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Cytotechnologists and On-Site Evaluation of Adequacy

Jennifer A. Collins[1] · Anna Novak[2]
Syed Z. Ali[2,3] · Matthew T. Olson[2]

[1]Department of Pathology, University of Maryland; Departments of [2]Pathology and [3]Radiology, Johns Hopkins University School of Medicine, Baltimore, MD, USA

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Corresponding Author
Matthew T. Olson, M.D.
Department of Pathology, The Johns Hopkins Hospital, Pathology 406A, 600 N. Wolfe St., Baltimore, MD 21287, USA
Tel: +1-410-955-1180
Fax: +1-410-614-9556
E-mail: molson8@jhmi.edu

While fine needle aspiration (FNA) is certainly not a new biopsy technique, recent developments in advanced imaging techniques, molecular testing, and targeted therapies have coincided with a rapid increase in the number of FNA procedures being performed. Concurrently, the demand for on-site evaluation of adequacy (OSEA) has also increased, outstripping the capacity of available cytopathologists at some institutions. Among the several alternatives to cytopathologist-performed OSEA, cytotechnologist-attended OSEA stands out because it preserves the representation of the pathology service at the time of the procedure. Herein, we review the current literature about OSEA and the necessity of cytotechnologists to expand access of this useful pathology service to a broader patient population. We also examine how cytotechnologists are likely to fit into the emerging practice of telecytology.

Key Words: Biopsy, fine needle aspiration; Rapid on-site evaluation; On-site evaluation of adequacy; Cytotechnology; Telepathology; Telecytology

Fine-needle aspiration (FNA) is a well-established and widely used biopsy technique for the initial tissue diagnosis of many diseases. FNA is minimally invasive and usually safe. For this reason, it is the sampling method of choice for tumors in a variety of sites in the human body, including the head and neck, thyroid, liver, pancreas, bone, soft tissue, lung, and mediastinum.[1-5] While FNA is certainly not new, parallel developments in advanced imaging techniques, molecular testing, and targeted therapies have coincided with a rapid increase in the number of FNA procedures. For example, endoscopic ultrasound (EUS)-guided FNA now provides adequate material to diagnose, characterize, and stage pancreatic, biliary and ampullary cancers without the need for diagnostic abdominal surgery.[6-8] Similarly, endobronchial ultrasound (EBUS)-guided FNA has replaced mediastinoscopy as the method of choice for staging lung cancer.[9]

In addition to being less invasive, radiologically advanced sampling techniques that involve FNA are also cost-effective compared with their more invasive alternatives.[10] However, their costs are non-trivial, and the expenses involved have required an increased emphasis on ensuring sample adequacy at many institutions. Several strategies proposed to ensure adequacy have included the upfront collection of a large number of passes[11,12] and the non-microscopic examination of the direct smear.[13-15] Alternatively, an on-site evaluation of adequacy (OSEA, also known as rapid on-site evaluation, or ROSE) has been used as a more consistent and potentially safer option. Traditionally, OSEA involved the physical presence of a cytopathologist at the procedure,[16,17] although cytotechnologists have been shown to be capable of providing this service with equivalent accuracy.[18-20] While telecytology is gaining popularity,[21] this technology only partially solves the problem of increased cytopathologist demand; an individual capable of microscopy must still be present in or near the procedure room to prepare the direct smear and operate the microscope. Additionally, given the pauci-cellularity of many specimens and the low resolution of currently available real-time telepathology solutions, the microscope driver should also ideally possess diagnostic capabilities in order to maximize efficiency. Thus, with or without telecytology, cytotechnologists appear well-suited to meet the demands for OSEA of FNA biopsy procedures. In this article, we provide a brief review of the literature regarding OSEA and outline key areas in which cytotechnologists are necessary in order to meet

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the increasing demand of this useful pathology service.

OSEA IN PERSPECTIVE

Ultimately, the ability to make a pathologic diagnosis of either a malignant or benign lesion relies on the ability to obtain adequate cellular material during a procedure. Previous studies have shown that OSEA enhances the accuracy and efficiency of EUS-FNA.[3,22,23] At institutions without immediate OSEA, up to 32% of FNAs in organs such as the thyroid, breast and lung are non-diagnostic due to scant cellularity and poor smear preparation.[24,25] In a single institutional study, Iglesias-Garcia *et al*.[26] showed that the introduction of OSEA decreased the number of inadequate samples from 12.6% to 1% (p=.002), increased their diagnostic sensitivity from 78.2% to 96.2% (p=.002) and increased their overall accuracy from 86.2% to 96.8% (p=.013).[26] Chang *et al*.[27] reported that OSEA during EUS-guided FNA of pancreatic lesions resulted in up to 100% adequacy, while 29% of procedures without OSEA required a second procedure to obtain an adequate specimen. Klapman *et al*.[3] reported similar findings. Erickson *et al*.[28] showed that OSEA for EUS-guided FNA of the pancreas increased the number of diagnostic cases by 10% to 15%. They also reported that OSEA resulted in a significant reduction in the number of needle passes in about one-third of cases.[28] While OSEA almost uniformly increases adequacy rates, it does not consistently reduce the number of passes; in a different article, OSEA improved adequacy rates for EUS-guided FNA of pancreatic lesions independently of the number of passes, indicating that continuous feedback allows for prompt sampling of the diagnostic portion of the lesion.[29] Similar reductions in additional procedures have been demonstrated for OSEA of EBUS-guided FNA for staging lung cancer.[30]

The two strongest studies arguing against OSEA both have arisen out of thyroid FNA. One institutional experience showed statistically insignificant adequacy gains for OSEA,[31] and one cost-benefit analysis revealed that OSEA was only cost-effective on an individual level if the institutional adequacy rate was less than 85%.[32] Even if taken at face value, these would not be compelling enough to discontinue OSEA programs because other studies have shown that small adequacy gains translate into tangible and significant savings on an institutional level.[33,34] Cost-benefit analyses at the institutional level are the most relevant to consider given the increasing shift of healthcare expense management to accountable care organizations. Additionally, both of the studies arguing against OSEA involved thyroid sampling procedures, which usually have high adequacy rates; other organs have *a priori* adequacy rates that are significantly lower. Finally, the OSEA process involves non-adequacy benefits, including proper specimen preservation and procurement of tissue for appropriate ancillary testing based on informal preliminary diagnoses.[19,20,33] These benefits have yet to be analyzed with cost-effectiveness modeling, and the multiplicity of diseases that can be encountered during procedures of the same organ make controlled trials impractical to perform.

CYTOTECHNOLOGIST-ATTENDED OSEA

Despite the compelling results for OSEA, many institutions do not have sufficient cytopathologist coverage to support its routine practice. The lack of availably of these professionals has led to the use of practitioners in other medical specialties for OSEA, often with suboptimal results.[23,35] Thus, a clear opportunity exists for cytotechnologists to participate in this pathology service. The initial role of cytotechnologists in OSEA involved preparing direct and indirect specimens onsite with minimal diagnostic interpretation.[36] This role has evolved over time so that cytotechnologists now perform OSEA in large academic centers without direct cytopathologist supervision.[18-20] As cytotechnology training requires expertise in cellular morphology and attendance at OSEA, the participation of cytotechnologists as the primary onsite screener in OSEA is not unreasonable. Additionally, cytotechnologists play a significant role in the subsequent diagnostic process and therefore have a vested interest in specimen adequacy and integrity.

Many studies have shown the benefits of cytotechnologist performance of OSEA; these studies are summarized in Table 1. Cleveland *et al*.[37] reported an association between cytotechnologist-attended OSEA with an increase in adequacy that was disproportionate to all other factors in their analysis, including needle gauge, number of passes, endoscopist, and biopsy site. One small study demonstrated a lack of difference with and without a cytotechnologist present for OSEA in EUS-guided FNA of the pancreas; however, this study lacked an adequate number of patients to assess clinically relevant differences.[38] A larger study with more substantive data by Redman *et al*.[16] showed that cytotechnologists were accurate in 93% of EUS-guided pancreas FNA as compared to the accuracy of cytopathologists, which was 97% (p=.0015). These results were contradicted by an equivalently small study that found that cytotechnologist-attended OSEA significantly improved the accuracy of EUS-FNA.[29] Additionally, Petrone *et al*.[39] reported that

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Table 1. Cytotechnologists in on-site evaluation of adequacy (OSEA)

Study	Sample size	Site of FNA	Comparison group	Results	Statistical significance (p-value)
Alsohaibani *et al*.[29]	109	Pancreas	Endoscopy nurse	Inconclusive diagnosis: 47% for nurses, 23% for cytotechnologist	.001
Burlingame *et al*.[18]	4,729	Multiple body sites	Final diagnosis	Accuracy: 93.8-95.3%	.0064
Cleveland *et al*.[37]		Pancreas	No OSEA	Adequacy: 96% with cytotechnologist, 84% without cytotechnologist	< .00083
Nayar *et al*.[38]	179	Pancreas	No OSEA	No difference	Not significant
Nguyen *et al*.[14]	37	Pancreas	Gross examination of direct smear	'Fair agreement'	Kappa = .2
Olson *et al*.[20]	2,261	Thyroid	Cytopathologist	Accuracy difference not statistically significant	.33
Olson and Ali[19]	2,252	Pancreas	Cytopathologist	Accuracy difference not statistically significant	.13
Olson *et al*.[40]	1,995	Bone and soft tissue	Cytopathologist	Accuracy difference not statistically significant	.64
Petrone *et al*.[39]	107	Pancreas	Cytopathologist	Pre-training adequacy: 68.2% Post-training adequacy: 95.8% (cytopathologist)	.008
Redman *et al*.[16]	574	Thyroid	Final diagnosis	Accuracy: 97% for cytopathologist, 93% for cytotechnologist	.0015
Savoy *et al*.[23]	117	EUS-guided sites	Endosonographers	Accuracy: 89% for cytotechnologists, 69-72% for endosonographers	< .001
Wotruba *et al*.[34]	167	Thyroid	Cytopathologist (paired specimen)	Concordance between cytopathologis and cytotechnologists diagnosis, 98.8%, discordance 1.2%	Not reported

FNA, fine-needle aspiration; EUS, endoscopic ultrasound.

the diagnostic accuracy of a cytotechnologist can improve with advanced training in histology from a cytopathologist. A much larger retrospective study at our institution revealed that the accuracy of the cytotechnologist-attended OSEA of thyroid FNA biopsy (96%) is similar to that of the cytopathologist (95%); these accuracies are independent of experience.[20] This publication also reported that the final adequacy was greaer than the OSEA adequacy for cytotechnologist-attended than for cytopathologist-attended OSEA: 26% versus 17%, $p < .001$. This latter finding was explained by the shift of OSEA from cytopathologists to cytotechnologists; this disparity in overall accuracy is likely related to operator variables and institutional experience with EUS-guided FNA.

In one large retrospective analysis that included all body site FNAs, it was reported that cytotechnologist-performed OSEA had an acceptable level of adequacy regardless of body site or level of experience.[18] This finding was correlated with our own institutional experiences in which we demonstrated through multiple studies that, regardless of body site, pancreas,[19] thyroid,[20] and non-sarcoma metastases found in the bone and soft tissue.[40] OSEA is also important because it places a pathology representative in the procedure room to ensure proper tissue procurement, a detail that is extraordinarily important in cytopathology given the scant nature of most specimens. In a study by Alsohaibani *et al*.,[29] there were 17% fewer crush artifacts and 24% fewer inconclusive diagnoses in the specimens prepared by the cytotechnologists relative to those prepared by endoscopic nurses. At our own institution, we showed that cytotechnologists can appropriately encourage the preservation of tissue for flow cytometric studies in lymphoma.[40] Together, these studies demonstrated a cytotechnologist's capacity to independently utilize good specimen handling protocols on-site.

THE ECONOMICS OF CYTOTECHNOLOGIST-PERFORMED OSEA

There is a strong economic motivation for institutions to utilize cytotechnologists for OSEA assessments. The largest incentive is to avoid the absence of a pathologist for extended and unpredictable amounts of time. This absence can have a major impact on the number of cases signed out and also on the turnaround-time. These delays ultimately may have a tangible negative effect on the department or practice's billing potential and also an intangible effect on its reputation for making timely diagnoses, particularly for community hospitals, which have a more limited number of practicing pathologists. Furthermore, physician compensation for OSEA from Medicaid reimbursement fees is well below the professional fee required to cover the pathologist's time per procedure. In one study, the time expenditure on FNA adequacy ranged from 35 to 56 minutes and resulted in a revenue loss of up to $50 per procedure, which occurred at the expense of attaining additional revenue from per-

forming other diagnostic services.[41] Eedes and Wang[11] also reported inefficient time expenditure, showing that it cost 220 minutes of a cytologist's time for each additional adequate case.

If laboratories could bill a reasonable fee for diverting cytotechnologists to OSEA duties, the economics of cytotechnologist-performed OSEA would be straightforward. However, there is currently no mechanism for billing cytotechnologist-attended OSEA, so the costs are borne at the institutional level in order to increase adequacy and reduce the need for re-biopsy. This procedure makes most sense in accountable care organizations that try to contain costs by billing per disorder rather than per procedure. In a large review, OSEA saved an institution approximately $404,525/yr as a result of decreasing repeat FNAs.[33] A prospective study has also shown that using a cytotechnologist instead of a cytopathologist for OSEA procedures in a thyroid clinic provided the laboratory a cost savings of $464.10/nodule.[34]

TELECYTOLOGY AND CYTOTECHNOLOGISTS

One of the ways in which laboratories have demonstrated cost-effective use of cytotechnologists OSEA is through telecytology.[34] Ideally, the time-intensive portions of the OSEA could be performed by the cytotechnologist with a billable adequacy assessment made remotely by a cytopathologist.[42] Telecytology OSEAs have been shown to be equivalent to physical OSEAs in a number of contexts.[43-46] However, current limitations in internet bandwidth hinder live streaming of high-resolution video feeds over an internet connection. In some practice settings, bandwidth may only be sufficient for low-resolution images. Additionally, technical malfunctions should be expected, and a cytopathologist with remote OSEA responsibilities in numerous locations may not be available to physically appear at a technically malfunctioning telecytology workstation in a timely fashion in order to assess adequacy. Thus, in order for telecytology to work effectively, the on-site cytology professional handling the tissue and operating the microscope should also be a diagnostic provider. With the exception of pathology trainees, cytotechnologists are the only logical members of the laboratory team who can fill this role.

CONCLUSIONS

As we have discussed, a growing number of practices and academic investigations have shown cytotechnologists to be an invaluable component of the OSEA service of a pathology laboratory. To date, there has been no randomized, controlled clinical trial to demonstrate the usefulness of cytotechnologists in this new role; there are also no published regulations, competencies, or proficiency testing mechanisms for these new duties. Therefore, cytotechnologist OSEA is currently an evolving field in which each laboratory must determine its own comfort level and financial exposure. The existing evidence strongly suggests that, if these obstacles can be overcome, cytotechnologists will be able to perform at a high level of competency and thus address the expanding utilization of OSEA in FNA procedures in this minimally invasive medical era. This new role will also ensure the preservation of the cytotechnology field in an era when most institutions are experiencing a decreasing gynecologic smear volume.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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