The Current Status of Peripheral Atherectomy

Samuel S. Ahn and Blessie Concepcion

UCLA Center for the Health Sciences, Section of Vascular Surgery, Los Angeles, California, U.S.A.

Introduction

Recent advances in endovascular technology have generated a variety of alternative procedures and instruments in treating peripheral arterial occlusive disease. Mechanical atherectomy has been developed as an alternative to conventional percutaneous transluminal angioplasty (PTA) because of its limitations. Atherectomy devices can selectively remove atheroma by cutting or pulverising it in atherosclerotic diseased arteries percutaneously with angiographic guidance or openly through a small arteriotomy distant from the diseased site under fluoroscopic or angioscopic control. Theoretically, atherectomy offers three advantages over PTA: (1) greater immediate success rate with lower rates of intimal dissection and acute occlusion due to the controlled removal of atheroma from the lumen; (2) wider application to complex lesions not readily amenable to PTA; and (3) reduction of restenosis rate due to the debulking of atheromatous mass.

There are currently two types of atherectomy devices: extirpative and ablative. Extirpative atherectomy is characterised by shaving, cutting, or directly removing atheroma and collecting the excised material from the vessel lumen and wall. Ablative atherectomy, on the other hand, uses a high-speed rotational device to pulverise atheroma into fragments small enough to be aspirated or removed through the reticuloendothelial system. Among the numerous atherectomy devices currently available, only four have undergone extensive clinical trials: the extirpative catheters—the Simpson Atherocath and the transluminal extraction catheter (TEC); and the ablative devices—the Trac-Wright catheter and the Auth Rotablator. Recently, a new directional atherectomy device, the Omnicath, has undergone clinical investigative trials but only animal results have been published so far.1

Results

Studies of the Simpson atherectomy device have reported impressively high initial success rates.2–4 Graor and Whitlow2 reported a patency rate of 93% for lesions ≤ 5 cm and 86% for lesions > 5 cm at 1 year. However, 2 year patency results of 42% and 35% reported by Lugmayr et al.3 and Vroegindewij et al.4 respectively, are no better than those reported for PTA.

The initial technical success and immediate clinical success rates of TEC atherectomy seem promising, but late follow-up has been either lacking or relatively short. Wholey and Jarmolowski5 reported an impressive 92% technical success rate and a 90% clinical success rate. However, 2 year patency results of 42% and 35% reported by Lugmayr et al.3 and Vroegindewij et al.4 respectively, are no better than those reported for PTA.

The initial technical success and immediate clinical success rates of TEC atherectomy seem promising, but late follow-up has been either lacking or relatively short. Wholey and Jarmolowski5 reported an impressive 92% technical success rate and a 90% clinical success rate. However, only 16 (17%) patients had undergone angiography at 6 months, 12 of whom revealed patent atherectomised lesions. Myers et al.6 obtained an initial technical success of 86% and a clinical success of 74% in treating stenotic and occlusive lesions. Primary patency rates at 6 months were 80% for lesions ≤ 5 cm and 64% for lesions > 5 cm. No long term patency results are available.

The initial technical success rates of the Trac-Wright catheter have ranged widely from 58% to 100% and clinical success rates from 33% to 80%.7–10 However, follow-up has shown suboptimal patencies ranging from 25% to 68% at 6 months and 25% to 45% at 12...
months. One should also note that most of the clinical trials using the TEC and Trac-Wright catheters required adjunctive PTA to obtain an adequate arterial lumen since these catheters have no expansion ratio.

Peripheral atherectomy with the Auth Rotablator has achieved promising initial technical and clinical success rates in several clinical trials. However, most series report only a short follow-up of 6 months and patencies during this time interval are poor ranging from 47% to 82%.

Furthermore, later patency at 1 and 2 years is worse; the Collaborative Rotablator Atherectomy Group (CRAG) reported a disappointing patency of 31% at 1 year and 18.6% at 2 years.

Complications

Major complications of peripheral atherectomy devices include dissection, distal embolisation, haematoma, perforation, and thrombosis. With the Simpson device, Graor and Whitlow reported seven cases of haematoma that required major intervention, including one patient who also developed a pseudoaneurysm. The TEC device, on the other hand, have caused various complications; Myers et al. reported two deaths (1%) in patients with critical ischaemia, fracture of catheters requiring removal and replacement in two (1%), thromboembolism in two (1%), and bleeding at the puncture site in three (2%) within 30 days. In contradistinction to previous studies, the dissections and perforations encountered by some of the investigators suggest that the arterial wall did not always remain intact. Desbrosses et al. reported that perforation induced by the rotating cam of the Trac-Wright catheter occurred mostly in heavily calcified lesions due to the catheter’s tendency to follow the path of least resistance, which is often away from hard calcified plaque. Distal embolisations caused by atherectomy devices have been documented by some investigators. Contrary to previous canine studies, the CRAG and Henry et al. demonstrated that some of the atherectomised particles generated by the Auth Rotablator can cause embolic complications. Furthermore, the CRAG and Henry et al. reported nine (11%) and 12 (8%) early thromboses, respectively.

Limitations

Similar to PTA, restenosis and reocclusion are the primary constraints of atherectomy devices. At 6 months, Myers et al. reported restenosis in 26 lesions (18%) and reocclusion in 51 (35%) with the TEC. Reo occlusion also limits the applicability of the Trac-Wright catheter. Wholey et al. reported 4/12 early reocclusions (33%); Desbrosses et al. reported 5/46 reocclusions (11%) within 48 h; and Lukes et al. reported 2/12 reocclusions (17%). Late restenoses and reocclusions also occurred in 32 limbs during a follow-up period of 15–41 months by the CRAG. Thus, contrary to initial expectations, debulking atheroma does not reduce or solve PTA’s main problem, restenosis and reocclusion.

Discussion

Each atherectomy device has been designed to address restenosis, reocclusion, and other problems that frequently plague the results of PTA. Each one has utilised remarkable technology to produce the aesthetic result of a smooth lumen without flaps, dissections, perforations, or other abnormalities and consequently reduce the likelihood of thromboembolisation, restenosis, and reocclusion. The Simpson AtheroCath has a retrieval chamber to collect the excised plaque; the TEC utilises a suction to aspirate the debris; the Trac-Wright catheter has a high speed rotating cam to micropulverise atheroma without damaging the arterial wall; the Auth Rotablator uses a high speed rotating burr to micropulverise hard calcified atheroma; and the OmniCath uses an anchoring deflector wire pad to prevent vessel wall injury and neointimal proliferation.

A review of the clinical investigations utilising atherectomy devices clearly establishes the feasibility of peripheral atherectomy in the treatment of arterial occlusive disease. However, in spite of the impressive and appealing technology of these devises, the efficacy of atherectomy remains questionable. Furthermore, none of the devices fulfill the aforementioned expectations without complications. Moreover, although the initial technical and clinical patencies are promising, intermediate and long-term patencies are either similar or perhaps even worse than those of PTA.

Inconsistencies in reporting endovascular procedures plague most of the clinical data available in the literature. Discrepancies in reporting clinical and haemodynamic assessment, description of lesions, various criteria in reporting early and continued success (short vs. intermediate vs. long-term follow-up), complications, and the comparison of different treatment modalities make it difficult, if not impossible, to precisely evaluate the efficacy of atherectomy devices.
Peripheral Atherectomy devices. Thus, the comparison of these inaccurate results with those of other treatment modalities such as PTA is invalid. In reporting endovascular procedures, clinical investigators should refer and follow the guidelines described in detail by the Ad Hoc Subcommittee on Reporting Standards for Endovascular Procedures.15

Peripheral atherectomy currently has limited applications in the treatment of arterial occlusive disease. The problem of restenosis, reocclusion, and other complications must be solved before atherectomy devices can be used generally as an alternative to standard vascular reconstruction procedures or PTA. These problems can be solved only by addressing technological, mechanical, and biological factors in a rigorously scientific manner.

References

Eur J Vasc Endovasc Surg Vol 10, August 1995