TRANS-ATLANTIC DEBATE

Thomas L. Forbes, MD, and Jean-Baptiste Ricco, MD, PhD, Section Editors

The role of completion imaging following carotid artery endarterectomy

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A variety of completion imaging methods can be used during carotid endarterectomy to recognize technical errors or intrinsic abnormalities such as mural thrombus or platelet aggregation, but none of these methods has achieved wide acceptance, and their ability to improve the outcome of the operation remains a matter of controversy.
It is unclear if completion imaging is routinely necessary and which abnormalities require re-exploration. Proponents of routine completion imaging argue that identification of these abnormalities will allow their immediate correction and avoid a perioperative stroke. However, much of the evidence in favor of this argument is incidental, and many experienced vascular surgeons who perform carotid endarterectomy do not use any completion imaging technique and report equally good outcomes using a careful surgical protocol. Furthermore, certain postoperative strokes, including intracerebral hemorrhage and hyperperfusion syndrome, are unrelated to the surgical technique and cannot be prevented by completion imaging.
This controversial subject is now open to discussion, and our debaters have been given the task to clarify the evidence to justify their preferred option for completion imaging during carotid endarterectomy. (J Vasc Surg 2013;57:1432-9.)

PART I: COMPLETION ANGIOGRAPHY SHOULD BE USED ROUTINELY FOLLOWING CAROTID ENDARTERECTOMY

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The principle tenet for all surgeons who perform carotid endarterectomy (CEA) should be a commitment to increase the safety of surgery, but there is no agreement on whether the routine use of intraoperative completion imaging should be performed to confirm the technical adequacy of CEA.[1,2] This divergence is partially due to the positive outcome of CEA in patients without the use of completion imaging[3-5] and to the fact that some postoperative strokes are unrelated to the surgical technique. But does a careful technique with the use of intraoperative magnification eliminate the need to further examine the adequacy of the surgical repair? Many authors have shown that detection by completion imaging and correction of any significant technical defect lowers the risk of postoperative stroke.[6-14]

The purpose of this debate is to review the use of completion imaging to assess the prevalence of residual defects after CEA and its effect on both postoperative stroke and follow-up results including restenosis.

Completion angiography. We have previously reported in a prospective study,[15] the results of 1179 consecutive primary CEA with routine completion angiography (CA). In this series, the decision to perform a surgical revision was decided only for significant defects including (1) a residual stenosis of more than 50% of the internal carotid artery (ICA) or common carotid artery (CCA) and of more than 70% of the external carotid artery (ECA), (2) any flap, and (3) any intraluminal-filling defect. Adopting these criteria, CA revealed significant defects in 72 cases (6.1%) warranting revision for external carotid artery flap (n = 30), thrombus in contact with the patch (n = 7), distal ICA flap or stenosis (n = 20), and CCA flap or residual plaque (n = 15). Logistic regression analysis showed that total length of the carotid plaque >6 cm (odds ratio [OR], 2.31; 95% confidence interval [CI], 1.21-3.72), blind eversion endarterectomy of the external carotid artery (OR, 3.41; 95% CI, 2.10-5.94), and trainee as first operator (OR, 2.42; 95% CI, 1.81-4.23) were independent predictors of operative defects. No complication in relation to carotid catheterization or injection of contrast media occurred in this series.

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The 30-day combined stroke and death rate was 1.5% and similar between senior surgeons and trainees. There was no significant difference in the combined stroke or death rate observed in patients with normal CA (1.4%) compared with patients with a defect corrected (2.8%), (OR, 0.67; 95% CI, 0.22-2.09), but there was an increased incidence of postoperative transient ischemic attack (TIA) in the group with re-exploration. After 7 years, the freedom rate from >50% carotid restenosis or occlusion was 87.5% ± 6.7% in patients with normal completion angiography and 92% ± 5.4% in patients who underwent a surgical revision. Everybody will agree that leaving an intimal flap in the ICA in 2.3% of these patients would have been potentially devastating. If the results of CEA are to be improved to a near-zero postoperative stroke rate, this finding alone validates the use of completion imaging in this series.

But residual disease was also found in the CCA and in the ECA. As the series progressed, we became more aggressive in the stitching of the sectioned intima of the CCA and in extending the endarterectomy on the CCA to avoid any significant step that has been shown by Archie to be a harbinger of early emboli and late restenosis.[16] Besides, completion angiography has also shown flap or thrombosis of the ECA in 2.5% of cases with thrombus bulging into the ICA in six patients (Fig 1). We consider, with others,[7,17] that defects occurring in the ECA are potentially harmful, with thrombus formation secondary to a flap that may embolize into the ICA (Fig 2). In this series, the majority of defects in the ECA occurred in patients having an eversion endarterectomy of the ECA. In comparison, division of the plaque at the origin of the ECA, even with a residual stenosis or feathering at the origin of the ECA, resulted in a significantly lower incidence of ECA defects. In addition, even when revised successfully, these severely obstructed ECAs had a poor long-term patency with a 40% rate of restenosis or occlusion comparable to that of 45.9% observed by Archie.[18] Considering these results, and as recommended by Ascher et al,[14] we decided to avoid as much as possible any attempt at external CEA and transect the plaque at the origin of the ECA with the use of tacking stitches (Fig 3). In this aspect also, completion angiography was useful to improve our technique.

Even if completion angiography makes sense, immediate re-exploration itself may be associated with a higher risk of stroke, and we observed, in this group of patients, an increased risk of postoperative TIA but not stroke. This risk, confirmed by other authors, has thrown doubt on the value of completion imaging followed by re-exploration.[1,2] But we don't know what might have happened to these patients if they had not been re-explored. Even if it is reasonable to assume that surgeons who re-explore patients do so because they consider the risk of stroke is higher if the abnormality is not fixed,[19] it is important, however, to define what is a "significant defect." In this series, we ignored 39 minor defects; no need to be too sensitive and incite unnecessary re-exploration.

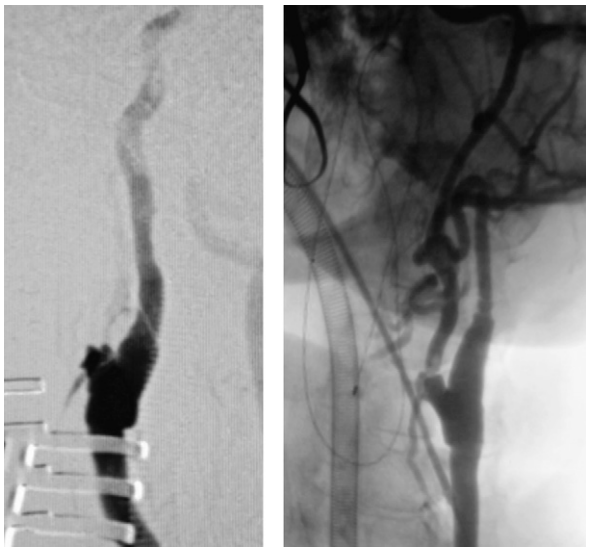

Fig 1. Intraoperative completion angiography showing two different types of defect in the external carotid artery (ECA) after carotid endarterectomy with a case showing a complete occlusion of the ECA and another case showing an intimal flap with a thrombus in the ECA. Both cases occurred after blind eversion endarterectomy of the ECA.

In a recent study, van der Kolk et al[20] have shown, using postoperative computed tomographic angiography, that residual defects after CEA were very common, simple fingerprints of the operative procedure, with no clear clinical consequence. However, a large retrospective study of completion imaging study after CEA by the Vascular Study Group of New England[19] has shown that selective use of completion imaging was associated with a significantly lower risk of restenosis at 1 year, with a hazard ratio for restenosis of 0.52 (95% CI, 0.29-0.09; $P = .02$) when comparing selective use of completion imaging vs rare use.

Pratesi et al[2] suggested also that completion angiography was useful only in some difficult situations and for less-experienced surgeons, but this study lacked objective criteria for revision. When introducing quality control in carotid surgery, particularly in the setting of a teaching hospital, we considered it essential to set up guidelines including predefined criteria for revision. We used intraoperative angiography because it was quick, safe, and produces excellent biplane images without the need for any added expertise. Using this protocol, we have shown by logistic regression analysis that trainee, as first operator, was an independent predictor of substantial operative defects seen on completion angiography (OR, 2.4; 95% CI, 1.8-4.2; $P = .02$) but with a 30-day stroke rate of 1.09%, was comparable to that of senior surgeons (1.35%).

Completion duplex ultrasonography. Many authors have suggested that intraoperative duplex scanning with B-mode imaging (CDU) and hemodynamic assessment of the CEA could be less invasive than completion angiography and as useful to lower the risk of stroke in this group of patients.[10,13,14] The problem with CDU in our practice

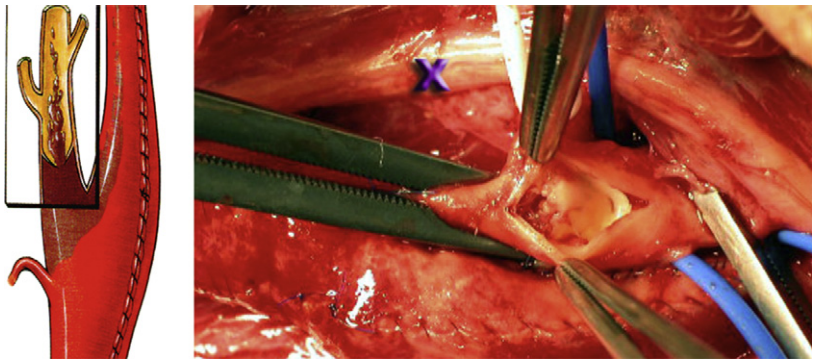

Fig 2. Re-exploration of the external carotid artery (ECA) after a completion angiography showing a flap in the ECA. A vascular clamp is placed at the origin of the ECA leaving the internal carotid artery open. The intimal flap was resected and the distal intima was affixed using U-stitches. Illustration showing a thrombus in the ECA secondary to a flap with the risk of embolism in the distal internal carotid artery (ICA). Reprinted with permission from Berguer R and Kieffer E. Repair of the internal and external carotid arteries. In: Surgery of the arteries to the head, 1st ed. New York: Springer-Verlag; 1992. p. 116.

was the availability of the technologist, even if CDU seems to be more cost-effective than completion angiography.[21] Using CDU with small 10- or 15-MHz hockey stick probes, Asher et al[14] found, in a series of 650 consecutive cases, 2.3% of CEAs (n = 15) requiring a surgical revision. In this series, no patient had TIAs, and the combined 30-day death and stroke rate was 0.8%. According to Asher et al,[14] re-exploration using CDU should be limited to cases in which peak systolic velocity was 150 cm/second or greater and was associated with B-mode imaging abnormality. These authors elected not to rely on peak systolic velocity ratio because of the size disparity generated by the patched segment and the distal ICA. These authors were also quite conservative with residual plaques on the CCA and adopted a policy of leaving the ECA undisturbed during CEA. These authors also emphasized that CDU not only identifies unsuspected major defects but also contributes to improve the surgeon's overall technical expertise.

CEA without completion imaging. Despite evidence that completion imaging can effectively detect technical problems during CEA, the benefit of completion imaging remains a matter of debate for many vascular surgeons. Is completion imaging routinely necessary outside a teaching center? Which abnormalities require re-exploration? Is re-exploration harmful? Studies struggling to answer these questions have consisted mainly of noncomparative or inadequately powered single-center series. To answer these questions appropriately, Wallaert et al[19] assessed the use of completion imaging in New England and its effect on outcomes after CEA. In this retrospective analysis, they studied 6115 CEAs and categorized surgeons based on use of completion imaging as rare (<5%), selective (5% to 95%), or routine (100%). Practice patterns varied: 51% of surgeons performed completion imaging rarely, 22% selectively, and 27% routinely. After adjusting for patients' characteristics predictive of stroke, the effect of surgeon practice pattern was not statistically significant when considering 30-day stroke/death rates. Restenosis at 1 year showed a trend toward the lowest rate for surgeons who performed completion imaging (rarely, 2.8%; selectively, 1.1%; and routinely, 1.1%; $P = .09$). After adjustment, this effect became significant for selective-use surgeons.

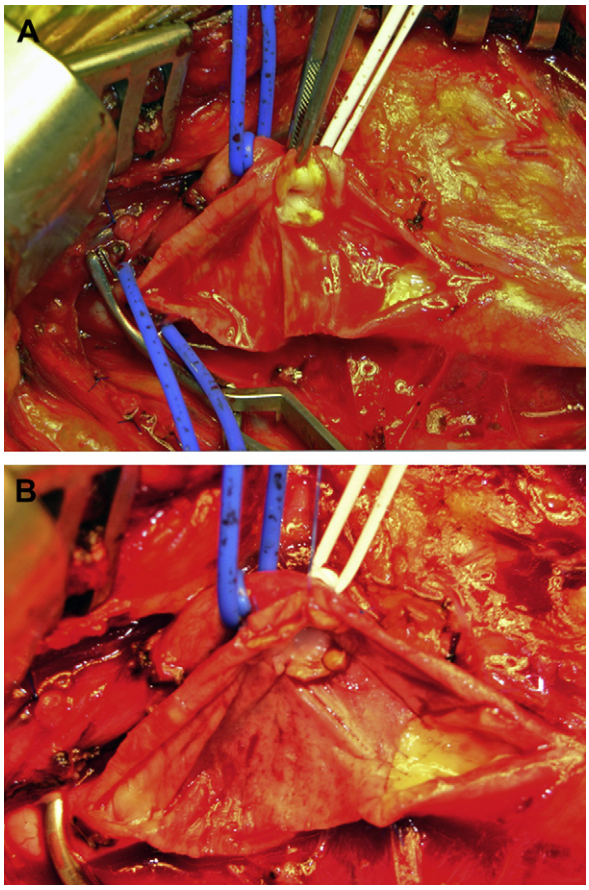

Fig 3. A, Circumferential section of the intima at the orifice of the external carotid artery. **B,** A moderate step is tolerated and secured with the use of tacking stitches.

Overall, 178 patients (2.9%) underwent re-exploration. Routine-use surgeons were most likely to perform re-exploration (7.6% routine, 0.8% selective, 0.9% rare; $P < .001$). Rates of stroke and death were higher among patients who underwent re-exploration (3.9% vs 1.7%; $P = .03$). However, this trend was attenuated after adjustment for patient characteristics predictive of stroke/death (OR, 2.1; 95% CI, 0.9-5.0; $P = .08$). The authors conclude that the use of completion imaging was not associated with a significantly lower risk of 30-day stroke or death. Further, surgeons who selectively use completion imaging have a significant reduction in restenosis at 1 year. In this study, the group of surgeons who selectively use completion imaging presented with the lowest crude and adjusted rates of stroke. One might have thought that rare users would miss significant abnormalities and routine users would be overly sensitive and detect minor defects resulting in unnecessary re-exploration and increased stroke risk.

Several prior studies have also assessed the relationship between completion imaging and late restenosis after CEA. Lipski et al[22] and Dykes et al[23] showed less residual stenosis in cases using completion angiography, and Kinney et al[24] reported significantly lower rates of recurrent stenosis at 48 months in those cases where completion angiography was performed. The same trend was found by Wallaert et al[19] but with a short follow-up of 12 months, limiting the value of their findings. Other authors,[25] not using completion imaging, have also reported a low rate of restenosis after CEA (5.4%) and insisted that they rarely required reintervention.

Conclusions. Even if this review of the literature and our experience give some arguments in favor of the selective use of completion imaging during CEA, the lack of a randomized controlled trial (RCT) contributes to the doubt as to whether it confers any real benefit. However, it is unlikely that the effectiveness of intraoperative assessment can be proven by an RCT. This is first because of the low stroke rate associated with CEA necessitating a large number of patients, and second, because in order to identify which defects should be corrected, there would need to be a group of patients in whom a defect detected would be left uncorrected, and this would raise obvious ethical issues. The last option is an RCT between imaging and no imaging that would include the potential risk of the completion study in the analysis.

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PART II: COMPLETION ANGIOGRAPHY IS UNNECESSARY FOLLOWING CAROTID ENDARTERECTOMY

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Stroke as a result of carotid endarterectomy (CEA) is usually attributed to technical complications.[1,2] Accordingly, some surgeons have instituted a policy of routine completion imaging (RCI).[3-8] Based on variously defined findings, these surgeons will re-explore with the intention of correcting the abnormality. It would seem self-evident that this approach would lead to elimination of all technical defects and result in an almost negligible incidence of postoperative stroke.

However, it is my contention, as well as that of others,[9-11] that RCI is unnecessary and may often result in the very complications that the surgeon is trying to avoid. So why is it that I can argue against a protocol that intuitively seems to be so appropriate? The answer to this supposed paradox requires an examination of the different methods of performing RCI.

Routine completion angiography (RCA). A major drawback to RCA is that defects that prompt re-exploration are ill-defined.[7,9,12] Surgeons cannot be sure that the problem, left alone, would impact outcome. For example, Ricco et al[3] will re-explore for an intimal flap, and this would seem entirely appropriate. However, is a tiny flap as worrisome as one clearly seen to be waving in the flow lumen? They also re-explore for residual stenosis of 50% or greater in the internal carotid artery (ICA) or common carotid artery (CCA) and of more than 70% in the external carotid artery (ECA). However, since their images are obtained only in an anterior and 45° oblique projection, can they really be sure about the diameter reduction?

Further, is leaving a CCA or ECA lesion of any clinical consequence? Although there are rare reports of emboli arising from the stump of an occluded ECA,[3,7,13] Ascher et al[14] suggested that residual stenoses in the external carotid artery are irrelevant. In a recent review of 1952 CEAs performed without RCI by our group, postoperative ECA occlusions were unusual (24 [1.2%]). However, only one patient complained of jaw claudication, and in no patient could we involve such lesions in early or late neurological events. It would seem that chasing these ECA lesions is unnecessary. Similarly, only two patients were discovered by follow-up duplex scans to have common carotid intimal flaps that required subsequent reintervention. Further, after we caused a stroke by inadvertently clamping a friable common carotid lesion, we now routinely evaluate the preoperative duplex scan to evaluate the extent of common carotid plaque. This allows us to plan the placement of the proximal clamp. Since then, there have been no common carotid injuries, and it is exceedingly rare that we leave behind a significant common lesion. Even so, Ascher et al[4] demonstrated in their experience that residual common carotid lesions did not result in perioperative stroke. In the study by Ricco where 6.1% of CEAs were re-explored, more than half were for ECA or CCA lesions.[3] If most of these could be considered unnecessary, then only 2.3% of their CEAs would have demonstrated a lesion that may have "required" correction.

Ricco et al also state that they will explore for "any intraluminal filling defect." I would presume that they must be ignoring some trivial findings since they describe only seven (0.6%) such defects in a series of 1107 CEAs. In fact, they do describe ignoring 39 minor defects. However, other surgeons might not consider them minor, instead subjecting the patient to unnecessary re-exploration.

These same authors[3] also describe having encountered 2.8% distal ICA spasm, all resolving using intra-arterial drugs. The implication is that had the spasm not been visualized and had it not been corrected by medications, neurological events would have resulted. This is clearly not the case. It implies that surgeons who do not identify and treat these spastic events would invariably notice additional stroke rates of up to 2% to 3%. Further, if this is something they believe happens so frequently and always corrects with drugs, why not simply inject these agents at the completion of the CEA? Ricco et al[3] report a stroke rate, which at 1.2% is commendable, but is not any better than reports from surgeons who never perform RCA such as our group.[15] Further, I would suggest a type 1 error in data analysis refutes their claim that there was no statistical difference between stroke rates in patients with a normal carotid arteriogram (0.2%) and those with a corrected defect (2.7%). There were just too few strokes overall (15) and too few patients undergoing correction (72) to compare to the uncorrected group (1107). Irrespective, 2.7% is worse than 0.2% regardless of statistical insignificance. Further, they acknowledge a significant increase in TIA in the revised group (5.5% vs 0.9%) as well as more postoperative hematomas (4.2% vs 0.3%). Equally damaging was the finding that, despite a normal arteriogram, three patients still occluded their ICA and one even after a "correction." Interestingly, they report that, even when an ECA stenosis was corrected, 40% restenosed or occluded. They did not list any clinical event related to these findings. So why bother looking for and correcting ECA stenosis in the first place?

Another large study of completion imaging was performed by Zanetti et al[12] who retrospectively evaluated the EVEREST study, which was designed to test the durability of eversion CEA. There are many problems with this study, especially that imaging was left to the discretion of the surgeon, not necessarily routine, and 22% were by completion angioscopy. Also, only single-projection X-rays were used. Further, they did not define major or minor strokes, which were found in 4% and 5% of 1302 CEAs respectively. Irrespective, 35 ICA or CCA lesions were corrected, resulting in a statistically significant increase in perioperative ipsilateral stroke in the patients requiring revision. In contrast, there was no significant increase in patients with minor defects. It does not appear that the 13 major ECA lesions encountered in EVEREST were corrected.

Routine completion angioscopy (RCANG). This method of visualization is seldom performed in North America. The largest reported study with this technique, Sharpe et al,[16] studied 1600 CEAs over four consecutive cohorts of 400 patients. In the first cohort, there were 4.9% intimal flaps that were repaired, but as they became more meticulous, only 0.8% required correction in the last cohort. Instead of claiming that angioscopy could be beneficial in 0.8%, they averaged the intimal flap rates (2.1%) thus making RCANG appear to be more important. They also describe finding retained thrombus in 7% of CEAs. However, they acknowledge that this includes small and large thrombi, an indeterminate proportion of which would not have caused any problem. Further, they state that thrombi that were adherent to the endarterectomy site were remarkably resistant to flushing and "blind" irrigation, yet it appears to have been effective in all patients. So might we assume that we could achieve the same results with our standard flushing and irrigation without need for an angioscope? In addition, this instrument was either unavailable or broken in up to 7% of CEAs. They also make a salient point against all immediate CI techniques, that is that some neurological events are due to platelet thrombi occurring in the recovery room and could not have been visualized at the time of CEA.

Routine completion duplex ultrasonography (RCD). Proponents of RCD explain that it is easy to perform, inexpensive and allows for a magnified image of the artery.[2,4] Further, in comparison to RCA, it avoids the possibility of air embolization and allows full evaluation of the entire artery, therefore more regularly allowing visualization of the proximal common carotid. However, RCD does involve the indirect expense of tying up a technologist as well as the time to do the test.[17] More importantly, proponents remain unsure as to which lesions need repair.[18] Although some place store in peak systolic velocity of >150 cm/second,[11,19,20] Ascher et al have shown that, in the absence of B-mode abnormalities, such increased velocities may be due to size disparity between the patch and the distal internal carotid artery.[4] Distal spasm may also cause increased velocities that would not require re-exploration. In fact, only 15 of their 650 procedures (2.3%) "required" surgical revision. None of these patients suffered a stroke, but it is premature to conclude based on such a small number that revision is safe. Surprisingly, no patient in their series suffered a stroke or TIA in the immediate postoperative period.

No completion imaging (NCI). Despite NCI in 2084 CEAs, our group's 30-day stroke and TIA rate are now both 0.91%. Assuming that 12 strokes evident immediately could not have been prevented by RCI, theoretically only six patients (0.29%) of our series could have benefited from RCI. These would have included:

- Three patients that presented with a minor stroke within 24 hours but who had a completely normal carotid duplex study and so were not re-explored. Conceivably, they may have embolized retained material that would have been visualized by RCI.
- One patient who occluded his carotid the following morning.
- The two patients who required reoperation when common carotid flaps were encountered 6 weeks after the original CEA.

We did return 12 patients to the operating room for neurological findings occurring within 24 hours of CEA, but in seven, no abnormality was detectable, and the arteriotomy was not reopened. All but one awoke neurologically intact from the exploration. In the other four, platelet clots were removed without any technical abnormality to explain their occurrence. All four patients made an uneventful recovery. One patient had the patch reopened, but no defect was noted, and she also woke from the exploration without any deficit.

Proponents of completion imaging also suggest that correcting lesions can prevent recurrent stenosis.[21] However, we have previously reported that recurrences are rare with NCI (5.4%), usually self-limiting, and very rarely require reintervention.[22]

Conclusions. Despite claims that routine RCI is beneficial, I remain convinced that there is no strong argument in its favor. Rather, I would suggest the following:

- There is no guarantee that re-exploration will correct the problem.
- Not only is there the expense of RCI, but prolonging operating time adds to the cost of the procedure.
- After re-exploration, another RCI will be required, further adding to operative time and cost.
- Large studies suggest that re-exploration leads to more complications.
- RCI that results in re-exploration will require repeat anticoagulation with potential postoperative hemorrhage.
- Re-exploration will result in repeat exposure to cerebral ischemia.
- Some neurological events, such as intracerebral hemorrhage and hyperperfusion syndrome, are unrelated to technical complications of the surgery and so would not be impacted by RCI.
- Some neurological events occurring soon after completion of the endarterectomy are unrelated to technical error but rather development of platelet thrombi that would not have been visualized by any current RCI.
- No one is really certain which imaging findings require correction.
- The majority of identified "problem" defects are in the ECA, and these do not require correction.
- Many patients will undergo re-exploration that was unnecessary, exposing them to increased risk.
- Preoperative evaluation of the carotid duplex may prevent events related to the common carotid.
- Most correctable lesions could be prevented by more meticulous surgery.
- Most surgeons do not utilize RCI, yet they report complication rates easily as good if not better

than those reported by surgeons who routinely do RCI.

- Stated another way, in competent hands, the neurological complication rate of CEA is so low that it is unlikely that adding RCI can achieve clinically relevant improvement in outcome.

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EDITORS' COMMENTARY

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Although many aspects of carotid endarterectomy (CEA) surgery have been well analyzed with robust clinical studies, the role of completion imaging remains unclear. Randomized controlled trials are lacking in this regard, and those studies that have reviewed this issue tend to lack sufficient numbers of patients or an appropriate comparative group. Additionally, some causes of postoperative neurologic events, including hyperperfusion syndrome, hypotension, and intracerebral hemorrhage, are not necessarily directly related to technical skill and not visible to the standard methods of post-CEA imaging. Into this knowledge breach step our debaters.

Proponents of post-CEA imaging, Ricco et al[1] and Asher et al[2] demonstrated, in 6.1% and 2.3% of cases, respectively, that completion imaging reduces causes (intimal flaps, residual plaque) of thromboembolic stroke at the site of endarterectomy. Even when these abnormalities do not generate perioperative complications, they may contribute to recurrent stenosis during longer term postoperative observation. However, van der Kolk et al[3] have shown that postoperative carotid artery defects on computed tomographic angiography are common, and mostly of little clinical consequence. In fact, Ricco et al ignored 39 (3.3%) "minor defects." Furthermore, Samson, citing Zanetti et al,[4] reminds us that completion imaging may result in the very complications that the surgeon is trying to avoid. However, other authors[2,5,6] report that completion imaging can be done without increasing the risk of stroke. Furthermore, Asher[2] and Ricco[1] suggest that routine imaging can improve a surgeon's expertise by indentifying technical defects, and can be a valuable teaching and quality assurance tool in training centers.

Considering the impact of completion imaging on practice patterns, the Vascular Study Group of New England[7] has shown, in a large retrospective series, that selective use of completion imaging was associated with a significantly lower risk of restenosis at 1 year when compared with rare use. In this study, surgeons who selectively used completion imaging had the lowest rates of stroke. One explanation could be that rare-users would miss significant defects, while routine-users would pay too much attention to minor defects resulting in unnecessary re-exploration and increased