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Telecytology for Rapid On-Site Evaluation: Current Status

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Minimally invasive procedures such as fine needle biopsies and core biopsies have been increasing in number recently. This increase is driven by our ability to provide a diagnosis with less material and the aid of enhanced ancillary studies. The advent of multiplex molecular testing has permitted the analysis of hundreds of genes with minimal material, allowing the use of material obtained from minimally invasive procedures for both diagnostic and prognostic purposes. Coinciding with advancements in imaging techniques, expansion of the different biopsy platforms such as endobronchial ultrasound guided (EBUS) biopsies and endoscopic ultrasound biopsies (EUS) as well as increased use of molecular studies, the role of cytology has dramatically increased.

Several prior reports have shown the benefit of rapid on-site evaluation (ROSE), which has been demonstrated to improve quality care and decrease health care costs by reducing the rate of non-diagnostic specimens, unnecessary passes and repeat procedures.[1–5] Furthermore, ROSE allows proper triage of the material collected, directing the operator to obtain material for cultures if an infectious etiology and for flow cytometry studies if a lymphoproliferative disorder is a diagnostic consideration as well improving the adequacy rate for molecular studies.[6, 7]

As the number of platforms for minimally invasive procedures increases, the number of operating sites that require ROSE also expands. These minimally invasive procedures are often performed in distinct locations in the same institution. Endoscopic ultrasound guided biopsies are often performed in dedicated room suites while fine needle aspiration (FNA) and core biopsies of deep organs are typically done in radiology suites. These locations are usually not contiguous or adjacent to the cytology laboratory and might be distant from each other. The array of different locations in which ROSE is expected requires an ever-increasing number of cytology personnel that can outstrip the cytology staff capacity at most institutions.

Telecytology (TC) represents a reasonable solution to increase the efficiency of the personnel performing ROSE while also justifying adequate reimbursement for the ROSE activity. Due to the multitude of sites that might be performing procedures at the same time,

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it would not be cost effective, and probably, not physically possible for a pathologist to be present in every location where the procedure is being performed, especially in high volume services. Additionally, the amount of time required for a pathologist to reach the location where the procedure is being performed and the downtime between passes is not appropriately reimbursed.[8] The use of telecytology allows the pathologist to stay in the laboratory while the images are sent from the location where the procedure is being performed by a cytotechnologist or cytopathology fellow. Furthermore, ROSE billing without pathologist involvement remains controversial as the billing of the technical component of ROSE is questionable if a pathologist is not directly involved in the process. Some practices do not bill the technical component of ROSE if a pathologist is not involved.

Although cytotechnologists (CTs) in many institutions have shown to be able to perform ROSE independently with satisfactory results,[9, 10] the increased complexity of the cases and billing requirements mandates the inclusion of a pathologist in the workflow. The emergence of fast and high-resolution digital imaging technologies has made telecytology for ROSE possible and allows marked increase in time efficiency as one attending pathologist can support multiple sites while performing other tasks in between the procedures and obtaining consensus opinion if necessary.[11–14] The images obtained for telecytology can be sent through static image transmission, live image streaming, and robotic live image streaming.

Static image transmission is a simple economical solution for low volume settings with limited resources. The hardware required includes a microscope, digital camera and a computer connected to the microscope camera or a smartphone. The cytotechnologist or cytopathology fellow can take digital pictures from relevant diagnostic fields and send the images to the pathologist, who can view them at their computer, tablet or even smartphone. Static image transmission requires a high level of expertise by the on-site cytology staff, as the pathologist relies solely on the images selected/sent to make an assessment.[15] Furthermore, the process takes longer than live image transmission as the person on-site needs to screen the slide, select the images to be photographed, save them and then send the images. Another disadvantage is the inability to have all cells in focus. The main advantage of this system is the low cost and basic technical requirements as the main cost associated with this telecytology modality would be the camera and computer employed to send the images. Historically, static image transmission was initially evaluated for cervical cytology where it showed some limitations. Raab et al.[16] found that use of the monitor-based diagnosis was approximately 10% less accurate than the one obtained with glass slides and performance varied between individuals. Ziol et al.[17] noted that the process was hindered by the inability to focus and lack of resolution, particularly for small cells. In nongynecologic applications, a variety of organ system telecytology studies has been reported. Several studies using static images to diagnose breast fine needle aspirations demonstrated no major diagnostic differences between the static images and glass slides, with a satisfactory rate of 84%.[18, 19] Briscoe et al. reported that the results were dependent on the observer's experience in the evaluation of breast fine-needle aspiration static digital images.[20] In their study, the pathologist with the most experience had the highest level of concordance and diagnostic confidence. Ayatollahi et al.[21] reported between 83 and 87% accuracy for the interpretation of static images from pleural effusion specimens compared to the final diagnosis versus 89% accuracy for interpretation of the glass slides. In studies of pancreatic

fine-needle aspiration biopsies by static images, Marchevsky et al. reported improved performance over light-microscopic examination in the discrimination of chronic pancreatitis from low-grade adenocarcinoma. They did report considerable inter- and intraobserver variability in diagnosis, which might be expected for this often difficult discrimination, but less was reported using the static-image approach. This conclusion might be predicted on the fact that the images selected might be the best representative of the pathology present, and would not be 'diluted' by all the other appearances on the entire glass slide.[22] This hypothesis speaks to the fact that image selection quality and bias may play an important role in the variable quality of static-image telecytology. For a variety of aspiration specimens in a cytology service, Jialdasani et al.[23] reported a 'clinically useful' diagnosis in 91% of cases using static-image telecytology. Yamashiro et al. reported on their introduction of a static image-based telecytology system for primary diagnosis in Japan.[24] Over a 2-year period, 614 routine cases were transmitted by cytotechnologists to pathologists working 300 km away, with case discussion simultaneously via e-mail. The concordance between telecytology and subsequent glass slide interpretation was 88.6%. The overall accuracy was 91.4%, and was not statistically different from the 'glass slide by mail' accuracy noted in the prior year. There were only 5 cases (0.8%) in which a 'severely inappropriate diagnosis' was made by evaluation of digital static images. These cases were all difficult differential diagnoses, including lymphoma, bile duct and salivary gland neoplasia, in which routine glass slide diagnosis might be fraught with difficulty. The authors conclude that this system worked adequately for routine use.[24] It is possible that recent improvements in the technology used for static transmission of images with higher quality images might lead to increase the satisfactory rate with this process. Nonetheless, static image transmission is still better suited for low volume settings and dependent on the on-site cytology personnel skills.

Live image streaming is another option for telecytology and offers several advantages over static image transmission. It allows review of the whole slide by the pathologist and it is more time efficient as the pathologist is looking at the slide simultaneously with the on-site operator. Another advantage is the fact that it requires the same hardware as static image transmission, except for the equipment/software required for live image streaming. There are off the shelf videoconferencing software as well as dedicated systems for live image transmission that can be used for ROSE. The selection of the software should be based on the needs and resources of each service/institution. It should take into account image quality, ease of use, reliability and security. As an example, Memorial Sloan Kettering Cancer Center (MSK) prioritized user friendliness for both CTs and cytopathologists, secure remote access, and excellent image quality. User friendliness was a high priority to ensure workflow efficiency for both CTs and pathologists. An intuitive product was critical due to the varying levels of technological knowledge and comfort among the staff. The selected telecytology equipment provided by Remote Medical Technologies (RMT®) allowed the images to be viewed inside the institution's firewall through any computer with an internet browser. It required only the input of the pathologist's user identification, password, and selection of the equipment location on a website page. The first 2 steps could be auto-filled if the same computer was used frequently and the information saved. Therefore, access to the image required only 3 clicks by the pathologist if the browser was already open. The remote access to the on-site camera by the pathologist without need of any input from the on-site staff was

critical to the workflow as it enabled CTs or fellows to share images with pathologists without delays or effort on their part. The CTs would communicate with the pathologist through hands free voice communications devices, therefore, CTs could focus on the process of screening the slide in question instead of spending time and effort facilitating the image-sharing process. (Table 1) Using the RMT system and the workflow at MSK, Sirintrapun et al. have shown an accuracy rate of 93.1% between the images seen through TC and final diagnosis when all cytologic material submitted was available for evaluation.[25] These results are comparable to previous reports, which have demonstrated an 80% to 95% concordance rate for TC and 66.7% to 97% for conventional on-site methods.[16, 19, 20, 26–28] These concordance rates are important as they can be used as threshold benchmarks for user competency in TC. A prior TC study proposed a benchmark interobserver/intra observer passing rate of 90%,[29] but sample size was limited with only 10 cases used for validation.[30]

Sirintrapun et al. indicated that several factors contributed to relative high concordance rate in their study of live image transmission for ROSE, including CT diagnostic skills, TC equipment and workflow.[25] The ability of the person on-site to show regions of interest is critical for this TC activity using this platform as the pathologist is not able to select the best areas for review. The adequacy upgrade rate in which lesions initially designated as non-diagnostic became diagnostic on the evaluation of the entire specimen was low (6.7%) in his study. Adequacy upgrades are not unexpected as not all diagnostic material is available for review at the time of ROSE. The slide used for adequacy assessment is only part of the specimen. Furthermore, most cases initially considered non-diagnostic and later deemed adequate were soft tissue lesions or lesions associated with marked fibrosis. Smears and touch preparations of such lesions frequently yield a very limited number of cells on the adequacy assessment slide, preventing an accurate assessment. Despite the high concordance rate in their study, 0.01% of the cases were initially considerate adequate but subsequently considered inadequate on final evaluation. The leading cause of downgraded cases was misinterpretation of benign cells as malignant cells. Examples of such cases include misinterpretation of renal tubular cells as neoplastic oncocytoma cells or cases in which clusters of lymphocytes were misinterpreted as follicular cells in thyroid FNAs. Similar results were also encountered by other authors when using a Nikon® camera. Alsharif et al. reported an adequacy rate was 94.0% for TC cases and a discrepancy rate of 1.8% among 371 telecytopathology cases when using a Nikon® system.[31]

The RMT or Nikon systems are not the only viable solution for live image transmission. Other commercial solutions exist for live image streaming through videoconferencing systems such as WebEx®, Go to Meeting®, and Join.Me® among others. These platforms are suitable for telecytology but entailed a number of manual steps for both system configuration and image access that would take time away from the on-site staff that could be used for screening the slide. The on-site staff would need to send an invitation to the pathologist to join the session. The pathologist would then need to click the link provided to access the on-site monitor and the on-site staff would need to approve and grant screen sharing privileges. This process can take at least 45 to 60 seconds, even for an expert-level user. Conversely, the RMT® and Nikon® systems do not require any manual input from the on-site staff to initiate the live image transmission.

Another advantage of the RMT® and Nikon® systems is the high image quality through a streaming resolution at 1920 × 1080 pixels. In comparison, WebEx® streams at 1280 × 1024 pixels and MicroSuite5 software with NetCam® feature (Olympus®) streams at 800 × 600 pixels.[32] Other more economical options include free smartphone mobile applications like Apple's FaceTime® and Skype®.[33–35] However, institutional security issues and high case volume might prevent their effective use. These applications create outbound streams to proprietary servers outside the institutional firewall that might not be allowed in some institutions. Issues to be considered when selecting live image transmission as a platform for ROSE are cost and staff skills. Live image transmission can be more expensive than static image transmission as additional software and licenses might be required to transmit the images through proprietary software. On-site cytology skills are also critical as the pathologist will review the images shared by the on-site staff.

The third option for telecytology is the use of robotic microscopes for ROSE. The use of robotic microscopes in pathology has been previously reported primarily for frozen section diagnosis and non-cytology teleconsultation.[36–38] Experience with remote dynamic robotic functionality in cytology is more limited.[26, 36] Robotic microscopes allow full control of the field of view, including location, magnification and focus. In the absence of on-site cytology staff, the smear can be prepared and stained by on-site licensed staff such as non-pathology physicians or laboratory technicians, who will then load the slides into the equipment. One of few robotic microscopes available, VisionTek® by Sakura, allows the visualization of an entire slide in approximately 10 seconds after it is loaded. The images obtained by the VisionTek® can be accessed and controlled remotely through dedicated secure software such as Remote Desktop®, among others. The system requires a high-speed internet to reduce the slight lag when sending commands to the machine, which is minimal but perceptible. Nonetheless, ROSE with a robotic microscope is useful especially in low volume settings in which there is no on-site staff with cytology expertise to select the fields of interest for the cytopathologist.

Sirintrapun et al. has reported the largest experience with the use of a robotic microscope for ROSE.[39] In their series, the concordance between the preliminary adequacy assessment versus the final cytopathologist-rendered adequacy assessment for cellular content and adequacy was at 92.7% (407/439). Similar to live image streaming, the percentage of cases in which lesions initially designated as inadequate became adequate on the evaluation of the entire specimen was low. The rate of such cases was 6.6% and very similar to the rate obtained with the live image transmission without a robotic microscope. Their study demonstrated that only 0.7% (3/439) were initially considered adequate but subsequently considered inadequate. Such overinterpretations are not restricted to ROSE through robotic telecytology and, arguably, it would still occur with conventional on-site cytologic evaluation. An important consideration in the use of robotic telecytology is the cost of the equipment, which is higher than the setup used for live image streaming discussed before. However, cost analysis of ROSE for low volume sites suggests that the cost of the equipment can offset the salary costs of a full time employee that the laboratory would need to hire to support a low volume site. Another consideration in the implementation of ROSE with a robotic microscope is the willingness and eligibility of on-site personnel to prepare the smears when there is no on-site cytology personnel. Although physicians are eligible to

perform such tasks, they might not available to. In some states, radiology technicians or nurse aides are not licensed to perform these tasks even though they are not highly complex tasks.

A potential future option is the use of whole slide scanners. These scanners are currently not suitable for ROSE due to technical reasons. Cytology preparations require multiple levels of scan (Z-stacking) for proper visualization of the cytology images due to the three-dimensional nature of cytology specimens. One problem is not all scanner vendors offer Z-stacking capable scanners. Vendors offering Z-stacking capable scanners include 3DHistech®, Hamamatsu®, Roche® and Leica®, among others. The number of levels and length of time required for Z-stacking scan varies from vendor to vendor and needs to be standardized. Nonetheless, none of the currently available whole slide scanners is fast enough for ROSE. In our experience (unpublished), cytology preparations will take at least 10 minutes to have the whole scan available. This lengthy scanning time would inhibit its acceptance by interventional radiologists or surgeons as a suitable solution when there are solutions that are faster and cheaper. Therefore, whole slide image scanners are currently not the best option for ROSE, particularly in high volume settings. Technological improvements will most likely allow the use of these scanners for ROSE in the near future; however, cost might still be an impediment for its implementation.

Independent from the platform selected for ROSE, a validation is required before the equipment is used for clinical purposes in the United States. As remote review for adequacy assessment using telecytology does not result in a diagnosis and is not considered primary screening, the validation does not need to be submitted for review by the inspecting agency. Nonetheless, Center for Medicare and Medicaid Services (CMS) does consider ROSE a test and, therefore, a CLIA number, and in New York State, a New York State clinical laboratory permit is necessary. The validation should closely imitate the actual clinical environment and workflow in which the system will be used. A pathologist adequately trained to use the system should be involved in the validation study. Ideally, the validation study should follow the College of American Pathologists guidelines for validation of whole slide imaging for diagnostic purposes with a minimum set of 60 slides.[40] The gold standard should be the initial adequacy assessment determined using the optical light microscope. The performance expectations in terms of accuracy, precision, sensitivity and specificity should be preset. In regards to ROSE with a robotic microscope without on-site cytology personnel, non-Pathology physicians, such as radiologists, pneumologists and surgeons participating in this activity on-site need to be trained for smear preparation and staining as per NYS regulation. This training must be verified for proficiency and documented.

In summary, telecytology for ROSE is currently suitable for clinical use in large volume settings and it increases time efficiency without loss of quality and improves patient care. There are multiple platforms available and the selection of equipment (hardware and software) should be based on the volume, budget and workflow of each institution. Table 1 provides a summary of the main advantages of each telecytology platform. Validation before implementation for clinical use is mandatory.

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Highlights

This manuscript discusses the current platforms alternatives telecytology for ROSE. It demonstrates how ROSE can increase efficiency in a Cytology laboratory while improving patient care. It also discusses the importance of validation before implementation.

Table 1

Telecytology modalities. Advantages and disadvantages

Platform	Advantages	Disadvantages
Static image transmission	- Simple - Low cost	- Requires on-site expertise - Time consuming - Inability to view whole slide - Inability to have all cells in focus
Live image transmission	- Simple - Review of entire slide possible	- Requires on-site expertise - Software compatibility required - Cost
Live image transmission with robotic microscope	- Review of entire slide possible - No on-site cytology expertise required	- Software compatibility required - Non-Pathology staff training and proficiency maintenance required - Cost
Whole slide scanner image transmission	- Review of entire slide possible - No on-site cytology expertise required	- Image not immediately available - Cost