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It's Not Just Narrowing, It's Instability! Why Cardiologists Need to Focus on Plaque Vulnerability, Enhanced by Drug-Coated Balloon Therapy and Whole-Food Plant-Based Diets

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Abstract

Traditional cardiovascular risk assessment primarily focuses on identifying and managing significant luminal stenoses. Emerging clinical evidence, however, increasingly underscores plaque vulnerability (PV) as a superior predictor of acute coronary syndromes (ACS) compared to stenosis severity alone. Advanced imaging techniques, particularly coronary computed tomography angiography (CCTA) and fractional flow reserve derived from computed tomography angiography (FFR-CT), reveal that the characteristics of vulnerable plaque (VP) significantly elevate cardiovascular risk, independent of lesion stenosis severity. This article advocates a paradigm shift toward prioritizing PV in cardiovascular risk assessment, integrating innovative therapeutic approaches such as Drug-Coated Balloon (DCB) therapy and Whole-Food Plant-Based Diets (WFPBD). Observational data from Bethsaida Hospital, guided by Prof. Dasaad Mulijono, involving nearly a couple thousand patients managed with DCB angioplasty combined with WFPBD, demonstrate markedly superior clinical outcomes, including minimal major adverse cardiovascular events (MACE), absence of mortality, significantly lower restenosis rates (2% compared to the national average of 10–20%), and elimination of stent thrombosis. Integrating advanced biomarker assessments [high-sensitivity C-reactive protein (hs-CRP), oxidized LDL, trimethylamine-N-oxide (TMAO), salivary nitric oxide (NO) levels] further enhances predictive accuracy, enabling precise risk stratification and personalized preventive strategies. This comprehensive, biologically focused approach provides a robust framework for revolutionizing cardiovascular care.

Keywords: Plaque Vulnerability; Acute Coronary Syndrome; Coronary Computed Tomography Angiography; Fractional Flow Reserve-Computed Tomography; Drug-Coated Balloon Therapy; Whole-Food Plant-Based Diet; Biomarkers (hs-CRP, TMAO, Oxidized LDL, Nitric Oxide); Cardiovascular Risk Stratification, Preventive Cardiology; Bethsaida Hospital; Prof. Dasaad Mulijono; Restenosis

Introduction

Historically, interventional cardiology has prioritized treating stenotic lesions, assuming that luminal narrowing is directly proportional to cardiac risk [1,2]. However, extensive clinical data reveal that ACS predominantly arises from rupture-prone, non-obstructive plaques rather than severely stenotic lesions [3-11]. This discovery necessitates a reorientation toward PV as the cornerstone of cardiovascular risk stratification.

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Early Study: PV as a Superior Predictor Compared with Stenotic Severity: Evidence from Imaging Studies employed CCTA to assess plaque characteristics and stenosis severity, demonstrating conclusively that VP morphology strongly predicted cardiac event rates [12]. Their findings elucidated:

- Patients exhibiting VP and significant (>70%) stenosis faced a 30-fold greater risk of event rates.
- Those with VP but non-significant (<70%) stenosis still possessed a substantially elevated risk of 25-fold.
- Conversely, significant stenoses without vulnerability markers indicated only a moderate risk elevation of 4-fold.
- Non-VPs with minimal stenosis were associated with a modest 2-fold increased risk compared to normal coronaries. These results compellingly shift clinical focus toward plaque characteristics, such as positive remodelling, low-attenuation lipid cores, and the napkin-ring sign, as critical determinants of adverse outcomes.

The study's limitation was that it did not utilize FFR in its study population. Nevertheless, the population being studied is quite large.

Latest study: Comparison of Event Rates in Patients with and without VP According to FFR-CT Status: This chapter discusses the significant findings of event rates among patients with chronic coronary syndrome (CCS), focusing on the interplay between VP and FFR derived from FFR-CT. The analysis contrasts explicitly patients based on the positivity or negativity of FFR-CT and the presence or absence of VP [13].

Event Rates in Patients with Positive FFR-CT and VP: Patients presenting both positive FFR-CT (<0.80) and VP experienced the highest incidence of adverse cardiac events. Notably, this group's event rate was significantly influenced by the management strategy:

- Without revascularization, the event rate was exceptionally high, at 30-fold.
- Conversely, with revascularization, the rate dropped markedly to 3-fold.

These findings underscore the critical impact of timely revascularization in patients with combined high-risk features (abnormal FFR-CT and VP).

Event Rates in Patients with Positive FFR-CT Regardless of Plaque Status: Considering only FFR-CT positivity, patients demonstrated an overall event rate of 10-fold, reinforcing the clinical importance of abnormal FFR-CT as a standalone predictor of future cardiac events.

Event Rates in Patients with VP but Negative FFR-CT: Patients identified with VP but with a negative FFR-CT (≥0.80) presented an intermediate risk profile, showing a 7-fold event rate. This intermediate risk status suggests that while the presence of VP alone poses a significant risk, the functional severity assessed by FFR-CT further stratifies the risk level.

Event Rates in Patients without Vulnerable Plaque and with Negative FFR-CT: Patients without VP and exhibiting negative FFR-CT showed the lowest risk for adverse cardiac events, at merely 0.5 per 100 vessel-years, which we use for standard comparison. This group represents a significantly safer clinical profile, highlighting the reassuring nature of combined negative structural and functional evaluations.

Integrating structural (VP presence) and functional (FFR-CT) assessments provides crucial prognostic value. Patients exhibiting abnormal FFR-CT and VP carry the highest risk and benefit significantly from revascularization. Patients with VP but negative FFR-CT occupy an intermediate risk category, warranting careful monitoring and potentially preventive management strategies. Conversely, patients negative for both parameters exhibit a remarkably favourable prognosis, supporting conservative management approaches.

Revolutionizing Management Strategies

Integrating DCB Therapy and WFPBD: DCB angioplasty represents an advanced, non-stenting intervention designed to administer anti-proliferative agents directly to atherosclerotic lesions without the use of permanent implants. This approach reduces chronic inflammatory reactions, preserves arterial compliance, and facilitates natural vessel healing. Clinical outcomes from Bethsaida Hospital have demonstrated excellent effectiveness in managing various lesions using DCB technology [14-61], frequently characterized by VP pathology based on CCTA findings.

Systemic modulation through nutritional interventions, particularly utilizing a WFPBD, has gained increasing recognition as an effective strategy for mitigating inflammation, oxidative stress, and endothelial dysfunction—critical factors in the pathogenesis of PV [62-66]. Clinical observations from our institution have consistently demonstrated significant improvements in cardiovascular risk profiles, including marked reductions in lipid levels, inflammatory biomarkers, and indicators associated with cardiovascular risk, such as hs-CRP, oxidized LDL, and TMAO, alongside enhancements in salivary NO levels.

Furthermore, adherence to a WFPBD has substantially improved patient-reported outcomes, particularly in terms of quality of life and dietary adherence, underscoring its practicality and acceptability among patients. Emerging evidence suggests that WFPBD also effectively reduces angina symptoms [67-71]. Based on this clinical observation, we hypothesize that the anti-inflammatory, antioxidative, endothelial reparative, mitochondrial restorative, and vascular smooth muscle inhibitory properties inherent to WFPBD may facilitate a transformation of lesions initially identified

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as fractional flow reserve (FFR)-positive into FFR-negative. Indeed, this will reduce the likelihood of future events.

Additionally, the multifaceted biological effects of WFPBD particularly its capacity to modulate inflammatory pathways, enhance endothelial integrity, inhibit vascular smooth muscle proliferation, counteract oxidative stress, and support mitochondrial function—may collectively contribute to stabilizing VPs. Consequently, we propose that WFPBD interventions hold potential for stabilizing VPs and may also alter the hemodynamic significance of coronary lesions, thereby transitioning lesions from an FFR-positive to an FFR-negative status.

Supporting these hypotheses, observational data from almost a thousand patients undergoing DCB angioplasty and implementing WFPBD at our institution revealed remarkable clinical outcomes. Over follow-up periods extending up to four years, we observed no cases of mortality or stent thrombosis, and an exceptionally low target lesion revascularization (TLR) rate. Notably, our restenosis rate was only 2%, significantly lower than the national average of 10–20%. Furthermore, our strategy minimized the use of dual antiplatelet therapy (DAPT), resulting in zero occurrences of major bleeding events. These results strongly suggest that combining WFPBD with DCB angioplasty enhances plaque stability, improves lesion hemodynamics, and significantly reduces clinical events and complications associated with coronary interventions.

Clinical Parameters for Enhanced Risk Stratification

It is essential to note that specific clinical parameters are crucial for assessing a patient's vulnerability to coronary events. A family history of premature cardiovascular events, uncontrolled hypertension, obesity, type 2 diabetes (including prediabetes), hyperlipidaemia, platelet hyperaggregation, heightened inflammatory states such as autoimmune diseases, and chronic kidney disease should be meticulously assessed [72-77]. These parameters aid in accurately estimating the risk of coronary events and considering the presence of VP and the degree of stenosis identified.

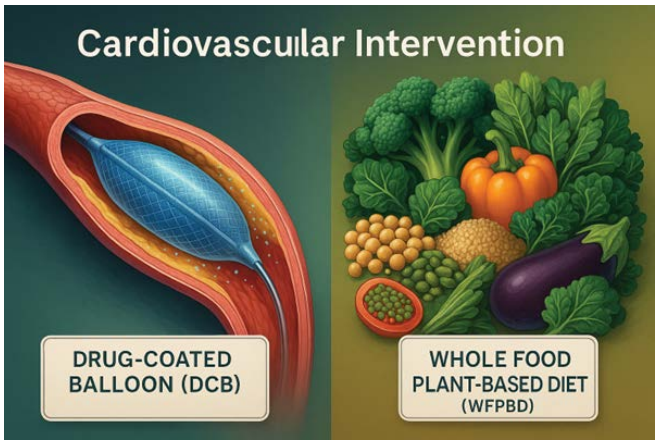
Advanced Biomarkers for Enhanced Risk Stratification: Conventional diagnostic modalities, such as stress tests and angiography, lack sufficient sensitivity for detecting biological precursors of acute coronary syndrome (ACS). Incorporation of targeted biomarkers significantly enhances the prediction and preventive capacity [78-82]:

- High-Sensitivity CRP: Strongly correlated with vascular inflammation and plaque instability, allowing for early identification of high-risk individuals.
- TMAO: A metabolite reflecting gut microbiome health, directly linked to enhanced platelet aggregation and accelerated atherosclerosis.
- Oxidized LDL: Prominent in foam cell formation and endothelial injury; serves as a direct biomarker of PV and progression.
- Salivary NO: This is an endothelial health marker; diminished NO levels indicate endothelial dysfunction and increased cardiovascular risk. Integrated monitoring of these biomarkers can significantly refine clinical decision-making, optimize therapeutic interventions, and offer real-time tracking of treatment efficacy.

Clinical Implications and Future Perspectives

Future cardiovascular care must embody preventive, predictive, personalized, and nutritional strategies. This includes:

- Preventive: Prioritizing early, minimal-risk intervention (DCB) plus WFPBD to halt or reverse disease progression before clinical manifestation.
- Predictive: Functional imaging should be employed as non-invasively as possible, and biomarker profiling should be used to dynamically stratify and monitor patient risk.
- Personalized: Tailoring interventions based on individual biological markers, genetics, lifestyle, and adherence capacities.
- Nutritionally Optimized: Dietary interventions target systemic inflammation and oxidative stress, foundational elements of atherosclerosis and PV. The convergence of these principles through novel therapies, such as DCB, dietary strategies (WFPBD), and biomarker utilization, represents the future of cardiology, potentially transforming the global management of cardiovascular disease.



Conclusion

The evolving understanding of CAD emphasizes PV, rather than stenosis severity, as the pivotal determinant of cardiovascular events. Integrating structural (VP

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presence), functional (FFR-CT), nutritional (WFPBD), and interventional (DCB therapy) assessments significantly refines cardiovascular risk stratification and management. Observational experiences from Bethsaida Hospital robustly support the combined implementation of DCB angioplasty and WFPBD, resulting in remarkable clinical outcomes, including substantial reductions in restenosis, no mortality or stent thrombosis, and marked improvements in inflammatory and metabolic profiles. Advanced biomarkers (hs-CRP, TMAO, oxidized LDL, and salivary NO) are critical for monitoring therapeutic efficacy and predicting cardiovascular events. Embracing this integrative, preventive, and personalized approach, rooted in PV and holistic cardiovascular care, represents a transformative shift with potential global implications for significantly improving patient outcomes and reshaping cardiovascular disease management paradigms.

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