

ELMO WARD PROTOCOL



Diagnosis of hypoxemic respiratory failure by COVID-19

- Inclusion criteria**
- Adults > 18 years of age, of both genders
 - Be alert, oriented, and cooperative
 - Use oxygen therapy by nasal cannula with flow > 4 liters per minute or by mask with reservoir > 8 liters per minute, maintaining SpO₂ higher than 92%
 - Arterial blood gas analysis with pH > 7.35 (no acidosis), PaO₂ > 60 mmHg and PaCO₂ < 46mmHg up to 30 minutes before starting therapy
 - Chest Computed tomography (CT) scan obtained within the last 24 hours showing bilateral parenchymal opacities

- Exclusion criteria**
- First use of Elmo after extubation
 - Exacerbation of asthma or COPD
 - Use of more than 0.5 microgram/kg/min of norepinephrine
 - Pneumothorax or pneumomediastinum increasing expansion
 - Persistent signs of respiratory muscles fatigue
 - Uncontrolled claustrophobia
 - Uncontained vomiting or nausea
 - Imminent risk of cardiorespiratory arrest

Patient preparation: Removal of dental prosthesis, accessories (earrings, necklace, glasses), use of hair cap, ear protectors, eye lubricant and lip balm.

PROTOCOL

- Start therapy with flow rate of 60L/min (O₂ and compressed air), sufficient FIO₂ to maintain oxygen saturation range 92-96%, and PEEP of 10cmH₂O checked with a cuff pressure manometer
- Collect arterial blood gas 30 minutes before the start and during the first therapy session (between 2-24 hours after the start)
- Maintain therapy continuously within the first 24h of admission to the ward and verify the therapy maintenance checklist at 1h, 6h, 12h, and 24h
- After the first 24h, apply the therapy intermittently with at least 3h of duration per session, keeping the maximum tolerable by the patient per session. It is recommended 2 daily sessions (morning and afternoon), sleeping with Elmo if possible in the first 3 days of therapy. Oxygen therapy by nasal catheter or reservoir mask was alternated with the sessions.

Start ELMO-CPAP

- STANDARD PRESCRIPTION**
- Fasting for the first 24 hours of therapy
 - Dexamethasone 20mg per day (D1/5) + Dexamethasone 10mg per day (D6/10)
 - Dexmedetomidine by continuous intravenous infusion (0.2-0.6 mcg/kg/min) to achieve a RASS level of 0 to -1
 - Clonazepam oral drops to achieve a RASS level of 0 to -1
 - Ivermectin or albendazole for prophylaxis of Strongyloides infection
 - Lactulose solution
 - Nasal lavage with 0.9% sodium chloride 3 times a day

MAINTENANCE OF THERAPY ASSESSMENT CHECKLIST

- Evaluate maintenance of therapy and clinical response at 1h, 6h, 12h, and 24h
- Tachypnea with abdominal press or persistent use of accessory muscles
 - Patient non-tolerance of the device
 - Oxygen saturation < 92% with FIO₂ of 100% for an additional 5 minutes
 - Hypercapnia with respiratory acidosis
 - Glasgow Coma Scale score < 12 without medication to justify the decreased sensory
 - Uncontrolled nausea or vomiting
 - Tracheal secretions not cleared
 - Norepinephrine > 0,5 microgram/kg/min
 - No clinical improvement measured by the responsible team

If any item is present

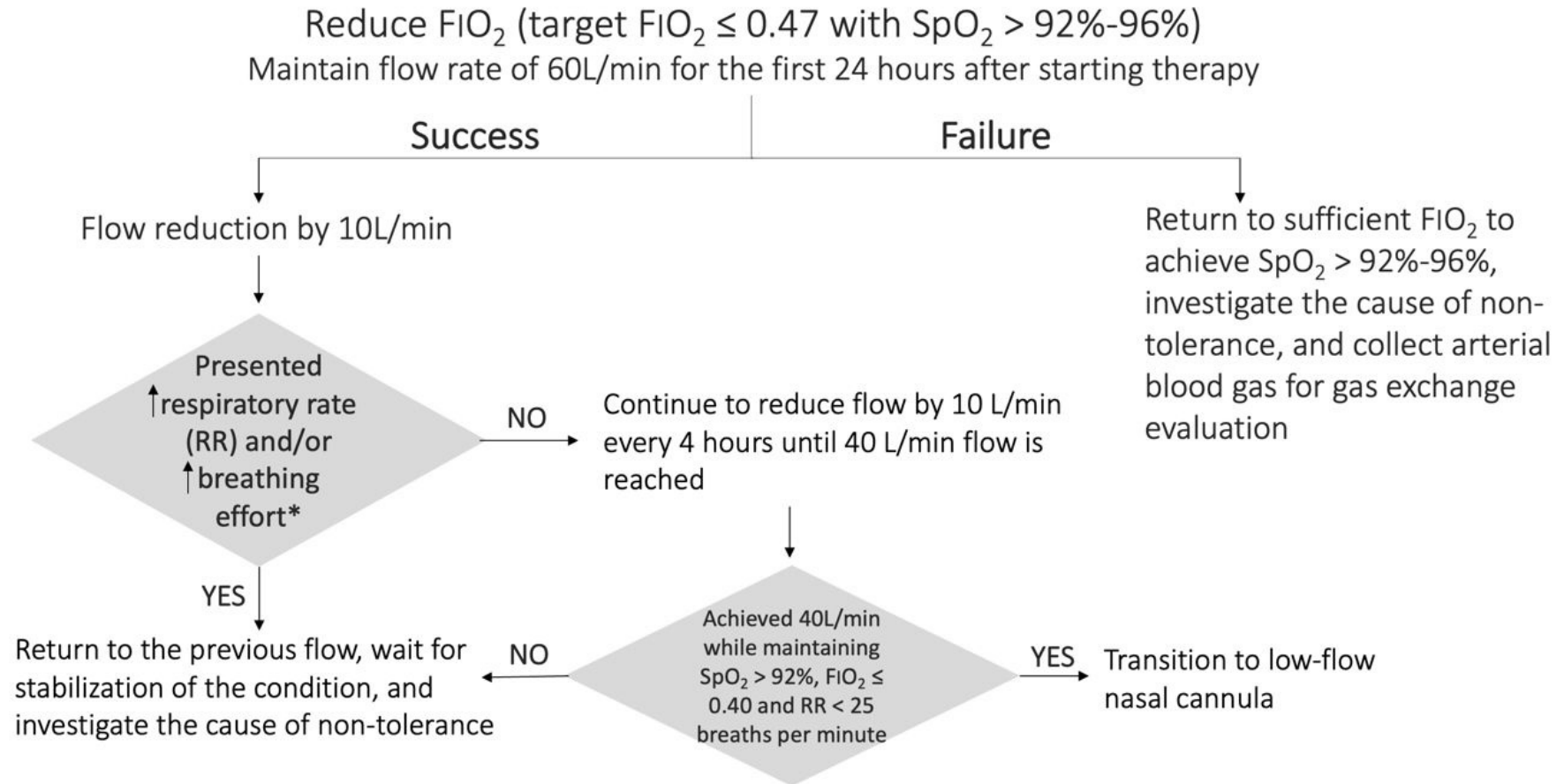
Orotracheal intubation

If none of these criteria were

Continue therapy

Supplementary Figure 1. Elmo ward protocol.

Flowchart of the weaning from ELMO-CPAP



Supplementary Figure 2. Flowchart of the weaning from ELMO-CPAP.

* RR > 25 breaths per minute, increased breathing effort (use of sternocleidomastoid muscle and other accessory muscles of respiration)

Supplementary Table 1. Patient's characteristics, applied treatments and hospital outcomes comparing the Hospital discharge vs Death

Variables	All patients n=180	Group		p-value
		Hospital discharge n=146 Death n=34		
Demographic data				
Age, y	55 (45-63)	54 (43.7-60)	66.5 (56-74)	0.001*
Male, No. (%)	116 (81)	94 (64.4)	22 (64.7)	0.38
SOFA score	2 (2-2)	2 (2-2)	2 (2-3.2)	0.02*
Comorbidities				
Hypertension, No. (%)	77 (42.8)	63 (43)	14 (41)	0.83
Diabetes mellitus, No. (%)	51 (28.3)	39 (26)	12 (35)	0.31
Obesity, No. (%)	46 (25.5)	41 (28)	5 (14)	0.10
Heart failure, No. (%)	22 (12.2)	16 (11)	6 (17)	0.28
Cerebrovascular accident, No. (%)	3 (1.7)	3 (2.1)	2 (5.9)	0.22
Atrial fibrillation, No. (%)	2 (1.1)	1 (0.7)	1 (2.8)	0.25
COPD No. (%)	5 (2.8)	2 (1.4)	1 (2.1)	0.15
Asthma, No. (%)	6 (3.3)	6 (4.1)	0 (0)	0.22
Anxiety, No. (%)	4 (2.2)	4 (2.7)	0 (0)	0.32
Other, No. (%)	17 (9.4)	12 (8.2)	5 (14.7)	0.24
None, No. (%)	53 (29.4)	46 (31)	7 (20)	0.20
Radiological and laboratory data				
Pulmonary involvement in Chest				
CT images No. (%)				

≤50%	39 (21.7)	35 (25)	4 (11)	
51%-75%	101 (56.1)	85 (58)	16 (47)	
>75%	40 (22.2)	26 (17) ^a	14 (41) ^b	0.01*
Hemoglobin (13-18g/dL)	13.5 (12.6-14.5)	13.5 (12.7-14.5)	13.3 (12.6-14.7)	0.20
Haematocrit (40-54%)	40.4 (37.7-43)	40.6 (37.2-43.5)	39.7 (37.5-42.5)	0.30
Leucocytes (4000-10000/mm ³)	9050 (7000-12350)	9200 (7200-12725)	7700 (5725-10775)	0.02*
Lymphocytes (1500-4500/mm ³)	864 (630-1170)	868 (632-1194)	828 (612.2-1062.7)	0.585
Plaquetas (140.000-500.000/mm ³)	215000 (170250-268500)	215000 (174000-275250)	210500 (155250-239500)	0.14
D-dimer (<0.500µg/mL)	810 (530-1160)	790 (515-1120)	1105 (692-1705)	0.004*
LDH (140-271UI/L)	381 (303-512)	373 (296-503.5)	412 (333.7-622.2)	0.038*
C-Reactive Protein (mg/dL)	9.6 (6.52-14.6)	9.2 (6.4-14.7)	12.6 (9.3-15)	0.002*
Urea (mg/dL)	32 (25-42)	32 (24.5-41)	39 (25.5-51)	0.143
Creatinine (mg/dL)	0.8 (0.66-0.96)	0.8 (0.6-0.9)	0.8 (0.6-1)	0.335
Arterial blood gas analysis				
pH mmHg	7.45 (7.43-7.47)	7.45 (7.43-7.47)	7.45 (7.42-7.48)	0.703
PaCO ₂ mmHg	35.8 (32.9-38.2)	36.7 (33-38.9)	33.8 (30.2-38)	0.041*
PaO ₂ mmHg	76 (67.5-89.0)	76.1 (68.5-89.4)	75.6 (63.5-88.2)	0.472
SaO ₂ %	95.2 (93.5-96.6)	96 (94-98)	95.5 (93-96.7)	0.220
Lactate (mmol/L)	1.68 (1.28-2.39)	1.7 (1.1-2.4)	1.6 (1.2-2.1)	0.904
PaO ₂ / FIO ₂	138 (116.5-163)	142 (119-163.7)	117.5 (100.7-136.7)	0.002*
Concomitant medications				

Dexamethasone, No. (%)	180 (100)	180 (100)	180 (100)	NA
Albendazole or Ivermectine, No. (%)	180 (100)	180 (100)	180 (100)	NA
DVT prophylaxis, No. (%)	132 (73.3)	115 (78.8)	17 (50)	0.01*
Anticoagulation, No. (%)	13 (7.2)	8 (61)	5 (38)	0.06
Antibiotics, No. (%)	173 (96.1)	139 (95.2)	34 (100)	0.22
Days of symptoms preceding ELMO-CPAP use	10 (8-12)	10 (8-12)	9.5 (7.5-11.5)	0.94
Duration of 1 st ELMO CPAP session _h	39 (24-48)	42 (26-48)	28 (18.7-45)	0.048*
Total duration of CPAP ELMO _{days}	4 (2-5)	4 (2-5)	4 (3-7)	0.392
Outcomes				
Length of hospital stay _{days}	13 (9-23)	12 (8.7-21)	20 (15.7-26.2)	0.001*
Intubation	49 (27.2)	19 (38.8)	30 (61.2)	0.001*
Complications				
Pneumothorax, No (%)	2 (1.1)	0 (0)	2 (5.9)	0.003*
Pneumomediastinum, No (%)	9 (5)	5 (3.4)	4 (11.8)	0.044*

Frequencies are expressed as numbers (No.) and percentages (%)

Continuous variables are expressed as median, first and third quartile (q1–q3)

In case of missing data, statistics were performed on available data

Differences in frequencies were tested with the chi-square test

Differences in continuous variables were tested with the Mann-Whitney test

^a Chi-square test and post hoc analysis for pairwise comparisons for success group

^b Chi-square test and post hoc analysis for pairwise comparisons for failure group

* $P < 0.05$, significant

SOFA= sequential organ failure assessment

CT= computed tomography

NA= not applicable

DVT= deep venous thrombosis