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Article

Cost-Effectiveness and Clinical Outcome of Transcatheter Versus Sutureless Aortic Valve Replacement

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Abstract

Background: Sutureless aortic valve replacement (SU-AVR) and transcatheter aortic valve implantation (TAVI) are becoming increasingly common. The aim of this study is to compare the clinical outcome and cost-effectiveness of the two methods. **Methods**: In this study, cross-sectional retrospective data were collected on 327 patients who underwent SU-AVR (n = 168) and TAVI (n = 159). Homogeneous groups were provided by the "propensity score matching" method, and 61 patients from the SU-AVR group and 53 patients from the TAVI group were included in the study sample. **Results**: The two groups did not have statistically different death rates, complications after surgery, lengths of hospital stays, or visits to the intensive care unit. It is stated that the SU-AVR method provides an additional 1.14 Quality-Adjusted Life Year (QALY) compared to the TAVI method. The TAVI was more expensive than the SU-AVR in our study, but the difference was not statistically significant ($40,520.62 *vs.* $38,405.62, $p > 0.05$). For SU-AVR, the most expensive factor was the length of stay in the intensive care unit; for TAVI, it was arrhythmia, bleeding, and renal failure. **Conclusions**: These bioprostheses are safe and effective treatments for valve stenosis. Clinical outcomes were similar between the two groups. Therefore, clinicians may find it difficult to determine an effective treatment strategy. According to the evaluation made in terms of cost-effectiveness, it was found that the SU-AVR method gave a higher QALY at a lower cost compared to the TAVI method. However, this result is not statistically significant.

Keywords

cost-effectiveness; transcatheter aortic valve implantation; sutureless aortic valve replacement

Introduction

The prevalence of cardiovascular diseases is increasing due to the aging of the population [1]. Conventional aortic valve replacement (sAVR) is the most common surgical treatment for severe aortic stenosis [2]. "Transcatheter Aortic Valve Implantation" (TAVI) techniques are applied in patients who are contraindicated for aortic valve replacement [3–5]. An alternative to the sAVR method in patients with high surgical risk is "Sutureless Aortic Valve Replacement" (SU-AVR) [6].

Knowing the cost of treatment methods is important for health [7]. Low cost may not mean that a treatment method is more economical. An expensive treatment method or a low mortality rate in the early period may lead to the misconception that long-term results are perfect [8,9]. Medical cost-effectiveness studies are not easy as different methodologies and variables are used [10].

This study aims to compare both the cost-effectiveness analysis and clinical results of SU-AVR and TAVI in the treatment of aortic stenosis.

Methods

This study used cross-sectional retrospective data from 327 patients who underwent SU-AVR (n = 168) and TAVI (n = 159) procedures at Kosuyolu High Specialization Education and Research Hospital between January 1, 2015 and February 28, 2020. In the study, homogeneous groups were provided by the Propensity Score Match (PSM) method, and 61 patients from the SU-AVR group and 53 patients from the TAVI group were included in the study sample. Ethical approval of the study was obtained from the local ethics committee (the date was November 10, 2020, and the decision number was 2020/12/386).

The SU-AVR and TAVI decisions were made by a council of surgeons and cardiologists [5,6]. Severe aortic stenosis echocardiography signs: Severe aortic stenosis was defined as a valve area index of 1.0 cm^2 or 0.6 cm^2/m^2, a jet velocity greater than 4.0 m/s, or a mean gradient greater

than 40 mmHg.When the patient is normotensive (systolic blood pressure 140 mmHg), the aortic valve area is 1.0 cm^2, the aortic Vmax is 4 m/s, and the stroke volume index is 35 mL/m^2.The risk scoring of patients was calculated according to the Short-Term Risk Score (STS) and Euroscore II scoring systems [5–12]. Hypertension was defined as a systolic blood pressure of 140 mmHg and a diastolic blood pressure of 90 mmHg and/or above, or the patient's use of antihypertensive medication [13].

Implantation was performed with models of TAVI prostheses (*Evolut R* Medtronic, MN, USA; *Portico* Abbot, Santa Clara, CA, USA; Sapien, Sapien XT, and Sapien 3 Edwards Lifesciences Inc., CA, USA) and replacement was applied with a single model of SU-AVR prostheses (*Perceval*, Sorin Biomedica Cardio, Saluggia, Italy).

General endotracheal anesthesia was administered with the endotracheal tube in both groups. All TAVI procedures were performed using the transfemoral technique. Patients with endocarditis, emergency patients, and aortic valve regurgitation were excluded.

Clinical data were obtained by retrospectively examining the automation database and patient chart information. Cost data was obtained from the hospital finance department based on the group matrix. Cost analysis was collected from 10 cost parameters: hospital room, intensive care unit (ICU), dialysis, operating room. Costs are calculated based on the sum of bundle pricing and non-bundle pricing, according to the pricing of the "Social Security Institution Health Implementation Communique" [14]. Economic outcomes are converted to US dollars ($) with Organization for Economic Cooperation and Development purchasing power parity for international comparisons [15].

The impact on clinical outcomes was evaluated with length of stay (LOS)-ICU, LOS-hospital, rates of 1 (hospital mortality), 3, 6, and 12 months.

In this study, a cost-effectiveness analysis was carried out by comparing the additional cost of both methods with the additional QALY values gained. The postoperative quality of life of the treatment groups was provided by the literature review. Results for the cost-effectiveness analysis are expressed in terms of additional cost-effectiveness per year of survival gained and additional cost-effectiveness per QALY gained. QALY evaluate the success or failure of a treatment method or alternative. For this reason, QALY are used to compare different treatment modalities. Quality-adjusted life years (QALYs) are often used as an additional benefit value. One QALY is equal to one year of life in perfect health. The QALY combines morbidity and mortality on a single scale [16].

The economic evaluation of the procedures was calculated by cost effective analysis. Analysis results were defined by the "Incremental Cost Effectiveness Ratio" (ICER) value. ICER can be calculated in different units using different economic evaluation methods. While ICER evaluates the additional cost in return for the additional natural units (incremental natural units) gained in a cost effectiveness study; the additional benefit gained and the additional cost are evaluated together in the study.

Statistical Method

Homogeneous groups were obtained by PSM. Preoperative and postoperative characteristics of the groups were evaluated separately before and after PSM with an independent sample-*t* test and chi-square test [17]. The *t*-test was used to analyze whether there was a difference between the groups in terms of continuous numerical variables such as age, Euroscore II, STS score, hemoglobin, platelets, creatinine, urea, ejection fraction, and pulmonary artery pressure. On the other hand, a chi-square test was used to evaluate whether there was a difference between the groups in terms of categorical variables such as gender, New York Heart Association Functional Classification (NHYA) classification, hypertension, dysrhythmia, cerebral vascular disease, permanent pacemaker, redo surgery, peripheral vascular disease, coronary artery disease, Insulin Dependent Diabetes Mellitus (IDDM), Non-Insulin Dependent Diabetes Mellitus (NIDDM), Acute coronary syndrome within 90 days before procedure (ACS/90), renal dysfunction, and Chronic Obstructive Pulmonary Disease (COPD). The frequency values of additional procedures performed in relation to the procedure applied to patients in both treatment groups are given. The factors affecting the total cost of treatment methods were evaluated by linear regression analysis. Both operative and postoperative mortality were compared with chi-square analysis. All of the statistical analyses in this study were performed with SPSS 23.0 software (SPSS, New York, NY, USA).

Results

There was a statistically significant difference between the groups in terms of preoperative age, Euroscore II, STS score, and pre-PSM ejection fraction values (Table 1). According to the results of the analysis after PSM, the treatment groups differ only in terms of the age variable.

The categorical characteristics of the groups were evaluated with the Pearson chi-square test (Table 2). Before PSM, the patients' heart failure, NHYA distribution, peripheral artery disease, coronary artery disease, renal dysfunction, and COPD status differed between treatment groups. As a result of the analysis made on the selected sample after PSM, it was seen that there was no significant difference between the treatment groups in terms of all preoperative variables of the categorical type.

In SU-AVR, 39 additional surgeries were performed before PSM and 18 after PSM. In TAVI, 7 additional procedures were performed before PSM (only 1 permanent pacemaker) and 1 additional procedure was performed af-

Table 1. Preoperative characteristics of the patients according to treatment method groups.

	Before PSM					After PSM				
	Mean		95% Confidence Interval of the Difference		*p*-value	Mean		95% Confidence Interval of the Difference		*p*-value
	SU-AVR (n = 168)	TAVI (n = 159)	Lower	Upper		SU-AVR (n = 61)	TAVI (n = 53)	Lower	Upper	
Age	71.298	77.648	–8.349	–4.352	0.000	72.344	78.038	–8.400	–2.987	0.000
Euroscore II	2.552	3.726	–1.825	–0.522	0.000	2.726	3.348	–1.747	0.503	0.276
STS Score	4.816	5.769	–1.454	–0.452	0.000	4.989	5.860	–1.780	0.039	0.060
Hemoglobin	11.243	11.549	–0.741	0.128	0.166	11.233	11.378	–0.897	0.607	0.704
Platelet	225.282	263.837	–105.027	279.169	0.255	196.379	230.090	–67.446	844.761	0.56
Creatinine	1.240	1.112	–0.480	0.736	0.679	1.803	1.237	–1.186	2.317	0.523
Urea	46.746	77.392	–75.919	14.627	0.184	49.229	51.954	–12.284	6.834	0.573
Ejection Fraction	56.577	53.283	0.476	6.113	0.022	55.574	53.019	–2.012	7.121	0.270
Pulmonary Artery Pressure	31.905	34.119	–5.724	1.295	0.215	34.262	38.302	–8.581	0.502	0.081

PSM, Propensity Score Match; SU-AVR, Sutureless aortic valve replacement; TAVI, transcatheter aortic valve implantation; STS, Short-Term Risk Score.

Table 2. Preoperative categorical variables of patients according to treatment method groups.

		Before PSM		*p*-value	After PSM		*p*-value
		n	(%)		n	(%)	
		SU-AVR	TAVI		SU-AVR	TAVI	
Sex	Erkek	74 (44%)	65 (40.9%)	0.563	31 (50.8%)	24 (45.3%)	0.555
	Kadın	94 (56%)	94 (59.1%)		30 (49.2%)	29 (54.7%)	
NHYA	Class I	111 (66.1%)	49 (30.8%)	0	34 (55.7%)	26 (49.1%)	0.793
	Class II	45 (26.8)	66 (4.5%)		19 (31.1%)	21 (39.6%)	
	Class III	10 (6%)	34 (21.4%)		6 (9.8%)	5 (9.4%)	
	Class IV	2 (1.2%)	10 (6.3%)		2 (3.3%)	1 (1.9%)	
Hypertension		71 (42.3%)	55 (34.6%)	0.154	27 (44.3%)	20 (37.7%)	0.48
Dysrhytmia		23 (13.7%)	17 (10.7%)	0.408	8 (13.1%)	7 (13.2%)	0.988
Cerebro Vascular Disease		14 (8.3%)	23 (14.5%)	0.084	2 (3.3%)	6 (11.3%)	0.094
Permanent Pacemaker		3 (1.8%)	6 (3.8%)	0.326	1 (1.6%)	0 (0%)	0.349
Redo Surgery		17 (10.1%)	21 (13.2%)	0.394	7 (11.5%)	10 (18.9%)	0.269
Peripheral Vascular Disease		23 (13.7%)	40 (25.2%)	0.009	9 (14.8%)	6 (11.3%)	0.589
Coronary Artery Disease		58 (34.5%)	73 (45.9%)	0.036	27 (44.3%)	22 (41.5%)	0.767
IDDM		17 (10.1%)	16 (10.1%)	0.987	9 (14.8%)	5 (9.4%)	0.388
NIDDM		22 (13.1%)	10 (6.3%)	0.06	9 (14.8%)	4 (7.5%)	0.227
ACS/90		22 (13.1%)	14 (8.8%)	0.215	9 (14.8%)	4 (7.5%)	0.227
Renal Disfunction*		12 (7.1%)	24 (15.1%)	0.022	5 (8.2%)	5 (9.4%)	0.816
COPD		16 (9.5%)	29 (18.2%)	0.022	5 (8.2%)	5 (9.4%)	0.816

*Renal Disfunction: Creatinine clearance $\leq$59 mL/min/1.73m^2 (Cockcrof–Gault formula). NHYA, New York Heart Association Functional Classification; IDDM, Insulin Dependent Diabetes Mellitus; NIDDM, Non-Insulin Dependent Diabetes Mellitus; ACS/90, Acute coronary syndrome within 90 days before procedure; COPD, Chronic Obstructive Pulmonary Disease.

ter PSM. Cross Clemp Time (mean minute) before PSM 78.78, after PSM 76.93, Cardiopulmonary Bypass Time (mean minute) before PSM 122.83, after PSM 117.56.

Strokes occurred in three SU-AVR patients and three TAVI patients, according to PSM. Extracorporeal membrane oxygenation was not used in both groups. Vascular emergency surgery was absent in the SU-AVR; it occurred in 1 patient in the TAVI. Permanent renal dysfunction was seen in 1 patient in both groups; acute renal dysfunction between SU-AVR and TAVI was 4 *vs.* 5 patients (Table 3).

There was a significant difference between the groups of total cost, LOS-Hospital, and LOS-ICU prior to PSM. After PSM, this difference was not found with the independent sample-*t* test ($p > 0.05$).

The average cost of the TAVI method is higher than SU-AVR. While TAVI was approximately $6800 more ex-

Table 3. Distribution of post-operative complications.

	Before PSM		After PSM	
	n		n	
	SU-AVR	TAVI	SU-AVR	TAVI
Stroke	6	4	3	2
Cardiac Emergency Operation	8	9	0	3
Vascular Emergency Operation	0	1	0	1
Paravalvular Leak	2	5	0	0
Intra Aortic Baloon Pump	3	0	1	0
Extracorporeal Membrane Oxygenation	6	1	0	0
Acut Renal Dysfunction*	14	5	4	5
Permanent Renal Dysfunction	3	2	1	1
Permanent Pacemaker	7	9	0	0

*Creatinine clearance <30 mL/min or temporary hemodiafiltration.

pensive than SU-AVR before PSM, it was calculated to be approximately $2100 more expensive than SU-AVR after PSM ($p > 0.05$) (Table 4).

A chi-squared analysis was used to compare the mortality rates of patients in the SU-AVR and TAVI groups. Mortality rates between SU-AVR and TAVI were 1 (1.6%) *vs.* 2 (3.8%) in-hospital mortality, 3 (4.9%) *vs.* 4 (7.5%) three-month mortality, 3 (4.9%) *vs.* 4 (7.5%) six-month mortality, and 4 (6.6%) *vs.* 5 (9.4%) 12 months. There was no statistically significant difference in all-cause mortality between the two groups ($p > 0.05$).

Factors affecting hospital costs were determined by linear regression analysis. Independent variables in the model are approximately 90% explanatory in estimating the total cost of the SU-AVR; this ratio was 41% for the cost of TAVI. It was observed that the STS score, revision, ACS/90, and LOS-Hospital and LOS-ICU had a significant effect on the cost of SU-AVR. The same variables did not have an effect on TAVI (Table 5).

According to meta-analysis, it is stated that the SU-AVR method provides an additional 1.14 QALY compared to the TAVI method. Considering the cost results in our study, it can be stated that the SU-AVR method far outweighs the TAVI method due to its lower cost and higher QALY [16] (Table 6).

Discussion

In this study, detailed cost-effectiveness and clinical evaluations of the SU-AVR and TAVI methods were made.

There was a statistically significant difference in the age variable between the two groups. TAVI patients are older. There were not statistically significant differences in cost, mortality, LOS-hospital and LOS-ICU, postoperative complications between the two groups.

All mortality rates in the SU-AVR were lower than TAVI in our study ($p > 0.05$). TAVI's 30-day mortality rate was 7%. The reason for this is the high-risk patient group. Our center is one of the top reference hospitals in the patient referral chain. In addition, there are both junior surgeons and cardiologists who are always in the training process. In a multicenter study, the 30-day mortality rate of SU-AVR patients was found to be lower than that of TAVI in elderly patients. The 5-year mortality rate was also lower in the SU-AVR [18]. In a study in which two methods were compared, the early mortality rates for both methods were 2.5% and 5%, respectively [19]. While the hospital mortality rate in the medium and high-risk groups was lower in the SU-AVR, there was no difference in hospital mortality in the other study [16,20].

It is stated that the SU-AVR method provides an additional 1.14 QALY compared to the TAVI method [16]. Considering the cost results of our study, the SU-AVR method has a lower cost and a higher QALY value. Although the average cost of the TAVI was higher than the SU-AVR in our study. This difference ($40,520.62 *vs.* $38,405.62) was not statistically significant. The SU-AVR method saves $1.855 per QALY compared to the TAVI method. However, according to the results without propensity score matching, it is worth considering that there was a statistically significant difference between the costs of SU-AVR ($37,490.11) and TAVI ($44,352.3). This result may be important for "sustainable health payment systems".

In this study, the STS value, surgical revision, ACS before 90 days, and total length of stay in the intensive care unit and hospital had a significant effect on the cost of SU-AVR. The most significant cost is LOS-ICU. It was observed that the same variables did not affect the total cost in the TAVI. The costs of both methods are calculated similarly when device costs are excluded [20]. In the cost-effective study conducted on patients in medium- and high-risk groups, SU-AVR is found to be cost-effective [16].

In this study, the additional survival gain for SU-AVR compared to TAVI was calculated at 1.25 life years. The SU-AVR hospital cost is low, with savings of $2500 to $18,000 per patient. In different countries, SU-AVR has

Table 4. Comparing post-processing variables of patients according to treatment method groups.

	Before PSM					After PSM				
	Mean		95% Confidence Interval of the Difference		*p*-value	Mean		95% Confidence Interval of the Difference		*p*-value
	SU-AVR (n = 168)	TAVI (n = 159)	Lower	Upper		SU-AVR (n = 61)	TAVI (n = 53)	Lower	Upper	
Cost	$37,490.11	$44,352.3	–11,763.8	–1960.56	0.006	$38,405.62	$40,520.62	–5884.041	1654.055	0.267
LOS-Hospital	17.786	22.730	–9.413	–0.475	0.030	23.836	20.962	–7.356	13.104	0.577
LOS-ICU	7.101	10.371	–5.553	–0.987	0.005	7.934	8.925	–4.428	2.448	0.569

LOS, Length of stay; ICU, Intensive Care Unit.

Table 5. Factors affecting total hospital costs of treatment methods.

	SU-AVR						TAVI				
	Unstandardized Coefficients		Standardized Coefficients		*p*	VIF	Unstandardized Coefficients		Standardized Coefficients	*p*	VIF*
	B	Std. Error	Beta (β)	t			B	Std. Error	t		
(Constant)	36,745.211	10,827.574		3.394	0.001		51,619.020	9708.096		0.000	5.317
Age	–33.066	137.962	–0.014	–0.240	0.812	1.677	63.988	111.588	0.079	0.569	0.573
Euroscore II	–752.454	701.912	–0.099	–1.072	0.289	4.467	242.114	323.626	0.169	0.459	0.748
STS score	3234.261	1136.390	0.359	2.846	0.006	8.242	152.072	476.265	0.083	0.751	0.319
NHYA	–3620.500	2240.405	–0.138	–1.616	0.112	3.806	–1233.759	855.239	–0.193	0.157	–1.443
Previously cardiac surgery	–9436.163	5065.374	–0.145	–1.863	0.068	3.127	–1295.595	2122.486	–0.109	0.545	–0.610
Revision operation	21,950.306	9562.471	0.134	2.295	0.026	1.769	865.916	2535.466	0.043	0.734	0.342
ACS/90	533.174	124.171	0.273	4.294	0.000	2.095	–71.608	126.345	–0.109	0.574	–0.567
LOS-ICU	281.536	45.729	0.512	6.157	0.000	3.589	124.759	82.458	0.304	0.138	1.513
LOS-Hospital	152.623	27.445	0.347	5.561	0.000	2.016	287.143	148.116	0.298	0.059	1.939

*VIF: Variance Inflation Factor, R = 0.951, R = 0.641, R^2 = 0.904, R^2 = 0.411, F = 46,917, F = 2935; Dependent Variable: Total treatment cost, $p = 0.000$, $p = 0.007$, $p < 0.001$, $p < 0.001$, Durbin-Watson: 2.112, Durbin-Watson: 2.387. Std., Standart.

Table 6. Incremental cost effectiveness of treatment methods.

	Total Cost $	Survival (%)	Incremenatal Cost $	Incremental QALY	ICER per Incremental QALY	Cost per survival
SU-AVR	38,405.62	98.4	—	1.14	–1855.26	390.30
TAVI	40,520.62	96.2	2115	—	—	421.21

QALY, Quality-adjusted life year; ICER, Incremental Cost Effectiveness Ratio.

been found to be both cheaper and more effective than TAVI [16,21,22]. The ICER value of the SU-AVR method was found to be $27,593.42 compared to the sAVR method, and at the same time, the SU-AVR method was accepted as the dominant method over TAVI in terms of both cost and health outcomes [22]. It has been concluded that the TAVI method is cost-effective in patients who cannot be operated on due to high risk and that it is not cost-effective in patients who can be operated on. The most important reason for this is the cost of the prosthetic valve [23].

Although the clinical results are better in intermediate- and high-risk patients, the cost of TAVI is significantly higher than that of sAVR [24,25].

Bleeding, arrhythmias, and post-procedure renal failure appear to cause the greatest increase in overall hospital costs [26]. At least one complication develops in 48.9% of TAVI patients. These complications accounted for approximately 25% of TAVI costs. The main reasons for TAVI cost increases are complications and valve costs [26–28]. In our study, four TAVI complications necessitated emergency surgery. Complications and early mortality are lower in TAVI performed with sedation [29]. TAVI's cost-effectiveness for high-risk patients, on the other hand, varies [22,23].

Paravalvular leak (PVL) is an important cause of mortality for TAVI. PVL was significantly lower in the SU-AVR [18]. In our study, PVL was not detected in the population of the PSM.

Atrial fibrillation and intubation rates are lower with SU-AVR [30].

Prosthesis brand-name, procedure improvements, and complications determine cost-effectiveness according to the sensitivity analysis of TAVI costs [31,32].

Commercial competition between valve-producing companies can significantly alter cost-effectiveness [33]. Decision-making traditions and habits of the council may affect the SU-AVR/TAVI indication decision. With the advancement of TAVI technology and the average life-span, it is expected that more TAVI decisions will be made in the future. No one knows if expensive treatments are a risk to the sustainable health budget [7,34,35]. Innovations in prosthetic technologies can improve clinical outcomes [35].

Conclusions

SU-AVR is performed more easily with minimally invasive surgical techniques. Budgetary savings may affect the treatment payment rules and may have effects on the treatment options [36]. According to our evaluation made in terms of cost-effectiveness, it was found that the SU-AVR gave a higher QALY at a lower cost compared to the TAVI, but this result is statistically non-significant.

It should not be forgotten that the benefit outweighs the cost for patients.

Future Outlook

In 2050, it is predicted that 850,000 AVR operations will be performed annually. 6% of AVR patients are high risk [34]. The US Food and Drug Administration approved TAVI for low-risk patients in 2019 [37]. The TAVI procedure is likely to increase incrementally. The long-term clinical and cost effects of this situation are unpredictable.

Study Limitations

It is important to highlight the limitations of this study. The fact that it is a single-center study may affect the results. The number of articles on the long-term benefits of SU-AVR and TAVI is limited. Therefore, it was not possible to compare the results of the articles. In the SU-AVR procedure, no distinction was made for patients in terms of full/mini sternotomies and thoracotomies. TAVI results were not written with brand-names in accordance with commercial laws. Both procedures have been performed by different surgeons and cardiologists.

Abbreviations

ACS/90, Acute coronary syndrome within 90 days before procedure; BSA, Body Surface Area; CAD, Coronary Artery Disease; COPD, Chronic Obstructive Pulmonary Disease; CVD, Cerebro Vascular Disease; EF, Ejection Fraction; ICU, Intensive Care Unit; IDDM, Insulin Dependent Diabetes Mellitus; LOS, Length of stay; NHYA, New York Heart Association Functional Classification; NIDDM, Non-Insulin Dependent Diabetes Mellitus; QALY, Quality-adjusted life year; sAVR, Surgical Aortic Valve Replacement.

Availability of Data and Materials

Datasets used and/or analyzed for this study are available from the corresponding author upon appropriate request.

Author Contributions

CI, MS and KK designed and gave the main idea of the research study. CI, TB, BCK, and EE performed the research and collected the data. AK analyzed the data and made statistical measurements. CI and AK wrote the manuscript. KK and MS conducted a control and critical review of the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of it.

Ethics Approval and Consent to Participate

For this study (dated November 10, 2020 and decision number 2020/12/386) was received from the Ethics Committee of Kartal Kosuyolu Research and Education Hospital.

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Conflict of Interest

The authors declare no conflict of interest.

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