SAGES – AHPBA Recommendations for Surgical Management of HPB Cancer Patients During the Response to the COVID-19 Crisis

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Note: these recommendations are subject to change and update.

Introduction

The care for all patients with cancer requires multidisciplinary review and decision-making, and entails the consideration of many factors in order to develop a sound plan of treatment. This requires a detailed assessment of patient, disease, surgical team, and hospital resources. (1) These principles remain critical and in fact, arguably more important now as we combat the COVID-19 pandemic than ever before. Thus a "one size fits all" recommendation would be unwise due to significant variability in patient presentation, individual comorbidities, disease severity, regional pandemic burden, and hospital-regional resources. It is important to recognize this document presents general recommendations. These are meant to be helpful to the surgeon while recognizing that the individual surgeon and patient will need to decide upon the course of therapy depending on local resources and individual situations.

The recommendations below are aimed to help guide practicing surgeons by providing a framework to address more urgent cancer cases, and to help stratify options that may diminish risk and improve outcomes. To address these concerns, we refer to several resources including the Elective Surgery Acuity Scale (ESAS) (2) as published by the American College of Surgeons (ACS).

As each surgeon assesses their patient, it should be kept in mind that at of the date of this publication, no region in the USA is thought to have peaked in this epidemic. Thus, conditions are expected to get worse before improving. Having said that, when areas experience a "flattening of the curve", some non-emergent surgeries may be considered.

ESSENTIAL POINTS TO HELP WITH CANCER CARE TRIAGE

Important Considerations for all Cancer Patients:

1. The **comorbidities and age** of the patient are paramount in assessing the relative risk and benefit of exposing the patient to coronavirus versus pursuing alternative, next-best options such as neoadjuvant chemotherapy prior to operation.
2. The **resources** available to the surgeon and hospital at the time of assessment are also critical. Since this pandemic is dynamic in terms of patient acuity, volume, and hospital resources, the current state and immediate potential future state of the hospital system at the time of the proposed operation and anticipated postoperative inpatient recovery needs to be considered.

COVID-19 PHASE of Hospital or Healthcare System:		
Phase	**Condition**	**Description**
0	**Unaffected**	No COVID-19 patients, hospital operating as normal
I	**Semi-urgent**	COVID-19 patients are in the hospital, but resources and ICU beds/ventilators are not threatened

II	**Urgent**	Many COVID-19 patients are in the hospital, ICU beds/ventilator availability is strained and operative and/or PPE resources are limited
III	**Emergent**	Crisis situation where most ICU/ventilator resources are directed to COVID-19 patients and operating room and/or PPE equipment are minimally or entirely unavailable

3. The **urgency of the operation** proposed. Most hospital systems are endorsing that, as hospital resources allow, patients with cancer should undergo curative resection if delaying surgery by more than 3 months will adversely impact tumor and oncologic outcomes.
4. **Testing for coronavirus prior** to operation is strongly encouraged, contingent on testing availability. This is encouraged as a precaution for your patients who may be about to become ill, as well as for staff and the surgical provider, who need to be stewarded as fundamental workforce resources for our patients. A complex surgical procedure will likely affect a patient's immune system, and deferral should be considered for COVID-positive patients until the COVID disease process has stabilized.
5. **Open surgery and minimally invasive approaches** - Consideration should be given when performing open, laparoscopic or robotic surgical approaches to risks of aerosolization of the virus. As long as the patient is negative for the virus either approach is appropriate. However, for patients who are positive for the virus and require more urgent operation, each approach has its own considerations. Concerns exist regarding potential viral contamination with pneumoperitoneum during laparoscopic and robotic surgery. Even though there is no clear evidence it occurs with COVID-19, the risk cannot be overlooked and there are ways of mitigating the risk as we previously described (see link below). During open surgery, the risk of viral spread within the plumes generated by electrosurgery or other energy sources is also to be considered. Robotic approaches in confirmed or suspected COVID-19 patients also had the added consideration of potential contamination of the robotic equipment. https://www.sages.org/resources-smoke-gas-evacuation-during-open-laparoscopic-endoscopic-procedures/ https://www.sages.org/recommendations-surgical-response-covid-19/
6. **Likelihood for need of ICU -** Patients who are expected to require significant time in the hospital, or have a higher risk of peri-operative complications potentially requiring ICU or step-down unit/telemetry services that may be needed for acutely ill COVID patients, should be have their operation timed to avoid surge resource constraints and contamination, if possible.
7. **Length of time for recovery** - The benefits of MIS surgery with reduced hospital stay and higher rate of discharge to home, rather than a nursing home, should be considered in planning surgical approaches. (3, 4)

8. **Consenting the patient for surgery –** The potential risks and implications of doing surgery during the COVID-19 pandemic, particular to the local institution, should be clearly discussed with the patient and family when obtaining consent for surgery.

General management strategies for patients with cancer during COVID-19 pandemic (Tier-based):

Generally, cancer patients require resources and support services that are typically stressed during pandemics. Further, early reports in this pandemic show that viral infection with COVID-19 tends to be specifically more lethal in cancer patients (5). This highlights that surgeons and systems must recognize that all cancer patients are in a high-risk category.

Tier 1a	Tier 1b	Tier 2a	Tier 2b	Tier 3a	Tier 3b
Low acuity surgery/healthy patient *Outpatient surgery* *Not life-threatening illness*	**Low acuity surgery/unhealthy patient**	**Intermediate acuity surgery/healthy patient** *Not life threatening but potential for future morbidity and mortality.* *Requires in hospital stay*	**Intermediate acuity surgery/unhealthy patient**	**High acuity surgery/healthy patient**	**High acuity surgery/unhealthy patient**

Modified from COVID-19: Guidance for Triage of Non-Emergent Surgical Procedures. American College of Surgeons, Clinical Issues and Guidance (2)

General comments on cancer patients as they relate to the ESAS tier system:

- **Tier 3a or 3b (ESAS):** All patients in this Tier should undergo appropriate procedures to remedy their urgent or emergent condition.**
- **Tier 2a or 2b (ESAS):** The majority of cancer patients will fall in Tier 2. The guiding principle here is that these patients will require multidisciplinary input (done virtually as needed), and also that the surgeon carefully assess all variables listed above. Patients falling in the high-risk category, i.e. personal high-risk features or high-risk due to environment and resource issues (as outlined by the considerations above), should preferentially be offered non-operative alternative measures in-lieu of surgery. If surgery cannot be avoided, measures to reduce inpatient LOS are recommended.***
- **Tier 1a or 1b (ESAS):** All patients in this Tier are considered elective and should be delayed until pandemic is stabilized, resources are rebalanced, and risk is returning to baseline levels.

***When multiple options exist, especially for Tier 3b, the surgeon is encouraged to choose the treatment option that minimizes use of resources and decreases risk to patient and healthcare. (1)*

****Disease site specific non-operative alternative measures are outlined below.*

Site Specific Recommendations:

II. Management strategies for patients with Hepato-Pancreatic-Biliary (HPB) cancers during COVID-19 pandemic:

Generally, surgeons are encouraged to avoid operative management of HPB oncologic surgery in high risk patients (see variables noted above) until locoregional pandemic status improves. It is worth noting that following the recommendations below may result in an endoscopic procedure, which harbors the risk of aerosolization, in-lieu of operative management. This is thought to be appropriate since it protects the overall resources used to manage patients in this pandemic. It goes without saying that healthcare providers performing any high-risk procedure should be equipped and follow strict PPE precautions as outlined in other recommendations. [https://www.sages.org/recommendations-surgical-response-covid-19/]

In the table below are various treatment options that are employed in treating HPB disease.

Treatment options in the HPB cancer patient include:	
Liver	• Resection (MIS, Open) • Transplantation • Chemotherapy • Ablation (percutaneous, MIS, open) (thermal, non-thermal) • Embolic therapies (radio-embolization, TACE) • Radiosurgery • Biliary stents
Pancreatico-Biliary	• Resection (MIS, Open) • Transplantation (biliary) • Chemotherapy • Radiation therapy • Targeted & immunotherapies

The clinical presentation of the patient along with the stress on hospital resources by the COVID-19 patient volume will determine the best treatment option. While surgery has maintained its primacy in the treatment of HPB cancers, there are clearly roles for each of the above therapies, which may offer a preferred "next-best option" depending on the COVID-19 Phase of the hospital. For the purpose of this discussion we will exclude COVID-19 Phase 0 situations as that essentially falls into a business as usual category.

Treatment of common HPB conditions as it relates to COVID PHASE of Hospital or Healthcare System (see above for phase description):				
Organ	**Clinical Situation**	**Phase I**	**Phase II**	**Phase III**
LIVER	HCC (12) Very early stage(0)/ Early Stage (A) / < 3cm * *For later stages consider TACE, Medical therapy, supportive care as appropriate (e.	Consider ablation/resection/transplant as appropriate	Consider TACE, ablation, or observation (ie delay of definitive tx)	
	Colorectal mets (13, 14)	Consider chemotherapy (Tier 2b or greater) vs resection (Tier 2a)	Chemotherapy	

Organ	Clinical Situation	Phase I	Phase II	Phase III
BILIARY 15	Intrahepatic cholangiocarcinoma	Consider chemotherapy (Tier 2b or greater) vs resection (Tier 2a)	Consider chemotherapy, embolic therapy	
	Hilar cholangiocarcinoma	Stenting as indicated. resection, transplantation as indicated	Stenting as indicated. consider chemotherapy, chemoradiation, and/or transfer*	
PANCREATIC AND EXTRA-HEPATIC BILIARY 16,17,18	Resectable	Resection or consider chemotherapy	Neoadjuvant chemotherapy	
	Borderline	Neoadjuvant chemotherapy		
	Pancreatic IPMN, Cysts, low-mod grade neuroendocrine neoplasms	All: observation (i.e. delay surgical management) Neuroendocrine: if metastatic or progressing, consider targeted therapy		

**transfer to a facility in a region in Phase 0 - II*

Patients who have completed neoadjuvant treatment and are waiting for surgery - these patients are difficult to manage although from last chemotherapy to operation there is a window of up to 12 weeks during which surgery can be planned without losing the opportunity for potential cure. For some patients, consider discussing with the medical oncology team about adding an additional 1-2 cycles of chemotherapy to bridge the patient through the worst of this crisis and plan surgery thereafter (17). Alternatively, patients with borderline tumors who have completed their induction short course chemotherapy can undergo chemoradiation as indicated.(18)

General Comment

Optimally managing cancer patients within the confines of limited medical resources is a hurdle rarely encountered in modern times in the USA. Never before has our Hippocratic Oath come more into play. This document will be updated as new scenarios or suggestions are posted. Again, it is of paramount importance to recognize these as general recommendations are meant to be helpful to the surgeon, while recognizing that the individual surgeon and patient will need to decide upon the course of therapy depending upon local resources and individual situations.

We will all make difficult decisions and all stand behind one another, as we should always strive to do. Prioritizing the patient's needs and wishes, the family, and standing by them in the surgeon-patient relationship whatever course is necessitated, remains our professional calling and commitment.

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