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A PARALLEL OBSERVATIONAL COMPARATIVE STUDY OF CERVICAL CAROTID ARTERY STENTING APPROACH VERSUS GROIN APPROACH VERSUS CAROTID ENDARTERECTOMY IN HIGH-RISK PATIENTS.

Surgery

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ABSTRACT

Purpose: To compare carotid artery endarterectomy (CEA) to trans-femoral carotid artery stenting (F-CAS) and trans-cervical carotid artery stenting (C-CAS). Primary endpoints are stroke, myocardial infarction (MI) or death within 30 days after the procedure. Secondary endpoints included patency, re-intervention rates and 5-year stroke free survival.

Methods: Out of 9585 carotid patients referred, we performed 690 carotid interventions over 12 years. We matched 53 CEA and 53 CAS (34 F-CAS and 19 C-CAS) patients. Multiple logistic regressions were used to control for co-morbidity and anatomical high risk factors. Propensity scoring was used to adjust for baseline characteristics and selection bias, by matching co-variables.

Results: Our total 30-day stroke/death for 690 carotid interventions was 0.9%. %. Thirty day stroke rate were 2.9%, 0% and 1.9% in the F-CAS, C-CAS and CEA respectably (P = .75). Thirty day MI was 0% in CAS group versus 1.9% in the CEA group (P = .32).Thirty-day mortality was 1.9% in CEA, 2.9% in F-CAS and 0% in C-CAS (P = .75). . 5-year stroke free survival was 94.3% in CEA, 97.1% in F-CAS and 100% in C-CAS (P = .55). 5-year restenosis-free rates were 97.7% in CEA, 100% in F-CAS and 88.2% in C-CAS (P = .01). 5-year re-intervention-free rates were 100% in CEA, 97.1% in F-CAS and 100% in C-CAS (P = .46).

Conclusion: C-CAS provides a safer option with significantly less risk of peri-operative stroke and combined postoperative stroke, MI and death.

KEYWORDS

Carotid Artery Stenosis; Carotid Endarterectomy; Stents

Introduction

Atherosclerotic carotid artery stenosis is a major risk factor for disabling stroke and death.[1] Carotid endarterectomy (CEA) was the standard method of revascularization in patients with carotid stenosis.[2] Although CEA is a highly effective intervention for stroke prevention, carotid artery stenting (CAS) is emerging as a suitable alternative.[2]

According to the 2014 American Heart Association (AHA) guidelines, CAS is an alternative to CEA in centres where perioperative stroke/death rates are <6% in symptomatic patients[3]. Both CEA and CAS are appropriate in highly selected average risk patients with asymptomatic stenosis, in centres with perioperative stroke/death rates of <3%.[3]

Although there are many clinical trials comparing CEA and CAS, there is no consensus as to whether one procedure is superior or if they are equivalent. The Stenting and Angioplasty in Patients at High Risk for Endarterectomy (SAPPHIRE) study showed that CAS had equivalent or lower rates of adverse events than CEA in the overall study population and within subgroups of asymptomatic versus symptomatic stenosis.[4] In The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), there were similar short and long-term outcomes between CAS and CEA.[5] A systematic review of 21 registries found that CAS was associated with significantly higher procedural stroke/death rates in asymptomatic and symptomatic patients classified as "average risk for CEA".[6] The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) demonstrated equal efficacy between protected CAS and CEA.[7]

CAS has many advantages compared to CEA. An endovascular technique can decrease the risk of wound complications and cranial nerve injury.[8] This may translate into shorter hospital stays and less healthcare resource utilization.[8] CAS is performed under minimal sedation, avoiding the complications of general anaesthesia.[9] A less invasive approach may be most suitablefor patients with hostile necks due to previous surgery or radiotherapy and for those with anatomically high lesions.[9-12]

A major limitation of CAS is the periprocedural risk of distal embolization to the brain, which may be influenced by the access site[12]. A transfermoral approach (F-CAS) is associated with technical challenges including complex aortic arch and circumferential internal carotid artery (ICA) calcification. A transverical approach (C-CAS) has emerged as a safe alternative to F-CAS as it adverts the risks associated with a transfemoral approach, including cerebral and peripheral embolism and access site complications.[13]

The long-term safety and efficacy of CAS compared to CEA remains uncertain.[14] We reviewed our experience with carotid surgery to compare outcomes between CEA and CAS.

Objectives

We aim to compare the safety and efficacy of CEA to F-CAS and C-CAS. Our primary endpoint is the incidence of stroke, myocardial infarction (MI) or death any time after carotid surgery. Secondary endpoints include:

- Restenosis rates
- Reintervention rates
- 5-year freedom from stroke, mortality and reintervention

Methods

Patients and Data

Over 13 years, 9585 patients with carotid disease were referred to our tertiary vascular centre and 690 carotid interventions were performed (633 CEA, 54 CAS, 3 bypass). All patients who underwent F-CAS and C-CAS were included in the study; with the exception of one CAS

procedure as the case notes were destroyed by hospital administration in accordance with its medical records protocol. Propensity scoring analysis was used to establish matched cohorts of 53 cases treated with CEA and with CAS in order to adjust for baseline characteristics and selection bias.

The Clinical Research Ethics committee approved our study. Individual informed consent was not specifically required due to the nature of this specific analysis.

Data were collected from our prospectively collated database (Vascubase™, Version 5.2, Consensus Medical Systems Inc., Richmond, BC, Canada), patients' hospital charts and our institutional patient administration system (PAS). Radiographic imaging details were reviewed in an unblinded manner on our Picture Archiving and Communication System (PACS) by a radiologist and the surgical team.

The Society for Vascular Surgery (SVS) Carotid Reporting Standards were used as a guideline in the assessment of patient demographics, risk factors and clinical presentation. The demographic factors analyzed were age and gender. The risk factors analyzed were smoking, diabetes, hypertension, hyperlipidemia, hyperfibrinogenemia, atrial fibrillation, ischemic heart disease, chronic renal disease and chronic lung disease. The clinical presentation was analyzed in terms of mode of admission, symptomatic status, degree of ipsilateral and contralateral stenosis, plaque morphology, previous ipsilateral or contralateral carotid surgery, previous neck radiation, perioperative cardiac medications and ASA grade.

Procedure

Patients underwent CEA or CAS. Patients underwent CEA under general anaesthesia using systemic heparinisation, intravenous prophylactic antibiotics and selective shunting. The arteriotomy was repaired by direct closure, patching or an eversion endarterectomy.

Patients underwent CAS under local anesthesia. Access was gained via the femoral artery. A wire reached the carotid vessel after negotiating the aortic arch. An Emboshield (Abbott, Chicago, Illinois, USA) protection device was used routinely. Most cases involved stenting using an XACT carotid stent (Abbott, Chicago, Illinois, USA) followed by post-dilatation.

In C-CAS, a small cut-down incision of less than one centimeter in diameter was performed immediately above the clavicle, directly on the common carotid artery (CCA). The CCA was secured and slinged. Direct puncture of the CCA would be performed under direct vision. No EPD device was used. However, a negative pressure 50-milliliter syringe was utilized to create negative pressure that would cause reversal of flow. This negative pressure would be deployed during stenting, post-dilatation and during any manipulation.

Follow up

All patients were managed with dual antiplatelet therapy (aspirin and clopidogrel) for 6 months and were maintained on aspirin alone thereafter. DUS was performed postoperatively at 6 weeks and then at 6-monthly intervals for the next 3 years following procedure. Beyond that, patients were followed with DUS on an annual basis until 10 years post-procedure.

Outcome Variables

Outcome variables were defined according to the SVS reporting guidelines .[15]

The primary outcome of this analysis was perioperative and 30-day clinical success following CEA and CAS procedures. Clinical success was defined as freedom from any stroke , MI or mortality in the periprocedural period or within 30 days postoperatively. Stroke was defined as any disabling or nondisabling, ischemic or hemorrhagic stroke that occurred within 30 days of the procedure, ipsilateral to the site of carotid surgery. Perioperative mortality was defined as death that occurred due to any cause within 30 days of surgery. MI was diagnosed according to clinical presentation, electrocardiogram and troponin levels.

Secondary analysis focused on restenosis and reintervention rates and 5-year survival from stroke, mortality and reintervention. Restenosis was defined using the NASCET criteria as >50% occlusion of the carotid artery detected at any stage during follow-up on DUS . This corresponds to a peak systolic velocity ratio of >2 on DUS . Reintervention was defined as any ipsilateral carotid surgical procedure performed for any cause.

Statistical Analysis

All collected data was analyzed using IBM Statistical Package for the Social Sciences (SPSS) Statistics Version 22 (IBM corp., Armonk, NY, USA). Using logistic regression analysis, each CAS patient was given a propensity score based on the predictor variables (demographics, vascular-related risk factors, degree of stenosis on DUS). The propensity scores were then used to find 53 matched CEA patients from our overall cohort. Once the matched groups were created, chi-square analysis was used to test for group differences. All missing variables were coded and omitted from analysis. Continuous data was analyzed using t-tests or Mann-Whitney U where appropriate. Categorical data was assessed with chi-square and Fischer's exact analysis where suitable and an odds ratio was performed. Cox regression analysis was performed taking outcome measures (stroke, MI, mortality, restenosis and reintervention) as dependent variables and entering the vascular-related risk factors with significant p values ($p<0.05$) from univariate analysis as independent variables. All non-significant variables were then removed and cox regression analysis was repeated. The time to event endpoints (restenosis, reintervention, stroke and death) over a 10-year follow-up period were calculated using Kaplan-Meier survival estimates with significance assessed with a log rank test.

Results

Patient Characteristics

Patient demographics and vascular-related risk factors were remarkably similar between CEA, F-CAS and C-CAS patients (Table 1). Significant differences in creatinine levels and diastolic blood pressure were observed (Table 1). When comparing clinical presentation at the time of surgery, the degree of ipsilateral stenosis, previous ipsilateral carotid surgery and previous contralateral carotid surgery were significantly different between the three procedures (Table 2). Contralateral carotid artery stenosis >70% was present in 20.5% (n=7) of F-CAS, 15.8% (n=3) of C-CAS and 20.7% (n=11) of CEA patients (p=0.417). EPDs were used in 65.4% (34) of the patients assigned to stenting.

Follow-Up

Follow-up information was available for 102 (96.2%) patients (50 CEA, 33 F-CAS, 19 C-CAS). There were 4 patients lost to follow-up. The mean follow-up time was 45.8 ± 42.9 months with a median follow-up time of 38 months [IQR 7-72].

Of the patients lost to follow-up, 3 were CEA and 1 was F-CAS (p=0.514). There were no significant differences in baseline demographics and clinical presentation between patients who were followed up compared to those who were not.

Stroke

Within 30 days of surgery, 1.9% (n=1) of CEA, 2.9% (n=1) of F-CAS and 0% (n=0) of C-CAS patients developed a stroke (P = .752). CAS group had an odds ratio (OR) of 1.000 in developing a stroke compared to the CEA group (95%-CI:0.061-16.417). Within CAS, C-CAS had an OR of 0.635 in having a stroke within 30 days postoperatively compared to F-CAS (95% CI 0.516-0.780).

The overall stroke rate, at any time after procedure, was 5.7%, 2.9% and 0.0% in the CEA, F-CAS and C-CAS groups (P = .514), respectively. CEA had an OR of 3.120 in developing a postoperative stroke compared to CAS (95%-CI:0.314-31.002). Within CAS, C-CAS had an OR of 0.635 in developing a postoperative stroke compared to F-CAS (95%-CI:0.516-0.780).

5-year stroke free survival was 94.3% in CEA, 97.1% in F-CAS and 100% in C-CAS, respectively (log rank P = .552)(Figure 1).

Cox regression analysis did not find CEA or CAS to be independent predictors of stroke (P = .268).

Patient demographics and vascular-related risk factors did not significantly influence development of stroke in the three procedure groups.

There were 18 (34.6%) asymptomatic CEA and 20 (38.5%) asymptomatic CAS. Among asymptomatic patients, postoperative stroke rates were 11.1% (n=2) in the CEA group and 0% (n=0) in the CAS group (P = .218), respectively. There were 35 (66.0%) symptomatic CEA and 33 (62.3%) symptomatic CAS patients. Among symptomatic patients, postoperative stroke rates were 2.9% (n=1) in CEA and 3.0% (n=1) in CAS (P = .966), respectively. In our overall cohort of 690 carotid procedures, 1.4% of asymptomatic and 0.5% of symptomatic patients developed a postoperative stroke (P = .388).

There were 9 (17.0%) CEA patients and 10 (18.9%) CAS patients with <70% ipsilateral stenosis. None of these patients suffered a postoperative stroke. There were 44 (83.0%) CEA patients and 43 (81.1%) CAS patients with >70% ipsilateral stenosis. Among these patients, postoperative stroke rates were 6.8% (n=3) in CEA and 2.3% (n=1) in CAS (P = .618), respectively.

Myocardial Infarction

Thirty-day rate of myocardial infarction was 1.9% (n=1) in CEA and 0% in F-CAS and C-CAS, respectively (P = .320). CEA had an OR of 0.500 to develop a myocardial infarction within 30 days post-procedure, compared to CAS (95%-CI:0.413-0.606). An OR comparing F-CAS and C-CAS was not performed as none of the patients developed myocardial infarctions in these groups.

Multivariate analysis did not find CEA or CAS to be independent predictors of myocardial infarction (P = .309).

Patient demographics and vascular-related risk factors were not significantly associated with postoperative development of myocardial infarction.

Among asymptomatic patients, 5.6% (n=1) of CEA and 0% of CAS patients developed a postoperative myocardial infarction (P = .285), respectively. Among symptomatic patients, none suffered a myocardial infarction postoperatively.

There were no patients with ≤70% ipsilateral stenosis in CEA or CAS who developed a myocardial infarction postoperatively. Among patients with ≥70% stenosis, 1.9% (n=1) of CEA and 0% of CAS developed a postoperative myocardial infarction (P = .329), respectively.

Mortality

Thirty-day mortality was 1.9% in CEA, 2.9% in F-CAS and 0% in C-CAS (P = .752). CAS had an OR of 1.000 to suffer mortality within 30 days post-procedure compared to CEA (95%-CI:0.061-16.417). Within CAS, F-CAS had an OR of 0.635 to suffer mortality compared to C-CAS (95%-CI:0.516-0.780).

5-year freedom from mortality was 77.4% in CEA, 52.9% in F-CAS and 100% in C-CAS (log rank P = .384). CEA had an OR of 0.677 in dying postoperatively compared to CAS (95%-CI:0.283-1.616). Within CAS, F-CAS had an OR of 0.486 of dying postoperatively compared to C-CAS (95%-CI:0.349-0.677).

Multivariate analysis did not find CEA or CAS to be independent predictors of mortality (P = .503).

Patient demographics and vascular-related risk factors were not significantly associated with morality among the three procedures.

There was no significant difference in mortality rates between asymptomatic and symptomatic patients undergoing CEA and CAS (P = .239 and .893), respectively.

None of the patients with <70% ipsilateral stenosis died postoperatively. Among patients with >70% ipsilateral stenosis, 23.1% (n=12) in CEA and 32% (n=16) in CAS died postoperatively (P = .313), respectively.

Restenosis

Restenosis occurred in 2.3% of CEA patients, 0.0% of F-CAS and 11.8% of C-CAS patients, respectively (P = .079). CAS had an OR of 0.535 in developing restenosis compared to CEA (95%-CI:0.047-6.113). Within CAS, C-CAS had a 0.326 likelihood of developing restenosis compared to F-CAS (95%-CI:0.215-0.494).

5-year freedom from restenosis was 97.7% in CEA, 100% in F-CAS and 88.2% in C-CAS, respectively (log rank P = .011) (Figure 2).

Reintervention

Reintervention of previous ipsilateral carotid surgery occurred in 0% of CEA, 2.9% of F-CAS and 0% of C-CAS patients, respectively (P = .343). CAS had an OR of 0.495 to undergo reintervention compared to CEA (95%-CI:0.408-0.601). Within CAS, F-CAS had a 0.635 likelihood of undergoing reintervention compared to C-CAS (95%-CI:0.516-0.780). 5-year reintervention-free rates were 100% in CEA, 97.1% in F-CAS and 100% in C-CAS, respectively (log rank P = .457)(Figure 3).

Other Postoperative Complications

7.5% (n=4) of CEA patients and 0% (n=0) of CAS patients developed postoperative hypertension (systolic blood pressure ≥180 mmHg) (P = .169). There was no significant association between CEA and CAS and postoperative respiratory complications (3.8% vs. 0%, P = .368). 7.5% (n=4) of CEA and 7.7% (n=4) of CAS patients developed a postoperative cervical hematoma (P = .978).

There were no patients in the CEA or CAS groups who developed cranial nerve injury, renal complications, deep vein thrombosis, pulmonary embolism, procedural site pseudoaneurysm or infection (Table 3).

Discussion

There is a lack of consensus on the safety and efficacy of CAS compared to CEA in current literature.

The Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial was discontinued due to higher stroke rates following CAS.18 A systematic review of 21 registries found that procedural risks exceeded the AHA thresholds for both symptomatic and asymptomatic patients undergoing CAS.6 Inappropriate case selection and interventionalist inexperience in the studies we included in our review may have contributed to the higher stroke/death rates.[6]

The Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE) trial randomized patients to open or endovascular repair and found that CAS was non-inferior to CEA 30 days postoperatively and that outcomes between both were equivalent after 2 years of follow-up.19 The SAPPHIRE trial was conducted on a mixed cohort of symptomatic and asymptomatic patients and showed equivalent outcomes between CEA and CAS at medium-term and long-term follow up.[20] Our findings are consistent with the SPACE and SAPPHIRE trial as CAS or CEA were not found to be independent predictors of stroke, myocardial infarction and mortality (P = .268, .503 and .384), respectively.

The incidence of myocardial infarction within 30 days of surgery was lower after CAS than CEA (0% vs. 1.9%, P = .320). These results are consistent with those of the CREST trial.[5]

The choice of carotid repair intervention may be influenced by symptom status at the time of surgery as equally stenotic symptomatic and asymptomatic lesions may vary considerably in terms of carotid plaque morphology and structure.21 Manipulation of an unstable carotid plaque during CAS in symptomatic patients may result in embolization.[16,21] In our centre, CAS is only performed in patients with hostile necks either due to previous surgery or neck radiation.

Giacovelli et al found that symptomatic patients treated with CAS had three times higher mortality rates compared to CEA and that asymptomatic patients had similar outcomes following CEA and CAS.16 In our study, no significant difference in postoperative stroke rates in asymptomatic (P = .126, P = .239) and symptomatic (P = .966, P = .893) patients following CAS and CEA were observed, respectively. This is similar to the results of the CREST trial where symptomatic and asymptomatic patients had similar outcomes following CEA and CAS.[5]

The incidence of other post-operative complications may be procedure-specific. One study found that CEA patients are at increased risk of respiratory, venous thromboembolic and catheter-related complications.21 This may be attributed to more frequent use of

intubation, greater immobility and Foley catheter placement in open procedures.[21] At our institution, no significant differences were observed in the development of respiratory complications between CEA and CAS (P = .368). No patients in our study developed venous thromboembolism and catheter-related infections postoperatively.

In two studies, CAS patients were found to be at an increased risk of device complications and hypotension.[16, 21, 22] These findings are inconsistent with those observed at our centre. No patients in our study developed patch complications. Postoperative hypotension occurred in 3.0% (1) of F-CAS patients and in no patients undergoing C-CAS or CEA (P = .388).

There is considerable debate about the appropriate techniques used to perform CAS. At our institution, CAS procedures were initially performed via transfemoral access and EPDs. There are many technical challenges associated with this approach including difficult femoral arterial access, complex aortic arch anatomy and circumferential ICA calcification.[23] We now use a transcervical approach with ICA flow reversal under local anaesthesia. This technique effectively decreases the incidence of intracranial embolization.[24, 25] Cervical access is superior to a transfemoral approach as it eliminates the risk of embolization from the aortic arch, does not require preprocedural mapping of aortic arch configuration and allows for easy conversion to CEA if necessary.[23]

The effect of protected CAS over no neuroprotection has not been established.[23] EPDs reduce, but do not eliminate the risk of embolization.[23, 26] A World Registry reported a 2.23% stroke/mortality rate in 4221 cases of CAS with cerebral protection versus 5.29% in patients without protection.[26] In our study, 65.4% (34) of CAS procedures were performed with EPDs. The 1 patient with F-CAS who suffered a stroke had an EPD.

Conclusion

We found that CAS was not inferior to CEA in appropriately selected patients. Stenting resulted in rates of complications for all adverse events that were statistically equivalent to CEA. Cervical access to the carotid artery during stenting resulted in lower rates of perioperative and overall stroke, perioperative mortality and reintervention rates when compared to a transfemoral approach and CEA. 5-year freedom from restenosis was significantly lower in C-CAS. Symptom status at the time of surgery and degree of ipsilateral carotid artery stenosis did not influence the development of postoperative complications in both CEA and CAS patients. Further understanding of plaque stability and tensile strength is required in order to achieve the optimum endovascular approach.

Table 1. Baseline Demographics and Risk Factors According to Treatment Group

Characteristic	Transfemoral CAST (n = 34)	Transcervical CAST (n = 19)	CEA (n = 53)	p
Age, y	72.2 + 8.6	67.2 + 9.8	70.3 + 8.1	0.138
Male	61.8 (21)	63.2 (12)	67.9 (36)	0.825
Symptomatic	60.6 (20)	63.2 (12)	65.4 (34)	0.905
Hypertension	88.2 (30)	84.2 (16)	81.1 (43)	0.731
Hyperlipidemia	82.4 (28)	73.7 (14)	81.1 (43)	0.723
Diabetes Mellitus	17.6 (6)	10.5 (2)	20.8 (11)	0.665
Current Smoking	32.4 (11)	10.5 (2)	28.8 (15)	0.200
Ischemic Heart Disease	52.9 (18)	52.6 (10)	52.8 (28)	1.000
Chronic Heart Failure	8.8 (3)	0 (0)	3.8 (2)	0.478
Atrial Fibrillation	17.6 (6)	15.8 (3)	13.2 (7)	0.823
Chronic Pulmonary Disease	29.4 (10)	15.8 (3)	23.1 (12)	0.563
Renal Insufficiency	17.6 (6)	5.3 (1)	15.1(8)	0.498
Hyperfibrinogenaemia	18.8 (6)	27.8 (5)	37.5 (18)	0.195
Serum Creatinine	114.0 + 42.8	87.8 + 17.4	96.9 + 25.3	0.007
Serum Fibrinogen	3.5 + 0.7	3.7 + 1.4	3.9 + 1.0	0.132
Systolic Blood Pressure, mm Hg	135.5 + 26.9	141.7 + 18.5	132.9 + 17.4	0.184
Diastolic Blood Pressure, mm Hg	66.6 + 8.6	74.7 + 9.3	70.8 + 9.3	0.009

Table 2. Clinical Presentation According to Treatment Group

Characteristic	Transfemoral CAST (n = 34)	Transcervical CAST (n = 19)	CEA (n = 53)	p
Emergency Admission	47.1 (16)	26.3 (5)	30.8 (16)	0.202
Symptomatic	60.6 (20)	63.2 (12)	65.4 (34)	0.891
Plaque echolucency				
Ipsilateral Stenosis, > 70%	82.3 (28)	78.9 (15)	83.0 (44)	0.007
Previous Ipsilateral Treatment	26.5 (9)	78.9 (15)	0.0 (0)	0.000
Contralateral Stenosis, >70%	20.5 (7)	15.8 (3)	20.7 (11)	0.417
Previous Contralateral Treatment	14.7 (5)	31.6 (6)	7.5 (4)	0.036
Previous Neck Radiation	2.9 (1)	5.3 (1)	0.0 (0)	0.302
ASA Grade, > 3	32.4 (11)	52.6 (10)	47.2 (25)	0.241

Table 3. Cumulative Incidence of Adverse Events According to Treatment Group

Complication	Transfemoral CAST (n = 34)	Transcervical CAST (n = 19)	CEA (n = 53)	p
Stroke < 30 Days	0 (0)	0 (0)	4.9 (2)	0.200
Stroke	2.9 (1)	0 (0)	5.7 (3)	0.514
Myocardial Infarction	0 (0)	0 (0)	1.9 (1)	0.609
Mortality	47.1 (16)	0 (0)	22.6 (12)	0.001
Pulmonary Complications	0 (0)	0 (0)	3.8 (2)	0.368
Heart Complications	3.0 (1)	0 (0)	1.9 (1)	0.744
Groin or Cervical Hematoma	9.1 (3)	5.3 (1)	7.5 (4)	0.882
Access Site or Wound Infection	3.0 (1)	0 (0)	1.9 (1)	0.744
Access Site Pseudoaneurysm	0 (0)	0 (0)	0 (0)	0.736
Procedural Site Bleeding	0 (0)	0 (0)	0 (0)	0.736
Cranial nerve injury <30 days	0 (0)	0 (0)	9.8 (4)	0.078

Hypotension	0 (0)	0 (0)	5.6 (1)	0.460
Patch/Stent Complications	0 (0)	0 (0)	1.9 (1)	0.609
Duration of Critical Care Stay	0.25 ± 0.76	1.37 ± 1.17	1.47 ± 0.89	0.089

Figure 1

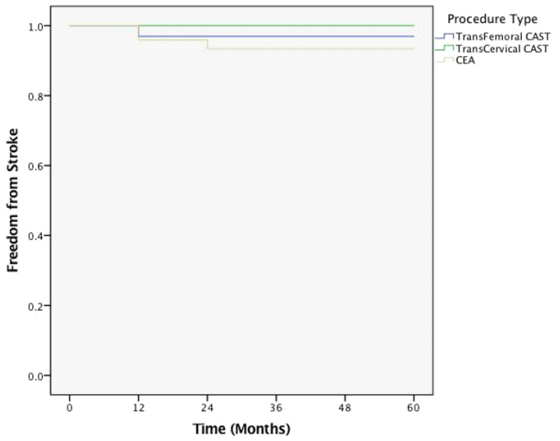


Figure 2

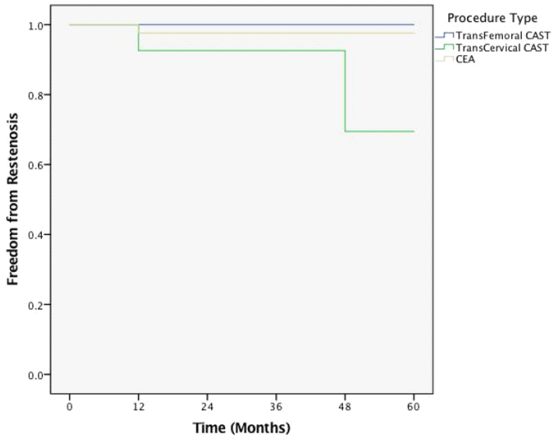
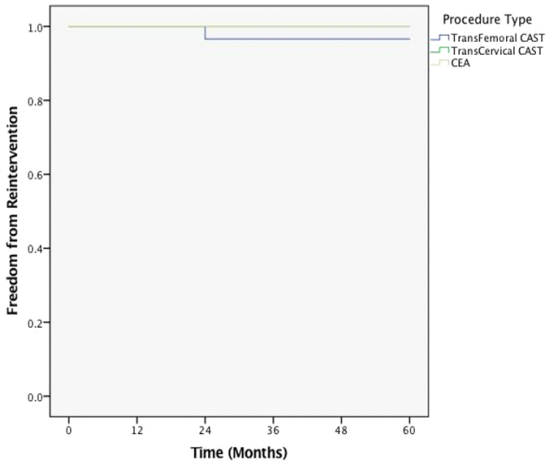


Figure 3



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