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Original Article

Development and validation of a model to predict the need for emergency front-of-neck airway procedures in trauma patients

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Summary

The present study aimed to develop and validate a model for predicting the need for emergency front-of neck airway (eFONA) procedures among trauma patients. This was a multicentre retrospective cohort study using data from the Japan Trauma Data Bank between January 2004 and December 2017. Only adult trauma patients were included. The cohort was divided into development and validation cohorts. A simple scoring system was developed to predict the necessity for emergency front-of neck airway procedures in the development cohort using a logistic regression model. The external validity and diagnostic ability of the scoring system was assessed in the validation cohort. In total, 198,182 out of 294,274 patients were included; emergency front-of-neck airway occurred in 467 patients (0.24%) they were divided into development (n = 100,120 with 0.22% undergoing emergency front-of neck airway) and validation (n = 98,062 with 0.25% undergoing emergency front-of neck airway) cohorts. The 'eFONA' prediction scoring system was developed in the development cohort, with a score of +1 for each of the following: Eye opening (no eye opening in response to any stimuli); Fall from height or motor bike; Oral–maxillofacial injury; Neck tracheal injury; and Airway management by paramedics. In the validation cohort, the C-statistic of the scoring system was 0.820. Setting the cut-off value at one for rule-out, the sensitivity and negative likelihood ratios were 0.86 and 0.22, respectively. Setting the cut-off value at two for rule-in, the specificity and positive likelihood ratios were 0.91 and 6.6, respectively. The present scoring system may assist in predicting the need for emergency front-of neck airway procedures among the general trauma population.

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Introduction

Difficult airway is defined as the clinical situation in which conventionally trained experts experience difficulties performing facemask ventilation of the upper airway, tracheal intubation or both [1]. A small subset of difficult airway situations will result in a 'cannot intubate, cannot oxygenate' (CICO) emergency; a life-threatening situation associated with high morbidity and mortality [1–3]. Trauma

places patients at high risk of both difficult airway and CICO due to a multitude of factors, including airway obstruction or injury; potential cervical spine injury; injuries to the face or neck; and critical conditions including shock from several aetiologies, agitation or coma [2–4]. As part of an airway strategy, the ability to perform an emergency front-of-neck airway (eFONA) is an essential skill to save a life [1–3].

Although the importance of eFONA is widely understood, individual clinician experience with eFONA is limited. In emergency medicine, eFONA, generally in the form of cricothyroidotomy, occurs in approximately 0.8–0.9% of all attempted tracheal intubations, and 0.2–0.6% in the setting of trauma [5–9]. Lack of adequate experience and practice may lead to delay in the decision making required to proceed to an eFONA, potentially resulting in cerebral hypoxia and cardiac arrest [3]. Sufficient time for risk assessment may be unavailable in emergency trauma cases [2–4, 10, 11]. A prediction tool to prepare for an eFONA procedure before patient hospital arrival may be useful for both communication and risk stratification in trauma patients.

Two case series [7, 8], totalling 169 cases, reported that cricothyroidotomy was required for trauma patients with facial fractures, suspected cervical spine injury, traumatic airway obstruction and failed tracheal intubation. In a study of 44 patients undergoing pre-hospital eFONA over a 20-year period, Lockey et al. [9] reported that severe burns, road traffic collisions, fall from a height and head and facial injuries were often associated with the need for eFONA. Although the characteristics of patients who have received an eFONA procedure are described in these publications, prediction tools for stratifying the chance of a patient requiring an eFONA procedure are limited.

The aims of this study were to develop a prediction scoring system to anticipate the need for an eFONA procedure in a retrospective cohort of trauma patients, and to assess the validation and diagnostic abilities of this scoring system among a second retrospective cohort of trauma patients.

Methods

This study developed and validated a multivariable prediction model. The methodology has been reported according to the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) statement [12]. The ethics committees of all the institutions and the Japanese Association for the Surgery of Trauma approved the participation of the registry and retrospective analyses using anonymised data from the Japan Trauma Data Bank (JTDB) (see also Supporting Information, Appendix S1 for participating trauma centres). The anonymised JTDB data were available to the institutional members of the Japan Trauma Care and Research for research purposes.

We conducted a retrospective analysis using epidemiological and clinical data from the JTDB based on 235 registered hospitals throughout Japan. The JTDB is a nationwide, multicentre, observational trauma registry, established in 2003 by the Trauma Registry Committee of the Japanese Association for the Surgery of Trauma, and the Committee for Clinical Care Evaluation of the Japanese Association for Acute Care Medicine [13]. The database is managed by the Japan Trauma Care and Research, a non-profit organisation for trauma research [14]. This database includes pre-hospital information, clinical information from Emergency Departments, diagnoses based on the Abbreviated Injury Scale (AIS) and Injury Severity Scores (ISS) [15, 16] (see also Supporting Information, Appendix S2) and mortality outcomes. Almost all institutions participating in the JTDB are government-certified tertiary emergency and critical care centres. In Japan, 284 government-certified tertiary emergency and critical care centres are dedicated to 349 secondary medical regions, with each region serving approximately 500,000 Japanese residents [13, 15, 17, 18]. Trauma patients transferred to participating hospitals with injuries coded > 2 using the AIS severity scale in least one body region, or patients with severe trauma who are registered based on the hospitals' discretion, are eligible for inclusion in the JTDB [14]. Patients or their relatives who refuse to be registered are not included. Clinical data are registered in a voluntary web-based registration system using pre-specified data sheets. This is performed by data managers or administrators in each hospital, using in-hospital charts and pre-hospital records submitted by paramedics. Participation of JTDB is utilised by the government to assess the quality of certified tertiary emergency and critical care centres [18].

We included all adult trauma patients (≥ 16 years of age) registered in the JTDB between January 2004 and December 2017. We did not include patients who suffered cardiac arrest, defined as a heart rate (HR) of 0 or systolic blood pressure (BP) of zero at the scene of injury. These patients were not included because, with the exception of patients with obvious signs of death such as rigor mortis, paramedics in Japan are not approved to declare death at the scene of injury. In addition, patients with an unknown mechanism of injury, injury due to burns or those not transferred directly from the scene by ambulance (e.g. physician-staffed helicopter or transferred from other

hospitals) were also not included. Patients with burns or an unknown type of injury were not defined as a general trauma population and patients not directly transferred from the scene by ambulance might have received medical intervention before hospital arrival. Thus, we did not include those patients to ensure the prediction model specifically targeted trauma patients managed by paramedics who may require eFONA upon arrival to hospital.

We divided the included institutions randomly and equally into two cohorts. One cohort was used to develop the prediction scoring system (development cohort), and the other cohort was used to assess the validation and diagnostic abilities of the scoring (validation cohort). Further cohort details can be found in the Supporting Information (Appendix S3).

We collected patient characteristics including: age (ranges 16–39, 40–59, 60–79 and ≥ 80 years); sex; mechanism of injury (penetrating or blunt); systolic BP (unmeasurable, < 90, 90–139 and ≥ 140 mmHg); and disturbance of consciousness at the scene of injury (mild, moderate or severe). Severe disturbance of consciousness was defined as no eye opening to any stimuli (Japan Coma Scale level 3), equivalent to E1 of the Glasgow Coma Scale [19, 20]. Details regarding the disturbance of consciousness are described in the Supporting Information (Appendix S4). The proportion of each cohort defined as major/polytrauma patient (ISS > 15) [16], requiring tracheal intubation in the emergency department and in-hospital mortality was also recorded. Injury Severity Scale scores are globally accepted values to assess trauma severity; the scores range from 1 to 75, and ISS ≥ 16 is generally considered major trauma or polytrauma (details in the Supporting Information, Appendix S2). Missing covariates were categorised as 'unknown'.

The primary outcome was the performance of eFONA, defined as emergency cannula or scalpel cricothyroidotomy. Tracheostomy was not included in the primary outcome. These are registered in the JTDB in category 'Emergency life-saving procedures on hospital arrival'. This category also includes other emergency life-saving invasive procedures in trauma resuscitation (e.g. tracheal intubation, chest compressions, aortic cross-cramp, needle thoracostomy, chest tube insertion etc.). The decision to perform eFONA was determined by individual physicians caring for each patient, according to the criteria of the Japan Advanced Trauma Evaluation and Care [13].

For the selection of predictors from the pre-hospital information, we referred to previous studies on airways or eFONA procedures among trauma patients. These studies reported several potential predictors including: road traffic

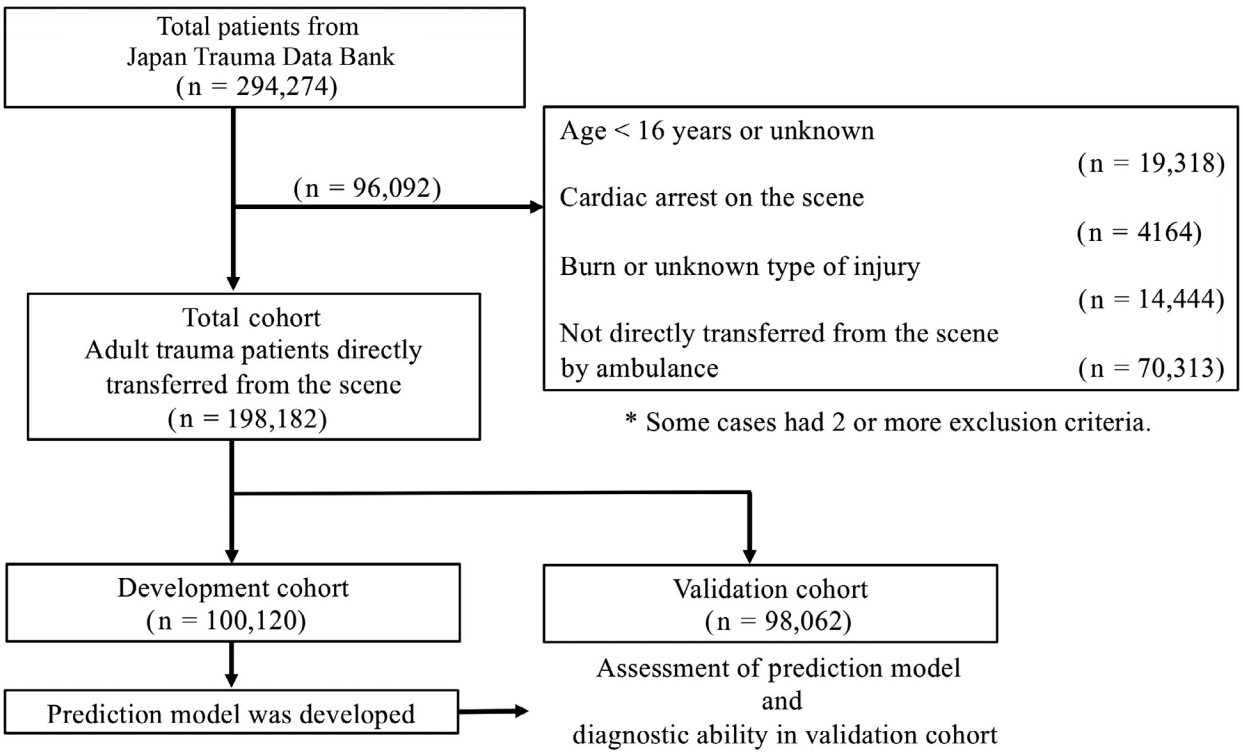

Figure 1 Study flow chart.

collision; fall from a height; the presence of head, maxillofacial, tracheal and neck injuries; neck immobility; and coma [3, 4, 7–9, 21–25]. We then selected the predictors from the available data of the JTDB corresponding to the pre-hospital information (mechanism of injury; injuries suspected; symptom/vital sign; and treatment). We also considered the results (crude odds ratio) of exploratory univariate analysis for the requirement of eFONA placement in the development cohort. With this information, and the extensive experience of the authors managing trauma patients, the predictors chosen for the model were motor bike accident or fall from height; oral/maxillofacial, neck or tracheal injury suspected; no eye opening to any stimuli; and basic airway management (e.g. jaw-thrust manoeuvres or placement of an oropharyngeal/nasopharyngeal airway) by paramedics. Paramedics in Japan do not perform tracheal intubation or supraglottic airway device placement except in the cases of out-of-hospital cardiac arrest. Detailed definitions of these chosen predictors are seen in the Supporting Information (Appendix S4).

We considered other important risk factors such as blood or vomitus in the airway, failed tracheal intubation or obesity; however, information regarding these variables

Table 1 Baeline characteristics in the total, development and validation cohort. Values are number (proportion) or median (IQR [range]).

Variables	Total cohort n = 198,182	Development cohort n = 100,120	Validation cohort n = 98,062
Men	126,315 (63.7%)	61,910 (61.8%)	64,405 (65.7%)
Missing	127 (0.06%)	22 (0.02%)	105 (0.11%)
Age; years	61 (39–76 [16–115])	63 (41–78 [16–106])	59 (38–75 [16–115])
16–39	50,033 (25.2%)	23,327 (23.3%)	26,706 (27.2%)
40–59	44,911 (22.7%)	21,901 (21.9%)	23,010 (23.5%)
60–79	65,232 (32.9%)	33,256 (33.2%)	31,976 (32.6%)
≥ 80	38,006 (19.2%)	21,636 (21.6%)	16,370 (16.7%)
Mechanism of injury			
Penetrating	7022 (3.5%)	3397 (3.4%)	3625 (3.7%)
Blunt	191,160 (96.5%)	96,723 (96.6%)	94,437 (96.3%)
Motor bike accident	26,549 (13.4%)	12,334 (12.3%)	14,215 (14.5%)
Free fall from height	20,515 (10.4%)	9851 (9.8%)	10,664 (10.9%)
Systolic blood pressure; mmHg			
≥ 140	77,398 (39.1%)	40,585 (40.5%)	36,813 (37.5%)
90–139	79,639 (40.2%)	39,918 (39.9%)	39,721 (40.5%)
< 90, unmeasurable	9579 (4.8%)	4642 (4.6%)	4937 (5.0%)
Missing	31,566 (15.9%)	14,975 (15%)	16,591 (16.9%)
Disturbance of consciousness			
Mild–moderate	150,302 (75.8%)	76,035 (75.9%)	74,267 (75.7%)
Severe	27,193 (13.7%)	12,531 (12.5%)	14,662 (15.0%)
Missing	20,687 (10.4%)	11,554 (11.5%)	9133 (9.3%)
Airway management	7789 (3.9%)	3609 (3.6%)	4180 (4.3%)
Face or neck injuries			
Oral–maxillofacial injury	7949 (4.0%)	3827 (3.8%)	4122 (4.2%)
Neck tracheal injury	278 (0.14%)	142 (0.14%)	136 (0.14%)
eFONA	467 (0.24%)	217 (0.22%)	250 (0.25%)
Tracheal intubation	28,322 (14.3%)	14,733 (14.7%)	13,589 (13.9%)
ISS	13 (9-21 [1–75])	10 (9-20 [1–75])	13 (9-22 [1–75])
≥ 16	82,233 (41.5%)	41,028 (41.0%)	41205 (42.0%)
In-hospital mortality	19,792 (10.0%)	9687 (9.7%)	10,105 (10.3%)

Airway management: Jaw-thrust manoeuvres or using oropharyngeal and nasopharyngeal airways performed by paramedics. ISS, Injury Severity Score (ISS ≥ 16 is generally considered to indicate major trauma or polytrauma [16]). Details of missing values are shown in the online Supporting Information.

Table 2 Univariable and multivariable logistic regression analysis in development cohort.

	Univariable analysis		Multivariable analysis		
Variables	**Crude OR**	**95%CI**	**Co-efficient β**	**AOR**	**95%CI**
No eye opening to any stimuli	9.77	7.45–12.80	1.74	5.67	4.19–7.69
Motor bike accident	2.25	1.65–3.07	0.49	1.63	1.16–2.29
Fall form height	2.54	1.84–3.51	0.50	1.65	1.16–2.35
Oral–maxillofacial injury	17.54	13.35–23.05	2.36	10.62	7.94–14.19
Neck tracheal injury	24.63	11.3–53.30	2.66	14.35	6.28–32.79
Airway management[a]	7.27	5.24–10.09	0.53	1.70	1.18–2.45

[a]Airway management: jaw-thrust manoeuvres or using oropharyngeal and nasopharyngeal airways by paramedics. AOR, adjusted odds ratio.

was unavailable from the JTDB. In the patient characteristics, we described variables with missing data as 'missing'. For the model development and validation, we performed complete case analysis for the variables with less than 3% missing data, based on the recommendation by Harrel et al. [26]. If any missing value exceeded 3%, we performed simple imputation based on the distribution (e.g. median or most frequent category substitution) [26].

We created the prediction model and then applied it to the validation cohort. In the development cohort, we calculated the crude odds ratio (OR) of potential predictors with a 95%CI for performance of eFONA, using univariable logistic regression analysis to consider predictor selection. We then performed multivariable logistic analysis to identify the coefficient β and adjusted OR with a 95%CI. We subsequently created the simple scoring system to predict the outcomes by two approaches; in one approach, the predictors were weighted based on the co-efficient β values, whereas in the other approach predictors were unweighted, similar to that of previous studies [27]. In the validation cohort, we calculated the C-statistic of the weighted and unweighted scoring systems, and subsequently selected the one with best fit for clinical use.

Diagnostic tests including sensitivity, specificity and positive and negative likelihood ratios (with 95%CI) were calculated using the better fit scoring system. We set the appropriate cut-off value for a rule-in and rule-out approach and divided the patients into four groups. The relationships between predicted and observed eFONA in each risk group were indicated for calibration. We also calculated the OR and 95%CI of the risk groups compared with the low-risk group. Additionally, we identified a stratum-specific likelihood ratio in each risk group. We considered a p value of < 0.05 to be statistically significant. Two-sided statistical analyses were performed for this study using the JMP Pro® 14 software (SAS Institute Inc., Cary, NC, USA).

Results

A flow chart of the study can be seen in Fig. 1. Out of the 294,274 patients in the JTDB, 96,092 patients were not included based on our pre-determined criteria. In total, 198,182 patients registered from 231 hospitals were analysed, with eFONA being required in 0.24% (467/198,182) (Fig. 1; Table 1). The development cohort consisted of 100,120 patients from 116 hospitals. Tracheal intubation was required in 14.7% (14,733/100,120) and eFONA in 0.22% (217/100,120). The validation cohort consisted of 98,062 patients from 115 hospitals. Tracheal intubation was required in 13.9% (13,589/98,062) and eFONA in 0.25% (250/98,062). The characteristics and distributions were similar between cohorts (Table 1). Missing values in the 'level of consciousness' category exceeded 3%. Among patients with missing values, most of the recorded GCS scores on hospital arrival were 9 or more (80%, 16,471/20,687). We have previously found that the

Table 3 The 'eFONA' scoring system.

Predictors	**Unweighted score**	**Weighted Score**
Eye response (No eye opening in response to any stimuli)	+1	+3
Fall from height or Motor bike	+1	+1
Oral–maxillofacial injury	+1	+5
Neck tracheal injury	+1	+5
Airway management[a] by paramedics	+1	+1
Sum	/5	/15

A weighted risk scoring system based on the coefficient β value and the unweighted value was created. The predictors were summarised by the mnemonic 'eFONA' (E: Eye response: no opening in response to any stimuli, F: Fall from height or motor bike, O: Oral–maxillofacial injury, N: Neck tracheal injury and A: Airway management by paramedics).
[a]Airway management: Jaw-thrust manoeuvres or using oropharyngeal and nasopharyngeal airways.

Table 4 Diagnostic ability of 'eFONA' scoring system (unweighted scoring system) in the validation cohort.

Cut-off	Specificity	Sensitivity	LR+	LR−	True positive	False positive	True negative	False negative
≥ 4	1.00	0.05	26.68	0.95	12 (0.01%)	176 (0.2%)	97,636 (99.6%)	238 (0.24%)
≥ 3	0.98	0.23	12.04	0.78	58 (0.06%)	1885 (1.9%)	95,927 (97.8%)	192 (0.20%)
≥ 2	0.91	0.59	6.61	0.45	148 (0.15%)	8758 (8.9%)	89,054 (90.8%)	102 (0.10%)
≥ 1	0.62	0.86	2.29	0.22	215 (0.22%)	36,724 (37.4%)	61,088 (62.3%)	35 (0.04%)
≥ 0	NA				250 (0.25%)	97,812 (99.7%)	0 (0.0%)	0 (0.00%)

LR+, positive likelihood ratio; LR−, negative likelihood ratio; NA, not applicable.

pre-hospital level of consciousness is strongly correlated with the GCS on hospital arrival [19]. Consequently, we performed single imputation of the missing level of consciousness using 'mild-moderate' for model development and validation.

In the development cohort, the crude OR, adjusted OR and co-efficient β were determined using logistic regression analysis (Table 2). We also created a weighted risk scoring system based on the coefficient β value and the unweighted value (Table 3). The scoring system was summarised by the mnemonic 'eFONA'; E: (Eye response: no opening in response to any stimuli); F: Fall from height or motor bike; O: Oral maxillofacial injury; N: Neck tracheal injury; and A: Airway management by paramedics.

In the validation cohort, the C-statistic of the scoring system, weighted based on coefficient β and unweighted, were 0.838 (95%CI 0.808–0.863) and 0.820 (95%CI 0.791–0.846), respectively. Although the C-statistic value of weighted scoring was slightly higher, we selected the unweighted scoring system for clinical ease-of-use. The diagnostic ability and accuracy of the unweighted 'eFONA' score for eFONA is seen in Table 4.

Based on unweighted scoring, we divided the patients into three risk groups as follows: very low-risk (score 0), low-risk (score 1); moderate-risk (score 2); and high-risk (score of 3 or higher). The predicted probability was well-calibrated to the observed eFONA procedures in the validation cohort (Fig. 2; Supporting Information). The ORs, stratum-specific likelihood ratios and predicted probability for eFONA in the risk groups are demonstrated in the Supporting Information.

Discussion

In the present study using the nationwide trauma database in Japan, the 'eFONA' scoring system using pre-hospital information was effective in predicting the requirement for eFONA placement with good discrimination and calibration performance. Based on the scoring system, it is reasonable to maximise preparation for eFONA in trauma patients in the moderate- to high-risk groups (score 2 or more). Conversely, preparation for eFONA may not be required in patients in the very low-risk group (score 0). As an adjunct to the conventional risk assessment of airway difficulties, this scoring system may aid in the preparation and predication

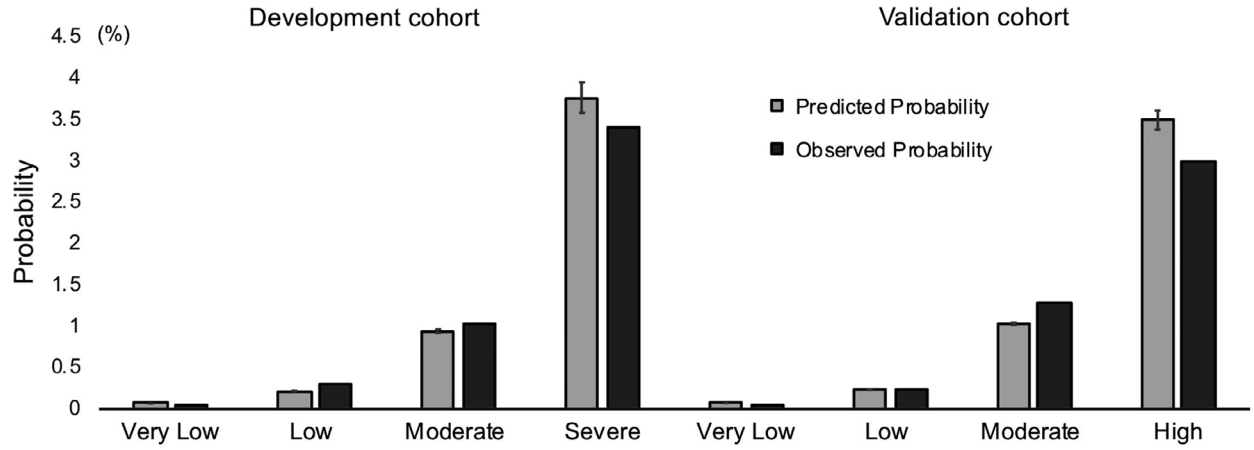

Figure 2 The predicted, observed probability and diagnostic ability in each risk group by 'eFONA' score. The predicted and observed probability grouped by sum of the risk score are shown in each cohort. The observed probability is the proportion of actual eFONA procedures performed. The predictions are well-calibrated with the observations. Error bars, 95%CI.

of the need for the infrequent performance of an eFONA procedure.

The strength of our scoring system lies in that it may be used before patients present to the Emergency Department, as it is based on pre-hospital information. In contrast, most conventional assessments require a physical examination [28]. Consequently, the 'eFONA' score may enable mental preparation before encountering these patients, and may help in avoiding delays in decision-making. Notably, even after applying the scoring system, the predicted probability (post-test probability) in the validation cohort remained low (score 2: 1.03%, score ≥ 3: 3.49%) (Fig. 2). This may be explained by the fact that the post-test probability is influenced by the pre-test probability; the prevalence of eFONA procedures in the validation cohort was extremely low (0.25%), in keeping with previous literature as to the incidence of eFONA in emergency medicine [5–9]. Although the setting differs from our study, a multicentre peri-operative database in the USA reported that the incidence of eFONA was extremely rare (1/176, 679) in an elective general anaesthesia population [27]. In such a cohort, the positive predictive value would be expected to be extremely low, possibly leading to false positives. Therefore, to predict with higher accuracy, we suggest using the 'eFONA' scoring in conjunction with other airway assessments. Patients at higher risk may be identified by other assessments [2, 28, 29], thereby increasing post-test probability. Therefore, in situations where the pre-test probability is very low, a combination of other airway assessments may offer better and appropriate predictions.

This study has several limitations. First, with respect to outcomes, although this study included a relatively large sample size, the proportion of eFONA procedures was very low (0.22–0.25%). Consequently, this model may increase the risk of overfitting, defined as a modelling error to fit the statistical model with too many degrees of freedom in the modelling process, and may reduce generalisability [30]. Second, the injury findings including AIS codes were defined retrospectively by administrative data collectors through patient chart review after trauma care was delivered. This could lead to deficits in the detection of important information (detection bias). Third, the JTDB data do not include complete details, such as the clinical course after admission, or details of eFONA such as type and success of eFONA performed or accurate timing of eFONA with respect to hospital presentation. Finally, the utility of this prediction model in an actual clinical setting is unclear. Further prospective research is needed to assess the implementation and evaluate the utility of our scoring system in clinical settings. Given the very low incidence of eFONA, these prospective studies would be observational in nature and may require years to capture enough eFONA events.

In conclusion, the pre-hospital 'eFONA' scoring system demonstrated good diagnostic ability and calibration in predicting eFONA placement among trauma patients. This scoring system may help anaesthetists and emergency physicians to make prior preparations for eFONA procedures, mobilise experienced staff and maintain an appropriate mindset.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Participating institutions in Japan Trauma Data Bank.

Appendix S2. Abbreviated Injury Scale (AIS).

Appendix S3. Cohort details.

Appendix S4. The definition of the measurement.