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Resuming Breast Imaging Services in the Aftermath of the COVID-19 Pandemic: Safety and Beyond

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Abstract

As the Coronavirus disease 2019 (COVID-19) epidemic begins to stabilize, different medical imaging facilities not directly involved in the COVID-19 epidemic face the dilemma of how to return to regular operation. We hereby discuss various fields of concern in resuming breast imaging services. We examine the concerns for resuming functions of breast imaging services in 2 broad categories, including safety aspects of operating a breast clinic and addressing potential modifications needed in managing common clinical scenarios in the COVID-19 aftermath. Using a stepwise approach in harmony with the relative states of the epidemic, health care system capacity, and the current state of performing breast surgeries (and in compliance with the recommended surgical guidelines) can ensure avoiding pointless procedures and ensure a smooth transition to a fully operational breast imaging facility.

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Introduction

Seven months after the emergence of Coronavirus disease 2019 (COVID-19) as a worldwide health and economic issue, the pandemic has taken a flattened trajectory in some and fluctuating courses in many countries, depending on the social distancing and contact tracking strategies used locally. There is still no effective treatment or vaccine available, and disease control is dependent on proper patient tracking and effective social distancing.

Deferring many important but non-urgent procedures has taken its toll on patients with cancer in whom survival depends on timely treatment. Patients have been put on non-surgical treatment whenever one has been available, and treatments have been left

incomplete waiting for health resources to be freed from the more urgent deadly outbreak. Even in communities that are not heavily affected, reallocation of resources and containment measures have disrupted routine health care. World economics, especially health care economics, has also been struck. The dilemma of how to move from a halt of all non-urgent procedures to resuming regular practices is uncharted territory, and a road never traveled before.

As the COVID-19 epidemic begins to stabilize, different medical imaging facilities not directly involved in the COVID-19 epidemic face the dilemma of how to return to regular operation. The disease may not be eradicated anytime soon. The stabilizing state is defined by the health system as gaining the capacity to safely diagnose, treat, and isolate COVID-19 cases and their contacts while the disease trajectory is not rising, and resources being available for managing other patients. However, some physical distancing, using adequate personal protective equipment (PPE) for both patients and health care workers, will still need to be in place to prevent transmission from accelerating again. Some degree of continued social distancing is crucial for the protection of those who have underlying health conditions, or who are otherwise at high risk for COVID-19.¹

Another decisive aspect of resuming normal clinical services is the fact that asymptomatic carrier transmission has been recognized as a major cause of the spread of the epidemic.² The possibility of asymptomatic carriers transmitting the disease imposes significant risk for health care workers in particular. We hereby discuss various

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fields of concern in resuming breast imaging services. We examine the concerns for resuming functions of breast imaging services in 2 broad categories, including safety aspects of operating a breast clinic and addressing potential modifications needed in managing common clinical scenarios in the COVID-19 aftermath. Although our recommendation is based on international guidelines, including the American College of Surgeons (ACS), it encompasses suggestions for different aspects of a breast clinic workflow ranging from initial scheduling of a patient to the interventional procedures and surgery discussed in 2 separate sections. The recommendations are made by a team of local university-affiliated radiologists, a breast surgeon, and an epidemiologist, in collaboration with international experts, and are tailored according to our available resources and department workflow.

Section 1. Safety Aspects of Operating a Breast Clinic in the COVID-19 Aftermath

For safe re-opening of imaging clinics and, in particular, a breast imaging service, in the aftermath of the COVID-19 pandemic, the entirety of clinical practices needs rethinking and redesigning.³ For almost every procedure, modified protocols need to be established. Major areas of concern include proper scheduling, safety, and disinfection of various clinic areas, protection for staff and patients, and reevaluating the usual procedure protocols.

Regarding scheduling, stepwise ratcheting up to regular schedules can protect the patients and staff. At each phase of resuming regular activities, only those diagnostic procedures should be scheduled for which effective intervention is available. This depends on the disease phase in terms of COVID-19 prevalence and the relative capacity of the health care system. We thus advise every breast imaging clinic to have a questionnaire for internet-based or telephone-based scheduling to screen for patients with proper indications based on current health care system capacities and also for COVID-19 symptoms before actual in-person referral of the patient. Scheduling should be done such that the waiting time inside the clinic's waiting area is minimized.

Various physical spaces in the clinic need proper disinfection, housekeeping, and social distancing protocol. For each area, disinfecting procedures in the form of checklists can be followed in-between patients, when changing dayshifts, and at the end of working hours. For the reception area, given the possibility of asymptomatic transmission of the disease, both PPE for the receptionist, adopting a policy of providing surgical masks and gloves for the patients, and physical barriers such as cellophane shields at the reception table are advisable. The reception table should be cleaned and disinfected at least at the beginning and end of each shift.^{1,3}

In the waiting areas, adequate ventilation, limiting the number of accompanying people, and distancing of the waiting area seats should be considered. Regular disinfection between shifts is a minimum requirement.

The ultrasound room is a high-risk area by nature because of the lengthy duration of most procedures and the proximity of the patient and sonographer. A cellophane shield between the ultrasound machine and the patient bed with a proper opening for the probe and operator's hand is desirable to limit droplet transmission. Also, disposable plastic shields over the probe and connecting cable or

disinfecting the connecting cable and probe between patients, also disposable table covers, or disinfecting the table with alcohol between patients should be considered. PPE, including surgical masks and face shields or N95 masks and goggles, is needed for the sonographer, especially when performing biopsies. There is a lot of room for improvement and innovative solutions in optimizing the safety of performing ultrasounds and keeping up with the workflow needed to maintain imaging centers.

The mammography technician is also at risk because of close contact with the patient. PPE, including surgical masks and shields or N95 masks and goggles, is needed for the mammography technician. Disinfection of the equipment, especially the plate (with a disinfectant approved by the vendor), is also necessary between patients.

Section 2. Reevaluating Common Clinical Scenarios in the COVID-19 Aftermath

As a general principle, recommendations for diagnostic procedures are based on 4 areas of concern, including the (1) effectiveness and impact on patient management; (2) availability; (3) risk (to the patient and the staff); and (4) cost of each procedure. In the uncertain and fluid aftermath of COVID-19, all 4 aspects are altered. The impact of a diagnostic procedure on patient care is inevitably modified in a scenario of the shutdown of non-urgent surgeries. The availability of diagnostic procedures can change. Hospital units and staff may have been reallocated to COVID-19 or may not be available owing to their sickness. Occasionally, radiology residents have been asked to volunteer in COVID-19 wards, and guidelines for performing cancer surgery have been modified to accommodate the new conditions. Risks of diagnostic procedures to patients and staff have dramatically increased as a result of concerns for getting infected. Costs of imaging centers and procedures have also increased as a result of placing additional protective systems. The cost of each procedure has increased because of the extra costs of disinfection, PPE for the staff, and reduced workflow (also caused by the necessary social distancing and the time penalty of disinfections between the patient procedures). In addition, the ability of society to compensate for health care expenses has decreased because of uncertain economic conditions and rising unemployment.

ACS-defined Phases for Resuming Breast Cancer Surgery

The principles that apply to various procedures performed in breast imaging clinics in the aftermath of COVID-19 are very similar to that of breast cancer surgeries. Because there are already recommendations out for performing elective and cancer surgery, the re-opening of breast imaging facilities can follow the same path.⁴ The ACS has updated its guidelines for performing elective surgery based on the status of the COVID-19 epidemic and the capacity of the health care system to contain the epidemic.⁴ Although these categories are originally described in the initial phases of the pandemic,⁵ they can also be used in reverse order to organize resuming breast care as well. It must be noted that, based on circumstances and fluctuations in the number of patients, caused by social interventions, these phases do not necessarily follow a predetermined order. Most likely, the system will fluctuate back and forth between those phases as needed, based on the disease

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prevalence fluctuation. We will, however, presume a simple linear normalizing course for the case of simplicity.

ACS Phase 3. This is the worst-case scenario at the height of the epidemic, when patients with COVID-19 have consumed all the available resources, and there are no more supplies available for any other patient. At this stage, no breast surgery is indicated except for an occasional abscess or hematoma drainage. Accordingly, no form of breast imaging is indicated except for a limited ultrasound in case of urgent abscess drainage. Outpatient breast imaging facilities remain closed.

ACS Phase 2. This is an urgent setting when the disease is rapidly escalating, and only limited resources are still available. For breast imaging facilities, this phase is considered the equivalent of phase 3, and breast imaging services remain closed.

ACS Phase 1. This is the semi-urgent phase when the disease is present but not escalating, and the health care system has both reserve resources put in place to accommodate the trajectory of the disease and limited extra resources to allocate to other patients. At this stage, surgery is advisable in 5 groups of patients. These include patients who have finished their neoadjuvant therapy, patients with clinical stage T2 or N1 estrogen receptor-positive/progesterone receptor-positive/human epidermal growth factor receptor 2 (HER2)-negative tumors, triple-negative, or HER2-positive disease, and also patients with discordant biopsies

likely to be malignant and those with recurrence of malignant tumors.

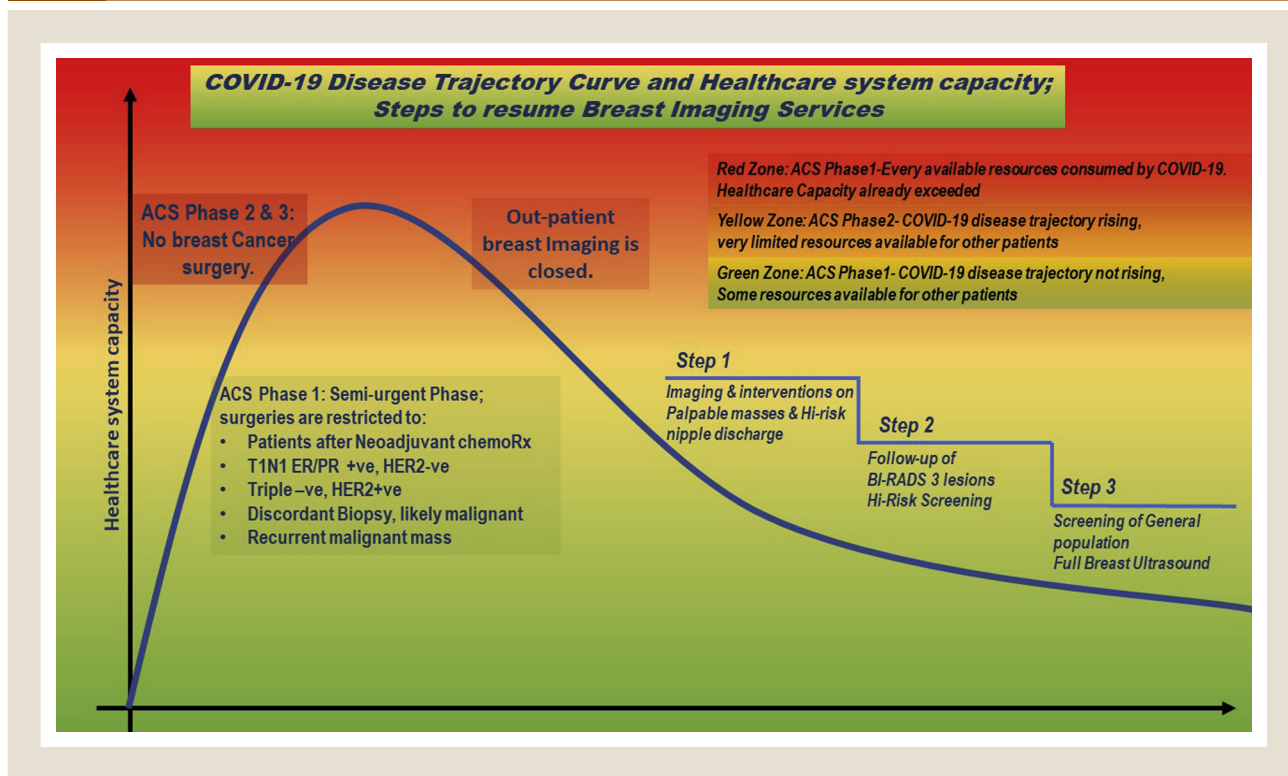
Proposed 3-step Approach for Resuming Breast Imaging Clinic Services

At this stage of health system operation during the pandemic (semi-urgent phase or phase 1) breast imaging clinics need to resume providing services in a stepwise fashion. We propose a 3-step approach to re-opening breast imaging clinics, starting when the health care system is back to operating at ACS phase 1 or semi-urgent conditions (Figure 1).

Step 1. Services are limited to palpable or previously detected suspicious masses or high-risk (bloody/serous) nipple discharge. In the very first weeks of resuming breast imaging services, in concordance with the ACS guidelines, breast imaging clinics are advised to offer only limited services during the semi-urgent phase. These include diagnostic mammograms, targeted ultrasounds, and biopsies on patients with suspicious palpable masses or suspicious nonpalpable previously imaged lesions. Breast magnetic resonance imaging (MRI) for preoperative re-staging of patients after neoadjuvant chemotherapy should also be considered.

According to ACS, it is advisable to defer excision of benign or high-risk lesions, tumors with favorable response to neoadjuvant chemotherapy, in situ lesions, duct excisions, re-excisions, T1N0 estrogen receptor/progesterone receptor-positive, HER2-negative malignant masses, and also inflammatory and locally advanced

Figure 1 COVID-19 Disease Trajectory Curve and Health Care System Capacity: Steps to Resume Breast Imaging Services



Abbreviations: ACS = American College of Surgeons; BI-RADS = Breast Imaging Reporting and Database System; COVID-9 = Coronavirus disease 2019; ER = estrogen receptor; HER2 = human epidermal growth factor receptor 2; PR = progesterone receptor.

Table 1 Resuming Ultrasound-guided Breast Procedures After the COVID-19 Pandemic

Procedure	Performed on	Advantages	Potential Patient Risks	Potential Staff Risks	Other Disadvantages
US-guided FNA	Any palpable or image-detected lesion	Can be done with no prep at time of detection => potentially fewer referrals	No additional risk in the patient	Expelling aspirates from needle, making smears, and air-drying is droplet/aerosol producing.	Can frequently result in inadequate sample
US-guided CNB	Any palpable or image-detected lesion	Can be done with minimal prep at time of detection => potentially fewer referrals	Minor risk of hemorrhage, pneumothorax, and infection	Formalin kills the virus but minimal potential risk of handling COVID-19 infested samples before (ref)	Time penalty of performing the procedure
US-guided VAB	Scattered microcalcifications and papillary lesions	Larger sample size compared with CNB, no general anesthesia required	Larger risk of hemorrhage and pain, cost	Risks of handling COVID-19 infested samples, potentially higher risk of aerosol compared with CNB (ref)	Need to discontinue anticoagulants
US-guided wire localization	Non-palpable lesions before surgery, usually after some biopsy is done	Can be done with minimal time penalty	Surgery associated risks	Surgery-associated risks	Costs of surgery
US-guided marker insertion	Biopsy-proven malignancy before neoadjuvant Rx	Can be used to postpone surgery when elective surgery is not done per protocol	Minor risk of hemorrhage, pneumothorax, and infection	Minimal risk of aerosol formation	Possible marker migration, cost of markers

Abbreviations: CNB = core needle biopsy; COVID-9 = Coronavirus disease 2019; FNA = fine needle aspiration; US = ultrasound; VAB = vacuum-assisted biopsy.

cancers.⁴ Therefore, to be able to make a distinction between the patients who would benefit from urgent reoperation and those that can be deferred, the breast imaging clinics need to provide limited services as described above.

Step 2. While in Step 1, services should only be offered to patients with significant symptoms, follow-up imaging of Breast Imaging Reporting and Database System (BI-RADS) 3 lesions, and high-risk screening is better saved for step 2. The gradual move from step 1 to step 2 can ensure monitoring and fine-tuning the epidemiologic response of the disease while guaranteeing the patients in need of urgent intervention to get treated in due time. At this step, biopsy of mildly suspicious microcalcifications can also be resumed. Whole breast ultrasound is still discouraged owing to the long duration and

close proximity of the sonographer/radiologist and the patient and the potential risk imposed on both of them. The risk-benefit ratio of incrementally added cancers detected in ultrasound as an adjunct to mammogram in the dense breast might not be high enough to justify the risk of getting infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Step 3. Transition to full service is advisable only after the disease course is not escalating, the health system can safely diagnose, adequately treat, and isolate COVID-19 cases and their contacts in the community, and there are adequate resources for full elective surgery services. Ultrasound as an adjunct to mammograms in the dense breast in the general population is probably the last service to be resumed.

Table 2 Mammogram-guided Procedures During the COVID-19 Pandemic

Procedure	Performed on	Advantages	Potential Patient Risks	Potential Staff Risks	Other Disadvantages	Recommendations in COVID-19 Era
MG-guided CNB	Non-palpable B3-4-5 lesions that are not visible in ultrasound	Can be done with minimal prep at time of detection => potentially fewer referrals	Minor risk of hemorrhage, pneumothorax, and infection	Risks of handling COVID-19 infested samples (ref)	Time penalty of performing the procedure	If billing/legal concerns allow, biopsy any B3, B4, or B5 lesions
MG-guided VAB	Non-palpable B3-4-5 lesions that are not visible in ultrasound	Larger sample size compared with CNB, no general anesthesia required	Larger risk of hemorrhage and pain, cost	Risks of handling COVID-19 infested samples, potentially higher risk of aerosol compared with CNB (ref)	Need to discontinue anticoagulants	Save for proper lesions, start no earlier than phase 1, step 2
MG-guided wire localization	Non-palpable lesions that are not visible in ultrasound before surgery, usually after biopsy	Can be done with minimal time penalty	Surgery associated risks	Surgery-associated risks	Costs of surgery	Indicated for any non-palpable suspicious lesion early in phase 1.
MG-guided marker insertion	Biopsy-proven malignancy before neoadjuvant Rx	Can be used to postpone surgery when elective surgery is not done per protocol	Minor risk of hemorrhage, pneumothorax, and infection	Minimal risk of aerosol formation	Cost of equipment and markers, possible marker migration, time penalty	Indicated for biopsy-proven malignancy before neoadjuvant Rx, to be resumed at phase 1, step 1

Abbreviations: CNB = core needle biopsy; COVID-9 = Coronavirus disease 2019; MG = mammogram; VAB = vacuum-assisted biopsy.

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The decision for exactly when screening mammograms and MRIs should be resumed depends on the trajectory of the disease, how long we expect phase 1 to continue, and how much confidence we have in the local health care system's ability to accommodate possible comebacks. This can be any time during Step 2 or 3 based on the mentioned factors.

Indications and practice of breast MRI are also subject to local conditions of the epidemics and elective surgery. In decreasing order of priority, we believe breast MRI should be done for preoperative evaluation of patients following neoadjuvant chemotherapy or as a part of re-opening Step 1 during phase 1. Screening with breast MRI is subject to the same considerations as screening mammography. At whichever stage we start performing breast MRI, the step-by-step priority will be in this order; first on high-risk patients with dense breasts, then increased risk population with dense breasts, then high/increased risk patients with American College of Radiology (ACR) 1 and 2 breasts, and finally in the general population with dense breasts who wish to have breast MRI as an adjunct to screening.

Rethinking Breast Intervention Procedures During the COVID-19 Aftermath

Image-guided breast biopsies, wire, and marker insertion are among the earliest required services as breast surgeries are resumed (Tables 1 and 2). These procedures need to be reevaluated for the possibility of aerosol/droplet production at the time of biopsies. Core-needle biopsy samples and procedures are not considered a high risk of aerosol/droplet production. The virus is killed by formalin, so once the outer surface of the container is decontaminated, there is no significant risk of disease transmission. As for fine needle aspiration (FNA), the expelling of the aspirate from the needle, making smears, and air-drying is potentially aerosol/droplet producing.⁶ For high-risk and potentially infected specimens, Class 2 biosafety cabinets are recommended for handling and air-drying of the specimens.⁶ However, breast aspirates in asymptomatic subjects are considered low risk even if the subject is transmitting the virus through respiratory droplets. Class 2 biosafety cabinets are not deemed necessary for handling FNA aspirates in asymptomatic individuals for low-risk specimens, including thyroid and breast aspirates. FNA and core needle biopsy should be performed with both the performer of the procedure and the aide having appropriate PPE, including gloves, gowns, and goggles or face shields for eye protection as well as a properly fit-tested filter respirator (N-95 or FFP2 or higher). Vacuum-assisted biopsy might prove a safe replacement for selective

excisional re-biopsies done for discordant core needle biopsies while surgeries are still done sparingly.

We also advocate a temporary change in recommendations for managing lesions deemed as BI-RADS 3 during the aftermath of COVID-19. As long as social distancing is advisable in communities, it is advisable to directly biopsy BI-RADS 3 lesions whenever detected to avoid the need for multiple referrals. This is especially true about circumscribed solid masses detected in ultrasound. Focal asymmetries and groups of round microcalcifications in mammograms without an ultrasound correlate can be followed in longer intervals, preferably once a year instead of twice a year at 6-month intervals.

Conclusion

Deferring all breast imaging services during the ACS stages II and III of the COVID-19 epidemic can avoid inadvertent exposure of patients and staff to the infection when no effective surgical intervention is possible. As the system approaches phase 1 or the semi-urgent phase of the epidemic, and in order to accommodate the needs of patients requiring urgent surgery, the breast imaging clinics are to provide limited services accordingly. Using a stepwise approach in harmony with the relative states of the epidemic, health care system capacity, and the current state of performing breast surgeries (and in compliance with the recommended surgical guidelines) can ensure avoiding pointless procedures and ensure a smooth transition to a fully operational breast imaging facility.

Disclosure

The authors have stated that they have no conflicts of interest.

References

1. Mossa-Basha M, Azadi J, Klein J, et al. RSNA COVID-19 Task Force: best practices for radiology for radiology departments during COVID-19. Available at: <https://www.rsna.org/-/media/Files/RSNA/covid-19/RSNA-COVID-19-PostSurgePreparedness.pdf>. Accessed: May 10, 2020.
2. Bai Y, Yao L, Wei T, et al. Presumed asymptomatic carrier transmission of COVID-19. *JAMA* 2020; 323:1406-7.
3. Society of Breast Imaging. SBI recommendations for a thoughtful return to caring for patients. [https://www.sbi-online.org/Portals/0/Position Statements/2020/SBI-recommendations-for-a-thoughtful-return-to-caring-for-patients_April-16-2020.pdf](https://www.sbi-online.org/Portals/0/Position%20Statements/2020/SBI-recommendations-for-a-thoughtful-return-to-caring-for-patients_April-16-2020.pdf). Accessed: May 10, 2020.
4. American College of Surgeons. COVID 19: elective case triage guidelines for surgical care. (2020, March 24), Available at: <https://www.facs.org/covid-19/clinical-guidance/elective-case/breast-cancer>. Accessed: May 10, 2020.
5. Shahi F, Mirzania M, Dabiri M, et al. Modifications in breast cancer guidelines in COVID19 pandemic: an Iranian consensus. *Arch Breast Cancer* 2020;14-7.
6. Pambuccian SE. The COVID-19 pandemic: implications for the cytology laboratory. *J Am Soc Cytopathol* 2020; 9:202-11.