## Perioperative & Critical Care: Short Report

# Optimum Timing of Tracheostomy After Cardiac Operation: Descriptive Claims Database Study

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## ABSTRACT

**BACKGROUND** Suitable tracheostomy timing after cardiac operation remains controversial; hence, this study compared the effectiveness of early and late tracheostomy after cardiac operation.

**METHODS** By using the nationwide administrative claims database in Japan, patients who underwent cardiac operation between April 2010 and March 2020 were identified and included in this study. In-hospital mortality, incidence of deep sternal wound infection, and ventilator-free days were analyzed and compared by dividing patients into 2 groups: an early group (patients who underwent tracheostomy 1-14 days postoperatively) and a late group (patients who underwent tracheostomy 15-30 days postoperatively). Baseline characteristics were adjusted by propensity score weighting.

**RESULTS** Of 1240 patients who underwent cardiac operation and postoperative tracheostomy, 784 were included in the main analysis cohort. As the number of days between the operation and tracheostomy increased, in-hospital mortality increased, whereas ventilator-free days decreased. The early and late groups comprised 284 and 326 patients, respectively. After adjustment of baseline characteristics, the in-hospital mortality (odds ratio, 0.65; 95% Cl, 0.46–0.91; P = .01) was lower in the early group than in the late group, the incidence of deep sternal wound infection (odds ratio, 0.59; 95% Cl, 0.23–1.52; P = .27) was not significantly different between the 2 groups, and the early group had more ventilator-free days compared with the late group (mean difference, 5.1; 95% Cl, 3.6–6.5; P < .001).

**CONCLUSIONS** Early tracheostomy may be considered in patients expected to require prolonged ventilation.

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The number of cardiovascular operations performed is increasing annually, and surgical indications are expanding to include older patients and patients with complex comorbidities.<sup>1,2</sup> However, these patients are more likely to experience postoperative respiratory failure and occasionally require prolonged ventilation.

Various studies have been conducted to determine the appropriate time for performing tracheostomy for patients with respiratory failure, including

# **IN SHORT**

- This report describes tracheostomy status after cardiac operation and examines the appropriate timing of tracheostomy by using a Japanese nationwide database.
- There was no difference in in-hospital mortality and deep sternal wound infection incidence by the timing of tracheostomy, but patients who underwent tracheostomy earlier had more ventilator-free days.

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those patients who have undergone cardiovascular operation.<sup>1,3-7</sup> Many studies have shown benefits such as reducing the total dose of sedative agents; however, no improvements in mortality have been reported.

A special aspect of post-cardiovascular operation status is that tracheostomy increases the risk of developing deep sternal wound infection (DSWI).<sup>8</sup> However, several studies have shown that early postoperative tracheostomy does not increase the risk of DSWI compared with late tracheostomy.<sup>3-5</sup>

In this study, we aimed to describe tracheostomy status after cardiac operation and examine the appropriate timing of tracheostomy by using a Japanese nationwide database.

### PATIENTS AND METHODS

DATA SOURCE. The Japanese administrative claims database provided by Medical Data Vision Co, Ltd (Tokyo, Japan) was used in this study. The data cover more than 31 million patients treated at 400 hospitals up to the end of March 2020.<sup>9</sup> The data contain anonymous information from the Diagnosis Procedure Combination (DPC) database. The DPC is a payment system administered by the Ministry of Health, Labour, and Welfare of Japan. DPC data contain details on patient demographics and medical procedures, including surgical information, prescriptions, and diagnoses. The study protocol was approved by the Institutional Review Board of Kyoto University, Kyoto, Japan, on July 9, 2020, and the requirement for individual informed consent from participants was waived because of the anonymous and retrospective nature of the data (approval number: R2548).

STUDY POPULATION AND OUTCOMES. This study included patients aged  $\geq$ 20 years who underwent cardiac operation between April 1, 2010, and March 1, 2020. Endoscopic procedures were excluded (Supplemental Table 1). We excluded patients who required ventilation for >91 days. These patients likely had difficulty weaning from the ventilator, and the significance of assessing ventilatory duration was considered low. Data on the number of surgical procedures per fiscal year, mortality rate, DSWI rate, and ventilatorper day from operation to free days tracheostomy were extracted. The 2 groups were then compared, by defining the early group (patients who underwent tracheostomy 1-14 days postoperatively) and the late group (patients who underwent tracheostomy 15-30 days postoperatively). The primary outcome was inhospital mortality, and the secondary outcomes were the incidence of DSWI and ventilator-free days, the latter defined as the number of days alive and free from mechanical ventilation for at least 48 consecutive hours.

**COVARIATES**. The following patient variables were examined: patient characteristics, hospital volume, emergency operation, surgical category (coronary artery bypass grafting, valve operation, aortic operation, and others), comorbidities, mechanical circulatory support devices, and preoperative glucocorticoid medication (Supplemental Table 1).

**STATISTICAL ANALYSIS.** The early and late groups were compared using the  $\chi^2$  test. After excluding patients with missing values, the propensity score (PS) was calculated as the predicted probability that a patient would be assigned to the early group. PSs were estimated using the foregoing variables in a logistic regression model. To adjust the background of the early and late groups, stabilized inverse probability of treatment weighting (IPTW) analyses were performed using PSs.<sup>10</sup> Standardized differences were used to assess the balance of covariates before and after stabilized IPTW, and a standardized difference  $\leq 0.1$  was considered acceptable.

Logistic regression models were used to estimate the adjusted odds ratio (OR) with a 95% CI for comparing in-hospital mortality and incidence of DSWI between the 2 groups. The ventilator-free days of the 2 groups were assessed using the mean differences presented with 95% CIs.

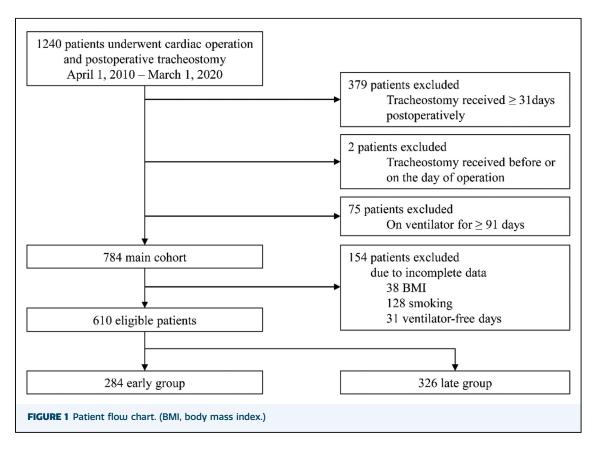
We performed post hoc subgroup analyses (separated at 75 years of age and type of operation) and several sensitivity analyses.

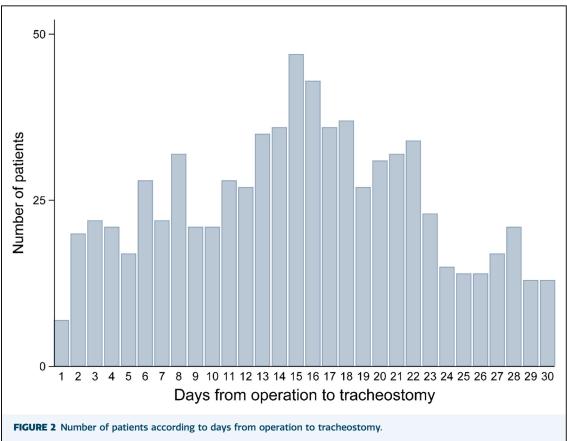
Analyses were conducted using Stata IC software version 16 (StataCorp). Statistical significance was defined as a 2-sided P < .05.

# RESULTS

Of the 1240 patients who underwent cardiovascular operation and postoperative tracheostomy during the study period, 784 patients were included in the main analysis cohort (Figure 1). The baseline characteristics of the main cohort are presented in Supplemental Table 1.

The number of patients increased each fiscal year (Supplemental Figure 1), with the number of individuals undergoing tracheostomy gradually increasing from the day after operation, peaking at day 15, and then decreasing (Figure 2). An increase in in-hospital mortality was observed each day. In contrast, ventilator-free days decreased





over time (Figure 3). Missing values were found in 31 patients with ventilator-free days (4.0 %).

After excluding patients with missing values, the early and late groups comprised 284 and 326 patients, respectively. In the unadjusted analysis, the in-hospital mortality (OR, 0.63; 95% CI, 0.45-0.88; P = .007) was lower in the early group than in the late group, the incidence of DSWI (OR, 0.61; 95% CI, 0.24-1.55; P = .30) was not significantly different between the groups, and the early group had more ventilator-free days compared with the late group (mean difference, 5.6; 95% CI, 4.2-7.1; P < .001) (Supplemental Table 2). After stabilized IPTW, the baseline characteristics were well balanced between the 2 groups (Supplemental Table 1). The PS distribution is presented in Supplemental Figure 2. With similar results after adjustment by stabilized IPTW, the in-hospital mortality (OR, 0.65; 95% CI, 0.46-0.91; P = .01) was lower in the early group than in the late group, the incidence of DSWI (OR, 0.59; 95% CI, 0.23-1.52; P = .27) was not significantly different between the 2 groups, and the early group had more ventilator-free days compared with the late group (mean difference, 5.1; 95% CI, 3.6-6.5; *P* < .001) (Table).

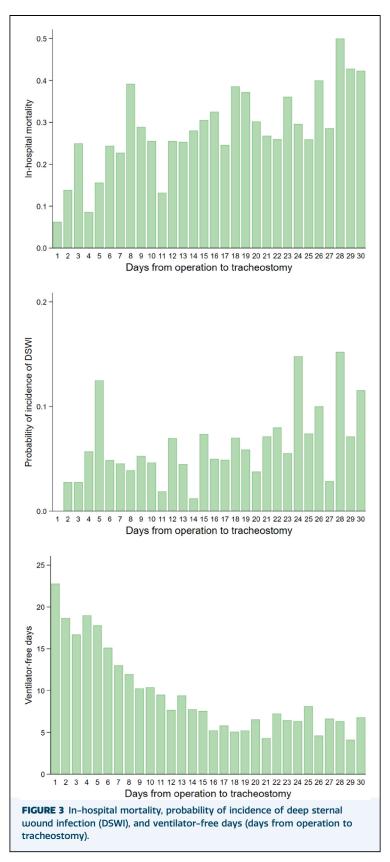
The subgroup and sensitivity analysis results are presented in Supplemental Tables 3 to 10 and Supplemental Figures 3 to 5.

## COMMENT

As the number of days from the date of cardiovascular operation to the date of tracheostomy increased, in-hospital mortality increased, and the number of ventilator-free days decreased. Tracheostomy performed  $\leq 14$  days postoperatively was not inferior to tracheostomy performed  $\geq 15$  days postoperatively for all of these outcomes.

Two studies have examined the time at which tracheostomy was performed after cardiac operation by using the National Inpatient Sample database in the United States.<sup>3,4</sup> These studies concluded that the early group was not inferior to the late group regarding DSWI incidence and mortality. The results of our study were similar to those of the 2 previous studies. In addition, this study also examined the number of ventilator-free days, which was found to be greater in the early group.

In addition, several randomized controlled trials have been conducted to determine the time for



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Variables	Early Group n = 283	Late Group n = 327	Odds Ratio	Mean Difference	95% CI	<i>P</i> Value
In-hospital mortality, n (%)	87 (30.3)	133 (40.7)	0.65		0.46-0.91	.01
DSWI, n (%)	7 (2.5)	13 (4.0)	0.59		0.23-1.52	.27
Ventilator-free days, d (SD)	11.2 (10.3)	6.2 (8.3)		5.1	3.6-6.5	<.001

performing tracheostomies in intensive care unit patients.<sup>5-7</sup> In each study, early and late groups were not assigned or were different from the rate observed in the current study's population. The results of these studies suggest that even trained clinicians have difficulty determining the indication for tracheostomy. In addition, using protocols that determine the need for tracheostomy at an early stage have resulted in tracheostomy performed in patients who do not need it. Therefore, the results of observational studies should also be considered in determining the appropriate timing of tracheostomy.

Additionally, the number of patients who underwent tracheostomy after cardiac operation peaked at day 15 postoperatively, a finding suggesting that tracheostomy was avoided before 14 postoperative days. This result is similar to those of previous studies conducted using the US database.<sup>3,4</sup> Several possible reasons can be attributed to this finding; for instance, the risk of developing DSWI may be higher, patients may have been more unstable as a result of the early stage, there was an expectation that respiratory status would improve and extubation would be possible, or patients' general condition was deemed too poor to tolerate tracheostomy. Therefore, stabilized IPTW was used to adjust for patient severity in the early and late groups for comparison.

In the current study, the early group had more ventilator-free days in all the analyses except for the analysis with the other operation subgroup. For the other operations, the number of ventilator-free days may not have differed between the early and late groups because of the small number of patients. Our study examined ventilator-free days in patients from a large database.

This study had some limitations. First, because this was a retrospective cohort study, there may be some bias in terms of patient selection regarding disease severity. Second, the indication for tracheostomy for each patient was unknown. In addition, the early group may have included some patients who were extubated without a tracheostomy, thus resulting in more ventilator-free days in the early group. Third, Japanese data were used in this study. Therefore, it is unclear whether the results of this study can be extrapolated to non-Japanese populations. Fourth, there is a possibility of immortal time bias in this study. However, the late group had 14 days of immortal time, which may have favored the late group. In addition, to address immortal time bias, patients who died  $\leq$ 14 days in the early group were excluded from the analysis, and the results were not different from those of the main analysis.

In conclusion, a tracheostomy performed  $\leq$ 14 days of cardiac operation was not inferior to a tracheostomy performed between 15 and 30 days after cardiac operation in terms of hospital mortality, the incidence of DSWI, or ventilator-free days Early tracheostomy may be considered in patients who are expected to require prolonged ventilation. However, there is a risk of unnecessary tracheostomies; therefore, careful decisions should be made at an early stage.

The Supplemental Tables and Supplemental Figures can be viewed in the online version of this article [https://doi.org/10.1016/j.atssr.2024.04.029] on http://www.annalsthoracicsurgery.org.

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#### DISCLOSURES

Koji Kawakami reports a relationship with LEBER, Inc, JMDC, Inc, Shin Nippon Biomedical Laboratories, Ltd, and Advanced Medical Care, Inc, that includes: consulting or advisory: with Cancer Intelligence Care Systems, Inc, that includes: board membership; and with Pharma Business Academy and Toppan, Inc, that includes: speaker and lecture fees. All other authors declare that they have no conflicts of interest to disclose.

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