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University College Cork, Ireland Coláiste na hOllscoile Corcaigh **Observational Study** 

# Ionizing Radiation Dose Exposure to the Ocular Region of Pain Physicians During C-arm Guided Pain Interventions

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Free full manuscript: www.painphysicianjournal.com **Background:** The growth of interventional pain medicine in recent years has resulted in more procedures being carried out under fluoroscopic guidance. The proximity of the pain physician (PP) to ionization radiation (IR) potentially increases the risk of radiation exposure to the ocular region. A European directive has reduced the limits of occupational ocular dose 7.5-fold.

**Objectives:** The objectives of this study are to quantify the typical IR exposure in the ocular region of PP and to compare it to recommended international guidelines.

**Study Design:** Three consultants involved in the pain unit service were enrolled in the study to reflect the dose implications involved with different caseloads, training obligations, and procedure types. All 3 consultants were experienced primary operators.

**Setting:** The study was undertaken at the pain management suite in the South Infirmary Victoria University Hospital (SIVUH). Annually, this unit performs 2,800 fluoroscopic guide pain procedures.

**Methods:** Thermoluminescent dosimeters (TLDs) calibrated to measure eye lens doses [Hp (0.07)] and whole-body doses (WBDs) were fitted to 3 pain consultants while they undertook imaging-guided pain procedures using mobile C-arm fluoroscopy over a 3-month period. The duration of radiation exposure, screening time (seconds), and procedure type were recorded. Radiation dose was calculated to estimate the effective radiation dose to the ocular region using (i) dose-area product (DAP) in milliGray per centimeter squared (mGycm<sup>2</sup>) and (ii) Air Kerma (AK) values in mGy.

**Results:** IR doses were effectively recorded in 682 cases over 3 months and the data extrapolated. The estimated annual lens dose experienced by pain physicians performing fluoroscopy-guided procedures is less than the recommended international guidelines. A significant linear relationship between screening time and IR exposure was estimated (rs = 0.93, P < 0.01)

**Limitations:** In many centers, including our own, fluoroscopy procedures are undertaken by nonconsultant staff. Therefore, a small single-center cohort recruiting experienced consultant staff and not including pain fellows or registrars/residents with varying levels of experience is a limitation.

**Conclusion:** While IR to the ocular region was significantly less than the recommended European safety guidelines, the annual dose needs to be confirmed in pain physicians with a lesser degree of clinical experience.

Key words: Ionizing radiation, ocular, radiation protection, pain medicine, interventional

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he growth of interventional pain medicine in recent years has resulted in more procedures being carried out under fluoroscopic guidance. In Ireland between 2005 and 2011, for example, pain medicine procedures increased by 80% from just under 4,700 to 8,430 (1). The increase in procedure frequency, complexity, and patient numbers has meant that pain physicians are now exposed to greater levels of ionizing radiation than in the past. While technological improvements have made the use of fluoroscopy safer, guidelines on radiation protection for the pain physician have not kept pace with these advances in technology.

The human eye is more radiosensitive than previously thought. The proximity of the pain physician to ionization radiation (IR) potentially increases the risk of radiation exposure to the ocular region and there is a recognized risk for the development of a cataract (2-4).

The International Commission on Radiological Protection (ICRP) and the European Union-led Optimisation of Radiation Protection for Medical Staff (ORAMED) project have recommended equivalent dose limits calculated from large longitudinal studies (5). A European directive has reduced the limits of the occupational ocular dose 7.5-fold. Anecdotal evidence suggests that ocular or head protection such as shielding screens or lead glasses that other interventionists (e.g., interventional cardiologists) employ are not routinely used by pain clinicians (6,7).

The objective of this study is to quantify the typical IR exposure in the ocular region of pain physicians

Procedure Description
Lumbar facet joint injection
Lumbar epidural injections
Thoracic facet injections
Cervical facet injections
Nerve root blocks
Pulsed radiofrequency procedures
RACZ lysis procedures
Sacroiliac joint injections
Coccygeal injections
Ganglion impars injection
Facet joint thermal denervation
Piriformis injections
Sympathetic block injections

Table 1. Nonexhaustive list of typical procedures performed.

and to compare it to recommended international guidelines.

# METHODS

The study was undertaken at the pain management suite in the South Infirmary Victoria University Hospital (SIVUH). Ethical approval was obtained from the Cork Research Ethics Committee (CREC). Annually, this unit performs 2,800 fluoroscopy-guided pain procedures. The room is a lead-lined procedural room with dimensions of approximately 32 m<sup>2</sup>. This is in contrast to the National Health Service (NHS) recommendation of 39-45 m<sup>2</sup> for fluoroscopic or nonvascular interventional fluoroscopy imaging examination rooms that are remote from the radiology department (8). The room was similar to most other pain procedure settings in all other aspects including features such as a radiolucent procedure table, lead-lined doors, and appropriate warning lights similar to those used in a theater.

A GE OEC Fluorostar 7900 Digital Mobile C-arm (GE Healthcare, Dublin, Ireland) is used to provide the imaging guidance in this suite. Quality assurance (QA) based on recommended standards and guidelines for radiology equipment was confirmed (9). An under-couch position in relation to the C-arm was adopted for all fluoroscopic procedures. The dose area product (DAP) tolerance levels, measure in milliGray per centimeter squared (mGycm<sup>2</sup>), were within normal limits, displaying results were within 13% of actual measured DAP at the radiation source which is within normal limits as per QA standards.

# Patients

The 3 consultants involved in the pain unit service were enrolled in the study to reflect the dose implications involved with different caseloads, training obligations, and procedure types. A record of the typical procedures was compiled (Table 1). All 3 consultants were experienced primary operators (i.e., more than 5 years post-higher specialist training qualification). They all wore wrap-around lead aprons with 0.25 mm lead equivalence in each front panel when overlapped, providing 0.5 mm lead equivalence total at the wearer's front, and a thyroid collar with 0.5 mm lead equivalence. One of the pain physicians routinely wears lead protection glasses. All patients wore personal monitoring thermoluminescent dosimeters (TLD) dose badges in accordance with department and legal requirements (10).

## **Patient Compliance**

Because consultant compliance would have a huge bearing on the accuracy of results, compliance and adherence were addressed in 3 ways:

- (a) The pain consultants were sent an SMS text message 30 minutes prior to their list starting, reminding them to wear their dose badge, and again immediately after the procedure session, requesting the number of patients on their list for whom they were primary operator
- (b) The nursing manager was asked to ensure that the pain consultants wore the TLD badge, which was to be attached to the thyroid shield outside the lead coat and not caught up beneath the jacket, which would render dose results falsely low
- (c) One author (RK) attended the pain management unit at the start of several lists to ensure that all dosimeters were worn and stored correctly, and to obtain patient feedback.

#### **Ocular Radiation Dose Measures**

Ocular radiation dose, calculated as effective dose in milliSieverts [mSv], was measured. Two different types of TLD dosimeters were used to record ocular radiation dose (Fig. 1). The most accurate eye lens dosimeter (ELD) has been specially calibrated to  $H_p(3)$ . The dosimeters available for this study were the same as those used for eye dose measurement; however, they were calibrated to calculate skin dose,  $H_p(0.07)$  (LANDAUER, Glenwood, IL). Literature provided by LANDAUER indicate that these dosimeters are suitable for the purpose we required, with the caveat of slightly overestimating dose values by small amounts (11-14).

Multiple studies have also shown that the wholebody dosimeter (WBD) can be used to calculate ocular dose satisfactorily when compared to an ELD, provided similar radiation protection measures are used (15). These studies outline how an unprotected WBD on the thyroid collar can be used to estimate eye lens dose in eyes unprotected by lead glasses (11,16,17). An accepted conversion factor to use is: eye dose = 0.75 x neck dose (18,19).

Following the measurement periods, the dosimeters were returned to medical physics and sent for analysis.

## **Dose Metrics Recorded**

Three dose metrics were recorded for every procedure undertaken by the pain clinician throughout the 3-month study period:

- Fluoroscopy time recorded in seconds
- Dose-area product (DAP) in milliGray per centimeter squared (mGycm<sup>2</sup>)
- Air kerma (AK) value in mGy



While fluoroscopy time is easy to measure, it is not strongly correlated with radiation risk because fluoroscopy dose rates fluctuate over a wide range of values throughout the duration of a procedure, and adjust automatically to provide optimal image quality when imaging different body areas and densities. Reference AK and DAP can more accurately estimate the risk of radiation injury, though they are usually used to record patient dose.

DAP is defined as the integral of AK across the x-ray beam. The same DAP value can occur with a large field and low skin dose as with a small field and high skin dose. DAP provides no information regarding the spatial distribution of the entrance beam on the patient's skin. It is a proxy measure of the amount of energy delivered to the patient as it is the absorbed radiation dose multiplied by the area irradiated (20-22). AK defines the radiation dose accumulated at a specific point in space. Although recording these values may not add any value to our dosimeter results, we felt it prudent to record all available dose data for use in correlating dose readings.

These values were recorded by the radiographer and scanned into the Picture Archiving and Communication System (PACS). They are also archived automatically on the C-Arm as part of the metadata with the stored images from the procedure. This data is deleted manually in chronological order when the local disk space nears capacity. Two archives of data ensured that all procedures were accurately recorded and could be cross-checked in the event of any doubt.



## Procedures

#### Pilot Study

A 4-week pilot study was undertaken to ensure the feasibility of accurate data collection. During this time, 2 eye dosimeters fixed to lead protection glasses were worn by one consultant for all interventional procedures using ionizing radiation. While evidence shows that the left eye gets irradiated to a greater degree in C-Arm-guided interventional procedures, the primary operator's movement during pain procedures – allied to the movement of the C-Arm position (Anteroposterior [AP] to Oblique to Lateral position) – meant that there may be similar exposure to the right eye. Therefore, dosimeters for both eyes were analyzed by medical physics.

The pain physician participating in the pilot study routinely wore lead glasses while performing pain management procedures, and the left and right dosimeters were mounted on the arms of the glasses as close to the eyes as possible without impeding vision (Fig. 2). The dosimeters were in place for 35 procedures over a 4-week period. The pilot study was completed when the dose data was obtained and analyzed. Once confirmed that it was technically viable to proceed with the study, other consultants could be enrolled.

All dosimeters were stored in a locked unit or at the nurses' station in the pain department to prevent accidental exposure. Control dosimeters were returned along with exposed dosimeters at the end of the pilot study.

#### Main Study

Three pain consultants were enrolled for the 3-month period. All pain physicians were monitored by the whole-body chest dosimeter worn on the thyroid shield, to address concerns that using dosimeters fixed close to the ocular region via a headband would not be tolerated. One of the consultants continued to use the eye dosimeters in addition to the whole-body dosimeter secured to the thyroid shield, as illustrated in Fig. 3.

#### **Statistical Analysis**

Statistical analysis was performed using SPSS software (23). Non-parametric tests were used due to the abnormal distribution of the data. The correlation coefficient between the DAP and screening time was used to measure the strength of the linear association between the 2 values and support the  $H_p(0.07)$  and  $H_p$  (10) values obtained. Homogeneity of variances across

recorded values of screening time and DAP was tested prior to discussing the pilot study findings with data from the main study.

## RESULTS

The pilot study confirmed that positioning of the TLD would capture the IR exposure to the ocular region (Table 2).

Over the 3-month period, a total of 682 fluoroscopy procedures were included in the study. The number and type of procedures undertaken are reported in Table 3.

Of the 682 procedures monitored, consultant 1 performed 26.2% (n = 179) of the procedures, consultant 2 performed 54.8% (n = 374), and consultant 3 performed 18.9% (n = 129) of the procedures. It is important to note that, although consultant 2 was present for more procedures, he may not have been the primary operator for the full duration of the procedures. This would have been reflected on his whole-body dosimeter reading, but not in his screening time or DAP readings. Table 4 illustrates the average values for all 3 pain physicians.

The eye dose values recorded over the 3-month period were extrapolated to represent annual eye lens dose. Percentage figures are in relation to the accepted new dose limit of 20mSv. The key finding is that the estimated annual lens dose experienced by pain physicians performing fluoroscopy-guided procedures is less than the new recommended international guideline of 20mSv per year (4,24-27).

Variation in the exposure patterns was assessed using a stem and leaf plot (represented by the box and whisker plots) (Fig. 4). Analysis of these exposure patterns revealed that consultant 1 had 7 procedures deemed extreme by SPSS in terms of screening time, when compared to the other recorded 171 values. With respect to DAP, 11 procedures were deemed extreme in value compared to the mean (23). Consultant 2 had 20 procedures deemed extreme in relation to screening time and 22 in relation to DAP. Consultant 3 had 12 procedures deemed extreme in both screening time and DAP values.

These outlier values were retained as part of the analysis in an effort to present a realistic record of a typical procedure profile in our unit. They also highlight the abnormal distribution of data across patients.

There was a significant positive relationship between the recorded DAP and the duration of screening time for all 3 consultants (Table 5), where a Spearman's correlation coefficient of 1 denotes a perfect correlation and values close to 1 indicate a strong correlation



Fig. 3. Position of dosimeter on thyroid shield.

Table. 2. Pilot study estimating the annual dose to the unprotected eye lens.

4 week values				
Consultant Pain	Screening time	DAP Gy/cm <sup>2</sup>	ELD reading H <sub>p</sub> (3) (mSv)	
Physician 1	14 min 48 sec	76.51	0.9	

Table 3. Basic breakdown of frequency of procedure type by description, where n = number of procedures.

Region Examined	n (%)
Cervical region	31 (4.5%)
Thoracic region	19 (3%)
Lumbar region	265 (38%)
Sacroiliac/Coccygeal region	64 (9%)
Epidural Injection region unspecified	115 (17%)
Facet joint region unspecified	98 (14%)
Others:	36 (5%)
Superior hypogastric plexus block	
Ganglion impars sacrococcyl injection	
Pudendal nerve block	
Ischial tuberosity injection	
Piriformis injection	
Intra-articular injection-Ankle/hip	
Plantar fascia injection	

	Screening time (min) +1 s.d	Total DAP (mGycm²) +1 s.d	Whole body dosimeter (mSv) +1 s.d	Conversion factor applied (0.75) +1 s.d	
Mean of Main Study (n = 3)	68.4 + 52.6	307.04 + 260.8	0.91 + 0.5	0.68 + 0.38	
Extrapolated Annual Dose (mSv)					
	Screening time (min)	Total DAP (mGycm <sup>2</sup> )	Whole body Dosimeter (mSv)	% of annual dose	
Mean of Main Study (n = 3)	273.6 + 210.42	1228 + 1043	2.73 + 1.51	13.7 + 7.55	

Table 4. Average values for the group using the whole-body dosimeters and extrapolated annual values.



A) Screening times and B) DAP (where DAP = . The o and \* represent outliers where \* is an "extreme" outlier as determined by the SPSS formula: 1.5 x interquartile range).

Table 5. Shows the correlation between DAP and duration of screening time for each consultant ( $r_s = Spearman$  correlation;  $R_s^2 = correlation coefficient squared$ ).

	Spearmans (rs)	$r_s^2$	P (one-tailed)
Consultant 1	0.9	0.81	< 0.01
Consultant 2	0.94	0.88	< 0.01
Consultant 3	0.94	0.89	< 0.01
Average	0.93	0.86	< 0.01

between the 2 outlined variables, despite nonlinearity. Squaring the data allows one to represent the proportion of shared variance in the 2 ranked variables, DAP and screening time. Figure 5 depicts this relationship and indicates a positive linear association between DAP and screening time despite the data being nonparametric.

# DISCUSSION

Our study has shown that pain physicians are exposed to measurable IR to the ocular region; however, no pain physician received more than 24% of the new ocular dose limit being brought into effect in 2018. Our results confirm that a significant linear relationship exists between the screening time duration of the procedures and DAP.

We believe that this is the first study to quantify the eye lens IR dose received by pain physicians using real time data. It highlights the importance of good interventional practice/skills in maintaining safe IR levels and complying with current legislation (28).

With respect to effective radiation dose received in the workplace, the health and safety of staff is legally protected. The new directive on ocular dose means that even more stringent controls in relation to operator eye dose are required. Pain medicine continues to be



Fig. 5. Scatterplot depicting rank correlation between DAP and screening time readings recorded for the 3 physicians. The positive  $R^2$  values indicate a positive association between the 2 variables. Spearman's correlation coefficient provides a more accurate assessment of monotonic yet nonparametric data, however linear association between the variables is seen.

dependent on ionizing radiation in image-guided procedures (1). Keeping radiation doses as low as reasonably achievable is one of the main tenets of radiation protection, and adhering to this principle will help to ensure that the pain medicine departments complie with current legislation (24). We believe that this study provides valuable information on eye dose estimates that a typical pain physician may be exposed to during a typical work week. This information has potentially significant technical and economic implications for all concerned. Our study confirmed that the level of IR used in pain procedures can vary substantially between different types of procedures, and among individual pain physicians who specialize in different procedures. Based on this anticipated variation, an approach based on "dose per procedure" would have had little clinical value. Other factors influencing operator radiation dose include the distance of the operator from the patient, the orientation of the operator's head, the distance of the image detector from the patient, the beam collimation, the tube configuration, the tube voltage and filtration, and the complexity of the procedure.

Post hoc analysis showed low annual extrapolated values in the main study. We used average dose and screening time results from the main study, bearing in mind that we had dose information from two sources: the C-arm and the dosimeters.

One physician (consultant 1) received almost 3 times the ocular dose per unit DAP as the next closest consultant (Table 6). This may be due to various factors influencing operator radiation dose, as discussed above, but is most likely due to the high screening time and DAP values incurred during certain procedures, possibly reflecting the complexity across either the range of different procedures or the anatomy and pathologies encountered during pain management procedures. Regardless, these results highlight the need for further monitoring to understand this variation. Observing workflow may also provide some insight into this pattern, as no major differences in practice were observed.

The effective dose values recorded indicate that, in general, good clinical practice occurs at our site. Consultants engaged in good practice will have a positive influence on trainee pain physicians and allied health staff. Good clinical practice will also ensure that staff and trainees who may be unfamiliar with radiation risks early in their career learn safe techniques when using ionizing radiation.

Interestingly, we did not demonstrate any difference in IR values for the left and right eye monitors worn by consultant 1 in either the pilot or the main study. A higher dose to the left eye is a trend that has been observed in several other studies in this field (29,30). This difference may be explained by the fundamental difference between the work practices of pain physicians and other interventionalists, such as those in cardiology and radiology. Pain physicians are not static in one position and very often need to move within the exposure field, potentially receiving IR on either side of the body/face. We should also consider that this data reflects the work practices of an individual practitioner. Additional bi-ocular monitoring over a larger cohort

Table 6. Normalized eye dose by DAP.

	Total DAP (mGycm <sup>2</sup> )	Whole body dosimeter (mSv)	H <sub>p</sub> (3)/DAP
Consultant 1	715	3.69	5.16 x 10-3
Consultant 2	2429	3.51	1.44 x 10-3
Consultant 3	541	0.99	1.83 x 10-3

would be required to make inferences in regard to this observation.

## Limitations

We recognize that the level of interventional experience is a fundamental factor influencing operator radiation dose, and therefore a small single-centered cohort is a limitation. However, we sought to establish "best practice" and so we enrolled only the most experienced individuals (all consultant staff at this site). We ensured that we achieved full compliance. For these reasons, we believe that this study is a reasonable representation of activity in an average pain unit, thereby making it clinically relevant to the practice of a typical pain physician. Even if the IR and DAP were underestimated in our center, the fact that the level of IR was significantly less than recommended guidelines allows for significant scope in this regard.

We are conscious that in many centers, including our own, fluoroscopy procedures are undertaken by pain fellows or resident/registrar with varying levels of experience. We would anticipate that individuals with less experience in pain interventions would have greater screening time and therefore higher DAP and IR exposure. Acknowledging the variety of individual experiences should be considered in future assessments.

We had some technical limitations associated with our study. Firstly, we did not perform concurrent monitoring of Consultant 1 with both ELDs and WBDs. This was a missed opportunity for comparison of dose estimation methods, which would have provided an interesting technical aspect to the recorded doses. Secondly, it is possible that because the consultants in the study were aware that they were being monitored, they may have paid greater attention to their technique relative to their typical practices. Prolonging the duration of the study and using double blinding could reduce this potential bias. Thirdly, the ELDs used, while deemed suitable in the literature, were not calibrated to H<sub>a</sub>(3) using a cylindrical phantom representative of a head. Instead, the ELDs used in this study were calibrated to  $H_{n}(0.07)$ . However, there are many dosimeters calibrated to  $H_{n}(3)$ available and under the circumstances, it can be argued that this study used the 2 most accepted methods of dose estimation in the absence of dosimeters calibrated to H<sub>2</sub>(3).

It is accepted that the use of WBDs to determine level of risk is reasonable, and that other dosimeters can then provide more accurate estimations via ELDs (18). This would have been incumbent on us if the estimations provided by the WLDs had been closer to the new dose limit of 20mSv.

### CONCLUSION

We report that exposure to IR in the ocular region associated with pain procedures is well below the new recommended level. Therefore, it is most likely that, in many centers, no additional equipment or room modifications will be required to meet the new recommendations. We do recommend that future research should consider the use of multiple sites, a longer study duration, greater blinding, and expansion of the study to include a mixture of personnel with different levels of experience to confirm these findings. We also encourage departments to discuss the importance of good interventional technique to minimize IR exposure to healthcare workers and their patients.

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