Journal of Medical Radiation Sciences

Open Access

ORIGINAL ARTICLE

Radiation dose in coronary angiography and intervention: initial results from the establishment of a multi-centre diagnostic reference level in Queensland public hospitals

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Keywords
Coronary angiography, coronary intervention, diagnostic reference level, radiation dose

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Funding Information
Financial support for this project was provided by the Allied Health Professions' Office of Queensland, Queensland Health.

Received: 28 January 2014; Revised: 5 June 2014; Accepted: 16 July 2014

Journal of Medical Radiation Sciences **61** (2014) 135–141

doi: 10.1002/jmrs.67

Abstract

Introduction: Radiation dose to patients undergoing invasive coronary angiography (ICA) is relatively high. Guidelines suggest that a local benchmark or diagnostic reference level (DRL) be established for these procedures. This study sought to create a DRL for ICA procedures in Queensland public hospitals. **Methods**: Data were collected for all Cardiac Catheter Laboratories in Queensland public hospitals. Data were collected for diagnostic coronary angiography (CA) and single-vessel percutaneous intervention (PCI) procedures. Dose area product (P_{KA}), skin surface entrance dose (K_{AR}), fluoroscopy time (FT), and patient height and weight were collected for 3 months. The DRL was set from the 75th percentile of the $P_{KA.}$ **Results**: 2590 patients were included in the CA group where the median FT was 3.5 min (inter-quartile range = 2.3–6.1). Median K_{AR} = 581 mGy (374–876). Median P_{KA} = 3908 uGym^2 (2489–5865) DRL = 5865 uGym^2. 947 patients were included in the PCI group where median FT was 11.2 min (7.7–17.4). Median K_{AR} = 1501 mGy (928–2224). Median P_{KA} = 8736 uGym^2 (5449–12,900) DRL = 12,900 uGym^2. **Conclusion**: This study established a benchmark for radiation dose for diagnostic and interventional coronary angiography in Queensland public facilities.

Introduction

Cardiovascular disease (CVD) is the leading cause of death in Australia with coronary artery disease (CAD), the most common form of CVD being the largest single cause of death.[1,2] Invasive coronary angiography (ICA) has been utilised in the diagnosis and treatment of CAD for over 30 years and there is consistent growth in the numbers of these procedures being performed each year.[3]

One disadvantage of ICA is the radiation dose to the patient from the fluoroscopy used during the procedure. At high X-ray exposures, there is a risk of deterministic radiation effects to the skin, such as erythema, permanent

epilation and at very high doses, dermal atrophy and ulceration. There is evidence to suggest that these effects are being increasingly reported.[4,5] There is also the increased stochastic risk by way of cancer. The risk of cancer from medical imaging procedures is largely unknown but is related to the cumulative effective dose received from imaging procedures.[6] A comparison of the effective doses for medical imaging procedures, including coronary angiography and intervention, is demonstrated in Figure 1. Radiation doses delivered during ICA procedures have not changed significantly over the years and remain one of the highest of any X-ray examination in the acute care setting.[7,8] By way of ensuring patient safety, there are maximum permissible X-ray outputs for cardiac catheterisation laboratory (CCL) systems in fluoroscopy mode in Queensland. However, there is no such limit for digital acquisitions, where the radiation dose can be up to 15 times that of fluoroscopy for the same beam on time.[9] Operator dose from scattered radiation from the patient is also a consideration as procedures become more lengthy and complicated. The long-term effects by way of cancer to operators from long-term exposure to low-energy ionising radiation are being increasingly recognised.[10–12]

Unsurprisingly, radiation protection and advisory bodies suggest that the radiation dose for radiological procedures should be monitored closely at a local, regional and national level.[13] In order to keep doses low, whilst also maintaining adequate image quality, physicians and their support staff require established, evidence-based data to benchmark against and to date in Queensland and Australia, there is no benchmark. The publication of a benchmark or diagnostic reference level (DRL) has been performed numerous times by radiation regulatory bodies around the world. It is most commonly used in providing a benchmark for diagnostic radiological imaging but can equally be utilised for interventional procedures.[13] They are a guide to good practice, but are neither dose limits nor thresholds that define competent performance of the operator or the equipment.[14] The DRL provides physicians with a guide for which the median dose of a particular procedure type should fall below and should be used as a tool for optimising patient dose. The DRL is most commonly derived from the dose area product (DAP or P_{KA}) value for fluoroscopy procedures and is a product of the dose output and the area exposed.[13]

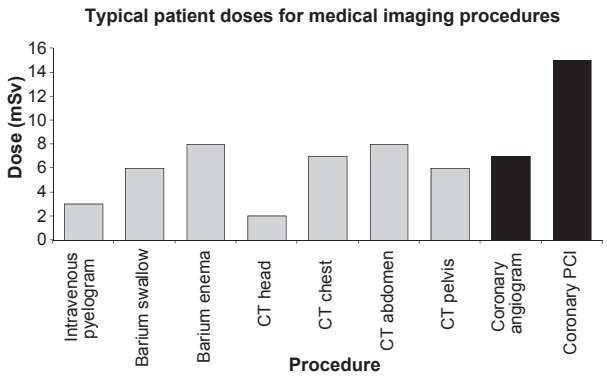

Figure 1. Relative patient effective dose for medical imaging procedures. Typical doses for medical imaging procedures. Adapted from data from Mettler et al.[7] mSv, millisievert; CT, computed tomography; PCI, percutaneous coronary intervention.

The purpose of this study is to establish Queensland Public Facility (Queensland Health) radiation DRLs for cardiac catheter procedures, for the purpose of providing benchmarks for ongoing quality assurance and audit.

Methods

Site participation

All seven public hospitals in the state of Queensland, Australia, with a CCL were invited to participate in the study.

Procedures included

The study included patients undergoing ICA procedures from January 2013 through to April 2013 inclusive. Procedures were separated into two groups:

- Diagnostic coronary angiography-only group (CA): adult patients undergoing coronary angiography ± left heart catheterisation and/or left ventriculography.
- Diagnostic coronary angiography in conjunction with single vessel percutaneous coronary intervention (PCI): adult patients undergoing coronary angiography ± left heart catheterisation and/or left ventriculography plus PCI.

The study included all adult patients that matched the above criteria. All other procedures, including graft studies and complex multi-vessel PCI, were eliminated from the study.

Data collection

Radiation data, automatically stored by each X-ray machine, were prospectively entered into an electronic image and reporting system (Impax CV; Agfa Healthcare, Mortsel, Belgium) at the time of procedure for all cases. Data were extracted from the cardiac catheter laboratory image and reporting system using structured query

language and exported into SPSS version 20 (IBM Corporation, Armonk, NY, USA) for analysis. Radiation data collected were as follows:

- Examination type
- Patient height/weight/BMI
- Fluoroscopy time
- Dose area product (DAP or P_{KA})
- System-calculated skin surface entrance dose (K_{AR}).

Data analysis

In line with the ICRP recommendations, the DRL was set from the entire population for each procedure and is determined by the 75th percentile of the P_{KA}.[13]

Patient size is known to affect dose.[4] Therefore, patient height, weight and body mass index (BMI) were additional measures for comparison. Fluoroscopy time (FT) was collected as it demonstrates 'beam on' time. K_{AR} was measured because in Queensland, the trigger value for a reportable dose and subsequent patient follow-up is determined by exceeding an entrance surface dose of 5 Gy. Individual centres were de-identified and allocated a number for analysis.

Additional measures

The dose area product meter (DAP meter) housed within the X-ray tube was calibrated on all systems within the 12 months prior to the data collection for each CCL. A variation of ±25% was deemed acceptable and was in line with similar studies.[15,16] CCL X-ray equipment in Queensland Health facilities (QH) is serviced by equipment vendors on a regular basis and the X-ray output of the systems is measured annually by QH radiation physicists to ensure compliance and quality assurance. Ethics approval was granted for this study by the Prince Charles Hospital Human Research Ethics Committee, Queensland Health.

Results

All seven QH facilities identified as performing ICA participated in the study – a total of twelve individual X-ray suites. Eleven of the twelve X-ray units were supplied by one manufacturer, with only one from a different manufacturer. All were <10 years old and incorporated flat detector technology.

A total of 3537 procedures fitted the criteria of the two groups and were included in the study. Of those, 2590 were CA and 947 were PCI. Overall data collection rates for the specified fields were 97.95% in the CA group and 98.33% in the PCI group.

The dose results and patient-related data for CA and PCI procedures are demonstrated in Table 1. Distribution curves are demonstrated in Figure 2 for the overall populations. How the different facilities/sites contributed to the data is outlined in Table 2**.** The DRL, as determined by the 75th percentile of the P_{KA} value for the study population, was 5865 uGym^2 for CA, and 12,900 uGym^2 for single-vessel PCI procedures. How these results compare to the literature is demonstrated in Tables 3 and 4**.**

Discussion

The investigation and publication of a DRL for coronary angiography has been performed in the UK every 5 years since 1992.[17] This has subsequently been followed by studies in Europe[18] and the United States.[16] Studies in the UK have found an incremental drop in radiation dose since they started investigating and reporting radiation dose.[17]

Many different factors affect radiation dose in ICA procedures and these factors have been evaluated before.[19–22] Factors such as X-ray system set-up, operator technique and clinical practice all play a part and it may well be beneficial to locally investigate these factors on a site by site basis in future. The complexity of the procedure has also been demonstrated to significantly affect radiation dose,[23,24] but again was not measured as part of this initial study.

It is advantageous to collect the height and weight of patients for these studies. Previous studies have

Table 1. Baseline results in this study for the two identified groups, demonstrating the various dose measures collected in this study.

Measure	Coronary angoigraphy	Percutaneous coronary intervention
Number of patients	2590	947
Median patient age	62.71 (54–72)	61.73 (53–71)
Median patient height (cm)	170 (177–162)	172 (165–178)
Median patient weight (kg)	83 (71.0–96.0)	82 (73–94)
Median patient BMI	28.7 (24.9–32.9)	27.8 (24.8–31.9)
Median fluoro time (min)	3.5 (2.3–6.1)	11.2 (7.7–17.4)
Median P_{KA} (uGym^2)	3908 (2489–5865)	8736 (5449–12,900)
Median K_{AR} (mGy)	581 (374–876)	1501 (928–2224)
Calculated DRL (uGym^2)	5865	12,900

Numbers in parenthesis indicate the interquartile range. BMI, body mass index; K_{AR}, patient skin surface entrance dose; P_{KA}, dose area product; DRL, diagnostic reference level; CA, coronary angiography; PCI, percutaneous coronary intervention.

Table 2. How each site enrolled in the study contributed to the data for P_{KA} and the DRL.

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	All
Diagnostic coronary angiography (CA)	(*n* = 193)	(*n* = 230)	(*n* = 542)	(*n* = 331)	(*n* = 261)	(*n* = 571)	(*n* = 462)	(*n* = 2590)
Mean	3263	4301	4909	4701	3620	4740	5601	4448
Median	2774	3826	4235	4197	2899	3886	4641	3908
SD	2033	2386	3168	2769	2617	3630	4057	2952
25th %	1798	2594	2893	2827	1955	2531	2605	2489
75th %	4178	5472	6288	5788	4461	5779	7176	5865
Percutaneous coronary intervention (PCI)	(*n* = 76)	(*n* = 127)	(*n* = 186)	(*n* = 119)	(*n* = 68)	(*n* = 215)	(*n* = 156)	(*n* = 947)
Mean	8303	10,023	10,615	10,034	6912	12,350	8655	9566
Median	7071	8445	9283	8710	6528	10,801	7291	8736
Std. Dev.	5111	6177	6986	6401	3483	7580	5690	5918
25th %	4707	5424	5917	5463	4525	6753	4853	5449
75th %	9471	12,403	12,900	11,089	6528	15,973	11,789	12,900

The values given are all in uGym^2. DRL, diagnostic reference level; P_{KA}, dose area product; Std. Dev., one standard deviation; 25th %, 25th percentile; 75th %, 75th percentile.

Table 3. Demonstration of how the results from this study compare to those previously published and the country where the data originates – diagnostic coronary angiography.

Country	Author	Median P_{KA} (uGym^2)	75th percentile
CA group			
Switzerland (non-academic centres)	Samara et al.[15]	5800	10,200
USA	Miller et al.[16]	4900	8300
Turkey	Bor et al.[24]	4910	–
Switzerland (academic centres)	Samara et al.[15]	4500	9000
Italy	Neofotistou et al.[29]	4240	–
Australia	This study	3908	5864
Finland	Neofotistou et al.[29]	3960	–
Greece	Neofotistou et al.[29]	3800	–
Ireland	Neofotistou et al.[29]	3330	–
Ireland	D'Helft et al. [4]	3100	4200
Italy	Neofotistou et al.[29]	2820	–
Spain	Neofotistou et al.[29]	2780	–
United Kingdom	Hart et al.[17]	2350	2900
England	Neofotistou et al.[29]	1910	–

CA, coronary angiogram; P_{KA}, dose area product.

Table 4. Demonstration of how the results from this study compare to those previously published and the country where the data originates – percutaneous coronary intervention.

Country	Author	Median P_{KA} (uGym^2)	75th Percentile
PCI group			
USA	Miller et al.[16]	11,700	19,300
Turkey	Bor et al.[24]	10,690	–
Switzerland (academic centres)	Samara et al.[15]	9000	17,000
Australia	This study	8736	12,900
Italy	Neofotistou et al.[29]	8200	
Switzerland (non-academic centres)	Samara et al.[15]	6700	12,000
Finland	Neofotistou et al.[29]	6690	–
Ireland	Neofotistou et al.[29]	4850	–
Italy	Neofotistou et al.[29]	4240	–
Ireland	D'Helft et al. [4]	4200	8400
United Kingdom	Hart et al.[17]	3600	5000
Greece	Neofotistou et al.[29]	3900	
Spain	Neofotistou et al.[29]	3900	–
England	Neofotistou et al.[29]	2710	–

PCI, percutaneous coronary intervention; P_{KA}, dose area product.

normalised their P_{KA} results to patient weight.[25] This is in line with a paper by Chapple et al. to an average of 70 kg.[26] Normalising the dose to a particular patient weight is advantageous for a comparison between X-ray systems. Normalising the dose data to a reference patient weight is difficult with a large number of facilities. Most multi-centre studies have not elected to do this[16,27–29] and this was not performed as part of this study. A higher P_{KA} value than some of the literature may be the result, due to the higher median patient weight of 83 kg seen in this study. Another method utilised to normalise the P_{KA} data is to exclude patients outside a weight range of 80 ± 5 kg, with the same aim.[17] Normalising may not be logical in establishing a DRL for practical routine use, as the DRL would only be relevant to a small portion of patients that fall within a certain weight range.

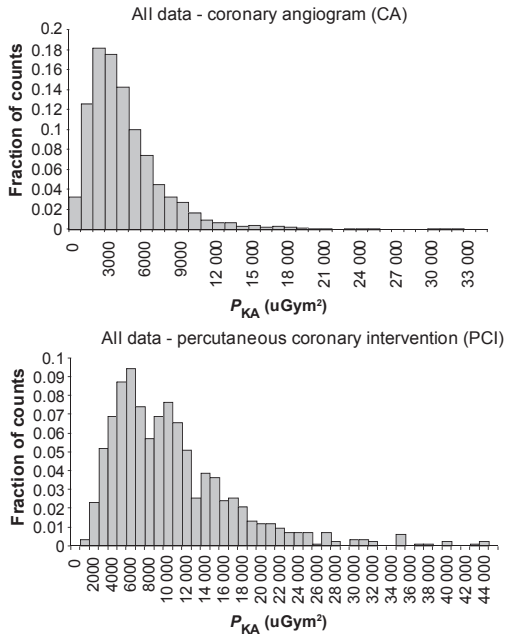

Figure 2. Distribution plots of the two groups included in this study. Distribution charts demonstrating how the distribution of P_{KA} is non-normal in both diagnostic coronary angiography and percutaneous coronary intervention groups. The *y*-axis demonstrates the fraction of procedures that fell within a particular P_{KA} range. P_{KA}, dose area product.

The results obtained from this study are comparable with those from other studies in the literature. Tables 3 and 4 show how this study compares to similar studies. It is evident that there is a great variation between these multi-centre studies. As an example, reference levels for CA range from between 2900 and 10,200 uGym^2, with this study sitting just below the average of 6744 uGym^2 at 5865 uGym^2. Neofotistou et al. attributed higher doses to teaching hospitals in their study,[29] as it is known that in their first year of training, operators use higher levels of radiation due to extended fluoroscopy.[30] It is noteworthy therefore that all seven facilities involved in this study are teaching hospitals, training registrars and fellows in ICA, and this has the potential to affect the results. Neofotistou et al. also attributed the possible difference in dose between the highest and lowest centres in its study to the dose rate under fluoroscopy.[28] Although dose rates of individual X-ray units were not measured in this study, all units are measured annually in terms of fluoroscopy dose, which is governed by state regulations. Sample size may also be important. There are differences in study population size within the literature, with sample sizes for CA examinations ranging from 311 patients[15] to 34,236 patients.[17] It has been proposed that 50 examinations from each facility will produce sufficient statistical power in these kind of studies.[16,31] With that in mind, the sample sizes of 2590 CA examinations and 947 PCI examinations seen in this study should make one confident that the DRLs calculated here are based on a sufficiently sound sample size.

This study would indicate that Queensland public facilities are delivering appropriate levels of radiation to patients during ICA procedures. However, there is always work that can be done to reduce dose and audits such as this are a good starting point in raising awareness. They are a fundamental foundation for ongoing audits as part of a quality assurance programme for radiation dose.[14]

In line with recommendations,[14] it is planned that doses for cardiac angiography and intervention be measured against benchmarks on an annual basis and for a study such as this to be repeated in 3–5 years. The DRL should be seen a guideline only, as it is well recognised that fluoroscopy procedures are difficult to benchmark and that each individual procedure may deviate from the DRL for many legitimate reasons.[13] DRLs are intended to provide guidance on what is achievable with current good practice rather than optimum performance.[14] However, to date, there is no DRL for these procedures in Australia and this study could be used as an interim yardstick for other cardiac catheter laboratories in Queensland and Australia, until a larger national study can be performed.

Conclusion

This study allowed for the calculation of a DRL for diagnostic and interventional coronary angiography procedures in Queensland health facilities. The establishment of a benchmark means that these DRLs can be used for ongoing audit in these and new facilities across Queensland and potentially other similar facilities in Australia.

Acknowledgements

Financial support for this project was provided by the Allied Health Professions' Office of Queensland, Queensland Health. The authors thank Mr Ian Smith for his advice and technical support. The authors also thank the State-wide Cardiac Clinical Network for their support and the individual staff of each facility involved in collection of the data. The following individuals were responsible for data collection and access of data at each facility: Steven Coverdale and Kim Duffy (Cairns Base Hospital, Cairns, Qld); Rohan Jayasinghe and Michael Trikilis (Gold Coast Hospital, Southport, Qld); Carmel McErlean and Peter Larsen (Nambour Hospital, Nambour, Qld); Paul Garrahy (Princess Alexandra Hospital, Woolloongabba, Qld); Peter Stewart (Royal

Brisbane and Women's Hospital, Herston, Qld); Michael Savage, Christopher Raffel and Darren Walters (The Prince Charles Hospital, Chermside, Qld); Bernard McGuire and Raiban Yadav (The Townsville Hospital, Townsville, Qld).

Conflict of Interest

The authors declare no conflict of interest.

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