



Effect of fusion imaging on reducing radiation and contrast exposure during revascularization of iliac stenosis

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Abstract

The purpose of this research is to evaluate the feasibility, safety and efficiency of fusion imaging in order to guide the vessels of iliac stenosis. In this study, we identified twenty-six patients (20 men, with a mean age of 63 ± 8) suffering from chronic vascular occlusion ($n=6$; %23) or severe stenosis ($n=20$) of the common and/or external iliac artery. The median lesion length was 33mm (IQR 20-60). In one group of patients (new group; $n=11$), fusion imaging with 2-D/3-D registration was used to guide revascularization. None Baseline digital subtraction angiography (DSA) was not obtained in these patients. In another group of patients (old; $n=15$), no fusion imaging was used and at least one DSA was performed to guide the procedure. In both Final DSA group of treated lesions was performed. Number of DSA sessions, exposure to radiation and contrast material, technical success (residual stenosis $< \%30$) and complications were analyzed. Median DSA runs needed in old age for guidance $n= 2$ (IQR 3-2) and in the new $n= 0$ (IQR 0-0; $p=0.001$). Compared to OLD, the median dose (DAP) was reduced by 17118ml (IQR -10407 23614; $p=0.016$) if Fusion imaging guidance was used (new). Based on the median DAP of the final angiography in the new, the median DAP reduction was 6007mGy * cm²(IQR -16,105 5012; $p=0.1$). The median volume of the total injected contrast material was 45ml (IQR 30-90) in the new and 120ml (IQR 100-140; $p=0.001$) in the old. Technical results for both groups were %100. A minor complication (embolism) occurred in 27/1patients (%3.7) and fusion imaging proved to be a safe procedure and significantly reduced radiation and contrast exposure during revascularization of iliac stenosis. to give.

Keywords: iliac artery, fusion imaging, endovascular treatment, computed tomography, angiography, magnetic resonance angiography

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Introduction

Recently, computed tomography angiography (CTA) or magnetic resonance angiography (FI)-based fusion imaging has been commonly developed to guide endovascular aortic repair (EVAR) procedures. For them, the FI technique has shown a significant reduction in cumulative radiation dose and contrast material (CM) exposure [1,2,3,4], which may reduce the risk of long-term radiation side effects and has the potential to . To reduce the burden on kidney function and also reduce the risk of acute kidney injury [5,6,7,8,9].

2D-3D and 3D-3D FI are methods for guiding interventions such as EVAR or chemical embolization. In the case of 2D-3D FI, CTA, MRA or cone beam CT (CBCT) images (on the table) are registered with two orthogonal fluoroscopic images before the intervention. Thus, CTA or MRA images are superimposed on live fluoroscopic images. Alternatively, 3D-3D FI is performed by integrating intraoperative CBCT with preoperative MRA/CTA images to guide intervention [10 , 11].

To date, three studies with a limited number of patients and no control group have focused on FI to guide peripheral artery interventions in peripheral artery disease (PAD) patients using 3D-3D registration [12,13,14]. The present study was designed to evaluate the feasibility, safety and efficacy of fusion imaging with 2D-3D registration for revascularization of iliac stenosis.

Post-stenting coronary artery occlusion occurs when a blocked artery, treated after angioplasty or stenting, narrows again. There are several treatment options for patients with coronary artery restenosis after stenting. The first step for treatment is to see a heart surgeon.

According to the location of the blocked stent, the extent of its obstruction and the characteristics of the patient, including:

- Age
- Type of cardiovascular disease
- health condition

The surgeon can determine the best treatment method. During the operation, the doctor

observes the inside of the artery and checks its blockage by performing angiography and using some tests. These tests include intravascular ultrasound (IVUS) and optical coherence tomography (OCT).

Symptoms of coronary artery occlusion after stenting

In case of blockage of heart vessels after stenting, symptoms appear after three months. Angina-like symptoms that occur during exercise. But its diagnosis is done by using tests and by a doctor.

Treatment of coronary artery occlusion after stenting

The stent may not be properly positioned or fully opened. By doing IVUS or OCT tomography, the presence of these problems is checked, and if the stent is not opened, the stent can be opened again using a balloon. Sometimes, with the help of laser rays, it is possible to loosen the stiff tissue around the stent and prevent the stent from closing. Among other treatments, the following can be mentioned:

Re-stenting:

Depending on whether or not the original stent is fully expanded, the number of stents that are stacked, and the degree of obstruction, the method of doing this will vary. If the stent is completely open and the problem is the growth of the tissue of the welding site inside the stent, it is possible to reduce the growth of the tissue around the stent by placing another stent that is impregnated with medicine. However, the more stents are placed on top of each other, the more likely reocclusion will occur.

If there are already 2 or 3 stents at the site of obstruction, the doctor usually recommends brachytherapy or the use of a drug-impregnated balloon. Obstructions that are shorter in length respond better to these methods.

Drug treatment of reocclusion of heart vessels

In some patients, taking sirolimus or cilostazol tablets can be useful. Although these drugs usually have side effects, they can help reduce the narrowing of the tissue around the stent. The use of these drugs is prescribed for people who have repeated stenosis in the same area several times.

Disease control:

Taking some medicines and making lifestyle changes can be helpful in treating some patients who suffer from coronary artery stenosis. In these patients, the goal of treatment is to control the symptoms of coronary artery disease or prevent the disease from worsening.

Open heart surgery

In open heart surgery, a surgeon takes a blood vessel called a graft from another part of the body and attaches it to the blocked artery to restore blood flow to the blocked area. Grafts or

transplanted vessels are removed from the patient's own arteries and veins in the chest, leg, or arm. Grafts actually create new pathways for oxygenated blood to reach the heart.

Bypass surgery is a suitable treatment method for patients (especially patients with diabetes) who have re-narrowed heart vessels.

Care after opening the heart

Use of anti-platelet drugs:

Until the artery in which the stent is placed heals, there is a possibility of a blood clot forming on the stent. Patients with metal stents should use antiplatelet drugs for at least 4 weeks after surgery and patients with drug-eluting stents should use antiplatelet drugs for up to 1 year after surgery. There are different types of these drugs.

The most commonly used drugs are clopidogrel, prasugrel and ticagrelor. Daily aspirin may also be recommended to reduce the risk of heart attack. No medication should be started or stopped without consulting a doctor.

Making lifestyle changes:

Having a healthy lifestyle plays an important role in preventing the recurrence of coronary artery stenosis and the success of the treatment. People who have re-stenosis of the coronary arteries

should observe the following:

- Reducing the consumption of fats
- Eat a heart-healthy diet

Diabetes control (if any)

- Reaching the ideal weight and maintaining it
- Taking prescribed medications
- Quit Smoking
- Regular exercise
- See a doctor for follow-up after treatment (follow-up)

materials and methods

In this study, we identified 26 consecutive PAD patients (20 men, mean age 63 ± 8 years) with iliac stenosis ($n=20$, 77%) or obstruction ($n=6$, 23%). Of these, 11 patients underwent iliac artery bypass grafting after FI became available in the interventional radiology (IR) department on 10/2017. This set represents the FI study group (new group). During the 6-month period before the development of FI, we identified another cohort of 15 consecutive patients who underwent revascularization for obstructive iliac artery disease. This group represents the control group (OLD group). Patient characteristics as well as characteristics of treated lesions and devices used are summarized in Tables 1 and 2.

Table 1 Patient characteristics

	New group	Old group	
Number of patients treated (<i>n</i>)	11	15	
Age (years)	62 ± 8	63 ± 8	
Gender			
Male	7 (64)	13 (87)	
Female	4 (36)	2 (13)	
	New group	Old group	<i>p</i>
Body mass index	30.8 (25.9–34)	25.6 (21–28.4)	0.1

Table 2 Characteristics of lesions treated and devices used

	New group	Old group	
Anatomic location of lesion (<i>n</i>)			
CIA	3 (27)	6 (40)	
EIA	7 (64)	8 (53)	
CIA/EIA	1 (9)	1 (7)	
	New group	Old group	<i>p</i>
Lesion length in mm	35 (20–70)	30 (15–60)	0.5
Side treated			
Left	6 (55)	5 (33)	
Right	5 (45)	10 (67)	
Lesion type			
Stenosis	7 (64)	13 (87)	
Chronic total occlusion	4 (36)	2 (13)	
Pre-dilatation (POBA)	10	14	
Diameter	6 (5–6)	6 (6–6)	
Length in mm	40 (40–80)	40 (40–80)	
Number of self-expandable nitinol stents	9	7	
Diameter in mm	8 (8–10)	10 (8.5–10)	
Length in mm	60 (40–90)	80 (65–80)	
Number of balloon-expandable stents	4	13	
Diameter in mm	8 (8–8.75)	9 (8–9)	
Length in mm	56 (33–56)	38 (25–38)	
Kissing stent maneuver	1 (9)	4 (27)	
Post-dilatation (POBA) (<i>n</i>)	9	5	
Diameter in mm	7 (6–8)	7 (6.5–8)	

	New group	Old group	
Length in mm	60 (40–80)	60 (60–90)	
Vascular closure (<i>n</i>)			
Manual compression	2 (18)	9 (60)	
Closure device	9 (82)	6 (40)	
C-arm position for baseline DSA runs (<i>n</i>)		< 30° 12 > 30° 3	

In the older group (control group, $n=15$), iliac target lesions were traditionally observed by baseline DSA before treatment. In the new group ($n=11$), instead of performing this baseline DSA, FI was used during passage and (pre)dilatation of the target lesion and also to guide stent implantation.

We evaluated the differences in the target area with the dose (DAP, $\text{mGy} \cdot \text{cm}^2$) and volume of contrast medium injected (volume (ml)) as well as in the number of digital angiography runs (n) between both groups.

The following variables were compared between the two groups:

Technical success, defined as successful intra- or subintimal reconstruction with < 30% residual stenosis at completion angiography.

Clinical success, which was defined as an increase in the Rutherford category by at least one stage.

Hemodynamic success, which was defined as an improvement in ABI (>0.2) compared to the baseline value. In addition, major complications and side effects were evaluated 24 hours after the intervention.

Preoperative imaging

In the new group, all patients had a routine CTA before surgery. CTA had a scan range from the diaphragmatic slit to the forefoot and was performed on a 128-slice CT scanner obtained

using the following parameters: tube voltage 120 kV, reference tube current-time product 200 mA with tube current modulation, Rotation time 0.3 seconds and collimation 0.6 mm. CTA was performed with the patient in the supine position. A 100 mL dose of 300 mg/mL imeprolol followed by a 30 mL saline flush was infused, both at a flow rate of 4.0 mL/s. through a 20 g or larger intravenous cannula preferably placed in the antecubital vein. Arterial phase images were acquired 15 seconds after bolus detection in the suprarenal aorta (threshold 150 HU). For vascular evaluation, images were first reconstructed using a medium soft kernel (B30f) with a field of view of 500/100 mm and an effective slice thickness of 1.0 mm. Second, images were reconstructed with the same field of view and slice thickness of 5.0 mm. Sagittal and coronal corrections were also performed in each patient.

Endovascular method using fusion imaging (new group)

CTA images were typically obtained less than 3 months before the intervention. These preoperative images (source images with a slice thickness of 1 mm) were imported into a stand-alone workstation for FI in the angiography suite (FD20/15). Before restenosis, three steps were performed to prepare for the use of FI.

first stage:

By using an independent workstation, the segmentation of the images before the intervention was done semi-experimentally. Optimal angulation of the c-arm was manually (eg, to visualize the iliac or femoral bifurcation) and preset. This step takes about 5 minutes.

second stage:

In the angio suite, two fluoroscopic images were acquired at 45° LAO and RAO projections (2D registration) and automatically registered with the preoperative CTA scan. This step takes

approximately 1 minute).

third level:

Manual correction of fusion images was performed from pre-intervention images and fluoroscopic images. This manual correction step took approximately 1 minute. Primarily, the bony boundaries of the pelvis and lumbar spine were used as landmarks.

After that, a live 3D vascular model was shown on an additional screen next to the conventional

live fluoroscopy monitor, and the preparation was finalized. All procedures were performed under local anesthesia. Lesion junction and expansion (pre) as well as final stent implantation were performed only under FI guidance. The reference diameter of the vessel was determined pre-interventionally using 3D post-processing software in order to choose the appropriate size of balloons and stents. After the operation, digital angiography was performed (injection parameters: 10 ml/s, volume 20 ml). Femoral-popliteal and below-knee drains were examined by DSA using manual contrast injection through the sheath. Figures 1A–C and 2A–C show two examples of FI-guided methods.

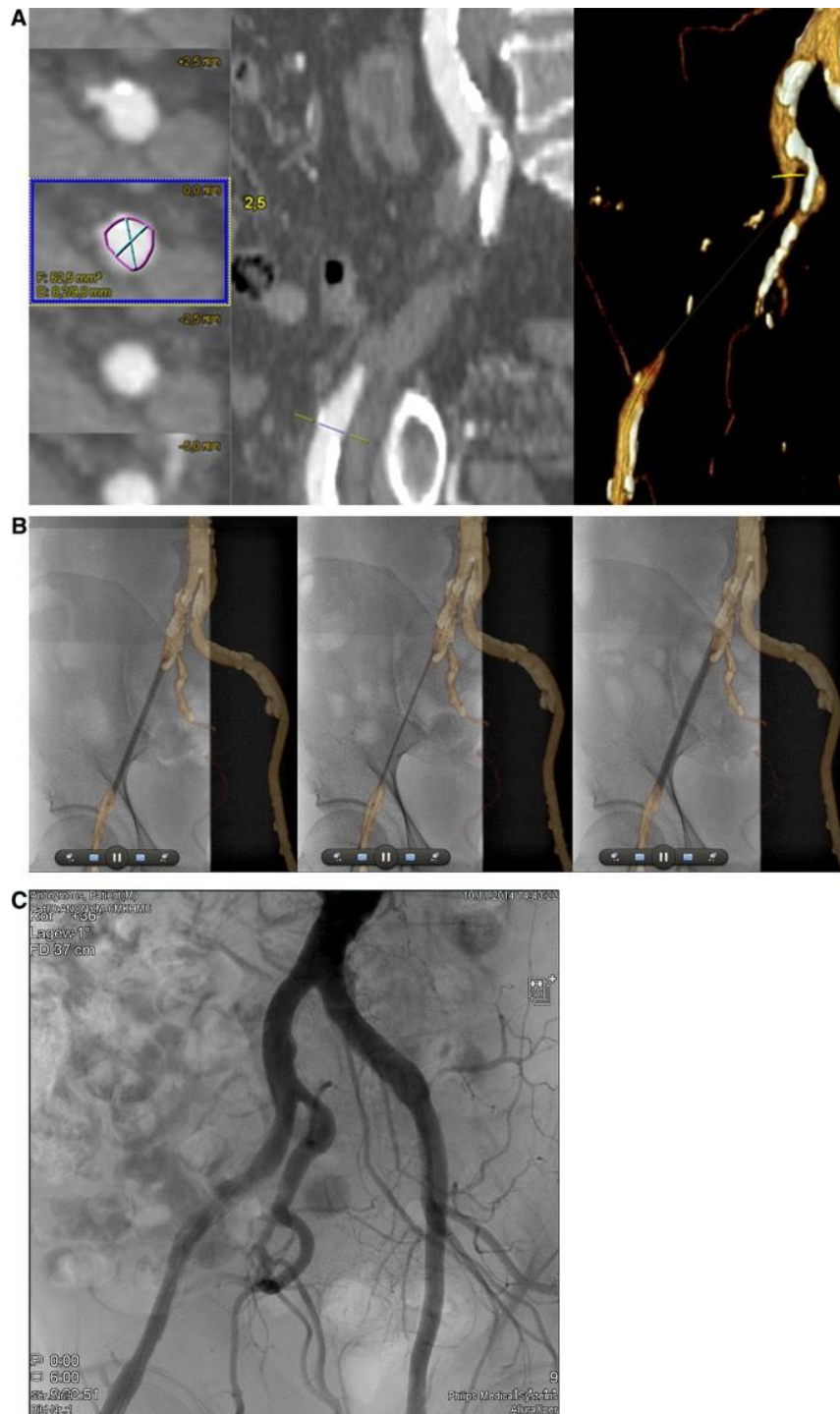


Figure 1: 3D reconstruction of CTA and CTA showing external iliac artery occlusion. B After fusion-guided occlusion, conventional PTA was performed after implantation of a self-contained stent and after dilatation. C Final angiography shows no residual stenosis.

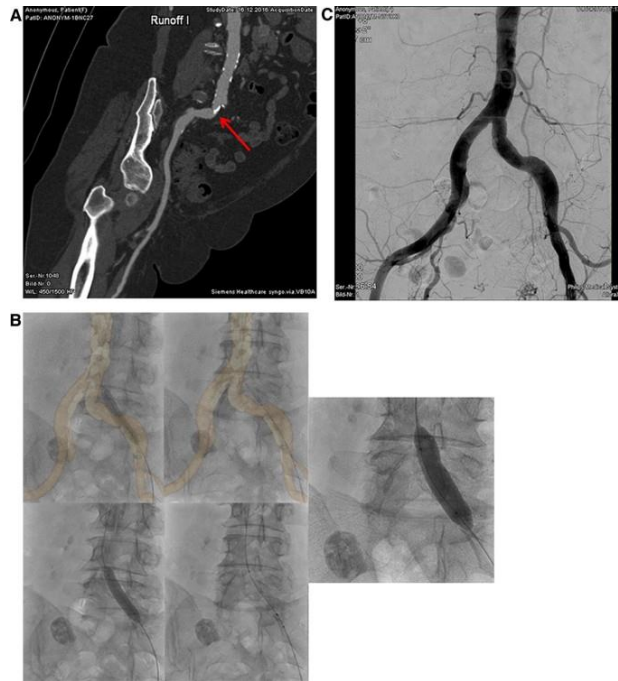


Figure 2: CTA shows a short calcified stenosis in the proximal left common iliac artery (red arrow). B In this case, it flattens the vessel, which makes it more difficult to optimally combine CTA with fluoroscopic images. After conventional PTA, a self-expandable stent was implanted and positioned after expansion. C Final angiography does not show stenosis.

Endovascular method without fusion imaging (old group)

Percutaneous access was performed after local anesthesia. After crossing the lesion using fluoroscopy, a pigtail catheter was placed in the subrenal aorta above the bifurcation and DSA was performed. Another DSA (injection parameters above) was obtained in an oblique projection with magnification of the desired lesion area. More than two primary angiograms were performed only for optimal visualization of the internal iliac artery if the lesions reached the iliac bifurcation or crossed and tortuous lesions. Using a baseline DSA-derived overlay, PTA followed by stent implantation was performed. After that, the final DSA (injection parameters above) was obtained to confirm technical success and rule out complications. Femoral-popliteal and below-knee drains were examined by DSA using manual contrast injection through the sheath.

Data collection and statistical analysis

Total DAP (mGy*cm²), cumulative DAP for DSA (mGy*cm²), cumulative DAP for fluoroscopy (mGy*cm²) as well as cumulative fluoroscopy time (min) and DAP for each DSA run (mGy*cm²) from the production dose protocol The automatic angiography unit was obtained. In both groups, acquisition parameters for fluoroscopy and for DSA runs, ie, pulse rate for fluoroscopy and frame rate for DSA acquisition, were the same. Total CM volume and CM volume per DSA run injected during the procedures were counted for each group. Data were compared between the two groups. The median DAP of the baseline DSA run of the old group was calculated and compared with the mean baseline DAP of the new group. In addition, the median DAP of the final angiography of the new group was calculated. To achieve a statistically correct, significant reduction in DAP using FI and to calculate the mean reduction in DAP in the new cohort itself, the final angiographic DAP was set as the DAP of a significant baseline DSA run not performed due to the use of FI. The mean volume of CM was compared in both groups. After the normal distribution test, the difference between the old and new groups was tested using the non-parametric Mann-Whitney U test. Statistical significance was determined as $p < 0.05$. Data analysis was done by software (SPSS 25 for Windows; IBM, Armonk, NY, USA).

Results

The median DAP in the new group was 28742 mGy*cm² (IQR 19668-42172) and in the old group was 43791 mGy*cm² (IQR 27966-84633) (p=0.048).

DAP obtained by fluoroscopy was 82146 mGy*cm² (IQR 14393-3703) in the new group and 8763 mGy*cm² (IQR 15798-2327) in the old group (p=0.82).

The data of DAPs and CM for both groups are shown in Table 3. The average baseline DSA

performance was n=2 (IQR 2-3) in the old group and 0 (0-0) in the new group (p=0.001). Between-group median DAP reduction based on stored baseline DSA runs was 17,118 mGy*cm² (IQR 23,614-10,407) (p = 0.016).

In the new group, the mean DAP reduction within the group was (6007 mGy*cm²; IQR 16,105-5012) (p=0.1) (Figure 3). The median volume of cumulative contrast injected in the new group was 45 ml (IQR 90-30) and in the old group 120 ml (IQR 140-100) (p=0.001). The median cumulative volume of CM for baseline and final DSA was 20 ml (IQR 20-20) in the new group and 60 ml (IQR 80-40) in the old group (p = 0.001).

Table 3 DAPs and contrast medium volume

New group	Old group	p	
Fluoroscopy time in minutes	5.33 (3.12–6.17)	6.01 (2.14–10.19)	0.38
Total DAP in mGy*cm ²	28,742 (19,668–42,172)	43,791 (27,966–84,633)	0.048
Cumulative fluoroscopy DAP in mGy*cm ²	8214 (3703–14,393)	8763 (2327–15,798)	0.82
Cumulative DSA-DAP in mGy*cm ²	22,355 (12,982–30,043)	34,131 (24,125–66,307)	0.02
Final DSA-DAP in mGy*cm ²	6007 (5012–16,105)	7655 (4367–8834)	0.69
Number of baseline DSA runs (n)	0 (0–0)	2 (2–3)	0.001
Number of final DSA runs (n)	1 (1–1)	1 (1–1)	1.0
Number of all DSA runs (n)	2.5 (1.5–4)	6 (5–7)	0.001
Cumulative CM volume for baseline and final DSA runs in ml	20 (20–20)	60 (40–80)	0.001
Cumulative CM volume in ml	45 (30–90)	120 (100–140)	0.001

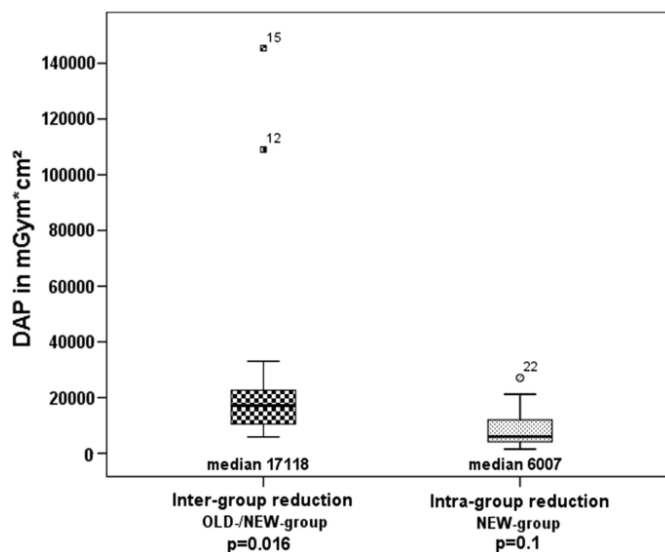


Figure 3: Boxplot: average reduction of DAP between groups and within groups

Technical success was 100%. The Rutherford category increased by at least one category after the intervention in all patients (100% clinical success). After the intervention, ABI increased by 0.25 ($p=0.01$) in the new group and 0.3 ($p=0.001$) in the old group (hemodynamic success: 100%). One procedure-related

complication was reported in the new group (peripheral thromboembolism). In this case, the patient was a Rutherford class III patient with a 70-mm occlusive lesion in the left external iliac artery that showed no calcified plaque. CTA was performed 6 weeks before the lesion. This was successfully performed during a secondary procedure through an antegrade approach using manual aspiration thrombectomy. Table 4 summarizes the results.

Table 4 Endpoints

New group	Old group	
Technical success (< 30% residual stenosis)	11 (100)	15 (100)
Complication rate	1 (9)	0 (0)
ABI		
New group		
Baseline	0.56 (0.43–0.61)	0.6 (0.5–0.72)
post-interventional	0.81 (0.73–0.97)	0.9 (0.89–0.96)
	$p = 0.01$	$p = 0.001$
Rutherford category (increase of at least one category) (n = 26)	11 (100)	15 (100)
Inter-group DAP reduction in mGy*cm ²	17,118 (10,407–23,614)	
	$p = 0.016$	

New group	Old group
Intra-group DAP reduction in mGy*cm ²	6007 (5012–16,105)
	p = 0.1
Median CM reduction between NEW and OLD group in ml	40 (40–60) ml
	p = 0.001

Discuss

The results showed that fusion imaging is valuable for endovascular guidance in complex EVAR procedures and guiding vessel selection during liver embolization procedures [2, 3, 15, 16]. These studies showed that FI derived from CTA images significantly reduces CM volume and radiation exposure as well as procedure time. The reduction of radiation exposure during (complex) endovascular interventions for patients is not only due to short-term certainty but also due to long-term incidental effects that may cause cancer years or decades after the intervention [5, 6, 17], [18,19]., the implementation of DSA by FI can be limited to a minimum, which not only reduces radiation exposure, but also significantly reduces CM. It is known that exposure to CM can lead to decreased kidney function and is associated with acute kidney injury [7,8,9, 20].

Irardi et al evaluated preoperative CTA and MRA with fluoroscopy for roadmapping in five patients with obstructive aorto-iliac stenosis [13]. All cases were technically successful and a significant reduction in CM was achieved. In addition, it was stated that fusion imaging has the potential to reduce radiation in iliac procedures. Salier et al evaluated fusion conduction in 17 patients with PAD [12]. In 12 patients, iliac stenosis or obstruction was observed. In 3 out of 17 patients, patient movement prevented the use of the fusion roadmap. In addition, PTA and stenting were successfully performed only under fusion guidance in half of the patients (8 of 17). At the end of the intervention, accurate stenting and iliac drainage were checked by conventional DSA. Seiler et al also conclude that fusion imaging can reduce the volume of contrast material. Godekting et al confirmed the validity

of 3D-3D FI for revascularization of iliac artery occlusions and, in particular, the accuracy of FI in catheterized and non-catheterized iliac vessels [14].

Our study is the only one in which 2D-3D FI has been used for pre-guidance FI registration of iliac artery procedures in PAD patients. We compared a new cohort in which iliac stenosis or occlusion was revascularized by guided fusion with an older cohort in which at least one initial angiography was performed for guidance purposes. All procedures in both groups were technically and hemodynamically successful. In the new group, a median DAP reduction of 17,118 mg*cm² (IQR 10,407-23,614) (p=0.016) was achieved, saving at least one DSA run compared to the old group. In addition, to demonstrate the potential for radiation reduction with the use of FI, the DAP of the final angiography in the new group was set equal to the DAP of a significant baseline angiography in the same group that was not performed due to the use of FI. Therefore, a significant reduction of DAP 6007 mGy * cm² (IQR 16,105-5012) (p=0.1) was obtained in the new group. Furthermore, as the DSA implementation decreased, the amount of CM decreased correspondingly. Although the patients were not sedated, in contrast to the report of Salyer et al [12], no relevant body movements were detected during the intervention, nor did the patients' physiological breathing impair fusion accuracy. This is probably explained by the posterior pelvic anatomy of the iliac vessels, which are more vulnerable to abdominal motion compared to the abdominal aorta or visceral arteries. However, anxious patients can be sedated to avoid unnecessary movements and delays in the procedure.

A problem we encountered in one patient (Figure 2A-C) was flattening of the target vessel, which interfered with combining CTA with fluoroscopic images. In this case, however, technical success was achieved because the short lesion was located in the middle part of the common iliac artery with adequate distal and proximal landing zones. In addition, there were no cases where re-adjustment of the combined images was performed. Godekting et al confirmed the accuracy of FI in catheterized and non-catheterized iliac vessels and found no significant difference in both groups [14]. As in our study, they used only

guidewires and soft catheters to explore the vessels, which apparently in most cases do not change the anatomical configuration of the vessel to the extent that compromises its compliance. We believe that minor FI inaccuracy is relevant only in those parts of the vessel where absolute optimal stent reduction is necessary, for example, at the aortic/iliac bifurcation or in the distal part of the external iliac artery, so that technical success is not compromised in those cases. A conventional approach should be considered.

An alternative approach to 2D-3D registration used in this study is 3D-3D registration, in which preoperative contrast-enhanced MRA or CTA is segmented and semi-automatically mapped to a cone-beam computed tomography image. The beginning of the action is obtained, recorded. In the case of EVAR, it has been shown that this method is more accurate than 2D-3D registration [21]. Nevertheless, at least for the patient, cone-beam CT scanning contributes to a higher cumulative DAP and thus a greater risk for random or definite effects of radiation.

Regarding radiation exposure during iliac vascular procedures, the optimal combination may be indicated by combining 2D-3D registration based on MRA. However, according to logistics in our clinic, in most patients, a CTA is available as preoperative imaging.

Lalis et al recently published a study comparing the accuracy of a new image fusion system with 2D-2D registration with 2D-3D registration during femoropopliteal revascularization of PAD patients [22]. Both methods were equally accurate. Therefore, 2D-3D image fusion may not only be a supportive tool during iliac operations, but also during femoro-popliteal interventions.

As in our study, Seiler and Iradi performed the last conventional angiography to confirm the correct position of the stent and rule out possible complications [12, 13]. In future cases, Irardi suggested replacing the final DSA with aortic and iliac pressure measurements distal and proximal to the treated lesion [13]. Thus, a pressure difference < 10 mm Hg can indicate a successful hemodynamic procedure. In our opinion, this technique may confirm improved flow in the treated vascular segment. However, it

cannot confirm correct stent placement or rule out complications (such as embolism). Another radiation alternative to DSA is IVUS, which can detect stent misplacement or residual stenosis. Nevertheless, even if final angiography is required in most cases to rule out complications and document technical success, baseline angiography, which is still common in almost every intervention in most departments, can easily be replaced by using FI in departments. . the future.

The limitations of this study are the retrospective and non-randomized study design and the small study population. In addition, a general awareness of exposure to radiation and contrast material has been reported to affect radiation and contrast dose, which may influence outcomes [23].

Result

In conclusion, CTA-based fusion imaging using 2D-3D registration is feasible and safe to guide endovascular treatment of obstructive iliac stenosis. Compared to the traditional method, it significantly reduces the radiation dose and helps to minimize the risk of the operator and patients for the potential short-term and long-term effects of radiation exposure. In addition, it significantly reduces the volume of the contrast material and thus can limit the risk of kidney dysfunction in patients.

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