

Duplex Guided Angioplasty for Femoro-popliteal Arterial Occlusive Diseases; Feasibility and Short-term Outcomes

Ahmad Gamal¹, Haitham A. Eldmarany¹, Ahmed Farghaly¹,
Ahmed Elmarakby¹, Ayman Refaat².

¹Vascular Surgery Department, Kasr Alainy Hospital, Cairo University

²Vascular Surgery Department, Beni Suef University

ABSTRACT

Introduction: Contrast-induced nephropathy (CIN) is a well-known complication of conventional fluoroscopy guided angioplasty procedures and is associated with increased patient morbidity and mortality. In this feasibility study, we tried to perform the angioplasty procedures under duplex guidance alone without the need to give the potentially nephrotoxic contrast agents especially in renal impairment patients while reducing the radiation exposure. **Objectives:** To examine the feasibility of performing peripheral femoro-popliteal endovascular procedures under duplex guidance alone with assessment of initial technical success, procedural complications, and clinical improvement after 3 & 6 months. **Patients and method:** This study included patients with peripheral arterial diseases (PAD); (Rutherford category: 3-6) and laboratory evidence of renal insufficiency presented to the outpatient clinic between (January 2014 to October 2015), who proved by arterial duplex examination to have >50% stenosis or complete total occlusion (CTO) of the femoro-popliteal arterial segment affecting the middle or lower 1/3 of the superficial femoral artery (SFA) and/or popliteal artery (PA). **Results:** 21 patients (15 males & 6 females) with serum creatinine levels of ≥ 1.5 mg/dL were selected. Ages ranged from 50 to 72 years (mean: 61 ± 3.5 years). Disabling claudication was the indication in 11 cases (52%) and critical ischemia in 10 (48%). Isolated popliteal artery lesions were found in 3 cases (14 %) and lesions involving the SFA alone were found in 6 cases (29 %), while significant lesions in both the SFA and PA were found in 12 cases (57%). The mean length of the lesions in this study was 14 ± 4 cm. Immediate technical success was confirmed by completion duplex scan and was documented in all cases. Procedure duration ranged from 45 to 130 minutes (median: 87 minutes). Placement of nitinol self-expandable stents was needed in 13 (62%) cases. The reason for stent placement included: arterial dissection in 9 cases (43%) and plaque recoil in 4 cases (19%). 10 cases needed a single stent while in 3 cases 2 stents were necessary. 11 stents were deployed in the SFA and the remaining 5 stents were in the above knee popliteal segment. For stenotic lesions, the mean peak systolic velocity (PSV) prior to treatment was 340 mm/s and was 120 mm/s after angioplasty with an average reduction of 64%. Mean PSV 2 weeks following duplex guided angioplasty (DGA) was 129 mm/s, showing a reduction of 62%. For all lesions, mean preoperative ABI was 0.64 and improved to 0.83 postoperatively. No distal emboli were detected on completion duplex scans. Three procedural complications were observed in the form of 2 groin hematomas and 1 vessel perforation which was detected by color flow imaging. **Conclusion:** Patients at risk of developing contrast induced nephropathy, or those with proven allergies to iodinated contrast media, duplex ultrasound guided PTA presents a fairly safe and performable alternative to conventional PTA.

Key Words: Duplex guided angioplasty, Femoro-popliteal occlusive disease

INTRODUCTION

The technique of balloon angioplasty and possible stenting of femoro-popliteal arterial segment requires arteriography and fluoroscopic guidance. Contrast-induced nephropathy (CIN) defined as ($\geq 20\%$ decrease in renal function within 24 hours) is a well-known complication of

percutaneous transluminal angioplasty (PTA) and is associated with increased patient morbidity and mortality.¹ A study of 213 patients with peripheral vascular disease documented transient acute renal dysfunction in 12% of cases within 24 hours of PTA. Contrast dosage together with a pre-existing renal insufficiency were independent predictors of acute renal failure (ARF).² The Risk factors for ARF included congestive heart failure (CHF),

hypertension, raised HbA1c levels, and coronary artery disease.^{1,2}

The pathogenesis of CIN is not fully understood but the iodinated contrast agents may exert some toxic effects on the kidneys like: 1- direct toxic effect on renal tubules causing acute tubular necrosis, 2- prolonged vasoconstriction of vessels at the cortico-medullary junction, 3- loss of nitric oxide production due to impairment of the renal auto regulatory capacity under the high osmolar effect of the dye. Any of these factors or all together may result finally into the syndrome of CIN.² CIN may be minimized by use of N-acetylcysteine in addition to good hydration³, and the use of carbon dioxide as an alternative contrast medium; however CO₂ arteriography gives poor visualization below the knee.⁴ Also, PTA is contraindicated in patients with known allergy to iodinated contrast media as severe anaphylaxis with potentially life-threatening airway compromise may occur.⁵ For all these limitations, duplex-guided angioplasty may represent a good alternative for patients with a possible risk for CIN or with contrast allergy.⁶

The aim of This study is to evaluate the feasibility, patency and short-term outcomes of duplex guided angioplasty of femoro-popliteal arterial occlusive diseases in patients with laboratory evidence of renal dysfunction using duplex as a sole guide for the whole revascularization procedure.

PATIENTS & METHODS

This is a prospective study of 21 patients with peripheral arterial disease (PAD) (Rutherford category: 3-6) and laboratory evidence of any degree of renal dysfunction who presented to Kasr Alainy hospital, vascular department between January 2014 and October 2015, for whom arterial duplex examination revealed > 50% stenosis or complete total occlusion (CTO) of the femoro-popliteal arterial segment sparing the proximal 1/3 of the superficial femoral artery (SFA); to be suitable for antegrade puncture. Patients with poor lesion localization by duplex scanning were excluded. The Trans-Atlantic Inter-Society Consensus (TASC II) classification was used for morphologic classification of the femoro-popliteal lesions.⁷

Technique

The procedures were performed under duplex imaging in the angio-suite in case fluoroscopic guidance is needed. In the first few cases, Duplex image optimization was performed by a dedicated sonographer and as the learning curve for the procedure increases, the rest of cases were done by the vascular surgeons assisted by the radiologist. A linear 5 MHz probe in a sterile cover with lubricant sterile gel was used for imaging of the arteries in relatively non-obese patients (arteries \leq 4 cm deep), another probe (curved 2 MHz probe) was used for deeper arteries. Prior to draping and local anesthesia, duplex assessment was done to confirm the findings of the preoperative duplex and to confirm adequate visualization of the diseased arterial segment. The length of the diseased segment was measured with the duplex machine.

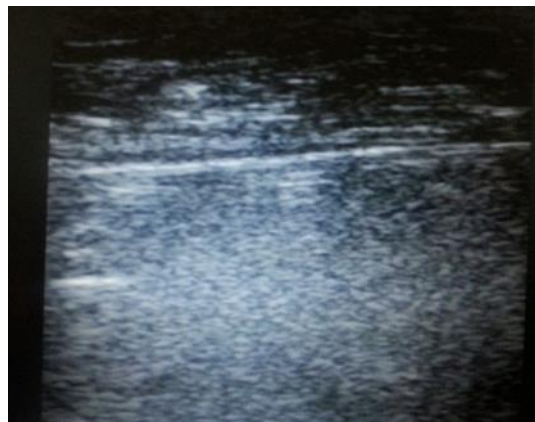


Fig. 1: B-mode image showing a guidewire crossing a segment of complete total occlusion (CTO)

The field of the duplex image on the screen usually allows visualization of approximately 4 cm of the examined arterial segment. So, for lesions longer than 4 cm, we used skin marker while progressing along the examined artery to accurately measure the length of the lesion. All procedures were done under local anesthesia (lidocaine 1%) supplemented with light sedation using propofol in only 2 cases. After successful antegrade puncture with the aid of duplex probe, a 6-F sheath (11 cm) was inserted. Heparin (100 IU/kg) was administered intra-arterially. A standard hydrophilic 0.035" guide wire (260 cm) was manipulated through the SFA, across the lesion and into the popliteal artery and left down in one of the crural vessels. A 4F angled

catheter (Berenstein) or 0.035 balloon were used to support the wire and help crossing the lesion in 11 (52 %) out of the 21 cases. A suitable balloon was then chosen and used to dilate the lesion. The length and diameter of the selected balloons were based on the available duplex assessment of the lesion length and diameter of the native artery above and below the diseased segment. The commonly used balloon diameters were 4, 5 and 6 mm. The balloon was inflated for about 3 minutes and then gradually deflated and withdrawn keeping the guidewire in place across the angioplasted lesion until assessment of both the morphological and the functional results. B-mode scale was used to assess the morphological results to detect any dissection or elastic recoil of the lesion while the color mode was used to measure the peak systolic velocity (PSV) ratio to assess the functional outcome and also for detection of any vessel perforation. Plaque dissections and recoils causing stenosis of $\geq 30\%$, a peak systolic velocity (PSV) ratio of ≥ 2 , or both were absolute indications for stent placement. The main limitation of duplex-guided PTA is the inability to definitively document all crural arteries. SO, after the procedure; distal runoff was checked by doppler measurements and clinically by palpation of peripheral pulses.

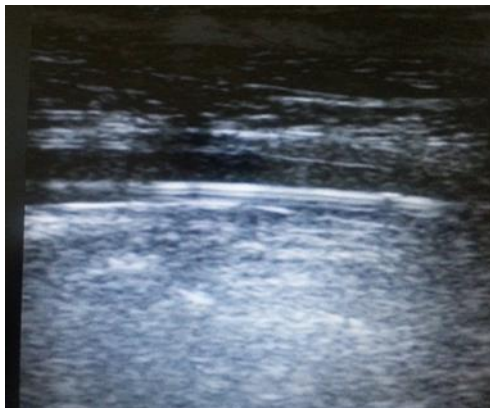


Fig. 2: B-mode image showing balloon dilation of the lesion after crossing.

Post-procedure evaluation and follow-up:

Patients were followed at the outpatient clinic for early detection of re-stenosis or re-occlusion 2 weeks after the procedure then 3 and 6 months thereafter. Arterial patency at each visit was confirmed in the absence of a recurrent occlusion or stenosis ($>30\%$) by duplex scanning. If a recurrent stenosis or occlusion was detected in the

follow up visit, re-intervention in the form another session of duplex guided angioplasty was carried out so long as the target limb is stable with no acute ischemic signs.

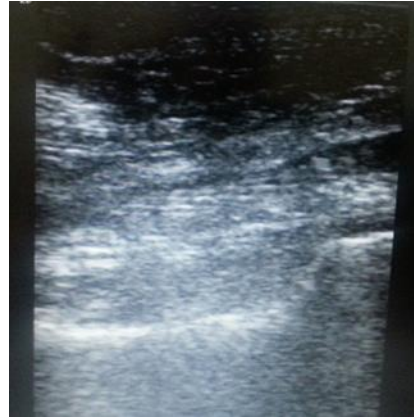


Fig. 3: B-mode image showing a stent after deployment to scaffold open a CTO lesion after balloon dilation

RESULTS

21 patients (15 males and 6 females) with serum creatinine levels of ≥ 1.5 mg/dL were selected. Ages ranged from 50 to 72 years (mean: 61 ± 3.5 years). Incapacitating claudication was the indication in 11 patients (52%) and critical limb ischemia (CLI) in the remaining 10 patients (48%).

TASC classification:

There were 6 (28.5%) TASC II A lesions, 7 (33.3%) TASC II B lesions, and 8 (38%) TASC II class C lesions in this study. The lesion sites and types are listed in table 1.

Table 1: lesion site and type:

Lesion site	Lesion type (No. of patients %)	
	Stenosis	CTO
SFA*	3 (14.2%)	3 (14.2%)
Popliteal	3 (14.2%)	0 (0%)
SFA+PA**	6 (28.5%)	6 (28.5%)

* SFA: Superficial femoral artery.

**PA: Popliteal artery.

Of the 12 cases with combined disease (stenosis or CTO) in the SFA/PA segment, 7 lesions were continuous lesions extending from the middle or distal SFA down to the above knee

PA (P1) in 2 cases, behind the knee (P2) in 4 cases, and below the knee (P3) in 1 case. In the remaining 5 cases, the popliteal lesions were not continuous with the SFA and were localized to P1 segment in 3 cases, P2 segment in 1 case and P3 segment in 1 case. All SFA lesions (18 patients, 86%) were limited to the mid and distal SFA with no extension to the proximal SFA. Patients with extensive atherosclerotic disease involving proximal SFA or common femoral artery (CFA); TASC II D lesions, were excluded. The mean length of the lesions in this study was 14 ± 4 cm.

Technical success:

Technical success was defined as patency of the treated arterial segment with less than 30% stenosis, no flow limiting dissection and an absence of distal emboli. In all cases, there was immediate technical success which was confirmed by completion duplex scan with absence of any evidence of distal embolization either clinically or by color flow imaging.

Stenting:

Our study was in the arm of angioplasty with selective stenting in case of flow-limiting dissection or $\geq 30\%$ elastic recoil of the lesion. Placement of nitinol self-expanding stents was needed in 13 (62%) cases. The reason for stent placement included: arterial dissection in 9 cases (43%) and plaque recoil in 4 cases (19%). 10 cases required a single stent while in 3 cases 2 stents were necessary, 11 stents were deployed in the SFA and the remaining 5 stents in the above knee popliteal segment.

Intraoperative and early postoperative complications:

Two patients (9.5%) developed groin hematoma which was managed conservatively and one patient (5%) had vessel perforation which was detected by color mode duplex flow image and was treated by prolonged balloon dilatation for approximately 5 minutes. No distal embolization was found in any of the cases as confirmed both clinically and by duplex scanning. No intraoperative complications were observed during balloon inflation or stent deployment.

Procedure duration:

The duration ranged from 45 to 130 minutes (median: 87 minutes). We noticed significant decrease in procedure time in the last few cases after all steps have been standardized and with increase in the learning curve. It should be noted that, the procedure time was highly dependent on

the lesion type whether it was a stenosis or CTO lesion.

Postoperative follow-up:

The mean follow-up period in this series was 6 ± 1.5 months (range: 4.5 - 6.5 months; average 5.5 months). For cases presented by arterial stenosis (12 patients 57%), the Mean PSV prior to treatment was 340mm/s, mean PSV post procedure was 120mm/s with an average reduction of 64%. Mean PSV 2 weeks following duplex guided angioplasty (DGA) was 129 mm/s, showing a reduction of 62%. For all cases, the mean preoperative ABI was 0.64 and improved to 0.83 postoperatively.

Patency rates:

At 3 month, the primary patency rate was 85.7% (18 cases) and the secondary patency rate was 95.2% (20 cases), while at 6 month, the primary patency rate was 61.9% (13 cases) and the secondary patency rate was 71.4% (15 cases) as shown in table 2

Table 2: Patency rates at 3 & 6months:

	Patency rates	
	Primary	Secondary
3 months	18 (85.7%)	20 (95.2 %)
6 month	13 (61.9%)	15 (71.4%)

DISCUSSION

The use of duplex ultrasound as a guide for some vascular procedures is not new, many recent duplex guided interventions have been reported including: thrombin injection for pseudoaneurysms of the femoral arteries, insertion of inferior vena cava filters and radiofrequency or laser ablation of incompetent saphenous veins.^{8,9,10,11} Many authors reported the use of duplex image to guide some infrainguinal revascularization procedures mostly at the femoro-popliteal arterial segment with fairly acceptable technical success rates.⁶

Ultrasound guidance does not add considerably to the overall duration of the procedures and technical aspects for the operators are comparable to the conventional technique. Among the major benefits of duplex-guided PTA, the most obvious is the avoidance of ionizing radiation, which is usually a minor problem for the patient but a discomfort and potential hazard for medical personnel. More important for the patient is the lack of a contrast agent with duplex

guidance. The frequencies of contrast-induced nephrotoxicity or adverse reactions after angiography range from 3% to 10%¹². Although cardiac and allergic events are infrequent, therapeutic options to prevent and treat contrast-induced renal dysfunction remain poor; dopamine, acetylcysteine, and forced diuresis provide only a relative benefit.¹³ Pre-existing impaired renal function and contrast agent dosage are independent predictors of contrast-induced acute renal failure; arterial hypertension, congestive heart failure, and diabetes mellitus are other contributing factors². In those patients at high risk for post-intervention renal problems, duplex-guided angioplasty may be a practical alternative strategy⁶.

Nearly 48% of patients included in this study presented with CLI with the remaining 52% of patients suffering from life style limiting claudication. Regarding risk factors; 13 patients were smokers (61.9%), hypertension was present in 5 patients (23.8%), and diabetes mellitus in 18 patients (85.7%). on the other hand, in the their study Rmazanali et al.,⁶ the average percentages were 43.6% for smoking, 47.1% for hypertension, and 46.1% for diabetes mellitus. In comparison to Rmazanali et al., we had more diabetics (85.7% vs 46%) and this may be related to the fact that only 11 % of the patient group in Rmazanali et al study had critical limb ischemia compared to 47.6 % in our patient group. In this study analysis of co-morbidities showed that 9 patients (42.8%) were cardiac, in Rmazanali Ahmadi et al., the averages of the percentages were 44.2 % for cardiac patients.

The technical success in our study was documented in all cases and this is comparable to Enrico Ascher et al., who reported a technical success rate about 93% in duplex guided angioplasty of femoropopliteal occlusive disease in 37 cases,¹⁴ while Ramazanali et al., in their case-controlled study of duplex versus fluoroscopy guidance during femoropopliteal PTA of 104 patients who underwent duplex guided femoro-popliteal angioplasty compared to 104 patients undergoing fluoroscopically- guide procedure, technical success was achieved in 88 (84.6%) patients from the duplex-guided group and in 102 (98.1%) fluoroscopy control patients; technical success of duplex-guided procedures was significantly lower compared to fluoroscopic angioplasty.⁶ In our study we did not face much

difficulty in re-entering the true lumen and this 100% technical success can be explained by the relatively small number of patients.

The primary patency rate at 3 month was 85.7% (18 cases) and the secondary patency rate was 95.2 % (20 cases) while at 6 month, the primary patency rate was 61.9% (13 cases) and the secondary patency rate was 71.4% (15 cases).

The overall limb salvage in our study was 100%; no patient required major amputation during the follow-up period, and the reason beneath the fact why limb salvage rate is higher than the patency rates is that endovascular intervention may provide sufficient blood supply needed for healing then by the time the vessels is occluded, the demand of blood supply is decreased and the collaterals developed are enough for the tissue viability.

An important key point for successful results after an endovascular procedure is an appropriate follow-up protocol. We agree with the strategy of Florenes et al. who attributed their excellent results to the fact that all the patients were placed in a duplex surveillance program and any significant stenosis was treated with PTA or, in selected cases, with PTA & stenting.¹⁵

It is to be noted that our follow up period was relatively short (average 5.5 month) compared to other studies. The follow up period in the study of Ramazanali et al., (2002) was 12 months. We couldn't assess the difference in outcomes between cases with stenosis and those with complete total occlusion (CTO) due to the fact that although this study is prospective, it does not scrutinize all the variables that may have influenced the outcome of the procedure (e.g., calcification and run-off vessel number, as analyzed by other authors).

This series of duplex guided angioplasty (DGA) supports our belief that duplex scan could be safely used to adequately direct guide wires, sheaths, balloons, and stents for the treatment of occlusive lesions in superficial femoral (SFA) and popliteal (PA) arteries. Also, we can address some important advantages that we found in DGA and not available in the conventional fluoroscopy guided procedures and have been highlighted by several other studies^{6,14} including: 1- Ability to exact localization of the arterial lesion, 2- Continuous monitoring of the guide wire while in the true lumen and ability to direct it to the sub intimal plane with minimal risk of vessel

perforations, 3- Accurate measurements of the vessel diameter which give us the chance to select a suitable balloon size, 4- The ability to assess the relationship between the stent and vessel wall, and most importantly, the chance of confirming the adequacy of the revascularization at the end of the procedure and to assess the functional outcomes at the same time.

In our opinion, the major technical advantage of ultrasound that we realized in this study is the accurate measurements that can be made for the occlusive lesions. It is known that conventional digital subtraction angiography (DSA) provides images of the intraluminal diameter of a stenotic lesion. True vessel diameter can be measured by ultrasonography, as opposed to DSA. Duplex provides real time reliable measurements of the stenotic lesions. Subsequently, more detailed attention can be given to sizing of balloons and stents. Moreover, after balloon dilation it is possible to directly measure the improvement in PSVs, giving accurate information concerning the possibility of any elastic recoil. Duplex can also provide reliable information regarding the hemodynamic significance of dissections. Angiography cannot provide reliable measurements to determine whether a dissection is hemodynamically significant or not. On the other hand, in order to avoid any difficulties or hazards during the duplex guided revascularization, Ascher et al., in his study of 253 cases have identified some important technical points that are worth reporting¹⁶: (1) The echolucent tip of the guidewire needs to be visualized at all times until it is well beyond the most distal lesion. (2) The presence of a long heavily calcified segment that prevents good visualization of the arterial lumen should discourage one from proceeding with duplex guidance alone. However, short heavily calcified segments may need gentle attempts at crossing so long as the guide wire tip can be adequately monitored within the arterial lumen.¹⁶

Obviously, our proposal of duplex guided angioplasty limits or eliminates radiation exposure, so it seems safer to the patient, the surgeon and all medical personnel. As pointed out by Lipsitz et al, the deleterious effects of radiation exposure are cumulative and permanent, and the onset of signs and symptoms can be delayed. Endovascular procedures become an increasingly significant portion of the daily vascular surgery

practice, radiation exposure may represent a real risk that needs to be minimized.¹⁷ Accordingly, duplex-guided procedures may become a good alternative for vascular interventionists, who are more frequently exposed to radiation for longer periods¹⁸.

The relatively small number of the patients in this study and the lack of a long follow up makes our results rather early outcomes only, moreover, this study lacks randomization and our first approach to duplex guided interventions for SFA/PA lesions is probably an important bias as well and this adds to the study limitations. Although this was set as a feasibility study, our preliminary data with DGAs and stenting for management of occlusive lesions in femoropopliteal segment showed that this approach is feasible and effective in achieving excellent anatomical and hemodynamic improvement regardless of the lesion extent. Therefore, duplex can represent a good safer and adequate alternative for patients with contrast allergy or at risk of contrast induced renal problems. However, because of the small sample size and the short follow up period, we emphasize that a larger study with longer follow up is required before a more liberal adoption of this technique is advised.

CONCLUSION

Patients at risk of developing contrast induced nephropathy or those with proven allergies to iodinated contrast media, duplex ultrasound guided angioplasty with or without stenting presents a fairly safe and performable alternative to conventional PTA.

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