Comparison of Outcomes following Conventional and Eversion carotid Endarterectomy – A Retrospective study

THESIS

Submitted for the partial fulfillment for the requirement of the degree of

MCh in Vascular Surgery

By

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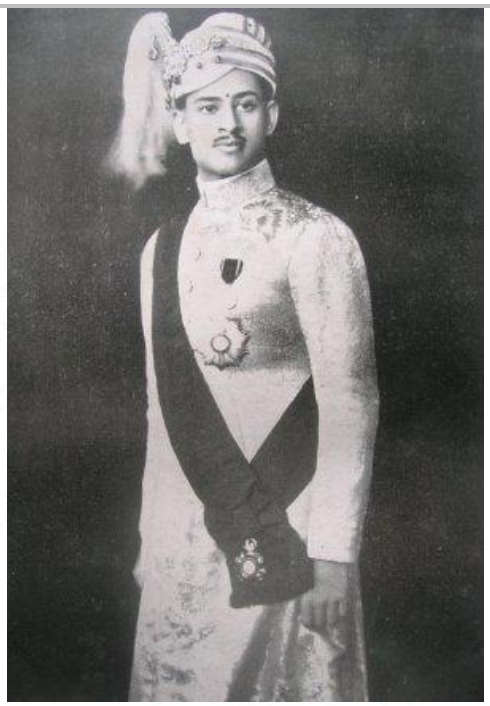

Travancore, an erstwhile province of pre-independent India, was ruled by Maharaja Sree Chitra Tirunal Balarama Varma until the country became independent in 1947. The Government of India took over the province after independence and was incorporated into the state of Kerala.

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DECLARATION

I, **Vineeth kumar P M,** hereby declare that the project in this book was undertaken by me under the supervision of **Dr.Varghese.T.Panicker**, Addl. Professor, Dept. of CTVS, **Dr Shivanesan Pitchai,** Program Coordinator, Division of Vascular Surgery, Dept of CVTS, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram.

Date:26/08/2020

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We hereby certify that the above statement is true and the candidate, ***Vineeth kumar P M****, had carried out the minimum required work in this project.*

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CERTIFICATE

Certified to be the bonafide record of ***Dr.Vineeth Kumar PM*** *the work done at Vascular Surgery division, Department of CVTS, as part of MCh Programme in Vascular Surgery at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, for a period of three years from January 1st, 2018 to December 31st, 2020.*

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SYNOPSIS

Comparison of Outcomes following Conventional and Eversion carotid Endarterectomy - A Retrospective study

INTRODUCTION

There are two surgical techniques that are available for CEA conventional and eversion technique .Most of the centres are performing conventional CEA routinely because it is technically easier and can be done under the protection of a shunt BUT there will be a longitudinal incision on the internal carotid artery (ICA) that need be closed with either a saphenous vein patch or bovine pericardial patch. In eversion CEA, ICA is cut from carotid bulb, everted, plaque removed and re anastomosed in an end to side fashion to common carotid artery (CCA). This study compares the outcome of above two surgical techniques of carotid endarterectomy.

MATERIALS AND METHOOD

A retrospective review of 62 patients who underwent carotid endarterectomy in Division of Vascular Surgery, SCTIMST (conventional CEA, n=31; eversion CEA, n=31) from January 2018 to December 2019 were done by principle investigator and co-investigator.All symptomatic patients with h/o of TIA/ stroke and >50% ipsilateral ICA stenosis on CT angiogram with or without contralateral ICA stenosis/occlusion who underwent CEA by either Conventional or Eversion technique were included in the study. The exclusion criteria were all asymptomatic patients >60% ICA stenosis, symptomatic patients <50% ICA stenosis, asymptomatic patients <60% ICA stenosis who underwent BMT, those patients who underwent Carotid artery stenting (CAS) and all Patients who underwent CEA along with CABG. Primary aim of the study is to find out any difference in the incidence of early postoperative major stroke and death, carotid restenosis or occlusion following two surgical techniques. Secondary endpoint of the study is to determine any difference in perioperative hypertension (PEH), minor stroke, transient ischemic accident, myocardial infarction, cranial nerve injuries, neck hematoma, bleeding, re-exploration, shunt usage, clamp time, between two treatment groups In this retrospective analysis, the choice of e CEA or c CEA were decided based

on the discretion of surgeon who performed the procedure. The pre-operative evaluation were same for both eversion and conventional CEA. Prior to surgery neck vessel doppler and CT/MRI brain as per Stroke protocol was taken. Neck vessel Doppler was done to measure the velocities across the stenosis. Degree of stenosis was calculated both by CTA/MRA images (NASCET Criteria) and by duplex velocity criteria. All patients were started on dual antiplatelets (Aspirin and Clopidogrel) with high dose statin therapy (Atorvastatin 40/80mg or Rosuvastatin 20/40mg). Around 2-4 days prior to procedure, clopidogrel was withheld but Aspirin was continued during the perioperative period.

RESULTS

The study population were divided into eversion(n=31) and conventional(n=31) groups. The age, sex, distribution of risk factors like smoking, dyslipidemia, Coronary artery disease, diabetes, hypertension both controlled and uncontrolled, COPD, CKD, thyroid dysfunction, POAD, unilateral and bilateral ICA disease, severity of stroke assessed by NIHSS and mRS score were evenly distributed between two study groups(p value >0.05). 58% in eversion CEA group and 58% within conventional CEA group had stroke prior to CEA (p value 1). The percentage of patients with TIA were 41.9 % in eversion CEA and 43.3% in conventional CEA group (p value 0.912). So, the number of patients with stroke and TIA were similar in both groups (p value 1.00). The were no difference in the primary outcome of the study in terms of major stroke or stroke related death am. One patient in eversion CEA had carotid occlusion and presented as minor stroke which was noted as as secondary outcome in our study. There was no significant difference in the overall secondary endpoints like minor stroke(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%, p value 1), TIA (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.3)post-operative MI(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%), p value 1), hematoma (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.313),re exploration (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.313) and reperfusion syndrome(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%), p value 1). The incidence of Cranial nerve dysfunction were significantly higher in eversion group as compared to conventional CEA (eversion CEA n=6(19.4%), conventional CEA n=1, (3.2%) p value 0.045). The most common CN involved is marginal mandibular nerve (n=4/6 in eCEA and n=1/1 in cCEA) followed by hypoglossal (n=1; e CEA) and RLN (n=1; c CEA). CN dysfunction were in the form of

neuropraxia as fascial deviation, tongue deviation and hoarseness of voice recovered in the due course of time.

CONCLUSION

The preliminary results of our study suggest that eversion CEA is safe, rapid, easy-to-perform procedure like conventional CEA. Some surgeons prefer eversion endarterectomy over conventional CEA technique because there is no need to use patch and anastomosis can be completed quickly. Moreover, eversion CEA offers distinct advantages in certain anatomical situations like elongated or kinked ICA; other than that, choosing the technique depends on surgeon's experience in performing a technique of endarterectomy over other. We think that familiarity with both techniques is important, while neither one is superior or inferior. The current data shows that until further evidence is available, the choice of the CEA technique depends on the experience and familiarity of the individual surgeon.

INTRODUCTION

Stroke is the third most frequent reason of deaths worldwide. Yearly stroke incidence is reported to be approximately 160 cases in a 100,000 population[1]. The causes of stroke are ischemia in 80% of cases and hemorrhage in 20%. Among the ischemic causes 50% are due to extra cranial carotid artery disease out of which 90% due to atherosclerotic stenosis of internal carotid artery. Rest of the carotid stenosis in 10% percentage is associated with aneurysms, arteritis, carotid dissection, radiation, vasospasm and infective diseases[2].

Extracranial carotid artery is named by ancient Greeks with the term "Karoo" which means "to stupefy". In 1875 first medical literature on carotid occlusion was described by Growers for a patient with right hemiplegia. The relationship between carotid disease and stroke was put forward by Hunt and he described it as "cerebral intermittent claudication". Carotid endarterectomy (CEA) is a surgical procedure done to prevent future embolic stroke in patients already having critical carotid artery stenosis. Several modifications are presented for carotid endarterectomy procedure since the first description of surgical resection and anastomosis came in 1954 by Eastcott, Pickering and Rob[3]. DeBakey took credit for the first endarterectomy for carotid bifurcation atherosclerosis in 1953, who reported a 19-year symptom-free follow-up in the Journal of the American Medical Association in 1975[4].

A lot of studies have documented that surgical treatment is superior to medical treatment in patients with significant carotid stenosis. The North American Symptomatic Carotid Endarterectomy Trial (NASCET) has showed the superiority of the surgical treatment in symptomatic patients with carotid stenosis[5]. Likewise, the Asymptomatic Carotid Atherosclerosis Study (ACAS) and the Asymptomatic Carotid Surgery Trial (ACST) have showed the superiority of the surgical treatment in asymptomatic patients with significant carotid stenosis[6].

There are two surgical techniques that are available for this , one is conventional CEA and the other is eversion CEA[7] .Most of the centres are performing conventional CEA routinely because it is technically easier and can be done under the protection of a shunt BUT there will be a longitudinal incision on the internal carotid artery (ICA) that need be closed with either a saphenous vein patch or bovine pericardial

patch. In eversion CEA, ICA is cut from carotid bulb, everted, plaque removed and re anastomosed in an end to side fashion to common carotid artery (CCA).Stroke, cranial nerve injury with symptoms of hypoglossal and recurrent laryngeal nerve injuries are the most common complications after surgery[8]. Re-stenosis may occur in 1% - 20% of cases[9]. In general, surgical results are favorable in symptomatic carotid stenosis when compared to medical treatment and/or carotid artery stenting(CAS) in symptomatic carotid stenosis[10].

This study compares the outcome of two surgical techniques of carotid endarterectomy. Department of vascular surgery, SCTIMST is one of the major centre in our country doing CEA routinely, hence the individual institutional results remains the benchmark for comparing results.

AIM OF THE STUDY

1. Primary end point of our study is to find out any difference in the incidence of early postoperative major stroke and death, carotid restenosis or occlusion following two surgical techniques.
2. Secondary endpoint of our study is to determine any difference in perioperative hypertension (PEH), minor stroke, transient ischemic accident, myocardial infarction, cranial nerve injuries, neck hematoma, bleeding, re-exploration, shunt usage, clamp time, between two treatment groups

REVIEW OF LITERATURE

There are two types of carotid Endarterectomy (CEA). The more commonly performed is conventional carotid Endarterectomy (c CEA) in which a longitudinal arteriotomy is performed extending from the common carotid into the internal carotid artery, plaque is removed and arteriotomy closed with patch either using GSV or prosthetic and very rarely primarily in some centers. There is an alternative technique in which ICA is transected, everted and plaque is removed termed as eversion Carotid endarterectomy (eCEA). A number of retrospective and even randomized control trials (RCT) have compared eCEA and cCEA techniques, and both techniques have demonstrated very good results[11,12]. However, publications regarding these results have generally came from single centers, or in the case of randomized prospective trials, from vetted highvolume centers with a strong technical expertise in this area and may not represent outcomes in other centers.

Eversion carotid Endarterectomy versus Standard Trial [EVEREST] is the first multicenter randomized trial of eversion CEA versus conventional CEA conducted in Italy from October 1994 through March 1997[13]. The study population included 1353 patients recruited from the seven centers were randomized to conventional (n = 675) or eversion (n = 678) CEA. Primary end points of the study were carotid occlusion, major stroke, death, and restenosis rate. Secondary end point was minor neurologic complications, local complications, intraoperative imaging on early and late outcomes, role of risk factors on early and late outcomes, and incidence of symptomatic restenosis. Carotid stenosis was defined using angiogram based on North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria as mild (0% to 29%), moderate (30% to 69%), or severe (70% to 99%) according to the methods for measurement. Carotid occlusion, stroke and death were defined as early when they occurred perioperatively <30 days and late when they occurred > 30 days. Stroke was defined as an acute disturbance of focal neurologic function lasting more than 24 hours. Stroke was classified as major or minor based on Rankin scale (Major stroke = Rankin ≥3 and Minor stroke = Rankin <3). The results of the study came as no significant differences were

found between eversion and standard CEA with respect to incidence of perioperative transient ischemic accident (TIA), minor stroke, cranial nerve injuries, neck hematoma, myocardial infarction, or surgical defects as detected with intraoperative quality controls. The rate of perioperative major stroke and death (1.3% for each study group) and the incidence of early carotid occlusion (0.6% for eversion vs 0.4% for standard) were similar. Clamping time was significantly shorter for eversion CEA compared with conventional CEA (31.7 ± 15.9 vs 34.5 ± 14.4 minutes, p = 0.02). A shunt was inserted in 11% of patients undergoing eversion CEAs and in 16% of patients undergoing conventional CEA. Overall, 30-day events occurred in 13.3% of the eversion group and in 11.4% of the conventional group (p = 0.3).

Earlier it was believed that eversion CEA technique was not adequate to secure the distal end point of the endarterectomy plaque in the ICA. However, in EVEREST trial, 96% of patients underwent intra op completion imaging by angiography, angioscopy, or duplex scanning and found no differences between two groups w.r.t intra operative revision surgeries. Moreover, early carotid occlusion and neurologic perioperative events were same in two groups which rejects the hypothesis that eversion CEA is unsafe to secure the distal endpoint of the carotid plaque.

Shunt placement during eversion CEA was considered as a difficult task but in the eversion group of EVEREST, shunt was placed in 11% of patients. Although this percentage was significantly lower compared to conventional group who received the shunt, it was not that small to consider the eversion technique prohibitive for shunt placement. In addition, there were no significant differences in the perioperative stroke or death rate between the two groups. During eversion CEA, a shunt can be placed before or after plaque removal.

It was believed that eversion CEA requires more extensive dissection at the carotid bifurcation and the distal ICA which resulted in high rate of nerve injuries. EVERST trial showed that eversion CEA neither resulted in high rate of Nerve injuries nor caused more frequent neck hematomas compared with conventional CEA.

The preliminary results of EVEREST trial suggested that eversion CEA is a safe, rapid, easy-to-perform procedure with a high percentage of feasibility. Some surgeons prefer eversion endarterectomy over conventional CEA technique because there is no need to use patch and anastomosis can be completed quickly. Moreover, eversion CEA offers distinct advantages in certain anatomical situations like elongated or kinked ICA,

other than that choosing the technique depends on surgeon's experience in performing a technique of endarterectomy over other.

After the EVERST trial several small RCTs and observational studies have compared eversion CEA with conventional CEA with regard to short-term and long term outcome[14]. One of them is a 6 year retrospective study from China comparing Eversion CEA and conventional CEA by Yong-Jun Li et al on 441 patients to assess the postoperative outcome in terms of patency, bleeding, infection, cranial nerve injury, stroke, and death related to intervention. Restenosis was defined as more than 50% stenosis of the lumen in that study .The results of the study came as no significant difference w.r.t early complications including stroke or transient ischemic attack, cranial nerve injury, and infection/bleeding (all P>0.05) and long-term complication, including stroke or heart attack, recurrent stenosis rate, and mortality rate (all P>0.05) in two group study group but patients in the conventional CEA group had a significantly higher percentage of antibiotic use (58.3% vs. 27%, respectively; P<.0001) and shunt use (86.6% vs. 16.1%, respectively; P<.0001), longer postoperative hospital stay (7.23±0.25 days vs. 6.38±0.20 days, respectively; P<.009) and a higher medical cost (24110±1058 ¥ vs. 17257±747.6 ¥, respectively; P<.0001). In that study local cranial nerve injury was the most common complication in the early post- operative period, but most patients recovered with little effect on their quality of life. One important point noted in that study was eversion CEA obviously shortened the postoperative hospital stays by approximately 0.85 days.

Several studies have shown that eversion CEA and patch CEA are equally effective surgical approaches for extracranial carotid occlusive disease in terms of the long-term results. A 2001 Cochrane systematic review of five RCTs comparing e CEA (n ¼ 1303) with c CEA (n ¼ 1286) were done[15]. This study reported no significant differences in peri-operative stroke (1.4% vs. 2.0%), perioperative death (0.6% vs. 0.7%), peri-operative stroke and/or death (1.7% vs. 2.6%), peri-operative MI (0.5% vs. 0.6%), cranial nerve injuries (3.8% vs. 5.6%), and long-term stroke (1.4% vs. 1.7%). However, the meta-analysis suggested that e CEA was associated with significantly lower rates of restenosis >50%, compared with c CEA (2.5% vs. 5.2%, p ¼ .00036).

In 2011, an updated systematic review was done[16]. They reported early and late outcomes following 8530 e CEAs and 7721 c CEA. That meta-analysis included data from 7 RCTs and 15 observational studies(OS) and reported that e CEA was associated with significant reductions in peri-operative stroke (OR 0.46; 95% CI 0.35e 0.62; p <

.001) and peri-operative death (OR 0.49; 95% CI 0.34e0.69; p < .001) compared with c CEA. In addition, patients undergoing e CEA had significantly lower rates of late ICA occlusion (OR 0.48; 95% CI 0.25e0.90; p¼.02) and late mortality (OR 0.76; 95% CI 0.61e0.94; p ¼ .001).

In the first meta-analysis of 2001, there were no significant differences between c CEA and e CEA, except for a higher rate of late restenosis (>50%) following c CEA but in 2011 updated meta-analysis (involving a much larger cohort of patients from mainly non-randomized studies) suggested that e CEA conferred significant benefits relating to 30 day death, 30 day stroke, 30 day death/stroke, as well as lower rates of restenosis and late ipsilateral stroke

Given the discordance between the findings of the 2001 and 2011 meta-analyses (especially that e CEA may be safer than c CEA), a further meta-analysis was undertaken in 2017 to determine whether e CEA conferred significant benefit over c CEA[17]. PubMed/Medline, Embase, and the Cochrane databases were independently searched by two investigators from 2010 to 2017 for studies comparing early (<30 days) and late outcomes (>30 days) following e CEA and c CEA. This metanalysis included 25 studies (5 RCTs, 20 OSs) with a total of 49,500 CEAs (16,249 e CEAs; 33,251 c CEAs).The results of the metanalysis was presented in three separate headings, results based on only RCT data, only OS data , RCT and OS study combined. They also presented a separate analysis of Eversion CEA vs. patched CEA in RCTs and OSs combined results. The outcome of analysis from observational study alone showed that e CEA was associated with significant reductions in 30 day ipsilateral stroke, death, stroke/death, stroke/death/MI, but no significant differences in 30 day rates of MI, cranial nerve injury (CNI), or neck hematoma. The outcome of analysis from observational study and RCTS combined showed that e CEA was associated with significant reductions in 30 day ipsilateral stroke, death, death/stroke, neck haematoma, and late >50% restenosis BUT no differences in 30 day MI, 30 day death/stroke/MI, or CNI. The clinical outcome of e CEA when compared with clinical outcomes in patched CEA from combined RCT and OS data showed that e CEA was NOT associated with significant reductions in 30 day death, stroke, MI, death/stroke, CNI, neck hematoma, late >50 restenosis. On the other hand, e CEA was associated with lower rates of 30-day stroke/death/MI, but because of small numbers, the statistical analysis did not produce reliable outcomes. E CEA was associated with lower rates of neck hematoma compared with p CEA.

The relevance of 2017 meta-analysis in contemporary clinical practice is that, before concluding that e CEA is preferable to c CEA, the important aspect is whether c CEA patients underwent primary closure or patch plasty. The meta-analysis of 10 RCTs containing a total of 2157 patients, which compared routine patch plasty versus routine primary closure, observed that patch plasty CEA was associated with significant reductions in 30 day ipsilateral stroke, compared with routine primary closure CEA (patch 1.5% vs. 4.5% for primary closure p ¼ .001), along with significant reductions in 30 day ICA occlusion (0.5% pCEA vs. 3.1% for dCEA ; p ¼ .0011). In addition, routine patching was associated with significantly lower rates of late restenosis (4.3% patch closure CEA vs. 13.8% direct closure CEA; p < .01), as well as significant reductions in late ipsilateral stroke (1.6% pCEA vs. 4.8% dCEA; p¼.001) ie when data from RCTs and OSs were combined and then stratified for whether the conventional CEA patient underwent either primary closure or patch angioplasty, all of the significant benefits apparently conferred by e CEA disappeared. Compared with patch c CEA, e CEA was now not associated with significant reductions in 30 day death, death/stroke, or late >50% restenosis. Thus the data from the updated 2017 meta-analysis suggested that patients undergoing c CEA have very similar 30 day outcomes as well as late outcomes to patients undergoing e CEA, provided the arteriotomy is patched.

The limitation of above meta-analysis is that many of the studies included have not analyzed the direct closure CEA(d CEA) and patch closure CEA(p CEA) group separately[18]. Moreover some of the studies included only patch closure CEAs only and also there is a vast majority of inconsistency in the type of patch used (prosthetic vs. autologous vein)[19].The quality of some observational study was low (NOS <5). However, a sensitivity analysis which excluded OSs with a NOS <5 did not observe any changes in the principle findings that had been reported for the cohort as a whole[20] . The percentage of symptomatic / asymptomatic patients and the time from the occurrence of the cerebrovascular event to CEA varied both within, as well as between studies. In addition, majority of studies have not used a randomization protocol for the selection of e CEA or c CEA.

The potential for overlap between two studies from the same centre were recognized[21]. Cao et al published two consecutive series on outcomes after c CEA and e CEA[22,23], but there was no overlap in terms of patient recruitment but in Ballotta's study a small number of patients (n¼26) were common to both cohorts[21]. The results of the current metanalysis are in agreement with the 2017 European Society for Vascular Surgery

(ESVS) guidelines for the management of atherosclerotic carotid disease, which suggested that e CEA provides equivalent outcomes to c CEA provided the arteriotomy is closed with a patch[24].

Another area studied while comparing eversion CEA and conventional CEA was the immediate postoperative blood pressure alteration called post endarterectomy hypertension (PEH). Ahn et al suggested a central mechanism for post-carotid endarterectomy HTN because he noted an increase in cranial norepinephrine levels[25]. This may be the result of reflex inhibition of the vasomotor center, which is probably linked to baroreceptor-reflex breakdown. Baroreceptors are located in the adventitia and media of the carotid sinus which is supplied by afferent fibers through the nerve of Hering, which run in the glossopharyngeal nerve. Increased BP causes stretching of the elastic blood vessel and activate these receptors which send stimuli to the corresponding brain centers which in turn decrease sympathetic outflow and increase parasympathetic stimuli, resulting in a drop in BP. In 1836, Cooper was among the first to describe the role of the baroreceptor system in the regulation of BP[26]. More than 85 years later, Hering demonstrated, in dogs, that electrical stimulation of the carotid sinus nerve induced both bradycardia and hypotension, and that transection of the nerve reversed these effects. He was also able to show that bilateral transection of the carotid sinus nerve resulted in systemic hypertension. Later, similar results were reported by Korner, who in rabbits observed an increase in BP, as well as in cardiac output and heart rate, after bilateral transection of the carotid nerves[27]. In addition, several investigators noted that BP became very unstable after denervation of the baroreceptors.

Taken together, these data suggested that the primary function of the baroreceptor system was to stabilize BP and prevent large short-term fluctuations in pressure. There is evidence from human studies that baroreflex dysfunction is associated with increased cardiovascular morbidity and mortality. Farrel et al. found that baroreflex dysfunction after MI was a significant independent risk factor for the development of malignant cardiac arrhythmias and sudden cardiac death[28].

Baro-reflex breakdown and consequent hypertension may also be associated with the development of the cerebral hyper perfusion syndrome. Cerebral hyper perfusion syndrome is a cause of perioperative stroke following CEA. Diminished cerebrovascular

reserve, postoperative hypertension, and hyper perfusion lasting more than several hours to days after CEA seem to be the most important risk factors.

Previous studies have shown that the presence of atheroma in the carotid sinus region can impair the sensitivity of baroreceptors and this impairment seems to be greater in patients with stiffer, more echogenic carotid plaques. However, it is currently unclear whether the reduced sensitivity of such baroreceptors, following surgical damage, correlates with the echogenicity of the removed carotid plaque at CEA.

The incidence of post endarterectomy HTN is in the range of 11% to 56%[29]. HTN after CEA may result in prolonged hospital admission or, more seriously, may be associated with neurological. Mehta et al.[30] retrospectively compared the incidence of postoperative HTN between E-CEA and C-CEA and showed that patients who underwent E-CEA had a significantly increased requirement of intravenous antihypertensive medication (24%), compared with patients having a C-CEA (6%; p value 0.001). However, the BP recordings were available only for the initial 24 hours in post op.

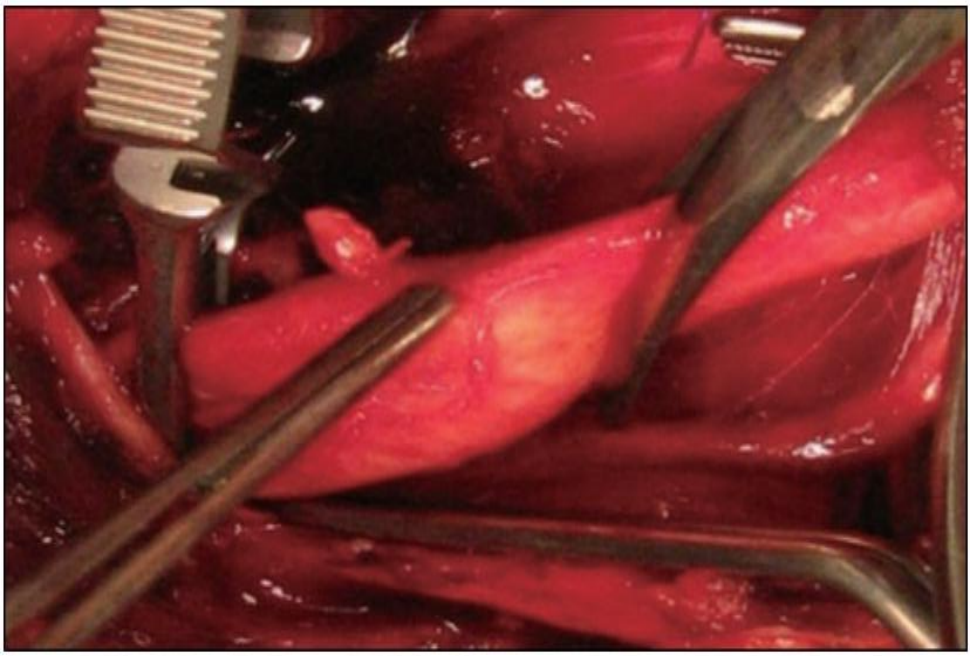
Hirschl et al. highlighted that, in patients undergoing CEA, the occurrence of postoperative baroreflex dysfunction, followed by BP instability, was associated with a 3.3- fold higher risk of early major cardiovascular complications and an eightfold elevated risk of cardiovascular mortality in the first 5 postoperative years[31]. Wong et al. observed that hemodynamic instability was commonly present after CEA, but only postoperative hypertension was associated with stroke or death[32]. Toorop et al. demonstrated that the adventitial excision of the proximal portion of the ICA is effective in carotid sinus syndrome[33]. Following this clinical experience, Toorop et al. identified the precise location of the carotid baroreceptors in medial portions of the proximal ICA. This discovery led to the visualization of baroreceptors in the human carotid bifurcation by light microscopy using PGP 9.5 and VGLUT2 as immunohistochemical markers.

Several reports showed that injury of the baroreceptors during CEA results in postoperative hypertension. This phenomenon is more evident in Eversion-CEA as ICA is divided at bifurcation, which involves baroreceptor damage. Some vascular surgeons advocate local anesthetic blockade of the carotid sinus nerve during CEA to minimize fluctuation of BP but, with this technique, prevention of postoperative hemodynamic instability remains unclear. A review by Tang et al, based on four randomized controlled trials, suggests that there is no conclusive evidence supporting the routine use of local

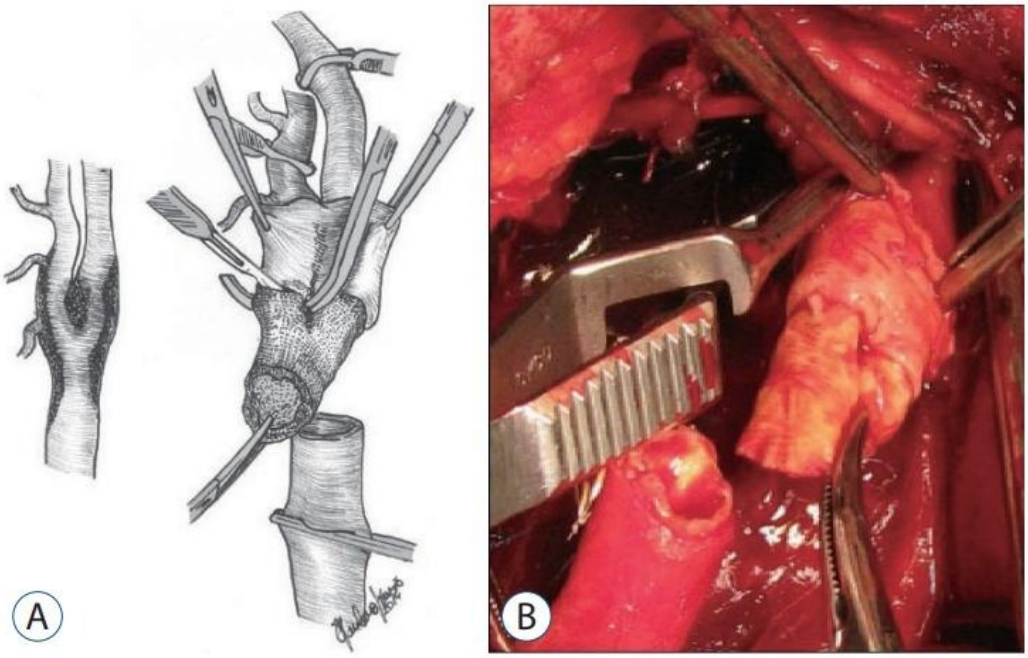
anesthetic to block the carotid sinus nerve in order to reduce postoperative BP fluctuation[34].

First surgery on atherosclerotic carotid artery was performed in Argentina in 1951 by Carrea, Molins and Murphy by ligating the stenosed proximal segment of the internal carotid artery (ICA) and doing an end-to-end anastomosis between proximal segment of an external carotid artery (ECA) and distal patent segment of ICA[3]. During 1954 in London Eastcott, Pckering and Rob excised the stenosed common carotid artery (CCA) and done an end-to-end anastomosis between the CCA and ICA. During the procedure carotid artery was clamped for 28 minutes and patient`s body temperature was reduced to 28 degrees by external cooling[35]. In the same year Denman et al. done the resection of occluded ICA, and restored arterial flow with homograft[36]. In 1955 Doyle et al. used saphenous vein graft instead of homograft for the same procedure[37]. The first CEA has been performed by famous Michael De Bakey, the father of modern cardiovascular surgery in 1953, but published the article only in 1959[38]. In that article De Bakey and his coworkers explained two techniques of CEA: conventional and eversion. Conventional CEA involves a longitudinal arteriotomy from the common carotid artery (CCA) into the internal carotid artery (ICA), plaque removal and closure either primarily or with a patch. In eversion CCA, ICA and ECA was disconnected, endarterectomized and arterial continuity restored by end-to-end anastomosis with CCA. This procedure did not require carotid patch for closure. Majority of vascular surgeons continued with conventional carotid endarterectomy (CEA) and only after Seventeen years Etheredge who again popularized the Debakey's eversion CEA[39]. However, conventional CEA continued to be the dominant procedure of carotid surgery. At the beginning of the 19th century Kasprzak ,Raithel and Vanmaele et al. introduced another modification of the eversion CEA[11].

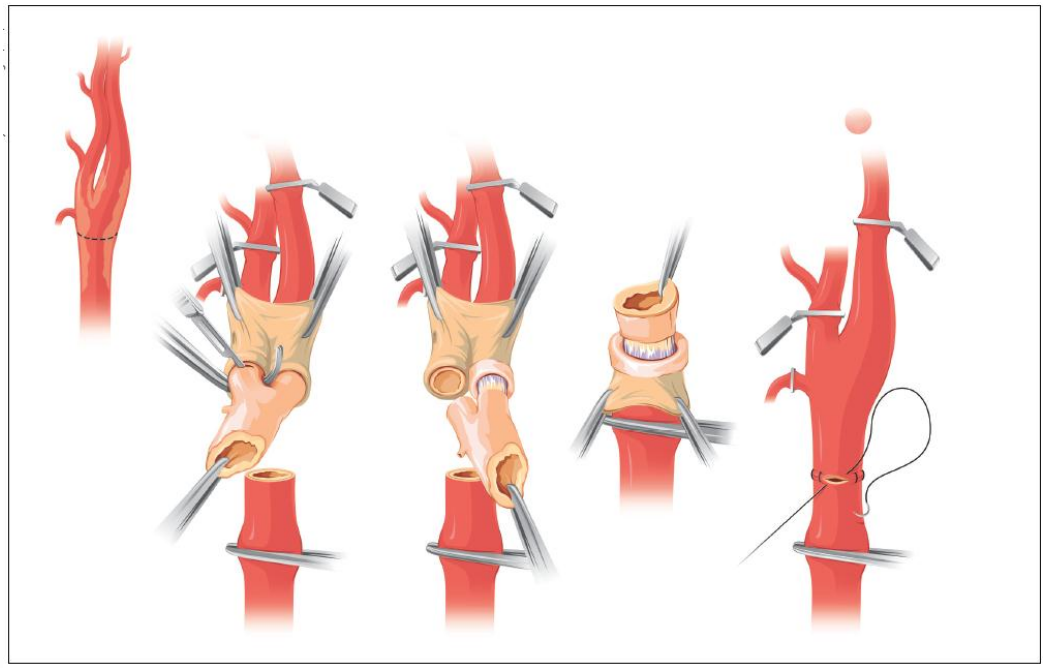
So there are two modifications of eversion CEA in current surgical practice- De Bakey-Etheredge modification and Kasprzak-Raithel-Vanmaele modification. De Bakey-Etheredge modification of the eversion CEA is indicated if atherosclerotic process involves only CCA bifurcation without extending much distally into ICA. The procedure begins with the transection of the CCA 0.5 to 1.0 cm proximal to carotid bifurcation followed by distal eversion endarterectomy of the ECA and ICA together followed by proximal eversion endarterectomy of the CCA. The end to end anastomosis was performed by simple over and over continuous suture. This type of CEA is performed without carotid shunt since its placement will be difficult.



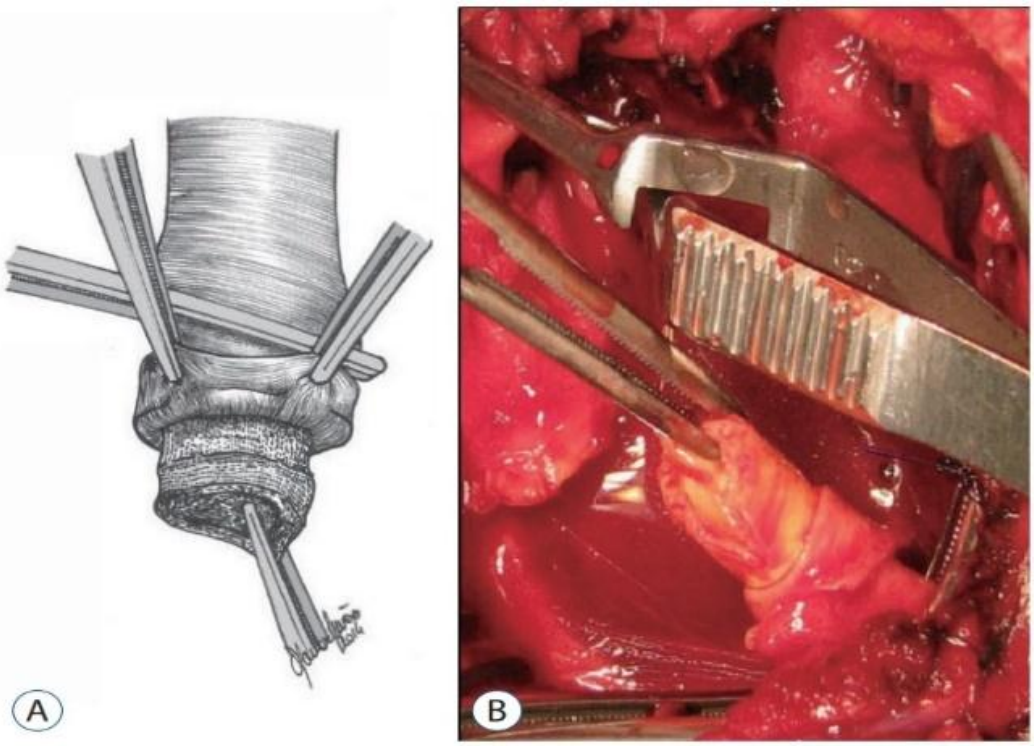
De Bakey-Etheredge modification of the eversion carotid endarterectomy : transection of common carotid artery – intraoperative review.



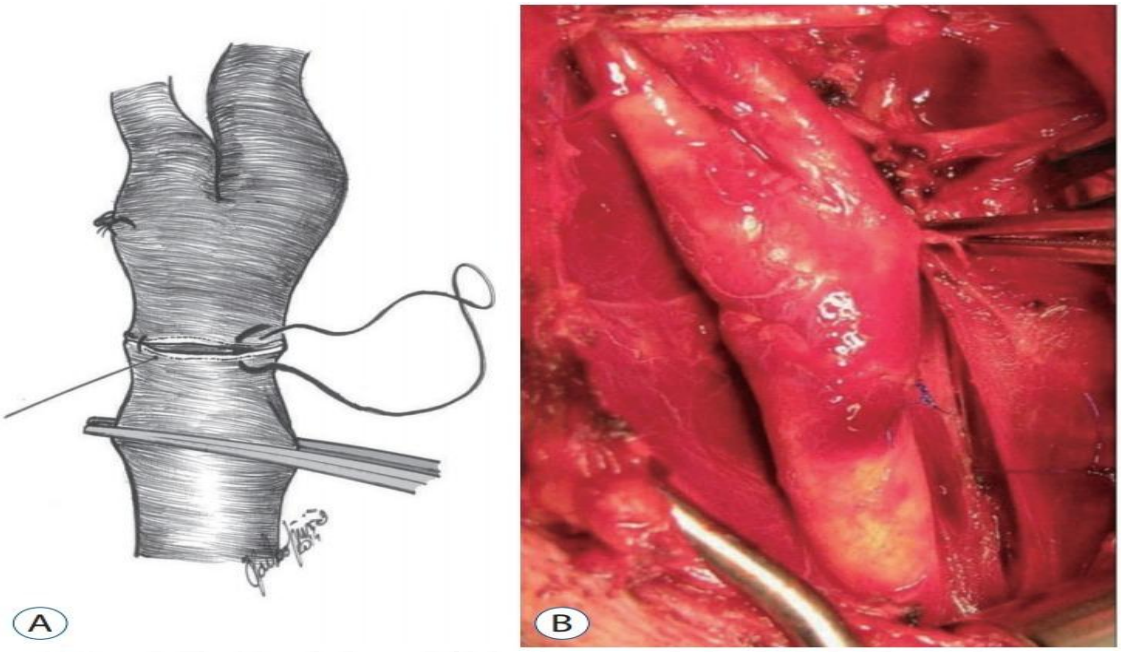
De Bakey-Etheredge modification of the eversion carotid endarterectomy: distal eversion endarterectomy of internal and external carotid artery (A) shematic review and (B) intraoperative review.



In patients with plaque that is isolated to the carotid bulb and very proximal ICA and ECA, the distal CCA can be transected, and proximal and distal eversion can be performed.

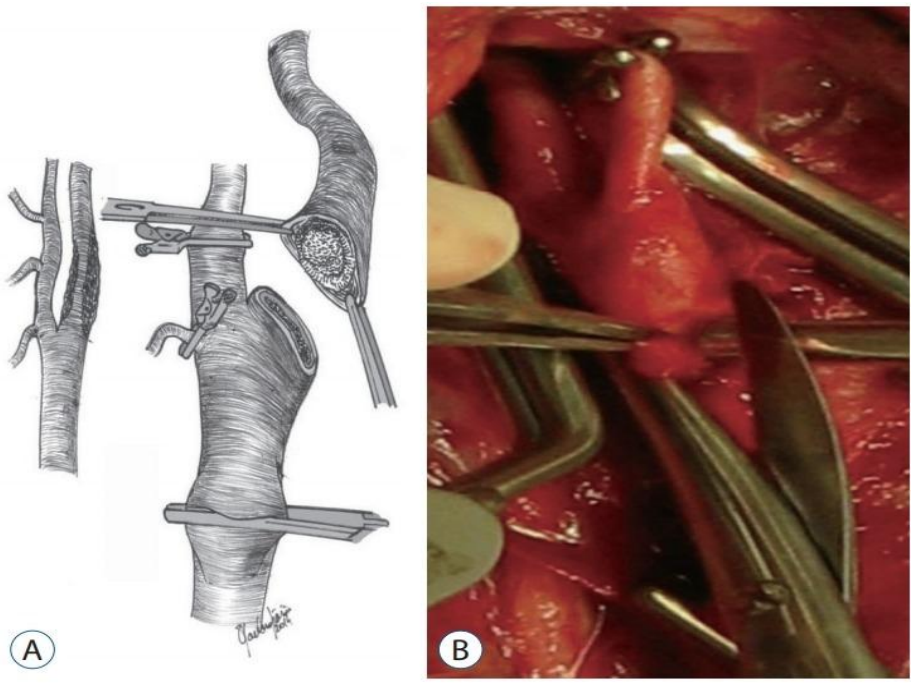


De Bakey-Etheredge modification of the eversion carotid endarterectomy: proximal endarterectomy of common carotid artery (A) shematic review and (B) intraoperative review.

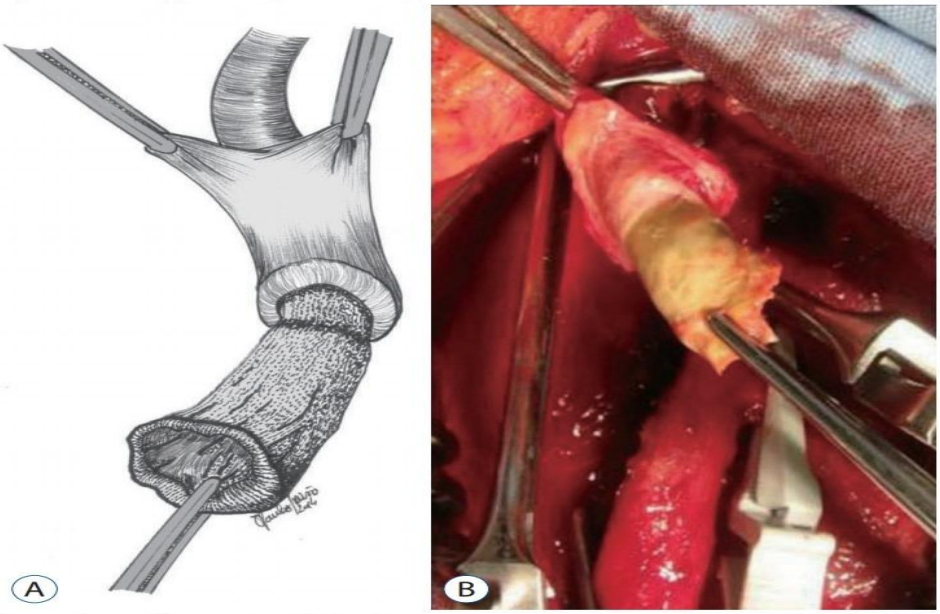


De Bakey-Etheredge modification of the eversion carotid endarterectomy: reanastomosis (A) shematic review and (B) intraoperative review.

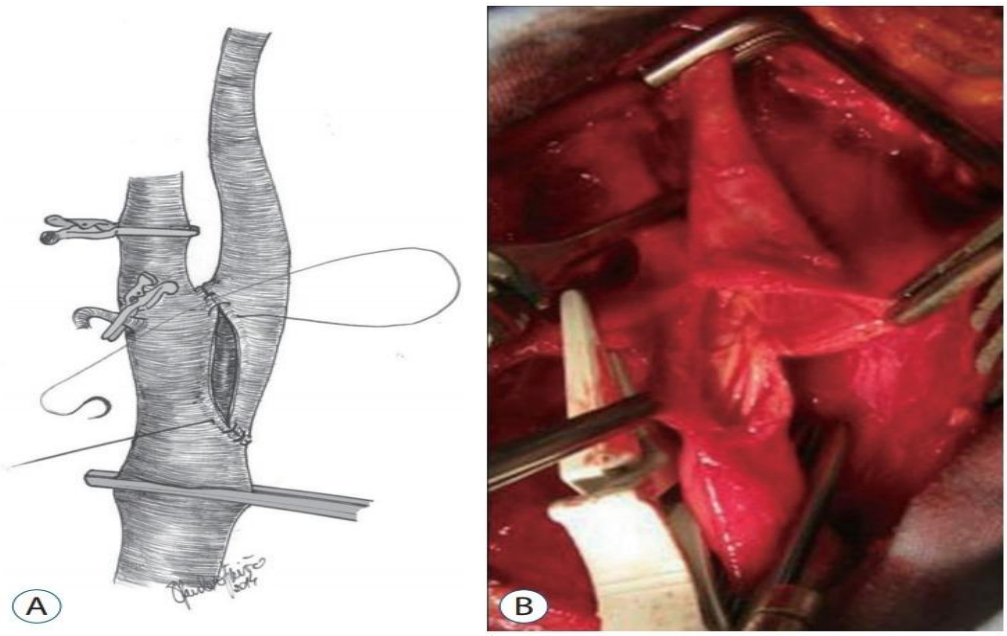
In the De Bakey-Etheredge modification of eversion CEA, the feathering of distal intima edge is uncertain if the plaque extends distally into ICA. Due to this Kasprzak-Raithel-Vanmaele modification of the eversion CEA came in. This procedure begins with oblique transection of the ICA from CCA. The distal eversion endarterectomy of the ICA is done in a similar manner as in De Bakey-Etheredge modification. After that endarterectomy of the CCA and ECA is performed. ICA is then re-anstomosed to CCA by continuous running sutures.



Kasprzak-Raithel-Vanmaele modification of the eversion carotid endarterectomy: oblique transection of internal carotid artery from the common carotid artery (A) shematic review and (B) intraoperative review.

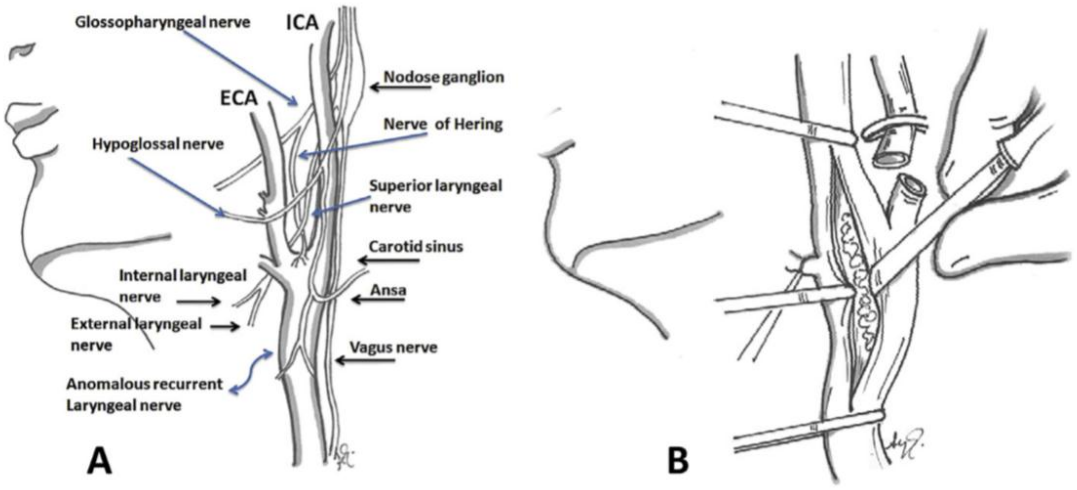


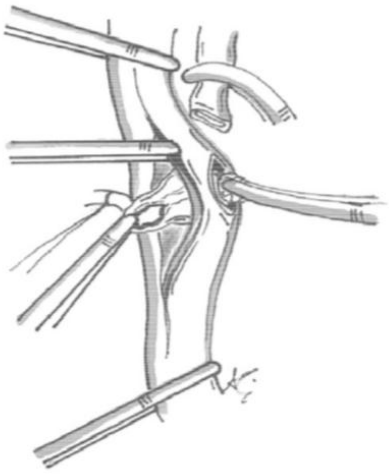
Kasprzak-Raithel-Vanmaele modification of the eversion carotid endarterectomy: distal endarterectomy of internal carotid artery (A) shematic review and (B) intraoperative review.



Kasprzak-Raithel-Vanmaele modification of the eversion carotid endarterectomy: reattachment of endarterctomized internal carotid artery (A) shematic review and (B) intraoperative review.

Later in 1995, Reigner et al. modified the eversion CEA technique by obliquely transecting the ICA downstream from the plaque and an additional longitudinal arteriotomy of the CCA, extended to the origin of external carotid artery (ECA) which was later popularized as Chevalier- eversion CEA [Ce-CEA])[40].This kind of section spares the fibers of the carotid sinus nerve, without modifying the sensitivity of baroreceptors in the carotid bulb





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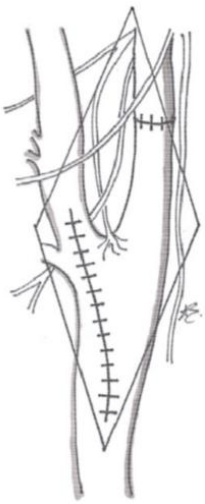


D

A retrospective review was undertaken among 380 patients who underwent carotid endarterectomy (120 Chevalier-c CEA; 260 conventional/standard- s CEA) from December 2002 to November 2012. [41]The changes of blood pressure baseline during the postoperative course in C-CEA and S-CEA group were analyzed and compared. Post endarterectomy hypertension (PEH) was defined as an elevation of systolic pressure >180 mm Hg or >40% rise above baseline. The patients with Chevalier eversion technique did not develop a significantly higher blood pressure in the postoperative course compared to those operated with the standard technique. In the recovery room, the mean systolic blood pressure was 134 ± 21.9 mm Hg in C-CEA group versus 132 ± 24.6 mm Hg in S-CEA group. In the first postoperative day it was 132 ±17.2 mm Hg in C-CEA versus 133 ±17.4 mm Hg in S-CEA group. During the first six hours in the recovery room, the need for intravenous antihypertensive drugs were similar in the two groups. The dosage of pre- operative antihypertensive therapy was increased in 6 patients (4.9%) of C-CEA group and in 12 patients (4.9%) of S-CEA group, without significant difference (p value =1). The study concluded that Chevalier-CEA has the same rate of postoperative hypertension of conventional-CEA, which is probably related to the sparing of baroreceptor apparatus, compared to standard E-CEA. The Chevalier procedure could represent an E-CEA technique with its inherent advantages, without penalties related to postoperative hypertension, commonly observed after E-CEA.

In conclusion, all these updated systematic reviews, metanalysis, RCTs and observational studies in nearly 50,000 CEA procedures has shown that e CEA was associated with similar outcomes to c CEA, provided the arteriotomy was closed with a patch. The current evidence shows that until further data are available, the choice of the CEA technique depends on the experience and familiarity of the individual surgeon.

MATERIALS AND METHODS

A retrospective review of 62 patients who underwent carotid endarterectomy in Division of Vascular Surgery, SCTIMST (conventional CEA, n=31; eversion CEA, n=31) from January 2018 to December 2019 were done by principle investigator and co-investigator

Inclusion criteria:

1. All symptomatic patients with h/o of TIA/ stroke and >50% ipsilateral ICA stenosis on CT angiogram with or without contralateral ICA stenosis/occlusion who underwent CEA by either Conventional or Eversion technique.

Exclusion criteria:

1. All asymptomatic patients >60% ICA stenosis who underwent CEA by either Conventional or Eversion technique.
2. All symptomatic patients <50% ICA stenosis and all asymptomatic patients <60% ICA stenosis who underwent BMT.
3. All Patient who underwent Carotid artery stenting (CAS) during the study time period
4. All Patients who underwent CEA along with CABG

In this retrospective analysis, the choice of e CEA or c CEA were decided based on the discretion of surgeon who performed the procedure. The pre-operative evaluation were same for both eversion and conventional CEA. Prior to surgery neck vessel doppler and CT/MRI brain as per Stroke protocol was taken. Neck vessel Doppler was done to measure the velocities across the stenosis. Degree of stenosis was calculated both by CTA/MRA images (NASCET Criteria) and by duplex velocity criteria. Apart from that, routine blood investigations (which included hemogram, coagulation profile, liver, and renal function test), baseline noninvasive cardiac workup including ECG, echocardiogram and chest X-ray were performed. Invasive testing for cardiac fitness was decided by the cardiologist based on patient's cardiac symptoms and functional class. If found to have significant cardiac disease, the patient was either advised concomitant coronary revascularization with CEA (exclude from the study) or percutaneous coronary intervention (PCI) followed by staged CEA. All patients were started on dual

antiplatelets (Aspirin and Clopidogrel) with high dose statin therapy (Atorvastatin 40/80mg or Rosuvastatin 20/40mg). Around 2-4 days prior to procedure, clopidogrel was withheld but Aspirin was continued during the perioperative period.

Preoperative parameters recorded in study were ,demographic profile including risk factors ,antecedent event before CEA eg stroke vs TIA, timing of CEA, NIHSS and mRS score for stroke severity assessment, U/L or B/L carotid disease, SBP,DBP and MAP recordings, class of individual antihypertensive medication e.g. betablockers, CCB, ACE etc and its dosage in mg. Baseline BP values were obtained on the day of admission and BP was always measured on both arms and the higher pressure was taken into consideration. Intra operatively induction and intra op BP recordings, total clamp time, shunt usage, heparin protamine reversal was noted. Postop in ICU the need of vasodilators, duration of vasodilator usage in hrs and total dose in mg till it is discontinued. At the time of discharge BP of the patient dose of previous antihypertensives in mg or any antihypertensives newly added were noted. At 3 months follow up BP recording, any neurological deficit, any increase in dose of antihypertensives or any class of antihypertensives newly added after discharge were recorded.

Operative Procedure details of conventional CEA:

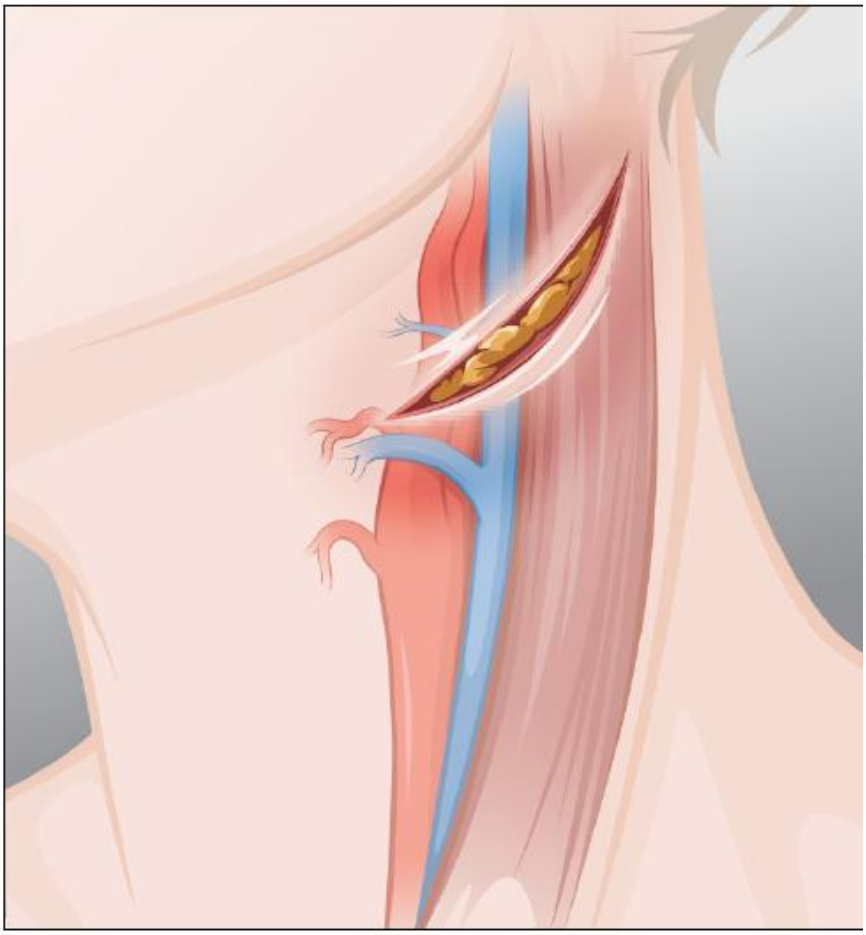
All the patients underwent conventional CEA under general anesthesia. Longitudinal incision along the anterior border of sternocleidomastoid muscles (SCLM), from the angle of mandible to 5 cm above clavicular head. The carotid sheath was opened and the common carotid artery (CCA) was dissected and looped for control. External carotid artery (ECA) and Superior thyroid artery (STA) were controlled and looped. Without disturbing the carotid bifurcation, the distal internal carotid artery (ICA) beyond the disease was dissected and looped for control. Heparin (1 mg/kg) was given intravenously. Neuro protective medications such as Methyl Prednisolone (30mg/kg) and Thiopentone (1mg/Kg) were administered. ICA, CCA, ECA and STA were clamped in sequence. The arteriotomy begins 2 cm on the distal CCA and proceeded over the carotid bulb, gradually extending to visualize the atheromatous endpoint in ICA. A subintimal plane was created and the plaque was extracted feathering away from ICA end point with gentle traction while the ICA clamp was momentarily released The endarterectomized artery was then carefully irrigated with heparinized saline and any loose intimal tags

were peeled off. In all conventional CEAs Pruitt Inhara shunt (LeMaitre® vascular, USA) were used to maintain antegrade cerebral blood flow. The shunt was first inserted into the CCA end followed by ICA end and snugged. Stump pressure was measured by placing a rubber shod on the CCA end, using an arterial line extension attached to T segment of the shunt. Once the stump pressure was recorded, continuous perfusion pressure to brain was recorded with the removal of rubber shod. Systemic arterial pressure was monitored via the radial arterial line and around 90 mm of mean blood pressure is maintained while ipsilateral carotid is cross clamped. The arteriotomy was then repaired using a patch (Supramaleolar great saphenous vein mostly). In patients with peripheral vascular disease or those having poor quality vein, Bovine pericardial patch was used. Before completing the suture line, the carotid shunt was removed, and clamps reapplied. Patient was then placed in Trendelenberg position and adequate de-airing was done after which the sutures were tied. ECA first and then CCA clamp was released, and initial perfusion restarted to ECA. ICA was perfused a minute later. Hemostasis secured and heparin reversal with protamine was done. A suction drain was placed and the wound was closed in layers. The patient was then shifted to the ICU and kept on assisted ventilation. Once the patient becomes awake and neurological assessment is done, he/she was extubated.

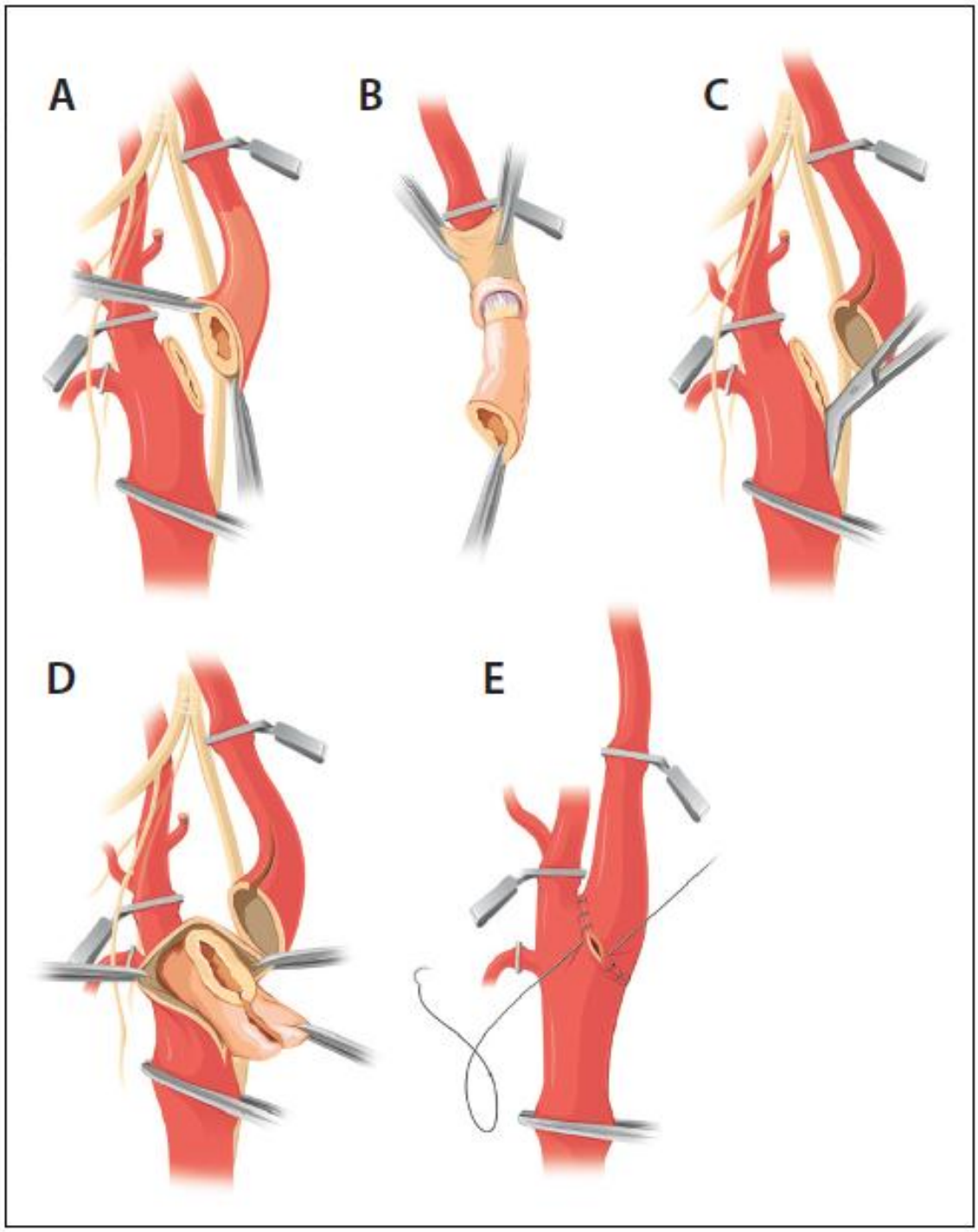
Operative Procedure details of Eversion CEA:

All eversion CEAs were also performed under general anesthesia. Usually a transverse skin crease incision is made centered over the carotid bifurcation. The CCA, ECA, and ICA were exposed in a similar fashion similar as in conventional CEA adhering to "non touch technique". The proximal ICA at the carotid bifurcation was mobilized circumferentially such that no attempt will be made to preserve carotid sinus nerve. Distal ICA equal to the length of the plaque is exposed (to facilitate eversion). After systemic heparinization, the CCA, ECA, and ICA were clamped. The ICA is then disconnected from the carotid bulb using a long, oblique arteriotomy. Any remaining circumferential adhesions of proximal ICA is cleared with sharp dissection. The above is done under the protection of clamped ICA to prevent iatrogenic embolization of plaque. An endarterectomy plane is developed between the arterial media and adventitia, and the adventitia is rolled cephalad while maintaining downward gentle traction on the plaque by a Kelly's clamp. The distal endpoint is identified, and the plaque removed in a circumferential fashion like a "donut". The distal endpoint is inspected to make sure that

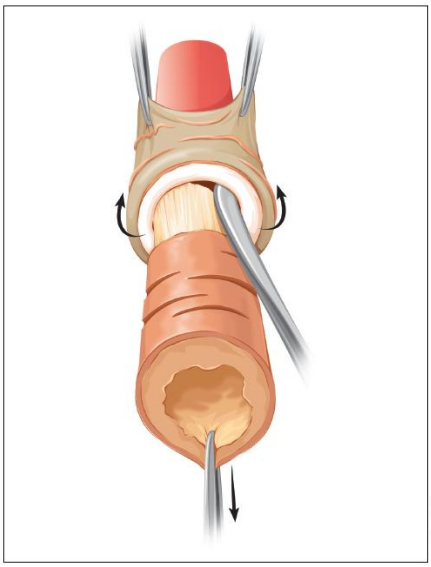
there is no persistent flap or intimal defect. Any remaining small pieces of loose atheroma and medial muscle fibres are removed under loupe magnification. This is followed by the endarterectomy of the distal CCA, carotid bulb, and ECA. Sometimes tacking sutures are used to secure the proximal CCA cuff. In case of redundant ICA, the artery is transected before anastomosing to the carotid bulb. After obtaining complete hemostasis, the incision was closed over a suction drain.



A small (typically < 4-cm length) transverse incision is made over the carotid bifurcation



The eversion endarterectomy technique. After proximal and distal control have been obtained with atraumatic clamps, the ICA is disconnected from the carotid bulb with an oblique arteriotomy (A). The ICA is everted, and the plaque is removed (B). The arteriotomy on the CCA is extended proximally (C). If the ICA is redundant, it can be shortened. Endarterectomy of the CCA and ECA (D). The ICA is reconnected to the carotid bulb with continuous polypropylene sutures (E).



Management of the distal endpoint.

Perioperative period:

In our centre the target of perioperatively blood pressure maintenance was less than130/80 mm Hg. Any increase in BP above 130/80 will managed by oral antihypertensives or iv vasodilators. Antiedema measures, which include intra venous steroids and diuretics, were started and continued minimum for 1-2 days after procedure. In ICU BP was recorded continuously with intra-arterial blood pressure monitoring (Datex Ohmeda; GE Healthcare, Little Chalfont, UK) for the first 24 to 36 hrs till patients BP is fully controlled with oral antihypertensives. After that patient is followed up in ward by non-invasive blood pressure measurements taken four times daily until discharge and later at 3 months during OPD follow up. From post op day (POD) 1 oral feeds started and a single antiplatelet medication was started (usually Aspirin) along with high dose statins and oral antihypertensives. Patient was observed in Intensive care unit (ICU) for 24-48 hours and then shifted to the ward. On POD 5 or 6, sutures were removed, and patient was discharged.

Follow up at 3 months:

Patients were followed up by the stroke team and reassessed for any fresh neurological deficit and NIHSS score & mRS were recorded. Duplex scan was done at 3rd month. All demographic data, vitals, duplex findings and neurological assessment are noted in EMR. If any restenosis was found or patient develops ipsilateral symptoms, the case was again discussed in the comprehensive stroke meet and further treatment was initiated.

DEFINITIONS

Symptomatic patients: - Patients with carotid stenosis are considered symptomatic if they present with a history of stroke, amaurosis fugax, or transient ischemic attacks (TIA) involving the ipsilateral carotid territory that occurred within 180 days of the initial assessment

Asymptomatic patients: - Patients with no neurologic symptoms referable to the cerebral hemisphere ipsilateral to the carotid stenosis or a history of previous neurologic events without subsequent event within 180 days.

Stroke: - Defined as a cerebral infarction that manifests as sudden onset of focal neurological deficits that persists for more than 24 hours

Transient Ischemic Attacks: Defined as a temporary focal neurologic deficit that persists for <24 hours with a return to baseline or complete resolution of the event.

Minor stroke: - A new neurologic event that persists for more than 24 hours but completely resolves or returns to baseline within 30 days with NIHSS score of ≤4

Major stroke: - A new neurologic event that persists for >24hours with NIHSS score >4

Post Procedural myocardial Infarction:- Chest pain or equivalent symptoms consistent with myocardial ischemia and ECG evidence of ischemia including new ST segment depression or elevation> 1mm in 2 or more contiguous leads along with elevation of cardiac enzymes (CK-MB or Troponin T) to a value 2 or more times the institute's laboratory upper limit of normal

Cranial Nerve injury: - Temporary or permanent deficits secondary to injury to cranial nerves that occurred because of carotid intervention, particularly those that have not resolved by 30 days after the initial procedure

Essential Hypertension - defined as a systolic BP (SBP) > 140 mm Hg or a diastolic BP > 90 mm Hg before surgery or those patients with BP <140/90 mm Hg taking oral antihypertensives.

Post endarterectomy hypertension (PEH)- defined as those patients with SBP >140 or diastolic BP > 90 mm Hg in the immediate perioperative period or those patients requiring iv vasodilators

STATISTICAL ANALYSIS

Student *t* test was used to compare the group's baseline characteristics and continuous measures. $\chi 2$ statistical analysis was used to compare the groups with discontinuous variables. All statistical tests were 2-tailed, and *P* values < .05 were considered to represent statistical significance. Karl Pearson correlation co- efficient was used for comparing the mean values of BP preoperatively and in immediate post OP. All data analysis was done using the Windows Excel 2010 and SPSS statistical analysis software.

RESULTS

Demographic profile

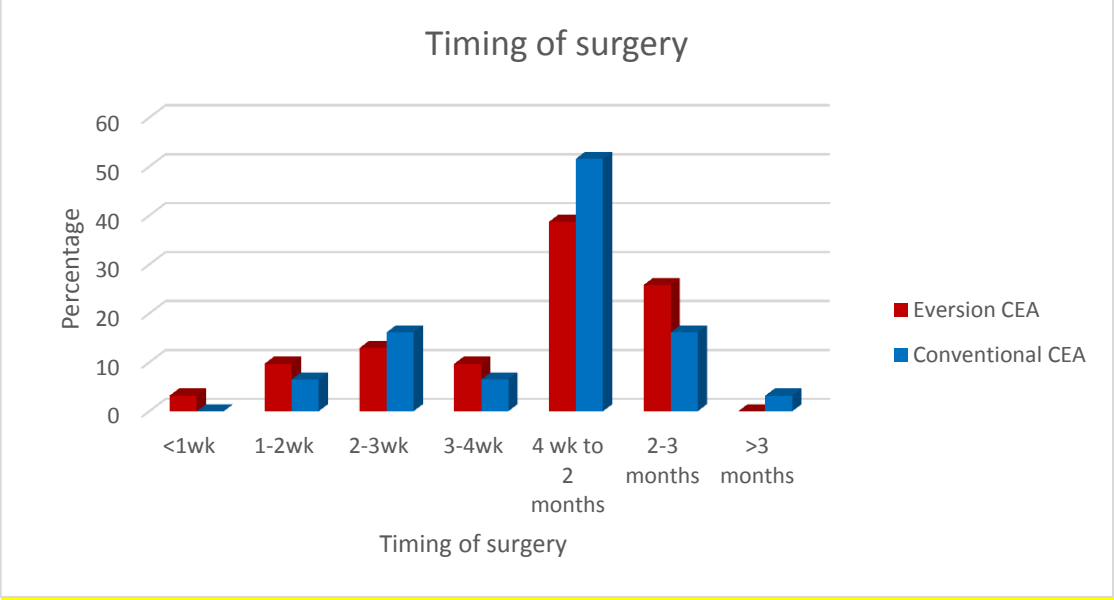
Demographics data are listed in Table 1. The study population were divided into eversion(n=31) and conventional(n=31) groups. The age, sex, distribution of risk factors like smoking, dyslipidemia, Coronary artery disease, diabetes, hypertension both controlled and uncontrolled, COPD, CKD, thyroid dysfunction, POAD, unilateral and bilateral ICA disease, severity of stroke assessed by NIHSS and mRS score were evenly distributed between two study groups(p value >0.05). 58% in eversion CEA group and 58% within conventional CEA group had stroke prior to CEA (p value 1). The percentage of patients with TIA were 41.9 % in eversion CEA and 43.3% in conventional CEA group (p value 0.912). So, the number of patients with stroke and TIA were similar in both groups (p value 1.00).

	Eversion		Convention		p	OR	95% CI for OR	
	N	%	N	%				
Male	10	32.3	5	16.1	0.138	2.48	0.73	8.37
Female	21	67.7	26	83.9				
Age in years (mean±sd)	61.0±9.2		63.3±9.6		0.342	1.027	.973	1.084
SMOKER	10	32.3	8	25.8	0.576	0.73	0.24	2.20
DYSLIP	14	45.2	13	41.9	0.798	0.88	0.32	2.40
CAD	1	3.2	4	12.9	0.162	4.44	0.47	42.26
DM	21	67.7	24	77.4	0.393	1.63	0.53	5.05
Uncontrolled HTN	19	61.3	13	41.9	O.127			
Controlled HTN	12	38.7	18	58.1				
COPD	2	6.5	1	3.2	0.554	0.48	0.04	5.62
POAD	0	0	3	9.7	0.076			
Stroke	18	58.1	18	58.1	1.00	1.00	0.37	2.74
TIA	13	41.9	13	41.9	1.00	1.00	0.37	2.74
Bilateral Carotid Stenosis	7	22.6	11	35.5	1.00	1.00	0.37	2.74
NIHSS	2.19	4.39	1.71	2.10	.582 .566	.957 .905	.819 .646	1.119 1.269
MRS	1.35	1.87	1.13	1.12	.582	.957	.819	1.119
					.566	.905	.646	1.269

Timing of CEA

The timing of CEA was analyzed by dividing the patients into those done in first week, second week, third week, fourth week, second month, third month and after three months in both eversion and conventional group. The maximum number patients (45.2%) underwent CEA between first and second months in both eversion and conventional CEA group and very less number of patient(3.2%) with in first week as emergency CEA due to recurring TIA. There was no difference in the distribution of patients w.r.t timing before CEA (p value 0.707).

Timing of surgery	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
<1wk	1	3.2	0	0.0	1	1.6			
1-2wk	3	9.7	2	6.5	5	8.1			
2-3wk	4	12.9	5	16.1	9	14.5			
3-4wk	3	9.7	2	6.5	5	8.1	3.775	6	.707
4 wk to 2 months	12	38.7	16	51.6	28	45.2			
2-3 months	8	25.8	5	16.1	13	21.0			
>3 months	0	0.0	1	3.2	1	1.6			
Total	31	100.0	31	100.0	62	100.0			



CEA in patients with C/L disease

The patients with asymptomatic contra lateral carotid stenosis were 19.35 % in eversion CEA and 29.03 % in conventional CEA. There were 1 patient in eversion CEA and 2 patients in conventional CEA with C/L ICA occlusion. There were no significant difference in the number of patients with asymptomatic contra lateral carotid stenosis in both eversion and conventional CEA (p value 0.263) The right and left sided CEA were matched in both eversion and conventional group (p value 0.793).

	Eversion CEA		Conventional CEA		p	OR	95% CI for OR	
	N	%	N	%				
Patients with C/L ICA stenosis	6	19.35	9	29.03	0.263	1.87	.62	5.77

Side	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Right CEA	20	64.5	19	61.3	39	62.9	0.069	1	0.793
Left CEA	11	35.5	12	38.7	23	37.1			
Total	31	100	31	100	62	100			

Primary end point of the study

The were no major stroke or stroke related death in both study group. One patient in eversion CEA had carotid occlusion and presented as minor stroke which was noted as as secondary outcome in our study.

	Eversion		Convention	
	N	%	N	%
MAJOR STROKE	0	0	0	0
STROKEDEATH	0	0	0	0
CAROTID OCCLUSION	1	0.03	0	0

Secondary end points of the study

The secondary endpoints studied were minor stroke/TIA, postoperative MI, cranial nerve dysfunction, bleeding, hematoma, re-exploration, reperfusion syndrome and wound infection. There was no post-operative bleeding and re- exploration in study group(n=0). There was no significant difference in the overall secondary endpoints like minor stroke(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%, p value 1), TIA (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.3)post-operative MI(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%), p value 1), hematoma (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.313),re exploration (eversion CEA n=1(3.2%), conventional CEA n=0, p value 0.313) and reperfusion syndrome(eversion CEA n=1(3.2%), conventional CEA n=1(3.2%), p value 1). The incidence of Cranial nerve dysfunction were significantly higher in eversion group as compared to conventional CEA (eversion CEA n=6(19.4%), conventional CEA n=1, (3.2%) p value 0.045). The most common CN involved is marginal mandibular nerve (n=4/6 in eCEA and n=1/1 in cCEA) followed by hypoglossal (n=1; e CEA) and RLN (n=1; c CEA). CN dysfunction were in the form of neuropraxia as fascial deviation, tongue deviation and hoarseness of voice recovered in the due course of time.

	Eversion		Convention		p	OR	95% CI for OR	
	N	%	N	%				
Minor stroke	1	3.2	1	3.2	1			
TIA	1	3.2	0	0	0.313			
Postop MI	1	3.2	1	3.2	1.000	1	0.06	16.737
CRANIAL N DYSFUNCTION	6	19.4	1	3.2	0.045	.14	.02	1.23
BLEEDING	0	0	0	0				
HEMATOMA	1	3.2	0	0	0.313	0	.	.
REEXPLORATION	1	3.2	0	0	0.313	0	.	.
REPERFUSIO SYNDROME	1	3.2	1	3.2	1	1	0.06	16.737
WOUND INFECTION	0	0	0	0				

Clamp timing in Eversion vs Conventional CEA

Since all conventional CEA were performed under shunt,the clamp time was calculated by adding the time from carotid clamping to the time of shunt insertion in the beginning of procedures and from removing the shunt till completion of anastomosis, deairing and restoration of flow to ICA towards the end of the procedure. The clamp time in evrsion CEA were calculated from the time of carotid clamping to declamping and final restoration of flow to ICA. It was found that the clamping time in eversion CEA was significantly higher as compared to conventional CEA, and this difference was statistically significant (eversion 20.77 ± 8.504 minutes vs conventional 34.5 ± 14.4 minutes; $p = 0.001$).

Group	N	CLAMP TIME in minutes		t	p
		Mean	sd		
Eversion	31	20.77	8.504	3.659	0.001
Convension	31	13.81	6.332		

HEMODYNAMIC INSTABILITY AFTER CEA - EVERSION vs CONVENTIONAL

All patients with preoperative HTN undergoing CEA were divided into 2 groups: controlled HTN if <140/90 and uncontrolled HTN if ≥140/90. In retrospective analysis we found that invariably all the patients in the cohort were hypertensives. It was found that 38.7% of patients had controlled HTN in eversion CEA group and 58.1% of patients had controlled HTN in conventional CEA group. There were 61.3 % of patients had uncontrolled HTN in eversion CEA group and 41.9 % of patients had uncontrolled HTN in conventional CEA group. There was no difference in the distribution of controlled and uncontrolled HTN in two arms of the study group.

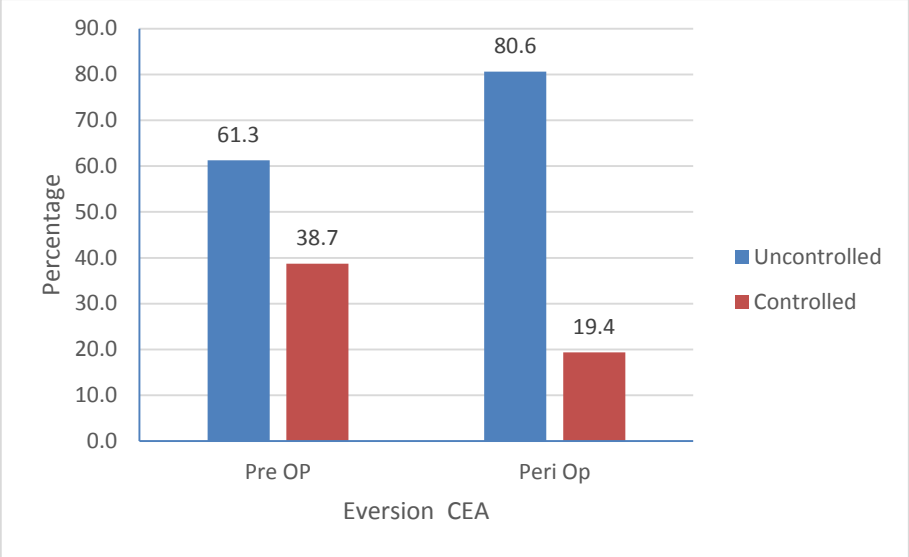
Classification of Pre op HTN	Eversion		Convention		Total N	χ^2 %	df		p
	N	%	N	%					
Uncontrolled	19	61.3	13	41.9	32	51.6	2.325	1	.127
Controlled	12	38.7	18	58.1	30	48.4			
Total	31	100.0	31	100.0	62	100.0			

Increase in the number of patients with uncontrolled HTN at discharge after eversion CEA

Preoperatively 61.3% of patients had uncontrolled hypertension and 38.7% had controlled hypertension prior to eversion CEA. At the time of discharge 80.6% of patients had uncontrolled hypertension and 19.4% of patients had controlled HTN. The change in blood pressure occurring after surgery was statistically significant (p value 0.031) which means that there is a significant increase in the number of patients with uncontrolled HTN post eversion CEA in immediate peri operative period.

Eversion		At discharge				Total	
		Uncontrolled		Controlled			
		n	%	n	%	n	%
Pre Op	Uncontrolled	19	100	0	0	19	61.3
	Controlled	6	50	6	50	12	38.7
Total		25	80.6	6	19.4	31	100

P=0.031

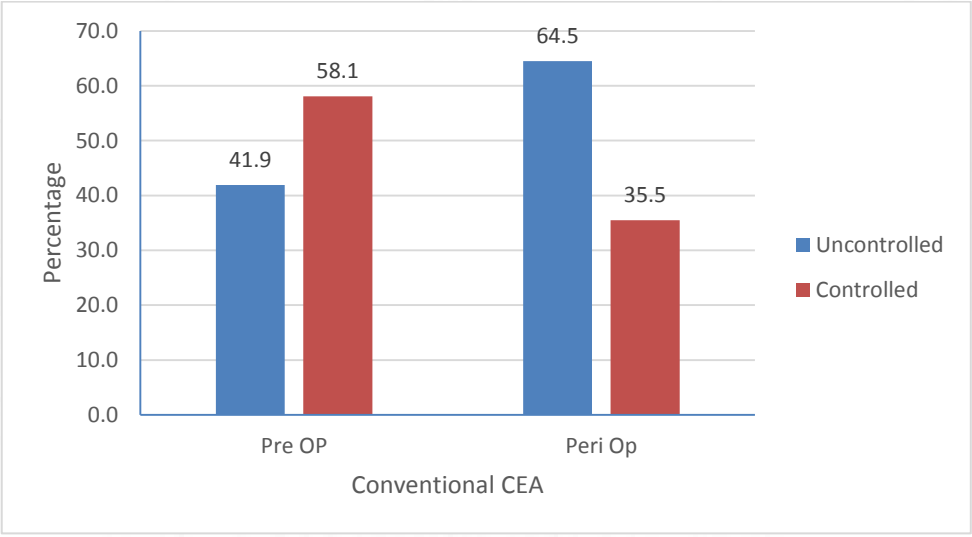


Significant increase in the number of patients with uncontrolled HTN at discharge after conventional CEA

Pre-operatively 41.9% of patients had uncontrolled hypertension and 58.1% had controlled hypertension prior to conventional CEA. After surgery in immediate perioperative period 64.5% of patients had uncontrolled hypertension and 35.5% of patients had controlled HTN. The change in blood pressure occurring after surgery was statistically significant (p value 0.039) which means that there is a significant increase in the number of patients with uncontrolled HTN post conventional CEA in immediate peri operative period.

Conventional		At discharge				Total	
		Uncontrolled		Controlled			
		n	%	n	%	n	%
Pre Op	Uncontrolled	12	92.3	1	7.7	13	41.9
	Controlled	8	44.4	10	55.6	18	58.1
Total		20	64.5	11	35.5	31	100

P=0.039

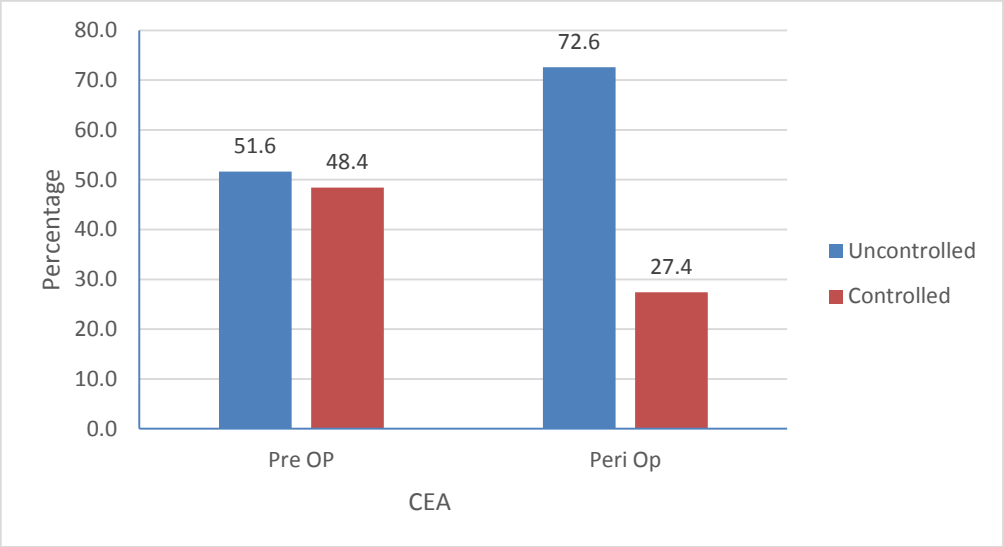


Overall increase in the number of patients with uncontrolled HTN at discharge irrespective of the technique of CEA

Preoperatively 51.6 % of patients had uncontrolled hypertension and 48.4 % had controlled hypertension prior to CEA. After surgery in immediate perioperative period 72.6 % of patients had uncontrolled hypertension and 27.4 % of patients had controlled HTN. The change in blood pressure occurring after surgery was statistically significant (p value 0.001) which means that there is a significant increase in the number of patients with uncontrolled HTN post CEA in immediate peri operative period. Thus it was found that there was significant increase in the number of patients with uncontrolled hypertension after CEA irrespective of the technique used for CEA.

Total		At discharge				Total	
		Uncontrolled		Controlled			
		n	%	n	%	n	%
Pre-Op	Uncontrolled	31	96.9	1	3.1	32	51.6
	Controlled	14	46.7	16	53.3	30	48.4
Total		45	72.6	17	27.4	62	100

P=0.001

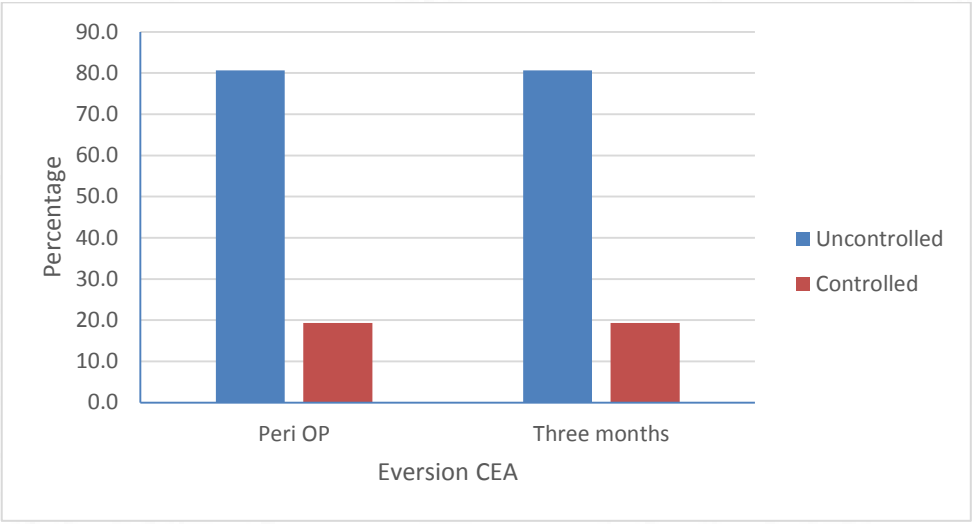


Follow up of patients with uncontrolled HTN 3 months after eversion CEA

After eversion CEA 80.6 % of patients had uncontrolled hypertension and 19.4% had controlled hypertension at the time of discharge. At 3 months of follow up it was found that same number patients ie 80.6% and 19.4% had uncontrolled and controlled HTN, respectively. There was no statistically significant change in the blood pressure of patients after surgery and at 3 months (p value 1) which means those patients with elevated BP post CEA remained same with high BP even at 3 months. This indicates the longterm impact of CEA on baseline HTN

Eversion		Three months				Total	
		Uncontrolled		Controlled			
		n	%	n	%	n	%
Peri Op	Uncontrolled	24	96	1	4	25	80.6
	Controlled	1	16.7	5	83.3	6	19.4
Total		25	80.6	6	19.4	31	100

P=1.00

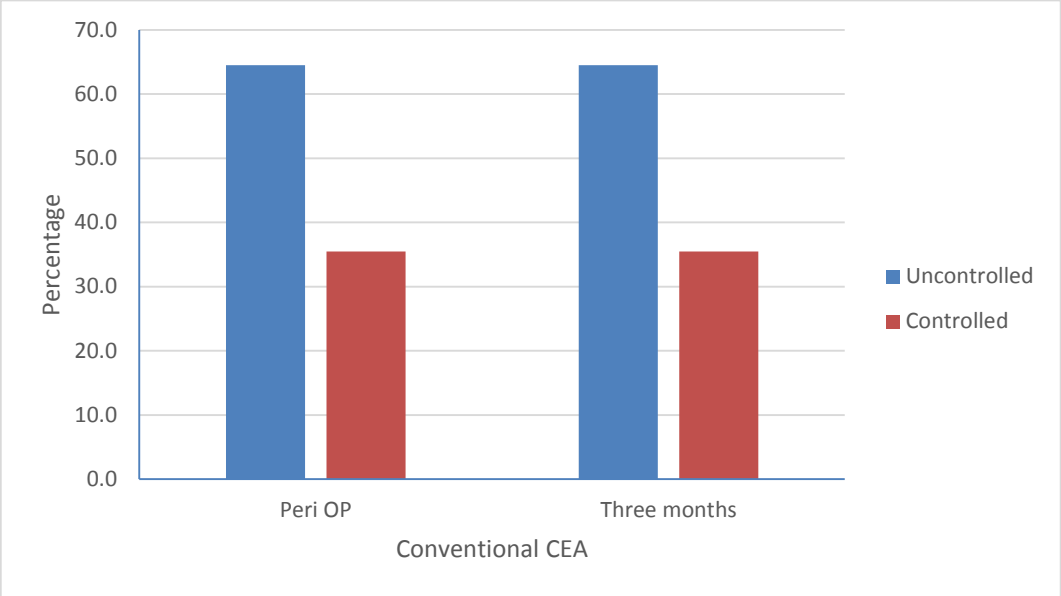


Follow up of patients with uncontrolled HTN 3 months after conventional CEA

After conventional CEA 64.5 % of patients had uncontrolled hypertension and 35.5% had controlled hypertension at the time of discharge. At 3 months of follow up it was found that same number patients ie 64.5% and 35.5 % had uncontrolled and controlled HTN, respectively. There was no statistically significant change in the blood pressure of patients after discharge and at 3 months (p value 1) which means those patients with elevated BP post conventional CEA remained same with high BP even at 3 months. This indicates the longterm impact of conventional CEA on baseline HTN.

Conventional		Three months				Total	
		Uncontrolled		Controlled			
		n	%	n	%	n	%
Peri Op	Uncontrolled	20	100	0	0	20	64.5
	Controlled	0	0	11	100	11	35.5
Total		20	64.5	11	35.5	31	100

P=1.00



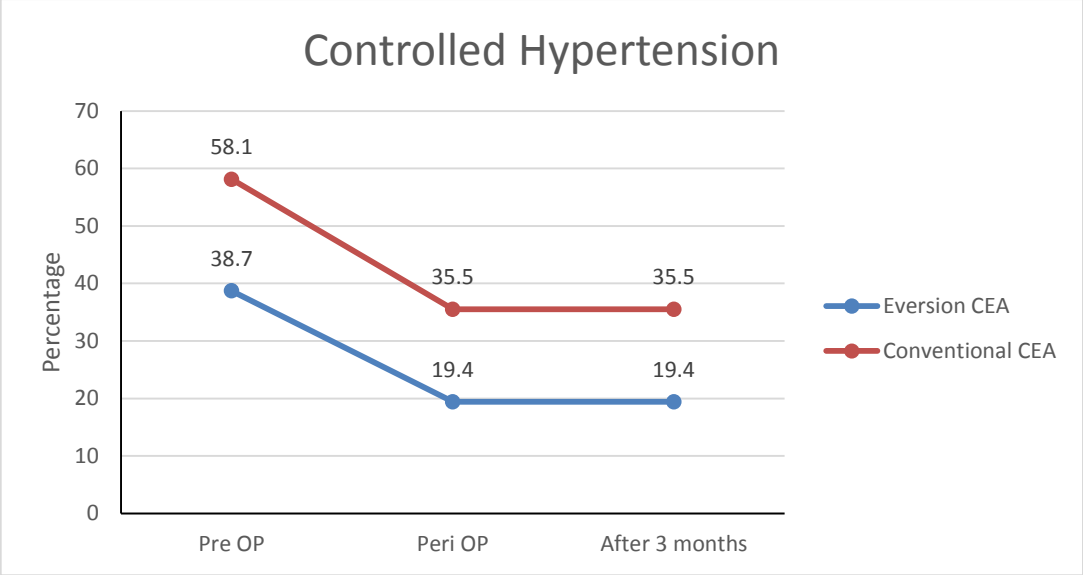
Does the technique of CEA (Eversion vs Conventional) affected the overall increase in the number of patients with uncontrolled HTN ?

The number of patients with controlled hypertension after eversion and conventional CEA were followed in perioperative period and at three months following surgery. The distribution of patients with controlled hypertension were plotted over a graph to know the general trend of BP which showed a decrease in the number of patients with controlled hypertension from pre operative period to perioperative period even though the decrease doesn't make a statistical significance

There were 38.7% of patients with controlled hypertension prior to eversion CEA and 58.1% of patients with controlled hypertension prior to conventional CEA. After CEA the number of patients in controlled HTN group decreased to 19.4% in eversion CEA and 35.5% in conventional CEA and at 3 months after surgery the number of controlled HTN patients remained same as peri operative period.

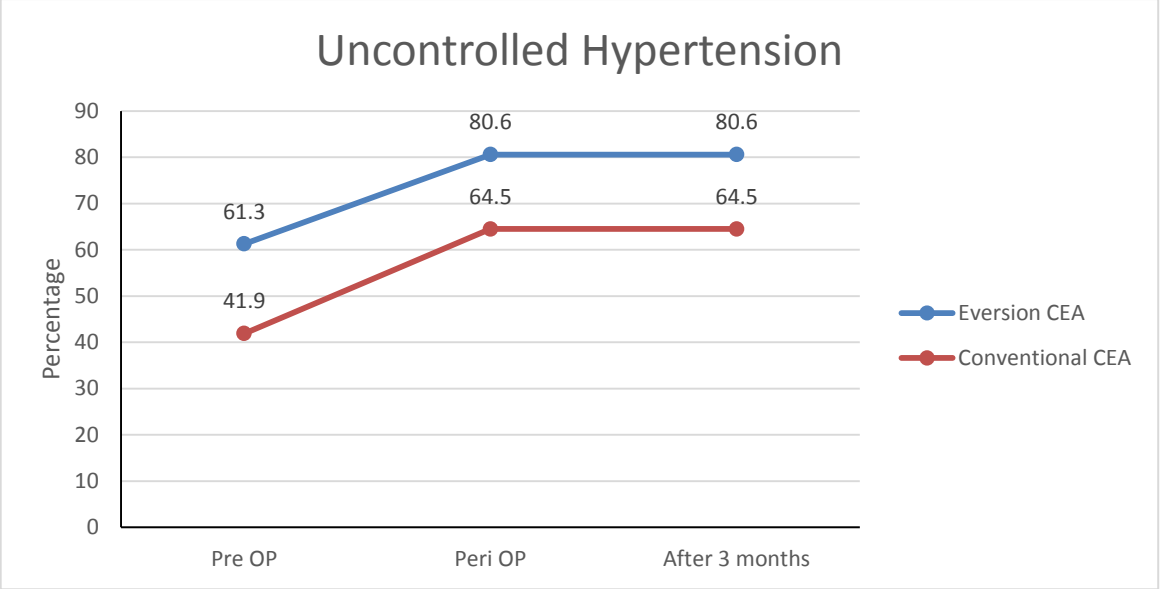
This decrease in the number of patients were happening in both eversion and conventional group but the analysis using BP recordings at fixed interval showed no statistical difference (p value 0.127,0.155).

	Eversion		Convention		p	OR	95% CI for OR	
	N	%	N	%			L	U
Controlled HTN Pre OP	12	38.7	18	58.1	0.127	2.19	0.79	6.05
Controlled HTN Post OP	6	19.4	11	35.5	0.155	2.29	0.72	7.28
Controlled HTN after 3 months	6	19.4	11	35.5	0.155	2.29	0.72	7.28



Similarly, there were 61.3% of patients with uncontrolled hypertension prior to eversion CEA and 41.9 % of patients with controlled hypertension prior to conventional CEA. After CEA the number of patients in controlled HTN group increased to 80.6 % in eversion CEA and 64.5 % in conventional CEA and at 3 months after surgery the number of uncontrolled HTN patients remained same as in peri operative period. This increase in the number of patients were happening in both eversion and conventional group ie. there was no statistical difference in the increase in the number of uncontrolled HTN patients between the two techniques of eversion and conventional CEA. (p value 0.127,0.155) .

	Eversion		Convention		p	OR	95% CI for OR	
	N	%	N	%			L	U
Uncontrolled HTN Pre OP	19	61.3	13	41.9	0.127	2.19	0.79	6.05
Uncontrolled HTN Peri OP	25	80.6	20	64.5	0.155	2.29	0.72	7.28
Uncontrolled HTN after 3 months	25	80.6	20	64.5	0.155	2.29	0.72	7.28



61.3% and 38.7% of patients had uncontrolled HTN in eversion and conventional CEA group in preoperative period remained same in postoperative period also. 19.4% and 32.3% of patients had controlled HTN in eversion and conventional CEA group preoperative period remained same in postoperative period. 19.4% and 25.8% of patients in eversion and conventional CEA group had controlled HTN in preoperative period had uncontrolled in postoperative period.

Change in Bp Pre to Post op	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Uncontrolled HTN in Pre-operative and Postoperative period	19	61.3	12	38.7	31	50	3.866	3	0.276
Uncontrolled HTN in Preoperative period to Controlled HTN in Postoperative period.	0	0	1	3.2	1	1.6			
Controlled HTN in Preoperative period to Uncontrolled HTN in Postoperative period	6	19.4	8	25.8	14	22.6			
Controlled HTN in Pre-operative period and Post-operative period	6	19.4	10	32.3	16	25.8			
Total	31	100	31	100	62	100			

77.4% and 64.5% of patients had uncontrolled HTN in eversion and conventional CEA group in postoperative period remained same at 3 months also. 16.1% and 35.5% of patients had controlled HTN in eversion and conventional CEA group post-operative period remained same at 3 months. Only 3.2% in eversion group and none of the patient in conventional group change in BP between controlled and uncontrolled HTN and vice versa from post-operative period to 3 months

Change in Bp Peri to 3 months	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Uncontrolled HTN in Post-operative period and at 3 Months	24	77.4	20	64.5	44	71	4.614	3	0.202
Uncontrolled HTN in Post-operative period to Controlled HTN at 3 Months	1	3.2	0	0	1	1.6			
Controlled HTN in Post-operative period to Uncontrolled HTN at 3 Months	1	3.2	0	0	1	1.6			
Controlled HTN in Post-operative period and 3 at months	5	16.1	11	35.5	16	25.8			
Total	31	100	31	100	62	100			

58.1% and 38.7% of patients had uncontrolled HTN in eversion and conventional CEA group remained same in preoperative, post-operative and at 3 months period. 16.1% and 32.3% of patients had controlled HTN in eversion and conventional CEA group remained same in preoperative, post-operative and at 3 months period. 19.4% and 25.8 % of patients had controlled HTN in eversion and conventional CEA group preoperative period changed to uncontrolled HTN group in postoperative period and at 3 months but only very less number of patients ie 3.2% had change in BP between controlled and uncontrolled HTN and vice versa from post-operative period to 3 months.

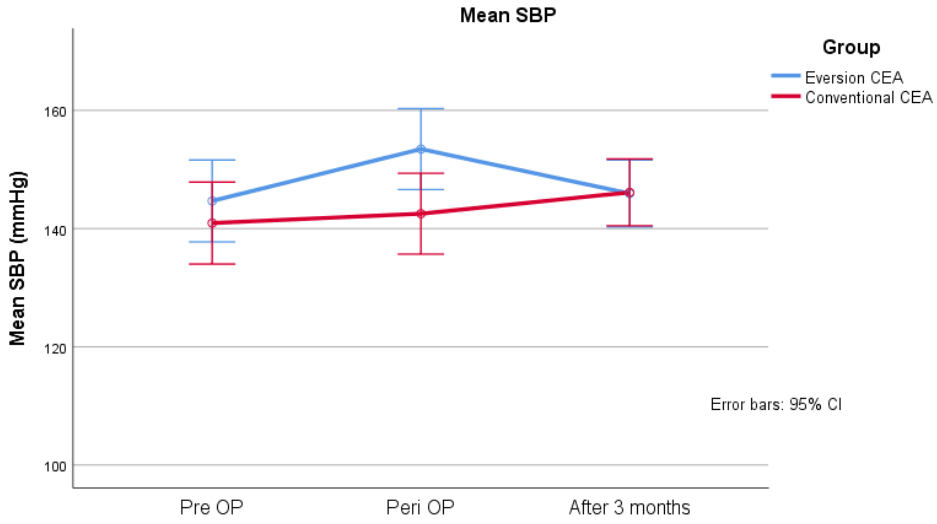
Change in Bp Pre to Peri to 3 months	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Uncontrolled HTN in preoperative, postoperative period and at 3 months	18	58.1	12	38.7	30	48.4	6.152	5	0.292
Uncontrolled HTN in Pre and Postoperative period, Controlled at 3 months	1	3.2	0	0	1	1.6			
Uncontrolled HTN in Preoperative period, Controlled HTN in Postoperative period and at 3 months.	0	0	1	3.2	1	1.6			
Controlled HTN in Preoperative period, uncontrolled HTN in Postoperative period and at 3 Months	6	19.4	8	25.8	14	22.6			
Controlled HTN in Pre and Post-operative period, uncontrolled at 3 Months	1	3.2	0	0	1	1.6			
Controlled HTN pre, post-operative period and at 3 months	5	16.1	10	32.3	15	24.2			
Total	31	100	31	100	62	100			

Fixed interval BP recordings in immediate perioperative period for the assessment of Post endarterectomy hypertension-Disadvantages

The mean SBP, DBP and MAP recording of the individual patients in eversion and conventional CEA in pre-operative, peri operative and 3 months after surgery were calculated. The statistical significance of change in mean BP recordings from pre-operative period to post-operative period at the time of discharge and 3 months post-surgery were calculated in eversion and convention group. These changes in mean BP recording were plotted over time to know the general trend as given below.

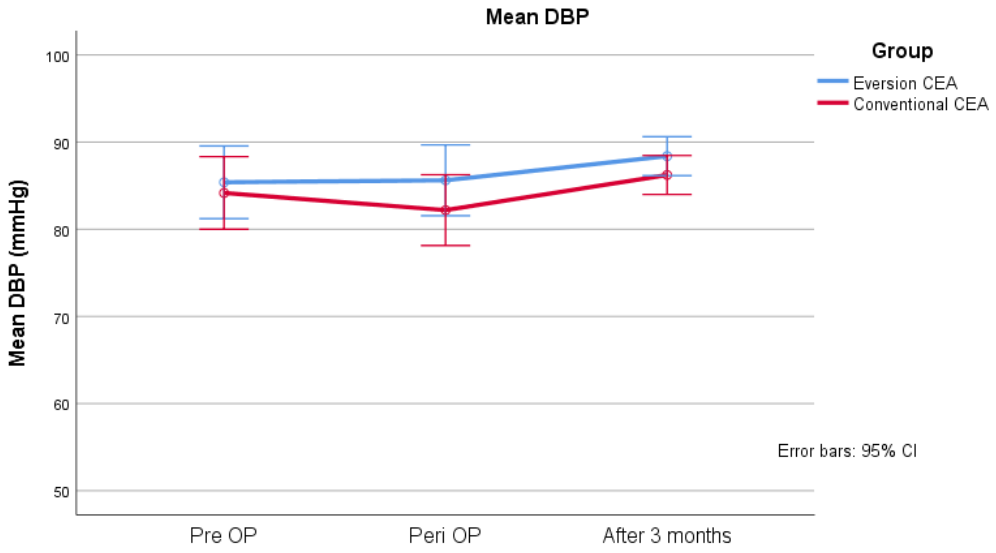
The mean SBP increased from 144.7 ±19.7 in pre-operative period to 153±22 in peri operative period in evrsion group and 140±18.9 in pre-operative period to 142.5±15.5 22 in peri operative period in conventional group, but this change was happening in both group without any statistical significant difference (p value 0.099 in eversion, p value 0.590). Similarly the mean SBP decreased from 153±22 in peri operative period to 145.9±13.9 at 3 months post-surgery in eversion group and increased from 142.5±15.5 in perioperative period to 146.1±17.3 at 3 months post-surgery in conventional group but this change was also not statistically significant.

SBP	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre-Operative	144.7	19.7	140.9	18.9	0.764	0.448
Peri Operative	153.5	22.0	142.5	15.5	2.260	0.027
After 3 months	145.9	13.9	146.1	17.3	-0.048	0.962
P value of Significant Change in SBP from preop to periop	0.099		0.590			
P value of Significant Change in SBP from periop to 3 months	0.134		0.266			



The mean DBP increased from 85.4 ±9.1 in pre-operative period to 85.6±11.2 in peri operative period in evrsion group and decreased from 84.2±13.7 in pre-operative period to 82.2±11.4 in peri operative period in conventional group, but this change was happening in both group without any statistical significant difference (p value 0.923 in eversion, p value 0485). Similarly the mean SBP increased from 85.6±11.2 in peri operative period to 88.4±5 at 3 months post-surgery in eversion group and increased from 82.2±11.4 in perioperative period to 86.2±7.2 at 3 months post-surgery in conventional group but this change was also not statistically significant(p value 0.139 in eversion, p value 0.066 in convention)

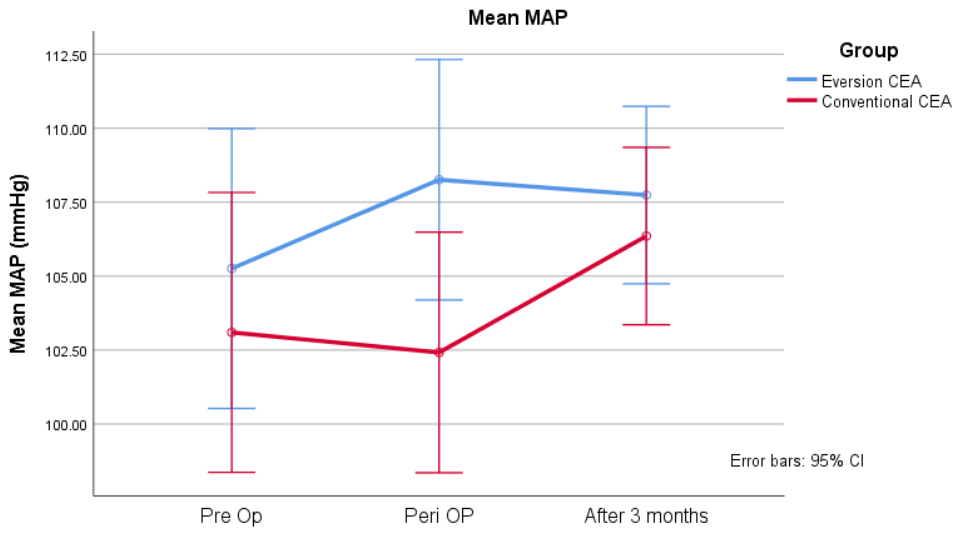
DBP	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre-Operative	85.4	9.1	84.2	13.7	0.416	0.679
Peri Operative	85.6	11.2	82.2	11.4	1.191	0.238
After 3 months	88.4	5.0	86.2	7.2	1.369	0.176
P value of Significant Change in DBP from preop to periop	0.923		0.485			
P value of Significant Change in DBP from periop to 3 months	0.139		0.066			



The mean of MAP increased from 105.3 ±11.4 in pre-operative period to 108.3 ±11.6 in peri operative period in eversion group and decreased from 103.1±14.7 in pre-operative period to 102.4±11.0 in peri operative period in conventional group, but this change was happening in both group without any statistical significant difference (p value 0.246 in eversion, p value 0.796). Similarly, the mean of MAP decreased from 109.3±11.6 in peri operative period to 107.7±6.8 at 3 months post-surgery in eversion group and increased from 102.4±11. in perioperative period to 106.4 ± 9.7 at 3 months post-surgery in

conventional group but this change was also not statistically significant (p value 0.81 in eversion, p value 0.066 in convention)

MAP	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre-Operative	105.3	11.4	103.1	14.7	0.646	0.521
Peri Operative	108.3	11.6	102.4	11.0	2.031	0.047
After 3 months	107.7	6.8	106.4	9.7	0.654	0.515
P value of Significant Change in MBP from preop to periop	0.246		0.796			
P value of Significant Change in MBP from periop to 3 months	0.81		0.066			



Vasodilator dose in immediate perioperative period for the assessment of Post endarterectomy hypertension- Advantages

Since in the immediate post op period BP of all patients were maintained below 140/90 by titrating the dose of vasodilators, the PEH analysis with mean BP won't reflect the true post op HTN. So rather than analyzing the mean BP of the patients, we have calculated the dose of vasodilator in every hour required to maintain the normal BP and then calculated the total dose of vasodilators for each patient. This increased dose and duration of vasodilator indirectly indicates the severity of HTN post-surgery which was

taken as a measurement of PEH .The vasodilator requirement of each patients in eversion and convention group were separately analyzed for any statistical significant difference between two groups.

The mean dose of NTG used in eversion CEA were 78.8±64.4 mg and in conventional CEA were 75.4±63.5 mg. The duration of NTG used in eversion CEA were 17±10 hrs and in conventional CEA 13±8 hrs. There is no statistical significant difference in the mean dose and duration of NTG used in eversion CEA and conventional CEA (p value 0.882 &0.313).

	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
NTG DOSE	78.864	63.5447	75.459	63.4561	0.178	0.86
NTG DTN	17.73	10.561	13.82	8.016	1.383	0.174
SNP DOSE	107.52	69.2348	41.333	22.0303	1.564	0.169
SNP DTN	18	9.798	10	5.292	1.279	0.248

As described earlier the PEH analysis was done classifying patients whether they required iv vasodilator in perioperative period or not. 87.1% of patients after eversion CEA and 74.2% of patients after conventional CEA developed PEH and there is no statistical significant difference in the incidence of PEH between two groups(p value 0.199).So the technique of surgery had no impact on development of PEH.

PEH	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Absent	4	12.9	8	25.8	12	19.4	1.653	1	.199
Present	27	87.1	23	74.2	50	80.6			
Total	31	100.0	31	100.0	62	100.0			

Then we compared whether those patients requiring increased vasodilator in immediate post op with the patients having increased BP at the time of discharge (p value 0.039 and 0.050) but there is no significant association between increased BP at 3 months and increased vasodilator requirement in immediate perioperative period. This analysis shows that baroreceptor failure occurring after CEA is short lasting otherwise those patients with increased vasodilator requirement in immediate perioperative period will remain hypertensive at 3 months also, but some unknown mechanism is involved in the development of long term HTN.

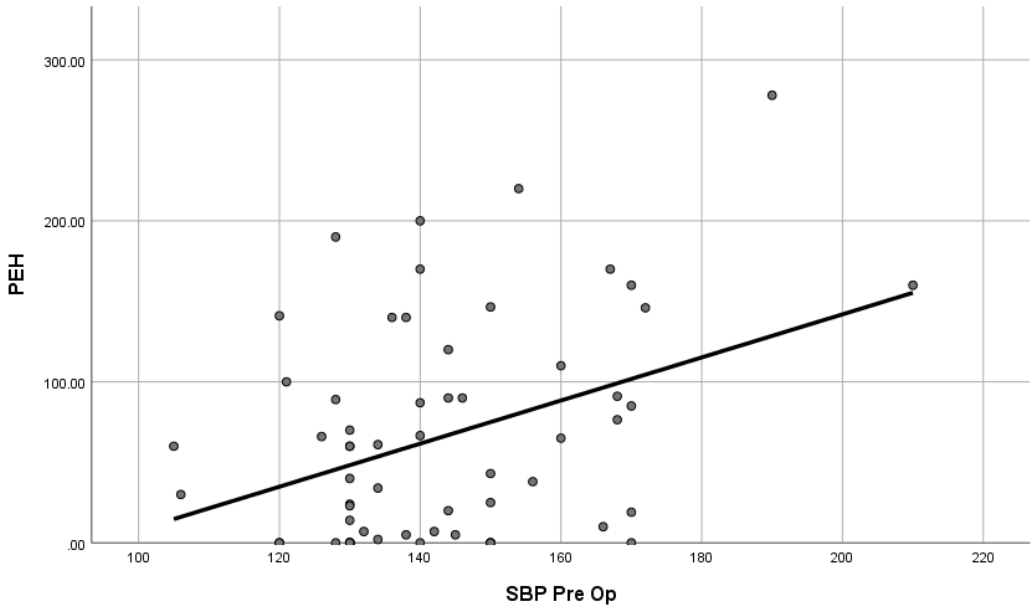
	HTN	N	NTG Dose		p
			Mean	sd	
At Discharge	Uncontrolled	34	87.7	66.3	0.039
	Controlled	10	41.5	29.6	
At 3 months	Uncontrolled	34	85.3	67.7	0.114
	Controlled	10	49.5	30.1	

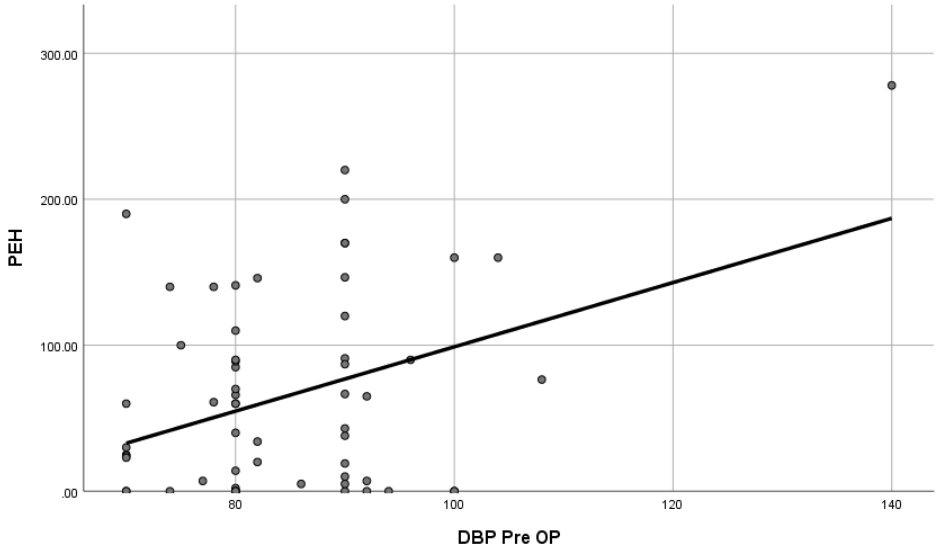
		N	NTG Duration		p
			Mean	sd	
At Discharge	Uncontrolled	34	17.21	9.88	0.050
	Controlled	10	10.9	6.064	
At 3 months	Uncontrolled	34	16.71	10.008	0.233
	Controlled	10	12.6	6.867	

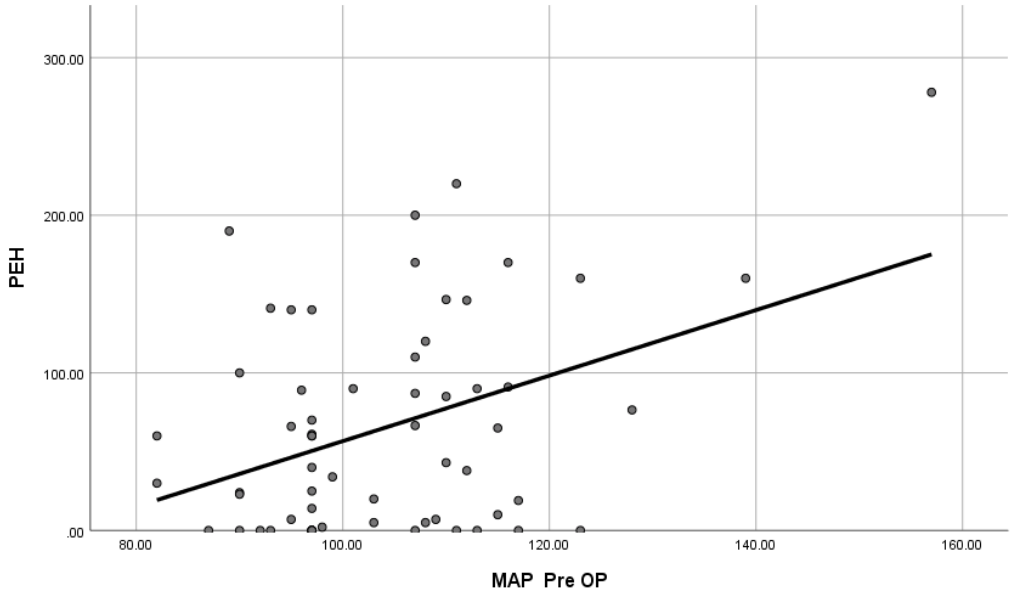
Pre operative SBP,DBP and MAP and it relationship with PEH

Those patients with uncontrolled hypertension in preoperative period were optimized using oral antihypertensives and taken up for surgery. After surgery we looked into whether the same patients are developing uncontrolled hypertension post-surgery using Karl Pearson correlation coefficient. Since all r value more than 0 and all p values less than 0.05 which shows that those patients having high SBP, DBP and MAP are having more chance of getting PEH in post op

Correlation of PEH with PreOP SBP, Pre OP DBP and Pre OP MAP	Karl Pearson coefficient of Correlation	
	r	p
SBP	0.38	0.002
DBP	0.375	0.003
MAP	0.402	0.001





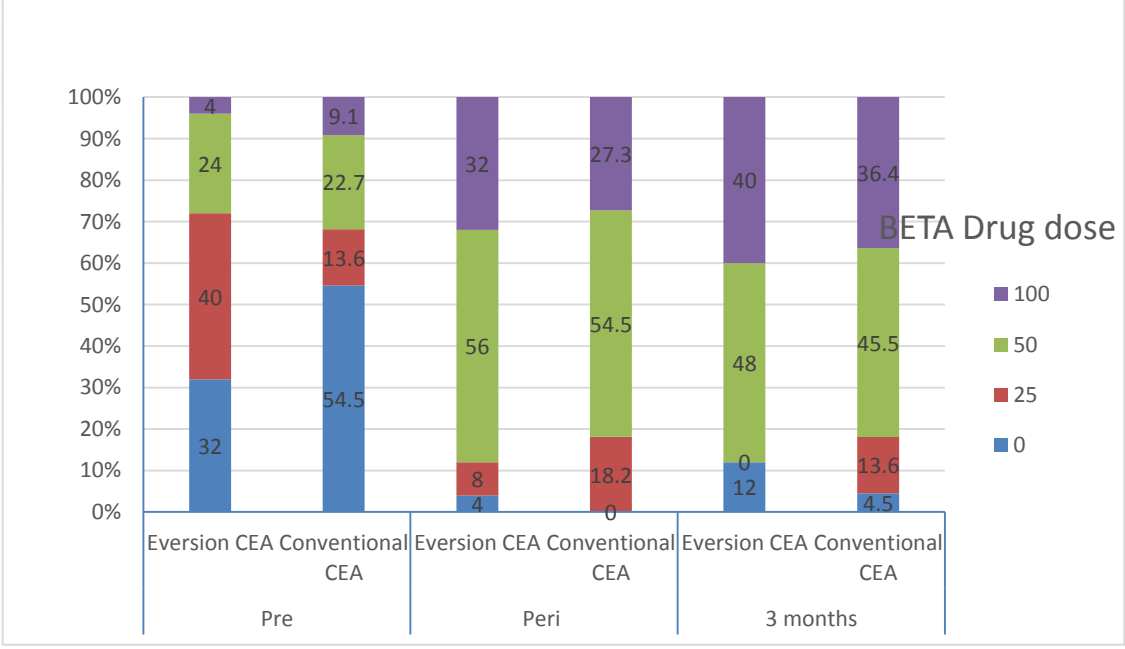


How does PEH alters the antihypertensive medications for essential HTN – A 3 months follow up

This analysis was done by calculating the dose of antihypertensive in each class for eg betablockers preoperatively and comparing with their dosage at discharge and 3 months after surgery. It is worth mentioning that when a patient develops HTN in post-operative period, then same class of antihypertensive is started in post op. when the maximum dose is attained, then only a new class of antihypertensives are added. For the study purpose increase in dose of same antihypertensive as well addition of new class of antihypertensive is considered as indirect evidence of uncontrolled HTN in post-operative period.

The mean dose of oral beta blocker was 18.95±26.66 mg in pre-operative period was increased to 45.766±35.85 at the time of discharge and this change in dose was statistically significant (p value 0.000). Three months after discharge the mean dose of beta blocker was 47.58±38.864 which was not significantly different from the dose at the time of discharge(p value 0.585). This shows that after CEA there is a significant increase in the dose antihypertensive medications and the effect lasted till 3 months follow up.

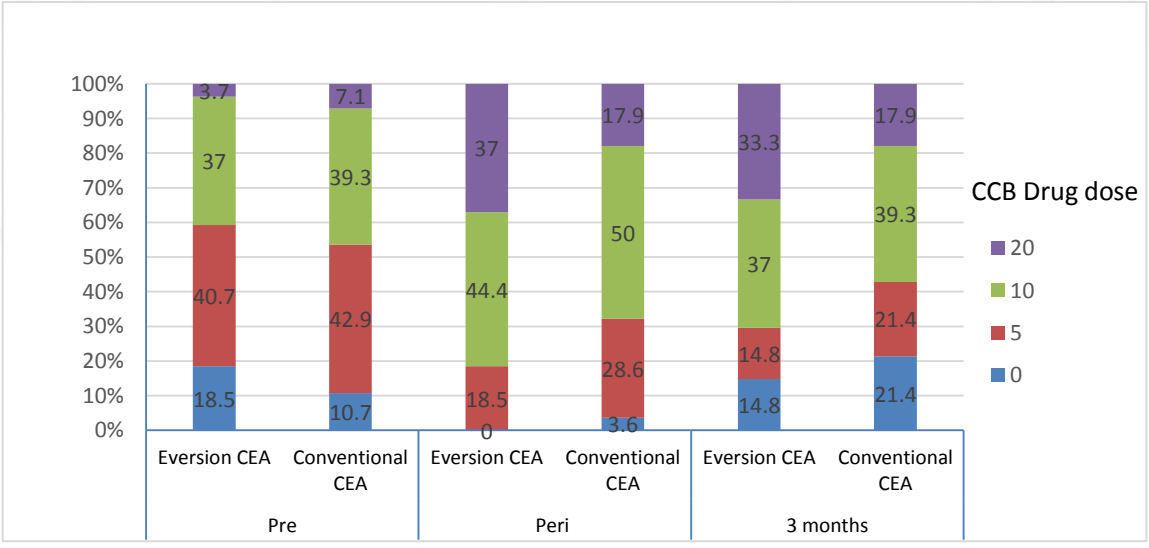
	Beta Blocker Dose	Pre operative		At discharge		At 3 months	
		n	%	n	%	n	%
Eversion	0	8	32	1	4	3	12
	25mg	10	40	2	8	0	0
	50mg	6	24	14	56	12	48
	100mg	1	4	8	32	10	40
	Total	25	100	25	100	25	100
Conventional	0	12	54.5	0	0	1	4.5
	25	3	13.6	4	18.2	3	13.6
	50	5	22.7	12	54.5	10	45.5
	100	2	9.1	6	27.3	8	36.4
	Total	22	100	22	100	22	100



BETA	Total (n=62)		Paired comparison	p
	mean	sd		
Pre-Operative	18.95	26.66	Pre-Operative Vs At discharge	0.000
At discharge	45.766	35.8549	Pre-Operative VS 3 months	0.000
After 3 months	47.58	38.864	Peri Operative Vs 3 months	0.585

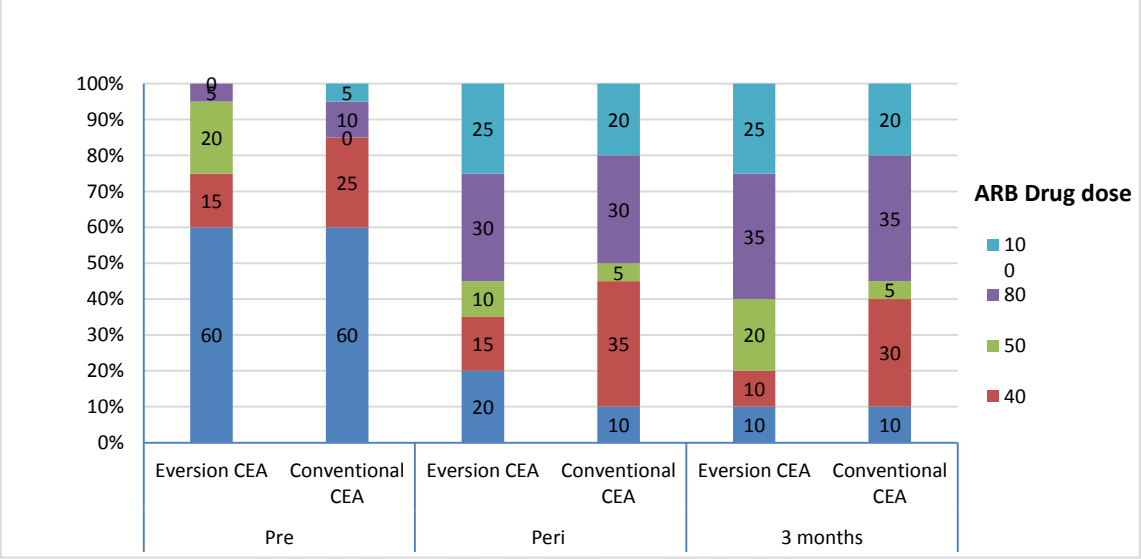
Similar analysis were done with calcium channel blockers(CCB), angiotensin receptor blockers (ARB) and found that there was statistically significant increase in the dose of respective oral anti hypertensives from pre-operative period to post surgery at the time of discharge and the effect persisted for 3 months of follow up.

	CCB Dose	Pre		Peri		3 Months	
		n	%	n	%	n	%
Eversion	0	5	18.5	0	0	4	14.8
	5	11	40.7	5	18.5	4	14.8
	10	10	37	12	44.4	10	37
	20	1	3.7	10	37	9	33.3
	Total	27	100	27	100	27	100
Convension	0	3	10.7	1	3.6	6	21.4
	5	12	42.9	8	28.6	6	21.4
	10	11	39.3	14	50	11	39.3
	20	2	7.1	5	17.9	5	17.9
	Total	28	100	28	100	28	100



CCB	Total (n=62)		Paired comparison	p
	mean	sd		
Pre-Operative	6.21	5.0761	Pre-Operative Vs Peri Operative	0.000
Peri Operative	9.798	6.8097	Pre-Operative VS 3 months	0.018
After 3 months	8.992	8.3649	Peri Operative Vs 3 months	0.396

	ARB Dose	Pre		Peri		3 Months	
		n	%	n	%	n	%
Eversion	0	12	60	4	20	2	10
	40	3	15	3	15	2	10
	50	4	20	2	10	4	20
	80	1	5	6	30	7	35
	100	0	0	5	25	5	25
	Total	20	100	20	100	20	100
Convension	0	12	60	2	10	2	10
	40	5	25	7	35	6	30
	50	0	0	1	5	1	5
	80	2	10	6	30	7	35
	100	1	5	4	20	4	20
	Total	20	100	20	100	20	100

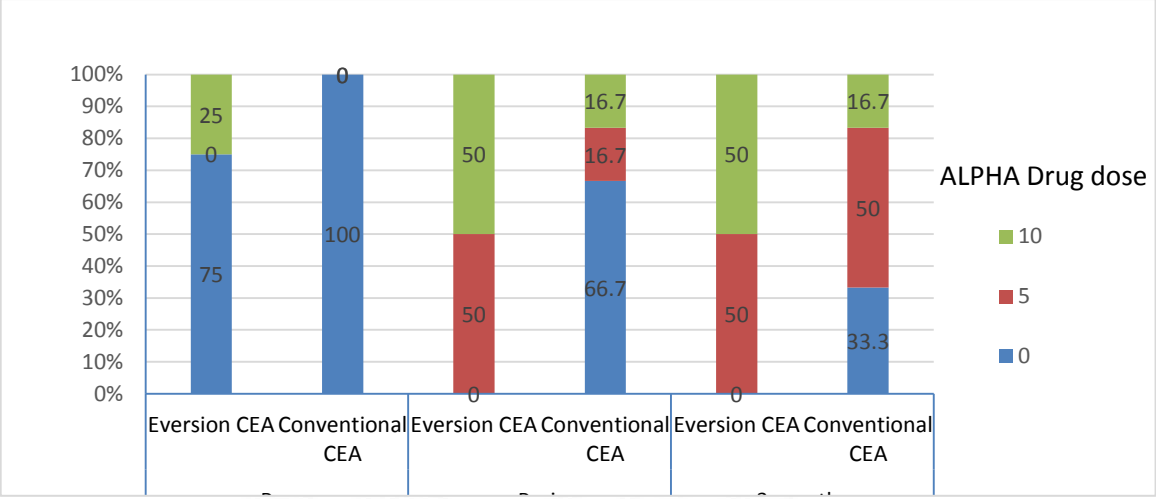


ARB	Total (n=62)		Paired comparison	p
	mean	sd		
Pre-Operative	14.03	25.891	Pre-Operative Vs Peri Operative	0.000
Peri Operative	38.23	40.134	Pre-Operative VS 3 months	0.000
After 3 months	41.13	40.198	Peri Operative Vs 3 months	0.373

Post endarterectomy HTN is better controlled in patients on preoperative Alpha blockers

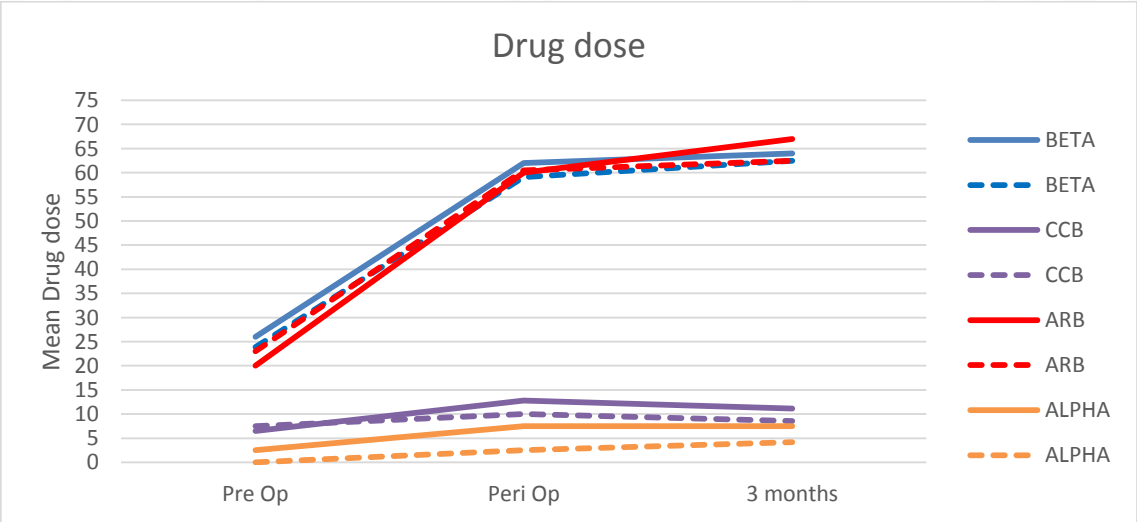
Similar analysis with alpha blocker showed that those patients maintained on alpha blocker didn't showed any statistical significant increase in dose of antihypertensives at the time of discharge and at 3 months follow up. This shows that those patients with BP well controlled with alpha blockers pre operatively are better controlled in post operatively and at 3 months. This indirectly shows that the impact of CEA on sympathetic system which was nullified by the alpha blocker in post operative period.

	ALPHA Dose	Pre		Peri		3 Months	
		n	%	n	%	n	%
Eversion	0	3	75	0	0	0	0
	5	0	0	2	50	2	50
	10	1	25	2	50	2	50
	Total	4	100	4	100	4	100
Convension	0	6	100	4	66.7	2	33.3
	5	0	0	1	16.7	3	50
	10	0	0	1	16.7	1	16.7
	Total	6	100	6	100	6	100



ALPHA	Total (n=62)		Paired comparison	p
	mean	sd		
Pre-Operative	0.16	1.27	Pre-Operative Vs Peri Operative	0.271
Peri Operative	3.74	25.409	Pre-Operative VS 3 months	0.275
After 3 months	5.484	38.073	Peri Operative Vs 3 months	0.290

Overall increase in the mean dose of antihypertensive medication from the time of surgery to 3 months post op



Does the technique of CEA affect the antihypertensive medications after surgery – A 3 months follow up

The change in mean dose of each class of oral antihypertensives in beta blockers, calcium channel blockers (CCB), angiotensin receptor blockers (ARB) and alpha blockers were separately analyzed for both eversion and conventional CEA. The increase in mean dose from pre-operative period to that at the time of discharge and 3 months were tested for any statistical significance found that all the p values are > 0.05. This shows that there is no significant difference in the increase of antihypertensive dose between eversion and conventional CEA

BETA	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre Operative	38.2	20.0	52.5	27.5	-1.557	0.132
Peri Operative	64.6	26.5	58.5	28.2	0.752	0.456
After 3 months	71.6	24.8	65.5	29.0	0.745	0.461

CCB	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre Operative	7.7	3.9	8.6	4.5	-0.708	0.483
Peri Operative	12.1	5.6	10.8	6.3	0.835	0.408
After 3 months	12.5	5.8	12.3	8.8	0.103	0.919

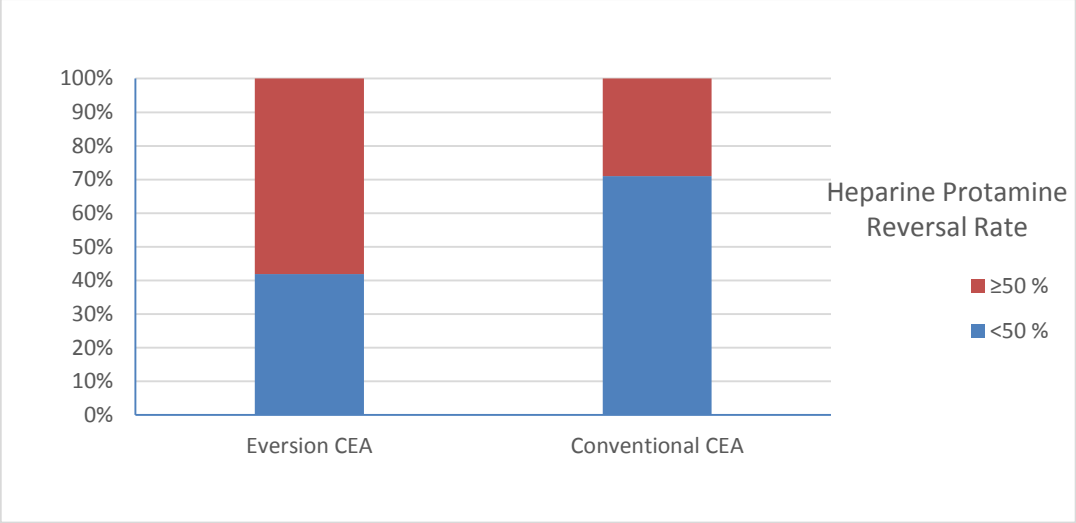
ARB	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre Operative	51.3	13.6	57.5	24.9	-0.623	0.543
Peri Operative	73.4	27.6	66.4	26.3	0.761	0.452
After 3 months	73.1	26.0	68.6	25.7	0.517	0.609

ALPHA	Eversion (n=31)		Convention (n=31)		t	p
	mean	sd	mean	sd		
Pre Operative	10.0	.	.	.		
Peri Operative	54.8	96.9	6.5	5.0	0.664	0.543
After 3 months	80.0	146.7	5.0	3.5	1.022	0.346

HEPARIN PROTAMINE REVERSAL AFTER CEA

Heparin given before carotid clamping were routinely neutralized with protamine at the end of surgery in both conventional and eversion CEA. 1mg of heparin =100U and 1mg of protamine is used to neutralize the effect of 1mg of Heparin ie 1:1 ratio or 100% reversal. Those patients who received less than half the dose of protamine to neutralize the heparin were classified into less than half reversal group and those who received more than half the dose to full dose of protamine to neutralize the effect of heparin were classified into half to full reversal group. It was found that more number of patients received half to full reversal with protamine in eversion CEA (eversion CEA 58% (n=18); vs conventional CEA 29%(n=9); whereas less than half dose of protamine were received in majority of patients with conventional CEA (conventional CEA 71% (n=22); vs eversion CEA 41.9 %(n=13); p value <0.021)

Heparine Protamine Reversal Rate	Eversion		Convention		Total		χ^2	df	p
	N	%	N	%	N	%			
Less than half reversal	13	41.9	22	71.0	35	56.5	5.314	1	.021
half to full reversal	18	58.1	9	29.0	27	43.5			
Total	31	100.0	31	100.0	62	100.0			



Heparin Protamine reversal and its relationship to postoperative bleeding after CEA The difference in the heparin protamine reversal in eversion and conventional group were separately analyzed to find out any association with post-operative complications like bleeding, hematoma, re-exploration, stroke and post-operative MI and found that heparin protamine reversal has no statistical significant association with the above, even though there is significant higher dose of protamine dose is used in eversion CEA than conventional CEA.

		N	Heparine Protamine Reversal Rate (%)		p
			Mean	sd	
Bleeding	0	62	34.63	26.34	
Hematoma	No	61	34.54	26.55	0.839
	Yes	1	40.00	.	
STROKE	No	60	34.00	26.54	0.306
	Yes	2	53.55	5.02	
Death	No	62	34.63	26.34	
CARDIAC	No	60	35.07	26.38	0.477
	Yes	2	21.45	30.33	
TIA	No	61	35.19	26.18	0.187
	Yes	1	0.00	.	
REEXPLORATION	No	61	34.54	26.55	0.839
	Yes	1	40.00	.	

DISCUSSION

In our study all eversion CEA were performed by Kasprzak-Raithel-Vanmaele modification[11]. Patients in the two study groups were well balanced for overall demographic characteristics and comorbidities. All conventional CEA were performed with intra cerebral shunting shunt and patch closure preferably supramalleolar GSV whereas all eversion endarterectomies were performed without shunt. The mean age of the study population was (61.0±9.2 years in eversion group and 63.3±9.6 years in conventional group (p value 0.342) equally balanced in both study group. The age distribution is very important because it was believed that advanced age represents a high-risk factor for CEA, but later on meta-analysis from 20 institutional series and over 3000 elderly patients, with a minimum age of 75 or 80 who underwent CEA, showed that perioperative stroke rate was 2.2% and the mortality rate was 1.5%. A recent subgroup analysis of NASCET data showed that patients 75 years and older with 50% to 99% symptomatic carotid stenosis had greater benefit from CEA than younger patients[42]. The distribution of female patients were also equal in both arms (67.7% females in eversion CEA group and 83.9% females in conventional CEA) so that it won't come as a distribution bias because previously ACAS study showed that the CEA benefit of 5-year ipsilateral stroke reduction rate were less for women than in men (4.1% vs. 7.3%).

The risk factors like smoking, dyslipidemia, Coronary artery disease, diabetes, hypertension both controlled and uncontrolled, COPD, CKD, thyroid dysfunction, POAD, unilateral and bilateral ICA disease, severity of stroke assessed by NIHSS and mRS score were equally distributed between two study population(p value >0.05) .

The primary endpoint of study showed that there were no statistically significant differences in major stroke/carotid occlusion (3.2%(n=1) in eversion CEA and 3.2%(n=1) in conventional CEA) between two study groups(p = 0.3). There was no stroke related death (n=0) in either eversion or conventional group. In EVEREST trial also there is no significant differences between the rate of perioperative major stroke and death between two study group (1.3% for each study group)[23].

The secondary endpoint of the study showed no significant difference in minor stroke, TIA, post-operative MI, hematoma, re-exploration and reperfusion syndrome between

eversion and conventional CEA. In EVEREST trial[23] also there were no difference in two groups with respect to incidence of perioperative transient ischemic accident (TIA), minor stroke, cranial nerve injuries, neck hematoma, myocardial infarction. The clamp time in eversion CEA was significantly higher in our study when compared to conventional CEA and this difference was statistically significant (eversion 20.77 ± 8.504 minutes vs conventional 34.5 ± 14.4 minutes; p = 0.001). Contrary in EVEREST trial[23], the clamp time in eversion CEA was shorter (31.7 ± 15.9 vs 34.5 ± 14.4 minutes, p = 0.02). In conventional CEA, the clamp time is calculated from time of application of ICA clamp till the insertion of carotid shunt and time from the removal of carotid shunt till removal of ICA clamp. The carotid shunt provides antegrade cerebral blood during CEA, duration of surgery performed under shunt was not taken into consideration for calculation of total clamp time in conventional CEA. Since all our conventional CEAs were performed with carotid shunt, the effective clamp time got reduced but in EVERST trial shunt was inserted only in 16% of patients in conventional CEA.

In our study none of the eversion CEA carotid shunt was used but in the eversion group of EVEREST[23], shunt was placed in 11% of patients. The reason behind no shunt for eversion CEA in our study were because of the surgeon preference. There are two school of thoughts regarding carotid shunting during CEA. Routine non shunters argue that shunt can prevent only the ischemic stroke, but it will increase the risk for embolic stroke if not performed properly. Moreover, when compared to embolic stroke, intraoperative cerebral ischemia is a relatively rare cause of intraoperative stroke. However, we are not denying the fact that when cerebral ischemia occur, it can lead to perioperative stroke. In addition, there were no significant differences in the perioperative stroke or death rate between the two groups with or without shunt. There was statistically higher rate of Cranial nerve dysfunction in eversion group as compared to conventional CEA (eversion n=6(19.4%), conventional n=1, (3.2%) p value 0.045). This may be due to the excessive dissection required for circumferential mobilization of ICA during eversion CEA. In EVERST[23] trial eversion CEA neither resulted in high rate of Nerve injuries nor caused more frequent neck hematomas compared with conventional CEA

A similar subgroup analysis of the SPACE-1[43] trial demonstrates similar 2-year outcome after E-CEA or C-CEA. However, interesting differences in the frequency of early and later complications with the 2 techniques was there. The risk of ipsilateral stroke or death within 30days after surgery was significantly higher in eversion CEA

(9% versus 3%; *P*_0.005) whereas the 2-year risk of ipsilateral stroke was significantly higher in the conventional CEA(2.9% versus 0%; *P*_0.017). These findings should be interpreted with caution noting the limitations of the post hoc, nonrandomized nature of the above analysis.

A 2001 Cochrane systematic review[15] showed no significant differences between c CEA and e CEA, except for a higher rate of late restenosis (>50%) following c CEA but 2011 updated meta-analysis[16] (involving a much larger cohort of patients from mainly non-randomized studies) suggested that e CEA conferred significant benefits relating to 30 day death, stroke, death/stroke combined, as well as lower rates of restenosis and late ipsilateral stroke. Due to the discordance between the findings of the 2001 and 2011, a further meta-analysis was undertaken in 2017[17], before concluding e CEA is preferable to c CEA. This analysis revealed an important aspect whether c CEA patients underwent primary closure or patch closure. When data from RCTs and OSs were stratified whether the conventional CEA patient underwent primary closure or patch angioplasty, all the significant benefits apparently conferred by e CEA disappeared. Compared with patch c CEA, e CEA was now not associated with significant reductions in 30-day death, death/stroke, or late >50% restenosis provided the arteriotomy is patched. In our study all patients in conventional CEA underwent patch closure with supra malleolar GSV. So similar to 2017 updated metanalysis our study also showed that patients undergoing c CEA have very similar 30-day outcomes when compared to eversion CEA. The limitation of our study is due to small sample size and not a randomized study. Moreover we were more interested in comparing hemodynamic changes following eversion CEA which we are going to describe in following sessions rather than comparing the long term restenosis and stroke rate because all these data are well available from the above all metanalysis.

The immediate postoperative hemodynamic alterations occurring after CEA is called post endarterectomy hypertension (PEH). The incidence of post endarterectomy HTN varies from 11% to 56%[29]. PEH results in prolonged hospital admission and can lead to increased peri-operative morbidity and mortality after. In our study, the incidence of PEH was 72.6 % (p value 0.001). This high incidence may be due to the fact that almost all the patients in our study had pre-operative essential HTN, among them more than half of the patients had uncontrolled hypertension. We have divided all patients with essential HTN into 2 groups: controlled HTN if <140/90 and uncontrolled HTN if

≥140/90. We found that 51.6 % of patients had uncontrolled hypertension and 48.4 % had controlled hypertension prior to CEA. After surgery the number of patients with controlled HTN decreased to 27.4% and there was significant increase in the number of patients with uncontrolled hypertension after CEA 72.6% (p value 0.001)

Next, we investigated whether the technique of CEA influenced this BP instability. In majority of studies BP reading in perioperative period was measured at fixed intervals and mean BP were analyzed to find out whether the technique of endarterectomy influenced the PEH. The cut off value for PEH varies in different studies ranging from 140/90 to 160/110[44]. Similarly we also recorded the BP in eversion and conventional CEA at pre-operative, peri operatively,at the time of discharge and 3 months after surgery and tested for any statistical significance. The Mean arterial blood pressure changes were happening in both group without any statistical significant difference to make any meaningful conclusion. This is because fixed interval BP recording in PEH analysis has an inherent drawback. Most of the centers use iv vasodilators to minimize the BP fluctuations happening in immediate post op such that BP of the patients will be tightly maintained with in normal range. So, PEH analysis using mean BP won't reflect the true fluctuations of BP in reality. The above analysis showed that if we take the mean value of BP recording made at fixed intervals before and after surgery and use it for PEH analysis, significant statistical change was not observed.

Eversion-CEA involves oblique circumferential transection of the internal carotid artery at the level of the carotid bulb, this increases the chance of sinus nerve getting transected. This may results in decreased baroreceptor sensitivity (BRS) leading to an increased sympathomimetic activity[45]. This increased sympathomimetic activity was reflected as elevated BP at least in the early postoperative period which requires iv vasodilator to normalise the BP below the target range which varies from centre to centre. So rather than analyzing with the mean BP we have measured the dose of vasodilator required to maintain the target BP of patients (in our study below 140/90) in ICU every hour and then calculated the total dose of vasodilators for each patient. This increased dose of vasodilator required to suppress the increased sympathomimetic activity because of BRS breakdown indirectly indicates the severity of PEH. The vasodilator requirement in eversion and convention group were separately analyzed for any statistically significant difference between two. The mean dose of NTG used in

perioperative period for eversion CEA were 56.0±64.4 mg and in conventional CEA were 53.6±63.5 mg. The duration of NTG used in eversion CEA were 12.6±12 hrs and 9.8±9.3 hrs. In our study it was statistically proven that there is no significant difference in vasodilator requirement to control the increased sympathetic activity between the eversion and conventional CEA (p value 0.199).

So, what causes the PEH still remain unclear, even though several theories have been postulated. These include (1) baroreceptor dysfunction due to carotid sinus denervation (2) increased norepinephrine production in cerebral and peripheral level, and (3) increased cerebral renin production[46]. In a study by Newman et al showed that there was a significantly greater incidence of PEH in patients with higher pre-operative SBPs and this association has also been observed by others[47]. Similarly in our study also those patients having high SBP, DBP and MAP are having more chance of getting PEH in post op (Karl pearson coefficient r value for SBP= 0.38, DBP= 0.375, MAP= 0.402). There was also a strong association between PEH and patient age, being more common in younger patients. No other pre-operative patient demographics or clinical variables were significantly associated with PEH, including the degree and severity of ICA stenosis (as well as severe bilateral disease) or any preoperative cerebral haemodynamic measurements.

The influence of operative technique on postoperative BP has been investigated first by Mehta et al. in 2001[30]. Study group consists of E-CEA (n=82) and C-CEA (n =137). All patients remained in the recovery room for at least 6 hours. Subsequently, they were transferred to the surgical ward, when patient's blood pressures were stabilized, and they no longer required intravenous antihypertensive drugs. In recovery room, No. (%) of study subjects requiring vasodilator agents were 20 in eversion CEA and 8 in conventional CEA (p value.0001) The main limitation of this study was the absence of BP determinations beyond the first 24 postoperative hours. In a 2017 meta-analysis of PEH in four nonrandomized prospective studies and two retrospective studies, consisting a total of 1361 CEA procedures (602 E-CEA; 759 C-CEA) by Damirel et[44] al, the maximum duration of the postoperative study period were 6 days when all studies taken together.

To the best of our knowledge this is the first study to analyse the hemodynamic instability occurring after CEA upto 3 months and first of its kind to evaluate the effect

of CEA on antihypertensive medication before and after surgery. This was done by statistically correlating for any association between those patients with increased vasodilator in immediate post op and those patients having persistently high BP 3 months after surgery and found that significant association between increased vasodilator requirement in immediate peri operative period and high BP till the patient got discharged. If this is due to baroreceptor failure occurring after CEA this change should be more in eversion group, but we found that irrespective of the technique of CEA, a certain group of patients are becoming hypertensive. So, some unknown mechanisms are involved in the development of long term HTN.

Theoretically BRS function should improve after CEA, because a previously non-distensible baroreceptors are brought back into neuronal circuit by removal of the atherosclerotic carotid intima and media during CEA. As a result the increased diameter of the carotid sinus due to weakening and thinning of the vessel wall should leads to increased sinus nerve activity[48]. This improvement should be more evident in conventional CEA as it does not involve sinus nerve transection compared to eversion CEA. So, this improvement in BRS function should be reflected in the the dose of antihypertensive ie it should come down especially after c-CEA. In our study the analysis was done by calculating the dose of medication in each class of antihypertensive; for eg betablockers and comparing with the dosage pre operatively, at discharge and 3 months after surgery. It is worth mentioning here that for the simplicity of analysis when a patient develops HTN in postoperative period, then same class of antihypertensive is started in post op and when the maximum dose of that particular antihypertensive is attained, then only a new class of antihypertensive is added. For the study purpose increase in dose of same antihypertensive as well addition of new class of antihypertensive is considered as indirect evidence of uncontrolled HTN. The mean dose of oral beta blocker was 18.95±26.66 mg in preoperative period was increased to 45.766±35.85 at the time of discharge and this change in dose was statistically significant (p value 0.000). Three months after discharge the mean dose of beta blocker was 47.58±38.864 which was not significantly different from the dose at the time of discharge (p value 0.585). This shows that after CEA there was no decrease in the dose antihypertensive medications till 3 months after surgery.

Similar changes were noted with all other antihypertensives except alpha blockers ie those patients on preoperative alpha blocker did not showed any statistically

significant increase in dose of antihypertensives at the time of discharge and at 3 months follow up. This shows that those patients BP well controlled with alpha blockers preoperatively are better controlled in post operatively and at 3 months. Logically thinking the fluctuations of sympathetic system from baroreceptor break down during CEA were better controlled in patients who had adequate sympathetic blockade preoperatively. In other words, whether alpha blocker can be considered as a drug of choice for PEH if started preoperatively, is a question that needs to be addressed in future RCT. Moreover, change in mean dose of each class of oral antihypertensives in beta blockers, calcium channel blockers (CCB), angiotensin receptor blockers (ARB) and alpha blockers were compared between eversion and conventional CEA. The increase in mean dose from pre-operative period is persisting even at 3 months in both groups (all the p values are > 0.05). This shows that irrespective of the technique of CEA the increased sympathetic activity is persisting till 3 months post-surgery in some group of patients by some unknown mechanism.

Lastly as a part of our study we investigated the heparin protamine reversal after CEA and its relationship with post op complications. We all know that 1mg of heparin =100U and 1mg of protamine is used to neutralize the effect of 1mg of Heparin. This reversal of 1:1 ratio is hereafter called as full reversal or 100% reversal. The patients were classified into less than half reversal group and half to full reversal group. It was found that higher dose of protamine were used in eversion CEA (eversion CEA 58% (n=18); vs conventional CEA 29%(n=9); whereas less than half dose of protamine were received in conventional CEA (conventional CEA 71% (n=22); vs eversion CEA 41.9 %(n=13); p value <0.021). This difference in the heparin protamine reversal in eversion and conventional group were separately analyzed to find out any association with post-operative complications and found that no statistical significant association between heparin protamine reversal with bleeding, hematoma, re-exploration, stroke and post-operative MI even though there is significant higher dose of protamine dose is used in eversion CEA than conventional CEA

CONCLUSION

The preliminary results of our study suggest that eversion CEA is safe, rapid, easy-to-perform procedure like conventional CEA. Some surgeons prefer eversion endarterectomy over conventional CEA technique because there is no need to use patch and anastomosis can be completed quickly. Moreover, eversion CEA offers distinct advantages in certain anatomical situations like elongated or kinked ICA; other than that, choosing the technique depends on surgeon's experience in performing a technique of endarterectomy over other. We think that familiarity with both techniques is important, while neither one is superior or inferior. The current data shows that until further evidence is available, the choice of the CEA technique depends on the experience and familiarity of the individual surgeon.

This study proved beyond doubt that Carotid endarterectomy procedure subjects the patients to the increased risk of uncontrolled hypertension in future. This may be in the form of PEH in immediate post op or as an uncontrolled essential HTN till 3 months postop according to our study. The cause of PEH may be linked to BRS breakdown even though it is happening in both eversion and conventional CEA but some unknown hemodynamic equilibrium is broken down after CEA so that in certain group of patients BP is persistently elevated. Further randomized controlled trials are needed before making fruitful conclusins.

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Technical Advisory Committee (Clinical Studies)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2018/755 **Date: 24.05.2019**

Project title: COMPARISON OF OUTCOMES FOLLOWING CONVENTIONAL CAROTID ENDARTERECTOMY AND EVERSION CAROTID ENDARTERECTOMY- A RETROSPECTIVE STUDY

Principal Investigator
Dr. Vineeth Kumar PM, Senior Resident, Division of Vascular Surgery, Department of CVTS, SCTIMST Degree: MBBS, MS
Co-Principal Investigator(s)
Dr Varghese T Panicker, Additional Professor , Department of CVTS, SCTIMST Degree: MS, Mch CVTS
Dr. P. Shivanesan, Assistant Professor, Division of Vascular Surgery, Department of CVTS, SCTIMST Degree- MS, MCh (Vascular surgery)

Members who participated in the TAC meeting on 16/06/2018
Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Krishna Kumar K
Dr. Sankara Sarma P
Dr. Bijulal S
Dr. Jayadevan ER
Dr. Syam K
Dr. Varghese T. Panicker
Dr. K. Shivakumar (Member Secretary)

Dr. Varghese T Panicker, Dr. Rupa Sreedhar, Dr. Jayadevan ER, Dr. Syam K, Dr. Krishna Kumar K, and Dr. Bijulal S stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#762, 768, 769, 772, 775, 776, 778, 782, 784, 785).

Risk Classification of the project (Minimum/ Moderate/ High): Moderate

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

Recommendations of TAC:
Recommended for consideration of IEC in the light of the responses received from the investigator

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC
Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

Appendix-1

Advantages and disadvantages of each method can be written clearly in consent form, from available published data (incidence of stroke, long term patency etc)

Answer: Consent form was completely changed based on the model consent form given by the TAC committee especially describing in detail about the advantages and disadvantages of each technique from available published data

This can only be an observational study – not randomized

Answer: Study has been changed from "A randomized control trial comparing conventional and eversion carotid Endarterectomy" to an observational type of study with heading "Comparison of Outcomes Following Conventional carotid Endarterectomy and Eversion carotid Endarterectomy - A Prospective Observational study"

The investigators have to specify in the TAC/ IEC form if they are including the participants after the surgery is done or prior to same. In the Participant information sheet, it is mentioned that the decision regarding the mode of surgery (conventional vs eversion CEA) is not part of the study. But in the TAC/IEC form, this has to be reflected in the methods including eligibility criteria

Answer:
1) We are including participants only after surgery is performed. The decision regarding the mode of surgery (Conventional vs Eversion) is not the part of the study .
2) Study design is "Comparison of Outcomes Following Conventional carotid Endarterectomy and Eversion carotid Endarterectomy - A Retrospective study"

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/ 1387/JUNE-2019 17.03.2020

Dr. Vineeth Kumar PM
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Vineeth Kumar,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "COMPARISON OF OUTCOMES FOLLOWING CONVENTIONAL CAROTID ENDARTERECTOMY AND EVERSION CAROTID ENDARTERECTOMY- A RETROSPECTIVE STUDY (IEC/1387)" on 15th June, 2019.

The following documents were reviewed:
Original submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 24.05.2019 with checklist*
2. *TAC Approval Letter*
3. *Forwarding Letter from the HOD*
4. *IEC Application Form*
5. *Project Proposal*
6. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co- Principal Investigators*

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 20.02.2020 with checklist*
2. *TAC Approval Letter*
3. *Forwarding Letter from the HOD*
4. *IEC Application Form*
5. *Project Proposal*
6. *Patient Information Sheet*
7. *CV of Principal Investigator and Co- Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 15th June, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
5.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
8.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
9.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
10.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
11.	Mr. Satheesh Chandran	MSW, PGDPM	Male	Lay person/ NGO/ Social Scientist	No
12.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

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

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PLAGIARISM CHECK CERTIFICATE

URKUND

Document Information

Analyzed document	Vineeth Thesis for Plagiarism.docx (D78177265)
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PATIENT INFORMATION PROFORMA

PROFORMA No:

AGE/SEX

RISK FACTORS:

- Hypertension
- Diabetes
- Coronary Artery disease
- Peripheral Arterial disease
- Dyslipidemia
- Smoker

PRESENTING NEUROLOGICAL SYMPTOMS

- Type of Event (stroke/TIA)
- Duration since onset
- Completely recovered or not
- Modified Rankin Score (mRS)
- National Institute of Health Stroke score (NIHSS)

PREOPERATIVE IMAGING

- Neck Vessel Doppler
- CT Angio
  - Aortic Arch
  - Ipsilateral Carotid Vessels
  - Contralateral Carotid Vessels
  - Vertebral System
  - Intracranial Disease
- MR Angio
  - Aortic Arch

- Ipsilateral Carotid Vessels
- Contralateral Carotid Vessels
- Vertebral System
- Intracranial Disease

Intraoperative Findings

- Bifurcations
- Lesion characteristics
- Type of patch used
- Mean shunt pressure
- Stump pressure
- Duration of carotid clamp

Immediate Post OP

- Stroke(minor/major)
- Cardiac Event
- Respiratory distress
- Bleeding
- Reperfusion Syndrome
- Uncontrolled Hypertension
- Cranial Nerve Palsy
- Wound Infection

Follow Up

- 3 Months/12 months
  - Any New neurological Event
  - Neck Vessel Doppler

LIST OF ABBREVIATIONS

e CEA	-	Eversion Carotid endarterectomy
c CEA	-	Conventional Carotid endarterectomy
d CEA	-	Direct closure Carotid endarterectomy
p CEA	-	Patch closure Carotid endarterectomy
PEH	-	Post Endarterectomy Hypertension
HTN	-	Hypertension
SBP	-	Systolic BP
DBP	-	Diastolic BP
MAP	-	Mean Arterial Pressure
NTG	-	Nitroglycerine
SNP	-	Sodium nitroprusside
BETA	-	Betablocker
CCB	-	Calcium channel blocker
ARB	-	Angiotensin Receptor blocker
ALPHA	-	Alpha Blocker
CAS	-	Carotid Artery Stenting
CCA	-	Common Carotid Artery
ECA	-	External Carotid Artery
ICA	-	Internal Carotid Artery
GA	-	General Anesthesia
LA	-	Local Anesthesia
COPD	-	Chronic Obstructive Pulmonary Disease

CAD	-	Coronary Artery Disease
PAD	-	Peripheral Artery Disease
CVD	-	Cerebrovascular Disease
DM	-	Diabetes Mellitus
HTN	-	Hypertension
CKD	-	Chronic Kidney Disease
DLP	-	Dyslipidemia
CT Angio	-	Computed Tomography Angiography
MR Angio	-	Magnetic Resonance Angiography
NIHSS Score	-	National Institute of Health Stroke Scale Score
mRS	-	modified Rankin Scale

APPENDIX 1- NIHSS Score

Category	Score/Description		Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials
1a. Level of Consciousness (Alert, drowsy, etc.)	0 = Alert 1 = Drowsy 2 = Stuporous 3 = Coma						
1b. LOC Questions (Month, age)	0 = Answers both correctly 1 = Answers one correctly 2 = Incorrect						
1c. LOC Commands (Open/close eyes, make fist/let go)	0 = Obeys both correctly 1 = Obeys one correctly 2 = Incorrect						
2. Best Gaze (Eyes open - patient follows examiner's finger or face)	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation						
3. Visual Fields (Introduce visual stimulus/threat to pt's visual field quadrants)	0 = No visual loss 1 = Partial Hemianopia 2 = Complete Hemianopia 3 = Bilateral Hemianopia (Blind)						
4. Facial Paresis (Show teeth, raise eyebrows and squeeze eyes shut)	0 = Normal 1 = Minor 2 = Partial 3 = Complete						
5a. Motor Arm - Left **5b. Motor Arm - Right** (Elevate arm to 90° if patient is sitting, 45° if supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
6a. Motor Leg - Left **6b. Motor Leg - Right** (Elevate leg 30° with patient supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
7. Limb Ataxia (Finger-nose, heel down shin)	0 = No ataxia 1 = Present in one limb 2 = Present in two limbs						
8. Sensory (Pin prick to face, arm, trunk, and leg - compare side to side)	0 = Normal 1 = Partial loss 2 = Severe loss						
9. Best Language (Name item, describe a picture and read sentences)	0 = No aphasia 1 = Mild to moderate aphasia 2 = Severe aphasia 3 = Mute						
10. Dysarthria (Evaluate speech clarity by patient repeating listed words)	0 = Normal articulation 1 = Mild to moderate slurring of words 2 = Near to unintelligable or worse X = Intubated or other physical barrier						
11. Extinction and Inattention (Use information from prior testing to identify neglect or double simultaneous stimuli testing)	0 = No neglect 1 = Partial neglect 2 = Complete neglect						
	TOTAL SCORE						

APPENDIX 2- modified Rankin 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

Sl.No	Hosp No:	Name	AGE	SEX	LEFT	RIGHT	STROKE	TIA	NIHSS	mRS	I/L ICA	PSV	OPP ICA	PSV	I/L ICA	C/L ICA	I/L VERT	C/L VERT	ARCH	BRAIN	TIMING	SMOKER	THYROID	DYSLIP	CAD	DM	COPD	CRF	pre opC HTN
1	435656	Mathai Thomas	66	1	1	0	0	1	0	0	70		0		70	0	0	0	0	0	30	0	0	1	0	0	0	0	0
2	435812	Suseela M	67	0	0	1	0	1	2	3	80	340	0		80	0	0	0	0	1	60	0	0	1	0	1	0	0	1
3	436861	Appukuttan Pillai	74	1	0	1	0	1	0	0	90		55		90	70	0	0	0	0	30	0	0	1	0	0	1	0	1
4	437460	Raje. V. Issac	54	1	1	0	0	1	1	2	70		0		80	0	0	0	0	0	30	0	0	0	0	1	0	0	1
5	438710	Samuel P S	77	1	1	0	1	0	0	0	70		0		70	0	0	0	0	1	90	0	0	0	0	1	0	0	0
6	440689	Sasidharan K	73	1	0	1	0	1	0	0	70		50		90	0	0	0	0	0	25	0	0	0	0	1	0	0	0
7	440918	Sumeera Beevi	68	0	0	1	1	0	1	1	80		0		80	0	0	0	0	1	20	0	0	1	0	1	0	0	0
8	441716	Suresh Kumar B	47	1	0	1	0	1	1	1	100		0		99	0	0	0	0	1	10	0	0	0	0	0	0	0	1
9	442467	Velukutty Nair K	76	1	0	1	1	0	1	1	90		100		90	0	0	0	0	0	80	1	0	0	0	0	1	0	1
10	442542	Sabeena A ©	57	0	1	0	0	1	0	0	90		0		90	0	0	0	0	0	50	0	0	1	1	1	0	0	1
11	443436	Yousuf A	72	1	0	1	1	0	2	2	90		0		85	0	0	0	0	1	16	0	0	1	0	1	0	0	0
12	445862	Chandrika Devi	69	0	0	1	0	1	0	0	70		0		70	0	1	1	0	0	16	0	0	0	0	1	0	0	0
13	453454	ornana under LA	60	0	0	1	1	0	2	0	90		70		90	70	0	1	0	1	21	0	0	1	0	1	0	0	0
14	455084	radhakrishna pillai under LA	60	0	0	1	1	0	5	3	90		50		90	50	0	0	0	1	28	1	0	1	0	1	0	0	1
15	455512	thampi	52	1	0	1	0	1	0	0	90		0		90	0	0	0	0	0	60	1	0	0	0	0	0	0	1
16	451434	jayanthi kumar	56	1	0	1	0	1	0	0	90		0		90	0	0	0	0	1	90	1	0	0	0	1	0	0	1
17	453299	Hassanar Kunju	48	0	0	1	1	0	3	2	70		60		90	0	0	0	0	1	30	0	0	0	0	1	0	0	0
18	451426	pechiyammal	70	1	1	0	1	0	7	3	80		0		90	40	0	0	0	1	45	0	0	0	0	1	0	0	0
19	448955	kamalasanan	50	0	0	1	1	0	0	0	70		70		80	50	0	0	0	1	90	1	0	0	0	0	0	0	0
20	449897	vasudevan	41	1	1	0	1	0	3	3	80		0		80	0	0	0	0	1	60	0	0	1	0	1	0	0	0
21	447487	santhi g	55	0	0	1	1	0	0	0	80	580	0		80	0	0	0	0	1	90	0	0	1	0	1	0	0	0
22	447831	asokan	61	1	0	1	1	0	0	0	80		0		90	0	0	0	0	1	26	1	0	1	0	1	0	0	0
23	446719	neelakandan	55	1	0	1	1	0	1	2	90		50		90	0	0	0	0	1	60	0	0	0	0	1	0	0	0
24	445673	kutty	67	1	0	1	1	0	3	2	90		50		90	50	0	0	absent A1-ACA	1	34	0	0	1	0	0	0	0	0
25	444612	baby	67	1	0	1	0	1	0	0	75		0		90	0	0	0	0	0	5	1	0	0	0	0	0	0	1
26	442312	bronnan michael	52	1	1	0	1	0	23	9	90		40		90	40	0	0	0	1	90	0	0	0	0	1	0	0	1
27	460647	sathyan	62	1	0	1	1	0	4	3	90		0		90	0	0	0	0	1	61	1	0	0	0	1	0	0	1
28	458772	vijayakumar	66	1	1	0	0	1	0	0	65	0	0	0	95	0	0	0	1 SMALL PCOM	0	63	0	0	1	0	1	0	0	1
29	461110	vikraman pillai	56	1	1	0	0	1	0	0	75		0		70	0	0	0	0	0	13	1	0	0	0	0	0	0	1
30	455144	chandrika	60	0	1	0	1	0	1	2	60		55		70	0	0	0		1	40	0	0	1	0	1	0	0	1
31	460631	christu dasan	54	1	1	0	1	0	8	3	50	129	0	0	80	0	0	0	0	1	14	1	0	0	0	0	0	0	1

pre op U HTN	CCB PRE	ACE PRE	ARB PRE	ALPHA PRE	DIU PRE	NTG DOSE	NTG DTN	SNP DOSE	SNP DTN	CLAMP TIME	C-IND	U-IND	STUMP P	HEPARIN	PROTAMINE	BETA POST	CCB POST	ACE POST	ARB POST	ALPHA POST	DIU POST	STROKE	TIA	DEATH	CARDIAC	CN
1	10	0	40	0	0	0	0	146	19	21	1	0		75	30	50	20	0	40	0	0	0	0	0	0	0
0	5	0	0	0	0	38	8	0	0	24	0	1		60	60	0	5	0	0	0	0	0	0	0	0	0
0	5	0	0	0	0	0	0	0	0	26	1	0		75	40	0	10	0	0	0	0	0	0	0	0	0
0	10	0	0	0	0	61	17	0	0	20	1	0		60	30	100	10	0	0	0	0	0	0	0	0	7
1	10	0	0	0	0	60	20	0	0	27	0	1		60	30	100	10	0	0	0	0	0	0	0	0	0
1	0	0	50	0	0	91	24	0	0	30	0	1		70	30	50	10	0	50	0	0	0	0	0	0	0
1	0	0	0	0	0	0	0	66.6	21	30	0	1		70	30	50	10	0	80	0	0	0	0	0	0	0
0	20	0	0	0	0	66	18	0	0	22	1	0		70	30	0	20	0	0	0	0	0	0	0	0	0
0	10	0	50	0	0	170	23	0	0	0	1	0		50	0	50	15	0	0	200	0	0	0	0	0	7
0	0	0	0	0	0	30	9	0	0	0	0	1		60	50	100	20	0	100	0	0	0	0	0	0	0
1	5	0	50	0	0	87	23	0	0	30	1			75	50	100	10	0	100	0	0	0	0	0	0	0
1	10	0	0	0	0	220	40	0	0	16	0	1		80	40	50	10	0	100	4	0	0	0	0	0	0
1	5	0	0	0	0	0	0	160	25	20	0	1		60	0	100	20	0	60	0	0	0	1 INTRA OP	0	0	0
0	0	0	40	0	0	0	0	0	0	33	1	0		70	30	50	0	0	80	0	0	0	0	0	0	12
0	0	0	0	0	0	0	0	0	0	27	1	0		70	20	0	10	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	70	20	0	0	14	1	0		90	50	25	0	0	40	0	0	0	0	0	0	0
1	5	0	0	0	0	1	1	0	0	20	1	0		80	0	25	5	0	100	0	0	0	0	0	0	0
1	0	0	40	0	0	170	36	0	0	19	0	1		50	25	50	0	0	80	0	0	R ICA thrombosis left UL1	0	0	0	0
1	10	0	0	0	0	0	0	160	24	22	0	1		75	40	100	20	0	0	5	0	0	0	0	0	HUSKY VOICE10
1	10	0	0	0	0	25	17	0	0	20	1	0		55	0	50	20	0	0	0	0	0	0	0	0	0
1	2.5	0	80	0	0	90	20	0	0	16	1	0		100	50	50	2.5	0	80	0	0	0	0	0	0	7
1	5	0	0	0	0	65	21	0	0	28	0	1		70	40	50	15	0	80	0	0	0	0	0	0	7
1	5	0	0	0	0	120	25	0	0	25	0	1		60	30	50	10	0	0	0	0	0	0	0	0	0
1	10	0	0	0	0	200	34	0	0	20	0	1		60	30	100	15	0	100	0	0	0	0	0	0	0
0	0	0	60	10	0	110	11	0	0	20	1	0		75	25	50	0	0	80	10	0	0	0	0	0	0
0	10	0	0	0	0	0	0	0	0	0	0	1		70	30	50	10	0	5	0	0	0	0	0	1	0
0	0	0	0	0	0	7	7	0	0	20	1	0		100	75	0	5	0	0	0	0	0	0	0	0	0
0	5	0	0	0	0	7	6	0	0	19	1	0		75	0	50	10	0	0	0	0	0	0	0	0	0
0	2.5	0	0	0	0	24	5	0	0	28	0	1		50	25	0	10	0	0	0	0	0	0	0	0	0
0	10	0	0	0	0	23	5	0	0	16	1	0		80	50	100	20	0	0	0	0	0	0	0	0	0
0	5	0	0	0	0	0	0	5	1	31	1	0		100	50	0	5	0	0	0	0	0	0	0	0	0

BLEEDING	HEMATOMA	REEXPLORATION	REPERFUSIO	WOUND INF	SBP pre	DBP pre	SBP peri	DBP peri	SBP 3	DBP 3	NO PRE	NO POST	NO 3	BETA PRE	BETA 3	CCB3	ACE 3	ARB 3	ALPHA3	DIU 3
0	1	1	0	0	172	82	140	90	150	92	3	3	2	100	50	0	0	80	0	0
0	0	0	0	0	156	90	190	90	142	92	1	1	2	0	100	0	0	100	0	0
0	0	0	0	0	120	80	120	80	130	80	1	1	1	0	0	10	0	0	0	0
0	0	0	0	0	134	78	138	80	138	80	2	2	2	25	100	10	0	50	0	0
0	0	0	0	0	130	80	190	90	140	90	1	2	2	0	100	10	0	0	0	0
0	0	0	0	0	168	90	160	60	140	90	1	3	2	0	0	10	0	100	0	0
0	0	0	0	0	140	90	160	90	140	90	1	3	2	25	50	10	0	80	0	0
0	0	0	0	0	126	80	138	80	138	80	1	1	1	0	0	20	0	0	0	0
0	0	0	0	0	167	90	140	90	180	90	3	3	2	25	0	15	0	0	300	0
0	0	0	1bleed craniotomy	0	106	70	190	90	140	90	1	3	3	25	100	20	0	100	0	0
0	0	0	0	0	140	90	140	90	130	80	3	3	2	25	100	10	0	0	0	0
0	0	0	0	0	154	90	180	100	140	90	2	4	3	25	50	0	0	100	5	0
0	0	0	0	0	170	100	180	100	160	90	2	3	3	50	100	20	0	60	0	0
0	0	0	0	0	140	90	140	90	142	92	2	2	2	50	50	0	0	80	0	0
0	0	0	0	0	130	80	140	90	140	90	0	1	1	0	0	10	0	0	0	0
0	0	0	0	0	130	80	140	90	140	90	0	2	2	0	50	0	0	40	0	0
0	0	0	0	0	130	80	140	90	160	90	1	3	3	0	50	10	0	100	0	0
0	0	0	0	0	140	90	160	90	140	90	2	2	2	25	50	0	0	80	0	0
0	0	0	0	0	210	104	140	90	170	90	2	3	3	50	100	20	0	0	5	0
0	0	0	0	0	150	70	140	90	140	90	2	2	2	25	50	20	0	0	0	0
0	0	0	0	0	146	96	140	90	140	90	3	3	3	50	50	2.5	0	80	0	0
0	0	0	0	0	160	92	180	90	140	90	2	3	3	25	50	15	0	80	0	0
0	0	0	0	0	144	90	161	73	140	90	1	2	3	0	100	10	0	0	0	0
0	0	0	0	0	140	90	197	62	150	90	2	3	2	25	100	0	0	50	0	0
0	0	0	0	0	160	80	140	90	160	90	3	3	3	50	75	0	0	80	10	0
0	0	0	0	0	150	100	183	99	140	90	1	3	3	0	50	10	0	5	0	0
0	0	0	0	0	142	92	140	90	142	92	0	1	1	0	0	5	0	0	0	0
0	0	0	0	0	132	77	130	70	190	92	1	2	2	0	50	20	0	0	0	0
0	0	0	0	0	130	70	160	100	154	92	1	1	2	0	0	5	0	50	0	0
0	0	0	0	0	130	70	130	60	130	70	2	2	1	50	0	20	0	0	0	0
0	0	0	0	0	138	86	130	70	138	88	1	1	1	0	0	5	0	0	0	0

Sl.No	Hosp No:	Name	AGE	SEX	LEFT	RIGHT	STROKE	TIA	NIHSS	mRS	I/L ICA	PSV	OPP ICA	PSV	I/L ICA	C/L ICA	I/L VERT	C/L VERT	ARCH	BRAIN	TIMING	SMOKER	THYROID
1	434927	Kushan T K	72	1	0	1	1	0	5	2	75	520	30	140	80	0	0	0	0	1	30	1	0
2	435513	Thomas C B	53	1	0	1	0	1	0	0	90	465	0	0	90	0	0	0	0	0	50	0	0
3	438161	Lalitha S	61	0	0	1	0	1	0	0	95		100		95	100	0	0	0	0	30	0	0
4	438387	Anusuyamma	81	0	0	1	1	0	1	1	80	190	100	0	90	90	0	0	0	0	43	0	0
5	438776	Vijayanatha kurup	55	1	0	1	0	1	0	0	99		40		99	0	0	0	0	0	90	0	0
6	439074	Abdul Azeez T	56	1	0	1	0	1	0	1	90	340	0		99	0	0	0	50 CAVAERNOUS ICA	0	80	0	0
7	440119	Gopalakrishnan C	67	1	0	1	1	0	0	0	90	215	60	133	90	0	0	0	0	1	20	1	0
8	440943	Wilson Mathew	66	1	0	1	0	1	0	0	85	626	0	0	99	0	0	0	0	0	30	0	0
9	444686	Mohanan	61	1	1	0	0	1	0	0	70	200	0	0	70	0	0	0	0	0	90	0	0
10	446721	Stanly V C	62	1	0	1	1	0	5	3	90		50		90	50	0	0	0	1	30	0	0
11	9701712	Babuchandran Achari D	58	1	0	1	1	0	4	2	90		80		90	80	0	0	0	1	60	1	0
12	456344	sakthivel	67	1	1	0	1	0	3	2	95		0		95	0	0	0	0	1	20	0	0
13	454766	azad divakaran	65	1	1	0	1	0	0	0	95		40		95	0	0	0	0	1	60	1	0
14	453298	rajan pillai	62	1	1	0	1	0	4	2	90		0		90	70	0	0	0	1	90	0	0
15	446702	sunny	64	1	1	0	1	0	2	2	90	179	100		100	80	0	0	C/L ACOM FILLING	1	50	1	0
16	446874	ismail	50	1	0	1	0	SEIZURES RT0	0	0	99		70		100	70	0	0	0	1	20	0	0
17	448394	santhosh kumar	43	1	1	0	1	0	3	3	90	258	20	60	90	0	0	0	0	1	40	1	0
18	451229	joy varghese	61	1	0	1	0	1	0	0	90		80		90	80	0	0	0	0	26		
19	451196	mariyappan	56	1	0	1	0	1	0	0	80		100		80	100	0	0	0	0	60	0	0
20	451862	sheela vijayan	49	0	1	0	0	1	0	0	90		70		90	70	0	0	0	0	90	0	0
21	453124	das LA TO GA	65	1	1	0	0	1	0	0	70	191	0	0	70	0	0	0	0	0	25	0	0
22	9200696	raveendran	65	1	1	0	1	0	6	3	90		0		90	0	0	0	0	0	120	1	0
23	456727	sadasivam	79	1	0	1	0	1	1	2	90	368	0	0	90	0	0	0	0	0	60	0	0
24	458265	subramaidaru	71	1	1	0	1	0	3	1	70		0		70	0	0	0	0	1	13	0	0
25	457255	reghu	53	1	0	1	1	0	3	2	70		0		70	0	0	0	0	1	50	1	0
26	461220	krishnankuttynair	80	1	0	1	1	0	0	0	70		0		70	0	0	0	50 ICA	1	30	0	0
27	466721	john cs	73	1	1	0	1	0	0	1	70		0		90	50	0	0	C/L 50	1	15	0	0
28	444579	velupillai N	67	1	0	1	0	1	3	2	70		0		70	0	0	0	0	1	60	0	0
29	467964	lissy thomas	53	0	1	0	1	0	1	1	90		50		90		60	0	0	1	12	0	0
30	468100	vanajabhai	80	0	0	1	1	0	7	3	60		0		80	0	0	0	0	1	15	0	0
31	471012	alikutty	68	1	0	1	1	1	2	2	90	0	0		90	0	0	0	50 ica	1	40	0	0

POAD	DYS LIPIDEMIA	CAD	DM	COPD	CRF	pre op C-HTN	pre op U-HTN	NO PRE	BETA PRE	CCB PRE	ACE PRE	ARB PRE	ALPHA PRE	DIU PRE	DOSE	DTN	DOSE	DTN	CLAMP TIME	C-IND	U-IND	STUMP P	HEPARIN	PROTA	ACE POST	ALPHA POST	DIU POST	STROKE	TIA
0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	214	24	64	12	16	0	1	84	75	30	0	0	0	0	0
0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	65	10	20	4	21	0	1	49	110	70	0	0	0	0	0
0	1	0	1	0	0	1	0	2	0	20	0	100	0	0	190	20	0	0	11	1	0		75	0	0	0	0	0	0
	1	CABG1	1	0	0	1	0	2	0	5	0	40	0	0	34	13	0	0	16	1	0	27	100	75	0	0	0	0	0
SFA PLASTY1	1	1	1	0	0	1	0	1	50	0	0	0	0	0	89	11	0	0	35	1	0		100	0	0	0	0	0	0
1	0	0	1	0	0	1	0	2	25	5	0	0	0	0	140	16	0	0	22	1	0	40	100	0	0	0	0	0	0
0	0	1	1	1	0	0	1	2	25	5	0	0	0	0	0	0	0	0	24	0	1	55	60	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	141	19	0	0	11	1	0	53	100	0	0	0	0	0	0
0	0	0	1	0	0	1	0	1	0	5	0	0	0	0	0	0	0	0	12	1	0	30	60		0	0	0	0	0
0	0	0	1	0	0	0	1	1	0	10	0	0	0	0	90	20	0	0	18	0	1	54	90	50	0	0	0	0	0
1	0	post CABG1	1	0	0	1	0	2	0	10	0	0	0	40	0	0	0	0	11	1	0	28	60	0	0	0	40	0	0
0	0	0	1	0	0	1	0	2	50	10	0	0	0	0	100	21	0	0	14	1	0		105	10	0	0	0	0	0
1	0	0	1	0	0	1	0	2	0	5	0	80	0	0	20	10	0	0	11	0	1	40	75	40	0	0	0	0	0
	0	0	1	0	0	0	1	1	0	0	0	40	0	0	76.5	24	0	0	15	0	1		100	30	0	0	0	0	0
0	1	0	1	0	0	1	0	2	50	5	0	0	0	0	2.1	3	0	0	8	1	0	34	70	40	0	0	0	0	0
0	0	0	1	0	0	1	0	2	50	10	0	0	0	0	60	12	0	0	11	1	0	35	75	0	0	0	0	0	0
0	0	0	1	0	0	1	0	2	0	5	0	0	0	0	140	21	0	0	16	0	1		75	20	0	0	0	0	0
	1	0	0	0	0	0	1	3	0	20	0	40	0	0	19	4	0	0	10	1	0	36	60	0	0	0	0	0	0
0	0	0	1	0	0	1	0	1	0	5	0	0	0	0	5	2	0	0	11	1	0	36	50	0	0	0	0	0	0
0	0	0	1	0	0	1	0	1	0	10	0	0	0	0	0	0	40	14	12	1	0	44	75	20	0	0	0	0	0
0	1	0	0	0	0	1	0	1	0	5	0	0	0	0	0	0	0	0	18	1	0		105	40	0	0	0	0	0
	1	0	1	0	0	0	1	2	100	10	0	0	0	0	0	0	0	0	14	1	0		115	30	0	0	0	0	0
0	0	0	0	0	0	0	1	1	25	0	0	0	0	0	10	4	0	0	14	1	0	40	80	0	0	0	0	0	0
	1	0	0	0	0	0	1	1	0	10	0	40	0	0	0	0	0	0	18	1	0		115	40	0	10	0	0	0
	1	0	1	0	0	0	1	2	0	10	0	40	0	0	43	15	0	0	9	1	0		100	50	0	0	0	0	0
	0	0	0	0	0	1	0	1	0	5	0	0	0	0	14	7	0	0	18	1	0		100	50	0	0	0	0	0
	0	1	1	0	0	1	0	3	50	10	0	80	0	0	0	0	0	0	7	1	0		60	0	0	3	0	0	0
	1	0	1	0	0	0	1	2	100	15	0	0	0	0	146.5	28	0	0	12	0	1	35	50	30	0	0	0	0	0
0	1	0	1	0	0	1	0	1	0	10	0	0	0	0	60	19	0	0	4	1	0	32	50	10	0	0	0	0	0
0	1	0	1	0	0	0	1	1	0	5	0	0	0	0	1	1	0	0	4	1	0		50		0	0	0	0	0
0	1	0	1	0	0	1	0	1	0	5	0	0	0	0	0	0	0	0	5	1	0		70	40	0	0	0	1minor rt UL ataxia	0

DEATH	CARDIAC	CN	BLEEDING	HEMATOMA	REEXPLORATION	REPERFUSIO	WOUND INF	SBP pre	pre	SBP peri	DBP peri	SBP 3	DBP 3	NO POST	NO 3	BETA POST	BETA 3	CCB POST	CCB3	ACE 3	ARB POST	ARB 3	ALPHA 3	DIU 3	I/L ICA	PSV	OPP ICA	PSV
0	0	0	0	0	0	0	0	206	140	142	92	140	90	2	2	25	50	0	0	0	100	100	0	0	0			
0	0	0	0	0	0	0	0	170	80	185	90	150	90	2	2	50	50	0	0	0	40	40	0	0				
0	0	0	0	0	0	0	0	128	70	142	92	170	90	2	2	0	0	10	0	0	100	100	10	0				
0	0	0	0	0	0	0	0	134	82	130	70	138	80	2	2	0	0	5	5	0	40	40	0	0				
0	0	0	0	0	0	0	0	128	80	130	82	120	80	1	1	50	50	0	0	0	0	0	0	0				
0	0	0	0	0	0	0	0	138	74	142	92	160	90	2	2	100	100	10	10	0	0	0	0	0				
0	0	0	0	0	0	0	0	150	92	138	60	130	70	3	3	100	100	5	0	0	80	80	5	0				
0	0	0	0	0	0	0	0	120	80	140	92	150	90	3	3	100	100	5	10	0	80	80	0	0				
0	0	0	0	0	0	0	0	120	70	120	70	138	88	1	1	0	0	5	5	0	0	0	0	0				
0	0	0	0	0	0	0	0	144	80	157	92	160	92	3	3	50	50	10	0	0	25	50	0	0				
0	1 PULM OEDEMA	0	0	0	0	0	0	130	70	140	90	140	90	2	2	0	0	10	10	0	0	40	0	0				
0	0	0	0	0	0	0	0	121	75	140	70	140	90	2	2	100	100	20	20	0	0	0	0	0				
0	0	0	0	0	0	0	0	144	82	160	60	140	90	4	2	0	0	30	30	0	80	80	0	0				
0	0	0	0	0	0	DISORIENTATION HEADACHE	0	168	108	160	90	140	90	3	3	100	100	20	20	0	40	40	0	0				
0	0	0	0	0	0	0	0	134	80	140	90	170	90	2	2	50	50	5	0	0	0	25	0	0				
0	0	0	0	0	0	0	0	105	70	130	80	115	70	2	2	50	50	10	10	0	0	0	0	0				
0	0	0	0	0	0	0	0	136	78	150	90	140	90	2	2	50	50	0	40	0	40	0	0	0				
0	0	0	0	0	0	0	0	170	90	170	92	170	90	3	4	25	25	20	20	0	40	80	2.5	0				
0	0	7	0	0	0	0	0	145	90	142	92	142	92	1	1	0	0	5	5	0	0	0	0	0				
0	0	0	0	0	0	0	0	130	80	140	80	180	90	2	2	50	50	10	10	0	0	0	0	0				
0	0	0	0	0	0	0	0	128	74	130	80	138	78	3	2	12.5	25	10	10	0	50	0	0	0				
0	0	0	0	0	0	0	0	170	100	140	90	180	90	3	3	100	100	10	10	0	100	100	0	0				
0	0	0	0	0	0	0	0	166	90	140	90	140	90	1	2	25	100	0	10	0	0	0	0	0				
0	0	0	0	0	0	0	0	150	94	140	90	140	90	3	2	0	0	10	10	0	80	80	0	0				
0	0	0	0	0	0	0	0	150	90	150	90	175	95	3	2	50	0	10	10	0	40	40	0	0				
0	0	0	0	0	0	0	0	130	80	120	60	138	72	3	2	50	100	10	0	0	100	100	0	0				
0	0	0	0	0	0	0	0	130	80	130	70	120	70	4	3	50	25	10	5	0	80	80	0	0				
0	0	0	0	0	0	0	0	150	90	180	92	160	90	3	3	50	50	20	0	0	80	80	2.5	0				
0	0	0	0	0	0	0	0	130	80	130	80	138	88	2	2	50	50	10	10	0	0	0	0	0				
0	0	0	0	0	0	0	0	130	80	130	60	130	80	1	1	0	0	5	5	0	0	0	0	0				
0	0	0	0	0	0	0	0	130	80	130	80	138	88	1	1	0	0	5	5	0	0	0	0	0				