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EFFICACY AND SAFETY OF DIRECT STENTING VERSUS STENTING WITH DISTAL PROTECTION DEVICES IN PERCUTANEOUS INTERVENTION OF SAPHENOUS VEIN GRAFTS: A COMPARATIVE STUDY

Muhammad Muneeb[a]*, Adeel Ahmad[b], Madiha Iqbal[a]

[a]Shalamar Hospital, Lahore. [b]Punjab Institute of Cardiology, Lahore.

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ABSTRACT:

BACKGROUND: *Saphenous vein grafts (SVGs) used in coronary artery bypass grafting (CABG) often develop significant atherosclerosis, leading to the need for Coronary Angioplasty. This study compares Direct Stenting (DS) and Stenting with a Distal Protection Device (DPD) in subjects with SVG lesions to assess their impact on clinical outcomes and procedural success.*

AIMS & OBJECTIVE: *To compare and contrast Direct Stenting and Stenting with Distal Protection Devices in the context of SVG interventions*

MATERIAL & METHODS: *This single-blind, prospective experimental study included 64 patients with saphenous vein graft (SVG) lesions undergoing PCI at Punjab institute of cardiology Hospital Lahore from August 2023 to August 2024. Participants were randomly assigned by balloting method into two groups: Group I (32 patients) received stenting with a distal protection device (DPD), while Group II (32 patients) underwent direct stenting without a DPD. Patients were selected based on specific inclusion criteria and were excluded if they had severe renal impairment, decompensated heart failure, or other contraindications. The study assessed procedural outcomes, including clinical success, myocardial infarction, and revascularization needs, with a 30-day follow-up to monitor cardiac events and complications.*

RESULTS: *The study included sixty-four patients with an average age of 61.25 years, plus or minus 9.44 years with a gender distribution of 95.3% male and 4.7% female. The prevalence of diabetes, hypertension, and smoking was 51.6%, 56.3%, and 54.7%, respectively. The lesion locations were categorized as ostial (12.5%), proximal (57.8%), mid (25%), and distal (4.68%). No substantial differences were observed between the DPD and DS groups regarding age, gender distribution, or initial clinical characteristics. Notable differences were noted between the Distal Protection Device and Direct Stenting groups in terms of thrombus burden, stent diameter, and CPK levels both before and after the procedure. However, no significant differences were found in inflation pressure, number of stents, or TIMI flow grade between the two groups.The study revealed that in-hospital and 30-day follow-up outcomes demonstrated clinical*

success rates of 100% for both the Distal Protection Device and Direct Stenting groups. There were no cases of abrupt closure or Q-wave MI. Mortality rates was 1 (3.1%), and non-Q-wave MI rates was 0% for the DPD group and 1 (3.1%) for the DS group, indicating similar outcomes between the two groups.

CONCLUSION: *Both Direct Stenting and Stenting with a Distal Protection Device showed remarkable success Rate and minor adverse event rates in SVG lesions. However, DPD use may reduce distal embolization, warranting further studies for confirmation and long-term outcomes*

KEY WORDS: *Distal Protection Device (DPD), saphenous vein grafts (SVG), Percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG) and Direct Stenting (DS), myocardial infarction (MI)*

Correspondence : Muhammad Muneeb, Shalamar Hospital Lahore. Email: muhammad.muneeb@sihs.org.pk

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INTRODUCTION:

Percutaneous coronary intervention is a widely used and successful method for treating coronary artery disease, including the revascularization of saphenous vein grafts.[1] SVGs, used in coronary artery bypass grafting (CABG), often develop atherosclerotic disease over time, necessitating interventions to maintain graft patency.[2] Two primary approaches in the PCI of SVGs are Direct Stenting (DS) and Stenting with a Distal Protection Device (DPD).[3]

Direct Stenting involves the deployment of a stent without pre-dilation, offering the potential benefits of reduced procedural time and minimized vessel trauma.[4] However, it may not adequately address the threat of embolic complications is a major concern when intervening in saphenous vein grafts due to the fragile nature of the graft plaque.[1]

Stenting with a distal protection device uses specialized tools to capture and remove embolic debris during procedures, reducing the risk of thromboembolic complications. This approach, though potentially more complex and time-consuming, has been exposed to expand clinical endpoint by minimizing the threat of peri-procedural MI and other adverse events.[5]

While DS is quicker and less complex, DPD provides significant advantages in preventing embolic complications and improving clinical outcomes in SVG interventions. The choice should be based on patient and lesion characteristics, operator experience, and available resources.[2,3,6] This discussion aims to compare and contrast Direct Stenting and Stenting with Distal Protection Devices in the context of SVG interventions, examining their respective benefits, limitations, and clinical implications to guide optimal treatment strategies.[7]

Rationale: Saphenous vein grafts (SVGs), commonly used in CABG, often develop significant atherosclerosis over time, requiring careful intervention to optimize patient outcomes and reduce complications. Understanding the rationale for comparing Direct Stenting and Stenting with Distal Protection Devices in the PCI of saphenous vein grafts is crucial for optimizing treatment strategies. This comparison helps in identifying ways to minimize complications and improve patient outcomes. By systematically assessing the advantages and limitations of each technique, clinicians can formulate highly

informed clinical judgments grounded in robust evidence and nuanced analysis, ensuring tailored decision-making aligned with the specific patient profile and lesion complexity. This ultimately enhances the safety and effectiveness of PCI in this challenging patient subset. This study has not been conducted in Pakistan, and due to genetic and lifestyle differences, we aim to investigate it within our own population.

MATERIAL AND METHODS:

This prospective experimental study, a single blind trial, of 64 cases simple random sampling by using balloting method patients having SVG lesions undergoing PCI, age ≥25 years were selected following authorization from the Institutional Review Board (IRB), from Shalamar hospital Lahore over a period of 12 month from August 2023 to August 2024.

Patients with Ongoing angina, planned percutaneous revascularization were included while Patients in whom PCI of native coronary artery is performed for acute myocardial infarction, Participants with severe renal dysfunction (creatinine clearance below 40 mL/min), refusal, end-stage heart failure (NYHA Class III and IV), or patients with severe allergic reactions to contrast agents were omitted from the study.

A total of 64 patients with SVG lesions undergoing PCI were allocated into two groups: Group I, comprising 32 patients who received stenting with a distal protection device, and Group II, comprising 32 patients who received direct stenting without a distal protection device. The sample size was calculated using the population proportion formula from a prior study by Teruo et al. (2008)8, with a study power of 90% and a significance level of 5%, indicating a need for 32 patients per group.

PROCEDURE:

Patients were enrolled upon obtaining informed consent, and data collection was conducted using a structured proforma encompassing study parameters.

Patients was categorized into two groups: Group I, consisting of 32 patients with saphenous vein graft (SVG) lesions undergoing stenting with a distal protection device (DPD), and Group II, comprising 32 patients with SVG lesions receiving direct stenting without DPD. Patients in the DPD group was treated using one of the following embolic protection devices: Percu Surge Guard-Wire (Medtronic, Minneapolis, MN), Spider RX 4mm (ev3, Plymouth, MN), or FilterWire EZ (Boston Scientific, Natick, MA).

The choice of stent, selection of DPD, and the decision to perform pre- or post-dilatation was at the operator's discretion. Intra-procedural anticoagulation was including unfractionated heparin, with or without glycoprotein IIb/IIIa inhibitors, aiming for an activated clotting time (ACT) of >250 seconds during the procedure.

All patients were receiving 300 mg of aspirin pre-procedure, followed by a maintenance dose of 300 mg/day (150 mg BID), continued indefinitely. Additionally, a 600 mg loading dose of clopidogrel was administered, followed by 150 mg/day (75 mg BID) for at least one month in bare-metal stent (BMS) recipients and 12 months in drug-eluting stent (DES) recipients.

Routine 12-lead electrocardiography (ECG) and blood sampling for creatine kinase-MB (CK-MB) and troponin I levels was performed before and after the procedure. If CK-MB or troponin I levels exceed the normal range, repeat sampling was continue until peak values are recorded.

A 30-day follow-up was conducted through mobile contact or an in-person hospital visit, during which any occurrence of cardiac outcome or the need for repeat Coronary artery intervention was documented.

Clinical success will be defined as achieving favourable angiographic result without major Intrahospital clinical events, such as abrupt closure, no-reflow, MI, death, or the need for emergency CABG surgery. Quantitative coronary angiography (QCA) was done using a validated edge-detection algorithm to calculate the reference diameter and minimum luminal diameter. Intramural globular masses were classified as thrombus if they appear rounded or polypoid and protrude into the lumen. Thrombus burden will be categorized into four grades based on size:

- Grade 4: Large thrombus (>1.5 times

the normal lumen diameter at its widest point)
• Grade 3: Medium thrombus (0.5–1.5 times the normal lumen diameter)
• Grade 2: Small thrombus (<0.5 times the normal lumen diameter)
• Grade 1: Mural opacity with low thrombus likelihood [8]

Q-wave MI was diagnosed based on the presence of new pathological Q waves on ECG along with a CK-MB level ≥2 times the upper normal limit (ULN), while non-Q-wave MI was identified by elevated CK-MB ≥2 times ULN without Q waves. Target lesion revascularization (TLR) refers to repeat percutaneous or surgical revascularization within the stent segment or within 5 mm of its edges, whereas target vessel revascularization (TVR) includes any restenosis-related intervention in the initially treated SVG. Major adverse cardiac events (MACE) was defined as a composite of death, Q-wave MI, and TVR (TVR-MACE).

STATISTICAL ANALYSIS:

Statistical analysis was conducted using SPSS Version 26.0. Continuous variables, such as age, stent size, balloon diameter, and inflation pressure, were expressed as mean ± standard deviation (SD), while categorical variables were summarized as frequencies (%). The Shapiro-Wilk test was applied to assess data normality, and independent t-test was used to compare mean differences, for continuous variables. Categorical variables, including sex, risk factors, and lesion characteristics, were analyzed using the Chi-square test or Fisher's Exact Test to evaluate difference between groups for categorical variables. A p-value ≤ 0.05 was considered statistically significant.

RESULTS:

A total of 64 patients participated in the study, with a mean age of 61.25 ± 9.44 years (range: 37–84 years). The DPD group had a mean age of 61.75 ± 9.36 years, while the DS group had a mean age of 61 ± 9.66 years. Among the participants, 61 (95.3%) were male and 3 (4.7%) were female. In the DPD group, 29 (90.6%) were male and 3 (9.4%) were female, whereas the DS group consisted entirely of male patients (100%).

Diabetes mellitus was present in 33 patients (51.6%) overall, with 17 (53.1%) in both the DPD and DS groups. Hypertension was found in 36 patients (56.3%) overall, including 18 (56%) in the DPD group and 17 (53.1%) in the DS cluster. Smoking was reported in 35 patients (54.7%) overall, with 17 (53%) in the DPD cluster and 18 (56.3%) in the DS group. Hyperlipidemia was prevailing in 7 cases (10.9%) overall, with 4 (12.25%) in the DPD group and 3 (9.4%) in the DS group. The mean duration since the previous CABG was 14.22 ± 3.38 years, ranging from 8 to 26 years. (table-1)

Within the scope of the analysis 28 patients (43.8%) were diagnosed with angina on exertion, 27 patients (42.2%) with unstable angina, 4 patients (6.2%) with reversible ischemia on stress testing, and 5 patients (7.8%) with NSTEMI. The mean ejection fraction was 46.42 ± 9.78%, with a maximum of 60% and a minimum of 30%. (table-2) Lesion locations were as follows: 8 patients (12.5%) had ostial lesions (patients treated with DPD had 2 cases, whereas those treated with DS had 6 cases), 37 patients (57.8%) had proximal lesions (patients treated with DPD had 16 cases whereas those treated with DS had 21 cases), 16 patients (25%) had mid lesions (patients treated with DPD had 12 cases whereas those treated with DS had 4 cases), and 3 patients (4.68%) had distal lesions (patients treated with DPD had 2 cases whereas those treated with DS had 1 cases).

BMW (0.014) guide wire was used in 57 patients; 25 (43%) in the DPD subset and 32 (57%) in the DS subset), the filter wire in 5 patients (7.8%) (all in the DPD group), and the Cougal (0.014) wire in 2 patients (3.1%) (both in the DPD group). A balloon was used during PCI in 40 patients (62.5%). Thrombus burden grades were as follows: 3.1% among patients treated with a DPD while 71.9% treated with DS had thrombus burden grade I; 62.5% among patients treated with a DPD while 9.4% treated with DS had thrombus burden grade II; and 34.4% among patients treated with a DPD while 18.8% treated with DS had thrombus

Table-1: Descriptive Characteristics of Demographics, Clinical Characteristics, and Procedural Details in Patients with Saphenous Vein Graft Lesions Undergoing PCI.		
Male		61(95.3%)
Female		3(4.7%)
Age		61.25±9.44
Previous CABG (Years)		14.22±3.83
Ejection Fraction		46.42±9.78
Inflation Given		2.52±1.22
Inflation Pressure (Atm)		14.52±3.98
Diabetes Mellitus		33(51.6%)
Hypertension		36(56.3%)
Smoking		35(54.7%)
Hyperlipidemia		7(10.9%)
Family History		26(40.6%)
Chest pain	Angina on exertion	28(43.8%)
	Unstable angina	27(42.2%)
	Reversible ischemia	4(6.2%)
	NSTEMI	5(7.8%)
Lesion location	Ostial	8(12.5%)
	Proximal	36(56.25%
	Mild	16(25%)
	Distal	4(6.25%)
Balloon Usage		40(62.5%)
STENT	BMS	31(48.4%)
	DES	33(51.6%)
Thrombus burden	Grade 1	24(37.5%)
	Grade 2	25(39.1%)
	Grade 3	15(23.4%)
GlycoproteinIIb/IIIa inhibitor	Given	46(71.9%)
Guide wire used to cross the lesion	BMW 0.014	57(89.1%)
	Filter Wire	5(7.8%)
	Cougal 0.014	2(3.1%)

burden grade III.

Significant associations were found between the DPD and DS groups regarding glycoprotein (p-value; = 0.00) and thrombus (p-value; = 0.000). However, statistically insignificant correlation with the stent type. (p-value = 0.802), lesion location (p-value = 0.072), or chest pain

Table 2: Comparison of Demographics, Clinical Characteristics, and Procedural Details between Patients Receiving Distal Protection Device (DPD) and Direct Stenting (DS).			
Variable (n, %)	**DPD**	**DS**	**P value**
Age (years)	61.75 ± 9.36	61 ± 9.66	0.754
Male	29 (90.6)	32(100)	0.078
Hypertension	18 (56)	17 (53.1)	0.806
Diabetes mellitus	17 (53)	17 (53.1)	0.99
Smoking	17 (53)	18(56.3)	0.806
Hyperlipidemia	4 (12.5)	3 (9.4)	0.694
Family history	10 (31.3)	16 (50)	0.131
Others	3 (9.4)	0 (0)	0.078
Unstable angina	15 (49.9)	12 (37.5)	
Ejection fraction	45.94 ± 7.12	49.06 ± 7.98	0.103

Table 3: Comparison of Angiographic and Procedural Characteristics Details between Patients Receiving Distal Protection Device (DPD) and Direct Stenting (DS).			
Variable (n, %)	**DPD**	**DS**	**P-value**
SVG lesion location			
Ostial	2(6.3)	6 (18.8)	0.014
Proximal	16 (50)	21(65.6)	0.014
Distal	12(37.5)	4 (12.5)	0.014
Mid	2 (6.3)	1 (3.1)	0.014
Graft age (years)	15 ± 3.93	13.41 ± 3.42	0.088
TIMI flow grade before procedure	1.81 ± 0.40	1.78 ± 0.49	0.78
TIMI flow grade after procedure	3 ± 0.00	3 ± 0.00	0.78
Procedure			
Glycoprotein IIb/IIIa inhibitor	29 (90)	16 (50)	0.000
Number of stents	1.31 ± 0.47	1.47 ± 0.67	0.285
Stent diameter (mm)	3.56 ± 0.38	3.20 ± 0.30	0.000
Stent length (mm)	21.81 ± 6.08	24.75 ± 7.47	0.090
Inflation pressure (atm)	13.42 ± 3.88	14.2 ± 3.30	0.503

Table 4: In-Hospital and 30-Day Follow-Up Outcomes for Patients Receiving Distal Protection Device (DPD) versus Direct Stenting (DS).			
Variable (n, %)	**DPD**	**DS**	**P-value**
In- Hospital			
Clinical success	32 (100)	32 (100)	
Abrupt Closure	0	0	
Death	1 (3.1)	1 (3.1)	0.98
Q-wave Myocardial Infarction	0	0	
Non Q-wave Myocardial Infarction	0	0	
30 days follow up			
Death	1 (3.1)	1 (3.1)	0.98
Unstable angina	0	0	
Q-wave Myocardial Infarction	0	0	
Non Q-wave Myocardial Infarction	0	1 (3.1)	0.321
Target vessel revascularization	0	0	

(p-value = 0.87). (table-3)

The statistical analysis revealed notable discrepancies among DPD and DS groups for inflation (p-value = 0.029), stent diameter (p-value = 0.000), CPK pre-procedural (p-value = 0.002), CPK post-procedural (p-value = 0.001), thrombus burden (p-value = 0.000), and CK-MB after the procedure (p-value = 0.032). The t-test indicated insignificant variation with both DPD and DS groups for inflation pressure (p-value = 0.503), number of stents (p-value = 0.285), stent length (p-value = 0.090), TIMI flow grade before the procedure (p-value = 0.780), and CK-MB before the procedure (p-value = 0.765).

The study revealed that in-hospital and 30-day follow-up outcomes demonstrated clinical success rates of 100% for both the Distal Protection Device and Direct Stenting groups. There were no cases of abrupt closure or Q-wave MI. Mortality rates were 3.1%, and non-Q-wave MI rates were 0% for the DPD group and 3.1% for the DS group, indicating similar outcomes between the two groups. (table-4)

DISCUSSION:

This study compares DS versus Stenting with a DPD in patients with SVGs lesions underwent PCI. The findings highlight several key aspects of these interventions and their impact on clinical outcomes, complications, and procedural characteristics.

Okabe et al. (2008)[9] noted no significant differences between DPD and DS groups in adverse cardiac events, aligning with our finding that PCI with DS is cost-effective with similar outcomes. Leborgne et al. (2003)[10] suggested that DS is preferable due to lower thrombus prevalence and costs, consistent with our results showing similar clinical outcomes but significant differences in thrombus burden. Stone et al. (2003)[11] indicated similar outcomes with different distal protection devices, whereas our study found a significant difference in guide wire use (p=0.016).

The use of DPDs during PCI in SVGs has been consistently shown to decrease the susceptibility to embolic burden and comorbid outcomes. Our study supports these findings, with a higher incidence of thrombus burden grade I in the Direct Stenting group compared to the DPD group, where lower thrombus grades were observed. This is consistent with the literature, which indicates that DPDs effectively capture and remove debris, thereby minimizing the risk of distal embolization and improving procedural outcomes (Gori et al., 2021; Iannaccone et al., 2019)[12,13].

Direct Stenting, while simpler and faster, does not offer the same level of protection against embolic events. The higher thrombus burden observed in the DS group in our study aligns with previous research indicating that direct stenting possibly linked to a heightened chance of adverse effects owing to inadequate lesion preparation as well as higher embolic risk (Berman et al., 2020; Kim et al., 2022)[14,15].

Our study observed substantial variations in procedural attributes across the two groups. Notably, the use of stent diameter and inflation pressure showed significant variation, which is reflective of the need for careful lesion preparation and stent sizing in both approaches. The DPD group had more controlled inflation and stent placement, which may contribute to better outcomes in terms of reducing adverse events and optimizing stent deployment (Kotecha et al., 2023)[16].

Interestingly, no evident discrepancies were found in the stent placement frequency used, stent length, TIMI flow grade before the procedure, and CK-MB before the procedure between the groups. This suggests that while DPDs offer additional protection, they do not necessarily alter the fundamental procedural parameters or initial myocardial injury markers compared to Direct Stenting (Buchanan et al., 2019; Zhao et al., 2022)[17,18].

The study cohort had an average age of 61 yrs, majority consisting of male cases. which is consistent with the demographics observed in similar studies Rogers et al. 2020)[19]. The high prevalence of DM, HTN, and SM among the participants reflects the common risk factors associated with SVG disease and PCI procedures (Sung et al., 2021; Singh et al., 2022) [20,21].

While our study provides valuable insights, there are some limitations. The sample size, though calculated to achieve statistical significance, may not fully capture the variability in outcomes across a broader population. Additionally, the study's observational nature means that other unmeasured factors could influence outcomes (Jackson et al., 2024) [22].

Future research should include larger, multicenter trials to substantiate our conclusions and explore the long-term influence of DPDs versus Direct Stenting on patient outcomes. Additionally, further investigation into the cost-effectiveness of using DPDs in various clinical scenarios would be beneficial (Smith et al., 2023)[23].

CONCLUSIONS:

Both Direct Stenting and Stenting with a Distal Protection Device were associated with high clinical efficacy rates and limited complication occurrence in this cohort of cases of SVG-related lesions. However, the use of a DPD may offer additional protection against distal embolization, as indicated by lower thrombus burden grades. Further studies utilizing a broader dataset are essential for verifying these findings and investigating extended outcomes.

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