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INTRAVASCULAR IMAGING (ALEXANDER G. TRUESDELL, SECTION EDITOR)

Integrating Intracoronary Imaging into PCI Workflow and Catheterization Laboratory Culture

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Abstract

Purpose of Review Intracoronary imaging, including intravascular ultrasound (IVUS) and optical coherence tomography (OCT), has become an increasingly important tool in all stages of invasive coronary disease management, from diagnosis to lesion assessment and percutaneous coronary intervention (PCI) optimization. Despite the robust and growing evidence base supporting imaging-guided PCI, there has been a slow uptake in practice, particularly in the USA. This article aims to explore barriers to the use of intracoronary imaging during PCI and potential strategies to improve the uptake of intracoronary imaging in the catheterization laboratory.

Recent Findings Over the past decade, several randomized trials have supported the use of intracoronary imaging in PCI to improve outcome. However, registry data has suggested that the uptake of intracoronary imaging has been particularly slow in the USA. Important barriers to the use of intracoronary imaging include procedural time, cost, perceived risk, and lack of familiarity with imaging use and interpretation. Potential strategies to improve the uptake of intracoronary imaging in the catheterization laboratory include improving training and technical support, monthly audit on PCI imaging data, and incorporation of the prescriptive imaging workflow. Preliminary analysis shows that prescriptive image-guided workflow can reduce contrast and radiation use in procedures, and result in shorter procedure time.

Summary Despite the numerous barriers to the use of intracoronary imaging in the catheterization laboratory, these challenges can be overcome to improve patient's outcome after PCI.

Keywords Intracoronary imaging · PCI · Cath lab · IVUS · OCT · Workflow

Introduction

Intracoronary imaging has become an increasingly important tool in all stages of invasive coronary disease management, from diagnosis to lesion assessment and percutaneous coronary intervention (PCI) optimization. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are the two major modalities of intracoronary imaging. IVUS uses an ultrasound catheter with a wave source typically operating at 40–60 MHz, whereas OCT relies on near-infrared spectrum light [1]. While the uses for IVUS and OCT are evolving rapidly, IVUS is generally preferable for visualization of aorto-ostial lesions and large vessels and for use in patients with suspected significant dissection or important renal function impairment. OCT, on the other hand, offers higher image resolution, which is especially informative for the evaluation of lesion morphology and in-stent restenosis (ISR).

The clinical impact of intracoronary imaging is well established. Table 1 summarizes the major prospective randomized trials on use of intracoronary imaging in PCI. IVUS-XPL was a randomized trial including 1400 patients at 20 centers in Korea undergoing PCI of lesions ≥ 28 mm in length [2]. Patients assigned to IVUS-guided stent implantation had significantly lower rates of a composite of cardiac death, target lesion–related myocardial infarction, or ischemia-driven target lesion revascularization at 1 year and

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Table 1 Randomized trials of intracoronary imaging

	Year	Patients, *n*	Angiography	IVUS	OCT	Remarks
IVUS-XPL [2]	2015	1400	✓	✓		IVUS-guided everolimus-eluting stent implantation associated with lower risk of target-lesion revascularization at 1 year and 5 years
ULTIMATE [3•]	2018	1448	✓	✓		IVUS-guided DES implantation associated with lower risk of target lesion failure at 1 year and 3 years, and stent thrombosis at 3 years
DOCTORS [5]	2016	240		✓	✓	In patients with NTE-ACS, OCT-guided PCI associated with higher postprocedural FFR
OPINION [6]	2017	829		✓	✓	OCT-guided PCI non-inferior to IVUS-guided PCI in all clinical outcomes at 12 months
ILUMIEN III [7•]	2016	450	✓	✓	✓	OCT-guided PCI non-inferior and not superior to IVUS-guided PCI, and also not superior to angiography alone in all clinical outcomes at 30 days
ILUMIEN IV [8•]	Results expected in 2022	2,490–3,656 (tentative)	✓		✓	Ongoing

5 years. ULTIMATE was another randomized trial in which 1448 patients were randomized to angiography guidance or IVUS guidance in drug-eluting stent (DES) implantation [3•]. IVUS guidance was shown to result in lower incidence of target vessel failure at 1 year and 3 years as well as lower rates of stent thrombosis at 3 years. In a meta-analysis of 10 randomized trials, including IVUS-XPL and ULTIMATE, IVUS-guided PCI was associated with decreased cardiovascular mortality, myocardial infarction, target lesion revascularization, or stent thrombosis [4].

Observational data have added further insight regarding the use of IVUS. ADAPT-DES [9] was a prospective, non-randomized study which enrolled 8583 patients undergoing PCI at 11 US and German centers. IVUS guidance was associated with lower rates of stent thrombosis, myocardial infarction, and major adverse cardiac events after DES implantation.

Regarding OCT, CLI-OPCI, and ILUMIEN I investigated the impact of OCT on intraprocedural decision-making compared with angiographic guidance alone [5, 10]. From the CLI-OPCI registry, it was further shown that suboptimal stent deployment according to OCT criteria was associated with higher rates of adverse clinical outcomes. The ILUMIEN I study demonstrated that the use of OCT during PCI impacts physician decision-making during PCI and is associated with lower rates of mortality. The DOCTORS study, which was the first randomized controlled trial of OCT-guided PCI in NSTEMI, found that OCT-guided PCI resulted in higher post-procedural fractional flow reserve (FFR) values compared to angiography alone [11]. More recently the LightLab Initiative, a multiphase program including 16 US centers, examined the real-world impact of OCT use under a standardized workflow [12•]. Early-phase data have shown that OCT guidance impacted decision-making in 88% of PCI cases program-wide, with majority of changes occurring during diagnosis and planning of treatment strategy from pre-PCI OCT pullback.

In a matched-pair post hoc analysis comparing OCT-guided stenting in patients in the ILUMIEN study and IVUS-guided stenting in patients in the ADAPT-DES study, OCT and IVUS guidance resulted in comparable degrees of stent expansion [13]. The OPINION trial was the first head-to-head comparison between OCT and IVUS in patients undergoing PCI in the setting of a prospective randomized trial [6]. The primary endpoint was a composite of cardiac death, target vessel-related myocardial infarction, and ischemia-driven target vessel revascularization at 12 months. With 829 patients randomized at 1:1 ratio to OCT- and IVUS-guided PCI, the study reported that OCT-guided PCI was non-inferior to IVUS-guided PCI. The ILUMIEN III study was a randomized controlled trial comparing use of OCT, IVUS, and angiography in 450 patients undergoing PCI [7•]. All patients underwent OCT after PCI to measure the minimum stent area as the primary efficacy endpoint. OCT guidance was non-inferior to IVUS and did not show superiority over angiography alone. This latter finding is largely attributed to inadequate adherence to the OCT treatment protocol in the trial and the long-term clinical impact of OCT-guided PCI is now being evaluated in the ongoing ILUMIEN IV randomized trial [8•].

Table 2 summarizes major society guidelines on use of intracoronary imaging. Guidelines have mainly addressed the diagnostic value of intracoronary imaging, particularly in left main coronary artery disease (CAD) and in ISR. Conversely, the use of intracoronary imaging for PCI optimization has received little attention in international guidelines. The 2011 ACCF/AHA/SCAI Guideline for PCI provided a class IIb recommendation for the use of IVUS for guidance

Table 2 International Society Guidelines on use of intravascular ultrasound in coronary artery disease

Society guidelines	Recommendations	Class of recommendation(level of evidence)
ACC / AHA / SCAI [14]	Assessment of angiographically indeterminant left main CAD	Class IIa (level B)
	Determination of mechanism of stent restenosis	Class IIa (level C)
	Assessment of non-LMCA with angiographically intermediate coronary stenoses (50–70% diameter stenosis)	Class IIb (level B)
	Guidance of coronary stent implantation, particularly in LMCA stenting	Class IIb (level B)
	Determination of mechanism of stent thrombosis	Class IIb (level C)
ESC [15]	Assessment of severity of unprotected left main lesions	Class IIa (level B)
	Detection of stent-related mechanical problems leading to restenosis	Class IIa (level C)
	Optimization of stent implantation in selected patients	Class IIa (level B)
	Optimization of treatment of unprotected left main lesions	Class IIa (level B)

of left main coronary artery PCI and gave no recommendation regarding the use of OCT [14] (Table 3). The 2018 ESC/EACTS Guidelines on Myocardial Revascularization gave a class IIa recommendation for the use of IVUS or OCT in selected patients to optimize stent implantation, and specifically for IVUS to optimize treatment of unprotected left main CAD [15]. A position statement from SCAI endorsed use of intravascular imaging in calcified lesions, left main CAD, and chronic total occlusion (CTO) PCI [16].

Despite the robust and growing clinical evidence supporting imaging-guided PCI, there has been slow uptake in practice, particularly in the USA. Using data from the National Inpatient Sample, Smilowitz et al. reported that the rate of coronary imaging during PCI was only 6.6% in 2013–2014 [17]. Similarly, a report from 2017 found a rate of IVUS use of 5.6% among patients undergoing PCI for STEMI [18]. In comparison, IVUS has been reported to be used in over 80% of PCI procedures in Japan [19].

Barriers to Intracoronary Imaging Use

Here, we aim to describe barriers to the use of intracoronary imaging in the catheterization laboratory and possible strategies for improvement. There are several important barriers to the use of intracoronary imaging, including procedural time, cost, perceived risk, and lack of familiarity with imaging use and interpretation [20].

Time

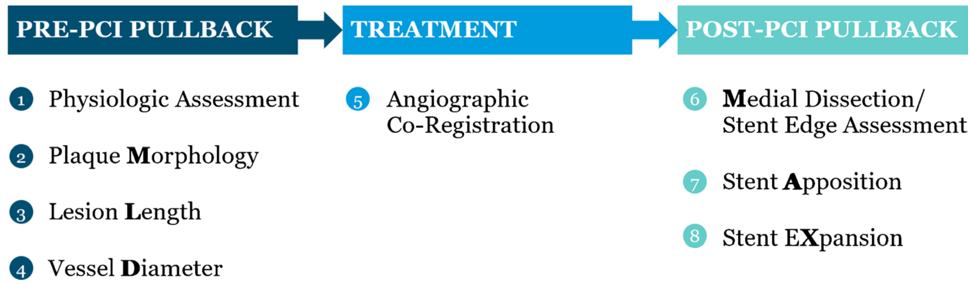
There is a long-standing belief that the use of intracoronary imaging adds time to PCI procedures. At face value, the addition of a procedure would certainly be expected to add time, particularly one that might prompt additional action, such as further post-dilatation. Early data give credence to this concern. In the ULTIMATE study, IVUS guidance was associated with longer procedural times (61 vs 46 min; $p<0.001$) [3•]. Similarly, in the ILUMIEN III study, OCT guidance was associated with longer procedure duration compared with angiography alone (71 vs 58 min; $p<0.0001$) and there was no significant difference between OCT and IVUS guidance (71 vs 73 min; $p=0.99$) [7•].

The conceptual framework in which intracoronary imaging is essentially obligated to increase procedural time is now outdated, however. New efforts are underway to incorporate a prescriptive image-guided PCI revascularization strategy where pre-PCI OCT is used to plan the stenting strategy and post-PCI OCT is used to optimize the PCI result [12•]. This prescriptive image-guided workflow has the potential to reduce procedural time by increasing the precision over visual angiographic assessment and by decreasing the number of steps needed to optimize the PCI result. The most widely adopted MLDMAX OCT prescriptive workflow (Morphology, Length, Diameter, Medial dissection, Apposition, eXpansion) is being studied in the LightLab prospective registry (Fig. 1). The MLDMAX workflow aims

Table 3 International Society Guidelines on use of optical coherence tomography in coronary artery disease

Society guidelines	Recommendations	Class of recommendation (level of evidence)
ACC/AHA/SCAI	None	
ESC [15]	Detection of stent-related mechanical problems leading to restenosis	Class IIa (level C)
	Optimization of stent implantation in selected patients	Class IIa (level B)

Fig. 1 MLDMAX workflow [12•]



to utilize the full range of information from OCT including pre-PCI and post-PCI data to guide decision-making during stenting. Preliminary data from LightLab demonstrates that the pre-PCI OCT has a major impact on procedural decision-making compared to angiogram-based planning. In addition, MLDMAX provides prescriptive data-based criteria for treatment vs conservative management of issues such as malapposition, distal edge dissection, and under-expansion. Preliminary LightLab analysis shows that MLDMAX OCT–guided procedures use less contrast and radiation and result in shorter procedure time compared to cases where OCT is only used after stenting is completed [21•].

Cost

Extra equipment cost is a commonly cited reason for low imaging uptake [20]. According to a study based on data from the Nationwide Inpatient Sample from 2008 to 2011, IVUS-guided PCI is associated with a higher cost of hospitalization compared to angiography-guided PCI (US$ 19,779 vs US$ 18,019, $p < 0.001$) [22]. Regarding OCT, in the randomized FORZA study, OCT guidance was shown to be associated with significantly higher costs in comparison with FFR guidance in patients with angiographically intermediate stenoses [23]. While direct equipment costs are certainly a consideration, these analyses do not account for the overall health savings from reduced clinical events with imaging-guided PCI especially in light of the fact that the number needed to treat to prevent a major adverse cardiovascular event at 2 years is estimated to be about 40 imaging-guided PCIs [24]. In one cost-effectiveness analysis attempting to address this question, IVUS-guided PCI yielded net financial benefit over angiography guidance alone from a healthcare system perspective when IVUS benefit is assumed to persist beyond the first year [25]. The benefit was greatest for the highest risk patients, namely those with diabetes, renal insufficiency, and acute coronary syndrome.

Reimbursement

Closely related to cost is the issue of reimbursement. In Japan, IVUS has been reimbursed separately since 1994 even for diagnostic purposes, which may be a factor in the high uptake of intracoronary imaging in that country [1]. In many countries, there is no separate reimbursement to the hospital for intracoronary imaging use [26]. In the USA, hospitals do not receive additional reimbursement from Medicare for intracoronary imaging when performed in conjunction with PCI [27, 28]. In these circumstances, even if a physician would like to use IVUS or OCT there may be direct or indirect healthcare system pressures to limit these procedures. Appropriate compensation by payors reflecting the clinical benefit and expertise required for imaging-guided PCI would likely have a positive impact on rates of use.

Risks

Some operators perceive there to be additional risk from intracoronary imaging procedures. Complications from IVUS or OCT appear to be quite rare, but this point does deserve discussion. In a retrospective study based on US inpatient data, overall complication rates were similar between IVUS- and angiography-guided PCI [22]. However, there was a higher rate of cardiac complications in patients undergoing IVUS-guided PCI such as cardiac tamponade and hemopericardium. The authors suggested that this could be a result of suboptimal IVUS interpretation leading to stent over-dilatation and perforation. This highlighted the importance of recognizing the difference in sizing algorithms between IVUS and OCT (see Fig. 2). In general, the lumen diameter obtained by OCT is smaller than by IVUS [29]. Indeed, it is important to keep in mind that randomized trials of intracoronary imaging specifically enroll at sites with experienced operators. Efforts to expand imaging usage more broadly must be paired with education—misinterpretation may indeed pose a significant risk among new users without adequate training.

Additionally, optimal OCT image acquisition often involves the use of contrast and requires appropriate injection techniques to achieve adequate blood clearance in the vessel. As a result, there are at least theoretical risks of contrast-related complications such as nephropathy and coronary dissection secondary to forceful injection. In the OPINION trial, rates of imaging-related complications were similar between OCT and IVUS groups [6]. The DOCTOR study reported significantly higher

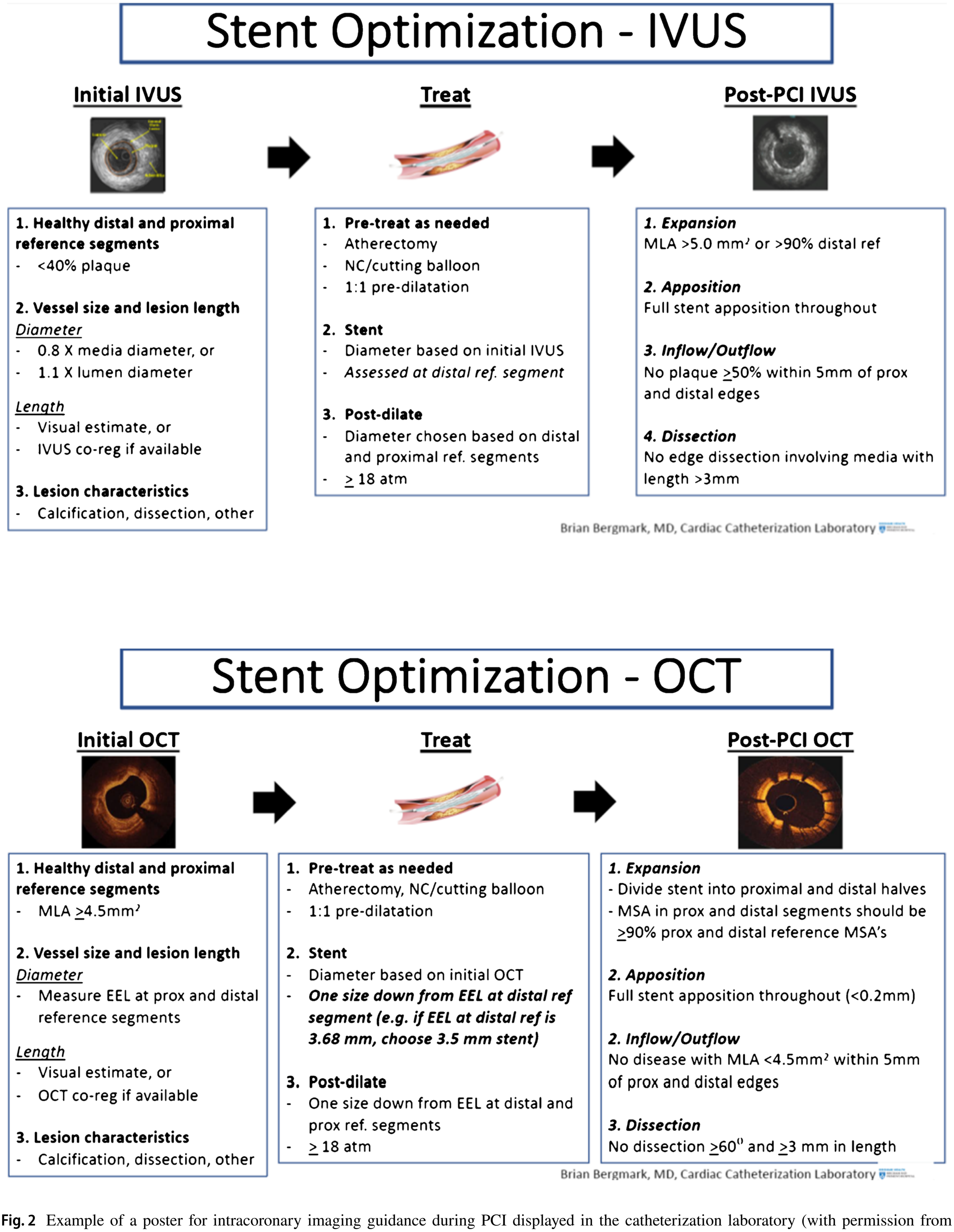
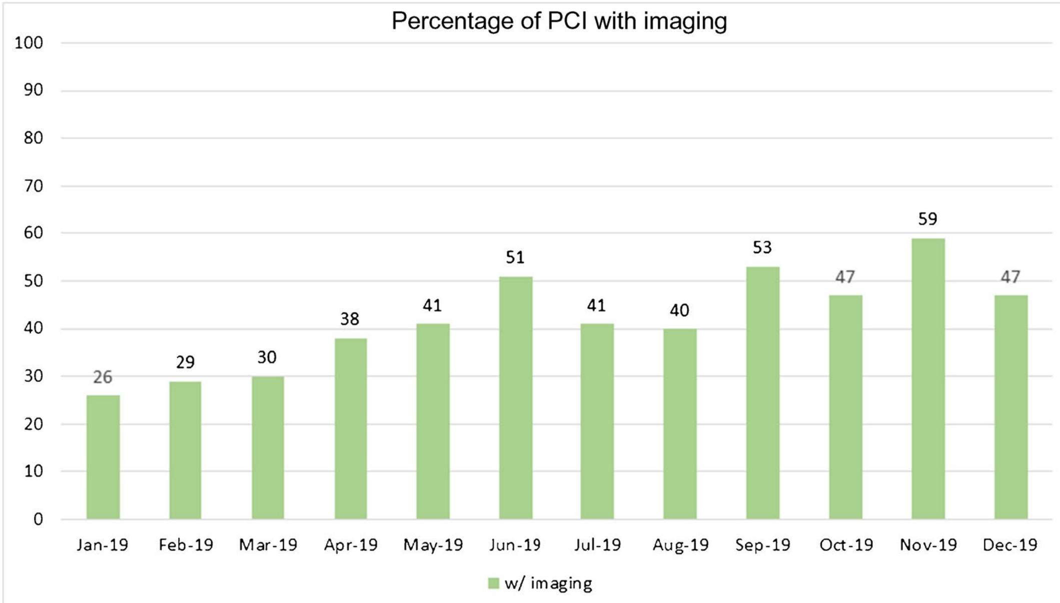


Fig. 2 Example of a poster for intracoronary imaging guidance during PCI displayed in the catheterization laboratory (with permission from Brigham and Women's Hospital Cardiac Catheterization Laboratory)


Percentage of PCI with imaging
100
90
80
70
60
50
40
30
20
10
0
26
29
30
38
41
51
41
40
53
47
59
47
Jan-19
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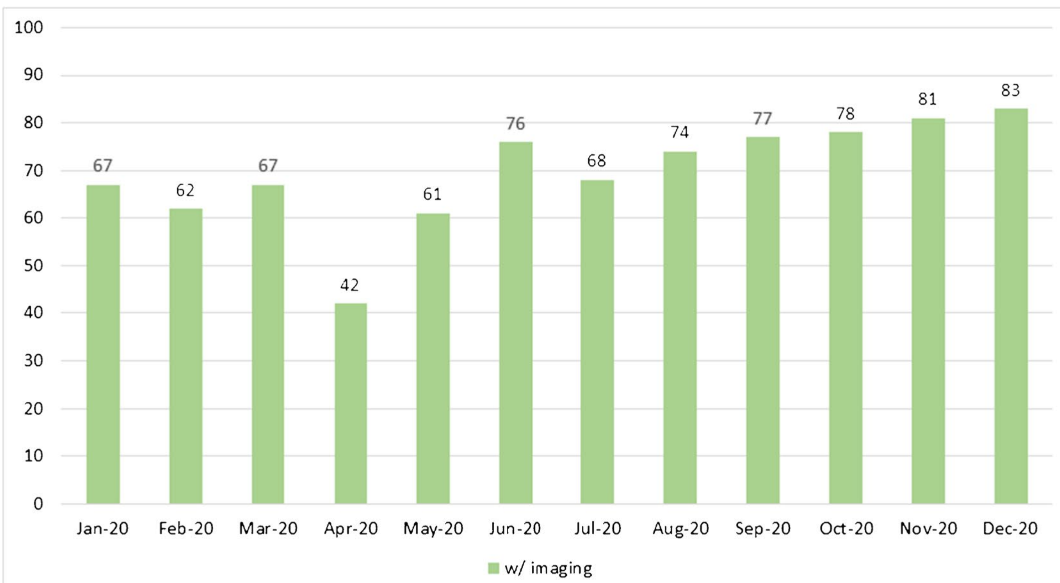
Nov-19
Dec-19
w/ imaging


100
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80
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Jan-20
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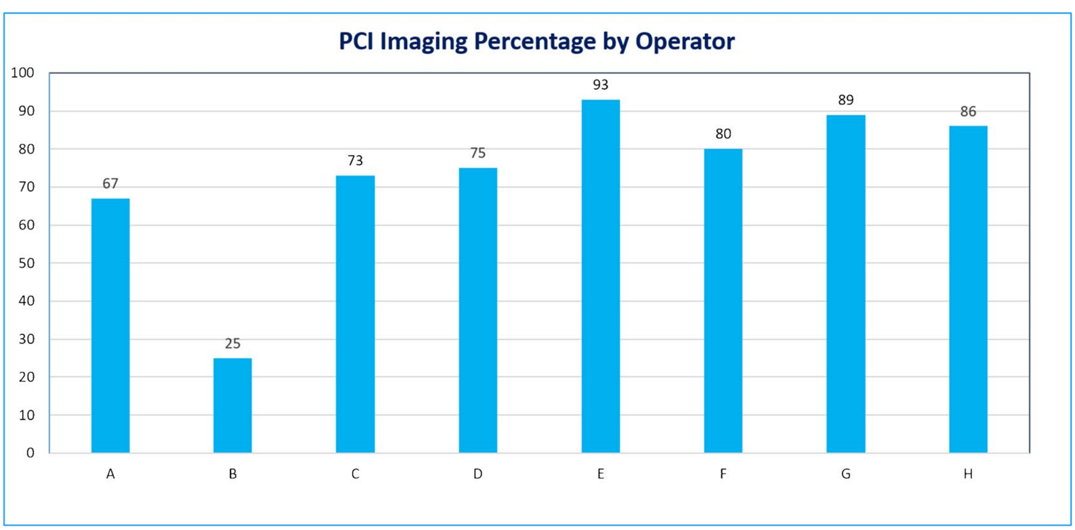
Nov-20
Dec-20
w/ imaging


PCI Imaging Percentage by Operator
100
90
80
70
60
50
40
30
20
10
0
67
25
73
75
93
80
89
86
A
B
C
D
E
F
G
H

◂**Fig. 3** Example of internal monitoring of intracoronary imaging use during PCI (with permission from Brigham and Women's Hospital Cardiac Catheterization Laboratory)

contrast volume use, fluoroscopy time, and radiation dosage compared with angiography alone [5]. However, rate of acute kidney injury did not differ between the two groups. In the ILUMIEN III trial, procedural complication rates were similar between OCT and IVUS and between OCT and angiography alone [7•]. There was significantly higher contrast volume use in the OCT group in comparison to IVUS or angiography; however, no patient developed acute renal failure in this study. Forthcoming data from the LightLab collaboration suggest that with incorporation of an OCT workflow, total PCI contrast volume might be reduced [21•]. Additionally, use of dextran-based OCT in patients with advanced kidney disease might be considered to minimize contrast use [30]. Saline-based OCT protocols are also showing promise as a method to lessen the risk of contrast-induced nephropathy in OCT-guided PCI [31].

Technical and Cultural Barriers

Image acquisition with IVUS is relatively straightforward. Delivery of the IVUS catheter was enhanced with the introduction of low-profile catheters with tapered tips. Image acquisition was conventionally performed by manual pullback, but automated pullback at a set speed is currently available with the benefit of obtaining longitudinal dimensions of the vessel in the study. Automated pullback allows for precise measurement of lesion length, informing stent selection, and also allows for angiographic co-registration [32]. Image acquisition with OCT can be more challenging. Optimal guide catheter engagement and appropriate injection techniques are required to obtain images with excellent quality. Guide extension catheters can be used to improve contrast delivery and reduce contrast volume used, though must be used carefully to avoid hydraulic dissection.

Interpretation of both IVUS and OCT images, especially in lesion morphology, requires adequate training, and experience. According to a survey among interventional cardiology fellows in the USA, only 15% and 18% of the respondents reported independence and preparedness for practice in IVUS and OCT respectively [33].

Lack of comfort with the technical use and interpretation of these modalities is surely a central barrier to intravascular imaging uptake. The issue of training extends beyond the operator to the entire catheterization laboratory team; when technical staff is unfamiliar with the device and is called upon to set it up during a procedure, there can often be resistance. When unfamiliarity is paired with perceptions of greater time use and cost, there can be an enormous cultural barrier to adoption of these technologies.

Strategies to Improving Uptake of Intracoronary Imaging

Training and Technical Support

Adequate training by experts in intracoronary imaging and technical support from industry are essential in preparing operators for successful imaging acquisition and interpretation. According to the ACGME Program Requirements, IVUS is a core skill that interventional cardiology fellows must show competence in [34]. There is no further elaboration on the requirements on IVUS image interpretation and OCT is not mentioned in the program requirements.

Existing operators with limited experience in intracoronary imaging may also benefit from similar training. Nationwide courses such as PCI Masters (https://www.cardiovascular.abbott/us/en/hcp/education-training/coronary-education-training/in-person-courses.html) sponsored by Abbott Vascular are an example of this type of educational opportunity. Importantly, persistent use of intracoronary imaging in daily practice after training is key to maintain proficiency, develop further expertise, and optimize team efficiency. On-site support from industry partners can also provide educational support on image interpretation and instant feedback to any technical issues during the procedure as an effort to encourage operators to continue using intracoronary imaging on a regular basis. Recent improvement in imaging technology such as automated luminal assessment and co-registration with angiography enhances the application of imaging data on decision-making during the procedure and may facilitate uptake [35]. Ongoing efforts to use artificial intelligence (AI) to simplify intravascular imaging interpretation are showing great promise and AI has been used to assist characterization of atherosclerotic plaques on OCT [36] and guide image interpretation and stent strategy. Software updates that use AI algorithms to detect vessel size and calcium burden are due out later this year. For non-expert operators, AI may also hold potential for simultaneous training and learning at the same time.

Monthly Audit on PCI Imaging Data

Quality assurance meetings are routinely used to monitor catheterization laboratory clinical effectiveness and improvement initiatives across the country. Including data on the use of intracoronary imaging might also encourage utilization. For example, monthly data by de-identified operator can be provided to show team use of intracoronary imaging over time. Specific challenges and difficulties encountered can then be discussed and addressed.

Single-Center Experience Improving Imaging Uptake

Recognizing the clinical evidence to support the use of intracoronary imaging in most stenting procedures, the Brigham and Women's Hospital Cardiac Catheterization Laboratory adopted several measures to facilitate and encourage optimized PCI as the default technique in 2019. With these efforts, the rate of imaging use during PCI has increased from 42% overall in 2019 to > 80% at present.

Incorporation of a Standardized Imaging Workflow

To improve operator proficiency and to promote consistency across all operators, standard OCT and IVUS clinical workflows were recommended as part of the intravascular imaging adoption initiative. The recommended OCT prescriptive workflow was the MLDMAX strategy employed in the LightLab study [12•] and the recommended IVUS prescriptive workflow was based on the strategy from the ULTIMATE trial [3•]. Several training sessions on the prescriptive imaging workflows were conducted during catheterization laboratory clinical conference and physician champions (see below) were available for case support to help with adoption.

Step-by-Step Guidance Posters in the Catheterization Laboratory Rooms

Intracoronary imaging has become an integral part of the culture and regular educational sessions in the catheterization laboratory. Fellows, nurses, and technologists receive didactic teaching from faculty and outside experts on background knowledge, techniques of image acquisition, and image interpretation. Posters providing simple instructions on the workflow of imaging-guided PCI are displayed in every room in the catheterization laboratory (Fig. 2).

Monthly Auditing on Intracoronary Imaging Use

Monthly statistics regarding the use of intracoronary imaging in the cardiac catheterization laboratory are presented in the regular quality assurance conference. Faculty members are additionally provided their individual rates of IVUS/OCT use compared to their colleagues in an anonymized fashion which has motivated operators to standardize their approach to PCI. Figure 3 illustrates an example of slides used in the monthly quality assurance conference.

Assignment of Physician Champions

Two of our complex coronary interventional operators have taken up the role of lead physicians in intracoronary imaging. This strategy could be particularly helpful for programs with limited experience in intracoronary imaging. After appropriate training, these physician champions become the go-to specialists in all matters of intracoronary imaging and are ready to proctor other colleagues in the catheterization laboratory. They would also be monitoring relevant monthly data in the catheterization laboratory to ensure adequate and appropriate use of imaging. This approach is well established in the adoption of new techniques in the catheterization laboratory, for example, radial access.

Conclusion

Despite the robust and growing evidence base showing superior long-term outcomes with imaging-guided PCI, clinical uptake remains low in the USA. Numerous barriers to the use of routine optimized PCI exist, including cost, time, familiarity, and cultural resistance. These challenges can be overcome and doing so is essential to ensure the best possible results for our patients.

Declarations

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

Conflict of Interest **JGS**—None.
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