

Combined Duplex Guided Angioplasty with Contrast-free Fluoroscopy for Treatment of Femoro-popliteal Arterial Lesions in Patients with Renal Insufficiency. A multicenter experience

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Background: The combination of duplex guided angioplasty (DGA) and contrast free fluoroscopy can be used as an alternative method to contrast media for the treatment of femoro-popliteal arterial occlusive diseases in renal patients.

Patients and methods: 67 patients (38 males) with femoro-popliteal arterial lesions underwent combined duplex guided angioplasty with contrast-free fluoroscopy. Patients with impaired renal functions of serum creatinine level >1.5 mg/dl and patients with hypersensitivity to contrast media were included in the study. We excluded patients with the ability to perform classic fluoroscopy with contrast. Also, aorto-iliac or infragenicular lesions were excluded from the study.

Results: Technical success was achieved in 63 cases (94%). In all stenotic lesions (36 cases) crossing was achieved spontaneously using contrast free fluoroscopy. In cases with occlusion (31 cases) crossing was tried under fluoroscopic and duplex guidance with successful transluminal crossing occurred in 19 cases of the occluded lesions while the remaining 12 cases under went subintimal angioplasty. Successful reentry achieved in 5 cases while 3 cases with failed reentry underwent retrograde approach through distal SFA puncture. Stenting was done in 29 cases (43%), 19 cases (28%) were having floating intimal flap; while the other 10 cases (25%) had residual stenosis > 30%. A primary patency rate of 91% was obtained by the end of the 1 year follow up.

Conclusion: This technique is feasible and effective for the treatment of femoropopliteal arterial lesions Patients with renal insufficiency or allergy to contrast.

Key words: Angioplasty, renal patients, contrast allergy.

Introduction

Peripheral arterial disease (PAD) has become a serious public health problem that impacts a large number of patients worldwide and, this number is expected to rise. Endovascular procedures utilizing contrast media has been widely adopted for the treatment of PAD due to its minimally invasive nature.¹ Patients with impaired renal function or contrast allergy pose a challenge to the safe and effective performance of peripheral endovascular interventions using contrast media. The use of carbon dioxide can be considered a valuable alternative in these patients however, it has some limitations which prevents its wide use.² The use of duplex guided angioplasty (DGA) can be considered another alternative. The accuracy of duplex is well confirmed by comparing the degree of peripheral vascular disease noted on arteriography.³⁻⁵ Ultrasound can clearly visualize guide wires, sheaths, balloons, and stents used

for arterial balloon angioplasties and stenting. Certainly, the contemporary quality and reliability of duplex imaging of the arterial tree has become possible only because of excellent resolution of the newer duplex machines.⁶ However, DGA has also some limitations, as it lacks the panoramic view provided by fluoroscopy which is important in crossing difficult occlusions. The combination of DGA and contrast free fluoroscopy can overcome these limitations without adding risk of contrast induced nephropathy (CIN).

This study aimed to support our belief that duplex can be used as an alternative method to contrast media for the treatment of femoro-popliteal arterial occlusive diseases. However, the pitfalls in DGA technique make it insufficient to replace the classic fluoroscopy. For this reason, we combined both methods without use of contrast media in renal patients.

Patients and methods

This is a prospective study that was conducted on 67 limbs in 67 patients during the period from January 2018 to January 2022 who were admitted to Tanta University Hospital, Kafr elshikh university Hospital, and Alexandria university hospital, Egypt. A written informed consent was obtained from all patients before enrollment in the study.

The study included patients suffering from chronic lower limb ischemia of grade IIb, III and IV (According to Fontaine Classification), resulting from femoro-popliteal arterial lesions (Occlusion or stenosis) of TASC II A, B and C. Patients with impaired renal functions of serum creatinine level >1.5 mg/dl and patients with hypersensitivity to contrast media were included in the study.

Patients with the ability to perform classic fluoroscopy with contrast media (patients with normal renal functions and patients with no history of contrast allergy) were excluded from the study. Renal patients who are already on dialysis were excluded from the study. Also, aorto-iliac or infragenicular lesions were excluded from the study.

Preoperative workup: Preoperative data were collected including, personal history, associated comorbidities. Thorough clinical examination was carried out for all patients, as well as, ankle brachial index (ABI) measurement and routine preoperative laboratory investigations.

Meticulous precise duplex scanning (Using Philips Affinity 50G ultrasound machine with L12-4 MHz linear probe) was performed preoperatively to each patient demonstrating the site and nature of the lesion (stenosis or occlusion), length of the lesion, peak systolic velocity (PSV), and velocity ratio across the lesion. For measuring the length of the lesion; the size of the arterial segment shown in the display screen by the linear probe was only 4 cm. For lesion's length more than 4 cm, we used the skin marks along the course of the scanned artery. Also, metal marks were applied to the skin at the site of the lesion to serve as a guide while performing contrast free fluoroscopy. Magnetic Resonance Angiography (MRA) without iodinated contrast was done in selected patients (for example, patients with long lesions) who could benefit from bypass surgery. Aspirin and clopidogrel were started 48 hours before the procedure and continued during the follow-up period.

Technique: The procedure was performed in an operating room with the facility of performing open surgery, duplex guided procedure, and also fluoroscopic guided procedure using C Arm (Ziehm vision R, manufactured by Ziehm Imaging, Germany). Patients were operated in a supine position under local anesthesia (10 cc xylocaine 2%

at the puncture site). After skin preparation and draping, the L12-4 MHz linear probe was inserted into sterile protection cover with its scan head inserted into a sterile plastic sleeve with coupling gel. Access site was obtained by puncture of the ipsilateral common femoral artery (CFA) under duplex guidance using AVANTI® 6 Fr. × 11cm sheath (Cordis, USA), followed by intravenous administration of 5000IU of unfractionated heparin (**Figures 1a,b**).

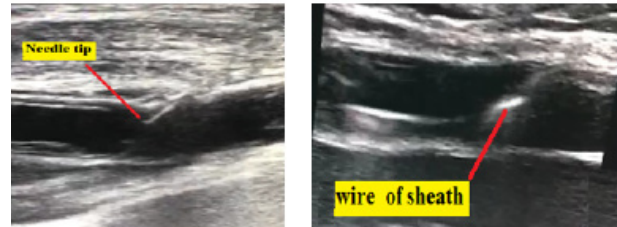


Fig 1a,b: Arterial access under duplex guidance.

In cases with superficial femoral artery (SFA) osteal lesion, access was obtained from contralateral CFA under duplex guidance using cross-over sheath (Flexor® 6 Fr. × 55cm, Cook, USA) and with the help of fluoroscopy to cross the aortic bifurcation. After sheath insertion a standard 0.035-inch x 260 cm ZIP hydrophilic guide-wire (Boston Scientific, USA) is advanced under fluoroscopic guidance without contrast media depending only on the anatomy of the artery. When the lesion is reached (Which was previously determined by duplex and marked on the skin by metal marker), trials to cross the lesion intraluminally under duplex guidance by directing the wire through the microchannels (**Figure 2**).

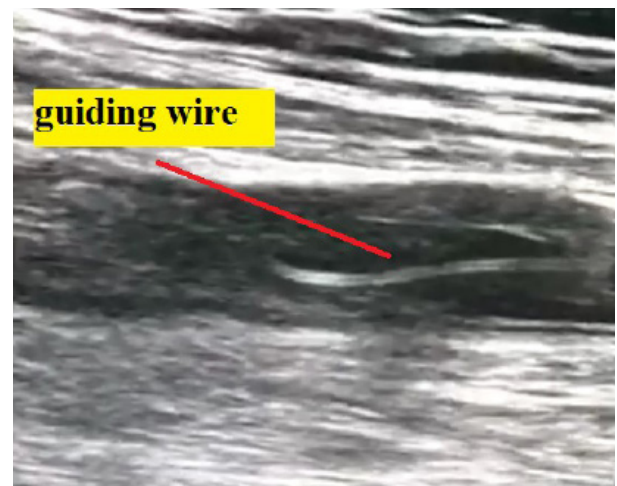


Fig 2: Advancing the guide wire across SFA.

In cases of failure of intra-luminal passage of the guide-wire, subintimal approach was performed. Wire loop formation was confirmed by duplex imaging and fluoroscopic guidance. Then advancement of the wire through the occlusion was followed to the patent arterial segment which is identified by the presence of color signal in the lumen using duplex.

Re-entry attempts should be initiated within the first 1–2 cm after flow reconstitution to minimize the length of angioplasty. The arterial segment with the least amount of calcification and thinnest intima-media layer should be preferably chosen for reentry. After the guide-wire enters the true arterial lumen, its position was confirmed with duplex imaging in both longitudinal and transverse views also by the free moving tip of the wire under fluoroscopy. In some cases, with difficult re-entry after subintimal angioplasty, ipsilateral retrograde puncture of the distal SFA or tibial vessels was performed under duplex guidance; and after crossing the lesion by the retrograde wire, snaring of the wire was performed under fluoroscopic guidance without contrast.

The diseased segment(s) was then balloon-dilated (Mustang PTA balloon, Boston Scientific, USA) under duplex guidance. Balloon diameter and length was chosen according to direct arterial measurements obtained by duplex (**Figure 3**).

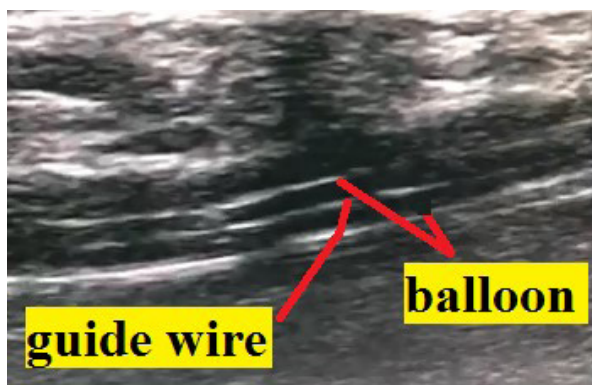


Fig 3: Balloon inflated across the diseased segment.

A smooth flow can be clearly seen after forceful injection of heparinized saline through the sheath without turbulence indicating successful dilatation. A detailed duplex examination was performed following removal of the balloon angioplasty catheters to identify possible areas of plaque dissection (**Figure 4**), thrombi and plaque recoil (**Figure 5**).

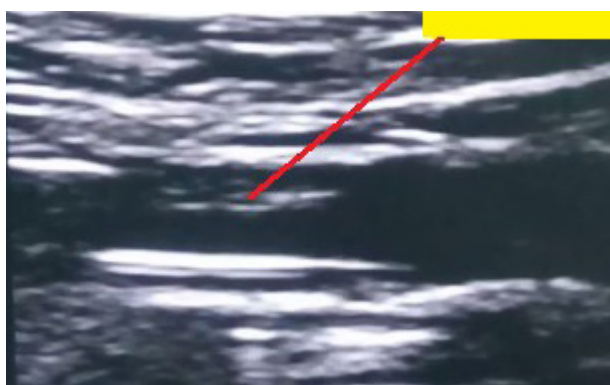


Fig 4: Dissection flap after balloon dilatation.

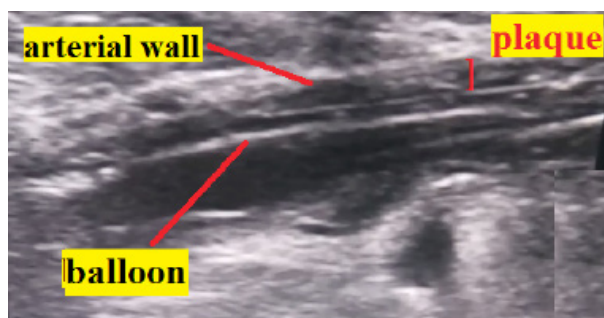


Fig 5: Plaque recoil while deflating the balloon.

Plaque dissection and residual stenosis were treated by placement of self-expanding stents (6 Fr. Innova self-expandable stent, Boston Scientific, USA) under duplex guidance. (**Figure 6**).

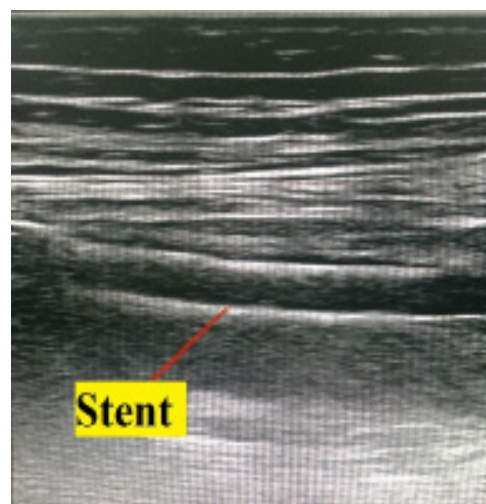


Fig 6: Stent deployed across diseases SFA segment.

So the added value of the guidance of duplex was easier arterial access through direct visualization of the artery by duplex during the needle puncture, guiding the wire through the microchannels to help intraluminal crossing, better choice of the re-entry site in case of subintimal angioplasty, proper choice of balloon and stent size by duplex arterial lumen measurement. In addition, duplex can assess the need for stenting if flow limiting dissection or residual stenosis or plaque recoil occurred after ballooning. lastly, evaluation of the adequacy of angioplasty and the velocity after stenting.

Post-procedural workup: A scheduled follow up visits in the outpatient clinic were carried out at 2 weeks, 1, 3, 6 and 12 months after the procedure. Patients underwent clinical assessment for distal pulse, healing of ischemic ulcer, improvement of claudication distance and limb salvage or amputation. They went ABI measurements, as well as, duplex scan to detect the blood flow pattern and velocity, the presence of re-stenosis (And its degree) or re-occlusion.

Definitions

Technical success was defined as crossing the lesion with the guidewire and dilatation with/out stenting with less than 30% stenosis.⁷

Residual stenosis were defined as luminal defects of >30% diameter reduction with peak systolic velocity (PSV) ratio ≥ 2 across the stenosis.⁸

Primary patency was identified as absence of occlusion or significant restenosis (>30% diameter reduction) within the treated segment.

Statistical analysis

The collected data were organized, tabulated and statistically analyzed using SPSS statistical package for social studies version 25 manufactured by SPSS, an IBM Company, United States of America. For categorical data, the number and percentage were calculated for each observation. For numerical data, the range, mean and standard deviation were calculated. The level of significance was considered at probability value of $P < 0.05$ using the Wilcoxon signed rank test.

Results

From January 2018 to January 2022 our study included 67 limbs in 67 patients (38 males, and 29 females) with mean age 62 ± 7 years (ranged between 55 and 83 years) suffering from chronic lower limb ischemia caused by femoro-popliteal lesions. Sixty-one patients (91%) had CKD with creatinine level ranged from 1.5 to 3.8 mg/dl, and 6 patients (9%) had previous history of allergy to iodinated contrast media. TASC II A was found in 11 patients (16%), TASC II B was found in 38 patients (57%), while TASC C was found in 18 patients (27%)

Disabling claudication was present in 12%, while 21% suffered rest pain, and 67% had grade IV ischemia according to Fontaine classification. Concomitant risk factors included Diabetes, smoking and hypertension in 85%, 52% and 67% respectively (**Table 1**).

Duplex study showed that 36 cases (54%) were having stenotic lesions, while 31 cases (46%) suffered from completely occluded segment with TASC classifications illustrated in (**Figure 7**). The length of the occlusion ranged between 1.5 to 17 cm (mean 8 ± 3.6).

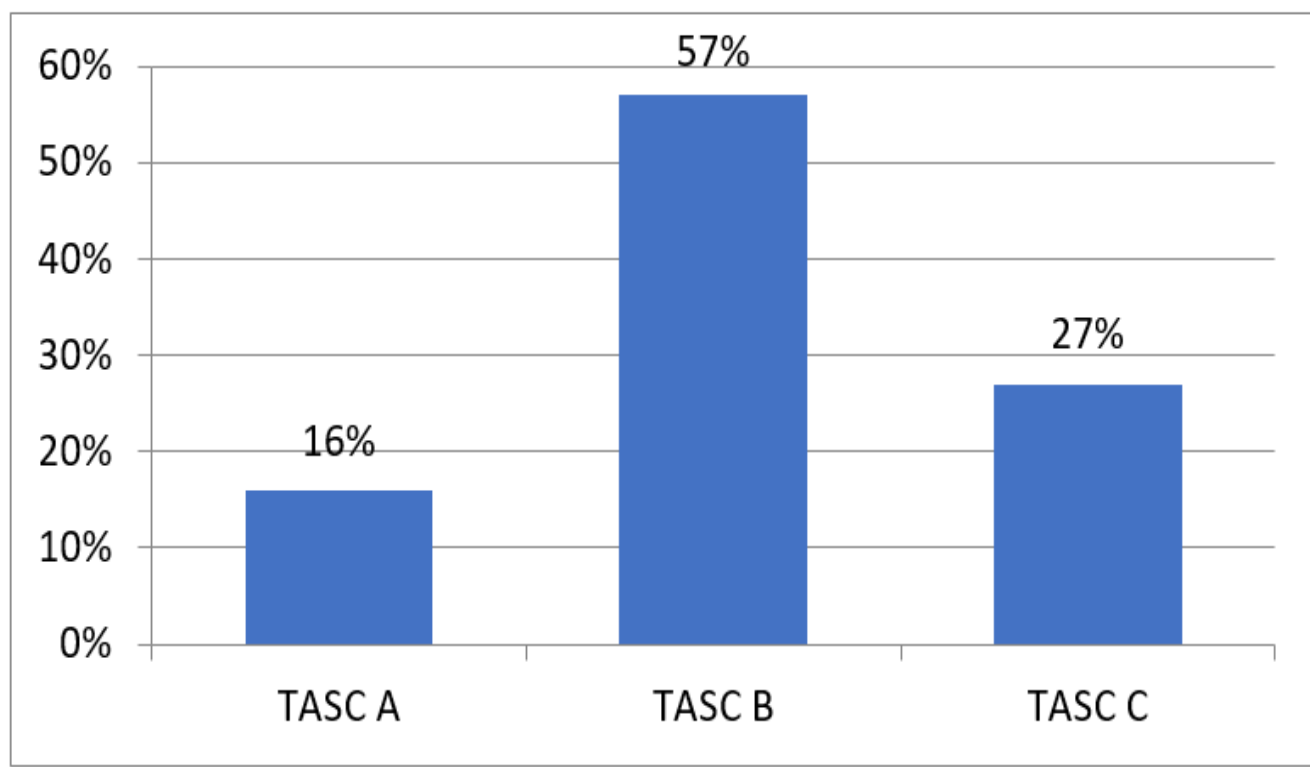


Fig 7: Distribution of TASC classifications.

The duration of the procedure: ranged from 35 to 90 minutes with mean duration length 45 minutes ± 13 .

Arterial access: 59 cases (88%) underwent duplex guided puncture through ipsilateral antegrade approach. eight cases (12%) with osteal SFA lesion underwent contralateral approach using cross-over

sheath with the help of fluoroscopy crossing the aortic bifurcation.

Technical success: Was achieved in 63 cases (94%). In all stenotic lesions (36 cases) crossing was achieved spontaneously using contrast free fluoroscopy. In cases with occlusion (31 cases) crossing was tried under fluoroscopic and duplex guidance with successful transluminal crossing occurred in 19 cases of the occluded lesions while the remaining 12 cases under went subintimal angioplasty. Successful reentry achieved in 5 cases while 3 cases with failed reentry underwent retrograde approach through distal SFA puncture. 4 cases (6%) showed failure to cross and underwent surgical bypass and considered technical failure.

Stenting: Stenting was done after duplex guided dilatation in 29 cases (43%), 19 cases (28%) were having floating intimal flap; while the other 10 cases (15%) had residual stenosis > 30%.

Post-procedural complications: 12 cases (18%) had post procedural groin ecchymosis. Small hematoma at the puncture site occurred in 3 cases (4%) which required no surgical intervention and resolved spontaneously. No life-threatening complications or retroperitoneal hematoma occurred in any patient.

Limb salvage: Minor amputation of preoperatively

gangrenous toes was performed in 41 cases (61%) after successful revascularization, while above knee amputation was done in 4 cases due to spread of infection to knee level.

Hemodynamic changes: ABI changed preprocedural from a mean of 0.34 ± 0.17 (Range, 0.29 - 0.68) to postprocedural of 0.89 ± 0.3 (Range, 0.75 - 1). P value of 0.003 demonstrated a significant increase of ABI after the procedure. The velocity ratio across the lesion changed preprocedural from a mean of 2.5 ± 0.3 (Range 2.1 - 2.8) to postprocedural of 1 ± 0.2 (Range, 0.6 - 1.5). The mean PSV at the stenotic lesions changed preprocedural from $294 \text{ cm/sec} \pm 84$ (Ranged 178 - 397 cm/sec) to $67 \text{ cm/sec} \pm 20$ postprocedural (Ranged, 55 - 85 cm/sec). Also, the mean PSV post lesions (Occlusion and stenosis) changed preprocedural from $29 \text{ cm/sec} \pm 7$ (Range, 9 - 38 cm/sec) to $75 \text{ cm/sec} \pm 19$ postprocedural (range 50 - 88 cm/sec). p value of 0.001 demonstrated a significant change of PSV whether at or beyond lesions before and after the procedure (**Figure 8, Table 2**).

by the end of the 6 months follow up. Six cases (9%) showed SFA restenosis (4 of them were still having unhealed wound) and went successful revascularization with combined approach while 2 cases with completely healed ulcer left untreated.

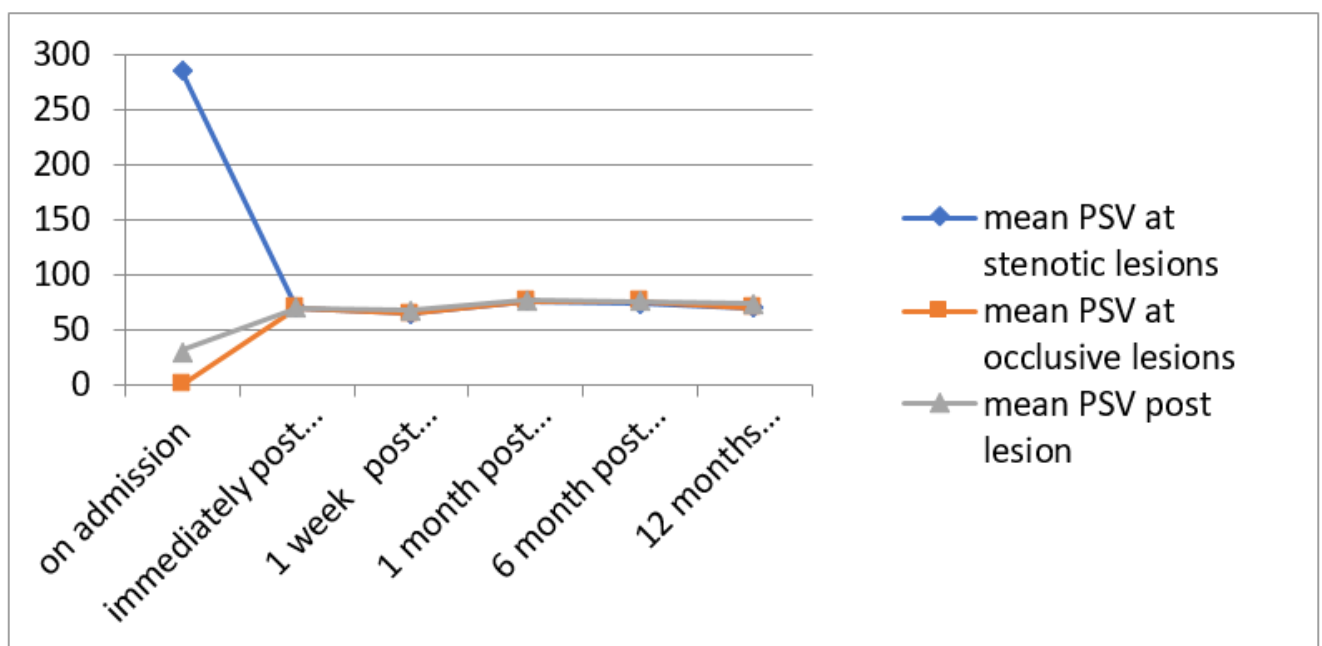


Fig 8: Changes in mean PSV during follow up visits.

Table 1: Demographic data

Patient characteristics	N=67
Sex	
Male	38 (57%)
Female	29 (43%)
Age (years)	
Mean \pm SD	62 \pm 7
Comorbidities	
Diabetes	57 (85%)
Smoking	35 (52%)
Hypertension	45 (67%)
Ischemic heart disease	29 (43%)
Carotid artery disease	21 (31%)
Hyperlipidemia	38 (57%)
Cerebrovascular disease	40 (60%)
Renal impairment (serum creatinine level > 1.5 mg/dl)	61 (91%)
Allergy to contrast media	6 (9%)
Fontaine Classifications	
IIb	8 (12%)
III	14 (21%)
IV	45 (67%)

Table 2: Results

Technical success	63 (94%)
Stenting	29 (43%)
Flow limiting dissection	19 (28%)
Residual stenosis > 30%	10 (15%)
Death	0 (0%)
Groin ecchymosis	12 (18%)
Hematoma	3 (4%)
ABI	Mean \pmSD
Preprocedural	0.34 \pm 0.17
Immediate postprocedural	0.89 \pm 0.3
1 month postprocedural	0.84 \pm 0.08
3 months postprocedural	0.82 \pm 0.06
6 months postprocedural	0.79 \pm 0.04
12 months postprocedural	0.77 \pm 0.09
Primary patency	61 (91%)

Discussion

While endovascular treatment has become the first line therapy in most cases of PAD, a number of challenges remain unresolved.⁹ One of these challenges is the intravenous contrast media administration which may cause adverse reactions especially in patients with chronic kidney disease. Contrast induced nephropathy (CIN) remains responsible for a third of all hospital-acquired acute kidney injury and affects between 1% and 2% of the general population.¹⁰ Another problem with contrast media is immediate hypersensitivity reactions which are largely non-immunologic. Skin testing and graded dose are ineffective at predicting the risk of having an immediate hypersensitivity reaction to contrast media.¹¹

In such cases, alternative contrast media may be used to perform the procedure. Current options include carbon dioxide, gadolinium, and dilute contrast media. Each of these alternatives has its own advantages and limitations.² Foremost, CO² is non-allergenic and non-nephrotoxic, making it safe for use in patients with either contrast allergy or kidney disease.¹² However, CO² is not without limitations. The CO² is relatively contraindicated in patients with chronic obstructive pulmonary disease. Moreover, it requires a special delivery system to prevent air contamination and gas compression which is not always available in many institutions.¹³ The quality of angiograms with CO² is inferior when compared to iodinated contrast media.¹⁴ Improper injection of CO² can lead to errors in diameter measurement. CO² is floating relative to blood and

therefore rises to the nondependent portion of the vessel. If insufficient volumes of CO² are injected into large vessels, the operator may underestimate the true size of the vessel. Alternatively, if the bolus is delivered in an explosive way, the operator may overestimate vessel diameter.¹⁵ Fujihara et al.¹⁶ performed complete and thorough evaluation of vessel lumen by CO² alone was in only 63% of the superficial femoral artery (SFA) cases. For this reason, there is common adjunctive use of iodinated contrast agents with CO² imaging to obtain complete vessel information.¹⁶ However, the amount of contrast that can be safely administered to patients with baseline chronic kidney disease to prevent CIN is not known. Therefore, the surest method to avoid CIN is to avoid using contrast totally if possible.¹⁷ Moreover, diluted contrast media cannot be used as an alternative in patients with allergy to contrast media.²

Gadolinium was signaled as an alternative contrast agent in patients with CKD. However, since its association with the disease nephrogenic systemic fibrosis in 2006, its use as an angiographic agent in patients with CKD has appropriately declined rapidly.¹⁸

Another alternative to the use of contrast media in renal patients is duplex guided angioplasty. Technically, duplex guided angioplasty (DGA) provides both anatomical, as well as, hemodynamical information of the whole arterial tree involved. Starting from ultrasound-guided gaining arterial access, helping to prevent local complications as arterial dissection and profunda femoris artery puncture; passing through measuring the diameter of the vessel from adventitia to adventitia, helping precise sizing of the balloons and stents. And most important, real time visualization of various hemodynamic parameters such as flow direction, velocity and waveform.¹⁹ In spite of all these advantages of DGA, there are some limitations of its wide use. The ability to follow the moving guidewire using ultrasound requires following the vessel and then looking for the wire inside, which can be lagging behind or proceeding forward as ultrasound alone lacks wide panoramic view which is important to follow the behavior of the guidewire on moving towards, negotiating, and then crossing the lesion. These limitations of duplex can be overcome by combining it with contrast free fluoroscopy. For this reason; we combined both techniques in our study.

Ahmadi et al.⁷ used DGA as the first option and fluoroscopic PTA as a backup in case of technical failure. Ascher et al.²⁰ performed intraoperative completion arteriogram to confirm the adequacy of the procedure and duplex results in their initial 41 cases (17%), also they used combined duplex guidance with contrast-based fluoroscopy in

1.6%, and contrast-free fluoroscopy in 2% with contralateral CFA access.

The resolution of duplex image is decreased in aortoiliac segment due to abdominal gases and in tibial arteries due to its small size. For this reason, we choose femoropopliteal lesions. Ahmadi et al.⁷ and Ascher et al.^{20,21} also used DGA technique for femoro-popliteal lesions. Krasznaei et al.²² used DGA technique for iliac lesions, however, they applied spinal anesthesia for all patients to relaxes the abdominal muscles for optimal visualization of the iliac arteries, also bowel gases was the most common cause of failed duplex imaging, so all patients in their study were starved overnight. Ascher et al.²¹ used DGA technique for infrapopliteal lesions, however the incidence of acute thrombosis of the outflow vessel was (12.5%) which is higher than that reported in the literature for fluoroscopic guided angioplasty, also duplex visualization was difficult in obese patients and heavily calcifies tibial vessels.

In our study (61) patients had renal impairment with creatinine levels of ≥ 1.5 mg/dl and (6) patients had experienced hypersensitivity reactions to contrast media. Also, Ascher et al.²³ reported 28 patients with serum creatinine levels of ≥ 1.5 mg/dl, and Mazzaccaro et al.²⁴ published a case report of a severe renal insufficiency patient with creatinine level 4 mg/dl

In our study the average duration of the procedure ranged from 35 to 90 minutes with mean duration length 55 minutes ± 11 .

Performing the intervention under duplex guidance alone will take much time due to its limited field of view that requires slower guidewire motions for sufficient visualization. However, the average time for the combined procedures doesn't seem to exceed those previously reported in literature or our experience with fluoroscopy-based interventions alone.

In the present study we achieved technical success in 63 cases (94%), 4 cases (6%) showed failure to cross the lesion and underwent surgical bypass and considered technical failure. Also, Ahmadi et al.⁷ reported technical success in 88 patients (84.6%) using duplex guidance alone, and 9 patients (8.6%) with the help of contrast-based fluoroscopy. Ascher et al.²⁰ reported overall technical success of 93% using DGA, of which, 45 cases (17.8) were combined with contrast-based fluoroscopy.

We achieved hemodynamic success in our study as there was significant increase in post procedural ABI with significant improvement in post procedural PSV whether at or beyond the lesion site, also there was significant improvement in velocity ration across the

lesion post procedural.

Small hematoma at the puncture site occurred only in 3 cases due to careful duplex guided arterial access as well as post procedural duplex assisted compression.

Although, the combined approach seems to be feasible and effective, further studies with longer follow-up and comparison with other alternatives to contrast media will help to fully evaluate its broader applicability.

Conclusion

Combined use of Duplex guided angioplasty with contrast free fluoroscopy is feasible and effective for the treatment of femoropopliteal arterial lesions. Patients with renal insufficiency or those with severe allergy to contrast media will get the most benefit from this approach.

Nowadays, the new technology in duplex machines permits an excellent resolution that makes the quality of duplex imaging is promising to depend more and more on this technique.

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