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Comparison of Radiation Exposure in Patients Undergoing Single Vessel PCI (Requiring Single Stent) with and without Clear Stent and Clear Stent Live Technology.

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ABSTRACT

Background: Invasive cardiology procedures provide great diagnostic and therapeutic benefit to patients but also subject them to considerable radiation exposure. CLEAR stent Live is the unique real time stent enhancement and gives a clear display of the undeployed stent. **Aims & Objectives:** To compare the radiation exposure in patients requiring single stent having single vessel coronary artery disease With & Without CLEAR stent and CLEAR stent Live Technology. **Methods:** It was a non-randomized study and included 246 patients. Group A included 123 patients who underwent Single vessel stenting using Clear stent technology as compared to group B who underwent stenting with conventional flouroscopic imaging. Radiation exposure between the two groups was compared. **Results:** The mean age of patients in Group A was 57.3±11.87 years while as in Group B it was 58.6±10.72 years (p=0.368). Majority of patients were males [(89(72.4%) vs 94(76.4%) (p=0.46) Group A vs B respectively] in both groups. The fluoro time in Group A was 10.6 minutes vs Group B = 11.2 minutes(p=0.15) The difference in procedure time between two groups(37.8 vs 35.9 min ,Group A vs Group B p=0.2) was statistically insignificant.The number of cine shots was significantly less in Group A as compared with Group B(26.9 vs 30.1(Group A vs Group B) (p<0.002). The mean radiation exposure (mGy) in GroupA was significantly less as compared to Group B(581.7 ±293.6 vs 658.4 ±287.1 p= 0.039). The benefit of less radiation of Clear Stent technology was consistent across all vessels. **Conclusion:** The present study suggests that in selected patients, compared with conventional X-ray fluoroscopy imaging, the use of live clear stent technology can be performed with less radiation dose to patient.

Keywords: Radiation, Clear Stent, Flouro.

INTRODUCTION

Invasive cardiology procedures provide great diagnostic and therapeutic benefit to patients but also subject them to considerable radiation exposure. On average, a coronary angiography corresponds to a radiation exposure to the patient of about 300 chest x-rays, while coronary stent implantation corresponds to 1000 chest x-rays and a radiofrequency ablation procedure up to 1500 chest x-rays.[1,2] It is estimated that radiation induced cases of cancer per year in the UK is 280 cases per million of coronary angiographies whereas for CT scans, screening mammography and chest X-rays the cases of radiation induced cancer is 60, 8 and 1 cases per million examinations respectively.[3] Exposure to ionizing radiation during endovascular procedures depends on numerous factors such as BMI, field of view, fluoroscopy pulse rate, acquisition frame rate, variable beam filtration, total fluoroscopy time, and total acquisition time. The radiation dose is also dependent of the equipment-related factors such as beam collimation, servicing, filter usage, field of view size, movement capabilities of the X-ray source, fluoroscopic, software image filtering, and X-ray photon energy spectra.[1-5]

The most evident approach to reduce radiation dose is by minimizing the beam-on time both for

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fluoroscopy and acquisition6. Other methods to reduce radiation include by focussing on only the anatomic region of interest, image intensifier to be positioned as close to the patient's body as possible while the height of the table to be adjusted to keep the body of the patient as further away from the x-ray tube as possible,[7] using pulsed-fluoroscopy mode as compared to a non-pulsed system, using last image hold feature .CLEARstent is the software for stent enhancement after stent is deployed.This software also provides us facility for fade in/fade out if contrast is given.This is the software of Siemens.(Made in Germany). CLEARstent Live is the unique real time stent enhancement and gives a clear display of the undeployedstent [Figure 1]. It zooms the image during imaging. We hypothesized that CLEAR Live stent Technology by improving image qualities would decrease the need for repeated cines and hence decrease radiation exposure

Aims & Objectives:

To compare the radiation exposure in patients requiring single stent having single vessel coronary artery disease With & Without CLEAR stent and CLEAR stent Live Technology

MATERIALS AND METHODS

The present comparative, non-randomized study was conducted in the Department of Cardiology, Sher-i-Kashmir Institute of Medical Sciences, Srinagar from 2017-2019. A total of 1300 patients who underwent coronary angiography and 246 patients who qualified the inclusion criteria were included in the study group. 123 patients admitted with stable, unstable angina, NSTEMI, STEMI, and requiring single vessel percutaneous coronary intervention with single stent (using CLEARstent and CLEARstent Live Technology)- comprised Group A. In 123 patients admitted with similar profile (stable, unstable angina, NSTEMI, STEMI) underwent coronary intervention with one stent for single vessel coronary artery disease with conventional angiography technique, comprised Group B. Radiation exposure was compared in two groups.

Inclusion criteria:

Patients having:

- Stable Coronary Artery Disease.
- Acute Coronary Syndromes (UNSTABLE ANGINA, NSTEMI, STEMI).
- Primary PCI requiring one stent only.

Exclusion criteria:

- Left Main Stenting.
- Multivessel PCI.
- Single vessel disease requiring more than one stent.
- Patients requiring the use of an intravascular ultrasound and/or pressure wire during the procedure.
- Past history of coronary artery bypass graft and/or PCI.
- Any complications during PCI (e.g., no-reflow, slow flow or dissection).
- PCI with hemodynamic instability requiring implantation of temporary pacemaker and/or intra-aortic balloon pump treatment.
- Concomitant diseases such as malignancy, CKD.

RESULTS

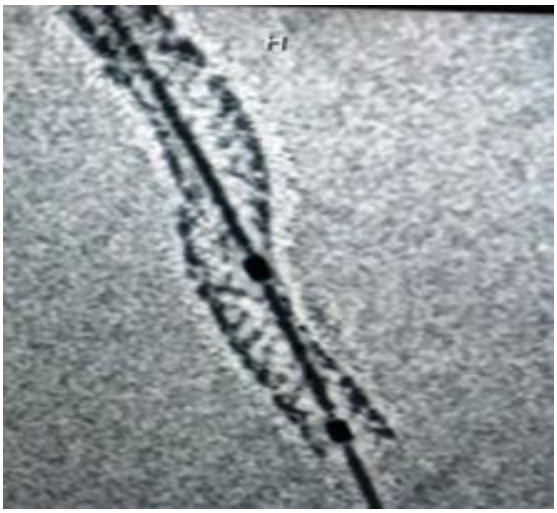

Figure 1: Showing enhanced visualization of single vessel stent with Live Clear Stent

Table 1: Baseline Characteristics

Baseline characterisics	Group A N(%)	GroupB N(%)	P value
Age (Years)	57.3±11.87	58.6±10.72	0.36
Male	89(72.4)	94(76.4)	0.46
DM	87(70.7)	79(64.2)	0.27
HTN	75(61)	81(65.9)	0.42
DLP	46(37.4)	51(41.5)	0.51
Smoking	71(57.7)	68(55.3)	0.69
LAD	47(38.2)	53 (43)	0.52
RCA	34(27.6)	31 (25)	0.69
LCX	42(34.1)	39 (31.2)	0.68

DM: Diabetes mellitus, HTN : Hypertension, DLP : Dyslipidemia, LAD : Left Anterior Descending, RCA : Right Coronary Artery , LCX: Left Circumflex Artery

Table 2: Comparison based on radiation exposure (mGy) in two groups as per vessel involved

Radiation exposure (mGy)	Group A		Group B		P-value
	Mean	SD	Mean	SD	
LAD	613.5	218.6	708.4	237.3	0.021*
LCX	537.9	236.6	619.7	210.6	0.037*
RCA	587.6	312.6	661.3	299.6	0.045*

The mean age of patients in Group A was 57.3±11.87 years while as in Group B it was 58.6±10.72 years (p=0.368). Majority of patients were males [(89(72.4%) vs 94(76.4%) (p=0.46) Group A vs B respectively] in both groups. The base line characteristics of two groups are shown in [Table 1]. The fluoro time in Group A was 10.6 minutes vs Group B = 11.2 minutes (p=0.15) The

difference in procedure time between two groups (37.8 vs 35.9 min ,Group A vs Group B p=0.2) was statistically insignificant. The number of cine shots was significantly less in Group A as compared with Group B (26.9 vs 30.1 (Group A vs Group B) (p<0.002). The mean radiation exposure (mGy) in GroupA was significantly less as compared to Group B(581.7 ±293.6 vs 658.4 ±287.1 p= 0.039). The benefit of less radiation of Clear Stent technology was consistent across all vessels as shown in [Table 2].

DISCUSSION

The present study was conducted in 246 patients to compare the radiation exposure in patients of single vessel coronary artery disease requiring single stent with and without use of CLEARstent/ CLEARstent Live during these procedures. In both groups the most common age group was 60 to 69 years (group A 42.3% and group B 39.8%). The most common risk factor in group A was diabetes(70.7%) followed by hypertension(61%) and smoking(55.3%) whereas hypertension (65.9%) was most common risk factor followed by diabetes(64.2%) and smoking(55.3%) in group B. Dyslipidemia was found in both the groups(37.4% and 41.5%) respectively. The difference was statistically insignificant with each variable. LAD was most common artery stented (38.2 Vs43.1%) followed by RCA (34.1 & 31.7%) and LCX (27.6 & 25.2%) in both groups respectively with no statistical significance. Number of cine shots in group A were significantly less (26.9± 7.67) as compared to Group B (30.1± 8.39(p-value<0.05). This difference was statistically significant. Since the CLEAR Live technology enhances the visualization of the stent, more cine shots were required in group B to identify the adequate stent deployment using conventional fluoroscopic imaging. Number of cine shots required to place stent in LAD were (32+/-5) Vs. (35+/-4) followed by LCX(27+/-4) Vs. (30+/-3) and RCA(23+/-5) Vs.(26+/-4) in group A and group B respectively. This difference was statistically significant. Radiation exposure in group B(658.4± 287.1 mGy) was more than group A (581.7±293.7 mGy) and this difference was statistically significant(p value< 0.05) . Tsigkas et al.[8] have reported a 5-fold average increase in effective dose to patient with Stent Boost application than that with plain fluoroscopic imaging application in a similar duration of cine time. However, our study has shown that using Clear Stent technology is associated with decreased radiation dose to patient while maintaining high quality visvualization and optimization of stent. Compared to Stent Boost and Live Clear Stent Technology. Since the Live Clear enhances the visualization of the stent, more cine shots were required in group B to identify the adequate stent deployment using conventional fluoroscopic imaging. Kuon et al.[9] demonstrated that using radiation-reduction techniques has resulted in a very low level of DAP for PCI.

Even though radiation exposure is less in patients undergoing stent deployment with the use of live clear stent technology, Interventional cardiologists should have sufficient knowledge or experience of safe operating practices in radiation protection. In the study of Tsapaki et al,[10,11] they pointed out that increasing number of stents, bifurcation stenting, as well as the complexity of coronary operator, it suggests that the operator's experience to perform PCI have an important impact on patient radiation dose, which has also been proved by the Zhigeng Jin et al (2013).[12,13] We should pay attention to using live clear stent technique to get an overall reduction in radiation dose during the procedures.

Limitations:

We should be aware of certain limitations of the present study. First, the main limitation is that this is a non-randomized, observational, single-center study, and comparisons between two groups do not allow conclusions of causality. Hence a large, multicenter, prospective studies will be needed. Second, a expert and qualified medical radiation technologist was routinely in our catheterization laboratory to assist the operator optimizing radiation protection. The results cannot be applied to other centers where no radiation technologists are routinely available. However, we should understand the importance of radiation protection. There is a need to further improve the radiologic work environment of interventional cardiologists. Third, selection bias and potential confounding of factors related to radiation dose are always possible

CONCLUSION

The present study suggests that in selected patients, compared with conventional X-ray fluoroscopy imaging, the use of Live clear stent technology can be performed with less radiation dose to patient. To the best of our knowledge, this is the first study assessing the impact of live clear versus conventional cine imaging on patient radiation dose during PCI with single stent in India.

REFERENCES

1. Baker S .Sones FM Jr . . Brancato R. Radiation exposure to the operator performing cardiac angiography with U-arm systems . Circulation 1978: 58:925-32,
2. GustafssonM .Lunderquist A. Personnel exposure to radiation at some angiographic procedures. Radiology 1981 ;140:807-11 .
3. Gertz EW, Wisneski'A . Gould RG, Akin JR. Improved radiation protection for physicians performing cardiac catheterization . Am J Cardiet 1982 50:l283-6.
4. Dash H, Leaman DM. Operator radiation exposure during percutaneous transluminal coronary angioplasty. J Am CollCardiol 1984;4:725-8 .

5. Jeans SP, Faulkner K, Love HG, BardsleyRP . An investigation of the radiation dose to staff during cardiac radiological studies . Br J Radial 1985 :58:419-28.
6. Gorson RD, Lassen M, Rosenstein M. Patient dosimetry in diagnostic radiology .In : Waggener RG, Kereiakes JG, Shalek RJ . eds. CRC Handbook of Medical Physics, Vol. 2. fioa Raton, FL : CRC Press, 1984-467-526.
7. ICRP Publication 60 . 1990 Recommendations of the International Commission on Radiological Protection. Oxford: Pergamon Press, 1991 :21, Table 4 . JACC Vol. 22, No . 4 October 1993 :1044-51 21 . 1:CRP Publication
8. Tsigkas G, Moulias A, Alexopoulos D (2011) The StentBoostimaging enhancement technique as guidance for optimaldeployment of adjacent-sequential stents. J Invasive Cardiol23(10):427–429.
9. Kuon E, Dahm JB, Schmitt M, et al. Short communication: time of day influences patient radiation exposure from percutaneous cardiac interventions. Br J Radiol. 2003; 76: 189–91.
10. Tsapaki V, Maniatis PN, Magginas A, Voudris V, PatsilinakosS,Vranzta T, Vano E, Cokkinos DS (2008) What are the clinicaland technical factors that influence the kerma-area product inpercutaneous coronary intervention? Br J Radiol 81(972):940–945. doi:10.1259/bjr/30604628
11. Tsapaki V, Magginas A, Vano E, Kottou S, Papadakis E, DafnomiliP, Kyrozi E, Kollaros N, Neofotistou V, Cokkinos D(2006) Factors that influence radiation dose in percutaneouscoronary intervention. J IntervCardiol 19(3):237–244. doi:10.1111/j.1540-8183.2006.00137.x
12. Agostoni P, Verheye S (2007) Bifurcation stenting with a dedicatedbiolimus-eluting stent: X-ray visual enhancement of thefinal angiographic result with ‘‘StentBoost Subtract’’. CatheterCardiovascInterv 70(2):233–236. doi:10.1002/ccd.21096.
13. Agostoni P, Verheye S (2009) Novel self-expanding stent systemfor enhanced provisional bifurcation stenting: examination byStentBoost and intravascular ultrasound. Catheter CardiovascInterv 73(4):481–487. doi:10.1002/ccd.21878.

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