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Strategies to Prevent Restenosis After Drug-Coated Balloon Angioplasty

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Abstract

Despite advances in drug-coated balloon (DCB) technology, restenosis remains a persistent challenge in percutaneous coronary intervention (PCI). At Bethsaida Hospital in Indonesia, chaired by Prof. Dasaad Mulijono, we've reduced restenosis rates from 10–20% to just 2% through an integrated approach that combines precise lesion preparation, imaging-guided intervention, and a groundbreaking lifestyle strategy: the plant-based diet (PBD).

This review challenges the conventional, drug-heavy paradigm by highlighting PBD as a potent, non-pharmacological tool for combating atherosclerosis and restenosis. Backed by mechanistic insights—ranging from nitric oxide (NO)-mediated vasodilation to gut microbiome modulation—PBD offers profound cardiovascular protection while enhancing glycaemic control, blood pressure, lipid profiles, and overall metabolic health.

Moreover, our centre's deployment of artificial intelligence (AI) has revolutionized patient education and dietary adherence, accelerating real-world outcomes. Our data show that combining AI-driven personalization with lifestyle medicine is feasible and transformative.

It's time to disrupt the status quo in cardiology. This review calls for a bold paradigm shift: integrate cutting-edge interventional techniques with evidence-based nutrition and digital innovation to redefine restenosis prevention and reshape the future of cardiovascular care.

Keywords: Bethsaida hospital; Prof. Dasaad Mulijono; Restenosis; Drug-coated balloon; Plant-based diet; Lesion preparation; Lifestyle medicine; Artificial intelligence

Introduction

Atherosclerosis is characterized by the accumulation of lipid-rich plaques within arterial walls, leading to vascular narrowing and increased cardiovascular events. Restenosis, the re-narrowing of arteries following interventions such as angioplasty, remains a clinical challenge. Risk factors, including hypertension, hyperlipidaemia, obesity, diabetes, and chronic inflammation, accelerate disease progression [1,2]. Emerging evidence suggests that dietary interventions, primarily PBDs rich in antioxidants, fibre, and bioactive compounds, are pivotal in preventing and reversing vascular disease [3-7].

PCI has evolved significantly, with DCBs emerging as an alternative to stent implantation in select patient populations. DCBs deliver antiproliferative agents directly to the vessel wall, avoiding the need for permanent metallic

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scaffolds and mitigating late stent-related complications. However, restenosis remains a significant challenge, necessitating a thorough understanding of its mechanisms and the development of optimal preventive strategies.

Pathophysiology of Restenosis Following DCB Angioplasty

Restenosis after DCB therapy is multifactorial and involves [8-15]:

1. **Acute Recoil**

- Immediately after post-dilation, the vessel contracted, reducing lumen size.
- Successful DCB treatment requires residual stenosis to be less than 30%.

2. **Flow-Limiting Dissection**

- Excessive vascular trauma causing dissections significant enough to impair blood flow.
- Optimal lesion preparation aims to achieve a non-flow-limiting dissection.

3. **Insufficient Drug Delivery**

- Suboptimal transfer of paclitaxel or sirolimus, leading to inadequate suppression of future neointimal growth.

4. **Drug Washout**

- Uneven drug absorption or rapid clearance, reducing therapeutic efficacy.
- Effective drug delivery to the target vessel should occur within 1–2 minutes.

5. **Vascular Calcification**

- Calcific plaques impede drug penetration and limit vessel remodelling induced by balloon angioplasty.

6. **Inflammatory Response**

- Excessive inflammation after balloon angioplasty significantly contributes to neointimal hyperplasia.
- Factors amplifying inflammation include smoking, diabetes mellitus, and an unhealthy diet.

7. **Neointimal Hyperplasia**

- Pathological proliferation and vascular smooth muscle cell migration lead to excessive tissue formation within arterial walls.
- Triggered by premature drug washout, insufficient drug delivery, inadequate DCB inflation duration, or substantial vessel calcification.

8. **Vascular Negative Remodelling**

- Structural alterations resulting in reduced vessel diameter and lumen size following balloon angioplasty.
- Driven by excessive vascular injury, impaired endothelial regeneration, and heightened inflammatory responses.

9. **Progression of Atherosclerosis**

- Continuous progression of atherosclerosis leading to potential re-blockage of the treated artery.
- Ongoing management of underlying disease systemic processes is critical for long-term outcomes.

10. **Genetic Predisposition**

- Genetic traits increase susceptibility to restenosis post-angioplasty.
- Genetic polymorphisms in inflammation (e.g., interleukin genes), cellular proliferation, endothelial dysfunction, and excessive thrombosis pathways significantly influence restenosis.
- Variants may heighten the healing response and severity of neointimal hyperplasia despite optimal treatments.
- Recognizing genetic predispositions can inform personalized treatment strategies and improve clinical outcomes.

Incidence and Risk Reduction Strategies

Historical restenosis rates following DCB therapy ranged from 10% to 20% [8-15]. However, at Bethsaida Hospital, seven years ago, utilizing an integrative approach that encompasses lesion preparation, advanced imaging, and pre- and post-intervention care, including the adoption of plant-based practices, our restenosis rates have declined significantly to 2%, representing a substantial improvement in clinical outcomes.

Optimizing DCB Outcomes: Key Considerations

Several procedural and adjunctive strategies have proven instrumental in reducing restenosis risk [8-15]:

1. **Minimizing Acute Recoil and Optimizing Vessel Expansion and Enhancing Endothelial Function —** To minimize acute recoil, achieving adequate vessel expansion while preventing excessive elastic recoil through proper pre-dilation techniques is essential. Adopting a PBD before the procedure can reduce acute recoil primarily due to its NO-mediated vasodilatory effects. The role of vasodilators in mitigating acute recoil is well-documented and should be considered an integral part of the preventive strategy.
2. **Preventing Flow-Limiting Dissection**—Optimizing Balloon Sizing and Inflation Technique. Special balloons, such as scoring and cutting balloons, should be considered.
3. **Enhancing Drug Delivery**: Prolonged inflation time (60-90 seconds) ensures adequate drug absorption.

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4. **Addressing Calcification** – Utilizing specialized techniques for effective lesion modification, including rotational atherectomy, orbital atherectomy, and intravascular lithotripsy.
5. **Optimizing Drug Exposure** – Ensuring complete contact between the balloon and the vessel wall.
6. **Guidance with Intravascular Imaging and FFR**— Utilize intravascular ultrasound (IVUS) or optical coherence tomography (OCT) to assess lesion preparation and optimize therapy. FFR may sometimes be required to ensure that no residual ischemia post-DCB intervention is achieved.
7. **Prevent edge restenosis** by ensuring the DCB covers the entire diseased segment, including 2 mm proximal and distal to the target lesion.
8. **Slow or halt the progression of atherosclerosis** — Implement comprehensive lifestyle modifications, primarily focusing on transitioning to a PBD, optimizing metabolic parameters, and selecting the most appropriate pharmacological interventions.
9. **Smoking, Diabetes, and Chronic Inflammation** – Stop smoking, adopt a PBD, combined with optimal medical treatment, effectively manages diabetes and reduces chronic inflammation.

Expanding Clinical Indications for DCB Therapy

Initially introduced for treating small vessel disease and in-stent restenosis (ISR) [16,17], DCBs are now being increasingly adopted for a broader spectrum of coronary interventions, including complex lesions such as:

- De novo lesions in vessels of all sizes [18-27]
- Acute myocardial infarction (AMI) [28-32]
- Left-main and ostial lesions [33-35]
- Chronic total occlusions (CTO) [36-38]
- Bifurcation lesions [39-42]
- Severely calcified lesions [43-46]
- Long, diffuse lesions [47-49]
- High bleeding risk patients [50-52]
- Vulnerable plaques [53-55]

Integrative Pre and Post-Intervention Strategy

Beyond procedural optimization, long-term vascular health is influenced by comprehensive management of risk factors. At Bethsaida Hospital, we have implemented a holistic approach incorporating [56,57]:

1. **PBD** – A dietary regimen to enhance endothelial function, reduce systemic inflammation, decrease reactive oxygen species (ROS), and improve metabolic function. PBD should be commenced even before the patients have their procedures.
2. **Body Mass Index (BMI) Target less than 22 kg/m²** – Reducing obesity-related cardiovascular risk.
3. **Optimal Blood Pressure Control** – Mitigating hypertension-induced endothelial dysfunction.
4. **Reduce low-density Lipoprotein Cholesterol (LDL-C) to less than 30 mg/dL—**Use aggressive lipid-lowering strategies to slow the progression and even help to regress atherosclerosis.
5. **Glycaemic Control (HbA1c less than 5.8%)** – Preventing hyperglycaemia-induced vascular complications.
6. **Enhancement of Endothelial NO Production** – Supporting vasodilation and vascular health.
7. **Reduction of Trimethylamine N-Oxide (TMAO) Levels** – Targeting gut microbiome-derived pro-atherogenic metabolites.

Mechanisms of PBD in Cardiovascular Health

A PBD has significantly reduced the risk of atherosclerosis and restenosis through multiple physiological and biochemical pathways [3-7, 56-61]. The following mechanisms elucidate its cardioprotective effects:

1. Attenuation of Adverse Effects Induced by an Unhealthy Diet

An unhealthy diet precipitates endothelial dysfunction, oxidative stress (including lipid peroxidation), hypertension, adiposity, dyslipidaemia, systemic inflammation, and the amplification of pro-inflammatory mediators such as TMAO and advanced glycation end-products (AGEs). A PBD counteracts these detrimental effects through its anti-inflammatory, antioxidative, and metabolic regulatory properties.

2. Enhancement of Endothelial Function and Blood Pressure Regulation

- **Nitrate-Rich Foods:** Green leafy vegetables (e.g., spinach, arugula, beetroot) provide dietary nitrates, which are metabolized to NO, promoting vasodilation and lowering blood pressure.
- **Antioxidant Properties:** Polyphenols and flavonoids (e.g., those found in berries, cocoa, and green tea) stabilize NO, thereby preserving vascular integrity.
- **Anti-Inflammatory and Oxidative Stress Reduction:** PBDs mitigate NO degradation by free radicals, fostering endothelial health.
- **Modulation of the Gut Microbiome:** Fiber-rich diets

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cultivate microbial populations that enhance nitrate metabolism, augmenting NO production.

- **Electrolyte Optimization:** Reduced sodium intake and increased potassium and magnesium facilitate vasodilation and NO activity.

3. Optimization of Lipid Profile

- **Fiber-Rich Intake:** Soluble fibre (e.g., found in oats, legumes, and flaxseeds) helps enhance bile acid excretion, reducing LDL-C levels.
- **Beneficial Lipid Composition:** The monounsaturated and polyunsaturated fats found in nuts, seeds, and avocados help elevate high-density lipoprotein cholesterol (HDL-C) levels while lowering LDL-C.
- **Plant Sterols and Stanols:** These compounds, abundant in nuts, seeds, and whole grains, impede intestinal cholesterol absorption.
- **Minimized Saturated and Trans Fat Consumption:** Avoiding animal-derived fats helps prevent LDL-C elevations. Some animal fats may decrease HDL-C and oxidize it to become even dangerous HDL-C.
- **Antioxidant and Polyphenol Activity:** Found in fruits, vegetables, and dark chocolate, these agents prevent HDL oxidation, preserving its function.
- **Gut Microbiome Contributions:** Short-chain fatty acids (SCFAs) derived from fibre fermentation modulate cholesterol metabolism.

4. Facilitation of Weight Management

- **Reduced Caloric Density:** Whole plant foods promote satiety with fewer calories.
- **Dietary Fiber's Role:** Slows digestion, enhances satiety, and regulates appetite hormones.
- **Gut Microbiome Modulation:** SCFAs derived from fibre enhance metabolism and fat oxidation.
- **Exclusion of Processed and High-Fat Foods:** A PBD restricts the consumption of energy-dense, nutrient-poor foods.
- **Improved Glycaemic Control:** Stabilized insulin levels mitigate adiposity.
- **Enhanced Thermogenesis:** Certain phytochemicals, such as capsaicin and catechins, elevate the metabolic rate.

5. Regulation of Blood Glucose and Insulin Sensitivity

- **Fiber-Induced Glycaemic Control:** Soluble fibre helps modulate glucose absorption, thereby preventing postprandial spikes.
- **Reduced Glycaemic Load:** Whole plant foods promote glucose homeostasis.
- **Polyphenol-Mediated Insulin Enhancement:** Berries, nuts, and green tea reduce inflammation and improve insulin receptor function.
- **Saturated Fat Reduction:** Minimizing dietary saturated fats mitigates insulin resistance.
- **Weight and Visceral Fat Reduction:** PBDs lower adiposity, improving insulin sensitivity.
- **SCFA Production by Gut Microbiota:** Supports glucose metabolism and insulin efficiency.

6. Attenuation of Systemic Inflammation

- **Polyphenols and Antioxidants:** Neutralize free radicals and mitigate oxidative stress.
- **Fiber-Driven Microbiome Health:** SCFAs exert anti-inflammatory effects.
- **Reduction of Pro-Inflammatory Lipids:** Avoiding saturated fats and arachidonic acid curtails inflammation.
- **Omega-3 Fatty Acid Intake:** Omega-3s, found in flaxseeds, chia seeds, and walnuts, lower inflammatory biomarkers.
- **Glycaemic Stability:** Prevents glycation and oxidative stress-related inflammation.
- **Endotoxin Reduction:** A PBD decreases gut-derived endotoxin production, lowering immune activation.

7. Mitigation of Oxidative Stress

- **Antioxidant-Enriched Nutrition:** Vitamins C, E, and polyphenols from plant-based sources counteract ROS.
- **Phytochemical-Rich Foods:** Flavonoids, carotenoids, and resveratrol protect against oxidative damage.
- **Glutathione Augmentation:** Sulphur-rich vegetables (e.g., garlic, onions) enhance endogenous antioxidant defence.
- **Reduction in Pro-Oxidative Lipids:** PBDs help limit the accumulation of oxidized cholesterol.
- **Mitochondrial Efficiency:** Improved metabolic efficiency curtails ROS production.
- **Anti-Inflammatory Modulation:** The resolution of chronic inflammation reduces the oxidative burden.

8. Promotion of a Healthy Gut Microbiota

- **SCFA-Induced Vaso regulation:** Gut metabolites influence NO-mediated vascular relaxation.
- **Inflammatory Homeostasis:** A balanced microbiome mitigates CRP and systemic inflammation.
- **Cholesterol and Triglyceride Regulation:** Microbial metabolites optimize lipid homeostasis.
- **TMAO Reduction:** Decreased production of this

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atherogenic compound reduces the risk of cardiovascular disease.

- **Insulin Sensitivity Improvement:** Enhances glucose metabolism through interactions with gut microbiota.
- **Obesity Prevention:** The gut microbiota regulates adiposity and appetite signalling.
- **Nutrient Bioavailability:** Facilitates absorption of polyphenols, omega-3 fatty acids, and essential micronutrients.

9. Enhancement of Mitochondrial Function

- **Mitochondrial Biogenesis Stimulation:** Polyphenols and nitrates activate AMPK and PGC-1α pathways, fostering ATP production.
- **Oxidative Stress Reduction:** Antioxidants neutralize ROS within mitochondria.
- **Membrane Fluidity Optimization:** Omega-3 fatty acids and Coenzyme Q10 (CoQ10) enhance mitochondrial function.
- **NO Enhancement:** Improves mitochondrial oxygenation and efficiency.
- **Autophagy and Mitophagy Activation:** Cellular maintenance processes eliminate dysfunctional mitochondria.
- **Insulin Sensitivity and Energy Regulation:** Fiber-rich foods sustain mitochondrial efficiency.
- **Chronic Inflammation Modulation:** Phytochemicals alleviate inflammatory stress on mitochondria.

10. Telomere Preservation and Longevity Support

- **Antioxidant and Polyphenol Enrichment:** Reduces oxidative stress, a primary driver of telomere attrition.
- **Inflammatory Suppression:** Dietary modulation decreases telomere-shortening inflammation.
- **DNA Repair Enhancement:** Nutrients such as folate and vitamin C bolster genomic stability.
- **Metabolic Stress Reduction:** Maintaining glycaemic control and insulin sensitivity supports telomere maintenance.
- **Gut Microbiota Contributions:** A diverse microbiome mitigates oxidative and inflammatory stress.
- **Avoidance of Processed and Toxin-Rich Foods:** Minimizes dietary AGEs and other telomere-damaging agents.
- **NO and Vascular Health:** Supports oxygen delivery for cellular longevity.
- **Weight and Cortisol Regulation:** Prevents obesity- and stress-induced telomere erosion.

This mechanistic overview underscores the profound impact of a PBD on cardiovascular health, positioning it as a crucial dietary intervention for preventing and managing cardiovascular disease.

Management of Restenosis after DCB

Managing restenosis after DCB requires identifying the underlying cause as the primary step, followed by selecting the most appropriate treatment approach, which may include repeat DCB, DES implantation, or bypass surgery. Based on our experience, most cases can be effectively managed by repeating DCB coated with a drug different from that previously administered.

Experience at our Cardiology Centre, Bethsaida Hospital, Indonesia

Over the past few years, we have effectively leveraged AI to disseminate educational content, provide evidence-based information on PBD, and curate meal plans tailored for our cardiology patients. The outcomes have been auspicious, with a notable increase in patient adherence to plant-based dietary patterns and significant improvements in overall health outcomes.

At our cardiology centre, we have observed remarkable clinical benefits among our patients. Many individuals with hypertension have successfully discontinued antihypertensive medications following sustained blood pressure normalization. Overweight patients have achieved substantial weight loss, attaining a healthy BMI of 21–22. Similarly, patients with hyperlipidaemia have completed their target LDL-C levels—below 30 mg/dL—through a comprehensive intervention that integrates PBD with high-intensity statin and ezetimibe therapy. Moreover, patients with moderate renal impairment have experienced normalization of their serum creatinine levels, while those with diabetes have demonstrated significant glycaemic control, with glycated haemoglobin (HbA1c) levels consistently below 6%. In numerous cases, many individuals have successfully minimized pharmacological interventions, including insulin cessation [56-65].

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Most notably, our cardiology patients have exhibited the lowest restenosis rate—approximately 2%—with compelling evidence of atherosclerotic stabilization and, in many cases, regression of coronary plaque burden. Despite these remarkable clinical findings, many of our medical colleagues acknowledge these outcomes and remain reluctant to integrate lifestyle medicine into their practice.

To address this gap, we aim to make extensive contributions to the scientific literature, with the aspiration that future generations of clinicians will adopt and disseminate this paradigm-shifting approach. By advancing the integration of lifestyle medicine into mainstream clinical practice, we seek to enhance the standard of patient care and contribute to mitigating and eradicating chronic disease.

Conclusion

Bethsaida Hospital has emerged as a pioneer in integrating PBDs as a core strategy for reducing atherosclerosis and restenosis in interventional cardiology. Our centre's innovative approach—combining state-of-the-art PCI techniques with a comprehensive lifestyle modification program—has yielded unprecedented clinical outcomes, including significantly reducing restenosis rates. Despite mounting scientific evidence supporting the role of PBDs in cardiovascular health, many cardiologists in leading cardiac centres worldwide remain largely unaware of or reluctant to incorporate these findings into routine clinical practice. Our experience underscores the transformative potential of dietary interventions in conjunction with advanced interventional strategies, highlighting the need for a paradigm shift in managing cardiovascular disease. We advocate for increased awareness, research, and implementation of PBD in cardiology to advance patient care and improve global health outcomes.

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