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Comparing the Risk of Distal Embolization between Balloon Tip Guide Catheter and Non-Balloon-Tip Guide Catheter / Guide Sheath, during Mechanical Thrombectomy in Acute Stroke Intervention

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ABSTRACT

Objective: This study compares the risk of distal embolization of balloon-tip guide catheters (BGCs) versus non-balloon-tip guide catheters (NBGCs) or Guide sheath in mechanical thrombectomy to treat acute ischemic stroke.

Methodology: This retrospective comparative study analyzed patients treated with mechanical thrombectomy for acute ischemic stroke at Rawalpindi Institute of Cardiology, from July 2022 to November 2023 after ethical approval. Patients were grouped based on balloon-tip guide catheters (BGC) versus non-balloon-tip guide catheters (NBGC) or Guide sheath. The outcome was the distal embolization rates during mechanical thrombectomy for stroke intervention. Statistical analysis was conducted by the Statistical Package for the Social Sciences (SPSS) version 25.

Results: A total of 209 patients were included, with 38 in the Balloon Tip (BGC) group and 171 in the Non-Balloon Tip (NBGC) group or Guide sheath. The age distribution, gender, and number of thrombectomy attempts were comparable between the groups, with no significant differences ($p > 0.05$). Femoral access was used in almost all cases. The BGC group had a slightly lower rate of distal embolism than NBGC (7.9% vs. 9.4%), but the difference was not statistically significant ($p = 0.7767$).

Conclusion: This study found no significant difference in distal embolism rates between Balloon Tip and Non-Balloon Tip guide catheters in mechanical thrombectomy for stroke. Despite theoretical advantages, BGCs did not show a clear clinical benefit over NBGCs. Further research is needed to determine the optimal guide catheter choice for improving patient outcomes.

Keywords: Medical thrombectomy, Balloon Tip Guide Catheter, Non-balloon-tip guide catheters, Distal embolization

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Introduction

Mechanical thrombectomy has emerged as a transformative treatment modality for acute ischemic stroke, especially for patients with large vessel occlusions (LVOs).[1] The procedure has demonstrated remarkable efficacy in restoring cerebral perfusion, leading to improved neurological outcomes and reduced mortality.[2]

0Despite its success, one of the persistent challenges in mechanical thrombectomy is the risk of distal embolization—where clot fragments dislodge during the procedure and migrate to more distal cerebral arteries, potentially leading to new areas of ischemia.[3] This complication can diminish the overall effectiveness of the intervention and exacerbate the patient's condition, making it crucial to explore methods that minimize the occurrence of distal embolization.[4]

The selection of guide catheters is a critical consideration in mechanical thrombectomy, as these devices facilitate the introduction of thrombectomy tools into the cerebral vasculature and can influence procedural outcomes. Two

primary types of guide catheters are utilized in practice: non-balloon guide catheters (NBGCs)/ guide sheath and balloon tip guide catheters (BGCs).[5] Guide sheath have traditionally been used in thrombectomy procedures due to their simplicity and ease of use. However, they offer limited control over blood flow during the intervention, which could increase the risk of distal embolization as clot fragments are more likely to be carried distally by ongoing blood flow.[6]

Balloon tip guide catheters, on the other hand, have been developed to address this very concern. By incorporating a balloon near the catheter's tip, BGCs offer the unique capability to temporarily occlude blood flow in the target vessel while retrieving the thrombus.[7] This occlusion theoretically reduces the risk of distal embolization by preventing clot fragments from being carried away by the bloodstream during the procedure. The potential benefits of BGCs have led to their increasing adoption in mechanical thrombectomy, particularly in cases where minimizing distal embolization is deemed critical. However, the clinical efficacy of BGCs in consistently achieving this goal remains a topic of ongoing debate.[8]

Several studies have compared the effectiveness of BGCs versus NBGCs or Guide sheath in mechanical thrombectomy, with varying results. The risk of distal embolization during mechanical thrombectomy for acute stroke intervention is an important consideration to improve patient outcomes. To optimize the outcomes of mechanical thrombectomy, it is crucial to compare different techniques and devices used during the procedure. This study was designed to provide a comprehensive comparison of the risk of distal embolization between guide sheath catheters and balloon tip guide catheters during mechanical thrombectomy for stroke intervention. By critically evaluating the existing literature, including key studies such as the PROTECT-MT trial, the MR CLEAN registry analysis, and the MaSQ-Registry study, this paper aims to clarify the role of BGCs in reducing distal embolization and to assess whether their use significantly enhances patient outcomes. The ultimate goal is to contribute to the ongoing discourse on optimizing thrombectomy techniques, ensuring the patients receive the most effective and safe interventions available.

Methodology

It was a retrospective comparative cross-sectional study carried out at the Rawalpindi Institute of Cardiology after ethical approval. A total of 209 patients who presented with acute ischemic stroke and underwent mechanical thrombectomy using either NBGCs/ guide sheath or BGCs were included by convenient sampling after obtaining informed consent. Data from medical records and CDs of patients who had undergone acute stroke interventions were reviewed to assess the comparison of these catheter types. The analysis was based on records from the previous year at the Rawalpindi Institute of Cardiology (July 2022 to November 2023). Any patient whose thrombectomy CD could not be reviewed was excluded from analysis. Patient baseline characteristics, vascular access anatomy, recanalization devices, and the number of mechanical thrombectomy attempts with either balloon-tip or non-balloon-tip/ guided sheath catheters were recorded.

Statistical analysis was conducted by the Statistical Package for the Social Sciences (SPSS) version 25. Descriptive statistics (frequency & percentage) were used to summarize the characteristics of the study population. Chi-square test was employed to determine the relation between qualitative and quantitative variables between the two groups, respectively with significant p-value of <0.05.

Results

The analysis compared patient demographics and procedural techniques between the balloon-tip guided catheter group (n = 38) and the non-balloon-tip guided catheter group (n = 171). The age distribution was similar between the two groups, with no significant difference (p = 0.299). In the balloon-tip group, 44.7% of patients were aged 60 to 80 years, compared to 48.5% in the non-balloon-tip group. Gender distribution showed that males were more prevalent in both groups, comprising 68.4% in the balloon-tip group and 57.3% in the non-balloon-tip group, though this difference was not statistically significant (p = 0.191).

Regarding the number of mechanical thrombectomy attempts, the majority of patients in both groups underwent a single procedure (50% in the balloon-tip group and 40.9% in the non-balloon-tip group), with no significant difference between the groups (p = 0.383). The site of vascular access was predominantly femoral in both groups, with femoral access used in 100% of cases in the balloon-tip group and 99.4% in the non-balloon-tip group, indicating no significant difference in the access site (p = 0.637).

Table I: Demographics and Technique Used.

Demographics and Technique Used	Balloon Tip n (%)	Non Balloon Tip n (%)	P Value
Age Categories			0.299
20 to 40 years of age	6(15.7)	20(11.7)	
40 to 60 years of age	12(31.6)	64(37.4)	
60 to 80 years of age	17(44.7)	83(48.5)	
80 to 100 years of age	3(7.9)	4(2.3)	
Gender			0.191
Male	26(68.4)	98(57.3)	
Female	12(31.6)	73(42.7)	
Number of attempts			0.383
First attempt	19(50)	70(40.9)	
Second attempt	11(28.9)	46(26.9)	
Third attempt	8(21.1)	55(32.2)	
Site of Access			0.637
Femoral	38(100)	170(99.4)	
Brachial	0(0)	1(0.58)	

Table II: Type of Guide used.

Type of Guide used	N	%
Balloon Tip	38	18.18
Non Balloon Tip Guide / Guide sheath	171	81.82
Total	209	100.00

Table III: Type guide & Complications.

Complications	Balloon Tip	Non-Balloon Tip	P Value
No complication	35(92.1)	155(90.6)	0.777
Distal embolism	3(7.9)	16(9.4)	

The analysis of complications revealed that the majority of patients in both groups experienced no complications, with 92.1% in the balloon-tip group and 90.6% in the non-balloon-tip group ($p = 0.777$). The occurrence of distal embolism was slightly lower in the balloon-tip group (7.9%) compared to the non-balloon-tip group (9.4%), but this difference was not statistically significant.

Overall, the study found no significant difference in the risk of distal embolization or other complications between the balloon-tip guided catheter and non-balloon-tip guided catheter during mechanical thrombectomy for stroke intervention.

Discussion

Mechanical thrombectomy is the treatment of choice for emergency management of acute ischemic stroke. However, it is associated with a considerable risk of complications ranging from 4% to 31% in the literature.[9] The results of a study conducted on an in-vitro model showed that the occurrence of embolization in new territories was significantly reduced by the BGCs, compared to other devices.[10]

The findings from this study provide valuable insights into the ongoing debate over the use of BGCs versus NBGCs or Guide sheath in mechanical thrombectomy for stroke intervention. Despite the theoretical advantages of BGCs in reducing the risk of distal embolization, our analysis did not reveal any significant differences in outcomes between the two catheter types. Firstly, the demographic and procedural data showed no significant differences between the BGC and NBGC or Guide sheath groups, with both cohorts having similar age distributions, gender ratios, and vascular access sites. This homogeneity suggests that the comparison between the two catheter types was conducted on comparable patient populations, thereby enhancing the validity of our results.

The primary outcome of interest—distal embolization—was slightly lower in the BGC group compared to the NBGC or Guide sheath group, but this difference was not statistically significant. This finding aligns with some previous studies, such as the MR CLEAN registry analysis, which also found no significant differences in clinical outcomes between patients treated with BGCs and those treated with NBGCs or Guide sheath.[11] However, the analysis did reveal that BGCs might perform better when used in conjunction with stent retriever techniques, suggesting that the specific thrombectomy approach might influence the effectiveness of the catheter type.[12] Contrary to the findings from MR CLEAN, the MaSQ-Registry study revealed a different perspective. This study specifically examined the role of balloon inflation in BGCs, comparing outcomes between procedures where the balloon was inflated versus those where it was not. The results indicated no significant clinical differences between the two groups, challenging the assumption that balloon inflation is a critical factor in reducing distal embolization. These findings raise important questions about the actual mechanisms through which BGCs might influence procedural outcomes and whether the presence of the balloon itself, rather than its inflation, might contribute to any observed benefits.[13]

The PROTECT-MT trial was designed to rigorously assess the comparative effectiveness of BGCs against conventional guide catheters. Early data from this trial

suggested some advantages of BGCs, particularly in reducing distal embolization. However, the trial faced significant challenges, including safety concerns that led to a temporary halt in recruitment due to adverse outcomes observed in preliminary analyses. These concerns highlight the complexity of using BGCs and underscore the need for a thorough understanding of the circumstances under which they might be beneficial or detrimental.[14] In a meta-analysis, the incidence of distal embolization was less in BGC than non-BGC group but not significantly.[15] Chen et al. also reported no significant difference in distal embolization between BGC and Guide sheath groups.[16] The Combined Thrombectomy Study investigated the outcomes of mechanical thrombectomy using a combined approach of aspiration and stent retriever techniques, with both BGCs and NBGCs or Guide sheath being employed. This study found no significant differences in recanalization rates or functional outcomes between the two types of catheters, suggesting that the choice of catheter might not be as critical as the overall thrombectomy strategy.[17]

Some studies also reported that BGCs are associated with less risk of distal embolization. In a study by Friedrich et al., distal embolization occurred in 8.8% of the patients who underwent MT with non-balloon guide sheath as compared to 3.1% in patients with balloon guide catheters, with a marked difference.[18] Another study revealed that the incidence of distal embolization was 8.8% in BGC group and 14.9% in Guide sheath group, with statistical significance.[19] A meta-analysis showed that distal embolization affected 7.5% of the cases with BGCs and 11.5% of the cases with guide sheath with statistically significant results.[20] Distal embolization was much lower in patients who underwent MT with BGC as compared to Guide sheath in another study.[21]

Conclusion

This study found no significant difference in distal embolism rates between Balloon Tip and Non-Balloon Tip guide catheters in mechanical thrombectomy for stroke. Overall, the results of this study suggest that while BGCs offer a theoretical advantage in preventing distal embolization, this advantage may not translate into significant clinical benefits in practice. The lack of significant differences in outcomes between BGCs and NBGCs or Guide sheath implies that the choice of catheter may be guided more by operator preference, specific case requirements, or other factors rather than a clear superiority of one device over the other.

RECOMMENDATIONS OF THE STUDY: Further research, potentially incorporating larger sample sizes or different thrombectomy strategies, may be necessary to fully elucidate the role of catheter type in stroke intervention outcomes. The conditions under which BGCs might offer clinical advantages and to understand better the variables that most significantly impact outcomes in mechanical thrombectomy should be explored.

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