

iPROVE-EAL

**Individualized Perioperative Open lung Ventilatory approach in
Emergency Abdominal Laparotomy/scopy. A prospective multicenter
randomized controlled trial**

Identifier	
HOSPITAL	
PATIENT IDENTIFICATION	
RESEARCHER 1	
RESEARCHER 2	

CASE REPORT FORM (CRF)
Version 01.0 05-08-2019

CONFIDENCIAL

HOSPITAL		SUBJECT	
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PREOPERATIVE DATA

DEMOGRAPHIC DATA								
Age (years):			<input type="checkbox"/> Male <input type="checkbox"/> Female			Height(cm):		
weight (kg):			IMC (kg/m ²):			Ideal body weight (kg/m ²):		
Admission date (dd/mm/yyyy):			Surgery date (dd/mm/yyyy):			Date of hospital discharge (dd/mm/yyyy):		

Inclusion criteria	YES	NO
Age equal to or older than 18 years	<input type="checkbox"/>	<input type="checkbox"/>
Emergency laparo-tomy/scopy	<input type="checkbox"/>	<input type="checkbox"/>
Informed consent	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion criteria	YES	NO
Pregnancy or lactation	<input type="checkbox"/>	<input type="checkbox"/>
Participation on another RCT with similar intervention or outcome	<input type="checkbox"/>	<input type="checkbox"/>
Moderate or severe ARDS	<input type="checkbox"/>	<input type="checkbox"/>
Mechanical ventilation on the last 15 days due to acute or chronic pathology	<input type="checkbox"/>	<input type="checkbox"/>
Diagnosed or suspected intracranial hypertension (> 15 mmHg)	<input type="checkbox"/>	<input type="checkbox"/>
Pneumothorax or giant bullae on chest X-ray or CT	<input type="checkbox"/>	<input type="checkbox"/>
Refractory shock	<input type="checkbox"/>	<input type="checkbox"/>

Informed Consent
<input type="checkbox"/> No Specify the reason: <input type="checkbox"/> Rejected by patient or relatives <input type="checkbox"/> Rejected by the physician <input type="checkbox"/> Absence of investigator <input type="checkbox"/> Yes Indicate date/time of getting the informed consent. ___/___/___ (dd/mm/yyyy) hour ___:___

HOSPITAL		SUBJECT	
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CO-MORBIDITIES	YES	NO	CO-MORBIDITIES	YES	SI
Arterial hypertension	<input type="checkbox"/>	<input type="checkbox"/>	Dyslipemia	<input type="checkbox"/>	<input type="checkbox"/>
Ischemic cardiopathy	<input type="checkbox"/>	<input type="checkbox"/>	OSA	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes mellitus II	<input type="checkbox"/>	<input type="checkbox"/>	COPD	<input type="checkbox"/>	<input type="checkbox"/>
smoker	<input type="checkbox"/>	<input type="checkbox"/>	Chronic renal failure	<input type="checkbox"/>	<input type="checkbox"/>
Ex smoker (> 3 months)	<input type="checkbox"/>	<input type="checkbox"/>	Chronic liver failure	<input type="checkbox"/>	<input type="checkbox"/>
Alcohol consumption (more than two drinks per day)	<input type="checkbox"/>	<input type="checkbox"/>	Oncological	<input type="checkbox"/>	<input type="checkbox"/>
Neuromuscular disease	<input type="checkbox"/>	<input type="checkbox"/>	Immunosuppression	<input type="checkbox"/>	<input type="checkbox"/>

Surgery	
<input type="checkbox"/> Laparotomy	<input type="checkbox"/> Laparoscopy
<input type="checkbox"/> Mesenteric ischemia	<input type="checkbox"/> Anastomotic leak
<input type="checkbox"/> Hemoperitoneum	<input type="checkbox"/> Adhesiolysis
<input type="checkbox"/> Colorectal resection	<input type="checkbox"/> Small bowel resection
<input type="checkbox"/> Gastrectomy	<input type="checkbox"/> Gastrointestinal perforation
<input type="checkbox"/> Hemoperitoneum (urological, gynecological)	<input type="checkbox"/> Cholecystectomy
<input type="checkbox"/> Exploratory laparotomy	<input type="checkbox"/> Hepatic transplant
<input type="checkbox"/> Vascular (Aneurysmal surgeries)	<input type="checkbox"/> Urological other
<input type="checkbox"/> Hepatic transplantation	<input type="checkbox"/> Kidney transplantation

PREOPERATIVE DATA			
Primary diagnosis:			
ASA <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV			
ARISCAT <input type="checkbox"/> Moderate (26-44 points) <input type="checkbox"/> severe (> 44 points)			
SpO ₂ (FIO ₂ 0.21)	%	Preoperative Hb (g/dl)	
Lung infection on the last month <input type="checkbox"/> yes <input type="checkbox"/> No			
Clinical Frailty Scale (from 1 to 9):		Charlson:	

HOSPITAL		SUBJECT	
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INTRAOPERATIVE DATA

NOTE: It is mandatory to ask for /obtain the informed consent **before** randomization.

Data should be reported also for the non-randomized patients.

RANDOMIZATION		
<input type="checkbox"/> No	<input type="checkbox"/> Negative Air-Test	<input type="checkbox"/> Other reason
<input type="checkbox"/> Yes	Date and time: _ / _ / _ and _ : _	<input type="checkbox"/> STD-O2 <input type="checkbox"/> iOLA-iHFNC

**Only if
catheterization*

INTRAOPERATIVE DATA			
VARIABLE	T0	T1	T2
	(10 min after intubation)	(60 min after intubation)	(pre-extubation)
PEEP (cmH ₂ O)			
RR			
VT (ml)			
FiO ₂ (%)			
*PaO ₂ (mmHg)			
*PaO ₂ /FiO ₂ (mmHg)			
*PaCO ₂ (mmHg)			
*pH			
Peak pressure (cmH ₂ O)			
Plateau pressure (cmH ₂ O)			
Cdyn (ml/cmH ₂ O)			
Raw (ml/cmH ₂ O)			
PAM (mmHg)			
IC (ml/min/m ²)			
Air-Test (0.21 FiO ₂ during 5 min or SpO ₂ 97%)			
SpO ₂ (%) a FiO ₂ 21%			

arterial

Fluids (ml)			
Fluids		Red blood cells	
Estimated blood loss		Urinary output	
Additional information			
Duration of surgery (min)		Duration of MV (min)	
Surgical position. Supine <input type="checkbox"/> Trend <input type="checkbox"/> Reverse trend <input type="checkbox"/>			
Use of vasoactive drugs <input type="checkbox"/> Yes No <input type="checkbox"/> Drug/dose:			Pneumoperitoneum pressure. (mmHg):

HOSPITAL		SUBJECT	
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Anesthetic management	
Hypnotic maintenance <input type="checkbox"/> Intravenous <input type="checkbox"/> Halogenated	Antibiotic prophylaxis. Yes <input type="checkbox"/> No <input type="checkbox"/>
Neuromuscular blockade Yes <input type="checkbox"/> No <input type="checkbox"/>	Epidural Analgesia Yes <input type="checkbox"/> No <input type="checkbox"/>
Quantitative Neuromusc Monitorization Yes <input type="checkbox"/> No <input type="checkbox"/>	Temperature monitoring Yes <input type="checkbox"/> No <input type="checkbox"/>
NMB reversion Yes <input type="checkbox"/> No <input type="checkbox"/>	Depth of anesthesia monitoring Yes <input type="checkbox"/> No <input type="checkbox"/>
TOFr >0,9 before extubation Yes <input type="checkbox"/> No <input type="checkbox"/>	

Open lung approach				
<i>First RM only if positive air-test after induction (SpO2 < 97% while breathing room air)</i>				
First alveolar recruitment maneuver (RM)	Opening pressure	OL- PEEP	Cdyn	SpO2 (FIO2 21%) 5 min after the OL- PEEP
Following RM only if SpO2 < 97% while breathing room air + a drop in Cdyn > 10%				
60 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				
120 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				
180 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				
240 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				
300 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				
360 minutes <input type="checkbox"/> YES <input type="checkbox"/> No,				

RM DUE TO INCIDENTAL DISCONNECTION			
<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate the number of RM:			
RM failure			
First RM	<input type="checkbox"/> Yes <input type="checkbox"/> No	After ephedrine/phenylephrine administration	<input type="checkbox"/> Yes <input type="checkbox"/> No
Followings RM	<input type="checkbox"/> Yes <input type="checkbox"/> No	After ephedrine/phenylephrine administration	<input type="checkbox"/> Yes <input type="checkbox"/> No
Intraoperative Rescue maneuvers (See protocol criteria)			
<input type="checkbox"/> Yes <input type="checkbox"/> No			

POSTOPERATIVE DATA

HOSPITAL		SUBJECT	
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POSTOPERATIVE DATA		
High-flow nasal cannula (iOLA-iHFNC group) (Only if SpO₂ <97% (FIO₂ 0.21))		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
Postoperative rescue maneuvers (see protocol criteria)		
<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate: <input type="checkbox"/> NIMV <input type="checkbox"/> IMV		
Extubated patient in the OR		
<input type="checkbox"/> Yes <input type="checkbox"/> No If not, indicate: <input type="checkbox"/> Respiratory <input type="checkbox"/> Hemodynamic <input type="checkbox"/> Neurological <input type="checkbox"/> Other: :		
MV time until extubation (min)		
Postoperative management according to protocol?		
<input type="checkbox"/> Yes <input type="checkbox"/> No If not, indicate:		
* (In case of no intraoperative extubation data from days 0, 1 and 3 will be collected after extubation. Data from days 7 and 30 (primary and secondary outcome) will be collected from the day of surgery)		
Analgesic management		
Drug		
<input type="checkbox"/> Morfine <input type="checkbox"/> Fentanil <input type="checkbox"/> If Other, specify which:		
Epidural		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
Paravertebral		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
VAS (VAS evaluation will be done prior to the diagnose of atelectasis/hypoxemia)		
Minutes after surgery	VAS	Rescue with morphine or derivatives?
15-30		<input type="checkbox"/> Yes <input type="checkbox"/> No

NOTE: Before the Air-Test a VAS < 4 must be guaranteed

Air Test after 15-30 min at PACU	SpO ₂ : %
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SAEs
It is considered a SAE when it appears directly related with RM The local principal investigator must inform the coordinating center during the first 24h
Hemodynamic shock. <input type="checkbox"/> Yes <input type="checkbox"/> No

HOSPITAL		SUBJECT	
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Arrhythmia with hemodynamic instability. <input type="checkbox"/> Yes <input type="checkbox"/> No
Pneumothorax. <input type="checkbox"/> Yes <input type="checkbox"/> No
Cardiorespiratory arrest <input type="checkbox"/> Yes <input type="checkbox"/> No

PROTOCOL NON FULFILLMENT
INTRAOPERATIVE
Related to the specific ventilatory protocol
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify which:
Related to the RM
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify which:
POSTOPERATIVE
Related with the air-test
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify which:
Related with the HFNT
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify which:
Related with the rescue maneuvers
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, specify which:
Observations

<i>HOSPITAL</i>		<i>SUBJECT</i>	
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HOSPITAL		SUBJECT	
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POSTOPERATIVE DATA	
Acute postoperative respiratory failure at PACU	
Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, indicate treatment: <input type="checkbox"/> Increase in FIO ₂ <input type="checkbox"/> HFNT <input type="checkbox"/> CPAP <input type="checkbox"/> NIMV <input type="checkbox"/> IMV	
Was the patient extubated in the OR*	
Yes <input type="checkbox"/> No <input type="checkbox"/> If not, indicate: <input type="checkbox"/> Respiratory <input type="checkbox"/> Hemodynamic <input type="checkbox"/> Neurological <input type="checkbox"/> Others:	
¿ICU due to MV requirement? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, indicate: Time until extubation (min):	

6h postoperative arterial blood gas analysis			
SpO ₂		PaO ₂ (mmHg)	
FIO ₂		PaO ₂ /FIO ₂ (mmHg)	
PaCO ₂ (mmHg)		pH	
SpO ₂ (FiO ₂ 21%)			

OUTCOMES

Day 0		
Does the patient have any pulmonary complication BEFORE surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrhythmia	<input type="checkbox"/> Delirium	

HOSPITAL		SUBJECT	
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<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage

Day 1		
Does the patient have any pulmonary complication until the first day after surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrhythmia	<input type="checkbox"/> Delirium	
<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus	
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage	
ICU admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Per protocol	<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> Multiorgan failure	
<input type="checkbox"/> Renal failure	<input type="checkbox"/> Hemodynamic failure	
<input type="checkbox"/> Others:	ICU length of stay (hours):	
Re-intervention <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Bleeding	<input type="checkbox"/> Anastomotic leakage	
<input type="checkbox"/> Infection	<input type="checkbox"/> Others:	

HOSPITAL		SUBJECT	
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OUTCOMES

Day 3		
Does the patient have any pulmonary complication until the first day after surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrhythmia	<input type="checkbox"/> Delirium	
<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus	
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage	
ICU admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Per protocol	<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> Multiorgan failure	
<input type="checkbox"/> Renal Failure	<input type="checkbox"/> Hemodynamic failure	
<input type="checkbox"/> Others:	ICU length of stay (hours):	
Re-intervention <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Bleeding	<input type="checkbox"/> Anastomotic leakage	
<input type="checkbox"/> Infection	<input type="checkbox"/> Others:	

OUTCOMES

HOSPITAL		SUBJECT	
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Day 5		
Does the patient have any pulmonary complication until the first day after surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrhythmia	<input type="checkbox"/> Delirium	
<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus	
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage	
ICU admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Per protocol	<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> Multiorgan failure	
<input type="checkbox"/> Renal Failure	<input type="checkbox"/> Hemodynamic failure	
<input type="checkbox"/> Others:	ICU length of stay (hours):	
Re-intervention <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Bleeding	<input type="checkbox"/> Anastomotic leakage	
<input type="checkbox"/> Infection	<input type="checkbox"/> Others:	

OUTCOMES

Day 7	
Does the patient have any pulmonary complication until the first day after surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No	

HOSPITAL		SUBJECT	
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<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrythmia	<input type="checkbox"/> Delirium	
<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus	
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage	
ICU admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Per protocol	<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> Multiorgan failure	
<input type="checkbox"/> Renal failure	<input type="checkbox"/> Hemodynamic failure	
<input type="checkbox"/> Others:	ICU length of stay (hours):	
Re-intervention <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Bleeding	<input type="checkbox"/> Anastomotic leakage	
<input type="checkbox"/> Infection	<input type="checkbox"/> Others:	

HOSPITAL		SUBJECT	
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OUTCOMES

Day 30		
Does the patient have any pulmonary complication until the first day after surgery? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Mild acute respiratory failure	<input type="checkbox"/> Severe acute respiratory failure	<input type="checkbox"/> Weaning failure
<input type="checkbox"/> ARDS mild. <input type="checkbox"/> ARDS moderate. <input type="checkbox"/> ARDS severe	<input type="checkbox"/> Respiratory infection	<input type="checkbox"/> Pleural effusion
<input type="checkbox"/> Atelectasis	<input type="checkbox"/> Pneumothorax	<input type="checkbox"/> Bronchoespasm
<input type="checkbox"/> Aspiration pneumonitis	<input type="checkbox"/> Pulmonary edema	<input type="checkbox"/> Pulmonary embolism
Imaging technique:		
<input type="checkbox"/> Chest X-ray	<input type="checkbox"/> LUS	<input type="checkbox"/> CT
Does the patient have any systemic complication? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Surgical site infection	<input type="checkbox"/> Urinary infection	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> AKI I <input type="checkbox"/> AKI II <input type="checkbox"/> AKI III	
<input type="checkbox"/> Cardiac failure	<input type="checkbox"/> Myocardial ischemia	
<input type="checkbox"/> De novo Arrhythmia	<input type="checkbox"/> Delirium	
<input type="checkbox"/> Multiorgan failure	<input type="checkbox"/> Paralytic ileus	
<input type="checkbox"/> Postoperative hemorrhage	<input type="checkbox"/> Anastomotic leakage	
ICU admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Per protocol	<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Septic shock. <input type="checkbox"/> Sepsis	<input type="checkbox"/> Multiorgan failure	
<input type="checkbox"/> Renal failure	<input type="checkbox"/> Hemodynamic failure	
<input type="checkbox"/> Others:	ICU length of stay (hours):	
Re-intervention <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Bleeding	<input type="checkbox"/> Anastomotic leakage	
<input type="checkbox"/> Infection	<input type="checkbox"/> Others:	
Clinical Frailty Scale (from 1 to 9):		

HOSPITAL		SUBJECT	
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Was the patient excluded from the study?
<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, indicate the cause
<input type="checkbox"/> The patient revoked his consent
<input type="checkbox"/> The surgical intervention is not performed
<input type="checkbox"/> The patient meets some exclusion criteria

Survival	Alive	Death
Status at 7 days post-surgery	<input type="checkbox"/>	<input type="checkbox"/>
Status at 30 days post-surgery	<input type="checkbox"/>	<input type="checkbox"/>
Status at 365 days post-surgery	<input type="checkbox"/>	<input type="checkbox"/>

Signed (Local investigator):	
Name and family name:	Data:

NOTE:
**At the end of the study, a copy of the CRF will be collected on
paper completed and signed by the Investigator**

APPENDIX 12: iPROVE-EAL Case Report Form (CRF)