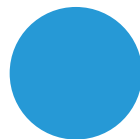


Pocket Guidelines

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**Vaginal
Cancer**



THE EUROPEAN VOICE
OF GYNAECOLOGICAL
ONCOLOGY



POCKET GUIDELINES

Based on

**ESTRO-ESGO-SIOPe Guidelines
for the management of patients
with vaginal cancer**

Nout, R, Calaminus, G., ... Fotopoulou, C. (2023).
ESTRO/ESGO/SIOPe Guidelines for the management of patients with vaginal cancer.
International Journal of Gynecological Cancer (in press)

As part of its mission to improve the quality of care for women with gynecological cancers across Europe, the European Society of Gynaecological Oncology (ESGO) jointly with the European Society for Radiotherapy & Oncology (ESTRO) and the European Society of Pediatric Oncology (SIOPe) developed evidence-based guidelines in order to improve the management of patients with vaginal cancer within a multidisciplinary setting.

These guidelines cover comprehensively the diagnostic pathways as well as the surgical, radiotherapeutical and systemic management and follow-up of adult patients (including those with rare histological subtypes) and pediatric patients (vaginal rhabdomyosarcoma and germ cell tumours) with vaginal tumours.

The guidelines were developed using a five-step process as defined by the ESGO Guideline Committee:



The objective of these ESGO Guidelines is to improve the quality of care for women with vaginal cancer across Europe and worldwide. They are intended for use by all health professionals who are involved in the management of patients with vaginal cancer, across all allied disciplines.

These guidelines do not include any economic analysis of the strategies. Any clinician seeking to apply or consult these guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

To ensure that the statements were evidence based, the current literature was reviewed and critically appraised. A systematic literature review of relevant studies published between January 2000 and January 2022 was carried out.

The guidelines were adopted if they were supported by sufficient high level of scientific evidence and/or when a large consensus among experts was obtained. An adapted version of the “Infectious Diseases Society of America-United States Public Health Service Grading System” was used to define the level of evidence and grade of recommendation for each of the recommendations:

LEVELS OF EVIDENCE

- I** Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well conducted, randomised trials without heterogeneity
- II** Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity)
- III** Prospective cohort studies
- IV** Retrospective cohort studies or case-control studies
- V** Studies without a control group, case reports, and/or expert opinions

GRADES OF RECOMMENDATIONS

- A** Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
 - B** Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
 - C** Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs...), optional
 - D** Moderate evidence against efficacy or for adverse outcome, generally not recommended
 - E** Strong evidence against efficacy or for adverse outcome, never recommended
-

ESGO would like to thank the international development group for their constant availability, work, and for making possible the development of these guidelines for the management of patients with vaginal cancer (see below). ESGO is also very grateful to the 112 international external reviewers for their participation (list available on the ESGO website).

NAME	SPECIALTY	AFFILIATION
Remi Nout	Radiation oncologist (chair)	Erasmus MC Cancer Institute, Rotterdam (Netherlands)
Christina Fotopoulou	Gynecologic oncologist (chair)	Queen Charlotte's & Chelsea Hospital, London (United Kingdom)
Gabriele Calaminus	Paediatric oncologist (chair)	University Children's Hospital, Bonn (Germany)
François Planchamp	Methodologist	Institut Bergonié, Bordeaux (France)
Cyrus Chargari	Radiation oncologist	Hôpital Universitaire Pitié Salpêtrière, Paris (France)
Sigurd F. Lax	Pathologist	Hospital Graz II, Graz and School of Medicine, Johannes Kepler University, Linz (Austria)
Hélène Martelli	Paediatric surgeon	Hôpital Universitaire Bicêtre, Paris (France)
W Glenn McCluggage	Pathologist	Belfast Health and Social Care Trust, Belfast (United Kingdom)
Philippe Morice	Gynecologic oncologist	Institut Gustave Roussy, Villejuif (France)
Maja Pakiz	Gynaecologist	University Medical Centre Maribor, Maribor (Slovenia)
Maximilian Paul Schmid	Radiation oncologist	Comprehensive Cancer Center Vienna, Vienna (Austria)
Jonáh Stunt	Methodologist	Erasmus MC Cancer Institute, Rotterdam (Netherlands)
Beate Timmermann	Radiation oncologist	University Hospital Essen, West German Proton Therapy Centre Essen (WPE), West German Cancer Center (WTZ), German Cancer Consortium (DKTK), Essen (Germany)
Christian Vokuhl	Paediatric pathologist	Universitätsklinikum Bonn, Bonn (Germany)
Daniel Orbach	Paediatrician	SIREDO Oncology Center (Care, Innovation and Research for Children, Adolescents and Young Adults with Cancer), PSL University, Institut Curie, Paris (France)

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General recommendations

A

Decision-making regarding treatment, across all stages, should be decided based on objective clinical, radiological and pathologic work-up following discussion in a dedicated multidisciplinary team of specialists in the diagnosis and management of vaginal cancer.

A

Patients should be carefully counseled on the suggested treatment plan and alternative options. Potential risks and benefits of all treatment options, including the option for second opinion, should be discussed and tailored to the individual patients needs.

A

Centralization of care in specialized centers and referral networks is recommended given the low incidence and complexity of care.

A

Enrolment of patients with vaginal cancer in clinical trials or registries when possible is strongly encouraged.

B

Use of patient reported outcome measures is encouraged.

Diagnosis work-up (local, regional, distant): clinical examination, colposcopy, histology, imaging

Staging and characterization of vaginal cancer, TNM classification and International Federation of Gynecology and Obstetrics (FIGO)

A

Vaginal cancers should be staged according to the TNM classification, and FIGO classification.

A

The method used to determine tumour status (T), lymph node status (N), and systemic status (M), i.e., clinical (c), including imaging, and/or pathological (p) should be documented.

A

For rhabdomyosarcoma (RMS) in childhood, it is recommended to use the IRS classification in addition to the TNM classification.

A

Localization (upper, middle, lower third) and maximum size of the primary tumour, and of any nodal disease should be specified and documented.

B

Even though these staging systems are designed for epithelial carcinomas of the vagina they may be used for non-epithelial malignancies where specific staging systems are not available.

A

HPV association should be determined for tumour classification.

A

Unusual and rare morphological tumour types should undergo specialist pathology review.

Initial clinical and radiological diagnostic work-up

A

Pelvic and vaginal examination is the first step in the diagnosis of vaginal cancer.

C

Examination under general anesthesia may be required to obtain tissue for histological confirmation and to determine the full extent of the disease.

A

Examination under colposcopic guidance is recommended particularly in stage I disease for exact mapping of any (pre-)invasive disease. Full documentation of the initial extent of the lesions visualized by clinical diagrams and/or photographs is recommended.

A

Magnetic resonance imaging (MRI) is the standard imaging modality to determine local tumour extent.

C

Expert pelvic ultrasound may be complementary.

A

Computed tomography (CT) chest-abdomen-pelvis is recommended as first step in the assessment of local and distant disease spread.

C

Positron emission tomography-computed tomography (PET-CT) may be considered for provision of additional information, especially in locally advanced disease in adults.

Management of stage I (T1N0M0) in adult patients: surgery versus (chemo)radiation therapy and brachytherapy

General recommendations

A

A histological diagnosis should be made before undertaking any treatment.

A

The combination of radical surgery and radiotherapy should be as principle avoided in any treatment planning due to the increased risk of complications and side-effects after combined treatment.

Surgery

A

The surgical route should be considered only for small size lesions (maximum size up to 2 cm) that are not in close relation to critical structures (urethra, anal canal) to ensure free margins with acceptable morbidity.

A

The surgical treatment consists of (partial) colectomy and lymph node assessment depending on the location of the primary lesion.

C

In patients with a tumour in the upper vagina, with a uterus in situ, a combination of hysterectomy and parametrial/paracolpion resection may be required together with the (partial) colectomy to ensure free margins.

C

A fertility sparing approach may be considered in selected patients with adequate distance of the tumour to the cervix, but at any resection highest care should be undertaken not to result in obstructive symptoms such as haematometra or inability to access the cervix for cytology and HPV screening.

A

In patients undergoing surgery for tumours involving the upper two thirds of the vagina pelvic lymph node assessment is recommended.

A

In patients undergoing surgery with tumours involving the lower third of the vagina, surgical inguinal lymph node assessment is recommended.

D

Use of sentinel lymph node principle alone is not yet established in vaginal cancers.

C

In selected patients after initial incomplete excision upon referral, surgical treatment may be considered when free margins can be ensured with acceptable morbidity.

Radiotherapy and brachytherapy - Adjuvant (chemo-)radiotherapy

A

Adjuvant radiotherapy is recommended in patients with tumour positive resection margins, or lymph node metastasis.

A

The addition of concomitant cisplatin-based chemotherapy is recommended in case of histologically confirmed lymph node metastasis.

B

This addition can be considered in case of positive surgical margins.

Radiotherapy and brachytherapy - Primary (chemo-)radiotherapy

A

A combination of external beam radiation therapy (EBRT) and brachytherapy is recommended in stage I.

A

Concomitant cisplatin-based chemotherapy is recommended.

B

Ovarian transposition should be discussed up front in premenopausal women undergoing radiotherapy.

Management of adult patients with stages T2-T3-T4, N0M0 or any T-stage , N1M0

A

Definitive platinum-based chemoradiotherapy and brachytherapy is the preferred treatment.

A

In patients with T4a tumours and fistulation, GI and GU diversion should be considered before chemoradiotherapy.

C

There is no valid evidence to support (neo-)adjuvant systemic therapy in vaginal cancer outside of clinical trials.

Distant metastatic disease at presentation and recurrent disease

Distant metastatic disease

C

Patients with oligo-metastatic disease at presentation may be treated with definitive chemoradiotherapy including brachytherapy, in combination with systemic therapy.

A

Referral to a palliative care specialist is recommended early on.

A

In medically fit patients with widespread distant metastatic disease at presentation, platinum-based systemic combination therapy, equivalent to cervical cancer regimens, is recommended.

A

In rare histological types, the preferred systemic therapy regimen should be adapted accordingly.

B

Selection of cytotoxic agents depends on the previous oncologic treatment, performance status and associated co-morbidities.

C

Treatment of oligometastatic sites depends on the site of disease and symptoms and may consist of (stereotactic)radiotherapy, or surgical resection and radio-frequency ablation in selected cases.

A

Palliative radiotherapy (single fraction/short course) to control bleeding, discharge, and pain due to pelvic disease or bone metastases should be considered.

A

Surgical interventions including diversion stoma and/or stenting should be considered as appropriate, for example, in case of obstructive symptomatic disease.

Local recurrent disease

A

Treatment of recurrent disease with curative intent requires centralization and involvement of a broad dedicated multidisciplinary team. A structured program for multidisciplinary diagnostic work-up, treatment, and follow-up must be present in centres responsible for the treatment.

A

Each centre involved in the primary treatment of vaginal cancer should have an established network for discussion of difficult cases and willingness for referring patients with recurrence for treatment to highly specialized units.

A

Relevant imaging including PET-CT is recommended to establish the status of the disease locally, regionally, and systemically.

A

The recurrence should be confirmed by histological examination, also to rule out any metastasis from another primary site.

B

In selected cases of central pelvic recurrence where clear margins can be achieved, a pelvic exenteration should be considered.

B

Reirradiation with image-guided adaptive brachytherapy for central recurrences may be considered in experienced centres.

A

In radiotherapy naïve patients, chemoradiation and brachytherapy is recommended.

A

If active local therapy is not an option, palliative treatments as described in the section on distant metastatic disease should be considered.

Rare histological subtypes

Adenocarcinomas

A

Recommendations for women exposed to diethylstilbestrol in utero are to have their first gynecologic examination at menarche with a careful colposcopic and cytological assessment of the cervix and vagina that should continue annually.

B

In general, treatment recommendations for vaginal adenocarcinomas are aligned with the recommendations for vaginal squamous cell carcinoma.

Sarcomas

A

These very rare forms of vaginal cancer should be jointly managed within a multidisciplinary setting together with a dedicated sarcoma team.

A

Registration in rare cancer networks is strongly encouraged.

Melanomas

A

These patients should be jointly managed within a multidisciplinary setting together with a dedicated melanoma team.

A

Registration in rare cancer networks is strongly encouraged.

Other rare subtypes

A

Other rare subtypes such as neuroendocrine and haematopoietic neoplasms of the vagina should be treated as per the guidelines of the respective tumour entity.

A

Registry in centralized databases for rare cancers is strongly encouraged.

Vaginal cancer in childhood and adolescents

Pediatric RMS

Vaginal RMS - Diagnosis

A

Full clinical examination including systematic evaluation with vaginoscopy under general anesthesia, as soon as this is feasible, with tumour mapping including detailed description (this can include photographic documentation and vaginal impression) is recommended.

A

Biopsy for histological confirmation should occur.

C

In case of a large polypoid lesion, resection could be performed but without excision of the vaginal wall.

A

Histopathological diagnosis including immunohistochemistry and/or molecular analysis (FISH, RT-PCR and/or RNA sequencing) is needed to confirm the diagnosis. In these rare tumours, it is recommended to seek the opinion of a specialist pediatric, gynaecological or sarcoma pathologist or reference network.

A

At diagnosis, initial tumour resection attempt should be avoided due to the high chemo-sensitivity of RMS, and therefore the evaluation of the necessity of any delayed local ablative techniques after neoadjuvant chemotherapy is recommended.

Vaginal RMS - Initial work-up

A

Pelvic and abdominal MRI is recommended for the initial work-up of the local tumour extent.

A

To rule out nodal and systemic metastasis, FDG PET-CT or whole body MRI, and low-dose chest CT are recommended.

A

Only in case of a radiologically suspicious pelvic, inguinal or abdominal nodal involvement, lymph node biopsy for histological or cytological confirmation is recommended.

Vaginal RMS - Chemotherapy schedule

A

The chemotherapy schedule should be adapted to risk factors (IRS stage, age, tumour size, nodal or distant spread, molecular and pathology findings).

A

Neoadjuvant and adjuvant combination chemotherapy, including an alkylating (cyclophosphamide, ifosfamide) agent, is recommended.

A

In rare cases with regionally involved lymph nodes and/or with a fusion positive RMS subtype additional maintenance strategies, after adjuvant therapy, should be considered.

Vaginal RMS - Local therapy

A

Highest consideration of any local therapy should be the organ preservation. After neoadjuvant therapy, local treatment should be discussed at a multidisciplinary team that includes different specialists who are experienced in treatment of pediatric patients (including a radiation oncologist specialized in brachytherapy). Radical, potentially mutilating surgical procedures during first line treatment should be avoided.

A

Local therapy is adapted to the tumour response and histological type, assessed by pelvic MRI and vaginoscopy after 3 and 6 courses of neoadjuvant chemotherapy. Any suspicious residual vaginal lesions should be biopsied during this exam. In case of stable or progressive disease after 3 courses, second line chemotherapy should be proposed.

A

EBRT is recommended in rare cases with lymph node metastasis, preferably using proton therapy.

A

In case of complete remission of an embryonal RMS after 6 courses of neoadjuvant chemotherapy confirmed by a negative pelvic MRI and a negative vaginoscopy (including biopsies of any suspicious areas), no local treatment is indicated. A strict follow-up schedule is recommended.

A

A strict follow-up schedule should consist of pelvic MRI (grade A) with or without vaginoscopy every 3 months during the first 2 years, and MRI every 4 months during the 3rd year, and every 6 months up to 5 years follow-up.

Vaginal RMS - Local therapy (continued)

B

Omission of any local treatment, including radiotherapy, can only be considered in case of complete remission and if at least a certain amount of alkylating agents (i.e., cyclophosphamide >8 gr/m²) was part of the neoadjuvant chemotherapy:

B

- Surgery:

A

- o At initial diagnosis, surgery is limited to a diagnostic biopsy for histological confirmation that may or may not include resection of any exoplytic/polypoid lesions but without any associated vaginal wall resections.

A

- o In case of residual tumour after neoadjuvant therapy:

- Unifocal small residue: partial vaginectomy (resection of the vaginal wall recommended/biopsy not sufficient)/ partial excision of the cervix

C

- If the residual tumour is located in the fornix/cervix: trachelectomy (or brachytherapy with cervix catheter) is recommended

B

- If the tumour involves more than half of the vagina or is multifocal: brachytherapy should be preferred over total vaginectomy depending on the patients risk profile and available options.

C

- o A minority of patients may undergo a limited, but complete tumour resection with organ preservation. For tumours of the upper part of the vagina, partial vaginectomy, partial or total excision of the uterine cervix or trachelectomy (removal of the cervix, surrounding tissue, and the upper part of the vagina) are considered organ-salvaging procedures.

D

In rare tumours not responding to chemotherapy, radical surgical procedures, such as total vaginectomy with or without hysterectomy, may be discussed.

C

- o Regional nodal spread: in the case of initial widespread nodal metastasis, systematic removal of lymph nodes is not recommended.

B

However, in the rare case of initial isolated nodal metastasis in very young patients (<3 years), removal of this lymph node may be considered with the aim to tailor the extent of the EBRT target volume.

B

- o Ovarian transposition is recommended in situations where relevant radiation dose to the ovaries is anticipated.

B

- Radiotherapy is generally recommended for:

- o Embryonal RMS, if no complete response is reached after induction chemotherapy and if conservative surgery with free margins is not possible.

- o In rare case of alveolar RMS with fusion transcript.

- o In cases of histologically, cytologically or radiologically confirmed regional nodal involvement.

- Brachytherapy is preferred over EBRT for treatment of the primary tumour. A total dose of 50-60 Gy EQD2 is prescribed. If external irradiation is however required (e.g. pelvic lymph node involvement), proton beam therapy is preferred. Brachytherapy is the preferred irradiation modality to boost the primary tumour and minimize doses to organs at risk.

B

- There are few systematic indications for EBRT in vaginal RMS. Only the rare cases with initial lymph node involvement, should receive EBRT. In this case, proton beam therapy is the preferred modality.

Vaginal RMS - Metastatic sites

C

In patients with limited (oligo) metastatic disease and favourable response after chemotherapy, focal treatment of metastatic sites could be considered.

C

There is insufficient data to recommend specific focal treatment for metastatic tumour sites (i.e. surgery, stereotactic radiotherapy) and management should be individualized depending on each patients' and tumor profile and also symptoms.

Pediatric germ cell tumours (GCT)

GCT - Diagnosis

A

Full clinical examination including vaginostomy under general anesthesia is recommended.

A

Biopsy for histologic confirmation is not mandatory in the presence of high AFP levels, but should be undertaken if the risk of morbidity is low. In very young patients (<2 years) a biopsy should always be obtained for histological confirmation due to the physiological higher serum AFP levels.

A

At diagnosis, initial tumour resection should always be avoided as vaginal GCT are highly chemo-sensitive.

A

In case of biopsy, histopathological diagnosis should include immunohistochemical analysis (e.g., with antibodies against AFP, PLAP, glypican-3, cytokeratin, etc.). In these rare tumours, it is recommended to strive for confirmation by an expert pathologist or reference network.

GCT - Initial work-up

A

Pelvic and abdominal MRI is recommended for local and regional work-up.

A

Low dose chest CT scan is recommended to exclude lung metastases.

GCT - Chemotherapy schedule

A

Neoadjuvant chemotherapy is recommended as standard approach.

A

As a principle, chemotherapy should include platinum derivatives regimens. The number of courses, the dose and the used drugs (3 to 4) should be adapted to extent of disease, dissemination pattern and the age of the patient.

GCT - Tumour assessment during neoadjuvant therapy

A

Regular ultrasound evaluation is recommended for response assessment during treatment, consolidated by an MRI at the end of cytotoxic treatment.

A

Tumour biomarker evaluation should include regular measurement of serum AFP.

GCT - Local therapy

A

Surgery should be reserved for situations where there is still persistent disease after completion of neoadjuvant chemotherapy. Surgery should aim for complete removal of the lesion and should be adapted to the anatomical site so that unnecessary radical or mutilating treatment is avoided. In the case of extravaginal, including lymph node spread, an initial surgical resection is not recommended, as this is treated by chemotherapy with excellent response and surgical discussion should be postponed after tumour reduction following induction chemotherapy.

B

Local therapy for the primary tumour is adapted to the tumour response, assessed by pelvic MRI after at least 3 courses and clinically with vaginoscopy. In case of a suspicious residual vaginal nodule it is preferable to remove any residual vaginal lesion by a partial resection of the adjacent vaginal wall, even if AFP levels are normal, than to perform a simple biopsy of the nodule that then will require a re-resection to achieve clear margins. If conservative surgery is not feasible, brachytherapy can be proposed as local treatment. If the resected nodule is completely resected; no further chemotherapy is needed even if viable cells present.

C

In case of complete remission after neoadjuvant chemotherapy confirmed by a negative pelvic MRI and negative vaginoscopy and normal AFP, no local treatment is indicated if a strict follow-up is possible.

A

Strict follow-up in patients with vaginal GCT after the end of treatment is recommended, consisting of AFP and ultrasound every 3 months during the first 2 years, then every 4 months during the 3rd year, and every 6 months up to 5 years follow-up. In case of rising serum biomarker (AFP) or suspicious findings on ultrasound an abdominal and pelvic MRI and vaginoscopy are recommended.

B

Adjuvant radiotherapy is individualized and decided within a multidisciplinary team. Radiotherapy is only indicated if no complete response can be achieved by chemotherapy ± organ sparing surgery. In case of radiotherapy, vaginal brachytherapy is preferred over EBRT to minimize long term morbidity. If EBRT is needed, proton beam therapy is preferred.

B

Ovarian transposition is recommended if radiotherapy is part of the treatment plan.

Neovaginal reconstructive surgery

A

When considering neovaginal reconstruction the age, performance status, sexual activity and patients' wishes should be evaluated and discussed. Patients who are sexually active and wish to pursue sexual activity are the optimal surgical candidates. Otherwise, there is a risk of stenosis of neovagina/obliteration.

B

The standardized questionnaires (such as: female sexual function index scores, quality of life scores, depression scales) in the preoperative screening of patients suitable for neovaginal reconstruction are valuable in order to identify pre-existing sexual function disorders. Preoperative sexual disorders may cause the postoperative and long term use of the neovagina challenging again with the risk of obliteration/stenosis.

A

The preoperative discussion should include counselling with psychologists and clinical nurse specialists. Partner(s) should ideally be involved, where applicable, in preoperative counseling. A supportive network for patients is important especially in the immediate postoperative period to keep the neovaginal cavity open and functions (vaginal dilators, sexual intercourse, etc.).

B

The choice between different procedures depends on several major criteria: previous irradiation, type of surgery (colpectomy, anterior, posterior or total pelvic exenteration), anatomy, weight, age, free or pedicled flap, previous history (smoking, cardio-vascular disease), previous abdominal surgery.

Follow-up of patients after treatment of vaginal cancer

A

Primary objectives of follow-up for patients with vaginal cancer should include the following:

- Early detection of recurrent disease.
- Patient education and support.
- Cancer rehabilitation with the goal to prevent and reduce psychosocial, physical, social, and existential consequences of cancer and its treatment starts at time of diagnosis. The efforts should optimize physical ability and quality of life of women affected by cervical cancer and include family members/caregivers. Several professions for counseling should be available, for example, psychologist, sex therapist, physiotherapist, and dietitian.
- Assessment of long-term outcome and iatrogenic toxicity.
- Quality control of care.

D

Data on patient initiated follow-up in primary vaginal cancer are lacking, and therefore cannot yet be safely recommended.

A

Follow-up should be composed of the following:

- Patient history (including elicitation of relevant symptoms).
- Physical examination (including a speculum examination and bimanual pelvic examination, detailed vulvar examination as well as inguinal lymph node assessment). If uterus has been left in situ screening of cervical cancer, including HPV, should continue. After radiotherapy cytology screening is not reliable.
- Physician assessment of adverse events using validated scales (eg, Common Terminology Criteria for Adverse Events).
- Prevention and management of cancer- and treatment related adverse-effects, for example, sexual dysfunction (eg, counseling, vaginal dilators and lubricants, local estrogen) and lymphedema.
- In case of the appearance of treatment-related symptoms, a referral to a dedicated specialist (eg, gastroenterologist, urologist/gynecologist) should be considered.
- Patients should be educated about symptoms of potential recurrence and potential long-term and late effects of treatment. Patients should also be counseled on sexual health, lifestyle adaptation, nutrition, exercise, obesity, and cessation of smoking.
- Follow-up schemes may be individualized, taking into account patients age, prognostic factors, treatment modality, and estimated risk and/or occurrence of adverse effects. Since the majority of relapses occur within the first two years after treatment, in general, follow-up intervals of 3 to 4 (6) months for the first 2 years and then 6 to 12 months up to 5 years are recommended.

Follow-up after (radical) surgery

A

Follow-up should be carried out by physician experienced with follow-up care after surgery following the general recommendations.

A

In patients with a neovagina secondary cancer related to the tissue/organ used may occur and should be anticipated. The neovagina should be examined by a surgeon experienced with the surgical procedure and examination of the neovagina.

Follow-up after definitive chemoradiotherapy

A

The same imaging method should be used for evaluation of tumour response as was used at baseline.

**A
D**

Initial evaluation of tumour response, should be performed not earlier than 3 months following completion of treatment. In unclear response, a re-evaluation should not be performed before 8-12 weeks thereafter.

**A
D**

Follow-up should be performed by a physician experienced with follow-up care after radiotherapy. Vaginal vault cytology is not recommended in these patients.

A

Providers should inform and educate on sexual and vaginal health and rehabilitation because of the vaginal and sexual morbidity that may occur as consequence of the cancer and the treatment. Vaginal dilation should be offered, as well as vaginal lubricants and local estrogen.

Access full ESGO Guidelines: www.esgo.org/explore/guidelines



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ESGO Office
7, Rue François-Versonnex
1211 Geneva 6, Switzerland
Email: adminoffice@esgo.org
www.esgo.org