Original Article

DOI: 10.4274/haseki.galenos.2026.85547
Med Bull Haseki 2026;64(4):237-243

Long-term Outcomes According to Final Single-stent or Two-stent Treatment for Culprit Medina 1.1.1 Bifurcation Lesions in ST-elevation Myocardial Infarction

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Abstract

Aim: Long-term data comparing stenting strategies for culprit bifurcation lesions during primary percutaneous coronary intervention (PCI) are limited. We compared final single- and two-stent strategies in patients with ST-elevation myocardial infarction (STEMI) and Medina 1.1.1 lesions.

Methods: We retrospectively reviewed 2,452 patients undergoing primary PCI between January 2018 and December 2019. The study included 112 patients: 46 had a final single-stent result, and 66 were treated with two stents. The primary endpoint was the first occurrence of target lesion revascularization (TLR) or all-cause death. Kaplan-Meier, log-rank test, Cox regression, and logistic regression analyses were used.

Results: Mean follow-up was 61.5±22.4 months. The primary endpoint occurred in 12 patients in the single-stent group and 13 patients in the two-stent group. Event-free survival did not differ significantly [log-rank p=0.307; hazard ratio, 0.67; 95% confidence interval (CI), 0.30-1.47]. Each 5% decrease in ejection fraction was associated with higher odds of the composite endpoint (adjusted odds ratio, 1.31; 95% CI, 1.05-1.63; p=0.017).

Conclusion: Long-term outcomes were not significantly different between the two strategies. Lower ejection fraction remained associated with the composite endpoint after adjustment. Strategy selection may be guided by lesion anatomy and the procedural result.

Keywords: ST-elevation myocardial infarction, percutaneous coronary intervention, coronary bifurcation, provisional stenting, two-stent strategy

Introduction

Primary percutaneous coronary intervention (PCI) is the preferred reperfusion strategy for ST-elevation myocardial infarction (STEMI). When the culprit lesion involves a coronary bifurcation, treatment is more challenging because rapid restoration of main-vessel flow must be balanced against preservation of a clinically relevant side branch (1). The Medina classification defines bifurcation involvement according to disease in the proximal main vessel, distal main vessel, and side branch (2). During STEMI, thrombus burden, impaired baseline flow, vasoconstriction, bifurcation geometry, and hemodynamic instability may further complicate procedural decision-making (3-5).

A provisional single-stent approach is generally preferred for many bifurcation lesions, whereas planned two-stent treatment may be appropriate in selected complex anatomies. Long-term findings from EBC MAIN supported a stepwise provisional strategy in many true left-main bifurcations, while pooled DKCRUSH X data

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Received: 29.04.2026 **Accepted:** 01.08.2026 **Publication Date:** 24.09.2026

Cite this article as: Turna F, Yilmaz D. Long-term outcomes according to final single-stent or two-stent treatment for culprit medina 1.1.1 bifurcation lesions in ST-elevation myocardial infarction. Med Bull Haseki. 2026;64(4):237-243

favored systematic DK-crush in selected complex lesions (6,7). The STEMI-BIF registry added a different perspective by highlighting the potential importance of active side-branch protection during primary PCI (8). More recent studies suggested that intravascular imaging and active side-branch protection may improve procedural outcomes, although evidence specific to STEMI remains limited (9,10).

We hypothesized that long-term outcomes would not differ significantly between patients with a final single-stent result and those treated with two stents. We, therefore, compared the time to first target-lesion revascularization or all-cause death between the two strategies in patients with culprit Medina 1.1.1 bifurcation lesions undergoing primary PCI. We also examined clinical factors associated with the composite endpoint. This study may contribute to clinical decision-making by providing long-term real-world data supporting an anatomy-guided and procedural-result-guided choice between final single-stent and two-stent strategies in this high-risk setting.

Materials and Methods

Compliance with Ethical Standards

The study protocol was approved by the Sakarya University Local Institutional Ethics Committee (approval no: 71522473/050.01.04/617, date: 20.11.2020). The study was conducted in accordance with the Declaration of Helsinki. Because the study was retrospective and all patient data were analyzed anonymously, the requirement for written informed consent was waived by the ethics committee.

Study Design and Patient Selection

We retrospectively reviewed patients who underwent primary PCI for STEMI at our center between January 2018 and December 2019. Angiography records, procedural reports, hospital charts, electronic medical records, and follow-up files were examined. The patient selection process is shown in Figure 1.

Patients were included if they had undergone primary PCI for an index STEMI and had a true bifurcation lesion classified as Medina 1.1.1. The side branch was considered clinically relevant when its reference diameter was greater than 2.5 mm, or when it exceeded 2.0 mm and supplied a substantial myocardial territory. All included patients had been treated with drug-eluting stents and had complete clinical, angiographic, procedural, and follow-up data.

Patients were excluded if the treated bifurcation had a Medina classification other than 1.1.1, if the bifurcation lesion was not responsible for the index STEMI, or if angiographic documentation was insufficient to confirm lesion anatomy. Patients with missing procedural or follow-up data were also excluded. In addition, surviving patients with documented absence or premature discontinuation of dual antiplatelet therapy during the first year were not included.

Angiographic Assessment and Percutaneous Coronary Intervention Strategy

All coronary angiograms were reviewed to confirm the culprit bifurcation lesion and its Medina 1.1.1 anatomy. The following procedural variables were recorded: bifurcation angle, main-vessel stent diameter and length, presence of multivessel disease, final kissing balloon inflation, side-branch loss, and conversion from an initially provisional approach to a two-stent technique.

The choice of stenting strategy was left to the treating operator. Decisions were based on side-branch size, the amount of myocardium supplied by the side branch, lesion morphology, thrombus burden, baseline coronary flow, bifurcation angle, procedural feasibility, and the patient's clinical condition.

In patients treated through a provisional pathway, the main vessel was stented first. Side-branch balloon dilatation, proximal optimization technique (POT), POT-side-POT, final kissing balloon inflation, or implantation of a second stent were performed when considered necessary according to the angiographic results. Two-stent techniques include mini-crush, T-and-protrusion (TAP), and culotte.

Patients who initially underwent provisional treatment but subsequently required a second stent were assigned to the two-stent group based on the final procedural result. Guideline-directed medical treatment was prescribed after PCI. Dual antiplatelet therapy was planned to continue for at least 12 months, unless death or a clinically relevant contraindication occurred.

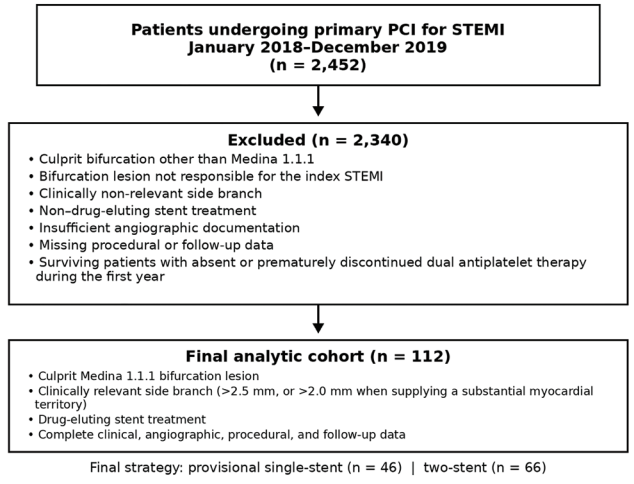

Figure 1. Patient flow diagram
PCI: Percutaneous coronary intervention, STEMI: ST-elevation myocardial infarction

Follow-up and Study Endpoints

Follow-up information was obtained from hospital records, outpatient files, electronic medical records, and telephone contact when necessary. Follow-up duration was recorded in months. For patients who died during follow-up, the follow-up period ended in the month of their death.

Target lesion revascularization (TLR) was defined as the repeat revascularization of the previously treated target lesion. The primary endpoint was the time from the index PCI to the first occurrence of TLR or all-cause death. Cause-specific mortality was not consistently available in the retrospective records; therefore, cardiovascular and non-cardiovascular deaths could not be analyzed separately.

When a patient experienced more than one qualifying event, only the first event was included in the Kaplan-Meier analysis. Subsequent events were not counted again. Patients without an event were censored at their last documented follow-up. Secondary time-to-event endpoints were all-cause death and first TLR, analyzed separately.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 30.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using visual methods (histograms and Q-Q plots) and the Shapiro-Wilk test. Normally distributed continuous variables were expressed as mean ± standard deviation and compared using Student's t-test, whereas non-normally distributed variables were presented as median (interquartile range) and compared using the Mann-Whitney U test. Categorical variables were reported as numbers and percentages and were compared using the chi-square test or Fisher's exact test, as appropriate.

Event-free survival was estimated using the Kaplan-Meier method, and the groups were compared with the log-rank test. A univariable Cox proportional hazards model was used to calculate the unadjusted hazard ratio for the primary endpoint in the final two-stent group compared with the final single-stent group. The proportional hazards assumption was assessed using Schoenfeld residuals, with no evidence of violation.

Exploratory univariable logistic regression analyses were performed to examine the associations of final stenting strategy, age, ejection fraction (EF), and diabetes mellitus with the composite endpoint. Variables associated with the endpoint in univariable analyses were considered for inclusion in the multivariable model. The final stenting strategy was retained regardless of its univariable p-value, because it was the main exposure of interest. Because only 25 patients reached the primary endpoint, the multivariable model was limited to final stenting strategy, EF, and diabetes mellitus. Ejection fraction was entered into the model per 5% decrease.

The results of the logistic regression analyses were reported as odds ratios with 95% confidence intervals (CIs). Model discrimination was assessed using the area under the receiver operating characteristic curve. Calibration was evaluated with the Hosmer-Lemeshow goodness-of-fit test using 10 groups based on deciles of predicted probability. The Akaike information criterion and McFadden's pseudo-R^2 were also calculated. All tests were two-sided, and a p-value below 0.05 was considered statistically significant.

Results

Study Population and Procedural Characteristics

Among 2,452 patients screened, 112 met the prespecified criteria and were included in the final analysis. The patient selection pathway is shown in Figure 1.

The final single-stent group included 46 patients, and the final two-stent group included 66 patients. Baseline characteristics were broadly comparable. Observed follow-up was 56.9±24.1 months in the single-stent group and 64.7±20.6 months in the two-stent group (p=0.070). Overall follow-up was 61.5±22.4 months, with a median of 67.5 months. Final kissing balloon inflation was more frequent in the two-stent group, whereas side-branch loss occurred only in cases with a final single-stent result. Baseline, procedural, and clinical characteristics were presented in Table 1.

In the two-stent group, the mini-crush technique was used in 30 patients, and TAP and culotte were each used in 18 patients. Among the 54 patients initially treated through a provisional pathway, 8 required a bailout conversion to a two-stent technique. The final procedural pathways among initially provisional cases were summarized in Table 2.

Time-to-event Outcomes

The primary endpoint occurred in 12 patients in the single-stent group and 13 in the two-stent group. Kaplan-Meier analysis showed no statistically significant difference in event-free survival (log-rank p=0.307; Figure 2). The unadjusted Cox hazard ratio for the two-stent strategy was 0.67 (95% CI, 0.30-1.47; p=0.316). Death-only and first-TLR analyses also did not differ significantly (log-rank p=0.393 and p=0.329, respectively).

Patients who reached the composite endpoint had lower baseline EF and a higher frequency of diabetes mellitus. Clinical characteristics according to composite endpoint status are shown in Table 3.

Regression Analyses

Lower EF and diabetes mellitus were associated with the composite endpoint in univariable logistic regression analysis (Table 4).

In the parsimonious multivariable model, EF remained significant, whereas final strategy and diabetes mellitus were not significant. Model discrimination was modest (area under the curve, 0.688). The Hosmer-Lemeshow test did not provide evidence of poor model fit (chi-square =4.13, df=8; p=0.845). Akaike information criterion was 116.04, and McFadden's pseudo-R^2 was 0.092. Multivariable estimates were presented in Table 5.

The adjusted estimates from the multivariable model were illustrated in Figure 3.

Discussion

In this cohort of patients with STEMI and a culprit Medina 1.1.1 bifurcation lesion, long-term clinical outcomes did not differ significantly between patients with a final single-stent result and those treated with two stents. The same pattern was observed in the analyses of the composite endpoint, all-cause death, and first TLR. These findings should not be taken as evidence that the two approaches are equivalent, because treatment was not randomized and the number of events was limited. They do, however, suggest that the final number of stents was less closely related to the outcome than the patient's underlying clinical risk. Among the variables examined, lower baseline EF was most consistently associated with the composite endpoint.

Bifurcation PCI during STEMI differs from elective procedures in several practical respects. The operator must restore flow quickly, often in the presence of thrombus, vasoconstriction, unstable hemodynamics, and poor visualization of the side-branch ostium. Under these conditions, a technique that is straightforward in an elective case may be difficult to complete or prolong the procedure unnecessarily. European Bifurcation Club recommendations support beginning with a provisional approach in many lesions and adding a second stent when side-branch flow, residual stenosis, or dissection remains unacceptable (3-5). Our results are consistent with this approach. Most patients who entered the provisional pathway were treated without a second stent, whereas eight required bailout conversion because the final angiographic result was unsatisfactory.

Table 1. Baseline, procedural, and clinical characteristics according to final stenting strategy

Parameter	Single-stent (n=46)	Two-stent (n=66)	p-value
Age, years	63.2±11.2	61.3±12.4	0.400
Follow-up duration, months	56.9±24.1	64.7±20.6	0.070
Main-vessel stent length, mm	21.3±8.1	23.4±6.6	0.139
Main-vessel stent diameter, mm	3.00±0.50	2.97±0.40	0.703
Bifurcation angle, degrees	54.2±16.5	53.1±14.9	0.721
EF, %	48.3±9.5	47.5±11.1	0.668
Male sex	33 (71.7)	53 (80.3)	0.290
Diabetes mellitus	18 (39.1)	20 (30.3)	0.331
Hypertension	31 (67.4)	49 (74.2)	0.429
Chronic kidney disease	8 (17.4)	9 (13.6)	0.603
Previous coronary artery disease	18 (39.1)	25 (37.9)	0.893
Multivessel disease	23 (50.0)	40 (60.6)	0.265
Previous PCI	10 (21.7)	15 (22.7)	0.902
Final kissing balloon inflation	22 (47.8)	66 (100.0)	<0.001
Side-branch loss	3 (6.5)	0 (0.0)	0.067

Data were presented as mean ± SD or n (%). Student t-test was used for continuous variables; chi-square or Fisher's exact test was used for categorical variables, as appropriate
EF: Ejection fraction, PCI: Percutaneous coronary intervention, SD: Standard deviation

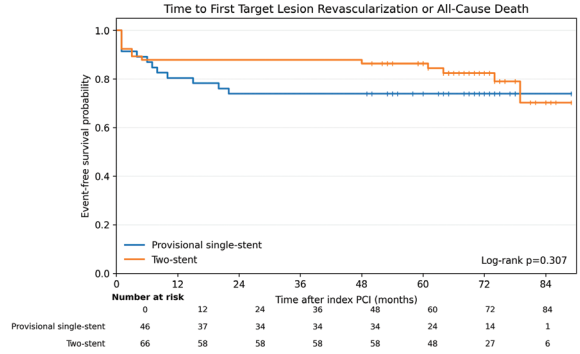

Figure 2. Kaplan-Meier event-free survival for time to first target lesion revascularization or all-cause death according to final stenting strategy. Censoring marks and numbers at risk were shown
PCI: Percutaneous coronary intervention, TLR: Target lesion revascularization

Table 2. Final procedural pathway among patients initially treated with a provisional strategy

Final procedural pathway among initially provisional cases (n=54)	n (%)
Successful single-stent result without documented SB compromise and without final kissing balloon inflation	14 (25.9)
Successful single-stent result without documented SB compromise, with final kissing balloon inflation	5 (9.3)
SB ballooning/POT-side-POT	7 (13.0)
Final kissing balloon inflation + POT	17 (31.5)
Conversion to TAP	6 (11.1)
Conversion to culotte	2 (3.7)
Side-branch loss	3 (5.6)

Data were presented as n (%). No inferential statistical comparison was performed
POT: Proximal optimization technique, SB: Side branch, TAP: T-and-protrusion

Table 3. Clinical characteristics according to the occurrence of the composite endpoint

Parameter	No endpoint (n=87)	Endpoint present (n=25)	p-value
Age, years	61.1±11.3	65.4±13.8	0.111
Main-vessel stent length, mm	22.4±7.4	23.0±7.1	0.738
Main-vessel stent diameter, mm	2.95±0.36	3.08±0.56	0.179
Bifurcation angle, degrees	53.3±15.3	54.5±16.8	0.741
EF, %	49.4±9.0	42.6±13.6	0.004
Diabetes mellitus	25 (28.7)	13 (52.0)	0.030
Hypertension	65 (74.7)	15 (60.0)	0.151
Chronic kidney disease	12 (13.8)	5 (20.0)	0.526
Previous coronary artery disease	34 (39.1)	9 (36.0)	0.780
Multivessel disease	50 (57.5)	13 (52.0)	0.627
Previous PCI	20 (23.0)	5 (20.0)	0.752
Final kissing balloon inflation	71 (81.6)	17 (68.0)	0.144

Data were presented as mean ± SD or n (%). Student t-test, chi-square test, or Fisher's exact test was used as appropriate. The composite endpoint was first TLR or all-cause death
EF: Ejection fraction, PCI: Percutaneous coronary intervention, TLR: Target lesion revascularization, SD: Standard deviation

Table 4. Univariable logistic regression analysis for the composite endpoint

Variable	Crude OR	95% CI	p-value
Two-stent strategy	0.69	0.28-1.70	0.426
Age, per 1-year increase	1.03	0.99-1.07	0.113
EF, per 5% decrease	1.34	1.08-1.67	0.007
Diabetes mellitus	2.69	1.08-6.69	0.034

Univariable binary logistic regression
CI: Confidence interval, EF: Ejection fraction, OR: Odds ratio

Table 5. Multivariable logistic regression analysis for the composite endpoint

Variable	Adjusted OR	95% CI	p-value
Two-stent strategy	0.68	0.26-1.77	0.433
EF, per 5% decrease	1.31	1.05-1.63	0.017
Diabetes mellitus	2.08	0.79-5.46	0.136

Multivariable binary logistic regression. Model n=112; composite events =25; AUC=0.688; Hosmer-Lemeshow chi-square =4.13, df=8, p=0.845; AIC=116.04; McFadden pseudo-R^2=0.092
CI: Confidence interval, EF: Ejection fraction, OR: Odds ratio, AUC: Area under the curve, AIC: Akaike information criterion

Previous studies have not identified a single strategy that is suitable for all bifurcation lesions. The extended EBC MAIN follow-up favored a stepwise provisional approach in many true left-main bifurcations, while the

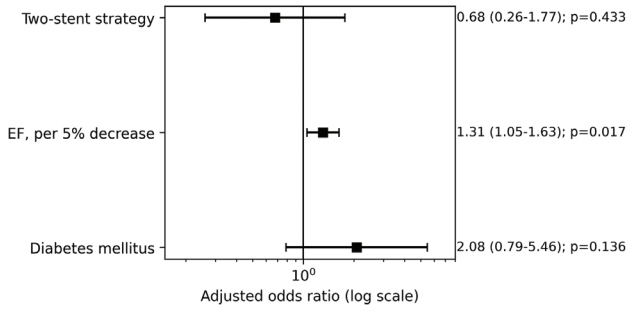

Figure 3. Forest plot of the parsimonious multivariable logistic regression model for the composite endpoint
EF: Ejection fraction

pooled DKCRUSH X analysis reported better long-term outcomes with systematic DK-crush in selected true complex lesions (6,7). Similar findings were reported in DEFINITION II and DKCRUSH-V, both of which enrolled patients with anatomically complex bifurcations (11,12). By contrast, earlier randomized trials and pooled analyses generally supported a simpler provisional strategy for many bifurcation lesions, although most of those studies included elective or mixed clinical populations (13-15). The STEMI-BIF registry added a different perspective by highlighting the potential importance of active side-branch protection during primary PCI (8). These data indicate that Medina 1.1.1 anatomy alone is not sufficient to determine treatment. Side-branch size, lesion length, ostial disease, the amount of myocardium supplied, bifurcation angle, thrombus burden, and flow after main-vessel stenting all need to be considered.

The quality of the final procedural result is also relevant. Final kissing balloon inflation was performed more often in the two-stent group, as expected; however, the present dataset did not include sufficient detail to assess the individual effect of each optimization step. Recent data from DKCRUSH VIII supported the use of intravascular imaging in complex bifurcation PCI (9). A recent systematic review also reported a lower risk of side-branch compromise with active protection techniques than with wire-only protection in selected patients (10). Intravascular imaging, quantitative side-branch measurements, and detailed information on stent expansion were not routinely available in our cohort. We, therefore, could not determine whether differences in procedural optimization influenced the association between stenting strategy and long-term outcome.

Lower EF was associated with higher odds of the composite endpoint in both univariable and multivariable analyses. This finding is clinically expected after STEMI, because reduced ventricular function reflects the extent of myocardial injury and is closely related to subsequent heart failure and mortality (16,17). Diabetes mellitus was

associated with the composite endpoint in the univariable analysis but did not remain statistically significant after adjustment. Diabetes is an established predictor of adverse outcomes after primary PCI for STEMI (18). In the present cohort, attenuation of this association after adjustment may reflect the limited number of events and reduced statistical power. Accordingly, this finding should not be interpreted as evidence that diabetes lacks prognostic importance in this population.

From a practical standpoint, our findings do not support the routine use of either a single-stent strategy or a two-stent strategy for all culprit Medina 1.1.1 lesions. A provisional approach may be appropriate when the side branch remains patent and the angiographic result is acceptable after main-vessel stenting. A second stent may be required when a relevant side branch has persistent flow limitation, severe residual ostial stenosis, or dissection. The present study was not designed to compare individual two-stent techniques or to define an optimal procedural algorithm. Instead, its findings support choosing the final strategy based on lesion anatomy, the clinical setting, and the result obtained during the procedure.

Study Limitations

This study has several limitations. Its retrospective, single-center design limits the generalizability of the findings. The stenting strategy was selected by the treating operator rather than randomly assigned; therefore, residual confounding and confounding by indication cannot be excluded. The exclusion of surviving patients with documented premature discontinuation of dual antiplatelet therapy may also have introduced selection bias. The sample size was modest, and only 25 patients reached the primary endpoint. This reduced statistical power and limited the number of variables that could be included in the multivariable model.

The two-stent group also included different techniques, which may have introduced procedural heterogeneity. Detailed measures of lesion complexity, thrombus burden, side-branch dimensions, intravascular imaging findings, coronary physiology, and stent expansion were not consistently available. Clinical outcomes were identified retrospectively, and some events may therefore have been missed or incompletely documented. Cause-specific mortality data were not consistently available; therefore, cardiovascular and non-cardiovascular deaths could not be analyzed separately. This limitation restricts the interpretation of the all-cause mortality component of the composite endpoint. Competing-risk methods were not used to analyze the first TLR, although death precluded its subsequent occurrence. Consequently, the Kaplan-Meier analysis may have overestimated the cumulative incidence of TLR, and this secondary endpoint should be interpreted cautiously. The exploratory logistic regression did not account for differences in event timing or censoring and should therefore be interpreted cautiously. The logistic regression model showed only modest discrimination, and its calibration was assessed in the same small cohort in which it was developed. External validation was not performed. The study nevertheless included a clearly defined population with culprit Medina 1.1.1 bifurcation lesions and a long-term follow-up based on time to first event.

Conclusion

In patients undergoing primary PCI for STEMI with a culprit Medina 1.1.1 bifurcation lesion, long-term event-free survival was not significantly different between those with a final single-stent result and those treated with two stents. Lower baseline EF was the variable most consistently associated with the composite endpoint. Given the retrospective design, limited sample size, and non-randomized treatment selection, these findings should be interpreted with caution and do not establish the superiority or equivalence of either strategy. In daily practice, interventional cardiologists may consider a provisional approach when the side branch remains patent and the angiographic result after main-vessel stenting is acceptable, reserving a second stent for persistent side-branch flow limitation, severe residual ostial stenosis, or dissection. Larger prospective studies are needed to clarify the long-term effects of the stenting strategy in this clinical setting.

Ethics

Ethics Committee Approval: The study was approved by the Sakarya University Local Institutional Ethics Committee (approval no: 71522473/050.01.04/617, date: 20.11.2020).

Informed Consent: The requirement for written informed consent was waived because of the retrospective, anonymized design.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F.T., D.Y., Concept: F.T., Design: F.T., Data Collection or Processing: F.T., D.Y., Analysis or Interpretation: F.T., D.Y., Literature Search: F.T., D.Y., Writing: F.T.

Conflict of Interest: The authors declared that there were no conflicts of interest.

Financial Disclosure: The authors declared that this study received no financial support.

Artificial Intelligence (AI)-Assisted Technologies Statement: The authors declare that artificial intelligence–assisted technologies (such as large language models) were used only for language editing and grammar

improvement. The authors take full responsibility for the scientific content, data interpretation, and conclusions of the manuscript.

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