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DRUG-COATED BALLOON ANGIOPLASTY IN REAL-WORLD CLINICAL PRACTICE: SINGLE-CENTRE EXPERIENCE FROM KAZAKHSTAN

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Abstract

Introduction. Drug-coated balloons (DCB) deliver an antiproliferative agent to the vessel wall during a single balloon inflation without leaving a permanent implant. Real-world data from Kazakhstan and Central Asia remain limited.

Aim. To assess the procedural safety and mid-term clinical outcomes of DCB angioplasty in a consecutive real-world cohort with de novo coronary lesions and in-stent restenosis treated at a single interventional cardiology centre in Kazakhstan.

Materials and methods. This retrospective, single-centre observational study included 102 consecutive patients treated with the MagicTouch™ sirolimus-coated balloon (Concept Medical) between August 2024 and May 2025 (data cut-off 31 May 2026). The cohort comprised de novo lesions, in-stent restenosis, small-vessel disease (<2.5 mm), distal and bifurcation lesions, and hybrid procedures. Clinical outcomes were assessed at 3, 6 and 12 months. The primary endpoint was major adverse cardiovascular events (MACE): cardiac death, non-fatal myocardial infarction and clinically driven target lesion revascularization.

Results. Mean age was 63.2 ± 9.4 years; 66.7% were male; 37.3% had diabetes and 21.6% chronic kidney disease. A bail-out stent was required in 17.6%. Procedural success was achieved in 97.1%. At 12 months, MACE occurred in 5 of the 92 patients with complete follow-up (5.4%); all events were clinically driven target lesion revascularization (5/92; 5.4%), with no non-fatal myocardial infarction (0/92) and no cardiac death (0/92). Freedom from angina (CCS class 0) was documented in 66/92 (71.7%) and CCS class 0–II in 85/92 (92.4%). No vessel thrombosis was recorded.

Conclusion. In this observational cohort, DCB angioplasty was associated with high procedural success, progressive symptomatic improvement and no observed vessel thrombosis across small-vessel disease, in-stent restenosis, and distal and bifurcation lesions. As a single-arm study, it cannot establish comparative safety or efficacy versus drug-eluting stents; prospective multicentre studies with angiographic endpoints are warranted.

Key words: coronary balloon angioplasty, coronary restenosis, coronary artery disease, sirolimus, percutaneous coronary intervention.

Introduction. Coronary artery disease (CAD) causes approximately 9 million deaths each year and remains the leading cause of cardiovascular death worldwide [1]. Over the past three decades, percutaneous coronary intervention has evolved from plain balloon angioplasty to contemporary drug-eluting stents, substantially improving outcomes across the spectrum of obstructive CAD, from stable angina to acute coronary syndromes [1,2].

Despite these advances, revascularization with drug-eluting stents (DES) is associated with persistent limitations. The permanent metallic scaffold may contribute to early and late stent thrombosis, particularly after premature discontinuation of antiplatelet therapy [1,2]. In-stent restenosis (ISR), resulting from neointimal tissue proliferation within the stented segment,

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remains one of the most challenging problems in contemporary interventional cardiology [3]. In addition, prolonged dual antiplatelet therapy (DAPT) increases bleeding risk in older patients, those with chronic kidney disease (CKD) and patients requiring anticoagulation. The accumulation of permanent metal may also impair vascular remodelling and constrain future surgical bypass options [4,5].

Drug-coated balloons (DCB) provide an alternative approach based on the "leave nothing behind" principle. As a device class, DCB deliver an antiproliferative agent – historically paclitaxel and, more recently, sirolimus – directly to the vessel wall during a single transient balloon inflation, without implanting a permanent scaffold. The device used in the present study, the MagicTouch™ sirolimus-coated balloon, delivers sirolimus, which inhibits smooth muscle cell proliferation by blocking the mammalian target of rapamycin (mTOR) pathway, whereas paclitaxel acts through microtubule stabilization. Irrespective of the coating agent, the intended effect is suppression of the neointimal hyperplasia that underlies both de novo restenosis and ISR. The absence of an implant preserves vasomotor function, removes a surface that may promote late thrombosis and may permit shorter antiplatelet therapy compared with DES [6–9].

The evidence base for coronary DCB has expanded. In ISR, meta-analyses and long-term randomized trials have shown that DCB are superior to plain balloon angioplasty and comparable to DES, with a potential safety benefit in terms of major adverse events [3–5,10]. In small, non-complex coronary arteries (reference diameter <2.5 mm), randomized studies, including the three-year results of the PICCOLETO II trial, have shown DCB to be non-inferior or superior to DES [11,12]. The 2024 European Society of Cardiology (ESC) Guidelines on chronic coronary syndromes list DCB as an acceptable alternative to DES for ISR and for challenging anatomy [1]. Additional evidence supports their use in de novo bifurcation lesions, diffuse disease, larger vessels and patients at high bleeding risk [13–16].

Despite this growing evidence, published real-world data on DCB from Kazakhstan and Central Asia remain scarce, and it is uncertain to what extent results from clinical trials are reproduced in local practice [17–22]. To address this gap, we conducted a retrospective observational study to assess the safety and mid-term clinical outcomes of DCB angioplasty in 102 consecutive patients treated at the Catheterization Laboratory of the JSC "National Scientific Medical Center", Astana, Kazakhstan.

Materials and methods.

Ethical issues

The research protocol was reviewed and approved by the Ethics Committee of the JSC "National Scientific Medical Center", Republic of Kazakhstan (Protocol No. 095/K4-89 dated 13.05.2024). All participants provided written informed consent prior to inclusion in the study. During data collection and analysis, anonymity and confidentiality were strictly observed.

Study design and setting

This was a retrospective, single-centre observational study conducted at the Catheterization Laboratory of the JSC "National Scientific Medical Center". This tertiary cardiac centre holds national accreditation and performs between 3,500 and 4,000 diagnostic coronary angiographies annually, with individual operators performing 600 to 800 such procedures per year. All interventions were consistent with national clinical protocols of Kazakhstan and current ESC guidelines [1,2].

Study population

Patients were consecutively enrolled if they underwent DCB angioplasty between August 2024 and May 2025. The database was locked on 31 May 2026 (data cut-off); no event occurring after this date was included. The cut-off was defined so that every enrolled patient had the opportunity to complete the full 12-month follow-up window before database lock;

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consequently, no patient was excluded from the 12-month analysis because of insufficient elapsed follow-up time, and the only reason for a missing 12-month assessment was loss to follow-up. Inclusion criteria were age 18 years or older and documented obstructive CAD with stenosis of 70% or greater (or 50% or greater with confirmed ischaemia) requiring revascularization. DCB had to be used as the primary or adjunctive treatment strategy, including de novo lesions, ISR, small vessels (<2.5 mm), distal or bifurcation lesions, and combined DCB-and-stent approaches. Patients were excluded for cardiogenic shock at presentation, active malignancy with projected survival under 12 months, severe hepatic failure, inability or unwillingness to adhere to prescribed antiplatelet therapy, or incomplete procedural documentation.

Interventional procedure

All procedures were performed by experienced interventional cardiologists. Access was radial or femoral, using 6 Fr guiding catheters in all cases. For intermediate stenoses (40–70%), the operator decided whether fractional flow reserve (FFR) or the instantaneous wave-free ratio (iFR) was used to assess haemodynamic significance.

Before DCB deployment, lesions were prepared in two steps. A semi-compliant balloon was inflated to 6–10 atm for at least 30 seconds; when required, a non-compliant high-pressure balloon was subsequently used. This step reduced elastic recoil and ensured uniform vessel preparation, a prerequisite for even drug transfer. Adequate preparation was confirmed angiographically by TIMI III flow and the absence of type A or B dissection.

The MagicTouch™ sirolimus-coated balloon (Concept Medical) was used for angioplasty, delivering sirolimus at 1.27 μg/mm^2. Balloon size was matched to the vessel at a ratio of 0.9:1 to 1.0:1. Inflation was performed at 10–16 atm for at least 60 seconds to allow complete drug transfer, followed by a 60-second interval before the final angiogram to permit sufficient drug absorption. When the result was inadequate (residual stenosis exceeding 30%, type C or worse dissection, or TIMI flow below III), a drug-eluting stent was implanted as a bail-out, resulting in a hybrid strategy.

Pharmacological treatment

Unfractionated heparin was administered at 50–60 IU/kg during the procedure. After DCB-only PCI, patients received DAPT comprising aspirin 100 mg daily indefinitely and clopidogrel 75 mg daily; clopidogrel was continued for at least one month in elective cases and for 3–6 months in acute coronary syndrome, consistent with national protocols and ESC recommendations [1,2,23]. When a bail-out DES was implanted, DAPT was continued for 12 months. High-intensity statin therapy, renin-angiotensin system inhibitors and beta-blockers were prescribed according to current guidelines [1,2].

Definitions of endpoints

Procedural success was defined as residual stenosis of the target lesion below 30% with TIMI III flow and no significant procedural complications (in-hospital mortality, Q-wave myocardial infarction or need for emergency bypass surgery). MACE comprised cardiac death, non-fatal myocardial infarction (Fourth Universal Definition) and clinically driven target lesion revascularization (TLR). TLR was defined as any re-intervention at the target lesion prompted by objective evidence of ischaemia together with angiographic restenosis of 50% or greater. Vessel thrombosis was assessed by Academic Research Consortium (ARC) criteria. Non-adherence was recorded when a patient discontinued antiplatelet agents or statins for more than seven consecutive days.

Follow-up

Patients attended scheduled outpatient visits at 3, 6 and 12 months. At each visit, the Canadian Cardiovascular Society (CCS) angina class, MACE components, non-target vessel revascularization, cardiovascular rehospitalization, medication adherence and signs of heart

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failure were systematically recorded. Adverse events were adjudicated by the treating cardiologist after review of all available medical records and angiograms. A visit was counted as completed when performed within ±1 month of the scheduled 3- and 6-month dates and within ±2 months of the scheduled 12-month date. A patient was classified as lost to follow-up when neither an in-person visit nor a documented telephone contact could be obtained within the corresponding window or at any later point up to the data cut-off. Outcomes were analysed at each time point on an as-assessed basis; denominators therefore differ between visits and are stated explicitly for every reported proportion.

Statistical analysis

Normally distributed continuous variables are reported as mean ± standard deviation (SD); skewed variables are reported as median with interquartile range (IQR). Normality was assessed with the Shapiro–Wilk test. Categorical variables are presented as absolute counts and percentages. MACE rates are reported cumulatively at each time point. Given the retrospective, descriptive design, formal hypothesis testing was not the primary aim, and subgroup comparisons were regarded as exploratory. Analyses were performed with IBM SPSS Statistics v. 26.0 (IBM Corp., Armonk, NY, USA); a two-sided p-value below 0.05 was considered statistically significant.

Results.

Patient flow

Between August 2024 and May 2025, 102 consecutive patients underwent DCB angioplasty and all 102 were included in the analysis. The database was locked on 31 May 2026. By that date all 102 patients (100%) had passed the scheduled 12-month follow-up window, so no patient was censored for insufficient elapsed follow-up time. Follow-up was complete in 100 of 102 patients at 3 months (98.0%), 96 of 102 at 6 months (94.1%) and 92 of 102 at 12 months (90.2%). Cumulatively, 10 of 102 patients (9.8%) were lost to follow-up: 6 could not be contacted at any subsequent visit and 4 had relocated outside the region; the corresponding cumulative losses were 2 by 3 months, 6 by 6 months and 10 by 12 months. Outcomes at each time point were analysed only in the patients actually assessed at that visit (n=100, 96 and 92 at 3, 6 and 12 months, respectively); the 12-month analysis was therefore based on the 92 patients with complete 12-month follow-up rather than the full cohort of 102. Baseline characteristics are reported for the entire cohort of 102 patients.

Mean age was 63.2 ± 9.4 years, and 68 patients (66.7%) were male. Cardiovascular risk factors were common. Arterial hypertension was present in 84 patients (82.4%), diabetes mellitus in 38 (37.3%) and dyslipidaemia in 76 (74.5%). Current or former smoking was reported in 42 patients (41.2%). CKD, defined as an eGFR below 60 mL/min/1.73 m^2, was present in 22 patients (21.6%), reflecting the multisystem burden of the cohort. Prior PCI had been performed in 29 patients (28.4%), of whom 6 (5.9%) had previously undergone coronary artery bypass grafting (CABG). Acute coronary syndrome was the initial presentation in 31 patients (30.4%), while the remaining 71 (69.6%) presented with stable angina. Left ventricular systolic dysfunction (ejection fraction below 50%) was present in 24 patients (23.5%). Baseline characteristics are detailed in Table 1.

Table 1. Baseline patient characteristics (n=102).

Characteristic	n (%) or mean ± SD
Age, years	63.2 ± 9.4
Male sex	68 (66.7%)
Arterial hypertension	84 (82.4%)
Diabetes mellitus (total)	38 (37.3%)

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Characteristic	n (%) or mean ± SD
insulin-treated	14 (13.7%)
non-insulin-treated	24 (23.5%)
Dyslipidaemia	76 (74.5%)
Smoking (current or former)	42 (41.2%)
CKD (eGFR <60 mL/min/1.73 m²)	22 (21.6%)
on dialysis	4 (3.9%)
Obesity (BMI ≥30 kg/m²)	31 (30.4%)
Prior PCI	29 (28.4%)
Prior CABG	6 (5.9%)
ACS at presentation	31 (30.4%)
NSTEMI	19 (18.6%)
unstable angina	12 (11.8%)
Stable angina	71 (69.6%)
Baseline CCS class III–IV	52 (51.0%)
LV ejection fraction <50%	24 (23.5%)

Note: ACS – acute coronary syndrome; BMI – body mass index; CABG – coronary artery bypass grafting; CCS – Canadian Cardiovascular Society classification; CKD – chronic kidney disease; eGFR – estimated glomerular filtration rate; LV – left ventricle; NSTEMI – non-ST-elevation myocardial infarction; PCI – percutaneous coronary intervention; SD – standard deviation.

Lesion characteristics and angiographic data

A total of 118 lesions were treated during the 102 index procedures (mean 1.16 per patient). De novo lesions accounted for 85 (72.0%) of treated segments and ISR for 33 (28.0%), of which 26 (78.8%) involved a DES and 7 (21.2%) a bare-metal stent (BMS). Small-vessel disease (<2.5 mm) was present in 52 lesions (44.1%), distal lesions in 36 (30.5%) and bifurcation lesions in 19 (16.1%). By coronary territory, the left anterior descending artery (LAD) accounted for 47.5%, the right coronary artery (RCA) for 28.8%, the left circumflex artery (LCx) for 22.0% and the left main for 1.7%. Complex morphology (ACC/AHA type B2/C) was present in 54.2% of lesions. Angiographic data are presented in Table 2 and Figure 1.

Table 2. Lesion characteristics and angiographic data (n=118 lesions).

Characteristic	n (%)
De novo lesion	85 (72.0%)
In-stent restenosis (ISR)	33 (28.0%)
ISR after DES	26 (78.8% of ISR)
ISR after BMS	7 (21.2% of ISR)
Small-vessel disease (<2.5 mm)	52 (44.1%)
Distal lesion	36 (30.5%)
Bifurcation lesion	19 (16.1%)
Multivessel disease at index procedure, % of patients (n=102)	24 (23.5%)
LAD territory	56 (47.5%)
RCA territory	34 (28.8%)

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ISSN 2524 – 0684 e-ISSN 2524 – 0692

Characteristic	n (%)
LCx territory	26 (22.0%)
Left main coronary artery	2 (1.7%)
Complex morphology B2/C (ACC/AHA)	64 (54.2%)
Pre-procedural stenosis, %	82.1 ± 11.4
Reference vessel diameter, mm	2.6 ± 0.5
Lesion length, mm	18.4 ± 7.2
SYNTAX score, median (IQR)	16.4 (11–22)

Note: BMS – bare-metal stent; DES – drug-eluting stent; IQR – interquartile range; ISR – in-stent restenosis; LAD – left anterior descending artery; LCx – left circumflex artery; RCA – right coronary artery.

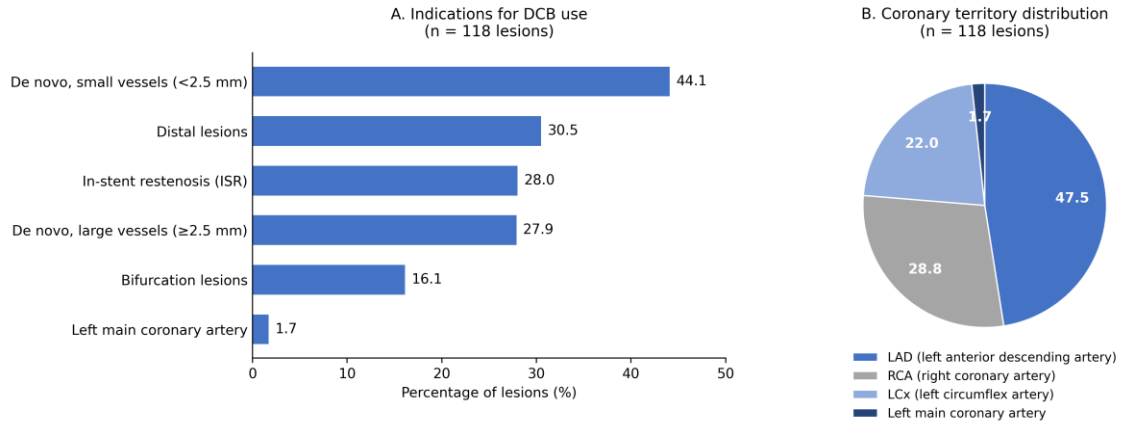


Figure 1. Distribution of lesion types and coronary territories (n=118 lesions). Hybrid strategy (DCB + stent) was used in 18/102 patients (17.6%) and is reported separately from lesion-level percentages. Panel A – indications for DCB use. Panel B – distribution by coronary territory. DCB – drug-coated balloon; ISR – in-stent restenosis; LAD – left anterior descending artery; LCx – left circumflex artery; RCA – right coronary artery.

Procedural characteristics

Radial access was used in 88 patients (86.3%) and femoral access in 14 (13.7%). All procedures used 6 Fr guiding catheters. Mandatory pre-dilatation with a semi-compliant balloon was performed in 100% of cases, and a non-compliant high-pressure balloon was additionally used in 62 patients (60.8%) to optimize lesion preparation.

The MagicTouch™ sirolimus-coated balloon was deployed at a mean inflation pressure of 14.2 ± 2.8 atm, and an inflation time of at least 60 seconds was maintained in all cases. DCB diameter was 2.0–2.5 mm in 66 patients (64.7%) and 2.75–3.5 mm in 36 (35.3%). Bail-out DES implantation was required in 18 patients (17.6%): for type C or worse dissection in 11 (61.1%) and for residual stenosis exceeding 30% in 7 (38.9%). Procedural success was achieved in 99 of 102 patients (97.1%). No no-reflow, coronary perforation, acute vessel occlusion or periprocedural myocardial infarction was recorded. One vascular access-site complication requiring management was observed (1.0%). Procedural data are presented in Table 3.

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ISSN 2524 – 0684 e-ISSN 2524 – 0692

Table 3. Procedural characteristics (n=102).

Parameter	n (%) or mean ± SD
Radial access	88 (86.3%)
Femoral access	14 (13.7%)
6 Fr guiding catheter (all cases)	102 (100%)
Mandatory pre-dilatation with SC balloon	102 (100%)
Additional NC high-pressure balloon	62 (60.8%)
DCB diameter 2.0–2.5 mm	66 (64.7%)
DCB diameter 2.75–3.5 mm	36 (35.3%)
DCB length, mm	20.1 ± 6.4
DCB inflation pressure, atm	14.2 ± 2.8
Inflation time ≥60 s	102 (100%)
Residual stenosis after DCB, %	14.3 ± 9.1
Hybrid strategy (bail-out DES)	18 (17.6%)
dissection ≥ type C	11 (61.1%)
residual stenosis >30%	7 (38.9%)
Procedural success	99 (97.1%)
Contrast volume, mL	158 ± 42
Fluoroscopy time, min	18.4 ± 7.8
Radiation dose, mGy	1280 ± 380
Periprocedural MI / perforation / no-reflow	0 (0%)
Vascular access-site complication	1 (1.0%)

Note: DCB – drug-coated balloon; DES – drug-eluting stent; MI – myocardial infarction; NC – non-compliant; SC – semi-compliant; SD – standard deviation.

Clinical outcomes during follow-up

Symptomatic improvement was consistent and progressive across all time points. The complete CCS distribution at each visit is given in Table 4 and Figure 2; the four CCS categories (0, I, II and III–IV) are mutually exclusive and exhaustive and sum to 100% of the patients assessed at each time point. Freedom from angina (CCS class 0) was documented in 63 of 100 patients (63.0%) at 3 months, 65 of 96 (67.7%) at 6 months and 66 of 92 (71.7%) at 12 months. CCS class I was recorded in 17 of 100 (17.0%), 14 of 96 (14.6%) and 11 of 92 (12.0%), and CCS class II in 13 of 100 (13.0%), 9 of 96 (9.4%) and 8 of 92 (8.7%) at 3, 6 and 12 months, respectively. The proportion of patients in CCS class 0–II was therefore 93 of 100 (93.0%) at 3 months, 88 of 96 (91.7%) at 6 months and 85 of 92 (92.4%) at 12 months. Persistent angina (CCS class III–IV) was recorded in 7 of 100 (7.0%), 8 of 96 (8.3%) and 7 of 92 (7.6%) at 3, 6 and 12 months, respectively. Recurrent angina requiring adjustment of antianginal therapy occurred in 13 of 100 (13.0%), 10 of 96 (10.4%) and 9 of 92 (9.8%); these patients are already contained within CCS classes I–II and III–IV and do not form a separate category.

For hard clinical endpoints, the cumulative MACE rate was 2 of 100 patients (2.0%) at 3 months, 4 of 96 (4.2%) at 6 months and 5 of 92 (5.4%) at 12 months. All five MACE events were clinically driven TLR (5/92; 5.4% at 12 months) and occurred predominantly in patients with small-vessel disease and diffuse distal lesions; no non-fatal myocardial infarction (0/92) and no cardiac death (0/92) was recorded at any time point. Non-target vessel revascularization

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ISSN 2524 – 0684 e-ISSN 2524 – 0692

was required in 3 patients (3.3%) at 12 months, reflecting disease progression in previously untreated segments.

No definite or probable vessel thrombosis was recorded at any time point during the 12-month follow-up (ARC criteria). DAPT adherence declined from 94 of 100 patients (94.0%) at 3 months to 81 of 92 (88.0%) at 12 months; statin adherence remained high at 84 of 92 (91.3%). Follow-up results are presented in Table 4 and Figure 3.

Table 4. Clinical outcomes during follow-up (3, 6 and 12 months).

Outcome	**3 mo (n=100)**	**6 mo (n=96)**	**12 mo (n=92)**
Freedom from angina (CCS 0)	63 (63.0%)	65 (67.7%)	66 (71.7%)
CCS class I	17 (17.0%)	14 (14.6%)	11 (12.0%)
CCS class II	13 (13.0%)	9 (9.4%)	8 (8.7%)
CCS class III–IV (persistent angina)	7 (7.0%)	8 (8.3%)	7 (7.6%)
CCS class 0–II (sum of classes 0, I and II)	93 (93.0%)	88 (91.7%)	85 (92.4%)
Total CCS distribution (0 + I + II + III–IV)	100 (100%)	96 (100%)	92 (100%)
Recurrent angina, therapy adjusted*	13 (13.0%)	10 (10.4%)	9 (9.8%)
Clinically driven TLR	2 (2.0%)	4 (4.2%)	5 (5.4%)
Non-target vessel revascularization	1 (1.0%)	2 (2.1%)	3 (3.3%)
Non-fatal MI	0	0	0
Cardiac death	0	0	0
MACE (composite)	2 (2.0%)	4 (4.2%)	5 (5.4%)
Vessel thrombosis (ARC definite/probable)	0	0	0
Cardiovascular rehospitalization	3 (3.0%)	5 (5.2%)	6 (6.5%)
DAPT adherence	94 (94.0%)	91 (94.8%)	81 (88.0%)
Statin therapy adherence	96 (96.0%)	93 (96.9%)	84 (91.3%)

Note: ARC – Academic Research Consortium; CCS – Canadian Cardiovascular Society classification; DAPT – dual antiplatelet therapy; MACE – major adverse cardiovascular events (cardiac death + non-fatal MI + TLR); MI – myocardial infarction; TLR – target lesion revascularization. Percentages are calculated against the number of patients actually assessed at each time point (n=100, 96 and 92 at 3, 6 and 12 months). CCS classes 0, I, II and III–IV are mutually exclusive and sum to 100% at each time point.

* Recurrent angina requiring adjustment of antianginal therapy is a descriptive overlapping category: these patients are already counted within CCS classes I–II and III–IV and do not form an additional class.

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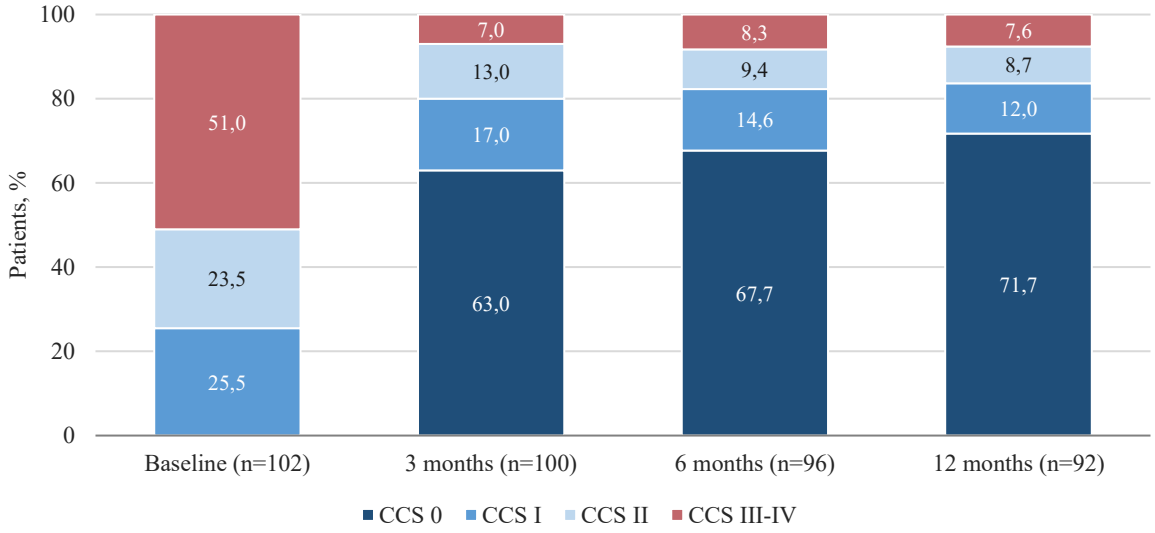


Figure 2. Complete distribution of angina functional class (CCS) at baseline (n=102) and at 3 (n=100), 6 (n=96) and 12 months (n=92). Each column shows all four mutually exclusive CCS categories and totals 100% of the patients assessed at that time point; absolute numbers are given in Table 4. CCS – Canadian Cardiovascular Society classification.

Subgroup observations

Subgroup rates were recalculated from the primary database against the denominator of patients actually assessed at 12 months. Of the 92 patients with complete 12-month follow-up, 34 had diabetes mellitus and 58 did not. All five MACE events were clinically driven TLR: 3 occurred in patients with diabetes (3/34; 8.8%) and 2 in patients without diabetes (2/58; 3.4%), so that the subgroup counts add up exactly to the 5 events reported for the whole cohort. Four of the five TLR events occurred in patients treated for small-vessel disease, and the two late events (between the 6- and 12-month visits) both occurred in patients with diabetes and diffuse distal CAD. Among the 11 patients with low DAPT adherence at 12 months, angina recurrence was observed in 7 (7/11; 63.6%), underscoring the importance of medication adherence. CCS class dynamics are illustrated in Figure 2. Because these subgroups are small and the total number of events is only five, no formal statistical comparison was performed; the observations are exploratory and hypothesis-generating and should not be interpreted as confirmatory.

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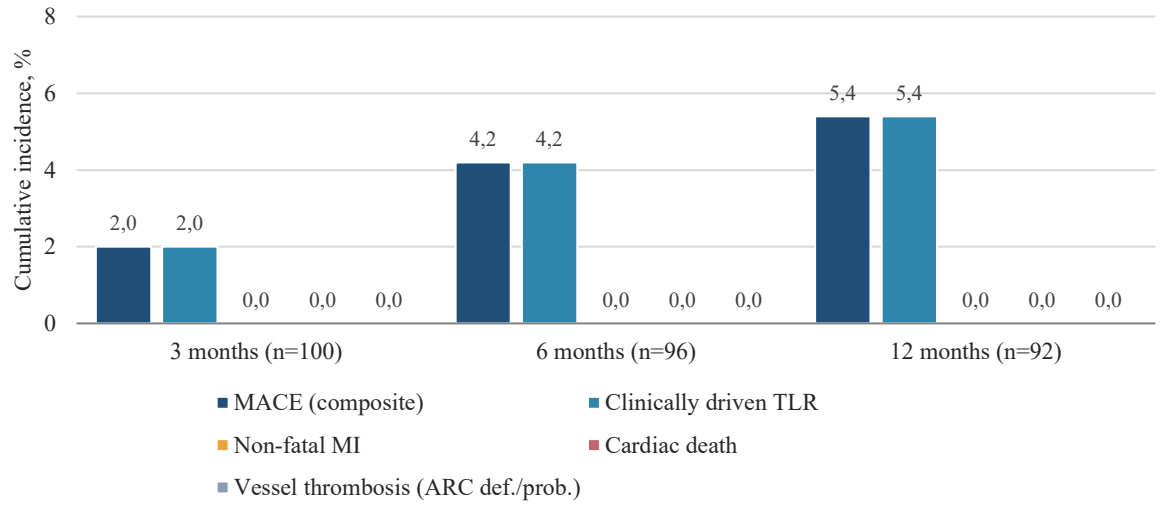


Figure 3. Cumulative incidence of adverse clinical events over 12 months of follow-up. All components of the primary endpoint are plotted on a single 0–8% scale so that low-frequency and zero values remain legible. Denominators: n=100 at 3 months, n=96 at 6 months and n=92 at 12 months. Symptom status and treatment adherence are presented in Table 4 and Figure 2. MACE – major adverse cardiovascular events; TLR – target lesion revascularization; ARC – Academic Research Consortium.

Discussion. This single-centre, real-world series describes the procedural and mid-term clinical outcomes of DCB angioplasty in a heterogeneous Central Asian cohort. Among 102 patients with a range of coronary lesions – de novo stenoses, ISR, small-vessel disease, and distal and bifurcation lesions – DCB angioplasty was procedurally successful in 97.1%. Symptomatic improvement was progressive and sustained over one year. The 12-month MACE rate of 5.4% is broadly consistent with other real-world series, and no vessel thrombosis was observed. To our knowledge, published real-world data on coronary DCB from the Central Asian region remain limited, and the present series adds regional evidence to the existing literature.

The 12-month MACE rate of 5.4% is broadly consistent with large real-world DCB registries. Pan et al. reported a rate of 8.2% in a prospective all-comers cohort of 581 patients, and Shin et al. reported 9.6% in a series of 1,117 patients with multivessel DCB use [8,9]. A 2024 scientific update by Lazar et al. described consistently favourable DCB outcomes across varied patient groups and healthcare settings, a view also supported by the Second Report of the Asia-Pacific DCB Consensus Group by Her et al. in 2025 [6,23,24]. The TLR rate of 5.4% at 12 months is consistent with the 7.0% at 12 months in PICCOLETO II and with long-term ISR data reported by von Koch et al. in 2024 [11,19]. The absence of vessel thrombosis during follow-up is mechanistically plausible: in the absence of a permanent metallic scaffold, a principal substrate for early and late thrombosis is removed [6,23].

Small-vessel disease was the most frequent indication in our series, accounting for 44.1% of lesions. Stenting of vessels smaller than 2.5 mm carries a high risk of restenosis, related to a less favourable neointima-to-lumen ratio, difficulty achieving full stent expansion in calcified or tortuous segments, and limited options for future re-intervention [16,25]. Meta-analyses by Sanz Sánchez et al. (2021) and Angheluta et al. (2024) found DCB to be non-inferior to DES at both one and three years [12,26]. In a head-to-head randomized trial, Ninomiya et al. (2023) showed that sirolimus-coated balloons were non-inferior to paclitaxel-coated devices in de novo small-vessel disease, a finding directly relevant to the MagicTouch™ sirolimus-coated balloon used in our series [27]. Further supporting evidence was provided by Xu et al. (2022) for

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biolimus-coated devices [21]. In our cohort, patients with diabetes had a numerically higher 12-month MACE rate (3/34; 8.8%) than patients without diabetes (2/58; 3.4%); with only five events in total, this difference is hypothesis-generating rather than confirmatory. This is consistent with the meta-analysis by Verdoia et al. (2024) and with data from Seeger et al. (2023) reporting higher event rates in insulin-treated patients [7,28], and with the real-world observation by Li et al. (2022) in diabetic patients with small-vessel disease [20]. These findings underline the importance of enhanced secondary prevention and closer follow-up in this population.

ISR accounted for 28.0% of treated lesions, consistent with the referral pattern of a tertiary centre. The use of DCB for ISR is supported by strong evidence: meta-analyses by Zhu et al. (2021) [5] and a systematic review by Kulyassa et al. (2023) [10] showed DCB to be superior to plain balloon angioplasty and comparable to DES. The 10-year results of ISAR-DESIRE 3, reported by Giacoppo et al. in 2023 [4], provide the most extensive long-term safety data for ISR. Von Koch et al. (2024) [19], in a long-term real-world ISR population, found comparable MACE rates for DCB and DES. Accordingly, the 2024 ESC Guidelines endorse DCB as an alternative to DES for ISR, which is particularly relevant for patients with multiple stent layers, elevated bleeding risk or complex anatomy [1,3]. These features were common among the ISR patients we treated.

The avoidance of permanent metallic implants is of increasing clinical relevance, particularly for patients with diffuse CAD, diabetes or hypertension, all common in our cohort. A DCB-first or DCB-only strategy preserves the native vessel architecture for future intervention, reduces the amount of foreign material and facilitates subsequent surgical bypass when required [6,17,29]. Yang et al. (2022) showed durable results with DCB in diffuse coronary disease, and the SCRAP study by Meunier et al. (2023) confirmed the feasibility of a stent-free strategy in stable CAD [17,29]. Our approach, which used DCB whenever feasible and reserved a drug-eluting stent as a bail-out, was applied in 17.6% of participants. This hybrid strategy represents a reasonable balance between immediate procedural safety and the longer-term goal of minimizing implanted metal [6,24].

Regarding DAPT adherence, the association between poor adherence and recurrent angina (7 of 11 non-adherent patients; 63.6%) merits attention. After DCB angioplasty, DAPT serves to protect against ischaemic events beyond the treated segment and to support local healing at the intervention site; premature discontinuation, typically within the first one to three months, may interfere with this process. The optimal duration of DAPT after DCB has been examined by Zhang et al. (2021) [23]. Räsänen et al. (2023) and Jones et al. (2022) reported that shortened DAPT regimens are feasible in patients at elevated bleeding risk [18,30]. The principle demonstrated by the MASTER DAPT trial (Valgimigli et al., 2021), which confirmed the efficacy of abbreviated DAPT after DES-based PCI at high bleeding risk [31], is directly applicable, and perhaps even more so, after DCB. Our 12-month adherence rate of 88.0% compares favourably with other published registries. These results support the value of structured programmes to improve adherence and simplify treatment regimens.

Bifurcation lesions accounted for 16.1% of treated lesions (19/118). A provisional DCB strategy predominated, with a DCB used in the side branch and a drug-eluting stent in the main vessel when required. Fezzi et al. (2025) summarized the accumulating data on DCB at bifurcation sites [32]. In the HYPER study, Pellegrini et al. (2023) showed that combining DCB with DES is feasible [33], and Her et al. (2025) reported encouraging outcomes for left main bifurcation lesions [34]. Dash et al. (2022) provided a comprehensive review of the potential and current limitations of this approach [22]. Beyond bifurcations, meta-analyses by Sun et al. (2024) and Gobbi et al. (2025) support the non-inferiority of DCB to DES in de novo large-

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vessel disease (≥2.5 mm), suggesting a broader potential role for DCB-based revascularization [13,14].

Study limitations

The retrospective, single-centre design is a limitation and is subject to selection bias; it does not allow firm causal inference. The absence of a randomized comparator group means that the observed outcomes cannot be attributed to the DCB strategy alone. Routine angiographic follow-up was not mandated by protocol, so the true rate of angiographic restenosis is likely underestimated. Intravascular imaging (OCT or IVUS) was not performed in every patient, which limits precise lesion characterization and assessment of procedural optimization. The cohort reflects the case mix of a single tertiary centre, so the findings may not be fully generalizable. The subgroup analyses should be regarded as hypothesis-generating only, given the small numbers and the absence of formal statistical testing.

Conclusion. In this series of 102 consecutive patients treated at a single centre under real-world conditions, DCB angioplasty with the MagicTouch™ sirolimus-coated balloon was associated with high procedural success (97.1%) and no observed vessel thrombosis. Mid-term outcomes were favourable, with a 12-month MACE rate of 5.4% and 71.7% of patients free from angina at 12 months. These outcomes were observed across a diverse population, including small-vessel disease, ISR, distal and bifurcation lesions, and patients with diabetes mellitus and CKD.

To our knowledge, this is among the first reports of coronary DCB outcomes from Central Asia. The findings add regional real-world data to the global evidence base and are consistent with the feasibility and safety of the “leave nothing behind” approach as an option that may complement, or in selected lesions replace, permanent stenting. As a single-arm observational study, it cannot establish the comparative efficacy of DCB versus DES. Prospective, multicentre studies with angiographic assessment, intravascular imaging and predefined subgroup analyses are warranted to better define the optimal patient and lesion criteria for DCB-based PCI.

Conflict of interest. The authors declare no conflict of interest. The MagicTouch™ sirolimus-coated balloon was used as part of routine institutional practice; this study was not funded, commissioned or supported by Concept Medical or any other commercial entity.

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Data availability statement. The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to institutional data confidentiality requirements.

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ДӘРІЛІК ЖАБЫНДЫ БАЛЛОНДЫ АНГИОПЛАСТИКАНЫҢ НАҚТЫ КЛИНИКАЛЫҚ ТӘЖІРИБЕДЕ ҚОЛДАНЫЛУЫ: ҚАЗАҚСТАНДАҒЫ БІР ОРТАЛЫҚТЫҚ ТӘЖІРИБЕ

А. ТӨЛЕГЕН, Б.С. ЕРМАГАМБЕТ, Б.С. ЖАКЕНОВ, А.Н. АХАТОВ, С.Ж. СЕЙТБЕКОВ, Н.Б. ИСА, Д.А. СУЛТАНОВ, А.Ж. САЛМАКОВА

«Ұлттық ғылыми медициналық орталық» АҚ, Астана, Қазақстан

Түйіндеме

Кіріспе. Дәрілік жабынды баллондар (ДЖБ) антипролиферативті препаратты бір реттік баллон инфляциясы кезінде тамыр қабырғасына жеткізіп, тұрақты имплантат қалдырмайды. Қазақстан мен Орталық Азиядан алынған нақты клиникалық тәжірибе деректері шектеулі.

Мақсаты. Қазақстандағы бір интервенциялық кардиология орталығында de novo коронарлық зақымданулары мен стент ішіндегі рестенозы бар науқастарда ДЖБ ангиопластикасының процедуралық қауіпсіздігі мен орташа мерзімдегі клиникалық нәтижелерін бағалау.

Материалдар мен әдістер. Ретроспективті бір орталықты бақылау зерттеуіне 2024 жылдың тамызынан 2025 жылдың мамырына дейін (деректер қимасы 2026 жылғы 31 мамыр) MagicTouch™ сиролимус жабынды баллонымен (Concept Medical) емделген 102 науқас қатарынан енгізілді. Топқа de novo зақымданулары, стент ішіндегі рестенозы, ұсақ тамырлар ауруы (<2,5 мм), дистальдық және бифуркациялық зақымданулар, сондай-ақ гибридті процедуралар кірді. Клиникалық нәтижелер 3, 6 және 12 айда бағаланды. Бірінші реттік соңғы нүкте – үлкен жағымсыз жүрек-қантамыр оқиғалары (ҮЖЖҚО): жүректен болған өлім, өлімге әкелмеген миокард инфаркті және клиникалық негізделген нысаналы зақымдануды реваскуляризация.

Нәтижелер. Орташа жасы 63,2 ± 9,4 жыл; 66,7% ер адамдар; 37,3%-да қант диабеті, 21,6%-да созылмалы бүйрек ауруы болды. Bail-out стент 17,6%-да қажет болды. Процедуралық сәттілік 97,1%-да тіркелді. 12 айда ҮЖЖҚО толық бақылаудан өткен 92 науқастың 5-інде (5,4%) тіркелді; барлық оқиғалар клиникалық негізделген нысаналы зақымдануды реваскуляризация болды (92-нің 5-і; 5,4%); өлімге әкелмеген миокард инфаркті (92-нің 0-і) және жүректен болған өлім (92-нің 0-і) тіркелмеді. Стенокардияның болмауы (ККҚ 0-класы) 92-нің 66-сында (71,7%), ККҚ 0–II класы 92-нің 85-інде (92,4%) тіркелді. Тамыр тромбозы тіркелмеді.

Қорытынды. Осы бақылау когортасында ДЖБ ангиопластикасы жоғары процедуралық сәттілікпен, стенокардия симптомдарының прогрессивті жақсаруымен және тамыр тромбозының болмауымен байланысты болды. Бір топты зерттеу ретінде ол дәрілік жабынды стенттермен салыстырғанда қауіпсіздік пен тиімділікті дәлелдей алмайды; ангиографиялық соңғы нүктелері бар проспективті көп орталықты зерттеулер қажет.

Түйінді сөздер: баллондық коронарлық ангиопластика, коронарлық рестеноз, жүректің ишемиялық ауруы, сиролимус, тері арқылы коронарлық араласу.

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АНГИОПЛАСТИКА С ПРИМЕНЕНИЕМ БАЛЛОНОВ С ЛЕКАРСТВЕННЫМ ПОКРЫТИЕМ В РЕАЛЬНОЙ КЛИНИЧЕСКОЙ ПРАКТИКЕ: ОДНОЦЕНТРОВЫЙ ОПЫТ КАЗАХСТАНА

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Аннотация

Введение. Баллоны с лекарственным покрытием (БЛП) доставляют антипролиферативный препарат в стенку сосуда при однократной инфляции баллона, не оставляя постоянного имплантата. Данные реальной клинической практики из Казахстана и Центральной Азии ограничены.

Цель. Оценить процедурную безопасность и среднесрочные клинические исходы ангиопластики с применением БЛП в последовательной когорте пациентов с поражениями de novo и рестенозом внутри стента, пролеченных в одном интервенционном кардиологическом центре Казахстана.

Материалы и методы. В ретроспективное одноцентровое наблюдательное исследование включены 102 последовательных пациента, пролеченных сиролимус-покрытым баллоном MagicTouch™ (Concept Medical) с августа 2024 по май 2025 года (дата среза 31 мая 2026 года). Когорта включала поражения de novo, рестеноз внутри стента, поражение малых сосудов (<2,5 мм), дистальные и бифуркационные поражения, а также гибридные процедуры. Исходы оценивались через 3, 6 и 12 месяцев. Первичная конечная точка – большие неблагоприятные сердечно-сосудистые события (БНССС): сердечная смерть, нефатальный инфаркт миокарда и клинически обусловленная реваскуляризация целевого поражения.

Результаты. Средний возраст 63,2 ± 9,4 года; мужчины 66,7%; сахарный диабет у 37,3%, хроническая болезнь почек у 21,6%. Bail-out стент потребовался в 17,6%. Процедурный успех достигнут в 97,1%. За 12 месяцев БНССС зарегистрированы у 5 из 92 пациентов с полным наблюдением (5,4%); все события – клинически обусловленная реваскуляризация целевого поражения (5 из 92; 5,4%); случаев нефатального инфаркта миокарда (0 из 92) и сердечной смерти (0 из 92) не было. Отсутствие стенокардии (0 класс по ССС) достигнуто у 66 из 92 (71,7%), класс ССС 0–II – у 85 из 92 (92,4%). Тромбоза сосуда не зарегистрировано.

Заключение. В данной наблюдательной когорте ангиопластика с БЛП сопровождалась высоким процедурным успехом, прогрессивным уменьшением симптомов стенокардии и отсутствием тромбоза сосуда. Будучи одногрупповым, данное исследование не позволяет установить сравнительную безопасность или эффективность относительно стентов с лекарственным покрытием; необходимы проспективные многоцентровые исследования с ангиографическими конечными точками.

Ключевые слова: баллонная коронарная ангиопластика, коронарный рестеноз, ишемическая болезнь сердца, сиролимус, чрескожное коронарное вмешательство.

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