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The Role of MRI-Guided Tissue Marker Placement without Concurrent Breast Biopsy in Preoperative Localization of Breast Disease

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Abstract

Objective: This retrospective study evaluates breast MRI-Guided Clip Marker Placement (MRCMP) without concurrent biopsy for preoperative surgical localization where a component of disease extent can only be seen on MRI. Achievement of negative surgical margins was the primary outcome.

Material and Methods: 28 patients with 30 lesions underwent breast MRCMP without a concurrent biopsy between May 2008 and February 2019. Age, lesion type (Mass or Non-Mass Enhancement (NME)), size, type of localization, pathology, surgical margins (positive or negative) and post-surgical course were recorded.

Results: 23 patients had malignant breast pathology and were included in the study. 12(52%) presented as a mass and 11(48%) as NME. Mean lesion size was 3.6 cm (median 2 cm, range 0.4-13.5 cm). No difference in lesion size or type was identified between the positive and the negative surgical margin groups ($p = 0.53$ and $p = 0.51$, respectively). 17(74%) underwent preoperative image-guided surgical localization following MRCMP. Seven (41%) were localized with radioactive seeds, seven (41%) with wire guidance and three (18%) with magnetic seeds. 13(57%) received neoadjuvant chemotherapy. Final pathology for eight (35%) was invasive and in situ ductal carcinoma (DCIS), five (22%) invasive lobular carcinoma, three (13%) pure IDC, three (13%) pure DCIS, one (4%) invasive mammary carcinoma, one (4%) pleomorphic Lobular Carcinoma in Situ (LCIS), one (4%) angiosarcoma, and one (4%) showed no evidence of residual disease. 17(74%) had negative surgical margins and 6(26%) positive margins. All positive margins underwent BCS at initial surgery. The use of Neoadjuvant Chemotherapy (NAC) before BCS was the only statistically significant factor between positive and negative margins ($p = 0.02$). Patients achieving negative margins at surgery received NAC at a higher rate (75%) than positive margins (17%).

Conclusion: MRCMP without concurrent breast biopsy is a practical technique for achieving negative margins in patients desiring BCS when a component of disease can only be seen on MRI. This technique has demonstrated utility in facilitating successful excision of disease measuring up to 13.5 cm in our patient population. The MRCMP technique should be considered while MRI compatible wireless localization devices remain unavailable for widespread commercial use.

INTRODUCTION

Breast cancer is the most common cancer diagnosed in women and accounts for more than 10% of cancer diagnoses each year.. While most early-stage breast cancers are detected as small non-palpable cancers by screening mammography and ultrasound, a subset of breast cancers may have additional disease extent that cannot be detected by mammography and ultrasound alone [1-3]. The utility of contrast-enhanced breast Magnetic Resonance Imaging (MRI) in the detection of mammogram and ultrasound occult breast cancer, particularly in high-risk patient population has demonstrated efficacy in recent years.

A number of studies have demonstrated that the sensitivity of contrast-enhanced MRI is superior to that of mammography and ultrasound, performing in a range of 89% to 100% sensitivity [2-3]. The utility of preoperative MRI in patients newly diagnosed with breast cancer continues to be a topic of debate. In the setting of a patient with known breast cancer, the identification of suspicious enhancement often prompts MRI guided biopsy to ensure that disease extent is fully accounted for. Some contend that MRI can detect additional disease not appreciated on conventional ultrasound and mammogram imaging that can ultimately guide treatment. Conversely, others assert that routine preoperative MRI results in a higher incidence of unnecessary ipsilateral and

bilateral mastectomies without impact on morbidity or mortality [2-3].

Breast Magnetic Resonance Imaging (MRI) and MRI-guided interventions are increasingly being utilized to evaluate nonpalpable breast lesions that are occult by ultrasound and mammography [1-4]. MRI-guided tissue marker placement is a minimally invasive interventional procedure that relies on high quality MRI imaging, expertise in imaging interpretation and operator experience [5-14].

While MRI-guided tissue marker placement is rarely performed in the absence of a concurrent tissue biopsy, there are instances when clip marker placement may be indicated to guide pre-operative image-guided surgical localization and excision [5]. Indications for MRI-guided marker placement without a biopsy include patients with partially documented and/or contiguous multifocal disease requiring additional delineation of disease extent to guide successful excision, periareolar or far posterior chest wall lesions that cannot be sampled safely under MRI guidance, patients with concern for residual disease at the surgical bed, and clip migration or failed clip marker deployment following MRI-guided biopsy [5,6,13-15]. After successful clip marker placement, these lesions can then be localized by mammographic guidance in preparation for surgical excision.

MRI-guided clip marker placement in the absence of a concurrent breast biopsy differs from standard localization techniques as the targeted areas remain un-biopsied and are presumed to be suspicious or contiguous with a known malignant lesion. It is unclear if factors such as lesion type (Mass *Versus* Non-Mass Enhancement), lesion size, or method of localization influence the success of one-step surgical excision of the targeted lesions. This retrospective study investigates the role of MRI-guided breast clip marker placement in the absence of a concurrent breast biopsy in breast cancer patients desiring breast conservation. Achievement of negative margin status at surgery was the primary outcome.

MATERIALS AND METHODS

Patient Demographics and MRI Lesion Features, Penultimate Sentence

All participants diagnosed with breast cancer undergoing breast MRI-guided clip marker placement without a concurrent biopsy were retrospectively enrolled into our study. A waiver of informed consent was granted by the institutional review board for this HIPAA-compliant study. All eligible cases occurring between May 1, 2008 and February 20, 2019 were retrospectively reviewed. The decision for MRI-guided clip marker placement without concurrent biopsy was at the discretion of the operating surgeon and the patient agreeing to proceed with planned breast conservation. Patient age, MRI lesion type (Mass or Non-Mass Enhancement), lesion size, number of clip markers placed, type of localization device used (wire, radioactive or magnetic seed), final surgical pathology, surgical margin status (positive or negative margins), adjuvant treatment (chemotherapy and/or radiation therapy), re-excision, and mastectomy conversion were obtained from the patients' electronic medical records. All available and relevant images, imaging reports, pathology and clinical notes were reviewed by two dedicated fellowship-trained breast imaging radiologists with eight and 30 years of breast imaging experience. Lesions were classified according to their appearance using the American College of Radiology BI-RADS standardized lexicon [16] and classified as a mass or a region of non- mass enhancement. For the purposes of this study, all foci were grouped into the mass group to allow for a binary assessment of margin status. Lesion size was based on the largest dimension reported on diagnostic breast MRI. The number of clip markers placed, the type of device (wire, radioactive or magnetic seed) and the modality (mammography and/or ultrasound) subsequently used for preoperative localization were also recorded.

MRI-Guided Clip Marker Placement - Pre-procedural Planning and Equipment

As with all breast imaging procedures, successful pre-procedural planning for MRI-guided clip marker placement requires review of all pertinent imaging studies, imaging reports and pathology reports [12]. Communication with the surgeon is an essential component of the planning process to ensure that there is clarity in the procedural objectives in preparation for localization, especially in complex cases. All cases were reviewed between 1-10 days prior to the scheduled procedures by one of 17 fellowship trained breast radiologists with one to 30 years of experience. All patients scheduled for MRI-guided clip marker placement had a preceding diagnostic MRI within 1 month of their MRI-guided clip marker placement procedure and had completed neoadjuvant chemotherapy where applicable.

The type, location and size of the targeted lesions, shape and the number of existing clip markers in the ipsilateral breast, and the number of clip markers needed were reviewed and informed consent was obtained. MRI-guided clip marker placement was performed on either a 1.5 T (Signa, GE Healthcare, Waukesha, WI) or 3-T (Signa Excite HDx, GE Healthcare, Waukesha, WI) MRI unit. The MRI-guided clip marker placement and initial diagnostic breast MRI were performed on the same scanner whenever possible. A bilateral 7-channel phased-array breast coil (Open Breast Array Coil, *Invivo*, Gainesville, FL) and a fenestrated grid localization apparatus were used.

MRI Clip Marker Placement - Procedure Technique

Clip marker placement was performed by one of 17 fellowship trained breast radiologists with one to over 30 years of experience along with trainees under their supervision. Preprocedural sagittal breast MRI images were obtained prior to and after the administration of gadolinium contrast (gadobenate dimeglumine [MultiHance, Bracco] or gadobutrol [Gadovist, Bayer HealthCare)]. The same type of contrast agent and the same dose of the contrast agent was utilized at both the diagnostic MRI and the procedural MRI whenever possible. Utilizing a manual technique and calculation based on localization of the targeted lesion relative to the fiducial marker placed in the fenestrated

grid, the targeted lesion was localized. Utilizing sterile technique, local anesthetic was administered, and a small skin incision was made to advance the obturator into the lesion. Axial images were then obtained to confirm positioning of the obturator within the targeted lesion prior to marker placement. Once the appropriate position was confirmed, the clip marker was deployed. (Figure 1A) A T1-weighted post-contrast image was obtained in the majority of cases at the radiologist's discretion for assessment of clip deployment and post-procedural hematomas (Figure 1B,1C). The patient was then escorted to the mammography suite where craniocaudal and lateral medial or mediolateral mammograms were obtained. These images were evaluated to confirm successful clip marker deployment and to document potential clip migration (Figure 1D,1E). All patients subsequently underwent surgical excision with total mastectomy or breast conservation with mammographic localization utilizing wire, magnetic seed or radioactive seed guidance.

Surgical Margin Assessment

For all patients, intraoperative specimen radiography was performed to document excision of the targeted lesions and retrieval of all deployed clips and localization devices. The final surgical pathology report was used to assess the surgical margin status. Positive margin status was defined as a lesion in direct contact with the inked specimen margin [17-19]. For the purposes of our study, close and negative margin lesions were grouped together and referred to as "negative margins" to allow for binary assessment of margin status.

Statistical Analysis

All lesions were treated independently to account for independent margin status reporting at the time of final surgical pathology. Comparisons were made between patients with positive margins and patients with negative margins. Selected continuous variables were compared between groups using the Wilcoxon rank-sum test. Selected categorical variables were compared between groups using Fisher's exact test. All statistical analyses were performed using R version 3.6.1. All statistical tests used a significance level of 5%. No adjustments for multiple testing were made.

RESULTS

Lesion Morphology, Pathology and Localization

A total of 23 patients with malignant pathology underwent MRI-guided clip marker placement without a concurrent biopsy during the study timeframe (Figure 2A,2B). The median patient age was 52 years (age range, 34-77 years). The distribution of lesions by MRI morphology, localization modality, localization device, final surgical pathology, margin status and post-operative course is summarized in (Table 1).

Of the 23 malignant lesions identified, 12(52%) presented on breast MRI as a mass and 11(48%) as non-mass enhancement. Mean lesion size was 3.6 cm (median 2 cm, range 0.4-13.5 cm) (Figure 2C,2D). No differences in lesion size or type were identified between the positive and the negative surgical margin groups (p = 0.53 and p = 0.51, respectively). 17(74%) of the 23 patients underwent preoperative image-guided surgical localization following MRI-guided clip marker placement. The remaining six (26%) patients did not undergo localization as the treatment planned was changed to mastectomy at their initial surgery (Figure 2E). Of the 17 patients undergoing breast conservation with pre-surgical localization, seven (41%) were localized with radioactive seeds, seven (41%) with wire guidance and three (18%) with magnetic seeds.

Table 1: Summary of characteristics for patients undergoing MRI-guided clip marker placement.

VARIABLE	DESCRIPTOR	N	%
MRI Lesion Type	Mass	10	43
	Nonmass Enhancement	11	48
	Hematoma	2	9
Localization Modality	Radioactive Seed	8	35
	Wire Localization	7	30
	Magnetic Seed	2	9
	Mastectomy	6	26
Neoadjuvant Chemotherapy	Yes	13	57
	No	10	43
Surgical Pathology	IDC + DCIS	8	35
	IDC	3	13
	DCIS	3	13
	ILC	5	22
	ILC +1DC	1	4
	Pleomorphic LCIS	1	4
	Angiosarcoma	1	4
	No Residual Disease	1	4
Margin Status	Negative	17	74
	Positive	6	26
Post-Surgical Course	Chemotherapy + Radiation	3	13
	Chemotherapy + Radiation + Re-excision	1	4
	Mastectomy	1	4
	Re-excision	1	4

Key: IDC = Invasive Ductal Carcinoma; DCIS = Ductal Carcinoma in Situ; LCIS = Lobular Carcinoma in Situ

13 out of 23 patients (57%) received neoadjuvant chemotherapy, while 10(43%) did not. The pathology at final surgery for eight patients (35%) was invasive and in situ ductal carcinoma. An additional five patients (22%) had invasive lobular carcinoma, three (13%) had pure invasive ductal carcinoma, three (13%) had pure in situ ductal carcinoma, one (4%) was invasive mammary carcinoma, one (4%) had pleomorphic LCIS, one (4%) had angiosarcoma, and one patient (4%) showed no evidence of residual disease (Figure 2F,2G).

Surgical Margin Results

17 out of 23 patients (74%) had negative margins at surgery

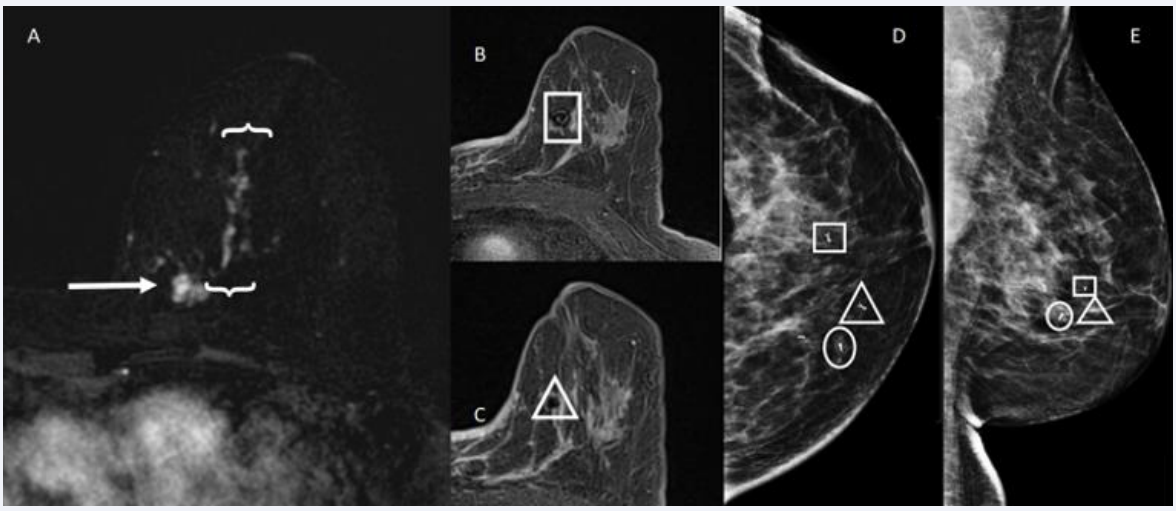

Figure 1: A: T1-weighted post-contrast subtraction MRI shows a lobular mass with irregular margins in the left breast upper inner quadrant (arrow). This finding is consistent with the index carcinoma. There is associated malignant appearing segmental, reticular non mass enhancement contiguous with the index mass extending anteriorly and laterally (brackets). B and C: Post-contrast MRI show clip marker placement in the anterior-superior (square) and lateral (triangle) most extent of enhancement. D and E: Craniocaudal and lateral post-clip mammography shows the index tumour (circle) and two ribbon clip markers delineating the anterior (triangle and square) and lateral (square) most extent of disease. Final pathology showed invasive and in situ ductal carcinoma with negative margins.

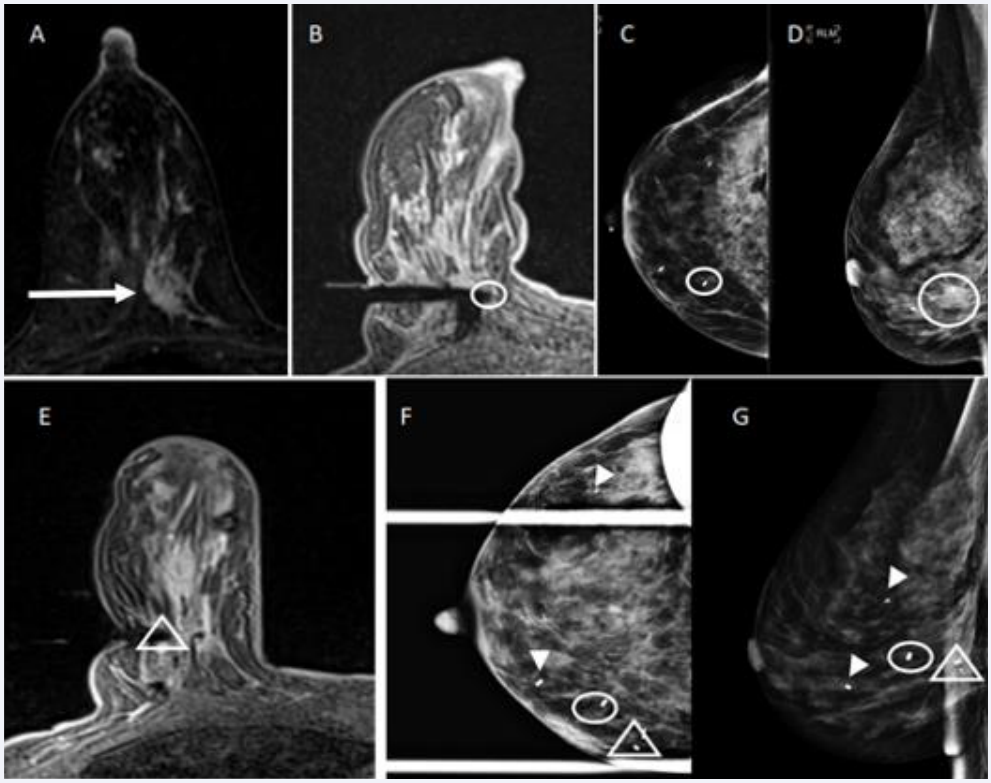

Figure 2: A: T1-weighted post-contrast subtraction MRI image demonstrates non-mass enhancement in the central right breast (arrow). B: MRI-guided core biopsy with clip marker placement (circle) showed carcinoma in situ with predominantly lobular features and focal pleomorphism. C and D: Craniocaudal and lateral post-clip mammography images show anterior and inferior migration of the post-biopsy clip (circle). Figure E: Subsequent MRI-guided clip marker images show satisfactory positioning of the clip marker into the area of non-mass enhancement targeted for initial biopsy (triangle). F and G: Post-clip mammography images following same day I125 radioactive seed insertion document appropriate positioning of the MRI clip marker and successful localization (triangle). The migrated clip marker is seen anteriorly and laterally (circle). Two clips from benign stereotactic biopsies are noted in the upper outer and lower inner quadrants (arrowhead). Final pathology showed pleomorphic LCIS with negative margins.

and 6 (26%) had positive margins. All six patients with positive margins underwent Breast Conservation (BCS) at initial surgery. Of the six patients with positive margins, two (33%) underwent re-excision with subsequent negative margin status, three (50%) were treated with adjuvant chemotherapy and radiation therapy, and one (17%) underwent total mastectomy. Two of the three patients (67%) undergoing immediate oncoplastic reconstruction with tissue rearrangement at the time of surgery had close margins and subsequently underwent adjuvant chemotherapy and radiation therapy. Of the parameters considered, the use of Neoadjuvant Chemotherapy (NAC) was the only statistically significant factor that differed between patients with positive and negative surgical margins (p = 0.02). Patients with negative margins at initial surgery received NAC at a higher rate (75%) than patients with positive margins (17%). As of December 31, 2021, there was no documented evidence of recurrence for any of the patients in our cohort in the electronic medical records. A single patient was deceased from non-breast cancer related sequelae.

DISCUSSION

Our retrospective study suggests that breast MRI-guided clip marker placement without a concurrent biopsy can aid in guiding successful excision with negative margins in the majority of patients. This technique has been shown to be useful in facilitating excision of extensive disease measuring up to 13.5 cm in our patient population and serves as a supplemental tool for breast imaging and surgical teams to consider in the setting of patients who desire breast conservation.

In our study, the majority of patients undergoing breast conservation returned with negative margins. Six patients out of 23(26%) had positive margins, mirroring the rate of margin positive resections at breast conservation in the National Cancer Database [18]. Roughly equivalent margin status was achieved with seed versus wire localization, data that also closely aligns with the current literature [19].

Our study had several limitations. The retrospective design over a short study period resulted in limited power of the study data presented. Additionally, there were six patients who went from clip marker placement to mastectomy, with no attempt at breast conservation, at the discretion of the operating surgeon, effectively removing them from the margin assessment category. Furthermore, the type of localization device utilized was solely at the discretion of the operating surgeon. Multiple studies have consistently shown at least equivalence in surgical margin status when comparing seed localization to wire guidance [20-22].

Although MRI-guided clip marker placement aids in mapping the disease extent in preparation for surgery, an additional variable to consider is the additional time and resources required to carry out this procedural step. These cases routinely follow multiple diagnostic mammography, ultrasound and MRI evaluations, which can take an emotional and physical toll and leave the patient fatigued [2,9]. Additionally, costs should also be considered. Although a cost analysis was not a component of this study, it is presumed that, in a bundled payment system, MRI-guided clip marker placement may result in an overall savings in cost per patient when extrapolating for differences in rates of margin positivity and the need for possible additional surgeries.

At the time of this study, no commercially available single step MRI safe nonwire localization device was available on the market - leaving breast conservation candidates with mammography or sonographically occult disease to have MRI only findings localized under a minimum of a two-step procedure involving biopsy or clip marker placement followed by localization, usually under mammographic guidance. This procedure adds time to the patient's presurgical localization process, requiring additional coordination and scheduling with localization to follow on the same day as the MRI-guided clip marker placement unit or on subsequent days. The formation of a hematoma after biopsy may result in clip migration, presenting a subsequent challenge to mammographic localization of the clip when excision is required. Additionally, some patients have difficulty tolerating the prone position and also encounter challenges with claustrophobia or contrast intolerance which underscores the importance of proactively identifying and vetting eligible patient candidates prior to the procedure [23].

Of the parameters considered, the use of NAC was the only statistically significant factor that differed between patients with positive and negative surgical margins after MRI-guided clip marker placement without a concurrent biopsy. Accurate assessment of NAC response plays a significant role in estimating the residual disease burden with tumor downsizing and achievement of pathologic complete response being the main aims of NAC [22,24,25]. Recent studies have shown that less than 30% of patients achieve a pathologic complete response and roughly 5% of patients show disease progression while receiving NAC [26]. The likelihood of achieving significant response is also largely predicated on the cancer phenotype and the histologic subtype [24,27]. Sheikhbahaei, et al performed a meta-analysis to compare the diagnostic accuracy of MRI and PET/CT for the prediction of pathological response following NAC in breast cancer patients [27]. The study results showed that FDG-PET/CT imaging outperformed MRI for assessment during NAC treatment, whereas the overall performance of MRI was higher at the completion of NAC, before surgery [27]. When compared with PET/CT, MRI has a higher sensitivity but a lower specificity in predicting pathologic response. The study also concluded that MRI assessment was also shown to be most accurate in HER2-positive and triple negative breast cancers [27].

In summary, MRI-guided clip marker placement without a concurrent breast biopsy in the setting of preoperative localization is a valuable and practical technique for achieving negative margin status in patients desiring breast conservation where a component of disease extent can only be seen by MRI. This study underscores the potential utility in developing an MRI compatible non-wire guided device in order to avoid multiple procedures over the course of several days. Until such devices are readily available in the marketplace, MRI-guided clip marker placement helps to facilitate breast conservation treatment with

possible oncoplastic reconstruction in patients with large volume disease.

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