Original Article

RFID for Intraoperative Localization of Non-Palpable Breast Lesions: A Single-Center Experience

RFID para Localização Intraoperatória de Lesões Mamárias Não Palpáveis: uma Experiência de um Único Centro

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ABSTRACT

Introduction: Breast cancer screening has increased the detection of non-palpable lesions, requiring accurate intraoperative localization to ensure oncologic safety and preserve cosmesis. Wire-free methods such as radiofrequency identification (RFID) provide radiation-free, patient-friendly alternatives to traditional wire-guided techniques.

Methods: We conducted a retrospective single-center study of patients undergoing breast-conserving surgery with RFID localization between June 2021 and August 2023. Collected data included timing of device placement and surgery, number of devices, device–lesion and device–skin distances, specimen and lesion volumes, margin, and complications of the device and surgery were evaluated.

Results: A total of 131 RFID devices were placed for 108 lesions; two devices were required in 22% of cases. Devices were implanted a mean of 3 days before surgery (range 0–42). The mean distance to the lesion was 0.3 mm and to the skin 30 mm. The mean specimen volume was 144 cm^3, and mean lesion volume 5 cm^3. Malignancy was confirmed in 91% of lesions, with a mean tumor size of 13 mm. Negative margins were achieved in 88% of malignant cases. Twelve patients (12.2%) required re-excision, with residual disease in 67%. All devices were successfully retrieved. No device-related complications occurred; surgical complications were observed in 4% of cases.

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Conclusion: RFID localization with LOCalizer™ is a safe, effective and radiation-free technique for non-palpable breast lesions. It enables accurate excision with high negative margin rates, low re-excision rates, and no device-related morbidity and allows scheduling flexibility.

Keywords: Breast Neoplasms/diagnostic imaging; Breast Neoplasms/surgery; Radio Frequency Identification Device

RESUMO

Introdução: O rastreio do cancro da mama aumentou a deteção de lesões não palpáveis, exigindo localização intraoperatória precisa para garantir segurança oncológica. Métodos sem fio, como a identificação por radiofrequência (RFID), oferecem alternativas sem radiação e mais confortáveis para a doente face às técnicas tradicionais.
Métodos: Realizámos um estudo retrospetivo, incluindo doentes submetidas a cirurgia conservadora da mama com localização por RFID, entre junho de 2021 e agosto de 2023. Foram recolhidos dados sobre a data de colocação do dispositivo e da cirurgia, número de dispositivos, distâncias dispositivo–lesão e dispositivo–pele, volumes da peça e da lesão, margens cirúrgicas, bem como complicações relacionadas com o dispositivo e com a cirurgia.
Resultados: Foram colocados 131 dispositivos para 108 lesões; em 22% dos casos foram necessários dois. O tempo médio de colocação foi de 3 dias antes da cirurgia (0–42). A distância média foi 0,3 mm até à lesão e 30 mm até à pele. O volume médio da peça foi 144 cm^3 e da lesão 5 cm^3. Malignidade foi confirmada em 91% das lesões, com tamanho médio de 13 mm. Margens negativas foram obtidas em 88% dos casos malignos. Doze doentes (12,2%) necessitaram de reintervenção, com doença residual em 67%. Todos os dispositivos foram recuperados. Não ocorreram complicações relacionadas com o dispositivo; complicações cirúrgicas verificaram-se em 4%.
Conclusão: A localização por RFID é segura, eficaz e sem radiação para lesões mamárias não palpáveis, permitindo excisão precisa, elevadas taxas de margens negativas, baixas reintervenções e flexibilidade de agendamento.

Palavras-chave: Dispositivo de Identificação por Radiofrequência; Neoplasias da Mama/cirurgia; Neoplasias da Mama/diagnóstico por imagem

INTRODUCTION

The widespread adoption of population-based breast cancer screening programs has led to an increasing detection of non-palpable breast lesions.[1] These small tumors have shifted surgical management toward breast-conserving surgery, where precise intraoperative localization is essential to achieve negative margins while minimizing cosmetic impact.

Wire-guided localization (WGL) has long been the standard technique.[2] However, it is associated with several limitations, including patient discomfort, risk of wire migration, operative scheduling constraints, and occasional difficulty in orienting excision.[3] To overcome these challenges, alternative wire-free methods have been introduced. Radioactive seed localization (ROLL) achieves accurate targeting but requires strict radiation safety regulations.[4] Magnetic seed localization offers radiation-free localization but may be limited by interference with metallic instruments.[5]

Radiofrequency identification (RFID) devices represent a promising alternative. They enable accurate lesion localization without radiation exposure, can be placed days or even weeks before surgery, and improve both patient comfort and surgical logistics. Early studies have shown comparable or superior margin negativity rates compared with WGL, but most published series are relatively small and originate from North American centers.[6-12]

We therefore conducted a single-center retrospective study to evaluate the feasibility, safety, and oncological outcomes of RFID localization for non-palpable breast lesions in a European breast unit. Our primary aim was to assess surgical margin status and complication rates, and our secondary aim was to analyze scheduling flexibility and procedural safety.

METHODS

We performed a retrospective, single-center descriptive study at the Breast Unit of Centro Hospitalar Universitário Santo

António, Porto, Portugal. The study period extended from June 2021 to August 2023. The protocol was reviewed and approved by the institutional board, and informed consent for the surgical procedures was obtained from all patients.

All consecutive patients undergoing breast-conserving surgery for non-palpable breast lesions localized with radiofrequency identification (RFID) using the LOCalizer™ system (Hologic Inc., Marlborough, MA, USA) during the study period were eligible. Exclusion criteria were: palpable tumors, lesions localized with other methods, and patients undergoing mastectomy.

RFID tags (LOCalizer™) were inserted under ultrasound or stereotactic guidance by experienced breast radiologists, according to lesion characteristics. Each device was placed within or adjacent to the target lesion, and its position was confirmed radiographically. The distance between the tag and both the lesion and the skin surface was recorded. Devices could be placed up to six weeks before surgery, depending on scheduling availability.

Surgical excision was guided intraoperatively with the handheld LOCalizer™ probe, which detects the unique radiofrequency signal emitted by each tag. Specimens were oriented and radiographed to confirm complete excision of the lesion and retrieval of the device.

Collected data included patient demographics, type of lesion (benign vs malignant), number of RFID devices used, interval between placement and surgery, device–lesion distance, device–skin distance, specimen volume, lesion size, and margin status. Margins were classified as negative, close, or positive. Re-excision rates, device retrieval success, and perioperative complications were recorded.

The primary endpoint was successful localization and excision with negative margins using RFID (LOCalizer™).

Secondary endpoints included complication rates (device- and surgery-related), need for re-excision, and scheduling interval between placement and surgery.

Descriptive statistics were used. Continuous variables are reported as mean ± standard deviation (SD) or median and range, depending on distribution. Categorical variables are presented as frequencies and percentages. Statistical analyses were performed using IBM SPSS Statistics © v29.0.

RESULTS

A total of 131 RFID tags (LOCalizer™) were placed to localize 108 non-palpable breast lesions. In 24 lesions (22.2%), two RFID devices were required.

RFID devices were implanted a mean of 3 days prior to surgery (range 0–42). The mean distance from the device to the lesion was 0.3 mm (0–6), and the mean distance to the skin surface was 30 mm (4–72). All devices were successfully retrieved intraoperatively.

The mean specimen volume was 144 cm^3 (6–1,318), and the mean lesion volume was 5 cm^3 (0.001–120).

Histology confirmed malignancy in 98/108 lesions (91%). The mean tumor size was 13 mm.

Negative margins were obtained in 86/98 malignant cases (88%). Twelve patients (12.2%) had positive or close margins and underwent re-excision; residual disease was identified in 8/12 cases (67%).

No RFID-related complications occurred. Surgical complications were observed in 4/108 cases (4%): two wound infections, one hematoma, and one superficial skin necrosis.

Patient and lesion characteristics are summarized in Table 1, and surgical and pathological outcomes in Table 2.

Table 1 – Baseline patient and lesion characteristics of the study cohort.

Variable	Value
Number of patients	108
Number of RFID tags placed	131
Lesions requiring 2 tags	24 (22.2%)
Mean interval placement–surgery	2.8 days (range 0–42)
Mean distance device–lesion	0.3 mm (range 0–6)
Mean distance device–skin	30.1 mm (range 4.1–72.2)
Mean specimen volume	144.4 cm^3 (range 6.1–1317.5)
Mean lesion volume	4.7 cm^3 (range 0.001–120)

Table 2 – Surgical and pathological outcomes after RFID localization.

Variable	Value
Malignant lesions	98 (90.7%)
Mean tumor size	12.7 mm
Negative margins	86 (87.8%)
Positive/close margins	12 (12.2%)
Re-excision required	12 (12.2%)
Residual disease at re-excision	8 (66.7%)
Device retrieval	100%
RFID-related complications	0%

DISCUSSION

This study reports our single-center experience with 131 RFID (LOCalizer™) localizations for 108 non-palpable breast lesions, representing one of the largest European series to date. We observed high rates of successful excision with negative margins (88%), no device-related complications, and minimal surgical morbidity.

The performance of RFID localization in our series is comparable or superior to wire-guided localization (WGL), which remains the traditional standard. Reported rates of positive margins with WGL vary between 15% and 30%,[2,3] often necessitating re-excision procedures. In contrast, the margin positivity rate in our cohort was 12%, with residual disease identified in 67% of re-excised specimens. These outcomes are consistent with previously published international RFID studies, which demonstrate reliable localization accuracy and favorable oncologic results.[7-12]

Other wire-free alternatives have been explored, including radioactive seed localization (ROLL) and magnetic seed localization (Magseed). While effective, ROLL requires adherence to radiation safety protocols, limiting its widespread adoption.[4] Magseed provides radiation-free guidance but may be affected by metallic interference and availability constraints.[5] RFID devices overcome many of these limitations: they are radiation-free, can be placed up to several weeks before surgery, and improve scheduling flexibility for both patients and operating theaters. Importantly, patient comfort is enhanced by the absence of an external wire, and surgeons benefit from accurate real-time intraoperative detection.

The clinical implications of these findings are significant. RFID localization allows institutions to optimize workflow by decoupling radiology and surgery scheduling, which is particularly advantageous in high-volume breast units. The consistent retrieval rate (100%) and absence of device-related complications confirm the safety and reproducibility of this technique.

Nevertheless, our study has limitations. It is retrospective and based on a single center, which may limit external generalizability. We did not perform a direct comparison with other localization methods during the study period, and long-term oncological outcomes were not assessed. Additionally, cost-effectiveness was not evaluated, which remains a relevant factor for health systems considering adoption.

In conclusion, RFID localization provides robust European evidence of a safe, effective, and patient-friendly alternative to wire-guided techniques. Beyond oncologic safety, its workflow flexibility and absence of radiation makes it particularly suited for integration into modern, high-volume breast units.

LEARNING POINTS / TAKE HOME MESSAGES

- RFID localization is a safe and effective method for non-palpable breast lesions, with a high success rate for achieving negative surgical margins (88% in this study).
- The technique is radiation-free and associated with no device-related complications, enhancing patient safety.
- RFID allows for significant scheduling flexibility, as devices can be placed days or weeks before surgery, decoupling radiology and surgical procedures.
- This method demonstrates a low re-excision rate (12.2%), comparable or superior to traditional wire-guided localization.

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ETHICAL DISCLOSURES

Conflicts of Interest: The authors have no conflicts of interest to declare.
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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of patient data.
Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2024).
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RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.
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Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.
Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.
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CONTRIBUTORSHIP STATEMENT

All authors contributed to the design, analysis, and writing of the manuscript and contributed to the final manuscript.
All authors approved the final version to be published.

DECLARAÇÃO DE CONTRIBUIÇÃO

Todos os autores contribuíram para a concepção, análise e redação do manuscrito e contribuíram para o manuscrito final.
Todos os autores aprovaram a versão final a ser publicada.

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