Systematic Comparison of the Early Outcome of Angioplasty and Endarterectomy for Symptomatic Carotid Artery Disease

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Systematic Comparison of the Early Outcome of Angioplasty and Endarterectomy for Symptomatic Carotid Artery Disease

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Background and Purpose—Endoluminal treatment is being increasingly used for carotid artery disease. The aim of this study was to compare the stroke and death risk within 30 days of endovascular treatment or endarterectomy for symptomatic carotid artery disease.

Methods—A systematic comparison of the 30-day outcome of angioplasty with or without stenting and endarterectomy for symptomatic carotid artery disease reported in single-center studies, published since 1990, was performed.

Results—Thirty-three studies (13 angioplasty and 20 carotid endarterectomy) were included in this analysis. Carotid stents were deployed in 44% of angioplasty patients. Mortality within 30 days of angioplasty was 0.8% compared with 1.2% after endarterectomy (OR 0.68, 95% CI 0.43 to 1.05; $P=0.6$). The stroke rate was 7.1% for angioplasty and 3.3% for endarterectomy (OR 2.22, CI 1.62 to 3.04; $P<0.001$), while the risk of fatal or disabling stroke was 3.2% and 1.6%, respectively (OR 2.09, CI 1.3 to 3.33; $P<0.01$). The risk of stroke or death was 7.8% for angioplasty and 4% for endarterectomy (OR 2.02, CI 1.49 to 2.75; $P<0.001$), while disabling stroke or death was 3.9% after angioplasty and 2.2% after endarterectomy (OR 1.86, CI 1.22 to 2.84; $P<0.01$).

Conclusions—In the treatment of symptomatic carotid artery disease, the risk of stroke is significantly greater with angioplasty than carotid endarterectomy. At present, carotid angioplasty is not recommended for the majority of patients with symptomatic carotid artery disease. **(*Stroke*. 2000;31:1439-1443.)**

Key Words: angioplasty ■ carotid endarterectomy ■ carotid stenosis

Randomized controlled trials have demonstrated the value of carotid endarterectomy in patients with transient ischemic attack (TIA) or stroke with good recovery and severe carotid artery stenosis, with a reduction in risk of major stroke or death of ≈2-fold compared with medical treatment alone.[1,2] Carotid surgery can be associated with other morbidity, including myocardial infarction or other cardiac complications (≈1%), cranial nerve palsy (≈7%), and wound infection or hematoma (≈5%).[2,3] Over the last decade, endovascular treatment of carotid disease has been introduced as an alternative to endarterectomy. Initially, angioplasty alone was used; more recently, stent placement has been employed with increasing frequency. Endovascular treatment has the advantage over endarterectomy of avoiding a neck incision and dissection of the carotid bifurcation. However, for angioplasty of a tight carotid stenosis, a guidewire must be passed across the narrowing and the plaque dilated or stented. This process is associated with a high frequency of cerebral embolization demonstrated on transcranial Doppler insonation of the middle cerebral artery.[4]

A number of randomized trials have been commenced to compare the results of endoluminal therapy and endarterectomy for carotid stenosis.[5] The findings of only 1 trial have been published.[6] This trial was stopped after only 17 patients had received their treatment allocation, because the complications of carotid angioplasty were so high: 5 of the 7 patients who underwent carotid angioplasty had strokes, 3 of which were disabling at 30 days. In contrast, there were no complications after the 10 carotid endarterectomies.[6] Another trial, the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), has been completed, and limited data have been presented in abstract form.[7] In contrast to the findings of the Leicester trial, CAVATAS reported equivalent combined stroke and mortality rate for angioplasty and endarterectomy of ≈10% at 30 days.[7] Although the results of CAVATAS have not yet been published in a full manuscript, the trial has already received criticism for its method of patient selection.[8] On the basis of the presented results to date, some authors have argued that angioplasty is a worthwhile alternative to endarterectomy,[9] while others feel that widespread use of endovascular therapy for carotid artery disease should await the results of further randomized trials.[10]

To address the debate regarding the role of angioplasty in carotid artery disease, a systematic comparison of the re-

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TABLE 1. Carotid Angioplasty Series: Patient Characteristics and Technical Outcome

Author	Carotid Arteries	TIA	Stroke	VBI	Technical Failure	Cerebral Protection	Stent
Gaines et al[12]	187	NG	NG	0	NG	No	NG
Abrahamsen et al[13]	23	17	6	0	2	No	3
Henry et al[14]	57	28	27	2	1	11	56
Naylor et al[6]	7	3	4	0	0	No	7
McCleary et al[15]	9	8	1	0	0	No	9
Yadav et al[16]	74	44	30	0	0	No	74
Wholey et al[17]	61	25	36	0	4	No	57
Criado et al[18]	24	20	4	0	NG	No	24
Gil-Peralta et al[19]	85	46	39	0	10	No	0
Eckert et al[20]	61	29	32	0	12	No	0
Kachel[21]	71	NG	NG	NG	5	71	0
Markus et al[22]	14	8	6	0	3	No	0
Munari et al[23]	41	37	1	3	0	No	0
Total*	714	265 (58%)	186 (41%)	5 (1%)	37 (7%)	82 (11%)	230 (44%)

NG indicates not given; TIA, amaurosis fugax or transient ischemic attack; and VBI, vertebrobasilar insufficiency.
*Percentages based on studies reporting results.

ported results of angioplasty and endarterectomy has been performed. Because sufficient data are not yet available from randomized trials, the results from single-center reports from 1990 to 1999 have been used to carry out a meta-analysis.

Methods

Studies for comparison were identified from PUBMED with the advanced search option. The terms used were "carotid artery," "angioplasty," "stent," and "endarterectomy." Studies were included if the following criteria were fulfilled: (1) number of strokes occurring within 30 days of carotid endarterectomy or endoluminal treatment were reported for patients with symptomatic carotid stenosis; (2) the report was a single-center study, since very few multicenter angioplasty series have been published; (3) the study was published between 1990 and 1999; and (4) only 1 series from any center was included unless there was clearly no overlap in cases.

For each study, the presenting symptom of the patient, the frequency of any stroke, disabling or fatal stroke, death, and TIA per operation was recorded. The risk of stroke and/or death and TIA were calculated using the OR, with 95% CIs, and the χ^2 test.[11]

Results

Thirteen studies of angioplasty with or without stenting[6,12–23] and 20 endarterectomy studies fulfilled our inclusion criteria.[24–43]

Presenting Symptoms

Most studies did not state separately the number of patients presenting with amaurosis fugax and cortical TIA, despite the differing results of endarterectomy in these groups.[34] Two of the angioplasty studies and 2 of the endarterectomy series did not separate patients presenting with TIA and stroke.[12,21,27,28] Excluding these studies, 58% of patients treated by angioplasty compared with 70% of patients undergoing endarterectomy presented with a TIA (Tables 1 and 3; $\chi^2=8.49$, $P<0.01$). Because a previous systematic review[44] has shown no difference in the outcome of endarterectomy for patients with cortical TIA and stroke (OR 1.01) the ORs for stroke and death were not adjusted. A small number of patients presented with symptoms of vertebrobasilar insufficiency in both angioplasty and endarterectomy series.

Angioplasty Series

In early series angioplasty alone was performed,[19–23] while in more recent studies primary stent placement has become more common.[6,14–18] For ease, the endovascular treatment studies will be referred to as the angioplasty series. Overall, 44% of patients were stented (Table 1). A distal internal carotid cerebral protection balloon was used in 2 studies (11% of patients). Technical success was defined in most studies as balloon dilatation of the carotid stenosis so that a residual stenosis of <50% remained. With these criteria, technical failure occurred in 37 cases (7%); most of these patients went on to have an endarterectomy, although the morbidity associated with this extra procedure has not been stated in most publications. The technical failures included some patients in whom it was not possible to cross the stenosis with a guidewire, in addition to cases in which a residual stenosis was present.

Comparison of Complications of Angioplasty and Endarterectomy

The odds of stroke, death, and TIA within 30 days of procedure are compared for angioplasty and endarterectomy in Table 4. There was a >2-fold increased risk of stroke, whether minor or major, within 30 days of angioplasty compared with endarterectomy (any stroke $\chi^2=26.5$, $P<0.001$; fatal/disabling stroke $\chi^2=8.8$, $P<0.01$). Death within 30 days of the procedure was less common after angioplasty (0.8%) than after endarterectomy (1.2%), but this difference was not significant (95% CI 0.4 to 1.1; $\chi^2=0.57$, $P=0.6$). Combined stroke or death was 7.8% following angioplasty and 4% after endarterectomy ($\chi^2=20.6$, $P<0.001$). TIA was reported in only 7 of the 20 endarterectomy series, thus making comparison with the endovascular series very difficult (Tables 3 and 4). There is no clear

TABLE 2. Early Outcome of Carotid Angioplasty

Author	Carotid Arteries	Any Stroke	Disabling/ Fatal Stroke	Death	TIA	Any Stroke or Death*	Disabling Stroke or Death*
Gaines et al[12]	187	17	5	3	23	20	8
Abrahamsen et al[13]	23	1	0	0	4	1	0
Henry et al[14]	57	3	3	0	2	3	3
Naylor et al[6]	7	5	3	0	NG	5	3
McCleary et al[15]	9	1	1	0	NG	1	1
Yadav et al[16]	74	7	2	1	NG	8	3
Wholey et al[17]	61	4	2	2	1	5	3
Criado et al[18]	24	1	0	0	0	1	0
Gil-Peralta et al[19]	85	4	4	0	3	4	4
Eckert et al[20]	61	3	1	0	8	3	1
Kachel[21]	71	1	1	0	1	1	1
Markus et al[22]	14	0	0	0	1	0	0
Munari et al[23]	41	4	1	0	1	4	1
Total†	714	51 (7%)	23 (3%)	6 (1%)	44 (7%)	56 (8%)	28 (4%)

NG=not given.

*Numbers presented are patients affected, eg, a fatal stroke counted as 1 event.

†Percentages based on studies reporting results.

relationship between the year of publication of the angioplasty series and the reported complications (Table 2).

Discussion

Principally, 3 mechanisms have been implicated in stroke complicating carotid endarterectomy.[37] First, cerebral embolization during dissection of the carotid arteries and from the endarterectomy surface[45]; second, stroke as a result of hypoperfusion during clamping of the carotid arteries[46]; and third, stroke due to cerebral hemorrhage following clamp release and hyperperfusion.[47] During carotid angioplasty, while the risk of hypoperfusion is likely to be less, the frequency of embolization has been demonstrated to be much greater.[22] The findings of our systematic review suggest that this increased frequency of embolization is associated with a much greater risk of a perioperative neurological event. The risk of stroke is 2-fold greater after angioplasty than after endarterectomy for patients with symptomatic carotid artery disease (Table 4). Comparison of the incidence of TIA is hampered by the lack of reporting in the endarterectomy series; however, where this was stated, the incidence appeared to be much greater in the endovascular group (Tables 3 and 4). Furthermore, technical failure of angioplasty was reported in 7% of patients, many of whom went on to require endarterectomy. The complications of this additional treatment are usually not included in the report. Although many surgeons do not routinely perform imaging of the endarterectomy site after surgery, it is very rare for repeat surgery to be required for residual stenosis.

Because angioplasty can be performed percutaneously with local anesthetic, whereas endarterectomy is often carried out under general anesthetic, it might be assumed that angioplasty would be associated with a lower risk of perioperative death. A previous systematic review has suggested the complications of endarterectomy are lower when the operation is performed under regional block.[48] The mortality was slightly lower in the angioplasty series, but the difference was not statistically significant.

As with any systematic review, a number of issues must be borne in mind when assessing the results. First, because the studies compared are not randomized, it is possible that patients in both series are different. For example, more unfit patients may have been selected for angioplasty, since this technique is considered less invasive. Of note, the frequency of TIA as a presenting symptom was more common in the endarterectomy series. Similarly, patients with more stable carotid stenosis may have been selected for angioplasty; indeed, in some studies authors state that balloon dilatation is delayed until 3 months after symptoms.[19] Second, the care with which perioperative complications were identified may have differed between the 2 series. A neurologist was noted to have assessed the patients at follow-up in 9 of the 13 angioplasty studies (69%), whereas this was the case for only 6 of the 20 endarterectomy studies (30%). These differences in follow-up might have allowed the detection of more subtle neurological deficits in the angioplasty patients. However, the 2-fold increase in fatal or disabling stroke following angioplasty support the present superiority of carotid surgery (Table 4). Third, it could be argued that the results reported in single-center series are not representative of the everyday outcomes of carotid surgery. For example, the outcomes reported in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the European Carotid Surgery Trial (ECST) are different from those reported in most of the endarterectomy studies presented here. In NASCET the 30-day stroke rate was 5.5% (1.8% disabling/fatal strokes); in ECST the perioperative stroke rate was 6.6% (3.1% disabling/fatal strokes). However, this criticism is likely to apply equally to both endarterectomy and angioplasty studies. Fourth, endovascular treatment of carotid disease is in a process of development, with new techniques such as primary stenting and cerebral protection being introduced; therefore,

TABLE 3. Early Outcome of Carotid Endarterectomy

	Presenting Symptom				Outcome					
Author	Carotid Arteries	TIA	Stroke	VBI	Any Stroke	Disabling/ Fatal Stroke	Death	TIA	Any Stroke or Death*	Disabling Stroke or Death*
Cantelmo et al[24]	80	63	17	0	2	0	0	0	2	0
Hamdan et al[25]	575	491	84	0	11	5	2	2	13	7
Blohme et al[26]	272	157	113	2	15	6	4	NG	16	7
Anderson et al[27]	126	NG	NG	NG	4	2	0	1	4	2
Fearn et al[28]	233	NG	NG	NG	6	0	0	NG	6	0
Hallett et al[29]	254	175	79	0	9	4	4	NG	13	8
Zbornikova et al[30]	63	42	19	2	5	1	1	4	5	1
Wilkinson et al[31]	163	116	47	0	13	8	4	NG	16	11
Hertzer et al[32]	750	514	236	0	20	8	5	NG	22	10
Plestis et al[33]	671	452	135	84	10	8	6	NG	15	13
Golledge et al[34]	460	309	151	0	16	8	11	13	19	11
Perler et al[35]	126	74	35	17	5	2	3	NG	6	3
McClearly et al[36]	62	38	24	0	1	1	1	NG	2	2
Riles et al[37]	1997	1320	677	0	61	NG	NG	NG	NG	NG
Gaunt et al[38]	100	69	31	0	4	2	0	NG	4	2
Naik et al[39]	82	67	15	0	9	4	3	5	9	4
Kadwa et al[40]	382	313	69	0	20	15	13	NG	27	22
Burns et al[41]	130	88	42	0	8	2	2	NG	8	2
Maini et al[42]	210	178	24	8	6	1	1	NG	6	1
Hoyne et al[43]	234	158	76	0	8	1	1	5	8	1
Total†	6970	4624 (70%)	1874 (28%)	113 (2%)	233 (3%)	78 (2%)	61 (1%)	30 (2%)	201 (4%)	107 (2%)

NG indicates not given; TIA, amaurosis fugax or transient ischemic attack; and VBI, vertebrobasilar insufficiency.
*Values are no. of patients affected, eg, a fatal stroke counted as 1 event.
†Percentages based on studies reporting.

the results reported in Table 2 may improve with technical advances. Finally, our comparison does not take into account complications other than stroke or death, such as nonfatal myocardial infarction or cranial nerve palsy, which appear too rarely in publications to be assessed.

The best level of clinical evidence is obtained from randomized controlled trials or meta-analysis of such studies. Despite the poor outcome of carotid angioplasty in the only trial published to date,[6] the frequency of angioplasty reports appears to be increasing. This may be due to the relatively small number of patients included in the Leicester trial before the study had to be stopped, and therefore the possibility that the findings may be a type 2 error. Alternatively, the findings from CAVATAS,[7] which have been presented in abstract form and suggest an equivalent outcome for angioplasty and endarterectomy, may have encouraged interventionists to expand their practice. The findings of this systematic review support that of the Leicester trial. At present, angioplasty or stenting would not appear suitable for most patients presenting with a symptomatic severe carotid stenosis. In the future, it may be possible to identify certain subgroups, such as high-risk surgical patients and those with symptomatic restenoses or distally positioned stenoses, that are better suited to angioplasty than surgery. More information is also

TABLE 4. Comparison of Odds of Stroke and Death Within 30 Days of Carotid Angioplasty and Endarterectomy

		Events per Procedure		Relative Odds	
Complication	Studies, n	Angioplasty	Endarterectomy	OR	95% CI
Any stroke	33	51/714	233/6970	2.22	1.62–3.04
Disabling or fatal stroke	32	23/714	78/4973	2.09	1.3–3.33
TIA	17	44/624	30/1620	4.02	2.51–6.46
Death	32	6/714	61/4973	0.68	0.43–1.05
Any stroke or death	32	56/714	201/4973	2.02	1.49–2.75
Disabling stroke or death	32	28/714	107/4973	1.86	1.22–2.84

required regarding the long-term results of endovascular treatment of carotid artery disease.

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