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Time to go wireless? A 15-year single institution experience of radioisotope occult lesion localisation (ROLL) for impalpable breast lesions

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Abstract

Introduction: Wire guided localisation (WGL) is the standard localisation technique for impalpable breast lesions. Radio-guided occult lesion localisation (ROLL) has been proposed as an alternative. We have been performing ROLL for therapeutic wide local excisions (WLE) and diagnostic excision biopsies (DEB) for the last 15 years. We present the largest reported consecutive series of ROLL excisions to date.

Patients and methods: One thousand thirty nine consecutive patients who underwent ROLL for impalpable breast lesions were identified from a prospectively collected database. 673 patients underwent WLE and 366 patients underwent DEB. Data were analysed from proformas completed at the time of the procedure by the radiologist and operating surgeon. These data were supplemented with an analysis of patient electronic records including specimen radiograph and histopathology reports.

Results: 99.1% of ROLL WLE revealed histological diagnoses of invasive cancer or DCIS. 98.7% of radiological abnormalities were identified on WLE post-excision radiographs (97.5% following DEB). Complete excision was recorded in 79.0% of the WLE patients following histological evaluation. 31.7% of DEB cases were pathologically upgraded to a malignant diagnosis. The presence of microcalcification, preoperative underestimation of the lesion size and symptomatic referral predisposed to incomplete excision status.

Discussion: ROLL is a safe and effective technique to localise impalpable breast lesions. In addition ROLL has potential technical and logistic advantages over WGL.

Keywords: Breast cancer; Breast-conserving surgery

Introduction

The traditional method for the intraoperative identification of clinically impalpable lesions of the breast has been with wire guided localisation (WGL).[1] However, there are recognized disadvantages with WGL. These include the need for the surgeon to follow the wire through healthy breast tissue until the lesion is identified. In addition the wire may be displaced either pre or intra-operatively, may be difficult to place in the dense breast and high re-operation rates have been reported.[2–7]

In the late 1990's Luini proposed the Radio-isotope Occult Lesion Localisation technique (ROLL) as an alternative.[8] This approach involved injecting a small amount of radiotracer to localise the tumour under image guidance. Subsequent excision was guided by a handheld Gamma probe. The original report was supplemented in 2007 with the publication of a series of 959 ROLL excisions from the same European institute of Oncology in Milan, which reported successful localisation rates of 99.6%.[9] During the last decade this technique has gained popularity and has been associated with an increased accuracy of localisation and improved cosmetic outcomes.[6]

We have used ROLL as our preferred method of impalpable breast lesion localisation since 1999. We present an analysis of the procedural and surgical outcomes of the

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largest series of ROLL excisions performed to date in a single institution.

Patients and methods

A prospective database was created in 1999. For the purpose of this study we included patients on the database up to the end of 2013. Patients who had been treated with ROLL excision for non-palpable breast lesions either with a Diagnostic Excision Biopsy (DEB) or a Therapeutic Wide Local Excision (WLE), with or without a Sentinel Lymph Node Biopsy were included. Data were collected prospectively using two bespoke proformas, which recorded data on specific aspects of the ROLL localisation and the surgical procedure. Regional Research Ethics committee approval was obtained.

The primary objective of the study was to identify the accuracy of the ROLL technique by examining confirmed rates of invasive and pre-invasive breast cancer diagnoses following WLE after a biopsy proven pre-operative diagnosis (B5a-Non Invasive Carcinoma or B5b-Invasive Carcinoma).

Secondary objectives included identification of rates of histopathological upgrade to a diagnosis of pre-invasive or invasive breast cancer following Diagnostic Excision Biopsy procedures. This included procedures where a pre-operative needle biopsy had not established a definitive diagnosis of breast cancer according to the B classification (B1-Normal tissue, B2-Benign, B3-Indeterminate, B4-Suspicious of Malignancy).

In addition, the identification of complete excision rates following histopathological evaluation for the WLE subgroup (according to unit excision margin protocols) and the identification of factors predisposing to incomplete excision were included as secondary objectives.

Whilst sentinel node biopsy localisation was frequently performed in association with the breast lesion localisation (SNOLL) an evaluation of the SLNB outcomes was not included due to significant variations in SLNB practice over a 15-year period.

All patients underwent preoperative imaging in the form of mammography and ultrasonography and the radiological reports were stored on prospectively collected electronic patient records. All cases examined in the WLE group had a preoperative biopsy proven diagnosis of invasive breast cancer or DCIS. All cases without definite preoperative evidence of breast malignancy were considered in the DEB sub-group.

The ROLL localisation proforma collected routine patient demographic data, the timing of the localisation procedure, radioisotope dosage, ease of localisation using simple Likert scales (Easy/Moderate/Difficult) and immediate complication data. The localisation proforma was completed by the performing radiologist.

The surgical proforma recorded prospective data on the timing of excision, time for specimen removal, the maximal recorded radioactivity count of the excised lesion and excision bed, and ease of surgical localisation within the breast using a simple Likert scales (Easy/Moderate/Difficult). The surgical proforma was completed by the operating surgeon.

Localisation procedure

A standardised approach to localisation was followed for all patients. Localisation was performed using either stereotactic or ultrasound guided modalities dependent upon the characteristics of the radiological anomaly and was performed either on the day of surgery or the day before. Patients scheduled for an excision biopsy or a wide local excision for DCIS (without the need for SLNB) on the same day as surgery, received a single "localisation" dose of 6MBq of Tc99m nanocolloid in a 0.35 ml delivery volume. All other patients received a single "nodal" dose of 30MBq of Tc99m nanocolloid in the same delivery volume using an identical delivery technique. The "nodal" dosing regimen then facilitated "next day" surgery and/or localised the sentinel lymph nodes where required (in association with Patent V blue dye administered peri-operatively).

For stereotactic localisations a mammographic scout view was taken followed by a pair of stereotactic images to facilitate lesion targeting. A Spinocam 88 mm needle was then inserted followed by a second pair of stereotactic images to check the position of the needle tip in relation to the lesion. Ideal positioning of the needle tip was considered to be within 2 mm of the target lesion. Following correct needle tip placement a Luer Lock delivery syringe was then connected and the 0.35 ml dose was injected. Ultrasound localisations were performed using the same technique and parameters under ultrasound guidance. After stereotactic or ultrasound guided localisation the positioning and presence of radioactive tracer within the breast was confirmed using a hand-held gamma probe.

Surgical localisation procedure

Surgical excision was performed using a standardised approach for DEB and WLE. For WLE the local protocol is to excise breast tissue from skin to pectoral fascia with the intention of achieving histological evidence of clear circumferential margins of $\geq$2 mm for DCIS and any clear margin ($>$0 mm) for invasive cancer. In cases where a pre-operative diagnosis of invasive or pre-invasive breast cancer had not been made a more limited diagnostic excision biopsy was routinely performed with the aim of obtaining a specimen of less than 20 g following the introduction of national guidelines.[10]

A gamma probe was used intra-operatively to orientate the surgeon to the position of the impalpable lesion in three dimensions following a preoperative check of the position of the lesion within the breast. The resection aimed to excise the area of maximal radioactivity within the breast. Resection volume was determined by intraoperative