

## Original Article

# Absence of calvarial fracture could predict the need for tracheostomy in traumatic brain injury

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**Aim:** Tracheostomy is a common procedure for intubated patients with traumatic brain injury (TBI) in the intensive care unit (ICU) but optimal timing and the predictors of tracheostomy are still unclear. The aim of our study was to explore whether the traumatic variables of head injury predict the need for tracheostomy in intubated TBI patients.

**Methods:** A single-center, retrospective observational study including a series of TBI patients admitted to Fukui Prefectural Hospital from April 1, 2004 to March 31, 2020 was carried out. Our primary outcome was tracheostomy. Patients with TBI who were intubated and admitted into the ICU within 24 h after injury were enrolled. Exclusion criteria were age less than 18 years, pregnancy, mortality within 24 h, post-cardiac arrest syndrome, and patients for whom life-sustaining interventions were withheld. Radiologic images were also reviewed and the morphology of the head injury was categorized.

**Results:** Seventy-six patients were included. Forty-six patients (60.5%) underwent tracheostomy and 30 patients (39.5%) were successfully extubated. Calvarial fracture (odds ratio [OR] 0.34; 95% confidence interval [CI], 0.13–0.88;  $P = 0.03$ ), Injury Severity Score (OR 1.07; 95% CI, 1.00–1.15;  $P = 0.04$ ), and Glasgow Coma Scale score (OR 0.84; 95% CI, 0.73–0.96) were statistically significant in the univariable analysis. Multivariate logistic regression identified calvarial fracture as an independent predictor for tracheostomy. The model involving calvarial fracture, Injury Severity Score  $\geq 16$ , and Glasgow Coma Scale score  $\leq 8$  showed the area under the receiver operating characteristic curve for the model was 0.737 (95% CI, 0.629–0.846).

**Conclusions:** The absence of calvarial fracture could predict the necessity for tracheostomy in intubated TBI patients when combined with other factors. Further prospective randomized trials are necessary to confirm the findings.

**Key words:** Calvarial fracture, tracheostomy, traumatic brain injury

## INTRODUCTION

TRAUMATIC BRAIN INJURY (TBI) is a huge public health burden globally, with enormous economic consequences. Approximately 50–60 million new TBI cases occur globally and TBI costs the global economy approximately \$400 billion annually.<sup>1</sup>

Although tracheostomy for severe head trauma has been a common procedure carried out for TBI patients in the intensive care unit (ICU), there are considerable variations in the

rate and timing of tracheostomy among institutions.<sup>2</sup> The ideal timing of tracheostomy and the patients who will benefit from the procedure are unclear. Although any survival benefit has not yet been clearly established,<sup>3,4</sup> early tracheostomy (ET) (i.e., within 3–7 days) is recommended for TBI patients because it is associated with the reduced need for mechanical ventilation, shorter ICU length of stay (LOS),<sup>2–4</sup> and improved neurological outcomes.<sup>2</sup>

In contrast, overemphasis on ET involves the potential risk of undertaking the procedure in patients who would have been successfully extubated if more time had been provided.<sup>5</sup> Complications of tracheostomy might not be as rare, and the procedure might not be as safe as previously expected.<sup>3</sup> A more recent study revealed that the incidence of tracheostomy complications was observed among 5%–40% patients and mortality occurred in up to 2% patients.<sup>6</sup> Another survey indicated that a significant number of

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tracheotomy complications leading to death or permanent disability occurred at the national level.<sup>7</sup> In the United States, there are an estimated 500 tracheostomy-related deaths annually.<sup>7</sup> Additionally, the potential danger of tracheostomy could be difficult to recognize because complications are likely to occur more than a week after the procedure.<sup>7</sup> In view of the significance of the results, complications of tracheostomy should not be overlooked and unnecessary tracheostomy should be avoided as much as possible.

Therefore, there is a strong demand for the predictors of tracheostomy. Previously, several studies have attempted to determine the predictive factors of tracheostomy,<sup>2,5,8–14</sup> but solid evidence has not been established. Factors available early in the clinical course are desirable for decision-making of ET and we hypothesized that the morphological classification of head injury might contribute to the prediction of tracheostomy. The aim of our study was to explore whether the classification of head injury predicts the need for tracheostomy for TBI patients who were intubated and admitted to the ICU.

## METHODS

**T**HIS WAS A single-center, retrospective observational study. We reviewed a consecutive series of TBI patients admitted to Fukui Prefectural Hospital (comprising 10 ICU beds out of a total of 872 hospital beds) from April 1, 2004, to March 31, 2020. Patient data were obtained from the hospital's electronic chart records.

In addition to patient characteristics, computed tomography images were reviewed and the morphology of the head injury was categorized. The thickness of the subdural hematoma (SDH) or epidural hematoma (EDH) and the diameter of the intracranial hematoma (ICH) or brain contusion were also measured in the axial view. The Abbreviated Injury Scale (AIS) was scored based on the AIS 2005 update 2008. Diffuse axonal injury (DAI) was also defined based on prolonged traumatic coma (>6 h) as well as imaging validations that are exemplified in AIS 2005 update 2008. Initial Glasgow Coma Scale (GCS) was defined as GCS on the arrival at the emergency department. Circulatory shock was defined as a Shock Index >1, according to the ratio of heart rate as compared with systolic blood pressure, or systolic blood pressure <90 mmHg on arrival at the emergency department.

Throughout the study period, the indication for tracheostomy was judged by a board-satisfied intensive care physician or anesthesiologist when the prolonged intubation more than 14 days was expected due to persistent dysfunction of consciousness, the failure of extubation, mechanical ventilation for dyspnea, and airway protection.

This study was carried out in line with the principles of the Declaration of Helsinki. Institutional review board approval was obtained before study initiation.

## Study cohort

All patients with TBI admitted to the hospital during this period were screened for eligibility, and those patients who met the inclusion criteria of admission to the ICU and intubation within 24 h after injury were enrolled in the study.

For the purpose of assessing predictive factors for tracheostomy, the following exclusion criteria were set: (i) age <18 years, (ii) pregnancy, (iii) mortality within 24 h, (iv) post-cardiac arrest syndrome, and (v) patients for whom physicians withheld life-sustaining interventions, including tracheostomy, due to a devastating condition or persistent deep coma.

Sample size was determined from the number of cases in the facility during the study period.

## Outcome

The primary outcome evaluated in our study was tracheostomy. The patients who were intubated and admitted to the ICU underwent extubation or tracheotomy before moving to the general ward. The decision to extubate was made by intensive care physicians or anesthesiologists who were independent of neurosurgeons. Tracheostomy was performed by intensive care physicians or neurosurgeons, depending on the situation.

The secondary outcomes of tracheostomy were in-hospital mortality, ICU-LOS, Hospital-LOS and modified Rankin Scale (mRS) score at discharge.

## Statistical analysis

Summary statistics are presented as the median and interquartile range or number and percentage, as appropriate. The Mann–Whitney *U*-test and Fisher's exact test were used to compare variables between the tracheostomy and extubation groups. *P*-values <0.05 were considered statistically significant. Univariate regression analysis was used to evaluate variables. Multiple logistic regression analysis was used to adjust for confounders about the primary outcome. Inclusion of variables in the multiple logistic regression analysis was based on previous published reports and existing clinical knowledge. The standard method was used to estimate sample size for multiple logistic regression, with at least 10 outcomes needed for each included independent variable. Variance inflation factor (VIF) was used to check for multicollinearity. Predictive and complexity characteristics of the

model were considered during modeling. The model's discrimination was evaluated using the area under the receiver operator characteristic (AUROC) curve. All statistical analyses were undertaken using R (version 3.3.2; R Foundation for Statistical Computing).

## RESULTS

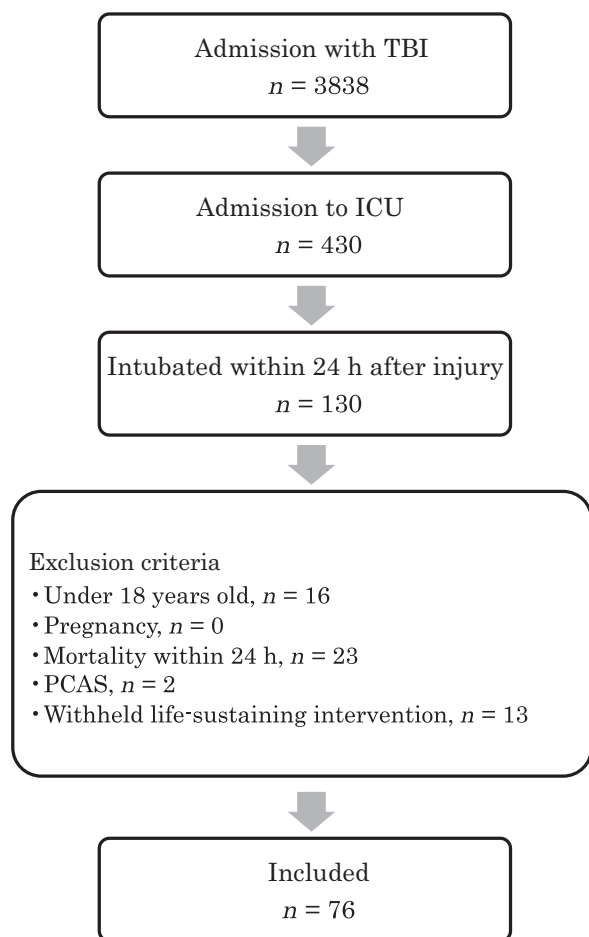
**S**EVENTY-six patients were included during the study period. A flowchart of patient inclusion is shown in Figure 1.

Overall, 46 patients (60.5%) underwent tracheostomy, and 30 patients (39.5%) were successfully extubated in the ICU. Baseline characteristics were similar between the two groups, except for the mechanism of injury ( $P = 0.046$ ) (Table 1). The mean durations until extubation and

tracheostomy were 4 (3–6) and 7 (5–9.7) days, respectively. In tracheostomy group, 47.8% of the patients were finally decannulated; the mean duration until decannulation was 37.5 (26.0–49.2) days and the minimum was 14 days. In the tracheostomy group, one patient, once extubated, was intubated again and finally underwent a tracheostomy. In the extubation group, one patient was extubated, then intubated again, and finally extubated again. As far as we could ascertain, the main reasons tracheostomy was not carried out were chest injury dyspnea or ventilator-associated pneumonia/ventilator-associated lung injury, nor was tracheostomy carried out in a patient with coexisting spinal cord injury and another patient with coexisting facial injury with persistent consciousness disorder due to TBI. Thus, all of the indications of tracheostomy were associated with TBI in this study. The main reason for intubation was the dysfunction of consciousness or craniotomy (52/76), followed by coexisting hemorrhagic shock or hemostasis procedure (8/76). There were patients in each group who underwent intubation out of concern for airway burn because of a history of falling at a fire scene, but were eventually tracheostomized due to persistent disturbance of consciousness. Intubation due to falling into water or seizures was considered to be secondary to head injury.

Initial GCS (7 [4.25–10] vs. 9 [7–13],  $P = 0.01$ ), calvarial fracture (37.0% vs. 63.3%;  $P = 0.03$ ), mechanism of injury ( $P = 0.046$ ) and AIS-abdomen (0 [0] vs. 0 [0],  $P = 0.0352$ ) were significantly different between the tracheostomy and extubation groups (Table 2). Univariate regression analysis was carried out for morphological classification and other covariates selected based on previous published reports. Calvarial fracture (odds ratio [OR] 0.34; 95% confidence interval [CI], 0.13–0.88;  $P = 0.03$ ), Injury Severity Score (ISS) (OR 1.07; 95% CI, 1.00–1.15;  $P = 0.04$ ), and Glasgow Coma Scale (GCS) score (OR 0.84; 95% CI, 0.73–0.96) were determined to be independently associated with undergoing tracheostomy (Table 3). Multivariate logistic regression analysis including calvarial fracture, ISS  $\geq 16$  and GCS  $\leq 8$  was carried out (Table 4). None of the VIF values were up to 10 and the mean VIF of the model was less than 5, proving no collinearity. The AUROC for the model was 0.737 (95% CI, 0.629–0.846).

For the secondary outcomes, the tracheostomy group showed a higher mRS (5 [3.2–5] vs. 1 [1–3.7];  $P < 0.01$ ) and a longer ICU-LOS (11 [8.2–14] vs. 7 [5–10];  $P < 0.01$ ). Although the mortality rate was not significantly different (6.5% vs. 0%;  $P = 0.274$ ), three cases of unexpected in-hospital mortality were observed in the tracheostomy group. Asphyxia (day 6), myocardial ischemia (day 10), and progression of cerebral hernia (day 11) were considered as causes of death.



**Fig. 1.** Flowchart of patient inclusion in the study. ICU, intensive care unit; PCAS, post-cardiac arrest syndrome; TBI, traumatic brain injury.

**Table 1.** Baseline characteristics of study patients with traumatic brain injury (TBI)

	Tracheostomy, <i>n</i> = 46	Extubation, <i>n</i> = 30	<i>P</i> -value
Age (years)	65 (40.5–76.7)	58 (40.5–66.7)	n.s.
Male (%)	31 (67.4)	21 (70.0)	n.s.
Mechanism			
MVA (%)	34 (73.9)	15 (50.0)	0.046*
Fall (%)	5 (10.9)	11 (36.7)	
Stumbling (%)	4 (8.7)	3 (10.0)	
Other (%)	3 (6.5)	1 (3.3)	
SBP (mmHg)	131 (117.5–156.7)	137 (113.2–151.0)	n.s.
HR (bpm)	94 (80.0–103.0)	103.5 (85.5–120.0)	n.s.
Shock Index >1 (%)	11 (23.9)	7 (23.3)	n.s.
Lone TBI (%)	10 (21.7)	7 (23.3)	n.s.
Multiple trauma (%)	36 (78.3)	23 (76.7)	n.s.
Craniotomy (%)	16 (34.8)	8 (26.7)	n.s.
Duration until tracheostomy (days)	7 (5–9.75)	ND	ND
Decannulation of tracheostomy (%)	22 (47.8)	ND	ND
Duration until decannulation (days)	37.5 (26.0–49.2)	ND	ND
Duration until extubation (days)	ND	4 (3–6)	ND

Data are shown as *n* (%) or median (interquartile range).

HR, heart rate; MVA, motor vehicle accident; ND, no data; n.s., not significant; SBP, systolic blood pressure.

\*Statistically significant.

## DISCUSSION

**T**HIS STUDY EXAMINED whether variables available in the early stage of clinical course could predict the necessity for tracheostomy. To the best of our knowledge, this is the first study to reveal that the morphological classification of head injury might contribute to the prediction of tracheostomy.

Interestingly, our results revealed that the presence of calvarial fracture was independently protective against tracheostomy. A small number of studies have implied that calvarial fracture predicts poor outcomes in patients with mild TBI (GCS 14–15),<sup>15</sup> but these studies did not answer our question about the presentation of patients for whom tracheostomy should or should not be carried out among intubated TBI patients in the ICU. In contrast, Wu *et al.* reported that TBI patients without calvarial fractures showed a lower rate of good outcomes than those with single or multiple calvarial fractures.<sup>16</sup> In their study, TBI patients who underwent craniotomy within 48 h after trauma were included and the initial GCS was 8 (5–12) for no calvarial fracture, 10 (6–14) for a single calvarial fracture, and 8 (5–12) for multiple calvarial fractures, suggesting that their study included patients with moderate to severe TBI for whom maximal treatment was attempted. This is consistent with our finding that calvarial fractures could predict extubation. However, Wu *et al.* investigated neurological outcome,

whereas we set tracheostomy as the primary outcome for the reason of clinical utility in the ICU. The mRS did not show a significant difference in our study, thus caution is required when interpreting these findings. The mechanics of injury could also affect the outcome. Several studies have implied that calvarial fractures are associated with a good prognosis. Kleiven reported that SDH, DAI, ICH, concussion, and contusion were caused by oblique impact, whereas skull fracture, EDH, and contusions secondary to skull fracture were caused by linear kinematics.<sup>17</sup> In addition, a calvarial fracture could work as a shock absorber. Ren *et al.* reported that a skull fracture could significantly reduce the risk of brain injury under medium and high velocities.<sup>18</sup> Moreover, Ruan *et al.* reported that the brain's iso-stress curve was higher than that of the skull, indicating that a skull fracture can occur more easily than concussion.<sup>19</sup> A space-occupied lesion, its volumetric effect, and evacuation could affect the severity of neurologic damage. A previous study revealed that evacuated mass lesion, including EDH, was a type of TBI for which therapeutic hypothermia was effective,<sup>20</sup> suggesting that EDH is potentially recoverable with proper management, and it could function as a confounding factor for calvarial fracture. However, craniotomy, SDH, EDH, ICH, and its thickness or size did not show a significant difference (Table 2) or independent predictive utility (Table 3). We had set tracheostomy as the primary outcome for the purpose of determining practical predictors for tracheostomy

**Table 2.** Variables and outcomes in patients with traumatic brain injury

	Tracheostomy, n = 46	Extubation, n = 30	P-value
GCS	7 (4.2–10.0)	9 (7.0–13.0)	0.01*
ISS	25 (22.5–29.0)	25 (14.7–25.0)	n.s.
AIS			
Head	4 (2.0–4.0)	3 (2.0–5.0)	n.s.
Face	0 (0.0–2.0)	0 (0.0–1.0)	n.s.
Neck	0 (0.0)	0 (0.0)	n.s.
Chest	2 (0.0–3.0)	0 (0.0–3.0)	n.s.
Abdomen	0 (0.0–0.0)	0 (0.0–0.0)	0.04*
Pelvis/extremity	0 (0.0–2.0)	0 (0.0–2.0)	n.s.
Spine	0 (0.0–2.0)	0 (0.0–1.5)	n.s.
Radiographic findings			
SDH	24 (52.2)	11 (36.7)	n.s.
EDH	7 (15.2)	10 (33.3)	n.s.
SDH or EDH	27 (58.7)	17 (56.7)	n.s.
Thickness of hematoma (mm)	11 (6.0–18.5)	9 (5.0–22.0)	n.s.
Contusion	29 (63.0)	16 (53.3)	n.s.
ICH	4 (8.7)	0 (0.0)	n.s.
Diameter of hematoma (mm)	21.5 (11.2–33.0)	15.5 (13.2–17.7)	n.s.
SAH	32 (69.6)	22 (73.3)	n.s.
Calvarial fracture	17 (37.0)	19 (63.3)	0.03*
Skull base fracture	9 (19.6)	4 (13.3)	n.s.
DAI	6 (13.0)	2 (6.7)	n.s.
Secondary outcomes			
ICU-LOS (days)	11 (8.2–14.0)	7 (5.0–10.0)	<0.01*
Hospital-LOS (days)	73 (49.0–142.5)	68 (28.2–149.0)	n.s.
mRS	5 (3.2–5.0)	1 (1.0–3.7)	<0.01*
In-hospital mortality (%)	3 (6.5)	0 (0.0)	n.s.

Data are shown as n (%) or median (interquartile range).

AIS, Abbreviated Injury Scale; DAI, diffuse axonal injury; EDH, epidural hematoma; GCS, Glasgow Coma Scale; ICH, intracranial hematoma; ICU, intensive care unit; ISS, Injury Severity Score; LOS, length of stay; mRS, modified Rankin Scale; n.s., not significant; SAH, subarachnoid hemorrhage; SDH, subdural hematoma.

\*Statistically significant.

in well-treated TBI patients. Thus, the most severe patients for whom life-sustaining support was withheld were excluded from the study because tracheostomy is usually also withheld for those patients. Our results could provide practical information for physicians, but the process of deciding to withhold life-sustaining support is still complicated because it involves ethical matters. However, although seemingly paradoxical, the results of these basic studies on mechanics<sup>17–19</sup> might explain the results of our clinical observational study, namely that calvarial fractures are associated with avoiding tracheostomy.

Our findings are consistent with previous reports that lower GCS scores were related to tracheostomy.<sup>2,5,8–14</sup> However, some studies revealed the predictive value of GCS on days 4 or 5.<sup>5,10,13</sup> Considering that ET is

recommended from day 3,<sup>3</sup> the practical utility of these studies was limited and predictors should be obtained early in the clinical course, thus, we focused on initial GCS on arrival at the emergency department. Gurkin *et al.* and Robba *et al.* reported an initial GCS cut-off of 8<sup>2,14</sup> and we followed this guideline. Injury Severity Score was also reported to be independently associated with tracheostomy, but the cut-off values were inconsistent.<sup>8,14</sup> We used ISS  $\geq 16$  because it was widely accepted as a definition of severe injury. Trauma at sites other than the head was expected to be a potential confounder, but was evaluated in different ways in previous studies,<sup>2,8,9</sup> thus we decided to evaluate using ISS instead.

Our other study findings also have implications. Hematoma thickness and diameter did not show a significant

**Table 3.** Univariate regression analysis of variables in patients with traumatic brain injury

	OR	95% CI	P-value
Age	1.02	0.99–1.04	0.18
Male sex	0.89	0.33–2.40	0.81
GCS	0.84	0.73–0.96	0.01*
GCS ≤8	1.53	0.97–2.43	0.07
ISS	1.07	1.00–1.15	0.04*
ISS ≥16	3.82	1.03–14.10	0.04*
AIS			
Head	1.39	0.94–2.04	0.10
Face	1.36	0.87–2.14	0.18
Neck	0.96	0.43–2.14	0.92
Chest	1.04	0.78–1.39	0.77
Abdomen	0.59	0.31–1.12	0.11
Pelvis/extremity	0.98	0.69–1.38	0.89
Spine	1.20	0.78–1.85	0.40
Chest injury (AIS-chest ≥1)	1.25	0.50–3.13	0.64
Multiple trauma	1.10	0.37–3.29	0.87
Shock Index >1	1.03	0.35–3.05	0.95
Craniotomy	1.47	0.53–4.03	0.46
Radiological findings			
SDH	1.88	0.74–4.83	0.19
EDH	0.36	0.12–1.09	0.07
SDH or EDH	1.09	0.43–2.76	0.86
Thickness of hematoma (mm)	0.99	0.93–1.05	0.68
Contusion	1.49	0.59–3.80	0.40
ICH	1	Reference	0.99
Diameter of hematoma (mm)	1.07	0.97–1.17	0.16
SAH	0.83	0.30–2.32	0.72
Calvarial fracture	0.34	0.13–0.88	0.03*
Skull base fracture	1.58	0.44–5.69	0.48
DAI	2.10	0.40–11.20	0.38

AIS, Abbreviated Injury Scale; CI, confidence interval; DAI, diffuse axonal injury; EDH, epidural hematoma; GCS, Glasgow Coma Scale; ICH, intracranial hematoma; inf, in full; ISS, Injury Severity Score; OR, odds ratio; SAH, subarachnoid hemorrhage; SDH, subdural hematoma.

\*Statistically significant.

difference between the two groups (Table 2), which might imply that the dynamics at impact could have a larger effect on brain damage than the mass effect of intracranial space-occupied lesions. The difference in the mechanism might also have been related to different injury dynamics. In addition, longer ICU-LOS in the tracheostomy group (11 [8.25–14] vs. 7 [5–10] days), the observed shorter duration until extubation (median, 4 days) than the duration until

**Table 4.** Multivariable logistic regression analysis of variables in patients with traumatic brain injury

	OR	95% CI	P-value
Calvarial fracture	0.22	0.07–0.67	<0.01*
GCS ≤8	1.95	0.71–5.39	0.20
ISS ≥16	6.54	1.51–28.40	0.01*

CI, confidence interval; GCS, Glasgow Coma Scale; ISS, Injury Severity Score; OR, odds ratio.

\*Statistically significant.

tracheotomy (median, 7 days), the low chance of decannulation (47.8%), and the long duration until decannulation (median, 37.5 days; minimum, 14 days) indicate that tracheostomy successfully shortened ICU-LOS and was undertaken for appropriate patients in our study. Although nearly half of the tracheostomy group were finally decannulated, there is little scientific evidence regarding decannulation in tracheotomized patients.<sup>21</sup> One report showed that 57% of tracheotomized patients were decannulated. However, the study was carried out at a rehabilitation hospital and TBI accounted for no more than 14.0% of patients; considering that we could not track every decannulation after transfer to a rehabilitation hospital in our study, the results are not comparable.<sup>22</sup> With respect to coexisting pathophysiology, the univariable analysis showed that Shock Index >1 did not predict tracheostomy, which was consistent with our prior expectation that hemorrhagic shock does not affect tracheostomy after hemodynamic status is stabilized within a few days. Regarding prognosis, a significant difference in mRS ( $P < 0.001$ ) between the tracheostomy and extubation groups implied that initial GCS was strongly related to neurologic outcome. Moreover, although it was not statistically significant, three cases (6.5%) of in-hospital mortality occurred in the tracheostomy group after tracheostomy. Even though it is unclear whether tracheostomy is the cause or the result of the potential mortality risk, unnecessary tracheostomy should be avoided.

Our study stands out from previous studies in that it revealed that the absence of calvarial fracture, along with other factors, contributes to predicting the necessity for tracheostomy. Because the absence of calvarial fracture means mild and severe TBI, interpretation should be carried out in conjunction with other factors such as GCS and ISS. It is practical to recommend ET for intubated TBI patients with an initial GCS ≤8, ISS ≥16, and without calvarial fracture for the expectation of improvement in prognosis.<sup>2–4,21</sup> This provides clinicians with useful information on the decision-making and timing of tracheostomy in TBI patients.

This study has some limitations. First, the data were collected over the course of 16 years, hence, the clinical practice might have changed throughout the period. Second, the most severe cases, for whom life-sustaining support was withheld, were excluded from the study. Third, the effect of coexisting clinical conditions except for TBI on intubation or tracheostomy is an important concern due to the complexity of the pathophysiology of multiple trauma, thus external validity could be compromised. This study included both lone TBI and multiple traumas to evaluate injuries other than head injury as predictive factors of tracheostomy, but further study targeting TBI alone might be more appropriate to evaluate the correlation between head trauma and tracheostomy. Finally, this was a single-center, retrospective study involving a small cohort, thus, unidentified residual confounders are undeniable. Despite these limitations, the absence of calvarial fracture, along with other factors, could predict the necessity for tracheostomy in intubated TBI patients. Further prospective randomized trials with more participants are necessary to clarify the involvement of coexisting pathophysiology and determine the subgroup whose need for tracheostomy is accurately predictable.

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## DISCLOSURE

Approval of the research protocol: This study was approved by the institutional review board of Fukui Prefectural Hospital (approval no. 19-63).

Informed consent: Based on the opt-out approach, we disclosed information about this study and excluded data when the patient declined to participate directly or by proxy.

Registry and the registration no. of the study: N/A.

Animal studies: N/A.

Conflict of interest: None.

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