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Original article

Radioguided occult lesion localisation (ROLL) is available in the UK for impalpable breast lesions

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***Introduction*: To test the feasibility and reliability of ROLL in a district general hospital (DGH) dealing with screening detected breast lesions.**
***Patients and Methods*: [^{99m}Tc]-labelled colloidal human serum albumin was injected in the core of the breast lesion under ultrasound or stereotactic guidance 2–4 h prior to surgery. At operation, the radioactivity is localised using a γ-probe. This allows optimal placement of the skin incision and subsequent WLE of the abnormal area.**
***Results*: ROLL was utilised on 36 patients (median age, 61 years; range, 43–75 years); of these, 33 B5 lesions had a therapeutic one-step procedure (lumpectomy and axillary dissection) and 3 B4 patients had the lesion excised for diagnostic purposes. Localisation lasted a median of 8 min (range, 5–15 min), ROLL-guided wide tumour excision lasted 20 min (range, 15–30 min), and median postoperative hospital stay was 2 days (range, 1–3 days). Median cancer diameter was 12 mm (range, 6–40 mm). Margins were clear in 29 patients, while 7 patients with DCIS had involved margins. Median minimal clearance was 5 mm (range, < 1–10 mm). Patients had either excellent (24/36) or good (12/36) cosmetic results.**
***Conclusions*: ROLL successfully localised all lesions; this technique can be implemented in any DGH with a Nuclear Medicine Department. The learning curve is short, cost effectiveness is proven, and cosmetic results are highly rewarding. ROLL could rapidly become the standard localisation technique in the UK.**

Key words: Sub-clinical breast neoplasms – ROLL – Radioguided surgery

Only a few years ago, surgeons were rarely asked to excise non-palpable breast lesions detected following imaging. Our practice has significantly changed, and almost 30% of surgically removed breast lesions are non-palpable.[1]

To define the exact area to be excised, whilst avoiding excessive removal of healthy breast tissue, the ROLL technique was developed in 1996 at the European Institute of Oncology, Milan.[2,3]

Technical details have previously been described[4–6] and results reported. The advantages of this technique can be summarised as: (i) precise localisation and accurate surgical removal; (ii) reduction of tissue damage in the

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final pathological specimen (as the wire is not present in the specimen); (iii) accurate frozen section (if indicated); (iv) improved rate of clear margins; (v) reduced size of the excised specimen; (vi) increased patient comfort; (vii) decreased operative time; and (viii) reduced number of re-operations (cost effectiveness).[5,7]

At present, the most popular technique in the UK is the placement of a guide wire under mammographic or ultrasound guidance. Drawbacks of this technique have been reported (displacement, transection of the wire, foreign body affecting the pathological dissection/investigation, interference with the surgical incision).[5] Consequently other techniques have been developed (*e.g.* intralesional tracer administration,[8] carbon localisation,[9,10] and intra-operative ultrasonography[11,12]).

Our experience from a district general hospital (DGH) in implementing ROLL might be helpful to make the technique available to every breast surgeon's armamentarium.

Patients and Methods

The original research protocol was obtained from the European Institute of Oncology in Milan, Italy. A literature search was performed and alternative techniques were discussed with colleagues who have mastered ROLL in Europe. A hand held γ-probe was already available at our Trust as this was used by plastic surgeons for sentinel node biopsy on melanoma patients. Sentinel node biopsy is presently considered a standard procedure world-wide for breast cancer and melanoma, but it cannot be performed on breast cancer patients in the UK unless they are entered in the ALMANAC trial. Therefore, sentinel node biopsy was not attempted in this study.

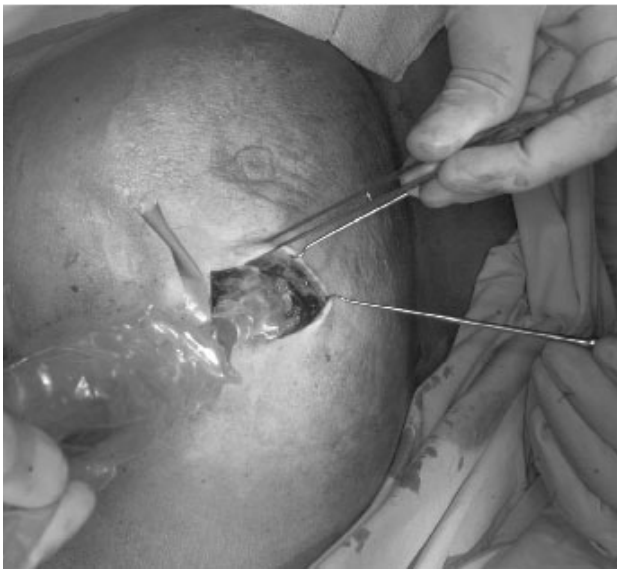

Figure 1 The targeted wide excision is completed and the persistence of hot signals is ruled out at the cavity.

To perform the technique, an application for addition to the certificate of the Administration of Radioactive Substances Advisory Committee (ARSAC) holder was required with details of the procedure, activity per test (in megabecquerels) and effective dose per test. Local policy has been developed in keeping with the radiation protection regulations. We undertook dose measurement to the surgeon's hands during the procedure and the radiographer's hands during injection, both of which showed no traceable activity.

[^{99m}Tc]-labelled colloidal albumin was utilised (Macro-aggregate 10:150 Micro m). Whilst Gennari used 3.7 MBq [^{99m}Tc]-labelled colloidal albumin,[6] we used a smaller dosage (1.0 MBq). This change in the technique not only decreased the radioactivity, but also entailed injecting the radio-isotope only a few hours prior to surgery, thereby eliminating the need for overnight stay. The use of a γ-camera for imaging prior to performing surgery was also avoided.

Furthermore, unlike the original technique, we decided not to inject contrast medium followed by double projection mammography. Accuracy of the injection was confirmed and documented while the localisation was being performed.

[^{99m}Tc]-labelled colloidal human serum albumin was injected directly into the lesion under ultrasound guidance (25 patients) or stereotactic radiographic guidance (11 patients) 2–4 h before the patients was anaesthetised. The hot area was confirmed and localised allowing a skin incision takes close to the site of highest radioactivity. The incision used was decided on a cosmetic basis, with no need to follow a wire through the breast parenchyma. Following wide excision the cavity was checked for any residual signal (Fig. 1).

Patients' short-term clinical outcomes and pathological findings were recorded. A four-point scoring system of breast cosmesis was used to assess the cosmetic outcomes[13] before adjuvant radiotherapy was started.

Results

As summarised in Table 1, we used ROLL in 36 female patients with a median age of 61 years (range, 43–75 years). Patients presented with non-palpable image detected B4 and B5 lesions (3 and 33 patients, respectively). The majority showed a mass (23 subjects), the remaining micro-calcifications and asymmetrical density (9 and 4 patients, respectively). The isotope marker was successfully injected into the lesion in all cases. Localisation times with ultrasound and a stereotactic technique were on average 6 min (range, 5–7 min) and 11 min (range, 10–14 min), respectively.

Twenty-eight subjects underwent a therapeutic wide excision and axillary dissection in keeping with our local protocol; 8 patients had only the lump removed (3 B4 lesions, and 5 subjects DCIS).

The surgical excision (from skin incision to skin closure) took 20 min on average (range, 15–30 min), and the median postoperative hospital stay was 2 days (range, 1–3 days).

Table 1 *Clinical features of patients localised with ROLL*

Overall number of patients	36
Median age	61 years
(range)	(43–75 years)
Radiological abnormality	
Micro-calcifications	9
Micro-calcification + stromal deformity	2
Stromal deformity	1
Asymmetrical density	1
Mass	23
Median length of localisation procedure	7 min
(range)	(5–14 min)
Pre-operative core biopsy	
B4 = probably malignant	3
B5 = malignant	33
Type of primary procedure	
Wide local excision	8
Wide local excision + axillary dissection	28
Median length of procedure (range)	20 min (15–30 min)
Median length hospital stay (range)	2 days (1–3 days)
Median size of tumour (range)	12 mm (6–40 mm)
Median weight of specimen (range)	30 g (6–112 g)
Final pathological diagnosis	
Invasive ductal	21
Invasive with associated DCIS	8
DCIS	6
Radial scar	1
Grade	
I	10
II	14
III	5
Lymph node status	
Clear	22
Involved	7
Margins	
Clear	29
Involved	7
Median minimal clearance (range)	5 mm (1–10 mm)
Cosmetic outcomes	
Excellent	24
Good	12
Postoperative complications: infection	1
Type of secondary procedure	
Mastectomy	6
Redo WLE	1
Axillary dissection	1

The size of the specimen was conveniently small with a median weight of specimen of 30 g (range, 6–112 g). The median tumour diameter was 12 mm (range, 6–40 mm; Fig. 2a,b).

Final pathology confirmed 29 invasive breast cancers, 8 of which had associated DCIS. Pure DCIS was detected in 6 patients and there was 1 radial scar.

It is our policy to advise re-excision if the margins are < 1 mm for invasive cancer and < 5 mm for DCIS. In the present series, margins were clear in 29 patients, while there was sign of involvement in 7 of the DCIS patients. The median minimal clearance was 5 mm (range, < 1–10 mm). Of the 29 subjects who had axilla dissection, 22 were node negative and 7 node positive.

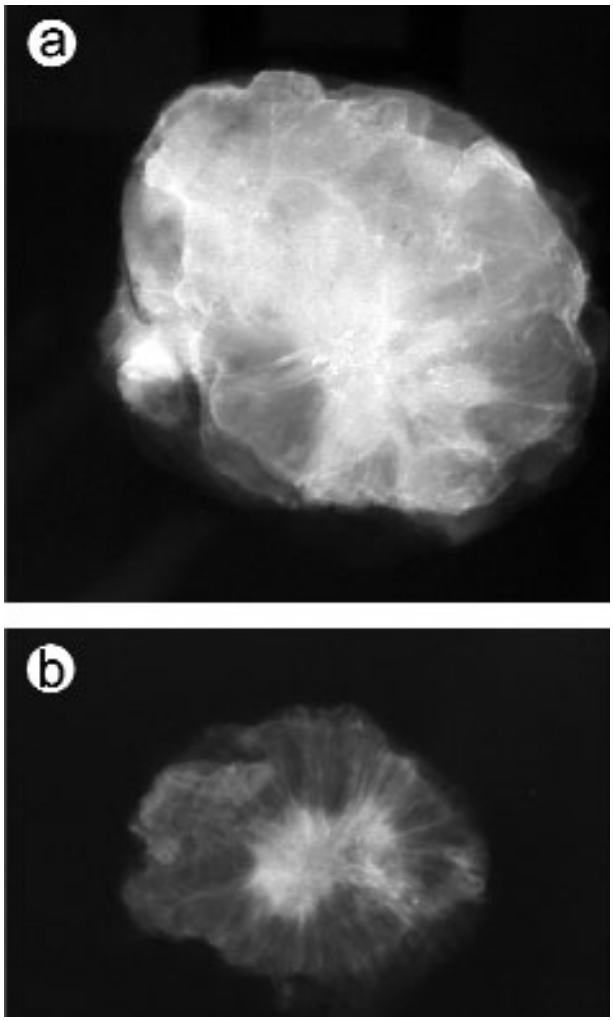

Figure 2 (a,b) X-ray of the excised specimen, showing the targeted area completely excised.

The cosmetic outcomes were excellent with the treated breast being almost identical to the untreated mammary gland in 24 patients and good in 12 patients. Only one patient developed a localised wound infection which was conservatively treated with antibiotics. Eight patients were re-operated: six had a mastectomy for DCIS, one had a redo-wide excision, and one had axillary clearance as unsuspected invasion was pathologically proven.

Discussion

The wide-spread use of mammographic screening results in a significant reduction in size of breast cancer at diagnosis,

with 50% cases smaller than 15 mm.[14,15] Hence, the number of non-palpable lesions has doubled[9] and several techniques are presently available for localising sub-clinical lesions. The use of a hooked wire is a standard in the UK, although randomised trials have shown the superiority of alternative strategies (*e.g.* per-operatively ultrasound-guided excision) with respect to margin clearance.[12]

Another method is the injection of [^{99m}Tc]-labelled albumin. This technique was applied to over 1000 patients in a single institution; it appeared to be simple and reliable,[2] but it had never been implemented in any UK district general hospital. Our experience suggests that the ROLL technique is feasible and easy to implement, without breaching any relevant radiation and safety regulations. The learning curve is short, and all four surgeons participating in the experience felt confident with the technique after a limited number of supervised procedures. ROLL is also cost effective, requiring no localisation wire or post-localisation mammogram (localisation with X-REIDY wire £35 versus ROLL localisation £28). A reduction in radiation dose is also achieved. The modification from the original Milan technique results in no need for overnight stay or pre-operative localisation with a γ-camera. This modification makes ROLL a viable technique for any breast unit with basic nuclear medicine facilities. Finally, familiarisation with the γ-probe might help with the implementation of the sentinel node technique.[16]

ROLL is a precise, user-friendly, cheap and quick technique; it allows clear identification of the hot area containing the tumour. The accuracy of pre-operative localisation has been shown to be a key factor for success. The failure rate of the wire-guided technique (*i.e.* incomplete cancer resection) has been reported in the range of 40–50%.[17] Our failure rate is 19% (7/36 patients), including patients with unexpectedly extensive DCIS. The advantages of reducing the number of involved margins are obvious. Reduced need for a second operation with less stress for the patient, fewer local complications, better cosmetic outcomes, cost effective, more appropriate pathological examination, and handling of the specimen. Cosmetic results are improved when compared to a standard wire guided lumpectomy, as an aesthetic incision to the skin is allowed, irrespective of the puncture site chosen by the radiologists.[5]

On the basis of our experience we recommend excising non-palpable breast lesions with the ROLL technique. We would welcome any application to visit our Trust in order to share the practical details as well as the appropriate paperwork to accredit other breast units.

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