Ir Med J; March 2022; Vol 115; No. 3; P558

March 16th, 2022

Assessment of Newer Radiation Dose Reduction Techniques During Coronary Angiography

L. Maher[1], V. Collins [2], J. McCullagh[3], A. McGarrigle[4], C. Vaughan[1, 5]

1. Department of Cardiology, Cork University Hospital, Ireland.
2. Department of Radiology, Bon Secours Hospital, Cork, Ireland.
3. Department of Medical Physics, Cork University Hospital, Ireland.
4. Cork Radiation Protection Services, Cork, Ireland.
5. Department of Cardiology, Bon Secours Hospital, Cork, Ireland.

Abstract

Aims

To evaluate the impact of Allura Clarity technology on radiation exposure in patients undergoing diagnostic coronary angiography.

Methods

A retrospective analysis was undertaken of invasive coronary angiograms performed by a single experienced operator in Cork University Hospital (CUH) (Allura Xper FD10 angiography system). In order to reduce operator variability, we also analysed cases performed by the same operator in the Bon Secours Hospital Cork (BSHC) (Allura Clarity FD10 angiography system). Cases were selected consecutively, having excluded those involving percutaneous coronary intervention, graft studies, aortography, ventriculography, right heart studies or fractional flow reserve studies.

Results

A total of 178 patients were included, equally distributed between the CUH arm (n=89) and the BSHC arm (n=89). Cohorts were very well matched in terms of age, gender, Body Mass Index, and procedural approach. The median radiation dose in CUH was a Dose Area Product (DAP) of 10,460 mGy.cm^2 vs. median DAP of 12,795 mGy.cm^2 in BSHC (p=0.148). The median fluoroscopy time in CUH was 2.25mins vs. median fluoroscopy time of 2.17mins in BSHC (p=0.675).

Conclusion

The use of the Allura Clarity system for diagnostic coronary angiography did not result in a significant difference in radiation dose or fluoroscopy time when compared to the reference Allura Xper system. Further research is needed to investigate the benefit of this new image noise reduction technology in diagnostic coronary angiography.

Introduction

Diagnostic cardiac catheterisation was first introduced by Cournand and Richards in the early 1940s[1]. This field has seen an extraordinary amount of progress since then with the development of coronary angiography, huge improvements in image quality, the advent of percutaneous coronary intervention, and reduction of patient radiation dose for such procedures. Given that ischaemic heart disease remains the single largest cause of death in countries of all income groups[2] and an ever-ageing population, it is no wonder that the rates of cardiac catheterisation per capita are increasing[3]. Current European Society of Cardiology guidelines recommend either non-invasive functional testing or Coronary CT Angiography as the first line test in evaluation of low-risk patients with stable coronary artery disease. However, invasive coronary angiography is still indicated in cases of inconclusive non-invasive testing, in patients with typical angina at low exercise levels, in patients with typical angina unresponsive to medical therapy, and of course in acute coronary syndromes[4]. Invasive coronary angiography does involve significant exposure to ionising radiation[5]. A great amount of time and money has been invested in research focusing on radiation dose reduction by means of inclusion of dose reduction features on imaging equipment, optimisation of exposure parameters and operator technique, and the use of personal protective equipment. This objective has heralded the development of more advanced interventional fluoroscopy image acquisition and processing systems. Philips Healthcare (Best, the Netherlands) have designed the Allura Clarity x-ray system with ClarityIQ technology, a system purported to significantly reduce patient exposure and improve image quality for both fluoroscopy and cine modes of operation. This is supposedly achieved through spatial and temporal image noise reduction algorithms, real-time compensation of movement artefacts, edge enhancement, contrast enhancement, background contrast reduction and brightness control[6]. Significant radiation dose reduction with use of the Allura Clarity system compared to other interventional fluoroscopy systems has been demonstrated in studies using anthropomorphic phantoms[7,8], during electrophysiological ablative and device insertion procedures[6,9-11], during percutaneous coronary interventions[12], during paediatric coronary angiography[13], and during diagnostic +/- interventional coronary angiography studies involving multiple different operators[14-17]. In order to standardise any possible variability in operator technique or procedural complexity, we took the unique approach in this study of focusing on a single experienced operator working out of two centres that use two different x-ray systems and concentrating on diagnostic coronary angiograms only. Thus, the objectives of this study were as follows; the primary endpoint was to examine the effect of the Allura Clarity technology on patient radiation exposure, using the measurable dose index of Dose Area Product (DAP). A secondary endpoint was to investigate the effect of the Allura Clarity technology on fluoroscopy time.

Methods

This study protocol was approved by and performed within the standards laid down by the Clinical Research Ethics Committee of Cork Teaching Hospitals and the Clinical Ethics Committee of the Bon Secours Health System.

This was a retrospective cohort study involving the comparison of coronary angiograms performed by a single experienced operator in Cork University Hospital (CUH) and the Bon Secours Hospital Cork (BSHC). CUH uses the Allura Xper FD10 system (Philips Healthcare). BSHC uses the Allura Clarity FD10 system. CUH uses 'Fluroflavor 1' as their standard of care fluoroscopy setting, with the pulse rate set at 7.5pps, with a corresponding dose rate of 4.068mGy/min for a 25cm field of view. BSHC also uses 'Fluroflavor 1' as their standard of care fluoroscopy setting, but with the pulse rate set at 15pps and corresponding dose rate of 4.91mGy/min for a 25cm field of view. Both centres use 'Coronary medium 15 frames per second' as their standard protocol setting for cine runs. Data was available for cases performed in CUH from July 2019 to December 2019, and for cases performed in the BSHC from September 2018 to August 2019. Data was collected from a combination of radiographer's records and official angiogram reports. Cases were included if they satisfied all the following criteria: coronary angiogram performed by operator 1, diagnostic coronary angiograms only, and procedural DAP and fluoroscopy time data all available. Cases were excluded if they involved any of the following: percutaneous coronary intervention, graft studies, fractional flow reserve studies (FFR), aortography, ventriculography and/or right heart studies. After applying the inclusion and exclusion criteria, cases were selected consecutively. For each case, the following information was gathered: age, gender, Body Mass Index (BMI), Dose Area Product (DAP), Fluoroscopy Time (FT), and procedural approach. Anonymised data was stored on a password-protected computer. All data analyses were performed with IBM SPSS Statistics, version 24 (SPSS, Inc., Chicago, Illinois, USA). A P-value of <0.05 was considered to be statistically significant. Patient demographics were compared between study groups using the t-test of means for normally distributed data. A Chi-square test with resultant Fisher's exact test was performed to test for significance of difference in procedural approach. A Shapiro-Wilk's test demonstrated a skewed data distribution with large variability of DAP values across both CUH and BSHC ($p< .000$) and thus we employed the Independent-samples Mann-Whitney U test to determine the level of significance. Fluoroscopy time values were also abnormally distributed and so the Independent-Samples Mann-Whitney U test was also applied to test for significance in this regard.

Results

General findings

A total of 178 patients were included in this study, equally distributed between the CUH arm (n=89) and the BSHC arm (n=89). The mean age was 65.1 +/- 9.9 years in CUH vs 65.8 +/- 9.6 years in BSHC. The mean BMI was 28.8 +/- 5.3 kg/m^2 in CUH vs 29.4 +/- 5.2 kg/m^2 in BSHC. Of note, Chi-squared testing failed to demonstrate a significant association between BMI and DAP ($p= 0.218$). 77.5% of patients were male in both centres (where gender data was available). These findings are summarised in Table 1.

Characteristic	CUH Patients (Allura Xper FD10) (N=89)	BSHC Patients (Allura Clarity FD10) (N=89)	P-value
Age (years):			
35-45	5 (5.6%)	4 (4.5%)	
46-55	9 (10.1%)	8 (9.0%)	
56-65	25 (28.1%)	32 (36.0%)	
66-75	35 (39.3%)	32 (36.0%)	
76-85	11 (12.4%)	13 (14.6%)	
No data available	4 (4.5%)	0	
Mean (+/- SD)	65.1 +/-9.9	65.8 +/- 9.6	0.873
Body Mass Index (kg/m^2):			
<18.5	1 (1.1%)	0	
18.5-24.9	13 (14.6%)	11 (12.4%)	
25-29.9	32 (36.0%)	36 (40.4%)	
30-34.9	12 (13.5%)	27 (30.3%)	
35-39.9	9 (10.1%)	8 (9.0%)	
>40	2 (2.2%)	3 (3.4%)	
No data available	20 (22.5%)	4 (4.5%)	
Mean (+/- SD)	28.8 +/-5.3	29.4 +/-5.2	0.473
Gender:			
Male	66 (74.2%)	69 (77.5%)	
Female	19 (21.3%)	20 (22.5%)	
No data available	4 (4.5%)	0	0.985

Table 1: *Patient demographics.*

With regard to procedural approach, 84.7% of cases involved the right radial approach in CUH vs 93% in BSHC. Chi-square testing failed to demonstrate statistical significance of this difference (p=0.094).

Dose Area Product

The radiation dose in CUH was represented by the median DAP of 10,460 $mGy.cm^2$ (I.Q. range 6775-17,770 $mGy.cm^2$) (mean 19,591 $mGy.cm^2$). The difference in averages may be explained by a small number of extreme outliers in this cohort. The equivalent median DAP in BSHC was 12,795 $mGy.cm^2$ (I.Q. range 8886-19,503 $mGy.cm^2$) (mean 15,246 $mGy.cm^2$). This difference in DAP between different angiography systems failed to achieve statistical significance (p=0.148). These results are displayed graphically in Figure 1.

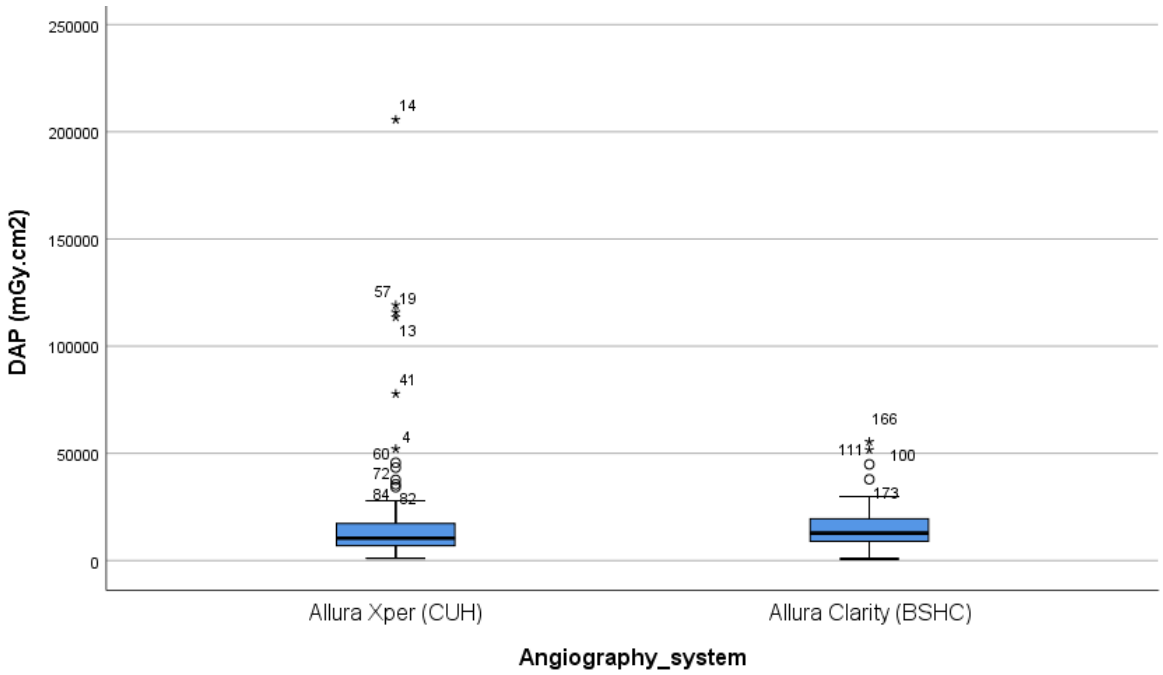

Figure 1: *Box and Whisker plot of Dose Area Product (DAP) (mGy.cm^2) across CUH (Allura Xper FD10 system) and BSHC (Allura Clarity FD10 system).*

Fluoroscopy time

The median fluoroscopy time in CUH was 2.25mins (I.Q. range 1.15 – 3.35mins) (mean 2.88mins). The median fluoroscopy time in BSHC was 2.17mins (I.Q. range 1.35 - 4.04mins) (mean 3.22mins). This difference in fluoroscopy time between the different angiography systems did not achieve statistical significance (p=0.675). These results are displayed graphically in Figure 2.

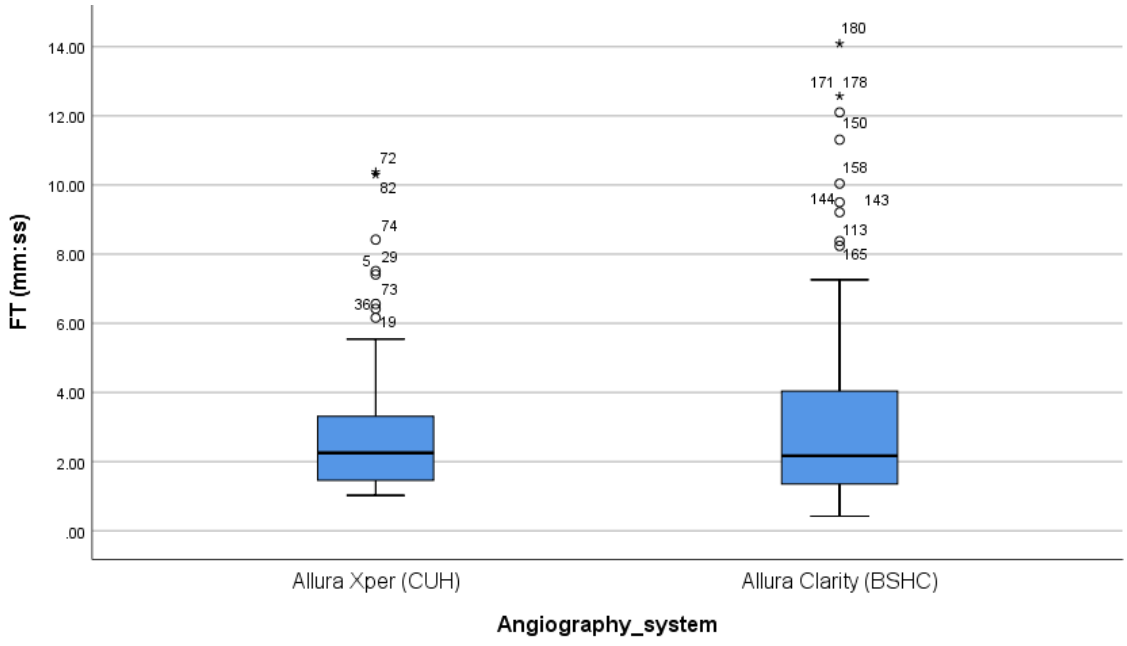

Figure 2: *Box and Whisker plot of Fluoroscopy Time (FT) (mm:ss) across CUH (Allura Xper FD10 system) and BSHC (Allura Clarity FD10 system).*

Discussion

The main finding of this study was the absence of significant difference in DAP or fluoroscopy time with use of the Allura Clarity system, when compared to the older generation Allura Xper system for diagnostic coronary angiography. Given the existing literature pertaining to radiation dose reduction with use of the Allura Clarity technology, the findings of this study were somewhat unexpected. While the Allura Clarity software has been shown to have a significant benefit in an electrophysiological setting and in patients undergoing percutaneous coronary intervention to chronic thrombotic occlusions, its benefit in purely diagnostic coronary angiograms remains less certain.

The three principles of radiation protection are justification of exposure, optimisation of exposure to ensure all radiation doses are kept 'As Low As Reasonably Achievable' (ALARA), and dose limitation for staff and members of the public[18]. In the case of patients, dose limits do not apply but Diagnostic Reference Levels (DRLs) are established and are used as part of the optimisation process in medical exposures. Patients are at risk of deterministic side-effects including radiation-induced skin injuries[19], particularly where procedures involve long screening times and the use of steep-angled c-arm configurations for complex cases. Additionally, occupational exposure arising from scattered radiation from the patient increases the risk of cataracts, may impair fertility, and increases the lifetime risk of cancer in interventional cardiologists[20]. Cancers of the head and neck are of particular concern, with one paper finding an 85% preponderance of brain tumours to be left sided among interventionalists[21]. The ceaseless effort to reduce radiation exposure of both operator and patient to ALARA while maintaining image quality, is multifaceted[22]. Lead-based personal protective equipment has evolved to include aprons, gloves, thyroid shields, head shields, shin covers, disposable sterile radiation shields and glasses. Operators are encouraged to reduce the fluoroscopy frame rate, reduce acquisition time by means of using last image hold/store, keep hands out of the primary beam, keep the detector as close as possible to the patient, optimise patient and x-ray equipment positioning, and to avoid steeply angulated projections to reduce their own personal exposure. And hospitals have invested millions in advanced hardware and software systems such as the Allura Clarity system.

The Health Information and Quality Authority of Ireland have produced national DRL's which are benchmark radiation dose levels set to aid optimisation of various diagnostic and interventional medical procedures. The national DRL for angiography of the coronary arteries, is taken at a Kerma-Area Product of 55,000 mGy.cm^2 [23]. This is considerably higher than our operator's median patient radiation dose in both centres. BSHC have set their local facility DRL for coronary angiography at 19,000 mGy.cm^2, while CUH have set their local facility DRL for coronary angiography at 19,500 mGy.cm^2. Our operator's lower doses may be explained by our decision to exclude longer, more complex diagnostic procedures such as fractional flow reserve studies, graft studies, etc.

We must acknowledge that the Allura Clarity system was compared to only one reference angiography x-ray system. Extending this study to include other interventional x-ray systems may be worthwhile in future. Some other studies divided the population up into BMI bands which may have yielded some interesting findings. However, it should be noted that there was no statistically significant association between BMI and DAP. Image quality was not recorded for each procedure.

However, this study involved the same operator, and they did not retrospectively report noticing any significant difference in image quality between the two systems. Unfortunately, given the retrospective nature of this study, direct operator radiation exposure data was unavailable. However, DAP is the accepted standard dose metric for expressing patient radiation exposure, and operator dose is loosely proportional to DAP. Other data that may have proved interesting but was not available retrospectively includes the number of runs, total DAP distribution between fluoroscopy and cine modes, volume of contrast used, and patient comorbidities.

It must be remembered that the Allura Xper system had pulse rate set at 7.5pps for Fluroflavor 1, compared to 15pps for same fluoroscopy setting on Allura Clarity system, with a resultant lower dose rate with former. This difference could potentially have attenuated the advertised radiation dose reduction benefit of the Allura Clarity technology. Lowering the pulse rate on the Allura Clarity system in BSHC and re-analysis may allow better comparison of the two systems and optimisation of the Allura Clarity system. This information has proven very useful to staff at BSHC and will serve as the basis for a protocol review across all procedures to investigate potential areas for further optimisation. The net result should benefit both patients and staff working in the Catheterisation Laboratory.

This is the first study, to our knowledge, to focus specifically on radiation dose reduction using Allura Clarity technology in diagnostic-only coronary angiograms. We believe this is also the first single-operator two-centre trial of its kind. It appears that longer procedures such as electrophysiology procedures, percutaneous coronary interventions and longer diagnostic angiograms involving FFR, graft studies, etc. clearly benefit from radiation dose reduction with the Allura Clarity technology. This retrospective cohort study did not demonstrate a significant difference in patient radiation exposure or fluoroscopy time with use of the Allura Clarity FD10 system for diagnostic coronary angiography, when compared to the reference Allura Xper FD10 system. Further research is needed to investigate the benefit of this new image noise reduction technology in diagnostic coronary angiography.

Declaration of Conflicts of Interest:
The corresponding authors have no conflicts of interest to declare.

Corresponding author:
Professor Carl Vaughan
Department of Cardiology,
Cork University Hospital &
Bon Secours Hospital,
Cork, Ireland.
E-Mail: carlvaughan1111@gmail.com

References:

1. Bourassa MG. The History of cardiac catheterisation. *Can J Cardiol*. 2005 Oct; 21(12):1011-1014
2. Nowbar A, Gitto M, Howard J, Francis D, Al-Lamee R. Mortality from ischaemic heart disease: Analysis of data from the World Health Organisation and Coronary Artery Disease risk factors from NCD risk factor collaboration. *Circ Cardiovasc Qual Outcomes*. 2019 Jun; 12(6): e005375.
3. Jennings S, Bennett K, Shelley E, Kearney P, Daly K, Fennell W. Trends in percutaneous coronary intervention and angiography in Ireland, 2004–2011: Implications for Ireland and Europe. *Int J Cardiol Heart Vessel*. 2014 Aug; 4:35-39.
4. Knuuti J, Wijns W, Saraste A, Capodanno D, Barbato E, Brentano C, *et al*. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. *Eur Heart J*. 2020; 41: 407-477.
5. Task Force Members, Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C, *et al*. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. 2013; 34(38): 2949–3003.
6. Dekker L, Van der Voort P, Simmers T, Verbeek X, Bullens R, Van't Veer M, et al. New image processing and noise reduction technology allows reduction of radiation exposure in complex electrophysiologic interventions while maintaining image quality: A randomised clinical trial. *Heart Rhythm*. 2013 Nov; 10(11): 1678-1682.
7. Studzińska E, Staniszewska M. Impact of Allura Clarity Technology on Radiation Dose Exposure during Left Atrial Appendage Closure. *Pol J Radiol*. 2017; 82: 598-602.
8. Christopoulos G, Christakopolous G, Rangan B, Layne R, Grabarkewitz R, Haagen D, *et al*. Comparison of Radiation Dose between Different Fluoroscopy Systems in the Modern Catheterization Laboratory: Results from Bench Testing Using an Anthropomorphic Phantom. *Catheter Cardiovasc Interv*. 2015 Nov; 86(5): 927-932.
9. Hoffmann R, Langenbrink L, Reimann D, Kastrati M, Becker M, Piatkowski M, Michaelsen J. Image noise reduction technology allows significant reduction of radiation dosage in cardiac device implantation procedures. *Pacing Clin Electrophysiol*. 2017 Dec; 40(12): 1374-1379.
10. Sharma M, Khalighi K. Reducing Radiation Exposure in an Electrophysiology Lab with Introduction of Newer Fluoroscopic Technology. *Clin Pract*. 2017; 7(3): 976.
11. Schmidt M, Tesche C, Hapfelmeier A, Finsterer S, Valassis G, Ebersberger U, *et al.* Significant Radiation Dose Reduction Using a Novel Angiography Platform in Patients Undergoing Cryoballoon Pulmonary Vein Isolation. *J Thorac Imaging*. 2020 May; 35(3): 167-172.
12. McNeice A, Brooks M, Hanratty C, Stevenson M, Spratt J, Walsh S. A retrospective study of radiation dose measurements comparing different cath lab X-ray systems in a sample population of patients undergoing percutaneous coronary intervention for chronic total occlusions. *Catheter Cardiovac Interv*. 2018 Sep; 92(3): e254-e261.
13. Sullivan P, Harrison D, Badran S, Takao C, Ing F. Reduction in radiation dose in a paediatric cardiac catheterisation lab using the Philips AlluraClarity X-ray system. *Pediatr Cardiol*. 2017 Dec; 38(8): 1583-1591.
14. Gunja A, Pandey Y, Xie H, Wolska B, Shroff A, Ardati A, Vidovich M. Image noise reduction technology reduces radiation in a radial-first cardiac catheterisation laboratory. *Cardiovasc Revasc Med*. 2017 Apr-May; 18(3): 197-201.

15. Ten Cate T, van Wely M, Gehlmann H, Mauti M, Camaro C, Reifart N, Suryapranata H, de Boer M. Novel X-ray image noise reduction technology reduces patient radiation dose while maintaining image quality in coronary angiography. *Neth Heart J.* 2015 Sep; 23(11): 525-530.
16. Nakamura S, Kobayashi T, Funatsu A, Okada T, Mauti M, Waizumi Y, Yamada S. Patient radiation dose reduction using an x-ray imaging noise reduction technology for cardiac angiography and intervention. *Heart Vessels*. 2016 May; 31(5): 655-663.
17. Kastrati M, Langenbrink L, Piatkowski M, Michaelsen J, Reimann D, Hoffmann R. Reducing radiation dose in coronary angiography and angioplasty using image noise reduction technology. *Am J Cardiol*. 2016 Aug; 118(3): 353-356.
18. Do K. General Principles of Radiation Protection in Fields of Diagnostic Medical Exposure. *J Korean Med Sci.* 2016 Feb; 31(1): 6-9.
19. Shope T. Radiation-induced skin injuries from fluoroscopy. *Radiographics*. 1996 Sep; 16(5): 1195-1199.
20. Chodick G, Bekiroglu N, Hauptmann H, Alexander B, Freedman D, Doody M, *et al*. Risk of cataract after exposure to low doses of ionising radiation: A 20 year prospective cohort study among US radiologic technologists. *Am J Epidemiol*. 2008 Sep; 168(): 620-631.
21. Roguin A, Goldstein A, Bar O, Goldstein JA. Brain and neck tumours among physicians performing interventional procedures. *Am J Cardiol*. 2013 May; 111(9): 1368-1372.
22. Strauss K, Kaste S. The ALARA (as low as reasonably achievable) concept in paediatric interventional and fluoroscopic imaging: striving to keep radiation doses as low as possible during fluoroscopy of paediatric patients--a white paper executive summary. *Pediatr Radiol*. 2006; 36(Suppl 2): 110-112.
23. Health Information and Quality Authority 2020, accessed 5 June 2020, <https://www.hiqa.ie/reports-and-publications/guide/guidance-establishment-use-and-review-diagnostic-reference-levels>