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Pulsed radiofrequency (PRF) therapy in spinal pain management: A direct approach to reduction in occupational radiation exposure

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Abstract
A method of optimising radiation protection methods for clinical staff was sought after temporary skin changes and radiation dose measurements suggested dose limits were being exceeded. Scatter radiation emitted from the patient, during the relatively new fluoroscopically guided pulsed radiofrequency (PRF) therapy procedures, was identified as the probable cause of this increased exposure. The aim of this study was to quantify the benefits of a secondary radiation barrier, in the form of customised re-usable radiation-resistant shields, in reducing radiation dose to clinical personnel. Sub-problems assessed were the possible technical difficulty involved in potential interference by the shield with field-of-view of the attending specialist and the risk of cross-infection. The objective was to reduce high occupational radiation exposure.

Materials and methods Thermoluminescent dosimeters (TLDs) and a ring dosimeter were used for dose measurements. A detailed log of clinical details was kept. A set of four customised shields were implemented and data collected on 275 lesions treated over six months. Summated procedural time was 97 hours.

Results Results demonstrated a 69% reduction in the amount of backscatter radiation reaching the neurosurgeon. Shields were practical to implement in 87.5% of procedures. Deep dose and thyroid dose results were within limits but suggested a higher than expected lens dose. No instances of disturbed field-of-view of the specialist, or of cross-infection, were recorded.

Conclusion This study concludes that the shields are effective to implement and achieve considerable reduction in scatter radiation dose to clinical staff. Further study into uses of the shields during other interventional fluoroscopically-guided procedures, and investigation into clinician lens dose, may be warranted.

Keywords
backscatter, shield, image intensifier, fluoroscopy

Introduction

Pulsed radiofrequency (PRF) therapy is an intraoperative procedure which was first introduced in South Africa in 2003. It is a non-ablative pain treatment [1] indicated in the management of spinal pain conditions, primarily nociceptive and neuropathic pain [2]. It is a minimally invasive, image-guided, percutaneous technique performed to interrupt afferent nociceptive pathways [3] in the region of the dorsal horn of the spinal cord, thereby modulating the flow of pain impulses at the so-called gate [4] through which these impulses pass to reach the brain. The target area is heated with pulses of high voltage radiofrequency, to a temperature of 42 degrees centigrade [5] via electrodes inserted into the bore of specialized needles placed under fluoroscopic guidance into the desired target point by the clinician. Needle position is then confirmed by electrostimulation [2]. Fluoroscopy is used to increase precision of the needles and confirm needle placement, as specific potential risks for these procedures include pneumothorax, and perforation of the spinal dura [6]. The conservative nature and low morbidity of PRF therapy, where indicated, provides a cost-effective and attractive option over invasive surgical intervention procedures [1].

Percutaneous injection techniques in the management of spinal pain have been performed for many years and were historically carried out without image-guidance [6]. Due to this history, certain healthcare schemes have been in dispute with healthcare service providers concerning the necessity for using fluoroscopic guidance during PRF therapy procedures, which cost approximately R15 000.00 today.

PRF therapy gained popularity and the number of PRF therapy procedures performed increased. Measured radiation doses received by clinical staff increased and instances of radiation dermatitis, nail growth retardation, and temporary hair loss, were noted on the forearms of the treating neurosurgeon, suggesting skin threshold doses of 2Gy [7] had been exceeded [8]. Consultation with the office of The Directorate Radiation Control of Belville, Cape Town, confirmed information that PRF therapy is not generally associated with high levels of dose to patients or long fluoroscopy times. In light of the physical signs of undesirable levels of exposure and the elevated occupational dose reports, the potential for radiation risk to medical personnel performing PRF therapy procedures was accepted for monitoring. Following monitoring, attempts to reduce individual radiation exposure would include rotation of staff. This option is not readily available in the current medical climate in South Africa because there is a shortage of medical specialists. Hence, a practical means of improving radiation protection for clinical staff during image-guided spinal pain management procedures, preferably without involving great increase in cost, would be desirable.

Background and rationale

Procedure and fluoroscopy times are known to decrease with operator experience [8]. Scatter radiation from the patient is the main source of occupational dose, particularly from fluoroscopically guided procedures [10]. Studies have shown that exposure is greatest to the hands and then

the eyes of interventionalists, according to Botwin as stated by Manchikanti [11].Best methods of applying treatment needles have been devised [11] and methods of improving radiation protection during various fluoroscopically guided procedures are still being investigated [12]. Exposure risk depends on procedure technique, training of the operator, and mode of fluoroscopy. An interventionalist must at all times have unhindered access to the patient, precluding the use of bulky shields [11]. It is difficult to extrapolate radiotherapy depth-dose data to a threshold for interventional radiation beam qualities to quantify actual absorbed dose for deterministic effects [13]. X-ray equipment made for performing interventional neuroradiology procedures needs to be optimized in terms of dose. It has been shown that a multidisciplinary approach to optimization and radiation protection of these procedures helps reduce deterministic effects [13].

Review of the operational protocol for PRF therapy procedures was undertaken to assess possible areas where existing radiation protection measures could be amended or adapted to reduce exposure. Pulse-mode fluoroscopy had been implemented thereby reducing exposure by up to 80% [9]. Dose reducing features, including intermittent fluoroscopy, collimation and last-image hold, have been utilized. Fluoroscopy times were in the region of one to two minutes per patient. The C-arm was positioned, during fluoroscopy, with the image intensifier (II) side up, or in an inverted position. When compared with measurements taken during tube-side-up fluoroscopy at the level of the eyes of the interventionalist, the former reveals both a significant isodose contour variation of a 60% decrease in dose rate [14], and a reduction in staff dose by a factor of three or more [15]. Certain distance factors relating to dose intensity could not be improved as the neurosurgeon was unable to alter his normal working position of being within a one meter (m) radius of the primary beam, and the height of the custom-made perspex patient bed was fixed. According to the "Golden Rules" of staff protection listed by the International Atomic Energy Agency (IAEA), the II must be kept close to the patient [15]. This enables the II to serve as a scatter barrier [10]. In the United States of America (USA), the II is classified by the Food and Drug Administration (FDA) as a primary radiation barrier [16]. As depicted in Figures 1 and 2, the separation between exit skin and intensifier, measured as 24 centimetres (cms), is notably greater than that generally achieved as optimum fluoroscopic technique. This separation is required by the neurosurgeon to insert and manipulate sterile needles under fluoroscopic guidance. The length of the needles are either 10 or 15 cms and are selected according to patient thickness and the expected depth of the lesion in the affected area. While the increased patient-II separation and the resultant image magnification had no negative impact on the neurosurgeon's field-of-view (FOV), attention was drawn to the possible negative influence this separation may have on scatter radiation and occupational exposure (Figures 2 and 3).

Joseph [16] states that for fluoroscopic energies, a significant amount of between 30% and 50% of forward scatter coming from the patient is propagated at 90 degrees from the primary beam. These scattered photons retain most of their energy after deflection. Together with multidirectional scatter, the overall exposure of a worker in close proximity to the patient, equates to standing in the primary beam itself [16]. Staff dose increases with volume of irradiated tissue [15]. The prevalence of significant back pain is associated with higher levels of body mass index (BMI) [17]. High BMI patients form the greater proportion of PRF therapy patients. The increased volume and depth of tissue, and higher intensity fluoroscopic beams required to achieve acceptable monitor image quality for high BMI patients, result in substantial increase in the level of scatter [15].

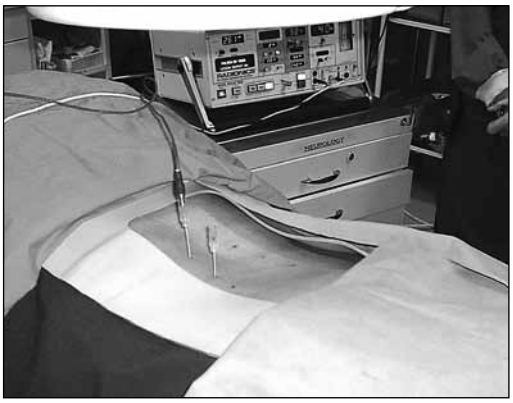

Figure 1: Shield S3 in position.

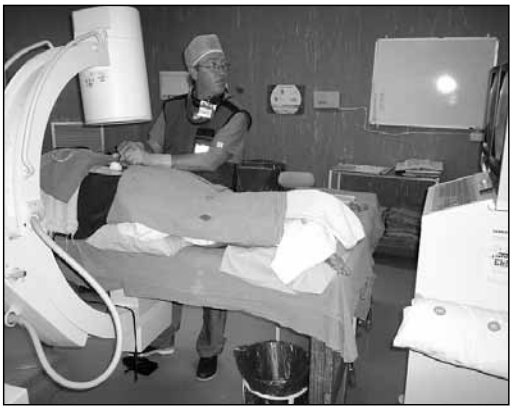

Figure 2: PRF therapy setup.

Figure 3: Shield S3 dimensions and dosimeter position.

The combination of these factors suggested greatly increased exposure risk to the neurosurgeon. A means of limiting exposure, by intercepting exit scatter from the patient before it reached the neurosurgeon, was desirable. Available literature provided clear guidelines on entrance dose rate limits and on dose reduction methods predominantly aimed at modifying the incident beam. Information on methods of reducing scatter in the uncommon setting of increased patient-II separation was scarce. In 2004, a new radiation protection system designed specifically to protect electrophysiology (EP) laboratory physicians and staff was introduced at the North American Society of Pacing and Physiology (NASPE) Heart Rhythm Society 2004 meeting in San Fransisco, USA. The system comes as stand-alone shields or full drapes [19]. These drapes are disposable, sterile, and lead-free. In tests, they were shown to absorb 55% to 97% of the dose normally received during EP lab procedures [12, 18, 19]. These products are not available in South Africa but can be imported. Current landed cost in South Africa per disposable drape would mean an approximate 40% increase in cost per procedure. In applying the ALARA (as low as reasonably achievable) principle in South

Africa, economic and social factors must be taken into account [20]. The piloting of South Africa's National Health Insurance in April 2011 [21], may potentially result in significant increase in patient referrals for PRF therapy and increase in cumulative dose rate for clinicians.

Applied to the PRF therapy setting, the shielding technique used in deep x-ray (DXR) radiotherapy underpins the principle used in this study. DXR therapy is delivered through fixed length applicators of different field size applied onto the patient's skin. Additional limitation of the treatment field is achieved by the placement of lead cut-outs in apposition to the skin. The cut-outs match applicator field size and protect adjacent skin or sensitive structures by absorbing scattered radiation [22].

Aims and objectives

This study aimed at quantifying the benefits of implementing a secondary radiation barrier in the form of a customised, re-usable, radiation-resistant shield, positioned on the patient so as to absorb scatter radiation normally incident on the neurosurgeon. A sub-problem was the possible technical difficulty involved in potential interference by the shield with field-of-view of the attending specialist.

Materials and methods

All patients undergoing pain management procedures done under fluoroscopic guidance, for both diagnostic and therapeutic reasons, were included in this study. Procedures were classified into types, and all procedures done at the hospital were performed by the same neurosurgeon. Ethics and colleague approval for this study was obtained. Informed consent for the procedure was obtained as part of the detailed consent required for operating theatre procedures. Subjects' identities were not recorded.

A set of four customized radiation-resistant shields of 0.25mm lead (Pb) equivalent material were designed, 38cms square, each with a different shaped cut-out, expected to accommodate the different areas of interest with adequate view of adjacent bony anatomy. Cut-out shapes were designed from measurements taken from radiographs of an average subject. The suitable shield chosen for the procedure was positioned to lie on the upper side of the patient during the procedure and protected with sterile covers. As depicted in Figure 3, cut-out shapes were designed to be off-centre to allow extra protection on the side of the clinician. The implemented shield was cleaned and disinfected between consecutive patients.

The X-ray machine used for fluoroscopy was a Siemens Siremobil Compact Unit. Fluoroscopy time and fluoroscopy automatic exposure settings were recorded as the machine was not equipped with a dose area product (DAP) meter. The machine was operated by registered radiographers under authorization of the treating specialist with no attempts to influence standard safe fluoroscopic technique. Fluoroscopic time was displayed and recorded in units of 0.1 minute and fluoroscopic mode was stabilized to pulsed fluoroscopy.

A Radionics RFG-3C Graphics RF Lesion Generator System was used for the PRF therapy, with standard operating voltage of 45 volts, temperature of the radiofrequency needles 42 degrees Centigrade, and impedance 450-500 ohm. Pulsed radiofrequency therapy was applied for 120 seconds per target area.

All personnel within a 3m radius of the primary beam wore lead rubber aprons. The neurosurgeon additionally wore a 0.25mmPb equivalent thyroid shield and radiation-resistant gloves which specify a 49% skin dose reduction in a 80kV beam according to BS EN 388 Mechanical Hazard testing.

Dosimeters supplied by the South African Bureau of Standards (SABS) Radiation Protection Service (RPS) were used to measure personnel dose and monthly dose reports were provided.

Four additional dosimeters, named T1 to T4, were used for this study. T1, T2 and T3 were thermoluminescent dosimeters (TLDs) and one, named T4, a ring dosimeter. The position of dosimeters T1 and T2 is shown in Figure 3. T1 was placed on the patient-side of the shield to measure radiation incident on the shield, having been generated from within the patient. T2 was placed on top of the shield, to measure radiation transmitted through the shield. Measuring position was marked onto all four shields of the set, to ensure that T1 and T2 positions did not overlap, and that consistency and replication of measuring position was maintained. T3 was worn by the neurosurgeon at thyroid position, over the thyroid shield. T4 was worn by the neurosurgeon under the radiation-resistant gloves.

The assigned radiographer recorded a detailed clinical data sheet for each day. Radiation dose to circulating nurses was not measured, DAP meter readings were not taken, and radiation-resistant glasses were not worn. Figure 2 depicts a lumbar PRF therapy setup. A monitor view of a treatment area, effectively limited by the shield during dynamic needle placement, for the treatment of two unilateral target areas, is depicted in Figure 4.

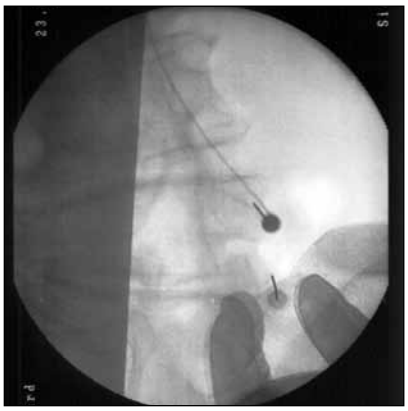

Figure 4: Monitor view.

Results

Data were collected on 275 instances of fluoroscopically guided pain management procedures carried out over a period of six months under controlled settings. The total procedural time was summated to be 97 hours. The shields were practical to implement during 87.5% of procedures, with 22 instances proving unsuitable. Of the 22 instances, three were PRF therapy procedures performed in the upper cervical spine region which required either lateral beam projections, or lateral patient position. Procedural time spent repositioning the shield due to interference with neurosurgeon field-of-view amounted to less than 1%. A shield effectiveness showing a 69% reduction in radiation emitted from the patient was achieved.

Total fluoroscopy times were compared with deep dose, T1, T2 and T3 measurements using a secondary y-axis as presented in Figure 5. It was observed that lesion numbers correlated closely with fluoroscopy times. Zero seconds was recorded by the fluoroscopy timer for 'flash' exposures which were used to check positioning. One session of 12 consecutive 'flash' exposures recorded zero fluoroscopy time. No instance of cross-infection risk was observed or recorded. Over the six months of this study, total deep dose received by the neurosurgeon, at normal operating distance of within one meter of the primary beam

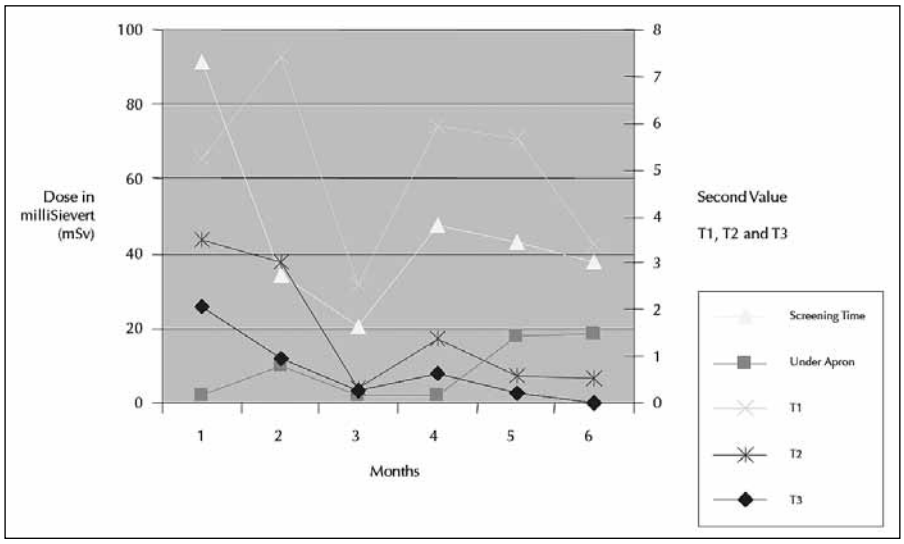

Figure 5: Relationship of fluoroscopy time with measured dose.

and measured under the lead apron, was recorded as 4.2 mSv; thyroid dose outside the thyroid shield as 4.2 mSv, and extremity dose under radiation-resistant gloves as 15.1 mSv. The respective deep dose, to attending scrub sister, and radiographer, was less than 0.2 mSv.

Discussion

The dose data in this study represent updated safe practise which is performed at the centre where this study was undertaken. The use of the shields yielded considerable limitation of radiation exposure to clinical staff. This factor, combined with the benefit of wearing radiation-resistant gloves, also suggests a considerable reduction in extremity dose to the attending clinician. Whilst being within dose limits for the thyroid, the 4.2 mSv deep dose measured outside the thyroid shield in six months suggests a possibility that lens' doses may exceed the 5 mSv annual dose limit. The 4.2 mSv under-apron deep dose in six months provides an average of 0.7 mSv per month which is within the average monthly limit of 1.5 mSv. The 69% reduction in scatter radiation achieved through use of the shields compares closely with the known 65% attenuation of the useful beam by 75kVp x-rays through a 0.25mm Pb equivalent material [16]. Radiation dose measurements for the rest of the attending clinical staff during this study fell well within dose limits.

For the geometry of this study, scatter radiation from the patient follows the rules of an extended source [16]. Inverse square law is thus not used to extrapolate T1 and T2 measurements to determine doses received by the neurosurgeon to radiosensitive structures in the region of the head. In forming a model of dose for PRF therapy procedures, fluoroscopy times would best be correlated with the number of lesions treated rather than with the number of procedures done as multiple lesions may be treated per procedure. The effect of unmeasured fluoroscopy time from repeat short burst fluoroscopy exposures suggests a higher dose measurement by the TLDs in relation to the recorded fluoroscopy times. Images produced by short burst exposures do not register a reading on the C-arm timer, as they are shorter than the minimum time which the machine is set to record. With fluoroscopy time and exposure settings being the most accurate indicators of dose in older equipment without DAP meters, the influence of 'flash' exposures on absorbed dose may be difficult to define.

Factors affecting this study

Since the results of this study, in respect of skin dose limits, differ from that expected from the initial reported changes, it is appropriate to consider factors which might be responsible for this difference. There are a number of explanations. Firstly, manipulation of needles took considerably longer at the outset of performing PRF therapy procedures, resulting in longer fluoroscopy times, until more efficient placement was achieved. Secondly, this study did not take into account the concurrent radiation dose received by the clinician from a second medical facility where he had performed an approximately equal number of PRF therapy procedures before the inception of this study; and thirdly, radiation-resistant gloves were not used prior to the inception of this study.

Limitations of this study

Medical physicist guidance was not provided and comparative representation of scatter intensity, using isokerma contour patterns, was not performed. Inclusion of this information would provide a more objective view of the differences in scatter intensity between various patient-II separations. Shields of differing attenuation properties were not studied. Shields constructed of 0.35mm Pb equivalent material would achieve greater reduction of scatter.

Conclusion

The adoption and use of these shields provides a cost-effective, simple, and easy to implement means of reducing occupational radiation exposure and improving on radiation protection methods for clinicians involved in fluoroscopically-guided pain management procedures. Further study into the implementation of these shields for other interventional applications using fluoroscopy may be warranted. Radiation dose to sensitive structures in the region of the head may be higher than expected, also warranting further study.

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