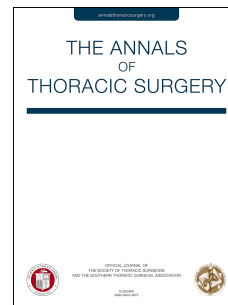


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COVID-19 Guidance for Triage of Operations for Thoracic Malignancies: A Consensus Statement from Thoracic Surgery Outcomes Research Network

Thoracic Surgery Outcomes Research Network, Inc



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COVID-19 Guidance for Triage of Operations for Thoracic Malignancies: A Consensus

Statement from Thoracic Surgery Outcomes Research Network

Running Head: COVID-19 Triage Guidelines

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Abstract:

The extraordinary demands of managing the COVID-19 pandemic has disrupted the world's ability to care for patients with thoracic malignancies. As a hospital's COVID-19 population increases and hospital resources are depleted, the ability to provide surgical care is progressively restricted - forcing surgeons to prioritize among their cancer populations.

Representatives from multiple cancer, surgical and research organizations have come together to provide a guide for triaging patients with thoracic malignancies, as the impact of COVID-19 evolves as each hospital.

The COVID-19 pandemic has forced hospitals to progressively reduce surgical volumes to both minimize disease transmission within the hospital, and to preserve human and Personal Protective Equipment (PPE) and other resources needed to care for COVID-19 patients. In response, many hospitals have abruptly reduced or eliminated elective surgeries. As the COVID-19 burden on a hospital increases, procedures that improve survival may similarly have to be reduced or eliminated (i.e. semi-elective, urgent, and perhaps some emergent operations). For some cancer patients, surgery may be delayed for months, or even years without negative consequences. However, in other scenarios, failure to perform an indicated cancer surgery in timely fashion may have long term implications on a patient's survivorship or significant permanent deficits in their quality of life. Therefore, cancer patients and the oncology teams that treat them are likely to face difficult decisions between suboptimal management strategies. Thoracic oncology decisions are further complicated by the fact most of the patients with lung, esophageal and other thoracic malignancies would be considered to be a "high risk" group for poor outcomes with COVID-19 (advanced age, emphysema, heart disease). Further, the indicated therapeutic procedures can both impair lung function (i.e. lung isolation, removal of lung tissue), and expose clinical teams to aerosolized viral load (bronchoscopy, double-lumen endotracheal tube placement, airway surgery, laparoscopy and possibly lung surgery particularly with parenchymal lung leaks). We have assembled a document to offer guidance, intended to facilitate these difficult decisions when caring for patients with thoracic malignancies during the COVID-19 pandemic (Table 1).

Assumptions

Much of the impact, timeline, duration, risks and ultimate recovery from the COVID-19 pandemic remain unknown. In an effort to give context to this triage guide, several assumptions have been made:

- Risk of nosocomial infection (patients and clinicians infected while in hospital)¹⁻⁵ and competition for resources (surgical and medical patients) will increase in proportion to the prevalence of hospitalized COVID-19 patients
- The duration of restriction on elective surgery will last approximately *3 months*
- Each facility's progression through the phases of care restriction will be variable, but surgeons should be prepared for rapid changes in hospital status (i.e. consider what eligible surgeries could or should be performed as soon as possible)
- Surgical leadership are provided with daily updates regarding a hospital's COVID-19 population and resource status

Process of priority status determination for individual patients

There are nuances to each patient's management approach (i.e. proceeding with surgery, delaying surgery, or pursuing alternative treatment) that will impact risk tolerance for both patient and surgeon. Ideally, when traditional cancer treatment is not logistically feasible, a patient's care plan will be made with input from a group of clinicians with expertise in thoracic malignancies (i.e. case conference or tumor board). We encourage the use of this multidisciplinary strategy as guidance as appropriate for each individual hospital or clinic

setting. Several considerations may cause a group's consensus approach to differ from what is proposed in Table 1:

- Risk of delay may not be specifically captured by the outlined descriptors (i.e. tumor may have aggressive growth kinetics or histology).
- Resource limitations (clinicians, supplies, facilities) affecting surgical, medical and radiation oncology departments may pose heterogeneous restrictions from hospital to hospital
- Clinicians will need to keep in mind the important concept of social distancing in modifying management to limit the number of visits to the hospital for any reason.

In addition, because the duration of surgical volume restriction is unknown (3 months is presumed), patients who are delayed or deferred should be tracked (i.e. a patient registry or database). Considerations for the database should include the following:

- Indication if reassessment during the period of delay could influence care plan (i.e. follow up CT scan). This should be extremely selective, as access to imaging will likely be increasingly restricted with increased COVID-19 prevalence.
- An indication of case priority (i.e. first group, second group, third group) for rescheduling when restrictions are lifted, to best care for patients whose survival may be most impacted by additional delay.
- Alternative treatment strategies employed in lieu of surgical resection (i.e. systemic chemotherapy, SBRT or other ablative strategies, palliative stent placement, etc.) should also be tracked

Disclaimers

This guidance document is meant to serve patients based on estimates of risk for *average* patients (in terms of tumor behavior, patient health, hospital resource availability) associated with each strategy.

- These should not be considered rigid guidelines. This guide is not intended to supplant clinical judgement or the development of consensus regarding institutional approaches to cancer treatment. There is a great deal of uncertainty around this evolving pandemic and information may change rapidly.
- Critical portions of the transition are not addressed. In reality, there is likely to be a Phase “1a”, “1b”, “1c”, where only fraction of the priority cancer patients may have access to surgery. Clinicians may have to further restrict of surgery, likely across specialties (i.e. colon cancer, breast, hepatobiliary) based on the perceived magnitude of risk of delay, and over shorter time periods (i.e. impact of 8-week delay, then 4 weeks, etc).
- Preoperative evaluation is likely to be impacted (i.e. pulmonary function testing), and preoperative screening for COVID-19 is evolving (survey for symptoms, temperature assessment, possible selected testing for COVID-19 where available).
- It is possible that the strategies outlined in this document could be replaced as our understanding of unique challenges that COVID-19 poses within each country, state, and healthcare environment evolves.
- This document is not intended as a guide for other clinical scenarios, epidemics, or pandemics.

Shared Decision Making and Transparency

Transparency regarding the potential risks of deferring or proceeding with an operation remains a priority. Surgeons should discuss these decisions individually with their patients. Multidisciplinary teams are encouraged to develop alternative treatment strategies if surgical resection is declined or infeasible.

Origins of Consensus Statement

This initiative is an *extension* of the American College of Surgeons and Commission on Cancer (CoC) effort to provide guidance for surgeons to make difficult triaging decisions in the face of progressively limited access to operating rooms (there may be some slight differences in this document compared to the CoC-published documents). A partnership was formed between the CoC (Tim Mullett, Larry Shulman, Linda Martin and Matt Facktor), the Thoracic Surgery Outcomes Research Network (ThORN - a research collective of board-certified general thoracic surgeons) and leaders from the American College of Surgeons (Heidi Nelson, Valerie Rusch, Douglas Wood), and reviewed by leadership from the Society of Thoracic Surgeons and the American Association of Thoracic Surgery (David Jones and Shaf Keshavjee). The limited data was discussed in an open exchange and the resulting guide is best characterized as being based on “expert opinion” (in terms of strength of evidence). The authors recognize that multiple resources are becoming available to triage all types of surgical treatment. We intentionally avoided language that is currently being used to structure guidance based on procedures (i.e.

tiers) or patient status (i.e. emergent, urgent, semi-urgent) to avoid confusion, and have instead organized recommendations based on the conditions that exist within each hospital (“phases”).

Final Thought

There are times when the right decision becomes easier – as the impact of the decision evaporates. This is one of those times. We hope that this document facilitates the timely execution, of what are sure to be increasingly difficult decisions.

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Table 1. Guidance for the Triage of Patients with Thoracic Malignancies

Table 1 defines three phases of hospital status based on: A) the prevalence of COVID-19 patients within the hospital, B) availability of hospital resources, and C) the rate of change (in terms of increasing prevalence of infections and resource depletion). Because there are unique considerations for individual patients, each phase is accompanied by a “compass statement” which is meant to give additional direction to navigate volume restriction, based on perceived risk to patients and hospital staff. NOTE - for each phase, surgeons should operate for recommended scenarios (first column), but also for recommended scenarios from all higher phases (i.e. appropriate surgeries during Phase 2, include first column under both Phase 2 or Phase 3)

Phase I		
<ul style="list-style-type: none"> - Few COVID 19 patients in hospital - Hospital resources intact (e.g. ICU beds, ventilators, clinicians, Personal protective equipment PPE) - COVID-19 trajectory not in rapid escalation phase <p><i>Compass Statement: Surgery restricted to patients whose survivorship likely to be compromised by surgical delay of 3 months</i></p>		
Surgery performed as soon as feasible	Surgery deferred (estimate 3 months)^a	Alternative treatment CONSIDERED^b
<ul style="list-style-type: none"> • Solid or predominantly solid (>50%) lung cancer or presumed lung cancer ≥ 2cm, clinical node negative • Node positive lung cancer • Post induction therapy cancer • Esophageal cancer T1b or greater • Chest wall tumors of high malignant potential • Stenting for obstructing esophageal tumor • Staging to start treatment (EBUS, mediastinoscopy, diagnostic VATS for pleural dissemination)^d • Symptomatic mediastinal tumors – diagnosis not amenable to needle biopsy • Patients enrolled in therapeutic clinical trials 	<ul style="list-style-type: none"> • Predominantly ground glass (<50% solid) nodules or cancers • Solid nodule or lung cancer < 2 cm • Indolent histology (e.g. carcinoid, slowly enlarging nodule) • Thymoma (non-bulky, asymptomatic) • Pulmonary Oligometastases - unless clinically necessary for pressing therapeutic or diagnostic indications (i.e. surgery will impact treatment) • Patients likely to require prolonged ICU needs (i.e. particularly high-risk patients) • Tracheal resection (unless aggressive histology) • Bronchoscopy^e • Upper Endoscopy^e • Tracheostomy^e 	<ul style="list-style-type: none"> • Endoscopic therapy for Early stage esophageal cancer (stage T1a/b superficial) • If eligible for adjuvant therapy, then consider neoadjuvant therapy (e.g. chemotherapy for 5cm lung cancer)^b • Stereotactic Ablative Radiotherapy (SABR)^f • Ablation (e.g. cryotherapy, radiofrequency ablation) • Stent for obstructing cancers then treat with chemoradiation • Debulking^e (endobronchial tumor) only in circumstance where alternative therapy is not an option due to increased risk of aerosolization (e.g. stridor post obstructive pneumonia not responsive to antibiotics)

		<ul style="list-style-type: none"> • Nonsurgical staging (EBUS, Imaging, Interventional Radiology biopsy)^e • Follow patients after their neoadjuvant for “local only failure” (i.e. salvage surgery)^g
<p>Phase II</p> <ul style="list-style-type: none"> - Many COVID 19 patients - Resources limited (e.g. ICU beds, ventilators, clinicians, PPE), - COVID trajectory within hospital in rapidly escalating phase <p><i>Compass Statement: Surgery restricted to patients likely to have survivorship compromised if surgery not performed within next few days</i></p>		
Surgery performed as soon as feasible	Surgery deferred (estimate 3 months)	Alternative treatment RECOMMENDED^h
<ul style="list-style-type: none"> • Perforated cancer of esophagus – not septic • Tumor associated infection – compromising, but not septic (e.g. debulking for post obstructive pneumonia) • Tumor associated with hemorrhage, not amenable to nonsurgical treatment • Management of surgical complications (hemothorax, empyema, infected mesh) – in a hemodynamically stable patient 	<ul style="list-style-type: none"> • All thoracic procedures typically scheduled as routine/elective 	<ul style="list-style-type: none"> • Transfer patient to hospital that is in Phase I • If eligible for adjuvant therapy, then give neoadjuvant therapy • Stereotactic Ablative Radiotherapy (SABR) for Ablation (e.g. cryotherapy, radiofrequency ablation) • Reconsider neoadjuvant as definitive chemo-radiation, and follow patients for “local only failure” (i.e. salvage surgery)
<p>Phase III</p> <ul style="list-style-type: none"> - Hospital resources are predominately routed to COVID 19 patients - Resources critically limited/exhausted <p><i>Compass Statement: Surgery restricted to patients likely to have survivorship compromised if surgery not performed within next few hours</i></p>		
Surgery performed as soon as feasible	Surgery deferred (estimate 3 months)	Alternative treatment AT ALTERNATE FACILITY

<ul style="list-style-type: none"> • Perforated cancer of esophagus – septic patient • Threatened airway • Tumor associated sepsis • Management of surgical complications – unstable patient (active bleeding not amenable to nonsurgical management, dehiscence of airway, anastomotic leak with sepsis) 	<ul style="list-style-type: none"> • All non-emergent surgeries 	<ul style="list-style-type: none"> • See above
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Footnotes – there is very limited data to inform many key decisions. The data and references in this section are meant to serve as an estimate of effect size, using the largest datasets available. They are not complete, and therefore should not be used as definitive data, only *suggestive* of the magnitude of effect.

^a A study from the National Cancer Database suggests that interval between diagnosis and surgery (i.e. time-to-treat) for stage I lung greater than 8 weeks is associated a reduction in 5-year survival (54.8% vs. 48.7%, $p > 0.001$)⁶. For stage III lung cancer patients, a delay of greater than 3 months between neoadjuvant therapy and surgery was associated with shorter median survival (33.2 months vs. 39.8 months, $p = 0.03$)⁷. Smaller institutional studies have not revealed a clear association between the diagnosis-treatment interval and long-term outcomes in patients with esophageal cancer⁸. A delay of greater than 8 weeks between neoadjuvant therapy and surgery for esophageal cancer is not associated with decrement in long-term survival⁹.

^b Availability of alternative treatments may vary across health systems and over time. The decision to pursue alternative treatment must balance risk of deferring alternative treatment (chemotherapy and radiation) with risk of exposure of both patients and staff to COVID-19 infection. In Phase I, alternative treatments predominately considered in patients felt to be harmed by delay (i.e. the first column of table).

^c At the time of writing, the risk of mortality with COVID-19 infection is felt to be higher among patients receiving chemotherapy, but the data is incredibly limited (18 cancer patients in China)¹⁰.

^d Although the accuracy of the clinical staging examination may be enhanced by invasive staging procedures, the magnitude of survival benefit from superior staging, may be considered by some to be modest. In the setting of strained resources and potential exposure risk to clinical staff from staging procedures (bronchoscopy and mediastinoscopy), treating a patient based exclusively on a noninvasive staging evaluation (i.e. imaging alone) is reasonable.

^e These procedures are currently felt to be associated with a particularly high potential to disseminate COVID-19. They should be done selectively, and ideally in patients that have been screened for active COVID-19 infection.

^fThere is incomplete data comparing surgery to SABR for early stage lung cancer in patients eligible for surgery. Observational data, which is likely biased with patients that were not surgical candidates, suggests a modest survival advantage of surgery (5-15% higher 5-year survival)¹¹⁻¹³.

^gAmong presumably highly selected patients, salvage resection has been associated with reasonable survivorship after definitive nonsurgical therapy for esophageal cancer, particularly if the patient has had a good response by imaging^{14, 15}.

^h Recommended for patients in whom a delay would likely compromise survival (i.e. first column from Phase I section)

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