Long-Term Outcomes after Re-entry Device Use for Recanalization of Common Iliac Artery Chronic Total Occlusions

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BACKGROUND

- Chronic total occlusions (CTOs) comprise up to 20-40% of lesions undergoing treatment for symptomatic peripheral artery disease (PAD).
- Subintimal angioplasty (SIA) is often used to facilitate CTO crossing. However, SIA leads to unpredictable wire re-entry and is not always feasible.
- Re-entry devices (RED) are an alternative treatment option that can increase recanalization success rate and optimize the distal re-entry point while decreasing procedure and fluoroscopy times.

METHODS

- We performed a two-center retrospective study of 115 patients (140 lesions) undergoing CIA CTO endovascular intervention between 2006 and 2016.
- Cox proportional hazard model was developed to determine if RED use was associated with target lesion revascularization (TLR) or major adverse limb events (MALE) within five years.

RESULTS

- There were no significant differences in baseline demographics or other major comorbidities between the two groups (Table 1).
- RED use was safe and not associated with an increase in intraprocedural complications (Table 2).
- RED use had no statistically-significant association with changes in TLR (P = 0.619) and MALE (0.601) rates after five years (Figures 1 and 2).

Table 1. Baseline Patient Characteristics

Variables	Total (N=115)	No re-entry (N=75)	Re-entry (N=40)	P value
Male, n (%)	80 (69.6)	52 (69.3)	28 (70)	1
Caucasian, n (%)	86 (74.8)	56 (74.7)	30 (75)	0.818
Stroke History, n (%)	14 (12.3)	8 (10.8)	6 (15)	0.557
MI history, n (%)	29 (28.2)	19 (27.1)	10 (30.3)	0.816
Diabetes, n (%)	32 (28.1)	21 (28.4)	11 (28)	0.655
Smoking, n (%)	107 (93.9)	71 (94.7)	36 (92.3)	0.689
Hypertension, n (%)	84 (73)	53 (70.7)	31 (77.5)	0.512
CAD, n (%)	47 (40.9)	29 (38.7)	18 (45)	0.554
Dyslipidemia, n (%)	87 (75.7)	56 (74.7)	31 (77.5)	0.822
CHF, n (%)	12 (10.4)	8 (10.7)	4 (10)	1
Age, mean (SD)	63.9 (10.1)	63.6 (9.4)	63.9 (10.9)	0.823
EGFR, mean (SD)	88.2 (33.6)	86.7 (30)	88.9 (39.2)	0.869
ABI, mean (SD)	0.58 (0.17)	0.57 (0.18)	0.6 (0.14)	0.194

Figure 1. Five-Year Freedom from Target lesion Revascularization

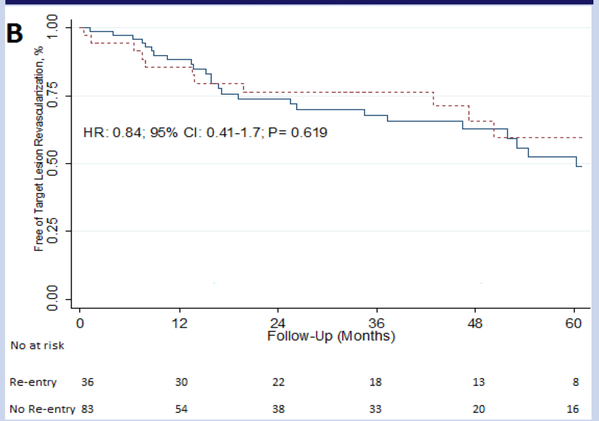

Table 2. Angiographic and Procedural Characteristics

Variables	Total (N=115)	No re-entry (N=75)	Re-entry (N=40)	P value
Anterograde Primary Approach, n (%)	29 (25.2)	21 (28)	8 (20)	0.378
Primary approach successful, n (%)	89 (77.4)	62 (82.7)	27 (67.5)	0.1
Anterograde Final Approach, n (%)	26 (22.6)	22 (29.3)	4 (10)	0.02
Final approach successful, n (%)	104 (90.4)	70 (93.3)	34 (85)	0.187
Approach change, n (%)	17 (14.8)	9 (12)	8 (20)	0.278
Multivessel intervention, n (%)	99 (86.1)	65 (86.7)	34 (85)	0.785
No/Mild Calcification, n (%)	40 (35.1)	29 (39.2)	11 (27.5)	0.226
Moderate/Severe Calcification, n (%)	74 (64.9)	45 (60.8)	29 (72.5)	
Restenosis, n (%)	16 (13.9)	16 (21.3)	0	<0.001
TASC A-B, n (%)	58 (50.4)	36 (48)	22 (55)	0.871
TASC C-D, n (%)	55 (47.8)	37 (49.3)	18 (45)	
Target Lesion Stenting, n (%)	98 (85.2)	65 (86.7)	33 (82.5)	0.587
TARGET LESION COMPLICATIONS, N (%)				
Perforation	3 (2.6)	3 (4)	0	0.249
Dissection	3 (2.6)	1 (1.3)	2 (5)	
Embolization	3 (2.6)	3 (4)	0	
Procedural Success, n (%)	105 (91.3)	69 (92)	36 (90)	0.737

Figure 2. Five-Year Freedom from Major Adverse Limb Event

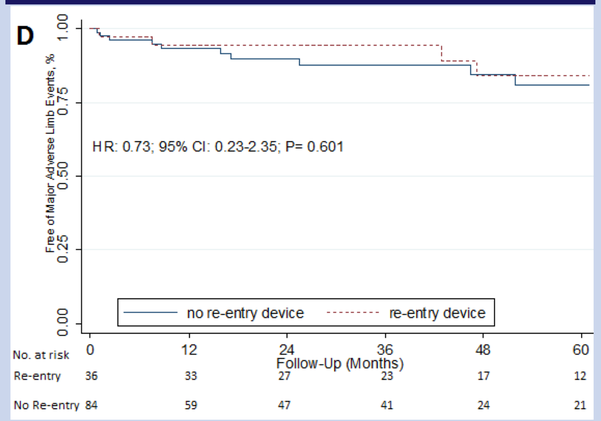

Table 3. Outcomes

Variables	Total (n=115)	No re-entry (75)	Re-entry (40)	P value
Primary Patency	37 (67.3)	23 (69.7)	14 (63.6)	0.126
Primary Assisted Patency	40 (72.7)	23 (69.7)	17 (77.3)	
Secondary Patency	46 (83.6)	28 (84.9)	18 (81.9)	
One year TLR	10 (8.9)	7 (9.6)	3 (7.5)	1
Death	19 (16.5)	15 (20)	4 (10)	0.198
MI	3 (2.6)	3 (4.1)	0	0.551
Stroke	4 (3.5)	3 (4.1)	1 (2.5)	1
Target Limb Bypass	10 (10.6)	8 (12.1)	2 7.1	0.718
Target Limb Loss	2 (1.8)	2 (2.7)	0	1

CONCLUSION

- **Our findings indicate that RED does not increase intraprocedural complications or lead to worse long-term outcomes (TLR and MALE).**
- Future studies in larger cohorts - directly comparing RED vs. SIA treated cases without RED – may yield more definitive results.

DISCLOSURES

Dr. Laird is a consultant/advisory board member for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Medtronic, WL Gore and receives research support from WL Gore, Medtronic, Bard Peripheral Vascular. Dr. Armstrong is a consultant to Abbott Vascular, Boston Scientific, Cardiovascular Systems Incorporated, Medtronic, and Spectranetics.