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PUBLICATION SPOTLIGHT

OSNA in cervical and endometrial cancer

Fast and accurate molecular lymph node analysis going beyond ultra-staging

Metastatic lymph node (LN) involvement is a major prognostic factor in gynaecological cancers and impacts the surgical approach as well as therapy choice. Nodal staging by systematic pelvic lymphadenectomy is associated with high risk of complications and post-surgical morbidity. Furthermore, its utility in early stage disease is challenged by the low frequency of nodal positivity and controversy about its curative effect.

Sentinel lymph node biopsy (SLNB) is gaining increasing acceptance as an alternative to lymphadenectomy in the management of early stage cervical (CeC) and endometrial (EC) cancer patients, with the aim to avoid unnecessary lymphadenectomies and enable less radical surgical interventions to benefit the patient's quality of life.

Assessment of a smaller number of LNs permits more detailed examination to determine the nodal status. However, this is hindered by intrinsic limitations of ultra-staging by serial sectioning and immunohistochemical staining. In contrast, OSNA (one step nucleic acid amplification) is a highly sensitive and standardised molecular method for assessment of whole LNs in a very short time frame. By quantifying the level of CK19 mRNA expression, OSNA accurately indicates the presence or absence of metastasis.

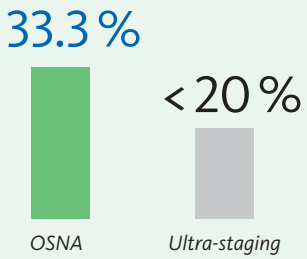
Limitations of ultra-staging

- ✗ Not suitable for intraoperative analysis
- ✗ Limited sensitivity to detect low volume disease
- ✗ Time-consuming and labour-intensive
- ✗ No standardised protocol established

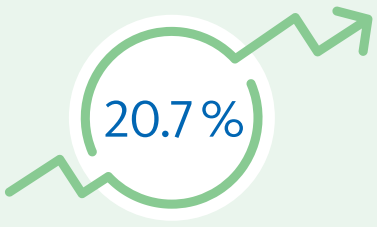
Solution with OSNA

- ✔ Fully informed intraoperative results
- ✔ No risk of overlooking occult metastases
- ✔ Fast availability of results and easy to operate
- ✔ Standardised whole node analysis

Sensitivity of OSNA in detecting LN metastasis in EC patients [7]



33.3 % of early stage CeC patients had low-volume metastasis in LN detected during surgery by OSNA [2]



EC patients were upstaged to FIGO stage III by OSNA due to its higher sensitivity in detecting micrometastasis [5]

www.sysmex-europe.com/osna

OSNA – Accurate nodal staging with OSNA supporting treatment decisions already during surgery

Publications

[1] 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. doi: 10.1136/ijgc-2019-000937. [abstract]*

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

[2] 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.*

[3] Raffone A et al. (2019): *Accuracy of One-Step Nucleic Acid Amplification in detecting lymph Node metastases in endometrial cancer. Pathol Oncol Res. doi: 10.1007/s12253-019-00727-9. [abstract]*

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

[4] 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 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 EC patients for better risk stratification and individualisation of adjuvant therapy.*

[5] 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: *A combination of OSNA and SLNM approaches in EC patients has great potential for the highly sensitive detection of metastatic LN as well as application of adjuvant therapy.*

[6] 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. [abstract]*

Key message: *OSNA together with SLNM could represent an efficient intraoperative tool for the selection of early stage EC patients to be submitted for systematic lymphadenectomy.*

[7] 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.*

[8] Nagai T et al. (2015): *A new diagnostic method for rapid detection of lymph node metastases using a one-step nucleic acid amplification (OSNA) assay in endometrial cancer. Ann Surg Oncol. 22(3):980-6. [abstract]*

Key message: *The OSNA assay using CK19 mRNA is useful for the detection of LN metastases in EC patients and in combination with SLN may facilitate individualised treatments.*

[9] 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. [abstract]*

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 CeC patients.*

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