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PUBLICATION SPOTLIGHT

OSNA

Enhancing the power of nodal staging in the neoadjuvant setting of breast cancer

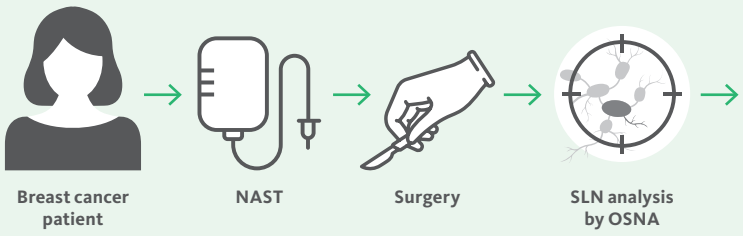
Enlarged admission of breast cancer patients to neoadjuvant systemic therapy (NAST) has also led to an increased usage of OSNA for assessing sentinel lymph nodes (SLN) in eligible patients undergoing surgery after completion of therapy.

In consequence, significant clinical evidence could be gained demonstrating that molecular quantification of CK19 mRNA expression by OSNA performs on the same level of accuracy in detecting nodal metastases after NAST as in the conventional adjuvant setting. Accurate SLN assessment is essential as any amount of residual metastatic disease in lymph nodes constitutes an important prognostic factor.

Moreover, the advantage to obtain intraoperatively fully informed results due to the possibility to analyse the whole lymph node tissue in a very short time, allows surgeons to take an immediate decision to abandon (in case of SLN-) or proceed to axillary lymph node dissection (in case of SLN+) which spares patients potential second surgeries.

Recent study results indicate that the OSNA quantitative result can be used to predict non-SLN involvement as well as for the assessment of patient's prognosis also in the NAST setting further confirming the predictive and prognostic capabilities of OSNA in breast cancer.

OSNA cut-off values supporting prediction of non-SLN involvement and patient's prognosis



Prediction of non-SLN involvement[1]	
250 cp/µL	NPV 99 %
5,000 cp/µL	NPV 93.1 %
15,000 cp/µL	NPV 90.5 %

Prognosis – higher risk of disease recurrence[1]	
25,000 cp/µL	HR 2.95

Fig. 1 *Overview of OSNA molecular cut-off values. Abbreviation cp/µL corresponds to copies/µL of CK19 mRNA.*

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OSNA – Enhancing the power of nodal staging in the neoadjuvant setting of breast cancer

Selected publications

[1] Vieites B et al. (2021): *Predictive and prognostic value of total tumor load in sentinel lymph nodes in breast cancer patients after neoadjuvant treatment using one-step nucleic acid amplification: the NEOVATTL study. Clin Transl Oncol. Published online Jan 31. doi: 10.1007/s12094–020–02530–4. [article]*

Key message: *OSNA provides intraoperative, highly accurate and definitive results also in the neoadjuvant treatment. A total tumour load (TTL) in the SLNs of > 15,000 mRNA copies/µL is predictive of non-SLN involvement while TTL > 25,000 mRNA copies/µL is associated to higher risk of disease recurrence.*

[2] Peña KB et al. (2021): *Total Tumor Load of mRNA Cytokeratin 19 in the Sentinel Lymph Node as a Predictive Value of Axillary Lymphadenectomy in Patients with Neoadjuvant Breast Cancer. Genes (Basel). 12(1):77. [abstract]*

Key message: *OSNA is a highly sensitive, specific and reproducible diagnostic method applicable also for the analysis of SLNs after neo-adjuvant chemotherapy. Moreover, the Total Tumour Load assessed by OSNA can help predicting the probability of additional axillary metastases.*

[3] Espinosa-Bravo M et al. (2017): *Intraoperative assessment of sentinel lymph node by one-step nucleic acid amplification in breast cancer patients after neoadjuvant treatment reduces the need for a second surgery for axillary lymph node dissection. Breast. 31:40–45. [abstract]*

Key message: *The accurate and standardised intraoperative SLN analysis by OSNA decreases the need of a second surgery in 18.5 % of breast cancer patients with a positive SLN after neoadjuvant therapy.*

[4] Parada D et al. (2016): *Intraoperative molecular analysis of sentinel lymph nodes following neoadjuvant chemotherapy in patients with clinical node negative breast cancer: An institutional study. Mol Clin Oncol. 5(5):507–510. [abstract]*

Key message: *The OSNA assay is a highly sensitive, specific and reproducible method to assess SLN metastases upon NAST. The total tumoral load may help predicting further non-SLN metastases in the axilla.*

[5] Vieites B et al. (2016): *CK19 expression in breast tumours and lymph node metastasis after neoadjuvant therapy. Histopathology. 69(2):239–49. [article]*

Key message: *The expression of CK19 protein is preserved after neoadjuvant therapy. This indicates that OSNA is a suited approach for lymph node analysis also upon neoadjuvant treatment.*

[6] Osako T et al. (2013): *Molecular detection of lymph node metastasis in breast cancer patients treated with preoperative systemic chemotherapy: a prospective multicentre trial using the one-step nucleic acid amplification assay. Br J Cancer. 109(6):1693–8. [abstract]*

Key message: *The OSNA method can detect lymph node metastases as accurately as conventional pathology despite the presence of chemotherapy-induced histological changes.*

[7] Navarro-Cecilia J et al. (2013): *Intraoperative sentinel node biopsy by one-step nucleic acid amplification (OSNA) avoids axillary lymphadenectomy in women with breast cancer treated with neoadjuvant chemotherapy. Eur J Surg Oncol. 39(8):873–9. [abstract]*

Key message: *The OSNA result can predict the axillary status with a high accuracy also in clinically node negative patients at initial presentation who underwent neoadjuvant therapy.*

[8] Rebollo-Aguirre AC et al. (2012): *Sentinel lymph node biopsy in patients with operable breast cancer treated with neoadjuvant chemotherapy. Rev Esp Med Nucl Imagen Mol. 31(3):117–23. [abstract]*

Key message: *The approach of SLN biopsy after NAST can predict the axillary status with a high accuracy, thus avoiding unnecessary ALND. In this setting, OSNA offers the advantages of standardisation and highly sensitive and specific results.*

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