JACC: ASIA VOL. 5, NO. 3, 2025

CUTTING-EDGE TECHNOLOGY

A Multicenter Feasibility and Safety Study of a Novel Hybrid IVUS-OCT Imaging System

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ABSTRACT

Currently, precise stent manipulation and placement in percutaneous coronary intervention remain compromised. Intravascular imaging techniques are often limited by either spatial resolution or depth of penetration. A hybrid intravascular ultrasound (IVUS)-optical coherence tomography (OCT) system would be a better choice for interventional cardiologists. To validate the image quality and safety of the novel IVUS-OCT system for guiding coronary intervention in Chinese patients, a total of 114 cases were included. The proportion of clear imaging length was 96.21% ± 10.16%. Device success rate was 99.1%, technical success rate was 98.2%, and excellent image rate was 96.5%. No catheter-related adverse events occurred, and the incidence of device defects was 0.9%. This study preliminarily verified the image quality and safety of the novel Hybrid IVUS and OCT imaging system. (The StUdy to Evaluate the Performance and safEty of the Novasight HybRid System Using Objective PeRformance Criteria [SUPERIOR]; NCT04617899) (JACC Asia. 2025;5:396–400) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Intravascular imaging techniques may provide accurate and adequate information in assessing vessel and plaque composition, which could be used to optimize treatment decisions. Recent guidelines have recommended intravascular ultrasound (IVUS) or optical coherence tomography (OCT) to optimize percutaneous coronary intervention (PCI); however, these 2 techniques happen to be complementary functionally: IVUS provides sufficient imaging depth to show complete vascular structure and can be used to determine plaque burden, and OCT attains higher tissue resolution and provides more accurate information about plaque composition and thrombus. To address single-model imaging limitation, the research and development of hybrid IVUS-OCT intravascular imaging techniques has been a hot spot. In 2018, a hybrid IVUS-OCT system for clinical application was reported for the first time and obtained U.S. Food and Drug Administration approval.[1] Subsequently, a single-center, exploratory clinical trial in Canada evaluated the feasibility and safety of the system for simultaneous acquisition of IVUS and OCT coronary images in clinical applications, which providing preliminary evidence that the images acquired by hybrid system meet the clinical requirements.[2] Nowadays, another novel hybrid imaging system (PANOVISON, Panovision Co, Ltd) was also approved for clinical use.[3] This study

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received October 15, 2024; revised manuscript received January 16, 2025, accepted January 22, 2025.

ISSN 2772-3747 https://doi.org/10.1016/j.jacasi.2025.01.009

was the first multicenter trial designed to evaluate the imaging quality and the safety of Novasight Hybrid system (Conavi Medical Inc) in Chinese patients.

METHODS

STUDY DESIGN AND POPULATION. This prospective, multicenter trial evaluated the performance and safety of the hybrid IVUS-OCT system in PCI patients. The protocol was approved by all ethics committees responsible for all participating centers. The major inclusion criteria were the following:1) age 18 to 85 years; and 2) unstable angina or acute myocardial infarction suitable for PCI. Major exclusion criteria were as follows: 1) left ventricular ejection fraction <35%; 2) high bleeding risk, active peptic ulcers, or cerebrovascular accident or transient ischemic attack within the past 6 months; 3) contraindication to anticoagulants and antiplatelets therapy; 4) left main or ostium lesion, severe calcification, or severe tortuosity in the target vessel; and 5) multiple contiguous stent implantation in the target vessel. Eligible patients who provided written informed consent were enrolled at 3 sites in China.

STUDY DEVICE. This Hybrid image system consists of 3 parts: the Acquisition and Display Module, a patient interface acquisition and display module, and a catheter. There are 2 models in 1 catheter, the IVUS alone and the IVUS-OCT model, which can be flexibly switched during the PCI without changing another catheter. The catheter had a 2.8-F imaging window distally. Its compatible guidewire size was 0.014 inch. It had a built-in rotating probe, consisting of an IVUS imaging unit and an OCT imaging unit coaxially, which can simultaneously acquire IVUS and OCT images with a pull back speed of 10 or 25 mm/s while the imaging core rotates at a frame speed of 100 frames/s. A maximum pull back distance was 100 mm.

PROCEDURE. After implantation of the stent, intravascular Hybrid IVUS-OCT imaging examination was mandatory. The imaging catheter was advanced more than 5 mm to the distal stent. After placement of the imaging catheter, a 50-mm-length pull back image is automatically acquired at a rate of 10 or 25 mm/s. All adverse events (AEs) during the trial were recorded by the clinical events committee, which consisted of 3 independent cardiologists who did not participate in the clinical trial and were blinded to the patient information and results of the study.

QUANTITATE OF IVUS AND OCT IMAGING. The images were evaluated by third-party medical imaging core laboratory for imaging length, clear imaging length (CIL), excellent rate of image quality, and length of clear drug-eluting stents (DES). Clear image frame requires the following standards: 1) simultaneous imaging of IVUS and OCT; and 2) imaging angle is no <270°.

STUDY ENDPOINTS. The primary endpoint was the proportion of clear images, defined as the proportion of CIL acquired within the total image length. The safety endpoint was incidence of catheter-related major AEs, which are composed of myocardial infarction, coronary revascularization, target lesion restenosis, death, coronary coarctation, in-stent thrombosis, bleeding, acute coronary occlusion, DES deformation, and cerebrovascular events, and so on.

The secondary endpoint included the rate of device success, the rate of technical success, excellent image quality for clinical evaluation, and length of clear DES, as well as intraoperative evaluation by the surgical operator of the stability and maneuverability of the hybrid imaging catheter.

STATISTICAL ANALYSIS. Continuous variables were described as mean ± SD or median (IQR) and categorical variables as counts and percentages. For the proportion of CIL, point estimate and its 95% CI was given separately, and the lower limits of the 95% CI obtained were compared with predefined target values. Sites were heterogeneity assessed using meta-analysis methods. All analyses were completed using SAS software version 9.4.

RESULTS

BASELINE AND PCI PROCEDURE CHARACTERISTICS OF SUBJECTS. A total of 118 patients were recruited at 3 clinical centers in local hospitals (Beijing Anzhen Hospital, Peking University Third Hospital, and the first medical center of PLA General Hospital) in China from March to December 2021. Four subjects were excluded because no catheter was used. Baseline and PCI procedure characteristics of the 114 subjects are shown in Table 1.

EFFECTIVENESS AND SAFETY ENDPOINT. The proportion of CIL was 96.21% ± 10.16% (95% CI: 94.33%-98.10%). There was no significant difference in the results of the heterogeneity test among the centers ($P = 0.1607$). 99.1% subjects (n = 113) completed the

ABBREVIATIONS AND ACRONYMS

AE = adverse event(s)

CIL = clear image length

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

TABLE 1 Baseline Characteristics and Endpoints

Baseline characteristics (n = 114)	
Age, y	59.98 ± 9.56
Male	88 (77.2)
LVEF, %	63.08 ± 6.41
Prior myocardial infarction	15 (13.2)
Prior PCI or CABG	19 (16.7)
Arterial access	
Radial	111 (97.4)
Femoral	2 (1.8)
Guidance catheter	
5-F	1 (0.9)
6-F	109 (95.6)
7-F	4 (3.5)
Vascular target lesions	
LAD	70 (61.4)
LCX	15 (13.2)
RCA	29 (25.4)
Diameter of the lesion, mm	3.00 (3.00-3.50)
Stenosis of the lesion, %	90.00 (80.00-90.00)
Diameter of drug-eluting stents, mm	3.00 (2.75-3.50)
Length of drug-eluting stents, mm	23.00 (18.00-29.00)
Device effectiveness endpoint (n = 114)	
Rate of device success	113 (99.1)
Rate of technical success	112 (98.2)
Stability during examination	
Operate stably and examine smooth	111 (97.4)
Unstable but examine smooth	2 (1.8)
Retreatment after experimental equipment (n = 113)	8 (7.1)
Image analysis (n = 113)	
Target vessel imaging length, mm	50.20 (50.10-51.20)
CIL, mm	50.20 (47.58-50.20)
Clear stent length (IVUS), mm	22.50 (18.90-30.20)
Clear stent length (OCT), mm	22.50 (18.60-28.80)
Clear stent length (IVUS + OCT), mm	22.20 (18.50-28.80)
Excellent rate of image by clinical evaluation	
Excellent	109 (96.5)
Good	4 (3.5)

Values are mean ± SD, n (%), or median (Q1-Q3).

CABG = coronary artery bypass grafting; CIL = clear image length; LVEF = left ventricular ejection fraction; LAD = left anterior descending artery; LCX = left circumflex; PCI = percutaneous coronary intervention; RCA = right coronary artery.

PCI procedure with no damage to the catheter. In 1 subject, the imaging catheter could not cross the stent and there was no image data. In all, 112 patients had the catheter pass smoothly through the target vessel lesion, and in 1 subject, the catheter passed with difficulty. OCT image evaluation revealed more detailed information than IVUS (Figure 1). All 26 cases of AE that occurred during the trial were identified as unrelated to the Hybrid system, including 1 case of revascularization caused by nontarget vessel myocardial infarction and 1 perioperative myocardial infarction. There was no death, in-stent thrombosis, bleeding, acute coronary occlusion, stent deformation, or cerebrovascular events during the trial. One case of device defect (0.9%) occurred during the trial. More detailed information can be seen in Table 1.

DISCUSSION

The main findings of this study were as follows: 1) the proportion of CIL acquired by the Hybrid IVUS-OCT system was 96.21% (95% CI: 94.33%-98.10%); and 2) no catheter-related AEs occurred, and the incidence of device defect was only 0.9% (1 of 114).

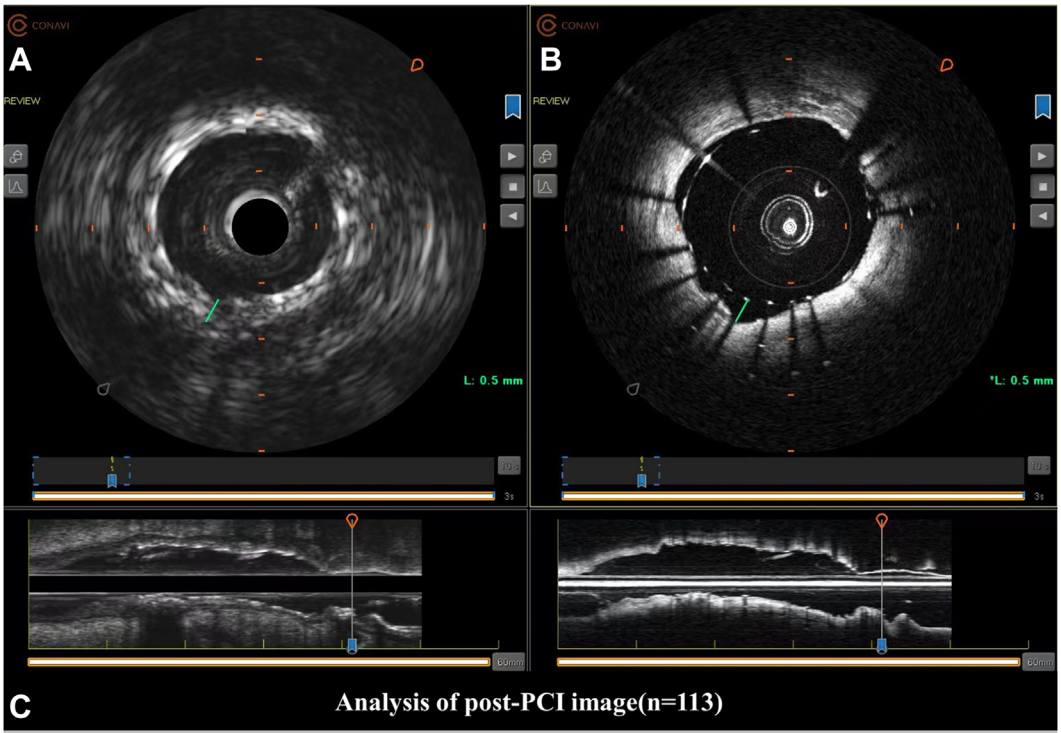
In this multicenter study, the hybrid IVUS-OCT system was able to acquire both IVUS and OCT images at the same time in a single pull back. The success rate of the device was 99.1% and the technical success rate of image acquisition in this study was 98.2%, comparable with the success rate reported in previous studies.[4] Although the hybrid imaging system can customize the pull back length from 0 to 100 mm, the total pull back length was set as 50 mm in this study. The proportion of CIL was 96.21% (95% CI: 94.33%-98.10%). The higher than 80% lower limit of 95 CI demonstrates that compared with the single-mode imaging system, the novel hybrid IVUS-OCT imaging system could achieve a high level of clarity in clinical practice. The complementary information of IVUS and OCT images reduces the interference of image artifacts on the evaluation of the plaque and stent, which may explain the higher technical success rate in the Hybrid system.

In terms of safety, all AEs in this study occurred post-PCI procedure. There are no catheter-related AEs. In previous studies, 0.6% of patients with OCT and 0.5% of IVUS experienced transient ST-segment elevation, coronary spasm, thrombosis, and other AEs.[5]

The hybrid IVUS-OCT imaging system, which proved to be safe and effective in the clinical study, may have potential advantages in the several clinical applications:

1. Acute coronary syndromes (ACS): complementary IVUS and OCT image information characterizes morphological structure and plaque tissue, assisting in differentiating subtypes of ACS mechanisms.[1,2] The Hybrid imaging system that switches imaging model flexibly between IVUS and IVUS-OCT may be a better choice for ACS patients.[6]
2. Plaque characteristics: high-risk plaque characteristics, such as plaque burden, minimum lumen area, lipid content, thickness of fibrous cap, and

FIGURE 1 **Post-PCI Image**



C **Analysis of post-PCI image(n=113)**

Stent edge dissection, n (%)	7 (6.2%)
IVUS	4 (3.5%)
OCT	7 (6.2%)
Tissue prolapses in stent, n (%)	9 (8.0%)
IVUS	6 (5.3%)
OCT	9 (8.0%)
stent malapposition, n (%)	20 (17.7%)
IVUS	4 (3.5%)
OCT	20 (17.7%)

(A) Intravascular ultrasound (IVUS) image showed good stent expansion and no stent malapposition. (B) The same frame optical coherence tomography (OCT) image showed good stent expansion and mild stent malapposition; there is distance between the stent strut and vessel intima (green line). The furthest distance is at the 7 o'clock position, with a distance of approximately 0.5 mm. (C) Detailed hybrid image analysis of post-percutaneous coronary intervention (PCI).

the presence of macrophages, are predictors of plaque vulnerability and increase the risk of future major adverse cardiovascular events in patients.[7] Hybrid imaging may be used to improve high-risk plaque assessment and make proper treatment decisions for high-risk patients in the future.[8]

3. Assessment of the efficacy of medical therapies: Changes in plaque burden (evaluated by IVUS) and

JACC: ASIA, VOL. 5, NO. 3, 2025
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fibrous cap thickness (evaluated by OCT) are associated with a high risk of coronary events, which could predict the potency of medical therapies.[9]

4. Stent optimization: hybrid imaging combines advantages of IVUS in pre-PCI measurement of vessels and the benefits of OCT for post-PCI assessment.[10] In this study, after hybrid examination post-PCI, 8 patients (7%) needed provisional stenting or postdilation again.

STUDY LIMITATIONS. First, the sample size of this study was relatively small, although it was the first multicenter trial to evaluate the performance of the novel Hybrid IVUS-OCT system in Chinese patients. Second, this was only a simple feasibility and safety study after PCI. More evidence should be accumulated to explore the usage of hybrid imaging systems in lesion assessment, identification of high-risk plaques, and risk management.

CONCLUSIONS

This study is the first multicenter clinical trial of a novel Hybrid IVUS and OCT system and verified the imaging quality and safety of the system for intravascular interventions in Chinese population.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

This work was supported by CardioNavi MedTech (Wuhan) Co., Ltd. The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REFERENCES

1. Sheth TN, Pinilla-Echeverri N, Mehta SR, Courtney BK. First-in-human images of coronary atherosclerosis and coronary stents using a novel hybrid intravascular ultrasound and optical coherence tomographic catheter. *JACC Cardiovasc Interv*. 2018;11:2427–2430.

2. Akl E, Pinilla-Echeverri N, Garcia-Garcia HM, et al. First in-human evaluation of a novel intravascular ultrasound and optical coherence tomography system for intracoronary imaging. *Catheter Cardiovasc Interv*. 2022;99:686–698.

3. Jia HB, Zhao C, Yu H, et al. Clinical performance of a novel hybrid IVUS-OCT system: a multicentre, randomised, non-inferiority trial (PANOVISION). *EuroIntervention*. 2023;19:e318–e320.

4. Zhou SS, Tian F, Zhang T, et al. Evaluation on the safety and accuracy of domestic optical coherence tomography system in clinical application. *Chin J Interven Cardiol*. 2018;28:199–202.

5. van der Sijde JN, Karanasos A, van Ditzhuijzen NS, et al. Safety of optical coherence tomography in daily practice: a comparison with intravascular ultrasound. *Eur Heart J Cardiovasc Imaging*. 2017;18:467–474.

6. Kubo T, Terada K, Ino Y, et al. Combined use of multiple intravascular imaging techniques in acute coronary syndrome. *Front Cardiovasc Med*. 2021;8:824128.

7. Prati F, Romagnoli E, Gatto L, et al. Relationship between coronary plaque morphology of the left anterior descending artery and 12 months clinical outcome: the CLIMA study. *Eur Heart J*. 2020;41:383–391.

8. Fujii K, Hao H, Shibuya M, et al. Accuracy of OCT, grayscale IVUS, and their combination for the diagnosis of coronary TCFA: an ex vivo validation study. *JACC Cardiovasc Imaging*. 2015;8:451–460.

9. Raber L, Ueki Y, Otsuka T, et al. Effect of alirocumab added to high-intensity statin therapy on coronary atherosclerosis in patients with acute myocardial infarction: the PACMAN-AMI randomized clinical trial. *JAMA*. 2022;327:1771–1781.

10. Ono M, Kawashima H, Hara H, et al. Advances in IVUS/OCT and future clinical perspective of novel hybrid catheter system in coronary imaging. *Front Cardiovasc Med*. 2020;7:119–134.

KEY WORDS coronary arteriosclerosis, hybrid intravascular imaging, intravascular ultrasound, multimodality intravascular imaging, optical coherence tomography