Injury, Int. J. Care Injured 46 (2015) 2457–2460

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Defining reference levels for intra-operative radiation exposure in orthopaedic trauma: A retrospective multicentre study

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ARTICLE INFO

Article history:
Accepted 5 October 2015

Keywords:
Ionising radiation
Reference levels
Dose area product
Exposure time
Orthopaedic trauma

ABSTRACT

There is currently limited data to define reference levels for the use of ionising radiation in orthopaedic trauma surgery. In this multicentre study, we utilise methodology employed by the Health Protection Agency in establishing reference levels for diagnostic investigations in order to define analogous levels for common and reproducible orthopaedic trauma procedures.

Four hundred ninety-five procedures were identified across four Greater London hospitals over a 1-year period. Exposure was defined in terms of both time and dose area product (DAP). Third quartile mean values for either parameter were used to define reference levels. Variations both between centres and grades of lead surgeon were analysed as secondary outcomes.

Reference levels; dynamic hip screw (DHS) 1.9225000 Gycm^2/70.50 s, intramedullary (IM) femoral nail 1.5837500 Gycm^2/126.00 s, open reduction internal fixation (ORIF) clavicle 0.2042500 Gycm^2/21.50 s, ORIF lateral malleolus 0.32250500 Gycm^2/35.00 s, ORIF distal radius 0.1300000 Gycm^2/56.00 s. Grade of surgeon did not influence exposure in dynamic hip screw, and was inversely related to exposure in intramedullary femoral nails. Less variation was observed with exposure time than with DAP.

This study provides the most comprehensive reference to guide fluoroscopy use in orthopaedic trauma to date, and is of value both at the point of delivery and for audit of local practice.

Introduction

Outside of natural background sources, over 90% of public exposure to ionising radiation is attributable to its use in medicine [1]. The potentially harmful effects of this have been well documented since the mid 19th century [2], and the requirement to produce the minimum possible dose consistent with the purpose of the examination is now formalised in UK legislation [3].

Although X-ray imaging of the extremities utilises relatively low radiation doses when compared with modalities such as computed tomography [1], the importance of minimising usage remains significant here. The linear no threshold (LNT) hypothesis sets out that there is no minimum dose required for radiation to produce malignant transformation. Higher doses of radiation are associated with a higher probability of disease because of the statistical effect of more photons interacting with more DNA molecules. This produces a linear relationship between radiation exposure and risk for malignancy, which is cumulative not only over an individuals' lifetime, but also across a population [4]. Given this cumulative effect, small incremental reductions in fluoroscopy use may therefore be associated with an appreciable reduction in risk for patient and surgeon, both long-term and at a population level.

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 [5], commissioned by the department of health is made as criminal law, and sets out the duties of the trust and practitioners to keep radiation exposure as low as reasonably practicable. For diagnostic uses, it states that investigations must be assigned a reasonable radiation exposure, the 'diagnostic reference level' (DRL) [3]. This provides valuable feedback both at point of use, and for local audit. Although these figures may be based on local data, national figures are published in the National Patient Dose Database (NPDD) as a recommended guide [6].

Where radiation is used for interventional procedures, including trauma surgery, subtle variations in technique and complexity

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http://dx.doi.org/10.1016/j.injury.2015.10.010
0020–1383/

present a challenge in establishing reference levels [3]. Recent national review of DRLs by the Health Protection Agency called for stratification of interventional procedures by anatomical location and complexity, with a view to including these alongside diagnostic investigations in subsequent review [6]. The IR(ME)R working party also acknowledge the need for interventional procedures to be assigned reference figures [3]. However, with this work pending, the trauma surgeon is left with little guidance as to what constitutes reasonable use of the image intensifier.

A review of the current literature found two studies, which seek to address this problem [7,8]. A significant limitation of both is that each utilises data from only one centre. Figures for diagnostic procedures in the NPDD [5] show significant variation between centres, as well demonstrating the existence of outliers. Single centre studies are not therefore appropriate to guide practice. Further limitations include expression of data as a mean value [7], not rounded third quartiles as per the NPDD [6], and assessment of only a single procedure [8].

The primary objective of this retrospective multicentre study was to apply the methods used by the Health Protection Agency in creating the NPDD, in order to establish reference levels of ionising radiation exposure for common orthopaedic trauma procedures.

Materials and methods

Orthopaedic trauma cases were identified retrospectively from the electronic records of procedures carried out at four Greater London district general hospitals, over a 12 month period (01/10/2013–01/10/2014). Data from a single centre (centre 4) was used as a representative sample to identify the five most frequently performed orthopaedic trauma procedures, which both utilised fluoroscopy, and were felt to have sufficient reproducibility of technique to provide meaningful analysis. Decision regarding reproducibility was based on consensus between the first and second authors (JH and ME). Procedures identified for analysis were: dynamic hip screw (DHS), intramedullary (IM) femoral nail (long femoral nail, inserted via antegrade technique, for treatment of either trochanteric or proximal shaft fractures), open reduction and internal fixation (ORIF) clavicle, ORIF lateral malleolus, ORIF distal radius. Frequently performed procedures rejected on the basis of variability in technique were: ORIF of both bi- and tri-malleolar ankle fractures, and closed reduction with Kirschner wire fixation of distal radius fracture.

Multiple injuries managed in a single theatre session could not be included in the analysis, as fluoroscopy data is logged cumulatively over each session and cannot be attributed to any one procedure retrospectively. Open or extensively comminuted fractures were excluded due to the added complexity of managing these injuries. Non-traumatic indications for surgery, such as prophylactic IM nails in metastatic disease, were similarly excluded in order to maintain consistency.

Further exclusions were carried out in line with methodology employed by the National Protocol for Patient Dose Measurement in Diagnostic Radiology [9]. Firstly, this requires that children are further subcategorised according to age. This would be unlikely to yield meaningful results in a study of this size, so patients under 16 years were excluded. Secondly, it states that the mean weight of the sample must lie within 5 kg of 70 kg, and that all patients outside of the 50–90 kg range should be excluded. However, as data regarding patient weight is not always available retrospectively, they negate the issue by specifying a minimum of 10 patients in any individual sample where weight is not included [5]. The same inclusion criteria is applied here, and data for any procedure is only included where the centre reports on a minimum of 10 cases.

From 502 suitable procedures, 7 were excluded due to there being less than 10 procedures of that type reported from an individual centre. Four hundred ninety-five procedures remained for analysis.

Cases were cross-referenced with imaging to ensure accurate documentation of procedure. Data regarding exposure was obtained from the electronic imaging records, and recorded both in terms of total exposure time and dose area product (DAP); the absorbed radiation dose per unit of surface area. Where available, grade of lead surgeon was also recorded, and stratified as senior house officer (SHO), registrar, or consultant.

As per the NPDD, reference levels for DAP and exposure time were calculated from the rounded third quartile means of the respective parameter [9].

In order to establish if either local variation or grade of lead surgeon lead to statistically significant differences in exposure, a two-tailed *t*-test was used to define a *p* value for the subset of data from each centre, or cohort of surgeons, versus the data for the remaining population ($p < 0.05$ considered statistically significant).

No information regarding grade of lead surgeon was available at centre 3, or for four of the cases at centre 4. Data was available for a total of 339 cases, across three centres.

Results

DHS and ORIF distal radius were performed in sufficient number to permit analysis from all four centres. Sufficient data was available at three centres for analysis of ORIF clavicle and ORIF lateral malleolus, and at two centres for analysis of long IM nail femur.

Based on the third quartile means, reference levels established were; DHS 1.9225000 Gycm^2/70.50 s, IM femoral nail 1.5837500 Gycm^2/126.00 s, ORIF clavicle 0.2042500 Gycm^2/21.50 s, ORIF lateral malleolus 0.32250500 Gycm^2/35.00 s, ORIF distal radius 0.1300000 Gycm^2/56.00 s. These results, along with corresponding figures for mean and range are summarised in Table 1.

Table 1
Summary of reference levels.

Procedure	Total	Number of centres	DAP (Gycm^2)			Time (s)		
			Mean exposure	Range	Reference level (*Rounded 3rd quartile*)	Mean exposure	Range	Reference level (*Rounded 3rd quartile*)
DHS	206	4	1.5689320	(0.0828000–16.8740000)	1.9225000	60.37	(13–267)	70.50
IM nail femur	24	2	1.3502917	(0.2110000–3.2300000)	1.5837500	114.29	(30–198)	126.00
ORIF clavicle	54	3	0.1837822	(0.0023000–1.4800000)	0.2042500	14.85	(<1–46)	21.50
ORIF lateral malleolus	71	3	0.2071183	(0.0052000–1.3540000)	0.3225000	26.34	(10–107)	35.00
ORIF distal radius	140	4	0.2071041	(0.0012100–14.1210000)	0.1300000	45.05	(5–361)	56.00

DHS, dynamic hip screw; IM, intramedullary; ORIF, open reduction and internal fixation; DAP, dose area product.