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T H E S E

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DES de Chirurgie Générale

par

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« Impact de la technologie de fusion d'image automatisée sur la radioprotection du patient et de l'equipe soignante en chirurgie vasculaire : une étude pilote randomisée controlée »

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Titre de Thèse : Impact de la technologie de fusion d'image automatisée sur la radioprotection du patient et de l'équipe soignante en chirurgie vasculaire : une étude pilote randomisée contrôlée.

RESUME

Objectif : Comparer l'irradiation et le volume de produit de contraste iodé nécessaires lors des procédures de revascularisation endovasculaire des axes iliaques, avec et sans fusion d'image automatisée en per-opératoire.

Méthodes : Étude prospective monocentrique ayant inclus tous les patients ayant bénéficié d'une angioplastie iliaque, avec un angioscanner pré-opératoire, entre janvier 2019 et février 2020. Le critère de jugement principal était le PDS (Gy/cm2).

Résultats : 37 patients furent inclus, 18 dans le groupe Fusion, 19 dans le groupe contrôle. Le PDS médian était inferieur dans le groupe fusion (18.515 vs 21,852) mais non significativement (p=0,892). Les médianes des autres indicateurs radiographiques sont également inférieurs dans le groupe Fusion, mais non significativement.

Conclusion : La fusion d'image automatisée pour les procédures endovasculaires à l'étage iliaque sur la pathologie occlusive semble avoir un intérêt, à confirmer par une étude prospective multicentrique avec une cohorte plus grande.

MOTS-CLES

Angioplastie, Artère iliaque, AOMI, CYDAR, Endovasculaire, Fusion d'image, PDS, Prospectif, Nantes.

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LISTE DES ABREVIATIONS

2D, 3D : 2 dimensions, 3 dimensions

ALARA: As Low As Reasonably Achievable

BMI: Body Mass Index

CTA: Computed Tomography Angiography

CT scan: Computed Tomography

DAP: Dose Area Product (en francais PDS = Produit Dose Surface)

DSA: Digital Substraction Angiography

EVAR: Endo Vascular Aneurysm Repair

Gy/cm2: Gray per Square centimeter

HBP: High Blood Pressure

IU/Kg: International Unit per Kilogram

mL : milli Liter

Sec : seconds

Sv : Sieverts

TASC: Trans-Atlantic inter-Society Consensus

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INTRODUCTION

Endovascular treatment of symptomatic aorto-iliac occlusive disease has become the first line therapy, and open surgery is only considered after prior failed endovascular attempts and unresolved symptoms (1). However, the use of X-rays for endovascular treatment in every day practice is associated with an inherent risk of exposing patient, physicians and supporting medical staff members to harmful ionizing radiation. Countless studies have shown that any amount of exposure increases the risk of deterministic and stochastic effects for both patient and staff (2,3). As far as the risks of iodinated-contrast nephrotoxicity was well described (4,5). Many people are currently working on solutions to reduce X-rays radiations and iodinated contrast uses, as the Fiber Optic RealShape (FORS) technology, the use of echography or advanced imaging guidance systems. X-rays imaging systems provide only 2D fluoroscopic images and do not show soft tissues like vessels (anatomy, tortuosity, calcifications, lesion length). Advanced imaging techniques allow fusion imaging (overlay of a 3D vascular mask from a pre-operative computed tomography angiography (CTA) onto 2D live fluoroscopic image). and provides perioperative guidance as a "3D roadmap" to the operator during endovascular repair. Initially, this technology was only available in expensive hybrid rooms, but currently 2 fusion software are available on the market and suitable for any theatre including those equipped with mobile C-arm (Cydar imaging guidance, CYDAR medical, Cambridge UK; and Endonaut, THERENVA, Rennes France).

The use of fusion imaging guidance has been shown to reduce both radiation exposure and contrast volume during endovascular aortic aneurysms repairs (6-9). The feasibility of fusion imaging for peripheral arteries has also been demonstrated (10,11), but to date, no prospective study has assessed the use of a fully automated fusion imaging system during aorto-iliac occlusive disease endovascular revascularisation

To add a better understanding of the benefits of image fusion, we conducted a prospective trial using a new fully automated fusion system (CYDAR) during the endovascular treatment of symptomatic aorto-iliac occlusive lesions. The aim of this study is to assess the radiation exposure and patient safety during aorto iliac revascularisation performed using Cydar imaging guidance, compared with controls performed by the same operators, but without fusion guidance.

METHODS

TRIAL DESIGN

This trial was a single center, prospective, controlled and randomized open pilot interventional study, designed to assess the role of fusion imaging using the CYDAR system in reducing X-ray exposure and iodinated-contrast volume in the treatment of aorto-iliac occlusive disease. The study complied with the Declaration of Helsinki and was conducted in accordance with the French good clinical practice guidelines. All patients provided written informed consent before the procedure and the study was approved by the local institutional review board. The trial was prospectively registered on Clinical Trial.gov (NCT03713450). Eligible patients were randomly assigned in a 1:1 ratio to CYDAR use (fusion group) or classic procedure without fusion imaging (control group). Simple randomization was performed with the use of a web-based system. Patients and treating physicians were aware of study-group assignments.

PATIENTS

From January 2019 to February 2020, we prospectively screened for inclusion all consecutive patients who presented symptomatic aorto-iliac occlusive disease. Inclusion and exclusion criteria are provided in detail in Table 1. Briefly, patients were eligible for enrolment if they had symptomatic aorto-iliac occlusive lesions, scheduled for a procedure in the Hybrid Room (Philips, Alura Flexmove) and had an available pre-operative diagnostic CTA (the pre-operative CTA was requested to perform the 3D vascular mask used as an overlay during the procedure). Excluded were patients requiring an associated procedure (renal, mesenteric or infra-inguinal angioplasty), emergency procedures, or procedures performed using the mobile C-arm.

Inclusion criteria
• Male aged of 18 years or over or female aged of 50 years or over • Presence of lower-limb arterial disease (Rutherford 2 to 6) • Aorto-iliac occlusive lesions • Available Pre-operative diagnostic CTA • Written informed consent • Affiliated with French social security system
Exclusion criteria
• Women <50 years old • Asymptomatic lesions • Patients without pre-operative CTA • Patients requiring an associated procedure: renal mesenteric or infra-inguinal angioplasty (excepted common femoral artery angioplasty) • Emergency procedures • Procedures performed using the mobile C-arm • Minors, pregnant women and adults under guardianship or trusteeship • Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study.

TABLE 1 : CRITERIA

HOW CYDAR WORKS ?

CYDAR is an advanced imaging application allowing automated 3D overlay guidance in any theatre. The software, combined with secure and certified cloud high-performance computing, deduces the patient position from comparing the body anatomy (especially the lumbar vertebrae) visible on the 2D fluoroscopic images to that on the patient's CT scan, enabling it to produce and update accurate and reliable overlays of the diagnostic CT 3D vascular mask throughout the procedure. At least 2 vertebrae had to be visible on the screen and within 3 to 8 seconds, the vascular mask appeared. This new product presented as an additional screen in theatre and the image with the overlay was also displayed on the main screen of the theatre (Figure 1). The overlay registration process was radiation and contrast free; and was fully automated. The 3D vascular masks were created prior to surgery by the radiographers for every patient eligible then used only if the patient was randomised in the Fusion group. During the procedure, prior to stent implantation, the accuracy of the layout was assessed by a short angiography and if necessary, the layout was refined by the deformation tool, to match accurately the target vessel's anatomy

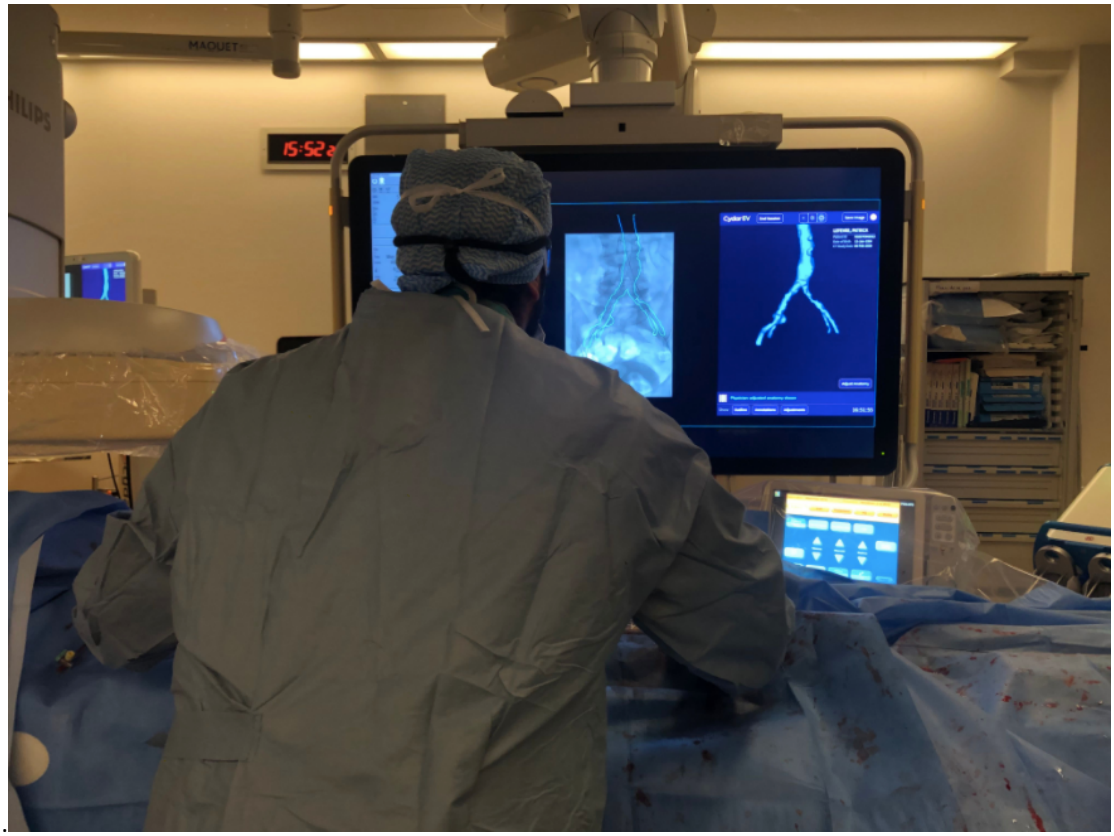

FIGURE 1 : THE MAIN SCREEN

PROCEDURE

Procedures were performed by 5 senior vascular surgeons in a hybrid room (Alura Flexmove Clarity, Philips) under local anesthesia and sedation. Low-dose settings were set by default at a frame rate of 7.5 frames/sec. In order to assess minimum radiation exposure, the leading operator applied the ALARA principles, minimizing fluoroscopy time, maximizing collimation, using radiation protection barriers, and limiting steep angulations for all patients. Randomization was performed in the hybrid room, just before the procedure, by a clinical research associate. If the patient was randomized in the Fusion group, the layout was used to locate the area of interest and to identify the critical vessels origins. If patient was randomised in the non-fusion group, the procedure was realised using graphy road mapping. The type of revascularization and the access to the culprit lesion was left to the discretion of physicians. All patients received intra-operatively 50 IU/Kg of unfractionated heparin. In both groups, an angiography was performed before device implantation.

ENDPOINTS

The primary endpoint of the study was patient safety during aorto iliac peripheral endovascular revascularization procedures, which was assessed by the radiation exposure through the dose area product (DAP; Gy.cm2). The DAP was provided by the system and was an indirect measurement of radiation dose delivered to the patient. It represents a good surrogate of patient exposure. Secondary endpoints were : the total Air Kerma (AK, in Gy), the number of DSA runs, the Fluoroscopy Time (FT, min), the radiation exposure to the operator (Sv), the iodinated contrast volume (in ml), and the total operative time from arterial puncture to catheter removal (in min). The other data collected were : the type of revascularization (Balloon angioplasty / stenting), the number of stent(s) used, the need of additional angioplasty or stenting of the common femoral artery, the type of the lesion, the technical success and the procedure's difficulty level (< physician feeling). Technical success was defined as successful vascular access, completion of the endovascular procedure and immediate morphological success with less than 30% residual diameter reduction of the treated lesion on completion angiography. The procedure's difficulty level was defined as easy, medium or complex.

STATISTICAL ANALYSIS

We used hypothesis that fusion imaging guidance should result in 25 % reduction in radiation exposure compared with the control group performed without imaging guidance, which is results that were demonstrated in other trial on endovascular aortic repair. We calculated that a sample of 40 patients, randomly assigned in a 1:1 ratio, would be required to ensure 80% power for detection of a 25% reduction in radiation exposure between the groups. The null hypothesis was that the use of imaging guidance will not modify the radiation exposure comparing to the two groups. Demographic and co-morbidity data were recorded per patient and compared between the 2 groups. For binary variables such as gender, counts, percentages, 95% confidence intervals were calculated, and p-values presented for hypothesis generating purposes. Pearson's Chi-squared test or Student T-test test were performed when appropriate. For continuous variables such as age, means, standard deviations, was calculated and p-values were presented for hypothesis generating purposes. The dose area product, at the end of the procedure, was analysed such as continuous variables using median, interquartile range, minimum and maximum. Values were compared between the two groups with Mann Whitney tests. The others parameters on radiation exposure were analysed as our primary endpoint. Hypothesis testing of the primary endpoint was two-sided and performed at a 5% significance level. Analyses of secondary endpoints were descriptive in nature. A P-value <.05 was considered statistically significant. Data were analyzed with the SAS packages (SAS Institute Inc version 9.4, Cary, NC).

RESULTS

POPULATION AND PROCEDURE CHARACTERISTICS

From January 2019, to February 2020, we enrolled 37 patients (Table 2). Eighteen patients were randomly assigned to undergo the procedure with fusion-imaging (Fusion group) and nineteen had the procedure without fusion (Control Group). Of these, two patients assigned to the fusion group had their procedure performed without fusion imaging, due to technical considerations (Figure 2). The characteristics of the patients in the intention-to-treat population were well balanced between both study groups.

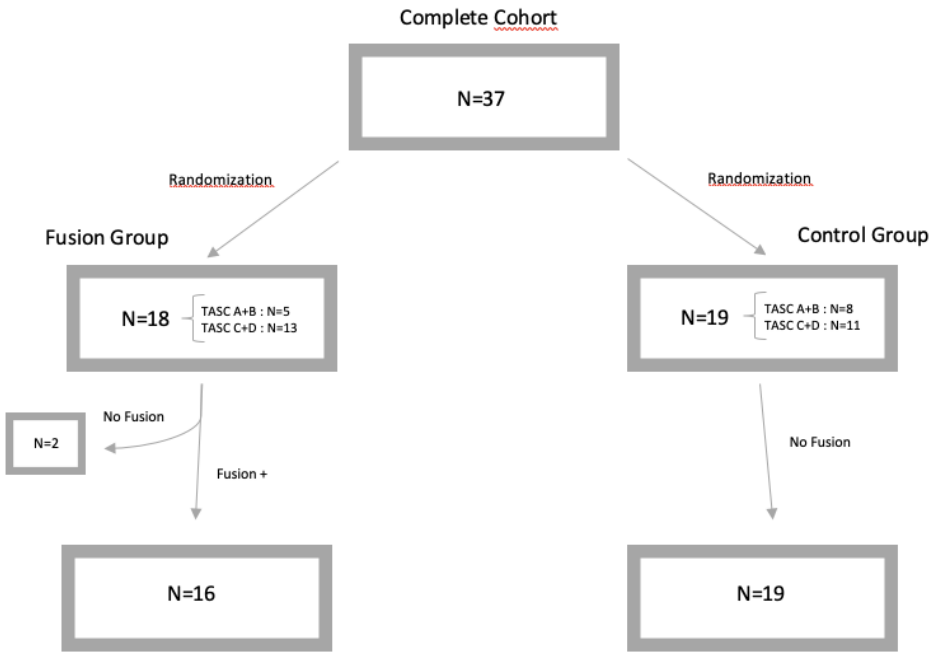

FIGURE 2 : FLOWCHART

The median age of the patients was 62 years (IQR, [56-71]; range, [45-85]), and most of them were men (28; 75%), and claudicant (27; 72.9%). Age, gender, and comorbidities were found to be similar between both groups. There were no significant differences between the two groups regarding Rutherford-Becker classification (P=.72), the TASC classification (P=.78), restenosis (P=.44), and outflow common femoral lesions (p=.48).

		Fusion Group	Control Group	Total	p-value
Number of patients		18	19	37	
Medium Age		63.78 [58-72]	60.47 [52-71]	62 [55-71]	.50
Extreme Ages		[45-85]	[45-79]	[45-85]	
BMI		24.17 [21-27]	25.47 [23-27]	24.83 [22-27]	.29
Male		14 (78%)	14 (74%)	28 (76%)	
Female		4 (22%)	5 (26%)	9 (24%)	
HBD		12 (67%)	14 (74%)	26 (70%)	.64
Diabetes		5 (28%)	4 (21%)	9 (24%)	.71
Smoking		14 (78%)	17 (89%)	31 (84%)	.40
Dyslipidemia		10 (56%)	13 (68%)	23 (62%)	.42
Rutherford	0	1 (6 %)	0	1 (2%)	**.72**
	1	0	0	0	
	2	4 (22%)	7 (37%)	13 (34%)	
	3	9 (50%)	6 (32%)	15 (40%)	
	4	2 (11%)	3 (16%)	5 (12%)	
	5	2 (11%)	2 (10%)	4 (10%)	
	6	0	1 (5%)	1 (2%)	
TASC	A	1 (6%)	1 (5%)	2 (5%)	**.79**
	B	4 (22%)	7 (37%)	11 (30%)	
	C	8 (44%)	5 (26%)	13 (35%)	
	D	5 (28%)	6 (32%)	11 (30%)	
Restenosis		5 (28%)	3 (16%)	8 (22%)	.45
Outflow Common Femoral Lesion		0	2 (10%)	2 (5%)	.49

TABLE 2 : PATIENTS CHARACTERISTICS

Procedure characteristics are given in Table 3. The technical success was 100% in the Fusion group and 94% in the control group. There were no significant differences between the groups considering the puncture sites, the number of stent implantation (p=.91), the associated angioplasties on common femoral artery (p=1), and the need of bilateral iliac treatment (p=.64).

		Fusion Group (n=18)	Control Group (n=19)	p-value
Femoral Puncture		14 (78%)	17 (89%)	.40
Humeral Puncture		5 (28%)	8 (42%)	.36
Number of Stents	0	1 (6%)	2 (10%)	**.91**
	1	6 (33%)	6 (32%)	
	2	8 (44%)	7 (38%)	
	3	1 (6%)	2 (10%)	
	4	0 (0%)	1 (5%)	
	>4	2 (11%)	1 (5%)	
Common Femoral Procedure		3 (17%)	3 (16%)	1
Bilateral iliac procedure		8 (44%)	7 (37%)	.64
Procedure Failure		0	1 (5%)	

TABLE 3 : PROCEDURE DETAILS

OUTCOMES

The median DAP was 18.5 Gy.cm2 in the fusion group, versus 21,8 Gy.cm2 in the control group (P=.89). No difference was seen between the groups in terms of fluoroscopy dose (4.2 Gy.cm2 vs 5.1 Gy.cm2; P=.43), fluorography dose (14.1 Gy.cm2 vs 15.1 Gy.cm2; P=.75), number of DSA (7.5 vs 8; P=.98), Air Kerma (.10 Gy.cm2 vs 0.12 Gy.cm2; P=.70), fluoroscopy time (305 sec vs 340 sec; P=.41), iodinated contrast volume (41 mL vs 30 mL; P=.20), and the total procedure time (60min vs 60 min; P=.69) (table 4).

	Fusion Group (n=18)	**Control Group (n=19)**	**p-value**
DAP (Gy.cm2)	18.515 [6.909-45.464]	21.852 [9.942-36.763]	.89
Fluoroscopy (Gy.cm2)	4.225 [3.231-14.463]	5.101 [1.253-9.984]	.43
Fluorography (Gy.cm2)	14.123 [4.721-24.981]	15.142 [7.904-29.146]	.75
Number of DSA	7.5 [5-11]	8 [4-11]	.98
Air Kerma (Gy)	.10 [.04- .27]	.12 [.06- .21]	.70
Time of scopy (sec)	305 [223-924]	340 [109-650]	.41
Contrast Volume (ml)	41 [30-60]	30 [22-55]	.20
Procedure time (min)	60 [42-90]	60 [30-90]	.69

TABLE 4 : X-RAYS & CONTRAST DETAILS

DAP analysis in TASC-based sub-groups didn't show a benefit of fusion-imaging in complex lesions procedures (table 5).

		Fusion Group (n=18)	Control Group (n=19)	p-value
DAP (Gy.cm2)	TASC A+B (n=13)	(n=5) 5.76 [3.88-8.87]	(n=8) 10.40 [8.67-31.70]	.06
	TASC C+D (n=24)	(n= 13) 29.70 [16.20-80.80]	(n=11) 27.50 [15.20-44.70]	.56

Table 5 : TASC and DAP

The DAP distribution in the two groups are illustrated in Figure 2. Three procedures in the Fusion group required very high DAP compared to the other procedures.

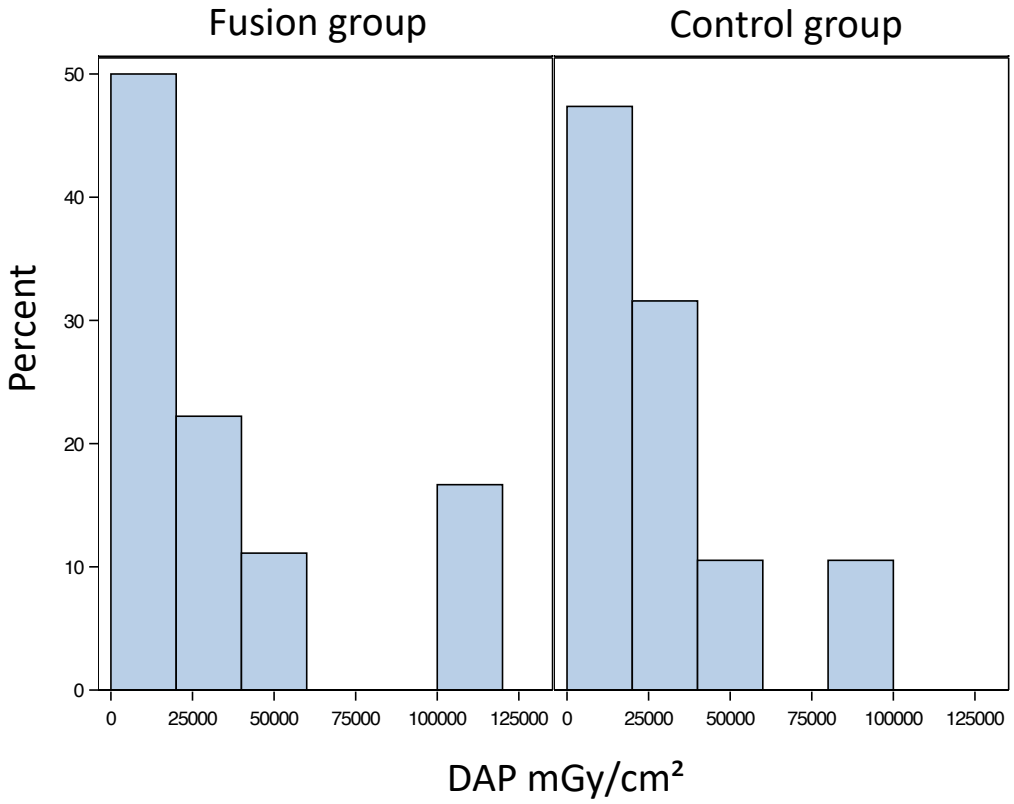

FIGURE 3 : DAP DIAGRAM

DISCUSSION

This pilot study is the first randomized controlled trial assessing the impact of using a fully automated fusion imaging guidance during the endovascular treatment of aorto iliac occlusive disease. In our trial, the use of an automated image fusion guidance failed to show a significant benefit regarding patient and staff safety among 37 patients who underwent iliac endovascular procedures.

Minimally invasive procedures are nowadays routinely performed thanks to the integration of sophisticated medical imaging devices into the interventional suite. Despite the numerous benefits of minimally invasive surgery, the exposure to harmful ionizing radiation remains an issue in procedures employing X-ray based medical imaging systems (2-5). Recent studies evaluate fusion-imaging technology in the treatment of aortic aneurysm (12,13). In a meta-analysis, Goudeketting et al report significant reduction in the volume of contrast, radiation doses, procedure times, and fluoroscopy times when 3D fusion imaging was used (12). Kaladji et al showed that fusion imaging for EVAR is feasible with a mobile C-arm in a conventional operating room, and EVAR procedures might be facilitated with the angionavigation system (13). However, the data regarding image fusion in the treatment of peripheral artery occlusive disease are mainly limited to case reports (10) and small non-comparative studies (14).

We herein report a head to head comparison of image fusion using the CYDAR system and endovascular treatment without image fusion. Image fusion failed to demonstrate a significant advantage in terms of DAP, AK, number of DSA and time of radiation. Despite the lack of statistical significance, there were trend to have an overall reducing of DAP (18.5 vs 21.8 Gy.cm^2) and Air Kerma (0.10 vs 0.12 Gy)in the fusion group. In a recent mono-centric retrospective study, Stahlberg and al evaluate the feasibility, the safety and the efficacy of fusion imaging in endovascular revascularization of iliac occlusive disease (11). The median dose area product (DAP) was significantly reduced by 17.1 mGy*cm^2 (P=0.01). As far as the median total contrast medium volume injected was significantly reduced in the fusion group (45 ml in the fusion group vs 120 ml in the control group, p=0.001). However, the median DAP reported in the control group was higher (43.7 Gy.cm^2) (11) than in our study, (control group 21.8 Gy.cm^2).The low rate of DAP in our study compared to the literature is one of the hypothesis to explain that we did not find any significant difference regarding DAP between groups. This may

be related to the application of the ALARA principles and the low dose setting by default set in our theatre. In another study, Leradi et al also reported a DAP3 times higher than in our study (60.21 Gy*cm^2) in the control group. (PMID 26134039)

Another explanation to the lack of statistical dose reduction using automated fusion in our study may be the learning curve of the various operators. Indeed, one other way to reduce the radiation exposure is to reduce the number of high consuming Digital Subtraction Angiography (DSA). Modern imaging systems enable digital storage of fluoroscopic loops, far less radiation consuming that can replace most DSA runs. These fluoroscopy loops can be used to adjust fusion accuracy or assess the result of the revascularization. In our study, the median number of DSA runs was similar between the two groups, underlying that high consuming DSA were performed in both groups, either to adjust the accuracy of the fusion mask in the fusion group, or to perform the road mapping in the non-fusion group. The replacement of DSA by fluoroscopy loops to assess the accuracy of the fusion mask may be one of the main point to reduce X-rays and is part of the learning curve of the operators for an optimal use of the fusion guidance.

The Cydar RTRS EV software is a new technology able to supply similar fusion imaging guidance to any interventional equipment with digital imaging display. It is a Cloud based high performance computing and software that allows an automated 3D vascular mask overlay during X-ray guided surgery, as well as a deformation of the vascular mask to adjust its accuracy. The software, deduces the patient position by comparing the bony anatomy visible on the X-ray to that on the patient's preoperative CTA, enabling it to produce and update overlays of the diagnostic CTA 3D vascular mask throughout the operation. The main advantage of this registration process is to be radiation and contrast free; and fully automated thus user friendly for the operator avoiding any additional requirement. However, the registration employing image matching techniques requires at least 2 consecutive vertebrae visible on the screen without digital magnification. Consequently, at the level of the iliac arteries, the collimation is not possible as much as during a road mapping guidance. this is one of the reasons explaining the lack of statistical advantage of using fusion on X-rays exposure.

Finally, the wide range of procedure complexity may have had an impact on our results, as our groups were not stratified on TASC lesion severity. Even if the fluoroscopy time – which reflect the complexity of the procedure - was similar between the two groups, we observed a trend to a lower median DAP in the fusion group (5.8 Gy.cm2 vs 10.4) among the easiest procedures (lesions TASC A and B), but during complex procedures, (TASC C and D), the complexity of the procedure may go beyond the potential benefits of the fusion guidance in this limited area of interest (iliac arteries).

Our study has several limitations. First, the small number of comparable cases limited the power to detect a difference in treatment safety and efficacy. Second, all physicians did not perform the same number of procedures. As it's the case for every new device, a learning curve exists in the use of Cydar. Some of the physicians performed very few procedures with the device and may not have reached the same mastery as those who performed several procedures with the system. Third, our evaluation focused on aorto-iliac occlusive lesions. Our findings cannot be extrapolated to femoro-popliteal lesions. Finally, Cydar trial physicians could not be blind to treatment assignment, so evaluation bias cannot be excluded.

CONCLUSION:

In conclusion, our study suggests that during the treatment of aorto iliac occlusive disease, the use of automated fusion imaging guidance does not facilitate the procedure enough to have an impact on radiation exposure. The use of fusion imaging guidance seems to require a change in work habit to be associated with X-ray dose reduction and especially, the substitution of DSA runs by fluoroscopy loops seems of outmost importance. Studies with larger patient cohorts are required.

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