Comparative assessment of patient outcomes with intraluminal or subintimal crossing of infrainguinal peripheral artery chronic total occlusions

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Abstract

This study compares procedural complications and clinical outcomes between subintimal crossing versus intraluminal crossing during endovascular treatment of infrainguinal peripheral artery chronic total occlusions (CTO). We identified 1335 CTO interventions in 1001 patients from the multicenter Excellence in Peripheral Artery Disease (XLPAD) registry from January 2005 to October 2015. Outcomes included 30-day and 12-month all-cause death, non-fatal myocardial infarction or stroke, peripheral artery stent, or vessel, thrombosis (ST), need for any target limb endovascular or surgical revascularization, target limb major amputation and procedural complications. A subintimal crossing technique was necessary in 388 lesions (27% overall in 1335 lesions; 34% (n=351) in 1023 femoropopliteal lesions, and 12% (n=37) in 312 infrapopliteal lesions, $p<0.01$) with a lower procedural ($p<0.01$) and technical ($p<0.01$) success than the intraluminal in both femoropopliteal and infrapopliteal interventions. There were no significant differences in procedural complications, major adverse cardiac events, or clinically driven target limb revascularization at 1 year between the two groups, except a higher residual dissection rate in the subintimal crossing group than the intraluminal group in femoropopliteal target vessels ($p = 0.04$).

Keywords

Introduction

Chronic total occlusions (CTO) represent a challenging subset of lesions in lower extremity peripheral artery endovascular interventions. CTOs are associated with a higher failure rate during attempted lesion crossing, peripheral artery dissection, perforation or loss of collaterals, and other adverse patient and lesion outcomes.[1] An alternative crossing technique, known as the extraluminal recanalization or subintimal crossing technique, has been developed and successfully employed.[2] The subintimal crossing technique involves the creation of an extraluminal passage between the intimal and medial or adventitial layers of the target artery that bypasses the occluded segment of the vessel.[3] Thus, the intentional subintimal technique involves extending a dissection plane into the subintimal space. It has been used as an effective recanalization method for crossing peripheral artery CTOs.[4] Passage of a guidewire or crossing device into the subintimal space can also be unintentional and requires bail-out techniques to re-enter the distal target vessel true lumen to successfully complete the procedure.

While prior studies have examined patency rates and complications for each crossing technique separately,[5] few have conducted a comparative study of patient outcomes following lower extremity peripheral artery endovascular intervention between intraluminal and subintimal crossing

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techniques to recanalize infrainguinal peripheral artery CTOs. This study compares patient, lesion, and procedural characteristics, along with 30-day and 12-month clinical outcomes, as well as periprocedural complications between the intraluminal and subintimal crossing techniques for femoropopliteal and infrapopliteal peripheral artery CTOs, using retrospective data from the multicenter Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851).

Methods

Data from the XLPAD registry catalogues procedural information and outcomes of consecutive infrainguinal peripheral artery interventions performed at 11 centers in the United States between January 2005 and October 2015. Details of this ongoing registry have been previously published.[6] All procedural images are adjudicated by the Veterans Affairs North Texas angiographic and ultrasound core laboratory. Baseline features, demographics, laboratory values, medical therapy and procedure data, and patient outcomes are recorded in the registry.

Patients were categorized into two groups based on the techniques utilized to cross infrainguinal peripheral artery CTO lesions: intraluminal (true lumen) and subintimal groups. Assignment to a crossing strategy was based on operator description indicated in the registry data capture form. However, final assignment of a case to a crossing strategy was based on the following criteria: (a) subintimal crossing: defined based on either use of a re-entry device, specific operator description of distal true lumen re-entry with a guidewire, or extraluminal passage of a guidewire confirmed by intravascular ultrasound (IVUS) imaging performed at the discretion of the operator; (b) intraluminal crossing: in the absence of any of the above criteria defining subintimal crossing, the procedure was assigned to the intraluminal group.

Technical success was defined as crossing the CTO and placement of a guidewire or crossing device in the distal true lumen confirmed by either angiography or IVUS. Procedural success was defined as successful treatment of the CTO lesion with ≤30% angiographic residual stenosis without complications. The crossing technique employed was at the discretion of the operator.

Patient outcomes included patient adverse events at 30 days and 12 months post-procedure and include: all-cause death, non-fatal myocardial infarction (MI) or stroke, peripheral artery stent, or vessel, thrombosis (ST), the need for any target limb endovascular or surgical revascularization, and target limb major amputation. Periprocedural complications included residual dissection, access-site or retroperitoneal hematoma, bleeding diathesis, distal embolization, perforation, or the need for emergency surgery. Peripheral artery ST, complications, and adverse events are defined based on the established XLPAD registry criteria.[6]

Analyses were conducted separately by target vessel, femoropopliteal and infrapopliteal artery locations treated during the endovascular intervention.

Descriptive statistics are reported and Cochran-Mantel-Haenszel (CMH) statistics were used for overall association of crossing techniques with categorical baseline patient and lesion characteristics and outcomes. |Standard residual| >3 was set as a criterion for a true association for baseline characteristics with more than two categories. Two-sided *t*-tests were conducted to examine a crossing technique group difference in continuous baseline characteristics. Kaplan-Meier curves were used to conduct time to event analysis and log-rank chi-squared statistics w used to compare a median time of event between intraluminal and subintimal CTO crossing technique groups. A *p*-value <0.05 was set for statistical significance. SAS software, Version 9.4 (SAS Institute Inc., Cary, NC, USA) was used for all statistical analyses.

Results

This study identified 1335 CTO lesions from 1179 procedures to examine crossing technique associations with procedural success and patient outcomes in 1001 unique patients. An intraluminal crossing technique was used in 71% (*n*=947) of CTO lesions and the remaining were crossed using a subintimal technique (*n*=388, Figure 1). Within the subintimal crossing group, approximately 20% used IVUS and 80% (*n*=314) used a re-entry device. About 17% of the subintimal crossings (*n*=68) were for a bail-out indication (*n*=63 in femoropopliteal and *n*=5 in infrapopliteal locations). Patient baseline characteristics are described in Table 1.

While there were no differences in most baseline patient characteristics between the intraluminal and subintimal crossing technique groups, the subintimal group was less likely to have critical limb ischemia (CLI) and below the knee (BTK) disease. A subintimal crossing technique was used more frequently in the femoropopliteal target vessel (34.3%), but significantly less frequently in the BTK vessels (11.9%; *p* < 0.0001).

Further analysis was stratified by femoropopliteal versus infrapopliteal target vessel interventions (Table 1). When considering femoropopliteal target vessels only (*n* = 1070 lesions treated), use of the subintimal crossing technique was also less frequently used for treating occluded in-stent restenosis lesions. The subintimal crossing group had significantly longer lesions, but larger reference vessel diameters and a greater number of BTK run-off vessels compared with the intraluminal crossing group (Table 1). For infrapopliteal target vessel interventions (*n* = 265 lesions treated), there were no significant group differences in any of the baseline lesion characteristics between the intraluminal and subintimal crossing technique groups (Table 1). Duration of procedure and fluoroscopy times were significantly longer in the subintimal crossing group; however, there were no significant differences in periprocedural complications between the two groups (Table 2).

Bare metal stents (BMS) use was significantly more often in the subintimal group relative to the intraluminal group in treating femoropopliteal disease, while drug-eluting stents (DES) use was at a similar rate. There were no differences in the use of stents when treating infrapopliteal disease CTOs. For femoropopliteal and infrapopliteal disease, atherectomy use was significantly more prevalent in the intraluminal group than the subintimal
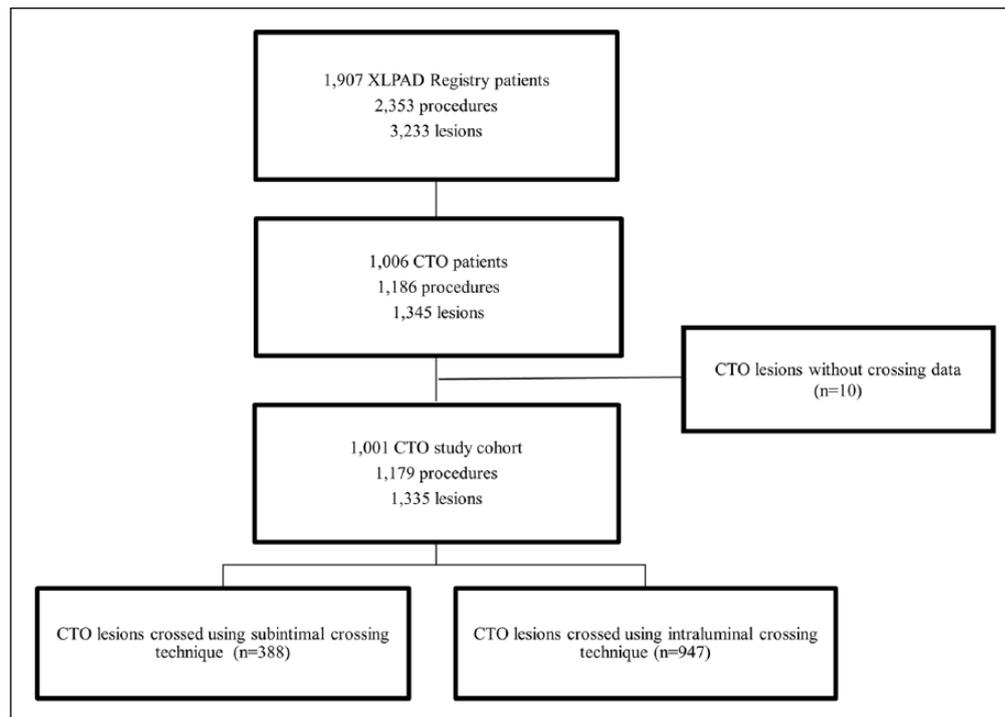
Figure 1. A flow chart of the study data selection: chronic total occlusion (CTO) lesion and crossing technique.

group (Table 2). The rates of subintimal crossings were similar with the use of either antegrade or retrograde tibiopedal access for crossing femoropopliteal or infrapopliteal CTOs (Table 2).

Technical failure (12.6% vs 7.9%, $p = 0.0186$, femoropopliteal disease; 28.0% vs 7.8%, $p = 0.0018$, infrapopliteal disease) and procedural failure (14.6% vs 10.1%, $p = 0.0383$, femoropopliteal disease; 32.0% vs 8.9%, $p = 0.0008$, infrapopliteal disease) rates were significantly higher with subintimal crossing in treating both femoropopliteal and infrapopliteal diseases than with intraluminal crossing. There were no group differences in procedural complications between the two crossing groups except a significantly higher rate of residual dissection in the subintimal group (3%) compared to the intraluminal group (1%, $p = 0.0356$; Table 3) treating femoropopliteal disease. Thirty-day outcomes between the two crossing groups were similar in both femoropopliteal and infrapopliteal diseases (online Supplementary Figures 1 and 2).

For both femoropopliteal and infrapopliteal target vessel interventions, there were no significant group differences in rates of death, non-fatal MI or stroke, or repeat revascularization at 12 months between the intraluminal and subintimal groups (Figures 2 and 3). Kaplan-Meier analyses showed no significant differences between the two crossing groups in the median time to death (log rank $\chi^2 = 0.09$, $p = 0.7670$, femoropopliteal; log rank $\chi^2 = 0.99$, $p = 0.3199$, infrapopliteal), non-fatal MI or stroke (log rank $\chi^2 = 0.02$, $p = 0.8658$, femoropopliteal; log rank $\chi^2 = 2.56$, $p = 0.1095$, infrapopliteal), or target limb endovascular or surgical revascularization events in 12 months (log rank $\chi^2 = 0.53$, $p = 0.4678$, femoropopliteal; log rank $\chi^2 = 0.34$, $p = 0.5616$, infrapopliteal). There were no significant group differences in 12-month ST rates between the two crossing technique groups in either femoropopliteal (Figure 2) or infrapopliteal interventions (Figure 3).

Discussion

Crossing of infrainguinal peripheral artery CTOs involves passage of a guidewire, catheter or a CTO crossing device through the proximal cap, body of the total occlusion, distal cap and entry into the true lumen distal target vessel. A hardened proximal or distal cap, long lesion length and failure to re-enter the distal true lumen are frequent challenges encountered by operators during CTO interventions. Often, the guidewire takes the path of least resistance and dissects the vessel intima and enters into the subintimal space. Traditionally, the subintimal crossing technique was used as a bail-out crossing strategy after failure to cross intraluminally. However, as minimally invasive approaches to treat long and occluded segments of infrainguinal arteries have become commonplace and routine, the subintimal approach is sometimes adopted preferentially by operators to cross CTO lesions. Baseline characteristics that predict use of the subintimal crossing technique are presence of collaterals at the proximal stump, heavy calcification, long occluded lesions and full length tibial artery occlusions.[7] The technical difficulty in subintimal crossing of long CTOs commonly arises with re-entry into the distal true lumen,[8] which can be overcome with use of re-entry devices – Outback™ (Cordis, Miami Lakes, FL, USA), Pioneer™ (Medtronic, Minneapolis, MN, USA), Enteer™ (Medtronic), and OffRoad™ (Boston Scientific Corporation, Marlborough, MA, USA) – specifically designed for subintimal re-entry.

In our study, about 30% of CTO lesions were crossed subintimally. Given the retrospective capture of these data in the registry, the decision to employ a subintimal

Table 1. Baseline patient and lesion characteristics by chronic total occlusion (CTO) crossing technique groups (intraluminal versus subintimal groups).

Patient characteristics[a]		Intraluminal (*n*=691)	Subintimal (*n*=310)	Analysis[b]
Age, years	mean (SD)	65.39 (9.69)	65.66 (9.59)	*p* = 0.912
Male sex	*n* (%)	549 (81.09)	282 (90.97)	*p* < 0.0001
Diabetes mellitus	*n* (%)	396 (58.49)	162 (52.94)	*p* = 0.169
Hypertension	*n* (%)	624 (92.17)	281 (91.83)	*p* = 0.827
Dyslipidemia	*n* (%)	574 (84.79)	259 (84.64)	*p* = 0.897
Current smoker	*n* (%)	385 (56.87)	186 (60.78)	*p* = 0.823
Coronary artery disease	*n* (%)	436 (64.40)	202 (66.01)	*p* = 0.627
Prior MI	*n* (%)	170 (25.11)	84 (27.45)	*p* = 0.366
Prior stroke	*n* (%)	64 (9.45)	27 (8.82)	
Prior heart failure	*n* (%)	123 (18.17)	64 (20.92)	*p* = 0.212
Chronic kidney disease	*n* (%)	136 (19.68)	51 (16.45)	*p* = 0.226
Rutherford category, 1–5	mean (SD)	3.62 (1.02)	3.43 (0.90)	*p* = 0.004
Critical limb ischemia	*n* (%)	307 (45.35)	98 (31.04)	*p* < 0.001
Ankle–brachial index	mean (SD)	0.67 (0.23)	0.68 (0.21)	*p* = 0.398
BTK disease	*n* (%)	159 (23.01)	42 (13.55)	*p* = 0.005
Aspirin	*n* (%)	458 (67.65)	231 (75.49)	*p* = 0.005
Dual antiplatelet	*n* (%)	300 (44.31)	136 (44.44)	*p* = 0.706

Lesion characteristics[c]

Femoropopliteal target vessel (*n*=1070)		Intraluminal (*n*=716)	Subintimal (*n*=354)	Analysis[b]
Number of BTK vessel run-offs	mean (SD)	1.99 (0.81)	2.06 (0.87)	*t* = −0.83, *p* = 0.404
In-stent restenosis	*n* (%)	154 (22.51)	24 (6.78)	*p* < 0.001
Heavily calcified	*n* (%)	361 (50.42)	214 (60.45)	
Reference vessel diameters, mm	mean (SD)	4.97 (1.00)	5.24 (0.67)	*p* = 0.007
Lesion length[d], mm	mean (SD)	163.9 (102.09)	185.78 (99.42)	*p* = 0.001
0–50	*n* (%)	67 (9.36)	11 (3.11)	|Standard residual| = 3.700
51–100	*n* (%)	112 (15.64)	47 (13.28)	|Standard residual| = 1.024
101–150	*n* (%)	89 (12.43)	65 (18.36)	|Standard residual| = 2.601
151–200	*n* (%)	92 (12.85)	55 (15.54)	|Standard residual| = 1.201
>200	*n* (%)	153 (21.37)	106 (29.94)	|Standard residual| = 3.081
Popliteal occlusion	*n* (%)	84 (11.73)	23 (6.50)	*p* = 0.007
Crossing approach				
Retrograde	*n* (%)	9 (1.26)	9 (2.54)	|Standard residual| = 1.538
Antegrade	*n* (%)	686 (95.81)	329 (92.94)	|Standard residual| = 2.001
Combined	*n* (%)	23 (3.21)	18 (5.08)	|Standard residual| = 1.501

Infrapopliteal target vessel (*n*=265)		Intraluminal (*n*=231)	Subintimal (*n*=34)	Analysis[b]
Number of BTK vessel run-offs	mean (SD)	1.76 (0.78)	2.08 (0.86)	*t* = −0.04, *p* = 0.964
In-stent restenosis	*n* (%)	4 (1.73)	0 (0.00)	*p* = 0.602
Heavily calcified	*n* (%)	75 (32.47)	9 (26.47)	
Reference vessel diameters, mm	mean (SD)	2.59 (1.01)	2.72 (0.99)	*p* = 0.8918
Lesion length[d], mm	mean (SD)	114.5 (82.56)	106.8 (96.32)	*p* = 0.601
<50	*n* (%)	32 (13.85)	9 (26.47)	|Standard residual| = 1.900
51–100	*n* (%)	34 (14.72)	3 (8.82)	|Standard residual| = 0.926
101–150	*n* (%)	15 (6.49)	6 (17.65)	|Standard residual| = 2.248
151–200	*n* (%)	13 (5.63)	0 (0.00)	|Standard residual| = 1.419
>200	*n* (%)	21 (9.09)	3 (1.13)	|Standard residual| = 0.051
Crossing approach				
Retrograde	*n* (%)	10 (4.33)	2 (5.88)	|Standard residual| = 0.407
Antegrade	*n* (%)	204 (88.31)	25 (73.53)	|Standard residual| = 2.348
Combined	*n* (%)	17 (7.36)	7 (20.56)	|Standard residual| = 2.600

BTK, below the knee; MI, myocardial infarction; SD, standard deviation.
[a]1001 patients.
[b]*T*-statistics and Cochran-Mantel-Haenszel (CMH) statistics were used to test a crossing technique group difference in continuous characteristics and associations between crossing technique groups and categorical characteristics, respectively. |Standard Residual| >3 is set for a true association for baseline characteristics with categories > 2.
[c]1335 lesions.
[d]Missing data are 273 in femoropopliteal and 129 in infrapopliteal.

Table 2. Procedure characteristics and treatment modality by target vessel.

Femoropopliteal procedure (*n*=974)		Intraluminal (*n*=632)	Subintimal (*n*=342)	Analysis[a]
Procedure duration, min	mean (SD)	124.6 (47.41)	144.7 (57.91)	*p* < 0.0001
Fluoroscopy time, min	mean (SD)	35.67 (16.97)	44.12 (21.32)	*p* < 0.0001
Contrast volume, (mL)	mean (SD)	188.5 (91.52)	195.1 (97.93)	*p* = 0.2947
Treatment modalities				
BMS	*n* (%)	293 (46.36)	183 (51.69)	*p* = 0.0008
DES	*n* (%)	61 (8.52)	32 (9.04)	*p* = 0.7763
Atherectomy	*n* (%)	263 (36.73)	75 (21.19)	*p* < 0.0001
PTA	*n* (%)	553 (87.50)	288 (84.21)	*p* = 0.1536
Infrapopliteal procedure (*n*=205)		Intraluminal (*n*=180)	Subintimal (*n*=25)	Analysis[a]
Procedure duration, min	mean (SD)	125.4 (52.6)	169.3(68.5)	*p* = 0.0002
Fluoroscopy time, min	mean (SD)	35.6 (19.2)	44.5 (19.9)	*p* = 0.0318
Contrast volume, (mL)	mean (SD)	172.3 (93.1)	193.6 (98.7)	*p* = 0.2898
Treatment modalities				
BMS	*n* (%)	16 (6.93)	4 (11.76)	*p* = 0.3196
DES	*n* (%)	4 (1.73)	0 (0.00)	*p* = 0.4394
Atherectomy	*n* (%)	94 (35.47)	5 (14.71)	*p* = 0.0035
PTA	*n* (%)	168 (93.33)	21 (84)	*p* = 0.1039

BMS, bare metal stents; DES, drug eluting stents; SD, standard deviation; PTA, plain balloon angioplasty.
[a]*T*-statistics and Cochran-Mantel-Haenszel statistics were used to test a group difference in continuous and categorical variables, respectively.

Table 3. Periprocedural complications by target vessel.

Femoropopliteal procedure (*n*=974)		Intraluminal (*n*=632)	Subintimal (*n*=342)	Analysis[a]
Residual dissection	*n* (%)	8 (1.27)	11 (3.22)	*p* = 0.0356
Access site and retroperitoneal hematoma	*n* (%)	9 (1.42)	5 (1.46)	*p* = 0.9621
Bleeding diathesis	*n* (%)	0 (0.00)	1 (0.29)	*p* = 0.1738
Distal embolization	*n* (%)	17 (2.69)	8 (2.34)	*p* = 0.8650
Perforation	*n* (%)	4 (0.63)	3 (0.88)	*p* = 0.6666
Emergency surgery	*n* (%)	1 (0.16)	0 (0.00)	*p* = 0.4617
Infrapopliteal procedure (*n*=205)		Intraluminal (*n*=180)	Subintimal (*n*=25)	Analysis[a]
Residual dissection	*n* (%)	2 (1.11)	0 (0.00)	*p* = 0.597
Access site and retroperitoneal hematoma	*n* (%)	0 (0.00)	0 (0.00)	–
Bleeding diathesis	*n* (%)	0 (0.00)	0 (0.00)	–
Distal embolization	*n* (%)	2 (1.11)	0 (0.00)	*p* = 0.597
Perforation	*n* (%)	1 (0.56)	1 (4.00)	*p* = 0.102
Emergency surgery	*n* (%)	0 (0.00)	0 (0.00)	–

BMS, bare metal stents; DES, drug eluting stents; SD, standard deviation.
[a]*T*-statistics and Cochran-Mantel-Haenszel statistics were used to test a group difference in continuous and categorical variables, respectively.

crossing technique prior to the start of the procedure based on baseline lesion characteristics cannot be confirmed. However, about 17% of the subintimal crossing was a bail-out strategy in our study. The subintimal technique was more frequently employed in longer CTO lesions and with bigger vessel diameters at baseline. And, as expected, its use was less frequent during crossing of occluded in-stent restenotic lesions. The subintimal group had significantly higher stenting and residual dissection rates. Although the residual dissection rates were low, this observation may be due to the fact that all areas of dissections, especially non-flow-limiting, may not have received a stent scaffold.

While there were no significant differences in 30-day or 12-month mortality, non-fatal MI or stroke, ST, or repeat revascularization events between subintimal and intraluminal crossing groups, utilizing the subintimal technique was associated with longer procedures, and higher technical and procedural failure rates.

Soga et al. compared intraluminal versus subintimal crossing techniques in long lesions (>10 cm) and found no significant differences in patient outcomes, but decreased duration of procedure with the subintimal crossing technique. In contrast, we observed an increased procedure duration and fluoroscopy time in the subintimal group. This difference could most likely be due to the use of the subintimal crossing technique for more difficult CTO procedures, involving longer lesion lengths.[9] The mean lesion length in the subintimal
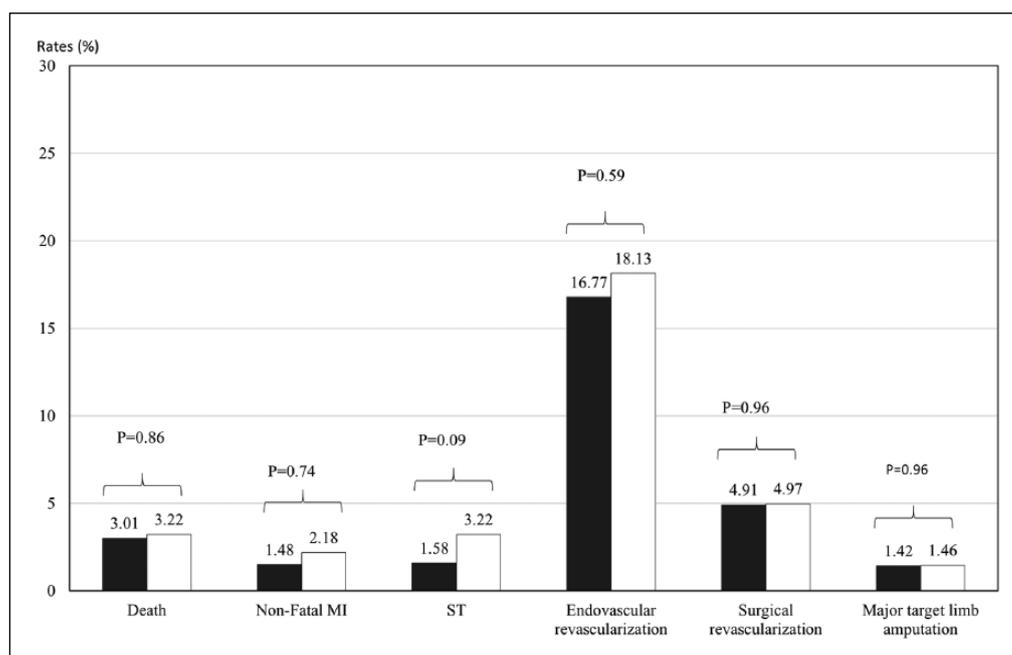
Figure 2. Twelve-month adverse event rate by crossing technique in femoropopliteal target vessel.
(Intraluminal (black); subintimal (white); MI, myocardial infarction; ST, stent thrombosis.)
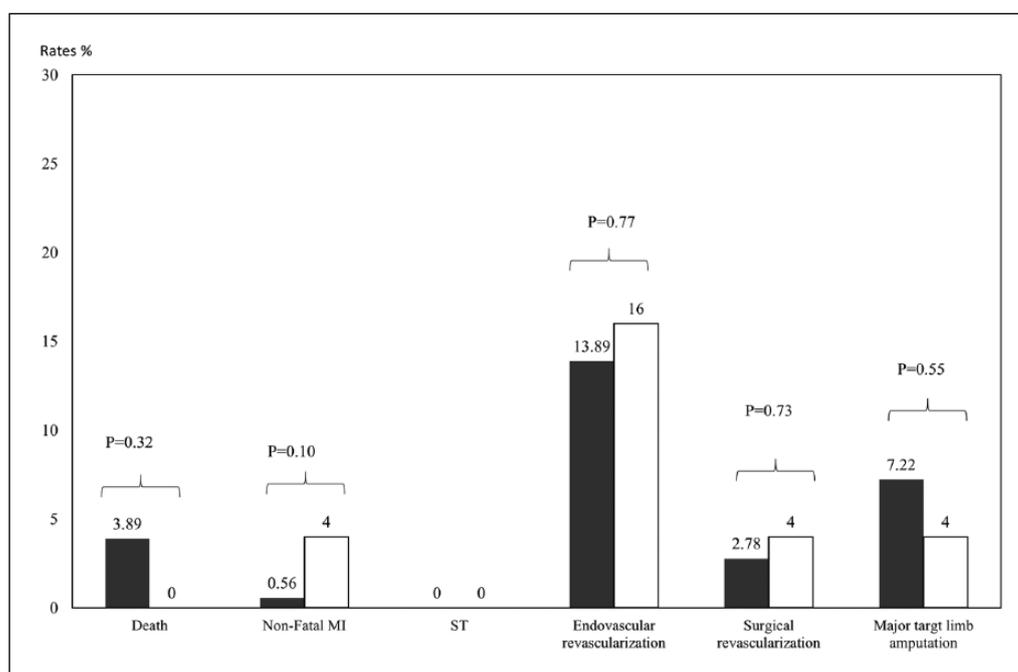
Figure 3. Twelve-month adverse event rate by crossing technique in infrapopliteal target vessel.
(Intraluminal (black); subintimal (white); MI, myocardial Infarction; ST, stent thrombosis.)

crossing group in our study was significantly higher than in the intraluminal group in both the studies; however, in the study by Soga et al., the analysis was conducted from a prospective database based on an intent-to-treat principle. In contrast, our study includes a retrospective cohort of subintimal crossing with a guidewire or crossing device.

We also observed similar 30-day and 12-month ST rates between the subintimal and intraluminal groups. Ishihara et al. have reported a similar Zilver PTX ST rate with

intraluminal and subintimal crossing of femoropopliteal CTOs.[10]

The presence of a pre-existing stent or in-stent restenotic lesions provides a clear fluoroscopically identifiable target for crossing and hence it is not surprising that the subintimal crossing technique is less frequently used for such lesions. It is nevertheless an invaluable approach when the occluded previously stented segment has multiple levels of complex stent fractures or other structural deformations that preclude intraluminal crossing.

Limitations

Our study from a large adjudicated observational peripheral artery intervention registry has important limitations associated with retrospective data capture and therefore we are unable to define the intent of the subintimal approach, intentional versus bail out, leading to possible overestimation of the technical success of the intraluminal approach. In addition, retrograde CTO crossing is under-represented in our study, although it is being increasingly used in contemporary clinical practice.

Conclusion

In conclusion, the results of this study indicate that the subintimal crossing strategy to traverse infrainguinal peripheral artery CTO is often employed to tackle more complex lesions. Subintimal crossing can be successfully performed with low periprocedural complications, and favorable short and intermediate term clinical outcomes, compared with an intraluminal approach.

Declaration of conflicting interests

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Supplementary material

The supplementary material is available online with the article.

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