Original Article

Characteristics and outcome of patients triaged by telephone and transported by ambulance: a population-based study in Osaka, Japan

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Aim: Details such as diagnosis and outcome of patients transported by ambulance after telephone triage have not been fully revealed. The aim of this study was to reveal profile and outcome about patients transported by ambulance via telephone triage with dataset of telephone triage and population-based registry for emergency patients.

Methods: This retrospective descriptive study with a one-year study period from January 1, 2016 to December 31, 2016 included patients selected from the telephone triage dataset who were transported by ambulance. Key parameters such as age, sex and date and time of ambulance dispatch were used to identify patient data from the ORION registry. We assessed the profile and outcome of the patients in a descriptive epidemiological analysis.

Results: We included 4,293 patients in the selected datasets whose data were merged, of whom 2,998 patients (69.8%) returned home from the emergency department, 1,255 (29.2%) were hospitalized, 32 (0.7%) were transferred to other hospitals, and 8 (0.2%) died. The most common diagnosis in the emergency departments was "infectious gastroenteritis and colitis, unspecified [A09] (219, 5.1%)". Among the 1,255 hospitalized patients, 905 patients (72.1%) were discharged home, 254 patients (20.2%) remained hospitalized, 52 patients (4.1%) were transferred to other hospitals, 38 patients (3.0%) died, and 5 patients (0.5%) had missing data. The most common diagnosis was "cerebral infarction [I63.0-I63.9] (138, 11.0%)".

Conclusion: This study revealed the profile and outcome of patients transported by ambulance after telephone triage.

Key words: Ambulance dispatch, emergency medicine, epidemiology, outcome, telephone triage

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INTRODUCTION

PREVIOUS STUDIES HAVE reported an increase in emergency visits of patients with minor illnesses,^{1,2} and while some have found that patients with public insurance and the uninsured, as well as elderly and critically ill patients, disproportionately depend on ambulance transport to the emergency department (ED).^{3,4} The number of ambulance transports in Japan has been increasing in recent years,⁵ with 58.2% of transported patients returning home

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after visiting the ED.⁶ Too many patients with minor emergencies may reduce the availability of emergency medical resources for those truly requiring emergency care and may worsen the prognosis of severely ill or injured patients. There is a limit to the amount of emergency medical resources that can be allocated for increased ambulance calls and ED visits. Therefore, new emergency medical services (EMSs) need to be established for patients with minor emergencies.

Telephone triage service is provided worldwide as a medical consultation service for patients who suddenly become ill or injured but do not necessarily require an ambulance. In Osaka, Japan, a telephone triage service has been provided to the local population since 2012. However, the details of patients transported by ambulance via telephone triage, such as diagnosis and outcome, have not been fully revealed. Revealing the diagnoses and outcomes of these patients could help to revise the telephone triage protocol and validate the usefulness of telephone triage. In 2015, the Osaka prefectural government established a population-based registry system (ORION) for emergency patients transported by ambulance, which collects patient information from the ambulance call to hospital discharge.⁶ The aim of this study was to reveal the profile and outcome about the patients transported by ambulance via telephone triage with the merged dataset of telephone triage dataset and ORION registry.

METHODS

Study design, population, and settings

THIS WAS A retrospective observational study with a 1year study period from January 1, 2016 to December 31, 2016. Osaka Prefecture is located in the central area of western Japan and covers an area of 1,905 km² with a population of 8.8 million.⁷ EMS such as ambulance calls and telephone triage is a public service available to everyone free of charge. In this study, we included patients who were transported by ambulance after telephone triage and were registered in the ORION database. Hence, we excluded those patients not transported by ambulance or who were not registered in the ORION database. This study was approved by the Ethics Committee of Osaka University Graduate School of Medicine (approval no. 16070). As the telephone triage data and ORION registry data were anonymized without specific personal data, such as the patient's name, date of birth, and address, the requirement of obtaining patient's informed consent was waived. This manuscript was written based on the Strengthening the Reporting of Observational Studies in Epidemiology statement to assess the reporting of cohort and cross-sectional studies.⁸

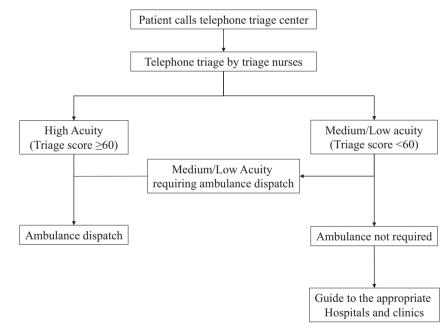
Telephone triage in Osaka Prefecture

Nurses working in the telephone triage service in Osaka prefecture receive telephone calls from people and judge the urgency of the patient's chief complaints and symptoms using software based on a telephone triage protocol in Japan. These nurses provide responses such as ambulance dispatch and guidance to hospitals based on the urgency judged with the software (Table 1). Figure 1 shows a flowchart of telephone triage in Osaka, Japan. If the patient's condition is very urgent, the telephone call is forwarded to the ambulance dispatch center of each fire department in Osaka prefecture and an ambulance is dispatched. For less urgent patients who do not require an ambulance, telephone triage nurses will direct them to appropriate hospitals or clinics depending on their chief complaint. Even if a patient is not urgent and does not require an ambulance, an ambulance may be dispatched for patients who have no means of transportation to a hospital, such as the elderly. In Japan, the telephone triage protocol is categorized by each of 97 chief complaints,⁹ and the urgency of patients is judged by selecting signs and symptoms related to chief complaints. Similar to telephone triage services in the United States, Canada, and Australia,^{10–14} the telephone triage service in Japan provides ambulance dispatch and guidance to available hospitals and clinics based on the telephone triage result.¹⁵ Our software records information such as sex and age group of the patients, beginning to end time of the telephone triage, chief complaint and signs during telephone triage, urgency of the telephone triage, and whether an ambulance was dispatched.

The ORION system

Information on the system configuration of ORION was previously described in detail (Fig. 2).^{6,8} EMS personnel at the scene use the ORION smartphone app for each emergency patient. All data input into the smartphone app, such as vital signs and time of call to the hospital to enquire about acceptance, are also recorded. The smartphone app data are accumulated in the ORION cloud server, and in cooperation with the dispatched EMS personnel, a data manager at each fire department directly inputs or uploads the ambulance record of each emergency patient so that it can be connected with the app data. Furthermore, personnel at each hospital directly input or upload the patient's data, such as diagnoses and outcomes, after hospital acceptance. Diagnosis names are recorded according to ICD-10 codes. The results of the data aggregated in the ORION system are fed back to every fire department and emergency hospital. The Department of Public Health of Osaka Prefecture can also analyze the

Triage score	Category	Example symptoms or signs	Action after telephone triage
≥60	Immediate ambulance dispatch	Not breathing, unconsciousness, convulsion, intolerable pain	Transfer to ambulance dispatch center
20–59	Need to visit hospital or clinic immediately	Chest pain during deep breathing, bloody urine, painful itching	Visit emergency hospitals, guided by the information system for emergency medical institution in Osaka Prefecture
10–19	Need to visit hospital or clinic within approximately 6 h	Elderly people without urgent symptoms and signs	Visit emergency hospital, other hospitals, or clinics, guided by the information system for hospitals or clinics in Osaka Prefecture
5–9	Need to visit hospital or clinic within approximately 24 h	Children without urgent symptoms and signs	Visit emergency hospital, other hospitals, or clinics, guided by the information system for hospitals or clinics in Osaka Prefecture
0	No need to visit hospital or clinic immediately	People with no urgent symptoms and signs	Visit hospitals or clinics, guided by the information system for hospitals or clinics in Osaka Prefecture, or observation at home with advice provided by telephone triage nurses or visit hospitals or clinics





effects of health policy on the emergency medical system using these collected data. We previously reported that the data on 97.9% of all emergency patients transported by ambulance were captured and collected with the ORION system.⁶

Patient selection

We selected patients transported by ambulance from the telephone triage data set. Next, key parameters such as age, sex, and date and time of ambulance dispatch were used to

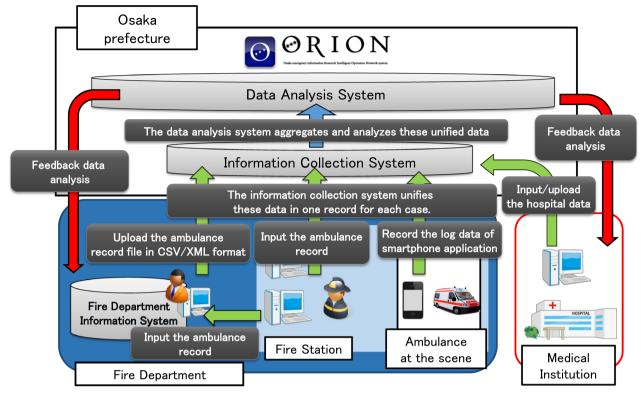


Fig. 2. System configuration of the Osaka Emergency Information Research Intelligent Operation Network (ORION) system.

identify patient data from the ORION registry. Each selected data set was merged, and we then analyzed the merged data set. Age differences of up to 2 years and time differences of ambulance dispatch of up to 5 min were allowed. All data that did not match between the two data sets were excluded from this study.

Statistical analysis

Continuous variables are indicated by median and interquartile range (IQR) and categorical variables by percentage. Age groups were categorized as infant and young children (0–5 years old), children (6–17 years old), adults (18– 64 years old), and elderly (\geq 65 years old). Statistical analyses were carried out with SPSS version 23.0J (IBM, Armonk, NY, USA).

RESULTS

 $\mathbf{F}^{\text{IGURE}}$ 3 shows the patient flow in this study. There were 105,763 patients triaged by the telephone triage service in Osaka during 2016, of whom 4,999 patients were transported by ambulance. Among them, we excluded 706

patients whose data did not match with ORION registry data, and thus, 4,293 patients were included in this study.

Table 2 shows the patients' characteristics in this study. The median age was 48 years (IQR 22-73). There were 2,070 males (48.2%) and 2,223 females (51.8%), of whom 671 patients (15.6%) were infants and young children, 275 (6.4%) were children, 1,786 (41.6%) were adults, and 1,561 (36.4%) were elderly. The most frequent time of calling was 16:00-23:59 in 1,714 patients (41.2%). The most frequent day of the week was Sunday (854 patients, 19.9%), followed by Saturday (614 patients, 14.3%) and Thursday (604 patients, 14.1%). Calls were made by 1,761 patients (41.0%) inside Osaka city and 2,532 patients (59.0%) outside Osaka city. The most common signs and symptoms were abnormal vital signs such as not breathing and nonresponsive (886 patients, 20.6%), followed by dyspnea (543 patients, 12.6%) and chest pain (329 patients, 7.7%). Telephone triage nurses judged 4,240 (98.8%) patients to be highly urgent.

Table 3 shows the diagnoses and outcomes in the EDs. Among the patients, 2,998 (69.8%) returned home from the ED, 1,255 (29.2%) were hospitalized, 32 (0.7%) were transferred to other hospitals, and 8 (0.2%) died. The most common diagnosis in the EDs was "infectious gastroenteritis and

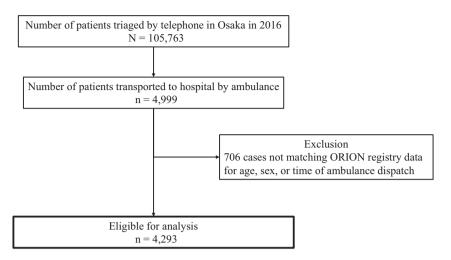


Fig. 3. Patient flow in this study.

colitis, unspecified [A09; 219 patients (5.1%)]" among all patients, "febrile convulsion [R56.0; 144 patients (21.5%)]" in infants and young children, and "cerebral infarction [I63.0–I63.9; 112 patients (7.2%)]" in the elderly.

Table 4 shows the diagnoses and outcomes at 21 days after hospital admission in the 1,255 hospitalized patients: 905 (72.1%) were discharged home, 254 (20.2%) remained hospitalized, 52 (4.1%) were transferred to other hospitals, 38 (3.0%) died, and 5 patients (0.5%) had missing data. The most common diagnosis was "cerebral infarction [I63.0–I63.9]" in 138 patients (11.0%), followed by "disorder of vestibular function [H81.0–H81.9]" in 47 patients (3.7%) and "pneumonia, unspecified organism [J18.0–J18.9]" in 44 patients (3.5%).

DISCUSSION

TO OUR KNOWLEDGE, this is the first populationbased study in Japan to reveal the profile and outcome of patients transported by ambulance to a hospital after judging the urgency of their signs and symptoms by telephone triage. Although most of the patients transported by ambulance were judged to be highly urgent by telephone triage, most of them returned home after only visiting the ED. The most common diagnosis in the ED was febrile convulsions in infants and young children, infectious gastroenteritis in adults, and cerebral infarction in the elderly. Cerebral infarction was the most common diagnosis among hospitalized patients and in the elderly. The results of this study may help to assess the usefulness of the telephone triage service.

After merging the telephone triage data and populationbased registry data for patients transported by ambulance, we found that most of the patient data matched. The ORION system has been implemented in all fire departments and emergency hospitals in Osaka prefecture but not in the hospitals or clinics that do not provide emergency care. Therefore, the ORION system is missing data for patients transported by ambulance to these non-emergency facilities. In fact, of the 573,384 patients for whom an ambulance was dispatched in Osaka prefecture in 2016, 77,998 were not transported to medical facilities and 24,734 were transported to non-emergency medical facilities in Osaka prefecture.⁶ Thus, it is likely that the unmatched cases in this study were either not transported at all or not transported to emergency medical facilities in Osaka prefecture. In a previous Australian study that matched secondary telephone triage data to hospital data, 37.2% of cases were missing data in the ED among patients transported by ambulance.¹⁰ Compared with this previous study, the proportion of data matching in this study was high, and the matched data set may be suitable for analysis.

Among all patients transported by ambulance in Osaka prefecture in 2016, the median age was 67 (IQR 40–80) years, and the proportion of new born infants (<28 days), young children (\geq 28 days to <7 years), older children (\geq 7 years to <18 years), adults (\geq 18 years to <65 years), and elderly (\geq 65 years old) were 0.2%, 5.5%, 4.0%, 36.5%, and 53.8%, respectively.⁶ Compared with these results, the patients in this study were younger, with a higher proportion of infants and children and, especially, a lower proportion of elderly patients. Telephone triage services have been available in Osaka prefecture since 2012, and these services may be more frequently used by parents caring for their infants and children than by the elderly. Because elderly people tend to use ambulances to visit the emergency room¹⁶ and for less urgent emergencies,¹⁷ it is important to promote the

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	Total (N = 4,293)	Infants and young children (0–5 years old) (N = 671)	Children (6–17 years old) (N = 275)	Adults (18–64 years old) (N = 1,786)	Elderly (>65 years old ($N = 1,561$)
Characteristics					
Age (years), median (IQR)	48 (22–73)				
Sex, n (%)					
Male	2,070 (48.2)	375 (55.9)	170 (61.8)	822 (46.0)	703 (45.0)
Female	2,223 (51.8)	296 (44.1)	105 (38.2)	964 (54.0)	858 (55.0)
Time of day, <i>n</i> (%)					
0:00–7:59	1,233 (28.7)	182 (27.1)	59 (21.5)	647 (36.2)	345 (22.1)
8:00–15:59	1,346 (31.4)	199 (29.7)	84 (30.5)	490 (27.4)	573 (36.7)
16:00–23:59	1,714 (41.2)	290 (43.2)	132 (48.0)	649 (36.3)	643 (41.2)
Day of the week, n (%)					. ,
Sunday	854 (19.9)	122 (18.2)	56 (20.4)	352 (19.7)	324 (20.8)
Monday	570 (13.3)	114 (11.6)	32 (11.6)	240 (13.4)	184 (11.8)
Tuesday	574 (13.4)	94 (14.0)	32 (11.6)	241 (13.5)	207 (13.3)
Wednesday	556 (13.0)	87 (13.0)	38 (13.8)	230 (12.9)	201 (12.9)
Thursday	604 (14.1)	82 (12.2)	42 (15.3)	258 (14.4)	222 (14.2)
Friday	521 (12.1)	78 (11.6)	33 (12.0)	218 (12.2)	192 (12.3)
Saturday	614 (14.3)	94 (14.0)	42 (15.3)	247 (13.8)	231 (14.8)
Area					
Inside Osaka City	1,761 (41.0)	274 (40.8)	107 (38.9)	840 (47.0)	540 (34.6)
Outside Osaka City	2,532 (59.0)	397 (59.2)	168 (61.1)	946 (53.0)	1,021 (65.4)
Main presenting problem on telephone	riage				
Abnormal vital signs	886 (20.6)	181 (27.0)	62 (22.5)	361 (20.2)	282 (18.1)
(e.g., not breathing/Nonresponsive)					
Dyspnea	543 (12.6)	76 (11.3)	28 (10.2)	260 (14.6)	179 (11.5)
Chest pain	329 (7.7)	1 (0.1)	2 (0.7)	173 (9.7)	143 (9.2)
Dizziness and vertigo	300 (7.0)	O (O)	4 (1.5)	127 (7.1)	169 (10.8)
Abdominal pain	300 (7.0)	18 (2.7)	30 (10.9)	204 (11.4)	48 (3.1)
Disturbance of consciousness	241 (5.6)	56 (8.3)	16 (5.8)	53 (3.0)	116 (7.4)
Headache	219 (5.1)	0 (0)	5 (1.8)	171 (9.6)	43 (2.8)
Numbness and paralysis	192 (4.8)	0 (0)	1 (0.4)	76 (4.3)	115 (7.4)
Heart palpitations	122 (2.8)	0 (0)	2 (0.7)	42 (2.4)	78 (5.0)
Fever	114 (2.7)	37 (5.5)	15 (5.5)	18 (1.0)	44 (2.8)
Convulsions and seizures in children	103 (2.4)	89 (13.3)	14 (5.1)	0 (0)	O (O)
Urgency of symptoms on telephone tria	ge				
Urgent	4,240 (98.8)	655 (97.6)	288 (97.5)	1,774 (99.3)	1,543 (98.9)
Not urgent	53 (1.2)	16 (2.4)	7 (2.5)	12 (0.7)	18 (1.1)

use of telephone triage to elderly people to reduce the use of ambulances for low-urgency emergencies. In addition, the proportion of patients discharged home was higher in this study than in the previous study in which 58.2% of the patients transported by ambulances were discharged home.⁶ This difference may have been influenced by the lower proportion of elderly patients compared to the usual patients transported by ambulances and may also be related to the fact that most of the patients were suffering from diseases that did not require hospitalization, such as infectious gastroenteritis and headache. However, cerebral infarction was the most common diagnosis among the hospitalized patients,

	Total (N = 4,293)	Infants and young children (0–5 years old) ($N = 671$)	Children (6–17 years old) (N = 275)	Adults (18–64 years old) (N = 1,786)	Elderly (\geq 65 years old ($N = 1,561$)
Outcome at emergency departme	nt, <i>n</i> (%)				
Hospitalization	1,255 (29.2)	123 (18.3)	62 (22.5)	387 (21.7)	683 (43.8)
Discharge home from emergency department	2,998 (69.8)	540 (80.5)	212 (77.1)	1,392 (77.9)	854 (54.7)
Interhospital transfer	32 (0.7)	7 (1.0)	1 (0.4)	7 (0.4)	17 (1.1)
Dead	8 (0.2)	1 (0.1)	0 (0)	0 (0)	7 (0.4)
Diagnosis at emergency departme	nt (ICD-10 code),	n (%)			
Infectious gastroenteritis and colitis, unspecified (A09)	219 (5.1)	35 (5.2)	28 (10.1)	125 (7.0)	31 (2.0)
Febrile convulsions (R56.0)	162 (3.8)	144 (21.5)	16 (5.8)	2 (0.1)	0 (0)
Cerebral infarction (I63.0– I63.9)	150 (3.5)	0 (0)	0 (0)	38 (2.1)	112 (7.2)
Disorders of vestibular function (H81.0–H81.9)	141 (3.3)	0 (0)	1 (0.4)	69 (3.9)	71 (4.6)
Headache (R51)	123 (2.9)	1 (0.1)	9 (3.3)	94 (5.3)	19 (1.2)
Calculus of kidney and ureter (N20.0–N20.9)	117 (2.7)	0 (0)	0 (0)	104 (5.8)	13 (0.8)
Dizziness and giddiness (R42)	110 (2.6)	0 (0)	2 (0.7)	54 (3.0)	54 (3.5)
Superficial injury of scalp (S00.0–S00.8)	100 (2.3)	39 (5.8)	19 (6.9)	18 (1.0)	24 (1.5)
Pain in the throat and chest (R07.0–R07.8)	92 (2.1)	0 (0)	1 (0.4)	65 (3.6)	26 (1.7)
Abnormalities of heart beat and palpitations (R00, R00.2)	79 (1.8)	0 (0)	2 (0.7)	33 (1.9)	44 (2.8)

ICD, International Classification of Disease.

especially the elderly patients. Because cerebral infarction presents with a variety of symptoms, including hemiplegia, dysarthria, and vertigo, it may be difficult for the elderly to accurately identify these symptoms and visit hospitals on their own. Thus, it may be useful for triage nurses to interview and triage the patient's condition via telephone. In this way, the telephone triage, which can accurately recognize patients with time-sensitive conditions such as cerebral infarction, is useful in an aging society such as Japan's.

Many of the main problems presenting at telephone triage in the post-triage patients transported by ambulance were abnormal vital signs such as not breathing, nonresponsive, dyspnea, and chest pain. In an Australian study of secondary telephone triage, Eastwood et al. found that abdominal pain, back pain, dizziness, and vertigo were more common as the main presenting problems in secondary telephone triage.¹⁰ In Australia, cases classified as low acuity during primary triage are then triaged by qualified nurses or paramedics to further elucidate the patient's presenting problem. By contrast, patients in Japan classified as high acuity by telephone triage are then transferred to the ambulance dispatch center. The differences between the ambulance dispatch and telephone triage in Australia and Japan may have influenced the differences in results. Although the number of patients identified as highly urgent by telephone triage was extremely high in this study, many of these patients transported by ambulance returned home after their ED visit. High falsepositive rates have been reported for triage protocols that prioritize ambulance dispatch for patients in prehospital settings.^{13,19} Revision of the telephone triage protocols will be necessary to ensure efficient use of the resources of the emergency medical system such as ambulances.

Finally, there was the issue of indicators to assess triage acuity. In this study, we used hospitalization after emergency department visits as the outcome of telephone triage. Indicators for assessing the validity of triage protocol are controversial. In a systemic review of reliability of various triage protocols for emergency pediatric patients, studies

	Total (N = 1,255)	Infants and young children (0–5 years old) ($N = 123$)	Children (6–17 years old) ($N = 62$)	Adults (18–64 years old) (<i>N</i> = 387)	Elderly (\geq 65 years old) ($N = 683$)
Outcome at 21 days after hospitalization, <i>n</i> (%)					
Continuation of hospitalization	254 (20.2)	4 (3.3)	2 (3.2)	51 (13.2)	197 (28.8)
Discharge home	905 (72.1)	116 (94.3)	59 (95.2)	323 (83.5)	407 (59.6)
Interhospital transfer	52 (4.1)	3 (2.4)	0 (0)	8 (2.1)	42 (6.1)
Dead	38 (3.0)	O (O)	1 (1.6)	3 (0.8)	34 (5.0)
Missing data	6 (0.5)	O (O)	0 (0)	2 (0.5)	4 (0.6)
Diagnosis at 21 days after hospitalization, n (%)					
Cerebral infarction (163.0–163.9)	138 (11.0)	O (O)	0 (0)	33 (8.5)	105 (15.4)
Disorders of vestibular function (H81.0–H81.9)	47 (3.7)	O (O)	0 (0)	23 (5.9)	24 (3.5)
Pneumonia, unspecified organism (J18.0–J18.9)	44 (3.5)	5 (4.1)	0 (0)	8 (2.1)	31 (4.5)
Angina pectoris (I20.0–I20.9)	33 (2.6)	O (O)	0 (0)	18 (4.7)	15 (2.2)
Nontraumatic intracerebral hemorrhage (I61.0–I61.9)	31 (2.5)	0 (0)	0 (0)	14 (3.6)	17 (2.5)
Heart failure (I50.0–I50.9)	28 (2.2)	0 (0)	0 (0)	4 (1.0)	24 (3.5)
Infectious gastroenteritis and colitis, unspecified (A09)	27 (2.2)	4 (3.3)	1 (1.6)	18 (4.7)	4 (0.6)
Pneumonitis due to inhalation of food and vomit (J69.0)	21 (1.7)	O (O)	O (O)	1 (0.3)	20 (2.9)
Febrile convulsions (R56.0)	19 (1.5)	14 (11.4)	5 (8.1)	O (O)	0 (0)
Unspecified convulsions (R56.8)	13 (1.0)	8 (6.5)	4 (6.5)	O (O)	1 (0.1)

Table 4. Prognosis and diagnosis at 21 days after hospitalization

used the agreement of triage nurses and pediatric emergency medicine physicians as an indicator of the reliability of triage protocol.²⁰ On the other hand, studies for various ambulance dispatch protocols revealed the validation specific conditions such as stroke, acute coronary syndrome, outof-hospital cardiac arrest, and trauma.^{21–27} Based on these previous studies, we selected hospitalization as a measure to assess the validity of telephone triage protocol in this study. We will examine the validation of our telephone triage protocol for each symptom or condition in the future.

Limitations

There are several limitations in this study. First, we analyzed patients transported by ambulance after telephone triage in Osaka prefecture. Therefore, these results may not be valid in areas where the system of telephone triage and ambulance dispatch is different. Second, we analyzed only patients transported to emergency hospitals in Osaka prefecture and did not analyze patients transported to other hospitals. Third, selection bias may be present because we did not include cases in which the telephone triage data and ORION data did not match. Fourth, we could not assess cases of low urgency for which ambulances were not dispatched. In Japan, the law restricts the tracking of individuals, and this is a problem that must be resolved in the future. Finally, because this study was conducted over a single year, the number of cases was small. Therefore, we will continue to accumulate data for further analysis in the future.

CONCLUSION

IN THIS STUDY, we combined the telephone triage data with the registry data of patients transported by ambulance to emergency hospitals and revealed the profile and outcome of the patients transported by ambulance after telephone triage. Most of the patients who were transported by ambulance after telephone triage returned home after visiting the ED, and cerebral infarction was the most common diagnosis among the patients who were hospitalized.

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DISCLOSURE

Approval of the research protocol: The protocol was approved by the Ethics Committee of Osaka University as the corresponding institution.

Informed Consent: The requirement for informed consent of the patients was waived.

Registry and the Registration No. of the study/Trial: This study was not registered.

Animal studies: N/A.

Conflict of Interest: None declared.

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