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ORIGINAL ARTICLE

Efficacy of three-dimensional road mapping by fusion of computed tomography angiography and fluoroscopy in endovascular treatment of aorto-iliac chronic total occlusion

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Abstract

The efficacy of multimodality image fusion road-mapping technique for endovascular therapy has been reported recently. Our aim was to evaluate the efficacy of endovascular therapy (EVT) with three-dimensional (3D) road mapping by fusing computed tomography (CT) and angiographical volumetric data for aorto-iliac chronic total occlusion (CTO). We retrospectively analyzed 36 patients with aorto-iliac CTO from June 2017 to November 2019 and classified them into two groups: EVT using a CT fused 3D roadmap (CTf3D-RM; 3D group, $n = 14$) and standard EVT (standard group, $n = 22$). Primary endpoint was wiring time and secondary endpoints were procedural success rate, number of guidewires, procedure time, radiation dose, contrast medium dose, and complications. Wiring time was significantly shorter in the 3D group than the standard group (3D, 15.6 ± 10.23 min vs. standard, 44.6 ± 35.3 min; $p = 0.0052$). Both groups had high procedural success rates (3D, 100% vs. standard, 100%) and low complication rates (3D, 0.0% vs. standard, 9.1%; $p = 0.51$). There were significantly fewer guidewires in the 3D group than the standard group (3D, 2.78 ± 1.31 vs. standard, 4.36 ± 2.01; $p = 0.0138$). The 3D group trended towards shorter procedural time (3D, 78.8 ± 32.5 min vs. standard, 107.5 ± 52.5 min; $p = 0.076$), lower radiation dose (3D, 28.6 ± 18.9 $Gycm^2$ vs. standard, 48.9 ± 49.2 $Gycm^2$; $p = 0.15$), and lower contrast medium dose (3D, 102.2 ± 30.6 vs. standard, 127.5 ± 51.3; $p = 0.11$) than the standard group. Therefore, we concluded that EVT with CTf3D-RM is effective for aorto-iliac CTO. This method may improve the quality of aorto-iliac CTO interventions.

Keywords Endovascular therapy · Three-dimensional roadmap · Fusion imaging · Chronic total occlusion

Introduction

The efficacy of endovascular therapy (EVT) for the aorto-iliac artery is well established [1, 2]. However, some difficult cases remain, including a long chronic total occlusion (CTO). The passage of the guidewire is very important because once the guidewire is passed, a good result can be obtained by stent or stent graft implantation in aorto-iliac lesions. Additionally, as a fatal outcome caused by vascular perforation or injury is possible in patients with aorto-iliac lesions, the guidewire should be passed through the most optimal route. Furthermore, there are some reports of pseudoaneurysms after subintimal angioplasty [3]. Thus, we always aim for intraluminal angioplasty for aorto-iliac CTO if possible.

Various methods have been developed for passing the guidewire to a CTO lesion, including intravascular ultrasound (IVUS)-guided wiring, duplex-echo guidance, intravenous ultrasound guidance, and subintimal angioplasty [4–8]. However, there are no gold standard methods because each method has its own weaknesses and limitations. Moreover, intraluminal angioplasty for complex aorto-iliac CTO tends to require a higher procedure time and more guidewires compared with subintimal angioplasty. The multimodality image fusion road-mapping technique was reported recently [9, 10]. The 3D roadmap technique allows assessment of the correct position of the guide wire in real time in CTO patients. The aim of this retrospective study was to

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evaluate the efficacy of EVT with computed tomography (CT) fused three-dimensional roadmap (CTf3D-RM) for aorto-iliac CTO.

Materials and methods

Patients and study design

Between January 2017 and September 2019, we performed a retrospective study on consecutive patients with aorto-iliac CTO who underwent EVT at Asahi General Hospital. A total of 46 patients received EVT for aorto-iliac CTO during the study period. All patients had symptomatic peripheral artery disease (PAD) (Rutherford class 2–6) and an ankle–brachial index < 0.9. Patients with acute limb ischemia and three patients with thrombotic occlusion were excluded because of differences in the quality of the occluded vessel. Thrombotic occlusions were defined as cases in which a guidewire could be passed through the lesion using only floppy wire. Five patients with aorto-iliac occlusive disease (Leriche syndrome) and one patient who underwent EVT by a physician at another institution, were excluded. Thirty-six patients were classified into two groups: those treated with CTf3D-RM (3D group, $n = 14$) and those treated with conventional methods (standard group, $n = 22$). Patients were assigned to the 3D group when preprocedural-enhanced CT was performed within 6 months and when a radiation technical physician was available to create the 3D roadmap. A flowchart of the procedures is shown in Fig. 1.

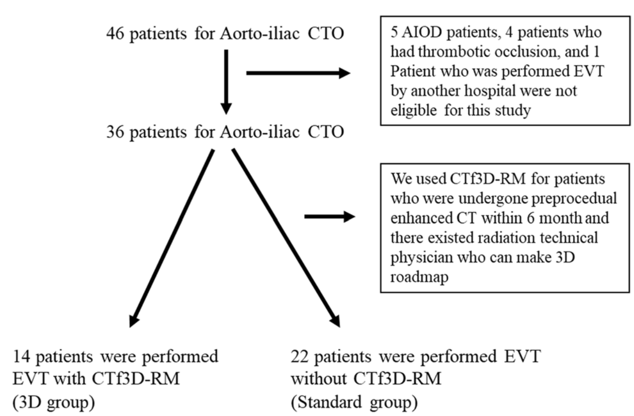

Fig. 1 Participants' flowchart. Forty-six patients received endovascular therapy (EVT) for aorto-iliac chronic total occlusion (CTO) during the study period. Ten patients were excluded by exclusion criteria. Finally, 36 patients were classified into two groups

CT fused 3D roadmap

An Allura Xper FD10 angiography machine (Philips, Amsterdam, The Netherlands) and an AZURION 7M20C angiography machine (Philips) were used in all cases. The AZURION 7M20C was used in all cases in the 3D group. These machines were typically used for standard EVT and coronary interventions in daily practice. The computer workstation was a SYNAPSE VINCENT (FUJIFILM, Tokyo, Japan). The 3D roadmap was created as follows. First, a virtual occlusive vessel was constructed by a radiation technical physician by analysis of the central line of the occluded vessel to be treated with curved multiplanar reconstruction images obtained from thin-slice data of the preprocedural-enhanced CT (Fig. 2a, b) [11]. Next, we performed 3D rotational angiography without contrast medium using an angiography machine and reconstructed the acquired volume

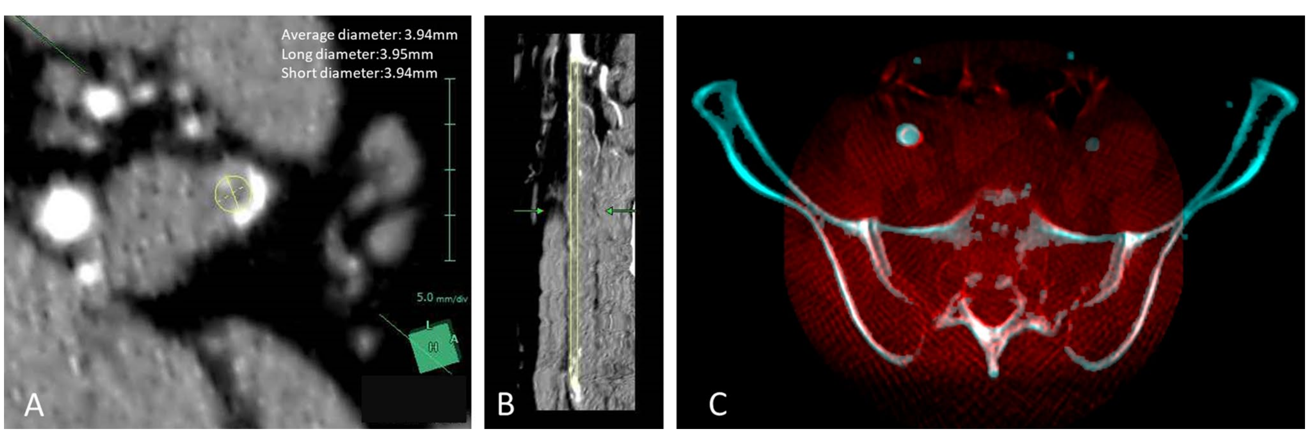

Fig. 2 **a**–**c** Creation of the computed tomography (CT) fused 3D roadmap (CTf3D-RM). **a**, **b** A virtual occlusive vessel created by analyzing the central line of the constructed occluded vessel. Axial view (**a**) and straight view (**b**) of the curved multiplanar reconstruction image. **c** The CTf3D-RM was made by fusing the preprocedural-enhanced CT data and the angiographical volumetric data using the positions of the bones. The red zone represents angiographical volumetric data. The blue zone represents preprocedural-enhanced CT data

data of the pelvic region. The volumetric data were automatically transferred to a workstation. Finally, the CT data with the virtual vessels and the actual angiography image using the positions of the bones were fused (Fig. 2c). We typically used a VacLoc® device (Toyo Medic Co., Tokyo, Japan), which can fix the position of the patient using negative-pressure aspiration. The typical time of fusion and making roadmap was < 5 min. CTf3D-RM can be performed even when the flat panel angle, panning, inch size, and magnification are changed.

EVT procedure

Three interventional cardiologists performed procedure, while operator 1 performed approximately 90% of the cases (Table 1). The endovascular procedure was performed with local anesthesia. After sheath insertion from the ipsilateral or contralateral femoral artery or brachial artery, at least 5000 units of heparin were administered. Digital angiography and digital subtraction angiography were performed. The exposure framerate of digital subtraction angiography was three frames per second. The contrast medium was iopamidol 300 mg/mL (BYSTAGE 300®; Teva Takeda Pharma Ltd., Aichi, Japan). We typically used 0.014-inch guidewire or 0.035-inch guidewire, with rare use of 0.018-inch guidewire. If the guidewire passed the lesion, we used the IVUS catheter to check the guidewire route and examine the appropriate vessel diameter in all cases. Next, pre-dilatation was performed using a balloon of the appropriate size. A bare nitinol stent or covered stent was used in all cases.

A representative image showing use of the CTf3D-RM for navigation of puncture of the femoral artery and wiring is shown in Fig. 3 (Fig. 3). During the procedure, the CTf3D-RM was presented in real time on the screen next to the standard angiography data. We could assess the correct guidewire position inside the arteries in real time, because the CTf3D-RM could follow the C-arm projection angles and inch size (Fig. 4).

Table 1 Clinical and lesion characteristics

	3D ($n = 14$)	Standard ($n = 22$)	p value
Age	72.1 ± 8.2	73.9 ± 10.8	0.61
Male	12 (85.7%)	14 (63.6%)	0.25
BMI	22.93 ± 3.56	21.33 ± 3.81	0.24
Critical limb ischemia	2 (14.3%)	4 (18.2%)	1
Coronary artery disease	3 (21.4%)	11 (50%)	0.16
Cerebrovascular disease	4 (28.6%)	6 (27.3%)	1
Hypertension	11 (78.6%)	20 (90.9%)	0.36
Dyslipidemia	8 (57.1%)	9 (40.9%)	0.495
Diabetes mellitus	7 (50%)	13 (59.1%)	0.73
Chronic kidney disease	3 (21.4%)	7 (31.8%)	0.71
Hemodialysis	1 (7.1%)	4 (18.2%)	0.63
Lesion number	1.5 ± 0.94	1.23 ± 0.75	0.34
Lesion length	103.0 ± 39.3	98.6 ± 37.3	0.73
EIA	4 (28.6%)	6 (27.3%)	1
CIA	3 (21.4%)	7 (31.8%)	0.71
CIA-EIA	7 (50.0%)	10 (45.5%)	1
TASCII B	2 (14.3%)	3 (13.6%)	1
TASCII C	6 (42.9%)	8 (36.4%)	0.74
TASCII D	6 (42.9%)	11 (50.0%)	0.74
TASCII C/D	12 (85.7%)	19 (86.4%)	1
Operator 1	13 (92.9%)	19 (86.3%)	1
Operator 2	0 (0%)	1 (4.6%)	1
Operator 3	1 (7.1%)	2 (9.1%)	1
Pre ankle-brachial index	0.57 ± 0.14	0.56 ± 0.16	0.74
Post ankle-brachial index	0.97 ± 0.12	0.92 ± 0.20	0.37

EIA external iliac artery, *CIA* common iliac artery, *TASC* Trans Atlantic Inter-Society Consensus, *BMI* body mass index

Study endpoints

The primary endpoint was wiring time of the CTO lesion. Wiring time was defined as the time from the start of the wiring to crossing the CTO lesion. The secondary endpoints were successful EVT (leaving < 30% residual stenosis), wire numbers, procedure time, complications, the radiation dose, and the contrast medium dose. The wire numbers were defined as the number of guidewires used directly for EVT procedures. The procedure time was defined as the time from first puncture to final angiography. Complications were defined as any morbidity during the peri-operative period. The radiation dose was used in terms of dose area product ($Gycm^2$). Clinical evaluation was performed within 7 days after the procedure. We investigated the clinical symptoms.

Statistical analysis

All analysis was performed using statistical software (JMP v13.0; SAS Institute, Cary, NC, USA). All data are presented as mean ± standard deviation. An unpaired Student's t test was used to compare the values between the two groups. Categorical variables were analyzed by the Fisher's exact test. In all analyses, $p < 0.05$ was considered statistically significant.

Results

There were almost no differences in the baseline clinical and lesion characteristics between the two groups (Table 1). Lesion length was approximately 100 mm in both groups (3D, 103.0 ± 39.3 mm vs. standard, 98.6 ± 37.3 mm, $p = 0.76$), while the TASCIIC/D of lesions was > 85% in both groups (3D, 85.7% vs. standard, 86.4%, $p = 1.0$). The

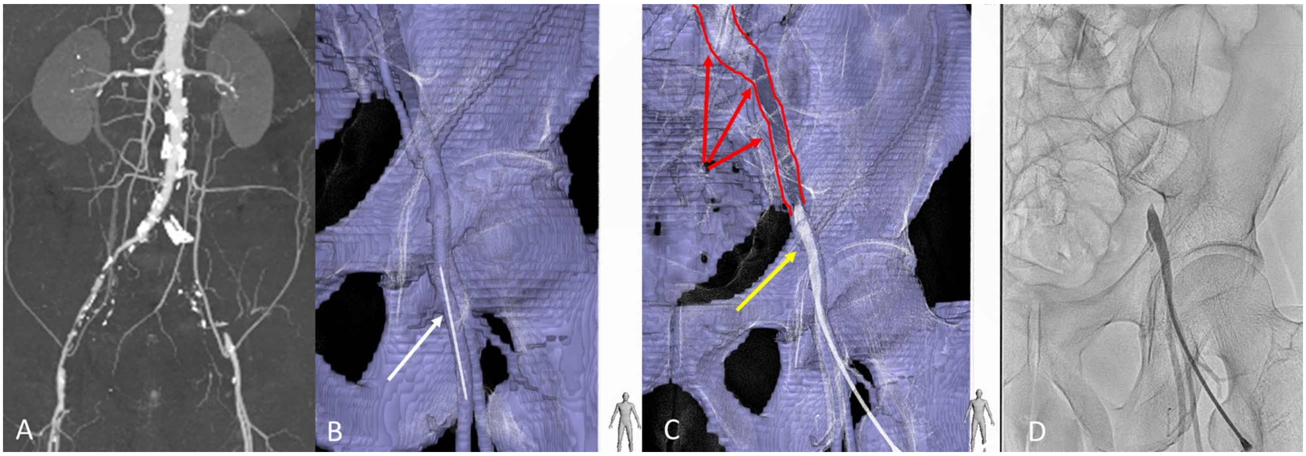

Fig. 3 **a**–**d** Computed tomography (CT) fused 3D roadmap (CTf3D-RM). **a** Preprocedural-enhanced CT revealed total occlusion from the proximal region of the left common iliac artery (CIA) to the distal end of the external iliac artery. **b** Puncture of the left common femoral artery using CTf3D-RM guidance. The white arrow shows the puncture needle. **c**, **d** Matched images of the control angiography and CTf3D-RM. The yellow arrow shows the opened common femoral artery. The red arrow shows the virtual occluded vessels

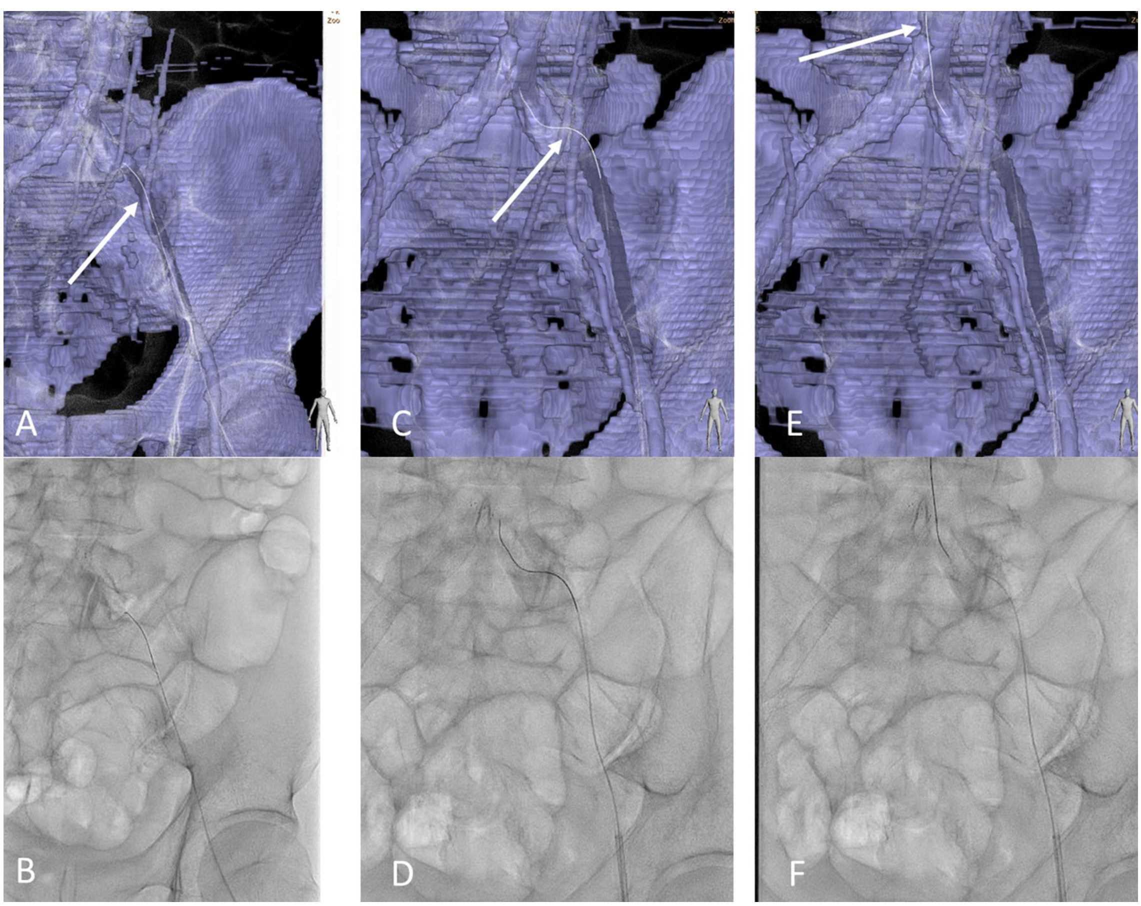

Fig. 4 **a**–**f** Computed tomography (CT) fused 3D roadmap (CTf3D-RM) guided wiring for CTO lesion. **a**, **b** The guidewire was advanced while aiming at the center of the virtual occluded external iliac artery on the CTf3D-RM image (**a**) and fluoroscopy image (**b**). The white arrow shows the guidewire. **c**, **d** The guidewire was manipulated into the center of the curved common iliac artery on the CTf3D-RM image (**c**) and fluoroscopy image (**d**). **e**, **f** Finally, the guidewire could be passed into the aorta only via a retrograde approach on the CTf3D-RM image (**e**) and fluoroscopy image (**f**)

number of cases performed by the operators was similar in both groups.

The results related to the procedural characteristics are shown in Table 2. Wiring time was significantly shorter in the 3D group than the standard group (3D, 15.6 ± 10.23 min vs. standard, 44.6 ± 35.3 min; $p = 0.0052$). The procedural success rate was 100% in both groups. The rate of bi-directional wiring (3D, 85.7 vs. standard, 86.4, $p = 1.0$), the number of stents (3D, 1.93 ± 1.2 vs. standard, 1.5 ± 0.51, $p = 0.15$), the rate of subintimal wire route (3D, 0% vs. standard, 4.6%, $p = 1.0$), and the complication rate (3D, 0% vs. standard, 9.1%, $p = 0.51$) were similar between the groups. The number of wires (3D, 2.78 ± 1.31 vs. standard, 4.36 ± 2.01, $p = 0.014$) was significantly lower in the 3D group compared with the standard group. The 3D group trended towards lower procedural time (3D, 78.8 ± 32.5 min vs. standard, 107.5 ± 52.5 min, $p = 0.076$), lower radiation dose (3D, 28.6 ± 18.98 Gycm^2 vs. standard, 48.9 ± 49.2 Gycm^2, $p = 0.15$), and lower contrast medium dose (3D, 102.2 ± 30.6 ml vs. standard, 127.5 ± 51.3 ml, $p = 0.11$) than the standard group.

Discussion

The results of present study suggest that CTf3D-RM is a feasible technique to treat aorto-iliac CTO, because the wiring time was significantly shorter and the number of guidewires was markedly lower than that with the standard EVT procedure. Furthermore, CTf3D-RM showed a trend towards a lower procedure time, contrast medium dose, and radiation dose than standard EVT. We also achieved a very high procedural success rate (100%) and a very low complication rate (0%) using CTf3D-RM compared with previous clinical studies [1, 2, 12]. Although there was a problem of selection bias because of the retrospective nature of our study, there were no differences in the patient or lesion characteristics between the two groups. Furthermore, treatments were generally performed by the same operators at the same time, so there should be a limited effect of differences in surgical skills. Thus, the conditions were largely the same between both groups. Notably, the lesion length in the present study was longer than that in previous reports, while the procedure times were shorter, despite the high proportion of TASCIIC/D lesions [12]. Additionally, all cases received intraluminal angioplasty, with no cases crossing the subintimal route.

Our CTf3D-RM method enables the operator to perform highly objective guidewire manipulation, which involves advancing the guidewire using the virtual occluded vessel displayed on the angiographic image. This method does not require a special wiring technique or crossing devices to perform the CTO intervention. This technique only requires a computer workstation and an angiography machine to provide volumetric information. Our data suggest that CTf3D-RM may improve the quality of aorto-iliac CTO interventions, particularly for the wiring time and the number of guidewires. The lack of a difference in the procedure time may relate to the time it took to create a 3D roadmap during its early use in our hospital, or the treatment time for lesions other than CTO. The CTf3D-RM method may improve the selection of an appropriate puncture site of the common femoral artery, or deploying of a stent into the correct position because an image of the whole image can be obtained.

Interestingly, we also found a trend towards a lower radiation exposure dose and contrast medium dose in the CTf3D-RM group. Although there are some limitations in this study related to the retrospective design, these data suggest that CTf3D-RM may reduce the procedural radiation dose and contrast medium dose. In our study, the BMI did not significantly differ between the two groups. Thus, it is unlikely that the variation in BMI affected the radiation dose. The procedure time and radiation dose tended to be smaller in the 3D group than in the standard group. However, the fluoroscopic time did not significantly differ between the two groups. This suggests that there was a difference in the total amount of digital subtraction angiography (DSA) and digital angiography (DA), as the amount of exposure increases as the amount of DSA and DA increases, even though the fluoroscopic time does not increase. The 3D group may have had a reduced total amount of DSA and DA due to the use of a 3D roadmap. Furthermore, it is difficult to compare the fluoroscopic time in the present study with that of pure aorto-iliac intervention, as some patients underwent other diagnostic tests such as coronary angiography or peripheral angiography for another lesion. However, as the fluoroscopic time was similar in the two groups and the total exposure was less in the 3D group than the standard group, this suggests that the 3D group had reduced exposure to

Table 2 Procedural characteristics

	3D ($n = 14$)	Standard ($n = 22$)	p value
Success	14 (100%)	22 (100%)	1
Bi-directional	12 (85.7%)	19 (86.4%)	1
Stent number	1.93 ± 1.2	1.5 ± 0.51	0.15
Complication	0 (0%)	2 (9.1%)	0.51
Subintimal	0 (0%)	1 (4.6%)	1
Wire number	2.78 ± 1.31	4.36 ± 2.01	0.0138
Wiring time (min)	15.6 ± 10.23	44.6 ± 35.34	0.0052
Procedure time (min)	78.8 ± 32.5	107.5 ± 52.5	0.076
Fluoroscopy time (min)	54.29 ± 26.4	59.16 ± 30.3	0.63
Cumlative DAP (Gycm^2)	28.6 ± 18.98	48.9 ± 49.2	0.15
Contrast medium (ml)	102.2 ± 30.6	127.5 ± 51.3	0.11

DAP dose area product

contrast mediums in DSA and DA. In infrainguinal lesions, effective methods for reducing contrast agents have been reported, including carbon dioxide angiography and diluted contrast angiography, although these methods are difficult to use in aorto-iliac lesion because of complications and image quality problems [13, 14]. In support of our findings, it was previously reported that CT fusion road mapping can reduce the amount of contrast medium in aorto-iliac lesions [10]. The radiation dose and contrast medium dose tended to be lower in the 3D group than in the standard group; the inclusion of more cases might have resulted in statistically significant intergroup differences.

The feasibility of multimodality image fusion road-mapping techniques, such as preoperative multidetector CT, cone-beam CT, or magnetic resonance angiography, with intraprocedural fluoroscopy was recently reported [15–19]. However, the majority of those studies created roadmaps for opened vessels to place wires and devices, without using contrast medium. However, a key aspect of our technique was the ability to visualize details of the occluded vessel for use as a support tool for precise wiring in CTO lesions [11]. Thus, our method emphasizes the construction of a virtual vessel based on an accurate tracing of the central line of the occluded vessel and accurate reconstruction of the posture during the preoperative CT imaging. To the best of our knowledge, there are no other reports on specialized aorto-iliac CTO intervention using 3D fusion road mapping. We consider the wiring time for the CTO lesion to be the most important parameter affecting the technical efficacy of our CTf3D-RM technique. Therefore, we defined the wiring time as the primary endpoint in the present study. However, the procedural success, radiation dose, contrast medium dose, and procedure time are very important parameters in the clinical setting; these parameters were, therefore, chosen as the secondary endpoints.

The main problems related to our CTf3D-RM involved patient movement and image artifact, as well as different patient positions during preoperative CT and interventional procedures. Nevertheless, it was previously reported that a mismatch of several millimeters may not be clinically significant in aorto-iliac lesions [10]. Although the posture and vessel course sometimes change and the roadmap may shift because of the prolonged procedure time, it is easy to readjust the roadmap using bone and artery calcification because there are usually many landmarks in the pelvic region. Even if the image shifts during the procedure, the radiology technical physician at the workstation can correct the roadmap. We rarely required significant corrections of the 3D roadmap during the procedure, because the iliac artery is located within the pelvis and is relatively unaffected by changes in position. Additionally, the present study had no cases in which CTf3D-RM did not help at all or cases in which standard EVT was performed because images could not be created. Although the procedure can be performed without a fixation device to maintain the position of the patient, we prefer its use because of the convenience long-term position fixation.

Limitations

This study was a retrospective, non-randomized, single-center study. Thus, the number of patients was very small. Although there were no significant difference between the two groups in terms of patient and lesion characteristics, selection bias cannot be ruled out. Additionally, no core laboratory was available. These factors may have affected the results and further clinical trials are required to confirm our findings. As our study was retrospective, some cases included pure aorto-iliac CTO, while some cases included aorto-iliac CTO plus other diagnostic tests. This seems likely to have had little effect on the wiring time and procedure time, but may have affected the radiation exposure dose, fluoroscopic time, and contrast medium dose. However, as the patient and procedural background data did not significantly differ between the two groups, it seems likely that the performance of other diagnostic tests did not significantly affect the clinical results.

Conclusions

EVT with CTf3D-RM for aorto-iliac CTO provides a high procedural success rate and low complication rate, with fewer guidewires and shorter wiring time to pass through the CTO. This method may improve the quality of complex aorto-iliac CTO interventions.

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Compliance with ethical standards

Conflict of interest The authors declare no potential conflicts of interest regarding the research, authorship, and/or publication of this article.

Research ethics All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study was approved by the Institutional Review Board (IRB) of Asahi General Hospital.

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