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Early detection of recurrent ovarian cancer, current use of oncomarkers, imaging methods, and future perspectives

Včasná detekce rekurentního karcinomu vaječníků, současné využití onkomarkerů, zobrazovací metody a budoucí perspektivy

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Summary: Ovarian carcinoma is one of the most serious types of gynecological tumors. It is usually diagnosed in advanced stages, mainly due to an asymptomatic course or non-specific symptoms in the early stages. It is also characterized by a tendency to recur frequently, thus reducing the overall survival of patients. This article focuses on the possibility of detecting recurrence of the disease during follow-up of patients after complete remission. According to the analyzed literature, the monitoring of CA-125 and HE4 oncomarker levels in combination with imaging methods such as expert ultrasonography, CT, and positron emission techniques offers the potential for early detection of recurrence. The most advanced type of computed tomography, photon-counting CT, with high detection capability and lower radiation burden, also holds promise. The question of further management of early-detected asymptomatic recurrence is open for further discussion.

Key words: ovarian cancer – recurrence – follow-up care – tumor markers – early diagnosis – diagnostic imaging

Souhrn: Karcinom ovaria patří mezi nejzávažnější typy gynekologických nádorů. Obvykle bývá diagnostikován v pokročilých stadiích, a to zejména kvůli asymptomatickému průběhu či nespecifickým příznakům časných stadií. Vyznačuje se také tendencí často recidivovat, a snižovat tak celkové přežití pacientek. Tento článek se zaměřuje na možnosti detekce návratu onemocnění v rámci follow-up pacientek po kompletní remisi. Podle analyzované literatury přináší potenciál časného záchytu recidiv sledování hladin onkomarkerů CA-125 a HE4 v kombinaci se zobrazovacími metodami, jako je expertní ultrasonografické vyšetření, CT a pozitronové emisní metody. Příslib přináší i nejmodernější typ počítačové tomografie – photon counting CT s vysokou detekční schopností a zároveň menší radiační zátěží. Prostor pro další diskuzi pak přináší otázka dalšího postupu u časně detekované asymptomatické recidivy.

Klíčová slova: rakovina vaječníků – recidiva – následná péče – nádorové markery – včasná diagnóza – diagnostické zobrazování

Introduction

Ovarian carcinoma is the second most frequent and the first most lethal gynecological malignancy worldwide [1]. The vast majority of ovarian carcinomas are of epithelial origin (about 90%); only rarely are carcinomas of other histological origins present [2]. Ovarian carcinoma is usually diagnosed at an advanced stage due to late and non-specific symptoms. This is due not only to the aggressiveness of the tumor itself but also to the localization of the ovary in the abdominal cavity. Symptoms accompanying even the early stages of this disease include bloating, pelvic and abdominal pain, a feeling of fullness and eating disorders, urinary difficulties – urgency [3]. Although primary treatment (optimal surgery and platinum-based chemotherapy) leads to complete remission in many patients, the risk of recurrence remains high – up to about 70% in advanced stages. Overall, 5-year survival is less than 50% despite radical treatment [4].

Follow-up aims at early detection of recurrence of the disease and thus enabling the initiation of second-line treatment. Suspicion of recurrence may be based on clinical symptoms, laboratory values (elevation of tumor markers) or imaging results. It is essential to educate patients about the clinical signs of recurrent symptoms – weight loss, lack of appetite, fatigue, and other symptoms consistent

with early symptomatology mentioned above. Patients with this diagnosis after fertility preserving surgery represent a separate, individualized group.

In patients with an initial elevation of CA-125, laboratory monitoring is recommended during follow-up to detect early recurrence of the disease in addition to clinical and imaging examinations. However, the value of early detection of recurrence, before clinical symptoms, was questioned in a prospective study published in 2010 by Rustin et al. (MRC OV05/EORTC 55955). This demonstrated that administration of chemotherapy already at asymptomatic CA-125 rise did not lead to prolonged overall survival compared to delaying treatment until symptom onset [5,6]. Too early administration of treatment for recurrence may even be associated with a decrease in patients' quality of life [7]. Despite the findings of this study, follow-up is a standard part of care and patients are dispensed every 3–4 months for the first 2 years and then every 6 months until 5 years after treatment. However, there is no consensus protocol for follow-up and the frequency of follow-up should consider individual risk factors and prognosis [8]. Thus, a key question remains as to which methods of follow-up are most beneficial for early detection of ovarian cancer recurrence and whether they can improve treatment outcomes.

Oncomarkers

CA-125

The long-term standard for detecting ovarian cancer recurrence in biochemical follow-up is CA-125 monitoring. However, its sensitivity for detecting disease recurrence is not 100% – it is reported to be around 80%. The tumor marker CA-125 (Cancer Antigen 125) is a high molecular weight glycoprotein (product of the *MUC16* gene) on the surface of ovarian cancer cells. It was historically discovered in the 1980s as a serum marker of ovarian cancer and is still part of the diagnosis and monitoring of this disease. CA-125 is elevated in approximately 80% of epithelial ovarian carcinomas, especially serous ovarian carcinomas, especially in advanced stages. CA-125 levels correlate with tumor mass volume. Thus, in early stages of the disease, up to 50% of the levels may be within the normal range, whereas in advanced stages only about 10% [9,10]. After successful treatment, the CA-125 level typically decreases to the normal range, and the rebound often precedes clinical or radiological detection of recurrence. This is the so-called biochemical relapse of the disease. An elevation of this marker is present but without clinical correlation or imaging findings. Clinical relapse is usually preceded by 2–6 months [6]. In such a situation, observation and waiting for the onset of clinical symptoms or initiation of therapy is currently a legitimate approach, but tamoxifen administration is also an option and has a proven effect in these patients [11]. The limitation of CA-125 is its lack of specificity: it may be elevated in benign conditions (endometriosis, fibroids, inflammation) and is not reliable in about 20% of ovarian cancers (e.g., mucinous, non-epithelial, clear cell, undifferentiated or limited to the ovary). In other words, some recurrences may occur without CA-125 elevation, especially in patients who did not have elevated CA-125 even at the time of diagnosis of the primary tumor [12,13]. Nevertheless, CA-125 is still the most widely used tumor marker in the follow-up of patients after treatment for ovarian cancer. A level < 35 IU/mL is considered normal; a repeated rise above this level during dispensary is suspicious of disease recurrence and always requires further confirmation (clinical examination, imaging) [14].

HE4

HE4 (Human Epididydimis Protein 4) is a newer tumor marker, a protein of the WFDC (Whey-acidic four-disulfide core) domain family, encoded by the WFDC2 gene [15,16]. It is physiologically expressed in the epithelium of the epididymis and airways, but elevated serum levels have been found in epithelial ovarian cancer (EOC), even in cases where CA-125 may be normal [17]. HE4 was approved in 2008 by the Food & Drug Administration (FDA) for use in monitoring progressive and recurrent disease [18]. In 2012, HE4 was also approved for use in the diagnosis of pelvic tumors (in the ROMA Combined Index) [19]. Due to its higher specificity (as opposed to CA-125), HE4 elevations tend to be less common in benign gynecologic conditions such as endometriosis [20]. However, HE4 concentrations may falsely increase with reduced renal function, which must be considered (renal excretion is the main route of HE4 elimination). The clinical use of HE4 in oncogynaecology includes not only preoperative diagnosis (ROMA index) but also to detect disease recurrence. Several papers published to date report that HE4 has at least comparable, if not higher, accuracy than CA-125 in detecting relapse and the advantage of earlier detection of relapse by 3–8 months [21,22]. For example, a study from Japan (Uno et al.) of patients in remission found that at relapse, HE4 rose in 84% of cases, whereas CA-125 rose in only 56% of cases [23]. Similarly, Manganaro et al. reported that among patients with no evidence of disease during follow-up, no false-positive HE4 rise was observed, whereas an isolated CA-125 rise in the absence of relapse was seen in 50% of them [24]. This demonstrates the higher specificity of HE4 – isolated CA-125 fluctuations may be due to benign influences, whereas such a phenomenon is less common in HE4. The normal cut-off in postmenopausal women is reported to be ≤ 140 pmoL/L (approximately ≤ 70 pmoL/L in premenopausal women), however, the optimal cut-off in the context of post-treatment follow-up has not yet been clearly established [16].

The combination of both markers has the potential to increase the

detection of recurrences. In their prospective study, Plotti et al. reported that CA-125 alone detected recurrence with a sensitivity of 35% (with a standard cut-off of 35 IU/mL) and a specificity of 59%. In contrast, the combination of CA-125 + HE4 (at a HE4 cut-off of 70 pmoL/L) achieved a sensitivity of 76% and a specificity of 100% [17]. This offers potential extra scope for scheduling imaging investigations and early therapeutic intervention. It should be mentioned that absolute marker values should be evaluated dynamically, as single measurements may show fluctuating values. The trend is important. A repeated rise above a certain threshold or a doubling of the level compared to the previous minimum may be considered significant. For CA-125, it has been previously established that twice the upper normal ($2 \times 35 = 70$ IU/mL) reliably indicates recurrence [5]. For HE4, a similar consensus criterion has not yet been established. However, the data suggest that a small absolute rise in HE4 may be significant if consistent. For example, even a 15 pmoL/L increase in HE4 from baseline shows a relatively high yield – see below for the results of the OX-01 study by Presl et al. [25].

Therefore, it seems optimal to monitor both markers in parallel, with a significant rise in either marker considered suspicious. If a rise in both occurs simultaneously, the likelihood of recurrence is very high. Conversely, if both values remain normal over the long term, recurrence is unlikely [16].

Imaging methods used in ovarian cancer follow-up

In addition to the monitoring of tumor markers, imaging methods are used in the dispensary care of ovarian cancer. Their use increases the chance of early detection of disease recurrence.

Expert ultrasound examination

Since up to 50% of recurrences are localized in the pelvis [26], clinical gynecological examination in combination with sonography is the cornerstone of follow-up examinations. In the hands of an experienced oncogynaecologist (expert sonographer), ultrasound examination can detect recurrence not only in the pelvis. It can also localize enlarged pelvic or paraaortic nodes or peritoneal implants accessible from a transvaginal or transabdominal approach and other pathologies in the abdominal cavity. The advantage of ultrasound is the high resolution for soft tissues in the pelvis and the possibility of repeated performance without radiation burden. In addition, an expert sonographer can distinguish benign postoperative changes (scars, granulomas, fluid collections) from suspected tumor deposits. Ultrasound is therefore valuable for the investigation of any suspicious finding (e.g., palpable resistance or pain) and is often used as a first-line imaging modality when markers rise [27]. A major advantage of this method is the possibility of performing a tru-cut biopsy under ultrasound guidance for primarily inoperable findings, thus allowing the initiation of neoadjuvant chemotherapy without the need for a diagnostic laparoscopic procedure that burdens the patient with general anesthesia [28]. The limitation of the method is the availability of a sufficiently experienced expert sonographer, as well as the lower yield of ultrasound to detect distant or small peritoneal metastases (e.g. on the surface of the diaphragm, liver, etc.). Whole-body imaging, whether CT, MRI or hybrid imaging using PET, is the global standard for detecting recurrent ovarian cancer [29].

CT, PET-CT, PET-MRI

Whole-body CT scanning represents a widely available standard investigation in this context. The sensitivity and specificity of CT for the detection of recurrent ovarian cancer is reported to be around 80% when indicated for symptomatology suspicious for recurrent disease [29,30]. However, CT and MRI have been criticized for their lower ability to detect recurrent disease in the form of smaller peritoneal implants or normal-sized lymphadenopathy of the nodes compared to more modern methods. MRI is suboptimal in discriminating postoperative changes [31].

PET-CT, i.e. positron emission tomography combined with CT, is one of the most sensitive methods for detecting recurrent ovarian cancer. PET-CT with radioactive glucose (18F-FDG) can image metabolically active tumor lesions with very high sensitivity and specificity (reported to be around 90–98%), including small nodules or superficial peritoneal metastases that may escape conventional CT. PET has the advantage of a whole-body view – it can detect unexpected localizations of relapse (e.g. in distant nodes, liver, lungs) [29,30]. The disadvantages are the lower availability of this equipment worldwide and the higher radiation burden.

An alternative is PET-MRI, which uses simultaneously performed magnetic resonance imaging instead of CT. There is an 80% lower radiation exposure compared to PET-CT and higher contrast soft tissue imaging [32]. PET-MRI can better characterize pelvic findings (e.g., distinguish a tumor in the vaginal stump from a fibrotic scar) and eliminate false-positive PET signals in postoperative changes [33]. The use of PET/MR in follow-up is not yet routine, but it is a promising method, especially in patients where repeated CT is not appropriate (younger patients, need for multiple follow-ups). In general, PET scanning is indicated when recurrence is suspected (e.g., when markers rise or unclear findings on US or CT), not universally in asymptomatic patients.

Photon-counting CT, PC CT

Classical computed tomography (CT) is the standard in ovarian cancer imaging – it is used for staging and to confirm

or exclude recurrence. However, its resolution limits the detection of very small lesions. Photon-counting CT (spectral CT with photon counting) represents a new generation of CT devices that use semiconductor detectors capable of registering individual photons and their energy instead of conventional detectors [34]. This technology brings significantly higher spatial resolution – the detector does not require a so-called septum, which allows for a reduction in pixel size. Clinical PC CT systems achieve resolutions up to about 0.15–0.2 mm, significantly better than conventional CT (typically ~0.5–1 mm). As a result, even very small lesions can be imaged. In addition, the ability to measure the energy of each photon enables spectral imaging – distinguishing the material composition of tissues like dual energy, but with higher accuracy. This can be used to improve contrast between tumor implants and the surrounding area (e. g., highlighting iodine contrast agent or calcium) [34,35].

Initial studies suggest that photon-counting CT could significantly improve the detection of early peritoneal metastases. In an experimental model of colorectal carcinomatosis, PC CT demonstrated 100% specificity and significantly higher sensitivity than conventional CT in detecting lesions < 5 mm. In clinical practice, case reports have been published in which PC CT imaged small tumor implants unrecognized by standard CT. Thus, the benefit for early detection of ovarian cancer recurrence is that PC CT can detect the tumor when it is only a few millimeters in size and the patient is asymptomatic. Importantly, modern PC CT can achieve this at a reduced radiation dose due to its higher photon detection efficiency [34–36].

Discussion

The CEEGOG OX-01 study from 2024 (Presl et al.) was a prospective multicenter study under the CEEGOG umbrella focused on the role of HE4 in the follow-up of advanced ovarian cancer [25]. It enrolled 117 patients with stage III–IV epithelial ovarian, fallopian tube, or primary peritoneal carcinoma who had elevated CA-125 and/or HE4 levels at disease onset and achieved complete remission after first-line treatment (negative CT findings and normalization of markers).

Patients were followed up clinically and with HE4 and CA-125 markers every 3–4 months during the first 2 years and every 6 months thereafter. When markers rose above a defined threshold or by > 20% from the previous elevated value, surveillance imaging (CT) was indicated. The primary objective of the study was to evaluate whether monitoring HE4 (in addition to CA-125) improves detection of recurrence and whether a single value or a trend of repeated measurements is more significant.

During follow-up, 73% of patients relapsed. Data analysis confirmed that dynamic changes in markers are a better indicator of imminent recurrence than a single exceedance of normal cut-off values. For predicting disease recurrence, a CA-125 rise of ≥ 10 IU/mL had a sensitivity of 83% and specificity of 93%, while a HE4 rise of ≥ 15 pmoL/L had a sensitivity of 74% and specificity of 92%. The combination of both markers (simultaneous rise above these values) had a lower sensitivity (63%) but very high specificity (97%). In patients without recurrence, the values of both markers were stationary.

Using the oncomarker norm limits without monitoring dynamics, the following values were achieved: the norm limit for CA-125 of 35 IU/mL was exceeded by 77% of relapsing patients (sensitivity 77%, specificity 94%), and the norm limit for HE4 of 140 pmoL/L was exceeded by only 37% (sensitivity only 37%, but specificity 100%). Thus, many patients relapsed before HE4 values reached the traditional upper limit of the norm – however, an upward trend was evident. In practical terms, this means that fixed cut-off values (e. g. HE4 > 140 pmoL/L) may delay detection of relapse.

The CEEGOG OX-01 study showed that the inclusion of HE4 in routine monitoring makes sense due to its higher potential to detect disease recurrence. Routine CT scans in asymptomatic patients did not show benefit for earlier detection. Therefore, a reduction in the frequency of CT scans may be considered in patients with consistently normal values.

As noted in the text, biochemical detection of recurrence precedes CT findings by 2–8 months. The use of next-generation imaging modalities such as PC CT could have the potential to significantly reduce this gap between laboratory and imaging methods.

However, the actual potential benefit of early detection of asymptomatic disease recurrence remains an unresolved issue; the impact on overall survival has not yet been demonstrated. However, in the era of new therapeutic options (antiangiogenic therapy, PARPi...) and personalized medicine, it can be expected that early detection of asymptomatic recurrence will become of clinical importance.

Conclusion

Due to the very high recurrence rate, follow-up after treatment of ovarian cancer is an important element in the care of these patients. The traditional part of patient follow-up is the monitoring of oncomarker levels of CA-125 and HE4 (this marker has established itself as an important adjunct in recent years). The combination of these two markers increases the probability of early detection of recurrence. With the development of modern imaging modalities such as PET-CT or PET-MRI, the ability to detect and localize recurrences early is also increasing. A completely new and not yet widely available generation of CT – photon-counting CT – promises to further expand the possibilities of detecting recurrences, moreover with

a lower radiation burden for patients. This trend is in line with an increasingly personalized approach to the care of patients with this problem.

Currently, only the University Hospital in Pilsen is equipped with three PC CT scanners (on a global scale). Therefore, a study focusing on the use of the unique PC CT technology for the detection of ovarian cancer recurrences can be expected to start soon.

At the same time, ongoing studies investigating the role of secondary surgical cytoreduction in early detection of recurrence will hopefully soon provide an answer to the question of how to effectively use early detection of recurrence to benefit patients.

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