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How Can Carotid Angioplasty (CAS) Be Made Safer and Become a True Alternative to Carotid Endarterectomy (CEA)

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Multiple prospective randomized trials have now documented that Tran's femoral carotid stent/angioplasty (CAS) with distal embolic protection carries twice the risk of procedure related stroke and death when compared to carotid endarterectomy (CEA). In the French EVA 3S trial the 30 stroke morbidity/mortality for CAS was 9.6% compared to 3.9% for CEA [1]. The International Carotid Stenting Study (ICSS) showed that CAS had an 8.5% stroke/death rate compared to 4.7% for CEA [2]. And, in addition, pre and post MRI studies showed that 50% of CAS patients demonstrated a new embolic infarct compared to 17% for CEA [3]. Finally, the CREST trial which had the best reported results in the literature for both CAS and CEA, still demonstrated the CAS carried twice the risk compared to CEA [4].

It is noteworthy that these events appear to be front loaded in that the vast majority occurs around the time of the procedure and certainly within the first 30 days. After 30 days, the Kaplan-Meyer curves for event rates become parallel for CEA and CAS. This suggests that if the periprocedural event rates for CAS could be lowered to those achieved with CEA, then the long term efficacy and durability with CAS would equal and be competitive with CEA.

In order to achieve a lower periprocedural event rate with CAS, it is necessary to identify the reasons periprocedural stroke complications associated with CAS. First of all, it is well documented that the aortic arch may harbor atherosclerotic plaques with embolic potential. Thus when guide wires, sheaths, and catheters are passed from the femoral artery they must traverse the aortic arch before selective catheterization of the carotid arteries can be achieved. During this time, while selective catheterization is being attempted, catheter manipulation together with arterial pulsation can disrupt aortic arch lesions and lead to the release of emboli with the potential for embolic stroke. The next source of brain emboli comes from the target carotid lesion itself. In order to reduce the risk of cerebral emboli during stenting, the use of distal embolic protection devices has been advocated. However, before the distal embolic protection device can be deployed, it is necessary to first traverse the carotid lesion in order to position the protection device distal to the lesion. During this positioning, embolic material can be released from the carotid lesion and will go to the brain. The emboli will not be captured until the device is opened and deployed.

These two sources of embolic potential associated with trans femoral CAS were addressed in two seminal publications in 2004. Two groups of investigators, working independently, proposed the use of direct carotid catheterization for CAS, in order to avoid the diseased aortic arch, and the use of flow reversal as a means of embolic protection without the need for first traversing the carotid lesion. Chang and colleagues, adapting available components, carried out direct carotid stent/angioplasty with flow reversal in 21 patients with 0% stroke morbidity/mortality [5]. In that same year, Criado and colleagues carried out direct carotid stent/angioplasty with flow reversal in 50 patients with a technical success rate of 100% and 0% stroke morbidity/mortality [6].

The excellent results achieved in these two preliminary studies inspired industry to develop specific components for this direct carotid approach. The Silkroad company produced the Michi system for direct carotid stent angioplasty with flow reversal which they have used the acronym, TCAR. The Michi system consists of a carotid artery sheath, a femoral vein sheath, and connector tubing with a flow regulator. The carotid sheath has a working channel for arteriography and stent placement. It also has a side arm which when attached to the connecting tubing, carries flow reversal blood to the sheath in the femoral vein. The technique includes the following steps: The common

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carotid artery is surgically exposed thru a short supraclavicular incision. The carotid sheath is inserted over a guide wire. A sheath is then placed in the femoral vein. The two sheath are joined with connecting tubing containing a filter and flow regulator. A carotid angiogram is performed to document and localize the lesion. The common carotid artery is clamped, proximal to the carotid sheath, and flow reversal is initiated by the pressure differential between carotid artery back pressure and the lower femoral vein pressure. The stent is then placed thru the working channel followed by balloon angioplasty, a completion angiogram is performed to document the result. The clamp and sheaths are then removed.

The safety and efficacy of TCAR was documented in the PROOF study. Pinter and colleagues in Dusseldorf, Germany treated 44 patients using the Michi system with 0% stroke morbidity/mortality. They also demonstrated that the incidence of silent brain infarction, as seen on MRI, was 17%. This was equal to that seen following CEA and substantially less than the 50% seen in the ICSS trial following trans femoral CAS [7].

Following the success of this feasibility study, the ROADSTER trial was initiated in the United States. One hundred forty one, high risk patients, were treated with TCAR in 20 institutions. The technical success rate was 100%. There were no major strokes. There were two (1.4%) minor strokes and two deaths. There were no permanent cranial nerve injuries [8,9]. Thus, in comparison, the stroke rate for trans femoral CAS in the CREST trial was 4.1%, for CEA in the CREST trial was 2.3%, and for TCAR in the ROADSTER trial was 1.4%.