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BALLOON ASSISTANCE IN COILING OF RUPTURED ANEURYSMS: A NECESSARY EVIL.

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ABSTRACT

PURPOSE: Balloon assisted coiling is an established treatment for Ruptured intracranial aneurysms. The aim of this retrospective study was to evaluate the indications of balloon assistance and establish its comprehensive utilities.

METHODS: A total of 68 patients with Ruptured intracranial aneurysms treated with endovascular coiling using balloon were retrospectively evaluated. Various indications of Balloon inflation were evaluated such as to prevent coil prolapse, negotiating tortuous bends at ICA bifurcation and hemostasis in the event of intraprocedure rupture. Immediate and delayed complications associated with balloon use were also studied.

RESULTS: Balloon inflation was done in 45/68 patients. In 36 (52%) patients it was used for assistance in coiling, in 03 (4%) patients it was inflated after rupture of the aneurysm, in 04 (5.8%) patients it was inflated to help the wire and microcatheter to enter A1 segment of Anterior cerebral artery due to acute angulation at ICA bifurcation. In 03(4%) patients the balloon was inflated to visualize the lumen of the parent artery as the aneurysm was not able to be seen in profile. Immediate complications such as thrombus formation around the balloon was seen in 03 cases (4%), distal embolism in 02 cases (3%), arterial dissection in 01 case (1.4%) and prolapse of coil during deflation in 01 case (1.4%). On short term follow up of 06 months there was regrowth of the aneurysm neck seen in 03(4%) cases.

CONCLUSION: The Use of Balloon in endovascular coiling remains an essential tool to aid adequate and safe coiling of Ruptured aneurysm.

KEYWORDS :

Introduction

Ruptured Aneurysm presenting with Subarachnoid hemorrhage (SAH) and Intracranial hemorrhage (ICH) is a life threatening ailment and needs urgent management. Both options of Surgical clipping and Endovascular treatment are available at specialized centers however decision of either is generally taken after discussion between Neurointerventionist and Neurosurgeon. Despite ISAT (International Subarachnoid Aneurysm Trial) favoring Endovascular Management over surgical clipping[1], there are various factors that decide the management such as, Patients general condition, co morbidities, Grade of SAH, Vasospasm, dome to neck ratio, size, location and morphology of Aneurysm. Morphology of aneurysm includes the number of sacs, direction of the aneurysm dome and angle of the neck of aneurysm with the parent artery. The extensive advancement in the hardware has significantly reduced the concern for Risk of recanalisation and re-rupture after endovascular coiling. Wide neck aneurysms (Dome to neck ratio less than 1.5) are world wide being treated with balloon assistance[2], stent assistance or Flow divertor placement. Balloon assistant endovascular coiling was a landmark innovation in treating difficult wide neck aneurysms which were equally challenging when Surgical clipping was performed.

In the present scenario Endovascular management of ruptured aneurysms need to be done with utmost safety measures keeping in mind the success of reasonable complete coiling with prevention of rupture risk while coiling. The breakthrough balloon remodeling technique (BRT) has been introduced by Moret et al[3] two decades ago for wide necked aneurysms who achieved 77% complete occlusion rate in ruptured aneurysms. Since then BRT was unanimously accepted as a gold standard technique for wide necked aneurysms. The journey with low compliant balloons in the past to more compliant present day balloons like Hyperfoam (ev3 Inc., Plymouth, MN), Sceptor XC (Microvention) and Transform (Stryker), have made the job of Neurointerventionist easier due to their easy trackability and more stability. The ability of extra-compliant balloons to bulge into the aneurysm neck and conform to the anatomical vessel bifurcation allows better Coil packing.[4]

We, in our Practice routinely use balloon as a mandatory hardware in all ruptured aneurysm cases taken up for coiling, irrespective of wide or narrow neck. We believe Balloon stabilizes the microcatheter tip in the aneurysm, prevents coil prolapse into parent artery, permits better coil packing density, reconstructs the anatomy in bifurcation aneurysms and provides protection by way of minimizing blood extravasation in the event of rupture of the aneurysmal sac while coiling.[5] In addition the balloon also assists in negotiating the wire-microcatheter assembly across difficult anatomy and angioplasty of the vessel in vasospasm. Balloon is also useful in delineating the lumen of the parent vessel during coiling when in large aneurysms the neck of the sac overlaps the vessel of origin and despite various angiographic views, the neck and parent vessel may not be separately discerned. Balloon assistance has shown better occlusion rates of the aneurysms on long term follow up.[6,7]

Some studies have shown that Balloon remodeling technique is associated with increase rate of thrombus formation and peri and post procedure embolic events, however still no significant association could be estabilished.[8] Balloon however poses a potential trigger for platelet aggregation if kept for a longer duration. In this article we share our experience to find the various utilities of balloon in coiling ruptured aneurysms other than in wide necked aneurysms, highlight technical issues and complications of balloon use and establish its importance as a possibly mandatory hardware that may be used despite the risk of associated complications.

MATERIAL AND METHODS

Type of study: It was a retrospective observational and interventional study. Necessary approval from the Institutional Ethical Committee was taken.

Study area: The study was conducted at Interventional Radiology Centre of a large multispecialty tertiary care government (public) hospital. This apex centre has got an adequate workload of neurosurgery, neurology and neuro-intervention with a dedicated team and state-of-art equipments.

Study duration : The study included cases done between Jan 2014 to Dec 2016.

Study population: The study included patients with clinical and imaging features of ruptured aneurysm admitted to this hospital for management by neuro interventionists that underwent Balloon

assisted coiling. All these patients were discussed jointly in multidisciplinary neuro-radiology clinics with Neurosurgeons prior to intervention. Total of Sixty eight patients who underwent balloon assisted coiling were included in the study.

Study technique: The images, electronic data and medical records of patients undergoing neuro intervention during the study period was retrieved and perused. A note was made of clinical diagnosis, imaging features, indication of balloon, and type of intervention done. Various parameters regarding patient's demographic profile, type of intervention, efficacy and safety of the intervention were studied and inferences drawn.

The important features studied included age, sex, Presentation, aneurysm morphological characteristics, indication of balloon, procedure details, drug history, post procedure complications and long term follow up. Aneurysm neck more than 4mm and dome to neck ratio of less than 1.5 was categorized as wide neck and less than 4mm was treated as narrow neck.

Patients planned for stent assisted coiling were put on antiplatelet regime of Tab Clopidrogrel 75mg and Tab aspirin 150mg for 05 to 07 days. Antiplatelets were not started when simple balloon assisted coiling was contemplated, however when an on table decision of stent assisted coiling was taken, then a loading dose of antiplatelets (600mg Tab Clopidrogrel and 300 mg Tab Aspirin) was given prior to the stent deployment. Location of the Aneurysm was classified as in the region of ICA (Internal Carotid Artery), ACA (Anterior Cerebral Artery), MCA (Middle Cerebral Artery), Basilar Top and Vertebral Artery.

Procedure Details:

Informed written consent was obtained from the family members of the patient. All cases were performed through Transfemoral arterial puncture in the biplane angiographic machine under General Anesthesia. 7F Sheath was secured in the femoral artery. Base line ACT (Activated clotting time) was taken and a loading dose of 5000IU of heparin was given. Heparin was repeated every one hour and dose was adjusted to maintain the ACT values between 200 to 250 seconds. We selected 6F Guiding catheters (Envoy, Cordis, Neurovascular, Miami lakes, Fla or Neuron; Penumbra) and sheaths (Shuttle; Cook Indianapolis, Ind) based on the anatomy of the Arch of the Aorta and Internal carotid artery (ICA). Angiographic runs were obtained for localization of the aneurysm. Suitable working position was obtained, Under road map the available Balloons like Hyperfoam and hyperglide (eV3, Plymouth, Minn), Scepter C and XC (Microvention) and Ascent (Codman) were bridged across the neck of the aneurysm in deflated state. Subsequently, a suitable Microcatheter was advanced into the aneurysm sac for coil embolisation. Initially attempt at coiling without balloon inflation was made, and only if coil prolapse or instability of microcatheter seen, the balloon was inflated. (Fig 1)

At times if there was difficulty in negotiating across tortuous bends at bifurcation especially while entering A1 segment, balloon was navigated into MCA (M1 segment) and inflated so that the microcatheter –microguidwire assembly could enter the ACA. Balloon was immediately distended to its maximum inflation diameter in the parent artery when there was suspicion of rupture of aneurysmal sac. Occasionally balloon was inflated to expand the partially open stent. Balloon was always inflated under road map image. (Fig 2) Maximum inflation duration was limited to 05 minutes at one time. Slow deflation of the balloon was done with careful observation for coil movement. Maximum reinflation upto five times was done when required. After every inflation-deflation check angiogram was done to assess the patency of parent artery, thrombus formation in the form of filling defects and distal vessel opacification. If prolapse or migration of coil was seen, then the procedure was converted to stent assisted coiling. If thromboembolic complications were seen, then Heparin dose was adjusted with ACT values. Also loading dose (0.25mg/kg) of intra-arterial Abciximab (GP IIb/IIIa inhibitor) was given if thrombus was seen progressing. Post procedure Patient was managed in Intensive Care Unit.

OBSERVATIONS & RESULTS

There were 68 patients of ruptured aneurysms in whom balloon was used. The mean age of patients presented to our hospital was 54 years (30- 78 years). 53% (n-36) were males and 47% (n-32) were females. The age-wise distribution is given in Table-1.

Most common location of the aneurysm was in ICA [41% (n - 28)] followed by ACOM [23% (n - 16)], MCA[17% (n - 12)], Basilar Artery [11% (n - 8)] and Vertebral Artery [5% (n - 4)]. Subarachnoid Hemorrhage, as a result of ruptured aneurysm was classified according to Hunt and Hess grading scale. (Table- 2). 20% patients present with Hunt and Hess Grade I (n - 14) SAH, 41% patients presented Grade II (n - 28) SAH, 23% with Grade III (n - 16) SAH, and 14% with Grade IV (n - 10) SAH. 23% patients underwent coiling within 03 days (n - 16), 56% at 03—6 days (n - 38), and 21% at > 06 days (n - 14) of ictus onset.

The Maximum length (Dome to neck) of the aneurysms ranged from 3mm to 14mm, 66% of which were 3-6mm (n - 45), 31% between 07-10mm (n - 21) and 03 % being more that 10mm(n - 2). The neck of the aneurysms was narrow (dome to neck ratio > 1.5) in 68% (n - 46) and Broad (dome to neck ratio < 1.5) in 32% (n - 22). The Orientation of the neck in relation to the parent artery showed acute angulation in 23% (n - 15), was perpendicular to the parent artery in 36% (n - 25), (Fig 3) and obtuse angulation in 41% (n - 28).

Most of the aneurysms were having single sac [77 % (n - 52)], with 18 %(n - 12) showing a second daughter sac and 05% (n - 4) being complex with multiple sacs. The balloon was introduced in all cases (68), however it was not inflated in 23 cases (34%) as its need did not arise. (Fig 4) Balloon was inflated only once in all the 24 cases (34%) and multiple times in 21 cases (31%).

There were various indications of balloon inflation in the 45/68 patients. In 36 (52%) patients it was used for assistance in coiling, in 03 (4.4%) patients it was inflated after rupture of the aneurysm, in 04 (5.8%) patients it was inflated to help the wire and microcatheter to enter A1 segment of Anterior cerebral artery due to acute angulation at ICA bifurcation. In 03 patients the balloon was inflated to visualize the lumen of the parent artery as the aneurysm was not seen in profile. (Fig -5). In 07 patients simple balloon assisted coiling was converted into stent assisted coiling.

We used Extra-compliant balloon in 46 patients and compliant balloons in 22 patients. In majority of cases (50) the size of the balloon was almost equal to the parent artery and in rest of the cases (38) the selected balloon was slightly lower in size compared to the parent artery.

Balloon was kept in the parent artery, either inflated or deflated, for a total duration of <2hrs in 32% (21) cases, 2-4hrs in 47% (32) and > 4hrs in 21% cases (15). Balloon was kept inflated for a duration of < 3minutes in 44% (30) cases and 3-5 minutes in 56 % (38). Balloon was never inflated for more than 05 minutes at a given time.

Immediate complications such as thrombus formation around the balloon was seen in 03 cases (4%), distal embolism in 02 cases (3%), arterial dissection in 01 case (1.4%) and prolapse of coil during deflation in 01 case (1.4%).

The neck of the aneurysm was broad in two cases of thrombus formation. One of the case was later converted into stent assisted coiling. The aneurysm neck was narrow in the third case. In both the cases of broad neck aneurysms, the duration of balloon inflation was more than 03 minutes. All the cases with local thrombus formation were seen in whom the balloon was kept for >4 hrs and was inflated multiple times. 0.25 mg/Kg bolus dose of Intra-arterial Inj Abciximab (Reopro) was administered in all three cases of thrombus formation. Subsequently one of the patient with broad neck aneurysm in whom stent was not deployed developed persistent sensory aphasia at 01 month follow up, however no focal neurological deficit was seen in rest of the two patients.

Both the cases of the distal embolism patients had narrow neck aneurysm and balloon was inflated for less than 03 minutes. 01 case with distal embolism was seen in patient in whom the balloon was inflated multiple times and the second case of distal embolism was seen with single time balloon inflation. Surprisingly none of the patients with distal embolism showed thrombus formation initially. Distal embolism was managed conservatively. Both patients with embolic events developed focal neurological deficits in the form of limb weakness and memory deficit which recovered completely at 01 month follow up. The patient with dissection of MCA (M1 segment), developed contralateral hemi paresis. The one case of coil prolapse was managed with stent placement and dual antiplatelets regime.

Subsequently the patient did not develop any neurological deficit. No significant correlation between age, sex, location of aneurysm and Grade of SAH with balloon related complications was seen.

On short term follow up of 06 months, there was regrowth of the aneurysm neck seen in 03(4%) cases. In 72% (n - 49) cases balloon was planned at the beginning and in 28% (n - 19) cases we used it subsequently due to failure of simple coiling. In 87% (n - 59) cases we could achieve complete coiling with balloon assistance and in 13% (n - 9) cases we could only do partial coiling. Out of these 09 cases of aneurysms, 07 cases were having broad neck and 02 cases were narrow neck. Follow up DSA for all the partial coiling patients at 06 months revealed stable morphology of the neck in 06 patients and regrowth of neck in 03 cases. All the cases of regrowth underwent second sitting stent assisted coiling with complete obliteration of the aneurysm.

DISCUSSION

Endovascular management of broad neck ruptured aneurysms remains a challenge, despite availability of various treatment options like balloon remodeling technique, Stent assisted coiling and Flow divertor placement. We selected all the cases of balloon assisted coiling in ruptured aneurysms in our study. Balloon was used primarily to assist coiling in broad neck aneurysms and as a protection device in case of rupture of aneurysm during coiling. We also used balloon for manipulation of wire at tortuous bends and to visualize the parent artery during coiling in large aneurysms overlapping the neck of aneurysm and vessel. Due to concern for adverse effects associated with balloon remodeling technique, we did not plan balloon at the beginning in some cases and choose to use it later as we didn't anticipate any difficulty due to amicable neck morphology.

Whenever it was difficult to do balloon assisted coiling due to complex anatomy or prolapse of coil into the parent artery, we converted it to stent assisted coiling after giving loading dose of antiplatelets. Overall in our series we could attain initial occlusion rates of 84% with 3% recanalisation rates on 06month follow up DSA. There was a direct relation between thrombus formation around the balloon with broader neck of aneurysm, longer duration of balloon placement in the vessel and multiple balloon inflations (4%). This relation could not be established with embolic events. Interestingly out of the 09 cases in which partial coiling was done only 03 showed recanalisation and rest showed no regrowth at 06 month follow up DSA suggesting that not all aneurysms undergo coil compaction with regrowth/recurrence. One case with recanalisation was seen in the case with initial complete coiling.

Henkes et al reported a risk thromboembolic events and iatrogenic rupture of aneurysms in upto 38.5% cases due to Balloon remodeling technique in his 26 cases done with balloon remodeling, out of 1811 aneuryms.[9] Sluzewski et al also reported upto 14.1 % complication rate in the arm of balloon remodeling cases against only 3% in non balloon assisted coiling.[10]

However this notion of increased complication rates with balloon remodeling technique was diluted with subsequent studies which showed insignificant complications against the benefits of balloon.

In our series we observed 8.4% (06/68) cumulative risk of thromboembolism and dissection during the procedure. However at 01 month follow up only one of the 05 cases of thromboembolism continued to have sensory aphasia and the case with dissection of the MCA (M1 segment) continued to have left hemi paresis thus constituting an end result of 2.9% morbidity. This satisfactory recovery of all patients with thromboembolism can be attributed to the early detection of the complication and administration of intra-arterial Abciximab. We did not encounter iatrogenic rupture of the aneurysm due to balloon inflation in our series of cases, which can be attributed to the conservative selection of balloon size, that was either equal or less than the size of the parent artery and also its judicial use in only 66% (45/68) cases. Balloon aided us to control the bleeding in rupture of the aneurysm while coiling in two cases and proved to be life saving. We also did not encounter any mortality related to balloon remodeling technique.

Our results show lower morbidity associated with balloon remodeling then previously reported studies. Gallas et al reported 1.4 % procedural mortality and 8.6% morbidity in his study of 43 balloon assisted cases.[11] Henkes et al reported morbidity of 5.3%.[9] Our study was comparable with a larger study by Murayama et al, in their series of 916 aneurysms documented 8.4% procedure related complications with 4.4 % thromboembolic complications.[12]

Our series of cases emphasizes the use of balloon in all cases of ruptured aneurysms as mandatory with minimal long term morbidity risks. Also we find the balloon useful for other indications such as manipulation of wires and parent artery visualization. Balloon definitely increases the confidence level to achieve better coil compaction and obliteration of aneurysmal sac.

CONCLUSION

Balloon remodeling technique is a well accepted method for endovascular coiling of wide-neck aneurysms; however there are other utilities of balloon such as its use to control bleeding after intraprocedure rupture of aneurysm, visualization of tortuous parent artery in overlapping neck and aid to navigate microguidwire wires at acute bends. Balloon remains an essential adjunct for endovascular coiling in significant number of cases, despite higher complication rate with Balloon remodeling technique.

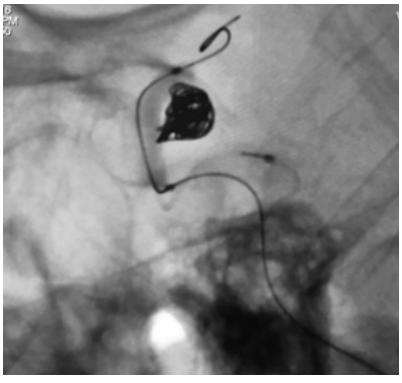

Fig 1: Case of prolapsed coil mass into the parent Artery. Balloon was inflated to push the coil back into the aneurysmal sac.

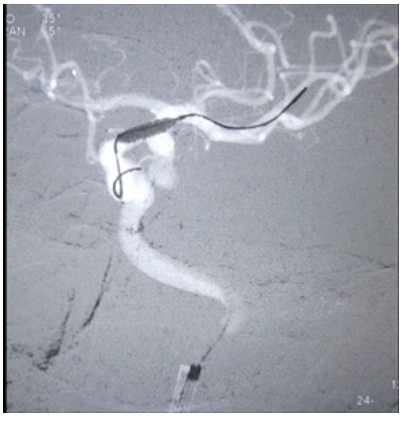

Fig 2: Image showing Balloon inflation under Road map.

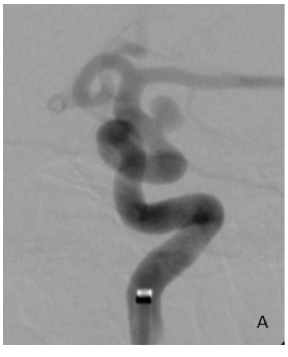

Fig 3A : Case of Left Paraclinoid ICA Aneurysm. Neck of the Aneurysm is oriented perpendicular to the parent artery.

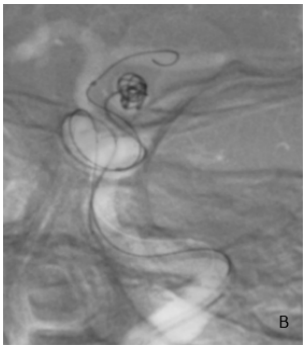

Fig 3B: Balloon was essentially inflated during coiling.

Fig 4 : Image showing non-inflated Balloon placed in the parent artery.

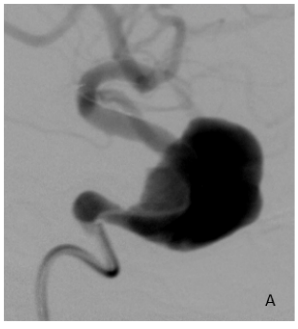

Fig 5A : Case of large Right Cavernous ICA aneurysm.

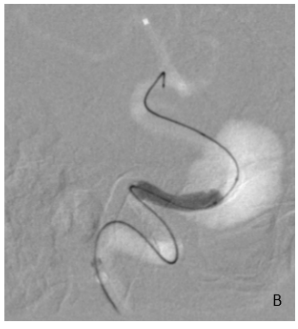

Fig 5B : Balloon was inflated to visualize the parent artery lumen.

Table-1: Age- wise distribution of patients included in Study.

Sr No	Age slab (Years)	Number of patients
1	21-30	5 (7%)
2	31-40	9 (13%)
3	41-50	12 (17%)
4	51-60	19 (28%)
5	61-70	14 (20%)
6	> 70	9 ((13%)
	Total	68

Table- 2: Hunt and Hess Scale for grading of SAH.

Grade	Criteria
0	Unruptured Aneurysm
1	Asymptomatic or minimal Headache, nuchal Rigidity
2	Moderate to Severe Headache, no neurological deficit except for cranial palsy
3	Drowsiness, Confusion, mild focal deficit
4	Stupor, moderate to severe hemiparesis, early decerebrate
5	Deep Coma, decerebrate posturing, moribound

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