Original Article
Yonsei Med J 2021 Nov;62(11):990-996
https://doi.org/10.3349/ymj.2021.62.11.990
Yonsei Medical Journal
YMJ
pISSN: 0513-5796 · eISSN: 1976-2437

Transcatheter Aortic Valve Replacement with Minimal Contrast Dye in Patients with Renal Insufficiency

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Purpose: Concerns have been consistently raised in regards to the considerable amount of contrast dye used during transcatheter aortic valve replacement (TAVR) in patients with renal insufficiency. In the present study, we introduced minimal contrast TAVR and compared its 30-day clinical outcomes with conventional TAVR.

Materials and Methods: We retrospectively investigated 369 patients who underwent TAVR between July 2011 and April 2020 in our institute. Among them, 93 patients with severe aortic stenosis and renal insufficiency (estimated glomerular filtration rate ≤50 mL/min/1.73 m^2) were included and divided into a conventional TAVR group (n=56) and a minimal contrast TAVR group (n=37). In the minimal contrast TAVR group, the total amount of contrast was <10 mL during the entire TAVR procedure. Thirty-day major adverse clinical events (MACE), including death, stroke, implantation of permanent pacemaker, and initiation of hemodialysis, were investigated.

Results: The incidence of MACE was significantly lower in the minimal contrast TAVR group than the conventional TAVR group (16.2% vs. 42.9%, p=0.010). Death occurred in 9 patients (16.1%) in the conventional TAVR group and in 0 patients in the minimal contrast group (p=0.011). Hemodialysis was initiated in 2 patients (5.4%) in the minimal contrast TAVR group and in 7 patients (12.5%) in the conventional TAVR group (p=0.256). Multivariate regression analysis showed that the minimal contrast TAVR procedure was an independent predictor for reducing MACE (hazard ratio 0.208, 95% confidence interval: 0.080–0.541, p=0.001).

Conclusion: Minimal contrast TAVR is feasible and shows more favorable short-term clinical outcomes than conventional TAVR in patients with renal insufficiency.

Key Words: Aortic stenosis, renal insufficiency, transcatheter aortic valve replacement

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is now an accepted treatment option for high and intermediate risk patients suffering from severe aortic stenosis (AS). Significant advances in TAVR have been achieved since it was first introduced in 2002, such as procedural experience, cooperation between multi-disciplinary cardiac teams, and device evolution.[1] Consequently, TAVR has become widespread, and results from recent randomized trials have extended the indications for TAVR to patients with intermediate[2,3] and even low surgical risk.[4,5] However, as the population ages, the number of high risk patients with multiple comorbidities continues to grow. Among several comorbidities, chronic kidney disease (CKD) is one of the most frequent and serious, potentially affecting clinical outcome in patients who undergo TAVR.[6-8] Indeed, advanced CKD has been shown to be associated with a higher rate of mortality in previous TAVR studies.[7,9,10] In patients with CKD, it is well known that excessive use of contrast dye during an interventional procedure is signif-

Received: April 28, 2021 **Revised:** August 26, 2021
Accepted: September 3, 2021
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The study was presented at American Heart Association (AHA) Scientific Sessions 2019 and the Korean Society of Cardiology (KSC) 2019.
•Myeong-Ki Hong and Young-Guk Ko are proctors of Medtronic. The other authors have nothing to disclose.

icantly associated with aggravation of renal function:[11] considerable amounts of contrast are used in several steps before, during, and after TAVR and might be associated with poor clinical outcomes due to aggravation of renal function, despite successful TAVR procedures, in patients with CKD. Recently, "minimal contrast TAVR," in which the use of contrast is restricted under comprehensive evaluation by ultrasound, was introduced.[12,13] In the present study, the feasibility and safety of the minimal contrast TAVR procedure were investigated, and the clinical outcomes between conventional and minimal contrast TAVR were compared in patients with both severe AS and renal insufficiency.

MATERIALS AND METHODS

Study population

From a database of 369 consecutive patients who underwent TAVR between July 2011 and April 2020, 113 patients with renal insufficiency defined by an estimated glomerular filtration rate (eGFR) ≤50 mL/min/1.73 m^2 were identified. Among the 113 patients with renal insufficiency, 20 were under hemodialysis and were excluded from analysis. The remaining 93 patients with renal insufficiency were included in the present study and were divided into two groups: conventional TAVR group (n=56 patients) and minimal contrast TAVR group (n=37 patients). The minimal contrast TAVR group comprised patients who received a total amount of contrast ≤10 mL during the entire TAVR procedure. The self-expandable CoreValve/Evolut R/Evolut PRO valve (Medtronic, Minneapolis, MN, USA), balloon expandable Sapien 3 valve (Edwards Lifescience, Irvine, CA, USA), mechanically implanted Lotus valve (Boston Scientific SciMed Inc, Maple Grove, MN, USA) were used. The study protocol was approved by the Institutional Review Boards of Severance Hospital, Yonsei University Health System (IRB No.1-2009-0018, 1-2011-0099), and all participants provided written informed consent.

Pre-procedural evaluation for minimal contrast TAVR

During the pre-evaluation period, various imaging modalities that use contrast, such as heart computed tomography (CT) and CT angiography of the brain, neck, aorta, and periphery, were replaced by ultrasound and non-contrast CT (Supplementary Fig. 1, only online). The only exceptions to contrast use were coronary angiography and percutaneous coronary intervention with minimal use of contrast dye.

Although measurement of the aortic annulus using transesophageal echocardiogram (TEE) provided good clinical results in a previous study,[14] there has been consistent concern regarding its accuracy because of the complex crown-like structure of the aortic annulus. Recently, various specified three-dimensional (3D) and four-dimensional (4D) analysis systems of echocardiography have been introduced.[15,16] Using an analysis system (eSie Value™ Advance Analysis Package, Siemens Healthcare, Mountain View, CA, USA), 4D TEE images were reconstructed from a two-dimensional TEE image, and crucial parameters, such as diameter, perimeter, or area of the aortic annulus and coronary height, were analyzed (Supplementary Fig. 1A and B, only online). Non-contrast cardiac CT allowed measurement of the aortic annulus and other parameters (Supplementary Fig. 1C, only online). Evaluation of the peripheral vascular structure and the course of aorta were possible with ultrasound for peripheral vessels and non-contrast CT for the aorta and lower extremities. In patients without neurologic deficits, brain and neck angiography were replaced with carotid ultrasound.

Performing the TAVR procedure with minimal use of contrast dye

During the procedure, the main steps of TAVR were performed exclusively with guidance from TEE. All patients underwent TAVR with a percutaneous transfemoral approach. Femoral artery and vein punctures were performed with support of peripheral ultrasound and without use of contrast. The key steps of TAVR are confirmation of placement of a pigtail catheter on the non-coronary cusp (Supplementary Fig. 2A, only online), pre-dilation with a balloon catheter (Supplementary Fig. 2B, only online), and implantation of a TAVR valve and its consequent hemodynamic state (such as interference of mitral valve or newly developed mitral regurgitation) and were continuously monitored by TEE (Supplementary Fig. 2C, only online). After the valve was deployed, an imaging specialist evaluated the degree of paravalvular leakage (PVL) and decided whether to perform post-balloon dilation or not (Supplementary Fig. 2D, only online). Therefore, the total amount of contrast used during the entire TAVR procedure could be ≤10 mL.

Clinical events

Major adverse clinical events (MACE) were defined as a composite of clinical events that included all-cause death, initiation of hemodialysis, implantation of permanent pacemaker, and stroke within 30 days after TAVR. The occurrence of any clinical event of interest was ascertained by review of hospital records. The additional event included the development of acute kidney injury (AKI), which was defined as an increase in serum creatinine at least 50% from baseline or an increase of 0.3 mg/dL.[17,18] The degree of PVL was evaluated by TEE immediately after the TAVR procedure, which was defined using the circumferential extent of PVL according to current guidelines.[19]

Statistical analysis

Continuous variables are presented as a mean±standard deviation, and categorical variables are expressed as a number and percentage. The patient groups were compared using Student's t-test for continuous variables and χ^2 statistics for categorical variables. Kaplan-Meier survival curves were employed to plot all clinical events according to the duration from first event.

The prognostic significance between minimal contrast TAVR and clinical outcome was investigated using univariate and multivariate Cox proportional hazards regression analysis. For multivariate analysis, variables with $p<0.25$ in univariate analysis were included in a stepwise manner (Model 1). As Society of Thoracic Surgeons (STS) score already includes age, sex, coronary artery disease, baseline Cr level, we separately performed multivariate analysis including minimal contrast TAVR and STS score (Model 2). All statistical analyses were performed using SPSS v. 22.0 (IBM Corp., Armonk, NY, USA). A value of $p<0.05$ was considered to indicate statistical significance.

RESULTS

The baseline clinical characteristics, laboratory findings, and echocardiographic results of the two groups are shown in Table 1. There were no statistically significant differences in baseline clinical characteristics between the two groups, except baseline serum creatinine and eGFR. There was a tendency for higher STS risk scores in the conventional TAVR group (10.5% vs. 7.1% in the minimal contrast TAVR group, $p=0.07$). AKI occurred in 11 patients (19.6%) in the conventional TAVR group and in 6 patients (16.2%) in the minimal contrast TAVR group, and initiation of new hemodialysis was required in 7 patients (12.5%) and in 2 patients (5.4%), respectively (Fig. 1). The 30-day clinical outcomes are shown in Table 2 and Fig. 2. The rates of MACE

Table 1. Baseline Characteristics

	Conventional TAVR (n=56)	Minimal contrast TAVR (n=37)	*p* value
Age, yr	82.6±5.7	82.0±4.5	0.544
Male	18 (32.1)	19 (51.4)	0.064
Height, cm	155.2±8.9	153.7±9.6	0.483
Weight, kg	56.3±10.8	57.9±10.9	0.529
Hypertension	48 (85.7)	30 (81.1)	0.552
Diabetes mellitus	25 (44.6)	21 (56.8)	0.253
Dyslipidemia	28 (51.9)	16 (43.2)	0.420
Chronic obstructive lung disease	5 (8.9)	0 (0.0)	0.062
Stroke	5 (8.9)	6 (16.2)	0.287
Atrial fibrillation	10 (17.9)	10 (27.0)	0.292
Coronary artery disease	33 (58.9)	18 (48.6)	0.330
History of myocardial infarction	7 (12.5)	4 (10.8)	0.805
Percutaneous coronary intervention	23 (41.1)	11 (29.7)	0.266
Coronary artery bypass grafting	4 (7.1)	2 (5.4)	>0.999
Peripheral artery disease	10 (17.9)	4 (10.8)	0.352
Serum creatinine (mg/dL)	1.63±0.59	1.96±0.58	0.012
eGFR (mg/dL)	38.5±9.2	32.5±7.2	0.001
STS score	10.5±13.0	7.1±4.2	0.070
Echocardiographic finding			
LVEF (%)	56.5±18.8	58.1±13.5	0.630
Peak AV pressure gradient (mm Hg)	80.4±32.9	83.5±21.8	0.595
Mean AV pressure gradient (mm Hg)	48.9±22.4	50.3±14.8	0.742
Aortic valve area (cm^2)	0.70±0.20	0.73±0.21	0.469
Procedural data			
Self-expandable device	49 (87.6)	33 (89.2)	0.625
CoreValve	23 (41.1)	0 (0.0)	<0.001
Evolut R	24 (42.9)	25 (67.6)	0.016
Evolut PRO	2 (3.6)	8 (21.6)	0.008
Balloon-expandable device	5 (8.9)	4 (10.8)	0.764
SAPIEN 3			
Mechanically implanted device	2 (3.6)	0 (0.0)	0.245
LOTUS			
Contrast amount (mL)	147.7±62.7	2.6±4.4	<0.001

AV, aortic valve; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; TAVR, transcatheter aortic valve replacement; STS, Society of Thoracic Surgeons.
Data are presented as mean±SD or n (%).

https://doi.org/10.3349/ymj.2021.62.11.990

were 42.9% in the conventional TAVR group and 16.2% in the minimal TAVR group (p=0.010), and the rates of all-cause death were 16.1% and 0%, respectively (p=0.011). The detailed description of mortality cases in conventional TAVR group are demonstrated in Supplementary Table 1 (only online). Among 9 patients, six underwent hemodialysis after TAVR, and 3 patients suffered from bleeding events that might be related to mortality. In Cox regression analysis, the minimal contrast TAVR pro-

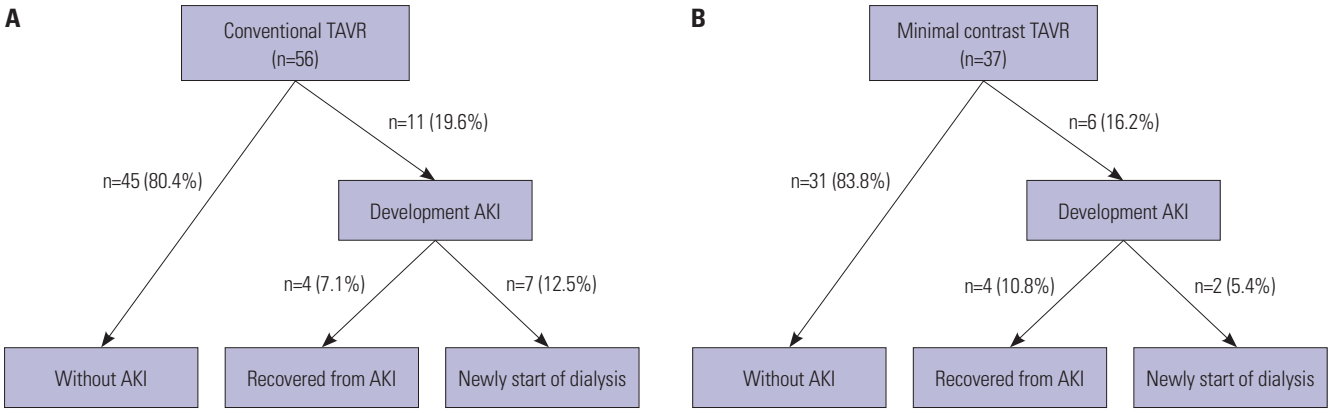

Fig. 1. Development of AKI and initiation of dialysis in conventional TAVR (A) and minimal contrast TAVR (B). AKI, acute kidney injury; TAVR, transcatheter aortic valve replacement.

Table 2. Clinical Outcomes at 30 Days

Clinical outcomes	Conventional TAVR (n=56)	Minimal contrast TAVR (n=37)	*p* value by log-rank test
Major adverse clinical events (all-cause death, stroke, implantation of permanent pacemaker, or initiation of dialysis)	24 (42.9)	6 (16.2)	0.010
All-cause death	9 (16.1)	0 (0.0)	0.011
Initiation of dialysis	7 (12.5)	2 (5.4)	0.256
Implantation of a permanent pacemaker	12 (21.4)	2 (5.4)	0.037
Stroke	2 (3.6)	2 (5.4)	0.663

TAVR, transcatheter aortic valve replacement.
Data are presented as n (%).

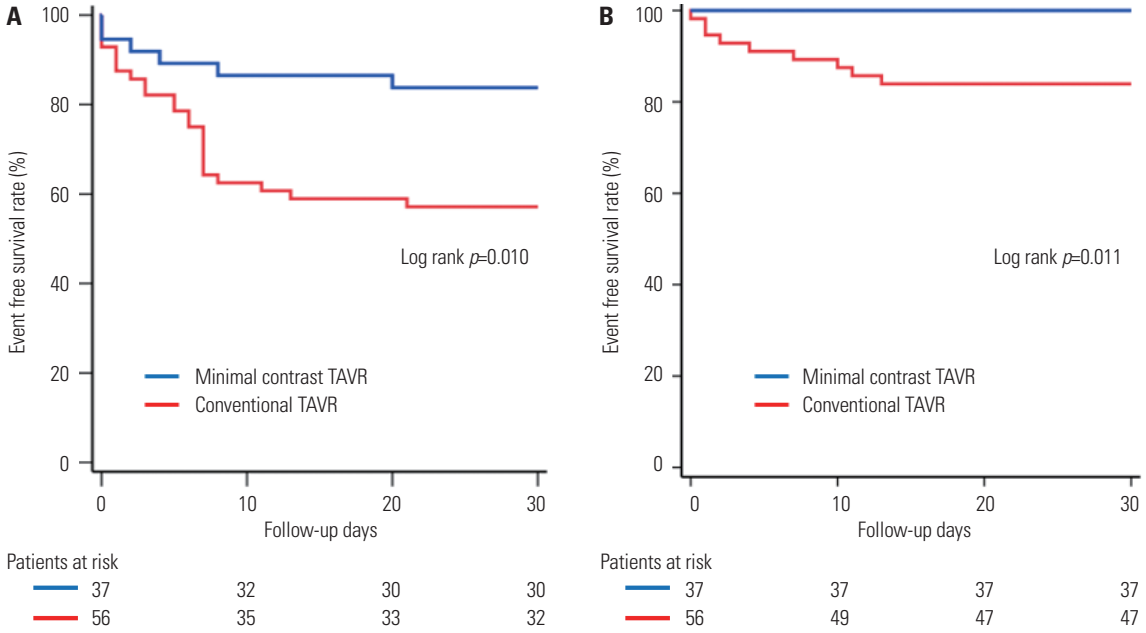

Fig. 2. Cumulative incidence of (A) major adverse events, including all-cause death, permanent pacemaker implantation, initiation of dialysis, or stroke, and (B) all-cause death within 30 days. TAVR, transcatheter aortic valve replacement.

Table 3. Predictors for Major Adverse Clinical Events

	Univariate		Multivariate (Model 1)		Multivariate (Model 2)	
	HR (95% CI)	*p* value	HR (95% CI)	*p* value	HR (95% CI)	*p* value
Age	0.982 (0.912–1.057)	0.630				
Female sex	0.570 (0.278–1.166)	0.124	0.495 (0.230–1.065)	0.072		
Baseline serum Cr (mg/dL)	1.486 (0.909–2.427)	0.114	1.718 (1.021–2.891)	0.042		
Previous PCI or CABG	1.264 (0.617–2.590)	0.523				
STS score	1.047 (1.021–1.075)	<0.001			1.042 (1.015–1.069)	0.002
Minimal contrast TAVR	0.330 (0.135–0.808)	0.015	0.208 (0.080–0.541)	0.001	0.372 (0.150–0.922)	0.033

CABG, coronary artery bypass grafting; CI, confidence interval; HR, hazard ratio; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.
Major adverse clinical events comprised composite events of all-cause death, stroke, implantation of permanent pacemaker, or initiation of dialysis.

Table 4. Incidence of Paravalvular Leakage

	Conventional TAVR (n=53)	Minimal contrast TAVR (n=37)	*p* value
No	10 (18.9)	8 (21.6)	0.748
Mild	29 (54.7)	27 (73.0)	0.079
Moderate	12 (22.6)	2 (5.4)	0.026
Severe	2 (3.8)	0 (0.0)	0.232
≥Moderate to severe	15 (26.8)	2 (5.4)	0.009

TAVR, transcatheter aortic valve replacement.
Data are presented as n (%).

cedure was an independent predictor for reductions in MACE (hazard ratio 0.208, 95% confidence interval 0.080–0.541, *p*=0.001) (Table 3).

When we additionally analyzed the data for patients who underwent TAVR in the late period of the study, after 2015, favorable clinical outcomes in MACE and all-cause death in minimal contrast TAVR group (n=37) were still demonstrated (Supplementary Table 2, only online). Moreover, minimal contrast TAVR was a significant prognostic factor for lower MACE after adjusting for STS scores or other variables, such as age, baseline Cr, and previous revascularization (Supplementary Table 3, only online).

When comparing the incidence of moderate-to-severe PVL between the two groups, the minimal contrast TAVR group showed a lower incidence of moderate-to-severe PVL than the conventional TAVR group (5.4% vs. 26.8%, *p*=0.009) (Table 4). However, when additionally analyzing the patients' data in the late period of the study, after 2015, there was no significant difference between the two groups (5.4% vs. 16.7% in moderate-to-severe PVL, *p*=0.122).

DISCUSSION

The present study showed that, compared to conventional TAVR, minimal contrast TAVR might be associated with more beneficial clinical outcomes (reduction of MACE and all-cause death) in patients with both severe AS and renal insufficiency. Minimal contrast TAVR was an independent prognostic factor for favorable clinical outcome in those patients.

Although the indications for TAVR are expanding to patients with lower surgical risk and younger age, there is a growing population of patients with severe AS and multiple co-morbidities that not only poses high surgical risk but also high procedural risk. CKD is a common underlying disease in patients with severe AS. Even in randomized studies with a large study population with high surgical risk, the incidence of patients with CKD was approximately 10% to 13%.[20,21] However, real-world registry data revealed a substantial number of patients with CKD who underwent TAVR, ranging from 37.9% to 73.0%.[6,7,9,10] Previous studies have consistently reported that advanced CKD is associated with worse clinical outcomes, including higher incidences of short and long term mortality and bleeding events, after TAVR.[4,7,10,22,23] Meanwhile, observational research on 30-day mortality after TAVR in advanced CKD patients has reported rates ranging from 8% to 26%.[24-26] The requirement for dialysis after TAVR, in particular, has been shown to be associated with poor clinical outcomes, eliciting a 30-day mortality rate of 35%, which is 6.44 times higher than that of patients without dialysis.[7] All of these findings suggest that there is a need for studies on risk stratification, prevention strategies, and postoperative management of TAVR in patients with both severe AS and CKD. However, there are scarce data regarding these patients. Interestingly, one small study reported a benefit from pre- and post-procedural fluid therapy accompanied by furosemide-induced diuresis for prevention of contrast-induced nephropathy.[9]

Research has shown that requirement of dialysis and onset of AKI after TAVR depends on the amount of contrast agent used during the TAVR procedure.[11] Therefore, the key for prevention of deteriorating renal function and worsening clinical outcomes in patients with CKD may involve minimizing the use of contrast dye during both the TAVR procedure and pre-TAVR assessment (i.e., heart, aorta, and peripheral vessel CT). Although sufficient use of contrast dye might allow TAVR to be performed more successfully, it simultaneously poses a higher risk of deterioration of renal function. On the other hand, there might be a concern for a higher possibility of procedural failure or unexpected complication when no or minimal contrast is used during both the TAVR procedure and pre-TAVR assessment.

https://doi.org/10.3349/ymj.2021.62.11.990

However, accumulating experience with TAVR has revealed that the limitations of minimal contrast TAVR can be overcome with the help of ultrasound and non-contrast CT: TEE-based 3D and 4D reconstruction in the pre-TAVR assessment; guidance and determination of successful TAVR during the procedure; and peripheral vessel Doppler ultrasound for evaluation of the status of peripheral vessels and sonography-guided femoral artery puncture.

The present study has some limitations. First, this study was a single-center, retrospective, observational study that had inherent limitations. Second, the sample size was small, and the study period was too broad to provide strong statistical power to show clinical differences. Actually, individual clinical outcomes, such as newly starting dialysis and development of AKI were numerically lower in the minimal contrast TAVR group, although the differences were not statistically significant. In addition, as minimal contrast TAVR was performed in the late period of the study with the next generation TAVR valves, it may affect the degree of PVL and possibly clinical outcomes, and data on some parameters, including calcification score, that might affect the degree of PVL were lacking. Notwithstanding, we achieved a procedural success rate of 100% with minimal contrast TAVR, and there was no 30-day mortality, with relatively low incidences of pacemaker implantation and significant PVL. From these results, we suggest that minimal contrast TAVR with TEE guidance is feasible and safe and may be considered as an alternative treatment strategy for severe AS patients with renal insufficiency. Further studies with a larger study population could clarify the clinical benefit of minimal contrast TAVR in patients with severe AS and renal insufficiency.

In conclusion, minimal contrast TAVR under TEE guidance is feasible and safe in severe AS patients with renal insufficiency and may provide more favorable clinical benefits in terms of MACE and all-cause death.

ACKNOWLEDGEMENTS

This work was supported by grants from the Korea Health Technology Research & Development Project through the Korea Health Industry Development Institute, funded by the Ministry of Health & Welfare, Republic of Korea (No. HI17C0882, HI16C2211, and HI15C2782), the Bio & Medical Technology Development Program of the National Research Foundation funded by the Korean government (No. 2015M3A9C6031514), and the Cardiovascular Research Center, Seoul, Korea.

AUTHOR CONTRIBUTIONS

Conceptualization: Myeong-Ki Hong and Geu-Ru Hong. Data curation: all authors. Formal analysis: Jah Yeon Choi. Funding acquisition: Myeong-Ki Hong. Investigation: Jah Yeon Choi, Geu-Ru Hong, Sung-Jin Hong, Chi Young Shim, Chul-Min Ahn, Jung-Sun Kim, Byeong-Keuk Kim, Young-Guk Ko, and Myeong-Ki Hong. Methodology: Jah Yeon Choi, Geu-Ru Hong, Chi Young Shim, Chul-Min Ahn, Young-Guk Ko, and Myeong-Ki Hong. Project administration: Jah Yeon Choi, Geu-Ru Hong, Chi Young Shim, Chul-Min Ahn, Young-Guk Ko, and Myeong-Ki Hong. Resources: Myeong-Ki Hong and Geu-Ru Hong. Software: Jah Yeon Choi, Geu-Ru Hong, and Myeong-Ki Hong. Supervision: Geu-Ru Hong, Myeong-Ki Hong, Donghoon Choi, and Yangsoo Jang. Validation: Jah Yeon Choi, Sung-Jin Hong, Geu-Ru Hong, and Myeong-Ki Hong. Visualization: Jah Yeon Choi. Writing—original draft: Jah Yeon Choi. Writing—review & editing: Sung-Jin Hong, Geu-Ru Hong, and Myeong-Ki Hong. Approval of final manuscript: all authors.

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https://doi.org/10.3349/ymj.2021.62.11.990