Original Article

Value of the New Dynamic Coronary Roadmap System in Percutaneous Coronary Intervention for Patients With Chronic Coronary Syndrome

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ABSTRACT

Background: Chronic ischemic heart disease is the primary cause of acute and chronic heart failure. Cardiac failure due to exacerbated coronary heart disease occurs in 1 of every 4 cases. Variable degrees of heart failure are present in two-thirds of coronary patients who undergo conventional percutaneous coronary intervention (PCI). In an attempt to lower the occurrence of acute kidney injury and contrast-induced nephropathy, the current study aimed to evaluate the effects of PCI using the new dynamic coronary roadmap (DCR) system on the contrast medium volume.

Methods: This observational study enrolled 80 patients undergoing PCI for chronic coronary syndromes. Patients were assigned to 2 equal groups. Group I consisted of patients who underwent the DCR technique (the DCR group), and Group II was composed of patients who underwent the normal PCI technique without DCR (the normal group). The patients had detailed history taking, comprehensive clinical examinations, the DCR system, and PCI.

Results: Group II demonstrated significantly higher contrast medium volume (179 ± 62 vs 37 ± 11 mL; $P < 0.001$), fluoroscopy time (12 ± 3 vs 6 ± 2 min; $P < 0.001$), air kerma (744 ± 85 vs 285 ± 60 mGy; $P < 0.001$), and dose area product (47 ± 5 vs 36 ± 7 Gy/cm^2). In contrast, Group I had a significantly higher estimated glomerular filtration rate post-PCI ($P = 0.015$).

Conclusions: Contrast volume and fluoroscopy time can be reduced by using DCR during PCI.

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KEYWORDS: Percutaneous coronary intervention, Dynamic coronary roadmap, Chronic coronary syndrome

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Chronic ischemic heart disease is the primary cause of acute and chronic heart failure. Cardiac failure due to exacerbated coronary heart disease occurs in 1 out of every 4 cases. Variable degrees of heart failure are present in two-thirds of coronary patients who undergo conventional percutaneous coronary intervention (PCI). [1,2] PCI is a safe and effective treatment for ischemic heart disease with minimal risk of consequences. Nevertheless, the infusion of contrast during the operation may result in toxicity. [3,4]

Unfortunately, lumen visibility and device navigation need contrast. Acute kidney injury (AKI) patients have a much worse prognosis than individuals who do not have the condition. [5] In patients scheduled for PCI, impaired kidney function and other associated comorbidities increase the AKI risk after contrast administration. [6] To avoid AKI or CIN, it is crucial to provide saline hydration before and during therapy and to utilize as little contrast as possible during the operation. [7]

In recent years, much work has been devoted to improving medical equipment, such as stents and catheters, whereas recording technology has received less attention. In the past 3 decades, pulsed imaging and the switch from analog to digital recording have drastically decreased radiation exposure. [8]

The number of contrast agents required for PCI depends on operator competence, rotational or biplane imaging, and the complexity of the procedure, which is the most significant. During PCI, it is very difficult to maneuver wires, balloons, and stents inside the coronary arteries. The cardiologist must often inject a contrast agent to evaluate and monitor the location of the device. [9]

The dynamic coronary roadmap (DCR) is a software program that offers a dynamic overlay of the coronary tree on fluoroscopy to facilitate device navigation across the coronaries and decrease the need for extra contrast puffs. Thus, this device may minimize contrast use during PCI. [4] The current study aimed to evaluate the effects of PCI using the innovative DCR technology on the contrast medium volume in PCI as part of regular clinical care.

METHODS

The present observational study enrolled 80 patients undergoing PCI for chronic coronary syndromes. Patients were recruited from the National Heart Institute outpatient clinics and treated with a drug-coated balloon or a drug-eluting stent (DES) implantation.

The study was done after approval from the Institutional Review Board (IRB), Benha Faculty of Medicine. Signed consent was collected from all patients included.

The inclusion criteria were age over 18 years and chronic coronary syndrome refractory to medical therapy. Chronic coronary syndrome is a phrase used to describe coronary artery disease as a progressive, chronic condition that may be adjusted, stabilized, or improved through lifestyle adjustments, medication, and coronary revascularization. This phrase has replaced “stable coronary artery disease”. Long periods of stability are conceivable, although the condition may become unstable at any moment due to a sudden atherothrombotic event brought on by plaque erosion or rupture. Despite this, the disease is persistent and progressive even during clinical stability. [10]

The exclusion criteria were hemodialysis, acute coronary syndrome, and chronic total occlusion lesions.

The patients were classified into 2 groups: Group I consisted of patients using the DCR technique (the DCR group), and Group II was composed of patients receiving the ordinary PCI technique without DCR (the normal group).

All cases underwent a thorough medical history taking, including age, sex, place of residence, occupation, special habits, medications, previous medical conditions, hospitalization, and heart failure symptoms, such as fatigue and weakness, dyspnea on exertion or lying down, edema in ankles, feet, and legs, irregular or rapid heartbeat, reduced exercise ability, or persistent wheezing or cough with white or pink blood-tinged mucus.

The general examination included consciousness and mental state, jaundice or

pallor, pulse, blood pressure, capillary filling time, respiratory rate, temperature, lower limb edema, body mass index (BMI), and waist circumference. The systemic examination included a cardiovascular examination (to detect abnormal heart sounds or murmurs), a respiratory examination (to detect any abnormal breath sounds, adventitious sounds, and respiratory distress), a gastrointestinal tract examination (to detect organomegaly or ascites), and central nervous system and musculoskeletal system examinations (through the assessment of the Glasgow coma score, pupillary reaction, and the examination of the motor system, including power, tone, and reflexes).

Routine investigations consisted of random blood sugar, liver function tests, kidney function tests, lipid profile, complete blood count, electrocardiography, and echocardiography.

The DCR System: On fluoroscopy, the DCR system generates a dynamic, motion-compensated, real-time overlay of the coronary arteries. Each frame of coronary angiography is utilized to generate a coronary route map. DCR provides coronary artery navigation using angiography for a live, motion-compensated overlay. In the comparison of the angiography and live fluoroscopy pictures for moving sections, a realistic coronary vascular tree overlaps and moves in sync with the cardiac and respiratory movements. It might decrease the need for contrast during wire navigation, balloon inflation, and stent placement.

The PCI Strategy: Invasive coronary angiography was done according to the American College of Cardiology/American Heart Association Guidelines for Coronary Angiography. [11]

Sample Size Estimation: Based on prior research exploring the impact of PCI using the novel DCR system, [12] the sample size was estimated using version 3.1.2 of the Power and Sample Size software. This study reported a mean contrast volume of 118.8 mL and 152.17 mL in the DCR and control groups, respectively. Alpha and power were adjusted at 0.05 and 0.8, respectively. Therefore, 40 patients were assigned to each group.

Statistical Analysis

Version 28 of SPSS was utilized for data management and statistical analysis (IBM, Armonk, New York, United States). Through the Shapiro-Wilk test and direct data visualization approaches, the normality of quantitative data was evaluated. Means and standard deviations were used to summarize numerical data. Percentages and numbers were utilized to summarize categorical data. The independent *t* test compared quantitative data between the study groups. The χ^2 or Fisher exact test compared categorical data. The significance of the obtained results was judged at a 5% level.

RESULTS

Regarding general characteristics, age, sex, BMI, hypertension, diabetes mellitus, dyslipidemia, current smoking, atrial fibrillation, prior myocardial infarction, prior coronary artery bypass graft surgery, creatinine, aspirin, thienopyridines, and anticoagulants were statically insignificant between the studied groups (Table 1).

Concerning lesion characteristics, target artery, lesion site, lesion type, bifurcation, calcification, and in-stent restenosis were nonsignificantly different between the studied groups (Table 2).

With respect to procedural characteristics, Group II demonstrated significantly higher contrast medium volume (179 ± 62 vs 37 ±

11 mL; $P < 0.001$), fluoroscopy time (12 ± 3 vs 6 ± 2 min; $P < 0.001$), air kerma (744 ± 85 vs 285 ± 60 mGy; $P < 0.001$), and dose area product (47 ± 5 vs 36 ± 7 Gy/cm^2) (Table 3, Fig. 1 & Fig. 2).

In contrast, Group I had a significantly higher estimated glomerular filtration rate (eGFR) post-PCI (84 ± 24 vs 72 ± 17 mL/min/1.73 cm^2; $P = 0.015$). The guide size, intravascular ultrasound (IVUS) use, predilatation, DES implantation, and the number of stents were insignificantly different between the studied groups (Table 3).

Table 1: General characteristics of the studied groups

	Group I (n = 40)	Group II (n = 40)	*P* value
Age, y	57 ±10	59 ±10	0.281
Sex			
male	22 (55)	24 (60)	0.651
female	18 (45)	16 (40)	
BMI, kg/m^2	29 ±4	29 ±4	0.828
Hypertension	27 (67.5)	27 (67.5)	1.0
Diabetes mellitus	29 (72.5)	26 (65)	0.469
Dyslipidemia	37 (92.5)	36 (90)	1.0
Current smoking	16 (40)	17 (42.5)	0.82
Atrial fibrillation	2 (5)	3 (7.5)	1.0
Chronic kidney disease	10 (25)	0 (0)	<0.001*
Prior MI	10 (25)	16 (40)	0.152
Prior CABG	1 (2.5)	4 (10)	0.359
Creatinine (mg/dL)	0.98 ±0.27	0.9 ±0.14	0.093
Aspirin	15 (37.5)	18 (45)	0.496
Thienopyridines	12 (30)	14 (35)	0.633
Anticoagulants	5 (12.5)	2 (5)	0.432

Data are presented as mean ± SD or numbers (percentages).
BMI: body mass index; MI: myocardial infarction; CABG: coronary artery bypass graft
* significant as a *P* value < 0.05

Table 2: Lesion characteristics in the studied groups

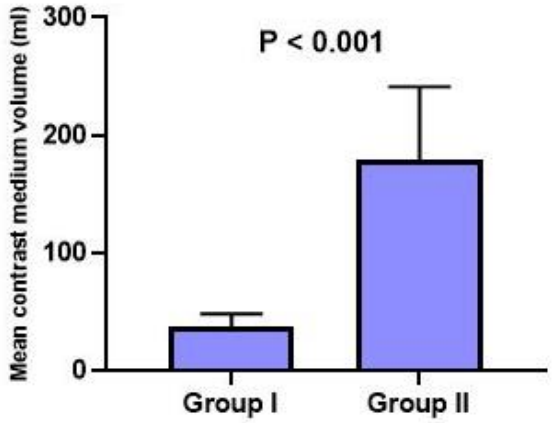
	Group I (n = 40)	Group II (n = 40)	*P* value
Target Artery			
LAD	22 (55)	16 (40)	0.609
LCX	9 (22.5)	12 (30)	
RCA	7 (17.5)	9 (22.5)	
Left main	2 (5)	3 (7.5)	
Lesion site			
Proximal	16 (40)	14 (35)	0.268
Mid-segment	21 (52.5)	18 (45)	
Distal	3 (7.5)	8 (20)	
Type of the Lesion			
A	28 (70)	26 (65)	0.874
B	9 (22.5)	10 (25)	
B2	3 (7.5)	4 (10)	
C	0 (0)	0 (0)	
Bifurcation	7 (17.5)	9 (22.5)	0.576
Calcification	8 (20)	12 (30)	0.302
In-stent restenosis	5 (12.5)	6 (15)	0.745

Data are presented as numbers (percentages).
LAD: left anterior descending artery; LCx: left circumflex artery; RCA: right coronary artery

Table 3: Procedural characteristics in the studied groups

	Group I (n = 40)	Group II (n = 40)	*P* value
Size of the Guide, Fr			1.0
6	39 (97.5)	40 (100)	
7	1 (2.5)	0 (0)	
IVUS use	3 (7.5)	7 (17.5)	0.176
Predilatation	23 (57.5)	26 (65)	0.491
DES implantation	39 (97.5)	40 (100)	1.0
Number of Stents			
1	30 (76.9)	31 (77.5)	1.0
2	9 (23.1)	8 (20)	
3	0 (0)	1 (2.5)	
Contrast medium volume, mL	37 ±11	179 ±62	<0.001*
Fluoroscopy time, min	6 ±2	12 ±3	<0.001*
Air kerma, mGy	285 ±60	744 ±85	<0.001*
Dose area product, Gy/cm^2	36 ±7	47 ±5	<0.001*
Angiographic success	40 (100)	40 (100)	-
Procedural success	40 (100)	40 (100)	-
eGFR post-PCI (mL/min/1.73 cm^2)	84 ±24	72 ±17	0.015*

Data are presented as mean ± SD or numbers (percentages).
IVUS: intravascular ultrasound; eGFR: estimated glomerular filtration rate
* significant as a *P* value < 0.05



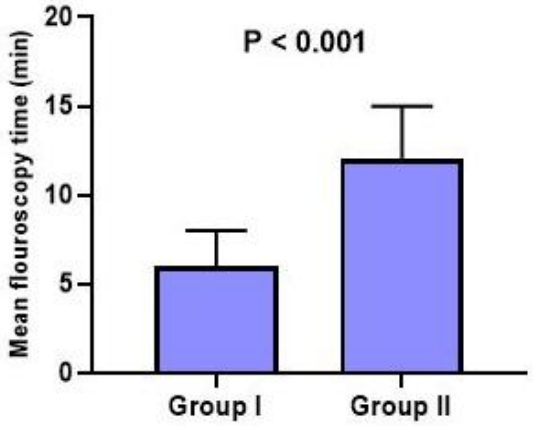


Figure 1: The image depicts the contrast medium volume in the studied groups. **Figure 2:** The image presents the fluoroscopy time in the studied groups.

DISCUSSION

PCI is a safe and efficient therapy for ischemic heart disease with a low risk of complications. Nonetheless, some components of the PCI technique, such as contrast injection, may induce toxicity. [3]

In the current study, Group II demonstrated significantly higher contrast medium volume, fluoroscopy time, air kerma, and dose area product ($P < 0.001$). In contrast, Group I had significantly higher eGFR post-PCI ($P = 0.015$).

Yabe et al [11] revealed that contrast fluoroscopy time and medium volume were significantly lower in the DCR group than in the controls ($P < 0.05$). They demonstrated that DCR facilitated the safe avoidance of contrast-induced nephropathy (CIN). The

contrast medium volume is a major modifiable risk factor for CIN. [13,14]

Patients with CIN have higher in-hospital and long-term mortality rates than those without CIN ($P < 0.001$). [15] Consequently, avoiding CIN is the most effective way to improve postoperative PCI short- and long-term outcomes. CIN incidence is higher in patients with risk factors such as diabetes and chronic kidney disease [16] than in normal patients. [17]

Piayda et al [9] showed that the DCR method created an anatomically accurate overlay of the coronary veins in over 98% of instances but with significant inter- and intraobserver heterogeneity. Additionally, adverse events and procedural components were observed. Compared with bigger PCI studies, the number of adverse events was much greater. The limited sample size may account for these findings. The observed major adverse cardiovascular events (1 cardiac arrest and 1 STEMI case) could not be attributed to the specialized software since the researchers used standard fluoroscopy pictures and the dynamic coronary pathway map on separate displays. Due to the prototype nature of the software, interventionists were prohibited from utilizing it extensively.

DCR reduces radiation dosage, contrast volume, and procedure time, according to studies using phantoms, research software, or first-time clinical interventions with commercially available technology. [12,18,19]

According to Baka et al, [20] the motion of the catheter tip during PCI is a combination of cardiac and respiratory motions. As catheter tip displacement can only correct translational motion, the authors proved that simulating the translational component of respiratory motion solely affected accuracy marginally, corroborating that the rotating component of respiratory motion was minimal. [21] These results demonstrate the validity of catheter-tip tracking for DCR correction in fluoroscopic X-ray pictures.

Ma et al [22] examined DCR between the suggested way of tracking, manual tracking, and no tracking. For route selection, all 3 systems used the same electrocardiography (ECG) matching method. By controlling just cardiac motion via roadmap selection and ECG matching without tracking, DCR accuracy may be reduced to less than 3 mm. The proposed method produces median DCR distances of about 1.4 mm and mean DCR distances of approximately 2 mm. For each of the 409 assessment frames, boxplots displaying the distances between every pair of points and the average distance between points per assessment frame were generated. Comparing the 3 DCR approaches reveals that the suggested DCR method is more precise than the DCR method without tip tracking and slightly less precise than the DCR method with manual tip tracking.

In 31 patients with an eGFR of 16.8 mL/min/1.73 m^2 and an eGFR of 16.8 mL/min/1.73 m^2 a few days after ultra-low-contrast-volume coronary angiography, Ali et al [23] established a unique technique for performing PCI without CM. This technique was supported by coronary physiology testing, IVUS imaging, and metallic road mapping. Before stent implantation, fractional and coronary flow reserves were assessed to determine the physiological significance and outcome of the lesions. IVUS was used to identify the proximal and distal landing zones, guide stent selection and postdilation, and confirm the final result. Monitoring on a short-term basis revealed that none of the patients who had PCI using this approach developed major adverse renal and cardiovascular events.

Iodixanol did not substantially decrease CI-AKI among chronic kidney disease patients having PCI, according to a recent meta-analysis (P = 0.08) that included just this group of patients. [24]

CONCLUSIONS

Despite similar clinical and procedural characteristics, DCR use during PCI was associated with a substantial reduction in contrast volume and fluoroscopy time.

Conflict of Interest: None

Acknowledgments: None

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