Research article

Airway complications in traumatic lower cervical spinal cord injury: A retrospective study

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Objective: To investigate risk factors for pneumonia in patients with traumatic lower cervical spinal cord injury.
Design: Observational study, retrospective study.

Setting: Spinal cord unit in a maximum care hospital.

Methods: Thirty-seven patients with acute isolated traumatic spinal cord injury at levels C4–C8 and complete motor function injury (AIS A, B) treated from 2004 to 2010 met the criteria for inclusion in our retrospective analysis. The following parameters were considered: ventilation-specific parameters, re-intubation, creation of a tracheostomy, pneumonia, antibiotic treatment, and length of intensive care unit (ICU) stay and total hospitalization.

Results: Among the patients, 81% had primary invasive ventilation. In 78% of cases a tracheostomy was created; 3% of these cases were discharged with invasive ventilation and 28% with a tracheostomy without ventilation. Pneumonia according to Centers for Disease Control criteria occurred in 51% of cases within 21 ± 32 days of injury, and in 3% at a later date. The number of pre-existing conditions was significantly associated with pneumonia. Length of ICU stay was 25 ± 34 days, and average total hospital duration was 230 ± 144 days. Significant factors affecting the duration of ventilation were the number of pre-existing conditions and tetraplegia-specific complications.

Conclusions: Our results confirm that patients with traumatic lower cervical spinal cord injuries defined by lesion level and AIS constitute a homogeneous group. This group is characterized by a high rate of pneumonia during the first 4 weeks after injury. The number of pre-existing general conditions and spinal injury-specific comorbidities are the only risk factors identified for the development of pneumonia and/or duration of ventilation.

Keywords: Lower cervical spinal cord injury, Acute tetraplegia, Airway complications, Pneumonia, Airway management

Introduction

Patients with cervical spinal cord injury (cSCI) are differentiated into high and low cervical level^{1,2} and into motor complete and incomplete SCI¹ because these factors determine the rate of respiratory failure and respiratory complications. In this work, we focused on patients with lower cSCI (lcSCI) defined as lesions at levels C4–C8, and with complete motor SCI, corresponding to the American Spinal Injury Association (ASIA) Impairment Scale (AIS) A or B. These patients have complete failure of intercostal and abdominal muscles. Breathing is mainly controlled by the diaphragm and the cervical

accessory respiratory muscles. Therefore, patients with this type of injury present with hypoventilation, decreased tidal volume with pulmonary hypoventilation, deterioration of gas exchange, and incompetent insufficient coughing, rendering these patients susceptible to atelectasis and pulmonary infections.

Airway management in cSCI continues to be controversial. There is still insufficient evidence to establish valid guidelines, and only a few publications on single-center concepts exist. Weaning and treatment measures have been shown to influence pulmonary complications.^{3–5} They include the indication for primary intubation,^{6–8} attempts at extubation,^{8–10} tracheostomy,^{7,11,12} weaning, and therapeutic measures to combat pulmonary complications.^{3–5}

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Healthcare-associated infections may be caused by infectious agents from endogenous or exogenous sources.¹³ Thus, pneumonia is one of the most common pulmonary complications in cSCI and has various causes. Ventilator-associated pneumonia increases proportionally to the duration of intubation¹⁴ and is associated with increased mortality,¹⁵ but also with increased treatment costs.^{15–18} Noteworthy, cSCI pneumonia and atelectasis are the most common complications during the first 5 days after the accident.¹⁷ Overall, the incidence of respiratory complications in the acute phase is up to 80%.^{2,5,6,17,19,20} The rate of respiratory complications varies with the degree of motor deterioration^{1,16,19,21,22} and the anatomical and neurological level of SCI.^{1,2,19} The mortality rate is up to 3.5% and increases with age^{1,5,21,22} and pre-existing morbidity.^{1,21}

The goal of this retrospective study was to define a baseline for patients with airway complications associated with lSCI during the first inpatient treatment. Our analysis is based on patients with SCIs treated at a single center specializing in the treatment of SCIs from 2004 to 2010.

Methods

Subjects

Patients with lSCI treated in the Trauma Hospital Berlin (Unfallkrankenhaus Berlin) from 2004 to 2010 were included in our retrospective analysis. Inclusion criteria were acute isolated traumatic SCI with a neurological level of C4–C8 and complete motor function loss as well as an indication for spinal surgery. The ASIA Impairment Scale (AIS) adapted to the 2011 revision of the International Standards for Neurological Classification of Spinal Cord Injury was used for classifying patients.²³ Exclusion criteria were multiple spinal cord lesions, central cord syndrome, Brown-Séquard syndrome, anterior cord syndrome, history of head injury or cerebral stroke, and the presence of any unstable medical or psychiatric conditions. Details of

the neurological classification and criteria are summarized in Table 1.

Treatment protocol and analysis

The patients included in the present analysis were treated according to an interdisciplinary acute trauma protocol established by our hospital for the management of spinal injuries. All patients included in our retrospective analysis had spinal surgery within the first 6 hours. This means that all patients were intubated, either because of their respiratory status or for surgery. In addition, all patients were treated with anesthetic medication. In the acute phase with respiratory insufficiency, patients were administered opiates, benzodiazepines, and muscle relaxants. In the subacute phase, opiates, benzodiazepines, and analgesics were given. To prevent delirium, opiates and benzodiazepines were tapered to a minimum dose using standardized regimens before termination.

Steroids were administered according to the following scheme: 30 mg/kg body weight methylprednisolone as a bolus over 15 minutes within the first hour of injury, followed by continuous administration of 5.4 mg/kg per hour for the period from 2 to 24 hours after injury.

In the acute phase of injury, we started with rapid weaning in the intensive care unit (ICU). Before the first extubation attempt, patients had to meet the criteria presented in Table 2. Using the criteria of Seidl *et al.*,⁷ we performed tracheostomy when accompanying injuries, illnesses, complex cervical spine trauma, or a combined surgical approach required extended weaning for more than 4 days.

In the subacute phase, patients with unsuccessful rapid weaning were subjected to discontinuous weaning at daytime and, if successful, followed by night-time weaning under capnometry monitoring and arterial blood gas analysis. Weaning was started in the ICU or in a peripheral ward using mobile home care ventilation. The weaning protocols were screened by medical doctors.

Table 1 Neurological characteristics of the study population

	N	AIS A	AIS B
NL C4	12	10	2
NL C5	16	6	10
NL C6	7	5	2
NL C7	2	1	1
NL C8	0	0	0
Motor score (mean ± SD)	37	15 ± 12	24 ± 11
Sensory score (mean ± SD)	37	26 ± 14	40 ± 25

NL, neurological level; AIS, ASIA Impairment Scale; Motor score = maximum of 100 points; Sensory points = pin prick score + light touch score = maximum of 224 points.

Table 2 Criteria for first extubation

Breathing parameters	Airway clearance
Spontaneous breathing	Assisted removal of mucus $\leq 3\times$ per day
Average tidal volume > 300 ml	Patient is able to expectorate mucus
Respiratory rate $< 15/\text{min}$	
Vital capacity ≥ 1000 ml	
$\text{FiO}_2 \leq 35\%$	
PEEP $\leq 5\text{--}6$ mbar	
Peak ≤ 10 mbar	

A physical therapist performed respiratory therapy as part of routine daily care. In cases of retention of secretion, a therapeutic bronchoscopy was performed. A tracheostomy closure was only performed in cases where swallowing without aspiration and strong peak cough flow existed, and tracheal suction was no longer required. Patients who did not meet these criteria despite successful weaning were discharged with the tracheostomy but without a ventilator. In cases of weaning failures, use of a home ventilator was initiated for invasive ventilation after discharge.

Risk factors and analysis

We identified and assessed possible risk factors contributing to failed extubation and need for re-intubation, tracheostomy, duration of mechanical ventilation, length of ICU stay, and incidence of pneumonia. Risk factors included in our analysis were age, body mass index (BMI), level of neurological injury, pre-existing conditions, associated injuries, and paraplegia-specific complications. Pre-existing diseases were defined as those existing before the accident and having effects on respiration. They are listed in Table 3. All additional injuries impairing respiration were documented such as injuries of the abdomen, thorax, thoracic vertebrae, and

head. Details on the occurrence of paraplegia-specific complications are given in Table 4.

Statistics

Data are presented as means $\pm$ standard deviation (SD). Essential hallmarks for stratification were the occurrence of pneumonia and mechanical ventilation. The descriptive analysis of continuous variables includes means, medians, deviations, and ranges. Primary analysis for duration of mechanical ventilation and length of stay in the ICU (days) was performed with the Cox proportional hazard model. The influence of clinical parameters on a binary parameter (pneumonia and tracheostomy: 0 = no, 1 = yes) was analyzed using logistic regression analysis to test for individual effects and the multivariate model (adjusted analysis) to test for simultaneous effects of all variables. Statistical significance was assumed at $P < 0.05$.

Results

Subjects

From 2004 to 2010, 37 patients met the criteria for inclusion in the overall analysis. There were 35 men (94.6%) and 2 women (5.4%). The men had an average age of 42.8 years (range, 16–81 years) and the

Table 3 Pre-existing comorbidities that might affect respiration

Pre-existing comorbidities that might affect respiration	<i>n</i>
Hypertension	7
Smoking	5
Alcohol abuse	4
Diabetes mellitus	4
Cardiovascular disease	3
Depression	3
Ankylosing spondylitis	3
Tumor	2
Hypothyroidism	1
Epilepsy	1
Cholecystitis	1
Coagulation deficiency	1
Hepatitis	1
Drug addiction	1

Table 4 Secondary medical conditions

Secondary medical conditions	<i>N</i>
Rectum paralysis/fecal incontinence	37
Urinary incontinence	37
Urinary tract infection	33
Emotional adaptation disorder	18
Circulatory dysregulation/orthostatic dysregulation	16
Difficulty in swallowing (dysphagia)	13
Inflammatory gastrointestinal disorders (gastritis, enteritis)	11
Decubitus grade 2 (skin defects)	11
Decubitus grade 1 (localized redness, skin preserved)	6
Bacteremia/sepsis with positive blood culture (Gram-negative, Gram-positive)	6
Decubitus grade 3 (deep skin defects with muscle, tendons, ligaments affected)	4
Epilepsy	3
Thrombosis, pulmonary embolism	2
Necrotic fasciitis	2
Rib fractures due to resuscitation	1

Table 5 Demographic data of the patient population

	N	Minimum	Maximum	Mean	SD
Age (year)	37	16	81	42.8	20.4
Height (m)	37	1.60	1.97	1.77	0.08
Weight (kg)	37	50.0	126.0	77.1	16.1
BMI (kg/m ²)	37	12.9	38.0	24.7	5.4

BMI, body mass index; SD, standard deviation.

women an average age of 42.0 years (range, 40–44 years). The demographic data are summarized in Table 5. The SCIs were surgically treated (32% single segment, 65% multiple segments) using a primary anterior approach in 75%, a primary posterior approach in 3%, and a combined anterior–posterior approach in 16%. Thirty-two percent of all patients underwent a second spinal operation for planned counter stabilization of the spinal fracture (21%) or for complications related to the first operation (11%).

Weaning rate and tracheostomy

All 37 patients were intubated because of respiratory insufficiency and/or vertebral surgery. Nineteen percent of all patients ($n = 7$) were extubated within 24 hours after surgery. In 81% of all cases ($n = 30$), more than 1 day of invasive ventilation and weaning were necessary post-operatively. Fifty-seven percent of this subgroup ($n = 17$) weaned successfully on the first attempt. Thirteen patients showed pulmonary

deterioration (dyspnea, pneumonia, or other) requiring a re-intubation. Sixty-two percent of patients ($n = 8$) weaned successfully on the second attempt. Sixty percent of patients ($n = 3$) weaned successfully on third attempt. One patient could not be weaned. One patient died during hospitalization.

In 78% of all cases ($n = 29$), tracheostomy was indicated on average 8 ± 4 days after the first spinal surgery. The closure took place in 62% of these patients ($n = 18$) after 74.5 ± 48.9 days. Nine patients were discharged with the tracheostomy without ventilation and one patient with invasive ventilation. Fig. 1 summarizes the clinical data.

Pneumonia

Pneumonia according to Centers for Disease Control criteria¹³ occurred in 51% of the cases within 21 ± 32 days after injury, and in 3% of the cases at a later date. An 81-year-old patient died due to acute respiratory failure, as he refused reinstitution of intermittent invasive ventilation. Pneumonias were treated with

Figure 1 Course of treatment in 37 patients with neurological deficits at levels C4–C8 and complete functional injury.

standard antibiotics for a standard duration of 2 weeks. In patients with persistent signs of infection (C-reactive protein, leukocytes), another search for possible infectious foci was performed to rule out infections such as urinary tract infections. Antibiotic medication was adapted to the specific resistance profile. The average number of drugs administered per patient to treat pneumonia was 7.6 ± 4.3 . The average total cost of prescribed antibiotics per patient was €1030.

Time in intensive care and other hospital units

The average time spent in the ICU was 20.7 ± 32.0 days. After transfer to the general spinal cord-specific ward, 39% of cases had to be readmitted to the ICU. Causes for the renewed ICU stay were pulmonary insufficiency, pneumonia (together 27%), pulmonary embolism (2.7%), and other causes (9.3%). The average duration of the second ICU stay was 12.9 ± 16.2 days. In patients with a third ICU stay, the average duration of this stay was 6.0 ± 5.4 days.

The total duration of hospitalization was 230.2 ± 143.8 days.

Risk factors

We analyzed factors such as age, BMI, neurological injury level, and AIS and their possible impact on the need for tracheostomy, duration of ventilation, extubation and re-intubation, length of ICU stay, and incidence of pneumonia.

Our risk factor analysis revealed that the ASIA scores A and B or the neurological injury levels of C4–C8 are not risk factors. This result indicates that we identified a homogeneous group from which a general clinical statement can be drawn.

The factors were assessed using logistic regression for binary parameters and Cox regression for the analysis of duration of assisted respiration until the time of extubation and length of ICU stay with the results given below. The coefficient parameter $\text{Exp}(B)$ is reported as odds ratio (OR) for logistic regression and as hazard ratio for Cox regression.

Tracheostomy

Our analysis showed that the number of comorbidities had a significant influence on whether a patient required a tracheostomy ($P = 0.04$). The analysis of the coefficient parameter $\text{Exp}(B)$ revealed that an increase of one in the number of spinal cord-specific complications resulted in an over 1.99-fold higher likelihood of tracheostomy.

The multivariate analysis revealed no further risk factors.

Duration of assisted respiration until time of extubation

The number of pre-existing conditions ($P = 0.01$) and the number of paraplegia-specific complications ($P = 0.09$) did affect the duration of assisted respiration to the time of successful extubation. The univariate analysis revealed that an increase of one in the number of pre-existing conditions resulted in an over 1.72 times lower likelihood of successful extubation. An increase of one in the number of spinal cord-specific complications reduced the likelihood of extubation by a factor of 1.25.

The multivariate analysis further indicates that pre-existing medical conditions ($P = 0.001$) and BMI ($P = 0.05$) are clear risk factors. An increase of one in the number of pre-existing conditions reduced the likelihood of extubation by a factor of 3.23.

Length of ICU stay

The number of pre-existing conditions ($P = 0.01$) influenced the duration of intensive care. The analysis of the coefficient parameter $\text{Exp}(B)$ revealed that an increase of one in the number of pre-existing conditions resulted in a 1.47 times lower likelihood of discharge from an episode of ICU treatment. No further risk factors were identified by multivariate analysis.

Pneumonia

The number of pre-existing conditions influenced the occurrence of pneumonia ($P = 0.03$). Our analysis showed that patients with pre-existing medical conditions were two times more likely to develop pneumonia (2.14). The multivariate analysis did not uncover further risk factors. The data on factors affecting the occurrence of pneumonia are summarized in Table 6.

Discussion

The patient population analyzed in this study underwent standardized airway management, which includes the indications for in- and extubation, tracheostomy, weaning, and respiratory therapy for improving respiratory function and cough. Velmahos *et al.*⁶ defined three independent risk factors for the need of early intubation: injury severity score >16 , higher neurological level, and above C5 complete quadriplegia. Early intubation is indicated when at least two of these risk factors are present. All patients included in our study were intubated, either because they met these criteria or because they were operated on. Contraindications to spinal surgery included non-antagonizable blood-thinning medications, large vessel injuries, and head and brain injuries. The rate of pulmonary complications has

Table 6 Statistical analysis of different variables and their impact on pneumonia rates

Variable	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Age	1.01 (0.98–1.04)	0.53	0.98 (0.91–1.05)	0.54
BMI	1.01 (0.90–1.14)	0.83	0.87 (0.66–1.14)	0.31
Spine fracture (simple = 1, multiple = 2)	0.84 (0.21–3.43)	0.81	5.05 (0.16–158.8)	0.36
AIS (B = 1, A = 2)	3.97 (0.95–16.52)	0.06	24.57 (0.42–1414)	0.12
Spinal level affected	1.26 (0.58–2.73)	0.55	0.85 (0.19–3.79)	0.83
Number of pre- existing comorbidities	2.14 (1.06–4.30)	0.03	3.44 (0.78–15.08)	0.10
Number of additional injuries	1.36 (0.80–2.31)	0.26	1.46 (0.62–3.46)	0.38
Number of secondary medical conditions	1.69 (0.99–2.91)	0.06	3.17 (0.75–13.38)	0.12
Number of ICU stays	1.80 (0.61–5.28)	0.28	0.80 (0.11–5.81)	0.82
Duration of ICU stays	1.00 (0.98–1.02)	0.70	0.98 (0.92–1.03)	0.35
Total duration of hospitalization	1.00 (0.99–1.00)	0.12	0.99 (0.98–1.01)	0.20

CI, confidence interval; ICU, intensive care unit; OR, odds ratio.
Statistical significance was set at $P < 0.05$.

been shown to be lower in patients undergoing early spinal surgery (i.e. within 24 hours).^{24,25} The aims of early surgical stabilization include prevention of further damage to the spinal cord, early patient mobilization, potentially better training of respiratory muscles in the sitting position, and better expectoration. All of these factors need to be investigated in future studies.

In our study, 36% of all patients required re-intubation due to pulmonary deterioration such as respiratory failure, pneumonia, or other complications. Extubation failures are reported to be mainly due to mechanical pulmonary insufficiency and inadequate pulmonary toilet.²⁶ Fromm *et al.*⁸ recommend a short period of weaning and extubation after primary intubation. Solely if extubation fails after one or two attempts, they recommend performing a tracheotomy. Another group has shown that the failure rate be lowered by additional assessment of forced vital capacity, the volume of secretion, and pulmonary gas exchange.⁹ One or more re-intubations are associated with increased mortality^{10,26} and longer ICU and hospital durations.²⁶

In our study, 78% of all cases were surgically tracheostomized. A major risk factor affecting the need for tracheostomy was the number of spinal injury-specific comorbidities. The primary tracheotomy was performed according to the criteria proposed by Seidl *et al.*,⁷ which

include neurological level C4–C8 lesions with ASIA scores of A or B, accompanying injuries or illnesses, and need for a combined surgical approach due to complex cervical spine trauma.⁷ In addition, a tracheostomy was created when weaning took more than 4 days. Our analysis revealed the number of spinal cord-associated complications to be a specific risk factor for tracheostomy. While the tracheostomy rate was high in our study, the tracheostomy could be closed due to good swallowing without aspiration and or a strong peak cough flow without the support of tracheal suction cleaning in 62% of these cases.

Data from clinical monitoring indicate that pulmonary function decreases markedly in the acute period after injury. After the spinal shock phase, pulmonary function subsequently recovers, allowing most patients with injury levels at C4 or lower to be weaned from ventilator support.²⁷ In our study, 97% of all patients could be weaned, confirming these observations.

A study in the literature reported SCI-associated complications to occur in 78% of all patients in the first 2 weeks of hospitalization.²¹ One of the most common complications of lSCI is the development of pneumonia. Healthcare-associated pneumonia¹³ arose in our study primarily within the first 4 weeks after trauma and was diagnosed in 51.4% of cases. Overall, our analysis revealed no significant differences in pneumonia rates

between the different neurological lesion levels included (C4–C8) and patients with AIS scores of A and B. Due to differences in the definition of high-level and low-level quadriplegia, our results are difficult to compare with published data. Significant differences exist between higher-level (C3–C5) vs. lower-level spinal injuries (C6–C8) with complete loss of motor function (AIS A or B): In the study of Fishburn *et al.*,² 74% of all higher-level spinal lesion patients had atelectasis or pneumonia compared to 33% of patients with lower-level spinal lesions. In another study, higher-level injuries (C4 and above) were associated with a significantly higher incidence of pneumonia (39.5%) than lower-level spinal lesions (C5–C8) (25.9%).¹ High AIS (A, B) were associated with a higher incidence of pneumonia (61.9 vs. 17.4%).¹

Our statistical analysis revealed no significant influence of pneumonia on length of ICU stay. Most likely, this is due to continuing pneumonia therapy or weaning in the peripheral wards. There was also no significant influence of pneumonia on total hospital duration. This is attributable to the selection of patients treated by our hospital. Completion of primary treatment is dependent on factors such as the time of sitting in a wheel chair or duration of tracheostomy. Patients with a work-related accident or tracheostomy are rehabilitated in our hospital. All other patients are transferred to another facility for rehabilitation.

In this study, the number of administered antibiotics was very high and the duration of drug treatment for pneumonia was very long. As a result, the total cost of antibiotic treatment was also very high.

A higher number of pre-existing comorbidities was identified as a major risk factor for the occurrence of pneumonia. Aging is associated with a decrease in tidal volume and an increase in comorbidity, resulting in a higher risk of pulmonary complications. Thus, in elderly patients, continuing treating of pre-existing conditions is an essential part of emergency care. However, our study population included no case of chronic lung disease. We attribute this lack to the fact that we mostly treat patients with work-related accidents at our hospital.

The only risk factors we identified for complications were the number of pre-existing conditions and spinal injury-specific comorbidities. Noteworthy, we did not identify individual pre-existing conditions or spinal injury-specific that had a significant effect on the complication rate. This can be explained by the fact that single comorbidities or spinal injury-related conditions can be well compensated for. Only combined lesions lead to decompensation or compromise the immune

system, promoting the development of pneumonia. However, the number of cases included is too small for a powerful statistical analysis of these observations.

To reduce the pneumonia rate, standardized ventilation modes, weaning concepts, and therapeutic and medical technical approaches are required. Important therapeutic measures affecting respiration and cough were early mobilization of patients in the wheelchair, respiratory therapy, and physical therapy. Besides decreased pulmonary function, patients may suffer from weak cough with retention of pulmonary secretions. Thus, mobilization in the seated position²⁸ was found to contribute to the prevention of pulmonary complications. During acute rehabilitation, use of a cough-assisting device for pulmonary toileting in ventilator-dependent spinal cord-injured patients led to a lower rate of pneumonia.³ In our patients, we used additional therapeutic options to improve coughing including physical therapy, suctioning, and mechanical insufflation–exsufflation. In an experimental setting, another group accomplished activation of abdominal muscles using electrical stimulation of an anterior surface.²⁹ In cSCI patients, expiratory muscle function should be regularly trained.^{30,31} Besides manually assisted cough training, active respiratory muscle workout or electrical stimulation of the expiratory muscles helps improve airway clearance, as recent evidence has shown.³²

Limitations of the study

Our study is limited by the small number of patients, the retrospective data analysis, and the single-center design. The small number of patients in the subgroups (e.g. with vs. without tracheostomy) limits the power of the multivariate analysis. Nevertheless, our analysis provides significant insights into the course of airway complications in lower cervical spinal trauma patients. Furthermore, our study reveals healthcare-associated complications and risk factors specific to patients with this type of injury.

Conclusions

The acute phase (until 4 weeks) after the occurrence of lower cervical spinal cord trauma (C4–C8) is characterized by a high rate of airway complications. Our analysis reveals that pneumonia rates do not differ significantly between lesion levels (C4–C8) and AIS (A and B). Important risk factors for the occurrence of pneumonia in the acute phase are pre-existing conditions and spinal injury-specific comorbidities. In the acute phase, polymorbid patients have a longer ventilation time and an increased pulmonary risk. Thus, it appears to be

important to continue the treatment of pre-existing conditions and to integrate this into the intensive care concept. The number of paralysis-specific complications affects a patient's assisted ventilation management, i.e. ventilation duration and tracheostomy. Thus, the aim should be to reduce the number of spinal cord lesion-associated complications by appropriate therapeutic measures. The results of this study provide the basis for further studies and may guide the development of improved therapeutic concepts. Future studies should aim at reducing the pneumonia rate through optimization of therapeutic algorithms and development of therapeutic methods that improve respiration and cough in the acute phase of lcsCI.

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Contributors TL, AN, BE, and ROS should be cited as authors.

Conflicts of interest None.

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