Quantitative assessment of the radiation hazards and risks in sentinel node procedures

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Abstract. Sentinel node localization using an injected radiopharmaceutical and a gamma probe is performed in many hospitals. Employers have a duty to give appropriate training to staff who may not have been previously formally trained to work with unsealed radioactive sources. A study was performed to assess hazards and risks at all stages of the localization procedure. Whole body doses and finger doses of imaging, surgery and pathology staff were determined. The activity remaining in the tumour specimen, excised nodes and disposable waste from the operating theatre was measured. Any radioactive contamination of the operating theatre and equipment was also ascertained. All results were then assessed in light of current UK radiation protection legislation for the protection of staff and members of the public.

Results showed that radiation doses are low and no additional procedures are required for protection of staff, provided the usual procedures for biohazards are in place. However, an information sheet has been prepared for the reassurance of staff, and theatre swabs may need to be stored temporarily before disposal. Injecting and imaging on the day before surgery is preferred, compared with injecting and imaging before surgery on the same day, since this gives lower radiation doses to staff, lower activity in excised specimens and waste, and provides a higher count rate giving better image quality.

Lymphatic imaging and sentinel lymph node (SLN) localization was initially developed for nodal staging of malignant melanoma by Morton et al [1]. The SLN is the first lymph node that drains from the tumour, and there may be more than one depending upon the lymphatic drainage pattern. In patients with melanoma, it has been found that if SLNs are pathologically negative for metastatic disease, the remaining lymph nodes are also likely to be negative [2, 3]. Hence by locating and analysing SLNs, further removal of the lymphatic drainage may become unnecessary. This then avoids complications such as oedema associated with removal of lymphatic drainage. The value of the technique is now being investigated in the treatment of breast cancer as part of the Axillary Lymphatic Mapping against Nodal Axillary Clearance (ALMANAC) trial [4] to potentially prevent unnecessary removal of the axillary bed, and is also being investigated in other carcinomas.

To locate SLNs, the patient receives an injection of radioactive colloid, with a quarter of the volume injected at each of four points around the tumour. The patient may then undergo lymphoscintigraphy to visualize the lymphatic drainage of the tumour and the position of lymph nodes before continuing to surgery for removal of the breast cancer. During surgery, a gamma probe is used to detect any concentrations of radioactivity and hence locate the SLNs. SLNs are then removed as part of four-node sampling or axillary clearance, and analysed histopathologically. It is hoped that, in the future, initially only sentinel nodes will be removed and the patient return to theatre and undergo further lymphatic removal only if these nodes are found to be histologically positive.

Although operating theatre staff may have some experience of working with ionizing radiation, e.g. with X-rays in theatre, many will not have worked with unsealed radioactive material. The surgeon, and his/her fingers in particular, come into close contact with tissue containing a concentrated though small amount of radioactivity. If sentinel node location is carried out at a hospital without a nuclear medicine department, there may not be staff on site with the expert knowledge to advise on suitable precautions.

Approaches to radiation protection are fairly consistent throughout the world. The Recommendations of the International Commission on Radiological Protection [5] have been adopted by many governments, including the European Community and the UK government. Three basic principles of radiation protection are advocated: justification, optimization and dose limitation. The justification for the use of radioactive material in sentinel node localization is being addressed in the ALMANAC trial. Optimization and dose limitation (if applicable) in terms of any special measures that may be required are addressed in this paper.

A number of papers [6–11] have indicated, either by measurement of specimen activity or exposure dose rate, that risks are minimal. However, there appears to be no comprehensive set of exposure and specimen activity data covering both same and next day surgical excision. Such data can be compared with relevant national guidance.

In assessing whether special measures are needed to protect members of staff or the public, and for compliance with UK legislation, all aspects of the sentinel node procedure were examined with regard to radiation protection. External dose rates, levels of contamination and specimen...
activity levels were all measured to ascertain whether controls were needed to protect staff and the public under the Ionising Radiation Regulations 1999 (IRR99) [12], and to protect the public and the environment under the Radioactive Substances Act 1993 (RSA93) [13]. IRR99 has a requirement for a prior risk assessment of any new activity involving work with ionizing radiation. This was not formally required under its predecessor, IRR85 [14]. This assessment requires the nature and magnitude of the risks to employees and other persons to be evaluated. This work enabled this centre to quantify the risks, and the data will help other centres considering this type of activity to carry out a suitable prior risk assessment.

Consideration should also be given to the regular calibration of the gamma probe and accounting procedures for any radioactive test sources, although this was not part of this study. Requirements under IRMER 2000 [15] are also not considered. The medical physics expert and radiation protection advisor (RPA) should be consulted on these two matters.

**Materials and methods**

**Sentinel node protocol**

The patients followed had been recruited into the ALMANAC trial [4] and clinical procedure therefore followed the specified protocol. $^{99}$Tc$^{99m}$-Nanocoll (Amersham Healthcare, Buckinghamshire, UK), a radiolabelled microcolloid, was employed as the agent for visualization of lymphatic drainage and for identification of sentinel nodes by uptake in the nodes. A total activity of 20 MBq was injected peritumourally for patients undergoing breast surgery the same day. For patients undergoing surgery the following day, 40 MBq was injected to ensure adequate activity for intraoperative sentinel node detection. Four injections each of 0.5 ml were made around the tumour. These injections may be subcutaneous or intradermal, according to local practice.

Patients were imaged in a supine position on a gamma camera (Toshiba, Japan, GCA-7100A) immediately post injection to visualize the lymphatic drainage, and at 3 h post injection to visualize sentinel node uptake. Anterior, anterior oblique and lateral views were acquired for 300 s with a 256 × 256 matrix and a high resolution collimator. A Cobalt-57 ($^{57}$Co) flood source (nominal activity 740 MBq) was placed posteriorly or laterally to the patient to provide an outline of the body to assist in localization of sentinel node uptake. Images (Figure 1) were sent to theatre to help locate sentinel nodes. The position of sentinel nodes was also marked on the skin of the patient. This was performed using a $^{57}$Co point source (nominal activity 4 MBq) on the view producing the clearest image of the nodes, usually the anterior oblique. The majority of sentinel nodes were located in the axilla but a small number were found in the internal mammary chain.

At surgery, after induction and draping, the patient was also injected with patent Blue V dye subcutaneously around the tumour. The lymphatic vessels were readily visualized with the dye and those leading to the sentinel node identified. The location and excision of sentinel nodes took place before lumpectomy or mastectomy, unless close siting of the node and tumour led to an excessive radiation background at the site of the node. The later removal of the tumour after excision of the sentinel nodes helped maintain patency of the lymphatic vessels and retention of the dye in the vessels. The sentinel node was detected using a small hand-held collimated radiation detector (Navigator GGS RMD Inc., MA, USA (USSC) with 14 mm cadmium telluride probe) connected to a ratemeter/scaler timer (Figure 2). The position of maximum count rate was located and the counts in a period of typically 10 s recorded. In the ALMANAC [4] trial protocol, a sentinel node must have a count at least 10 times the background count, have taken up blue dye or have taken up both radioactivity and blue dye. The sentinel node was excised and counted ex vivo with the probe to confirm it was radioactive. The gamma probe was then used to explore the axilla for further sentinel nodes.
and these were recorded and excised in the same way. Axillary surgery was then completed by either four node sampling or axillary clearance. Surgical removal of the tumour then took place.

Post-surgery procedures

Before the excised tumour was sent to the pathology department, it was radiographed (specimen radiography) to check that there were adequate margins of normal tissue surrounding the tumour. The film image was returned to theatre to enable the surgeon to check the adequacy of the margins and excise further tissue if necessary before the operation was concluded. Swabs were collected and counted in the conventional way but kept separate and labelled as radioactive waste. These were taken to the nuclear medicine department for measurement of their radioactivity and storage before disposal.

The excised tumour and nodes were then sent to the pathology department for histopathology, where, they were first fixed by embedding in paraffin wax (Figure 4). The fixing was left to stabilize for at least 24 h before further specimen preparation took place. During this period, $^{99}$Tc-m activity decayed considerably and any radiation hazard to pathology staff only arose from initial handling for fixation.

Counting methods

The procedure was critically examined to identify where hazards might arise. Those identified were:

- whole body dose to nuclear medicine staff,
- finger doses to nuclear medicine staff during injection,
- whole body doses to theatre staff,
- finger doses to surgeons,
- whole body dose to specimen radiographer,
- contamination of surgical instruments,
- retained activity in surgical swabs and on surgeons’ gloves, and
- external dose hazard to pathology staff.

Whole body doses to the nuclear medicine staff and specimen radiographer were assessed using standard NRPB whole body dosemeters containing thermoluminescent material. A Szintomat scintillation dose rate meter, Autoness, Germany, was used to measure the dose rates at 30 cm from each patient immediately prior to surgery. Whole body doses of the staff groups in theatre were then estimated using the inverse square law and the observed time and distance from the source of radioactivity.

Finger doses of staff involved were measured using NRPB finger stalls containing thermoluminescent dose meters (TLDs) in which thermoluminescent powder was situated at the finger tip. These were worn on the index finger by the injector, surgeon and pathologist.

Retained activity in the specimens was measured by counting the sentinel nodes and the tumour following excision and prior to pathology. For excised nodes, a well counter (EG&G Ortec, MD, USA) was used. The tumour specimens were counted on a gamma camera (Toshiba, Japan, GCA-7100A). Activities in MBq were determined by also counting “standards” of similar geometry containing known activities measured in a dose calibrator.

The level of radioactivity in the waste produced in the operating theatre was assessed by collecting swabs and removing them to the Nuclear Medicine Department for counting in the well counter. They were also weighed to obtain a value of MBq g$^{-1}$.

To assess the level of contamination at the end of the theatre session, the surgical instruments used in the operation were monitored using a contamination monitor (Mini monitor series 900 with 44B scintillation probe, Perspective Scientific, London, UK).

Results

Whole body doses

To calculate whole body doses of theatre and pathology staff, an estimate of the time and distance from the source of radioactivity throughout the surgery or sample preparation had to be established. Estimated values based on observation are shown in Table 1.

Using the times and distances stated in Table 1 and the measured dose rates given in Table 2, estimates of whole body doses were obtained. For comparison, the maximum
Table 1. Maximum times and typical distances from the source (tumour) for calculation of whole body doses to various staff members

<table>
<thead>
<tr>
<th>Staff</th>
<th>Time (min)</th>
<th>Distance (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Pathologist</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 2. Dose rates at 30 cm from the tumour site immediately prior to surgery

<table>
<thead>
<tr>
<th>No. of cases</th>
<th>Measured dose rate at 30 cm (μSv h⁻¹)</th>
<th>Maximum calculated dose rate at 30 cm* (μSv h⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next-day procedure</td>
<td>3</td>
<td>0.2–0.5</td>
</tr>
<tr>
<td>Same-day procedure</td>
<td>3</td>
<td>1.6–1.9</td>
</tr>
</tbody>
</table>

*Calculated from the injected activity and assuming a point source.

calculated dose rates, assuming a point source and total retention in the tumour, are also given.

The measured whole body doses of the nuclear medicine staff and specimen radiographer, along with estimated doses of other staff involved in the sentinel node procedure, are tabulated in Table 3. In all cases, the worst case is quoted.

Cumulative finger doses

The finger doses received by all staff groups (Table 4), excluding the surgeon, are below the threshold dose measurable with the TLDs used (0.1 mSv). The surgeon agreed to wear his TLDs for a prolonged period of time so a better estimate of finger doses could be obtained. In this case, it is the left hand that has received the higher dose although the surgeon is right handed.

Table 3. Highest whole body doses (μSv) received by staff per study

<table>
<thead>
<tr>
<th>Staff</th>
<th>Dose per case (μSv)*</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Same day</td>
<td>Next day</td>
</tr>
<tr>
<td>Nuclear medicine staff</td>
<td>&lt;0.2</td>
<td>&lt;0.2</td>
</tr>
<tr>
<td>and radiography staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeons</td>
<td>1.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Nurses and other theatre staff</td>
<td>0.2</td>
<td>0.05</td>
</tr>
<tr>
<td>Pathology</td>
<td>2.5</td>
<td>0.6</td>
</tr>
</tbody>
</table>

*aNo account has been taken of the radioactive decay that will have occurred since the start of the operation.

Table 4. Cumulative finger doses (mSv) and dose per case (μSv)

<table>
<thead>
<tr>
<th>Staff</th>
<th>No. of cases</th>
<th>Cumulative finger dose (mSv)</th>
<th>Dose per case* (μSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Left hand</td>
</tr>
<tr>
<td>Surgeon</td>
<td>32 (27 next day)</td>
<td>0.4</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Pathologist</td>
<td>11</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Injector</td>
<td>8</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>

*aWorst case assuming that all cases were next-day cases with administered doses of 40 MBq.

Table 5. Specimen activity (MBq) remaining in the tumour and nodes

<table>
<thead>
<tr>
<th>No. of cases</th>
<th>Specimen activity (MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour (range)</td>
<td>Nodes (range)</td>
</tr>
<tr>
<td>Same day</td>
<td>3</td>
</tr>
<tr>
<td>Next day</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 6. Activity (MBq) in the swabs

<table>
<thead>
<tr>
<th>No. of cases</th>
<th>Activity (MBq) (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same day 5</td>
<td>0.2–1.9</td>
</tr>
<tr>
<td>Next day 10</td>
<td>0.001–0.1</td>
</tr>
</tbody>
</table>
four half lives; 40 MBq having decayed to 2.5 MBq compared with more than 10 MBq for the same day cases where surgery will take place within 6 h of radioactive agent injection. Doses at worst are 2 μSv per case, which, for reassurance purposes, is comparable with the additional cosmic radiation dose received from a 30 min air journey. Measured doses to staff reported by other authors [6, 8, 9, 11] are of the same order of magnitude (μSv per case) but vary depending on activity injected, time between injection and surgery and the assumed time and distance from the patient or specimen for the relevant staff member. The dose limit under IRR99 [12] for employees exposed to ionizing radiation is 20 mSv per annum and clearly no member of staff will approach 10% of this (or even the 1 mSv dose limit for a member of the public). Routine whole body monitoring of staff is therefore not required.

Whole body doses are also not likely to cause a problem should a member of staff be pregnant. IRR99 [12] Regulation 8 states that, after the employer has been notified of pregnancy the equivalent dose to the foetus shall be no more than 1 mSv for the remainder of the pregnancy. This is equivalent to 1.3 mSv to the surface of the abdomen for 99mTc. There is, however, an emphasis in Regulation 14 (information, instruction and training) for the employer to inform the employee of any risk to pregnant staff. This work shows that there is likely to be minimal risk to pregnant pathology or nursing staff, particularly if surgery takes place on the day after injection. Female surgeons are unlikely to receive significant doses but the situation may require careful consideration if the same-day protocol is followed.

The fingers of the surgeon during surgery and those of the pathologist may be very close to the radioactivity contained in the tumour, but the finger monitoring results (Table 4) demonstrate that the dose per case, although higher than the whole body dose (as expected from the inverse square law) is very small and less than 13 μSv per case. Workload, even at 150 cases per year, is unlikely to result in finger doses approaching the annual dose limit of 500 mSv. Doses were measured to be higher for the left hand of a right-handed surgeon. This is not unexpected as the left hand is used to hold the tissue surrounding the tumour and is therefore closer to the radiation source. Doses for the injector were of the same order of magnitude as the surgeon, and very small. Even if the surgeon injects the material, results demonstrate that finger monitoring is unlikely to be required. Doses were typically measured to be below the threshold of sensitivity for the TLD (0.1 mSv) and so doses are likely to be less than the maximum quoted. Other authors [6, 8, 9, 11] have measured finger doses and the results, although of the same order of magnitude, are very dependent on the method used.

The activities in the tumour specimens and nodes (Table 5) are also significantly lower for next-day cases than same-day cases. The activity measured in the samples is of the expected order of magnitude, allowing for decay of the injected activity and assuming that not all of the activity remains in the tumour. Summing the activity measured in the tumour samples and the swabs used in the operation accounted for up to 60% of injected activity for same-day cases. This is expected as up to 50% of activity will have decayed between injection and surgery. Waddington et al [9] measured activity in samples at two different time periods between injection and surgery and obtained results similar to those in Table 5.

Consideration was given to the movement of the tumour tissue and nodes between theatre, specimen radiography and pathology. The whole body and finger dose received by both porter and specimen radiographer in respect to the specimens is minimal, and the specimens should be treated as a biohazard rather than a radiation hazard.

Loss of samples during movement was also considered. Under IRR85 [14], which was in place when this work was started, loss of tissue with 5 MBq of 99mTc would require notification to the HSE and a contingency plan had to be in place for such an event. This level for 99mTc under IRR99 [12] is now 100 MBq and a contingency plan is no longer required.

In some circumstances, the specimen may need to be transported to a pathology laboratory remote from the operating theatre. In this case the sample will have to be transported under conditions that comply with the Road Transport Regulations 1996 [16]. From the measured activity in the specimens, both same-day and next-day specimens can be transported as excepted packages. For this, the container must be able to withstand routine transport conditions, the package will have to be identifiable as radioactive if opened and must have appropriate transport documentation. There is no legal requirement for driver training under the Carriage of Dangerous Goods Regulations 1996 [17], although local instruction may be of benefit. This is at the discretion of the employer. External marking of the vehicle is also not normally required. The Nuclear Medicine Department should be consulted about driver training, although nuclear medicine staff may carry out the training.

Clinical waste (swabs used in surgery) varied in activity from 0.2–1.9 MBq for same-day surgery and 0.001–0.1 MBq for next-day surgery (Table 6). Waddington et al [9] and Cremonesi et al [11] measured similar activities in swabs collected in theatre from surgery performed the day after initial injection. Under the hospital exemption order to the Radiactive Substances Act (RSA93) [13], the waste can be disposed of in an incinerator if it is less than 0.4 MBq. Hence, swabs from same-day cases would need to be stored but those from next-day surgery can be disposed of in the same manner as clinical waste. If, however, the hospital has authorization to store and dispose of radioactive waste under RSA93 [13], they can only incinerate items that are below 0.4 Bq g⁻¹. Consequently the waste from same-day surgery cases will need to be stored for up to 3 days before disposal. The waste from next-day cases will need to be stored for 2 days. Swabs need to be double bagged, labelled “radioactive”, and stored in a safe, secure place. Radioactive labels must be removed before disposal, once they are “inactive”. For this reason it is probably easier to store the swabs in the Nuclear Medicine Department rather than the theatre. The dose rate from swabs is minimal and, like the specimens, is a biohazard rather than a radiation hazard.

No detectable activity was measured on most of the surgical instruments using the contamination monitor. A few items that had come into contact with patients’ blood had activity on them. This was measured to be less than 30 Bq cm⁻² when measured over a 10 cm² area. Guidance
in IRR85 [14] suggests using a derived working limit for surface contamination of 300 Bq cm\(^{-2}\) averaged over 100 cm\(^2\) for \(^{99}\)Tc\(^{m}\). Guidance has not yet been published to IRR99 [12], but it is expected that any levels for contamination of surfaces will not be lower than this. Contamination of the theatre and instruments is not therefore a concern. Decay and cleaning in the hospital’s sterile supplies unit will adequately remove any activity on the instruments or equipment. Owing to the biohazard in theatre, staff wear gloves and other protective clothing. This will prevent any personal radioactive contamination.

Other regulations in IRR99 [12] that affect this work include notification of the work to the HSE under Regulation 6, prior risk assessment under Regulation 7, designation of areas under Regulation 16 and local rules under Regulation 17.

It is necessary under IRR99 [12] to notify the HSE that work with unsealed radioactive material is being carried out if it involves activities greater than 10 MBq or 100 Bq g\(^{-1}\) (Regulation 6). This has implications for some hospitals. If a hospital is already using radioactive substances, the HSE will probably already have been notified. If a hospital uses radioactive material for the first time, notification may be necessary.

Sentinel node work does not have to be performed in a radiation controlled area since the external dose rates are low and there is little or no risk of radioactive contamination. However, the local RPA may take a different view and should be consulted. There is also no legal requirement for local rules or appointment of a radiation protection supervisor. However, staff should be given adequate information regarding the risks to which they may be exposed, particularly as there may be concerns about radioactivity in the event of pregnancy. This may be addressed in local rules or an information sheet. A basic information sheet has been written at the Royal Surrey County Hospital, which is proving invaluable in the theatres. It explains the whole body doses in the context of other radiation risks, the risks of contamination and procedures for dealing with clinical waste.

**Conclusion**

From radiation protection considerations, surgery on the date after dose administration and imaging is preferred. This will give rise to better quality images but result in the least dose to staff and reduce activity in samples and waste. This is in keeping within the “as low as reasonably achievable” principle of doses [5]. Any hospital considering this work should consult their RPA about these matters. They may find the data from this work useful in carrying out a prior risk assessment in consultation with the surgical team.

**References**