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ORIGINAL RESEARCH

INTERVENTIONS, COMPLICATIONS AND ICU COURSE AS PREDICTORS OF OUTCOME IN ACUTE RESPIRATORY DISTRESS SYNDROME: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Patients with acute respiratory distress syndrome (ARDS) frequently require organ support and develop intensive care unit (ICU)–acquired complications. How these relate to severity and mortality is less well described in Indian cohorts.

Methods: In this prospective observational study in the medical ICU of a tertiary care hospital, 100 patients fulfilling the Berlin definition of ARDS were enrolled. Acute kidney injury (AKI), renal replacement therapy (RRT), non-invasive (NIV) and invasive ventilation, tracheostomy, ventilator-associated pneumonia (VAP), transfusion and ICU length of stay were related to Berlin severity and in-hospital outcome using Fisher's exact test.

Results: In-hospital mortality was 27%. AKI occurred in 70 patients and was associated with death (34.3% versus 10.0%; odds ratio [OR] 4.63, 95% confidence interval [CI] 1.23–26.28; p=0.014); RRT, required by 8, carried a steeper risk (75.0% versus 22.8%; OR 9.85; p=0.005). Invasive ventilation (33 patients) was strongly associated with death (63.6% versus 9.0%; OR 17.07; p<0.001), as was tracheostomy (82.4% versus 15.7%; OR 23.92; p<0.001). Patients managed with NIV alone had lower mortality (10.2% versus 43.1%; OR 0.15, 95% CI 0.04–0.47; p<0.001). Neither VAP (23.5% versus 27.7%; OR 0.80; p=1.00) nor transfusion (OR 2.19; p=0.113) was associated with mortality. No patient with mild ARDS required RRT, invasive ventilation or tracheostomy, or developed VAP. Mean ICU stay rose from 9.3 to 17 days.

Conclusion: The depth of organ failure requiring active support, rather than the underlying complication, most sharply distinguished non-survivors. VAP showed no mortality association, most plausibly because it can only arise in patients surviving 48 hours of ventilation.

Keywords: *Acute respiratory distress syndrome; mechanical ventilation; acute kidney injury; tracheostomy; ventilator-associated pneumonia; intensive care unit length of stay; mortality*

INTRODUCTION

Acute respiratory distress syndrome (ARDS) is defined by the acute onset of bilateral radiographic opacities and hypoxaemia not fully explained by cardiac failure or fluid overload, graded as mild, moderate or severe by the ratio of arterial oxygen tension to fractional inspired oxygen (PaO_2/FiO_2) at a positive end-expiratory pressure of at least 5 cmH_2O.[1] In the international LUNG SAFE cohort it accounted for approximately one in ten ICU admissions, with hospital mortality rising across the Berlin strata and exceeding 40% in severe disease.[2] Most deaths follow multi-organ dysfunction rather than refractory hypoxaemia alone, reflecting the systemic inflammatory and endothelial disturbance of which the lung injury is one manifestation.[3]

Acute kidney injury is the most frequent extrapulmonary organ failure in ARDS, and its severity is graded in step with mortality.[4] Standardised staging by the Kidney Disease: Improving Global Outcomes (KDIGO) criteria distinguishes injury from the need for renal replacement therapy (RRT),[5] a distinction that matters prognostically: organ-failure scoring

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systems such as the Sequential Organ Failure Assessment weight the depth of dysfunction and the requirement for active support rather than the mere presence of injury.[6]

Respiratory support in ARDS is likewise graded. Lung-protective ventilation with low tidal volumes reduces mortality,[7] and driving pressure appears to be the ventilatory variable most strongly related to survival.[8] Non-invasive ventilation (NIV) is widely used in milder disease, but a propensity-matched analysis of the LUNG SAFE cohort found that among patients with PaO_2/FiO_2 below 150 mmHg NIV was associated with higher mortality than invasive ventilation, so that the apparent advantage of NIV in observational data is heavily confounded by the severity of the patients selected for it.[9] Prolonged ventilator dependence in turn leads to tracheostomy and exposes patients to ventilator-associated pneumonia (VAP), a common ICU-acquired complication whose diagnosis, management and prevention are the subject of established guidelines.[10,11] Whether VAP itself causes death, however, remains contested; causal analyses accounting for the competing risk of early death and for the time-dependent nature of the exposure have estimated its attributable mortality to be far smaller than crude comparisons suggest.[12]

While each of these interventions and complications is individually well described, their comparative distribution across Berlin severity strata and outcome within a single cohort, and their combined contribution to a recognisable high-risk ICU trajectory, are less well characterised in Indian tertiary-care practice. This study describes their frequency among patients with ARDS admitted to a medical ICU and examines their association with severity, in-hospital outcome and ICU length of stay.

MATERIALS AND METHODS

Study design and setting

This was a prospective, single-centre observational cohort study conducted in the Medical Intensive Care Unit of a tertiary care teaching hospital from 1 January 2019 to 30 April 2020. The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.[13] The present analysis addresses interventions, complications and ICU course; the admission clinical, haematological, biochemical and arterial blood gas findings of the same cohort are reported separately.

Participants

Consecutive patients aged more than 14 years admitted to the medical ICU who fulfilled the Berlin definition of ARDS[1] were enrolled after written informed consent, to a total of 100. Patients were excluded if they or their surrogates declined participation; if ARDS was a sequel of active pulmonary tuberculosis; if there was pre-existing ischaemic heart disease; if death occurred within 24 hours of admission; or if they were surgical admissions. The exclusion of deaths within 24 hours was applied so that the interventions and complications of interest, several of which require days of ICU care to arise, had the opportunity to occur.

Definitions

ARDS severity was graded by the Berlin oxygenation criteria as mild (PaO_2/FiO_2 >200 to ≤300 mmHg), moderate (>100 to ≤200 mmHg) or severe (≤100 mmHg).[1] Acute kidney injury was defined by the KDIGO criteria as an increase in serum creatinine of at least 0.3 mg/dL within 48 hours, a rise to at least 1.5 times baseline within seven days, or urine output below 0.5 mL/kg/h for six hours.[5] Ventilator-associated pneumonia was defined by fever, leucocytosis, new or progressive infiltrates on chest radiography arising more than 48 hours after the initiation of mechanical ventilation, and growth on tracheal aspirate culture.[10] Interventions recorded were the need for renal replacement therapy, non-invasive versus invasive mechanical ventilation, tracheostomy and blood product transfusion. ICU length of stay, days of invasive ventilation and days of tracheostomy dependence were recorded. Patients were followed to ICU discharge or in-hospital death, which was the outcome of interest.

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Statistical analysis

Categorical variables are expressed as number and percentage. For each intervention and complication, mortality among patients in whom it occurred was compared with mortality among all patients in whom it did not, using Fisher's exact test. Fisher's test was used in preference to Pearson's chi-square test because several subgroups contained fewer than five expected events, a condition under which the chi-square approximation is unreliable. Odds ratios are reported with exact conditional 95% confidence intervals, and confidence intervals for single proportions were calculated by the Wilson score method. The distribution of interventions and complications across the three Berlin severity strata is presented descriptively, because several cells contained zero or single-digit counts for which formal significance testing would be unreliable. Data were entered in Microsoft Excel and analysed using IBM SPSS Statistics version 21.0 (IBM Corp., Armonk, NY) with confirmatory computation in R. A two-sided p-value below 0.05 was considered statistically significant. All comparisons are univariate and unadjusted; no multivariable model was fitted and no adjustment was made for multiplicity.

Ethical considerations

The study protocol was approved by the Institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki and the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Written informed consent was obtained from all patients or their attendants.

RESULTS

Cohort and frequency of interventions

One hundred patients were enrolled and all were followed to ICU discharge or death. Twenty-seven died in hospital, giving an in-hospital mortality of 27.0% (95% confidence interval [CI] 19.2–36.6).

Acute kidney injury was the commonest complication, affecting 70 patients (70%), of whom 8 (8% of the cohort) required renal replacement therapy. Forty-nine patients (49%) were managed with non-invasive ventilation and 33 (33%) required invasive mechanical ventilation. Seventeen patients (17%) underwent tracheostomy and 17 (17%) developed ventilator-associated pneumonia. Blood products were transfused in 45 patients (45%) (Table 1, Figure 1).

Distribution across Berlin severity strata

The distribution of interventions and complications across severity strata was strongly graded (Table 1, Figure 1B). No patient with mild ARDS required renal replacement therapy, invasive mechanical ventilation or tracheostomy, or developed ventilator-associated pneumonia. Of the 17 tracheostomies, 15 (88.2%) were performed in patients with severe ARDS, and of the 17 episodes of ventilator-associated pneumonia, 12 (70.6%) occurred in severe disease. Conversely, non-invasive ventilation was concentrated at the milder end of the spectrum, 28 of 49 recipients (57.1%) having mild ARDS and only 5 (10.2%) severe disease. Acute kidney injury was the least differentiated, with 30 of 70 affected patients (42.9%) in the mild stratum.

Table 1. Interventions and complications by Berlin severity stratum (n = 100)

Intervention / complication	Total n (% of cohort)	Mild n (%)	Moderate n (%)	Severe n (%)
Acute kidney injury	70 (70)	30 (42.9)	20 (28.6)	20 (28.6)
Renal replacement therapy	8 (8)	0 (0)	3 (37.5)	5 (62.5)
Non-invasive ventilation	49 (49)	28 (57.1)	16 (32.7)	5 (10.2)
Invasive ventilation	33 (33)	0 (0)	15 (45.5)	18 (54.5)
Tracheostomy	17 (17)	0 (0)	2 (11.8)	15 (88.2)
Ventilator-associated pneumonia	17 (17)	0 (0)	5 (29.4)	12 (70.6)
Blood product transfusion	45 (45)	12 (26.7)	14 (31.1)	19 (42.2)

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Percentages in the three severity columns are of the patients receiving that intervention or developing that complication, not of the severity stratum; each row therefore sums to 100%. The distribution is presented descriptively because several cells contain zero or single-digit counts.

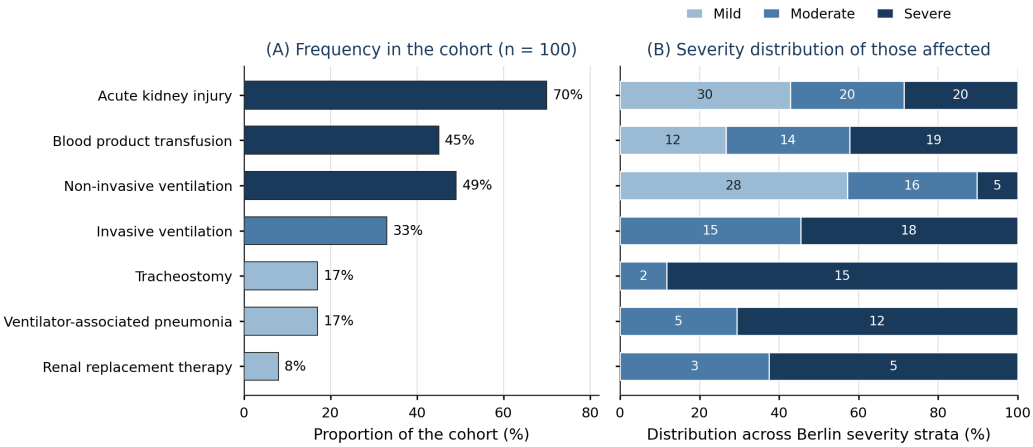

Figure 1. *(A) Frequency of each intervention and complication in the whole cohort (n = 100). (B) Distribution of the affected patients across the three Berlin severity strata; segment labels give absolute numbers. No patient with mild ARDS required renal replacement therapy, invasive ventilation or tracheostomy, or developed ventilator-associated pneumonia.*

Association with in-hospital outcome

Mortality rose in step with the depth of organ support required (Table 2, Figures 2 and 3). Acute kidney injury was associated with death, 24 of 70 affected patients (34.3%) dying compared with 3 of 30 (10.0%) without it (odds ratio [OR] 4.63, 95% CI 1.23–26.28; p=0.014). The 8 patients who required renal replacement therapy showed a steeper gradient still, 6 (75.0%) dying against 21 of 92 (22.8%) who did not require it (OR 9.85, 95% CI 1.61–106.79; p=0.005), although the confidence interval is correspondingly wide.

The contrast between modes of ventilatory support was the most striking finding. Of 33 patients requiring invasive mechanical ventilation, 21 (63.6%) died, compared with 6 of 67 (9.0%) who did not (OR 17.07, 95% CI 5.33–63.51; p<0.001). Of the 49 patients managed with non-invasive ventilation, only 5 (10.2%) died, against 22 of 51 (43.1%) not receiving NIV (OR 0.15, 95% CI 0.04–0.47; p<0.001). Tracheostomy carried the highest crude mortality of any intervention, 14 of 17 patients (82.4%) dying compared with 13 of 83 (15.7%) (OR 23.92, 95% CI 5.64–147.94; p<0.001).

Two variables showed no association with outcome. Ventilator-associated pneumonia, although concentrated in severe disease, was not associated with mortality: 4 of 17 affected patients (23.5%) died compared with 23 of 83 (27.7%) without it (OR 0.80, 95% CI 0.17–2.97; p=1.00). Blood product transfusion was likewise not significantly associated with death (16 of 45, 35.6%, versus 11 of 55, 20.0%; OR 2.19, 95% CI 0.82–6.04; p=0.113).

Table 2. Interventions and complications by in-hospital outcome (n = 100)

Intervention / complication	n	Died (%)	Survived	Died if absent (%)	OR (95% CI)	p
Tracheostomy	17	14 (82.4)	3	13/83 (15.7)	23.92 (5.64–147.94)	<0.001
Invasive ventilation	33	21 (63.6)	12	6/67 (9.0)	17.07 (5.33–63.51)	<0.001
Renal replacement therapy	8	6 (75.0)	2	21/92 (22.8)	9.85 (1.61–106.79)	0.005
Acute kidney injury	70	24 (34.3)	46	3/30 (10.0)	4.63 (1.23–26.28)	0.014
Blood product transfusion	45	16 (35.6)	29	11/55 (20.0)	2.19 (0.82–6.04)	0.113
Ventilator-associated pneumonia	17	4 (23.5)	13	23/83 (27.7)	0.80 (0.17–2.97)	1.000
Non-invasive ventilation	49	5 (10.2)	44	22/51 (43.1)	0.15 (0.04–0.47)	<0.001

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Rows are ordered by descending crude mortality. OR = odds ratio for in-hospital death comparing patients with the intervention or complication against all patients without it, with exact conditional 95% confidence interval (CI); p by Fisher's exact test. Cohort mortality 27.0% (27/100). Categories are not mutually exclusive.

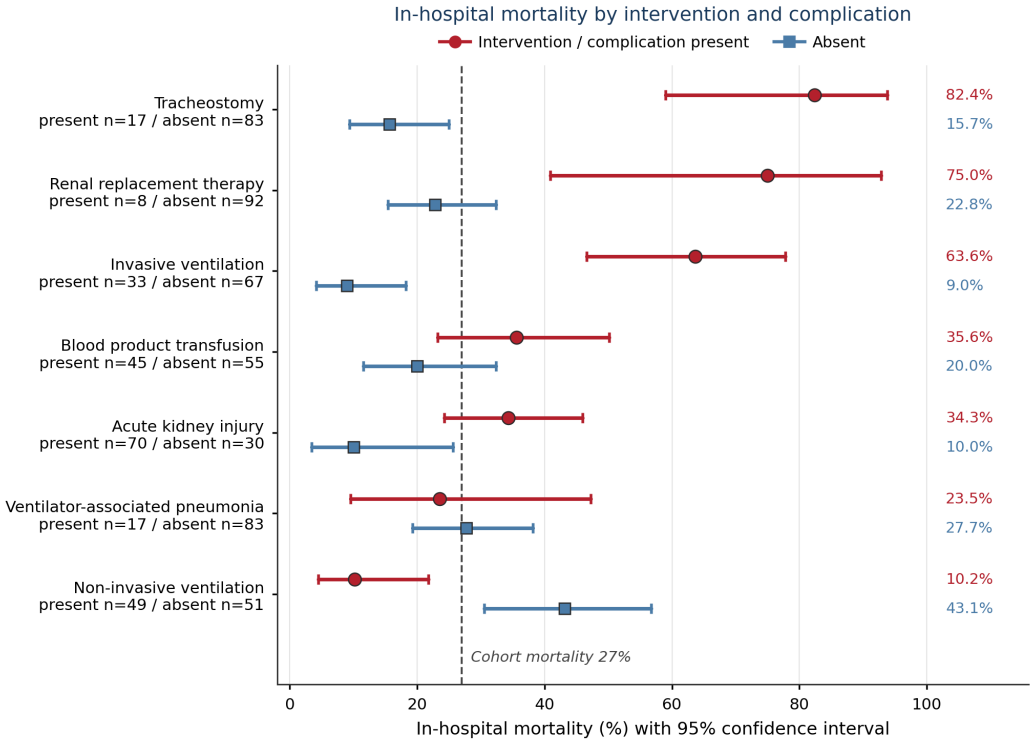

Figure 2. *In-hospital mortality according to the presence or absence of each intervention and complication, with 95% Wilson score confidence intervals. The dashed vertical line marks the mortality of the whole cohort (27%). The intervals for ventilator-associated pneumonia and for blood product transfusion overlap substantially, whereas those for tracheostomy, invasive ventilation and non-invasive ventilation are widely separated.*

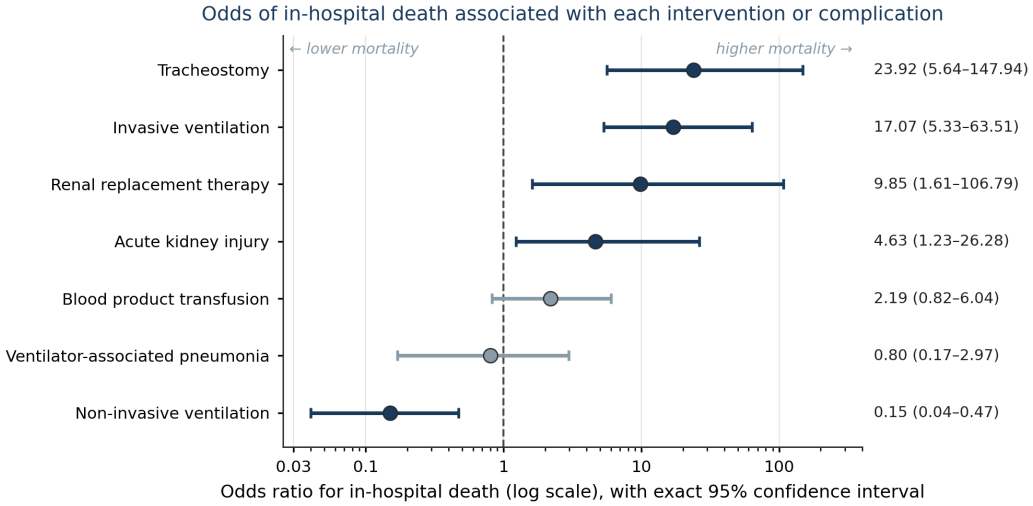

Figure 3. *Odds of in-hospital death associated with each intervention and complication, plotted on a logarithmic scale with exact conditional 95% confidence intervals. Estimates whose interval excludes unity are shown in dark blue and those consistent with no association in grey. Note the gradient from acute kidney injury to renal replacement therapy, and the position of non-invasive ventilation to the left of unity.*

ICU length of stay and duration of support

Mean ICU length of stay rose from 9.3 days in mild ARDS to 11.0 days in moderate and 17.0 days in severe disease, an increase of approximately 80% from the mildest to the most severe stratum. The mean duration of invasive ventilation rose

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from none in mild disease to 3.6 days in moderate and 12.9 days in severe ARDS, and mean tracheostomy dependence from none to 0.5 and 9.5 days respectively (Table 3, Figure 4).

Table 3. ICU length of stay and duration of organ support by Berlin severity stratum

Parameter	Mild	Moderate	Severe
ICU length of stay (days)	9.3	11.0	17.0
Duration of invasive ventilation (days)	0	3.6	12.9
Duration of tracheostomy dependence (days)	0	0.5	9.5

Values are group means, calculated across all patients in each stratum including those who received no ventilatory support, so the ventilation and tracheostomy values represent stratum-wide averages rather than durations among those supported.

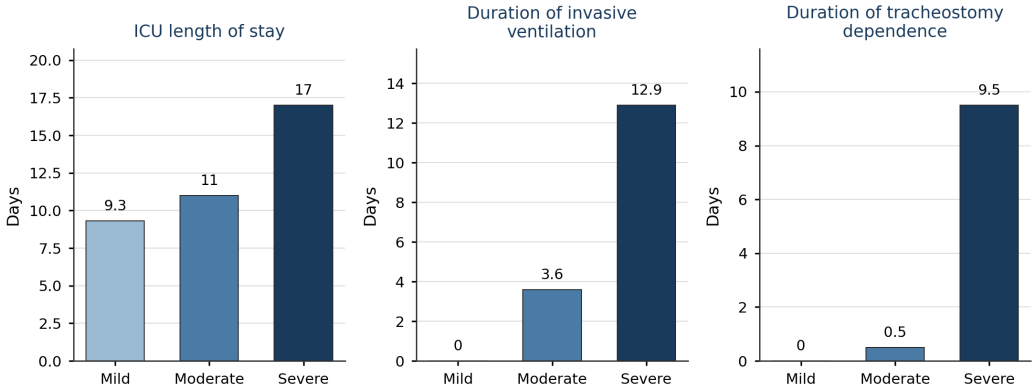

Figure 4. *Mean ICU length of stay, duration of invasive ventilation and duration of tracheostomy dependence by Berlin severity stratum. Values are stratum-wide means including patients who received no ventilatory support.*

DISCUSSION

In this cohort of 100 patients with ARDS, the variables that most sharply separated survivors from non-survivors were not the underlying complications but the interventions required to support failing organs. Acute kidney injury, present in 70% of patients, roughly quadrupled the odds of death; the need for renal replacement therapy, present in only 8%, raised them approximately tenfold. The same gradient appeared in the respiratory domain, where invasive ventilation was associated with a seventeenfold increase in the odds of death and tracheostomy with a twenty-fourfold increase, while patients managed with non-invasive ventilation alone had markedly lower mortality than the rest of the cohort.

This pattern is consistent with the principle underlying organ-failure scoring systems such as SOFA, in which each organ domain is graded by the depth of dysfunction and by the need for active support rather than by the presence of injury alone.[6] It also accords with data from ARDS-specific cohorts in which the stage of acute kidney injury, rather than its mere occurrence, determines the excess risk of death, patients with stage I injury having outcomes indistinguishable from those without.[4] The practical implication is that the transition from injury to supported failure — the decision to start dialysis, to intubate — is a more useful trigger for reassessment of prognosis and for goals-of-care discussion than the appearance of the complication itself.

The apparent protective association of non-invasive ventilation requires careful interpretation and should not be read as evidence that NIV improves outcome. NIV in this unit was preferentially used in less hypoxaemic patients: 57.1% of NIV recipients had mild ARDS and only 10.2% severe disease, exactly the reverse of the distribution for invasive ventilation. The comparison is therefore confounded by indication, and the odds ratio of 0.15 measures the severity of the patients selected for NIV rather than any effect of the technique. The point is not academic: in a propensity-matched analysis of the LUNG SAFE cohort, NIV in patients with PaO_2/FiO_2 below 150 mmHg was associated with *higher* mortality than invasive ventilation, and NIV failure requiring subsequent intubation identifies a particularly high-risk group.[9] Our data

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are equally consistent with appropriate patient selection and with delayed intubation in patients failing NIV, and cannot distinguish between them; we did not record the number of patients who crossed over from NIV to invasive ventilation, which would be required to do so.

Ventilator-associated pneumonia produced the most instructive negative finding. It occurred in 17% of the cohort and was heavily concentrated in severe disease, with no case in the mild stratum and 70.6% of cases in severe ARDS, yet it showed no association whatever with mortality (23.5% versus 27.7%; OR 0.80; p=1.00). This apparent paradox has a well-recognised explanation. VAP cannot by definition arise before 48 hours of mechanical ventilation, so a patient must survive that period, and remain ventilated through it, in order to be eligible to develop it. Patients who die early — precisely those at highest risk — are structurally excluded from the exposed group, which biases crude comparisons toward the null or beyond it. Causal analyses that account for this competing risk and for the time-dependent nature of the exposure have estimated the attributable mortality of VAP to be far lower than crude case-fatality comparisons imply.[12] The absence of an association in our data should therefore not be read as evidence that VAP is harmless. It remains a cause of prolonged ventilation, antimicrobial exposure and ICU stay, and the case for ventilator-bundle care — head-of-bed elevation, minimisation of sedation, oral care and cuff pressure monitoring — rests on those outcomes and on trial evidence rather than on crude mortality comparisons of this kind.[11]

Blood product transfusion was more frequent in severe disease, with 42.2% of transfused patients in the severe stratum, but was not significantly associated with mortality (OR 2.19; p=0.113). This most likely reflects the greater prevalence of anaemia, thrombocytopenia and coagulopathy in severe ARDS, described in the companion analysis of this cohort, so that transfusion practice was reactive to disease severity rather than a driver of outcome. An observational design cannot separate these possibilities, and the confidence interval remains compatible with a sixfold increase in risk.

The progressive rise in ICU length of stay and in the duration of ventilatory and tracheostomy support with increasing severity quantifies the resource burden of severe ARDS. A severe case occupied an ICU bed for approximately eight days longer than a mild case and required, on average, nearly thirteen days of invasive ventilation. In resource-constrained settings where ICU beds and ventilators are the binding constraint, these figures bear directly on capacity planning, and they also indicate the scale of the rehabilitation need among survivors.

Limitations

Several limitations apply. The study is single-centre and observational, so no causal inference can be drawn about whether the interventions themselves influenced outcome or simply marked greater underlying severity; the strong likelihood is the latter, and this is the central interpretive caution attaching to every association reported here. The analysis is univariate throughout, and no multivariable model was fitted, so the associations are unadjusted and their independence is unknown; logistic regression incorporating severity stratum, age and comorbidity would be required to establish which carry information beyond Berlin classification alone. Several subgroups were small, most notably the 8 patients requiring renal replacement therapy, and the corresponding confidence intervals are correspondingly wide. Ventilatory management was not protocolised for the purposes of this study, and tidal volumes, plateau and driving pressures and adherence to lung-protective targets were not recorded, so the ventilator-day metrics are not directly comparable with cohorts reporting protocolised care,[7,8] and no standardised weaning or extubation protocol was in force. Criteria for the timing of tracheostomy were likewise at the discretion of the treating team. Finally, the enrolment period extended into the first months of the COVID-19 pandemic in India, and the case mix in the closing weeks may not be representative of the remainder.

CONCLUSION

In this ARDS cohort the need for organ-supportive intervention distinguished non-survivors from survivors more sharply than the underlying complication did. Acute kidney injury conferred a fourfold increase in the odds of death and the need for renal replacement therapy a tenfold increase; invasive mechanical ventilation and tracheostomy conferred seventeen- and twenty-fourfold increases respectively. Patients managed with non-invasive ventilation alone had substantially lower

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mortality, but this reflects the milder disease for which NIV was selected rather than any demonstrated benefit of the technique. Ventilator-associated pneumonia, although concentrated in severe disease, showed no association with mortality, most plausibly because it can only arise in patients who survive long enough to be ventilated for 48 hours; this should not be taken as evidence that it is benign. ICU length of stay and duration of ventilatory support rose substantially with severity, with direct implications for capacity planning. Because these associations are univariate and drawn from a single centre, they describe a recognisable high-risk trajectory rather than independent predictors, and confirmation in larger multicentre cohorts with multivariable adjustment is required.

DECLARATIONS

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Conflicts of Interest

The authors declare that they have no competing interests.

Author Contributions

All named authors contributed to the conception and design of the study, participated in acquisition of data and its analysis and interpretation, took part in drafting the article or revising it critically for important intellectual content, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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