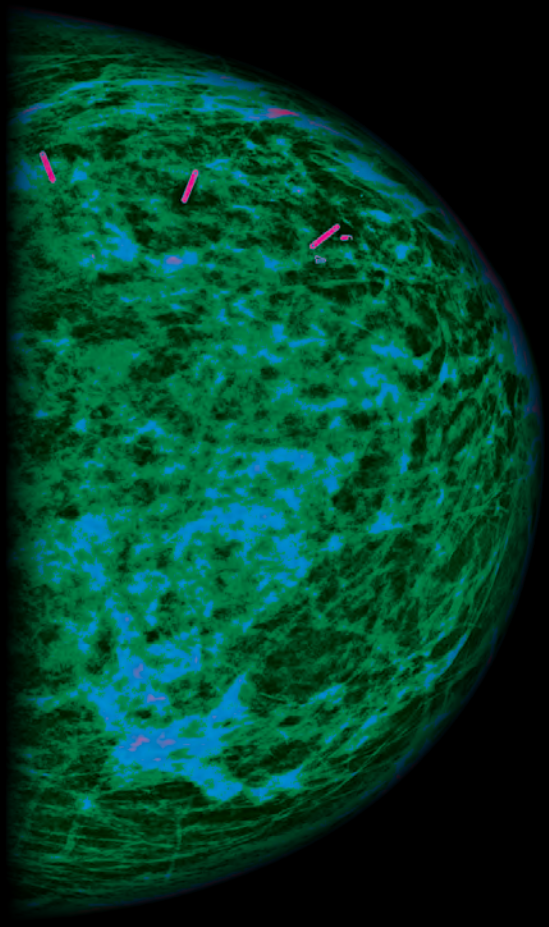
July / August 2024
Volume 53, Number 4

AppliedRadiology®

The Journal of Practical Medical Imaging and Management



CME A Practical Guide to Wireless Breast Localization Devices

Challenges of Workflow Optimization in Mammography

Optimizing Monitoring of Pulmonary Airway Interventions With Digital Tomosynthesis

Virtual Imaging Trials: The Next Big Thing?

In AI, Experience Matters: A Guide to Navigating the Regulatory and Governance Environment

www.appliedradiology.com

Applied Radiology
July / August 2024 Volume 53, Number 4

CT Suite | MR Suite | Injectors and Digital Solutions

SmartInject
SOLUTIONS FROM BRACCO

Point-of-care imaging solutions that help promote patient safety and streamline workflow

NEXO®
Contrast management system

Advance patient care with smart injectors and digital solutions from Bracco.

Learn more at **SmartInject.com**

Bracco Diagnostics Inc.
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831 USA

Phone: 609-514-2200
Toll Free: 1-877-272-2269 (U.S. only)
Fax: 609-514-2446

BRACCO
LIFE FROM INSIDE

Committed to Science,
Committed **to You.**™

AppliedRadiology®

The Journal of Practical Medical Imaging and Management

Anderson Publishing, Ltd
180 Glenside Avenue,
Scotch Plains, NJ 07076
Tel: 908-301-1995
Fax: 908-301-1997
info@appliedradiology.com

Editorial Advisory Board

Applied Radiology®

The Journal of Practical Medical Imaging and Management

July / August 2024
Vol 53 No 4

ONLINE PEDIATRIC CASE SUPPLEMENT AT APPLIEDRADIOLOGY.COM

Applied Radiology (ISSN 0160-9963, USPS 943180) is published in print 6 times a year, January, March, May, July, September, and November, by Anderson Publishing Ltd at 180 Glenside Ave., Scotch Plains NJ 07076. Periodicals postage paid at Scotch Plains, NJ and additional mailing offices. Free subscriptions for US-based qualified radiology professionals. Subscriptions for the US and its territories and possessions: $115 per year, $225 for two years. Foreign and Canadian subscriptions $215 for one year payable in US funds, international money orders, or by credit card only. Postmaster: Please send address changes to Applied Radiology, PO Box 317, Lincolnshire, IL 60069-0317 (847-564-5942) or email AppliedRadiology@0meda.com.

The Good Ol' Days?

Erin Simon Schwartz, MD

Dr Schwartz is the editor-in-chief of *Applied Radiology*. She is the chief of the Division of Neuroradiology and holds the Robert A Zimmerman Endowed Chair in Pediatric Neuroradiology in the Department of Radiology at the Children's Hospital of Philadelphia. She is also professor of radiology, Perelman School of Medicine, University of Pennsylvania. She can be reached at erin@appliedradiology.com.

Another academic year has begun and, I have to be honest, I worry about those transitioning from training to practice. At the risk of offending Doug Phillips (Isn't mimicry the highest form of flattery?[1]), we want them to be "doing that good work"— but are we setting them up for success?

Back when I was a resident (the worst stories always start like that), around the time Roentgen was retiring, there was no such thing as an attending radiologist in house overnight. While perhaps less than ideal, one thing we were unequivocally forced to learn is how to "make the call." Writing down those impressions and moving to the next case, knowing that an attending radiologist would not review those images for 6-12 hours and that the care team would act on our interpretation, was terrifying and nearly impossible.

Now pressures are even more immense for rapid radiology interpretations, and images per study have increased exponentially. Many centers have an attending radiologist actively working with and overseeing trainees 24/7/365, albeit sometimes virtually. This means, for many trainees, their first opportunity to be the sole arbiter of image interpretation comes during their first days in their first "real job."

This massive professional stressor also often coincides with many life stressors — relocation, home purchase, relationship changes, caregiving responsibilities, and so forth — it's a recipe for overwhelm.

What's the solution? I wish I knew.

The old way taught me a great deal. Although it was likely suboptimal for the patients on evenings I worked alone, in the long run did it better equip me for the demands of a radiology career? Maybe.

Or maybe demands on radiology have increased such that even the most experienced and capable (including folks far faster and more knowledgeable than I am) feel overwhelmed. So how can we expect those coming out of training to survive, let alone, thrive?

I don't have a good answer. But know that if you are a junior or even a newly minted attending, you are not alone. Reach out to your colleagues and mentors when you have questions. Take time to support your own wellness. And know that it will get better.

Transitions

At *Applied Radiology* (*AR*), we are delighted to welcome a new leader to our editorial team! **Sharon Breske** is certainly not new to the Anderson Publishing family as she has been the outstanding managing editor of our sibling publication, *Applied Radiation Oncology* (*ARO*), for many years. Sharon is now the editorial director of *AR* as well as *ARO,* and I am thrilled to have the opportunity to work more closely with her. She brings a wealth of expertise to *AR,* and we appreciate having her on our team now, too.

[1]Actually, the original quote from Oscar Wilde is "Imitation is the sincerest form of flattery that mediocrity can pay to greatness." Read into that what you will. And thank you for reading all the way to the footnote.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0022

A Practical Guide to Wireless Breast Localization Devices

Description

Until recently, wire-guided localization was the gold standard for preoperative localization of nonpalpable breast cancers, a technique prone to unique complications and challenges, including wire dislodgement or migration, interference with the dissection route, and the need for coupling radiology and surgery services. Wireless localization devices such as radioactive seed localization, Scout, LOCalizer, EnVisio navigation system, and Magseed can help avoid these limitations. This activity is designed to educate radiologists about wireless localization devices, including their techniques, advantages, and limitations.

Learning Objectives

Upon completing this activity, the reader should be able to:

- Understand the advantages of wireless-guided localization techniques vs wire-guided techniques.
- Recognize the radiologic appearance of different wireless localization devices.
- Learn about common wireless localization devices, including their limitations and deployment mechanisms to incorporate their use into practice.

Target Audience

- Radiologists
- Related imaging professionals

Authors

Jessica J. De Sabato, MD; James Kim, BS; Saadiya Sehareen, DO; Nina Vincoff, MD; Sofya Kalantarova, MD

Affiliation: Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Northwell Health, New Hyde Park, NY

Commercial Support

None

Accreditation/Designation Statement

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Institute for Advanced Medical Education (IAME) and Anderson Publishing.

IAME is accredited by the ACCME to provide continuing medical education for physicians. IAME designates this activity for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Instructions

1. Review this article in its entirety.
2. Visit appliedradiology.org/SAM2.
3. Log in or create an account.
4. Complete the post-test and review the discussion and references.
5. Complete the evaluation.
6. Print your certificate.

Estimated Time for Completion

1 hour

Date of Release and Review

July 1, 2024

Expiration Date

June 30, 2025

Disclosures

Planner: Erin Simon Schwartz, MD, discloses no relevant financial relationships with any ineligible companies.

Authors: The authors disclose no relationships with ineligible companies.

IAME has assessed conflicts of interest with its faculty, authors, editors, and any individuals who were in a position to control the content of this CME activity. Any relevant financial relationships were mitigated with an independent peer review of this activity, and no conflicts or commercial bias were detected. IAME's planners, content reviewers, and editorial staff disclose no relationships with ineligible entities.

A Practical Guide to Wireless Breast Localization Devices

Jessica J. De Sabato, MD; James Kim, BS; Saadiya Sehareen, DO; Nina Vincoff, MD; Sofya Kalantarova, MD

Introduction

Despite the increasing incidence of breast cancer in the US, the 5-year survival rate for all stages of breast cancer approaches 91%, with more than 4 million breast cancer survivors living in the US. Breast-conserving surgery with or without adjunct endocrine therapy, chemotherapy, and/or radiation has become the standard of care for noninvasive and localized invasive breast cancers. For breast-conserving surgery to be successful, that is, have clear margins with an acceptable cosmetic result, it is essential that the cancer be localized accurately.

Until recently, wire-guided localization was the gold-standard technique for preoperative localization of nonpalpable breast cancers and entails anchoring a flexible wire to a lesion under image guidance, usually on the morning of surgery. With 1 end anchored to the lesion and the other end protruding from the patient's breast, the patient would be transferred from radiology to the operating room (OR) for surgery. This technique is prone to unique complications and challenges, including wire dislodgement or migration, interference with the dissection route, and the need for coupling radiology and surgery services. Wireless localization devices can avoid these limitations.

Initial alternative nonwire localization techniques involved tagging the lesion with radioactive material that would then be detected in the OR with gamma cameras. However, these methods come with their own unique set of challenges related to the use and management of radioactive materials.[1,2] Recently, nonradioactive localization methods have been introduced and use various techniques such as RADAR (Scout, Merit Medical), magnetic seed localization (Magseed, Endomag), and radiofrequency identification (RFID) tagging (LOCalizer, Hologic; EnVisio, Elucent Medical).

This article aims to review the wireless localization devices commonly used at our institution, including the techniques, advantages, and limitations. Of note, other wireless localization devices are on the market but will not be discussed here. These include Pintuition (Sirius Medical), MOLLI (MOLLI Surgical Inc.), and TAKUMI (Matrix Cell Research Institute Inc.).

Radioactive Seed Localization

The first of the nonwire localization techniques discussed is radioactive seed localization, which most commonly uses iodine-125 (I-125)-labeled radioactive seeds. The 5-mm titanium radioseeds contain a maximum amount of 0.3 mCi of I-125 and are detected in the breast via a handheld gamma counter.[2] The radiologist places them in the breast up to 5–7 days before surgery under ultrasound or mammographic guidance. The seeds are preloaded in an end-deploy needle and advanced to the target lesion percutaneously under image guidance. The deployment mechanism and lengths of the needle vary based on vendor. Multiple radioseeds can be placed in the same breast either for bracketing a single lesion or localizing multiple lesions. On the day of surgery, the surgeon precisely locates the seed using a gamma probe.

The surgeon can concurrently detect technetium-99mm for lymph node mapping, a unique advantage of the radioseed localization. Compared with wire-guided localization, there is a lower

Affiliation: Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Katz Institute for Women's Health, Northwell Health, New Hyde Park, NY.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0001

Figure 1. The Scout deployment devices are shown in (A). Radiology Scout console and probe (B) used to detect the wireless radar device once placed in the breast.

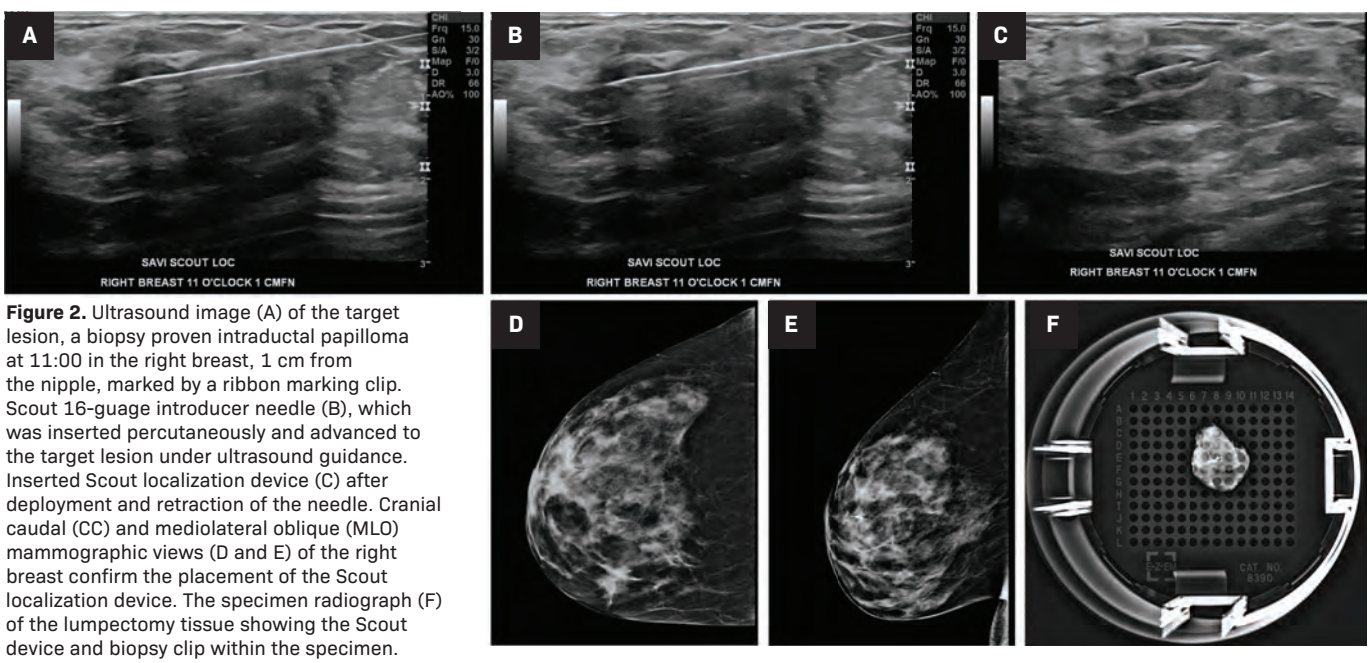


Figure 2. Ultrasound image (A) of the target lesion, a biopsy proven intraductal papilloma at 11:00 in the right breast, 1 cm from the nipple, marked by a ribbon marking clip. Scout 16-guage introducer needle (B), which was inserted percutaneously and advanced to the target lesion under ultrasound guidance. Inserted Scout localization device (C) after deployment and retraction of the needle. Cranial caudal (CC) and mediolateral oblique (MLO) mammographic views (D and E) of the right breast confirm the placement of the Scout localization device. The specimen radiograph (F) of the lumpectomy tissue showing the Scout device and biopsy clip within the specimen.

incidence of positive margins and decreased need for repeat surgery.[3]

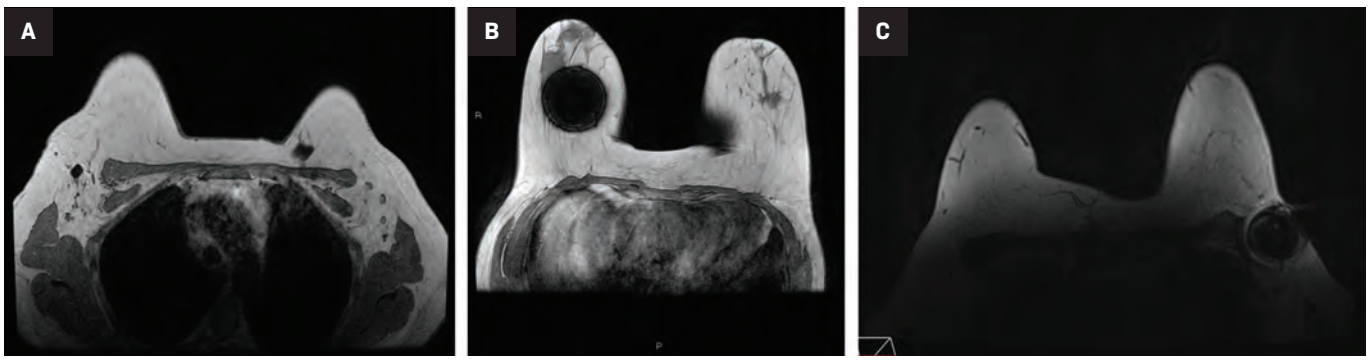
The major disadvantage of this technique is the regulatory challenges associated with the use of radioactive material, including the need for oversight by a radiology safety officer and proper facility licensing.[1,2]

Impulse-Reflecting System

The Scout (Merit Medical) wireless localization device uses radar to locate the precise location of a breast tumor via an implanted 1.2-cm reflector and a handheld micro-impulse generating probe (Figure 1). Using ultrasound or mammographic guidance, the reflector device is placed prior to surgery to mark the soft tissue intended for surgical removal. The reflector comes preloaded in a single-use deployment device consisting of a handpiece attached to a 16-gauge introducer needle of various lengths (5 cm, 7.5 cm, and 10 cm). After the target is identified on imaging, the needle can be percutaneously advanced. Once the needle tip is confirmed to be at the desired target, the Scout reflector can be deployed. The introducer needle is then removed, and the radiologist uses a console to confirm the placement of the reflector and its signal. Postplacement imaging with a 2-view mammogram is recommended (Figure 2). No patient aftercare is required, and the reflector can be left in situ indefinitely. Multiple devices can be placed in the same breast.[4]

On the day of surgery, the surgeon uses a micro-impulse-generating probe to scan the

Figure 3. MR susceptibility artifact produced by the Scout, Magseed and LOC localization devices. Axial MR image (A) showing a small amount of susceptibility artifact emanating from the Scout localization device in the right axillary region. Note the susceptibility artifact in the left chest wall from the patient's subcutaneous port. Axial MR (B) from a different patient showing a 6-cm signal void artifact stemming from a first-generation Magseed localization device in the right breast. Newer, second-generation Magseed devices produce less artifact, about 2-4 cm. Axial Vibrant MR image (C) from a third patient showing the susceptibility artifact associated with the LOC wireless localization device in the left axillary region.



breast and find the precise location of the reflector. The reflector contains 2 antennas that signal back to the probe. This signal is then processed by the console, which provides real-time directionality and proximity information via audible and visual cues to guide the surgeon during dissection. The probe can detect the location of the reflector at a maximum depth of 6 cm. The radiologist can use the handpiece and console, if available, to confirm the placement of the reflector after implantation.

Compared with wire-guided localization, the Scout radar localization system results in statistically significant lower re-excision rates and positive margins.[5] The Scout reflector also has an advantage over other nonwireless localizers due to its smaller MR artifact.[6] The Scout reflector produces minimal signal void, whereas the Magseed and Loc RFID tag produce 2-6 cm and 2 cm of signal void, respectively (Figure 3). When patients are newly diagnosed with breast cancer, they may need to undergo additional imaging with MR to assess the extent of the disease.[7] Additionally, if a patient is treated with neoadjuvant chemotherapy, MR may be considered to evaluate treatment response. The minimal MR artifact of the reflector makes it a feasible option for localization of lymph nodes in the neoadjuvant setting[8] (Figures 4, 5).

Merit Medical recently received FDA approval for the Scout Bx delivery system, which allows the Scout reflector to be placed at the time of stereotactic or MRI-guided biopsy. This newer device is MR-compatible with an end-deploy mechanism and can be used with most biopsy devices.

A disadvantage of the Scout localization device is disruption of the signal when placed within a hematoma or calcified fibroadenoma.[9] Also, the device cannot be detected at depths greater than 6 cm, limiting its use in deep lesions. Owing to its shape, the Scout device can be more difficult to deploy than the alternative wireless localization devices. Additionally, if either antenna is damaged during deployment, issues detecting the signal may occur. Contraindications to placing a Scout localizer include a nickel allergy and the presence of a pacemaker (Table 1).

Radiofrequency Identification Systems

The LOCalizer (Hologic) wireless device uses unique RFID numbered tags to localize breast lesions. The tags are approximately 10.6 mm × 2 mm with a polypropylene cap to prevent migration postimplantation (Figure 6).[10] Each tag is preloaded into a 12-gauge, stainless steel needle (5 cm, 7 cm, or 10 cm). Under sonographic or mammographic guidance, a tag is inserted proximal to the focal tumor within 6 cm of the breast surface by depressing the tag applicator's plunger and removing the safety lock (Figure 7). If more than 1 tag is placed, they must be placed at least 2 cm apart to reduce RFID signal interference during tag localization. Each device has a distinct signal, and the console displays the unique ID number of each tag. To localize the tag on the day of surgery, the single-use surgical probe plugs into a handheld reader, which displays the distance to the tag in millimeters and emits audible cues.[11] The small, portable, handheld reader device is a unique advantage of the LOCalizer

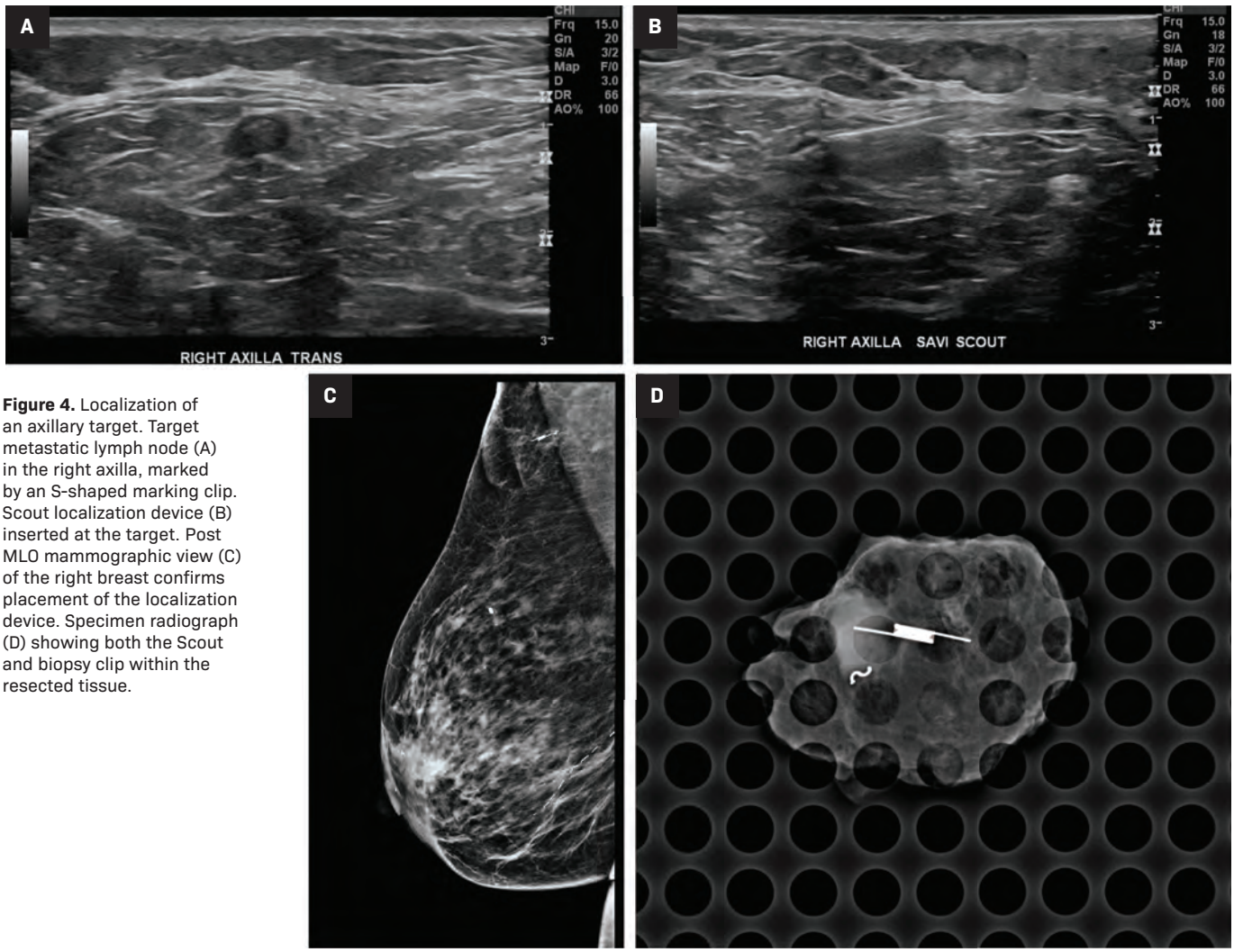


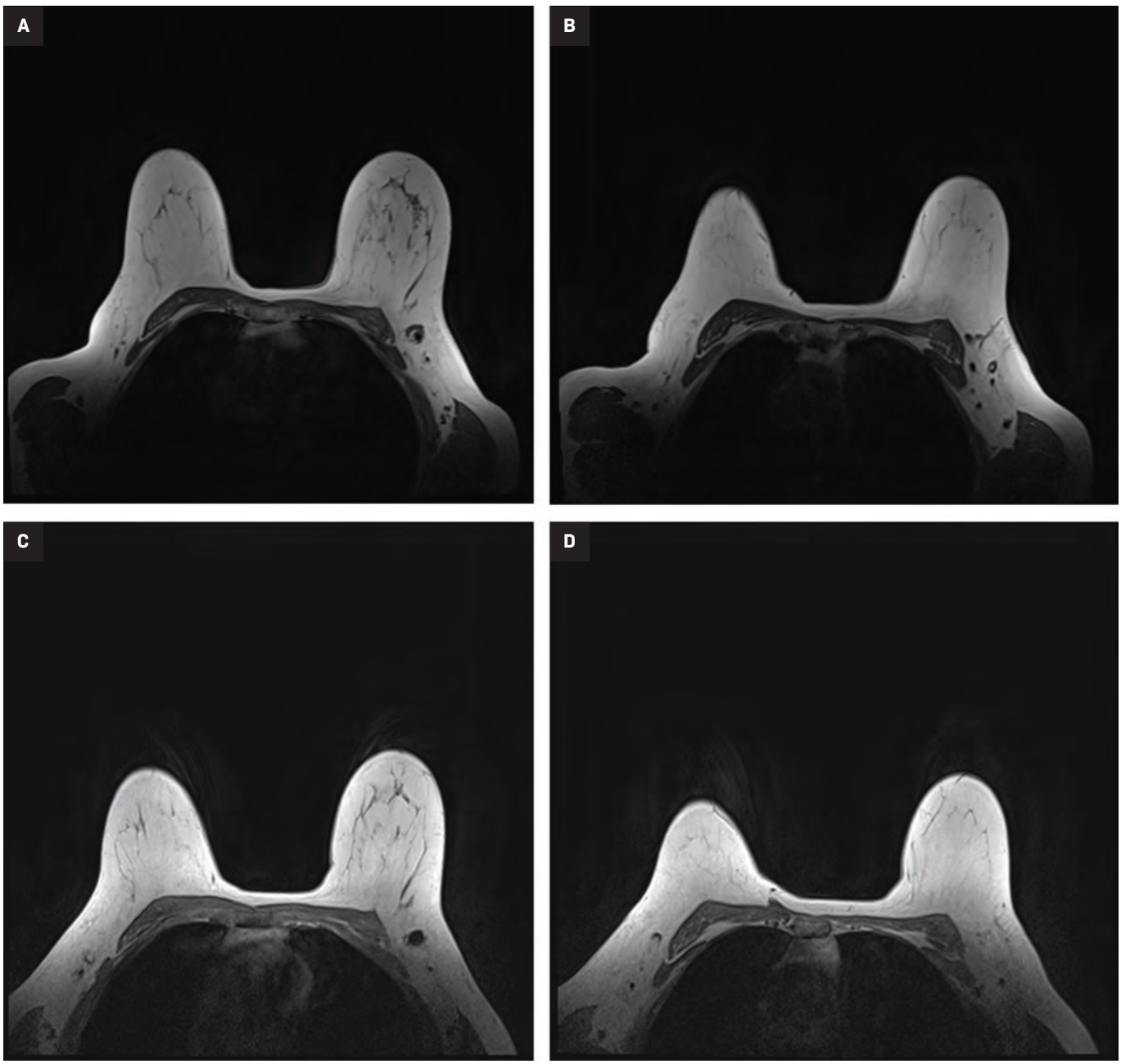
Figure 4. Localization of an axillary target. Target metastatic lymph node (A) in the right axilla, marked by an S-shaped marking clip. Scout localization device (B) inserted at the target. Post MLO mammographic view (C) of the right breast confirms placement of the localization device. Specimen radiograph (D) showing both the Scout and biopsy clip within the resected tissue.

device. The size of the tag, however, poses disadvantages to this system over the alternatives. The larger tag requires a larger deployment needle. To prevent skin deformations, a small preplacement skin incision is needed.[12] When placed in superficial lesions, intraoperative migration is a risk.[13]

The EnVisio navigation system (Elucent Medical) is another common RFID tag system for wireless localization. This system allows deployment of up to 3 different colored SmartClips, each measuring 1.4 mm × 8 mm (Figure 8). Under mammographic or ultrasound guidance, a SmartClip can be placed at any time prior to surgery using a preloaded 15-gauge deployment device, available in lengths of 5 cm, 7.5 cm, and 10 cm. The deployment device has an unlock-and-slide deployment to insert the preloaded SmartClip, which can be placed in the breast indefinitely (Figure 9). On the day of surgery, the patient lies on an EnVisio Patient Pad for the surgeon to localize the signal of each SmartClip using a single-use NavSlim transducer attached to an electrocautery device. Each SmartClip emits a unique number that can be detected by a transducer on the surgeon's electrocautery device, providing coordinates in 3 planes. The single-use, attachable transducer prevents the need for sterilization between use, decreases possible high costs of maintenance, and reduces surgical clutter.

A potential disadvantage of the EnVisio Surgical Navigation System is the smooth exterior coating of each SmartClip, decreasing its ability to anchor to its surroundings. However, 1 study found that this posed no significant risk of postplacement migration.[14] Another limitation is that the patient must remain in the supine position throughout the operation to stay within the boundaries of the EnVisio Patient Pad. Alternative positions may disrupt the localization signal.

Figure 5. MR images of a patient status post biopsy of a left breast mass and axillary lymph node revealing metastatic breast carcinoma. Initial MR images (A, B) showing multiple left axillary lymph nodes, including the enlarged biopsy-proven metastatic lymph node marked by a biopsy marking clip as seen in (A). Repeat imaging 3 months later (C, D) after undergoing neoadjuvant chemotherapy and interval Scout localization of the biopsy marking clip in the left axilla, showing that the left axillary lymph nodes have decreased in size and the biopsy-proven metastatic node has normalized.

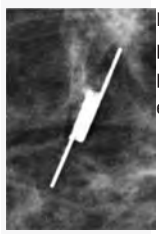
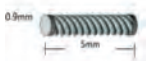


Furthermore, an active cardiac device may interfere with the signal from the electromagnetic pad, although the cardiac device may be deactivated with a magnet during the operation. In addition, the Patient Pad precludes the use of certain intraoperative equipment, such as padding for prolonged operative cases. Lastly, although SmartClips are MRI safe, they create a 2-cm signal void artifact.

Magnetic Localization System

Magseed (Endomag) is a 5 mm × 1 mm paramagnetic wireless localization device made of medical-grade stainless steel and iron oxide

Table 1. Breast Localization Devices

	LOCALIZATION SEED	DEPLOYMENT DEVICE	SEED SIZE	DEPLOYMENT DEVICE SIZE	MR ARTIFACT	MAMMOGRAM APPEARANCE	CONTRAINDICATIONS
Scout (Merit Medical) Radar Reflector			12 mm	16-Gauge; 5 cm, 7.5 cm, 10 cm	Minimal signal void on MR		Nickel allergy, presence of pacemakers, evidence of infection
Magseed (Endomag) Magnetic Seed			5 mm	18-Gauge; 7 cm or 12 cm	4-6 cm signal void on MR		Nickel allergy, presence of pacemaker, clinical evidence of infected tissue.
LOCalizer (Hologic) Radiofrequency ID Tag			11 mm	12-Gauge; 5 cm, 7 cm, 10 cm	~2 cm of signal void on MR		Clinical evidence of infected tissue
Smartclip (Elucent) Radiofrequency ID Tag			8 mm	15-Gauge; 5 cm, 7.5 cm, 10 cm	~2 cm of signal void on MR		Active cardiac device, clinical evidence of infected tissue

(Figure 10). The seed is preloaded in an 18-gauge deployment device, available in lengths of 7 cm or 12 cm, and can be placed under ultrasound or stereotactic guidance. Similar to the other wireless devices, multiple Magseeds can be placed within the same breast. After the target is visualized on imaging, the Magseed needle is advanced percutaneously to the target, and then deployed via a 1-step push mechanism. Placement is confirmed using 2-view mammography (Figure 11). On the day of surgery, the surgeon detects the Magseed via the SentiMag probe, which generates a temporary magnetic field. The Magseed is transiently magnetized and the SentiMag displays the distance of the Magseed to the probe in millimeters while providing audible cues.

Magseed has a 99.9% successful localization rate.[15] Compared with wire-guided localization, it is more successful in terms of index lesion removal and fewer failed localizations. It has no significant difference in terms of identification rates, re-excision rate, specimen size and weight, and lesion-to-specimen size ratio.[16]

The major advantage of this system is its deployment device, which is the thinnest on the market and has a 1-step mechanism, which is likely more comfortable for patients. The SentiMag probe can also be used to localize sentinel lymph nodes through Magtrace. Magtrace is a nonradioactive superparamagnetic iron lymphatic

Figure 6. Single tag (10.6 mm × 2 mm) (A) that may be inserted into a breast to localize a lesion, each with a unique radiofrequency identification (RFID) number for localization. Twelve-gauge, stainless steel needles (B) in 3 lengths (5 cm, 7 cm, 10 cm) to insert the tags into the breast. Integrated reader, loop probe, and pencil-shaped surgical probe (C). The reader is a digital screen that shows the distance from the probes to each tag in millimeters, along with its unique RFID number. The loop probe (the circular shape on top of the reader) is integrated into the reader to confirm tag placement. The pencil-shaped surgical probe (attached to the reader by a wire) localizes each tag during surgical excision.

Figure 7. Ultrasound-guided localization of a biopsy-proven invasive ductal carcinoma, marked by a biopsy clip, with a Hologic LOC device. Target marked by a clip (A). Deployed LOC device with the needle still in site (B), which was subsequently removed (C). Post-MLO mammographic view (D) of the right breast confirms the position of the wireless LOC device in the upper breast. Perioperative radiograph of a specimen (E) from another patient shows both the LOCalizer and biopsy clip within the resected tissue.

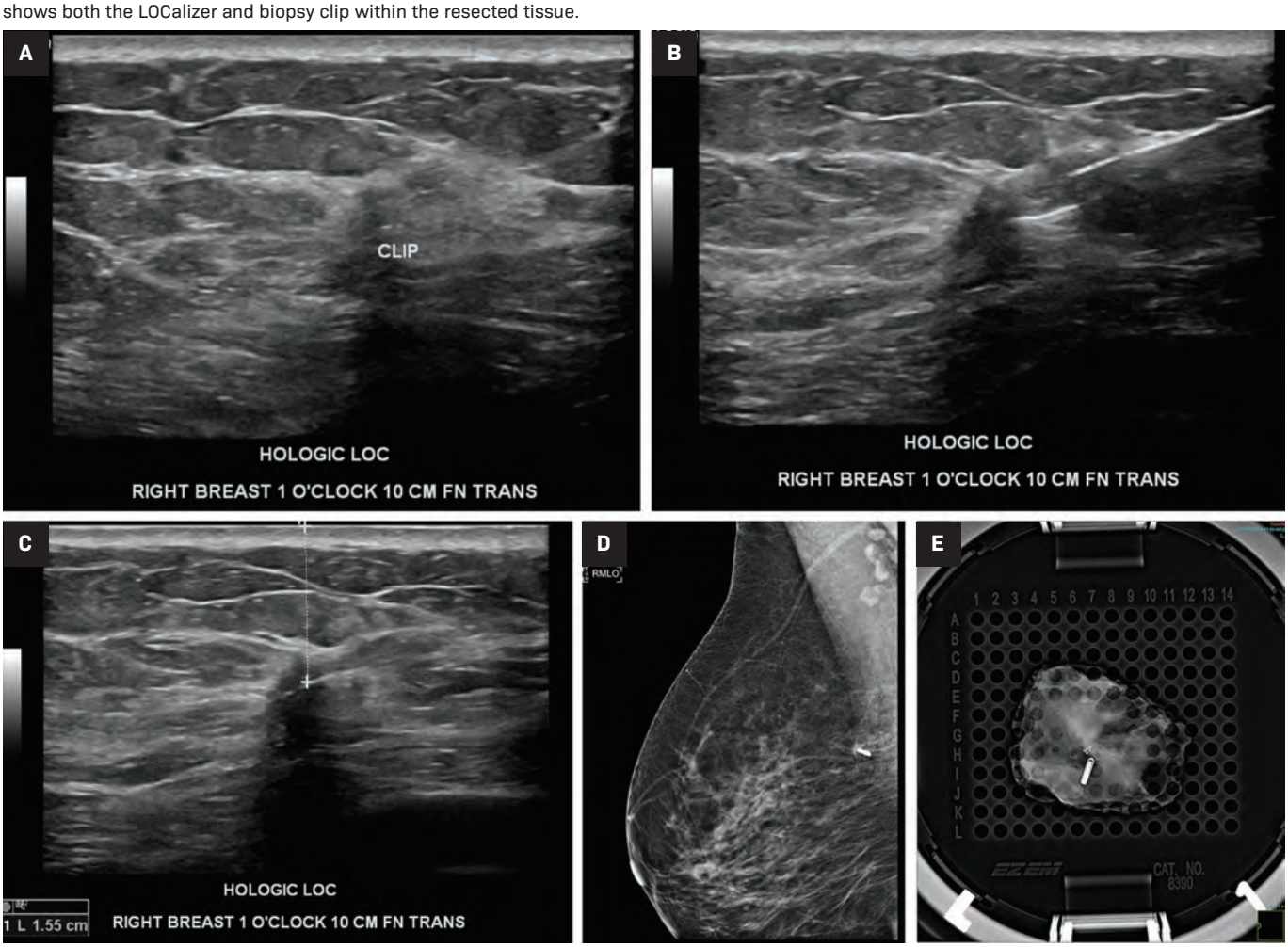
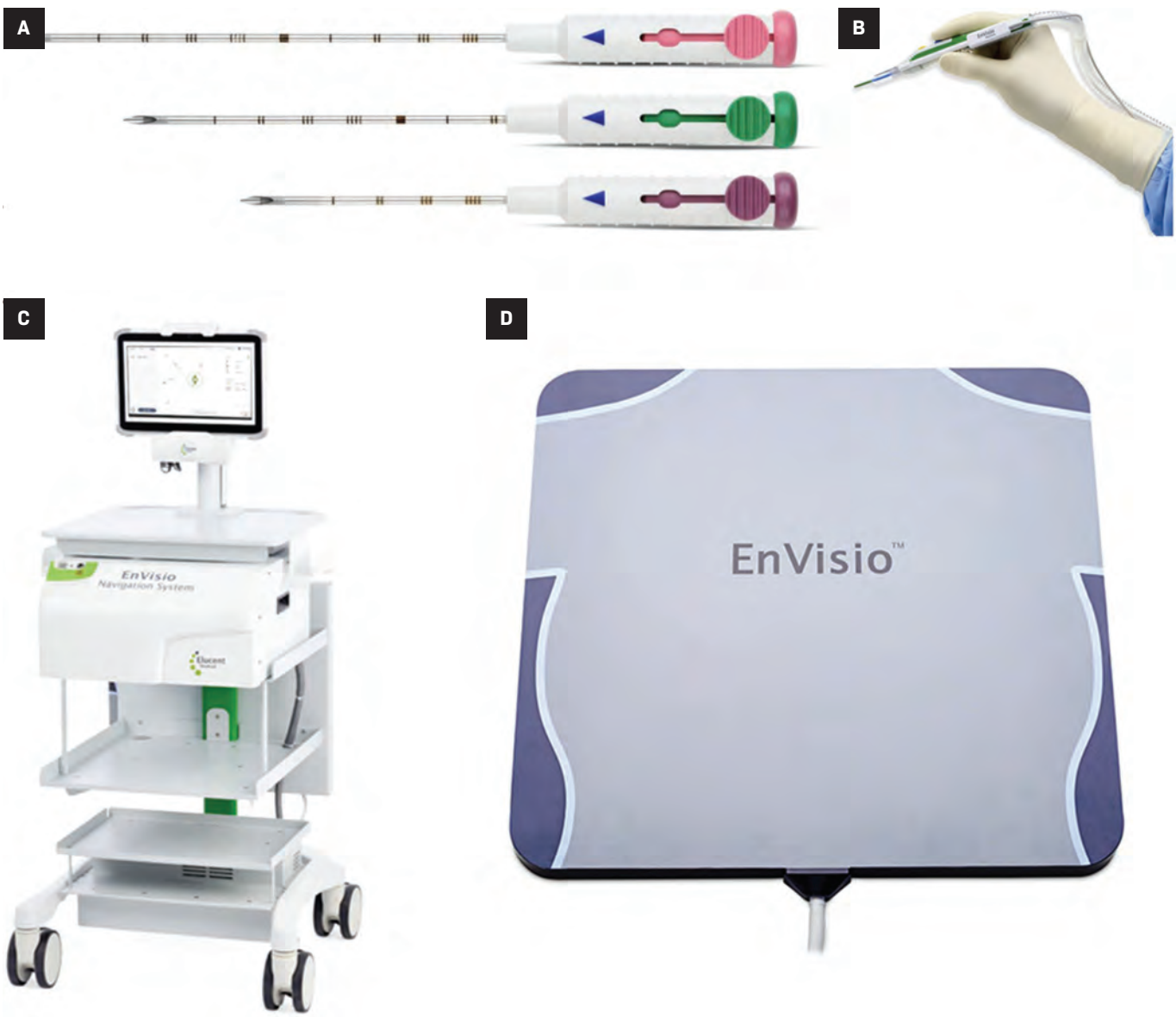


Figure 8. Fifteen-gauge SmartClip unlock-and-slide deployment devices of differing lengths (5 cm, 7.5 cm, 10 cm) (A) to insert the SmartClips into the breast. Single-use NavSlim transducer (B) attached to an electrocautery device to localize each SmartClip. Heads Up Display (C) providing real-time navigation during localization of each SmartClip, providing coordinates in 3 planes: medial/lateral, superior/inferior, and anterior/posterior (x, y, z). EnVisio Patient Pad (D) generates electromagnetic waves that detect the implanted SmartClip.



tracer that can be used in place of traditional radioisotope tracers for localizing sentinel lymph nodes. Magseeds can be placed within a lymph node prior to neoadjuvant chemotherapy for targeted axillary dissection.[17] However, its 2-6-cm signal void artifact on MR limits its utility in this setting.

Given this significant signal void, individual Magseeds within the same breast would need to be placed at least 2 cm apart for accurate detection on MR. A major drawback of the Magseed system is that intraoperative equipment such as electrocautery or paramagnetic surgical equipment can interfere with the electromagnetic signal and must be removed from the operating field. Nonconductive surgical tools must be used, and if there is interference with conductive surgical instruments, the SentiMag probe requires recalibration.[18]

Conclusion

Wireless localization devices are replacing wire-guided localization and radioactive localization methods to guide breast-conserving surgical

Figure 9. Placement of 3 SmartClips under mammographic guidance. CC mammographic view (A) of the left breast showing 3 separate targets of calcifications, the most anterior of which is marked by a biopsy-marking clip and pathologically proven to be ductal carcinoma in situ. Three separate deployment needles in place (B). Post-CC view (C) of the left breast confirms the position of all 3 SmartClips, denoted by their corresponding colors. Specimen radiograph of the lumpectomy tissue(D), showing all 3 clips and the targets calcifications within the specimen.

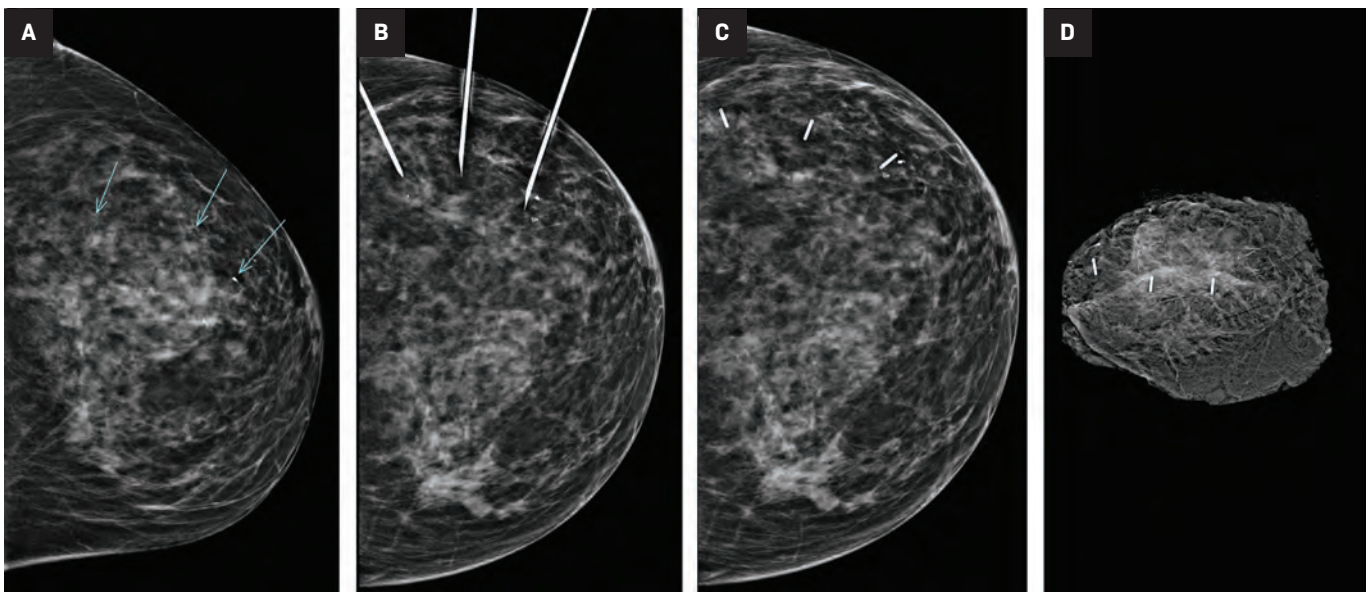
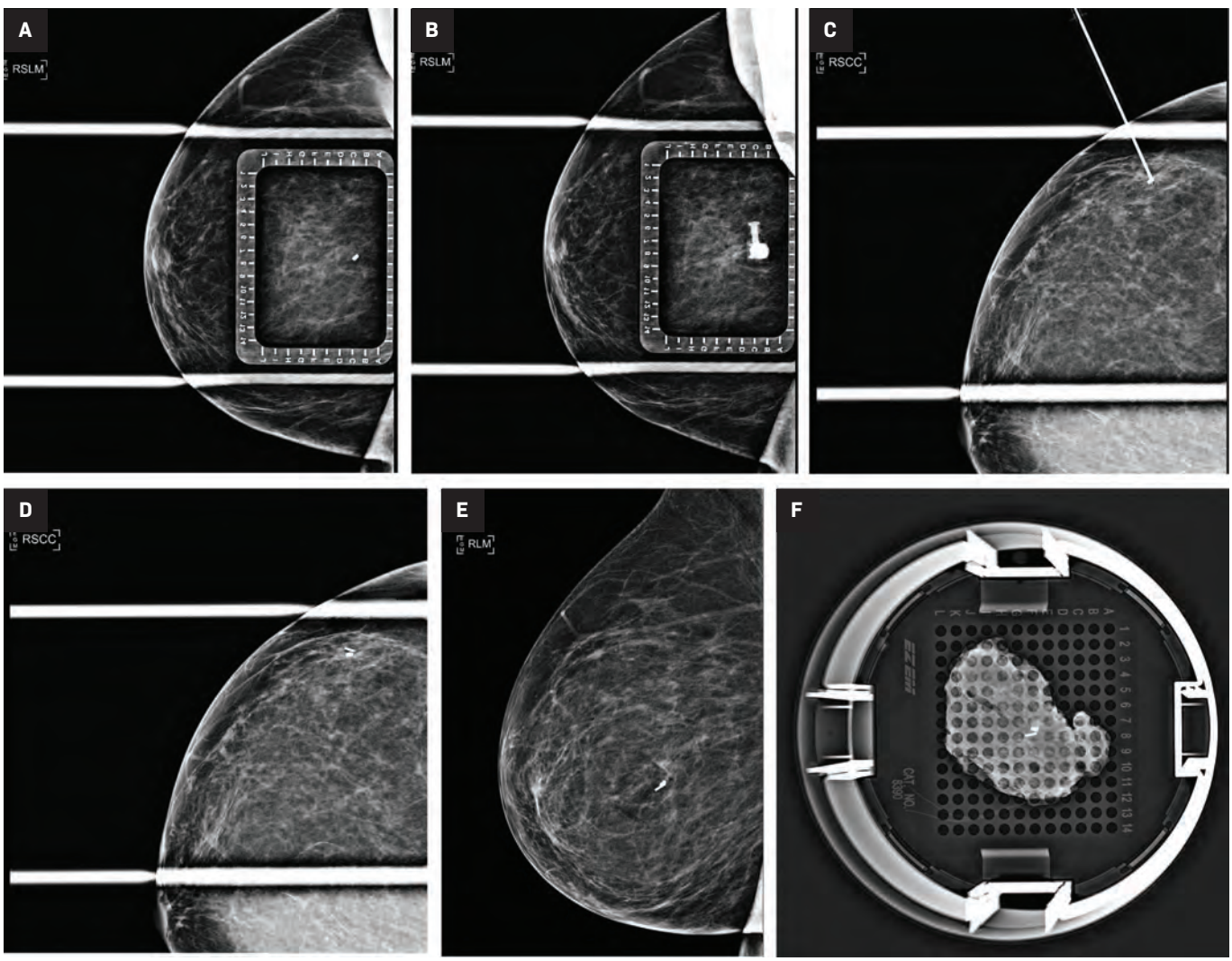


Figure 10. Magseed wireless localization device (A), the deployment needle (B), and the SentiMag probe and console (third generation) used to detect it (C).

treatment of breast cancer. While not all commercially available devices have been included, a variety of options have been presented, including their comparable technical specifications, advantages, and limitations. Breast imagers and their patients will benefit from familiarity with these devices.

Figure 11. Step by step placement of the Magseed localization device under mammographic guidance. Spot compression lateromedial (LM) view (A) of the right breast with an overlying alphanumeric grid showing the target, a cork clip marking the site of biopsy-proven atypical ductal hyperplasia, at C-7. Repeat imaging (B) after introduction of the Magseed introducer needle showing the needle hub en face at EC-7 on the grid. CC view (C) of the right breast confirms the needle tip is at the target. Deployed Magseed postplacement (D). Postplacement MLO view (E) was also performed. Postlumpectomy specimen radiograph (F) showing both the biopsy clip and the Magseed within the resected tissue.



References

1) Pavlicek W, Walton HA, Karstaedt PJ, Gray RJ. Radiation safety with use of I-125 seeds for localization of nonpalpable breast lesions. *Acad Radiol*. 2006;13(7):909-915. doi: 10.1016/j.acra.2006.03.017

2) Yeh ED, Portnow LH. Transitioning from the traditional wire localization to the wireless technology for surgical guidance at lumpectomies: part A. Radioseed localization. *Seminars in Ultrasound, CT and MRI*. 2023;44(1):8-11. doi:10.1053/j.sult.2022.10.003

3) Goudreau SH, Joseph JP, Seiler SJ. Preoperative radioactive seed localization for nonpalpable breast lesions: technique, pitfalls, and solutions. *Radiographics*. 2015;35(5):1319-1334. doi:10.1148/rg.2015140293

4) Jadeja PH, Mango V, Patel S, et al. Utilization of multiple SAVI SCOUT surgical guidance system reflectors in the same breast: a single-institution feasibility study. *Breast J*. 2018;24(4):531-534. doi:10.1111/tbj.12979

5) Shirazi S, Hajiesmaeili H, Khosla M, et al. Comparison of wire and non-wire localisation techniques in breast cancer surgery: A review of the literature with pooled analysis. *Medicina (Kaunas)*. 2023;59(7):1297. doi:10.3390/medicina59071297

6) Hayes MK. Update on preoperative breast localization. *Radiol Clin North Am*. 2017;55(3):591-603. doi:10.1016/j.rcl.2016.12.012

7) Lobbes MBI, Prevos R, Smidt M, et al. The role of magnetic resonance imaging in assessing residual disease and pathologic complete response in breast cancer patients receiving neoadjuvant chemotherapy: a systematic review. *Insights Imaging*. 2013;4(2):163-175. doi:10.1007/s13244-013-0219-y

8) Baker JL, Haji F, Kusske AM, et al. SAVI SCOUT® localization of metastatic axillary lymph node prior to neoadjuvant chemotherapy for targeted axillary dissection: a pilot study. *Breast Cancer Res Treat*. 2022;191(1):107-114. doi:10.1007/s10549-021-06416-z

9) Mango VL, Wynn RT, Feldman S, et al. Beyond wires and seeds: reflector-guided breast lesion localization and excision. *Radiology*. 2017;284(2):365-371. doi:10.1148/radiol.2017161661

10) Almalki H, Rankin AC, Juette A, Youssef MG. Radio-frequency identification (RFID) tag localisation of non-palpable breast lesions a single centre experience. *Breast*. 2023;69:417-421. doi:10.1016/j.breast.2023.04.005

11) Heindl F, Schulz-Wendtland R, Jud S, et al. Evaluation of a wireless localization system for nonpalpable breast lesions - feasibility and cost-effectiveness in everyday clinical routine. *In Vivo*. 2022;36(5):2342-2349. doi:10.21873/invivo.12965

12) Lamb LR, Gilman L, Specht M, et al. Retrospective review of preoperative radiofrequency tag localization of breast lesions in 848 patients. *AJR Am J Roentgenol*. 2021;217(3):605-612. doi:10.2214/AJR.20.24374

13) Lowes S, Bell A, Milligan R, Amonkar S, Leaver A. Use of hologic localizer radiofrequency identification (RFID) tags to localise impalpable breast lesions and axillary nodes: experience of the first 150 cases in a UK breast unit. *Clin Radiol*. 2020;75(12):942-949. doi:10.1016/j.crad.2020.08.014

14) Hefelfinger L, Doherty A, Wahab R, et al. Nonradioactive seed, a novel wireless localization method for the breast: initial clinical experience and surgical outcome. *Am Surg*. 2024;90(4):592-599. doi:10.1177/00031348231199171

15) Gera R, Tayeh S, Al-Reefy S, Mokbel K. Evolving role of magseed in wireless localization of breast lesions: systematic review and pooled analysis of 1,559 procedures. *Anticancer Res*. 2020;40(4):1809-1815. doi:10.21873/anticanres.14135

16) Banys-Paluchowski M, Kühn T, Masannat Y, et al. Localization techniques for non-palpable breast lesions: current status, knowledge gaps, and rationale for the MELODY study (EUBREAST-4/ibra-NET, NCT 05559411). *Cancers (Basel)*. 2023;15(4):1173. doi:10.3390/cancers15041173

17) Simons JM, Scoggins ME, Kuerer HM, et al. Prospective registry trial assessing the use of magnetic seeds to locate clipped nodes after neoadjuvant chemotherapy for breast cancer patients. *Ann Surg Oncol*. 2021;28(8):4277-4283. doi:10.1245/s10434-020-09542-y

18) Jeffries DO, Dossett LA, Jorns JM. Localization for breast surgery: the next generation. *Arch Pathol Lab Med*. 2017;141(10):1324-1329. doi:10.5858/arpa.2017-0214-RA

Challenges of Workflow Optimization in Mammography

Alexander M. Satei, MBBS; Cory Z. Trivax, MD

Introduction to Breast Imaging Workflow

Over the last few decades, radiology workflow has changed significantly, fundamentally altering the day-to-day workload of radiologists. With the advent of the picture archiving and communication system (PACS) and transition to digital imaging, most changes have improved efficiency of the average radiologist.[1,2] Despite this, many technical and practical challenges remain when interpreting radiology studies beyond the complexity of the case. Therefore, attempts to improve daily workflow remain, especially in breast imaging.

Workflow Differences Between Diagnostic and Screening Examinations

The process of completing a diagnostic breast examination is a complicated act, with multiple participants and moving parts. This is a phased examination involving many steps, where the images are obtained, the radiologist is consulted for their interpretation, and recommendations for further imaging or follow-up are made, all in the same visit. Similar steps are taken at most institutions for a complete diagnostic examination, illustrated in Figure 1.

This process allows for examination results to be communicated to the patient prior to discharge from the facility. To facilitate the prompt interpretation of diagnostic studies, coordination between the radiologist and the technologist must be precise, which is difficult in real-life practice. If an issue arises in the steps above, workflow will be disrupted and examination outcome delayed.

In comparison, screening examinations do not require as much immediate oversight. By definition, if further imaging is required, a Breast Imaging-Reporting and Data System (BI-RADS) score of 0 can be assigned and the patient can be brought back for additional imaging. Therefore, screening mammograms are triaged as the least urgent examination in breast imaging, with priority given to diagnostic studies and procedures. As a result, it is not uncommon to see screening mammograms from the prior week on a worklist, especially in busy centers. The Mammography Quality Standards Act (MQSA), which is the federal standard of care, allows for 30 days when reporting the results of screening studies.

Despite this, patients undergoing screening mammography have shown a preference for obtaining results within 48 hours or even waiting at the breast imaging center for their results.[3] Additionally, if the results of screening mammograms are communicated on the same day, in a similar fashion to diagnostic studies, nearly half of the patients would be more satisfied with their cancer screening experience.[4] Obtaining results within a short period reduces anxiety and improves compliance with future annual screening studies.[5]

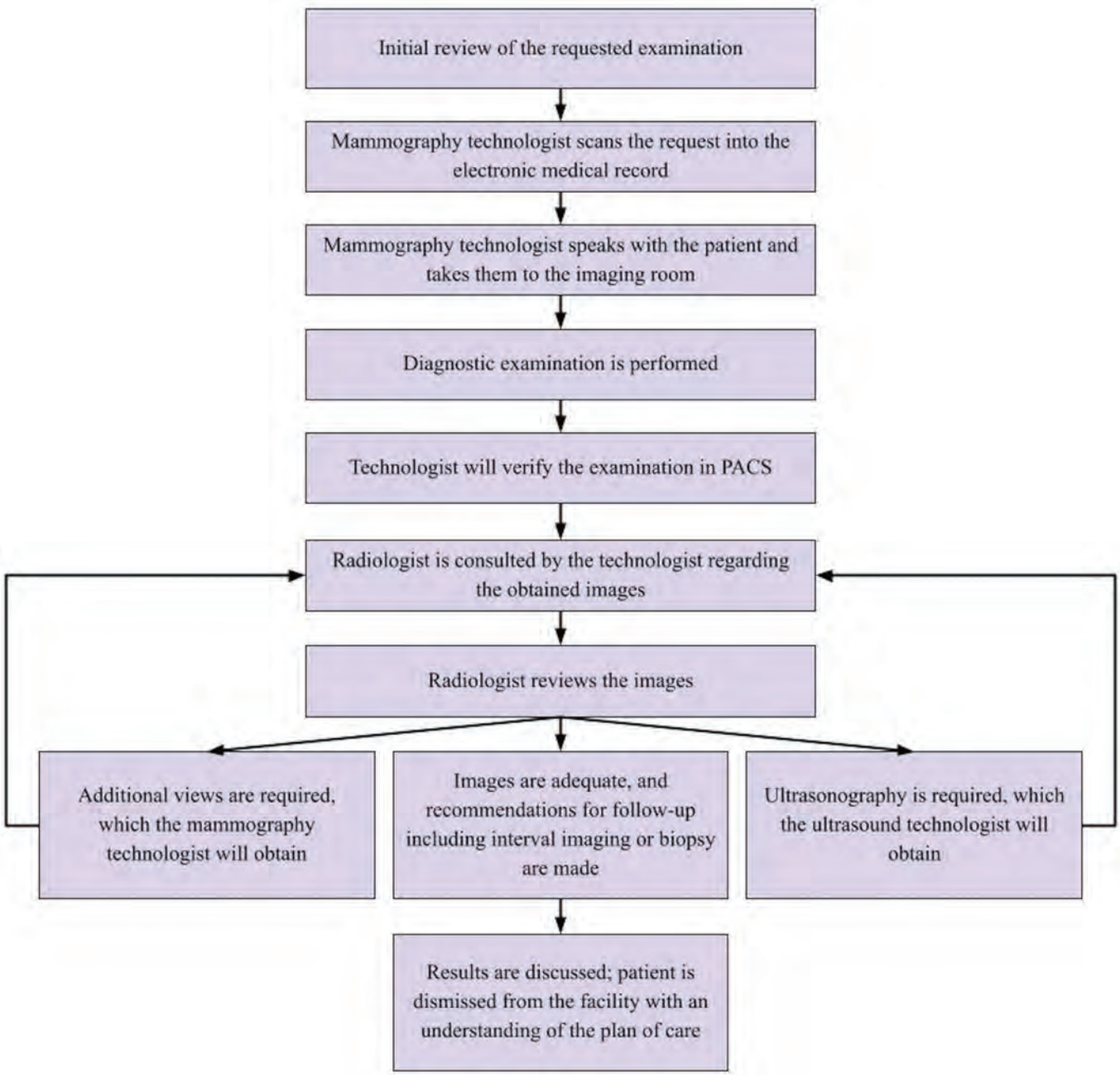
How Do We Optimize Breast Imaging Workflow?

Efforts to maximize workflow when reading from the breast

Affiliations: Trinity Health Oakland Hospital, Pontiac, MI (Satei, Trivax). Wayne State University, Detroit, MI (Satei, Trivax). Huron Valley Radiology, Ypsilanti, MI (Trivax).
Disclosures: The authors have no conflicts of interest to disclose. None of the authors received outside funding for the production of this original manuscript and no part of this article has been previously published elsewhere.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0025

Figure 1. Steps involved in completing a diagnostic mammogram



imaging list have been underway, many of which apply to all imaging modalities and subspecialties; these are known as global workflow changes. Most initiatives specific to breast imaging apply to screening mammograms, which make up the bulk of studies interpreted at our breast center, although some also extend to diagnostic examinations.

Global Workflow Changes

Single PACS. Imaging studies from outside institutions, including those performed at satellite facilities, are shown on a single list. This minimizes interruption from logging into multiple PACS in a day.

Prior studies. Prior relevant studies are automatically pulled by the system for comparison, reducing the time a radiologist spends searching for prior studies individually. However, it is worth

noting that errors can occur when PACS automatically retrieves prior studies.

Universal templates. Many of our radiologists use a universal template for reporting a wide variety of imaging studies. Those utilized by our breast radiologists include the information required per BI-RADS standards, with autofilled fields for the date, type of study, reason for examination, individual and familial risk factors, available comparison studies, technique, findings that include a description of the breast composition (eg, "The breasts are extremely dense, which lowers sensitivity of mammography"), impression, BI-RADS assessment category, and follow-up recommendation. The use of universal templates bolsters reporting efficiency, while simplifying and improving consistency of results for requestors and patients.

Workflow Changes Specific to Mammography

Cancer risk assessment models. The use of a cancer risk assessment model is included in the report and the patient's electronic medical record (EMR) for the radiologist to review. At our institution, the Gail model is used as it is one of the earliest prediction tools of its kind and has been used by radiologists to stratify individual patient risk. Modified versions of the Gail model have been released since its inception, with changes made to improve its application to non-white patients. The model remains insensitive to patients with BRCA mutations and a personal history of cancer.

Trainee-specific improvements. Radiology residents and fellows can mark which studies on the PACS they have dictated, thus alerting the attending physician to not initiate a report on the same study. This step prevents confusion since the attending physicians and trainees read from the same list. Reviewing cases with the trainee can occur in batches after a certain number of cases have been sent to the attending radiologist. For example, depending on the trainees's level of training, an attending physician may opt to review 10 cases at a time with a trainee, minimizing interruptions while focusing educational efforts.

Artificial intelligence. The use of artificial intelligence (AI) detection software for interpreting mammograms has been an ongoing effort. Computer-aided detection (CAD) can help radiologists detect abnormalities in mammography. However, this technology is still relatively new, and its ability to contribute consistently is questionable. CAD has been shown to demonstrate a high false-positive rate.[6]

Many of these initiatives are used at other institutions successfully, improving efficiency when reading mammograms. In one study, similar workflow changes were made: the worklist was consolidated, trainees had cases assigned to them, and efforts were made to improve paperwork upload time. The study found a significant reduction in the average time spent on each study and report turnaround time.[1]

Obstacles in Optimizing Mammography Workflow

The biggest hurdle in the breast imaging workflow involves the real-time radiologist review of diagnostic examinations. This is more striking given the relative complexity of completing a diagnostic mammogram, as compared with a screening study. Issues can arise at any of the steps outlined in Figure 1, preventing the successful review and dictation of the diagnostic examination. Therefore, any changes made to streamline diagnostic workflow will benefit the radiologist, technologist, and patient.

At our institution, we have made new efforts to reduce workflow interruptions by using the EMR to communicate when diagnostic examinations require review. Using the EMR, the technologist sends a message to the radiologist, including the name of the patient and the reason for the examination, at which point the radiologist reviews the images and provides recommendations. The goal of this initiative is to reduce in-person interruptions, exemplifying an ongoing attempt to optimize workflow wherever possible, although its effectiveness has yet to be definitively proven.

Improvements in dictation efficiency of screening studies have also been pursued. For example, institutions have implemented the use of AI triage software to establish efficient screening mammogram worklists.[7] Examinations given high AI scores for cancer detection are placed in an enhanced assessment stream where they receive a more prompt evaluation by the radiologist. The ultimate goals of such an initiative is to convert a positive screening study to a diagnostic study in real time or potentially reduce the need for a radiologist review of studies considered negative by AI; in this study, AI did not miss cancer in women with the lowest 60% of scores.[7] However, currently, all mammograms require review by radiologists, given the developing nature of this technology and possible medicolegal implications of using this type of algorithm.

From the patient's perspective, another potential area for improvement involves the timing between the diagnostic examination and biopsy. Despite the significant

stress and importance related to these procedures, clearly defined MQSA standards are lacking regarding the timeliness of breast biopsy.[8] Ideally, the diagnostic examination and biopsy would be performed on the same day. However, currently, the average time from diagnostic imaging to biopsy is approximately 7 days, although these wait times have significantly decreased over the past 15 years.[9]

The Future of Breast Imaging Workflow

The last few decades have demonstrated steady improvements in the daily workflow among breast imaging technologists and radiologists, which have enhanced patient care, timeliness, and availability of examination results. Future advances involving the use of the EMR and AI software integration, for example, will continue to boost overall satisfaction of the patient—and the radiologist.

References

1) Pham R, Forsberg D, Plecha D. Improved screening mammogram workflow by maximizing PACS streamlining capabilities in an academic breast center. *J Digit Imaging*. 2017;30(2):133-140. doi:10.1007/s10278-016-9909-6

2) Srinivasan M, Liederman E, Baluyot N, Jacoby R. Saving time, improving satisfaction: the impact of a digital radiology system on physician workflow and system efficiency. *J Healthc Inf Manag*. 2006;20(2):123-131.

3) Shah BA, Staschen J, Pham N, Johns A. Communicating mammography results: by what method and how quickly do women want their screening mammogram results?. *J Am Coll Radiol*. 2019;16(7):928-935. doi:10.1016/j.jacr.2018.12.006

4) Shah BA, Mirchandani A, Abrol S. Impact of same day screening mammogram results on women's satisfaction and overall breast cancer screening experience: a quality improvement survey analysis. *BMC Womens Health*. 2022;22(1):338. doi:10.1186/s12905-022-01919-3

5) Donato F, Bollani A, Spiazzi R, et al. Factors associated with non-participation of women in a breast cancer screening programme in a town in northern italy. *J Epidemiol Community Health*. 1991;45(1):59-64. doi:10.1136/jech.45.1.59

6) Džoić Dominković M, Ivanac G, Radović N, Čavka M. WHAT can we actually see using computer aided detection in mammography? *Acta Clin Croat*. 2020;59(4):576-581. doi:10.20471/acc.2020.59.04.02

7) Dembrower K, Wåhlin E, Liu Y, et al. Effect of artificial intelligence-based triaging of breast cancer screening mammograms on cancer detection and radiologist workload: a retrospective simulation study. *Lancet Digit Health*. 2020;2(9):e468-e474. doi:10.1016/S2589-7500(20)30185-0

8) Rauscher GH, Tossas-Milligan K, Macarol T, Grabler PM, Murphy AM. Trends in attaining mammography qualitybenchmarks with repeated participation in a quality measurement program: going beyond the mammography quality standards act to address breast cancer disparities. *J Am Coll Radiol*. 2020;17(11):1420-1428. doi:10.1016/j.jacr.2020.07.019

9) Donovan CA, Kaufman CS, Thomas KA, et al. Timeliness of breast diagnostic imaging and biopsy in practice: 15 years of collecting, comparing, and defining quality breast cancer care. *Ann Surg Oncol*. 2023;30(10):6070-6078. doi:10.1245/s10434-023-13905-6

REVIEW

Optimizing Monitoring of Pulmonary Airway Interventions With Digital Tomosynthesis

Lauren Hahn, MCR, RT; Shannon Sullivan, MD; Benjamin Young, MD; N. Scott Howard, MD, MBA; Lisa Youngblood, RT; Kathleen Thaler, RT; Jennifer Sposato, RT; Victoria Uram, MPH; Robert Gilkeson, MD; Ariel Godel, BS

Introduction

With its wide availability, low cost, and low radiation dose, the chest radiograph remains the most performed radiographic procedure worldwide. Despite its ease of use, the chest radiograph has diagnostic limitations. The 2D planar acquisition of the chest radiograph limits the spatial delineation of the complex 3D structures within the thorax. The wide latitude and dynamic range of the chest radiograph can also preclude the differentiation of the complex tissue pathologies contained within the thorax.[1]

More recent advances in the detection of cardiothoracic disease have been made possible with the incorporation of flat-panel detector technology in chest radiography. The flat-panel detector enables several advances: it improves contrast independent of exposure level, the availability of image data in electronic form, and the ability to acquire multiple images in rapid sequence.[1] Sequential image acquisition capability made possible with flat-panel detectors has enabled 2 important technologies in chest radiography: dual-energy subtraction radiography and digital tomosynthesis.

While first proposed as a technology in the 1950s, dual-energy radiography was only first performed in the 1980s.[2] Early literature with dual-energy radiography demonstrated improved detection of lung nodules compared with conventional radiography.[3] Utilizing flat-panel technology, dual-energy subtraction was enabled with a sequential dual exposure of high- and low-energy x-ray acquisitions.[4] Dual-energy radiography has also been reported to better delineate calcified from noncalcified structures.[5] This improved delineation has also enabled a better depiction of a large range of calcified cardiovascular structures.[6]

The rapid sequential acquisitions made possible with flat-panel technology have more recently enabled the adoption of another advanced imaging technique, digital tomosynthesis. This advanced application has demonstrated improved detection of breast cancer,[7] orthopedic pathology,[8] and urological imaging.[9] In the thorax, digital tomosynthesis has demonstrated improved pulmonary nodule detection.[10] Further reports have compared pulmonary nodule detection between conventional radiography, dual-energy radiography, and digital tomosynthesis. Digital tomosynthesis demonstrated clearly superior performance compared with dual-energy and conventional acquisitions.[11] Simultaneously, chest tomosynthesis has the radiation dose equivalent of 2 posteroanterior and lateral x-rays; therefore, the average dose of a digital tomosynthesis examination is 0.3-0.4 mSv. Compared with a diagnostic chest CT, typically 4-8 mSv, the average chest digital

Affiliations: Division of Cardiothoracic Imaging, Department of Radiology, University Hospitals Cleveland Medical Center, Cleveland, Ohio (Hahn, Sullivan, Youngblood, Thaler, Sposato, Uram, Gilkeson). Division of Pulmonary and Critical Care Medicine, University Hospitals Cleveland Medical Center, Cleveland, Ohio (Young). Department of Otolaryngology, University Hospitals Cleveland Medical Center, Cleveland, Ohio (Howard). Northeast Ohio Medical University, Rootstown, Ohio (Godel).
Disclosures: Dr Gilkeson receives research support from GE Medical Systems. The remaining authors report no conflicts of interest.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0024

tomosynthesis dose is 5%-10% that of a diagnostic chest CT.

Advancements in dual-energy radiography and digital tomosynthesis have also further improved visualization and evaluation of the airways.[12,13] The focus of this review is the enhanced capabilities of digital tomosynthesis in the assessment of suspected airway disease. In addition to effectively detecting airway stenosis, digital tomosynthesis proves valuable in the evaluation and management of patients with suspected airway disease, including the improved detection of airway stents and endobronchial valves (EBV).

Postintubation Tracheal Stenosis

During the peak of the COVID-19 global pandemic, reports from regions that were more profoundly affected by COVID-19 found that up to 88% of critically ill patients with COVID-19 required endotracheal intubation for a median of 18 days.[14] The complications of prolonged or repeated intubation and endotracheal cuff overinflation have been well documented, including tracheal ischemia, ulceration, and necrosis.[15] Such tracheal injury can lead to tracheal stenosis, resulting in chronic or progressive respiratory symptoms after extubation. Treatment options for tracheal stenosis include endoscopic balloon dilation and open surgery with partial tracheal resection and anastomosis. Mattioli et al highlighted the advantage of balloon dilation in patients with COVID-19 over the more invasive approach of open surgery.[16] After treatment, patients undergo serial endoscopic examinations to assess patency and integrity of their airways. Diagnostic imaging has a role in assessing the airway in the periprocedural setting, both for the detection of tracheal stenosis, preprocedural planning, and postprocedural follow-up. Cross-sectional imaging with CT is often used to assess the severity of tracheal stenosis and is complementary to the more definitive but invasive diagnostic approach of direct endoscopic evaluation. Additionally, the use of dynamic CT and MRI has been described for further characterizing tracheal stenosis.[17] However, digital tomosynthesis can be valuable in this setting, particularly when cross-sectional imaging is not available (Figure 1).

Malignant Bronchial Stenosis

Central airway stenting is a common, minimally invasive interventional pulmonary procedure performed to maintain airway patency in patients with malignant airway pathologies, including tumor invasion into the airway lumen, as well as extrinsic mass compression of the airway.[18] While not curative, airway stenting relieves symptoms and improves the quality of life for the patient. Conventional radiography is often the initial imaging requested to assess the thoracic anatomy. However, due to overlapping mediastinal anatomic structures, conventional radiographs have a relatively low sensitivity for detecting central airway pathology, often resulting in suboptimal evaluation of the airways.[19] Digital tomosynthesis provides an alternative or intermediate step in detecting malignant airway stenosis and determining the integrity of the airways (Figure 2). Studies evaluating inter-reader diagnostic performance found increased sensitivity and accuracy for detecting airway pathologies using digital tomosynthesis over conventional radiography.[13]

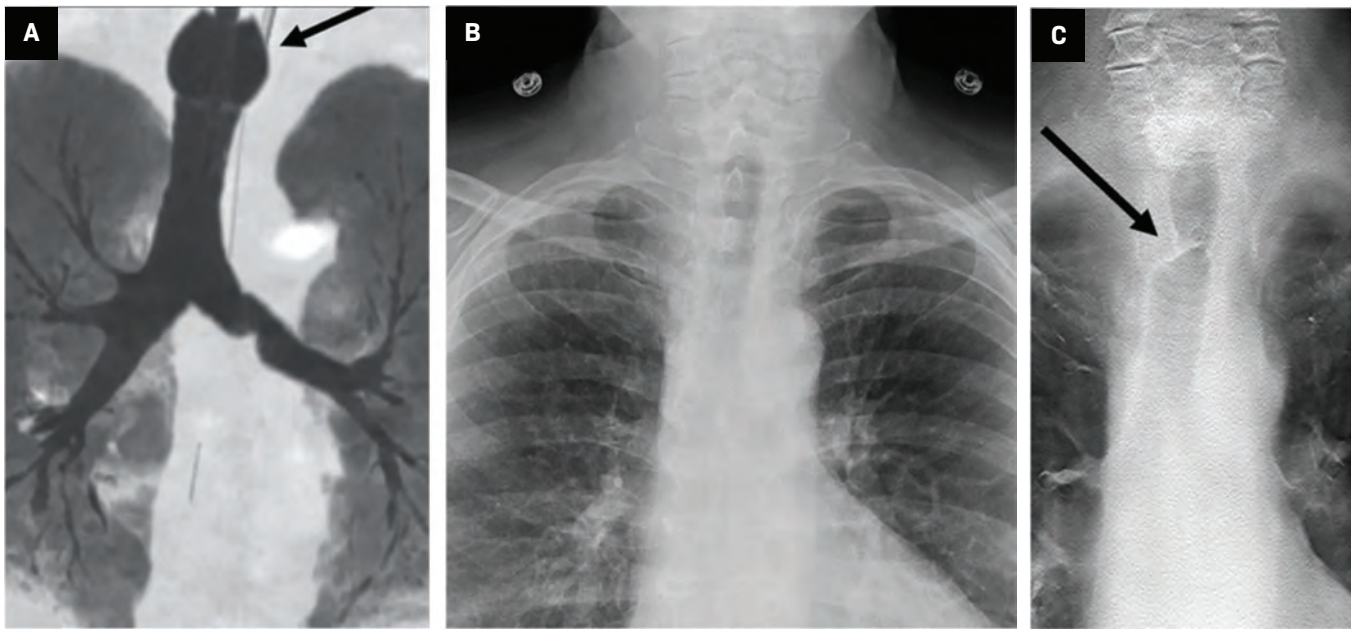
Postoperative Airway Complications

Lung Transplantation

Patients with end-stage lung disease undergo an extensive assessment of transplant eligibility prior to receiving a lung transplant. Radiologists are becoming increasingly more involved in the care of these patients both before and after transplantation. In addition to assessing post-transplant infection or sequelae of transplant rejection, assessing the airway anastomosis site is critical. Central airway stenosis at the anastomotic site between the donor and recipient mainstem bronchi is one of the common post-transplant complications.[20] Placement of an airway stent is an important treatment option for post-transplant anastomotic strictures. However, complications may occur after the stent is placed, and follow-up imaging can help assess the possibility of stent migration and/or obstruction (Figure 3). In 1 series, stent-related complications were seen in 23% to 34% of patients.[21] In another study by Kim et al, evaluating patients undergoing airway stent placement, 47% required 2 or more procedures, with stent-related complications occurring in the first 2 to 3 months after the initial procedure.[22] Digital tomosynthesis can change the treatment plan without the need for additional CT imaging.[23]

Endobronchial Valve Placement

Patients with refractory chronic obstructive pulmonary disease (COPD) owing to severe lung hyperinflation and air trapping may benefit from minimally



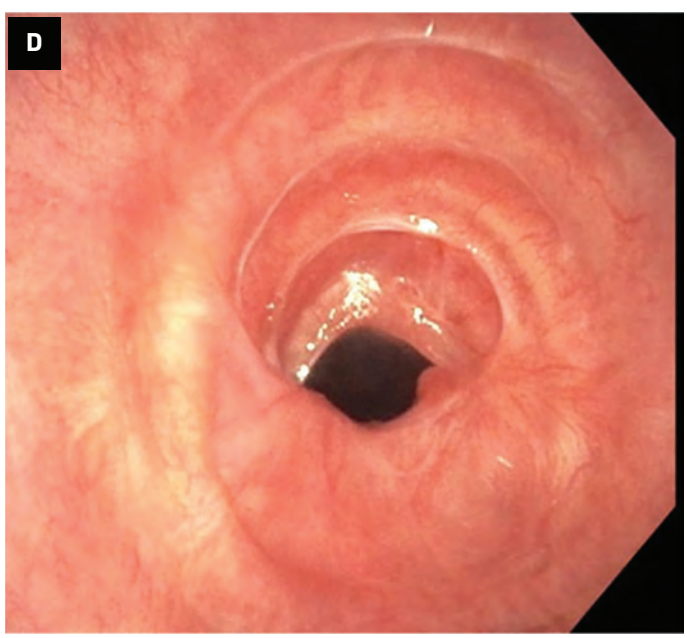


Figure 1. Adult with COVID-19 pneumonia. Coronal CT (A) in minimum intensity projection at the level of the trachea and central airway demonstrates tracheal distention secondary to overinflated endotracheal tube cuff (arrow). Postextubation radiograph (B) is suboptimal in the assessment of the trachea due to overlapping mediastinal and osseous structures. Digital tomosynthesis (C) centered at the trachea reveals severe narrowing of the tracheal lumen (arrow). Preintervention bronchoscopy (D) confirms a smooth, circumferential tracheal stricture.

invasive procedures, which aim to selectively reduce lung volume, improve lung function, and relieve symptoms. In fact, the placement of an EBV is a standard-of-care treatment option for advanced COPD in many countries.[24] After placement of an EBV, serial imaging follow-up is necessary to assess lung volume changes in addition to postprocedural complications. A pneumothorax is a common complication, with some reporting a 15% to 25% occurrence rate.[24] However, making the distinction between a bulla or pneumatocele, which has been shown to resolve on its own,[25] and a pneumothorax, for which the valves may need to be removed, may impact the patient's clinical and treatment course. Conventional radiography may not have the resolution to definitively visualize the thin-walled cyst of a pneumatocele.[26] However, by scrolling through slices provided by digital tomosynthesis, the outline of the pneumatocele can be better appreciated (Figure 4).

Limitations of Digital Tomosynthesis in Thoracic Imaging

The diagnostic value and added benefit of digital tomosynthesis in the monitoring of patients with a variety of airway pathologies

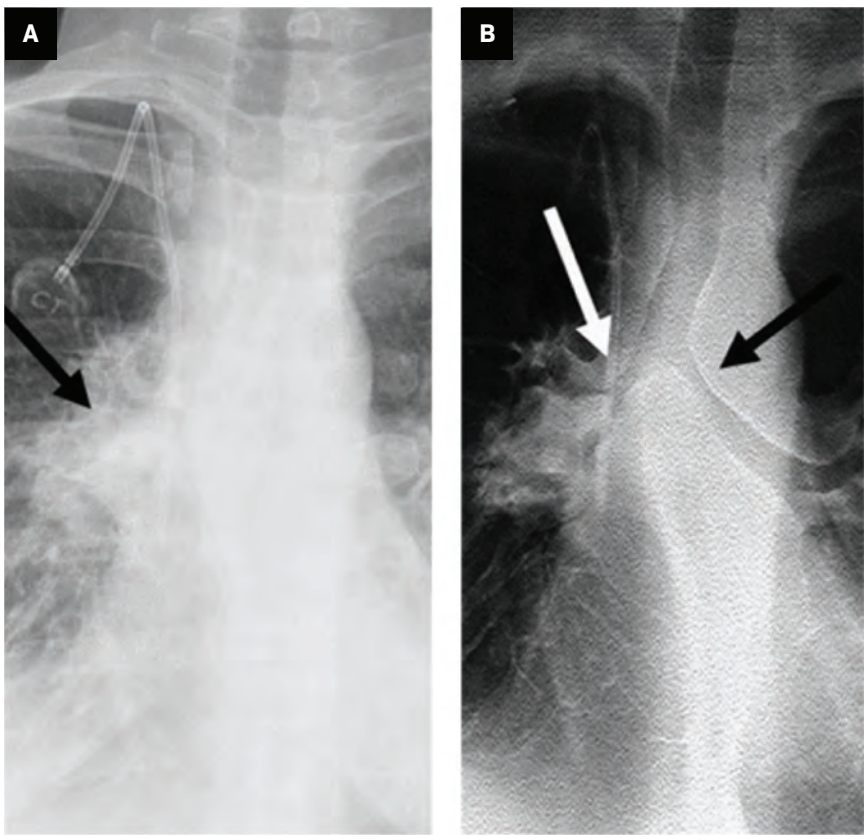


Figure 2. Adult with malignant bronchial stenosis. Chest radiograph (A) demonstrates an irregular, lobular, mass-like density projecting over the right perihilar region (arrow). Note the limited visualization of the mainstem and segmental bronchi secondary to underpenetration. Digital tomosynthesis (B) improves visualization of underlying severe stenosis of the right-sided tracheobronchial structures (white arrow). There is moderate stenosis of the left mainstem bronchus (black arrow).

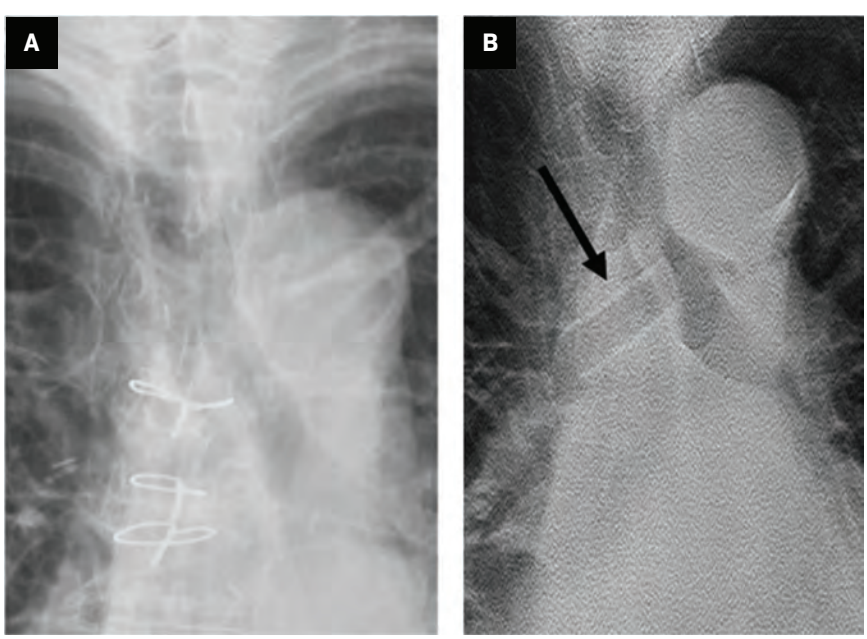
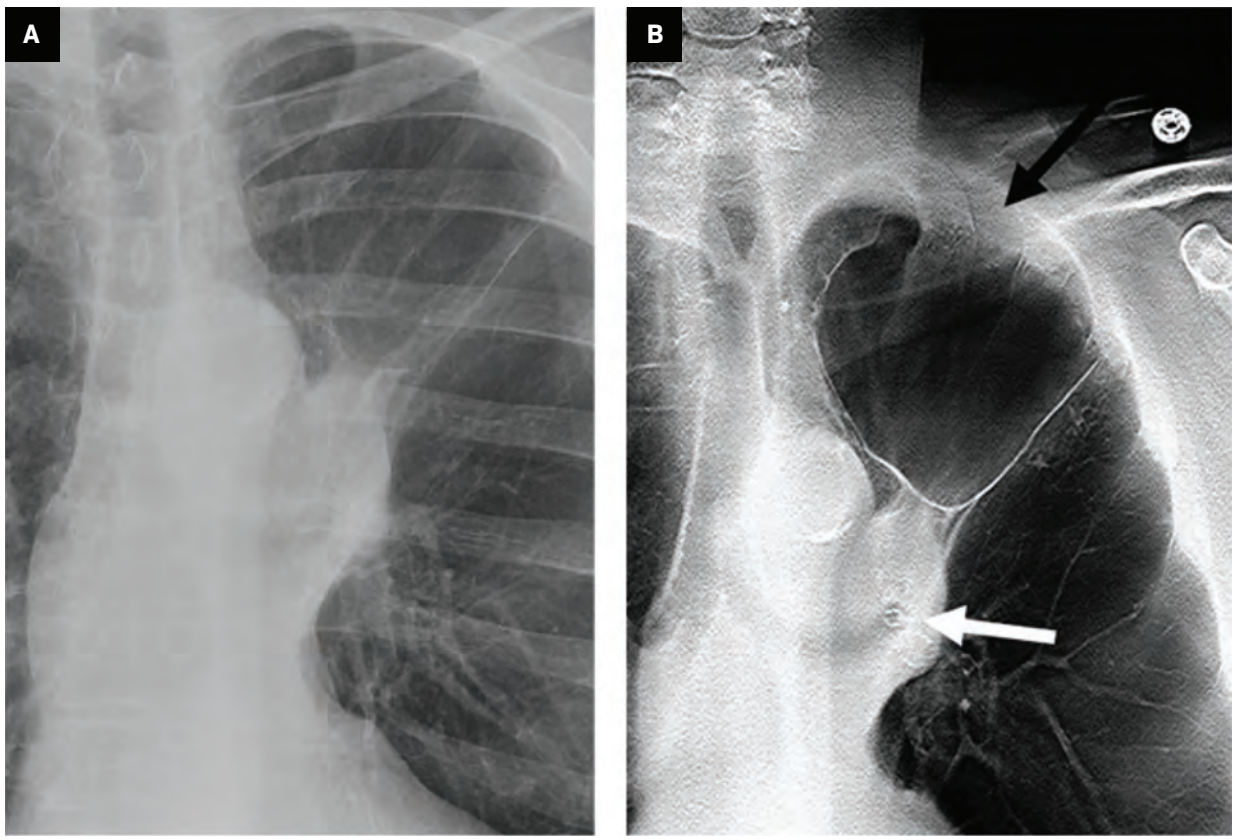


Figure 3. Adult lung transplant patient who underwent right mainstem bronchus stent placement for postprocedural bronchial stenosis. Conventional radiograph (A) shows poor visualization of the right mainstem bronchus owing to overlying anatomy and sternal wires. Digital tomosynthesis (B) demonstrates markedly improved visualization of the stented right mainstem bronchus (black arrow), which appears intact.

and airway interventions are clear. However, digital tomosynthesis technology has limitations. Current digital tomosynthesis platforms are not portable, precluding their use in the intensive care unit setting. Additionally, blurring artifact may occur in patients who have difficulty cooperating with the examination, given that the acquisition requires a 10-second breath hold (Figure 5); however, we are not aware of specific literature indicating a significant rate of nondiagnostic digital tomosynthesis examinations.



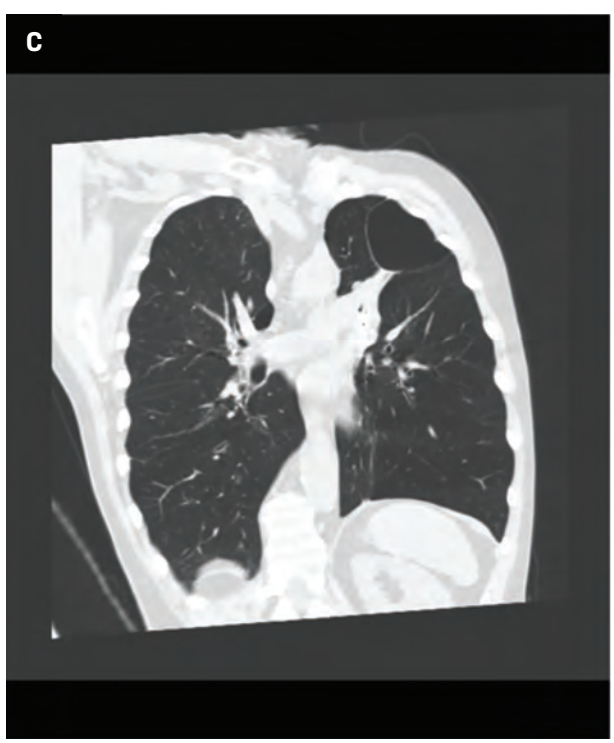


Figure 4. Adult with chronic obstructive pulmonary disease following left upper lobe EBV placement. Conventional chest radiograph (A) following left upper lobe EBV placement. Postprocedural digital tomosynthesis image (B) following EBV placement enhances demonstration of left apical lucency consistent with postprocedural pneumatocele (black arrow). Note improved visualization of the EBV within the left upper lobe airways (white arrow). Coronal chest CT reformation (C) following EBV placement confirms the digital tomosynthesis diagnosis of postprocedural pneumatocele.

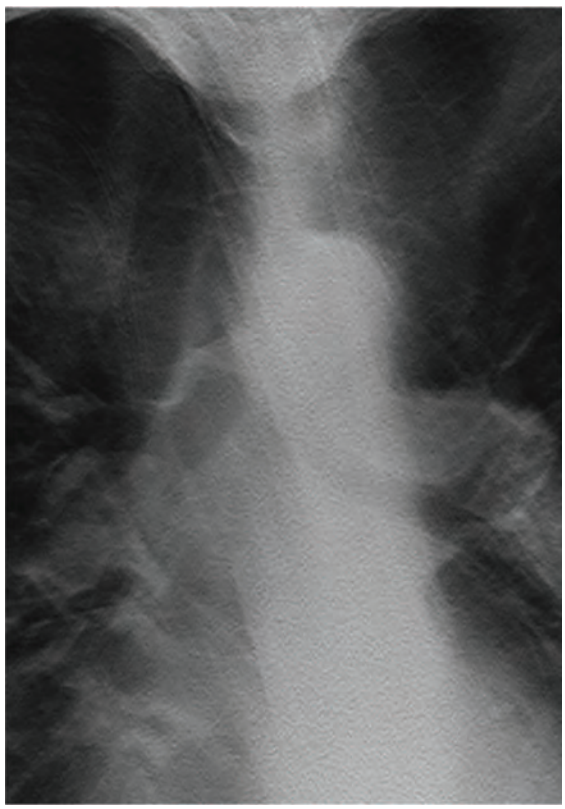


Figure 5. Limitations of digital tomosynthesis. Digital tomosynthesis centered over the trachea and central airways shows blurring artifact owing to patient motion during the acquisition. As a result, there is poor delineation of the contour and luminal integrity of the trachea and central airways.

Conclusion

The expanding scope and advances in the field of interventional pulmonology have paralleled the growth of advanced imaging techniques to better evaluate the results of interventions, including removable silicone stents,[27] balloon/laser ablation,[28] and EBV therapy,[29] and have increased the opportunity for accurate, noninvasive monitoring of these interventions.

These technological advances are not without their own complexities, and patients undergoing airway intervention commonly return for follow-up evaluation for complications. Due to the inherent limitations of standard film-screen and digital radiographic techniques, CT has been used to monitor the preprocedural and postoperative appearance of interventional pulmonology techniques.[30] While the rapid acquisition and advanced 3D capabilities of modern-day CT have clear advantages, digital radiographic technologies, with significantly lower cost and radiation dose, offer a potentially attractive alternative for the patient with suspected airway disease.[13,31]

In patients undergoing silicon stent placement, digital tomosynthesis demonstrated clear superiority to conventional radiography in the detection of these stents and associated complications.[22] Recent experience demonstrates the significant diagnostic value of digital tomosynthesis in the post-lung transplant patient with endobronchial stents.

Additional opportunities for therapy monitoring with digital tomosynthesis exist in patients undergoing EBV therapy. Well-recognized complications in patients include postprocedural pneumothoraces, EBV migration, and airway granulation/stenosis.[32] Early results suggest digital tomosynthesis may also improve pneumothorax detection in patients undergoing EBV therapy.[33]

Digital tomosynthesis has advantages over plain radiography in the detection of airway disease, and its role in the effective, low-cost and low-radiation-dose monitoring of these therapies. Future advances in pulmonary intervention will continue to define the important role of digital tomosynthesis in this growing population.

References

1) McAdams HP, Samei E, Dobbins J, Tourassi GD, Ravin CE. Recent advances in chest radiography. *Radiology*. 2006;241(3):663-683. doi:10.1148/radiol.2413051535

2) Kido S, Ikezoe J, Naito H, et al. Single-exposure dual-energy chest images with computed radiography. Evaluation with simulated pulmonary nodules. *Invest Radiol*. 1993;28(6):482-487.

3) Kelcz F, Zink FE, Peppler WW, et al. Conventional chest radiography vs dual-energy computed radiography in the detection and characterization of pulmonary nodules. *AJR Am J Roentgenol*. 1994;162(2):271-278. doi:10.2214/ajr.162.2.8310908

4) Gilkeson RC, Sachs PB. Dual energy subtraction digital radiography: technical considerations, clinical applications, and imaging pitfalls. *J Thorac Imaging*. 2006;21(4):303-313. doi:10.1097/01.rti.0000213646.34417.be

5) Fischbach F, Freund T, Röttgen R, et al. Dual-energy chest radiography with a flat-panel digital detector: revealing calcified chest abnormalities. *AJR Am J Roentgenol*. 2003;181(6):1519-1524. doi:10.2214/ajr.181.6.1811519

6) Ansari-Gilani K, Tandon YK, Jordan DW, et al. Dual-energy subtraction chest radiography: application in cardiovascular imaging. *J Thorac Imaging*. 2020;35(3):W75-W81. doi:10.1097/RTI.0000000000000472

7) Rafferty EA, Park JM, Philpotts LE, et al. Assessing radiologist performance using combined digital mammography and breast tomosynthesis compared with digital mammography alone: results of a multicenter, multireader trial. *Radiology*. 2013;266(1):104):104-113:. doi:10.1148/radiol.12120674

8) Gazaille RE 3rd, Flynn MJ, Page W 3rd, Finley S, van Holsbeeck M. Technical innovation: digital tomosynthesis of the hip following intra-articular administration of contrast. *Skeletal Radiol*. 2011;40(11):1467-1471. doi:10.1007/s00256-011-1247-7

9) Neisius A, Astroza GM, Wang C, et al. Digital tomosynthesis: a new technique for imaging nephrolithiasis. specific organ doses and effective doses compared with renal stone protocol noncontrast computed tomography. *Urology*. 2014;83(2):282-287. doi:10.1016/j.urology.2013.10.004

10) Kim JH, Lee KH, Kim K-T, et al. Comparison of digital tomosynthesis and chest radiography for the detection of pulmonary nodules: systematic review and meta-analysis. *Br J Radiol*. 2016;89(1068):20160421. doi:10.1259/bjr.20160421

11) Dobbins JT, McAdams HP, Sabol JM, et al. Multi-institutional evaluation of digital tomosynthesis, dual-energy radiography, and conventional chest radiography for the detection and management of pulmonary nodules. *Radiology*. 2017;282(1):236):236-250:. doi:10.1148/radiol.2016150497

12) Odagiri K, Fujiwara T, Andoh K, et al. Single exposure dual-energy subtraction radiography of the upper airways using computed radiography. *Acta Radiol*. 1992;33(3):281-283.

13) Choo JY, Lee KY, Yu A, et al. A comparison of digital tomosynthesis and chest radiography in evaluating airway lesions using computed tomography as a reference. *Eur Radiol*. 2016;26(9):3147-3154. doi:10.1007/s00330-015-4127-z

14) Tapias LF, Lanuti M, Wright CD, et al. COVID-19-related post-intubation tracheal stenosis: early experience with surgical treatment. *Ann Surg*. 2022;275(1):e271):e271-e273:. doi:10.1097/SLA.0000000000004884

15) Gaspar M da C, Maximiano LF, Minamoto H, Otoch JP. Tracheal stenosis due to endotracheal tube cuff hyperinflation: a preventable complication. *Autops Case Rep*. 2019;9(1):e2018072. doi:10.4322/acr.2018.072

16) Mattioli F, Marchioni A, Andreani A, et al. Post-intubation tracheal stenosis in COVID-19 patients. *Eur Arch Otorhinolaryngol*. 2021;278(3):847-848. doi:10.1007/s00405-020-06394-w

17) Parshin VD, Koroleva IM, Mishchenko MA. Evolution of diagnostic methods for cicatrical tracheal stenosis and tracheomalacia. *Khir Z im NI Pirogova*. 2016;5:17. doi:10.17116/hirurgia2016517-25

18) Murgu SD, Egressy K, Laxmanan B, et al. Central airway obstruction: benign strictures, tracheobronchomalacia, and malignancy-related obstruction. *Chest*. 2016;150(2):426-441. doi:10.1016/j.chest.2016.02.001

19) Oberg C, Folch E, Santacruz JF. Management of malignant airway obstruction. *AME Med J*. 2018;3:115-115. doi:10.21037/amj.2018.11.06

20) Kim SJ, Azour L, Hutchinson BD, et al. Imaging course of lung transplantation: from patient selection to postoperative complications. *Radiographics*. 2021;41(4):1043-1063. doi:10.1148/rg.2021200173

21) Guibert N, Saka H, Dutau H. Airway stenting: technological advancements and its role in interventional pulmonology. *Respirology*. 2020;25(9):953-962. doi:10.1111/resp.13801

22) Kim B-G, Chung MJ, Jeong B-H, Kim H. Diagnostic performance of digital tomosynthesis to evaluate silicone airway stents and related complications. *J Thorac Dis*. 2021;13(10):5627):5627-5637:. doi:10.21037/jtd-21-1032

23) Banifadel M, Vonau M, Young B, et al. "Digital tomosynthesis" as a technique for the evaluation of endobronchial stents in lung transplant recipients. *Transplantation*. 2022;106(12):2462-2465. doi:10.1097/TP.0000000000004248

24) Klooster K, Slebos DJ. Endobronchial valves for the treatment of advanced emphysema. *Chest*. 2021;159(5):1833-1842. doi:10.1016/j.chest.2020.12.007

25) Skowasch D, Pizarro C, Valipour A, et al. Endobronchial valve-induced pneumatocele: a case report. *Pneumologie*. 2013;67(11):639-640. doi:10.1055/s-0033-1344640

26) Cant J, Snoeckx A, Behiels G, Parizel PM, Sijbers J. Can portable tomosynthesis improve the diagnostic value of bedside chest X-ray in the intensive care unit? A proof of concept study. *Eur Radiol Exp*. 2017;1(1):20. doi:10.1186/s41747-017-0021-6

27) Shin B, Kim K, Jeong B-H, et al. Clinical implications of differentiating between types of post-tracheostomy tracheal stenosis. *J Thorac Dis*. 2017;9(11):4413-4423. doi:10.21037/jtd.2017.10.99

28) Chan CL, Frauenfelder CA, Foreman A, et al. Surgical management of airway stenosis by radiofrequency coblation. *J Laryngol Otol*. 2015;129(s1):S21-S26. doi:10.1017/S0022215114002783

29) Valipour A, Burghuber OC. An update on the efficacy of endobronchial valve therapy in the management of hyperinflation in patients with chronic obstructive pulmonary disease. *Ther Adv Respir Dis*. 2015;9(6):294-301. doi:10.1177/1753465815599693

30) Ferretti GR, Kocier M, Calaque O, et al. Follow-up after stent insertion in the tracheobronchial tree: role of helical computed tomography in comparison with fiberoptic bronchoscopy. *Eur Radiol*. 2003;13(5):1172-1178. doi:10.1007/s00330-003-1820-0

31) Chou S-HS, Kicska GA, Pipavath SN, Reddy GP. Digital tomosynthesis of the chest: current and emerging applications. *Radiographics*. 2014;34(2):359-372. doi:10.1148/rg.342135057

32) Koster TD, Klooster K, Ten Hacken NHT, van Dijk M, Slebos D-J. Endobronchial valve therapy for severe emphysema: an overview of valve-related complications and its management. *Expert Rev Respir Med*. 2020;14(12):1235-1247. doi:10.1080/17476348.2020.1813571

33) Avasarala SK, Young B, Gilkeson RC. Enhanced postbronchoscopic lung volume reduction pneumothorax detection with digital tomosynthesis. *Am J Respir Crit Care Med*. 2023;207(6):e47-e48. doi:10.1164/rccm.202206-1028IM

Global Health Care Inequalities of Head and Neck Cancer Imaging and Treatment Protocols Emphasizing PET/CT Availability

Gloria J. Guzmán Pérez-Carrillo, MD, MSc, MPH, MBA

With more than 660,000 new cases and 325,000 deaths annually worldwide, head and neck cancer is the seventh most common cause of global cancer, with a disparate incidence and mortality between low- and middle-income countries (LMICs) and high-income countries (HICs), the latter demonstrating higher incidence but lower mortality.[1,2]

Moreover, there seems to be an increasing growth of the world cancer burden, with a steep-slope rate in LMICs compared with HICs.[3–5] Positron emission tomography / computed tomography (PET/CT) imaging plays a crucial role in enabling the detection, staging, and restaging after treatment of head and neck cancers[6] and is an essential tool for reducing morbidity and mortality.

However, there are significant discrepancies in availability, cost, and accessibility, particularly in the US compared with LMICs.[7,8] This, in turn, results in health care disparities that negatively impact health outcomes for the LMIC populations.[9] While the primary driver of health care inequities in access to imaging for head and neck cancers is the number of scanners, such as PET/CT and MRI and the number of radiologists in LMICs, this article discusses other potential factors and strategies to address them.

Specific Health Care Disparities

PET/CT Scanners Per Capita

The US and other HICs boast a high number of PET/CT scanners compared with many other lower-income nations, owing to their extensive health care infrastructure and technological advancements, with an average of 3522 PET scanners per million people (Figure 1).[2] In contrast, many LMICs struggle with a scarcity of PET/CT scanners, with an average of 301 per million residents for upper-middle-income countries and none at all in most of Africa (Figure 1).[2] These shortages limit access to this important imaging technology for a significant portion of the LMIC population, delaying diagnosis and treatment and ultimately compromising patient outcome.[2]

A direct consequence of this undersupply is that while the incidence of cancer (Figure 2) in Africa (aside from Namibia) is less than or equal to 7.7 while in the US it is 7.7-19.5, the mortality rate in Africa is significantly higher (Figure 3; up to 10.8 in multiple countries in Africa vs 1.2-1.6 in the US).

Radiologists Per Capita

Significantly more radiologists are available to interpret head and neck PET/CT studies in HICs vs LMICs, (Figure 4)[2] paralleling the availability of PET/CT scanners. For example, in HICs, there are 93 radiologists per million residents compared with as few as 1 radiologist per million in low-income countries. This lack of trained professionals to monitor and interpret these studies limits accessibility to this critical diagnostic imaging tool.

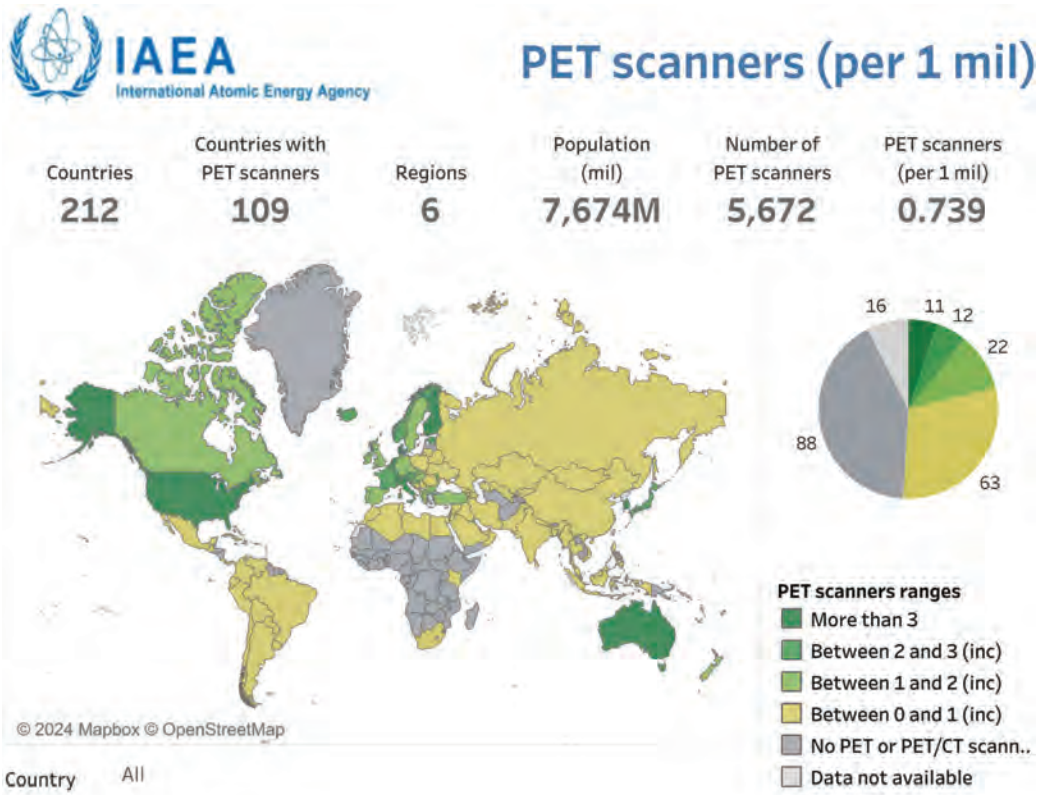
Cost and Socioeconomic Barriers

The high cost of PET/CT scans may deter them from seeking necessary

Affiliation: Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, Missouri.
Disclosures: Dr Guzmán is a speaker for Siemens Healthineers and MRI Online.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0006

Figure 1. PET scanners per 1 million residents. Data generated from IAEA IMAGINE.[6]



Income Group

Income Group	Countries	Countries with PET sca..	Population (mil)	Number of PET scanners	PET scanners (per 1 mil)
High Income	75	51	1,237M	4,356	3.522
Upper-Middle Income	54	35	2,854M	860	0.301
Lower-Middle Income	50	20	2,913M	451	0.155
Low Income	30	1	669M	3	0.004
Temporary Unclassified	1	1	0M	1	2.751

UN Regions

UN Region Name	Countries	Countries with PET sca..	Population (mil)	Number of PET scanners	PET scanners (per 1 mil)
Australia/New Zealand	2	2	30M	85	2.807
Central and Southern Asia	14	9	1,993M	390	0.196
Eastern and South-Eastern Asia	19	12	2,298M	1,011	0.440
Europe and Northern America	48	40	1,110M	3,592	3.235
Latin America and the Caribbean	39	20	647M	313	0.484
Northern Africa and Western Asia	25	21	517M	263	0.509
Oceania (excluding Australia and ..	15	0	12M	0	0.000
Sub-Saharan Africa	49	4	1,066M	17	0.016

Figure 2. The 2022 head and neck cancer global age-standardized incidence rates. The map was generated using the GLOBOCAN website mapping tool (https://gco.iarc.fr/today/online-analysis-map) by selecting "lip, oral cavity," "oropharynx," "hypopharynx," and "larynx" cancers.[2]

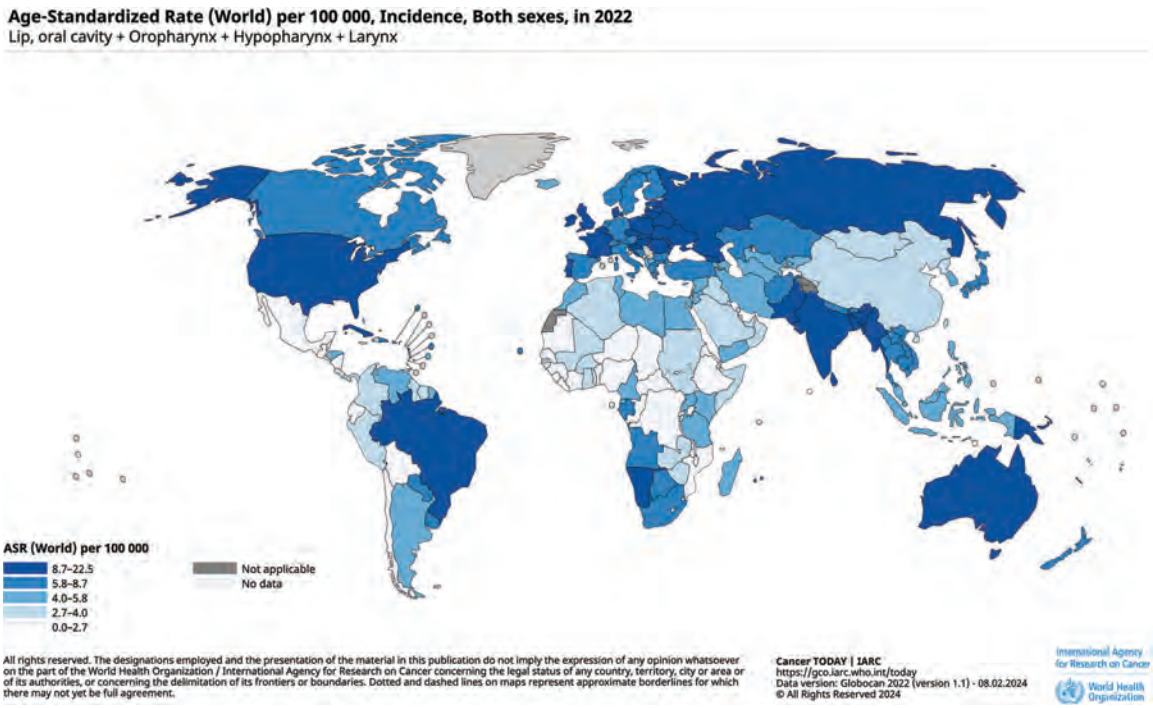


Figure 3. The 2022 head and neck cancer global age-standardized mortality rates. The map was generated using the GLOBOCAN website mapping tool (https://gco.iarc.fr/today/online-analysis-map) by selecting "lip, oral cavity," "oropharynx," "hypopharynx," and "larynx" cancers.[2]

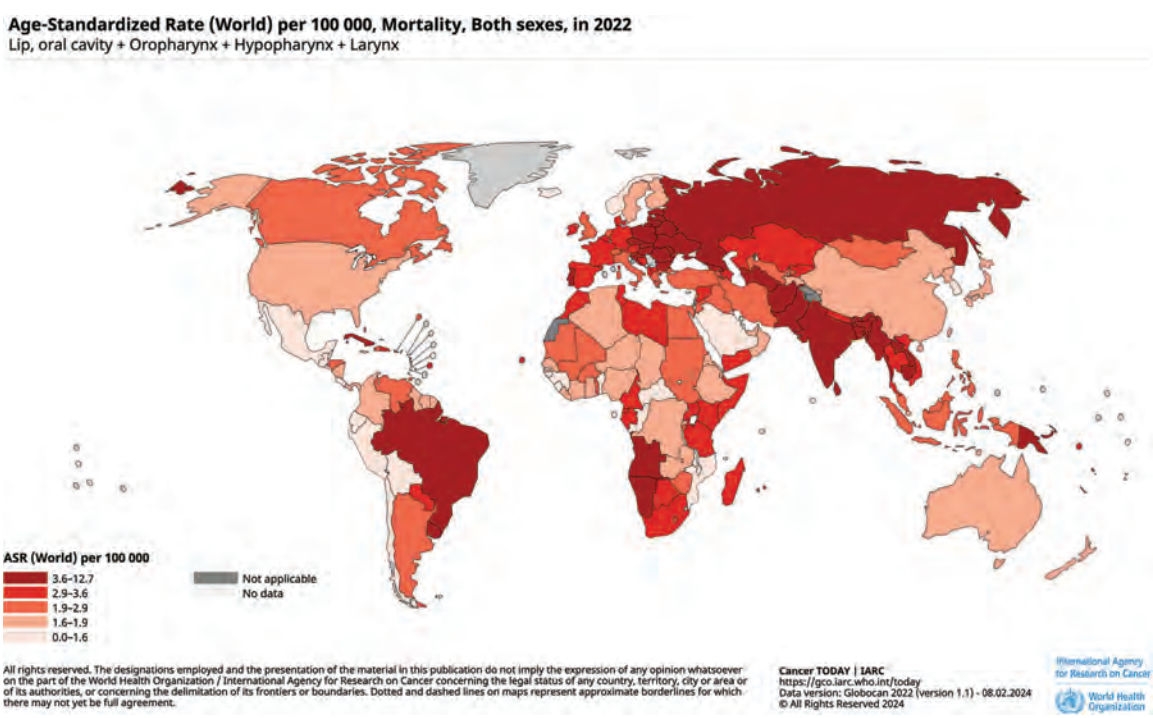
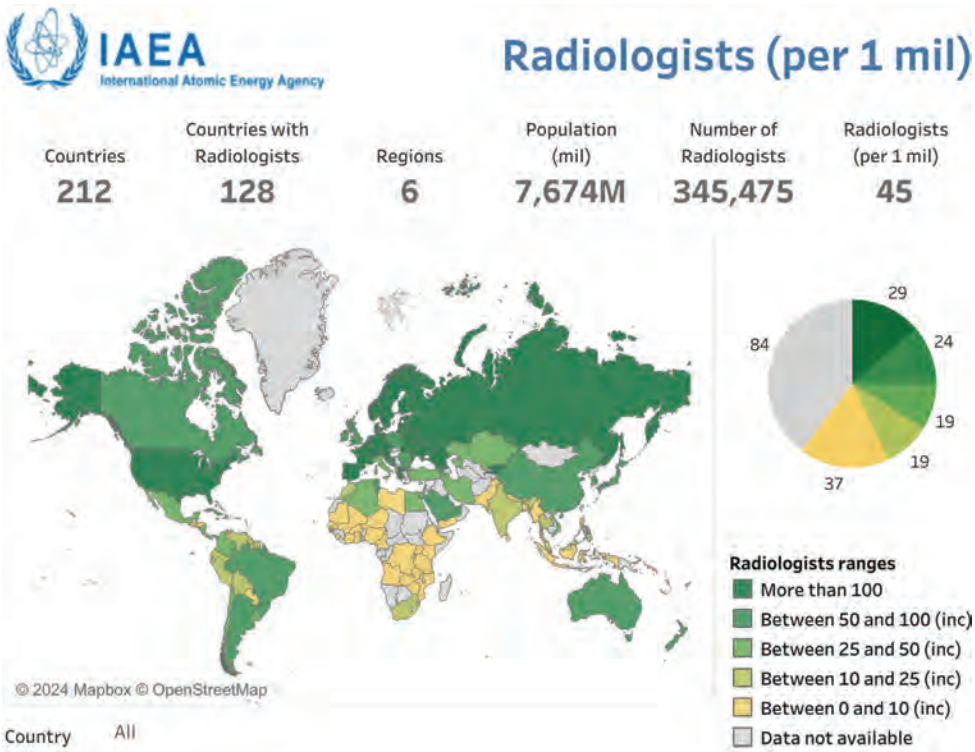


Figure 4. Radiologists per 1 million residents. Data generated from IAEA IMAGINE.[6]



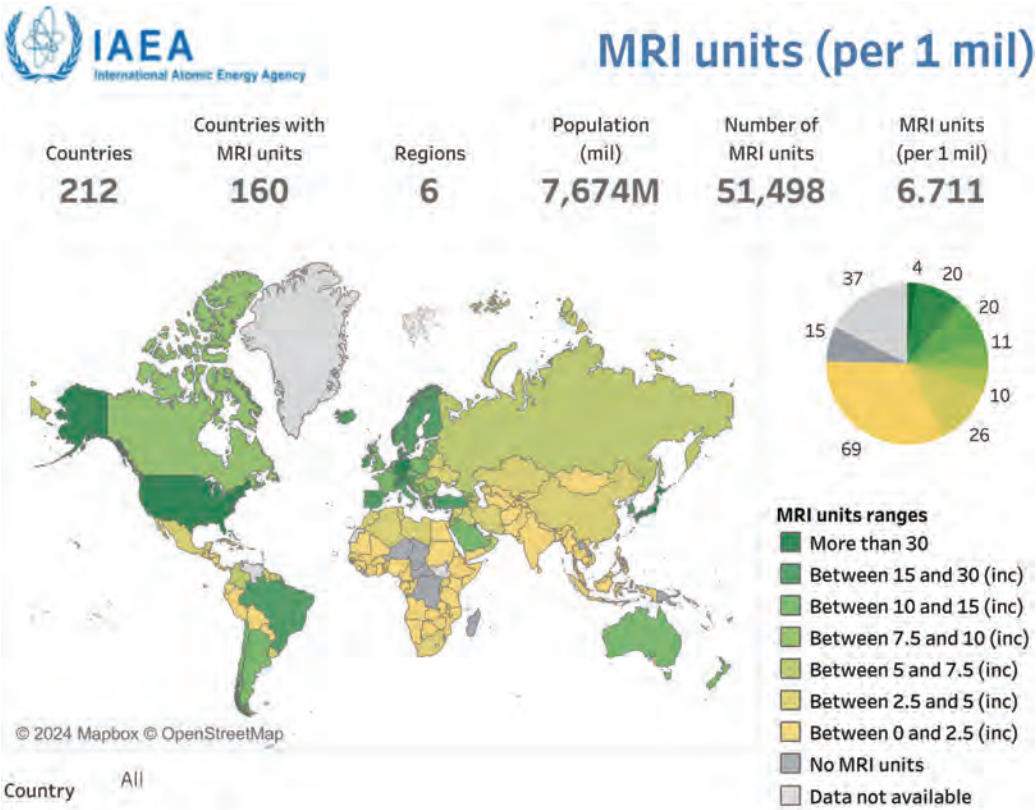
Income Group

Income Group	Countries	Countries with Radiolo..	Population (mil)	Number of Radiologists	Radiologists (per 1 mil)
High Income	75	46	1,237M	114,701	93
Upper-Middle Income	54	38	2,854M	185,172	65
Lower-Middle Income	50	32	2,913M	44,808	15
Low Income	30	12	669M	794	1

UN Regions

UN Region Name	Countries	Countries with Radiologists	Population (mil)	Number of Radiologists	Radiologists (per 1 mil)
Australia/New Zealand	2	2	30M	2,491	82
Central and Southern Asia	14	9	1,993M	27,518	14
Eastern and South-Eastern Asia	19	10	2,298M	140,785	61
Europe and Northern America	48	37	1,110M	129,066	116
Latin America and the Caribbean	39	30	647M	26,723	41
Northern Africa and Western Asia	25	15	517M	16,761	32
Oceania (excluding Australia an..	15	0	12M		
Sub-Saharan Africa	49	25	1,066M	2,131	2

Figure 5. MR scanners per 1 million residents. Data generated from IAEA IMAGINE.[6]



Income Group

Income Group	Countries	Countries with MRI uni..	Population (mil)	Number of MRI units	MRI units (per 1 mil)
High Income	75	56	1,237M	32,814	26.529
Upper-Middle Income	54	46	2,854M	15,307	5.363
Lower-Middle Income	50	39	2,913M	3,251	1.116
Low Income	30	19	669M	126	0.188

UN Regions

UN Region Name	Countries	Countries with MRI uni..	Population (mil)	Number of MRI units	MRI units (per 1 mil)
Australia/New Zealand	2	2	30M	434	14.332
Central and Southern Asia	14	14	1,993M	2,677	1.344
Eastern and South-Eastern Asia	19	13	2,298M	15,137	6.586
Europe and Northern America	48	41	1,110M	24,696	22.243
Latin America and the Caribbean	39	29	647M	5,010	7.741
Northern Africa and Western Asia	25	23	517M	3,207	6.203
Oceania (excluding Australia an..	15	2	12M	2	0.167
Sub-Saharan Africa	49	36	1,066M	335	0.314

medical care or force them to choose less-effective diagnostic methods. Lack of universal health care or affordable health insurance is the biggest driver of these limitations for radiological imaging and medicine in general.[10] A review of the literature found that the costs associated with head and neck cancer have only been evaluated in the US[11]; no peer-reviewed English literature articles exploring the global costs of head and neck cancer could be found.

Accessibility and Infrastructure

Accessibility encompasses factors beyond the physical presence of PET/CT scanners and cost, including geographic proximity, referral pathways, and appointment waiting times. Similarly, accessibility issues arise due to inadequate transportation infrastructure and limited health care facilities in remote areas, further exacerbating health inequalities. All of these factors cause health care inequalities.[12]

Strategies to Address Health Care Disparities

Improving Educational Opportunities for Global Radiology Trainees and Faculty

In the US, we have several pathways to provide subspecialized radiological education to our global colleagues, and these programs serve as terrific initiatives that other societies can emulate. For example, the Iberolatinoamerican Society of Diagnostic and Therapeutic Neuroradiology (SILAN is the Spanish acronym) offers scholarships to Latino-American or Spanish neuroradiology fellows to train at US institutions.[13]

The American Society of Neuroradiology (ASNR) has an international neuroradiology teaching program, the Anne G. Osborn ASNR International Outreach Professor Program, which currently operates in Asia, Africa, and Latin America.[14] This program was started by sending neuroradiologists to 5 countries and has now expanded to 9 sites in 8 countries, with plans for future expansion.

Many of the faculty from these programs have formed long-lasting relationships with radiologists and trainees in their host countries.

Research

Although PET/CT is the recognized workhorse in the diagnosis and follow-up of head and neck cancers, other lower-cost imaging options are available, such as multiparametric MRI, including diffusion-weighted imaging.[6,15,16] Specifically, in the US, a PET/CT may cost $1564 vs $956 for an MRI.[17] More research is needed to standardize these MR modalities, which is especially urgent and pertinent in the global arena, as MR is more available than PET/CT (Figure 5).[6] For example, LMICs have 188-5363 MR scanners per million residents, significantly higher than the 0-301 PET/CT scanners per million residents, as detailed in Figure 1.

Access to More Units, Improved Infrastructure, and Better Health Coverage

Governments and health care authorities should prioritize investment in PET/CT imaging infrastructure, particularly in underserved regions and low-resource settings. Addressing these problems may involve expanding existing facilities or establishing new PET/CT centers that are more accesible to remote communities.

Improving insurance coverage or providing universal health care could also help mitigate health care disparities and adverse outcomes arising from lack of access to PET/CT imaging in countries with adequate imaging infrastructure.[18]

Conclusion

Health inequalities in PET/CT imaging persist between the US and other HICs and compared with LMICs, driven by disparities in the number of PET/CT scanners, cost, and accessibility. These inequities have profound implications for patient outcomes and contribute to delayed diagnosis and treatment, furthering outcome disparities. Addressing these challenges requires collaborative efforts from policymakers, health care professionals, and community stakeholders to ensure equitable access to PET/CT imaging services for all individuals. US radiologists play a unique role in driving these changes, primarily through educational outreach and novel research tools that may allow lower-cost imaging tools to detect and monitor head and neck cancers.

REFERENCES

1) Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA A Cancer J Clinicians*. 2021;71(3):209-249. doi:10.3322/caac.21660

2) International Agency for Research on Cancer, World Health Organization. GLOBOCAN website. Accessed February 26, 2024. https://gco.iarc.fr/today/online-analysis-map

3) International Agency for Research on Cancer (IARC). Latest global cancer data: cancer burden rises to 19.3 million new cases and 10.0 million cancer deaths in 2020. Press release Lyon, France, December 15, 2020. Accessed February 27, 2024. https://www.iarc.who.int/wp-content/uploads/2020/12/pr292_E.pdf

4) Hricak H, Ward ZJ, Atun R, et al. Increasing access to imaging for addressing the global cancer epidemic. *Radiology*. 2021;301(3):543-546. doi:10.1148/radiol.2021211351

5) Gormley M, Creaney G, Schache A, Ingarfield K, Conway DI. Reviewing the epidemiology of head and neck cancer: definitions, trends and risk factors. *Br Dent J*. 2022;233(9):780-786. doi:10.1038/s41415-022-5166-x

6) Guzmán Pérez-Carrillo GJ, Ivanidze J. PET/CT and PET/MR imaging of the post-treatment head and neck: traps and tips. *Neuroimaging Clin N Am*. 2022;32(1):111-132. doi:10.1016/j.nic.2021.09.003

7) International Atomic Agengy (IAEA). IAEA Medical imAGIng and Nuclear mEdicine (IMAGINE). Accessed February 25, 2024. https://humanhealth.iaea.org/HHW/DBStatistics/IMAGINE.html

8) Gallach M, Mikhail Lette M, Abdel-Wahab M, et al. Addressing global inequities in positron emission tomography-computed tomography (PET-CT) for cancer management: a statistical model to guide strategic planning. *Med Sci Monit*. 2020;26:e926544. doi:10.12659/MSM.926544

9) Corry J, Ng WT, Ma SJ, et al. Disadvantaged subgroups within the global head and neck cancer population: how can we optimize care. *Am Soc Clin Oncol Educ Book*. 2022;42(42):1-10. doi:10.1200/EDBK_359482

10) National Academies of Sciences, Medicine Division, Board on Health Care Services, Committee on Health Care Utilization, & Adults with Disabilities. Health-care utilization as a proxy in disability determination. 2018.

11) Wissinger E, Griebsch I, Lungershausen J, Foster T, Pashos CL. The economic burden of head and neck cancer: a systematic literature review. *Pharmacoeconomics*. 2014;32(9):865-882. doi:10.1007/s40273-014-0169-3

12) Baeten R, Spasova S, Vanhercke B, Coster S. *Inequalities in Access to Healthcare*. European Commission; 2018.

13) Iberolatinoamerican Society of Diagnostic and Therapeutic Neuroradiology (SILAN). Scholarships. Accessed February 27, 2024. https://www.silan.org/en/scholarships

14) Anne G, American Society of Neuroradiology (ASNR). Osborn ASNR International Outreach Professor Program. Accessed February 27, 2024. https://www.asnr.org/international-collaboration/anne-g-osborn-asnr-international-outreach-professor-program/

15) Driessen JP, van Kempen PMW, van der Heijden GJ, et al. Diffusion-weighted imaging in head and neck squamous cell carcinomas: a systematic review. *Head Neck*. 2015;37(3):440-448. doi:10.1002/hed.23575

16) Martin O, Schaarschmidt BM, Kirchner J, et al. PET/MRI versus PET/CT for whole-body staging: results from a single-center observational study on 1,003 sequential examinations. *J Nucl Med*. 2020;61(8):1131-1136. doi:10.2967/jnumed.119.233940

17) Burian E, Palla B, Callahan N, et al. Comparison of CT, MRI, and F-18 FDG PET/CT for initial N-staging of oral squamous cell carcinoma: a cost-effectiveness analysis. *Eur J Nucl Med Mol Imaging*. 2022;49(11):3870-3877. doi:10.1007/s00259-022-05843-4

18) Institute of Medicine (US) Committee on the Consequences of Uninsurance. *Care Without Coverage: Too Little, Too Late*. National Academies Press (US); 2002. https://www.ncbi.nlm.nih.gov/books/NBK220636/

In AI, Experience Matters: A Guide to Navigating the Regulatory and Governance Environment

Demetri Giannikopoulos

As artificial intelligence (AI) becomes more prevalent in health care, discussions around regulation and governance are on the rise. How can patient data be secured and protected? How does responsible AI deployment and monitoring occur? Should health systems be skeptical that technology can be a diagnostic aid and potentially impact treatment decisions? Health system leaders are navigating this evolving frontier as well as AI regulations, which seem to be outpaced only by the innovation of the technology itself.

While navigating between codified regulations and guidelines, many leaders are grappling with how to have effective conversations around the latest regulatory requirements while establishing governance structures. While no governing body or group currently has complete authority over AI governance, regulatory measures such as the White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence[1] and the Office of the National Coordinator for Health Information Technology's Health, Data, Technology, and Interoperability (HTI-1) Final Rule[2] establish rules for AI use in health care.

Guidelines such as the American Medical Association Principles,[3] Evaluating Commercial AI Solutions in Radiology (ECLAIR) Guidelines,[4] and Developing, Purchasing, Implementing and Monitoring AI Tools in Radiology: Practical Considerations. A Multi-Society Statement from the ACR, CAR, ESR, RANZCR and RSNA,[5] meanwhile, offer recommendations for various aspects of AI from accountability to transparency, vendor, and value assessments.

It is no secret that clinical AI is a burgeoning field, one that has witnessed incredible growth over the past few years. As of October 2023, the Food and Drug Administration (FDA) listed 691 approved AI/machine learning-enabled medical devices,[6] of which roughly 15% were approved in 2023 alone.

As AI's role expands throughout health systems, so should the conversations across teams. But what should those discussions entail and who can help provide much-needed insights to navigate this ever-changing landscape?

AI partners can play a vital role in this regard. Similar to how one might entrust a financial advisor to manage their money, an experienced AI partner often garners a deep familiarity with FDA requirements, in-depth industry expertise, a wealth of health system experience with AI, and is able to facilitate collaboration between institutions. This experience in these relatively novel regulatory realms can prove invaluable to health systems.

To maximize AI support, an AI partner should proactively be discussing and have knowledge or experience to help navigate the following key areas:

Understanding of the AI partner's infrastructure in place to ensure regulatory compliance alongside the increasingly complex landscape. It stands to reason that many AI products, while offering great potential for impacting specific use cases, may not have the infrastructure required to direct health systems through the complexities of AI regulation. With constant development on this horizon, and even signs of regional AI measures (see the recent Utah enactment of AI-focused consumer protection),[7] partners with dedicated regulatory and legal

Mr Giannikopoulos is the chief transformation officer at Aidoc, New York, NY.

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0005

teams are ahead of the curve as they can ensure compliance even in the most nuanced circumstances.

Direct experience with regulatory pathways such as FDA clearance and/or CE marking processes for European conformity. Many AI partners have a keen understanding of the intricacies involved in navigating the regulatory clearance process(es). Those with experience serve as a better partner for health systems that have reservations about AI adoption, owing to their experience in addressing issues surrounding risk mitigation and interoperability against the highest standards.

Real-life experience measuring the performance and value of AI in clinical environments. AI regulations, guidelines, and publications focus on demonstrating real-world performance and value, and there are multiple ways to measure these impacts. With radiology, AI might start with interpretation and turnaround times, but value is often demonstrated with additional service-line impact, for example, when utilizing AI to integrate and streamline pulmonary embolism response teams. Downstream impacts could include reduced length of stay for specific pathologies or enhanced disease awareness that led to early diagnosis and treatment.

Plans to adapt to the changing environment. A strong AI partner should have a comprehensive plan to adapt to the evolving regulations and ensure the long-term success of your AI investment. This includes strategies for drift mitigation, model retraining, ongoing maintenance, and proxies for performance. Additionally, they should demonstrate the ability to scale AI solutions beyond radiology and across the entire health care enterprise, showing a commitment to innovation and growth in AI implementation.

As AI becomes increasingly integrated into clinical workflows, AI partner scrutiny will become even more important to sustaining AI success. The ECLAIR guidelines,[4] for example, are already setting a framework for those seeking commercial AI solutions in radiology.

With varying regulations and guidelines shaping the decisions of health care leaders, it is essential to remain prudent in assessing partners beyond their promises to improve workflow or care delivery; this includes evaluating their regulatory infrastructure and experience in navigating regulatory environments.

Overall, a resilient AI ecosystem that lives up to the hype must focus on enhancing patient care, fostering health system innovation, and upholding the highest technological integrity and accountability standards as AI becomes indispensable.

REFERENCES

1) The White House. Executive order on the safe, secure, and trustworthy development and use of artificial intelligence; 2023. Accessed July 16, 2024. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/

2) HealthIT.gov. Office of the national coordinator for health information technology. Health data, technology, and interoperability: Certification program updates, algorithm transparency, and information sharing (HTI-1) final rule. Accessed July 16, 2024. https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program

3) American Medical Association. AMA issues new principles for AI development, deployment & use; 2023. Accessed July 16, 2024. https://www.ama-assn.org/press-center/press-releases/ama-issues-new-principles-ai-development-deployment-use

4) Omoumi P, Ducarouge A, Tournier A, et al. To buy or not to buy-evaluating commercial AI solutions in radiology (the ECLAIR guidelines). *Eur Radiol*. 2021;31(6):3786-3796. doi:10.1007/s00330-020-07684-x

5) Brady AP, Allen B, Chong J, et al. Developing, purchasing, implementing and monitoring AI tools in radiology: practical considerations. A multi-society statement from the ACR, CAR, ESR, RANZCR & RSNA. *Radiol Artif Intel*. 2024;6(1):230513. doi:10.1148/ryai.230513

6) Joshi G, Jain A, Araveeti SR, et al. FDA-approved artificial intelligence and machine learning (AI/ML)-enabled medical devices: an updated landscape. *Electronics*. 2024;13(3):498. doi:10.3390/electronics13030498

7) GreenbergTraurig. GreenbergTraurig. Utah Enacts First AI-Focused Consumer Protection Legislation in US. Accessed July 16, 2024. https://www.gtlaw.com/en/insights/2024/4/utah-enacts-first-ai-focused-consumer-protection-legislation-in-us

Virtual Imaging Trials: The Next Big Thing?

Kerri Reeves

Kerri Reeves is a contributing editor based in Ambler, PA.

Advances in computational resources such as software, processing, and storage have paved the way for exciting applications in the relatively new field of computational medicine, which uses data-driven methods to gain individualized insights into diseases and treatments. In recent years, expanding computational resources has been foundational to many developments in machine learning, artificial intelligence, and digital simulations, to name a few. Using representations or models, computational approaches are expected to have a major impact on research and care delivery across disciplines, particularly in radiology.

Emulating reality using representational and computational methods through virtual means is being explored as an alternative to clinical trials. In particular, representing real medical entities or processes in the form of digital twins in virtual trials is gaining ground to meet the challenges in evaluating imaging innovations.

"We need to have more proficient ways to evaluate the effectiveness of medicine," says Ehsan Samei, PhD, Rice distinguished professor of radiology at Duke University and director of the Center for Virtual Imaging Trials (CVIT) in Durham, North Carolina. "Evaluation of medical innovations is ideally done through trials on humans, but such trials are extremely cumbersome," he says. Barriers include costs, trial duration, ethical concerns, and diversity of subjects, among other logistical constraints.

Virtual trials provide realistic and validated simulations as an alternative approach to assessing the impact of treatments and technologies on outcomes. The models present "a very sophisticated 'cartoon' of the patient as complete and as realistic as we can make it," says Dr Samei, noting that a virtual representation can be "almost and effectively as real as the real thing."

"*In silico* imaging trials are the next big revolution in radiology, which will enable us to accelerate the development of imaging systems," says Alejandro (Alex) Frangi, PhD, Bicentennial Turing Chair in Computational Medicine at the University of Manchester, England. Not surprisingly, interest is high among clinicians, researchers, policymakers, regulatory bodies, insurance companies, and vendors.

"While virtualizing reality has been implemented in various industries and scientific pursuits, it has not been fully embraced as an essential resource in medical imaging," says Dr Samei. To discuss research, development, and use cases surrounding the concept, more than 130 stakeholders attended the first Virtual Imaging Trials in Medicine (VITM) summit held at Duke University in April. Presentations focused on applications for virtual imaging trials in CT, digital tomosynthesis, SPECT, dental imaging, breast density estimation, imaging technique optimization, cancer care, and personalized medicine.

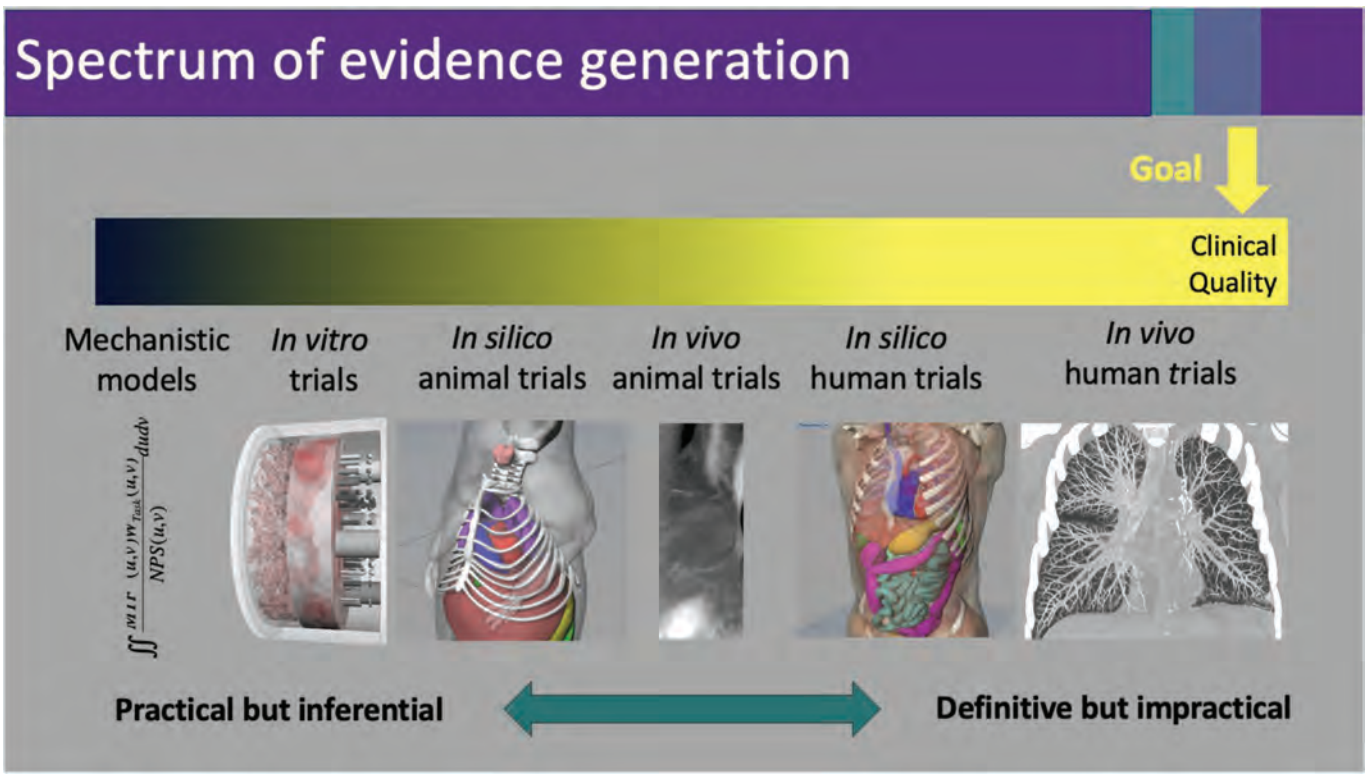
Technology Applications

Among benefits, creating simulations of trials enables a ground truth comparison allowing researchers and imaging scientists to optimize imaging processes and performance. Individualized cancer care is one area of application.

"[Researchers are creating] individualized models of patients' tumors so they can predict whether the tumor is progressing or regressing," explains Francesco Ria, PhD, assistant professor of radiology at Duke's CVIT. "We can use this

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0004

Figure 1. The left-sided metrics tend to be more practical, while those on the right tend to more closely represent the clinical reality, the ultimate goal. Graphic provided by Ehsan Samei, PhD.



methodology to personalize care for individualized patients."

Virtual trials can help inform the design of human trials. Benefits, which are applied in product design and development, include simplified experiments, evidence for effective medicine, and individualized patient care. Another advantage is a more cost-effective evaluation of developing technologies since ensuring that prototypes are safe and effective is an expensive, cumbersome process, says Dr Samei.

"[Vendors] need evidence to prove what they've produced is of high clinical quality," says Dr Samei. This is achievable within the same continuum of practical to definitive evidence generation as shown in Figure 1.

For example, VITM summit poster presenter Gustavo Pacheco of Radboud University Medical Center in the Netherlands studied the optimization and validation of a compression model for realistic digital breast phantoms in mammography and digital breast tomosynthesis simulations. While breast compression is essential for achieving optimal image quality and reducing patient radiation exposure, it is necessary to pinpoint the optimal protocol and quantitatively assess the actual benefit of the procedure, which is often uncomfortable and negatively affects compliance with mammography recommendations, notes Dr Samei.

"Those questions need to be answered in the context of individual patients based on clinical effectiveness, not some back-of-envelope calculation," he says. "No one has ever done a systematic trial [on] reducing breast compression to see what the results would be."

"Virtual trials also enable studies on realistic populations of computational patients spanning ages, genders, and races for a wide variety of conditions, including uncommon diagnoses for which enrolling an adequate number of patients might be difficult." In such scenarios, virtual data can supplement real data to provide more robust answers, says Dr Ria.

Consider CT imaging of patients with emphysema. When assessing treatment effectiveness, clinicians try to optimize the imaging technique to tease out the signatures of the disease in the best

way possible, which is typically done as a "best guess," says Dr Samei. By creating emphysema in virtual patients with the exact extent of their disease, the clinician can determine the utility of images to assess disease progression or regression and, thus, how to best manage each patient.

Future Directions

Another example of virtual trial potential involves volumetric measurement of organs through deep-learning, automated virtualization of CT images, the topic of a study presented at the VITM by Duke's Mobina Ghojogh Nejad, MD. By studying organ size, virtual models enable accurate assessment of organs and, thus, anatomical progressions that are associated with certain conditions.

"If we found some correlation between organ volume and age or BMI [body mass index], we can use this data to inform our models to reflect real subjects' changes associated with age," says Dr Ria.

The use of VITM may also offer an approach to engineer new imaging biomarkers that "exploits our understanding of the imaging physics and disease mechanisms more fundamentally than in current biomarker discovery approaches for diagnosis and monitoring of drug effects that largely rely on trial and error," says Dr Frangi. "These techniques could be adopted more broadly as part of the [research and development] lifecycle of imaging systems and biomarker engineering."

For virtual trials to grow, however, tools must be democratized for all to use clinically and scientifically, says Dr Samei.

"We need to have consistent protocols, vocabulary, and ways of communicating to be able to cross-operate across resources that have been developed in multiple places, making them easily accessible and available to everyone," he says. "We need a cohesive vision and a dedicated focus across the health care enterprise to move [virtual trials] forward."

Anterior Sacral Meningocele

Syed M.R. Naqvi, MD; Syed Anam Asim, BSc, MSc

Case Summary

A toddler presented to the emergency department with abdominal pain. The patient had a history of constipation and recurrent urinary tract infections (UTIs). The patient had no neurologic deficits. Recent pelvic ultrasound in the community demonsrated a large cystic pelvic mass.

Imaging Findings

Pelvic MRI (Figure 1) demonstrated a large, ovoid, well-circumscribed fluid collection in the presacral space that was contiguous with the spinal subarachnoid space through an osseous defect in the sacrum. There was turbulent cerebrospinal fluid (CSF) flow within the presacral collection. The features were overall in keeping with an anterior sacral meningocele (ASM). There wasassociated mass effect on regional structures, including anterior displacement and partial attenuation of the rectum and urinary bladder. The sacrum appeared dysplastic, with partial agenesis of the inferior sacrum. No anorectal malformation was identified.

Diagnosis

Anterior sacral meningocele.

The differential diagnosis includes sacrococcygeal teratoma, neuroenteric cyst, sacral chordoma, cystic neuroblastoma, rectal duplication cyst, and ovarian cyst.[1]

Discussion

Anterior sacral meningocele is a hernia of the dural sac through a defect in the ventral sacral wall[1] and can be categorized as acquired or congenital. The most common causes of acquired sacral meningoceles include Marfan syndrome, neurofibromatosis type 1, and Ehlers-Danlos syndrome, all of which lead to dural ectasia.[1,2] Congenital forms of ASM are the most common and can be either familial (X-linked dominant) or occur sporadically.[1,3]

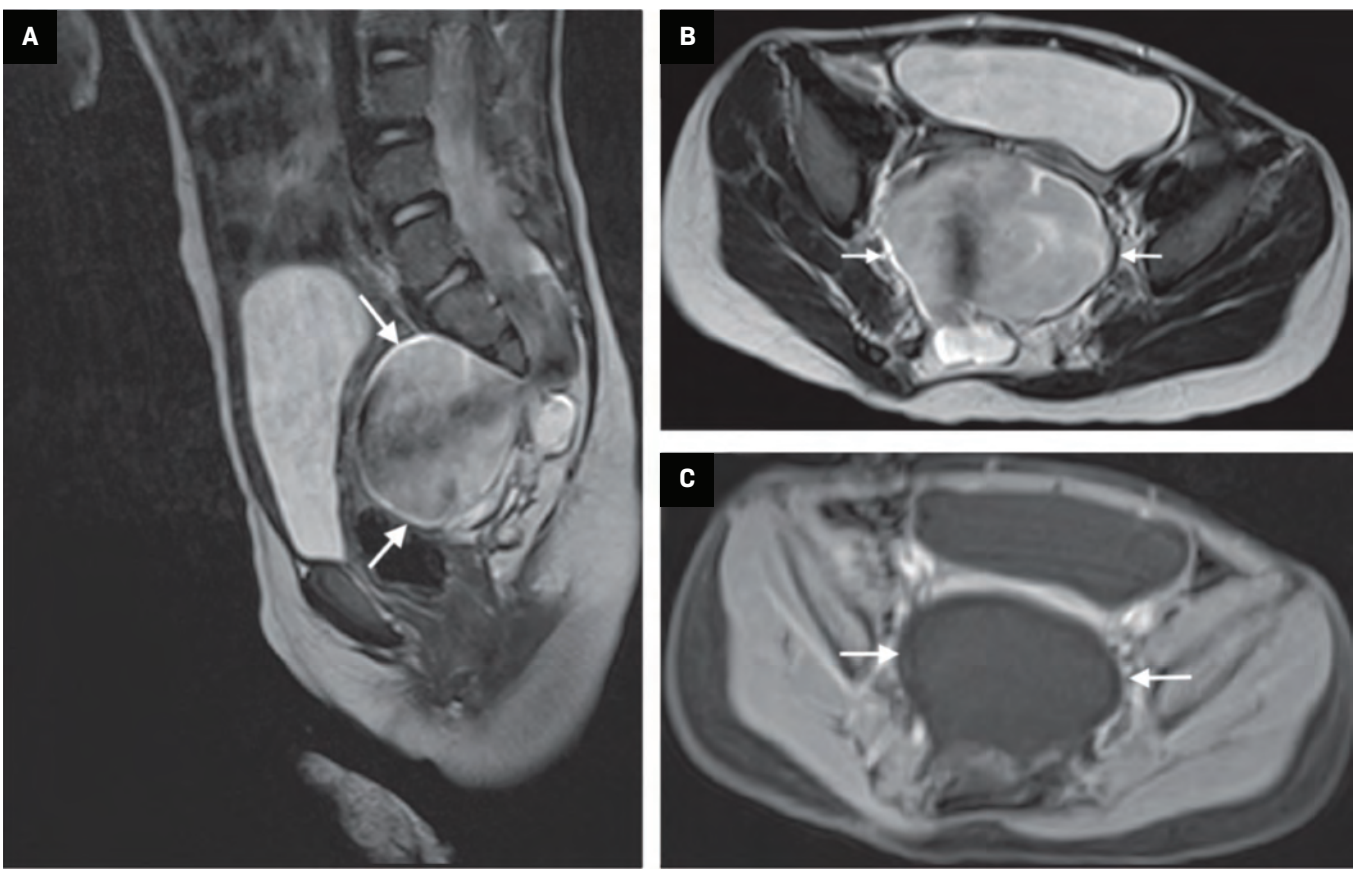
The pathogenesis of congenital ASM can be traced to the secondary neurulation during embryogenesis, where the sacral segments of the spinal cord from S2 to the coccyx are formed from a mass of pluripotent stem cells referred to as the caudal eminence.[4] Malformation of the sacral segments in association with CSF pulsations leads to the extension of the meninges out of the sacral spinal canal, typically at the level of the S1-S2 junction, and into the retroperitoneal space, forming an ASM.[1] The caudal eminence gives rise to multiple other structures, including the hindgut. As a result, sacral malformations leading to ASM are frequently associated with other congenital defects involving the urogenital or hindgut structures.[1] Anterior sacral meningocele may be associated with Currarino syndrome, a triad of presacral mass (typically ASM or teratoma), anorectal malformation, and sacral bony defect.[5]

Patients commonly diagnosed with ASM include those with long-standing complaints of constipation, gynecological or obstetrical manifestations, and neonates who present with other congenital defects such as those seen in Currarino syndrome.[6] The signs and symptoms associated with ASM are related to its impact on surrounding genitourinary organs (eg, dysuria, UTIs, polyuria, dysmenorrhea, dyspareunia), reproductive organs (eg, dystocia and meningocele sac rupture), and colorectal (eg, constipation or obstipation) and neurological dysfunctions (eg, compression of the nerve roots exiting from the sacrococcygeal region leading to pelvic pain, radicular pain, and paresthesia).[1,6]

Affiliations: Windsor Regional Hospital, Windsor, Ontario (Naqvi); Schulich School of Medicine and Dentistry, Windsor, Ontario (Asim).

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0008

Figure 1. Pelvis MRI. (A) Sagittal T2 demonstrates a large, heterogeneous fluid collection in the presacral space (arrows) that communicates with the spinal canal through a hypoplastic sacrum, which terminates at the S2-S3 level. (B) Axial T2 shows the defect in the sacrum and turbulent CSF flow within the presacral collection (arrows). (C) Axial T1 fat-saturated post-contrast sequence demonstrates no enhancing solid component in the meningocele.



Compression of ASM from Valsalva maneuvers or postural changes can affect the CSF flow, resulting in headaches.[2] The clinical signs associated with ASM include retro-rectal mass, which can be palpated on a digital rectal examination in nearly all patients.[1] Patients may also present with other congenital anomalies such as vaginal duplication, anal stenosis, anal atresia, sacral bone defect (scimitar sign), club foot, and leg-length discrepancies.[1]

The diagnosis of ASM can involve the use of multiple modalities, including radiographs, US, CT, and MRI.[1] Features that should be evaluated include the identification of the neck of the ASM, abnormalities of the meninges and vertebral components of the sacrum such as sacral defect; cystic nature of the mass; the relationship between the meningocele and the sacral nerve roots; and the relationship between the pelvic viscera and the meningocele.[7] Radiography is useful in detecting the scimitar sign, which appears as a unilateral sickle-shaped distortion of the sacral bone.[7] Ultrasound can help identify the contents of the presacral mass and enlargement of the meningocele sac.[8] CT can help identify the communication of the subarachnoid space and may help differentiate ASM from other solid masses in the presacral location.[9] The modality of choice to diagnose ASM is MRI.[1] It can help identify other associated anomalies such as spinal cord tethering.[1] Meningocele has the same signal intensity as the CSF and a thickened filum terminale, with or without fatty infiltration, may be present.[1] The management of ASM is surgical, which involves obliteration of the communication between the meningocele and the subarachnoid space.[1]

Conclusion

Anterior sacral meningocele most commonly results from a malformation in which the meninges protrude

through a developmental osseous defect in the sacrum. Patients may present with associated abnormalities of other genitourinary structures. The most useful imaging modality to diagnose ASM is MRI, which will reveal communication between the meningocele and the spinal subarachnoid space. The treatment of ASM is surgical.

References

1) Shedid D, Roger EP, Benzel EC. Presacral meningocele: diagnosis and treatment. *Semin Spine Surg*. 2006;18(3):161-167. doi:10.1053/j.semss.2006.06.002

2) Oren M, Lorber B, Lee SH, Truex RC, Gennaro AR. Anterior sacral meningocele: report of five cases and review of the literature. *Dis Colon Rectum*. 1977;20(6):492-505. doi:10.1007/BF02586588

3) Cohn J, Bay-nielsen E. Hereditary defect of the sacrum and coccyx with anterior sacral meningocele. *Acta Paediatrica*. 1969;58(3):268-274. doi:10.1111/j.1651-2227.1969.tb04716.x

4) Pang D. Sacral agenesis and caudal spinal cord malformations. *Neurosurgery*. 1993;32(5):755-778. doi:10.1227/00006123-199305000-00009

5) Currarino G, Coln D, Votteler T. Triad of anorectal, sacral, and presacral anomalies. *AJR Am J Roentgenol*. 1981;137(2):395-398. doi:10.2214/ajr.137.2.395

6) Villarejo F, Scavone C, Blazquez MG, et al. Anterior sacral meningocele: review of the literature. *Surg Neurol*. 1983;19(1):57-71. doi:10.1016/0090-3019(83)90212-4

7) Lancon JA, Benzel EC, Tibbs RE. Anterior sacral meningocele. In: Benzel EC, ed. *Spine Surgery*. 3rd ed. Vol. 2005. Churchill Livingstone. :1156-1165. doi:10.1016/B978-0-443-06616-0.50088-2

8) McCreath GT, Macpherson P. Sonography in the diagnosis and management of anterior sacral meningocele. *J Clin Ultrasound*. 1980;8(2):133-137. doi:10.1002/jcu.1870080207

9) Balériaux-Waha D, Osteaux M, Terwinghe G, de Meeus A, Jeanmart L. The management of anterior sacral meningocele with computed tomography. *Neuroradiology*. 1977;14(1):45-46. doi:10.1007/BF00399889

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Meningoencephalitis

Andrew A. Wigger, MD, MPH; Alexander J. Towbin, MD; Daniel Morgan, DO; Richard B. Towbin, MD

Case Summary

A child presented to the emergency department with a 6-week history of intermittent fevers, weakness, upper abdominal pain, emesis, and headaches with photophobia. The patient had recently been treated with antibiotics for strep throat and a urinary tract infection.

On physical examination, the patient had a 38.6°C fever, severe photophobia, hyperreflexia, and mild imbalance when walking in tandem. Otherwise, the patient was awake, alert, and interactive. A lumbar puncture showed an elevated opening pressure (33 cm H_2O), cerebrospinal fluid (CSF) pleocytosis (97 cells/mm^3), and low glucose. Laboratory studies showed an elevated erythrocyte sedimentation rate and C-reactive protein, an elevated white blood cell count (13×10^9/L), and slight anemia with a low mean corpuscular volume. Urinalysis showed hematuria and glucosuria. Of the CSF antigen and antibody tests performed, the antimyelin oligodendrocyte glycoprotein (MOG) antibody titer was positive at 1:10,000.

Imaging Findings

Brain MRI (Figure 1) showed nonenhancing, increased T2 signal abnormality involving the basal ganglia (most prominently the heads of the caudate nuclei), left thalamus, brainstem, and left inferior corona radiata.

The MRI findings were suggestive of encephalitis. However, because the patient was not encephalopathic and had a wide range of nonspecific subacute symptoms, MOG antibody-associated disease (MOGAD) was suspected.

Diagnosis

Myelin oligodendrocyte glycoprotein antibody-associated meningoencephalitis.

The differential diagnosis for this presentation and MRI findings is broad and includes neuromyelitis optica spectrum disorder (NMOSD), infectious meningitis, acute disseminated encephalomyelitis (ADEM), and multiple sclerosis (MS).

Discussion

Myelin oligodendrocyte glycoprotein antibody-associated disease is an autoimmune disorder that results from the antibodies directed against a myelin glycoprotein found within the central nervous system (CNS).[1] Like many autoimmune disorders, the clinical presentation of MOGAD varies depending on the areas of the CNS that are involved. One of the most common presenting symptoms is visual difficulty from optic neuritis.[2,3] The antibodies can attack and cause demyelination in throughout the CNS. When the cerebral hemispheres are affected, an ADEM-like presentation may dominate, while spinal cord involvement may result in signs and symptoms more typical of transverse myelitis.[4] Cerebral hemispheric involvement may result in altered mental status and other nonspecific neurological deficits. Alternatively, patients with spinal cord involvement may present with paralysis, sensory disturbances, and bowel and bladder dysfunction.[1,4]

The MOG antibody was discovered in 2007 but widespread testing was not available until 2015; therefore, only a relatively

Affiliations: East Tennessee State University Quillen College of Medicine, Johnson City, Tennessee (Wigger); Department of Radiology, Cincinnati Children's Hospital, Cincinnati, Ohio (AJ Towbin); Department of Radiology, University of Cincinnati College of Medicine, Cincinnati, Ohio (AJ Towbin, Morgan); Department of Radiology, Phoenix Children's Hospital, Phoenix, Arizona (RB Towbin).

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0020

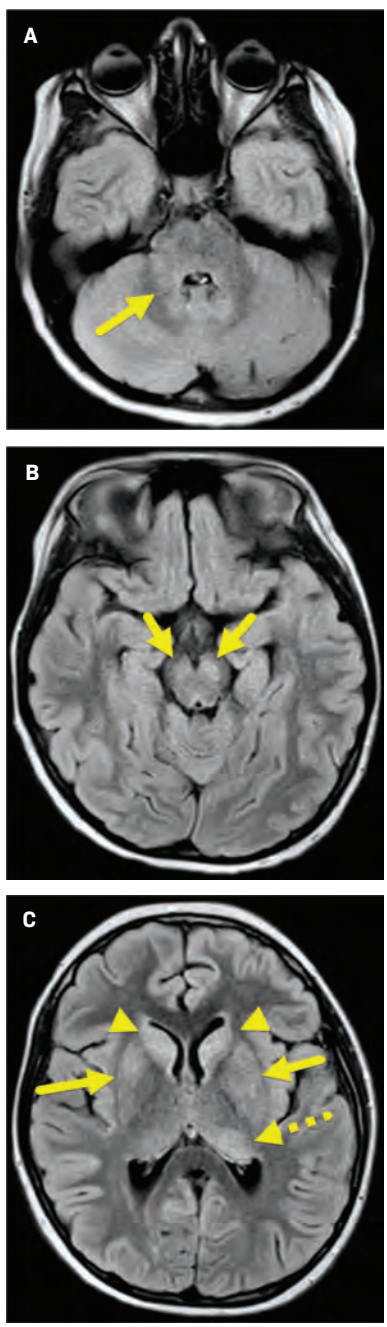
small amount of data is available on the incidence and prevalence of MOG encephalitis.[1] However, it is thought that children account for approximately 50% of those diagnosed with MOGAD.[1,3] One nationwide Dutch study found the incidence of MOGAD to be approximately 0.16 per 100,000 people.[5] In that study, there was a higher seropositivity in children than adults.[5] It was also found that up to 56% of children who tested positive for the antibody presented with an ADEM-like illness.[5] Other studies have shown that MOGAD occurs more often in White children and does not have a gender predilection.[1]

In MOGAD, the areas of the brain most often affected are the deep white matter, cortical gray matter with adjacent subcortical white matter, pons, cerebellum, midbrain, medulla, and corpus callosum. The periventricular white matter, area postrema, and deep gray nuclei are affected less frequently (Figure 1).[1] It can be challenging to differentiate MOGAD from other inflammatory and demyelinating diseases of the CNS. However, key laboratory, clinical, and imaging features can help narrow the differential diagnosis. For instance, patients with NMOSD often test positive for the astrocytic cell protein APQ4 antibody instead of the MOG antibody.[1] Signs, symptoms, and MRI findings for ADEM and MOGAD can appear similar, but ADEM usually follows a monophasic course while MOGAD may relapse.[1] While CNS involvement with MS commonly produces relatively more focal brain lesions, the lesions of NMOSD and MOGAD are often larger, even more than 3 cm in diameter.[6] Spinal cord lesions have also been reported to span 3 or more continuous vertebral body segments in NMOSD and MOGAD.[6] Additionally, serial MRI can be helpful to assess lesion evolution, as lesions are more likely to resolve entirely in patients with MOGAD than in those with MS or NMOSD.[6,7] Multiple sclerosis lesions may decrease in size and/or conspicuity after an attack, but the lesions are often still apparent after signs and symptoms have resolved.[6] Follow-up MRI may be particularly useful when the MOG antibody titers are low and there is concern for a false positive diagnosis of MOGAD, allowing one to assess for lesion evolution to support a diagnosis of MOGAD.[6]

Clinical diagnosis of MOGAD includes the combination of clinical findings suggestive of CNS involvement, testing positive for the MOG antibody by cell-based assay, and exclusion of other conditions.[7] Use of CSF sampling and MRI of the orbits, brain, and spinal cord may also aid in diagnosis.[1,3] The CSF of MOG seropositive patients often shows a lymphocytic pleocytosis and a normal to slightly elevated protein level, often without oligoclonal bands.[1]

Current treatment of MOGAD includes pulsed intravenous methylprednisolone over 3-5 days, followed by a slow oral steroid taper.[1] Patients may also be treated with intravenous immunoglobulin (IVIG) or plasma exchange.[1] If there are relapsing signs and symptoms, then long-term immunosuppression with rituximab or mycophenolate mofetil may be used.[1,3]

Figure 1. Axial FLAIR MRI of the brain shows multiple foci of increased signal within the left middle cerebellar peduncle (A, arrow) and cerebral peduncles (B, arrows); right and left caudate nuclei (C, arrowheads); left posterior thalamus (dashed arrow); right globus pallidus and bilateral putamina.



The overall prognosis of MOGAD is generally good, and better for children than adults.[1] Cobo-Calvo et al[2] found that adults were more likely to experience relapse than children (hazard ratio of 1.41). Additionally, using the Expanded Disability Status Scale, adults had more difficulty recovering than children.[2] When the degree of MOG antibody titers is elevated and persists, risk for relapse increases.[1] A study by de Mol et al[5] showed that 89% of patients who became seronegative did not relapse. A different study of 98 children also showed that 64.2% of nonrelapsing children were seronegative for the MOG antibody after 2 years.[2] Therefore, a patient's MOG titer should be rechecked later to determine their risk of repeat CNS attacks and the need for further immunosuppressants.

The patient was treated with pulse dose methylprednisolone for 3 days and a steroid taper. There was no relapse of symptoms.

Conclusion

Myelin oligodendrocyte glycoprotein antibody-associated disease is an autoimmune disorder caused by an antibody directed against MOG in CNS myelin. The clinical presentation varies depending on where inflammation and demyelination occur. Studies have shown that optic neuritis is the most common presenting symptom, but patients may also present with an ADEM-like presentation or transverse myelitis. Myelin oligodendrocyte glycoprotein encephalitis is more common in children than adults, and children are more likely to present similar to ADEM. However, children seem to recover faster and have a lower risk of relapse. Diagnosis is based on clinical presentation of CNS abnormalities, MOG seropositivity, and exclusion of other similar illnesses. Current treatment relies on steroid administration with more aggressive and/or longer--term immunosuppression considered for more severe presentations and relapsed disease.

References

1) Salama S, Khan M, Pardo S, Izbudak I, Levy M. MOG antibody-associated encephalomyelitis/encephalitis. *Mult Scler*. 2019;25(11):1427-1433. doi:10.1177/1352458519837705

2) Cobo-Calvo A, Ruiz A, Rollot F, et al. Clinical features and risk of relapse in children and adults with myelin oligodendrocyte glycoprotein antibody-associated disease. *Ann Neurol*. 2021;89(1):30-41. doi:10.1002/ana.25909

3) Ramanathan S, Mohammad S, Tantsis E, et al. Clinical course, therapeutic responses and outcomes in relapsing MOG antibody-associated demyelination. *J Neurol Neurosurg Psychiatry*. 2018;89(2):127-137. doi:10.1136/jnnp-2017-316880

4) Jurynczyk M, Messina S, Woodhall MR, et al. Clinical presentation and prognosis in MOG-antibody disease: a UK study [published correction appears in *Brain*. 2018;141(4):e31]. *Brain*. 2018;140(12):3128-3138. doi:10.1093/brain/awx276

5) de Mol CL, Wong Y, van Pelt ED, et al. The clinical spectrum and incidence of anti-MOG-associated acquired demyelinating syndromes in children and adults. *Mult Scler*. 2020;26(7):806-814. doi:10.1177/1352458519845112

6) Sechi E, Krecke KN, Messina SA, et al. Comparison of MRI lesion evolution in different central nervous system demyelinating disorders. *Neurology*. 2021;97(11):e1097-e1109. doi:10.1212/WNL.0000000000012467

7) López-Chiriboga AS, Majed M, Fryer J, et al. Association of MOG-IgG serostatus with relapse after acute disseminated encephalomyelitis and proposed diagnostic criteria for MOG-IgG-associated disorders. *JAMA Neurol*. 2018;75(11):1355-1363. doi:10.1001/jamaneurol.2018.1814

Retroperitoneal Leiomyosarcoma Invading the Inferior Vena Cava

Isabella M. Sabato, BA; Nicholas W. Russo, MD; Gabriel Vahi-Ferguson, MD; Joel Erickson, MD

Case Summary

An adult with a history of type 2 diabetes and hypertension presented with abdominal pain. Physical examination demonstrated abdominal fullness. Complete blood count and basic metabolic panel were within normal limits with preserved renal function. Imaging demonstrated a large retroperitoneal mass with invasion into the inferior vena cava (IVC). The tumor was unresectable due to extensive vascular involvement. CT-guided core biopsy was performed. The patient subsequently developed a pulmonary embolism, with US imaging negative for deep vein thrombosis (DVT). Given the near-total occlusion of the IVC by tumor thrombus and lack of other explanatory mechanisms (eg, DVT), the embolism was presumed to be secondary to tumor thrombus. The patient was started on apixaban with and symptoms resolved.

Imaging Findings

CT of the abdomen and pelvis with oral and intravenous contrast demonstrated a 10.5 × 8.9 × 13.2-cm mass extending from the right psoas muscle into the IVC, indicating a retroperitoneal tumor with IVC extension (Figure 1). Tumor invaded the IVC at the level of the renal veins, with extension superior to the intrahepatic IVC (Figure 2). CT-guided core biopsy demonstrated immunohistochemical staining consistent with leiomyosarcoma.

Diagnosis

Leiomyosarcoma.

The differential diagnosis of retroperitoneal masses includes liposarcoma; lymphadenopathy or lymphoma, neurofibroma; and nonmalignant pathologies, including hematoma.

Discussion

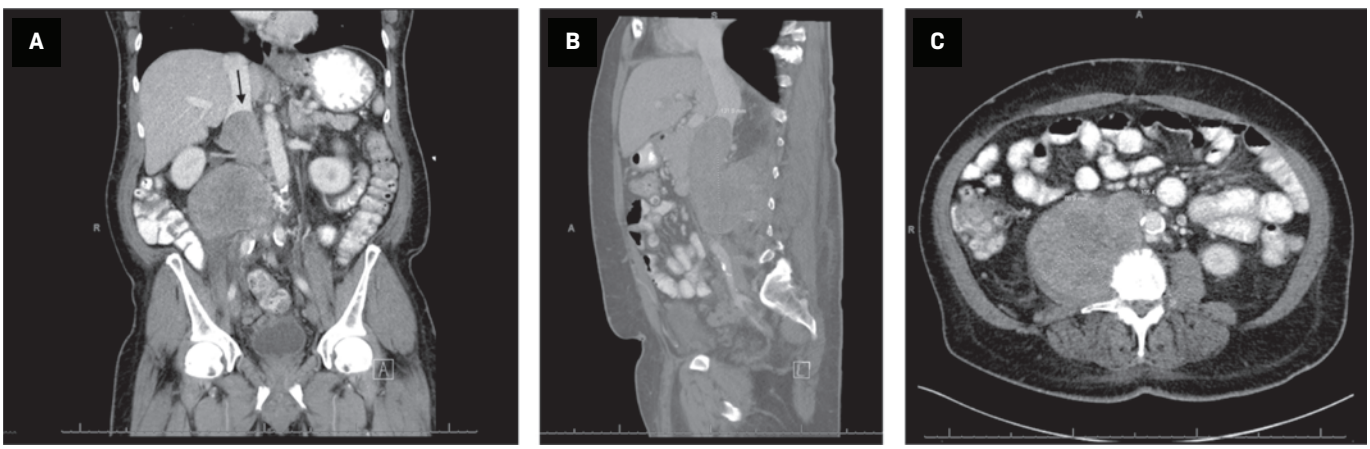
Leiomyosarcoma is a malignant tumor demonstrating smooth muscle differentiation occurring in the retroperitoneum in 10-20% of cases.[1] It is the second most common sarcoma in the retroperitoneum after liposarcoma.[2] Poorly differentiated liposarcomas contain variable amounts of fat, making it more challenging to distinguish these from leiomyosarcoma.[2] When leiomyosarcomas involve the IVC, they account for approximately 0.5% of adult soft-tissue sarcomas.[3] Retroperitoneal masses often grow to large sizes before detection and are often detected incidentally during imaging for other indications or secondary to compressive symptoms.[2] Contributing to this delayed picture is the relative sparing of visceral and vascular structures; however, those affecting the vasculature often present earlier. Luminal invasion of the IVC by a retroperitoneal leiomyosarcoma can produce signs and symptoms relative to distal venous congestion. Suprahepatic invasion may lead to signs and symptoms of Budd-Chiari syndrome or right upper quadrant tenderness, while infrahepatic but suprarenal invasion may present with renal dysfunction; a patient with infrarenal invasion may demonstrate bilateral leg edema.[2] Finally, leiomyosarcoma with IVC involvement, regardless of location, has the potential for pulmonary embolism. Contributing to this increased risk is the hypercoagulable state seen in malignancy as well as the propensity for tumors with vascular involvement to form thrombus with subsequent embolization.

Retroperitoneal leiomyosarcomas are most commonly diagnosed using CT or MRI.[4] Extravascular growth pattern is the most common, accounting for more than 60% of cases, while extravascular tumor growth with intravascular involvement occurs in approximately 30% of cases.[4] Vascular involvement

Affiliation: Broward Health North, Deerfield Beach, Florida

Published: August 1, 2024. https://doi.org/10.1016/10.37549/AR-D-24-0011

Figure 1. Coronal reformation of CT of (A) the abdomen/pelvis with oral and intravenous contrast demonstrates a retroperitoneal mass extending into the intrahepatic IVC, (arrow). Sagittal reformation (B) demonstrates IVC invasion by the tumor. Axial CT (C) demonstrates the large, heterogeneous mass originating from the right psoas muscle.



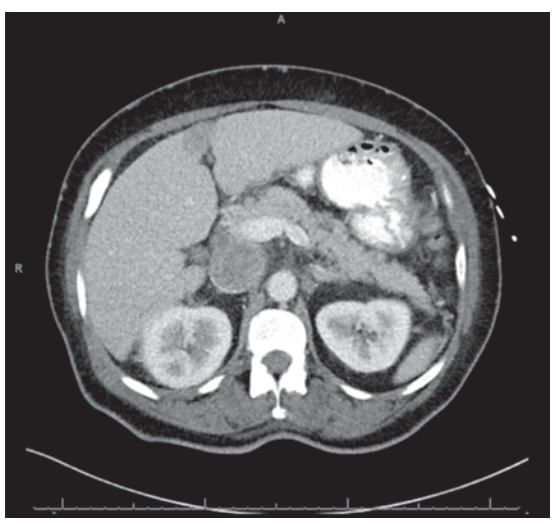


Figure 2. Contrast-enhanced imaging demonstrates obstruction of the suprarenal IVC.

increases the chances of metastasis during diagnosis, with metastases seen in 9% and 23% of extravascular tumors vs tumors with intravascular involvement, respectively.[5] Common sites of metastasis include the lung, liver, and peritoneum.

Retroperitoneal leiomyosarcomas generally demonstrate a heterogeneous pattern on CT. In tumors with vascular involvement, a relatively smaller extravascular component may suggest that the tumor originates from the IVC smooth muscle itself, whereas a large extravascular component suggests an extraluminal etiology with secondary IVC involvement. Definitive histological diagnosis is required for planning of neoadjuvant therapy.[6] Image-guided biopsy enables the correct diagnosis, including establishing the tumor subtype.[7]

Surgical resection offers the best opportunity for survival, demonstrating a 5-year disease-free survival of 20-56%.[3] In comparison, patients who do not undergo resection typically survive less than 1 year. Resectability in patients with vascular involvement depends on the tumor location and structures involved; IVC reconstruction may be an option.[8] In patients demonstrating signs and symptoms from IVC occlusion, including downstream organ dysfunction, bridging stent placement may benefit the patient. The aim of stent placement is to improve quality of life and optimize overall preoperative patient status via restoration of vessel patency.[9] Literature on stenting in malignant IVC syndrome is scarce, but data are promising, with reported success rates of 78-100%.[10] Stent placement has risks including stent migration and vessel perforation; therefore, this primary palliative management option should be reserved for patients experiencing severe symptoms and decreasing quality of life or who could otherwise become surgical candidates with improvement of status. In patients who are not candidates for surgical resection, treatment options include chemotherapy and radiation therapy.

Conclusion

Retroperitoneal leiomyosarcoma is a rare soft-tissue malignancy with an often delayed presentation.

Imaging aids in determining the diagnosis however, biopsy is typically required. Patients with vascular involvement generally present earlier owing to signs and symptoms however, these patients are also less likely to be surgical candidates. Bridging stent placement for symptomatic improvement has shown promise in these patients.

References

1) Francis IR, Cohan RH, Varma DGK, Sondak VK. Retroperitoneal sarcomas. *Cancer Imaging*. 2005;5(1):89-94. doi:10.1102/1470-7330.2005.0019

2) Marko J, Wolfman DJ. Retroperitoneal leiomyosarcoma from the radiologic pathology archives. *RadioGraphics*. 2018;38(5):1403-1420. doi:10.1148/rg.2018180006

3) Teixeira FJR, do Couto Netto SD, Perina AL de F, et al. Leiomyosarcoma of the inferior vena cava: survival rate following radical resection. *Oncol Lett*. 2017;14(4):3909-3916. doi:10.3892/ol.2017.6706

4) von Mehren M, Kane JM, Agulnik M, et al. Soft tissue sarcoma, version 2.2022, NCCN clinical practice guidelines in oncology. *J Natl Compr Cancer Netw*. 2022;20(7):815-833. doi:10.6004/jnccn.2022.0035

5) Cooley CL, Jagannathan JP, Kurra V, et al. Imaging features and metastatic pattern of non-IVC retroperitoneal leiomyosarcomas: are they different from IVC leiomyosarcomas? *J Comput Assist Tomogr*. 2014;38(5):687-692. doi:10.1097/RCT.0000000000000097

6) Trans-Atlantic RPS Working Group. Management of primary retroperitoneal sarcoma (RPS) in the adult: a consensus approach from the trans-atlantic RPS working group. *Ann Surg Oncol*. 2015;22(1):256-263. doi:10.1245/s10434-014-3965-2

7) Marcu RD, Diaconu CC, Constantin T, et al. Minimally invasive biopsy in retroperitoneal tumors. *Exp Ther Med*. 2019;18(6):5016-5020. doi:10.3892/etm.2019.8020

8) Ghose J, Bhamre R, Mehta N, et al. Resection of the inferior vena cava for retroperitoneal sarcoma: six cases and a review of literature. *Indian J Surg Oncol*. 2018;9(4):538-546. doi:10.1007/s13193-018-0796-9

9) Zander T, Caro VD, Maynar M, Rabellino M. Bridging stent placement in vena cava syndrome with tumor thrombotic extension in the right atrium. *Vasc Endovascular Surg*. 2021;55(1):69-72. doi:10.1177/1538574420954579

10) Friedman T, Quencer KB, Kishore SA, Winokur RS, Madoff DC. Malignant venous obstruction: superior vena cava syndrome and beyond. *Semin Intervent Radiol*. 2017;34(4):398-408. doi:10.1055/s-0037-1608863

"Never confuse movement with action."
—Ernest Hemingway

Actionable Reports

C. Douglas Philips, MD

Dr Philips is a professor of Radiology, director of Head and Neck Imaging, at Weill Cornell Medical College, NewYork Presbyterian Hospital, New York, New York. He is a member of the *Applied Radiology* Editorial Advisory Board.

A new item we are all talking about, meeting about, doing "projects" on, and perseverating on at a very unhealthy level is this concept of "actionable" elements in reports. You found something, someone needed to do something to further figure it out, you suggested how. We're told that is part of our job; I think the residents and fellows have been filled to the brim with this concept. There are IT programs now to look at your reports, find "actionable" items, and follow up on them. Dive into the EMR and see if this is being "actioned."

Okay, everyone gets an opinion. You are going to hear mine.

I do NOT have an issue with radiologists finding things (obviously), occasionally not knowing what those things are, suggesting ways to figure out those things, and signing off on a report, sending it along to the referring clinician and into the EMR. However, I have a real issue with being held responsible if the people I suggest ways to figure things out then choose to totally and utterly ignore me. Some of these programs I have seen literally go as far as to harass the other parties to "act" on your suggestion.

Here's the deal: In a way, by doing nothing they have "acted" on your suggestion. They chose to ignore it. I get it; perhaps they are busy and just overlooked the suggestion in an expensive study performed for a patient with a presumably real, legitimate problem. Maybe it was an incidental thing, and they are working on the current issue right now and will get to the incidental thing later. I don't know. But, do I really contribute to patient care by pestering someone over and over again with my previous suggestion?

When I did some clinical medicine, people would ask for "consults" and the consultant might get a little off track, suggest a mega-workup or millions of tests for something they were concerned about, and occasionally the treating docs would view it all in the context of the patient and the things they knew, and then just say no, maybe laugh it off, thank the consultant for the input, and move along.

We as radiologists can't seem to take no for an answer. We have an "actionable" item in our report and we want you on it. Today. And we will hassle you until you do.

I think many folks way smarter than me have likely already dove into this and have some answers. I'd like to hear them. Hemingway was on point here, as was often the case. Even if we see movement, maybe that's not an appropriate action. Responsibility for the action, in my opinion, seems to lie a bit further afield.

Keep doing that good work. Mahalo.

The 2024 Leaders on the Horizon Residents' Program

This exclusive program is designed to identify, cultivate, and highlight the future stars in medical imaging.

Residents are encouraged to submit a clinical research paper and/or a clinical review article for consideration. All papers should be focused on topics related to medical imaging and will be reviewed by a committee of key opinion leaders in radiology.

Residents authoring the top three (3) papers selected for each category will receive a scholarship.

Clinical Research Papers	
1st place	$7500
2nd place	$5000
3rd place	$3000

Clinical Review Papers	
1st place	$3000
2nd place	$2000
3rd place	$1000

Paper Submission Deadline: October 1, 2024

Visit appliedradiology.com/leaders to submit a paper topic today!

Supported through an unrestricted educational grant from Bracco Diagnostics, Inc.

BRACCO

LIFE FROM INSIDE

CT Suite | MR Suite | Injectors and Digital Solutions

SmartInject
SOLUTIONS FROM BRACCO

Point-of-care imaging solutions that help promote patient safety and streamline workflow

NEXO®
Contrast management system

Advance patient care with smart injectors and digital solutions from Bracco.

Learn more at **SmartInject.com**

Bracco Diagnostics Inc.
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831 USA

Phone: 609-514-2200
Toll Free: 1-877-272-2269 (U.S. only)
Fax: 609-514-2446

BRACCO
LIFE FROM INSIDE

Committed to Science,
Committed **to You.**™