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Trauma airway management in emergency departments: A multicenter, prospective, observational study in Japan

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Complete List of Authors:	Nakao, Shunichiro; University of Ottawa / The Ottawa Hospital - Civic Campus, Department of Emergency Medicine Kimura, Akio; National Center for Global Health and Medicine, Department of Emergency Medicine and Critical Care Hagiwara, Yusuke; Tokyo Metropolitan Children's Medical Center, Department of Emergency Medicine Hasegawa, Kohei; Massachusetts General Hospital, Harvard Medical School, Department of Emergency Medicine
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Manuscripts

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
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5 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
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17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
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32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
39

40 Email: shunichiro-nakao@umin.ac.jp
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45

46 **Co-authors' address**
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48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49 akimura@hosp.ncgm.go.jp
50
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52 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
53 +810423005111, Email: yusukehagiwara-tky@umin.ac.jp
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3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
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5 khasegawa1@partners.org
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14 sequence intubation
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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among the 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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5 **Article summery**
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7 **Article focus**
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9 This paper characterizes the current practice of airway management for trauma patients in the
10 emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway
11 Network (JEAN) Study.
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15 **Key messages**
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17 The method of intubation, success rates, and adverse event rates were highly variable among
18 EDs. Development and dissemination of nationwide protocols are warranted to achieve safer
19 airway management for trauma victims in Japan.
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25 **Strengths and limitations of this study**
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27 This is the first to report disparities in trauma airway management based on multicenter,
28 prospective data.
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32 The passive surveillance of the data is subject to self-reporting bias, leading to a possible
33 underestimation of failed intubations and adverse events.
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1. Introduction

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients. [1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients. [1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe. [6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere. [10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this analysis. We excluded an ED in which the number of trauma intubations was less than 10 from the current analysis.

Data Collection

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3 Data collection was passive, relying on self-reports by the intubators on duty. After each
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5 intubation, the intubators completed a standardized data sheet, including the patient's age, sex,
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7 estimated weight, primary indication for intubation, methods used to facilitate intubation,
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9 intubator's level of training and specialty, number of attempts, success or failure, and
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11 intubation-related adverse events. Method was defined as the set of medications and devices used,
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13 such as RSI with a Macintosh laryngoscope. An intubation attempt was defined as a single
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15 insertion of the laryngoscope (or other device) past the teeth [2 10-13]. For nasal intubations, an
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17 attempt was defined as a single insertion of a tracheal tube past the turbinates. An attempt was
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19 successful if it resulted in the tracheal tube being passed through the vocal cords. One or more
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21 methods could be used in each patient, and each method could be attempted several times.
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29 Adverse events were recorded using a pre-specified list, with the option to include additional
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31 comments, if necessary. We monitored compliance with data form completion by reviewing
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33 professional billing records. Where the data collection form was missing, the intubator was
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35 interviewed by one of the investigators within 2 weeks of the patient encounter, to fill out the
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37 data form.
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43 The outcomes of interest were the primary indication for intubation, initial method used for
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45 intubation, intubation success rates (on the first attempt and within three attempts), and adverse
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47 event rates.
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53 **Statistical Analysis**

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55 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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3 patient-level, we described patient demographics, the primary indication for intubation, initial
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5 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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7 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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9 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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11 after stratifying the patients as non-cardiac arrest patients and cardiac arrest patients. All
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13 *P*-values were two-tailed, with $P < 0.05$ considered statistically significant.
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3. Results

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), 3370 patients underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis. Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5% (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the first attempt in 71.2% (95% CI, 65.1%-76.6%) and in within 3 attempts in 99.2% (95% CI,

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3 97.0%-99.8%) of the patients. Intubation-associated adverse event rates were 10.8% (95% CI,
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5 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in non-cardiac arrest
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7 patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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12 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
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14 **(Figure 2)**. For example, RSI as the initial intubation method was performed in 0% to 50.9% of
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16 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
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18 wide variation in the success rates and adverse event rates across the EDs **(Figure 3)**. The range
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20 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
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22 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
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24 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
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26 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation†	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension‡	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Pulse oximetry saturation less than 90% during intubation attempt, not a result of esophageal intubation.

‡Hypotension was defined as systolic blood pressure less than 90 mm Hg.

4. Discussion

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Alternatively, it is also possible that non-RSI methods were more frequently used in certain EDs because of the physicians' preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. We did not assess the reasons for the variations among the EDs; however, inter-hospital differences in patient population, skills or education backgrounds of intubators, drug or device availability in the ED, or any

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3 combination of these factors may have contributed to these variations. Alternatively, the
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5 observed wide variation in the intubation method may have led to these variations in success and
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7 adverse event rates.
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12 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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14 initial method of emergency airway management in most trauma patients, [1 4 5] the evidence
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16 for accurately predicting patients in whom RSI should be avoided remain limited. [14 15] It is,
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18 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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20 across the EDs. Our observations should facilitate further investigation of any barriers to the
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22 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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24 airway management, coupled with improved dissemination of these findings, could decrease the
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26 variations in trauma care across the EDs in Japan.
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34 Our study has several potential limitations. First, this passive surveillance of the study data is
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36 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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38 adverse events. However, active independent monitoring of ED intubations is difficult to
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40 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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42 definitions, and a high capture rate. Second, we did not design this study to measure patient
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44 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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46 and outcomes requires following the patients for a longer period. Third, we did not account for
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48 several potential confounders, such as severity of cases and training levels of physicians. Finally,
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50 all EDs in this study were designated as tertiary or academic general hospitals, and all but one of
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52 the EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
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3 inferences may not be generalizable to trauma airway management in non-academic EDs or other
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5 developed nations. These observations, however, are highly relevant from a policy standpoint. As
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7 these EDs provide advanced care for trauma victims and train the majority of emergency
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9 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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13 14 15 **5. Conclusion**

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17 In this multicenter prospective study of emergency airway management in Japan, we found an
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19 acceptable overall success rate in trauma airway management. However, we also found that the
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21 method of intubation, success rates and adverse event rates were highly variable among EDs.
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24 Our findings suggest that development and dissemination of nationwide protocols are warranted
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26 to achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis. S.N. wrote the manuscript, which A.K. reviewed.

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Conflict of Interest: None of the authors have any conflict of interest to declare.

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5 **Data Sharing Statement**
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8 No additional data available
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Figure Legends

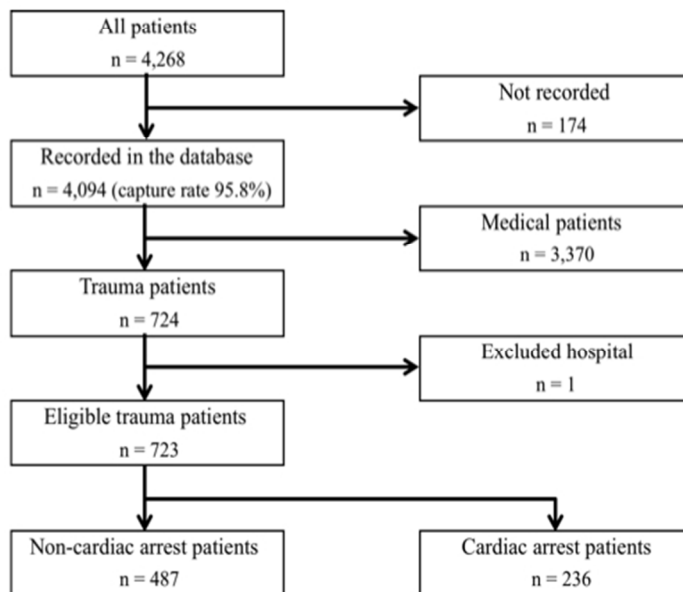
Figure 1. Flow chart showing inclusion of patients in this study

Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

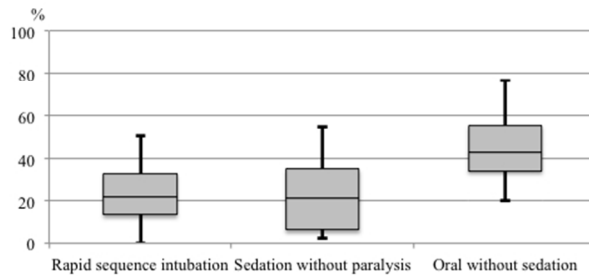
Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.



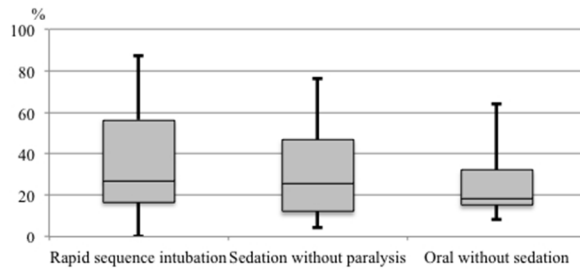
Flow chart showing inclusion of patients in this study
254x190mm (72 x 72 DPI)

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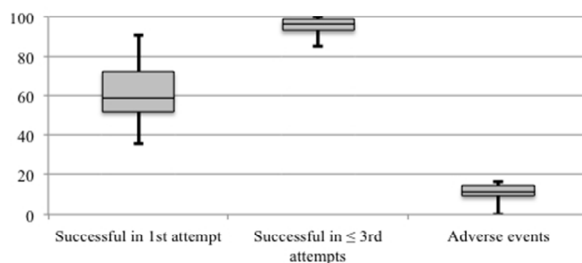
a. Among all trauma patients



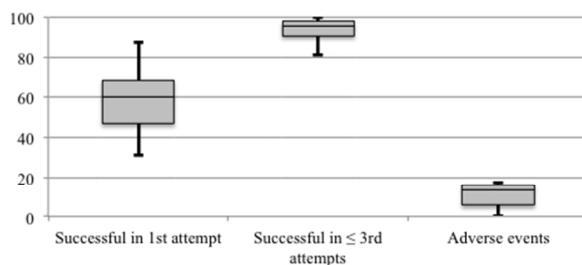
b. Among non-cardiac arrest patients

Inter-hospital variations in initial methods of intubation
Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.
254x338mm (72 x 72 DPI)

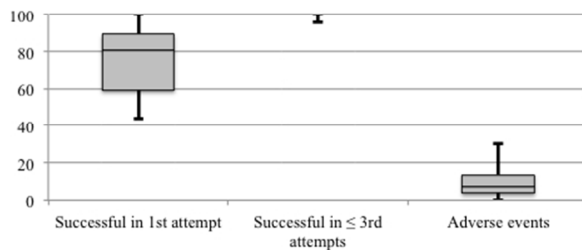
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a. Among all trauma patients



b. Among non-cardiac arrest patients



c. Among cardiac arrest patients

Inter-hospital variations in success rates and adverse event rates
 Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.
 254x338mm (72 x 72 DPI)

BMJ Open

Trauma airway management in emergency departments: A multicenter, prospective, observational study in Japan

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Manuscripts

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
4 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
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14
15

16
17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
21 States
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31

32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
39

40 Email: shunichiro-nakao@umin.ac.jp
41
42
43
44
45

46 **Co-authors' address**
47

48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49

50 akimura@hosp.ncgm.go.jp
51
52

53 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
54

55 +810423005111, Email: yusukehagiwara-tky@umin.ac.jp
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1
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3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
4
5 khasegawa1@partners.org
6
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16 manuscript for publication.
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27 **Keywords:** Airway management, intubation, emergency department, practice variation, rapid
28 sequence intubation
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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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5 **Article summary**
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7 **Article focus**
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9 This paper characterizes the current practice of airway management for trauma patients in
10 emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway
11 Network (JEAN) Study.
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16 **Key messages**
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18 The method of intubation, success rates, and adverse event rates are highly variable among EDs.
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20 Development and dissemination of nationwide protocols are warranted to achieve safer airway
21 management for trauma victims in Japan.
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26 **Strengths and limitations of this study**
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28 This is the first study to report disparities in trauma airway management based on multicenter,
29 prospective data.
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32 Passive surveillance of data is subject to self-reporting bias, leading to a possible
33 underestimation of failed intubations and adverse events.
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1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients. [1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients. [1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe. [6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere. [10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this analysis. We excluded an ED in which the number of trauma intubations was less than 10 from the current analysis.

Data Collection

Data collection was passive, relying on self-reports by the intubators on duty. After each intubation, the intubators completed a standardized data sheet, including the patient's age, sex, estimated weight, primary indication for intubation, methods used to facilitate intubation, intubator's level of training (emergency physicians, resident physicians, and transitional year residents) and specialty (emergency physician or not), number of attempts, success or failure, and intubation-related adverse events. Method was defined as the set of medications and devices used, such as RSI with a Macintosh laryngoscope. Transitional-years residents were post-graduate year 1-2 physicians who rotate through the ED. An intubation attempt was defined as a single insertion of the laryngoscope (or other device) past the teeth [2 10-13]. For nasal intubations, an attempt was defined as a single insertion of a tracheal tube past the turbinates. An attempt was successful if it resulted in the tracheal tube being passed through the vocal cords. One or more methods could be used in each patient, and each method could be attempted several times.

Adverse events were recorded using a pre-specified list, with the option to include additional comments, if necessary. We monitored compliance with data form completion by reviewing professional billing records. Where the data collection form was missing, the intubator was interviewed by one of the investigators within 2 weeks of the patient encounter, to fill out the data form.

The outcomes of interest were the primary indication for intubation, initial method used for

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3 intubation, intubation success rates (on the first attempt and within three attempts), and adverse
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5 event rates.
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10 **Statistical Analysis**

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12 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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14 patient-level, we described patient demographics, the primary indication for intubation, initial
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16 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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18 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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20 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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22 after stratifying by indication (non-cardiac arrest vs. cardiac arrest) and specialty (emergency
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24 physicians vs. non-emergency physicians). All *P*-values were two-tailed, with *P*<0.05 considered
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26 statistically significant.
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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis.

Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5% (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,

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3 97.0%-99.8%) of the patients. In the stratified analysis by the specialty (i.e., emergency
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6 physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a higher
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8 success at the first attempt (72.8 % vs. 50.2 %, $p<0.001$) compared to non-emergency physicians.
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10 Intubation-associated adverse event rates were 10.8% (95% CI, 8.7%-13.3%) in overall trauma
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12 patients, 11.5% (95% CI, 9.0%-14.6%) in non-cardiac arrest patients, and 9.3% (95% CI,
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14 6.2%-13.7%) in cardiac arrest patients.
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20 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
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22 **(Figure 2)**. For example, RSI as the initial intubation method was performed in 0% to 50.9% of
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24 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
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26 wide variation in the success rates and adverse event rates across the EDs **(Figure 3)**. The range
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28 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
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30 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
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32 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
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34 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Alternatively, it is also possible that non-RSI methods were more frequently used in certain EDs because of the physicians' preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. The reasons for the variations among the EDs are likely multifactorial; the potential explanations include inter-hospital differences in patient population, skills or education backgrounds of intubators,[14]

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3 drug and device availability in the ED, or any combination of these factors. Alternatively, the
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5 observed wide variation in the intubation method may have led to these variations in success and
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7 adverse event rates. Furthermore, there are no requirements for procedural credentials to perform
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9 ED intubations both in individuals and institutions in Japan. [10] This lack of procedural
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11 requirements would have contributed, at least partially, to the observed inter-hospital variations
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13 in the success rates.
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20 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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22 initial method of emergency airway management in most trauma patients, [1 4 5] the evidence
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24 for accurately predicting patients in whom RSI should be avoided remain limited. [15 16] It is,
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26 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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28 across the EDs. Our observations should facilitate further investigation of any barriers to the
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30 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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32 airway management, coupled with improved dissemination of these findings, could decrease the
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34 variations in trauma care across the EDs in Japan.
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41 Our study has several potential limitations. First, this passive surveillance of the study data is
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43 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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45 adverse events. However, active independent monitoring of ED intubations is difficult to
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47 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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49 definitions, and a high capture rate. Second, we did not design this study to measure patient
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51 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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53 and outcomes requires following the patients for a longer period. Third, we did not account for
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3 several potential confounders, such as severities (the Injury Severity Score, the Revised Trauma
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6 reflect the current airway management in the natural setting of a “real” population and current
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8 clinical practice, therefore enhancing the potential generalizability of the findings. Finally, all
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10 EDs in this study were designated as tertiary or academic general hospitals, and all but one of the
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12 EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
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14 inferences may not be generalizable to trauma airway management in non-academic EDs or other
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16 developed nations. These observations, however, are highly relevant from a policy standpoint. As
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18 these EDs provide advanced care for trauma victims and train the majority of emergency
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20 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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29 **5. CONCLUSION**

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31 In this multicenter prospective study of emergency airway management in Japan, we found an
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33 acceptable overall success rate in trauma airway management. However, we also found that the
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35 method of intubation, success rates and adverse event rates were highly variable among EDs. For
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37 researchers, our observations should facilitate further investigations to identify the reasons of the
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39 inter-hospital variations. Additionally, for policy makers and professional organizations, our
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41 findings suggest that development and dissemination of nationwide protocols are warranted to
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43 achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis.

S.N. wrote the manuscript, which A.K. reviewed.

Conflict of Interest: None of the authors have any conflict of interest to declare.

Data Sharing Statement

No additional data available

Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
4 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
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16

17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
21 States
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31

32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
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40 Email: shunichiro-nakao@umin.ac.jp
41
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45

46 **Co-authors' address**
47

48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49

50 akimura@hosp.ncgm.go.jp
51
52

53 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
54

55 +810423005111, Email: yusukehagiwara-tky@umin.ac.jp
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1
2
3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
4
5 khasegawa1@partners.org
6
7
8
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11

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33 sequence intubation
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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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Article summary

Article focus

This paper characterizes the current practice of airway management for trauma patients in emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway Network (JEAN) Study.

Key messages

The method of intubation, success rates, and adverse event rates **are** highly variable among EDs. Development and dissemination of nationwide protocols are warranted to achieve safer airway management for trauma victims in Japan.

Strengths and limitations of this study

This is the first **study** to report disparities in trauma airway management based on multicenter, prospective data.

Passive surveillance of data is subject to self-reporting bias, leading to a possible underestimation of failed intubations and adverse events.

1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients. [1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients. [1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe. [6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere. [10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. **These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients.** The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this analysis. We excluded an ED in which the number of trauma intubations was less than 10 from

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3 the current analysis.
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8 **Data Collection**

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10 Data collection was passive, relying on self-reports by the intubators on duty. After each
11 intubation, the intubators completed a standardized data sheet, including the patient's age, sex,
12 estimated weight, primary indication for intubation, methods used to facilitate intubation,
13 intubator's level of training **(emergency physicians, resident physicians, and transitional year**
14 **residents)** and specialty **(emergency physician or not)**, number of attempts, success or failure,
15 and intubation-related adverse events. Method was defined as the set of medications and devices
16 used, such as RSI with a Macintosh laryngoscope. **Transitional-years residents were**
17 **post-graduate year 1-2 physicians who rotate through the ED.** An intubation attempt was
18 defined as a single insertion of the laryngoscope (or other device) past the teeth [2 10-13]. For
19 nasal intubations, an attempt was defined as a single insertion of a tracheal tube past the
20 turbinates. An attempt was successful if it resulted in the tracheal tube being passed through the
21 vocal cords. One or more methods could be used in each patient, and each method could be
22 attempted several times.
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43 Adverse events were recorded using a pre-specified list, with the option to include additional
44 comments, if necessary. We monitored compliance with data form completion by reviewing
45 professional billing records. Where the data collection form was missing, the intubator was
46 interviewed by one of the investigators within 2 weeks of the patient encounter, to fill out the
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3 The outcomes of interest were the primary indication for intubation, initial method used for
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5 intubation, intubation success rates (on the first attempt and within three attempts), and adverse
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7 event rates.
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10 11 12 **Statistical Analysis**

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14 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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16 patient-level, we described patient demographics, the primary indication for intubation, initial
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18 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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20 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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22 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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24 after stratifying **by indication (non-cardiac arrest vs. cardiac arrest) and specialty**
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26 **(emergency physicians vs. non-emergency physicians)**. All *P*-values were two-tailed, with
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31 *P*<0.05 considered statistically significant.
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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis.

Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5% (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,

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3 97.0%-99.8%) of the patients. **In the stratified analysis by the specialty (i.e., emergency**
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5 **physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a**
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7 **higher success at the first attempt (72.8 % vs. 50.2 %, p<0.001) compared to**
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9 **non-emergency physicians.** Intubation-associated adverse event rates were 10.8% (95% CI,
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11 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in non-cardiac arrest
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13 patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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20 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
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22 **(Figure 2).** For example, RSI as the initial intubation method was performed in 0% to 50.9% of
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24 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
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26 wide variation in the success rates and adverse event rates across the EDs **(Figure 3).** The range
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28 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
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30 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
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32 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
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34 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Alternatively, it is also possible that non-RSI methods were more frequently used in certain EDs because of the physicians' preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. **The reasons for the variations among the EDs are likely multifactorial; the potential explanations include** inter-hospital differences in patient population, skills or education backgrounds of intubators,^[14]

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3 drug and device availability in the ED, or any combination of these factors. Alternatively, the
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5 observed wide variation in the intubation method may have led to these variations in success and
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7 adverse event rates. **Furthermore, there are no requirements for procedural credentials to**
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9 **perform ED intubations both in individuals and institutions in Japan. [10] This lack of**
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11 **procedural requirements would have contributed, at least partially, to the observed**
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13 **inter-hospital variations in the success rates.**
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20 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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22 initial method of emergency airway management in most trauma patients, [1 4 5] the evidence
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24 for accurately predicting patients in whom RSI should be avoided remain limited. [15 16] It is,
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26 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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28 across the EDs. Our observations should facilitate further investigation of any barriers to the
29
30 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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32 airway management, coupled with improved dissemination of these findings, could decrease the
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34 variations in trauma care across the EDs in Japan.
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41 Our study has several potential limitations. First, this passive surveillance of the study data is
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43 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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45 adverse events. However, active independent monitoring of ED intubations is difficult to
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47 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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49 definitions, and a high capture rate. Second, we did not design this study to measure patient
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51 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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53 and outcomes requires following the patients for a longer period. Third, we did not account for
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3 several potential confounders, such as severities **(the Injury Severity Score, the Revised**
4 **Trauma Score, etc.)** of cases and training levels of physicians. **However, this prospective**
5 **multicenter data reflect the current airway management in the natural setting of a “real”**
6 **population and current clinical practice, therefore enhancing the potential generalizability**
7 **of the findings.** Finally, all EDs in this study were designated as tertiary or academic general
8 hospitals, and all but one of the EDs were affiliated with an emergency medicine residency
9 program in Japan. Therefore, our inferences may not be generalizable to trauma airway
10 management in non-academic EDs or other developed nations. These observations, however, are
11 highly relevant from a policy standpoint. As these EDs provide advanced care for trauma victims
12 and train the majority of emergency physicians, these EDs have a disproportionate impact on
13 current and future trauma care in EDs.
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32 **5. CONCLUSION**

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34 In this multicenter prospective study of emergency airway management in Japan, we found an
35 acceptable overall success rate in trauma airway management. However, we also found that the
36 method of intubation, success rates and adverse event rates were highly variable among EDs.
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38 **For researchers, our observations should facilitate further investigations to identify the**
39 **reasons of the inter-hospital variations. Additionally, for policy makers and professional**
40 **organizations,** our findings suggest that development and dissemination of nationwide protocols
41 are warranted to achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis.

S.N. wrote the manuscript, which A.K. reviewed.

Data Sharing Statement

No additional data available

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For peer review only

Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

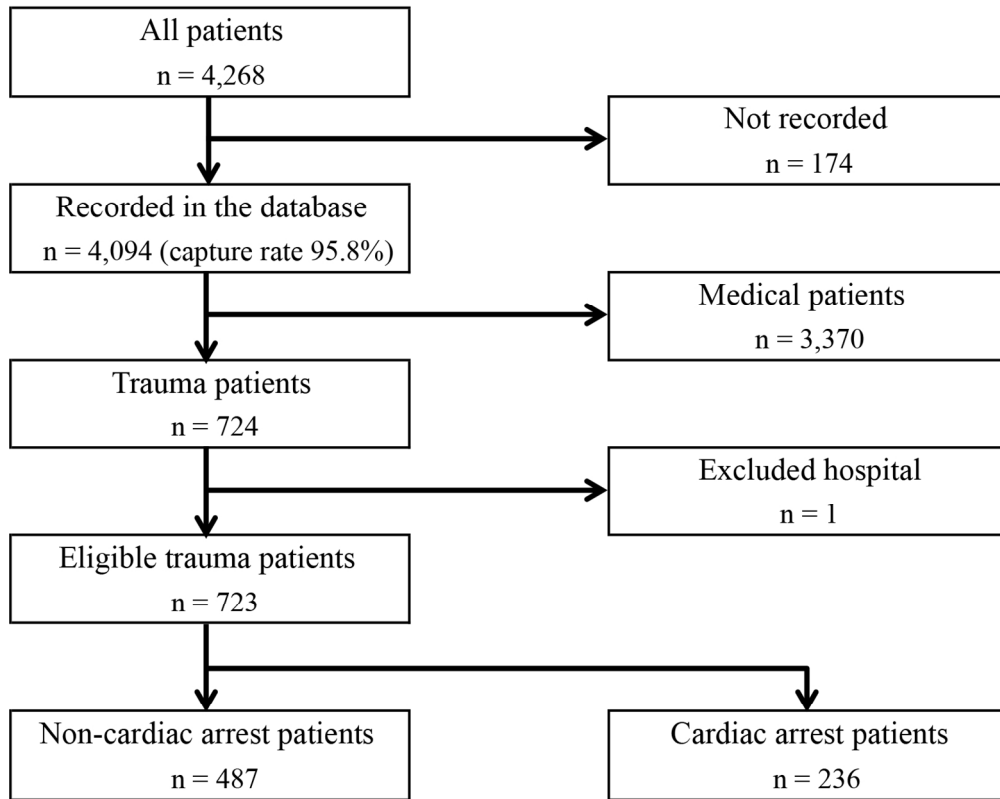
Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

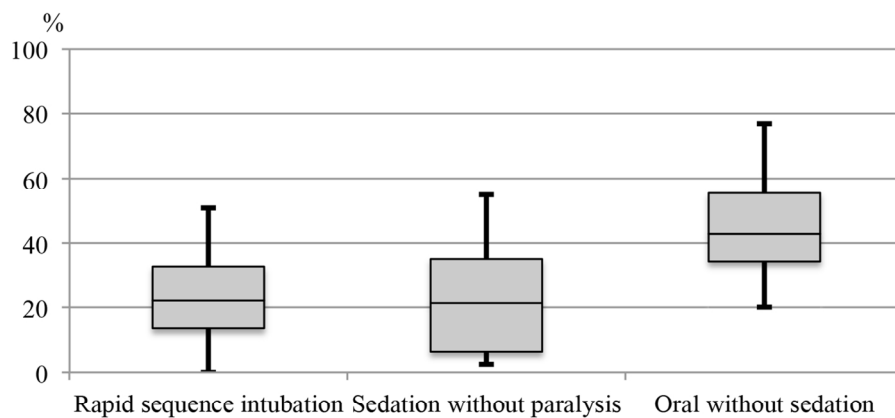
Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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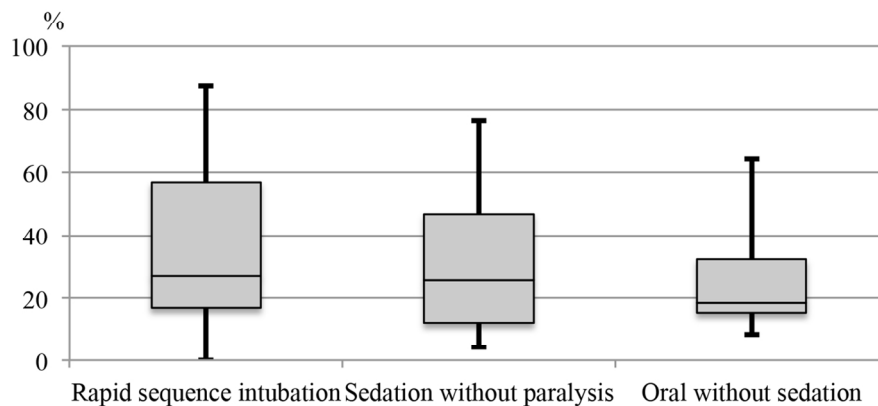


Flow chart showing inclusion of patients in this study

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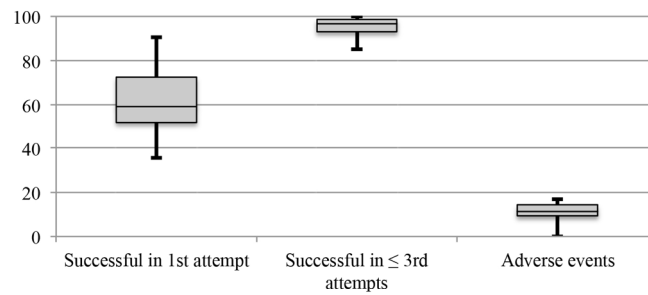


a. Among all trauma patients

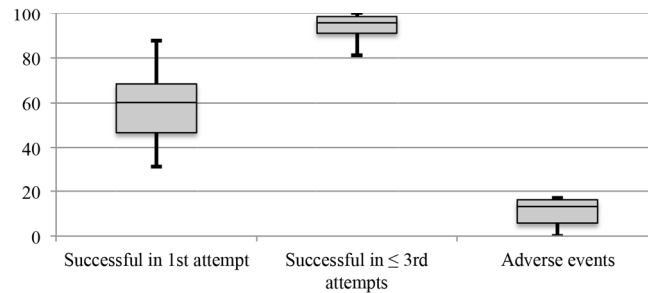


b. Among non-cardiac arrest patients

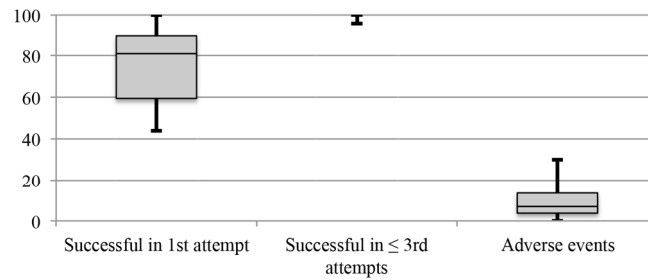
Inter-hospital variations in initial methods of intubation
 Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.
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a. Among all trauma patients



b. Among non-cardiac arrest patients



c. Among cardiac arrest patients

Inter-hospital variations in success rates and adverse event rates

Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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Trauma airway management in emergency departments: A multicenter, prospective, observational study in Japan

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Manuscripts

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
4 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
12
13
14
15

16
17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
21 States
22
23
24
25
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30
31

32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
39

40 Email: shunichiro-nakao@umin.ac.jp
41
42
43
44
45

46 **Co-authors' address**
47

48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49

50 akimura@hosp.ncgm.go.jp
51
52

53 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
54

55 +810423005111, Email: yusukehagiwara-ky@umin.ac.jp
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1
2
3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
4
5 khasegawa1@partners.org
6
7
8
9
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11

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32 **Keywords:** Airway management, intubation, emergency department, practice variation, rapid
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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients. Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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Article summary**Article focus**

This paper characterizes the current practice of airway management for trauma patients in emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway Network (JEAN) Study.

Key messages

The method of intubation, success rates, and adverse event rates are highly variable among EDs. Development and dissemination of nationwide protocols are warranted to achieve safer airway management for trauma victims in Japan.

Strengths and limitations of this study

This is the first study to report disparities in trauma airway management based on multicenter, prospective data.

Passive surveillance of data is subject to self-reporting bias, leading to a possible underestimation of failed intubations and adverse events.

1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients.[1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients.[1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe.[6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere.[10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this analysis. We excluded an ED in which the number of trauma intubations was less than 10 from the current analysis.

Data Collection

Data collection was passive, relying on self-reports by the intubators on duty. After each intubation, the intubators completed a standardized data sheet, including the patient's age, sex, estimated weight, primary indication for intubation, methods used to facilitate intubation, intubator's level of training (emergency physicians, resident physicians, and transitional year residents) and specialty (emergency physician or not), number of attempts, success or failure, and intubation-related adverse events. Method was defined as the set of medications and devices used, such as RSI with a Macintosh laryngoscope. Transitional-years residents were post-graduate year 1-2 physicians who rotate through the ED. An intubation attempt was defined as a single insertion of the laryngoscope (or other device) past the teeth.[2 10-13] For nasal intubations, an attempt was defined as a single insertion of a tracheal tube past the turbinates. An attempt was successful if it resulted in the tracheal tube being passed through the vocal cords. One or more methods could be used in each patient, and each method could be attempted several times.

Adverse events were recorded using a pre-specified list, with the option to include additional comments, if necessary. Adverse events were defined as cardiac arrest, hypotension, hypoxemia, dysrhythmia, vomiting, esophageal intubation, mainstem bronchial intubation, and airway trauma that are considered to be intubation-related.[11] Cardiac arrest included asystole, bradycardia, or dysrhythmia with nonmeasurable blood pressure and cardiopulmonary resuscitation during or after intubation. Hypotension was defined as systolic blood pressure less than 90 mm Hg. Hypoxemia was defined as pulse oximetric saturation less than 90% during an

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3 intubation attempt, not a result of esophageal intubation. Preexisting hypotension or hypoxemia
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5 before an intubation attempt were not counted as an adverse event. Esophageal intubation was
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7 defined as misplacement of the endotracheal tube in the upper esophagus or hypopharynx, with a
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9 lapse of time and desaturation (pulse oximetric saturation <90%) before the removal of the
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11 misplaced tube. We monitored compliance with data form completion by reviewing professional
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13 billing records. Where the data collection form was missing, the intubator was interviewed by
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15 one of the investigators within 2 weeks of the patient encounter, to fill out the data form.
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22 The outcomes of interest were the primary indication for intubation, initial method used for
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24 intubation, intubation success rates (on the first attempt and within three attempts), and
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26 intubation-related adverse event rates.
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32 **Statistical Analysis**

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34 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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36 patient-level, we described patient demographics, the primary indication for intubation, initial
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38 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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40 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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42 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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44 after stratifying by indication (non-cardiac arrest vs. cardiac arrest) and specialty (emergency
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46 physicians vs. non-emergency physicians). All *P*-values were two-tailed, with *P*<0.05 considered
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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis.

Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients. The direct laryngoscope was used in most of intubations (n=654, 90.5%), and the remaining were intubated using a video laryngoscope (n=30,

4.1%), a bronchoscope (n=17, 2.4%), a lighted stylet (n=1, 0.1%) on the first attempt.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5%

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3 (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the
4 first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,
5 97.0%-99.8%) of the patients. In the stratified analysis by the specialty (i.e., emergency
6 physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a higher
7 success at the first attempt (72.8 % vs. 50.2 %, p<0.001) compared to non-emergency physicians
8 (including all transitional-year residents [n=237]). Intubation-associated adverse event rates were
9 10.8% (95% CI, 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in
10 non-cardiac arrest patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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24 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
25 (**Figure 2**). For example, RSI as the initial intubation method was performed in 0% to 50.9% of
26 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
27 wide variation in the success rates and adverse event rates across the EDs (**Figure 3**). The range
28 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
29 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
30 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
31 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Therefore, some of the patients might have been inappropriately considered as “difficult intubation,” and intubated with non-RSI methods. Alternatively, it is also plausible that non-RSI methods were more frequently used in certain EDs because of the physicians’ preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. The reasons for the variations among the EDs are likely multifactorial; the potential explanations include

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3 inter-hospital differences in patient population, skills or education backgrounds of intubators,[14]
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5 drug and device availability in the ED, or any combination of these factors. Alternatively, the
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8 observed wide variation in the intubation method may have led to these variations in success and
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10 adverse event rates. Furthermore, there are no requirements for procedural credentials to perform
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12 ED intubations both in individuals and institutions in Japan.[10] This lack of procedural
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14 requirements would have contributed, at least partially, to the observed inter-hospital variations
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16 in the success rates. Indeed, we observed that intubation success rates performed by
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18 non-emergency physicians were significantly lower; this was, at least in part, explained by the
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20 intubation attempts by transitional-year residents. However, it is well documented in the
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22 literature that first-pass success is important in critically-ill patients[11]; therefore, the observed
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24 lower success rate by these non-skilled physicians cannot be justified. Our data underscore the
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26 reinforcement of Japanese methodology of training for non-skilled physicians (e.g., the use of
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28 simulators and training in a more controlled setting[15-17] to improve their intubation skill set,
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30 which will, in turn, improve patients' outcomes.
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39 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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41 initial method of emergency airway management in most trauma patients,[14 5] the evidence for
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43 accurately predicting patients in whom RSI should be avoided remain limited.[18 19] It is,
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45 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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47 across the EDs. Our observations should facilitate further investigation of any barriers to the
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49 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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51 airway management, coupled with improved dissemination of these findings, could decrease the
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53 variations in trauma care across the EDs in Japan.
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6 Our study has several potential limitations. First, this passive surveillance of the study data is
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8 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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10 adverse events. However, active independent monitoring of ED intubations is difficult to
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12 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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14 definitions, and a high capture rate. Second, we did not design this study to measure patient
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16 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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18 and outcomes requires following the patients for a longer period. Third, we did not account for
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20 several potential confounders, such as severities (the Injury Severity Score, the Revised Trauma
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22 Score, etc.) of cases and training levels of physicians. However, this prospective multicenter data
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24 reflect the current airway management in the natural setting of a “real” population and current
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26 clinical practice, therefore enhancing the potential generalizability of the findings. Finally, all
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28 EDs in this study were designated as tertiary or academic general hospitals, and all but one of the
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30 EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
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32 inferences may not be generalizable to trauma airway management in non-academic EDs or other
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34 developed nations. These observations, however, are highly relevant from a policy standpoint. As
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36 these EDs provide advanced care for trauma victims and train the majority of emergency
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38 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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48 **5. CONCLUSION**

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50 In this multicenter prospective study of emergency airway management in Japan, we found an
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52 acceptable overall success rate in trauma airway management. However, we also found that the
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54 method of intubation, success rates and adverse event rates were highly variable among EDs. For
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3 researchers, our observations should facilitate further investigations to identify the reasons of the
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5 inter-hospital variations. Additionally, for policy makers and professional organizations, our
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7 findings suggest that development and dissemination of nationwide protocols are warranted to
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9 achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis.

S.N. wrote the manuscript, which A.K. reviewed.

Data Sharing Statement

No additional data available

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Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

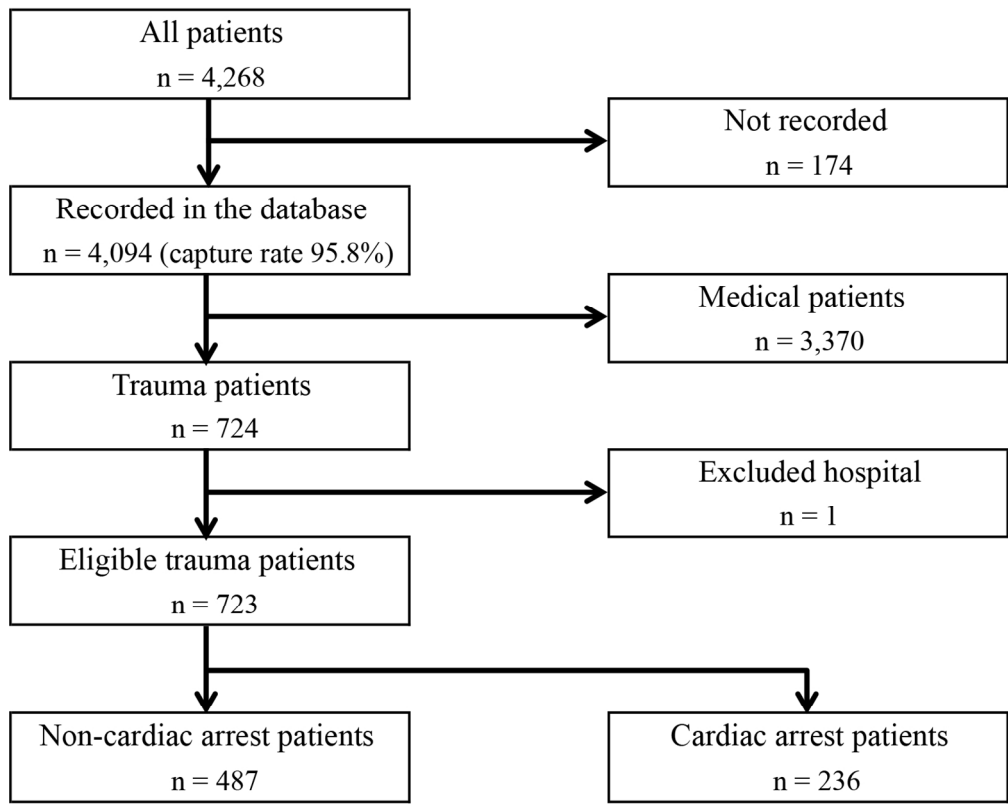
Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

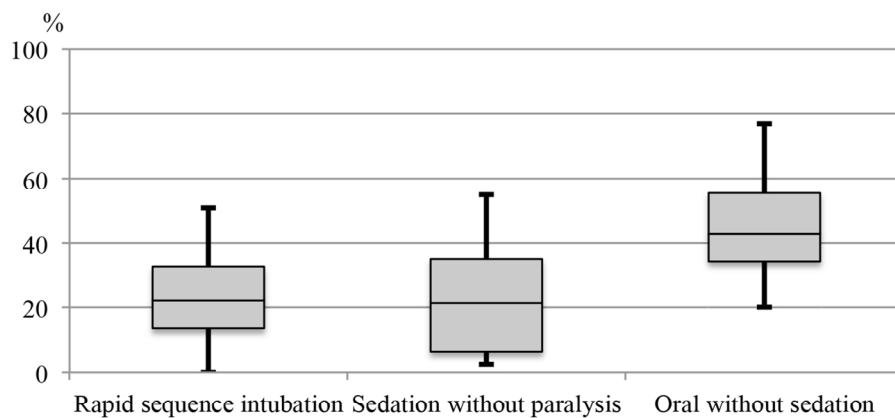
Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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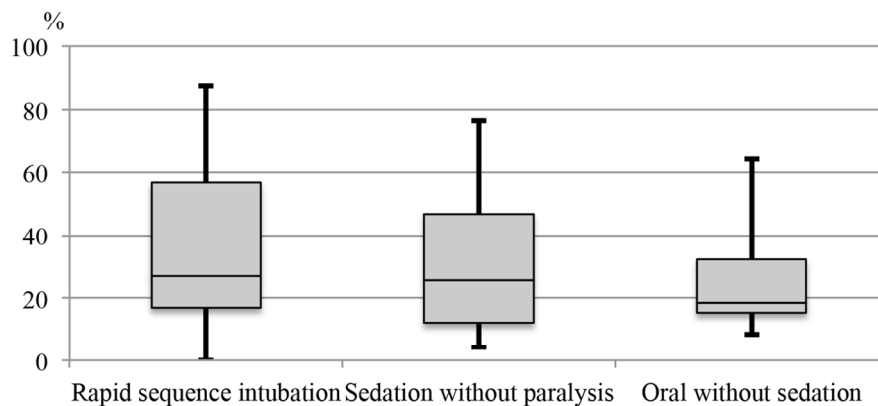


Flow chart showing inclusion of patients in this study

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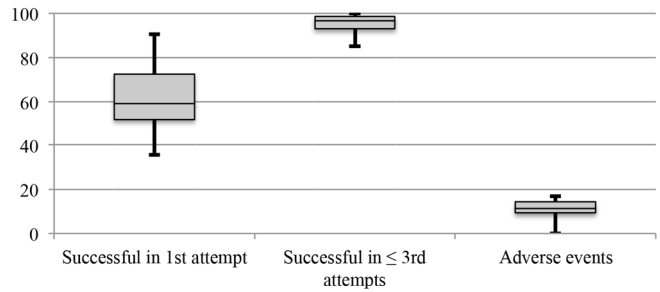
a. Among all trauma patients



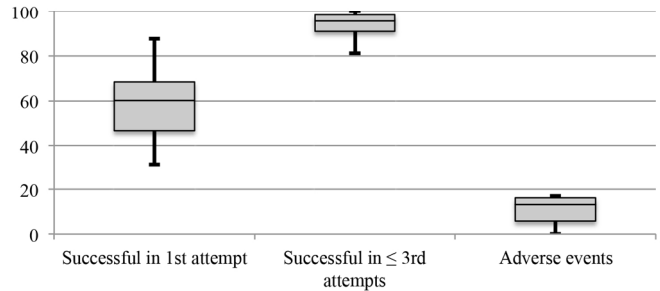
b. Among non-cardiac arrest patients

Inter-hospital variations in initial methods of intubation
 Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.
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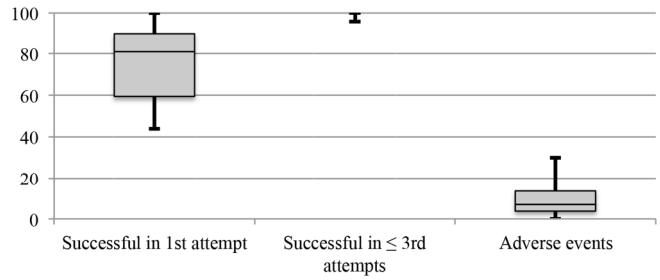
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a. Among all trauma patients



b. Among non-cardiac arrest patients



c. Among cardiac arrest patients

Inter-hospital variations in success rates and adverse event rates
 Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.
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9 **Trauma airway management in emergency departments: A multicenter, prospective,**
10 **observational study in Japan**
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14 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
15 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
16
17
18

19
20 ¹ Department of Emergency Medicine and Critical Care, National Center for Global Health and
21 Medicine, Shinjuku, Tokyo, Japan; ² Department of Emergency Medicine, Tokyo Metropolitan
22 Children's Medical Center, Fuchu, Tokyo, Japan; ³ Department of Emergency Medicine,
23 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
24 States
25
26
27
28
29

30
31 **Address correspondence to:** Dr. Shunichiro Nakao
32

33 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
34 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
35

36
37 Tel: 613.798.5555 ext. 15976
38

39 Email: shunichiro-nakao@umin.ac.jp
40
41

42
43 **Co-authors' address**
44

45 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
46 akimura@hosp.ncgm.go.jp
47

48 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
49 +810423005111, Email: yusukehagiwara-ky@umin.ac.jp
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Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
khasegawa1@partners.org

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Conflict of Interest: None of the authors have any conflict of interest to declare.

Keywords: Airway management, intubation, emergency department, practice variation, rapid sequence intubation

Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

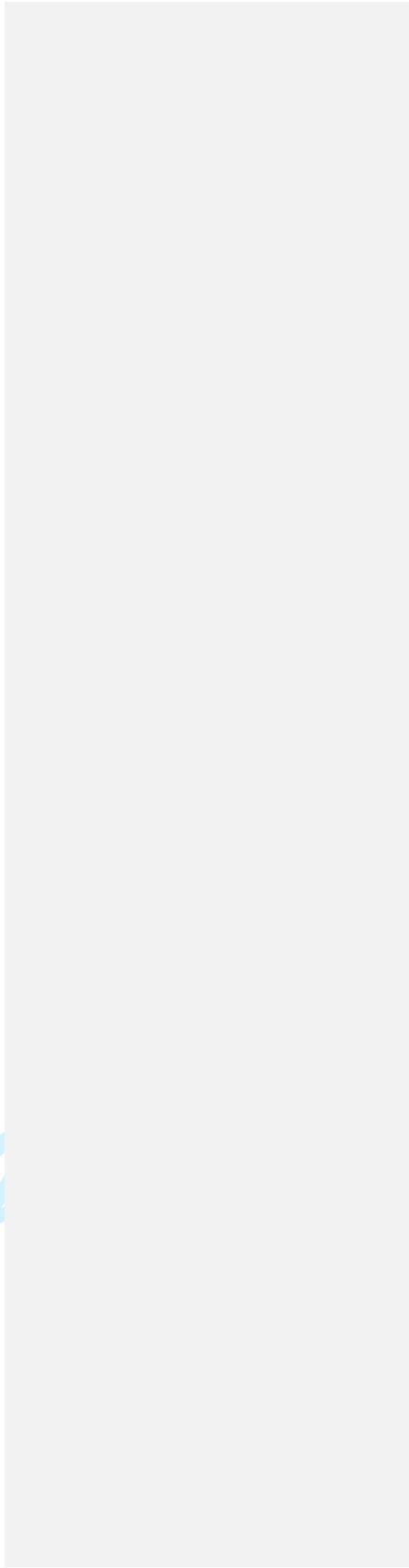
Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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Conclusion: In this multicenter prospective study in Japan, we observed a high overall success rate in airway management during trauma care. However, the methods of intubation and success rates were highly variable among hospitals.

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10 **Article summary**

11 **Article focus**

12 This paper characterizes the current practice of airway management for trauma patients in
13 emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway
14 Network (JEAN) Study.
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18 **Key messages**

19 The method of intubation, success rates, and adverse event rates are highly variable among EDs.
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21 Development and dissemination of nationwide protocols are warranted to achieve safer airway
22 management for trauma victims in Japan.
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26 **Strengths and limitations of this study**

27 This is the first study to report disparities in trauma airway management based on multicenter,
28 prospective data.
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30 Passive surveillance of data is subject to self-reporting bias, leading to a possible
31 underestimation of failed intubations and adverse events.
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1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients.[1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients.[1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe.[6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere.[10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this analysis. We excluded an ED in which the number of trauma intubations was less than 10 from the current analysis.

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Data Collection

Data collection was passive, relying on self-reports by the intubators on duty. After each intubation, the intubators completed a standardized data sheet, including the patient's age, sex, estimated weight, primary indication for intubation, methods used to facilitate intubation, intubator's level of training (emergency physicians, resident physicians, and transitional year residents) and specialty (emergency physician or not), number of attempts, success or failure, and intubation-related adverse events. Method was defined as the set of medications and devices used, such as RSI with a Macintosh laryngoscope. Transitional-years residents were post-graduate year 1-2 physicians who rotate through the ED. An intubation attempt was defined as a single insertion of the laryngoscope (or other device) past the teeth.[2 10-13] For nasal intubations, an attempt was defined as a single insertion of a tracheal tube past the turbinates. An attempt was successful if it resulted in the tracheal tube being passed through the vocal cords. One or more methods could be used in each patient, and each method could be attempted several times.

Adverse events were recorded using a pre-specified list, with the option to include additional comments, if necessary. **Adverse events were defined as cardiac arrest, hypotension, hypoxemia, dysrhythmia, vomiting, esophageal intubation, mainstem bronchial intubation, and airway trauma that are considered to be intubation-related.[11] Cardiac arrest included asystole, bradycardia, or dysrhythmia with nonmeasurable blood pressure and cardiopulmonary resuscitation during or after intubation. Hypotension was defined as systolic blood pressure less than 90 mm Hg. Hypoxemia was defined as pulse oximetric**

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9 **saturation less than 90% during an intubation attempt, not a result of esophageal**
10 **intubation. Preexisting hypotension or hypoxemia before an intubation attempt were not**
11 **counted as an adverse event. Esophageal intubation was defined as misplacement of the**
12 **endotracheal tube in the upper esophagus or hypopharynx, with a lapse of time and**
13 **desaturation (pulse oximetric saturation <90%) before the removal of the misplaced tube.**

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18 We monitored compliance with data form completion by reviewing professional billing records.

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20 Where the data collection form was missing, the intubator was interviewed by one of the
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22 investigators within 2 weeks of the patient encounter, to fill out the data form.

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26 The outcomes of interest were the primary indication for intubation, initial method used for
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28 intubation, intubation success rates (on the first attempt and within three attempts), and
29 **intubation-related** adverse event rates.

30 31 32 33 **Statistical Analysis**

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35 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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37 patient-level, we described patient demographics, the primary indication for intubation, initial
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39 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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41 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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43 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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45 after stratifying by indication (non-cardiac arrest vs. cardiac arrest) and specialty (emergency
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47 physicians vs. non-emergency physicians). All *P*-values were two-tailed, with *P*<0.05 considered
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49 statistically significant.

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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis. Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients. The direct laryngoscope was used in most of

intubations (n=654, 90.5%), and the remaining were intubated using a video laryngoscope (n=30,

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4.1%), a bronchoscope (n=17, 2.4%), a lighted stylet (n=1, 0.1%) on the first attempt.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5%

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9 (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the
10 first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,
11 97.0%-99.8%) of the patients. In the stratified analysis by the specialty (i.e., emergency
12 physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a higher
13 success at the first attempt (72.8 % vs. 50.2 %, p<0.001) compared to non-emergency physicians
14 **(including all transitional-year residents [n=237])**. Intubation-associated adverse event rates
15 were 10.8% (95% CI, 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in
16 non-cardiac arrest patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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26 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
27 **(Figure 2)**. For example, RSI as the initial intubation method was performed in 0% to 50.9% of
28 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
29 wide variation in the success rates and adverse event rates across the EDs **(Figure 3)**. The range
30 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
31 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
32 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
33 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

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4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. **Therefore, some of the patients might have been inappropriately considered as “difficult intubation,” and intubated with non-RSI methods. Alternatively, it is also plausible** that non-RSI methods were more frequently used in certain EDs because of the physicians’ preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. The reasons for the variations among the EDs are likely multifactorial; the potential explanations include

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9 inter-hospital differences in patient population, skills or education backgrounds of intubators,[14]
10 drug and device availability in the ED, or any combination of these factors. Alternatively, the
11 observed wide variation in the intubation method may have led to these variations in success and
12 adverse event rates. Furthermore, there are no requirements for procedural credentials to perform
13 ED intubations both in individuals and institutions in Japan.[10] This lack of procedural
14 requirements would have contributed, at least partially, to the observed inter-hospital variations
15 in the success rates. Indeed, we observed that intubation success rates performed by
16 non-emergency physicians were significantly lower; this was, at least in part, explained by the
17 intubation attempts by transitional-year residents. However, it is well documented in the
18 literature that first-pass success is important in critically-ill patients[11]; therefore, the observed
19 lower success rate by these non-skilled physicians cannot be justified. Our data underscore the
20 reinforcement of Japanese methodology of training for non-skilled physicians (e.g., the use of
21 simulators and training in a more controlled setting[15-17] to improve their intubation skill set,
22 which will, in turn, improve patients' outcomes.

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37 Although international and Japanese trauma care guidelines recommend the use of RSI as the
38 initial method of emergency airway management in most trauma patients,[14 5] the evidence for
39 accurately predicting patients in whom RSI should be avoided remain limited.[18 19] It is,
40 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
41 across the EDs. Our observations should facilitate further investigation of any barriers to the
42 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
43 airway management, coupled with improved dissemination of these findings, could decrease the
44 variations in trauma care across the EDs in Japan.

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11 Our study has several potential limitations. First, this passive surveillance of the study data is
12 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
13 adverse events. However, active independent monitoring of ED intubations is difficult to
14 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
15 definitions, and a high capture rate. Second, we did not design this study to measure patient
16 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
17 and outcomes requires following the patients for a longer period. Third, we did not account for
18 several potential confounders, such as severities (the Injury Severity Score, the Revised Trauma
19 Score, etc.) of cases and training levels of physicians. However, this prospective multicenter data
20 reflect the current airway management in the natural setting of a “real” population and current
21 clinical practice, therefore enhancing the potential generalizability of the findings. Finally, all
22 EDs in this study were designated as tertiary or academic general hospitals, and all but one of the
23 EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
24 inferences may not be generalizable to trauma airway management in non-academic EDs or other
25 developed nations. These observations, however, are highly relevant from a policy standpoint. As
26 these EDs provide advanced care for trauma victims and train the majority of emergency
27 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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45 5. CONCLUSION

46 In this multicenter prospective study of emergency airway management in Japan, we found an
47 acceptable overall success rate in trauma airway management. However, we also found that the
48 method of intubation, success rates and adverse event rates were highly variable among EDs. For
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9 researchers, our observations should facilitate further investigations to identify the reasons of the
10 inter-hospital variations. Additionally, for policy makers and professional organizations, our
11 findings suggest that development and dissemination of nationwide protocols are warranted to
12 achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis. S.N. wrote the manuscript, which A.K. reviewed.

Data Sharing Statement

No additional data available

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Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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Manuscripts

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
4 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
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16
17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
21 States
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31

32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
39

40 Email: shunichiro-nakao@umin.ac.jp
41
42
43
44
45

46 **Co-authors' address**
47

48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49

50 akimura@hosp.ncgm.go.jp
51
52

53 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
54

55 +810423005111, Email: yusukehagiwara-tky@umin.ac.jp
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1
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3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
4
5 khasegawa1@partners.org
6
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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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Article summary**Article focus**

This paper characterizes the current practice of airway management for trauma patients in emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway Network (JEAN) Study.

Key messages

The method of intubation, success rates, and adverse event rates are highly variable among EDs. Development and dissemination of nationwide protocols are warranted to achieve safer airway management for trauma victims in Japan.

Strengths and limitations of this study

This is the first study to report disparities in trauma airway management based on multicenter, prospective data.

Passive surveillance of data is subject to self-reporting bias, leading to a possible underestimation of failed intubations and adverse events.

1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients.[1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients.[1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe.[6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere.[10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). The participating hospitals had a median trauma admission of 1,000 per year (range, 300 to 1,500).[14] All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this

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3 analysis. We excluded an ED in which the number of trauma intubations was less than 10 from
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5 the current analysis.
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10 **Data Collection**

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12 Data collection was passive, relying on self-reports by the intubators on duty. After each
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14 intubation, the intubators completed a standardized data sheet, including the patient's age, sex,
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16 estimated weight, primary indication for intubation, methods used to facilitate intubation,
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18 intubator's level of training (emergency physicians, resident physicians, and transitional year
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20 residents) and specialty (emergency physician or not), number of attempts, success or failure,
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22 and intubation-related adverse events. Method was defined as the set of medications and devices
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24 used, such as RSI with a Macintosh laryngoscope. Transitional-years residents were
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26 post-graduate year 1-2 physicians who rotate through the ED. An intubation attempt was defined
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28 as a single insertion of the laryngoscope (or other device) past the teeth.[2 10-13] For nasal
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30 intubations, an attempt was defined as a single insertion of a tracheal tube past the turbinates. An
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32 attempt was successful if it resulted in the tracheal tube being passed through the vocal cords.
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34 One or more methods could be used in each patient, and each method could be attempted several
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36 times.
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46 Adverse events were recorded using a pre-specified list, with the option to include additional
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48 comments, if necessary. Adverse events were defined as cardiac arrest, hypotension, hypoxemia,
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50 dysrhythmia, vomiting, esophageal intubation, mainstem bronchial intubation, and airway
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52 trauma that are considered to be intubation-related.[11] Cardiac arrest included asystole,
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54 bradycardia, or dysrhythmia with nonmeasurable blood pressure and cardiopulmonary
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3 resuscitation during or after intubation. Hypotension was defined as systolic blood pressure less
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5 than 90 mm Hg. Hypoxemia was defined as pulse oximetric saturation less than 90% during an
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7 intubation attempt, not a result of esophageal intubation. Preexisting hypotension or hypoxemia
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9 before an intubation attempt were not counted as an adverse event. Esophageal intubation was
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11 defined as misplacement of the endotracheal tube in the upper esophagus or hypopharynx, with a
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13 lapse of time and desaturation (pulse oximetric saturation <90%) before the removal of the
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15 misplaced tube. We monitored compliance with data form completion by reviewing professional
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17 billing records. Where the data collection form was missing, the intubator was interviewed by
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19 one of the investigators within 2 weeks of the patient encounter, to fill out the data form.
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27 The outcomes of interest were the primary indication for intubation, initial method used for
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29 intubation, intubation success rates (on the first attempt and within three attempts), and
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31 intubation-related adverse event rates.
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36 **Statistical Analysis**

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38 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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40 patient-level, we described patient demographics, the primary indication for intubation, initial
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42 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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44 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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46 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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48 after stratifying by indication (non-cardiac arrest vs. cardiac arrest) and specialty (emergency
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50 physicians vs. non-emergency physicians). All *P*-values were two-tailed, with *P*<0.05 considered
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52 statistically significant.
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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis.

Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients. The direct laryngoscope was used in most of intubations (n=654, 90.5%), and the remaining were intubated using a video laryngoscope (n=30,

4.1%), a bronchoscope (n=17, 2.4%), a lighted stylet (n=1, 0.1%) on the first attempt.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5%

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3 (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the
4 first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,
5 97.0%-99.8%) of the patients. In the stratified analysis by the specialty (i.e., emergency
6 physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a higher
7 success at the first attempt (72.8 % vs. 50.2 %, p<0.001) compared to non-emergency physicians
8 (including all transitional-year residents [n=237]). Intubation-associated adverse event rates were
9 10.8% (95% CI, 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in
10 non-cardiac arrest patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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24 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
25 (**Figure 2**). For example, RSI as the initial intubation method was performed in 0% to 50.9% of
26 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
27 wide variation in the success rates and adverse event rates across the EDs (**Figure 3**). The range
28 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
29 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
30 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
31 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Therefore, some of the patients might have been inappropriately considered as “difficult intubation,” and intubated with non-RSI methods. Alternatively, it is also plausible that non-RSI methods were more frequently used in certain EDs because of the physicians’ preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. The reasons for the variations among the EDs are likely multifactorial; the potential explanations include

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3 inter-hospital differences in patient population, skills or education backgrounds of intubators,[15]
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5 drug and device availability in the ED, or any combination of these factors. Alternatively, the
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8 observed wide variation in the intubation method may have led to these variations in success and
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10 adverse event rates. Furthermore, there are no requirements for procedural credentials to perform
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12 ED intubations both in individuals and institutions in Japan.[10] This lack of procedural
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14 requirements would have contributed, at least partially, to the observed inter-hospital variations
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16 in the success rates. Indeed, we observed that intubation success rates performed by
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18 non-emergency physicians were significantly lower; this was, at least in part, explained by the
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20 intubation attempts by transitional-year residents. However, it is well documented in the
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22 literature that first-pass success is important in critically-ill patients[11]; therefore, the observed
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24 lower success rate by these non-skilled physicians cannot be justified. Our data underscore the
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26 reinforcement of Japanese methodology of training for non-skilled physicians (e.g., the use of
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28 simulators and training in a more controlled setting[16-18] to improve their intubation skill set,
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30 which will, in turn, improve patients' outcomes.
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39 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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41 initial method of emergency airway management in most trauma patients,[14 5] the evidence for
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43 accurately predicting patients in whom RSI should be avoided remain limited.[19 20] It is,
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45 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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47 across the EDs. Our observations should facilitate further investigation of any barriers to the
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49 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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51 airway management, coupled with improved dissemination of these findings, could decrease the
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53 variations in trauma care across the EDs in Japan.
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6 Our study has several potential limitations. First, this passive surveillance of the study data is
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8 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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10 adverse events. However, active independent monitoring of ED intubations is difficult to
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12 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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14 definitions, and a high capture rate. Second, we did not design this study to measure patient
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16 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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18 and outcomes requires following the patients for a longer period. Third, we did not account for
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20 several potential confounders, such as severities (the Injury Severity Score, the Revised Trauma
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22 Score, etc.) of cases and training levels of physicians. However, this prospective multicenter data
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24 reflect the current airway management in the natural setting of a “real” population and current
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26 clinical practice, therefore enhancing the potential generalizability of the findings. Finally, all
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28 EDs in this study were designated as tertiary or academic general hospitals, and all but one of the
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30 EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
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32 inferences may not be generalizable to trauma airway management in non-academic EDs or other
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34 developed nations. These observations, however, are highly relevant from a policy standpoint. As
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36 these EDs provide advanced care for trauma victims and train the majority of emergency
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38 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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48 **5. CONCLUSION**

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50 In this multicenter prospective study of emergency airway management in Japan, we found an
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52 acceptable overall success rate in trauma airway management. However, we also found that the
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54 method of intubation, success rates and adverse event rates were highly variable among EDs. For
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3 researchers, our observations should facilitate further investigations to identify the reasons of the
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5 inter-hospital variations. Additionally, for policy makers and professional organizations, our
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7 findings suggest that development and dissemination of nationwide protocols are warranted to
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9 achieve safer airway management for trauma victims in Japan.
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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis.

S.N. wrote the manuscript, which A.K. reviewed.

Data Sharing Statement

No additional data available

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Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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3 **Trauma airway management in emergency departments: A multicenter, prospective,**
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5 **observational study in Japan**
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10 Shunichiro Nakao, MD¹; Akio Kimura, MD, PhD¹; Yusuke Hagiwara, MD, MPH²; and Kohei
11 Hasegawa, MD, MPH³, on behalf of the Japanese Emergency Medicine Network Investigators
12
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14

15
16
17 ¹Department of Emergency Medicine and Critical Care, National Center for Global Health and
18 Medicine, Shinjuku, Tokyo, Japan; ²Department of Emergency Medicine, Tokyo Metropolitan
19 Children's Medical Center, Fuchu, Tokyo, Japan; ³Department of Emergency Medicine,
20 Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, the United
21 States
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23
24
25
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30
31

32 **Address correspondence to:** Dr. Shunichiro Nakao
33

34 Department of Emergency Medicine, University of Ottawa / The Ottawa Hospital - Civic
35 Campus, 1053 Carling Ave, Room F653, Ottawa, ON K1Y 4E9
36
37

38 Tel: 613.798.5555 ext. 15976
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40 Email: shunichiro-nakao@umin.ac.jp
41
42
43
44
45

46 **Co-authors' address**
47

48 Akio Kimura, MD, PhD; 1-21-1, Toyama, Shinjuku, Tokyo, Japan, Tel: + 81332027181, Email:
49

50 akimura@hosp.ncgm.go.jp
51

52 Yusuke Hagiwara, MD, MPH; 304 Keyaki-ryo, 2-9-2 Musashidai, Fuchu, Tokyo, Japan, Tel:
53

54 +810423005111, Email: yusukehagiwara-tky@umin.ac.jp
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1
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3 Kohei Hasegawa, MD, MPH; 326 Cambridge Street, Suite 410, Boston, Tel: 6177245276, Email:
4
5 khasegawa1@partners.org
6
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11

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Abstract

Objectives: Although successful airway management is essential for emergency trauma care, comprehensive studies are limited. We sought to characterize the current trauma care practice of airway management in the emergency departments (EDs) in Japan.

Design: Analysis of data from a prospective, observational, multi-center registry – the Japanese Emergency Airway Network (JEAN) registry.

Setting: 13 academic and community EDs from different geographic regions across Japan.

Participants: 723 trauma patients who underwent emergency intubation from March 2010 through August 2012.

Outcome measures: ED characteristics, patient and operator demographics, methods of airway management, intubation success or failure at each attempt, and adverse events.

Results: A total of 723 trauma patients who underwent emergency intubation were eligible for the analysis. Traumatic cardiac arrest comprised 32.6% (95% CI, 29.3%-36.1%) of patients.

Rapid sequence intubation (RSI) was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients, and in 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest trauma patients. Overall, intubation was successful in ≤ 3 attempts in 96.0% of patients (95% CI, 94.3%-97.2%). There was a wide variation in the initial methods of intubation; RSI as the initial method was performed in 0% to 50.9% of all trauma patients among 12 EDs. Similarly, there was a wide variation in success rates and adverse event rates across the EDs. Success rates varied between 35.5% and 90.5% at the first attempt and 85.1% and 100% within 3 attempts across the 12 EDs.

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6 Conclusion: In this multicenter prospective study in Japan, we observed a high overall success
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8 rate in airway management during trauma care. However, the methods of intubation and success
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10 rates were highly variable among hospitals.
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Article summary**Article focus**

This paper characterizes the current practice of airway management for trauma patients in emergency departments (EDs) in Japan by using data from the Japanese Emergency Airway Network (JEAN) Study.

Key messages

The method of intubation, success rates, and adverse event rates are highly variable among EDs. Development and dissemination of nationwide protocols are warranted to achieve safer airway management for trauma victims in Japan.

Strengths and limitations of this study

This is the first study to report disparities in trauma airway management based on multicenter, prospective data.

Passive surveillance of data is subject to self-reporting bias, leading to a possible underestimation of failed intubations and adverse events.

1. INTRODUCTION

Successful airway management is a cornerstone in the modern practice of emergency and trauma care. Failure of emergency airway management is often associated with morbidity and mortality in trauma patients.[1-3] Consequently, training in and understanding of airway management is a distinct discipline that is essential for successful trauma resuscitation.

Evidence-based recommendations for airway management during trauma care exist within international and national guidelines of the United States. These guidelines indicate rapid sequence intubation (RSI) as the initial method of emergency airway management in most trauma patients.[1 4 5] Recent studies reported that RSI is the most common airway management method in emergency departments (EDs) in North America and Europe.[6-9] Despite the ubiquitous practice of emergency airway management in trauma patients, little is known about its current practice and performance in other industrialized nations. Therefore, we sought to describe the current practice of airway management for trauma patients in the EDs in Japan.

2. METHODS

Study Design and Setting

We analyzed the data of a prospective, observational, multi-center registry, the Japanese Emergency Airway Network (JEAN) registry. The study design, setting, methods of measurement, and measured variables have been reported elsewhere.[10-13] Briefly, the registry is a consortium of 13 academic and community EDs from different geographic regions across Japan. These EDs consisted of 10 tertiary medical centers that have a capability to manage the most severe trauma patients and 3 secondary medical centers that are designated to treat moderately severe trauma patients. The participating EDs had a median ED census of 30,000 patient visits per year (range 9,000 to 67,000). **The participating hospitals had a median trauma admission of 1,000 per year (range, 300 to 1,500).[14]** All 13 EDs were staffed by attending emergency physicians, and 12 had affiliations with emergency medicine residency training programs. Each hospital maintained individual protocols, policies, and procedures for emergency airway management. Intubations were performed by attending physicians or by resident physicians at the discretion of the ED attending physician. The ethics committee of each participating center approved the protocol, with waiver of informed consent before data collection.

Patients

The registry prospectively collected information on consecutive patients who underwent airway management in the participating EDs during a 30-month period, from March 2010 to August 2012. All adult and pediatric trauma patients who underwent intubation were eligible for this

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3 analysis. We excluded an ED in which the number of trauma intubations was less than 10 from
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5 the current analysis.
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10 **Data Collection**

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12 Data collection was passive, relying on self-reports by the intubators on duty. After each
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14 intubation, the intubators completed a standardized data sheet, including the patient's age, sex,
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16 estimated weight, primary indication for intubation, methods used to facilitate intubation,
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18 intubator's level of training (emergency physicians, resident physicians, and transitional year
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20 residents) and specialty (emergency physician or not), number of attempts, success or failure,
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22 and intubation-related adverse events. Method was defined as the set of medications and devices
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24 used, such as RSI with a Macintosh laryngoscope. Transitional-years residents were
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26 post-graduate year 1-2 physicians who rotate through the ED. An intubation attempt was defined
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28 as a single insertion of the laryngoscope (or other device) past the teeth.[2 10-13] For nasal
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30 intubations, an attempt was defined as a single insertion of a tracheal tube past the turbinates. An
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32 attempt was successful if it resulted in the tracheal tube being passed through the vocal cords.
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34 One or more methods could be used in each patient, and each method could be attempted several
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36 times.
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46 Adverse events were recorded using a pre-specified list, with the option to include additional
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48 comments, if necessary. Adverse events were defined as cardiac arrest, hypotension, hypoxemia,
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50 dysrhythmia, vomiting, esophageal intubation, mainstem bronchial intubation, and airway
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52 trauma that are considered to be intubation-related.[11] Cardiac arrest included asystole,
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54 bradycardia, or dysrhythmia with nonmeasurable blood pressure and cardiopulmonary
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3 resuscitation during or after intubation. Hypotension was defined as systolic blood pressure less
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5 than 90 mm Hg. Hypoxemia was defined as pulse oximetric saturation less than 90% during an
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7 intubation attempt, not a result of esophageal intubation. Preexisting hypotension or hypoxemia
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9 before an intubation attempt were not counted as an adverse event. Esophageal intubation was
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11 defined as misplacement of the endotracheal tube in the upper esophagus or hypopharynx, with a
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13 lapse of time and desaturation (pulse oximetric saturation <90%) before the removal of the
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15 misplaced tube. We monitored compliance with data form completion by reviewing professional
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17 billing records. Where the data collection form was missing, the intubator was interviewed by
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19 one of the investigators within 2 weeks of the patient encounter, to fill out the data form.
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27 The outcomes of interest were the primary indication for intubation, initial method used for
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29 intubation, intubation success rates (on the first attempt and within three attempts), and
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31 intubation-related adverse event rates.
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36 **Statistical Analysis**

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38 We performed all analysis with JMP 10 software (SAS Institute Inc., Cary, NC, USA). At the
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40 patient-level, we described patient demographics, the primary indication for intubation, initial
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42 method of intubation, success rates, and adverse event rates as proportions with 95% confidence
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44 intervals (CIs) and medians with interquartile ranges (IQR). Then, at the ED-level, we described
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46 medians, IQR and ranges for each outcome for all trauma patients. We also repeated the analysis
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48 after stratifying by indication (non-cardiac arrest vs. cardiac arrest) and specialty (emergency
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50 physicians vs. non-emergency physicians). All *P*-values were two-tailed, with *P*<0.05 considered
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52 statistically significant.
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3. RESULTS

During the 30-month study period, 4,268 patients required emergency airway management. Of these, the registry recorded 4,094 intubations (capture rate, 95.9%; **Figure 1**), of which 3370 patients who underwent airway management for medical reasons were excluded from the analysis. One of the 13 hospitals, in whom only 1 trauma patient required airway intervention during the study period, was excluded because the number of intubations for trauma care was less than 10 during the study period. Hence, 723 trauma patients were eligible for analysis.

Emergency physicians, including emergency medicine residents, performed the first intubation attempts in 60.0% (95% CI, 56.4%-63.5%) of all trauma patients and 66.7% (95% CI, 62.4%-70.8%) of non-cardiac arrest patients. Transitional-year residents (postgraduate years 1 and 2) performed the first intubation attempts in 31.4% (95% CI, 28.1%-34.9%) of all trauma patients and 25.7% (95% CI, 22.0%-29.7%) of non-cardiac arrest patients.

Table 1 shows the baseline characteristics and primary indications in patients who required trauma airway management. Median age was 56 years; two-thirds of the patients were male. Traumatic cardiac arrest was the reason for intubation in 32.6% (95% CI, 29.3%-36.1%) of all trauma patients, while head trauma accounted for 30.4% (95% CI, 27.2%-33.9%). **Table 2** shows the initial method of airway management in the trauma patients. RSI was the initial method chosen in 23.9% (95% CI, 21.0%-27.2%) of all trauma patients and 35.5% (95% CI, 31.4%-39.9%) of non-cardiac arrest patients. Cricothyrotomy was performed as the initial airway management strategy in 2.2% (95% CI, 1.4%-3.6%) of all trauma patients and 0.4% (95% CI, 0.1%-1.5%) of non-cardiac arrest patients. The direct laryngoscope was used in most of intubations (n=654, 90.5%), and the remaining were intubated using a video laryngoscope (n=30,

4.1%), a bronchoscope (n=17, 2.4%), a lighted stylet (n=1, 0.1%) on the first attempt.

Table 1. Characteristics of the 723 trauma patients who required intubation

Patient characteristics		
Age (y), median, (IQR)	56	(34 - 73)
Male, % (95% CI)	66.9	(63.4 - 70.3)
Estimated weight (kg), median, (IQR)	60	(50 - 70)
Indication for intubation, % (95% CI)		
Cardiac arrest	32.6	(29.3 - 36.1)
Head trauma	30.4	(27.2 - 33.9)
Shock	16.6	(14.1 - 19.5)
Facial/Neck trauma	8.4	(6.6 - 10.7)
Airway burn	6.8	(5.2 - 8.8)
Others	5.1	(3.3 - 8.0)

Abbreviations: CI, confidence interval; IQR, interquartile range

Table 2. Initial method of intubation

	All trauma patients			Non-cardiac arrest patients		
	n	%	95% CI	n	%	95% CI
Rapid sequence intubation	173	23.9	(21.0 - 27.2)	173	35.5	(31.4 - 39.9)
Sedation without paralysis	153	21.2	(18.3 - 24.3)	153	31.4	(27.5 - 35.7)
Paralytics without sedation	19	2.6	(1.7 - 4.1)	19	3.9	(2.5 - 6.0)
Oral without sedation	349	48.3	(44.6 - 52.0)	127	26.1	(22.4 - 30.2)
Surgical	16	2.2	(1.4 - 3.6)	2	0.4	(0.1 - 1.5)
Nasal intubation	13	1.8	(1.1 - 3.1)	13	2.7	(1.6 - 4.5)
Total	723	100		487	100	

Abbreviations: CI, confidence interval

Table 3 summarizes the intubation success rates and adverse event rates. Overall, intubation was successful in the first attempt in 63.8% (95% CI, 60.2%-67.2%) and within 3 attempts in 96.0% (95% CI, 94.3%-97.2%) of all trauma patients. In non-cardiac arrest patients, intubation was successful in the first attempt in 60.2% (95% CI, 55.8%-64.4%) and within 3 attempts in 94.5%

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3 (95% CI, 92.1%-96.2%) of patients. In cardiac arrest patients, intubation was successful in the
4 first attempt in 71.2% (95% CI, 65.1%-76.6%) and within 3 attempts in 99.2% (95% CI,
5 97.0%-99.8%) of the patients. In the stratified analysis by the specialty (i.e., emergency
6 physicians [n=434] vs. non-emergency physicians [n=289]), emergency physicians had a higher
7 success at the first attempt (72.8 % vs. 50.2 %, p<0.001) compared to non-emergency physicians
8 (including all transitional-year residents [n=237]). Intubation-associated adverse event rates were
9 10.8% (95% CI, 8.7%-13.3%) in overall trauma patients, 11.5% (95% CI, 9.0%-14.6%) in
10 non-cardiac arrest patients, and 9.3% (95% CI, 6.2%-13.7%) in cardiac arrest patients.
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25 At the ED-level, there was a wide variation in the methods of intubation across the 12 EDs
26 (**Figure 2**). For example, RSI as the initial intubation method was performed in 0% to 50.9% of
27 all trauma patients, and in 0% to 87.5% of non-cardiac arrest patients. Similarly, there was a
28 wide variation in the success rates and adverse event rates across the EDs (**Figure 3**). The range
29 of overall success rates for intubation in the first attempt ranged from 35.5% to 90.5%, and from
30 85.1% to 100% within 3 attempts. Likewise, overall adverse event rates varied widely (range,
31 0%-16.7%) across the EDs. These wide variations in intubation success rates and adverse event
32 rates persisted across the non-cardiac arrest and cardiac arrest strata.
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Table 3. Success rates and intubation-associated adverse events

	All trauma patients			Non-cardiac arrest patients			Cardiac arrest patients		
	n	%	95% CI	n	%	95% CI	n	%	95% CI
Successful in 1st attempt	461	63.8	(60.2 - 67.2)	293	60.2	(55.8 - 64.4)	168	71.2	(65.1 - 76.6)
Successful in ≤ 3rd attempts	694	96.0	(94.3 - 97.2)	460	94.5	(92.1 - 96.2)	234	99.2	(97.0 - 99.8)
Adverse events	78	10.8	(8.7 - 13.3)	56	11.5	(9.0 - 14.6)	22	9.3	(6.2 - 13.7)
Details of adverse events*									
Esophageal intubation	25	3.5	(2.2 - 5.1)	15	3.1	(1.7 - 5.0)	10	4.2	(2.0 - 7.7)
Mainstem bronchus intubation	18	2.5	(1.5 - 3.9)	9	1.8	(0.8 - 3.5)	9	3.8	(1.7 - 7.1)
Airway trauma	17	2.4	(1.4 - 3.7)	14	2.9	(1.6 - 4.8)	3	1.3	(0.3 - 3.7)
Hypotension†	8	1.1	(0.5 - 2.2)	8	1.6	(0.7 - 3.2)			
Vomiting	6	0.8	(0.3 - 1.8)	6	1.2	(0.5 - 2.7)			
Hypoxia‡	3	0.4	(0.1 - 1.2)	3	0.6	(0.1 - 1.8)			
Cardiac arrest	1	0.1	(0.0 - 0.8)	1	0.2	(0.0 - 1.1)			

Abbreviations: CI, confidence interval

*Patients may have more than 1 adverse event.

†Hypotension was defined as systolic blood pressure less than 90 mm Hg.

‡Hypoxia was defined as pulse oximetric oxygen saturation of less than 90% during intubation attempts, not as a result of esophageal intubation.

4. DISCUSSION

In this prospective, multicenter, observational study in Japan, we observed an acceptable success rate of airway management in trauma patients in EDs. However, we also found a wide range of variation in the initial method of intubation, success rates, and adverse event rates during trauma airway management across the EDs. Indeed, the overall success rates in the first intubation attempt ranged from 35.5% to 90.5%.

We were struck by the high degree of variation in the methods of airway management in trauma cases across the 12 EDs. The reasons for the observed practice variations are unclear and are likely multifactorial. It is possible that non-RSI methods were attempted in patients who were predicted to have a difficult intubation. However, the difference in the patient population across the EDs cannot fully explain the observed three-fold difference in the use of RSI. Therefore, some of the patients might have been inappropriately considered as “difficult intubation,” and intubated with non-RSI methods. Alternatively, it is also plausible that non-RSI methods were more frequently used in certain EDs because of the physicians’ preference, procedural experiences, training background, or differences in ED staffing and institutional policies.

Our study also demonstrated a high degree of variations in success and adverse event rates among the EDs. Particularly, the success rate at first attempts was highly variable. To the best of our knowledge, this is the first study to demonstrate such inter-hospital variations in success and adverse event rates in trauma airway management in different EDs. The reasons for the variations among the EDs are likely multifactorial; the potential explanations include

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3 inter-hospital differences in patient population, skills or education backgrounds of intubators,[15]
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5 drug and device availability in the ED, or any combination of these factors. Alternatively, the
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7 observed wide variation in the intubation method may have led to these variations in success and
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9 adverse event rates. Furthermore, there are no requirements for procedural credentials to perform
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11 ED intubations both in individuals and institutions in Japan.[10] This lack of procedural
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13 requirements would have contributed, at least partially, to the observed inter-hospital variations
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15 in the success rates. Indeed, we observed that intubation success rates performed by
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17 non-emergency physicians were significantly lower; this was, at least in part, explained by the
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19 intubation attempts by transitional-year residents. However, it is well documented in the
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21 literature that first-pass success is important in critically-ill patients[11]; therefore, the observed
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23 lower success rate by these non-skilled physicians cannot be justified. Our data underscore the
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25 reinforcement of Japanese methodology of training for non-skilled physicians (e.g., the use of
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27 simulators and training in a more controlled setting[16-18] to improve their intubation skill set,
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29 which will, in turn, improve patients' outcomes.
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39 Although international and Japanese trauma care guidelines recommend the use of RSI as the
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41 initial method of emergency airway management in most trauma patients,[14 5] the evidence for
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43 accurately predicting patients in whom RSI should be avoided remain limited.[19 20] It is,
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45 therefore, plausible that the scarcity of evidence may have contributed to the practice variations
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47 across the EDs. Our observations should facilitate further investigation of any barriers to the
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49 delivery of safer trauma care nationally. Additionally, building more robust evidence on trauma
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51 airway management, coupled with improved dissemination of these findings, could decrease the
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53 variations in trauma care across the EDs in Japan.
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6 Our study has several potential limitations. First, this passive surveillance of the study data is
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8 subject to self-reporting bias, leading to a possible underestimation of failed intubations and
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10 adverse events. However, active independent monitoring of ED intubations is difficult to
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12 accomplish. We did, however, use a self-reporting system with structured data forms, uniform
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14 definitions, and a high capture rate. Second, we did not design this study to measure patient
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16 outcomes, such as long-term mortality or morbidity. A more detailed analysis of adverse events
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18 and outcomes requires following the patients for a longer period. Third, we did not account for
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20 several potential confounders, such as severities (the Injury Severity Score, the Revised Trauma
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22 Score, etc.) of cases and training levels of physicians. However, this prospective multicenter data
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24 reflect the current airway management in the natural setting of a “real” population and current
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26 clinical practice, therefore enhancing the potential generalizability of the findings. Finally, all
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28 EDs in this study were designated as tertiary or academic general hospitals, and all but one of the
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30 EDs were affiliated with an emergency medicine residency program in Japan. Therefore, our
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32 inferences may not be generalizable to trauma airway management in non-academic EDs or other
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34 developed nations. These observations, however, are highly relevant from a policy standpoint. As
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36 these EDs provide advanced care for trauma victims and train the majority of emergency
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38 physicians, these EDs have a disproportionate impact on current and future trauma care in EDs.
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48 **5. CONCLUSION**

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50 In this multicenter prospective study of emergency airway management in Japan, we found an
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52 acceptable overall success rate in trauma airway management. However, we also found that the
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54 method of intubation, success rates and adverse event rates were highly variable among EDs. For
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3 researchers, our observations should facilitate further investigations to identify the reasons of the
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5 inter-hospital variations. Additionally, for policy makers and professional organizations, our
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7 findings suggest that development and dissemination of nationwide protocols are warranted to
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9 achieve safer airway management for trauma victims in Japan.
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For peer review only

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Author Contribution

K.H. designed the study, for which S.N. and Y.H. contributed to the data collection and analysis.

S.N. wrote the manuscript, which A.K. reviewed.

Data Sharing Statement

No additional data available

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Figure Legends

Figure 1. Flow chart showing inclusion of patients in this study

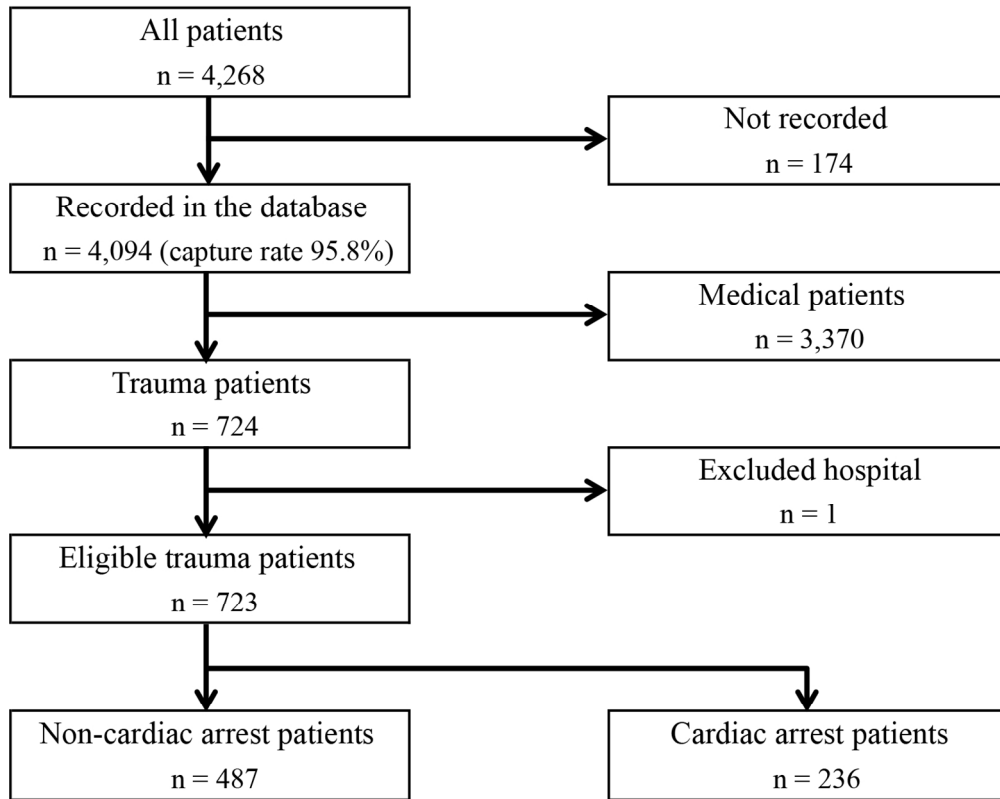
Figure 2. Inter-hospital variations in initial methods of intubation

Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.

Figure 3. Inter-hospital variations in success rates and adverse event rates

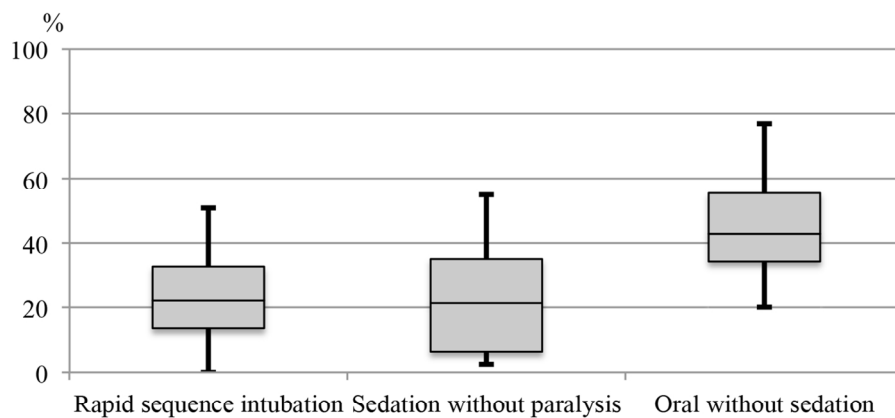
Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.

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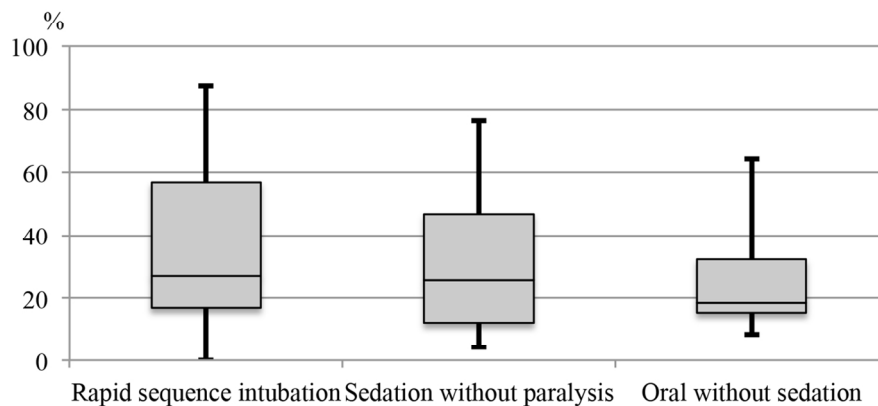


Flow chart showing inclusion of patients in this study

136x108mm (300 x 300 DPI)



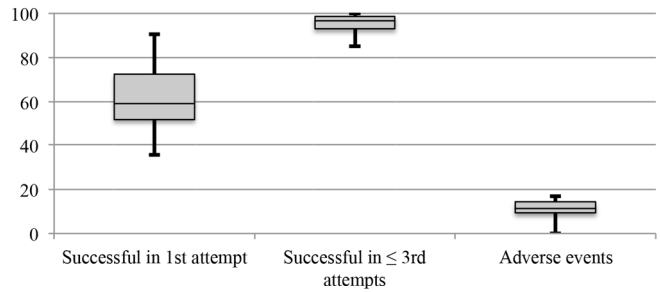
a. Among all trauma patients



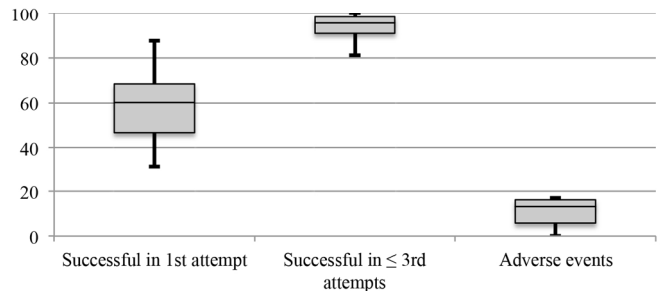
b. Among non-cardiac arrest patients

Inter-hospital variations in initial methods of intubation
 Boxplots of inter-hospital variations in the initial methods of intubation. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles, respectively. The whiskers from the box extend to the minimum and maximum values.
 140x165mm (300 x 300 DPI)

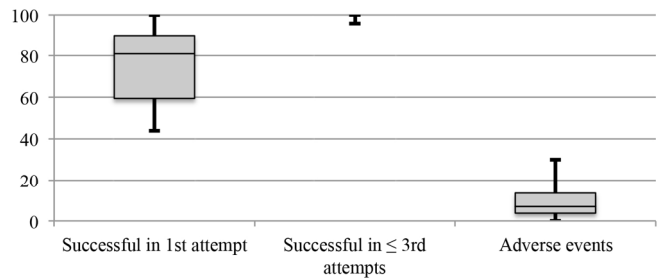
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a. Among all trauma patients



b. Among non-cardiac arrest patients



c. Among cardiac arrest patients

Inter-hospital variations in success rates and adverse event rates
 Boxplots of inter-hospital variations in success rates and adverse event rates. The line in the middle of the box represents the median, with the lower and upper limits of the box representing the 25th and 75th percentiles. The whiskers from the box extend to the minimum and maximum values.
 137x233mm (300 x 300 DPI)