Acute Therapy Systems

Novalung Therapy

From CO_2 Removal to Full Oxygenation

novalung

FRESENIUS MEDICAL CARE

Status Quo and Challenges on the ICU

The critical care environment for mechanically ventilated patients in acute and acute on chronic lung failure is associated with high mortality caused by sedation and consequent immobility, ventilator associated lung injury (VALI), ventilator associated pneumonia (VAP) and ventilator induced diaphragm dysfunction (VIDD).

Sedation

❝ Various data have indicated a consistent and strong association between early deep sedation and poor long-term outcomes, including mortality, cognitive decline and psychological complications."[1)]
Suggested systematic approach

… and its series of reactions:

- Immobility
- Non-spontaneous breathing (mechanical ventilation)
- Lack of self-determination
- Reduced quality of life

VALI, VAP, VIDD

VAP has a drastic effect on cost-effectiveness through a longer length of stay in intensive care and a doubling of the overall hospital stay.[2)]
Review

ICU acquired muscle weakness

❝ […] is associated with prolonged duration of ventilator weaning and increased risk of ICU and hospital readmission."[3)]
Review

Our Solution

Novalung therapy allows to mitigate, prevent or replace mechanical ventilation by extracorporeal gas exchange. It enables caregivers to give the lung **time to heal** and change the therapy environment in the ICU – from CO_2 removal to full oxygenation.

Prevent intubation

“ […] preemptive application of extracorporeal carbon dioxide removal is a feasible therapeutic option to prevent intubation and invasive mechanical ventilation in selected patients with episodes of acute hypercapnic respiratory failure.”[4)]
Retrospective study

Allow mobilization

“ Physical therapy in critically ill patients is increasingly being recognized not only as safe, but also as a significant determinant of important clinical outcomes.”[5)]
Review

Enable spontaneous breathing

“ […] awake, spontaneous breathing leads to better results in acute disease in children and adults.”[6)]
Review

Reduce costs

“ […] potential cost reduction through a shorter length of hospital and ICU stay […] reduce overall resource utilization and treatment costs.”[7)]
Retrospective cost analysis

“ […] improve […] low tidal volume ventilation in patients with acute lung injury reduces death.”[8)]
Hypothetical interventional study

Xenios Products :
The Full Range of Extracorporeal Support

Xenios console

The Xenios platform enables therapies for heart and lung failure on one single platform.

“ iLA activve is a compact extracorporeal gas exchange system driven by a small centrifugal pump and thus resembles a miniaturized VV-ECMO system able to handle blood flow rates from 0.5 to 8 l/min, depending on cannula size and gas exchange membranes used.”[9)]
Observational study

Patient kits

The Novalung and iLA activve patient kits offer therapy options for a broad spectrum of patients and indications, certified for 29 days application period. The patient kits include a powerful membrane lung, the DP3 pump head (¼" and ³⁄₈" connectors) and safe integrated pressure sensors (only available in Novalung kits).

- Powerful **membrane lungs** in four different sizes and five different configurations adapted to the patients’ needs.
- **DP3 pump** technology with high hydraulic performance and reduced priming volume.

iLA membrane ventilator (AV)

The iLA membrane ventilator offers an alternative vascular access mode, utilizing the pressure gradient between femoral artery and vein. Like all Novalung therapy products it assists the native lung with gas exchange. Certified for 29 days application period.

NovaPort cannulas

NovaPort one single lumen and NovaPort twin double lumen cannulas are designed specially to meet the needs of extracorporeal lung and heart support circuits.

A case report suggests that the system might be capable of removing much of the body’s CO_2 production. This would allow ventilator settings and modes prioritizing oxygenation and lung protection.[10)*]

* Further research is required to obtain more reliable results

From CO_2 removal to full oxygenation

Therapy	Cannulation mode	Xenios solution				
		Xenios console	Patient kits	iLA membrane ventilator	NovaPort one	NovaPort twin
CO_2 removal	Arterio-venous (AV)			X	X	
	Veno-venous (VV)	X	X		X	X
CO_2 removal with partial oxygenation	Veno-venous (VV)	X	X		X	X
Oxygenation	Veno-venous (VV) Veno-arterial (VA)	X	X		X	

Xenios Product Features

Safety Features

- **Back-up pump drive**
- **0-Flow mode when reverse blood flow and air bubbles are detected**

  ▸ *"The flow control allows flow adjustments even at flow ranges below 0.5 l/min, and enables application in patients ranging from neonates to adults."*[11)]
  Retrospective data analysis

- **Blood flow regulation**

  ▸ *"It is the prevention of backflow and features for pressure, bubble and flow control offering fine adjustments down to zero, which make the DP3 safe."*[12)]
  Retrospective data analysis

- **P1 limiter**

  ▸ *"Several control systems offer safety functions: the preload control (p1 Limiter) prevents cannula aspiration; the zero-flow mode allows even a brief interruption of the flow without backflow."*[11)]
  Retrospective data analysis

- **Nurse call system**
- **Integrated pressure sensors (IPS)**

  ▸ *"Luer Connections have a potential to entrain air or leak blood."*[13)]
  Retrospective data analysis

- **Hot swappable batteries with an operating time of 120–420 minutes (without external power supply)**

Comfort Features

- **Fast and simple priming of Novalung kits with one person in less than two minutes**
- **Cannulas are flexible and kink resistant**
- **ΔP monitoring of the pre and post gas exchange resistance**
- **Connection to Philips central patient monitoring**
- **PDMS data interface**
- **USB port for data download**

Prospective Evaluation: Veno-venous extracorporeal CO_2 removal in 10 patients with hypercapnic lung failure[14)]

Therapeutic goal

- Minimize ventilation invasiveness
- Avoid intubation

Initial situation

Pressure controlled mechanical ventilation, established sedation without spontaneous breathing.

Novalung therapy (VV)

- NovaPort twin, 22 Fr double lumen cannula
- Jugular venous access
- iLA activve iLA kit
- Blood flow: 0.9–1.7 l/min
- Sweep gas flow: 2–12 l/min

Patient characteristics

Patients	SAPS II	Diagnosis	CO (l/min)	Blood flow (l/min)	Sweep gas flow (l/min)
1	38	AECOPD	4.2	0.9	2
2	48	BOS, Re-LuTX	5.4	0.9	12
3	59	COPD, LuTX	5.1	1.2	4
4	35	BOS, Re-LuTX	5.1	1.4	10
5	45	AECOPD	6.8	1.2	3
6	57	Status asthmaticus	5.1	1.5	3
7	70	ARDS	6.0	1.0	10
8	42	CF, LuTX	6.9	1.7	4
9	43	Pulmonary fibrosis, LuTX	4.7	1.4	3
10	43	AECOPD	6.9	1.2	2

Conclusion:

With the Novalung therapy it seems to be possible to significantly decrease $PaCO_2$ with:*

- **Reduction of ventilator driving pressure**
- **Reduction of tidal volume**

* Further research is required to obtain more reliable results

AECOPD = acute exacerbated chronic obstructive pulmonary disease; ARDS = acute respiratory distress syndrome; BOS = bronchiolitis obliterans syndrome; CF = cystic fibrosis; CO = cardiac output; COPD = Chronic obstructive pulmonary disease; LuTX = lung transplantation; Re-LuTX = lung re-transplantation; SAPS = simplified acute physiology score

Novalung Therapy for COPD

Case Report: Extracorporeal CO_2 Removal in a Patient with Chronic Obstructive Pulmonary Disease (COPD)[15)]

Therapeutic goal

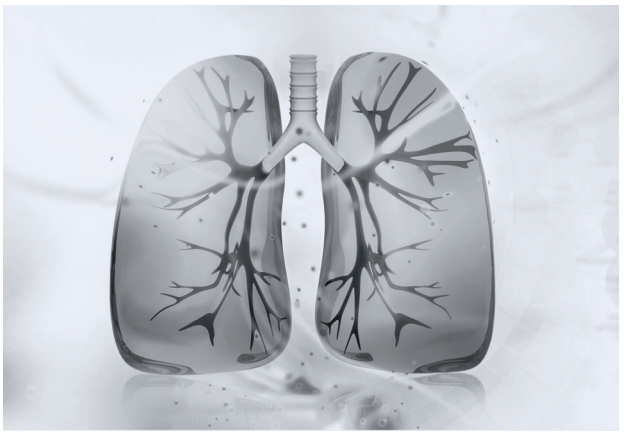
- Patients decree – no further invasive therapies for lung support than NIV
- No intubation and no tracheotomy

Patient

66-year-old male, hospital admission: advanced COPD, respiratory insufficiency.

Initial situation

During hospital stay increasing dyspnoea and work of breathing.



Novalung therapy (VV)

- 18 Fr NovaPort twin double lumen cannula
- Jugular venous access
- Start: iLA activve MiniLung kit; upgrade to iLA activve iLA kit
- Blood flow: 0.7 l/min
- Sweep gas flow: 5 l/min

Therapeutic effect:

	Pre-Novalung therapy	After 4 h Novalung therapy
Ventilation	NIV with FiO_2 = 0.35	**Spontaneous breathing**
P_{max}	13.2 cmH_2O	
PEEP	3 cmH_2O	
Tidal volume	570 ml	
Minute ventilation	7.8 l/min	
Blood gases		
PCO_2	102 mmHg	**82 mmHg**
pH	7.31	**7.37**
PO_2	165 mmHg	**77 mmHg**

Conclusion:

With the Novalung therapy it seems to be possible to:*

- **Avoid intubation**
- **Increase quality of life**
- **Maintain self-determination**

* Further research is required to obtain more reliable results

Novalung Therapy for ARDS Patients

Case Report: Extracorporeal CO_2 Removal in a Patient with Acute Respiratory Distress Syndrome (ARDS)[16)]

Therapeutic goal

- Effectively eliminate carbon dioxide
- Improve oxygenation
- Reduce the applied ventilatory pressures

Patient

19-year-old female, hospital admission: for treatment of a ketoacidosis triggered by new onset diabetes – day 2: progressive dyspnoea with bilateral pulmonary infiltrates.

Initial situation

Transfer to the ICU for endotracheal intubation and mechanical ventilation with high ventilatory pressures due to ARDS.

Novalung therapy (VV)

- 24 Fr NovaPort twin cannula
- Right femoral vein
- iLA activve MiniLung kit
- Blood flow: 1.5 l/min

Conclusion:

With the Novalung therapy it seems to be possible to:*

- **Decrease tidal volume**
- **Decrease carbon dioxide**
- **Improve oxygenation**
- **Improve hemodynamic**

* Further research is required to obtain more reliable results

Therapeutic effect:

	Pre-Novalung therapy	After 2 h Novalung therapy
Ventilation	IMV with FiO_2 = 0.55	**Lung-protective ventilation with FiO_2 = 0.3**
P_{max}	44 cmH_2O	**13 cmH_2O**
PEEP	25 cmH_2O	**5 cmH_2O**
Tidal volume	329 ml	**200 ml**
Minute ventilation	11.1 l/min	**3.2 l/min**
Respiratory rate	35/min	**16/min**
Blood gases		
PCO_2	73.5 mmHg	**34.5 mmHg**
pH	7.27	**7.48**
PO_2	65.25 mmHg	**87.75 mmHg**
SaO_2	89.1%	**95.9%**

Further Possible Indications

The following statements are based e.g. on case reports, observational studies and restrospective analysis.

Status asthmaticus

It was described in a case report that the mechanical ventilation could be reduced to a lung-protective minimum in a case where the VV $ECCO_2R$ therapy started only shortly after admission to the ICU.[17)*]

Bridging

“ Bridging to LTX with VV $ECCO_2$ R delivered by arteriovenous pumpless or venovenous pumpdriven iLA is feasible and associated with high transplantation and survival rates.”[18)]
Data analysis

Trauma

“ The technique of extracorporeal lung support is a promising and life-saving treatment option in severe post-traumatic ARDS.”[19)]
Review

Thoracic surgery

“ A case report states that the intraoperative application of extracorporeal lung support devices during thoracic surgical procedures represents a modern concept with promising results. In addition there is observed that this novel concept contributed to the safe performance of complex surgery in pulmonary compromised patients avoiding the possible complications of other forms of extracorporeal support.”[20)*]

* Further research is required to obtain more reliable results

By Your Side

Clinical Support

We accompany use of our technology and implementation of our therapies with far-reaching individual support and application-oriented service excellence. This includes a 24/7 support hotline.

Our console is always accompanied by comprehensive support from our Clinical Support Team. Each of our application specialists has many years of real-world experience from specialists working in clinics. These highly qualified experts provide on-site support – comprising instructions/training and help in implementing our therapy in the day-to-day business of your clinic.

Technical Service

Our Technical Service Team is available to answer any and all technical questions in and around the Xenios platform. In addition to this, the Academy offers you professional events for both basic and advanced training. The Xenios campus - our e-learning platform - offers diverse study modules and videos tailored to your specific areas of interest.

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End of 2016, Xenios with its brands Novalung and Medos has become part of the FME family, the worldwide market leader in renal support.

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EN_003_2019_02