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Preliminary Exploration of Long-Term Patient Outcomes After Tracheostomy in Burns: A BMS Study

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Abstract

Background: Upper airway management is crucial to burn care. Endotracheal intubation is often performed in the setting of inhalation injury, burns of the face and neck, or large burns requiring significant resuscitation. Tracheostomy may be necessary in patients requiring prolonged ventilatory support. This study compares long-term, patient-reported outcomes in burn patients with and without tracheostomy.

Materials and Methods: Data from the Burn Model System Database, collected from 2013–2020, were analyzed. Demographic and clinical data were compared between those with and without tracheostomy. The following patient-reported outcomes, collected at 6-, 12-, and 24-month follow-up, were analyzed: VR-12, SWL, CIQ, PROMIS-29, employment status, and days to return to work (RTW). Regression models and propensity-matched analyses were used to assess the associations between tracheostomy and each outcome.

Results: Of 714 patients included in this study, 5.5% received a tracheostomy. Mixed model regression analyses demonstrated that only VR-12 PCS scores at 24-month follow-up were significantly worse among those requiring tracheostomy. Tracheostomy was not associated with VR-12 MCS, SWL, CIQ, or PROMIS-29 scores. Likewise, tracheostomy was not found to be independently associated with employment status or days to RTW.

Conclusion: This preliminary exploration suggests that physical and psychosocial recovery, as well as the ability to regain employment, are no worse in burn patients requiring tracheostomy. Future investigations of larger scale are still needed to assess center- and provider-level influences, as well as the influences of various hallmarks of injury severity. Nonetheless, this work should better inform goals of care discussions with patients and families regarding use of tracheostomy in burn injury.

Keywords

Burn; Burn Rehabilitation; Quality of Life; Patient-Reported Outcomes; Tracheostomy

Introduction:

Management of the upper respiratory tract is crucial to burn care. During the immediate post-burn period, endotracheal intubation is often performed to establish the airway. Thereafter, tracheostomy may be necessary in patients requiring prolonged ventilatory support, particularly those sustaining inhalation injury, burns of the face and neck, or large burns requiring significant resuscitation and multiple returns to the operating room (1). Unlike other areas of critical care medicine (2–5), the use of tracheostomy is more controversial in the setting of burn injury, with no clear consensus on specific indications or optimal timing. Investigations regarding the effects of tracheostomy on pulmonary sepsis,

ventilator-free days, ICU and hospital LOS, and mortality are numerous (6–8). However, its relationship to long-term, health-related quality of life (HRQL) remains incompletely studied and poorly understood (9–12).

Funded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), the Burn Model System (BMS) National Longitudinal Database was created in 1993 as a means to explore the long-term functional and psychosocial recovery of burn survivors (13). Among its many data elements, the BMS captures performance on the Veterans RAND 12-Item Health Survey (VR-12), Satisfaction with Life (SWL) scale, Community Integration Questionnaire (CIQ), and Patient-Reported Outcomes Measurement Information System 29-Item Profile Measure (PROMIS-29). Additionally, it captures social outcomes, including employment status and number of days to return to work (RTW). The BMS collects each of these measures at the time of hospital discharge and at 6-, 12-, 24-months, and every five years post-injury. Thus, the BMS represents an incredibly valuable resource for long-term HRQL study.

Using the BMS, the present study examines the relationship between tracheostomy and long-term, patient-reported outcomes among burn survivors over an eight-year period. In particular, it aims to assess the hypothesis that performance on the VR-12, SWL, CIQ, and PROMIS-29, as well as ability to regain employment, are no worse in burn patients requiring tracheostomy. As a preliminary exploration, it seeks to identify areas for future, larger-scale investigation aimed at optimizing physical and psychosocial recovery, RTW, and rehabilitative resource allocation for burn patients requiring tracheostomy.

Methods:

Burn Model System National Longitudinal Database

Currently, four burn centers in the United States contribute to the database, though as many as six have participated since its creation. A patient with a burn injury at one of the BMS centers is determined to be eligible for participation in the BMS Database if:

1. They meet the inclusion criteria listed below.
2. They sign a Consent Form.
3. They agree to scheduled follow-up assessments at 6-, 12-, 24-months, and every five years post-injury.

In addition to requiring burn surgery for wound closure, patients must meet one of the following inclusion criteria:

1. 0–64 years of age with a burn injury ≥20% total body surface area (TBSA) OR
2. ≥65 years of age with a burn injury ≥10% TBSA OR
3. Any age with a burn injury to their face/neck, hands, or feet OR
4. Any age with a high-voltage electrical burn injury

And;

- Received primary treatment in the BMS Center from the time of burn (outpatient or inpatient) for primary burn wound closure.
- Surgery for closure of burn wound must occur within 30 days of burn injury.

Of note, autografting is considered wound closure; those patients that have only received xenografting or allografting are not eligible.

Modifications have been made to the BMS Database inclusion criteria over time. Further details regarding data collection, inclusion criteria, and data sites have been previously published and can be found at http://burndata.washington.edu (5).

BMS data are subsequently collected from participants either by paper and pencil, in person or over phone interviews, or using online surveys. This is done at the time of hospital discharge and at 6-, 12-, 24-months, and every five years post-injury. Each center's Institutional Review Board oversees the data collection. The BMS Database is a centralized database that utilizes REDCap electronic data capture tools and is housed at the BMS National Data and Statistical Center at the University of Washington (14). It is publicly available.

All adult participants with burns between 2013 and 2020 with available tracheostomy data were included in this study. The "*tracheostomy*" variable was used to stratify subjects into two groups: those with and without tracheostomy.

Demographic and Clinical Characteristics

Demographic data included age, sex, race/ethnicity, highest level of education completed, pre-injury employment status, and pre-injury impairment of physical function/mobility. Clinical data included primary etiology of injury, employment-related injury, inhalation injury, total body surface area (TBSA) burned, number of trips to the operating room (OR), ventilator days, and acute hospital length of stay (LOS). Demographic and clinical characteristics were collected through self-report or medical record data abstraction at discharge.

Patient-Reported Outcome Measures

The following patient-reported outcome measures were used to evaluate physical and mental health, life satisfaction, social integration, and employment at 6-, 12-, and 24-month follow-up:

Veterans RAND 12-Item Health Survey

The Veterans RAND 12-Item Health Survey (VR-12), a derivative of the Veterans RAND 36-Item Health Survey (VR-36) and the 36-Item Short Form Health Survey (SF-36), measures the domains of physical functioning, vitality, bodily pain, general health perceptions, role limitations due to physical or emotional functioning, social functioning, and mental health (15). The VR-12 is comprised of two sub-scores: the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. PCS and MCS scores are based on the U.S. population and standardized through t-score transformation with a mean

of 50, standard deviation of 10 (16). Higher PCS and MCS scores are associated with better physical and mental health, respectively.

Satisfaction with Life Scale

The Satisfaction with Life (SWL) scale is a validated scale comprised of 5 items regarding life satisfaction and well-being. The SWL is validated in the spinal cord, traumatic brain, and burn injury populations for use in evaluating trauma outcomes (17). Each of the 5 items are scored on a 1–7 Likert scale, with a maximum score of 35; higher scores are associated with greater satisfaction with life. Total summary SWL scores are assigned qualitative grades by increments of 5 points (e.g., 5–9 indicates extremely dissatisfied; 31–35 indicates extremely satisfied) (18).

Community Integration Questionnaire—The Community Integration Questionnaire (CIQ) score is intended to provide a measure of an individual's level of social integration (home and community integration). Gerrard et al. have validated this questionnaire in the adult burn injury population (19). Sub-scores include home integration, social integration, and productivity, with higher scores indicating greater integration. For the purposes of this study, only the social integration sub-score was used (items 6–11 were summed, with possible scores ranging from 0 to 12). Most items are scored on a 3-point scale from 0 to 2. Most questions touch on individual performance on a specific activity within the household or community and whether it's performed alone or by someone else.

Patient-Reported Outcomes Measurement Information System 29-Item Profile Measure—The Patient-Reported Outcomes Measurement Information System 29-Item Profile Measure (PROMIS-29) is a relatively new instrument meant to efficiently and comprehensively assess a broad range of HRQL domains. It includes four items from each of the seven PROMIS domains (anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, and ability to participate in social roles), as well as an additional pain intensity item (20, 21). PROMIS-29 scores are based on the U.S. population and standardized through t-score transformation with a mean of 50, standard deviation of 10, and a maximum score of 100. Higher scores equate to more of the domain being measured (e.g., more fatigue, more physical function). This can be a desirable or undesirable outcome, depending upon the domain being measured. There is strong evidence for reliability and validity of PROMIS-29 domain scores among adult burn survivors (22).

Employment—Employment status was collapsed into two categories (working; not working) and self-reported at 6-, 12-, and 24-month follow-up. The number of days to return to work (RTW) was also collected.

Statistical Analysis

Chi-square (or Fisher's exact) and Wilcoxon-Mann Whitney tests were used for demographic and clinical characteristic comparisons between those with and without tracheostomy. Chi-square tests were applied to categorical variables; Fisher's exact tests were used when n was less than 5. Wilcoxon-Mann Whitney tests were applied due to the nonnormality of multiple continuous variables; normality was assessed via Kolmogorov-

Smirnov tests (p>0.05) and normal Q-Q plots. Differences between cohorts for each long-term, patient-reported outcome (VR-12 PCS, VR12-MCS, SWL, CIQ, PROMIS-29) were similarly assessed, using Chi-square (or Fisher's exact) and Wilcoxon-Mann Whitney tests, then followed by multivariate regression modeling. To account for multiple tests, a Bonferroni adjustment of significance was applied to univariate analyses, with a p-value less than 0.002 considered statistically significant. Linear regression models were used to examine the association between tracheostomy and VR-12 PCS, VR12-MCS, SWL, CIQ, and PROMIS-29, each at 6-, 12-, and 24-month follow-up. A logistic model was used to examine the association between tracheostomy and employment status at 6-, 12-, and 24-month follow-up. All regression models controlled for age, sex, race/ethnicity, and TBSA. These variables were included in regression analyses regardless of significance. Robust standard errors were calculated for all models. To account for multiple regressions, a Bonferroni adjustment of significance was applied to multivariate analyses with a p-value less than 0.0042 considered statistically significant. Model assumptions examined multicollinearity, linearity, normality, homoscedasticity, and outlying or high leverage points. Due to the non-linearity of TBSA, it was converted to a categorical variable (TBSA 0-≤10% [reference category], >10-≤30%, >30-≤60%, >60%). Post-hoc multivariate regression and propensity-matched analyses were performed to further examine the associations between tracheostomy and outcomes identified as significant in a priori regression models. To better control for center- and provider-level effects, as well as injury severity, these post-hoc analyses included BMS site, burns to the face (yes or no), and number of trips to the OR as additional covariates; VR-12 PCS and PROMIS-29 Physical Function scores at each time point were set as the dependent variable in respective linear regression models. Ventilator days, which was converted to a categorical variable (0, 1–5, >6), was also added as a covariate in each regression model; it was removed as a covariate in propensity-matched analyses due to poor model fit and violation of treatment overlap assumption. For post-hoc propensity-matched analyses, matching was based on propensity scores obtained by logistic regression and carried out in a one-to-one nearest neighbor fashion without replacement; VR-12 PCS and PROMIS-29 Physical Function scores at each time point were set as the dependent variables.

Results:

Demographic and Clinical Characteristics

A total of 714 patients were included in this study; 39 (5.5%) received a tracheostomy and 675 (94.54%) did not. The two groups were similar in age (43.0 years ± 17.2 vs. 46.6 years ± 16.0; p=0.12), sex (79.5% Male vs. 69.5% Male; p=0.185), and across all other demographic data collected. Patients requiring tracheostomy were more likely to have flame injury (89.7% vs. 53.4%; p<0.001), inhalation injury (69.2% vs. 8.0%; p<0.001), larger burn size (49.7% TBSA ± 22.1 vs. 14.2% TBSA ± 15.4; p<0.001), more trips to the OR (10.7 ± 7.3 vs. 2.3 ± 2.4; p<0.001), greater number of days on a ventilator (37.4 ± 26.9 vs. 1.6 ± 4.6; p<0.001), and longer hospital stay (97.9 days ± 69.4 vs. 21.2 days ± 20.4; p<0.001). Full demographic and clinical characteristics of the study populations are presented in Table 1. Full univariate comparisons are presented in Table 2.

Mixed Model Regression Analyses

Controlling for age, sex, race/ethnicity, and TBSA, mixed multivariate analyses were performed to examine the relationship between tracheostomy and each long-term, patient-reported outcome. Linear regression demonstrated that receiving a tracheostomy was significantly associated with decreased VR-12 PCS scores at 12- and 24-months (Coeff = −11.53 and −10.84; all $p \leq 0.001$; Table 3). Increased age, black/non-Hispanic relative to white/non-Hispanic race/ethnicity, and TBSA >30% each correlated with decreased VR-12 PCS scores at various time points (all $p < 0.0042$; Supplemental Table 1). Linear regression also demonstrated that receiving a tracheostomy was not associated with VR-12 MCS scores at any time point (all $p > 0.0042$; Table 3). Hispanic relative to white/non-Hispanic race/ethnicity correlated with increased VR-12 MCS scores at all time points, while female sex correlated with decreased scores at 6- and 12-months (all $p < 0.001$; Supplemental Table 2).

Linear regression failed to identify a significant association between tracheostomy and SWL scores at any time point (all $p > 0.0042$; Table 3). Hispanic relative to white/non-Hispanic race/ethnicity correlated with increased SWL scores at all time points (all $p < 0.0042$; Supplemental Table 3). Female sex correlated with decreased scores at 6-months, and TBSA of 10–60% correlated with decreased scores at 24-months (all $p < 0.0042$; Supplemental Table 3).

Linear regression also failed to identify a significant association between tracheostomy and CIQ scores at any time point (all $p > 0.0042$; Table 3). Increased age and Hispanic relative to white/non-Hispanic race/ethnicity correlated with decreased CIQ scores at 6-months (all $p < 0.0042$; Supplemental Table 4).

Among PROMIS-29 domains, linear regression demonstrated that receiving a tracheostomy was associated with decreased physical function at all time points (Coeff. = −7.40, −9.58, −11.34; all $p < 0.001$; Table 3). There were no differences identified in the remaining PROMIS-29 domains based on tracheostomy requirement (all $p > 0.0042$). Full PROMIS-29 multivariate analyses are presented in Supplementary Tables 5–11.

Finally, logistic regression failed to demonstrate a significant association between tracheostomy and employment status (all $p > 0.0042$; Table 3). Black/non-Hispanic relative to white/non-Hispanic race/ethnicity and TBSA >30% each correlated with an increased likelihood of unemployment at various time points (all $p \leq 0.003$; Supplemental Table 12).

Post-Hoc Analyses

To better control for center- and provider-level influences, as well as the influence of injury severity, additional post-hoc multivariate modeling was performed on outcomes identified as significant in a priori regressions (Table 4A). After the addition of BMS site, burns to the face, ventilator days, and number of trips to the OR as covariates, tracheostomy remained independently associated with decreased VR-12 PCS scores, but only at 24-months (Coeff = −5.85; $p = 0.004$). In contrast, tracheostomy did not remain associated with decreased PROMIS-29 Physical Function scores at any time point after the inclusion of the additional covariates (all $p > 0.0042$; Table 4A).

Post-hoc propensity-matched analyses similarly controlled for age, sex, race/ethnicity, BMS site, TBSA, burns to the face, and number of trips to the OR. The estimated average treatment effect of tracheostomy on both VR-12 PCS and PROMIS-29 Physical Function was negative and statistically significant (Table 4B). For VR-12 PCS, this was identified at 12-(Coeff = −15.31; $p<0.001$) and 24-month follow-up (Coeff = −13.20; $p<0.001$). For PROMIS-29 Physical Function, this was identified at 6- (Coeff = −10.99; $p<0.001$) and 24-month follow-up (Coeff = −13.37; $p<0.001$).

Discussion:

Using the Burn Model System (BMS) National Longitudinal Database, the present study is a preliminary exploration of long-term patient outcomes following tracheostomy in burns. Congruent with prior large database investigation (23), retrospective review identified tracheostomy in roughly 5% of burn patients. From 2013 to 2020, mixed model regression analyses demonstrated that only VR-12 PCS scores at 24-month follow-up were significantly worse among those requiring tracheostomy. Tracheostomy was not associated with VR-12 MCS, SWL, CIQ, or PROMIS-29 scores. Likewise, tracheostomy was not found to be independently associated with employment status or number of days to RTW.

With no clear consensus on its specific indications or optimal timing (6–8), the use of tracheostomy in the setting of burn injury remains controversial. Practically speaking, tracheostomy facilitates patient comfort and simplifies pulmonary toilet (24). In theory, it should also shorten duration of sedation, allowing for earlier rehabilitation, which in turn contributes to improved outcomes following ICU admission (25–27). On the other hand, tracheostomy may introduce significant morbidity, increasing rates of pulmonary sepsis (8, 28), tracheal stenosis or fistulazation (29), and anterior neck disfigurement (30). To date, little has been published specifically investigating the associations between tracheostomy and long-term HRQL after burn injury.

During the acute hospitalization, Smailes et al. identified that early tracheostomy in patients with severe burns enabled earlier initiation of active exercise and was associated with improved functional independence at hospital discharge (31). However, other studies conducted at long-term follow-up have failed to demonstrate any association between tracheostomy and physical function when using the PCS (9, 10, 12). Likewise, post-hoc regression models performed herein identified little correlation between tracheostomy requirement and measures of physical health, either by VR-12 PCS or PROMIS-29 Physical Function. In fact, tracheostomy was only found to be independently associated with decreased VR-12 PCS scores at 24-months.

This lone observed difference can be better contextualized through interpretation via Minimal Clinically Important Difference (MCID). An MCID is defined as the smallest change in domain score that patients perceive as beneficial (32). In populations with pseudarthrosis, an MCID as high as >6.1 in PCS has been reported (33). Similarly, in populations with cervical spondylotic myelopathy, an MCID >9.6 in PCS has been described (34). The present study identified a decrease of 5.85 in VR-12 PCS at 24-months among those requiring tracheostomy. Although an MCID for PCS has yet to be established in

the burn population, it is notable that this difference falls below MCIDs of both the aforementioned populations (33, 34). This suggests that the disparity in physical health observed in VR-12 PCS at 24-months, while statistically significant, is not *clinically* significant.

Despite this study's largely negative findings, it remains a preliminary exploration, and the extent of conclusions drawn from it should be tempered. As mentioned previously, a variety of indications can trigger the decision to pursue tracheostomy after burn injury. These include deep burns of the face and neck; respiratory failure requiring prolonged ventilatory support; or large burn injuries requiring significant resuscitation and frequent wound care with repeated endotracheal intubation. Though the post-hoc analyses in the present study attempt to assess center- and provider-level influences, as well as the influence of injury severity, the relatively small number of patients identified requiring tracheostomy (n = 39) significantly limits the potential to explore these associations meaningfully. For example, propensity-matched analyses identified negative and statistically significant treatment effects of tracheostomy on VR-12 PCS and PROMIS-29 Physical Function at various time points. However, resultant SEs and 95% CIs were large due to the n of 39. As such, interpretations using these models were difficult to make with any precision. This highlights the need for further investigations of larger scale to fully characterize the relationship between tracheostomy and long-term HRQL. Future studies should aim to better assess factors like tracheostomy indication and type, management protocols, timing of decannulation, burn size and depth, burn location, and infection for effect modification with respect to patient outcomes after tracheostomy in burns.

Limitations:

In addition to those discussed above, this work does have other limitations to consider. First, the BMS Database is contextual to the burn centers it represents and may not be indicative of the experiences of burn survivors across the entire US. That said, data suggest that the BMS Database does reflect the National Burn Repository (35). Second, the BMS Database does not capture comorbid medical conditions or specific lifestyle factors, which may confound the long-term outcomes measured. The present study is also unable to control for burn depth, infection, or timing of tracheostomy, which might strengthen multivariate regression and propensity-matched analyses. Again however, these data elements are not captured by the BMS Database. Finally, it is worth noting that by nature, retrospective review of patient-reported outcomes is inherently susceptible to recall and response biases.

Conclusion:

This preliminary exploration suggests that physical and psychosocial recovery, as well as the ability to regain employment, are no worse in burn patients requiring tracheostomy. That said, investigations of larger scale are still needed to fully characterize the relationship between tracheostomy and long-term HRQL after burn injury. Future study should specifically assess center- and provider-level influences (i.e., tracheostomy indication and type, management protocols, timing of decannulation, etc.) and the influences of various hallmarks of injury severity (i.e., burn size and depth, burn location, infection, etc.).

Future findings will better inform efforts in providing anticipatory guidance and allocating rehabilitative resources for burn survivors undergoing tracheostomy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Demographic and Clinical Characteristics

	With Tracheostomy (n=39)	Without Tracheostomy (n=675)	p-value*^
Age, mean years (SD)	43.0 (17.2)	46.6 (16.0)	0.12
Sex, % (n)			0.185
Male	79.5 (31)	69.5 (469)	
Race, % (n)			
White	84.2 (32)	82.2 (537)	0.857
Black/African American	7.9 (3)	10.0 (65)	
Asian	--	2.1 (14)	
Other	7.9 (3)	5.7 (4)	
Ethnicity, % (n)			
Hispanic	26.3 (10)	15.1 (96)	0.064
Non-Hispanic	73.7 (28)	84.9 (541)	
Race/Ethnicity, % (n)			
White, Non-Hispanic	61.5 (24)	69.8 (457)	0.325
Black, Non-Hispanic	7.7 (3)	9.8 (64)	
Hispanic	23.1 (9)	12.7 (83)	
Other	7.7 (3)	7.8 (51)	
Highest level of education, % (n)			
Less than high school	33.3 (13)	20.2 (116)	0.936
High school diploma/GED	48.7 (19)	50.5 (290	
Associate degree	7.7 (3)	8.5 (49)	
BA/BS or higher	10.3 (4)	20.7 (119)	
Pre-injury employment status, % (n)			
Working	68.4 (26)	66.5 (395)	0.183
Not Working	21.1 (8)	20.2 (120)	
Retired	10.5 (4)	13.3 (79)	
Pre-injury physical impairment, % (n)			0.480
Yes	15.4 (6)	20.0 (113)	
Primary etiology of injury, % (n)			
Fire/flame	89.7 (35)	53.4 (360)	*<0.001***
Electricity	2.6 (1)	5.3 (36)	
Flash	2.6 (1)	2.8 (19)	
Scald	2.6 (1)	14.5 (98)	
Other	2.6 (1)	0.3 (2)	
Chemical	--	2.7 (18)	
Contact with hot object	--	7.0 (47)	
Grease	--	12.9 (87)	

	With Tracheostomy (n=39)	Without Tracheostomy (n=675)	p-value*^
Tar	--	0.9 (6)	
UV light	--	0.2 (1)	
Employment-related injury, % (n)			0.02
Yes	5.1 (2)	20.5 (137)	
Inhalation injury, % (n)			<0.001
Yes	69.2 (27)	8.0 (54)	
TBSA burned, mean % (SD)	49.7 (22.1)	14.2 (15.4)	<0.001
Number of trips to the OR, mean (SD)	10.7 (7.3)	2.3 (2.4)	<0.001
Days on ventilator, mean (SD)	37.4 (26.9)	1.6 (4.6)	<0.001
Length of stay, mean days (SD)	97.9 (69.4)	21.2 (20.4)	<0.001

*Non-parametric t-tests used for continuous variables (Wilcoxon Mann Whitney), Chi-2 or Fisher's exact (when an n was less than 5) tests used for categorical variables

**Fire/flame versus other tested

^Bonferroni's adjustment applied to account for multiple tests. New significant level of 0.002 applied, significant values represented with italics

Table 2.

Patient-Reported Outcome Measures

	With Tracheostomy Mean (SD), n	Without Tracheostomy Mean (SD), n	p-value*^
VR-12 PCS			
6-months	32.9 (9.6), 20	43.3 (11.1), 387	*0.0001*
12-months	31.9 (10.8), 24	45.6 (11.4), 319	*<0.001*
24-months	37.2 (10.0), 16	45.8 (11.1), 202	0.0025
VR-12 MCS			
6-months	46.1 (15.3), 20	50.5 (12.8), 387	0.1657
12-months	48.0 (13.3), 24	51.0 (12.5), 319	0.2197
24-months	50.8 (15.7), 16	51.8 (12.4), 202	0.8724
SWL			
6-months	19.4 (10.3), 21	22.9 (8.9), 395	0.1508
12-months	19.8 (9.3), 24	22.9 (8.9), 333	0.0957
24-months	23.1 (9.1), 16	24.0 (8.8), 201	0.6813
CIQ			
6-months	7.0 (2.3), 19	8.2 (2.2), 371	0.0281
12-months	7.2 (2.2), 23	8.4 (2.5), 317	0.0222
24-months	8.3 (2.3), 15	8.3 (2.4), 200	0.9342
PROMIS-29 Anxiety			
6-months	53.0 (11.3), 21	49.7 (9.9), 397	0.1586
12-months	53.2 (10.4), 25	49.5 (10.2), 336	0.0738
24-months	52.7 (11.9), 16	49.7 (10.3), 207	0.2977
PROMIS-29 Depression			
6-months	52.3 (10.7), 21	49.6 (10.0), 396	0.1789
12-months	52.0 (9.0), 25	49.0 (10.3), 335	0.0584
24-months	53.1 (9.2), 15	49.0 (10.3), 205	0.0639
PROMIS-29 Fatigue			
6-months	52.1 (12.9), 21	48.1 (11.8), 399	0.1417
12-months	52.6 (10.9), 24	48.2 (12.0), 334	0.0455
24-months	49.8 (10.9), 16	48.4 (11.8), 203	0.4972
PROMIS-29 Pain Interference			
6-months	57.9 (9.6), 20	52.2 (10.5), 400	0.0095
12-months	56.8 (11.2), 25	50.0 (10.2), 336	0.0020
24-months	55.8 (10.2), 16	49.5 (10.0), 205	0.0164
PROMIS-29 Physical Function			
6-months	37.7 (7.5), 21	46.6 (9.6), 394	*<0.001*
12-months	37.9 (9.5), 25	48.6 (9.6), 337	*<0.001*
24-months	39.4 (7.5), 16	48.7 (9.4), 208	*0.0001*

	With Tracheostomy Mean (SD), n	Without Tracheostomy Mean (SD), n	p-value*^
PROMIS-29 Sleep Disturbance			
6-months	53.8 (11.0), 21	50.5 (10.6), 404	0.1596
12-months	52.9 (9.7), 25	49.0 (10.8), 337	0.0567
24-months	49.6 (12.3), 16	49.0 (11.6), 209	0.8492
PROMIS-29 Participate in Social Roles			
6-months	47.4 (11.3), 15	53.2 (11.0), 341	0.0442
12-months	46.5 (10.0), 19	54.1 (11.0), 322	*0.0014*
24-months	49.3 (11.9), 16	54.3 (10.6), 205	0.0990
	%, n	%, n	
Employment Status			
Working at 6-months	9.1, 2	56.1, 207	*<0.001*
Working at 12-months	19.1, 2	62.6, 181	*<0.001*
Working at 24-months	28.6, 4	65.9, 118	0.005
Number of days to return to work	317.4 (177.7), 5	117.9 (102.6), 162	0.005

* Non-parametric t-tests used for continuous variables (Wilcoxon Mann Whitney), Chi-2 or Fisher's exact (when an n was less than 5) tests used for categorical variables

^ Bonferroni's adjustment applied to account for multiple tests. New significant level of 0.002 applied, significant values represented with italics

Table 3.

Mixed model regression analyses examining association between tracheostomy[a] and VR-12 PCS, VR-12 MCS, SWL, CIQ, PROMIS-29, and Employment Status, controlling for demographic and clinical factors

	6 months				12 months				24 months			
	Coeff.	**SE**	**95% CI**	**P-value^**	**Coeff.**	**SE**	**95% CI**	**p-value^**	**Coeff.**	**SE**	**95% CI**	**p-value^**
VR-12 PCS	−6.65	2.64	−1.46, −11.84	0.012	−11.53	2.70	−6.21, −16.85	*<0.001*	−10.84	3.36	−4.21, −17.47	*0.001*
VR-12 MCS	−5.33	3.14	−0.85, −11.50	0.091	−4.23	2.97	1.60, −10.07	0.154	−3.27	4.03	4.67, −11.23	0.417
SWL	−4.05	2.08	0.04, −8.13	0.052	−3.04	2.11	1.10, −7.19	0.150	−0.67	2.81	4.86, −6.20	0.812
CIQ	−0.97	0.56	0.13, −2.07	0.083	−1.24	0.63	−0.01, −2.48	0.049	−0.54	0.81	1.06, −2.15	0.505
PROMIS-29												
Anxiety	4.35	2.40	9.07, −0.37	0.071	3.83	2.40	8.55, −0.88	0.111	2.85	3.22	9.20, −3.49	0.377
Depression	2.89	2.42	7.65, −1.88	0.235	2.43	2.42	7.19, −2.33	0.316	6.03	3.46	12.86, −0.80	0.083
Fatigue	5.15	2.75	10.55, −0.26	0.062	4.62	2.77	10.08, −0.83	0.096	4.46	3.52	11.40, −2.48	0.206
Pain Interference	3.15	2.55	8.17, −1.87	0.218	5.29	2.41	10.03, 0.55	0.029	5.29	3.15	11.51, −0.92	0.095
Physical Function	−7.40	2.22	−3.03, −11.76	*0.001*	−9.58	2.23	−5.21, −13.96	*<0.001*	−11.34	2.83	−5.77, −16.91	*<0.001*
Sleep Disturbance	3.41	2.56	8.44, −1.62	0.184	4.53	2.47	9.39, −0.34	0.068	−0.92	3.58	6.14, −7.98	0.798
Participate in Social Roles	−4.36	3.15	1.83, −10.54	0.167	−5.58	2.90	0.14, −11.29	0.056	−5.73	3.24	0.65, −12.12	0.078
	OR	**SE**	**95% CI**	**p-value**	**OR**	**SE**	**95% CI**	**p-value**	**OR**	**SE**	**95% CI**	**p-value**
Employment	5.17	4.10	1.09, 24.51	0.039	5.91	4.02	1.56, 22.44	0.009	4.97	4.04	1.01, 24.41	0.048

Covariates: age, sex, race/ethnicity, TBSA category

[a]Without tracheostomy is reference category

^Bonferroni's adjustment applied to account for multiple tests. New significant level of 0.0042 applied, significant values represented with italics

Table 4A.

Post-hoc linear regression analyses examining association between tracheostomy[a] and outcomes significant in a priori regressions *(covariates: age, sex, race/ethnicity, BMS site, TBSA, burns to the face, ventilator days, number of trips to the operating room)*

	6 months				12 months				24 months			
	Coeff.	**SE**	**95% CI**	**p-value^**	**Coeff.**	**SE**	**95% CI**	**p-value^**	**Coeff.**	**SE**	**95% CI**	**P-value^**
VR-12 PCS	−3.11	2.79	−8.60, 2.37	0.265	−5.59	2.62	−10.84, −0.44	0.034	−5.85	3.07	−14.89, −2.80	*0.004*
PROMIS-29 Physical Function	−2.59	2.35	−7.22, 2.04	0.271	−4.45	2.40	−9.16, 0.27	0.065	−6.50	3.14	−12.69, −0.32	0.039

Table 4B.

Post-hoc propensity-matched analyses examining association between tracheostomy[a] and outcomes significant in a priori regressions *(covariates: age, sex, race/ethnicity, BMS site, TBSA, burns to the face, number of trips to the operating room)*

	6 months				12 months				24 months			
	Coeff.	**Robust SE**	**95% CI**	**p-value^**	**Coeff.**	**Robust SE**	**95% CI**	**p-value^**	**Coeff.**	**Robust SE**	**95% CI**	**p-value^**
VR-12 PCS	−2.60	7.04	−16.41, 11.21	0.712	−15.31	4.21	−23.56, −7.07	*<0.001*	−13.20	0.78	−14.72, −11.67	*<0.001*
PROMIS-29 Physical Function	−10.99	2.55	−15.99, −5.98	*<0.001*	−11.55	5.67	−22.67, −0.34	0.042	−13.37	3.55	−20.33, −6.41	*<0.001*

[a]Without tracheostomy is reference category

^Bonferroni's adjustment applied to account for multiple tests. New significant level of 0.0042 applied, significant values represented with italics