

**Utility of intracoronary imaging in the cardiac
catheterization laboratory: comprehensive evaluation with
intravascular ultrasound and optical coherence tomography**

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Keywords:	Intravascular ultrasound, optical coherence tomography, percutaneous coronary intervention

**Utility of intracoronary imaging in the cardiac catheterization laboratory:
comprehensive evaluation with intravascular ultrasound and optical coherence
tomography**

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Short title: Intracoronary Imaging in the Cath Lab

Abstract

Background: Intracoronary imaging is an important tool for guiding decision making in the cardiac catheterization laboratory.

Sources of data: We have reviewed the latest available evidence in the field to highlight the various potential benefits of intravascular imaging.

Areas of agreement: Coronary angiography has been considered the gold standard test to appropriately diagnose and manage patients with coronary artery disease, but it has the inherent limitation of being a 2-dimensional x-ray lumenogram of a complex 3-dimensional vascular structure.

Areas of controversy: There is well established inter- and intra-observer variability in reporting coronary angiograms leading to potential variability in various management strategies. Intracoronary imaging improves the diagnostic accuracy while optimizing the results of an intervention. Utilization of intracoronary imaging modalities in routine practice however remains low worldwide. Increased costs, resources, time and expertise have been cited as explanations for low incorporation of these techniques.

Growing points: Intracoronary imaging supplements and enhances an operator's decision-making ability based on detailed and objective lesion assessment rather than a subjective visual estimation. The benefits of intravascular imaging are becoming more profound as the complexity of cases suitable for revascularization increases.

Areas timely for developing research: While the clinical benefits of intravascular ultrasound have been well validated, optical coherence tomography in comparison is a newer technology, with robust clinical trials assessing its clinical benefit are underway.

Keywords: Intravascular ultrasound, optical coherence tomography, percutaneous coronary intervention

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Topic: Percutaneous transluminal coronary angioplasty, cardiology, stent, intravascular imaging, percutaneous coronary intervention, optical coherence tomography, revascularization, coronary arteriosclerosis, angiogram, coronary angiography

For Peer Review

Introduction

Coronary angiography is considered the gold standard for the assessment of coronary artery disease.¹ Cardiologists perform millions of coronary angiograms annually worldwide.² Angiography is a 2-dimensional lumenogram of a complex 3-dimensional arterial structure; therefore, it is limited in providing accurate diagnostic information. An angiogram using multiple orthogonal views with visual estimation can provide information about a patient's coronary artery anatomy; however, this approach has several limitations due to inherent operator variability, which can lead to wide differences in interpretation of stenosis severity obtained from angiography in comparison to non-invasive imaging, expert core lab assessment, computer assisted measurements, and autopsy comparisons.^{3,4} Though conventional coronary angiography is universally available and has good spatial and temporal resolution, it is limited in its ability to provide anatomical intravascular data and offers no insight into the physiologic correlation of the disease process.^{1,5} These shortcomings are most obvious in challenging situations; for instance, coronary artery calcification is underdiagnosed with angiography in as many as half the cases compared to intravascular ultrasound (IVUS).³

Intracoronary imaging can help reduce the high intra- and inter-observer variability in the interpretation of stenosis severity and morphology of lesions that exists with angiographic assessment.³ The technology provides precise and computerized measurements that help guide the decision-making process and reduces the variability in reporting.^{6,7} Intravascular imaging (IVI) can provide detailed information about vessel anatomy, extent and severity of the disease process, plaque morphology, and precise vessel sizing for stent selection (Figure 1). This information helps guide decision making and facilitates revascularization with percutaneous coronary interventions (PCI). Modern advances with IVI have made the technology user-friendly and available for routine use in the cardiac catheterization laboratory.⁸ Its use is of particular importance when treating complex higher risk indicated patients including for treatment decisions involving the left

main stem and bifurcation disease.^{4, 5, 9, 10} Adjunctive IVI can help us understand the mechanisms underlying stent failures. Despite the well-established role of IVI and innovations in technology, the everyday use of these modalities remains low worldwide.¹⁰

IVUS

IVUS is a sound-based technology that uses a specially designed catheter with an ultrasound probe to visualize intracoronary anatomy¹¹. IVUS has been in use for more than half a century; its clinical utility has been validated in multiple randomized trials, and there are ongoing studies demonstrating the role of IVUS in improving clinical outcomes.¹² Real-time 360° cross-sectional images are obtained with IVUS, providing additional information and enhancing what is known from the lumen contours obtained by angiography. Detailed information in regard to the lumen, vessel size, and plaque morphology can be valuable in the decision-making process. IVUS has the capacity to provide information on perivascular structures (perivascular damage) due to higher penetration power. IVUS can be used at any stage of the procedure. As part of a diagnostic assessment, IVUS can help to assess the plaque morphology, selecting the stent sizing based on lumen dimensions and selecting the precise length of a stent. During the procedure IVUS can confirm stent expansion and maximal luminal gain. Post procedure imaging can help identify possible complications including dissections, underexpansion, malapposition, tissue protrusion, and hematomas.

Large-scale data from randomized trials have demonstrated that an IVUS-guided revascularisation strategy compared with angiography-guided PCI can lead to improved clinical outcomes.¹³ The Impact of Intravascular Ultrasound Guidance on Outcomes of Xience Prime Stents in Long Lesions (IVUS-XPL) randomized, multicenter trial was conducted in 1,400 patients with long coronary lesions (implanted stent ≥28 mm in length) and demonstrated that IVUS-guided everolimus-eluting stent implantation, compared with angiography-guided stent implantation, resulted in a significantly lower rate of the composite endpoint of major adverse cardiac events at 1 year.¹⁴

An in-depth review by Mintz. demonstrated the importance of imaging-guided revascularization in its review of nine randomized trials and 30 registry studies comparing IVUS-guided DES implantation with conventional angiographic guidance.¹³ Specifically IVUS guidance was associated with a reduction in adverse events in all of the 9 meta-analyses to date on this topic and was a cost-effective strategy.

The Assessment of Dual Antiplatelet Therapy with Drug-Eluting Stents (ADAPT-DES) study was a large study that included a pre-specified substudy that demonstrated the benefit of utilization of IVUS therapy in the 3349 (39%) patients treated with IVUS-guided PCI.⁷ Utilization of IVUS changed the PCI strategy in 74% of cases. Not only did IVUS impact decision making at the time of PCI, but the changes led to improved clinical outcomes compared with angiographic guidance. At 1 year, there was a significant reduction in definite/probable stent thrombosis (0.52% versus 1.04%, $p=0.003$) and MI (2.5% versus 3.7%, $p=0.004$) as well as the composite of major adverse cardiac events (3.1% versus 4.7%, $p=0.002$).

The utility of IVUS has been recognized by various cardiac societies and recommended in the decision-making process in the cardiac catheterization laboratory. The use of IVUS has been encouraged in the assessment of intermediate lesions, for guiding stent implantation, and for determining the cause of stent thrombosis (Table 1).

Angiography	Intravascular Ultrasound/Optical Coherence Tomography
2 Dimensional	360° View
Planar	Tomographic and sagittal
Shadow of lumen	Visualization of shape and location
Wall structure not imaged	Visualisation of inner wall structures and morphology
Vessel is seen for short time period during the contrast injection	Confluent imaging; the whole vessel can be imaged
Quantitative coronary angiography analysis with mistakes	Spatial imaging precise assessment

Guideline updates now include a new class IIa recommendation that supports using IVUS for the assessment of angiographically indeterminate left main coronary artery disease (Table 2). **Table 2** Current guideline recommendations for use of intravascular ultrasound and optical coherence tomography.

ACCF/AHA/SCAI Guidelines for PCI Recommendations (2011) ^{15, 16}	ESC Guidelines in Myocardial Revascularization (2014) ¹⁷
Intravascular Ultrasound	
• IVUS is reasonable for the assessment of angiographically indeterminate left main coronary artery disease. (Class IIa, Level of Evidence: B) • IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor coronary artery disease, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information. (Class IIa, Level of Evidence: B) • IVUS is reasonable to determine the mechanism of stent restenosis. (Class IIa, Level of Evidence: C) • IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenosis (50% to 70% diameter stenosis). (Class IIb, Level of Evidence: B) • IVUS may be considered for the guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting. (Class IIb, Level of Evidence: B) • IVUS may be reasonable to determine the mechanism of stent thrombosis. (Class IIb, Level of Evidence: C) • IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. (Class III, Level of Evidence: C)	• IVUS to assess severity and optimize treatment of unprotected left main lesions. (Class IIa, Level of evidence B) • IVUS in selected patients to optimize stent optimization. (Class IIa, Level of evidence B) • IVUS to assess mechanisms of stent failure (Class IIa, Level of evidence C)
Optical Coherence Tomography	
• The appropriate role for optical coherence tomography in routine clinical decision making has not been established.	• OCT should be considered in patients to understand the mechanism of stent failure. (Class IIa, Level of evidence C) • OCT in selected patients to optimize stent implantation. (Class IIb, Level of evidence C)

C)

ACCF = American College of Cardiology Foundation; AHA = American Heart Association; IVUS = intravascular ultrasound; OCT = optical coherence tomography; SCAI = Society for Cardiovascular Angiography and Interventions.

For Peer Review

Serial surveillance with IVUS to monitor intima-media thickness post-heart transplantation has also been included in the recommendations for 4-6 weeks post-cardiac transplant and at 1 year follow-up.¹⁸ Another benefit of IVUS is with high-risk groups including patients with renal insufficiency undergoing percutaneous revascularization; in these patients, IVUS guidance can help reduce the volume of contrast administered.¹⁹ IVUS-guided PCI has been used to develop a “zero contrast” PCI strategy to treat patients at high risk of developing contrast-induced nephropathy.²⁰ IVUS can also be useful in cases of apparently normal coronary arteries on angiography. Patients presenting with chest pain and positive non-invasive testing with discordant findings on angiography should undergo further evaluation with IVUS to exclude the presence of occult disease or clinical significance of an anomalous origin of a coronary artery.²¹ Lastly, in the setting of acute emergencies in patients presenting with acute chest pain, IVUS can facilitate the diagnoses of acute aortic and coronary dissections.²²

Optical Coherence Tomography (OCT):

Optical coherence tomography (OCT) is a newer intracoronary imaging modality in comparison to IVUS. Naohiro Tanno and James G. Fujimoto developed this technology during the 1990s with initial ophthalmologic applications that led to the first OCT-based imaging catheter used in a coronary artery, with the first in-man report published in 2001.²³ This light-based technology has differences in comparison to sound-based IVUS.²⁴ OCT has higher axial resolution of 10-15 µm in contrast to the 150–200 µm resolution achieved with conventional IVUS catheters.²⁵ The high resolution helps delineate the three layers of an arterial wall and can differentiate between different tissue characteristics, providing detailed assessment for dissection, tissue prolapse, thrombi, and stent apposition.²⁶ While OCT has higher resolution, the penetration is lower compared with IVUS. To obtain images, OCT requires displacement of blood from the segment being evaluated during imaging acquisition. While initially achieved by proximal balloon occlusion with time-domain OCT, in

contemporary practice this is routinely achieved by contrast injection using frequency domain-OCT.

The unique features of OCT offer the ability to identify a very thin fibrous cap covering the lipid core and can potentially be used to predict future coronary events by identifying vulnerable plaques.²⁷ Compared with IVUS, which uses ultrasound technology and cannot penetrate calcium, OCT can assess the depth of calcium in a coronary lesion.²⁸⁻³¹ This insight can alter patient management, as the operator can appropriately determine the need for lesion preparation and the use of atherectomy if indicated. OCT can improve PCI results with the precise and accurate information it provides, identifying the ideal landing zones for a stent and aiding the selection of appropriate stent sizing. One of the particular advantages of this technology is to provide detailed information during cases of stent failure to help understand the mechanism of failure.³²⁻³⁴ Small thrombi that may be missed by angiography or IVUS can be detected by OCT. The resolution of OCT can also provide detailed lesion assessment, identifying the etiology of restenosis, by helping to determine if restenosis is focal or diffuse, and detecting the presence of neo-intimal thickening, microvessels, stent under-expansion, and intraluminal calcification.^{32, 33, 35} Knowledge of the characteristics and morphology of in-stent restenosis influences the subsequent management, which can vary widely to include a change in antiplatelet therapy, laser atherectomy, or brachytherapy.

The CLI-OPCI study demonstrated that an OCT-guided strategy changed the decision-making process in 35% of cases. OCT-guided stent implantation reduced mortality and MI at 1 year. The CLI-OPCI study also demonstrated that select patients with ST-elevation MI could be identified who could be treated with thrombus aspiration alone based on an OCT finding of plaque erosion rather than fibrous cap rupture.³⁶

The clinical safety of OCT was demonstrated in the Does Optical Coherence Tomography Optimize Results of Stenting (DOCTORS) study, wherein 240 patients presenting with non-ST-elevation MI were randomized to either OCT-guided PCI or

angiography-guided PCI. The DOCTORS study found that OCT did not increase periprocedural complications, type 4a MI, or acute kidney injury. OCT-guided PCI was associated with higher postprocedure FFR than PCI guided by angiography alone.³⁷

In the EROSION study, a proof of concept study, patients with residual stenosis <70% and plaque erosion identified on OCT in the setting of ACS, were treated with anti-thrombotic therapy without stenting. OCT imaging helped to determine in which patients stenting could safely be avoided.³⁸

To determine the ideal OCT-based stent sizing strategy, the ILUMIEN III: OPTIMIZE PCI study randomized 450 patients to IVUS-guided, OCT-guided, or angiography-guided PCI.²⁶ The ILUMIEN III trial found that an external elastic lamina-based stent optimization strategy was safe and resulted in similar minimum stent area to that of IVUS-guided PCI. There was a trend toward benefit of OCT over angiography guidance.

A number of inherent limitations of OCT technology exist, as it requires the displacement of blood for adequate visualization. There are some difficulties obtaining the optimal image quality in cases of large diameter or aneurysmal vessels and in aorto-ostial lesions. As contrast is traditionally used to displace blood, OCT is often avoided in patients with renal failure as there are risks of contrast-induced kidney injury. Alternative non-contrast based flush agents are being evaluated in clinical studies for this patient population.

OCT is a safe and effective intracoronary modality used in cardiac catheterization laboratory that has been studied in multiple large scale studies with a favorable safety profile.³⁹ There are ongoing clinical trials to demonstrate the impact of this technology in improving long-term clinical outcomes.²⁶ As further data is published, insights into the economic impact of OCT can be ascertained.

We recommend an algorithmic approach with IVI for comprehensive evaluation of coronary lesions (Figure 2). Use of IVI both pre- and post-PCI can optimize results. Pre-PCI lesion assessment can determine the plaque morphology and provide guidance on when

lesion preparation is needed. IVI provides measurements of the lesion length and vessel dimensions guiding stent selection. This can result in fewer stents used as well as an increased likelihood of appropriate stent sizing.^{7, 26} Post-PCI imaging is critical to confirm adequate stent expansion and exclude the presence of significant edge dissections or hematomas. When cases of stent failure are encountered, IVI is particularly important to determine the mechanism of stent failure. Determining the etiology of stent failure will impact how the patient is subsequently treated.

Areas of controversy

Low utilization of IVI in routine practice is often explained by the following criticisms: (i) IVI is too complicated to obtain and interpret, (ii) results are already good enough with modern equipment and techniques, (iii) IVI is unlikely to significantly change patient management, (iv) IVI is too expensive, (v) IVI takes too much time, and (vi) IVI involves excessive risk. These issues can all be overcome by an understanding of the different technologies available and interpretation of the images (Table 3).

Clinical Feature	Angiography	IVUS	OCT	Evidence
Assessment of left main coronary artery stenosis	†	†††	†	IVUS ^{40, 41} vs OCT ⁴²
Assessment of non-left main coronary artery stenosis	††	††	†††	IVUS ^{43, 44, 46} vs OCT ^{26, 39, 45,}
Localize the culprit lesion	†	††	†††	IVUS ^{47, 48} vs OCT ⁴⁸⁻⁵⁰
Identify a vulnerable plaque	0	†† (VH-IVUS)	†††	IVUS ^{48, 51-53, 50, 54} vs OCT ^{27, 48,}
Determine the likelihood of distal embolization and periprocedural MI	0	††† (VH-IVUS)	††	IVUS ^{55, 56} vs OCT ^{57, 58}
Size the vessel undergoing stent implantation	††	†††	†††	IVUS ^{9, 14, 59, 60} vs OCT ⁶¹
Optimise stent results	†	†††	†††	IVUS ^{7, 14} vs OCT ^{26, 37}
Evaluate stent thrombosis or	†	††	†††	IVUS ⁶² vs OCT ³²⁻³⁵

restenosis

An algorithmic approach can allow an interventional cardiologist to incorporate IVI into his or her daily practice while individualizing therapy and tailoring treatment to each patient.

Growing points

As costs decline for IVI tools with improved reimbursement, utilization may improve. Additionally, further availability and integration into existing catheterization laboratory systems can improve utilization. Software including co-registration with angiography can improve diagnostic accuracy and utility of the data obtained with IVI.

Areas timely for developing research

There is large-scale evidence for utility of IVUS in clinical practice with a large number of trials currently ongoing. Clinical research interest in OCT is profound as well, with clinical studies underway to assess how best to incorporate OCT to improve the clinical outcomes for patients. The beneficial clinical role of OCT-guided therapy for assessment of plaque morphology and stent optimization is planned to be evaluated in the ILUMIEN IV multicenter trial.

Studies currently in progress include OPTICO-ACS (NCT03129503), which will assess the *in vivo* characterization of the ACS-causing “culprit lesion”; Optical Coherence Tomography Intravascular Ultrasound Dual Imaging (NCT02984891), which will compare IVUS and OCT; Optical Coherence Tomography Findings and Coronary Bifurcation Lesions (NCT03172845); 6-month Intracoronary Optical Coherence Tomography Evaluation of Three New Generation Drug Eluting Stent (CREBX-OCT) (NCT02850497); Optical Coherence Tomography to Improve Clinical Outcomes During Coronary Angioplasty (NCT02065102); Optical Coherence Tomography Assessment of Gender diVersity In Primary Angioplasty (OCTAVIA) (NCT02577965); [Optical Coherence Tomography Morphologic and Fractional](#)

Flow Reserve Assessment in Diabetes Mellitus Patients (COMBINE) (NCT02989740)⁶³, and
Evaluation of Statin-induced Lipid-rich Plaque Progression by Optical Coherence
Tomography Combined With Intravascular Ultrasound (NCT01023607).

Conclusions

Modern x-ray angiography is a valuable tool in the cardiac catheterization laboratory to obtain images of coronary arteries. There are inherent limitations of this 2-dimensional technique and adjunctive intravascular techniques (IVUS and OCT) provide precise and detailed data of the 3-dimensional coronary artery tree. Hurdles of procedure-related cost and time are overcome by the benefits gained with IVI. A number of randomized trials are ongoing evaluating the impact of intracoronary imaging on long-term clinical outcomes. Combining an algorithmic approach to IVI with sound clinical judgment can improve the decision-making process and can help improve the clinical outcomes.

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Table 1 Comparison of angiography and intravascular imaging modalities.

Angiography	Intravascular Ultrasound/Optical Coherence Tomography
2 Dimensional	360° View
Planar	Tomographic and sagittal
Shadow of lumen	Visualization of shape and location
Wall structure not imaged	Visualisation of inner wall structures and morphology
Vessel is seen for short time period during the contrast injection	Confluent imaging; the whole vessel can be imaged
Quantitative coronary angiography analysis with mistakes	Spatial imaging precise assessment

Table 2 Current guideline recommendations for use of intravascular ultrasound and optical coherence tomography.

ACCF/AHA/SCAI Guidelines for PCI Recommendations (2011) ^{15, 16}	ESC Guidelines in Myocardial Revascularization (2014) ¹⁷
Intravascular Ultrasound	
• IVUS is reasonable for the assessment of angiographically indeterminate left main coronary artery disease. (Class IIa, Level of Evidence: B) • IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor coronary artery disease, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information. (Class IIa, Level of Evidence: B) • IVUS is reasonable to determine the mechanism of stent restenosis. (Class IIa, Level of Evidence: C) • IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenosis (50% to 70% diameter stenosis). (Class IIb, Level of Evidence: B) • IVUS may be considered for the guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting. (Class IIb, Level of Evidence: B) • IVUS may be reasonable to determine the mechanism of stent thrombosis. (Class IIb, Level of Evidence: C) • IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. (Class III, Level of Evidence: C)	• IVUS to assess severity and optimize treatment of unprotected left main lesions. (Class IIa, Level of evidence B) • IVUS in selected patients to optimize stent optimization. (Class IIa, Level of evidence B) • IVUS to assess mechanisms of stent failure (Class IIa, Level of evidence C)
Optical Coherence Tomography	
• The appropriate role for optical coherence tomography in routine clinical decision making has not been established.	• OCT should be considered in patients to understand the mechanism of stent failure. (Class IIa, Level of evidence C) • OCT in selected patients to optimize stent implantation. (Class IIb, Level of evidence C)

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ACCF = American College of Cardiology Foundation; AHA = American Heart Association; IVUS = intravascular ultrasound; OCT = optical coherence tomography; SCAI = Society for Cardiovascular Angiography and Interventions.

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Table 3 Comparison of angiography, intravascular ultrasound, and optical coherence tomography for various clinical scenarios.

Clinical Feature	Angiography	IVUS	OCT	Evidence
Assessment of left main coronary artery stenosis	†	†††	†	IVUS ^{40, 41} vs OCT
Assessment of non-left main coronary artery stenosis	††	††	†††	IVUS ^{43, 44} vs OCT ^{26, 39, 45, 46}
Localize the culprit lesion	†	††	†††	IVUS ^{47, 48} vs OCT ⁴⁸⁻⁵⁰
Identify a vulnerable plaque	0	†† (VH-IVUS)	†††	IVUS ^{48, 51-53} vs OCT ^{27, 48, 50, 54}
Determine the likelihood of distal embolization and periprocedural MI	0	††† (VH-IVUS)	††	IVUS ^{55, 56} vs OCT ^{57, 58}
Size the vessel undergoing stent implantation	††	†††	†††	IVUS ^{9, 14, 59, 60} vs OCT ⁶¹
Optimise stent results	†	†††	†††	IVUS ^{7, 14} vs OCT ^{26, 37}
Evaluate stent thrombosis or restenosis	†	††	†††	IVUS ⁶² vs OCT ³²⁻³⁵

0 = no evidence; † = some evidence; †† = moderate evidence; ††† = strong evidence; IVUS = intravascular ultrasound; MI = myocardial infarction; OCT = optical coherence tomography

Figure Legends

Figure 1. Various plaque morphologies as seen by intravascular ultrasound (IVUS) (left) and optical coherence tomography (OCT) (right).

(A and B) Normal characteristics of the vessel wall. (C and D) Eccentric fibrotic plaque. (E and F) Lipid plaque. The lipid component of the plaque is echolucent (IVUS) and also appears as a low signal (low light reflection, OCT). (G and H) Calcium creates a deep acoustic shadowing that hides the underlying structures (asterisk) and hampers the delineation of the external elastic membrane. The posterior boundary of the calcium deposit (asterisk) appears sharp and well visible with OCT (H). (I and J) Stented segments.

Figure 2. Algorithmic approach for utilization of intracoronary imaging

DES = drug-eluting stent; ISR = in-stent restenosis; IVI = intravascular imaging; PCI = percutaneous coronary intervention; POBA = plain old balloon angioplasty.

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