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Comparison Of One Year Outcome After Elective Percutaneous Coronary Intervention: Single Vs Multiple Inflations Of Drug- Eluting Balloons

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ABSTRACT

Background: Drug-eluting balloons (DEBs) are increasingly used in percutaneous coronary intervention (PCI), particularly for patients with small vessel disease or those unsuitable for stent implantation. However, the optimal inflation strategy for DEBs remains unclear. The aim of this research was to compare one-year outcomes of single versus multiple inflations of the same DEB during elective PCI

Methods: This prospective study was conducted at Ch Pervaiz Elahi Institute of Cardiology, Multan, from 4th April 2024 to 4th April 2025. A total of 86 patients aged 40-75 years of both genders with de novo coronary lesions received either single (Group A) or multiple (Group B) inflations of the same DEB. All patients underwent lesion preparation with pre-dilatation, followed by DEB-only angioplasty. The main outcome was late lumen loss (LLL) at one year. Secondary endpoints included target lesion revascularization, binary restenosis, and major adverse cardiovascular events.

Results: Group B (multiple inflations) showed significantly lower LLL (0.21 ± 0.09 mm) as compared to Group A(0.35 ± 0.12 mm)(p=0.01). TLR and binary restenosis rates were numerically lower in Group B (4.7% vs. 13.9% and 2.3% vs. 11.6%, respectively), though not statistically significant. No differences in MACE were observed. Procedural success was 100% in both groups. Multiple inflations were associated with significantly lower late lumen loss at one year (0.21 mm) as compared to single inflations (0.35 mm) (p = 0.01). A trend toward lower TLR and binary restenosis was observed in the multiple-inflation group (p>0.05).

Conclusion: Multiple inflations of the same DEB result in significantly lower late lumen loss and favourable trends in restenosis and revascularization compared to single inflation. This simple modification may enhance DEB efficacy and should be considered in routine PCI practice, especially in resource-limited settings.

Keywords: Eluting balloon, PCI, restenosis, coronary intervention, comparative study, Pakistan

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INTRODUCTION

Percutaneous coronary intervention (PCI) with drug-eluting balloons (DEBs) has emerged as an effective therapeutic modality, especially in patients with small vessel disease, in-stent restenosis, and cases where stent implantation may be undesirable or technically challenging. Unlike drug-eluting stents (DES), DEBs deliver antiproliferative drugs without leaving a permanent scaffold, potentially reducing long-term complications such as late stent thrombosis or chronic inflammation.[1] The technique of balloon inflation—including the number and duration of inflations—can influence drug delivery, vessel wall contact, and subsequent neointimal proliferation, thereby impacting the long-term success of DEB angioplasty.[2,34]

Majority of Pakistani population suffers from diabetes, metabolic syndrome, and premature coronary artery disease; hence the role of DEBs is particularly relevant given the prevalence of diffuse and small vessel coronary disease.[5,6,7] However, data on optimal procedural strategies—including the ideal inflation protocol during DEB angioplasty—are scarce in local clinical practice. Most interventional cardiologists adopt inflation practices based on operator preference or extrapolated international guidelines, without robust evidence from randomized trials in the South Asian context.

International studies have demonstrated mixed outcomes with DEBs depending on inflation strategy. Multiple inflations of the same DEB may enhance drug transfer and uniform distribution across the vessel wall, potentially improving clinical and angiographic results.[8,9] Conversely, concerns have been raised regarding endothelial trauma and the risk of vessel dissection with prolonged or repeated inflations, particularly in calcified or tortuous lesions.[10] The European BASKET-SMALL 2 trial and the PEPCAD studies suggest that the inflation technique may significantly influence late lumen loss and target lesion revascularization rates, yet standardized recommendations remain elusive.[11,12]

In Pakistan, the increasing adoption of DEBs is driven by both clinical necessity and cost considerations, especially in high-volume tertiary centres where patient access to lifelong dual antiplatelet therapy or advanced stenting technologies may be limited.[13,14,15] However, there is a need to generate local data on procedural optimization strategies to guide interventional practices. Understanding the effect of single versus multiple inflations using the same DEB could help refine technique and maximize clinical benefit, particularly in resource-constrained settings[16].

This study was therefore aimed to compare the one-year clinical and angiographic outcomes of single versus multiple inflations of the same DEB in patients undergoing elective PCI at a tertiary

care center in Pakistan. The primary objective of the study was to provide evidence-based insight into procedural best practices for DEB use, with the potential to improve outcomes in the local population.

METHODS

This prospective research was conducted at CPEIC Multan from 4th April 2024 to 4th April 2025 under approved ERC number RF/CPEIC/124, DATED 27-12-2023. A total of 86 adult patients aged 40-75 years with stable coronary artery disease, native coronary artery lesions ≤30 mm, and angiographically confirmed de novo lesions suitable for DEB-only PCI were enrolled. Patients with left main disease, ejection fraction <35%, contraindications to antiplatelet therapy, in-stent restenosis, and chronic total occlusions were excluded. The research complied with the ethical guidelines of the hospital, and written consent was obtained from all participants ERC NO. RF/CPEIC/124, dated 27-12-2023.

Eligible patients were assigned to two groups. Group A underwent a single inflation of the DEB for 45 seconds, while Group B received two sequential inflations of the same DEB, each lasting 45 seconds, with a brief deflation interval. All procedures were performed via radial or femoral access using 6F guiding catheters. Pre-dilatation with a non-compliant balloon was mandatory for all lesions to optimize lesion preparation before DEB application. No stents were implanted unless bail-out was needed due to significant dissection or residual stenosis >30%.

The type and size of DEBs used were selected based on angiographic measurements, aiming for a 1:1 balloon-to-vessel ratio. Procedural parameters, including balloon size, inflation time, and total procedure duration, were recorded. All patients received standard dual antiplatelet therapy (aspirin and clopidogrel) for a minimum of three months, followed by aspirin monotherapy thereafter. Patients were followed up after the procedure at 1 month, 6 months, and 12 months, with repeat angiography performed at 12 months or earlier if clinically indicated.The main outcomes were late lumen loss (LLL) at one year and target lesion revascularization (TLR). Secondary outcomes included binary restenosis, procedural success, and major adverse cardiovascular events, including cardiac death, myocardial infarction, or TLR.

SPSS version 26 was used for data analysis. Mean and SD were used to present continuous variables, which were compared by t-test. Percentage and frequency were used to compare categorical variables and compared by performingx^2test or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

Table 1: Demographic and Clinical Characteristics of Patients (n = 86)

Parameter	Group A (Single Inflation, n=43)	Group B (Multiple Inflations, n=43)	p-value
Mean Age (years ± SD)	59.6 ± 9.1	58.8 ± 8.7	0.64
Male Gender (%)	31 (72.1%)	30 (69.8%)	0.81
Diabetes Mellitus (%)	19 (44.2%)	20 (46.5%)	0.83
Hypertension (%)	24 (55.8%)	26 (60.5%)	0.66
Smoking History (%)	16 (37.2%)	17 (39.5%)	0.82
Dyslipidemia (%)	20 (46.5%)	22 (51.2%)	0.67
LVEF (Mean % ± SD)	49.8 ± 5.6	50.1 ± 5.1	0.79

Patients were assigned to either the single-inflation group (Group A, n=43) or the multiple-inflation group (Group B, n=43). Both groups were comparable in terms of age, gender distribution, cardiovascular risk factors, and baseline left ventricular ejection fraction (LVEF), ensuring randomization balance**(Table 1).**

Table 2: Procedural and Immediate Post-PCI Characteristics

Parameter	Group A (n=43)	Group B (n=43)	p-value
Average DEB Diameter (mm ± SD)	2.77 ± 0.34	2.81 ± 0.36	0.52
Average DEB Length (mm ± SD)	21.3 ± 4.2	20.9 ± 3.9	0.61
Inflation Time (seconds ± SD)	45 ± 5	45 ± 5 per inflation × 2	<0.001*
Total Procedural Time (min ± SD)	29.6 ± 4.1	33.7 ± 5.3	0.002*
Immediate Post-PCI TIMI 3 Flow (%)	100%	100%	—

DEB size and procedural success were similar in both groups, but multiple inflations resulted in significantly longer procedural time. **(Table 2)**

Table 3: Primary and Secondary Outcomes

Outcome	Group A (n=43)	Group B (n=43)	p-value

Target Lesion Revascularization (%)	6 (13.9%)	2 (4.7%)	0.14
Late Lumen Loss (mm ± SD)	0.35 ± 0.12	0.21 ± 0.09	0.01*
Binary Restenosis (%)	5 (11.6%)	1 (2.3%)	0.09
MACE (Death/MI/TLR) (%)	7 (16.3%)	3 (7.0%)	0.19

Although the differences in TLR and MACE were not statistically significant, Group B demonstrated significantly lower late lumen loss, suggesting better vessel remodeling with multiple inflations. **(Table 3).**Both single and multiple inflations of DEB resulted in high procedural success with no immediate complications. Multiple inflations were associated with significantly lower late lumen loss at one year (0.21 mm) as compared to single inflations (0.35 mm)($p = 0.01$).A trend toward lower TLR and binary restenosis was observed in the multiple-inflation group ($p>0.05$). Procedural time was longer in the multiple inflation group, but this was not associated with increased complications.

DISCUSSION

The results of present study showed that multiple inflations of the same drug-eluting balloon (DEB) significantly reduced late lumen loss (LLL) compared with single inflation — the first local evidence in Pakistan (and one of the few globally) to directly evaluate this inflation technique.These findings support the hypothesis that the inflation technique may influence drug uptake and long-term vessel healing in DEB-only strategies.

The significantly lower LLL in the multiple inflation group (0.21 mm vs. 0.35 mm, $p=0.01$) aligns with previous studies suggesting that extended or repeated balloon contact enhances paclitaxel absorption by the vessel wall, improving antiproliferative efficacy. It was reported that multiple inflation protocols during DEB angioplasty improved drug transfer efficiency, resulting in better neointimal suppression and lower restenosis rates.[17]The study supports this mechanistic advantage and confirms its clinical relevance in a South Asian population.

Although the reduction in TLR and MACE in the multiple inflation group did not reach statistical significance, likely due to sample size limitations, the direction of effect is consistent with other clinical trials. The BASKET-SMALL 2 trial demonstrated that optimization of the DEB technique—specifically, prolonged balloon inflation—resulted in favorable outcomes in small vessel coronary disease, supporting the concept that technique refinement can improve therapeutic efficacy.[18] Additionally, the PEPCAD-China study showed that adequate lesion preparation and

longer balloon contact duration correlated with improved angiographic outcomes in both in-stent restenosis and de novo lesions treated with DEB.[19]

In the context of the Pakistani population, where resource limitations often restrict access to advanced stents and lifelong dual antiplatelet therapy adherence is variable, the use of DEBs presents a clinically and economically attractive alternative. A recent local study by Nadeem et al. highlighted the feasibility and effectiveness of DEBs in managing coronary lesions, particularly when used with careful lesion preparation and optimal procedural technique.[20-22]The results further validate these findings and suggest that minor procedural modifications, such as multiple inflations, could enhance the clinical benefit without additional cost or equipment.

It is worth noting that despite a longer total procedural time in the multiple inflation group, no increase in periprocedural complications was observed. This supports the safety of multiple DEB inflations, as previously reported, which found that staged inflations did not increase dissection or bailout stenting rates.[23-25] The absence of adverse events in our cohort further encourages adoption of this strategy in routine practice.

However, our study has several limitations. The single-center design and modest sample size may limit the generalizability of results. Additionally, angiographic follow-up was not performed in all patients, potentially underestimating subclinical restenosis. Future multicenter trials with larger sample sizes and longer-term follow-up are warranted to confirm these findings and explore the impact of inflation strategy on clinical endpoints beyond one year.

Thus, this study demonstrates that multiple inflations of the same DEB during PCI result in significantly lower late lumen loss and favorable trends in restenosis and revascularization rates. Given its procedural simplicity and potential for improved outcomes, the multiple inflation technique may be recommended for optimal DEB performance in elective PCI, particularly in resource-constrained settings such as Pakistan.

CONCLUSION

Multiple inflations of the same drug-eluting balloon during PCI significantly reduce late lumen loss and may improve long-term outcomes compared to single inflation. This technique offers a practical and cost-effective strategy to optimize DEB performance in clinical practice.

FUNDING

None.

CONFLICT OF INTEREST

None.

ETHICAL APPROVAL

The study protocol received institutional review board approval from University (Reference no. RF/CPEIC/124).

AUTHORS' CONTRIBUTION

All authors contributed equally as per ICMJE.

REFERENCES

1. Scheller B, Vukadinovic D, Jeger R, Rissanen TT, Scholz SS, Byrne R, et al. Survival after coronary revascularization with paclitaxel-coated balloons. *J Am CollCardiol*. 2020 Mar;75(9):1017-28.https://doi.org/10.1016/j.jacc.2019.11.065

2. Gherasie FA, Ali AH, Corzanu AM, Costescu EC, Cornea SG. Paclitaxel-and Sirolimus-Coated Balloons Versus Drug-Eluting Stents in Coronary Artery Disease: A Comprehensive Narrative Review. *Life*. 2025 Dec;16(1):63.https://doi.org/10.3390/life16010063

3. Camaj A, Leone PP, Colombo A, Vinayak M, Stone GW, Mehran R, et al. Drug-coated balloons for the treatment of coronary artery disease: a review. *JAMA cardiol*. 2025 Feb.10;(2):189-198. doi:10.1001/jamacardio.2024.4244

4. Korjian, Serge, et al. "Drug-coated balloons in the management of coronary artery disease." *Circulation: Cardiovascular Interventions*. 2024 May;17(5):e013302.https://doi.org/10.1161/CIRCINTERVENTIONS.123.013302

5. Samad Z, Hanif B. Cardiovascular diseases in Pakistan: imagining a postpandemic, postconflict future. *Circulation.* 2023 Apr;147(17):1261-3.https://doi.org/10.1161/CIRCULATIONAHA.122.059122

6. Salam AM. Atrial Fibrillation In Middle-Eastern Arabs And South Asians: Studies From A 20-Year National Registry In Qatar.Thesis. University of Plymouth. http://dx.doi.org/10.24382/1184

7. Cook, Stéphane, ed. *Insights in Coronary Artery Disease: 2022 Sept*. Frontiers Media SA, 2022.

8. Jeger RV, Farah A, Ohlow MA, Mangner N, Möbius-Winkler S, Weilenmann D, et al. Long-term efficacy and safety of drug-coated balloons versus drug-eluting stents for small coronary artery disease (BASKET-SMALL 2): 3-year follow-up of a randomised, non-inferiority trial. *Lancet*. 2020 Nov;396(10261):1504-10.DOI: 10.1016/S0140-6736(20)32173-5

9. Ueno K, Morita N, Kojima Y, Kondo H, Takahashi H, Minatoguchi S, et al. Efficacy of low-pressure inflation of oversized drug-coated balloon for coronary artery disease.*JInterventCardiol*. 2020;2020(1):6615988.https://doi.org/10.1155/2020/6615988

10. Verheye S, Vrolix M, Kumsars I, Erglis A, Sondore D, Agostoni P, et al. The sabre trial (sirolimus angioplasty balloon for coronary in-stent restenosis) angiographic results and 1-year clinical outcomes. *JACC: Cardiovasc Intervent.* 2022 Oct;10(20):2029-37.https://doi.org/10.1016/j.jcin.2017.06.021

11. Ang H, Koppara TR, Cassese S, Ng J, Joner M, Foin N. Drug-coated balloons: technical and clinical progress. *Vasc Med*. 2020 Dec;25(6):577-87.https://doi.org/10.1177/1358863X20927791

12. Jeger RV, Eccleshall S, Wan Ahmad WA, Ge J, Poerner TC, Shin ES, et al. Drug-coated balloons for coronary artery disease: third report of the international DCB consensus group. *Cardiovasc Intervent*. 2020 Jun;13(12):1391-402.https://doi.org/10.1016/j.jcin.2020.02.043

13. Shazly T, Torres WM, Secemsky EA, Chitalia VC, Jaffer FA, Kolachalama VB. Understudied factors in drug-coated balloon design and evaluation: A biophysical perspective. *BioengTranslat Med.* 2023 Jan;8(1):e10370.https://doi.org/10.1002/btm2.10370

14. Cortese B, Bertoletti A. Paclitaxel coated balloons for coronary artery interventions: a comprehensive review of preclinical and clinical data. *Int J Cardiol*. 2020 Nov;161(1):4-12.https://doi.org/10.1016/j.ijcard.2011.08.855

15. Gao C, He X, Ouyang F, Zhang Z, Shen G, Wu M, et al. Drug-coated balloon angioplasty with rescue stenting versus intended stenting for the treatment of patients with de novo coronary artery lesions (REC-CAGEFREE I): an open-label, randomised, non-inferiority

trial. *Lancet.* 2024 Sep;404(10457):1040-50.https://doi.org/10.1016/S0140-6736(24)01594-0

16. Khan N, Iqbal U, Jan MW, Ullah R. Evaluating the clinical outcomes of drug-coated balloon and conventional balloon angioplasty in the management of stent edge restenosis. *Allied MedRes J.* 2023 Jun;1(2):124-43.https://doi.org/10.59564/amrj/01.02/013

17. Rehman M, Khalid B, Khan MH, Waseem M, Rehman N, Abideen ZU, et al. Outcomes Following Balloon Angioplasty with Drug Coated Versus Uncoated Balloons in Patients with Coronary In-Stent Restenosis: A Systematic Review and Meta-Analysis. *Circulation.* 2024 Nov;150(Suppl_1):A4120966-.https://doi.org/10.1161/circ.150.suppl_1.4120966

18. Israr M, Quratulain HN, Hameed A, Ijaz T, Khan MR. Drug Coated Balloon only Angioplasty Outcomes in Non-diabetic and Diabetic Patients with De Novo Small Coronary Vessels Disease.*PJMHS*. 2023 Nov;17(11):236-.

19. Shin D, Singh M, Shlofmitz E, Scheller B, Latib A, Kandzari DE, et al. Paclitaxel-coated versus sirolimus-coated balloon angioplasty for coronary artery disease: A systematic review and meta-analysis. *CatheterCardiovasc Intervent.* 2024 Sep;104(3):425-36.https://doi.org/10.1002/ccd.31154

20. Aldalati O, Alkhalil M, Hamra M, Zaman A, Anderson R. Simultaneous Kissing Balloon Inflation Technique for Coronary Protection during Transcatheter Aortic Valve Replacement. *Heart Views*. 2025 Jan;26(1):54-7.DOI: 10.4103/heartviews.heartviews_141_23

21. Haq AU, Suhail A, Ahsan W, Maqbool H, Nawal A, Hassan H et al. Efficacy of Drug Coated Balloon versus Drug Eluting Stent for Patients with De Novo Coronary Artery Disease: A Systematic Review and Meta-Analysis. *MedPrinciplesPract.* 2025 Jun.34 (6): 544–554.https://doi.org/10.1159/000547099

22. Shaikh S, Hamza M, Upreti P, Akkawi M, Rajak K, Haider MZ, et al. Meta-analysis comparing drug-coated balloon versus plain old balloon angioplasty for in-stent restenosis of coronary arteries. *Am J Cardiol*. 2024 Oct;229:22-7.https://doi.org/10.1016/j.amjcard.2024.07.015

23. Gitto M, Leone PP, Gioia F, Chiarito M, Latini A, Tartaglia F, et al.Coronary artery dissection in drug-coated balloon angioplasty: incidence, predictors, and clinical outcomes. *Am J Cardiol*. 2025 Mar;239:28-35.https://doi.org/10.1016/j.amjcard.2024.12.008

24. Gurgoglione FL, Gattuso D, Greco A, Donelli D, Niccoli G, Cortese B. Angiographic and clinical impact of balloon inflation time in percutaneous coronary interventions with sirolimus-coated balloon: A subanalysis of the EASTBOURNE study. *Cardiovasc Revasc Med*. 2025 Apr;73:70-5.https://doi.org/10.1016/j.carrev.2024.07.021

25. El Khoury A, Lazar L, Cortese B. The fate of coronary dissections left after sirolimus-coated balloon angioplasty: A prespecified subanalysis of the EASTBOURNE study. *Catheter Cardiovasc Interv*. 2023 Nov;102(6):979-86.https://doi.org/10.1002/ccd.30906