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CASE REPORT

OSNA in endometrial cancer

Molecular nodal staging in patients with early-stage endometrial cancer using the OSNA system – outcome of the ENDO-OSNA multicentric study

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Introduction

Endometrial cancer (EC) is the most frequently diagnosed gynaecological malignancy in Europe [1,2]. For early-stage cancer, the primary treatment is surgery, which may be followed by adjuvant chemotherapy and/or radiotherapy depending on the outcome of staging and risk-group stratification. For lymph node staging, the latest ESGO/ESTRO/ESP guidelines recommend sentinel lymph node biopsy (SLNB) as an acceptable alternative to systematic lymphadenectomy in stage I–II disease [3], thus reducing the morbidity typically associated with such extensive procedure. Sentinel lymph nodes (SLNs) are analysed by pathological ultrastaging. Despite its improved sensitivity compared to the conventional histology, protocols for ultrastaging are not standardised, cost- and time-intensive and therefore not suited for rapid, intraoperative diagnoses [4]. One-step nucleic acid amplification (OSNA) is a fast molecular-based diagnostic test for the detection and quantification of metastases in whole lymph nodes, which overcomes these challenges. OSNA is CE-marked for a variety of cancer entities including endometrial and cervical cancer, allowing its use in routine practice.

The ENDO-OSNA study

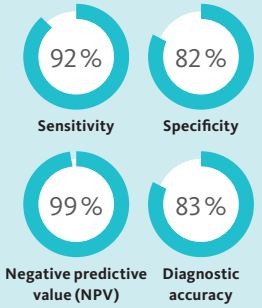
The aim of this multicentric, prospective study was to compare the performance of OSNA with standard pathological ultrastaging and validate its clinical usefulness for early-stage EC patient management.

For this, 147 patients with early-stage EC were recruited and their SLNs were analysed by both OSNA and pathological ultrastaging which includes serial sectioning of the SLN in combination with hematoxylin-eosin and immunohistochemical staining.

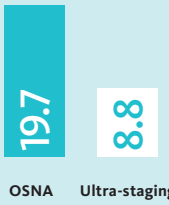
Results show that the OSNA method has higher sensitivity, specificity and diagnostic accuracy in the detection of SLN metastasis, including low-volume metastasis, than pathological ultrastaging [5].

OSNA resulted in an upstaging of 8.2% of patients to FIGO stage IIIC1. This has important clinical implications since the patients are considered high-risk and should be managed with adjuvant treatment.

This means that being able to detect SLN metastasis at the time of surgical treatment by OSNA could help identify those patients who could benefit from adjuvant therapy and ensure an early start of treatment, thus improving their prognosis and survival.



Overall performance



OSNA detected metastases in 19.7 % of patients, whereas pathological ultrastaging detected metastasis in 8.8 % of patients

OSNA resulted in an upstaging of 8.2 % of patients

10–15 % recurrence rate in node-negative EC patients

Clinical value

The main values of OSNA are the higher sensitivity, specificity and diagnostic accuracy in the detection of SLN metastasis, including low-volume metastasis, compared to standard pathological ultra-staging. Moreover, OSNA could aid in the identification of patients with intermediate or high-risk endometrial cancer, and lead to treatment decisions that could improve their prognosis and survival. We consider it an overall improvement.

Physicians' feedback

'The molecular ultrastaging of the sentinel lymph node in endometrial cancer by the innovative and intraoperative OSNA technology represents an efficient alternative to pathological ultrastaging. Moreover, the molecular approach reduces time during the sentinel lymph node analysis which helps to decrease the laboratory workload.'

– Dr David Hardisson
Head of pathology department
La Paz University Hospital, Madrid, Spain

'OSNA provides greater diagnostic precision and improves surgical upstaging to stages IIIC, providing the most appropriate adjuvant therapeutic planning for the patient, which could have a prognostic impact. OSNA could be successfully incorporated in the standard staging guidelines.'

– Dr Maria Dolorres Diestro
Gynaecologist, Onco-gynaecology department
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