



Use of Alternate Flush Media to Facilitate OCT Imaging of the Infra-popliteal Segment

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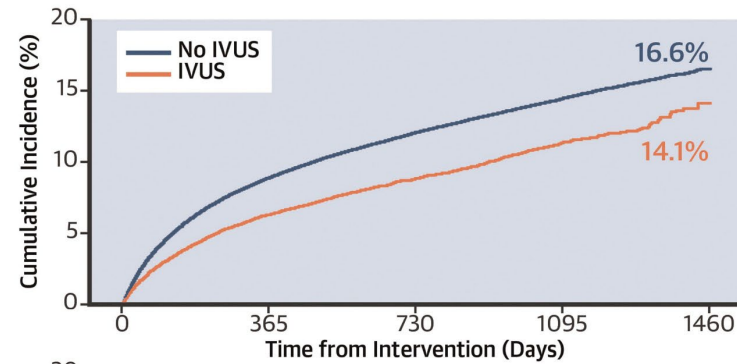
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Introduction

- Angiography has inherent limitations, including assessment of vessel size, stenosis severity, lesion length, and plaque morphology
- Intravascular imaging provides more accurate and comprehensive evaluation, enabling better procedural guidance
- In coronary interventions, intravascular imaging is associated with improved safety and clinical outcomes
- However, its role and benefits in peripheral interventions are less well established

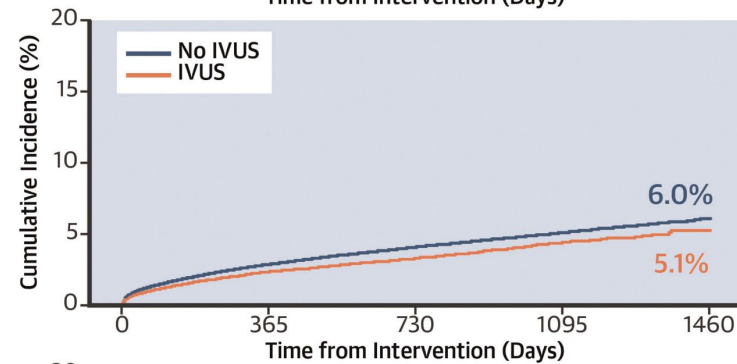
CENTRAL ILLUSTRATION: Cumulative Incidence of the Composite Endpoint of Major Adverse Limb Events and its Components After Lower Extremity Peripheral Arterial Intervention Stratified by Use of IVUS

Peripheral Arterial Intervention Among Medicare Beneficiaries
With Versus Without IVUS (2016-2019)
N = 543,488

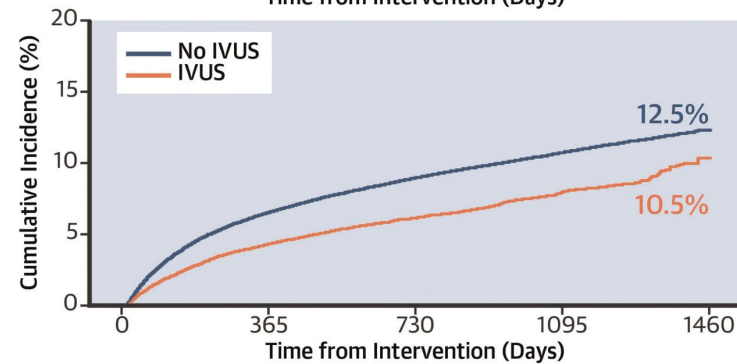


With IVUS:

↓ MALE
NNT = 40

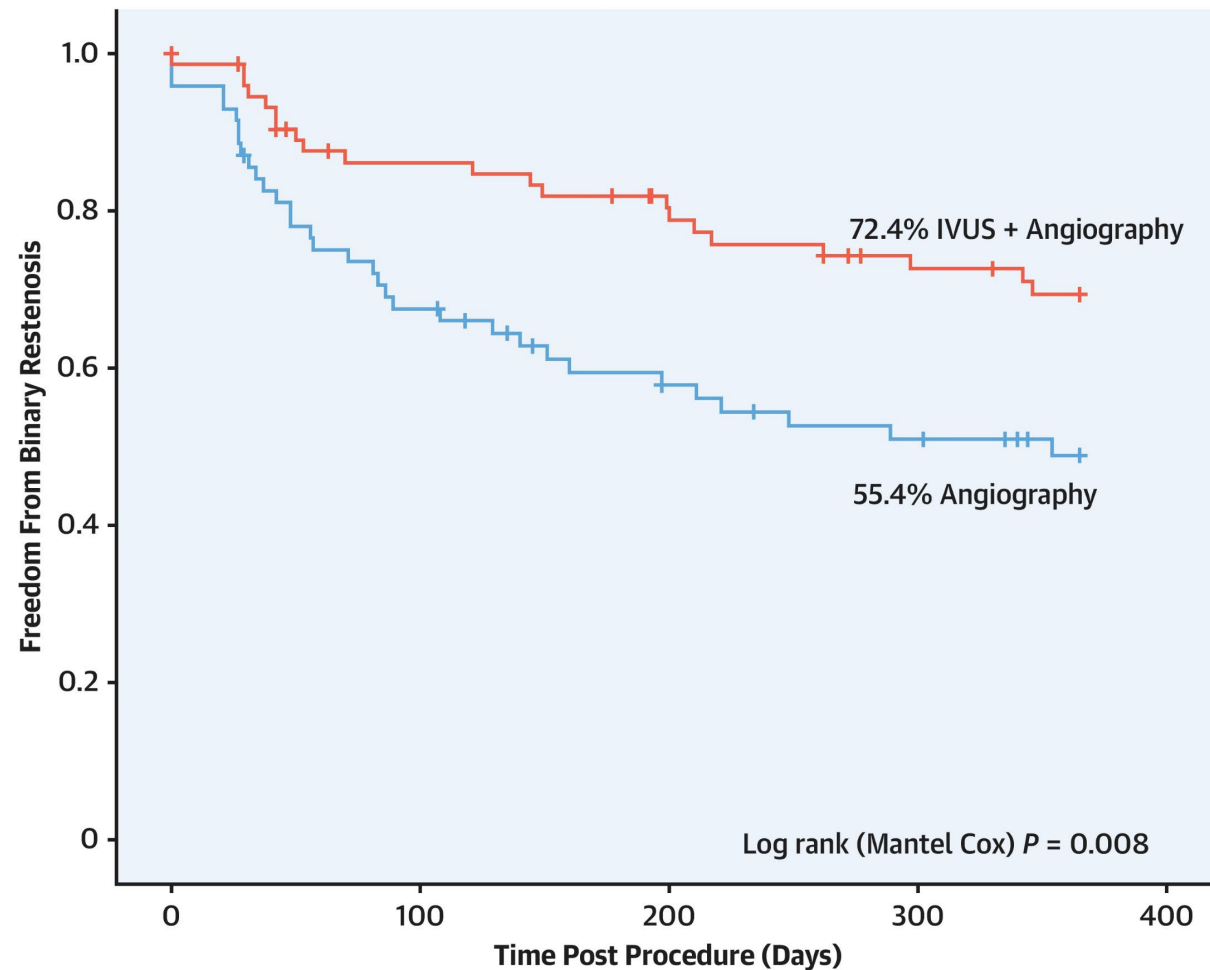


↓ ALI
NNT = 111



↓ Major Amputation
NNT = 50

CENTRAL ILLUSTRATION: Restenosis Following Randomization to Angiographic Guidance Versus Intravascular Ultrasound Plus Angiography for Femoropopliteal Interventions, N = 150



Allan, R.B. et al. J Am Coll Cardiol Interv. 2022;15(5):536-546.

Introduction

- Adjunctive IVUS use led to **changes in the treatment plan in 78.9%** of cases, mostly due to increases in treatment length and device sizes.
- **Angiography underestimates** infra-popliteal vessel diameters when compared with IVUS
- Adjunctive **IVUS results in use of larger balloon** diameters during infra-popliteal artery intervention
- With everolimus-eluting BRS available in infra-popliteal disease, accurate vessel sizing is essential to avoid under-sizing and scaffold dismantling, as seen in coronary use.

Introduction

- OCT, using near-infrared light, provides higher resolution than IVUS and has shown comparable benefits in PCI
- OCT may be advantageous in infra-popliteal disease given its complexity, including extensive medial calcinosis, long lesion lengths, and a predisposition to complications following angioplasty
- However, OCT adoption in peripheral interventions is **limited by the need for contrast**

Study Objectives

- To develop a strategy to facilitate OCT imaging of the infra-popliteal segment
- To assess the feasibility and safety of using alternative flush media for OCT in the infra-popliteal segment
- To evaluate the imaging quality of OCT with alternative flush media compared with the contrast

Methods

- Single-center, observational pilot study
- Inclusion Criteria
 - Adults aged ≥ 18 years
 - Patients undergoing elective diagnostic peripheral angiography or planned intervention
- Exclusion Criteria
 - Acute limb ischemia
 - Severe renal impairment (eGFR < 45 mL/min/1.73 m²)
 - Clinical instability or lesion complexity deemed unsuitable

Methods

- OCT was performed with three different media – 1) iodinated contrast, 2) saline, and 3) CO₂
- Procedural details
 - 6Fr multipurpose guide catheter positioned proximal to the infra-popliteal segments
 - Using a 50-cc syringe, each flushing medium (contrast ~20-30 cc, saline ~20-30 cc, and CO₂ 50 cc) was injected manually
 - OCT acquisition was manually triggered

Methods – OCT analysis

- Analysis performed at 0.2 mm intervals
- Frame-level image quality classification:
 - **Optimal**: clear vessel lumen and visible lumen contour 360°
 - **Acceptable**: visible lumen contour $\geq 270^\circ$
 - **Unacceptable**: visible lumen contour $<270^\circ$
- Predominant plaque morphology
 - Normal, fibrotic, calcified, lipidic, or indeterminate
- Feasibility of OCT-guided procedural planning, including device sizing

Study Outcomes

1. Primary outcome:

- **Clear Imaging Field (CIF):** visible lumen contour $\geq 270^\circ$

2. Secondary outcomes:

- Image quality
- Agreement on predominant plaque type
- Procedural feasibility
- Device sizing

Results

	N = 8
Age	79.0 (77.0–83.0)
Female	62.5%
Hypertension	75.0%
Hyperlipidemia	100.0%
Diabetes	37.5%
Chronic kidney disease	37.5%
Baseline eGFR (ml/min/1.73 m ²)	88.0 (75.0–90.0)

Results

	N=8
Target lesion for intervention	
Anterior tibial	37.5%
Tibioperonial	50.0%
Superficial femoral*	12.5%
Intervention	
DCB	37.5%
Balloon angioplasty	50.0%
SES†	12.5%

* OCT was still performed in tibioperonial segment

† SES placed in SFA

Results

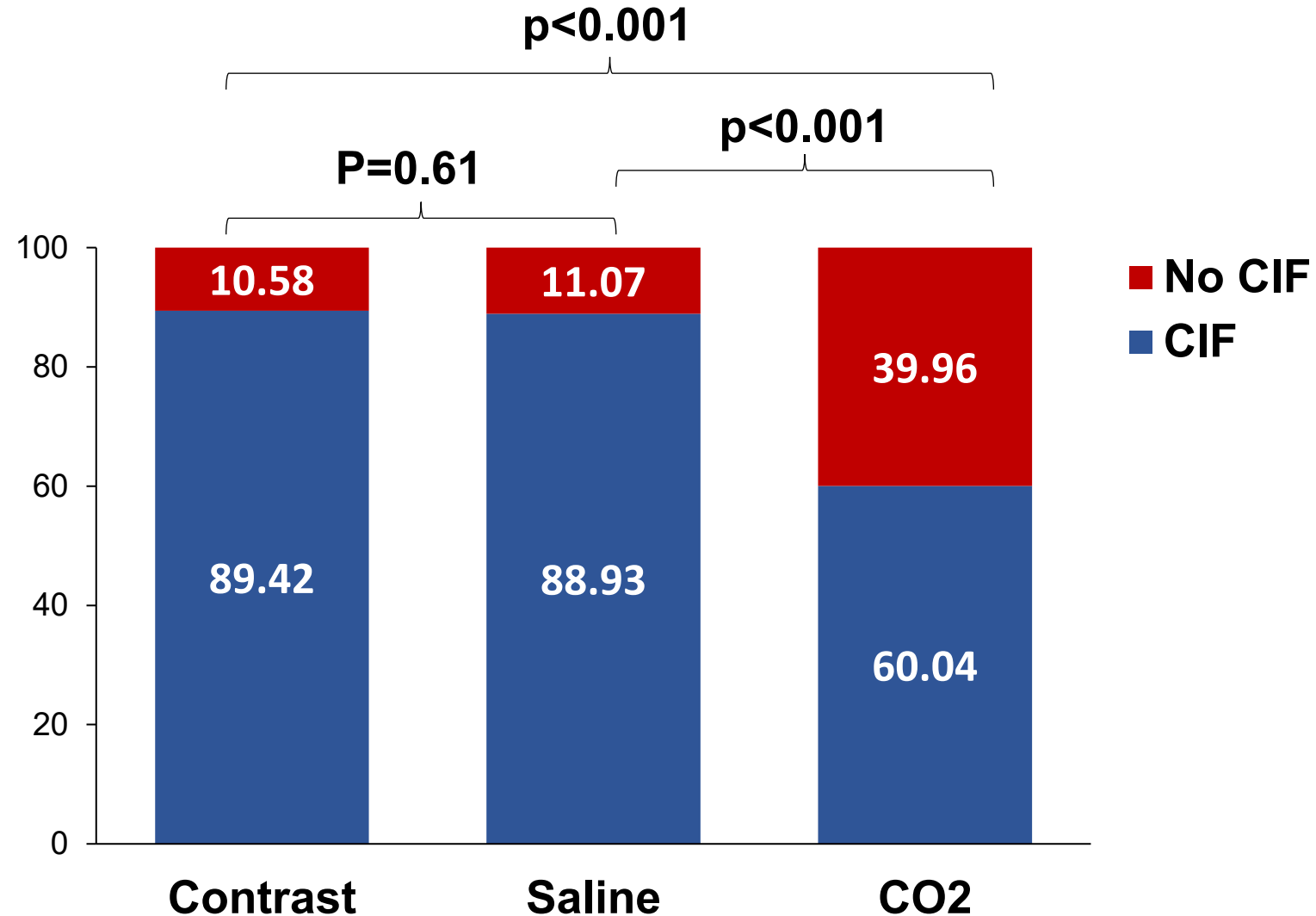
	N=8
Procedural success	100.0%
Contrast use for OCT (ml)	20 (20–25)
Complications	
Major bleeding	0.0%
Persistent pain*	0.0%
Hemodynamic changes†	0.0%
AKI	0.0% (0/5)
post GFR at 1-2 weeks	88.0
post-pre GFR	1.0 (-1.0–3.0)

* Pain that does not subside until the end of the procedure

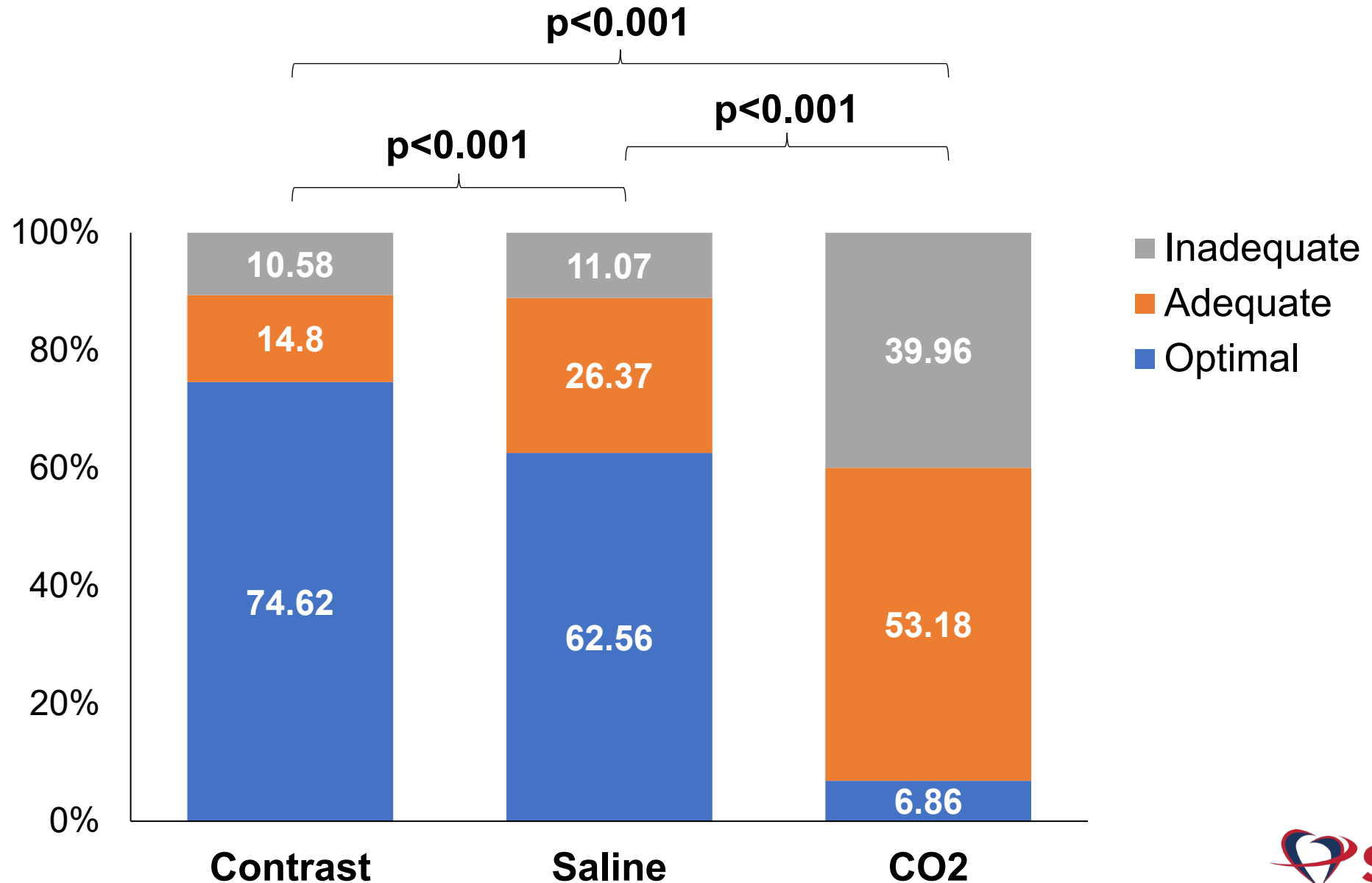
† SBP drop < 10 mmHg or HR increase > 20%

OCT results – CIF

Total frames analyzed: 6176
(Contrast: 2108; Saline: 2086; CO₂: 1982)



OCT results – Image Quality



Co-registered Cross-sections

Contrast

Saline

CO2

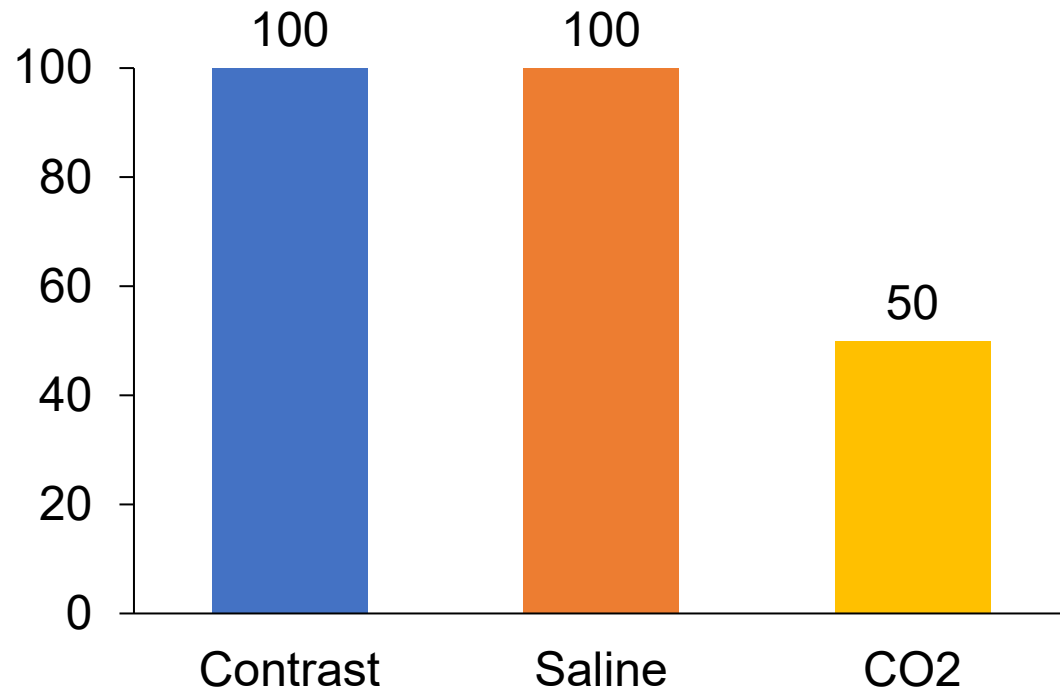
Optimal quality
CIF

Optimal quality
CIF

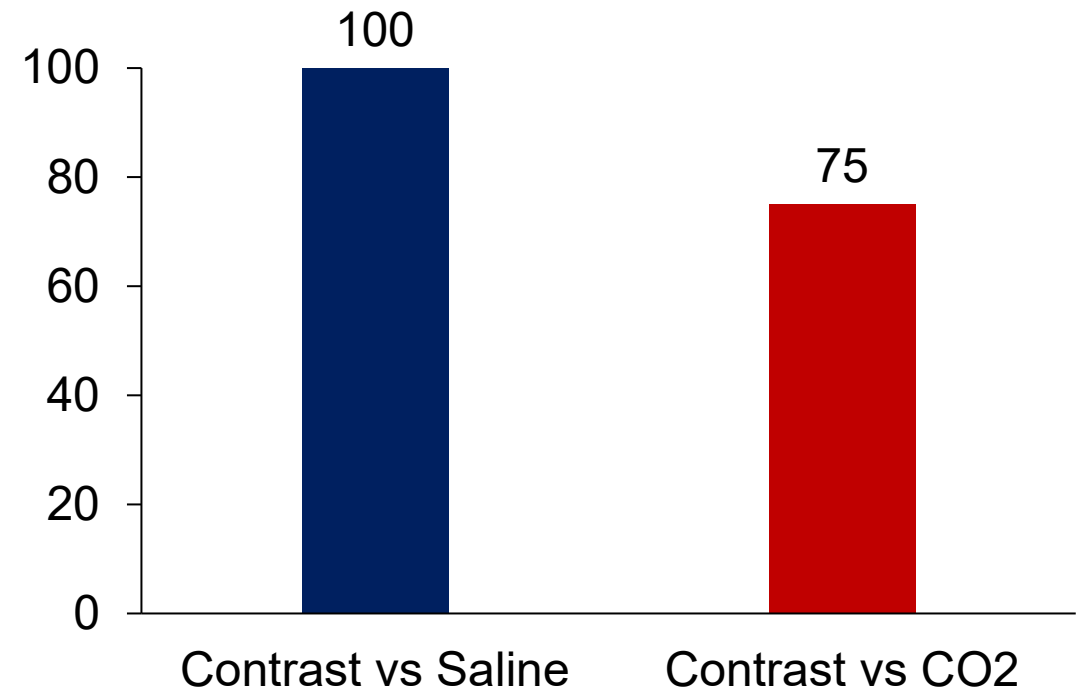
Inadequate quality
due to partial clearing
Not CIF

Secondary Outcomes

Feasibility for Intervention and Sizing



Agreement on Predominant Plaque Type

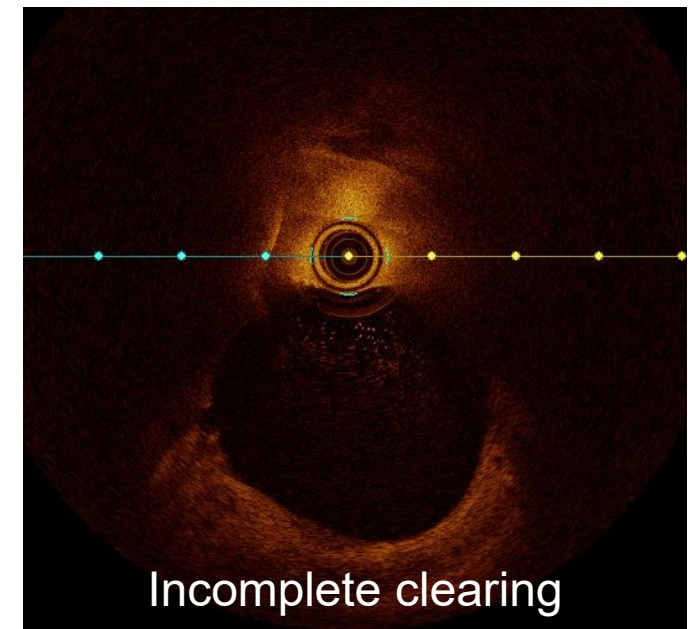
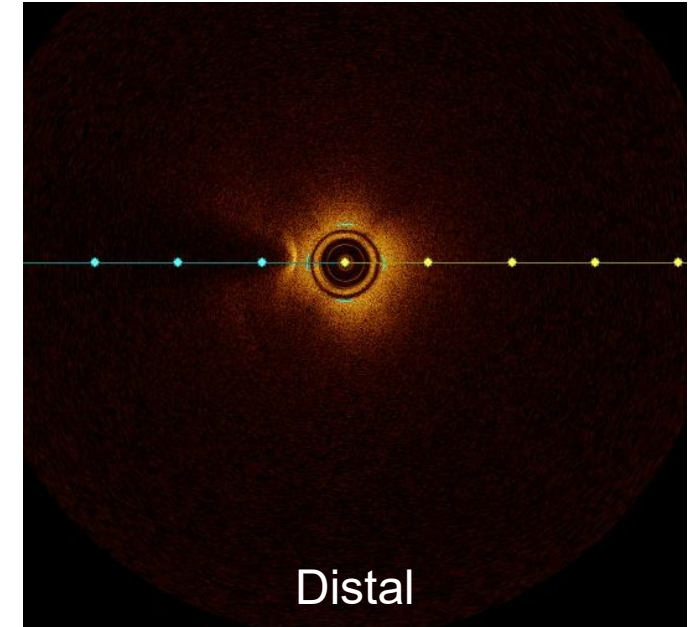


Discussion

- Saline OCT appears to be a comparable alternative to contrast, providing similar CIF ($p = 0.61$).
- From a technical standpoint, for the infra-popliteal segment, the guide catheter should be positioned close to popliteal level for OCT acquisition.

Discussion

- CO₂-OCT demonstrated **lower** image quality and reduced CIF
- Technical challenges in CO₂-OCT
 1. Precise coordination of OCT acquisition with CO₂ injection is required (especially for distal)
 2. Incomplete or partial blood clearance may occur
 3. Patient discomfort may occur but is generally well tolerated, with no major safety concerns.



Conclusion

- OCT was **safe and feasible** for imaging infra-popliteal segments during peripheral interventions
- Saline-OCT is feasible and provides **comparable** imaging quality to contrast, enabling procedural planning and device sizing in all cases
- CO₂-OCT was feasible and safe but resulted in lower imaging quality compared with contrast or saline, although procedural planning was possible in 50% of cases

Future Direction

- We will continue enrollment to reach our target sample size of 20 patients
- We plan to compare sizing differences between angiography- and OCT-guided decision-making
- The impact of OCT-derived information on clinical decision-making and outcomes warrants further investigation

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