RADIATION PROTECTION OF THE WORKERS IN RADIOGUIDED SURGERY OF BREAST CANCER

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1. INTRODUCTION

The methods of nuclear medicine are increasingly used to complement standard diagnostic examinations (echography and mammography) with the aim of facilitating conservative surgery in breast cancer[1]. Notable among these are the *radioguided detection of the sentinel lymph node* (SN) and the *radioguided localization of occult lesions* (ROLL)[2]. The SN technique is used in small-size (T1-T2) breast carcinoma and involves the identification, removal and immediate histological examination of the first lymph node draining the area containing the tumour; if the histological examination is negative the total armpit dissection is not necessary. The purpose of ROLL is to localize non-palpable breast lesions and to facilitate their removal during surgery, replacing the established hook wire method[3]. These two new methods are based on the use of particles that, because of their size, are either trapped at the injection site (ROLL), or move from the point of injection into the lymphatic ducts, to be trapped into the SN. Specifically, particles of colloidal human serum albumin are labelled with low activities of ^{99m}Tc and are inoculated into the breast lesion in the case of ROLL, or close to it in the case of SN biopsy. Subsequently, a hand-held γ−ray detecting probe is used to locate the lesion or the SN as a hot spot and guide its surgical removal[4,5]. The aim of this work is to present dosimetric evaluations of patients and hospital personnel involved in these techniques, and to determine whether specific radiation protection procedures are required.

2. METHODS

Administration of radiopharmaceutical and imaging - Fifty patients with non-palpable breast lesions undergoing ROLL, and 50 patients with breast cancer scheduled for SN intra-operative biopsy were enrolled in this study. Patients underwent surgery the day after injection of radiopharmaceutical. For SN biopsy, colloidal particles of human albumin of size range 0.2-1.0 μm, labelled with approximately 11 MBq of ^{99m}Tc, were injected in 0.2 ml close to the tumour. In ROLL, macroaggregates of human albumin of size range 10-150 μm, labelled with approximately 11 MBq of ^{99m}Tc, were injected directly into the lesion under radiological (mammography with stereotactic procedure) or US - guide. In order to determine the position of the first lymph node draining the tumour area (i.e. the SN), scintigraphic examinations were performed by a γ-camera. Oblique-anterior views of the breast with the detector very close to the armpit were acquired. A ^{57}Co point source was then used to mark the projection of the SN on the skin. To check the presence of a single radioactice spot in ROLL, anterior and lateral static images of the breast were acquired. Additional images in the same projections were obtained three hours later, if necessary.

Dosimetry of patients and hospital personnel - Absorbed dose and air kerma rate measurements were carried out using thermoluminescent dosimeters (TLD) properly calibrated and an ionisation chamber (450 P Victoreen, USA), respectively. *Patients*: After injection, TLDs were attached to the patient's skin over the injection site, the SN and healthy tissue (abdomen and the other breast) and were removed prior to surgery (16 h p.i.). The values measured by the TLDs give the absorbed doses in correspondence of the cutaneous projection of the activity in tissues. The air kerma rate was measured immediately after injection and before the operation (16 h later), over the injection site (at 0 cm, directly on the patient's skin) and at distances of 20, 50 and 100 cm from the patient. These values were compared to air kerma rates determined after bone scintigraphy (injection of 740 MBq ^{99m}Tc-methylene-diphosphonate) and thyroid scintigraphy (150 MBq of ^{99m}Tc-pertechnetate) performed on other patients. *Hospital personnel:* In order to evaluate the dose to the hands of the surgeons, a ring containing a TLD was given to them to be worn during all the surgical interventions performed over the period of approximately one month (8-10 SN or ROLL operations performed weekly by each surgeon). However, it proved impractical for the surgeons to wear the ring, as it could not be sterilised: for this reason, only a few dosimetrical values could be collected, showing dose values just a little above the background. We therefore decided to estimate the absorbed dose to the surgeons' hands by measuring the air kerma rate 20 cm from the injection site during surgery and multiplying this value by the total time spent by the surgeons for performing the interventions. Air kerma rates were also used to evaluate the absorbed doses to the pathologists and operating room nurses; for this purpose we estimated the mean duration of surgery and histological examination as 1 hour and 15 minutes, respectively.

Surgical technique and use of γ –ray detecting probe - A γ−detecting probe (Pol.hi.tech, Italy) calibrated with a 20% energy window centred at 140 keV was used during surgery to locate radioactivity, by manually scanning the region of interest. In the ROLL technique, the non-palpable lesion is identified as the region of highest count-rate ("hot spot") and the surgical incision is made around this site, in tissues where the count-rate has fallen to zero. In SN biopsy, the SN in the armpit is also identified with the probe, and a 2-3 cm incision is made to access the node and remove it, using the probe whenever necessary to guide this process. Residual activity on surgical instruments and removed tissues in the operating room was assessed using a γ−ray detector (NaI crystal, well counter geometry).

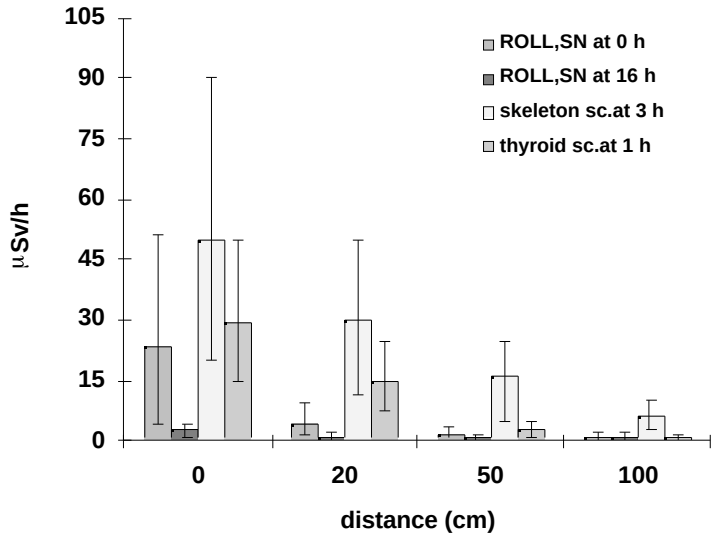
3. RESULTS

Imaging and patient dosimetry - The comparison of early and late images has demonstrated in all patients the presence of the radiotracer in the injection site and in the SN only, indicating that the biological half-life of the tracer particles in tissues can be considered infinite. The mean uptake ratios in tissues observed from the images obtained in 50 SN biopsy patients and 50 ROLL patients resulted as follows: 1300 for the injection site/ background ratio (range: 100–6500, 100 patients); 0.10 for the SN/injection site ratio (range: 0.005–0.110, 50 patients); 50 for the SN/background ratio (range: 5–200, 50 patients). The absorbed doses to patients, with percentage standard deviation and range, are shown in Table 1. The large ranges are due to the great variability in lymph node and tumour size. We did not distinguish between ROLL and SN biopsy patients in assessing the absorbed dose, as the activities of the injected material were approximately the same in both procedures.

Table 1. Absorbed doses in tissues after the administration of ~11 MBq ^{99m}Tc-labeled tracer (mean values ± %standard deviations and ranges in 50 SN biopsy and 50 ROLL patients)

Region	Mean dose (mGy) ± %SD	Range (mGy)
Sentinel node (50 patients)	0.45 ± 55 %	0.20 - 0.75
Injection site (100 patients)	8.50 ± 110 %	0.80 - 30.0
Abdomen (100 patients)	0.14 ± 70 %	0.02 – 0.32
The other breast (100 patients)	0.90 ± 170 %	0.05 - 3.25

Evaluation of absorbed dose to personnel. The histogram in Fig. 1 shows the air kerma rates measured at various distances from patients immediately after injection (0 h) and before surgery (16 h). Air kerma rates measured after injection of activity for bone and thyroid scintigraphy are also shown. From the air kerma rates the absorbed dose to hands and eye lenses of surgeons and pathologists, and effective doses to all involved personnel were calculated; these are shown in Table 2 in relation to the annual dose limits for the population recommended by the International Commission on Radiological Protection[6]. The radioactivity found in SN biopsies and excised breast lesions and the residual activity on several operating room objects are shown in Table 3.



.**Fig. 1** Air kerma rate (µGy/h) for SN and ROLL at 0, 20, 50, 100 cm from patient, 0 and 16 h after administration. Values are compared to the air kerma rate after bone and thyroid scintigraphy (dotted bars). Mean values and range over 50 patients.

Table 2. Effective doses to hospital personnel in 100 operations (SN biopsy and ROLL). Mean values and standard deviations were calculated from air kerma rates near the patient and the times required to perform surgery or histological analysis.

Category	**Mean dose (mSv) in 100 operations (± S.D.)**	**Annual dose limits (mSv) for the general population (8)**
-		50
- surgeons' hands	0.45 ± 0.02	50
- pathologists' hands	0.08 ± 0.01	15
- surgeons' eye lens	0.10 ± 0.03	15
- pathologists' eye lens	0.015 ± 0.005	1
- effective dose to surgeon	0.09 ± 0.03	1
- effective dose to pathologist	0.015 ± 0.004 0.07 ± 0.02	1
- effective dose to nurse		

Table 3. Radioactivity in biopsied SN and excised breast lesions (mean values and ranges for 50 patients undergoing each operation) and residual activity in operating room objects (means values and ranges of 20 measurements).

Tissue	**Activity (kBq)**
- Sentinel Node	9 (0.7-15)
- Breast lesion (injection site)	900 (400-1100)
Object in operating room	**Activity (kBq)**
- Gauze	13 (0-100)
- Surgical instruments (scalpel, scissors)	< 0.4
- Gloves	0.1 (0-9.5)
- Sterilised sleeve for γ - probe	< 0.4

4. DISCUSSION AND CONCLUSION

The use of radioactive substances in clinical practice must be justified by a demonstrable benefit to patients, without excessive risk to hospital personnel[Erreur ! Argument de commutateur inconnu.]. Sentinel node biopsy can accurately stage the armpit lymphnodes in breast cancer patients, enabling their dissection to be avoided in the case of negative SN[7]. The ROLL technique allows easier, more accurate and more rapid removal of non-palpable breast lesions compared to conventional localization techniques[Erreur ! Argument de commutateur inconnu.,Erreur ! Argument de commutateur inconnu.]. The results of this study show that these protocols are safe in terms of radiation protection, in part because of the low levels of the injected activity and also because of the optimal characteristics of ^{99m}Tc. Furthermore, tissues receiving the largest amounts of radioactivity (i.e. the injection site and the SN) are removed during the operation. The absorbed doses to healthy tissues are low (range of the absorbed dose to the breast: 0.05-3.25 mGy) compared to other diagnostic examinations (range of the absorbed dose to the breast: 1.5-8 mGy, for standard mammographic screening).

In 100 operations we estimated that the mean absorbed dose to the surgeon's hands was 0.45 mGy, and the mean effective dose was 0.09 mSv. These values are, respectively, equal to ~1% and ~10% of the recommended annual dose limits for the general population[Erreur ! Argument de commutateur inconnu.]. Since surgeons generally receive more radiation than operating room nurses and pathologists, and perform usually a maximum of 300 operations per year, we conclude that no additional radiation protection measures are required for these procedures and that classification of involved personnel as *non exposed workers* is justified. In the injection room we provided containers for radioactive wastes (needles, syringes, gloves, etc.) and radiation detectors (proportional counter, GM counter) in order to be able to monitor the possible contamination. Such measures, on the other hand, are not necessary in the operating room. In any case, the radioactive wastes produced must be treated according to laws and regulations specific for any given country. According to the italian laws, the total amount of radioactivity present in the wastes deriving from the procedure can be considered as "lacking in radiological relevance"[8].

We conclude that the procedures subject of this study involve negligible radiation risks for patients, medical staff and general population and do not require special radiation protection measures.

5. REFERENCES

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