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ORIGINAL RESEARCH

Comparison of residual gastric volume using ultrasound in fasting diabetic and non-diabetic older adults undergoing staged-bilateral total knee arthroplasty: a prospective non-randomized comparative study

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Abstract

Background: This study evaluated the residual gastric volume (GV) using ultrasonography in fasting older adults with and without diabetes undergoing staged bilateral total knee arthroplasty (TKA). **Methods**: This was a prospective, non-randomized, comparative study of 38 older adults aged >65 years who were scheduled for staged bilateral TKA at one-week intervals. All older adults fasted from midnight onwards and patients diagnosed with diabetes mellitus (DM group, n = 19) or not (non-DM group, n = 19) were matched for age, sex and body mass index. The primary outcome was residual GV, assessed using ultrasonography. **Results**: The residual GV (mean (standard deviation)) significantly differed between the DM (75.1 (43.2) mL) and non-DM (35.9 (25.9) mL) groups at the second TKA ($p = 0.002$) but not at the first TKA ($p = 0.096$). When comparing the GV at the first and second TKA in each group, a larger GV was observed in the second TKA than in the first surgery in the DM ($p < 0.001$) and non-DM ($p = 0.018$) groups. The mean difference in GV amount from the first to second TKA was greater in the DM group (42.5 mL; 95% confidence interval (CI), 26.6–58.5) than in the non-DM group (20.0 mL; 95% CI, 3.8–36.2; $p = 0.044$). **Conclusions**: In older patients undergoing staged TKA, the residual GV measured at the first TKA was comparable, irrespective of the presence of diabetes mellitus. However, it increased in older adults with diabetes compared with those without diabetes during the second TKA. The amount of change in residual GV measured from the first to second TKA was greater in diabetic patients than in non-diabetic patients. Hence, in older adults scheduled to undergo bilateral staged TKA, caution is required in preoperative fasting practice, especially at the second stage of surgery in older adults with diabetes. **Trial Registration**: ClinicalTrials.gov (NCT04815070).

Keywords

Gastric volume; Diabetes mellitus; Older adults; Ultrasound; Staged bilateral total knee arthroplasty

1. Introduction

Modern fasting guidelines recommend avoiding excessive fasting and encouraging the consumption of carbohydrate-containing fluids 2 h before surgery [1]. However, it should be noted that the rate of gastric emptying can be influenced by various factors, including comorbidities (*i.e.*, diabetes mellitus, chronic kidney disease and Parkinson's disease), advanced age and drug-induced gastroparesis [2–4]. Patients with diabetes have been reported to have a higher residual gastric volume (GV) than healthy controls, even after 8 h or more of fasting [5, 6].

In addition to the factors described above, other factors may be involved in increasing the risk of delayed gastric emptying and should be considered in patients undergoing surgery. First, patients undergoing surgery may experience anxiety [7, 8] and both emotional and surgical stress are associated with gastroparesis [9, 10]. Second, perioperative pain influences gastrointestinal motility [11]. Adequately-controlled pain can improve gastrointestinal motility via helping the process of controlling stress-released neuropeptides and sympathetic reflexes [12, 13]. Third, it is well known that opioid could hinder the migrating motor complex and propulsive motor activity related with gastrointestinal motility by binding to peripheral μ-opioid receptors [14]. To date, no clinical trial has reported the effects of these factors on residual GV in older adults.

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Based on the hypothesis that preoperative residual GV may increase in older adults with diabetes during a second total knee arthroplasty (TKA), this study evaluated and compared preoperative residual GV using ultrasonography in older patients with and without diabetes undergoing staged bilateral TKA.

2. Materials and Methods

2.1 Study design, and patients

This prospective, non-randomized, comparative study was conducted at Seoul National University Bundang Hospital between March 2021 and March 2022, according to institutional and Good Clinical Practice guidelines. The dates of recruitment of the first and last patients were 29 March 2021 and 07 March 2022, respectively.

The participants were aged 65–85 years and were scheduled to undergo staged bilateral TKA at weekly intervals. Inclusion criteria required an American Society of Anesthesiologists physical status classification of 1, 2, or 3 and a body mass index $<$35 kg/m^2. Patients with chronic kidney disease, previous surgery of the upper gastrointestinal tract, or achalasia were excluded. Patients were assigned to the DM or non-DM groups, according to whether they had diabetes mellitus, and they were matched for age (difference: $\pm$2 years), sex and body mass index (BMI, difference: $\pm$2 kg/cm^2) during the enrollment process.

2.2 Trial protocol

Patients were scheduled for TKA under spinal anesthesia and fasted from midnight on the day of surgery. For preemptive analgesia, pregabalin 75 mg, celecoxib 200 mg and acetaminophen 650 mg were administered with less than 20 mL of water 1 h before surgery.

In the preoperative holding area, ultrasound scanning was conducted in a semi-recumbent position. Immediately thereafter, measurements were conducted in the right lateral decubitus (RLD) position for the greatest sensitivity [15], at each stage of TKA. As a result, there was minimal time lapse between the two measurements. The anesthesiologist who performed ultrasound scanning was blinded to the patient group. A cross-sectional image of the gastric antrum was obtained using a low-frequency convex array transducer (probe rC60xi, 2–5 Hz, Fusifilm SonoSite Inc., Bothell, WA, USA) equipped with an ultrasound machine (SonoSite EDGE II; Fusifilm SonoSite Inc., Bothell, WA, USA). The gastric antrum was evaluated using a standard protocol [16]. We identified the gastric antrum along the edge of the left lobe of the liver anteriorly and anterior to the aorta on sagittal or sagittal oblique sonographic views at the epigastric level (Fig. 1). The gastric contents were assessed quantitatively and qualitatively, and the participants were taken to the operating room after GV measurements were completed.

Fentanyl, tramadol and morphine were administered to control the postoperative pain. Intravenous patient-controlled analgesia was prepared by mixing 700 μg of fentanyl with normal saline to make a total volume of 100 mL, which was initially set to be administered as a bolus of 2 mL with a lockout interval of 10 min. Nevertheless, 100 mg tramadol was additionally administered when the patient complained of a Numerical Rating Scale (NRS) score of 4 or higher. Tramadol was administered up to four times a day, at least 4 h apart. The use of rescue analgesics (morphine, 2.5 mg) was permitted for pain that was not controlled using the basic protocol described above.

2.3 Gastric ultrasound for preoperative assessment

Three images of the gastric antrum taken between the peristaltic contractions in the semi-recumbent and RLD positions were used for quantitative and qualitative evaluations. To determine the cross-sectional area (CSA) of the antrum in the RLD, we used a formula to calculate the area of an ellipse using two perpendicular diameters of the antrum, the anteroposterior (AP) and craniocaudal (CC) diameters:

$$CSA = \pi \times AP \times CC/4$$

The average value of three measurements was applied to the following formula to calculate the residual GV, which was previously validated [17].

$$GV\ (mL) = 27.0 + 14.6 \times RLD\text{–}CSA\,(cm^2) - 1.28 \times age\,(years)$$

In this formula, RLD-CSA refers to the antral CSA measured in the RLD position. A calculated GV of less than zero was considered 0 mL.

For qualitative assessment, a simple three-point grading system defined by Perlas *et al.* [18] was used. Grade 0 was defined as an empty antrum in the semi-recumbent and RLD positions. Grade 1 is an empty antrum in the semi-recumbent position but with visible fluid in the RLD position. Grade 2 was defined as visible fluid in the antrum at both positions, implying a high-volume state.

2.4 Outcome measurements

The primary outcome was GV. The qualitative grade (grades 0, 1 and 2) and the CSA of the antrum were included as secondary outcomes. Opioid consumption was also assessed.

2.5 Sample size

In the previous study, the preoperative GV (mean $\pm$ SD) in the overnight fasting patients was 29.7 $\pm$ 8.0 mL [19]. Considering that the 20% increase in GV in the second TKA was statistically significant in older patients with diabetes, 15 participants were required in each group for an alpha level of 0.05 and a power of 90%. Assuming an overall loss to follow-up rate of 25%, 40 participants were included in this study.

2.6 Statistical analysis

Continuous variables are presented as mean $\pm$ SD or median (interquartile range (IQR)) and categorical variables are presented as numbers (proportions). All continuous variables were tested for normality using the Shapiro-Wilk test. Sta-

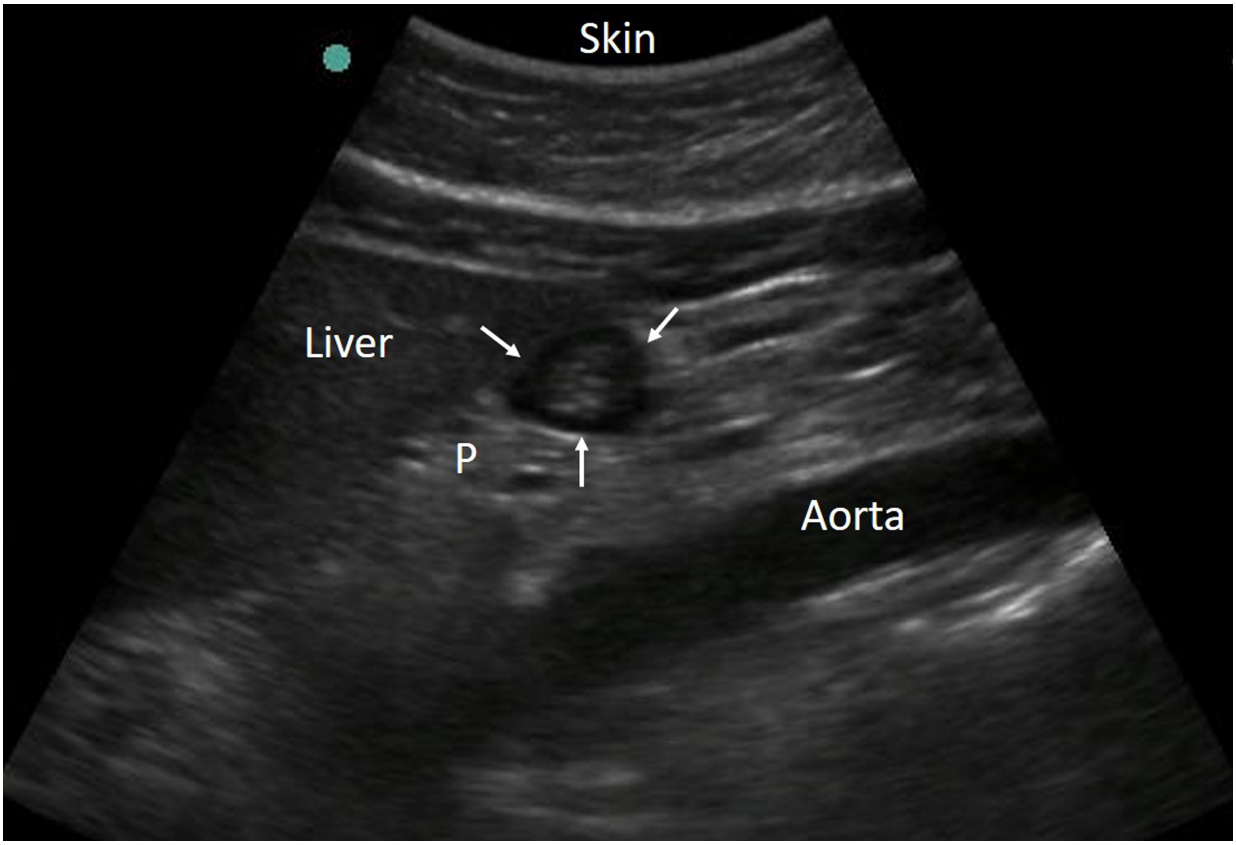

FIGURE 1. Ultrasound image of the gastric antrum in the epigastric area obtained in a sagittal or parasagittal plane. The arrows indicate the gastric antrum. P, pancreas.

tistical analyses were performed using either Student's *t*-test or a Mann-Whitney U-test, as appropriate, to compare the two groups. A paired *t*-test was used to compare the first and second stage values of GV within each group. The chi-square test or Fisher's exact test was used to compare the categorical data between the two groups. For the comparison of the qualitative assessment of GV (categorical data) between the two stages within each group, the McNemar test was used. Statistical Package for Social Sciences (SPSS; ver. 25; IBM Corp., Armonk, NY, USA) was used for calculations, and all *p*-values were considered significant at a level of < 0.05.

3. Results

A total of 43 patients who underwent TKA were screened for eligibility. After matching for age, sex and body mass index (BMI), 20 patients were included in the DM and non-DM groups. Among them, one patient from each group (two patients) was excluded because of poor ultrasound images (Fig. 2). Patient characteristics are shown in Table 1.

3.1 Quantitative and qualitative analysis of GV and content

Table 2 presents the residual GV of each group measured before the first and second TKA. The preoperative GV at the time of the first TKA did not differ between the DM and non-DM groups ($p = 0.096$). Compared with the GV at the first TKA, the GV at the second TKA was significantly higher in the DM ($p < 0.001$) and non-DM groups ($p = 0.018$). The increased amount of GV from the first to second TKA was 42.5 mL (95% confidence interval (CI), 26.6–58.5) in the DM group and 20.0 mL (95% CI, 3.8–36.2) in the non-DM group and this difference was significantly different ($p = 0.044$). Finally, the preoperative GV (mean $\pm$ SD) at the second TKA was significantly greater in the DM group (75.1 $\pm$ 43.2 mL) than in the non-DM group (35.9 $\pm$ 25.9 mL) ($p = 0.002$).

On qualitative assessment, none of the patients in either group had grade 2 gastric contents. Although there were differences in GV between the two groups, the ratios of grades 0 and 1 did not differ between the two groups or at each stage of TKA.

3.2 Opioid consumption

Table 3 shows the data on opioid consumption after the first TKA. No significant differences were observed in the doses of tramadol, fentanyl or morphine between the two groups. When the dose of each opioid administered to the patient was converted to a morphine-equivalent dose (MED), the total MED did not differ between the DM and non-DM groups ($p = 0.070$).

3.3 Complications

All participants did not exhibit any complications requiring additional treatment or surgery and there were no complications warranting a delay in surgery after the first TKA.

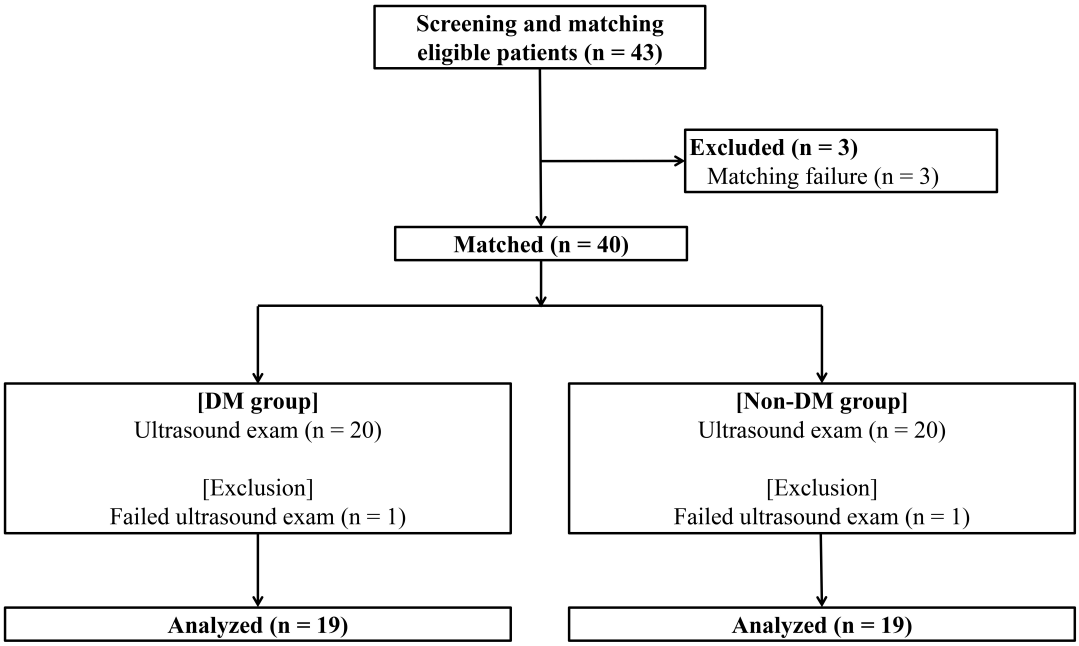

FIGURE 2. Patient inclusion flow chart. DM, diabetes mellitus.

TABLE 1. Patient baseline characteristics.

	DM (n = 19)	Non-DM (n = 19)	*p*
Age (yr)	73 ± 6	73 ± 5	0.907
Weight (kg)	63.9 ± 11.3	62.1 ± 7.8	0.563
Height (cm)	153.7 ± 8.6	153.1 ± 6.9	0.803
BMI (kg/m^2)	26.9 ± 3.1	26.5 ± 2.8	0.677
Gender			
Male	2 (11%)	2 (11%)	1.000
Female	17 (89%)	17 (89%)	
Fasting time (h)	9.5 ± 1.7	9.5 ± 1.5	0.175

Data are expressed as mean ± standard deviation or number of the patients (proportion). DM, diabetes mellitus; BMI, body mass index.

TABLE 2. Gastric volume of the first and the second operations.

	DM			Non-DM				
	First TKA	Second TKA	p_1	First TKA	Second TKA	p_1	p_2	p_3
Quantitative analysis								
Gastric volume (mL)	32.6 ± 35.9	75.1 ± 43.2	<0.001	15.9 ± 22.9	35.9 ± 25.9	0.018	0.096	0.002
Gastric volume (mL/kg)	0.5 ± 0.5	1.2 ± 0.6	<0.001	0.2 ± 0.3	0.6 ± 0.4	0.010	0.098	0.003
CSA (semi-recumbent, cm^2)	3.7 ± 1.1	5.2 ± 1.5	<0.001	3.0 ± 0.9	3.6 ± 0.9	0.038	0.033	<0.001
CSA (RLD, cm^2)	6.4 ± 2.8	9.7 ± 2.8	<0.001	5.0 ± 1.9	6.9 ± 1.9	0.007	0.082	0.001
Qualitative assessment								
Grade 0	12 (63%)	9 (47%)		14 (74%)	11 (58%)			
Grade 1	7 (37%)	10 (53%)	0.375	5 (26%)	8 (42%)	0.250	0.728	0.746
Grade 2	0 (0%)	0 (0%)		0 (0%)	0 (0%)			

Data are expressed as mean ± SD or number of the patients (proportion). DM, diabetes mellitus; CSA, cross-sectional area; RLD, right-lateral decubitus; TKA, total knee arthroplasty. p_1, compared the first and the second TKA values within the group; p_2, compared the first TKA values between the two groups; p_3, compared the second TKA values between the two groups.

TABLE 3. Opioid consumption after first TKA.

	DM (n = 19)	Non-DM (n = 19)	*p*
Tramadol (mg)	300 (200 to 500)	500 (200 to 1000)	0.070
Fentanyl (μg)	0 (0 to 70)	490 (0 to 810)	0.103
Morphine (mg)	0 (0 to 0)	0 (0 to 0)	0.863
Total MED of all opioids (mg)	50 (30 to 90)	110 (40 to 170)	0.070
Total MED of all opioids (mg/kg)	0.8 (0.4 to 1.8)	1.8 (0.7 to 2.9)	0.070

Data are expressed as median (IQR). TKA, total knee arthroplasty; DM, diabetes mellitus; MED, morphine equivalent dose; IQR, interquartile range.

4. Discussion

The present study showed that the preoperative residual GV after the second TKA was larger in older patients with diabetes than in non-diabetic patients, although they showed a similar preoperative residual GV after the first TKA. Preoperative residual GV at the second TKA increased significantly compared with that at the first TKA in all patients; however, the amount of change in GV was greater in patients with diabetes than in those without diabetes.

Goyal *et al*. [20] recently reported that patients with DM have varying degrees of normal, rapid or delayed gastric emptying regardless of upper abdominal symptoms. Only a few studies have evaluated preoperative GV in patients with diabetes [21]. Most studies have found that residual GV and the incidence of Pelras grade 2 increased in a diabetic patient cohort when examined using preoperative ultrasound [5, 6, 22, 23]. In addition to those with diabetes, our target patients were older. Age was used when GV was calculated from CSA using a mathematical model. Previously, it was suggested that liquid emptying time may be delayed in older adults [24]; however, recent studies have reported that gastric emptying time and residual GV are not affected, even after drinking preoperative carbohydrates [25]. To date, residual GV have not been studied in older patients with fasting diabetes.

When we compared the DM and non-DM patients, the CSA (semi-recumbent) at the first TKA in DM patients was statistically higher (p = 0.033) than that in non-DM patients. However, the same did not translate when GV was calculated using CSA (RLD). The mean residual GV of patients with DM was more than twice that of patients without DM at the first TKA; however, the difference was not statistically significant. Thus, we were not completely convinced that the gastric emptying rate at the first TKA was equally preserved between the two groups. Meanwhile, the preoperative residual GV during the second TKA increased in patients with and without diabetes. The increased amount of GV was greater in diabetic patients than in non-diabetic patients, resulting in significantly more residual GV with a larger CSA in patients with diabetes.

Stress, acute pain and opioid administration have been reported as causative factors of delayed gastric emptying [7, 9, 14], which could explain the increased GV in the second TKA rather than the first. After the first TKA, most patients experience acute pain and stress. After the first TKA, the administration of opioids for acute pain control may act as an additional factor that delays gastric motility during the second TKA. Interestingly, opioid consumption after the first TKA was lower in patients with DM, although the difference was not statistically significant. The greater increase in GV, despite low opioid consumption, may have additional significance in patients with DM. Another explanation for the greater GV in patients with DM at the second TKA is the pathophysiological features of gastrointestinal motility in diabetes mellitus. The incidence of diabetic gastroparesis is 32–47% in patients with type 2 DM, which may relate to the release of tumor necrosis factor α, interleukin-6 and other inflammatory cytokines [20]. These proinflammatory cytokines are released after surgical injuries [26] and may influence gastric motility, resulting in a larger residual GV at the second TKA in older adults with diabetes. Based on the above results, it is necessary to consider that gastric emptying may vary, depending on various factors in staged surgeries performed at short intervals. In particular, a preoperative GV evaluation is necessary for patients with diabetes.

In addition to the factors mentioned above, there are other postoperative factors that can induce postoperative ileus, such as electrolyte imbalance, major blood loss and infection [27, 28]. In this study, all participants underwent a second TKA one week after the first surgery without such complications. However, considering that various factors after surgery can influence gastrointestinal motility, careful consideration should be given when proceeding with surgery.

In the present study, we could not rule out the volume effect of water consumed preoperatively for preemptive analgesics. However, in the present study, the permitted volume of water was less than 20 mL. Even after drinking 400 mL of carbohydrate-containing fluid 2 h before surgery, the residual GV did not differ from that in fasting patients [25]. Furthermore, in some studies, the mean GV was approximately 37–83 mL even after 8 h of fasting before surgery [5, 29], which is larger (15.9 mL in the non-DM group) or similar (32.6 mL) to ours. Therefore, the small volume of water used for preemptive oral analgesic medication had little effect on the residual GV measured in this study.

This study had some limitations that should be considered when interpreting the findings. First, we did not assess the degree of stress or several proinflammatory cytokines that could affect gastric emptying time. Stress responses following surgical trauma cause abnormal gastrointestinal motility with the

release of stress hormones, catecholamines and inflammatory cytokines [9]. Future studies that evaluate these factors will provide clearer and more objective evidence for the results of our study. Second, this was not a randomized study. However, the preoperative care plans were identical between the two groups, except for blood glucose-related management and the baseline characteristics of each participant were matched for age, sex and BMI to reduce their effects on gastric emptying. Third, as described above, the GV at the first TKA and opioid consumption after the first TKA seemed to differ between the DM and non-DM groups; however, the difference was not statistically significant. Our sample size was used to calculate the difference in GV between the first and second TKA in older patients with DM; thus, it might not be sufficient to detect the statistical difference in GV at the first TKA and opioid consumption after the first TKA between the DM and non-DM patient groups. Future studies involving larger populations are needed to clarify these differences.

5. Conclusions

In older patients undergoing staged bilateral TKA, the residual GV measured at the first TKA was comparable, irrespective of the presence of DM. However, it increased in older adults with diabetes compared with those without diabetes during the second TKA. It can be said that the amount of change in preoperative fasting GV measured from the first to second TKA is greater in diabetic patients than in non-diabetic patients. Hence, in older adults scheduled to undergo bilaterally staged TKA, caution is required in preoperative fasting, especially in older adults with diabetes during the second stage of surgery.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this paper are available upon reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

HJS—conception and study design; data collection, analysis, interpretation, drafting of the manuscript, critical revision and final approval; JHB—development of methodology, data analysis and interpretation, revision of the manuscript and final approval; SHH—development of methodology, statistics, analysis and final approval; SHD—development of methodology, statistics, analysis and final approval; HSN—conception and study design, critical revision and final approval. All the authors have read and approved the final version of this manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study complied with the principles of the 1964 Declaration of Helsinki and its amendments. After approval by the Institutional Review Board on 16 March 2021 (B-2103/673-307; Chairperson, Hak Chul Jang; Seoul National University Bundang Hospital), the protocol was registered at ClinicalTrials.gov (NCT04815070, registered on 24 March 2021). All the patients provided written informed consent before participating in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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