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No conflict of interest. No financial disclosures.

Keywords: otolaryngology, oncology, SARS-CoV2

ABSTRACT

Background:

COVID-19 pandemic has strained human and material resources around the world. Practices in surgical oncology had to change in response to these resource limitations, triaging based on acuity, expected oncologic outcomes, availability of supportive resources, and safety of healthcare personnel.

Methods:

The MD Anderson Head and Neck Surgery Treatment Guidelines Consortium devised the following to provide guidance on triaging Head and Neck cancer (HNC) surgeries based on multidisciplinary consensus. HNC subsites considered included aerodigestive tract mucosa, sinonasal, salivary, endocrine, cutaneous, and ocular.

Recommendations:

Each subsite is presented separately with disease-specific recommendations. Options for alternative treatment modalities are provided if surgical treatment needs to be deferred.

Conclusion:

These guidelines are intended to help clinicians caring for HNC patients appropriately allocate resources during a healthcare crisis, such as the COVID-19 pandemic. We continue to advocate for individual consideration of cases in a multidisciplinary fashion based on individual patient circumstances and resource availability.

Introduction

The novel coronavirus (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) causing coronavirus disease 2019 (COVID-19) emerged in December 2019 and has spread on a global level leading to unprecedented health, social, and economical unrest. The virus is spread via respiratory droplets and causes mortality in up to 7% of infected patients[1]. Curative treatment and vaccines are non-existent, and the only protection is the prevention of spread of virus particles. Many asymptomatic patients might be carriers of disease, while current testing paradigms might have false negative rates as high as 40%[2]. As such, all patients and healthcare providers are considered a potential source of disease.

On March 11th, 2020, the World Health Organization (WHO) declared the SARS-CoV-2 outbreak a pandemic[3], at a time when the Center for Disease Control (CDC) reported 1,215 positive cases in the United States[4]. At the time of this report, the United States has reached 395,011 cases[4]. At the current rate of disease progression, intensive care unit (ICU) beds are projected to be at or over capacity with COVID-19 patients across the country. Health institutions in several states have implemented mandatory postponement of elective and/or non-urgent cases to decrease nonessential patient density in hopes of decreasing COVID-19 transmission and preserving hospital resources. As the current pandemic is rapidly evolving, the American College of Surgeons has recommended triaging surgeries according to a three-tier state of hospital resource availibility[5]. In the field of head and neck surgical oncology, postponing a surgery can significantly impact survival due to the increased risk of cancer progression. Furthermore, early reports suggest that cancer patients are at higher risk for COVID-19 associated severe events such as ICU admissions requiring mechanical ventilation or death[6,7].

Given the cancer patients' vulnerability to COVID-19 complications and potential hospital resource limitations, judicious selection of oncologic surgical cases is of utmost importance, not only in an attempt to alleviate the burden on the healthcare system, but also to ensure the safety of patients, their families, as well as their healthcare providers. Ultimately, one must balance healthcare priorities and the risk of cancer progression.

In this report, we outline guidelines based on expert consensus opinions from our experienced multidisciplinary team for the triage and prioritization of head and neck surgical cases in a subsite-specific manner. We present these guidelines to serve as a reference for practicing head and neck clinicians during this serious and unprecedented situation, recognizing that feasibility, pandemic intensity, and resource availability will vary widely geographically and over time.

Methods

The MD Anderson Head and Neck Surgery Consortium incorporates faculty and advanced practice providers from the five subsections of the Department of Head and Neck Surgery at the University of Texas MD Anderson Cancer Center: Head and Neck Surgical Oncology, Head and Neck Endocrine Surgery, Oral Oncology and Maxillofacial Prosthodontics, Ophthalmology, and Speech Pathology and Audiology. In a collaborative effort, the following guidelines were prepared to provide clinicians subsite-specific guidance for triaging surgical case acuity. Expertise was sought from our Radiation Oncology and Medical Oncology colleagues for non-surgical treatment options when surgery could be reasonably deferred, and for patients requiring multi-modality therapy. These guidelines are intended to serve as direction in a time of crisis

such as the COVID-19 pandemic and not as a strategy for permanent change in patterns of practice.

Our weekly Multidisciplinary Planning Conference is currently conducted over a web conferencing platform in accordance with institutional and national social distancing recommendations. When a case is selected for surgery, a case posting request is placed and sent to the Division of Surgery Surgical Posting Committee for daily institutional review. This committee is comprised of surgical department chairs and quality officers, the Operating Room Committee leadership, and anesthesiologists. In Head and Neck Surgery, the guidelines described below are currently being used to assess treatment decisions and to make recommendations to the Division of Surgery Surgical Posting Committee. Approved cases are forwarded to the surgical scheduling team. An institutional bioethicist is available as needed.

Head and Neck Surgery – Treatment/Management Guidelines during the COVID-19 pandemic

The following guidelines based on current expert clinical opinion are provided for management of patients with HNC during the COVID-19 pandemic given the potential limited resources available. Given the acute nature of this clinical dilemma, there is not sufficient time to perform clinical trials for level-one evidence. Our guidelines emphasize surgical treatment of intermediate and advanced disease where nonsurgical options are not available, and *risk of disease progression* would significantly affect patient function or disease outcome.

General considerations

- Ideally, where testing is readily and rapidly available, SARS-CoV-2 testing should be performed on all patients with mucosal lesions prior to HNS evaluation, and/or, at the least, 1 day prior to the planned surgery.
- Selected patients may be closely observed allowing for deferral/rescheduling of surgery.
- Significant functional loss or life-threatening disease requires immediate attention.
- Telemedicine is an essential tool in several medical fields during these times and has been recommended to be used when deemed appropriate by the American Academy of Otolaryngology-Head and Neck Surgery[8].
- At our institution, as a general guideline for scheduling, cases are deferred when performed for prophylactic intent, benign diseases, conditions unlikely to be adversely affected by an 8-12-week surgical delay, or for conditions which have available and appropriate alternative therapies.
- In-depth discussion and review is performed when patients have a severely depressed performance status, high comorbidity burden and/or advanced age, or when surgical cases may require significant blood transfusion (>4 units), ICU care, or a prolonged hospitalization is anticipated.
- While multi-modality input is sought after pre-operatively for patients requiring multi-modality therapy, we suggest deferring all head and neck radiation and medical oncology consultations to when needed to minimize exposure risks, unless neoadjuvant treatment is considered.
- Flexible naso-pharyngo-laryngoscopies are limited to when medically necessary. When performed, they are recorded by the healthcare provider for shared review to eliminate duplicate exposure risk.

SARS-CoV-2 Positive

No resection until viral resolution unless significant functional threat or life-threatening situation as patients testing positive are associated with a high rate of mortality in the post-operative period[9]

- Powered air-purifying respirator (PAPR) equipment required for all involved in the case
- Minimize nonessential personnel in the operating room (trainees, advanced practice providers, visitors, etc.)

SARS-CoV-2 Negative

Patient must pass symptom screening and appropriate testing completed 1 day prior to intended surgery date

Disease Subsites

Oral Cavity (high risk for viral aerosolization)

- Premalignant disease
  - Defer with telemedicine visits
  - Review clinical photographs to help rule out invasive cancer missed by biopsy

- Early malignant disease
  - Consider short-term deferral with weekly telemedicine visits[10]
  - Proceed with primary surgery
  - Continue to monitor while stable; proceed to surgery if primary progresses or if there is any evidence of cervical node involvement

- Intermediate malignant disease
  - Proceed with primary surgery

- Advanced malignant disease

- Consider neoadjuvant systemic therapy (discussion on a case-by-case basis – consider the risk of immunosuppression)

Oropharynx (high risk for viral aerosolization)

HPV status should be identified. As recommended by Topf *et al.*, if necessary, HPV-negative patients should be prioritized[11].

- Early disease
  - Consider short-term deferral with weekly telemedicine visits
  - Favor non-surgical treatment
  - Consider surgical treatment if high likelihood of single modality treatment, depending on the experience of the surgical team and institutional resources

- Intermediate disease
  - Consider deferral with weekly telemedicine visits
  - Favor non-surgical treatment

- Advanced disease
  - Proceed with non-surgical treatment

Larynx/Hypopharynx (high risk for viral aerosolization)

Begin with baseline airway evaluation to rule out risk of aspiration and/or the likelihood of becoming "at risk" for airway obstruction[12]. Nutritional status should also be evaluated, such as the patient's ability to feed by mouth versus being nasogastric/PEG-dependent.

- Early disease
  - Proceed with non-surgical treatment
  - Consider deferral with close-interval telemedicine visits

- Intermediate disease
  - Proceed with non-surgical treatment

- Advanced disease

- Proceed with non-surgical treatment where appropriate
- Primary surgery for patients presenting with advanced cartilage invasion, extra-laryngeal spread, recurrent disease, or high risk for aspiration post chemoradiation therapy
- Favor neo-adjuvant systemic therapy if surgery is indicated to allow deferral past peak incidence of pandemic

Sinonasal and Skull base (high risk for viral aerosolization)

All endoscopic sinus surgery/endoscopic endonasal approaches are considered high risk procedures for viral aerosolization[13], therefore all routine nasal endoscopy and debridement for follow-up should deferred when possible. Patients with inflammatory disease or non-malignant tumors should be deferred. Alternative non-surgical interventions should be considered for patients with active malignancies requiring treatment.

- Intermediate stage tumors
    - Consider for chemoradiation or radiation therapy alone

- Advanced mucosal derived malignancies
    - Sinonasal undifferentiated carcinoma or Squamous cell carcinoma should be considered for neoadjuvant chemotherapy
    - Sinonasal mucosal melanoma should be considered for neoadjuvant immunotherapy or targeted therapy
    - Skull base sarcomas should be considered for radiation therapy

- Low grade and slow growing neuroendocrine carcinoma (NEC) and olfactory neuroblastoma (ONB)
    - Defer and monitor with periodic imaging

- Tumors of minor salivary gland origin

- Defer and monitor with periodic imaging unless rapidly growing

- High grade NEC and Hyams Grade IV ONB
    - Consider neoadjuvant chemotherapy

Patients with unavoidable, emergent surgery (i.e. invasive fungal sinusitis, impending visual or neurological compromise): we recommend full PAPR equipment for all involved in the case and minimize nonessential personnel in the operating room (trainees, advanced practice providers, visitors, etc.).

Salivary Gland

- Low-Grade and/or slow growing intermediate grade
    - Defer to eight-week follow-ups with telemedicine visits

- Recommendations for intermediate grade lesions are determined on a case by case evaluation

- Surgery should be considered in the following cases
    - Pediatric population
    - High-grade malignancies such as salivary duct carcinoma/Carcinoma ex pleomorphic/High-grade mucoepidermoid carcinoma
        - Neoadjuvant systemic therapy may be considered prior to surgery

Sarcoma

- Many low-grade tumors can be observed with serial imaging at 3 months
    - Low to intermediate grade liposarcomas
    - Low-grade chondrosarcomas
    - Dermatofibrosarcoma protuberans
    - Desmoid tumors
- Advanced stage/High grade sarcomas
    - Consider preoperative chemotherapy and/or radiation therapy
    - Evaluate closely for immunosuppression risk
- Osteosarcoma or other sarcomas that are not candidates for preoperative chemotherapy

  (or for extending active preoperative chemotherapy) should proceed to surgery

Cutaneous disease

- Basal cell carcinoma
    - Defer when possible
    - If advanced and/or symptomatic requiring therapy sooner, consider hedgehog inhibitors
- Squamous cell carcinoma
    - Consider deferring wide local excision (WLE) or Mohs by 8-12 weeks, or consider topical options for early stage disease (e.g., imiquimod)
    - If advanced and/or symptomatic requiring therapy sooner, consider neoadjuvant non-surgical therapy (e.g., cemiplimab) to allow deferral past peak incidence of pandemic
- Melanoma (detailed report can be found in the NCCN COVID-19 working group[14])

- Melanoma *in situ*
    - Delay WLE of melanoma in situ for at least 3 months

- T1 melanoma
    - Delay WLE for up to 3 months or consider excision in office/outpatient setting

- Sentinel lymph node biopsy (SLNB)
    - Offer for melanoma >1 mm thickness, but defer SLNB for T1b melanoma (0.8-1.0 mm with or without ulceration), unless high risk features are evident (e.g., lympho-vascular invasion, very high mitotic rate, young patient age [≤40 years])

- T3/T4 melanomas should take priority over T1/T2 melanomas
    - Delay SLNB for up to 3 months, unless WLE in the OR is planned, in which case WLE/SLNB may be performed at the same time

- Stage III (regional nodal) Melanoma
    - As per current NCCN guidelines[15], defer completion lymph node dissection following a positive SLNB, and perform regional nodal ultrasound surveillance (if radiologic expertise available) or other imaging surveillance (CT, FDG PET-CT, MRI), as appropriate

- Defer therapeutic neck dissection in the setting of clinically palpable regional nodes, and offer neoadjuvant systemic therapy immune checkpoint blockade or BRAF/MEK inhibitors instead

- The NCCN Melanoma Panel does not consider neoadjuvant therapy as a superior option to surgery followed by systemic adjuvant therapy for stage III melanoma[15], but available data suggests this is a reasonable resource-conserving option during the COVID-19 outbreak

- Metastatic resections (stages III and IV) should be placed on hold unless the patient is critical/symptomatic and patients should continue systemic therapy

- Merkel cell carcinoma
  - Favor primary radiation therapy
  - Consider starting immunotherapy for locally advanced/locoregional recurrent disease

Endocrine (detailed report by Jozaghi Y, Zafereo M, *et al.*[16])

- Early stage: postpone surgery
  - Primary hyperparathyroidism
  - Indeterminate thyroid nodules without documented progression
  - Medically-controlled Grave's disease
  - Thyroid goiter (very rarely acutely symptomatic)

- Intermediate stage: postpone most surgeries
  - Large indeterminate thyroid nodules (particularly suspected malignancies) with documented progression
  - Differentiated thyroid cancer
  - Medullary thyroid cancer

- Advanced stage: proceed with most surgeries
    - Any thyroid tumor requiring acute airway management
    - Anaplastic thyroid cancer, poorly differentiated thyroid cancer, and some rapidly progressive/clinically aggressive differentiated and medullary thyroid cancers
        - Refer to Jozaghi Y, Zafereo M, *et al*.'s report for additional details on aggressive thyroid cancer management in the time of a pandemic
    - Suspected parathyroid carcinoma with significant symptomatic hypercalcemia
    - Medically-uncontrolled and significantly symptomatic Grave's disease

Mastoid and temporal bone surgery

The mastoid and middle ear mucosa may carry the same risk of viral aerosolization as sinus and nasal surgery due to the connection with the nasopharynx through the Eustachian tube. At a minimum, N95 mask is required for mastoid surgery. PAPR is required for the surgeon and OR staff in patients with SARS-CoV-2 positive status, and this equipment can interfere with the use of an operative microscope. Using an exoscope is an alternative, but this equipment might not be widely available.

- Low-Grade and/or slow growing intermediate grade
    - Defer
- Benign disease
    - Delay surgery for uncomplicated benign disease (e.g. uncomplicated cholesteatoma).

- Complicated benign disease (e.g. coalescent mastoiditis) might require surgical drainage limited to cortical mastoidectomy. Cholesteatoma with progressive facial paralysis generally requires surgical treatment to avoid progression to complete paralysis. This benefit needs to be weighed against the potential hazard and risk to the surgeon and operating room personnel in a COVID positive patient.

- Malignant disease

  - For early stage malignant disease of the ear canal, consider delaying for 4-6 weeks.
  - For advanced stage malignant disease of the ear canal and temporal bone, consider neoadjuvant chemotherapy or immunotherapy.

Dental Oncology

- Defer all elective oral surgical procedures (ambulatory and operating room)
- Continue oral surgery procedures as part of head and neck surgery team procedure (e.g., planned dental extractions)
- Continue fabrication of custom intra-oral stents for radiation therapy
- Emergency cases considered on a case-based assessment

Ophthalmologic Malignancies and Procedures

- Defer all benign cases unless they are sight threatening (certain hemangiomas)
- Defer all low-risk/low-grade malignant tumors such as lid tumors and basal cell carcinomas by 8-12 weeks[17]

- High-risk/higher-grade malignancies should be prioritized as delay is sight- and life-threatening

- Melanoma; retinoblastoma; rhabdomyosarcoma; choroidal metastasis
- Retinoblastoma and orbital rhabdomyosarcoma are of highest risk and surgery should be prioritized as delay is sight and life threatening
- Continue with ocular brachytherapy for selected cases

- Other surgical procedures that should be considered due to risk of blindness[18]

  - Temporal artery biopsy
  - Orbital decompression
  - Vitrectomy
  - Retinal detachment repair[19]

Discussion/Conclusion

The Institute of Medicine has established the goals of quality-based healthcare: safe, effective, patient-centered, timely, efficient and equitable for all patients[20]. In our head and neck program, we strive to provide patients with highly coordinated and efficient care. However, the current pandemic has significantly impacted our ability to meet these goals for care delivery. An urgent effort was needed to mitigate the impact of the pandemic on patient care requiring an assessment of our available resources in the context of this widespread communicable disease.

Using these guidelines has led to a significant shift in the management of head and neck cancer patients at our institution[21]. Advanced oral cavity lesions requiring a mandibulectomy and/or maxillectomy currently represent the majority of head and neck surgical cases. More in depth analyses on the overall effect of the COVID-19 pandemic on surgical volume, case deferral, and use of alternative therapeutic options are being described in the literature[21,22] and are beyond the scope and purpose of this current report. These recommendations are intended to provide a concise set of guidelines for the practicing head and neck clinician during a healthcare crisis,

such as the COVID-19 pandemic, and may serve as a foundation to be modified in the event of future pandemics. Furthermore, these guidelines should be used in the context of individual institutional priorities, healthcare personnel safety, pandemic intensity, and availability of resources. Lastly, we continue to advocate for consideration of individual cases in a multidisciplinary fashion based on patient circumstances, and risk of disease progression.

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