May 2019 Featured Articles, Volume 228

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Article 1: Endocrinology, Thyroid, Parathyroid; General Surgery
Enhancing parathyroid gland visualization using a near-infrared fluorescence-based overlay imaging system. McWade MA, Thomas G, Nguyen JQ, et al. J Am Coll Surg 2019;228:730–743

Article 2: Breast; General Surgery
Value of axillary ultrasound after negative axillary MRI for evaluating nodal status in high-risk breast cancer. Almerey T, Villacreses D, Li Z, et al. J Am Coll Surg 2019;228:792–797

Objectives: After reading the featured articles published in this issue of the *Journal of the American College of Surgeons* (JACS), participants in this journal-based CME activity should be able to demonstrate increased understanding of the material specific to the article featured and be able to apply relevant information to clinical practice.

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Article 3: Hernia; General Surgery
Clinical value of hernia mesh pathology evaluation. Fadaee N, Mazer L, Sharma R, et al. J Am Coll Surg 2019;228:776–781

ARTICLE 1

(Please consider how the content of this article may be applied to your practice.)

Enhancing parathyroid gland visualization using a near-infrared fluorescence-based overlay imaging system

McWade MA, Thomas G, Nguyen JQ, et al
J Am Coll Surg 2019;228:730–743

Learning Objectives: After the study of this article, surgeons should be able to have insights regarding the practical utilities of the described device—the overlay imaging system—and similar near-infrared–based systems inside the operating room. Insights include what these devices can do (merits) and what they cannot be applied for (demerits), in a realistic intraoperative setting during endocrine or head and neck operations.

Question 1

Overlay tissue imaging system (OTIS) can be used for:

a) Preventing accidental excision of parathyroid glands
b) Differentiating between normal and hyperactive parathyroid glands intraoperatively
c) Label-free evaluation of parathyroid perfusion
d) Discriminating between exposed parathyroid and nonparathyroid tissue in real time
e) Localizing hidden or missing parathyroid glands

Critique: The OTIS is a device designed for enhanced label-free parathyroid visualization, regardless of whether the parathyroid gland is normal or not. It is based on parathyroid near-infrared (NIR) autofluorescence, which is independent of vascular supply. OTIS can, however, be used alongside exogenous contrast agents, such as indocyanine green, for assessing parathyroid perfusion and determining its viability. On the other hand, due to the limited tissue penetration

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depth of NIR light used for imaging, the tissues (parathyroid) often need to be exposed before assessment with OTIS. Therefore, OTIS may not always be feasible for localizing missing parathyroid glands or minimizing accidental excision or damage of parathyroid glands.

Question 2

When a parathyroid gland has been visualized with the overlay tissue imaging system (OTIS), how are the findings of the device conveyed to the end user (surgeon)?

a) Quantitative fluorescence data from tissue are indicated on the device display.
b) A near-infrared (NIR) image with higher intensity in the region of parathyroid gland is displayed on a monitor.
c) Visible light is projected onto the parathyroid gland directly within the surgical field.
d) An auditory beep is emitted by the system when a parathyroid gland is visualized.
e) Signal from the parathyroid gland is visualized by special goggles worn by the surgeon during the operation.

Critique: The FDA has recently approved 2 devices: (1) Fluobeam (Fluoptics), an NIR imaging system and (2) PTeye (AiBiomed, Inc), a hand-held probe system for label-free intraoperative parathyroid identification using NIR spectroscopy. With NIR imaging systems, the operating room lights need to be briefly switched off, while requiring surgeons to hold a camera over the surgical field (patient's neck) and then look toward the NIR image depicted on a display monitor away from the surgical field. Switching off the operating room lights and diverting the surgeon's view away from the surgical field (while holding a camera) may prove disruptive to existing surgical workflow. In contrast, the hand-held probe system, PTeye, is functional with ambient operating room lights, while providing quantitative fluorescence data and an auditory beep when the hand-held probe touches parathyroid tissue. But the PTeye is a contact-based detection system and cannot be used for spatially mapping parathyroid glands. Researchers have recently tried to develop wearable goggles in which the NIR image is merged directly with the surgeon's view, but this modality is yet to be tested for label-free parathyroid identification. OTIS goes a step further by circumventing the need for goggles, by enabling overlay of the NIR fluorescence signal on the tissue in view. Both the wearable goggles and OTIS need further iterations before being cleared by the FDA for intraoperative parathyroid visualization.

Question 3

What subset of end-users will benefit the most from a device such as the overlay tissue imaging system (OTIS) or other similar near-infrared based systems?

a) Surgeons at institutions that perform a low volume of thyroid and parathyroid operations
b) Senior endocrine surgeons at high-volume institutions
c) Early career endocrine surgeons at high-volume institutions
d) All head and neck surgeons
e) All endocrine surgeons

Critique: A device such as OTIS could benefit endocrine surgeons as well as head and neck surgeons for both thyroid and parathyroid operations. However, the true value of OTIS to its end-user would lie in its ability to minimize the rate of postsurgical complications (eg hypoparathyroidism) during head and neck or endocrine operations. Postsurgical complications typically arise from the inability of the surgeon to accurately identify parathyroid glands and are mostly governed by (1) the number of surgeon's years of experience and (2) surgery volume at the institution. A surgeon with less experience at a high-volume center tends to have a higher complication rate than his/her senior counterpart, so the former may benefit more from an NIR-based technology such as OTIS. Even highly experienced surgeons can rely on NIR-based systems in certain conditions because he/she may still find it challenging to identify parathyroid glands during high-risk thyroidectomy (eg Graves' disease, papillary thyroid cancer) or reoperative parathyroidectomy (distorted anatomy from previous operations). Similarly, studies have demonstrated higher complication rates for low-volume surgeons when compared with high-volume surgeons, which means that OTIS would be useful for low-volume surgeons. However, it remains to be determined whether OTIS or other NIR-based modalities will be cost-effective in low-volume institutions. Furthermore, the modality can be used as an educative tool for surgical trainees, as the rapid device feedback can teach the trainee if the visualized structure is parathyroid or not.

Question 4

One beneficial impact with the overlay tissue imaging system (OTIS) and other similar NIR-based systems during head and neck or endocrine procedures would potentially be:

a) Replacing intraoperative parathyroid hormone (IOPTH) monitoring and periodic blood sampling during parathyroidectomy
b) Minimizing the number of frozen sections biopsies performed on parathyroid glands during head and neck or endocrine operations
c) Rapidly identifying devascularized parathyroid glands for quick autotransplantation
d) Reducing the duration of surgical exploration by detecting hidden or missing parathyroid glands
e) Decreasing incidences of hypocalcemia by completely preventing accidental excision of parathyroid glands

Critique: With the described study design, it is presently not known how OTIS could potentially affect patient outcomes, as the surgeon remained blinded in the study. It must be noted that because OTIS does not differentiate between normal and diseased parathyroid glands and will not detect glands that are not exposed in the surgical field, it must be used complementarily with IOPTH assays and surgeon judgment to ensure complete removal of hyperactive parathyroid glands during parathyroidectomy. The high specificity of OTIS, however, is valuable for excluding false positives and will be extremely useful in reducing the number of frozen sections and related costs required for confirming parathyroid glands in real time. Another aspect that needs to be taken into account is that all parathyroid candidates visualized with OTIS were exposed or were superficially visible before measurement. Therefore, the present system design of OTIS allows the surgeon to confirm the identity of a suspected parathyroid candidate that is surgically exposed, but may be limited in being able to localize a missing or deep parathyroid or prevent accidental excisions of aberrantly (intrathyroidal) located parathyroid glands.

ARTICLE 2

(Please consider how the content of this article may be applied to your practice.)

Value of axillary ultrasound after negative axillary MRI for evaluating nodal status in high-risk breast cancer

Almerey T, Villacreses D, Li Z, et al
J Am Coll Surg 2019;228:792–797

Learning Objectives: Axillary imaging in breast cancer is a very important subject due to the importance of lymph node metastases on long-term survival and its impact on treatment algorithm and surgical options provided to the patient.

Question 1

A 60-year-old woman with a 5-cm invasive ductal carcinoma presents to your office. Her work-up has included mammogram, breast ultrasound, and bilateral breast MRI. The MRI reports the axillary lymph nodes appear normal. Her axillary exam is clinically negative. You decide she should receive neoadjuvant chemotherapy to make her a better candidate for breast conservation. What is the best next step for evaluating the axilla?

a) No need for additional imaging
b) Obtain axillary ultrasound
c) Physical exam
d) Repeat MRI
e) CT scan

Critique: MRI missed <2% of clinically significant axillary disease. Most breast MRIs performed today can assess the axilla, and with increasing frequency, the radiologists are commenting about the appearance of the axilla on these exams. MRI is highly sensitive in detecting lymph node abnormalities and repeating ultrasound after negative MRI is not necessary. CT scan and repeating physical exam are not necessary.

Question 2

What is the false negative rate in detecting axillary lymph node metastases by physical exam?

a) 10% to 15%
b) 15% to 25%
c) 30% to 45%
d) 45% to 55%
e) 55% to 65%

Critique: Physical exam is unable to differentiate routinely between normally enlarged and palpable lymph nodes and clinically suspicious nodes. Further physical exam is not sensitive enough to detect small volume disease or cortical thickness alone. The reported false negative rate for detecting lymph node metastases by physical exam alone in the literature is 30% to 45% and therefore, additional imaging is commonly recommended for assessment of the axilla.

Question 3

The most common characteristic of an abnormal lymph node that was identified by both axillary ultrasound and MRI was:

a) An increase in size
b) Effaced hilum
c) Abnormal blood supply
d) Cortical thickness
e) Increased number of lymph nodes

Critique: Axillary ultrasound is challenging in high BMI patients due to subcutaneous fat, which decreases the ultrasonic wave transmission. In addition, axillary ultrasound can be operator-dependent, affecting reproducibility. Regardless, an enlarged lymph node was the most common characteristic identified when determining the presence of an abnormal lymph node. This may be an overly sensitive characteristic, however. While the other characteristics are also used to describe lymph node abnormalities, they are seen with less frequency.

Question 4

What is the most important factor in predicting long-term survival in breast cancer patients?

a) Size of the tumor
b) Surgical procedure
c) Presence of lymph node metastases
d) Grade
e) Age

Critique: All these factors play a role in long-term survival in breast cancer patients. Historically, lymph node metastasis has been considered the factor most linked to survival and outcome. Although lymph node metastases remain a finding that can increase the patient's tumor stage, tumor biology and targeted adjuvant therapies likely play a more significant role in survival and outcomes than nodal metastases alone. Robust randomized prospective trials with >25-year follow-up demonstrate no survival difference between breast conservation and mastectomy.

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ANSWERS

Article 1	Article 2
Question 1 _____	Question 1 _____
Question 2 _____	Question 2 _____
Question 3 _____	Question 3 _____
Question 4 _____	Question 4 _____

Evaluation Form

Article 1	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Topics and content were consistent with learning objectives.	O	O	O	O	O
2. Content was relevant to my educational needs.	O	O	O	O	O
3. I will seek additional information on this subject.	O	O	O	O	O
4. The article and questions were relevant to my practice.	O	O	O	O	O
5. Content was fair, objective, and unbiased.	O	O	O	O	O
(Please explain any specific instance[s] of bias or conflict of interest.)					
Article 2					
1. Topics and content were consistent with learning objectives.	O	O	O	O	O
2. Content was relevant to my educational needs.	O	O	O	O	O
3. I will seek additional information on this subject.	O	O	O	O	O
4. The article and questions were relevant to my practice.	O	O	O	O	O
5. Content was fair, objective, and unbiased.	O	O	O	O	O
(Please explain any specific instance[s] of bias or conflict of interest.)					

Questions? Call 312-202-5316. Email: jacscme@facs.org.