RWD64

Real-World Analysis of Healthcare Resource Utilization in Patients With Coronary Artery Disease Undergoing Paclitaxel-Coated Balloon Angioplasty With And Without Intravascular Ultrasound (IVUS) Guidance

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Introduction

Background:

- Ischaemic heart disease (IHD) is a leading cause of morbidity & mortality[1]
- Drug-eluting stents (DES) have improved percutaneous coronary intervention (PCI) outcomes; however, challenges remain, including late thrombosis, prolonged dual antiplatelet therapy (DAPT), and suboptimal healing[2-5]
- **Drug-coated balloons (DCBs)** provide a **scaffold-free alternative** and have shown promise, particularly in small vessels and in-stent restenosis (ISR)[6-8]
- Gap: Limited evidence on the **role of IVUS guidance in DCB angioplasty**

Objective:

To evaluate the real-world impact of **IVUS guidance during paclitaxel-DCB angioplasty in patients with coronary artery disease (CAD) on:**

- 12-month restenosis
- 12-month target lesion revascularization (TLR)
- Healthcare resource utilization (HRU)

Methods

Study design	• **Retrospective cohort study, tertiary cardiac center, Malaysia**
Data source	• **Medical records** • **Computed Tomography Angiography (CTA) and coronary angiograms & reports**
Population	• **1,245 patients (1,668 lesions)** • Adult IHD patients treated with **Paclitaxel-Coated Balloon** from 2019 to 2023
Groups	• **IVUS-guided vs. angiography-only (at operator's discretion)**
Endpoints	• **Primary: 12-month lumen restenosis (>50% stenosis)** • **Secondary:** - **12-month TLR** - **HRU: Rehospitalizations, Outpatient Department (OPD) visits, Emergency Department (ED) visits**
Analysis	• **Time-to-event outcomes (12-mo restenosis, TLR): Kaplan-Meier and Cox proportional hazards regression analyses**, with adjustment for patient and lesion characteristics • **HRU:** two-part regression models for rehospitalizations, OPD visits and ED visits, adjusted for clinical and lesion-level covariates; 95% CIs derived via bootstrap

Number of cases of DCB procedure =1,245 (mean age: 58.80 ± 10.37 years)

↓

Number of lesions treated with DCB =1,668

↓

IVUS guided: 656 (39.3%)

Non-IVUS guided: 1,012 (60.7%)

Figure 1. Study Flow Diagram

Results

Baseline Lesion Characteristics and Lesion Preparation

- **Baseline lesion complexity was higher** in the IVUS-guided group (Table 1)
- IVUS guidance **improved vessel measurement, optimized balloon sizing, detection of calcification, and enabled better lesion preparation using advanced plaque modification techniques (Table 2)**

Characteristics	Overall	Non-IVUS	IVUS	p-Value
n, number of lesions	1668	1012	656	
Lesion type, n (%)				
In-Stent Restenosis (ISR) or Restenosis (No Prior Stent)	215 (12.9)	**79 (7.8)**	**136 (20.7)**	**<0.001**
Lesion complexity: Type C, n (%)	1098 (65.8)	**570 (56.3)**	**528 (80.5)**	**<0.001**
Calcified lesion, n (%)	126 (7.6)	**54 (5.3)**	**72 (11.0)**	**<0.001**
Ostial, n (%)	208 (12.5)	**98 (9.7)**	**110 (16.8)**	**<0.001**
Pre-PCI reference vessel diameter (mm), mean (SD)	2.80 (0.55)	**2.65 (0.45)**	**3.03 (0.62)**	**<0.001**
Pre PCI TIMI flow grade, n (%)				
TIMI-0	139 (8.3)	**74 (7.3)**	**65 (9.9)**	**<0.001**
TIMI-1	299 (17.9)	**162 (16.0)**	**137 (20.9)**	
Total lesion length (mm), mean (SD)	38.05 (26.78)	**34.59 (23.86)**	**43.43 (30.01)**	**<0.001**

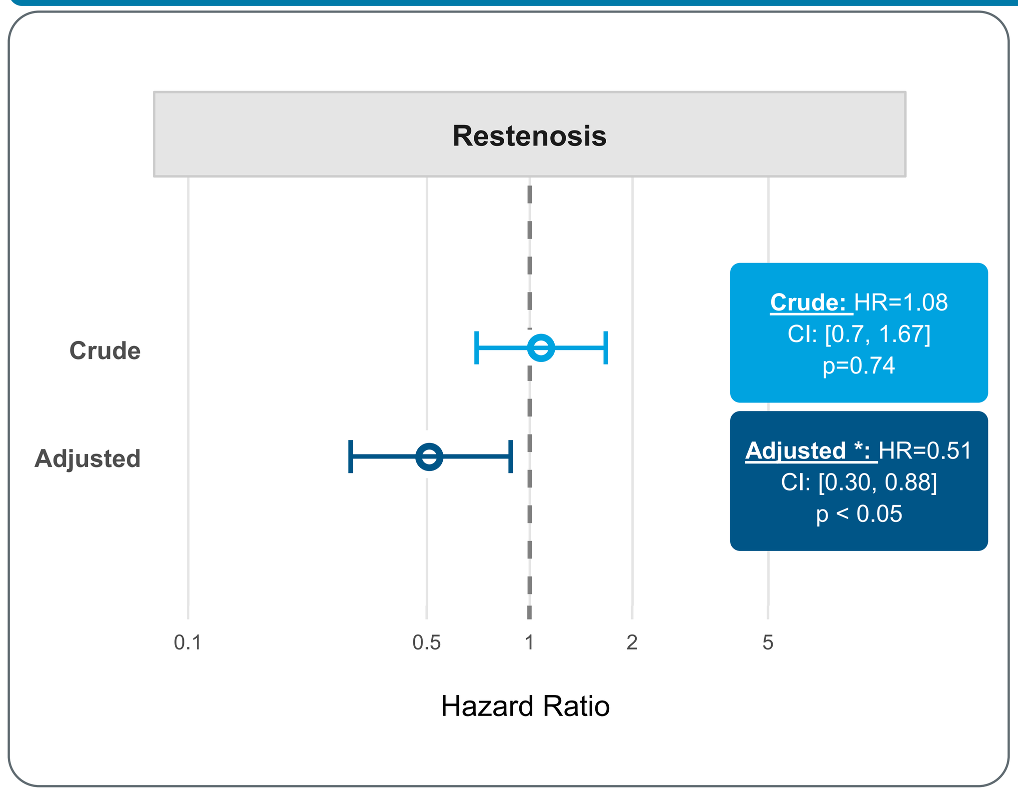
PCI: Percutaneous coronary intervention; TIMI: Thrombolysis in Myocardial Infarction

Table 1: *Baseline lesion characteristics and vessel complexity*

Lesion preparation	Overall	Non-IVUS	IVUS	p-Value
Conventional balloon, n (%)	1163 (69.7)	**768 (75.9)**	**395 (60.2)**	**<0.001**
Super high-pressure balloon, n (%)	315 (18.9)	**136 (13.4)**	**179 (27.3)**	**<0.001**
Scoring balloon, n (%)	464 (27.8)	**262 (25.9)**	**202 (30.8)**	**0.033**
Cutting balloon, n (%)	235 (14.1)	**118 (11.7)**	**117 (17.8)**	**0.001**
Atherectomy devices, n (%)	36 (2.2)	**15 (1.5)**	**21 (3.2)**	**0.029**
Maximum balloon post-dilatation size (mm), mean (SD)	3.49 (0.71)	**3.25 (0.66)**	**3.74 (0.67)**	**<0.001**

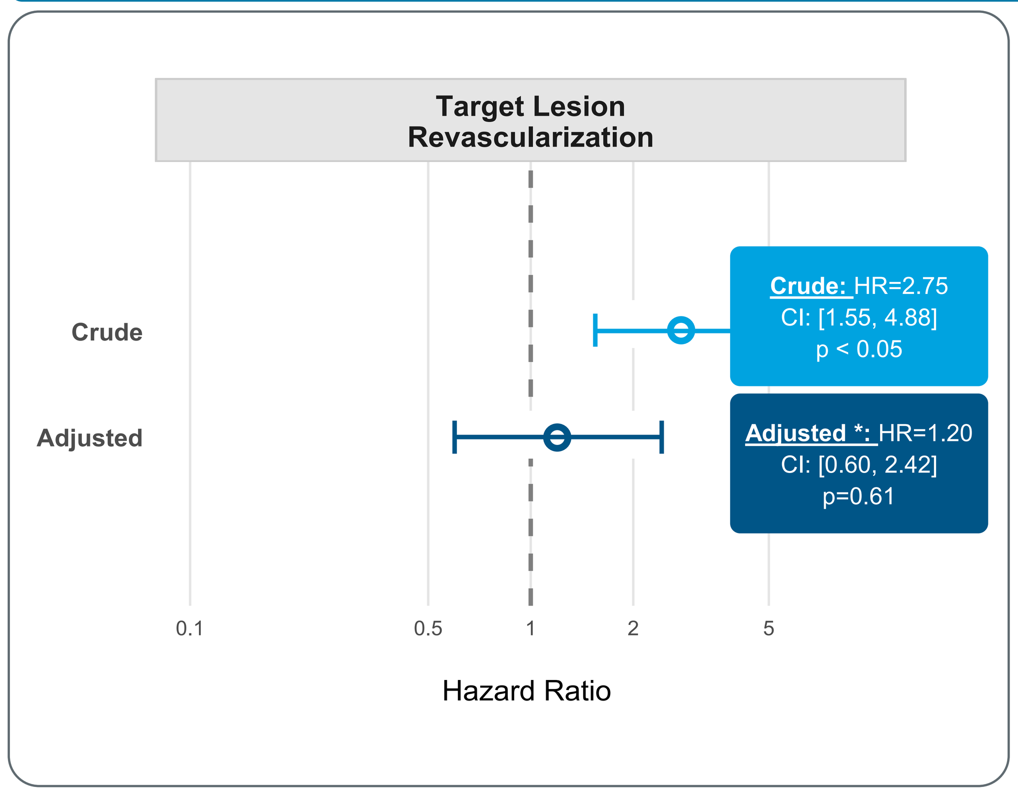
Table 2: *Lesion preparation*

Primary Endpoint: Restenosis



- **Follow-up Angiographic Data**: Available for **510 lesions (30.6%)**
- **Restenosis Rate (>50% Diameter Stenosis)**:
  - **Overall**: 15.5% (92 lesions)
  - **Crude Comparison**:
    - › IVUS-guided: **17.4% (32 lesions)**
    - › Non-IVUS-guided: **14.6% (60 lesions)** (HR p=0.74)
- **Adjusted Analysis**: Restenosis **↓ 49%** with IVUS (HR 0.51; p<0.05) after adjusting for lesion complexity and other confounders

Secondary Endpoint: TLR



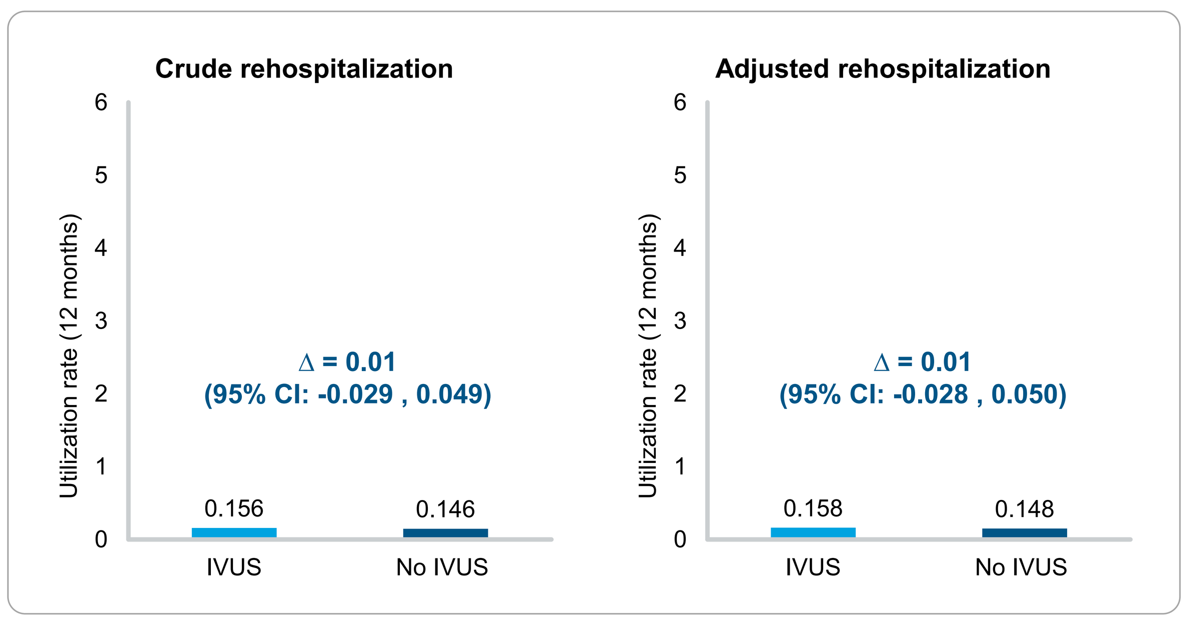
- **Follow-up Clinical Data**: Available for **all patients**
- **12-month TLR rate**
  - **Overall**: 1.5% (19 lesions)
  - **Crude Comparison**:
    - › IVUS-guided: **2.0% (10 lesions)**
    - › Non-IVUS-guided: **1.2% (9 lesions)** (HR p<0.05)

  Note: Higher baseline lesion complexity in IVUS group
- **Adjusted analysis**: IVUS group achieved a **comparable TLR rate** compared to non-IVUS group

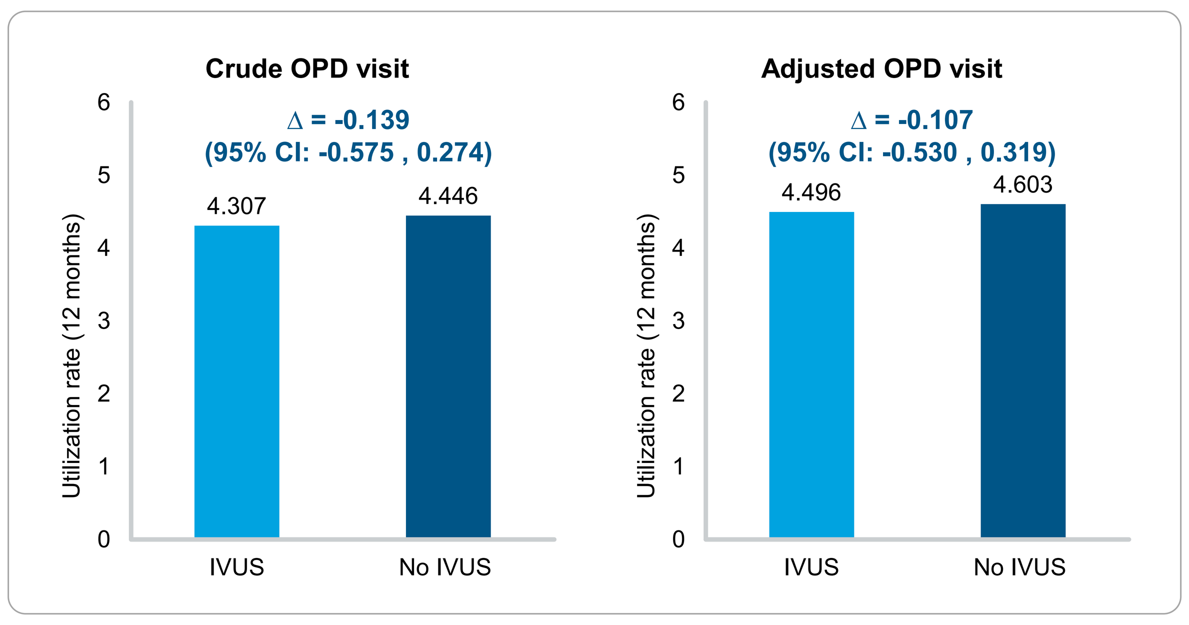
**After adjustments for age, sex, lesion type, lesion complexity, LMS, ostial, reference vessel diameter, pre-PCI TIMI flow grade, pre-procedure stenosis diameter, total lesion length, bifurcation, lesion in side branch, DCB predilatation diameter, HbA1c, serum creatinine, documented significant CAD, new onset angina, and previous PCI*

Secondary Endpoint: Healthcare Resource Utilization

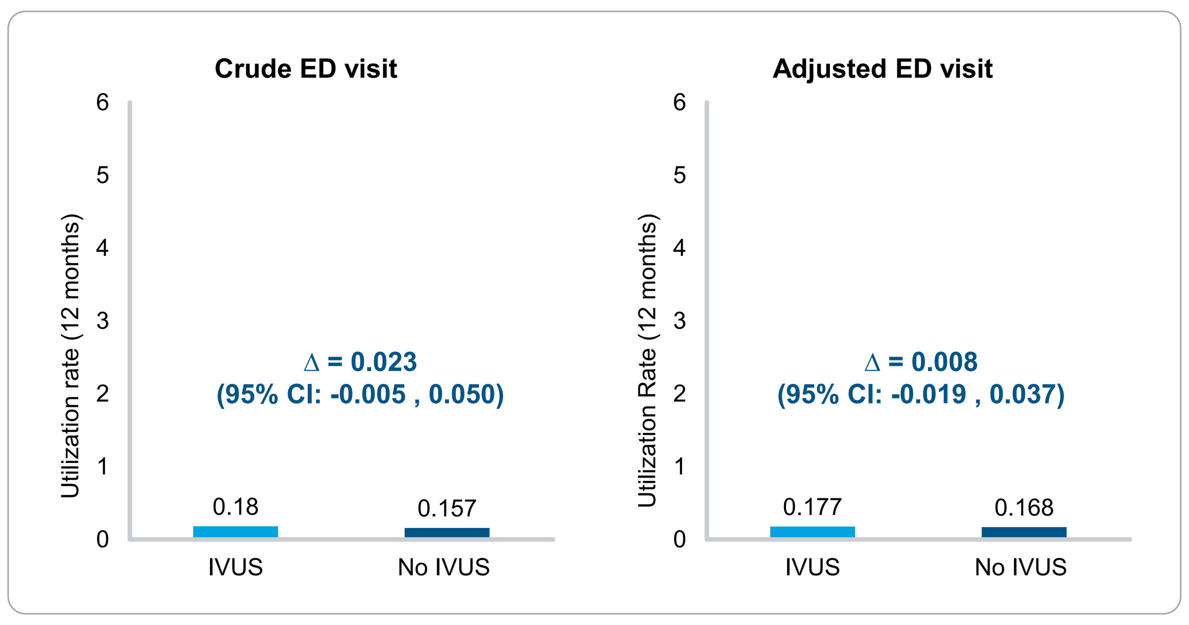
Rehospitalizations



Outpatient Department (OPD) Visits



Emergency Department (ED) Visits



**After adjustments for age, BMI, smoking status, lesion type, lesion location, lesion complexity, pre-PCI TIMI flow grade, HbA1c, serum creatinine, LDL level and hypertension*

Conclusions

IVUS guidance improves clinical and procedural outcomes

- **Mechanistic advantages:** Enhances vessel sizing, lesion preparation, and calcification detection
- **Reduced restenosis risk**
- **Low event rates of TLR;** Comparable rates after adjusting for lesion and baseline characteristics, including lesion complexity

Healthcare utilization remains comparable

- **No increase in HRU** in a population with high lesion complexity
- By lowering restenosis risk, IVUS may reduce downstream need for repeat revascularization and associated costs

Value-based adoption of IVUS-guided DCB PCI

- IVUS shows potential as valuable adjunct to standard practice
- Supports **value-based adoption**: **IVUS use in high-risk anatomies may maximize clinical benefit and healthcare system efficiency**

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