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Original Article

Practical application of heart modularization based on Personalized Patient Protocol Technology combined with Sinogram-Affirmed Iterative Reconstruction technology in coronary angiography

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Abstract: Objective: This study aimed to evaluate the application value of personalized patient protocol technology (P3T) modular cardiac injection technique combined with the iterative reconstruction algorithm, sinogram-affirmed iterative reconstruction (SAFIRE) in coronary computed tomography angiography (CCTA). Methods: A retrospective analysis was performed on 40 patients who underwent CCTA at the Central Hospital Affiliated to Shandong First Medical University. Patients were divided into two groups: control group (n=20), which received the traditional contrast agent injection with fixed iodine load and injection flow rate, and filtered back projection reconstruction with filtered back projection (FBP), and experimental group (n=20), which employed a dosing protocol calculated based on P3T cardiac modular parameters, with SAFIRE strength 3 reconstruction. The two groups were compared regarding CT values (proximal, middle, and distal segments), signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), coronary imaging quality score, contrast agent flow rate, injection volume, and effective radiation dose (ED). Results: There were no significant differences in CT values of the right coronary artery, anterior descending artery, or circumflex artery at the proximal and middle segments between the two groups (P>0.05). However, the experimental group exhibited significantly higher CT values at the distal segments of these coronary arteries compared to the control group (P<0.05). SNR, CNR, and coronary imaging quality scores showed no significant differences between the two groups (P>0.05). The contrast agent flow rate and injection volume in the experimental group were significantly lower than those in the control group (P<0.05). Additionally, the volume CT dose index (CTDIvol), dose length product (DLP), and ED were significantly reduced in the experimental group compared to the control group (P<0.05). Conclusion: The combination of P3T technology with SAFIRE reconstruction in CCTA effectively reduces contrast agent flow rate, injection volume, and radiation dose without compromising image quality. This approach enables individualized, standardized, and consistent injection schemes.

Keywords: Coronary artery disease, computed tomography angiography, tube voltage, radiation exposure, contrast agent

Introduction

Coronary artery disease (CAD) is characterized by atherosclerotic narrowing of the coronary arteries. While often asymptomatic in its early stages, it may lead to stable or unstable angina, and/or myocardial infarction due to the progressive thickening or plaque rupture of the arterial wall [1-4]. The common risk factors for CAD encompass dyslipidemia, tobacco abuse, hypertension, a family history of CAD, diabetes mellitus, and obesity [1]. Complications arising from CAD include acute coronary syndrome (ACS), ST-elevation myocardial infarction (STEMI), acute heart failure, arrhythmias, and sudden cardiac death [1-5]. CAD remains the leading cause of death both in the United States and globally [1-4].

Computed tomography angiography (CTA) has plays an important role in the diagnosis and treatment of CAD. Current guidelines recommend the use of CTA in patients with suspected CAD who exhibit persistent symptoms despite a prior normal test, inconclusive exercise or pharmacological stress test, or those unable to

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undergo stress testing with nuclear myocardial perfusion imaging [6, 7]. Coronary computed tomography angiography (CCTA) offers a non-invasive means for diagnosing CAD, yet it is associated with high radiation exposure, raising concerns about the potential risks [8, 9]. It is suggested that the square of tube voltage is positively correlated with CT radiation dose, leading to clinical strategies aimed at reducing tube voltage as a means to decrease radiation dose. Nevertheless, this approach can lead to increased image noise, which can compromise image quality and diagnostic accuracy [10].

Recent advancements in CT imaging have introduced Sinogram-affirmed iterative reconstruction (SAFIRE) technology, a novel algorithm designed to enhance image reconstruction. Unlike traditional reconstruction methods, the SAFIRE algorithm continuously optimizes the image through repeated iterations, incorporating both the acquired raw data, prior knowledge, and physical models. This process effectively reduces image noise and improves the signal-to-noise ratio (SNR), generating high-quality CT images even under low-dose conditions. These capabilities are critical in minimizing patient radiation exposure while enhancing safety. SAFIRE enhances image clarity by establishing a systematic noise model and utilizing iterative noise reduction techniques. This approach effectively reduces image noise, improves SNR, and ensures diagnostic quality. In addition to SAFIRE, the P3T cardiac software provides patients with individualized contrast injection protocols. It calculates the total iodine amount by multiplying body weight by a preset body weight factor and then dividing by the injection time. This further automatically computes the iodine flow rate, optimizing the total contrast volume administered during the CCTA examination. Therefore, this study aims to evaluate the synergistic application of P3T technology and SAFIRE in CCTA to enhance clinical applicability.

Materials and methods

Study design and participants

This retrospective study analyzed data from 40 patients who underwent CCTA at Jinan Central Hospital between September and December 2023. Patients were divided into a control group (n=20) and an experimental group (n=20). The control group received a traditional fixed iodine load and injection flow rate contrast injection scheme with filtered back projection (FBP), while the experimental group (n=20) followed a dosing scheme based on P3T cardiac modular parameters, along with SAFIRE strength 3 reconstruction (**Figure 1**). Ethical approval for this study was obtained from the Ethics Committee of Jinan Central Hospital.

Inclusion criteria

Participants were eligible if they had suspected CAD or had been diagnosed with CAD and required follow-up reexamination.

Exclusion criteria

Exclusion criteria included the following: 1) history of stent implantation or bypass surgery; 2) severe renal insufficiency or decompensated heart failure; 3) history of iodine allergy; and 4) severe arrhythmia.

Sample size calculation

The sample size was determined based on a 1:1 parallel control design, with equal numbers of patients in the two groups. Similar designs comparing the effectiveness of effective dose (ED) were referenced. The average score of ED was 2.8 mSv, and the ED in the observation group was 2.0 mSv, with a standard deviation of s=1. Considering a 10% dropout rate, and assuming a Type I error probability of a=0.05 and a power (1-β) of 80%, the sample size was estimated. According to the design of this clinical study and the primary efficacy measure, the sample size estimation was conducted using the following formula:

$$n1 = n2 = \frac{2(Za/2 + Z\beta)2 \times \sigma^2}{(\mu 1 - \mu 2)^2}$$

Where μ1=2.8, μ2=2.0, σ=1, Za=0.05, and Zβ=0.2. Substituting these values into the equation yields the results of n1=n2=18 cases, indicating that the minimum sample size for this study is 36. To enhance the reliability of the results, all 40 eligible patients during the study period were included.

Coronary artery injection and CTA examination

Control group: The patients underwent contrast-enhanced CT angiography using a traditional fixed iodine load and injection rate proto-

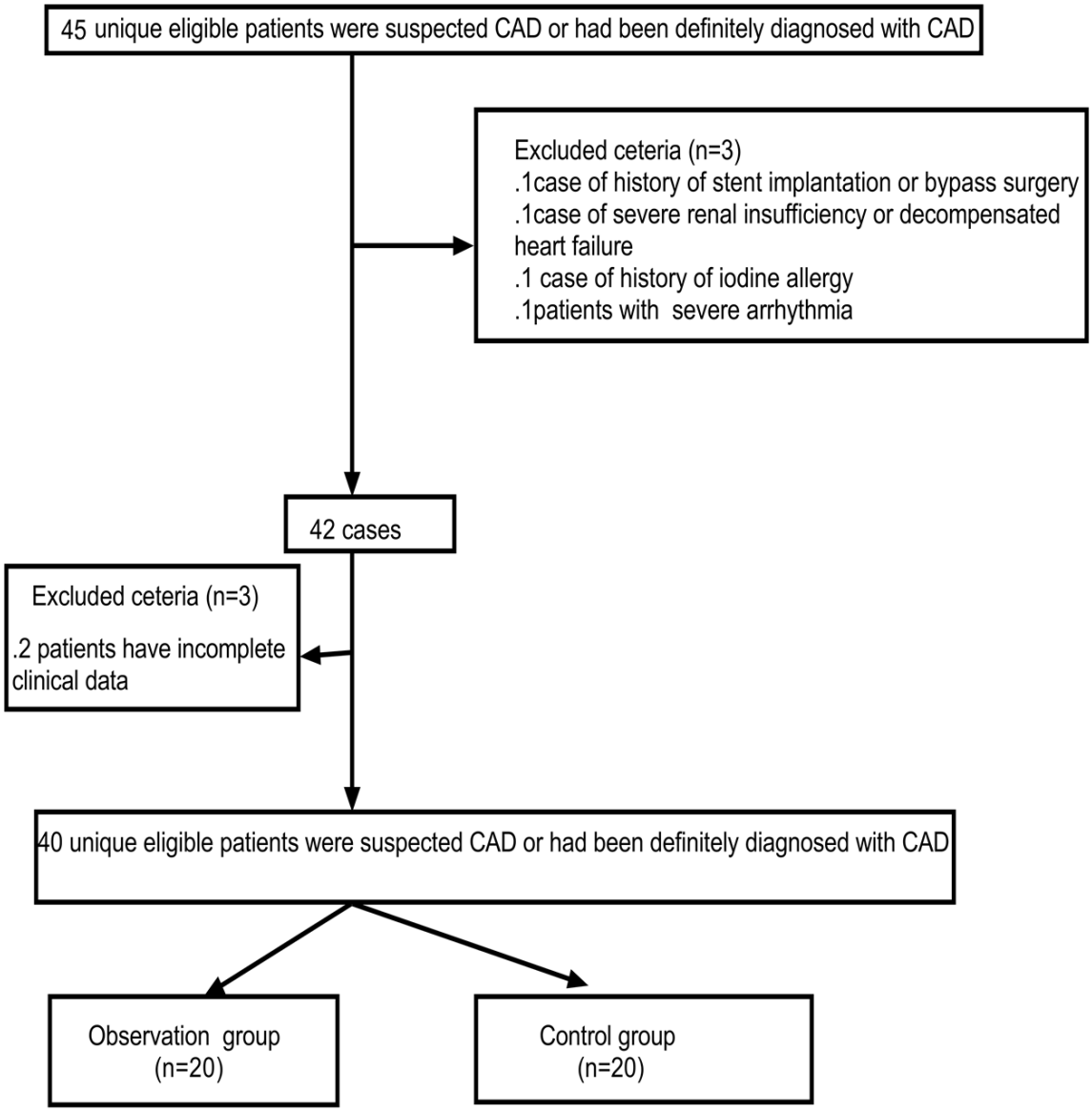

Figure 1. Flow chart of patients enrolled in this study. CAD: Coronary artery disease.

col, followed by reconstruction with filtered back projection. (1) Pre-examination preparation: Patients were prepared using a Definition AS+ 128-slice spiral CT scanner (Siemens, Germany) and the Medrad Stellant high-pressure injector with dual flow function and P3T cardiac software module. Each patient's body weight was measured and recorded. Iohexol, containing 370 mg/mL iodine (Shanghai Bracco Sine Pharmaceutical Corp. Ltd., China), was administered through an 18G catheter inserted into the right elbow vein. (2) CCTA scan: Patients were scanned in the supine position with their arms raised and bent overhead, positioning the heart centrally within the scan field. The scan range extended from 1 cm below the tracheal carina to 2 cm below the left diaphragm. Scanning parameters included prospective ECG-gated axial scanning with CARE Dose 4D activated, a reference mAs of 180, a delay time of 3 seconds, a reconstruction slice thickness of 0.75 mm, and an increment of 0.4 mm. The B26f kernel, cardiac window, 128×0.6 mm slice, rotation time of 0.3 s, automatic heart rate estimation, and auto pitch were adopted.

Experimental group: Patients in this group received a contrast dosage regimen calculated

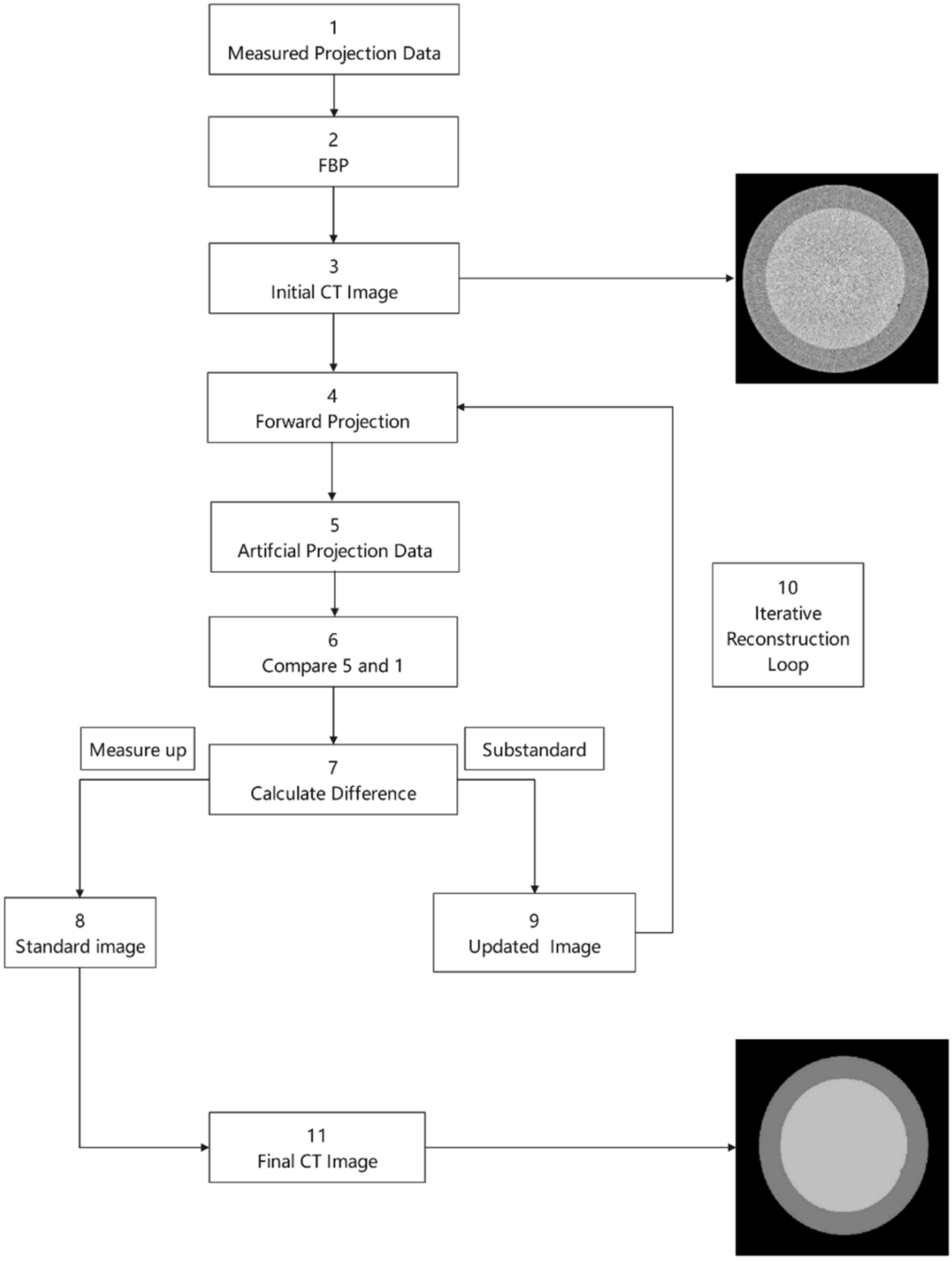

Figure 2. Working principles of FBP and P3T. FBP: filtered back projection; P3T: personalized patient protocol technology.

based on the parameters from the P3T cardiac modular input, and SAFIRE 3 reconstruction was used concurrently. The operational principles of FBP reconstruction and P3T are shown in **Figure 2**. Steps (1) and (2) were the same as those in the control group. In step (3), for con-

Table 1. Comparison of baseline data between the two groups

Group	Control group	Experimental group	t/χ^2	P
Age	57.8±4.2	58.0±4.4	-0.147	0.884
Gender (n, %)			1.905	0.168
Male	12 (60)	16 (80)		
Female	8 (40)	4 (20)		
Heart rate	60.8±2.2	61.2±2.1	-0.588	0.560
Hypertension	11 (55)	8 (40)	0.902	0.342
Diabetes	4 (20)	6 (30)	0.533	0.465
Hyperlipidemia	6 (30)	8 (40)	0.440	0.507

trast agent injection and FBP reconstruction, the tube voltage was reduced by one level compared to the control group, the dosage regimen was calculated using P3T cardiac modular input parameters (body weight, contrast agent iodine content, scan duration, and a body mass index factor (0.4 for <60 kg, 0.33 for 60-90 kg, 0.29 for >90 kg)), and SAFIRE strength 3 reconstruction was employed.

Observation indicators and evaluation methods for coronary imaging quality

1. CT values: Comparisons were conducted between the two groups in terms of the CT values of the right coronary artery in the proximal, middle, and distal segments, as well as the CT values and standard deviations for the proximal, middle, and distal segments of the left anterior descending artery and the left circumflex artery. The region of interest (ROI) was set at 3 mm.

2. Proximal coronary imaging quality SNR and contrast-to-noise ratio (CNR): SNR was determined by dividing the vessel lumen CT value by the standard deviation of the vessel lumen, while CNR was calculated as the difference between the vessel lumen CT value and the surrounding fat CT value divided by the standard deviation of the vessel lumen.

3. Coronary imaging quality score [11]: The criteria for coronary imaging quality score are as follows: 4 points: images with vessels displaying clearly without artifacts, with good contrast; 3 points: images with uneven or excessive vessel enhancement, but with clear boundaries and sufficient contrast, not impairing diagnosis; 2 points: images showing uneven vessel enhancement, faint display, moderately blurred boundaries, and average contrast, though still suitable for diagnosis; 1 point: images with insufficient and uneven vessel enhancement, poor contrast, and failing to meet diagnostic requirements. The final quality score was determined as the average of the scores given by two radiologists.

4. Effective radiation dose (ED): The radiation dose report was obtained from the CT console, which provided the volume CT dose index (CTDIvol) and the dose-length product (DLP). The ED was calculated using the formula ED = K × DLP [K = 0.026 (mSv/mGy × cm)].

Statistical analysis

Data analysis was performed utilizing SPSS 21.0 statistical software. The normality of continuous variables was assessed using the Shapiro-Wilk test, confirming that the data followed a normal distribution. The normally distributed continuous data were presented as mean ± standard deviation ($\bar{x}$ ± sd), while categorical data were expressed as (n, %). For comparisons between groups, independent t-tests were employed for continuous data, while chi-square tests were used for categorical data. Statistical significance was set at a threshold of $P<0.05$.

Results

Comparison of general data between the two groups

This study revealed no significant differences between the two groups in terms of medical history, age, gender, complications, or other general data (all $P>0.05$) (**Table 1**). Therefore, the two groups of patients were comparable.

Comparison of CT values of cardiac chambers and great arteries between the two groups

There were no significant differences in the CT values for the left ventricular cavity, right ventricular cavity, main pulmonary artery, ascending aorta, and descending aorta between the two groups (all $P>0.05$) (**Table 2**).

Comparison of coronary imaging quality between the two groups

The experimental group achieved higher rates of standard subjective image quality scores

Table 2. Comparison of measured values in various locations between the two groups

Group	Control group	Experimental group	t	P
Left ventricular cavity	406.8±47.9	433.6±57.3	-1.605	0.117
Right ventricular cavity	162.9±63.8	174.1±47.8	-0.628	0.534
Main pulmonary artery	226.9±56.5	242.3±64.2	-0.805	0.426
Ascending aorta	437.5±63.3	420.5±47.9	0.958	0.344
Descending aorta	408.7±47.9	378.4±55.4	1.850	0.072

Table 3. Comparison of subjective image quality scores between the two groups

Group	Control group	Experimental group	χ^2	P
5	10	8		
4	5	2		
3	3	2	3.906	0.048
2	1	1		
1	2	7		
Compliance rate	19/20	13/20		

Table 4. Comparison of coronary artery imaging quality CT values between the two groups

Coronary artery	Control group	Experimental group	t	P
RCA proximal	452.38±59.51	457.48±58.67	-0.273	0.786
Middle	428.33±54.89	421.64±52.76	0.393	0.697
Distal	323.56±54.25	367.36±50.41	-2.645	0.012
LAD proximal	452.16±61.44	455.43±56.25	-0.176	0.862
Middle	370.47±60.39	376.28±54.84	-0.319	0.752
Distal	274.44±65.37	321.57±41.49	-2.722	0.010
LCX proximal	441.78±54.74	450.49±55.84	-0.498	0.621
Middle	371.28±62.05	370.49±55.21	0.043	0.966
Distal	273.23±48.47	315.28±52.24	-2.636	0.012

RCA: right coronary artery; LAD: left anterior descending; LCX: left circumflex.

compared to the control group, with a significant difference (all P<0.05) (**Table 3**).

Comparison of the CT values of coronary artery imaging quality (proximal, middle, and distal segments) between the two groups

No significant differences were observed in the CT values of the right coronary artery, anterior descending artery, or circumflex artery at the proximal and middle segments between the two groups (all P>0.05). However, the experimental group exhibited significantly higher CT values at the distal segments of these coronary arteries compared to the control group (all P<0.05, **Table 4** and **Figure 3**).

There were no significant differences in SNR and CNR of the proximal right coronary artery, anterior descending artery, or circumflex artery (all P>0.05, **Table 5** and **Figure 4**).

Comparison of contrast agent flow rate and injection volume during coronary artery imaging between the two groups

The experimental group had significantly lower contrast agent flow rates and injection volumes compared to the control group, (all P<0.05, **Figure 5**).

Comparison of radiation doses between the two groups

The radiation indicators CTDIvol, DLP, and ED levels were significantly lower in the experimental group compared to the control group, (all P<0.05, **Table 6**).

Discussion

Coronary heart disease is a common illness among middle-aged and elderly populations, with low cure rates, high mortality, and a relatively high incidence, thereby posing a considerable threat to patient health [12]. CCTA has emerged as a pivotal diagnostic tool for coronary heart disease due to its high sensitivity and specificity, establishing it as the gold standard in the field. It employs advanced computer imaging techniques to perform multi-angle and multi-layer scans of the coronary arteries, facilitating a rapid and accurate assessment of vascular morphology and function [13]. Compared to traditional coronary angiography, CCTA has several notable advantages such as being non-invasive, fast, and cost-effective. First, its non-invasive nature eliminates the need for punctures, thus avoiding associated pain and potential complications from invasive procedures [14]. This feature is particularly beneficial for elderly or frail patients who may be deterred by traditional invasive examinations. Second, the high sensitivity and specificity of CCTA allow it to effec-

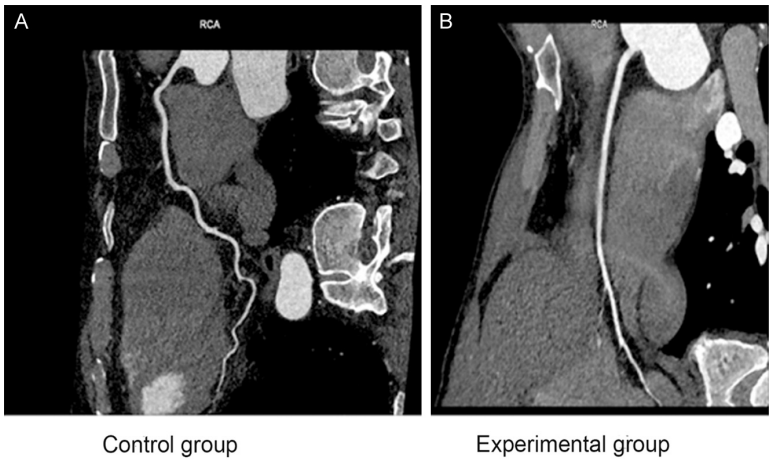

Figure 3. CT values of coronary artery imaging in the two groups. A: CT values in the control group; B: CT values in the experimental group.

Table 5. Comparison of SNR and CNR in proximal coronary artery imaging quality between the two groups

Coronary artery	Control group	Experimental group	t	P
RCA SNR	13.37±3.69	13.48±4.10	-0.089	0.929
CNR	22.47±6.59	22.73±5.69	-0.134	0.894
LAD SNR	22.74±3.76	24.93±7.52	-1.165	0.251
CNR	23.55±3.35	23.86±6.15	-0.170	0.866
CX SNR	12.68±3.67	13.53±3.44	-0.756	0.454
CNR	24.05±6.92	23.39±5.93	0.324	0.748

RCA: right coronary artery; SNR: signal-to-noise ratio; CNR: contrast-to-noise ratio; LAD: left anterior descending; CX: circumflex.

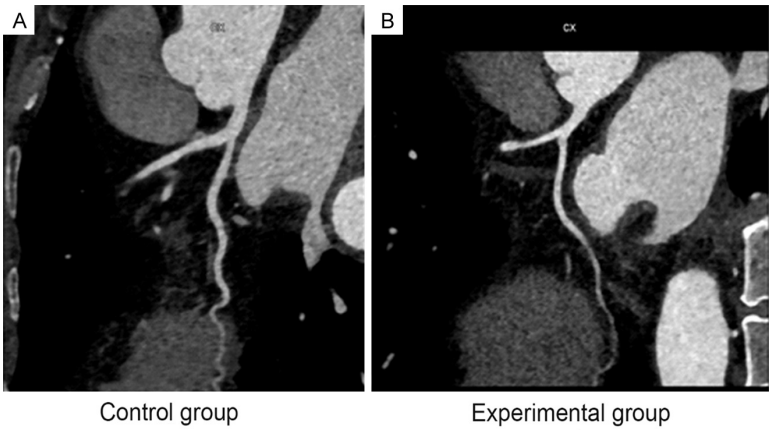

Figure 4. Coronary imaging quality of the two groups. A: Coronary artery SNR and CNR in the control group; B: Coronary artery SNR and CNR in the experimental group. SNR: signal-to-noise ratio; CNR: contrast-to-noise ratio.

tively identify the causes of coronary heart disease among complex clinical symptoms. Studies have shown that CCTA has an accuracy rate exceeding 90% in detecting coronary artery stenosis, significantly reducing the likelihood of misdiagnosis and missed diagnosis [15]. This high accuracy not only provides reliable diagnostic evidence for clinicians but also offers reassurance to patients. Furthermore, the efficiency of CCTA is a considerable advantage. The examination typically takes 15 to 30 minutes, allowing for prompt acquisition of clear imaging results. This quick turnaround enhances the utilization of medical resources and enables the timely initiation of targeted treatment plans, thereby avoiding severe consequences caused by delayed treatment. However, it is important to note that the radiation dose during CCTA is generally between 10 and 12 mSv, and improper use of contrast agents may significantly increase the risk of precancerous lesions. FBP was previously used as a common method for image reconstruction due to its speed and quality. Nevertheless, it is associated with higher noise levels in low-dose CT scans, which can compromise image quality [16-18].

The results of this study indicate that patients with coronary heart disease undergoing CT scans with P3T showed significantly higher CT values in the proximal, middle, and distal segments of the right coronary artery, left anterior descending artery, and circumflex artery compared to those obtained through traditional examination methods. These differences can be attributed to the limitations of traditional methods, which often result in inconsistent image quality across different coronary segments due to imprecise contrast agent injection. Such inconsistencies can hinder accurate clinical assessment and subse-

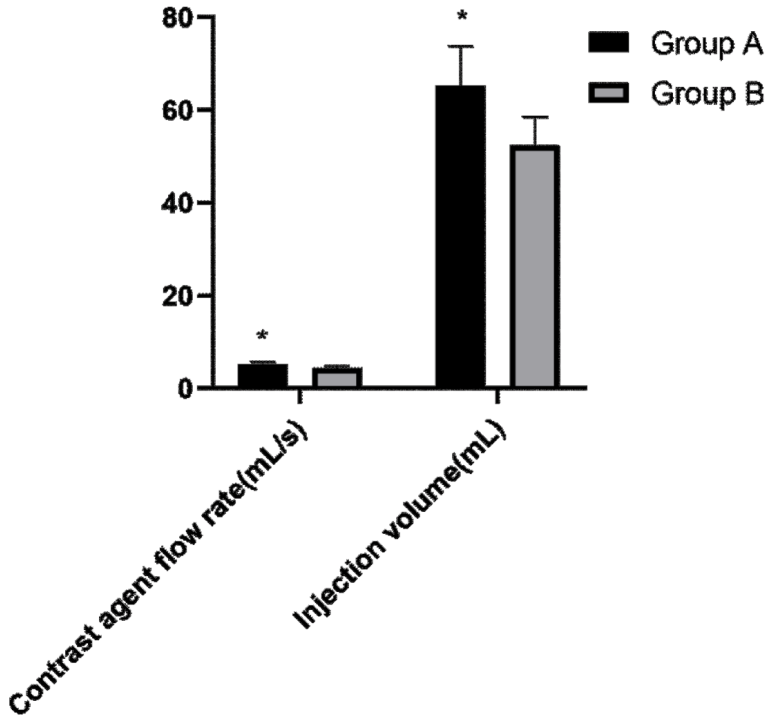

Figure 5. Comparison of infusion rates and injection volumes between the two groups. *: Indicates that the difference between control group and experimental group is significant at P<0.05.

Table 6. Comparison of radiation doses between the two groups

Radiation dose	Control group	Experimental group	t	P
CTDIvol (mGy)	20.57±1.70	13.22±1.66	13.834	0.001
DLP (mGy·cm)	147.9±8.3	85.4±4.5	29.605	0.001
ED (mSv)	12.74±3.76	24.93±7.52	-6.484	0.001

CTDIvol: CT volume dose index; DLP: dose length product; ED: effective radiation dose.

quent treatment planning [19]. P3T technology, however, incorporates mathematical models with clinical data to design individualized injection protocols, thereby improving overall image quality and allowing for a more accurate assessment of coronary pathology during diagnosis. Furthermore, the advantages of P3T technology extend beyond image quality, since it also significantly reduces radiation exposure and contrast agent usage. Studies have revealed that patients examined by P3T receive lower radiation doses and require less contrast agent compared to those examined through traditional methods [20]. This is particularly important for patient safety, as cumulative radiation exposure from repeated imaging can pose long-term health risks, especially in coronary heart disease patients who require frequent examinations. By reducing both radiation dose and contrast agent usage, P3T technology can maximize patient safety while ensuring high-quality imaging [21]. A key factor contributing to the success of P3T technology is its personalized approach to contrast agent injection. By calculating the optimal contrast agent volume, flow rate, iodine-to-saline ratio, and scan delay parameters based on patient-specific factors and the scanning protocol, P3T ensures a more rational use of contrast agents, thereby reducing unnecessary waste. This finding aligns with previous research [22, 23].

There were statistical differences in image quality between the two groups, which may have been related to the use of the SAFIRE method for image processing [24, 25]. SAFIRE progressively eliminates image noise, hardening artifacts, and scatter through multiple iterations, thereby dynamically improving image quality. This method compensates for the decline in image quality caused by reduced radiation dose, offering a significant advantage over traditional filtered back projection algorithms by reducing image noise and enhancing image quality [26]. Additionally, SAFIRE offers multiple reconstruction strengths and allows for personalized adjustment. Higher iteration levels correlate with reduced image noise and improved resolution, which is particularly beneficial for visualizing small coronary vessels. These findings support previous research conclusions [27, 28].

However, in clinical practice, excessively high iteration intensities may result in overly smooth images, possibly compromising diagnostic efficacy in coronary heart disease [29]. Therefore, selecting an appropriate iteration level is cru-

cial to balancing contrast agent reduction and image quality. Based on our center's experience, an iteration reconstruction intensity of 3 appears to achieve a favorable signal-to-noise ratio while minimizing contrast agent usage. However, this is based on single-center experience, and further multi-center studies are needed to explore the optimal iteration intensity [30].

In summary, the application of P3T combined with SAFIRE in CCTA offers significant benefits, including reduced contrast agent usage, higher image quality, decreased radiation exposure, and enhanced safety. These advantages are particularly relevant for organ protection in patients with renal insufficiency undergoing CCTA, making it worth promoting. However, this study has certain limitations: 1. This is a single-center retrospective study with a small sample size, which may impact the evidence level of the findings; 2. The criteria for selecting iteration intensity require further validation in future studies; 3. Differences in the proficiency of imaging physicians may influence the study conclusions, underscoring the need for larger-scale investigations to validate the findings.

Conclusion

The combination of P3T with SAFIRE technology in CCTA can avoid excessive artifacts in the superior vena cava affecting cardiac vascular structures, while also effectively reducing contrast agent flow rate, injection volume, and radiation dose. This allows for individualized and standardized injection protocols, ensuring examination consistency and achieving better image quality. This is beneficial for clinical diagnosis, and given the current limited clinical use of P3T technology, it holds significant clinical value.

Disclosure of conflict of interest

None.

Abbreviations

SAFIRE, sinogram-affirmed iterative reconstruction; CTA, computed tomography angiography; CCTA, coronary computed tomography angiography; P3T, Personalized Patient Protocol Technology; FBP, filtered back projection; SD, standard deviation; SNR, signal-to-noise ratio; CNR, contrast-to-noise ratio; CTDIvol, volume CT dose index; DLP, dose length product; ED, effective dose; CAD, coronary artery disease; ACS, acute coronary syndromes; STEMI, ST-elevation myocardial infarction; HR, heart rate; ROI, region of interest; LM, left main; LAD, left anterior descending; LCX, left circumflex; RCA, right coronary artery; DLP, dose length product; ED, effective dose.

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