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Comparison of 30 Day Stroke and Death in Hybrid Intervention and Open Surgical Reconstruction for the Treatment of Tandem Carotid Bifurcation and Supra-aortic Trunk Disease☆

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WHAT THIS PAPER ADDS

Optimal treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease remains controversial. This paper uses American College of Surgeons — National Surgical Quality Improvement Program (ACS-NSQIP) data to perform the first cohort comparison of hybrid *vs.* open repair of such lesions. No differences in 30 day stroke or death were found. In appropriately selected patients, both may be reasonable strategies with the recent European Society for Vascular Surgery guideline recommendation of retrograde access for SAT treatment as the initial consideration being sensible.

Objective: The optimal approach for the treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease remains controversial. The hybrid technique of carotid endarterectomy (CEA) with ipsilateral proximal endovascular intervention (IPE) has provided an attractive alternative to CEA with open SAT reconstruction (SATr). However, no studies have compared cohorts treated by these two approaches.

Methods: Using the National Surgical Quality Improvement Program (2005–2017), patients who underwent CEA + IPE and CEA + SATr were identified. Non-occlusive indications were excluded. Primary outcomes included 30 day stroke, death, and their composite (stroke and/or death [SD]). Univariable and logistic regression analyses were performed.

Results: In total, 372 patients were identified: 319 CEA + SATr and 53 CEA + IPE. SATr included 19 (5.9%) aorta to carotid bypasses, 22 (6.9%) carotid subclavian transpositions, 96 (30.1%) carotid carotid bypasses, 179 (56.1%) carotid subclavian bypasses, and three (0.9%) SAT endarterectomies. The mean age was 69 ± 10 years. The majority were men (53%), white (85%), and had a history of hypertension (84%). There were no demographic differences between the operative cohorts except that those having CEA + SATr were more likely to have hypertension (86% *vs.* 74%; $p = .031$). CEA + SATr had longer operative times and longer hospital length of stay. There were no differences in outcomes between the cohorts: stroke (CEA + SATr 4.1% *vs.* CEA + IPE 3.8%; $p = .92$), death (1.6% *vs.* 0%; $p = .36$), or SD (5.3% *vs.* 3.8%; $p = .63$). After risk adjustment, predictors of SD included symptomatic status (odds ratio [OR] 3.9, 95% confidence interval [CI] 1.1–13.5; $p = .034$), congestive heart failure (OR 16.5, 95% CI 2.0–136; $p = .011$), and return to the operating room (OR 8.5, 95% CI 2.3–30.8; $p = .001$). Operative method was not predictive ($p = .63$).

Conclusion: Outcomes following CEA + SATr and CEA + IPE are similar. Although proposed as a safer, less invasive alternative, the hybrid approach did not reduce the risk of operative stroke or death relative to open reconstruction for the treatment of occlusive, tandem carotid/SAT disease. Based upon lesion and patient factors, both may be considered management options in select patients.

Keywords: Balloon angioplasty, Brachiocephalic trunk, Carotid endarterectomy, Treatment outcome
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INTRODUCTION

While relatively uncommon, the management of patients with tandem carotid bifurcation and supra-aortic trunk (SAT) disease can be challenging.[1,2] This is especially true in symptomatic patients as the embolic potential of each individual lesion is difficult to determine. Thus, the general practice is to treat both areas of disease. In the past, SAT lesions had been exclusively treated by open repair via

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trans- or extrathoracic reconstruction with bypass or endarterectomy. The most recent analyses have described peri-operative stroke and death rates ranging from 3% to 7% following open SAT reconstruction.[3,4]

Owing to concerns about high peri-operative morbidity, hybrid techniques for the treatment of tandem lesions have been investigated.[5] This approach, first described in 1996 by Diethrich *et al.*,[6] involves open surgical carotid exposure followed by retrograde stenting of more proximal lesions combined with carotid endarterectomy (CEA).[6] Favourable outcomes of hybrid intervention have been reported; in recent meta-analysis, a 1.5% combined peri-operative stroke and death rate following CEA with ipsilateral proximal endovascular intervention (IPE) was highlighted.[7] Following concerns over cross institutional results, a contemporary analysis of patients undergoing this hybrid approach in the Vascular Quality Initiative was performed, which found an overall peri-operative stroke and death risk of 3.5%.[8] In symptomatic patients, a stroke and death rate of 6% was noted. Further, in a prior assessment of the National Surgical Quality Improvement Program (NSQIP), a similar stroke and death rate of 5% was seen in patients undergoing combined CEA with open SAT reconstruction.[9] Thus, while CEA combined with IPE provides an attractive, less invasive alternative to CEA with concomitant open SAT reconstruction, its effectiveness in risk reduction remains unclear and no direct analysis of cohorts managed by these two approaches exists. To that end, a comparison of operative outcomes in open and hybrid techniques for the treatment of tandem lesions using a contemporary national database was performed.

MATERIALS AND METHODS

Study sample

The American College of Surgeons' NSQIP is a national, multi-institutional clinical database.[10] Data are collected prospectively at the institutional level and centralised. These processes have been described and validated previously.[11] Participation in this registry as a quality assurance tool is approved, and direct informed consent waived, by each centre's Institutional Review Board. More information about NSQIP can be found at www.facs.org/quality-programs/acs-nsqip.

Patients, data collection, definitions, and end points

A retrospective review of patients in the NSQIP database from 2005 to 2017 was performed. Inclusion criteria were patients undergoing CEA (current procedural terminology [CPT] codes 35301 and 35390) concomitantly with either ipsilateral proximal endovascular intervention (CPT codes 35458, 37207, 37217, and 37218) or open surgical reconstruction for SAT disease (CPT 35506, 35507, 35606, 35509, 35601, 35694, 35695, 35511, 35612, 35526, 35626, 35021, and 35311). Only patients with a primary discharge diagnosis related to atherosclerotic occlusive indications were included.[4] Patients undergoing CEA concomitantly with SAT reconstruction (SATr) comprised the CEA + SATr cohort, while those undergoing CEA combined with IPE represented the CEA + IPE group.

Demographics, clinical variables, and operative details were reviewed. Chronic kidney disease (CKD) was defined as a baseline creatinine of >1.5 mg/dL (133 μmol/L). Symptomatic status was defined as prior ipsilateral stroke or transient ischaemic attack. All NSQIP definitions, as outlined in the participant use data files, can be found at: https://www.facs.org/quality-programs/acs-nsqip/participant-use. Primary end points included peri-operative (30 day) stroke, death, and the composite of stroke and/or death (SD).

Statistical analysis

Statistical analysis was performed with Stata/SE 13 software (StataCorp, College Station, TX, USA). Dichotomous variables are described as a percentage of the cohort. Continuous variables are expressed as median (interquartile range [IQR]). Univariable analysis was performed to compare baseline clinical features and post-operative complications. The chi square test was used for discrete variables and the Mann—Whitney test for continuous variables. Significant factors in univariable analysis were included in a logistic regression model to determine independent predictors of 30 day outcomes. Goodness of fit Hosmer—Lemeshow testing was performed. A p value of $< .05$ was considered significant.

RESULTS

Demographics

After review and exclusion, 372 patients were identified. In total, 319 (85.8%) underwent open SAT reconstruction with CEA (CEA + SATr) and 53 (14.2%) patients had CEA with concomitant IPE (CEA + IPE). Most patients were male ($n = 195$; 52.4%) and white ($n = 317$; 85.2%). The median age was 69 years (IQR 62—76 years). Symptomatic cerebrovascular disease was present in 34% ($n = 102$) of patients. Patient demographics were similar between the operative cohorts. With respect to comorbidities, hypertension was more common in the CEA + SATr cohort (86% *vs.* 74%; $p = .031$). There was a trend towards higher rates of CKD in CEA + SATr (13% *vs.* 6%; $p = .18$). Similar American Society of Anesthesiologists' classification scores and pre-operative laboratory values were noted between cohorts (Table 1).

Operative characteristics

Most procedures were elective (CEA + SATr 83% *vs.* CEA + IPE 80%; $p = .65$). Operative times were longer in the CEA + SATr cohort (median 3.1 h *vs.* 2.9 h; $p = .024$). Most procedures were performed by vascular surgeons (CEA + SATr 97% *vs.* CEA + IPE 98%; $p = .70$). Breakdown of SATr included aorto-great vessel reconstruction performed in 22 patients (6.9%); carotid carotid bypass in 96 (30.1%); carotid subclavian bypass in 179 (56.1%); and carotid subclavian transposition in 22 (6.9%) (Table 2).

Peri-operative outcomes

Overall, the 30 day mortality rate was 1.3%, stroke rate was 4.0%, myocardial infarction (MI) rate 2.2%, and SD rate 5.1%. Eight percent of patients ($n = 29$) required any return to the

Table 1. Demographic and clinical features of 372 patients undergoing treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease by carotid endarterectomy (CEA) combined with open SAT reconstruction (SATr) or ipsilateral proximal endovascular intervention (IPE) recorded in the American College of Surgeons' National Surgical Quality Improvement Program database in 2005–2017

Demographic	Total cohort (n = 372)	CEA + SATr (n = 319; 85.8%)	CEA + IPE (n = 53; 14.2%)	p
Age – y	69 (62–76)	68 (62–75)	71 (62–76)	.30
Gender – male	195 (52.4)	169 (53.0)	26 (49)	.69
White	317 (85.2)	271 (84.9)	46 (86.8)	.73
Comorbidities				
Hypertension	312 (83.9)	273 (85.6)	39 (73.6)	.031
CHF	6 (1.6)	6 (1.9)	0 (0)	.31
Current smoker	155 (41.7)	132 (41.4)	23 (43.4)	.78
COPD	72 (19.3)	64 (20.1)	8 (15.1)	.40
Diabetes	98 (26.3)	85 (26.6)	13 (24.5)	.75
Obese	117 (31.4)	101 (31.7)	16 (30.2)	.83
Creatinine $\geq$ 1.5 mg/dL	43 (11.6)	40 (12.5)	3 (5.7)	.18
Symptomatic disease	102 (34)	88 (34)	14 (33)	.95
BMI – kg/m^2	27 (24–31)	27 (24–31)	27 (23–31)	.31
Independent ADL	245 (95)	212 (95)	33 (100)	.17
ASA classification				.72
No disturbance (1)	3 (0.8)	3 (0.9)	0 (0)	
Mild disturbance (2)	16 (4.3)	15 (4.7)	1 (2)	
Severe disturbance (3)	243 (65.3)	205 (64.3)	38 (72)	
Life threatening (4)	109 (29.3)	95 (29.8)	14 (26)	
Moribund (5)	1 (0.3)	1 (0.3)	0 (0)	
Pre-operative laboratory values				
Creatinine – mg/dL	1 (0.8–1.2)	1 (0.8–1.2)	0.9 (0.8–1.2)	.76
Haematocrit – %	39 (35–42)	39 (35–42)	39 (35–42)	.88
Platelets – 10^3/μL	222 (184–271)	221 (183–271)	230 (189–272)	.47
INR	1 (1–1.1)	1 (1–1.1)	1 (1–1.1)	.80

Data are presented as n (%) or median (interquartile range). CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; BMI = body mass index; ADL = activities of daily living; ASA = American Society of Anesthesiologists; INR = international normalised ratio.

operating room, and this was similar between operative cohorts (p = .94). Length of stay was shorter for CEA + IPE (p = .027). No statistical difference was seen in stroke (CEA + SATr 4.1% *vs.* CEA + IPE 3.8%; p = .92), death (1.6% *vs.* 0%; p = .36), or MI (2.5% *vs.* 0%; p = .24) between cohorts, but a trend towards higher death and MI rates was appreciated in the CEA + SATr cohort. SD was also similar between groups (CEA + SATr 5.3% *vs.* CEA + IPE 3.8%; p = .63) (Table 3). Within the CEA + SATr cohort, there was a trend towards higher 30 day SD in anatomical reconstruction *vs.* extra-anatomical reconstruction (9% *vs.* 5%; p = .42). Overall, in symptomatic patients, SD occurred in 7.8%, while in asymptomatic patients it was 3.5% (p = .10).

Predictors of stroke/death

After risk adjustment, predictors of SD included symptomatic status (odds ratio [OR] 3.9, 95% confidence interval [CI] 1.1–13.5; p = .034), congestive heart failure (OR 16.5, 95% CI 2.0–136; p = .011), and return to the operating room (OR 8.5, 95% CI 2.3–30.8; p = .001). Operative method was not predictive (p = .63) (Table 4).

DISCUSSION

Approaches to managing tandem SAT lesions and carotid bifurcation stenosis remain controversial. In this NSQIP analysis, 372 patients undergoing CEA with either open SAT reconstruction or IPE were studied. Comparing these two treatment strategies, the demographics and comorbidities of patients were similar. Across all major cardiovascular end points, there were no statistically significant differences in operative outcomes. Specifically, no differences in peri-operative MI, stroke, death, or SD were seen; however, a trend towards more MIs and higher SD in the CEA + SATr cohort was appreciated. On logistic regression, one approach was not associated with increased risk of combined stroke and death over the other with only symptomatic status and congestive heart failure predictive. These results suggest no clear advantage in peri-operative cardiovascular outcomes between these two approaches to tandem, extracranial lesions.

The use of an open carotid operation with hybrid, retrograde SAT endovascular treatment was first identified in 1996.[6] This approach has several technical advantages, which include short, more direct arch access, avoidance of other aortic and arch disease, surgical carotid clamp neuroprotection, ability to flush intervention debris directly, and avoidance of sternotomy or thoracic inlet exposure. Further, quicker recovery and shorter length of stay, as seen here, are recognised. Such described advantages have led to many small, institutional experiences describing the ease and success of CEA + IPE, culminating in an accumulation of these in 2011. This meta-analysis relayed a stroke and death rate with this hybrid procedure of 1.5%.[7] The authors suggested that this was a risk reducing procedure with little additive risk to standard CEA.

Enamoured with the potential technical advantage of this hybrid strategy, but concerned over perceived outcomes, institutional and regional multi-institutional results were reviewed. These suggested that CEA + IPE was indeed more risky neurologically than originally appreciated.[12,13] Moreover, long term results were not ideal as five year freedom from restenosis and re-intervention were 66% and 81%, respectively. Subsequently, the VQI was used to investigate how the addition of IPE to CEA affected operative outcomes. Overall, CEA + IPE resulted in a 30 day stroke and death rate of 3.5%. The rate was 1.4% in neurologically asymptomatic

Table 2. Peri-operative findings in 372 patients undergoing treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease by carotid endarterectomy (CEA) combined with open SAT reconstruction (SATr) or ipsilateral proximal endovascular intervention (IPE) recorded in the American College of Surgeons National Surgical Quality Improvement Program database in 2005–2017

Peri-operative details	Total cohort (n = 372)	CEA + SATr (n = 319; 85.8%)	CEA + IPE (n = 53; 14.2%)	p
Elective	194 (83)	170 (83)	24 (80)	.65
Surgery performed by vascular surgeon (*vs.* cardiac, thoracic, or general surgeon)	362 (97.3)	310 (97.1)	52 (98.1)	.70
Procedure time – h	3.1 (2.4–4.0)	3.1 (2.4–4.0)	2.9 (2.1–3.6)	.024
Length of stay – d	2 (1–5)	2 (1–5)	2 (1–3)	.027
Reconstruction type				
Aorta to great vessel reconstruction	22 (6.9)	22 (6.9)		
Carotid carotid bypass	96 (30.1)	96 (30.1)		
Carotid subclavian bypass	179 (56.1)	179 (56.1)		
Carotid subclavian transposition	22 (6.9)	22 (6.9)		

Data are presented as n (%) or mean (interquartile range).

patients and 6% in symptomatic patients.[8] The addition of IPE to CEA nearly doubled the risk of operative stroke and death. Others have also more recently appreciated the technical simplification, but agreed that the procedure carried more risk than CEA alone.[14,15] Herein, the CEA + IPE cohort showed a similar overall stroke and death risk of 3.8% as these previous reports.

Full open surgical management of tandem lesions has been done for decades. The stroke and death risk of open SAT reconstruction is reported to be 3%–7%.[3,4,16,17] However, only 8%–17% of patients in these SATr series underwent concomitant CEA and the risk profile of adding CEA to SATr is less clear. Risty *et al.* found that the addition of CEA to open carotid subclavian bypass or transposition led to a 3.6% stroke risk, which was significantly higher than the <1% for a carotid–subclavian operation alone.[18] Recent study has indicated that adding CEA to SATr does not substantially change the risk of stroke and death *vs.* isolated SATr.[9] The current analysis illustrates that regardless of whether IPE or SATr is performed in conjunction with CEA to correct tandem carotid lesions, both carry similar additive procedural cardiovascular risk.

Table 3. Thirty day post-operative complications in 372 patients undergoing treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease by carotid endarterectomy (CEA) combined with open SAT reconstruction (SATr) or ipsilateral proximal endovascular intervention (IPE) recorded in the American College of Surgeons National Surgical Quality Improvement Program database in 2005–2017

30 d complications	Total cohort (n = 372)	CEA + SATr (n = 319; 85.8%)	CEA + IPE (n = 53; 14.2%)	p
Return to the OR	29 (7.8)	25 (7.8)	4 (7.5)	.94
Stroke	15 (4.0)	13 (4.1)	2 (3.8)	.92
Death	5 (1.3)	5 (1.6)	0 (0)	.36
MI	8 (2.2)	8 (2.5)	0 (0)	.24
Stroke and/or death	19 (5.1)	17 (5.3)	2 (3.8)	.63

Data are presented as n (%). OR = operating room; MI = myocardial infarction.

Both CEA and SATr are durable, with long term patency of >90% at five years, with low re-intervention rates.[3,16,17,19–22] As noted, prior assessment of CEA + IPE would suggest that the longer term results of the hybrid procedure are inferior to CEA + SATr, and restenosis, re-intervention, and a reduction in stroke risk clearly need to be better defined in the future. Thus, the current study's recommendation is that lesion characteristics, patient comorbidities, and longevity should drive selection of CEA + IPE or CEA + SATr for these lesions. The recent European Society for Vascular Surgery guidelines recognise that in many patients these features probably favour CEA + IPE.[23] This study indicates that this is reasonable, but in the correct patient CEA + SATr remains valuable, with good results. Moreover, the guidelines recommend that treatment of asymptomatic patients with proximal SAT lesions should be avoided. Indeed, these results discourage repair in asymptomatic individuals. Other described approaches to tandem arch and bifurcation stenoses include total transfemoral endovascular treatment, transfemoral arch treatment with CEA clamp protection, and CEA + IPE with or without contralateral neuroprotection.[24–27] All remain descriptive in small series.

There are several limitations to this analysis, the first of which lies in the retrospective assessment of a prospectively

Table 4. Predictors of 30 day stroke and/or death in patients undergoing treatment of tandem carotid bifurcation and supra-aortic trunk (SAT) disease by carotid endarterectomy (CEA) combined with open SAT reconstruction or ipsilateral proximal endovascular intervention (IPE) recorded in the American College of Surgeons National Surgical Quality Improvement Program database in 2005–2017

Risk factor	Stroke and/or death at 30 d*	
	OR (95% CI)	p
CEA + IPE	0.6 (0.1–5.0)	.63
Symptomatic	3.9 (1.1–13.5)	.034
Congestive heart failure	16.5 (2.0–136)	.011
Return to operating room	8.5 (2.3–30.8)	.001

OR = odds ratio; CI = confidence interval.
* Adjusted for operative procedure, symptomatic status, pre-operative functional health status, CHF, and return to the operating room.

collected database. NSQIP is susceptible to entry errors, as well as missing data, but routine quality reviews are performed to mitigate these issues. Owing to relatively infrequent presentations of patients with tandem carotid bifurcation and SAT disease, these combined procedures are uncommon. This results in smaller numbers of cases available for analysis and introduces limitations for extrapolation and interpretation. This assessment is underpowered, particularly in the CEA + IPE group, and may have led to a type II error. It may be that most CEA + IPE were performed in a few centres, yet centre specific data are not available in NSQIP, and adjustments for differences in indication and approach were not done. Within NSQIP, symptomatic status is only described as prior stroke or transient ischaemic attack. Tandem lesion clinical sequelae such as hypoperfusion, or non-specific symptoms with imaging findings, may have been missed. While cohort numbers did not allow specific analysis by symptomatic status, it is interesting that, overall, 34% of patients were noted as symptomatic. This is similar to the 41% in the recent VQI analysis of CEA + IPE.[8] Coding terms changed over the timeframe of study; however, an attempt was made to use codes that would have identified open access for proximal intervention. Some procedures for tandem lesions may have been missed. Stenosis characteristics, and contralateral and vertebrobasilar extracranial cerebrovascular disease are not captured in this data set. Additionally, it is appreciated that both trans- and extrathoracic reconstructions are included in the SATr cohort and there may be nuances associated with morbidity that are not presented herein. Finally, granular intra-operative details are not provided, and thus conduct or temporal sequencing (SATr/IPE first *vs.* CEA first) of repair cannot be commented on, and the true conduct of neurological protection in these cases cannot be described. Long term durability and ipsilateral stroke risk reduction cannot be studied using NSQIP.

Conclusion

Herein, operative outcomes in CEA combined with either open SATr or IPE were compared. The peri-operative risk of stroke and death were similar between cohorts. Although a less invasive alternative, the hybrid approach does not appear to reduce the procedural risk of stroke or death relative to open reconstruction for the treatment of occlusive, tandem carotid bifurcation, and SAT disease. The selection of treatment strategy in tandem lesions should depend upon lesion characteristics, patient comorbidity profile, and projected longevity. Both approaches may be reasonable options. The current European Society for Vascular Surgery guidelines, established in 2018, recommend retrograde open access for SAT lesions as the first line therapy. The current study suggests not only that this is a reasonable approach, but also that open reconstruction in the correct patient is valuable. A better understanding of long term risk reduction effectiveness and clinical durability in tandem lesion treatment is needed.

CONFLICT OF INTEREST

None.

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COUP D'OEIL

Gastroduodenal Artery as an Inflow Artery for Right Hepatic Artery Reconstruction

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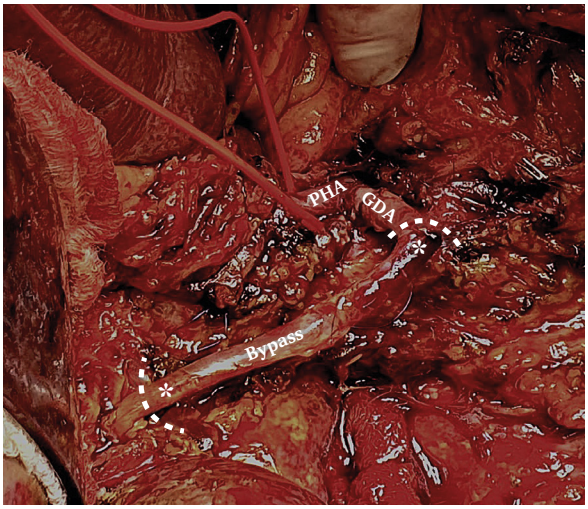

Two days after laparoscopic cholecystectomy, a complete loss injury to the right hepatic artery and a Strasberg E3 bile duct injury with signs of liver ischaemia were found at surgical revision. A hepaticojejunal anastomosis was performed and a reversed great saphenous vein bypass was sutured end to end (asterisks) between a distally ligated and transposed gastroduodenal artery (GDA) and the hilar part of the right hepatic artery (dashed lines). This technique circumvents anastomoses of the proper hepatic artery (PHA), complications of which may compromise blood supply to both hepatic arteries. The post-operative course was uncomplicated, and at discharge computed tomography angiography showed a patent bypass.

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