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

There has been an increase in the use of neoadjuvant systemic therapy (NAST) in breast cancer patients in recent years. The main indications include shrinking the primary tumour, thus reducing the extent of surgery, or enabling breast conserving surgery instead of mastectomy. Moreover, it allows an assessment of the tumour's response to systemic therapy.

Pathologic complete response (pCR) is currently considered the most significant indicator of the success of NAST and is evaluated in the tumour as well as in the axillary lymph nodes. An accurate nodal staging after NAST is of utmost importance since any residual metastatic burden in the axillary nodes affects the patient's survival, even in the case of pCR in the primary tumour[1,2].

ypN

Nodal status post chemotherapy is a strong predictor of outcome[1]

However, the effects of the anticancer drugs on the tissue's morphology complicate any objective judgement of the presence of vital cancer cells. Furthermore, only a limited amount of tissue is usually examined and there is no uniform definition of pCR[3], thus complicating the final judgement.

These constraints lead to low sensitivity as well as a lack of standardisation and reproducibility of the results[4].

67 – 81 %

Reported sensitivity of intraoperative frozen section after NAST[5]

OSNA – Objective, standardised and reproducible

OSNA – One Step Nucleic Acid Amplification – is a well-established technique for sentinel lymph node (SLN) analysis, has proven its usefulness in more than a hundred studies and is recommended in European guidelines and several national guidelines. The high level of sensitivity of the method enables the identification of the smallest metastatic burden, an essential requirement in the NAST setting for an optimal treatment decision and prognostic information. The fast availability of results allows immediate decision-making in the same surgical procedure and reduces the time to further treatment steps.

Diagnosis

- Accurate and standardised lymph node assessment thanks to whole node analysis.
- Confidence that residual metastatic burden will not be overlooked.
- More precise staging of the axilla.

Surgery

- Immediate, fully-informed decision during the surgical procedure.
- Helps to spare unnecessary lymphadenectomies.
- Helps to avoid second surgeries in cases of positive post-operative histology.

Therapy

- Confidence in nodal staging after completion of neoadjuvant therapy.
- Reliable basis for further treatment decisions.

'Definitive, intraoperative assessment of the SLN by OSNA reduces the need for second surgery for ALND in 18.5 % of cases[6].'

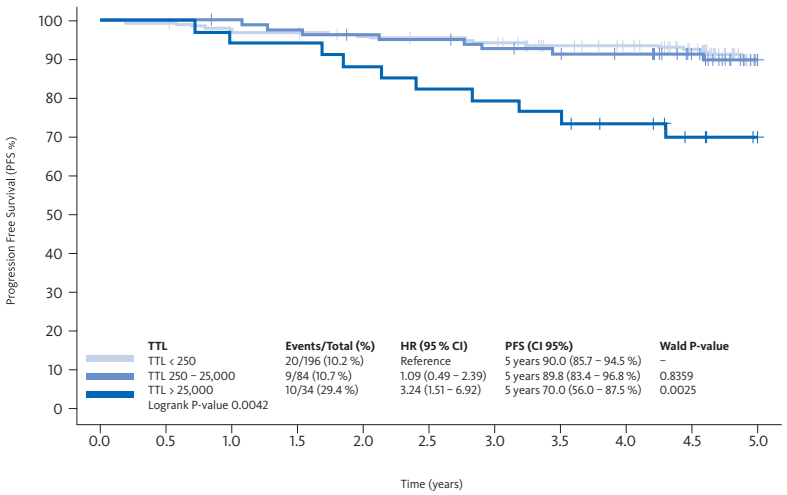
18.5 %

'It allows decisions to be taken on whether an axillary dissection should be performed immediately, thus avoiding any delay in the administration of chemotherapy and benefiting patients thanks to a single surgical procedure[7].'

'Recent findings indicate that the Total Tumour Load derived from OSNA provides prognostic information on patients who have received NAST[8], as has already been shown in the conventional setting[9].'*

** Total Tumour Load is the total number of CK19 mRNA copies in all positive SLN.*

Results of the NEOVATTL study



'The clinical value of a SLN biopsy is changing. The OSNA method provides more information (i.e. prediction, prognosis) than conventional histology in the adjuvant and neoadjuvant setting. Nodal involvement (TTL >25,000 copies) after NAST has a significant impact on survival. TTL should be taken into account for a multidisciplinary approach to breast cancer.'

Dr B. Vieites

'Molecular analysis gives our patients greater therapeutic certainty compared to traditional methods, especially in the surgical field, though also at the time a decision is taken on further chemotherapy treatments.'

Dr J.I. Sanchez-Mendez

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