Cardiovasc Intervent Radiol (2016) 39:1684–1691
DOI 10.1007/s00270-016-1436-9

Day-Case Treatment of Peripheral Arterial Disease: Results from a Multi-Center European Study

Stavros Spiliopoulos[1,4] · Dimitrios Karnabatidis[1] · Konstantinos Katsanos[3] · Athanasios Diamantopoulos[3] · Tariq Ali[2] · Panagiotis Kitrou[1] · Alessandro Cannavale[2] · Miltiadis Krokidis[2]

Received: 4 May 2016 / Accepted: 26 July 2016 / Published online: 1 August 2016
© Springer Science+Business Media New York and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) 2016

Abstract

Purpose The purpose of the study was to investigate safety and feasibility of day-case endovascular procedures for the management of peripheral arterial disease.

Materials and Methods This was a multi-center, retrospective study including all patients treated over a 30-month period with endovascular angioplasty or stenting for intermittent claudication (IC) or critical limb ischemia (CLI) on a day-case basis, in Interventional Radiology (IR) departments of three European tertiary hospitals. Exclusion criteria were not related to the type of lesion and included unavailability of an adult able to take care of patient overnight; high bleeding risk and ASA score ≥4. Primary efficacy outcome was the rate of procedures performed on an outpatient basis requiring no further hospitalization and primary safety outcome was freedom from 30-day major complications' rate.

Results The study included 652 patients (male 75 %; mean age 68 ± 10 years; range: 27–93), 24.6 % treated for CLI. In 53.3 % of the cases a 6Fr sheath was used. Technical success was 97.1 %. Haemostasis was obtained by manual compression in 52.4 % of the accesses. The primary efficacy outcome occurred in 95.4 % (622/652 patients) and primary safety outcome in 98.6 % (643/652 patients). Major complications included five (0.7 %) retroperitoneal hematomas requiring transfusion; one (0.1 %) common femoral artery pseudoaneurysm successfully treated with US-guided thrombin injection, two cases of intra-procedural distal embolization treated with catheter-directed local thrombolysis and one on-table cardiac arrest necessitating >24 h recovery. No major complication was noted after same-day discharge.

Conclusions Day-case endovascular procedures for the treatment of IC or CLI can be safely and efficiently performed in experienced IR departments of large tertiary hospitals.

Keywords Day cases · Peripheral arterial disease · Angioplasty · Stenting

✉ Stavros Spiliopoulos
stavspiliop@med.uoa.gr; stavspiliop@upatras.gr

Dimitrios Karnabatidis
karnaby@med.upatras.gr

Konstantinos Katsanos
katsanos@med.upatras.gr

Athanasios Diamantopoulos
adiamantopoulos@gmail.com

Tariq Ali
tariq.ali@addenbrookes.nhs.uk

Panagiotis Kitrou
panoskitrou@gmail.com

Alessandro Cannavale
alessandro.cannavale@hotmail.com

Miltiadis Krokidis
miltiadis.krokidis@addenbrookes.nhs.uk

[1] Department of Interventional Radiology, Patras University Hospital, Patras, Greece

[2] Department of Interventional Radiology, Addenbrooke's University Hospital, NHS Foundation Trust, Cambridge, UK

[3] Department of Interventional Radiology, Guy's and St Thomas' Hospitals, NHS Foundation Trust, King's Health Partners, London, UK

[4] 2nd Radiology Department, Division of Interventional Radiology, Attikon University General Hospital, 1st Rimini St, Chaidari, 12461 Athens, Greece

Introduction

The number of percutaneous endovascular interventions for the management peripheral arterial disease (PAD) has been constantly increasing over the past years, as angioplasty and stenting have become established methods for the treatment of both intermittent claudication (IC) and critical limb ischemia (CLI) [1, 2].

Main advantage of endovascular techniques is the combination of high technical success rates of revascularization with low complication rates and significantly decreased hospitalization time and overall hospital costs, as well as almost immediate return to daily activities, due to the minimal invasive nature of the procedures [3].

Over the past decades, endovascular specialists have endorsed overnight stay as a standard of post-angioplasty patient care in everyday clinical practice. This strategy was mainly based on experience and was supported by certain consensus guideline documents, as to ensure patient safety [4]. Specifically, the Society of Interventional Radiology (SIR) 2003 guidelines recommended that patients undergoing percutaneous vascular interventions should be observed in an acute care environment overnight [5]. However, this was only a consensus opinion of the committee mainly based on the fact that a very small number of outpatient angioplasties were then reported, while high-level of evidence regarding the actual time of postprocedural hospitalization in patients undergoing endovascular interventions for PAD is still missing.

With the advent of novel low-profile endovascular materials and arterial closure devices, both time to ambulation and hospitalization time have decreased, while growing experience in large tertiary centers has led experienced Interventional Radiologists to consider the fact that PAD could actually be treated on an outpatient basis [6–10]. Notably, Interventional Cardiologists have already endorsed day cases using trans-radial coronary angioplasty as a safe and cost-effective procedure [11].

The present multi-center study investigated the safety and feasibility of outpatient endovascular procedures for the management of peripheral arterial disease, performed within Interventional Radiology (IR) departments.

Materials and Methods

Study Design

This was a multi-center, retrospective, single-arm study conducted in interventional radiology (IR) departments of three large tertiary European Hospitals with long-standing experience in endovascular PAD treatment (Center 1: PUH, Center 2: CUH, and Center 3: GSTH). Institutional review board approval was not required for this retrospective analysis. Hospitals' and departments' databases were searched and analyzed. Medical records of all patients treated for symptomatic chronic peripheral arterial disease (intermittent claudication; IR or critical limb ischemia; CLI), with elective percutaneous endovascular angioplasty, stenting or both, on an outpatient basis, between January 2013 and June 2015 in the abovementioned departments were analyzed. Any percutaneous endovascular procedure used for management of aorto-iliac and/or femoropopliteal and/or infrapopliteal interventions was included in the analysis. Patients treated with endovascular means for reasons other than PAD were excluded from the analysis. Patients with known allergies to contrast media and eGFR <30 ml/min were excluded for safety reasons, as hospitalization was deemed necessary in order to hydrate or manage possible delayed allergic reactions. The inclusion and exclusion criteria are listed in Table 1. Patient's demographics, procedural details and clinical follow-up up to 30-day postprocedure, were assessed. Statistical analysis was performed by the SPSS statistical software (IBM, USA).

The primary efficacy outcomes were the rate of procedures that were actually performed on an outpatient basis and required no further hospitalization for medical or nonmedical reasons (unexpected schedule changes or patient's preference, sudden nonavailability of the person chosen for overnight care or similar) and technical success rate, defined as the successful treatment of the target lesion(s) with less than 30 % remaining stenosis. The primary safety outcome of the study was freedom from early (30-day) major complications rate. Major complications were defined according to the SIR reporting standards as those (i) requiring therapy, minor hospitalization (48 h), (ii) requiring major therapy, unplanned increase in level of care, prolonged hospitalization (48 h), (iii) have permanent adverse sequelae, or (iv) resulted in death [12]. Secondary endpoints included minor complications defined as those (i) requiring no therapy and no consequence, or (ii) those requiring nominal therapy but with no consequence, including overnight admission for observation only. Other secondary endpoints were initial technical success rate defined as successful lesion crossing and treatment with <30 % remaining stenosis, the 30-day re-admission rates and the identification of possible predictors influencing the primary safety outcome.

Day-Case Setting

Patients had a preprocedural visit for medical examination, risk factor screening and to be informed on the elective outpatient procedure. Pre- and postprocedural protocols

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
ASA score 1 to 3	No responsible adult available to take care of patient overnight
Iliac, femoral and/or infragenicular arterial angioplasty or stenting or both	No telephone availability
Patient suitable for local anesthesia alone	Living more than 1 h from a medical facility
Availability to stay overnight if any complication occurs	High risk of bleeding (Plts <50,000, INR >1.5)
Creatinine clearance >30 mL/min	ASA score ≥4
No allergy to iodinated contrast media	Major mobility difficulty
	Patient willingness

varied slightly between the three departments. In all centers, preprocedural imaging with Duplex ultrasound or computed tomography or magnetic resonance angiography was performed and assessed during preprocedural visit. Informed consent was obtained prior to procedure and blood tests were performed at admission, unless recent blood results (within the last month) were available. Blood tests included full blood count, eGFR, plasma creatinine, glucose levels, and coagulation screening (PT, PTT, and INR). Patients were admitted early in the morning, at the date of the procedure and scheduled in the morning list. In Centers 1 and 3, patients were given specific written pre-admission instructions and were prescribed to receive antiplatelet therapy at least one week prior to the procedure (if not already on antiplatelet therapy), while in Center 2 dual antiplatelet therapy was stopped 6 days prior to the procedure (patients were receiving only aspirin 100 mg daily) and was commenced again the day after, if deemed necessary. Procedures were performed by experienced interventional radiology consultants. Fellows and residents in interventional radiology also performed some of the procedures under the direct supervision of a consultant. Lidocaine 1 % local anesthetic was used at the intended puncture site. In general, 4-French catheters were used for diagnostic studies, and 5-French catheters and 5- to 7-French sheaths were used for interventional procedures. If angioplasty or stent insertion was performed, intra-arterial unfractionated heparin was given before the intervention at doses of 2500–5000 U per patient, the dose depending on the estimated time required for the intended procedure. If the procedure was expected to take up to 1 h, as was usually the case, then 5000 U was routinely given. ECG, blood pressure, and pulse oximetry were monitored. If the patient suffered from diabetes, blood glucose levels were monitored before, during, and after the procedure. Sedation was not routinely used. Arterial access was obtained using ultrasound guidance, while both standard 19G needles and 21G micro-puncture arterial access sets were utilized, according to the operator's choice. Conscious sedation was used as per patient preference, but not as a standard of practice. Procedures were performed according to international guidelines [4, 13]. A variety of contrast agents were used, but in the majority of the cases Visipaque 320 mg/ml (GE Healthcare) was administrated. For all >5Fr accesses, a closure device was used, unless the operator assessed that the use of a closure device was contraindicated due to a heavily calcified and/or atheromatous or small diameter artery, or in cases in which an appropriate closure device was not available in the department (65/380 cases). The type of arterial closure devices used was also left to the operator's preference. In all Centers, following the procedure, patients were transferred to the recovery room, situated within the interventional radiology department, and postprocedural care was undertaken by interventional radiology nurse staff. Postprocedural care included monitoring of vital signs, regular puncture site inspection and abdominal palpation. In Centers 1 and 3, the patient was advised to remain flat on the bed for 5 h, while in Center 2 the patient was recommended to stay in flat position for 2 h and bed rest and for other 2 h after the procedure if a 4Fr sheath was used (total 4 h), 3 h for a 5Fr (total 5 h) and 4 h for a 6Fr sheath (total 6 h). If no bruising or hematoma occurred during this time period, the patient was allowed to gradually sit up and then ambulate under supervision prior to discharge. After discharge, patients were advised not to drive a vehicle and had to be accompanied the first night after the procedure. If any significant bruising, hematoma or bleeding from the vascular access was noted, groin compression for 15–20 min was repeated and Duplex US exam was performed. If any major complication occurred, overnight recovery was planned (failure of ambulatory management).

Results

In total, 652 patients (male 74.5 %; mean age 68.1 ± 10.1 years) with 662 limbs were treated. Most of the patients suffered from hypertension (53.6 %) and were characterized with ASA score 2 (82.5 %), while 44.6 % of

the patients were diabetics, 33.6 % suffered from cardiac disease and 12.4 % were on dialysis. The majority of the patients were treated for IC (492 patients; 75.4 %) and 140 patients were treated for CLI (24.6 %). Patients' demographics are analytically reported in Table 2. Procedures performed were mainly femoropopliteal interventions (49.2 %) but in many cases (30.2 %) multilevel disease involving femoropopliteal and/or iliac and/or infrapopliteal lesions was treated. An occlusion was treated in 264 of 661 limbs (29.9 %). Stenting was performed in 287/662 cases (43.3 %). The main artery used for access was the common femoral artery (CFA) [448/662 antegrade (67.7 %) and 209/662 retrograde punctures (31.6 %)], while access was obtained in three cases from the brachial and in two cases from the popliteal artery, the latter after failed attempt to revascularized superficial artery occlusions using standard antegrade CFA access. In the majority of the cases (53.3 %), 6Fr sheaths were used for access. Popliteal artery access was obtained with 4Fr sheaths and 6Fr sheaths were used in the three cases of brachial artery access. Manual compression was successfully used for haemostasis in these cases. In nine cases (1.4 %) both limbs were treated in the same session using 4Fr (3/9; 33.3 %), 5Fr (1/9; 11.1 %), 6Fr (4/9; 44.4 %), and 7Fr (1/9; 11.1 %) arterial sheaths. Closure devices were used in 47.6 % of the cases (315/662 accesses). Procedural details are reported in Table 3.

Immediate technical success rate was 97.6 % (645/661 limbs). In 16 patients endovascular approach failed either for failure to re-enter the true lumen after crossing the lesion through a subintimal channel (14 cases) or impossible antegrade access (1 case) or for tibial extravasation (1 case).

The primary efficacy outcome of procedures performed on an outpatient basis occurred in 95.4 % (622/652 patients), as the total unexpected admission rate was 4.6 % (30/652 patients) and was mainly attributed to procedure-related complications (Table 4). Of those, two (2/30, 6.6 %) dialysis patients were admitted for medical reasons other than procedure-related complications and in particular an evening dialysis session. Another two (2/30 cases, 6.6 %) patients were admitted for nonmedical reasons (unexpected change in patient's preference and nonavailability of the person chosen for overnight care). The remaining 26/30 cases (86.6 %) were admitted due to immediate procedure-related complications (major 9/652; 1.4 % and minor 17/652; 2.6 %). Major complications requiring hospitalization included six puncture-site-related complications [five (0.7 %) retroperitoneal hematomas (three patients admitted for observation and two patients transfused); one (0.1 %) CFA pseudoaneurysm successfully treated with US-guided thrombin injection and overnight observation], two cases of intra-procedural distal embolization which were treated with trans-catheter local thrombolysis (rt-PA 1 mg/h) and discharged the next day with a good final angiographic result and one case of intra-procedural on-table cardiac arrest requiring Intensive Care Unit recovery (>24 h). Two out of five retroperitoneal hematoma cases were hospitalized for 48 h.

Table 2 Patient demographics and clinical characteristics

Clinical characteristics	Value
Patients	652
Age, years (range)[a]	68.1 ± 10.1 (27–93)
Male	486 (74.5)
Diabetes	291 (44.6)
Cardiac disease	219 (33.6)
TIA/Stroke	49 (7.5)
Dialysis	81 (12.4)
High cholesterol[b]	313 (48.0)
Hypertension	287 (53.6)
Past/current smoker	98 (35.8)
Severe obesity (BMI > 35)	78 (11.9)
Rutherford category: 2–3	492 (75.4)
4	96 (14.7)
5–6	44 (6.8)
ASA score: 1	64 (9.8)
2	498 (76.4)
3	90 (10.8)
Previous vascular surgery	41 (6.3)
Previous endovascular procedure	116 (17.8)

Categorical data are given as counts and percentages in the parentheses

[a] Data presented as mean ±standard deviation (SD)

[b] Abnormal blood cholesterol levels, or drug therapy

Minor complications requiring overnight surveillance without further treatment included one hypoglycemic episode and two episodes of uncontrollable hypertension not responding to initial periprocedural anti-hypertensive medical therapy, one anterior tibial artery extravasation due to guide wire injury treated conservatively and 13 medium or large groin hematomas. Duplex scan was performed in all cases of hematoma/suspected bleeding prior to discharge, but not significant findings were reported. The total procedure-related complication rate leading to unexpected hospitalization was 3.5 % (23/652 cases). Overall rate of major and minor bleeding complications was 0.9 % (6/652) and 2.1 % (14/652). According to subgroup analysis dual antiplatelet therapy started before and continued during the procedure did not influence bleeding events as 11/20 (55.0 %) major and minor bleeding complications occurred in patients receiving dual antiplatelet therapy at the day of the procedure and in 9/20 in patients who were on single antiplatelet therapy with aspirin 100 mg or dual

Table 3 Procedural details

Variable	Values, *n* (%)
Arterial access	662
Limbs treated	661
Iliac	95/661 (14.4)
Femoropopliteal	325/661 (49.2)
Infrapopliteal	41/661 (6.2)
Multilevel	200/661 (30.2)
Occlusions	264/661 (39.9)
Patients with both limbs treated	9/652 (1.4)
Sheath size (Fr):	
4	165/662 (24.9)
5	117/662 (17.7)
6	353/662 (53.3)
7	27/662 (4.1)
CFA access:	657/662 (99.2)
Retrograde	209/662 (31.6)
Antegrade	448/662 (67.7)
Brachial access	3/662 (0.4)
Popliteal access	2/662 (0.3)
Antiplatelet therapy the day of procedure	
None	273/652 (41.9)
Single	31/652 (4.7)
Dual	347/652 (53.2)
Type of treatment	
Angioplasty	375/662 (56.7)
Stenting	287/662 (43.3)
Manual compression	347/662 (52.4)
Closure device	315/662 (47.6)
Starclose	287/315 (91.1)
Angioseal	27/315 (8.6)
Exoseal	1/315 (0.3)

Categorical data are given as counts and percentages in the parentheses

Table 4 Study outcomes

Outcomes	Values
Technical success	97.1 % (642/661)
Outpatient procedures	95.4 % (622/652)
Hospitalization	4.6 % (30/652)
Overnight	4.1 % (27/652)
> 24 h	0.4 % (3/652)
Immediate major complications	1.4 % (9/652)
Retroperitoneal bleeding	0.77 % (5/652)
CFA pseudoaneurysm	0.15 % (1/652)
Intra-procedural distal embolization	0.3 % (2/652)
On-table cardiac arrest	0.15 % (1/652)
Immediate minor complications:	2.6 % (17/652)
Hypoglycemic episode	0.15 % (1/652)
Uncontrollable hypertension	0.3 % (2/652)
Anterior tibial artery extravasation	0.15 % (1/652)
Medium or large groin hematomas	2.0 % (13/652)
30-day major complications	1.4 % (9/652)
30-day minor complications	2.7 % (18/652)
30-day re-admissions	0.4 % (3/652)

Categorical data are given as counts and percentages in the parentheses

antiplatelet therapy was discontinued 6 days prior the procedure ($p = 0.263$). Puncture-related bleeding complications occurred similarly ($p = 0.257$) after manual compression (11/19; 57.9 %) and after haemostasis with a closure device (9/19, 47.4 %).

One-month follow-up was available in all patients. The primary safety outcome of freedom from 30-day procedure-related major complications' rate was 98.6 % [1.4 % major complications (9/652 patients)]. The 30-day procedure-related minor complications' rate was 2.7 % (18/652), as one additional delayed minor complication was recorded in one patient who developed a puncture site, small groin hematoma, 2 days after the procedure. The 30-day unplanned re-admission rate was 0.4 % (3/652), as three cases were readmitted for re-intervention due to relapse of IC symptoms. In total, one SFA and two iliac arteries occlusions were successfully treated with endovascular means in two cases, while in one case an above the knee, femoropopliteal, vein bypass was successfully performed. Study outcomes are reported in Table 4.

Discussion

This is the only multi-center study and the largest series of patients treated with peripheral endovascular angioplasty and/or stenting on an outpatient basis in Interventional Radiology departments. According to the herein presented results, outpatient endovascular treatment of IC or CLI can be performed safely in experienced IR departments of large tertiary hospitals. In total, 95.4 % of the cases (622/652 patients) were discharged few hours after the procedure without resorting in hospital admission. Pretreatment protocol included examination and consultation at the IR departments, while procedures were scheduled in the morning list, patients were monitored after the procedure during the rest of the shift in the IR department and the vast majority was discharged without the need of overnight surveillance or further hospitalization. Overnight surveillance was necessary in 30 out of 652 patients treated mainly due to procedure-related minor complications (mostly puncture-related groin hematomas; 13/26

complications). Major complications occurred in 9 cases and usually remained for 24-h surveillance. Only two cases of retroperitoneal hematoma requiring transfusion were hospitalized for over 24 h. No events were noted during the 30-day periprocedural follow-up period apart from one small-sized groin hematoma developed 2 days after discharge. Very few cases were admitted overnight for reasons other than a complication such as patients who had to undergo late-evening dialysis, changed preference or finally did not have a person available for overnight observation at home. Very satisfactory procedural success and short-term re-intervention rates were noted, and although no control group investigating patients treated and admitted for overnight surveillance was available, these results are comparable to those reported in the literature for standard angioplasty and stenting procedures [13, 14].

This trial provided data from real-life outpatient peripheral multilevel angioplasty and stenting procedures, following antegrade and retrograde punctures using 6Fr arterial sheaths in more than half the procedures. Bleeding complications were kept at minimum and occurred following various size sheath insertion. Bleeding complications were not correlated with sheath size and notably, the single case of femoral pseudoaneurysm occurred after 4Fr access. Twenty-seven 7Fr sheaths were used with only one groin hematoma requiring overnight surveillance. Popliteal and brachial accesses were obtained in four cases without complications or further hospitalization; however, the number of these cases was small and not performed in routine, but only in selected cases of unsuccessful femoral access. Manual compression for haemostasis was widely used in nearly half of the cases. Both haemostatic methods were equally safe and effective and in 65 cases in which 6Fr sheaths were deployed and the use of a vascular device was not recommended or a suitable device was not available, prolonged 30–40 min manual compression was applied without a significantly increased bleeding complication rate. However, the comparison between manual compression and vascular closure device was beyond the scope of this study and prolonged manual compression remains an issue, especially in high-volume centers. In addition, our results suggest that a 4-h period represents a minimum safety bed rest time for patients undergoing either antegrade or retrograde 4Fr CFA puncture. Notably, cases included in this study were typical PAD patients suffering in majority from diabetes, hypertension, and hypercholesterolemia, while nearly 150 cases of CLI were treated, with no major amputations occurring during 30-day follow-up, demonstrating that endovascular revascularization of patients with rest pain or tissue loss or both is feasible on an outpatient basis.

Both limbs treated in the same session occurred only in nine cases and were generally avoided as not only to increase bleeding risk, but also to minimize the risk of nephrotoxicity from excessive contrast media use. However, in the particular nine cases, focal iliac or femoropopliteal stenosis were treated and procedural time and level of difficulty were deemed low, while all procedures were uneventful and patients were discharged as a day case without any adverse event during follow-up.

Although this was a retrospective study, all three centers followed similar treatment protocols. A difference in the prescription of preprocedural antiplatelet regimen was noted. In Centers 1 and 3, dual antiplatelet therapy was prescribed or continued prior the intervention, while in Center 2 dual antiplatelet therapy was discontinued at least 6 days before the procedure and commenced the day after. Nonetheless, no statistical difference was noted in primary efficacy and safety endpoints or in bleeding rates between centers, indicating that both antiplatelet strategies were safe. Intra-procedural, thrombo-embolic events rate was in accordance with the literature [15].

Interventional radiologists are becoming more clinically involved in patient management. Nevertheless, ambulatory IR patients are usually admitted to other wards, when recent data demonstrate that IRs can optimize both economical and clinical outcomes when managing pre- and postprocedural patient care in IR outpatient clinics [16]. So far, data about day-case angioplasty are sparse and not properly described, while there is an increasing body of literature reporting different ambulatory managements of endovascular procedures either with the use of VCD or not. However, most of the described units host the ambulatory patients of several surgical specialties [17–19]. Differently, we described outcomes from organized IR departments where patients are referred only for IR procedures and pre- and postprocedural care is also performed.

Initial experience with peripheral angioplasty day cases was published during the 80s and reported the safety of performing angioplasty on an outpatient basis in small series of PAD patients [20, 21]. However, according to the 2003 SIR guidelines for peripheral endovascular procedures the number of patients was insufficient to establish the safety of outpatient endovascular PAD clinic [12]. Nonetheless, in the years to come, growing experience in peripheral percutaneous revascularization procedures as well as the development of lower profile endovascular devices facilitated the concept of day-case angioplasty among experienced centers and led to the largest single-center, prospective trial which included a total of 403 peripheral arterial angioplasty and/or stenting procedures among 2248 patients undergoing various diagnostic or therapeutic endovascular procedures. The authors reported that in a total of 2.436 procedures no procedure-related death occurred, while in the Interventional Radiology procedures subgroup complications noted were mainly

access site minor complication such as hematoma, bruise and local pain (124/441 cases; 28.1 %), while major complications associated with hematoma were observed in 1.6 % of the interventional cohort. More serious complication such as infected hematoma, anaphylaxis, rash or pulmonary edema necessitating hospitalization were noted in only 4.9 % of the cases, a number quite similar to that reported in the present study [22]. Interestingly, significantly fewer complications were recorded following peripheral interventions performed during 1999–2002 compared to those performed during 1997–1999. This was attributed to the lower profile arterial sheaths and devices used after 1999, the increasing experience among interventional radiologists performing peripheral procedures, as well as the improvement of the nursing and medical stuff in postprocedural care. Ten years ago, in an audit investigating elective day-case peripheral angioplasty with nurse-led admission, discharge and follow-up in 183 patients, the authors reported only five patients that returned to the department the next day due to groin symptoms and four of them required no treatment. In the remaining, a false aneurysm was diagnosed, while another false aneurysm was detected 6 days after the procedure, resulting in a re-admission rate of 1.1 % (2/183) [22]. A recent study, retrospectively investigated outcomes of various endovascular procedures in an outpatient setting, including 111 patients undergoing PAD-related procedures, reported comparable adverse events and hospitalization rates of 1.8 %, but also considerably lower procedural success rate of 82 % [23]. Finally, in a study which included 191 patients undergoing 368 office-based arterial interventions, only 10 (2.7 %) complications have been reported and the authors concluded that selected PAD patients could be treated with endovascular methods within office-based practice [24].

Several issues regarding the ambulatory management of peripheral vascular interventions are still ongoing. First, suitability criteria should be discussed. There is wide variability between reported inclusion and exclusion criteria among available studies. Criteria included mostly safety issues such as availability of a responsible person to accompany patients to hospital and back home and who can stay with them at home 24 h after procedure and patients to be reachable by phone and live <1 h from a medical facility [17, 25]. The exclusion criteria reported were an age over 80 years, not suspended anticoagulation therapy (generally high risk of bleeding), previous groin vascular surgery operation, body mass index >35 or 40, planned bilateral CFA puncture or critical limb ischemia [8, 17]. Criteria in this study were not related to patients' age but to the physical status, assessed by the ASA score [26]. Criteria such as the availability of a responsible adult to take care of the patient during the first day and the phone availability are essential [27]. Early mobilization of patients with same-day discharge remains a highly debated issue since 2000 [8, 28]. Until today, there is no high level of evidence data supporting a specific postprocedural regiment. As a result, bed rest period was based on expert consensus and empirical standard protocols which differed slightly between the three institutions [4, 13]. The main argument to overnight stay is that most complications occur early after angioplasty, while decision to adopt overnight stay following peripheral interventions is not really evidence-based, hence overnight stay for uncomplicated patients is not currently justified [5, 29–31]. In fact in the present study only one patient reported a delayed occurring of groin hematoma, which did not require re-admission. Finally, US-guided arterial punctures are routinely performed as a standard of practice in the specific IR departments. It is used as a last check for CFA atheromatosis and in order to increase single anterior wall puncture accuracy, avoiding multiple punctures and hematoma formation [32]. Nonetheless, five retroperitoneal hematomas occurred. On the other hand, the rate of major bleeding complications could have been higher, if US-guided puncture was not used.

The main limitation of this study is the retrospective design which certainly influenced data quality, such as precise bed rest time period, minor complications such as mild allergic reactions not necessitating any treatment and ABI measurements, as well as a possible bias in patient selection excluding patients due to the level of technical difficulty. Other limitations were the heterogeneity between periprocedural antiplatelet regiments and post-procedural protocols, again attributed to the retrospective nature of study design.

To conclude, data from this large-scale multi-center analysis indicate that outpatient, percutaneous, endovascular procedures for the treatment of intermittent claudication or critical limb ischemia can be safely and efficiently performed in experienced IR departments of large tertiary hospitals.

Acknowledgments None.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.This study was a retrospective research involving human participants. For this type of study formal consent is not required.

References

1. Rowe VL, Lee W, Weaver FA, Etzioni D. Patterns of treatment for peripheral arterial disease in the United States: 1996–2005. J Vasc Surg. 2009;49(4):910–7.

2. Tendera M, Aboyans V, Bartelink ML, Baumgartner I, Clément D, et al. ESC Committee for Practice Guidelines. ESC guidelines on the diagnosis and treatment of peripheral artery diseases: document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC). Eur Heart J. 2011;32:2851–906.
3. Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005;366:1925–34.
4. van Overhagen H, Spiliopoulos S, Tsetis D. Below-the-knee interventions. Cardiovasc Intervent Radiol. 2013;36(2):302–11.
5. Society of Interventional Radiology Standards of Practice Committee. Guidelines for percutaneous transluminal angioplasty. J Vasc Interv Radiol. 2003;14(9 Pt 2):S209–17.
6. Szymański RJ, Kiesz RS, Wiernek SŁ, et al. Utilization of bivalirudin and vascular closure devices for same day discharge after percutaneous coronary and peripheral interventions. Kardiol Pol. 2015;. doi:10.5603/KP.a2015.0240 **(Epub ahead of print)**.
7. Spiliopoulos S, Katsanos K, Karnabatidis D, Diamantopoulos A, Nikolaos C, Siablis D. Safety and efficacy of the StarClose vascular closure device in more than 1000 consecutive peripheral angioplasty procedures. J Endovasc Ther. 2011;18(3):435–43.
8. Kasthuri R, Karunaratne D, Andrew H, Sumner J, Chalmers N. Day-case peripheral angioplasty using nurse-led admission, discharge, and follow-up procedures: arterial closure devices are not necessary. Clin Radiol. 2007;62(12):1202–5.
9. Dauerman HL, Rao SV, Resnic FS, Applegate RJ. Bleeding avoidance strategies. Consensus and controversy. J Am Coll Cardiol. 2011;58(1):1–10.
10. Criado FJ, Abdul-Khoudoud O, Twena M, Clark NS, Patten P. Outpatient endovascular intervention: is it safe? J Endovasc Surg. 1998;5(3):236–9.
11. Wiper A, Kumar S, MacDonald J, Roberts DH. Day case transradial coronary angioplasty: a 4-year single-center experience. Catheter Cardiovasc Interv. 2006;68(4):549–53.
12. Omary RA, Bettmann MA, Cardella JF, et al. Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for the reporting and archiving of interventional radiology procedures. J Vasc Interv Radiol. 2003;14(9):293–5.
13. Katsanos K, Tepe G, Tsetis D, Fanelli F. Standards of practice for superficial femoral and popliteal artery angioplasty and stenting. Cardiovasc Intervent Radiol. 2014;37(3):592–603.
14. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASCII). Eur J Vasc Endovasc Surg. 2007;33(1):1–75.
15. Spiliopoulos S, Katsanos K, Fragkos G, Karnabatidis D, Siablis D. Treatment of infrainguinal thromboembolic complications during peripheral endovascular procedures with AngioJet rheolytic thrombectomy, intraoperative thrombolysis, and selective stenting. J Vasc Surg. 2012;56(5):1308–16.
16. Burgmans MC, Chung K, van Erkel AR. Impact on patient safety and satisfaction of implementation of an outpatient clinic in interventional radiology (ipsipoli-study): a quasi experimental prospective study. Cardiovasc Intervent Radiol. 2015;38(3):543–51.
17. Albert B, Davaine JM, Chaillet MP, et al. Clinical and economic evaluation of ambulatory endovascular treatment of peripheral arterial occlusive lesions. Ann Vasc Surg. 2014;28(1):137–43.
18. Gouicem D, Palcau L, Le Hello C, et al. Feasibility of ambulatory percutaneous femoral access without the use of arterial closure systems. Ann Vasc Surg. 2014;28(1):132–6.
19. Maurel B, Paumier A, Jacobi D, Bleuet F, Martinez R, Lermusiaux P. Ambulatory percutaneous angioplasty in patients with claudication. Ann Vasc Surg. 2011;25(2):191–6.
20. Manashil GB, Thunstron BS, Thorpe CD, Lipson SR. Outpatient transluminal angioplasty. Radiology. 1983;147:7–8.
21. Lemarbre L, Hudson G, Coche G, Bourassa MB. Outpatient peripheral angioplasty: survey of complications and patient's perceptions. AJR. 1987;148:1239–40.
22. Gradinscak DJ, Young N, Jones Y, O'Neil D, Sindhusake D. Risks of outpatient angiography and interventional procedures: a prospective study. AJR Am J Roentgenol. 2004;183(2):377–81.
23. MesbahOskui P, Kloner RA, Burstein S, et al. The safety and efficacy of peripheral vascular procedures performed in the outpatient setting. J Invasive Cardiol. 2015;27(5):243–9.
24. Jain K, Munn J, Rummel MC, Johnston D, Longton C. Office-based endovascular suite is safe for most procedures. J Vasc Surg. 2014;59(1):186–91.
25. Wilde NT, Bungay P, Johnson L, Asquith J, Butterfield JS, Ashleigh RJ. Outpatient angioplasty and stenting facilitated by percutaneous arterial suture closure devices. Clin Radiol. 2006;61(12):1035–40.
26. Fitz-Henry J. The ASA classification and peri-operative risk. Ann R CollSurg Engl. 2011;93(3):185–7.
27. Shindelman LE, Ninnul GB, Curtiss SI, et al. Ambulatory endovascular surgery: cost advantage and factors influencing its safe performance. J Endovasc Surg. 1999;6:1607.
28. Butterfield JS, Fitzgerald JB, Razzaq R, et al. Early mobilization following angioplasty. Clin Radiol. 2000;55(11):874–7.
29. Akopian G, Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. J Vasc Surg. 2006;44(1):115–8.
30. Vlasic W, Almond D, Massel D. Reducing bed rest following arterial puncture for coronary interventional procedures impact on vascular complications: the BAC trial. J Invasive Cardiol. 2001;13:788e92.
31. Chambers CE, Dehmer GJ, Cox DA, et al. Defining the length of stay following percutaneous coronary intervention: an expert consensus document from the Society for Cardiovascular Angiography and Interventions—endorsed by the American College of Cardiology Foundation. Catheter Cardiovasc Interv. 2009;73:84758.
32. Spiliopoulos S, Katsanos K, Diamantopoulos A, Karnabatidis D, Siablis D. Does ultrasound-guided lidocaine injection improve local anaesthesia before femoral artery catheterization? Clin Radiol. 2011;66(5):449–55.