Radiation protection issues with the use of mini C-arm image intensifiers in surgery in the upper limb

OPTIMISATION OF PRACTICE AND THE IMPACT OF NEW REGULATIONS

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Hospital practice in all areas is constantly evolving because of new medical concepts and technological advances. This is partly driven by the influences of clinical governance and a rigorous medicolegal climate. The search for higher standards of health care has led to the introduction of technological innovations and the need therefore of regulating their use.

The mini C-arm image intensifier has made a major contribution to surgery of the upper limb, combining a superior quality of image, ease of use, and relatively low doses of emitted ionising radiation. Low as these radiation doses may be, the protection of those exposed remains a matter of importance. Current regulations make hospital trusts accountable for the safety of all staff and patients exposed to ionising radiation within the hospital. Breaches of the regulations are a criminal offence under the Health and Safety at Work Act and can result in criminal and civil liabilities. The need therefore is to have well-trained personnel with appropriate equipment and systems in place to carry out justified, optimised and safe medical procedures and to be able to identify and deal with accidents, errors and poor practice. The requirement for justification and optimisation is contained within the Ionising Radiation Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER 2000). This and the medicolegal climate have made it essential for all trusts to have formal written local rules and protocols for the safe use of medical radiation.

Radiation protection in clinical practice – a brief history

Awareness of protection issues for ionising radiation date back to the early days of radiography. In 1928 the International Society of Radiologists met in Stockholm and formed the International X-ray and Radium Protection Committee to consider these issues. This body was restructured in 1950 in the wake of the nuclear end to World War II. With the greater use of radioactive substances and atomic energy in clinical practice it was renamed the International Commission on Radiological Protection (ICRP) and its role was extended to include non-medical exposure to radiation. Its aim has been to advance the science of radiation protection for public benefit and it has published a series of important guidelines and recommendations. In 1990 the ICRP60 document ‘Recommendations of the International Commission on Radiological Protection’ was issued. This influenced the development of the National Protocol for Patient Dose Measurement in Diagnostic Radiology (IPEM 1992). These papers discussed the biological dose effects of ionising radiation, further developed the concepts of the effective dose (the best overall measure of the anticipated risks of radiation), tissue-weighting factors, the entrance surface dose (dose to the skin), the dose-area product and the collective dose. In 1998 the National Radiation Protection Board developed guidelines for the protection of women of childbearing age to prevent inadvertent exposure and protect the fetus, and to offer counselling and advice. The Ionising Radiation Regulations 1999 were introduced to protect those working with ionising radiation. They arose from the European Basic Safety Standard Directive of 1996 and linked radiation protection issues to the Health and Safety Executive. The hospital trusts (radiation employer) were made accountable for the employee’s protection but the regulations also recognised the personal responsibility of the employee for using the radiation protection measures available. They stipulated occupational dose limits for various categories of persons and stated that exposure had to be restricted to the lowest practicable levels. They also discussed the requirement for local rules, risk assessments, quality assurance systems and contingency plans for accidents and near misses. It was pro-
posed that these should be developed with the advice of the Radiation Protection Adviser and monitored locally by the Radiation Protection Supervisor. The trusts were required to justify the use of radiographic equipment and have their use authorised by the Health and Safety Executive.

The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER 2000) superseded the Ionising Radiation Regulations of 1999 and are enforced by the Department of Health through the Health and Safety at Work Act 1974 to cover the exposure of patients to medical radiation for diagnostic, therapeutic, research, medicolegal, occupational health and health-screening purposes and to ensure that the benefits of such exposure outweigh the detriments. They require medical exposures to be justified, optimised and delivered by trained medical personnel and to be clinically evaluated.

They define specific roles for the following individuals. **Referrer.** This is an authorised professional entitled to refer individuals for medical exposure and to provide necessary information with the request. **Practitioner.** He or she is an authorised health professional entitled to take responsibility for an individual exposure and to be able to justify the request in accordance with the employer’s procedures. **Operator.** This is an individual who is entitled to carry out practical aspects of the exposure in accordance with the employer’s procedures.

For surgery on the upper limb using the mini C-arm image intensifier the same person may have all three roles. This is an area of concern since one person takes complete responsibility for exposure to x-rays. Good audit techniques are therefore essential. The employer must have protocols in place for medical exposures with the compliance of the operator and practitioner. Lists of referral criteria must also be in place and be available to the referrer. Dose constraints are stipulated for research exposures where there is no direct clinical benefit for the exposed individual. Diagnostic reference levels need to be established for radiodiagnostic work but are not required for therapeutic activity. The employer is responsible for ensuring that all practitioners and operators are fully trained using theoretical and supervised practical sessions and that they comply with the written procedures. A record of the dose of radiation must be recorded in the patient’s notes. For the mini C-arm intensifier this means that the exposure time should be recorded in both the notes and the theatre log book. This is to allow audit systems to identify inappropriate use.

The IRMER 2000 thus have a major impact on our practice and have significant medicolegal implications.

**The mini C-arm image intensifier**

The Fluoroscan (Hologic Inc, Bedford, Massachusetts) is typical of mini C-arm intensifiers currently available. It has a micro focus x-ray tube which uses 0.02 to 0.10 mA of current with a tube potential of 40 to 75 kV and thus uses a narrow field (10 to 15 cm in diameter) and less ionising radiation than the usual instruments which use a few mA of current and about 120 kV with field sizes of between 13

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*Fig. 1*

Photograph showing the mini C-arm image intensifiers.
and 23 cm. It has a compact image intensifier and a TV camera placed close to the patient in order to generate images of good quality on multiple screens. The quality of the picture can be modified digitally with reduced noise which improves contrast or edge enhancement and reduces blurring. Normally, for any dynamic imaging, the noise suppression is turned off to eliminate a ghosting effect from moving the patient. The field sizes of 10 cm and 15 cm are sufficient for most operations on the upper limb. Magnification is of limited use when screening the upper limb. If it is not possible to obtain an image of suitable quality from the automatic exposure, a manual override is available. The IRMER regulations state that the manual facility should only be used when justified and experience has shown such
occasions to be rare. Images can be printed, video recorded or stored on hard discs in a PC or PACS-compatible format as required.

Mini C-arm intensifiers are compact, light, well-balanced and easy to position (Fig. 1). They are mainly automated and have foot pedals to control most operations. This makes them ideal for direct use by surgeons eliminating the need for further personnel. There are therefore considerable logistical and manpower advantages to their use.

Radiation protection issues with the mini C-arm image intensifier
The mini C-arm intensifier is a relatively safe device, but for best practice the following issues are important.

Screening time. This is the main variable with the device and is displayed on the monitor. Typically, it will be low for normal surgical procedures, about ten seconds for most wire or screw fixations and 30 seconds for plating. The quality of the picture and the ease of use can be optimised with supervised training, proper positioning and a well-rehearsed surgical plan.

Screening times are recorded. While diagnostic reference levels for therapeutic procedures are not necessary under IRMER 2000, typical screening times should be generated locally for audit and used for best practice as part of the protocols. A reassessment time should be included within the protocols. This is the screening time at which techniques and procedures should be re-evaluated. When re-assessment times are approached or exceeded the surgical plan should be reviewed and a more senior surgeon called or the technique changed unless completion is imminent.

Controlled area distance. A risk assessment of the use of the C-arm intensifiers was carried out in accordance with the requirements of the Ionising Radiations Regulations 1999. Measurements with a calibrated dose-rate monitor show that the scattered radiation dose falls off rapidly with distance from the equipment because of the low-energy beam (typically about 60 kV) and relatively small parts of the body in the beam such as hands and wrists. Beyond two metres it was found that personal protective equipment was of little benefit and is not recommended. It is, however, important for all persons to stay as far away from the beam as is practicable during exposures and to ensure that the hands and head of the operator are kept out of the primary beam.

Protective barriers. The surgeon, scrub nurse and anaesthetist should wear a lead rubber apron within the two-metre zone, but lighter aprons of 0.25 mm lead equivalent are sufficient. The skirt-and-top-apron format is the best for protection below the surgical table. The Radiation Protection Adviser does not consider that fixed barriers are necessary with mini C-arm intensifiers because of the rapid decline in radiation dose with distance. For the reassurance of patients when pregnant or of childbearing age, protection can be provided with a half lead shield over the lower abdomen to block scatter, although the radiological benefit is marginal.

Set-up geometry. The x-ray source should be kept as far from the patient as possible (30 cm minimum according to British Law) and the intensifier must be kept as close as is possible. This will reduce the entrance surface dose to the patient and reduce magnification of the image. The narrower field of 10 cm should be used whenever possible.

Monitoring. Previous dose measurements on staff using the Fluoroscan have shown that monitoring badges are not required if lead aprons are used. This is mainly due to the low scatter produced and the short overall screening times used on most patients.

Using a Fluoroscan mini C-arm system we have generated pilot protocols for use in the fixation of fractures with optimum screening time decided after auditing our Fluoroscan theatre log. The reassessment time functions as a concurrent and retrospective audit tool and is not meant as a dose limit to prevent the use of more radiation exposure on a patient where it is justified. An audit loop would be completed to validate this, particularly identifying individual and groups of patients in whom the reassessment time needs to be exceeded. We offer this protocol (Fig. 2) as an example for use with mini C-arm image intensifiers.

Conclusion
The ideal medical radiation exposure should give the best picture using the smallest practicable radiation dose. In our experience mini C-arm systems come closest to this ideal for surgery on the upper limb because of their basic design features, user-friendly nature and low emission levels.

Their use, however, can be optimised further by proper training, enforcing local rules, having protocols in place and careful auditing. This does not simply represent an ideal. Under IRMER 2000 it is now a legal requirement.

References

Internet resources