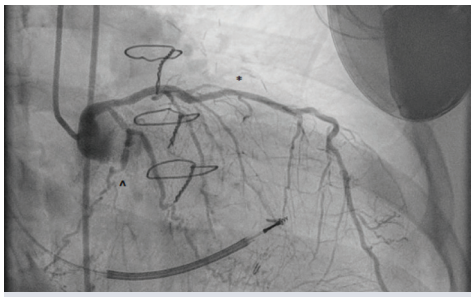
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Crossing a Severe Complex Lesion With a Rapid Exchange Low-Profile Angioplasty Balloon After Crossing Failure of Two Microcatheters

Prospero B. Gogo, Jr., MD, FACC, FSCAI

Complex percutaneous coronary interventions are encountered frequently during coronary angiography, occurring in approximately 1 in 5 of all patients referred for angiography, and in up to 50% of patients with a prior history of known coronary artery disease.[1] On the other hand, revascularization rates of these lesions with percutaneous coronary intervention (PCI) have historically been low, with only 10%-15% of patients undergoing an attempt with complex PCI.[2] Complex lesions are also a significant driver of referrals for revascularization via coronary artery bypass graft (CABG) surgery.

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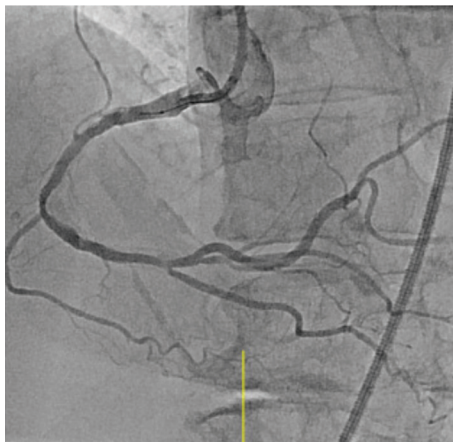
CALCIUM CORNER

The PCI Gender Gap in Treating Calcified Lesions: A Paradigm Shift

CLD talks with Suzanne J. Baron, MD, MSc, FSCAI.



Historically, why have women experienced worse percutaneous coronary intervention outcomes than men?

In general, our studies have shown us time and time again that both short and long-term mortality rates in women are higher after percutaneous coronary intervention (PCI), even in the contemporary era. The cause for this persistent finding is likely multifactorial and includes atypical presentations of coronary artery disease (CAD) with resulting delays in diagnosis, and invasive and noninvasive evidence-based treatment in female patients.

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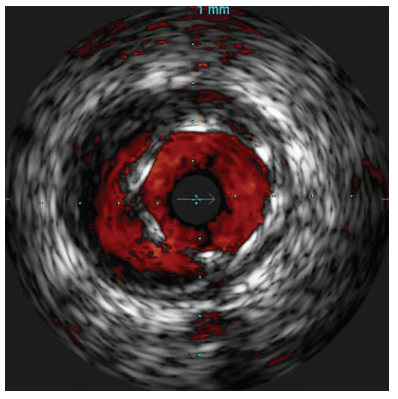
IMAGING IN PVD

The Consensus for Intravascular Ultrasound Use in Peripheral Vascular Intervention

CLD talks with Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM.



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The PCI Gender Gap in Treating Calcified Lesions: A Paradigm Shift

CLD talks with Suzanne J. Baron, MD, MSc, FSCAI.

The new gender consensus statement in the *Journal of the Society for Cardiovascular Angiography and Interventions* (*JSCAI*) talks about how women are underdiagnosed and under-represented with underwhelming PCI outcomes. Can you elaborate on that?

Women have been historically underrepresented in cardiovascular clinical trials, often only accounting for 20%-25% of the study population, despite the fact that women do account for half of our patient population. With this under-representation, it follows that we do not have a good understanding of sex-based differences in drug or device outcomes. The SCAI Expert Consensus Statement on Sex-Specific Considerations in Myocardial Revascularization published in *JSCAI* earlier this year[1] highlights the gaps in knowledge regarding sex-specific management of CAD and should serve as a call to action for further research into this area. For example, the average coronary diameter, mean vessel area, and mean luminal area have been shown to be smaller in women than in men. However, there are no sex-specific recommendations for optical coherence tomography (OCT)- or intravascular ultrasound (IVUS)-guided thresholds for minimal luminal area cut-offs that should trigger intervention. When intervention is determined to be appropriate, there is little data to suggest what mode of revascularization is most appropriate for women. Indeed, a recent meta-analysis suggested that women with multivessel CAD and/or left main coronary artery disease may benefit more from treatment with CABG as compared to PCI.[2] That said, these data are limited by the fact that women comprised less than 25% of the study population for many of the included trials. As such, further research is needed to assess whether women with multivessel CAD should preferentially receive coronary artery bypass graft surgery over PCI.

Figure 1A. Initial angiogram. The patient is an 82-year-old female with a calcified right coronary artery.

What role does unconscious bias potentially play in the undertreatment of frail, elderly women with calcified disease?

I believe that unconscious bias may play a role in the undertreatment of female patients with CAD in two ways: (1) Women present more commonly than men with atypical symptoms (decreased exercise tolerance, fatigue, nausea, shortness of breath). Accordingly, providers may be less likely to look for CAD as a cause of their symptoms and defer cardiac work-up, even when indicated. (2) Since women have been shown to have smaller diameter and more tortuous arteries, there may be a concern that calcium modification could lead to a greater risk of perforation and so advanced techniques for optimal PCI may not be used as aggressively in female patients.

Intravascular lithotripsy data were included in the SCAI gender consensus statement. What impact could intravascular lithotripsy have on improving outcomes in women with calcified lesions?

Intravascular lithotripsy (IVL) has been shown to be both safe and effective in the treatment of calcified coronary artery disease, with low rates of device-related adverse events, as shown in the DISRUPT CAD study series.[3-6] Certainly, any device that may assuage operator concerns regarding complications when treating complex lesions could translate to an increase in use of calcium modification where indicated. Since we know that inadequate lesion preparation may lead to higher rates of in-stent restenosis and stent thrombosis, it follows that IVL could help lower suboptimal PCI rates in both men and women.

How do the coronary IVL in women-related data coming out of the SCAI 2022 meeting substantiate coronary IVL use as a first-line therapy for women with calcified lesions?

Small retrospective studies have suggested that women may be at an increased risk for procedural complications after atherectomy. Procedural complications are often related to vascular injury during plaque modification. As post-menopausal women have been shown to have increased arterial stiffness, less vessel compliance, and increased vascular fragility, it is not surprising that these factors, in conjunction with smaller coronary artery size, could lead to higher rates of coronary perforation and dissection during treatment of calcified plaque. The sex-specific analysis of the DISRUPT CAD series of studies presented at SCAI 2022 demonstrated that there was no difference in angiographic complications, successful stent delivery, and 30-day adverse cardiovascular events between men and women.[7] These are certainly reassuring data, which suggest that the possible safety signals seen in women treated with atherectomy may not be present with IVL.

Are the results of the analyses presented at the Transcatheter Cardiovascular Therapeutics (TCT) 2021 and SCAI 2022 meetings are strong enough to change the historical paradigm of a risk for worse safety outcomes in women with calcified lesions versus men?

First, it is important to note that the single-arm design of the DISRUPT CAD studies does not allow for comparisons of IVL with other calcium modification techniques and additionally, only 23% of patients in these studies were female. As such, it is difficult to say that we have definitive data that IVL will improve outcomes in female PCI patients with calcified lesion(s). That being said, I do believe that the DISRUPT CAD safety data could lead to an uptick in IVL use in female patients in particular, which could certainly contribute to not only lower rates of procedural complications, but also to the performance of more optimal PCI in female patients, with resulting better long-term clinical outcomes.

What are the other key initiatives that the interventional cardiology community is working on to narrow gender disparities of PCI outcomes in calcified lesions?

Part of the reason for gender disparities in PCI outcomes is that women remain severely underrepresented in cardiac device trials and this fact has been recognized by the medical community and industry. SCAI-WIN (Women in Innovations), as well as other groups, such as Women as One and ACC-WIC (Women in Cardiology), are actively working with industry as well as regulatory agencies on ways to increase female representation in these trials through initiatives supporting increased female representation in study leadership, and programs aimed at understanding and then alleviating barriers to female enrollment in trials. ■

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Learn more about coronary intravascular lithotripsy use by visiting Cath Lab Digest's Calcium Corner. Click on the QR Code or start at cathlabdigest.com: CLD home page –> Topics –> Calcium Corner

Use this QR code to access the Calcium Corner directly.

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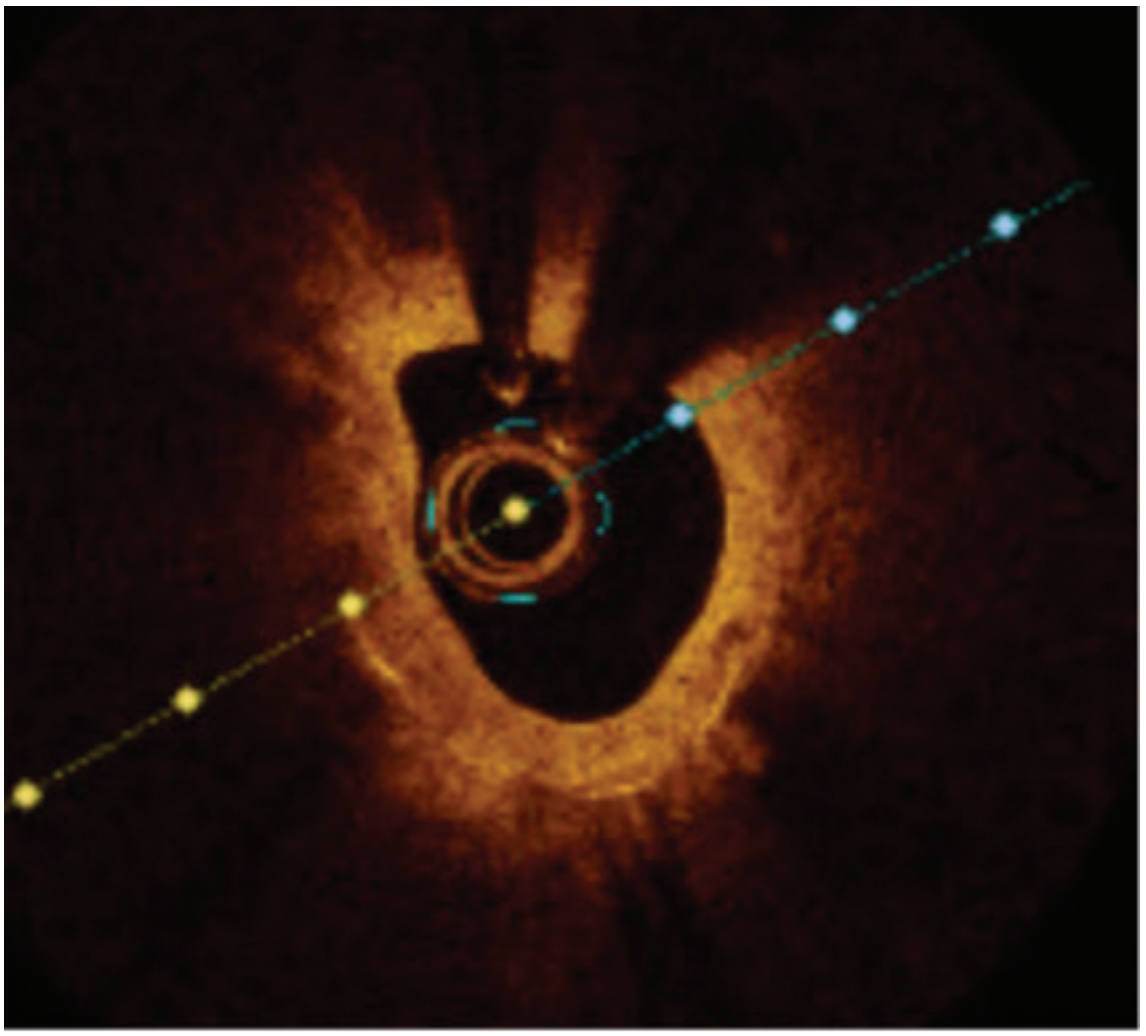

Figure 1B. Optical coherence tomography (OCT) image pre intervention.

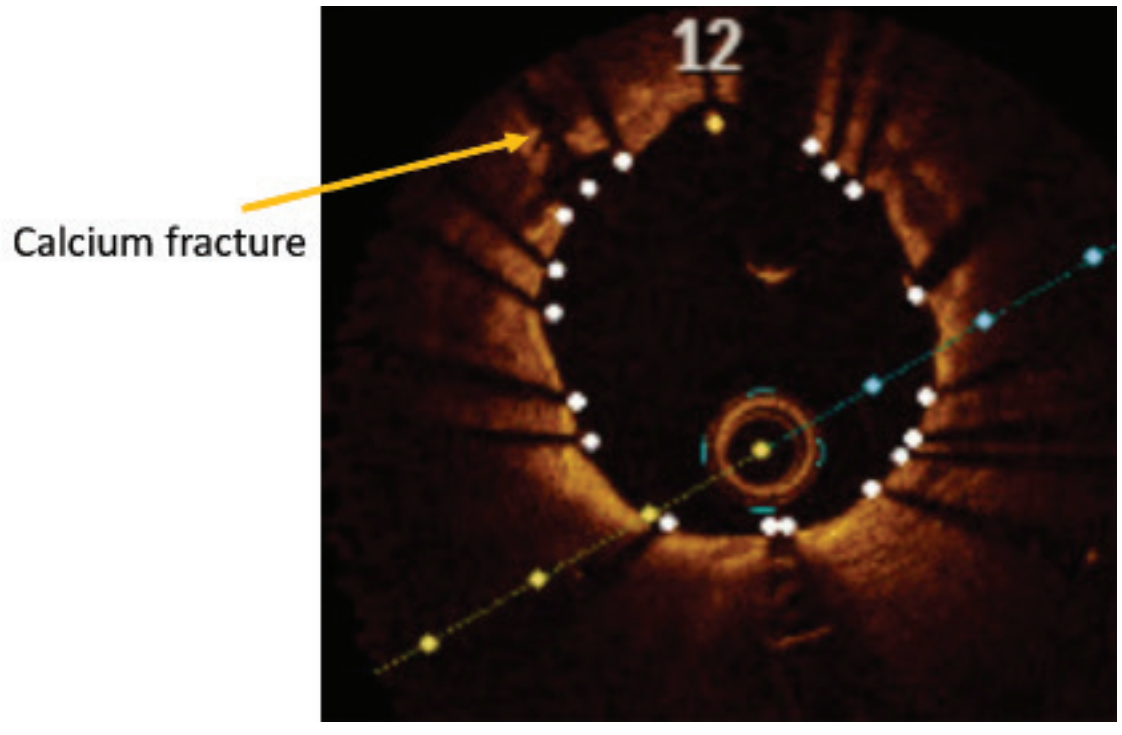

Figure 1C. OCT image showing post intravascular lithotripsy (IVL) and stenting.

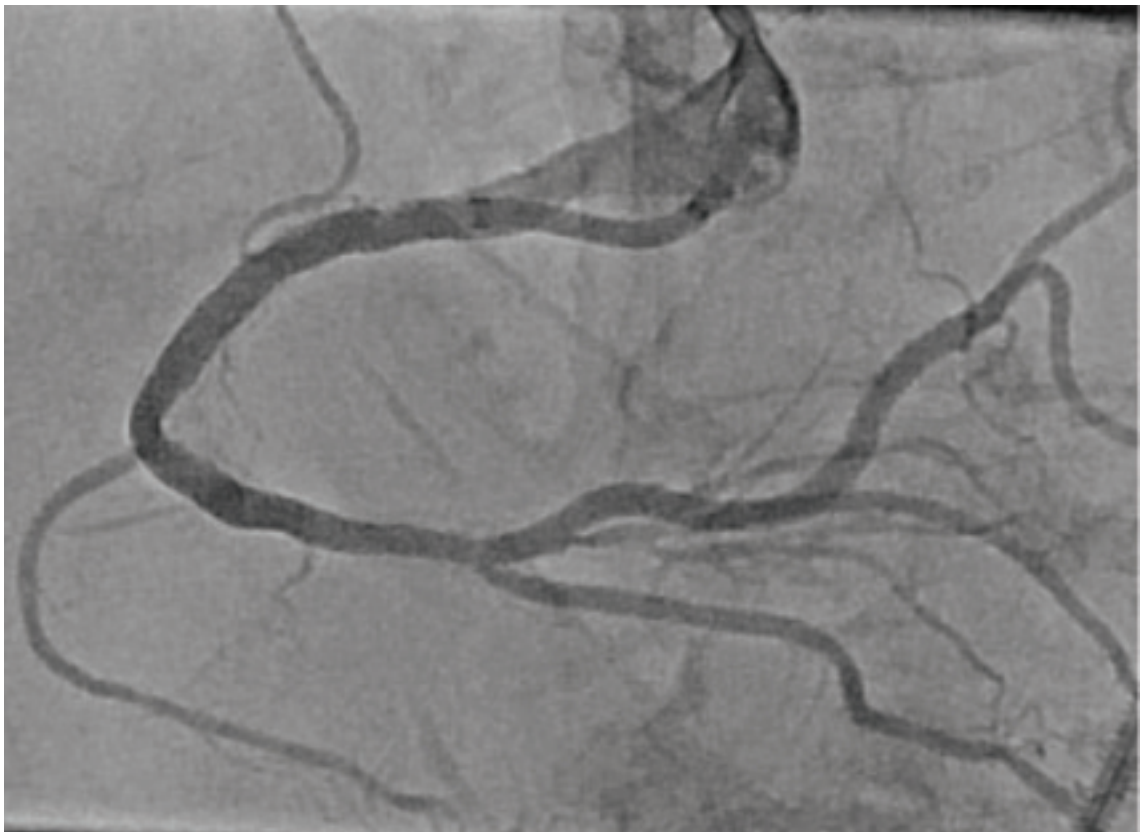

Figure 1D. Final angiogram.

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