress syndrome; PaO<sub>2</sub>: partial pressure of arterial oxygen; FiO<sub>2</sub>: inspired fraction of oxygen; PEEP: positive end-expiratory pressure; CPAP: continuous positive airway pressure

\*: chest X-ray or CT scan

\*\*: if altitude higher than 1,000 meters, correction factor should be made as follows: PaO<sub>2</sub> / FiO<sub>2</sub> 9 (barometric pressure/760)

\*\*\*: this may be delivered non-invasively in the mild ARDS group

• Pulmonary infection:

Defined as new or progressive radiographic infiltrate plus at least two of the following: antibiotic treatment, tympanic temperature > 38<sup>a</sup>C, leukocytosis or leucopenia (WBC count < 4,000cells/mm3 or > 12,000cells/mm3) and/or purulent secretions

#### Atelectasis:

Suggested by lung opacification with shift of the mediastinum, hilum, or hemidiaphragm towards the affected area, and compensatory overinflation in the adjacent nonatelectatic lung

• Cardiopulmonary edema:

Defined as clinical signs of congestion, including dyspnea, edema, rales and jugular venous distention, with the chest X–ray demonstrating increase in vascular markings and diffuse alveolar interstitial infiltrates

• Pleural effusion:

Chest X-ray demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm in upright position, evidence of displacement of adjacent anatomical structures, or (in supine position) a hazy opacity in one hemithorax with preserved vascular shadows

Pneumothorax:

Defined as air in the pleural space with no vascular bed surrounding the visceral pleura

Pulmonary infiltrates:

Chest X-ray demonstrating new monolateral or bilateral infiltrate without other clinical signs

Prolonged air leakage

Air leak requiring at least 7 days of postoperative chest tube drainage

• Purulent pleuritis

Receiving antibiotics for a suspected infection, as far as not explained by the preoperative patient condition alone

Pulmonary embolism

As documented by pulmonary arteriogram or autopsy, or supported by a ventilation/perfusion radioisotope scans, or documented by echocardiography and receiving specific therapy

Lung hemorrhage

Bleeding through the chest tubes requiring reoperation, or three or more red blood cell packs

#### **Extended PPCs**

Bronchospasm:

Defined as newly detected expiratory wheezing treated with bronchodilators

• Mild respiratory failure:

SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen  $\leq$  2l/min

## **DEFINITIONS** of extra–pulmonary post–operative complications

• Systemic inflammatory response syndrome (SIRS):

Presence of two or more of the following findings: Body temperature  $< 36^{\circ}$ C or  $> 38^{\circ}$ C – Heart rate > 90 beats per minute – Respiratory rate > 20 breaths per minute or, on blood gas, a P<sub>a</sub>CO<sub>2</sub> < 32 mmHg (4.3 kPa) – WBC count < 4,000 cells/mm3 or > 12,000 cells/mm3 or > 10% band forms

• Sepsis:

SIRS in response to a confirmed infectious process; infection can be suspected or proven (by culture, stain, or polymerase chain reaction (PCR)), or a clinical syndrome pathognomonic for infection. Specific evidence for infection includes WBCs in normally sterile fluid (such as urine or cerebrospinal fluid (CSF), evidence of a perforated viscera (free air on abdominal x-ray or CT scan, signs of acute peritonitis), abnormal chest x-ray (CXR) consistent with pneumonia (with focal opacification), or petechiae, purpura, or purpura fulminans

• Severe sepsis:

Sepsis with organ dysfunction, hypoperfusion, or hypotension

• Septic shock:

Sepsis with refractory arterial hypotension or hypoperfusion abnormalities in spite of adequate fluid resuscitation; signs of systemic hypoperfusion may be either end-organ dysfunction or serum lactate greater than 4 mmol/dL. Other signs include oliguria and altered mental status. Patients are defined as having septic shock if they have sepsis plus hypotension after aggressive fluid resuscitation, typically upwards of 6 liters or 40 ml/kg of crystalloid

• Extra-pulmonary infection:

Wound infection + any other infection

Coma:

Glasgow Coma Score  $\leq 8$  in the absence of the rapeutic coma or sedation

• Acute myocardial infarction:

Detection of rise and/or fall of cardiac markers (preferably troponin) with at least one value above the 99<sup>th</sup> percentile of the upper reference limit, together with: symptoms of ischemia, ECG changes indicative of new ischemia, development of pathological Q-waves, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality *Or:* sudden unexpected cardiac death, involving cardiac arrest with symptoms suggestive of cardiac ischemia (but death occurring before the appearance of cardiac markers in blood)

• Acute renal failure:

Renal failure documented as follows: Risk: increased creatinine x1.5 or GFR decrease > 25% or urine output (UO) <  $0.5 \text{ ml/kg/h} \times 6 \text{ hr} - \text{Injury}$ : increased creatinine x2 or GFR decrease > 50% or UO <  $0.5 \text{ ml/kg/h} \times 12 \text{ hr} - \text{Failure}$ : increase creatinine x3 or GFR decrease > 75% or UO <  $0.3 \text{ ml/kg/h} \times 24 \text{ hr}$  or anuria x 12 hrs – Loss: persistent ARF = complete loss of kidney function > 4 weeks

• Disseminated intravascular coagulation:

DIC score documented as follows: Platelet count < 50 (2 points), < 100 (1 point), or  $\ge$  100 (0 points) – D–dimer > 4 µg/ml (2 points), > 0.39 µg/ml (1 point) or  $\le$  0.39 µg/ml (0 points) – prothrombin time > 20.5 seconds (2 points), > 17.5 seconds (1 point) or  $\le$  17.5 seconds (0 points); if  $\ge$  5 points: overt DIC

• Stroke

New clinical signs of stroke lasting longer than 24 hours and corresponding findings in radiologic imaging.

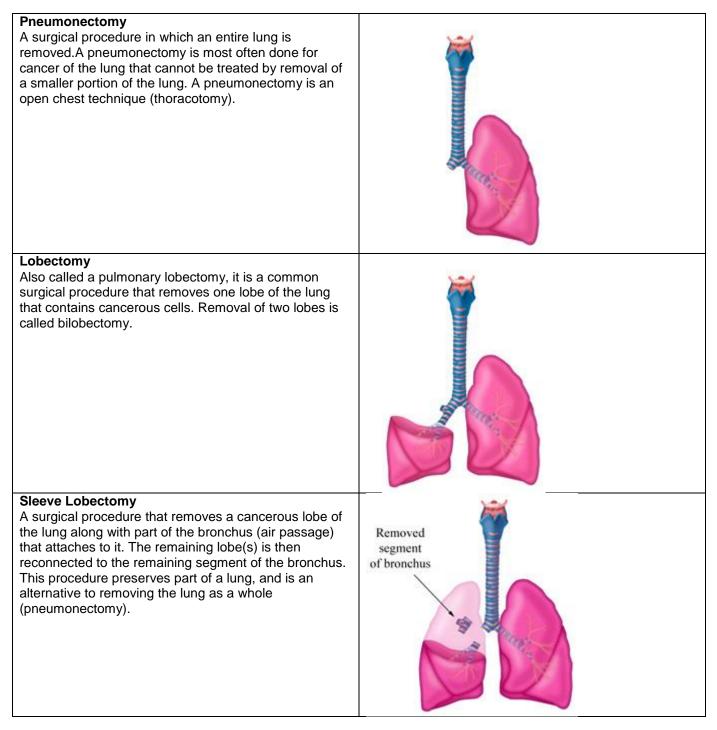
• Hepatic failure:

Hepatic failure during short term follow up (5 postoperative days) is considered as follows: Ratio of total bilirubin on postoperative day 5 to postoperative day 1 > 1,7 and ratio of international normalized ratio (INR) on postoperative day 5 to postoperative day 1 > 1,0; during long term follow up (until postoperative day 90) at new presence of hepatic encephalopathy and coagulopathy (INR > 1,5) within 8 weeks after initial signs of liver injury (e.g. jaundice) without evidence for chronic liver disease

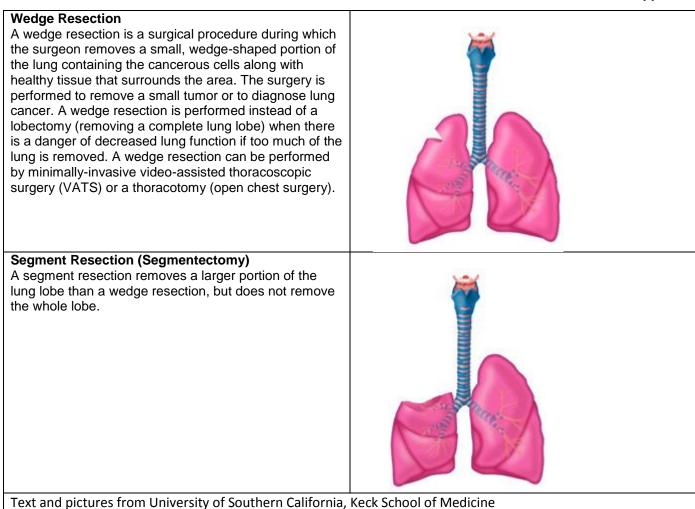
#### • Gastro-intestinal failure

Any type of gastro-intestinal bleeding or gastro-intestinal failure (GIF) score documented as follows: 0 = normal gastrointestinal function; 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after abdominal surgery; 2 = food intolerance (FI)*or*intra-abdominal hypertension (IAH); 3 = FI and IAH; and 4 = abdominal compartment syndrome (ACS)

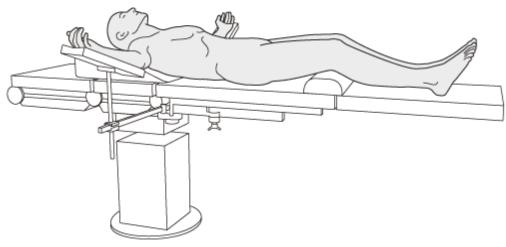
# **Types of Lung Surgery**



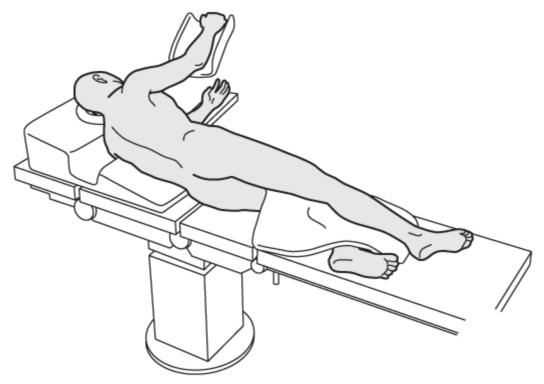
5 Appendix



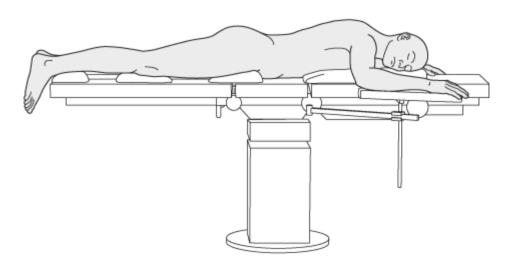
## Definitions of body position during surgery



**Supine position** 



### Lateral position



### Prone position

## Table of body height correlated to ideal body weight

Formula:

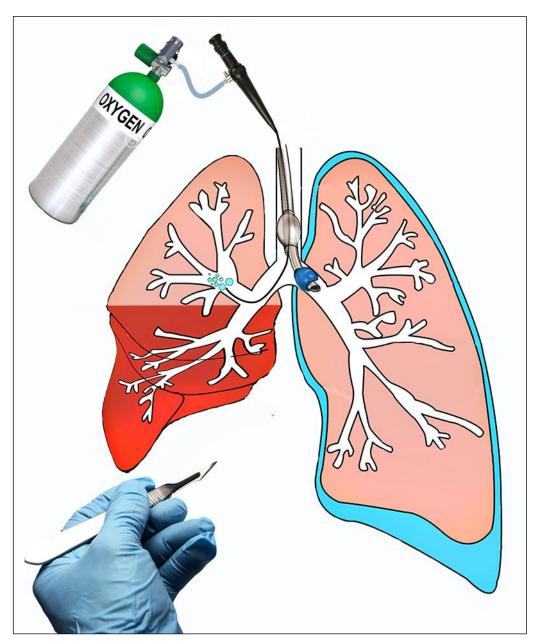
Male: 50+0.91\*(height-152.4)

Female: 45.5+0.91\*(height-152.4)

Ideal body weight(kg)				
Height				
cm	male	female		
145	43,3	38,8		
146		39,7		
146		39,7		
147		40,6		
147	45,1	40,6		
		41,5		
148	46,0	41,5		
149	46,9	42,4		
149	46,9	42,4		
150		43,3		
		43,3		
		44,2		
151	48,7	44,2		
152	49,6			
		45,1		
		46,0		
		46,0		
154	51,5	47,0		
		47,0		
		47,9		
		47,9		
		48,8		
156	53,3	48,8		
157	54,2	49,7		
		49,7		
158	55,1	50,6		
158	55,1	50,6		
159	56,0	51,5		
159	56,0	51,5		
160	56,9	52,4		
160	56,9	52,4		

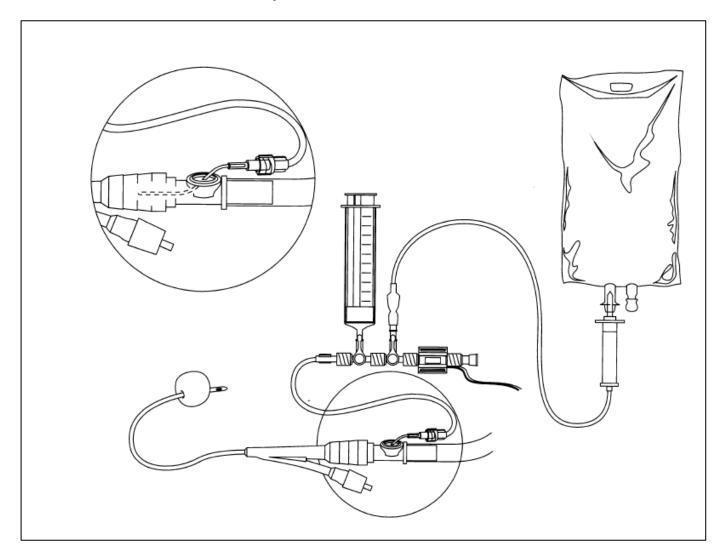
161	57 <i>,</i> 8	53,3
161	57,8	53,3
162	58,7	54,2
162	58,7	54,2
163	59 <i>,</i> 6	55,1
163	59 <i>,</i> 6	55,1
164	60,6	56,1
164	60,6	56,1
165	61,5	57,0
165	61,5	57,0
166	62,4	57,9
166	62,4	57,9
167	63,3	58 <i>,</i> 8
167	63,3	58,8
168	64,2	59 <i>,</i> 7
168	64,2	59 <i>,</i> 7
169	65,1	60,6
169	65,1	60,6
170	66,0	61,5
170	66,0	61,5
171	66,9	62,4
171	66,9	62,4
172	67 <i>,</i> 8	63,3
172	67,8	63,3
173	68,7	64,2
173	68,7	64,2
174	69,7	65,2
174	69,7	65,2
175	70,6	66,1
175	70,6	66,1
176	71,5	67,0
176	71,5	67,0
177	72,4	67,9
177	72,4	67,9

178	73,3	68 <i>,</i> 8
178	73,3	68,8
179	74,2	69,7
179	74,2	69,7
180	75,1	70,6
180	75,1	70,6
181	76,0	71,5
181	76,0	71,5
182	76,9	72,4
182	76,9	72,4
183	77,8	73,3
183	77,8	73,3
184	78,8	74,3
184	78,8	74,3
185	79,7	75,2
185	79,7	75,2
186	80,6	76,1
186	80,6	76,1
187	81,5	77,0
187	81,5	77,0
188	82,4	77,9
188	82,4	77,9
189	83,3	78,8
189	83,3	78 <i>,</i> 8
190	84,2	79,7
190	84,2	79,7



Scheme of selective oxygen insufflation during one lung ventilation

Selective oxygen insufflation to the right upper lobe via fiberscope during one lung ventilation. The remaining part of the right lung is collapsed. The left lung is ventilated through the double lumen tube.

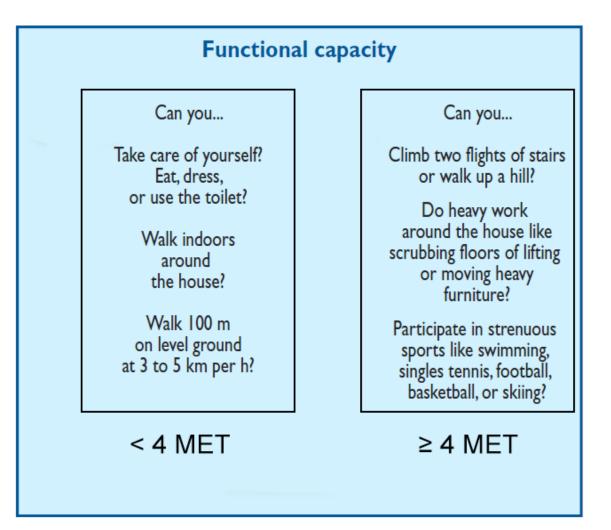


## Measurement of abdominal pressure

A closed, needle-free system for measurement of intravesicular pressure. Normal saline (1,000 mL), a 60-mL Luer lock syringe, and a segment of pressure tubing are attached to a disposable pressure transducer connected to two stopcocks. An 18-gauge angiocatheter is inserted into the culture aspiration port of the urinary drainage tubing and the needle removed leaving the plastic infusion catheter in place. The infusion catheter is connected to the pressure tubing and the system flushed with normal saline. The infusion catheter may be taped to the urinary drainage tubing for added security.

To measure intraabdominal pressure, the urinary drainage tubing is clamped immediately distal to the catheter. The stopcocks are turned "off" to the patient and to the pressure transducer. Normal saline is aspirated from the IV bag using the 60-mL syringe. The first stopcock is turned "on" to the patient and the normal saline instilled into the bladder through the urinary catheter. The process is repeated until a total of 100 mL of normal saline has been instilled into the bladder. The stopcocks are then turned "off" to the syringe and IV tubing. The clamp on the urinary drainage tubing is momentarily released to ensure that all air is flushed from the urinary catheter. The patient's intraabdominal pressure is then measured at end-expiration. The clamp is removed, the bladder allowed to drain, and the 100 mL of fluid subtracted from the patient's urinary output for that hour.

(from: Intraabdominal Pressure: A Revised Method for Measurement; Michael L Cheatham, MD, and Karen Safcsak, RN; 1998 by the American College of Surgeons)



# Assessment of metabolic equivalents

Estimated energy requirements for various activities.

One MET equals the basal metabolic rate. Exercise testing provides an objective assessment of functional capacity. Without testing, functional capacity can be estimated from the ability to perform the activities of daily living. One MET represents metabolic demand at rest; climbing two flights of stairs demands 4 METs, and strenuous sports, such as swimming, > 10 METS. The inability to climb two flights of stairs or run a short distance (<4 METs) indicates poor functional capacity and is associated with an increased incidence of post-operative cardiac events. Abbreviations: km per h = kilometres per hour; MET = metabolic equivalent.

Based on **Hlatky MA, et al**. A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). Am J Cardiol 1989;64:651–654. and **Fletcher GF et al**. Exercise standards for testing and

training: A statement for healthcare professionals from the American Heart Association. Circulation 2001;104:1694–1740)

From: 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management. European Heart Journal (2014) 35, 2383–2431