The GENERATOR Trial

INTRAOPERATIVE CASE REPORT FORM

Driving Pressure During General Anesthesia For Minimally Invasive Abdominal Surgery

CONTROL GROUP

Patient Identification Number: |__|__|__|__|__|__|

Day of Surgery (*dd-mm-yy*): |__|__|-|__|__|-|__|__|

Local Investigator 1 or 2 (preoperative) _____

Local Investigator 1 (intraoperative) _____

Local Investigator 2 (postoperative) _____

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Print and store pre- and intraoperative CRF separately from postoperative CRF

Mechanical ventilation settings	
Mechanical ventilation settings for the duration of anesthesia	Volume controlled mechanical ventilation during the entire period of surgery
	PEEP 5 cm H_2O
	I:E ratio = 1:2
	Respiratory rate adjusted to normocapnia ($ETCO_2$ between 35-45 mm Hg or 4.6-5.9 kPa)
	Tidal volume 8 ml/kg Predicted Body Weight (PBW), as calculated by Castor EDC in eCRF
	FiO_2 0.40 or higher (target SpO_2 >90%)
	Inspiratory pause of 15%.

Intraoperative

1. Anesthetic overview

Predicted bodyweight: |__|__|__|,|__| kg *For calculation see preoperative CRF page 4 or preoperative eCRF in Castor*	Tidal Volume: |__|__|__| ml *Tidal volume = 8 x predicted bodyweight. For automatic calculation see preoperative eCRF in Castor EDC.*

Start of anesthesia |__|__|:|__|__| (hh:mm) *i.e. time of induction*	End of anesthesia |__|__|:|__|__| (hh:mm) *i.e. time of extubation or discharge from operation room in case patient remains on mechanical ventilation*	Body temperature at end of surgery >35.0 °C ☐Yes ☐No

Maintenance of anesthesia ☐Volatile ☐TIVA (total intravenous anesthesia) ☐Combined

Epidural ☐Yes ☐No *If yes:* ☐Thoracic ☐Lumbar

Neuromuscular blocking agents administered ☐Yes ☐No *If yes:* ☐ Non-depolarizing (e.g., rocuronium) ☐Depolarizing (e.g., succinylcholine *If non-depolarizing agent:*

What was used for maintenance of muscle relaxation after succinylcholine? ☐No maintenance ☐Non-depolarizing ☐Depolarizing

Neuromuscular function monitoring during surgery ☐Yes ☐No

TOF ≥ 90 at end of surgery without antagonization ☐Yes ☐No *If no:*

Used antagonist*:* ☐Sugammadex ☐Cholinesterase inhibitor ☐No antagonist

Surgical overview

Start of surgery \|__\|__\|:\|__\|__\| (hh:mm)
i.e. time of surgical incision

End of surgery \|__\|__\|:\|__\|__\| (hh:mm)
i.e. time skin closed

Randomization

Randomization group: ☐**Standard PEEP group**

2. Intraoperative variables*

** Record intraoperative variables hourly after induction and immediately after the RM.*

		After induction *directly after induction*	**hr 1** □N/A	**hr 2** □N/A	**hr 3** □N/A	**hr 4** □N/A	**hr 5** □N/A	**hr 6** □N/A
Respiratory parameters	Time [*hh:mm*]							
	PEEP [*cm H_2O*]							
	VT [*mL*]							
	Ppeak [*cm H_2O*]							
	Pplateau [*cmH_2O*]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR *[/min]*							
	FiO_2 *[0-1]*							
	SPO_2 [%]							
	$ETCO_2$ *[kPa or mmHg]*							
	IAP [*cm H_2O*]							
HD	Systolic BP [*mmHg*]							
	Diastolic BP [*mmHg*]							
	Position* *Trendelenburg: 15-30 degrees head-down; *Extreme Trendelenburg: >30 degrees head-down.*	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐ Neutral ☐ Trendelenburg ☐Extreme Trendelenburg ☐ Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg
Did the following intraoperative complications occur in the corresponding hour or RM:								
Rescue strategy for desaturation (SpO_2 ≤ 90% or if preoperative SpO_2 <90% an absolute decrease in SpO_2>5%) ** see page 6 for rescue therapy*		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no

2. Intraoperative variables*

** Record intraoperative variables hourly after induction and immediately after the RM.*

		hr 7 □N/A	**hr 8** □N/A	**hr 9** □N/A	**hr 10** □N/A	**hr 11** □N/A	**hr 12** □N/A	**hr 13** □N/A
Respiratory parameters	Time [*hh:mm*]							
	PEEP [*cm H_2O*]							
	VT [*mL*]							
	Ppeak [*cm H_2O*]							
	Pplateau [*cmH_2O*]							
	I:E	1:	1:	1:	1:	1:	1:	1:
	RR *[/min]*							
	FiO_2 *[0-1]*							
	SPO_2 [%]							
	$ETCO_2$ *[kPa or mmHg]*							
	IAP [*cm H_2O*]							
HD	Systolic BP [*mmHg*]							
	Diastolic BP [*mmHg*]							
	Position* **Trendelenburg: 15-30 degrees head-down; Extreme Trendelenburg: >30 degrees head-down.*	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐ Neutral ☐ Trendelenburg ☐Extreme Trendelenburg ☐ Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg	☐Neutral ☐Trendelenburg ☐Extreme Trendelenburg ☐Anti Trendelenburg
	Did the following intraoperative complications occur in the corresponding hour or RM:							
	Rescue strategy for desaturation (SpO_2 ≤ 90% or if preoperative SpO_2 <90% an absolute decrease in SpO_2>5%) ** see page 8 for rescue therapy*							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	A decrease in mean arterial pressure (MAP) below 65 mmHg and lasting for >1 minute							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	Vasoactive drugs defined as more than needed to compensate for vasodilating effects of anesthesia, according to decision of the anesthesiologist in charge							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
	New arrhythmias needing intervention as suggested by the Advanced Cardiac Life Support Guidelines							
		☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no

Rescue therapy for desaturation standard low PEEP group

Step	PEEP	FiO_2
1	5	0.4
2	5	0.5
3	5	0.6
4	5	0.7
5	5	0.8
6	6	0.8
7	Recruitment maneuver	

- **Perform rescue strategy if $SpO_2 \leq 90\%$**
- **Please note (encircle) to which step rescue strategy is performed**

3. Did the patient receive the allocated PEEP level during surgery? ☐ yes ☐ no *If no, adjusted PEEP level to:* |__|__| cm H_2O *If no, specify reason:*

Decrease in mean arterial pressure below 65 mmHg for more than one minute not responding to fluids and/or vasoactive drugs	☐ yes ☐ no
New arrhythmias not responding to the treatment suggested by the Advanced Cardiac Life Support Guidelines	☐ yes ☐ no
Need for a dosage of vasoactive drugs at the highest level tolerated, according to decision of the anesthesiologist in charge	☐ yes ☐ no
Need of massive transfusion, more than 5 units of blood to maintain Ht>21% (Hb>7 mg/dl)	☐ yes ☐ no
Surgical complication determining life-threatening situations	☐ yes ☐ no
Other reason (specify):	☐ yes ☐ no

4. Where other ventilation settings changed (TV, FiO_2, e.g.) for clinical reasons (pre-approved protocol deviations) ☐ yes ☐ no

If yes, specify:

5. Protocol violation? *Misinterpretation of study protocol, thus no clinical reason for changing ventilation.* ☐ yes ☐ no

If yes, specify: ☐ Difference between selected PEEP and correct PEEP >2 cm H_2O ☐ Difference between selected PEEP and correct PEEP ≤2 cm H_2O ☐ Other

If other, specify:

6. Conversion to laparotomy? *If intervention group, please repeat the decremental PEEP trial.* ☐ yes ☐ no

If yes, in which corresponding hour was the conversion?

7. Intraoperative medication

	Cumulative dose		**Cumulative dose** mL		**Cumulative dose** mL
Vasoactive or inotropic drugs	Dobutamine ☐Yes ☐No _____ mg Dopamine ☐Yes ☐No _____ mg Epinephrine ☐Yes ☐No _____ mg Ephedrine ☐Yes ☐No _____ mg Norepinephrine ☐Yes ☐No _____ µg Phenylephrine ☐Yes ☐No _____ µg Other ☐Yes ☐No _____ If other, specify: _____	Fluids	Crystalloids ☐Yes ☐No If yes, cumulative dose: _____ Colloids ☐Yes ☐No If yes, cumulative dose: _____ Albumin ☐Yes ☐No If yes, cumulative dose: _____	Transfusion	Red blood cells* ☐Yes ☐No _____ FFP ☐Yes ☐No _____ Platelets ☐Yes ☐No _____ Omniplasma ☐Yes ☐No _____ Other ☐Yes ☐No _____ If other, specify: _____ * E.g. packed red blood cells, cell saver
	Cumulative mL				
Total Out	Urine production ☐Yes ☐No _____ ☐NM* Blood loss ☐Yes ☐No _____ ☐NM* Ascites ☐Yes ☐No _____ ☐NM* Other ☐Yes ☐No _____ ☐NM* If other, specify: _____				

*NM = Not measured

8. Intraoperative blood gas variables*

**only if deemed clinically necessary*

	After induction	**hr 1**	**hr 2**	**hr 3**	**hr 4**	**hr 5**	**hr 6**
pH							
PaO_2							
$PaCO_2$							
HCO_3							
	hr 7	**hr 8**	**hr 9**	**hr 10**	**hr 11**	**hr 12**	**hr 13**
pH							
PaO_2							
$PaCO_2$							
HCO_3							

Measurement unit PaO2	☐mmHg	☐kPa
Measurement unit PaCO2	☐mmHg	☐kPa
Measurement unit HCO3	☐mmol/L	☐mEq/L

9. Central venous catheter	
**only if deemed clinically necessary*	
	CVD
After placement	
Hour 1	
Hour 2	
Hour 3	
Hour 4	
Hour 5	
Hour 6	
Hour 7	
Hour 8	
Hour 9	
Hour 10	
Hour 11	
Hour 12	