

Overview Of Technical And Cost Considerations In Complex Percutaneous Coronary Intervention

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Abstract

Complex percutaneous coronary intervention (PCI), encompassing an ever-expanding range of challenging lesion sets and patient populations, accounts for a significant proportion of PCI procedures being performed currently. Specific lesion types associated with lower rates of procedural success and higher rates of recurrence or major adverse cardiac events (MACE) include multivessel disease, unprotected left main coronary artery disease, fibrocalcific or undilatable lesions, chronic total occlusions, degenerated saphenous vein graft lesions, thrombotic lesions, and bifurcation disease. Validated tools and technical strategies currently exist to address most procedural scenarios encountered and should be familiar to the complex PCI operator. Anticipated clinical outcomes, projected resource utilization, and cost considerations should all factor into the decisions of when, how, and in whom to intervene.

Keywords

Percutaneous coronary intervention, complex coronary artery disease, bifurcation lesion, multivessel disease, drug-eluting stents, cost-effectiveness

Disclosure

J Raider Estrada, MD, and Jonathan D Paul, MD, have no conflicts of interest to declare. Atman P Shah, MD, is a Consultant/on the speakers bureau for Medtronic, Abbott, and Maquet. Sandeep Nathan, MD, MSc, is a Consultant/on the speakers bureau for Medtronic, Boston Scientific, and Maquet.

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While the breadth of procedural offerings in interventional cardiology (IC) has exponentially expanded over the past four decades to include cardiac structural, peripheral arterial, and venous interventions, percutaneous coronary intervention (PCI) remains at the core of the field, accounting for the greatest percentage of therapeutic catheter-based procedures performed by IC practitioners in the US. Beginning with the historic series of coronary angioplasties performed by Dr Andreas Grüentzig in 1977, PCI has steadily advanced in its range of application and technical sophistication.^{1,2} Shortly after the landmark procedures were performed and reported at the Annual Scientific Sessions of the American Heart Association in 1977, a percutaneous transluminal coronary angioplasty (PTCA) registry was established at the National Heart, Lung and Blood Institute (NHLBI) in order to track the expansion, progress, and outcomes of this then fledgling procedure.^{3,4} Dorros and colleagues reported on clinical outcomes and complications in the first 1,500 patients undergoing

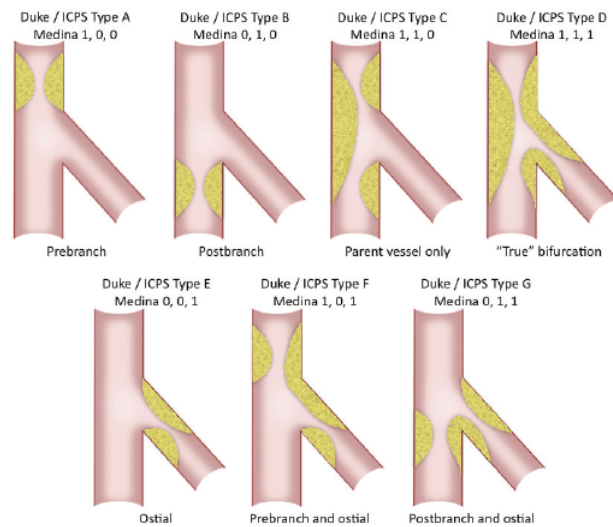
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Figure 1: Duke/ICPS (SYNTAX) and Medina Bifurcation Classification Systems



The SYNTAX bifurcation classification combines elements of both the Duke and Institut Cardiovasculaire Paris Sud (ICPS) systems, assigning letter designations A–G to the various patterns of obstructive plaque shown above. In the Medina classification of coronary bifurcation lesions, a binary value is assigned depending on the presence (1) or absence (0) of stenosis in each of three lesion segments: prebranch parent vessel, postbranch parent vessel, and side branch ostium, yielding a 3-digit sequence separated by commas.

systems, additive or multiplicative numerical values are assigned via a computerized algorithm to each obstructive lesion noted, based on dominance, number of lesions, segments involved per lesion, and six additional groups of queries relating to lesion characteristics (see Table J).¹³ The total SYNTAX score represents the sum of the individual lesions scores and has prognostic value independent of medical comorbidity and other patient-specific metrics. In the SYNTAX trial, which randomly assigned 1,800 patients with multivessel or left main coronary artery (LMCA) disease to coronary artery bypass graft (CABG) surgery versus PCI with DES, higher scores portended poorer outcomes with multivessel PCI.^{13–15}

Challenges in contemporary catheter-based therapy for CAD generally stem from one or more of the following factors: the extent, severity, distribution, and characteristics of the coronary lesions, number of vessels diseased, LMCA involvement, presentation acuity and procedural urgency, burden of ischemia, hemodynamics/ventricular function, and medical comorbidities. Specific lesion sets that are associated with lower rates of procedural success and higher rates of recurrence or major adverse cardiac events (MACE) include multivessel disease, unprotected LMCA disease, fibrocalcific or undilatable lesions, chronic total occlusions, degenerated saphenous vein graft lesions, thrombotic lesions, hemodynamically unstable patients, and bifurcation/trifurcation disease. Broad technical considerations relevant to each of these lesion subtypes are summarized in Table 2, with bifurcation disease also addressed below in greater detail. In a published Dynamic Registry PCI experience that predated the advent of DES, the majority (55.1 %) of attempted lesions fulfilled at least one of the aforementioned criteria for complexity with over a quarter of lesions demonstrating two or more complex characteristics.⁷ Similarly, following the introduction of DES in the US in 2003, investigators from the EVENT (Evaluation of Drug Eluting Stents and Ischemic Events) Registry found that the majority (60.2 %) of intervened lesions fulfilled either ACC/AHA B2 or C lesion criteria.¹⁶ Thus, a large proportion of contemporary PCI procedures invoke some measure of technical complexity. While it is beyond the scope of this article to discuss each of the aforementioned complex lesion subtypes in detail, suffice it to say that tools and validated strategies currently exist for each scenario listed. It is incumbent upon the operator aspiring to tackle complex disease in the catheterization laboratory, to gain intimate familiarity with these data and technical strategies.

Table 2: Technical Considerations Relevant to Various Complex Lesion Subtypes

	Major Concerns	Tools	Technical Approach
Multivessel disease	Objective assessment of lesion severity, selection of lesions, complete revascularization, renal function, cost concerns	Non-invasive assessment of ischemia, FFR, DES with adjunctive lesion preparation tools, intravascular imaging	SYNTAX score to guide case selection, FFR- or ischemia-guided PCI, staging of multivessel PCI when appropriate
Unprotected left main coronary artery disease	Objective assessment of lesion severity/extent, stent sizing and apposition, bifurcation/ trifurcation disease	DES, intravascular imaging, mechanical circulatory support (when necessary)	Selection of ostial and mid-shaft lesions versus distal bifurcation/trifurcation, bifurcation techniques when necessary
Fibrocalcific disease	Inability to dilate lesions, pass devices Inability to fully expand stents	Rotational atherectomy, orbital, atherectomy cutting/scoring balloon angioplasty	Lesion debulking/plaque modification with atherectomy, cutting/scoring balloon use
Chronic total occlusions	Inability to traverse occluded segment or advance therapeutic devices	Specialty wires, large-bore guide catheters, guide catheter extensions, subintimal dissection re-entry tools, microcatheters, DES	Wire escalation/microcatheter support, subintimal tracking and re-entry, reverse CART
Degenerated saphenous vein graft disease	Distal atheroembolization, 'no reflow,' high restenosis, aggressive disease progression	Distal embolic protection devices, intracoronary vasodilators, DES	Use of embolic protection filters and pre-treatment of graft with vasodilators, covering length of entire diseased vessel with DES
Thrombotic lesions	Thromboembolization, 'no reflow,' sidebranch compromise, stent malapposition, and thrombosis	Aspiration thrombectomy catheters, rheolytic thrombectomy, platelet GPI	GPI use and thrombectomy prior to stent implantation, intravascular imaging to confirm DES sizing/apposition
Hemodynamically unstable patients	Hypotension/hypoperfusion, ventricular arrhythmias, circulatory collapse	IABP, mechanical circulatory support devices (TandemHeart [®] , Impella [®] , ECMO/ECLS)	Early use of mechanical circulatory support devices in patients with hemodynamic compromise
Bifurcation lesions	Complete lesion/ostial coverage, side branch compromise, restenosis/thrombosis, DES usage	Dedicated bifurcation stent (outside of US), DES, intravascular imaging	Mandatory vs. provisional side branch stenting techniques, 1 vs. 2 vs. 3 DES techniques, lesion debulking

CART—controlled antegrade and retrograde subintimal tracking; DES—drug-eluting stent; ECMO/ECLS—extracorporeal membrane oxygenation/life support; FFR—fractional flow reserve; GPI—glycoprotein inhibitor; IABP—intra-aortic balloon pump; PCI—percutaneous coronary intervention. 1. CardiacAssist, Pittsburgh, Philadelphia; 2. Abiomed, Danvers, Massachusetts.

Bifurcation Disease Classification and Percutaneous Intervention Options on this page you are giving your consent for us to set cookies.

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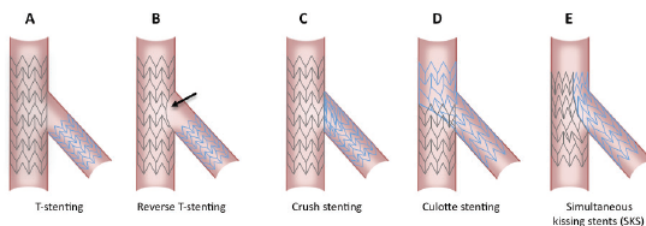
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consideration as it is encountered frequently, accounting for 15-25 % of PCIs in some series, and has been associated with higher-than-average technical complexity and lower success rates.^{7,17,18} Optimal percutaneous treatment of bifurcation disease is guided by an extensive body of bench and clinical investigation with available data bearing out the potential consequences of inappropriate treatment, such as restenosis and/ or thrombosis of one or both vessels involved. Multiple bifurcation classification systems have been developed with the common goal of clarifying optimal interventional strategy and predicting complication risk.¹⁷⁻²⁰ All schemas quantify the extent and location of plaque burden with some also incorporating the angle between parent and daughter vessel. The SYNTAX bifurcation classification, modified from the wellknown Duke and Institut Cardiovasculaire Paris Sud (ICPS) criteria, along with the Medina classification, representing a contemporary, simplified system, are shown in *Figure 1*.^{13,20,21} Side branch angulation is missing from both of these classification systems, although it is now well-recognized as an additional metric with important prognostic value.²¹ Whichever the system applied, 'true' bifurcation disease is characterized by obstructive disease in the parent vessel, pre- and post-side branch, as well as obstructive disease within the ostium of the side branch.

Even more numerous than bifurcation classification systems are the technical approaches described to date, varying widely in terms of the number of stents mandatorily used, completeness of coverage of the side branch ostium, and procedural complexity. A consensus classification of families of bifurcation techniques was proposed by the European Bifurcation Club (EBC) some years ago.^{21,22} This system, referred to as the MADS classification, is an acronym with each letter corresponding to a different choice for first vessel/segment addressed and approach to initial stent deployment. 'M' stands for Main proximal vessel first, 'A' for main Across side branch first, 'D' for Distal first, and 'S' for Side branch first. Various bifurcation techniques, including those double-stent techniques detailed in *Figure 2* along with several others, are categorized under each lettered group and further broken out by the use of one, two, or three stents. Two-stent techniques that do not insure complete side branch coverage include the variations on the T-stent technique (see *Figure 2*) including classical and reverse T-stenting. More advanced techniques that allow for complete side branch coverage include variations on crush stenting, culotte stenting, and classical or modified simultaneous kissing stent (SKS) techniques.^{17,20,22}

Figure 2: Commonly Used Double-stent Bifurcation Techniques

Figure 2: Commonly Used Double-stent Bifurcation Techniques



A. 1-stenting; B. Reverse 1-stenting; C. Crush; D. Culotte; E. Simultaneous kissing stents (SKS).
Diagrammatic representations of bifurcation stenting techniques grouped by incomplete/ absent side branch ostial coverage (A, B) versus complete ostial coverage (C, D, E). Note in Figure 2B, the side branch stent is placed in a provisional fashion and therefore requires dilatation of a cell of the parent vessel stent to allow passage (arrow).

strategy using provisional side branch stenting, when feasible, is superior to complex (double stent) strategies with respect to rates of myocardial infarction and stent thrombosis.²³⁻³¹ If a satisfactory angiographic result is obtained with parent vessel stenting ± side branch ballooning, forgoing side branch stenting is appropriate based on the available data and, moreover, will save on procedural time and cost, radiation exposure, and contrast usage.^{17,20-22} As fractional flow reserve (FFR) was demonstrated to be an important discriminatory tool for guiding the performance of single- or multivessel PCI in the Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 (FAME-2) study, so too has the value of FFR been demonstrated in assessing the functional significance of jailed side branch stenoses.³² Ahn et al. studied 230 jailed side branch stenoses in bifurcation lesions where main vessel stenting was performed and found that only 17.8 % of jailed side branch lesions were associated with functional significance (FFR <0.80).³³ Moreover, visual discrimination of 'significant' side branch stenoses by angiography alone was limited at best.

However, specific situations exist where one may wish to commit early to a complex bifurcation strategy. Intermediate to large side branches (>2.5 mm diameter), particularly those that are comparably sized as the parent vessel, side branches evidencing contiguous obstructive disease extending away from the ostium, side branch territories with demonstrable ischemia, or significant/flow-limiting dissection may merit consideration of a more complex bifurcation strategy with deliberate stenting of the side branch. *Figure 3* depicts step-wise detail of a culotte stenting procedure in which calcified de novo and restenotic disease in the bifurcation of an LAD and large diagonal branch warranted a complex, multistent approach following debulking with rotational atherectomy. In planning percutaneous therapy for complex bifurcation disease, careful pre-procedure consideration of the coronary anatomy, aforementioned criteria, and various technical strategies, is therefore warranted.^{17,20-22}

Cost-effectiveness Considerations in Routine and Complex Percutaneous Coronary Intervention

When broadly considering the cost impact of treatment strategies in patients with CAD, multiple therapeutic comparisons are of clinical and fiscal relevance. The first set of considerations relates to medical management versus revascularization in the setting of stable CAD. The next relates to mode of revascularization, surgical versus percutaneous, with the additional matter of routine versus selective use of DES in the latter group. In the interim, you are giving your consent for use of site cookies.

Figure 3: Rotational Atherectomy and Culotte Stenting of a Medina 1,0,1 Bifurcation

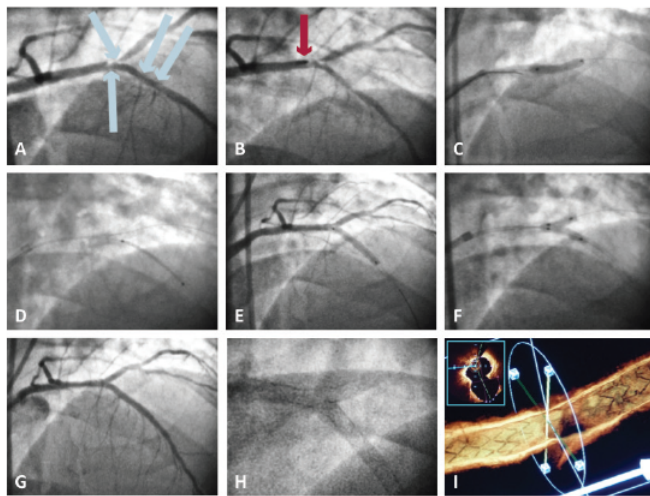
The results of numerous published clinical trials and registries of bifurcation technique have been evaluated in the context of several meta-analyses.²³⁻³¹ These systematic reviews have found with great consistency that in the current era of DES, a simple, single-stent



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Figure 3: Rotational Atherectomy and Culotte Stenting of a Medina 1,0,1 Bifurcation



Calcified de novo and restenotic disease of the left anterior descending (LAD)/diagonal bifurcation is seen in Panel A with blue arrows at areas of disease confirmed to be obstructive by angiography and fractional flow reserve. Rotational atherectomy (B, red arrow) was first performed on both the LAD and the first diagonal branch followed by culotte stenting. After predilatation, a drug-eluting stent is placed from LAD into the diagonal (C), jailing the continuation of the LAD. The LAD was re-wired through the first stent, which is then dilated and a second stent advanced into the mid-LAD through the fenestration in the first stent (D). Care is taken upon deployment to ensure that the second stent is not completely occluding the diagonal ostium (E). Kissing balloon inflations are performed in the stented bifurcation (F) yielding an excellent angiographic result (G) and complete stent coverage of the entire diseased area (H) with minimal distortion of the native carina. Repeat angiography and optical coherence tomography with spectral domain longitudinal reconstruction (I) performed 3 years later reveals widely patent and well-healed bifurcation stents.

patients with complex disease. While it is beyond the scope of this article to explore economic modeling in detail, it bears mention that variability and complexity of cost modeling methodology, differences in individual costs within the US healthcare system and across countries, and local trends in the practice of IC have all contributed to the lack of uniformity in conclusions regarding the cost-effectiveness of various revascularization strategies.³⁴

Since commercial approval in the US in 2003, use of DES has grown, peaking in late 2005 at nearly 90 % and since settling into its current usage rate in over two-thirds of PCI procedures.³⁵ Numerous randomized and non-randomized comparisons of BMS versus DES in PCI have been conducted and have uniformly found a reduction in target vessel revascularization (TVR)

without significant reduction in death or myocardial infarction.^{36,37} Available economic analyses have not, however, uniformly upheld the cost-effectiveness of DES use in contemporary PCI. As noted, given the lack of mortality benefit with DES, the economic case to be made in favor of DES usage rests primarily with the ratio of incremental cost of these devices over BMS to enhanced quality of life (QoL) for patients who enjoy greater freedom from repeat revascularization following DES implant.³⁸ Groeneveld et al. conducted a systematic review of the published literature on costs and QoL metrics associated with DES versus BMS use, incorporating eight QoL and four cost publications.³⁸ In this analysis, patients receiving DES had \$1,600 to \$3,200 higher initial costs with the 1-year total cost differential dropping to \$200 to \$1,200. Wide variability in the relative rates of restenosis between BMS and DES in the studies included drove the large observed range in cost per revascularization avoided (\$1,800–\$36,900). Although all included studies were in agreement that restenosis negatively affects QoL, routine use of DES to avoid restenosis was found unlikely to be cost-effective.

In another systematic review of DES cost-effectiveness, Ligthart and colleagues similarly found wide variability in the reported cost-effectiveness of DES that the authors concluded was influenced by the quality of the studies analyzed, source of study funding, and the country in which the studies were conducted.³⁴ Ryan et al. have suggested however that DES usage would be economically favorable if used selectively in patients at moderate to high risk of BMS restenosis with sensitivity analyses demonstrating an acceptable cost-effectiveness ratio of < \$10,000 per repeat revascularization avoided if the expected BMS TVR rate in a given population exceeded 11 % and cost savings if the BMS TVR rate exceeded 19 %.³⁹ As noted, use of FFR guidance in single or multivessel PCI with implantation of second-generation DES in the FAME-2 trial yielded substantial reductions in the ischemic composite endpoint over optimal medical therapy (4.3 % in the PCI group and 12.7 % in the medical therapy group, hazard ratio [HR] with PCI 0.32; 95 % confidence interval [CI] 0.19 to 0.53; $p < 0.001$).³² An economic analysis of these data found that while initial costs of drug-eluting stent PCI performed in the setting of FFR < 0.80 were significantly higher compared with FFR followed by optimal medical therapy (\$9,927 versus \$3,900; $p < 0.001$), the observed \$6,027 difference decreased over the study's 1-year follow-up to \$2,883 ($p < 0.001$), offset by the cost of subsequent revascularization procedures in the medical therapy arm. The incremental cost-effectiveness ratio (ICER) of PCI guided by an abnormal FFR in FAME-2 was \$36,000 per quality-adjusted life year (QALY), an economically favorable value as it is below the standard willingness to pay threshold of \$50,000 per QALY.⁴⁰ Taken together, these data indicate that cost-containment strategies in PCI should include objective assessment of functional significance to guide lesion selection and estimation of restenosis/revascularization risks to help guide the use of DES versus BMS along with strategies to minimize the number of stents implanted and experience-based choices regarding adjunctive device use.

Relevant to the economics of complex PCI, a few recent studies have re-examined the age-old controversy of CABG versus drug-eluting stent PCI in multivessel CAD. As mentioned above, the SYNTAX trial randomly assigned 1,800 patients with multivessel or unprotected LMCA disease to CABG surgery versus PCI with paclitaxel-eluting DES. Twelvemonth rates of major adverse cardiac or cerebrovascular events were significantly higher in the PCI group (17.8 % versus 12.4 % for CABG; $p = 0.002$), primarily due to an increased rate of repeat revascularization (13.5 % versus 5.9 %; $p < 0.001$) with no difference in all-cause mortality, thus failing to demonstrate a primary benefit for either treatment arm.¹⁵ However, when outcomes were stratified by

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tertiles of SYNTAX score there was noted to be an interaction between the SYNTAX score and treatment allocation with comparable MACE rates between PCI and CABG in those subjects with low (0–22) or intermediate (23–32) scores. A formal cost-effectiveness analysis conducted by Cohen et al. based on the SYNTAX data found that in the overall study population total costs for the index procedure and hospitalization were \$5,693/patient higher in the CABG group, but follow-up costs \$2,282/patient higher in the PCI group (driven primarily by the need for repeat TVR), thus economically favoring PCI at 1 year despite high resource utilization for PCI (average 4.5 DES per procedure; range 0–14 DES).⁴¹ Although PCI was deemed to be the economically dominant strategy in the primary analysis, disease complexity as quantified by tertiles of SYNTAX score once again served as an interaction term. The 1-year cost savings with PCI diminished from \$6,154/patient among patients with low SYNTAX scores to \$3,889/patient in patients with intermediate SYNTAX scores to \$466/patient in patients with high SYNTAX scores. A similar interaction was also found in terms of disease complexity and quality-adjusted life expectancy with CABG strongly favored in patients with the highest SYNTAX scores. In 1,900 patients with diabetes randomized to drug-eluting stent PCI versus CABG in the Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM), total 5-year costs were similarly \$3,641 higher per CABG patient. However, when the trial data were projected over a lifetime survival horizon, CABG posted significant gains in quality-adjusted life expectancy relative to PCI.⁴² Careful assessment of up-front costs, anticipated intermediate- and long-term outcomes, and the need for repeat procedures and hospitalization must therefore accompany technical planning of revascularization in patients with complex multivessel CAD.

Percutaneous chronic total occlusion (CTO) revascularization is another sector of contemporary interventional practice that has recently seen renewed interest and utilization driven by advances in technology as well as the development of hybrid percutaneous treatment algorithms.⁴³ Limited data exist regarding cost-effectiveness of percutaneous revascularization of CTOs versus medical management and, at the time of writing, no formal cost-modeling versus CABG exists although the presence of one or more CTOs is often cited as the primary reason for CABG referral.⁴⁴ Gada et al. used a decision-analytic model to evaluate the morbidity and costs associated with CTO PCI versus optimal medical therapy in patients with Canadian Cardiovascular Society class III–IV angina.⁴⁵ Assuming a reference case mean age of 60 years and CTO PCI success rate of 67.9% and 5 years of simulated follow-up, along with literature-defined assumptions regarding procedural probabilities, costs, and outcomes, CTO PCI was more costly than optimal medical therapy (\$31,512 versus \$27,805), but resulted in greater QALYs (2.38 versus 1.99), thus resulting in an economically favorable ICER of \$9,505 per QALY. As experience grows with use of the hybrid CTO algorithm as well as with current strategies for tackling bifurcation lesions with conventional DES or with dedicated bifurcation stent systems available outside the US, additional cost modeling data addressing these complex PCI subsets will hopefully be forthcoming.⁴⁶

Conclusions

Technically complex PCI procedures, while increasingly performed, remain associated with lower rates of procedural success and higher rates of MACE compared with more straightforward catheter-based interventions. Multivessel and unprotected LMCA disease, fibrocalcific lesions, chronic total occlusions, and bifurcation disease comprise many of the lesion sets requiring additional resource allocation, procedural planning, and sophistication. Bifurcation lesions, in particular, have been the subject of intense systematic study and some degree of controversy. Current consensus supports a simple, single-stent/provisional side branch strategy when possible. Cost considerations in PCI are perhaps most relevant to patients with extensive, multivessel disease in whom CABG may also be a viable therapeutic option. Objective assessment of disease complexity, estimation of technical feasibility, and consideration of medical comorbidities should all factor into the decision regarding optimal revascularization strategy.

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