

• 临床研究 •

冠状动脉造影及介入治疗患者辐射剂量的影响因素分析及预测模型构建

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[摘要] 目的: 探究影响冠状动脉造影(coronary angiography, CAG)及介入治疗(percutaneous coronary intervention, PCI)患者辐射剂量的因素, 并构建辐射剂量的临床预测模型。方法: 回顾性纳入2020年1月—2024年12月于南京医科大学第一附属医院就诊并行CAG的293例阻塞性冠心病患者, 按7:3比例随机分为训练集(208例)和测试集(85例)。以术中辐射剂量为结局, 基于临床特征及介入相关变量, 采用多种变量筛选和建模方法建立多因素线性回归预测模型并构建列线图, 在测试集中采用均方根误差(root mean square error, RMSE)、平均绝对误差(mean absolute error, MAE)、决定系数 R^2 和校准曲线评价模型性能。结果: 最终模型纳入年龄、体重指数(body mass index, BMI)、甘油三酯、高密度脂蛋白胆固醇(high-density lipoprotein cholesterol, HDL-C)、左室舒张末期内径(left ventricular end-diastolic diameter, LVDd)、左室射血分数(left ventricular ejection fraction, LVEF)、手术时间及透视时间8个变量。多因素分析显示BMI、LVDd、LVEF、手术时间和透视时间与辐射剂量呈正相关, HDL-C与辐射剂量呈负相关。模型在测试集中表现良好, RMSE为170.1, MAE为136.1, R^2 为0.55。校准曲线显示观测值与预测值的一致性较好。结论: 基于常规可获得的临床特征及介入相关指标构建的辐射剂量预测模型在内部验证中具有较好的预测性能, 可为CAG及PCI患者的辐射剂量风险评估和剂量管理提供参考。

[关键词] 冠心病; 冠状动脉造影; 冠状动脉介入治疗; 辐射剂量; 影响因素分析; 预测模型

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Analysis of influencing factors and development of a prediction model for radiation dose in patients undergoing coronary angiography and percutaneous coronary intervention

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[Abstract] **Objective:** To investigate the influencing factors of radiation dose in patients undergoing coronary angiography (CAG) and percutaneous coronary intervention (PCI), and to develop a clinical prediction model for radiation dose. **Methods:** A total of 293 patients with obstructive coronary artery disease who underwent CAG at the First Affiliated Hospital of Nanjing Medical University from January 2020 to December 2024 were retrospectively enrolled. Patients were randomly divided into a training set ($n=208$) and a testing set ($n=85$) at a ratio of 7:3. Intraoperative radiation dose was defined as the outcome variable. Based on clinical characteristics and interventional procedure-related variables, multiple variable selection and modeling methods were applied to establish a multivariable linear regression prediction model, and a nomogram was constructed. Model performance was evaluated in the testing set using the root mean square error (RMSE), mean absolute error (MAE), coefficient of determination (R^2), and calibration plot. **Results:** The final model included age, body mass index (BMI), triglycerides, high-density lipoprotein cholesterol (HDL-C), left ventricular end-diastolic diameter (LVDd), left ventricular ejection fraction (LVEF), procedure time, and fluoroscopy time. Multivariate analysis showed that BMI, LVDd, LVEF, procedure time, and fluoroscopy time were positively associated with radiation dose, whereas HDL-C was negatively associated with radiation dose. The model demonstrated good predictive performance in the testing set, with an RMSE of

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170.1, MAE of 136.1, and R^2 of 0.55. The calibration plot showed good agreement between the observed and predicted radiation doses. **Conclusion:** The radiation dose prediction model based on routinely available clinical and interventional variables showed good predictive performance in internal validation, and may provide a useful reference for radiation risk assessment and dose management in patients undergoing CAG and PCI.

[Key words] coronary heart disease; coronary angiography; percutaneous coronary intervention; radiation dose; analysis of influencing factors; prediction model

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冠状动脉造影(coronary angiography, CAG)及经皮冠状动脉介入治疗(percutaneous coronary intervention, PCI)是冠心病诊疗的关键技术。然而,这两类操作高度依赖透视和采集成像,患者及医务人员在操作过程中均会不可避免地暴露于电离辐射之下,可能增加皮肤损伤等组织反应以及远期致癌风险^[1-2]。因此,在保证图像质量和手术成功率的前提下实现剂量最优化,如遵循“尽可能低且合理可及”的原则,已成为介入心脏病学质量管理的重要组成部分^[1]。

近年来,多项研究显示,CAG及PCI患者术中辐射剂量在不同个体和不同医疗机构间存在显著差异,且其形成机制具有多因素、交互性和场景依赖性特征^[3]。既往研究表明,患者的体型如体重指数(body mass index, BMI)、冠状动脉病变数量和复杂程度(如分叉病变或慢性完全闭塞)、手术类型和操作策略,以及术者经验等因素均可对患者辐射负荷产生重要影响^[4-5]。在临床实践中,累积空气比释动能和剂量面积乘积被广泛用于量化患者接受的辐射剂量水平^[6-8]。同时,真实世界研究显示,以医疗团队为单位的辐射防护体系建设和流程化剂量管理措施可明显降低术中辐射剂量,提示该领域具有明确且可实现的干预空间^[7,9]。

然而,既往研究主要聚焦于CAG及PCI中辐射剂量的影响因素分析或剂量管理现状的描述,尚缺乏基于常规临床资料、可在术前或术中早期应用的个体化辐射剂量预测模型^[3-5]。尽管已有研究报道多种与辐射剂量相关的危险因素,但多数研究仅基于单一统计方法或单一维度进行变量筛选,结果的稳健性和可解释性相对不足^[4-5]。基于此,本研究拟整合临床指标及介入治疗相关参数,综合采用随机森林、单因素线性回归、最优子集回归、最小绝对值收敛和选择算子(least absolute shrinkage and selection operator, LASSO)回归和逐步向后回归等多种算法进行变量筛选和模型构建,并比较不同模型的预测性能,最终建立首个个体化辐射剂量预测模型,以

期为导管室辐射防护、剂量控制和质量改进提供更具可操作性的科学依据。

1 对象和方法

1.1 对象

本研究为单中心、回顾性、观察性研究,按照临床个体预后或诊断多变量预测模型的透明报告+人工智能(transparent reporting of a multivariable prediction model for individual prognosis or diagnosis+artificial intelligence, TRIPOD+AI)进行撰写及呈现^[10]。研究对象为2020年1月—2024年12月在南京医科大学第一附属医院行CAG和/或PCI的阻塞性冠心病患者。纳入标准:①经临床诊断为阻塞性冠心病;②年龄 ≥ 18 岁;③临床资料及影像学信息完整。排除标准:①既往行PCI或冠状动脉旁路移植术;②PCI未成功完成或患者拒绝PCI;③急性心肌梗死;④精神神经系统障碍、严重肝肾功能不全或妊娠期妇女;⑤合并恶性肿瘤、自身免疫性疾病、血液系统疾病或其他难治性疾病。阻塞性冠心病定义为CAG提示 ≥ 1 支心外膜下冠状动脉主要分支直径狭窄超过50%^[11]。严重肝功能不全诊断标准参考《肝衰竭诊治指南(2024年版)》中的肝衰竭诊断标准,包含急性、亚急性、慢加急性和慢性肝衰竭^[12]。根据改良肾脏病膳食改善(modification of diet in renal disease, MDRD)公式估算肾小球滤过率(estimated glomerular filtration rate, eGFR)^[13],并依据改善全球肾脏病预后组织指南定义严重肾功能不全为 $\text{eGFR} < 30 \text{ mL}/(\text{min} \cdot 1.73 \text{ m}^2)$ ^[14]。纳入患者按照7:3的比例随机分为训练集和测试集,分别用于预测模型的建立和内部验证。本研究方案已通过南京医科大学第一附属医院伦理委员会批准(伦理批号:2024-SR-1038),并豁免签署知情同意书。

1.2 方法

本研究的主要结局指标为患者术中辐射剂量,通过血管造影设备在CAG及PCI过程中自动计算并

累积记录的累积空气比释动能进行量化,辐射防护相关要求参照国家职业卫生标准执行^[15-16]。候选影响因素基于临床易用性、临床指南或共识及既往研究证据进行预先设定,主要包括人口学特征、基础疾病及用药史、实验室检查指标、心电图参数、超声心动图参数、冠状动脉病变特征以及介入相关参数(如手术时间和透视时间)。

1.3 统计学方法

统计分析采用R语言(版本4.5.1)软件完成。缺失数据通过多重插补进行处理。采用Shapiro-Wilks检验判断连续变量的正态性。正态分布的连续变量以均数±标准差($\bar{x} \pm s$)表示,组间比较采用 t 检验;非正态分布的连续变量以中位数(四分位数) $[M(P_{25}, P_{75})]$ 表示,组间比较采用Mann-Whitney U 检验;分类变量以频数(百分比) $[n(\%)]$ 表示,组间比较采用 χ^2 检验。预测模型的构建在训练集中完成。为实现数据降维和避免过拟合,首先采用随机森林算法对候选变量进行重要性评估并完成初步筛选,随后结合单因素线性回归、最优子集回归和LASSO回归等方法进一步筛选变量,并分别采用逐步向后法构建最终的预测模型。采用方差膨胀因

子评估变量间的多重共线性。为检验结果的稳健性,采用完整案例分析处理缺失数据后,重新拟合上述多因素线性回归模型作为敏感性分析。分别在训练集与测试集中评估模型的预测性能,主要评价指标包括均方根误差(root mean square error, RMSE)、平均绝对误差(mean absolute error, MAE)、决定系数(coefficient of determination, R^2),并绘制校准曲线。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 研究对象及基线特征

本研究共筛查299例行CAG及PCI的阻塞性冠心病患者,排除6例(其中5例不符合纳入标准,1例拒绝PCI),最终纳入293例阻塞性冠心病患者。按照7:3的比例随机分配至训练集208例和测试集85例(图1)。两组患者的人口学特征、实验室检查指标、心电图参数、超声心动图参数及介入相关参数等基线资料见表1。结果显示,两组患者的上述基线特征具有可比性,其中手术时间、透视时间及辐射剂量等关键指标在两组间差异均无统计学意义(P 均 >0.05)。

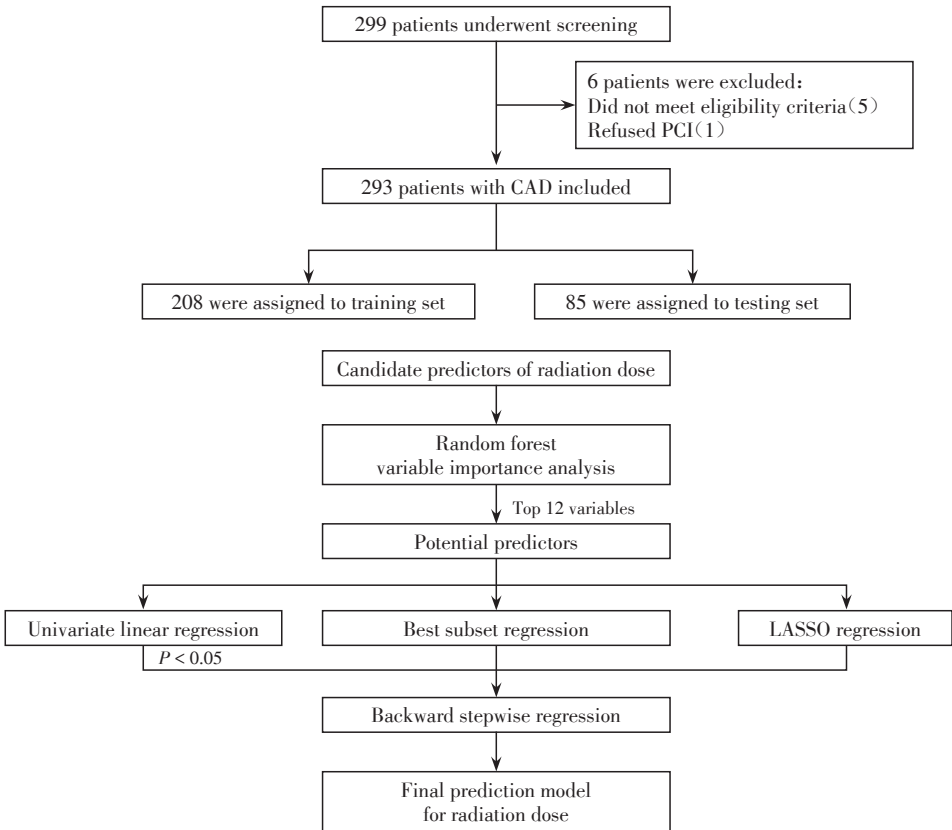


图1 研究对象筛选及辐射剂量预测模型构建流程图

Figure 1 Flowchart of patient selection and development of the radiation dose prediction model

表1 训练集和测试集患者的基线特征及冠状动脉造影和介入治疗特征的比较

Table 1 Comparison of baseline clinical characteristics and coronary angiographic and interventional findings between the training and testing cohorts

Characteristics	Total (<i>n</i> =293)	Training set (<i>n</i> =208)	Testing set (<i>n</i> =85)	<i>ν</i> / <i>Z</i> / <i>χ</i> ²	<i>P</i>
Demographics					
Age(years, $\bar{x} \pm s$)	61.5 $\pm$ 10.3	61.6 $\pm$ 10.6	61.4 $\pm$ 9.6	-0.142	0.887
Male[<i>n</i> (%)]	209(71.3)	148(71.2)	61(71.8)	<0.001	1.000
Smoking history[<i>n</i> (%)]	126(43.0)	88(42.3)	38(44.7)	0.061	0.805
Alcohol consumption[<i>n</i> (%)]	96(32.8)	69(33.2)	27(31.8)	0.009	0.924
BMI(kg/m ² , $\bar{x} \pm s$)	24.9 $\pm$ 3.2	25.1 $\pm$ 3.4	24.6 $\pm$ 2.9	-1.111	0.268
SBP[mmHg, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	132.0(121.0, 143.0)	131.0(121.0, 143.0)	133.0(121.0, 141.0)	0.019	0.985
DBP(mmHg, $\bar{x} \pm s$)	78.6 $\pm$ 10.6	78.2 $\pm$ 11.0	79.7 $\pm$ 9.7	1.188	0.236
Family history of CAD[<i>n</i> (%)]	11(3.8)	7(3.4)	4(4.7)	0.044	0.834
Duration of CAD[years, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	4.0(0.7, 24.3)	5.0(0.5, 24.3)	3.0(1.0, 12.2)	0.622	0.533
Laboratory tests					
TC[mmol/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	3.8(3.2, 4.6)	3.8(3.2, 4.7)	3.9(3.2, 4.5)	0.343	0.732
TG[mmol/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	1.4(1.0, 1.9)	1.4(1.1, 2.0)	1.4(1.0, 1.8)	0.814	0.416
HDL-C[mmol/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	1.0(0.9, 1.2)	1.0(0.9, 1.2)	1.0(0.9, 1.2)	-0.065	0.949
LDL-C[mmol/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	2.3(1.8, 3.0)	2.3(1.8, 3.0)	2.4(1.9, 2.8)	0.386	0.700
Lp(a)[mg/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	176.0(66.0, 420.0)	193.5(73.0, 454.5)	145.0(58.0, 357.0)	1.166	0.244
eGFR[mL/(min·1.73 m ²), $\bar{x} \pm s$]	104.0 $\pm$ 25.3	104.9 $\pm$ 26.6	102.0 $\pm$ 21.8	-0.962	0.337
hs-cTnT[ng/L, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	9.6(7.0, 14.0)	9.8(6.8, 14.7)	9.2(7.3, 12.8)	0.672	0.502
CK-MB[ng/mL, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	1.4(1.0, 1.9)	1.4(1.0, 1.9)	1.3(1.0, 1.9)	0.797	0.425
Instrumental examinations					
ECG abnormalities[<i>n</i> (%)]	133(45.4)	89(42.8)	44(51.8)	1.616	0.204
LVDd[mm, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	47.0(45.0, 50.0)	47.0(45.0, 50.0)	47.0(45.0, 49.8)	0.656	0.510
LVDs[mm, <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	31.0(30.0, 33.0)	31.0(30.0, 33.0)	31.0(30.0, 33.0)	0.806	0.416
LVEF[% , <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	63.3(61.9, 64.7)	63.0(61.9, 64.7)	63.6(62.1, 64.8)	-1.170	0.242
Coronary artery calcification[<i>n</i> (%)]				0.043	0.979
No	88(30.0)	62(29.8)	26(30.6)		
Yes	175(59.7)	125(60.1)	50(58.8)		
Mixed plaque	30(10.3)	21(10.1)	9(10.6)		
Coronary angiography					
Access site[<i>n</i> (%)]				3.673	0.159
Radial	289(98.6)	205(98.6)	84(98.8)		
Femoral	1(0.4)	0(0)	1(1.2)		
Radial and femoral	3(1.0)	3(1.4)	0(0)		
Special cardiac examinations[<i>n</i> (%)]				1.415	0.702
None	185(63.1)	132(63.5)	53(62.3)		
IVUS	74(25.3)	52(25.0)	22(25.9)		
OCT	31(10.6)	21(10.1)	10(11.8)		
FFR	3(1.0)	3(1.4)	0(0)		
Number of diseased coronary arteries[<i>n</i> (%)]				1.273	0.259
Single-vessel disease	166(56.7)	113(54.3)	53(62.4)		
Multi-vessel disease	127(43.3)	95(45.7)	32(37.6)		
Minimum luminal area stenosis[% , <i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	90.0(85.0, 95.0)	90.0(85.0, 95.0)	90.0(90.0, 95.0)	-0.772	0.425
Number of treated coronary vessels[<i>M</i> (<i>P</i> ₂₅ , <i>P</i> ₇₅)]	1.0(1.0, 2.0)	1.0(1.0, 2.0)	1.0(1.0, 2.0)	0.079	0.926

(续表 1)

Characteristics	Total (n=293)	Training set (n=208)	Testing set (n=85)	$t/Z/\chi^2$	P
Number of coronary stents[$M(P_{25}, P_{75})$]	1.0(1.0, 2.0)	1.0(1.0, 2.0)	1.0(1.0, 2.0)	0.199	0.831
Total stent length[mm, $M(P_{25}, P_{75})$]	33.0(22.0, 55.0)	33.0(22.0, 55.8)	33.0(24.0, 53.0)	-0.152	0.879
Minimum stent diameter[mm, $M(P_{25}, P_{75})$]	2.8(2.5, 3.0)	2.8(2.5, 3.0)	2.8(2.5, 3.0)	-0.826	0.402
Number of conventional balloons[$n(\%)$]				0.006	0.937
< 3	111(37.9)	78(37.5)	33(38.8)		
≥3	182(62.1)	130(62.5)	52(61.2)		
Number of drug-coated balloons[$n(\%)$]				0.923	0.337
None	218(74.4)	151(72.6)	67(78.8)		
≥1	75(25.6)	57(27.4)	18(21.2)		
Tube voltage[$n(\%)$]				< 0.001	0.990
70–80 kV	281(95.9)	200(96.2)	81(95.3)		
80–90 kV	12(4.1)	8(3.8)	4(4.7)		
Procedure time[$\text{min}, M(P_{25}, P_{75})$]	73.0(57.0, 93.0)	74.0(57.0, 93.0)	71.0(58.0, 87.0)	0.760	0.447
Fluoroscopy time[$\text{min}, M(P_{25}, P_{75})$]	13.6(9.5, 19.1)	13.9(9.6, 19.4)	12.6(9.1, 18.2)	0.595	0.552
Radiation dose[mGy, $M(P_{25}, P_{75})$]	270.0(148.0, 423.0)	265.0(148.0, 423.5)	270.0(143.0, 411.0)	0.114	0.909
Medical history[$n(\%)$]					
Hypertension	176(60.1)	127(61.1)	49(57.6)	0.168	0.682
DM	73(24.9)	53(25.5)	20(23.5)	0.041	0.840
Hyperlipemia	25(8.5)	21(10.1)	4(4.7)	1.609	0.205
AF	7(2.4)	3(1.4)	4(4.7)	1.534	0.215
Stroke	38(13.0)	30(14.4)	8(9.4)	0.935	0.333
Medication use[$n(\%)$]					
ACEI/ARB	90(30.7)	69(33.2)	21(24.7)	1.654	0.198
Beta-blocker	36(12.3)	22(10.6)	14(16.5)	1.436	0.231
CCB	78(26.6)	60(28.8)	18(21.2)	1.446	0.229
Statin	80(27.3)	59(28.4)	21(24.7)	0.244	0.622

ACEI: angiotensin-converting enzyme inhibitor; AF: atrial fibrillation; ARB: angiotensin II receptor blocker; BMI: body mass index; CAD: coronary artery disease; CCB: calcium channel blocker; CK-MB: creatine kinase-MB; DBP: diastolic blood pressure; DM: diabetes mellitus; ECG: electrocardiogram; eGFR: estimated glomerular filtration rate; FFR: fractional flow reserve; HDL-C: high-density lipoprotein cholesterol; hs-cTnT: high-sensitivity cardiac troponin T; IVUS: intravascular ultrasound; LDL-C: low-density lipoprotein cholesterol; Lp(a): lipoprotein(a); LVDd: left ventricular end-diastolic diameter; LVDs: left ventricular end-systolic diameter; LVEF: left ventricular ejection fraction; OCT: optical coherence tomography; SBP: systolic blood pressure; TC: total cholesterol; TG: triglyceride.

2.2 随机森林模型初步筛选辐射剂量的潜在影响因素

将52个候选变量纳入随机森林模型,分别基于平均准确率下降和节点纯度增加方法对变量重要性进行评估。各方法分别选取变量重要性排名前12位的变量,并取两种方法筛选结果的并集,最终得到16个与辐射剂量相关的潜在影响因素(图2)。上述变量包括年龄、BMI、收缩压、神经系统症状、总胆固醇、甘油三酯、高密度脂蛋白胆固醇(high-density lipoprotein cholesterol, HDL-C)、低密度脂蛋白胆固醇、eGFR、高敏肌钙蛋白T、左室舒张末期内径(left ventricular end-diastolic diameter, LVDd)、左室收缩末

期内径(left ventricular-end systolic diameter, LVDs)、左室射血分数(left ventricular ejection fraction, LVEF)、置入支架最小直径、手术时间和透视时间(表2)。

2.3 单因素线性回归、最优子集回归和LASSO回归进一步筛选辐射剂量的潜在影响因素

在随机森林初筛结果的基础上,进一步分别采用单因素线性回归(以 $P < 0.05$ 为判断标准)、最优子集回归和LASSO回归方法对候选变量进行筛选。3种方法分别筛选得到8、8、7个潜在独立影响因素。不同方法组合进入后续建模的变量情况见表2。随机森林+单因素线性回归模型纳入的候选变量为BMI、甘油三酯、HDL-C、LVDd、LVDs、置入支

架最小直径、手术时间和透视时间。随机森林+最优子集回归模型纳入的候选变量为年龄、BMI、甘油三酯、HDL-C、LVDd、LVEF、手术时间和透视时间。

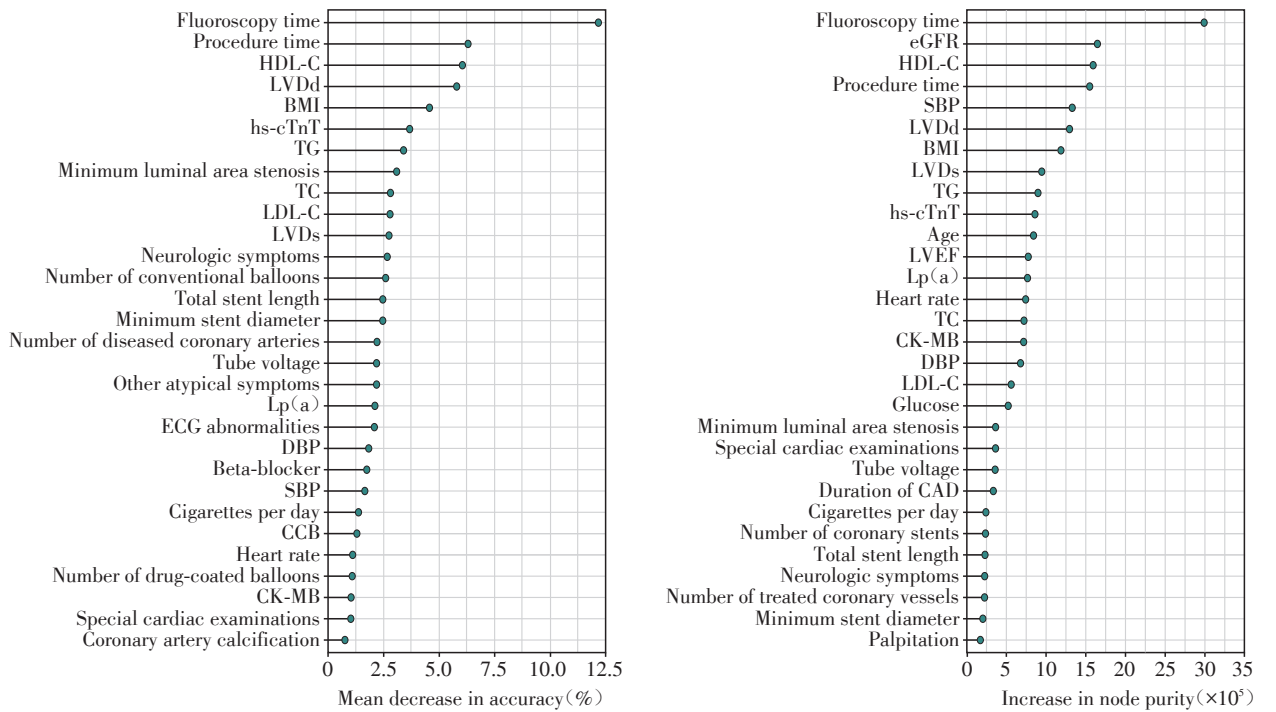
随机森林+LASSO回归模型纳入的候选变量为BMI、

表2 不同变量筛选和建模策略下辐射剂量预测模型的构建及性能比较

Table 2 Development and performance comparison of radiation dose prediction models using different variable selection and modeling strategies

Algorithm	Initially included variables	Finally included variables	Training set			Testing set		
			RMSE	MAE	R ²	RMSE	MAE	R ²
Random forest algorithm	Age,BMI,SBP,neurologic symptoms,TC,TG,HDL-C,LDL-C,eGFR,hs-cTnT,LVDd,LVDs,LVEF,minimum stent diameter,procedure time,fluoroscopy time	-	-	-	-	-	-	-
Random forest algorithm+univariate linear regression	BMI,TG,HDL-C,LVDd,LVDs,minimum stent diameter,procedure time,fluoroscopy time	BMI,HDL-C,LVDd,procedure time,fluoroscopy time	289.5	168.7	0.38	174.1	139.7	0.51
Random forest algorithm+best subset regression	Age,BMI,TG,HDL-C,LVDd,LVEF,procedure time,fluoroscopy time	Age,BMI,TG,HDL-C,LVDd,LVEF,procedure time,fluoroscopy time	282.8	168.8	0.41	170.1	136.1	0.55
Random forest algorithm+LASSO regression	BMI,neurologic symptoms,TG,HDL-C,LVDd,procedure time,fluoroscopy time	BMI,neurologic symptoms,HDL-C,LVDd,procedure time,fluoroscopy time	287.5	169.7	0.39	175.9	141.4	0.50

BMI: body mass index; eGFR: estimated glomerular filtration rate; HDL-C: high-density lipoprotein cholesterol; hs-cTnT: high-sensitivity cardiac troponin T; LASSO: least absolute shrinkage and selection operator; LDL-C: low-density lipoprotein cholesterol; LVDd: left ventricular end-diastolic diameter; LVDs: left ventricular end-systolic diameter; LVEF: left ventricular ejection fraction; MAE: mean absolute error; RMSE: root mean square error; SBP: systolic blood pressure; TC: total cholesterol; TG: triglyceride.



A: Variable importance measured by mean decrease in accuracy. B: Variable importance measured by increase in node purity.

图2 随机森林模型中辐射剂量潜在影响因素的重要性排序

Figure 2 Variable importance of potential predictors of radiation dose based on the random forest model

神经系统症状、甘油三酯、HDL-C、LVDd、手术时间和透视时间。

2.4 逐步向后回归模型的比较

分别基于以上3组候选变量,采用逐步向后回归方法构建最终的预测模型。3种模型在训练集和测试集中的预测性能比较结果见表2。其中,随机森林+最优子集回归+逐步向后回归模型在训练集中表现最佳,其RMSE为282.8,MAE为168.8, R^2 为0.41,故选定该模型作为最终的预测模型。

2.5 辐射剂量预测模型的构建

基于随机森林+最优子集回归+逐步向后回归模型,最终共纳入8个变量,包括年龄、BMI、甘油三酯、HDL-C、LVDd、LVEF、手术时间和透视时间(表2)。多因素线性回归分析结果显示,BMI($\beta=14.77$, 95%CI: 0.98~28.56, $P=0.037$)、HDL-C($\beta=-296.87$, 95%CI: -483.49~-110.24, $P=0.002$)、LVDd($\beta=15.60$, 95%CI: 4.07~27.12, $P=0.009$)、LVEF($\beta=9.92$, 95%CI: 0.80~19.04, $P=0.034$)、手术时间($\beta=1.74$, 95%CI: 0.04~3.44, $P=0.046$)和透视时间($\beta=13.03$, 95%CI: 6.85~19.20, $P<0.001$)与辐射剂量显著相

关;年龄和甘油三酯在模型中呈边缘相关或差异无统计学意义(表3)。各变量的方差膨胀因子均 <2.5 ,无明显多重共线性。敏感性分析证实上述关联模式具有稳健性(表4)。基于该模型绘制列线图,从而用于个体化辐射剂量的预测(图3)。

表3 冠心病患者辐射剂量最终预测模型的多因素线性回归分析

Table 3 Multivariable linear regression analysis of the final prediction model for radiation dose in patients with coronary artery disease

Characteristics	Multivariate analysis		
	β (95% CI)	P	VIF
Age	3.99(0.01-7.98)	0.051	1.150
BMI	14.77(0.98-28.56)	0.037	1.386
TG	34.53(-7.46-76.52)	0.109	1.179
HDL-C	-296.87(-483.49~-110.24)	0.002	1.183
LVDd	15.60(4.07-27.12)	0.009	2.042
LVEF	9.92(0.80-19.04)	0.034	1.732
Procedure time	1.74(0.04-3.44)	0.046	2.042
Fluoroscopy time	13.03(6.85-19.20)	<0.001	2.240

VIF: variance inflation factor.

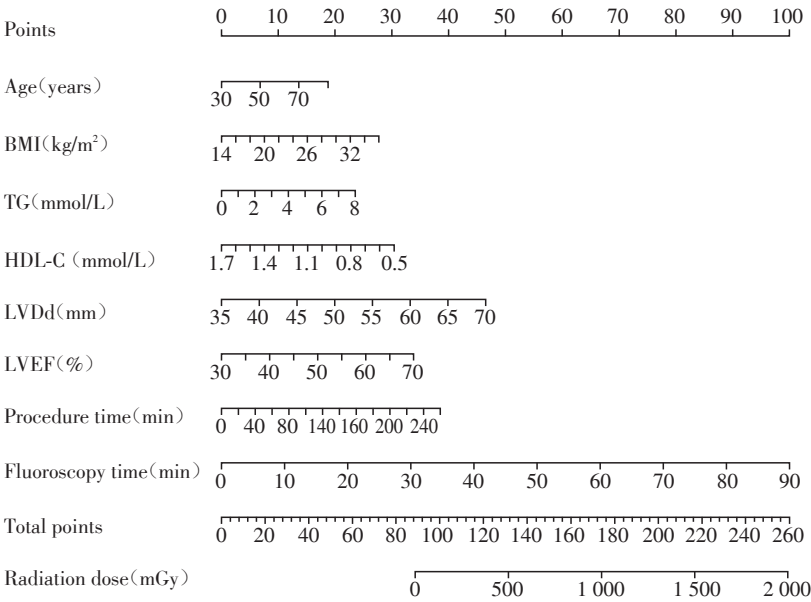


图3 基于多种变量筛选及建模策略构建的辐射剂量最优预测模型列线图

Figure 3 Nomogram of the optimal radiation dose prediction model developed using multiple variable selection and modeling strategies

2.6 辐射剂量预测模型的性能评估

最终模型在训练集和测试集中均显示观测值与预测值具有良好一致性和相关性。其中,测试集的RMSE为170.1、MAE为136.1、 R^2 为0.55($P<0.001$)。分别基于训练集和测试集数据绘制模型的校准曲

线,结果显示校准度良好(表2,图4)。

3 讨论

CAG及PCI是诊治冠心病的重要手段,但在操作过程中不可避免地会产生电离辐射暴露。随着

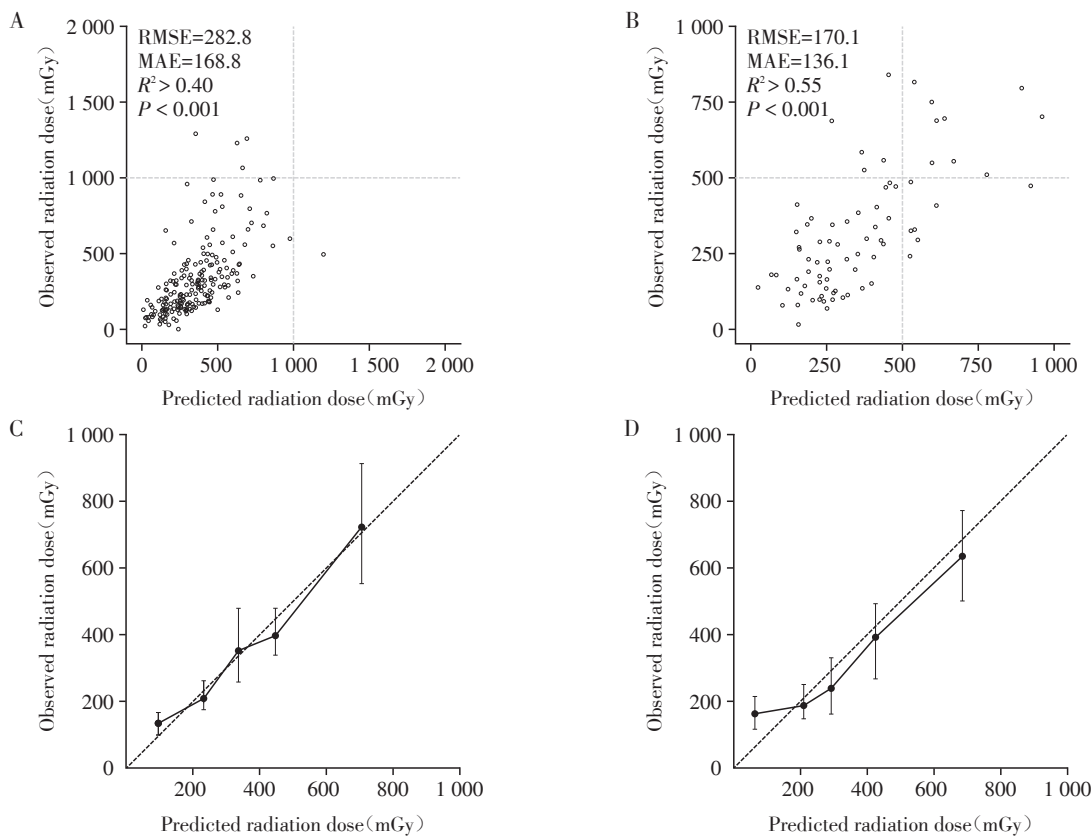
表4 完整案例分析下冠心病患者辐射剂量最终预测模型的多因素线性回归分析

Table 4 Multivariable linear regression analysis of the final prediction model for radiation dose in patients with coronary artery disease based on complete case analysis

Characteristics	Multivariate analysis		
	β (95% CI)	<i>P</i>	VIF
Age	4.11(0.05–8.18)	0.048	1.153
BMI	14.55(0.67–28.43)	0.041	1.377
TG	36.26(–6.08–78.59)	0.095	1.180
HDL-C	–290.53(–478.66–102.41)	0.003	1.182
LVDd	15.42(3.79–27.04)	0.010	2.032
LVEF	9.63(0.44–18.82)	0.041	1.736
Procedure time	1.77(0.06–3.49)	0.043	2.025
Fluoroscopy time	12.90(6.68–19.12)	< 0.001	2.213

介入技术的广泛应用,患者在术中的辐射剂量逐渐受到关注,过高的辐射剂量可导致皮肤损伤和远期辐射相关风险升高等不良健康结局^[1–2]。识别术中辐射剂量的影响因素并实现辐射剂量的准确评估,对于优化操作策略和降低辐射暴露具有重要意义。

既往关于辐射剂量的研究多侧重于危险因素分析、临床或技术复杂度分层以及诊断参考水平的建立,而针对单个患者进行辐射剂量个体化预测的研究仍相对有限^[4, 17]。基于此,本研究基于单中心真实世界中接受CAG及PCI的阻塞性冠心病患者,整合临床指标和介入治疗相关参数,采用多种变量筛选和建模方法系统分析术中辐射剂量的影响因素,并构建可视化列线图模型,以实现术中辐射剂量的个体化预测和评估。最终模型纳入年龄、BMI、甘油三酯、HDL-C、LVDd、LVEF、手术时间和透视时



Comparison of the observed versus predicted radiation doses in the training set (A, $n=208$) and the testing set (B, $n=85$). Calibration plots of the model in the training set (C) and the testing set (D).

图4 最优预测模型在训练集和测试集中的一致性分析

Figure 4 Agreement analysis of the optimal prediction model in the training and testing sets

间,在测试集中具有较好的解释度和可接受的预测误差,提示该模型在阻塞性冠心病患者术中辐射剂量的个体化评估方面具有一定的应用价值^[18–19]。

本研究发现 BMI、透视时间和手术时间与辐射

剂量呈显著正相关,提示患者体型因素、操作时长和透视负荷仍是驱动介入操作中患者受照剂量差异的核心决定因素^[4, 7]。既往研究证实,体型和体表相关指标可通过增加射线衰减而提高设备曝光

需求,而透视时间则与射线出束时长直接相关,二者均是心血管介入过程中辐射剂量升高的关键因素^[3-4,20]。本研究结果与上述证据相一致,进一步支持在辐射剂量管理实践中优先关注体型差异和操作时长控制^[3,7]。

低HDL-C常与不良心脏代谢谱并存,并与斑块进展和冠状动脉粥样硬化负荷增加独立相关^[21-22]。在介入操作中,当冠状动脉病变呈弥漫性、多支受累、钙化、长病变或复杂分叉等特征时,通常需要进行更多角度的重复造影、器械交换和病变预处理,并采用更复杂的分叉支架策略。LVDD增加通常提示左心室重构或容量负荷增加,而左心室重构往往与更严重的冠状动脉病变特征相关^[23]。同时,LVDD增加可伴随心脏结构改变、心影增宽及冠状动脉重叠增加,可能需要采用更多投照角度及重复确认^[24]。此外,在左心室收缩功能较好、病变相对较轻且整体风险较低的患者中,术者更倾向于实施更为积极和完整的PCI重建策略,通常需要进行更多器械操作、影像指导和重复验证^[25-27]。因此,本研究发现HDL-C与辐射剂量呈显著负相关,而LVDD和LVEF与辐射剂量呈显著正相关,该结果可能在一定程度上反映“复杂病变-复杂操作-辐射剂量增加”的间接作用路径,不宜直接作线性因果解释。

在多因素线性回归分析中,年龄和甘油三酯未达统计学显著性水平,但在随机森林+最优子集回归的变量筛选阶段均被选入候选变量集,且在逐步向后回归中保留上述变量后模型性能未见明显劣化,提示二者对模型整体解释能力具有一定贡献。从临床角度来看,年龄和甘油三酯均与冠状动脉粥样硬化负荷和病变复杂度独立相关,可能影响介入操作的复杂程度和成像需求^[28-29]。因此,本研究最终仍将年龄和甘油三酯纳入最终预测模型,但应注意其统计学效应可能受到样本量或未测混杂因素的影响,有待在更大样本或外部队列中进一步评估。

从临床的角度来看,介入放射防护的核心目标是在保证诊疗获益的前提下落实医疗照射的正当化和最优化原则,并通过流程化剂量管理及医疗团队层面的辐射安全文化建设减少不必要的照射^[1-3]。我国现行的职业卫生与医疗照射防护标准亦对医疗放射防护的基本要求和实施原则作出了明确规范^[15-16]。本研究所构建的模型使用的变量多为临床及导管室常规可获取的信息,若能在院内信息化系统或导管室质控流程中加以集成,有望在术前或术中早期识别潜在高剂量暴露风险患者,支持针对性

的参数优化和操作策略调整,从而为机构层面的辐射安全管理、质量改进及诊疗过程规范化提供量化决策依据^[1,24,30]。

本研究仍存在一定局限性。首先,单中心回顾性研究设计可能引入选择偏倚,且本研究仅完成内部验证,模型在不同医疗机构、不同设备配置及不同术者操作习惯下的泛化能力,仍需通过外部验证及必要的模型更新进行评估^[18-19]。其次,本研究的结局指标只能反映设备记录的剂量水平,未能同步纳入剂量面积乘积或峰值皮肤剂量等更全面的剂量学终点,后续研究中可结合国际放射防护委员会更推荐的剂量指标体系进行补充和对照分析^[1,6,24]。再次,部分可能影响辐射剂量的重要信息(如帧率与脉冲模式、准直使用情况、投照角度分布、病变复杂度的精细分型和术者相关因素)未能完全纳入模型构建过程,故模型仍有进一步优化空间^[1,7,24,31-32]。最后,本研究所采用的设备型号和术者均相对固定,但在实际临床实践中,CAG及PCI中设备型号和介入术者的操作习惯和经验水平可能存在一定差异,该预测模型的外部适用性仍有待在不同医院和不同医疗背景下通过多中心研究加以验证。

综上,本研究构建的辐射剂量预测模型在内部验证中表现良好,且核心影响因素与既往研究证据总体一致,提示该模型具备一定的临床转化潜力。未来有必要进一步开展多中心外部验证,补充设备与疾病复杂度的相关变量,并结合院内剂量预警与质量改进措施,系统评估其在降低高剂量暴露风险及提升放射防护依从性方面的真实世界效果。

利益冲突声明:

所有作者声明无利益冲突。

Conflict of Interests:

All authors declare no conflicts of interest.

作者贡献声明:

冯婕、渠强、雷心仪负责研究设计、数据收集与分析、论文初稿撰写。陈思彤、鲍志鹏、左智参与数据收集、整理与统计分析。李新立负责研究方法指导与数据验证。王晖、姚文明负责研究整体指导、论文构思、最终稿修订与审阅。

Author's Contributions:

FENG Jie, QU Qiang, and LEI Xinyi were responsible for the study design, data collection and analysis, and drafting of the manuscript. CHEN Sitong, BAO Zhipeng, and ZUO Zhi participated in data collection, organization, and statistical analysis. LI Xinli provided methodological guidance and data validation. WANG Hui and YAO Wenming supervised the overall research, conceptualized the study, and reviewed and revised the final manuscript.

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