Comparison of short-term mortality and morbidity between parenteral and enteral nutrition for adults without cancer: a propensity-matched analysis using a national inpatient database[1,2]

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ABSTRACT

Background: Proper artificial nutrition for patients who are unable to eat normally is an ongoing, unresolved concern in geriatric medicine and home medical care. Controversy surrounds prognostic differences between parenteral and enteral nutrition, 2 methods for artificial nutrition.

Objectives: Short-term outcomes of parenteral and enteral nutrition for patients who are unable to eat normally were compared and analyzed.

Design: Data were acquired from patients selected from a national inpatient database covering 1057 hospitals in Japan. Participants had received artificial nutrition between April 2012 and March 2013, were aged ≥20 y, and did not have cancer. They were separated into 2 groups: those who received parenteral nutrition and those who received enteral nutrition. We performed one-to-one propensity score matching between the groups. The primary outcome measurements were mortality rates at 30 and 90 d after the start of the procedure. The secondary outcomes were postprocedural complications, pneumonia, and sepsis. We analyzed survival length of stay after the procedure with the use of a Cox proportional hazards model.

Results: There were 3750 patients in the parenteral group and 22,166 patients in the enteral group. Propensity score matching created 2912 pairs in the 2 groups. Patients with a similar propensity score (probability of being assigned to the enteral group) calculated from the baseline condition were matched. Mortality rates at 30 and 90 d after start of treatment were 7.6% and 5.7% ($P = 0.003$) and 12.3% and 9.9% ($P = 0.002$) in the parenteral and enteral groups, respectively. In Cox regression analysis, the HR for the enteral group relative to the parenteral group was 0.62 (95% CI: 0.54, 0.71; $P < 0.001$). The incidences of postprocedural pneumonia and sepsis were 11.9% and 15.5% ($P < 0.001$) and 4.4% and 3.7% ($P = 0.164$) for the parenteral and enteral groups, respectively.

Conclusion: The present analysis showed the better survival rate with enteral compared with parenteral nutrition for adults who were not suffering from cancer. This trial was registered at clinicaltrials.gov as NCT02512224. *Am J Clin Nutr* 2015;102:1222–8.

Keywords: elderly, mortality, morbidity, parenteral nutrition, enteral nutrition

INTRODUCTION

Artificial nutrition is an option in cases in which patients are unable to eat normally, although the indication for its use is not agreed on. There are 2 options for artificial nutrition: parenteral nutrition, also called intravenous feeding and often achieved by central venous port insertion, and enteral nutrition, in which nourishment is introduced directly into the stomach. Parenteral nutrition is considered to carry risks of catheter infection and suppression of intestinal immunity, and for this reason, enteral nutrition is thought to be superior to parenteral nutrition. The American Society for Parenteral and Enteral Nutrition recommends that enteral nutrition, if feasible, rather than parenteral nutrition should be used (1). In 2004 and 2010 it was estimated that enteral nutrition was used in at least 145,000 cases in the United States and at least 119,000 cases in Japan (2), respectively.

However, enteral nutrition is not without risks. For example, 2 options for enteral nutrition, percutaneous endoscopic gastrostomy and percutaneous transesophageal gastrotubing, carry a risk of postprocedural aspiration pneumonia caused by gastroesophageal reflux. In addition, low survival rates after percutaneous endoscopic gastrostomy have been reported (2–8).

Only a few studies have compared mortality between parenteral and enteral nutrition in patients who need artificial nutrition. Home parenteral nutrition was shown to be a safe substitute for percutaneous endoscopic gastrostomy in patients with amyotrophic lateral sclerosis (9), and there was no difference in mortality between 546 elderly patients that could be attributed to type of artificial nutrition (10). In fact, there is one study in patients with traumatic brain injury in which patients who received parenteral

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ORTHOPAEDIC SURGERY

Association between dementia and postoperative complications after hip fracture surgery in the elderly: analysis of 87,654 patients using a national administrative database

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Abstract

Introduction Mortality following hip fracture surgery is higher in patients with dementia than those without; however, few large-scale studies have investigated postoperative in-hospital complications in such patients. The aim of this study was to elucidate the complications that occur after hip fracture surgery in patients with and without dementia using a large national database.

Materials and methods We retrospectively identified patients aged ≥70 years who underwent hemiarthroplasty, osteosynthesis for femoral neck fracture or osteosynthesis for intertrochanteric fracture, and compared the occurrence of postoperative complications between patients with and without dementia. Multivariate logistic regression analysis was performed to adjust for patient characteristics and hospital factors.

Results A total of 87,654 patients were included in this study, including 9419 with dementia. Compared with the non-dementia group, the dementia group showed a higher incidence of overall postoperative complications [odds ratio (OR) 1.45; $p < 0.001$), surgical site infection (OR 1.58; $p = 0.004$), urinary tract infection (OR 1.87; $p < 0.001$) and respiratory complications (OR 1.49; $p < 0.001$). The rate of postoperative complications was higher for all types of hip fracture surgery. The occurrence of a postoperative complication was significantly higher in patients aged ≥80 years (OR 1.37; $p < 0.001$) and those with dementia (OR 1.45; $p < 0.001$), any type of malignancy (OR 1.42; $p < 0.001$), a history of cardiovascular disease (OR 1.33; $p < 0.001$), a history of cerebrovascular disease (OR 1.15; $p = 0.029$), chronic renal failure (OR 1.36; $p < 0.001$), liver cirrhosis (OR 1.41; $p < 0.001$) or blood transfusion after surgery (OR 1.49; $p < 0.001$).

Conclusions Our results highlight the need to pay particular attention to surgical site infection, urinary tract

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Effectiveness of surgical rib fixation on prolonged mechanical ventilation in patients with traumatic rib fractures: A propensity score–matched analysis

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ABSTRACT

Purpose: We investigated whether surgical rib fixation improved outcomes in patients with traumatic rib fractures.
Materials and Methods: This was a retrospective study using a Japanese administrative claim and discharge database. We included patients with traumatic rib fractures admitted to hospitals where surgical rib fixation was available from July 1 2010, to March 31, 2013. We detected patients who underwent surgical rib fixation within 10 days of hospital admission (surgical group) and those who did not (control group). The main outcome was prolonged mechanical ventilation, defined as that performed for 5 or more days, or death within 28 days. One-to-four propensity score matching was performed between the 2 groups with adjustment for possible confounders.
Results: Among 4577 eligible patients, 90 (2.0%) underwent the surgical rib fixation. After the matching, we obtained 84 and 336 patients in the surgical and control groups, respectively. Logistic regression analyses showed that the surgical group was significantly less likely to receive prolonged mechanical ventilation or die within 28 days than the control group (22.6% vs 33.3%; odds ratio, 0.59; 95% confidence interval, 0.36-0.96; $P = .034$).
Conclusions: Surgical rib fixation within 10 days of hospital admission may improve outcomes in patients with traumatic rib fractures.

1. Introduction

Most rib fractures are treated nonoperatively. In fact, a study using the National Trauma Data Bank showed that only 0.7% of patients with flail chest, which is one of the most severe conditions in multiple rib fractures, received surgical fixation for rib fractures [1]. However, patients who received conservative treatments for rib fractures often had long-lasting disability [2]. Thus, the current nonoperative treatments for rib fractures are not necessarily ideal for the patients.

Several previous studies have shown the benefits of surgical rib fixation, including 3 randomized controlled trials [3–5]. Nevertheless, these studies involved small sample sizes. Consequently, operative management is not recognized as a standard treatment option, even for flail chest. A previous study in the United States involving trauma, orthopedic, and thoracic surgeons reported that only 26% had performed or assisted on surgical fixation for rib fractures [6]. Because of the potential benefits for patients with rib fractures, the effects of surgical rib fixation on outcomes need to be further evaluated.

We investigated the effects of surgical fixation for rib fractures on patient outcomes in a real-world clinical setting, using a national administrative claims and discharge database in Japan.

2. Materials and methods

2.1. Study design and setting

The present study was a retrospective cohort study. We used a Japanese national administrative claims and discharge abstract database called the Diagnosis Procedure Combination (DPC) database [7,8]. This database collects data for all inpatients discharged from participating hospitals. In 2013, approximately 1000 hospitals including 82 university hospitals participated in the database system.

The DPC database contains the following information for individual patients: age; sex; diagnoses including primary diagnoses, complications during hospitalization, and preexisting comorbidities; medical and surgical procedures performed; drugs used; and discharge status. Diagnoses are recorded by both *International Classification of Diseases,*

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Outcomes of Argatroban Treatment in Patients With Atherothrombotic Stroke

Observational Nationwide Study in Japan

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Background and Purpose—Argatroban, a selective thrombin inhibitor, is recommended for the use in patients with atherothrombotic stroke by the Japanese Guidelines for the Management of Patients with Acute Ischemic Stroke. We performed a nationwide Japanese study to investigate whether argatroban improved early stroke outcomes in patients with acute atherothrombotic stroke.

Methods—This retrospective observational study, using the Diagnosis Procedure Combination database in Japan, included patients who were hospitalized from July 1, 2010, to March 31, 2012, with a diagnosis of atherothrombotic stroke within 1 day of stroke onset. Patients were divided into 2 groups: those receiving argatroban on admission (argatroban group), and those who did not receive argatroban during hospitalization (control group). To balance the baseline characteristics and concomitant treatments during hospitalization between the 2 groups, one-to-one propensity-score matching analyses were performed. The main outcomes were the modified Rankin Scale score at discharge and the occurrence of hemorrhagic complications during hospitalization. An ordinal logistic regression analysis evaluated the association between argatroban use and modified Rankin Scale at discharge.

Results—After propensity-score matching, 2289 pairs of patients were analyzed. There were no significant differences in modified Rankin Scale at discharge between the argatroban and the control groups (adjusted odds ratio, 1.01; 95% confidence interval, 0.88–1.16). The occurrence of hemorrhagic complications did not differ significantly between the argatroban and the control groups (3.5% versus 3.8%; P=0.58).

Conclusions—The present study suggested that argatroban was safe, but had no added benefit in early outcomes after acute atherothrombotic stroke. **(*Stroke*. 2016;47:471-476. DOI: 10.1161/STROKEAHA.115.011250.)**

Key Words: anticoagulants ■ argatroban ■ propensity score ■ stroke ■ thrombin

In Western countries, there are no specific recommendations for anticoagulant drug use in patients with acute ischemic stroke.[1,2] In the Japanese guidelines, it is stated that there is no scientific evidence for the use of heparin, heparinoid drugs, or low molecular weight heparin in patients with acute ischemic stroke. In contrast, argatroban, a selective thrombin inhibitor, is recommended in Japan for the use in patients with acute atherothrombotic stroke except those with lacunar infarction.[2]

To the best of our knowledge, there are only 3 randomized controlled trials on argatroban use in patients with acute ischemic stroke: 1 from North America[3] and 2 from Japan.[4,5] These studies suggested that argatroban was effective and safe for the use as early anticoagulant therapy in acute ischemic stroke. However, the sample sizes of these studies were small. A previous meta-analysis of 23 748 patients from 24 studies, including the 3 studies on argatroban, concluded that early anticoagulant therapies were not beneficial in patients with acute ischemic stroke.[6] However, patients from the 3 studies on argatroban accounted for only 1.3% (303 patients) of all patients included in the meta-analysis.[3–5] Thus, it is still uncertain whether argatroban is beneficial in patients with acute ischemic stroke.

A previous in vivo study suggested that argatroban was a neuroprotective agent and an anticoagulant.[7] In fact, argatroban directly inhibits thrombin, which damages neurovascular units during acute ischemia.[8] Thus, there is a possibility that argatroban could improve outcomes in patients with acute ischemic stroke.

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ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Effect of early rehabilitation on activities of daily living in patients with aspiration pneumonia

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Aim: To assess the effect of early rehabilitation on improving activities of daily living (ADL) in elderly patients with aspiration pneumonia.

Methods: Using the Japanese Diagnosis Procedure Combination inpatient database, we retrospectively analyzed consecutive patients with aspiration pneumonia at admission who received early rehabilitation (n = 48 201) or did not receive any rehabilitation (n = 64 357) from July 2010 to March 2013. Early rehabilitation was defined as any type of physical rehabilitation initiated within 7 days after admission. The proportions of improved ADL scores from admission to discharge were compared between the early rehabilitation group and the non-rehabilitation group using a multivariable logistic regression analysis and instrumental variable analysis.

Results: The proportion of improved ADL scores was higher in the early rehabilitation group than in the non-rehabilitation group (25.4% *vs* 33.9%; $P < 0.001$). The multivariable logistic regression analysis showed that the early rehabilitation group exhibited significant improvement in ADL (odds ratio 1.57; 95% confidence interval 1.50–1.64; $P < 0.001$). The instrumental variable analysis showed that early rehabilitation was associated with increased proportion of improved ADL (risk difference 8.2%; 95% confidence interval 6.9–9.5%; $P < 0.001$).

Conclusions: The present results suggest that early rehabilitation might improve ADL during hospitalization in patients with aspiration pneumonia. **Geriatr Gerontol Int ••; ••: ••–••.**

Keywords: activities of daily living, aspiration pneumonia, early rehabilitation, elderly patient, Japanese Diagnosis Procedure Combination inpatient database.

Introduction

Early rehabilitation is considered essential for acute diseases. Clinical guidelines have described the importance of early rehabilitation for various acute illnesses, including stroke[1] and cardiovascular diseases.[2] However, strict evidence for early rehabilitation in other diseases, including aspiration pneumonia (AP), has not yet been provided.

AP is a common and serious disease in elderly patients.[3] It can occur as a post-hospital syndrome,[4] and as a hospitalization-associated disability.[5] Early rehabilitation, including early mobilization, strength exercises and endurance training, can potentially prevent this hospitalization-associated disability in elderly people. A previous meta-analysis showed that inpatient rehabilitation specifically designed for geriatric patients had the potential to improve outcomes, including not only physical function, but also mortality.[6] Momosaki *et al.* described that early rehabilitation by physical therapists was associated with a reduction in 30-day in-hospital mortality in patients with severe AP.[7] However, it remains unclear whether early rehabilitation is effective for improving activities of daily living (ADL) in patients with AP.

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RESEARCH ARTICLE Open Access

Procedure-based severity index for inpatients: development and validation using administrative database

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Abstract

Background: Risk adjustment is important in studies using administrative databases. Although utilization of diagnostic and therapeutic procedures can represent patient severity, the usability of procedure records in risk adjustment is not well-documented. Therefore, we aimed to develop and validate a severity index calculable from procedure records.

Methods: Using the Japanese nationwide Diagnosis Procedure Combination database of acute-care hospitals, we identified patients discharged between 1 April 2012 and 31 March 2013 with an admission-precipitating diagnosis of acute myocardial infarction, congestive heart failure, acute cerebrovascular disease, gastrointestinal hemorrhage, pneumonia, or septicemia. Subjects were randomly assigned to the derivation cohort or the validation cohort. In the derivation cohort, we used multivariable logistic regression analysis to identify procedures performed on admission day which were significantly associated with in-hospital death, and a point corresponding to regression coefficient was assigned to each procedure. An index was then calculated in the validation cohort as sum of points for performed procedures, and performance of mortality-predicting model using the index and other patient characteristics was evaluated.

Results: Of the 539 385 hospitalizations included, 270 054 and 269 331 were assigned to the derivation and validation cohorts, respectively. Nineteen significant procedures were identified from the derivation cohort with points ranging from −3 to 23, producing a severity index with possible range of −13 to 69. In the validation cohort, c-statistic of mortality-predicting model was 0.767 (95 % confidence interval: 0.764–0.770). The ω-statistic representing contribution of the index relative to other variables was 1.09 (95 % confidence interval: 1.03–1.17).

Conclusions: Procedure-based severity index predicted mortality well, suggesting that procedure records in administrative database are useful for risk adjustment.

Keywords: Administrative data, Mortality, Risk adjustment, Severity

Background

Risk adjustment is an important component in clinical epidemiology and health services research using administrative databases, but its methods remain controversial. Administrative databases are widely used in studies because of their availability and large sample sizes, and risk-adjusted mortality is employed as one of the outcome measures. However, the validity of risk-adjustment models for administrative data has been questioned repeatedly [1–4]. It has been argued that administrative data lack important clinical information [5–8] and often do not make distinctions between conditions present on admission and complications occurring during hospitalization [6–10]. Inadequate risk adjustment can lead to misleading consequences such as confounding by indications and low rating of facilities that care for sicker patients. Thus, appropriate risk-adjustment models are desired.

Previous studies have shown that the performance of risk-adjustment models using administrative databases improves when detailed clinical information is added. In

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ORIGINAL ARTICLE

Comparison of in-hospital mortality in patients with COPD, asthma and asthma–COPD overlap exacerbations

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ABSTRACT

Background and objective: **Obstructive airway diseases, such as asthma and chronic obstructive pulmonary disease (COPD), have airflow limitation associated with chronic inflammation. Using a national inpatient database in Japan, we aimed to evaluate factors affecting in-hospital mortality in patients with asthma, COPD or asthma–COPD overlap (ACO).**

Methods: **We retrospectively collected data for inpatients (age >40 years) with exacerbation of COPD and/or asthma in 1073 hospitals across Japan between July 2010 and May 2013. We performed multivariable logistic regression analysis to examine the association of various factors with all-cause in-hospital mortality, including diagnosis of ACO, asthma alone and COPD alone.**

Results: **Of 30 405 eligible patients, in-hospital mortality in patients with ACO, asthma alone and COPD alone was 2.3%, 1.2% and 9.7%, respectively. COPD patients had a significantly higher mortality than ACO patients (odds ratio 1.96; 95% confidence interval: 1.38–2.79); patients with asthma alone showed lower mortality (0.70; 0.50–0.97). Higher mortality was also significantly associated with older age, male gender, lower body mass index, more severe dyspnoea, lower level of consciousness, worse activities of daily life and higher daily dose of corticosteroids.**

Conclusion: **Asthma alone was associated with lower mortality, but COPD alone was associated with higher mortality than ACO.**

Key words: asthma, asthma–chronic obstructive pulmonary disease overlap syndrome, chronic obstructive pulmonary disease, in-hospital mortality, obstructive airway disease.

Abbreviations: ACO, asthma–COPD overlap; COPD, chronic obstructive pulmonary disease

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SUMMARY AT A GLANCE

We evaluated all-cause in-hospital mortality in patients with asthma, COPD and asthma–COPD overlap (ACO), who were admitted for exacerbation. The in-hospital mortality in patients with ACO was lower than that in patients with COPD alone, but worse than that in patients with asthma alone.

INTRODUCTION

Obstructive airway diseases, such as asthma and chronic obstructive pulmonary disease (COPD), cause airflow limitation, which is associated with chronic airway inflammation and may lead to respiratory failure.[1–3] These two diseases have a distinct pathogenesis and clinical features, and each demands an individual treatment strategy.

Asthma is characterized by reversible airway obstruction and is associated with airway hyperresponsiveness and airway inflammation; the prognosis is generally favourable, and the response to corticosteroids is good.[1] Conversely, COPD is characterized by persistent airflow limitation, which is progressive and is associated with a chronic inflammatory response to noxious particles and parenchymal emphysema; COPD has a worse prognosis related to chronic respiratory failure, and generally the response to corticosteroids is poor.[2] These two different diseases have individual diagnostic criteria; however, in clinical practice, the diseases often coexist, and this coexistence can affect clinical course and lead to exacerbation, which is related to high mortality. Recently, therefore, there has been increased emphasis on the comorbid condition of asthma and COPD, which is termed asthma–COPD overlap (ACO) syndrome.[3]

Several studies have demonstrated that compared with patients with asthma alone or COPD alone, ACO patients have a lower health-related quality of life,

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RESEARCH ARTICLE Open Access

Comparison of clinical characteristics and outcomes between aspiration pneumonia and community-acquired pneumonia in patients with chronic obstructive pulmonary disease

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) patients often have dysphagia through age and several co-morbidities, leading to aspiration pneumonia (AsP). COPD patients also have increased risk of developing community-acquired pneumonia (CAP). Using a national inpatient database in Japan, we aimed to compare clinical characteristics and outcomes between AsP and CAP in COPD patients and to verify the factors that affect in-hospital morality.

Methods: We retrospectively collected data on COPD patients (age ≥40 years) who were admitted for AsP or CAP in 1,165 hospitals across Japan between July 2010 and May 2013. We performed multivariable logistic regression analyses to examine the association of various factors with all-cause in-hospital mortality for AsP and CAP.

Results: Of 87,330 eligible patients, AsP patients were more likely to be older, male and have poorer general condition and more severe pneumonia than those with CAP. In-hospital mortality in the AsP group was 22.7 % and 12.2 % in the CAP group. After adjustment for patient background, AsP patients had significantly higher mortality than CAP patients (adjusted odds ratio, 1.19; 95 % confidence interval, 1.08–1.32). Subgroup analyses showed higher mortality to be associated with male gender, underweight, dyspnea, physical disability, pneumonia severity, and several co-morbidities. Further, older age and worse level of consciousness were associated with higher mortality in the CAP group, whereas those were not associated in the AsP group.

Conclusions: Clinical characteristics differed significantly between AsP and CAP in COPD patients. AsP patients had significantly higher mortality than those with CAP.

Keywords: Aspiration pneumonia, Chronic obstructive pulmonary disease, Community-acquired pneumonia, Mechanical ventilation, Mortality

Background

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the world [1]. COPD is characterized by persistent airflow limitation associated with chronic airway inflammation [2]. Often, exacerbation of COPD occurs in the clinical course of the disease, accelerates the rate of decline in lung function [3], and is associated with significant mortality, particularly in patients requiring hospitalization [4]. The most common cause of exacerbation appears to be respiratory tract infection; it has been reported that exacerbation is caused by bacterial infection in approximately 50 % of cases [5]. Further, COPD is one of the most frequent co-morbid conditions associated with the development of community-acquired pneumonia (CAP) [6]; COPD is the most common underlying disease in patients with CAP who require hospitalization [7], and such patients

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The Japanese Society of Gastroenterology

No weekend effect on outcomes of severe acute pancreatitis in Japan: data from the diagnosis procedure combination database

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Abstract

Background In the early phase of severe acute pancreatitis, timely multidisciplinary management is required to reduce mortality. The aim of this observational study was to evaluate the impact of weekend hospital admission on outcomes using population-based data in Japan.

Methods Data on adult patients (≥20 years) with severe acute pancreatitis were extracted from a nationwide Japanese administrative database covering over 1000 hospitals. In-hospital mortality, length of stay, and total costs were compared between weekend and weekday admissions, with adjustment for disease severity according to the current Japanese severity scoring system for acute pancreatitis, and other potential risk factors.

Results In total, 8328 patients hospitalized during the study period 2010–2013 were analyzed (2242 admitted at weekends and 6086 on weekdays). In-hospital mortality rates were not significantly different: 5.9 vs. 5.4 % for weekend and weekday admissions, respectively (multivariate-adjusted odds ratio, 1.06; 95 % confidence interval, 0.83–1.35). The impact of weekend admission was not significant either for length of hospitalization (median, 18 vs. 19 days) and total costs (median, 6161 vs. 6233 US dollars) (both $p > 0.19$ in multivariate-adjusted linear regression). The rates of, and time to, specific treatments were also similar between patients with weekend and weekday admissions.

Conclusions A weekend effect in severe acute pancreatitis admissions was not evident. Adjustments to weekend staffing and selective hospital referral of patients admitted at weekends are not indicated for severe acute pancreatitis in current clinical practice in Japan.

Keywords Acute disease · Database · Mortality · Prognosis · Severity of illness index

Introduction

Evidence is accumulating to suggest that there is a 'weekend effect' in acute diseases: i.e., weekend admission is associated with poorer clinical outcomes, such as higher mortality, compared with weekday admission [1–8]. This epidemiological phenomenon was identified in a wide spectrum of emergency diseases, including upper gastrointestinal bleeding [6, 7], myocardial infarction [5], and pulmonary embolism [9]. Poorer outcomes associated with weekend admission have been attributed to reduced hospital staffing and less accessibility to specialist treatments at weekends. Identification of a weekend effect can potentially improve patient outcomes through referral of patients to select hospitals at weekends.

Acute pancreatitis is an acute-onset inflammatory disorder of the pancreas, which is frequently encountered in clinical practice and usually requires inpatient medical care. It encompasses a broad spectrum of severity and

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ORIGINAL ARTICLE

Early β-blocker use and in-hospital mortality in patients with Takotsubo cardiomyopathy

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ABSTRACT

Objective A catecholamine-mediated mechanism has been implicated in the pathogenesis of Takotsubo cardiomyopathy (TC). However, the impact of β-blockers in acute-phase management of TC remains uncertain. This study aimed to examine whether early β-blocker use in TC was associated with lower in-hospital mortality.

Methods This was a retrospective cohort study using the Diagnosis Procedure Combination nationwide inpatient database in Japan. Patients with TC aged ≥20 years who were admitted to acute-care hospitals between 2010 and 2014 were identified. Thirty-day in-hospital mortality was compared between patients who started β-blocker therapy on hospitalisation day 1 or 2 (early β-blocker group) and those who did not receive a β-blocker during hospitalisation (control group) using propensity score-matching and instrumental variable analyses.

Results Of 2672 eligible patients (female, 81.5%; 423 early β-blocker therapy, 2249 controls) from 615 hospitals, 1:4 propensity score-matching created a cohort of 2110 patients (422 early β-blocker therapy, 1688 controls). There was no significant difference in 30-day in-hospital mortality between the early β-blocker group and control group (2.4% vs 2.0%, p=0.703; risk difference, 0.4%; 95% CI, −1.2% to 2.0%). Logistic regression analysis did not show a significant association between early β-blocker use and 30-day in-hospital mortality (OR, 1.17; 95% CI 0.58 to 2.37). Instrumental variable analysis also found that early β-blocker use was not associated with lower 30-day in-hospital mortality (risk difference, 1.2%; 95% CI −3.1% to 5.5%).

Conclusions This study found no significant association between early β-blocker use and in-hospital mortality in patients with TC.

INTRODUCTION

Takotsubo cardiomyopathy (TC) is a cardiac syndrome with acute reversible ventricular dysfunction, generally triggered by extreme stress in the absence of culprit coronary artery disease.[1–5] Recent observational studies revealed that the in-hospital prognosis of TC was not as favourable as previously expected, with in-hospital mortality ranging from 2.5% to 8.4%.[6–11] However, if patients with TC overcome the acute critical phase, ventricular dysfunction generally recovers within days or weeks.[1–5] It is important to establish optimal therapy for the acute phase of TC. However, no evidence-based therapy has been established as yet because of the lack of rigorous studies. Thus, TC is generally managed with supportive therapy, despite its severity in the acute phase.[1 2 4 5 12]

β-Blockers are now established as one of the key drugs for patients with heart failure with reduced ejection fraction and for acute myocardial infarction (AMI) in current major guidelines.[13–15] β-Blockers are reported to be useful in preventing acute life-threatening complications in AMI.[16 17] The acute-phase complications of TC are similar to those of AMI.[7–10 18] Several pathophysiological mechanisms of TC have been proposed. A catecholamine-mediated mechanism remains controversial; some early studies supported a role of catecholamines, but subsequent studies did not confirm this mechanism.[19–22] A recent experimental study showed that β-blocker therapy was not effective but rather harmful in rats with induced TC.[23] Furthermore, most recently, a large-scale multinational study showed that the use of β-blockers at hospital discharge was not significantly associated with improved 1-year survival in patients with TC.[6] No study has shown that β-blocker use is effective in reducing mortality in patients with TC. The use of β-blockers in the acute phase of TC remains a matter of debate, because ventricular dysfunction in TC is transient and β-blockers may actually worsen haemodynamics through negative inotropic and chronotropic effects.[4]

The purpose of the present study was to examine whether β-blocker use in the acute phase of TC was associated with lower short-term mortality, using a large-scale national inpatient database.

METHODS

Study design and data source

This study was a retrospective cohort study using the Diagnosis Procedure Combination (DPC) nationwide inpatient database, which has been described in detail elsewhere.[7] The database includes the following information: unique hospital identifier; admission and discharge dates; patient age and sex; diagnosis for admission, comorbidities already present at admission and postadmission complications, described by the International Classification of Diseases, 10th Revision (ICD-10) codes and Japanese text; consciousness level at admission measured with the Japan Coma Scale[7]; drugs and devices during hospitalisation; surgical and non-surgical procedures; and discharge status (dead or alive). The database includes dates of application of drugs, devices and procedures used during hospitalisation. In the DPC database, all

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Risk Factors for Free Flap Failure in 2,846 Patients With Head and Neck Cancer: A National Database Study in Japan

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Purpose: The risk factors for an unfavorable outcome after microvascular free flap reconstruction in head and neck cancer are not fully understood. We sought to identify factors affecting the occurrence of free flap failure.

Materials and Methods: This was a retrospective cohort study using data from the national inpatient database in Japan between 2010 and 2012. We identified patients diagnosed with head and neck cancer who underwent tumor resection and consecutive free flap reconstruction. Cox proportional hazards regression was used to assess risk factors for free flap failure. The threshold for significance was $P < .05$. Missing data were imputed by using multiple imputation.

Results: We identified 2,846 eligible patients. The overall proportion of free flap failure was 3.3%. Free flap failure was associated with diabetes mellitus (hazard ratio [HR], 1.80; 95% confidence interval [95% CI], 1.18 to 2.76; $P = .007$), peripheral vascular disease (HR, 4.49; 95% CI, 1.61 to 12.52; $P = .004$), renal failure (HR, 3.67; 95% CI, 1.45 to 9.33; $P = .006$), preoperative radiotherapy (HR, 2.14; 95% CI, 1.11 to 4.13; $P = .022$), and duration of anesthesia greater than 18 hours (compared with <12 hours; HR, 2.72; 95% CI, 1.19 to 6.22; $P = .018$).

Conclusions: Diabetes mellitus, peripheral vascular disease, renal failure, preoperative radiotherapy, and a longer duration of anesthesia were significant predictors of the occurrence of free flap failure.

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Flap reconstruction allows swallowing and articulatory function to be maintained in patients undergoing resection of head and neck cancer and improves their postoperative physical appearance.[1] Microsurgical vascular anastomosis has been a highly specialized and complex surgical technique, but the success rate of flap reconstruction has been increased with improvement of surgical instruments, microscopes, and surgical techniques. However, free flap failure has still occurred in 1 to 10% of cases.[2]

Previous studies have reported that risk factors for free flap failure include female gender,[3] older age,[4,5] diabetes mellitus,[6-8] undernutrition,[9] cigarette smoking,[9] a higher Charlson Comorbidity Index,[10]

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Proton Pump Inhibitors versus Histamine-2 Receptor Antagonists and Risk of Pneumonia in Patients with Acute Stroke

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Background: Pneumonia is a serious complication of stroke. Several studies have indicated that certain gastric acid suppressants may be associated with an increased risk of pneumonia in hospitalized patients. However, the association between type of acid suppressant and pneumonia in acute stroke patients remains controversial. The purpose of this study was to clarify the association between the type of acid suppressant and the occurrence of pneumonia in acute stroke patients. *Methods:* This retrospective observational study used data from the national Japanese Diagnosis Procedure Combination inpatient database. We identified patients who were admitted to acute-care hospitals with stroke. The outcome was the occurrence of pneumonia assessed using diagnostic codes. We performed propensity score-matched analysis to compare the outcome between proton pump inhibitor (PPI) users and histamine-2 receptor antagonist (H2RA) users. *Results:* A total of 77,890 stroke patients were identified, of whom 63,980 were prescribed H2RAs and 13,910 were prescribed PPIs. Overall, 1490 (10.7%) of the patients receiving PPIs and 6401 (10.0%) of the patients receiving H2RAs developed pneumonia after stroke. After propensity score matching, the incidence of pneumonia in PPI users was not different from that in H2RA users (odds ratio: 1.10, 95% confidence interval: .99-1.21). *Conclusion:* No significant difference in the incidence of pneumonia was seen between users of PPIs and H2RAs after acute stroke. **Key Words:** Pneumonia—acute stroke—proton pump inhibitors—histamine-2 receptor antagonists.

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Very Early versus Delayed Rehabilitation for Acute Ischemic Stroke Patients with Intravenous Recombinant Tissue Plasminogen Activator: A Nationwide Retrospective Cohort Study

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Key Words
Early rehabilitation · Acute ischemic stroke · Tissue plasminogen activator · Cerebral hemorrhage

Abstract
Background: Although the safety and feasibility of very early rehabilitation for stroke are well recognized, the initiation of rehabilitation is sometimes delayed after thrombolysis. The purpose of this study was to clarify the association between very early rehabilitation and outcomes in acute ischemic stroke patients who received tissue plasminogen activator, using a national inpatient database in Japan. ***Methods:*** We identified patients who were admitted to acute-care hospitals with ischemic stroke and were treated with intravenous recombinant tissue plasminogen activator on the same day of stroke onset and received rehabilitation within 3 days from admission. The primary outcome was functional independence on discharge. We compared the outcomes of a very early rehabilitation group with a comparison group. ***Results:*** We identified 6,153 eligible patients, of whom 4,266 received very early rehabilitation. The proportion of functional independence on discharge was 41.2 and 36.6% in the very early rehabilitation group and the comparison group, respectively. Multivariable logistic regression analysis showed that the very early rehabilitation was significantly associated with a higher proportion of functional independence after adjustment for confounding factors. There was no significant difference in 7-, 30-, 90-day mortality or incidence of intracerebral hemorrhage between the groups after adjusting for baseline characteristics. Instrumental variable analysis confirmed a higher proportion of functionally independent patients in the very early rehabilitation group. ***Conclusion:*** Patients with acute ischemic stroke undergoing very early rehabilitation after thrombolysis were more likely to achieve functional independence without an increase in adverse outcomes.

Introduction

Thrombolysis with intravenous recombinant tissue plasminogen activator (rtPA) is one of the standard treatments for acute ischemic stroke [1]. However, rtPA has a potential for adverse events, such as cerebral hemorrhage after intervention. The incidence of symptomatic cerebral hemorrhage after rtPA treatment reported in clinical trials ranges from 2.4 to 11% [2–7], and from 1.8 to 4.8% in several large observational studies [8–10].

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Impact of Body Mass Index on the Outcomes of Open Reduction for Mandibular Fractures

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Purpose: Little is known about the impact of body mass index (BMI) on the postoperative outcomes of open reduction for mandibular fractures. The aim of this study was to investigate the relationship between BMI and short-term outcomes of surgery for mandibular fractures.

Materials and Methods: We searched the Japanese Diagnosis Procedure Combination database to identify patients who underwent open reduction for mandibular fractures from July 2010 to March 2013. BMI was divided into three groups: less than 18.5 kg/m^2 (underweight), 18.5 to 24.9 kg/m^2 (normal weight), and 25 kg/m^2 or greater (overweight). The outcomes included postoperative complication rates, duration of anesthesia, length of stay, and total costs. We analyzed the relationships between BMI and the outcomes by multivariable regression analyses.

Results: We analyzed 309 patients who underwent open reduction for mandibular fractures during the study period. The group with a BMI of 25 kg/m^2 or greater had a significantly longer hospital stay (3.8 days; 95% confidence interval, 0.5 to 7.1 days, $P = .03$) than the group with a normal BMI. BMI was not significantly associated with duration of anesthesia, postoperative complication rates, or total costs.

Conclusions: Regarding open reduction for mandibular fractures, overweight status may be associated with a prolonged length of stay, but may have little impact on operating time, postoperative morbidity, or overall costs.

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Oral and maxillofacial surgery for overweight patients is more difficult than that for normal-weight or underweight patients because of excessive soft tissue and restricted mouth opening. These conditions as well as poor general health of the patients can result in unfavorable postoperative outcomes.[1-3]

Previous studies on body mass index (BMI) and outcomes of oral and maxillofacial surgery were based on small sample sizes. Several studies reported that increasing BMI was correlated with a longer operative time in general surgery, whereas postoperative mortality and complication rates varied among different

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Medicine

OBSERVATIONAL STUDY

OPEN

Factors Associated With Mortality of Thyroid Storm

Analysis Using a National Inpatient Database in Japan

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Abstract: Thyroid storm is a life-threatening and emergent manifestation of thyrotoxicosis. However, predictive features associated with fatal outcomes in this crisis have not been clearly defined because of its rarity.

The objective of this study was to investigate the associations of patient characteristics, treatments, and comorbidities with in-hospital mortality.

We conducted a retrospective observational study of patients diagnosed with thyroid storm using a national inpatient database in Japan from April 1, 2011 to March 31, 2014.

Of approximately 21 million inpatients in the database, we identified 1324 patients diagnosed with thyroid storm. The mean (standard deviation) age was 47 (18) years, and 943 (71.3%) patients were female. The overall in-hospital mortality was 10.1%. The number of patients was highest in the summer season. The most common comorbidity at admission was cardiovascular diseases (46.6%). Multivariable logistic regression analyses showed that higher mortality was significantly associated with older age (≥60 years), central nervous system dysfunction at admission, nonuse of antithyroid drugs and β-blockade, and requirement for mechanical ventilation and therapeutic plasma exchange combined with hemodialysis.

The present study identified clinical features associated with mortality of thyroid storm using large-scale data. Physicians should pay special attention to older patients with thyrotoxicosis and coexisting central nervous system dysfunction. Future prospective studies are needed to clarify treatment options that could improve the survival outcomes of thyroid storm.

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Abbreviations: ATD = antithyroid drug, HD = hemodialysis, JCS = Japan Coma Scale, MMI = methimazole, PTU = propylthiouracil, TPE = therapeutic plasma exchange, TRAb = thyroid-stimulating hormone receptor antibody.

INTRODUCTION

Thyroid storm, an emergent manifestation of thyrotoxicosis, is a life-threatening metabolic crisis.[1] The occurrence of this disorder is rare; the estimated incidence of thyroid storm in Japan was reported to be 2.0 per million per year in a nationwide questionnaire survey from 2004 to 2008, conducted by the Japan Thyroid Association.[2]

Owing to its rarity, predictive features associated with enhanced survival or mortality of this disorder remain to be further elucidated. Currently, administration of antithyroid drugs (ATDs), including methimazole (MMI) and propylthiouracil (PTU), is regarded as a standard approach for treatment of thyroid storm induced by severe thyrotoxicosis.[3–5] Plasmapheresis can be used as a rescue treatment to remove thyroid hormones, catecholamines, and cytokines if conventional medical treatments such as ATDs, steroids, iodine, and β-blockade are ineffective or contraindicated.[6,7] However, any recommendations for the treatment of thyroid storm have merely been based on clinical experience and case series studies.[3–7]

The reported mortality rates of thyroid storm vary widely, being 10.7% (38 of 356 patients), 25.0% (7 of 28 patients), and 8.0% (2 of 25 patients).[2,8,9] The above-mentioned hospital-based questionnaire survey conducted by the Japan Thyroid Association suggested that shock, disseminated intravascular coagulation, and multiple organ failure were associated with mortality in patients with thyroid storm, but did not include microdata of individual patients.[2] Therefore, which factors are associated with mortality of thyroid storm remains incompletely defined.

The objectives of the present study were: to describe the patient characteristics and current clinical practices for treating thyroid storm, including ATD therapy and supportive measures; and to examine the factors associated with in-hospital mortality of thyroid storm, using a national inpatient database in Japan.

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YO and HY are the guarantors of this work and had full access to all of the data in the study, and take responsibility for the integrity of the data and accuracy of the data analysis.
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Risks and Benefits of Stress Ulcer Prophylaxis for Patients With Severe Sepsis

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Objectives: The Surviving Sepsis Campaign Guidelines recommend stress ulcer prophylaxis for patients with severe sepsis who have bleeding risks. Although sepsis has been considered as a risk factor for gastrointestinal bleeding, the effect of stress ulcer prophylaxis has not been studied in patients with severe sepsis. Furthermore, stress ulcer prophylaxis may be associated with an increased risk of hospital-acquired pneumonia or *Clostridium difficile* infection. The aim of this study was to investigate the risks and benefits of stress ulcer prophylaxis for patients with severe sepsis.

Design: Retrospective cohort study.

Setting: Five hundred twenty-six acute care hospitals in Japan.

Patients: A total of 70,862 patients with severe sepsis.

Interventions: None.

Measurements and Main Results: One-to-one propensity score matching created 15,651 pairs of patients who received stress ulcer prophylaxis within 2 days of admission and those who did not. Patient characteristics were well balanced between the two groups. No significant differences were seen between the stress ulcer prophylaxis group and the control group with regard to gastrointestinal bleeding requiring endoscopic hemostasis (0.6% vs 0.5%; $p = 0.208$), 30-day mortality (16.4% vs 16.9%; $p = 0.249$), and *Clostridium difficile* infection (1.4% vs 1.3%; $p = 0.588$). The stress ulcer prophylaxis group had a significantly higher proportion of hospital-acquired pneumonia (3.9% vs 3.3%; $p = 0.012$) compared with the control group.

Conclusions: Since the rate of gastrointestinal bleeding requiring endoscopic hemostasis is not different comparing patients with and without stress ulcer prophylaxis, and the increase in hospital-acquired pneumonia is significant, routine stress ulcer prophylaxis for patients with severe sepsis may be unnecessary. (*Crit Care Med* 2016; XX:00–00)

Key Words: *Clostridium difficile* infection; gastrointestinal bleeding; hospital-acquired pneumonia; severe sepsis; stress ulcer prophylaxis

The prevalence of severe sepsis is increasing (1–4) and becoming a major healthcare problem. The mortality associated with severe sepsis has been reported as high as 30% (5–7). Gastrointestinal bleeding is one of the most serious complications in patients with severe sepsis. The reported incidence varies widely from 1.1% to 9.2% (8, 9), because of different definitions used in the studies. Furthermore, clinically significant gastrointestinal bleeding has been reported to be associated with a 1–4 times increased risk of death in critically ill patients (10).

The Surviving Sepsis Campaign Guidelines (11) were introduced in 2004 and have been revised periodically. In the latest version (12), stress ulcer prophylaxis is recommended for patients with a risk of bleeding. Although sepsis itself has been considered as a risk factor for gastrointestinal bleeding (13, 14), few studies have investigated the effects of stress ulcer prophylaxis specifically in patients with severe sepsis and the recommendation is based on evidence from the general population in an ICU (15, 16). Furthermore, stress ulcer prophylaxis may be associated with an increased risk of ventilator-associated pneumonia (17) or *Clostridium difficile* (*C. difficile*) infection (18).

The aim of this study was to investigate the risks and benefits of stress ulcer prophylaxis in patients with severe sepsis, using a national inpatient database in Japan.

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This study was performed at the University of Tokyo, Tokyo, Japan.

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ORIGINAL ARTICLE

Pharyngocutaneous fistula and delay in free oral feeding after pharyngolaryngectomy for hypopharyngeal cancer

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ABSTRACT: *Background.* Risk factors for pharyngocutaneous fistula and associated delay in free oral feeding after pharyngolaryngectomy for patients with hypopharyngeal cancer remain uncertain.

Methods. We used a Japanese national inpatient database to perform a retrospective cohort study between 2007 and 2013. We performed multivariable logistic regression analysis to identify patient characteristics associated with pharyngocutaneous fistula formation, and Cox regression analysis to evaluate factors affecting the interval from pharyngolaryngectomy to free oral feeding.

Results. Among 549 eligible patients, 33 had developed pharyngocutaneous fistula, 19 of whom required surgical closure. Preoperative radiotherapy significantly increased risk of pharyngocutaneous fistula (odds ratio [OR] = 3.17; 95% confidence interval [CI] = 1.10–9.12; $p = .033$). Pharyngocutaneous fistula significantly prolonged the interval to oral feeding (median days, 67 vs 20 in those with and without pharyngocutaneous fistula, respectively; hazard ratio [HR], = 0.26; 95% CI = 0.15–0.44; $p < .001$).

Conclusion. Preoperative radiotherapy was associated with increased occurrence of pharyngocutaneous fistula and subsequent delay in free oral feeding. © 2015 Wiley Periodicals, Inc. *Head Neck* **38:** E625–E630, 2016

KEY WORDS: hypopharyngeal cancer, pharyngolaryngectomy, pharyngocutaneous fistula, free oral feeding

INTRODUCTION

Hypopharyngeal cancer accounts for approximately 20% of newly diagnosed head and neck cancer in Japan.[1] Although early-stage hypopharyngeal cancer is potentially curable, this disease is usually diagnosed at a locally advanced stage. Despite advances in organ preservation strategies involving chemotherapy and radiotherapy, pharyngolaryngectomy remains an important primary treatment option for stage III and IV resectable hypopharyngeal cancer.

One of the important determinants of quality of life after pharyngolaryngectomy is swallowing function. Pharyngocutaneous fistula formation, which although rarely fatal[2] is nonetheless the most annoying postsurgical complication,[3–5] inevitably delays initiation of free oral feeding. Patients with pharyngocutaneous fistula suffer not only from the presence of the fistula itself, but also from the psychological and traumatic effects of tube feeding.

Numerous studies have reported the risk of fistula formation after total laryngectomy[6,7] and the appropriate timing for recommencing oral feeding after total laryngectomy.[8] However, only a few studies have addressed the risk of pharyngocutaneous fistula formation after pharyngolaryngectomy.[9–11] Further, to our knowledge, there is a lack of data on the interval from pharyngolaryngectomy to free oral feeding in patients with hypopharyngeal cancer and little is known about factors affecting this interval.

The purposes of our retrospective observational study were twofold. First, we used a national inpatient database in Japan to investigate the factors that contribute to the development of pharyngocutaneous fistula after pharyngolaryngectomy. Second, we assessed the interval from pharyngolaryngectomy to the start of free oral feeding.

MATERIALS AND METHODS

Data source

Data from the Diagnosis Procedure Combination database, which is a national inpatient database in Japan that includes administrative claims data and discharge abstract data,[12] were analyzed for each patient. This database contains: (1) main diagnoses, comorbidities at admission, and complications after admission, with the corresponding International Statistical Classification of Diseases-10 codes; (2) surgical interventions, with the original Japanese codes; (3) age, sex, and patient characteristics (weight, height, Brinkman Index); (4) TNM classification

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Medicine

OBSERVATIONAL STUDY

OPEN

Factors Associated With Neck Hematoma After Thyroidectomy

A Retrospective Analysis Using a Japanese Inpatient Database

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Abstract: To identify risk factors for post-thyroidectomy hematoma requiring airway intervention or surgery ("wound hematoma") and determine post-thyroidectomy time to intervention.

Post-thyroidectomy hematoma is rare but potentially lethal. Information on wound hematoma in a nationwide clinical setting is scarce.

Using the Japanese Diagnosis Procedure Combination database, we extracted data from records of patients undergoing thyroidectomy from July 2010 to March 2014. Patients with clinical stage IV cancer or those with bilateral neck dissection were excluded because they could have undergone planned tracheotomy on the day of thyroidectomy. We assessed the association between background characteristics and wound hematoma ≤2 days post-thyroidectomy, using multivariable logistic regression analysis.

Among 51,968 patients from 880 hospitals, wound hematoma occurred in 920 (1.8%) ≤2 days post-thyroidectomy and in 203 (0.4%) ≥3 days post-thyroidectomy (in-hospital mortality = 0.05%). Factors significantly associated with wound hematoma ≤2 days post-thyroidectomy were male sex (odds ratio [OR] 1.52, 95% confidence interval [CI] 1.30–1.77); higher age (OR 1.01, 95% CI 1.00–1.02); overweight or obese (OR 1.22, 95% CI 1.04–1.44); type of surgery (partial thyroidectomy for benign tumor compared with: total thyroidectomy, benign tumor [OR 1.95, 95% CI 1.45–2.63]; partial thyroidectomy, malignant tumor [OR 1.21, 95% CI 1.00–1.46]; total thyroidectomy, malignant tumor [OR 2.49, 95% CI 1.82–3.49]; and thyroidectomy for Graves disease [OR 3.88, 95% CI 2.59–5.82]); neck dissection (OR, 1.53, 95% CI 1.05–2.23); antithrombotic agents (OR 1.58, 95% CI 1.15–2.17); and blood transfusion (OR 5.33, 95% CI 2.39–11.91).

Closer monitoring of airway and neck is recommended for patients with risk factors, and further cautious monitoring beyond 3 days post-thyroidectomy.

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Abbreviations: BMI = body mass index, CI = confidence interval, DPC = diagnosis Procedure Combination, HV = hospital volume, ICD = International Classification of Diseases, OR = odds ratio.

INTRODUCTION

Thyroidectomy is generally safe and commonly performed for benign or malignant tumors and Graves disease and in the United States, short-stay thyroidectomy on an outpatient basis is increasingly common.[1–3] A potentially devastating early complication after thyroidectomy is the formation of a neck hematoma resulting in airway obstruction. Acute airway distress such as this deserves special attention because it is unpredictable and potentially lethal unless promptly evaluated and relieved emergently with surgical procedures. However, concern remains regarding the time interval from initial thyroidectomy to the onset of hematoma in light of the safety of short-stay thyroidectomy.

According to recent studies with large sample sizes (n ≥ 1000), the incidence of postsurgical neck hematoma ranges from 0.30% (42/13,817)[4] to 1.7% (519/30,142).[5] Also, several reports indicate that hematoma formation can occur more than 24 h after initial thyroidectomy: 10% (7/70) (n = 6830)[6]; 17% (1/6) (n = 837)[7]; 17% (36/207)[8]; 19% (8/42) (n = 13,817)[4]; and 28.5% (2/7) (n = 504).[9]

A recent study using the US Nationwide Inpatient Sample revealed that male sex, inflammatory thyroid conditions, partial thyroidectomy, chronic renal disease, and bleeding disorders were predictors of hematoma formation after inpatient thyroidectomy.[1] However, the results were limited because the database included only inpatient data and lacked information on airway intervention or readmission for hematoma after discharge following short hospital stay.

The present study used a Japanese national inpatient database to investigate adverse events after thyroidectomy. Unlike the United States, most patients undergoing thyroidectomy remain in hospital for several days after surgery in Japan, which enabled us to conduct a relatively long-term observational study of patients after thyroidectomy.

METHODS

The study protocol was approved by the institutional review board of the University of Tokyo. Because the data were anonymous, the requirement for informed consent was waived.

Data Source

The Diagnosis Procedure Combination (DPC) database, a Japanese nationwide inpatient database, contains administrative