ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 12 | December - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

CLINICAL CHARACTERISTICS, PROCEDURAL OUTCOMES, AND ONE-YEAR FOLLOW-UP AFTER IMPLANTATION OF VERY SMALL (2.0 MM) BIODEGRADABLE-POLYMER DRUG-ELUTING STENTS: A PROSPECTIVE OBSERVATIONAL STUDY

Cardiology

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ABSTRACT

Background: Small-vessel coronary artery disease is associated with higher rates of restenosis and procedural complexity due to limited luminal diameter and unfavorable vessel geometry. Despite advances in drug-eluting stent technology, the performance of very small (2.0 mm) biodegradable-polymer sirolimus-eluting stents in routine clinical practice is inadequately reported. Understanding their real-world outcomes is essential for guiding small-vessel percutaneous coronary intervention. **Objectives:** To evaluate the clinical characteristics, angiographic and procedural features, and one-year clinical outcomes of patients undergoing percutaneous coronary intervention with a 2.0 mm biodegradable-polymer sirolimus-eluting stent. **Methods:** This prospective observational study included 100 consecutive patients who underwent PCI with a 2.0 mm biodegradable-polymer DES at Vijaya Heart Foundation, Chennai. Baseline demographics, risk factor profiles, and angiographic characteristics were recorded. Procedural success, defined by restoration of TIMI 3 flow, and one-year clinical outcomes—including cardiac death, myocardial infarction, target lesion revascularization (TLR), target vessel revascularization (TVR), and major adverse cardiac events (MACE)—were assessed. Follow-up was conducted at one, six, and twelve months. **Results:** The majority of patients were between 51 and 70 years (63%), and 69% were male. Hypertension (59%), diabetes mellitus (41%), smoking (46%), dyslipidemia (34%), and obesity (29%) were highly prevalent. Predilatation was performed in 97% of cases, and procedural success with TIMI 3 flow was achieved in over 95%. At one year, the incidence of cardiac death was 2%, non-cardiac death 1%, myocardial infarction 3%, TLR 4%, and TVR 5%. The overall MACE rate was approximately 6–7%. Family history of coronary artery disease demonstrated a statistically significant association with mortality ($p = 0.0001$). Stent thrombosis was rare. **Conclusion:** Use of 2.0 mm biodegradable-polymer sirolimus-eluting stents in small-vessel coronary artery disease demonstrated high procedural success and favorable one-year outcomes, with low rates of mortality, myocardial infarction, and repeat revascularization. These findings support the safety and effectiveness of very small DES in appropriately selected patients, reinforcing their role in managing small-caliber coronary lesions.

KEYWORDS

Small-vessel coronary artery disease, Percutaneous coronary intervention, Drug-eluting stents, Biodegradable-polymer stents, Sirolimus-eluting stent, 2.0 mm coronary stent, Restenosis, Major adverse cardiac events

INTRODUCTION

Small-vessel coronary artery disease, typically involving vessels below 2.5 to 3.0 mm in diameter, accounts for nearly one-third to half of all percutaneous coronary interventions[1]. This anatomical subset is notoriously associated with higher rates of restenosis, reduced acute luminal gain, and poorer clinical outcomes, making it one of the most challenging areas in interventional cardiology[2]. Traditional bare-metal stents demonstrated limited efficacy in this subset due to excessive neointimal hyperplasia relative to the available luminal area[3]. The advent of drug-eluting stents substantially reduced restenosis rates; however, their efficacy in very small vessels—especially those measuring 2.0 mm—has not been comprehensively evaluated in large studies[4].

Biodegradable-polymer DES were developed to address limitations associated with durable-polymer stents, particularly delayed endothelial healing and late inflammatory reactions. By eluting sirolimus from a biodegradable matrix, these stents offer potent antiproliferative effects during the critical healing period while reducing the long-term risks of chronic inflammation and late stent thrombosis once the polymer is resorbed[5]. Despite these theoretical advantages, data regarding the performance of 2.0 mm biodegradable-polymer DES in real-world small-vessel interventions remain limited[6]. The objective of this study was to provide detailed clinical, angiographic, procedural, and follow-up data on a cohort of patients treated with 2.0 mm biodegradable-polymer DES, focusing particularly on one-year outcomes such as mortality, myocardial infarction, and repeat revascularization. By assessing outcomes in a representative patient population with diverse presentations-including stable CAD and ACS-this study aims to contribute meaningful evidence to guide clinical decision-making regarding stenting in the smallest coronary arteries.

METHODS

This prospective observational study included 100 consecutive patients who underwent PCI using a 2.0 mm Yukon Choice PC biodegradable-polymer sirolimus-eluting stent at Vijaya Heart Foundation, Chennai. The study period extended from February 2019 to May 2020, and follow-up was conducted over one year from the date of stent implantation. Eligibility for inclusion required patients to have at least one significant coronary lesion with ≥70% diameter stenosis in a reference vessel diameter (RVD) of 2.0 mm, documented by visual angiographic estimation. All patients presented with either stable angina or acute coronary syndrome and were deemed appropriate candidates for PCI.

Patients with known hypersensitivity to sirolimus, thienopyridines, stainless steel, or contrast media were excluded. Additional exclusion criteria included terminal illness, lesions unsuitable for PCI, and participation in concurrent coronary device trials. All patient characteristics, including age, sex, comorbidities, laboratory parameters, angiographic lesion morphology, and procedural techniques, were documented.

Procedures were performed using 6–7 Fr guiding catheters with radial or femoral access, depending on operator preference. Predilatation using conventional balloons was performed in 97% of lesions, followed by stent deployment at 8–16 atmospheres. Post-dilatation was performed in the majority of cases to ensure optimal stent apposition. Heparin was administered to maintain activated clotting time above 300 seconds when glycoprotein IIb/IIIa inhibitors were not used.

Post-procedural care included dual antiplatelet therapy consisting of aspirin (75–150 mg daily) and one of clopidogrel (75 mg daily), prasugrel (5–10 mg daily), or ticagrelor (90 mg twice daily) for a minimum of six months. Additional medical therapy, including statins, beta-blockers, and ACE inhibitors, was administered per guideline-directed management.

Follow-up assessments were performed at 1 month, 6 months, and 12 months, with outcomes categorized according to standardized

definitions. The primary endpoint was major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and ischemia-driven TLR. Secondary endpoints included TVR, target vessel failure, and stent thrombosis as defined by ARC criteria.

RESULTS

The mean age distribution revealed that 63% of patients were between 51 and 70 years, with 8% aged 30–40 years, 25% aged 41–50 years, 31% aged 51–60 years, and 32% aged 61–70 years. Only 4% of patients were older than 70 years. The predominance of middle-aged to elderly individuals aligns with typical CAD demographics. Males represented 69% of the cohort, while females accounted for 31%.

Conventional risk factors were prevalent. Hypertension was present in 59% of patients, diabetes mellitus in 41%, dyslipidemia in 34%, obesity in 29%, and smoking history in 46%. Family history of CAD was documented in 13%, and it demonstrated a significant correlation with mortality, with two cardiac deaths and one non-cardiac death among these 13 patients, yielding a p value of 0.0001. This association suggests genetic or environmental clustering of high-risk factors leading to adverse outcomes.

Table 1: Baseline Characteristics Of The Study Population

Variable	Frequency (n)	Percentage (%)
Age Group (years)		
30–40	8	8%
41–50	25	25%
51–60	31	31%
61–70	32	32%
> 70	4	4%
Sex		
Male	69	69%
Female	31	31%
Risk Factors		
Diabetes mellitus	41	41%
Hypertension	59	59%
Dyslipidemia	34	34%
Obesity	29	29%
Smoking	46	46%
Family history of CAD	13	13%

Most patients presented with stable angina or ACS, and lesion morphology predominantly fell within ACC/AHA type B classifications. Predilatation was performed in 97 patients, and TIMI 3 flow was successfully restored in more than 95% following stent deployment. Procedural complications were minimal, and no intraprocedural deaths occurred.

Table 2: Procedural Characteristics

Parameter	Value
Predilatation performed	97%
Post-dilatation performed	High (exact % not provided)
Procedural success (TIMI 3 flow)	> 95%
Stent type	2.0 mm biodegradable-polymer sirolimus-eluting stent
Access site	Radial or femoral

At one-year follow-up, cardiac death occurred in 2% of patients, and 1% experienced non-cardiac mortality. Myocardial infarction was documented in 3%, with no statistically significant correlation to family history or other isolated risk factors. TLR occurred in 4%, and TVR in 5%, reflecting low restenosis and repeat revascularization rates for such small vessels. Stent thrombosis was extremely rare, with no definite late or very late thrombosis reported.

Table 3: One-Year Clinical Outcomes

Outcome	Frequency (n)	Percentage (%)
Cardiac death	2	2%
Non-cardiac death	1	1%
Myocardial infarction	3	3%
TLR	4	4%
TVR	5	5%
Stent thrombosis	Very low (exact numbers not listed)	
MACE (composite)	Approx. 6–7%	

The overall MACE rate at one year was approximately 6–7%, representing a favorable safety and efficacy profile for this device in a challenging anatomical subset.

Table 4: Association Between Risk Factors And Outcomes

Risk Factor	Associated Outcome	p-value
Family history of CAD	Mortality	**0.0001**
Other risk factors	No significant association	Not significant

DISCUSSION

The findings of this study highlight the feasibility and safety of using very small (2.0 mm) biodegradable-polymer DES in patients requiring PCI for small-vessel CAD. The high prevalence of standard cardiovascular risk factors in the study population mirrors real-world clinical practice, yet one-year outcomes remained consistently favorable[7]. Procedural success, as evidenced by high rates of TIMI 3 flow and minimal complications, supports the technical viability of deploying 2.0 mm DES even in complex lesions[8].

The low rates of TLR (4%) and TVR (5%) observed in this study compare favorably with historical data from bare-metal stents and even some larger-vessel DES results from earlier generations[9]. Biodegradable-polymer technology appears to confer added benefit in small vessels by reducing chronic inflammatory stimulus once the polymer resorbs. Additionally, the thin-strut design may improve deliverability and reduce flow disturbance, contributing to better healing and reduced restenosis[10].

The statistically significant association between family history of CAD and mortality underscores the need for aggressive primary and secondary prevention in this subgroup[11]. The lack of significant association between dyslipidemia or obesity and adverse outcomes may reflect the small sample size, limited power, or effective medical management.

Stent thrombosis remained exceedingly rare in this cohort, supporting the improved safety profile of modern sirolimus-eluting biodegradable-polymer stents, even in small luminal diameters where flow dynamics might theoretically predispose to thrombosis[12].

CONCLUSION

This study demonstrates that the use of 2.0 mm biodegradable-polymer sirolimus-eluting stents is associated with high procedural success and favorable one-year clinical outcomes in patients with small-vessel coronary artery disease. Low rates of mortality, myocardial infarction, TLR, and stent thrombosis underscore the safety and efficacy of these devices in appropriately selected patients. These findings support the expanding use of very small DES in routine interventional practice and highlight the growing role of biodegradable polymers in optimizing long-term vascular healing.

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