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One Year Outcomes in Patients with Acute Respiratory Distress Syndrome Enrolled in a Randomized Clinical Trial of Helmet versus Facemask Noninvasive Ventilation

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Abstract

Objective—Many survivors of acute respiratory distress syndrome (ARDS) have poor long term outcomes possibly due to supportive care practices during *invasive* mechanical ventilation. Helmet noninvasive ventilation (NIV) in ARDS may reduce intubation rates; however it is unknown if avoiding intubation with helmet NIV alters the consequences of surviving ARDS.

Design—Long-term follow up data from a previously published randomized controlled trial

Patients—Adults patients with ARDS enrolled in an previously published clinical trial

Setting—Adult ICU

Intervention—None

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Contributors:

BKP, ASPohlman, JBH, and JPK participated in the conception of the trial. BKP, ASP, JBH, JPK participated in study design. BKP, ASPohlman, and JPK recruited patients and collected data. KSW, EM, DS, CLE, ASPawlik, MS, CK, MT, EZ, JM collected data alone. BKP, KSW, EM, ASP, JBH, JPK analyzed the data. All authors participated in the interpretation of the results. BKP drafted the manuscript. All authors have seen and approved the final version of the manuscript.

Conflicts of interest

We declare that we have no relevant conflicts of interest.

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Measurements and Main Results—The primary outcome was functional independence at one year after hospital discharge defined as independence in activities of daily living and ambulation. At one year, patients were surveyed to assess for functional independence, survival,, and number of institution free days, defined as days alive spent living at home. The presence of ICU acquired weakness (ICU-AW) and functional independence was also assessed by a blinded therapist on hospital discharge. On hospital discharge, there was a greater incidence of ICU-AW (79.5% vs 38.6%; p=0.0002) and less functional independence (15.4% vs 50%; p=0.001) in the facemask group. One year follow-up data were collected for 81 of 83 patients (97.6%). One year mortality was higher in the facemask group (69.2% vs 43.2%; p=0.017). At one year, patients in the helmet group were more likely to be functionally independent (40.9% vs 15.4%; p=0.015) and had more institution free days (median 268.5 [0–354] vs 0 [0–323]; p=0.017).

Conclusions—Poor functional recovery after invasive mechanical ventilation for ARDS is common. Helmet NIV may be the first intervention that mitigates the long term complications that plague survivors of ARDS managed with noninvasive ventilation.

Clinical Trial Registration—clinicaltrials.gov Identifier: NCT01680783

Keywords

Acute Respiratory Distress Syndrome; Helmet; noninvasive ventilation; ICU-Acquired weakness; Early Mobilization

Introduction

Surviving acute respiratory distress syndrome (ARDS) is only the beginning of a prolonged recovery phase marked by neuromuscular weakness, functional impairment, and increased health care utilization.[1] The complications that many ARDS survivors are set to inherit may be a consequence of supportive care practices that include deep sedation, neuromuscular blockade, and bed rest, which lay the foundation for persistent disability. Although some have shown that early mobilization during invasive mechanical ventilation improves functional impairment,[2] data regarding its long term benefits are lacking.[3] Furthermore, despite its short-term benefits, implementation of early mobilization in invasively mechanically ventilated may be challenging[4,5] given that the mere presence of an endotracheal tube is often considered a major barrier to therapy.[6] Therefore if the cost of surviving invasive mechanical ventilation for ARDS is not readily modified by early mobilization, we wondered if successful use of noninvasive ventilation in ARDS has the potential to alter short and long term outcomes. Our group has recently shown in a randomized clinical trial that noninvasive ventilation using a helmet interface can reduce intubation rates and improve mortality in patients with ARDS in comparison to facemask NIV. [7] However, it remains unknown if helmet NIV alters the long-term complications of surviving ARDS. The primary aim of this one-year follow-up study is to describe and compare the functional outcomes patients of ARDS patients enrolled in a randomized clinical trial of helmet versus facemask NIV.

Methods

The results from helmet versus facemask NIV, a single-center randomized clinical trial in patients with ARDS, have been previously reported. [7] Briefly, patients admitted to the medical ICU with ARDS requiring facemask NIV for at least 8 hours were eligible for enrollment. The institutional review board approved the study and informed written consent was obtained from participants or their authorized surrogate decision maker. Patients were randomly assigned to continue on NIV using the facemask (n=39) or switch to the helmet interface (n=44). The primary endpoint was the intubation rate, which was observed to be over 40% lower in the helmet NIV group. This result and other considerations led to discontinuation of the trial, as described in the primary report.[7]

Baseline functional independence was determined by Barthel Index score ≥70 obtained from a proxy describing patient function two weeks before admission.[8,9] All enrolled patients received physical and occupational therapy during their ICU stay. The number of mobility sessions completed during the ICU stay and mobilization milestones such as completion of upper/lower extremity exercises, bed mobility, sitting on edge of bed, standing, sitting in a chair, and ambulating were also recorded for each ICU mobility session. If patients were not mobilized, the treating therapist was required to provide a reason for deferring the session.[10] Given that ICU length of stay was different between groups, the total number of ICU days patients were mobilized was divided by the total number of ICU days to calculate the proportion of ICU days that patients were mobilized in each group. Delirium was assessed after interruption of sedation,[11] using the Confusion Assessment Method (CAM-ICU).[12] Patients with contraindication to sedative interruption (ie neuromuscular blockade) were assessed while on sedative. The proportion of days spent in delirium, coma, or CAM-ICU normal were calculated by dividing the total number of days in each cognitive category by the total ICU or hospital days for each group.

All patients who survived to hospital discharge had a functional and strength assessment using the Medical Research Council (MRC) scale by a therapist who was blinded to study allocation.[13] A combined MRC score of <48 defined the presence of ICU acquired weakness (ICU-AW).[14] Patients who died during their hospitalization without a strength assessment were recorded as having ICU-AW. Functional independence at hospital discharge was defined as independence in all activities of daily living (ADLs) and independent ambulation as determined by a blinded therapist.[2]

At one year after hospital discharge, patients were interviewed by phone to assess survival and functional independence. Functional independence at one year was defined as independence in all ADLs and independent ambulation as reported by the patient. We prospectively collected data on hospital, skilled nursing, long-term acute care, and rehabilitation facility admissions using patient interview corroborated by medical records to calculate the number of health care institution-free days, defined as days alive spent living at home. Deaths were also assessed using the social security death index.

Statistical analysis

All analyses were performed on the basis of an intention-to-treat approach. We used the χ^2 test or Fischer's exact test as appropriate to compare categorical outcomes between groups. Wilcoxon-Mann-Whitney two-sample rank-sum test (for medians) or t-tests (for means) were used to compare continuous outcomes. To evaluate the effect of the intervention on one year survival, we used the Kaplan-Meier procedure to estimate survival distributions in each group, with the effect of the intervention compared between groups using the log-rank test. Additional analyses were done with Cox-regression models that adjusted for baseline factors that predict outcomes (age and APACHE II) and the presence of the helmet intervention. Hazard ratios (HRs), together with 95% confidence intervals (CI) were estimated using this model. We used Stata 11.0 (StataCorp LP) software. This trial was registered with ClinicalTrials.gov, number NCT01680783.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Baseline characteristics

The majority of the patients who survived to hospital discharge resided at home (50 out of 52 survivors; 96%) and were functionally independent (43 out of 52 survivors; 87%) prior to their hospitalization (Table 1). There was no difference in severity of ICU illness between groups (APACHE II score 24 in the facemask group vs 25 in helmet group; p=0.97).

Short-term Functional and Neuromuscular outcomes

Patients in the helmet group had a greater proportion of ICU days with early mobilization as compared to patients in the facemask group (51.6% [111/215 ICU days] vs 38.4% [110/286 ICU days]; p=0.003). This difference in the number of mobilization sessions was primarily seen during the time patients were on noninvasive ventilation (Table 2). Patients in the helmet group participated in mobilization 63.6% of the days while on NIV as compared to 43.9% in the facemask group (p=0.02). There was no difference in completion of upper/lower extremity (90.9 vs 76.9%; p=0.13) or bed mobility exercises (90.9 vs 74.4%; p=0.08) between groups. However, more patients in the helmet group were able to sit at the edge of the bed (90.9 vs 69.2%; p=0.02), stand (84.1 vs 56.4%; p=0.006), transfer to a chair (77.3 vs 51.3%; p=0.01), and walk (70.5 vs 41%; p=0.007) as compared to the facemask group.

Upon hospital discharge, there was a significant reduction in the proportion of patients with ICU-acquired weakness in the helmet group as compared to the facemask group (38.6%vs 79.5%; p=0.0002). In addition more patients in the helmet group were functionally independent on hospital discharge than the facemask group (50% vs 15.4%; p=0.001). After excluding patients who died during their hospitalization, these differences in the incidence of ICU-acquired weakness (helmet 18.8% vs facemask 60%; p=0.002) and functional independence (helmet 68.8% vs facemask 30%; p=0.006) remained statistically significant.

Neurocognitive outcomes

Both groups had similar sedative use (Table 3) with the exception of increased propofol use in the facemask group than in the helmet group due to greater intubation rates in the former group (helmet 15.9% vs facemask 41%; p=0.01). Overall, the incidence of delirium was lower in the helmet group in the ICU (15.8% [34/215 ICU days] vs 28.7% [82/286 ICU days]; p=0.0007) and entire hospitalization (15.7% [70/446 hospital days] vs 31.9% [132/414 hospital days]; p=0.0001); There were no differences in the proportion of days spent in coma. There was also a significant increase in the proportion of days spent as CAM-ICU normal in the ICU (62.7% [150/215 ICU days] vs 57.3% [164/286 ICU days]; p=0.004) and overall hospitalization (76.7% [342/446 hospital days] vs 58.7% [243/414 hospital days]; p=0.00001) in the helmet group.

One year follow-up outcomes

Eighty-one of the 83 enrolled patients underwent one-year follow-up (97.6%) (Supplemental Figure 1). Upon hospital discharge, 47.7% of the helmet group (Table 4) returned home in comparison to 20.5% of patients in the facemask group (p=0.009). A greater proportion of patients in the helmet group were alive and functionally independent at one year than in the facemask group (40.9 vs 15.4%; p=0.015). After excluding patients who died during their hospitalization, 30% of the patients in the facemask were functionally independent at one year as compared to 56.3% in the helmet group (p=0.06). In addition, patients in the helmet group had significantly more health care institution-free days than patients in the facemask group (268.5 vs 0 days; p=0.017). Finally, the helmet group had lower one year mortality than the facemask group (43.2 vs 69.2%; log-rank test for difference in survival distributions; p=0.007) (Fig 1). The unadjusted hazard ratio (HR) for death at one year was 0.46 (95% confidence interval (CI) [0.25–0.82]; p=0.009) in the helmet NIV group. APACHE II score was also independently associated with death at 90 days (HR 1.08 [1.02–1.14]; p=0.008). No association was detected with age (HR 1.01[0.99–1.04]; p=0. 34). The risk of death at one year remained significantly lower in the helmet NIV group after adjustment for APACHE II score (HR 0.48 [0.26–0.86], p=0.01).

Discussion

In a long-term follow-up study of our trial of helmet noninvasive ventilation,[7] we found that patients in the helmet group were more likely to be discharged home functionally independent and remain independent at one year after ICU admission in comparison with facemask NIV. The helmet group also had improved one year survival and less health care utilization. These findings are in stark contrast to prior work demonstrating persistent functional limitations, poor quality of life, and increased health care utilization in invasively mechanically ventilated ARDS survivors after critical illness.[1] The complications described by Herridge et al [1,15] may be a direct result of supportive care practices in the management of ARDS which include bed rest, neuromuscular blockade, and deep sedation during invasive mechanical ventilation. One should be cautious directly comparing our work with the Herridge et al cohort,[1,15] since all of those patients were intubated whereas many in our cohort did not require endotracheal intubation. However, interventions aimed at mitigating the complications of invasive mechanical ventilation such as mobilization, while possible in

intubated patients,[2] are more challenging to implement than in non-intubated patients.[6] While noninvasive ventilation has the promise to avoid the complications of *invasive* ventilation,[16] many have cautioned against its use in hypoxemic respiratory failure due to high failure rates[17,18] and concerns for excess mortality[19] possibly from delayed intubation and/or large tidal volumes.[20,21] Our prior work suggests mortality and endotracheal intubation rates for noninvasive ventilation in ARDS may be significantly improved when the interface for the delivery of noninvasive ventilation is a helmet.[7] Therefore the avoidance of complications of invasive mechanical ventilation could be possible with helmet ventilation without excess risk from high failure rates and mortality. Further work is needed to draw more definitive conclusions on this issue.

The prevention of functional and neuromuscular complications in the helmet group may be explained by the avoidance of immobility and deep sedation practices that may be associated with invasive mechanical ventilation. Indeed, the helmet group was mobilized more reliably in the ICU, had less delirium, and less neuromuscular weakness on hospital discharge. The ability to effectively implement early mobilization during the noninvasive ventilation was key to setting a path for functional recovery after ARDS.

Our study has several limitations. First, the original trial of helmet NIV was stopped early for efficacy and safety concerns in accord with pre-defined criteria by our Data Safety and Monitoring Board. This may alter the magnitude of the long term effects of this intervention. Second, functional independence at one year was determined by patient self-report, which can underestimate any impairment. However, there are data suggesting acceptable agreement in ADL proficiency by self-report and direct observation.[22] Third, the study was not blinded which may introduce bias especially with the implementation of early mobilization. To investigate this possibility, therapists cited reasons for deferred mobility sessions. There was no difference in most reasons for missed mobility sessions, except for increased neuromuscular blockade on potential mobility days in the helmet group (16 vs 4%; p=0.0002). The reasons for missed mobility sessions were not expected to be all inclusive and thus secondary reasons omitted by the therapists for the control group may have included neuromuscular blockade. In addition therapists cited graduation from therapy due to achievement of functional independence more commonly in the helmet group (3% vs 0%; p= 0.02) and increased patient refusal of mobilization in the facemask group (10% vs 1%; p=0.001). The most common reason cited as to why patients refused was fatigue in the facemask group (15 out of 18 times; 83.3%). These data support our observation of patient intolerance of the facemask which limited the implementation of early mobilization during noninvasive ventilation in the control group.

Recent work has cautioned against the use of noninvasive ventilation in the management of ARDS in deference to the primacy of instituting lung protective strategy with invasive mechanical ventilation.[21,23] This choice may reduce the risk of perpetuating lung injury but often necessitates deep sedation practices and bed rest which are at the cost of functional independence. Our work suggests a possible alternative approach in which helmet ventilation obviates the need for invasive mechanical ventilation and its associated detrimental supportive care practices. Patients have the opportunity to be awake and animated in spite of highly assisted spontaneous breathing during ARDS to set a foundation

for functional *recovery* after ARDS. To date there have been no interventions shown to improve long term outcomes in ARDS survivors. Although these findings are preliminary, the potential of helmet noninvasive to alter the landscape of ARDS survivorship warrants further study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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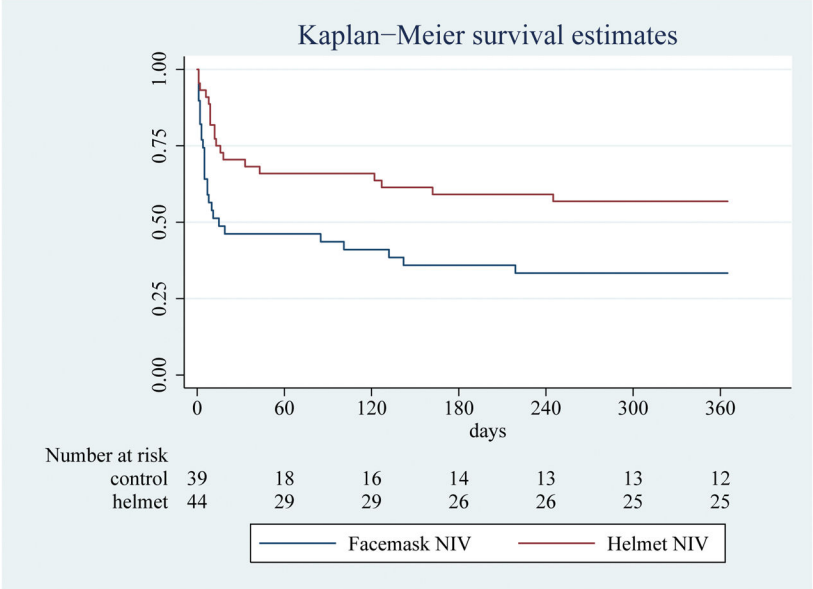

Figure 1.
Kaplan Meier Analysis of One Year Survival

Table 1

Baseline characteristics of survivors

Baseline Characteristic	Facemask NIV (n=20)		Helmet NIV (n=32)		p-value
Age (years)	58.4	[50.8–71.5]	58.2	[49.7–66.6]	0.52
Female	10	50%	16	50%	1
APACHE II	24	[22–27]	25	[20–28]	0.87
Pre admission Residence					
Home	18	90%	32	100%	0.14 *
Nursing Home	2	10%	0	0%	
Functionally independent **	15	75%	28	87.5%	0.28
Past Medical History					
Congestive Heart Failure	8	40%	8	25%	0.25
Hematologic malignancy	2	10%	4	13%	1
Cancer, solid tumor	3	15%	2	6%	0.36
Stem cell transplant	1	5%	3	9%	1
Solid organ transplant	1	5%	4	13%	0.64

Data are expressed in n (%) or median [Interquartile Range], where appropriate;

* Comparison of patients who lived at home vs not home

** Functional independence defined as a Barthel Index score≥70 [89]

Table 2

Ease of Early Mobilization and Short-term Functional/Neuromuscular Outcomes

Mobilization Outcomes	Facemask NIV (N=39)		Helmet NIV (N=44)		p-value
#ICU days mobilized *	110/286	38.4%	111/215	51.6%	0.003
# Mobility sessions during:					
Endotracheal intubation **	34/125	21.7%	16/56	28.6%	0.76
Noninvasive ventilation **	29/66	43.9%	50/77	63.6%	0.02
Supplemental oxygen **	52/95	50.5%	48/82	56.1%	0.46
Mobility Milestones while on NIV					
Upper and lower extremity exercises	30	76.9%	40	90.9%	0.13
Bed mobility	29	74.4%	40	90.9%	0.08
Sit at edge of bed	27	69.2%	40	90.9%	0.02
Stand	22	56.4%	37	84.1%	0.006
Chair	20	51.3%	34	77.3%	0.01
Ambulation	16	41%	31	70.5%	0.007
Reasons for missed mobility session					
Cardiovascular	16	8.6%	6	5.2%	0.26
Respiratory	41	22.2%	25	21.6%	0.9
Neurologic	24	13.0%	12	10.3%	0.49
Neuromuscular Blockade	7	3.8%	19	16.4%	0.0002
Procedure	10	5.4%	7	6.0%	0.82
Comfort Care	28	15.1%	12	10.3%	0.23
Cardiac Arrest	4	2.2%	3	2.6%	1
Intermittent HD	4	2.2%	4	3.4%	0.49
Patient Refusal	18	9.7%	1	0.9%	0.001
Discharged from therapy	0	0%	4	3.4%	0.02
Logistics	25	13.51%	18	15.5%	0.63
Unspecified	8	4.3%	5	4.3%	1
Outcomes on Hospital Discharge					
ICU- Acquired Weakness **	31	79.5%	17	38.6%	0.0002

Mobilization Outcomes	Facemask NIV (N=39)		Helmet NIV (N=44)		p-value
Functional Independence **	6	15.4%	22	50%	0.001

* Data are expressed as # of days with early mobility/#ICU days

** Data are expressed as # mobility sessions/# days on specified respiratory support and proportion of ICU days the patient was mobilized (%), where appropriate

*** Determined by therapist blinded to study allocation

Table 3

Sedative Use and Neurocognitive outcomes

Outcome	Facemask NIV (n=39)		Helmet NIV (n=44)		p-value
No. ICU days spent in:	*286 ICU days*	*215 ICU days*			
Delirium	82/286	28.7%	34/215	15.8%	0.0007
Coma	40/286	14.0%	31/215	14.2%	0.89
CAM-ICU Normal	164/286	57.3%	150/215	62.7%	0.004
No. Hospital days spent in:	*414 Hospital days*		*446 Hospital days*		
Delirium	132/414	31.9%	70/446	15.7%	0.00001
Coma	39/414	9.4%	34/446	7.6%	0.34
CAM-ICU Normal	243/414	58.7%	342/446	76.7%	0.00001
Sedative Details					
No. receiving dexmedetomidine	13	33.3%	17	38.6%	0.62
No. receiving propofol	16	41%	7	15.9%	0.01
No. receiving midazolam	16	41%	15	34%	0.52
No. receiving IV opiate	27	69%	23	52.3%	0.12

Data are expressed in n (%), where appropriate

ICU= Intensive Care Unit; CAM= Confusion Assessment Method

Table 4

Discharge Destination and One-Year Outcomes

Outcome	Facemask NIV (n=39)		Helmet NIV (n=44)		p-value
Discharge Destination					
Home	8	20.5%	21	47.7%	0.009 *
Long term acute care	3	7.7%	4	9.1%	
Acute rehab	4	10.3%	1	2.3%	
Subacute rehab	0	0%	4	9.1%	
Skilled nursing facility	2	5.1%	0	0%	
Hospice	3	7.7%	2	4.5%	
Died	19	48.7%	12	27.3%	
One Year Outcomes					
One-Year Mortality	27	69.2%	19	43.2%	0.007
Functional Independence	6	15.4%	18	40.9%	0.015
Institution Free Days (days) **	0	[0–323]	268.5	[0–354]	0.017

Data are expressed in n (%) or median [Interquartile Range], where appropriate

* Indicates comparison of proportion of patients who went home versus any other discharge destination

** Equals one year (365 days) minus days in a health care institution, rather than home