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ORIGINAL ARTICLE

Drug Coated Balloon only Angioplasty Outcomes in Non-diabetic and Diabetic Patients with De Novo Small Coronary Vessels Disease

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ABSTRACT

Background: Small artery coronary disease is a known predictor of terrible outcomes after PCI, and it is quite challenging to identify the best course of action for treating coronary disease in small vessels.

Objective: The aim of this study was to explore the Drug-Coated Balloon-Only Angioplasty Outcomes in Non-diabetic and Diabetic patients with De Novo Small Coronary Vessels Disease.

Methodology: This correctional multi-centre study was carried out at the Cardiology Department BMCH Quetta and Cardiology department Al Qasimi hospital Sharjah, UAE from January, 2023-June, 2023 after taking permission from the ethical board of the institute. Over all 1200 participants with vascular disorder cured with Drug-Coated Balloon -Test method were examined. Angiographic and clinical follow-up were scheduled for 12 months. The key outcomes were non-primary large detrimental cardiac activities and target lesion failure. Both the 2-tailed Fisher's actual test and chi-squared test were used to assess express variables, and the unbiased samples t-test (also known as the "Student's t-test") was used to assess non-stop variables. When the bilateral P is less than 0.05, it is deemed statistically significant.

Results: A total of 1200 participants were enrolled in this study out of which 832(69.33%) were male and 368(30.6%) were female. 431(35.9%) were diabetes and 769 (64.0%) were non diabetic. A total of 1352 lesions were treated; 484 were identified within the diabetes treatment group and 869 among the non-diabetic group. In the diabetes and non-diabetic groups, standard artery thickness was comparable (P value 0.366); however, the operating voltage inflation level and period were also comparable (P value 0.416 and 0.474, correspondingly).There have been notable differences in TLF incidence costs between companies, with a higher incidence among the diabetic population (P value0.006). There have been no statistically significant variations of the MACE comparing many of the two firms (P value 0.120).

Conclusion: Our study concluded that the drug-covered balloon alone decreased the incidence of target lesion failure and significant detrimental cardiac events in patients with de novo small coronary artery disease.

Keywords: Drug-Coated Balloon; Angioplasty; Non-diabetic; Diabetic; Coronary Vessels Disease.

INTRODUCTION

Small artery coronary disease is a known predictor of undesirable outcomes after PCI, and it affects 30-50% of all-comers coronary intervention procedures performed annually [1–4].It is quite challenging to identify the best course of action for treating coronary disease in small vessels [5]. One of the main drawbacks of DES treatment in individuals with small vessel disease is late lumen loss, which raises the risk of stent failure, restenosis, and recurrent revascularization and results in significant costs [6–8]. This is actually because DES cause the treatment endothelium to contain metallic arches and a polymeric framework, both of which act as acute inflammatory stimuli and inhibit the endothelium's ability to regenerate fully and the lumen's ability to expand to its full potential [9- 10].This expanded late lumen loss is connected to the tiny vessel's limited capacity to treat even little neointimal growth following stent insertion.[12-13] There is a well-established correlation between diabetes mellitus and small artery coronary disease, and the two conditions are also highly predictive of terrible outcomes following PCI.[14-16] There is data currently suggesting that drug-coating balloons might be the choice for treating small vessel disease, and they have proven to be a better way to avoid the issues associated with DES.[17]Because of the increased prevalence of SVD in this impacted character group of people, individuals with diabetes are more expected to have drug-blanketed balloon therapy. No data available that compare the effects of drug-coating balloons in individuals with diabetes to those with SVD who do not have diabetes. Given that DCB enhances DES's recovery goals without replicating its drawbacks and restrictions, it is questionable whether or not the same kind of outcomes are found when DCB is used in assessment as when DES is employed. Therefore the current study was conducted to determine the DCB -Only Angioplasty Outcomes in Diabetic and Non diabetic Patients with De Novo Small Coronary Vessels disorder

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METHODOLOGY

This correctional multi-centre study was carried out at the Cardiology Department BMCH Quetta and Cardiology department Al Qasimi hospital Sharjah, UAE from January, 2023-June, 2023 after taking permission from the ethical board of the institute. A total of 1200 participants with small vascular illness treated with Drug-Coated Balloon -Test method were examined. A reference vessel diameter of 2.75 millimeter or smaller is identified by the researchers as suggestive of small vessel disease. Individuals were classified as either having diabetes or no longer having it. Individuals who had a fasting plasma glucose level greater than 126 mg/dL (7.0 mmol/L), two-hour plasma glucose levels that exceeded 200 milligrams per (11.1 mmol/L) at any point during a test for oral glucose tolerance, and/or HbA1c levels greater than 6.5& had been classified as diabetic. For follow-up therapy, individuals were seen at the medical facility 365 days after the surgery, or sooner if required. a troubled asset relief stent implantation is needed for a number of reasons, including end-stage renal disease, renal failure requiring dialysis, restenosis within the angioplasty, combination treatments of the danger lesion, handling smaller and larger vessel lesions simultaneously, treating blood clots inside the implants and gene expression lesions simultaneously, and renal failure requiring dialysis. The main objective of the experiment is now target lesion failure (TLF). Ischemia-induced revascularization of the purpose lesion, myocardial infarction linked to the purpose vessel, and purpose vessel-related cardiac mortality were all included in TLF. When it became unclear whether or not the purpose vessel was now responsible, myocardial infarction and death were categorized as TLFs. Revascularization within the targeted artery (TVR),

myocardial infarction, and all-purpose mortality were among the secondary goals of major damaging cardiac events (MACE). Revascularization of a lesion must be achieved because of stenosis more than 50% ischemia, or a recurrence of medical situation for which the first surgery was performed in order for it to be deemed therapeutically recommended (TLR). The term "tolerable late intervention" (TLR) was coined to describe the need for bypass surgery on the target vessel or repeat percutaneous coronary intervention of the target lesion, including 10 mm proximal and 10 mm distal to the index device, because of the presence of recanalization or other complications. Myocardial infarction is the term used to describe a heart attack brought on by a blood clot. The following circumstances resulted in a myocardial diagnosis:

The infarction Myocardial ischemia symptoms include: increase or decrease in cardiac biomarkers; at least 1 result that is afar the 90th to 99th percentile of the typical level.The development of pathologic Q waves or alterations in the electrocardiogram (ECG) that are indicative of new ischemia or sensations and/or symptoms strongly imply ischemia, as do imaging results indicating sudden l myocardial blood supply loss or neighboring wall signal issues. The term "cardiac loss of life" was thought to encompass coronary heart failure, stroke, acute myocardial infarction, sudden cardiac failure, unwitnessed expiry, cardiovascular events, cardiovascular hemorrhage, and special cardiovascular causes of death. For our purposes, "all-purpose loss of life" means death from any cause, whereas "purpose vessel revascularization" means that an open-coronary coronary heart surgery or endovascular procedure is required to bypass an artery's previously treated location. The treatment and recovery of patients would be covered if they were handled in compliance with our predetermined standards. Patients received 300 mg of aspirin by mouth at least 24 hours before the intervention, seventy five milligram of aspirin, 75 mg of clopidogrel, or ninety mg of ticagrelor orally at least 6 hours before the procedure was administered, and then continued taking these medications daily, with the notable exception of healthy patients who had been taking dual antiplatelet medication continuously for a favorable amount of time. Upon admission prior to surgery, those with severe coronary artery disease received loading doses of 300 mg of aspirin and either 100–80 mg of ticagrelor or 600 mg of clopidogrel orally. There were two options: ticagrelor and clopidogrel. The doctor may also choose the one they believe would work best for them. All patients received an intravenous bolus of enoxaparin ranging from 0.5 to 0.75 mg/kg prior to percutaneous coronary intervention (PCI). Although she or he became unfastened to choose the method for lesion education and the balloons to utilize, the operator no longer hired balloons for post-dilation once the DCB was put into effect. All cases of residual stenosis after percutaneous coronary intervention (PCI) that were visually assessed to be significantly less than 30% were deemed to have been successfully managed using the intervention's methods. For a minimum of six months after the procedure, patients were administered a DAPT regimen that included 75 mg of aspirin daily, in addition to either 75 mg of clopidogrel or 90 mg of ticagrelor twice daily. The balloon catheter, coated with paclitaxel, was utilized on each patient. At a dosage of 3g/mm2, a hydrophilic spacer and a matrix coating of paclitaxel are applied to the balloon floor. The medicine must be inflated for forty seconds in order to be propelled into the vessel wall; only 4.5% of the drug remains at the balloon after that. Using a standardized questionnaire, we assessed each patient's medication, quality of life, and negative activities over a 12-month medical follow-up that included both in-person and telephone appointments. Appointments for angiogram follow-up had been scheduled after one year, or sooner if needed. Each endpoint of the trial was monitored by an impartial medical committee, and the correctness of the angiograms was examined by a blinded middle lab.The propose and significant variation of a continuously variable are supplied, whereas the frequencies and probability of an express variable's occurrences are presented. Both the 2-tailed Fisher's actual test and Pearson's chi-squared test were used to assess express variables, and the unbiased samples t-test (also known as the "Student's t-test") was used to assess non-stop variables.. When the bilateral P is less than 0.05, it is deemed statistically significant.

RESULTS

A total of 1200 participants were enrolled in this study out of which 832(69.33%) were male and 368(30.6%) were female as presented in figure1. 431(35.9%) were diabetes and 769 (64.0%) were non diabetic (figure2) Compared to those without diabetes, patients with diabetes were significantly older as well as more inclined to have hyperlipidemia, hypertension, and renal failure. A total of 1352 lesions were treated; 484 were identified within the diabetes treatment group and 869 among the non-diabetic group. (Figure 3) Even though there were not any statistically significant differences of the two. Bifurcation, ostial lesion, clotting, and disseminated lesion all occurred more commonly inside the diabetic individuals. As compared to the diabetic statistically significant increase in the frequency of calcified lesions, permanent total occlusion, and longer advised lesion duration is observed in the non-diabetic firm. In the diabetes and non-diabetic groups, standard artery thickness was comparable (2.5, 0.2 verses. 2.5, 0.8) (the P value 0.366); however, the operating voltage increase stage and duration were also comparable (59.9, 3.76s via. 60.1, 4.93s) (the P value 0.416 and 0.474, correspondingly). Five hundred and thirty-six (44.66%) of the 1200 individuals who were initially chosen had their angiograms completed. Luminal length, dichotomous revascularization (4.8% via 1.1 %(P value 0.003), and lowest membrane length (MLD) were all substantially different between the diabetic and non-diabetic persons (1.89. 0.53 respectively. 2 0.39; p =0.07). There have been notable differences in TLF incidence costs between companies, with a higher incidence among the diabetic population (3.9 percent via 1.4%; P value equal to 0.006).

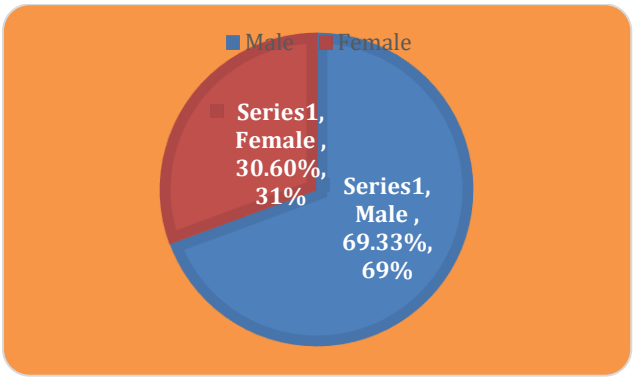

Figure1: Gender wise distribution of the study population

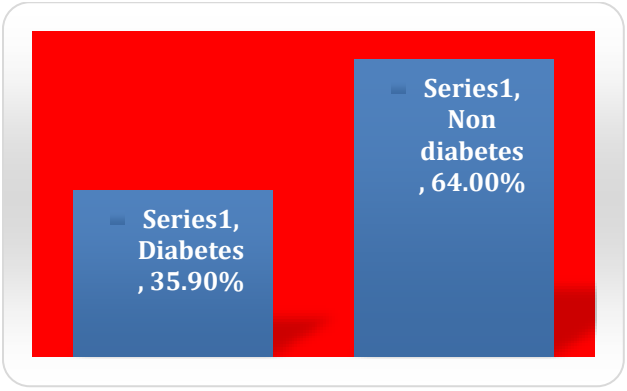

Figure 2: Prevalence of diabetic individuals in the study population

At the same time when TLF components were examined separately, TLR costs were significantly higher inside the diabetic commercial organization (2 vs. 0.5 percent) (P value 0.014).

However, across several of the firms, there was no significant difference in myocardial infarction inside the target artery (0.6% versus. 0.1percent) (P value 0.110). There have been no statistically significant variations of the MACE comparing many of the two firms (4.4% vs. 2.7%) (P value 0.120). After controlling for several variables, the multivariate logistic regression analysis for TLF and TLR indicated that diabetes was still a significant predictor of each TLF and MACE.

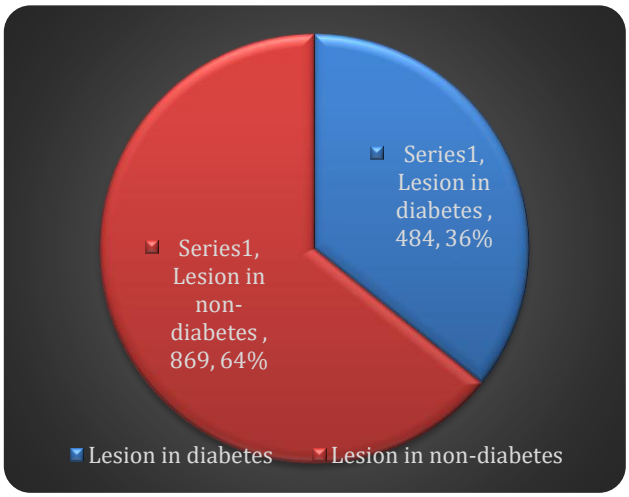

Figure 3: Frequency of lesion in the study population

DISCUSSION

The cutoff component used for small vessel definition in the majority of DCB study on small vessels was 2.8 mm, which is in line with the suggested ideal exclusion to raise understanding of tiny vessels. A relative vascular length of around 2.7 mm was used to define a micro artery. Research[18-20] indicates that DCB is just as successful in treating tiny coronary arteries as DES. The outcomes of DCB in diabetics and non-diabetics with newly developed small coronary arteries are yet to be directly compared. Our study analysis demonstrated that diabetes had significantly greater target lesion failure (3.9 percent vs. 4 percent; P=0.006) and tolerable late intervention (2.0 percent vs. 0.5 percent; P value 0.014) costs. Diabetics experienced major cardiovascular events more frequently (4.4 percent vs. 2.7; P value 0.120). The difference is no longer statistically significant, despite the fact that it still exists. Diabetes patients exhibited an above-average risk of acquiring (P value 0.033) even after controlling for confounding factors. We found that Drug-Coated Balloon had optimally low target lesion failure and MACE costs inside the small vessel. But previous study showed 6.1% MACE event rates at 12 months, whereas the BASKET-SMALL 2 trial's DCB arm showed 7.5% MACE event rates at 23 and 31 months.[21]The research indicates that in older patients with SVD, the 9-month MACE with DCB angioplasty is 4.2%.In the RESTORE SVD China Randomized Study, the incidence of TLF occurrences was 4.3%. Our prices for target lesion failure (2.3%) and MACE episodes (3.0%) have significantly dropped in comparison to those various trials. With the use of drug-covered balloons, SVD's "depart not anything in the back of strategy" is thought to be a factor in the decrease of MACE fees. DCB-best angioplasty for post system luminal enlargement has been found, and acetylcholine testing has demonstrated significantly less severe coronary endothelial disease and neither acute nor past-due Thrombosis[4]. We found that the diabetic organization's MACE expenses had significantly decreased from what was previously apparent. According to research conducted by Magaly et al.[18] The smaller pattern sizes of all the mentioned studies compared to ours may also help to explain why our analysis showed a lower MACE prevalence than previous studies. Secondly, different criteria have been used for inclusion; for instance, Sinega et al. recruited older men and women who are more likely to exhibit a greater percentage of all the traditional danger factors for MACE than the general population. Negative outcomes are anticipated separately during DCB angioplasty and shown through bailout BMS implantation.[22] we no longer included any bailouts stenting in our assessment when compared to the previously reported study. Additionally, as that is the most crucial element in a successful outcome, we discussed the most basic strategies when the given rules for lesion treatment have been followed. [23] Our results are consistent with those of the Jalaluddin trial, which found that the diabetic institution had a much higher prevalence of tolerable late intervention (1.4 percent vs. 0.6%; P value 0.049).[24] In contrast to the metabolic and hematologic changes observed in the general population, these outcomes support the changes observed in individuals with diabetes. Diabetes is linked to endothelial dysfunction, hypercoagulability, accelerated atherosclerosis development, and increased platelet aggregation and clotting. Compared to non-diabetic patients, diabetics experience a higher incidence of residual plaque during the reference phase. Additionally, a recent study using intravascular ultrasound found a link between a higher incidence of plaque and an increased risk of part stenosis with DES and BMS. This ultimate effect is most likely duplicated when DCB is used. Following DCB, diabetic patients saw a statistically significant increase in the cost of residual stenosis.[25] In comparison to our results, Jalaluddin[22] found that the diabetic group experienced higher rates of MI (2.6 percent vs. 0.4 percent ; P value 0.002) and MACE episodes (4.3 percent compared to 0.6%; P value 0.000). It has been proven that the effect of DCB on the TVR 40 4 is unaffected by the diabetes technique, consistent with a met assessment using the Sánchez et al. method. The differing results may be due, at the very least, in part, to the excellent inclusion criteria used in our research, which eliminated all bailout stenting and best recruited individuals with a vascular diameter of 2.75 millimeter or less. Jalaluddin did, however, count every patient, regardless of the size of their arteries. It is important to keep in mind the heterogeneity of the covered trials with regard to vessel size (3, 2.8.1, as well as 2.75 millimeters), given that the risk of restenosis following PCI reduces with increasing vessel size.[22]

CONCLUSION

Our study concluded that the drug-covered balloon alone decreased the incidence of target lesion failure and significant detrimental cardiac events in patients with de novo small coronary artery disease. We found that the target lesion failure and tolerable late intervention event fees were significantly higher in the population with diabetes than in the population without the disease. A higher normal charge of MACE, TVR, MI, and cardiac mortality was seen in the diabetic organization, despite the lack of a statistically significant difference between the diabetic and non-diabetic groups. Diabetes became an unbiased predictor of TLF and TLR over the 12-month follow-up period, however it is no longer a predictor of MACE.

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