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# Surgical Management of Acute Complications Arising from Endovascular Interventions in Peripheral Arterial Disease of the Lower Extremities: Everlasting Novel

Alt Ekstremite Periferik Arter Hastalığında Endovasküler Girişimlerden Kaynaklanan Akut Komplikasyonların Cerrahi Yönetimi: Eskimeyen Yeni

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## Abstract

**Aim**: The importance of endovascular procedures in the diagnosis and treatment of peripheral vascular diseases has seen a notable rise in recent years. Nevertheless, this surge has resulted in a corresponding rise in iatrogenic vascular complications and subsequent interventions associated with peripheral endovascular procedures. This study involved a retrospective evaluation of acute complications associated with endovascular treatments performed for lower limb peripheral artery diseases as well as a closer look at the related therapeutic strategies for these challenges.

**Material and Method:** A retrospective evaluation was conducted on a cohort of 400 patients who received endovascular intervention for lower extremity peripheral artery disease at our clinic. The study included 27 patients (6.7%) from this cohort who received surgical or endovascular treatment for acute complications following endovascular intervention. Our preference for endovascular or surgical treatments was chosen based on the type and localization of the complications.

**Results**: The mean age of patients who experienced complications was 63.7±6 years. The complications were as follows in order of frequency: dissection in 14 (51.9%) patients, arterial perforation in 5 (18.5%) patients, major hematoma in 3 (11.1%) patients, pseudoaneurysm in 2 (7.4%) patients, distal embolism in 2 (7.4%) patients and arterio-venous fistula in 1 (3.7%) patient. In the treatment of complications, endovascular methods were preferred in 19 (4.7%) patients and surgical approaches were used in 8 (2%) patients. Following endovascular intervention, a minor amputation was performed in one patient.

**Conclusion**: The rapid and effective management of complications related to peripheral endovascular procedures in the lower extremities is of utmost importance. Despite the notable advancements in endovascular procedures in recent years, there are scenarios where these interventions may be insufficient for dealing with complications. The management of such problems may necessitate surgical intervention. Hence, the integration of well-established and validated vascular surgical techniques with endovascular interventions is believed to yield optimal outcomes.

**Keywords**: Endovascular treatment, complications, peripheral artery disease, vascular surgery

## Öz

**Amaç**: Son yıllarda periferik vasküler hastalıkların tanı ve tedavisinde endovasküler işlemlerin önemi artmıştır. Ancak bu artış, periferik endovasküler işlemlere bağlı iyatrojenik damar yaralanmalarının ve buna bağlı girişimlerin artmasına neden olmuştur. Bu çalışmada, alt ekstremite periferik arter hastalıklarında gerçekleştirilen endovasküler işlemlere bağlı akut komplikasyonlar ve bu komplikasyonların yönetimi retrospektif olarak değerlendirilmektedir.

Gereç ve Yöntem: Kliniğimizde alt ekstremite periferik arter hastalığı nedeniyle endovasküler girişim yapılan 400 hasta retrospektif olarak değerlendirildi. Bu gruptan, endovasküler müdahale sonrası akut komplikasyonlarına cerrahi veya endovasküler tedavi uygulanan 27 (%6.7) hasta çalışmaya dahil edildi. Komplikasyonların tipi ve lokalizasyonuna bağlı olarak endovasküler veya cerrahi müdahale tercihimizi belirledik.

**Bulgular**: Komplikasyon gelişen hastaların yaş ortalaması 63.7±6 yıl olarak belirlendi. Görülen komplikasyonlar sıklık sırasına göre şu şekildeydi: diseksiyon 14 (%51.9) hasta, arteriyel perforasyon 5 (%18.5) hasta, majör hematom 3 (%11.1) hasta, psödoanevrizma 2 (%7.4) hasta, distal emboli 2 (%7.4) hasta ve arteriyo-venöz fistül 1 (%3.7) hasta. Komplikasyonların tedavisinde, 19 (%4.7) hastada endovasküler yöntemler tercih edilirken 8 (%2) hastada ise cerrahi yaklaşımlara başvuruldu. Endovasküler girişimi takiben, bir hastada minör amputasyon gerçekleştirilmiştir.

**Sonuç**: Alt ekstremite periferik endovasküler işlemlere bağlı komplikasyonlara hızlı ve etkili müdahale önemlidir. Endovasküler teknikler son yıllarda önemli ilerlemeler kaydetmiş olsa da, bazı durumlarda komplikasyonların tedavisinde yetersiz kalabilmektedir. Bu tür komplikasyonların yönetimi için cerrahi müdahale kaçınılmaz olabilir. Dolayısıyla, uzun yıllara dayanan ve etkinliği kanıtlanmış damar cerrahisi yaklaşımlarının endovasküler tedavilerle birleştirilmesinin, en etkili sonuçların elde edilmesini sağlayacağı düşünülmektedir.

Anahtar Kelimeler: Endovasküler tedavi, komplikasyon, periferik arter hastalığı, vasküler cerrahi

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#### INTRODUCTION

The introduction of peripheral angioplasty throughout the 1960s marked a significant milestone in the management of peripheral artery diseases.<sup>[1]</sup> As a result of the rapid development of balloon and catheter technology, these endovascular procedures are now commonly used in the treatment of peripheral artery disorders. The utilization of endovascular therapies in the treatment of lower extremity peripheral arterial disease during the past five decades, particularly atherosclerotic disease affecting the iliac and distal arteries, has resulted in a substantial rise in complications. The aforementioned challenges may potentially arise due to complications with vascular access or the use of guidewires, catheters, balloons, or stents. The most common acute complications associated with peripheral endovascular procedures include residual stenosis, dissection, arterial perforation (AP), hematoma, pseudoaneurysm (PA), arterio-venous fistula (AVF), and distal embolism (DE).<sup>[2]</sup> These kinds of complications, which could develop in peripheral endovascular treatments, can typically be addressed by endovascular techniques, although in certain cases, urgent surgical interventions may be warranted. The crucial aspect to consider is carrying out timely and appropriate interventions for these types of issues.

The objective of this study is to provide a retrospective assessment of the acute complications linked to endovascular procedures for peripheral artery disease in the lower extremities as well as the strategies employed to address these issues.

#### MATERIAL AND METHOD

The study was approved by the KTO Karatay University Faculty of Medicine, Pharmaceutical and Non-Medical Device Research Ethics Committee (Date: 17.06.2022, Decision No: 2022/034). The study was conducted in accordance with the principles of the Declaration of Helsinki. We retrospectively evaluated 400 adult (≥18 years) patients who underwent endovascular intervention for lower extremity peripheral arterial disease. Among these patients, 27 patients who developed acute complications after the endovascular procedure and underwent surgical or endovascular treatment for these complications were included in the study.

Demographic data, preoperative, intraoperative, and postoperative records, as well as follow-up outcomes of the patients, were acquired from the hospital's data system. Data included age, gender, comorbidities, endovascular procedure-associated complications and their anatomical locations, interventions used to treat these complications using surgical and/or endovascular approaches, amputations, mortality rates, length of stay in the intensive care unit, and length of hospitalization.

Individuals presenting with lower extremity claudication, rest pain, or acute ischemia underwent a thorough assessment employing arterial Doppler ultrasonography, computed tomography angiography, or magnetic resonance angiography. Those displaying morphological lesions in alignment with the TASC II classification and concurrently falling under the clinical classification of Rutherford classes 3 to 6 were deemed eligible for inclusion in the endovascular intervention.

All patients underwent a physical examination, routine blood tests, echocardiography (ECHO), and electrocardiography before the endovascular procedure. All endovascular procedures were performed under local anesthesia in the hybrid cardiovascular surgery room. Percutaneous transluminal angioplasty (PTA), stent implantation, and mechanical thrombectomy were performed as peripheral endovascular procedures. Subsequent to the intervention, meticulous post-procedural monitoring was executed within the intensive care unit and ward settings.

We determined our preference for endovascular or surgical intervention based on the nature and location of the complication that occurs during the procedure or follow-up. Complications that may arise from the endovascular procedure of lower limb arteries that necessitate rapid action to preserve the extremities or the patient include dissection, arterial perforation (AP), hematoma, pseudoaneurysm (PA), arteriovenous fistula (AVF), and distal embolism (DE). In instances of pseudoaneurysm necessitating surgical consideration, primary attention was accorded to its symptomatic manifestation, unsuitability for alternative treatments, progressive enlargement, and dimensions exceeding 3 cm. For dissection, arterial perforation, and AVF cases, a preference was extended to percutaneous transluminal angioplasty (PTA) as the initial approach. Open or covered stent implantation was entertained, with recourse to surgical intervention if endovascular approaches proved insufficient. Urgent surgical intervention was reserved for hematomas characterized by rapid and pronounced diameter increase at the intervention site, substantial hematocrit value reduction demanding blood transfusion, and in cases of complications engendering limb-threatening ischemia or severe hemorrhage. Moreover, immediate emergency intervention was executed in instances where complications induced limb-threatening ischemia or severe hemorrhage. Conversely, for other patients, the intervention was planned on an elective basis, guided by their clinical condition and laboratory findings. Predominantly, surgical procedures were conducted under local anesthesia, with only a handful performed under general anesthesia. Postoperative monitoring of lower extremity blood flow was standard practice, encompassing manual distal pulse evaluation and hand Doppler assessment immediately following the surgical procedure.

#### **Statistical Analysis**

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, N.Y., USA) software. Nominal variables were expressed as numbers and percentages. The distribution of continuous variables was evaluated by the Kolmogorov-Smirnov test. Normally distributed continuous variables were expressed as mean±standard deviation.

#### RESULTS

This study examined a cohort of 400 patients who received endovascular intervention for lower extremity peripheral artery disease. Among this group, a subset of 27 patients (6.7%) who experienced complications related to endovascular procedures either during the intervention or while in their hospital stay were included in the analysis. Of these, 11 (40.7%) were female and 16 (59.3%) were male. The mean age of the patients was  $63.7\pm 6$  years. When the patients' preoperative comorbidities and risk factors were analyzed, smoking (16, 59.3%), hypertension (18, 66.7%), diabetes mellitus (12, 44.4%), and coronary artery disease (10, 37%) were found to be the most prevalent comorbidities. **Table 1** displays the patients' demographic information.

Table 1. Demographic information and comorbid diseases of the patients					
Variables	Mean	Standard deviation	Number (n=27)	Percentage (%)	
Age (years)	63.7	6			
Female / Male			11/16	40.7 / 59.3	
Smoking			16	59.3	
HT			18	66.7	
DM			12	44.4	
CAD			10	37	
HT: Hypertension: DM: Diabetes mellitus: CAD: Coronary artery disease					

The complications associated with the endovascular treatment were categorized based on their location of occurrence. Out of the total complications, 1 (3.7%) took place in the iliac region, 21 (77.8%) in the femoropopliteal region, and 5 (18.5%) in the infrapopliteal region, as seen in **Figure 1**.



**Figure 1:** illustrates the classification of complications linked to endovascular treatment according to the site of their occurrence.

The prevailing major complication observed in the study was dissection, accounting for a substantial proportion of cases (n=14, 51.9%). Among these dissections, their distribution across different anatomical regions indicated that 1 case (7.1%) was located in the iliac region, while the femoropopliteal region saw a significantly higher incidence with 11 cases (78.6%), and 2 cases (14.3%) were documented in the infrapopliteal region. In all cases, the management approach for dissections involved ballooning or stenting. Specifically, 11 cases (78.6%) underwent treatment through ballooning, while the remaining 3 cases (21.4%) received stenting. Notably, percutaneous methods took precedence in addressing dissections that arose during the course of endovascular intervention, with surgical intervention being considered as a secondary option. Other complications were as follows: arterial perforation in 5 (18.5%) patients; major hematoma in 3 (11.1%) patients; pseudoaneurysm in 2 (7.4%) patients; distal embolism in 2 (7.4%) patients; and arterio-venous fistula in 1 (3.7%) patient.

Arterial perforation emerged as the prevailing complication subsequent to dissection. Among the cases of perforation, two (40%) were localized in the anterior tibial artery (TA), and three (60%) were situated in the superficial femoral artery (SFA). An instance of rupture in the SFA necessitated primary repair of the femoral artery, while endovascular techniques were employed to address the other instances of perforation.

Subsequent to the endovascular intervention, three patients encountered significant hematomas that necessitated blood transfusion. The femoral region was the site of detection for all major hematomas. Surgical intervention under general anesthesia was the chosen approach for all hematoma cases. The procedure included hematoma evacuation and primary repair of the catheter access site.

Following the endovascular procedures, pseudoaneurysms were identified in two patients. In cases where a pulsatile and dilatation tendency was observed, surgical interventions were carried out. The mean diameter of the pseudoaneurysms was 44.4±13.8 mm. All two surgeries were performed under local anesthesia. The pseudoaneurysms were located in the femoral artery, and both cases underwent primary repair of the femoral artery.

Two instances of DE were identified within the femoropopliteal artery territory. Embolectomy was deemed appropriate for these cases. Moreover, a single patient experienced the formation of an AVF between the anterior tibial artery and vein subsequent to the endovascular procedure. In this particular instance, successful closure of the AVF was achieved through prolonged balloon inflation. A comprehensive depiction of major complications and their corresponding treatments is outlined in **Table 2**.

Table 2. Major complications and treatments					
Variables	Surgical treatment (n=8)	Endovascular treatment (n=19)	Total (n=27)		
Dissection		14	14 (51.9%)		
Arterial perforation	1	4	5 (18.5%)		
Major hematoma	3		3 (11.1%)		
Pseudoaneurysm	2		2 (7.4%)		
Distal embolism	2		2 (7.4%)		
Arterio-venous fistula		1	1 (3.7%)		

Within the cohort of patients considered for this study, endovascular techniques were primarily favored for addressing complications (19 patients, 4.7%), while surgical interventions were employed in the remaining cases (8 patients, 2%). The mean duration of stay in the intensive care unit was calculated at 0.63±0.49 days, with a mean hospitalization period of 2.48±1.58 days. Notably, in 26 out of 27 cases (96.3%) where complications emerged, critical amputations were prevented, resulting in the preservation of the extremities. Only one case, which underwent embolectomy, necessitated a minor amputation during the follow-up period. The ischemia of the patient's finger did not resolve despite all medical treatments, including ilomedin therapy, and amputation was necessitated. Regrettably, the study observed a single case of mortality during hospital stay.

#### DISCUSSION

The first successful attempt of percutaneous dilatation of the stenotic vessel was accomplished by Charles Theodore Dotter in 1964. The balloon angioplasty catheter was then introduced by Grüntzig and Hopff in 1974, which marked a substantial advancement in catheter-mediated therapy. Over the past 50 years, endovascular procedures have become widely used in both the diagnosis and treatment of peripheral vascular disease.<sup>[2]</sup> However, this increase in the number of peripheral endovascular procedures has led to a rise in iatrogenic vascular injuries and related surgical interventions. In the literature, it has been reported that 2.7% of patients who underwent peripheral endovascular interventional procedures developed complications requiring surgical intervention.<sup>[3]</sup> The incidence of vascular complications necessitating surgical intervention was determined to be 2% in our study, which is consistent with the literature.

The majority of patients with peripheral artery disease have comorbid conditions including diabetes, hypertension, renal dysfunction, and coronary artery disease. The management and outcome of endovascular procedures are significantly influenced by these comorbid situations. Therefore, a detailed patient assessment should be performed before endovascular interventions, and precautions should be taken against possible complications. Furthermore, it is imperative to develop personalized treatment strategies that consider several characteristics influencing the likelihood of challenges, including but not limited to advanced age, obesity, atherosclerosis, gender, and smoking behavior.<sup>[2,4]</sup> By employing this approach, the efficacy of endovascular procedures can be improved, leading to a notable enhancement in patients' quality of life. The age, gender distribution, and presence of concomitant conditions among the patients in our study group were consistent with the existing literature.<sup>[5,6]</sup>

There are several important factors that can significantly affect the rate of complications following peripheral endovascular treatments. These factors include the size of the catheter used, the characteristics of the arteries being treated, the patient's previous experiences with catheterization, the specific anticoagulation regimen being employed, the severity of the underlying medical condition, and the administration of thrombolytic agents.<sup>[2]</sup> In the study conducted by Dariushnia et al.<sup>[7]</sup> 1% was considered an acceptable rate for all major complications that may develop in patients undergoing diagnostic angiography. However, Singh et al.<sup>[8]</sup> reported that the total rate of complications following balloon angioplasty should not exceed 10%, while the rate of severe complications should not exceed 5%. These findings suggest that endovascular procedures, particularly PTA, increase the risk of vascular complications. We attribute the relatively elevated rate of complications associated with endovascular interventions in our patient cohort (6.7%) in comparison to existing literature due to the extensive application of balloon-stent procedures within our patient group. Moreover, the inclusion of patients necessitating more complex interventions, a characteristic of our vascular surgery clinic, could also contribute to this observed variance.

In the existing literature, dissection has been consistently documented as the prevailing complication associated with endovascular procedures.<sup>(9,10)</sup> Remarkably, our study's observed incidence of dissection, which aligns with this trend, corroborates the literature's findings. The SFA became the primary site of dissection, with balloon intervention emerging as the prevailing approach. In cases where the dissection extended over a vessel segment exceeding 5 cm and successful flow restoration wasn't achieved through ballooning alone, stenting was subsequently employed. Importantly, within our dissection cases, surgical intervention wasn't necessary, and favorable outcomes were achieved exclusively through endovascular modalities.

Arterial perforation was another complication we experienced in our patient population. Five patients (18.5%) developed perforation, of which two were localized in the TA and three in the SFA. In one of the three patients with SFA rupture, primary repair was performed, while covered stents were preferred in the other two cases. All instances of TA perforations were effectively managed through the application of prolonged, low-pressure balloon inflation over the affected lesion. Upon comparing our findings with those

reported in the existing literature, we observed similarities in both our complication rates and the cases necessitating surgical approach.<sup>[11]</sup> Despite the typically elevated risk of mortality in such cases, it is noteworthy that our timely and appropriate actions have resulted in a complete absence of operative and interventional mortality. However, it is important to note that these ruptures may arise in individuals who have calcified plaques, vasculitis, or when utilizing big diameter balloons that are not appropriate for angioplasty. <sup>[2]</sup> Hence, it is imperative to pay attention to the selection of catheter, balloon, and stent diameters, as well as the conduct of procedures, in order to mitigate the occurrence of complications and to enable the development of successful therapeutic approaches in the context of endovascular interventions.

Significant hematomas at the intervention site were one of the complications we observed. All hematomas requiring transfusion were found in the femoral region. All of the hematoma cases underwent surgical treatment under general anesthesia, and all of these patients required primary repair with hematoma evacuation as an additional procedure because of active bleeding at the catheter entry site in the femoral artery. The results of the hematoma cases in our study were successful and consistent with the series in the literature. <sup>[12]</sup> The causes of intervention site-related major hematomas, a serious complication of peripheral endovascular procedures, depend on various factors. Potential causes of hematomas include damage to the vessel wall during catheter insertion, the use of large-diameter catheters or balloons, and severe vascular calcification.<sup>[2]</sup> These factors may increase the likelihood of hematoma formation during peripheral endovascular procedures. Preventing and effectively treating such complications is a crucial step in ensuring the efficacy and safety of peripheral endovascular interventions. Accordingly, experienced healthcare professionals with the appropriate training to improve the outcomes of peripheral vascular interventions, particularly cardiovascular surgeons with the ability to make prompt decisions and switch to open surgery when necessary, will play a crucial role in addressing these complications.

Pseudoaneurysm was another complication associated with the site of peripheral endovascular intervention. In our study, two cases of femoral pseudoaneurysms necessitating surgical intervention were detected. Primary repair was performed under local anesthesia in both cases. The incidence of pseudoaneurysms after percutaneous intervention in the femoral artery is approximately 1.2%.<sup>[13]</sup> Risk factors in such cases include female gender, advanced age, hypertension, arterial calcification, large arterial catheters, and anticoagulation use. Pseudoaneurysms can lead to distal embolization, arterial and venous occlusion, compression of adjacent nerve structures, and even rupture. Treatment is determined depending on the size of the pseudoaneurysm, the diameter of the neck, and the patient's coagulation status. Pseudoaneurysms, usually

smaller than 2 mm, tend to thrombose spontaneously and can therefore be monitored by serial ultrasonography follow-up.<sup>[2,14]</sup> The occurrence of pseudoaneurysms following peripheral endovascular interventions can have devastating effects on mortality and morbidity. Therefore, careful patient assessment, close follow-up, and appropriate precautions should be taken to prevent such complications. Especially following the procedure, the arterial access site should be kept under compression with a certain force and duration.

In our study, we observed two cases of distal embolism requiring urgent surgical intervention. Both patients developed distal embolism in the femoropopliteal region, leading to critical leg ischemia. An embolectomy was performed under emergency conditions. Distal flow was maintained in both cases, and one of the patients required minor amputation during the follow-up period. Our distal embolism results related to endovascular procedures are similar to the literature.<sup>[15]</sup> Distal embolism is a rare but serious complication following endovascular procedures. Embolism occurs when plaques or thrombi are carried into the distal vessels during the endovascular intervention. Distal embolism typically remains asymptomatic when involving small emboli; however, a significant thrombus can prompt acute limb ischemia, eliciting intense leg pain and other associated symptoms. In such cases, it is critical that the thrombus be removed as guickly as possible. To reduce the risk of distal embolism, it is important that appropriate techniques are used and procedures are performed by experienced professionals. Close monitoring of patients and timely action to deal with distal embolism and other complications are of vital importance.

In our study, AVF, a rare but potentially serious complication during endovascular interventions, was seen in one of our patients. The localization of the AVF was between the anterior tibial artery and vein. The fistula was successfully repaired with prolonged PTA balloon inflation. Neither the implementation of covered stents nor surgical closure were deemed necessary. Both the incidence of complications and the type of interventions administered aligned closely with existing literature findings.<sup>[14]</sup> AVF is more common in patients with hypertension, female gender, and high-dose anticoagulants. AVF usually affects the SFA and profunda femoral arteries and less frequently involves the main femoral artery. AVF may present with symptoms including pain, pulsatile mass, distal ischemia, limb swelling, dermatitis, skin ulceration, or congestive heart failure. Balloon-stenting may be used for the closure of short-segment AVFs. However, placement of a covered stent at the bifurcation of the CFA is contraindicated because it may lead to the occlusion of the PFA.<sup>[14]</sup> In such cases, surgical repair should be considered first. During endovascular interventions, caution should be taken against the possibility of AVF complications, and appropriate treatment methods should be utilized if they occur.

There are several noteworthy limitations associated with our study that warrant discussion. First and foremost, our research design is retrospective in nature. Furthermore, our study was conducted at a single medical center, which may limit the generalizability of our findings to a broader population. Another limitation pertains to the size of our patient cohort. While we analyzed a substantial number of cases, it is important to acknowledge that a larger sample size would provide greater statistical power and potentially more robust conclusions. Lastly, the absence of a control group is a limitation that should be acknowledged. Comparative studies with control groups are valuable for drawing stronger causal inferences and assessing the true impact of interventions. In light of these limitations, the interpretation of our findings should be made with caution, and future research, ideally employing prospective designs and larger, more diverse patient populations, is warranted to further investigate and validate the outcomes observed in our study.

### CONCLUSION

In contemporary medical practice, peripheral endovascular treatments have gained significant prominence, often rivaling conventional surgical approaches. Undoubtedly, this surge in popularity has introduced its own set of associated complications. When treating serious complications arising from peripheral endovascular procedures, prompt and effective surgical intervention is essential. Healthcare professionals in this field must possess the necessary knowledge, expertise, and clinical experience to effectively manage these severe complications. Since cardiovascular surgeons have adequate training and expertise in the natural course of peripheral arterial diseases and their response to treatment, we believe they are able to assess medical, surgical, and endovascular approaches holistically when evaluating lower extremity peripheral arterial diseases and decide on the most appropriate approach for primary treatment and emergency complications. Although endovascular techniques have made significant advances in recent years, they have the potential to be inadequate in some cases when dealing with complications. As our study shows, surgical intervention may become inevitable for the management of such complications. The enduring importance of traditional vascular surgical techniques is well recognized, as they are believed to yield the best results when combined with modern endovascular methods.

#### ETHICAL DECLARATIONS

**Ethics Committee Approval:** The study was approved by the KTO Karatay University Faculty of Medicine, Pharmaceutical and Non-Medical Device Research Ethics Committee (Date: 17.06.2022, Decision No: 2022/034)

**Informed Consent:** All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

**Conflict of Interest Statement**: The authors have no conflicts of interest to declare.

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