ROBOTIC PERIPHERAL VASCULAR INTERVENTION WITH DRUG COATED BALLOONS IS FEASIBLE AND REDUCES OPERATOR EXPOSURE

Results of the Robotic-Assisted Peripheral Intervention for Peripheral Artery Disease (RAPID) Study II

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INTRODUCTION

- A robotic-assisted platform (CorPath 200 System, Corindus Vascular Robotics, Inc., Waltham MA) is feasible for peripheral vascular interventions (PVI) for the treatment of femoropopliteal lesions.
- This study was designed to evaluate 1) robotic PVI feasibility and safety for treating femoropopliteal lesions with drug-coated balloons (DCB), and 2) the effect of robotic and table-side operator radiation exposure during robotic PVI procedures.

METHODS

- Prospective, single-arm, single-center, nonrandomized study.
- Twenty subjects enrolled with symptomatic peripheral artery disease.
- Inclusion: femoropopliteal lesions >50% stenosis; occlusions ≤120 mm length.
- Exclusion: target arteries with prior bypass surgery, acute thrombus, prior perforation/dissection/aneurysm.
- Primary outcome was clinical success: 1) <50% residual stenosis in robotic PVI treated lesions, and 2) absence of device-related serious adverse events within 72 hours or prior to discharge.
- Secondary procedural outcomes: fluoroscopy time, contrast volume, procedure time, patient and operator radiation exposure, and adverse events.
- Secondary clinical outcomes: ankle-brachial index, toe-brachial index, peak systolic velocity ratio, percent diameter stenosis.

RESULTS

Figure 1: CorPath 200 Vascular System
Remote operator console with joystick controls for table side robotic unit. Single-use robotic cassette facilitates precise movement of guidewires and rapid-exchange catheters during robotic PVI.

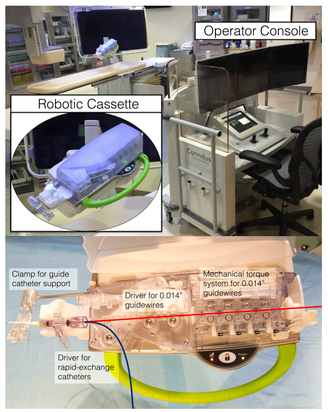


Table 1: Subject Characteristics

Age (years)	65.6 ± 9.9
Male gender	12 (60)
Diabetes mellitus	8 (40)
Hypertension	17 (85)
Dyslipidemia	18 (90)
Smokers	3 (15)
Coronary artery disease	4 (20)
Cerebrovascular disease	11 (55)
Dialysis	0 (0)
Intermittent claudication	17 (85)
Critical limb ischemia	3 (15)
Ankle brachial index	0.7 ± 0.2
Rutherford classification	
Class 2	5 (25)
Class 3	12 (60)
Class 4	3 (15)

Overall N=20. Values are mean ± SD or n (%).

Table 2: Lesion & Vessel Characteristics

Lesion location (n=24)	
Superficial femoral artery	22 (91.7)
Popliteal artery	2 (8.3)
Lesion length, mm (n=24)	49.8 ± 37.5
Vessel tortuosity (n=21)	
Mild	21 (100)
Moderate	0 (0)
Severe	0 (0)
Lesion angulation >45° (n=21)	0 (0)
Eccentric lesion (n=21)	11 (52.4)
Calcification (n=21)	
Mild	14 (66.7)
Moderate	5 (23.8)
Heavy	2 (9.5)

Overall N=20. Values are mean ± SD or n (%).

Table 3: Procedural Characteristics & Clinical Success

Total procedure time, min	47.5 ± 14.4
Interventional procedure time, min	29.4 ± 9.8
Fluoroscopy time, min	7.3 ± 3.3
Contrast volume, mL	57.3 ± 21.8
Patient radiation (dose-area product), Gy*m^2	566.7 ± 391.5
Provisional stenting required (n=24)	1 (4.2)
Clinical success* (n=20)	**20 (100)**

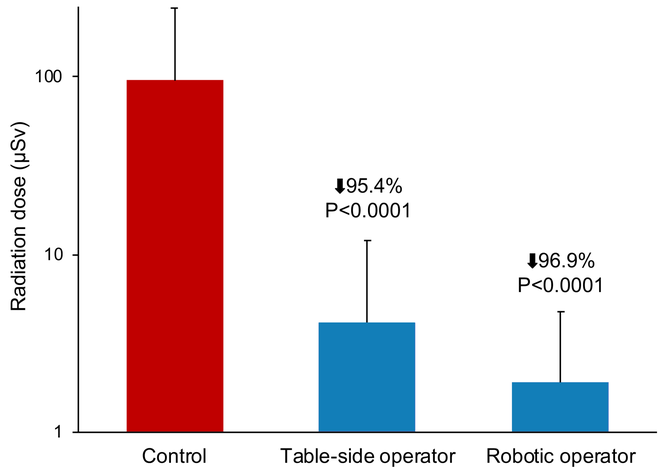
Values are mean ± SD or n (%).

Table 4: Pre- and Post-Procedure Clinical Assessment

	Pre-PVI	Post-PVI	P value
Ankle Brachial Index	0.7 ± 0.2 (20)	1.0 ± 0.2 (20)	<0.0001
Toe Brachial Index	0.5 ± 0.2 (19)	0.4 ± 0.3 (20)	0.3682
Peak Systolic Velocity Ratio	4.3 ± 3.4 (19)	1.0 ± 0.3 (23)	0.0006
Percent Diameter Stenosis	86.3 ± 10.5 (24)	8.8 ± 10.8 (24)	<0.0001

Values are mean ± SD (N).

Figure 2: Operator Radiation Exposure During Robotic PVI
Compared to a shielded table-side dosimeter control, radiation exposure for both the table-side operator (loading devices into the robotic cassette) and the robotic operator (seated within the shielded operator cockpit) was significantly reduced during robotic PVI.



CONCLUSIONS

- Robotic-assisted femoropopliteal peripheral vascular intervention is feasible and safe using contemporary treatment strategies and drug-coated balloons.
- Clinical success was observed in all 20 subjects without any device-related periprocedural adverse events.
- Both robotic and table-side operator radiation exposure were significantly reduced during robotic PVI compared to a tableside control.

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