

PUBLICATION SPOTLIGHT

OSNA in cervical and endometrial cancer

As fast as frozen section, as sensitive as ultra-staging – Confident nodal information beyond micro/macro

Nodal involvement is a major prognostic factor in gynaecological cancers and impacts the surgical approach as well as therapy choice. Nowadays, sentinel lymph node biopsy (SLNB) is a widely accepted alternative to systematic lymphadenectomy for the purpose of lymph node (LN) staging in early-stage patients. The morbidity typically associated with such a radical surgical procedure is therefore reduced, sparing unnecessary pain and distress for the women while enabling a more comprehensive examination of a smaller number of LNs, called sentinel lymph nodes (SLNs), in order to assess the nodal status.

The method commonly used for the analysis of SLNs is pathological ultra-staging which combines serial sectioning and immunohistochemical staining, thus allowing a thorough evaluation of the nodes and detection of low-volume disease. However, despite its improved sensitivity compared to conventional histology, pathological ultra-staging carries a few limitations such as the lack of standardised protocols and it is cost- and time-intensive which means it is not suited for rapid, intraoperative diagnoses. One-step nucleic acid amplification (OSNA) is a rapid, highly sensitive and standardised molecular diagnostic test for the detection and quantification of metastases in whole lymph nodes, which overcomes these challenges.

Solution with OSNA

- ✓ Whole node analysis
- ✓ Automated
- ✓ Definitive results within ~ 20-30 min
- ✓ High sensitivity and specificity
- ✓ No tissue allocation bias
- ✓ No risk of overlooking low-volume metastases
- ✓ Only 3 workflow steps
- ✓ Less workload and allocation of resources

Limitations of ultra-staging

- ✗ Variety of sectioning protocols
- ✗ User variability
- ✗ Not available in an intraoperative time frame
- ✗ Sensitivity and specificity vary
- ✗ Risk of tissue allocation bias
- ✗ Risk of overlooking very small metastases
- ✗ Up to 12 workflow steps depending on protocol
- ✗ More intensive allocation of resources required

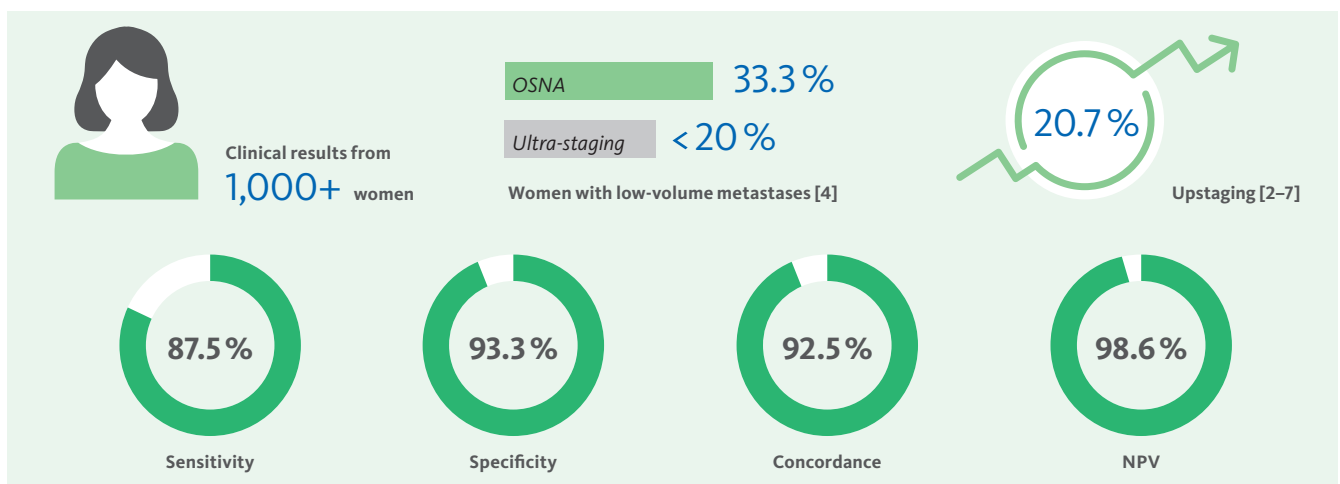


Fig. 1 Outcome of a meta-analysis of all performance evaluations in OSNA endometrial and cervical cancers until June 2022. Median values are shown.

OSNA – Definitive molecular nodal staging within 30 min – Supporting treatment decisions already during surgery

Selected publications

[1] **Togami S et al. (2022):** One-step nucleic acid amplification (OSNA) assay for detecting lymph node metastasis in cervical and endometrial cancer: a preliminary study. *J Gynecol Oncol.* 33(2): e11. [article]

Key message: OSNA could enhance the accuracy of conventional pathological examination for the detection of LN metastasis by reducing the false negative rate in endometrial and cervical cancer patients.



[2] **Diestro MD et al. (2021):** One-Step Nucleic Acid Amplification (OSNA) of Sentinel Lymph Node in Early-Stage Endometrial Cancer: Spanish Multicenter Study (ENDO-OSNA). *Cancers (Basel).* 13(17): 4465. [article]

Key message: OSNA can accurately detect SLN metastasis in early-stage disease, resulting in an upstaging rate of 8.2% and could aid in the identification of patients requiring adjuvant treatment at the time of diagnosis.

[3] **Fanfani F et al. (2020):** Standard ultra-staging compared to one-step nucleic acid amplification for the detection of sentinel lymph node metastasis in endometrial cancer patients: a retrospective cohort comparison. *Int J Gynecol Cancer.* 30(3): 372–377. [abstract]

Key message: Higher detection rate of micrometastasis by OSNA when compared to ultra-staging, though both methods showed a similar overall rate of SLN positivity in endometrial cancer patients.



[4] **Bizzarri N. et al. (2020):** Role of one-step nucleic acid amplification (OSNA) to detect sentinel lymph node low-volume metastasis in early-stage cervical cancer. *Int J Gynecol Cancer.* doi: 10.1136/ijgc-2019-000939. [abstract]

Key message: Detection rate of micrometastasis with OSNA seems to be slightly higher than with ultra-staging/immunohistochemistry and may indicate a superior accuracy of molecular methods.

[5] **Raffone A et al. (2019):** Accuracy of One-Step Nucleic Acid Amplification in detecting lymph Node metastases in endometrial cancer. *Pathol Oncol Res.* 26: 2049–2056. [abstract]

Key message: OSNA appears to be a highly accurate tool for intraoperative assessment of SLN in endometrial cancer.



[6] **Monterossi G et al. (2019):** Intra-operative assessment of sentinel lymph node status by one-step nucleic acid amplification assay (OSNA) in early endometrial cancer: a prospective study. *Int J Gynecol Cancer.* 29(6): 1016–1020. [abstract]

Key message: Data shows a correlation between the size of metastasis in the SLN and non-SLN positivity suggesting that the OSNA results could support surgical tailoring of early-stage endometrial cancer patients for better risk stratification and individualisation of adjuvant therapy.

[7] **Kostun J et al. (2019):** One-step nucleic acid amplification vs ultrastaging in the detection of sentinel lymph node metastasis in endometrial cancer patients. *J Surg Oncol.* 119(3): 361–369. [abstract]

Key message: The combination of OSNA and SLNM approaches in endometrial cancer patients carries a great potential for the highly sensitive detection of metastatic LN as well as the application of adjuvant therapy.



[8] **Fanfani F et al. (2018):** One-Step Nucleic Acid Amplification (OSNA): A fast molecular test based on CK19 mRNA concentration for assessment of lymph-nodes metastases in early-stage endometrial cancer. *PLoS One.* 13(4): e0195877. [article]

Key message: OSNA together with SLNM could represent an efficient intraoperative tool for the selection of early-stage endometrial cancer patients to undergo systematic lymphadenectomy.

[9] **López-Ruiz ME et al. (2016):** One-step nucleic acid amplification (OSNA) for the detection of sentinel lymph node metastasis in endometrial cancer. *Gynecol Oncol.* 143(1): 54–59. [abstract]

Key message: OSNA allows the analysis of the entire LN, thus it avoids missing metastases due to partial tissue analysis by standard H&E examination.



[10] **Okamoto S et al. (2013):** Detection of sentinel lymph node metastases in cervical cancer: assessment of KRT19 mRNA in the one-step nucleic acid amplification (OSNA) method. *Gynecol Oncol.* 130(3): 530–6. [article]

Key message: OSNA can detect LN metastasis as accurately as conventional histopathology and may be an effective method for rapid intraoperative examination of SLN in cervical cancer patients.

Last update October 2022

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