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Value of the Novel Dynamic Coronary Roadmap in Percutaneous Coronary Intervention

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Abstract: Background: An innovative technological advancement, the dynamic coronary roadmap (DCR) superimposes the coronary arteries on a fluoroscopic image in real-time while compensating for motion. Aim: to determine the value of DCR in percutaneous coronary intervention. Methods: This study was conducted on 193 patients with anginal pain, who come for Percutaneous coronary intervention (PCI) on elective basis, who found to have multiple/complex lesions suitable for PCI, and expected to have a long procedure time and large contrast volume. They divided into two groups; DCR group which included 93 patients in which PCI was done with DCR while control group included 100 patients in which PCI was done without DCR. All patients subjected to clinical assessment, full resting 12-Lead ECG, history taking, routine pre-catheter laboratory investigations and transthoracic Echocardiography. Conventional coronary angiography followed by PCI was done then we used Dynamic Roadmap system. Results: The DCR group had considerably lower levels of total air kerma and DAP than the control group (p0.001). In addition, the DCR group compared to the control group regard as fluoroscopy duration was significantly reduced in (p0.001). 100 percent of procedures were successful in both the control and DCR groups. In the control group, there were no significant variations in radiation dosage between operators 1 and 2, however operators 2 had considerably less fluoroscopy duration and contrast volume (p=0.002 and 0.023, respectively). No significant were recorded in contrast volume, radiation dose, or fluoroscopy time between operators 3 and 4 in the DCR group. Conclusion: Dynamic coronary road map significantly reduces contrast volume, Total air kerma and DAP, fluoroscopy time with 100% procedural success.

Keywords: Percutaneous Coronary Intervention, Dynamic Coronary Roadmap, Coronary Artery Disease

1. Introduction

Coronary artery disease continues to be a prominent contributor to morbidity and mortality on a global scale, underscoring the ongoing need for innovative diagnostic and interventional methods [1].

Percutaneous coronary intervention (PCI) is regarded as a safe, efficacious, and complication-free treatment for ischemic heart disease. Although ongoing endeavors have been devoted to the advancement and refinement of medical apparatus, including catheters and stents, the recording technique has not garnered significant attention in recent times. The majority of radiation exposure reductions over the last three decades have been accomplished with pulsed imaging and the transition from analog to digital recording [2].

Decreased kidney function, a comorbidity on the rise among PCI patients, is a risk factor for contrast-induced AKI. It is essential to take all practicable precautions to limit the risk of CIN or AKI prior to, during, and after the surgery, as there is no documented way to prevent these disorders totally [3].

The "Dynamic Coronary Roadmap (DCR)" is one such innovative technique that has changed coronary intervention. During cardiac catheterization operations, this novel technology combines cutting-edge imaging technologies and real-time image processing to generate dynamic, high-resolution maps of the coronary arteries. Utilizing a software tool that superimposes a dynamic picture of the coronary tree

onto fluoroscopy, the DCR provides interventional cardiologists with in-depth knowledge of the coronary anatomy. This assistance facilitates the navigation of the device through the coronaries and possesses the capacity to decrease the necessity for supplementary distinction puffs. Especially throughout PCI, In order to control the position of stents, wires, and balloons within the coronary arteries, the cardiologist must repetitively administer contrast agent., which makes navigation difficult. Thus, this instrument possesses the capacity to decrease the necessity for contrast during PCI [4].

An innovative software algorithm produces a digital overlay of the vessel, superimposed on live fluoroscopic images, on the basis of a conventional coronary angiogram. The cardiologist is able to navigate this DCR without the need for additional contrast agent administration [5].

We aimed to evaluate the possible benefits of DCR in decreasing the amount of contrast volume used in prolonged, and complex PCIs, and in decreasing the fluoroscopy time - Radiation exposure to both patient and operator-; So decreasing the incidence of the hazards expected form the contrast injection and radiation, and slightly decreasing the cost of the procedure.

2. Patients and Methods

This prospective Case-Control study was done between January 2022 and May 2023 at the Cardiology Department of Al-Azhar University and the National Heart Institute. The study was authorised by the ethical council of the Faculty of Medicine at Al-Azhar University, and informed consent was acquired from each patient.

Inclusion Criteria:

This study included patients with angina pain, who come for PCI on elective basis, whom found to have multiple/complex lesions suitable for PCI and expected to have a long procedure time and large contrast volume.

Exclusion Criteria:

We excluded patients with ACS, CTO lesions with not known coronary anatomy, patients with age <18 y, active infection and pregnancy.

Methods

All patients subjected to clinical assessment, routine pre-cath lab (CBC, urea, creatinine, INR, HBV Ab, HCV Ab, HIV, PT, PTT and INR), full history taking and r*esting 12-Lead ECG.*

Transthoracic Echocardiography: Conventional 2-D echocardiography including M-Mode according to ASE recommendation, left ventricular ejection fraction, left ventricular end diastolic diameter, Left ventricular end systolic diameter, aortic root diameter, and chambers quantification.

Conventional coronary angiography followed by PCI according to the standard guidelines, then using Dynamic Roadmap system in Philips Azurion in NHI, as we inject one contrast injection along a 3 consecutive heart beats, and then wiring the targeted vessel using dynamic coronary mapping.

Statistical analysis:

The data was collected, coded, and entered into a spreadsheet using Microsoft Excel 2016 for Windows, which is part of the 2016 Microsoft Office package and was developed by the United States-based Microsoft Corporation. The data were analysed using the 21st edition of IBM Statistical Package for the Social Sciences (SPSS) software (IBM, United States). To determine the distribution's normality, the Kolmogorov-Smirnov test was utilized. Categorical data were given as numbers and percentages, whereas continuous data were provided as mean standard deviation, median, and interquartile range (IQR). Utilizing graphs and tables, the data was presented. A p-value less than or equal to 0.05 showed statistical significance, whilst a p-value less than or equal to 0.001 indicated strong statistical significance. The Mann Whitney test, the chi-squared test, Fisher's exact test, and the student T-test were all used.

3. Results

This study was managed on 193 patients with anginal discomfort who presented for PCI on an elective basis, were determined to have multiple/complex lesions appropriate for PCI and were anticipated to have a lengthy procedure time and substantial contrast volume. They separated the patients into two groups: DCR group, consisting of 93 patients who underwent PCI with DCR, and control group, consisting of 100 patients who underwent PCI without DCR. The age average of the control group was 60.55 ±7.04 years and that of the DCR group was 61.19 ±8.25 years. In the control group, there were 73 percent males and 27 percent females, whereas in the DCR group, there were 74.2 percent males and 25.8 percent females. Regarding age and gender, there was no significant difference between the two groups ($p>0.05$).

Regarding ECG results, 8% of cases in the control group and 3.2% of cases in the DCR group exhibited AF or atrial flutter. Ischemic alterations were observed in 29 % of individuals in the control group and 41.9% of cases in the DCR group. about ECG results No significant differences were noted down between the two groups ($p>0.05$). Echocardiography demonstrated that 26% of cases in the control group and 19.4% of cases in the DCR group exhibited SWMA alterations, with no statistically significant difference ($p>0.05$). The mean LVEF in the control group was 59.99 ±7.51 percent and in the DCR group it was 57.30 ±5.64 percent. LVEF declined significantly in the DCR group versus the control group ($p<0.001$) (Table 1).

On assessment of lesion characteristics prior to PCI between the control group and DCR group, there were no significant differences in affected vessels, target site (except mid site which showed higher prevalence in DCR group, $p=0.008$), type of lesion (except type B which showed higher prevalence in DCR group, $p=0.03$), bifurcation, or in-stent restenosis ($p>0.05$). Yet, coronary calcification was more pronounced in the DCR group than in the control group (30% vs. 18%, $P = 0.047$) (Table 2).

Femoral access was used usually (87 percent) in both the

control and DCR groups (86 percent). In the control group, the mean size of the guiding catheter was 6.08± 0.27 Fr, while in the DCR group P, it was 6.04 ±0.20 Fr. Intravascular ultrasonography (IVUS) was utilized in 4% and 4.3% of all lesions in the two groups, respectively. The mean number of pre-dilatation attempts was 2.07 ± 0.74 in the control group and 1.98± 0.74 in the DCR group. The average number of post-dilatation attempts was 1.54± 0.81 in the control group and 1.54 ±1.05 in the DCR group. The average number of stents utilized in the control group was 1.66 ±0.67, whereas the DCR group used 1.80± 0.75. The mean contrast volume in the control group was 218.97± 41.18 ml while in the DCR group it was 179.79± 44.40 ml. Access, size of the guiding catheter, IVUS, pre- dilatation number of efforts, post-dilatation number of attempts, and number of stents did not differ significantly between the two groups (p>0.05). The DCR group had a considerably lower contrast volume than the control group (p<0.001) (Table 3).

The mean total air kerma was 1217.80± 162.93 mGy in control group and 1113.13 ±194.35 mGy in DCR group. The mean DAP was 76.07±17.72 Gy cm^2 in control group and 67.09±18.73 Gy cm^2 in DCR group. The mean fluoroscopy time was 21.76± 4.61 min. in control group and 18.53±5.52 min. in DCR group. DCR group had considerably lower levels of total air kerma and DAP than the control group (p<0.001). Additionally, fluoroscopy duration was considerably shorter in DCR group compared to control group (p<0.001) (Table 4).

In both the control group and the DCR group, the rate of procedural success was 100 percent.

In the control group, between operators 1 and 2, there were no significant variations regarding radiation dosage, however operators 2 had much less fluoroscopy time and contrast volume (p=0.002 & 0.023 respectively). In DCR group, no significant were differed in contrast volume, radiation dose, and fluoroscopy time between operators 3 and 4. (Table 5).

Table 1. *ECG and Echocardiography between the studied groups.*

Variable		Control group (N=100)		DCR group (N=93)		Test value	P-value
		No.	%	No.	%		
ECG							
AF, AFL	No	92	92.0%	90	96.8%	X^2= 2.044	0.153 (NS)
	Yes	8	8.0%	3	3.2%		
Ischemic Changes	No	71	71.0%	54	58.1%	X^2= 3.533	0.060 (NS)
	Yes	29	29.0%	39	41.9%		
Echocardiography							
LVEF (%)	Mean± SD	59.99± 7.51		57.30± 5.64		Z_{MWU} = 3.963	<0.001 (HS)
	Median	60.62		58.18			
	Range	35.80 – 75.85		35.0 – 68.54			
SWMA	No	74	74.0%	75	80.6%	X^2= 1.209	0.272 (NS)
	Yes	26	26.0%	18	19.4%		

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, X2: Chi-Square Test, ZMWU: Mann-Whitney U Test

Table 2. *Characteristics of lesions among the analyzed groups.*

Variable		Control group (N=100)		DCR group (N=93)		Chi-Square Test	
		No.	%	No.	%	Test value	P-value
Affected vessels	LM	3	3.0%	6	6.5%	1.291	0.256 (NS)
	LAD	69	69.0%	67	72.0%	0.214	0.643 (NS)
	LCX	38	38.0%	35	37.6%	0.003	0.958 (NS)
	RCA	47	47.0%	42	45.2%	0.066	0.798 (NS)
Lesion/s site	Proximal	43	43.0%	40	43.0%	0.000	0.999 (NS)
	Mid.	62	62.0%	74	79.6%	7.148	0.008 (HS)
	Distal	22	22.0%	19	20.4%	0.071	0.790 (NS)
Lesion/s type	Type A	16	16.0%	8	8.6%	2.422	0.120 (NS)
	Type B	79	79.0%	84	90.3%	4.706	0.030 (S)
	Type C	4	4.0%	7	7.5%	1.115	0.291 (NS)
Calcifications	No	82	82.0%	64	68.8%	4.546	0.033 (S)
	Yes	18	18.0%	29	31.2%		
Bifurcation	No	94	94.0%	86	92.5%	0.178	0.672 (NS)
	Yes	6	6.0%	7	7.5%		
In- Stent Restenosis	No	96	96.0%	89	95.7%	0.011	1.00^{FET} (NS)
	Yes	4	4.0%	4	4.3%		

P value< 0.05 is significant, P value< 0.01 is highly significant, Chi-Square Test, FET: Fischer exact test

Table 3. *The operational dynamics of the investigated groups.*

Variable		Control group (N=100)		DCR group (N=93)		Test value	P-value
		No.	%	No.	%		
Access	Femoral	87	87.0%	80	86.0%	X^2= 0.040	0.842 (NS)
	Radial	13	13.0%	13	14.0%		

Variable		Control group (N=100)		DCR group (N=93)		Test value	P-value
		No.	%	No.	%		
IVUS use	No	96	96.0%	89	95.7%	X^2= 0.011	0.599^{FET} (NS)
	Yes	4	4.0%	4	4.3%		
G.C (f)	Mean± SD	6.08± 0.27		6.04± 0.20		Z_{MWU} = 1.061	0.289 (NS)
	Median	6.0		6.0			
	Range	6.0 – 7.0		6.0 – 7.0			
Pre-dilatation No of attempts	Mean± SD	2.07± 0.74		1.98± 0.88		Z_{MWU} = 0.677	0.499 (NS)
	Median	2.0		2.0			
	Range	1.0 – 5.0		0.0 – 5.0			
Number of Stent/s and/or DEB/s	Mean± SD	1.66± 0.67		1.80± 0.75		Z_{MWU} = 1.201	0.230 (NS)
	Median	2.0		2.0			
	Range	1.0 – 4.0		1.0 – 4.0			
Post-dilatation No of attempts	Mean± SD	1.54± 0.81		1.51± 1.05		Z_{MWU} = 0.554	0.580 (NS)
	Median	2.0		2.0			
	Range	0.0 – 4.0		0.0 – 5.0			
Contrast Volume (ml)	Mean± SD	218.97± 41.18		174.52± 40.48		Z_{MWU} = 7.299	<0.001 (HS)
	Median	210.0		172.0			
	Range	148.0 – 338.0		90.0 – 292.0			

Chi-Square Test, FET: Fischer exact test, ZMWU: Mann-Whitney U Test, P value< 0.05 is significant, P value< 0.01 is highly significant

Table 4. *Dose of Radiation among the examined groups.*

	Control group (N=100)					DCR group (N=93)					Mann-Whitney U Test	
	Mean	±SD	Median	Min.	Max.	Mean	±SD	Median	Min.	Max.	Test value (Z_{MWU})	P-value
Total air kerma (mGy)	1217.80	±162.93	1213.0	994.0	2306.0	1113.13	±194.35	1082.0	690.0	2255.0	6.091	<0.001 (HS)
DAP (Gy cm2)	76.07	±17.72	72.5	31.0	148.0	67.09	±18.73	63.0	33.0	158.0	4.137	<0.001 (HS)
Fluoroscopy time (min)	21.76	±4.61	21.0	12.0	42.0	18.53	±5.52	17.0	9.0	39.0	5.485	<0.001 (HS)

SD: Standard deviation, ZMWU: Mann-Whitney U Test, P value< 0.05 is significant, P value< 0.01 is highly significant

Table 5. *Procedural characteristics for each of the analyzed groups' operators.*

	Control group (N=100)				Mann-Whitney U Test		DCR group (N=93)				Mann-Whitney U Test	
	Operator 1 (n = 61)		Operator 2 (n = 39)		Test value (Z_{MWU})	P-value	Operator 3 (n = 70)		Operator 4 (n = 30)		Test value (Z_{MWU})	P-value
	Mean	±SD	Mean	±SD			Mean	±SD	Mean	±SD		
Years of Experience	6 years		11 years				16 years		9 years			
Contrast Volume (ml)	228.00	±40.52	204.85	±38.62	3.089	0.002	163.03	±28.06	179.98	±44.38	1.607	0.108
Total air kerma (mGy)	1224.00	±194.55	1208.10	±96.12	0.512	0.608	1074.10	±97.22	1131.71	±224.81	1.064	0.287
DAP (Gy cm2)	76.41	±18.92	75.54	±15.87	0.382	0.703	62.17	±12.71	69.43	±20.68	1.226	0.220
Fluoroscopy time (min)	22.67	±5.11	20.33	±3.26	2.281	0.023	17.70	±3.83	18.92	±6.16	0.376	0.707

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, *ZMWU: Mann-Whitney U Test*

4. Discussion

A 2% overall incidence of intraprocedural complications distinguishes PCI and coronary angiography as safe and effective procedures [6]. Despite this, contrast medium administration continues to pose certain risks, including radiation exposure and kidney failure. 30% of patients who have pre-existing renal impairment may develop acute kidney failure. Notably, in comparison to diagnostic angiography, PCI necessitates a significantly greater dosage of radiation, duration of the procedure, and amount of contrast medium [7].

The purposefulness of this study was to estimate the potential benefits of DCR in PCI. On comparison of lesion characteristics before PCI between control group and DCR group, in affected vessels, target site (except mid site that showed higher prevalence in DCR group, p=0.008), type of lesion (except type B that showed higher prevalence in DCR group, p=0.03), bifurcation and in-stent restenosis between both groups were no significant differences (p>0.05). In conflict, the DCR group exhibited a significantly greater degree of coronary calcification compared to the control group. (30% vs. 18%, P = 0.047).

Yab et al. discovered that the target location, target arteries, coronary calcification, type of lesion, and in-stent restenosis did not differ substantially between the two groups. Consequently, the incidence of bifurcation lesions was substantially higher in the DCR group (37.2% vs. 20.3%, P = 0.033) than in the control group (20.3%). It is likely that this difference is the result of diverse study designs [8].

87 percent of cases in the control group and 86 percent of cases in the DCR group involved femoral access, according to our findings. Contrary to the control group (6.04± 0.20 Fr), The mean guiding catheter size for DCR group P was 6.08± 0.27 Fr. IVUS was utilized to analyze 4% and 4.3% of all lesions in each group, respectively. The average pre-dilatation number of attempts was 2.07± 0.74 in control group and 1.98± 0.88 in DCR group. The mean post-dilatation number of attempts was 1.54± 0.81 in control group and 1.51± 1.05 in DCR group. The mean number of stents used was 1.66± 0.67 in control group and 1.8± 0.75 in DCR group. The mean contrast volume was 218.97± 41.18 ml in control group and 179.79± 44.86 ml in DCR group. Access, size of the guiding catheter, IVUS, pre- dilatation number of efforts, post- dilatation number of attempts, and number of stents between the two groups significantly did not differ (p>0.05).

Consistent with our findings, Yab et al. [8] reported that ad hoc PCI, the mean size of the guiding catheter, IVUS, predilatation of the main channel, and radiation dose were significantly associated with each other.

In comparison to the control group, contrast volume was dramatically reduced in the DCR group (p<0.001). Maher et al. [9] achieved the same conclusion when they compared the contrast volume utilized throughout coronary intervention to that of the control group. In comparison, the control group's mean volume was substantially bigger than that of the DCR group (190 ±57.5).

An observational study was described in a 2018 European Journal of Medical Research article, wherein PCI was performed subsequent to diagnostic coronary angiography on 36 patients. 78% of the patients existing with non-STEMI acute coronary syndrome. The research investigated the efficacy of the dynamic road map software in furnishing the operator with suitable visual aids to facilitate the intervention. Additionally, post-procedural complications were assessed subsequent to the procedure. A satisfactory quality rating was assigned to 28.4% of the acquired roadmap cines, while 71% were deemed to be of well quality. The procedure was completed in 58.2 minutes on average, with a standard deviation of 24.1 minutes. A volume of contrast averaging 157.8 ml was employed, with a minimum of 70 ml utilized. Dynamic Road Mapping is feasible and has promising potential during coronary interventions, according to the study's findings [10].

Controlling the volume of contrast medium utilized during PCI is the most effective method the operator can employ to prevent CIN. Although contrast volume is restricted in patients with CKD, there are a few methods available for conducting PCI. Optical coherence tomography and IVUS-guided PCI are two examples. -PCI without contrast medium guidance [11, 12].

Nevertheless, PCI employing OCT and IVUS is only capable of diminishing the volume of the contrast medium while stent and balloon insertion. For guidewire position confirmation, side branch management, and target vessel operation, a modest to moderate amount of contrast medium is necessary. This is because complications involving a guidewire, such as dissection and perforation, cannot be disregarded. Even though these technologies are technically probable albeit complex, we contend that the process can be carried out further securely and effortlessly through the use of DCR [13].

Contrast volume dose is a risk factor for the formation of CIN; hence, contrast volume utilization should be reduced during PCI [14]. In order to limit the risk of CIN, Brown et al. [15] suggest using contrast medium in PCI in a quantity not exceeding twice the eGFR, and according to a research by Gurm et al. [16] CIN can be averted by reducing the volume of the contrast medium to less than three times the predicted creatinine clearance (CC), Recent studies, however, indicate that extra CIN can be avoided by employing a volume of contrast medium equal to or less than the patient's estimated CC [17].

Total air kerma and DAP were significantly lower in the DCR group compared to the control group (p<0.001). Also, fluoroscopy time was much shorter in the DCR group compared to the control group (p<0.001).

A recent randomized controlled experiment with 30 individuals (6) was published in the Journal of the American College of Cardiology in 2021. Sixty-three patients were administered dynamic road mapping (DRM), while 67 patients were not. Between the DRM group and the control group, there was a statistically significant reduction in contrast volume utilization (mean _SD: 36.8 _ 19.2 mL vs _control: 69.4 _ 27.3 mL, P < 0.001) [18].

The DCR system significantly decreased fluoroscopy time, according to Yab et al (normal group: 16.34± 11.22 min; DCR group: 11.41± 5.53 min, P=0.007). DCR's provision of navigation support expedites the delivery of devices. Primarily, it assists in the positioning of guidewires by enabling the selection of branches at points of division. Alternatively stated, the guidewire's passage time might be shortened due to the gradual advancement of the guidewire towards the target branch. Furthermore, delivery of an imaging apparatus (e.g., OCT or IVUS) and/or pressure wire to the lesion is facilitated by DCR due to the overlaying of the lesion location on the roadmap. (Yabe et al., 2020).

We observed that Percentage of procedural success was 100% in both control group and DCR group. Consistency Maher et al. [9] stated that the success rates of the two groups were not statistically distinct; 100% success was attained by the control group., while the DRM group achieved a success rate of 85% (P-value = 0.198).

Our study has some limitations. Firstly, our results did not evaluate the incidence of post procedural complications. Secondly, we did not measure eGFR for evaluation of kidney

function. Finally, our study depended on multiple operators with different years of experience and variable acceptance in using the technique.

5. Conclusion

Dynamic coronary road map significantly reduces contrast volume, Total air kerma and DAP, fluoroscopy time with 100% procedural success, indicating that dynamic roadmap technology should be utilized in all coronary interventions, particularly for CKD patients who are at high risk for CIN.

Abbreviations

ACS: Acute Coronary Syndrome
AF: Atrial Fibrillation
AFL: Atrial Flutter
AKI: Acute Kidney Injury
ASE: American Society of Echocardiography
CBC: Complete Blood Count
CC: Creatinine Clearance
CIN: Contrast-Induced Nephropathy
CKD: Chronic Kidney Disease
CTO: Chronic Total Occlusion
DAP: Dose Area Product
DCR: Dynamic Coronary Roadmap
DRM: Dynamic Roadmap
ECG: Electrocardiogram
eGFR: Estimated Glomerular Filtration Rate
G.C: Guiding Catheter
HBV Ab: Hepatitis B Virus Surface Antibody
HCV Ab: Hepatitis C Virus Surface Antibody
HIV: Human Immunodeficiency Virus
INR: International Normalized Ratio
IQR: Interquartile Range
IVUS: Intravascular Ultrasound
LAD: Left Anterior Descending Artery
LCX: Left Circumflex
LM: Left Main Coronary
LVEF: Left Ventricular Ejection Fraction
mGy: Milligray
NHI: National Heart Institute
Non-STEMI: Non-ST Elevation Myocardial Infarction
OCT: Optical Coherence Tomography
PCI: Percutaneous Coronary Intervention
PT: Prothrombin Time
PTT: Partial Thromboplastin Time
RCA: Right Coronary Artery
SPSS: Statistical Package for the Social Sciences
STEMI: ST Elevation Myocardial Infarction
SWMA: Segmental Wall Motion Abnormalities

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Conflicts of Interest

The authors declare no conflicts of interest.

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