Original Article

Development of a patient-report pressure algometer for the quantification of abdominal examination

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ABSTRACT

Background: Abdominal examination (AE), one of the primary diagnostic tools used in traditional Korean medicine (TKM), has a limitation of being subjective due to depending on individual practitioner's experience. Therefore, we devised a novel patient-report pressure algometer (PA) and performed a clinical trial to investigate its validity.

Methods: In total, 44 participants with functional dyspepsia and 44 healthy participants completed the study. The participants were allocated into one of two groups according to the existence of abdominal stiffness at 5 acupoints or abdominal tenderness at 12 acupoints diagnosed by TKM doctors. The pressure depth and pressure pain threshold (PPT) were evaluated using the PA at the same acupoints. We assessed the validity (sensitivity and specificity) of PA and calculated the area under the curve (AUC) and optimal cutoff value of the test variables (pressure depth and PPT) to criterion standards (abdominal stiffness and tenderness).

Results: Pressure depth and PPT assessed by PA showed high sensitivity and specificity in diagnosing abdominal stiffness and tenderness. The validity at CV-14 of diagnosing abdominal tenderness with PPT by PA had a sensitivity of 73.1%, specificity of 77.8%, and an AUC of 0.807 with a *P* value of < 0.001.

Conclusion: This study may provide evidence of standardization and quantification of AE through PA.

1. Introduction

Abdominal examination (AE) is defined as an examination of the chest and abdomen by touching and pressing in combination with other examinations for the purpose of determining a morbid condition and diagnosis.[1] AE in Traditional Korean Medicine (TKM) is a key step in determining the status of internal organs, and deficiency and excess of *qi* and blood by evaluating abdominal signs such as abdominal lumps, mass, pain, stiffness, and distention.[2] AE was first recorded in an ancient medical book titled "*Huangdi Neijing* (*Huangdi*'s Internal Classic)" and was systemically organized for clinical use in other texts known as "*Shang Han Lun* (Treatise on Cold Damage Diseases)" approximately 2,000 years ago.[3,4] AE has played a crucial role in deciding TKM treatments, including acupuncture and herbal medicine, and predicting prognosis and response to TKM treatments. However, AE is mainly dependent on the skills or experience of individual practitioners; as a result, an accurate diagnosis is not always guaranteed. As this subjective feature of AE hinders development and communication among practitioners of TKM, TKM doctors have invested considerable effort in the standardization and quantification of AE. To this end, Ko et al.[5] successfully distinguished similar TKM diagnoses "*Simhabi*" (SH) and "*Simhabikyung*" (SHK) using an algometer as a diagnostic device. Subsequently, Park et al.[6] developed a modified algometer (MA) in order to achieve more reliable AE results by maintaining a constant pressure/pressing speed in the absence of manipulation by the operator. However, the algometer used in the previous study had limitations that the contact surface to patients' skin were different from the actual AE, and only one variable of pressure pain threshold (PPT) was measured, and there was a gap between the time of patient's complain of abdominal pain and actual recording leading to inaccurate recording. Through this study, we devised novel patient-report pressure algometer (PA) which has the sim-

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ilar contact surface to actual AE, measures both PPT and pressure depth, and minimizes the gap between the time of patient's appeal and recording by automated measurement process. We assessed the pressure depth and PPT of PA and aimed to derive higher validity to two corresponding AE components—abdominal stiffness and tenderness compared with previous versions of algometer. The participants were divided into two groups, healthy and functional dyspepsia (FD) group, and measurements were taken at 12 acupoints. Sensitivity, specificity, and the optimal cutoff value of PA were assessed and compared with previous versions of algometer.

2. Methods

2.1. Study design and setting

This was prospective diagnostic study to investigate the validity of PA for diagnosing abdominal stiffness and tenderness with the pressure depth and PPT respectively by PA. The study was performed at Kyung Hee University Hospital in Gangdong from May 2016 to December 2017. The study was approved by the Institutional Review Boards of Kyung Hee University Hospital of Gangdong (KHNMCOH 2016-05-002) and conducted according to the good clinical practice established by the International Conference on Harmonization. The protocol of this study was retrospectively registered at Research Registry; identifying number is researchregistry6120.

2.2. Participants

In total, 44 participants from the age of 20 to 65 with FD and complaints of epigastric discomfort or pain and 44 healthy participants without any digestive problems were screened. The participants with FD fulfilled the Rome III diagnostic criteria for FD.[7] Healthy participants were required to have a visual analog scale (VAS, 0–100) of overall dyspepsia under 20. Both FD and healthy participants who had any of following conditions were excluded from the study.

(1) Participants who had had erosive esophagitis, peptic ulcer, dysplasia, lymphoma, esophageal cancer, and gastric cancer evaluated by esophagogastroduodenoscopy
(2) Participants who had distinct clinical symptoms of irritable bowel syndrome
(3) Participants who had alarm symptoms such as weight loss, black stool and dysphagia
(4) Participants with mental illness
(5) Participants who had a history of abdominal surgery
(6) Participants who are pregnant or breast feeding
(7) Participants who have participated in another clinical study within the previous month
(8) Participants who had HIV
(9) Participants who had difficulties in attending the study (e.g., paralysis, serious drug addiction, time constraint, severe disorder of vision or hearing, and illiteracy)

Informed consent was obtained from all participants following a full explanation of the purpose of the study. Informed consents contained decisional capacity, voluntarism, and details of the study. Adverse events were recorded on the case report form in detail.

2.3. Variables and data sources/measurement

2.3.1. Evaluation of abdominal stiffness and tenderness

The existence of abdominal stiffness and tenderness were diagnosed by the consensus of TKM doctors (SJK, JWP and SHL) based on previous studies.[5,6] TKM doctors with more than 10 years of clinical experience independently examined the participants in separate offices. The TKM doctor was located on the right side of the patient, and the patient was placed in the supine decubitus position on the bed with both knees open while relaxing the whole body. The TKM doctor used the three right fingertips (second, third, and fourth fingers) and slowly pressed on the acupoints of the patient's abdomen in order to evaluate the existence of abdominal stiffness and tenderness. The 5 points of abdominal stiffness, including Left ST-21, Right ST-21, Left ST-25, Right ST-25, and CV-6, were measured. When judging abdominal tenderness, 12 points (Supplement 1a), including CV-14, CV-12, Left ST-21, Right ST-21, CV-10, CV-9, Left ST-25, Right ST-25, Left KI-16, Right KI-16, CV-6, and CV-4, were measured.[8] The 5 points of abdominal stiffness and 12 points of abdominal tenderness were selected according to previous review and clinical papers on AE.[5,9] The final diagnosis of abdominal stiffness or tenderness as a criterion standard was determined by the consensus of 2 among 3 TKM doctors according to the Delphi method. A standard operating procedure of AE was applied to this study,[10] and TKM doctors were well-trained before initiation of the study.

2.3.2. Development of PA

The PA was devised for assessing pressure depth and PPT. The PA is a digital algometer (FPIX 50. Wagner, USA) that has been modified to evaluate the physical quantity in the patients' abdomen in a similar manner to that measured by TKM doctors. First, it was necessary to change the skin contact form and materials. We made the skin contact surface of the FPIX in a shape similar to human fingers when pressing, and printed a prototype using a 3D printer. The final version of the contact surface was made of aluminum and had round corners 40 mm in width and 10 mm in length. The contact part to the skin was composed of 2 mm-thick rubber material. An external housing with a laser sensor was developed to measure the pressure depth to the abdomen. The external housing comprised a moving part fixed to the FPIX, and a part fixed at the initial measurement position of the abdomen as a reference point. A laser sensor (OWRB4040 AAS1, Welotec) was attached to the top of the external housing to evaluate the vertical movement distance of the algometer. PA was made by 3D printing to enable a hardware interface (Supplement 1b and 1c). The measurement interface of abdominal pressure and depth was configured using Labview USB DAQ. During pressurizing, the monitor was configured to observe the change of pressure with time; thus, the pressure graph provided a guideline that indicated the boundary of the error of ± 0.5 kgf, which made it possible for the operator to press the abdomen of participants with a constant speed. In the pressure depth graph, a guide indicating the boundary of the error of ± 5 mm was displayed on the screen. The PA was manufactured such that the operator could immediately cease the measurement by pressing the buzzer when the patient communicated abnormal feeling.

2.3.3. Evaluation of pressure depth and PPT

The pressure depth on the 5 acupoints and PPT on the 12 acupoints (the same as the AE measurement sites) was evaluated by proficient TKM doctors using the PA. Both the participant and the PA operator maintained the same AE posture as described above. The operator held the PA vertically against the abdomen of the participant and pressure was gradually applied to the graph displayed on the monitor at a rate of 1 kg/cm^2/s. The participant was instructed to press the buzzer immediately when they began to feel pain. When the buzzer was pressed, the operator immediately stopped applying pressure, and the pressure depth and PPT were automatically recorded on the monitor.

Table 1
Baseline characteristics of participants ($n = 88$).

Category	Total mean ± SD	Range	FD group ($n = 44$)	Healthy group ($n = 44$)
Age (years)	33.80 ± 10.68	20 – 65	37.21 ± 11.34	30.39 ± 8.90
Weight (kg)	59.99 ± 10.66	40.20 – 87.10	58.32 ± 11.12	61.66 ± 10.07
BMI (kg/m^2)	21.84 ± 3.11	16.10 – 33.10	21.74 ± 3.58	21.94 ± 2.59
Male/Female (n)			10/34	20/24

Data in FD and healthy group are represented as Mean ± SD
SD, Standard deviation; BMI, Body mass index; FD, Functional dyspepsia.

2.4. Analysis and statistical methods

2.4.1. Comparison between FD and heathy group according to the existence of abdominal stiffness or tenderness

The FD and the healthy group were divided into 2 groups according to the presence or absence of abdominal stiffness or tenderness. The numbers of each group in a 2 × 2 table were analyzed by Pearson's chi-square test or Fisher's exact test to confirm association between functional dyspepsia and abdominal stiffness or tenderness.

2.4.2. Comparison of pressure depth and PPT between groups divided by abdominal stiffness or tenderness

The pressure depths of a total of 88 participants were compared between groups that were divided according to the presence or absence of abdominal stiffness as diagnosed by TKM doctors. PPTs were also compared between groups that were divided according to the presence or absence of abdominal tenderness. The mean values of the continuous variable between the two groups were compared by two sample independent t-test.

2.4.3. Evaluation of the validity of the PA

The sensitivity, specificity, and optimal cutoff values for the PA were calculated using the receiver operating characteristic (ROC) curve. In ROC curve analysis, a consensus of TKM doctors (abdominal stiffness or tenderness) was considered as a criterion standard, and the pressure depth or PPT value measured by PA was considered as a test variable. Abdominal stiffness corresponded to pressure depth, while abdominal tenderness corresponded to PPT. The sensitivity and specificity were calculated from a 2 × 2 table, and the positive predictive value and negative predictive value were also obtained. The area under the curve (AUC) and sensitivity and specificity at maximum Youden index (J = sensitivity + specificity) were calculated to evaluate the accuracy of the test variables in relation to the criterion standard. An AUC of 0.9 and above indicated high accuracy, 0.7–0.9 indicated moderate accuracy, and 0.5–0.7 indicated low accuracy.[11]

2.4.4. Validity of the PA at CV-14 in functional dyspepsia patients for comparison with previous studies

Sensitivity, specificity at maximum Youden index, and optimal cutoff value diagnosing abdominal tenderness at CV-14 by PPT were acquired through ROC curve analysis and compared with previous studies.[5,6] Only the FD patient group was included in this validity analysis.

2.4.5. Statistics

Continuous variables are presented as mean ± standard deviation (SD), and categorical variables are presented as percentages (n, %). The data of continuous or categorical variables between two groups were compared by two sample t-test or Fisher's exact test depending on whether the data followed a normal distribution. A P value of < 0.05 was considered statistically significant. ROC curve analysis and determination of the optimal cutoff value were performed with MedCalc 12.3.0 (MedCalc software

bvba, Belgium), and the remainder of the analysis was performed using PASW Statistics 18.0 (SPSS Inc., USA).

3. Results

3.1. Baseline characteristics of the participants

A total of 88 participants (44 in the FD group and 44 in the healthy group) completed the study. Because participants only had to visit the study center once, no dropouts were recorded during the study (Supplement 2). The baseline characteristics of the total participants, such as age and sex, are shown in Table 1.

3.2. Comparison between FD and heathy group according to the existence of abdominal stiffness or tenderness

FD and abdominal stiffness have significant association at 2 acupoints, whereas FD and abdominal tenderness have significant association at all acupoints (Table 2).

3.3. Comparison of pressure depth and PPT between groups divided by abdominal stiffness or tenderness

A pressure depth of 4 among 5 acupoints showed a statistical difference, whereas the PPT of all 12 acupoints showed statistical difference between the two groups (Table 3) using two sample independent t-test.

3.4. Validity of PA

3.4.1. Pressure depth by PA to diagnose abdominal stiffness

The AUC and P value at the 4 acupoints were > 0.700 and < 0.001, respectively (Table 4, Supplement 3).

3.4.2. PPT by PA to diagnose abdominal tenderness

The AUC was above 0.800 at all 11 acupoints, and the P value at all acupoints was < 0.001 (Table 4, Supplement 4).

3.5. Validity of PPT by PA to diagnose abdominal tenderness at CV-14 in the FD group

The sensitivity and specificity at the maximum Youden index were 73.1% and 77.8%, respectively. The optimal cutoff value was 2.44 kg/cm^2, and the AUC was 0.807 with a P value of < 0.001 (Table 4, Supplement 5).

4. Discussion

In the present study, we attempted to quantify and standardize the components of AE diagnosis (abdominal stiffness and tenderness) using a newly developed PA. We have recently discovered that abdominal stiffness can be distinguished by pressure depth evaluated by a PA, and reaffirmed that tenderness can be differentiated by PPT. Abdominal stiffness was diagnosed by pressure depth in 4 of the total 5 acupoints with statistical significance, and tenderness was diagnosed by PPT in all 12 abdominal acupoints.

Table 2
Analysis of association between existence of functional dyspepsia and existence of abdominal stiffness or tenderness.

Acupoints	FD group		Healthy group		P value
	Presence	Absence	Presence	Absence	
Abdominal stiffness					
Left ST-21	27	17	15	29	0.010*
Right ST-21	17	27	10	34	0.106
Left ST-25	26	18	23	21	0.520
Right ST-25	19	25	14	30	0.271
CV-6	20	24	11	33	0.045*
Abdominal tenderness					
CV-14	26	18	2	42	< 0.001***
CV-12	36	8	3	41	< 0.001***
Left ST-21	24	20	0	44	< 0.001***
Right ST-21	18	26	0	44	< 0.001***
CV-10	38	6	3	41	< 0.001***
CV-9	37	7	4	40	< 0.001***
Left ST-25	27	17	2	42	< 0.001***
Right ST-25	20	24	2	42	< 0.001***
Left KI-16	35	9	4	40	< 0.001***
Right KI-16	30	14	4	40	< 0.001***
CV-6	38	6	2	42	< 0.001***
CV-4	22	22	0	44	< 0.001***

Analyzed by Pearson's chi-square test or Fisher's exact test. P value < 0.05 is considered as statistically significance.
FD, functional dyspepsia.
*** : $P < 0.001$;
* : $P < 0.05$.

Table 3
Comparison of pressure depth or pressure pain threshold by patient-reported pressure algometer.

Acupoints	Abdominal stiffness or tenderness		P value
	Presence	Absence	
Abdominal stiffness (Pressure depth)			
Left ST-21	29.86 ± 7.11 (42)	37.57 ± 8.59 (46)	< 0.001***
Right ST-21	28.26 ± 9.24 (27)	35.00 ± 8.93 (61)	0.002**
Left ST-25	32.92 ± 8.11 (49)	39.51 ± 8.60 (39)	< 0.001***
Right ST-25	33.18 ± 8.85 (33)	37.25 ± 10.93 (55)	0.074
CV-6	27.32 ± 7.39 (31)	33.26 ± 8.05 (57)	< 0.001***
Abdominal tenderness (Pressure pain threshold)			
CV-14	2.15 ± 0.78 (28)	3.98 ± 1.41 (60)	< 0.001***
CV-12	2.34 ± 0.99 (39)	3.98 ± 1.38 (49)	< 0.001***
Left ST-21	2.12 ± 0.75 (24)	3.71 ± 1.45 (64)	< 0.001***
Right ST-21	2.03 ± 0.58 (18)	3.73 ± 1.46 (70)	< 0.001***
CV-10	2.17 ± 0.87 (41)	3.61 ± 1.18 (47)	< 0.001***
CV-9	2.06 ± 0.79 (41)	3.14 ± 0.97 (47)	< 0.001***
Left ST-25	1.98 ± 0.87 (29)	3.58 ± 1.35 (59)	< 0.001***
Right ST-25	2.16 ± 0.97 (22)	3.33 ± 1.44 (66)	< 0.001***
Left KI-16	1.93 ± 0.67 (39)	3.14 ± 1.13 (49)	< 0.001***
Right KI-16	2.04 ± 0.87 (34)	3.17 ± 1.21 (54)	< 0.001***
CV-6	2.10 ± 0.88 (40)	3.27 ± 1.23 (48)	< 0.001***
CV-4	2.04 ± 0.84 (22)	3.30 ± 1.25 (66)	< 0.001***

Analyzed by two sample independent t-test. All data are presented by mean ± SD. P value < 0.05 is considered as statistically significance.
*** : $P < 0.001$;
** : $P < 0.01$.

FD has been chosen as target disease in this study due to its heterogeneous symptoms including abdominal discomfort and pain involving varied pathophysiology.[12] There is currently no standard therapy for FD, and due to unsatisfactory results from conventional treatments, complementary and alternative therapies, including herbal medicine, are increasingly being sought.[13,14] In Korea, FD is the eighth most common disease in TKM outpatient clinics, and it is the only inner medical disease among the top 10 most common diseases.[15] TKM has shown many strengths in chronic and functional diseases with no known organic cause, and FD has been the most studied disease in the AE field.[16] In addition, symptoms and signs are represented similarity between FD and abdominal stiffness (or tenderness) in TKM,[10] and the same TKM drugs such as *Banha-sasim-tang* showed effectiveness for treating both FD and abdominal tenderness.[17,18] Since the standard criteria for diagnosing abdominal stiffness (or tenderness) has not yet been established, we used the FD diagnostic criteria as the closest one. Our study also confirmed the association between FD and abdominal stiffness (or tenderness).

The presence of abdominal stiffness and tenderness can be standards for selecting herbal prescriptions in TKM. For example, stiffness at ST-25 (rectus tension) can be a target sign for the prescription of *Paeonia lactiflora*, stiffness at CV-4 (lower abdominal contracture) can suggest treatment with the herbs *Rehmannia glutinosa* or *Prepared aconite*, and *Pinellia ternate* can be used for tenderness at CV-14.[9,19] Many previous studies have attempted to determine abdominal stiffness and tenderness.[5,6] Ko et al., successfully distinguished abdominal tenderness at CV-14 using an algometer which had been applied to measure PPT in subcutaneous muscles.[5] The coefficient of correlation (CC) and intraclass correlation coefficient (ICC) of PPT by the original algometer was 0.82 and 0.58. The sensitivity, specificity, and optimal cutoff value of the original algometer were 84.6%, 60.9%, and 1.9 kg/cm^2 respectively. More recently, a semi-automatically upgraded version of the algometer (MA) was developed that showed more precise ICC (0.849) with 76.9% of sensitivity, 60.9% of specificity and 1.92 kg/cm^2 of optimal cutoff value.[6] According to our pilot study using PA,[20] CC and ICC of PPT by PA was 0.836 and 0.866, respectively, with statistical significance observed in both ($P < 0.001$). PA showed elevated test-retest and inter-rater reliability when evaluating PPT compared to the original algometer and MA, possibly due to the more automated process. According to our study, the sensitivity, specificity, and optimal cutoff value of the PA to diagnose abdominal tenderness at CV-14 were 73.1%, 77.8%, and 2.44 kg/cm^2 respectively. The AUC of the PA was 0.807 compared to 0.741 of that of the original algometer and 0.726 of MA. The sensitivity of the PA was decreased, while the specificity and AUC were markedly increased compared to conventional algometers. Due to various confounding factors, such as the severity of symptoms, abdominal obesity, and the depth of the subcutaneous fat layer, there might be some variation in the cutoff value.

Table 4

Sensitivity, specificity and optimal cut-off value of pressure depth and pressure pain threshold by patient-reported pressure algometer to abdominal stiffness and tenderness.

Acupoints	Sensitivity	Specificity	AUC	Cut-off value	P value
Pressure depth to abdominal stiffness					
Left ST-21	42.9	93.5	0.755	26	< 0.001***
Right ST-21	70.4	73.8	0.731	30	< 0.001***
Left ST-25	55.1	79.5	0.703	32	< 0.001***
Right ST-25	81.8	40.0	0.622	41	0.046*
CV-6	80.6	54.4	0.707	32	< 0.001***
PPT to abdominal tenderness					
CV-14	85.7	80.0	0.882	2.69	< 0.001***
CV-12	76.9	75.5	0.847	2.86	< 0.001***
Left ST-21	87.5	73.4	0.844	2.67	< 0.001***
Right ST-21	88.9	82.9	0.888	2.45	< 0.001***
CV-10	73.2	89.4	0.866	2.40	< 0.001***
CV-9	73.2	85.1	0.820	2.22	< 0.001***
Left ST-25	61.2	98.3	0.862	1.85	< 0.001***
Right ST-25	63.6	92.4	0.792	1.99	< 0.001***
Left KI-16	84.6	67.3	0.842	2.55	< 0.001***
Right KI-16	70.6	81.5	0.800	2.21	< 0.001***
CV-6	80.0	77.1	0.818	2.42	< 0.001***
CV-4	81.8	72.7	0.807	2.34	< 0.001***
PPT to abdominal tenderness in FD group#					
CV-14	73.1	77.8	0.807	2.44	< 0.001***

Analyzed by receiver operating characteristics (ROC) analysis. Sensitivity, specificity and the optimal cut-off values were derived from Youden's index. Sensitivity and specificity are presented as percent (%). P value < 0.05 is considered as statistically significant.

*** : $P < 0.001$;
* : $P < 0.05$.
# Analysis of PPT to abdominal tenderness at CV-14 in FD group was conducted for comparison with previous studies. AUC, Area under the curve; FD, Functional dyspepsia; PPT, Pressure pain threshold.

The PA in this study had several strong points compared to the conventional algometer: (1) The contact area of the PA was manufactured in the shape of an elongated ellipse of 3 cm^2 which was improved from the 1 cm^2 of the conventional algometer since it is more consistent with the area of the doctor's finger touching the abdomen; (2) other than the conventional algometer, which was limited to evaluate only PPT, depth-sensitive laser sensors were attached to the PA, which enabled assessment of additional factors such as pressure depth corresponding to abdominal stiffness; and (3) in order to obtain more reliable data, a buzzer and pressure graph were applied to the PA. In the previous algometer version, due to the gap between the point of pain and the cessation of pressure, the PPT was likely to be overestimated.[21] In this study, the participant pressed the buzzer when they felt pain and the data at that exact time were automatically linked to the PA, leading to a reduction in the error caused by different operator response rates. Additionally, the pressurization rate of 1 kg/cm^2/s was maintained by providing a pressure graph and pressure guidelines that could be confirmed in real time.

Although the PA has many advantages, there are limitations and considerations for further research. (1) It is necessary to control confounding factors affecting AE components such as the length of waistline and the depth of abdominal fat layer. For example, ultrasound attached PA is being developed to acquire more accurate data through covariate analysis of confounding factors.[22] (2) The measuring points of algometers, including PA, might vary slightly depending on several variables such as body mass index of the patient or the skill of the operator, therefore, advanced algometers are required to automatically designate the measuring points. (3) Since the studies in FD focused on upper AE components, further studies are required to target functional diseases of the lower abdomen, such as irritable bowel syndrome, to also quantify the lower AE components. (4) Since AE is judged by the systemic synthesis of various AE components,[16] standardization and quantification of other AE components should be attempted in the future.

In conclusion, pressure depth and PPT assessed by PA showed high validity in diagnosing abdominal stiffness and tenderness. The PA was advanced compared to previous algometers and MA in terms of both consistency and objectivity. The PA can be applied widely in TKM and will provide evidence for standardization and quantification of AE. However, additional large-scale studies on other AE components are needed.

Author contributions

Conceptualization: KHK and JWP. Methodology: KHK, SHL, and JWP. Formal Analysis: SJK and MHY. Writing – Original Draft: SJK and JWP. Writing – Review & Editing: SJK, KHK, and JWP. Supervision: SHL and JWP.

Conflict of interest

The authors have no conflict of interests to report.

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Ethical statement

The study was approved by the Institutional Review Boards of Kyung Hee University Hospital of Gangdong (KHNMCOH 2016-05-002) and conducted according to the good clinical practice established by the International Conference on Harmonization. Written permission was obtained from all participants and the participants received explanations of the purpose and contents of the study. Informed consents contained decisional capacity, voluntarism, and details of the study.

Data availability

The data used to support the findings of this study are included within the article.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2021.100742.

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