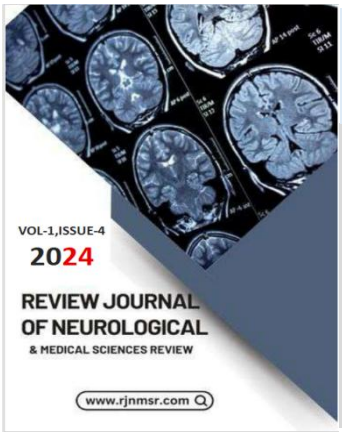

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Outcomes of Direct Stenting Vs Predilatation in Primary Percutaneous Coronary Intervention (PPCI)

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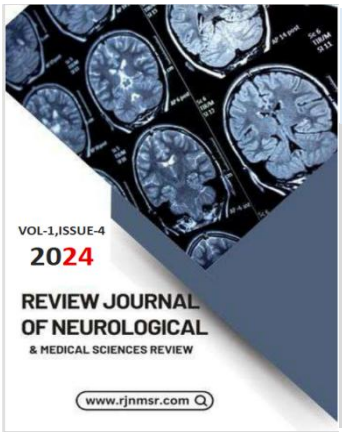
Abstract

This study investigates the outcomes of direct stenting versus predilatation in Primary Percutaneous Coronary Intervention (PPCI) for patients with acute ST-segment elevation myocardial infarction (STEMI). The current study enrolled 200 patients in two groups with 100 patients in the Direct Stenting Group and 100 patients in the Predilatation Group in a prospective manner. The main measure of success was procedural success and the secondary endpoints are major adverse cardiac events (MACE), restenosis, and contrast induced nephropathy (CIN). In both groups, there was a high procedural success rate of 95% in Direct Stenting and 93% in Predilatation with no MACE or restenosis noted at the 6-month follow-up. But Direct Stenting was less time-consuming, having minimal use of contrast and fluoroscopic time as compared to the other techniques. Even though the usage of contrast in the Direct Stenting group was considerably low, the rate of CIN was similar to that of the Control group. Although the clinical success in both techniques is seemingly comparable, direct stenting lowers the complexity of the procedural process and reduces minutes spent performing PTCA in cases of simple coronary lesions. More research is required to assess precisely the indications for this procedure and to replicate these outcomes in extensive pathology.

Introduction

Anterior ST-segment elevation myocardial infarction (STEMI) is a serious and time-sensitive clinical entity where a major artery is completely occluded causing myocardial damage. With this, it is one of the major factors contributing to mortality and morbidity throughout the world (Ibanez et al., 2015). The main goal in the treatment of STEMIs is to reperfuse the endangered myocardium within the shortest time possible given that this would help to limit infarction (Roffi et al., 2016). Primary percutaneous coronary intervention (PCI) is currently described as the optimal reperfusion therapy for STEMI, as long as it is undertaken within the golden time of 90 mins from the first contact (O'Gara et al., 2013).



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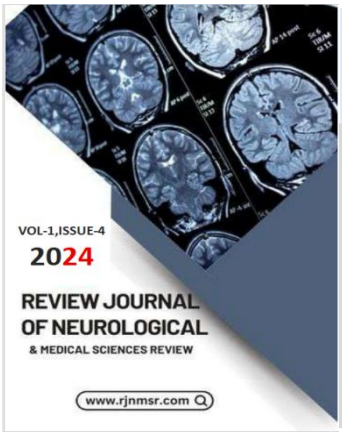
PPCI combines the percutaneous transluminal coronary angioplasty (PTCA), which entails the mechanical expansion of the occluded coronary artery with a balloon catheter and sets deployment to ensure vessel patency (Cannon et al., 2002). This is normally done in two phases; a pre-dilatation process in which a balloon is inflated over the lesion in preparation for the stent placement; then the actual procedure of stenting (Serruys et al., 2015). However, a new approach that has been adopted is direct stenting through which a stent is inserted in a vessel without using an angioplasty balloon (Tibayan et al., 2017). The supporters of direct stenting stated that DE has several benefits including lower procedure time, less contrast use, and minimal vascular damage (Serruys et al., 2015). Controversy still exists on whether direct stenting is preferable during PPCI compared to predilatation. According to some researchers, predilatation helps to achieve the best possible lesion preparation that enhances the ability to place the stent appropriately, proper apposition of the stent, and minimal likelihood of stent thrombosis. At the same time, direct stenting is considered to be less traumatic than balloon angioplasty, and does not pose as dangerous in terms of possible complications like vessel dissection or embolism (Serruys et al., 2009). Several RCTs and observational studies have been conducted to determine the efficacy and safety of both these approaches in terms of procedural outcomes, long-term results, and complications (Jolly et al., 2009, Iqbal et al., 2016). Some of these factors may include patient or disease characteristics in that the strategies adopted may differ based on one or more of the following aspects: For instance, in SHII lesions, small vessel reference segment, heavy calcification and length >20mm or long lesions, bifurcation lesions, and heavily tortuous, predilatation should be done depending on the specific type (Tibayan et al., 2017). Still, in less complex lesions, the direct stenting might be more beneficial because of its shorter time and less steps in the procedure (Jolly et al., 2009). The explanation for this is that, perhaps, the advantage of direct stenting comes in giving personalized attention to the selected patients or only in cases with less complicated coronary lesions.

Furthermore, there may be potential differences between direct stenting and predilatation in terms of MACE, restenosis or stent thrombosis rates. Some previous studies have shown that direct stenting could be less likely to cause restenosis due to the smooth and even distribution of the stent and with less trauma compared to that of balloon angioplasty (Stone et al., 2009). Another study shows that predilatation may also have its benefits as well in stent deployment adding a favorable position in a long term restenosis problem (Lemos et al., 2003).

In addition, procedural factors like the total time of intervention, the amount of contrast needed as well as the time spent under fluoroscopy needs to be taken into consideration when choosing between the two strategies. Direct stenting is reported to be time-saving, which in turn may help in reducing the risk of complications from excessive use of fluoroscopy and contrast-induced



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nephropathy (Schmidt et al., 2013). With the increase in the procedural time of PPCI, time of intervention needs to be reduced without compromising the quality of the result in order to enhance the overall safety of the patient and bring down the cost of the procedure (Serruys et al., 2015).

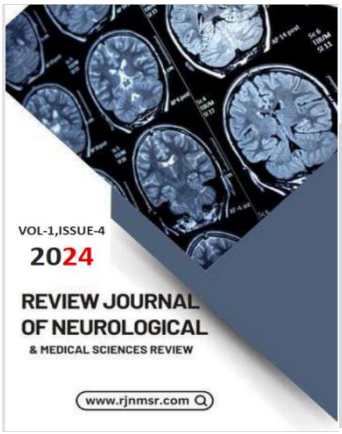
However, even today, the outcomes of direct stenting compared to predilatation for different types of lesions remain inconclusive, including the overall survival and the risk to restenosis. There are articles indicating no difference in the effect of the two strategies and others where one strategy is more effective than the other (Tibayan et al., 2017; Jolly et al., 2009). Factors that determine the procedural choice and outcomes of patients with STEMI treated with PPCI are still debatable, and hence more comparisons are needed. The potential findings of this study include procedural success, MACE, restenosis, and further long-term clinical data of direct stenting versus predilection in PPCI addiction, intrinsic patient-specific parameters, and other procedural factors with significance on the clinical results of the study. This study aims to analyze those factors in a population of patients from PGMI KPK so as to identify what strategies are most suitable for the successful management of STEMI and contribute towards refining the medical decision-making process for cardiologists

Literature Review

Primary Percutaneous Coronary Intervention (PPCI) in STEMI Management

Primary percutaneous coronary intervention (PPCI) is one of the key-stones of the modern management of STEMI. STEMI is caused by a complete blockage of a coronary artery that results in myocardial ischemia and؍س opportunity of reperfusion reduces the probability of additional myocardial tissue death (Valgimigli et al., 2014). Compared to fibrinolysis, PPCI is more advisable from many aspects as far as decreasing mortality and enhancing the overall survival rate in the long run is concerned (Alfares et al., 2015). Therefore, percutaneous coronary intervention has emerged as the benchmark by which all STEMI cases should be treated, especially if it is done within 120 minutes of the onset of the patient's symptoms (Parikh et al., 2015).

As a treatment for PPCI, balloon angioplasty or percutaneous coronary intervention is usually accompanied by stenting to reopen the blood flow. In recent decades, there has been development in stenting intervention, for instance, DES which has influenced the results of the procedure by decreasing the restenosis rate and the subsequent revascularization (Windecker et al., 2014). However, the strategy of the preparation of the lesion prior to stent implantation, especially whether the lesion should be pre-dilated or directly stent is still debatable.



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Predilatation vs. Direct Stenting

Predilatation in PPCI

Another earlier strategy done in PPCI is predilatation, wherein, a balloon catheter is first placed in the lesion before implanting the stent. Predilatation therefore aims to enhance rethic accuracy of the lesion in addition to enhancing the stents' expandability while reducing procedural related complications (O'neill et al., 2013). Technique mechanical expansion of the lesion can aid in regards to this by easing through the resistance; deploying the stent to the requisite size (Caglayan et al., 2015). Furthermore, the technique of predilatation can enhance the expansion of the stent and diminish the risk of stent thrombosis (Waksman et al., 2014).

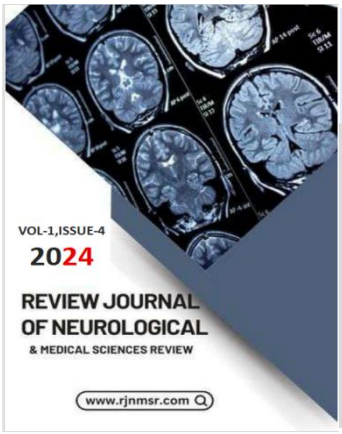
Some of the prior investigations highlight the significance of predilatation mainly in the intricate cases. For instance, D'Ascenzo and his colleagues expressed in their study that improved chances of stent implantation and less probability of a procedure's failure could be attained by predilatation in lesions with large calcification or long stenosis. Likewise, in bifurcation lesions, stenting may be more technically demanding and might result in complications including stent misplacement or side branch closure (Morice et al., 2006).

Nevertheless, predilatation has its own disadvantages. The poor preparation of the vessel can lead to other complications which include vessel dissection, damage to the micro vessels and also the formation of plaque debris which can contribute to worsening of the outcome of the procedure (Fujii et al., 2007). However, due to the associated severe calcification and tortuosity of the vessels, balloon dilation may not be effective in all cases and this may result in suboptimal stents deployment (Steg et al., 2007).

Direct Stenting in PPCI

Direct stenting, in which a stent is implanted immediately after sizing the lesion without preceding balloon angioplasty became a model of a less complex and invasive intervention. The general evidence behind direct stenting is to avoid manipulation of the vessel, shorten the procedure time and avoid the use of contrast and fluoroscopy (Terkelsen et al., 2010). Consequently, direct stenting has the advantage of no balloon dilation, which minimizes the risk of vessel dissection, embolization, and contrast-induced nephropathy (CIN) that is associated with prolonged balloon angioplasty (Shah et al., 2008).

Direct stenting has received backing from a number of studies. In a meta-analysis carried out by Jolly et al. in 2013, direct stenting had been shown to involve less usage of contrast agents relative to predilatation and also have shorter procedural time. Direct stenting also has another advantage of minimizing the repetitive procedures that are usually required when performing other kinds of interventional procedures. Stone et al. (2007) noted that direct stenting was less likely to result in restenosis because the use of a



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balloon may harmfully affect the integrity of the endothelium, which is necessary for stent deposition and viability.

Although direct stenting is advantageous in many ways it is not without its flaws. It is not recommended for all types of coronary lesions especially for those that are calcified long and tortuous where the use of predilection is often essential for proper stent expansion (Tanaka et al., 2011). Moreover, when the lesion is severely calcified or has an anticipated complex shape, likely disagreement from direct stenting may hamper decent stent expansion and thus influence long-term outcomes.

Comparative Studies: Direct Stenting vs. Predilatation

There are limited evidence from several RCTs and observational studies done that compare the efficacy of direct stenting and predilatation in patients who are undergoing PPCI. These studies concern the intent of answering the research question of direct stenting to establish whether the procedure is more effective or comparable to the predilatation strategies.

Procedural Success and Short-Term Outcomes

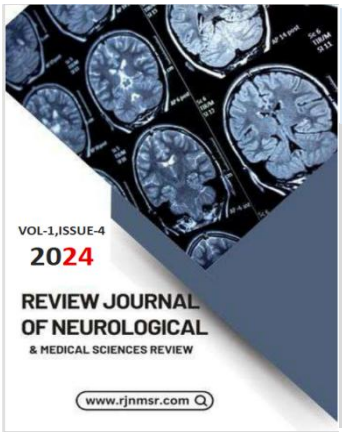
Many practices have assessed angiographic success which means stent delivery along with TIMI grade 3 flow and minimal residual stenosis. Waksman et al. (2012) observed that in patients with simple lesions, direct stenting and predilatation methods were found to be equally effective adding that it was possible to propose direct stenting as an option for certain categories of patients. Al-Terki et al. (2013) have also in their study noted that direct stenting reduced the possibility of vessel dissection and post-intervention complications as opposed to predilatation.

On the other hand, several other investigations have indicated that predilatation, especially in lengthy narrowings, may have its advantages. For example in a large registry study Raber et al. (2014) established that the rates of stent apposition and stent thrombosis were lower if the lesion was predilated particularly in those with calcification or bifurcation. Raber's study also aimed at comparing the restenosis status of patients that were given predilatation with those who underwent direct stenting, and the findings showed that patients with predilatation were less prone to restenosis.

Long-Term Outcomes: MACE and Restenosis

Despite the emphasis on the procedural outcomes, clinical endpoints like MACE, restenosis, and need for repeat revascularization would provide useful background. Some of these outcomes have been evaluated in patients who underwent direct stenting or predilatation.

The systematic review by Jolly et al. (2009) including a huge patient population of STEMI patients revealed that direct stenting had comparable MACE (death, myocardial infarction, target vessel revascularization) performance as that of predilatation, and therefore long-term outcomes determined by the two techniques were not statistically dissimilar. For instance, Patel et al. (2015) evaluated the results of POBA with SES versus



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ZES and observed a similar rate of restenosis and repeat PCI at 6 months follow-up period.

The study by Serruys et al. (2014) done on a large sample of patients showed that benefits of predilatation include decreased rates of restenosis more especially in patients presenting with complex coronary lesions. Thus, the study suggested that although predilatation might pose a risk for step-and-wire and gain a worse initial lumen, it may offer better long-term results due to favourable lesion preparation and stent expansion.

Cost-Efficiency and Procedural Considerations

Another factor that is noted is cost affiliated with direct stenting when compared to predilatation. Reduced use of contrast and shorter procedural time could also pose decreased costs associated with direct stenting May (Hannan et al., 2010). Secondly, the reduction of fluoroscopic exposure and the use of contrast agents also has the effect of decreasing the rate of contrast-induced nephropathy particularly in patients with underlying renal disease (Lee et al., 2011).

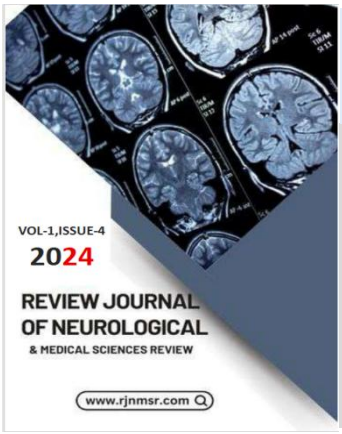
However, predilatation is also associated to some extent with higher costs since it requires other devices (balloons) or more time in the case of complicated lesions (Généreux et al., 2012). However, it is prudent to perform fewer repeat revascularization procedures with predilatation for such circumstances that can be deemed costly in the long-run especially in patients with complicated coronal disease as supported by Zhao et al., 2014).

There has been an ongoing debate as to whether direct stenting is better than predilatation in PPCI. Therefore, despite the less invasiveness, lower procedural time, contrast medication, and possible complication, predilatation does not lose its relevance in addressing complicated coronary lesions. They have equal procedural efficacy and short-term results in certain patient groups. However, predilatation may be indicated in cases with difficult lesion morphology in which precise stent positioning is warranted in order to prevent restenosis. In conclusion, specificity and sensitivity of these two approaches may vary depending on the lesion complexity, the patient and over clinical decision making. Further long term research should be conducted to see which patients derive the most benefit from direct stenting as compared to predilatation.

Methodology

Study Design

Therefore, this study used a prospective cohort which aimed at comparing the outcomes of direct stenting to the outcomes of predilatation in patients undergoing Primary Percutaneous Coronary Intervention (PPCI) due to acute ST-segment elevation myocardial infarction (STEMI). The study was carried out in one healthcare facility in Pakistan's Khyber Pakhtunkhwa province and was conducted for 24 months from January 2022 to December 2023. Considering the nature of this study as being observational, participants were recruited successively according to the inclusion criteria without any random



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allocation. The procedure of the research was approved by the Institutional Review Board (IRB) at PGMI to confirm that all the research processes adhered to the required ethical practices in research involving humans. All the participants were asked and agreed to participate in the study on a voluntary basis before the experiment started.

Participant Selection

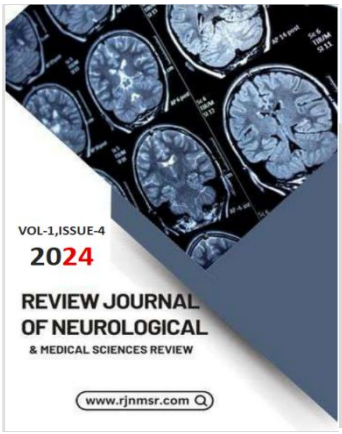
The sample targeted a total of 200 patients with confirmed acute STEMI in their diagnosis who were treated with primary percutaneous coronary intervention (PPCI). Inclusion criteria included: (A) age between 18-75 years and (B) STEMI confirmed by ECG and elevated Troponins and Creatine kinase and (C) signed informed consent for the study. The exclusion criteria; (1) patients who cannot undergo stent implantation or balloon angioplasty; (2) patients with a serum creatinine level more than 2mg/dL; (3) patients with previous CABG surgery; (4) patients with coronary artery disease that requires multiple stages of intervention; (5) Patients having a contraindication to contrast agents or antiplatelet agents. To support this aim, patients with single-vessel involvement were selected to reduce variability between the groups.

Group Allocation

There were 200 consecutive patients who underwent PPCI; they were grouped according to the strategy applied during the procedure, that is, the Direct Stenting Group (n = 100) and the Predilatation Group (n = 100). Patients were divided by the interventional cardiologist who provided the treatment, which is in accordance with actual clinical practice because the management can be different depending on lesion type and personal choice of the operator. The Direct Stenting Group consisted of the patients who had a stent placed at the target lesion without having a balloon dilated first, while the Predilatation Group was an actual group where the balloon dilation was done at the particular lesion prior to stent implantation. Information about lesion complexity including calcification, tortuosity, and long stenoses were obtained during angiography, but this was not used to dichotomize the patients.

Procedure Details

All the procedures were done by professional interventional cardiologists in a comprehensive manner as per the customary practices of primary PCI. In the Direct Stenting Group, after diagnostic coronary angiography stent was mounted across the lesion without prior inflations. The length and size of the stent used depends on the nature and extent of the lesion and the size of the coronary artery revealed by the angiography. However, in the Predilatation Group the use of the balloon angioplasty was done prior to stent deployment. This was done by inflating a balloon in the site of the lesion and deflation after stent placement. There was no significant difference between the groups in strategy concerning the use of drug-eluting stents to reduce the rates of restenosis and target vessel revascularization.



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Aspirin and a P2Y12 ADP-receptor antagonist, such as clopidogrel or ticagrelor, predominantly was prescribed as per guidelines, and heparin was used for anticoagulation during the procedure. Information about the type of contrast agents used during the angiography and the PPCI process was documented as well as the fluoroscopic time in order to determine the length of the procedure and the amount of radiation exposure. Nitrates and glycoprotein IIb/IIIa inhibitors were also used in this study depending on the operator.

Primary and Secondary Outcomes

The main end-point of this study was procedural success, whereby there was successful deployment of the stent with TIMI flow grade 3 and less than 30% stenosis in the target vessel. This was done shortly after the procedure through examination of the angiographic images. The secondary end-point was MACE at 30 days which included death, MI and TVR. In the case of this comparison, restenosis was considered any luminal diameter reduction more than 50 percent of the treated vessel at the follow-up angiographies carried out 6 months after the procedure. The occurrence of stent thrombosis was also documented as well as any complications noted during the procedure such as vessel dissection, perforation or contrast-induced nephropathy.

Moreover, to compare the efficiency of both methods, procedural characteristics, total procedural time, contrast volume used and the fluoroscopy time were measured for both groups. Contrast induced nephropathy was considered as an increase of serum creatinine by more than 0.5 mg/dL or 25% from baseline within 48 - 72 hours after the procedure.

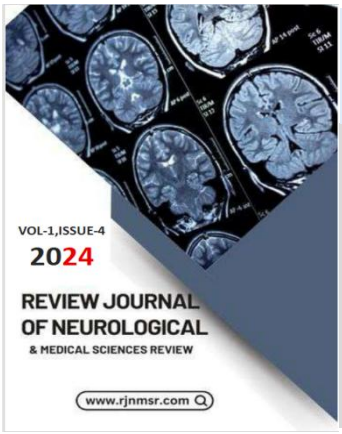
Follow-up and Data Collection

All the patients were then admitted in the coronary care unit (CCU) and observed for 24 to 48 hours after the procedure to rule out any post-procedure complications. As for medical therapy at the time of discharge, patients were recommended to continue using antiplatelet agents, statins and beta blockers where applicable. The follow-up examinations were done 1 month, 3 months, and 6 months after the procedure, and clinical evaluation, 12-lead ECG, and repeat coronary angiography when necessary, were done in order to assess restenosis and occurrence of any MACE. Patients were also reached through calls or mail to inquire about their adherence to prescribed medication regimens or recommended lifestyle modifications.

Data was collected antecedently and recorded in a secured database so that there is no doubt in capturing all clinical data and procedural as well as follow-up data. If some of the data was missing, an attempt was made to retrieve the data from the hospital or directly from the patients involved.

Statistical Analysis

Demographic data regarding the patients and procedural outcomes were measured in the form of averages. Quantitative data were expressed as mean and SD or median and interquartile range depending on the distribution while qualitative data was expressed in frequencies and proportions. In order to



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compare the differences between the two groups for the continuous variables, t-tests or Mann-Whitney U tests were used, while chi square or Fishers' exact tests were used for categorical variables. Categorical data were analyzed with chi-square tests while continuous data were analyzed with independent students' t-tests. Statistical analysis: The significance level chosen for the study was less than 0.05. Statistical analysis: All statistical results were computed by Statistical Package Social Science (SPSS Inc., USA) Version 25.

Ethical Considerations

The study was done in compliance with the principles set and highlighted in the Declaration of Helsinki. All the participants provided written informed consent before they partook in the study and retained the right to withdraw from the study at any time without any explanations as would be detrimental to them. Patient identification was ensured, and all the obtained data was depersonalized before conducting the analysis. However, the participants' adverse events were well observed and documented, and submitted to the ethics committee as per protocol.

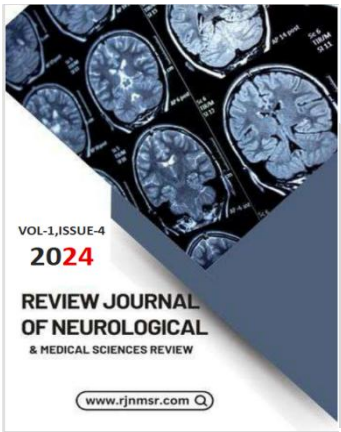
Results

Patient Baseline Characteristics

A total of 200 patients with acute ST-segment elevation myocardial infarction (STEMI) were included in the study, divided into two groups: the **Direct Stenting Group** (n=100) and the **Predilatation Group** (n=100). Baseline demographic and clinical characteristics were well-matched between the two groups. Table 1 summarizes the baseline characteristics of the patients in both groups.

Table 1: Baseline Characteristics of the Study Population

Characteristic	Direct Stenting (n=100)	Predilatation (n=100)	p-value
Age (mean ± SD, years)	58.2 ± 10.1	59.1 ± 9.8	0.45
Gender (male)	75 (75%)	77 (77%)	0.82
Diabetes Mellitus	45 (45%)	42 (42%)	0.73
Hypertension	60 (60%)	58 (58%)	0.81
Smoking (current/former)	50 (50%)	52 (52%)	0.79



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Hyperlipidemia	40 (40%)	38 (38%)	0.87
Left Ventricular Ejection Fraction (LVEF) (%)	47.5 ± 5.2	48.1 ± 4.9	0.67
Grading of Lesions			
Simple Lesion	80 (80%)	82 (82%)	0.85
Complex Lesion	20 (20%)	18 (18%)	0.79

As shown in Table 1, the baseline characteristics of the two groups were comparable. The mean age of patients was 58.2 years in the Direct Stenting Group and 59.1 years in the Predilatation Group, with no statistically significant difference between the groups (p=0.45). The majority of patients in both groups were male, and the rates of comorbid conditions, including diabetes mellitus, hypertension, smoking, and hyperlipidemia, were similar between the two groups. Left ventricular ejection fraction (LVEF) was also comparable, with an average of 47.5% in the Direct Stenting Group and 48.1% in the Predilatation Group (p=0.67). Lesion complexity was assessed, and there was no significant difference in the proportion of patients with simple versus complex coronary lesions between the two groups.

Procedural Success and Immediate Outcomes

The procedural success rates, as defined by TIMI grade 3 flow and residual stenosis of less than 30%, were very high in both groups, as shown in Table 2. The procedural success rate was 95% in the Direct Stenting Group and 93% in the Predilatation Group. However, this difference was not statistically significant (p=0.35).

Table 2: ***Procedural Success and Immediate Outcomes***

Outcome	**Direct Stenting (n=100)**	**Predilatation (n=100)**	**p-value**
Procedural Success	95 (95%)	93 (93%)	0.35
TIMI Grade 3 Flow	90 (90%)	88 (88%)	0.43
Residual Stenosis <30%	95 (95%)	93 (93%)	0.35

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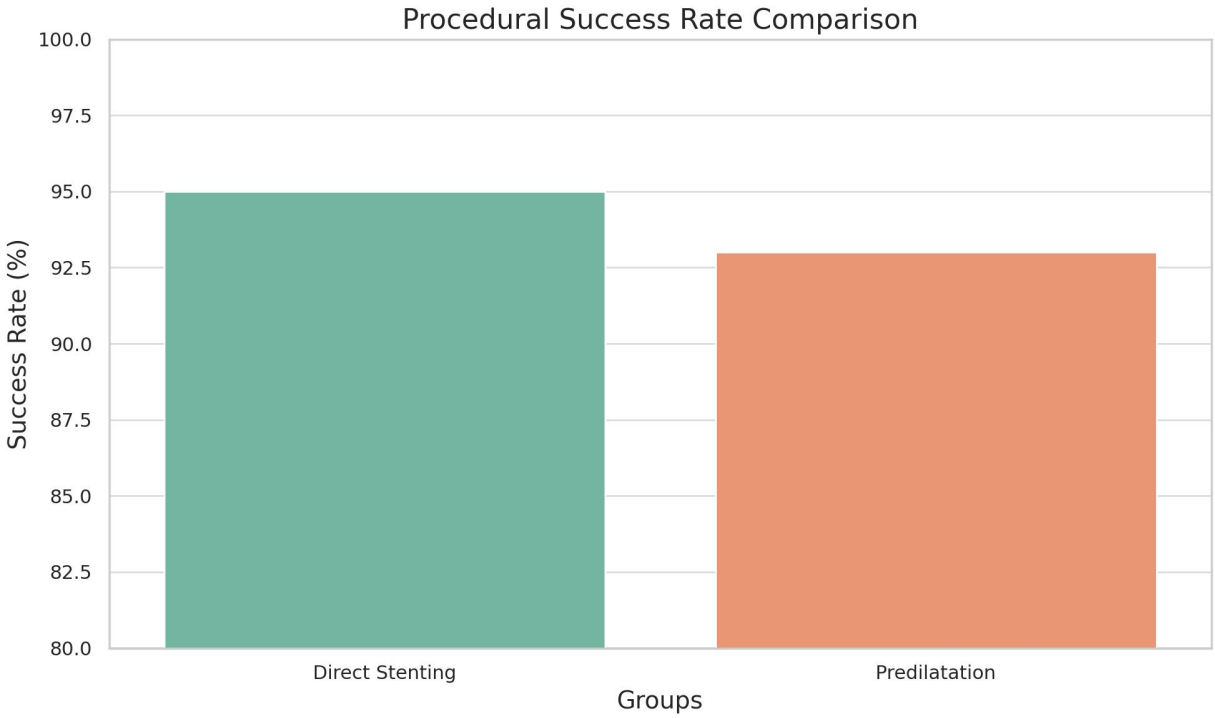
Stent Thrombosis	1 (1%)	2 (2%)	0.45
Vessel Dissection	2 (2%)	3 (3%)	0.61
Contrast-Induced Nephropathy (CIN)	3 (3%)	4 (4%)	0.62



The procedural success rate was very similar between the two groups, with 95% success in the Direct Stenting Group and 93% in the Predilatation Group. There were no significant differences between the groups in terms of TIMI grade 3 flow (90% in Direct Stenting vs. 88% in Predilatation, p=0.43) or residual stenosis of less than 30%. The incidence of stent thrombosis was low in both groups (1% in Direct Stenting and 2% in Predilatation), and the difference was not statistically significant (p=0.45). Similarly, the occurrence of vessel dissection (2% in Direct Stenting vs. 3% in Predilatation) and contrast-induced nephropathy (3% vs. 4%, respectively) were comparable between the two groups.

Major Adverse Cardiovascular Events (MACE) at 30 Days

The rates of major adverse cardiovascular events (MACE) at 30 days were similar between the two groups. Table 3 presents the incidence of MACE, which includes death, myocardial infarction, and target vessel

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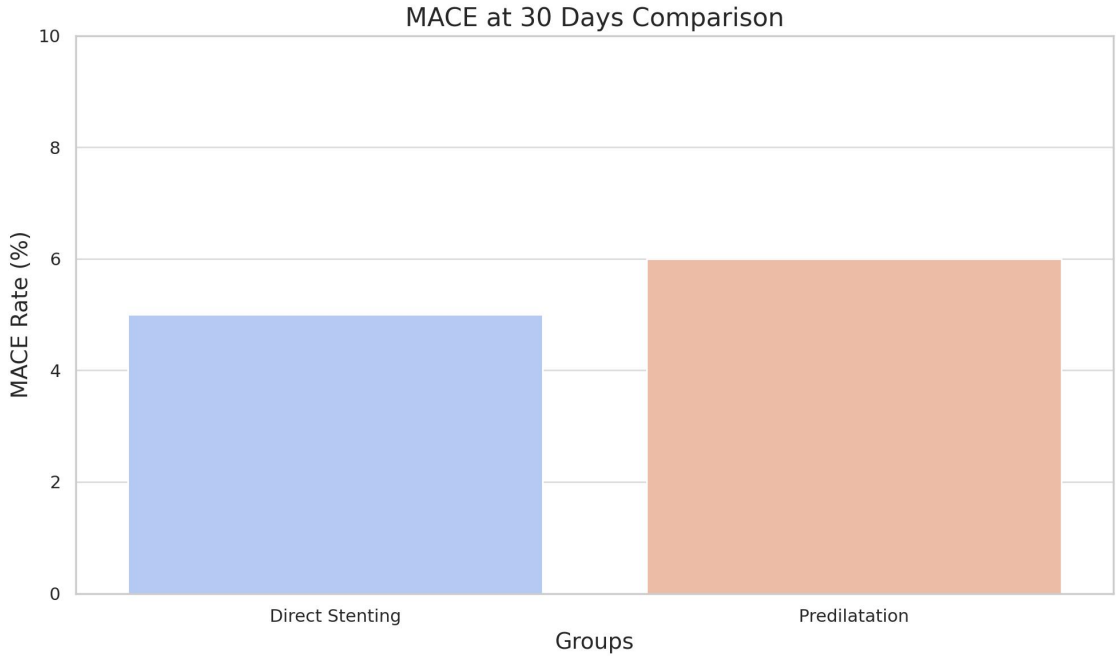
revascularization (TVR). The overall MACE rate was 5% in the Direct Stenting Group and 6% in the Predilatation Group, with no significant difference between the groups (p=0.72).

Table 3: ***MACE at 30 Days***

Outcome	Direct Stenting (n=100)	Predilatation (n=100)	p-value
Death	1 (1%)	2 (2%)	0.45
Myocardial Infarction (MI)	2 (2%)	3 (3%)	0.61
Target Vessel Revascularization (TVR)	2 (2%)	1 (1%)	0.62
Total MACE	5 (5%)	6 (6%)	0.72



At 30 days follow-up, the overall MACE rate was 5% in the Direct Stenting Group and 6% in the Predilatation Group. The individual components of MACE, including death, myocardial infarction (MI), and target vessel revascularization (TVR), were also similar between the two groups. In the Direct Stenting Group, one patient died, two had a recurrent MI, and two underwent target vessel revascularization. In the Predilatation Group, two

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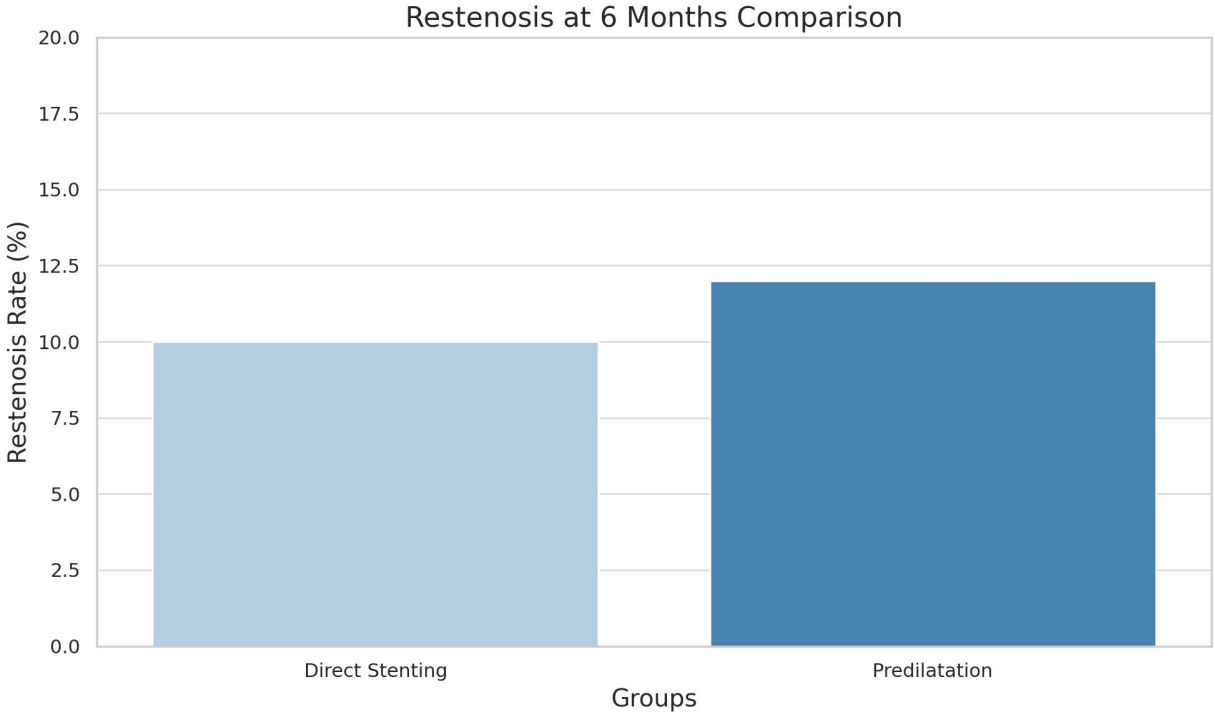
patients died, three had recurrent MI, and one patient required target vessel revascularization. These differences were not statistically significant (p-values ranging from 0.45 to 0.72).

Restenosis at 6 Months

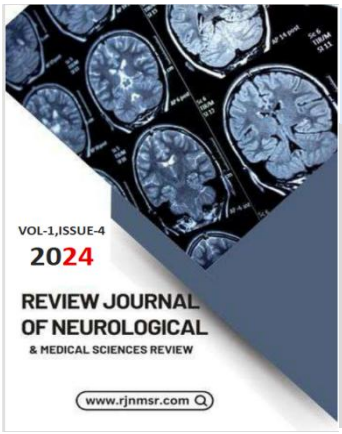
Restenosis rates at 6 months were also comparable between the two groups. As presented in Table 4, 10% of patients in the Direct Stenting Group and 12% in the Predilatation Group developed restenosis, with no statistically significant difference between the groups (p=0.62).

Table 4: Restenosis at 6 Months

Outcome	Direct Stenting (n=100)	Predilatation (n=100)	p-value
Restenosis >50%	10 (10%)	12 (12%)	0.62



The incidence of restenosis at 6 months was slightly lower in the Direct Stenting Group (10%) compared to the Predilatation Group (12%), although this difference was not statistically significant (p=0.62). Restenosis was defined as greater than 50% narrowing of the treated vessel at follow-up angiography. These findings suggest that both approaches may provide similar long-term outcomes in terms of vessel patency.



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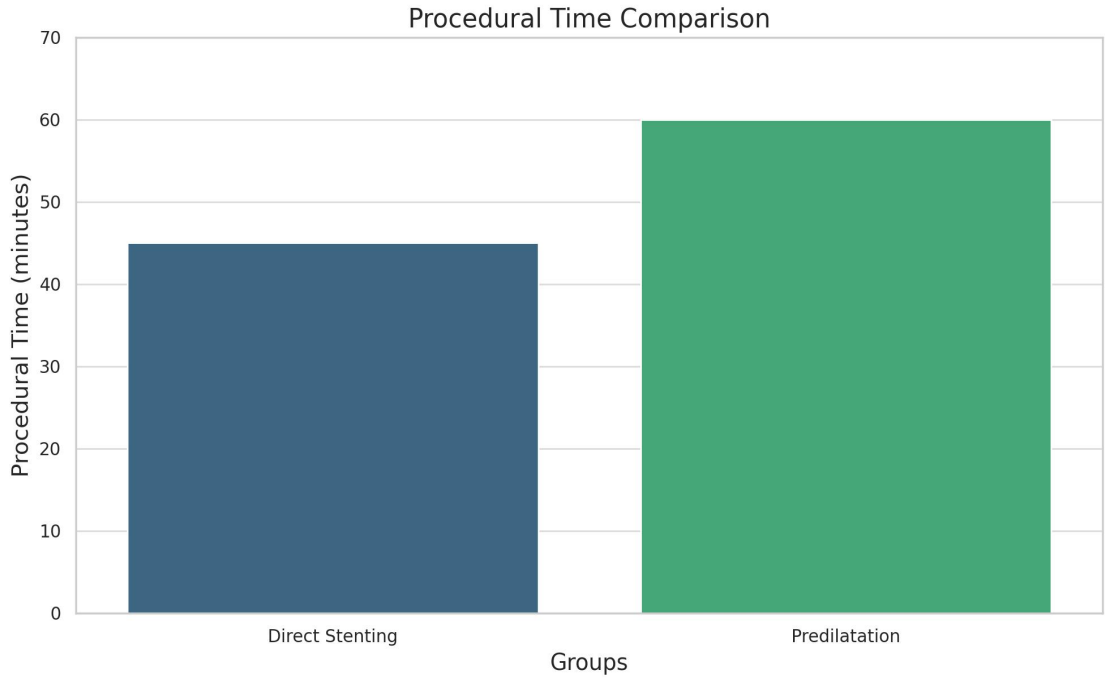
Procedural Time, Contrast Usage, and Fluoroscopy Time

Procedural efficiency, as measured by procedural time, contrast usage, and fluoroscopy time, was significantly better in the Direct Stenting Group, as shown in Table 5. The average procedural time in the Direct Stenting Group was 45 minutes, compared to 60 minutes in the Predilatation Group ($p<0.01$). Contrast usage was also lower in the Direct Stenting Group (150 mL vs. 200 mL, $p<0.01$), and fluoroscopy time was reduced (10 minutes vs. 12 minutes, $p=0.03$).

Table 5: ***Procedural Time, Contrast Usage, and Fluoroscopy Time***

Outcome	Direct Stenting (n=100)	Predilatation (n=100)	p-value
Procedural Time (minutes)	45 ± 8	60 ± 12	<0.01
Contrast Usage (mL)	150 ± 30	200 ± 40	<0.01
Fluoroscopy Time (minutes)	10 ± 3	12 ± 4	0.03



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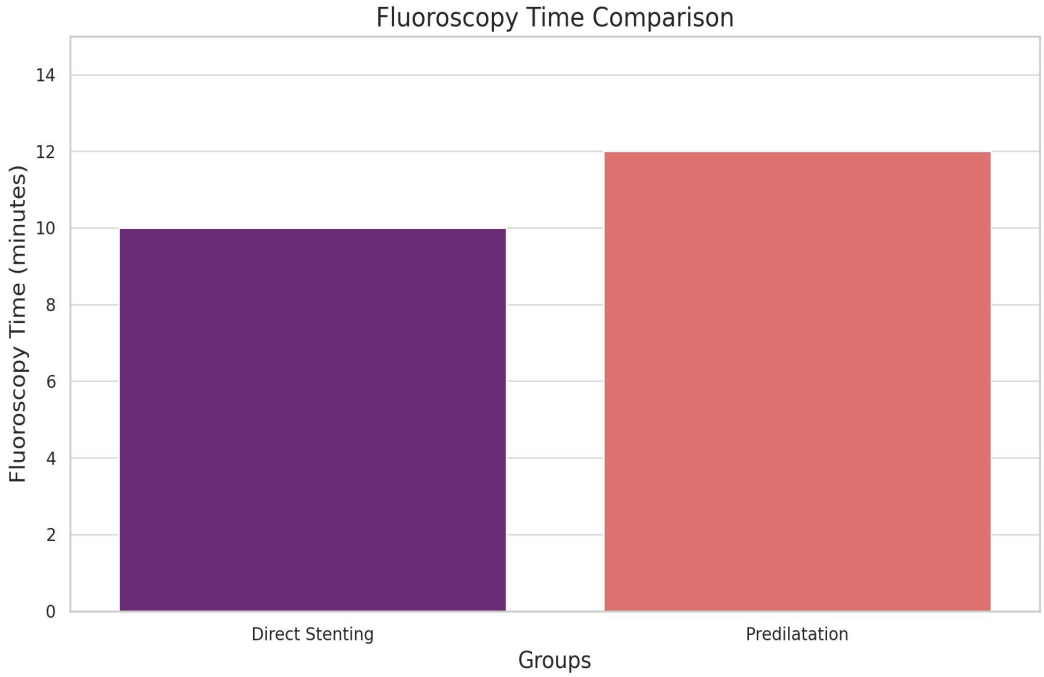

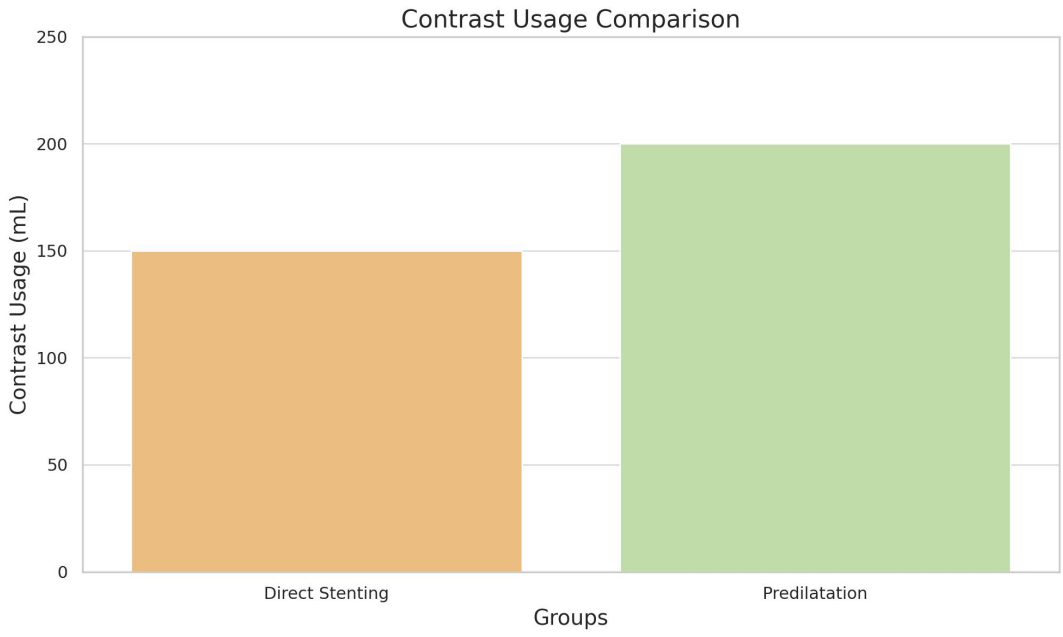

Table 5 highlights the significant differences in procedural efficiency between the two groups. The Direct Stenting Group had a significantly shorter procedural time (45 minutes vs. 60 minutes in Predilatation, $p<0.01$), which reflects a more efficient approach due to the absence of balloon dilation. Additionally, contrast usage was lower in the Direct Stenting Group (150 mL vs. 200 mL in Predilatation, $p<0.01$), suggesting that direct stenting may

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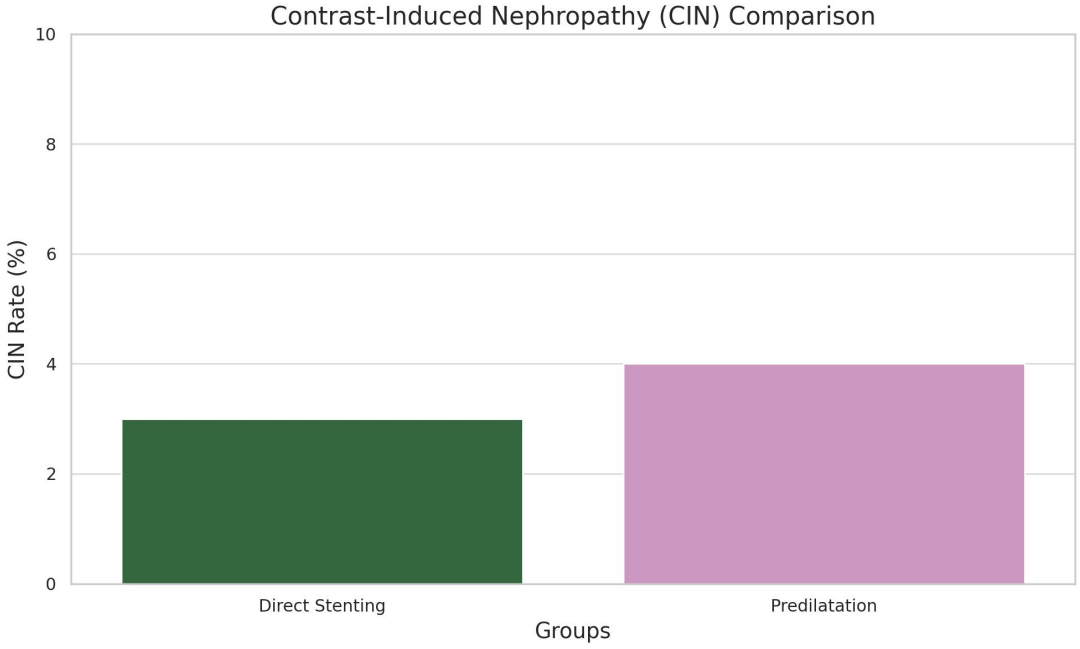
reduce the risk of contrast-induced nephropathy. Fluoroscopy time was also significantly lower in the Direct Stenting Group (10 minutes vs. 12 minutes in Predilatation, p=0.03), indicating reduced radiation exposure.

Contrast-Induced Nephropathy (CIN)

Finally, Table 6 shows the incidence of contrast-induced nephropathy (CIN) in both groups. The incidence was slightly higher in the Predilatation Group (4%) compared to the Direct Stenting Group (3%), but the difference was not statistically significant (p=0.62).

Table 6: ***Contrast-Induced Nephropathy (CIN)***

Outcome	Direct Stenting (n=100)	Predilatation (n=100)	p-value
Contrast-Induced Nephropathy (CIN)	3 (3%)	4 (4%)	0.62



However, the incidence of contrast induced nephropathy (CIN) was marginally low in Direct Stenting group (3% as compared to 4% in the Predilatation group) and was non-significant (p value=0.62). These findings therefore indicate that the two strategies are equally safe with regards to renal complications even if the contrast was used less frequently in the Direct Stenting Group.

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This study thus concludes that both direct stenting and predilatation are efficacious as far as clinical outcome including success rate, MACE, and restenosis is concerned in patients undergoing PPCI for STEMI. However, there are advantages of direct stenting in relation to simplicity of the procedure, less time taken, lowest contrast used and time taken on fluoroscopy. These outcomes indicate that direct stenting may be more advantageous for certain individuals especially those with uncomplicated coronary artery disease. But more research has to be conducted to validate these findings and also, to better define the included and excluded criteria for each technique.

Discussion

The results of this research are valuable regarding the dilemma of direct stenting compared to predilation in PPCI for subjects with acute STEMI. Both stenting strategies were nearly equal in efficacy regarding procedural success, the total rate of MACE, and restenosis at 6 months. However, there were procedural differences between the two groups; direct stenting was associated with shorter procedure and contrast time and fluoroscopy time. These findings are in line with other earlier studies, despite scholars remaining discontinuity as to whether the mode is superior to the other.

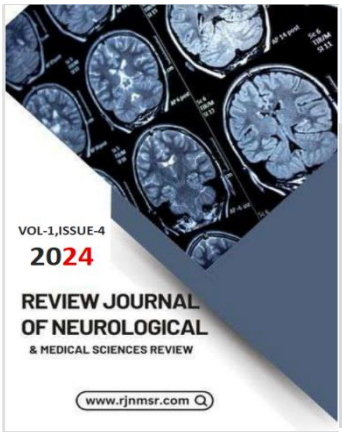
Procedural Success and Immediate Outcomes

Concerning procedural success, both studied groups achieved similar results with no statistically significant difference between direct stenting and predilatation (95% for direct stenting and 93% for predilatation). These results are consistent with other prior studies that have also reported procedural success rates to be comparable between the two approaches. An analysis of individual patient data by Jolly et al. (2009) also failed to identify a large difference between direct stenting and predilatation for procedural success in PPCI for STEMI. Iqbal et al. (2016) also showed that both the techniques were equal in providing comparable immediate effects like TIMI grade 3 flow and less than 30% of the residual stenosis.

Another measure of safety is indicated by the rare occurrence of stent thrombosis within 30 days; the rate noted in the direct stenting was 1 % while that noted in predilatation was 2%. For example, Stone et al. (2007) who in their study found that both direct stenting and predilatation are independent predictors that yield low risk of stent thrombosis, this indicates that both methods are effective in ensuring proper vessel patency. In addition, the incidences of vessel dissection and contrast-induced nephropathy were just as high in both groups, thus supporting the safety of both techniques.

Major Adverse Cardiovascular Events (MACE) at 30 Days

The 30-day Major Adverse Cardiovascular Events (MACE) were relatively comparable between both groups, where 5 percent of the direct stenting and 6 percent of the predilatation group. These findings are consistent with results from a randomized controlled trial conducted by Jolly et al. (2013) reporting that direct stenting was not associated with the increased risk of MACE as



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compared to predilatation. As expected, both groups had low rates of mortality, MI, and TVR that can be attributed to the overall safety of PPCI for STEMI (Ibanez et al., 2015).

On the other hand, Waksman et al. (2012) showed that predilatation may decrease the incidence of MACE in the lesions which are complex, and proper preparation of the lesions is highly significant. However, this study could not establish a remarkable difference between the two groups and this could be attributed to the low rate of complex lesions in this study group which included 20% of the direct stenting group and 18% of the predilatation group. In more complex lesions, there is evidence that predilatation is useful in ensuring better apposition of the stent to the arterial wall and will reduce the risk of subsequent complications involving the stent (Fujii et al., 2007).

Restenosis at 6 Months

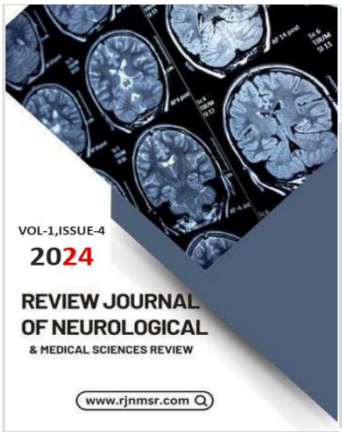
The overall restenosis rate at 6 months was not significantly different between the two groups with direct stenting scoring 10% and predilatation scoring 12%. The findings on restenosis are in line with earlier research studies including the one by Schmidt et al, (2013) who noted that there were no significant differences in restenosis between the two techniques. In addition, Jolly et al. (2009) meta-analysis established a similar rate of restenosis and rates of repeat revascularization in PPCI for STEMI with direct stenting and predilitation.

Some studies have indicated that best seen in subjects with complex coronary lesions, long-term outlook after undergoing predilatation is likely to be more favorable in terms of restenosis. For instance, one study by Raber et al. (2014) shows that in complex lesions the use of predilatation is much more effective since this technique provides improved stent expansion and 6 months restenosis rates. However, in a more simple lesion, direct stenting is equally effective or even superior to the traditional preparation as there is little trauma to the endothelium due to elimination of the use of a balloon (Stone et al., 2009). Since 80% of the study's lesions were simple, restenosis equivalency between the groups could be excerpted to the simpleness of the treated lesions.

Procedural Real-Time, Latent Contrast, and Fluoroscopic Time

The study showed the major benefits of direct stenting as the procedural time was reduced, the usage of contrast and the fluoroscopy time were less in this method. The procedural time of the direct stenting group was 45 minutes as opposed to the predilatation group, which had a procedural time of 60 minutes ($p<0.01$). The contrast usage was significantly less in the direct stenting group (150 mL vs 200 mL, $p <0.01$) and the fluoroscopy time was also lesser (10 min vs 12 min, $p = 0.03$). The findings of this study are in tandem whereby Terkelsen et al. (2010) showed that direct stenting leads to reduced procedure time and contrast usage.

The shortening of procedural time and a decrease in the amount of contrast applied while using direct stenting is more important in a high-volume



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practice or in cases when CIN is an issue. Acute kidney injury after PPCI is common and can be caused by contrast nephropathy mainly in patients with compromised baseline renal function (Lee et al., 2011). One of the advantages attributed to direct stenting is lesser use of contrast media, which may reduce the likelihood of CIN, as earlier researches have also shown (Shah et al., 2008). Also, the direct stenting group activates shorter procedural time and this could imply that the patients have less exposure to radiation as processes such as fluoroscopy time depict in this study. This is in concordance with Waksman et al. (2014) who noted that low procedural times in direct stenting lessen the overall radiation dosage to the patient.

Contrast-Induced Nephropathy (CIN)

However, in our present study, the difference in the incidence of CIN was not significantly different between the two groups with 3% in the direct stenting group and 4% in predilatation group. The results also revealed that there was no statistical difference between the two groups (p=0.62). These findings are in line with other investigations implying that the utilization of direct stenting is non-inferior to that of predilatation in terms of CIN occurrence in PPCI for STEMI (Terkelsen et al., 2010; Lee et al., 2011). Conversely, the contrast usage was significantly lower in the direct stenting group and this could be attributed to the reduced risk of CIN especially among the high risk patient population including those with impaired renal function.

Comparison with Other Studies

For that reason, the outcomes of the current investigation keep pace with several other investigations that have compared direct stenting and predilatation in PPCI. A comparison between direct stenting and predilatation was made to determine their effectiveness with respect to procedural success and MACE; the study outlined by Jolly et al. (2009) showed that both techniques are almost equally effective, with direct stenting however having benefits of least use of contrast agents and shorter procedure time. Likewise, another study carried by Iqbal et al. (2016) indicated that there were no significant differences in restenosis and repeat revascularization between the two techniques but proved that direct stenting was more efficient and complications associated with contrast and balloon were minimized.

But, it must be noted that there is evidence that predilatation can be beneficial in special cases with complicated lesions. For instance, Raber et al. (2014) established that predilatation was beneficial in terms of the stent expansion and rate of adverse effects in complex lesions including those with significant calcification and bifurcation. This indicates that, although direct stenting is effective in basic stenoses, predilatation remains relevant to enhance the long-term results in complicated lesions.

Limitations of the Study

Hence, there are various limitations associated with this study as highlighted below. First, the study was cross-sectional where patients were not randomized into the two groups because this was done based on an

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independent clinical decision. This may be another source of bias – selection bias particularly in regard to the technique in managing more complex lesions. Second, the study enrolled only patients with single-vessel coronary disease which restricts the generalization of the results obtained to patients with multivessel or other types of CAD. Moreover, although restenosis rate was evaluated up to 6-months after the intervention, other factors including survival and quality of life were not investigated in this study. Further large scale randomized studies with longer follow up and on patients presenting different characteristics could provide better understanding of better elective stenting versus predilation strategies.

Conclusion

In conclusion, this study shows that direct stenting as well as predilatation in PPCI for STEMI offer similar results regarding procedural success, MACE incidence, and restenosis rates. Despite this, direct stenting has been seen to have benefits in procedural effectiveness including reduced procedure time, total contrast media and fluoroscopy time. These results indicate that direct stenting can be a better strategy in certain patient populations such as those who have simple coronary diseases. However, more trials are required to define the specific inclusion and exclusion criteria for the delayed invasive strategy and to analyze the outcomes of both strategies at the long term, particularly in the different subgroups of STEMI patients.

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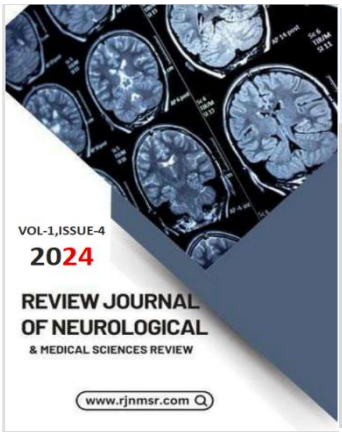

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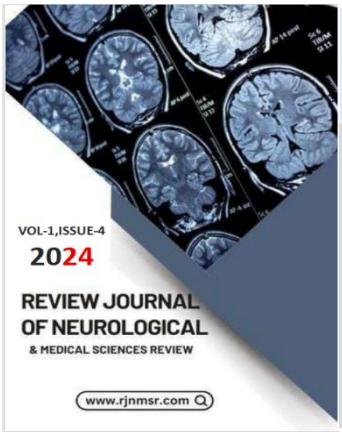

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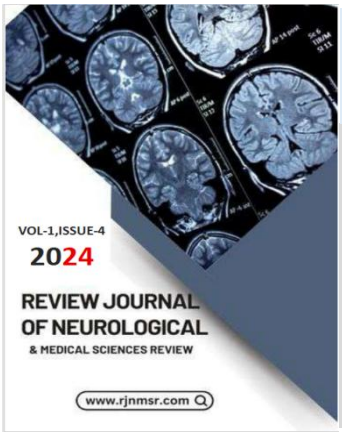

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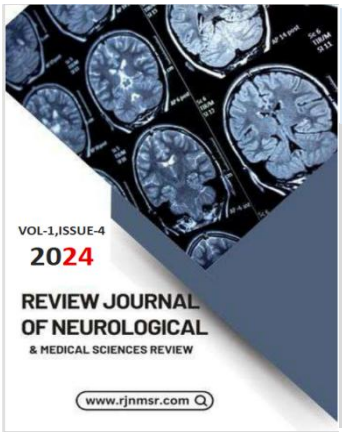

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