April 8, 2020

IANS Guidelines for the practice of HRA in the era of COVID-19

Key Points

- COVID-19 responses are rapidly changing and vary considerably with local epidemiology and resources.
- If resources allow, prioritize patients at highest risk of anal cancer risk – many/most will be able to be deferred for at least three months.
- Assess all patients for COVID-19 risk at time of booking and on day of procedure. HRA only indicated for those with highest risk of anal cancer and low risk of having COVID-19. Consider delaying HRA, even in these individuals, if they fall into any of the highly vulnerable COVID risk groups.
- If HRA is still indicated, then follow local Infection Control guidelines as a minimum.

1. Background

The situation is rapidly evolving and these guidelines represent our current understanding, which may change in the light of new research. Suggested policy is based on the following:

- This epidemic is likely to continue for some months, so any guidelines will need to be sustainable, and reviewed regularly in the light of new circumstances.
- Up-to-date local Infection Control procedures should be followed.
- The local availability of resources, such as appropriate Personal Protective Equipment (PPE) needs to be considered.

2. HRA Risk Assessment

- Digital Anal Rectal Examination (DARE) is an integral part of any assessment for anal cancer. If the DARE findings are suggestive of cancer, then further investigation (including HRA) is indicated.
- The rate of progression from HSIL to anal cancer is not fully characterised, but may be 1-2% per year in certain populations.
- In manners analogous to cervical disease, treatment of anal HSIL may prevent/delay progression to cancer. Definitive assessment of the value of treatment awaits data from studies currently underway.
- Factors potentially impacting progression from HSIL to cancer include: older age, degree of immunosuppression and extent/duration of HSIL. N.B.: these factors are also some of those that increase risk of severe COVID-19 infection (see later).
- Individual clinics will determine level of risk, according to local issues such as Infection Control policies and availability of resources, including availability of Personal Protective Equipment (PPE).

Table 1 may help prioritise patients:

Table 1: HRA risk prioritisation

It is recognized that some centers will have discontinued all HRA and related procedures, due to local conditions. These recommendations are not intended to circumvent local Infectious Control measures.

Risk assessment	**Category 1 High**	**Category 2 Intermediate**	**Category 3 Low**
Priority	**Urgent**	**As soon as possible**	**May be deferred**
Definition	HRA should occur within one month, unless epidemic situation is extreme - in which case, prioritise biopsy of clinically invasive lesions. Prioritized as first to be scheduled.	HRA performed within 6 months, if possible. Symptom check-in by phone or telemedicine, repeat at 3 months.	Defer HRA until resumption of normal clinic scheduling. Symptom check-in by phone or telemedicine, repeat at 3-6 months.
Principal objective			
Clinical cancer assessment	Clinically highly suspicious of cancer. Digital Anal Rectal Examinations are an integral part of such an assessment.	Within 6 months of first cancer treatment and those treated within 2 years ago.	Low risk of cancer (unlikely within one year).
HSIL surveillance	HSIL clinically suspicious for cancer. Cytology or histology suspicious, but not diagnostic of cancer.	Features concerning for progressive disease in previous exam (e.g. lesion characteristics that are very prominent). Cytology HSIL, not yet assessed with HRA.	No current evidence of HSIL. No concerning features in previous exam. Cytology <HSIL or ASC-H (PHSIL).
Investigation of symptoms/signs (lump, bleeding, pain, tenesmus)	Symptoms or signs that have worsened or recurred	Symptoms present but unchanged in 6 months > 1 year since last exam.	No symptoms/signs.

Specific considerations for the conduct of therapeutic HRA

Only cases with histologic confirmation of HSIL should be considered for treatment at this time.

Topical Therapies

- Topical therapies such as 5- fluorouracil 5%, imiquimod and veregen are less prone to generating air particles than physically destructive methods. Some units use trichloroacetic acid, however this may require multiple clinic visits.
- Clinician applied therapies still require follow up, but could potentially be performed using telehealth.
- Patient application may be sub-optimal, so cases should be reviewed as soon as possible, when services resume.

Ablative Therapies

- Ablative methods may have risk of generating air particles and should be avoided, unless you have access to full Personal Protective Equipment (PPE). The exact nature of PPE deployed will be determined by local Infection Control guidelines. PPE may include items such as N95/ FFP3 or FFP2 masks, full-arm gowns, goggles and air evacuation systems.

3. COVID-19 Risk Assessment

- Coronavirus disease spreads primarily through contact with an infected person. However, COVID-19 cases can also have digestive symptoms, including diarrhea.
- SARS-CoV-2 viral RNA has been isolated from stool. Whilst oro-fecal spread is not thought to be a major factor in the epidemic, HRA practitioners need to be aware of it as a potential source of infection.

The risk of COVID-19 infection in the last 14 days should be assessed, using the factors in Table 2, both at the time of booking an appointment, and also prior to performing any procedure.

Table 2: Classification of potential SARS-CoV-2 infection risk in patients undergoing High Resolution Anoscopy

	*Symptoms	‡Contact	Vulnerable Group
Low risk	No	No	<60
Intermediate risk - *either*	Yes	No	60-70 years
- or	No	Yes	HIV with CD4: 200-500/mm^3
High risk	≥1 symptom* and	Yes	>70 years
			HIV with CD4≤200/mm^3
			Innate/pharmacological immunosuppression
			Transplant recipient

*Symptoms include cough, fever, dyspnea and diarrhea
‡contact with known SARS-CoV-2–positive person

Based on: https://www.sciencedirect.com/science/article/pii/S0016510720302455?via%3Dihub

It is recommended that only those at low risk of having COVID-19 be seen for HRA. This may require waiting until the COVID-19 situation is clarified or resolved. Consider stopping all HRA services, in view of possible fecal-oral transmission from asymptomatic cases.

4. **Enhanced Local Infection Control Procedures**

There is evidence of spread of coronavirus within the air of a room following a procedure. The risk from fecal transmission of the virus is not known. In addition to usual infection control measures, consider allowing 30 minutes between cases, in order to ventilate the room and reduce the risk of airborne viral transmission between cases.

Medical staff to wear surgical face masks (ideally n95, if available), avoid shaking hands, gowns and gloves upon entering the room, and until the patient leaves.

Clean door handles, chairs, desks, any surfaces touched, as well as clinical areas after each patient.

Use strategies to avoid patients sitting in the waiting room. These may include having patients wait outside and be called in when the room is ready and accessing them by mobile/cell phone. Ensure all seats are at least 1.5 meters apart.

5. **Summary Recommendations**

These guidelines are subject to changes as the COVID-19 pandemic evolves.

1. Consider seeing only patients assessed to be at very high risk of anal cancer. DARE may provide a simple and relatively safe means of assessing risk.
2. Close liaison with local diagnostic laboratories and treatment facilities are important, to determine what procedures are possible at a given time. Prepare contingency plans if your hospital is not currently able to provide these.
3. HSIL rarely needs to be treated urgently. Risk assessment is key to appropriate allocation of resources.
4. Perform COVID-19 risk assessment at time of booking, and on day of procedure.
5. Local infection control procedures should be followed at all times, to ensure risks are minimized to both patients and practitioners. Consider enhancing these measures.
6. Ensure appropriate hand hygiene for patients/visitors/staff at entrance to department. Surgical masks for all staff and consider offering to patients.
7. Maximise social/physical distancing by reducing/eliminating waiting room, enforcing the 6 feet/2 metre rule and minimizing the number of people in the department at one time.

8. Only those at low risk of COVID-19 should be considered for HRA. This may require waiting until the COVID-19 situation is clarified, or resolved. Consider avoiding HRA or any office visits for patients in groups vulnerable to COVID-19.
9. A standard face mask is not fully protective for COVID-19, although probably cuts down transmission from a patient who coughs or sneezes.
10. PPE (Personal Protective Equipment), including n95 masks for both staff and patients will reduce risk of transmission. However, locally available resources need to be considered. Full PPE/n95 masks are unlikely to be widely available or practical for most patients. Using protective gear for any patient takes it away from the limited supply hospitals need to protect staff on the front lines.
11. Aerosol-generating procedures such as laser or electrocautery are rarely necessary in an urgent situation. They should only be undertaken with full PPE including FFP3/N95 masks.

12. Notes

These recommendations are not to be considered definitive management guidelines and recognize that some individuals with abnormal anal cancer tests and histologic findings will require case-by-case review. These guidelines are subject to change, due to the fluidity of the healthcare environment. Providers should continue use of tracking protocols, to ensure that patients with abnormal results may be recalled when concerns for COVID-19 have diminished to the point HRA services may be reinstated, with priority given to those at highest risk of invasive disease. Once the COVID-19 outbreak is contained, patients should again be managed as per local guidelines.

Disclaimer:
These recommendations should never be a substitute for clinical judgment. Clinical judgment should always be used when applying a recommendation to an individual patient since they may not apply to all patient-related situations.