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Analysis of Preoperative CT Scan Can Help Predict Technical Failure of Endovascular Treatment of TASC C-D Aortoiliac Chronic Total Occlusions

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1 **Title : Analysis of pre-operative CT-scan can help predict technical failure of**
2 **endovascular treatment of TASC C-D aorto-iliac chronic total occlusions**

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11 **Short running title : Predictors of failure of aortoiliac recanalization**

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29 **Keywords :** TASC C-D, aortoiliac chronic total occlusions, predictors, iliac rupture, technical
30 failure

31 **Conflicts of interest :** none

32

33

34 **ABSTRACT**

35 *Aims* : To evaluate if features of occlusion analyzable on pre-operative CT-scan could predict
36 risks of technical failure or iliac rupture of endovascular treatment of TASC C-D aorto-iliac
37 chronic total occlusion (CTO). *Methods and results* : All patients treated by endovascular
38 techniques for a TASC C-D aorto-iliac CTO between 2009 and 2016 were included (107
39 patients, 148 iliac arteries). We evaluated the location of the occlusion and the importance of
40 the arterial calcifications. For this factor, patients were divided into 3 groups : the *Black*
41 *occlusion group* (BO) with mild or no calcifications, the *white occlusion group* (WO) with
42 moderate no protrusive calcifications and the *white protrusive occlusion group* (WPO) with
43 heavy endoluminal calcifications. Technical failure occurred in 11 iliac arteries and per-
44 operative iliac rupture in 6. The location in the external iliac artery (EIA) is the most
45 significant risk factor of technical failure in univariate (OR = 9.93;p = 0.0012) and
46 multivariate analysis (OR = 15.26;p = 0.0006). The presence of heavy endoluminal
47 calcifications is a further significant risk factor (OR = 13.88;p = 0.0365). Rupture rate was
48 comparable between the 3 groups. *Conclusions* : Pre-operative CT-scan can predict risk of
49 technical failure but not of iliac rupture.

50 **Keywords** : TASC C-D, aortoiliac chronic total occlusions, predictors, iliac rupture, technical
51 failure

52

53

54 INTRODUCTION

55 Despite TASC II recommendations,⁽¹⁾ and because of good outcomes in several large
56 studies,^(2-4,6) endovascular treatment is now the first choice for complex aorto-iliac occlusions
57 in high-volume centers with high technical success (> 90 %) and very low major per-
58 operative complications including iliac rupture (< 5 %).⁽⁵⁻⁷⁾ But the risk of technical failure
59 and the fear of per-operative iliac rupture, especially in heavily calcified lesions limit the
60 widespread use of this technique. Predictors of failure have been studied for patency and
61 clinical outcomes for TASC C-D aorto-iliac occlusions.⁽⁸⁻¹⁰⁾ To the best of our knowledge,
62 anatomic risks factor for technical failure or per-operative rupture have been studied for
63 superficial femoral and popliteal arteries and for coronary disease but not for aortoiliac
64 arteries.⁽¹¹⁾ Oddly, predictors of technical failure and per-operative complications have been
65 studied recently for transbrachial or transradial accesses but not for femoral accesses.⁽¹²⁻¹³⁾
66 Yet, for the endovascular treatment of aorto-iliac TASC C-D chronic total occlusion (CTO),
67 transbrachial access alone cannot be sufficient because of the diameter of the stent used, the
68 necessity of kissing stent. Moreover, contrary to coronary occlusive disease,⁽¹⁴⁻¹⁷⁾ for
69 peripheral arterial disease there is no precise score analyzing the complexity of lesions. Most
70 technical failures are associated with failure to cross the occlusion or for re-entry in the
71 arterial lumen. In the TASC II classification,⁽¹⁾ diffuse multiple stenosis in the iliac artery is
72 TASC D whereas short occlusion of external iliac artery (EIA) is TASC B. For endovascular
73 treatment, the short occlusion of EIA is more technically difficult. Moreover, this
74 classification does not take into account the degree of calcifications of aorto-iliac lesions.
75 Thus, this classification seems relatively unsuitable to select between open surgical repair and
76 endovascular treatment as highlighted by Ohana et al. in 2013 for superficial femoral artery
77 occlusions.⁽¹⁸⁾ Moreover, as was well demonstrated for coronary disease,⁽¹⁷⁾ comparison
78 between open surgery and endovascular treatment of aorto-iliac occlusive disease is also

79 difficult because patients included can be relatively different (TASC D lesions are very
80 heterogeneous),⁽¹⁾ and series are heterogeneous including stenosis and occlusions, including
81 femoro-popliteal segments.^(2,5,7)

82 Technical success is very high (> 90 %) but for chronic total occlusion (CTO), failure persists
83 despite the use of re-entry devices and antegrade approach.⁽¹⁷⁻²¹⁾ Even if it is thought that
84 heavily calcified lesions are more at risk for this complication, this has never been clearly
85 defined.⁽⁵⁾

86 The aim of this study was to evaluate anatomic predictors of technical failure and per-
87 operative iliac rupture of endovascular treatment of TASC C-D aorto-iliac CTO with a
88 detailed analysis of pre-operative CT-scan.

89

90 **MATERIALS AND METHODS**

91 *STUDY DESIGN AND PATIENT SAMPLE*

92 This is a single-center retrospective analysis of a prospective cohort. All patients treated in
93 our department by endovascular techniques for an aorto-iliac CTO TASC C-D between
94 December 2009 and June 2016 were analyzed. Patients with no pre-operative CT-scan, with
95 stenosis and no CTO and with an acute or subacute ischemia were excluded. We included 148
96 iliac arteries from 107 patients. All CT-scan were analyzed by 2 surgeons independently
97 (NDS and AM); in case of discordance, the CT-scan was reviewed jointly. Mean age was 62
98 years (SD 51-73). The indication for treatment was claudication in 104 limbs (70,3 %), rest
99 pain in 28 limbs (18,9 %) and tissue loss in 16 limbs (10,8 %). Patients were TASC C in 32
100 cases and TASC D in 75 cases. Baseline patient characteristics are given in Table I. Detailed
101 lesions are described in Table II.

102 The study has been performed according to the principles of the Declaration of Helsinki and
103 approval has been obtained from ethic committee of the hospital.

104

105 *CTO EVALUATION*

106 We analyzed 2 characteristics of CTO: the location and the extension of the CTO on the aorta
107 or iliac artery and the degree of calcifications of the aorta and iliac arteries (Figure 1). For this
108 characteristics, we divided CTO into 3 groups: the black occlusion group (BO) was defined
109 by the presence of mild non-protrusive calcifications or the complete absence of calcifications
110 in the total lesion length; the white occlusion group (WO) was defined by moderate
111 calcifications of more of 50 % of the arterial circumference but little or no protrusive into the
112 arterial lumen; the white protrusive occlusion group (WPO) was defined by the presence of
113 heavy endoluminal arterial calcifications of more of 50 % of the arterial lumen.

114 Each iliac artery was analyzed separately.

115

116 *ENDOVASCULAR PROCEDURE*

117 The procedures were performed by a team of experienced vascular surgeons in a surgical
118 theater using a recent generation mobile C-arm. A detailed description of our technique has
119 been previously published.⁽²¹⁾ For external iliac artery (EIA) occlusions that involve the
120 common femoral artery (CFA), a superficial femoral puncture was performed if possible; if
121 not, an antegrade approach using the contralateral femoral access was used.⁽²²⁾ CFA lesions
122 were treated as described in the TECCO study.⁽²³⁾ In case of failure by a retrograde approach,
123 all patients had an antegrade approach by contralateral femoral access or by the brachial
124 access. No re-entry device was used.

125

126 *ENDPOINTS*

127 The primary endpoint was the technical failure rate defined by the impossibility to cross the
128 lesion or to re-entry in the true lumen. Secondary endpoint was the per-operative iliac rupture
129 rate defined by an extravasation of contrast agent in angiogram. For these two endpoints, each
130 iliac artery was analyzed separately.

131 *STATISTICAL ANALYSIS*

132 Means with standard deviations were presented for continuous data and counts with
133 percentages for categorical data. Groups were compared using Fisher's exact or Wilcoxon test
134 as appropriate. Univariate and multivariate logistic regression models were performed to
135 identify separately any independent predictors of technical failure and per-operative iliac
136 rupture. Values of $p < 0.05$ were considered statistically significant. All analyses were
137 performed using R Core Team Software (version 3.1.0, R Foundation for statistical
138 computing, Vienne, Austria)

139

140 **RESULTS**

141 Occlusions were located in the external iliac artery (EIA) in 37 cases (25 %), in the common
142 iliac artery (CIA) in 41 cases (27.7 %), in both the external and the common iliac artery (BIA)
143 in 42 cases (28.4 %), and in the on aortic bifurcation (AB) in 14 cases (18.9 %). There were
144 66 iliac arteries (44.6 %) in the BO group, 45 (30.4 %) in the WO group and 37 (25 %) in the
145 WPO group. In 70 patients and 83 iliac arteries (56.1 % of the total number of cases), an
146 antegrade access was attempted because of failure of the retrograde access, including 58
147 brachial accesses (39.2 %). For 93 iliac arteries (62.8 %), recanalization were subintimal. The
148 interpretation of CT-scan were concordant between the 2 surgeons in 90 % of cases.

149

150 *TECHNICAL FAILURE*

151 Technical failure occurred in 11 iliac arteries (7.4 % of cases). Technical failures were
152 impossibility to reentry in all the cases despite the use of antegrade and retrograde approach.
153 Cases with technical failure were comparable to those without with regard to all baseline
154 characteristics. Technical failure differed according to CTO location ($p = 0.001$), it was more
155 frequent when CTO was located in the EIA ($p = 0.001$), and less frequent when CTO was
156 located in CIA ($p = 0.035$; Table III)

157 In univariate analysis, the location of the CTO in the EIA was the only factor significantly
158 associated with technical failure (OR = 9.93; $p = 0.0012$; Table III). In multivariate analysis,
159 after adjustment on age and renal failure, the location of the occlusion on EIA was also
160 significantly and strongly associated with technical failure (OR = 15.26; $p = 0.0006$). The
161 presence of heavy endoluminal calcifications (WPO group) was a further risk factor of
162 technical failure in comparison with the WO group (OR = 13.88; $p = 0.0365$; Table IV).

163

164 *PER-OPERATIVE ILIAC RUPTURE*

165 Per-operative iliac rupture occurred in 6 iliac arteries (4 %). Four ruptures were successfully
166 treated with a cover stent; the 2 other ruptures led to the death of the patient.

167 There was no risk factor significantly associated with per-operative iliac rupture in univariate
168 model (Table V). There were 3 per-operative iliac ruptures in the BO group, 2 in the WO
169 group and 1 in the WOP group ($p = 0.881$). The occlusion of both the external and the
170 common iliac artery was more frequently found in the per-operative iliac rupture group,
171 although this difference was not significant ($p = 0.282$).

172

173 **DISCUSSION**

174 To the best of our knowledge, this is the first study to analyze specifically anatomic predictors
175 of technical failure and per-operative iliac rupture of endovascular treatment of TASC C-D

176 aorto-iliac CTO. The main risk factor for technical failure identified by this study was the
177 location of the CTO in the EIA. This can be explained by occlusive disease that can extend
178 into the common femoral artery (CFA). In such cases, the arterial access is difficult.
179 Superficial femoral artery puncture could be necessary and the proximity of the CTO leads to
180 a lack of “push”. For these cases, the antegrade approach seems really indispensable for us. We
181 make this antegrade approach for all cases, we don’t try retrograde recanalization. But for the
182 antegrade approach, the necessity of re-entry in CFA or more distal artery can be difficult and
183 controversial. However, we have previously published good results for stenting of CFA and
184 its bifurcation⁽²²⁾ and these results were confirmed by a recent multicenter randomized
185 study.⁽²³⁾ If there is an appropriate landing zone in the CFA, results are good but if there is
186 lesions of the bifurcation, it will be more complicated and results are worse. For these cases,
187 hybrid surgery seems to be very interesting. Moreover, it appears important to obtain good
188 results to use large diameter of stents in iliac arteries. If the CFA is of good diameter and with
189 no important lesion, there is no problem but in the contrary, there is a risk of incomplete
190 opening of the distal stent or even a risk of rupture of the CFA. So for all these reasons,
191 hybrid surgery can be used with acceptable midterm results.⁽²⁴⁾

192 The study shows that the degree of calcifications, especially endoluminal calcifications, is
193 associated with technical failure. In many series, CTO and heavy calcified lesions are
194 excluded.^(25,26) However, because most technical failures result in the impossibility to cross
195 the lesions or for re-entry in the true lumen, the degree of arterial calcifications is cited as a
196 risk factor for technical failure in several studies but is not scientifically proven.^(5,12,19,25) A
197 similar situation is found for per-operative iliac rupture.^(5,7) Despite vascular calcifications
198 having been extensively studied,^(26,27) their clinical implications for aortoiliac CTO remain
199 unknown. For coronary occlusive disease, several risk scores have been published.⁽¹⁴⁻¹⁶⁾
200 However, for peripheral arterial disease, the characterization of lesions is less well defined.

201 For example, Diehm et al. in 2008 published a largely undefined classification,⁽²⁸⁾ and in
202 2015, Peripheral Academic Research Consortium (PARC) published a semi-quantitative
203 classification but endoluminal calcifications were not studied.⁽²⁹⁾ For our statistical analysis
204 about the role of calcifications, we decide to adjust on age and renal failure because these
205 criteria have been described as risk factor of calcifications.⁽³⁰⁾ We don't adjust on diabetes
206 because for diabetes, calcifications concern more infra-inguinal disease.⁽³¹⁾

207 An interesting aside is that in the present study that included complex lesions, technical
208 success was high despite re-entry devices not being used. We believe that such devices are
209 interesting but relatively dangerous in case of re-entry in the abdominal aorta. The
210 complication rate is about 4.3 % while lesions treated are less severe and mostly infra-
211 inguinal lesions.^(19,20) Moreover, in a recent large study, technical success with the use of re-
212 entry device was similar to that reported herein.⁽¹⁹⁾ Heavy calcifications remains risk factor
213 for technical failure despite the use of these devices.^(19,20)

214 In our experience, the main trick to obtain good technical success is to try to make
215 intraluminal recanalization. Indeed, the main explanation for failure is the impossibility to re-
216 entry, particularly in the aorta. To make intraluminal recanalization, we use a straight and
217 rigid catheter immediately to prevent the guidewire from leaving the wall. We direct the guide
218 with the catheter to progress in the lumen. But in some cases, the occlusion is too hard and the
219 intraluminal crossing impossible. In such cases, the other trick to obtain technical success, is
220 to rapidly use antegrad approach. In the beginning of our experience, we try with a retrograde
221 approach for a long time. Actually, we try few minutes and rapidly we make the antegrad
222 approach. For all these procedures, we install the patient with an upper arm (generally the left)
223 in the surgical field as well as the 2 femoral accesses. If cross over is possible, we try and if
224 not we use the brachial access.

225 For per-operative iliac rupture, we did not identify risk factors. Per-operative iliac rupture
226 occurred similarly in the 3 CTO groups, which may suggest that heavily calcified lesions
227 should not be specifically excluded from endovascular treatment on the basis of this criterion
228 alone, but requires further investigation in large multicenter international studies.

229

230 *LIMITATIONS*

231 A general limitation of the study is that it was based on a single center. However, the cohort
232 was prospective, and this design ensured exhaustive recruitment leading to a homogeneous
233 and well defined population, but which was relatively small. This did not adversely affect the
234 evaluation of technical success, but precluded meaningful conclusions as to iliac rupture.

235 Another aspect to consider is the semi-quantitative evaluation of arterial calcifications used
236 herein. With specific 3D-reconstruction imaging software, quantitative analysis of arterial
237 calcifications is possible but such software is not widely available to the vast majority of
238 surgical teams. Although semi-quantitative, this classification is more precise than that
239 described in guidelines published by Diehm et al. in 2008.⁽²⁸⁾ This is more similar of a further
240 classification, published recently by the Peripheral Academic Research Consortium (PARC)
241 with more the analysis of endoluminal calcifications.⁽²⁹⁾

242 Another point to note is that we did not analyze specifically the length of lesions as a risk
243 factor for technical failure, however among the 11 such cases in the present study, there were
244 3 BIA occlusions but 8 EIA occlusions, which suggests that longer lesions were not more
245 technically difficult. Furthermore, the diameter of the vessel was not considered, but it is
246 reported that in case of CTO this can be underestimated with pseudostenosis and lead to
247 biased interpretation.⁽³²⁾ Moreover, recanalization are often subintimal so arteriel diameter
248 can't really affect technical failure.

249 Finally, as the event rate is too low, it is impossible to generate a robust model.

250 **CONCLUSION**

251 This study shows anatomic predictors of technical failure of endovascular treatment of aorto-
252 iliac TASC C-D CTO. Open surgery could be discussed in first choice in patients with these
253 risk factors especially in low-volume centers in order to avoid endovascular failure and its
254 medico-economic consequences.

255

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343

344

345 **FIGURE LEGENDS**

346 Figure 1 : Pre-operative CT-scan. (A) WO group (B) BO group, (C) WOP group

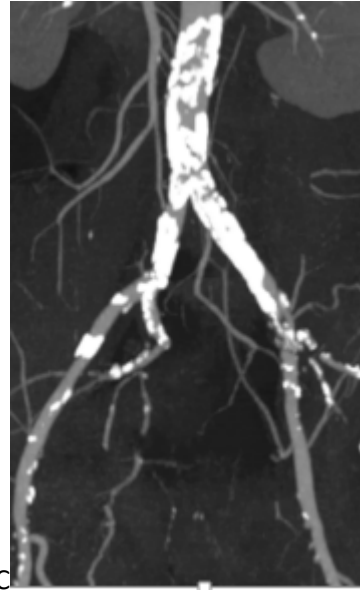
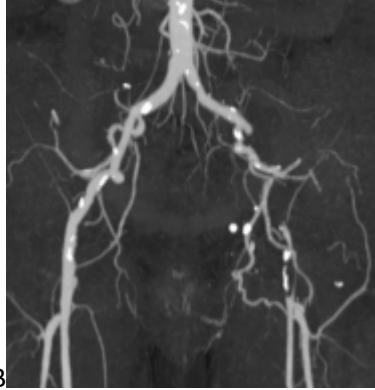


Table 1: Baseline Patient and Lesion characteristics^a

	<i>Total population, n = 107</i>
<i>Mean Age, years</i>	<i>62 (11.2)</i>
<i>Sex, male</i>	<i>86 (81.9)</i>
<i>Current smoker</i>	<i>61(57)</i>
<i>Former smoker</i>	<i>31(28,9)</i>
<i>Diabetes</i>	<i>26 (24.3)</i>
<i>Hypertension</i>	<i>66 (62.9)</i>
<i>Dyslipidemia</i>	<i>53 (50.5)</i>
<i>Obesity (BMI >30)</i>	<i>10 (9.5)</i>
<i>Renal failure (GFR < 60 ml/min)</i>	<i>8 (7.6)</i>
<i>Previous aorto-iliac surgery</i>	<i>28 (26.7)</i>
<i>Endovascular</i>	<i>24 (22.4)</i>
<i>Open surgery</i>	<i>4 (4.3)</i>
<i>Claudication</i>	<i>104 (70,3)</i>
<i>Critical limb ischemia</i>	<i>44 (29,7)</i>
<i>Rest pain</i>	<i>28 (18,9)</i>
<i>Tissue loss</i>	<i>16 (10,8)</i>
<i>TASC</i>	
<i>C</i>	<i>32 (29.5)</i>
<i>D</i>	<i>75 (70.5)</i>

^aContinuous data are presented as the means ± standard deviation;

Categorical data are presented as the counts (percentage).

Abbreviations: BMI, body mass index, GFR glomerular filtration rate,

TASC: Trans-Atlantic Inter-Society Consensus

Table 2. Detailed lesions according to TASC II classification






Type of lesions	N =
	26
	19
	11
	37
	14

Table 3: Technical failure^a

	no n = 137	yes n = 11	p-value ^b
Age, years	61.98 (11.53)	62.64 (6.30)	0.601
CTO group			
BO	55 (40.1%)	5 (45.5%)	0.148
WO	46 (33.6%)	1 (9.1%)	
WOP	36 (26.3%)	5 (45.5%)	
Location of occlusion			0.001
AB	28 (20.4%)	0 (0.0%)	
BIA	39 (28.5%)	3 (27.3%)	
EIA	29 (21.2%)	8 (72.7%)	
CIA	41 (29.9%)	0 (0.0%)	
Smoking			0.802
never	15 (10.9%)	1 (9.1%)	
previous	44 (32.1%)	2 (18.2%)	
current	78 (56.9%)	8 (72.7%)	
Diabetes			1
no	101 (73.7%)	9 (81.8%)	
insulino-dependant	8 (5.8%)	0 (0.0%)	
non insulino-dependant	28 (20.4%)	2 (18.2%)	
Hypertension			0.337
Dyslipidemia	70 (51.1%)	7 (63.6%)	0.537
Obese (BMI > 30)	14 (11.3%)	0 (0.0%)	1
Renal failure (GFR < 60 ml/min)	9 (6.6%)	1 (9.1%)	0.55
Previous aorto-iliac surgery			0.265
no	90 (72.0%)	4 (57.1%)	
endovascular	29 (23.2%)	2 (28.6%)	
open surgery	6 (4.8%)	1 (14.3%)	
Claudication	119 (90.2%)	8 (72.7%)	0.109
BIA occlusion	39 (28.5%)	3 (27.3%)	1
AB occlusion	28 (20.4%)	0 (0.0%)	0.125
EIA occlusion	29 (21.2%)	8 (72.7%)	0.001
CIA occlusion	41 (29.9%)	0 (0.0%)	0.035
WPO group	36 (26.3%)	5 (45.5%)	0.178
WO group	46 (33.6%)	1 (9.1%)	0.174
BO group	55 (40.1%)	5 (45.5%)	0.758

^aContinuous data are presented as the means \pm standard deviation; Categorical data are given as the counts (percentage).

^bFisher's exact test for categorical data and Wilcoxon test for continuous data

Abbreviations: AB, aortic bifurcation; BIA, both iliac arteries; BMI, body mass index; BO, black occlusion; CIA, common iliac artery; EIA, external iliac artery; GFR, glomerular filtration rate; WO, white occlusion; WPO, white protrusive occlusion.

Table IV. Predictors of technical failure from the multivariate model

Characteristics	Odds Ratio	95 % CI	p
Age	0.99	0.91 to 1.07	0.82
Renal failure	1.24	0.06 to 11.26	0.86
EIA lesion	15.27	3.59 to 87.77	0.0006
BO group	4.03	0.54 to 85.12	0.2361
WPO group	13.88	1.63 to 328.52	0.036

Abbreviations : BO, black occlusion; CI, confidence interval; EIA, external iliac lesion; WPO, white protrusive occlusion

Table V. Table 5. Per-operative iliac rupture

	no n = 142	yes n = 6	p-value ^a
Age, years			
Calcifications			0.881
group			
BO	57 (40.1%)	3 (50.0%)	
WO	45 (31.7%)	2 (33.3%)	
WPO	40 (28.2%)	1 (16.7%)	
Location of occlusion			0.282
AB	28 (19.7%)	0 (0.0%)	
BIA	38 (26.8%)	4 (66.7%)	
EIA	36 (25.4%)	1 (16.7%)	
CIA	40 (28.2%)	1 (16.7%)	
Antegrade access	77 (54.2%)	4 (66.7%)	0.69
recanalization			0.178
intraluminal	55 (38.7%)	0 (0.0%)	
subintimal	80 (56.3%)	6 (100.0%)	
smoking			0.704
no	16 (11.3%)	0 (0.0%)	
previous	45 (31.7%)	1 (16.7%)	
current	81 (57.0%)	5 (83.3%)	
diabetes			1
no	105 (73.9%)	5 (83.3%)	
Insulino-	8 (5.6%)	0 (0.0%)	
dependant			
non insulino-	29 (20.4%)	1 (16.7%)	
dependant			
hypertension	88 (62.0%)	3 (50.0%)	0.676
dyslipidemia	75 (52.8%)	2 (33.3%)	0.427
Obese (BMI > 30)	14 (11.2%)	0 (0.0%)	1
Renal failure (GFR < 60 ml/min)	10 (7.0%)	0 (0.0%)	1
			0.315
Previous aorto-iliac surgery			
no	91 (71.7%)	3 (60.0%)	
endovascular	30 (23.6%)	1 (20.0%)	
open surgery	6 (4.7%)	1 (20.0%)	
claudication	121 (88.3%)	6 (100.0%)	1

^aContinuous data are presented as the means +/- standard deviation; Categorical data are given as the counts (percentage).

^bFisher's exact test for categorical data and Wilcoxon test for continuous data

Abbreviations: AB, aortic bifurcation; BIA, both iliac arteries; BMI, body mass index; BO, black occlusion; CIA, common iliac artery; EIA, external iliac artery; GFR, glomerular filtration rate; WO, white occlusion; WPO, white protrusive occlusion.