

Early results of carotid endarterectomy versus carotid stenting: Outcomes from a Mediterranean country

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Abstract

Introduction and objectives: Which is the best carotid stenosis treatment remains a controversial issue. To present day, no study has compared the results of carotid artery stenting versus carotid endarterectomy in Portugal. We aim to provide *real life* numbers regarding the outcomes of both procedures in Portuguese public hospitals.

Methods: Every patient registered between 2005 and 2015 with the main diagnosis of carotid stenosis and submitted to carotid endarterectomy or carotid artery stenting was included. The information was obtained through the Central National Healthcare Administrative database, a mandatory registry for hospital refunding. Primary outcomes were hospital mortality and stroke. Patient demographics, comorbidities and hospital length of stay were also evaluated.

Results: The study included 6094 patients: 1399 were symptomatic (mention of prior stroke) and 4695 asymptomatic. Carotid artery stenting was performed on 22% of the symptomatic and 18% of the asymptomatic patients. In the symptomatic patients, the in-hospital mortality was significantly higher in those submitted to stenting (3.6% vs. 1.6% in carotid endarterectomy, $p = 0.025$). No significant differences in outcomes were observed in the asymptomatic group (mortality 0.9% vs. 0.8%, $p = 0.852$; stroke rate of 2.6% vs. 2.3%, $p = 0.652$ – carotid artery stenting vs. carotid endarterectomy). In both groups, there was an important increase in the proportion of stenting between 2005 and 2012, followed by a gradual decline until 2015.

Conclusion: Despite its increasing frequency, a higher early mortality was documented for CAS in symptomatic patients. No worse outcome was observed in asymptomatic patients.

Keywords

Carotid endarterectomy, endovascular procedures, database, registry, carotid artery stenting

Introduction

Carotid artery atherosclerosis remains an important and potentially preventable cause of stroke.¹ Current intervention options include carotid endarterectomy (CEA) and carotid artery stenting (CAS). The results of CEA and CAS were compared in multiple prospective studies and, from 2011 on, 11 meta-analyses have been published.^{2–4} Their main conclusions are somewhat similar, indicating an approximate 1.5- to 2-fold increase in periprocedural stroke and/or death for CAS compared with CEA, with no significant difference in mortality alone.^{2–4} Despite the increasing number of studies with fairly agreeing results, the relative role of CEA and CAS differs between different major

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guidelines.^{5–8} The American Heart Association and European Society of Cardiology support a role for CAS in symptomatic and high risk asymptomatic patients.^{6,7} The Society of Vascular Surgery (SVS) relegates the role of CAS to highly selected symptomatic patients, disapproving its use in asymptomatic patients outside randomized trials.⁵ The European Society of Vascular and Endovascular Surgery (ESVS) admits a role for CAS in both asymptomatic and younger symptomatic patients (<70 years), in low-risk centers.⁸ The ideal treatment of carotid stenosis, either in symptomatic or asymptomatic patients, remains therefore one of the most controversial themes in vascular pathology.

There are insufficient data regarding the results of these procedures in several countries. So far, no nationwide studies have compared the outcomes of CAS and CEA in Portugal. The present study aims to fill this gap. Data from this work provide new *real life* numbers regarding the procedures. Those numbers will further complement an ever-growing body of evidence concerning carotid treatment options and outcomes.

Materials and methods

All patients registered in the Central National Healthcare Administrative Database, between 2005 and 2015, with the main diagnosis of carotid stenosis (with or without prior neurological symptoms) and submitted to carotid endarterectomy or stenting were included in the study (Table 1). Patients submitted to synchronous heart surgery in the same hospital stay were excluded. These data include all patients treated by the Portuguese National Healthcare System hospitals. The registry of patients in this database is mandatory for Hospital refunding. The data are limited to the in-hospital results.

Primary outcomes were hospital mortality and stroke. Patient demographics, comorbidities and hospital length of stay were also abstracted, and a subgroup analysis of female patients and octogenarians was performed.

Mortality was defined as any in-hospital death occurring after carotid intervention. Stroke was defined as the presence of the following ICD-9-CM codes in the same hospital stay of the carotid intervention: 434.91;

434.11; 430, 431, 432.0–432.9; 434.01; 997.02. Due to this design, the stroke risk could not be evaluated in symptomatic patients: a stroke previous to the intervention, but in the same hospital stay, could not be excluded. ICD-9-CM coding for comorbidities was based on the coding algorithms for Elixhauser Comorbidities⁹ – ICD-9-CM codes – hypertension (complicated) – 402.x–405.x; hypertension (uncomplicated) – 401.x; coronary artery disease – 410, 411, 413, 414; peripheral vascular disease – 093.0, 437.3, 440.x, 441.x, 443.1–443.9, 447.1, 557.1, 557.9, V43.4; hyperlipidemia – 272; smoking – 305.1; heart failure – 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 425.4–425.9, 428.x; cardiac arrhythmias – 426.0, 426.130, 426.7, 426.9, 426.10, 426.12, 427.0–427.4, 427.6–427.9, 785.0, 996.01, 996.04, V45.0, V53.3; diabetes mellitus (complicated) – 250.4–250.9; diabetes mellitus (uncomplicated) – 250.0–250.3; chronic lung disease – 416.8, 416.9, 490.x–505.x, 506.4, 508.1, 508.8; chronic kidney disease – 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 585.x, 586.x, 588.0, V42.0, V45.1, V56.x; HIGH risk for CEA – High risk for CEA is defined as aged >80 years, history of heart failure, coronary artery disease or chronic lung disease.⁹ There was no available information regarding the degree of stenosis in the treated patients.

Statistical analysis was conducted with SPSS software (SPSS Inc, Chicago, Illinois, USA). Comparisons between the two groups were performed with the independent samples *T*-test for continuous variables with a normal distribution. The non-parametric Mann–Whitney U test was used for non-normal distributions and χ^2 tests for categorical variables. A *p* value below 0.05 was considered significant.

Results

The study included 6094 patients: 1399 were symptomatic (previous mention of stroke) and 4695 asymptomatic (Table 2). Demographic characteristics and comorbidities are summarized in Table 3. Carotid stenting was performed on 22% (*n* = 307) of the symptomatic and 18% (*n* = 854) of the asymptomatic patients. As shown in Figure 1, in symptomatic patients, there was an important increase in the

Table 1. ICD-9-CM codes for patient selection.

Classification of disease and injuries (as main diagnosis)		
433.10	Asymptomatic	Occlusion and stenosis of precerebral arteries without mention of cerebral infarction
433.11	Symptomatic	Occlusion and stenosis of precerebral arteries with cerebral infarction
Classification of procedures		
00.61	CAS	Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s)
38.12	CEA	Carotid endarterectomy

proportion of cases treated by CAS between 2005 and 2012 (from 0 to 44%), followed by a gradual decline until 2015 (from 44 to 21%). In the asymptomatic group, there was an increase in the proportion of CAS between 2005 and 2011 (from 0 to 24%), further maintaining a fairly steady relative frequency until 2015 (19%).

The mortality and stroke rates in both symptomatic and asymptomatic patients are summarized in Table 4. In symptomatic patients, the in-hospital mortality was significantly higher in those submitted to carotid stenting (3.6% vs. 1.6% in endarterectomy, $p=0.025$). No significant differences in the primary outcomes were observed in the asymptomatic group. Multivariate analysis showed positive correlation between early mortality and cardiac arrhythmias (OR 3.21 for 95% CI, 1.10–7.27) and CAS (OR 3.45 for 95% CI, 1.24–8.12) in symptomatic patients. No isolated factor was associated with worse outcome in asymptomatic patients. Overall, 1.6% of CEA ($n=81$) were reoperated due to hematoma. There are no available data regarding access complications in CAS.

Table 2. Patient sample.

	CEA	CAS	Total
Asymptomatic	3841	854	4695
Symptomatic	1092	307	1399
Total	4933	1161	6094

The results of the subgroup evaluation of octogenarians (≥ 80 years) are summarized in Tables 5 and 6. There were no significant differences in the outcomes of CAS vs. CEA for asymptomatic octogenarians (Table 5). However, the symptomatic octogenarians treated by CAS showed an increase in mortality: 3.3% vs. 0.0% in CEA $p=0.035$ (Table 5). The evaluation of the same procedure in both symptomatic and asymptomatic patients below and above 80 years of age did not show any significant difference for CEA or CAS (Table 6). However, in the CAS group, there was a trend for increased mortality (with no statistical significance) in octogenarians (2.1% vs. 0.6% in < 80 years, $p=0.093$).

The results of the subgroup evaluation of female patients are summarized in Tables 5 and 6. There were no significant sex-related differences in the primary outcomes. However, both the stroke rate in asymptomatic and the mortality in symptomatic female patients showed a trend favoring CEA – Stroke rate of 2.1% vs. 4.2% in CAS, $p=0.091$ and mortality of 1.1% vs. 3.9% in CAS, $p=0.099$ (Table 5). The evaluation of the same procedure in asymptomatic female vs. asymptomatic male patients demonstrated an increased tendency of stroke in CAS in female patients: 4.2% vs. 2.1% in males, $p=0.097$ (Table 6).

The median duration of the hospital stay is detailed in Table 3. The hospitalization was shorter in patients submitted to carotid stenting: four vs. six days in symptomatic ($p < 0.001$) and two vs. five days in asymptomatic ($p < 0.001$) patients.

Table 3. Patient demographics, comorbidities and hospital length of stay.

	Asymptomatic			Symptomatic		
	CEA	CAS	p	CEA	CAS	p
Mean age	69.2	70.5	$<0.001^*$	68.9	67.8	0.084*
Female gender, n (%)	909 (23.7)	192 (22.5)	0.460**	262 (24.0)	77 (24.4)	0.874**
Uncomplicated hypertension, n (%)	2965 (77.2)	536 (62.8)	$<0.001^{***}$	843 (77.2)	194 (63.2)	$<0.001^{***}$
Complicated hypertension, n (%)	180 (4.7)	48 (5.6)	0.251**	41 (3.8)	22 (7.2)	0.011**
Coronary artery disease, n (%)	643 (16.7)	204 (23.9)	$<0.001^{***}$	115 (10.5)	43 (15.0)	0.031**
Peripheral vascular disease, n (%)	478 (12.4)	66 (7.7)	$<0.001^{***}$	93 (8.5)	25 (8.1)	0.835**
Hyperlipidemia, n (%)	2263 (58.9)	448 (52.5)	0.001**	676 (62.9)	191 (62.2)	0.921**
Smoking, n (%)	535 (13.9)	54 (6.3)	$<0.001^{***}$	171 (15.7)	29 (9.4)	0.006**
Heart failure, n (%)	111 (2.9)	36 (4.2)	0.044**	29 (2.7)	17 (5.5)	0.012**
Cardiac arrhythmias, n (%)	324 (8.4)	90 (10.5)	0.050**	103 (9.4)	38 (12.4)	0.130**
Complicated diabetes mellitus, n (%)	175 (4.6)	16 (1.9)	$<0.001^{***}$	74 (6.8)	12 (3.9)	0.065**
Uncomplicated diabetes mellitus, n (%)	1091 (28.4)	245 (28.7)	$<0.868^{***}$	267 (24.5)	77 (25.1)	0.821**
Chronic lung disease, n (%)	236 (6.1)	40 (4.7)	0.101**	69 (6.3)	17 (5.5)	0.615**
Chronic kidney disease, n (%)	152 (4.0)	38 (4.4)	0.509**	36 (3.3)	12 (3.9)	0.603**
High risk for CEA, n (%)	1114 (29.0)	334 (39.1)	$<0.001^{***}$	273 (25.0)	85 (27.7)	0.340**
Median hospital stay (days)	5	2	$<0.001^{***}$	6	4	$<0.001^{***}$

CEA: carotid endarterectomy; CAS: carotid artery stenting.

*Independent samples T-test; **Pearson Chi-Square test; ***Mann-Whitney Test.

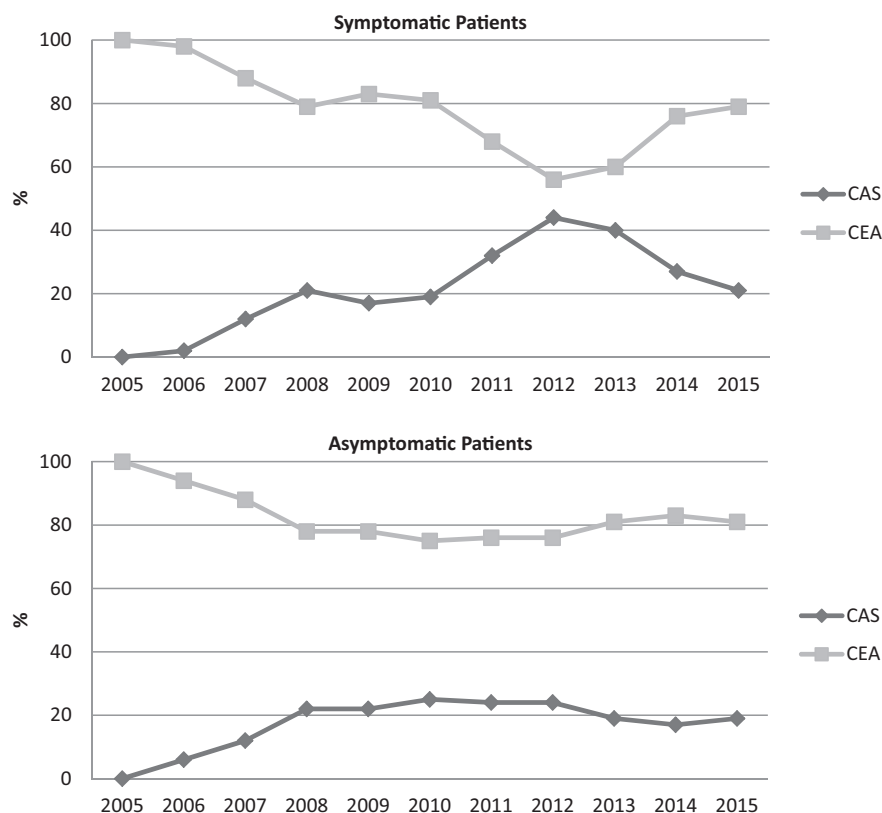


Figure 1. Yearly evolution by type of carotid intervention. In symptomatic patients, there was an important increase in the proportion of cases treated by CAS between 2005 and 2012 (from 0 to 44%), followed by a gradual decline until 2015 (from 44 to 21%). In the asymptomatic group, there was an increase in the proportion of CAS between 2005 and 2011 (from 0 to 24%), further maintaining a fairly steady relative frequency until 2015 (19%). CEA: carotid endarterectomy; CAS: carotid artery stenting.

Table 4. Primary outcomes – mortality and stroke.

	Asymptomatic			Symptomatic		
	CEA	CAS	<i>p</i> *	CEA	CAS	<i>p</i> *
Mortality, <i>n</i> (%)	34 (0.9)	7 (0.8)	0.852	17 (1.6)	11 (3.6)	0.025
Stroke, <i>n</i> (%)	89 (2.3)	22 (2.6)	0.652	NA	NA	NA
Combined, <i>n</i> (%)	109 (2.8)	24 (2.8)	0.965	NA	NA	NA

CEA: carotid endarterectomy; CAS: carotid artery stenting.

*Pearson Chi-Square test.

NA: The study design does not permit the stroke risk calculation in symptomatic patients: the patients were included in the symptomatic group if they had, as the main diagnosis of the hospital stay, "carotid stenosis with previous mention of stroke" and so a stroke previous to the intervention, but in the same hospitalization, could not be excluded.

Discussion

These study results are somehow unexpected. A recent elegant review of international registries performed by Paraskevas et al.¹⁰ described, in a fairly reproducible manner, an increased rate of stroke in asymptomatic patients submitted to CAS in comparison to CEA. Interestingly, the 854 asymptomatic patients submitted to CAS in our study did not show an increased rate of

stroke when compared to the 3841 asymptomatic patients submitted to CEA (stroke rate of 2.3% in CEA and 2.6 in CAS, $p = 0.852$). In contrast, the mortality of the symptomatic patients in our series is significantly higher than the one described by Paraskevas et al. in their systematic review.¹⁰ In fact, the 307 symptomatic patients submitted to CAS in Portugal demonstrated a two-fold increase in mortality when compared

Table 5. Subgroup analysis – octogenarian and females, by procedure.

		Asymptomatic			Symptomatic		
		CEA	CAS	<i>p</i> *	CEA	CAS	<i>p</i> *
Octogenarians	Procedures, <i>n</i> (%)	388 (10.1)	141 (16.5)	<0.001	133 (12.2)	30 (9.8)	0.245
	Mortality, <i>n</i> (%)	3 (0.8)	3 (2.1)	0.193	0 (0.0)	1 (3.3)	0.035
	Stroke, <i>n</i> (%)	12 (3.1)	4 (2.8)	0.879	NA	NA	NA
Female gender	Procedures, <i>n</i> (%)	909 (23.7)	192 (22.5)	0.460	262 (24.0)	77 (24.4)	0.874
	Mortality, <i>n</i> (%)	5 (0.6)	2 (1.0)	0.436	3 (1.1)	3 (3.9)	0.099
	Stroke, <i>n</i> (%)	19 (2.1)	8 (4.2)	0.091	NA	NA	NA

CEA: carotid endarterectomy; CAS: carotid artery stenting.

*Pearson Chi-Square test.

NA: The study design does not permit the stroke risk calculation in symptomatic patients: the patients were included in the symptomatic group if they had, as the main diagnosis of the hospital stay, “carotid stenosis with previous mention of stroke” and so a stroke previous to the intervention, but in the same hospitalization, could not be excluded.

Table 6. Subgroup analysis within the same procedure.

		Asymptomatic			Symptomatic		
		≥80 years	<80 years	<i>p</i> *	≥80 years	<80 years	<i>p</i> *
CAS	Procedures, <i>n</i> (%)	141 (16.5)	713 (83.6)	<0.001	30 (9.8)	277 (90.2)	<0.001
	Mortality, <i>n</i> (%)	3 (2.1)	4 (0.6)	0.093	1 (3.3)	10 (3.6)	0.707
	Stroke, <i>n</i> (%)	4 (2.8)	18 (2.5)	0.626	NA	NA	NA
CEA	Procedures, <i>n</i> (%)	388 (10.1)	3453 (89.9)	<0.001	133 (12.2)	959 (87.8)	<0.001
	Mortality, <i>n</i> (%)	3 (0.8)	31 (1.1)	0.749	0 (0.0)	17 (1.8)	0.250
	Stroke, <i>n</i> (%)	12 (3.1)	70 (2.2)	0.284	NA	NA	NA
		Females	Males	<i>p</i>	Females	Males	<i>p</i>
CAS	Procedures, <i>n</i> (%)	192 (22.5)	662 (87.5)	<0.001	77 (24.4)	230 (75.6)	<0.001
	Mortality, <i>n</i> (%)	2 (1.3)	4 (0.8)	0.540	3 (4.0)	8 (3.4)	0.727
	Stroke, <i>n</i> (%)	8 (4.2)	14 (2.1)	0.097	NA	NA	NA
CEA	Procedures, <i>n</i> (%)	909 (23.7)	2932 (76.3)	<0.001	262 (24.0)	830 (76.0)	<0.001
	Mortality, <i>n</i> (%)	5 (0.7)	29 (1.2)	0.222	3 (1.2)	14 (1.7)	0.548
	Stroke, <i>n</i> (%)	19 (2.1)	70 (2.4)	0.705	NA	NA	NA

CEA: carotid endarterectomy; CAS: carotid artery stenting.

*Pearson Chi-Square test.

NA: The study design does not permit the stroke risk calculation in symptomatic patients: the patients were included in the symptomatic group if they had, as the main diagnosis of the hospital stay, “carotid stenosis with previous mention of stroke” and so a stroke previous to the intervention, but in the same hospitalization, could not be excluded.

to the 1092 symptomatic patients submitted to CEA (3.6% vs. 1.6% in CEA, $p=0.025$). One of the major limitations of this study is the inability to assess the stroke rate in symptomatic patients. Due to the design of the study – the patients were included in the symptomatic group if they had, as the main diagnosis of the hospital stay, “*carotid stenosis with previous mention of stroke*” – a stroke previous to the intervention, but in the same hospitalization, could not be excluded, and so the stroke rate would be impossible to measure.

In asymptomatic patients submitted to CEA, the combined rate of mortality and/or stroke (2.8%) was similar to the one described in international literature¹⁰ and similar to the rate observed in the ACST study (3.0%).¹¹ On the other hand, the combined risk in

the asymptomatic patients submitted to CAS (2.8%) is significantly lower than that observed in most literature,¹⁰ and is even smaller than the one described in the CREST trial (4.4%).¹² These results show that the similar results between CAS and EAC in asymptomatic patients, in this series, are due not to poor EAC outcomes but rather to an unusually good performance of CAS.

In symptomatic patients, the mortality of CEA (1.6%) is somewhat comparable to the one described in the ECST (1.3%)¹³ and NASCET (1.1%)¹⁴ trials. In contrast, the mortality rate of CAS in symptomatic patients (3.6%) was startlingly high when compared to that demonstrated by SPACE (0.7%)¹⁵ or ICSS (1.3%)¹⁶ trials. The poor CAS results in symptomatic

patients can be partially related to the fact that in several Portuguese centers, symptomatic patients are referred by the stroke team to hospitals with no vascular surgery. In such cases, regardless the patient's endovascular suitability, CAS is the only offered treatment; on the other hand, most asymptomatic patients are referred to vascular centers where the best option for each specific case is presumably taken into account. A multidisciplinary approach focused on choosing the right treatment for the right patients may partially justify this paper's good CAS results in asymptomatic patients. The reason for this rather important asymmetry of CAS results in symptomatic vs. asymptomatic patients should be object of further analysis by prospective or randomized trials.

There is a growing discussion about the pertinence of CAS in octogenarian patients.¹⁷ In this study, we found a significant increase in mortality of CAS vs. CEA in symptomatic octogenarians. However, we found no difference in the primary outcomes of CAS in octogenarians when compared to the same procedure in patients <80 years of age. These results may be partially attributed to the low number of elders treated by CAS in our series – just 30 symptomatic and 141 asymptomatic patients. No differences in the primary outcomes were observed with CEA in older patients (≥ 80 years). In fact, CEA in the octogenarians demonstrated fairly good results, with 0 deaths in the 133 symptomatic and just 3 in the 388 asymptomatic patients. These results highlight that CEA remains a low-risk procedure even in the elderly population.

The potential benefit of carotid revascularization in female patients has been historically questioned by numerous studies.^{18–20} Despite extensive literature on this topic, it remains a concern that female patients might not derive a significant benefit from prophylactic CEA or CAS.²⁰ Our results did not show any sex-related significant difference in the assessed outcomes. There was, however, an increased tendency of stroke following CAS in female asymptomatic patients (4.2% vs. 2.1% in males, $p = 0.097$). These results are somewhat in line with the data from the American Nationwide Inpatient Sample that found no sex-related differences in CEA but highlighted an increased risk of CAS in woman.²⁰

Our results showed that 18% of the asymptomatic patients were submitted to CAS, which seems a rather high percentage, considering that the SVS recommendations do not support CAS in asymptomatic patients.⁵ However, the recent guidelines published by ESVS do support a role for CAS in low-risk centers (IIb, level B recommendation).⁸ Due to the surprisingly good results of CAS in our national administrative database, and in line with the new ESVS

recommendations, this procedure could be considered an alternative to CEA in selected asymptomatic patients.

In symptomatic patients, up to 44% were being treated by CAS in 2012. This number is significantly higher than the described in other countries.²¹ Possibly due to the overall recommendations to restrict CAS to patients technically not suited or of high risk for CEA,^{5,7} the number of CAS being performed in symptomatic patients started steadily decreasing in 2013, being just 21% in 2015. The CAS high mortality rate evidenced in this study highlights the imperative need of reflection on CAS indications in symptomatic patients in Portugal.

It was not surprising to note that the median duration of the hospital stay was inferior in patients submitted to carotid stenting: four vs. six days in symptomatic ($p < 0.001$) and two vs. five days in asymptomatic ($p < 0.001$) patients. This reduction could, at least in part, compensate the increased cost of the material in CAS.

Conclusion

Despite the high frequency of carotid stenting in Portugal and its association with a reduced hospital stay, these data reveal a higher mortality of this procedure in symptomatic patients. Paradoxically, in contrast with the published information from international administrative databases,¹⁰ our results found no increased rate of stroke following CAS in asymptomatic patients. There was no difference in the outcomes of CEA and CAS in octogenarians and in women.

Due to the surprisingly favorable results of CAS in asymptomatic patients, its indication can remain a plausible option in national hospitals.

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Ethical approval

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