



April 2008: VOLUME 1, NUMBER 7

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- Melinda Woofter, MD

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Melanoma-Sentinel Lymph Node Biopsy

In this Issue...

The optimal management of patients with newly diagnosed cutaneous melanoma and clinically negative regional nodal basins has changed over the past decade. Sentinel lymph node biopsy (SLNB) is a rational approach to evaluation of the regional nodes and has become the standard of care for patients at intermediate or high risk for regional lymph node metastases. The SLNB is a minimally invasive staging procedure that provides strong prognostic information, allows rational choice of clinical management strategy based on pathologic status of the regional nodes, improves disease-free survival, and lowers regional nodal recurrence rate. Sentinel node biopsy has thus become an important tool in the management of newly diagnosed melanoma patients who are considered at risk for regional nodal metastasis.

In this issue, we report on the role of the sentinel lymph node (SLN) status as a powerful prognostic tool, discuss which patients should undergo sentinel lymph node biopsy, explain how sentinel lymph node biopsy aids in the process of providing locoregional disease control while minimizing morbidity, elaborate on appropriate interpretation of sentinel node results, and describe the outcomes of patients who have undergone sentinel node biopsy.



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Dr. Lange has disclosed no relationship with commercial supporters.

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LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- Describe to colleagues the importance of regional node status in estimating prognosis for patients with newly diagnosed melanoma
- Summarize to colleagues the current indications for sentinel lymph node biopsy for patients with melanoma
- Discuss with colleagues the impact the sentinel lymph node status has in the treatment choices and outcomes of melanoma

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COMMENTARY

The studies reviewed herein show that, in patients with cutaneous melanoma, as in many other malignancies, the status of the regional lymph nodes is the single most important prognostic factor. Balch et al combined the data from 13 specialized centers of 17,600 evaluable melanoma patients in order to examine prognostic factors for newly diagnosed melanoma patients. This large study found that in patients without clinically evident regional or distant metastases, the pathologic regional nodal status was the most significant predictor of outcome, with stronger significance than Breslow thickness, ulceration, age, or anatomic site. The sentinel node status is today the most important prognostic feature in patients with newly diagnosed melanoma. This has been demonstrated in many large series, most notably in the 2006 landmark study by Morton et al, which shows that the hazard ratios of sentinel lymph node (SLN) status for both recurrence (3.04, 2.11-4.39 95% CI, $p < 0.001$) and death from melanoma (2.48, 1.54-3.98 95% CI, $p < 0.001$) eclipse the hazard ratios of any other factor, including Breslow thickness. As further seen in Scheri et al, even minute amounts of disease in the SLN can be clinically significant: isolated tumor cells (less than or equal to 0.2 mm) in SLN have prognostic significance.

SLN biopsy (SLNB) is able to identify among clinically node-negative melanoma patients those patients with positive regional nodes who would most benefit from completion lymph node dissection to complete their staging and provide regional disease control. SLNB also selects those patients who might benefit from adjuvant and research protocol-based therapy. Clinically node negative patients who should be considered for SLNB include those with a 5% or greater risk of occult regional nodal metastasis; in practice, this includes those with thickness over 1 mm. As seen in Wong et al, SLNB can also be considered in patients with thinner lesions (0.76-1 mm) if associated with high risk features such as histological ulceration or Clark level IV/V, as these patients have an incidence of occult nodal metastases of at least 5%. Patients who undergo shave biopsy and have a positive deep margin, and thus have an unknown thickness of the melanoma, can also be considered for SLNB. Such recommendation can be given without reservation, because, as seen in McMasters et al, SLNB is a minimally invasive procedure associated with low morbidity.

The results of the long-awaited Multicenter Selective Lymphadenectomy Trial-I (MSLT-I) demonstrate improved disease-free survival in patients randomized to SLNB. In MSLT-I, clinically node negative patients with intermediate risk melanomas were randomized to SLNB or nodal observation; patients with



pathologically positive SLN underwent immediate completion node dissection while those randomized to nodal observation underwent delayed lymph node dissection if clinically evident disease developed. At 5 years, Morton et al report a statistically significant improvement in disease-free survival favoring the SLNB group (78%.3 vs 73.1%). Also documented is a much lower regional nodal relapse rate (3.4% vs 15.6%) in the patients randomized to sentinel node biopsy than in those assigned to observation. Morton's study also strongly reinforces the role of the sentinel node status as a very strong prognostic factor. Most sentinel node biopsy patients will have pathologically negative nodes. Zogakis presents data documenting that while SLN negative patients clearly have favorable outcomes, they still can recur.

We can conclude that SLNB clearly provides excellent prognostic information and results in improved regional disease control. Prior to the common use of SLNB, regional nodal recurrence was the single most common site of melanoma recurrence, sometimes with symptomatic, bulky disease that was devastating for the patient and difficult or impossible to control. With the widespread use of SLNB, regional recurrence of melanoma is much less frequent. Even without clear indication of improvement in overall survival, the significant prognostic information and the improved regional control is cause enough for us to embrace it as an important procedure that should be offered to appropriately selected patients.

ANALYSIS OF PROGNOSTIC FACTORS

Balch CM, Soong S, Gershenwald JE, et al. **Prognostic Factors Analysis of 17,600 Melanoma Patients: Validation of the American Joint Committee on Cancer Melanoma Staging System.** *J Clin Oncol.* 2001; 19 (16): 3622-3634.

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Balch et al evaluated the combined data from 13 specialized centers and analyzed data for 17,600 evaluable melanoma patients; this study resulted in an assessment of prognostic factors in patients with melanoma that informed the most recent update to the American Joint Committee on Cancer staging of melanoma. For patients without clinically evident metastases who underwent either elective or sentinel lymphadenectomy, the regional nodal status was the single most significant predictor for outcome, with a higher risk ratio than Breslow thickness, ulceration, or anatomic site (which were also significant independent predictors of outcome). In patients who had tumor-positive lymph nodes, they reported that both an increasing number of nodal metastases and whether the metastases were clinically occult (non-palpable) or clinically apparent (palpable) were powerful prognostic factors that distinguished and predicted melanoma-specific survival rates. All of these data serve to corroborate the regional nodal status as the most important prognostic factor in the staging of melanoma.

The study provides detailed information on the heterogeneity of prognosis in patients with positive regional nodes. The three most important factors contributing to the prognosis are the number of positive nodes, whether the nodes are clinically palpable or not, and whether the primary tumor had histologic ulceration. Five year survival ranges from 69% in patients with a single microscopically positive node and a non-ulcerated primary to 13% in patients with four or more clinically positive nodes and an ulcerated primary. Also displayed are 15 year survival curves for patients with positive nodes. The curves are notable for two features. Prognosis is clearly related to the number of positive nodes: patients with a greater number of positive nodes showed distinctly poorer survival than those with fewer positive nodes. The shape of the curves is worth noting: most deaths occur in the first three years, with the curves all gradually plateauing thereafter. At fifteen years a substantial minority of patients are alive, even with a history of four or more positive nodes. Node positive melanoma, therefore, is a serious but treatable disease.

The node status of newly diagnosed patients is worth investigating and if positive further treatment is warranted. The treatment of patients with positive nodes,

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whether clinically positive or microscopically positive, today includes requires regional lymph node dissection. Regional lymph node dissection of positive nodes not only completes staging but provides regional disease control. Node positive melanoma is a treatable disease, and the literature provides strong evidence that many patients will have prolonged survival after initial treatment.

SENTINEL NODE BIOPSY VS NODAL OBSERVATION

Morton DL, Thompson JF, Cochran AJ, et al. **Sentinel-node Biopsy or Nodal Observation in Melanoma.** *N Eng J Med.* 2006; 355 (13): 1307-1317.

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The long-awaited Multicenter Selective Lymphadenectomy Trial-1 (MSLT-1) was reported in 2006. Patients with primary melanoma ≥ 1 mm in thickness and clinically negative nodes were eligible for randomization to undergo wide local excision with sentinel lymph node biopsy (60% of entire group) *versus* wide local excision with nodal observation (40% of entire group). In the nodal observation group, delayed lymph node dissection was performed if clinical disease developed in the regional nodes at a later time. This study reports the results of 1269 patients with melanoma 1.2-3.5mm — this prospectively planned analysis was targeted at the group of patients who were felt to be most likely to see benefit from sentinel node biopsy.

The incidence of SLN micrometastases was 16.0%, whereas the rate of nodal relapse in the observation group was 15.6%. Among those who were node positive, the mean number of tumor-involved nodes was 1.4 in the SLNB group versus 3.3 in the observation group, indicating that a delay in detection of nodal disease appears to be associated with disease progression in that node basin. The results revealed a 3% statistically non-significant overall survival advantage in the SLNB group observed at 3 years (93 vs. 90% at 3 years, and 87% and 86% at 5 years, $p = ns$). This lack of overall survival benefit may be attributable to an underpowered study: most of the randomized patients (as expected) are node negative and therefore could not possibly benefit from node surgery.

However, the study did demonstrate improved disease-free survival at 5 years in the group receiving sentinel node biopsy compared to the group receiving observation (78.3% vs. 73.1%, $p=0.009$). A secondary analysis compared the patients who had positive SLNs and underwent immediate lymphadenectomy versus patients in the nodal observation group who later developed clinical disease; this analysis revealed a 20% survival advantage for SLN-positive patients who underwent immediate lymphadenectomy.

Despite the lack of definitive evidence for overall survival benefit, the results of this study highlight several important points. First, they show the powerful prognostic information SLN conveys, by confirming that SLN positivity has a higher hazard ratio for death than thickness or ulceration; that melanoma-specific 5-year survival rates for SLN positive versus SLN negative are significantly different (72.3% vs 90.2%, $p < 0.0001$); that patients randomized to the SLNB group have improved 5-year disease free survival as compared to those who were randomized to initial nodal observation (78% vs 73%, $p = 0.009$); and that amongst SLN negative patients there was a only 3.4% nodal recurrence rate versus 15.6% in the patients in the observation group.

So, in addition to the powerful prognostic information SLNB clearly provides, the MSLT-1 study also showed a statistically significant regional control benefit among patients randomized to the SLNB group as compared to the patients randomized to the nodal observation group. This published report represents the third interim (out of a planned 5) analysis for this study. Ongoing survival data is being accrued and analyzed, and we await updated reports on whether an overall survival benefit will become evident over time.

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THE SUNBELT MELANOMA TRIAL

McMasters KM, Noyes RD, Reintgen DS, et al. **Lessons Learned from the Sunbelt Melanoma Trial.** *J Surg Oncol.* 2004; 86 (4): 212-223.

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The Sunbelt Melanoma Trial is a multicenter (79 sites) prospective randomized trial that is now closed to accrual (with 3600 patients) but whose endpoints have not yet been reported. Patients with 1 mm or greater primary melanoma, with no evidence of distant disease and with clinically negative nodes, were enrolled and underwent SLNB to attempt to determine whether patients with early nodal metastasis (single microscopically or RT-PCR positive SLN only) would benefit from adjuvant therapy with interferon- α 2b following lymph node dissection versus lymph node dissection alone. While the primary endpoints have not yet been reported, several results are available and are reviewed here.

The investigators found that no prospective clinicopathologic factors, alone or in combination, could predict whether SLN positive patients will or will not have tumor positive non-sentinel lymph nodes on completion lymph node dissection (only 15-20% will have additional positive nodes on completion lymph node dissection). Even patients with minimal sentinel node tumor burden have rates of positive non-sentinel nodes equal to patients with more significant burden in the sentinel node.

Importantly, McMasters et al is the first report from a large multicenter study that establishes that the SLNB procedure has significantly lower morbidity than regional lymphadenectomy. This study also reveals that when morbidity occurs it is usually minor, short-term, and easily manageable. They compared 2120 patients undergoing SLN biopsy alone to the 444 patients undergoing SLNB with completion lymph node dissection; complications of any type occurred in 4.6% of patients undergoing SLNB alone compared to 23.2% of patients who underwent SLNB with completion lymph node dissection. Hematoma/seroma and infection are the most frequent complication of SLNB and generally have no long-term consequence; a 0.7% rate of lymphedema was reported with SLNB.

SLNB & THIN MELANOMA

Wong SL, Brady MS, Busam KJ, et al. **Results of Sentinel Lymph Node Biopsy in Patients with Thin Melanoma.** *Ann Surg Oncol.* 2006; 13 (3): 302-309.

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This retrospective evaluation analyzed melanoma patients with tumor thickness ≤ 1 mm managed with SLNB at Memorial Sloan-Kettering Cancer Center from May 1991 to October 2004. This study is of great interest, as patients with thin melanoma (≤ 1 mm) comprise an estimated 70% of all patients with cutaneous melanomas and are expected to have an excellent prognosis. It is well understood, however, that a minority of these "excellent prognosis" patients will later suffer recurrence and eventually die of their disease. It would be very useful to find a way to determine at the time of diagnosis which patients with thin melanoma are likely to recur. The findings of this study are important because they provide information for a large group of patients that we see in everyday practice.

Wong et al identified 223 patients with thin melanoma (≤ 1 mm) who underwent sentinel node biopsy as part of their initial surgical management, usually because of high risk clinicopathologic features. Overall, nodal metastases were found in 8

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(3.6%) patients, all of whom had thickness ≥ 0.75 mm or Clark level IV. Among patients who had either thickness 0.75-1.0mm or Clark level IV, 7% (8/114) had nodal metastases. Age, sex, location, ulceration, regression, and mitotic rate were not associated with node positivity in this study. Of the patients with melanoma less than 0.75 mm in thickness, no matter what the additional features of the primary tumor, no patient was found to have a positive SLN and there were no recurrences or deaths. At a median follow-up of 25 months, 3 patients had died of melanoma, all of whom had melanoma between 0.75 and 1.0 mm with a negative sentinel node.

As expected, patients with thin melanoma are in general a low risk group but can have positive nodes. Of patients with a Breslow thickness of 0.75 to 1.0 mm and at least Clark level IV invasion, 7% had a positive SLN (thus greater than our 5% "threshold" for recommending SLNB), which is why SLNB should be considered for this subset of patients.

SIGNIFICANCE OF MINUTE AMOUNTS OF DISEASE IN SENTINEL NODES

Scheri RP, Essner R, Turner RR, et al. **Isolated Tumor Cells in the Sentinel Lymph Node Affect Long-term Prognosis of Patients with Melanoma.** *Ann Surg Oncol.* 2007; 14 (10): 2861-2866.

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With focused analysis of sentinel nodes with multiple serial sections and IHC staining, very small amounts of disease are often found. The significance of minute amounts of disease in the sentinel node has been questioned. Scheri et al reports that even a small amount of disease in the sentinel node is significant and argues that all patients with disease in the sentinel nodes should undergo completion lymph node dissection. The authors all identified all patients who underwent SLNB at John Wayne Cancer Institute from 1991 to 2003, and identified 57 patients among 1382 patients (4.0%) who had tumor deposits in their sentinel node classified as isolated tumor cells (≤ 0.2 mm). In these patients with only isolated tumor cells in the sentinel node, completion lymph node dissection identified positive non-sentinel lymph nodes in 12% of patients. This rate of non-sentinel node positivity is similar to published rates in patients with greater sentinel lymph node involvement (15-20%). This finding reinforces the lesson learned from the Sunbelt Melanoma Trial (McMasters et al) in which no consistent prospective clinicopathologic factors to date, alone or in combination, can predict whether SLN positive patients will have tumor-positive non-sentinel lymph nodes on completion lymph node dissection.

Furthermore, at a median follow-up time of 57 months, the 5 year and 10 year melanoma specific survival was significantly lower for patients with isolated tumor cells in their sentinel nodes than in patients whose nodes were negative. On multivariate analysis, ITC, greater primary tumor thickness, and histologic ulceration were the strongest predictors of poorer survival. All patients with tumor positive sentinel nodes today should undergo completion lymph node dissection unless future studies document that it is safe to omit dissection.

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Zogakis TG, Essner R, Wang H, et al. **Natural History of Melanoma in 773 Patients with Tumor-Negative Sentinel Lymph Nodes.** *Ann Surg Oncol.* 2005; 14 (5): 1604-1611.

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This retrospective analysis of the John Wayne Cancer Institute melanoma database evaluated the disease-free survival, overall survival, and recurrence patterns for all patients seen at their institution between 1995 and 2002 who had stage I or stage II (thin, intermediate, or thick) primary cutaneous melanoma with a negative sentinel node biopsy. Between 1995 and 2002, 773 patients met these criteria. The authors noted disease-free and overall survival rates of 88% and 93% at 5 years, with a 1.7% regional nodal basin recurrence rate. At a median follow-up of 3 years, 8.9% of patients with a negative SLN developed a recurrence, with local (1.8%), in-transit (1.2%), regional (1.7%), or distant (4.8%) recurrence; 5.2% died of their disease. So while SLN negative patients clearly have favorable outcomes, they still can recur; this study revealed that among this cohort, those with thicker, ulcerated, and/or head and neck melanomas had the higher rates of recurrence. Not surprisingly, amongst these SLN negative patients, thickness and ulceration were independently predictive of overall survival. Compared to the approximately 15% expected rate of nodal relapse in patients without initial nodal biopsy but with similar primary tumor features, the 1.7% regional nodal basin recurrence rate reported in these SLN negative patients reinforces the correct assessment of prognosis for newly diagnosed melanoma patients and demonstrates very good regional control.

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Learning Objectives — [back to top](#)

At the conclusion of this activity, participants should be able to:

- Describe to colleagues the importance of regional node status in estimating prognosis for patients with newly diagnosed melanoma
- Summarize to colleagues the current indications for sentinel lymph node biopsy for patients with melanoma
- Discuss with colleagues the impact the sentinel lymph node status has in the treatment choices and outcomes of melanoma

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