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Original Research Article

Drug-eluting balloon angioplasty: redefining percutaneous coronary intervention

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ABSTRACT

Background: Drug-eluting balloon (DEB) angioplasty has emerged as an effective alternative to stent-based coronary revascularization, offering comparable efficacy without the long-term complications associated with permanent metallic implants. Sirolimus-based drug-coated balloon platforms offer distinct mechanistic advantages through inhibition of the mammalian target of rapamycin (mTOR) pathway, enabling selective suppression of smooth muscle cell proliferation while preserving endothelial integrity. Herein, we report the clinical outcomes of a prospective cohort of 59 patients treated with sirolimus-DEB angioplasty.
Methods: We prospectively enrolled 59 consecutive patients undergoing sirolimus-Drug eluting balloon angioplasty for coronary artery disease at a single center over a two-year period (2023-2025). Primary endpoints were technical and procedural success. Secondary endpoints included major adverse cardiovascular events (MACE), restenosis, and target lesion revascularization (TLR) at 6-12 months of follow-up.
Results: The mean age of the cohort was 59.1±10.7 years; 40 (67.8%) were male and 19 (32.2%) were female, with male predominance. Clinical presentations included acute coronary syndromes in 29 (49.2%) and chronic coronary disease in 30 (50.8%). Sirolimus DEB was deployed in 56 of 59 cases (94.9%). Technical and procedural success was achieved in 59 of 59 cases (100%), with all procedures achieving Thrombolysis in myocardial infarction 3 flow and residual stenosis <30%. In-hospital MACE occurred in 1 of 59 patients (1.7%), attributable to refractory cardiogenic shock in the setting of anterior myocardial infarction with severe left ventricular dysfunction; no procedure-related mortality or major bleeding was recorded. At 6-12-month follow-up, available in 56 of 59 patients (94.9%), 53 of 56 (94.6%) were symptom-free with zero TLR and zero late MACE.
Conclusion: Sirolimus-eluting balloon angioplasty demonstrates excellent safety and efficacy in this single-center prospective cohort. The 59/59 (100%) technical success rate, 58/59 (98.3%) uneventful procedural course, and 1/59 (1.7%) MACE rate compare favorably with published benchmarks and support the continued adoption of sirolimus-based drug-coated balloon technology for percutaneous coronary revascularization in appropriately selected patients.

Keywords: Drug-eluting balloon, Sirolimus, Percutaneous coronary intervention, Restenosis, Angioplasty

INTRODUCTION

Percutaneous coronary intervention (PCI) has undergone profound transformation since the advent of plain old balloon angioplasty (POBA). Although POBA established the foundation of catheter-based coronary revascularization, it was substantially limited by high rates of restenosis attributable to elastic recoil and neointimal hyperplasia.[1] The introduction of bare-metal stents (BMS) during the 1990s mitigated acute recoil but failed to

eliminate restenosis driven by neointimal proliferation. Drug-eluting stents (DES) subsequently represented a paradigm shift, delivering anti-proliferative agents locally to suppress neointimal hyperplasia with considerable efficacy. Nevertheless, DES carry inherent limitations: the permanent metallic scaffold predisposes to late and very late stent thrombosis, impairs physiological vascular remodeling, and mandates prolonged dual antiplatelet therapy (DAPT) for a minimum of 12 months increasing bleeding risk, cost, and medication burden.[2]

Drug-coated balloons (DCB) were developed to address these limitations by delivering anti-proliferative medication transiently to the vessel wall during balloon inflation, without leaving a permanent implant.3,4 Unlike polymer-based DES, sirolimus-eluting DCBs transfer the active agent directly to the arterial wall during a single 60-second inflation, achieving high local drug concentrations while minimizing systemic exposure and circumventing the inflammatory sequelae of retained polymer matrices. Sirolimus (rapamycin) exerts its antiproliferative effect via mTOR pathway inhibition, selectively suppressing smooth muscle cell proliferation while potentially preserving superior endothelial function compared with paclitaxel, which acts through non-selective microtubule stabilization. These mechanistic differences may contribute to improved tissue biocompatibility, accelerated re-endothelialization, and superior vascular healing.[3,4]

Growing clinical evidence suggests sirolimus-eluting balloon angioplasty may achieve outcomes comparable to those of DES while avoiding the long term complications of permanent metallic implants.[5–7] Meta-analyses of randomised controlled trials comparing DCB with POBA have demonstrated 50-70% reductions in restenosis and 40-50% reductions in TLR.[5] Comparative studies against DES have shown non-inferior late lumen loss and restenosis rates, with potential advantages in in-stent restenosis, small-vessel disease, and patients in whom vessel preservation is paramount.[6,7]

The present study reports a single-center prospective experience with 59 consecutive patients treated with sirolimus-based drug-eluting balloon angioplasty. The objectives were to evaluate technical feasibility, procedural success, and acute and medium-term clinical outcomes in a heterogeneous patient population presenting with both acute and chronic coronary artery disease, and to benchmark results against published literature.

METHODS

Study design and patient population

This was a single-center, prospective observational study of 59 consecutive patients undergoing sirolimus-based drug-eluting balloon angioplasty for coronary artery disease at Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation, Chinna Avutapalli, Gannavaram, Vijayawada, Krishna District, Andhra Pradesh, India, between 2023 and 2025.

Inclusion criteria

Patients were eligible if they presented with one or more of the following: (i) anatomically suitable coronary lesions for DEB therapy (reference vessel diameter 2.5-3.0 mm, lesion length <30 mm); (ii) unstable angina or non-ST-elevation acute coronary syndrome (NSTEMI); or (iii) chronic stable angina with documented myocardial ischemia.

Exclusion criteria

Patients were excluded if they had: acute cardiogenic shock requiring mechanical circulatory support; refractory ventricular arrhythmias.

Intervention protocol

All procedures were performed via femoral or radial access, as clinically appropriate. Anticoagulation was achieved with intravenous unfractionated heparin (70-100 U/kg). Lesion preparation was performed using conventional or cutting-balloon angioplasty to optimize drug transfer to the vessel wall, consistent with current DCB guidelines.8 Sirolimus-eluting balloons were inflated at nominal pressure and maintained at the target lesion site for 60 seconds. Angiographic success was defined as TIMI 3 flow with less than 30% residual diameter stenosis on final angiography. Post-procedural intracoronary nitroglycerin was administered to exclude vasospasm.

Antiplatelet therapy

All patients received aspirin 300 mg as a loading dose pre-procedure, followed by 75-100 mg daily indefinitely, in combination with a P2Y inhibitor (clopidogrel 300 mg loading dose followed by 75 mg daily for six months, or ticagrelor/prasugrel as clinically indicated). The choice of P2Y inhibitor and dual antiplatelet therapy (DAPT) duration were at the discretion of the treating physician based on the patient presentation and vessel size.

Data collection

Comprehensive clinical, angiographic, and procedural data were collected prospectively for all patients. Baseline variables included demographics, clinical presentation, left ventricular function, lesion characteristics, and procedural details. Clinical follow-up was conducted at 6 and 12 months via outpatient review or structured telephone interview.

Definitions

Technical success: Successful balloon inflation and deflation with final diameter stenosis <20% on angiography.

Procedural success: Technical success without in-hospital MACE. MACE: Composite of all-cause death, myocardial infarction, or target lesion revascularization. TLR: Any repeat revascularization of the target lesion, whether percutaneous or surgical.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) with range. Categorical variables are expressed as absolute numbers and percentages. Ninety-five percent confidence intervals (95% CI) for proportions were calculated using the Wilson score method. No formal comparative statistical testing was performed given the observational, single-arm study design.

RESULTS

Baseline demographic and clinical characteristics

A total of 59 patients underwent sirolimus-eluting balloon angioplasty during the study period. The mean age was 59.1±10.7 years (range 33-81 years). Male patients comprised 67.8% (n=40) of the cohort, consistent with the well-established male predominance of obstructive coronary artery disease. Baseline demographic and clinical characteristics are summarized in Table 1.

Clinical presentation

The study population exhibited a broad spectrum of clinical presentations, reflecting the diverse applicability of sirolimus-DEB technology. Acute coronary syndromes accounted for 49.2% of presentations (n=29), comprising anterior wall myocardial infarction (AWMI) in 28.8% (n=17) and non-ST-elevation myocardial infarction (NSTEMI) in 20.3% (n=12). Chronic coronary disease was present in 50.8% (n=30) of patients, including chronic stable angina with coronary artery disease (28.8%, n=17), inferior wall myocardial infarction (11.9%, n=7), and heart failure with reduced ejection fraction (HFrEF; 5.1%, n=3).

Left ventricular function

Left ventricular function assessment demonstrated preserved function (defined as good or fair LV function) in 55.9% of the cohort (n=33). Mild LV dysfunction was present in 22.0% (n=13), moderate dysfunction in 8.5% (n=5), and severe dysfunction in 3.4% (n=2). The procedure was successfully performed across the full spectrum of LV function, including in patients with significant systolic impairment. Full details are presented in Table 1.

Table 1: Baseline demographic and clinical characteristics.

Demographics	N	%
Total patients (n=59)	59	100.0
Age (in years)	-	59.1 ± 10.7 (33–81)
Male	40	67.8
Female	19	32.2
Clinical presentation		
Anterior wall MI (AWMI)	17	28.8
Non-ST elevation MI (NSTEMI)	12	20.3
Inferior wall MI (IWMI)	7	11.9
Chronic stable angina	17	28.8
Heart failure with reduced EF (HFrEF)	3	5.1
Left ventricular function		
Good LV function	22	37.3
Fair LV function	11	18.6
Mild LV dysfunction	13	22.0
Moderate LV dysfunction	5	8.5
Severe LV dysfunction	2	3.4

Procedural characteristics

Sirolimus drug-eluting balloon angioplasty was performed as the primary intervention in 94.9% of cases (56/59). Conventional balloon angioplasty (PTCA) and POBA were employed in 1.7% (n=1) and 3.4% (n=2) of cases, respectively. The predominant lesion type was de novo coronary artery disease (88.1%, n=52), with in-stent restenosis (ISR) accounting for 11.9% (n=7). The left anterior descending artery (LAD) was the most frequently treated vessel (39.0%, n=23), followed by the right coronary artery (RCA; 22.0%, n=13) and left circumflex artery (LCX; 20.3%, n=12). Full procedural details are presented in Table 2.

Table 2: Procedural characteristics.

	N	%
Type of intervention		
Sirolimus DEB	56	94.9
PTCA	1	1.7
POBA	2	3.4
Lesion type		
De Novo lesions	52	88.1
In-Stent Restenosis (ISR)	7	11.9
Coronary vessel distribution		
Left anterior descending (LAD)	23	39.0
Right coronary artery (RCA)	13	22.0
Left circumflex (LCX)	12	20.3
Obtuse marginal (OM)	7	11.9
First diagonal (D1)	3	5.1
Second diagonal (D2)	1	1.7
Multivessel disease	2	3.4

Procedural and In-hospital outcomes

Technical and procedural success was achieved in all 59 patients (100%; 95% CI 93.9-100.0%). Final TIMI 3 flow and residual stenosis <30% were documented in every treated vessel. No acute procedural complications including vessel perforation, abrupt vessel closure, or distal embolization were recorded. In-hospital MACE occurred in 1.7% (1/59; 95% CI 0.3-9.0%). The single event was attributable to in-hospital mortality in a patient presenting with extensive anterior wall myocardial infarction, severe left ventricular dysfunction (ejection fraction <30%), and refractory cardiogenic shock requiring mechanical circulatory support. Death in this patient was consequent upon hemodynamic deterioration from cardiogenic shock rather than a direct complication of the DEB procedure. No major bleeding, vascular access complications, contrast-induced nephropathy, or device-related allergic reactions were observed. Detailed outcomes are presented in Table 3.

Table 3: Procedural and in-hospital clinical outcomes.

	N	%	95% CI
Technical success			
Procedural success	59	100.0	93.9–100.0
No procedural failures	59	100.0	93.9–100.0
Angiographic results			
Final TIMI 3 flow achieved	59	100.0	93.9–100.0
Residual stenosis <20%	59	100.0	93.9–100.0
In-hospital outcomes			
Uneventful procedural course	58	98.3	90.9–99.7
Major adverse cardiovascular events (MACE)	1	1.7	0.3–9.0
All-cause mortality	1	1.7	0.3–9.0
Periprocedural myocardial infarction	0	0.0	0.0–6.2
Target lesion revascularization (TLR)	0	0.0	0.0–6.2
Major bleeding requiring transfusion	0	0.0	0.0–6.2
Vascular access complications	0	0.0	0.0–6.2
Contrast-induced nephropathy	0	0.0	0.0–6.2

Follow-up outcomes (6-12 months)

Clinical follow-up data were available for 94.9% of patients (56/59); three patients (5.1%) were lost to follow-up. At 6-12-month assessment, 94.6% of patients with available data (53/56) were completely symptom-free. Two patients (3.6%) reported stable, mild symptoms not fulfilling criteria for restenosis, and no patient experienced recurrent symptoms consistent with target lesion restenosis. Zero TLR and zero late MACE events were recorded at follow-up. Follow-up outcomes are summarized in Table 4.

Table 4: Clinical outcomes at 6–12 months follow-up.

	N	%
Follow-up availability		
Patients with follow-up data	56	94.9
Lost to follow-up	3	5.1
Clinical status at follow-up		
Symptom-free / asymptomatic	53/56	94.6
Stable symptoms	2/56	3.6
Recurrent symptoms suggesting restenosis	0/56	0.0
Late MACE (Death, MI, TLR)	0/56	0.0
Target lesion revascularization (TLR)	0/56	0.0

Comparison with published literature

The outcomes observed in this cohort compare favorably with published data from major DCB trials and meta-analyses. Our 59/59 (100%) technical success rate is consistent with rates of 98–100% reported in contemporary DCB registries. The 1/59 (1.7%) in-hospital MACE rate is substantially lower than the 8–15% rates reported in randomized controlled trials of DEB therapy, though patient selection and the observational design of the present study preclude direct comparison. The estimated restenosis rate based on clinical presentation (0–5.1%) is markedly lower than the 30–40% historically reported with POBA1 and favorably approximates DES benchmarks.

DISCUSSION

This prospective single-centre study demonstrates that sirolimus-eluting balloon angioplasty is a technically reliable, safe, and clinically effective strategy for coronary revascularization across a heterogeneous patient population encompassing acute coronary syndromes, chronic coronary disease, de novo lesions, and in-stent restenosis.

Technical and procedural efficacy

The 59/59 (100%) procedural success rate observed in this cohort reflects both the technical maturity of the sirolimus-DEB platform and systematic adherence to optimal lesion preparation technique. Adequate pre-dilatation with conventional or cutting-balloon angioplasty is a recognized prerequisite for effective drug transfer and has been associated with improved DCB outcomes in randomized studies.[8]

Safety profile and MACE rate

The 1/59 (1.7%) in-hospital MACE rate is substantially lower than the 8-15% rates reported in randomized DCB trials and registries. The single mortality event was attributable to refractory cardiogenic shock in the context of anterior STEMI with severe LV dysfunction a patient who was at exceptionally high baseline risk and would have met standard exclusion criteria for most published trials. No procedural complications, major bleeding events, or access-site complications were recorded, underscoring the intrinsic safety of the DEB approach and the importance of meticulous vascular access management.

Mechanistic advantages of Sirolimus-based drug delivery

The superior outcomes observed in this cohort may in part reflect the mechanistic advantages of sirolimus over paclitaxel as the anti-proliferative agent in DCB platforms. Sirolimus exerts its antiproliferative effect through selective mTOR pathway inhibition, thereby suppressing smooth muscle cell proliferation while preserving endothelial cell viability and promoting accelerated reendothelialization. In contrast, paclitaxel acts as a cytotoxic microtubule-stabilizing agent with less selective cellular effects, potentially impairing endothelial healing and contributing to delayed vascular recovery. These biological distinctions may underlie the favorable long-term outcomes increasingly reported with sirolimus-based DCB platforms in contemporary literature.

Broad applicability across clinical scenarios

The present cohort demonstrates that sirolimus-DEB angioplasty can be safely and effectively applied across diverse clinical presentations, including high-acuity presentations such as AWMI and NSTEMI, as well as chronic stable disease. The 7/59 (11.9%) ISR subgroup is particularly noteworthy, as sirolimus-DCB therapy is well-established as an effective and guideline-endorsed strategy for the management of in-stent restenosis, offering meaningful clinical advantages over repeat stent-in-stent implantation by avoiding compounded metallic layers and preserving future revascularization options.

Comparison with published literature

Our outcomes are consistent with contemporary evidence. The DEBUT trial established the non-inferiority of DCB versus BMS for de novo lesions in small vessels.[9] The AGENT IDE trial similarly demonstrated the superiority of a paclitaxel-coated balloon over an uncoated balloon for

coronary in-stent restenosis, further reinforcing the evidence base for DCB-based strategies in this setting.[10] Subsequent meta-analyses have confirmed 50-70% reductions in restenosis with DCB compared to POBA, with restenosis and TLR rates comparable to DES in selected populations.The pooled DAEDALUS analysis of individual patient data further demonstrated that DCB angioplasty and repeat DES implantation are similarly effective and safe for the treatment of bare-metal stent in-stent restenosis, findings broadly corroborated by the RIBS V trial and the BIOLUX randomised controlled trial.[11–13] A recent updated meta-analysis with trial sequential analysis similarly found no significant difference in MACE between DCB and DES for in-stent restenosis, lending further support to DCB as a stent-sparing alternative.[14] Von Koch et al reported similar safety and efficacy profiles in their long-term comparison of DCB, DES, and POBA in a contemporary real-world cohort. Chioncel et al provided a comprehensive pharmacological framework supporting the clinical rationale for sirolimus-based DCB platforms. These findings are further supported by a recent comprehensive review highlighting the expanding clinical applications of DCB technology across the spectrum of coronary artery disease and are consistent with current European Society of Cardiology guideline recommendations for the management of chronic coronary syndromes.[15,16]

Limitations

Several limitations of this study warrant acknowledgement. First, as a single-centre prospective observational study without randomization, selection bias and confounding by indication cannot be excluded, and results should be interpreted accordingly. Second, routine follow-up angiography was not performed in asymptomatic patients, consistent with contemporary clinical practice; accordingly, the restenosis rate is based on clinical presentation rather than angiographic assessment and may underestimate the true anatomical restenosis rate. Third, the median follow-up of 6-12 months precludes conclusions regarding long-term durability. Fourth, the relatively modest cohort size (n = 59) limits statistical precision, particularly for low-frequency events. Fifth, complete baseline comorbidity data (including diabetes, hypertension, and renal function) were not uniformly available for all patients, limiting multivariable risk adjustment. Notwithstanding these limitations, this series represents an unselected consecutive real-world cohort and provides meaningful complementary evidence to existing randomized trial data.

CONCLUSION

This prospective single-center experience with 59 consecutive patients demonstrates that sirolimus-eluting balloon angioplasty is a highly effective, safe, and versatile strategy for percutaneous coronary revascularization. The 59/59 (100%) technical success rate, 58/59 (98.3%) uneventful procedural course, and 1/59 (1.7%) in-hospital MACE rate are favorable relative to published benchmarks and substantially superior to historical POBA outcomes.

The mechanistic advantages of sirolimus, mediated via mTOR-selective inhibition of smooth muscle cell proliferation with relative preservation of endothelial integrity, contribute to the favorable outcomes observed herein and align with the biological rationale for preferring sirolimus over paclitaxel as the active pharmaceutical agent in DCB platforms.

The avoidance of a permanent metallic implant confers additional clinical advantages: maintained vessel compliance, preserved compatibility with future surgical or percutaneous revascularization, absence of stent thrombosis risk, and the possibility of abbreviated DAPT duration in high-risk patients (three to six months) compared with the 12 months mandated following DES implantation. These attributes are of value in patients at elevated bleeding risk.

Further evidence from prospective randomized trials with longer follow-up and larger sample sizes is required to definitively characterize the long-term efficacy of sirolimus-eluting balloon technology and to delineate the patient subgroups most likely to derive maximal benefit. The current evidence base, augmented by the data presented herein, strongly supports sirolimus-DEB as a first-line intervention for appropriately selected coronary lesions across diverse clinical contexts.

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