A Prospective Clinical Study to Evaluate the Safety and Performance of Wireless Localization of Nonpalpable Breast Lesions Using Radiofrequency Identification Technology

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OBJECTIVE. The purpose of this study was to evaluate the safety and performance of localizing nonpalpable breast lesions using radiofrequency identification technology.

SUBJECTS AND METHODS. Twenty consecutive women requiring preoperative localization of a breast lesion were recruited. Subjects underwent placement of both a hook wire and a radiofrequency identification tag immediately before surgery. The radiofrequency identification tag was the primary method used by the operating surgeon to localize each lesion during excision, with the hook wire serving as backup in case of tag migration or failed localization. Successful localization with removal of the intended lesion was the primary outcome measured. Tag migration and postoperative infection were also noted to assess safety.

RESULTS. Twenty patients underwent placement of a radiofrequency identification tag, 12 under ultrasound guidance and eight with stereotactic guidance. In all cases, the radiofrequency identification tag was successfully localized by the reader at the level of the skin before incision, and the intended lesion was removed along with the radiofrequency identification tag. There were no localization failures and no postoperative infections. Tag migration did not occur before incision, but in three cases, occurred as the lesion was being retracted with fingers to make the final cut along the deep surface of the specimen.

CONCLUSION. In this initial clinical study, radiofrequency tags were safe and able to successfully localize nonpalpable breast lesions. Radiofrequency identification technology may represent an alternative method to hook wire localization.

Devices using radiofrequency technology have been approved by the U.S. Food and Drug Administration for implantation in humans for purposes of identification. A radiofrequency identification tag is implanted percutaneously, and information stored on the tag can be retrieved by placing a handheld reader device on the skin overlying the tag. Because the tag is not visible to the operator, the reader device makes an audible sound that increases in pitch as the device is moved closer to the tag’s location. This property of the system can thus be manipulated for use as a localization method, rather than for the purpose of retrieving stored information. As such, radiofrequency identification tags have been used for bedside determination of endotracheal tube position and intraoperative detection of surgical sponges inadvertently left in a body cavity [1, 2]. The use of radiofrequency identification technology for the purpose of localizing breast lesions has also been previously reported in proof-of-concept studies involving breast phantoms, turkey...
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Fig. 1—Radiofrequency identification tags. A, Photograph shows radiofrequency identification tag. B, Photograph shows two different-sized radiofrequency identification tags, lengths 8 and 12 mm. Dime is shown for scale.

Fig. 2—Radiofrequency identification reader (TagFinder, Health Beacons). A, Photograph shows radiofrequency identification reader with 6-cm range display screen indicating depth of 3 cm. B, Photograph shows radiofrequency identification reader with pencil probe attached.

breasts, and cadaver breasts [3, 4], but clinical data are lacking.

The purpose of this study was to evaluate the safety and performance of localizing nonpalpable breast lesions using radiofrequency identification technology in patients undergoing breast surgery.

Subjects and Methods

Consecutive women requiring intraoperative localization of a breast lesion were recruited to participate in this clinical trial, with the goal of enrolling 20 subjects. All patients had undergone a prior core needle biopsy with placement of a metallic clip that served as a discrete target. Patients were excluded if the breast lesion was palpable or located deeper than 6 cm from the skin when lying supine, or if a cardiac pacemaker or defibrillator device was present. Institutional review board approval was obtained before the recruitment of subjects, and informed consent was obtained from all enrolled participants.

In the radiology suite on the morning of the scheduled surgical excision, subjects underwent placement of both a hook wire and a radiofrequency identification tag under ultrasound or stereotactic guidance. All stereotactic procedures were performed with the patient in the prone position with paired images 30° apart. The UltraWire (Bard Biopsy Systems) was used for ultrasound-guided placements, and the Hawkins III Hardwire (Angiotech Pharmaceuticals) was used for stereotactically guided procedures. The hook wires were placed first, followed by placement of the radiofrequency identification tag beside the hooked end of the wire. The positions of both the wire and tag were intended to be through the lesion (ultrasound) or beside the metallic clip (stereotactic) and were confirmed radiographically. Age, breast density, and bra size were recorded for each subject, along with the intended lesion or the metallic clip and hook wire. On mammography, five patients had fat density, five had scattered fibroglandular density, five had heterogeneously dense breasts, and five were of no special type.

Successful localization and removal of the intended lesion using only the radiofrequency identification tag system was the primary outcome measured. This was determined on the basis of the specimen radiograph showing the tag and wire, along with the intended lesion or the metallic clip that was placed at the time of core biopsy. Tag migration before removal and postoperative infection within 30 days were also noted to assess safety. For malignant lesions, the number of subjects with positive margins requiring reexcision was recorded.

The radiofrequency identification system is composed of a passive 2 × 12 mm tag (Figs. 1A and 1B) and a handheld radiofrequency identification reader (Figs. 2A and 2B). Each radiofrequency identification tag is composed of a coil and a microchip housed in a biologically inert glass casing, and it stores a unique identification number that can be recognized by the radiofrequency identification reader. The tag is inserted percutaneously through a 12-gauge needle applicator. The radiofrequency identification reader, powered by a 9-V battery, works by sending a 134.2-kHz radiofrequency signal to the radiofrequency identification tag, which in turn absorbs, modifies, and reemits the signal. Two different examination modes of the reader can then be used to reabsorb the signal, one using a 6-cm-range loop probe and the other using a 3-cm-range pencil probe. The reader can then provide both an audible signal and a visual indicator on the screen of the distance to the tag along with the tag’s unique identification number.

Results

Twenty-eight women were approached to participate; 20 subjects enrolled. No woman was excluded because of a lesion greater than 6 cm in depth or an implanted cardiac device. Eight women did not wish to participate after being informed of the study details. The enrolled subjects were 38–64 years old (mean, 53 years) and underwent placement of a radiofrequency identification tag and hook wire. On mammography, five patients had fatty breast tissue, eight had scattered fibroglandular density, five had heterogeneously dense breasts, and five were of no special type.
remaining 15 patients had lesions that were lodged after being noted in the correct position on postplacement mammograms. In a separate case, the hook wire had been dislodged along the deep surface of the specimen. In eight lesions were placed with stereotactic guidance. In the radiology suite, 12 tags and wires were placed under ultrasound guidance and eight were placed with stereotactic guidance. Radiofrequency identification tag function was confirmed using the loop probe against the overlying skin in all cases after percutaneous placement of the tag within the lesion of interest. Twelve lesions were located in the upper outer quadrant of the breast, four in the upper inner quadrant, two in the lower outer quadrant, and two in the retroareolar area. Tags were placed 0–10 cm (median, 4 cm) from the nipple and 12–39 mm (median, 22 mm) deep to the overlying skin.

In the operating room, all 20 lesions were successfully removed using the radiofrequency identification tag as guidance. The intended lesion or metallic clip was seen within all 20 specimen radiographs. There were no localization failures. The tag was confirmed within the excised specimen in all cases using the handheld reader (Fig. 3). Tag migration did not occur before incision, but in three cases, migration occurred along the insertion track as the lesion was being retracted with fingers to make the final cut along the deep surface of the specimen. In a separate case, the hook wire had been dislodged after being noted in the correct position on postplacement mammograms.

Five patients had nonmalignant breast lesions containing atypical hyperplasia. The remaining 15 patients had lesions that were malignant, and four (27%) of these patients required reexcision of a positive margin. Additional cancer was not found in the subsequent specimens. There were no postoperative infections occurring within 30 days in any of the 20 subjects enrolled.

Discussion

It is well established that increases in screening mammography have led to higher detection rates of nonpalpable breast cancers, high-risk proliferative lesions, and suspicious mammographic abnormalities that require operative excision. Despite various inconveniences and problems, localization wires have remained the standard technique used to locate these nonpalpable abnormalities in the operating room. To our knowledge, this pilot study is the first clinical trial using radiofrequency technology as a method of marking and excising nonpalpable breast lesions. We found that a radiofrequency identification tag system was able to safely and successfully localize all 20 intended breast lesions, making it a potentially viable alternative to other localization devices such as hook wires.

Other localization techniques have been studied as alternatives to the hook wire, but several drawbacks remain. Ultrasound-visible markers composed of collagen or hydrogels have been developed to mark lesions up to weeks or months after the biopsy procedure [5, 6]. Although these markers are fully implanted at the time of core biopsy to avoid a second procedure for placement on the day of surgery and lack the problematic extracorporeal component, the visibility of the markers is variable and dependent on the surgeon’s expertise and skill with ultrasound [6]. Localization using small radioactive seeds implanted into the target lesion also avoids the need for same-day deployment and the risks associated with an extracorporeal component, but seeds can only be placed up to 5 days in advance and expose patients and health care workers to radioactivity during implantation and disposal [7, 8]. Special licensing for handling of radioactive materials is also required under the guidance of the U. S. Nuclear Regulatory Commission.

An ideal marker would be able to be inserted completely within the breast parenchyma; be placed days or weeks before the operation; resist migration, breakage, or complete dislodgement during dissection; avoid large learning curves by using familiar concepts and technology; be easily visible on ultrasound; be uniquely identified and distinguished from other markers; and indicate to the surgeon how much tissue is surrounding the marker so as to indicate how close he or she is to it, thus assisting with margin assessment. Radiofrequency identification technology provides potential benefits over current localization methods in each of these categories.

The radiofrequency identification tag is implanted within the breast with no extracorporeal component to cause patient discomfort and anxiety or inadvertent dislodgement from accidental tugging. It is nonradioactive and can therefore be placed weeks before the operation without worry of decay. This allows decoupling of the localization and surgical procedures, eliminating the risk of costly operating room delays when the localization procedure takes longer than anticipated. Surgeons who perform breast operations are allowed to proceed with their cases confident that the markers are in the correct position on the day of surgery.
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already familiar with the principle of using a handheld device to locate a signal within the breast, as is done with sentinel node biopsy. The tags are easily visualized using ultrasound (Fig. 4). In addition, each tag can be distinguished from another in the breast by an identification number displayed on the reader, allowing multiple tags to be used at one time. Perhaps the greatest advantage of the radiofrequency identification tag over other devices is that the distance from the reader to the tag is displayed on the screen, further assisting with accuracy of locating the lesion from a remote incision and ensuring an adequate margin. This may also eliminate the need for a specimen radiograph after excision.

Although we did not experience any migrations of the tag within the breast between the time of placement and the time of excision, we did note in three cases that the radiofrequency identification tag slipped along its insertion track when the specimen was manually compressed with fingers. Antimigration hooks have since been added to the tags to address this potential issue. Although none of the radiofrequency identification tags was malpositioned during deployment, the addition of antimigration hooks will likely preclude repositioning. Because long-term retaining of a radiofrequency identification tag has not yet been established as safe, removal of a rogue device would require surgical excision. Also, it is notable that, although MRI is feasible with the tag in situ, the artifact created by the tag would make it impractical to place the tag before the performance of breast MRI. Finally, interaction with electrocautery did not disrupt or destroy the signal.

In our study protocol, we excluded patients with breast lesions located greater than 6 cm deep to the skin because this is the limit of the reader device. However, we did not have any patients for whom this was an issue, even though eight of our patients had D-cup size breasts or larger. Given that the tags are removed when the patient is lying in a supine position and the breast can be mobilized over the chest wall to displace some of the fatty tissue, it is our thought that this exclusion would be extremely rare. Patients with cardiac pacemakers and defibrillators were also excluded as a precautionary measure because radiofrequency signals may interfere with the function of these devices.

In this initial clinical study of 20 subjects, radiofrequency tags were safe and able to successfully localize nonpalpable breast lesions. Further study and development are warranted for this promising technology. Future studies will need to address the duration of safe implantation, assessment of patient comfort scores, evaluation of positive margin rates for malignant lesions, and comparison of specimen volumes for nonmalignant lesions using radiofrequency identification tags versus other localization devices.

References