Original Article

# Good survival rate, moderate overall and good respirator quality of life, near normal pulmonary functions, and good return to work despite catastrophic economic costs 6 months following recovery from Acute Respiratory Distress Syndrome

*Rohan Thomas[1], Vijay Prakash Turaka[1], John Victor Peter[2], DJ Christopher[3], T Balamugesh[3], Gowri Mahasampath[4], Alice Joan Mathuram[1], Mohammed Sadiq[1], I Ramya[1], Tarun George[1], Vignesh Chandireseharan[1], Tina George[1], Thambu David Sudarsanam[1]*

[1]*Department of Medicine, Christian Medical College, Vellore, Tamil Nadu, India,* [2]*Department of Critical Care, Christian Medical College, Vellore, Tamil Nadu, India,* [3]*Department of Pulmonary Medicine, Christian Medical College, Vellore, Tamil Nadu, India,* [4]*Department of Biostatistics, Christian Medical College, Vellore, Tamil Nadu, India*

## ABSTRACT

**Introduction:** Long-term quality of life, return to work, economic consequences following Acute Respiratory Distress Syndrome (ARDS) are not well described in India. This study was aimed to address the question. **Methods:** A prospective cohort study of 109 ARDS survivors were followed up for a minimum of 6 months following discharge. Quality of life was assessed using the SF-36 questionnaire. Respiratory quality was assessed using the St Georges Respiratory Questionnaire. Time to return to work was documented. Costs-direct medical, as well as indirect were documented up to 6 months. **Results:** At 6 months, 6/109 (5.5%) had expired. Low energy/vitality and general heath were noted in the SF-36 scores at 6 months; overall a moderate quality of life. Pulmonary function tests had mostly normalized. Six-min walk distance was 77% of predicted. Respiratory quality of life was good. It took at the median of 111 days to go back Interquartile range (55–193.5) to work with 88% of previously employed going back to work. There were no significant differences in the severity of ARDS and any of these outcomes at 6 months. The average total cost from the societal perspective was ₹ 231,450 (standard deviation 146,430-, 387,300). There was a significant difference between the 3-ARDS severity groups and costs ($P < 0.01$). There were no independent predictors of return to work. **Conclusion:** ARDS survivors have low 6-month mortality. Pulmonary physiology and exercise capacity was mostly normal. Overall, quality of life is average was moderate, while respiratory quality of life was good. Return to work was excellent, while cost of care falls under a catastrophic heath expense.

**KEY WORDS:** Acute respiratory distress syndrome, quality of life, cost, return to work, cohort

**Address for correspondence:** Dr. Thambu David Sudarsanam, Department of Medicine, Christian Medical College, Vellore, Tamil Nadu, India.
E-mail: thambu@cmcvellore.ac.in

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## INTRODUCTION

Acute respiratory distress syndrome (ARDS) is seen in approximately 10.4% of intensive care unit (ICU) admissions both in the West[1] and India.[2] In-hospital mortality following ARDS is 40%; 35, 40, and 46% among mild, moderate, and severe ARDS.[1]

In India, infections are the most common cause for ARDS.[3] Early death following ARDS are caused by the underlying disease[4] while hospital-acquired pneumonia and sepsis later deaths.[5] There is some evidence of improved mortality reducing from 35% to 26% recently.[6] The elderly, those with cancer, immunosuppression and chronic liver disease have higher in-hospital mortality.[7-9] Some describe higher mortality associated with a hyper-inflammatory phenotype of ARDS.[10,11]

Those who survive ARDS may have long-term respiratory complications as well as non-respiratory medical morbidity. These include depression, anxiety, reduced autonomy, joblessness, and overall reduced quality of life.[12] Post-ARDS cognitive decline has ranged from 30% to 55%.[13-15] Depression and anxiety have been described in 36%–62%.[14] Posttraumatic stress disorder has also been well documented.[16] These have been known to persist up to 5 years.[17]

Reduced physical tolerance following ARDS has been documented; the 6-min walk distanced between 66% and 76% of predicted, 1 and 5 years after ARDS.[18] Nearly 20% will have obstructive or restriction spirometry findings on follow-up.[19] They tend to become normal in 6 months, while diffusing capacity may take up to 5 years.[18-20]

Quality of life after intensive care can be measured using validated instruments such as SF-36;[21] these have been described the general population[22,23] as well as those with illness in India.[23] Versions such as SF-12 and SF 6-D following ARDS have also been described. Respirator quality of life following ARDS in the same study used the St Georges Respiratory Questionnaire (SGRQ).[24]

Four subtypes based on physical and mental health have been described post-ARDS recovery at 6 months in the ARDS long-term outcome study cohort (ALTOS).[25] The family or caregivers can also be affected mentally, the postintensive care syndrome-family.[26]

Need for ventilation, long hospital stay, supportive care, and management of comorbidities add to a huge economic cost of ARDS; hospital costs, and direct fixed costs account for most of the total costs.[27] Among survivors more than 75% of those who were working prior to ARDS went back to work, while 17% could do house-hold work within 2-years.[18] However another study found that 1-year following discharge nearly 50% were unemployed following ARDS.[28] These add to the indirect costs to the society due to productivity loss.

Death a year after discharge was 41% in one cohort. Those who had comorbid illnesses or sent to another medical facility had higher probability of death.[29]

Long-term mortality (6 months), quality of life (general as well as respiratory), return to work, and cost following ARDS have not been well described in India. These were the aims of our study

## METHODS

This was a prospective, observational cohort study. The protocol was approved by the Institutional Review Board (IRB Min No. 11041 dated December 04, 2017). The study was funded by the Hospitals internal research fund. All patients were prospectively recruited between January 01, 2018 and April 30, 2019 and were followed up till October 2019.

This study was conducted in university teaching hospital in South India. We included adults 16 years or older, who had survived till hospital discharge following ARDS (defined by Berlin criteria),[30] willing for follow-up and from any neighboring state (to reduce lost to follow-up) Those who refused consent were not included. We too, k consecutive cases to limit selection bias; however we did have a few nonrespondents who were either very sick or not willing for follow-up.

The primary outcomes was 6-month mortality, time to return to work, quality of life both general (SF-36) and pulmonary (SGRQ), cost of illness including direct medical costs (hospital bill including medicines) as well as the indirect costs (wages lost during hospitalization as well as time to return to work). Spirometry and 6-min walk distance at 6 months were also studied. The SF 36 form used was developed by the RAND group as part of a medical outcomes study.

Comorbidities documented included diabetes, hypertension, dyslipidemia, smoking, obesity, and preexisting. All the data were collected in a study specific CRF. Some recall bias may have occurred while quality of life as this refers to the state of health just after illness. The data were collected from the patient or patient's relative if the patient was unable to furnish the necessary information by direct or telephonic interview.

Using a reduction in walking distance at the end of 6 months of 50 m with a standard deviation of 5 m and a precision of 1 m, we estimated sample of 100 subjects based on the prior cohort by Herridge *et al*.[31] Assuming 50% lost to follow-up, we planned to study 150 participants.

Data entry was done using Epidata version 3.1 software and then exported to SPSS Statistics for Windows, Version

17.0. Chicago: SPSS Inc. All baseline data that were categorical were described using numbers and percentages. Continuous data were described using mean and standard deviation. For skewed data median (interquartile range [IQR]) were used.

ANOVA statistics were used to compare the SF36 scores, SGRQ, time to return to work between mild, moderate and severe ARDS categories. Linear regression analysis was done to look for independent predictors of return to work.

## RESULTS

Of the 254 patients with ARDS admitted in the 3-month study period, 109/254 (40.9%) fulfilled the inclusion criteria and were alive at discharge. There were 22 mild, 50 moderate, and 37 severe cases of ARDS. Of the 109, 20 (7.9%) were lost to follow-up.

The mean age of patients in the study was 48 years; most were independent for all activities of daily living before the illness. Forty-one percent were financially lower middle class, 10% were underweight, while 35.5% were diabetics with a mean duration of the diabetes of 6.15 ± 6.18 years and mean HBA1C was 8.94 ± 1.88 [Supplementary Table 1].

The average duration of ICU and hospital stay was 7.5 and 16 days, respectively. The median duration of ventilation was 8 days. Forty-four percent received steroids during the course of the ARDS. Ninety-three of all patients had an infectious etiology for the ARDS; most common were pneumonia (44.7%) and scrub typhus (28.1%). Most patients had moderate severity of ARDS (46.4%).

Six patients (5%) had passed away in 6 months. These were 2 (9.1%), 3 (5.9%), and 1 (2.7%) among the mild, moderate, and severe category, respectively. One each had an acute coronary syndrome and a pulmonary embolism; 1 patient had a fall from stairs and later developed an intracranial bleed; 1 patient had a probable cerebrovascular accident with a hypertensive emergency. Another patient had a probable pneumonia 3 days after going home.

As shown in Supplementary Table 1, the quality of life 6 months after recovery from ARDS, the most affected domains were Vitality and General Health (65 or less) while other domains had 75 or more out of 100. There was no difference between the three ARDS categories with respect to these scores by the ANOVA.

The respiratory quality of life, however, was good (15.1 out of a possible 100 score) There was no difference between the three ARDS categories with respect to these scores (ANOVA $P = 0.276$).

The forced expiratory volume in 1 s (FEV1), forced vital capacity (FVC), and the FEV1/FVC ratios were more than 75% of predicted for all groups of ARDS severity at 6 months.

MMEF which indicates small airway involvement was more than 75% of predicted at 6 months in all ARDS groups. Reversibility on bronchodilator was 5% on average.

Of the impairments, according to the ATS guidelines, 47.7% were mild, 38.6% were moderate, 2.3% were severe, and 11.4% were very severe. Five patients were unable to do a spirometry at 6 months.

The mean distance walked was 415.9 ± 84.7 m [Supplementary Table 2]. The mean percentage of predicted distance walked in out cohort was 71.1%. The average distance saturation product was 400.6 ± 87.3.

The average hospital bill was ₹ 154,847 (101723-246635) with a pharmacy bill of ₹ 42,780 (27,070–87,080) and loss of ₹ 30,000 (10,000–60,000) in wages due to admission.) The average total cost of the hospital stay was ₹ 231,450. ANOVA suggested that the hospital bills were not different between groups, but the pharmacy bill was significantly more as severity of ARDS increased.

The median time (range) to return to work was 111 (11–559) days. Fifty-four of the 109 were working prior to illness; 88.9% of them returned to work within 6 months of illness. Including all 109 subjects, 37% had returned to work by 3 months, 65% by 6 months. Eight (88.9%), 18 (85.7%), and 22 (91.7%) among mild, moderate, and severe ARDS patients return to work at 6 months. There was no difference between the three groups with regard to return to work (ANOVA, $P = 0.136$). The linear regression model that included the etiology, ARDS severity, invasive/noninvasive ventilation, and alcohol use did not show any variable to independently predict return to work [Supplementary Table 3].

## DISCUSSION

Our study assessed clinical, economic, and quality of life of patients 6 months after surviving ARDS. Of the 109 ARDS hospital survivors, 5.5% expired in 6 months. Globally, ARDS mortality has reduced from 60% to 25% over the last 20 years.[32] However morbidity may last up to 5 years.[18]

Infection was the predominant etiology with many scrub typhus during the study period. This is similar to previous Indian ARDS data.[2,33] Comorbid illnesses are similar to other Indian data as well.[34] The median duration of ICU as well as total hospital stay of our cohort was shorter than a the Canadian cohort (47) days (reference); perhaps due to lower number of comorbidities and diseases such as scrub typhus which have a rapid resolution with appropriate antibiotics.

The level of independence for activities of daily living before illness was a predictor of mortality in a cohort study

from Taiwan.[29] Most of our patients were able to function independently before illness. Of the patients who were working prior to illness, 88.9% returned to work during the study follow-up with 37% having returned to work by 3 months and 65% by 6 months. The median time was 111 days; similar days for all severities of ARDS Herridge *et al*. found 32% of patients had returned by 6 months and 49% by 1 year.[35]

Most subjects could walk 70% of expected distance at 6 months. This compares to 64% in the Canadian cohort. An inverse relationship exists between duration of ICU stay and distance walked in the 6-min walk test at follow-up. The walk distance has been noted to improve until 1 year after illness and only mildly improve from then to 5 years. Although values for changes in the walk test which have clinical significance have been established in chronic obstructive pulmonary disease (COPD) and interstitial lung diseases, similar values are not available in ARDS.[36,37]

Lung function had recovered to a great degree among survivors by 6 months. This included small airway function, similar to the FEV1 75% of normal at 3 months and 80% by 6 months.[31] There was no significant difference in spirometry values between patients with different severity of ARDS. The spirometry outcomes have been correlated with impairment in the quality of life questionnaire on other studies.[38]

The quality of life domains on the SF-36 that were affected most affected at 6 months were vitality and general health. Loss of vitality or energy levels can affect productivity. Reduction on overall general health overall also suggests patients not feeling back to preillness overall well-being. Among ARDS survivors in the ALTOS cohort, which used the SF-36 to asses health-related quality, 40% reported a moderate degree of both mental and physical health impairment at 6 months.[25] The DACAPO cohort found more physical than mental domain being affected.[39]

Overall, the respiratory quality of life (SGRQ) was good. This correlates well with the spirometry suggesting reasonable lung function. In comparison to data from the OSCAR trial done in the UK[24] which had mean scores of 33, 46 and 22 in the symptoms, activity and impact domains, our scores were 19, 21, and 10, respectively. We cannot explain our lower scores; perhaps, Indian baseline respiratory scores are poor; we did not have baseline data for our patients. However, COPD patients in India in one study had much higher scores of 49.41 and 33, respectively.[40]

In a systematic review of 24 ARDS cohorts, baseline severity of disease did not predictor of quality of life or return to work.[41]

The average cost of care over 6 months for a survivor of ARDS was ₹231450. Most of the expenses (66%) were the hospital bills, whereas 18.5 and 13% were the medicine bill and wages lost, respectively. The cost for severe ARDS (INR 330,520 [195,470, 497,180]) was more than double that of mild ARDS (146,430 [98,960, 263,000]) This is similar to previous data.[27] Costs were different with varying severity of ARDS. The WHO defines catastrophic health expenditure as those whose costs are more than 40% of a family non subsistence income. In our population, 78% off households had an annual income of ₹ 2,059,092 which was less than the median costs of a single admission of ARDS.

Return to work, is an important outcomes for patients. Sadly, none of the variables we studied were able to predict this. Kamdar *et al.*, found that the number of co-morbidities, duration of mechanical ventilation and discharge to a health care facility predicted delayed return to work.[42]

The study limitations included a lack of baseline data on quality of life and spirometry as well as not assessing the impact on the family to study the post intensive care-family effect.

## CONCLUSIONS

ARDS survivors in our cohort had a 6-month mortality of 5% and residual morbidity in terms of spirometry abnormalities (38% restrictive) and a lower walking distance (415.9 m) than predicted (71%) in the 6-min walk test. 88.9% of all patients who were working prior to ARDS had returned to work by the end of the follow-up. Quality of life on SF 36 showed impairment in all domains, especially vitality and general health at 6 months. Respiratory quality of life on the SGRQ was good. The average total cost was ₹ 231,450, a catastrophic health expense.

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### Conflicts of interest
There are no conflicts of interest.

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## Supplementary Table 1: Baseline characteristics

| Characteristic | *n* (%) |
|---|---|
| Age, mean±SD | 47.39±14.99 |
| Gender (*n*=109) | |
| Male | 55 (50.5) |
| Female | 54 (49.5) |
| State of origin (*n*=109) | |
| Tamil Nadu | 80 (73.4) |
| Andhra Pradesh | 29 (26.6) |
| Karnataka | 0 |
| Kerala | 0 |
| Marital status (*n*=109) | |
| Married | 92 (84) |
| Unmarried | 11 (10) |
| Divorced | 2 (1.82) |
| Widowed | 4 (3.64) |
| Dependency (*n*=109) | |
| Independent for activities of daily living | 106 (97.2) |
| Dependent on relatives | 3 (2.8) |
| Needing professional care | 0 |
| Education of head (*n*=108) | |
| Illiterate | 4 (3.7) |
| Primary school certificate | 8 (7.4) |
| Middle | 19 (17.6) |
| High | 24 (22.2) |
| Intermediate or postgraduate | 32 (29.6) |
| Graduate | 17 (15.7) |
| Postgraduate | 4 (3.7) |
| Occupation of head (*n*=106) | |
| Unemployed | 3 (2.8) |
| Unskilled worker | 11 (10.3) |
| Semi-skilled worker | 14 (13.1) |
| Skilled worker | 17 (16) |
| Clerical/shop-owner/farmer | 32 (29.9) |
| Semi-professional | 17 (15.9) |
| Professional | 12 (11.2) |
| Family income per month (*n*=106) (₹) | |
| <2181 | 78 (73.6) |
| 2181-6477 | 21 (19.8) |
| 6478-10,795 | 27 (25.5) |
| 10,796-16,193 | 14 (13.2) |
| 16,194-21,591 | 13 (12.3) |
| 21,592-43,184 | 15 (14.1) |
| Above 43,184 | 9 (8.5) |
| Kuppuswamy class (*n*=106) | |
| Upper | 7 (6.6) |
| Upper middle | 26 (24.5) |
| Lower middle | 43 (40.5) |
| Upper lower | 29 (27.3) |
| Lower | 1 (0.9) |
| Salary of earning member (n=108), median (IQR) | $25^{th}$-$75^{th}$ ₹10,000 (6000-20,000) |
| Anthropometric data (n=81) | |
| Height (cm), mean±SD | 160.8±8.8 |
| Weight (kg), mean±SD | 65.6±16.3 |
| BMI (mean±SD), median | 25.4±6.1 |
| BMI category | |
| Underweight (<18.5) | 8 (9.8) |
| Normal (18.5-22.9) | 23 (28) |
| Overweight (23-34.9) | 12 (14.6) |
| Preobese (25-29.9) | 21 (26.6) |
| Obese type 1 (30-40) | 14 (17.1) |
| Obese type 2 (morbid obese) (40.1-50) | 3 (3.7) |
| Obese type 3 (super obese) (>50) | 0 |
| Comorbidities (*n*=109) | |
| None | 51 (47) |
| Diabetes mellitus | 39 (35.5) |
| Hypertension | 30 (27.7) |
| Dyslipidemia | 7 (6.3) |
| Coronary artery disease | 7 (6.4) |
| Valvular heart disease | 3 (2.73) |
| Previously diagnosed heart failure | 3 (2.73) |
| Chronic kidney disease | 2 (1.82) |
| Chronic liver disease | 1 (0.91) |
| Hypothyroidism | 7 (6.36) |
| Anemia requiring transfusions prior | 1 (0.91) |
| Past tuberculosis | 2 (1.82) |
| Past CVA | 0 |
| Atrial fibrillation | 3 (2.73) |
| Human immunodeficiency virus infection | 1 (0.91) |
| Systemic lupus erythematosis | 1 (0.91) |
| Rheumatoid arthritis | 1 (0.91) |
| Bronchial asthma | 2 (1.82) |
| Chronic obstructive pulmonary disease | 3 (2.73) |
| Pregnant during admission | 2 (1.82) |
| Past treatment for cancer | 1 (0.91) |
| Substance use | |
| Alcohol consumer | 21 (19.1) |
| Smoking | 19 (17.3) |
| Tobacco chewing | 4 (3.6) |
| Details of admission | |
| Duration of hospital stay (*n*=109) (days), mean±SD | 15.6±10.7 |
| Duration of ICU stay (*n*=94) (days), mean±SD | 7.47±5.7 |
| Type of ventilation | |
| Only noninvasive ventilation | 52 (47.3) |
| Invasive ventilation | 57 (52.7) |
| Duration of ventilation, median (IQR) | $25^{th}$-$75^{th}$ |
| Total days of ventilation | 8 (6-12) |
| Days of noninvasive ventilation | 3 (2-4) |
| Days of invasive ventilation | 6 (4-10) |
| Use of glucocorticoids | 49/109 (44.95) |
| Aetiologies of ARDS (*n*=109) | |
| Infection | 102 (93.6) |
| Noninfectious | 7 (6.4) |
| Type of infection (*n*=103) | |
| Pneumonia | 46/102 (44.7) |
| No organism isolated | 12/46 (26.1) |
| Influenza | 21/46 (45.7) |
| Ventilator associated pneumonia | 7/46 (15.2) |
| Staphylococcal pneumonia | 1/46 (2.1) |
| Burkholderia pseudomallei | 4/46 (8.7) |
| Burkholderia contaminensis | 1/46 (2.1) |
| Nonpneumonia | 56/102 (55.3) |
| Scrub typhus | 29/56 (51) |
| Urinary tract infections | 8/56 (13) |
| No focus found | 9/56 (16) |
| Dengue | 4/56 (6) |
| Leptospirosis | 1/56 (2) |
| Others | 7/56 (12) |
| Category | |
| 200-300 (mild) | 22 (20.0) |
| 100-200 (moderate) | 50 (46.4) |
| <100 (severe) | 37 (33.6) |

ARDS: Acute respiratory distress syndrome, IQR: Interquartile range, SD: Standard deviation, CVA: Cerebrovascular accident, BMI: Body mass index, ICU: Intensive care unit

## Supplementary Table 2: Six-month outcomes of general and respiratory quality of life, costs, and pulmonary function tests

| Variables | Overall | ARDS | | | *P* |
|---|---|---|---|---|---|
| | | Severe (≤100) (*n*=36) | Moderate (100-200) (*n*=52) | Mild (>200) (*n*=21) | |
| St Georges Respiratory Questionnaire | | | | | |
| Symptoms, median (IQR) | 13 (6-35) | 7 (6-35) | 15 (7-30) | 13 (7-41) | 0.24 |
| Activity, median (IQR) | 17 (0-36) | 21 (0-41) | 14 (0-32.5) | 12 (0-48) | 0.69 |
| Impact, mean±SD* | 10±16 | 9.1±15.53 | 8±11.6 | 16.3±23.3 | 0.40 |
| Total | 7 (2.5-24.5) | 8 (1-24) | 7 (3-18.5) | 12 (3-42) | 0.73 |
| SF-36 | | | | | |
| Physical function | 85 (60-95) | 85 (50-95) | 85 (60-95) | 80 (50-95) | 0.76 |
| Physical role | 100 (50-100) | 100 (0-100) | 100 (50-100) | 100 (75-100) | 0.69 |
| Emotional role | 100 (100-100) | 100 (68-100) | 100 (100-100) | 100 (70-100) | 0.10 |
| Vitality | 65 (50-80) | 70 (50-80) | 70 (55-80) | 60 (45-80) | 0.72 |
| Mean health | 80 (64-92) | 76 (60-92) | 84 (72-92) | 72 (64-84) | 0.19 |
| Social role | 100 (75-100) | 100 (75-100) | 100 (75-100) | 88 (75-100) | 0.71 |
| Body pain | 100 (68-100) | 100 (68-100) | 100 (68-100) | 80 (68-100) | 0.32 |
| General health | 70 (50-80) | 65 (50-85) | 70 (55-75) | 55 (45-75) | 0.65 |
| Economic outcomes | | | | | |
| Total cost in 1000 (INR) | 231.45 (146.43-387.3) | 330.52 (195.47-497.18) | 206.5 (145.37-374.51) | 146.43 (98.96-263) | <0.001 |
| Days to return to work, median (IQR) | 111 (55-193.5) | 165 (59-225) | 107.5 (42.5-149.5) | 91 (23-170) | 0.22 |
| Lung functions | | | | | |
| MMEF percentage predicted | 78 (51-94) | 83 (59-90) | 77.5 (40.5-94.5) | 80 (61-86) | 0.93 |
| MMEF, median (IQR) | 2.62 (1.56-3.49) | 3.11 (1.88-3.68) | 2.49 (1.16-3.5) | 2.6 (1.96-3.04) | 0.52 |
| FEV1 percentage predicted | 82.5 (67-93) | 86 (72-93) | 82 (59-91) | 83.5 (68-95) | 0.46 |
| FEV1, median (IQR) | 1.93 (1.55-2.67) | 2.46 (1.56-2.76) | 1.86 (1.46-2.46) | 1.91 (1.62-2.55) | 0.45 |
| FEV1/FVC percentage predicted | 83 (80-88) | 82 (77-85) | 84 (80-89) | 82.5 (80-87) | 0.42 |
| 6 min walk distance (m) | 421.5 (360-478) | 449.5 (383-509.5) | 390 (346-465) | 430 (367-474) | 0.09 |

*The median value for impact was zero and hence the mean is reported. ARDS: Acute respiratory distress syndrome, IQR: Interquartile range, SD: Standard deviation, INR: Indian rupees, FVC: Forced vital capacity, MMEF: Mid maximal expiratory flow, FEV1: Forced expiratory volume in 1 s

## Supplementary Table 3: Independent predictors of the time to return to work

| Daysreturn_t | *b* | Std. Error | *t* | *P*>\|*t*\| | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| Etiology | 1.477876 | 0.3333818 | 1.73 | 0.091 | 0.9374087 | 2.329954 |
| Ards_rec | | | | | | |
| <=100 | 1.847342 | 0.7635859 | 1.48 | 0.145 | 0.8021882 | 4.254205 |
| 100-200 | 1.315748 | 0.5288743 | 0.68 | 0.499 | 0.5846296 | 2.053216 |
| Mechvent | 1.159333 | 0.3283471 | 0.52 | 0.604 | 0.6546083 | 2.355328 |
| Alcohol | 1.189163 | 0.4027141 | 0.51 | 0.612 | 0.6003876 | 2.355332 |
| _Cons | 31.69956 | 17.13943 | 6.39 | 0.000 | 10.64573 | 94.39108 |