Electromagnetic Transthoracic Nodule Localization for Minimally Invasive Pulmonary Resection

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Background. **Increased use of chest computed tomography and the institution of lung cancer screening have increased the detection of ground-glass and small pulmonary nodules. Intraoperative localization of these lesions via a minimally invasive thoracoscopic approach can be challenging. We present the feasibility of perioperative transthoracic percutaneous nodule localization using a novel electromagnetic navigation platform.**

Methods. **This is a multicenter retrospective analysis of a prospectively collected database of patients who underwent perioperative electromagnetic transthoracic nodule localization before attempted minimally invasive resection between July 2016 and March 2018. Localization was performed using methylene blue or a mixture of methylene blue and the patient's blood (1:1 ratio). Patient, nodule, and procedure characteristics were collected and reported.**

Results. **Thirty-one nodules were resected from 30 patients. Twenty-nine of 31 nodules (94%) were successfully localized. Minimally invasive resection was successful in 93% of patients (28/30); 7% (2/30) required conversion to thoracotomy. The median nodule size was 13 mm (interquartile range 25%-75%, 9.5-15.5), and the median depth from the surface of the visceral pleura to the nodule was 10 mm (interquartile range 25%-75%, 5.0-15.9). Seventy-one percent (22/31) of nodules were malignant. No complications associated with nodule localization were reported.**

Conclusions. **The use of intraoperative electromagnetic transthoracic nodule localization before thoracoscopic resection of small and/or difficult to palpate lung nodules is safe and effective, potentially eliminating the need for direct nodule palpation. Use of this technique aids in minimally invasive localization and resection of small, deep, and/or ground-glass lung nodules.**

Lung cancer remains the most lethal cancer in the United States, accounting for more than 1 in 4 cancer deaths and an estimated 234,030 new cases in 2018.[1] The introduction of computed tomography (CT) has led to an increased detection of small incidental pulmonary nodules (PNs).[2] In addition, the National Lung Cancer Screening Trial finding that 24% of high-risk patients screened had a PN is expected to further increase the number of small PNs detected.[3] A significant proportion of these lesions will be risk stratified as either indeterminate or high risk for malignancy and as such the requirement for rapid and definitive histologic diagnosis is essential while minimizing morbidity and the number of diagnostic procedures.[4]

With the introduction of video-assisted thoracoscopic surgery followed by robotic-assisted thoracoscopic surgery, minimally invasive thoracic surgery (MITS) has offered patients a surgical option associated with improved mortality, decreased complication rates, decreased postoperative length of stay, and faster recovery.[5] Despite these advantages, resection of small and/or nonpalpable PNs (subsolid and/or deep lesions) using MITS can present a significant challenge because of limited tactile feedback.[6] This problem has led to a search for localization techniques, primarily via CT guidance (CTG) or electromagnetic navigation bronchoscopy (ENB). These studies have sought to localize lesions via

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implantation of fiducial markers, radiotracers, dyes, and hook wires in both the pre- and perioperative setting.[7-13] Despite the ability to localize PNs using CTG or ENB, several factors have limited their use. Limitations of CTG include preoperative pneumothorax, bleeding, wire dislodgement, and/or dye diffusion. Conversely, the primary limiting factor of ENB for PN localization has been the inability to successfully navigate to and mark the lesion in question.[14,15]

A new ENB platform has recently been introduced that uses electromagnetic tracking for both bronchoscopy and percutaneous transthoracic lung biopsy as a novel approach to PN sampling.[16] The aim of this study is to describe the feasibility of intraoperative electromagnetic transthoracic nodule localization (EMTTNL) of small/subsolid PNs during attempted diagnostic resection using MITS.

Patients and Methods

We performed an institutional review board–approved (UNC IRB 16-2986) retrospective evaluation of perioperative EMTTNL cases between July 2016 and March 2018 at 2 hospitals (University of North Carolina at Chapel Hill, Chapel Hill, NC, and Marietta Memorial Hospital, Marietta, OH). All cases in which EMTTNL were performed were included. Cases were discussed at a multidisciplinary thoracic oncology tumor board where it was agreed that surgical biopsy and resection should be offered. Patients were seen in the clinic, where discussion of the risks and benefits of the procedures were conducted. Selection of cases in need of localization was made at the discretion of the surgeon before resection.

Nodule Localization Technique

All patients underwent a procedural planning chest CT in either the supine or lateral decubitus position (Figure 1) to create a virtual lung airway map (SPiNDrive/Perc; Veran Medical, St Louis, MO) either immediately before or within 24 hours of the procedure, per protocol.[17] Using the ENB planning software, the target nodule was identified and a virtual skin entry site for EMTTNL selected. All procedures were performed in the operating room with the patient under general anesthesia. After anesthesia induction and intubation with either a single- or double-lumen endotracheal tube, the system was registered per protocol.[17] On completion of the registration phase, the scope was removed and the transthoracic needle entry site identified. The patient's chest was prepped and draped using sterile technique at the predetermined entry, and a 19G electromagnetic tracked needle (Figure 2) was introduced under navigational guidance during an exhalation breath hold without lung isolation. On reaching the distal margin of the target lesion (from the chest wall), the tracking sensor was removed from the inner cannula of the needle, and marking dye (methylene blue or mixture of methylene blue and patient's blood in a 1:1 ratio) was injected at the level of the lesion then tracked back to the skin (Figure 3).

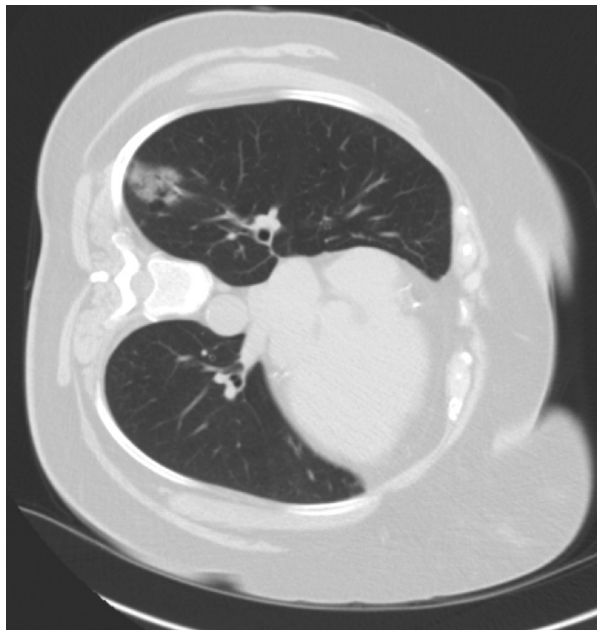

Figure 1. Lateral decubitus chest computed tomography used for electromagnetic transthoracic nodule localization.

Operative Technique

After lung lesion marking the ENB system was removed, and the patient was immediately prepped and draped in a sterile fashion for MITS. Lung isolation was performed. All surgical procedures were carried out via video-assisted thoracoscopic surgery or robotic-assisted thoracoscopic surgery. All video-assisted thoracoscopic surgerical procedures were performed with 3 standard port incisions (no rib spreading) as described in the CALGB 39802 study.[18] All robotic-assisted thoracoscopic surgery procedures were performed using the da Vinci Xi robotic surgical system (Intuitive Surgical, Mountain View, CA) with 4 standard ports in the 8th intercostal space and 1 assistant port placed in the 10th intercostal space, midaxillary line. Carbon dioxide insufflation (10-12 mm Hg) was used in all robotic procedures.

After insertion of the camera, the lung was inspected and the marking identified. Depending on the location of the marking, a diagnostic wedge, segment, or lobar resection (if the lesion was too deep or central for a diagnostic wedge resection) was performed. The specimens were collected with a tissue retrieval device and sent for frozen pathologic analysis. If malignancy was diagnosed during pathologic examination, a completion anatomic lung resection (lobectomy or segmentectomy) and mediastinal lymph node dissection were performed. Patients who underwent

Figure 2. Nineteen-gauge transthoracic percutaneous biopsy needle with tip-tracked internal stylet.

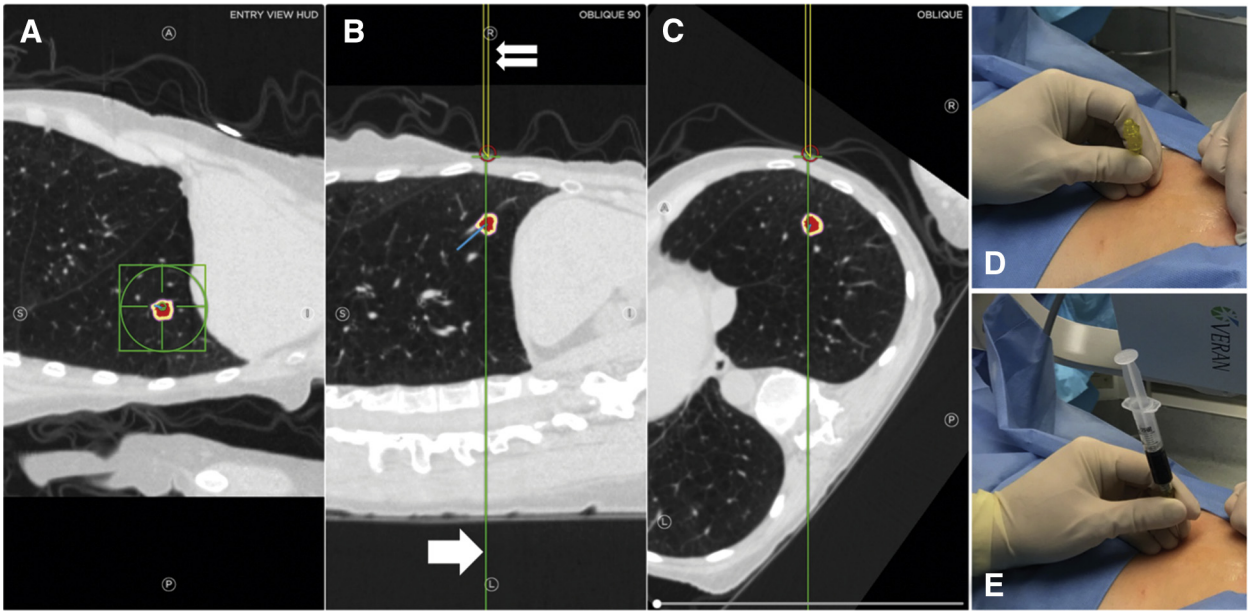

Figure 3. (A-C) Intraprocedural electromagnetic transthoracic nodule localization (EMTTNL). (A) Heads-up display view. Crosshairs represent the distal tip of the EMTTNL needle. Box represents the proximal end of the needle to assist in angulation of the needle from skin insertion site to the level of the lesion. (B) Oblique 90-degree view. Skin insertion site noted by circle at chest wall/skin level, virtual needle (double arrow), line of trajectory (large arrow; displays in yellow when not synced with respiration, green when synced). (C) Oblique view. (D) Patient's chest prepped and draped, 19-gauge electromagnetic tracked needle with tracking sensor removed from the inner cannula. (E) Syringe containing marking dye (methylene blue or 1:1 mixture of methylene blue and patient's blood) attached to the EMTTNL needle. Preparing to inject at the level of the lesion and track back to the skin.

diagnostic segmentectomy had a mediastinal lymph node dissection if the frozen analysis demonstrated malignancy. Conversion to a posterolateral thoracotomy through the fifth intercostal space was performed in cases in which the lung nodule could not be identified or palpated despite the localization and/or the patient was unable to tolerate single-lung ventilation.

Statistical Analysis

Descriptive statistics were used to summarize patient and procedural characteristics using proportions for categorical variables and median (interquartile range 25%-75% [IQR]). All analyses were performed using Microsoft Excel (Microsoft, Seattle, WA) or GraphPad Prism, version 7.03 (GraphPad Software Inc, La Jolla, CA).

Results

The median patient age was 66 years (IQR, 58-72). Twenty patients (67%) were women, and the median body mass index was 27.8 kg/m^2 (IQR, 24.4-30.75). Thirty-one nodules were resected in 30 patients. Nodule characteristics are summarized in Table 1. The median nodule size was 13 mm (IQR, 9.5-15.5), and the median depth from the surface of the visceral pleura to the nodule was 10 mm (IQR, 5.0-15.9). The median time from start of the system/patient registration to the end of nodule marking defined as withdrawal of the localization needle was 19 minutes (IQR, 16-25), and the median surgical time (incision to end) was 141.9 minutes (IQR, 85.5-208.8). The median volume of dye or dye-to-blood mixture injected was 0.6 mL (IQR, 0.5-1.0). Twenty-nine of 31 nodules (94%) were successfully localized.

Nodule removal was successful in all patients. Minimally invasive resection was successful in 93% of patients

Table 1. Lung Nodule Characteristics

Characteristic	Number of Nodules (N = 31)
Nodule size, mm	
<5	1
5-10	10
11-15	12
>15	8
Depth from visceral pleura, mm	
<5	6
5-10	12
10-15	5
>15	8
Lesion type	
Solid	11
Semisolid	9
Ground glass	10
Location	
Right upper lobe	11
Right middle lobe	0
Right lower lobe	6
Left upper lobe	11
Left lower lobe	3

Table 2. Lung Nodule Pathology

Final Pathology	Number of Nodules (N = 31)
Adenocarcinoma, lung primary	12
Granulomatous inflammation	3
Intraparenchymal lymph node	3
Squamous cell carcinoma, lung primary	2
Neuroendocrine tumor	2
Lymphoma	2
Nonspecific inflammation/fibrosis	2
Metastatic ductal breast carcinoma	1
Metastatic adenocarcinoma, nonlung	1
Metastatic urothelial carcinoma	1
Metastatic sarcoma	1
Cryptogenic organizing pneumonia	1

(28/30); 7% (2/30) required conversion to thoracotomy. Twenty-four nodules were successfully resected in the sublobar region (77%, 24/31), with the remaining 7 requiring lobectomy (23%, 7/31). Of sublobar resections performed, 21 were wedge resections and 3 were segmentectomies. Seventy-one percent of nodules (22/31) resected were malignant.

Final pathology is shown in Table 2. All lobectomies performed had a malignant diagnosis on final pathology. No complications associated with nodule localization were noted before or at the time of surgical port placement or initial visualization of the chest cavity.

Comment

Our study presents the largest case series to date demonstrating that use of EMTTNL to facilitate MITS is safe and feasible, leading to successful resection of small, deep indeterminate, and high-risk PNs. The goal of PN localization during MITS is to improve detection of small PNs and increase the success of sublobar lung resection without conversion to thoracotomy and/or performance of diagnostic lobectomy.

Despite advances in MITS small, deep (to the visceral pleura), and/or subsolid lung nodules present a distinct surgical challenge, namely the inability to localize the lesion via digital palpation of the lung.[6] Suzuki and colleagues[6] reported failure to visualize or palpate small PNs during MITS in 54% of patients. Video-assisted thoracoscopic surgery failure and conversion to thoracotomy were reported to be 63% when the lesion in questions was $\leq$10 mm in diameter and >5 mm from the visceral pleural surface.[6] The authors concluded that nodule size (<15 mm), depth from the visceral pleural (>5 mm), and subsolid consistency on CT chest were significantly associated with failure to localize the lesion in question, resulting in MITS sublobar resection failure and a high rate of conversion to thoracotomy and/or performance of a diagnostic lobectomy.[6] These data have resulted in a variety of localization practices; however, the modality most often reported is a CTG percutaneous approach typically performed in an interventional radiology suite remote from the operating room. This technique, although accurate, is associated with a number of complications and challenges that limit its utility, including pneumothorax, bleeding, marker embolization, delays, and dye diffusion.[14,15,19,20]

Recently Hsu and colleagues[21] presented 6 cases in which perioperative EMTTNL was used to aid in the resection of small PNs. Our present study is the largest analysis to date that used EMTTNL during MITS. Despite our concerns regarding periprocedural risk (bleeding, pneumothorax, and/or PN mismarking) resulting in increased difficulty during MITS and/or an inability to appropriately localize the PN in question, EMTTNL was found to be both accurate and without additional attributable risk or procedural delay. In addition, although 23% of patients in our study underwent diagnostic and therapeutic lobectomy, only 1 (3%) was because of the inability to localize the target lesion. Possible factors associated with our reported success rate may be because of the transthoracic approach used with EMTTNL, which allows for chest entry at a similar angle to that subsequently used during MITS.[22] In addition, tracking of the localizing compound from the lesion to the level of the

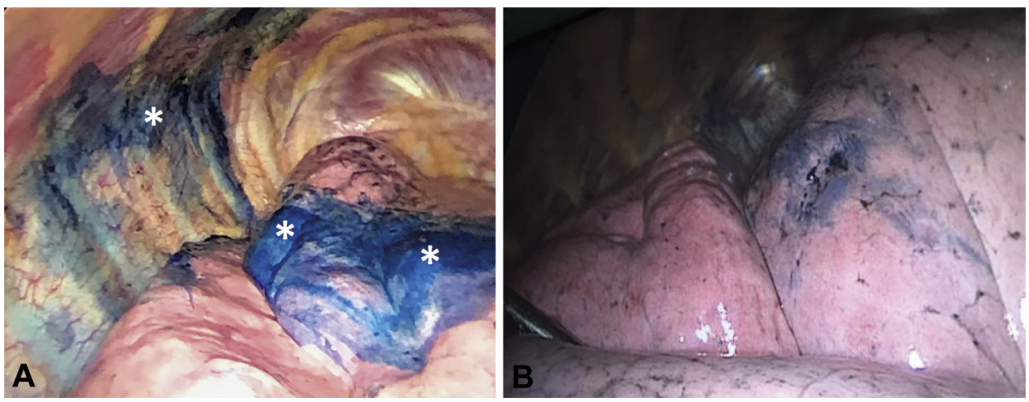

Figure 4. (A) Marking dye injected without patient blood admixture. Asterisks mark chest wall spillage and dye diffusion. (B) Marking dye injected with 1:1 patient blood admixture. Note the punctate dye marking on the visceral pleural surface.

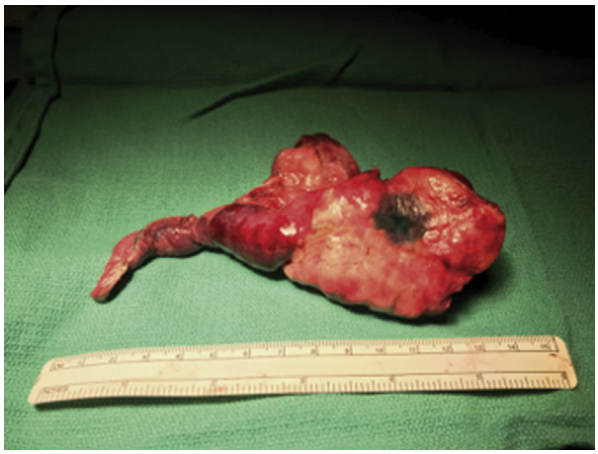

Figure 5. Robotic-assisted lingular segmentectomy for squamous cell lung cancer. Note the dye localization marking in relation to the margins.

skin provided a visual aid and plane of approach for the surgeon, facilitating the sublobar resection of small, deep nodules. These findings would suggest that use of EMTTNL aids in the identification of small, deep, and nonpalpable MITS target lesions, which in turn may lead to a decreased need for open surgical and/or diagnostic lobar resection.

Another consideration is whether ENB and/or EMTTNA should have been undertaken before localization and surgery. This is of particular interest because our benign resection rate was 29% (9/31 nodules). In addition, 2 patients were diagnosed with intraparenchymal pulmonary lymphoma that presented with peripheral nodular disease only and no radiologic evidence of regional or mediastinal nodal disease. Our reported benign resection rate (all wedge resections) is consistent with previously reported data concerning small nodule resection after localization.[10,11,23] This makes one consider the use of prelocalization EMTTNA with rapid on-site cytopathologic evaluation (ROSE) of fine needle aspirates to either spare the patient unnecessary surgery (ROSE–benign) or allow the surgeon to proceed directly to curative lobar resection (ROSE–malignant). This approach, however, is bound by the limitations of ROSE accuracy in the settings of small-tissue sampling and false-negative results.

All cases included in this study underwent review in a multidisciplinary conference, and based on historic data, patient and nodule characteristics, risk of malignancy, and lesion location, the consensus was that surgical resection would be pursued. This is in light of historical data suggesting that ENB[24,25] and/or CT-guided biopsy[26,27] would have a low diagnostic yield in this cohort of patients with small and deep peripheral lung nodules. When further considering prelocalization EMTTNA, the potential limitations in this approach include the added time of EMTTNA + ROSE and an unknown diagnostic yield of EMTTNA for small and deep lung nodules. Recently Mallow and coworkers[28] reported a diagnostic yield of 74.2% when using EMTTNA for peripheral nodule sampling; however, the mean nodule size was 27.3 mm, more than twice the median nodule size in our study. CT-guided biopsy of small and deep lung nodules has been shown to be associated with a significant decrement in diagnostic yield and unacceptably high pneumothorax rates, particularly in target lesions < 16 mm.[27,29-31] For these reasons MITS remains the gold standard for the evaluation and management of small lung nodules in those patients fit for surgery. Despite these potential limitations, future evaluation of prelocalization EMTTNA and its effect on the planned surgical resection is planned.

This technique met some challenges during its development, including initial use of supine chest CT and choice of dye for marking. Although the use of supine chest CT is acceptable, it was found to be suboptimal in patients with posterior PNs who required repositioning for EMTTNL, which caused significant electromagnetic–body registration error. Our initial approach used only methylene blue (first 10 patients) as the marking substance; however, variable degrees of diffusion from the planned marking site were noted. This included 1 failed case in which an overabundant diffusion of dye and intrapleural staining (Figure 4A) resulted in a performance of a diagnostic segmentectomy as opposed to the planned wedge resection. The second failed localization case involved a lack of dye identification. Before EMTTNL the volume of the needle was tested using methylene blue followed by flushing with saline. After completion of EMTTNL, no dye marking was seen. These obstacles were overcome by mixing the methylene blue with the patient's own blood (last 20 patients), aspirated from the arterial line immediately before marking, at a 1:1 ratio to increase the viscosity of the marking solution[31] (Figure 4B) and avoiding the dilution of methylene blue dye with saline before injection.

Several other substances or devices could be used as tools for localization including but not limited to microcoils, hook wires, and/or indocyanine green dye. In a recent study the use of EMTTNL for the placement of microcoils as fiducials for stereotactic body radiotherapy reported high procedural and subsequent stereotactic body radiotherapy success rates.[16]

In the current series conversion to thoracotomy with lobectomy was required in 1 patient because of dense pleural adhesions and the inability to tolerate 1-lung ventilation. In the other patient aberrant arterial and bronchial anatomy in the right upper lobe required thoracotomy for the performance of lobectomy. Concerning the other lobectomies performed, 1 was required because of failure of the dye to mark and an inability to palpate the nodule. The other 5 were in patients whose dye markings localized to a region between 2 segments, resulting in an inability to isolate the nodules to a specific segment, and were too deep for wedge resection. Diagnostic segmentectomy was performed in 2 patients because of nodule depth or centrality within a given lung segment for a wedge resection, and an additional diagnostic segment was performed because of dye diffusion throughout the entire segment, negating the possibility of a wedge

resection. It should be emphasized that a localization procedure is not required for every segmentectomy; however, localization may be helpful in cases where the nodule of interest is between segments or near a segment boundary to ensure that adequate resection margins are obtained (Figure 5). Cerfolio and colleagues[32] reported 100 planned robotic segmentectomies in which they used ENB localization in 16 cases. Even in this setting with an experienced surgeon, 7 patients underwent conversion to lobectomy because of inadequate segment margins, the inability to identify nodules within the segment of interest, and/or the absence of the nodule in the resected segment specimen.

There are several important limitations of this study to consider. First, the study was retrospective and limited to 2 sites and is therefore subject to all associated potential biases. There was no control arm by design, limiting our ability to make comparisons between the use of EMTTNL vs no localization or localization via different means (CTG or ENB). In addition, the 2 centers involved different personnel, with a multidisciplinary approach of thoracic surgery and interventional pulmonology at 1 and only thoracic surgery at the other. Improved generalizability of the results and evaluation of superiority to other localization techniques or no localization will require multicenter, prospective, randomized trials.

Our results indicate that perioperative EMTTNL of small, deep, and nonpalpable lung nodules is a safe and feasible technique for use during MITS. The importance of this technique should not be understated as the number of these nodules found and the need for surgical intervention increases. The technique presented here demonstrates a high degree of success with no associated complications while minimizing conversion to thoracotomy to identify the target lesion. Additional studies are needed to confirm our preliminary results in regard to EMTTNL effect on nodule localization, resection type, best practices, and planned surgical procedure.

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