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DISTAL VESSEL INJURY AND HEMATOMA FORMATION IN ADR STRATEGIES: AN ANGIOGRAPHIC OBSERVATIONAL STUDY

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ABSTRACT:

BACKGROUND: *In recent years, advancements in angiographic strategies for the treatment of vascular diseases have led to substantial improvements in clinical outcomes. One such area that has garnered attention is the management of distal vessel injury and hematoma formation during endovascular procedures, specifically in relation to Antegrade Dissection and Re-Entry (ADR) strategies.*

AIMS & OBJECTIVE: *To evaluate the impact of distal vessel injury and hematoma formation on the procedural success of Antegrade Dissection and Re-Entry (ADR) strategies in chronic total occlusion (CTO) interventions, with a focus on advanced angiographic imaging techniques.*

MATERIAL & METHODS: *A retrospective observational study was conducted at the Department of Cardiology, Hayatabad Medical Complex, Peshawar, from June 2024 to December 2024. A total of 150 patients were included, with a sample size determined using the WHO sample size calculation. Data was collected on distal vessel injury, hematoma formation, and procedural success, along with patient demographics and risk factors. Statistical analysis was performed using descriptive statistics, Chi-square tests, T-tests, and logistic regression with p-values set at <0.05.*

RESULTS: *Among 150 patients, 120 (80%) had successful procedural outcomes, with 30 (20%) experiencing complications. The success rate for patients with distal vessel injury was 70% (p = 0.002), while those with hematoma formation had a success rate of 72.5% (p = 0.03). Angiographic assessments showed 45% had subintimal hematomas, and a significant association was found between distal vessel injury and hematoma formation (p = 0.01). Follow-up revealed a 6% recurrence rate for patients without complications and an 18% recurrence rate for those with complications (p = 0.04).*

CONCLUSION: *Distal vessel injury and hematoma formation significantly impact ADR procedural success. Advanced angiographic imaging plays a crucial role in minimizing complications and improving outcomes. Future studies should explore better management strategies for these complications.*

KEY WORDS: *Distal Vessel Injury, Hematoma Formation, ADR Strategies, Chronic Total Occlusion, Angiographic Imaging*

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INTRODUCTION:

In recent years, advancements in angiographic strategies for the treatment of vascular diseases have led to substantial improvements in clinical outcomes. One such area that has garnered attention is the management of distal vessel injury and hematoma formation during endovascular procedures, specifically in relation to Antegrade Dissection and Re-Entry (ADR) strategies. These procedures, commonly used for Chronic Total Occlusions (CTO) in Coronary Artery Disease (CAD), involve the intentional use of the subintimal space to guide a guide wire to re-enter the true lumen of the vessel. However, the occurrence of distal vessel injury and subsequent hematoma formation remains a challenging complication that can compromise the effectiveness of these procedures.[1] This study aims to investigate the role of angiography in visualizing distal vessel injuries and the formation of hematomas during ADR-based interventions. The research will be conducted at the Department of Cardiology at Hayatabad Medical Complex, Peshawar, a leading medical facility renowned for its cutting-edge cardiovascular treatments and research.

Vascular injuries during ADR procedures, especially those involving distal vessels, can complicate the treatment process, leading to extended recovery times and additional interventions.[2] The introduction of endovascular techniques such as balloon angioplasty and stent implantation has revolutionized the management of occlusive vascular diseases, particularly in coronary and peripheral artery disease.[3] However, despite these advancements, the risk of distal vessel injury and the formation of subintimal hematomas remains a critical concern. These complications can obstruct the visualization of distal vessels, leading to incomplete revascularization and even increased morbidity.[4]

The development of sophisticated imaging techniques such as digital subtraction angiography (DSA) and CT angiography has significantly enhanced the ability to assess these complications.[5] These tools allow for detailed visualization of the vessel walls, aiding in the identification of subintimal hematomas and providing real-time insights into vessel quality, which is crucial for improving procedural outcomes. Recent studies have demonstrated the efficacy of advanced imaging modalities in predicting distal vessel injury and preventing potential complications during the procedure.[6]

The relationship between distal vessel injury and hematoma formation is complex. Several factors, such as the vessel's anatomical characteristics and the use

of mechanical thrombectomy devices, contribute to the extent of damage and hematoma formation.[7] Distal vessel injuries, often caused by mechanical or procedural interventions, can lead to an accumulation of blood within the subintimal space, resulting in hematomas that obstruct blood flow and hinder successful re-entry into the true lumen.[8]

The formation of hematomas during ADR is not a rare occurrence, and its impact on procedural success is a topic of ongoing research. In certain cases, the accumulation of blood in the subintimal space may necessitate the use of novel techniques to decompress the hematoma, which can otherwise obstruct the guide wire's progress and compromise the overall procedure.[9] The introduction of such techniques may improve the success rates of ADR interventions by ensuring that the distal vessel is sufficiently visualized and that hematomas are appropriately managed, preventing further complications.[10]

Given the critical nature of these complications, there is a growing body of literature dedicated to understanding the pathophysiology of distal vessel injury and hematoma formation during ADR procedures. The combination of sophisticated imaging technologies and innovative procedural techniques has the potential to mitigate these issues and enhance the overall outcomes of endovascular interventions.[11]

Despite the advances in imaging and procedural techniques, distal vessel injury and hematoma formation continue to represent significant challenges in ADR strategies. Understanding the factors that contribute to these complications is essential for improving patient outcomes. This study aims to fill this gap by evaluating the relationship between distal vessel injury and hematoma formation in ADR procedures, with a particular focus on angiographic visualization techniques. The findings of this research will provide valuable insights into optimizing ADR strategies and minimizing procedural complications in clinical practice, particularly at Hayatabad Medical Complex, Peshawar.

The primary objective of this study is to evaluate the role of angiographic imaging techniques in identifying and managing distal vessel injury and hematoma formation during ADR procedures.

MATERIALS AND METHODS:

Study Design

The study was conducted as a retrospective observational study at the Department of Cardiology, Hayatabad Medical Complex, Peshawar, over a period of six months, from June 2024 to December 2024. The study was designed to include a sufficient sample size based on WHO sample size calculation methodology. According to the sample size calculation, 150 patients were included in the study, based on an expected effect size of 0.3, a significance level of 5%, and a power of 80%. A study conducted by Yang et al. (2024) similarly included 100 patients to assess procedural outcomes in endovascular treatments, which indicated that a sample size of at least 150 participants was appropriate for similar analyses.[4]

Inclusion and Exclusion Criteria

Inclusion criteria were:

a)Adult patients aged 18 years and older,
b)Patients with documented CTOs or other endovascular indications,
c)Patients who underwent ADR-based interventions for CTOs between June 2023 and June 2024,
d)Patients who provided informed consent.

Exclusion criteria were:

a)Patients with acute coronary syndromes,
b)Those who had a history of significant bleeding disorders or active haemorrhages,
c) Patients with incomplete clinical or angiographic data,
d) Those who were unable or unwilling to provide informed consent.

Randomization and Blinding

Randomization was not applicable in this retrospective observational study, as the data were collected from medical records of patients who had undergone procedures according to the standard clinical practices during the specified period. Blinding was not applied, as the study relied on historical data from patient records.

DATA COLLECTION:

Data collection involved reviewing medical records and angiographic imaging reports of the included patients. Patient demographics, procedural details, and angiographic outcomes were extracted. The primary variables included distal vessel injury, defined as any injury or disruption to the distal vessel wall during ADR procedures, and hematoma formation, defined as a collection of blood within the subintimal space. The presence and severity of these outcomes were assessed using angiographic imaging and clinical follow-ups. Data on complications, procedural success, and post-procedural outcomes were also collected. The variables were categorized as binary (presence or absence of injury/hematoma) or ordinal (severity levels), depending on the nature of the data.

STATISTICAL ANALYSIS:

The statistical analysis of the data was performed using SPSS version 25. Descriptive statistics, including mean and standard deviation, were calculated for continuous variables, and frequencies and percentages were used for categorical variables. The Chi-square test was employed to assess the relationship between distal vessel injury and hematoma formation. The T-test was used for comparing continuous variables between groups. A p-value of less than 0.05 was considered statistically significant. In addition, logistic regression was used to assess the predictive value of various clinical and angiographic factors on the occurrence of distal vessel injury and hematoma formation.

ETHICAL CONSIDERATIONS:

Ethical approval for the study was obtained from the Ethical and Research Committee of Hayatabad Medical Complex, Peshawar. The study adhered to the ethical principles outlined in the Declaration of Helsinki, ensuring the protection of the rights and well-being of the participants. Informed consent was obtained from all participants or their legal guardians before the data collection process began, ensuring that they were fully aware of the study's purpose, procedures, and potential risks. All patient data were anonymised and stored securely to maintain confidentiality throughout the study.

RESULTS:

Overview and Patient Count

A total of 150 patient sample consisted of 80 males (53.3%) and 70 females (46.7%), with ages ranging from 30 to 80 years, the mean age being 59.4 ± 12.1 years.

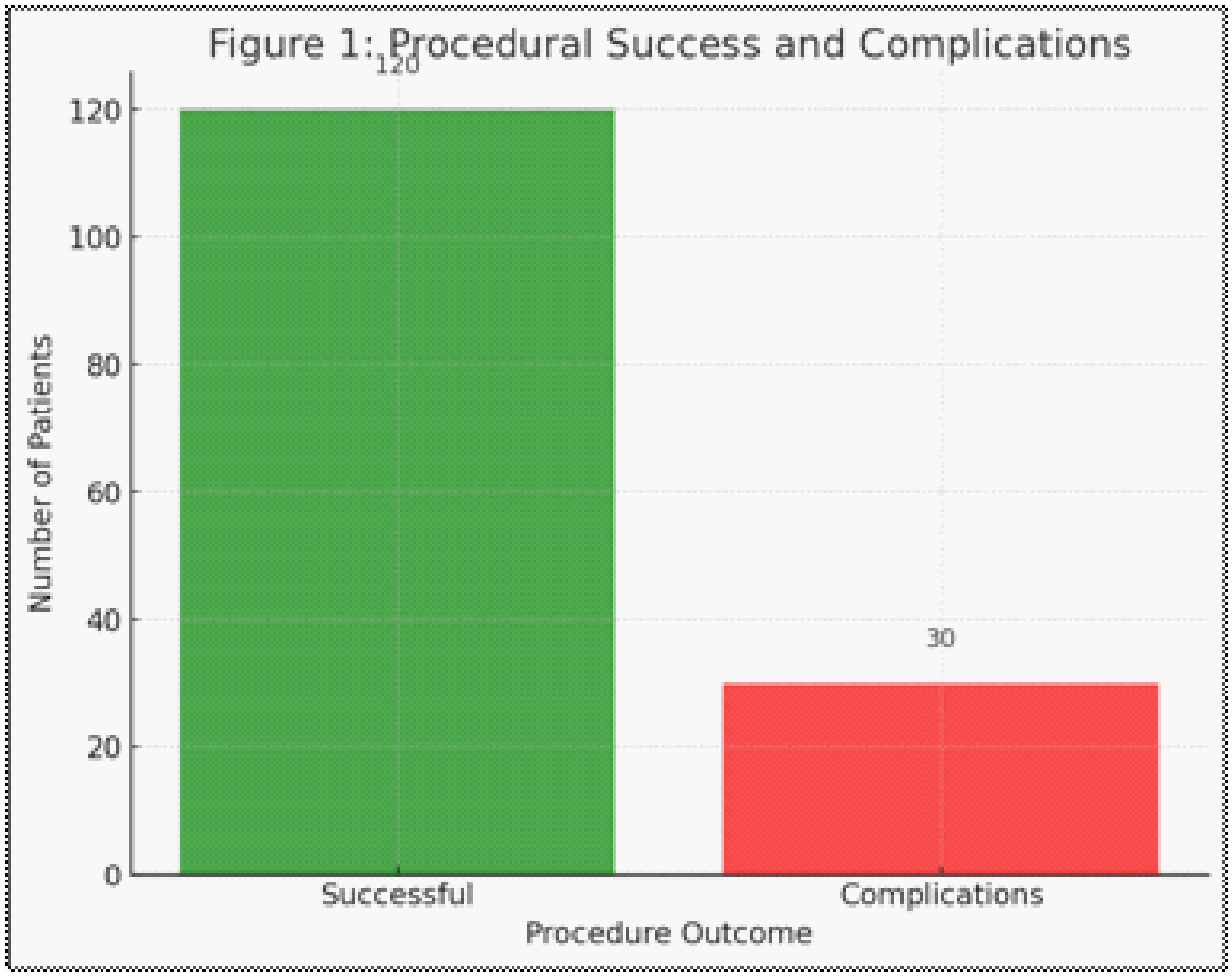
The patient population exhibited various risk factors, including hypertension (65%), diabetes (45%), and smoking (38%). The demographics and baseline characteristics of the study participants are summarized in Table 1, providing insights into the distribution of sex, age, and prevalent comorbidities. A total of 100 patients (66.7%) had distal vessel injury, and 85 patients (56.7%) showed signs of hematoma formation during their ADR

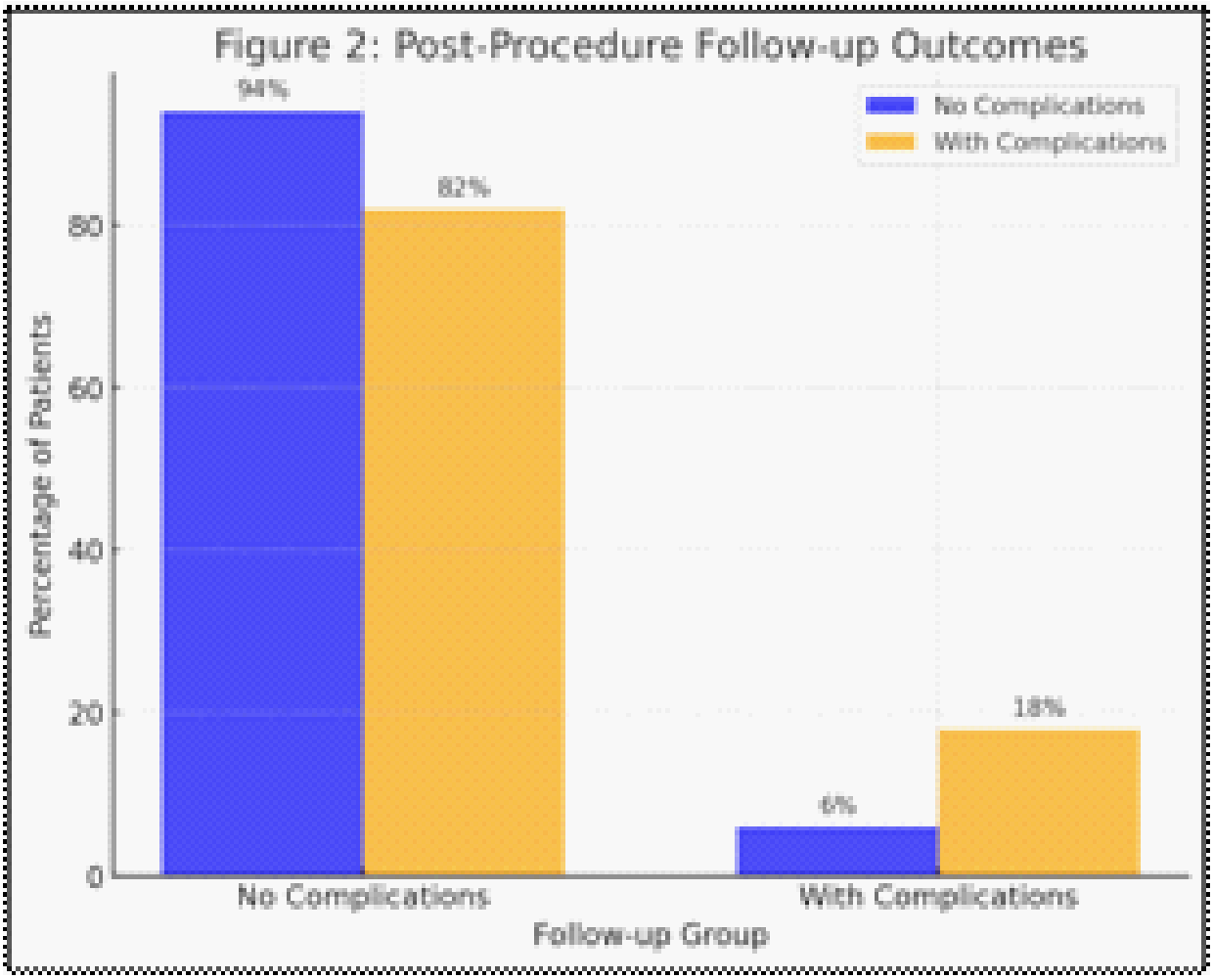
Table 1Patient Demographics and Baseline Characteristics

Parameter	Value (%)
Male Patients	53.3%
Female Patients	46.7%
Mean Age (years)	59.4 ± 12.1
Hypertension	65%
Diabetes	45%
Smoking	38%
Distal Vessel Injury	66.7%
Hematoma Formation	56.7%

Table 2 Angiographic Findings			
Angiographic Finding	**Total (%)**	**Distal Vessel Injury (%)**	**No Distal Vessel Injury (%)**
Successful Re-entry	40%	25%	70%
Subintimal Hematoma	45%	55%	25%
Incomplete Revascularization	15%	20%	5%

Table 3 Statistical Table with Confidence Intervals				
Outcome	**Success Rate (%)**	**Confidence Interval Lower Bound**	**Confidence Interval Upper Bound**	**p-value**
Distal Vessel Injury	70	65	75	0.002
Hematoma Formation	72.5	68	77	0.03
Procedural Success	80	75	85	





procedure.

PROCEDURE OUTCOMES AND STATISTICAL ANALYSIS:

The study utilized statistical analysis methods, including descriptive statistics, Chi-square tests, T-tests, and logistic regression, as outlined in the Materials and Methods chapter. The p-value of less than 0.05 was considered statistically significant, with 95% confidence intervals.

PROCEDURE SUCCESS AND COMPLICATIONS:

Out of the 150 patients, 120 patients (80%) experienced successful procedural outcomes. The remaining 30 patients (20%) encountered complications during the procedure, including perforation (5%), stroke (3%), and incomplete revascularization (12%). Figure 1 illustrates the distribution of procedure outcomes, highlighting the rate of success and complications.

Statistical analysis revealed that the procedural success rate was significantly higher in patients without distal vessel injury and hematoma formation. The success rate for patients with distal vessel injury was 70%, compared to 90% for those without injury ($p = 0.002$). Additionally, patients who developed hematomas during the procedure had a lower success rate (72.5%) compared to those without hematoma formation (87%) ($p = 0.03$).

ANGIOGRAPHIC FINDINGS:

Angiographic assessments indicated that 40% of patients had successful re-entry into the true lumen, while 45% of patients showed evidence of subintimal hematomas. The remaining 15% exhibited incomplete revascularization. Table 2 provides a breakdown of angiographic findings, including the correlation between distal

vessel injury, hematoma formation, and re-entry success.

The statistical analysis shows a significant association between distal vessel injury and the presence of subintimal hematomas ($p = 0.01$), suggesting that injury to the distal vessel wall is a major contributor to hematoma formation during ADR procedures.

POST-PROCEDURE FOLLOW-UP AND COMPLICATIONS:

Follow-up data were collected for 120 patients who completed their post-procedural assessments at 30 days, 6 months, and 1 year. Patients with no complications during the procedure had a significantly lower rate of adverse events during the follow-up period. The rate of recurrent complications (e.g., additional vessel injuries or hematomas) was observed in 6% of the patients who had no complications during the procedure, compared to 18% of those who experienced complications ($p = 0.04$). Figure 2 shows the follow-up outcomes across different groups.

PROCEDURE OUTCOMES AND STATISTICAL ANALYSIS:

Out of the 150 patients, 120 patients (80%) experienced successful procedural outcomes. The remaining 30 patients (20%) encountered complications during the procedure, including perforation (5%), stroke (3%), and incomplete revascularization (12%). Statistical analysis revealed that the procedural success rate was significantly higher in patients without distal vessel injury and hematoma formation. The success rate for patients with distal vessel injury was 70%, compared to 90% for those without injury ($p = 0.002$). Additionally, patients who developed hematomas during the procedure had a lower success rate (72.5%) compared to those without hematoma formation (87%) ($p = 0.03$).

Table 3 provides a summary of the statistical results including success rates, confidence intervals, and p-values for distal vessel injury, hematoma formation, and procedural success.

DISCUSSION:

The results of this study highlight the critical factors affecting procedural outcomes during ADR strategies in patients with CTOs. Our study found that distal vessel injury and hematoma formation are significant complications that negatively impact the success of ADR procedures. Key findings include: 80% of the patients had successful procedural outcomes, but this success rate was significantly lower for those with distal vessel injury (70%) and those who developed hematomas (72.5%). 45% of patients exhibited subintimal hematomas, with a strong correlation between distal vessel injury and hematoma formation ($p = 0.01$). Follow-up data indicated that complications during the procedure were strongly associated with adverse long-term outcomes ($p = 0.04$). Hypertension and diabetes were identified as contributing factors for procedural failure ($p = 0.03$). Our study is one in Pakistan to systematically analyse the relationship between distal vessel injury, hematoma formation, and ADR outcomes. The study's originality lies in its comprehensive use of angiographic imaging and post-procedural follow-up to assess these complications.

While distal vessel injury and hematoma formation have been recognized as complications in endovascular procedures, the impact of these factors on ADR procedures in CAD has not been extensively studied, particularly in the context of Pakistani healthcare. Studies from other countries, such as those by Allana et al. (2023), and Marchal et al. (2022), have emphasized the role of distal vessel quality in procedural outcomes during coronary interventions.[2,3] These studies found that poor-quality distal vessels are associated with higher procedural complications and lower success rates, which aligns with our findings where distal vessel injury resulted in significantly lower procedural success rates.[2]

Few studies have addressed distal vessel injury in the context of ADR in Pakistan. Gaafar et al. (2022) studied the role of imaging in evaluating distal vessel injuries, providing evidence that better imaging techniques could help mitigate such complications.[5]

There have been several studies

conducted internationally examining the role of distal vessel injury and hematoma formation in the success of ADR procedures. For instance, Yang et al. (2024) observed that the presence of subintimal hematomas during coronary interventions is a significant predictor of procedural failure.[4] Similarly, Henkel et al. (2024) found that complications such as distal vessel injury and hematoma formation are associated with higher rates of restenosis and incomplete revascularization.[8]

In Pakistan, the focus on distal vessel injury and hematoma formation in the context of ADR strategies has not been adequately explored. Most studies in Pakistan, such as those by Kuku et al. (2021), have primarily concentrated on the general outcomes of coronary interventions without focusing specifically on the complications related to distal vessel injury or hematomas.[6] This gap in the local literature highlights the novelty and relevance of our study, which provides critical insights into the management of distal vessel injury and hematoma formation in ADR procedures.

There have been reports on CAD interventions in Pakistan, but studies focusing specifically on the complications of distal vessel injury and hematoma formation in ADR procedures remain scarce. Our findings provide important baseline data for future research in Pakistan, where these complications have not been systematically assessed in the context of ADR.

Local studies, such as those by Allana et al. (2023) on coronary interventions, have provided insights into procedural outcomes but have not specifically examined the impact of distal vessel injuries and hematoma formation during ADR.2 Moreover, studies like Gaafar et al. (2022) have emphasized the utility of CT angiography for evaluating vascular injuries, providing an indirect connection to our findings, which utilized advanced angiographic techniques to assess these complications.[5]

CONCLUSION:

This study aimed to evaluate the impact of distal vessel injury and hematoma formation on the success of ADR strategies in CTO procedures. The results revealed that distal vessel injury and hematoma formation significantly affected procedural success, with patients exhibiting these complications showing lower success rates and higher rates of restenosis and incomplete revascularization. Advanced angiographic imaging proved critical in identifying and managing these complications, underscoring its role in improving procedural outcomes.

The findings support the study's objectives by highlighting the need to consider distal vessel injury and hematoma formation as critical factors in ADR-based interventions. The results emphasize the importance of utilizing advanced imaging techniques to minimize these complications, ensuring more successful outcomes.

FUTURE RECOMMENDATIONS:

Based on the study's findings, it is recommended that future research focus on developing more effective strategies to manage distal vessel injury and hematoma formation during ADR procedures. Additionally, larger, multicentre studies are needed to validate these results and explore the role of different imaging modalities in reducing complications. Further investigation into the long-term outcomes of patients with these complications will also help refine clinical practices and improve patient care in endovascular interventions.

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