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ORIGINAL ARTICLE

Factors Affecting Accuracy of Stereotactic Radioisotope-guided Occult Lesion Localisation for Breast Lesions

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ABSTRACT

Objectives: *To assess the surgical success rate of stereotactic radioisotope-guided occult lesion localisation (ROLL) and to identify factors affecting its accuracy.*

Methods: *We retrospectively identified all stereotactic ROLL procedures from June 2017 to August 2018 at a regional hospital in Hong Kong. Demographic data, imaging results, previous biopsy records, surgical records, and pathology results were reviewed. Independent-sample* t *tests and Fisher's exact test were used to assess the association of multiple factors (including age, breast thickness, depth of lesion, type of target, approach direction, pathology, operator experience) with localisation accuracy using a 5-mm deviation between the centres of the mammographic targets and the scintigraphic image as the threshold.*

Results: *A total of 77 ROLL procedures were identified. Of them, 55 were localisations of nonpalpable lesions and 22 were combined radioisotope-guided sentinel node and occult breast lesion localisations. The overall surgical success rate for removal of the target lesion was 85.7%, and for excision of malignant nonpalpable breast lesions with clear margins the success rate was 83.9%. Specimen mammogram and scintigraphic images were available in 68 cases for subsequent analysis for factors affecting localisation accuracy. A preoperative diagnosis of invasive carcinoma was associated with poorer target localisation ($p = 0.015$). Injection of radioisotope via a lateromedial direction was associated with better target localisation ($p = 0.044$).*

Conclusion: *Stereotactic ROLL is effective in localising nonpalpable breast lesions with a high surgical success rate. There is a significant association between invasive carcinoma with worse localisation. Injection of radioisotope in lateromedial directions is associated with better localisation accuracy.*

Key Words: *Breast neoplasms; Radioisotopes*

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Data Availability: All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics Approval: The study was approved by the Hospital Authority of Hong Kong Kowloon Central / Kowloon East Research Ethics Committee (Ref: KC/KE-18-0290/ER-1). The need for patient consent was waived by the ethics committee.

中文摘要

影響立體定向放射性同位素引導乳腺隱匿性病變定位準確性的因素

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目的：回顧研究2017年6月至2018年8月期間所有在一所香港地區醫院接受ROLL的患者。

方法：評估ROLL的手術成功率及研究與其定位準確度有關的因素。回顧了人口統計學數據、影像學結果、活檢記錄、手術記錄和病理結果。使用乳房X線照相目標和核素閃爍圖像的中心5毫米偏差作為閾值，通過獨立樣本*t*檢驗和 Fisher精確檢驗用於評估多個因素（包括年齡、乳房厚度、病變深度、病變類型、手術路徑、病理、操作者經驗）與定位精度的關聯性。

結果：共包括77個ROLL程序。當中，55個是不可觸及病變的定位，22個是結合放射性同位素引導的前哨淋巴結和隱匿性乳腺病變定位。切除目標病灶的總體手術成功率為85.7%，切除邊緣清晰的不可觸及的惡性乳腺病灶的成功率為83.9%。68個病例的樣本乳房X線照片和核素閃爍掃描圖像可供後續分析影響定位精度的因素。浸潤性癌的術前診斷與較差的目標定位相關（$p = 0.015$）。通過側內側方向注射放射性同位素與更好的目標定位相關（$p = 0.044$）。

結論：立體定向ROLL可有效定位不可觸及的乳房病變，手術成功率高。浸潤性癌與更差的定位之間存在顯著關聯。在側內側方向注射放射性同位素與更好的定位精度相關。

INTRODUCTION

Breast cancer is the leading cancer affecting women in Hong Kong, accounting for 26.6% of all new cancer cases among women in 2016, and has been increasing over the past decade.[1] As public awareness and the acceptance of screening for breast cancer are growing, many breast cancers are detected at a nonpalpable stage. For nonpalpable breast lesions such as microcalcifications, distortion, or asymmetric densities detected on screening mammogram and classified in the Breast Imaging Reporting and Data System as category ≥4, they are first evaluated with stereotactic guided percutaneous core biopsy or vacuum-assisted biopsy. If these lesions turn out to be malignant or of high risk pathologically, therapeutic or diagnostic surgical excision is warranted. Localisation of nonpalpable lesions is required to facilitate surgery.

Hookwire localisation has long been the gold standard in preoperative localisation of nonpalpable breast lesions.[2,3] However, the incidence of margin-positive excision can be as high as 47%.[4] There are also risks of inaccurate positioning and wire displacement after positioning. The first radioisotope-guided occult lesion localisations (ROLL) procedure was performed in 1996.[5] During the procedure, the nonpalpable lesion was marked by intratumoural injection of ^{99m}technetium (^{99m}Tc) labelled macroaggregate albumin or sulphur colloid under imaging guidance. The nonpalpable breast lesions were then localised by a handheld intraoperative gamma probe to facilitate surgical excision. Multiple studies have shown that it is a safe and effective procedure with less radiation dose to the patient as compared with hookwire localisation technique, since no postprocedural mammogram is required; yet good margin clearance rate of 75% to 100% can be achieved.[6] Intraoperative localisation time for the target is also significantly shorter for radioisotope-guided localisation than that for hookwire localisation.[6] Radioisotope-guided localisation also offers an additional benefit of localising sentinel lymph nodes, during the same procedure by injecting ^{99m}Tc labelled filtered sulphur colloid (<22 μm) instead.[4]

The aims of the present study were to assess the technical success rate of localisation and to investigate factors affecting the accuracy of ROLL in localisation of nonpalpable breast lesions.

METHODS

All patients who underwent stereotactic ROLL from 1 June 2017 to 31 August 2018 in the Diagnostic and Interventional Radiology Department of Kwong Wah Hospital, a regional hospital in Hong Kong, were included. Patients were identified and patient data extracted from the Radiology Information System and hospital electronic records.

Relevant information such as demographic data, previous mammogram and imaging reports (experience of the operator, categories of Breast Imaging Reporting and Data System, type and location of mammographic target, injection approach, breast thickness, depth of the target) and previous biopsy and surgical specimen pathology results were recorded. Clinical notes were reviewed for any occurrences of further excision within the same session, or a second operation. 'Surgical success' was defined as successful removal of the lesion for high-risk lesions and successful removal with clear margins in the first operative session for malignant lesions.

In our centre, stereotactic ROLL was performed by injection of approximately 0.2 mL of saline containing 0.5 mCi (18.5 MBq) ^{99m}Tc sulphur colloid using a 22G spinal needle on a prone table mammographic machine. For patients with biopsy-proven invasive carcinoma and high-grade ductal carcinoma in situ (DCIS), ^{99m}Tc labelled filtered sulphur colloid was used for additional localisation of sentinel nodes. A column of gas was injected before release of the breast compression and removal of the needle to push the residual tracer from the needle into the lesion. An anterior planar image of the patient's chest and upper abdomen was acquired 30 minutes post-injection to confirm adequate radioactivity at the injection site and to identify the sentinel lymph nodes in sentinel node localisation cases. The patients were operated on 4 to 6 hours after injection. Surgical excision was guided within the breast using a handheld gamma probe. Following excision, the surgical bed was checked for residual radioactivity. The specimen(s) would then be sent to our department; specimen radiography and scintigraphic images were obtained. Further surgical exploration was needed if residual activity remained high in the breast or if the specimen radiograph/scintigraphic image suggested incomplete excision. Cases with no specimen radiographs or scintigraphic images were excluded for subsequent analysis on factors affecting localisation accuracy.

To quantify localisation accuracy, specimen radiographs and scintigraphic images were reviewed to assess the distance between the centre of the mammographic target and the centre of maximum radioactivity (Figure 1). Patients with ≤5 mm between the centres were categorised as 'good', those with 5 to 15 mm between the centres were categorised as 'fair', and those with ≥15 mm between the centres were categorised as 'suboptimal'. The patient demographics, imaging results, and pathological information were compared among these groups to identify factors affecting localisation accuracy. Statistical analysis was performed with SPSS (Windows version 23.0; IBM Corp, Armonk [NY], United States). Age, breast thickness, and depth of target were compared with independent *t* tests. Pathology, injection approach, appearance on the 30-minute scintigraphic and specimen

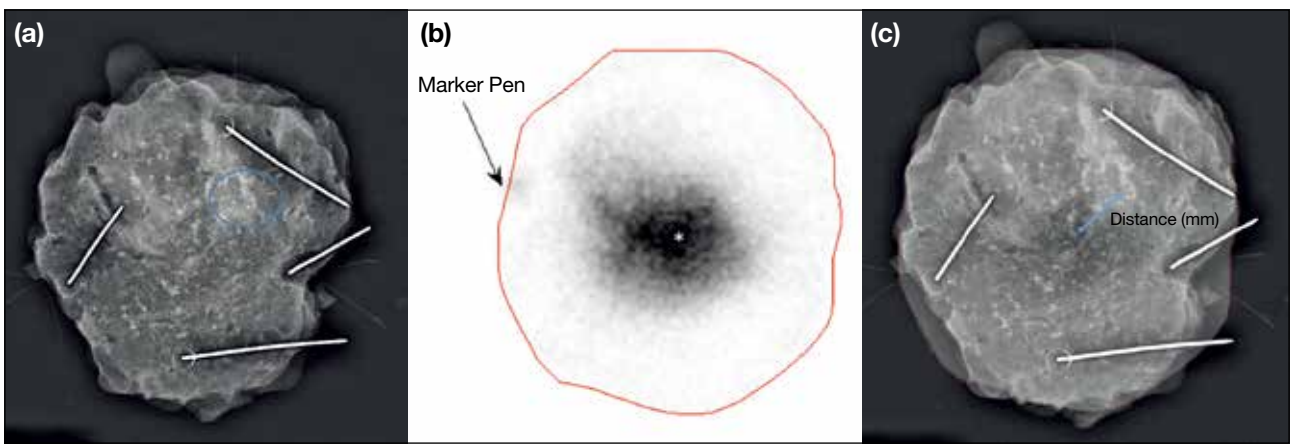

Figure 1. (a) Specimen mammogram with microcalcifications (circle); (b) specimen scintigraphic image with centre of maximum radioactivity (asterisk); (c) fusion image showing the measurement of distance between the centre of the mammographic target on the specimen radiograph and centre of maximum radioactivity on the scintigraphic image.

images, nature of mammographic target, and experience of operator were compared with Fisher's exact test. A p value of <0.05 was taken as statistically significant.

RESULTS

During the study period, a total of 77 stereotactic ROLL procedures were performed in 77 patients.

Table 1. Demographics of the patient undergoing the localisation procedure (n = 77).*

Age, y, mean (range)	54.9 (37-76)
Pathology	
High-risk/premalignant (atypical ductal hyperplasia, lobular neoplasia, mucocele-like lesions, papillary lesions and phyllodes tumour)	21 (27.3%)
Ductal carcinoma in situ	43 (55.8%)
Invasive	13 (16.9%)
Radioisotope	
Sulphur colloid	55 (71.4%)
Filtered sulphur colloid	22 (28.6%)
Mammographic target	
Microcalcifications	59 (76.6%)
Density	4 (5.2%)
Vacuum-assisted breast biopsy marker	10 (13.0%)
Coordinates	4 (5.2%)
Intraoperative re-excision	37 (48.1%)
Reoperation	
Among all cases	11 (14.3%)
Among malignant cases (n = 56)	9 (16.1%)

* Data are shown as No. (%), unless otherwise specified.

Table 1 shows the demographics and pathologies. The dose of radioisotope injected ranged from 0.16 mCi to 0.44 mCi (5.9 MBq to 16.3 MBq) (mean = 0.34 mCi/12.6 MBq). The mammographic targets were microcalcifications in 59 cases, focal asymmetry in four cases, and metallic markers in 10 cases. In four patients, the microcalcifications were too faint after biopsy and difficult to be visualised on preprocedural mammogram on the day of the procedure. The geometric coordinates from their previous stereotactic guided biopsy were used to assist in localisation of the lesion. Evidence of previous biopsy and concordant pathology were identified in the surgical specimens of these cases.

Additional excision within the same operation session after review of specimen radiographs was performed in 37 patients (48%). Of the additional excisions, 29 (78.4%) were required because of narrow resection margin around the mammographic target or the presence of scattered microcalcifications near the resection margin.

Among the 77 cases, 11 (14.3%) required a second operation (Figure 2). Two of them had a preoperative diagnosis of atypical ductal hyperplasia but were subsequently upgraded to DCIS and invasive ductal carcinoma on the basis of the pathology in the surgical

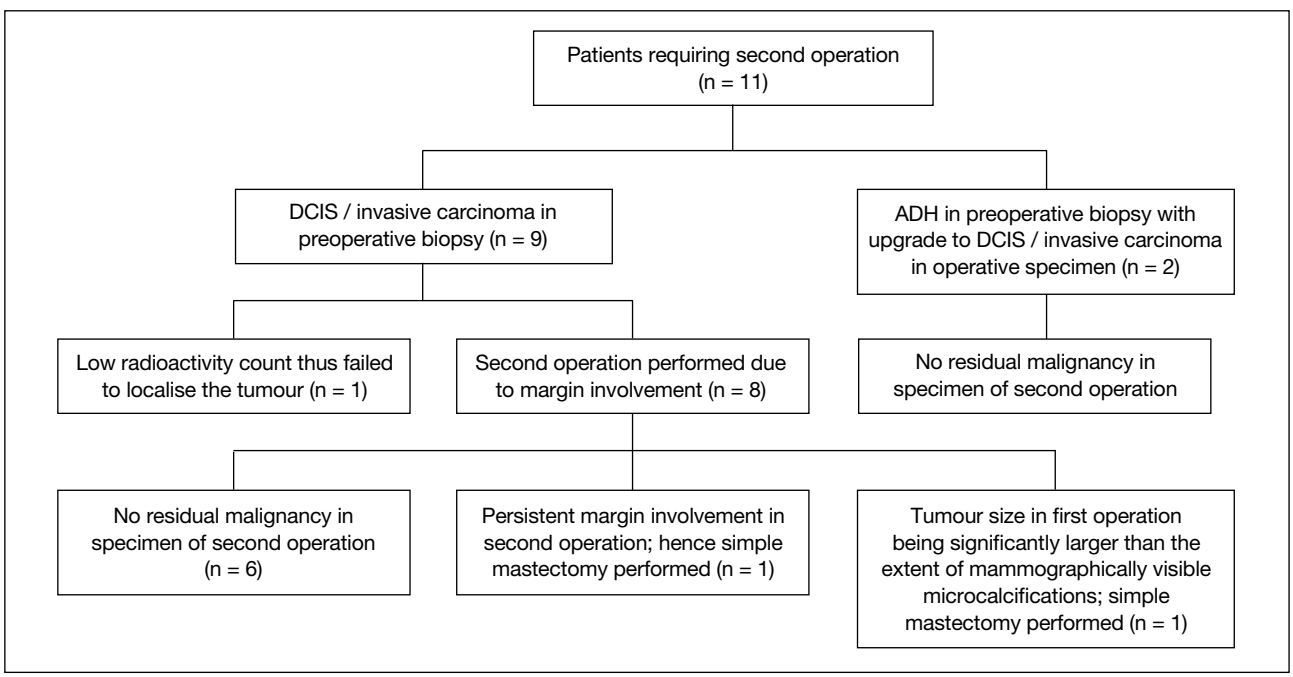

Figure 2. Flowchart showing treatment and outcomes of 11 patients requiring second operation among 77 patients who underwent stereotactic radioisotope-guided nonpalpable lesion localisation.
Abbreviations: ADH = atypical ductal hyperplasia; DCIS = ductal carcinoma in situ.

specimens. The other nine cases with preoperatively diagnosed DCIS or invasive carcinoma required second operations. Eight of these nine patients were reoperated for margin involvement. In the remaining one patient, 30-minute post-injection scintigraphy showed faint radioactivity; excision was performed according to the location with maximum radioactivity but failed to remove the tumour. Among these 11 patients with second operations, eight of them had had re-excision in the first operation.

Among the 77 cases, scintigraphic images were not available in five cases and specimen mammograms were unavailable in four cases; a total of 68 cases remained for analysis for factors affecting localisation accuracy. Of them, the distance between the centre of the mammographic target and the centre of maximum radioactivity was ≤5 mm in 39 (57.4%) patients and >5 mm in 29 (42.6%) patients. Of the cases, 39 (57.4%) were categorised as good, 17 (25.0%) as fair, and 12 (17.6%) as suboptimal. There were no significant differences in demographics between the patients of the good target and fair/suboptimal groups. Inaccurate lesion localisation was more frequently observed in patients with invasive cancer than in patients with DCIS or high-risk breast lesions significance ($p = 0.015$). There was a significant difference in the approach used for performing the injection of radioisotope between the two groups ($p = 0.034$). Significantly better lesion localisation was achieved by approaching the lesion in the lateromedial direction (i.e., in lateromedial or mediolateral projections) than in the craniocaudal (i.e., craniocaudal or reversed craniocaudal projections) or lateromedial oblique directions ($p = 0.044$).

The mammographic targets used for localisation, being vacuum-assisted breast biopsy markers, microcalcifications, or abnormal densities, did not affect the accuracy in localisation significantly. Whether the injection site appeared dispersed on the 30-minute scintigraphic image or on the specimen scintigraphic image did not cause significant difference. There was no statistically significant difference in the experience of the operators in the two groups. Detailed figures of the comparison of the parameters are shown in Table 2.

DISCUSSION

Use of radioisotopes is a safe and effective method to localise nonpalpable breast lesions. In terms of radiation safety, Cremonesi et al[7] calculated the effective dose of radiation involved in ^{99m}Tc-guided localisation to be 100 to 200 times less than the radiation exposure from the additional mammograms needed for hookwire localisation.[6,7] Rampaul et al[8] also demonstrated that the hand dose to breast surgeons and radiologists is also minimal when compared with the annual dose limit even if 100 radioisotope-guided localisation procedures were to be performed per year. A prior study conducted in our centre demonstrated that radioisotope-guided localisation is as good as hookwire localisation in terms of specimen margin clearance and need for second operation with a shorter procedural time.[6] There is also the additional benefit of localisation of sentinel nodes in the same procedure when filtered ^{99m}Tc sulphur colloid is used. In another local study, a high surgical success rate has been demonstrated.[9] In the present study, the surgical success rate for malignant lesions with adequate margins achieved by the first operation was 83.9% (47/56), which is comparable to the previous study performed by our centre as well as in other local and international studies, which ranged from 75% to 100%.[6] Of nine malignant cases with margin involvement in the present study, seven (78%) had their mammographic targets well localised in the first operative session. In one of the cases requiring reoperation, the tumour margin was focally involved in the first operation and no residual malignancy was identified in the surgical specimen of subsequent operation. In the remaining case, tumour extended beyond the visualised microcalcifications upon review of the pathology report, specimen radiograph, and scintigraphic images.

Accurate positioning of the localisation device is a key element for successful localisation of nonpalpable breast lesions. Stereotactically guided placement of localisation devices is often complicated by the effect of breast compression. With the problem of the accordion effect, even minimal deviation of the injection site from the target could be augmented when the breast compression is released.[10] In the present study, we have identified that injection along the lateromedial aspect could achieve significantly better localisation than along the craniocaudal or lateromedial oblique aspects. We postulated that it could be due to the relative difficulty in achieving the same positioning of the breast as in previous biopsy sessions due to a higher tendency of the breast to roll in craniocaudal or oblique image acquisitions that require the breast and ipsilateral arm to be extended through the opening in the table ('arm-through-the-hole' technique). Rolling of the breast is commonly be observed on craniocaudal view,[11] and may result in deviation of the injected radioisotope in an

Table 2. Factors affecting localisation accuracy, measured as the distance between the centre of the mammographic target and the centre of maximum radioactivity (n = 68).*

	Localisation accuracy (distance between centres)		p Value
	Good (≤5 mm), n = 39	Fair/suboptimal (>5 mm), n = 29	
Age, y	58.8±7.4	55.5±8.4	0.103
Breast thickness, mm	44.7±8.9	44.9±9.6	0.935
z-value, mm	23.5±6.4	25.7±8.5	0.259
Radioisotope			0.580
Sulphur colloid	30 (76.9)	20 (69.0)	
Filtered sulphur colloid	9 (23.1)	9 (31.0)	
Mammographic target			0.403
Microcalcifications	32 (82.1)	23 (79.3)	
Density	1 (2.6)	3 (10.3)	
VAB marker	6 (15.4)	3 (10.3)	
Projection			0.034
Lateromedial / mediolateral	36 (92.3)	21 (72.4)	
Craniocaudal / reversed craniocaudal	3 (7.7)	5 (17.2)	
Oblique	0	3 (10.3)	
Projection			0.044
Lateromedial / mediolateral	36 (92.3)	21 (72.4)	
Others	3 (7.7)	8 (27.6)	
Pathology			0.015
DCIS/high-risk lesions	37 (94.9)	21 (72.4)	
Invasive carcinoma	2 (5.1)	8 (27.6)	
Operator			0.809
Specialist	20 (51.3)	16 (55.2)	
Trainee	19 (48.7)	13 (44.8)	
Dispersed on 30 min image			1.00
Yes	7 (17.9%)	5 (17.2)	
No	32 (82.1%)	24 (82.8)	
Dispersed on specimen scintigraphic image			1.00
Yes	22 (56.4)	17 (58.6)	
No	17 (43.6)	12 (41.4)	

Abbreviations: DCIS = ductal carcinoma in situ; VAB = vacuum-assisted breast biopsy.
* Data are shown as No. (%) or mean±standard deviation.

unpredictable direction upon release of compression due to the accordion effect. Based on our findings, in the cases where the mammographic targets were visible on both craniocaudal and mediolateral views, the lateromedial approach was more accurate.

Posterior and deep targets usually require injection via an oblique projection using the 'arm-through-the-hole' (or 'drop-shoulder') technique.[12] A prior study on stereotactic guided breast biopsy has shown that successful retrieval of posteriorly located microcalcifications <15 mm from the pectoralis muscle was better achieved by a digital add-on unit (erect table) mammographic machine than on a prone table due to better resolution, especially when the microcalcifications were small or poorly delineated.[13] This suggests that radioisotope-guided localisation of such deep lesions would better be achieved by add-on unit on an erect table. However, this practice would be subjected to availability of the required equipment and further research on this area should be performed.

Our study demonstrated that invasive carcinoma was associated with worse localisation than DCIS and high-risk lesions, such as atypical ductal hyperplasia and papillary lesions. Loss of myoepithelial cells surrounding tumour cells is the hallmark of invasive breast carcinoma. Upon degradation of the basement membrane, desmoplasia with associated recruitment of fibroblasts, inflammatory cells and angiogenesis occur, causing the tumour to become fibrotic and hard in texture.[14,15] This can lead to difficulty in injection, unintended spread of the injected radioisotope, or spillage of the radioisotope.[16] Previous studies have recommended peritumoural rather than intratumoural injection if significant resistance is encountered.[17] Others have suggested modification of the procedure, using Luer Lock syringes for injection of the radioisotope to prevent disconnection of syringe and needle during injection.[16]

We identified four cases in which the biopsied microcalcifications were faintly seen on the prone table on the day of the localisation procedure. The scar position, projection, and coordinates from previous stereotactically guided biopsies; breast compression thickness; and the depth of the lesion were referred to for injection of radioisotope and resulted in successful radioisotope-guided excision. In order to aid future localisation, when residual microcalcifications are too faint or difficult to be localised, or if near-total removal is anticipated, we suggest that a marker should be placed at the biopsy site at the end of core needle biopsy procedures.

Advances have been made in interventional procedures for breast diseases in recent years. A prone stereotactic biopsy system with both two-dimensional and three-dimensional tomosynthesis breast imaging has been introduced. It utilises the same detector as its diagnostic counterpart with a wider field of view compared with the former two-dimensional stereotactic prone table; and hence better detection and localisation of subtle lesions, e.g., faint calcifications are to be expected. At the same time, the advantage of a prone table approach with better patient comfort compared with erect tomosynthesis biopsy systems can be maintained.[18] Accessories for performing hookwire insertion or radioisotope-guided localisation procedures are available for the prone table with tomosynthesis.

Because our centre is also used for training, ROLL procedures are performed by radiologists with varying amounts of experience (breast radiologists in-training to specialists with over 20 years of experience). Although the success rate is well maintained, the present study demonstrated no statistically significant difference in the success rate in good targeting between trainees and specialists. This could be attributed to the dedicated training and supervision, as well as the experience of the surgeons. We suggest that the ROLL technique can be acquired in a relatively short period of time and should be widely adopted.

There are a few limitations to the present study. Because it was a single-centre retrospective study, measurements of the original lesion size and location could not be retrieved for the cases referred from outside facilities because the images were not available. The relative perceptibility of the target on craniocaudal and mediolateral projections on the prone table could not be assessed. Some factors such as the size and weight of the operative specimen, and the intraoperative counts were not mentioned in the operative record to control the comparison.

CONCLUSION

Stereotactic ROLL is an effective method for localising nonpalpable breast lesions for surgical excision with a high surgical success rate. There is a significant association between invasive carcinoma with worse localisation. Injection of radioisotope in lateromedial directions is associated with better localisation accuracy and we would suggest injection of the radioisotope in this direction if technically feasible.

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