Privilege of adding noncontrast fluoroscopy to the standard duplex ultrasound-guided percutaneous transluminal angioplasty: a comparative study

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Background
The use of contrast agents in the context of conventional percutaneous transluminal angioplasty (PTA) may pose considerable risks for patients with pre-existing renal impairment, and/or allergic disorders. Duplex ultrasound-guided PTA is one of the established alternative modalities to avoid the risk for contrast use; however, it has its limitations.

Aim
The aim of the present study was to address the values of combining noncontrast fluoroscopy to duplex ultrasound-guided PTA to overcome the limitations of using the later alone, and to improve the overall outcome.

Patients and methods
The study was conducted from January 2012 to October 2014 on a total of 32 patients with severe chronic ischemia mainly due to significant femoropopliteal disease, with concomitant iliac and/or tibial lesions in some of them. Patients were randomized equally between two groups, duplex ultrasound-guided PTA and combined noncontrast fluoroscopy and duplex ultrasound-guided PTA. Both groups were compared regarding technically related points and also 6 and 12-month patency rates.

Results
In the duplex ultrasound-guided PTA group, the technical success rate was achieved in 13/16 (81.2%) patients. Balloon angioplasty was carried out in nine patients (eight with noncompliant balloon); stenting was needed in three patients, whereas hybrid treatment was needed in one patient. At 6 and 12 months, primary patency rates were 76.9 and 61.5%, respectively. In contrast, in the combined noncontrast fluoroscopy and duplex ultrasound-guided PTA group, technical success rate was achieved in 15/16 (87.5%) patients. Balloon angioplasty was carried out in 11 patients (seven with noncompliant balloon); stenting was needed in two patients whereas hybrid treatment was needed in two other patients. At 6 and 12 months, primary patency rates were 80 and 66.6%, respectively.

Conclusion
In this study, a pioneer step forward was assumed to improve the overall technicality in such situations by adding noncontrast fluoroscopic guidance to duplex guided-PTA, with significantly better periprocedural outcome.

Keywords:
duplex ultrasound-guided percutaneous transluminal angioplasty, noncontrast fluoroscopy, renal impairment

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Introduction

Percutaneous transluminal angioplasty (PTA) is a well established, minimally invasive procedure for the treatment of atherosclerotic occlusive disease. Patients who have impaired kidney functions and are indicated for PTA pose a management dilemma, as the use of contrast agent in such a category of patients can lead to the deterioration of the renal function in up to 12% of them [1,2]. In such situations, apart from using CO_2 angiography with its still doubtful image clarity, one of the other alternatives is to use duplex ultrasound-guidance. The evidence supporting these modalities is still lacking because of the lack of sufficient reports comparing them with conventional fluoroscopically guided PTA [3,4].

In this comparative study, we aimed to sort out the privilege of adding noncontrast fluoroscopy to standard duplex ultrasound-guided PTA in patients with impaired kidney functions focusing on the technical success, technical ease, complications, and patency rate.

Patients and methods

This study was conducted from January 2012 through October 2014 on 32 patients (23 men and nine women). Their mean age was 63 ± 11 years. The study patients had significant femoropopliteal disease, and concomitant iliac and/or tibial lesions were encountered in some of them. The study comprised a total of 51 attempted balloon angioplasties ± stenting for the above mentioned lesions. Variable presentations of severe ischemia were the indications for intervention in all patients: Rutherford class 3 in five patients, class 4 in 13, class 5 in 10, and class 6 in four patients.

Renal impairment due to chronic kidney disease was the main inclusion criterion. Other comorbidities included diabetes, hypertension, smoking, and coronary artery disease in 78.1, 71.8, 46.8, and 37.5% of patients, respectively. The Trans-Atlantic Inter-Society Consensus (TASC) classification was used for morphologic description of different arterial segment lesions. The studied patients were mainly TASC A and B, and few cases belonged to TASC C and D. Each patient was evaluated through proper history-taking, clinical examination, and color Doppler ultrasonography, with the occasional need for magnetic resonance angiogram without contrast in some patients.

Patients were randomized into two groups (16 patients each): PTA was carried out under duplex ultrasound-guidance in the first group (D-PTA), and PTA was carried out under combined noncontrast fluoroscopy and duplex ultrasound-guidance in the second group (FD-PTA). Furthermore, according to the type of balloon used for PTA, each group was subdivided into two equal subgroups (PTA using semicompliant balloon in the first subgroup and noncompliant balloon in the second subgroup). Randomization was carried out by selecting sealed envelopes containing the name of the group and subgroup. This was done by the patients in the operating theater. Both groups were compared regarding technical success, technical ease, procedural complications, and 6- and 12-month patency.

The potential benefits and risks of the procedure were explained to each patient, and informed written consent was obtained. The whole study was approved by the ethical committee, Faculty of Medicine, Cairo University.

Procedure

Before starting the procedure, reassessment by duplex scanning was carried out to confirm the preoperative data both hemodynamically and anatomically, and to mark the site of the lesion (s) on the skin using a marker pen for the D-PTA group and radio-opaque stickers for the FD-PTA group. The availability of all the needed tools to perform safe PTA was insured with special attention to the presence of different sizes and lengths of both semicompliant and noncompliant balloons.

The procedure was routinely performed in the Cath Lab, where both duplex ultrasound and noncontrast radiological guidance were available. The duplex ultrasound operator stands on the contralateral side of the vascular surgeon with the screens of both fluoroscopy and ultrasonography amenable to the visual field of all the operators. Although fluoroscopy was not used for the D-PTA group, it was adjusted as a standby; whereas in the FD-PTA group, it was used hand in hand with duplex guidance from the start. Occasionally, the procedure was performed in the operating room when a hybrid technique was planned, using a multipurpose C-arm with vascular intervention capabilities.

The rest of the procedure was completed according to the adopted basic endovascular rules with special concern for hemodynamically significant dissection flaps (causing diameter reductions >30% and peak systolic velocity ratios>2), which were stented with self-expandable stents. Completion duplex examinations and ankle-brachial indices (ABIs) were obtained routinely before hospital discharge.

Mainly on the basis of the results of this study, together with the past experience of the operating team in performing PTA for failing arteriovenous fistulae and superficial femoral artery (SFA) stenotic lesions using duplex guidance alone, the benefits and tips of combining fluoroscopy in addition were compared regarding the following details:

(1) The overall technical success in terms of successful lesion dilatation and/or recanalization with improvement in hemodynamics.
(2) Technical ease in terms of the ease of access site puncture, precise sheath positioning, the speed of wire/catheter maneuverability to reach the site of the lesion, the ease of wire/catheter manipulation to negotiate and cross the site of the lesion, clarity of visualization of proper balloon placement and full inflation/deflation, precise stent deployment and also the procedure time.
(3) Complications either at the access or the lesion sites.
(4) Primary patency rates at 6 and 12 months.

All the previous study points were compared not only in the two main groups but also in their subgroups. The primary end point was technical success together with

clinical improvement in the functional status, intended as ABI and maximum peak velocity ratio (PVR) improvement and maintenance through follow-up. The secondary end point was limb salvage rate and primary patency rate detected at 6 and 12 months. Continuous variables were described as mean ± SD. Categorical variables are described as *n* (%). Primary patency rates were calculated by using the Kaplan–Meier analysis. Statistical significance was set at 0.05.

Results

The study population in the two equal randomized groups (D-PTA and FD-PTA) were comparable regarding their age, sex, risk factors, and TASC classification (Table 1).

In the D-PTA group, initial technical success was achieved in 13 (81.2%) patients; the three case of failure were a femoropopliteal TASC D lesion, and two tibial TASC C (n = 1) and TASC D (n = 1) lesions. In successful patients, PTA was accomplished by using balloon angioplasty in 9/13 (69.2%) patients (eight with noncompliant balloon); stenting was needed in 3/13 (23%) patients, whereas hybrid treatment was needed in 1/13 (7.6%) patient. The mean ABI improved from 0.53 ± 0.07 at baseline to 0.83 ± 0.05 after the procedure. Maximum PVR decreased from 5.2 to 1.1 at the treated segment. The mean intervention time was 105 ± 29 min (range: 75–130 min). Two patients were complicated by access site hematoma; one of them required open surgical control and repair.

Table 1 Patients' demographics and clinical features

Characteristics	D-PTA group	FD-PTA group	*P* value
Age (mean±SD (range)) (years)	60.87±7.01 (49-71)	61.18±6.75 (50-73)	>0.05
Sex (male: female)	12 : 4	13 : 3	>0.05
Renal impairment	16	16	>0.05
Diabetes	12	13	>0.05
Hypertension	12	11	>0.05
Smoking	6	9	>0.05
Coronary artery disease	5	7	>0.05
Severity of ischemia			
Rutherford class 3	2	3	
Rutherford class 4	7	6	
Rutherford class 5	6	4	
Rutherford class 6	1	3	
TASC classification			
TASC A	7	6	
TASC B	5	9	
TASC C	2	1	
TASC D	2	2	
Location of treated lesions			
Femoral	18	15	
Popliteal	6	7	
Iliac	-	1 (TASC A), 1 (TASC D)	
Tibial	1 (TASC C), 1 (TASC D)	1 (TASC A)	

D-PTA, duplex ultrasound-guided percutaneous transluminal angioplasty; FD-PTA, combined noncontrast fluoroscopy and duplex ultrasound-guidance percutaneous transluminal angioplasty; TASC, Trans-Atlantic Inter-Society Consensus.

In the FD-PTA group, initial technical success was achieved in 15/16 (87.5%) patients; the failure case was an iliac TASC D lesion. However, the other iliac case belonged to TASC A and was successfully managed through a hybrid technique for an occluded and recently performed femoropopliteal ePTFE bypass graft. The iliac lesion in this case was missed at the time of the previous operation, and when the cause of graft failure was investigated, such iliac lesion was discovered and incriminated. The plan was to carry out graftotomy for both graft thrombectomy and deployment of iliac stent. In successful patients, PTA was accomplished by balloon angioplasty in 11/15 (73.3%) patients (seven with noncompliant balloon), stenting was needed in 2/15 (13.3%) patients, whereas hybrid treatment (noncompliant balloon was used in one) was needed in 2/15 (13.3%) patients. The mean ABI improved from 0.54 ± 0.08 at baseline to 0.85 ± 0.06 after the procedure. Maximum PVR decreased from 5.3 to 1 at the treated segment. The mean intervention time was 95 ± 20 min (range: 60–110 min). No significant complications were encountered in this group. Procedure details and outcome are shown in Table 2.

The mean duration of follow-up was 11 ± 6 months (range: 12–29 months). The overall 30-day survival rate was 100%. At 6 and 12 months, the overall limb salvage rates were 92.3 and 84.6%, respectively, in the D-PTA group, whereas they were 94.3 and 86.6%, respectively, in the FD-PTA group. Six- and 12-month primary patency rates were 76.9 and 61.5%, respectively, in the D-PTA group, whereas they were 80 and 66.6%, respectively, in the FD-PTA group. Fig. 1 shows the primary patency rate at 6 and 12 months.

Discussion

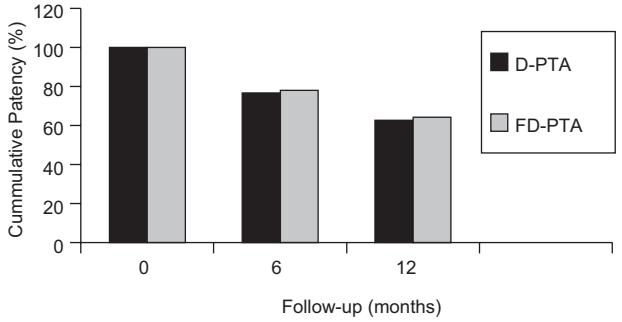
The use of contrast material for PTA in patients with impaired kidney functions is associated with considerable morbidity and mortality from the potential risk of contrast-induced nephropathy (CIN). Several mechanisms have been postulated to explain the role of contrast in CIN pathogenesis, ranging from vasoconstriction at the renal corticomedullary junction, impaired autoregulatory capacity of the kidney and ending to overt acute tubular necrosis [1]. The incidence of CIN depends on two main factors:

Table 2 Procedures and outcome

Group and subgroup	D-PTA (*n*=16)		FD-PTA (*n*=16)		*P* value
	Semicompliant balloon (*n*=8)	Noncompliant balloon (*n*=8)	Semicompliant balloon (*n*=8)	Noncompliant balloon (*n*=8)	
Initial technical success (*n* (%))	13 (81.2)		15 (87.5)		0.03
	5	8	7	8	
Procedure in technically successful cases					
Balloon angioplasty	9		11		
	1	8	4	7	
Stenting	3		2		
	3	-	2	-	
Hybrid procedure	1		2		
PTA + endarterectomy)	1	-	-	1	
Graft thrombectomy + Iliac stenting	-		1	-	
Operative time (mean±SD) (min)	15.48 (105±29)		11.07 (95±20)		0.021
	115.5±31.9	95.45±26.36	104.5±23	82.6±17.3	
Complications	Two access site hematoma One required surgery		-		0.01
Limb salvage rate (%) (months)					
6	92.3		94.3		>0.05
12	84.6		86.6		
Primary patency rate (%) (months)					
6	76.9		80		>0.05
12	61.5		66.6		

D-PTA, duplex ultrasound-guided percutaneous transluminal angioplasty; FD-PTA, combined noncontrast fluoroscopy and duplex ultrasound-guidance percutaneous transluminal angioplasty.

Figure 1



Primary patency rate at 6 and 12 months. D-PTA, duplex ultrasound-guided percutaneous transluminal angioplasty; FD-PTA, combined noncontrast fluoroscopy and duplex ultrasound-guidance percutaneous transluminal angioplasty.

intrinsic contrast media-related factors (osmolarity, ionicity, and molecular structure) and its volume. It is well known that using low volume of iso-osmolar, nonionic, high-quality contrast media is associated with lower risk for CIN. However, the amount of contrast that can be safely administered to patients with baseline chronic kidney disease to prevent CIN is not known [4]. Therefore, the surest method to avoid CIN is to avoid using contrast totally if possible.

CO_2 digital angiography and duplex ultrasound-guided PTA have been suggested as adjunctive contrast-sparing techniques that can be used when intravascular contrast injection is considered hazardous [5]. CO_2 injection has been proven to be a safe and effective method for the evaluation of peripheral arterial disease; however, its therapeutic role in the form of CO_2 angiography-guided endovascular therapy has not been proven. Moreover, not many prospective randomized controlled studies have proven the efficacy and safety of CO_2 angiography-guided endovascular therapy yet [6].

Several reports have proved the feasibility of duplex ultrasound-guided PTA as an alternative to conventional PTA with patency rate mounting to 93% [7]. In addition to avoiding radiation and contrast exposure, duplex ultrasound helps to confirm the adequacy of PTA by the combined hemodynamic and imaging parameters [8]. In spite of the advantages D-PTA offers, its results are still checked by the availability of an experienced sonographer. In addition, severe arterial calcification comprises a challenge because of the difficult insonation and limited field of view [9].

Being devoid of contrast enhancement, noncontrast fluoroscopy lacks opacified arterial tree visualization. However, it still has the ability to visualize radio-opaque structures, whether bony landmarks, arterial calcifications, or endovascular tools. This advantage was interpreted in this study in terms of technical feasibility, success rate, and complication rate when combined with D-PTA.

Duplex guidance was valuable in the visualization of the common femoral artery (CFA) and its bifurcation,

and, hence, identifying safe puncture site especially in obese patients. In addition, duplex ultrasound allows the visualization of healthy proximal segment of SFA for safe insertion of access sheath. On the other side, noncontrast fluoroscopy facilitates easier access to a proper puncture site opposite the medial one-third of femur head, which guarantees a safe effective compression and control after completion of the procedure. In the current study, patients who were subjected to duplex guidance alone experienced puncture site hematoma in two cases, whereas those with combined duplex and noncontrast fluoroscopy guidance were free from such complications, with its possible drastic consequences from either retroperitoneal or upper thigh hematoma. This is explained by the variable site of bifurcation of the CFA in relation to the head of femur, and, therefore, if the puncture targeted the CFA just above the bifurcation, it could be high or low in comparison with the femur head. Although ultrasonography can do this task, it is more easy and clearer with fluoroscopic guidance.

The addition of fluoroscopy with its panoramic capability in the FD-PTA group guides the easier passage of the guide wire into the SFA rather than into the profunda femoris artery by detecting the wire course while it is going down parallel rather than crossing the upper one-third of the femur. Duplex alone lacks this panoramic view with clear bone visualization. In the same context, the ghost of arterial calcification is a good landmark for fluoroscopic guidance in the FD-PTA group, whereas it was a true limiting factor of arterial insonation in the D-PTA group.

The shape and behavior of the catheter/guide-wire assembly on moving towards, negotiating, and then crossing the lesion in the FD-PTA group was definitely easier than in the D-PTA group. This can be explained by two main factors; the first is that the ability to follow the moving wire by fluoroscopy is easily achieved by just following it, while moving the table or the tower while the tip is always in the field of vision. Whereas, doing the same job by using duplex necessitates following the vessel and then searching for the wire inside, which can be lagging behind or proceeding forward. The second factor is that the way you visualize the whole wire (shaft, tip, and possible loops) in fluoroscopy is simply gained depending on its radio-opacity, whereas the same cannot be easily gained by duplex alone as wire visualization varies according to its lie inside the vessel in comparison with the ultrasound probe. It could be seen either as a hyperechoic dot or a line and then to interpret it accordingly – for example, if you see two adjacent dots, this means that the wire had made a loop.

The site of the lesion, whether stenotic or CTO, was identified and marked by the aid of duplex. However, it is interesting to know that the indentation of a gently pulled (not pushed), half-inflated, semicompliant balloon was very helpful in identifying and confirming the sites of previously marked significant nearby stenotic lesions and their lengths.

In chronic total occlusion lesions, although duplex guidance is more confirmatory of crossing the lesion and re-entry to the true lumen (by visualization of the wire not in the wall of the vessel but moving freely within its lumen), we cannot ignore the added tremendous role of noncontrast fluoroscopy during the step of crossing itself on the basis of its panoramic view.

Duplex use in either group has its distinct role in the assessment of hemodynamics and the visualization of possible flaps to assure completeness of angioplasty. The behavior of a characteristic atherosclerotic waist under fluoroscopy was an easy guide to indicate the completeness of lesion dilatation but it could not exclude the presence of post-deflation flow-limiting flaps. The use of noncompliant balloons in their corresponding subgroups obviated the need for stenting as it paved out these dissection flaps.

A combined procedure of noncontrast fluoroscopy and duplex ultrasound-guided PTA could be carried out effectively and safely. The technique offered easier safe identification of the anatomical landmarks, wire manipulation, lesion characteristics, and efficiency of balloon dilatation with overall impact on procedure time. The study indicated significant statistical superiority of the FD-PTA group in terms of technical success and technical ease with lower incidence of complications. However, there was no significant difference in patency rates in the successful cases from the two groups.

It is concluded that the pearls of combining duplex and noncontrast fluoroscopic guidance are gained when the pros of one compensate for the cons of the other. This means that the ease and precision are sometimes elicited when duplex guidance is added, and sometimes when noncontrast fluoroscopy is added. Therefore, both are complementary without predilection superiority when combined. Although, this technique holds considerable potential, longer follow-up will help to fully evaluate its broader applicability.

Conclusion

It is well known that when conventional PTA cannot be carried out because of contrast-related factors; the

alternatives are either using duplex ultrasound or CO_2 angiographic guidance. Yet, in this study, a pioneer step forward was assumed to improve the overall technicality in such situations by adding noncontrast fluoroscopic guidance to duplex guided-PTA, with significantly better periprocedural outcome.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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