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Development and Validation of a Quality of Life Questionnaire for Mechanically Ventilated Intensive Care Unit Patients

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Abstract

Objective—To develop and validate a new instrument for measuring health-related quality of life in mechanically ventilated patients in the intensive care unit (ICU).

Design—Expert panel consensus and a prospective longitudinal survey.

Setting—Urban, academic, tertiary care medical center.

Patients—One hundred and fifteen awake, mechanically ventilated, ICU patients who either received a tracheostomy or remained endotracheally intubated.

Interventions—A new quality of life instrument was developed and validated by using pilot study data; informal interviews of patients, families, and nurses; expert panel consensus; and item analyses. The new instrument was used to measure quality of life at three time points (5 days, 10 days, and 15 days post-intubation).

Measurements and Main Results—A new 12-item quality of life questionnaire for mechanically ventilated patients was developed. Patients' responses to the quality of life questionnaire revealed moderate to high correlations with EuroQol-5D scores ($r = -0.4$ to -0.9) and the EuroQol Visual Analog Scale ($r = 0.6$ to 0.9) across the three times, and a moderate correlation with the Sequential Organ Failure Assessment tool ($r = 0.5$) at 10 days post-intubation.

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Cronbach's alpha ranged from 0.80 to 0.94 across the three times. The quality of life instrument was responsive to changes in treatment modalities (tracheostomy vs. no tracheostomy; and early vs. late tracheostomy demarcated by 10 days of intubation). Exploratory factor analysis revealed that this instrument was unidimensional in nature.

Conclusions—The new quality of life questionnaire is valid and can reliably measure QOL in mechanically ventilated ICU patients. It may provide clinicians with an accurate assessment of patients' quality of life and facilitate optimal decision-making regarding patients' ICU plan of care.

Keywords

Quality of life; Mechanically ventilated; Tracheostomy; Instrument; Validity; Reliability

INTRODUCTION

It is becoming increasingly common for patients with respiratory failure to undergo prolonged mechanical ventilation (>96 hrs) in the intensive care unit (ICU).[1–3] This intervention has led to high healthcare resource utilization, as evidenced by a three-fold increase in hospital lengths of stay and an annual aggregated United States hospital cost greater than $16 billion.[4–6] With a continuing increase in healthcare costs, it is imperative to provide cost-beneficial care that is still of high quality. One way to improve patient care and satisfaction is by promoting health-related quality of life (QOL), but studies regarding QOL in mechanically ventilated ICU patients are limited.

In mechanically ventilated ICU patients, QOL is typically centered on issues concerning the head and neck, such as speech, swallowing, airway discomfort from the presence of an artificial airway, body image, and poor sleep quality owing to the location of an endotracheal or tracheostomy tube.[7–12] Unfortunately, instruments such as the Short-Form-36, Short Form-12, EuroQol-5D, and Richard Campbell Sleep Questionnaire, which are used to measure various aspects of QOL in ICU patients, were not developed to assess some of these important head and neck issues related to the presence of an artificial airway.[13] Furthermore, little is known about the responsiveness of these instruments to changes in treatment modalities (tracheostomy vs. no tracheostomy and early vs. late tracheostomy). A more appropriate instrument would be the modified University of Washington QOL instrument – Version 4 (UWQOL)[14,] because it has many QOL dimensions that relate to alterations in the head and neck regions pertinent to mechanically ventilated ICU patients and because the questions can be answered easily by critically ill patients. However, the UWQOL has not been validated for ICU patients. Hence, a robust instrument is needed to measure QOL in this population.

Therefore, the purpose of this study was to develop and validate a new instrument that can be used to evaluate QOL in mechanically ventilated (QOL-MV)ICU patients.

We proposed four hypotheses for the validation of the new instrument:

1. The QOL-MV scores will correlate moderately negatively with EuroQol-5D and positively with EuroQol-Visual Analog Scale and the Richard Campbell Sleep

Questionnaire scores (Increases in EuroQol-5D scores signify decreased QOL; increases in EuroQol-Visual Analog Scale and Richard Campbell Sleep Questionnaire scores signify increased QOL).

2. The QOL-MV scores will correlate moderately positively with severity of illness scores.
3. The proposed domains on the QOL-MV questionnaire will show high levels of internal consistency.
4. The QOL-MV scores will be significantly responsive to changes in treatment modalities (tracheostomy vs. no tracheostomy and early vs. late tracheostomy [demarcated by 10 days of intubation]).

MATERIALS AND METHODS

Development of a QOL Instrument

We developed the new QOL instrument in three phases: (1) pilot study, (2) face validation, and (3) content validation. The UWQOL served as an intellectual and structural model for the development of this new QOL instrument. The composite UWQOL score ranges from 0 to 1200 and includes three questions each for measuring transitional QOL, health-related QOL, and global QOL, and one question that queries domains important to QOL.[16, 17]

Pilot study—After obtaining Institutional Review Board approval from the Johns Hopkins Hospital, we initially conducted a prospective pilot study with repeated measures on five mechanically ventilated ICU patients at the Johns Hopkins Hospital to assess the feasibility of measuring QOL in critically ill patients.[18] We carried out this pilot study using a modified version of the UWQOL after removing non-pertinent domains such as chewing, shoulder mobility, taste, and consistency of saliva. The resulting modified questionnaire that was used for the pilot study consisted of eight items, and the total scores ranged from 0 to 800 (Appendix I).

Face validation—After the five patients completed the questionnaire for the pilot study, they were provided an opportunity to add items they thought would contribute to an understanding of their QOL in the ICU. Patients were also asked if they thought that the questionnaire captured their QOL in the ICU. Moreover, one significant family member and one nurse of the five pilot study participants were informally interviewed to critique the QOL instrument. In addition, one advanced practice nurse from each of the six ICUs and two high-acuity oncology units at the Johns Hopkins Hospital were formally interviewed to contribute to the face validation of the instrument. All participants indicated that the questionnaire required significant revision.

Content validation—For content validation, we chose a panel of eight expert physicians from a pool of attending physicians in the six specialty ICUs (medical, two surgical, cardiac, cardiothoracic, and neuroscience critical care) and two high-acuity oncology units at the Johns Hopkins Hospital. Each of these physicians had a research or clinical focus on QOL in patients who required mechanical ventilation. The experts were asked to judge the domain

and content relevance of each item and the instrument as a whole for measuring QOL in mechanically ventilated ICU patients on a scale of 1 – 4 (1 being the least relevant and 4 being the most relevant; Appendix II). Finally, the items and the revised instrument judged by the experts were quantified by calculating the content validity index. Content validity index calculates the proportion of items given a rating of quite or most relevant (3 or 4) by all raters involved.[19] All domains that had a content validity index ≥ 0.8 were included; those with a content validity index<0.8 were eliminated.[20] The result was a new 13-item instrument (QOL-MV) for measuring QOL in this patient population (Appendices III& IV). The scores for each domain range from 0 to 10, with a composite score of 0 to 130. Low scores indicate poor QOL, and higher scores indicate better QOL.

Assessment of Psychometric Properties of the QOL-MV Instrument

Design and setting—After obtaining a second approval from the Johns Hopkins Institutional Review Board for a larger study, we conducted a prospective longitudinal survey across the same six ICUs and two high acuity-oncology units at the Johns Hopkins Hospital to assess the validity and reliability of the13-item QOL-MV instrument. The QOL-MV was administered to each patient at three time points: 5days (T0),10days (T1), and 15days (T2) post-intubation. The median time to liberation from mechanical ventilation in the ICU has been reported to be 14 days (IQR: 6 – 51).[21] The three measurement times were intended to capture the trends in QOL during that 14-day period.

Subjects—Patients who were 18 years of age or older, already intubated for at least 96 hrs, predicted to be intubated for >7 days by the ICU team, awake, and able to speak or write English were offered enrollment. Exclusion criteria included patients with burns, those with head and neck cancer, those who were intubated at an outside hospital, and those who required reintubation prior to enrollment.

Data Collection—Eligible patients were requested to participate in the study. If a patient was physically unable to give consent, the patient's legally authorized representative was asked to provide consent, but the patient's assent was obtained. Patients were enrolled on the fifth day post-intubation. Before administering the new QOL-MV questionnaire, we used the Adaptive Cognitive Exam[22] and the Confusion Assessment Method in ICU[23, 24] tools to screen for cognitive impairments or delirium. Those who did not pass the screening tools (score < 75 on the 100-point Adaptive Cognitive Exam or a positive finding for delirium) were excluded from the study. Patients who passed both screening tools were asked to complete the QOL-MV questionnaire at each measurement time. In addition, the EuroQol-5D, EuroQol-Visual Analog Scale, and Richard Campbell Sleep Questionnaire were administered concurrently to validate the new QOL-MV questionnaire. Data regarding severity of illness were obtained from the patients' electronic records.

Validating Instruments—EuroQol-5D provides a simple generic measure of QOL that has been validated for use in ICU settings and consists of two sections.[25] The first section comprises questions related to five dimensions: (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort, and (5) anxiety/depression. The second section (EuroQol-Visual Analog Scale) consists of a 20-cm-long visual analog scale that ranges from "worst

imaginable health state" (0) to "best imaginable health state" (100) to describe their health over the last 7 days. The Richard Campbell Sleep Questionnaire is a 5-item visual analog scale (0–100 mm) designed to assess critically ill patients' perspectives of their sleep quality; a higher score indicates better quality of sleep.[26] We used this sleep questionnaire because it has been validated for use in ICU patients and was readily available to validate the new item in our instrument. The Sequential Organ Failure Assessment (SOFA) is a 6-item severity of illness assessment tool that can be used repeatedly in the ICU; higher scores suggest a greater severity of illness.[27–30]

Statistical Analysis—Validation of the 13-item instrument commenced with item analyses. Means and standard deviations were calculated for interval data, and percentages were calculated for categorical data. Inter-item and item-to-scale correlations were also calculated. Item-to-scale correlation is a correlation between the item score and the overall scale score. Because this was a new instrument, the correlation coefficient threshold for retaining an item in the instrument was set low at 0.30.[31] At each time point, we performed pairwise correlation analyses between the QOL-MV and EuroQol-5D scores, and between QOL-MV and the Richard Campbell Sleep Questionnaire scores to assess criterion validity. Similarly, we performed pairwise correlation analyses between QOL-MV and SOFA scores to assess construct validity. The correlation coefficient threshold for both criterion and construct validity was set at 0.40. Inter-item reliability was assessed by calculating Cronbach's alpha, a measure of how closely related a set of items are as a group.[32] Patients who receive a tracheostomy are expected to experience a higher QOL than those with endotracheal tubes because of their ability to speak and swallow. To evaluate the responsiveness of the QOL-MV instrument to variations in treatment modalities, we first calculated the change in QOL-MV scores. We evaluated the differences in the changes in QOL-MV scores between patients who received a tracheostomy and those who did not, and between those who received an early tracheostomy and those who received a late tracheostomy, using two sample *t*-tests with unequal variances. We also performed exploratory factor analyses on the QOL-MV items' scores at each measurement time to identify the number of domains represented. All analyses were conducted using IBM® SPSS® Premium GradPack 20 or Stata® 11.1.[33] A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Patient Characteristics

One hundred and fifteen patients out of 959 intubated patients met the inclusion/exclusion criteria and passed the screening tools administered at all three measurement times (Fig. 1). The mean age of the sample was 57 years (Range: 21–90 years) and 54% of the patients were men. Fifty-four percent of the patients were Caucasian, 44% were African American, and 2% were Asian. Eighty-seven percent of the patients had at least a high school diploma. The primary indications for admission to an ICU were either pulmonary (n = 32 [27.8%]) or neurologic (n = 32 [27.8%])in nature. Primary indications for mechanical ventilation included acute respiratory failure related to surgery (n=29), congestive heart failure (n=15), acute respiratory distress syndrome (n=10), pneumonia (n=10), and trauma (n=3). Eighteen

patients had acute respiratory failure in addition to chronic respiratory conditions such as interstitial lung disease (n=10), lung cancer (n=5), obesity-induced hypoventilation syndrome (n=2), and chronic obstructive pulmonary disease (n = 1). Thirty patients required mechanical ventilation for neuromuscular etiology (n = 30).

During data collection, questions were read to patients and repeated as many times as requested by the patient (n = 66). For 13 patients, we used large and easily legible questions and answers on flash cards when necessary to ease the reading and understanding by the patient. Flash cards were not used for all patients because many patients preferred to listen to the questions rather than attempt to read them. The remaining patients (n = 36) filled out the questionnaire themselves on a clipboard.

Item Analyses

Qualitative assessment of results from item analyses of the QOL-MV instrument revealed that the mean scores of all items except for body image increased from T0 to T2 (Table 1). Similarly, inter-item correlations revealed that all items except for body image correlated with each other at certain measurement times (T0, T1, or T2; Appendix V). Item-to-scale correlations suggest that speech (r = 0.16) and sleep (r = 0.20) did not correlate well with the scale at T0 and T2, respectively (Table 2). Moreover, body image had poor item-to-scale correlations at two time points (r = 0.22 at T0 and r = 0.24 at T2). Because body image did not have an acceptable inter-item or item-to-scale correlation, it was dropped from the new QOL-MV questionnaire prior to additional analyses.

Validity and Reliability

Pairwise correlations revealed that the QOL-MV scores had moderate to high correlations with EuroQol-5Dscores (r = −0.4 at T0, −0.7 at T1, and −0.9 at T2) and the EuroQol-Visual Analog Scale (r = 0.6 at T0, 0.8 at T1, and 0.9 at T2). The QOL-MV scores also had moderate correlations with the Richard Campbell Sleep Questionnaire scores at T0 and T2 (r = 0.5 at both time points) but weak correlations at T1 (r = 0.1).However, when the sleep scores from the QOL-MV questionnaire were analyzed separately with the Richard Campbell Sleep Questionnaire scores, strong correlations were noted at all three time points (r = 0.9). Pairwise correlation analyses of QOL-MV and SOFA scores revealed weak correlations at T0 and T1 (r = −0.1 and −0.2, respectively) but moderate correlations at T2 (r = −0.5). A moderate correlation was noted between the PaO_2/FiO_2 respiratory system score in SOFA and the comfort of breathing scores in the QOL-MV questionnaire (r = −0.36). In addition, the QOL-MV questionnaire showed high internal consistency or reliability at all three time points (Cronbach's alpha = 0.8 at T0 and 0.9 at T1 and T2).

Responsiveness

The QOL-MV questionnaire was responsive to changes in treatment modalities (tracheostomy vs. no tracheostomy and early vs. late tracheostomy). The overall change in QOL-MV scores was 31 points lower from T0 to T2 ($p<0.01$) and 23 points lower from T1 to T2 ($p<0.01$) for patients who had an endotracheal tube compared to those who received a tracheostomy (Table 3). Moreover, the changes in QOL-MV scores were 20 points higher

from T0 to T1 ($p<0.01$) and 17 points higher from T0 to T2 ($p<0.002$)for patients who received an early tracheostomy compared to those who received a late tracheostomy.

Exploratory Factor Analysis

We performed principal axis factor analysis of the items in the QOL-MV instrument with orthogonal varimax rotation to evaluate the dimensionality of the new instrument. Principal factor analysis yielded one factor with an eigenvalue exceeding 1.0 at each of the three time points, which accounted for 72.4% of the variance at T0, 88% at T1, and 83% at T2. A single factor was defined by all of the items in the QOL-MV questionnaire except for swallowing and speech at T0, and sleep at T0 and T1. At T2, all of the items loaded on one factor (Table 4).

DISCUSSION

Our research describes the main steps in the development and validation of a new QOL questionnaire for mechanically ventilated patients (QOL-MV). We used pilot study data; informal interviews of patients, nurses, and families; formal interviews of advanced practice nurses; expert panel consensus; and item analysis to effectively reduce the number of items in the final version to 12 (Appendix III) while ensuring content validity and conceptual structure of this questionnaire. The new QOL-MV questionnaire was further tested for psychometric properties and was shown to be valid, reliable, and responsive to treatment changes in mechanically ventilated ICU patients.

The moderate to high correlations between QOL-MV scores and EuroQol-5D / EuroQol-Visual Analog Scale scores, and high correlations between sleep scores from the QOL-MV questionnaire and Richard Campbell Sleep Questionnaire scores evident in this study support criterion validity. The correlations between QOL-MV scores and SOFA scores were weak at T0 and T1 but were moderate at T2. Similar correlations were evident when SOFA scores were compared with EuroQol-5Dscores and the EuroQol-Visual Analog Scale. Weak correlations were noted at T0 and T1 because most of the patients were critically ill, and the variance of their QOL scores was small. At T2, their QOL scores had a wider spread providing better correlations because at T2 some patients were able to speak and eat, and their scores improved. Another interesting finding was the correlation between the PaO_2/FiO_2 ratio and the comfort of breathing at T2. As expected, as the PaO_2/FiO_2 ratio decreased, the comfort of breathing decreased. In addition, because the QOL-MV questionnaire scores correlated well with previously validated QOL instruments (EuroQol-5D and EuroQol-Visual Analog Scale),[34] it likely has the same strengths in terms of construct validity, with the additional benefit of situation-specific domains. High internal consistency (Cronbach's alpha = 0.8–0.9) at all time points supports the notion that all 12 items in the QOL-MV are highly correlated with each other and suggests that the instrument is reliable or measuring the same dimension.

Because patients with a tracheostomy have opportunities to speak and swallow, we expected that the QOL of patients who received a tracheostomy would be higher than that of patients who did not.[7] In this study, all patients were endotracheally intubated at T0 (5days after intubation). Patients subsequently received a tracheostomy either before or after the T2

measurement. The changes in QOL scores over time suggest that QOL improved with the performance of a tracheostomy, specifically with a tracheostomy that was placed early, within 10 days of intubation. The change in QOL-MV scores from T0 to T1 did not differ significantly between patients who received a tracheostomy and those who did not. Likewise, there was no significant difference in the change in QOL-MV scores from T1 to T2 between early vs. late tracheostomy. Reproducibility of the scores was noted between T0 and T1 because of minimal clinical changes. Conversely, statistically significant changes indicating improvement or deterioration in QOL between patients who underwent a tracheostomy and those who did not, and between patients who received an early or late tracheostomy, provide strong evidence that the new QOL-MV questionnaire is responsive to changes in treatment modalities.

The results of the factor analysis also demonstrated that the new QOL-MV questionnaire is unidimensional in nature. Only one rotated factor was extracted in the factor analysis at each of the three measurement time points (Table 4). It is sometimes traditional to drop items that are not significantly loaded on a specific factor.[31] Swallowing and speech did not load on the factor at T0, and sleep did not load well at T0 or at T1, but all three items loaded adequately on a single factor at T2. Because all of the 12 items loaded in at least one of the three time points, they were all retained as the final set of items for the QOL-MV instrument.

The QOL-MV instrument was designed to minimize respondent burden by using a minimum number of items to cover relevant aspects of QOL in mechanically ventilated patients, and by using simple and clear language in both the questions and response options. In informal interviews, patients indicated that the questions were relevant to their perceptions about QOL, were easy to understand and respond to, and provided an accurate assessment of their QOL. The QOL-MV has the advantage of being more concise than any other instrument used to measure QOL in mechanically ventilated ICU patients.

This study demonstrates that the new QOL questionnaire coherently investigates the construct of QOL, as measured uniformly by its items, and offers several unique strengths. First, it addresses many pertinent domains, such as airway discomfort, comfort of breathing, swallowing, speech, sleep, and autonomy, that are not addressed by other QOL instruments developed for critically ill patients. Second, it allows administration of an appropriate questionnaire repeatedly over the clinical course. Third, the scale has a large effect size and is more responsive than the EuroQol-5D to clinical changes in mechanically ventilated ICU patients, making it a better instrument to measure the effects of tracheostomy on QOL. Finally, the brevity of the scale minimizes patient burden.

The study also has a few limitations. Though conducted at a single center, subjects were recruited from six ICUs and two high-acuity oncology floors at the Johns Hopkins Hospital; thus patients with varied indications for mechanical ventilation were included. We plan to validate these results in a multicenter study. Another limitation is that the QOL-MV was used only in mechanically ventilated ICU patients who were awake and interactive. Moreover, we did not test for differences between nodding or gesturing to questions and responding to questions by writing; however, we expect that there would be no or minimal

difference between data collected in these modes. In our study, only one person administered the questionnaire; therefore, future studies are needed to establish inter-rater reliability. Additional research is also required to evaluate the feasibility of this instrument among non-mechanically ventilated patients.

CONCLUSIONS

The number of patients being mechanically ventilated is increasing, and their lengths of stay in the ICU are usually longer than those of non-ventilated patients. Therefore, an emphasis on optimizing the QOL of such patients may yield substantial benefits. Patient cooperation, reduction in anxiety, improvement in feelings of self-worth and autonomy, and enhanced participation in their therapeutics and healthcare decision-making can be facilitated by improving patients' QOL. This validated QOL-MV questionnaire will serve as a new and useful instrument for measuring and improving QOL in awake and interactive mechanically ventilated ICU patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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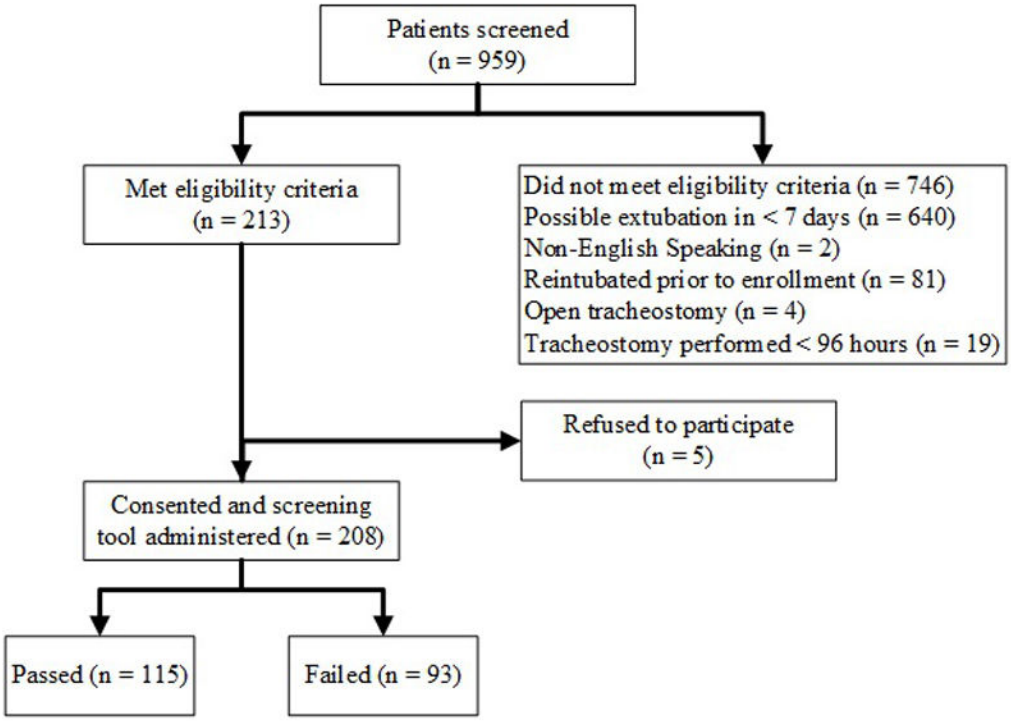

Figure 1.

This figure shows the study flow chart showing the number of patients included and excluded in the study and the reasons for exclusion. Screening tools used include Adaptive Cognitive Exam and Confusion Assessment Method-Intensive Care Unit.

Table 1

Item Statistics (Mean ± SD) for Quality of Life in Mechanically Ventilated Patients (QOL-MV) Questionnaire by Measurement Period (N = 115)

	Measurement Time Period		
QOL-MV Item	**T0**	**T1**	**T2**
Overall comfort	12.67 ± 18.97	26.37 ± 19.23	51.65 ± 35.18
Airway comfort	20.87 ± 15.51	30.32 ± 16.75	51.41 ±26.35
Comfort of breathing	13.83 ± 20.18	27.85 ± 24.59	50.31 ±32.90
Body image	37.08 ± 30.30	45.76 ± 22.09	44.58 ± 26.56
Activity	0.57 ± 4.33	11.64 ± 19.33	42.73 ± 33.99
Bedside recreation	3.73 ± 10.50	14.82 ± 22.16	42.31 ±28.86
Swallowing	22.10 ± 15.59	20.74 ±18.18	44.94 ±35.75
Speech	0.57 ± 4.33	4.94 ± 13.75	37.13 ± 37.68
Saliva control	9.26 ± 20.04	21.65 ± 28.89	61.56 ± 40.13
Mood	11.57 ± 21.68	20.06 ±21.91	43.23 ± 28.55
Anxiety	5.23 ± 16.92	9.87 ± 18.13	35.18 ± 27.09
Sleep	33.04 ±29.57	52.23 ± 21.85	71.01 ± 26.42
Autonomy	4.30 ± 11.16	10.21 ± 17.57	35.72 ± 30.64

SD = standard deviation; T0 = day 5 post-intubation; T1 = day 10 post-intubation; T2 = day 15 post-intubation.

Table 2

Item-to-scale correlation of items for QOL-MV scale by Measurement Time Period (N = 115)

	Measurement Time Period		
Item	**T0**	**T1**	**T2**
Overall comfort	0.641*	0.477*	0.755*
Airway comfort	0.381*	0.512*	0.647*
Comfort of breathing	0.622*	0.727*	0.761*
Body image	0.525*	0.222	0.238
Activity	0.366*	0.864*	0.835*
Bedside recreation	0.502*	0.835*	0.880*
Swallowing	0.334*	0.598*	0.743*
Speech	0.165	0.630*	0.832*
Saliva control	0.462*	0.734*	0.848*
Mood	0.711*	0.706*	0.766*
Anxiety	0.743*	0.775*	0.806*
Sleep	0.527*	0.197	0.503*
Autonomy	0.705*	0.637*	0.781*

T0 = day 5 post-intubation; T1 = day 10 post-intubation; T2 = day 15 post-intubation.

* Correlations ≥ 0.3.

Table 3

Responsiveness to Treatment Modalities based on Quality of Life for Mechanically Ventilated Patients between Measurement Time Periods

	Changes in the QOL-MV scores (Mean ± SD)			
	No Tracheostomy	**Tracheostomy**	**Difference**	***P* Value[a]**
Time 0 – Time 1	8.02 ± 9.50	11.79 ± 13.23	−3.77	0.11
Time 0 – Time 2	10.82 ±13.20	41.55 ± 22.96	−30.73	< 0.01
Time 1 – Time 2	6.84 ±12.88	30.06 ± 20.64	−23.22	<0.01
	Early Tracheostomy	Late Tracheostomy	Difference	*P* Value[a]
Time 0 – Time 1	24.76 ± 8.48	4.80 ± 9.53	19.96	<0.01
Time 0 – Time 2	52.65 ± 15.55	35.86 24.21	16.78	0.002
Time 1 – Time 2	28.10 ± 13.15	31.06 ± 23.67	−2.95	0.54

Time 0 = day 5 post-intubation; Time 1 = day 10 post-intubation; Time 2 = day 15 post-intubation.

[a] *P* value is based on two sample *t*-tests.

Table 4

Principal Axis Factor Loadings (Rotated, Orthogonal Varimax) by Measurement Time Period (N = 115)

	Factor Loadings		
	T0	T1	T2
Item	**Factor 1**	**Factor 1**	**Factor 1**
Overall comfort	0.602*	0.398*	0.728*
Airway comfort	0.324*	0.448*	0.617*
Comfort of breathing	0.531*	0.677*	0.735*
Activity	0.460*	0.877*	0.826*
Bedside recreation	0.493*	0.874*	0.883*
Swallowing	0.246	0.593*	0.743*
Speech	−0.087	0.639*	0.821*
Saliva control	0.431*	0.689*	0.311*
Mood	0.776*	0.696*	0.779*
Anxiety	0.854*	0.785*	0.823*
Sleep	0.278	0.079	0.465*
Autonomy	0.798*	0.594*	0.764*

T0 = day 5 post-intubation; T1 = day 10 post-intubation; T2 = day 15 post-intubation.

* Factor loadings (≥0.3).