

LONG-TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTIONS (ICP) IN PATIENTS WITH CORONARY ARTERY DISEASE AND DIABETES: A SCOPING REVIEW

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Abstract

Introduction: Percutaneous coronary interventions (PCI), stent implantation and balloon angioplasty, are critical therapeutic strategies for managing coronary artery disease (CAD), particularly in patients with diabetes. This scoping review aims to synthesize key findings from the literature on the long-term efficacy and prognosis of drug-eluting stents in diabetic patients, highlighting risks and benefits. **Methods:** This scoping review followed PRISMA-ScR guidelines, employing a comprehensive search strategy across PubMed (MEDLINE), Embase, and Web of Science. Studies focusing on drug-eluting stents in diabetic patients with coronary artery disease were included. **Results:** A total of 393 records were identified and, after removing duplicates, 288 records were screened. Following the eligibility assessment, 26 studies were included in the review. The studies indicate that drug-eluting stents reduce restenosis and major adverse cardiac events in diabetic patients, though complications such as stent thrombosis and the need for revascularization persist. Long-term outcomes vary significantly between different generations of stents, although the differences between various drug-eluting stents were not statistically significant. Diabetic patients, particularly those

*with high bleeding and ischemic risks, require rigorous follow-up due to elevated complication rates. **Conclusion:** Diabetic patients with high bleeding and ischemic risks require close monitoring and individualized antiplatelet therapy adjustments. Maintaining dual antiplatelet therapy (DAPT) for at least one year is recommended, potentially longer for high-risk patients. Optimizing glycemic control and managing hypertension and dyslipidemia can reduce long-term cardiovascular events post-stent placement.*

Keywords: Drug-Eluting Stents; Coronary Artery Disease; Diabetes; Angioplasty, Long-term

1. Introduction

PCI (Percutaneous Coronary Intervention) consists of balloon angioplasty, which temporarily widens the artery, and stent implantation, which provides permanent support to keep the artery open, thereby reducing restenosis. Drug-eluting stents (DES) have been utilized in interventional cardiology since 2002 to maintain the patency of coronary arteries narrowed by atherosclerosis. These stents integrate a metallic scaffold with a polymer coating that controls the release of an antiproliferative agent directly into the arterial wall. This mechanism effectively reduces cellular proliferation that could otherwise lead to restenosis, a common issue with conventional stents.⁽¹⁻³⁾

The antiproliferative drugs used in drug-eluting stents (DES) work by inhibiting the proliferation of vascular smooth muscle cells, thereby preventing neointimal hyperplasia, which is the primary cause of restenosis. Sirolimus and paclitaxel, used in the first generation of DES, act at different phases of the cell cycle to inhibit cell division. Paclitaxel inhibits microtubule disassembly, causing cell cycle arrest at the G0-G1 and G2-M phases.⁽⁴⁾ Sirolimus, on the other hand, binds to FKBP12 and inhibits the mTOR and PI3K pathways, arresting the cell cycle in the G1 phase.^(5,6) The effectiveness of these agents in reducing long-term restenosis, defined as greater than one year (>1 year), has been well-documented, making DES a widely utilized intervention⁽⁷⁾. In this study, we will conduct a comprehensive review of findings related to the long-term outcomes of DES use, focusing on clinical results and complications observed beyond the one-year mark.

Currently, it is widely acknowledged that stents significantly reduce the risk of restenosis, particularly drug-eluting stents. However, there is a paucity of data in the literature grouping only studies that have long-term follow-up (>1 year) of patients after stent implantation, especially with drug-eluting stents. Therefore, this scoping review aims to compile the principal findings from the literature on this topic, with a specific focus on patients with diabetes, whether controlled or uncontrolled. Our objective is to present all relevant studies, highlighting pertinent information as well as the strengths and limitations of these studies.

2. Methods

This scoping review followed the **PRISMA** extension for scoping reviews (**PRISMA-ScR**) guidelines.

Eligibility Criteria: Studies were included if they met the following criteria: focus on patients with both coronary artery disease and diabetes mellitus, involved the use of drug-eluting stents, reported long-term outcomes with a minimum follow-up duration of one year, included original data encompassing randomized controlled trials, cohort studies, and case-control studies, systematic reviews and meta-analysis and excluded editorials and studies not reporting relevant long-term outcomes.

Information Sources: A comprehensive search strategy was employed across major databases, including PubMed (MEDLINE), Embase, and Web of Science.

Search Strategy: The search terms included “coronary artery disease”, “CAD”, “diabetes mellitus”, “diabetic patients”, the effectiveness of drug-eluting stents (DES), particularly everolimus-eluting stents (EES), in various diabetic subgroups undergoing angioplasty or percutaneous coronary intervention (PCI), “long-term outcomes”, and “major adverse cardiovascular events” (MACE). Articles published after June 3, 2024, were excluded from this review.

Study Records and Data Extraction Process: Two reviewers independently screened the titles and abstracts. Studies were included if they reported long-term outcomes of DES in diabetic patients with CAD. Discrepancies were resolved by consensus or by involving a third reviewer. Data on study type, patient demographics, clinical methods, types of stents used, outcome measures, and adverse events were extracted by two independent reviewers. Any disagreements were resolved by consensus or by involving a third reviewer. Extracted data items included study type and setting, patient demographic characteristics, clinical and laboratory methods, types of drug-eluting stents used, and outcome measures, including major adverse cardiovascular events (MACE), stent thrombosis, restenosis, mortality, and adverse events.

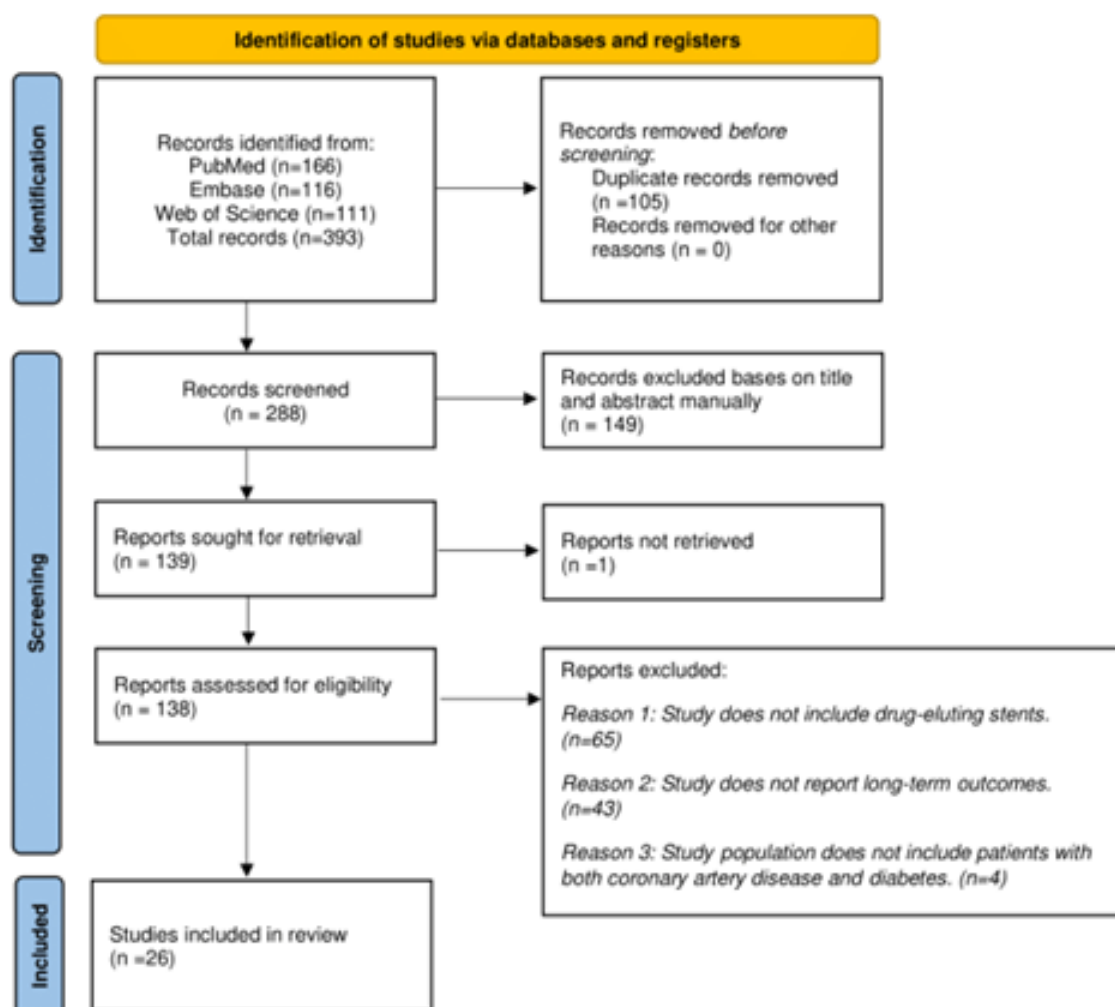
Risk of bias in individual studies: In this review, no specific tool for assessing the risk of bias was used. However, the study design of all included studies was critically analyzed. The characteristics of these studies were compiled into a table, which summarizes the key design features and relevant information.

Data Synthesis: Data were synthesized using Microsoft Excel to organize the extracted information into detailed spreadsheets.

3. Results

Study Selection: The PRISMA 2020 flow diagram below describes the study selection for our review on drug-eluting stents in patients with coronary artery disease and diabetes. A total of 393 records were identified according to the descriptors, with the following numbers: PubMed: 166, Embase: 116, Web of Science: 111. After removing 105 duplicate records, 288 records were screened. Of these, 149 were excluded based on title and abstract, leaving 139 records for retrieval, of which 1 was not retrieved. Of the 138 assessed for eligibility, 112 were excluded: 65 did not include drug-eluting stents, 43 did not report long-term outcomes, and 4 did not include patients with both conditions. Finally, 26 studies were included in the review.

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram for the selection of studies on drug-eluting stents in patients with coronary artery disease and diabetes.

Comparative Analysis of Studies: The 26 included studies were grouped into a comparative table with their main characteristics, interventions, and outcomes. This table highlights the main interventions on the effectiveness and safety of different drug-eluting stents (EES, SES, PES, ZES) in diabetic patients with coronary artery disease. It provides an overview of study designs, patient populations, and limitations

Estado	Ano	Tipo	Registro	N	Intervenção	Controle	Limitações
Jimenez-Quevedo et al	2019	Post-hoc RCT	NCT04082887	Total (n=1097) Non diabetic (n=288)	Everolimus-eluting stents (EES) and bare-metal stents (BMS) were the main interventions. All patients were treated with aspirin and clopidogrel for at least 1 year.	There was no placebo group.	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Goni et al	2020	Post-hoc RCT	NCT01905202, NCT03602878, NCT03612278, NCT03496927	2,700 patients with diabetes mellitus (DM).	Everolimus-eluting stents (DESICC 1/9)	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Nguyen et al	2019	Retrospective cohort	X	499 patients (591 events) (58)	Percutaneous coronary balloon specifically treating LAD (P1) and Secondaries (P2).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Hornmuller et al	2020	Post-hoc RCT	NTR2451 (NCT03893848) and NTR2452 (NCT03893849)	Total population 609 patients (E-DES (n=55) + EES (n=459))	Everolimus-eluting bioresorbable scaffolds (EES) and everolimus-eluting metal stents (EES).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Bangalore et al	2015	Retrospective cohort	X	Total patients: 5,809 CABG (n=1,506)	Everolimus-eluting stents (EES) were used for PCI, compared with coronary artery bypass grafting (CABG).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Bangalore et al	2019	RCT	CREDENCE (NCT01961080)	Total number of diabetic patients (N=1821)	Secondaries-eluting stents (EES) and everolimus-eluting stents (EES).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Barricelli et al	2016	Retrospective cohort	X	Total patients (N=7500) Diabetic: 4571 (60%) Non diabetic: 1526 (20%)	Everolimus-eluting stents (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Burneson et al	2015	Retrospective cohort	X	Total of patients (N = 439)	Secondaries-eluting stents (EES) / Cypher / Coreflex / Johnson & Johnson	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Campese et al	2017	Meta-analysis RCT	NCT01902739, NCT01980310, NCT00184976, NCT00070747	Total Population (N=1423)	Scaffold vascular bioabsorbable everolimus-eluting stents (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Fanari et al	2016	Meta-analysis	X	Population (N = 5123)	Drug-eluting stents (DES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Jensen et al	2016	RCT	NCT02621140	N=1431 Diabetic (N=408)	Bioresorbable stents (BMS) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Ischi et al	2021	RCT	NCT01698833	Total Population N = 3800 Diabetic (N = 1019 (26.8%))	Secondaries-eluting stents (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Kratcheltwall et al	2017	RCT	NCT02829975	(N = 135)	Secondaries-eluting stents (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Mang et al	2015	RCT	NCT01695827	Diabetic patients: 731 patients	Everolimus-eluting stents (EES) and secondaries-eluting stents (EES).	There was no placebo group	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Mahmoud et al	2017	Meta-analysis	X	N = 17,682 Patients: Diabetics: 4,794 (27%)	Everolimus-eluting stents (EES) and secondaries-eluting stents (EES).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Miyasaka et al	2016	Historical cohort	X	Total patients: 460 Diabetics: 300%	Secondaries-eluting stents (EES) and secondaries-eluting stents (EES).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Rajesh et al	2018	Prospective cohort	X	Total patients (N= 243) Diabetic patients: 158 patients (64.6%)	Secondaries-eluting stents (EES) and secondaries-eluting stents (EES).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Mehta et al	2016	Retrospective cohort	X	Patients (N=135) Diabetics: 135	Everolimus-eluting stents (EES)	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Riz et al	2020	Retrospective cohort	X	Total (N = 3271) Diabetics: 119 patients (3.6%)	Drug-eluting stents (DES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Tamirisa et al	2020	Prospective cohort	X	N (population) - 429 patients: Diabetic patients: 24	Coreflex EES stent (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Testa et al	2021	Prospective cohort	X	Total patients (N= 2500) Diabetic patients: 1000 (40%)	Abutment DES - stent (EES) - secondaries-eluting stents (EES).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Uthairatragom et al	2015	Prospective cohort	X	Total patients (N= 330) Diabetic patients: 158 patients (48%)	Drug-eluting stents (DES)	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Wahnekar et al	2019	RCT	NCT01935206	Total number of patients (N=1150) Diabetic Patients: 402 (29.6%)	Coreflex EES stent (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Widha et al	2015	Prospective cohort	X	Total (population) 170 patients: Number of diabetic patients: 20 patients	Coreflex EES stent (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.
Yam et al	2017	Retrospective cohort	X	Total Population: Diabetic Patients: 309	Stent-eluting endovascular DES (EES) - secondaries-eluting stents (EES) - percutaneous coronary intervention (PCI) - bare-metal stents (BMS).	N/A	Percent bleed for diabetic patients may be high. Effectiveness in diabetic patients may be lower. No comparison with newer stent technologies or with aspirin and clopidogrel for longer than 1 year.

Table 1. Comparative Table of Studies on Drug-Eluting Stents in Diabetic Patients

Legends: RCT: Randomized Controlled Trial; EES: Everolimus-Eluting Stent ; SES: Sirolimus-Eluting Stent ; MACE: Major Adverse Cardiac Events ; TLR: Target Lesion Revascularization ; BMS: Bare Metal Stent ; PCI: Percutaneous Coronary Intervention ; CABG: Coronary Artery Bypass Grafting ; ISR: In-Stent Restenosis; EE-BRS: Everolimus-Eluting Bioresorbable Scaffold (Scaffold Bioabsorvível Eluidor de Everolimus); DAPT: Dual Antiplatelet Therapy ;

ZES: Zotarolimus-Eluting Stent ; PES: Paclitaxel-Eluting Stent ; PLLA: Poly-L-Lactic Acid; NIDDM: Non-Insulin Dependent Diabetes Mellitus; IDDM: Insulin Dependent Diabetes Mellitus.

The analyzed studies demonstrate a diversity of interventions with drug-eluting stents (DES) in diabetic patients, highlighting varied clinical outcomes. Jimenez-Quevedo et al. (2019)⁸ and Goel et al. (2020)⁹ conducted retrospective analyses of randomized controlled trials, focusing on the effectiveness of everolimus-eluting stents (EES) in various diabetic subgroups, while Nguyen et al. (2019)¹⁰ compared paclitaxel-coated balloons in a retrospective cohort. Studies such as those by Hommels et al. (2020)¹¹ and Campos et al.¹⁷ (2017) explored the performance of bioresorbable scaffolds versus metallic everolimus-eluting stents, revealing similar rates of major adverse cardiac events (MACE). Fanari et al. (2014)¹⁸ conducted a meta-analysis comparing percutaneous coronary intervention (PCI) with coronary artery bypass grafting (CABG) in patients with multivessel coronary artery disease, showing a higher target vessel revascularization (TVR) rate with PCI. Bavishi et al. (2016)¹⁵ and subsequent studies reinforced the superiority of second-generation stents, such as EES and zotarolimus-eluting stents (ZES), in reducing MACE, myocardial infarction (MI), and stent thrombosis (ST) compared to first-generation and bare-metal stents. Buronova et al. (2015)¹⁶ highlighted elevated mortality in hemodialysis patients, while Bangalore et al. (2015)¹², (2019)¹³ and emphasized the need for personalized management and rigorous follow-up to optimize clinical outcomes in high-risk populations.

4. Discussion

4.1. Considerations on Long-Term Follow-Up Data

Goel et al. (2020)⁹, Bartorelli et al. (2016)¹⁴, and Mahmoud et al. (2017)²³ are studies that included over 1,000 diabetic patients, demonstrating their ability to accumulate robust data, enabling more reliable analyses and the identification of significant clinical trends. However, even in these large studies, the post-hoc nature limits causal inference, as these analyses are susceptible to selection biases and residual confounding. The lack of randomization in prospective studies and the absence of rigorous control for confounding variables compromise the internal validity of the results, a common and understandable limitation. The consistent use of drug-eluting stents, such as everolimus, sirolimus, and zotarolimus, reflects an effective and well-established treatment pattern, contributing to uniformity in the management of diabetic patients with heart disease. The heterogeneity in outcome definitions and variability in glycemic control and insulin use across studies introduce inconsistencies in the findings, requiring caution in generalizing the results to the broader diabetic population. Long-term follow-up (≥ 1 year) generally presented reliable data from well-conducted clinical trials with a larger number of participants, showing excellent outcomes but with important factors to be considered, which will be presented below:

4.2. Impact of Bleeding and Ischemic Risks on Major Adverse Cardiac Events (MACE) in PCI

The long-term outcomes (≥ 1 year) for diabetic patients undergoing percutaneous coronary intervention (PCI) with everolimus-eluting stents were analyzed by Ridhima Goel et al⁹. Patients with high bleeding risk and low ischemic risk (HBR/LIR) exhibited a major adverse cardiac events (MACE) rate of 11.6% (HR 2.17; 95% CI 1.45-3.24), while those with high bleeding risk and high ischemic risk (HBR/HIR) had a rate of 13.9% (HR 2.69; 95% CI 1.87-3.86). The rates of major bleeding (MB) were 5.2% (HR 2.56; 95% CI 1.38-4.73) for HBR/LIR and 5.6% (HR 2.74; 95% CI 1.55-4.84) for HBR/HIR, with p-values < 0.05 , indicating statistical significance in the association between bleeding risk factors and adverse outcomes, especially in the long term. Patients with high bleeding risk (HBR) were frequently on dual antiplatelet therapy (DAPT) and other antithrombotic medications. According to the study, over 80% of patients were on DAPT at the 1-year follow-up, except in the HBR/LIR group (75%). At the 4-year follow-up, 46% of low bleeding risk (LBR) patients and 41% of high bleeding risk (HBR) patients continued on DAPT.

The study by Bartorelli et al¹⁴. evaluated the long-term outcomes (≥ 1 year) of sirolimus-eluting stents (SES) in diabetic patients enrolled in the e-SELECT registry, demonstrating higher rates of major adverse cardiac events (MACE) in diabetics (6.8%) compared to non-diabetics (3.9%, $P < 0.001$), particularly in insulin-treated diabetics (10.6%, $P < 0.001$). Stent thrombosis (ST) was also higher in diabetics (1.7%) versus non-diabetics (0.7%, $P < 0.001$), primarily driven by insulin-treated diabetics (3.4%, $P < 0.001$). Despite these elevated risks, the overall response to SES was deemed acceptable, with a slightly higher but low bleeding rate (1.1%, $P = 0.1$), indicating the efficacy of SES while underscoring the need for personalized management in diabetic subgroups.

The long-term results (mean of 45.7 months) of Mahmoud et al²³'s study on the efficacy and safety of second-generation drug-eluting stents (DES) compared to bare-metal stents (BMS) indicate that DES significantly reduced the incidence of major adverse cardiac events (MACE) compared to BMS (17.3% vs. 22.3%, RR: 0.78, 95% CI: 0.69-0.88, $P < 0.0001$). Additionally, DES were associated with a lower incidence of definite stent thrombosis (0.7% vs. 1.5%, RR: 0.57, 95% CI: 0.41-0.78, $P < 0.0001$). The study also found that DES reduced the rates of myocardial infarction (RR: 0.67, 95% CI: 0.48-0.95, $P = 0.02$) and target lesion revascularization (RR: 0.47, 95% CI: 0.42-0.53, $P < 0.0001$).

Moreover, Maeng et al.²² conducted a study with 213 diabetic patients comparing everolimus-eluting stents (EES) and sirolimus-eluting stents (SES) in diabetic patients. At 10 months, the late lumen loss was similar between EES (0.20 ± 0.53 mm) and SES (0.11 ± 0.49 mm; $P = 0.28$). At 4 years, major adverse cardiac events (MACE) occurred in 20.4% of EES patients and 23.8% of SES patients (HR 0.84; $P = 0.55$). Target lesion revascularization (TLR) was

required in 5.6% of EES patients versus 9.5% of SES patients (HR 0.57; $P = 0.28$). Myocardial infarctions were less frequent in the EES group ($P = 0.067$). There was no significant difference in mortality between the groups. The results indicate that both stents are effective and safe, with EES showing a trend toward better outcomes in myocardial infarctions and TLR.

Goel et al. (2020) reported and reinforced that patients with high bleeding risk (HBR) and high ischemic risk (HIR) have a significantly higher rate of stent thrombosis (HR 2.74, 95% CI 1.55-4.84) and an increased incidence of target lesion revascularization (TLR) (HR 2.69, 95% CI 1.87-3.86) in the long term.

Bartorelli et al. (2016)¹⁴ observed a stent thrombosis rate of 1.7% in diabetics versus 0.7% in non-diabetics, with an overall increase in MACE suggesting a continuous need for revascularization. Mahmoud et al. (2017)²³ demonstrated variable but consistently higher stent thrombosis rates in diabetics, with a greater need for TLR in patients treated with bare-metal stents compared to drug-eluting stents (RR 1.75, 95% CI 1.25-2.45). Conclusively, diabetic patients, especially those with HBR and HIR, exhibit a higher risk of stent thrombosis and revascularization, underscoring the need for rigorous follow-up in this subgroup, again as other studies have reported.

In summary, to optimize the treatment of diabetic patients undergoing percutaneous coronary intervention (PCI), it is crucial to consider both bleeding and ischemic risks. Patients with high bleeding risk (HBR) and high ischemic risk (HIR) should be closely monitored due to their increased incidence of major adverse cardiac events (MACE) and stent thrombosis. The use of second-generation drug-eluting stents, such as everolimus-eluting stents (EES), is recommended as they have been shown to significantly reduce adverse events compared to bare-metal stents. Additionally, dual antiplatelet therapy (DAPT) should be carefully assessed, with personalized adjustments to balance bleeding and thrombosis risks, especially in HBR patients. Long-term DAPT should be periodically re-evaluated based on the patient's evolving clinical status. Personalized management and rigorous follow-up are essential to improve clinical outcomes and reduce the need for revascularization in diabetic patients.

4.3. Effectiveness and Safety of Stents in Diabetic Patients: Comparative Evidence

In the study by Jimenez-Quevedo et al., a 5-year follow-up of 1,497 STEMI patients showed that diabetics ($n=258$) treated with everolimus-eluting stents (EES) and bare-metal stents (BMS) exhibited similar rates of patient-oriented composite endpoints (POCE) (32.8% vs. 32.2%; $p=0.88$) and all-cause mortality (7.0% vs. 12.1%; $p=0.014$). In the study by Nguyen et al.¹⁰, involving 491 patients with coronary in-stent restenosis treated with paclitaxel-coated balloons, there was no significant difference between the Pantera Lux (PL, $n=127$) and SeQuent Please (SP, $n=364$) groups in major adverse cardiac events (MACE): PL-DCB had 16 MACEs (61 per 1000 person-years) vs. SP-DCB with 55 MACEs (60 per 1000 person-years),

$p=0.895$. In the study by Hommels et al.¹¹, an aggregate analysis of 499 diabetic patients with coronary artery disease, those treated with everolimus-eluting bioresorbable scaffolds (EE-BRS, $n=150$) and everolimus-eluting stents (EES, $n=249$) showed no significant difference in target lesion failure (TLF) rates (7.2 vs. 5.2 events per 100 patient-years, $p=0.39$) and major adverse cardiac events (MACE) (9.1 vs. 8.3 events per 100 patient-years, $p=0.83$).

Bavishi et al. (2016)¹⁵ studied 8,095 diabetic patients comparing everolimus-eluting stents (EES) with first-generation drug-eluting stents (DES), finding that EES reduced MACE by 18% (RR: 0.82, 95% CI: 0.70–0.96), myocardial infarction by 43% (RR: 0.57, 95% CI: 0.39–0.84), and stent thrombosis by 46% (RR: 0.54, 95% CI: 0.35–0.82). In the TUXEDO Trial by Bangalore et al.¹², involving 1,821 diabetic patients, 344 with chronic kidney disease (CKD), EES were superior to paclitaxel-eluting stents (PES), reducing TVF, myocardial infarction, stent thrombosis, and TVR. Patients with CKD had a 102% increase in MACE and a 140% increase in cardiac death/myocardial infarction compared to those without CKD. In a meta-analysis by Bangalore et al.¹², with 22,844 patient-years of follow-up, EES and zotarolimus-eluting stents (ZES) were superior to first-generation stents and bare-metal stents (BMS), particularly in reducing restenosis and stent thrombosis, significantly improving clinical outcomes in diabetic patients.

For diabetic patients with STEMI undergoing PCI, everolimus-eluting stents (EES) and bare-metal stents (BMS) show similar outcomes in major events and mortality. Paclitaxel-coated balloons also perform similarly, regardless of the type used. In diabetic patients with coronary artery disease, both everolimus-eluting bioresorbable scaffolds (EE-BRS) and EES are effective, with no significant differences in outcomes. EES significantly reduce major cardiac events, myocardial infarction, and stent thrombosis compared to first-generation drug-eluting stents (DES). The TUXEDO trial found EES better than paclitaxel-eluting stents (PES), especially in patients with chronic kidney disease. A meta-analysis confirms that EES and zotarolimus-eluting stents (ZES) are superior to older stents, reducing restenosis and stent thrombosis, thus improving outcomes in diabetic patients. Second-generation DES like EES and ZES are recommended for better long-term results.

4.4. Comparative Analysis of Stent Efficacy and Outcomes in Diabetic and Hemodialysis Patients with Recent Studies

Campos et al.¹⁷ compared diabetic patients treated with Absorb BVS and XIENCE EES, finding a similar incidence of MACE (HR 0.75; 95% CI 0.37–1.5; $P=0.40$), cardiac death (HR 0.72; 95% CI 0.19–2.70; $P=0.62$), and ID-TLR (HR 0.86; 95% CI 0.35–2.13; $P=0.75$). Buronova et al.¹⁶ highlighted that patients on hemodialysis had higher cardiac mortality (9.3% vs. 3.9%) and non-cardiac mortality (32.6% vs. 6.3%) compared to non-hemodialysis patients. Fanari et al.¹⁸ identified higher TVR with PCI (RR=2.31; 95% CI 1.80–2.96; $P<0.0001$) and lower stroke

rates (RR=0.35; 95% CI 0.19-0.62; P=0.0003) at 1 year, as well as higher mortality (RR=1.3; 95% CI 1.10-1.54; P=0.0026) and MI (RR=2.21; 95% CI 1.75-2.79; P<0.0001) at 5 years compared to CABG. Bavishi et al¹⁵. showed that EES reduced MACE (RR=0.82; 95% CI 0.70-0.96), MI (RR=0.57; 95% CI 0.39-0.84), and stent thrombosis (RR=0.54; 95% CI 0.35-0.82) in diabetics compared to first-generation DES.

The studies investigated significant patient samples using stents, with an emphasis on diabetics and individuals on hemodialysis. Campos et al¹⁷. focused on diabetics treated with bioresorbable stents (Absorb BVS) and second-generation drug-eluting stents (XIENCE EES). Buronova et al¹⁶. included both hemodialysis patients and those not on dialysis, all utilizing stents. Fanari et al¹⁸. conducted a meta-analysis of randomized clinical trials comparing PCI with drug-eluting stents and CABG in patients with multi-vessel coronary artery disease, with a specific analysis for diabetics. Bavishi et al¹⁵. evaluated second-generation drug-eluting stents (EES) in diabetic patients, comparing them with first-generation stents and highlighting the long-term reduction of major adverse events, including myocardial infarction and stent thrombosis. Thus, the use of stents and the inclusion of diabetic patients were common features, reflecting populations with higher cardiovascular risk and advanced revascularization interventions.

4.5. Long-Term Clinical Outcomes and Challenges in Diabetic Patients Undergoing Percutaneous Coronary Interventions with Drug-Eluting Stents:

The studies collectively highlight the clinical outcomes of diabetic patients undergoing percutaneous coronary interventions (PCI) with various drug-eluting stents (DES) over extended follow-up periods, typically exceeding one year. Across these trials, it was consistently observed that diabetic patients exhibited higher rates of adverse cardiovascular events compared to non-diabetic patients, underscoring the increased risk profile of this population^{19,20,21,24,26}. Despite advancements in stent technology, such as the use of new-generation zotarolimus-eluting stents (ZES) and everolimus-eluting stents (EES), the incidence of major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and target lesion revascularization (TLR), remained significant. For instance, in studies comparing EES and sirolimus-eluting stents (SES), long-term results indicated comparable safety and efficacy, although stent thrombosis and restenosis rates continue to be concerns (Rajesh et al²⁵; Maeng et al²²). These findings reinforce the critical need for personalized therapeutic strategies and vigilant long-term management in diabetic patients undergoing PCI to optimize clinical outcomes and reduce the burden of cardiovascular events⁽²⁷⁻³³⁾.

5. Conclusion

In conclusion, drug-eluting stents (DES), both everolimus-eluting and sirolimus-eluting, play distinct roles in the management of diabetic patients undergoing percutaneous coronary intervention (PCI). While everolimus-eluting stents have shown overall efficacy, particularly in patients with high bleeding risk and ischemic variables, sirolimus-eluting stents have demonstrated acceptable outcomes despite higher rates of adverse events in insulin-dependent patients. Moreover, second-generation DES have exhibited superiority in terms of long-term safety and efficacy, with significant reductions in major adverse cardiac events (MACE), stent thrombosis, and myocardial infarction compared to bare-metal stents (BMS).

The clinical application of these findings underscores the importance of careful antithrombotic treatment and the selection of stent type, especially in high-risk populations such as diabetics and hemodialysis patients. Continuation of dual antiplatelet therapy (DAPT) has shown variable results, necessitating an individualized approach. Despite the limitations presented in the studies, we recommend maintaining current practices while emphasizing the need for greater vigilance in high-risk populations and rigorous follow-up to achieve better outcomes with fewer adverse events.

6. Clinical recommendations:

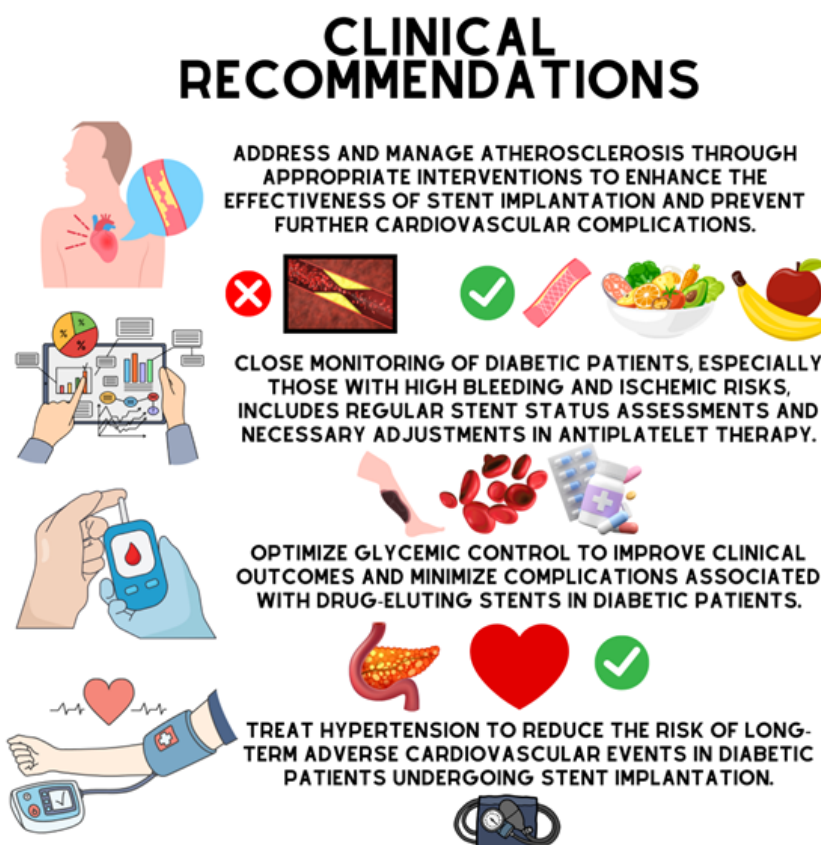


Figure 3. Synthesis clinical recommendations.

Diabetic patients, especially those with high bleeding risk (HBR) and high ischemic risk (HIR), should be closely monitored due to the elevated risk of stent thrombosis and the frequent need for target lesion revascularization (TLR). This includes regular assessments of stent status and adjustments in antiplatelet therapy as necessary to balance the risks of bleeding and ischemic events. Maintain dual antiplatelet therapy (DAPT) for an extended period as indicated by guidelines and the patient's risk profile. Most patients should continue DAPT for at least one year, with some high-risk patients continuing for longer periods. The decision on the duration of DAPT should be based on an individualized assessment of the risks of bleeding versus the benefits of preventing ischemic events. Optimize glycemic control and treat associated comorbidities such as hypertension and dyslipidemia to reduce the risk of long-term adverse cardiovascular events. Strict glucose level control and treatment of concurrent conditions are essential to improving clinical outcomes and minimizing the risk of complications associated with the use of drug-eluting stents.

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The authors declare that they have no competing interests.

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9. Author's contributions:

Conceptualizing and refining broad research objectives and aims. Creating and designing the methodology; developing models. Carrying out the research and investigative processes, including conducting experiments and gathering data/evidence. Overseeing tasks to annotate (generate metadata), clean data, and manage research data (including software code when essential for data interpretation) for both initial use and future reuse. VÉRAS, RFO; VÉRAS, SFO; FREIRE, DF, GUIMARÃES, PSS: Oversight and taking on leadership roles for planning and executing research activities, including providing mentorship outside the main team. Preparing, creating, and/or presenting published work by members of the original research group, particularly through critical review, commentary, or revision—encompassing both pre- and post-publication stages.

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