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ORIGINAL ARTICLE

Albumin Concentration Associates Linearly with Unfavorable Outcomes at Three Months Post-Acute Ischemic Stroke in Koreans

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SUMMARY

Background: **The role of serum albumin concentration as a predictor of prognosis in stroke is controversial. This study examined the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-acute ischemic stroke (AIS) in Korean patients.**
Methods: **Data for 1,903 patients with AIS between January 2010 and December 2016 were extracted from a prospective registry system at Seoul National University Hospital, South Korea. Univariate and multivariate binary logistic regression models were used to calculate odds ratios (ORs) and 95% confidence intervals (CIs) and estimate the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS.**
Results: **Multivariable regression analyses showed baseline serum albumin concentration (continuous variable) was significantly associated with unfavorable outcomes at 3 months post-AIS (fully adjusted OR = 0.4 [95% CI: 0.3 - 0.55]). Analysis of baseline serum albumin concentration as a categorical variable gave consistent results. Curve fitting showed a potential linear association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS (P for non-linearity = 0.789).**
Conclusions: **Low baseline serum albumin concentration is a potential risk factor for unfavorable outcomes at 3 months post-AIS in Korean patients.**
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KEYWORDS

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INTRODUCTION

Stroke is becoming a global epidemic, with approximately 12.2 million incident cases and 6 million deaths reported in 2019 [1]. Post-stoke impairments are common, with the prevalence of limb, speech, language, and visual impairments estimated at 20 - 80% [2-4]. Even with appropriate management, prognosis is poor in a substantial proportion (40%) of individuals suffering from acute ischemic stroke (AIS) [5,6]. There is an unmet clinical need for molecular biomarkers for use in risk assessment, guiding therapy, and evaluating re-

sponse to treatment in patients with stroke. In South Korea, ischemic stroke remains the most common type of stroke, with 41.7% of patients having poor outcomes at discharge, making it crucial to improve prognosis for Korean patients [7].

Albumin, the most prevalent circulating protein, is primarily produced in the liver [8]. Albumin has important physiological characteristics, including the ability to maintain colloid osmotic pressure of plasma, and antiplatelet aggregation and anti-inflammatory effects [9]. Albumin has been identified as a robust predictor of prognosis in cardiovascular diseases [10,11], but its role in stroke is controversial. In previous studies, low baseline serum albumin concentration was associated with poor prognosis and mortality [12] or there was no correlation between baseline serum albumin concentration and short-term prognosis in patients with AIS [13]. Currently, there are no studies on the relationship between baseline serum albumin concentration and short-term prognosis in patients with stroke in Korea.

Therefore, the objective of the present study was to examine the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS using previously published data from a cohort study conducted in South Korea.

MATERIALS AND METHODS

Data Sources

This study is a secondary analysis of data generously provided by Seoul National University Hospital, South Korea. The primary analysis explored the association between premorbid nutritional status and short-term outcomes in patients with AIS between January 2010 and December 2016 [14]. The primary analysis was approved by the Institutional Review Board (IRB) at Seoul National University Hospital [14]; therefore, the requirement for ethical approval and patient consent were waived for this secondary analysis (IRB No. 1009-062-332). Data from the current study are provided in the supplementary Table 1.

Study Population

The primary analysis included data for 1,906 patients with AIS admitted to hospital within seven days of symptom onset. Full inclusion and exclusion criteria are presented elsewhere [14]. The secondary analysis included data from 1,903 patients. None of these patients had received albumin therapy. Three patients were excluded from the secondary analysis due to missing data for modified Rankin Scale (mRS) score, history of previous stroke/transient ischemic attack (TIA), and leukocyte count.

Data collection

Data were extracted from the prospective registry system at Seoul National University Hospital [14]. Laboratory data, including leukocyte count, hemoglobin, platelets, triglycerides (TGs), low-density lipoprotein cholesterol (LDL-C), serum creatinine, C-reactive protein (CRP), and serum albumin were obtained from electronic medical records. Stroke subtypes were categorized based on etiology using the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification (large-artery atherosclerosis, cardioembolism, small-vessel occlusion, stroke of other determined etiology, stroke of undetermined etiology). The National Institutes of Health Stroke Scale (NIHSS) was administered by neurologists upon hospitalization and used to quantify stroke severity as mild (< 6 points), moderate (6 - 14 points), or severe (≥ 14 points). Missing data were limited; therefore, no imputation method was needed.

Covariates

The principle variables were baseline serum albumin concentration (independent variable), recorded as a continuous variable, and unfavorable outcomes at 3 months post-AIS (outcome variable), evaluated using the mRS score. The mRS was assessed through structured interviews conducted by telephone or during outpatient visits. Favorable outcomes were defined as mRS scores < 3, and unfavorable outcomes were defined as mRS scores ≥ 3 [14,15].

Covariates were selected based on published literature and clinical expertise. Continuous covariates included leukocyte count, hemoglobin, platelets, TGs, LDL-C, serum creatinine, CRP, and body mass index (BMI). Categorical covariates included age, gender, smoking, previous stroke/TIA, hypertension, diabetes mellitus, hyperlipidemia, atrial fibrillation, coronary heart disease, and stroke subtype.

Statistical analysis

Statistical analyses were performed using R software (available at http://www.R-project.org) and Free Statistics v 1.9. Continuous variables were reported as mean ± standard deviation for normally distributed data or median ± interquartile range (IQR) for non-normally distributed data. Continuous variables were compared with the *t*-test or Wilcoxon rank-sum test. Categorical variables were reported as frequencies (percentages) and were compared with the χ^2 test. Univariate and multivariate binary logistic regression models were used to calculate odds ratios (ORs) and 95% confidence intervals (CIs) and estimate the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS. Four models were considered: Model 1 (unadjusted), adjusted for age and gender; Model 2, adjusted for age, gender, leukocyte count, hemoglobin, platelets, TGs, LDL-C, serum creatinine, CRP, and BMI; and Model 3, adjusted as for Model 2 and for smoking, previous stroke/TIA, hypertension, diabetes mellitus, hyperlipidemia, atrial fibrillation, coronary heart disease, NIHSS scores at hospitalization, and stroke subtype. Curve fitting was used to assess the linear association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-

Table 1. Patient baseline characteristics stratified by 3-month outcomes.

Variables	Favorable outcome (n = 1,360)	Unfavorable outcome (n = 543)	p-value
Age, range, n (%)			
< 50 years	136 (84.5)	25 (15.5)	< 0.001
≥ 50 years	1,224 (70.3)	518 (29.7)	
Gender, n (%)			
Male	881 (75.6)	285 (24.4)	< 0.001
Female	479 (65)	258 (35)	
Leukocyte count, median (IQR), 10^3/μL	7.5 (6.2, 9.3)	8.0 (6.4, 10.1)	< 0.001
Hemoglobin, median (IQR), g/dL	13.9 (12.6, 14.9)	13.1 (11.5, 14.5)	< 0.001
Platelet, mean ± SD, 10^3/μL	224.7 ± 67.2	221.0 ± 80.7	0.313
Triglyceride, mean ± SD, mg/dL	109.1 ± 60.5	95.7 ± 57.3	< 0.001
LDL cholesterol, median (IQR), mg/dL	105.0 (81.0, 130.0)	100.0 (69.0, 127.5)	0.001
Creatinine, median (IQR), mg/dL	0.9 (0.8, 1.1)	0.9 (0.7, 1.1)	0.092
C-reactive protein, median (IQR),	0.1 (0.0, 0.3)	0.3 (0.1, 1.6)	< 0.001
Albumin, mean ± SD, g/dL	4.1 ± 0.4	3.8 ± 0.5	< 0.001
BMI, mean ± SD	23.8 ± 3.1	22.8 ± 3.5	< 0.001
Smoking, n (%)			
No	780 (67.5)	375 (32.5)	< 0.001
Yes	580 (77.5)	168 (22.5)	
Previous stroke/TIA, n (%)			
No	1,114 (74.2)	387 (25.8)	< 0.001
Yes	246 (61.2)	156 (38.8)	
Hypertension, n (%)			
No	522 (75.3)	171 (24.7)	0.005
Yes	838 (69.3)	372 (30.7)	
Diabetes Mellitus, n (%)			
No	954 (74)	336 (26)	< 0.001
Yes	406 (66.2)	207 (33.8)	
Hyperlipidemia, n (%)			
No	840 (69.8)	364 (30.2)	0.031
Yes	520 (74.4)	179 (25.6)	
Atrial fibrillation, n (%)			
No	1,118 (74.7)	379 (25.3)	< 0.001
Yes	242 (59.6)	164 (40.4)	
Coronary heart disease, n (%)			
No	1,204 (71.5)	479 (28.5)	0.846
Yes	156 (70.9)	64 (29.1)	
Baseline NIHSS score, n (%)			
< 6 scores	1,116 (82.1%)	181 (33.3%)	< 0.001
6 - 13 scores	186 (13.7%)	199 (36.6%)	
≥ 14 scores	58 (4.3%)	163 (30.0%)	
Stroke, mechanism, n (%)			
LAA	443 (73.1)	163 (26.9)	< 0.001
SVO	297 (81.4)	68 (18.6)	
CE	318 (64.6)	174 (35.4)	
Other determined	97 (56.7)	74 (43.3)	
Undetermined	205 (76.2)	64 (23.8)	

IQR interquartile range, SD standard deviation, LDL low-density lipoprotein, BMI body mass index, TIA transient ischemia attack, LAA large artery atherosclerosis, SVO small vessel occlusion, CE cardioembolism.

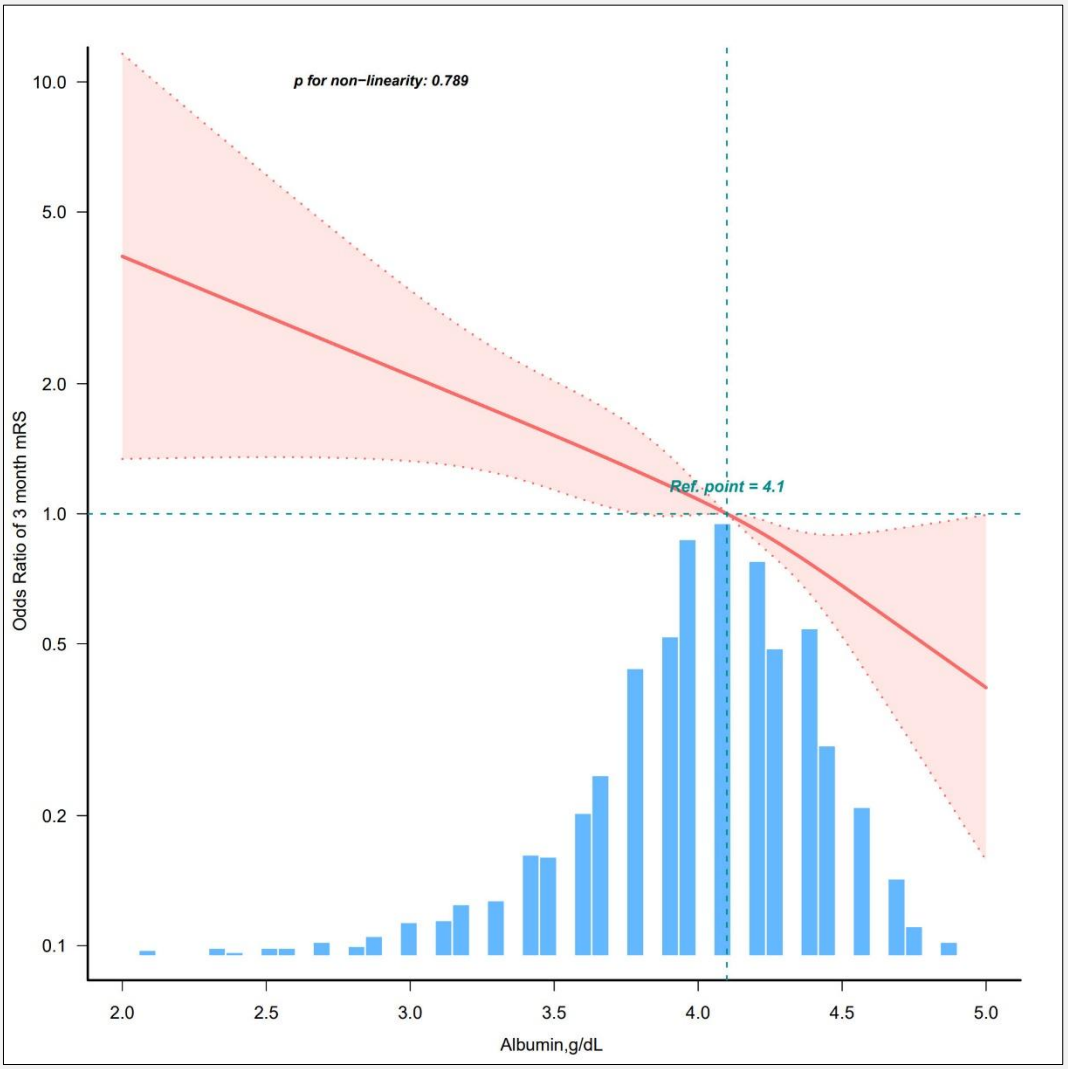

Figure 1. Fully adjusted odds ratios for the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS. Odds ratios (ORs) were adjusted for age, gender, leukocyte count, hemoglobin, platelets, triglycerides, LDL-cholesterol, serum creatinine, C-reactive protein, BMI, smoking, previous stroke/TIA, hypertension, diabetes mellitus, hyperlipidemia, atrial fibrillation, coronary heart disease, NIHSS score at hospitalization, and stroke subtype. p for non-linearity, 0.789.

AIS. Subgroup analyses were performed using logistic regression models to assess for interactions between gender, BMI, hypertension, diabetes mellitus, smoking, previous stroke/TIA, hyperlipidemia, atrial fibrillation, coronary heart disease, and stroke subtype and the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS. Significance was determined at $p < 0.05$.

RESULTS

Study population

The analysis included data for 1,903 patients (1,166 males [62.3%], 737 females [37.7%]). 543 patients (28.5%) had unfavorable outcomes at 3 months post-AIS. Mean baseline serum albumin concentration was significantly reduced in patients with unfavorable vs. favorable outcomes (Table 1).

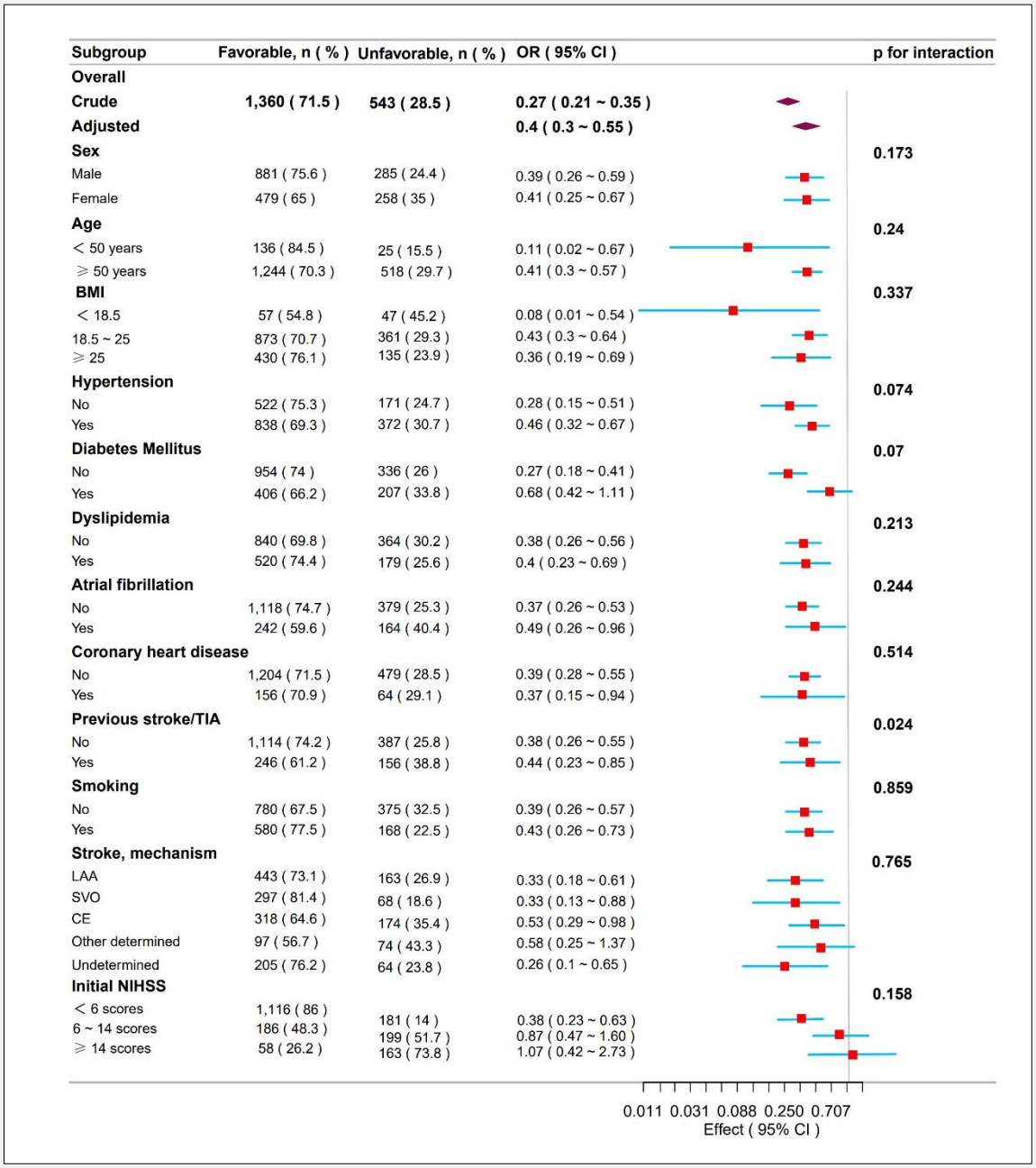

Figure 2. Subgroup analyses investigating the interaction between patient characteristics and the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS.

Multivariate analyses

Multivariable regression analyses showed baseline serum albumin concentration was significantly associated with unfavorable outcomes at 3 months post-AIS (fully adjusted OR = 0.4 [95% CI: 0.3 - 0.55]). Analysis of baseline serum albumin concentration as a categorical variable gave consistent results. Fully adjusted ORs for unfavorable outcomes in Q2, Q3, and Q4 were 0.68 (95% CI: 0.5 - 0.93), 0.54 (95% CI: 0.38 - 0.76), and 0.43 (95% CI: 0.3 - 0.61), and significantly different from Q1 (ref) (all $p < 0.05$) (Table 2). After adjusting for all covariates, curve fitting showed a potential linear asso-

ciation between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS (p for non-linearity = 0.789) (Figure 1).

Subgroup analyses

Subgroup analyses were performed to assess interactions between patient characteristics and the association between baseline serum albumin concentration (continuous variable) and unfavorable outcomes at 3 months post-AIS (Figure 2). The association was consistent across most subgroups (age [< 50, ≥ 50 years], gender [male, female], BMI [< 18.5, 18.5 - 25, ≥ 25 kg/m^2] smoking [yes, no], hypertension [yes, no], coronary heart disease [yes, no], diabetes mellitus [yes, no], hyperlipidemia [yes, no], atrial fibrillation [yes, no], and stroke subtype [large-artery atherosclerosis, cardioembolism, small-vessel occlusion, stroke of other determined etiology, stroke of undetermined etiology]), suggesting the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS was robust. However, previous stroke/TIA (yes, no) significantly modified the association, with worse outcomes in patients with history of previous stroke/TIA (history of previous stroke/TIA: OR 0.44 [95% CI: 0.23 - 0.85] vs. no previous stroke/TIA: OR 0.38 [95% CI: 0.26 - 0.55; p = 0.024]).

DISCUSSION

This study showed baseline serum albumin concentration was significantly associated with unfavorable outcomes at 3 months post-AIS (fully adjusted OR = 0.4 [95% CI: 0.3 - 0.55]) in Korean patients. The ORs of baseline serum albumin concentration remained significant across all models regardless of whether baseline serum albumin concentration was analyzed as a continuous or categorical variable, suggesting the association was robust. The association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS was linear.

The association between baseline serum albumin concentration and unfavorable outcomes post-stroke is controversial. Previously, a prospective observational study reported low baseline serum albumin concentration was associated with poor performance in activities of daily living 3 months post-AIS [16]. A meta-analysis examining the association of baseline plasma albumin concentration with poor functional outcomes demonstrated the risk ratio (RR pooled) for poor functional outcomes was 1.03 (95% CI 1.02 to 1.05) for every 1 g/L decrease in plasma albumin concentration in patients with AIS or TIA [17]. A retrospective, single-center, observational study revealed baseline serum albumin concentrations were significantly different between survivors and non-survivors in neuro-critically ill patients with stroke [18]. However, a one-year observational cross-sectional study showed no association between baseline serum albumin concentration and short-term prognosis in patients with AIS, based on functional improvement at the end of the first week assessed using the mRS [13]. Previous reports did not investigate if the association between baseline serum albumin concentration and unfavorable outcomes post-stoke was influenced by patient characteristics. Our study showed history of previous stroke/TIA may modify the association in Korean patients.

Albumin is the most abundant plasma protein in humans [19-21]. The pathophysiological mechanisms underlying the association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS may include the following: low serum albumin concentration may contribute to the progression of atherosclerosis as the antioxidant and anti-inflammatory effects of albumin are reduced [22,23]; low serum albumin concentration is associated with malnutrition or frailty [24], which may impact outcomes in patients with stroke [25]; low serum albumin concentration increases risk of experiencing complications following a stroke, particularly pneumonia, which is associated with morbidity and mortality [26]; and low serum albumin concentration disrupts the balance between coagulation and anticoagulation resulting in an increased risk for blood clots [27,28].

Notably, no previous studies have investigated the differences in baseline serum albumin concentrations among strokes of varying severities. In the subgroup analysis of our study, it was found that baseline serum albumin did not have a neuroprotective effect for patients with severe stroke with an NIHSS score of 14 or higher. We speculate that this may be due to the following reasons: First, the small sample size may have introduced bias in the results. Second, severe strokes are often complicated with pneumonia, malnutrition, and other complications due to severe neurological deficits after onset, and baseline serum albumin may not influence these additional sequelae [29-31]. Third, the NIHSS score at stroke onset is the most important independent risk factor for poor prognosis in patients with stroke [32,33]. High NIHSS score often suggests a large area of cerebral infarction, indicating extensive irreversible neuronal necrosis; therefore, baseline serum albumin could not improve short-term prognosis.

This study was associated with several limitations. First, the patients were all from Korea. Therefore, it is necessary to validate these findings in individuals from various geographical regions. Second, only one measurement of baseline serum albumin was available, which means potential fluctuations in the levels of serum albumin were not established. Third, cause and effect of low baseline serum albumin concentration as a mediator of inflammation and consequent adverse outcomes post-stroke was not investigated. Further prospective research is needed to confirm the results of this study.

There was a linear association between baseline serum albumin concentration and unfavorable outcomes at 3 months post-AIS in Korean patients. This finding may have important implications for improving short-term adverse outcomes in AIS in this patient population.

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Data Availability:
Data from the current study are provided in the supplementary Table 1. Further inquiries can be directed to the authors of the primary analysis.
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Declaration of Interest:
The authors declare they have no conflict of interest. The funding organizations had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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