Past. During the first years of PTA, developed by Dotter and Judkins in 1964, the Dotter set was a combination of 8 and 12 Fr coaxial Teflon catheters. Under these conditions, which involved the risk of severe afterbleeding, possible pulsating hematomas, av-fistulas and acute rethromboses in the groin arteries, it was more than reasonable to perform interventional radiological procedures instead of vascular surgery only under stationary conditions in the hospital, with follow-up controls for at least 2–3 days. To keep the puncture hole as small as possible, single Teflon catheters tapered from 5 to 9 Fr, varying in size, were used.

At that time, between December 1968 and November 1971, our primary success rate was 79.7%. Reobliterrations occurred within 14 days for 10% of these cases. Vascular surgery for acute rethrombosis was necessary in one patient.

When using the caged balloon catheter, or Fogarty balloon catheter in addition to the coaxial Dotter set, the primary success in iliac artery stenoses was 78%, under angiographic and ankle pressure control. Complications occurred in 11.7% of the 128 patients in the treatment of femoropopliteal obliterations. Two developed a pulsating hematoma, or false aneurysm at the puncture site, which required vascular surgery, and one patient needed vascular surgery after rethrombosis in the groin. Between the 8 and 12 Fr catheters, we found intima, media and atheromata with the risk for peripheral embolization.

Over the following years, the technique was refined. First, all patients received acetylsalicylic acid (ASA) as a thrombocyte aggregation inhibitor, in dosages between 1 and 1.5 g per day, before and after PTA. At the time of the procedure, each patient received 5,000 I.U. of heparin. During the following period of time there was some uncertainty as to whether patients should be treated only with aspirin, or with anticoagulation using Coumadin over a longer period — 6 months at a minimum — following the interventional measure.

The technique was further refined with the introduction of balloon catheters by Andreas Grüntzig and Fritz Olbert, and later several modifications by the industry considerably improved the procedure, as the arterial defect at the site where the catheter was inserted was smaller. This opened up the possibility of using 6 and 7 Fr balloon catheters. The former balloon catheter was often rigid after dilatation, and in several cases the balloon extended the puncture hole. In contrast, the Olbert catheter always provided a perfectly smooth, atraumatic retraction after dilatation. Nevertheless, for both types of balloon catheters, the use of a sheath catheter system in 6, 7, or 8 Fr became the standard to reduce traumatization at the puncture site, followed by bleeding complications.

Present. Current advances in PTA techniques include the production of catheters with smaller outer shaft diameters, with the result that present day balloon procedures are often performed with 4 or 5 Fr catheters. In addition, percutaneous aspiration thromboembolectomy and stent application have also enlarged the spectrum of interventional procedures. However, these again involved larger diameters of the
introducer sheath (7–8 Fr), just like some atherectomy\textsuperscript{15} and Rotablator systems.\textsuperscript{16,17} A further advance in PTA techniques is the percutaneous occlusion of the puncture site. This is a direct result of attempts to limit bleeding complications at the puncture site. We mainly use “Angioseal” as a hemostatic puncture hole closure device, after the use of 7 and 8 Fr introducer sheath systems.\textsuperscript{18}

In the last five years, the PTA technique has been standardized to a large degree, and complications that need stationary follow-up control show up very seldom. In most cases since 1996, we have been performing angioplasties of iliac artery stenoses and stenoses of the superficial femoral artery, the popliteal artery, and tibiofibular arteries, and occlusions up to 6 cm, as outpatient procedures.

**METHODS**

**Materials.** We have been using 5 or 6 Fr sheaths and small catheter systems of 4 or 5 Fr, with mainly standard balloon diameters. In special situations, we use atherectomy (2%) or stents (12%), but the balloon technique developed by A. Grüntzig is still the standard in most cases.

**Medication.** The premedication for 1 to 3 days is 300 mg of aspirin daily. At the time of the procedure, we inject 5,000 I.U. of heparin. For long-term medication, we administer aspirin (100–300 mg), whereas patients with critical limb ischemia are treated with heparin or low-molecular weight heparin (if an outpatient treatment is possible) for three days.

**Exclusion criteria.** Patients with arterial hypertension above 200, patients in renal failure or under dialysis, and patients within three months of myocardial or cerebral infarction are not candidates for an outpatient PTA.

**Inclusion criteria.** A clinical examination must be performed that notes ankle-brachial pressure measurements and personal information on the patient. In addition, laboratory data, including the patient’s creatinine level, thyroid function test, clotting factors, PTT, and Quick’s test are required. An angiography, such as a DSA or an optimal color-coded Doppler ultrasound angiography, should also be performed. The patient should be informed at least two days prior to the intervention about the procedure to be performed, possible complications, and the organization after PTA. We only recommend the outpatient procedure if the operating angio-suite can be reached by ambulance in less than 1 hour.

**Technique and Organization.** The most important part of outpatient PTA is the proper organization before, during, and after angioplasty. We recommend the following:

- The patient waits for about 1 hour before the PTA in the imaging center with the interventional unit. The intervention is preceded by a short examination with pulse control, supplementing history on changes that may have occurred recently, and control of the latest laboratory data. Then, the groin is cleaned and shaved.
- Following the successful angioplasty using 5 Fr catheter systems or sheaths, the puncture site is manually compressed for 15 minutes, followed by a compression bandage. In critical cases (obese patients, extended procedures, or after stent implantation and PTA), we apply the hemostatic puncture closure device.
- As soon as the bleeding at the puncture site is stopped, the patient is allowed to drink, and is served a small lunch. Three hours later, he is taken home by the ambulance in a flat position. The patient is recommended to stay in bed for 24 hours. Of course, he can go to the toilet with an accompanying person.
- After 24 hours, the patient is allowed to get up, with the bandage remaining in site. The compression bandage, should he have received one, is removed after 48 hours. At the third day, one or two 30 minute walks per day are begun.
- The patient is instructed to call the clinic during the second day, or immediately upon perception of any unfavorable symptom.
- Patients who develop problems are asked to notify the clinic within 7 days. All other patients are invited for a follow-up examination between the fourth and sixth week following the intervention. Eighty-seven percent of our patients appeared at that date.

**RESULTS**

During my time at the Nuremberg hospital (until the end of 1995), outpatient PTAs as described were performed in 5%, or 175 patients during the last 5 years. The follow-up was mainly carried out in other clinics, or care stations of old people’s homes and in a few cases at home.

Since 1996, we have been preferring outpatient PTA for all chronic obliterations in iliac and leg arteries except for in patients with critical limb ischemia with long SFA occlusions, iliac artery occlusions exceeding 5 cm, and multiple tibiofibular artery occlusions. These cases very often require the combined treatment of vascular surgery and PTA.

In 283 patients, 213 were male, mean age 63 (36–91 years of age), and 70 were female, mean age 67 (38–88 years of age).
years of age). We treated 252 femoropopliteal, 36 iliac, 16 tibiobifurcal, and 1 axillary, (total = 305) obliterations. Primary success according to the Rutherford criteria was achieved in 280 out of 283 patients, or 98%.

The unsuccessful cases were one 14 cm, superficial femoral artery occlusion, one common iliac artery occlusion, one total SFA occlusion, technically recanalized, but re-occluded 24 hours later (this patient suffered a blunt trauma at a soccer match, with an intramural hematoma). Two of these cases were sent to the cooperating vascular surgery department, and were successfully managed with two femoropopliteal bypass grafts, and the patient with failed iliac artery occlusion received a femorofemoral bypass.

During the follow-up period, 3% required a second angioplasty of the same lesion within 12 months. In seven cases, this was for superficial femoral artery restenosis, and in one case for an external iliac artery restenosis.

Complications we observed include afterbleeding within three hours in two cases, and in three cases peripheral embolism treated by percutaneous aspiration thromboembolectomy, or local thrombolysis.

**CONCLUSION**

After development of the initial Dotter technique into a perfect technique of balloon dilatation, completed by specific devices and adjuvants, PTA has proven to be a successful therapy even under outpatient conditions. The results in 283 patients with POVD were presented. The long-term success, and the economical aspects shall be confirmed by further studies.

Over the past several years, the medical equipment and medical care needed to perform PTAs has greatly improved. This, coupled with our experience performing thousands of angioplasties in iliac and leg arteries under stationary control, leads us to the unquestionable conclusion that PTA today is an outpatient procedure. The decision to perform outpatient PTAs is, of course, dependant upon the patient’s condition (for example, critically ill patients with large ulcers and several risk factors still require stationary treatment and follow-up), the doctor’s qualifications, and the organization of the outpatient clinic.

**REFERENCES**


**PANEL DISCUSSION**

TOM MACNAMARA: I want to congratulate Dr. Zeitzer on excellent work and for again being in the forefront of the changes in medicine, and I think that you are certainly to be congratulated on your high success rate and on the low complication rate. A couple of questions do come to my mind. What is your system’s cutoff in terms of blood pressure, either systolic or diastolic, that would prompt you to say that this patient must be treated in the hospital? Do you routinely place some form of a vascular closure system at a certain sheath size?

EBERHARD ZEITLER: Fantastic, you brought up all the things that are in the paper which I had pre-
pared. Number one, all patients with blood pressure above 200 mmHg systolic and 95 diastolic receive an interim medical treatment before. If the diastolic is below 90 and the systolic below 160, we ask the home doctor or the general practitioner to care for the follow-up. To answer your second question, we use 5 or 6 Fr sheaths for all patients undergoing outpatient treatment. This, without question, reduces the complications at the puncture site. I wish to say that in this group of patients (extremely overweight women, patients in whom we had used a stent and where bleeding problems had occurred at the time of the procedure, or if we couldn’t easily control the blood pressure) we used “AngioSeal” to occlude the puncture site. In one case, an early second intervention became necessary. In this case we exchanged the sheath for the puncture-hole occlusion system. I think, in such situations with higher risk, it is better to refer the patient to the clinic during the follow-up controls for 1 or 2 days.

FELIX MAHLER: Could you specify what you mean by outpatient and outclinic patient? How long do they actually stay at your institution?

EBERHARD ZEITLER: First, two days before the procedure, we check up on all patients, and there is a discussion explaining the treatment and its risk to enable the patient to give his “informed consent.” Second, the patients can only be treated on an outpatient basis if the distance from the institute performing the intervention to their home takes less than 1 hour of ambulance transportation. They come by car, but they leave the practice by an ambulance in the supine position. After the intervention, we apply a bandage at the groin and the patients are controlled in the department for up to 4 hours. The next day, all of them get a telephone call for control. At home, it is necessary to have a member of the family to continue the control.

ASHOK DHAR: Professor Zeitler, could you kindly tell us your strategy of taking the ipsilateral or contralateral approach while performing PTA of the vessels of lower extremity?

EBERHARD ZEITLER: In this population, we treated a group of 5 patients with contralateral procedures of iliac artery stenoses. But below the groin we have not had an indication for outpatient treatment at this point.

AUDIENCE: The great majority of our patients are inpatients. One of the reasons I like this is because the technician will do an AB index the following morning and of course we hope that the great majority will come back to close to normal. But occasionally there is no improvement and we may have to re-intervene the following day and that is a very convenient way. Do you get your patients to come back to the clinic?

EBERHARD ZEITLER: We phone the patient the next day, and we have follow-up controls of the AB index within 6 and 12 days. After 4 to 6 weeks, all patients come again for full clinical follow-up controls.

FRANK CRIADO: We have been doing outpatient interventions since 1992, but with a slightly different twist, although not as many as you do obviously. We do them all in the hospital as an outpatient procedure, but in the hospital.

EBERHARD ZEITLER: This is what we practiced until December 1995, with similar results.

FRANK CRIADO: I find that to be convenient in many ways, because one does not have to be as strict in the selection of patients and you can always change your mind during that 3 to 4 hour observation period and convert into an inpatient. I have another small question. I noted, of course, that you have a great deal of experience; I do not know what your denominator is but I notice an enormous amount of femoral popliteal procedures. What are your indications for femoral popliteal intervention?

EBERHARD ZEITLER: First, we have a very good cooperation with the vascular surgeon when we want to change from outpatient to an inpatient procedure. It only takes a phone call, and the patient can go to the hospital. I would say that we have done this in two patients. Second, our indications consider the official recommendations by the SCVIR, with some modifications. Classes I and II are preferred for outpatient procedures. If we have a diabetic patient with femoral popliteal and popliteal or tibioperoneal stenotic lesions and he has a class 3 or 4 gangrene, we know the clinical situation will only be changed by improvement of the hemodynamic plus the diabetic and local problems. This patient, no question, will later go to the intern medical clinic for treatment of his diabetic problems. The non-diabetics are mainly patients with claudication and a painless walking distance of less than 1000 meters. Patients with claudication are in Fontaine classes 2A or 2B. 2A means a walking distance of over 250 meters, whereas in class 2B it is less than 250 meters. Both groups are indicated for treatment, in several cases after a period of physical therapy. Several studies exist in which it was started with exercise first and if the patient did not have...
good results the dilation was indicated. But it is also possible to start first with angioplasty with low complication rates. Then, the patient’s pain is reduced quicker and the painfree walking distance improves. Exercise can then stabilize the result.

TOM MCNAMARA: Do you have the patient stop taking aspirin before this outpatient procedure?

EBERHARD ZEITLER: We administer 100 to 300 milligram ASA per day. The patient is not instructed to stop taking aspirin.

FELIX MAHLER: Who is treating the patients? Only you or do you train other people?

EBERHARD ZEITLER: I treat up to 75% now in this group and I’m teaching one who was with me before starting to learn angioplasty intervention in the clinic.