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Procedural and Clinical Outcomes of Coronary Intravascular Lithotripsy in Patients With Impaired Renal Function: A Multicenter Retrospective Study

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Chronic kidney disease (CKD) is a prevalent comorbidity in patients undergoing percutaneous coronary intervention (PCI), yet its impact on outcomes following intravascular lithotripsy (IVL) remains insufficiently studied. This study evaluated procedural and long-term outcomes of IVL-assisted PCI in patients with renal insufficiency compared to those with normal renal function. From the BENELUX-IVL registry (May 2019 −September 2024), 558 patients were included in a retrospective multicenter analysis. Renal insufficiency was defined as estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2 using the CKD-EPI formula. The primary endpoint was major adverse cardiovascular events (MACE) at one and two years of follow-up. Secondary endpoints included procedural, device, and technical success, as well as all-cause mortality. Multivariable logistic regression was used to identify independent predictors of mortality. A total of 586 lesions were treated in 558 patients: 190 (32.4%) with renal insufficiency and 396 (67.6%) with normal renal function. One-year MACE occurred in 14 (13.3%) versus 28 (10.9%) patients (p = 0.80), and between year one and two in 4 (5.6%) versus 5 (2.8%) patients (p = 0.46). Procedural success was similar between groups (88.6% versus 88.7%; p = 0.97). All-cause mortality was higher in the renal insufficiency group (*n* = 32, 18.2% versus *n* = 44, 11.5%; p = 0.03). On multivariable analysis, eGFR was independently associated with mortality (OR 0.98; 95% CI 0.97−1.00; p = 0.020). In conclusion, IVL-assisted PCI resulted in similar procedural and MACE outcomes regardless of renal function, although mortality was significantly higher in patients with renal insufficiency.

Abbreviations: CAC, coronary artery calcification; CKD, chronic kidney disease; DS, diameter stenosis; eGFR, estimated glomerular filtration rate; ICI, intracoronary imaging; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LM, left main coronary artery; MACE, major adverse cardiovascular events; MI, myocardial infarction; MLA, minimum lumen area; MLD, minimum lumen diameter; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; QCA, quantitative coronary analysis; RVD, reference vessel diameter; TIMI, thrombolysis in myocardial infarction

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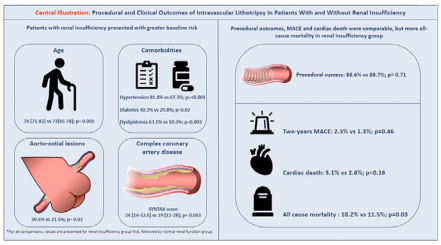

Central Illustration: Procedural and Clinical Outcomes of Intravascular Lithotripsy in Patients With and Without Renal insufficiency. MACE= major adverse cardiovascular events; SYNTAX= Synergy Between PCI with Taxus and Cardiac Surgery.

Chronic kidney disease (CKD) is a frequent comorbidity in patients undergoing percutaneous coronary intervention (PCI), with a reported prevalence of up to 30%.[1] Reduced renal function, defined as an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2, is associated with increased rates of major adverse cardiovascular events (MACE), all-cause mortality, and periprocedural complications such as contrast-induced nephropathy (CIN) and acute kidney injury (AKI).[2–6] CKD also contributes to the development and progression of coronary artery disease (CAD), primarily through accelerated vascular calcification and endothelial dysfunction.[7–9] As a result, patients with more advanced CKD frequently present with extensive coronary artery calcification (CAC), which complicates lesion preparation and stent deployment.[10–12] Intravascular lithotripsy (IVL) is a novel calcium modification technique that uses pulsatile sonic pressure waves to enhance lesion compliance and facilitate stent delivery.[13] Studies have demonstrated high procedural success and favorable outcomes with IVL in patients with heavily calcified lesions.[14] However, evidence on the safety and effectiveness of IVL specifically in patients with impaired renal function remains limited. While patients with moderate renal impairment (eGFR 30–60 mL/min/1.73 m^2) were included in studies such as the Disrupt CAD IV study, those with severe renal dysfunction—defined as serum creatinine >2.5 mg/dL or chronic dialysis—were explicitly excluded.[15,16] As a result, patients with renal insufficiency, particularly those with more advanced stages, remain underrepresented. This raises uncertainty about whether the procedural and clinical benefits observed in broader trial populations extend to the full spectrum of CKD patients undergoing PCI. In light of the limited available data, this study seeks to define the procedural feasibility and clinical relevance of IVL in patients with CKD undergoing PCI for calcified coronary lesions.

Methods

Study population and data collection

This multicenter prospective study with retrospective data analysis included adult patients (≥18 years) who underwent PCI incorporating IVL between May 2019 and September 2024. Data were obtained from the BENELUX-IVL registry (NCT06577038), an international all-comers observational database. The total study population consisted of 558 patients. For the primary analysis, patients were categorized as having renal insufficiency or not, based on baseline estimated glomerular filtration rate calculated using the CKD-EPI formula. Renal insufficiency was defined as eGFR <60 mL/min/1.73 m^2. For the subgroup analysis, the same cohort was stratified into three groups: <30 mL/min/1.73 m^2 ($n = 38$), 30–60 mL/min/1.73 m^2 ($n = 149$), and >60 mL/min/1.73 m^2 ($n = 367$). Baseline eGFR was missing in four patients, who were therefore excluded from the stratified analysis, resulting in a final sample size of 554 for eGFR-based comparisons. All procedures were performed using the Shockwave IVL Coronary System (Shockwave Medical, Santa Clara, CA), and procedural strategy and device selection were at the operator's discretion. Clinical, procedural, and follow-up data were extracted from electronic health records across participating centers. The study was conducted in accordance with the Declaration of Helsinki and was approved by local ethics committees at all participating sites.

Definitions and imaging analysis

Coronary angiograms were retrospectively evaluated in a centralized core laboratory. CAD complexity was assessed using the Synergy Between PCI with Taxus and Cardiac Surgery (SYNTAX) score, provided that all major coronary arteries were adequately visualized.[17] The presence and severity of CAC was determined by the operator during the procedure, using angiography and, when available, intracoronary imaging (ICI).

Angiographically, CAC was classified as none/mild, moderate (radiopacities visible only during the cardiac cycle before contrast injection), or severe (radiopacities apparent without cardiac motion prior to contrast injection).[18] On intravascular ultrasound (IVUS), CAC was defined as a hyperechoic signal with acoustic shadowing, while on optical coherence tomography (OCT), it was identified as a signal-poor area with sharply delineated borders. Severe calcification on ICI was defined as a calcium arc ≥270 degrees.[19,20] Long-segment calcification was defined as lesion length >20 mm, based on quantitative coronary analysis (QCA) or ICI. QCA was performed before and after IVL using Medis Suite software (version 4.0.24.4) to quantify minimum lumen diameter (MLD), diameter stenosis (DS), and reference vessel diameter (RVD). When available, IVUS or OCT images were analyzed using QCU-CMS 4.69 to assess minimum lumen area (MLA) and reference vessel area (RVA).

Study endpoints

The primary endpoint was the incidence of MACE at 1 and 2 years follow-up. MACE was defined as a composite of cardiovascular death, nonfatal myocardial infarction, or clinically driven target vessel revascularization.

Secondary endpoints included procedural, device, and technical success. Procedural success was defined as achieving final Thrombolysis in Myocardial Infarction (TIMI) 3 flow and residual stenosis <30% on QCA, in the absence of in-hospital MACE. Device success referred to successful IVL balloon delivery and energy emission without device-related complications. Technical success was defined as achieving final TIMI 3 flow with residual stenosis <30%. Additional secondary endpoints included all-cause mortality at 1- and 2-year follow-up, and the occurrence of procedural complications such as coronary dissection, coronary perforation, abrupt vessel closure, no-reflow, hemodynamic instability, or the need for resuscitation.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on data distribution as assessed by histogram inspection. For comparisons between two groups, the unpaired t-test was used for normally distributed variables and the Mann-Whitney U test for non-normally distributed variables. For comparisons across three eGFR strata, the Kruskal-Wallis test was used for continuous variables. Categorical variables were reported as counts and percentages, and compared using the Chi-square test or Fisher's exact test, as appropriate. To assess predictors of all-cause mortality, univariable logistic regression analyses were first performed. Variables with a p-value <0.25 in univariable analysis were entered into a multivariable logistic

regression model to identify independent predictors. Results are reported as odds ratios (OR) with 95% confidence intervals (CI). Kaplan-Meier analysis was used to estimate MACE-free survival and all-cause mortality up to 2 years. Differences between groups were assessed with the log-rank test. All statistical analyses were performed using SPSS Statistics, version 25.0 (IBM Corp., Armonk, NY, USA). A two-sided p-value <0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 558 patients were included in the study, with 176 (31.5%) having renal insufficiency and 382 (68.5%) having normal renal function. Patients with renal insufficiency were significantly older (76 years [71–82] vs 73 years [65–78]; p < 0.001). The proportion of male patients was similar between the two groups (*n* = 128, 72.7% vs *n* = 283, 74.1%; p = 0.70). Hypertension was more common in patients with renal insufficiency (*n* = 144, 81.8% vs *n* = 257, 67.3%; p < 0.001), as well as diabetes mellitus (*n* = 71, 40.3% vs *n* = 114, 29.8%; p = 0.02) and dyslipidemia (*n* = 111, 63.1% vs *n* = 192, 50.3%; p = 0.003). The SYNTAX score was significantly higher in the renal insufficiency group (24 [14–32.6] vs 19 [11–28]; p = 0.003). (see Table 1 for detailed baseline characteristics).

Lesion and procedural characteristics

A total of 586 lesions were treated with IVL, with 190 (32.4%) in patients with renal insufficiency and 396 (67.6%) in patients with normal renal function. Left main lesions were more common in the renal insufficiency group (*n* = 28, 14.7% vs *n* = 36, 9.1%; p = 0.04). Aorta-ostial lesions were significantly more frequent in patients with renal insufficiency (*n* = 58, 30.5% vs *n* = 85, 21.5%; p = 0.02). (see Table 2 for detailed lesion characteristics).

The number of IVL pulses was slightly lower in the renal insufficiency group (50 [30–80] vs 60 [60–80]; p = 0.02). predilatation (*n* = 156, 82.1% vs *n* = 332, 83.8%; p = 0.20) and postdilatation (*n* = 160, 84.2% vs *n* = 329, 83.1%; p = 0.93) rates were similar between groups. Bail-out IVL after stenting was more frequent in the normal renal function group (15.9% vs 8.9%; p = 0.013). The overall use of ICI was similar between groups (*n* = 83, 43.7% vs *n* = 201, 50.8%; p = 0.12). Stent implantation was performed in 152 (80.0%) lesions in the renal insufficiency group and 303 (76.5%) lesions in the normal renal function group (p = 0.34). Procedural time (80.5 [60–114.75] vs 81.0 [60–111] minutes; p = 0.85) and contrast volume (161.5 [120–226] vs 170 [130–231.3] mL; p = 0.38) were comparable between the groups.

Procedural outcomes

Pre-PCI, the RVD was significantly larger in the renal insufficiency group (3.4 mm [2.8–3.8]) compared to the normal renal function group (3.1 mm [2.73–3.6]; p = 0.02). Post-PCI, the RVD remained significantly larger in the renal insufficiency group (3.55 ± 0.6 mm) compared to the normal renal function group (3.40 ± 0.52 mm; p = 0.012). (see Table 3 for QCA results).

Procedural success was comparable between patients with renal insufficiency and those with normal renal function (*n* = 156, 88.6% vs *n* = 339, 88.7%; p = 0.97). Similarly, device success rates were high and similar between the groups (*n* = 156, 88.6% vs *n* = 339, 88.7%; p = 0.88), as were technical success rates (*n* = 159, 90.3% vs *n* = 342, 89.5%; p = 0.77). A total of 31 (5.6%) complications occurred, with 11 (6.3%) in the renal insufficiency group and 20 (5.2%) in the normal renal function group (p = 0.63). A detailed overview of procedural outcomes and complications is provided in Table 4, with a visual breakdown of specific complications shown in Figure 1.

Clinical outcomes

The median follow-up duration was 12.0 months [IQR 5–24] in the total population, with 12.0 months [3–24] in patients with renal insufficiency and 12.5 months [5–24] in those with normal renal function (p = 0.051). Complete one-year follow-up was available in (*n* = 105, 59.7% vs *n* = 256, 67.0%), and two-year follow-up in (*n* = 72, 40.9% vs *n* = 179, 46.9%). Cumulative one-year MACE occurred in 14 (13.3%) patients with renal insufficiency and 28 (10.9%) patients with

Table 1
Baseline demographics and medical history per group

	Overall *N* = 558	Normal renal function *N* = 382	Renal insufficiency *N* = 176	P-value
Age, years	74 [67–80]	73 [65–78]	76 [71–82]	**<0.001**
Male, n (%)	411 (73.7%)	283 (74.1%)	128 (72.7%)	0.70
BMI	26.51 [23.8–29.3]	26.45 [24.2–29.1]	26.6 [22.9–29.4]	0.37
eGFR, ml/min	71 [53–85]	80 [70–89]	46 [32–53]	**<0.001**
History of smoking, n (%)	232 (41.6%)	156 (40.8%)	76 (43.2%)	0.36
Diabetes mellitus, n (%)	185 (33.2%)	114 (29.8%)	71 (40.3%)	**0.02**
Hypertension, n (%)	401 (71.9%)	257 (67.3%)	144 (81.8%)	**<0.001**
Dyslipidemia, n (%)	303 (54.3%)	192 (50.3%)	111 (63.1%)	**0.003**
SYNTAX score	19.25 [11.75–29]	19 [11–28]	24 [14–32.6]	**0.003**
Fluoroscopic calcification				0.64
Not possible, n (%)	46 (8.2%)	32 (8.4%)	14 (8%)	
None/mild, n (%)	31 (5.6%)	25 (6.5%)	6 (3.4%)	
Moderate, n (%)	74 (13.3%)	52 (13.6%)	22 (12.5%)	
Severe, n (%)	268 (48%)	186 (48.7%)	82 (46.6%)	
Left ventricular ejection fraction				**0.047***
Good (>50%), n (%)	293 (52.5%)	215 (56.3%)	78 (44.3%)	
Reasonable (30–50%), n (%)	109 (19.5%)	71 (18.6%)	38 (21.6%)	
Poor (20–30%), n (%)	24 (4.3%)	13 (3.4%)	11 (6.3%)	
Very poor (<20%), n (%)	4 (0.7%)	1 (0.3%)	3 (1.7%)	
Unknown, n (%)	15 (2.7%)	11 (2.9%)	4 (2.3%)	
Previous MI, n (%)	204 (36.6%)	131 (34.3%)	73 (41.5%)	0.09
Previous PCI, n (%)	252 (45.2%)	165 (43.2%)	87 (49.4%)	0.16
Previous CABG, n (%)	100 (17.9%)	65 (17%)	35 (19.9%)	0.43

BMI = body mass index; CABG = coronary artery bypass graft surgery; eGFR; estimated glomerular filtration rate; MI = myocardial infarction; PCI = percutaneous coronary intervention; SYNTAX = Synergy between PCI with Taxus and Cardiac Surgery.
* Fisher-Freeman-Halton Exact Test.

Table 2
lesion and procedural characteristics

	Overall *N* = 586	Normal renal function *N* = 396	Renal insufficiency *N* = 190	P-value
Target vessel				
LM, n (%)	64 (10.9%)	36 (9.1%)	28 (14.7%)	**0.04**
LAD, n (%)	264 (45.1%)	178 (44.9%)	86 (45.3%)	0.94
LCx, n (%)	92 (15.7%)	59 (14.9%)	33 (17.4%)	0.44
RCA, n (%)	205 (35%)	141 (35.6%)	64 (33.7%)	0.65
Bypass, n (%)	7 (1.2%)	6 (1.5%)	1 (0.5%)	0.44
Lesion characteristics				
Bifurcation, n (%)	126 (21.5%)	84 (21.2%)	42 (22.1%)	0.81
Aorta-ostial, n (%)	143 (24.4%)	85 (21.5%)	58 (30.5%)	**0.02**
CTO, n (%)	44 (7.5%)	32 (8.1%)	12 (6.3%)	0.45
Long segment, n (%)	380 (64.8%)	265 (66.9%)	115 (60.5%)	0.13
In-stent, n (%)	176 (30%)	128 (32.3%)	48 (25.3%)	0.08
IVL				
IVL Balloon maximum diameter, mm	3.5 [3–4]	3.5 [3–4]	3.5 [3–4]	0.49
Number of pulses, n (%)	80 [60–80]	80 [60–80]	80 [50–80]	**0.02**
Pre- dilatation, n (%)	488 (83.3%)	332 (83.8%)	156 (82.1%)	0.20
Balloon size pre-dilatation, mm	3.0 [2.5–3.5]	3 [3–3.5]	3 [2.5–3.5]	0.13
Post- dilatation, n (%)	489 (83.4%)	329 (83.1%)	160 (84.2%)	0.93
Balloon size post-dilatation, mm	3.63 [3.5–4.0]	3.75 [3.5–4]	3.5 [3.31–4]	0.64
After stenting (bail out), n (%)	79 (13.5%)	63 (15.9%)	16 (8.9%)	**0.013**
ICI	284 (48.5%)	201 (50.8%)	83 (43.7%)	0.12
Pre- IVL ICI, n (%)	216 (36.9%)	151 (39.1%)	65 (34.2%)	0.36
IVUS, n (%)	194 (33.1%)	134 (33.8%)	60 (31.6%)	0.59
OCT, n (%)	24 (4.1%)	17 (4.3%)	7 (3.7%)	0.73
Post- IVL ICI, n (%)	234 (39.9%)	164 (41.4%)	70 (36.8%)	0.29
IVUS, n (%)	207 (35.3%)	144 (36.4%)	63 (33.2%)	0.45
OCT, n (%)	24 (4.1%)	18 (4.5%)	6 (3.2%)	0.43
Other plaque modification technique used				
RA (pre), n (%)	73 (12.%)	45 (11.4%)	28 (14.7%)	0.25
Cutting Balloon (pre), n (%)	5 (0.9%)	5 (1.3%)	0	0.18*
OPN balloon (pre), n (%)	1 (0.2%)	1 (0.3%)	0	1*
RA (post), n (%)	5 (0.9%)	3 (0.8%)	2 (1.1%)	0.66*
Cutting Balloon (post), n (%)	1 (0.2%)	0	1 (0.5%)	0.32*
OPN balloon (post), n (%)	3 (0.5%)	3 (0.8%)	0	0.56*
Treatment after IVL				
Stent implantation, n (%)	455 (77.6%)	303 (76.5%)	152 (80%)	0.34
Stent diameter, mm	3.5 [3.5–4.0]	3.5 [3.5–4]	3.5 [3.5–4]	0.80
Drug-coated balloon, n (%)	44 (7.5%)	25 (6.3%)	19 (10%)	0.11
Procedural time, min [IQR]	81 [60–111]	81 [60–111]	80.5 [60–114.75]	0.85
Fluoroscopy time, min [IQR]	24 [16–36]	23 [16–37]	25 [16–36]	0.92
Contrast volume, ml [IQR]	170 [130–230]	170 [130–231.3]	161.5 [120–226]	0.33

CTO = chronic total occlusion; ICI = intracoronary imaging; IVL = intravascular lithotripsy; IVUS = intravascular ultrasound; LAD = left anterior descending artery; LCx = left circumflex artery; LM = left main coronary artery; OCT = optical coherence tomography; OPN = ultra-high pressure balloon; RA = rotational atherectomy; RCA = right coronary artery.

* Fisher's exact test.

Table 3
quantitative coronary analysis

	Overall *N* = 586	Normal renal function *N* = 396	Renal insufficiency *N* = 190	P-value
Pre- PCI				
RVD, mm	3.2 [2.8–3.7]	3.1 [2.73–3.6]	3.4 [2.8–3.8]	**0.02**
MLD, mm	0.9 [0.5–1.4]	0.9 [0.5–1.4]	0.9 [0.6–1.3]	0.87
MLA, mm^2	0.6 [0.2–1.5]	0.6 [0.2–1.5]	0.6 [0.3–1.5]	0.73
DS, %	70.6 [56.7–83.6]	69.6 [55.3–84.2]	72.6 [58.6–81.8]	0.39
AS, %	91.3 [80.9–97]	90.7 [79.8–97.4]	92.6 [82.7–96.7]	0.33
Post- PCI				
RVD, mm	3.45 ± 0.55	3.40 ± 0.52	3.55 ± 0.6	**0.012**
MLD, mm	2.90 ± 0.68	2.86 ± 0.61	2.99 ± 0.81	**0.045**
MLA, mm^2	6.3 [4.8–8.4]	6.3 [4.8–8.4]	6.4 [4.9–8.8]	0.33
DS, %	15.45 [9.2–22.9]	14.15 [8.7–22.4]	16.8 [9.8–24]	0.18
AS, %	26.4 [14.2–39.1]	25.7 [15.3–38.9]	27.6 [11.9–40.3]	0.72

AS = area stenosis; DS = diameter stenosis; MLA = minimum lumen area; MLD = minimum lumen diameter; PCI = percutaneous coronary intervention; RVD = reference vessel diameter.

normal renal function (p = 0.80). Between year one and two, new MACE events were observed in 4 (5.6%) and 5 (2.8%) patients, respectively (p = 0.46) (Table 5 and Figure 2). All-cause mortality was significantly higher in the renal insufficiency group (*n* = 32, 18.2% vs *n* = 44, 11.5%; p = 0.03), while cardiac death occurred in 9 (5.1%) patients with renal insufficiency and 10 (2.6%) patients with normal renal function (p = 0.16) (Figure 3). The unadjusted odds ratio for all-cause mortality was 1.71 (95% CI 1.04–2.81; p < 0.05). Kaplan-Meier analysis showed no significant difference in MACE-free survival at one or 2 years (log-rank p = 0.669 and p = 0.425, respectively; Figure 4).

In the univariable analysis, age (OR 1.03 per year; 95% CI 1.00 –1.06; p = 0.050), SYNTAX score (OR 1.03 per point; 95% CI 1.00

Table 4
procedural outcomes and complications

	Overall *N* = 558	Normal renal function *N* = 382	Renal insufficiency *N* = 176	P-value
Procedural success, n (%)	495 (88.7%)	339 (88.7%)	156 (88.6%)	0.97
Device success, n (%)	543 (97.3%)	339 (88.7%)	156 (88.6%)	0.88
Technical success, n (%)	501 (89.8%)	342 (89.5%)	159 (90.3%)	0.77
Complications, n (%)	31 (5.6%)	20 (5.2%)	11 (6.3%)	0.63
Dissection, n (%)	6 (1.1%)	5 (1.3%)	1 (0.6%)	0.67*
Coronary perforation, n (%)	7 (1.3%)	7 (1.8%)	0	0.10*
Abrupt vessel closure, n (%)	4 (0.7%)	2 (0.5%)	2 (1.1%)	0.59*
Slow flow, n (%)	1 (0.2%)	1 (0.3%)	0	1*
No reflow, n (%)	2 (0.4%)	1 (0.3%)	1 (0.6%)	0.53*
Hemodynamic instability, n (%)	9 (1.6%)	4 (1%)	5 (2.8%)	0.15*
Resuscitation, n (%)	5 (0.9%)	3 (0.8%)	2 (1.1%)	0.65*

* Fisher's exact test.

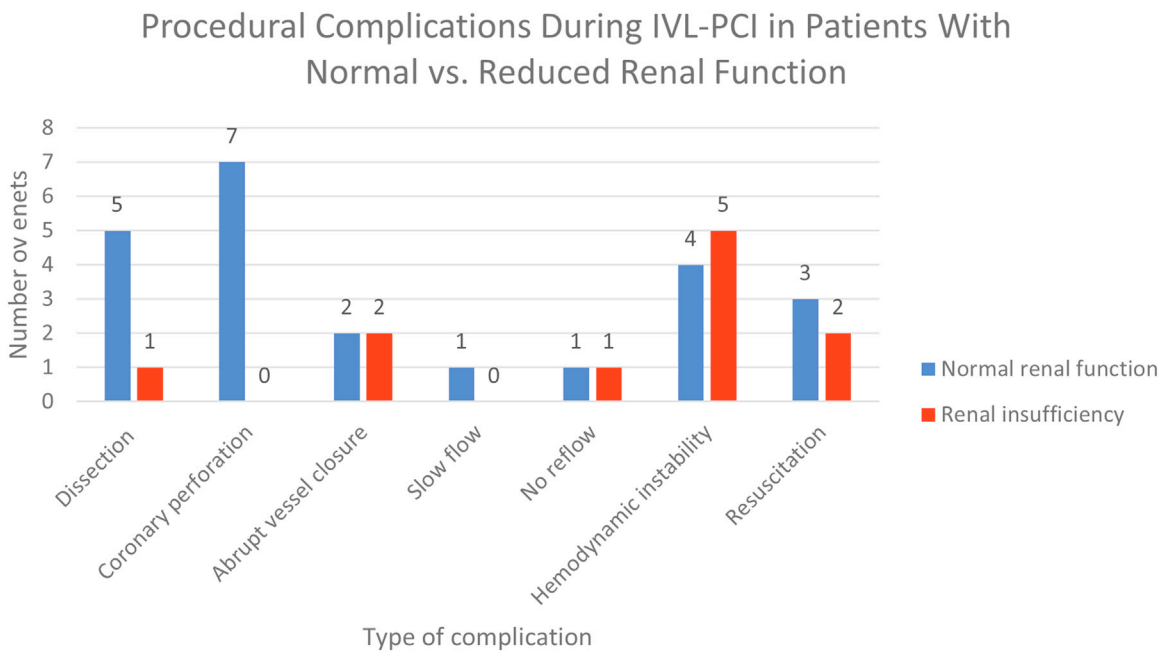

Figure 1. Distribution of Procedural Complications During IVL-PCI in Patients With Normal vs Reduced Renal Function. IVL= intravascular lithotripsy; PCI = percutaneous coronary intervention.

−1.05; p = 0.020), and baseline eGFR (OR 0.99 per unit; 95% CI 0.98 −1.00; p = 0.011) were significantly associated with all-cause mortality. In the multivariable model, only baseline eGFR remained independently associated with all-cause mortality (OR 0.98; 95% CI 0.97 −1.00; p = 0.020). See Table 6 for a complete overview.

Renal function stratified subgroup analysis

Patients were stratified by baseline estimated glomerular filtration rate into three groups: <30 (*n* = 38), 30–60 (*n* = 149), and >60 mL/min/1.73 m^2 (*n* = 367) (Supplementary Table 1). A progressive

Table 5
follow-up outcomes at 1 and 2 years: normal renal function versus renal insufficiency

	Overall *N* = 558	Normal renal function *N* = 382	Renal insufficiency *N* = 176	P-value
In- hospital MACE, n (%)	11 (2%)	6 (1.6%)	5 (2.8%)	0.32
30- days MACE, n (%)	7 (1.3%)	3 (0.8%)	4 (2.3%)	0.21*
6 months MACE, n (%)	15 (2.7%)	12 (3.1%)	3 (1.7%)	0.57*
One-year MACE, n (%)	10 (1.8%)	7 (1.8%)	3 (1.7%)	1*
Cumulative One-year MACE, n (%)°	*42/361 (11.6%)*	*28/256 (10.9%)*	*14/105 (13.3%)*	*0.80*
Two-year MACE, n (%)	9 (1.6%)	5 (1.3%)	4 (2.3%)	0.46*
Cumulative One-Year TVR, n (%)	26 (4.7%)	19 (5%)	7 (4%)	0.60
Cardiac death, n (%)	19 (3.4%)	10 (2.6%)	9 (5.1%)	0.16
All-cause mortality, n (%)	76 (13.6%)	44 (11.5%)	32 (18.2%)	**0.03**

MACE = major adverse cardiovascular events; ICI = intracoronary imaging;.
TVR = target vessel revascularization.
* Fisher's exact test.
° Percentages reflect the incidence of MACE among patients with complete one-year follow-up data (*n* = 361).

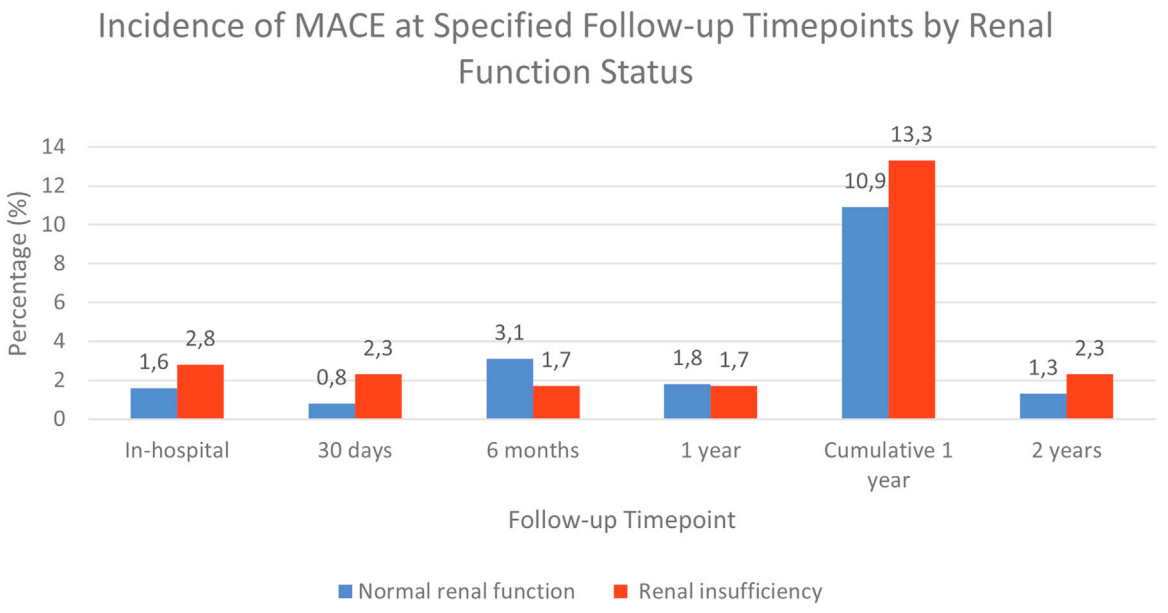

Figure 2. Incidence of MACE at Multiple Follow-Up Timepoints in Patients With Normal Versus Reduced Renal Function. MACE= major adverse cardiovascular events

decline in renal function was associated with several differences in baseline characteristics. Patients with severe renal insufficiency (eGFR <30) were older (74 [62–80] vs 76 [73–82] vs 72 [65–78] years; $p < 0.001$), had lower BMI values (23.7 [20.5–27.4] vs 27.4 [23.8–25.0] vs 26.5 [24.2–29.1]; $p < 0.001$), and higher SYNTAX scores (28 [16.3–36.3] vs 20 [11.6–31.8] vs 19 [11–28]; $p = 0.005$). Contrast volume was also significantly different across groups, with lower volumes observed in patients with severe renal insufficiency (150 [110–178.5] vs 180 [130–250] vs 170 [130–230] mL; $p = 0.007$). Despite these differences, procedural (89% vs 89% vs 89%; $p = 0.99$), device (95% vs 98% vs 97%; $p = 0.55$), and technical success (89% vs 91% vs 89%; $p = 0.81$) were similar among the three groups. One-year cumulative MACE (2.6% vs 8.7% vs 7.6%; $p = 0.48$), TVR (2.6% vs 3.4% vs 5.4%; $p = 0.49$), and cardiac death (0% vs 6.7% vs 2.5%; $p = 0.065$) did not differ significantly. However, patients with eGFR <30 had higher two-year MACE (7.9% vs 0.7% vs 1.4%; $p = 0.01$) and all-cause mortality (21.1% vs 18.1% vs 11.2%; $p = 0.046$). Kaplan-Meier analysis showed comparable MACE-free survival between groups (log-rank $p = 0.89$), but significantly lower overall survival in patients with severe renal impairment (log-rank $p = 0.028$; Supplementary Figure 1).

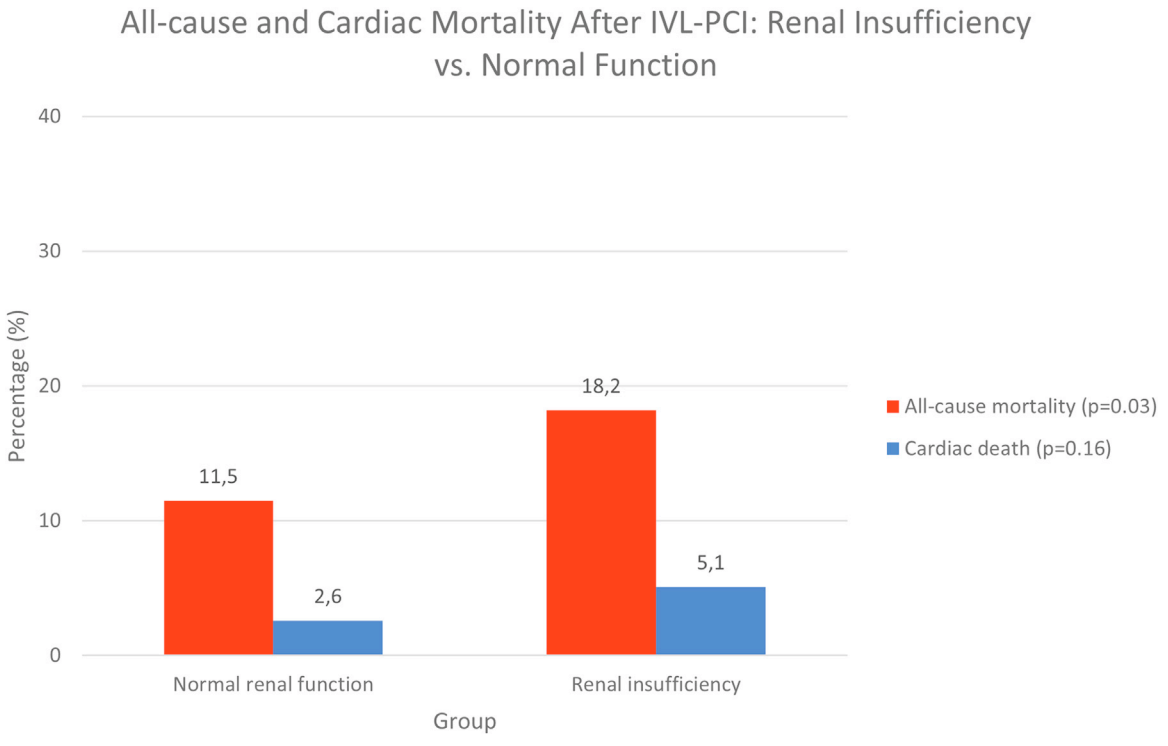

Figure 3. All-Cause and Cardiac Mortality Following IVL-PCI in Patients With and Without Renal Insufficiency. IVL= intravascular lithotripsy; PCI = percutaneous coronary intervention

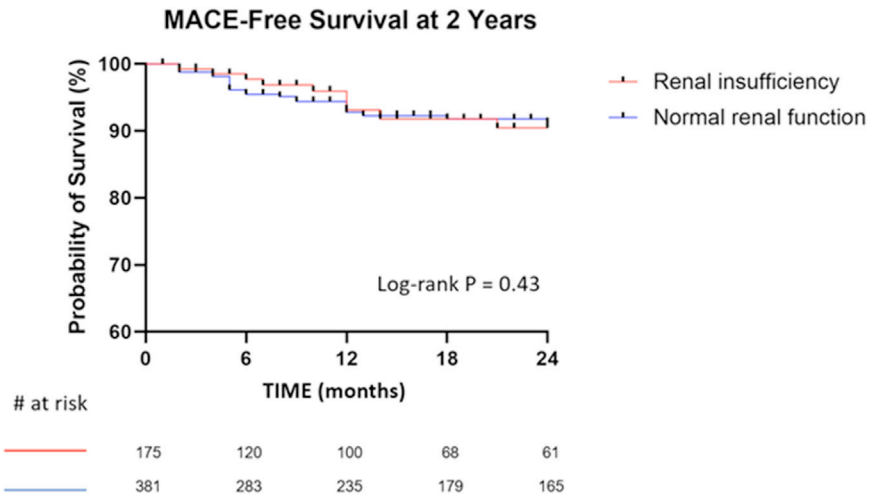

Figure 4. MACE- free survival up to 2 Years follow up. MACE= major adverse cardiovascular events

Table 6
univariable and multivariable logistic regression analyses for predictors of all-cause mortality

Variable	Univariable analysis			Multivariable analysis		
	Odds ratio	95% confidence interval	P-value	Odds ratio	95% confidence interval	P-value
Baseline characteristics						
Age	1.029	1.000–1.058	**0.050**	1.035	0.999–1.072	**0.059**
Sex (male)	0.85	0.497–1.454	0.554			
BMI	0.969	0.811–1.030	0.311			
Diabetes Mellitus	1.334	0.810–2.196	0.257			
Hypertension	1.268	0.711–2.262	0.42			
Dyslipidemia	0.916	0.563–1.49	0.723			
SYNTAX score	1.025	1.004–1.046	**0.020**	1.018	0.997–1.040	**0.098**
Previous MI	1.290	0.784–2.123	0.316			
Contrast volume	1.000	0.997–1.004	0.888			
eGFR baseline	0.987	0.976–0.997	**0.011**	0.985	0.972–0.998	**0.020**
Clinical presentation (ACS/CCS)	0.834	0.513–1.356	0.463			
Lesion characteristics						
Bifurcation	0.968	0.528–1.777	0.917			
Chronic total occlusion	1.540	0.684–3.466	0.297			
Ostial	1.327	0.768–2.293	0.310			
Long segment	1.058	0.636–1.761	0.828			

BMI= body mass index. MI= myocardial infarction. eGFR= estimated glomerular filtration rate. ACS= acute coronary syndrome. CCS= chronic coronary syndrome.

Discussion

This multicenter study, based on retrospectively analyzed prospective data, evaluated procedural and one- and two-year outcomes of IVL-assisted PCI in patients with reduced renal function. The main findings are: (1) procedural, device, and technical success rates were similar between patients with and without renal insufficiency; (2) no significant differences in procedural complications; and (3) although MACE rates were comparable, all-cause mortality was higher in the renal insufficiency group. Quantitative coronary analysis showed larger vessel diameters in these patients, likely reflecting more proximal and complex lesions (Central Illustration).

Patients with renal insufficiency had a higher prevalence of diabetes, hypertension, and complex coronary anatomy, consistent with previous literature on CKD and CAD progression.[5,7–9,21,22] Despite this elevated risk profile, IVL showed consistent safety and effectiveness, with low complication rates such as dissection and perforation. These findings support prior observations that IVL may be preferable to more aggressive plaque modification strategies, particularly in frail or comorbid patients.[23]

Although all-cause mortality was higher among patients with renal insufficiency, cardiovascular outcomes were similar. In multivariable analysis, lower baseline eGFR was independently associated with mortality, while age and SYNTAX score showed borderline associations. This suggests that renal dysfunction, more than clinical presentation or lesion complexity, is a key driver of long-term risk. Kaplan-Meier analysis confirmed lower survival in patients with severe renal impairment, aligning with studies linking CKD to both cardiovascular and noncardiovascular mortality, including progressive renal decline, malignancy, and infection.[24–26] However, in our population, despite a higher cardiovascular risk profile (including older age, higher prevalence of diabetes and more frequent left main or aorto-ostial lesions), patients with renal insufficiency did not experience significantly more cardiovascular events than those with normal renal function. This observation suggests that IVL may provide effective coronary plaque preparation in this high-risk population, potentially contributing to the comparable MACE rates observed between groups.

Interestingly, despite a higher cardiovascular risk profile—including older age, more diabetes, and more frequent left main or

aorto-ostial disease—patients with renal insufficiency did not have higher MACE rates. This may reflect effective lesion preparation with IVL in this high-risk population. Anatomically, patients with renal insufficiency more often had proximal lesions in large-caliber vessels, contributing to higher SYNTAX scores and larger reference diameters. This likely reflects CKD-associated vasculopathy, including medial calcification and vascular stiffness,[27–29] while small-vessel disease may have been treated more conservatively. Contrast volume was lower in patients with severe renal insufficiency in the eGFR-stratified subgroup analysis, but not in the main binary comparison (eGFR <60 vs ≥60). This may reflect guideline-based practice, as periprocedural hydration and contrast minimization are typically recommended for patients with eGFR <30 mL/min/1.73 m^2.[30] In patients with moderate impairment (eGFR 30–60), such measures are less consistently applied, highlighting an opportunity for more standardized procedural optimization in this vulnerable group.

Taken together, our findings confirm that IVL is a feasible and safe strategy in patients with CKD. However, procedural success alone is insufficient to mitigate the long-term risks in this population. A multidisciplinary follow-up strategy remains essential to address the systemic burden of renal insufficiency.

Limitations

This study has limitations. Its retrospective design may introduce selection bias and residual confounding, despite prospective data collection. Renal function was assessed only at baseline, limiting evaluation of dynamic changes or CIN. While QCA was performed centrally, detailed calcium burden and stent expansion data were available only in patients with ICI, which was not routinely used. The small number of patients with severe CKD limited statistical power for subgroup analyses. Finally, all centers were high-volume PCI institutions, which may limit generalizability to other clinical settings.

Conclusion

In this large, real-world cohort, IVL-assisted PCI resulted in similar MACE rates and procedural success among patients with and without renal insufficiency. However, all-cause mortality was significantly higher in patients with impaired renal function, particularly in those with severe CKD. These findings confirm the technical feasibility and safety of IVL in this high-risk population, while highlighting the need for multidisciplinary long-term follow-up addressing the systemic risks associated with CKD.

Clinical Implications

IVL is a safe and effective strategy for managing calcified coronary lesions in patients with impaired renal function. Despite greater comorbid burden and lesion complexity, MACE and procedural outcomes were comparable to those with normal renal function. These findings support the use of IVL as a first-line calcium modification approach in CKD, including advanced stages, while highlighting the importance of structured postprocedural care.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

During the preparation of this work the authors used ChatGPT 4.0 in order to detect grammatical errors. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Ethics Approval Statement

Our study received the proper ethical oversight and all authors have participated in the work and have reviewed and agree with the content of the article. None of the article contents are under consideration for publication in any other journal or have been published in any other journal. No portion of the text has been copied from other material in the literature.

Declaration of competing interest

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CRediT authorship contribution statement

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Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2025.07.023.

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