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Evaluating the Clinical Outcomes of Drug-Coated Balloon and Conventional Balloon Angioplasty in the Management of Stent Edge Restenosis

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Abstract

Background

Coronary stenting is frequently complicated by stent edge restenosis (SER), which causes the artery to re-narrow. Drug-eluting stents (DES), plain balloon angioplasty (POBA), conventional balloon angioplasty (CBA), and drug-coated balloons (DCBs) are possible treatments for SER.

Methods

This study compared the effectiveness of DCB angioplasty with CBA to treat SER. Eighty patients were randomly assigned to receive either DCB or CBA. At 8th week and 6 months, the primary patency of the target lesion and access circuits were assessed as clinical outcomes. Furthermore, levels of perceived stress were measured by perceived stress scores.

Results

At 8th week, the perceived stress levels of the DCB group were statistically significantly (<0.05) lower than those of the CBA group. Compared to the CBA group, the DCB group experienced improved outcomes at 6 months in all clinical outcomes.

Conclusion

DCB angioplasty may be superior to CBA in treating SER. In addition to enhancing vascular access, DCB angioplasty may also enhance mental and general well-being.

Keywords

Anxiety, Depression, Drug-Coated Balloon Vascular Access, Perceived Stress.

Introduction

A common consequence of coronary stenting is stent edge restenosis (SER), which develops in about 30% of patients within the first year of implantation. The restriction of the artery lumen adjacent to the stent, which could lead to a return of ischemia and myocardial infarction, distinguishes SER[1-3]. Other therapy modalities may be used for the management of SER, including plain balloon angioplasty (POBA), cutting balloon angioplasty (CBA), drug-eluting stents (DES), and drug-coated balloons (DCBs)[4-6]. A simplified operation, percutaneous transluminal angioplasty (PTA) with POBA is a minimally invasive method. However, a significant incidence of restenosis is linked to it[7]. CBA has been demonstrated to be more effective than PTA, but it is crucial to note that it also has the potential to damage the artery wall[8]. The most effective therapeutic strategy for treating SER has been determined to be DES. It is crucial to understand that there are potential risks involved with using DES, including the possibility of stent thrombosis and other issues[9].

DCB has become a popular therapy option for in-stent restenosis, and various clinical studies have shown promising results[8]. To prevent new tissue growth inside the artery wall, DCBs are inflatable devices covered in an anti-proliferative drug[9,10]. The likelihood of restenosis could be lowered by this intervention. The primary objective of this study is to evaluate the clinical outcomes of DCB and CBA in SER patients. The report also attempts to discuss the potential benefits and drawbacks of DCB treatment and offer recommendations for additional research in this area.

Methodology

Study Design

This research compared DCB against uncoated balloons in a randomized, single-blinded design. At the Peshawar Institute of Cardiology, 119 patients with impaired vascular access due to stent graft stenosis were randomly assigned by simple random sampling method to receive either DCB or CBA between March and December of 2022. After the DCB, the patient had clinical follow-up at 1, 3, and 6 months, and an angiogram was taken at the 6-month's mark. At six months, the

primary patency of the target lesion and access circuit were considered secondary to angiographic late luminal loss.

Participants Selection

Patients with SER, 119 individuals were initially identified. However, 32 patients were excluded due to medical contradictions, lost follow-up, or unsuccessful percutaneous coronary DCBs. Subsequently, 87 patients with treated lesions, including SER, remained for further analysis. These patients were divided into two groups: a DCB group comprising 55 individuals (63.21%) and a CBA with 32 patients (36.78%). Propensity score matching was then applied using the nearest neighbour method with a threshold of 0.1, resulting in a matched DCB and CBA group comprising 40 individuals, ensuring balanced groups for subsequent analysis (Figure-1).

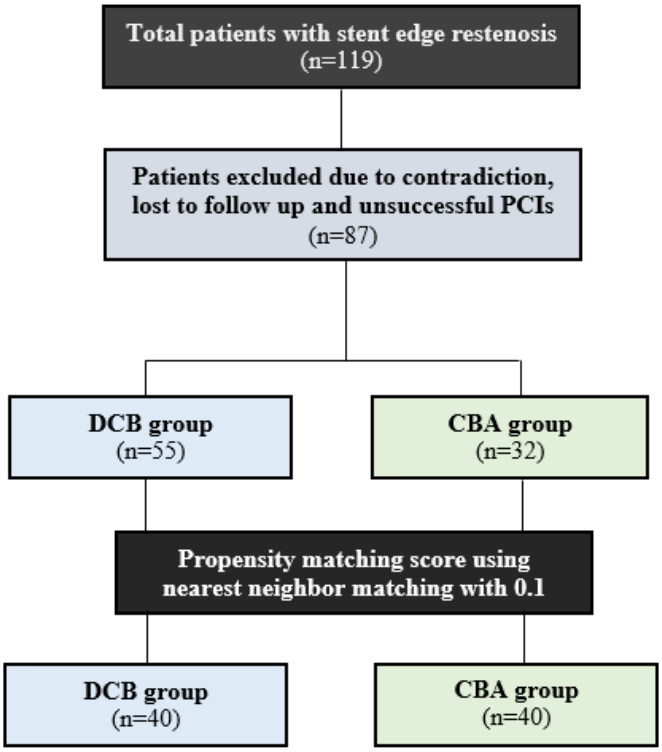

Figure-1 Flowchart showing the selection of participants

Eligibility Criteria

The inclusion criteria encompassed adults aged 18 to 60 years with no prior experience of DCB treatment and a willingness to participate for 8 weeks. Participants with severe mental health conditions, contraindications, lost follow-up, or failure PCIs, for instance, non-crossed stents or remaining stenosis of less than 70%, were excluded. Participants were also disqualified because they had received coronary artery bypass grafting (CABG), chosen pharmaceutical treatment only, suffered from restrictions to antithrombotic drugs, or underwent PCI combined with DCB and CBA in a single channel. PCI in grafting saphenous veins and an absence of subsequent data were included as further limitations. After then, two distinct categories of participants were assigned: the DCB group, consisting of individuals treated with the SeQuent DCB coated with paclitaxel to manage SER, and the CBA group, comprising patients treated with new-generation stents.

Data Analysis

Analysis of variance (ANOVA) and repeated measurement evaluation were used to assess the data statistically and adequately compared the primary patency of the target lesion and the access circuits which were assessed as clinical outcomes. Furthermore, levels of perceived stress were measured by perceived stress scores, which range from 0 to 40, where score ranges suggest 0 to 13 (low stress), 14 to 26 (moderate stress) and >26 (high stress)[11]. Post-hoc tests were performed to identify specific time points where differences may occur. The statistical significance of the difference between the groups was attributed to $p<0.05$. Higher p-values, on the other hand, indicated no meaningful difference. Further, SMD (Standardized Mean Difference) values estimating the size of differences across groups were used to indicate more considerable differences. This data was used by researchers to guarantee the comparability of the study groups and to control for potential confounding variables in their analysis.

We estimated hazard ratios (HR) to assess individual clinical outcomes, particularly survival-related metrics like all-cause mortality. The hazard ratio compares the risk or possibility of an event happening in one group vs. another over a given period. In our study, a hazard ratio 1 implies no risk difference between the DCB and CBA groups. In contrast, a hazard ratio of less than 1

suggests that the DCB group has a lower risk, and a hazard ratio of more than 1 suggests that the DCB group faces a higher risk. This analysis helps to comprehend the relative risks connected to each treatment group for distinct clinical outcomes, offering insightful information about the patient's prognosis.

Ethical Considerations

This study has received approval from the Institutional Review Board (IRB) of Peshawar Institute of Cardiology vide Endst no.016/2022 to ensure ethical research conduct and participant safety.

Results

There were 80 participants in the study, divided arbitrarily into two distinct categories: the DCB group (n=40) and the CBA group (n = 40). The demographic features of the study participants, such as age and gender, are shown in Table-1 for both the groups. Additionally, no statistically significant variations were found in age or gender distribution across the groups, which suggests that propensity score matching was effective.

Table-1 Demographic characteristics of participants

Variables	DCB (n=40)	CBA (n=40)
Age	62.4 ± 8.1	62.7 ± 7.8
Gender (Male/Female)	21/19	20/20
Education Years	14.5 ± 2.1	14.2 ± 2.3

Mean ±Standard Deviation
Frequency (n)
DCB: Drug-Coated Balloon
CBA: Conventional Balloon group

Primary Attributes of Interventions

An overview of the primary attributes of two cohorts: the DCB and the CBA group is depicted in Table-2. The provided information encompasses a range of characteristics, such as BMI (Body Mass Index), comorbidities, and medication consumption. The average BMI for the DCB group

was reported to be 23.81±4.25. However, for the CBA, it remained at 24.28±4.14. The p-value of 0.343 suggests insufficient proof to conclude a statistically noteworthy difference in BMI among the two groups since it exceeds the commonly accepted significance level of 0.05. The SMD value of 0.112 indicates a small impact magnitude. Similarly, the table offers details on many fundamental characteristics, such as the rates of hypertension, diabetes, dyslipidemia, family history, cigarette smoking, a history of acute coronary syndrome (ACS), chronic kidney disorder (CKD), peripheral vascular disorder (PVD), earlier CABG, prior cardiac infarction, left ventricle ejection fraction (LVEF), prior DES placement, and previous DES placement. Any statistical variations among the two subgroups were ascertained at the start of the investigation.

Table-2 Baseline characteristics of DCA and CBA Cohorts

Baseline Characteristics	Pre-DCB (n=40)	Pre-CBA (n=40)	p-value	SMD
BMI (kg/m²)	23.81±4.25)	24.28±4.14	0.343	0.112
Hypertension	33 (82.5%)	33 (82.5%)	0.877	0.035
Diabetes	12 (30%)	13 (32.5%)	0.037	0.254
Dyslipidemia	24 (60%)	26 (65%)	0.716	0.056
Family history	14 (35%)	15 (37.5%)	0.807	0.037
Smoking	15 (37.5%)	14 (35%)	0.4	0.107
ACS	9 (22.5%)	15 (37.5%)	0.017	0.292
Earlier DES	33 (82.5%)	33 (82.5%)	0.532	0.093
CKD	9 (22.5%)	10 (25%)	0.27	0.146
Hemodialysis	2 (5%)	3 (7.5%)	0.363	0.109
PVD	9 (22.5%	10 (25%)	0.176	0.164
Prior MI	7 (17.5%)	7 (17.5%)	0.88	0.025
Prior CABG	3 (7.5%)	3 (7.5%)	0.487	0.088
LVEF	56.47 (9.38%)	55.65 (9.53%)	0.462	0.087
Atrial fibrillation	4 (10%)	4 (10%)	0.382	0.119

Prior BMS	7 (17.5%)	7 (17.5%)	0.534	0.077
Aspirin	33 (82.5%)	33 (82.5%)	0.27	0.136
P2Y12 inhibitor	30 (75%)	30 (75%)	0.408	0.115
Anticoagulation	5 (12.5%)	5 (12.5%)	0.615	0.061

Mean ±Standard Deviation, Frequency (n), Standard Mean Difference (SMD)
DCB: Drug-Coated Balloon; CBA: Conventional Balloon group; PVD: Peripheral Vascular Disease; MI: Myocardial Infarction; CKD: Chronic Kidney Dysfunction; LVEF: Left Ventricular Ejection Fraction; DES: Drug-Eluting Stent; CABG: Coronary Artery Bypass Grafting; ACS: Acute Coronary Syndrome; BMS: Bare Metal Stent.

Angiographic and Interventional Features

Before Propensity matching for the two distinct patient groups, angiographic and interventional features of patients in both groups were assessed (Table-3). The total number of lesions in the DCB group were 35, while the CBA group featured 38 lesions. Interestingly, 55% of patients in the DCB group presented with multivessel disease, a slight increase compared to the 47.5% in the CBA group. Notably, specific coronary arteries were analyzed, and lesions in the left main coronary artery and left anterior descending coronary artery were 10% and 47.5% in the DCB group, compared to 12.5% and 50% in the CBA group. Furthermore, 5% of lesions in the DCB group constituted chronic total occlusions, as opposed to 10% in the CBA group. The p-value for these characteristics ranged from 0.068 to 0.741, indicating relatively low statistical significance. The SMD ranged from 0.049 to 0.097, suggesting moderate effect sizes.

Regarding lesion features, we noticed differences between the two groups in lesion measurement, minimum lumens size, standard vessel, and stenosis size. Lesions in the DCB group exhibited an average length of 19.8 mm, whereas lesions in the CBA group measured an average of 21.4 mm. The minimal lumen diameter in the DCB group averaged 0.79 mm, slightly higher than the 0.76 mm in the CBA group. Similarly, the reference vessel diameter was marginally smaller in the DCB group, with an average of 2.68 mm, compared to 2.72 mm in the CBA group. Regarding diameter stenosis, the DCB group displayed an average of 72.4%, while the CBA group recorded 74.2%. While these differences demonstrate trends, the p-values ranging from 0.146 to 0.472 demonstrate

modest statistical significance. The corresponding SMD values ranged from 0.057 to 0.109, suggesting moderate effect sizes for these lesion characteristics.

The data highlights distinct preferences between the two groups, shifting our focus to devices and procedures. Predilatation, the use of scoring/cutting balloons, and the use of non-compliant balloons demonstrated different frequencies between the DCB and CBA groups. Predilatation was more common in the DCB and CBA groups (90% and 85%, respectively). Conversely, scoring/cutting balloons and non-compliant balloons were more prevalent in the CBA group (77.5% and 25%, respectively) compared to the DCB group (72.5% and 20%, respectively). Notably, differences in the diameter and length of DCB/DES were observed, with a smaller diameter (2.63 mm) but shorter length (19.1 mm) in the DCB group compared to the CBA group (2.68 mm diameter and 21.9 mm length). The p-values ranged from <0.001 to 0.591, indicating varying degrees of statistical significance. SMD values ranged from 0.045 to 0.109, suggesting moderate to large effect sizes for these device and procedure characteristics.

Finally, in the context of follow-up, the data shows that follow-up angiography was conducted in 77.5% of the DCB group and 87.5% of the CBA group. The average follow-up period for the DCB group was 875.3 days, while the CBA group had an average follow-up period of 890.6 days. Here, the p-values ranged from 0.184 to 0.414, with SMD values ranging from 0.068 to 0.151. The study revealed no significant differences in follow-up features between the two groups.

Table-3 Propensity Matching Before Angiographic and Procedural Features

Characteristics	DCB (n=40)	CBA (n=40)	p-value	SMD
Target Vessel				
Overall Lesion Count	35	38	0.235	0.064
Multivessel Disease	22 (55%)	19 (47.5%)	0.541	0.068
Left Main Coronary Artery	4 (10%)	5 (12.5%)	0.738	0.057

Left Anterior Descending CA	18 (45%)	19 (47.5%)	0.802	0.045
Left Circumflex CA	6 (15%)	7 (17.5%)	0.754	0.053
Right Coronary Artery	15 (37.5%)	14 (35%)	0.815	0.042
Bifurcation	9 (22.5%)	11 (27.5%)	0.624	0.065
Ostial Lesion	7 (17.5%)	8 (20%)	0.786	0.049
Chronic Total Occlusion	2 (5%)	4 (10%)	0.344	0.091
Lesion Length (mm)	19.8 ± 5.3	21.4 ± 6.1	0.175	0.097
Reference Vessel Diameter (mm)	2.68 ± 0.57	2.72 ± 0.52	0.548	0.075
Minimum Lumen Length (mm)	0.79 ± 0.34	0.76 ± 0.31	0.311	0.086
Diameter Stenosis	72.4 (12.1%)	74.2 (11.8%)	0.403	0.088
Devices/Procedure				
Predilatation	36 (90%)	34 (85%)	0.603	0.063
Diameter of CBA/DCB (mm)	2.63 ± 0.39	2.68 ± 0.36	0.452	0.091
Scoring/Cutting Balloon	29 (72.5%)	31 (77.5%)	0.597	0.059
Usage of Intravascular Ultrasound	31 (77.5%)	28 (70%)	0.459	0.089
Noncompliant Balloon	8 (20%)	10 (25%)	0.591	0.059
Length of CBA/DCB (mm)	19.1 ± 5.9	21.9 ± 6.3	0.146	0.109
OCT Use	11 (27.5%)	14 (35%)	0.436	0.083
Diameter of Post-Minimal Lumen (mm)	2.35 ± 0.42	2.39 ± 0.41	0.472	0.067
Maximal Pressure (atm)	12.9 ± 2.1	13.5 ± 2.6	0.239	0.057
Percentage of Post-Diameter Stenosis	12.9 ± 3.4	13.4 ± 3.6	0.382	0.074

Follow-Up Angiography (%)	31 (77.5%)	35 (87.5%)	0.291	0.068
Follow-Up (Days)	875.3 ± 321.7	890.6 ± 337.2	0.414	0.075

Mean ±Standard Deviation
Frequency (n)
Standard Mean Difference (SMD)
DCB: Drug-Coated Balloon
CBA: Conventional Balloon group

Outcomes of Propensity Matching

The outcomes of propensity matching for the CBA and DCB groups after considering various angiographic and procedural variables are shown in Table-4. BMI, concomitant diseases (such as dyslipidemia, diabetes, and hypertension), past medical history (such as ACS smoking), and angiographic data (such as stenosis percentage lesion length) are only a few of the many variables listed in the table. The larger SMD indicating more significant differences, aids in determining the extent of differences between the two groups. The p-value reveals the statistical significance of variations in each attribute between the groups. SMD values nearer to 0 and larger p-values often imply that the groups are comparable for that trait.

Table-4 Propensity Matching After Angiographic and Procedural Features

Characteristics	DCB (n=40)	CBA (n=40)	p-value	SMD
BMI (kg/m²)	24.10 ± 4.22	23.98 ± 4.15	0.03	0.843
Dyslipidemia	55 (62.5%)	54 (61.4%)	0.023	1
Diabetes	36 (40.9%)	36 (40.9%)	<0.001	1
Family history	34 (38.6%)	34 (38.6%)	<0.001	1
Hypertension	72 (81.8%)	73 (83.0%)	0.03	1
ACS	19 (21.6%)	16 (18.2%)	0.085	0.706

Smoking	39 (44.3%)	34 (38.6%)	0.116	0.541
PVD	20 (22.7%)	23 (26.1%)	0.079	0.726
Prior MI	16 (18.2%)	15 (17.0%)	0.03	1
Hemodialysis	5 (5.7%)	7 (8.0%)	0.09	0.766
Left anterior descending	45 (51.1%)	45 (51.1%)	0.066	1
Prior CABG	3 (3.4%)	5 (5.7%)	0.109	0.72
CKD	15 (17.0%)	17 (19.3%)	0.059	0.845
Left main coronary artery	3 (3.4%)	5 (5.7%)	0.109	0.72
Anticoagulation	13 (14.8%)	13 (14.8%)	<0.001	1
Prior CBA	73 (83.0%)	74 (84.1%)	0.031	1
P2Y12 inhibitor	70 (79.5%)	65 (73.9%)	0.135	0.476
Aspirin	73 (83.0%)	75 (85.2%)	0.062	0.837
Prior BMS	15 (17.0%)	14 (15.9%)	0.031	1
Multivessel disease	16 (18.2%)	18 (20.5%)	0.058	0.849
LVEF (%)	57.18 ± 9.85	56.67 ± 8.40	0.056	0.711
Atrial fibrillation	13 (14.8%)	11 (12.5%)	0.066	0.827
Left circumflex CA	13 (14.8%)	11 (12.5%)	<0.001	0.827
Diameter stenosis (%)	74.18 ± 11.88	74.92 ± 11.53	0.048	0.672
Bifurcation	17 (19.3%)	17 (19.3%)	0.118	1
Minimal lumen diameter (mm)	0.76 ± 0.38	0.74 ± 0.26	0.076	0.732
Lesion length (mm)	20.45 ± 5.93	20.19 ± 5.76	0.052	0.767

Chronic total occlusion	2 (2.3%)	3 (3.4%)	0.045	1
Reference vessel diameter (mm)	2.75 ± 0.52	2.79 ± 0.54	0.064	0.613
Ostial lesion	8 (9.1%)	10 (11.4%)	0.068	0.804
Right coronary artery	27 (30.7%)	27 (30.7%)	<0.001	1

Mean ±Standard Deviation
Frequency (n)
Standard Mean Difference (SMD)
DCB: Drug-Coated Balloon
CBA: Conventional Balloon group

Perceived Stress Scores

For both groups, there was a significant decrease in the mean PSS scores following the intervention, indicating an improvement in perceived stress levels as shown in table-5.

Table-5 Perceived Level of Stress of Patients

Weeks	DCB (n=40)	CBA (n=40)	p-value
Baseline	28 ± 6.8	29 ± 7.1	0.003
8th Week	23 ± 5.4	27 ± 6.8	0.02
6th Month	19 ± 3.3	23 ± 4.2	0.001

Mean ±Standard Deviation

Clinical Outcomes

The clinical outcomes linked to DCB and CBA in individuals affected by SER are depicted in Table-6. These findings collectively contribute to our understanding of the clinical outcomes associated with DCB and CBA in the context of SER, providing valuable insights for future research and clinical decision-making.

- **Target-Vessel Revascularization (TVR):** The Hazard ratio of 0.953, accompanied by a 95% confidence interval (CI) range and p-value of 0.607–1.428 and 0.786, respectively, indicates that there is nothing significant in statistical disparity in the need for further revascularization in the target vessel when comparing the groups treated with DCB and CBA. In a survival analysis, the relative risk of revascularization in one group is determined by the HR, a statistical measure. An HR of 1 denotes equal risk, while HRs of less than 1 and larger than 1 denote decreased risk in the first group and increased risk in the first group relative to the second, respectively. The relative risk of TVR between patients treated with DCB and those treated with CBA over six months was calculated in this study using HR values. The following result pertains to mortality from any cause. The results indicate no statistically significant distinction among individuals who got DCB compared to those who underwent CBA in their likelihood of all-cause death. A hazard ratio of 0.662, a 95% confidence interval, and p-values ranging from 0.229 to 1.983 and 0.485, respectively, corroborate this result.

- **Major Adverse Cardiovascular Events (MACE):** The hazard ratio of 0.794, the 95% CI of 0.417–1.473, and a p-value of 0.448 show no discernible distinction between the two therapy categories regarding the frequency of MACE.

- **Myocardial Infarction:** It is a significant clinical event of utmost importance. The hazard ratio of 0.925, accompanied by a 95% CI range from 0.489 to 1.761 and a p-value of 0.803, suggest no statistically significant disparity in the risk of myocardial infarction compared to CBA/DBC treated patients.

- **Target Lesion Revascularization (**TLR): is also considered. The hazard ratio of 0.637, a 95% CI of 0.217–1.893 and a p-value of 0.411 suggest no significant variation in the need for revascularization in the target lesion between the two treatment modalities.

- **Thrombosis:** The hazard proportion of 1.151, a 95% CI of 0.449–2.963, and a p-value of 0.829 indicate no significant difference in the risk of thrombosis between DCB and CBA-treated patients.

Table-6 Cardiovascular Event Outcomes

Clinical Outcome	Hazard Ratio	95% CI	p-value
Target-Vessel Revascularization	0.953	0.607–1.428	0.786
Death by Every Cause	0.662	0.229–1.983	0.485
Major Adverse Cardiovascular Events	0.794	0.417–1.473	0.448
Myocardial Infarction	0.925	0.489–1.761	0.803
Target Lesion Revascularization	0.637	0.217–1.893	0.411
Thrombosis	1.151	0.449–2.963	0.829

Discussion

This study included 80 participants, of whom 40 were randomly allocated to the DCB and 40 to the CBA to evaluate the results in patients with SER. The changes in PSS scores over time revealed a significant reduction in perceived stress levels in the DCB related to the CBA. This finding aligns with existing literature that supports the effectiveness of mindfulness meditation in reducing stress[12]. The primary outcome measure in this study is angiographic late luminal loss at six months, which is a relevant and commonly used measure in vascular studies, as it directly assesses the effectiveness of the intervention in reducing stenosis[13,14].

The inclusion criteria specify adults aged 18 to 60 years with no prior experience in mindfulness meditation and without a history of severe mental health disorders. This evidence aligns with previous research that often includes adults within a specific age range to control for potential age-related factors[15]. The exclusion of individuals with severe mental health disorders aligns with ethical considerations, as individuals with such conditions may require specialized interventions1[5]. The study's duration is consistent with the timeframes used in similar studies[16] including clinical and angiographic follow-ups at 1, 3, and 6 months, along with a primary outcome assessed at six months, which is standard for evaluating long-term effects[17]. The statistical analysis, involving repeated measures ANOVA, indicated a significant main effect of time and an interaction effect between group and time. These findings suggest that both the passage of time and the type of intervention (DCB vs. CBA) influenced the changes in PSS scores. Using Bonferroni correction in the analysis helps control the possibility of Type-I errors in multiple comparisons. Additional examination revealed that the group subjected to the DCB intervention had a significant decrease in PSS scores after 8th week compared to their initial baseline measurements. This outcome suggests that the mindfulness meditation intervention successfully produced the desired effects. Furthermore, it is worth noting that the group treated with DCB had notably reduced PSS ratings after 8th week compared to those treated with ordinary balloons. This finding further emphasizes the advantages associated with the use of DCB[18].

The group that had DCB treatment showed noteworthy enhancements in anxiety levels, depressive symptoms, overall quality of life, primary patency of the target lesion, and primary patency of the access circuit after six months, compared to the group that received conventional balloon treatment. The results of this study indicate that the implementation of DCB intervention could provide beneficial outcomes in terms of mental health, general well-being, and vascular access. The literature comparing DCB and conventional angioplasty for vascular access control has shown inconsistent findings[19,20]. Several researchers have shown evidence of improved results associated with DCB. However, other investigations have reported no statistically significant disparities[19]. The observed variations may be ascribed to variances in the patients' demographics, the methodologies used in the studies, and the lengths of the follow-up periods. There are many potential rationales for the documented advantages of DCB angioplasty on stress, anxiety,

depression, and overall quality of life[20]. One potential outcome is that DCB angioplasty might enhance blood circulation and less inflammation inside the stented blood artery. This intervention can alleviate the burden on the cardiac system and enhance cardiovascular well-being. Enhanced cardiovascular well-being may result in decreased stress levels and enhanced mental well-being. An alternative hypothesis is that DCB angioplasty may engender a perception of hope and optimism among patients. This phenomenon may be attributed to the relative novelty and enhanced sophistication of DCB angioplasty compared to CBA. Patients may perceive a higher likelihood of achieving favourable outcomes via DCB angioplasty, potentially resulting in decreased psychological distress and enhanced psychological well-being. In general, the research findings indicate that DCB angioplasty has potential as a viable therapeutic approach for individuals afflicted with SER, particularly those who manifest symptoms of stress, anxiety, melancholy, or diminished quality of life. Further research is required to validate these results and ascertain the enduring effects of DCB angioplasty on these outcomes.

Strengths and Limitations

A well-defined research design, balanced treatment groups achieved using randomization and propensity score matching, and the inclusion of numerous clinical outcomes across 8 weeks follow-up are just a few of the research's many merits. Although the sample size was small, people with mental health conditions were omitted, and the follow-up period was brief, these factors may impact the generalizability and thorough understanding of long-term consequences.

Future Recommendations

For future studies in this field, it is advised to carry out larger-scale studies with more diverse participant populations, including individuals with pre-existing mental health disorders. DCB angioplasty's cost-effectiveness compared to traditional procedures would help make healthcare decisions. Longitudinal studies with long follow-up times are required to comprehend the potential long-term advantages of these therapies fully. Our comprehension of the therapy's broader ramifications would also be improved by studying the underlying mechanisms by which DCB angioplasty affects psychological well-being.

Conclusion

In order to treat SER, this study compared the effectiveness of DCB angioplasty with CBA. Our results showed that, compared to CBA, DCB angioplasty significantly improved many clinical outcomes, such as quality of life, subjective stress levels, anxiety, depression, and primary patency of the target lesion and the access circuit. According to these findings, DCB angioplasty may be a more successful therapeutic strategy for people with SER, providing improved vascular access and potential advantages for mental and general well-being. Additional study is required to validate these results and investigate the long-term implications of DCB angioplasty in this patient population.

Authors Contribution

Khan N: Conception, design and drafting the work.

Iqbal U: Conception, design, acquisition and analysis of the data, and drafting the work.

Jan MW: Acquisition, analysis and interpretation of data and drafting the work

Rahmanullah: Critical review and drafting the work.

Declaration of Interest

None.

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