A RETROSPECTIVE ANALYSIS OF THE EFFICACY OF BALLOON OCCLUSION TEST FOR ADEQUACY OF CROSS-CIRCULATION AFTER SACRIFICE OF INTERNAL CAROTID ARTERY

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in fulfillment of the requirements for the award of the degree of

DOCTORATE OF MEDICINE (D.M.)

in

NEUROIMAGING & INTERVENTIONAL NEURORADIOLOGY

By

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DECLARATION

I, ***Dr. Chinmay Pankajkumar Shah,*** *hereby declare that this dissertation titled "***A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery****", has been prepared by me under the direct supervision and guidance of* ***Dr. Jayadevan E R,*** *Associate Professor, Department of Imaging Sciences & Interventional Radiology, SCTIMST and is being submitted to the* ***Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram,*** *in fulfillment of the requirements for the award of the degree of* ***DOCTORATE OF MEDICINE (D.M.) IN NEUROIMAGING & INTERVENTIONAL NEURORADIOLOGY.***

I have not submitted this dissertation on any previous occasion to any University or Board for the award of any degree.

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CERTIFICATE

This is to certify that the dissertation titled ***"A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery",*** *is a bonafide work done by* ***Dr. Chinmay Pankajkumar Shah,*** *Senior Resident, Department of Imaging Sciences & Interventional Radiology, under my guidance and supervision and to my complete satisfaction, in fulfillment of the requirements of the* ***Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram*** *for the award of the degree of* ***DOCTORATE OF MEDICINE IN NEUROIMAGING & INTERVENTIONAL NEURORADIOLOGY.***

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Were not attained by a sudden flight,
But, they, while their companions slept,
Were toiling upwards in the night."

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Lastly, I thank each and every person in the institution, who has helped me in any possible form and from whomsoever I have learnt something.

This work is dedicated to all the patients who have subjected themselves in this study. I express my wholesome gratitude to all these patients.

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CONTENTS

INTRODUCTION

- Temporary balloon occlusion (TBO) of the ICA is a procedure performed for preoperative evaluation of patients with aneurysm or tumor involving the neck or skull base who are candidates for Internal Carotid Artery (ICA) sacrifice or are at risk for inadvertent sacrifice of the ICA. TBO is considered a possible part of the surgical or endovascular therapy.

- Along with cerebral blood flow analysis, Temporary balloon occlusion of the ICA is believed to help identify the subset of patients who will not tolerate permanent carotid occlusion.

- Permanent occlusion of the ICA with or without bypass graft placement is of occasional value in the management of patients with inoperable intracranial carotid aneurysms, fistulas, or neoplasms of the neck or skull base with ICA involvement.

- Although therapeutic ligation of ICA is an important option for many, it is limited by the potential for precipitating an ischemic stroke in patients without adequate collateral blood flow. Therefore, BTO has been frequently used to assess the hemodynamic change and predict the result of ICA occlusion.

- However, the test has associated complications and it may not be possible to adequately quantify cerebral blood flow. Hence, it may be possible that the patient may not tolerate sacrifice of internal carotid artery eventhough he has tolerated the Balloon Occlusion Test. There are some parameters like circulation time, venous delay and aqequacy of collaterals which can be accurately determined solely based on this test.

- This study aims to review the patient details, radiological features of disease entities, collateral circulation (Primary & Secondary) and complications in post-operative period. This study also makes appropriate recommendations in terms of future modifications of this valuable test in neurointervention / neurosurgery.

- Balloon occlusion test is an important provocative test in neurointervention / neurosurgery.

- Permanent sacrifice of the ICA is sometimes the only option for potential cure or palliation in patients with certain neoplasms, aneurysms or CCFs. In the past, this was an uncertain option with no adequate predictor of tolerance and was associated with a high morbidity and mortality.

- However, with the advent of BTO, the safety of ICA sacrifice has improved greatly, and today preoperative cerebrovascular assessment is mandatory.

- BTO remains an invaluable prognosticating tool in predicting cerebrovascular tolerance to planned PAS. In the elective setting, a clinical BTO performed with provocative hypotensive challenge and a venous phase evaluation appears superior to other adjuvant imaging measurements of cerebral blood flow.

- Reducing the incidence of a false negative BTO is optimized when the BTO balloon is positioned at the same site as the planned PAS.

- In the intraoperative setting of complicated endosurgical aneurysm repair, the venous phase BTO offers a relatively expeditious and reasonable assessment when considering emergent bail-out PAS.

- Future investigations are warranted with regard to understanding of the relationship between the occasional false negative BTO and PAS related ischemia. The proven efficacy of the endovascular PAS assures its continued

AIMS & OBJECTIVES

The present study entitled, "A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery" was carried out from 1st January, 2000 to 31st October, 2014 with the following aims and objectives:

- ✓ **To study the clinical and radiological features of the disease entities which require parent artery sacrifice following provocative Balloon Occlusion Test.**

- ✓ **To study the immediate, short term and long term complications in the cases undergoing successful Balloon Occlusion test.**

- ✓ **To make appropriate recommendations on future directions of research and management regarding the modification of protocol of Balloon Occlusion Test.**

- ✓ **To review the results at our centre with available data in International literature.**

REVIEW OF LITERATURE

HISTORY

- In **1805**, **Sir Astley Cooper** first described cerebrovascular arterial occlusion for the treatment of downstream carotid artery aneurysm.[1,2]

- In **1829**, **Chiari** ligated a carotid artery in Hunterian fashion by tying off the vessel proximal to the suspected distal aneurysm.[3,4]

- In **1849**, **Warren Stone** , a surgeon, selected the correct vessel for sacrifice in first curing a traumatic vertebral artery aneurysm.[5]

- In **1888**, an American surgeon, **Rudolph Matas** achieved success in obliterating a traumatic vertebral artery aneurysm by parent artery sacrifice (PAS).[6,7]

- **Matas** was the first to recognize the need for a 'preliminary test occlusion' in evaluating treatment options for carotid aneurysms.[8]

- **Matas** and his colleague **Carroll Allen** advocated a more reliable occlusive test procedure be carried out by

placing a temporary soft metal band on the carotid artery for 36–48 h before PAS.[2,6,8,9]

- During **1960s** and **1970s**, innovative endovascular catheters and balloons were evaluated.[10–14]

- In **1963**, **Fogarty** used his balloon catheter to temporarily occlude the carotid artery to protect against emboli arising during cardiothoracic surgery [15]

- In **1964**, **Luessenhop** and **Velasquez** demonstrated that a balloon catheter could be navigated to a supraclinoid aneurysm while achieving temporary aneurysm occlusion.[16]

- In **1964**, Russian neurosurgeon **Fedor Serbinenko** temporarily occluded the internal carotid artery (ICA) by inserting an endovascular balloon tipped catheter via a direct common carotid artery (CCA) needle puncture. He showed that superselective cerebral artery BTO can both map brain function and identify candidate vessels for sacrifice beyond the circle of Willis. [17]

- In **1904**, **Robert Dawbarn** injected a paraffin based slurry into an exposed external carotid artery for palliative treatment of head and neck cancer.[18]

- In **1931**, **Barney Brooks** reported the first successful internal carotid endovascular PAS by using a piece of muscle to embolize a patient's CCF.[19,20]

- In **October 1969**, **Prolo** and **Hanbery** used a No 3 Fogarty balloon catheter into the cavernous ICA to bridge a traumatic CCF. [11]

- In **1968**, **Kessler** and **Wholey** performed the first successful use of a balloon catheter in achieving PAS for an intracranial aneurysm.[21]

- In **December 1969**, the PAS technique, sometimes termed permanent balloon occlusion (PBO), was first performed to treat a cerebral aneurysm.[22 24]

- In the **1970s**, **Debrun et al** was the first to effectively use the detachable PBO technique in a patient with a subclinoid aneurysm.[25-29]

- In **1995**, **Segal et al** emphasized that BTO plays an important role in evaluation of patients with lesions involving ICA at the skull base.[30]

- In **1995**, **Mathis et al** revealed a low complication rate in their analysis of balloon test occlusion coupled with stable Xe CT cerebral blood flow in 500 patients.[34]

ENDOVASCULAR BALLOON TEST OCCLUSION

Before the availability of antibiotics and the practice of aseptic surgical technique, the short term mortality rate from either carotid resection or ligation was frequently above 50% and as high as 55%.[11, 28] In the post-listerian era, the mortality rate greatly improved, ranging from 0% to 29%.[30]

However, the morbidity from ischemic stroke continued to afflict 17–30% of patients subjected to empiric carotid ligation.[31] As originally demonstrated by Serbinenko, successful tolerance to BTO can correlate greatly with the likelihood of uncomplicated PAS. Still, many investigators have shown that despite an uneventful BTO, 4.7–25% of patients will nevertheless suffer immediate or delayed cerebral ischemia following PAS.[32–37]

PARENT ARTERY SACRIFICE

Ideally, aneurysmal repair involves a reconstructive approach that preserves the parent artery while excluding the aneurysm from the circulation thru either open surgical clipping or by endosurgical means. On the other hand, PAS represents a deconstructive way towards affecting aneurysmal thrombosis following open parent artery ligation or transvascular embosurgery. PAS can be an effective option for managing persistent or recurrent aneurysm disease due to failed reconstructive surgery and, PAS can also pose the best initial surgical choice in certain clinical presentations.[38]

Wide neck, multilobulated, giant or fusiform aneurysms have relatively poor long term obliteration rates following endovascular parent vessel preservation surgery. PAS may minimize distal embolic complications arising from endosaccular coiling of clot containing aneurysms since the latter are prone to ejecting thrombus during coil implantation.[39] Small peripherally located aneurysms as well as aneurysms arising from proximal but small caliber arteries are difficult to eliminate while preserving the parent artery, whether or not the approach is by coiling or by clipping with and without bypass. Furthermore, PAS of small vessel aneurysms is typically well tolerated and, any resulting deficit is usually mild or transient.[40, 41]

Numerous effective devices and techniques are available for endovascular PAS. While detachable balloons are effective and relatively inexpensive, balloons may migrate, rupture or deflate over time.[42] This trapping technique eliminates any filling of the aneurysm by either retrograde parent artery flow or by delayed recanalization from small nearby perforator vessels.

Packing the parent vessel with platinum or fibered coils is likewise effective; a stent may be used to minimize the total number of coils (and total expense) needed for PAS by keeping the coils from herniating into aneurysm.[43,44] The aneurysm should be trapped on both sides with the coils to prevent recanalization[45]

Peripheral aneurysms are best eliminated with liquid embolics, especially the cyanoacrylates such as nBCA glue, because the coil incompatible smaller microcatheters and microwires offer a less traumatic approach in negotiating the smaller delicate branches of the brain.[46,47,48]

Direct thrombin injection is a potent technique for inciting aneurysm thrombosis for which only two reports exist concerning its parent vessel sparing success in dealing with this disease in the cerebrovasculature.[49]

Anatomy of Circle of Willis[50-53]

Overview

The circle of Willis (circulus arteriosus cerebri) is an anastomotic system of arteries that sits at the base of the brain. The "circle" was named after Thomas Willis by his student Richard Lower. Willis was the author of Cerebri Anatome, a book that described and depicted this vascular ring. Although such a vascular ring had been described earlier, the name Willis has been eponymously propagated.

The Circle of Willis is an arterial polygon formed as the internal carotid and vertebral systems anastomose around the optic chiasm and infundibulum of the pituitary stalk in the suprasellar cistern. This communicating pathway allows

equalization of blood-flow between the two sides of the brain, and permits anastomotic circulation, should a part of the circulation be occluded.

Gross anatomy

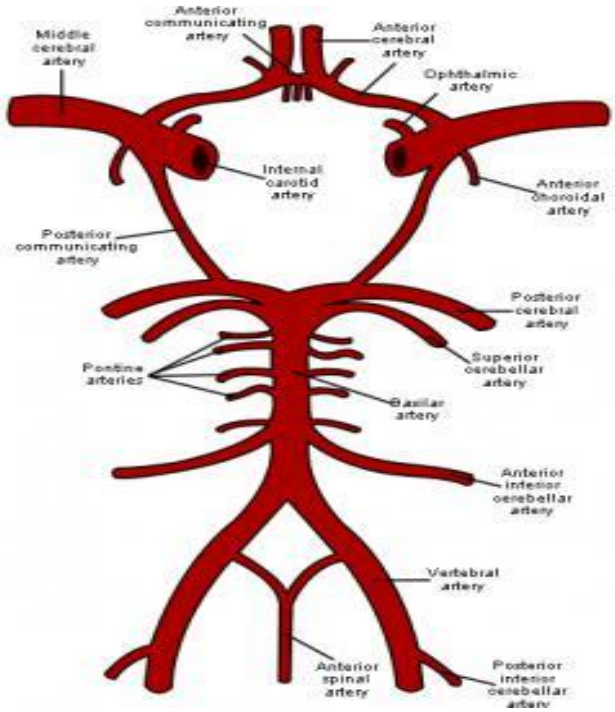


Figure 1: Schematic representation of the circle of Willis, arteries of the brain, and brainstem.

Vessels comprising the circle of Willis:

- *Anterior circulation*:
  - left and right **Internal Carotid Arteries (ICA)**
  - horizontal (A1) segments of the left and right **Anterior Cerebral Arteries (ACA)**
  - single **Anterior Communicating Artery (ACOM)**

- ♣ *Posterior circulation*:
    - left and right **Posterior Communicating Arteries (PCOM)**
    - horizontal (P1) segments of left and right **Posterior Cerebral Arteries (PCA)**
    - single **basilar artery** (tip)

- The basilar artery divides at the upper border of the pons to form the left and right PCAs.
- From each ICA, a PCOM arises at the anterior perforated substance and runs back through the interpeduncular cistern to join the ipsilateral PCA.
- Each ICA also gives off an ACA.
- The ACAs are united by the ACOM, a small vessel that runs in the chiasmatic cistern (below the rostrum of the corpus callosum), to complete the circle.

Branches of the circle of Willis :

- medial lenticulostriate arteries (from the A1 segment of ACA)
- thalamoperforating and thalamogeniculate arteries (from the basilar tip, proximal PCAs, and PCOMs)
- perforating branches (from the ACOM)

These branches supply optic chiasm and tracts, infundibulum, hypothalamus and other structures at base of brain.

Variant anatomy

A complete circle of Willis (in which no component is absent or hypoplastic) is only seen in 20-25% of individuals. Posterior circulation anomalies are more common than anterior circulation variants and are seen in nearly 50% of anatomical specimens.

Common variants

- hypoplasia of one or both PCOM ~30% (range 25-34%)
- hypoplastic/absent A1 segment of ACA ~15% (range 10-15%)
- absent or fenestrated ACOM ~12.5% (range 10-15%)
- origin of PCA from the ICA with absent/hypoplastic P1 segment (fetal PCOM) ~20% (range 17-25%)
- infundibular dilatations of the PCOM origin ~10% (range 5-15%)
- Congenital absence of one or both ICAs (rare). If one ICA is absent, intrasellar intercarotid communicating arteries are common and there is a high incidence of associated aneurysms.

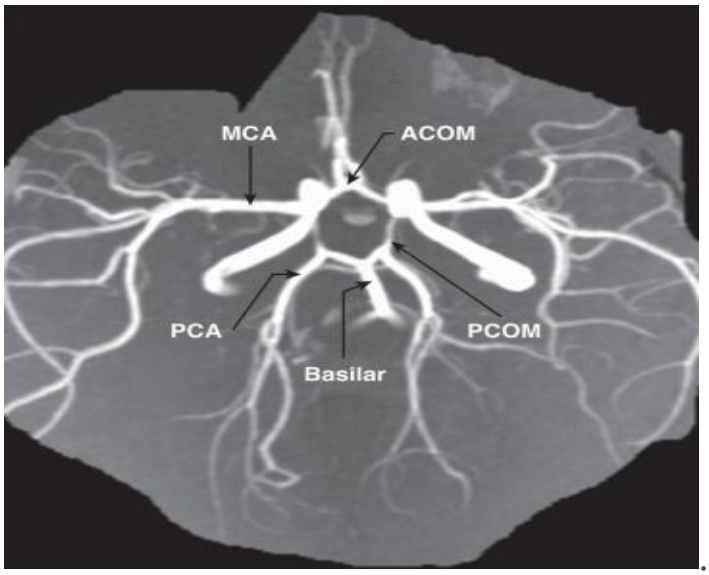


Figure 2 : Magnetic resonance arteriography illustrating the circle of Willis and its branches

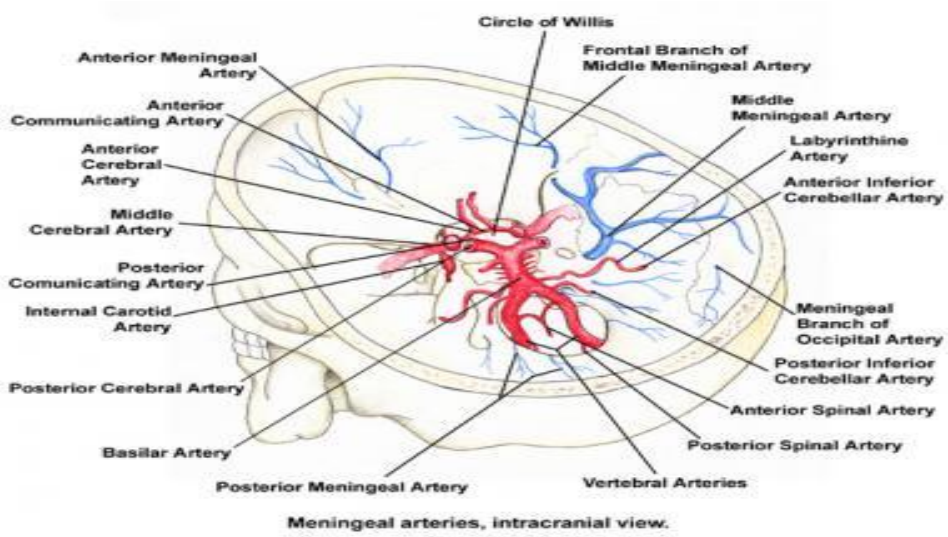


Figure 3 : Schematic representation of the circle of Willis found at the base of the skull.

Physiology of Cerebral Circulation

Under normal conditions, blood flow in the communicating arteries is negligible. However, if a subject has

an atypical Circle of Willis, e.g., missing one of the main arteries or communicating arteries or under pathological conditions such as complete or partial occlusion of one of the cerebral or carotid vessels, the flow can be redirected to perfuse deprived areas[57,58]. The borderzones are then perfused through the network of communicating arterioles. The ring-like structure of the Circle of Willis is often incomplete or not fully developed. It has been found that in more than 50% of healthy brains [54,60,61] and in more than 80% of dysfunctional brains[62,] the Circle of Willis contains at least one artery that is absent or underdeveloped.

The most common topological variations include missing communicating vessels, fused vessels, string-like vessels, and presence of extra vessels[55.] These topological variations may affect the ability to maintain flow through arteriols, which may increase the risk of stroke and transient ischemic attack in patients with atherosclerosis[59]. Limited technology exists to predict perfusion response to acute occlusion due to embolus (i.e. embolic stroke) and to chronic occlusion due to atherosclerosis (i.e. carotid or other 3 large vessel stenosis), in particular for patients with an incomplete Circle of Willis. These clinical scenarios typically occur in older patients, who have a limited ability to compensate to acute changes in blood flow and thus are at greater risk for developing an acute ischemia (stroke) or chronic hypofusion. The significance of these problems cannot be underestimated since stroke ranks third among leading causes of death and is the leading cause of disability in older adults[56]. Therefore patient specific modeling is critically important to plan and predict perfusion

needs in patients with significant carotid artery stenosis who need surgical repair.

TECHNIQUE OF BALLOON TEST OCCLUSION

Baseline neurological and physical examination of the patient is followed by a diagnostic four-vessel angiography to evaluate the intracranial vasculature and to determine the potential for collateral blood flow around the circle of Willis. The patient is given 70 to 100 units/kg intravenous (IV) heparin after arterial access is gained and the activated clotting time is titrated to two to three times baseline.[63,66,71,74] An angiographic catheter is introduced through a 6 to 7 F sheath in the femoral artery, and diagnostic angiography is performed. After the diagnostic angiogram, the catheter is replaced with a double-lumen balloon catheter over an exchange wire. The balloon catheter (Latex Arrow Balloon) is advanced into the ICA and inflated under fluoroscopic visualization in a relatively straight portion of the ICA, avoiding the carotid sinus and corresponding to the level of the first or second cervical vertebral body.[83,74] Occlusion may be confirmed by proximal or distal radiographic contrast injection and observation of a static column of contrast material.[63,64] Subsequent heparinized saline flush is used to clear residual contrast from the vessel.

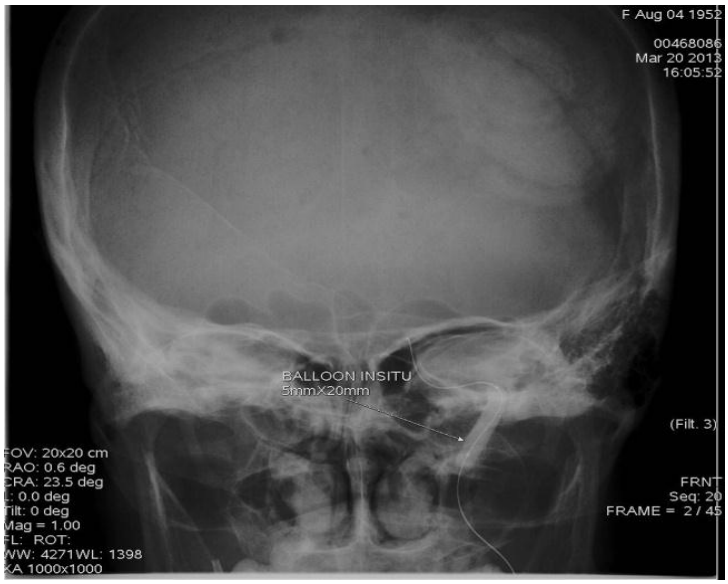


Figure 4: Digital substraction angiographic image showing balloon-in-situ (Frontal view)

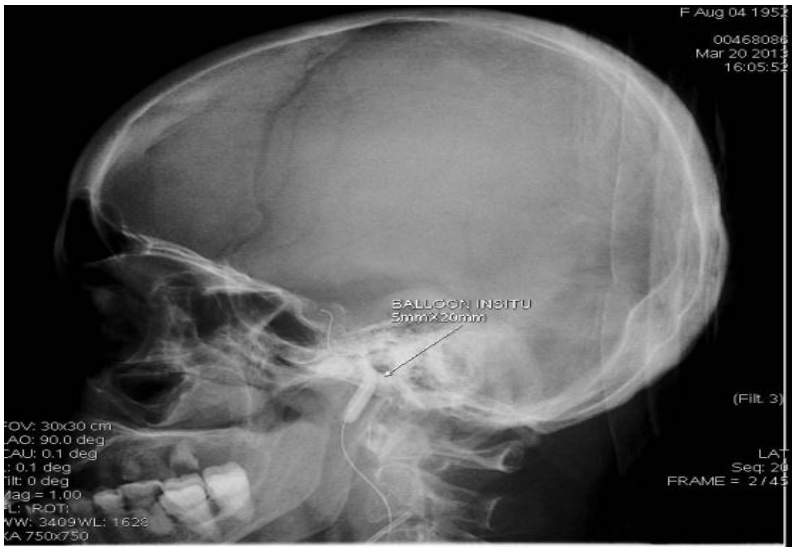


Figure 5 : Digital substraction angiographic image showing balloon-in-situ (Lateral view)

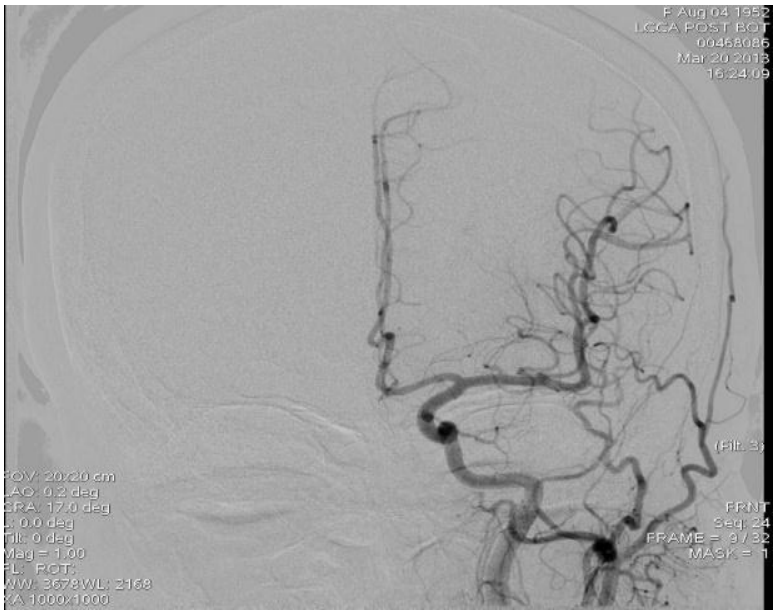


Figure 6 : Digital substraction angiographic image of Left Common Carotid Artery following balloon occlusion test (Frontal view)

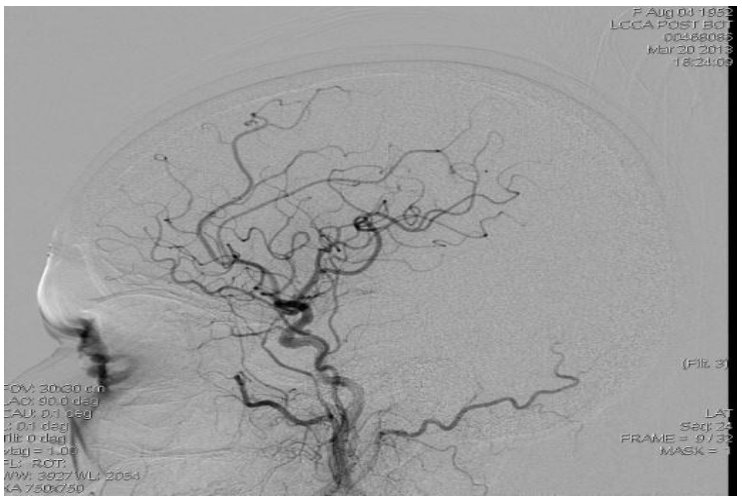


Figure 7 : Digital substraction angiographic image of Left Common Carotid Artery following balloon occlusion test (Lateral view)

Neurological testing is non-standardized and cumbersome due to patient draping constraints but should consist of: extremity and facial muscle testing ("squeeze my hand; show me your teeth; wiggle your toes"); sensation testing (touch) of the extremities; extraocular muscle examination ("follow my finger with your eyes"); visual examination and visual comprehension plus speech assessment by having the patient read large print and name common objects shown to the patient; memory and orientation assessment ("who is the President; what state do you live in"); basic calculation (what is 10 plus 5; count backwards from 20); judgment (interpretation of common proverbs by asking the patient "what does 'look before you leap' mean to you?"); and for the posterior circulation assessment, an evaluation for dysmetria is added (finger to nose testing).

Unlike the patient who passes the BTO, a positive or 'failed' BTO is documented for any baseline deviation regardless of subtly. Frequently, patients who fail BTO do so within the first minute or two. Neurological assessment is performed every 2 to 5 minutes while the balloon is inflated; the balloon is immediately deflated if the patient develops any neurological symptoms of ischemia. [63,66,71,74] If the patient tolerates the initial test occlusion without clinical deficits, some type of direct or indirect cerebral blood flow (CBF) evaluation is performed. [82] If the patient tolerated 30 minutes of normotension, hypotension was induced by the infusion of sodium nitroprusside (2.5 to 7.5 mm/kg body weight per minute) or labetalol (total dose, 5 to 20 mg). After the mean arterial pressure was reduced to two thirds of

baseline, hypotension was maintained for 20 minutes. The balloon then was deflated, and heparinization was reversed with intravenous protamine (1g protamine per 100 U heparin).

The study was terminated immediately if a new neurologic deficit developed during test occlusion under normotensive or hypotensive conditions. After 30 minutes, the balloon is deflated and anticoagulant therapy may be reversed with IV protamine sulfate or allowed to correct naturally before removal of the arterial sheath.[63,66,74] The internal carotid should be occluded for a minimum of 15 minutes; 20 to 30 minutes is standard.[78] A patient tolerating 30 minutes of occlusion without clinical or physiological evidence of impaired perfusion can probably tolerate permanent sacrifice of the ICA. Those who fail test occlusion may be candidates for revascularization or extracranial-intracranial bypass.[75,82]

The circle of Willis is an important collateral pathway for maintaining sufficient cerebral blood flow in patients with ICA obstruction. The function of this arterial anastomosis, which was first described by Sir Thomas Willis in 1664, is to provide collateral flow of blood and preserve cerebral perfusion in case of impaired supply.[83] The primary collateral pathways include the anterior communicating artery and the bilateral posterior communicating arteries. Other collateral channels that may be recruited include the external carotid to ophthalmic artery with reversal of flow in the latter and anastomoses between leptomeningeal collaterals.[83]

BTO RISKS

Complications associated with BTO are uncommon (< 10%) when compared with surgical ligation of the carotid artery, which can result in up to 54% incidence of stroke and 32 to 60% mortality.[84] Reported complications with BTO include puncture site hematoma, transient and permanent neurological deficits, and arterial dissection.[85] Russell et al[86] have brought attention to an ocular ischemic syndrome that can occur during carotid balloon occlusion. The use of a double-lumen balloon catheter that allows infusion of the distal ICA and ophthalmic artery with heparinized saline can cause partial or complete displacement of blood within the ophthalmic artery if infused too rapidly. The symptoms of ocular ischemic syndrome include ipsilateral orbital pain and visual loss and should not be mistaken for a positive occlusion test.[86]

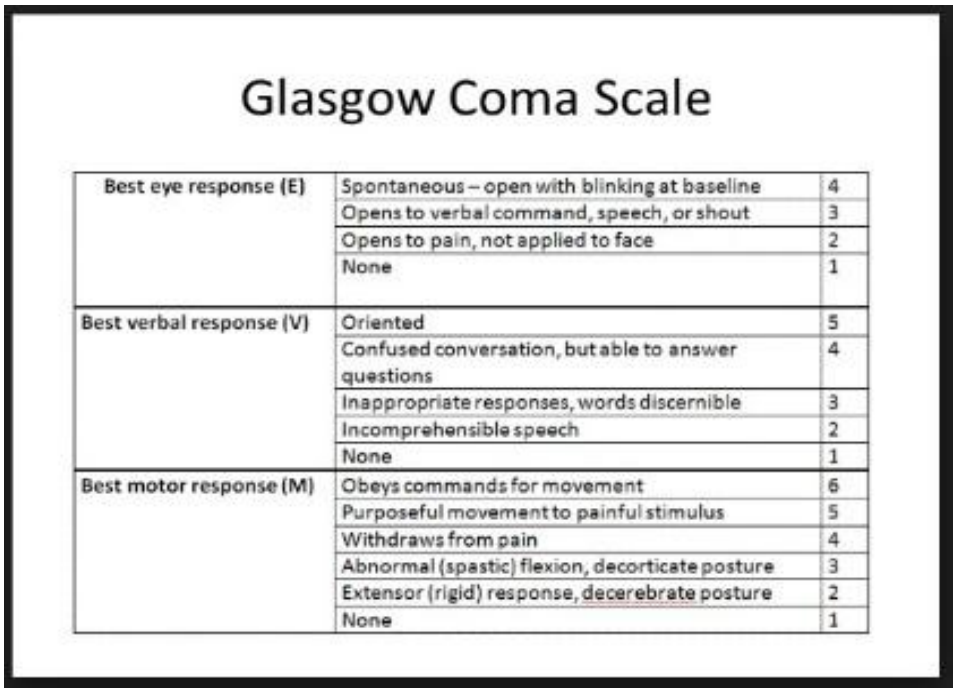
The largest reported study by Mathis et al[34] consisted of 500 cases with 2 patients with permanent neurological deficits (0.4%), 6 with transient neurological deficits (after deflation) (1.2%), and 8 with asymptomatic complications (1.6%). These rates are similar to those reported for diagnostic cerebral angiography.[87-89] In one prospective study of 1000 patients undergoing cerebral angiography, the incidence of persistent neurological deficits was 0.5%.[89] The reported complication rates in a series totaling 769 BTO

procedures between 1987 and 1995 ranged between 0 and 8.3%.[63] Thus, the risk of BTO should be low in experienced hands. Furthermore, this procedure can identify high-risk patients and, according to Standard et al,[68] has reduced the risk of stroke to 5 to 8%. The reported risk of delayed neurological deficits and stroke from carotid sacrifice after a negative BTO varies greatly.

Origitano et al[82] have reported that 4 (22%) of 18 patients developed ischemic sequelae after a negative BTO with a mortality rate of 5.5% (1 of 18 patients). Although preoperative evaluation with BTO followed by surgery results in fewer complications than with surgical ligation of the ICA without BTO, delayed hemodynamic ischemia and thromboembolic events remain moderate risks.[68,69,74]

NEUROLOGICAL EXAM

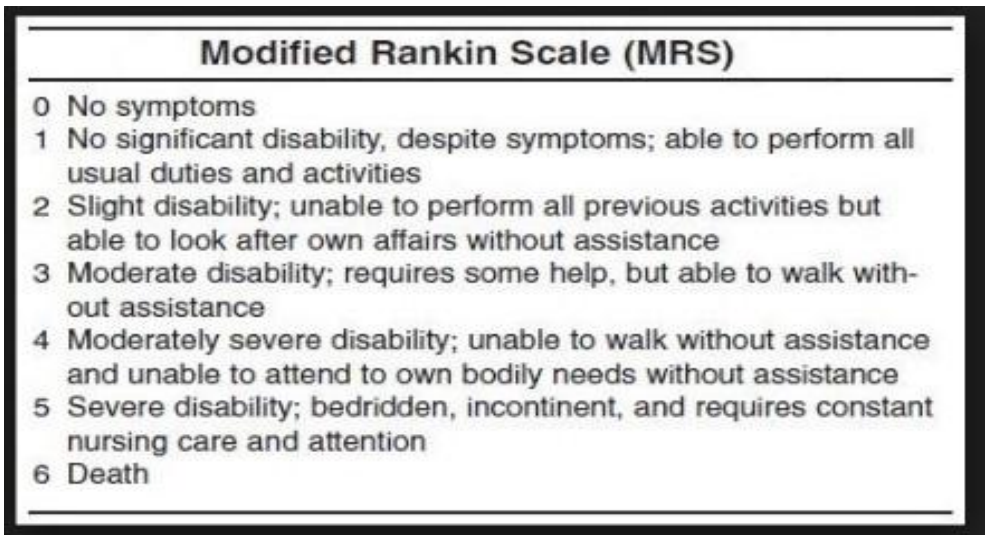
Most protocols for test occlusion consist of neurological monitoring in combination with one or more physiological imaging tests.[72] The neurological status of the patient is continuously monitored after inflation of the balloon catheter. The examination consists of assessing speech, motor strength, sensation, level of alertness, and cranial nerve function.[64] Any evidence of focal neurological deficits requires immediate deflation of the balloon. Some common clinical manifestations leading to test termination include reversible hemiparesis and aphasia.[74,78]



Glasgow Coma Scale

Best eye response (E)	Spontaneous – open with blinking at baseline	4
	Opens to verbal command, speech, or shout	3
	Opens to pain, not applied to face	2
	None	1
Best verbal response (V)	Oriented	5
	Confused conversation, but able to answer questions	4
	Inappropriate responses, words discernible	3
	Incomprehensible speech	2
	None	1
Best motor response (M)	Obeys commands for movement	6
	Purposeful movement to painful stimulus	5
	Withdraws from pain	4
	Abnormal (spastic) flexion, decorticate posture	3
	Extensor (rigid) response, decerebrate posture	2
	None	1

Figure 8: Glasgow Coma Scale



Modified Rankin Scale (MRS)

0 No symptoms
1 No significant disability, despite symptoms; able to perform all usual duties and activities
2 Slight disability; unable to perform all previous activities but able to look after own affairs without assistance
3 Moderate disability; requires some help, but able to walk without assistance
4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5 Severe disability; bedridden, incontinent, and requires constant nursing care and attention
6 Death

Figure 9: Modified Rankin Scale

STUMP PRESSURE

Stump pressure is the intraluminal arterial pressure

distal to the site of occlusion and has been used to provide an indirect assessment of CBF. Stump pressure can be monitored through the open distal lumen of a double-lumen catheter, and measurements are usually taken at approximately 5-minute intervals during ICA occlusion.[66] However, some suggest that stump pressure is a poor predictor for the occurrence of cerebral ischemia and that it does not correlate well with CBF.[66,90] In fact, stump pressure threshold for placement of a shunt during carotid endarterectomy varies greatly, and there seems to be great disagreement as to what pressure is required for adequate CBF. Steed et al[66] compared xenon CT CBF mapping with stump pressures and reported a wide range of pressure values (from 25 mm Hg to greater than 70 mm Hg) for maintenance of sufficient CBF. In this study, normal CBF was defined as greater than 40 cc/100 g per minute, and compromised but adequate CBF was 30 to 39 cc/11 g per minute. They also showed that 7 of 13 patients with inadequate CBF had stump pressures greater than 70 mm Hg. Of course, all this shows is that the stump pressures and xenon CT do not correlate well. Without outcome data, these results beg the question as to which test is more reliable, although opinion would favor the more direct and quantitative xenon CT. Another study comparing HMPAO SPECT and stump pressures showed that the ratio of mean stump pressure to mean systemic pressure may be a more useful index than absolute stump pressure is (i.e., the ratio correlates better with SPECT than with stump pressure alone).[65]

There are many pitfalls in the use of a stump pressure

threshold for predicting intolerance of occlusion. These include variation in autoregulatory mechanisms due to variability of intracranial pressures, chronic hypertension, chronic hypercarbia or hypocarbia, medications that cause vasodilation or vasoconstriction, and the instability of stump pressure during occlusion.[74,90] With a tortuous carotid, the tip of the balloon catheter may poke against the wall of the vessel, resulting in factitiously low pressure and a poor waveform. It is important to position the balloon in a straight segment both to avoid this pitfall and to prevent dissection. Although average stump pressures have been comparable to xenon CBF monitoring, the broad variability of the pressure values limits its sole use as a predictor of CBF after carotid artery occlusion. [66] When combined with a more direct and quantitative measure of CBF such as xenon CT, stump pressures can be a useful adjunct for gauging cerebral perfusion. [66,74]

HYPOTENSIVE CHALLENGE

During balloon inflation, pharmacologically induced hypotension can be used to increase the sensitivity of the test by imposing a challenge to the cerebral perfusion. This has been accomplished by decreasing the systolic blood pressure by 30% of the baseline blood pressure for 4 minutes of a 10-minute test occlusion.[64] Another approach is of induced hypotension to two thirds of mean arterial pressure for 20 minutes using infusion of sodium nitroprusside or

labetolol.[68] During this period, clinical neurological exams are performed to estimate tolerance to the trial occlusion. This technique has been accepted by some and rejected by others. Dare et al[67] found significant false-negative results in which 2 of 13 patients (15%) tolerated the hypotensive challenge without acute neurological deficits but ultimately developed delayed permanent neurological consequences. On the other hand, Standard et al[68] concluded that BTO with hypotensive challenge is a safe and economical method that increased the number of patients identified with deficient collateral capacity from 4 of 47 patients (9%) to 13 of 47 patients (28%). Overall, the hypotensive challenge is an easily performed method that has been shown to identify patients at risk for ischemia during permanent ICA occlusion.

TRANSCRANIAL DOPPLER ULTRASONOGRAPHY

TCD has been used to measure blood velocity in both middle cerebral arteries during ICA balloon occlusion to indirectly estimate cerebral blood flow.

Sorteberg et al[70] used TCD for 90 to 120 seconds of balloon inflation to calculate blood velocity (VMCA), pulsatility index (PIMCA), and hemodynamic tension (UMCA). They suggest that ICA sacrifice is tolerable when test occlusion results in an ipsilateral initial reduction in VMCA to no less than 60% of preocclusion velocity with the equivalent limit for

UMCA being greater than or equal to 40%.

Eckert et al[69] used TCD to record VMCA in patients having permanent ICA occlusion by positioning the probe with a headband and recording measurements every 7 seconds. In addition, VMCA was recorded after contralateral motor activation, called motor vasoreactivity, by intermittent fist clenching and finger movements before and after ICA occlusion. Their data showed that all patients with a decrease in VMCA of more than 50% developed neurological symptoms, and patients with VMCA reductions of 30% or less had no complications. Furthermore, in patients with a VMCA decrease between 30 and 50%, motor vasoreactivity can be an additional parameter used for assessment. They advocate TCD as a reliable predictor of hemodynamic changes after permanent ICA occlusion.

ELECTROENCEPHALOGRAPHY

EEG is commonly used for monitoring during carotid endarterectomy, but its use during BTO has been inadequately studied.[72] A test occlusion protocol by Willem et al[72] used a combination of neurological assessment and 21-channel EEG analysis for 20 to 30 minutes in four patients. All four patients tolerated the trial occlusion with normal clinical and EEG examinations. However, after permanent occlusion, two (50%) developed delayed infarction, resulting in

hemiplegia. Another investigation measured compressed spectral arrays (CSAs) of EEG and found that one of nine patients suffered a fatal ischemic event 3 days after surgical ligation of the ICA despite a negative balloon test.[73] Considering the lack of evidence to confirm or dispute the use of EEG during BTO, further evaluation with more patients and trials is necessary.

TECHNETIUM TC 99m–HMPAO SPECT

Technetium Tc 99m–HMPAO SPECT has a role in test occlusion by providing a quantitative glimpse of CBF by injecting radiotracers that diffuse into the cerebral vasculature. This method has been used extensively because of its simplicity and availability.[74] After a test balloon occlusion of 5 to 15 minutes, the tracer is injected intravenously in the angiography suite, and the ICA occlusion is maintained for an additional 15 minutes.[74] The radioisotope is rapidly disseminated in the brain tissue and remains active for sufficient time to allow SPECT study after removal of the catheter and completion of the BTO procedure.[74] The SPECT images are then analyzed for symmetrical distribution of the tracer (Fig. 4). Ryu et al[77] reported that this is an efficient method for predicting neurological deficits when the uptake of the middle cerebral arteries during BTO is less than 85% of preocclusion values. The greatest advantage of SPECT over xenon CT, PET, or perfusion MRI is that the agent can be administered in the angiographic suite and the catheter removed before transporting the patient.

Overall, technetium Tc 99m–HMPAO SPECT is an accepted and popular method to evaluate collateral blood flow reserves during ICA occlusion and enhances the safety of permanent carotid ligation.[64,74,75,76]

XENON CT PERFUSION

Xenon CT is a widely available and clinically useful methodology for assessing CBF. Xenon is a readily diffusible tracer that can be administered by inhalation and preferentially distributes within red blood cells of the brain. To facilitate this procedure, the patient can be positioned on the CT scanner table for the entire occlusion test, and a baseline stable xenon CT can be obtained prior to BTO. For CBF evaluation, Barr et al[78] demonstrated that the patient can be retracted into the CT scanner for inhalation of xenon during 5 minutes of balloon occlusion, and ligation of the ICA was considered safe when CBF exceeded 30 mL/100 g per minute during BTO. Steed et al[66] used xenon CT to divide patients into four groups based on CBF. They defined normal flow as > 40 mL/100 g per minute (group I), and compromised but adequate flow ranged from 30 to 39 mL/100 g per minute (group II). Patients in group III had < 30 mL/100 g per minute of flow in the ipsilateral middle cerebral artery, and group IV patients developed an immediate neurological deficit requiring deflation of the balloon before xenon CBF measurements. In this study, only 1 of 23 patients in groups I and II developed a stroke after permanent ICA occlusion. Xenon CT is a safe

and efficient method to quantitate CBF and assess hemodynamic reserve during BTO. [66,71,78]

TRANSCRANIAL NEAR INFRARED SPECTROSCOPY

Transcranial NIRS can be used to monitor the regional oxygen saturation of the brain (rSO2) to provide information about the changes in cerebral perfusion during certain procedures such as carotid endarterectomy and BTO. This method is achieved by using a cerebral oximeter on the forehead of the same side as the occlusion.[74] Kaminogo et al[74] used NIRS to evaluate rSO2 every 30 seconds in conjunction with SPECT analysis of CBF during balloon occlusion. rSO2 monitoring can be an effective means to detect bilateral symmetrical decreases of CBF, thus distinguishing false-negative SPECT studies. rSO2 evaluation is a simple and sensitive indicator of cerebral oxygenation and is very valuable as an adjunct to SPECT analysis of CBF during BTO.

PERFUSION MRI

Perfusion MRI is an imaging technique used for measuring CBF after injection of a contrast agent to obtain information about blood volume and flow. Michel et al[81] used perfusion MRI in conjunction with diffusion-weighted and contrast-enhanced turbo fluid attenuated inversion recovery (FLAIR) imaging for preliminary evaluation in patients undergoing sacrifice or permanent occlusion of the ICA. In

this series, each patient underwent pretest and intratest occlusion MR imaging consisting of noncontrast diffusion-weighted, contrast-enhanced perfusion-weighted, and contrast-enhanced TI-weighted and FLAIR sequences. Perfusion maps revealed delayed perfusion in all patients studied. In seven of nine patients who passed clinically, there were delays ranging from 0.7 to 3.2 seconds, as compared with the non-occluded hemisphere, whereas two of nine patients who failed clinically had delays ranging from 6.1 to 6.7 seconds. Contrast enhancement of the pial surfaces or subarachnoid spaces occurred on FLAIR imaging that corresponded to the areas of perfusion abnormalities. The cause of these hyperintensities was interpreted as contrast extravasation into the cerebral spinal fluid as a result of alterations of vascular permeability secondary to ischemia.

VENOUS PHASE ANGIOGRAPHY

Willem et al[72] used angiography to evaluate hemispheric venous flow rates during BTO to identify patient tolerance to ICA occlusion. This method assessed filling of the cortical veins in both the occluded and the collateral vascular territories, and permanent ICA occlusion was indicated if simultaneous venous saturation of both hemispheres was appreciated. A greater than 0.5 second delay in the venous filling of the vascular territory of the occluded vessel when compared with the non-occluded region prompted a repeat angiogram after a few minutes. A failed BTO was defined by

the lack of perfectly synchronous venous filling after 20 to 30 minutes of occlusion. In this study, 17 patients who demonstrated clinical and angiographic tolerance to BTO underwent permanent ICA occlusion, and no delayed ischemic events were reported after a mean follow-up of 21 months. In addition, 1 patient who passed clinically but evinced nonsynchronous venous filling had to undergo permanent occlusion and subsequently developed a hemispheric infarction. These data suggest that venous phase angiography during BTO can accurately predict tolerance to permanent ICA occlusion.

[15O]H2O PET

PET is a rapid quantitative method that can be used for evaluating CBF using radionuclide tracers. Okamoto et al[80] obtained PET images during BTO to assess hemispheric collateral perfusion prior to ICA resection. In this investigation, ICA resection was performed in 16 patients who demonstrated adequate CBF with PET, and no perioperative complications or delayed neurological impairments were reported. In another study by Brunberg et al,[79] CBF was assessed during and after BTO, and patients were classified into three groups based on clinical and CBF analysis. Patients in group I (16 of 22) had no clinical deficits and a CBF decrease of less than 10 mL/100 g per minute when compared with post-BTO levels. Group II patients (5 of 22) also had no clinical deficits, but CBF fell to 25 to 35 mL/100g per minute on the occluded side. Group III patients (1 of 22) could not

clinically tolerate test occlusion and had CBF of less than 20 mL/100 g per minute on the occluded side. None of the patients in group I developed neurological complications after undergoing permanent ICA occlusion, and only 1 patient in group II developed cerebral infarction after ICA occlusion. Overall, the data suggest that PET determination of CBF is a rapid and efficient method to predict the adequacy of collaterals.

MATERIALS AND METHODS

Source of data:

The present study, entitled "**A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery**", is a retrospective study, carried out in the Department of Imaging Sciences & Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram from 1st January 2000 to 31st October 2014.

Study subjects:

All patients, who have been managed with parent vessel sacrifice without bypass at our institution following provocative BOTas per the cath lab and neurosurgical records were included in the study.

Inclusion Criteria:

- ✓ All patients , who have been diagnosed to have intracranial aneurysms, mass lesions and carotico-cavernous fistula who have undergone Balloon Occlusion Test for the adequacy of cross-circulation and treated by surgical / endovascular methods (Sacrifice of the parent vessel) at this institute from 01 Jan 2000 till 31st October 2014.

Exclusion Criteria:

- x Patients who have not undergone balloon occlusion test due to inadequacy of cross-circulation on cross-compression study or due to any other reason.
- x Patients who have undergone ECA-MCA bypass before the parent vessel sacrifice.

Study area:

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram

Study period:

1st January, 2000 to 31st October , 2014

Study design:

Descriptive case series, which is *retrospective* in nature.

Sample size:

50 cases, selected according to inclusion and exclusion criterias.

Study instrument:

Patient discharge summaries, radiological reports and operation records.

Sampling technique-

The samples were selected by using purposive sampling.

Method of collection of data:

- Δ Patient discharge summaries, radiological reports and operation records from 1st Jan 2000 to 31st Oct 2014 were reviewed using various key word combinations such as 'balloon occlusion test', 'balloon and occlusion', 'parent vessel occlusion', 'aneurysms' or 'cerebral aneurysms'.
- Δ The data was later analyzed to select those patients who fulfill the inclusion and exclusion criteria.
- Δ This data was also correlated with imaging findings to analyse the imaging correlates influencing the clinical presentations and treatment outcomes.
- Δ The patients were followed up at 24 hours, 1 week, 6 weeks, 6 months and yearly thereafter following surgical or endovascular

therapy using Glasgow Coma Scale (GCS) and modified Rankin scale (mRs).

- ∆ For patients who were lost to follow up, an attempt was made to contact them over telephone or by mail.
- ∆ If communicated, they were advised for OPD visit to assess the present clinical status.

Technique of BOT in our Institute

- Baseline neurological and physical examination of the patient is followed by a diagnostic four-vessel angiography to evaluate the intracranial vasculature and to determine the potential for collateral blood flow around the circle of Willis.
- The patient is given 70 to 100 units/kg intravenous (IV) heparin after arterial access is gained and the activated clotting time is titrated to two to three times baseline.
- An angiographic catheter is introduced through a 6 to 7 F sheath in the femoral artery, and diagnostic angiography is performed.
- After the diagnostic angiogram, the catheter is replaced with a double-lumen balloon catheter over an exchange wire.
- The balloon catheter (Latex Arrow Balloon) is advanced into the ICA and inflated under fluoroscopic visualization in a relatively straight portion of the ICA, avoiding the carotid sinus and corresponding to the level of the first or second cervical vertebral body.
- Occlusion may be confirmed by proximal or distal radiographic contrast injection and observation of a static column of contrast material
- Subsequent heparinized saline flush is used to clear residual contrast from the vessel.
- Neurological testing is non-standardized and cumbersome due to patient draping constraints but should consist of: extremity and facial muscle testing ("squeeze my hand; show me your

teeth; wiggle your toes"); sensation testing (touch) of the extremities; extraocular muscle examination ("follow my finger with your eyes"); visual examination and visual comprehension plus speech assessment by having the patient read large print and name common objects shown to the patient; memory and orientation assessment ("who is the President; what state do you live in"); basic calculation (what is 10 plus 5; count backwards from 20); judgment (interpretation of common proverbs by asking the patient "what does 'look before you leap' mean to you?"); and for the posterior circulation assessment, an evaluation for dysmetria is added (finger to nose testing).

- Unlike the patient who passes the BTO, a positive or 'failed' BTO is documented for any baseline deviation regardless of subtly.
- Frequently, patients who fail BTO do so within the first minute or two.
- Neurological assessment is performed every 2 to 5 minutes while the balloon is inflated; the balloon is immediately deflated if the patient develops any neurological symptoms of ischemia.
- If the patient tolerated 30 minutes of normotension, hypotension was induced by the infusion of sodium nitroprusside (2.5 to 7.5 mm/kg body weight per minute) or labetalol (total dose, 5 to 20 mg).
- After the mean arterial pressure was reduced to two thirds of baseline, hypotension was maintained for 20 minutes.
- The balloon then was deflated, and heparinization was reversed with intravenous protamine (1g protamine per 100 U heparin).
- The study was terminated immediately if a new neurologic deficit developed during test occlusion under normotensive or hypotensive conditions.

- After 30 minutes, the balloon is deflated and anticoagulant therapy may be reversed with IV protamine sulfate or allowed to correct naturally before removal of the arterial sheath.
- The internal carotid should be occluded for a minimum of 15 minutes; 20 to 30 minutes is standard.
- A patient tolerating 30 minutes of occlusion without clinical or physiological evidence of impaired perfusion can probably tolerate permanent sacrifice of the ICA.
- Those who fail test occlusion may be candidates for revascularization or extracranial-intracranial bypass.

Study analysis:

The descriptive statistics were used. Results on continuous measurements were presented as Mean+/-SD(Min-Max) and results on categorical measurements were presented in numbers(%).

Ethical considerations-

The study did not require any investigation/ intervention to be conducted on patients or animals, solely, for the purpose of the study.

Therefore, the clearance from the Institutional Ethics committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram was obtained.

RESULTS

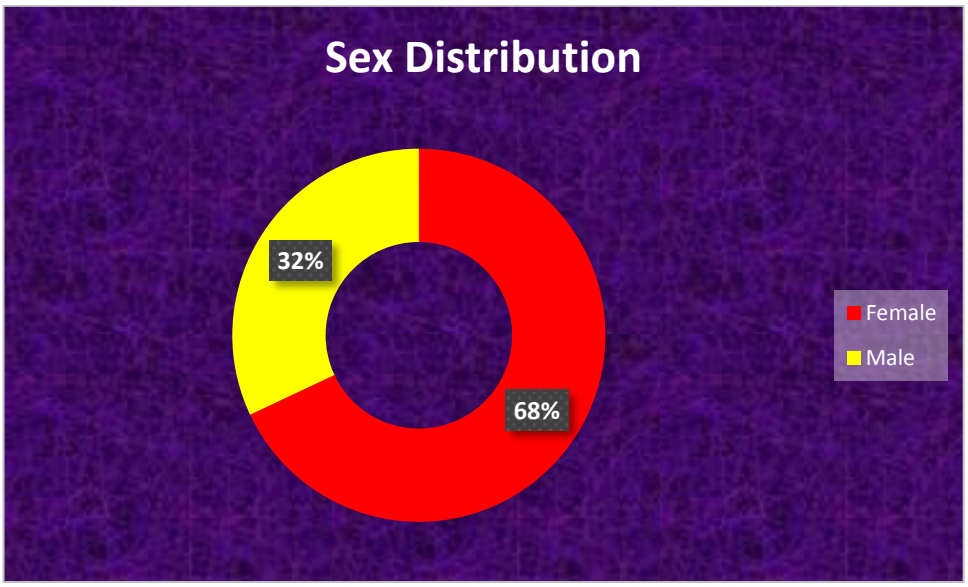


Chart 1 : Sex Distribution

- In the study, total number of patients were 50.
- Out of them, 34 (68%) patients were females and 16 (32%) patients were males.
- Thus, majority of patients in this study were females.

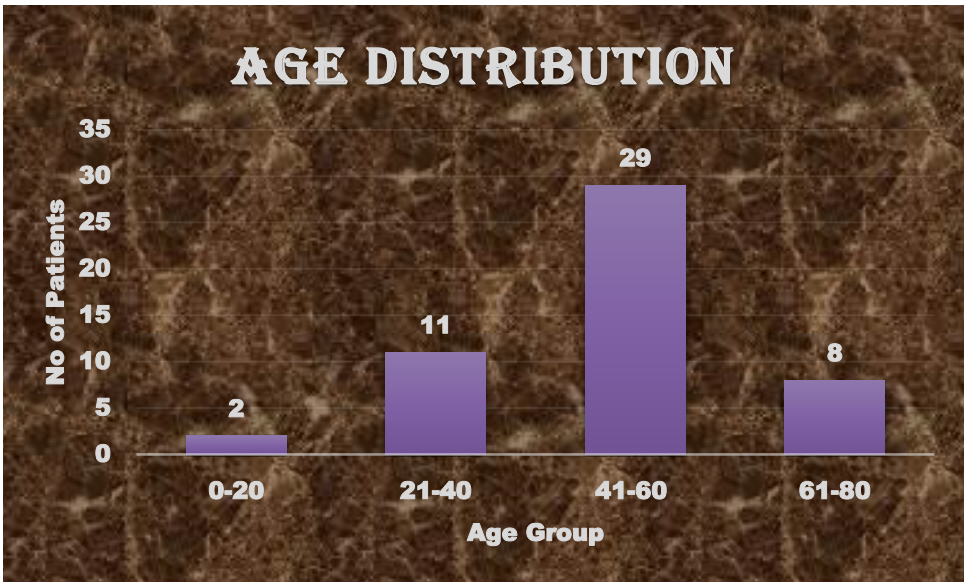


Chart 2 : Age Distribution

- In this study, maximum number of patients (29 i.e 58%) belonged to age group of 41-60 years.
- Among others, 11 (22%) patients belonged to age group of 21-40 years.
- 8 (16%) patients belonged to age group of 61-80 years.
- 2(8%) patients belonged to age group of 0-20 years.

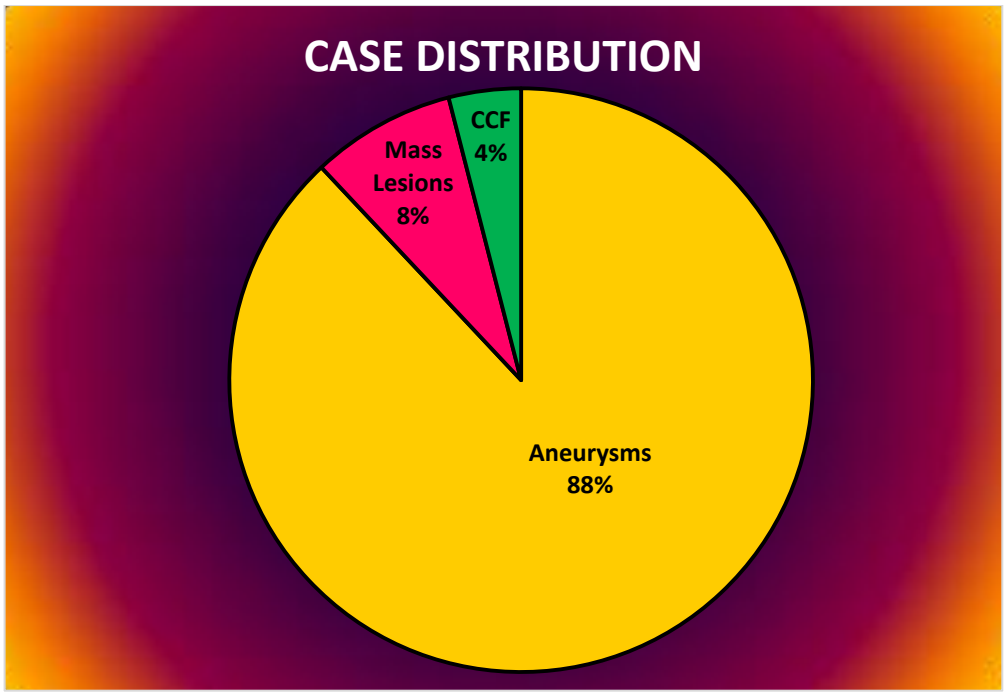


Chart 3 : Sex Distribution

- In the study, out of 50 cases, there were 44 (88%) cases of aneursyms.
- 4 (8%) cases were of mass lesions.
- 2(4%) cases were of Carotico-cavernous fistula (CCF).
- Thus, majority of patients had presented with aneurysm.

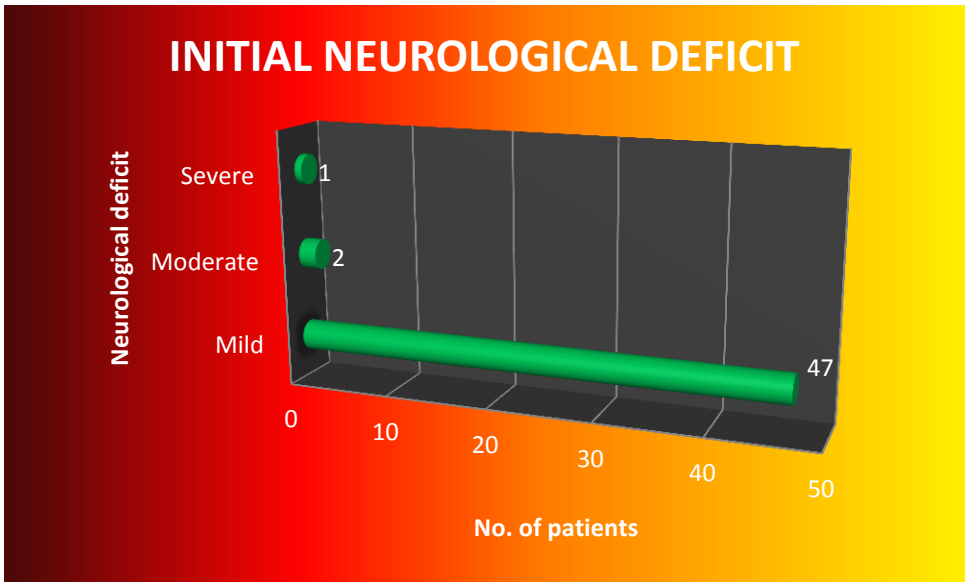


Chart 4 : Initial Neurological Deficit

- In the study, initial neurological assessment was done using Glascow coma scale and modified Rankin scale.

- Accordingly, the severity of neurological deficit was assessed.

- Out of 50 cases, 47(94%) patients had mild neurological deficits, 2 (4%) patients had moderate neurological deficits and 1(2%) patient had severe neurological deficits.

- Thus, majority of patients had no major neurological deficit at presentation.

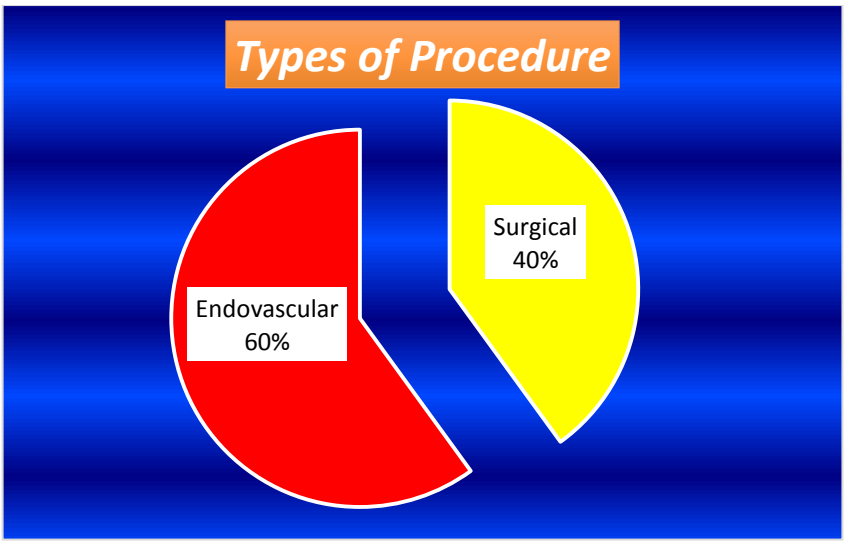


Chart 5 : Types of Procedure

- In the study, out of 50 cases, 30 (60%) cases had underwent endovascular procedures.
- 20 (40%) cases had underwent surgical procedures.
- Thus, majority of patients underwent endovascular procedures.

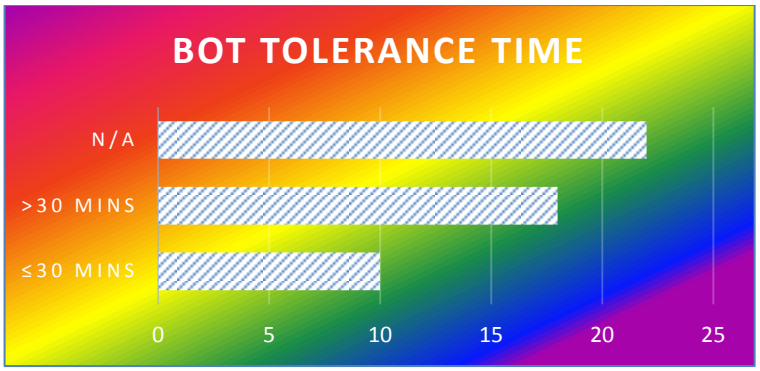


Chart 6A: BOT Tolerance Time

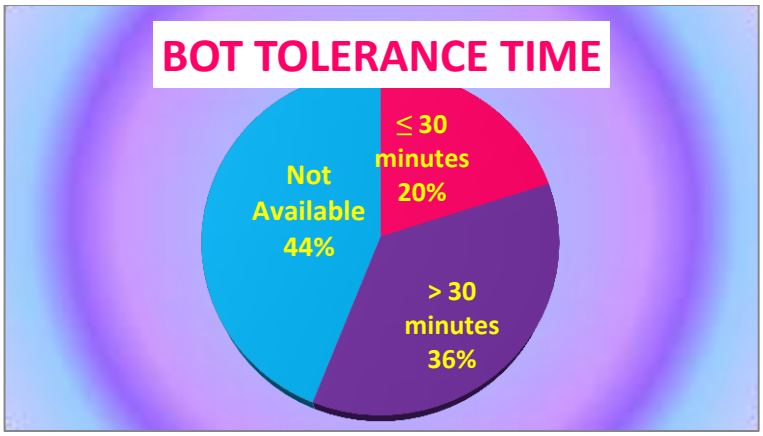


Chart 6B : BOT Tolerance Time

- In the study, Balloon occlusion test was tolerated for ≤30 minutes in 10 (20%) cases.

- Balloon occlusion test was tolerated for >30 minutes in 18 (36%) cases.

- No data regarding BOT tolerance time was available in 22 (44%) cases.

- There was no data available for the time of tolerance of Balloon Occlusion Test in majority of patients. However, from the data available from 28 patients, Balloon Occlusion Test was tolerated for ≤30 minutes in 10 patients (36%) and >30 minutes in 18 patients (64%).

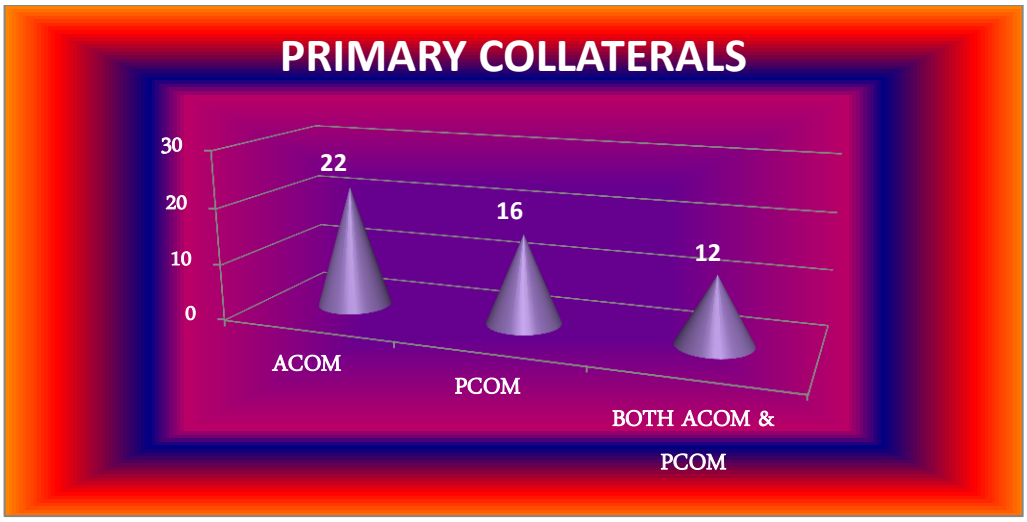


Chart 7 : Primary Collaterals

- In the study, assessment of primary collaterals (ACOM & PCOM) was done.
- In 22 cases (44%), presence of ACOM was noted.
- PCOM was seen in 16 cases (32%).
- Both ACOM and PCOM were noted in 12 cases (24%).

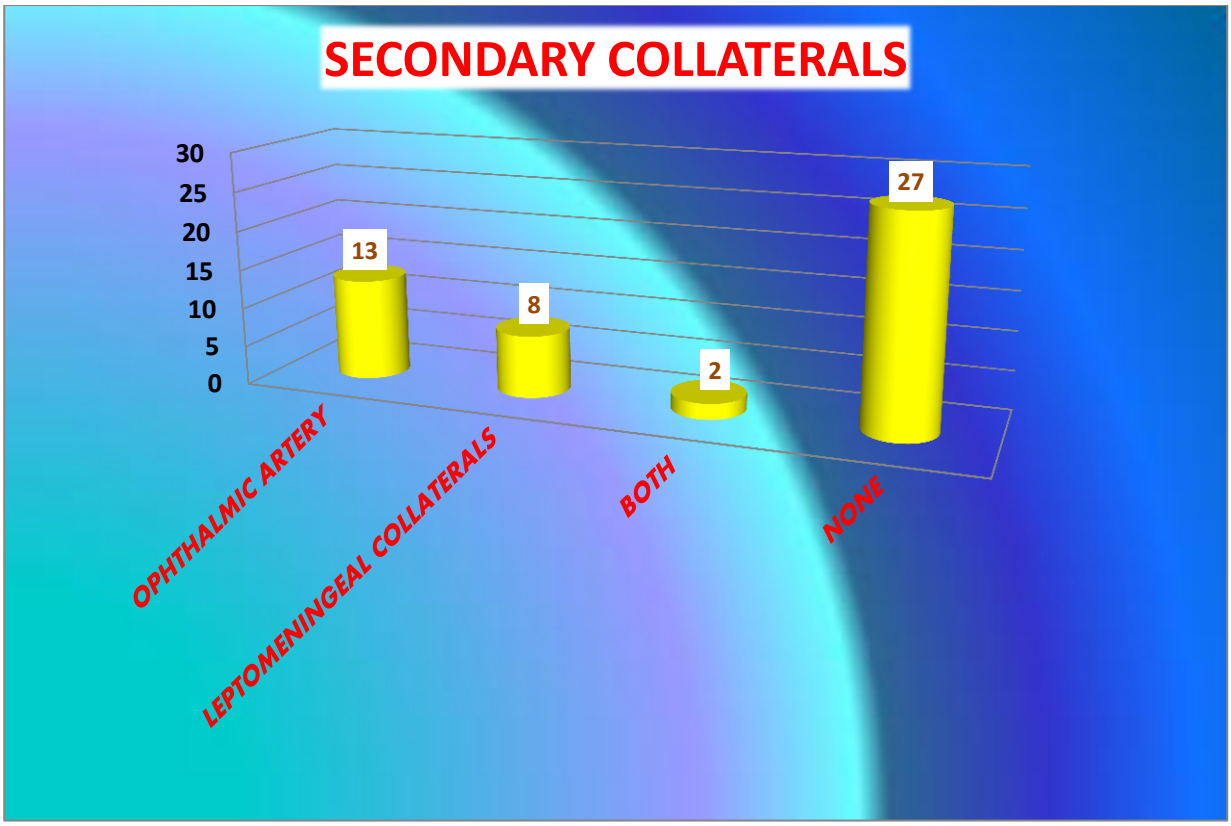


Chart 8 : Secondary Collaterals

- Assessment of secondary collaterals was also done, namely ophthalmic artery and leptomeningeal collaterals.

- Ophthalmic artery as an important secondary collateral pathway was noted in 13 patients (26%).

- Leptomeningeal collaterals were found in 8 patients (16%).

- Both ophthalmic collaterals and leptomeningeal collaterals were found in 2 patients (4%).

- None of the above two secondary collateral pathways were found in 27 patients (54%).

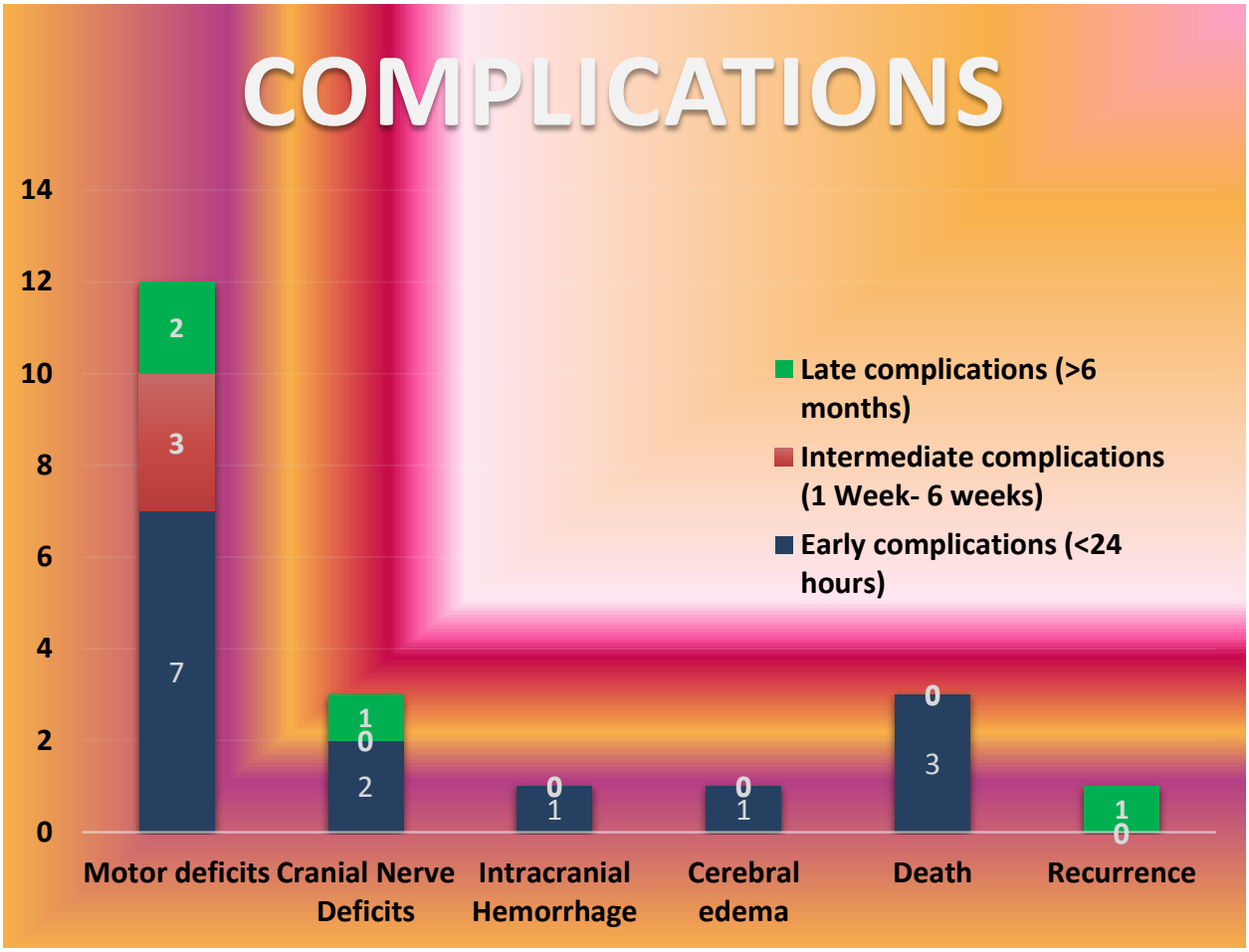


Chart 9 : Complications

- In the study, there were early (<24 hours) complications in 14 (28%) cases, Intermediate (1 week- 6 weeks) complications in 3 (6%) cases and late (>6 months) complications in 4 (8%) cases.

- Among the early complications, 7(14%) cases had motor deficits, 2(4%) cases had cranial nerve deficits, 1(2%) cases had intracranial hemorrhage, 1(2%) cases had cerebral edema and 3(6%) patients had died.

- Among the intermediate complications, 3(6%) cases had motor deficits.
- Among the late complications, 2(4%) cases had motor deficits, 1(2%) cases had cranial nerve deficits and 1(2%) cases had recurrence.
- Thus, motor deficits were the major complication during any time period.

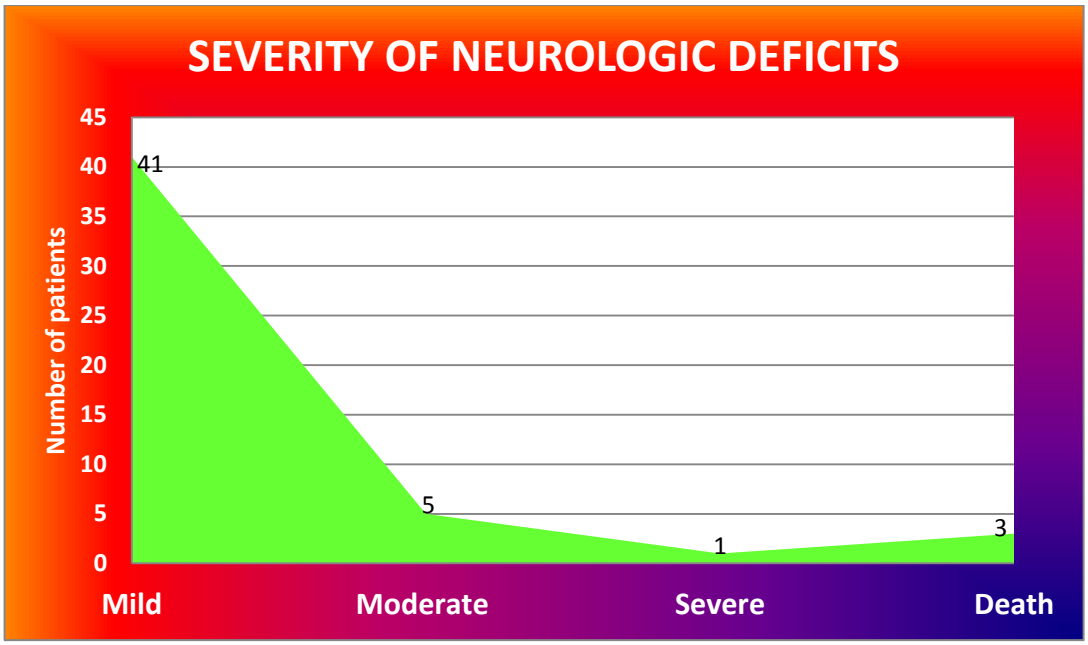


Chart 10 : Severity of Neurological Deficits

- In the study, post-op neurological assessment was done using Glascow coma scale and modified Rankin scale at 1 week.
- Accordingly, the severity of neurological deficit was assessed.
- Out of 50 cases, 41(82%) patients had mild neurological deficits, 5 (10%) patients had moderate neurological deficits,1(2%) patient had severe neurological deficits.
- Mortality was reported in 3 (6%) cases.
- Thus, majority of patients had mild neurological deficits.

DISCUSSION

- The present study, entitled "**A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery**", is a retrospective study, carried out in the Department of Imaging Sciences & Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram from 1st January 2000 to 31st October 2014.

- In the study, total number of patients were 50.

- Out of them, 34 (68%) patients were females and 16 (32%) patients were males. This was comparable to the data given in a case series by Standard et al,[68] where in a study of 47 patients, 34 were female and 14 were male.

- The maximum number of patients (29 i.e 58%) belonged to age group of 41-60 years. Among others, 11 (22%) patients belonged to age group of 21-40 years, 8 (16%) patients belonged to age group of 61-80 years and 2(8%) patients belonged to age group of 0-20 years.

- This is comparable to the data in given literature (Brain Aneurysm Foundation) where the most common age group is 35-60 years.[91]

- Out of 50 cases, there were 44 (88%) cases of aneursyms, 4 (8%) cases were of mass lesions and 2(4%) cases were of Carotico-cavernous fistula (CCF). This data of predominance of aneurysm in patients undergoing Balloon Occlusion Test is nearly similar to the case series by Abud et al[92] where aneurysms comprised of 35 out of 60 cases. undergoing Balloon Occlusion Test.

- In my study, initial neurological assessment was done using Glasgow coma scale and modified Rankin scale. Accordingly, the severity of neurological deficit was assessed.

- Out of 50 cases, 47(94%) patients had mild neurological deficits, 2 (4%) patients had moderate neurological deficits and 1(2%) patient had severe neurological deficits.

- BOT failed in 4 patients (8%). The cause of failure was clinical failure in all 4 cases where the patients could not tolerate balloon occlusion test for 30 minutes.

- 30 (60%) cases had underwent endovascular procedures and 20 (40%) cases had underwent surgical procedures.

- Majority of the patients in endovascular group underwent trapping and in the surgical group underwent ligation of internal carotid artery.

- Balloon occlusion test tolerance time was ≤30 minutes in 10 (20%) cases and was >30 minutes in 18 (36%) cases. No data regarding BOT tolerance time was available in 22 (44%) cases.

- In the majority of cases, data regarding time tolerated for BOT was not available, hence it was not possible to analyze data based on this parameter.

- In none of the described literature, time tolerated for BOT was a determining factor for predicting complication rate.

- Assessment for presence of primary collaterals was done, namely ACOM and PCOM.

- ACOM was present in 22 cases (44%). PCOM was present in 16 cases (32%). Both ACOM and PCOM were present in 12 cases (24%).

- Assessment of secondary collaterals was also done, namely ophthalmic artery and leptomeningeal collaterals.

- Ophthalmic artery as an important secondary collateral pathway was noted in 13 patients (26%). Leptomeningeal collaterals were found in 8 patients (16%).

- Both ophthalmic collaterals and leptomeningeal collaterals were found in 2 patients (4%).None of the above two secondary collateral pathways were found in 27 patients (54%).

- Patients are likely to develop neurological symptoms in absence of adequate collateral circulation.[101]

- In the study, there were early (<24 hours) complications in 14 (28%) cases, Intermediate (1 week- 6 weeks) complications in 3 (6%) cases and late (>6 months) complications in 4 (8%) cases.

- None of the cases had immediate procedure-related complications.

- In a study by Mathis et al[34], overall complication rate related to the procedure was 3.2%. Without any type of temporary test occlusion, the incidence of stroke after permanent carotid artery occlusion ranges from 17% to 30%[93-97]

- In another study, after BTO with clinical evaluation only, 198 patients underwent permanent ICA occlusion without bypass graft placement, with a 3.0% incidence of permanent neurologic deficits98-100.

- Among the early complications, 7(14%) cases had motor deficits, 2(4%) cases had cranial nerve deficits, 1(2%) case had intracranial hemorrhage, 1(2%) case had cerebral edema and 3(6%) patients had died.

- Among the intermediate complications, 3(6%) cases had motor deficits.

- Among the late complications, 2(4%) cases had motor deficits, 1(2%) cases had cranial nerve deficits and 1(2%) cases had recurrence. Thus, majority of patients had motor deficits irrespective of time period.

- There was 1 patient developing cerebral edema in immediate period, progressed to left hemiplegia in intermediate period.

- Out of the 3 patients developing complications in intermediate period, one patient had persistent neurological deficit in long-term period.

- In the study, post-op neurological assessment was done using Glascow coma scale and modified Rankin scale. Accordingly, the severity of neurological deficit was assessed.

- Out of 50 cases, 41(82%) patients had mild neurological deficits, 5 (10%) patients had moderate neurological deficits, 1(2%) patient had severe neurological deficits.

- Mortality was reported in 3 (6%) cases.

CONCLUSION

The present study, entitled "**A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery**", is a retrospective study, carried out in the Department of Imaging Sciences & Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram from 1st January 2000 to 31st October 2014.

As per the available data in the current retrospective descriptive study, following inferences can be drawn :

1) Majority of the cases undergoing Balloon Occlusion Test had giant intracranial aneurysms as compared to intracranial mass lesions / CCF.

2) Majority of patients in the initial neurological evaluation had mild / no neurological impairment as per GCS and mRS.

3) Patients undergoing endovascular treatment were higher than those undergoing surgical treatment.

4) Balloon Occlusion Test was tolerated for various times as per available data. In majority of cases, tolerance time for Balloon Occlusion Test was not available.

5) Data regarding time tolerated for Balloon Occlusion Test during hypotensive challenge was not available.

6) Data regarding Circulation time, Venous Delay and collateral pathways was not available.

7) Majority of patients had ACOM as primary collaterals as compared to PCOM alone or ACOM and PCOM both. Majority of patients had none of the secondary collaterals as compared to either Ophthalmic artery alone, Leptomeningeal collaterals alone or both of them. Patients are more likely to develop neurological complications in cases where collateral circulation in inadequate.
8) There were early (<24 hours) complications in 14 (28%) cases, Intermediate (1 week- 6 weeks) complications in 3 (6%) cases and late (>6 months) complications in 4 (8%) cases.

9) None of the cases had immediate procedure-related complications.

10) Majority of patients had motor deficits irrespective of time period.

11) Failure rate of BOT was 8% and cause of failure was patient intolerance to BOT.

12) Majority of patients in the post-operative neurological evaluation had mild neurological deficits as per GCS and mRS.

13) The overall mortality rate in my study was reported as 3 (6%) cases.

SUMMARY & FUTURE RECOMMENDATIONS

The present study, entitled "**A retrospective analysis of the efficacy of Balloon Occlusion Test for adequacy of cross-circulation after sacrifice of internal carotid artery**", is a retrospective study, carried out in the Department of Imaging Sciences & Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram from 1st January 2000 to 31st October 2014.

Based on the above inferences, following future recommendations can be made for evaluation of Balloon Occlusion Test :

1) Balloon Occlusion Test should be done as a part of pre-operative work up for assessment of collaterals and not just as a routine diagnostic imaging, due to inherent risks associated with the procedure.

2) Balloon occlusion test should be strictly done in the presence of neuroanaesthetist to overcome any neurological complications, especially during hypotensive challenge.

3) Ideally a silicon balloon should be used, not a latex balloon as the latex balloon causes intimal damage and allergic reactions.

4) During balloon occlusion test, following parameters should be given due emphasis and included in the report:
    a. Circulation time (seconds) of the occluded as well as non-occluded side.
    b. Venous delay (seconds) of the involved as well as uninvolved side.

c. Assessment of primary and secondary collaterals as well as their adequacy.
d. Measurement of stump pressure whenever feasible (to assess cerebral blood flow).

5) Overemphasis on the tolerance time is not mandatory either in normotensive or hypotensive challenge.

6) Appropriate post-procedure and post-operative care in intensive care unit for detection of possible complications and management of such complications.

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श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान
तिरुवनन्तपुरम - 695 011, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
THIRUVANANTHAPURAM - 695 011, INDIA
(An Institute of National importance under Govt. of India)

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013)

01-11-2014

SCT/IEC/ 694/OCTOBER -2014

Dr. Shah Chinmay Pankajkumar
Senior Resident
Department of IS & IR
SCTIMST, Thiruvananthapuram

Dear Dr. Shah Chinmay Pankajkumar,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "A RETROSPECTIVE ANALYSIS OF THE EFFICACY OF BALLOON OCCLUSION TEST FOR ADEQUACY OF CROSS-CIRCULATION AFTER SACRIFICE OF INTERNAL CAROTID ARTERY" (IEC/694) on 16th October, 2014.

The following documents were reviewed:

1. *Covering letter addressed to the Secretary, IEC, dated September 2014.*
2. *TAC Approval Letter.*
3. *IEC Application form.*
4. *Proposal for study.*
5. *Consent form in English and Malayalam.*
6. *Proforma.*
7. *CV of the Principal Investigators & Co-Principal Investigators.*

The following members of the Ethics Committee were present at the meeting held on 16th October, 2014 at G. Parthasarathi Board Room, AMCHSS, SCTIMST.

Sl. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Justice Gopinathan. P.S	BSc. LLB	Male	Legal Expert (Chairperson)	No
2.	Dr. J. M. Tharakan	MD	Male	Clinician (Cardiologist)	Yes
3.	Dr. O.S. Neelakandan Nair	BE	Male	Engineer	Yes
4.	Dr. Meenu Hariharan	DM	Female	Clinician (Gastro-Enterologist)	No
5.	Dr. M.D. Gupte	MD, DPH	Male	Public Health	No
6.	Dr. Rema M. N	MD	Female	Pharmacologist	No
7.	Dr. R V G Menon	PhD	Male	Lay Person	No
8.	Smt. Sathi Nair	MA	Female	Lay Person	No
9.	Dr. K. Jayakumar	MS, MCh	Male	Clinician (Surgeon)	Yes
10.	Dr. K R S Krishnan	ME, PhD	Male	Biomedical Scientist/Engineer	No
11.	Dr. Mala Ramanathan	MSc, PhD, MA	Female	Ethicist/Social Scientist (Member Secretary)	Yes

IEC Decision

The study is recommended for approval with consent waiver for the use of medical records component, under the following condition:

1. The patient record number/hospital number should be removed/not used in analysis. Instead, a master key can be maintained by the Principal Investigator, linking the proforma serial number with the hospital serial number, separately.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

Sr No.	Name	Age	Sex	Diagnosis	MON/YEAR	Initial mRS	Initial GCS	PROCEDURE	Tolerance Time (if availmary collate		Column1	econdary collateral	Column2	Post-procedure mRS	Post-procedure GCS	Complications if an	1 month F/U	3-month F/U
										ACOM	PCOM	Ophthalmic A.	Leptomeningeal					
1	V.R.	57	F	eft ICA aneurysı	Apr-00	0	15	Trapping	60 min.	absent	present	absent	absent	0	15	Right UL and Facial	NAD	NAD
2	I.R.	39	M	vernous ICA Ani	Jul-00	0	15	Trapping	30 min.	present	absent	absent	absent	0	15	nsient Left Hemiple	NAD	NAD
3	T.A.	45	F	al cavernous ICA	Aug-00	0	15	Trapping	90 min.	present	absent	present	absent	0	15	Nil	Left Hemiplegia	NAD
4	P.S.	46	F	t cavernous ICA	Sep-00	0	15	PAO	45 min.	present	absent	present	absent	0	15	Nil	NAD	NAD
5	S.K.	17	M	ıgiofibroma - Fe	Nov-00	0	15	Glue embolisation of ICA	N/A	present	absent	present	absent	0	15	Nil	NAD	NAD
6	T.T.	49	F	issue sarcoma r	Nov-00	0	15	Cervical ICA ligation	30 min.	present	absent	present	absent	0	15	Nil	NAD	NAD
7	N.E.	32	F	tal CCA Pseudoa	Mar-01	0	15	PAO	90 min.	present	absent	present	absent	0	15	Nil	NAD	NAD
8	A.K.	52	F	Supraclinoid ICA	Mar-03	0	15	Trapping	30 min.	present	absent	present	absent	2	12	Left MCA infarct	NAD	NAD
9	J.S.	55	F	Cavernous ICA	Mar-03	0	15	Trapping	30 min.	present	absent	present	absent	1	14	ıall left parietal infa	NAD	NAD
10	K.M.P	45	F	Cavernous ICA	Sep-03	0	15	ping - patient died due to large MCA in	80 min.	present	absent	present	absent	6	3	ıe MCA territory inf	Died	Died
11	J.K.N.	20	M	t cavernous ICA	Jun-03	0	15	Trapping	90 min.	present	absent	present	absent	0	15	Nil	NAD	NAD
12	V.R.	54	F	t cavernous ICA	Dec-03	0	15	Trapping	90 min.	present	absent	present	absent	1	14	plete ptosis of righ	NAD	NAD
13	K.P.	58	F	Cavernous ICA	Feb-04	0	15	Balloon Occlusion	N/A	present	absent	present	absent	0	15	Nil	NAD	NAD
14	S.N.	38	F	and Jugular Foss	May-04	0	15	ICA Sacrifice	45 min.	present	absent	present	absent	0	15	Nil	NAD	NAD
15	M.P.	42	M	ıvernous Hemar	Aug-04	0	15	During BOT - thrombosis of left ICA	N/A	present	absent	present	absent	3	10	ıemiparesis and dys	NAD	NAD
16	S.B.A.	52	F	Cavernous ICA	Dec-04	0	15	Ligation	N/A	present	absent	present	present	0	15	Nil	Left MCA Infarct	NAD
17	A.P.	29	M	Cavernous ICA	Jan-05	0	15	Ligatiom	N/A	present	absent	present	present	0	15	Nil	NAD	NAD
18	P.S.	67	F	teral ICA Aneury	Jul-05	3	10	Trapping	N/A	present	absent	absent	present	3	10	Left hemiparesis	NAD	NAD
19	N.C.	66	F	Cavernous ICA	Aug-05	0	15	Ligation	N/A	present	absent	absent	present	0	15	Nil	NAD	NAD
20	N.M.	57	F	Cavernous ICA	Nov-05	0	15	BOT Failed	N/A	present	absent	absent	present	0	15	Nil	NAD	NAD
21	A.B.	61	F	ınunicating Segr	Jan-06	0	15	gation - patient died due to large infarc	25 min.	present	absent	absent	present	6	3	Died	Died	Died
22	O.N.	62	F	s / Cavernous IC	Apr-06	0	15	Ligation	90 min.	present	absent	absent	present	0	15	Nil	NAD	NAD
23	M.J.	74	F	avernous ICA An	Jun-06	0	15	Ligation	90 min.	present	absent	absent	present	0	15	Nil	NAD	NAD
24	S.P.G.	41	M	Cavernous ICA	Aug-06	0	15	Trapping	45 min.	present	present	absent	present	0	15	Nil	NAD	NAD
25	S.K.	54	M	Para Pcom Aneu	Nov-06	0	15	BOT Failed	N/A	present	present	absent	present	0	15	Nil	NAD	NAD
26	S.H.A.	54	M	Segment ICA An	Mar-07	0	15	BOT Failed	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
27	C.D.S.	37	F	Cavernous ICA A	May-07	4	9	Surgical Trapping	N/A	present	present	absent	absent	0	15	eft 12th nerve pals	NAD	NAD
28	T.V	54	F	upraclinoid ICA /	Jun-07	0	15	t Awaiting Ligation - died due to massiv	N/A	present	present	absent	absent	6	3	Died	Died	Died
29	M.S.	57	F	vernous ICA An	May-08	0	15	BOT Failed	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
30	A.P.	51	F	praclinoid ICA A	Jul-08	0	15	Ligation	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
31	V.M.	46	M	avernous ICA An	Jun-10	0	15	BOT Only - Developed dissection	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
32	M.C.	59	F	t Cavernous ICA	Sep-10	0	15	PAO	45 min.	present	present	absent	absent	0	15	Nil	NAD	NAD
33	D.V.K.	24	F	vernous ICA An	Feb-11	0	15	Ligation	35 min.	present	present	absent	absent	0	15	Nil	NAD	NAD
34	S.K.E.	34	M	raclinoid ICA Ar	Mar-11	0	15	Ligation	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
35	R.S.	48	F	vernous ICA An	Apr-11	0	15	Ligation	N/A	present	present	absent	absent	0	15	Nil	NAD	NAD
36	S.M.	51	F	vernous ICA An	May-11	0	15	Ligation	20 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
37	B.S.	50	F	avernous ICA An	Jul-11	0	15	Ligation	N/A	absent	present	ab+L38:L39sent	absent	0	15	Nil	NAD	NAD
38	D.S.A.	30	M	t cavernous ICA	Sep-11	0	15	Ligation	30 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
39	K.C.N.	62	M	ı Right Petrous I	Mar-12	0	15	Trapping	40 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
40	K.L.B.	62	F	t cavernous ICA	Apr-12	0	14	Ligation	N/A	absent	present	absent	absent	0	14	Nil	NAD	NAD
41	B.N.	55	F	Supraclinoid ICA	Aug-12	0	15	Ligation	N/A	absent	present	absent	absent	0	15	Nil	NAD	NAD
42	M.P.M.	32	M	Direct CCF - Typ	Oct-12	0	15	Balloon Embolisation	40 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
43	M.N.	51	F	avernous ICA An	Dec-12	1	14	Trapping	N/A	absent	present	absent	absent	1	14	Nil	NAD	NAD
44	K.V.	40	F	hthalmic ICA An	Jan-13	0	15	PAO	N/A	absent	present	absent	absent	0	15	Nil	NAD	NAD
45	S.A.	23	M	Left Direct CCF	Jan-13	0	15	Balloon Embolisation	40 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
46	R.K.V.	52	M	praclinoid ICA A	Mar-13	0	15	PAO	30 min.	absent	present	absent	absent	3	9	ignant Cerebral Ed	Left Hemiplegia	ft Hemiplegi
47	N.A.	54	F	avernous ICA An	Mar-13	0	15	Trapping	40 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD
48	A.J.	60	F	imic ICA Aneury	Apr-13	0	15	Ligation	30 min.	absent	present	absent	absent	3	9	ft Frontal Hemator	NAD	NAD
49	S.P.K.	45	F	vernous ICA An	Apr-13	5	8	Ligation	30 min.	absent	present	absent	absent	5	8	Nil	NAD	NAD
50	N.A.	70	M	A Clinoid Segm	Apr-13	0	15	Trapping	20 min.	absent	present	absent	absent	0	15	Nil	NAD	NAD

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