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# Comparison of the effects of contrast medium and low-molecular-weight dextran on coronary optical coherence tomographic imaging in relatively complex coronary lesions

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ABSTRACT

*Background:* Optical coherence tomography (OCT) has gained increasing popularity in coronary artery intervention due to its high resolution and excellent tissue correlation as a novel intravascular imaging modality. However, the current use of OCT requires contrast agent injection for imaging, and excessive use of contrast agents may adversely affect renal function, exacerbate cardiac burden, and even lead to contrast agent-induced nephropathy and heart failure. In recent years, several researchers have proposed the use of low molecular weight dextran (LMWD) as a substitute for contrast agents in OCT imaging because of its low toxicity, low cost, and wide availability. However, the inclusion of lesions in these studies is relatively simple, and the image quality criteria remain to be optimized.
*Methods:* This study included 26 patients with coronary artery disease who were scheduled for OCT imaging in a real-world clinical practice involving various complex lesions. All patients underwent two OCT examinations at the same vascular site, one each using contrast agent and LMWD. Both contrast media and LMWDs were infused by an autoinjector. The primary endpoint of the study was the average image quality score. Secondary endpoints included clear image length, clear image segments, minimum lumen area, average lumen area, and contrast-induced nephropathy, among others.
*Results:* In terms of image clarity, the average image quality score was similar when comparing contrast media with LMWD (3.912 ± 0.175 vs. 3.769 ± 0.392, P = 0.071). The lengths of the clear images and the segments of the clear images were also similar between the two groups (50.97 ± 16.25 mm vs. 49.12 ± 18.15 mm, P = 0.110; 255.5 ± 81.29 vs. 250.5 ± 89.83, P = 0.095). Additionally, strong correlations were noted between the two flushing solutions regarding the minimum lumen area and mean lumen area. During their hospital stay, none of the patient exhibited deterioration in renal function, and no patient experienced any major adverse cardiovascular events.
*Conclusions:* The quality of coronary artery OCT imaging using LMWD may be comparable to that achieved with traditional contrast agents, even in real-world clinical practice involving various complex lesions. For high-risk patients, LMWD may serve as an excellent substitute for contrast agents in OCT examinations.

## 1. Introduction

Optical coherence tomography (OCT) is a technique that uses the backscatter of light waves to obtain cross-sectional images of tissue and is of great value in the evaluation of coronary lesions [1]. Due to its high resolution, good tissue correlation, high identification of plaque features, and important value in determining the extent of plaque rupture, fibrous cap erosion, stent apposition, and intimal hyperplasia, OCT is a Class IIa recommendation in the 2018 ESC guidelines on myocardial revascularization [2]. However, the mismatch between the refractive indices of red blood cells and plasma in blood will cause scattering of light in blood, which will result in a large attenuation of the

*Abbreviations:* PCI, percutaneous coronary intervention; OCT, optical coherence tomography; IVUS, intravascular ultrasound; LMWD, low-molecular-weight dextran; CIN, contrast-induced nephropathy; CIS, clear image segment; CIF, clear image frame; MLA, minimum lumen area; SA, stent area.

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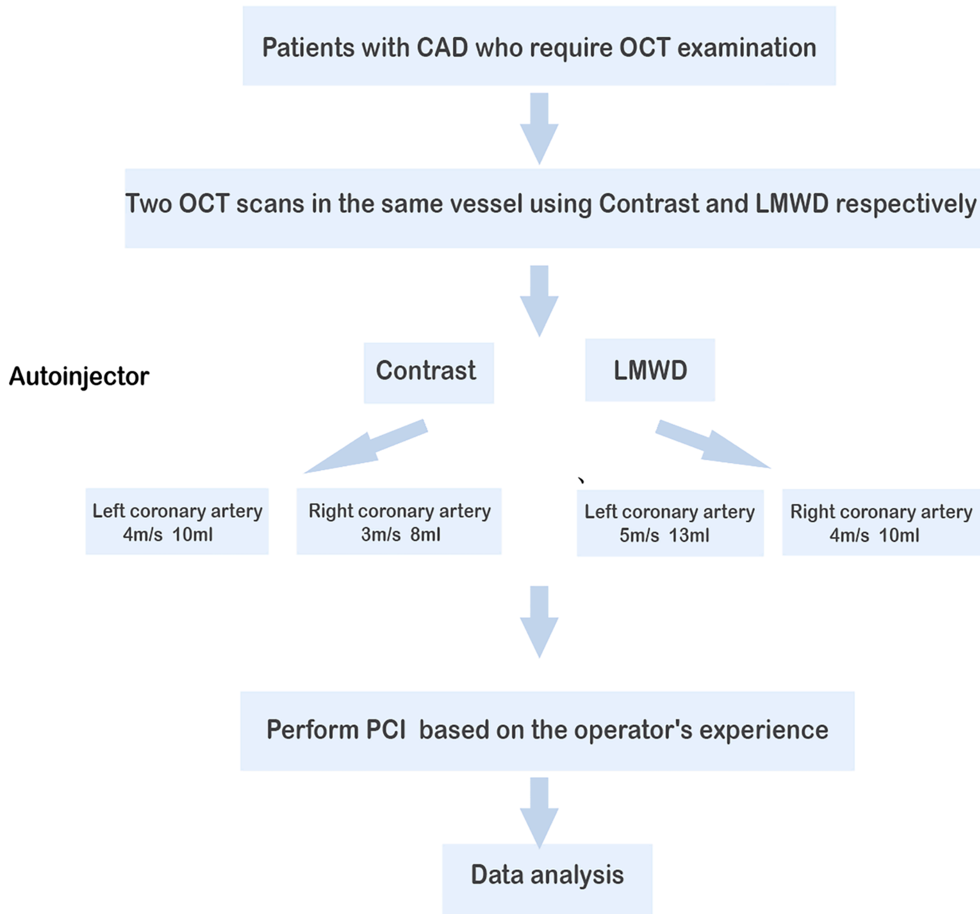


**Figure 1.** Flow chart of the study.

light signal [3]. Therefore, when examining coronary arteries on OCT, red blood cells must first be removed from the lumen to obtain a clear image [4]. Compared with saline, contrast agents have been shown to improve blood rejection and prolong imaging time, which is why they are currently used as the standard imaging medium in OCT examinations [5]. However, studies have shown that contrast media use can induce contrast nephropathy (CIN), which is linked to prolonged hospital stays, long-term morbidity, and mortality [6,7].

Low-molecular-weight dextran (LMWD), a colloid, has been widely used in clinical practice since World War II, and its primary purpose is to increase blood volume [8]. Subsequently, due to its ability to increase the refractive index of plasma and its ability to cause disaggregation of red blood cells, LMWD was also applied in the field of OCT technology to eliminate the scattering of light in the blood [5,9]. Studies have also shown that LMWD exerts antithrombotic and antiplatelet effects in vivo, which further supports its application as a suitable flushing medium in coronary OCT [10]. In 2012, Ozaki et al. [11] included 22 patients with 25 vessels and showed that there was no significant difference in the image quality and lumen measurement obtained using contrast medium and LMWD to obtain OCT images. However, the coronary lesions included in the study were relatively simple, excluding severe tortuosity, calcifications, and other complex lesions, limiting the generalizability to clinical scenarios characterized by a variety of complex lesions. Furthermore, the study only analyzed image quality at the single-frame image level and did not analyze clear image length at the vessel level.

Therefore, a broader range of lesions was included to better demonstrate the universality of the LMWD, and a more precise criterion for evaluating image quality was adopted in this work to evaluate image quality between contrast media and LMWD for OCT image collection in the evaluation of coronary stented lesions [12,13].

## 2. Methods

### 2.1. Subjects

We prospectively enrolled 26 patients with coronary artery disease who were scheduled to undergo OCT by prespecified operators (MG Zhou and Y He), each of whom had performed FD-OCT in more than 50 patients and used LMWD OCT pullback imaging at least 4 times to meet the learning curve requirements. The exclusion criteria were as follows: (1) hemodynamic instability; (2) lesion located in the left main coronary artery; (3) reference vessel diameter less than 2 mm; (4) total occlusion lesions; and (5) lesions that could not be passed by OCT catheters. The flow chart of the study is shown in Figure 1.

The protocol for this study was approved by the Biomedical Research Ethics Committee of West China Hospital (2022 Review No. 1245), and we obtained written informed consent from all patients before participation in this study.

### 2.2. Coronary angiography and OCT

In each patient, FD-OCT was performed via the continuous-flushing method using both contrast media Iopromide Injection (Bayer AG, Guangzhou Branch, China) and Dextran 40 and Glucose Injection (Sichuan Kelun Pharmaceutical Co., Ltd., Chengdu, China) once each (Figure 2). Both contrast media and LMWD were as the flushing solution via a guiding catheter by autoinjector. Contrast media was infused at a rate of 4 ml/s with a total volume of 10 ml in the left coronary artery and at a rate of 3 ml/s with a total volume of 8 ml in the right coronary artery. LMWD was infused at a rate of 5 ml/s with a total volume of 13 ml in the left coronary artery and at a rate of 4 ml/s with a total volume

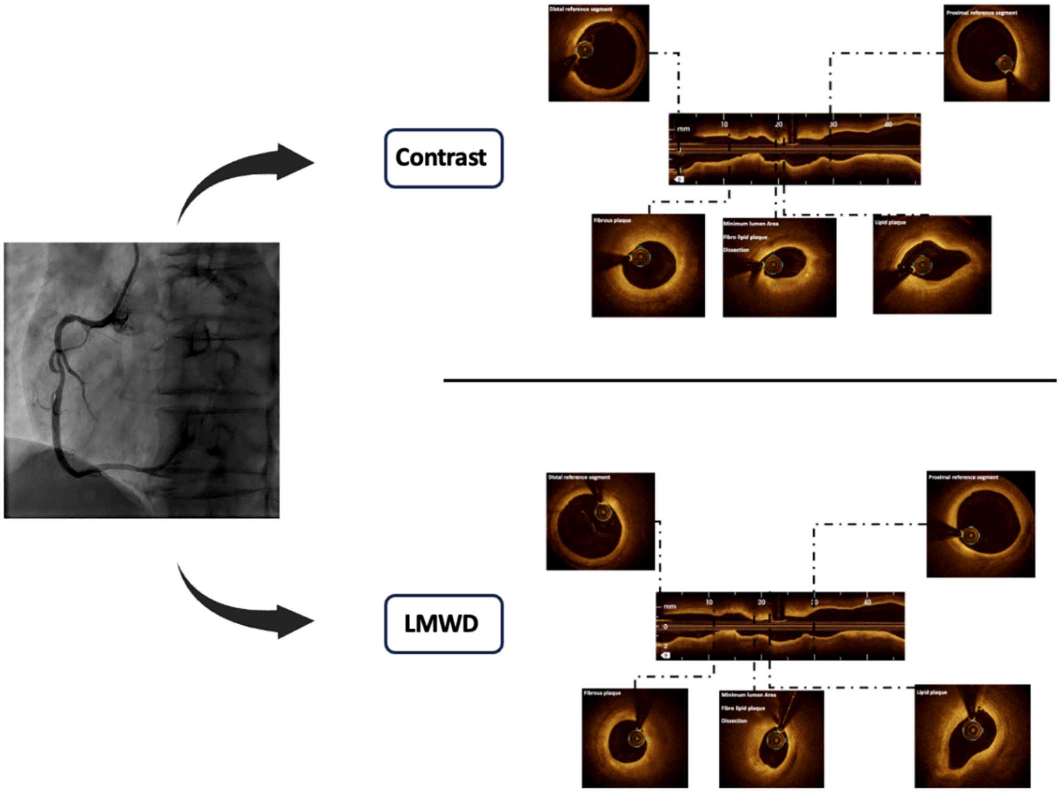


**Figure 2.** OCT imaging was performed using both contrast agent and LMWD in the same vessel. OCT, optical coherence tomography; LMWD, low-molecular-weight dextran.

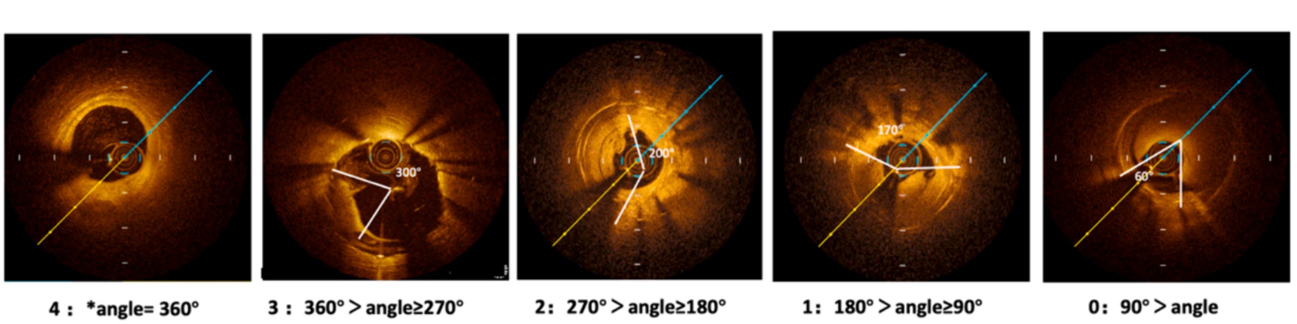


**Figure 3.** Definition of the average image quality score.

of 10 ml in the right coronary artery. During the injection of each flushing medium for image acquisition, beat-by-beat hemodynamic and electrocardiogram changes were recorded.

### *2.3. FD-OCT System and Catheter*

The FD-OCT system (P80; Conaris, Vivolight, Shenzhen, China) consists of an imaging engine, a probe interface unit, and a computer console, which also contains the data acquisition board. The 2.58-Fr intravascular OCT imaging catheter (Pathfinder 164; Vivolight) can be delivered as a mini-rail rapid exchange catheter over a 0.014-in (0.36 mm) coronary guidewire through a 6-Fr guiding catheter. After the OCT imaging catheter was positioned so that its imaging lens was distal to the target lesion or stent, contrast media and LMWD were infused. FD-OCT images were calibrated by adjusting the Z-offset before each pullback for image acquisition to obtain accurate measurements. All OCT images from the P80 system were obtained using an automatic pullback device traveling at a rate of 20 mm/s. The OCT images were recorded digitally.

The FD-OCT system utilized in this study is capable of automated matching of medium refractive indices. This function can be achieved through software algorithms that automatically calibrate for different media refractive indices and perform automated recognition and quantification of the vascular lumen [14]. The underlying principle involves acquiring OCT cross-sectional images of the vascular lumen under a given flushing medium, and then automatically identifying and segmenting the catheter outer wall and the vascular lumen. By utilizing the automatically identified catheter outer wall contour and diameter, the system can automatically calculate the image resolution, enabling the automated estimation and matching of the refractive index. Finally, based on the pixel count and pixel resolution of the OCT images, the diameter and area of the vascular lumen can be automatically computed [14,15].

### *2.4. FD-OCT Analysis*

For every pullback obtained from the FD-OCT (P80) system, two

**Table 1**
Patient demographics and baseline characteristics

| Characteristic | N = 26[1] |
|---|---|
| Age (years) | 60 ± 10 |
| Sex (Male) | 19 (73.1%) |
| BMI (kg/m2) | 24.5 ± 3.7 |
| Acute coronary syndrome | 20 (77.0%) |
| Hypertension | 15 (57.7%) |
| Diabetes mellitus | 14 (53.8%) |
| Atrial fibrillation | 1 (3.8%) |
| Chronic kidney disease | 1 (3.8%) |
| Prior MI | 6 (23.1%) |
| Prior PCI | 19 (73.1%) |
| Prior CABG | 1 (3.8%) |
| eGFR ( ml/min/1.73 mˆ2 ) | 86 ± 16 |
| LDL -C (mmol/L) | 1.73 (1.44, 2.12) |
| CTnT (ng/L) | 8 (7, 25) |
| BNP (ng/L) | 176 (42, 296) |
| LV (mm) | 48.08 ± 2.93 |
| LVEF (%) | 65.9 ± 4.0 |

[1] Mean ± SD; n (%); Median (IQR)

independent observers with significant experience conducted analyses utilizing the dedicated offline software provided by Vivolight. They analyzed the OCT pullback images at 1mm intervals across the entire length. In instances of disagreement between the observers, a consensus reading was employed to resolve the differences.

## 2.5. Study endpoint

### 2.5.1. Primary endpoint

The primary endpoint of this study was the average image quality score, which was defined as the mean value of all the analyzed image quality scores collected during a single pullback. A scoring system based on visual arcs is utilized to assess the clarity of blood vessel walls in single-frame OCT images [13]. The scores are distributed as follows: a score of 4 is assigned when the arc is equal to 360°, 3 points are awarded when the arc falls between 360° and 270°, 2 points are assigned when the arc is in the range of 270° to 180°, 1 point is assigned when the arc lies between 180° and 90°, and 0 points are assigned when the arc is less than 90°. It is important to note that this evaluation focused exclusively on blood interference, with guidewire artifacts not taken into consideration. The scoring details are shown in Figure 3.

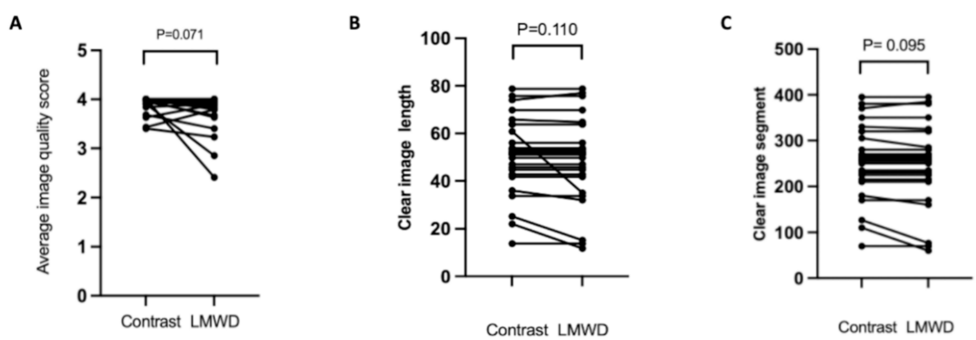


**Figure 4.** Comparison of the average image quality score (A), clear image length (B), and clear image segment (C) of OCT images between the Contrast and LMWD groups. OCT, optical coherence tomography; LMWD, low-molecular-weight dextran.

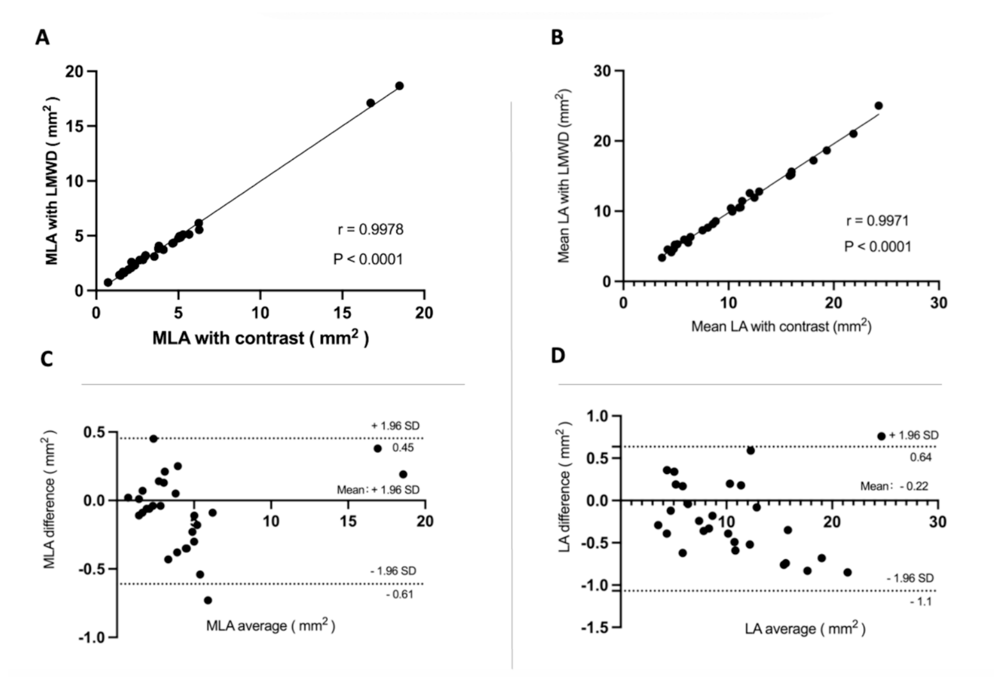


**Figure 5.** (A, B) Comparisons between contrast media and LMWD in terms of minimum lumen area (MLA) and mean lumen area (LA) and (C, D) Bland-Altman analysis using the two approaches. LMWD, low-molecular-weight dextran.

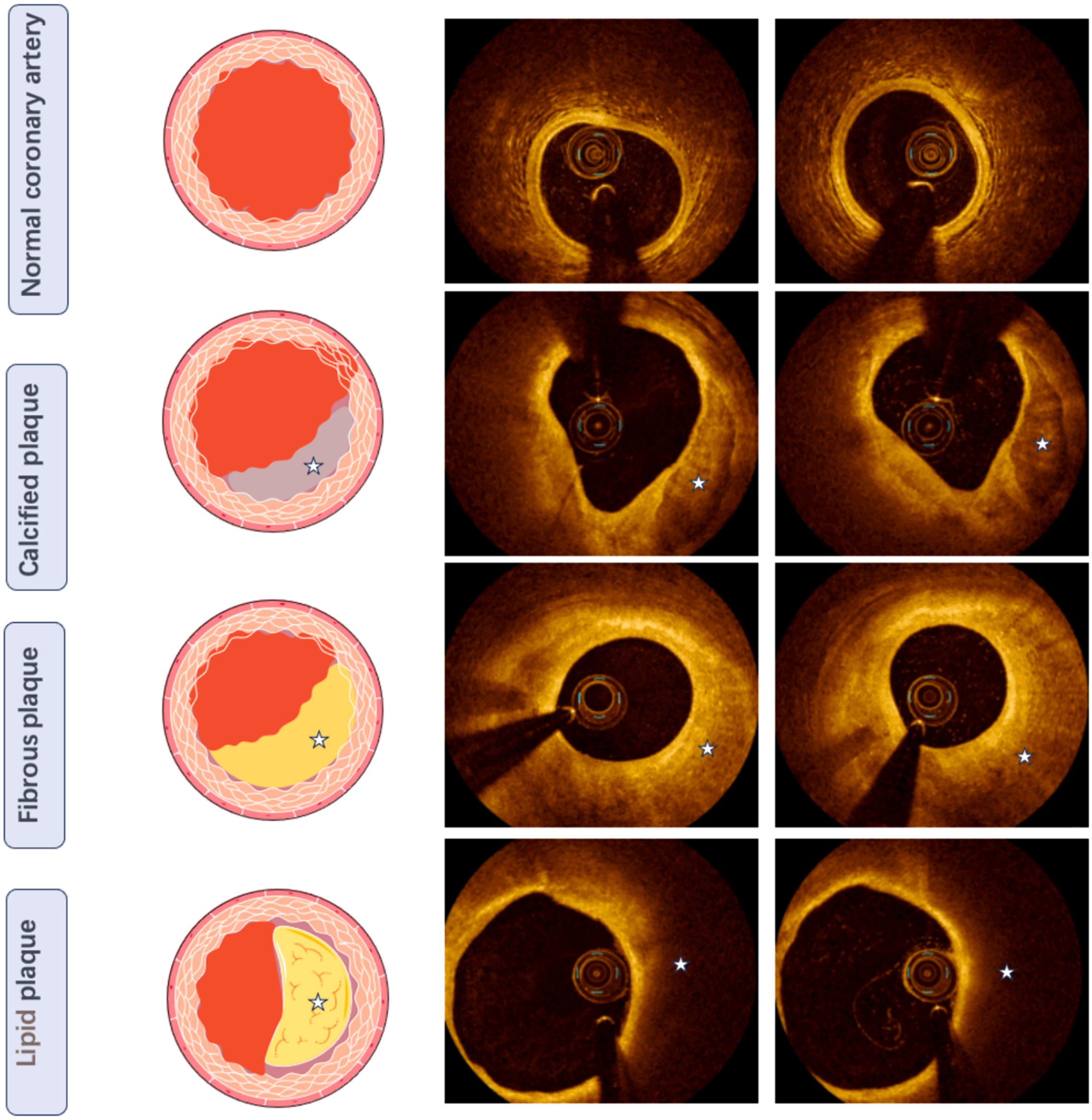


**Figure 6.** Comparative imaging outcomes of contrast agent and LMWD in normal vessels, fibrous plaques, lipid plaques, and calcified plaques. LMWD, low-molecular-weight dextran.

*2.5.2. Secondary endpoint*

Secondary endpoints included clear image length, clear image segments, minimum lumen area, average lumen area, and contrast-induced nephropathy, among others. The clear image length is defined as the product of the number of clear image frames and the interframe spacing in a single pullback. A clear image is defined as an arc equal to or greater than 270° [12]. Average lumen area is defined as the total lumen area across all image frames divided by the number of image frames. Contrast-induced nephropathy (CIN) is defined according to the European Society of Urogenital Radiology Contrast Media Safety Committee (ESUR CMSC) guidelines as a renal impairment marked by an increase in serum creatinine of more than 25% or 44 μmol/L (0.5 mg/dL) within three days after intravascular contrast medium administration, devoid of alternative causes [16,17].

## 2.6. Statistical analysis

All the data were analyzed using SPSS 26.0 (IBM, USA). Continuous variables are expressed as the means ± standard deviations and were compared using t tests; categorical variables are expressed as counts and percentages and were compared using chi-square tests or Fisher's exact tests. Consistency tests for the two sets of measurements were performed using Bland-Altman analysis; correlations were compared using Spearman's correlation coefficient. All hypothesis tests were two-sided, and $P < 0.05$ was considered to indicate a statistically significant difference.

# 3. Results

## 3.1. Baseline characteristics and procedural findings

This prospective study included 26 patients with CAD who were scheduled for OCT examinations. Each patient was selected for the study based on only one vessel. The baseline characteristics are shown in Table 1. In this study, the cohort comprised 26 CAD patients, with a mean age of 60 years (standard deviation [SD] = 10 years). Males accounted for 73.1% (n=19) of the cohort. Notable conditions included acute coronary syndrome in 77.0% (n=20), hypertension in 57.7% (n=15), and diabetes mellitus in 53.8% (n=14). Atrial fibrillation, prior myocardial infarction (MI), percutaneous coronary intervention (PCI), and coronary artery bypass grafting (CABG) were present in 3.8% (n=1),

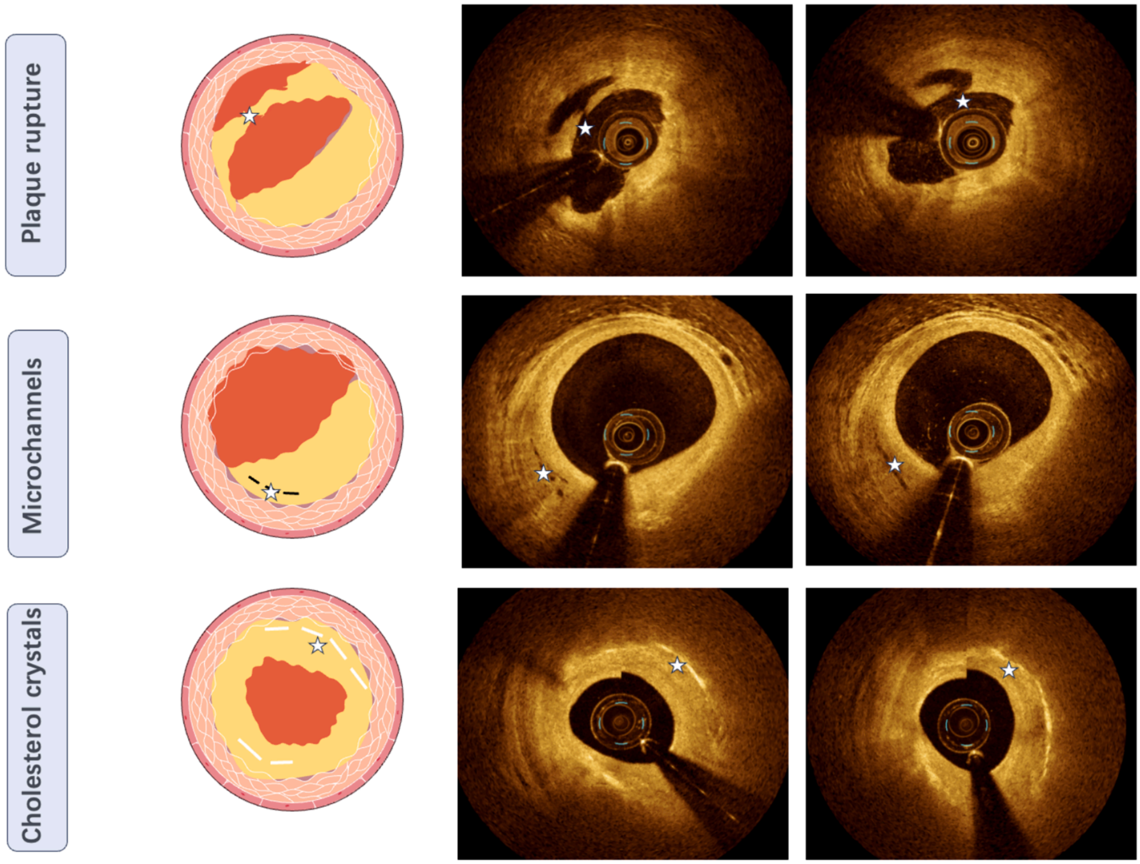


**Figure 7.** Comparative imaging outcomes of contrast media and LMWDs in cases of plaque rupture, microchannels, dissection, and cholesterol crystals. LMWD, low-molecular-weight dextran.

23.1% (n=6), 73.1% (n=19), and 3.8% (n=1) of the cohort, respectively, with chronic kidney disease also reported in 3.8% (n=1). From the vessel perspective, for the LAD, LCX, and RCA, there were 12 (46.1%), 4 (15.3%), and 10 (38.4%), respectively.

### *3.2. Quantitative Assessment of Image Quality*

Regarding the primary endpoint, the average image quality score, there was no statistically significant difference between the groups imaged with LMWD and contrast agent during OCT imaging. The image quality scores were similar (3.769 ± 0.392 vs. 3.912 ± 0.175, P = 0.071; Figure 4). For the secondary endpoints, neither the clear image segment nor the clear image length showed a significant difference. When comparing LMWD and contrast images, the clear image segments were 255.5 ± 81.29 and 250.5 ± 89.83, respectively (P = 0.095; Figure 4), and the clear image lengths were 50.97 ± 16.25 mm and 49.12 ± 18.15 mm, respectively (P = 0.110). Linear regression analysis and Bland-Altman analysis for the MLA and mean lumen area in 2 pullbacks with contrast media and LMWD are presented in Figure 5. The correlation coefficients were high for all measurements using the two methods, indicating strong agreement between them.

This study extensively incorporated a variety of coronary lesion characteristics, encompassing not only simple lesions such as fibrous plaques, lipid plaques, and calcified plaques (Figure 6) but also complex, realistic, and clinically relevant pathologies such as cholesterol crystals, microchannels, dissections, plaque ruptures, and intrastent thromboses (Figures 7-8). This further illustrates the efficacy of LMWD in actual clinical applications.

### *3.3. Influence on renal function and clinical safety endpoints*

The data presented in Table 2 indicate that there was no significant deterioration in renal function following the procedure. Specifically, the pre-OCT creatinine (Cr) level was 71.6 ± 3.8 mg/dl, with a nonsignificant increase to 74.2 ± 6.4 mg/dl post-OCT (p=0.411). Similarly, the estimated glomerular filtration rate (eGFR) demonstrated minimal variation, from a pre-OCT value of 90.2 ± 5.2 ml·min–1·1.73 $m^2$ to 87.8 ± 7.1 ml·min–1·1.73 $m^2$ post-OCT, with the change not reaching statistical significance (p=0.447). These findings underscore the safety of these procedures in patients with no evident postprocedural renal function compromise. During OCT imaging, the volume of contrast medium utilized amounted to 16.7 ± 2.0 ml, and for LMWD, it was 20.4 ± 2.2 ml.

All 26 patients successfully underwent the PCI procedure without experiencing any in-hospital severe adverse events. There were no complications associated with the OCT procedure, including but not limited to arrhythmias such as couplets or more, premature ventricular beats, ventricular tachycardia, or no instances of ST-segment elevation, bradycardia, or symptoms of chest oppression or pain.

## 4. Discussion

This research was the first to use a system capable of automatically correcting the refractive index of media to assess the variances in OCT image acquisition when using LMWD as opposed to traditional contrast agents in a real-world clinical practice involving various complex lesions. Our findings indicate that the quality of the images and measurements of the lumen obtained through FD-OCT using LMWD were comparable to those acquired using contrast media. Additionally, strong correlations were noted between the minimum lumen area and the mean

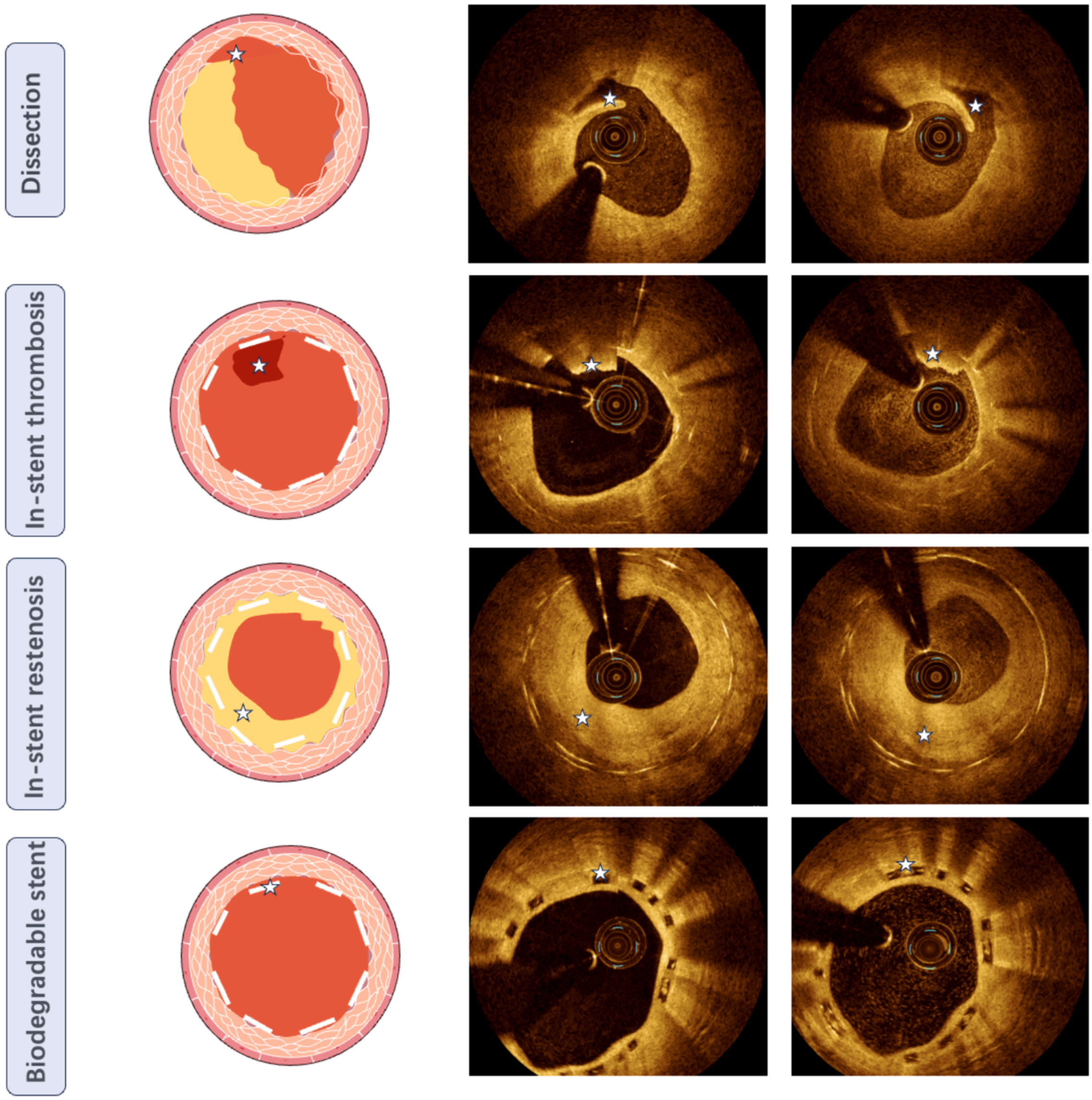


**Figure 8.** Comparative imaging outcomes of contrast agent and LMWD in in-stent thrombosis, in-stent restenosis, and biodegradable stents. LMWD, low-molecular-weight dextran.

**Table 2**
Contrast/dextran Volume and Renal Function

| | | |
|---|---|---|
| Pre-OCT Cr (mg/dl) | 71.6 ± 3.8 | p=0.411 |
| Post-OCT Cr (mg/dl) | 74.2 ± 6.4 | |
| Pre-OCT eGFR (ml·min–1 · 1.73 m–2) | 90.2 ± 5.2 | p=0.447 |
| Post-OCT eGFR (ml · min –1 · 1.73 m–2) | 87.8 ± 7.1 | |
| Contrast for OCT (ml) | 16.7 ± 2.0 | p=0.102 |
| Dextran for OCT (ml) | 20.4 ± 2.2 | |
| Contrast for CAG and PCI (ml) | 143.2 ± 16.4 | |

Mean ± SD

lumen area. These findings imply the potential of LMWD as an alternative to contrast media for acquiring FD-OCT images, both qualitatively and quantitatively.

Although OCT has been classified as a IIa recommendation in the 2023 ESC ACS Guidelines for guiding PCI [18,19], the frequent use of contrast agents as flushing media during OCT image acquisition may lead to renal impairment, thereby increasing the risk of contrast-induced nephropathy. Although the predominant clinical strategy for reducing the incidence of contrast-induced nephropathy is hydration, the amount of contrast agent used constitutes a major controllable risk factor for this condition [17,20]. Therefore, reducing the amount of contrast agent is necessary to prevent deterioration of renal function, especially in complex coronary lesions.

Dextran 40, also known as low molecular weight dextran (LMWD), has a molecular weight below the glomerular filtration threshold (60 kDa), allowing it to be excreted from the urine after renal filtration or transported to the interstitium [21]. Numerous prior studies have provided ample evidence of the safety of LMWD [5,21,22]. Additionally, LMWD demonstrates antithrombotic properties, including the inhibition of platelet aggregation and red blood cell agglutination, as well as the enhancement of fibrinolytic activity [10]. These characteristics suggest that LMWD as a flushing medium may reduce the risk of OCT-associated catheter thrombosis, as well as its potential application in the management of coronary artery disease with high thrombus burden, such as acute coronary syndromes.

Li et al. [23] conducted coronary artery OCT examinations using LMWD in both an in vitro circulatory system model and animal subjects. They found that the majority of OCT images obtained with the contrast agent and LMWD were clear (with clarity rates of 99.0% and 97.5%, respectively), suggesting excellent performance of LMWD in coronary artery OCT examinations. Similar results were observed by Vijayvergiya et al. [24] conducted in a study involving OCT examinations using contrast agents and LMWD in 5 patients undergoing PCI. Ozaki et al. [11] conducted OCT imaging on 22 patients with coronary artery disease utilizing both contrast agent and LMWD as contrast media. The results revealed no significant difference in image quality between the two groups (97.9% vs. 96.5%, P = 0.9). Furthermore, simple linear regression analysis and Bland-Altman analysis demonstrated that both flushing agents exhibited good correlations and consistency in terms of the minimum lumen area, mean lumen area, and mean stent area. However, this study has certain limitations. First, the definition of image clarity is relatively simple and lacks granularity, as it defines anything greater than 270° as a clear image segment without further detailed categorization. Second, the study excluded complex lesions, such as severe calcification, which ironically may require intracoronary imaging techniques for guidance. Third, the OCT device did not automatically match the refractive index of the LMWD, necessitating extensive manual corrections, making it less suitable for clinical practicality.

Therefore, building upon the research conducted by Ozaki et al., this study has established novel criteria for image quality assessment, namely, the use of an average image quality score as the primary endpoint, providing a more accurate description of the clarity of OCT images. Additionally, this study adopted broader inclusion criteria, encompassing a variety of clinically realistic scenarios such as calcification, bifurcation, and in-stent thrombosis, significantly expanding the applicability of LMWD. Finally, the OCT equipment used in this study features an LMWD-compatible design that is capable of automatically matching the refractive indices of LMWDs, thereby reducing the workload of manual matching and enhancing the feasibility of clinical use.

In fact, interventional cardiologists have exerted considerable efforts to reduce the use of contrast agents in OCT examinations, especially for high-risk groups such as elderly individuals, those with chronic kidney disease, and individuals allergic to contrast agents. Kang et al. [25] prospectively included 43 patients with 70 coronary artery lesions and used hydroxyethyl starch instead of contrast agents for flushing, demonstrating comparability between images obtained with contrast agents and those obtained with hydroxyethyl starch flushing (97.1% vs 96.5%; p = 0.160). Similarly, the Saline Optical Coherence Tomography-Guided Percutaneous Coronary Intervention (SOCT-PCI) study proposed the feasibility of using saline for flushing [26]. Gore et al. [27] also confirmed the feasibility of using saline for flushing. These studies represent cardiologists' strides towards "contrast-free PCI," but further validation with larger prospective studies is still needed.

## 5. Limitations

However, this study has two limitations: first, the number of patients observed in this study was small, necessitating further validation with an expanded sample size; second, the study included patients with nearly normal baseline renal function. Future research should focus on the chronic kidney disease population to further investigate whether LMWD can benefit these patients by reducing the amount of contrast agent used during PCI procedures.

## 6. Conclusion

In summary, this study employed an OCT device with fully automated matching of medium refractive indices to revalidate the feasibility of using LMWD as a contrast agent. We incorporated a more accurate image quality scoring system and included relatively complex lesions, thereby supplementing previous research. Our study suggested that for high-risk patients, LMWD may serve as an excellent substitute for contrast agents in OCT examinations. However, further large-scale prospective studies are required for validation. We also hope to identify a media with greater flushing efficiency and greater safety than existing media to revolutionize clinical decision-making.

## CRediT authorship contribution statement

**Junyan Zhang:** Writing – review & editing, Writing – original draft, Project administration, Formal analysis, Conceptualization. **Minggang Zhou:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Yong Chen:** Validation, Supervision, Project administration, Investigation, Conceptualization. **Zhongxiu Chen:** Validation, Supervision, Project administration, Funding acquisition, Conceptualization. **Hua Wang:** Validation, Supervision, Project administration, Data curation, Conceptualization. **Chen Li:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Data curation, Conceptualization. **Yong He:** Validation, Supervision, Project administration, Investigation, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**Ethical approval**

The study was approved by the Biomedical Research Ethics Committee of West China Hospital (2022 Review No. 1245), and we obtained written informed consent from all patients before participation in this study.

**Data availability statement**

The data underlying the findings of the paper are freely available upon request from the authors themselves. Yong He (Department of Cardiology, West China Hospital of Sichuan University, 37 Guo Xue Xiang, Chengdu, Sichuan, 610041, China; e-mail: heyong_huaxi@163.com) was contacted to request the data.

**Author contributions**

All the authors contributed to the study conception and design. JY Zhang and MG Zhou wrote the manuscript. Y He conceived, instructed, reviewed, and revised the manuscript. MG Zhou, Y Chen, C Li, H Wang and Y He contributed to the PCI procedure and OCT image acquisition. JY Zhang managed the cases clinically. JY Zhang, ZX Chen, H Wang, C Li and MG Zhou contributed to the data analyses and interpretation. All the authors have read and approved the final version of the manuscript.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2024.101513.

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