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Research Article

COMPARATIVE STUDY OF PCI USING DYNAMIC CORONARY ROADMAP VS PCI WITHOUT USING DYNAMIC CORONARY ROADMAP ON RADIATION DOSE, CONTRAST VOLUME AND FLUOROSCOPY TIME.

Dhammdeep Rahul Humane, Tirmale Rakesh, Rane Sandip, Rane Kavita, Rane Nandita, Desai Darshana

Mumbai Heart Clinic

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ABSTRACT

PTCA is widely practiced and has risks, but major procedural complications are rare.

Context: Dynamic Coronary Roadmap (DCR, Philips Healthcare, The Netherlands) is a novel technology that allows the users to see a moving roadmap of the coronary anatomy displayed on top of live fluoroscopy to provide guidance during navigation and positioning of devices.

Aims: Comparative study of PCI using dynamic coronary roadmap vs. PCI without using dynamic coronary roadmap on radiation dose, contrast volume and fluoroscopy time. Settings and Design: cross-sectional observational design was conducted in the tertiary care hospital.

Methods and Material: Three hundred and thirty-eight patients who underwent Percutaneous Coronary Angioplasty were enrolled. Patients were divided in DCR group and non DCR group. Statistical analysis used: Microsoft Excel and p value was calculated from online software.

Results: The 169 coronary angioplasty procedures performed with dynamic coronary roadmap resulted in a 2 % reduction in the average DAP compared with the 169 procedures performed without dynamic coronary roadmap. DCR vs without DCR (DCR: 148.7+_ 11.6 Gycm2 vs. PCI without **DCR:** 151.4 +_ 12.3 Gycm2, p, 0.003). In the subgroup who had primary angioplasty, patients without DCR had a 7 % increase in the mean contrast volume (DCR: 65.8 +-6.8 vs. No DCR 70.5+-8.2, p, 0.01).

Conclusions: This study found the use of DCR imaging to impart a significantly lower radiation exposure to the patient, shorter procedural time and contrast volume.

INTRODUCTION

Cardiac catheterization is one of the most widely performed cardiac procedures. In the United States, more than 1,000,000 cardiac catheterization procedures are performed annually.[1] PTCA is widely practiced and has risks, but major procedural complications are rare. The mortality rate during angioplasty is 1.2%. [2] People older than the age of 65, with kidney disease or diabetes, women and those with massive heart disease are at a higher risk for complications.

While substantial efforts have been made to improve and develop medical devices such as stents and catheters, the recording technique itself has not been a focus of interest in recent years. Within the past three decades, reduction of radiation exposure was mostly achieved through pulsed imaging and the changeover from analogue to digital recording. [3]

The amount of contrast agent necessary for coronary diagnostics and PCI depends on multiple factors: first, and most important, the interventionists experience, second, biplane or rotational imaging [4] and third, procedural complexity.

Static overlay techniques already exist for peripheral artery interventions and significantly decrease the applied amount of contrast medium.[5] Unfortunately, these software algorithms are not suitable for coronary imaging due to constant movement of the organ (heartbeat and breathing motion). Based on a conventional coronary angiogram, a novel software algorithm generates a digital overlay of the vessel, which is superimposed on live fluoroscopic images.[6] The cardiologist can navigate within this dynamic coronary roadmap without further application of contrast agent. In 2015, the first successful application of this novel software algorithm (PCI-Suite, Philips Healthcare, Eindhoven, Netherlands) in a single patient with a bifurcation lesion and real-time overlay guided

*Corresponding author: **Dhammdeep Rahul Humane**
Mumbai Heart Clinic

concomitant PCI [7]. Dynamic Coronary Roadmap (DCR, Philips Healthcare, The Netherlands) is a novel technology that allows the users to see a moving roadmap of the coronary anatomy displayed on top of live fluoroscopy to provide guidance during navigation and positioning of devices. This can provide additional confidence in the procedure, and reduce the need for extra cine runs or contrast puffs. The system extracts a coronary roadmap out of each frame of a cine run. An image registration technique compares moving structures that are present in both the roadmap and the live fluoroscopy images, to provide a precise overlay of the coronary vessel tree on top of the live fluoroscopy, moving exactly with the cardiac and breathing motion.

Aim to study the correlation of PCI using dynamic coronary roadmap vs PCI without using dynamic coronary roadmap on radiation dose, contrast volume and fluoroscopy time.

Objective to study the correlation of PCI using dynamic coronary roadmap vs PCI without using dynamic coronary roadmap on radiation dose, contrast volume and fluoroscopy time in primary coronary angioplasty patients and elective coronary angioplasty cases.

SUBJECTS AND METHODS

The present study, having a cross-sectional observational design, was conducted in the Mumbai Heart Clinic. Three hundred and thirty-eight patients who underwent Percutaneous Coronary Angioplasty between December 2018 and July 2020 were enrolled. Patient characteristics, such as height, weight and age, timing of procedure, on/off table time and total contrast volume, were routinely recorded by the Catheter Laboratory Technician in the DRIEFCASE software. Their risk factors like habits of smoking, tobacco, alcohol, demographic data, socioeconomic status, central obesity, BMI, Diabetes Mellitus, Hypertension, coronary artery disease was recorded. The clinical reports were comprised of information such as type of case (primary or elective), the degree of coronary artery disease and the details of each lesion targeted for angioplasty. The examination protocols were directly printed out from the angiography system and included the number of cine angiography runs acquired, total cine angiography and fluoroscopy time, DAP and the corresponding skin dose. All cases with their corresponding clinical reports, examination protocols and relevant laboratory parameters were stored in DRIEFCASE software. Patients were also examined during unscheduled visits in Emergency or Cardiology OPD as and when patients presented with symptoms.

Patients were divided in DCR group and non DCR group. Also whether to choose trans radial or trans femoral route was left at the discretion of the operator. Operator also decided for the number of stents, the contrast volume used, the fluoroscopy time required to complete the procedure.

Statistical analysis

The radiographic and clinical parameters were entered into a database in Microsoft Excel. Each procedure was grouped according to whether the case was performed with dynamic coronary roadmap or without dynamic coronary roadmap also primary or elective cases and the vascular territory (RCA, LAD and LCX) in which angioplasty was performed. Data analysis was performed with SPSS statistical software. Categorical clinical variables were compared using the x2 test for independence. Simple two-group comparisons of continuous variables were made with independent sample t-tests if the data were normally distributed, and Mann–Whitney U-tests if they were not. A series of 2 X 2 between-group univariate analyses of variance were used to explore the relationships between the independent variables of dynamic coronary roadmap and primary–elective angioplasty with the dependent variables DAP (Gycm2), fluoroscopy time (min), total air kerma (mGy), number of cine angiography runs and total contrast load (ml). All p-values were two-tailed and value of > 0.05 being statistically non-significant.

OBSERVATIONS AND RESULTS

This is an observational study of three hundred and thirty-eight patients undergoing coronary angioplasty in tertiary care hospital, regardless of indication, on all comer's basis with the aim to study the correlation of PCI using dynamic coronary roadmap vs PCI without using dynamic coronary roadmap on radiation dose, contrast volume and fluoroscopy time.
Those satisfying the inclusion criteria after taking the written informed consent were enrolled.

Table 1 Baseline characteristics of patients undergoing PCI with the use of dynamic coronary road mapping

BASELINE CHARACTERISTICS	DCR	NON DCR	P VALUE
Age	56.800 +_ 11.500 [a]	57.900 +_ 11.800[a]	0.3
Weight	61.600 +_ 13.100 [a]	62.400 _+ 12.900 [a]	0.5
SEX			
Male	107	101	
female	62	68	0.5
BMI	26.700 +_ 2.600 [a]	26.300 +_ 2.600[a]	0.1
Ejection fraction	47.500 +_ 4.100 [a]	48.200 +_ 3.900[a]	0.1
Serum creatinine	1.1 +_ 0.3 [a]	1.15 +_ 0.2	0.07
Diabetics mellitus	39	40	0.1
Hypertension	77	78	0.1
Dyslipidaemia	55	54	0.2
Case type			
Elective angioplasty	140	136	
Primary angioplasty	29	33	0.6
Vascular territory			
SVD	85	81	
DVD	51	54	
TVD	30	31	
LMCA	3	3	
Radial PTCA	46	41	
Femoral PTCA	123	128	

Demographic Profile of Case and Control Group

Out of total patients of 338 included in study, 169 patients were included in case group and 169 patients were included in control group. (Table 1) Mean age of cases was 56.800 +_ 11.5 years with 1 SD whereas mean age of control group was 57.900 +_ 11.8 years with 1 SD. The P value was 0.3 which was statistically non-significant. Mean weight of cases was 61.600 +_ 13.1 kg with 1 SD whereas mean weight of control group was 62.400 +_ 12.9 kg with 1 SD. The P value was 0.5 which was statistically non-significant. Total number of male patients were 107 and 101 in cases and control group respectively were as total number of female patients were 62 and 68 in cases and control group respectively. The P value was 0.5 which was statistically non-significant. Mean BMI of cases was 26.700 +_ 2.6 with 1 SD whereas mean BMI of control group was 26.300 +_ 2.6 with 1 SD. The P value was 0.1 which was statistically non-significant. Mean Ejection fraction of cases was 47.500 +_ 4.1 with 1 SD whereas mean Ejection fraction of control group was 48.200 +_ 3.9 with 1

SD. The P value was 0.1 which was statistically non-significant.

Mean serum creatinine of cases was 1.1 +_ 0.3 with 1 SD whereas mean serum creatinine of control group was 1.15 +_ 0.2 with 1 SD. The P value was 0.07 which was statistically non-significant.

Total number of diabetics mellitus, hypertension and dyslipidaemia patients in DCR group were 39, 77 and 55 whereas total number of diabetics mellitus, hypertension and dyslipidaemia patients in No DCR group were 40, 78 and 54 respectively. The P value was 0.1, 0.1 and 0.2 respectively which was statistically non-significant.

Total number of cases of SVD, DVD, TVD & LMCA were 85, 51, 30 & 3 whereas total number of SVD, DVD, TVD & LMCA in controls were 81, 54, 31 & 3 respectively.

Total number of Radial angioplasty and Femoral angioplasty in cases group were 46 & 123 whereas total number of Radial angioplasty and Femoral angioplasty patients in control group were 41 & 128 respectively. The P value was 0.6 which was statistically non-significant.

Total number of routine PTCA was 144 and 141 in cases and control group respectively where emergency PTCA was 25 and 28 in cases and control group respectively. The P value was 0.6 which was statistically non-significant. Number of patients with single, double and more than two cardiac co morbidities was 111, 50, 8 and 115, 57 and 7 respectively in cases and control group. Number of patients diagnosed with CSA, UA/NSTEMI and MI was 23, 68 and 78 in cases group and 14, 74 and 81 in control group. The mean SYNTAX Score of cases group was 22.8 +_0.6 with 1 SD whereas mean SYNTAX score was 22.7+_ 0.5 of control group with 1 SD. The P value was 0.09 which was statistically non-significant. Total number of patients with single stent, two stents and three or more stents deployed were 106, 43, 20 in cases group and 104, 51 and 14 in control group respectively. Overall operator experience was more than 2 years in both cases and control groups. Total Dose area product (dap) in cases was 148.7+_ 11.6 whereas total Dose area product (dap) in controls was 151.4 +_ 12.3 with 1 SD respectively. The P value was 0.03 which was statistically significant. Total number of cine runs in cases was 27 +_ 5 whereas total Number of cine runs in controls was 29 +_ 6 with 1 SD respectively. The P value was 0.001 which was statistically significant. Total Contrast volume (ml) in cases was 78 +_ 16 whereas total Contrast volume (ml) in controls was 82 +_ 17 with 1 SD respectively. The P value was 0.02 which was statistically significant. Total fluoroscopy time (min) in cases was 16.9 +_ 4.2 whereas total fluoroscopy time (min) in controls was 18.5 +_ 4.3 with 1 SD respectively. The P value was 0.0006 which was statistically significant. Total air kerma (mGy) in cases was 1117 +_ 126 whereas total air kerma (mGy) in controls was 1161 +_ 138 with 1 SD respectively. The P value was 0.0024 which was statistically significant.

Adverse events and procedural outcome

Procedural success was achieved if stent implantation with grade 3 TIMI flow could be documented. Additionally, MACE during hospital stay were assessed. Procedural success was 100 % in cases and controls. There were no Intra procedural adverse events in cases and control group.

RESULT

In the twenty-month period, 338 coronary angioplasty procedures of LMCA, LAD, RCA and LCX were performed. A total of 169 procedures were done with dynamic coronary roadmap and 169 procedures were performed without dynamic coronary roadmap. Out of the 338 procedures there were no significant differences in age, gender or weight between the group treated dynamic coronary roadmap and the group treated without dynamic coronary roadmap. Similarly, there were no significant differences in the target vessels treated, the number of primary or elective angioplasty cases, the timing of the cases, number of comorbidities, the level of operator experience, number of lesions treated and the number of stents deployed between the two imaging groups.

The 169 coronary angioplasty procedures performed with dynamic coronary roadmap resulted in a 2 % reduction in the average DAP compared with the 169 procedures performed without dynamic coronary roadmap. DCR vs without DCR (DCR: 148.7+_ 11.6 Gycm2 vs PCI without DCR: 151.4 +_ 12.3 Gycm2, p, 0.003).

In the subgroup who had primary angioplasty, patients without DCR had a 7 % increase in the mean contrast volume (DCR: 65.8 +-6.8 vs no DCR 70.5+-8.2, p, 0.01). There was a similar 6 % increase in contrast volume recorded in patients undergoing elective angioplasty (DCR: 80.8+-16 vs no DCR: 84.9+_16, P value: 0.03). There were statistically significant differences in the contrast volume between primary angioplasty with DCR (P Value: 0.017) and without DCR. Also, statistically significant difference was observed in the contrast volume between elective angioplasty with DCR (P value 0.03) and elective angioplasty without DCR. The significant difference was independent of vascular territory and operator experience.

In the subgroup who had primary angioplasty, patients without DCR had a 22 % increase in the mean fluoroscopy time (DCR 14.5+-4.1 vs no DCR 17.2+-3.8, p, 0.01). There was a similar 7 % increase in fluoroscopy time recorded in patients undergoing elective angioplasty (DCR: 17.6+-4.3 vs no DCR: 18.9+-4.6, P value: 0.01). The significant difference was independent of vascular territory and operator experience. There were statistically significant differences in the fluoroscopy time between primary angioplasty with DCR (P Value: 0.01) and without DCR. Also, statistically significant difference was observed in the fluoroscopy time between elective angioplasty with DCR (P value 0.01) and elective angioplasty without DCR.

In the subgroup who had primary angioplasty, patients without DCR had a 6 % increase in the mean total air kerma (DCR 1053+-114 vs no DCR 1121+-121, p,0.04). There was a similar 5 % increase in total air kerma recorded in patients undergoing elective angioplasty (DCR: 1167+-131 vs NO DCR: 1116+-138, P value: 0.002). The significant difference was independent of vascular territory and operator experience. There were statistically significant differences in the total air kerma between primary angioplasty with DCR (P Value: 0.04) and without DCR. Also, statistically significant difference was observed in the total air kerma between elective angioplasty with DCR (P value 0.002) and elective angioplasty without DCR.

Table 2 procedural data of patients undergoing PCI with the use of dynamic coronary road mapping.

PROCEDURAL DATA	DCR GROUP	NON DCR GROUP	P VALUE
Time of procedure			
Routine PTCA	144	141	0.6
Emergency PTCA	25	28	
Number of cardiac comorbidities			
1	111	115	
2	50	57	
>2	8	7	
Diagnosis			
CSA	23	14	
UA/NSTEMI	68	74	
MI	78	81	
SYNTAX score	22.8 +_ 0.6 [a]	22.7+_ 0.5[a]	0.09
Number of lesion treated			
Number of stent deployed			
1	106	104	
2	43	51	
>=3	20	14	
Operator experience	> 2 YEARS	> 2 YEARS	

[a] Mean +- 1 standard deviation (SD).

DISCUSSION

The use of DCR resulted in 2 % reduction in the average DAP as compared with procedures performed without DCR. Also, in the sub group analysis it was found that primary angioplasty cases without DCR had 5% increase in DAP as compared with primary angioplasty cases with DCR. Also, in the sub group analysis it was found that elective angioplasty cases without DCR had 2% increase in DAP as compared with elective angioplasty cases with DCR. There was a statistical significance in p valve in primary angioplasty cases with DCR and cases without DCR. Similar observation was made in elective angioplasty cases with DCR versus elective angioplasty cases without DCR. The use of DCR resulted in 12 % reduction in the average fluoroscopy time as compared with procedures performed without DCR. Also, in the sub group analysis it was found that primary angioplasty cases without DCR had 22 % increase in DAP as compared with primary angioplasty cases with DCR. Also, in the sub group analysis it was found that elective angioplasty cases without DCR had 7 % increase in fluoroscopy time as compared with elective angioplasty cases with DCR. There was a statistical significance in p valve of primary angioplasty cases and elective angioplasty cases with DCR and cases without DCR in the total fluoroscopy time required for the procedure. The technology of DCR uses precise overlay of the coronary vascular tree on top of the live fluoroscopy, moving exactly with the cardiac and breathing motion. This has resulted in lesser use of cine runs, fluoroscopy time and cine visualisation. Incidentally it also brings down the need for repeated confirmation cine angiograms during guide wire, balloon or stent positioning during angioplasty. Automatic and autonomous production and storage of roadmaps makes the application intuitive and simple. Whether such practice will help in reducing the incidence of hazard of radiation likewise skin malignancy, skin burns, cataract, neurological tumours was not studied in this study due to limited patient size and long term follow needed to study the abovementioned parameters.

The use of DCR resulted in 6 % reduction in the average contrast volume as compared with procedures performed without DCR. Also, in the sub group analysis it was found that primary angioplasty cases without DCR had 7% increase in DAP as compared with primary angioplasty cases with DCR. Also, in the sub group analysis it was found that elective angioplasty cases without DCR had 5 % increase in contrast volume as compared with elective angioplasty cases with DCR. There was a statistical significance in p valve of primary angioplasty as well as elective angioplasty cases with DCR and cases without DCR in the amount of contrast used for procedure. Repeated contrast injection for confirmation of position of guide wire, balloon and stent placement is avoided due to DCR. It helps to avoid excess contrast injection thereby also preventing contrast volume overload during procedure. It allows to do procedure at minimum amount of dye volume. It still needs to be studied whether such practice will also help to avoid contrast nephropathy in such patients. Although it was not studied but still the incidence of heart failure secondary to dye volume overload appears to be reduced in patients with DCR indirectly due to reduction in volume overload.

Table 3 procedural data of patients undergoing PCI with the use of dynamic coronary road mapping

PROCEDURAL DATA	DCR GROUP	NON DCR GROUP	P VALUE
Dose area product (dap)	148.7+_ 11.6 [a]	151.4 +_ 12.3 [a]	0.03
Number of cine runs	27 +_ 5 [a]	29 +_ 6 [a]	0.001
Contrast volume (ml)	78 +_ 16 [a]	82 +_ 17 [a]	0.02
fluoroscopy time (min)	16.9 +_ 4.2 [a]	18.5 +_ 4.3 [a]	0.0006
total air kerma (mGy)	1117 +_ 126 [a]	1161 +_ 138 [a]	0.0024
Procedural success	100%	100%	
Intra procedural adverse events	0	0	
contrast volume in primary angioplasty	65.8+-6.8 [a]	70.5+-8.2 [a]	0.017
contrast volume in elective angioplasty	80.8+-16 [a]	84.9+_16 [a]	0.03
dap in primary angioplasty	146.7+-12.2 [a]	153.7+-13.4 [a]	0.04
dap in elective angioplasty	149.3+_11.6 [a]	152.3+-12.6 [a]	0.03
fluoroscopy time in primary angioplasty	14.5+-4.1 [a]	17.2+-3.8 [a]	0.01
fluoroscopy time in elective angioplasty	17.6+-4.3 [a]	18.9+-4.6 [a]	0.01
total air kerma in primary angioplasty	1053+-114 [a]	1121+-121 [a]	0.04
total air kerma in elective angioplasty	1167+-131 [a]	1116+-138 [a]	0.002

a Mean +- 1 standard deviation (SD).

Limitations

The actual recording of the data was not monitored at all times by the researchers. Therefore, the results are based on the assumption that information was accurately recorded in DRIEFCASE software. All procedures were performed by senior cardiologist. Moreover, operators were not randomised in the use of DCR or no DCR group, and this could also have biased the results. Finally, this study investigated coronary angioplasty procedures undertaken at a single large tertiary hospital, and the findings cannot be generalised across all interventional cardiac procedures and other cardiac catheter laboratories. The radiation measurements presented on the examination protocols (dose rate, skin dose and DAP) were not corrected for table-top attenuation. Consequently, the correct DAP and skin dose to the patient may be lower than the values reported in this study.

CONCLUSION

This study found the use of DCR imaging to impart a significantly lower radiation exposure to the patient and to require a shorter procedural time. The contrast load between

DCR and no DCR angioplasty procedures was found to be statistically significantly different. These results were independent of whether the procedure was a primary or elective case, whether the angioplasty was performed in the RCA, LAD or LCX territory. The findings of this study illustrate that DCR may be as effective as previously assumed in reducing radiation dose, contrast load and fluoroscopy time in coronary angioplasty procedures.

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