

BACKGROUND

Endovascular interventions in infrapopliteal occlusive artery disease are becoming more complex and this frequently tests the standard method of treatment, plain balloon angioplasty. The potential that serration angioplasty could produce a more acceptable tibial artery lumen was assessed in this study. The aim of this single center subgroup analysis was to compare acute angiographic results after endovascular treatment using the Serranator serration balloon catheter in patients participating in the PRELUDE BTK trial to plain balloon angioplasty of the infrapopliteal arteries in patients with chronic limb threatening ischemia (CLTI). A secondary objective was to assess post-treatment hemodynamic improvements.

METHODS

Our center enrolled 15 subjects and treated 17 lesions within the multi-center prospective core laboratory adjudicated PRELUDE-BTK study for treatment of critical infrapopliteal lesions. A separate analysis of 25 lesions were treated with POBA and then compared to the Serranator subset. In both cohorts, lesions were treated with either plain balloon angioplasty or Serranator as a stand-alone therapy; subsequent methods such as drug-elution technologies were not utilized. Acute angiographic results were analyzed by the SynvaCor angiographic core laboratory. To assess volumetric flow rates data was analyzed with a fluid flow simulation software and compared against Poiseuille's Law.

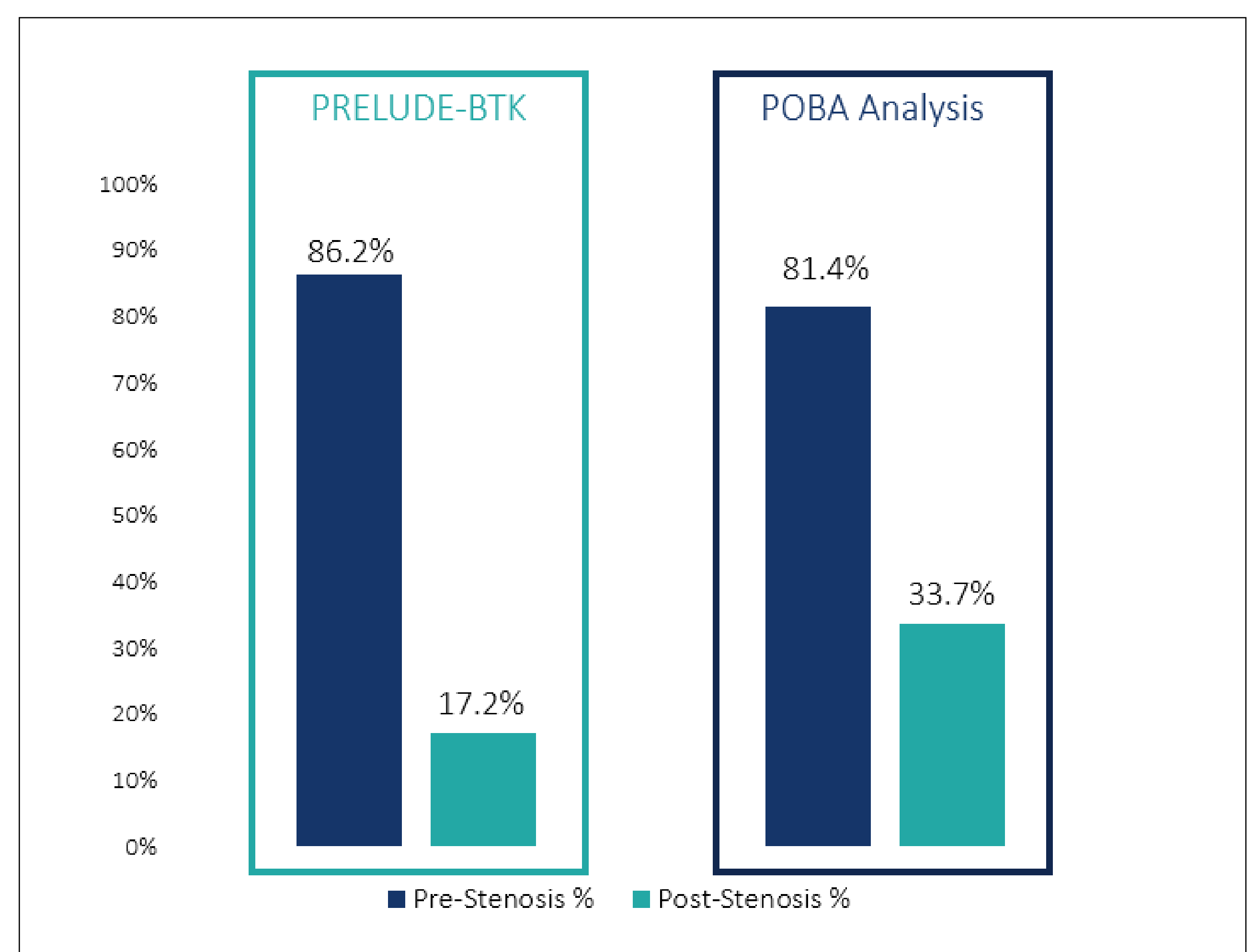
RESULTS

Final residual stenosis was 17.2±8.2% in the Serranator group versus 33.7±15.7% in the plain balloon group. The mean lumen diameter (MLD) gain were 1.64±.41 mm for the Serranator group and 1.37±.63 mm for the plain balloon group respectively. The average atmospheric balloon inflation pressure was 5 ATM in the Serranator group versus 9 ATM in the plain balloon group. Neither group required a bailout stent, however it was notable that there were significantly more chronic total occlusions (CTOs) treated in the Serranator group at 41.2% versus 12% in the plain balloon group. Regarding the effectiveness in improving hemodynamic blood flow for non-CTO lesions, the calculated average ratio of post-treatment to pre-treatment flow rates in the Serranator group was 238% than that for the plain balloon group. For CTO cases where pre-treatment flow rate was zero, final residual stenosis was used as the parameter for comparison. The Serranator group showed a 62% improvement in final residual stenosis over plain balloon angioplasty.

Table 1. Lesion characteristics and procedural details.

	Serration balloon angioplasty (PRELUDE study group)	Plain balloon angioplasty (control group)
Lesions treated, n	17	25
Lesion Location, n(%)		
Tibioperoneal trunk	5/17 (29%)	4/25 (16%)
Posterior tibial artery	1/17 (6%)	4/25 (16%)
Anterior tibial artery	8/17 (47%)	10/25 (40%)
Peroneal artery	2/17 (12%)	6/25 (24%)
Distal Popliteal	1/17 (6%)	1/25 (4%)
RVD, mm	2.4 ± 0.6	2.5 ± 0.7
Lesion length, mm	52.8 ± 39.1	86.7 ± 78.5
Pre-diameter stenosis, %	86.2 ± 16.4	81.4 ± 12.8
CTO, n (%)	7/17 (41.2%)	4/25 (16.0%)
Degree of calcification, n (%)		
None	8/17 (47.1%)	10/25 (80%)
Mild	6/17 (35.3%)	4/25 (16%)
Moderate	0/17 (0%)	2/25 (8%)
Severe	2/17 (11.8%)	1/25 (4%)
Unknown	1/17 (5.9%)	8/25 (32%)
Bailout stent rate, n (%)	0/17 (0%)	0/25 (0%)
Dissections by grade, n (%)		
Grade 0	14/17 (82.4%)	20/25 (80%)
Grade A	3/17 (17.6%)	4/25 (16%)
Grade B	0/17 (0%)	1/25 (4%)
Balloon inflation pressure, ATM		
Average	5	9
Range	4-6	6-14
Mean lumen diameter gain (mm)	1.64mm ± .41mm	1.33mm ± .63mm
Final residual stenosis (%)	17.2% ± 8.2%	33.7% ± 15.7%

Figure 1. Improvement in mean diameter stenosis achieved by Serranator treatment versus plain balloon treatment.



CONCLUSION

Endovascular treatment of the infrapopliteal arteries by use of the Serranator serration balloon provides a novel and promising method of action as compared to standard balloon angioplasty and, thus, may have a leading role in complex below the knee arterial lesions.

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