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Low Serum Albumin Levels are Associated with Short-Term Recurrence of Arteriovenous Fistula Failure

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Background: Vascular access intervention therapy (VAIVT) is widely used as a treatment for arteriovenous fistula (AVF) failure. However, recurrent AVF failure is a major concern for dialysis patients. By prospectively observing patients after an initial VAIVT, we attempted to identify risk factors for developing restenosis of AVF.

Methods: This single-center prospective study evaluated 57 patients who underwent their first VAIVT procedure at our hospital from April 2022 through March 2023. We performed blood and biochemical tests during the first VAIVT to collect data on clinical variables. Ultrasonography was used to measure vessel diameter reduction rate, flow volume (FV) reduction rate, and increase in resistance index (RI) rate over a 3-month period.

Results: Within 3 months, 24 patients developed short-term shunt stenosis and 30 did not. Three were not traceable. In a comparison of the two groups, significant differences were observed in albumin (ALB), FV, RI, and elbow shunt. Analysis of change rates in the three ultrasound findings identified five factors (hematocrit, platelet count, activated partial thromboplastin time, ALB, and FV). The results of logistic regression models revealed that ALB was the most significant predictive factor for short-term shunt stenosis ($p = 0.031$).

Conclusion: In conclusion, our findings suggest that low serum ALB at the time of initial VAIVT is a significant risk factor for short-term recurrence of AVF failure in hemodialysis patients. These findings emphasize the importance of careful routine monitoring to reduce the risk of AVF failure and associated complications. (J Nippon Med Sch 2024; 91: 383–390)

Key words: arteriovenous fistula, arteriovenous fistula failure, vascular access intervention therapy, albumin

Introduction

Securing vascular access (VA) is essential for end-stage renal disease patients undergoing hemodialysis. Types of VA include autogenous arteriovenous fistula (AVF), synthetic arteriovenous graft (AVG), arterial superficialization, direct arterial puncture, long-term implanted venous catheter, and temporary venous catheter. The type of VA selected can impose a substantial burden on patients in terms of hospitalization, procedures, and costs and can affect survival[1]. AVF is considered the best type of VA, as it has the lowest rate of major VA-related complications such as stenosis, occlusion, and infection[2–4].

Percutaneous transluminal angioplasty, referred to as VA intervention therapy (VAIVT), is widely performed as a treatment for dialysis shunt stenosis or occlusion. It is less invasive than surgery, can be repeated in cases of recurrence, and is performed in AVF or AVG failure cases[5,6]. However, stenosis may recur after a short period[7,8]. If restenosis occurs within 3 months of VAIVT, it poses major physical and economic burdens that require action.

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Although the pathophysiological mechanisms underlying VA complications are not fully understood, they are associated with activation and migration of vascular cells, extracellular matrix remodeling, and inappropriate remodeling due to complex interactions among cytokines, adhesion molecules, and inflammatory mediators[8]. Serum mineral metabolism concentrations such as fibroblast growth factor-23, parathyroid hormone, phosphate, calcium, and vitamin D may be related to post-AVF surgery functional impairment, but there is no consensus on this matter[9–11]. Discovering potential prognostic factors and subsequent intervention targets may aid in developing new prevention and treatment strategies.

Identifying the characteristics of such cases will help prevent recurrence of AVF stenosis and reveal cases in which a repeat surgery should be performed, thus reducing invasiveness for dialysis patients and contributing to healthcare economics.

Methods

In this single-center prospective study, we enrolled patients who provided written informed consent for study participation. Those who declined to participate in the trial were not enrolled. The study protocol was approved by the Ethics Committee of the Nippon Medical School Musashi Kosugi Hospital (approval number: 621-3-16) and registered. The study was performed in accordance with the principles of the Helsinki Declaration.

Subjects

The present participants were patients between 20 and 85 years of age who were undergoing hemodialysis for chronic kidney disease. The study was conducted between April 2022 and March 2023 at the Department of Nephrology, Nippon Medical School Musashi Kosugi Hospital. The patients selected for the study underwent their first VAIVT procedure during the above period and developed shunt stenosis. The selection criteria for the study were as follows: well-controlled uremia in a patient on dialysis for at least 3 months, no symptoms of heart failure, and provision of written informed consent.

Measurements

The survey included items such as age at the time of the first VAIVT, sex (37 males and 17 females), body mass index, history of smoking and alcohol consumption, presence of hypertension and diabetes, medication use (antiplatelet drugs such as aspirin, clopidogrel sulfate, and cilostazol, anticoagulants like warfarin potassium, and HMG-CoA reductase inhibitors such as atorvastatin calcium hydrate, pitavastatin calcium hydrate, and rosuvastatin calcium), VA site and type, and several hematological variables, including white blood cell count (WBC), red blood cell count (RBC), hemoglobin (Hb), hematocrit (Ht), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count (Plt), prothrombin time (PT seconds and %), international normalized ratio of PT, activated partial thromboplastin time (APTT), PT/APTT ratio, sodium (Na), potassium (K), chloride (Cl), calcium (Ca), phosphorus (P), total protein (TP), albumin (ALB), urea nitrogen (BUN), creatinine (Cr), total bilirubin (T-Bil), total cholesterol (TC), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), intact parathyroid hormone (iPTH), fibroblast growth factor-23 (FGF-23), adiponectin, high-sensitivity C-reactive protein (HS-CRP), protein C activity, protein S activity, total plasma homocysteine, and high-molecular-weight adiponectin.

Furthermore, endovascular ultrasonography was performed to measure VA, brachial artery blood flow volume (FV), and resistance index (RI) after the first VAIVT procedure.

Endovascular Ultrasonography

The vascular ultrasound examination was performed by a skilled operator using a Canon Aplio 300 ultrasound diagnostic device with a 7.5-MHz surface linear peripheral vascular ultrasound probe. The operator measured the FV and RI of the transvascular brachial artery in the AVF-implanted limb.

Exploration of forearm-to-upper arm veins was conducted using B-mode and color Doppler methods to determine the course of the vessels and the characteristics of any lesions. To assess the vessels, the longitudinal and biaxial directions were observed to determine vessel diameter, degree of stenosis, condition of the intima, calcification, and the status and extent of thrombosis.

In cases of occlusive lesions, the absence of color signals and the status of thrombosis were evaluated. For nonthrombotic occlusions, occluded cord-like vascular structures and collateral pathways were assessed. The functional assessment measured FV and RI. An FV of 500 mL/min or less and an RI of 0.6 or higher were considered abnormal, and in conjunction with the aforementioned measurements, suitability for VAIVT was determined[12].

Statistical Analysis

Differences in clinical characteristics and outcomes between the shunt stenosis and nonstenosis groups were compared using the unpaired t-test or Fisher's exact test.

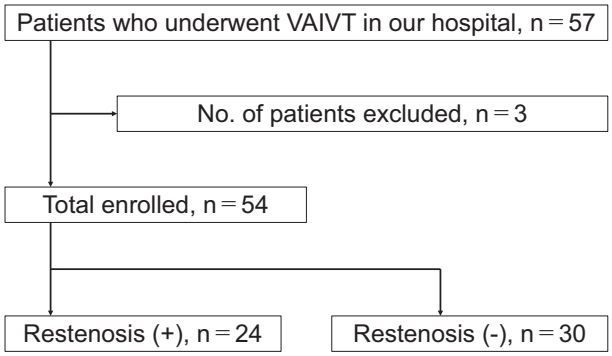

Fig. 1 Flowchart of the study design
Abbreviations: VAIVT, vascular access intervention therapy

To identify prognostic factors independently related to outcome, we first analyzed changes in three ultrasound findings: vessel diameter decrease rate, FV decrease rate, and RI increase rate. Factors associated with each of these variables were examined using multiple linear regression analysis.

To acquire covariates the factors obtained in the above analysis were compared with potential confounding factors reported in previous studies as clinical risk factors for shunt stenosis. Factors contributing to shunt stenosis were then examined using logistic regression analysis. Continuous variables are expressed as median and standard deviation, and categorical variables as numbers and percentages. A significance level of $p < 0.05$ was used. All statistical analyses were performed using Prism 10 (GraphPad Software, La Jolla, CA, USA).

Results

Patient Characteristics

A total of 57 patients were enrolled; 3 (5.3%) died or transferred to another hospital, and 54 patients were thus included in the final analysis (**Fig. 1**).

Within 3 months, 24 patients developed short-term shunt stenosis, while 30 did not. **Table 1** shows the baseline results for the two groups. In the intergroup comparisons (unpaired t-test), significant differences were observed in ALB ($p = 0.0283$), FV ($p = 0.0093$), RI ($p = 0.0057$), and elbow shunt ($p = 0.0358$).

Identification of Factors Associated with Changes in Ultrasound Findings

In our study, univariate analysis (simple linear regression) of the vessel diameter decrease rate identified APTT ($p = 0.0445$) and FV ($p = 0.0279$) as significant factors, leading to further analysis using multivariate regression. As shown in **Table 2**, both were found to be significant factors.

In the analysis of FV decrease rate, simple linear regression showed significant differences for Ht ($p = 0.0406$) and ALB ($p = 0.0412$), which were confirmed by multiple linear regression (**Table 3**).

For the RI increase rate, simple linear regression indicated significant differences for platelet count ($p = 0.0161$), APTT ($p = 0.0009$), and RI ($p = 0.0233$). In multiple linear regression, platelet count and APTT were identified as significant factors (**Table 4**).

Exploration of Predictive Factors for Shunt Stenosis in the Short Term

Among factors identified (Ht, Plt, APTT, ALB, FV) in the analysis of the change rates of the three ultrasound findings (vessel diameter decrease rate, FV decrease rate, and RI increase rate), we attempted to identify those that could potentially become predictive factors for shunt stenosis. All were considered to affect the outcome from a medical perspective. However, because of the relationship between the number of events and total number of patients, a maximum of three explanatory variables could be included in the analysis. On the basis of the results of univariate analysis, we selected APTT, ALB, and FV, and the examination results using logistic regression models revealed that ALB was the most significant predictive factor for short-term shunt stenosis ($p = 0.031$, **Table 5**).

Correlation of Serum ALB Levels with the Three Ultrasound Findings

On the basis of the above results, we used Spearman's rank correlation coefficients to test the correlation between ALB and the three ultrasound findings. The results showed that vessel diameter decrease rate was significantly correlated with ALB ($r = 0.3088$, $p = 0.0231$, **Fig. 2**) and that FV decrease rate and ALB were also correlated significantly ($r = 0.3653$, $p = 0.0066$, **Fig. 3**). These results indicate that each ultrasound finding tends to worsen with decreasing ALB. However, ALB and the RI increase rate were not significantly correlated.

Discussion

During the half century since the introduction of hemodialysis using AVF, advances in technology and postoperative care have led to an increase in the patency rate. However, AVF maturation failure and the incidence of stenosis have remained high, and cases of rapid restenosis or occlusion are not uncommon[13,14]. One study reported that approximately 60% of patients became unfit for dialysis within 6 years of AVF creation[15].

AVF stenosis is believed to result from vascular remod-

Table 1 Baseline characteristics and parameters of patients

total, n	Patients with shunt stenosis n = 24	Patients without shunt stenosis n = 30	*P* Value*
Female, n (%)	9 (37.5)	8 (26.7)	0.394
Age (years)	63.56 ± 11.75	61.99 ± 15.25	0.210
BMI (kg/m^2)	23.91 ± 4.10	23.84 ± 4.03	0.363
Physical disability, n (%)	2 (8.3)	2 (6.7)	0.816
Smoking, n (%)	3 (12.5)	5 (16.7)	0.668
Alcohol, n (%)	7 (29.2)	8 (26.7)	0.839
Hypertension, n (%)	22 (91.7)	24 (80.0)	0.231
Diabetes mellitus, n (%)	15 (62.5)	16 (53.3)	0.499
Antiplatelet drugs, n (%)	11 (45.8)	8 (26.7)	0.143
Anticoagulants, n (%)	1 (4.2)	2 (6.7)	0.690
Statin, n (%)	8 (33.3)	8 (46.7)	0.322
Brachial artery shunt, n (%)	0 (0.0)	5 (16.7)	0.036
WBC (10^3/μL)	6.296 ± 1.847	5.704 ± 1.479	0.197
RBC (10^6/μL)	3.803 ± 0.5805	3.737 ± 0.494	0.658
Hb (g/dL)	11.38 ± 1.313	11.49 ± 1.253	0.739
Ht (%)	36.54 ± 4.047	36.17 ± 3.812	0.730
PLT (10^3/μL)	196.3 ± 62.12	186.7 ± 54.45	0.548
PT (INR)	1.033 ± 0.170	1.060 ± 0.176	0.573
APTT (sec)	33.86 ± 10.62	33.51 ± 8.458	0.892
Na (mEq/L)	139.7 ± 2.79	139.5 ± 3.23	0.728
K (mEq/L)	4.68 ± 0.669	4.73 ± 0.644	0.796
Cl (mEq/L)	104.5 ± 2.34	103.2 ± 3.31	0.129
Ca (mg/dL)	8.45 ± 0.810	8.71 ± 0.642	0.201
P (mg/dL)	4.66 ± 1.553	4.54 ± 1.050	0.723
TP (g/dL)	6.51 ± 0.629	6.61 ± 0.612	0.569
ALB (g/dL)	3.51 ± 0.367	3.76 ± 0.413	0.028
BUN (mg/dL)	43.35 ± 17.74	43.66 ± 14.51	0.945
Cr (mg/dL)	7.005 ± 2.613	7.757 ± 2.628	0.299
UA (mg/dL)	4.63 ± 2.182	4.37 ± 1.654	0.622
T-Bil (mg/dL)	0.305 ± 0.127	0.293 ± 0.131	0.734
TC (mg/dL)	146.3 ± 26.69	149.2 ± 27.03	0.705
HDL-C (mg/dL)	48.8 ± 14.01	48.6 ± 14.89	0.945
LDL-C (mg/dL)	78.1 ± 24.09	79.1 ± 24.69	0.894
iPTH (pg/mL)	192.2 ± 101.06	200.6 ± 99.77	0.759
FGF23 (pg/mL)	2,296.8 ± 2,999.9	2,518.7 ± 2,871.1	0.783
Adiponectin LA (μg/mL)	19.56 ± 8.62	22.09 ± 16.74	0.505
HS-CRP (mg/dL)	0.981 ± 2.325	0.372 ± 0.601	0.174
Protein C activity (%)	89.5 ± 23.39	89.8 ± 24.62	0.956
Protein S activity (%)	85.6 ± 19.24	84.8 ± 20.11	0.883
Blood total homocysteine (nmol/mL)	23.97 ± 8.727	25.33 ± 8.607	0.568
High molecular weight adiponectin (μg/mL)	9.02 ± 4.838	10.22 ± 9.351	0.573
Vascular Diameter (mm)	1.29 ± 0.556	1.44 ± 0.489	0.295
Flow Volume (mL/min)	324.3 ± 162.1	504.0 ± 291.1	0.009
Resistance Index	0.657 ± 0.117	0.566 ± 0.113	0.006

Notes: Plus-minus values are means ± standard division.

*P values are for the comparisons between patients with and without shunt stenosis

Abbreviations: BMI, body mass index; WBC, white blood cell; RBC, red blood cell; Hb, Hemoglobin; Ht, hematocrit; PLT, platelet; PT, prothrombin time; APTT, activated partial thromboplastin time; Na, sodium; K, potassium; Cl, chlorine; Ca, calcium; P, phosphorus; TP, total protein; ALB, albumin; BUN, blood urea nitrogen; Cr, creatinine; UA, uric acid; T-Bil, total bilirubin; TC, total cholesterol; HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol; iPTH, intact-parathyroid hormone; FGF23, fibroblast growth factor-23; LA, Latex agglutination immunoassay; HS-CRP, high sensitive C-reactive protein.

Table 2 Multiple linear regression for Vascular diameter decrease rate

Variables	Estimate	Standard error	*t* value	*p* value
APTT (sec)	0.09636	0.2963	0.3252	<0.0001
Flow Volume (mL/min)	0.03445	0.01084	3.179	0.0025

Abbreviation: APTT, activated partial thromboplastin time

Table 3 Multiple linear regression for Flow Volume decrease rate

Variables	Estimate	Standard error	*t* value	*p* value
Ht (%)	1.319	1.91	0.6905	<0.0001
ALB (g/dL)	42.44	18.15	2.338	0.0233

Abbreviations: Ht, hematocrit; ALB, albumin

Table 4 Multiple linear regression for Resistance Index increase rate

Variables	Estimate	Standard error	*t* value	*p* value
PLT (10^3/μL)	–0.1566	0.06812	2.298	0.0258
APTT (sec)	–1.284	0.4362	2.945	0.0049
Resistance Index	–42.45	33.38	1.271	0.2094

Abbreviations: PLT, platelet; APTT, activated partial thromboplastin time

Table 5 Multiple logistic regression for Shunt stenosis

Variables	Estimate	Standard error	Odds ratio (95%CI)	*p* value
APTT (sec)	0.00407	0.02935	1.004 (0.9450-1.066)	0.214
ALB (g/dL)	–1.244	1.143	0.2883 (0.02491-2.241)	0.031
Flow Volume (mL/min)	–0.003495	0.001451	0.9965 (0.9934-0.9991)	0.073

Abbreviations: APTT, activated partial thromboplastin time; ALB, albumin

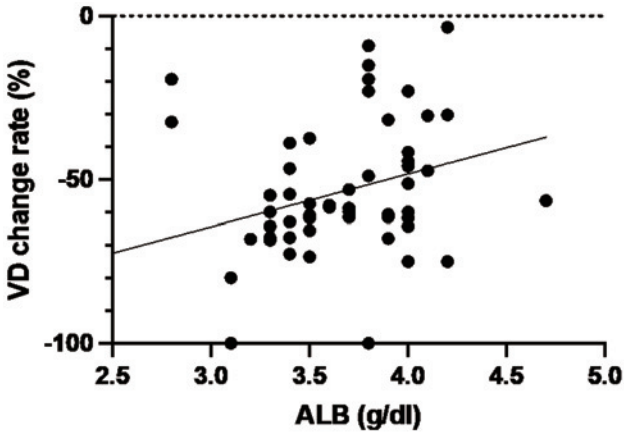

Fig. 2 Correlation of albumin and vessel diameter decrease rate
Equation: y = 16.06*x – 112.6, r = 0.3088, p = 0.0231
Abbreviations: ALB, albumin; VD, vessel diameter

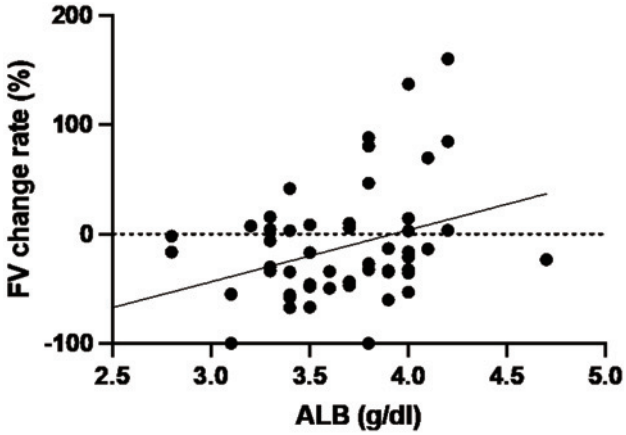

Fig. 3 Correlation of albumin and flow volume decrease rate
Equation: y = 47.24*x – 185.3, r = 0.3653, p = 0.0066
Abbreviations: ALB, albumin; FV, flow volume

eling failure caused by inflammation, oxidative stress, and hemodynamic stress, combined with subsequent excessive remodeling, leading to uncontrollable progressive neointimal hyperplasia[16–19]. Oxidative stress occurs throughout the entire process of AVF maturation, including the underlying vascular condition before surgery, surgical injury during the procedure, and hemodynamic changes after surgery[20,21].

VAIVT is less invasive than surgery and can be repeated in cases of recurrence and has thus been widely used at Nippon Medical School Musashi Kosugi Hospital to treat AVF and AVG stenosis and occlusion. We introduced ultrasound-guided VAIVT in 2018, and as of 2022, approximately 80% (200) of the 250 VAIVT procedures were performed under ultrasound guidance. We have been conducting ultrasound examinations every 3 months for approximately 150 outpatients and for patients suspected of having central stenosis. For other challenging cases, we have also elected to use ultrasound-guided VAIVT. Because of the number of such cases, we planned this research.

Patient Characteristics

A comparison of patients who developed shunt stenosis after the initial VAIVT and those who did not revealed significant differences in ALB, FV, RI, and elbow shunt. FV and RI of the shunt limb brachial artery have been reported as markers for evaluating the risk of shunt stenosis in hemodialysis patients[22,23]. Although no study has evaluated the patency rate for the diameter of each vessel of the arteriovenous access route, the size of the arteriovenous access route is an important factor for patency of the internal shun[24–26]. The patency rate is expected to be higher for elbow shunts than for forearm shunts, because of the larger diameter of the arteriovenous access route, which is consistent with clinical impressions.

Identification of Factors Associated with Changes in Ultrasound Findings

In our study, the analysis of the rate of decrease in FV showed that both Ht and ALB were significant factors (**Table 3**). Furthermore, in the analysis of the rate of increase in RI, platelet count and APTT were significant factors (**Table 4**). Although previous studies did not report a significant contribution to shunt stenosis, this study found a significant correlation between the rate of decrease in FV and Ht. APTT also showed a significant difference in the rate of increase in RI; however, similar to Ht, no previous report has indicated such an association. Although there were no reports of a significant difference in platelet count alone, a previous study found that in patients with AVF dysfunction, there was a significant increase over time in mean platelet volume (MPV) and MPV/platelet count ratio, as compared with patients with no AVF dysfunction[27,28]. Since a larger platelet count should lead to a decrease in MPV/platelet count ratio, our results are inconsistent with this previous finding.

Exploration of Predictive Factors for Shunt Stenosis in the Short Term

Our logistic regression model identified ALB as the strongest predictive factor in short-term shunt stenosis (**Table 5**). Testing the correlation between ALB and the rate of change of the three ultrasound findings, we found a significant correlation between the rate of decrease in FV and the rate of decrease in vessel diameter. The dependence of AVF patency on FV and vessel diameter has been previously reported and is widely recognized[29]. In general, as plasma volume decreases, serum ALB increases. Therefore, it is assumed that higher ALB levels would have a negative impact on AVF patency and correlate with worse ultrasound findings, which was not the case in our study. However, some reports support our results.

Previous studies have reported an association between preoperative C-reactive protein (CRP)/ALB ratio (CAR) and AVF dysfunction[30]. A study of a cohort of 726 hemodialysis patients, 29.2% of whom experienced AVF dysfunction during a median follow-up period of 36 months, found a dose-dependent correlation between CAR and AVF dysfunction. In addition, for each 1-unit increase in CAR, the risk of AVF dysfunction increased by 31%, and the highest CAR value was an independent predictor of AVF dysfunction[30]. Systemic inflammation can lead to scarring, stenosis, and clotting, thus reducing AVF function and patency[31–33]. Including the above, several reports have suggested that systemic inflammation may be a mechanism by which reduced ALB contributes to AVF stenosis[34,35].

In our study, high-sensitivity CRP was not a risk factor for AVF restenosis in patients after initial VAIVT. However, ALB correlated with AVF dysfunction and changes in FV and RI rates and was a risk factor for AVF restenosis in patients after the initial VAIVT. While previous reports explored the relationship between risk factors for access dysfunction after AVF creation, our study focused on the risk factors for restenosis after VAIVT in patients who had experienced access dysfunction after AVF creation. Even after AVF creation and VAIVT, the same

mechanism may be involved in AVF dysfunction, and ALB may play an important role in maintaining shunt patency.

Conclusion

In conclusion, our study suggests that low serum ALB levels at the time of initial VAIVT are a significant risk factor for short-term recurrence of AVF dysfunction in hemodialysis patients. Furthermore, AVF dysfunction should be noted in patients with high Ht and platelet counts and short APTT. However, given the limitations of this single-center study, future large-scale prospective studies are needed to clarify the causal relationship between serum ALB levels, Ht, platelet counts and APTT and AVF dysfunction. These findings emphasize the importance of careful consideration of routine monitoring in hemodialysis patients, to reduce the risk of AVF dysfunction and associated complications.

Data availability: All data generated or analyzed during this study are available from the corresponding author on request.

Authors' Contributions: YO wrote the first draft of the manuscript and collected the data. AI, TK, and MI helped design the study. YS coordinated the data analysis and helped revise the manuscript. All authors participated in discussions of the manuscript and read and approved the final manuscript.

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Conflict of Interest: None declared.

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