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A single center retrospective analysis of patency rates of intraluminal versus subintimal endovascular revascularization of long femoropopliteal occlusions☆

Anvar Babaev *, Pawan Hari, Rohit Gokhale, Susanna Zavlunova

New York University Department of Medicine, Division of Cardiology

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ABSTRACT

Objective: The evaluation of patency rates of intraluminal versus subintimal endovascular revascularization of long femoropopliteal (FP) lesions.

Background: Chronic total occlusions (CTO) of the FP artery in peripheral interventions are crossed either with a support catheter-guidewire based technique or subintimal dissection and re-entry device assisted approach. Both techniques have a high procedural success rate, but their long term patency is not well studied. There is also lack of comparative data addressing the patency of long non-CTO vs. CTO occlusions.

Methods: We performed a single center retrospective analysis, studying the patency rates in 215 patients (254 limbs) with TASC C and D FP lesions treated with stents. There were 3 patient groups: without CTO (non-CTO); CTO crossed using support catheter and guide-wire (CTO-SW) and CTO crossed with a re-entry device (CTO-RE).

Results: There were 155 limbs in CTO-SW group; 50 in CTO-RE group and 49 in non-CTO. Lesion length (mean ± SD) was 251.81 ± 7.48 mm in CTO-SW group; 280 ± 13.18 mm in CTO-RE group and 248.77 ± 13.31 in non-CTO group (p = non-significant).

In-stent restenosis (ISR) at a mean follow-up of 19.26 ± 16.14 months did not differ between groups occurring in 23 (47%) limbs in non-CTO; 66 (42%) in CTO-SW; and 24 (48%) in CTO-RE. Smoking and stent fracture were predictors of ISR by multivariate analysis.

Conclusion: In patients with long FP lesions, ISR rates were similar between patients with and without CTO. In the CTO group mid-term vessel patency was not affected by the crossing technique utilized.

1. Introduction

The burden of peripheral arterial disease (PAD) continues to increase with estimates of more than 8 million people affected in the United States alone [1]. Symptomatic patients are typically the elderly, with the prevalence of intermittent claudication increasing more than 15-fold in men aged over 65 (prevalence of 6 per 1000) compared to those 35–45 years of age (0.4 per 1000) as noted in the Framingham study [2]. A similar trend is also noted in women, albeit with a lower prevalence in younger age groups. Of the patients presenting for endovascular therapy, chronic total occlusions (CTO) constitute up to 50% of lesions and tend to be far more technically challenging [3]. Superficial femoral artery (SFA) CTOs are more common, likely due to mechanical factors, such as vessel compression, torsion and elongation that are unique to the femoropopliteal (FP) vascular bed, resulting in accelerated atherosclerosis [4,5]. Endovascular therapy has emerged as the preferred alternative to bypass surgery in most patients given the increasing age of presentation, higher surgical risks and improved techniques.

The ability to cross FP CTOs depends on lesion characteristics (lesion length, complexity and calcification) and operator experience [6–9]. The traditional approach has involved the use of a support catheter and guide wire but the development of specialized CTO crossing and re-entry devices have significantly improved the success rate of endovascular revascularization. Current clinical practice is based largely on operator experience and limited single-arm studies of devices, with a paucity of data on the efficacy of device based re-entry upon long term follow-up.

Abbreviations: PAD, Peripheral Arterial Disease; CTO, Chronic Total Occlusion; SFA, Superficial Femoral Artery; FP, Femoro-popliteal; IL, Intraluminal; SI, Subintimal; TASC, Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease; APTT, Activated Partial Thromboplastin Time; ABI, Ankle-brachial index; PVR, Pulse-volume recording; ISR, In-stent restenosis; GFR, Glomerular filtration rate; WBC, White blood cell; RE, Re-Entry; SW, Support catheter-wire; RCT, Randomized control trial.

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* Corresponding author at: NYU Langone Medical Center, 530 First Avenue, HCC14, New York, NY, 10069. Tel.: +1 212 263 5656; fax: +1 212 263 8534.

E-mail address: anvar.babaev@nyumc.org (A. Babaev).

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The most common reasons for failure are the inability to cross the CTO with a guidewire and balloon or subintimal dissection and an inability to re-enter the true lumen distally. There are several wire and device based techniques available for crossing CTOs. These can be divided broadly into intraluminal (IL) and subintimal (SI) approaches. In the intraluminal approach, the guidewire or a device is used to cross the lesion from true lumen to true lumen. The subintimal (SI) approach involves forming a track between the intima and media of the vessel thereby in effect bypassing the occlusion. Re-entry into the distal true lumen is then achieved via wire based or device based strategies [10].

While both these approaches have similar technical success rates and can be used as complementary rather than competitive techniques [6], the long term patency rates associated with these techniques are varied and direct comparisons have seldom been made [6–9].

In addition, there is a lack of comparative data addressing the patency rates of the long non-CTO vs. CTO occlusions. We therefore sought to assess the long-term patency associated with each technique in our study.

2. Methods

We performed a single center retrospective study of patients referred for treatment of obstructive FP disease treated with Nitinol self-expanding stents at our laboratory from May 2008 to May 2013. Our objective was to compare patients undergoing revascularization of long FP CTOs using a support-catheter and wire based crossing approach versus re-entry device assisted endovascular approach, specifically looking at the mid-term primary patency rates of the treated vessel. Based on lesion length of the treated segments of FP CTOs, we also studied a control group of treated patients without CTOs with comparable lesion length. We identified 215 patients (254 limbs) with TASC C and D FP disease, referred for endovascular treatment and considered to be poor surgical candidates or who declined surgery for their PAD. Patients eligible for the study were symptomatic with life style limiting claudication – (Rutherford Class III) despite exercise and medical therapy or with critical limb ischemia (Rutherford Class IV and higher). Data were gathered on demographics, baseline characteristics, clinical presentation, angiographic and treatment characteristics and clinical success rate through review of records and angiographic films. We included patients with de-novo lesions, that were crossed using an antegrade approach and stented with nitinol self-expanding stents (type of the stent used at operator discretion, Table 2).

Table 2
Stent characteristics and utilization.

Type of stent	CTO-SW (N = 155)	CTO-RE (N = 50)	Non-CTO (N = 49)
Protégé(EV3)	147 (42%)	39 (33%)	50 (43%)
Complete SE (Medtronic)	92 (26%)	56 (47%)	34 (30%)
SMART (Cordis)	35 (10%)	5 (4%)	1 (1%)
Viabahn (Gore)	6 (2%)	2 (2%)	1 (1%)
LifeStent (Bard)	17 (5%)	7 (6%)	–
Zilver (Cook)	33 (9%)	7 (6%)	20 (17%)
Supera (IDEV/Abbot)	10 (3%)	1 (1%)	–
Excel (JW Medical System)	1 (0.5%)	–	–
EverFlex (EV3)	1 (0.5%)	–	–
Absolute Pro (Abbott)	8 (2%)	1 (1%)	9 (8%)

2.1. Study groups

The study population was divided into three groups: 1) Support catheter and wire based CTO group (CTO-SW): This was defined as

Table 1
Patient demographic and lesion characteristics.

Variables	CTO-SW (n = 155)	CTO-RE (n = 50)	Non-CTO (n = 49)	P value (overall)	CTO-SW vs. CTO-RE	CTO-SW vs. non-CTO	CTO-RE vs. non-CTO
Patient characteristics							
Age in years [mean (SD)]	71.94 (0.73)	74.94 (1.29)	73.02 (1.30)	0.126	0.043*	0.467	0.295
Sex (female %)	38.06	34	47.92	0.335	0.604	0.24	0.217
Body mass index in kg/m2 [mean (SD)]	28.32 (0.39)	29.28 (0.69)	28.03 (0.70)	0.389	0.216	0.707	0.267
Co-morbidities							
Current smoker (%)	21.43	28.26	17.02	0.695	0.326	0.679	0.222
Diabetes (%)	58.71	50	69.39	0.144	0.279	0.181	0.049*
Hypertension (%)	96.77	94	91.84	0.326	0.381	0.143	0.678
Hyperlipidemia (%)	95.48	92	95.92	0.583	0.344	0.897	0.419
Coronary artery disease (%)	83.12	88	87.76	0.585	0.412	0.44	0.971
Chronic kidney disease (%)	15.48	24	20.83	0.345	0.17	0.388	0.711
Indication							
CLI (%)	22.73	32	32.65	0.239	0.193	0.187	0.99
Claudicants – Rutherford Class III (%)	77.27	68	67.35	"	"	"	"
Lesion/Procedural characteristics							
Stent length in mm [mean (SD)]	251.81 (7.48)	280 (13.18)	248.77 (13.31)	0.144	0.064	0.842	0.096
Stent width in mm [mean (SD)]	6.295 (0.05)	6.30 (0.08)	6.19 (0.08)	0.467	0.962	0.236	0.316
Number of stents	2.30 (0.07)	2.32 (0.12)	2.45 (0.12)	0.555	0.868	0.28	0.456
Run off score	3.91 (2.81)	3.97 (2.87)	5.07 (2.55)	0.036*	0.901	0.011	0.047*
Stent fracture (%)	8.39	14	12.24	0.457	0.244	0.418	0.796
Re-entry device							
Pioneer catheter (%)	NA	36.3	NA	NA	NA	NA	NA
Outback catheter (%)	NA	63.7	NA	NA	NA	NA	NA
Laboratory							
LDL in mg/dl [mean (SD)]	94.14 (4.07)	85.97 (6.93)	94.67 (7.43)	0.568	0.296	0.953	0.383
Glomerular filtration rate in ml/min [mean (SD)]	61.99 (1.70)	58.79 (2.99)	53.08 (3.06)	0.039	0.352	0.011	0.199
WBC count in 1000/mcL [mean (SD)]	8.46 (0.38)	7.45 (0.67)	7.39 (0.68)	0.238	0.233	0.209	0.895
Medications							
Statin (%)	95 (61%)	36 (72%)	32 (65%)	0.382	0.472	0.17	0.613
Aspirin (%)	142 (92%)	45 (90%)	44 (90%)	0.897	0.973	0.726	0.695
Clopidogrel (%)	145 (94%)	44 (88%)	43 (88%)	0.292	0.97	0.188	0.203
Cilostazol (%)	31 (20%)	18 (36%)	18 (16%)	0.032	0.026*	0.568	0.021*

CLI – Critical limb ischemia.
SD – Standard deviation.
* P value <0.05.

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