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Outcomes Profile of Balloon Angioplasty for Symptomatic Intracranial Atherosclerotic Stenosis at Pelni Hospital from January 2021 to July 2024

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ABSTRACT

Background: Intracranial atherosclerotic stenosis (ICAS) is a major cause of ischemic stroke, posing challenges due to its progressive nature and high recurrence risk. Endovascular interventions like balloon angioplasty show promise in improving blood flow and stabilizing stenotic arteries, particularly in symptomatic ICAS (sICAS) patients unresponsive to medical therapy. This study evaluates outcomes of balloon angioplasty for sICAS at Pelni Hospital over 3.5 years.

Methods: A retrospective cohort study of 31 sICAS patients undergoing balloon angioplasty (January 2021–July 2024) assessed demographics, lesion locations, procedural success, and outcomes. Standard endovascular techniques under fluoroscopic guidance were used, focusing on procedural success, complications, and patient stability.

Results: Balloon angioplasty was successful in all patients (100%). Most lesions were in the posterior circulation, particularly the vertebrobasilar artery (54.8%), with anterior circulation lesions in the internal carotid (25.8%) and middle cerebral arteries (19.4%). Complications occurred in 2 patients (6.5%), both resulting in adverse outcomes, including death. The remaining 29 patients (93.5%) experienced no significant complications and remained stable during follow-up.

Conclusions: Balloon angioplasty demonstrates high success with low complication rates for sICAS, offering a viable therapeutic option for severe stenosis unresponsive to medical therapy. Further research is needed to confirm long-term efficacy, refine patient selection, and enhance clinical outcomes.

Keywords: Balloon Angioplasty, Endovascular Treatment, Intracranial Atherosclerotic Stenosis

INTRODUCTION

Intracranial atherosclerotic stenosis is an important etiology and significant risk factor of ischemic stroke worldwide due to a much higher prevalence in Asians. Preliminary studies suggest that angioplasty and stenting may reduce the risk of stroke in patients with severe stenosis of intracranial arteries. Intracranial atherosclerotic Stenosis (ICAS) may occur concomitantly with systemic atherosclerosis. The middle cerebral arteries are the most common site, followed by the basilar artery, the internal carotid arteries, and the intracranial vertebral arteries. ICAS accounts for 30%–50% of strokes in the Asian population, with an annual risk of up

to 23% despite optimum medical management [1–4]

Angioplasty began being considered as a potential therapeutic option in patients with ICAS in the 1980s. It has usually been used when patients with >70% stenosis have ischemic events despite being on antithrombotic therapy. In Japan, angioplasty has been used to treat intracranial stenosis, primarily for refractory medical therapy. Since no stent was designed explicitly for the intracranial arteries before, treatment is often completed with balloon angioplasty alone, and stenting using a coronary stent is applied only in limited situations such as dissection after balloon angioplasty or restenosis. The Wingspan stent developed for the intracranial artery was approved in the US in 2005. [1,5]

Balloon angioplasty was the first endovascular revascularization method to be used in this disease, with a relatively long history and numerous articles addressing its feasibility, efficacy, and risks. In the early 2000s, stent reconstruction became technically feasible, and the initial results for intracranial stenosis treatment were auspicious. However, randomized controlled trials (RCTs) with different device designs (self-expanding and balloon-mounted stents) showed that stenting was significantly inferior to the best medical treatment in functional outcome and secondary stroke prevention in symptomatic stenosis patients. Based on these results, the endovascular treatment (despite balloon angioplasty or stenting) of intracranial stenosis is currently reserved for patients under the best medical treatment having recurrent strokes or TIA or for patients with progressive symptoms. The technique is still considered an investigational procedure without clear recommendations. [6]

The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) and Vitesse Intracranial Stent Study for Ischemic Stroke Therapy (VISSIT) trials have shown high perioperative complication rates and no significant advantage of endovascular stents compared with aggressive medical management in the long term. However, several previous meta-analyses also proved the safety and efficacy of balloon angioplasty for symptomatic ICAS (sICAS), which suggested that balloon angioplasty alone may be promising for sICAS. [4]. This study aims to analyze the outcomes profile of balloon angioplasty for symptomatic Intracranial Atherosclerosis Stenosis (sICAS) at Pelni Hospital from January 2021 to July 2024.

MATERIALS & METHODS

All 31 patients with symptomatic Intracranial Atherosclerosis Stenosis (sICAS) in our cathlab center were retrospectively reviewed in our study from January 2021 to July 2024. Experienced neuro interventions in our center confirmed clinical and angiographic data of ICAS patients with balloon angioplasty. The inclusion criteria include: (1) patients with symptomatic intracranial stenosis who received intracranial balloon angioplasty in both the anterior circulation (supra clinoid segment internal carotid artery (ICA), and middle cerebral artery (MCA)) and posterior circulation (vertebrobasilar artery (VBA)) (2) recurrent TIAs or symptomatic ischemic event despite aggressive medical management; (3) the clinical manifestations were directly related to ICAS; (4) imaging and clinical data were available. The exclusion criteria include (1) patients with stenosis of the extracranial segment treated with balloon angioplasty or stenting procedures and stenosis due to moya disease; (2) complete occlusive lesion; (3) high bleeding tendency, such as hematological diseases.

Data files from the medical record were used retrospectively to determine correlations between differences in the baseline characteristics of patients, procedures, or postoperative outcomes. Statistical analysis was performed using the Mann-Whitney test and SPSS Statistics.

RESULT

The baseline characteristics of patients, treatment locations, and treatment outcomes are shown in Table 1.

Variable	Frek.	%	Mean ± SD	Median (min-max)
Gender				
Male	18	58,1		
Female	13	41,9		
Risk Factor				
Diabetes Mellitus	10	32,3		
Hypertension	21	67,7		
Hyperlipidemia	18	58,1		
Smoking	16	51,6		
Age			55,35 ± 11,42	58 (20 – 76)
Balloon angioplasty location				
ICA supra clinoid	8	25,8		
MCA	6	19,4		
VBA	17	54,8		
Outcome				
Death	2	6,5		
Health	29	93,5		
mRS pre procedures			1,06 ± 1,00	1 (0 – 4)
mRS post procedures			1,19 ± 1,42	1 (0 – 6)

The mean age was 55,35 (20-76) years, and the proportion of male participants was as high as 58,1%. At baseline, the mean modified Rankin scale (mRS) was 1,19, and patients with a mRS of 0–2 accounted for 94 %. Of the 31 procedures, 8 cases (25,8%) were located in the ICA supra clinoid, 6 cases (19,4%) in the MCA, as an anterior circulation, and 17 (54,8%) in the posterior circulation vertebrobasilar artery (VBA). The risk factors were confirmed, which include high blood pressure (21 patients, 67.7%), diabetes mellitus (10 patients, 32.3 %), hyperlipidemia (18 patients, 58.1%), and smoking (16 patients, 51.6%). Clinical follow-up was available in all 31(100%) patients; the results demonstrate that two patients (6,5%) suffered from procedure complications and death after procedures; 29 patients (93.5%) were stable and did not experience complications after the angioplasty procedure. The baseline information of ICAS patients treated with balloon angioplasty was summarized.

The correlation between age and post-procedure outcomes is shown in Table 2.

mRS	Age	
	p	r
Pre	0,353	0,173
Post	0,353	0,173

The correlation between age with the mRS pre- and mRS post-procedures using Spearman's test, a p-value > 0.05, was obtained, so it can be concluded that there is no significant relationship between age and intracranial procedures on the outcome.

The correlation between each factor tested and post-procedure outcomes is shown in Table 3.

Variable	mRS pre		mRS post	
	Mean ± SD	p	Mean ± SD	p
DM				
Yes	1,20 ± 1,23	0,743‡	1,40 ± 1,78	0,743‡
No	1,00 ± 0,89		1,10 ± 1,26	
Hypertension				
Yes	1,05 ± 0,97	0,944‡	1,14 ± 1,32	0,944‡
No	1,10 ± 1,10		1,30 ± 1,70	
Hyperlipidemia				
Yes	1,17 ± 0,92	0,259‡	1,28 ± 1,32	0,259‡

No	0,92 ± 1,12		1,08 ± 1,61	
Smoking				
Yes	0,94 ± 1,06	0,284‡	1,06 ± 1,48	0,284‡
No	1,20 ± 0,94		1,33 ± 1,40	
Gender				
Male	0,94 ± 1,00	0,319‡	1,06 ± 1,39	0,319‡
Female	1,23 ± 1,01		1,38 ± 1,50	
Intracranial procedures				
ICA	1,00 ± 0,76	0,880¶	1,00 ± 0,76	0,880¶
MCA	1,33 ± 1,37		1,67 ± 2,16	
VB	1,00 ± 1,00		1,12 ± 1,41	

Note: ‡ Mann-Whitney ¶ Kruskal-Wallis

From the results of the mRS difference test based on gender, the p-value was > 0.05, so it can be concluded that there is no significant difference. The correlation between risk factors and procedure location with the mRS pre- and mRS post-procedures using the Mann-Whitney test and Kruskal-Wallis test, a p-value > 0.05, was obtained, so it can be concluded that there is no significant relationship between risk factors and intracranial procedures on the outcome.

DISCUSSION

This single-center retrospective study shows that intracranial balloon angioplasty is a safe and effective therapy for symptomatic ICAS. The outcomes in this study, two patients died after the procedure, according to a statement by Colin P. Derdeyn and Marc I. Chimowitz in Angioplasty and Stenting for Atherosclerotic Intracranial Stenosis: Rationale for a Randomized Clinical Trial. In more than 80% of patients, the rate of stroke or death within 30 days after angioplasty varies between 4% and 40% in several retrospective angioplasty studies. One reason for the wide variation in complication rates may be the variability in understanding patients being treated. Procedures that were mostly elective were associated with lower complication rates (4% to 6%). The restenosis rate after balloon angioplasty ranges from 24% to 40%. This can be caused by several technical disadvantages of angioplasty, including direct elastic recoil of the artery, dissection, acute vessel closure, residual stenosis > 50% after the procedure, and high restenosis rates. [3,7]

Meta-analysis of the SAMMPRIS trial discussing the safety of balloon angioplasty in symptomatic intracranial stenosis showed no difference in periprocedural complications (stenosis > 70%). While Better periprocedural outcomes are demonstrated in moderate stenosis (stenosis > 50%). The lower the degree of stenosis, the fewer technical difficulties may arise during procedures. The more severe the degree of stenosis, the more difficult it is to access and traverse the lesion with a relatively stiff balloon. So, it can cause plaque injury, thrombus formation, dissection, or rupture of blood vessels. [6,7]

The statement of Nordmayer H et al. in Angioplasty and stenting of intracranial arterial stenosis in perforator-bearing segments: A comparison between the anterior and the posterior circulation, that intracranial balloon angioplasty with or without stenting procedure is very dangerous for anterior circulation and posterior circulation with many perforating artery branches, causing high periprocedural complications or stroke complications in long-term follow-up due to occlusion of the perforating arteries, direct or delayed embolism. No differences in stroke rates between balloon angioplasty and intracranial stenting were observed. Lesions on DWI Magnetic Resonance Imaging (MRI) sequences occur in almost one-third of cases in all treated patients without distinction between anterior and posterior circulation. Most of the peri-procedural strokes in SAMMPRIS were perforator infarcts felt to be from the “snow-plowing” effect (pushing the atherosclerotic plaque into perforator

vessels during either the balloon dilation or the stent placement) or reperfusion hemorrhage. While the "snow-plowing" effect is likely to remain with any intervention, even angioplasty alone, the potential of new technology or modified endovascular procedures to mitigate these events may allow for improved outcomes of endovascular therapy. [7–9]

Different intracranial stenosis locations have various perioperative complications due to their anatomic features, especially the Middle cerebral artery (MCA) and basilar artery because these 2 locations involve a perforator-rich zone. Most of these lesions were in the basilar artery, and the subgroup with lesions in the basilar artery had the lowest risk of stroke during medical therapy in SAMMPRIS. Patients with higher-grade stenosis and poor antegrade flow will most likely benefit from flow augmentation by primary angioplasty. [10]

Sun Y et al. on Balloon Angioplasty vs. Stenting for Symptomatic Intracranial Arterial Stenosis study recommended that the risk of death was increased in cases treated with balloon angioplasty in pooled studies of low quality. Further, they noted that balloon angioplasty was associated with an increased risk of dissection when pooled studies had retrospective designs or were of moderate quality. The current study reported comprehensive pooled incidences of restenosis, TIA, stroke, death, and dissection after balloon angioplasty or stenting. While no significant differences were noted between balloon angioplasty and stenting for the risk of restenosis, TIA, stroke, and death, balloon angioplasty was found to be associated with an increased risk of dissection. This could be related to the grade of stenosis, and using balloon angioplasty without stenting could induce plaque injury and cause thrombus formation, dissection, or vessel rupture. However, there was significant heterogeneity for pooled incidences of restenosis, TIA, stroke, death, and dissection after balloon angioplasty or stenting, and the indirect comparison results could be affected by variant patient characteristics. [11]

Among the bleeding complications, most were caused by apparent manipulations such as vascular perforation and rupture, and bleeding by other factors, such as hyperperfusion syndrome, was as low as 0.2%. [5]

As an etiological factor, complications from balloon angioplasty and intracranial stent procedures were stated in the research of Toshihiro Ueda et al in Outcomes of Balloon Angioplasty and Stenting for Symptomatic Intracranial Atherosclerotic Stenosis at a High Volume Center, caused by delivery of the stent or balloon with a complex and thick catheter and the patient with acute and sub-acute stroke onset were included in the research criteria, although the incidence of stroke in subsequent follow-up did not differ. The SAMMPRIS trial showed no significant difference in new ischemic events between the stent and best medical treatment groups after the perioperative period. However, balloon placement without a stent may be an effective treatment option. [2]

The correlation between gender, age, risk factors, and procedure location was not significantly correlated with the mRS pre- and mRS post-procedures. However, this is different from the statement by Izumi T et al, in Endovascular therapy for intracranial artery stenosis: Results from the Japanese registry of neuroendovascular therapy (JR-NET)3 stated that when treating patients with asymptomatic stenosis, physicians who are not practicing should be given sufficient consideration. Treatment can be performed safely in cases where the lesion is located in the internal carotid artery stenosis or when the lesion length is less than 10 mm. Patients with pre-onset mRS of 3 or more have a higher complication rate and should be carefully judged for treatment indication. [5] The small research sample can cause this and only a single research center.

Balloon angioplasty is technically a much simpler procedure, where the stenosis is crossed with a micro guidewire, followed by a relatively low-profile angioplasty balloon,

without the need for additional stenting. However, despite this technical advantage, the periprocedural results were not better for balloon angioplasty alone, which may imply the fact that the drawbacks of stenting are balanced by the positive effect of the stent on stabilizing the lesion, which may not happen when angioplasty alone is applied (i.e., dissection caused by balloon angioplasty). Although a direct comparison with the follow-up data of previous RCTs on stenting and best medical treatment could not be made, the low incidence rates of ischemic stroke during the follow-up period and restenosis were worth noting. Although it doesn't allow for far conclusions, one may hypothesize that the low rate of ischemia beyond 30 days in the balloon angioplasty group is due to stenosis reduction and lack of stent implant (a potential cause of induced intimal hyperplasia). This hypothesis may be supported by the restenosis rates of 26.5% found in the VISSIT trial. [12]

Balloon angioplasty alone may be another feasible treatment option for sICAS due to its easy operation and lower rates of perioperative morbidity and mortality. Recent meta-analyses suggest that submaximal balloon angioplasty is a promising intervention for ICAS. However, compared with medical therapy, the long-term effectiveness of balloon angioplasty, including recurrent stroke and restenosis of target vessels, still needs to be discovered. [4]

From this outcome profile of balloon angioplasty in patients with symptomatic atherosclerotic intracranial stenosis at Pelni Hospital study, it can be concluded that balloon angioplasty in patients with symptomatic atherosclerotic intracranial stenosis may provide good outcomes with the proper patient selection and is carried out in a high-volume hospital. This is a preliminary study conducted at Pelni Hospital which shows that the balloon angioplasty procedure is feasible in treating intracranial atherosclerotic stenosis with a satisfactory procedure success rate, low complication rate, and good results with appropriate patient selection and carried out in a hospital with high volume. However, prospective studies with larger populations and extended follow-up should be conducted to evaluate the results and conclusions. Limited data on the long-term results of balloon angioplasty, retrospective research, causes some practitioners to support using stents, although many only recommend balloon angioplasty.

CONCLUSION

This study highlights that balloon angioplasty is a viable and effective treatment option for symptomatic intracranial atherosclerotic stenosis (sICAS), particularly when performed in a high-volume center with appropriate patient selection. The procedure demonstrated a high success rate (93.5%) with a low complication rate (6.5%), supporting its feasibility as an intervention for patients unresponsive to optimal medical therapy. Despite its promising outcomes, limitations such as restenosis and potential perioperative risks underscore the need for careful patient assessment and procedural planning. Further large-scale, prospective studies with extended follow-up are essential to validate these findings, refine patient selection criteria, and establish comprehensive long-term safety and efficacy profiles. By addressing these gaps, balloon angioplasty could emerge as a cornerstone therapy for managing sICAS effectively and safely.

Declaration by Authors

Ethical Approval: The study was approved by the Medical and Health Research Ethics Committee of the Faculty of Medicine Al-Azhar Islamic University (approval number 062/EC-04/FK-06/UNIZAR/VII/2024)

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