Ultrasonic Endarterectomy for Long Superficial Femoral Artery Atherosclerotic Occlusive Disease

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Objective. To report the long term results of ultrasonic superficial femoral artery endarterectomy (USFAE).

Design. Retrospective study.

Patients and methods. From January 1998 to June 2004 218 USFAE were performed in 202 selected patients (178 males, 192 procedures) with a median age of 65 years (46-87 years). Indications for operation were disabling intermittent claudication in 137 procedures (68%), rest pain in 24 procedures (12%), and limb salvage in 41 procedures (20%). The new medical technology of ultrasonic endarterectomy is based on the application of the mechanical vibrations in the range of low frequency ultrasound. The ultrasonic device consists of the ultrasonic generator, acoustic unit and the flexible wave concentrators with special working tips in the shape of a ring. Follow up consisted of clinical evaluation, ankle-brachial index measurements and duplex scanning.

Results. The mean follow-up time was 30.1 months. The mean length of the endarterectomised SFAs was 29 cm (range, 15–43 cm). The five year cumulative primary patency rate by means of life table analysis was 45.8 ± 4.4% (SE). Percutaneous transluminal balloon angioplasty and surgical re-interventions were performed in thirty three and five patients respectively resulting in a primary assisted patency rate of 57.5 ± 4.1%. The five year secondary patency rate was 65.6 ± 3.8%. Limb salvage was achieved in 35 of the 41 patients with gangrene.

Conclusions. The long term results of ultrasonic SFA endarterectomy suggest this is an effective technique.

Keywords: Ultrasonic endarterectomy; Superficial femoral artery; Peripheral arterial occlusive disease; Intermittent claudication.

Introduction

The surgical treatment of superficial femoral artery (SFA) occlusions is a challenging field in vascular surgery. The first choice treatment of long segmental SFA occlusions is venous above-knee (ABK) bypass grafting which offers a 5 year primary patency of up to 73%.1 There are several situations in which alternative treatment options are indicated, such as patients in which the great saphenous vein has been previously harvested.

The first thromboendarterectomy through two arteriotomies was performed by Cid dos Santos in 1946.2 During the past 6 decades several different methods for SFA recanalization have been suggested including percutaneous transluminal angioplasty (PTA), subintimal angioplasty, oscillating loop endarterectomy and remote endarterectomy (RSFAE).3–6 Despite the high initial technical success rate of PTA, long-term results are disappointing particularly for long occlusions.7,8 Stent placement has not resulted in improved patency.9,10 Subintimal angioplasty is feasible and can be effective in high risk patients, although the long-term results are poor.11,12 RSFAE is a minimal invasive endovascular procedure. It has been extensively described by various vascular surgeons with 5-year primary assisted patency rates similar to prosthetic ABK bypass surgery.13–17

Our vascular surgery department has been performing ultrasonic endarterectomies using flexible ultrasonic instruments since January 1998.18 It is minimally invasive and generally avoids a second proximal incision. It also avoids the use of prosthetic
graft material and can be used in the absence of the saphenous vein, preserving it for future coronary surgery.

The purpose of this study is to report the long term results of ultrasonic superficial femoral artery endarterectomy (USFAE), performed with flexible ultrasonic instruments, and to determine its place in the armamentarium of the vascular surgeon in the treatment of long segmental SFA occlusive disease.

**Materials and Methods**

**Patients**

Two hundred eighteen USFAE procedures were performed in 202 patients from January 1998 to June 2004. All operations were performed in the N. Semashko hospital Moscow, Russia. Enrolment of patients was equally spread over the years. Rutherford classification was used to assess the stage of ischemia.19 When intermittent claudication was diagnosed at the first visit, conservative treatment was established, including walking exercise, cessation of smoking, and antiplatelet drugs. If the conservative treatment was unsuccessful, the patients were scheduled for an USFAE after 3 months. The study was approved by the local ethics committee and written informed consent was obtained. Preoperative evaluation included ankle-brachial pressure indices, colour flow duplex scanning, and angiography. All patients suffered from SFA long segmental occlusion and had a patent popliteal artery with at least one crural runoff vessel.

**Technique of the USFAE procedure**

The new highly effective medical technology of ultrasonic endarterectomy is based on the application of mechanical vibrations in the range of low frequency ultrasound (Fig. 1). The ultrasonic device consists of the ultrasonic generator (USG), acoustic unit (AU), which serves as a handle for the surgeon, and flexible wave concentrators with special working tips in the shape of a ring. The rings come in different sizes, ranging from 4 to 10 millimeters in inner diameter. The generator is the source of the electrical ultrasonic vibrations. It is used to transform the sinusoidal electrical low frequency signal (50 Hz) into electrical ultrasonic signal (26 kHz). The generator is electrically connected with the acoustic unit converting electromagnetic vibrations into mechanical energy of the same frequency at an amplitude 40 microns. The flexibility of the endarterectomy instruments allows them to be passed along the length of the SFA (Fig. 2). Due to the ultrasonic vibrations applied, less effort is required to separate the layers of the artery. The facilitation of the separation of layers is explained by two major effects: vibroshock and hydrodynamic phenomenon. Due to the ultrasonic vibrations, the instrument moves smoothly and swiftly inside the artery, the surgeon needing to apply less force. This considerably reduces the danger of wall perforation. The hydrodynamic effect caused by the presence of the biological liquid in the artery wall also facilitates the separation effort. This effect can be strengthened by supplying physiological solution into the ultrasonic operation zone.

The popliteal artery is exposed through a standard incision above the knee Distal to the occlusion.

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Fig. 1. General view of the ultrasonic device for endarterectomy.

Fig. 2. Ultrasonic endarterectomy technique.
distal segment of artery is heparinized with a diluted heparin-saline solution and the distal popliteal artery is cross-clamped. The distal intima is tacked down with a 6-0 Prolene suture. The original instrument ring is passed proximally up the SFA and the occluding core is removed from the artery. If the proximal intimal core is not completely removed, a second incision is made to carry out a common femoral endarterectomy. If needed a profundoplasty can be performed.

In order to avoid arterial penetration blunt and sharp edges were developed in the ring of the endarterectomy device (Fig. 3). When the blunt side of the ring contacts atheroma at a side branch resistance to progress of the instrument is felt (Fig. 3a). In this case the instrument should be gently retracted and rotated along the longitudinal axis with subsequent forward movement (Fig. 3b). This techniques allow safe passage of the endarterectomy device (Fig. 3c). Finally, a Fogarty® Thrombectomy Catheter (Pan medical limited, England) is passed along the whole SFA in order to remove residual debris. The arteriotomy is closed by a vein patch sewn in with a 6-0 Prolene. The procedure takes approximately 60 minutes to complete.

After the procedure, outpatient examinations were performed at 4 weeks, 8 weeks and every 3 months for 1 year, and then annually. Routine surveillance consisted of colour-flow duplex scanning in the department of radiology (Toshiba Applio model SSA-770A, Fundamentals 2B 730-595 E¹, Japan). Clinical and haemodynamic results were evaluated by recurrent symptoms and ankle-brachial blood pressure index measurements at every follow-up visit. All patients were placed on antiplatelet agents, i.e. aspirin at the surgeon’s discretion. Adverse patient outcomes including wound complications, re-stenosis or re-occlusion and major amputation were recorded. Primary patency is defined as uninterrupted patency of the treated artery or its anastomoses without any further procedures. If PTA was necessary to prevent occlusion, the artery was classified as assisted primary patency. In the event arterial flow was restored by thrombectomy or by-pass procedure after an occlusion, the patency was classified as secondary. The decision for reintervention was made on the basis of the combination of recurrent clinical symptoms, reduced ankle-brachial indices, and restenoses seen on duplex scanning or angiography.

**Statistical methods**

Statistical analysis was performed by using the computer software programs SPSS/w 12.0 (Statistical Package for Social Sciences 12.0 for Windows, Inc., Chicago, IL, USA). Data are presented as real numbers (percentages), median (minimum-maximum), mean values and standard deviations (SD). Life table analysis was used to evaluate cumulative patency and survival rates. A $p$-value $<0.05$ was considered to indicate statistical significance.

**Results**

Two hundred and eighteen consecutive limbs in 202 patients underwent a successful ultrasonic endarterectomy. The median age (range) was 65 years (46–87 years). One hundred seventy eight patients were males (192 procedures) and 24 were females (26 procedures). The indications for surgical intervention were disabling intermittent claudication in 137 (68%) procedures (Rutherford category 3), rest pain in 24 (12%) procedures (Rutherford category 4), and gangrene of the toes in 41 (20%) procedures (Rutherford category 5). Thirty five patients had a medical history of previous peripheral vascular interventions. 12 patients had undergone an intervention within the ipsilateral femoro-popliteal segment. Other previous
interventions included aorto-bifemoral bypass (5), PTA (4), PTA with stent placement (1), and femoral profundoplasty (2). Twenty three patients had previously undergone other peripheral vascular interventions including aorto-biiliac bypass (6), PTA of ipsilateral iliac artery (10), PTA in the contralateral SFA (7). In 97% of all cases the SFA was occluded, of which 75% extended over more than half of the femoro-popliteal segment. In 179 (82%) cases there were two or three runoff arteries and in 39 (18%) cases there was single artery runoff. In 26 (12%) cases there was no suitable vein in the leg.

**Technical and procedural success**

The mean length (range) of the endarterectomised segment of SFA was 29 cm (15–43 cm). The intima core was usually removed in one piece. Postoperative complications, that needed additional treatment, were haematoma in five (2.4%) cases and wound infection in seven (3.2%) patients. In four patients the superficial femoral artery was perforated during endarterectomy. These patients all underwent successful femoropopliteal bypass under the same anesthetic. Two patients died as a result of a myocardial infarction within 30 days after the operation. The median ankle-brachial index improved from 0.50 (±0.12) preoperative to 0.94 (±0.12) postoperative. Clinical improvement of at least one stage, according to the SVS/ISCVS criteria, was achieved in all patients.

**Long-term follow up**

Median follow-up time was 30.1 months with a range from 1 to 84 months. Life table analysis shows a 1 and 5 year patient survival rate of 96.7 and 80.4%, respectively. The 5 year cumulative primary patency rate by means of life-table analysis was 45.8 ± 4.4% (SE) (Fig. 4, Table 1). Five year primary assisted patency rate was 57.5 ± 4.1%. Percutaneous transluminal balloon (31) and stent (2) angioplasty were performed in 33 patients (Fig. 4, Table 2), and surgical revision of the proximal and distal SFA was performed in one and four patients, respectively. The five-year secondary patency rate was 65.6 ± 3.8%, after embolectomy (4), fibrinolysis with actilyse (2) and grafting (14) (Table 3). In six of the 41 patients presented with gangrene of the toes four above-knee amputations and two below-knee amputations were performed.

**Discussion**

The effects of ultrasound energy on femoral artery occlusion were described by Drobinski G et al. In 10 patients with SFA occlusions the authors used an ultrasonic angioplastic technique developed by the group. The study shows that ultrasonic angioplasty is capable of recanalizing an occlusion of SFA with partial or total disruption of thrombi. The effects of ultrasound energy on femoral artery occlusion were described by Drobinski G et al. In 10 patients with SFA occlusions the authors used an ultrasonic angioplastic technique developed by the group. The study shows that ultrasonic angioplasty is capable of recanalizing an occlusion of SFA with partial or total disruption of thrombi.20

The ultrasonic endarterectomy offers a new safe and effective treatment of long segmental SFA

![Fig. 4. Cumulative primary, primary assisted and secondary patency after ultrasonic superficial femoral artery endarterectomy by life table method.](image)

**Table 1. Life table data of primary patency rate**

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<th>Interval start time (years)</th>
<th>Number entering interval</th>
<th>Withdrawing during interval</th>
<th>Number exposed to risk</th>
<th>Number of terminal events</th>
<th>Failure rate, %</th>
<th>Cumulative patency, %</th>
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occlusive disease. Previous operations in the ipsilateral SFA, are not necessarily a contraindication.

In USFAE the whole intima core is removed and a complete disobliteration of the SFA is performed. Perforation of the SFA is one of the intraoperative complications that can occur during the operation. In four cases of SFA perforation the superficial femoral artery was heavily calcified. These limbs all underwent successful standard above knee prosthetic bypass. Lerwick, Galland et al., Smeets et al. describe similar SFA perforation during oscillating loop endarterectomy and RSFAE.5,13,15 Superficial femoral artery endarterectomy can be performed by open, semi-closed, remote or ultrasonic techniques. Published results of SFA endarterectomy are sometimes difficult to interpret due to the heterogenous nature of the lesions treated.21 Following SFA endarterectomy is sometimes difficult to interpret due to the heterogenous nature of the lesions treated.21 Following SFA endarterectomy 1 and 5 year patency of approximately 80 and 60% are reported.22–24 The follow up after the procedure requires routine annual colour-flow duplex scanning. This is a reliable, patient friendly and cost effective procedure for diagnosing restenosis in the endarterectomized SFA.25 Primary patency of 45.8% was achieved with no reintervention at all. Only 33 radiological reinterventions and 5 surgical reinterventions were considered necessary, giving a primary assisted patency of 57.5%. Re-intervention was not required for all restenoses or all occlusions, because not all occlusions resulted in limb ischemia. The decision to reintervene was made on the basis of clinical symptoms or the time interval between the USFAE and reocclusion. Our clinical experience showed that revision of early (<1 year) recurrent stenoses improves the patency rates. Late restenoses developing after two or three years do not seem to progress to reocclusion and may be treated conservatively. Ho et al. describe similar results following RSFAE.26

In three prospective randomized studies, Green et al., Johnson et al., and Burger et al. presented 5 year primary patency rates of prosthetic above-knee bypass surgery, ranging from 38 to 45%.27–29 These results are similar to the 5-year primary patency rates of 45.8% of USFAE in our study. Smeets et al. presented the long-term results of remote endarterectomy in long segment SFA occlusive disease in 164 patients. Their 5-year primary patency rate was 37.8%.15 Rosental et al. reported the medium-term results of remote endarterectomy in long-segment SFA occlusive disease with a 3-year patency rate of 61%.30,31 However, these results have not been confirmed by all researchers. Indeed, Nelson et al. have abandoned the RSFAE technique, because the 1-year primary and primary-assisted patency rate were 40 and 59%, respectively.32 Devalia et al. reported primary and primary-assisted patency rates at 5 years following RSFAE of 16 and 60%, respectively. Based on these data RSFAE cannot be recommended for widespread use.33 USFAE is a minimally invasive procedure, having the advantage of no synthetic vascular graft for potential infection. It creates less operative trauma and a reduction of postoperative discomfort, leading to earlier recovery and discharge of the patients as

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Table 3. Life table data of secondary patency rate

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described in other reports. Following failure of USFAE other reconstruction techniques can still be performed. The five year results of USFAE in a single vascular surgery centre are presented here in order to introduce the new SFA disobliteration method to a wider circle of vascular surgeons. However, randomised trials are required to establish the place of USFAE in the armamentarium of the vascular surgeon in the treatment of long segmental SFA occlusive disease.

References