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

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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{13}

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 $P_{KA}$.\(^\text{13}\)

Patient size is known to affect dose.\(^\text{4}\) 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 $\pm 25\%$ was deemed acceptable and was in line with similar studies.\(^\text{15,16}\) 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 uGy\(^2\) for CA, and 12,900 uGy\(^2\) 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.\(^\text{17}\) This has subsequently been followed by studies in Europe\(^\text{18}\) and the United States.\(^\text{16}\) Studies in the UK have found an incremental drop in radiation dose since they started investigating and reporting radiation dose.\(^\text{17}\)

Many different factors affect radiation dose in ICA procedures and these factors have been evaluated before.\(^\text{19–22}\) 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,\(^\text{23,24}\) 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 angiography | 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 $P_{KA}$ (uGy\(^2\)) | 3908 (2489–5865)     | 8736 (5449–12,900)               |
| Median $K_{AR}$ (mGy)        | 581 (374–876)        | 1501 (928–2224)                  |
| Calculated DRL (uGy\(^2\))  | 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.
normalised their $P_{KA}$ results to patient weight.\textsuperscript{25} This is in line with a paper by Chapple et al. to an average of 70 kg.\textsuperscript{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\textsuperscript{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.\textsuperscript{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.

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

| Site  | Diagnostic coronary angiography (CA) | Percutaneous coronary intervention (PCI) |
|-------|--------------------------------------|----------------------------------------|
|       | (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      |

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 (non-academic | Samara et al.\textsuperscript{15} | 5800                        | 10,200          |
| centres)         |                   |                             |                 |
| USA              | Miller et al.\textsuperscript{16} | 4900                        | 8300            |
| Turkey           | Bor et al.\textsuperscript{24}  | 4910                        |                 |
| Switzerland      | Samara et al.\textsuperscript{15} | 4500                        | 9000            |
| Italy            | Neofotistou et al.\textsuperscript{29} | 4240                       |                 |
| Australia        | This study        | 3908                        | 5864            |
| Finland          | Neofotistou et al.\textsuperscript{29} | 3960                       |                 |
| Greece           | Neofotistou et al.\textsuperscript{29} | 3800                       |                 |
| Ireland          | Neofotistou et al.\textsuperscript{29} | 3330                       |                 |
| Italy            | D’Helft et al.\textsuperscript{4}      | 3100                        | 4200            |
| Spain            | Neofotistou et al.\textsuperscript{29} | 2820                       |                 |
| United Kingdom   | Hart et al.\textsuperscript{17}       | 2350                        | 2900            |
| England          | Neofotistou et al.\textsuperscript{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 (academic    | Miller et al.\textsuperscript{16} | 11,700                     | 19,300          |
| centres)         |                   |                             |                 |
| Switzerland      | Samara et al.\textsuperscript{15} | 9000                        | 17,000          |
| Italy            | Neofotistou et al.\textsuperscript{29} | 8200                       |                 |
| Australia        | This study        | 8736                        | 12,900          |
| Switzerland      | Samara et al.\textsuperscript{15} | 6700                        | 12,000          |
| Finland          | Neofotistou et al.\textsuperscript{29} | 6690                       |                 |
| Greece           | Neofotistou et al.\textsuperscript{29} | 4850                       |                 |
| Ireland          | Neofotistou et al.\textsuperscript{29} | 4240                       |                 |
| United Kingdom   | Hart et al.\textsuperscript{17}       | 3600                        | 5000            |
| Spain            | Neofotistou et al.\textsuperscript{29} | 3900                       |                 |
| England          | Neofotistou et al.\textsuperscript{29} | 2710                       |                 |

PCI, percutaneous coronary intervention; $P_{KA}$, 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 uGym², with this study sitting just below the average of 6744 uGym² at 5865 uGym². Neofotistou et al. attributed higher doses to teaching hospitals in their study, as it is known that in their first year of training, operators use higher levels of radiation due to extended fluoroscopy. 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. 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 to 34,236 patients. It has been proposed that 50 examinations from each facility will produce sufficient statistical power in these kind of studies. 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.

In line with recommendations, 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. DRLs are intended to provide guidance on what is achievable with current good practice rather than optimum performance. 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.

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**Conflict of Interest**

The authors declare no conflict of interest.

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