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A Call for Universal Acceptance of the Milan System for Reporting Salivary Gland Cytopathology

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Abstract

Objectives: The Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) established a standardized, tiered reporting system for salivary gland fine-needle aspiration (FNA) that has gained international acceptance among cytologists. Our goal was to review the key features of the MSRSGC to familiarize the surgical community with this system and its application to the FNA evaluation of salivary gland masses.

Methods: A comprehensive review of the MSRSGC and its application in clinical practice.

Results: The MSRSGC consists of six major diagnostic categories: 1) nondiagnostic, 2) non-neoplastic, 3) atypia of undetermined significance, 4) neoplasm (benign or salivary gland neoplasm of uncertain malignant potential), 5) suspicious for malignancy, and 6) malignant. Each diagnostic category is associated with an implied risk of malignancy with implications for clinical management.

Conclusions: The MSRSGC is similar to the system used for reporting thyroid FNA, which is familiar to most otolaryngologists and head and neck surgeons. As this reporting system continues to gain popularity among pathologists, widespread understanding by surgeons will be important to standardize communication and classification of salivary gland cytopathology to improve clinical care.

Keywords

Fine-needle aspiration; salivary gland; cytopathology; Milan system

INTRODUCTION

Proper management of salivary gland disease is often predicated on accurate cytopathologic diagnosis. Along with clinical history, physical exam, and radiologic imaging, fine-needle aspiration (FNA) plays an important role at most large institutions in the presurgical evaluation of salivary gland masses.¹⁻³ Salivary gland FNA is an effective means of diagnosing a majority of the most common neoplastic (e.g., pleomorphic adenoma and Warthin tumor) and non-neoplastic salivary gland lesions, which has direct implications on clinical management.⁴⁻⁹ Furthermore, FNA can also be useful to stratify low- and high-grade malignancies. Nonetheless, given the heterogeneity of salivary pathology, there is still a subset of salivary gland lesions where a specific diagnosis cannot be made based on cytologic features alone. Without a standardized reporting system, cytologic evaluation and reporting is a challenge.

Historically, there has been inconsistency in the terminology used for reporting the results of salivary gland FNA. This has resulted in confusion amongst clinicians and difficulty communicating clinically meaningful data between cytologists and treating clinicians, as well as standardizing treatment algorithms. To overcome these limitations, the ideal salivary gland FNA interpretation should be succinct, unambiguous, and clinically applicable. Furthermore, a standardized salivary gland FNA reporting system incorporating these principles should be universally accepted, much like The Bethesda System for Reporting Thyroid Cytopathology has become.¹⁰ Many of the guiding principles for creating an effective, universally accepted cytopathologic grading system were pioneered by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses in 1988.¹¹ Subsequently, there has been a significant trend toward the uniform reporting of cytology results for a variety of other specimen and tissue types, including thyroid, urine, breast, and effusions.

To address the need for a tiered diagnostic framework for salivary gland FNA, the Milan System for Reporting Salivary Gland Cytopathology (MSRSGC) was developed in 2015 by an international taskforce of cytopathologists, surgical pathologists, and head and neck surgeons through the American Society of Cytopathology and the International Academy of Cytology.¹² Similar to that of The Bethesda System for Reporting Thyroid Cytopathology, the objective of the MSRSGC is to standardize reporting of salivary gland cytology, promote better communication between clinicians and institutions, and ultimately improve patient care.¹² The MSRSGC has gained widespread international acceptance among cytologists, and is already used to report cytology results at many institutions in the United States and worldwide.

The MSRSGC consists of six diagnostic categories: 1) nondiagnostic, 2) non-neoplastic, 3) atypia of undetermined significance (AUS), 4) neoplasm (subdivided into benign and salivary gland neoplasm of uncertain malignant potential), 5) suspicious for malignancy (SM), and 6) malignant (Table I). In comparison to existing descriptions and schema for salivary gland FNAs, the MSRSGC is able to correlate and stratify cytologic diagnosis with a risk of malignancy (ROM), which more easily facilitates its integration and use in clinical management algorithms. As such, the MSRSGC is transferable and practical for institutions

with all levels of experience and expertise in salivary gland cytology. Here, we present an overview of each diagnostic category with proposed management strategies to familiarize clinicians and promote widespread acceptance of the MSRSGC in clinical practice.

Nondiagnostic

The nondiagnostic category includes salivary gland FNA samples limited by cellularity or preservation artifacts. Examples of nondiagnostic specimens include nonmucinous cyst contents, normal salivary gland elements in the setting of a clinically and radiographically defined mass, and samples with very scant or absent cellularity but without atypia. Specimens that should not be considered nondiagnostic include those containing mucinous cyst contents, atypia, abundant acellular matrix material, or inflammatory cells without an epithelial component. The nondiagnostic category carries a ROM of 25%.

If a nondiagnostic specimen is obtained, repeat FNA should be strongly considered. Ultrasound guidance (USG) is often useful for acquiring repeat samples when the original attempt was performed via palpation alone. If subsequent FNA specimens are also nondiagnostic despite USG and satisfactory sample preparation, ancillary studies may be necessary. Contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI) should be considered if cross-sectional imaging has not yet been performed. When a patient's clinical picture or imaging is concerning for malignancy, or if the nature of the lesion is in doubt, USG core needle biopsy (CNB), open biopsy, or surgical excision can be considered. However, both CNB and open biopsy are controversial due to the inherent risk of tumor spillage, and it is our belief that a standard parotidectomy approach (or submandibular gland resection) to these lesions, including facial nerve identification and dissection followed by frozen pathologic analysis, is preferred.

If a nondiagnostic sample returns with cyst contents only, complete aspirate of cyst contents under USG is warranted. If a solid component remains after aspiration, the lesion should be resampled. If the lesion disappears completely, ultrasound should be repeated in 3 to 4 months. Repeat FNA at the time of ultrasound surveillance is indicated when there is evidence of a recurrent lesion or if alternative surveillance imaging modalities such as CT or MRI redemonstrate the lesion.

Non-neoplastic

Non-neoplastic lesions of the salivary glands are common.^{13,14} The non-neoplastic category of the MSRSGC consists of benign entities such as reactive, metaplastic, and inflammatory changes associated with acute or chronic inflammation, sialolithiasis, or infection (Fig. 1). The implied ROM for the non-neoplastic category is approximately 10%, with studies ranging from 0% to 20%.^{15–17}

Management of non-neoplastic samples is largely nonsurgical. Patients may be followed closely until there is a change in physical examination or imaging, at which point repeat FNA would be warranted to confirm the cytological diagnosis. It is important to consider USG FNA to decrease inadequate sampling and false negative diagnoses. If FNA findings are insufficient or do not correlate to clinical or radiographic findings, tissue sampling

should be repeated. For reactive lymph nodes, flow cytometry studies are useful to confirm reactive lymphadenopathy and to exclude a low-grade lymphoproliferative lesion.

Atypia of undetermined significance (AUS)

The AUS category represents samples with morphological overlap between neoplastic and non-neoplastic processes, in which a clear distinction between the two cannot be made.¹⁸ The goal of AUS is to reduce the number of false-negative diagnoses in the non-neoplastic category while maintaining the significance of the neoplastic category.¹² The MSRSGC recommendation is that atypical diagnoses comprise less than 10% of all FNA diagnoses.¹⁸ Examples of AUS include reactive and reparative atypia, low cellularity samples suggestive but not diagnostic of a neoplasm, cystic lesions with abundant mucin and/or a scant epithelial component, and salivary gland lesions ambiguous for a lymphoproliferative disorder. The ROM for AUS is approximately 20%.^{16,19–21}

The suggested management of AUS begins with repeat FNA. USG FNA should be utilized if the initial sample was obtained by palpation alone. Cross-sectional imaging may also be used to further characterize these lesions. CNB, open biopsy, or surgical resection should be considered when clinical presentation is concerning for malignancy (e.g., coexisting facial nerve changes or history of cutaneous malignancy). Clinical judgment should guide the interval between follow-up, with 3 to 6 months as a general rule.

Neoplasm

Salivary gland neoplasms make up 6% of all head and neck tumors, with the parotid gland most commonly involved.^{13,15,22–25} The MSRSGC's neoplasm category is subdivided into two groups: 1) benign and 2) salivary gland neoplasm of uncertain malignant potential (SUMP). The general expectation for management of these categories is cross-sectional imaging, followed by tumor resection with a narrow cuff or margin of normal tissue.

Benign—This subcategory is assigned to aspirates whose features satisfy the classical cytomorphologic criteria for benign lesions. Specific examples include pleomorphic adenoma, Warthin tumor, lipoma, hemangioma and schwannoma (Fig. 2). The ROM for the benign neoplasm category is <5%.

Complete resection is generally suggested for benign neoplastic lesions. For parotid gland lesions, cross-sectional imaging should be performed for all lesions, with an exception for very small lesions with clearly palpable borders. Lesions may be excised via either extracapsular dissection or nerve-sparing parotidectomy. Patients who are poor surgical candidates or those who do not accept the risk of nerve injury may be closely followed clinically without surgery. Management of submandibular gland lesions includes cross-sectional imaging, followed by surgical resection of the lesion en bloc, with the submandibular gland in a suprafascial plane, with care and attention to the marginal mandibular branch of the facial nerve to avoid unintended injury.

Salivary gland neoplasm of uncertain malignant potential (SUMP)—The SUMP subcategory designates aspirates for which a specific diagnosis cannot be made, but

cytomorphologic features are consistent with a neoplastic process.^{12,26} Importantly, a malignant neoplasm cannot be entirely excluded with the differential diagnosis for SUMP aspirates including both benign and malignant lesions. The majority of corresponding pathologies will include cellular benign neoplasms, neoplasms with limited atypical features, and low-grade carcinomas. So-called basaloid neoplasms will typically be diagnosed by FNA in this category (Fig. 3). The ROM associated with SUMP aspirates is 35%.

Management with conservative surgical resection is necessary given the increased risk of low-grade malignancy. Intraoperative frozen section can be useful for improved histologic classification, which may also influence the decision for concomitant neck dissection (i.e., for intermediate and high-grade malignancies). For SUMP lesions involving the parotid gland, size and location of the tumor will dictate the type of parotidectomy and approach performed. Nerve-sparing parotidectomy is the most oncologically safe option and preferred by our group. For SUMP lesions of the submandibular gland, suprafascial excision should be performed, with the planned skin incision placed low enough to allow for neck dissection given the higher proportion of malignancy.

Suspicious for malignancy (SM)

Similar to AUS and SUMP, SM is an indeterminate diagnostic category. SM aspirates are highly suggestive of malignant neoplasms, but the cytomorphologic features alone are not definitive. Examples of SM specimens include those with a few markedly atypical cells or those suggestive of lymphoma without an adequate sample for immunophenotyping. Aspirates designated SM carry a ROM of 60% in the MSRSGC, with contributing studies reporting risk as high as 83%.²⁷ Furthermore, the risk of a neoplastic lesion with SM samples is roughly 95%.^{27,28}

Given the high ROM, salivary gland lesions in the SM group require cross-sectional imaging to evaluate extent of disease and staging prior to resection.^{29,30} Metastatic workup with chest imaging should also be performed. For parotid gland lesions, parotidectomy with facial nerve dissection and complete mass excision is required. The patient should also be informed and consented regarding facial nerve sacrifice, which will be dictated by intraoperative findings and frozen section. In this scenario, up-front facial reanimation procedures should also be discussed including, at a minimum, interposition grafting, nerve transfer, static slings, eye lid weight, and conservative measures such as eye care.

Elective, selective neck dissection should be performed for the clinically and radiographically N0 neck for tumors with size greater than 4 cm, high-grade features on frozen section of the primary site, extraglandular extension on imaging or intraoperative findings, or preoperative facial weakness.^{31,32} For SM aspirates with preoperative evidence of neck disease, selective neck dissection should be performed. Extent of dissection is based on location and stage of disease; however, levels II to IV are almost always required. When frozen section is unavailable, final histopathology may be used to guide the decision regarding a staged neck dissection. For all patients, the role of adjuvant radiation therapy versus neck dissection should be made in a multidisciplinary setting to optimize and standardize care.

Management of SM aspirates of the SMG is predicated on clinical and radiographic findings. For benign-appearing SM lesions without nodal disease, suprafascial SMG excision with a low skin incision should be considered, with concomitant selective neck dissection reserved for intermediate- or high-grade malignancies on frozen section. Submandibular gland excision with up-front neck dissection should be performed if cross-sectional imaging suggests a malignant process, frozen section shows a primary SMG malignancy, and pathological nodes are present.

Malignant

The malignant category includes primary salivary gland neoplasms, lymphomas, and sarcomas as well as metastatic carcinomas to salivary gland lymph nodes (Fig. 4). The application of ancillary immunohistochemical or molecular markers can be used to increase the specificity of the FNA diagnosis. To improve clinical management, FNA specimens should be classified when possible as low-grade or high-grade malignancy.^{33–35} For FNA cases where the grade is indeterminate, a definitive grade should not be assigned. The latter group will include a subset of difficult-to-grade, low-grade, and high-grade salivary gland cancers as well as most intermediate grade cancers. Additionally, an attempt should be made to correlate the FNA diagnosis with a specific diagnostic category as described in the 2017 World Health Organization Classification of Head and Neck Tumors.³⁶

After obtaining a malignant FNA sample, management should continue with CT of the neck and chest for staging and surgical planning. For low-grade parotid gland malignancies without neck involvement or other indications for neck dissection, complete excision with nerve-sparing parotidectomy is indicated. For intermediate- or high-grade malignancies, facial nerve dissection, total parotidectomy, and selective neck dissection should be performed regardless of neck status. Again, facial nerve sacrifice and reanimation procedures should be discussed preoperatively as described above.

For low-grade submandibular gland lesions without neck involvement or other indications for neck dissection, suprafascial submandibular gland resection is indicated. For intermediate or high-grade malignancies, suprafascial submandibular gland resection with selective neck dissection should be performed regardless of neck status.

For metastatic lesions with a confirmed origin, management should follow the standard of care based on primary tumor type. Cutaneous primaries often metastasize to intra- and periparotid lymph nodes and require nerve-sparing parotidectomy.^{37,38} A thorough skin examination for primary cutaneous lesions of the face, neck, and scalp (e.g., melanoma, Merkel cell carcinoma, cutaneous squamous cell carcinoma) should be completed by the otolaryngologist and a dermatologist. If a salivary gland lesion is metastatic from an unknown noncutaneous source, positron emission tomography/computed tomography may be indicated to locate the primary site. Selective neck dissection is usually indicated in this population, even when clinically N0, given the advanced nature of this disease.

CONCLUSION

Salivary gland FNA is a useful tool for the preoperative evaluation of salivary gland lesions and for guiding clinical management. The MSRSGC provides an evidence-based, tiered reporting framework for salivary gland FNA that stratifies samples, and therefore patients, based on risk of malignancy. Going forward, increased recognition and implementation of the MSRSGC will also allow for a better understanding of the risk of malignancy associated with salivary gland lesions in different diagnostic categories. Additionally, the ongoing discovery of genetic alterations and judicious use of assays such as immunohistochemistry and molecular testing will continue to increase the specificity of salivary gland FNA. The time for acceptance and implantation of a universal system for reporting salivary gland cytopathology is now. The MSRSGC is already being used by cytology labs internationally. It affords tremendous opportunity to improve patient care through standardized communication, consistent diagnosis, and safe and efficient clinical practice.

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Fig. 1. Non-neoplastic. This salivary gland fine-needle aspiration FNA sample shows features of chronic sialadenitis (Papanicolaou stain, 600 $\times$).

Fig. 2. Neoplasm: benign. This salivary gland fine-needle aspiration sample shows classical features of pleomorphic adenoma (Papanicolaou stain, 400 $\times$).

Fig. 3. Neoplasm: salivary gland neoplasm of uncertain malignant potential. This basaloid neoplasm was diagnosed at resection as a basal cell adenoma (Papanicolaou stain, 400×).

Fig. 4. Malignant. These salivary gland fine-needle aspiration samples show characteristic cytologic features of low-grade mucoepidermoid carcinoma (left: Papanicolaou stain, 600 $\times$) and salivary duct carcinoma (right: Papanicolaou stain, 400 $\times$).

TABLE I.

The Milan System for Reporting Salivary Gland Cytopathology: Implied Risk of Malignancy and Recommended Clinical Management.

Diagnostic Category	Risk of Malignancy (%)	Usual Management*
Nondiagnostic	25	Repeat FNA, clinical and radiological follow-up
Non-neoplastic	10	Clinical and radiological follow-up
Atypia of undetermined significance	20	Repeat FNA or surgery
Neoplasm: benign	<5	Surgery or clinical and radiological follow-up
Neoplasm: salivary gland neoplasm of uncertain malignant potential	35	Surgery
Suspicious for malignancy	60	Surgery
Malignant	>90	Surgery

* Actual management may depend on other factors (clinical, radiographic) besides the FNA interpretation.

FNA = fine-needle aspiration.