



Safety and efficacy of noninvasive ventilation for acute respiratory failure in general medical ward: a prospective cohort study

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Background: Noninvasive ventilation (NIV) is recommended for use in patients with acute respiratory failure of various etiologies. However, we do not know whether the use of NIV in general medical wards is safe and effective. This study aimed to evaluate the safety and efficacy of using NIV and factors associated with NIV failure in general medical wards.

Methods: A prospective cohort study was conducted in general medical wards of the University Hospital. Adult patients with acute respiratory failure treated with NIV were enrolled. The subjects were managed by a multidisciplinary care team that was well trained in the NIV device. The primary outcome was the rate of NIV failure at 48 hours. Secondary outcomes included hospital mortality and factors associated with NIV failure.

Results: A total of 86 patients were enrolled. The mean age was 70±17 years old. The Acute Physiology and Chronic Health Evaluation (APACHE) III and the Sequential Organ Failure Assessment (SOFA) scores were 56±17 and 4±3, respectively. The most common indication of NIV use was cardiogenic pulmonary edema (34.9%). The rate of NIV failure at 48 hours and hospital mortality were 20.9% and 12.8%, respectively. The SOFA score was associated with failure of NIV at 48 hours [odds ratio (OR) 1.48, 95% confidence interval (CI): 1.16–1.89; P=0.002].

Conclusions: NIV was safe and effective on general medical wards. Cardiogenic pulmonary edema was the most common indication for the application of NIV. The SOFA score was associated with the failure of NIV at 48 hours.

Keywords: Acute respiratory failure; general medical ward; noninvasive ventilation (NIV); outcomes; safety

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Introduction

Noninvasive ventilation (NIV) is widely used as first-line respiratory support in patients with acute respiratory failure of various etiologies. In a selected population, NIV

can reduce the need for endotracheal intubation, hospital length of stay, and mortality (1). Large epidemiological studies demonstrated a significant increase in NIV use in the intensive care unit (ICU) from 5% in the 1998 cohort

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to 14% in the 2010 cohort (2,3). The overall intubation rate in these studies was approximately 30–35% and there was a trend towards a decrease in ICU mortality from 30% in the 1998 cohort to 24% in the 2004 cohort (4).

The recent clinical practice guideline of the European Respiratory Society and the American Thoracic Society recommends the use of NIV in several conditions, such as patients with hypercapnia from exacerbation of chronic obstructive pulmonary disease (COPD), cardiogenic pulmonary edema, immunocompromised patients, and prophylaxis for post-extubation respiratory failure (5). However, the application of NIV in patients with acute *de novo* hypoxemic respiratory failure, for example, pneumonia and acute respiratory distress syndrome (ARDS), should be carefully considered because of the lack of evidence to demonstrate the benefit of NIV in terms of improving clinical outcomes in such conditions. Additionally, delay in endotracheal intubation in patients with NIV failure can worsen outcomes (6,7).

The application of NIV requires close monitoring and experienced staff who are well trained and familiar with the use of NIV devices. Many published clinical studies on NIV were performed in the ICU. However, NIV is now also employed outside the ICU, such as in the emergency department and general wards. In our hospital, many patients with acute respiratory failure have been managed with NIV in the general medical wards due to a shortage of ICU beds during their admission. The

objective of this study was to describe the indication for the use of NIV, clinical outcomes, and safety of patients with acute respiratory failure treated with NIV in the general medical wards of Siriraj Hospital and to identify the factors associated with NIV failure. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-732/rc>).

Methods

Study designs and participants

A prospective cohort study was conducted from October 2017 to March 2018 in the general medical wards of the Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Adult patients (>18 years old) who were admitted to one of eight general medical wards and who had received NIV for at least 24 hours were enrolled in the study. Patients with “do-not-intubate” orders or obstructive sleep apnea were excluded. Due to the limitations of the ICU beds in our hospital, patients with acute respiratory failure and patients after extubation who have stable hemodynamics, a normal level of consciousness, and no need for organ support are considered for admission to the general medical wards. The indication and settings of NIV are considered by the attending physician. Each ward has a capacity of 20 beds located in one large room, where nurses can observe all patients from the nursing station, with a nurse-to-patient ratio of 1:4 during the day shift and 1:6 during the night shift. Patients are taken care of and continuously monitored their clinical status, vital signs, oxygen saturation, and arterial blood gas if necessary by a multidisciplinary team, including one attending staff, a third-year resident, and two first-year residents in the Department of Medicine, and nurses trained in and familiar with the NIV device. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Siriraj Institutional Review Board (certificate of approval No. Si 563/2017) and informed consent was taken from all the subjects or their relatives.

Data collection

Baseline characteristics and clinical data, including age, gender, comorbidity, Acute Physiology and Chronic Health Evaluation (APACHE) III and Sequential Organ Failure

Highlight box

Key findings

- Cardiogenic pulmonary edema is the most common indication for noninvasive ventilation (NIV). The rate of NIV failure at 48 hours and hospital mortality were 20.9% and 12.8%. The Sequential Organ Failure Assessment (SOFA) score was associated with failure of NIV.

What is known and what is new?

- The application of NIV requires close monitoring. It is mostly used in the intensive care unit (ICU); however, NIV is now also employed outside the ICU. In our hospital, many patients with acute respiratory failure have been managed with NIV in the general medical wards due to a shortage of ICU beds during their admission.
- Application of NIV in general medical wards is effective and safe with well trained staff and familiar with the use of NIV devices.

What is the implication, and what should change now?

- This study supports the use of noninvasive ventilation outside the intensive care unit safe and effective. The SOFA score is associated with failure of noninvasive ventilation.

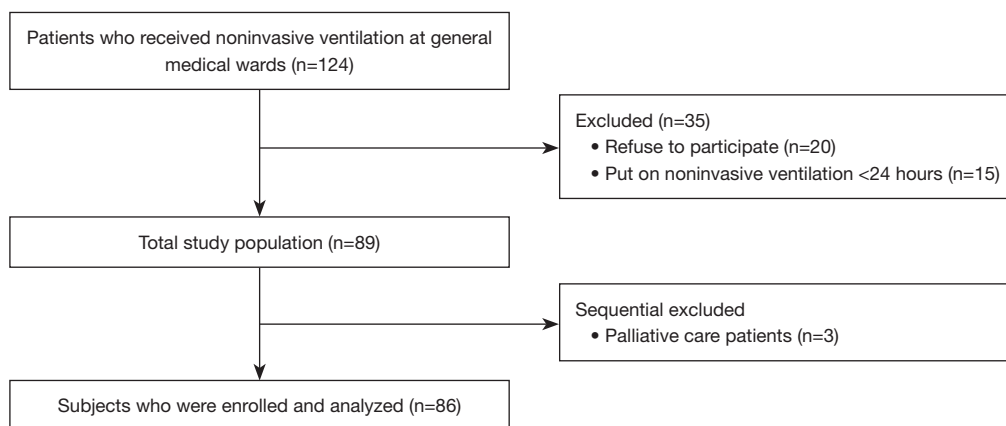


Figure 1 Patient population flow diagram.

Assessment (SOFA) scores (using the worst variable within 24 hours before enrollment), cause of acute respiratory failure, and indication for NIV use, were collected and recorded. Other data collected included the type of NIV (dedicated NIV or ICU ventilator) and NIV interface, the duration of NIV use, the daily recorded vital signs, oxygen saturation by pulse oximetry (SpO_2), and the setting of the NIV device at 9:00 a.m. during the first 3 days of NIV use.

Outcomes

The primary outcome was the rate of failure of NIV at 48 hours, which was defined as a subsequent requirement for endotracheal intubation, reintubation, or death within 48 hours of NIV use. Secondary outcomes were cause of NIV failure and in-hospital mortality. We performed subgroup analysis to evaluate the outcomes of patients with success and failure of NIV, and the outcomes in each indication for NIV use. We also analyzed the factors associated with NIV failure.

Statistical analysis

Normally distributed variables are expressed as mean \pm standard deviation, and were analyzed by an independent *t*-test. Nonnormally distributed variables are expressed as median (interquartile range) and were analyzed using the Mann-Whitney *U* test. The normality of the data distribution was tested using the Kolmogorov-Smirnov test. Categorical variables are presented as frequency and percentage, and were analyzed using the chi-square test. Univariate and multivariate backward stepwise logistic regression analyses were used to identify factors significantly

associated with NIV failure. Factors associated with NIV failure in the univariate analysis ($P < 0.10$) were put into the multivariate regression analysis, and these results are shown as odds ratio (OR) and 95% confidence interval (CI). Data were analyzed using PASW Statistics version 18 (SPSS, Inc., Chicago, IL, USA). A level of $P < 0.05$ was considered statistically significant.

Results

A total of 86 subjects were enrolled in the study (Figure 1). The mean age of the subjects was 70 ± 17 years and 47.7% of them were male. The mean APACHE III score and SOFA scores were 56 ± 17 and 4 ± 3 , respectively. The other baseline characteristics are presented in Table 1.

Characteristics of NIV use

According to the indication for NIV use, 34.9% of the subjects had cardiogenic pulmonary edema followed by prevention of post-extubation respiratory failure (25.6%), pneumonia (16.3%), exacerbation of COPD (14.0%), neuromuscular disease (7.0%), and extrapulmonary sepsis (2.3%) (Table 2). The dedicated NIV was used in 72.1% of the subjects and the oronasal mask was used in all subjects who received NIV (Table 2).

On day 1, pressure support ventilation was the most frequently used mode (52.3%), followed by pressure assist-control mode (27.9%), and pressure control ventilation (18.6%). Average volume-assured pressure support was used only in one subject (1.2%). The average pressure support level and the positive end-expiratory pressure were 13 ± 4

Table 1 Baseline demographics and clinical characteristics

Variables	Values (N=86)
Age (years)	70±17
Male	41 (47.7)
Body mass index (kg/m ²)	25.6±8.2
Comorbidity	
Hypertension	63 (73.3)
Diabetes mellitus	36 (41.9)
Cardiovascular disease	39 (45.3)
Respiratory disease	29 (33.7)
Chronic liver disease	7 (8.1)
Chronic kidney disease	33 (38.4)
Neurological disease	20 (23.3)
Malignancy	12 (14.0)
APACHE III score	56±17
SOFA score	4±3

Data are presented as mean ± standard deviation or n (%). APACHE III, Acute Physiologic and Chronic Health Evaluation III; SOFA, Sequential Organ Failure Assessment.

and 5±1 cmH₂O, respectively. Other NIV settings are shown in *Table 2*.

Clinical outcomes and factors associated with NIV failure

The overall rate of NIV failure at 48 hours was 20.9% and all subjects were intubated. Among the 18 subjects who developed NIV failure, increased work of breathing was the most common cause of NIV failure at 48 hours (61.1%), followed by airway and/or secretion obstruction (16.7%) (*Table 3*). According to the indication for NIV use, the rate of failure of NIV in each indication is presented in *Figure 2*. The hospital mortality was 12.8%.

Patients who failed NIV had higher disease severity compared to patients with NIV success according to the APACHE III score (65±15 *vs.* 53±17, respectively; P=0.009) and the SOFA score (6±3 *vs.* 3±2, respectively; P=0.001). Hospital mortality was significantly higher in patients with NIV failure than in NIV success (33.3% *vs.* 7.4%, respectively; P=0.009) (*Table 4*).

We performed univariate and multivariate analyses to identify factors associated with NIV failure using the logistic regression model. Multivariate analysis demonstrated that the male gender and higher SOFA score were significantly

Table 2 Indications, types, and settings of noninvasive ventilation

Variables	Values (N=86)
Indication for the use of NIV	
Cardiogenic pulmonary edema	30 (34.9)
Post-extubation prophylaxis	22 (25.6)
Pneumonia	14 (16.3)
Exacerbation of chronic obstructive pulmonary disease	12 (14.0)
Neuromuscular disease	6 (7.0)
Extrapulmonary sepsis	2 (2.3)
Type of NIV	
Dedicated NIV	62 (72.1)
ICU ventilator	24 (27.9)
Mode of NIV at day 1	
Pressure support ventilation	45 (52.3)
Pressure assist-control mode	24 (27.9)
Pressure control ventilation	16 (18.6)
Average volume-assured pressure support	1 (1.2)
NIV settings on day 1	
Pressure support or inspiratory pressure (cmH ₂ O)	13±4
Positive end-expiratory pressure (cmH ₂ O)	5±1
Set respiratory rate (breaths/min)	16±4
Oxygen flow (L/min)	8±3
Physiological variables on day 1	
Tidal volume (mL)	354±139
Tidal volume pre predicted body weight (mL/kg)	6.8±2.6
Respiratory rate (breaths/minute)	24±5
SpO ₂ (%)	97±3

Data are presented as mean ± standard deviation or n (%). NIV, noninvasive ventilation; ICU, intensive care unit; SpO₂, oxygen saturation by pulse oximetry.

associated with NIV failure (OR 4.59, 95% CI: 1.29–16.34; P=0.019 and OR 1.48, 95% CI: 1.16–1.89; P=0.002, respectively) (*Table 5*).

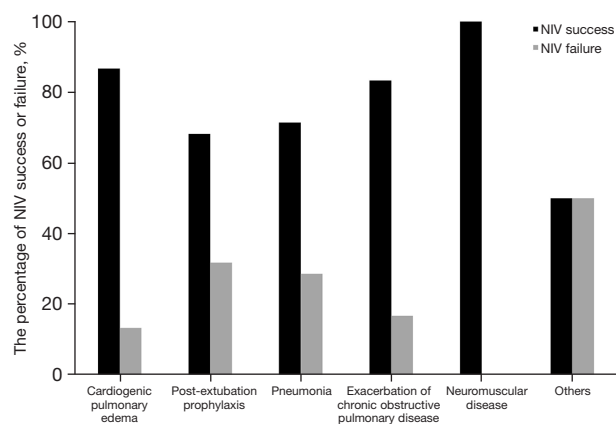
Discussion

In this prospective cohort study, we evaluated the characteristics, clinical outcomes, and safety of NIV use in 86 subjects who were admitted to general medical wards of

Table 3 Clinical outcomes of noninvasive ventilation application in general medical wards

Variables	N=86 (%)
Rate of NIV failure within 48 hours	18 (20.9)
Cause of NIV failure	
Increased work of breathing	11 (61.1)
Airway and/or secretion obstruction	3 (16.7)
Worsening hypoxemia	1 (5.6)
Alteration of consciousness	1 (5.6)
Hemodynamic instability	1 (5.6)
Cardiac arrest	1 (5.6)
In-hospital mortality	11 (12.8)

NIV, non-invasive ventilation.

**Figure 2** Rate of NIV failure in each indication of NIV use. NIV, noninvasive ventilation.

the university hospital. The primary outcome demonstrated that the rate of NIV failure at 48 hours was 20.9%, and the secondary outcomes showed in-hospital mortality of 12.8%. In addition, male gender and higher SOFA score were associated with the failure of NIV. Cardiogenic pulmonary edema was the most common indication for the use of NIV, followed by the prevention of post-extubation respiratory failure and the exacerbation of COPD.

NIV is increasingly used in patients with acute respiratory failure. Data from large cohort studies demonstrated an overall increase in NIV used in the past decades (3,8). Potential physiological benefits of NIV have been proposed, including improved oxygenation, unloaded respiratory muscles, reduced patient work of breathing, and

increased alveolar ventilation. Furthermore, several clinical studies demonstrated the advantages of NIV in avoidance of endotracheal intubation, a reduced incidence of nosocomial pneumonia, and a reduction in mortality in some specific populations (1,9). The recent clinical practice guideline of the European Respiratory Society and the American Thoracic Society recommends the use of NIV as first line treatment in patients with acute respiratory failure due to exacerbation of COPD, cardiogenic pulmonary edema, and prevention of post-extubation respiratory failure (5). However, patients receiving NIV is recommended to initiate in the ICU or within a care system capable of providing close monitoring and well-trained staff (10).

NIV has been used outside the ICU, such as in general wards, respiratory wards, or emergency departments due to limited ICU beds and financial limitations. Many studies demonstrated that NIV was implemented outside the ICU in a range of 18% to 70% (11-16). In our hospital, many patients with acute respiratory failure, who had stable hemodynamics, a normal level of consciousness, and no need for organ support, were admitted to the general medical wards of the Department of Medicine due to the shortage of beds in the ICU and NIV has been implemented in many patients with acute respiratory failure from various etiologies. Our study demonstrated that cardiogenic pulmonary edema was the most common cause of NIV use in this cohort followed by prevention of post-extubation respiratory failure and pneumonia that corresponded to the recommendation for NIV use according to the recent guideline (5). The overall rate of failure of NIV at 48 hours in the present study was 20.9% and the hospital mortality was 12.8%. We used the rate of NIV failure at 48 hours as the primary outcome because the previous studies demonstrated that late NIV failure, which defined as more than 48 hours after initiation of NIV, was associated with poor outcomes (17,18). Our study demonstrated that the use of NIV in general medical wards was effective and safe in selected patients with acute respiratory failure. The success rate of NIV and the mortality rate in the present study were similar to those in other studies (13,19,20).

Ozsancak Ugurlu *et al.* (14) reported the outcomes of 499 patients with acute respiratory failure who received NIV. Eighteen percent of these patients were treated in general wards and the success rate and the hospital mortality rate were 68% and 17%, respectively. A prospective observational study in 76 subjects who received NIV on regular floors by Farha and colleagues (21) demonstrated that the rate of NIV failure (defined as the need to

Table 4 Comparison of demographic and clinical variables between noninvasive ventilation success and failure

Variables	NIV success (N=68)	NIV failure (N=18)	P value
Age (years)	68±17	76±13	0.096
Body mass index (kg/m ²)	25.9±8.5	24.5±6.9	0.509
APACHE III score	53±17	65±15	0.009
SOFA score	3±2	6±3	0.001
NIV setting on day 1			
Pressure support or inspiratory pressure (cmH ₂ O)	13±4	13±3	0.513
Positive end-expiratory pressure (cmH ₂ O)	5±1	2±1	0.931
Oxygen flow (L/min)	8±3	7±3	0.531
Physiological variables on day 1			
Respiratory rate (breaths/minute)	24±4	24±7	0.789
SpO ₂ (%)	97±4	97±3	0.989
Mean arterial pressure (mmHg)	95±16	91±16	0.393
Heart rate (beats/minute)	100±21	96±36	0.501
Tidal volume (mL)	364±148	320±93	0.309
Tidal volume per predicted body weight (mL/kg)	7.0±2.9	5.9±1.0	0.187
In-hospital mortality	5 (7.4)	6 (33.3)	0.009

Data are presented as mean ± standard deviation or n (%). A level of P<0.05 was considered statistically significant. NIV, noninvasive ventilation; APACHE III, Acute Physiologic and Chronic Health Evaluation III; SOFA, Sequential Organ Failure Assessment; SpO₂, oxygen saturation by pulse oximetry.

Table 5 Univariate and multivariate logistic regression analyses for factors independently associated with noninvasive ventilation failure

Variables	Univariate analysis			Multivariate analysis		
	OR	95% CI	P value	OR	95% CI	P value
Age	1.04	0.97–1.12	0.289	–	–	–
Gender	4.65	0.98–22.10	0.053	4.59	1.29–16.34	0.019
Body mass index	0.98	0.87–1.10	0.696	–	–	–
APACHE III	0.99	0.93–1.05	0.686	–	–	–
SOFA	1.60	1.08–2.37	0.020	1.48	1.16–1.89	0.002
Pressure support or inspiratory pressure at day 1	1.06	0.90–1.26	0.471	–	–	–
Positive end-expiratory pressure on day 1	1.27	0.40–4.06	0.685	–	–	–
Respiratory rate on day 1	0.97	0.83–1.13	0.691	–	–	–
SpO ₂ on day 1	0.92	0.73–1.16	0.486	–	–	–
Mean arterial pressure on day 1	1.00	0.95–1.06	0.901	–	–	–
Heart rate on day 1	1.00	0.97–1.04	0.966	–	–	–

A level of P<0.05 was considered statistically significant. OR, odds ratio; CI, confidence interval; APACHE III, Acute Physiologic and Chronic Health Evaluation III; SOFA, Sequential Organ Failure Assessment; SpO₂, oxygen saturation by pulse oximetry.

transfer to the ICU) was 31% and the mortality rate was 13%. In addition, exacerbation of COPD and congestive heart failure were the most common causes of NIV use in this study. Furthermore, they found that patients with pneumonia had a high rate of NIV failure (26%) that was similar to our study (28.6%). This finding emphasizes that using NIV in patients with acute *de novo* hypoxemic respiratory failure, such as pneumonia or ARDS, should be taken with caution. A multicenter randomized study by Frat *et al.* (22) to compare high-flow nasal cannula, standard oxygen therapy, and NIV in subjects with acute hypoxemic respiratory failure demonstrated that subjects who received NIV in this study had the worst clinical outcomes in terms of intubation rate and survival compared to the other two groups. Furthermore, a post-hoc analysis of the LUNG SAFE study by Bellani and colleagues also showed that 15% of patients with ARDS were treated with NIV and was associated with a higher mortality rate in patients with an arterial partial pressure of oxygen/oxygen fraction ratio lower than 150 mmHg (7). Failure of NIV and poor outcome in patients with acute *de novo* hypoxemic respiratory failure may be explained by higher tidal volume and minute ventilation as a result of high respiratory drive and potentially injurious transpulmonary pressure so-called patient self-inflicted lung injury (23,24).

The delivery of NIV with a helmet which is a transparent plastic hood covering the entire head and sealed with a neck collar may be an alternative method for the administration of NIV in patients with acute hypoxemic respiratory failure. A single center, randomized study by Patel *et al.* (25) in 83 patients with ARDS comparing NIV administered by helmet and face mask for at least 8 hours demonstrated that helmet NIV treatment significantly resulted in a reduction in the rate of endotracheal intubation and 90-day mortality. In addition, Liu and colleagues demonstrated that NIV with a helmet significantly improved oxygenation and tolerance and decreased NIV-related complications compared to NIV with face mask in patients with chest trauma (26). A systematic review and meta-analysis also confirmed that helmet NIV was associated with a reduction in intubation rate and hospital mortality compared to NIV or CPAP delivered by face mask (27). However, our study did not use a helmet during NIV application and the use of helmet NIV outside the ICU should be studied in the future.

Many severity scores such as APACHE II, SOFA, or Simplified Acute Physiology Score (SAPS) II scores can be used to predict the outcome of NIV in critically ill patients. Two previous studies demonstrated that higher

SOFA score was a significant risk factor for NIV failure in patients after extubation (28,29). A prospective cohort study by Corrêa and colleagues (30) found that higher APACHE II score was a predictor of NIV failure in 85 patients with acute respiratory failure who received NIV. Furthermore, Carron *et al.* (31) demonstrated that patients with severe community-acquired pneumonia who failure NIV had significantly higher SAPS II score. Our study also found that higher SOFA score was associated with NIV failure. Thus, illness severity is an important predictor of NIV failure and this finding was consistent across several severity scores and in various conditions for NIV use.

Limitations

The present study had several limitations that may limit the generalizability of our findings. First, this is a single center, non-randomized study, and small sample size. Second, we did not compare the outcome with other respiratory support strategies, such as standard oxygen therapy or high-flow nasal cannula. Third, data was collected before the 2019 coronavirus pandemic that noninvasive respiratory support techniques including NIV and HFNC were implemented outside the ICU during the pandemic phase and the outcomes may differ from our study. Fourth, we did not use the helmet interface that has been shown to be beneficial in patients with acute hypoxemic respiratory failure. Last, the severity scores including APACHE III and SOFA are routinely used in ICU to predict the mortality; however, we used these scores in the present study because our enrolled subjects were critically ill patients. In addition, many studies have already used these scores in critically ill patients who were managed at general wards (17,32-34). Further well-designed studies are needed to evaluate the benefits of the use of NIV outside the ICU.

Conclusions

NIV was safe and effective for use in general medical wards. Cardiogenic pulmonary edema was the most common indication for the application of NIV. Patients who failed NIV had a higher mortality rate than those who had succeeded with NIV. The male gender and SOFA score are associated with NIV failure at 48 hours.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-732/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Siriraj Institutional Review Board (certificate of approval No. Si 563/2017) and informed consent was obtained from all individual participants or their relatives.

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