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INTERVENTIONAL CARDIOLOGY: AN OVERVIEW OF CURRENT APPLICATIONS, CHALLENGES, AND FUTURE PATHWAYS – THE ERA OF AI-ASSISTED PCI?

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ABSTRACT

Background: Interventional cardiology, which began in 1977, has evolved from primitive balloon angioplasty to sophisticated drug-eluting stents, fundamentally altering the treatment of coronary artery disease. We have reached a plateau in stent performance, where successive generations do not bring spectacular leaps forward. Consequently, the focus is shifting away from finding a universal gold standard toward a tailored, patient-specific approach that integrates a variety of revascularization strategies.
Methods: A comprehensive search was conducted in the PubMed, Scopus, and IEEE Xplore databases to identify relevant publications from January 2005 to October 2025. The search strategy employed combinations of the following keywords: "Percutaneous Coronary Intervention", "Fractional Flow Reserve", "Intravascular Ultrasound", "Artificial Intelligence", "Optical Coherence Tomography", "Coronary Artery Disease" and "Regulation"
Results: Interventional cardiology is moving away from purely mechanical innovations toward a future defined by information integration, advanced visualization, and data-driven procedures. However, widespread implementation faces significant obstacles: difficulties in scaling technology, funding constraints, and complex legal requirements for data collection for artificial intelligence algorithms.
Conclusion: It appears that despite regulatory and economic challenges, the field is inevitably moving from an era of simple tools to true partners, slowly considering at least partial autonomy in decision-making.

KEYWORDS

Percutaneous Coronary Intervention, Artificial Intelligence, Coronary Artery Disease, Clinical Decision Support

CITATION

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1. Introduction: The Plateau of Mechanical Revascularization

The discipline of interventional cardiology has come a long way since Andreas Grüntzig performed the first percutaneous coronary intervention (PCI) in 1977 (Castaldi et al., 2025). What began as a bold, mechanical attempt to dilate stenotic vessels using primitive balloon catheters, evolved into a sophisticated, technology-driven specialty that forms the cornerstone of treatment for ischemic heart disease. The transition from plain old balloon angioplasty (POBA) to bare-metal stents (BMS) in the 1990s, and subsequently to drug-eluting stents (DES) in the early 2000s, fundamentally altered the natural history of coronary artery disease (CAD). These innovations have gradually increased the effectiveness of treating increasingly complex lesions and dissections, while significantly alleviating the chronic problem of neointimal hyperplasia, consequence of early interventions (Azzi et al., 2021).

However, as we move into the third decade of the 21st century, the field faces a new existential challenge: the "stent performance plateau". Over the years, procedural techniques have been optimized to improve both safety and clinical outcomes. The introduction of drug-eluting stents significantly reduced the incidence of in-stent restenosis. However, it remains a persistent clinical challenge that often leads to repeat interventions or adverse cardiac events (Arh et al., 2025). Various combinations of platforms, polymers, and anti-proliferative drugs have been evaluated, with generally comparable results and no clear superiority demonstrated. We have seen the development of new technologies, including drug-coated balloons, bioresorbable scaffolds and gene-eluting stents. Since no single modality has proven to be definitively superior, the pursuit of the gold-standard therapy endures. Current evidence suggests that the optimal strategy may lie in a tailored, patient-specific approach that integrates various revascularization techniques.

The contemporary approach is based largely on the operator's visual assessment of two-dimensional angiographic images to treat complex three-dimensional biological structures. This reliance on the luminogram obtained by angiography seems to ignore the heterogeneous composition of atherosclerotic plaque, the biomechanical forces exerted by the stent on the vessel wall, and the physiological significance of intermediate stenoses (Bacigalupi et al., 2024, Ali et al., 2024). Advances in stent manufacturing have meant that current inefficiency is much more likely to be caused by limitations in the implantation process than by stent technology, in particular due to insufficient expansion, incorrect positioning, and incorrect placement, which are difficult to detect and predict in standard angiography (Ali et al., 2024).

In fact, we are on the cusp of a potential new revolution in interventional cardiology. A transition from mechanical revascularization to computer-assisted, robotic preventive medicine. The integration of artificial intelligence (AI), more accurate imaging, and robotics into the cardiac catheterization lab.

We can aim to break the impasse in outcomes with the help of deep learning (DL) for image analysis, computational fluid dynamics (CFD) for physiology, and, in subsequent steps, semi-autonomous robotics (Castaldi et al., 2025, Collet et al., 2018).

This paper is based on a narrative review of the scientific literature examining current standards in percutaneous coronary interventions, analyze limitations, examine specific mechanisms and validation of tools based on new technologies, aims to discuss the profound ethical and regulatory challenges that accompany the advent of the era of artificial intelligence assistance. A comprehensive search was conducted in the PubMed, Scopus, and IEEE Xplore databases to identify relevant publications from January 2005 to October 2025. The search strategy employed combinations of the following keywords: “Percutaneous Coronary Intervention”, “Fractional Flow Reserve”, “Intravascular Ultrasound”, “Artificial Intelligence”, “Optical Coherence Tomography”, “Coronary Artery Disease” and “Regulation”. This review synthesizes findings from peer-reviewed literature, emphasizing conceptual frameworks, large-scale clinical investigations, and systematic reviews published in high-impact journals.

2. The Current Standard of Care

The recently published ESC guidelines on chronic coronary syndromes provide new insights on decision-making regarding coronary intervention. Increasing importance is being placed on determining the full functional impact of coronary artery disease (CAD) before considering coronary intervention using FFR or iFR (Vrints et al., 2024). The role of intravascular imaging in the management of percutaneous coronary intervention is increasing, especially in complex lesions - the modern percutaneous coronary intervention (PCI) workflow seems to be a triad of angiography, intravascular imaging (IVI), and physiological assessment. However, this has its limitations, based on the lack of a complementary approach, technical difficulties, and operator variability.

2.1 Limitations of Angiography and Operator Variability

Coronary angiography is a basis method, that allows the operator to assess blood flow and perform the procedure. It provides a two-dimensional image of the vessel lumen, created by injecting contrast. Coronary angiography allows for excellent assessment of significant vessel stenosis, but it has major drawback - accuracy. The assessment is always based on the operator's experience, which may imply inaccuracy, especially in the case of tight stenoses. What is more, the two-dimensional nature of the imaging forces the operator to operate in different planes, which can be difficult, especially in complex lesions, lesions including bifurcations, left main disease and long lesions.

- Image limitations: angiography shows only the lumen of the vessel, without its wall. It does not visualize atherosclerotic plaques - it confirms the presence, ignoring their composition and exact thickness. The complex interactions between development, progression, and rupture of atherosclerotic plaque lead to CAD, and knowledge about them is still incomplete (Chen et al., 2006). It is not particularly helpful in diagnosing myocardial infarction with non-obstructive coronary arteries (MINOCA), due to culprit lesions that are not clearly visible on angiography (Ugo et al., 2025).
- Differences between observers: the interpretation of angiographic stenosis is known to be subjective. Studies have repeatedly shown significant disagreement among operators in the assessment of diameter stenosis, expressed as a percentage (Mitsis et al., 2024). Inaccuracy at this point extends to further steps - visual selection of stent length and diameter can lead to undersizing (which increases the risk of restenosis) or oversizing (increasing the risk of vessel rupture). Intraprocedural prediction of outcomes is difficult in this context.
- Functional Disconnect: a stenosis visible on angiography may not fully correlate with clinical symptoms. On the one hand, hemodynamic significance matters, and on the other - even a visually tight stenosis may not cause ischemia if collateral circulation is strong. There may also be lesions proving to be lethally ischemic, although their nature in imaging does not suggest this. These are fluctuations that cannot be assessed without physiological assessment of flow (Xie et al., 2025).

2.2 Limited Use of Intravascular Imaging

Intravascular imaging methods, specifically Intravascular Ultrasound (IVUS), Optical Coherence Tomography (OCT) and near-infrared spectroscopy (NIRS), were developed to overcome the limitations of angiography. They have become valuable tools in modern interventional cardiology, providing detailed insight into coronary anatomy, plaque characteristics and procedural guidance during percutaneous coronary intervention – gradually becoming and integral part of the procedures (Mitsis et al., 2024).

- IVUS: a method introduced in the early 1990s that provides high-resolution cross-sectional images of coronary arteries. It allows for detailed assessment of vessel dimensions, plaque morphology, and luminal stenosis. IVUS, due to significant improvements over the years, is now widely accessible in clinical practice to assess lesions, optimize stents, and guide PCI. It uses high-frequency sound waves (20-40MHz), providing cross-sectional images of arteries with an axial resolution typically ranging from 100 to 250µm (Hoang et al., 2016). Two types of IVUS are in use: mechanical and electro-optical. The first uses a rotating transducer, the second - a fixed transducer with a rotating mirror. The use of a mirror reduces operator variability at the expense of slightly lower resolution and higher costs. Based on the echo density, atherosclerotic plaques can be assigned certain characteristics, indicating, among other things, the risk of detachment.
- OCT: a method introduced in the early 2000s (Terashima et al., 2012), utilizing near-infrared light at a wavelength of 1310nm. Due to significant increased resolution in comparison to IVUS, it allows for the detailed characterization of atherosclerotic plaque morphology, including measurement of fibrous layer thickness - critical for identifying plaques that are susceptible to rupture (Mitsis et al., 2024).
- NIRS: a novel method, providing information about lipid content within coronary plaques. NIRS is useful for identifying lipid-rich plaques, which are associated with an increased risk of plaque rupture and acute coronary syndrome (ACS), particularly when used as a complement to other intravascular methods (Erlinge et al., 2021).

Despite the clear advantages of these methods in visualizing pathology and reliable clinical trial data, their use remains low. Even in the high-risk population of left main PCI, intracoronary imaging (ICI) is used in only 66% of cases (Chandramohan et al., 2024). There is still a belief that it prolongs the procedure without offering any significant benefits. Moreover, it places an additional load on contrast (Ali et al., 2024).

- Training requirements: A significant barrier appears to be the combination of money, time, and practice. Extensive staff training, which can sometimes be a financial barrier. This gap between data availability and the ability to interpret it is a perfect entry point for artificial intelligence.

2.3 The Physiological Burden and Occupation Safety

The current practice of interventional cardiology also involves considerable physical strain for the operator. The need to stand at the tableside, in close proximity to the X-ray lamp, requires the wearing of heavy lead protective aprons.

- Orthopedic complications: long-term use of heavy lead aprons leads to injuries, and as a result - lost workdays and decreased performance (Durand et al., 2024).
- Radiation risks: despite the use of shields, operators are exposed to chronic exposure to scattered ionizing radiation. The As Low As Reasonably Achievable principle is difficult to maintain during complex, prolonged procedures. The use of robotic assistance PCI has shown a dramatic reduction in radiation exposure for the primary operator, with slight increase in duration of the procedure (Durand et al., 2024).
- Cognitive fatigue: The combination of physical discomfort, pressure to shorten the procedure, and the need to manage hemodynamic instability leads to cognitive fatigue, which can result in an increased frequency of errors.

The combination of the above limitations is a strong argument for considering the integration of robotic assistance on the one hand and AI-based decision support on the other.

3. The Computational Revolution: AI in Diagnostics and Physiology

AI is becoming increasingly established in the minds of scientists, and its application in interventional cardiology is rapidly moving from theoretical research to proven clinical tools. One of the areas that seems to be benefiting most from this partnership is the possibility to simulate real-time fractional flow reserve (FFR) values without the use of invasive pressure catheters or hyperemic agents. Using AI, angiography data based on computed tomography (CT) can significantly expedite the interpretation of invasive coronary angiography results (Khelimskii et al., 2024).

3.1 Quantitative Coronary Analysis and Automated Segmentation

Traditional quantitative coronary analysis (QCA), time-consuming manual contouring of the vessel lumen, was too slow for routine clinical use. Efforts have been made to use it for surgical planning (Zhang, 2010). In recent years, deep learning has become the most commonly used method for heart image segmentation – including magnetic resonance imaging (MRI) and computed tomography (CT). AI models trained on thousands of annotated angiograms can now perform frame-by-frame semantic segmentation of the coronary tree in real-time, with instant calculation of vessel diameter, lesion length and percent stenosis. (Chen et al., 2020).

3.2 Angiography-Derived FFR and CT-FFR

Recently published ESC guidelines on chronic coronary syndromes emphasized the importance of fully characterizing the functional impact of coronary artery disease (CAD) before considering coronary interventions using fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) (Vrints et al., 2024). Invasively measured FFR is considered the clinical standard for hemodynamic assessment of coronary lesion significance. Despite its advantages, the method is largely underutilized in clinical practice due to its invasive nature, potential procedural complications, additional costs, the need for hyperemic agents, and the requirement for trained personnel. In contrast, non-invasive FFR calculation appears to be free of many of these disadvantages. Coronary CT angiography (CCTA) is an established non-invasive technique for the detection of coronary stenosis and plaque. However, conventional CCTA appears to tend to overestimate the degree of coronary stenosis. It also does not provide functional information, which is crucial for treatment decisions in clinical settings (Guo et al., 2024). The study compared the effectiveness of angio-FFR and CT-FFR in detecting hemodynamically significant aortic stenosis - both methods were found to be very accurate in detecting dangerous arterial stenosis, but angio-FFR performed slightly better, with greater specificity. Both Angio-FFR and CT-FFR can be effective and efficient tools for detecting cardiac ischemia without the need for invasive catheterization (Guan et al., 2023).

3.2.1 Mechanisms of Action

To create a 3D mesh of the vessel lumen, the operator performs at least two projections for a given vessel, at an angle of 30-90 degrees.

1. 3D Reconstruction: Using an algorithm, the software combines the two views to create a volumetric model of the artery, correcting for perspective distortion.
2. Flow Estimation: the software estimates flow based on the speed at which contrast fills the vessel or uses generic boundary conditions based on vessel mass (Collet et al., 2018).
3. Pressure Drop Calculation: software builds the 3D reconstruction based on provided angiograms and assesses the pressure drop across the stenosis. Quantitative coronary angiography (QCA) is used to determine the vFFR value. This allows for both anatomical and functional assessment of the stenosis (Duarte et al., 2021).

3.2.2 Clinical Validation

Latest ESC guidelines, in individuals with suspected CCS and low or moderate (>5%–50%) pre-test likelihood of obstructive CAD, CCTA is recommended to diagnose obstructive CAD and to estimate the risk of MACE (Class Ia) (Vrints et al., 2024). It appears that fractional flow reserve based on coronary computed tomography angiography (FFR-CT) may be complementary to CCTA (coronary CT angiography), providing calculated FFR values throughout the entire coronary tree. FFR-CT shows good agreement with invasive FFR measurement and has clinical utility, leading to a reduction in unnecessary invasive coronary angiography (ICA) procedures (Serruys et al., 2023). A major limitation is the lack of widespread availability and the fact that the accuracy of the calculations depends on image quality. The latest devices allow for a satisfactorily low rejection rate. (Celeng et al., 2019)

3.2.3 The CT-First Strategy

The evidence is in favour of CCTA: the SCOT-HEART study showed a small but statistically significant reduction in the composite endpoint of cardiovascular death or non-fatal myocardial infarction (from 3.9% to 2.3% during 5 years of follow-up) in patients who underwent CCTA (coronary computed tomography angiography) as a supplement to routine tests (electrocardiographic stress test). The mere knowledge of what the arteries looked like (even if the narrowing was not critical) led doctors to start treatment and motivate patients to change their lifestyle, what prevented future heart attacks (Newby et al., 2018).

4. AI in Intravascular Imaging

Based on the physiological assessment, we decide whether to implement treatment. Intravascular imaging shows us how to do it. In commonly available OCT and IVUS systems, there seems to be room for the use of machine learning algorithms to assist operators in the intraoperative analysis of the obtained images. These efforts will ensure that even in smaller medical centers, operators will have a full range of support tools at their disposal (Ihdayhid et al., 2024).

4.1 AI-OCT: The Ultreon™ System

The use of optical coherence tomography (OCT) in percutaneous coronary intervention (PCI) has limitations, requiring experience in real-time image interpretation. Ultreon™ 2.0 software, supported by artificial intelligence (AI), facilitates this task - in a study conducted on both experienced and inexperienced operators, a reduction in the time to first fixation, reduced total task time and increased dwell time in the area of interest (Cioffi et al., 2023). The software uses a convolutional neural network, trained on annotated OCT frames, to detect specific morphological features. The algorithm automatically identifies the external elastic layer (EEL) through the vessel wall to determine the optimal stent sizing and plan for precise stent placement. Furthermore, it takes into account the detected calcium.

4.2 AI-IVUS: Automated Tissue Characterization

Intravascular ultrasound (IVUS) has historically relied on gray scale interpretation. Steps have been taken to use intravascular ultrasound radiofrequency (IVUS-RF) to provide more information for evaluation of atherosclerotic plaque composition, and morphometry can provide insight into the biology of atherosclerotic plaque and the mechanisms of plaque-related thrombosis. Modern AI approaches apply deep learning to standard IVUS images to achieve this with greater accuracy. AI-assisted atherosclerotic plaque assessment provides rapid, reproducible, and comprehensive analysis of coronary artery imaging, but large multicenter studies are still needed (Pinna et al., 2025).

5. Robotic-Assisted PCI

We have already discussed the possibilities for prevention, preparation for surgery, and intraoperative imaging. AI can be a significant assistance in diagnosis and planning. However, it is also worth considering the possibilities offered by modern robotics. Something that seemed like a utopian dream two decades ago is now becoming a real possibility. We have come a long way from simple remote control tools to semi-automatic ones, chasing achievements in the field of surgical robots.

5.1 Current Robotic Platforms

One of the firsts commercial systems that have made their debut on the market was CorPath GRX - developed in 2012, provided by Siemens. Initial studies were promising, demonstrating the safety of robot-assisted PCI. This allowed for reduced radiation exposure to the patient and operator, no increase in contrast use, and a slight increase in procedure time. Unfortunately, in May 2023, Siemens announced its transition to neurosurgical interventions (Durand et al., 2024).

In 2019, the first patient was operated on using a R-one robotic system (Robocath), dedicated for PCI. The preliminary results are encouraging, but further studies on larger populations and more complex lesions are needed (Durand et al., 2023).

5.2 Clinical Evidence: Safety and Precision

The main factor driving the development of this technology was safety, but the precision of the procedure is also promising. Subsequent studies confirm this reduction in radiation exposure for the interventionalist (Gupta et al., 2024, Durand et al., 2023). The use of biomechanics allows for increased implementation accuracy, unattainable with a hand-operated tool. A propensity-matched analysis comparing R-PCI with manual PCI showed no significant difference in the annual incidence of MACE or mortality, confirming the safety of the robotic approach. Although procedure time and fluoroscopy time were slightly longer in the robotic group, contrast volume was often reduced due to improved catheter stability (Gupta et al., 2024).

5.3 Telerobotics: The Remote PCI

Further improvements may allow procedures to be performed remotely, with virtually no distance limitations. A study was conducted involving endovascular surgery based on a pre-planned algorithm. The method required considerable preparation, but proved that automated robotic EVAR can be performed with acceptable accuracy and safety, providing standard therapies, shortening operation times, and reducing patient exposure to radiation (Liang et al., 2025). Will the PCI be next?

6. Predictive Modeling: The Era of "In Silico" Medicine?

The combination of high-resolution imaging and AI has given rise to the concept of the digital twin - a patient-specific virtual replica used for simulation and risk stratification (Thangaraj et al., 2024).

6.1 The Digital Twin in Structural and Coronary Interventions

Digital twins enable virtual stenting of coronary arteries - operators can simulate the placement of stents of different sizes and lengths to predict stresses in the stent struts and the vessel wall. This allows for maneuvering of size and the balloon pressure to obtain satisfactory results. The knowledge of these parameters might give insights in the understanding of the process of restenosis (Gijsen et al., 2008).

6.2 Machine Learning for Risk Stratification

Traditional models are based on linear regression models derived from older cohorts. They often fail to capture the non-linear interactions of biological variables. Machine learning (ML) models, involved in the calculations of In-Stent Restenosis (ISR), can integrate variables such as stent diameter, length, diabetes status, and BMI – pursuing to predict the risk of ISR. This allows for a process, where a patient can be informed of their specific, personalized risk of failure before the procedure (Cui et al., 2023, Rudnicka et al., 2024).

7. Challenges, Ethics, and Barriers to Adoption

Despite the enormous potential of artificial intelligence and robotics, the transition to new technologies is not going smoothly. The field is subject to numerous regulations designed to protect patient safety. In addition to legislation, there are technical, economic, and ethical obstacles that must be overcome (Ong et al., 2024).

7.1 The Lack of Transparency

Deep learning models are inherently non-transparent. Due to the way they are trained and their multi-layered nature, scientists do not know the algorithm's thought process. They see the input data (e.g., patient group parameters) and then the output (e.g., the prediction of the chance of restenosis). It is not entirely clear which factors proved to be crucial (Karim et al., 2023). Clinicians, trained to rely on pathophysiology, are unwilling to trust algorithms they cannot examine (Ueda et al., 2024). Explainable artificial intelligence techniques, such as saliency maps (which highlight pixels in an angiogram that triggered the AI's action), are essential for building trust, but are still in development. AI bias is a major problem - an algorithm is only as good as its training material is diverse. With legal restrictions in mind, but also the cost of developing huge databases, developers sometimes have to accept compromises (Ratwani et al., 2024).

7.2 Data Privacy and Infrastructure

Training resilient AI requires huge, centralized data sets. However, patient health information is protected by strict regulations such as GDPR (Europe) and HIPAA (US). A possible solution is a country-wide system that would standardize data collection methods, leading to an anonymized national database. This would enable researchers to develop better algorithms, raising the standard of care. However, legislators are slow to act, failing to keep pace with scientific developments (Patel et al., 2025).

7.3 Economic Barriers

There are several issues that need to be addressed. The upfront cost of innovation can be significant: robotic systems have a high capital cost. Although long-term analyses suggest cost-effectiveness, the entry threshold is high for non-academic centers (Gupta et al., 2024). At this stage of technological development, some AI-based tools may not prove successful. Hospitals are effectively becoming founders - and only the largest centers can afford to do so (Zhao et al., 2025).

7.4 Regulatory Pathways

Regulatory authorities commonly recognize the medical use of AI algorithms as SaMD - Software as a Medical Device (Oloruntoba et al., 2024, Yu et al., 2023). While the FDA remains reluctant to accept algorithms that learn during operation (as opposed to “locked” algorithms that use DL during development), we are seeing some flexibility. It is worth mentioning Neuralink, a brain-computer interface, approved by the U.S. Food and Drug Administration for clinical human trials (Parikh et al., 2024).

7.5 Legal Liability

With increasing autonomy, devices that were previously considered tools in the hands of the operator may become both the cause and the perpetrator of errors. The question of where the line should be drawn seems critical. If not the operator, then who: the robot, the manufacturer, or the hospital? These challenges have only recently become real, and legislators seem to be facing a regulatory gap. It appears that the concept of final confirmation by the operator is becoming the current solution, but not for long (Hedderich et al., 2023, Prabhakar et al., 2021).

8. Conclusion: The Integrated Future of Interventional Cardiology

Interventional cardiology is currently undergoing a paradigm shift. The era of purely mechanical innovations - defined by thinner stents and better polymers - has brought diminishing returns. The future seems to lie in the growing integration of information - extended pre-diagnostics, intraoperative visualization, and then the use of this data in the implementation of mechanized procedures. In all these fields, we are seeing achievements whose pace, for the first time in history, depends solely on funding - the technology is available, it “only” needs to be implemented.

But is it really “just” a matter of implementation? Experience shows that scaling technology from firsts, small operating rooms to widespread availability, and above all, widespread functionality, seems to be a difficult path. Some of the tools seem to fail the final test, while others, such as Siemens' CorPath GRX robot, despite initial successes, are being redirected to other fields. One thing is certain: the impact of new technologies on interventional cardiology shows no signs of abating and brings measurable benefits.

Legal requirements appear to be one of the major obstacles, on the one hand to the implementation of technology, and on the other to efficient data collection. Algorithms using DL require vast amounts of well-prepared, anonymized data, used with respect for the patient.

Although economic and regulatory friction will determine the pace of this adaptation, the trajectory is clear. We are moving from the era of the “master craftsman” to the era of the “information-assisted pilot.” For the patient, this heralds a future in which the outcome of a procedure depends less on the variability of human hands and eyes and more on the consistent, data-driven precision of intelligent systems.

Disclosure

Authors’ contribution:

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