HN Cancer Care Guidelines during COVID-19 Epidemic

Kaiser Permanente Northern California

Permanente Medicine Head and Neck Surgical Oncology

Cancer Care Guidelines during COVID-19 Epidemic

Sunday, March 22, 2020, 2 – 3:30pm TEAMS Meeting

Attendees: Deepak Gurushanthaiah, Kevin Wang, Seo Moon, Fidelia Butt, Levi Ledgerwood, Thomas O'Toole, Bryan Fong, Charles Meltzer

Background:

COVID 19 information is evolving daily.

There is growing information to suggest that HNS surgery puts surgeons and the operative team at higher risk for infection. Otolaryngologists are at the highest risk for infection. New data shows that viral load in asymptomatic patients is similar to the viral load in symptomatic patients. Higher viral loads were noted in the nose compared with the throat.

Each surgical case puts at least 9-10 members of the health care team at risk

Purpose of meeting:

Formulate regional plan for head and neck oncologic surgery in the COVID era to optimize patient care, minimize risk to health care team and preserve resources

Agenda:

- Identify high risk vs low risk COVID transmission cases
- Review latest strategies to address COVID 19
- Review latest intubation protocol
- Identify urgent oncology cases that should proceed
- Identify non urgent HN cases that can be deferred
- Tracheotomy vs Intubation for oncology cases
- Resident involvement
- Head and Neck Cancer Case Conference Modifications

HN Cancer Care Guidelines during COVID-19 Epidemic

1. **Assessing High Risk vs Low Risk for COVID19 Transmission**
    a. Low risk: Non-mucosal surgery
        i. Neck dissection
        ii. Thyroid/parathyroid surgery
        iii. Salivary Gland surgery
        iv. Skin cancer resection
    b. High risk: Mucosal surgery
        i. Oral cancer resection
        ii. Oropharyngeal cancer resection
        iii. Laryngeal cancer resection
        iv. Sinonasal cancer resection
        v. Tracheotomy
        vi. Temporal bone resection
    c. **All cancer patients should be called 48 hours prior to surgery to confirm absence of fever, cough, malaise, hyposmia and for discussion of RBA of surgery in COVID setting**

2. **Review of Current Strategies external to KP NCAL to Mitigate Risk of Transmission**
    a. Stanford Rhinology/Neurosurgery Position statement (not head and neck oncology)
        i. 2 COVID negative tests separated by 24 hours, PAPR's for positive cases
        ii. N95, face shields, gowns for all endoscopies
    b. Stanford Head and Neck Oncology (John Sunwoo-Stanford Town Hall)
        i. No testing
        ii. N95 and face shield for "high risk" cases
        iii. High risk cases defined as surgery involving mucosa
    c. UCSF communication (Patrick Ha)
        i. No testing
        ii. No special PPE
    d. KP Southern California (Peter Martin, Seo Moon)
        i. No testing to date but plan to test patients for occult COVID disease going forward (PM)
        ii. 1 COVID test 48 hours preop (per Seo)
        iii. PAPR for untested (per Seo)
    e. Mount Sinai
        i. 2 COVID tests
        ii. N95 masks for all cases
        iii. No residents

Xiao Zhao, University Toronto, MD Anderson via Seo Moon

Recommendations for COVID19 Testing for Upper Aerodigestive Procedures Across Institutions

Princess Margaret Cancer Centre/UHN	Stanford	Michigan	Indiana	LSU	UK ENT guidelines	Portland VA	Singapore
48 hours prior **ANY** surgery of the upper airway	Prior to **ANY** surgery of the upper airway	48 hours prior **ANY** surgery of the upper airway	48 hours prior to **ANY** surgery and 2 negative tests 24 hours apart for tracheostomy	Prior to **ANY** surgery of the upper airway	All patients prior to elective trach	All patients prior to elective trach	Patients with fever or pneumonia

Recommendations for COVID19 Status Unknown Upper Aerodigestive Procedures

	Princess Margaret Cancer Centre/UHN	Stanford	Michigan	Indiana	LSU	Hong Kong	Singapore
Emergent Tracheostomy*	N95	PAPR/N95	PAPR/N95	PAPR	N95 until PAPR becomes available	N95	N95
Urgent mucosal cases (cancer)*	N95	PAPR/N95	PAPR/N95	PAPR	N95 until PAPR becomes available	N95	N95
Outpatient procedures (Nasal endoscopy)**	NA	N95	N95	N95	Clinic closed	N95	N95

*** Additionally require eye protection (face shield/goggles), gloves, and level 3 gown**
**** Additionally require eye protection (face shield, goggles), gloves, and gown**

f. Kaiser Permanente Northern California
   i. No testing (efficacy of testing asymptomatic patient is unknown per David Witt)
   ii. N95 or CAPR/PAPR for all members of the OR team or all airway cases.

PPE	Need loupes	Need microscope	Need headlight
N95	Y	Y	Y
CAPR/PAPR	Y	N	N

g. Question: Is preop COVID testing indicated for high risk surgeries?
    i. Is it feasible? How many? Will it alter the decision to operate?
    ii. Outcomes of testing
        1. If positive testing, wait 10-14 days to see if symptoms/serious infection develops (undergoing major HN resection may be detrimental in the setting of evolving COVID disease); Consult with ID regarding timing of future surgery
        2. If negative, proceed with surgery. Airway surgery: N95/PAPR/CAPR. Non airway: regular PPE
    iii. **Consensus: Single COVID testing is recommended for high risk procedures 48 hours before surgery pending availability of testing. If testing not available, surgery should not be delayed.**

3. Intubation strategy:

a. N95 with a face shield for intubation for anesthesiologist/CRNA and assisting provider (Circ RN). Just leave it on the entire case to avoid need to doff and use more PPE.
b. **Immediately prior to intubation:** The rest of the team should be outside the door for **20 minutes** before entering the OR. After this 20 min delay, okay to enter with normal contact/droplet precaution (ie- gown/mask/gloves) for non-airway cases. N95 or PAPR should be used for airway cases.
    i. Reason: after an aerosol generating procedure (AGP), the airborne pathogen could be present. Based on the OR air exchange per hour, 99% of pathogens should be clear in 14 min, and 99.9% by 21 min.
c. **Immediately prior to extubation**: Patient is moved to a gurney, all other staff/surgeons leave the room, everyone except the anesthesia provider and the Circ RN (both whom should have their original N95 in place. **For possible compromised airway, the HN surgeon will stay in the room until extubated and airway is stable.**

4. Identification of urgent oncologic cases that should PROCEED

a. COVID epidemic likely to be active for at least 2-3 months.
b. Cases in which a worse outcome is expected if surgery is delayed more than 6 weeks.
    i. SCCA of the oral cavity, oropharynx, larynx, hypopharynx
    ii. Cancers with impending airway compromise
    iii. Papillary thyroid cancer with impending airway compromise, rapidly growing, bulky disease
    iv. High grade or progressive salivary cancer
    v. T3/T4 melanoma (see new recommendations for treatment of melanoma)
    vi. Rapidly progressing cutaneous SCCA with regional disease

vii. Salvage surgery for recurrent/persistent disease
viii. High grade sinonasal malignancy without equally efficacious non-surgical option

c. **If non-surgical therapy is equivalent to surgery + radiation, non-surgical therapy is recommended. (i.e. p16 disease)**

5. **Urgent Thyroid/Parathyroid Surgery that should PROCEED**
    a. Graves' disease non-responsive to anti-thyroidal meds
    b. Large or substernal goiter with airway compression less than 1 cm tracheal diameter
    c. Hyperparathyroidism non-responsive to medical treatment with normal renal function and patient in crisis
        i. Ca >13

6. **Identification of non-urgent cases that should be DEFERRED**
    a. Well differentiated thyroid cancer without metastases or impending airway involvement
    b. Previously treated well differentiated thyroid cancer patients with increasing thyroglobulin levels
        i. Observe or treat with I-131
    c. Low grade salivary gland neoplasm, including benign and low-grade carcinomas
    d. Most melanomas, melanoma in situ (see new NCCN guidelines regarding margins, sentinel node biopsy)
    e. All benign disease (nerve tumors, paragangliomas, lipomas, etc)
    f. Cutaneous squamous cell carcinoma without regional disease
        i. Consider office procedure
    g. Cutaneous basal cell carcinoma

7. **Tracheotomy vs intubation for flap cases**

Airway Management	Pro	Con
Tracheotomy	Don't need ventilator Reduce need for critical care	Increased secretion exposure to hospital workers Increased risk of viral infection via trach
Intubation	Reduced risk of secretion exposure to staff	Need ventilator Need critical care

	Reduced risk of viral infection?	

a. Develop protocols at each facility to develop step down units or floor to accept tracheotomy

8. Resident Training, Involvement

a. Cases should be done with minimal number of assistant residents
b. Consider alternative forms of education as a supplement
    i. Case discussion, reviews
    ii. Record surgery if possible, review after surgery

9. Head and Neck Cancer Case Conference Modifications

a. Minimize contacts
    i. Consider using telephone encounter if appropriate information is present in chart to allow clinical decision making
    ii. 1 health care provider (HNS attending) in room
    iii. Limit visit to physical exam
    iv. Use pre and post visit TAV to obtain history and discuss treatment options
    v. Single person performing endoscopic exam in full PPE
        1. Defer endoscopy if adequate photos taken
b. Documentation
    i. Document if standard recommendations are modified due to COVID
    ii. Document whether surgery is urgent or can be deferred
    iii. Document time frame for surgery
c. Review cases scheduled for the next week to determine candidacy for surgery at Oakland, Walnut Creek, Santa Clara, South Sacramento

10. Surveillance

a. Conversion of Office Visits to Telephone visits
    i. Office visits for patients with concerning symptoms
b. Defer imaging routine imaging, lab testing in asymptomatic /stable patients to next cycle in follow up schedule (q3 mos year 1&2, q6 mos year 3&4, and then yearly)**.**
    i. Proceed with standard imaging for new patients or symptomatic patients under surveillance
c. Defer scoping in asymptomatic/stable patients to next cycle in follow up schedule.
    i. If scoping is necessary, use n95, googles/face shield, plastic gown

11. Palliative Care (from Jed Katzel)

a. For palliative treatments, particularly those on palliative systemic strategies, several modifications that reduces utilization and potential patient exposure during treatment may be considered. In particular, palliative nivolumab may be changed to every 4-week therapy. Some patients who have stable or well controlled disease may elect to postpone treatment based on discussion with their treating team.

12. Appendix – New NCCN guidelines for Cutaneous Melanoma Management

Short-term Recommendations for Cutaneous Melanoma Management During COVID-19 (Contributions from City of Hope, Cleveland Clinic, Fred Hutchinson Cancer Research Center/Seattle Cancer Alliance, Huntsman Cancer Institute, Massachusetts General Hospital, MD Anderson Cancer Center, and Stanford Cancer Institute)

PRIMARY CUTANEOUS MELANOMA (CM): Diagnostic Biopsy: • Attempt excisional/complete saucerization biopsy whenever possible with intent to remove the clinical lesion. Histologic transection of the in-situ component at the peripheral margin is of less consequence. • Broad (more superficial) shave biopsy should be performed for larger suspected melanoma in situ, lentigo maligna type lesions, i.e., melanoma on chronically sun damaged skin (CSD melanoma). • Arrange telehealth evaluation for new patients whenever possible; complete H&P on the day of surgery if needed.

Wide excision (WE) of in situ and invasive melanoma: • Delay WE of melanoma in situ (MIS) for at least 3 months. • Delay WE for up to 3 months for invasive melanomas of any depth, for which previous biopsy had clear margin or histologic peripheral transection of the in situ component. • Delay WE for T1 melanoma (≤1 mm thickness) for up to 3 months even for positive margin on biopsy, as long as the biopsy removed the majority of the lesion. Otherwise, perform complete/excisional biopsy with narrow surgical margins or elliptical excision with 1 cm surgical margins in the office/outpatient setting. • Depending on OR capabilities, offer sentinel lymph node biopsy (SLNB) for CM >1 mm thickness, but defer SLNB forT1b 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], or a combination of these factors). • Surgical management of T3/T4 melanomas (>2 mm thickness) should take priority over T1/T2 melanomas (≤2 mm thickness). The exception is any melanoma that is partially/incompletely biopsied in a which large clinical residual lesion is evident. Gross complete resection is recommended this case. • Delay SLNB for up to 3 months, unless WE in the OR is planned, in which case WE/SLNB may be performed at the same time. • Conduct all follow-up visits by telehealth with patient images sent to the provider (preferably using EHR systems in place). STAGE III (REGIONAL NODAL) MELANOMA: • As per current NCCN guidelines, 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 surveillance imaging (US, CT, FDG PET-CT, MRI) for 3-6 months in asymptomatic, surgically resected patients, who are not on systemic therapy. Delay for 3 months for those who are clinically NED but on systemic adjuvant therapy. • Defer therapeutic lymphadenectomy in the setting of clinically palpable regional nodes and offer neoadjuvant systemic therapy immune checkpoint blockade (ICB) or BRAFi/MEKi 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, but available data suggests this is a reasonable resource-conserving option during the COVID-19 outbreak. • Neoadjvuant considerations include higher-dose pembrolizumab (400 mg IV x 1-2 cycles every 6 weeks), two cycles of nivolumab (480 mg IV every 4 weeks), BRAFi/MEKi x 8 weeks followed by surgery, or two cycles ipilimumab 3/mg/kg and nivolumab 1 mg/kg (or ipilimumab 1 mg/kg and nivolumab 3 mg/kg) pre-operatively. Surgery should be performed 8-9 weeks after initiation of neoadjuvant therapy. Short-interval monitoring with imaging (ultrasound, if available, vs CT, FDG PET-CT) may be indicated. For patients with clinical and/or radiologic response, consider ongoing immunotherapy over surgery. • Metastatic resections (stages III and IV) should be placed on hold unless the patient is critical/symptomatic (assuming the hospital is not over capacity and the ORs are running); patients should be continued on systemic therapy. • For clinical surveillance of stage III patients who are not on therapy, may delay oncologic surveillance visit up to 3-6 months and/or conduct by telehealth, per physician discretion.

Stage III adjuvant therapy: • May initiate up to 12 weeks from time of surgical resection of melanoma. • Choose regimens that are the least taxing on the health system and patient. With less frequent clinic visits/infusions, telehealth interval symptom checks by staff are recommended. Options include: • Nivolumab 480 mg IV q 4 weeks x one year • Pembrolizumab, 200 IV q 3 weeks x one year • Pembrolizumab, 400 mg IV q 6 weeks x one year (Lala et al, ASCO 2018, Abstr 3062) • BRAFi/MEKi as per current NCCN cutaneous melanoma guidelines • While dabrafenib/trametinib is the evidence-based option, alternative BRAFi/MEKi regimens (encorafenib/benimetinib or vemurafenib/cobimetinib) may be substituted if drug supply is limited.

STAGE IV MELANOMA: • Carefully consider the toxicity of the regimen selected; decisions about ICB should be individualized, with preference for agents with the lowest toxicity profile. • It is currently unknown how patients infected with SARS-CoV-2 on ICB will react to the expected immune-related adverse events (irAEs). It is possible that patients on ICB could

experience more severe treatment-related adverse events during their treatment course. • Single agent PD-1 should be considered for every patient without brain metastasis. • Nivolumab/ipilimumab combination induces grade 3-4 irAEs more than twice as often as PD-1 monotherapy, frequently necessitating the use of high-dose and prolonged steroid or other immunosuppressive agents. Therefore, decisions about combination vs monotherapy need to be tailored to patient characteristics and with awareness of constrained capacity to manage toxicities. • A regimen of ipilimumab 1 mg/kg and nivolumab 3 mg/kg every 3 weeks for 4 infusions, with subsequent consideration for nivolumab monotherapy, is associated with lower rates of immune-mediated toxicity compared to the FDA standard.

Stage IV melanoma with brain metastasis: • Nivolumab/ipilimumab combination has a high rate of intracranial durable responses (55%), comparable to the extracranial activity of these agents. The

risk of irAEs is the same as patients without brain metastasis and may be lessened by the alternate dosing of ipilimumab 1 mg/kg and nivolumab 3 mg/kg in the 4 cycles of induction therapy. • In patients with BRAF-wild type melanoma, this may be the most reasonable approach for patients with small (<2-3 cm), asymptomatic metastases who do not require steroids for perilesional edema. • Patients with larger, symptomatic and/or steroid-dependent metastases should receive stereotactic radiosurgery (SRS) as a component of initial therapy (ideally first), and come off steroids, followed by single-agent PD-1 blockade. • Whole brain radiation therapy is not recommended for melanoma metastatic to the brain. • For patients with BRAF V600-mutated melanoma and brain metastasis, consideration should be given to BRAFi/MEKi, with an intracranial response rate of up to 58%. However, clinicians should take into account that the duration of response is limited, with median PFS around 5 months

General recommendations related to drug supply: • The melanoma panel recognizes that drug resources may become limited over the course of the pandemic, and therefore we can make the following recommendations: • Encorafenib/benimetinib or vemurafenib/cobimetinib combinations can be substituted for dabrafenib/drametinib in the adjuvant setting. • Single agent BRAF inhibitors can be used in the event of MEK inhibitor shortages. • For patients progressing beyond standard ICB and targeted therapy: • Hospice care conversation is recommended since chemotherapy is only of limited benefit and palliative in nature. • Oral temozolomide is the preferred option if palliative chemotherapy treatment is selected as it would limit resource utilization and contact with the medical system. For other regimens please refer to the current melanoma guideline version.