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Impact of a Non-Invasive Respiratory Support Strategy and Switches in Therapy During Acute Respiratory Failure Due to SARS-COV-2

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Abstract

Introduction: Non-invasive respiratory support (NIRS), high flow nasal cannula (HFNC) and non-invasive ventilation (NIV), have been used prior to mechanical ventilation (MV). We aimed to describe the use of initial NIRS and their subsequent changes and assess its impact on clinical outcomes among critically ill patients with acute respiratory failure (ARF) secondary to SARS-CoV-2 admitted to ICU.

Methods: Prospective, multicenter, observational cohort study comprising a secondary analysis of patients included in the SEMICYUC COVID-19 registry. All patients with ARF due to SARS-CoV-2 admitted to ICU and receiving respiratory support were enrolled. NIRS failure, ICU and hospital mortality, and length of stay (LOS) were evaluated.

Results: Among 3889 included patients, 43% initially underwent NIRS (75% HFNC and 25% NIV). NIV as first choice was associated with higher failure (74.4% vs 61.2%, p<0.001) and higher ICU and hospital mortality rates than HFNC (27% vs 20%, p=0.003 and 29% vs 21%, p=0.002). NIV to HFNC switch showed the lowest failure (43%), lowest ICU and hospital mortality rates (18% and 19%) and the shortest LOS (9 days [6-15] vs 21 days [14-32]). HFNC to NIV switch did not significantly worsen outcomes compared to HFNC failure, but patients who failed after the switch showed the highest mortality (42% both ICU and hospital) and the longest LOS (24 [13-34] and 30 [23-48]).

Conclusion: NIRS is common in the ICU and switching NIRS strategies is a frequent practice within different scenarios. Physicians should bear in mind the possibility of outcomes worsening when failure occurs after switching.

Keywords: Non-invasive positive pressure ventilation; Nasal cannula; Acute respiratory failure; Covid-19; SARS-COV-2

Abbreviations: NIRS: Non-Invasive Respiratory Support; HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation; MV: Mechanical Ventilation; ARF: Acute Respiratory Failure; LOS: Length of Stay; COPD: Chronic Obstructive Pulmonary Disease; SD: Standard Deviations; OR: Odds Ratios; CI: Confidence Intervals

Introduction

During the SARS-CoV-2 pandemic, severe acute respiratory failure (ARF) generated an unprecedented demand for intensive care resources in order to deliver respiratory support, and in many cases during the first wave of the pandemic led to ICU saturation. Although invasive mechanical ventilation (MV) remains the main support treatment in severe hypoxemic ARF with increased work of breathing, non-invasive respiratory support (NIRS) is commonly used as first strategy and can be applied by high flow nasal cannula (HFNC) and non-invasive ventilation (NIV). Several studies have suggested that HFNC is effective in patients with ARF, showing an improvement in ventilatory parameters and reducing the need for intubation, with a potential enhancement in patient survival compared to conventional oxygen therapy and NIV [1-6]. NIV has been extensively shown to improve hypercapnic ARF in patients with chronic obstructive pulmonary disease (COPD) and acute pulmonary oedema and has also shown benefits in hypoxemic ARF in so far as intubation can be avoided, but without clear benefits in mortality rates [7-15].

Despite its benefits, NIRS use carries the risk of patient self-inflicted lung injury and delayed intubation that detrimentally affects clinical outcomes [16-21]. In this regard, NIRS failure in patients with hypoxemic ARF is associated with increased mortality, especially when NIV is used to treat patients with pneumonia [12,19,20,22]. However, there are no formal recommendations in international guidelines regarding the procedure to follow when NIRS is started, and most importantly regarding when the treatment should be escalated [7]. This may lead to considerable differences between clinicians in terms of deciding which NIRS strategy to select as a first choice, when to consider it to have failed, and the timing of intubation and NIRS weaning, which may all impact clinical outcomes [23].

Moreover, in the SARS-CoV-2 scenario, pandemic overload meant that decisions had to be made based on resource availability, including switches of NIRS strategy in order to reserve MV for refractory cases. Studies have provided conflicting results about the efficacy of different NIRS in COVID-19 patients, and the currently available data are unable to identify the best NIRS first choice approach in these patients [24-29]. Moreover, little is known about the influence on outcomes of the use of more than one type of NIRS. In the present study, we sought to describe the use of initial NIRS (HFNC or NIV) and their subsequent changes and assess its impact on clinical outcomes in critically ill patients admitted to the ICU with hypoxemic ARF due to SARS-CoV-2 pneumonia.

Methods

Study design

Prospective, multicenter, cohort and observational study based on a secondary analysis of patients included in the SEMICYUC COVID-19 registry (the Spanish Society of Critical Care Medicine and Coronary Units). Between 1 February 2020 and 1 June 2021, data for all patients admitted to 73 Spanish ICUs due to ARF with COVID-19 pneumonia were recorded. COVID-19 was diagnosed by the presence of a SARS-CoV-2 positive rt-PCR test. The identities of patients were anonymized, and the review board waived the need for informed consent due to the non-interventional nature of the study. The registry was designed and conducted in accordance with the amended Declaration of Helsinki and the study was approved by the Institutional Review Boards of the participating centers.

Participants and study groups

All patients admitted to the ICU due to ARF with confirmed SARS-CoV-2 infection who received respiratory support at ICU admission were eligible for enrollment. Patients in whom the sequence of respiratory support at ICU admission could not be determined and those aged <18 years were excluded from the analysis. Patients who were initially treated with NIRS were classified according to the first NIRS choice used, HFNC or NIV. In each group, patients were subsequently classified as: 1) NIRS success; 2) NIRS failure, when MV was required or when the patient died having a do not intubation order (DNI); or 3) change of NIS, either HFNC-to-NIV or NIV-to-HFNC. The NIRS patients switched to a different NIRS method and were stratified according to success or failure. Patients who were directly intubated and mechanically ventilated were analyzed independently.

The primary outcome of the study was NIRS failure, described as the need for invasive MV or when patients were DNI. Secondary outcomes were all-cause mortality and ICU and hospital length of stay (LOS). These outcomes were evaluated in all the population and separately in each of the previously described patient subgroups. Comparisons of mortality and LOS between NIRS and MV groups excluded patients who were DNI and are shown in the Online Supplement.

Data collection

Demographics (age and gender), presence of comorbidities and usual treatment were registered, as well as severity of illness (APACHE and SOFA scores), biomarkers, respiratory status (PaO_2/FIO_2 ratio and presence of ≥ 3 quadrants infiltrated on chest radiography) and presence of shock at ICU admission, which was defined as the need for vasopressors [30], and COVID-related treatment received. Data collection also included ventilatory data and outcomes such as respiratory support and type of NIRS used as first choice, subsequent NIRS changes, NIRS failure, ICU and hospital mortality and ICU and hospital LOS.

Statistical analysis

Categorical variables were expressed as frequencies and percentages, and continuous variables as means and standard deviations (SD) when data were normally distributed, or otherwise as median and interquartile range (25th-75th percentile). Differences between groups were analyzed using the chi square test or Fisher's exact test for categorical variables, and ANOVA, Student's t-test or the Mann-Whitney U-test for continuous data. Statistical significance was set at a p-value ≤ 0.05. Logistic regression was used to assess independent factors associated with NIRS failure and mortality. Variables that were clinically relevant and presented significant differences in the bivariate analysis were included in the logistic regression. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. The data were analyzed using the Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) 18 version.

Results

Distribution of the population

From a total of 3889 patients admitted to the ICU for ARF and confirmed SARS-CoV-2 infection needing respiratory support, NIRS was used as the first respiratory support strategy in 1692 (43.5%) and MV in 2197 (56.5%) (Figure 1). Among NIRS patients, HFNC was used in 1275 (75.3%) patients and NIV in 417 (24.7%). Switch of NIRS was present in 11% of total NIRS and HFNC-to-NIV shifts were less frequent than NIV-to-HFNC shifts (7.4% vs 20.1%, p<0.001) (Figure 1). Thirty-six patients (2.1% of all NIRS patients) were DNI and were distributed equally in the two groups (HFNC 2.0% and NIV 2.4%). Main characteristics of patients included in the different groups are described in the

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Online Supplement (OS Table 1).

NIRS failure

Among all patients who received NIRS at ICU admission (n=1692), 63.2% failed (n=1069). The characteristics of NIRS success and NIRS failure groups are described in detail in the OS Table 2. Patients with successful NIRS were more likely to have received HFNC as the first NIRS choice, and they also presented higher rates of NIRS switch. However, the most frequently used switch was NIV-to-HFNC. Figure 2 shows a detailed flow chart of NIRS failure, indicating the initial NIRS therapy used and the subsequent changes. NIRS failure rates were higher in the NIV group compared with HFNC group (68.1% vs 61.6%, p=0.016). Taking into account only the first choice of NIRS therapy, NIV group had higher failure rate than HFNC group (74.4% vs 61.2%, p<0.001) (Figure 3A and 3B). Among patients in whom NIRS was changed, the HFNC-to-NIV switch presented higher failure rates than NIV-to-HFNC (66% vs 42.9%, p<0.001) (Figure 3C). Table 1 shows the characteristics of patients regarding NIRS failure, success, or switch in both initial NIRS groups, which are described in the Online Supplement.

Table 1: Comparison between characteristics of patients undergoing NIRS in whom it was succeed, failure or was changed, in the different NIRS analyzed groups.

	HFNC (n = 1275)			NIV (n = 417)		
	Success (n= 458)	Failure (n =723)	HFNC to NIV (n=94)	Success (n= 85)	Failure (n= 248)	NIV to HFNC (n=84)
Demographics						
- Age, years[a,b]	56 (48-66)	65 (55-71) ***	61 (54-70) ***	56 (47-66)	64 (57-70) ***	63 (54-70) **
- Gender (female)	146 (31.9)	204 (28.2)	31 (33.0)	24 (28.2)	70 (28.2)	21 (25.0)
Comorbidities[a,b]	296 (64.6)	534 (73.9) ***	71 (75.5) *	48 (56.5)	192 (77.4) ***	62 (73.8) *
- High blood pressure[a,b]	180 (39.3)	358 (49.5) ***	53 (56.4) **	24 (28.2)	126 (50.8) ***	40 (47.6) **
- Obesity	163 (35.6)	276 (38.2)	35 (37.2)	31 (36.5)	99 (39.9)	31 (36.9)
- Diabetes[a]	81 (17.7)	189 (26.1) ***	18 (19.1)	15 (17.6)	61 (24.6)	16 (19.0)
- Asthma	32 (7.0)	48 (6.6)	3 (3.2)	7 (8.2)	16 (6.5)	7 (8.3)
- Immunosuppressive Therapy	28 (6.1)	43 (5.9)	8 (8.5)	3 (3.5)	18 (7.3)	5 (6.0)
- Ischemic cardiomyopathy[a]	19 (4.1)	44 (6.1)	12 (12.8) ***†	3 (3.5)	15 (6.0)	4 (4.8)
- Chronic kidney disease	21 (4.6)	50 (6.9)	2 (2.1)	4 (4.7)	16 (6.5)	4 (4.8)
- Chronic obstructive pulmonary disease[a]	14 (3.1)	50 (6.9) **	3 (3.2)	6 (7.1)	20 (8.1)	5 (6.0)
- Cardiac Insufficiency	11 (2.4)	31 (4.3)	2 (2.1)	2 (2.4)	10 (4.0)	2 (2.4)
- Autoimmune Disease	9 (2.0)	25 (3.5)	4 (4.3)	3 (3.5)	11 (4.4)	0 (0.0)
- Hematologic Disease	7 (1.5)	25 (3.5)	5 (5.3)	1 (1.2)	12 (4.8)	3 (3.6)
- Neuromuscular Disease	4 (0.9)	7 (1.0)	1 (1.1)	1 (1.2)	2 (0.8)	1 (1.2)
- Pregnancy	4 (0.9)	4 (0.6)	1 (1.1)	0 (0)	0 (0)	0 (0)
- HIV	2 (0.4)	3 (0.4)	1 (1.1)	0 (0)	0 (0)	0 (0)
Usual treatment						
- ACE-Inhibitor[a]	45 (9.8)	132 (18.3) ***	20 (21.3) **	10 (11.8)	35 (14.1)	8 (9.5)
- ARBs	74 (16.2)	129 (17.8)	16 (17.0)	12 (14.1)	55 (22.2)	21 (25.0)
Severity						
- APACHE Score[a,b]	9 (7-12)	13 (10-17) ***	12 (9-15) ***††	8 (6-13)	14 (11-18) ***	11 (8-16) ***††
- SOFA Score[a,b]	3 (2-3)	4 (3-6) ***	3 (2-4) ***†††	4 (3-4)	4 (4-6) ***	4 (3-4) †††
- Days from symptoms to ICU admission	10 (7-12)	9 (6-11)	9 (7-12)	11 (7-13)	8 (6-12)	9 (6-12)
- Days from hospital to ICU admission	2 (1-3)	1 (0-3)	2 (0-3)	2 (1-3)	2 (0-3)	2.00 (1-4)

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Biomarkers at admission						
- Leukocytes (10^3u/µl)[b]	8.200 (5.800-11.000)	8.400 (6.100-11.700)	8.600 (5.700-12.200)	9.300 (6.795-13.100)	9.300 (6.710-12.750)	7.990 (5.500-11.000) †
- Lymphocytes (10^3u/µl)	0.82 (0.60-1.10)	0.70 (0.48-0.94)	0.81 (0.50-0.97)	0.61 (0.40-0.90)	0.70 (0.50-1.13)	0.70 (0.50-1.01)
- Creatinine (mg/dl)[a]	0.8 (0.6-0.9)	0.8 (0.7-1.1) ***	0.8 (0.7-0.9)	0.7 (0.6-0.9)	0.8 (0.7-1.1)	0.8 (0.6-0.9)
- Urea (mg/dl)[a,b]	38 (28-49)	42 (30-59) ***	42 (32-57) *	38 (31-48)	48 (36-64) ***	42 (30-56) ††
- Ferritin (ng/ml)	1025 (520-1709)	1112 (605-1709)	1061 (648-1950)	782 (335-1064)	1243 (501-1918)	1161 (552-1554)
- C-reactive protein (mg/dl)[b]	10.6 (5.7-16.4)	14.4 (7.8-22.0) ***	14.1 (4.8-23.4) *	11.6 (4.0-19.2)	14.4 (8.0-22.3) *	10.5 (4.5-21.6) †
- Procalcitonin (ng/ml)	0.12 (0.07-0.23)	0.20 (0.10-0.50)	0.14 (0.06-0.40)	0.12 (0.06-0.30)	0.20 (0.10-0.70)	0.10 (0.07-0.27)
- Troponin I (ng/l)	6 (2-14)	8 (3-18)	11 (4-18)	8 (4-19)	14 (7-34)	9 (3-17)
- D-Dimer (µg/l)	705 (412-1152)	807 (486-1448)	735 (492-1488)	721 (496-1225)	1200 (652-2372)	807 (530-1675)
- Lactate dehydrogenase (u/l)[a,b]	379 (307-477)	473 (359-599) ***	439 (328-598) **	392 (318-575)	520 (412-689) ***	463 (374-573) ††
- Creatine phosphokinase (u/l)[a]	64 (40-122)	100 (56-201) ***	66 (37-139) †	72 (34-108)	102 (52-195)	75 (45-231)
- Lactate (mmol/l)	1.2 (0.9-1.7)	1.4 (1.0-1.9)	1.3 (1.1-1.7)	1.2 (1.0-2.0)	1.4 (1.1-2.0)	1.3 (1.1-1.7)
Respiratory status at admission						
- PaO_2/F_iO_2 ratio[a,b]	134 (100-178)	97 (73-132) ***	107 (81-141) ***	146 (106-182)	109 (79-149) ***	122 (90-157) *
- > 3 quadrants infiltrates on chest radiography[a]	287 (62.7)	537 (74.3) ***	52 (55.3) †††	45 (52.9)	161 (64.9)	49 (58.3)
Hemodynamics at admission						
- Shock[a,b]	10 (2.2)	137 (18.9) ***	6 (6.4) *††	7 (8.2)	66 (26.6) ***	5 (6.0) †††
Covid-related treatment						
- Pneumonia-related corticosteroids[a]	347 (75.9)	531 (73.4)	83 (88.3) **††	66 (80.5)	189 (77.8)	74 (89.2)
- Tocilizumab[a,b]	67 (14.6)	112 (15.5)	14 (14.9)	11 (12.9)	64 (25.8) *	31 (36.9) ***
- Hydroxychloroquine	171 (37.3)	311 (43.0)	32 (34.0)	39 (45.9)	133 (53.6)	43 (51.2)
- Lopinavir/ritonavir	128 (27.9)	281 (38.9) ***	28 (29.8)	29 (34.1)	104 (41.9)	30 (35.7)

Data expressed as frequencies and percentages [n (%)] or medians and interquartile ranges (IQR or 25th-75th percentile).
[a]: ANOVA test with p≤0.05 for HFNC group. b ANOVA test with p≤0.05 for NIV group. * p≤0.05 vs Success; ** p≤0.01 vs Success; *** p≤0.001 vs Success; † p≤0.05 vs Failure; †† p≤0.01 vs Failure; ††† p≤0.001 vs Failure.
HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation; HIV: Human Immunodeficiency Virus; ACE: Angiotensin Converting Enzyme; ARBs: Angiotensin II Receptor Antagonists; APACHE: Acute Physiology and Chronic Health Evaluation; SOFA: Sequential Organ Failure Assessment.

NIRS mortality

Overall mortality in patients who received NIRS at ICU admission was 21.9% (n=371). Patients who received NIV as the first NIRS therapy were more likely not to survive (30.5% vs 23%, p<0.01) (Table 2). Characteristics of survivors and non-survivors in the different subgroups are shown in Table 2 and described in the Online Supplement. ICU and hospital mortality rates of each group and subgroups with their comparisons and significances are shown in Figure 4. The NIV group presented higher ICU and hospital mortality rates than the HFNC group (27% vs 20%, p=0.003 and 29% vs 21%, p=0.002). As shown in Figure 4A, ICU and hospital mortality rates in HFNC group were 20% and 21% respectively. When HFNC failed, these figures rose to 32% and 33% respectively. When HFNC was switched to NIV, ICU and hospital mortality rates rose to 28% and 29%, but when this switch failed both these rates rose to 42%. Mortality rates tended to be higher in the HFNC-to-NIV failure group than in the HFNC failure group (ICU mortality 42% vs 32%, p=0.11, all-hospital mortality 42% vs 33%, p=0.08).

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Table 2: Patient's characteristics regarding survivors and non-survivors, in total included population and independently by study groups (HFNC or NIV).

	Total NIRS n=1692		HFNC n=1275		NIV n=417	
	Total survivors (n = 1321)	Total non-survivors (n = 371)	Survivors (n = 1017)	Non-survivors (n = 258)	Survivors (n = 304)	Non-survivors (n = 113)
Demographics						
- Age, years	59 (50-67)	69 (62-75) ***	59 (50-67)	70 (63-76) ***	61 (52-68)	67 (60-74) ***
- Gender (female)	400 (30.3)	96 (25.9)	317 (31.2)	64 (24.8) *	83 (27.3)	32 (28.3)
Comorbidities	893 (67.6)	310 (83.6) ***	685 (67.4)	216 (83.7) ***	208 (68.4)	94 (83.2) **
- High blood pressure	550 (41.6)	231 (62.3) ***	426 (41.9)	165 (64.0) ***	124 (40.8)	66 (58.4) ***
- Obesity	479 (36.3)	156 (42.0) *	365 (35.9)	109 (42.2)	114 (37.5)	47 (41.6)
- Diabetes	261 (19.8)	119 (32.1) ***	203 (20.0)	85 (32.9) ***	58 (19.1)	34 (30.1) *
- Asthma	92 (7.0)	21 (5.7)	70 (6.9)	13 (5.0)	22 (7.2)	8 (7.1)
- Immunosuppressive Therapy	68 (5.1)	37 (10.0) ***	51 (5.0)	28 (10.9) ***	17 (5.6)	9 (8.0)
- Ischemic cardiomyopathy	56 (4.2)	41 (11.1) ***	44 (4.3)	31 (12.0) ***	12 (3.9)	10 (8.8) *
- Chronic kidney disease	51 (3.9)	46 (12.4) ***	40 (3.9)	33 (12.8) ***	11 (3.6)	13 (11.5) **
- Chronic obstructive pulmonary disease	52 (3.9)	46 (12.4) ***	33 (3.2)	34 (13.2) ***	19 (6.2)	12 (10.6)
- Cardiac Insufficiency	30 (2.3)	28 (7.5) ***	25 (2.5)	19 (7.4) ***	5 (1.6)	9 (8.0) ***
- Autoimmune Disease	41 (3.1)	11 (3.0)	31 (3.0)	7 (2.7)	10 (3.3)	4 (3.5)
- Hematologic Disease	32 (2.4)	21 (5.7) **	22 (2.2)	15 (5.8) **	10 (3.3)	6 (5.3)
- Neuromuscular Disease	13 (1.0)	3 (0.8)	10 (1.0)	2 (0.8)	3 (1.0)	1 (0.9)
- Pregnancy	9 (0.7)	0 (0.0)	9 (0.9)	0 (0.0)	0 (0)	0 (0)
- HIV	5 (0.4)	1 (0.3)	5 (0.5)	1 (0.4)	0 (0)	0 (0)
Usual treatment						
- ACE-Inhibitor	163 (12.3)	87 (23.5) ***	128 (12.6)	69 (26.7) ***	35 (11.5)	18 (15.9)
- ARBs	220 (16.7)	87 (23.5) **	158 (15.5)	61 (23.6) **	62 (20.4)	26 (23.0)
Severity						
- APACHE Score	11 (8-15)	15 (12-18) ***	11 (8-14)	15 (12-18) ***	11 (8-16)	15 (12-18) ***
- SOFA Score	3 (2-4)	4 (3-7) ***	3 (2-4)	4 (3-7) ***	4 (3-5)	4 (4-7) **
- Days from symptoms to ICU admission	9 (7-12)	8 (6-11) **	9 (7-11)	8 (6-11) *	7 (9-13)	8 (5-12)
- Days from hospital to ICU admission	2 (0-3)	2 (0-4)	2 (0-3)	2 (0-4)	2 (0-3)	2 (0-4)

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Biomarkers at admission						
- Leukocytes (10^3u/µl)	8.395 (6.000-11.600)	9.000 (6.375-12.625) *	8.300 (5.900-11.300)	8.700 (6.160-12.500)	8.900 (6.400-12.600)	10.000 (6.740-12.700)
- Lymphocytes (10^3u/µl)	0.77 (0.54-1.04)	0.61 (0.41-0.85) ***	0.78 (0.55-1.02)	0.68 (0.45-0.87) *	0.70 (0.50-1.10)	0.52 (0.40-0.73) **
- Creatinine (mg/dl)	0.8 (0.6-1.0)	0.9 (0.7-1.2) ***	0.8 (0.7-1.0)	0.9 (0.8-1.3) ***	0.8 (0.6-1.0)	0.8 (0.7-1.1) *
- Urea (mg/dl)	39 (29-52)	52 (38-74) ***	38 (28-51)	53 (38-76) ***	43 (31-57)	52 (37-69) ***
- Ferritin (ng/ml)	1020 (522-1632)	1332 (611-1879) *	1034 (548-1696)	1323 (713-1801)	966 (388-1518)	1355 (489-1954)
- C-reactive protein (mg/dl)	12.2 (6.7-20.0)	14.4 (7.5-22.3) **	12.2 (7.0-20.0)	13.4 (6.8-21.9)	11.9 (6.0-20.4)	16.2 (8.4-25.8) **
- Procalcitonin (ng/ml)	0.15 (0.08-0.32)	0.21 (0.10-0.64) ***	0.14 (0.08-0.31)	0.22 (0.10-0.63) ***	0.18 (0.09-0.34)	0.21 (0.10-0.76) *
- Troponin I (ng/ml)	8 (3-14)	13 (7-30) ***	7 (2-14)	13 (6-25) ***	10 (4-20)	17 (8-34) *
- D-Dimer (µg/l)	745 (469-1272)	1100 (638-2353) ***	721 (440-1183)	1008 (626-2114) ***	896 (502-1657)	1513 (750-4549) ***
- Lactate dehydrogenase (u/l)	425 (332-550)	511 (398-679) ***	417 (328-541)	484 (376-639) ***	451 (347-591)	571 (471-744) ***
- Creatine phosphokinase (u/l)	85 (46-160)	87 (50-195)	84 (46-153)	86 (51-196)	88 (47-186)	89 (43-195)
- Lactate (mmol/l)	1.3 (1.0-1.8)	1.5 (1.1-2.0) ***	1.3 (0.9-1.8)	1.5 (1.1-2.1) ***	1.3 (1.0-1.9)	1.6 (1.2-2.0) *
Respiratory situation at admission						
- PaO_2/F_iO_2 ratio	118 (89-162)	89 (66-123) ***	115 (85-158)	86 (64-121) ***	128 (97-181)	90 (74-128) ***
- ≥ 3 quadrants infiltrates on chest radiography	873 (66.1)	258 (69.5)	691 (67.9)	185 (71.7)	182 (59.9)	73 (64.6)
Hemodynamics at admission						
- Shock	150 (11.4)	81 (21.8) ***	105 (10.3%)	48 (18.6%) ***	45 (14.8)	33 (29.2) ***
Non-invasive support strategy used						
- First choice						
- HFNC	1017 (77.0)	258 (69.5) **	1017 (100)	258 (100)	--	--
- NIV	304 (23.0)	113 (30.5) **	--	--	304 (100)	113 (100)
- Change of initial strategy	137 (10.4)	41 (11.1)	68 (6.7)	26 (10.1)	69 (22.7)	15 (13.3) *
Covid-related treatment						
- Pneumonia-related corticosteroids	1005 (76.4)	285 (77.9)	761 (74.9)	200 (77.5)	244 (81.3)	85 (78.7)
- Tocilizumab	241 (18.2)	58 (15.6)	154 (15.1)	39 (15.1)	87 (28.6)	19 (16.8) *
- Hydroxychloroquine	591 (44.7)	138 (37.2) **	422 (41.5)	92 (35.7)	169 (55.6)	46 (40.7) **
- Lopinavir/ritonavir	461 (34.9)	139 (37.5)	341 (33.5)	96 (37.2)	120 (39.5)	43 (38.1)

Data expressed as frequencies and percentages [n (%)] or medians and interquartile ranges (IQR or 25th-75th percentile). * p≤0.05; ** p≤0.01; *** p≤0.001.
NIS: Non-Invasive Respiratory Support; HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation; HIV: Human Immunodeficiency Virus; ACE: Angiotensin Converting Enzyme; ARBs: Angiotensin II Receptor Antagonists; APACHE: Acute Physiology and Chronic Health Evaluation; SOFA: Sequential Organ Failure Assessment.

ICU and hospital mortality rates in the NIV group were 27% and 29% respectively. When NIV failed, these rates rose to 39% and 41% respectively. In contrast, when NIV was switched to HFNC, ICU and hospital mortality rates fell to 18% and 19% respectively, but when this switch failed these rates rose to 42% in both cases. No differences were found in mortality rates between NIV failure and NIV-to-HFNC failure groups (39% vs 42%, p=0.81 and 41% vs 42%, p=0.99). In patients who underwent NIRS switch, ICU and hospital mortality rates were higher in HFNC-to-NIV than in NIV-to-HFNC [28% vs 18%, p=0.12 and 29% vs 19%, p=0.06]. Other significant differences between groups are shown in Figure 4B.

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NIRS length of stay

Overall NIRS LOS was 12 days (6 - 24) for ICU and 22 days (14 - 37) for hospital. There were no differences in ICU and hospital LOS among the patients that received any form of NIS. However, NIRS failure groups (i.e., failure of HFNC, HFNC-to-NIV, NIV, or NIV-to-HFNC) were associated with longer ICU and hospital LOS. In contrast, the NIV-to-HFNC switch group had the shortest ICU and hospital LOS (Figures 5A and 5B). Additionally, non-survivors had longer ICU and hospital LOS than survivors in the different NIRS groups (OS Figure 2).

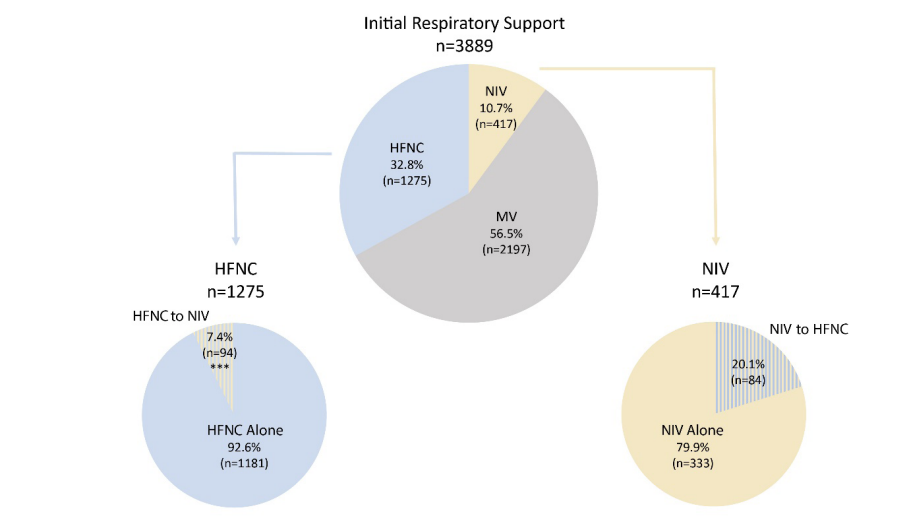

Figure 1: Main distribution of NIRS starts in the patients included and proportion of switches to other NIRS.
NIRS: Non-Invasive Respiratory Support; HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation, *** p<0.001 chi-squared test comparing HFNC-to-NIV vs NIV-to-HFCN.

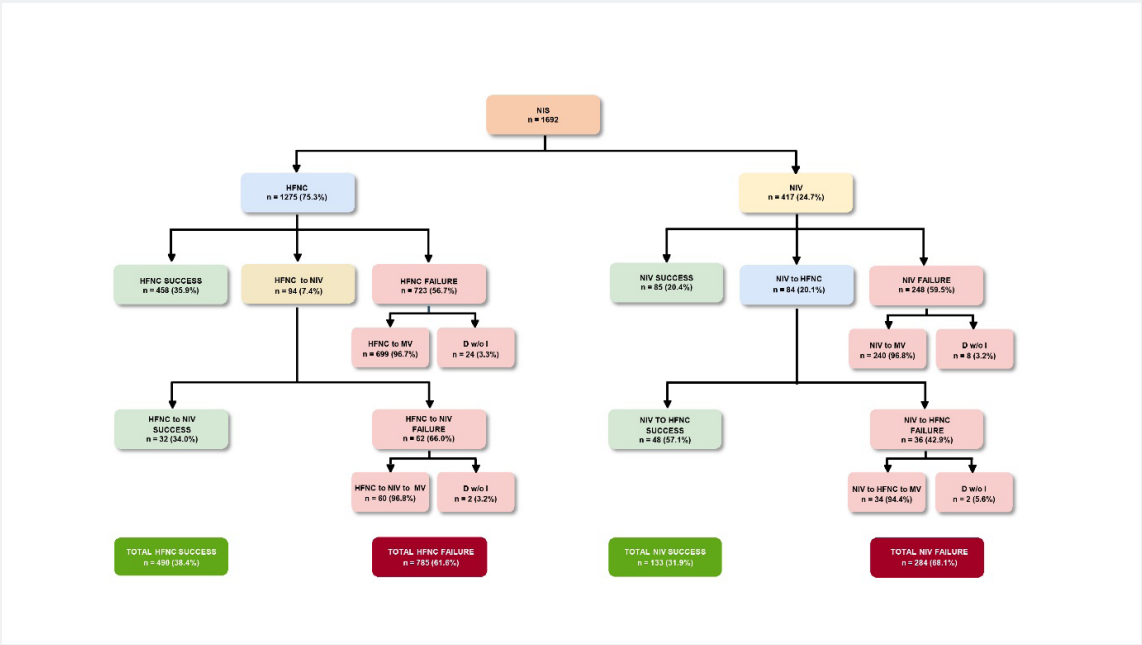

Figure 2: Flow chart including all the population related to study groups.
MV: Invasive Mechanical Ventilation; NIRS: Non-Invasive Respiratory Support; HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation; DNI: Do Not Intubation order.

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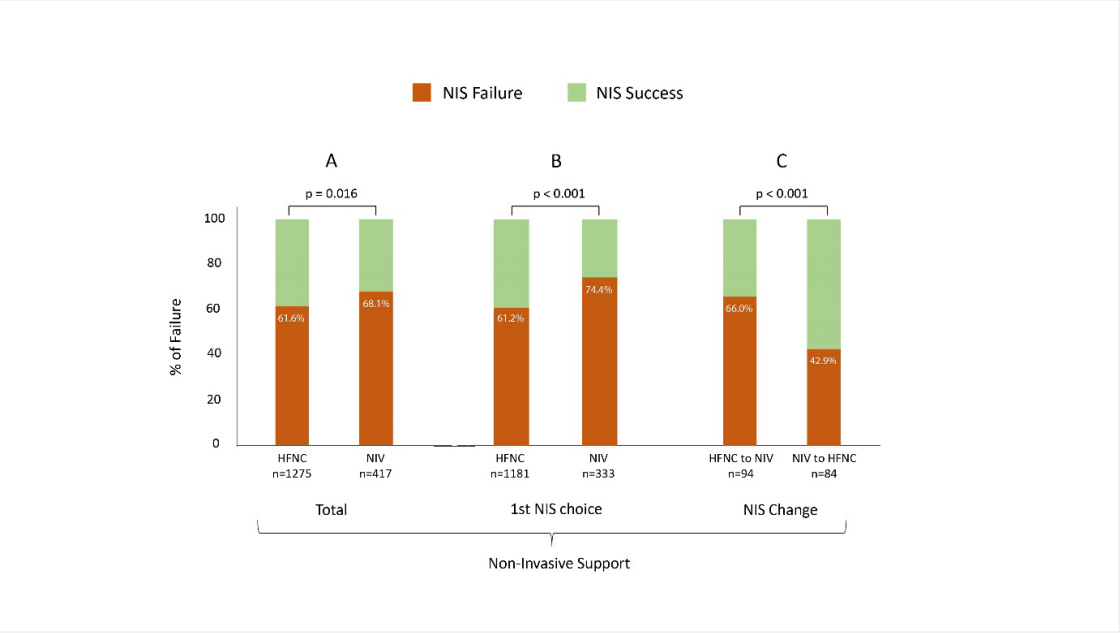

Figure 3: Comparison between success/failure rates in different groups regarding first choice of NIRS and NIRS change.
In first NIRS choice, only successful NIRS and patients who failed are included; patients who switched NIRS therapy are not shown. NIRS: non-invasive respiratory support; HFNC: High Flow Nasal Cannula; NIV: non-invasive ventilation.

Discussion

The key findings of this study in patients with SARS-CoV-2 admitted to the ICU due to ARF are that: 1) Use of NIRS is common in the ICU and switching NIRS strategies is a frequent practice within different scenarios. 2) HFNC was the most frequently used NIRS at admission and was less likely to be changed as initial NIRS support than NIV; 3) NIV at admission was associated with higher failure and mortality rates than HFNC; 4) The switch from HFNC to NIV did not present worse outcomes than HFNC failure, but when it failed, patients showed the highest mortality and the longest LOS rates of all subgroups.

In our cohort of patients, those who were initially treated with NIRS had lower disease severity, lower mortality, and shorter LOS than those who were initially mechanically ventilated. According to previous data, our results showed that NIRS failure were associated with worse outcomes [12,19,20,31]. Moreover, the outcomes worsening was more important after NIRS strategy switches, with similar mortality rates to patients who were first intubated and ventilated.

Our data show that switching NIRS in patients with ARF is a common practice in the ICU and that NIV-to-HFNC is more frequent than HFNC-to-NIV. NIRS switches have been described during the post-extubation period and in non-SARS-CoV-2 patients with ARF, but pandemic situation allowed us to evaluate the impact of NIRS switches when the use of NIRS had to be maintained to reserve MV for the most severe cases [32,33]. In the light of our results, we can speculate that even though ARF was the reason for starting NIRS, the decision to switch from one NIRS therapy to another was based on the particular situation of the patient. In this regard, patients switched from NIV to HFNC presented different baseline and evolution characteristics to those who were switched from HFNC to NIV. These characteristics may have been the reason for the switch. In this regard, the subgroup of patients who were switched from NIV to HFNC presented milder clinical characteristics at admission, similar to those in the HFNC group; they also presented the lowest failure and mortality rates and the shortest LOS. These findings may suggest that successful switches from NIV to HFNC are mostly performed as a de-escalation process during NIV weaning.

In contrast, our results suggest that failure after the switch from NIV to HFNC is the worst scenario, due to the major increase in mortality rates and LOS almost to the level of patients who were ventilated with MV at ICU admission and were more severely ill. In this case, the switch to HFNC might be used as a rest tool to increase NIV tolerability, as previously described by Frat et al. [32] in non-SARS-CoV-2 patients [32]. Nevertheless, in the subgroup of patients who were switched from HFNC to NIV, the move could be understood as an escalation of NIRS therapy. Although our results suggest that this switch did not worsen outcomes compared with patients who failed HFNC without switching, it should be considered that when failure occurs after the switch (in 66% of cases) mortality and LOS drastically increase, reaching the rates recorded in initially mechanically ventilated patients (who tended to be elderly, had more severe illness and poorer clinical parameters at admission).

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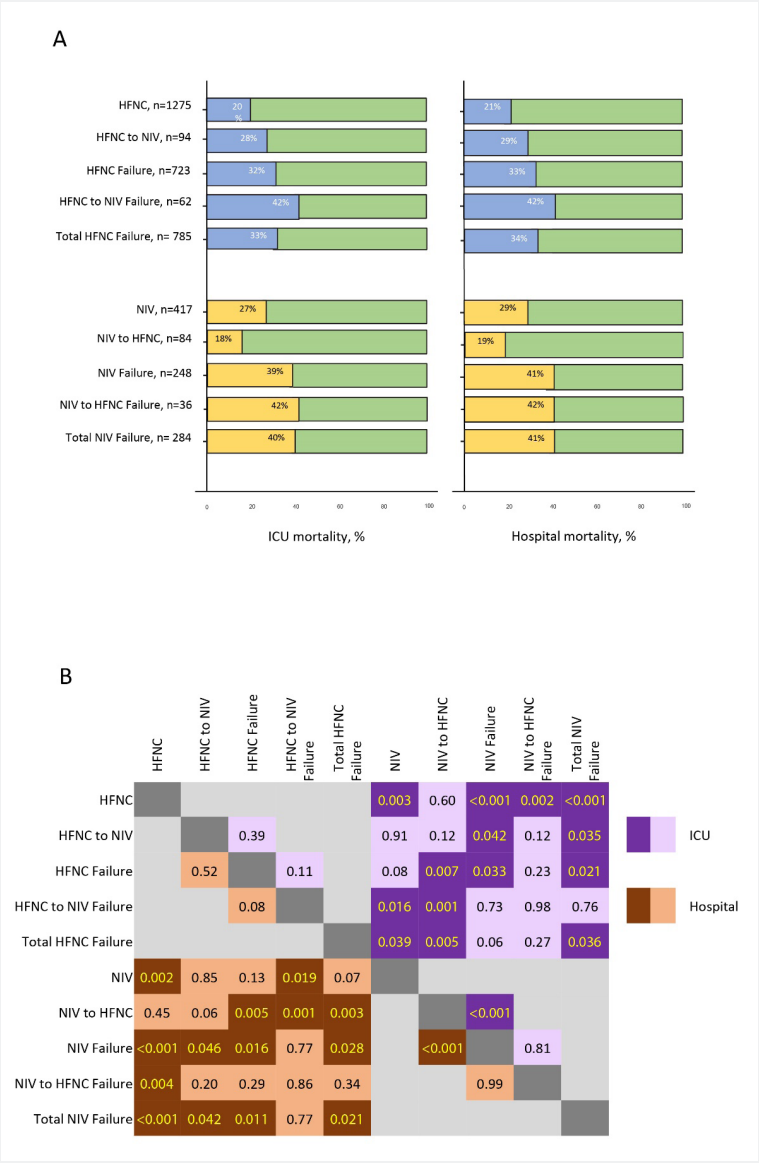

Figure 4: ICU and hospital mortality in all groups (Figure 4A) with all p values for each comparison (Figure 4B).
Magenta color represents ICU groups and orange color represents Hospital groups. In black are shown significant p-values. HFNC, High Flow Nasal Cannula; NIV: non-invasive ventilation; ICU, intensive care unit.

This study has several limitations that should be mentioned. First, it is a secondary analysis of a multicenter database which was not directly designed to evaluate the prognostic implications of NIRS switches. Although the results of this study suggest that NIRS therapy switching was common in clinical practice during the pandemics, it should be evaluated in the post-pandemic routinary ICU practice. Moreover, a lack of relevant information is present as the clinical parameters before the decision to intubate, the NIRS parameters at the time of failure, and the dynamic NIRS changes, which are key issues that future studies should consider. For instance, information regarding the reasons for NIRS switches and timing would help to elucidate whether NIRS therapies were used as de-escalation or escalation strategies. Second, we did not have information on the level of ventilatory support (CPAP or Pressure Support mode), the interface used or the use of heat humidifiers during NIV which might have influenced the outcomes [34]. However, diverse groups of subjects from several hospitals in Spain were enrolled and classified using a pragmatic approach, and the study results suggest differences in clinical practices in real-life settings. Moreover, these results show the need to further investigate switched NIRS groups in order to be able to implement new recommendations in future clinical guidelines.

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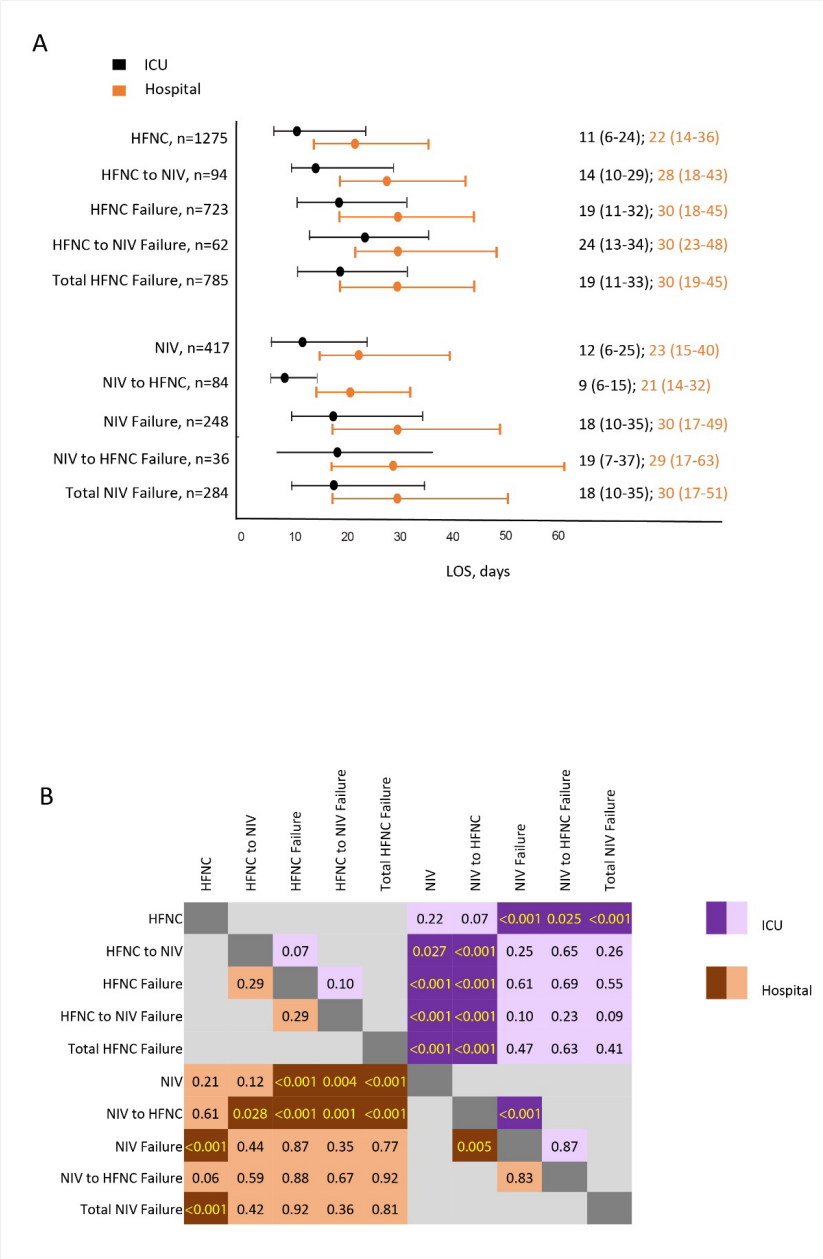

Figure 5: ICU and hospital length of stay in all groups (Figure 5A) with all p values for each comparison (Figure 5B).
Footnote (Figure 5) Magenta color represents ICU groups and orange color represents Hospital groups. In black are shown significant p-values. HFNC: High Flow Nasal Cannula; NIV: Non-Invasive Ventilation; LOS: Length of Stay; ICU: Intensive Care Unit.

In conclusion, this multicenter study shows that HFNC is the first NIRS used in most patients with ARF due to SARS-CoV-2 admitted to the ICU, and that it is associated with better outcomes regarding NIRS failure and mortality than NIV. We also report that the switch of NIRS strategies in these patients was a common practice in Spanish ICUs during pandemics, above all from NIV to HFNC. Moreover, the transition from HFNC to NIV or NIV to HFNC seems to respond to different needs or reasons that should be explored in greater depth in future studies. Although switching strategies do not seem to worsen outcomes, when making this decision, physicians should bear in mind the significant association with worse outcomes when failure occurs after switching. Further studies are also needed to better understand decisions regarding NIRS initiation and switching, as well as to identify predictive factors related to NIRS responders or non-responders before generalizing these findings in clinical practice.

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Conflict of Interest Statements

JRM: grants, travels and non-financial support from Fisher & Paykel, personal fees from Dextro; OR: research grant from Hamilton Medical AG and Fisher & Paykel Healthcare Ltd, speaker fees from Hamilton Medical AG, Fisher & Paykel Healthcare Ltd, Aerogen Ltd and Ambu, and non-financial research support from Timpel; all unrelated to this submission. None of the other authors have any conflicts of interest to declare.

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