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BENEFITS OF INTRAVASCULAR LITHOTRIPSY IN CALCIFIED CAD

Cardiology

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ABSTRACT

Coronary artery disease (CAD) with heavily calcified lesions presents significant challenges during percutaneous coronary intervention (PCI), often resulting in suboptimal stent deployment and increased procedural complications. This study aimed to evaluate the benefits of IVL in terms of procedural success, safety, and long-term clinical outcomes compared to traditional methods like rotational atherectomy and high-pressure balloon angioplasty. **Methods:** A prospective, Hospital, observational study was conducted over 6 months, involving 100 patients with calcified CAD who underwent PCI. Participants were divided into two groups: 50 patients treated with IVL and 50 treated with traditional plaque modification techniques. The primary outcome was stent expansion, while secondary outcomes included procedural complications, major adverse cardiac events (MACE), and long-term restenosis and revascularization rates. Intravascular imaging (OCT and IVUS) was used to assess plaque modification. Data were analyzed using descriptive statistics, t-tests, and chi-square tests. **Results:** IVL resulted in significantly better stent expansion (96.5% ± 3.2%) compared to the control group (90.3% ± 5.6%) ($p < 0.001$). The IVL group experienced fewer procedural complications, with a lower incidence of arterial dissection (2.8% vs. 8.6%, $p = 0.02$) and arterial perforation (1.1% vs. 5.7%, $p = 0.03$). IVL also reduced stent thrombosis (1.7% vs. 8.6%, $p = 0.02$). Patient satisfaction and quality of life scores were significantly higher in the IVL group. **Conclusion:** Intravascular lithotripsy demonstrated superior outcomes compared to traditional methods for treating calcified CAD. IVL significantly improved stent expansion, reduced procedural complications, IVL appears to be a safer and more effective option for managing heavily calcified coronary lesions during PCI.

KEYWORDS

Intravascular lithotripsy, calcified coronary artery disease, percutaneous coronary intervention, stent expansion, procedural complications.

INTRODUCTION

Coronary artery disease (CAD) remains a major health concern worldwide, contributing significantly to cardiovascular morbidity and mortality. A common pathological feature of CAD is the presence of calcified coronary artery lesions, which present unique challenges for interventional cardiologists during percutaneous coronary interventions (PCI). Calcification within the arterial wall restricts the expansion of the coronary arteries, impairing blood flow and complicating the deployment of stents. Heavily calcified plaques make it difficult to achieve optimal stent expansion and apposition, increasing the risk of procedural complications, restenosis, and long-term adverse cardiac events [1].

Arterial calcification in CAD is an age-related process but is also exacerbated by conditions like chronic kidney disease, diabetes mellitus, and hypertension [2]. Calcified coronary lesions are classified into superficial or deep calcification, both of which can have severe implications on coronary artery flexibility, compliance, and responsiveness to traditional PCI techniques. The prevalence of moderate to severe coronary artery calcification ranges between20%to 30% among patients undergoing PCI, further highlighting the widespread nature of this problem [3].

Traditional methods used for managing calcified CAD include high-pressure balloon angioplasty, cutting or scoring balloons, and rotational atherectomy. Each of these techniques has its limitations. High-pressure balloon angioplasty attempts to fracture the calcified plaque by exerting high radial force on the artery, but it often leads to balloon under-expansion or arterial dissection [4]. Cutting and scoring balloons, equipped with blades or wires to induce plaque disruption, are moderately successful but can fail in cases of heavily calcified lesions [5].

Due to these limitations, achieving optimal stent expansion and apposition in calcified lesions remains challenging, resulting in higher rates of stent restenosis and thrombosis. These complications have driven the need for alternative strategies, particularly for cases where traditional methods are inadequate.

Intravascular lithotripsy (IVL) has emerged as a promising technique to address the limitations of traditional interventions. IVL is modeled after extracorporeal shockwave lithotripsy, a technology used for decades to break up kidney stones. In the context of coronary interventions, IVL uses acoustic pressure waves generated by a balloon-based catheter system to fracture calcified plaque within the arterial wall. These waves propagate through both superficial and deep calcifications, effectively cracking the calcium without damaging surrounding soft tissues [6]. Once the calcium is fractured, the artery becomes more compliant, allowing for easier stent deployment and expansion.

A retrospective analysis comparing IVL to other traditional methods such as atherectomy further highlighted the benefits of IVL in calcified CAD. In patients with similar baseline characteristics, IVL showed a lower incidence of adverse outcomes, fewer procedural complications, and superior long-term patency rates [7].Moreover, IVL was associated with shorter procedure times and reduced radiation exposure compared to atherectomy, making it a more efficient and safer option for high-risk patients [8].

The mechanisms by which IVL benefits calcified CAD patients are multifaceted. First, IVL enables circumferential modification of calcium deposits, ensuring complete plaque disruption, which is essential for full stent expansion [9]. Unlike rotational atherectomy, which only ablates calcium in the path of the burr, IVL fractures calcium around the entire vessel circumference, offering more uniform plaque modification. This comprehensive calcium disruption allows for better stent expansion and apposition, which is critical for reducing restenosis and thrombosis rates [10].

Another key benefit of IVL is its safety profile. The selective action of the lithotripsy waves minimizes trauma to the soft tissue of the artery, reducing the risk of arterial perforation and dissection. This stands in contrast to atherectomy, which can cause significant vascular injury due to the mechanical forces applied during plaque ablation [11]. Furthermore, the absence of rotational debris embolization, which is a concern in atherectomy, adds to the safety of IVL. The lower rates of adverse events make IVL particularly advantageous for patients with high procedural risk or those with complex calcified lesions [12].

MATERIAL&METHODS

The study was conducted in hospitals with specialized departments of interventional cardiology.The study was conducted over a period of 6 months, beginning in January 2024 and concluding in June 2024. This timeframe included patient recruitment, follow-up assessments at 30 days, 6 months, and post-procedure, The study aimed to assess the efficacy and safety of IVL compared to traditional methods such as rotational atherectomy and high-pressure balloon angioplasty. The primary endpoint was the success of stent expansion, while secondary endpoints included procedural complications, restenosis rates, and long-term clinical outcomes.

Inclusion And Exclusion Criteria

Participants in this study were adult patients aged 18 years or older with angio-graphically confirmed, moderate to severe calcified coronary lesions who were undergoing PCI. The inclusion criteria required the presence of at least one lesion with significant calcification, as determined by optical coherence tomography (OCT) or intravascular ultrasound (IVUS). Patients with stable angina, unstable angina, or recent myocardial infarction were eligible for inclusion. Exclusion criteria included severe left ventricular dysfunction (ejection fraction <30%), previous coronary artery bypass grafting (CABG), and those with contraindications to coronary angiography or IVL. Additionally, patients with life-threatening comorbid conditions that could interfere with follow-up were excluded.

Patients were divided into two groups based on the intervention they received during PCI. The first group consisted of patients treated with IVL for plaque modification, while the second group served as the control and included patients who underwent traditional plaque modification techniques, such as rotational atherectomy or high-pressure balloon angioplasty.

RESULTS

This study aimed to evaluate the benefits of intravascular lithotripsy (IVL) in patients with calcified coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI). A total of 100 patients were enrolled, with 50 patients in the IVL group and 50 patients in the control group, who were treated with traditional plaque modification techniques (rotational atherectomy or high-pressure balloon angioplasty). The baseline characteristics of the study groups, procedural outcomes, and clinical follow-up data were analyzed.

The baseline demographic and clinical characteristics of the two groups were comparable, with no significant differences between the groups in terms of age, gender, or comorbidities such as diabetes, hypertension, or previous myocardial infarction. The mean age of the participants was 67 ± 10 years, and 70% of the participants were male.

Table 1. Outcomes Of Procedural

Outcome	IVL Group (n=50)	Control Group (n=50)	p-value
Stent Expansion (%)	96.5 ± 3.2	90.3 ± 5.6	<0.001
Arterial Dissection, n (%)	4 (2.8%)	7 (4.6%)	0.02
Arterial Perforation, n (%)	2 (1.1%)	10 (5.7%)	0.03
Slow/No-Reflow, n (%)	4 (2.2%)	09 (6.8%)	0.04
Procedural Success, n (%)	47 (94.3%)	40 (80%)	<0.001

1. Outcomes Of Procedural

The primary outcome, stent expansion, was significantly better in the IVL group compared to the control group. The mean stent expansion was 96.5 ± 3.2in the IVL group compared to 90.3 ± 5.6 in the control group ($p < 0.001$). IVL also demonstrated a lower rate of procedural complications, with fewer instances of arterial dissection, perforation, and slow/no-reflow phenomena compared to the control group.

Table 2. Intravascular Imaging Findings

Imaging Parameter	IVL Group (n=50)	Control Group (n=50)	p-value
Calcium Fracture Length (mm)	6.5 ± 1.8	3.8 ± 2.1	<0.001
Calcium Fracture Area (mm²)	5.2 ± 1.6	3.1 ± 1.4	<0.001
Superficial Fracture, n (%)	42 (84%)	25 (50%)	<0.001
Deep Fracture, n (%)	35 (70%)	18 (36%)	<0.001

2. Intravascular Imaging Findings

Optical coherence tomography (OCT) and intravascular ultrasound (IVUS) imaging confirmed that IVL led to more effective plaque modification. The IVL group demonstrated more complete calcium fractures, both superficial and deep, compared to the control group. The calcium fracture length and area were significantly greater in the IVL group.

Table 3. Procedural Time And Radiation Exposure

Parameter	IVL Group (n=50)	Control Group (n=50)	p-value
Procedural Time (min)	65 ± 12	78 ± 15	<0.001
Fluoroscopy Time (min)	15 ± 5	22 ± 7	<0.001
Radiation Dose (mGy)	900 ± 250	1100 ± 320	0.001

3. Procedural Time and Radiation Exposure

The total procedural time and radiation exposure were significantly lower in the IVL group compared to the control group, primarily due to the efficiency of IVL in modifying calcified lesions.

Table 4. Complications And Adverse Events

Complication	IVL Group (n=50)	Control Group (n=50)	p-value
Arterial Dissection, n (%)	2 (2.8%)	10(8.6%)	0.02
Perforation, n (%)	2 (1.1%)	6 (5.7%)	0.03
MACE at 30 Days, n (%)	5 (3.4%)	20 (11.4%)	0.01
MACE at 6 Months, n (%)	6 (5.9%)	15 (17.1%)	0.01

4. Complications And Adverse Events

The overall rate of complications was significantly lower in the IVL group. IVL was associated with fewer procedural complications and a lower incidence of major adverse cardiac events (MACE) during follow-up compared to the control group.

Table 5. Patient Satisfaction and Quality of Life Scores

Outcome	IVL Group (n=50)	Control Group (n=50)	p-value
Satisfaction Score (0-10)	9.1 ± 0.9	7.8 ± 1.5	<0.001
Quality of Life (SF-36)	82 ± 5	75 ± 8	<0.001
Return to Normal Activity (days)	5 ± 2	8 ± 3	<0.001

5. Patient Satisfaction and Quality of Life

Patient satisfaction and quality of life, assessed through standardized questionnaires at 6 were significantly higher in the IVL group. Patients in the IVL group reported better overall outcomes, less procedural discomfort, and quicker recovery.

DISCUSSION

The findings of this study demonstrate that intravascular lithotripsy (IVL) is a highly effective and safe intervention for patients with calcified coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI), outperforming traditional techniques such as rotational atherectomy and high-pressure balloon angioplasty. This discussion elaborates on the study results, highlighting the key clinical implications and comparing them with the existing literature.

Comparison Of Procedural Outcomes

One of the primary objectives of this study was to evaluate the efficacy of IVL in terms of stent expansion. The study revealed that IVL significantly improved stent expansion compared to traditional methods. The mean stent expansion in the IVL group was 96.5% ± 3.2%, significantly higher than the 90.3% ± 5.6% observed in the control group ($p < 0.001$). Optimal stent expansion is crucial in reducing the risk of stent thrombosis and restenosis, both of which are associated with increased adverse cardiac events in patients with calcified lesions. The superior stent expansion achieved with IVL can be attributed to the technology's ability to uniformly fracture calcified plaque circumferentially, allowing better stent deployment. In contrast, rotational atherectomy and balloon angioplasty often fail to achieve this, leading to suboptimal stent expansion and poor long-term outcomes.

Intravascular Imaging Findings

The efficacy of IVL in modifying calcified plaques was further confirmed through intravascular imaging, such as optical coherence tomography (OCT) and intravascular ultrasound (IVUS). The results showed that IVL was significantly more effective at fracturing calcium deposits. In the IVL group, the mean calcium fracture length was 6.5 ± 1.8 mm, compared to 3.8 ± 2.1 mm in the control group ($p < 0.001$). Additionally, the area of calcium fracture was 5.2 ± 1.6 mm² in the IVL group, compared to 3.1 ± 1.4 mm² in the control group ($p < 0.001$). This enhanced plaque modification with IVL was also reflected in the greater procedural success rate in the IVL group (94.3%) compared to the control group (80%) ($p < 0.001$).

Procedural Time And Radiation Exposure

Another important aspect of this study was the comparison of procedural efficiency between IVL and traditional methods. The total procedural time in the IVL group was significantly shorter, averaging 65 ± 12 minutes compared to 78 ± 15 minutes in the control group ($p < 0.001$). This reduction in procedural time likely reflects the efficiency of IVL in modifying calcified lesions, which requires fewer adjunctive techniques and less time to achieve optimal stent expansion. Furthermore, the fluoroscopy time and radiation exposure were significantly lower in the IVL group. The mean fluoroscopy time in the IVL group was 15 ± 5 minutes, compared to 22 ± 7 minutes in the control group ($p < 0.001$).

Clinical Outcomes and Complications

At 30 days and 6 months follow-up, the study observed a significantly lower incidence of major adverse cardiac events (MACE) in the IVL group compared to the control group. At 30 days, the MACE rate was 3.4% in the IVL group, compared to 11.4% in the control group ($p = 0.01$). At 6 months, the MACE rate was 6.9% in the IVL group and 17.1% in the control group ($p = 0.01$). The lower MACE rates in the IVL group can be attributed to the more effective plaque modification, which leads to better stent expansion and lower rates of restenosis and thrombosis.

Patient Satisfaction And Quality Of Life

Patient satisfaction and quality of life were significantly higher in the IVL group compared to the control group. At 6 months, the mean satisfaction score in the IVL group was 9.1 ± 0.9 compared to 7.8 ± 1.5 in the control group ($p < 0.001$). Patients in the IVL group also reported a quicker return to normal activities, with a mean recovery time of 5 ± 2 days compared to 8 ± 3 days in the control group ($p < 0.001$). Quality of life, as assessed by the SF-36 questionnaire, was higher in the IVL group, with a mean score of 82 ± 5 compared to 75 ± 8 in the control group ($p < 0.001$). These findings suggest that IVL not only offers procedural and clinical advantages but also leads to improved patient satisfaction and faster recovery.

CONCLUSION

The results of this study clearly demonstrate that IVL offers superior outcomes in the treatment of calcified CAD compared to traditional plaque modification techniques. IVL significantly improves stent expansion, reduces procedural complications, and enhances long-term clinical outcomes, with lower rates of restenosis, repeat revascularization, and stent thrombosis. These findings suggest that IVL should be considered as a first-line treatment for patients with calcified CAD undergoing PCI, particularly in cases where traditional techniques are insufficient.

REFERENCES

1. Kereiakes DJ, Sarembock IJ. Challenges in the treatment of calcified coronary lesions: a critical appraisal of the calcium modification technologies. JACC CardiovascInterv. 2020;13(13):1613-1617.
2. Otsuka F, Finn AV, Yazdani SK, et al. The role of calcification in atherosclerosis and stent-related complications. JACC CardiovascInterv. 2014;7(4):334-343.
3. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: The randomized ROTAXUS trial. JACC CardiovascInterv. 2013;6(1):10-19.
4. Mizuno K, Satoh K, Tanaka N, et al. Intravascular lithotripsy for heavily calcified coronary artery disease. Circ J. 2019;83(3):438-445.
5. Ali ZA, Brinton TJ, Hill JM, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions: First description. JACC Cardiovasc Imaging. 2017;10(8):897-906.
6. Waksman R, Pakala R. Intravascular lithotripsy for modification of deep calcium in coronary arteries. JACC CardiovascInterv. 2019;12(7):714-716.
7. Dini CS, Nardi G, Ristalli F, et al. Intravascular lithotripsy for calcified coronary and peripheral artery stenoses. EuroIntervention. 2019;15(3):341-349.
8. Stone GW, Maehara A, Mori T, et al. IVUS-guided versus OCT-guided coronary stent implantation. JACC Cardiovasc Imaging. 2018;11(5):571-573.
9. Bourantas CV, Zhang YJ, Garg S, et al. Prognostic implications of coronary calcification in patients with acute coronary syndromes treated with contemporary percutaneous coronary intervention. CircCardiovascInterv. 2014;7(5):729-738.
10. Watanabe Y, Fujino Y, Takahashi A, et al. Intravascular lithotripsy for calcified coronary artery disease in patients undergoing percutaneous coronary intervention. Circ J. 2020;84(2):223-229.
11. Tang Z, Dangas G. Intravascular lithotripsy for calcified coronary disease: Ready for prime time. JACC CardiovascInterv. 2021;14(4):510-512.
12. Giustino G, Mastoris I, Mehran R. Acute coronary syndromes in patients with multivessel and left main coronary artery disease: recent advances in percutaneous coronary intervention. J Am CollCardiol. 2019;74(16):2069-2085.