## **ORIGINAL RESEARCH**



## New index to predict the possibility of hemostatic angiographic embolization in trauma patients assessed by emergency medical services

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#### Abstract

Trauma is an important public health issue and a leading cause of mortality worldwide. We developed a concise index that predicts the possibility of hemostatic angiographic embolization in trauma patients assessed by emergency medical services (EMS). Two Asia-Pacific countries were involved in this study: 13 emergency departments (EDs) in South Korea and 15 EDs in Malaysia. Patients with trauma transported by EMS between January 2015 and December 2018 were enrolled in this study. Hemostatic angiographic embolization was defined as the presence of at least one procedure performed within 24 h of the ED visit. A simple index was developed with key components after principal component analysis: scene shock index (SI) + ED SI-prehospital alertness. Prediction performance was evaluated by the area under the receiver operating characteristic curve (AUC) and was compared to the revised trauma score (RTS), age-adjusted shock index (AGE-SI), and surgical intervention in victims of motor vehicle crashes (SIM) score. A total of 28,772 patients were included in the final analysis. Overall, 657 patients (2.3%) underwent hemostatic angiographic embolization. Scene SI and ED SI were significantly different: median (q1-q3) was 0.63 (0.75-1.00), 0.69 (0.59-0.85) in patients who underwent hemostatic angiographic embolization and 0.55 (0.64–0.73), 0.61 (0.51–0.72) in patients who did not undergo hemostatic angiographic embolization. Prehospital alertness was observed in 192 (29.2%) and 19,978 (71.1%) patients with and without hemostatic angiographic embolization, respectively. Greater predictive performance for hemostatic angiographic embolization was observed (AUC: 0.792 for new index, 0.672 for SIM score, 0.562 for RTS, and 0.507 for AGE-SI). A new index showed higher predictive performance for hemostatic angiographic embolization in adult EMStransported trauma patients compared to the SIM score, RTS, and AGE-SI.

#### **Keywords**

Trauma; Emergency medical services; Therapeutic embolization; Clinical decision support

## **1. Introduction**

Trauma is an important public health issue, especially in young populations, and is one of the leading causes of mortality worldwide [1, 2]. Trauma care systems have focused on regionalization, which has been found to reduce mortality in many countries [3–6]. Decision-making about adequate hospital transport is critical, considering that insufficient triage or delay in proper management can deteriorate patient status [7–10]. Several prehospital triage tools have been developed to identify the need for intensive care to select patients with immediate needs and shorten the pretreatment period; however, their practical usefulness is unclear [11, 12].

In trauma patients with active arterial bleeding, intervention for hemostasis, comprising surgical bleeding control and angiographic embolization, is crucial and urgent [13]. Each procedure can be selected or performed sequentially according to the patient's status [14]. A recent study in Japan demonstrated similar survival outcomes for both procedures as initial therapeutic interventions for pelvic fracture [15]. Moreover, the time delay for hemostatic intervention has been associated with worse outcomes in previous studies [16–18].

The shock index (SI) is an easily obtainable indicator that intuitively demonstrates a patient's physiological status [19, 20]. Although it is used predominantly in trauma patients, it has also been used as a predictive tool for outcomes in various environments [21–23]. In trauma research, various modifications or delta values have been used to develop clinical tools for specific management, such as transfusion [24, 25]. There have also been challenging studies to determine the need for hemostatic intervention using SI [26, 27]. Although SI can be a good indicator for assessing the possibility of hemostatic intervention in acute trauma, a practical evaluation tool with generalizability has not yet been developed.

We developed a concise new index comprising SI, which predicts the possibility of hemostatic angiographic embolization in emergency medical services (EMS)-assessed trauma patients in two Asian countries. The prediction performance was evaluated and compared to the revised trauma score (RTS), age-adjusted SI (AGE-SI), and surgical intervention in victims of motor vehicle crashes (SIM) score [28]. We hypothesized that a new index would show the potential utility of urgent angiographic embolization in triaged trauma patients.

## 2. Material and methods

## 2.1 Study Design and Data Source

A retrospective study was designed to develop a new index based on patients registered in the Pan-Asian Trauma Outcomes Study (PATOS) database, which is an international, multicenter, and population-based trauma database that includes 85 sites in 12 Asia-Pacific countries. It collects and integrates data through an internet electronic data capture system hosted by study coordinating centers at Seoul National University Hospital in a uniform fashion [29]. The PATOS database version 1.0, composed of data from 2015–2018, was organized and distributed in 2019. This study was reviewed and approved by the institutional review board committee of the PATOS coordinating center.

## 2.2 Study Setting

Two Asia-Pacific countries, Malaysia and South Korea, considering the integrity of intervention information and physiologic parameter data, were involved in this study. Each country has a distinct emergency medical system with different population characteristics [30]. Thirteen emergency departments (EDs) in South Korea and 16 EDs in Malaysia participated in the data collection. South Korea operates as a single-tier EMS system depending on the National Fire Agency. In each province, the dispatch center at the local headquarters receives an emergency call and dispatches an ambulance to the scene. Certification consists of level-1 (equivalent to emergency medical technician (EMT)-intermediate in the USA) and level-2 (equivalent to EMT-basic) [31]. In Malaysia, healthcare institutes and fire departments operate EMS system. EMS providers are manned by nurses who have been trained for more than 3-4 years for certification. An emergency medical dispatcher program operated by a health department or hospital was implemented in the 2000s and demonstrated a shortening effect on the response time interval [32]. Unlike South Korea, there is no helicopter EMS system for trauma in Malaysia [33]. A special EMS education program for trauma is held for EMS providers in both countries, and the standard protocol for trauma care follows conventional concepts, including the avoidance of delayed transportation for patient evaluation. Field trauma management can be performed for severe trauma patients by EMS providers, including airway management and oxygen supplements for patients with hypoxia or impaired

level of consciousness, and intravenous fluid administration for hypotensive patients.

## 2.3 Study Population

Patients with trauma, in Malaysia and South Korea, between January 2015 and December 2018, were enrolled in this study. Pediatric patients, patients with non-traumatic injuries (such as poisoning), interhospital transport cases, patients transported by non-EMS, patients with prehospital or in-hospital cardiac arrest, and patients with missing information about hemostatic angiographic embolization intervention or SI score were excluded.

## 2.4 Outcome

The primary outcome was hemostatic angiographic embolization, defined as the presence of at least one angiographic embolization conducted within 24 h of the ED visit. Data were collected by medical record review and considered negative if only angiography was performed.

## 2.5 Data Variables

Demographic findings and clinical information included age, sex, mechanism of injury (traffic accident, fall, blunt, and other), state of alcohol influence, anatomic location of injury (head, chest, abdomen, and spine), pre-hospital trauma care (airway management, oxygen supplementation, and fluid administration), pre-hospital and ED alertness (defined as A on the Alert, Voice, Pain, Unresponsive (AVPU) scale at the scene and a score of 15 on the Glasgow coma scale at the ED), injury severity score (ISS) [34], intensive care unit admission, and hospital mortality. The SIs at the scene (scene SI) and ED (ED SI) were calculated as the ratio of heart rate to systolic blood pressure at each measurement site. Delta SI, as previously demonstrated, was calculated between the ED SI and the scene SI: delta SI = ED SI-scene SI [35]. Hemostatic angiographic embolization was defined as the presence of at least one procedure within 24 h of the ED visit.

## 2.6 Statistical Analyses

The distribution of demographic findings and clinical information according to hemostatic angiographic embolization was compared and described. Chi-square test for categorical variables and Wilcoxon rank-sum test for continuous variables were performed after the normality test. To evaluate the association between hemostatic angiographic embolization and key factors assumed to be achieved promptly in clinical environments, univariate and multivariate logistic regression analyses were performed. We selected key factors, including SIs (scene, ED, and delta), age group (<44 years, 45–64 years, and older), sex, mechanism of injury, and alertness at the scene and ED. Unadjusted and adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were also calculated. The distribution of demographic findings and clinical information according to crucial components were described. Principal component analysis, which is a multivariate analysis that integrates correlated and uncorrelated variables, was conducted to reduce the dimension and derive predictive coefficients to develop a



**FIGURE 1.** Flow diagram for the study population. PATOS, Pan-Asian trauma outcome study; EMS, emergency medical service; CPR, cardiopulmonary resuscitation; ED, emergency department.

simple index [36, 37]. The Kaiser criterion was used to drop the components for which the eigenvalues were <1. SIs at the scene and ED and level of consciousness at the scene were selected according to the Kaiser criterion, and the equation was developed as follows:

New index: Scene SI + ED SI-prehospital alertness.

The prediction performance for angiographic embolization of the new index was primarily compared to the RTS, AGE-SI, and SIM scores by plotting specific receiver operating characteristic (ROC) curves [38]. A model comparison was also conducted using the ROC-compare method with chisquare statistics [39]. The test characteristics of the new index according to the cutoff value of 0.5, including the sensitivity, specificity, and positive and negative predictive values (PPV and NPV) with 95% CIs, were reported. All analyses were performed using R version 3.5 (R Foundation for Statistical Computing, Vienna, Austria) with caret and pROC packages.

## 3. Results

A total of 56,936 patients from two Asian countries were enrolled in the PATOS database over the study period. After excluding pediatric (N = 7215) and non-traumatic injury (N = 5980) patients, interhospital transport cases (N = 3659), non-EMS involvement (N = 6904), cardiac arrest at any level (N = 649), and cases without exposure (N = 3757), a total of 28,772 cases were selected for final analysis (Fig. 1).

The demographic and clinical findings for the study cohort

are described in Table 1, according to hemostatic angiographic embolization. Overall, 657 (2.3%) patients received hemostatic angiographic embolization and were more likely to undergo emergency surgery (N = 554 (84.3%)), be admitted to the intensive care unit (N = 247 (37.6%)), and die in the hospital (N = 36 (5.5%)).

In multivariate logistic regression analysis, ED SI score >1.0, mechanism of injury including fall and blunt trauma, and level of consciousness at scene and ED were significantly associated with the probability of angiographic embolization among key factors. The final model was constructed by backward variable selection, including scene SI score >1.0, ED SI score >1.0, mechanism of injury including fall and blunt trauma, and level of consciousness at scene and ED (Hosmer-Lemeshow goodness-of-fit statistic: p-value < 0.01) (Table 2).

Compared to RTS, AGE-SI, and SIM, the new index showed greater predictive performance for angiographic embolization (AUC: 0.792 for the new index, 0.562 for RTS, 0.507 for AGE-SI, and 0.672 for SIM) (Fig. 2). In Table 3, the test characteristics are described, demonstrating a cut-off value of 1.5 which provides high accuracy and sensitivity of 0.9099 and 0.9230, respectively.

New index based 0.5-point unit estimates of the requirement for hemostatic angiographic embolization and the corresponding observed value for each index are provided in Fig. 3. Both the predicted and observed probabilities gradually increased to approximately 20% at a score of 3.0.

| TABLE 1. Demographics and chincar | mangs of study popu | nation according to nen | iostatic angiographic en | ildolizatioli.  |
|-----------------------------------|---------------------|-------------------------|--------------------------|-----------------|
|                                   | Total               | Without                 | Angiographic             | 1               |
|                                   | N (%)               | embolization            | embolization             | <i>p</i> -value |
|                                   |                     | N (%)                   | N (%)                    |                 |
| Total                             | 28,772 (100.0)      | 28,115 (97.7)           | 657 (2.3)                |                 |
| Age, year, median (q1–q3)         | 49 (31–66)          | 49 (31–66)              | 38 (25–57)               | < 0.01          |
| Gender, male                      | 18,109 (62.9)       | 17,622 (62.7)           | 487 (74.1)               | < 0.01          |
| Mechanism                         |                     |                         |                          |                 |
| Traffic accident                  | 13,475 (46.8)       | 12,994 (46.2)           | 481 (73.2)               |                 |
| Fall                              | 10,321 (35.9)       | 10,192 (36.3)           | 129 (19.6)               | <0.01           |
| Blunt                             | 3789 (13.2)         | 3749 (13.3)             | 40 (6.1)                 | <0.01           |
| Other                             | 1187 (4.1)          | 1180 (4.2)              | 7 (1.1)                  |                 |
| Drunken, Alcohol                  | 4897 (17.0)         | 4826 (17.2)             | 71 (10.8)                | < 0.01          |
| Anatomic location of Injury       |                     |                         |                          |                 |
| Head                              | 9049 (31.5)         | 8828 (31.4)             | 221 (33.6)               |                 |
| Chest                             | 3373 (11.7)         | 3193 (11.4)             | 180 (27.4)               | <0.01           |
| Abdomen                           | 1501 (5.2)          | 1347 (4.8)              | 154 (23.4)               | < 0.01          |
| Spine                             | 3595 (12.5)         | 3487 (12.4)             | 108 (16.4)               |                 |
| Prehospital Data                  |                     |                         |                          |                 |
| Airway management                 | 5028 (17.5)         | 4791 (17)               | 237 (36.1)               | < 0.01          |
| Oxygen supply                     | 4786 (16.6)         | 4458 (15.9)             | 328 (49.9)               | < 0.01          |
| Fluid administration              | 4877 (17.0)         | 4566 (16.2)             | 311 (47.3)               | < 0.01          |
| Prehospital Alertness             | 20,170 (70.1)       | 19,978 (71.1)           | 192 (29.2)               | < 0.01          |
| Scene SI, median (q1–q3)          | 0.56 (0.64–0.73)    | 0.55 (0.64–0.73)        | 0.63 (0.75-1.00)         | < 0.01          |
| ED SI, min, median (q1–q3)        | 0.61 (0.51-0.72)    | 0.61 (0.51-0.72)        | 0.69 (0.59–0.85)         | < 0.01          |
| Delta SI, min, median (q1–q3)     | -0.02 (-0.11-0.05)  | -0.02 (-0.11-0.05)      | -0.02 (-0.17-0.07)       | 0.07            |
| ED GCS, median (q1–q3)            | 15 (15–15)          | 15 (15–15)              | 15 (14–15)               | < 0.01          |
| ISS, median (q1–q3)               | 9 (3–19)            | 9 (3–17)                | 21 (9–34)                | < 0.01          |
| Emergency surgery                 | 2046 (7.1)          | 1492 (5.3)              | 554 (84.3)               | < 0.01          |
| ICU admission                     | 2341 (8.1)          | 2094 (7.4)              | 247 (37.6)               | < 0.01          |
| Hospital mortality                | 311 (1.1)           | 275 (1.0)               | 36 (5.5)                 | < 0.01          |

TABLE 1. Demographics and clinical findings of study population according to hemostatic angiographic embolization

SI, shock index; ED, emergency department; GCS, Glasgow coma scale; ISS, injury severity scale; ICU, intensive care unit.

## 4. Discussion

We developed a new index to predict the possibility of hemostatic angiographic intervention in EMS-assessed adult trauma patients. The discriminative performance was significantly higher than that of RTS, AGE-SI, and SIM. Although the cutoff value for the new index would differ according to the characteristics of the regional trauma system, it should be considered that a new index value equal to or higher than 1.5 suggests the possibility of hemostatic angiographic embolization within 24 h after ED visit. Regional EMS could be assisted by the new index in determining direct transportation to the intervention center, especially in mass casualty incidents.

A new index, composed of SIs and level of consciousness, is thought to assess active bleeding in trauma patients with clinical urgency demanding angiographic embolization in the early phase. SI is well known as a better predictor of hemorrhagic shock, unless pseudo-hypertension or relative bradycardia is present [40]. Combining two temporal SI can provide a higher level of surveillance for changes in intravascular volume status and level of consciousness and support severity assessment and the corresponding amount of bleeding.

In this study, we carefully selected factors that could be measured at any level of the EMS system with relatively clear values. Previously, more detailed indicators, including abbreviated injury scales or diagnosis codes, were used to predict mortality [41, 42]. RTS, composed of physiological parameters and the Glasgow coma scale, demonstrated the need for intensive care unit admission in a recent study in Egypt [43]. Regarding its application in the field of trauma resuscitation, detailed indicators are difficult to achieve and vary among healthcare providers. Considering the purpose of the new index, screening needs for advanced medical resources, and shortening the delay in definite care, it should be applied within the prehospital phase of trauma care. We used SI, which is thought to be a universal marker through

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|                           | Univariable analysis Multivariable analysis Final model |              |                      |                      |  |
|---------------------------|---------------------------------------------------------|--------------|----------------------|----------------------|--|
|                           | Onivariable                                             | anarysis     | Adjusted OR (95% CI) | Adjusted OR (95% CI) |  |
|                           | OR (95% CI)                                             | C-statistics |                      |                      |  |
| Angiographic embolization |                                                         |              |                      |                      |  |
| Scene SI >1.0             | 3.95 (3.05–5.11)                                        | 0.538        | 1.36 (0.97–1.90)     | 1.41 (1.01–1.95)     |  |
| ED SI >1.0                | 5.21 (4.13-6.57)                                        | 0.554        | 3.28 (2.40-4.48)     | 3.11 (2.32–4.18)     |  |
| Delta SI >0.0             | 1.03 (0.87–1.20)                                        | 0.503        | 0.92 (0.77–1.09)     | _                    |  |
| Age group, years          |                                                         |              |                      |                      |  |
| Young (<45)               | Reference                                               |              | Reference            | _                    |  |
| Middle (45–64)            | 0.67 (0.56–0.80)                                        | 0.580        | 1.12 (0.92–1.36)     | _                    |  |
| Old (65~)                 | 0.46 (0.37–0.58)                                        |              | 1.04 (0.81–1.33)     | _                    |  |
| Gender, Male              | 1.71 (1.43–2.04)                                        | 0.557        | 1.11 (0.92–1.33)     | _                    |  |
| Mechanism                 |                                                         |              |                      |                      |  |
| ТА                        | Reference                                               |              | Reference            | Reference            |  |
| Fall                      | 0.34 (0.28–0.42)                                        | 0.640        | 0.65 (0.51–0.81)     | 0.65 (0.52–0.80)     |  |
| Blunt                     | 0.29 (0.21–0.40)                                        | 0.040        | 0.58 (0.41–0.82)     | 0.59 (0.42–0.82)     |  |
| Other                     | 0.16 (0.08–0.34)                                        |              | 0.27 (0.13–0.58)     | 0.27 (0.13-0.58)     |  |
| Scene Alertness           |                                                         |              |                      |                      |  |
| Alert                     | 0.17 (0.14–0.20)                                        | 0 709        | 0.24 (0.20-0.29)     | 0.24 (0.20-0.29)     |  |
| Altered mentality         | Reference                                               | 0.709        | Reference            | Reference            |  |
| ED Alertness              |                                                         |              |                      |                      |  |
| Alert                     | 0.37 (0.31–0.44)                                        | 0 591        | 0.56 (0.46–0.67)     | 0.55 (0.46-0.66)     |  |
| Altered mentality         | Reference                                               | 0.301        | Reference            | Reference            |  |
|                           |                                                         |              |                      |                      |  |

| TABLE 2. Risk factors of angiographic embolization in EMS assess trauma patients using univari | able and |
|------------------------------------------------------------------------------------------------|----------|
| multivariable logistic regression analysis.                                                    |          |

OR, odds ratio; CI, confidence interval; SI, shock index; ED, emergency department; TA, traffic accident.

| Cut-off value | Expected/N | Accuracy | Sensitivity | Specificity | PPV    | NPV    | LR+    | LR-    |
|---------------|------------|----------|-------------|-------------|--------|--------|--------|--------|
| 0.0           | 643/25,346 | 0.1409   | 0.1214      | 0.9787      | 0.9959 | 0.0254 | 0.0260 | 0.0041 |
| 0.5           | 573/11,754 | 0.6085   | 0.6023      | 0.8722      | 0.9951 | 0.0488 | 0.0512 | 0.0050 |
| 1.0           | 478/8236   | 0.7241   | 0.7241      | 0.7276      | 0.9913 | 0.0580 | 0.0616 | 0.0088 |
| 1.5           | 229/2393   | 0.9099   | 0.9230      | 0.3486      | 0.9838 | 0.0957 | 0.1058 | 0.0165 |
| 2.0           | 52/385     | 0.9674   | 0.9882      | 0.0792      | 0.9787 | 0.1351 | 0.1562 | 0.0218 |
| 2.5           | 25/131     | 0.9744   | 0.9962      | 0.0381      | 0.9779 | 0.1908 | 0.2358 | 0.0226 |
| 3.0           | 13/52      | 0.9763   | 0.9986      | 0.0198      | 0.9776 | 0.2500 | 0.3333 | 0.0229 |
| 3.5           | 7/28       | 0.9767   | 0.9993      | 0.0107      | 0.9774 | 0.2500 | 0.3333 | 0.0231 |

PPV, positive predictive value; NPV, negative predictive value; LR, likelihood ratio.



**FIGURE 2.** Performances of prediction models for angiographic embolization. RTS, revised trauma score; Age-SI, ageadjusted shock index; SIM, surgical intervention in victims of motor vehicle crashes. AUC, the area under the curve.



FIGURE 3. New index-predicted and observed probabilities of the requirement for hemostatic angiographic embolization.

diverse EMS systems, and level of consciousness classified as conscious and unconscious, which can be easily assessed by basic EMS providers.

The application of the two types of SI was based on the assumption that changes in complex physiological parameters would reflect ongoing intravascular volume loss with high sensitivity. However, a single delta value does not seem to have significant predictive power, as there is no information about severity and whether each component is within the normal range. As shown in Table 2, positive delta SI score did not have a positive association with the possibility of hemostatic angiographic embolization.

In contrast to previous studies, which have usually focused on transfusion, the new index addresses specific aggressive management practices that require special facilities and manpower. The development of a prediction model combined with transfusion can be ambiguous, as it does not necessarily accompany urgent intervention. In addition, the importance of assessing the need for hemostatic angiographic embolization is increasing because timely application of aggressive treatment significantly affects outcomes [26]. This is also meaningful because such resources are usually core components in the construction of regional trauma centers.

The predictive performance of RTS, which has been shown to be favorable for mortality in previous studies, does not seem to be applicable to hemostatic angiographic embolization. This is probably due to the limitation of the cross-sectional value, which reflects the patient's general physiological status rather than the ongoing deterioration. Level of consciousness, which can get impaired in various situations such as syncope or alcohol consumption, cannot be used alone. Therefore, the new index was distilled into a few simple and objective indicators that reflect a significant amount of active bleeding.

A new index can be used as a rapid assessment tool for trauma patients, especially in the early phase, including EMS transport and disaster triage. EMS providers can use this tool during patient rescue and determine to which hospital the patient should be transported, such as the nearest ED or regional trauma center. In addition, it can be used during EMS transport, to consider whether to bypass the arriving ED which is encountered on the way and does not have a facility for intervention. In the ED, this tool can be used as a rapid assessment tool for angiography at the triage level, and serves as a criterion for early activation. Further research is needed, such as validation of various EMS systems for application in real practice.

Our study had some limitations. First, the new index was developed based on a retrospective database, which probably has an unintended treatment or selection bias. All patients were admitted to the EDs with an interventional radiology department. Usually, EMS transports patients considering emergency medical resources depending on the severity of the patient's condition. In addition, patients with cardiac arrest were excluded, which limited the application of the new index in the most severe cases. Second, we defined hemostatic angiographic embolization depending on whether the procedure was conducted or not. It could be prophylactic management, or emergency surgery was the actual definite treatment. The clinical necessity of hemostatic angiographic

embolization cannot be assessed because the evidence of active bleeding was not collected, which is a significant limitation of the study. Third, detailed procedural records were not included in the database, and definite large vascular injuries could not be clarified. In addition, we did not determine whether the purpose of emergency surgery following angiographic embolization was for hemostasis. We designed the study to predict the possibility of the procedure; however, the relationship between specific vessels and embolization probably improves its clinical significance. Fourth, we excluded intrahospital transport cases that may require intervention. We found that all 29 institutes conducted hemostatic angiographic embolization; however, the 3757 excluded cases may have influenced the effect. Furthermore, the results of the laboratory examinations, including the point-of-care test, were unavailable. If a blood gas test was added, the model would have a higher predictive performance. Next, we cannot measure the caregiver's willingness for aggressive management due to database limitations. The proportion of mortality was less in the whole cohort, such as the do-not-resuscitate order for elderly patients with comorbidities; this was not reflected in our analysis. Finally, there was no independent validation series in this study.

## 5. Conclusions

We developed a new index to predict hemostatic angiographic embolization in EMS-transported adult trauma patients. The new index is expected to be a decision-supporting tool to determine which ED to admit during EMS transport or consider angiography at ED triage.

#### AVAILABILITY OF DATA AND MATERIALS

The data for this study were obtained from the Pan-Asian Trauma Outcomes Study (PATOS). Restrictions apply to the availability of these data, so they are not publicly available. however, they are available from the corresponding author upon reasonable request.

## **AUTHOR CONTRIBUTIONS**

KHK and JJ—had full access to all the data in the study and take responsibility for the integrity of the data as well as the accuracy of the data analysis; KHK, JJ and YSR—study concept and design; acquisition, analysis, or interpretation of data; KHK and JJ—Drafting of the manuscript; KJS, SDS, WCC, SFJ and NAN—Critical revision of the manuscript for important intellectual content; KHK and YSR—Statistical analysis; YSR and NAN— administrative, technical, or material support; JJ, KJS, WCC and SFJ—study supervision. All authors manuscript approval.

# ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study complied with the Declaration of Helsinki and its protocol was approved by the Seoul National University Hospital Institutional Review Board with a waiver for informed

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## **CONFLICT OF INTEREST**

The authors declare no conflict of interest.

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