American Journal of
Health, Medicine and Nursing Practice
(AJHMN)

Dynamic Coronary Roadmap for Contrast, and Radiation Time Reduction during Coronary Intervention (DRM-COR)

Mamdouh Maher, Bassem Zarif, Aya Elgamal, Hatem Khairy, and Ahmed Magdy

American Journal of Health, Medicine and Nursing Practice
ISSN 2520-4017 (Online)
Vol.7, Issue 12, pp 32 – 39, 2022
www.ajpojournals.org

Dynamic Coronary Roadmap for Contrast, and Radiation Time Reduction during Coronary Intervention (DRM-COR)

Mamdouh Maher[1], Bassem Zarif[1], Aya Elgamal[1], Hatem Khairy[1], and Ahmed Magdy[1]

[1]Department of Cardiology, the National Heart Institute-Egypt, 5 Ibn El Nafees st, Al Kit-Kat, Giza, 12651.

Corresponding Author's Email: mamdouhgordon@gmail.com

Abstract

Purpose: The regularly used contrast media in the angiography procedures and interventions are known to carry certain risks to the patient. This includes allergy, nephrotoxicity, and pulmonary edema. Additionally, radiation exposure is associated with high bone marrow depression, infertility, and other hazards. The purpose of the study was to compare the Dynamic Roadmap technology to the regular contrast used in coronary intervention regarding radiation exposure, fluoroscopy time, and incidence of Contrast Induced Nephropathy.

Methodology: Observational prospective cohort with 2 arms where 40 patients were randomly divided into 2 arms a case and control groups. The case group had DRM technology used in their procedures where the control group received the standard contrast used in the National Heart Institute.

Findings: Findings showed no statistically significant difference between the 2 groups in age, sex, and risk profile including status of Hypertension, Diabetes Mellitus, Smoking and history of Ischemic Heart Disease. There was no difference in echocardiographic findings of both groups. There was significant difference in creatinine level at the 5th day of intervention and volume of contrast used and fluoroscopy time. DRM reduced contrast volume, reduced radiation exposure despite not reducing fluoroscopy or procedure time. This resulted in reduction of elevation in serum creatinine levels with similar success rates.

Recommendations: Using the least possible contrast volume and radiation doses should always be target of the operator. Dynamic roadmap technology is recommended in all coronary interventions specially those at high risk of CIN with CKD.

Keywords: *Coronary, contrast, dynamic roadmap*

INTRODUCTION

Coronary artery diseases are the leading cause of death worldwide(1). Coronary interventions have been made in very high volumes to save millions of lives annually. The contrast used to view the coronaries and guide the procedure has some side effects. Some side effects are contrast allergy, nephrotoxicity, contrast induced nephropathy or Acute Kidney Injury, pulmonary edema and others.(2) In addition to that, the radiation in the catheterization laboratory has serious consequences such as thyroid dysfunction, infertility and cancer(3)(4).

Reduction of these side effects was a major area of research in the past years. A new technology was developed by Philips Medical system called (Dynamic Coronary Roadmap) DRM. This software generates images from the acquired angiograms in the same procedures and allows the physician dynamic 2D images without additional contrast usage. This is believed to reduce the amount of contrast used during the intervention.(5) It is also expected to reduce radiation dose needed.

This study compared the regular contrast to the new technology DRM in volume of contrast used and radiation exposure time.

METHODOLOGY

Observational prospective cohort study randomly recruited 40 patients divided randomly into equal 2 arms. One arm (control) received the ordinary coronary intervention used at the National Heart Institute-Egypt. The case group received the dynamic flow mapping technique during the intervention in combination with the regular intervention. The outcomes were difference in amount of contrast used, total radiation time, and dose, success rate, and incidence of complications. Patients with complex coronary interventions such as Chronic Total Occlusion (CTO), isolated ostial coronary arteries lesions, emergent intervention, or with contrast allergy or chronic Kidney Disease (CKD) were excluded.

Statistical Analysis

Data was viewed and normal distribution was assumed. Comparison between means was used through. Chi square test was used to compare the 2 groups' characteristics and risk profile and the intervention procedures. Independent t-test was used to compare the echocardiographic finding between the 2 groups and the basal and fifth day creatinine levels, and the contrast volume, fluoroscopy time and other end points. Paired t-test was used to compare the difference in creatinine level between the 2 groups before and after the procedure.

RESULTS

Sample of 40 patients was studied with mean age of 58.15 years with a standard deviation of 8.44 years. There were 27 males studied representing 67.5% of the group and 13 female with a percentage of 32.5%. Majority of the patients (75%) were hypertensive and 57.5% were diabetic while 47.5% were smokers. Most of the patients representing 47.5% had 2 vessels coronary artery disease. The mean basal serum creatinine level measured before the coronary intervention was 1.05 with 0.33 SD. All the cases resulted in TIMI III flow with 85% of the patients developing no per procedural complications while 10% developed Contrast Induced Nephropathy and single case developed pulmonary edema and another case developed both CIN and pulmonary edema.

It could be concluded that there is no statistically significant difference between the 2 groups receiving dynamic roadmap and regular contrast regarding age and sex with mean age of almost 57 and 59.5 respectively and P-value 0.37 and 0.09 in order. Additionally there was no

difference in the risk profile of the patients in the 2 groups regarding HTN, Diabetic status, history of ischemic heart disease or smoking. This is shown in table 1.

Table 1: Patient profile

		Control group		DRM group		Test value	P-value	Sig.
		No. = 20		No. = 20				
Age	Mean ± SD	56.95 ± 8.89		59.35 ± 8.00		-0.897•	0.375	NS
	Range	38 – 72		48 – 74				
Sex	Female	9 (45.0%)		4 (20.0%)		2.849*	0.091	NS
	Male	11 (55.0%)		16 (80.0%)				
HTN	No	4	20.0%	6	30.0%	0.533	0.465	NS
	Yes	16	80.0%	14	70.0%			
DM	No	8	40.0%	9	45.0%	0.102	0.749	NS
	Yes	12	60.0%	11	55.0%			
IHD	No	10	50.0%	5	25.0%	2.667	0.102	NS
	Yes	10	50.0%	15	75.0%			
Smoker	No	12	60.0%	9	45.0%	0.902	0.342	NS
	Yes	8	40.0%	11	55.0%			

P-value >0.05, Non-significant (NS), P-value <0.05, Significant (S), P-value< 0.01, highly significant (HS)

** Chi-square test, • Independent t-test*

There was no statistically significant difference between the DRM and control group in cardiac status assessed by 2D echocardiography as there was no difference in Ejection Fraction, Valvular Heart Disease or LV dimensions. Please refer to table 2.

Table 2: Clinical and echocardiographic characteristics

		Control group	DRM group	Test value	P-value	Sig.
		No. = 20	No. = 20			
EF (%)	Mean ± SD	52.50 ± 9.68	49.75 ± 6.96	1.032•	0.309	NS
	Range	35 – 70	40 – 60			
RWMA	No	5 (25.0%)	4 (20.0%)	0.143*	0.705	NS
	Yes	15 (75.0%)	16 (80.0%)			
Valvular D.	No	11 (55.0%)	10 (50.0%)	0.100*	0.752	NS
	Yes	9 (45.0%)	10 (50.0%)			
LV. Dimensions	No	17 (85.0%)	14 (70.0%)	1.290*	0.256	NS
	Yes	3 (15.0%)	6 (30.0%)			

HR	Mean ± SD	75.60 ± 7.21	81.60 ± 11.22	-2.012	0.051	NS
	Range	65 – 90	65 – 105			
SBP	Mean ± SD	144.00 ± 26.39	136.00 ± 25.01	0.984	0.331	NS
	Range	115 – 200	100 – 180			
DBP	Mean ± SD	91.00 ± 18.32	80.00 ± 13.38	2.168	0.036	S
	Range	70 – 140	60 – 110			

P-value >0.05, Non-significant (NS), P-value <0.05, Significant (S), P-value< 0.01, highly significant (HS)

** Chi-square test, • Independent t-test*

There was no significant difference between the groups in the heart rate or systolic blood pressure where there was statistically significant difference in only Diastolic Blood pressure. The control group had higher diastolic pressure with a mean of 91 mmHg with 18 mmHg SD while the DRM group had DBP of 80 mmHg with 13.3 mmHg SD. Finally, there was no statistically significant difference in the number of stents used for the control or the dynamic road map group. The mean number of stents was 1.45 with a SD of 0.75 in the DRM group while it was 1.6 with a SD of 0.68 in the control group.

There was significant difference between the control and DRM groups in the serum creatinine level measured in the 5th day post coronary intervention. The control group showed 5th day creatinine level of 1.98 with 0.93 SD while the DRM group had 1.37 serum 5th day creatinine levels with 0.54 SD with P-value of 0.015. Additionally, a highly significant difference in the serum creatinine level is detected between the control and DRM groups with mean level of 0.93 and 0.31 respectively with P-value of 0.006 as shown in table 3.

Table 3: Change in serum creatinine

		Control group	**DRM group**	**Test value**	**P-value**	**Sig.**
		No. = 20	**No. = 20**			
Basal creat	Mean ± SD	1.05 ± 0.34	1.06 ± 0.33	-0.042•	0.967	NS
	Range	0.54 – 1.7	0.61 – 1.77			
5th day creat	Mean ± SD	1.98 ± 0.93	1.37 ± 0.54	2.543•	0.015	S
	Range	0.63 – 3.5	0.7 – 2.88			
Difference	Mean ± SE	0.93 ± 0.18	0.31 ± 0.09	-2.938	0.006	HS
Angiographic diseased coronaries	1	9 (45.0%)	5 (25.0%)	4.767*	0.092	NS
	2	10 (50.0%)	9 (45.0%)			
	3	1 (5.0%)	6 (30.0%)			

P-value >0.05, Non-significant (NS), P-value <0.05, Significant (S), P-value< 0.01, highly significant (HS)

** Chi-square test, • Independent t-test*

Comparing the basal and 5th day creatinine levels in between the groups showed highly statistically significant difference in both groups with higher elevation in the control group with mean from 1.05 to 1.98 with SDs of 0.34 and 0.93 respectively and P-value of 0.000. In the DRM group there was also, significant difference from 1.06 to 1.37 serum creatinine level with SDs of 0.33 and 0.54 respectively with P-value of 0.003. Please refer to table 4.

Table 4: Follow up serum creatinine

Creat		Basal	5th day	Test value	P-value	Sig.
		No. = 20	No. = 20			
Control group	Mean ± SD	1.05 ± 0.34	1.98 ± 0.93	4.908	0.000	HS
	Range	0.54 – 1.7	0.63 – 3.5			
DRM group	Mean ± SD	1.06 ± 0.33	1.37 ± 0.54	3.415	0.003	HS
	Range	0.61 – 1.77	0.7 – 2.88			

P-value >0.05, Non-significant (NS), P-value <0.05, Significant (S), P-value< 0.01, highly significant (HS)

There was highly significant difference in the contrast volume used during the coronary intervention procedure between the control and DRM groups. The means of contrast volume used were 274 and 190 ml with SDs of 75.6 and 57.5 respectively with P-value of 0.000. Additionally, the radiation dose was reduced in the DRM group compared to the control group with mean radiation doses of 1220.7 mgy and 838.6 mgy respectively and SDs of 672.5 mgy and 306.9 mgy in order and P-value of 0.026. There was no statistically significant difference in Fluoro time or procedure time. The fluoro time was 53 minutes and 42.6 minutes in the control and DRM groups with SDs of 19 and 14.5 minutes respectively. The procedure time in the control group was 53 minutes with 19 minutes SD while 42 minutes in the DRM group with 14.5 minutes SD. P-value was 0.06.

There was no statistically significant difference between the 2 groups in success rate with success rates of 100% in the control group and 85% in the DRM group with P-value of 0.198. Additionally, there was no statistically significant cumulative difference regarding complications including Contrast induced nephropathy (CIN) or pulmonary edema. The incidence of CIN was 15% in the control group compared to 5% in the DRM group with P-value of 0.37. This is shown in table 5.

Table 5: Procedural dynamics

		Control group	DRM group	Test value•	P-value	Sig.
		No. = 20	No. = 20			
Contrast volume (ml)	Mean±SD	274.00 ± 75.61	190.25 ± 57.55	3.942	0.000	HS
	Range	175 – 450	100 – 300			
Fluro time (min)	Mean±SD	24.18 ± 10.03	21.85 ± 6.70	0.862	0.394	NS
	Range	12 – 56	12 – 33			
Procedure time (min)	Mean±SD	53.00 ± 19.06	42.60 ± 14.55	1.939	0.060	NS
	Range	30 – 90	25 – 78			

Radiation dose (mgy)	Mean±SD	1220.75 ± 672.55		838.60 ± 306.92		2.312	0.026	S
	Range	340 – 2790		418 – 1566				
Final TIMI	TIMI 3	20	100.0%	20	100.0%	NA	NA	NA
Success rate	Failure	0	0.0%	1	5.0%	3.243	0.198	NS
	Success	20	100.0%	17	85.0%			
	Mixed	0	0.0%	2	10.0%			
MACCE	No	16	80.0%	18	90.0%	3.118	0.374	NS
	CIN	3	15.0%	1	5.0%			
	Pul.odema	0	0.0%	1	5.0%			
	CIN + Pul.odema	1	5.0%	0	0.0%			

P-value >0.05, Non-significant (NS), P-value <0.05, Significant (S), P-value< 0.01, highly significant (HS)

** Chi-square test, • Independent t-test, ‡ Mann Whitney test*

DISCUSSION

There was no statistically significant difference between the group receiving Dynamic roadmap during their percutaneous coronary intervention and the control group receiving regular coronary intervention without road mapping in their risk profile regarding Diabetic status, HTN, Smoking or history of Ischemic Heart Diseases. In addition to that, there was no difference in basic risk stratification modalities such as echocardiographic findings, Systolic Blood pressure before intervention. Diastolic Blood pressure was different between the DRM and control groups (means 91-80 mmHg with SDs 18-13.8 mmHg respectively, P-value 0.036). This is not believed to be associated with increased incidence of contrast induced nephropathy, significant rise in creatinine levels or other major post coronary intervention's complications.

Few studies have been discussing the usage of dynamic road mapping in coronary interventions especially in more than single coronary artery disease, yet some studies done on computed tomography of the peripheral vasculature or peripheral angiography have shown similar results(6–8). The studies done on coronary interventions have also detected significant reduction in contrast volume used and the amount of radiation for which medical personnel and patients are exposed. Also, the incidence of post procedural complications has not been significantly different between the groups.

A recent Randomized Controlled Trial published in the Journal of the American College of Cardiology 2021 studied 130 patients (6). A total of sixty three patients received dynamic road mapping while 67 patients didn't receive DRM. The study detected that there was significant reduction in the used contrast volume in the DRM group compared to the other group (mean _SD]: 36.8 _ 19.2 mL vs _control: 69.4 _ 27.3 mL, P < 0.001). Additionally, it concluded that there was no associated higher incidence of in-hospital complications such as early in stent thrombosis, Myocardial Infarction, early embolization stroke or death(7). Most of the patients in this study received only 1 stent during the procedure.

Another study published in the Heart and Vessels Journal 2020 has studied Dynamic road map technology (7). The study divided the 130 patients into 2 groups with 92 patients received the normal treatment while 38 patients received DRM. The 152.17 ± 73.06 ml in the control group and 118.81 ± 49.70 ml in the DCR group (*P* = 0.006). Additionally, the DRM group had shorter fluoroscopy time with an average of 11.4 minutes and SD of 5.5 minutes compared to 16.3 minutes with SD of 11.2 minutes, P-value 0.007). On the contrary, no statistically significant difference have been detected between the 2 groups in radiation dose exposure (AK, 506.32 ± 375.33 mGy vs. 443.44 ± 307.90 mGy, *P* = 0.338; DAP, 31.46 ± 23.25 Gy cm2 vs. 25.94 ± 18.37 Gy cm2, *P* = 0.169).(9)

One observational study in published in the European Journal of Medical Research 2018 studied 36 patients undergoing diagnostic coronary angiography followed by PCI. 78% of the patients were in acute coronary syndrome in the form of Non-STEMI. The study addressed the quality of the dynamic road map software in providing appropriate imaging to guide the operator through the intervention. It also studied the post procedural complications. 71% of the acquired roadmap cines were considered of good quality while 28.4% were considered of accepted quality. The procedure time was 58.2 minutes with a SD of 24.1 minutes in average. The average used contrast volume was 157.8 ml with a SD of 70 ml. The study has concluded that Dynamic road mapping is feasible during coronary interventions and have a good potential.(8)

CONCLUSION

Dynamic Road Map in coronary intervention reduces contrast volume, reduces radiation exposure despite not reducing flouro or procedure time. This results in reduction of elevation in serum creatinine levels with similar success rates.

LIMITATIONS

The sample size was small to generalize the results on a wide scale. The study was conducted in a single center by multiple operators.

RECOMMENDATIONS

Using the least possible contrast volume and radiation doses should always be target of the operator. Dynamic roadmap technology is recommended in all coronary interventions specially those at high risk of CIN with CKD.

Fund

The authors didn't receive any fund for this trial at all its stages.

Conflict of Interest

There is no conflict of interest.

Ethical Approvals

This study has received the ethical committee approval from the institutional review board of the General Organization for Teaching Hospitals and Institute **(GOTHI)** with registration number **(IHC 00021)** on the date: **18/08/2021**

REFERENCES

1. Khan MA, Hashim MJ, Mustafa H, Baniyas MY, Al Suwaidi SKBM, AlKatheeri R, et al. Global Epidemiology of Ischemic Heart Disease: Results from the Global Burden of Disease Study. Cureus. 2020;12(7).

2. Lun Z, Liu L, Chen G, Ying M, Liu J, Wang B, et al. The global incidence and mortality of contrast-associated acute kidney injury following coronary angiography: a meta-analysis of 1.2 million patients. J Nephrol [Internet]. 2021;34(5):1479–89. Available from: https://doi.org/10.1007/s40620-021-01021-1

3. Bratschitsch G, Leitner L, Stücklschweiger G, Guss H, Sadoghi P, Puchwein P, et al. Radiation Exposure of Patient and Operating Room Personnel by Fluoroscopy and Navigation during Spinal Surgery. Sci Rep. 2019;9(1):1–5.

4. Hauptmann M, Daniels RD, Cardis E, Cullings HM, Kendall G, Laurier D, et al. Epidemiological studies of low-dose ionizing radiation and cancer: Summary bias assessment and meta-analysis. J Natl Cancer Inst - Monogr. 2020;2020(56):188–200.

5. Almendarez M, Gurm HS, Mariani J, Montorfano M, Brilakis ES, Mehran R, et al. Procedural Strategies to Reduce the Incidence of Contrast-Induced Acute Kidney Injury During Percutaneous Coronary Intervention. JACC Cardiovasc Interv. 2019;12(19):1877–88.

6. Albrecht MH, Vogl TJ, Wichmann JL, Martin SS, Scholtz JE, Fischer S, et al. Dynamic 4D-CT angiography for guiding transarterial chemoembolization: Impact on the reduction of contrast material, operator radiation exposure, catheter consumption, and diagnostic confidence. RoFo Fortschritte auf dem Gebiet der Rontgenstrahlen und der Bildgeb Verfahren. 2018;190(6):513–20.

7. Piayda K, Phinicarides R, Afzal S, Veulemans V, Jung C, Hellhammer K, et al. TCT-365 Dynamic Coronary Roadmap for Percutaneous Coronary Intervention Effectively Reduces Contrast Medium Exposure: Insights From an Open-Label, Randomized Trial. J Am Coll Cardiol [Internet]. 2021;78(19):B150. Available from: https://doi.org/10.1016/j.jacc.2021.09.1218

8. Piayda K, Kleinebrecht L, Afzal S, Bullens R, Ter Horst I, Polzin A, et al. Dynamic coronary roadmapping during percutaneous coronary intervention: a feasibility study. Eur J Med Res [Internet]. 2018;23(1):36. Available from: https://doi.org/10.1186/s40001-018-0333-x

9. Yabe T, Muramatsu T, Tsukahara R, Nakano M, Takimura H, Kawano M, et al. The impact of percutaneous coronary intervention using the novel dynamic coronary roadmap system. Heart Vessels [Internet]. 2020;35(3):323–30. Available from: https://doi.org/10.1007/s00380-019-01502-1