

# One step nucleic acid amplification (OSNA): one step ahead in gynecological surgical oncology

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## Summary

Neoplastic spread to lymph nodes is one of the most important prognostic factors in female cancer and one of the well known TNM classification parameters, together with tumor size and distant metastases. The nodal status is in fact a significant predictor, which supports clinicians to decide on the most appropriate surgical approach and subsequent therapy. The precise intraoperative assessment of sentinel lymph node and eventual metastatic burden is therefore decisive for providing high diagnostic quality and reliable staging. Since methodologies differ across institutions, standardization of results is also a challenge. Today, one step nucleic acid amplification (OSNA) meets all these needs.

**Key words:** One-step nucleic acid amplification (OSNA); Sentinel lymph node; Sentinel lymph node biopsy; Vulvar cancer; Gynecological surgical oncology.

The sentinel lymph node (SLN) is the hypothetical first lymph node to drain a primary cancer and the lymph node in its immediate vicinity is named “para-sentinel” lymph node [1, 2]. In surgical oncology, sentinel lymph node biopsy (SLNB) is the procedure in which SLN is, at first, intraoperatively identified through radionuclide, fluorescence or visual blue dye, then surgically removed and, finally, examined under the microscope by cryosection [3-5]. A negative SLNB suggests that cancer has not yet developed the competence to spread into nearby lymph nodes, while a positive SLNB indicates the achievement of this ability, with subsequent need for a wider regional lymph node dissection [3-5]. The quality of the slides obtained by cryosection is very low, if compared to those from formalin-fixed paraffin-embedded tissue; moreover, only a part of the removed SLN can be intraoperatively examined for lack of time. To overcome these limits, one step nucleic acid amplification (OSNA) has been implemented in the recent years [6]. It is based on the standardized and automated molecular evaluation of cytokeratin 19 mRNA copy number in the entire SLN, and it allows to distinguish negative samples (< 250 copies) from positive ones (> 250 copies) in about 30 minutes with high sensibility ( $\geq 95\%$ ) and specificity ( $\geq 94\%$ ), giving also an indication of the nodal carcinoma burden, known as micrometastasis (< 5,000 copies) or macrometastasis (> 5,000 copies) [6]. Moreover, it allows to close the surgical phase in a single session with advantages in regards to the patient and to the hospitalization costs [6]. Among the gynecological malignancies, vulvar

cancer is the most suitable for SLNB for two reasons: 1) it originates from the skin surface, thus making the tracer injection easier and 2) the SLN is always located in the groin [7]. According to the American Cancer Society, in 2018 there were about 6,190 new cases of vulvar cancer and 1,200 estimated deaths from this neoplasm [8]. The five-year survival rates is around 70% and the lymph node status is the most important prognostic factor [9]. Approximately 90% of vulvar cancers are squamous cell carcinomas and, therefore, well detectable by OSNA [6]. In the near future, similar to what occurred for the breast [10], OSNA could improve also vulvar cancer management, differentiating patients to be submitted to groin lymphadenectomy, with significant benefits for survival and lower extremity lymphedema.

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