IJMA

International Journal of Medical Arts

Volume 7, Issue 3 (March 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Neurosurgery]

Original Article

Safety and Efficacy of Balloon Remolding Technique in Wide Neck Aneurysm in Patients with Subarachnoid Hemorrhage

Mohamed Abd Elaziz Galal [1*]; Mostafa Abd Elsamea Rabee[1]; Khaled Mohamed Sobh[2]

[1] Department of Neurosurgery, Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt.
[2] Department of Neurosurgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Article information

Received: 20-01-2025

Accepted: 22-02-2025

DOI: 10.21608/ijma.2025.354122.2111

*Corresponding author
Email: mohamed.abdo6633@gmail.com

Citation: Galal MA, Rabee MA, Sobh KM. Safety and Efficacy of Balloon Remolding Technique in Wide Neck Aneurysm in Patients with Subarachnoid Hemorrhage. IJMA 2025 Mar; 7 [3]: 5508-5517. DOI: 10.21608/ijma.2025.354122.2111.

ABSTRACT

Background: Wide neck aneurysms are challenging in their treatment. There is a continuous improvement and introduction of new treatment approaches. However, no consensus was found for the optimal treatment.

Aim of the work: This study aimed to investigate the safety and efficacy of balloon remolding technique in the treatment of wide neck aneurysm in patients presented with subarachnoid hemorrhage.

Patients and methods: Thirty patients were included. All patients were submitted to standard assessment including history taking [current, past, and family history]. This was followed by clinical examination [general and detailed neurological examination]. The aneurysm was graded and the success rate and reported complications or recurrence were documented in the follow up period. The clinical outcome has been recorded using the modified Rankin Scale [mRS]. Occlusion of the aneurysm was assessed by Raymond–Roy occlusion classification [RROC].

Results: The mean age was 50.90 ± 10.84 years and 18 males [60%]. Hypertension was reported in 33.3% and diabetes milieus in 46.%. The Modified Rankin scale score showed that, there were 6 cases [20%] with scale 1, there were 14 cases with scale 2 [46.7%], there were 8 cases [26.7%] with scale 3 and there were 2 cases [6.7%] with scale 4. The mean timing of coiling was 6.3 ± 4.89 days. The Raymond-Roy occlusion classification showed that, complete obliteration was reported in 80%, Residual neck in 16.7% and Residual aneurysm in 3.3%. The most common balloon type was Hyperform type in 76.7% followed by Hyperglide in 13.3%. Complications were reported in 5 cases, rupture in 4 cases [13.3%] and ischemia in 3.3%. There was no significant difference between the different scores of mRS regarding the demographic data and associated risk factors.

Conclusion: Treatment with Balloon Remodeling has been associated with high success rate and low incidence of complications.

Keywords: Modified Rankin; Raymond–Roy occlusion; Subarachnoid Hemorrhage; Wide Neck Aneurysm.

INTRODUCTION

Aneurysms are defined as vascular malformations in the form of arterial wall bulge. It is of extreme importance in cerebrovascular diseases, as they are the commonest cause of spontaneous subarachnoid hemorrhage [SSH]. In addition, aneurysms are responsible for about a quarter of all intracranial hemorrhages. Microsurgical clipping or endovascular coil embolization are the main treatment options for intracranial aneurysms [1,2]. The exclusion of the aneurysmal sac from the systemic circulation was the basic idea for surgical treatment. Clipping of the aneurysm neck had been the method of choice to achieve this exclusion for many decades. It was used for treatment of both ruptured and unruptured aneurysms [3-5]. The endovascular treatment approaches were introduced and showed a low rate of morbidity and mortality. However, it is not suitable for all aneurysm. For example, aneurysms with complex form and wide neck, remains a challenge and had higher risk for recurrence, complications and mortality [6-8]. Aneurysms with wide neck can be treated by two strategies with endovascular treatment; Stent remodeling or stent-assisted coil embolization, where a stent was placed in the neck of the aneurysm to permit for adequate coil detachment. This may prevent recanalization of the aneurysm through redirection of flow and facilitation of endotheliazation at the neck of the aneurysm. The balloon assisted coil embolization [balloon-remodeling] consisted of the use of inflated balloon to compress and shape the coil inside the aneurysm. Thus, prevents protrusion of the coil into the parent vessel. The endovascular treatment with coil widely used. However, it is challenging from the technical point of view especially in wide-neck aneurysm [9-13]. Remodeling techniques can be used nearly for all aneurysms of different locations. However, it is used less frequently for anterior communication and anterior cerebral artery aneurysms. The remodeling and standard coiling techniques usually preserved for specific types of aneurysms for each method. However, the safety profile of both approaches are comparable, with higher efficacy for the remodeling techniques [14-15].

THE AIM OF THE WORK

The work was designed to investigate the safety and efficacy of balloon remolding technique in the treatment of wide neck aneurysm in patients presented with subarachnoid hemorrhage.

PATIENTS AND METHODS

This was a prospective interventional study. It was performed at the department of neurosurgery, Al Azhar University Hospital [Damietta], between March 2023 and July 2024. It included 30 patients, who had cerebral aneurysms and scheduled for endovascular treatment by balloon remodeling technique. **The inclusion criteria** were patient with cerebral aneurysm of grade III or IV according to Fisher grading system, a wide neck arterial aneurysm [AA] [ratio of AA dome width-AA neck < 2 or Neck width ≥4mm. In addition, patients with partially thrombosis AA or bifurcation or side AA, with neck diameter ≥ bearing artery diameter were also included. On the other side, **the exclusion criteria** were 1] patient refusal, 2] unsecured aneurysms, 3] severe atherosclerosis of cerebral arteries, 4] medical conditions which adversely affect mortality/ morbidity [e.g., renal failure, 5] poor Glasgow Coma Scale [GCS] scoring, and 6] patients with allergy to contrast.

Ethical consideration: all patients signed an informed written consent, after the explanation of the study aim, procedures and outcome. The study protocol was approved by the institutional review board of Al-Azhar Faculty of Medicine [Damietta]. The study was completed according to Helsinki declaration codes of research performance and reporting. The patient confidentiality was assured and the right to withdrawal of the study at any time was confirmed, without any consequences on the treatment plane. Finally, the collected data were only used for the purpose of the study.

All patients were submitted to standard assessment including history taking [current, past, and family history]. This was followed by clinical examination [general and detailed neurological examination]. The neurological examination was performed before intervention and directly after the procedure to assess any neurological manifestations [e.g., headache, delirium, altered mental state, transient ischemic attacks or stroke]. All patients were graded according to the Hunt and Hess [H & H] grading scale [16]. The investigation workup was composed of routine laboratory investigations [complete blood picture, blood glucose, liver and kidney functions, bleeding profiles, erythrocyte sedimentation rate and C-Reactive Protein], and radiological examination. The radiological investigations included computerized tomography scan [CT], computerized tomography angiography [CTA], magnetic resonance imaging [MRI], magnetic resonance angiography [MRA] and magnetic resonance venography [MRV],

The preoperative assessment included echocardiography for patients above 40 years. In addition, anesthesiologist [not involved in the study] revised the blood work, electrocardiography [ECG] and/or echocardiography to evaluate the patient eligibility for anesthesia. Nothing by mouth [NPO] for 6 hours before the procedure [except for medications], and two peripheral intravenous [IV] lines were inserted.

Surgical technique: General anesthesia was the anesthetic procedure for all patients. This was followed by the introduction of bladder catheter and the surgical procedure was completed according to **Harrigan and Deveikis** [17]. Briefly, a sheath 7F was placed in the femoral artery. If cook shuttle is anticipated, an 8F sheath was used. The systemic heparinization was achieved by antiplatelet agents when indicated. Then, a two-headed RHV [Rotating hemostatic valve] was attached to the guide catheter and a continuous heparinized saline infusion was we attached to the RHV. After bubbles in the system was watched, we placed a balloon catheter "[HyperGlide ™ or HyperForm ™ Medtronic Neurovascular, Minneapolis, MN; Transform™, Stryker Neurovascular, Fremont, CA, Eclipse [Balt Montmorency, France] single Lumen]]", deflated, in the parent vessel adjacent to the aneurysm. Then the microcatheter was navigated into the aneurysm. Alternatively, a dual lumen balloon, large enough to push coils was used. With advancement of coils through the central lumen, the Ascent™ [Codman Neurovascular, Raynham, MA] was inflated. Then, one loop of coil was inserted into the aneurysm, permitting the tip of the coil to point away from the dome. This guards against the wedging of catheter tip into the aneurysm dome at the time of balloon inflation. In addition, it limited the risk of aneurysm perforation, while coils were inserted. The balloon was inflated and the first-framing coil was deployed under roadmap guidance. However, before the assessment of the stability and detachment of the coil, the balloon was deflated. If the first coil seems to be stable, the coil was detached. Alternatively, another method was used to permit rapid deployment and detaching of multiple coils in the first inflation. It is best described as balloon- assisted rapid intermittent sequential coiling [BRISC]. It is used to stabilize the coil mass with multiple intertwining coils to the full stabilization. During transient inflation of the balloon, an extra-framing coils were placed. The balloon was deflated intermittently after each coil was placed with deployment of further coils. This prevents accumulation of blood and great volume of coils in the aneurysm. In addition, it permits reperfusion of the affected circulation. After the construction of a stable framing of coils has been created, additional filling and finishing coils can be safely inserted without inflating the balloon. To remove the microcatheter, we inflated the balloon a final time to stabilize the coil mass as the microcatheter was withdrawn.

After surgery, patient was transferred to the neurological intensive care unit [NICU] with complete examination for neurological system and groin checks. Most patients with un-ruptured aneurysms discharged on one day's post-procedure. Discharge on the day after elective aneurysm coiling was not associated with worse outcomes at 30 days [18].

Outcome: The clinical outcome has been recorded using the modified Rankin Scale [mRS] [19]. Occlusion of the aneurysm was assessed by Raymond–Roy occlusion classification [RROC] [20]. A complication was defined as any event, when occurred needing another intervention during or shortly after the procedure, or any events led to a perpetual neurological imbalance. However, morbidity was defined as a continuous negative effect on the life quality of a patient directly related to the procedure.

Statistical analysis of the data: A software computer package was used for statistical analysis. Initially data were anonymized and fed to the program. Then, descriptive measures were calculated to represent the continuous data [e.g., mean and standard deviations as measures of central tendency and dispersion, respectively, for normally distributed data. Otherwise median and interquartile range [IQR] were calculated for abnormally distributed data]. On the other side, the relative frequencies [numbers] and percentages were used to summarize categorical data. The association between two categorical variables was estimated by the Chi-square [$\chi 2$] test, or its equivalent [Fischer's exact if one cell has frequency less than 5] according to the statistical situation. The student "t" independent sample test was used to measure the differences between two means [groups] and p value < 0.05 was considered significant. The statistical package for social science, version 18 was the software used for all analyses [SPSS Inc., USA].

RESULTS

The current study included 30 presented with Wide Neck Aneurysm and Subarachnoid Haemorrhage. The mean age of the cases was 50.90 ± 10.84 years with range between 36 and 70 years. There were 18 males [60%] and 12 females [40%]. Hypertension was reported in 33.3%, diabetes milieus in 46.0% CKD in 43.3%, IHD in 30%. There were 43.3% smokers and hyperlipidaemia was reported in 53.7% [Table 1]. The Hunt and Hess score showed that, there were 8 cases [26.7%] with score 1, there were 16 cases with score 2 [53.3%] and there were 6 cases [20%] with score 3. The Modified Rankin scale score showed that, there were 6 cases [20%] with scale 1, there were 14 cases with scale 2 [46.7%], there were 8 cases [26.7%] with scale 3 and there were 2 cases [6.7%] with scale 4. The location of the aneurysm showed that, communicating arteries in 16 cases, [53.3%], anterior circulation in 10 cases [33.3%] and posterior circulation in 4 cases [13.3%]. The mean Aneurysm diameter was 6.9 ± 1.84 mm with range between 3 and 10 mm. The mean neck diameter was 4.10 ± 1.09 mm with range between 2 and 6 mm [Table 2].

The mean timing of coiling was 6.3 ± 4.89 days with range between 1 and 17 days. There were 50% of the cases who underwent coiling between 4 and 14 days. The Raymond-Roy occlusion classification showed that, complete obliteration was reported in 80%, Residual neck in 16.7% and Residual aneurysm in 3.3%. The most common balloon type was Hyperform type in 76.7% followed by Hyperglide in 13.3%. Complications were reported in 5 cases, rupture in 4 cases [13.3%] and ischemia in 3.3% [Table 3]. In the current work, there was no statistically significant difference between the cases with and without complications regarding the demographic data. In addition, there was no statistically significant difference between the cases with and without complications regarding the Associated diseases/risk factors. In addition, there was no statistically significant difference between the cases with and without complications regarding the scoring system and aneurysm related data [Table 4]. In the current work, there was no statistically significant difference between the different scores of Hunt and Hess score regarding the demographic data and associated diseases/risk factors [Table 5]. In addition, there was no statistically significant difference between the different scores of Modified Rankin scale scales regarding the demographic data and associated diseases/risk factors [Table 6].

Table [7] showed that there was no statistically significant difference between the cases with Complete obliteration or those with Residual neck/ aneurysm regarding the demographic data and associated diseases/risk factors. Table [8] showed that the cases with Residual neck/ aneurysm had statistically higher incidence of complications [p= 0.033].

Case Presentation: No [1] was female patient 57-year-old hypertensive, diabetic and dyslipidemic presented with severe headache and his Hunt &Hess score was 2. She was found on CT brain to had sub-arachnoid haemorrhage [Figures 1, 2 and 3]. **Case 2** was a female patient 30 year-old hypertensive, not diabetic presented with severe headache and his Hunt &Hess score was 2. She was found on CT brain to had SAH [Figures 4-6]. **Case 3** was a male patient 42-year-old hypertensive, not diabetic presented with severe headache and his Hunt &Hess score was 3. He was found on CT brain to had SAH Figures [7 – 10].

Table [1]: Demographic data and associated risk factors among studied population

		Statistics [n=30]
Age [years]	Mean±SD	50.90 ± 10.84
	Median [range]	50 [36 – 70]
Age group [n,%]	< 50 years	13 [43.3%]
	≥ 50 years	17 [56.7%]
Sex [n,%]	Male	18 [60.0%]
	Female	12 [40.0%]
BMI [Kg/m^2]	Mean ± SD	30.75 ± 4.43
	Median [Range]	29.85 [24.3 – 38.5]
BMI group [n,%]	< 30 Kg/m^2	15 [50.0%]
	≥ 30 Kg/m^2	15 [50.0%]
Residence [n,%]	Urban	17 [56.7%]
	Rural	13 [43.3%]
Associated disease [risk factors] [n,%]	Hypertension	10 [33.3%]
	Diabetes mellitus	14 [46.7%]
	Hyperlipidemia	16 [53.7%]
	Smoking	13 [43.3%]
	CKD	8 [26.7%]
	IHD	9 [30.0%]
	Positive family history	1 [3.3%]

Table [2]: Hunt and Hess score, and Modified Rankin scale [mRS] and aneurysm characteristics in the studied population.

Variables			Statistics [n=30]	
			n	%
Hunt and Hess score	score 1		8	26.7
	score 2		16	53.3
	score 3		6	20.0
Modified Rankin scale [mRS]	Scale 1		6	20.0
	Scale 2		14	46.7
	Scale 3		8	26.7
	Scale 4		2	6.7
Characteristics of aneurysm	Location	Communicating Arteries	16	53.3
		Anterior Circulation	10	33.3
		Posterior Circulation	4	13.3
	Aneurysm diameter [mm]	Mean ± SD	6.9 ± 1.84	
		Median [Range]	7 [3 – 10]	
	Neck diameter [mm]	Mean ± SD	4.10 ± 1.09	
		Median [Range]	4 [2 – 6]	

Table [3]: Timing of coiling [days], classification of occlusion, balloon type and complications in the studied population

Variables		Study cases [n = 30]	
		n	**%**
Timing of coiling [days]	Mean ± SD	6.3 ± 4.89	
	Median [Range]	5 [1 – 17]	
	≤ 3 days	12	40
	4- 14 days	15	50
	> 14 days	3	10
Raymond-Roy occlusion classification	Complete obliteration	24	80.0
	Residual neck	5	16.7
	Residual aneurysm	1	3.3
Balloon type	Hyperform	23	76.7
	Hyperglide	4	13.3
	Copernic	2	6.7
	Eclipse	1	3.3
Complications	No complications	25	83.3
	Rupture	4	13.3
	Ischemia	1	3.3

Table [4]: Comparison between cases with complications and those without complications regarding study variables

Variables		No complications [N= 25]	Complications [N= 5]	Test	p
Age [Years]		50.24 10.66	54.20 12.40	0.740	0.466
BMI [Kg/m^2]		30.20 4.23	33.46 4.89	1.536	0.136
Gender [n,%]	Males	16 [64%]	2 [40 %]	1.004	0.317
	Females	9 [36%]	3 [60 %]		
Residence [n,%]	Urban	15 [60%]	2 [40 %]	0.679	0.410
	Rural	10 [40%]	3 [60 %]		
Risk factors [n,%]	Hypertension	8 [32 %]	2 [40 %]	0.120	0.729
	Diabetes mellitus	10 [40 %]	4 [80 %]	2.679	0.102
	Hyperlipidemia	12 [48 %]	4 [80 %]	1.714	0.190
	Smoking	11 [44 %]	2 [40 %]	0.027	0.869
	CKD	7 [28 %]	2 [40 %]	0.286	0.593
	IHD	5 [28 %]	3 [40 %]	3.409	0.065
	Positive family history	1 [4 %]	0 [0 %]	0.207	0.649
Hunt and Hess Score [n,%]	Score 1	6 [24%]	2 [40 %]	1.650	0.438
	Score 2	13 [52%]	3 [60 %]		
	Score 3	6 [24%]	0 [0 %]		
Modified Rankin Scale [n,%]	Scale 1	4 [16%]	2 [40 %]	1.757	0.624
	Scale 2	12 [48%]	2 [40 %]		
	Scale 3	7 [28%]	1 [20 %]		
	Scale 4	2 [8%]	0 [0 %]		
Timing of coiling [days]	≤ 3 days	10 [40%]	2 [40 %]	0.643	0.790
	4- 14 days	12 [48%]	3 [60 %]		

Variables		No complications [N= 25]	Complications [N= 5]	Test	p
[n,%]	> 14 days	3 [12%]	0 [84.7 %]		
Aneurysm Location [n,%]	Communicating Arteries	12 [48%]	4 [80 %]	3.0	0.233
	Anterior Circulation	10 [40%]	0 [0 %]		
	Posterior Circulation	3 [12%]	1 [20 %]		
Aneurysm diameter[mm]	Mean±SD	6.82 ± 1.84	7.30 ± 2.02	0.526	0.603
Neck diameter [mm]	Mean±SD	4.06 ± 1.08	4.30 ± 1.25	0.440	0.664
Raymond-Roy occlusion classification [n,%]	Complete obliteration	21 [84%]	3 [60 %]	5.340	0.069
	Residual neck	4 [16%]	1 [20 %]		
	Residual aneurysm	0 [0%]	1 [40 %]		
Balloon type [n,%]	Hyperform	22 [88%]	1 [20 %]	5.863	0.053
	Hyperglide	2 [8%]	2 [40 %]		
	Copernic	1 [4%]	1 [20 %]		
	Eclipse	0 [0%]	1 [20 %]		

Table [5]: Relation of Hunt and Hess score with demographic data and risk factors among the patients.

	Variables	Score 1 [N=8]	Score 2 [N= 16]	Score 3 [N= 6]	Test of Sign.	p
Age [Years]	Mean±SD	47.75±11.57	54.56±10.66	45.33±7.55	2.212	0.129
Gender	Male	5 [62.5%]	11 [68.8%]	2 [0%]	2.309	0.315
	Female	3 [37.5%]	5 [31.3%]	4 [72.4%]		
Risk factors	Hypertension	4 [50%]	6 [37.5%]	0 [0%]	4.125	0.127
	Diabetes mellitus	3 [37.5%]	8 [50%]	3 [50%]	0.368	0.832
	Hyperlipidemia	4 [50%]	8 [50%]	4 [66.7%]	0.536	0.765
	Smoking	3 [37.5%]	9 [56.3%]	1 [16.7%]	2.963	0.230
	CKD	4 [50%]	2 [12.5%]	2 [33.3%]	4.006	0.135
	IHD	3 [37.5%]	6 [37.5%]	0 [0%]	3.214	0.200
	Positive family history	0 [0%]	0 [0%]	1 [16.7%]	4.138	0.126

Table [6]: Relation of Modified Rankin scale with demographic data, and risk factors of the patients

	Variables	Scale 1 [N=6]	Scale 2 [N=14]	Scale 3 [N=8]	Scale 4 [N=2]	Test	p
Age [Years]	Mean±SD	46.67 ± 10.17	52.71 ± 9.72	52 ± 14.44	46.50 ± 0.71	0.546	0.655
Sex [n,%]	Male	3 [50%]	11 [78.6%]	4 [50%]	0 [0%]	5.595	0.133
	Female	3 [50%]	3 [21.4%]	4 [50%]	2 [100%]		
Risk factors	Hypertension	3 [50%]	4 [28.6%]	3 [37.5%]	0 [0%]	1.955	0.582
	Diabetes mellitus	3 [50%]	6 [42.9%]	5 [62.5%]	0 [0%]	2.664	0.446
	Hyperlipidemia	3 [66.7%]	6 [42.9%]	5 [62.5%]	1 [50%]	1.325	0.723
	Smoking	1 [16.7%]	10 [71.4%]	2 [25%]	0 [0%]	5.862	0.061
	CKD	3 [66.7%]	2 [14.3%]	2 [25%]	1 [50%]	3.666	0.343
	IHD	2 [33.3%]	4 [28.6%]	3 [37.5%]	0 [0%]	1.177	0.713
	Positive family history	0 [0%]	0 [0%]	1 [12.5%]	0 [0%]	2.845	0.416

Table [7]: Relation of occlusion of the aneurysms and patient demographics and risk factors

	Variables	Complete obliteration [N=24]	Residual neck/ aneurysm[N=6]	Test	t
Age [Years]	Mean±SD	**51.54±10.48**	**48.33±12.93**	0.642	0.526
Gender [n,%]	Male	**14 [58.3%]**	**4 [66.7%]**	0.139	0.709
	Female	**10 [41.7%]**	**2 [33.3%]**		
Risk factors [n,%]	Hypertension	**8 [33.3%]**	**2 [33.3%]**	0.001	1.00
	Diabetes mellitus	**12 [50%]**	**2 [33.3%]**	0.536	0.464
	Hyperlipidemia	**12 [50%]**	**4 [66.7%]**	0.536	0.464
	Smoking	**10 [41.7%]**	**3 [50%]**	0.136	0.713
	CKD	**7 [29.2%]**	**1 [16.7%]**	0.384	0.536
	IHD	**7 [29.2%]**	**2 [33.3%]**	0.040	0.842
	Positive family history	**1 [4.2%]**	**0 [0%]**	0.259	0.611

Table [8]: Analysis of the scoring system, operative data, complications with the occlusion of the aneurysms

	Variables	Complete obliteration [N=24]	Residual neck/ aneurysm [N=6]	Test	p
Hunt and Hess Sore	Score 1	5 [20.8%]	3 [50 %]	2.135	0.344
	Score 2	14 [58.3%]	2 [33.3 %]		
	Score 3	5 [20.8%]	1 [16.7 %]		
Modified Rankin scale	Scale 1	3 [12.5%]	3 [50 %]	6.786	0.079
	Scale 2	12 [50%]	2 [33.3 %]		
	Scale 3	8 [33.3%]	0 [0 %]		
	Scale 4	1 [4.2%]	1 [16.7 %]		
Timing of coiling [days]	≤ 3 days	8 [33.3%]	4 [66.7 %]	1.024	0.342
	4- 14 days	13 [54.2%]	2 [33.3 %]		
	> 14 days	3 [12.5%]	0 [84.7 %]		
Aneurysm location	Communicating Arteries	13 [54.2%]	3 [50 %]	0.078	0.962
	Anterior Circulation	8 [33.3%]	2 [33.3 %]		
	Posterior Circulation	3 [12.5%]	1 [16.7 %]		
	Aneurysm diameter [mm]	6.94 ± 1.97	6.75 ± 1.29	0.220	0.828
	Neck diameter [mm]	4.15 ± 1.17	3.92 ± 0.74	0.652	0.652
Balloon type	Hyperform	19 [88%]	4 [66.7 %]	1.535	0.674
	Hyperglide	3 [12.5%]	1 [16.7 %]		
	Copernic	1 [4.2%]	1 [16.7 %]		
	Eclipse	1 [4.2%]	0 [0 %]		
Complications	Yes	2 [8.3%]	3 [50 %]	***4.252***	***0.033****
	No	22 [91.7%]	3 [50 %]		

Figure [1]: DSA shows ACom artery aneurysm with wide neck.

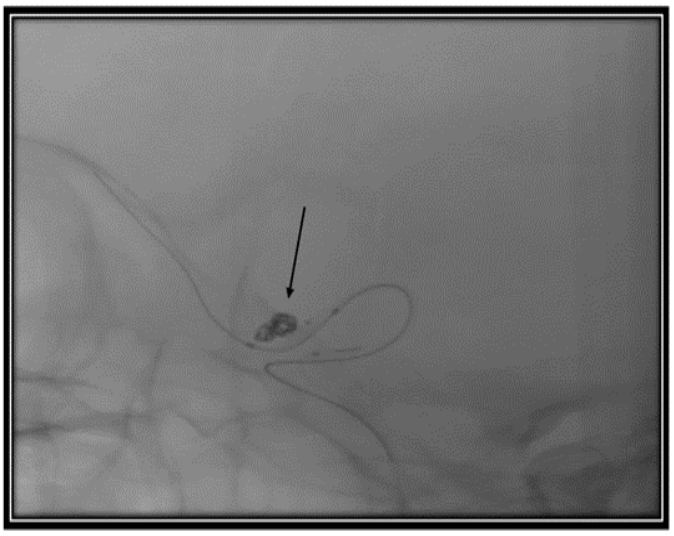

Figure [2]: Inflation the balloon under roadmap guidance and deploy the first-framing coil.

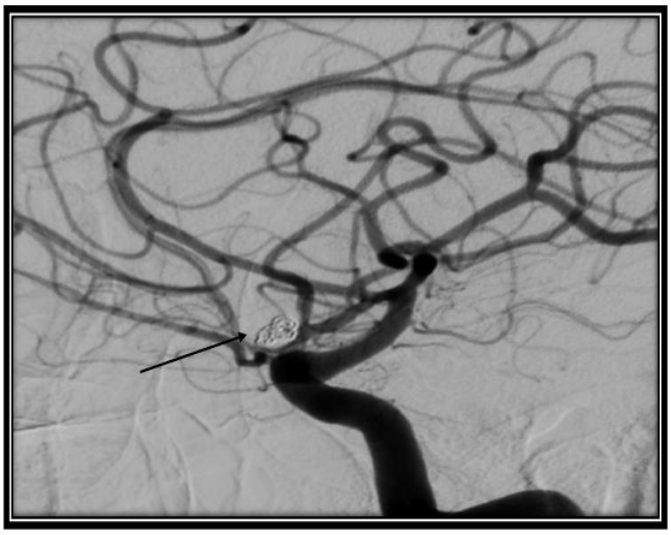

Figure [3]: DSA shows complete occlusion of ACom artery aneurysm.

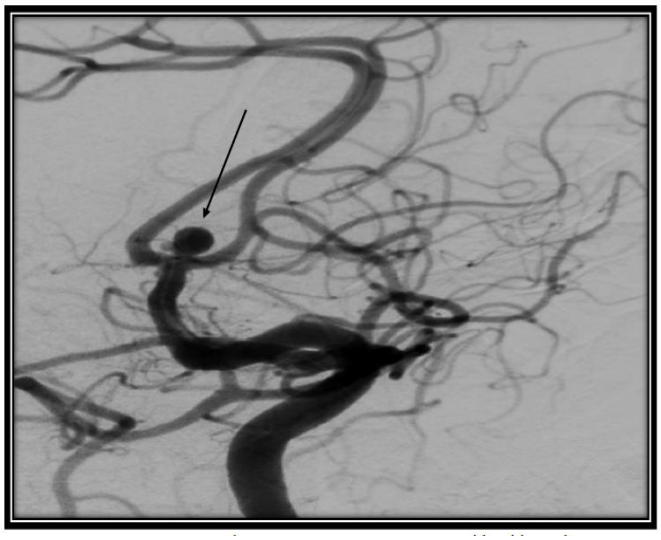

Figure [4]: DSA shows ACom artery aneurysm with wide neck.

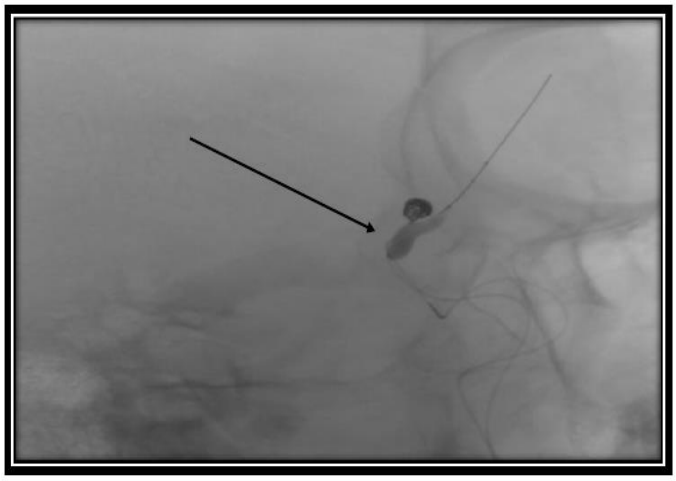

Figure [5]: Inflation the balloon under roadmap guidance and deploy the first-framing coil.

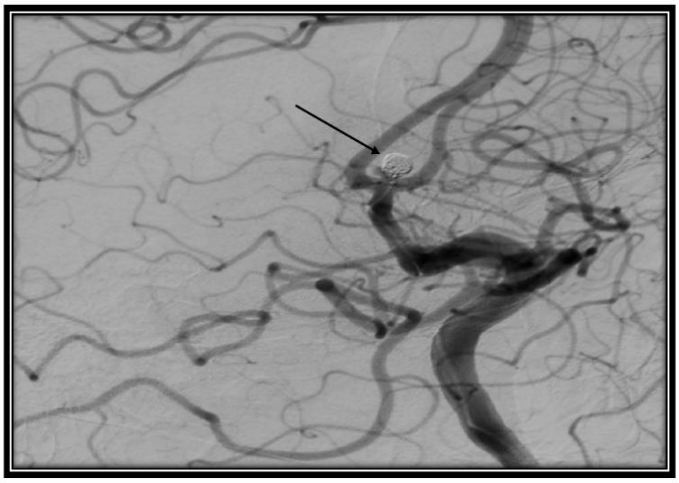

Figure [6]: DSA shows occlusion of ACom artery aneurysm with neck remnants.

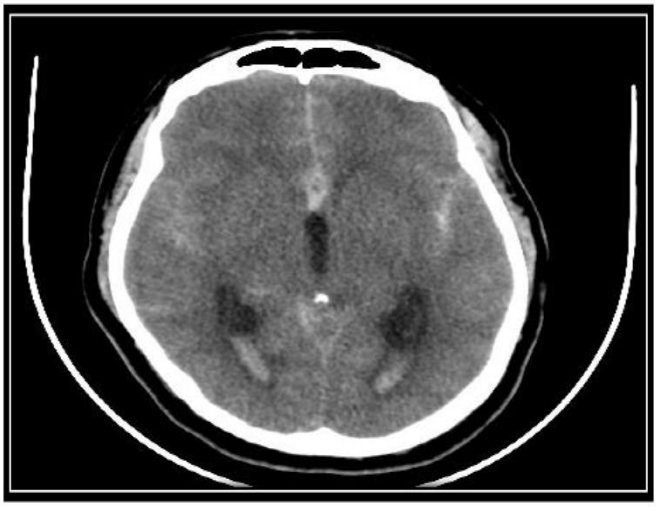

Figure [7]: CT brain shows that SAH.

Figure [8]: DSA shows ACom artery aneurysm with wide neck.

Figure [9]: Inflation the balloon under roadmap guidance and deploy the first-framing coil.

Figure [10]: DSA shows complete occlusion of ACom artery aneurysm.

DISCUSSION

WNAs are challenging to treat by endovascular therapy, due to high possibility of protrusion of the coil into the parent vessel. However, endovascular therapy of WNAs is associated with low rate of complications and mortality when compared to microsurgical clipping. It is proven to be effective in the prevention of re-bleeding after aneurysmal SAH [21-23]. However, some treatment approaches showed a low initial angiographic rate of occlusion and higher rate of recurrence [24, 25]. The data about this topic is not sufficient, and thus, the present study was designed to assess the safety and efficacy of balloon remodeling technique in treatment of WNAs in patients with subarachnoid hemorrhage. It included 30 patients, which WNAs and SAH. Their mean age was 50.90 years [ranged 36-70 years]. Males represented 60% of the study group, and more than the half of patients were above the age of 50 years. **Abdel-Tawab *et al.*** [26] conducted a similar work on 49 subjects, males represented 55.1%, the age range was 20 to 70 years [mean age 49 years]. These results are comparable to the current work. This was comparable to **Morsy *et al.*** [27] who included 40 patients who had WNAs, 22 patients were male [55%] and 18 patients were female [45%].

In the current work, the communicating arteries were the commonest site [53.3%], followed by anterior circulation [33.3%] and posterior circulation [13.3%]. The mean Aneurysm diameter was 6.9 ± 1.84 mm and the mean neck diameter was 4.10 ± 1.09 mm. these results are matched with **Morsy *et al.*** [27]**.** However, their study showed that the commonest site was the anterior circulation [87.5%] followed by 12.5% in the posterior circulation. The study by **Pierot *et al.*** [28] revealed that the aneurysm locations were 439 aneurysms in Anterior cerebral artery or anterior communicating artery [40.3%], 221 middle cerebral artery [20.3%], 338 intradural internal carotid artery [31.1%], 13 extradural internal carotid arteries [ICA] [1.2%] and 77 Vertebro-basilar [7.1%].

In the current study, the Hunt and Hess scoring system showed that, 8 cases [26.7%] were score 1, 16 were score 2 [53.3%] and there were 20.0% with score 3. **Cai *et al.*** [29] reported that, of 63 patients, 41 [65%] presented with subarachnoid hemorrhage [SAH]. Thirteen patients [31.7%] presented with high-grade SAH [Hunt and Hess Grade 3 or higher]. Twenty-eight [68.2%] patients presented with SAH of Hunt and Hess grade 1 or 2. On the other side, **Yang *et al.*** [30] **r**eported that according to the Hunt and Hess scale, 194 patients [91.9%] were classified as grade 1-3, and 17 [8.0%] were classified as grade 4–5.

Regarding the Modified Rankin scale score, there were 6 cases [20%] with scale 1, there were 14 cases with scale 2 [46.7%], there were 8 cases [26.7%] with scale 3 and there were 2 cases [6.7%] with scale 4. **Cai *et al.***[29] found that 46 patients [85%] classified as grade 0-1 and 3 patients [5.5%] as grade 2-3. There were 5 patients [9.2%] classified as grade 4-5.

With continuous advancement of micro-catheters, a new brand of micro catheters [HyperForm, ev3 Inc., Plymouth, MN] was introduced in the market. It offers trackability and precise positioning over a specified 0.01-inch guidewire, along with the capability to adjust its shape to the arterial bifurcation anatomy by bulging into the aneurysm neck or the its branches coming off the sac [31]**.** This was shown in the current study, as the most common balloon type was Hyperform type in 76.7% followed by Hyperglide in 13.3%. The current study showed that, according to the Raymond-Roy occlusion classification, complete obliteration was reported in 80%. Furthermore, residual neck was reported in 5 cases [16.7%] and residual aneurysm in one case [3.3%] with total number of 6 cases [20%]. These findings are comparable to **Morsy *et al.*** [27] who showed that iimmediate angiographic follow-up demonstrated 90% with Raymond-I and 2.5% with Raymond-II requiring further intervention with stent-assisted approaches. The authors also demonstrated that after one year of follow-up by angiography, 85% of patients were with Raymond-I, 5% with Raymond-II, and 2.5% with Raymond-III.

Within the same context, the current findings agreed with a large published results of 800 patients, with 864 aneurysms, who were treated by HyperForm balloon assistance. There were 80.8% with an existing SAH. The patients were managed within 24 hours of admission. The HyperForm balloon was position in the correct bifurcation vessel and bridging the neck of the aneurysm under simultaneous biplanar road mapping. Overall, their results showed that the initial rate of occlusion was 73%, 20.4% and 6.6% for classes 1, 2, 3 occlusions, respectively. The follow-up angiography was available for 87.6%, and showed a recanalization rate of 12% and additional thrombosis in 17%, resulting in complete obliteration [class 1 occlusion] in 82% and the retreatment rate was 9% [32]**.**

Our results were also comparable to the earliest study described balloon remodeling approach by **Moret *et al.*** [33]**.** Their study encompassed 56 aneurysms [54 patients], of whom 70% had SAH. The remodeling approach was successfully used for 52 aneurysms, with a complete occlusion rate of 77% and subtotal occlusion rate of 17%.

Our results are fairly different than **Chung *et al.*** [34]**,** who reported an immediate complete occlusion rates of SAC was 63.8%, double-catheter coiling was 46.7%, and BAC embolization was 63.2%. In the study conducted by **Chalouhi *et al.*** [35]**,** the preoperative Raymond scores were 1, and 2 in 34.4% and 65.6% of patients, respectively. After intervention, Raymond scores were 1, 2 and 3 in 50%, 34.4%, and 15.6% of patients, respectively. Also, the rate of occlusion was far from **Abouzeid and Hasan** [36] who showed complete primary occlusion in 36.6%, which increased to 54.5% during follow up period. Nearly total occlusion was reported for 63.6% and 27.4% at primary, follow up respectively. One patient representing 9% showed a subtotal occlusion with aneurysmal remnant, 6 months after intervention. It needs no more intervention and the patient was clinically improved.

The main limitation of BAC is the inability to pack the aneurysmal neck and this may explain the higher percentages of residual neck. In a large study, **Pierot *et al.*** [37]**.** Recognized three factors related to the quality of midterm occlusion of the aneurysm after endovascular intervention, namely, the neck size, the use of the balloon remodeling approach, and the quality of occlusion after intervention.

Assessment of safety and clinical outcomes of the procedure are essential to detect the best intervention approach for wide-neck aneurysms. In this study, complications were reported in 5 cases [16.7%], rupture in 4 cases [13.3%] and ischemia in 1 case [3.3%]. These findings are comparable to **Gory *et al.*** [38] who detected a low rate of peri-procedural complications [12.7%] as they used the Solitaire device. However, **Nishido *et al.*** [39]**.** recognized ischemic complication rates of 7% and 2.3% for haemorrhagic complications. The incidence of complications was slightly lower as compared to the results reported by **Chalouhi *et al.*** [35] where there were 9% pro-interventional complications, leaving permanent morbidity in 3%, aneurysmal rupture intraoperatively, which was rapidly controlled by balloon inflation and coil packing, intraprocedural thrombus treated by abciximab intra-arterial infusion; and hemiparesis due to a frontal paramedian infarct. Other previous reports showed that the procedural complications rate with BAC was 11.7% in un-ruptured and 17% in ruptured aneurysms [40,41]. **Cekirge and his colleagues** [32] reported thromboembolic complications in 1.9% and hemorrhagic complications in 1.7%, with a 3.6% total complication rate. The thrombi were entirely resolved, with no clinical consequences. Balloon inflation assisted the bleeding control in 11 of 14 patients in whom an intraoperative perforation was reported. A study results reported by **Gallas *et al.*** [42] included 705 ruptured aneurysms [the balloon use rate was 6%] and the overall morbidity rate was 8.6%. **Henkes *et al.*** [43]**]** demonstrated that, 5.3% of patients had morbidity related to the procedure. In addition, **Murayama *et al.*** [44] included 916 aneurysms, about 50% of which were ruptured. They a procedural complication rate of 8.4% [an intraprocedural perforation in 2.3% and a thromboemboli 4.4%]. However, the previous studies documented that, the remodeling approach does not complicate the interventional procedure by increasing risks.

Rupture aneurysm and ischemia are the two reported complications in the current study. Ruptured aneurysms were located proximal to or include small arteries distal to the circle of Willis were treated by the balloon remodeling approach whenever it was technically possible. Balloon assistance provides some advantages when compared to the standard coiling [e.g., bifurcation reconstruction with the protection of the parent artery, improved applicability of coil embolization, uniform and denser packing and increased the safety of the procedure during intraoperative rupture by limiting the extravasation of blood with inflation of the balloon at the neck of the aneurysm accompanied by rapid coil occlusion [32].

In treatment of acute SAH, that showed a high risk of rupture during the delivery of coil, the use of balloon to have a more stable position of the

microcatheter helps the safety improvement issue. This is because the tip of the microcatheter can be left just inside the entrance of the sac of the aneurysm when necessary. In such situations, the coil conformation in the aneurysm is often easier. Thus, the catheter tip repositioning may be avoided, which is frequently needed during simple coiling [32].

Ischemia is reported in more than one study following repair of wide neck aneurysm. Ischemia could be explained as ischemia is a potential devastating complication of SAH is vasospasm. Vasospasm can be associated with a severe constriction of the arteries and constrains the passage of the microcatheter to reach the target aneurysm. Moreover, defining the aneurysmal neck relation to the parent artery and the adjacent branches may be difficult in cases with sever vasospasm. In such situations, the use of the same HyperForm super-compliant balloon microcatheter to perform gentle angioplasty aids the vessels enlargement to permit the microcatheter passage and balloon microcatheter for additional embolization of the aneurysmal sac under balloon assistance. Thus, delayed ischemia could be prevented [26]. The balloon assistance advantages enabling us to treat the aneurysms which cannot be treated with primary coiling. In addition, it also permits us to achieve a more durable occlusion due to the existing inverse relationship between higher initial occlusion rates and recanalization [20, 46].

a balloon may also guard the side-branch from coil herniation and, in the intraprocedural aneurysmal rupture, offer proximal control. Thus, it prevents the devastating complications. In a critical review, **Pierot *et al.*** [37] reported that, many studies showed a similar safety profile between BAC and conventional coiling [except for one study included in their systematic review], with better initial and follow-up anatomic results in aneurysms when BAC was used for their treatment. However, a concert exists regarding the adjunctive use of balloon remodeling, as it may be associated with increased rate of adverse events after endovascular coiling of aneurysms. For example, in the analysis of a large series of 1,811 aneurysms, **Henkes *et al.*** [43] reported a significant increase of complication rate [38.5%] with the balloon remodeling approach. However, a potential bias was noted because the balloon remodeling was used in only 26 cases [1.4%]. In addition, **Sluzewski *et al.*** [47] reported a significantly higher rate of complications in the group treated by balloon assistance [14.1%] than the group treated with traditional coiling [3%]. However, the adjunctive use of balloon assistance was only applied for 8.6% of the total 827 aneurysms.

In short, WNAs are difficult to treat. However, endovascular treatment has proven safe, effective and feasible. Treatment with Balloon Remodeling has been associated with high success rate and low incidence of complications

Conflict of interests: None to be declared.

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International Journal of Medical Arts

Volume 7, Issue 3 (March 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780