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PUBLICATION SPOTLIGHT

OSNA in lung cancer

Definitive molecular nodal staging within 30 min – Quantitative nodal tumour burden beyond metastasis size in lung cancer

In lung cancer, the lymph node (LN) status is an important component of staging. It supports treatment decisions and also provides prognostic information, since the presence of metastatic LNs is associated with worse survival rates[1]. The five-year survival rate in Non-Small Cell Lung Cancer (NSCLC) decreases dramatically from 70.1% for pN0 to 54.3% for pN1, and 26.4% for pN2[2].

Not surprisingly, occult metastases have been associated with significantly worse disease-free (hazard ratio [HR] 1.50) and overall survival (HR 1.58)[3]. A low tumour burden in the LNs may remain undetected by conventional histopathological methods due to their limited sensitivity when analysing only a small fraction of the node.

In contrast, OSNA provides fast molecular whole-node analysis, suitable in the intra- as well as post-operative setting [2–3]. OSNA quantifies the tumour burden regardless of metastatic size or location in the node, thus supporting a more accurate diagnosis, and with this prognosis, enabling the right treatment choice for the patients. OSNA has been compared to histopathological examination in more than 3,000 LNs [1–9], where each node was analysed by both methods, achieving highly favourable results and a concordance rate of up to 97.7% [2]. Vodicka *et al.* [6] showed that, thanks to OSNA, 22% of patients were upstaged where conventional histology was not sensitive enough.

Recent data show that the quantitative OSNA Total Tumour Load (TTL) has prognostic value in lung cancer, allowing patients to be classified into high- and low-risk groups for disease recurrence and survival probability by defining pN more accurately (Fig 1) [1].

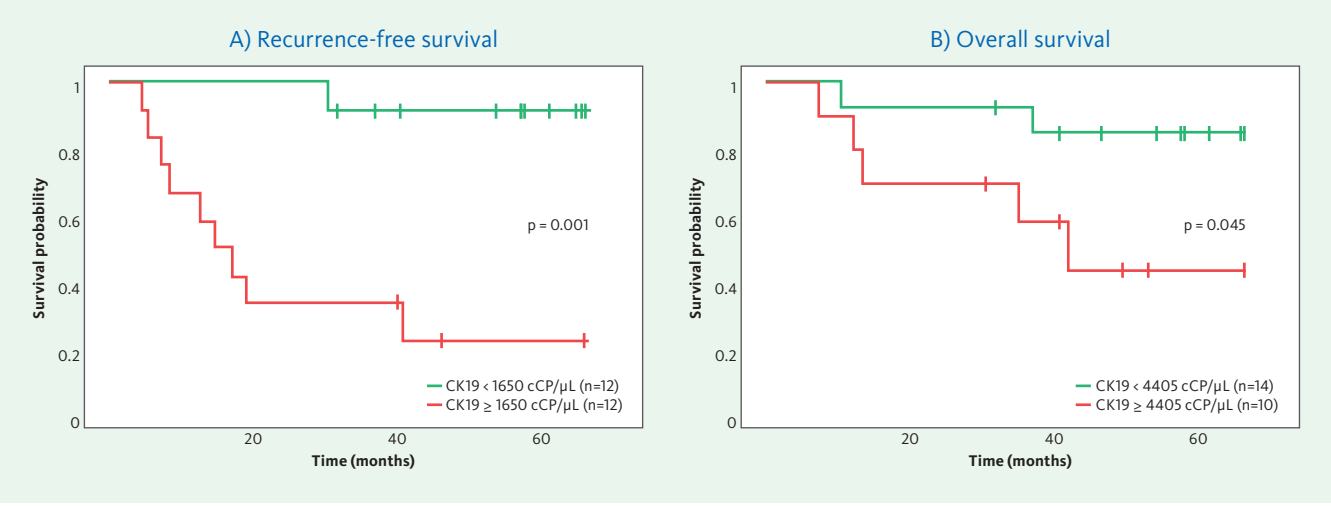

Fig. 1 *(A) Recurrence-free survival curve for patients without recurrence (< 1650 cCP/µL) vs. patients with recurrence (≥ 1650 cCP/µL), p-value = 0.001.*
(B) Overall survival curve for patients with high survival probability (< 4405 cCP/µL) vs. patients with low survival probability (≥ 4405 cCP/µL), p-value = 0.045.

[1] ***Maniwa T et al. (2020):*** *Number of metastatic lymph nodes and zones as prognostic factors in non-small-cell lung cancer. Interact Cardiovasc Thorac Surg. 31 (3): 305–314.*
[2] ***Citak N et al. (2020):*** *A Comparison of the Currently Used Nodal Stage Classification with the Number of Metastatic Lymph Nodes and the Number of Metastatic Lymph Node Stations for Non-Small Cell Lung Cancer; Which of These Is the Best Prognostic Factor? Zentralbl Chir. 145 (6): 565–573.*
[3] ***Rusch VW et al. (2011):*** *Occult metastases in lymph nodes predict survival in resectable non-small-cell lung cancer: report of the ACOSOG Z0040 trial. J Clin Oncol. 29 (32): 4313–9.*

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OSNA – Confident nodal information, choosing the right treatment for the right patient

Selected publications

[1] Hermida-Romero et al. (2022): *Molecular Detection of Lymph Node Metastases in Lung Cancer Patients Using the One-Step Nucleic Acid Amplification Method: Clinical Significance and Prognostic Value. Cells. 11 (24): 4010. [article]*

Key message: *For the first time, Total Tumour Load (TTL) determined by OSNA was shown to have a prognostic value in lung cancer, allowing patients to be classified into different risk groups for disease recurrence and survival probability by defining pN more specifically.*

[2] Namba et al. (2022): *One-step nucleic acid amplification for intraoperative diagnosis of lymph node metastasis in lung cancer patients: a single-center prospective study. Sci Rep. 12, 7297. [article]*

Key message: *This study demonstrated a high concordance between OSNA and intraoperative frozen-section pathological diagnosis. OSNA provides sufficient rapidity and diagnostic accuracy, thus it can be applied to the intraoperative diagnosis of nodal metastasis in lung cancer patients.*

[3] Ose et al. (2022): *Detection of lymph node metastasis in non-small cell lung cancer using the new system of one-step nucleic acid amplification assay. PLoS One. 17 (3): e0265603. [article]*

Key message: *The performance of the OSNA method is comparable to that of histopathology, demonstrating that OSNA can be effectively utilised during lung cancer treatment intraoperatively and postoperatively. OSNA could be the gold standard technique for the diagnosis of lymph node metastasis.*

[4] Vodicka et al. (2020): *Prognostic Significance of Lymph Node Examination by the OSNA Method in Lung Cancer Patients – Comparison with the Standard Histopathological Procedure. Cells. 9 (12): 2611. [article]*

Key message: *The higher sensitivity of OSNA was not reflected in a less favourable progress of the disease. However, OSNA allows the entire lymph node to be analysed, and, in comparison to histopathology, requires less experience from the health care professionals. Rising the cut-off value to 615 copies of mRNA of CK19/µL increased concordance between the OSNA and histopathology.*

[5] Pérez et al. (2019): *Detection of lymph node metastasis in lung cancer patients using a one-step nucleic acid amplification assay: a single-centre prospective study. J Transl Med. 17: 233. [article]*

Key message: *The high sensitivity of OSNA enables detection of tumour cells missed by pathological examinations. These occult metastases may be the key to explain why some patients staged pN0 or pN1 after surgery are progressing with worse prognosis.*

[6] Vodicka et al. (2018): *A more sensitive detection of micrometastases of NSCLC in lymph nodes using the one-step acid amplification (OSNA) method. J Surg Oncol. 117 (2): 163–170. [abstract]*

Key message: *OSNA has shown to be more sensitive by detecting more tumor cells in comparison with both H&E and IHC CK19, resulting in a higher pTNM stage in 22 % of patients.*

[7] Nakagawa et al. (2016): *The novel one-step nucleic amplification (OSNA) assay for the diagnosis of lymph node metastasis in patients with non-small cell lung cancer (NSCLC): results of a multicentre prospective study. Lung Cancer. 97: 1–7. [abstract]*

Key message: *OSNA has shown to be equivalent to the 3-level histological examination and can improve the detection of metastases by analysing the whole lymph node.*

[8] Hayama et al. (2014): *One-step nucleic acid amplification for detection of lymph node metastasis in lung cancer. Ann Thorac Cardiovasc Surg. 20(3): 181–4. [abstract]*

Key message: *OSNA can successfully detect lymph node metastasis in lung cancer, which was confirmed by conventional histopathology. The sensitivity of OSNA was 100 % and its specificity was 91.7 %.*

[9] Inoue et al. (2012): *An accurate and rapid detection of lymph node metastasis in non-small cell lung cancer patients based on one-step nucleic acid amplification assay. Lung Cancer. 78(3): 212–8. [abstract]*

Key message: *Among 16 target markers with high expression in lung carcinoma, CK19 reported the best performance for the detection of nodal metastases. Additionally, OSNA is a promising rapid method for intraoperative diagnosis required for the use of less invasive surgical procedures, such as sublobar resection.*

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