Reduced Quality of Life in Survivors of Acute Respiratory Distress Syndrome Compared With Critically Ill Control Patients

**Context** Health-related quality of life (HRQL) is reduced in patients who survive acute respiratory distress (ARDS), but whether this decline in HRQL is caused by ARDS or other aspects of the patient’s illness or injury is unknown.

**Objective** To determine if there are differences in the HRQL of ARDS survivors and comparably ill or injured controls without ARDS.

**Design** Prospective, matched, parallel cohort study.

**Setting** A 411-bed municipal medical and regional level I trauma center.

**Patients** Seventy-three pairs of ARDS survivors and severity-matched controls with the clinical risk factors for ARDS of sepsis and trauma admitted between January 1, 1994, and July 30, 1996.

**Main Outcome Measures** The HRQL of ARDS survivors and controls, assessed by generic and pulmonary disease–specific HRQL instruments (Medical Outcomes Study 36-Item Short Form Health Survey, Standard Form [SF-36] and St George’s Respiratory Questionnaire [SGRQ], respectively).

**Results** Clinically meaningful and statistically significant reductions in HRQL scores of ARDS survivors (n = 73) were seen in 7 of 8 SF-36 domains and 3 of 3 SGRQ domains compared with matched controls (P < .001 for all reductions). The largest decrements in the HRQL were seen in physical function and pulmonary symptoms and limitations. Analysis of trauma-matched pairs (n = 46) revealed significant reductions in 7 of 8 SF-36 domains (P < .02) and 3 of 3 SGRQ domains (P < .003). Analysis of sepsis-matched pairs (n = 27) revealed significant reductions in 6 of 8 SF-36 domains (P < .05) and 3 of 3 SGRQ domains (P < .002).

**Conclusions** Survivors of ARDS have a clinically significant reduction in HRQL that appears to be caused exclusively by ARDS and its sequelae. Reductions were primarily noted in physical functioning and pulmonary disease–specific domains.

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mize the long-term morbidity associated with ARDS.

METHODS

Subjects
As part of an ongoing ARDS Specialized Center of Research program, all intensive care unit (ICU) patients at Harborview Medical Center, Seattle, Wash, are prospectively screened daily to identify patients with ARDS or acute lung injury. Harborview Medical Center is a 411-bed municipal medical center with 38 critical care beds and the only level I trauma center in a 4-state area. For the purpose of this study, we selected all ARDS survivors with either trauma or sepsis as their clinical risk factor for ARDS who were admitted between January 1994 and July 1996. We used the clinical definition of ARDS used previously at our center,211 defined as: (1) diffuse bilateral pulmonary infiltrates involving more than 50% of at least 3 lung quadrants, (2) a PaO₂/FIO₂ ratio of less than 150 mm Hg, or (3) PaO₂/FIO₂ of less than 200 mm Hg with positive end expiratory pressure of 5 cm H₂O or more and (4) a pulmonary capillary wedge pressure of 18 mm Hg or less, or (5) if pulmonary capillary wedge pressure was not available, no clinical evidence of congestive heart failure.

We used previously published definitions of both trauma and sepsis as clinical risk factors for ARDS.11 Sepsis was defined as any 2 of the following: temperature higher than 39°C, white blood cell count of 12.0 × 10⁹/L (12 000/dL) or more, 20% or more band forms, or a known or strongly suspected source of infection. In addition, 1 of the following findings had to be present with no alternative explanation: anion gap of more than 20 mmol/L or base deficit greater than 5 mmol/L, systemic vascular resistance of less than 800 dyne/s per square centimeter, or systolic blood pressure of less than 90 mm Hg for more than 2 hours. Trauma was defined as 1 of the following: (1) fracture of 2 or more major long bones, (2) unstable pelvic fracture, (3) 1 major long bone and a stable pelvic fracture, (4) thoracic trauma including pulmonary contusion, (5) blunt abdominal trauma with liver, spleen, or bowel injury, (6) penetrating injuries (gunshot wound or stabbing), or (7) massive transfusion (≥15 U/24 h) associated with trauma.

Given that ARDS survivors with severe head injuries would be less likely to be able to participate in the HRQL telephone interview, patients with a Head-Abbreviated Injury Score12 of 4 or higher were excluded from study participation. Other exclusion criteria included age younger than 14 years, severe developmental disabilities, and nonfluency in English.

Controls
Our goal was to identify patients with a similar severity of illness to ARDS patients in all respects with the exception of ARDS. Controls consisted of patients admitted to the ICU with a diagnosis of trauma or sepsis. Trauma controls were identified through the Harborview Medical Center Trauma Registry13 and were included as potential controls if they were admitted to the ICU between January 1994 and December 1996 and were discharged alive from the hospital. The sepsis controls were identified from the screening logs of 3 sepsis studies (December 1989 to December 1997) at Harborview Medical Center and verified through chart review. The potential sepsis controls met a common definition of sepsis. The definition of sepsis included having all 4 of the following criteria: (1) temperature of 39°C or higher or of 35.5°C or less, (2) heart rate of 90/min or more, (3) respiratory rate of more than 20/min or ventilation of more than 10 L/min, and (4) a known or strongly suspected source of infection. In addition, sepsis controls met 1 of the following indicators of organ failure within 48 hours of meeting the above criteria: (1) ongoing metabolic acidosis with an anion gap of more than 20 mmol/L or base deficit of more than 5 mmol/L, (2) systemic vascular resistance of less than 800 dynes/s per square centimeter, (3) unexplained hypotension with a systolic blood pressure of 90 mm Hg or less for more than 2 hours or vasopressor use, (4) platelet count of less than 81 × 10⁹/L (81 000/mm³), (5) urine output of less than 0.5 mL/kg per hour or 30 mL/h or less, (6) PaO₂ of less than 70 mm Hg on room air or PaO₂/FIO₂ of less than 333 mm Hg, or (7) an alteration in mental status of 2 or more points from baseline in the Glasgow coma scale. The exclusion criteria for the control groups were identical to that of ARDS survivors.

Study Design
This was a prospective, matched, parallel cohort study. The ARDS survivors were matched in a 1-to-1 fashion with comparably ill or injured controls. The ARDS survivors with trauma as their clinical risk factor were matched to trauma controls by injury severity score14 within 5 points and date of injury within 12 months. The ARDS sepsis survivors were matched to controls by Acute Physiology and Chronic Health Evaluation (APACHE) III15 score within 15 points and date of illness within 12 months.

Patients and controls were initially contacted by a letter from their hospital attending physician, which stated that the attending physician had allowed the study coordinator to contact the patient. Potential patients were contacted by the investigators in writing and then by telephone regarding participation. All HRQL questionnaires were administered by telephone in an interviewer-administered format. All interviews were done by a single investigator (T.A.D.) who received instruction in administering HRQL questionnaires. The interviewer was not formally blinded to ARDS or control status of each subject. The study procedures were approved by the University of Washington Human Subjects Committee.

Subject Enrollment
A total of 222 patients with ARDS were discharged alive from the hospital during the study period. Of these ARDS survivors, 145 subjects (65%) had an ARDS clinical risk factor of trauma or sepsis. A total of 102 of these ARDS survivors with trauma or sepsis were eligible for the study. Reasons for study

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exclusion are listed in **Figure 1.** Of the eligible 102 patients, 80 (78%) were contacted by telephone. A total of 77 (75%) of 102 eligible ARDS survivors were enrolled and completed quality-of-life questionnaires (Figure 1). Matched controls were obtained for 73 (95%) of 77 ARDS survivors. The 4 ARDS survivors for whom matched controls were not available had sepsis as their ARDS clinical risk factor.

**Questionnaires**

The interview consisted of administering the Medical Outcomes Study 36-Item Short Form Health Survey, Standard Form (SF-36) and the St George’s Respiratory Questionnaire (SGRQ). The SF-36 is a brief, 36-item, generic HRQL questionnaire that has been shown to be reliable and valid in a wide range of acute and chronic diseases and shown to be responsive to small but important changes in HRQL. The results are grouped into 8 domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. Scores range from 0 to 100 with a lower score indicating better HRQL. A 4-point change in the SGRQ has been determined to be a clinically meaningful difference. The SGRQ is a 76-item pulmonary disease–specific HRQL questionnaire with well-demonstrated reliability and validity in patients with chronic lung diseases including chronic obstructive pulmonary disease, asthma, and bronchiectasis. The SGRQ results are grouped into 3 domains (symptoms, activity, and impacts) and a total score. Scores range from 0 to 100 with a lower score indicating better pulmonary-specific HRQL. A 4-point change in the SGRQ has been determined to be a clinically meaningful difference. Questionnaires were administered a median of 23 months following hospital admission for ARDS patients and 25 months following hospital admission for controls.

**Statistical Analysis**

Since ARDS survivors were matched to comparably ill or injured controls, the ARDS-control pair was the unit of analysis for statistical testing. Descriptive and severity of illness measures of ARDS survivors and matched controls were compared using Wilcoxon rank tests for matched pairs for continuous variables and $\chi^2$ tests for categorical variables. Mean values for the SF-36 and the SGRQ scales were compared using paired $t$ tests. Differences in HRQL between ARDS trauma patients and ARDS sepsis patients were tested using unpaired $t$ tests. Because there was a trend toward statistically significant differences in age between ARDS patients and controls in an unpaired analysis, we used linear regression to assess the effect of age on the differences in HRQL between cases and controls. There were no important differences in the results using this approach and the unadjusted paired analyses are shown. These tests were 2-sided and considered significant if $P<.05$.

To further explore the influence of comorbid diseases that patients may have had prior to admission to the ICU, we performed additional linear regression modeling. We used the physical functioning scale of the SF-36 and the SGRQ total score as outcome variables in 2 separate linear regression models. Comorbid illnesses (Table 1) were placed into the models along with age, sex, and the acute physiology score (from APACHE III) and then the cohort group (ARDS or control) was allowed to enter the model. The effect of the diagnosis of ARDS was considered significant if the regression coefficient associated with the diagnosis was statistically significant at $P<.05$.

### Table 1. Characteristics of Acute Respiratory Distress Syndrome Survivors and Critically Ill or Injured Controls Matched for Severity of Illness

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Acute Respiratory Distress Syndrome Survivors</th>
<th>Matched Controls</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), y</td>
<td>40.6 (15-81)</td>
<td>39.2 (18-75)</td>
<td>.07†</td>
</tr>
<tr>
<td>Severity of illness†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Physiology and Chronic Health Evaluation III15 in sepsis patients, median (range)‡</td>
<td>66 (27-109)</td>
<td>61 (28-106)</td>
<td>.08‡</td>
</tr>
<tr>
<td>Injury Severity Score in trauma patients, median (range)§</td>
<td>24 (4-43)</td>
<td>25 (4-43)</td>
<td>.65‡</td>
</tr>
<tr>
<td>≥1 Comorbid disease†</td>
<td>15 (21)</td>
<td>9 (12)</td>
<td>.18†</td>
</tr>
<tr>
<td>Comorbid diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>5 (7)</td>
<td>6 (8)</td>
<td>.75</td>
</tr>
<tr>
<td>Cirrhosis or hepatic failure</td>
<td>6 (8)</td>
<td>0 (3)</td>
<td>.01</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3 (4)</td>
<td>1 (1)</td>
<td>.31</td>
</tr>
<tr>
<td>Acquired immunodeficiency syndrome or immune suppressed</td>
<td>1 (1)</td>
<td>3 (4)</td>
<td>.31</td>
</tr>
<tr>
<td>Diabetes with end-stage complications</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Connective tissue disease</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>&gt;.99</td>
</tr>
</tbody>
</table>

†Values are number (percentage) unless otherwise indicated.
‡The number of pairs is 73.
§Values were calculated using the Wilcoxon signed rank test.
¶The number of pairs is 27.
$\chi^2$ test.

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There were 77 patients with ARDS, of whom 73 had severity of illness–matched controls. No significant differences were noted regarding age, APACHE III score, injury severity score, number of comorbid diseases, or specific comorbid diseases between ARDS survivors and matched controls (Table 1). Survivors of ARDS had a significantly longer median hospital length of stay (29 days) compared with matched controls (19 days) (P < .001). After examining all 77 ARDS survivors (those with and without matched controls), clinically meaningful reductions in the HRQL questionnaires were noted in all 8 SF-36 health domains (with a difference in scores ranging from 11 to 48 points per domain) and all 3 SGRQ domains compared with previously published population norms (differences ranging from 13 to 33 points per domain) (Table 2). The magnitude of decrements in the HRQL scores was largest in domains assessing physical activities and exceeded the minimal clinically meaningful difference of 5 points in all 8 domains of the SF-36 and of 4 points in all 3 of the domains of the SGRQ.

When compared with the severity-matched critically ill controls, being an ARDS survivor was associated with statistically significant reductions in the following 7 of 8 SF-36 domains: physical functioning, role-physical, bodily pain, general health, vitality, social function, and mental health (with a difference in score ranging from 6 to 24 points per domain) (Table 2). These reductions exceeded the minimal clinically meaningful difference of 5 points for all of these 7 domains. A nonstatistically significant reduction of 6 points in the role-emotional domain score was noted in survivors of ARDS compared with the matched controls. Likewise, being an ARDS survivor was associated with statistically worse pulmonary disease–specific HRQL for all 3 domains of the SGRQ compared with comparably ill or injured controls and these differences were greater than the clinically significant difference of 4 points for all 3 domains.

The subgroup comparison of the ARDS sepsis patients with the sepsis-control group revealed statistically significant and clinically meaningful reductions in 6 of 8 SF-36 domains (Table 3).
Only the role-emotional and mental health domains did not show significant differences between the ARDS sepsis and sepsis control group. Additionally, being an ARDS survivor was associated with statistically and clinically significant reductions for all 3 domains of the SGRQ. In a comparison of the ARDS trauma with the trauma control group, statistically significant and clinically meaningful reductions in SF-36 domain scores were noted in 7 of 8 domains for the ARDS trauma patients (Table 3). Once again, the reduction seen in the role-emotional score was not statistically significant. Statistically and clinically significant reductions of all 3 of the pulmonary disease–specific SGRQ domains were noted for the comparison of ARDS trauma and trauma controls.

The ARDS survivors who had sepsis as their risk factor for ARDS (n = 31) had worse HRQL scores for all domains of the SF-36 (Figure 2) and the SGRQ compared with ARDS survivors with trauma as their risk factor (n = 46) (Figure 3). These differences reached statistical and clinical significance for 3 of 8 domains of the SF-36 (physical functioning, general health, and vitality) and all 3 domains of the SGRQ (Table 4). Interestingly, despite these differences between the 2 ARDS groups, the incremental difference between ARDS and control patients was similar in the sepsis and trauma subgroups (Table 3).

To address the observed difference in the length of hospital stay between ARDS cases and matched controls, we examined whether prolonged mechanical ventilation or extended length of hospitalization was associated with HRQL among the survivors of ARDS. No significant differences were noted in 7 of 8 SF-36 and 3 of 3 SGRQ domains between ARDS survivors ventilated for 14 days or less (n = 47) or for more than 14 days (n = 30), and hospitalized for 21 days or less (n = 28) or for more than 21 days (n = 49). The ARDS survivors hospitalized for more than 21 days had a significantly worse physical functioning domain score than those hospitalized for 21 days or less (mean ± SD, 56.1 ± 25.5 vs 72.6 ± 21.8; P = .006).

To further explore the influence of comorbid diseases prior to admission to the ICU, we used linear regression modeling (as described in the “Methods” section). The physical functioning scale of the SF-36 and the total score of the SGRQ were used as outcome variables in 2 separate models to examine whether comorbid disease prior to ICU admission may have explained the differences in HRQL between the ARDS survivors and matched controls. After controlling for age, the acute physiology score, and the comorbid diseases listed in Table 1, the diagnosis of ARDS remained a significant predictor of HRQL as measured by the physical functioning scale of the SF-36 (P < .001) and the total score of the SGRQ (P < .001). Furthermore, if the variables for ARDS survivors vs controls were placed in the model first, the regression coefficient for ARDS survivors vs controls did not change substantially when the comorbid diseases were subsequently placed in the model.

**COMMENT**

This prospective, matched-parallel cohort study of 73 ARDS patients and 73 matched controls demonstrates that the survivors of ARDS had statistically significant and clinically meaningful reductions in generic and pulmonary disease–specific HRQL compared with comparably ill or injured patients without ARDS. While the type of the HRQL deficits were wide-ranging, affecting physical, emotional, and social aspects of ARDS survivors’ lives, the reductions in SF-36 scores were the most pronounced in domains that assess physi-
cal limitations and the effect of these limitations on one’s ability to perform specific roles in society. Only the role-emotional domain, which assesses the effect of emotional problems on one’s ability to perform societal roles, was not significantly lower in the ARDS survivors compared with matched controls. The role-emotional domain is considered to be the least sensitive of the 8 SF-36 domains, making it difficult to detect small differences in this area.

The pulmonary disease-specific HRQL of ARDS survivors was worse in all 3 domains of the SGRQ compared with comparably ill or injured controls. The domain scores that assess pulmonary symptoms (cough and dyspnea) and activity (extent to which symptoms limit daily activities) had the largest reduction compared with matched controls while the domain measuring the impact of disease on patients’ social and emotional lives did not show as large an effect. These findings suggest that the largest effect on HRQL of ARDS and its sequelae are in physical functioning and pulmonary symptoms and limitations.

Comparison of the ARDS patients with sepsis to ARDS patients with trauma revealed that patients with sepsis-induced ARDS had more severe reductions in generic and pulmonary disease-specific HRQL than trauma-induced ARDS patients. A potential explanation for this observation is that sepsis patients had more comorbid disease than trauma patients (data not shown). Since we did not assess HRQL prior to the development of the illness or injury leading to ARDS, we cannot determine how much of the difference in HRQL in ARDS sepsis patients vs ARDS trauma patients was due to the severity of the acute illness and how much was due to premorbid HRQL. Prior studies of HRQL following ICU care support the hypothesis that patients’ premorbid HRQL has a large effect on their HRQL after a critical illness. Regardless of the reason for this difference, future research assessing the HRQL of patients after ARDS, in clinical and cost-effectiveness studies, should account for these differences across ARDS risk groups.

Four prior studies have assessed HRQL in survivors of ARDS. In 2 of these studies, patients were followed up in a prospective manner and found that HRQL in ARDS survivors improves within the first 3 to 6 months and then stabilizes at a level significantly below that of the general population. The other 2 studies assessed patients at a median of 13 and 48 months after lung injury and found a reduction in SF-36 scores compared with published population norms. Like our study, 3 of 4 prior studies used the SF-36 in addition to other questionnaires to assess generic HRQL. Our study found similar reductions in the SF-36 scores when ARDS survivors were compared with population norms, as identified in these other studies. However, our study is the first to use the SGRQ in this patient population.

The major strength of this study is that it is the first to compare the HRQL of ARDS survivors with comparably ill or injured controls without ARDS. Our study design has minimized the chance that observed reductions in HRQL are due to factors such as comorbid disease and/or severity of trauma or illness and maximized the chance that the reductions are due to ARDS and its sequelae. We considered it to be important not to control for duration of mechanical ventilation or duration of hospital stay since these factors could have been part of the causal pathway for how ARDS and its sequelae affect HRQL. Interestingly, we found little statistically significant effect of duration of mechanical ventilation or hospital stay on HRQL in ARDS survivors. Similarly, we did not control for complications that might arise during an ICU stay, such as neuromyopathy, because these complications may be part of the mechanism by which ARDS reduces HRQL. If therapies are developed that could prevent or cure ARDS and thereby eliminate these sequelae, controlling for these sequelae in our analyses would underestimate the potential effect of these interventions. Since we prospectively screened all cases of ARDS, our data are representative of all survivors of ARDS due to sepsis or trauma at our institution. Another strength of this study is that it is the first to use a pulmonary disease-specific HRQL questionnaire with ARDS survivors. The SGRQ may be more sensitive to the changes in the HRQL of ARDS sepsis patients vs ARDS trauma patients, since it detected significant differences in 3 of 3 SGRQ domains whereas the SF-36 only detected differences in 3 of 8 domains. The SGRQ results also support the assertion that patients’ premorbid HRQL has a large effect on their HRQL after a critical illness.

<table>
<thead>
<tr>
<th>SGRQ Results for Sepsis- and Trauma-Induced Acute Respiratory Distress Syndrome (ARDS) Survivors Matched for Severity and Timing of Illness*</th>
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</thead>
<tbody>
<tr>
<td><strong>Table 4. Short Form 36 and St George’s Respiratory Questionnaire Results for Sepsis- and Trauma-Induced Acute Respiratory Distress Syndrome (ARDS) Survivors Matched for Severity and Timing of Illness</strong></td>
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<tr>
<td><strong>Sepsis ARDS Cases (n = 31)</strong></td>
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<tr>
<td>---------------------------------</td>
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<tr>
<td><strong>Short Form 36‡</strong></td>
</tr>
<tr>
<td>Physical functioning</td>
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<tr>
<td>Role-physical</td>
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<tr>
<td>Bodily pain</td>
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<tr>
<td>General health</td>
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<td>Vitality</td>
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<td>Social functioning</td>
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<tr>
<td>Role-emotional</td>
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<tr>
<td>Mental health</td>
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<tr>
<td><strong>St George’s Respiratory Questionnaire§</strong></td>
</tr>
<tr>
<td>Symptoms</td>
</tr>
<tr>
<td>Activity</td>
</tr>
<tr>
<td>Impacts</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

*Values are expressed as mean ± SD. †P values were calculated using the unpaired t test comparing ARDS trauma cases vs ARDS sepsis cases. ‡Higher score denotes better health-related quality of life. §Lower score denotes better health-related quality of life. ††Values indicate total average overall.

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that pulmonary disease limitations following ARDS may be contributing significantly to overall reductions in HRQL caused by this syndrome.

A potential limitation of this study was its inability to assess the baseline HRQL of patients prior to the development of ARDS. In an attempt to minimize this potential limitation, ARDS survivors were matched to comparably ill or injured controls without ARDS. Although we used state-of-the-art severity-of-illness measures to match ARDS patients to controls, it is possible that some component of the observed reduction noted in HRQL in ARDS survivors was due to residual confounding by severity of disease. However, it seems unlikely that the observed difference of 5 points in the APACHE III score between the 2 groups accounts for the large difference observed in HRQL. Another possible limitation was that our definitions of sepsis were slightly different for the ARDS separation was that our definitions of sepsis served in HRQL. Another possible limitation of this study was not formally blinded to whether patients were ARDS survivors or matched controls. While this could influence the results, established HRQL instruments were used and the interviewer administered each instrument in a standardized manner.

Our results suggest that ARDS survivors have a significant burden of illness due to the development and sequelae of ARDS and not due to duration of mechanical ventilation or hospital stay. This burden of illness was manifested as worse generic and pulmonary disease–specific HRQL scores when compared with matched critically ill control patients. This difference achieved clinical as well as statistical significance and was most prominent in physical functioning and pulmonary disease–specific limitations. The implication of these findings is that therapy designed to decrease the severity of ARDS may result in important improvements in the long-term quality of life for ARDS survivors. If future therapeutic trials in patients with ARDS measure quality-of-life outcomes, this hypothesis could be tested. Finally, data from this report about the health status of ARDS survivors may be useful in cost-effectiveness analyses of ARDS prevention and treatment.

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