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Radio-frequency identification (RFID) tag localisation of non-palpable breast lesions a single centre experience

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ABSTRACT

Aim: The purpose of this study is to report the surgical experience and outcomes with pre-operative localisation of non-palpable breast lesions using the RFID tag system.
Methods: The cohort for this prospective study included patients over the age of 18 with biopsy proven, non-palpable indeterminate lesions, DCIS or breast cancer requiring pre-operative localisation before surgical excision between September 2020 and July 2022.
Results: A total of 312 RFID tags were placed in 299 consecutive patients. Indications for localisation included non-palpable invasive cancer in 255 (85.3%) patients, in situ disease in 38 (12.7%) and indeterminate lesions requiring surgical excision in 6 (2.0%). Both in situ and invasive lesions had a median size of 13 mm (range 4–100 mm) on pre-operative imaging. The RFID tags were in situ for a median time of 21 days before surgery (range 0–233 days). Of the 213 tags, 292 (93.6%) were introduced using ultrasound (USS) guidance and stereotactically in 20 (6.4%). In 3 (1.0%) cases the RFID tag was either not satisfactorily deployed at the intended target or retrieved intra-operatively. Following discussion of post-operative histology by the multi-disciplinary team, further surgery for close or involved margins was for 26 (8.7%) patients.
Conclusion: The Hologic RFID tag system can be used for accurate pre-operative localisation of non-palpable masses as well as diffuse abnormalities such as mammographic distortions and calcifications. It has advantages of flexibility for scheduling image-guided insertion independently of scheduled operating lists and can be placed to localise lesions prior to initiating neoadjuvant systemic treatment.

1. Background

Breast cancer is the most common cancer to affect women worldwide, with around 55,900 new cases diagnosed in the UK every year [1]. The NHS Breast Screening Programme screened just over 2.5 million women between 2019 and 2020, identifying 16,775 invasive cancers, of which 8251 were less than 15 mm in size, and 4251 non-invasive cancers [2]. Detection of early small cancers which are not palpable presents a significant challenge to the operating surgeon. Several methods have been developed with the aim of accurately localising non-palpable tumours, facilitating a safe oncological resection and breast-conservation where possible.

Since the 1970s wire-guided localisation (WGL) has been the standard of care in many countries, including the UK. Although effective at providing pre-operative localisation with failure rates of between 1 and 7% [3] the technique has several disadvantages. The need for wire placement on the same day as surgery can negatively impact existing resources and interfere with breast one-stop clinics, theatre timing and utilisation, particularly if last minute problems are encountered. Pressures on surgical and imaging services have dramatically increased in the recent years with a 10% rise in 2-week-wait referrals into clinics, leaving little time for pre-booked interventional activity [4]. In case of a problem detected at the time of insertion, there is potential for delay and or loss of booked theatre time. In addition, there is potential for wire displacement between insertion and surgery, and excision can be technically difficult; further surgery to excise positive margins is reported to be 20–70% [5].

Several wire-free methods have since been developed including radioactive tracers detectable by intra-operative gamma probe such as Iodine-125 titanium seeds and Technetium-99 labelled micro albumin,

Abbreviations: RFID, Radio Frequency Identification.

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known as radio-guided occult lesion localisation (ROLL), can be introduced into the lesion under ultrasound (USS) or mammographic guidance. Radioactive seed localisation (RSL) has been shown to be as effective as WGL with a reduced incidence of involved margins and re-excision rates of 26% [6]. ROLL has been the standard of care at our unit for several years, however the technique has limitations including the strict licencing regulations required to store, handle and manage radioactive material, the short half-life of the tracer, and the smooth co-ordination required between breast imaging, nuclear medicine, and surgery departments on the day of surgery. Masses close to the peri-areolar region can produce inaccurate signal due to proximity to the sentinel lymph node localisation (SLNL) injection site (in case of radioactive tracer being used for SLNL) and require alternative localisation methods such as image guided skin marking or WGL.

Non-radioactive localisation technologies include Magseed® (Endomagnetics Inc. Cambridge, UK), a magnetic steel and iron seed retained by a wax plug which produces a magnetic field detectable intra-operatively with a probe [7]. The Sirius Pintuition ® (Sirius Medical, Eindhoven, the Netherlands) is a Magnetic Marker Localisation (MaMaLoc) seed and detection probe [8]. The Savi Scout® (Cianna Medical Inc., Aliso Viejo, California, USA) uses an infrared-activated 10 mm implant [9]. Cryo-assisted localisation (CAL) uses a cryoprobe and argon gas to freeze a lesion with a predetermined margin, forming a palpable iceball however had the highest rate of positive margins and reoperation in a meta-analysis by Davey et al. (2022) [10]. Intra-operative ultrasound (IOUS) requires no implantable device or probe. Two meta-analyses comparing IOUS with WGL and ROLL, IOUS showed a lower rate of margin positivity when compared with ROLL and WGL [11,12]. IOL is limited to sonographically visible lesions only and can be unreliable in mammographic microcalcification. Localisation using indocyanine green fluorescence (ICG-F) dye injected into the tumour under imaging guidance requires a near-infrared light source to display fluorescence and guide dissection [13]. Our centre currently uses the LOCalizer™ radiofrequency identification (RFID) tag (Hologic, Santa Carla, California, USA) method for localisation and was one of the earliest in the UK to adopt this technique. We previously published a retrospective audit of the first 59 patients undergoing localisation using RFID tags at our centre [14]. The purpose of this study is to report the surgical experience and outcomes with pre-operative localisation of non-palpable breast lesions using the RFID tag system.

2. Method

This study is a prospective analysis of a patients undergoing pre-operative RFID localisation at the Norfolk and Norwich University Hospital (NNUH), a high-volume tertiary referral centre seeing around 7000 referrals to breast clinic and treating 600 breast cancer patients per year. Patients over the age of 18 with biopsy proven, non-palpable indeterminate lesions, DCIS or breast cancer requiring pre-operative localisation between September 2020 and July 2022 were included. Decisions regarding proposed treatment recommendations were made following discussion within the breast cancer multidisciplinary team and recorded using the Somerset Cancer Registry (SCR) electronic patient record.

The Hologic RFID tag device system (Hologic, Santa Carla, California, USA) comprises a 10.6 mm long, 2 mm diameter miniature RFID tag with unique identification number encased in a polypropylene cap [15]. Pre-loaded in a needle applicator, each RFID tag was inserted by a specialist breast radiologist pre-operatively following informed consent, under ultrasound or stereotactic mammographic guidance using local anaesthetic. Tags were inserted either prior to surgery or prior to neo-adjuvant chemotherapy. The Hologic RFID tag was approved for long-term placement beyond 30 days in 2019, facilitating lesion localisation prior to neoadjuvant treatment and surgery [16]. The position of the tag in relation to the lesion was confirmed either with ultrasound, mammography or both if required (in case of difficult visualisation on ultrasound and to confirm absence of tag displacement within the needle track after introduction). On the day of surgery, the handheld LOCalizer ™ Reader was used to identify the tag position and plan the surgical incision. Intraoperatively a single-use sterile probe was used by one of four Consultant Breast Surgeons to guide dissection. A specimen radiograph was obtained as per standard protocol to confirm retrieval of the RFID tag and evaluate adequate excision of the tumour (Fig. 1).

The primary outcome of the study was successful excision of the target lesion as guided by the RFID tag, defined as confirmation of the lesion and presence of the RFID tag in the specimen radiograph. Secondary outcomes were successful visualisation of target lesion or clip, need for change in imaging technique, problems encountered during tag placement, rate of re-excision to clear margins, intra-operative events, post-operative complications, and overall operating time. Data was collected from imaging and histopathology reports and the SCR. The initial pathological diagnosis from core biopsy, tumour size on imaging, need for neoadjuvant treatment, time between RFID tag insertion and surgical retrieval, final pathological diagnosis, intra-operative and post-operative complications were recorded. Further surgery to re-excise margins was undertaken where final margins were <1 mm from the invasive cancer or DCIS as per national guidelines and following MDT (multi-disciplinary team) discussion [17].

Data was recorded and analysed using MS Excel. Continuous variables were summarized with mean, standard deviation, median and range.

3. Results

Baseline characteristics and pathological data are shown in Table 1. Over a 23-month period 312 RFID tags were placed in 299 patients. Of these, 201 (67.2%) patients were recalled from routine screening and 98 (32.8%) presented to a symptomatic one-stop clinic. Indications for localisation included non-palpable invasive cancer in 255 (85.3%) patients, in situ disease in 38 (12.7%) and indeterminate lesions requiring surgical excision in 6 (2.0%). Indeterminate lesions included radial scar with atypia, intraductal papilloma and myoid hamartoma. Lesions were multi-focal in 22 (7.4%), and in twelve patients more than one tag was placed for localisation either to bracket a tumour or localise two lesions in the same or contralateral breast. Seventy-six patients underwent neoadjuvant treatment with 57 (22.4%)

Receiving chemotherapy and 19 (7.5%) receiving endocrine therapy. In those having neoadjuvant chemotherapy, 46 tags were placed in advance of treatment (81.0%), 3 (5.3%) tags were placed during and 8 (14.0%) after completion of chemotherapy. The most appropriate imaging modality for assessing response to treatment was discussed at

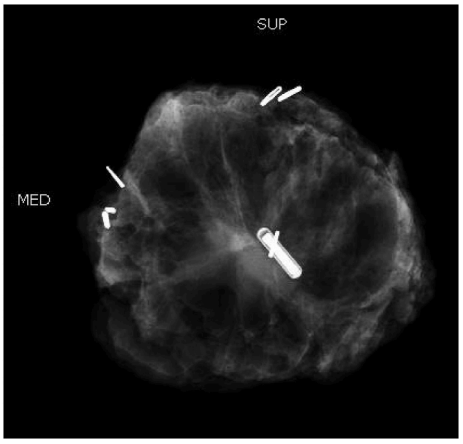

Fig. 1. Radiograph of surgical specimen shows successful retrieval of the mass and RFID tag, clips mark the anterior, superior and medial aspects of the excision.

Table 1
Baseline characteristics NHS breast screening programme (NHSBSP).

Variable	Category	No of patients (%) N = 299
Presentation	Symptomatic clinic	98 (32.8%)
	NHSBSP	201 (67.2%)
Pathology	Indeterminate lesions	6 (2.0%)
	In situ (DCIS, LCIS)	38 (12.7%)
	Invasive:	255 (85.3%)
	Ductal	**N = 255**
	Lobular	204 (80.0%)
	Mixed	28 (11.0%)
	Tubular	1 (0.4%)
	Mucinous	11 (4.3%)
	Papillary	5 (2.0%)
	Apocrine	3 (1.2%)
	Medullary	2 (0.8%)
		1 (0.4%)
Tumour size (median (range))	In situ	13 mm (4–50 mm)
	Invasive	13 mm (4–100 mm)
Neoadjuvant treatment (N = 255)	Chemotherapy	57 (22.4%)
	Endocrine	19 (7.5%)
Duration of RFID tag in situ (median, range)		21 days (0–233 days)
Operating time (median, range)		62.5 min (19–267 min)

MDT. For patients with tags placed before and during treatment, response was evaluated using USS in 40 (70.2%) cases, contrast enhanced mammography in 4 (7.0%), by clinical assessment in 3 (5.3%) and computed tomography (CT) in 1 (1.8%) case.

Both in situ and invasive lesions had a median size of 13 mm (range 1–100 mm) on pre-operative imaging. The median operating time was 62 min (range 19–267 min). Final histology showed complete pathological response in 23 (40.4%) cases of neoadjuvant chemotherapy and 2 (3.5%) cases of neoadjuvant endocrine therapy. The RFID tags were in situ for a median time of 21 days before surgery (range 0–233 days). Following discussion of post-operative histology by the multidisciplinary team, margin re-excision was required for 26 (8.6%) patients (Table 2) with one patient having completion mastectomy. Post-operative complications were recorded in 5 (1.7%) patients; 2 patients required conservative treatment for infected seroma, 2 patients were treated with oral antibiotics and dressing management for wound infection and one patient developed mild lymphoedema of the arm.

Of the 312 tags, 292 (93.6%) were introduced using USS guidance and 20 (6.4%) using stereotactic mammography. The USS localisation target was the tumour in 239 (81.8%) tags, Hydromark clip in 49 (16.8%) tags, and post biopsy haematoma in 4 (1.4%) tags. The localisation target for stereotactic insertion was mammographic calcification in 15 (75.0%) tags, and in 5 cases (25.0%) the stereotactic biopsy clip.

In 3 (1.0%) cases the RFID tag was either not satisfactorily deployed at the intended target or retrieved intra-operatively. In Case 1 an incidental 5 mm cluster of calcification was biopsied under stereotactic guidance and a ribbon clip introduced. A RFID tag was later inserted under USS guidance using the clip to localise the target lesion, however, on post-insertion mammogram the tag was seen 20 mm inferomedial to the clip. The lesion was then localised sterotactically and WGL used for wide local excision. Specimen histology showed close radial margins and the patient underwent successful margin re-excision. The RFID tag in case 2 was displaced intra-operatively during dissection. Specimen X-ray showed calcification extending to the medial margin of the specimen prompting a further medial margin excision. Histology showed this margin to be at least 4 mm from tumour, however a separate 2 mm focus of tumour was found to extend to the lateral margin. The patient underwent margin re-excision. For case 3, the RFID tag was targeted to the marker clip but due to breast density, the closest the tag could be placed was 15 mm anteromedial to the mass. The patient went on to have wide local excision with ROLL guided localisation and clear margins.

In 8.7% surgical margins were close or involved and patients required further surgery. This is much lower than the published UK national breast re-excision rate of 20% [18]. Our unit recorded no incidence of re-excision in 59 cases during the pilot phase, however in 17 of these, dual technique using a combination of radioisotope and RFID was used [14]. Comparison of rate of re-excision between the first and last six months of data shows a reduction, 12.5% versus 4.2% which reflects a relatively short learning curve for the technique.

Table 2
In situ disease and invasive cancer margin re-excisions.

Variable	Category	No of patients (%) N = 299
Margin re-excision		26 (8.7%)
	In situ	7 (2.3%)
	Invasive	18 (6.0%)
Completion mastectomy		1 (0.3%)

4. Discussion

Our results are consistent with other studies investigating outcomes for the RFID tag. One of the earliest, Dauphine et al. [19] placed 20 RFID tags concurrently with hook wires reporting 100% placement and retrieval of the tag with 27% requiring re-excision of margins. Lowes et al. [20] placed 177 tags an average of 7.8 days before surgery, reporting all retrieved successfully and a re-excision rate of 8.7%. A series from Massachusetts General Hospital, USA placed 1013 tags in 848 patients with successful placement achieved in 98.4%. Seven patients required additional tag or wire-guided localisation and 15.1% underwent further surgery for positive or close surgical margins [21]. Comparing the re-excision rate with other localisation techniques, a series of over 1000 patients undergoing ROLL reported a re-excision rate of 21% [22] while rates with radioactive seed localisation range from 5% to 32% [23]. The iBRA-NET localisation study compared standard WGL with magnetic seed localisation reporting similar safety and effectiveness with a re-excision rate of 13.2% (WGL) and 12.3% [24].

As noted by our previous study and other published literature [14, 25], one limitation of the RFID tag is that, whilst the device is MRI compatible, it can produce up to an 8 cm signal void artefact [14] which can make interpretation of breast MRI images challenging (Fig. 2). Of the 57 patients receiving neoadjuvant chemotherapy in our series, four patients required MRI prior to commencing treatment. The indication for MRI in these cases included breast density, and assessment of tumour size in consideration of breast conserving surgery. Three patients underwent tag placement prior to starting treatment and in all cases USS was used to assess tumour response to chemotherapy. One patient underwent tag placement on completion of systemic therapy.

The Magseed ® marker also produces a 2–4 cm void artefact [26] however, the SAVI-scout reflector produces minimal MRI artefact [27]. The needle delivery system for both devices is not MRI compatible, WGL is currently the only localisation method which can be performed under MRI-guidance. As a result, our unit has excluded tag placement for patients who may still require MRI imaging post neoadjuvant treatment, therefore any local staging or treatment response evaluation needs to be completed prior to tag placement.

The main strength of our study is the prospective collection of the data, eliminating the potential for recall bias. Additionally, the RFID tag was used for a variety of localisations from non-palpable masses as well as diffuse abnormalities such as mammographic distortions and calcifications, not excluding lesions based on type, thus reflecting the range of lesions encountered in routine practice. Our study is limited by reporting the outcomes from a single institution having the benefit of dedicated consultant breast radiologists and surgeons. In addition, we have limited experience of using the RIFD tag system to localise lymph nodes for targeted axillary dissection as this is a relatively recent

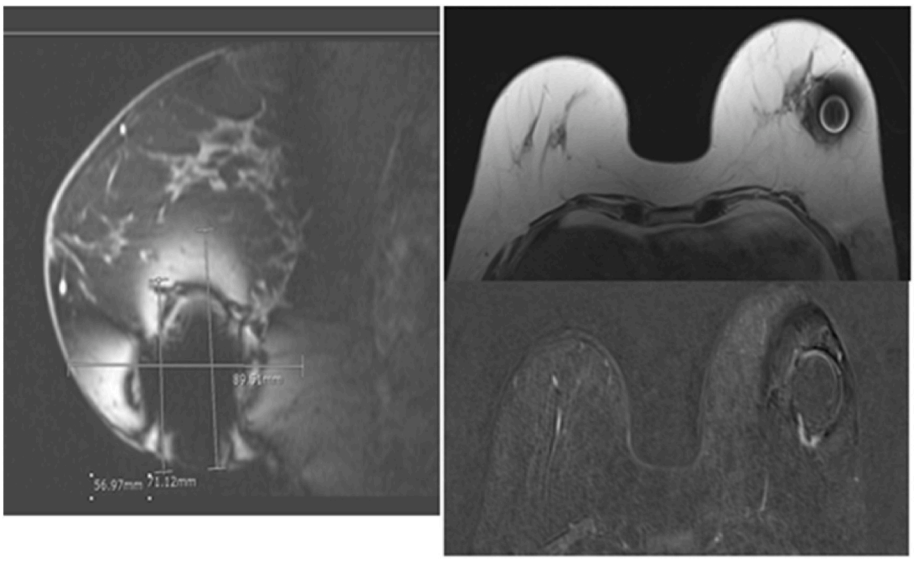

Fig. 2. MRI images of signal void artefact from RFID tag.

indication [14]. Malter et al. [28] reported the first use of the RFID tag to localised axillary lymph nodes for targeted dissection with 100% detection rate. A randomized trial evaluating RFID tag localisation versus intra-operative USS with Hydromark clip to facilitate targeted axillary dissection is currently recruiting [29] and two studies are currently in progress, evaluating the range of available image-guided localisation techniques. The iBRA-net audit is underway in the UK, investigating the clinical outcomes and providing qualitative feedback on the use of localisation devices including Magseed®, Savi Scout® and the Hologic LOCalizer™ [30]. The European Breast Cancer Research Association of Surgical Trialists (EUBREAST) are conducting the MELODY (Methods of Localisation of Different types of breast lesions) study is an international prospective cohort study evaluating oncological safety and patient-reported outcomes of image-guided localisation techniques [31]. These studies will add to the published data on the various localisation techniques but include qualitative feedback and patient-reported experiences of the techniques.

5. Conclusion

To the best of our knowledge, this study describes the largest series reported in the UK of the RFID tag localisation technique. It adds to the weight of available evidence reporting the efficacy of this still relatively new technique. The tag device has several advantages compared to traditional and alternative localisation techniques and is a safe and reliable method of localising non-palpable breast lesions.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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