



SPECIAL ARTICLE

Expert consensus from the Italian Society for Colposcopy and Cervico-Vaginal Pathology (SICPCV) for colposcopy and outpatient surgery of the lower genital tract during the COVID-19 pandemic

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SYNOPSIS: Correct selection of patients and adoption of safety measures are mandatory for colposcopy and outpatient surgery of the lower genital tract during the COVID-19 pandemic.

ABSTRACT

In the context of the COVID-19 pandemic, patients need to be evaluated within 2–4 weeks in the following cases: cytology result of “squamous cell carcinoma,” “atypical glandular cells, favor neoplastic,” “endocervical adenocarcinoma in situ,” or “adenocarcinoma”; histopathological diagnosis of suspected invasion from cervical/vaginal biopsy, or invasive disease after a cervical excision procedure, vaginal excision, or vulvar biopsy/excision; sudden onset of strongly suggestive symptoms for malignancy. Digital imaging technologies represent an important opportunity during the COVID-19 pandemic to share colposcopic images with

reference centers, with the aim of avoiding any concentration of patients. All patients must undergo screening for COVID-19 exposure and should wear a surgical mask. A high-efficiency filter smoke evacuation system is mandatory to remove surgical smoke. Electrosurgical instruments should be set at the lowest possible power and not be used for long continuous periods to reduce the amount of surgical smoke. The following personal protective equipment should be used: sterile fluid-repellant surgical gloves, an underlying pair of gloves, eye protection, FFP3 mask, surgical cap, and gown. The colposcope should be protected by a disposable transparent cover. A protective lens that must be disinfected after each use should be applied. The use of a video colposcope should be preferred.

1 INTRODUCTION

The pandemic spread of novel coronavirus and its related COVID-19 disease is radically changing the organization and structure of health systems around the world, with the need for urgent management of a massive influx of patients needing respiratory care, often in intensive settings. In the space of a few days, profound organizational changes have been adopted worldwide to optimize the resources of healthcare facilities.

In Italy, the Ministry of Health has indicated the need to postpone all non-urgent surgical activities and outpatient services, performing only urgent cases or operations for oncological indications. However, as far as outpatient services are concerned, cases requiring evaluation within 3 days (urgent priority) or 10 days (short-term priority) are considered “not postponable” and must still be guaranteed by the healthcare facilities [1]. Similar measures have been taken in several

countries, such as in the USA where the Centers for Disease Control and Prevention and the American College of Surgeons have issued recommendations to stop elective surgery and delay routine care for non-essential issues [2]. At the same time, new recommendations for the surgical management of suspected or confirmed COVID-19 patients are being published [3].

In this context, there is a need for clear guidance on how to manage patients included in the cervical cancer screening process, as well as those patients who would need an evaluation at a colposcopy clinic for outpatient surgery of the lower genital tract. Indeed, although most of these patients' evaluations can safely be postponed, there is a significant percentage of patients who need urgent contact to exclude or confirm an oncological diagnosis either of cervical cancer or other malignancies of the lower genital tract, such as patients waiting for the result of a screening test or diagnostic biopsy. In addition, there is an urgent need for clear guidance on the safety precautions that should be adopted while performing colposcopy or outpatient surgery of the lower genital tract in suspected or confirmed COVID-19 patients.

The present article provides an expert consensus from the Italian Society for Colposcopy and Cervico-Vaginal Pathology (SICPCV) for: (1) the correct selection of patients that need prompt evaluation for lower genital tract pathologies; and (2) the safety procedures that must be implemented concerning the COVID-19 emergency.

2 INDICATIONS TO PROMPT OUTPATIENT EVALUATION IN A COLPOSCOPY CLINIC

On March 19, 2020, the American Society for Colposcopy and Cervical Pathology published interim guidance [4] recommending that in cases of low-grade cervical cancer screening tests, diagnostic evaluation could be postponed by up to 6–12 months. In contrast, individuals with high-grade cervical cancer screening tests should have documented attempts made to contact them and diagnostic evaluation scheduled within 3 months. Moreover, in patients with high-grade cervical disease without suspected invasive disease, procedures should be scheduled within 3 months. Patients with suspected invasive disease should have a first contact attempted within 2 weeks followed by evaluation within 2 weeks of that contact (i.e. 4 weeks from the initial report or referral).

These recommendations are undoubtedly useful for the management of patients included in the screening programs for cervical cancer and can be adopted in different settings. However, there is a need for recommendations that also consider patients not included in the screening programs or with an urgent need for evaluation in a colposcopy clinic.

In the period 2015–2018, cervical screening coverage in Italy was at 79.7%; however, about 32.4% of global coverage was composed of women who underwent spontaneous screening [5]. In this screening modality, the protective effect toward cervical cancer is halved compared to women who undergo organized screening (OR 0.57; 95% CI, 0.3–1.1 vs OR 0.25; 95% CI, 0.1–0.5), [6] and therefore the timeliness of a second-level assessment (e.g. colposcopy) is crucial.

At present, in Italy, most screening centers have suspended their activities, causing a fragmentation of coverage at the national level. It is, therefore, reasonable to expect an increase in the percentage of patients who will undergo spontaneous screening or who will not be screened at all, with a potential increased risk of missed or delayed cervical cancer diagnosis. A substantial effort will be required by healthcare professionals involved in cervical cancer prevention to ensure a good level of assistance.

Considering the above, we recommend that the following categories of patients also need to be evaluated in a colposcopy outpatient clinic within 2–4 weeks:

- Patients with a cervical cytology result of “squamous cell carcinoma,” “atypical glandular cells, favor neoplastic (AGC-FN),” “endocervical adenocarcinoma in situ,” or “adenocarcinoma” [7].
- Patients with histopathological diagnosis of suspected invasive disease from cervical or vaginal biopsy who need excisional treatment to confirm the diagnosis.
- Patients with histopathological diagnosis of invasive disease after a cervical excision procedure, vaginal excision, or vulvar biopsy/excision who need contact to evaluate the clinical stage of the disease, to plan the treatment in a multidisciplinary team, or to refer the patient to a specialized center.
- Patients with sudden onset of strongly suggestive symptoms for malignancies of the lower genital tract.

In addition, we also stress the importance of a diagnostic evaluation scheduled within 3 months for:

- Patients with “high-grade squamous intraepithelial lesion (HSIL),” “atypical squamous cells that cannot exclude HSIL (ASC-H),” or “atypical glandular cells not otherwise specified (AGS-NOS)” at cervical cytology [7].
- Patients with a histopathological diagnosis of high-grade intraepithelial lesion without suspicion of invasion from a cervical biopsy (HSIL, CIN2–3), vaginal biopsy (HSIL, VAIN2–3), or a vulvar biopsy/excision (vulvar HSIL or differentiated VIN) [8].

Contact with patients with “positive high-risk HPV test with normal cervical cytology,” “low-grade squamous intraepithelial lesion (LSIL),” or “atypical squamous cells of undetermined significance (ASC-US)” at cervical cytology [7] or with a histopathological diagnosis of low-grade intraepithelial lesion from a cervical, vaginal, or vulvar biopsy/excision [8] could be postponed up to 6–12 months.

Follow-up after treatment for high-grade disease should not be postponed.

Patients who must complete the HPV vaccination schedule (two/three doses) can postpone administrations, provided that all doses are administered within 1 year [9].

All of these recommendations must be assessed and eventually applied on a case-by-case basis; it is not possible to exclude that some patients may need individualized management. These recommendations are not a substitute for clinical judgment and may vary over time in relation to the trend of the pandemic spread of COVID-19, including a return to standard management at the time when the non-urgent evaluation may be again scheduled.

The advent of new digital imaging technologies developed to support colposcopy, which, in some cases, can effectively replace the colposcope itself (i.e. mobile or digital colposcopy) [10,11], represents an important opportunity during the COVID-19 pandemic to share colposcopic images with reference centers, either during the examination or later by sending images or videos. This “teleconsultation” approach could be especially useful if the aim is to avoid concentrating patients in a few centers, and to perform examination with the same quality in different facilities, thus reducing the possibility of infection and spread of the virus. The digital connection could also contribute to the formation of a network between colposcopy clinics, by globally improving the quality of healthcare services. Digital colposcopy could be particularly useful in low-income countries, where the impact of COVID-19 is still unclear and potentially dangerous. One of the missions of SICPCV is to train colposcopists from low-income countries. For instance, to date there is a professional collaboration with Benin and Zambia that could be implemented with digital colposcopy.

3 PRECAUTIONS FOR OPERATORS DURING COLPOSCOPY AND OUTPATIENT SURGERY FOR LOWER GENITAL TRACT DISEASE

In the case of suspected or confirmed COVID-19 patients, an essential safety objective during colposcopy and outpatient surgery for lower genital tract disease is to protect healthcare workers at all levels from exposure to the disease. The main potential risk during surgery for lower genital tract disease is the risk of aerosol exposure when using electrosurgical or carbon dioxide (CO₂) laser instruments that can produce a large quantity of surgical smoke. Surgical smoke may contain viral

particles, as reported in studies of cervical excision procedures performed by LEEP or CO2 laser, whereby HPV was found in the upper airway mucosa of the surgeons [12,13]. Other viruses, such as HIV or hepatitis B, have also been detected in surgical smoke [14–16]. Even if this kind of transmission is more likely for blood-borne viruses and that at present there are no recorded cases of vaginal secretions testing positive for COVID-19 [17], we cannot underestimate the risk of COVID-19 infection by aerosol from surgical smoke. Therefore, all necessary safety precautions must be taken.

We recommend the following precautions/measures for outpatient surgery of the lower genital tract on suspected or confirmed COVID-19 patients:

- All patients must undergo detailed preoperative screening for COVID-19 exposure before having access to the outpatient facility.
- All patients should wear a surgical mask.
- A high-efficiency filter smoke evacuation system, directly connected to the speculum or electrosurgical handpiece, is mandatory to remove surgical smoke and aerosol and to provide satisfactory visualization during the procedure.
- Electrosurgical instruments should be set at the lowest power possible and not used for long continuous periods of time to reduce the amount of surgical smoke. As far as possible, it is recommended that hemostasis is obtained without electrosurgical instruments. LEEP and CO2 laser can both be used, whereas cold-knife surgery should not be the first choice for cervical or vaginal excision. Indeed, even if the problem of surgical smoke could be avoided with cold-knife conization, the risk of immediate and long-term complications would outweigh this benefit [18]. Vulvar procedures (biopsies or excisions) should be

done primarily with cold-knife instruments, limiting the use of electrosurgery to what is strictly necessary.

- The use of disposable devices and instruments is strongly recommended during the entire procedure. Non-disposable devices or instruments should be kept clean during procedures and should undergo separate disinfection and proper labeling. Clinical wastes should be labeled and disposed separately.
- Operator protection and personal protective equipment (PPE): perform hand hygiene before and after each procedure. Routinely use sterile fluid-repellant surgical gloves, an underlying pair of gloves, eye protection, FFP3 mask, surgical cap, and gown. PPE must be worn and removed according to standardized procedures.
- The colposcope should be protected by a disposable transparent cover, with the aim of reducing the possibility of contamination. A protective lens that must be disinfected after each use should also be applied. Finally, the use of a video colposcope, instead of a binocular support, should be preferred.
- Postoperative cleaning and disinfection of the operating room should be standardized according to national and local protocols and the new COVID-19 recommendations.

The listed procedures should be considered in addition to the standard procedures used for the safety of patients and operators, with the objectives of reducing the risk of infectious complications associated with outpatient surgery of the lower genital tract and preventing facility-related transmission of infections between different patients.

4 CONCLUSION

In conclusion, during the COVID-19 pandemic, correct selection of patients who need an evaluation in a colposcopy outpatient clinic, which cannot be postponed, is mandatory/highly recommended. The safety of patients and operators, as well as maintaining a high level of awareness of prevention strategies and occupational protection, must be the main objectives. All necessary procedures in this regard must be undertaken.

AUTHOR CONTRIBUTIONS

All authors contributed to the conception of the work, drafted the article, and subsequently reviewed it critically for important intellectual content. All authors provided their final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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