Comparing Calcium Modification Strategies for Calcified Lesions Using Data from the XLPAD Multicenter Core Lab Adjudicated Registry

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- Disclosures

Background & Rationale

- Calcified below-the-knee (BTK) PAD lesions remain challenging for endovascular treatment
- Multiple calcium-modifying strategies exist: atherectomy, IVL, cutting/scoring balloons
- Limited comparative data on optimal device selection, especially IVL vs atherectomy
- Clinical decision-making remains operator-dependent and heterogeneous
- Need for data-driven approach to guide device selection

Study Objectives

- Primary Objective: Compare outcomes of IVL vs atherectomy in calcified BTK lesions
- Secondary Objective: Evaluate procedural and 1-year outcomes across calcium-modifying strategies
- AI Objective:
  - Develop machine learning models to predict optimal device selection (IVL vs atherectomy)
  - Identify key clinical and lesion-level predictors influencing choice

Study Design & Data Source

- Retrospective cohort study using XLPAD multicenter core lab adjudicated registry
- Inclusion: calcified BTK lesions treated with calcium-modifying strategies
- Exclusion:Non-calcified lesions; Missing key procedural/follow-up data
- AI Substudy Dataset:
  - N = 844 patients
  - IVL: 196 | Atherectomy: 648
- Core lab adjudication ensured standardized lesion and outcome assessment

Statistical Plan and AI Component

- Propensity-score matching with 1:1 IVL: Atherectomy using baseline characteristics across treatment groups.
- Kaplan-Meier analysis and log-rank testing will evaluate time-to-event outcomes such as freedom from MALE and reintervention.
- Cox proportional hazards models used to estimate adjusted hazard ratios for IVL vs atherectomy and other pairwise comparisons.
- Machine learning models developed to predict optimal device selection using lesion and patient features.
- Model performance assessed using metrics such as AUC, precision, and recall.

AI Model for IVL vs Atherectomy selection

- **Objective:** Predict IVL vs atherectomy choice in calcified BTK PAD.
- **Cohort:** 844 patients total; 196 IVL, 648 atherectomy.
- **Features:** 30 candidate demographic, comorbidity, and lesion variables.
- **Preprocessing:** Median/mode imputation, one-hot encoding, zero-variance removal.
- **Model:** XGBoost with logistic objective, 5-fold cross-validation, early stopping, and imbalance adjustment.
- **Evaluation:** AUC, balanced accuracy, sensitivity, specificity, calibration, ROC, and Youden's index.
- **Explainability:** SHAP identified the top 15 features driving IVL selection.
- **Overfitting check:** DeLong's test compared train vs test AUC.

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Descriptive Analysis IVL vs Atherectomy

- We matched 150 IVL patients with 150 Atherectomy Patients from our Cohort of XLPAD 2.0 of 842 BTK patients.
- Matched by : Age, Gender, CKD, DM2, Smoking, CHF, Dyslipidemia, CLTI, Anterior Tibial, Diffuse, CTO, Stents, Prior PAD
- Using: 1:1, 0.25 caliper

Variable	Overall N = 300[1]	Atherectomy N = 150[1]	IVL N = 150[1]	p-value[2]
Age, Mean (SD)	71.68 (10.00)	72.01 (10.28)	71.34 (9.72)	0.4
Gender	208 (69.3%)	101 (67.3%)	107 (71.3%)	0.5
White	238 (82.9%)	117 (83.0%)	121 (82.9%)	0.2
Hispanic	43 (14.9%)	19 (13.6%)	24 (16.1%)	0.5
CLTI	183 (61.0%)	91 (60.7%)	92 (61.3%)	>0.9
HbA1c, Mean (SD)	7.26 (1.98)	6.74 (1.80)	7.52 (2.03)	0.019
HTN	280 (93.3%)	135 (90.0%)	145 (96.7%)	0.021
Atrial fibrillation	46 (15.3%)	17 (11.3%)	29 (19.3%)	0.054
Stent Used	84 (28.0%)	44 (29.3%)	40 (26.7%)	0.6
Filter used	53 (17.7%)	49 (32.7%)	4 (2.7%)	<0.001
Heavily Calcified Lesion	67 (22.3%)	45 (30.0%)	22 (14.7%)	0.001
Lesion length, Mean (SD)	117.78 (66.52)	110.95 (66.21)	124.78 (66.38)	0.069

[1]n (%)

[2]Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

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Outcomes

Characteristic	Overall N = 300[1]	Atherectomy N = 150[1]	IVL N = 150[1]	p-value[2]
Duration of procedure (Minutes), Mean (SD)	101.68 (44.95)	108.13 (45.00)	96.17 (44.31)	0.008
Technical success	264 (88.3%)	141 (94.0%)	123 (82.6%)	0.002
Procedural success	254 (84.7%)	136 (90.7%)	118 (78.7%)	0.004
Procedural complications	20 (6.7%)	12 (8.0%)	8 (5.3%)	0.4
1 Year Outcomes				
MALE	69 (23.0%)	32 (21.3%)	37 (24.7 %)	0.5
Death	20 (6.7%)	10 (6.7%)	10 (6.7%)	>0.9
Repeat Revascularization	49 (16.3%)	23 (15.3%)	26 (17.3%)	0.6
Major Amputation	8 (2.7%)	2 (1.3%)	6 (4.0%)	0.3
MALE timing				0.085
Mean (SD)	82.19 (89.27)	105.63 (103.70)	61.92 (69.86)	
Median (Q1, Q3)	50.00 (22.00, 116.00)	61.00 (22.50, 154.50)	41.00 (15.00, 79.00)	

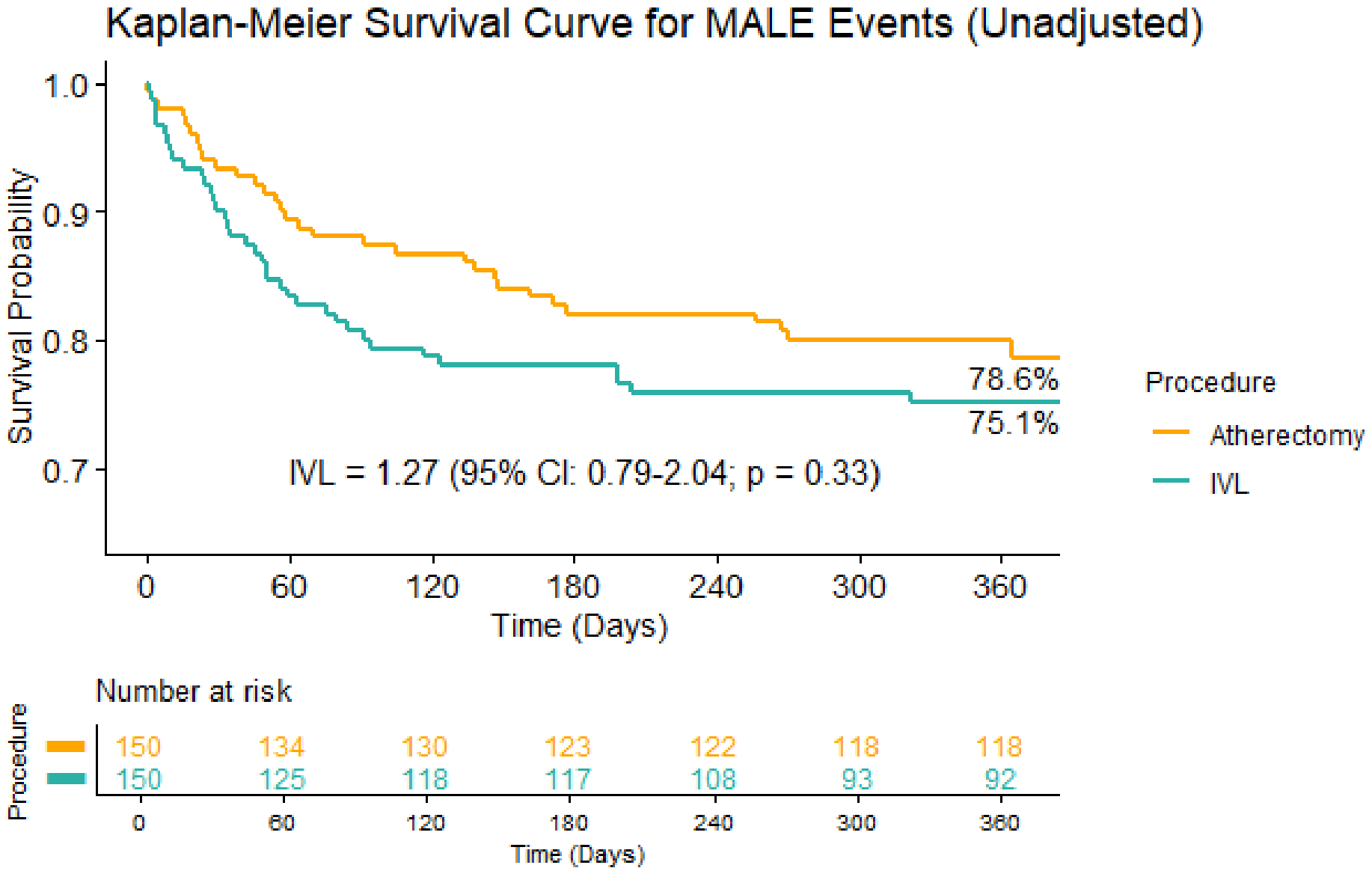
[1]n (%)

[2]Fisher's exact test; Wilcoxon rank sum test; Pearson's Chi-squared test; Wilcoxon rank sum exact test

Procedural Success Logistic Model:

- N = 278; procedural success in 238 patients. IVL has 63% lower odds of having procedural success

Variable	OR	Lower95	Upper95	p-value
IVL used vs Atherectomy	0.37	0.18	0.74	0.006
Hypertension	1.44	0.32	4.78	0.585
Atrial Fibrillation	0.49	0.23	1.09	0.071
Heavily Calcified Lesion	0.74	0.35	1.66	0.446


Kaplan-Meier Survival Curve for MALE Events (Unadjusted)
Survival Probability
1.0
0.9
0.8
0.7
78.6%
75.1%
IVL = 1.27 (95% CI: 0.79-2.04; p = 0.33)
0
60
120
180
240
300
360
Time (Days)
Procedure
Atherectomy
IVL
Number at risk
Procedure
150 134 130 123 122 118 118
150 125 118 117 108 93 92
0
60
120
180
240
300
360
Time (Days)

Cox Model for 1-Year MALE:

n = 300, number of events = 69
Concordance = 0.60 (se = 0.032)

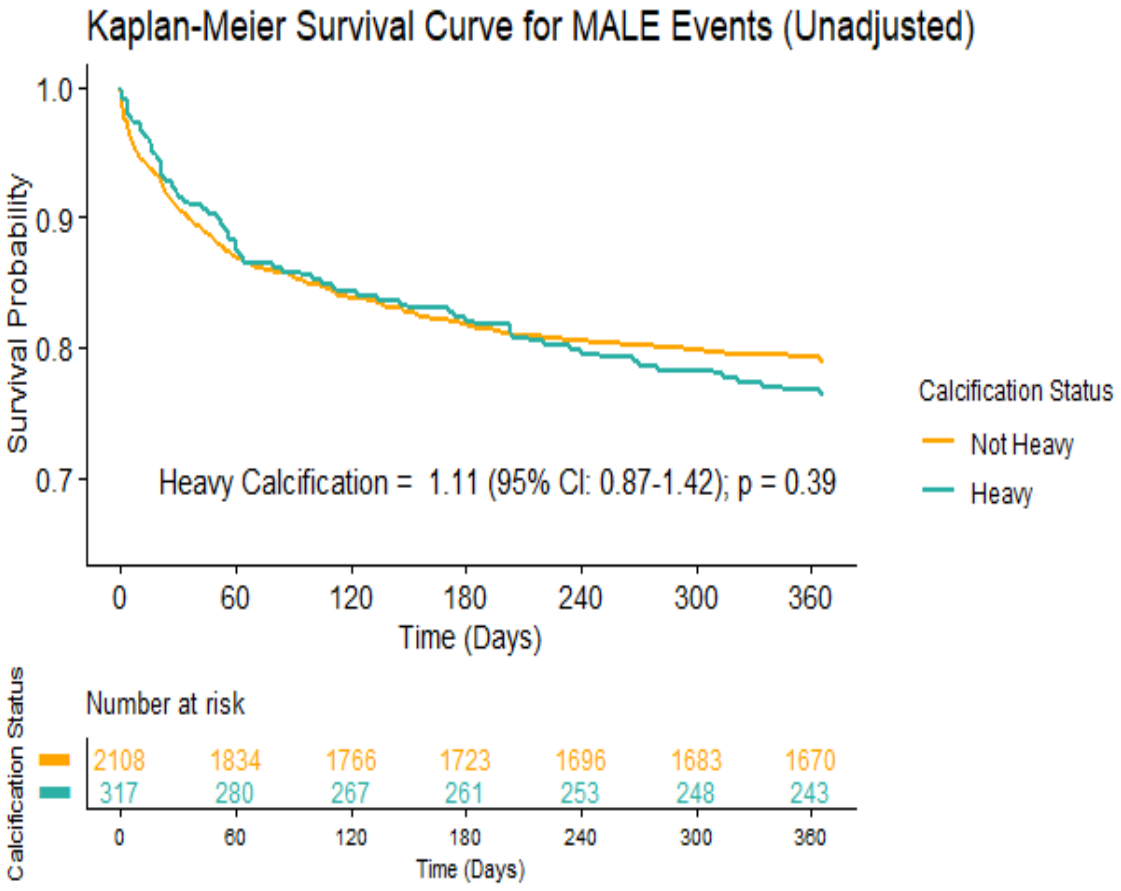
Variable	Hazard Ratio (HR)	95% CI	p-value
IVL used vs Atherectomy	1.17	0.72–1.91	0.52
Hypertension	0.62	0.27–1.46	0.28
Atrial Fibrillation	1.63	0.95–3.02	0.08
Heavily Calcified Lesion	0.77	0.42–1.43	0.41

Comparing all Calcium modifying techniques

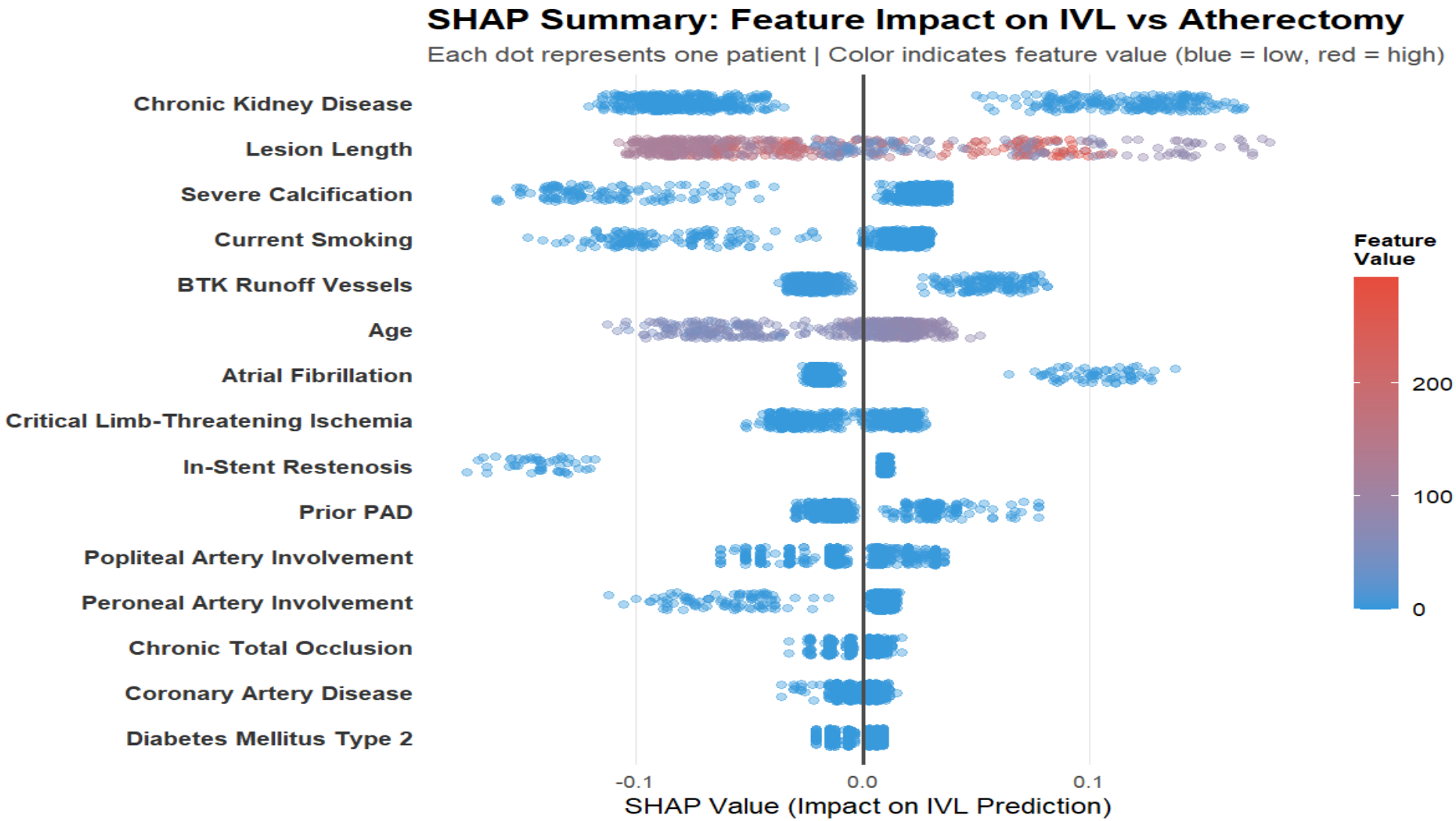
- Analyses were performed in the weighted pseudo-population using inverse probability of treatment weighting (IPTW). We compared IVL, Atherectomy, Cutting and Scoring Balloon, and PTA.
- Cox Model for 1-year MALE by Treatment type in BTK lesions after IPTW:
  - N = 2,331, Events = 500

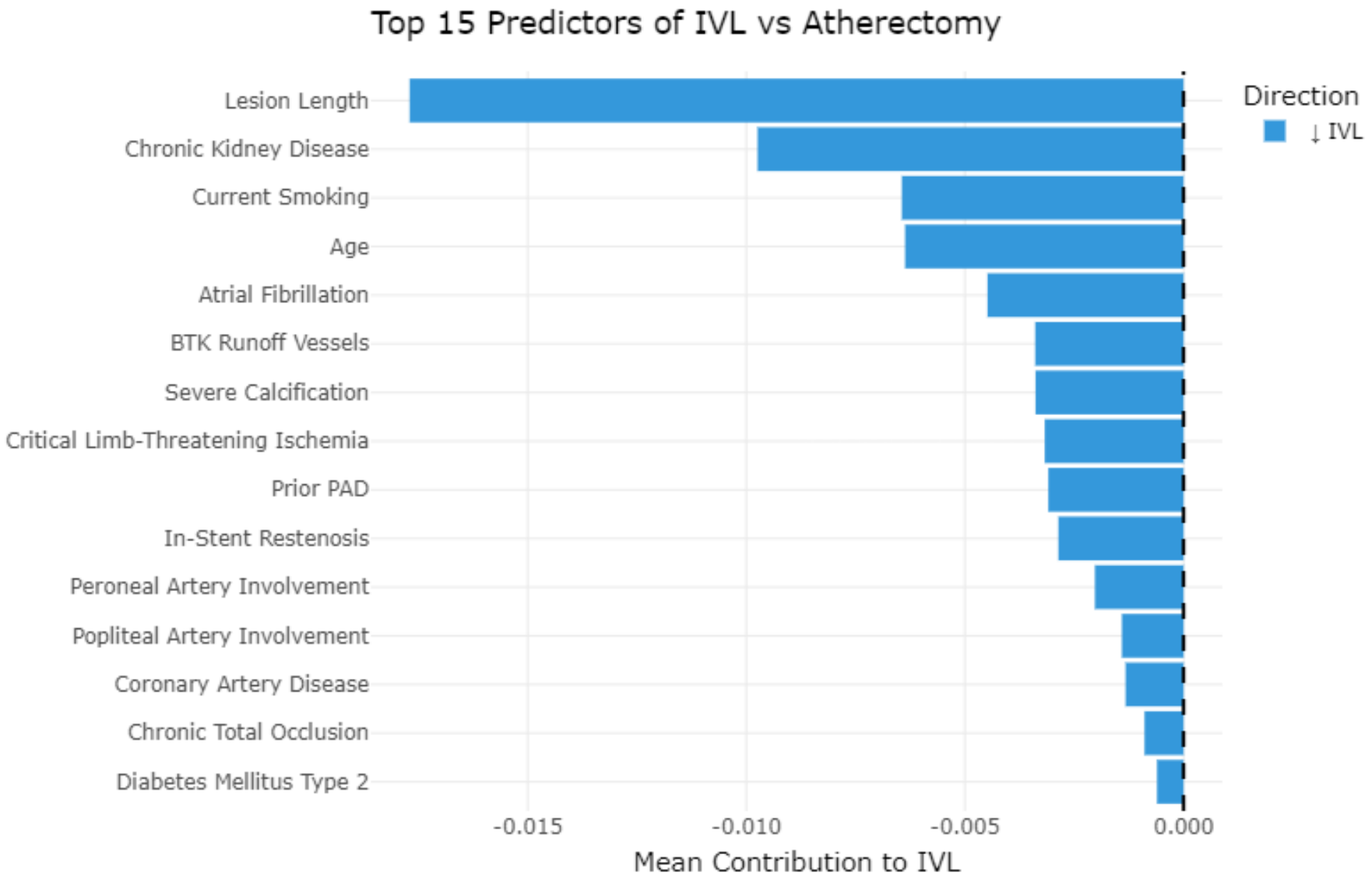
Variable	HR	95% CI	p-value
PTA	Ref		
IVL	1.11	0.77–1.59	0.574
Atherectomy	1.08	0.86–1.35	0.491
Cutting/ Scoring Balloon	1.09	0.78–1.52	0.631
HTN	1.32	0.85–2.05	0.22
Atrial fibrillation	1.53	1.11-2.10	0.009*
Heavily Calcified Lesion	0.96	0.69–1.32	0.786

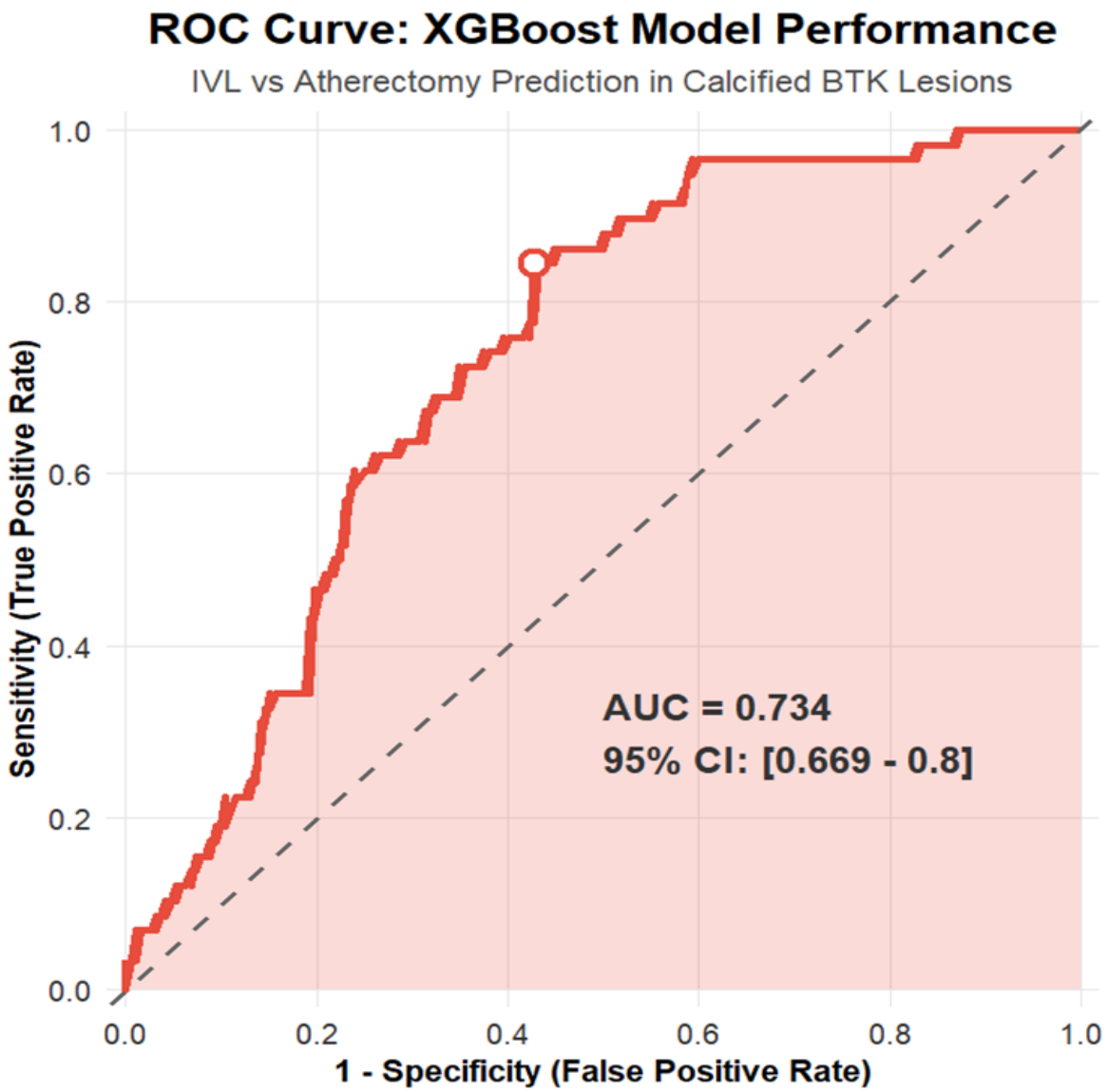
Secondary outcome: comparing 1-Year MALE outcomes by Heavy calcification



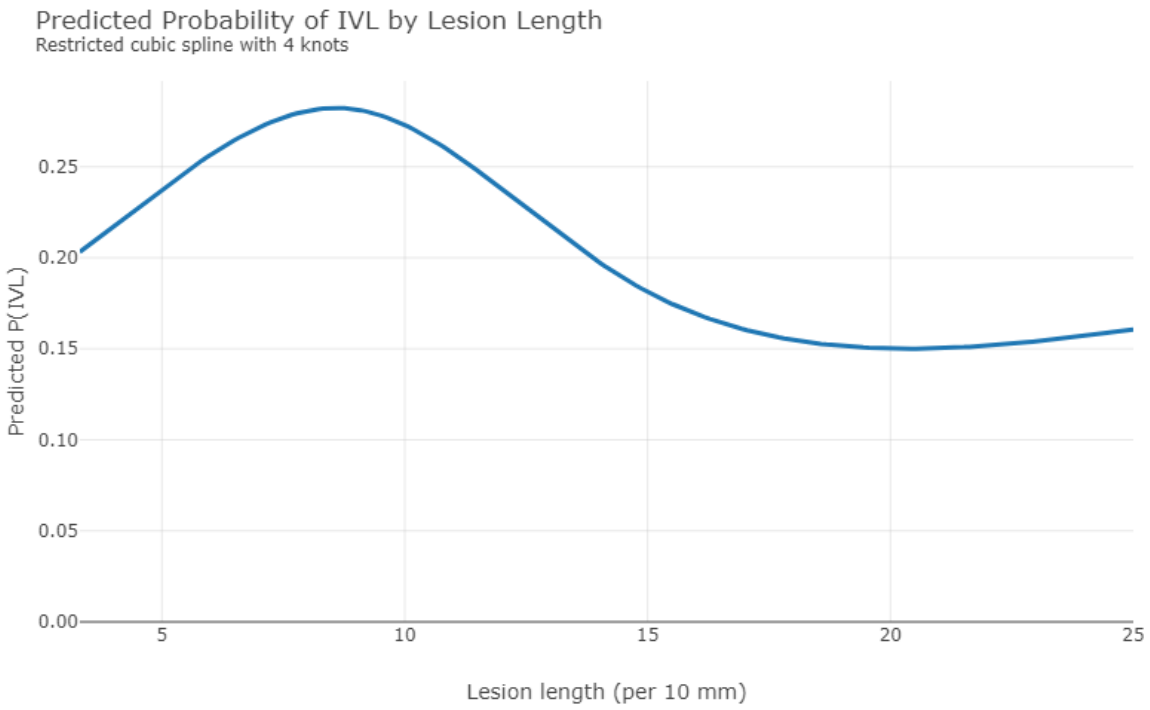
Variable	Hazard Ratio (HR)	95% CI	p-value
Heavy calcification Yes vs No	1.14	0.88–1.47	0.318
Age (years)	1.01	0.99–1.01	0.966
Gender (Male vs Female)	1.11	0.91–1.35	0.292
Smoking (Yes vs No)	1.02	0.81–1.27	0.892
CLTI (Yes vs No)	1.5	1.23–1.82	<0.001
Diabetes Mellitus Type 2	0.99	0.81–1.23	0.976
Chronic Kidney Disease	1.46	1.21–1.77	<0.001
Hypertension	0.91	0.66–1.25	0.554
Atrial Fibrillation	1.59	1.26–2.02	<0.001
Stents Used	1.01	0.83–1.22	0.921
PTA	Ref	Ref	Ref
IVL	1.04	0.75–1.42	0.824
Atherectomy	1.04	0.84–1.29	0.74
Cutting/Scoring Balloon	1.01	0.72–1.38	0.985


SHAP Summary: Feature Impact on IVL vs Atherectomy
Each dot represents one patient | Color indicates feature value (blue = low, red = high)
Chronic Kidney Disease
Lesion Length
Severe Calcification
Current Smoking
BTK Runoff Vessels
Age
Atrial Fibrillation
Critical Limb-Threatening Ischemia
In-Stent Restenosis
Prior PAD
Popliteal Artery Involvement
Peroneal Artery Involvement
Chronic Total Occlusion
Coronary Artery Disease
Diabetes Mellitus Type 2
-0.1
0.0
0.1
SHAP Value (Impact on IVL Prediction)
Feature Value
200
100
0


Top 15 Predictors of IVL vs Atherectomy
Lesion Length
Chronic Kidney Disease
Current Smoking
Age
Atrial Fibrillation
BTK Runoff Vessels
Severe Calcification
Critical Limb-Threatening Ischemia
Prior PAD
In-Stent Restenosis
Peroneal Artery Involvement
Popliteal Artery Involvement
Coronary Artery Disease
Chronic Total Occlusion
Diabetes Mellitus Type 2
-0.015
-0.010
-0.005
0.000
Mean Contribution to IVL
Direction
↓ IVL


ROC Curve: XGBoost Model Performance
IVL vs Atherectomy Prediction in Calcified BTK Lesions
Sensitivity (True Positive Rate)
1 - Specificity (False Positive Rate)
0.0
0.2
0.4
0.6
0.8
1.0
AUC = 0.734
95% CI: [0.669 - 0.8]

Logistic mode predicting choice of instrument (IVL vs Atherectomy):



Variable	OR_95CI	p-value
CKD	1.787 (1.258 to 2.537)	0.001
Smoking	0.623 (0.394 to 0.987)	0.044
Age every 10 years	1.034 (0.878 to 1.218)	0.685
Atrial Fibrillation	2.126 (1.333 to 3.391)	0.002
Heavily Calcified	0.508 (0.320 to 0.806)	0.004
BTK runoff vessels	0.895 (0.736 to 1.087)	0.264
RCS overall lP: Lesion length every 10 mm	LR test	0.008