Original Article

# Safety and Efficacy of Balloon Remodeling Technique for Treating Cerebrovascular Aneurysms

**Qasim Bashir,[1] Faisal Farooq,[2] Asim Ishfaq,[3] Javed Iqbal,[4]**


## Abstract

**Objective:** To assess the safety and efficacy of Balloon remodeling technique (BRT) for coil placement in Pakistani patients with wide neck cerebral aneurysms.

**Method:** This study included a total of 39 patients (23 females and 16 males) treated with BRT for 44 cerebral aneurysms over a period of six years, at Hameed Latif Hospital, Lahore. Characteristics of aneurysms were analyzed, and complications, occlusion rates, and outcomes were ascertained for relevant comparisons with the available literature on Balloon Remodeling Technique.

**Results:** Overall, 35 (79.5%) patients presented with ruptured aneurysms and 37 of the 44 aneurysms (84.1%) were located within the anterior circulation. The remodeling technique was successful in achieving complete or near complete occlusion of 39 of total 42 treated aneurysms (92.9%). Two procedures were aborted due to intraoperative complications. The rate of technical success achieved was 95.4%. Treatment related complications were seen in four cases (9.5%) and included intra-procedural aneurysmal ruptures and thromboembolic phenomena.

**Conclusion:** Balloon Remodeling Technique can achieve high rates of aneurysm occlusion with low rates of complications and is a good option for treatment of both ruptured and unruptured wide neck cerebral aneurysms in our population.


**Keywords:** intracranial aneurysm, endovascular procedures, balloon remodeling technique, Pakistan.

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## Introduction

Neuroendovascular management of intracranial aneurysms is a minimally invasive technique. Since its introduction, it has replaced more invasive surgical clipping of the same aneurysms.[1] However, aneurysms with wide necks are not amenable to conventional endovascular coil placement due to high risk of coil protrusion into the parent vessel. Balloon remodeling technique (BRT), initially described by Moret et al.[2] in 1994, offers an alternative solution for the endovascular coiling of such cerebral aneurysms, and ever since then its usage has been on the rise. Commonly used acronyms for this technique include; BRT (Balloon Remodeling Technique),[3] BACE (Balloon-assisted Coil Embolization)[4] and BAC (Balloon-assisted Coiling).[5,6]

Historically, wide neck cerebral aneurysms are defined as those in which the neck of an aneurysm is ≥4 mm, or when the dome to neck ratio is ≤2.[2,3,7] Briefly, BRT is performed using a non-detachable balloon that is inflated intermittently in front of the neck of an aneurysm at the time of each coil placement. The inflated balloon allows easy configuration of the coils inside the aneurysm dome and prevents their displacement into the parent vessel. It is removed at the end of the coil placement procedure.[4,8]

1. *Department of Clinical and Interventional Neurology, SIMS, Lahore*
2. *Department of Medicine, Govt. Mian Meer Hospital, Lahore*
3. *Department of Neurosurgery, CMH Lahore Medical College, Lahore*
4. *Department of Medicine, CMH Lahore Medical College, Lahore*

**Correspondence:**
Qasim Bashir *Professor, Department of Clinical and Interventional Neurology, SIMS, Lahore Email: qbashir@hotmail.com*

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Coil placement with BRT offers a higher rate of aneurysm occlusion and anatomic efficacy, offering at the same time a similar safety as the standard endovascular coiling.[9] This technique is frequently used in the treatment of both ruptured and unruptured aneurysms.[6,8,10] Over the years, in addition to being employed for sidewall aneurysms, this technique has also been used to treat aneurysms with complex origins, such as bifurcation or basilar apex aneurysms.[3,6]

Efficacy of BRT is judged from the aneurysm occlusion rates, whereas its safety from the rates of complications, as well as post-operative morbidity and mortality.[6,8,10] Most common complications encountered in BRT include thromboembolic and hemorrhagic phenomenon.[9,11-14] Previous BRT studies have reported 2.1 to 7.7% rates of hemorrhagic, whereas 4.5 to 7.1% rates of thromboembolic phenomenon.[8,10,15]

This technique has only recently seen the doors to this country and studies indicative of its application in Pakistan have been lacking.[16] Our initial experience from four patients that underwent BRT in the same setting was reported in our previous study.[16] The objective of present study is to establish the safety and efficacy of this technique in Pakistani population by presenting the findings of our data of six years, with relevant comparisons of our outcomes with those reported in other BRT studies.

## Material and Methods

Approval for this retrospective study was granted by the institutional ethical review committee of Hameed Latif Hospital, Lahore. Using OpenEpi (version 3.0), a minimum sample size of 39 was considered to be appropriate with a confidence interval of 95%. A retrospective review of the patient medical records, procedure notes, and angiograms was performed to collect data on patient demographics, degree of aneurysm occlusion, and any procedural complications (Table 1). A total of 39 patients harboring 44 wide neck cerebral aneurysms were selected. These patients had received treatment with BRT between December, 2013 to June, 2020, in the dedicated neuroendovascular angiographic suite of Hameed Latif Hospital, Lahore.

The inclusion criteria were that the patients should have been diagnosed with ruptured or unruptured wide neck cerebral aneurysm via cerebral CT angiography, must have been selected for neuroendovascular treatment with BRT via a consensus among institutional multidisciplinary team, comprising of neurology, neurosurgery, and neuroendovascular surgery departments, should have no history of bleeding diathesis or thrombophilia, and no history of any previous aneurysm treatment.

The degree of aneurysm occlusion was defined using a modified three-point scale comprising complete occlusion, near-complete occlusion (neck remnant), and incomplete occlusion (aneurysm or sac remnant) [7,17]. An aneurysm was graded as wide neck if the neck was 4 mm or greater and/or fundus-to-neck ratio <2.0 on digital subtraction angiography[2,3,7]. Cerebral aneurysms were broadly classified based on their location (basilar apex, other posterior fossa locations, anterior cerebral artery (ACA), anterior communicating artery (Acom), middle cerebral artery (MCA), or internal carotid artery (ICA)) and geometry i.e. originating either from a side wall or bifurcation/trifurcation (Table 2). None of the patients received pre-procedure antiplatelet therapy.

Statistical calculations were performed using SPSS version 21 (IBM, Chicago, IL, USA). Specific variables that were analyzed included age, gender, aneurysm location, aneurysm size, use of BRT, and aneurysm rupture status. Additional patient data collected included degree of aneurysm occlusion after coil placement and BRT related complications (i.e. thromboembolic events & ruptures).

All procedures were performed by using transfemoral access in a dedicated single plane Toshiba Japan Infinix 8000 Angiography suite under general anesthesia after obtaining informed patient consent. Briefly, after routinely obtaining femoral access using a 6F introducer sheath, all patients were administered 5000U of intravenous heparin followed by measurement of activated clotting time (ACT) after 10 minutes post administration. An additional 1000U bolus of intravenous heparin was administered every hour for the duration of the procedure. The systemic heparinization was adjusted to maintain the ACT between 250-300 seconds. Various 6Fr guiding catheters were used in our patients (Chaperone, Microvention, Tustin, CA, USA; Primum MPC, PendraCare International, Leek, Groningen, The Netherlands) and depending upon the aneurysm location, they were placed either in the ipsilateral internal carotid or the dominant vertebral artery. Both the microcatheter and the balloon catheter were coaxially placed through the guide catheter. HyperForm, HyperGlide (Medtronic, Minneapolis, MN, USA), Ascent (Cerenovus, Irvine, CA, USA), Sceptor C, and Sceptor XC (Microvention, Tustin, CA, USA) remodeling balloons were used (Table

1). In sidewall aneurysms, the balloon was placed directly across the neck of the aneurysm (Figure 1-2). In bifurcation aneurysms, such as basilar apex and carotid terminus aneurysms, a longer balloon length was used and balloon inflated sufficiently to completely cover the aneurysm neck. Balloons were inflated for initial framing of the coil, to prevent prolapse of the coil into the parent vessel, and for dense packing of the last coil. The balloons were removed after procedure was completed. Both balloon inflation and deflation were performed under direct fluoroscopic visualization to ensure that there was no over inflation or migration of the coil out of the neck before detachment. Control angiography runs were routinely obtained after each coil deployment to assess residual filling in an aneurysm and identify any thrombus formation adherent to the coil mass or within the parent vessel adjacent to the aneurysm neck. If thrombus formation was noted, an immediate ACT was measured followed by a loading dose of intravenous Tirofiban (4cc×25mcg=1mg). Post procedure, the groin sheath in such patients was sutured to the skin and attached to continuous non-heparinized saline infusion usually at 0.10mcg/kg/min for 8-12 hours. All patients were extubated in the neuroangiography suite and then monitored in intensive care unit for a minimum of 24 hours.

## Results

The remodeling technique was performed in 39 patients (mean age 45.2 ± 11.9) harboring 44 aneurysms. Of the 44 aneurysms, 37 (84.1%) were located within the anterior circulation. Morphologically, 26 (59%) aneurysms originated from a sidewall and the rest (40.9%) from either a bifurcation or a trifurcation (Table 2). Majority of the aneurysms were ruptured (79.5%). (Table 1). Technical success was achieved in 42 of the 44 (95.4%) aneurysms and the BRT failure rate was 4.6% (Table 3). In two of the 44 patients, the procedure was aborted because one of them had a wider than calculated aneurysm neck, and thus making BRT impossible, whereas the other patient experienced worsening of the feeding artery spasm upon introduction of the micro-catheter and the balloon catheter.

The initial rates of aneurysm occlusion, as seen on post-procedure angiograms, were complete occlusion in 17 (40.5%) patients, near-complete in 22 (52.4%) patients, and incomplete in 3 (7.1%) patients (Table 3). The remaining three incompletely occluded aneurysms had progressed to complete occlusion at 6 months as ascertained by MR angiography.

Of the 42 aneurysms successfully treated with BRT, treatment related complications were seen in four procedures (9.5%). There were two instances of aneurysm rupture during coil placement in two patients, and thromboembolic phenomena requiring intravenous Tirofiban in two others. Post procedure, no new deficits were identified in any of the four patients.

**Table 1:** *Patient Demographics*

| **Total Patients** | **39** | | |
|---|---|---|---|
| Total Aneurysms | 44 | | |
| Mean Age (years) | 45.23 ± 11.96 | | |
| Gender | Femle | | 23 |
| | Male | | 16 |
| Indications | A. Ruptured: | | |
| | | SAH | 31 |
| | | ICH | 4 |
| | B. Un-ruptured: | | |
| | | Headache | 3 |
| | | Aneurysm re-growth | 1 |
| Balloon Used | Hyper Glide | | 19 |
| | Hyper Form | | 09 |
| | Ascent Occlusion | | 05 |
| | Scepter C | | 05 |
| | Scepter XC | | 01 |

SAH= Subarachnoid Hemorrhage,
ICH = Intracerebral Hemorrhage

**Table 2:** *Aneurysm Morphology & Locations (N=44)*

| **Sidewall Aneurysms (*n*=26)*** | | **Bifurcation/Trifurcation Aneurysms (*n*=18)*** | |
|---|---|---|---|
| Paraophthalmic ICA | 1 (3.8) | ACA-Acom junction | 4 (22.2) |
| Supraclinoid ICA | 7 (26.9) | MCA trifurcation | 2 (11.1) |
| Paraclinoid ICA | 1 (3.8) | MCA bifurcation | 8 (44.4) |
| Cavernous ICA | 1 (3.8) | Vertebral Artery - PICA junction | 1 (5.5) |
| ACA | 1 (3.8) | PCA-SCA junction | 1 (5.5) |
| Acom | 5 (19.2) | Basilar apex | 1 (5.5) |
| MCA | 5 (19.2) | Carotid Terminus | 1 (5.5) |
| PCA | 1 (3.8) | | |
| Fetal PCA/Pcom | 1 (3.8) | | |
| Pcomm | 2 (7.7) | | |
| Vertebral Artery | 1 (3.8) | | |

*Data are number of patients. Numbers in parenthesis are percentages.
ACA = anterior cerebral artery, Acom = anterior communicating artery, ICA = internal carotid artery, MCA = middle cerebral artery, PCA = Posterior cerebral artery, Pcom = posterior communicating artery, PICA = posterior inferior cerebellar artery, SCA = superior cerebellar artery

**Table 3:** *Final Outcomes of BRT*

| | | |
|---|---|---|
| **Technical Success (n=44)** | **95.4%** | |
| Failure Rate (n=44) | 4.6 % | |
| Morphological Outcome (n=42) | Initial occlusion: | |
| | Complete | 17 (40.5%) |
| | Neck Remnant | 22 (52.4%) |
| | Aneurysm Remnant | 03 (7.1%) |
| Procedural Complications (n=42) | Rupture (asymptomatic) | 02 (4.8%) |
| | Thromboembolic (asymptomatic) | 02 (4.8%) |

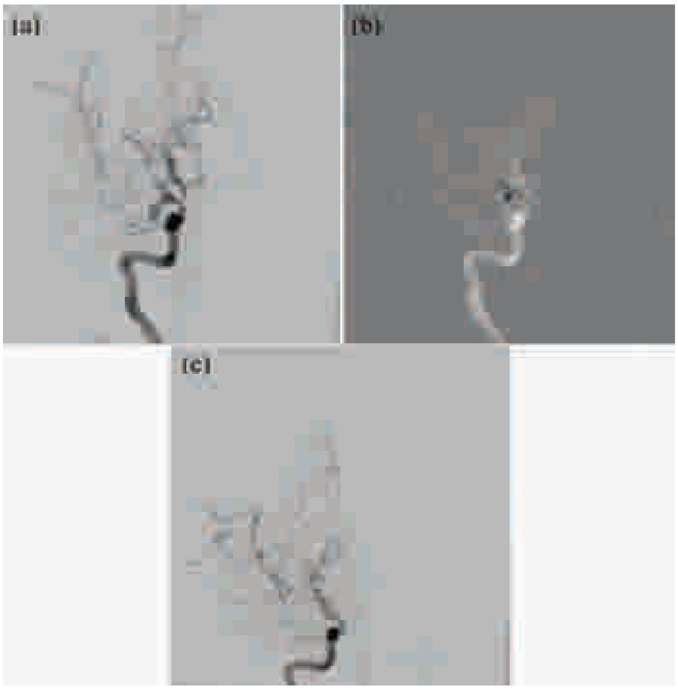

**Fig-1:** *A 48-year-old female with ruptured right supraclinoid ICA aneurysm. (a) Right carotid angiography showing a saccular inferiorly directed supraclinoid ICA aneurysm with a distal sac attached to a stem. BRT was thought appropriate to completely occlude the stem without smaller coils protruding into the parent ICA. (b) Road map image showing microcatheter tip within the aneurysm and last coil being deployed with inflated balloon mounted microcatheter across the aneurysm neck. (c) Post Balloon-Assist Coil placement, complete obliteration of the aneurysm achieved without compromising the fetal right posterior cerebral artery origin.*

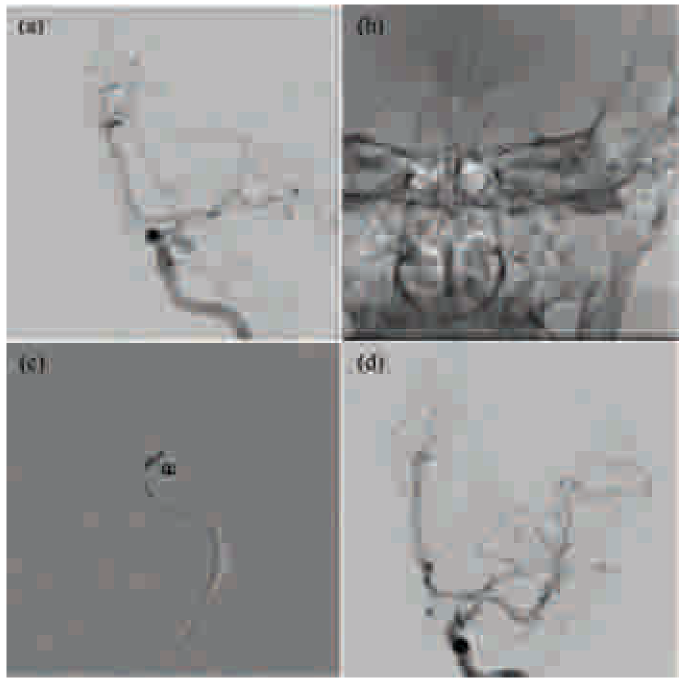

**Fig-2:** *A 50-year-old male with ruptured fetal left posterior cerebral artery aneurysm. (a) Note inferiorly directed relatively wide neck aneurysm. At this location with no proximal bridging, at times the last few coils can protrude into the parent vessel. (b) Native image showing distal marker of the microcatheter within the aneurysm dome and two markers of the balloon microcatheter across the aneurysm neck. (c) Road map Image showing coil placement in progress with balloon inflated. (d) Post balloon-assist coil placement control angiography demonstrates complete aneurysm occlusion and patency of fetal left PCA.*

## Discussion

This study presents a retrospective single operator two-center analysis in a consecutive series of 44 patients with both ruptured and unruptured cerebral aneurysms undergoing BRT. It shows procedural safety in terms of anatomical efficacy and perioperative complications. In this series, overall initial anatomic results in patients treated with remodeling technique were very good with complete occlusion in 40.5% patients, near-complete in 52.4%, and incomplete in 7.1% of them. Thus, adequate occlusion (complete to near-complete) with BRT was seen in 92.9% of the patients. During the follow-up period (range: 3-12 months), no patient required further treatment or developed a recurrent aneurysm neck or lumen. These results are comparable to those reported in a large prospective, multicenter CLARITY[8] study looking at only ruptured intracranial aneurysms, whereby the occlusion rates in the remodeling group with wide neck aneurysms were complete occlusion in 50.0% of cases, a neck remnant in 44.9%, and an aneurysm remnant in 5.1% of them. Similarly, ATENA[10] looking at outcomes of BRT in unruptured aneurysms reported the occlusion rates to be complete occlusion in 59.8% of the aneurysms and a neck remnant in 20.1% of them. Consoli et al[18] in their study of BRT in 164 patients, reported complete occlusion in 78% cases and near-complete in 14.6% of them. Similar results were reported by Gentric et al,[15] wherein an adequate occlusion rate (complete to near-complete) of 92.1% was achieved.

Present study showed the rate of peri-operative complications to be 9.5%, with 4.8% being thromboembolic in nature and the remaining (4.8%) being hemorrhagic. CLARITY,[8] showed that the remodeling group had thromboembolic events in 10 of the 52 (19%) cases, and intra-operative rupture in four of them (7.7%). Whereas, ATENA[10] showed the former in 7.1% patients, and the latter in 2.6% of them. Similarly, the rate of thromboembolic phenomenon reported by Consoli et al[18] was 0.6% and that of hemorrhagic phenomenon 4.6%. Dabus et al11 included 84 BRT-treated cerebral aneurysms in their study, and reported 3% thromboembolic and 6% hemorrhagic events.

Long-term outcomes of this technique have shown that it is a feasible option for both ruptured and unruptured cerebral aneurysms located in all locations.[6,9,19] The BRT failure rate of 4.6% in this study is in line with that reported by Consoli et al[18] of 1.2% and that by Cottier et al of 8%.[20] Common reasons for failure include completely unfavorable dome-to-neck ratio resulting in wider neck and rendering it difficult to form a stable coil mass configuration, tortuous cervical and intracranial vasculature limiting multiple microcatheter access, vessel going in spasm, and acute angle of the parent vessel e.g. paraophthalmic aneurysm location. In this study, clinical outcomes were favorable in all patients. However, the rates of treatment related morbidity and mortality were not determined. In the ATENA series,[10] the overall morbidity was 2.3% and mortality 1.4% in the BRT group. The CLARITY series[8] reported findings similar to those of the ATENA, with treatment related morbidity as 2.5% and mortality as 1.3% in the remodeling group. Dabus et al, reported a 2.6% rate of procedure-related morbidity.[11] Limitations of this study are not recording the rates of procedure-related morbidity and mortality, the total balloon inflation time, the number of inflations per case, maximum single inflation time and reperfusion time between inflations. However, the average inflation time observed in this study was no more than 5 minutes. Spiotta et al,[21] in their balloon remodeling series for unruptured aneurysms reported no significant relationship between balloon inflation practices and incidence of ischemic complications.

## Conclusion

The rates of adequate aneurysm occlusion and treatment related complications achieved in our aneurysm samples are similar to those reported in other studies on BRT. Majority of the ruptured and unruptured wide neck cerebral aneurysms can be successfully treated in our population with balloon remodeling technique for coil placement. This technique offers a safe and effective solution for endovascular treatment of wide neck and complex-origin cerebral aneurysms, where conventional non-assisted coil placement might not be possible.

**Conflict of Interest:** None to declare.

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## Authors Contribution

**QB:** Conceptualization of Project
**QB, FF:** Data Collection
**QB, FF, JI:** Literature Search
**FF, AI:** Statistical Analysis
**QB, FF, AI, JI:** Drafting, Revision
**QB, FF, AI, JI:** Writing of Manuscript