







Comparison of Radio-guided Occult Lesion Localization (ROLL) and Wire-guided Localization in Non-palpable Breast Lesions

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ABSTRACT

Objective: Breast cancer is the most commonly diagnosed malignancy and the second leading cause of cancer-related deaths in women. It is estimated that one in 11 women in developed societies, one in nine women in the UK, and one in eight women in the USA experience breast cancer at some point in their lives. Early diagnosis of breast cancer reduces mortality and morbidity. According that, in this retrospective study, the superiority of the radio-guided occult lesion localization (ROLL) method and the wire-guided localization (WGL) method to one another was investigated considering the data including lesion size, duration of surgical excision, surgical margin, and the need for re-resection in non-palpable lesions suspected of malignancy.

Methods: The study included 79 female patients who had non-palpable breast lesions and suspicious findings for malignancy on mammography and breast ultrasonography. The marking was made on the operation day at the radiology clinic for all patients. All surgeries were performed under general anesthesia. All surgical operations were performed by the same surgeon, all markings were made by the same radiologist, and the material was prepared for ROLL by the same nuclear medicine clinic.

Results: The specimen volume was 36.2 ± 19.6 cc in the ROLL group and 40.8 ± 22.8 cc in the WGL group ($p=0.34$). The duration of surgical excision was 13.2 ± 4.2 min in the ROLL group and 18.2 ± 6.7 min in the WGL group ($p<0.001$). The closest distance to the lesion was 4.5 ± 3.0 mm in the ROLL group and 4.0 ± 3.1 mm in the WGL group ($p=0.52$). Eight patients in the ROLL group and 14 patients in the WGL group required re-resection ($p=0.07$). No significant difference was found between the groups except for the duration of surgical excision.

Conclusion: In the ROLL method, the duration of the operation significantly shortens compared to WGL, and the re-resection rate is lower.

INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy and the second leading cause of cancer-related deaths in women.^[1] It is estimated that one in 11 women in developed societies, one in nine women in the UK, and one in eight women in the USA experience breast cancer at some point in their lives.^[1] Early diagnosis of breast cancer reduces mortality and morbidity. The spread of screening programs is the major factor enabling early diagnosis. In breast cancer cases, non-palpable breast lesions (NPBL) are more common. The increase in the rate of NPBL de-

tected has raised the need for percutaneous methods for the diagnosis and treatment of such lesions.

According to the pieces of evidence in the literature, adjuvant radiotherapy and breast-conserving surgery have the same survival rates in early breast cancers.^[2,3] However, intraoperative localization of small non-palpable malignant lesions and provision of optimal surgical treatment is challenging.

Today, the most commonly used method for the removal of such lesions is wire-guided localization (WGL).^[4] If the suspicious lesion can be detected with ultrasonography

(US), wire marking is preferably performed with US. However, lesions that can only be detected by mammography or magnetic resonance imaging (MRI) can only be marked using mammography or MRI.

WGL has several disadvantages such as migration of the wire, injury to patient or surgeon during the operation, and wire preventing comfortable pathological examination.^[5] For this reason, there was a need to develop additional marking methods. These methods include skin marking on the surface projection of a lesion, marking with paint, marking using perioperative US, carbon localization, and radio-guided occult lesion localization (ROLL).^[6,7]

Of all these methods, the ROLL method, which was developed at the European Institute of Oncology in 1996 in Italy, is becoming a more frequently preferred method considering the studies conducted in several countries.^[7] In the ROLL method, human serum albumin, which is generally labeled with Technetium-99m-macro-aggregated albumin, is used for marking. Under radiological guidance, before the operation (within 24 h), the radionuclide substance is injected into the lesion and the marking of the lesion is completed. Later, the lesion is excised with the help of a gamma-prop in an operation.

In this retrospective study, the superiority of the ROLL method and the WGL method to one another was investigated considering the data including lesion size, duration of surgical excision, surgical margin, and the need for re-resection in non-palpable lesions suspected of malignancy.

MATERIALS AND METHODS

The study included 79 female patients who had NPBL and suspicious findings for malignancy on mammography and breast US (Brest Imaging Reporting and Data Systems -4, or -5) performed at our Hospital between September 23, 2014, and February 2, 2017. These patients underwent WGL or ROLL depending on the radiologist's preference.

The patients who had an operation before September 23, 2014, were not included in this study because of missing data.

The marking was made on the operation day at the radiology clinic for all patients. All surgeries were performed under general anesthesia. The data including age, weight, height, and body mass index (BMI) data recorded for all patients on the day of surgery. In both methods, the lesions were attempted to be removed with at least 1 cm safety margin. The volume was measured with 100 cc beaker filled with 50 cc liquid. Weight measurement was done with precision digital scales after the lesion was removed. The duration of the operation was measured with a stop watch, starting from the skin incision to the moment when the lesion was taken out of the surgical field, and the duration was recorded in minutes. All surgical operations were performed by the same surgeon, all markings were made by the same radiologist, and the material was prepared for ROLL by the same nuclear medicine clinic. If the

nearest surgical margin for ductal carcinoma in situ (DCIS) was <10 mm, the surgical margin was considered positive for this study. The wire used for WGL is Ghiatas Breast Localization Wire, and human serum albumin labeled with Tc99m was used for ROLL.

Human serum albumin marked with Tc99m was prepared on the morning of the operation. Human serum albumin labeled with Tc99m was injected into the detected lesion with a 22G spinal needle with the help of either US or mammography depending on the radiologist's preference. Then, an additional 0.1–0.2 mL of serum was injected into the lesion with a different syringe to prevent unnecessary wide resection.

The patient was sent to the radiology clinic on the morning of the operation for WGL. Using either US or mammography based on the preference of the radiologist, the wire was inserted from the most suitable position and the hook of the wire was opened at the posterior of the lesion.

Both groups were taken to the surgical operation on the same day. The nearest skin projection of the lesion was marked by the radiologist to make the surgeon's job easier with a marker pen on the breast.

General anesthesia was applied to all patients. The operation was performed in the supine position for all patients.

In patients undergoing ROLL, Europrobe 3 device was used for the detection of radionuclide material. The area, from which signal was received by the gamma-probe, was taken out as a one piece with at least 1 cm safety margin. After the lesion was removed from the breast, it was ensured that there was no residual radioactivity in the breast lobe where the specimen was taken.

A single hooked wire was used under mammographic or ultrasound guidance for WGL patients. In patients undergoing WGL, an incision was made on the breast where the radiologist marked up on the skin (the closest point to the lesion), to reach the posterior of the wire. The lesion was tried to be excised as a one piece with at least a 1 cm safety margin. We tried not to excise any unnecessary breast tissue. After the lesion was excised, the elapsed time was noted. Reconstruction time was not taken into account for either group. Volume and weight were measured in the operating room.

If the lesion was detected with mammography, the specimen was sent out for control mammography (to ensure that all suspected area was removed). Then, the radiologist confirmed that the whole lesion was removed. If the lesion could not be removed completely, re-resection was performed at the same operation noting that re-resection was done for the patient. However, in some patients, the surgical border was reported to be positive (Clearance margins >10 mm for DCIS) at standard hematoxylin and eosin staining paraffin block section after surgery. Such patients needed a second operation, such occurrences were also noted as re-resection for the study data. Nevertheless, the volume or weight measurement of the re-resection materials was not included in the study data.

DCIS and invasive cancers were accepted as malignant lesions, atypical lobular hyperplasia, and atypical ductal hyperplasia were accepted as premalignant lesions. Others were accepted as benign lesions.

All statistical analyses were performed using the Statistical Package for the Social Sciences for Windows 22.0 software. Normality was tested using the Kolmogorov–Smirnov test and graphical methods. For normally distributed data, we used mean and standard deviation for the expression of study data. For non-normally variables, we expressed the data using the median and minimum-maximum values. In addition, we added the numeric (n) values and percentages (%) for the data. The Chi-square test was employed for the comparison of two categorical variables. However, when we compared one categorical variable with a numeric value, we used the Independent sample t-test for normally distributed data and the Mann–Whitney U test for the non-normally distributed data. All statistical calculations were two-sided, and $p < 0.05$ indicated statistical significance at a 95% of confidence interval.

RESULTS

The study evaluated 79 NPBL patients, with 42 patients in the ROLL group and 37 patients in the WGL group. All patients were women. The mean age of the patients in the ROLL group was 52.6 years and the mean age of the patients in the WGL group was 54.0 years. BMI index was 28.7 and 29.0 kg/m³ for the ROLL and WGL groups, respectively. In the ROLL group, the lesion was localized with US in 23 patients and with stereotactic technique in 19 patients versus 17 and 20 patients in the WGL group, respectively. No significant differences were found between the groups in terms of age, BMI, and scanning method of NPBL.

In the post-operative pathology reports, the lesions of 43 patients (54.5%) were malignant, 9 (11.4%) were premalignant and 27 (34.2%) were benign. Twenty of the lesions detected in USG were malignant and six of them were premalignant. Twenty-three of those found in mammography were malignant and three of them were premalignant. Malignant-premalignant lesion capture rate was 65% in USG and 66% in mammography ($p = 0.54$). No significant difference was found between mammography and USG in terms of capturing of malignant and premalignant lesions.

No complications related to marking were observed in the ROLL patients, and all markings were successfully applied. On the other hand, in only one patient that underwent wire marking, the wire broke off after contact with the electrocautery during the operation, resulting in the prolongation of the procedure, but the lesion was successfully removed.

The specimen volume was 36.2 ± 19.6 cc in the ROLL group and 40.8 ± 22.8 cc in the WGL group ($p = 0.34$). The duration of surgical excision was 13.2 ± 4.2 min in the ROLL group and 18.2 ± 6.7 min in the WGL group ($p < 0.001$). The closest distance to the lesion was 4.5 ± 3.0 mm in the

Table 1. Pathological and operational findings of ROLL and WGL

	ROLL	WGL	p
Volume (cc)	36.2 ± 19.6	40.8 ± 22.8	0.34
Weight (g)	34.2 ± 16.5	38.0 ± 21.8	0.38
Re-resection	8	14	0.07
Duration (min)	13.2 ± 4.2	18.2 ± 6.7	<0.001

ROLL: Radio-guided occult lesion localization; WGL: Wire-guided localization.

ROLL group and 4.0 ± 3.1 mm in the WGL group ($p = 0.52$). Eight patients in the ROLL group and 14 patients in the WGL group required re-resection ($p = 0.07$). No significant difference was found between the groups except for the duration of surgical excision (Table 1). However, the need for re-resection would have been significant if there had been more patients.

DISCUSSION

With the use of breast screening programs all over the world and the increase of awareness among women about periodic breast examinations, there has been an elevation in the number of detected NPBL. At the same time, the number of diagnosed early-stage breast cancers has increased, and both diagnostic procedures and surgical approaches have shifted toward minimally invasive methods.

At present, the standard method used for the localization of NPBL is the WGL technique. Diagnosis of a suspected microcalcification or excision of an NPBL are the most common indications for wire-guided biopsy. Indeed, catching malignant lesions in the early stages can provide a cure and improve the quality of life of the patient. However, complications seen in WGL have caused the method to be questioned. The most common (10%) complication of WGL is vasovagal reactions that appear during marking. Other rare complications include bleeding, pneumothorax, infection, migration of the wire before or during surgical excision, the possibility of cutting the wire, and the risk of contact with the electrocautery. One of the most important complications of the marking process is the inability to remove the lesion—a complication that has been reported between 0% and 17% in different series.^[8–10]

The ROLL method, which is used as an alternative to WGL, was introduced by Luini et al.^[11] in 1996 at the European Institute of Oncology in Milan. In that study, the ROLL method was compared with the WGL method. It was reported that the volume of the excised specimen was less in the ROLL group, and the location of the lesion had a better placement in the center of the specimen compared to the WGL group. The favorable results of this initial study of the ROLL method attracted attention worldwide and many centers have conducted studies on the ROLL method.^[12–19] In many of these studies, marking with radionuclide material has proven to be reliable and effective. After the literature review, we found eight comparative studies.

Tc99m was used in the majority of the studies we analyzed.^[12,15-17] Only Lovrics et al.^[18] and Gray et al.^[19] made use of titanium-containing 29 mCi I25 iodine in their studies. However, no advantage of using titanium-containing 29 mCi I25 iodine over Tc99m has been proven. In our study, we used Tc99m.

In three of the studies we examined, the complications related to ROLL were reported during marking.^[12,17,18] While two two complications were reported in one study^[18] and three complications in the other study, Lovrics et al.^[18] reported 13 complications.^[12] Only Lovrics et al. found a higher complication rate in the ROLL patients. In our study, there was no complication related to marking in ROLL. Wire-related complications have been reported in six studies. In our study, the operation time was extended as a result of wire breakage in one patient. We believe that the rate of complications related to marking will lower over time in parallel with increased experience in ROLL (Table 2).

There are two studies that examined specimen volume. In the study of Rampaul et al., no significant difference was found between the ROLL and WGL groups. Postma et al.^[12] that a higher amount of tissue was removed in patients undergoing ROLL ($p=0.017$).^[18] In our study, the specimen volume was 36.2 ± 19.6 cc in ROLL patients and 40.8 ± 22.8 cc in WGL patients. No significant difference was found between the two groups in terms of specimen volume ($p=0.34$).

Mariscal Martínez et al.^[14] and Rampaul et al.^[17] measured the weight of specimens in their studies and found that the methods had no superiority to one another.^[14,17] In our study, the average weight of the specimens was 34.2 ± 16.5

g and 38.0 ± 21.8 g in ROLL and WGL patients, respectively. Neither method was found to be superior to the other in terms of specimen weights ($p=0.38$).

The duration of operation was measured in all studies. Ocal et al.^[13] and Lovrics et al.^[18] found the duration of operation to be shorter in the ROLL group compared to the WGL group ($p=0.001$ and $p<0.001$ respectively). In the other six studies, no significant difference was found in terms of operation duration. In our study, on the other hand, the mean duration of operation was 13.2 ± 4.2 min in the ROLL group and 18.2 ± 6.7 min in the WGL group ($p<0.001$). As it is seen that the operation time was shorter in favor of ROLL (Table 2).

Surgical margin positivity and the need for re-resection were investigated in seven studies. In three studies, the need for rectification was significantly lower in favor of ROLL.^[13,16,19] In our study, eight patients who were diagnosed with malignancy with the ROLL method and 14 patients from WGL patients had to undergo re-resection ($p=0.07$). This p-value was reached in our study with a limited number of patients, and therefore, it might have changed significantly in favor of ROLL if the study has been done with a larger study sample.

The first study by Luini et al.^[11] reported that the volume of specimen in the ROLL group was lower and the location of the lesion had a better placement in the center of the specimen compared to the WGL group. In our study, the volume and weight of the specimen were measured to determine if the amount of removed tissue was greater than what was necessary. As a result, we found no superiority between the two groups. We think that developing a standard for the amount of radionuclide material that should

Table 2. Findings of different studies

	Group	Complication	Operation time	Re-Resection
Postma, 2012	ROLL	3	18 ($p=0.113$)	22 ($p=0.644$)
	WGL	1	16	18
Ocal, 2011	ROLL	0	31 ($p=0.01$)	1 ($p=0.05$)
	WGL	1	43	6
Mariscal Martínez, 2009	ROLL	0	32.7 ($p=0.657$)	7 ($p=0.357$)
	WGL	6	36.5	12
Moreno, 2008	ROLL	0	26 ($p=0.719$)	1 ($p=0.67$)
	WGL	2	37.2	2
Medina-Franco, 2008	ROLL	0	29 ($p=0.23$)	1 ($p=0.04$)
	WGL	1	33	3
Rampaul, 2004	ROLL	2	31 ($p=0.147$)	–
	WGL	0	35	–
Lovrics, 2011	ROLL	13	19.4 ($p=0.001$)	29 ($p=0.609$)
	WGL	3	22,2	33
Gray, 2001	ROLL	0	5.4 ($p=0.28$)	9 ($p=0.02$)
	WGL	0	6,1	35
Our Study	ROLL	0	13.2 ($p=0.001$)	8 ($p=0.07$)
	WGL	1	18.2	14

ROLL: Radio-guided occult lesion localization; WGL: Wire-guided localization.

be administered, better localization techniques such as giving radionuclide material to the center of the lesion, and increasing the experience of the radiology clinic will help to reduce the amount of tissue to be removed in the ROLL method.

Two large patient population meta-analyses were published in 2022 comparing ROLL and WGL.^[20,21] According to a meta-analysis of 3122 patient published in the European Journal of Surgery, ultrasound-guided surgery had decreased positive margin.^[20] There was also a statistically significant reduction in reoperation rate and operative time. All techniques were equivalent for successful excision, localization complications, and overall complications. The meta-analysis published in Asian Journal of Surgery shows that the use of ROLL is non-inferior to WGL for the localization of NPBL.^[21] Their results show that in certain cases, ROLL significantly reduces operative time, time for radiological localization of lesion, and also reduces the chances of having involved resection margins.

CONCLUSION

WGL is the first and widely used marking method in determining the localization of NPBL worldwide. However, considering the complications related to marking with wire, it does not seem to be an ideal method. In this respect, ROLL comes to mind as an alternative to WGL. In the ROLL method, the duration of the operation significantly shortens compared to WGL, and the re-resection rate is lower.

For these reasons, at the centers capable of performing ROLL, it may be more appropriate to apply the ROLL method first in the excision of NPBL.

Ethics Committee Approval

This study approved by the Kartal Dr. Lütfi City Hospital Clinical Research Ethics Committee (Date: 10.02.2021, Decision No: 2021/514/195/5).

Informed Consent

Retrospective study.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: F.M.; Design: F.M.; Supervision: M.E.; Fundings: C.B.O.; Materials: N.İ.; Data: M.E.; Analysis: A.E.K.; Literature search: F.M.; Writing: F.M.; Critical revision: M.M.A.

Conflict of Interest

None declared.

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Palpe Edilemeyen Meme Lezyonlarının Eksizyonunda Tel ve Radyoaktif Madde ile İşaretleme Yöntemlerinin Karşılaştırılması

Amaç: Memede erken zamanda yakalanan şüpheli malign lezyonların eksizyonunda uygulanan işaretleme yöntemlerinden radyo kılavuzlu (ROLL) ve Tel ile işaretleme karşılaştırılması ve varsa birbirlerine üstünlüklerinin bulunması.

Gereç ve Yöntem: 23 Eylül 2014 ile 02 Şubat 2017 tarihleri arasında hastanemizde tarama amaçlı yapılan mammografi ve ultrasonografide tespit edilen ancak muayenede palpe edilemeyen şüpheli malign lezyonu olan 79 hasta çalışmaya dahil edildi. Bu hastaların 42 tanesine ROLL, 37 tanesine tel ile işaretleme uygulandı. Hastaların işaretlemeyle ilgili komplikasyonları, piyes hacmi, operasyon süresi, son patoloji raporları ve rerezeksiyon ihtiyacı değerlendirildi.

Bulgular: Hastaların tümü kadındı. Hastaların yaş ortalaması 53.2 ve vücut kitle indeksi ortalaması 28.7 olarak bulundu. Olguların son patoloji raporlarında 43'ünün (%54.5) malign, 9'unun (%11.4) premalign, 27'sinin (%34.2) benign olduğu görüldü. Piyes hacmi ROLL hastalarında ortalama $36.2 \text{cc} \pm 19.6$, Tel hastalarında ise $40.8 \text{cc} \pm 22.8$ olarak bulundu ($p=0.34$). Ameliyat süresi ROLL hastalarında ortalama $13.2 \text{ dk} \pm 4.2$, Tel hastalarında ise $18.2 \text{ dk} \pm 6.7$ olarak bulundu ($p<0.001$). ROLL hastalarında toplam 8 hastaya rerezeksiyon gerekliliği oldu. Tel hastalarında ise toplam 14 tanesinde rerezeksiyon yapıldı ($p=0.07$).

Sonuç: Non-palpabl meme lezyonlarının tanısal amaçlı veya küratif eksizyonlarında, ROLL ile yapılan ameliyatın süresi tele göre anlamlı derecede kısa ve rerezeksiyon ihtiyacı daha azdır. ROLL yönteminde tele özgü komplikasyonlardan kaçınmak mümkündür.

Anahtar Sözcükler: Non-palpabl; palpe edilemeyen meme lezyonları; ROLL (Radioguided occult lesion localisation); tel ile işaretleme.