Impalpable breast lesion localisation, a logistical challenge: Results of the UK iBRA-NET national practice questionnaire.

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Abstract:

Introduction:

Breast conserving surgery of impalpable breast lesions requires safe and effective localisation techniques. Wire localisation has traditionally been used, but has limitations. Newer techniques are now being introduced to mitigate this. The iBRA-NET group aims to robustly evaluate these new techniques in well-designed prospective studies. We report the first phase of this evaluation, a survey to establish current practice and service provision of breast localisation techniques in the UK.

Methods:

A National practice questionnaire was designed using 'SurveyMonkey®' and was circulated to UK breast surgeons via the Association of Breast Surgery and the Mammary Fold. The questionnaire was live from 6th October 2018 to 6th April 2019. Only one response per unit was requested to reflect the unit's practice.

Results:

Complete responses were received from 98 breast units across the UK. Wires were the mostly commonly used localisation technique (n=82) with fewer units using Magseed® (n=9), Radioguided Occult Lesion Localisation (n=5) and Radioiodine Seed Localisation (n=2). There was significant variation in practice and logistics involved. Frequent delays and theatre overruns were reported in 39 and 16 units, respectively. The median satisfaction score of the current technique was 7 out of 10. The main perceived limitation of existing localisation methods was logistics affecting theatre scheduling and the main barrier to introducing a new technique was cost.

Conclusion:

Wires are currently the most commonly used localisation technique but are associated with significant logistical issues. Newer techniques may offer a better solution but will need robust evaluation before they are adopted to ensure safety and efficacy.

Key words: Breast localisation, questionnaire, iBRA-NET, Magseed, wire localisation

Introduction:

Detection of smaller breast cancers has increased with widespread implementation of breast screening programmes and improvement in breast diagnostic imaging[1]. Down-staging of tumour size by the use of neo adjuvant systemic therapy is increasingly being used to facilitate breast conserving surgery of smaller lesions[2][3][4]. These lesions require image-guided localisation prior to breast conserving surgery so they may be safely removed.

Historically, the majority of localisations have been performed by wire insertion under ultrasound or mammographic guidance. This has been the gold standard since its first introduction by Dodd in 1965[5]. Although the procedure is well tolerated and is thought to be cost effective, it has several limitations including interference in theatre scheduling, placement of incisions affecting cosmesis, wire migration and disruption, difficulties in locating the tip, depth sensing, re-excision rates and potentially poor acceptability to patients. Wire insertion on the day of surgery can cause additional patient stress and may lead to delays to surgery despite prior co-ordination between surgeons and radiologists[6][7][8][9][10]. Other impalpable lesion localisation techniques such as Radioguided Occult Lesion Localisation (ROLL) and Radioiodine Seed Localisation (RSL) have been used in some centres to overcome the disadvantages of wire localisation. However, they also have limitations, notable of which is the requirement for regulatory licences with their strict codes of practice[10][11][12].

The introduction of newer techniques like Radio Frequency Reflector (RFR) localisation and Magseed® for impalpable breast lesion localisation may mitigate some of the limitations of conventional localisation techniques[13]. The RFR is a non-radioactive, electromagnetic tagging system. SAVI SCOUT (Cianna Medical, Aliso Viejo, CA) was the first RFR to be introduced. Another recent device is LOCalizer (Faxitron, Tucson, AZ). These are commercially available and approved by the US Food and Drug Administration[13]. Magseed® consists of an implantable 5mm paramagnetic iron oxide pellet and a magnetic probe (Sentimag®) for intra-operative lesion identification.

While these new localisation devices may have many advantages, there is a need to robustly evaluate the new localisation devices before they become established in routine clinical practice. A study was designed by the iBRA-Net Localisation Steering Group to evaluate the safety and efficacy of current methods of localisation. The study design has two phases. Phase 1 aims to survey the current practice and service provision of breast localisation across the United Kingdom (UK). Phase 2 includes prospective national audits of the currently used breast lesion localisation techniques and of newly introduced techniques as described above.

We report the results of the Phase 1, national practice questionnaire of impalpable breast lesion localisations in the UK.

Methods:

The national practice questionnaire was developed by the study steering group to explore the current practice and relevant logistics involved in localising impalpable breast lesions within breast units in the UK. The questionnaire aimed to identify the techniques currently used, any perceived limitations, gauge desire for change to a new technique, and evaluate the effect of current localisation technique on patient pathways and logistics, including sentinel lymph node (SLN) injections. The respondents were also asked to rate their satisfaction about their current technique from a score of 0 to 10, with 0 being the least satisfied and 10, the most satisfied. The questionnaire was designed using 'SurveyMonkey®' and was piloted in three hospitals. Following the pilot in each hospital the questionnaire was revised based on qualitative feedback, to ensure that the questions asked were essential and that respondents could clearly identify the question and give clear responses. The finalised questionnaire was circulated through the iBRA-net group of UK breast surgeons via the Association of Breast Surgery (ABS) newsletter, social media and the Mammary Fold (UK organisation of breast surgery trainees). The questionnaire was completed online between 6th October 2018 and 6th April 2019. Only one response per unit was requested to reflect the practice of the unit as a whole rather than that of individual surgeons. Multiple responses from the same individual and from the same unit were excluded from the study. The most complete response was taken as that unit's entry for the analyses. Non responding units were encouraged to respond to the questionnaire by repeated reminders on the ABS newsletter but were not directly approached.

Simple summary statistics were calculated for each questionnaire item.

Results

Participation:

A total of 122 complete responses were received. This included multiple responses from four individuals and 20 breast units. In total, completed responses were obtained from 98 breast units. All the responses were from breast surgeons except one from a radiologist. Responses were received from all geographical regions in the UK (Table 1).

Unit infrastructure and localisation technique:

Of the 98 units that responded with a completed questionnaire, 85 were NHS breast screening units. All units, except one offered stereotactic localisations. Wire localisation was the predominant localisation technique for impalpable breast lesions that was used as the current standard in 82 breast units. The other techniques utilising radioactive substances were used in seven units. Amongst the respondents, 22 units had trialled Magseed®, and nine units were using Magseed® as their current localisation method.

Unit volume and personnel:

The number of impalpable lesion localisations performed by the units per year and the timing of localisations are shown in Table 1. Consultant radiologists primarily performed the localisations. In 57 units localisations were also performed by radiographers.

Localisation scheduling:

The localisations were predominantly performed on the same day (Table 1). In the two units using RSL, Iodine seeds were placed 3-14 days prior to surgery. In four units using Magseed® as the current standard, localisations were performed in a two week window prior to surgery.

Logistics:

In a majority of units (60), patients moved to a different part of the same hospital building for surgery following localisation either by walking or assisted by a porter. In four units, localisations were also performed by breast surgeons in the operating theatre (Table 1).

Theatre scheduling:

In units, where breast localisation was performed on the day of surgery without sentinel lymph node (SLN) injection, the average time from patient arrival in the radiology suite to readiness for anaesthesia varied significantly. Approximately half of units (n=48) reported the average time required was between 60 to 90 mins, resulting in the first patient requiring excision of an impalpable breast lesion being scheduled for surgery between 10 and 11am. In these units, the localisations happened in the same building and patients usually walked or were being portered. The time taken was 90 to 120 mins in 15 units, and up to 2 hours in 13 units. Six of these units had radiology suites in a different hospital site. This resulted in these patients being scheduled for surgery much later in the day (Table 1).

SLN injection:

In 54 breast units, radioisotope SLN injection was scheduled either the day of or the day before surgery, based on theatre scheduling. It was exclusively performed on the day of surgery in 25 units and the day before in 29 units. Breast surgeons from five units performed the SLN injection on the same day as surgery in the operating theatre or in the anaesthetic room. In a majority of the units (n=55), the injection was performed in the nuclear medicine department. In 11 units, it was administered in the radiology suite and in 18 units in a different hospital. Multiple locations for injections were described including; the breast unit, ward, day unit admission suite and breast outpatient clinic room (Table 1).

Satisfaction with current localisation method: (Figure 1)

The median score of the responses was 7. Both the RSL units who responded to this questionnaire gave a satisfaction score of 10. Of the remaining 21 who gave high scores of 9 and 10, two were using Magseeds® and the remaining 19 were using wires as their current localisation technique.

Limitations of current localisation technique:

The perceived limitations reported by individual units regarding their current localisation technique are summarised in Table 2. These mainly included logistical issues affecting theatre scheduling (n=74); concerns that the technique was not patient friendly (n=51), issues relating to accurate localisation of the lesion including wire migration (n=46); difficulty locating the tip of the wire (n=42) and excising too much

tissue (n=39). Cost and concern about depth sensing in dense and large breasts were highlighted by units using Magseeds®.

Desired improvements and barriers to change:

Improvements that the respondents felt would be desirable in a new localisation technique and the reasons that prevented trial and adoption of a new technique are listed in Table 2. The main barriers to change were cost (n=63) with concerns about licencing also highlighted in units wishing to change to a radioactive technique.

Preference to change:

Units were asked to indicate if they would consider changing localisation technique and which, if any alternative they would prefer. Slightly more than half of the respondents (56%) wished to change their localisation technique. In this cohort, 60% (n=49) of the wire localisation units preferred a change to a different technique. The stated preferences were to Magseed® in 38 units and RSL in eight, ROLL in two and radiofrequency technique in one. Twenty-one units did not wish to change, and 22 were undecided.

Discussion:

This study provides a valuable insight into the current practice of impalpable breast lesion localisation in the UK. It provides information on the different localisation techniques currently used and the logistics involved. It has also highlighted a significant proportion of units are dissatisfied with their current localisation technique with more than half of units wishing to change techniques to improve workflow and patient care. As the survey was completed by two-thirds of breast units this is likely to be representative of UK practice as a whole. This is the first worldwide and UK-based survey of non-palpable breast lesion localisation.

Wire localisation is still the predominant technique and the current standard for impalpable breast lesion in 85% of the units that responded. Wire insertions performed on the day of surgery or the day before adds pressure on the radiology team to provide these services at specified times. Localisations are increasingly performed by advanced practice radiographers (57 units) to support this as there is a UK wide shortage of consultant breast radiologists[14]. Theatre scheduling is affected in units practicing same-day localisations with potential for delay. This also has cost implications, but more importantly adds extra stress and anxiety to the patients on the day of their surgery. There was also significant variation in practice of SLN injections contributing to additional theatre delays.

Each localisation technique has its inherent drawbacks but many of these such as wire displacement and difficulty locating the wire tip are associated with wire localisations. In units using Magseed®: cost, learning curve and depth sensing in dense and large breasts were mentioned as potential concerns. Concerns about regulatory licenses were expressed by units practicing ROLL or RSL.

Forty three (44%) respondents were undecided or did not want to change their localisation technique. Amongst the units who did not want to change were the units using RSL and Magseed® (except one), including 11 wire localisation units. Twenty units were undecided which could be due to a multitude of

factors as elicited under 'Barriers to change'. This shows that a small proportion of wire users are content not to change, while those undecided will be evaluating the new technologies as their use and outcome data matures.

Newer technologies are emerging to mitigate the drawbacks of current localisation techniques. RFR localisation is a relatively new technique. It has advantages over wire localisation and radioactive localisation techniques as it can provide separate radiology and surgery scheduling without the need for stringent regulatory compliance. The other advantages are (i) multiple reflectors can be deployed as each reflector has a unique tag[13] (ii) RFR device is MR conditional and causes minimal signal void artefact as compared with Magseed®[15]. The disadvantages are relatively large size of the SAVI SCOUT® device (12mm) compared to Magseed® (5mm) and RSL (4.5mm). The LOCalizer® measures 11mm. These techniques may be more patient friendly and facilitate both more efficient theatre scheduling and use of radiology time but large-scale prospective multicentre trials are needed to establish their safety and efficacy.

The study has limitations which require consideration. This was a survey of current UK practice and actual practice may vary from that reported. In addition, despite a good response rate, does not capture all practice across the UK, potentially introducing selection bias. Despite these limitations, this survey provides a valuable insight into the current practice of breast lesion localisation and also about sentinel lymph node practice across the UK. The questionnaire reflects only the UK and NHS based practice. Many of the results will be transferable to other healthcare systems and countries, but the drivers for change, both logistically and financially will vary between healthcare systems.

Robust evaluation of new techniques will be vital and phase 2 of this study involves a National prospective audit of current localisation techniques and the newly introduced techniques with a primary endpoint of identification and excision of the index lesion. The main secondary endpoints are accuracy of localisation, complication and re-operation rate. Data is currently being collected from multiple participating centres across the UK and the results will be presented in the near future.

Conclusion:

Wire localisation is the most commonly used localisation technique for excision of impalpable breast lesions. It has its own limitations and newer techniques are being introduced to mitigate this. This national practice questionnaire of impalpable breast lesion localisation in the UK has shown wide variation in practice; perceived limitations of conventional localisation techniques and has highlighted a desire in many units to change. Any new localisation devices must be robustly evaluated and prospective audits that are ongoing will provide evidence to support future change.

Compliance with Ethical Standards

Conflict of interest: The authors declare that they have no conflict of interest.

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Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

Research involving human participants and/or animals: Not applicable

Informed consent: Not applicable

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Tables:

Geographical regions	Breast Units (n=98)

South West	13
West Midlands	10
Greater London	10
North West	9
South East	9
Yorkshire and The Humber	9
Scotland	8
East Midlands	7
East of England	7
Wales	5
Northern Ireland	5
North East	4
Central South East (Wessex)	1
Isle of Man	1
Current localisation method	
Wire	82
ROLL and wire	5
RSL	2
Magseed	9
Unit Volume (localisations per year)	
<100	17
100 - 200	45
200 - 300	19
300 - 400	9
400 – 500	5
>500	3
Personnel performing localisation other than radiologist	
Radiographer	57
Surgeon (Intra op USS in theatre)	4
Consultant Radiographer	1
Breast physician	1
Localisation schedule – When do patients have their preoperative localisation?	
Same day of surgery	67
Either same day or day before	25
2 to 14 days prior to surgery	6

Logistics - Following localisation, where does the patient's surgery take place?	
Different part of the same hospital building	60
Different building on same hospital site	17
A different hospital site	17
Same place as localization	4
Mode of travel to operating theatre after localisation	
Walk	65
Porter	45
Taxi	6
Hospital transport	4
Own transport	15
Other	
Time to arrive in theatre after same day localisation without SLN injection	
30 to 60 mins	28
60 to 90 mins	48
90 to 120 mins	13
>120 mins	9
What time could you schedule the first localization guided surgery after same day localisation without SLN injection?	
8 to 9am	15
9 to 10am	26
10 to 11am	42
11 to 12am	11
After 12 noon	4
When is the SLN injection performed?	
Same day (A)	25
Day prior (B)	29
A or B	54
Where is the SLN injection performed?	
Nuclear medicine department	55
Radiology suite	11
Different hospital	18
Other locations	4

Operating theatre / anaesthetic room	5
Theatre delays – waiting for patients after localisations	
Daily Once or twice a week Rarely – once or twice a month Never	6 33 44 15
Theatre overruns due to delays in localisation	
Daily Once or twice a week Rarely – once or twice a month Never	1 15 48 34
Change to a different technique	
Yes No Maybe	55 21 22

Table 1: Summary of the questionnaire responses

Perceived limitation of current localisation technique	Breast units
Logistical issue affecting theatre scheduling Not patient friendly	74 51

Migration of the localisation wire	46
Difficulties locating the tip of the wire	42
Excising too much tissue	39
Interference and delays when combined with SLN localisation	33
Depth sensing	29
Concern about not excising the index lesion	20
No concerns	13
X-ray / USS visibility	12
Localisation to be within < 24 hrs (Eg ROLL)	10
Infection risk	9
Regulatory licences	5
Preferred improvement in a new localisation technique	
Improved patient experience	69
Better organization of lists / theatre scheduling	67
Better use of radiology time	65
Accuracy in localisation	55
Decrease in re-excision rates	42
Smaller specimen weight	41
Cost efficiency	34
No regulatory licences	20
Barriers to change to a new localisation technique	
Cost	63
Organisational issues (Effecting management change)	60
Training	39
Learning curve	38
Evidence base	31
Time to effect change	30
Aversion to change in the unit	16

Table 2 –Perceived limitations of current localisation technique, preferred improvements and barriers to change to a new technique

Figures:

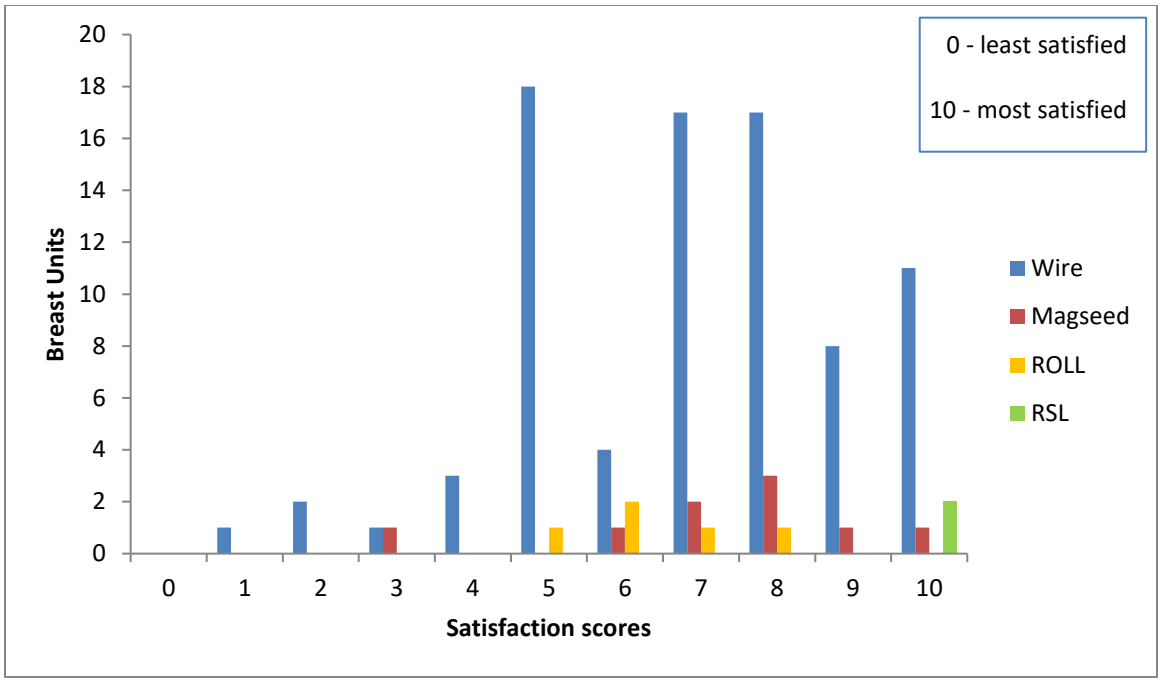

Figure 1: Distribution of satisfaction scores of current localisation technique