A Prospective Study of Intraoperative Lymphatic Mapping for Head and Neck Cutaneous Melanoma

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**Background:** Intraoperative lymphatic mapping and sentinel lymph node biopsy have been used successfully to stage regional lymphatics for trunk and extremity melanomas. However, the accuracy and applicability of these techniques in the head and neck have not been determined conclusively.

**Objective:** To report the results of a prospective trial of intraoperative lymphatic mapping and sentinel lymph node identification in patients with head and neck cutaneous melanoma.

**Methods:** Using technetium Tc 99m–labeled sulfur colloid and isosulfan blue, intraoperative lymphatic mapping and sentinel lymph node identification were performed in 43 patients with melanomas of intermediate thickness. After the sentinel lymph nodes were identified in situ, an elective dissection of levels I through V or II through V was performed, based on the location of the primary tumor. The parotid, postauricular, and suboccipital lymphatics were dissected as clinically indicated. The sentinel lymph nodes were isolated ex vivo and evaluated pathologically by serial sectioning, and the accuracy of the lymphatic mapping was determined.

**Results:** Intraoperative lymphatic mapping identified 155 sentinel lymph nodes in 94 nodal basins, with a mean of 3.6 sentinel nodes and 2.2 basins per patient. Sentinel nodes were located in the parotid gland in 19 patients (44%), necessitating superficial parotidectomies, and they were distributed throughout nonadjacent nodal basins in 18 patients (42%). Nine patients (21%) had metastatic disease in 1 or more sentinel nodes, 3 of whom had metastatic disease in a nonsentinel node. No patient who had negative sentinel nodes had a positive nonsentinel node (false-negative incidence, 0).

**Conclusions:** Although intraoperative lymphatic mapping accurately identifies sentinel lymph nodes for head and neck cutaneous melanomas, the multiplicity of these nodes, their widespread distribution, and their frequent location within the parotid gland may preclude sentinel lymph node biopsy in many patients. Therefore, we advocate selective lymphadenectomy of sentinel nodal basins, allowing histological staging of the regional lymphatics with limited morbidity. However, further study is necessary to define the true role of sentinel lymph node identification for head and neck cutaneous melanoma.


Although elective lymphadenectomy is an effective method of staging the regional lymphatics in patients with cutaneous melanoma, it has not been shown definitively to improve survival. Consequently, lymphatic mapping with sentinel lymph node (SLN) biopsy was devised as a way to detect the presence of occult metastases, without performing an extensive nodal dissection. This technique is based on the principle that the SLN, which is the first node to receive lymphatic drainage from the primary tumor, has the highest risk of harboring micrometastatic disease.

Lymphatic mapping and SLN biopsy have been used successfully for trunk and extremity melanomas, identifying SLNs in more than 80% of patients and establishing the presence or absence of micrometastases with 95% accuracy. The efficacy of these techniques was determined in large prospective trials, during which the results of SLN biopsy were confirmed histologically by performing a complete lymphadenectomy. However, similar trials have not been performed exclusively for head and neck primaries. Because the head and neck lymphatic system is more complex than that of other nodal basins, lymphatic mapping and SLN biopsy may not be as accurate or appropriate in this region. Therefore, the purpose of this study was to establish the accuracy and practical application of these techniques in the head and neck by performing them in conjunction with a comprehensive nodal dissection.

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PATIENTS AND METHODS

From November 1, 1996, to March 31, 2001, 43 patients with cutaneous melanomas of the head and neck underwent preoperative lymphoscintigraphy and intraoperative lymphatic mapping with SLN identification. Informed consent was obtained from all patients before their undergoing these procedures. The first 18 patients were part of a pilot investigation, after which a study protocol was established and approved by the institutional review board at M.D. Anderson Cancer Center, Houston, Tex.

Patients were eligible if they had a primary lesion of intermediate thickness (1.0-4.0 mm) or a lesion less than 1.0 mm that was ulcerated, with no clinical evidence of lymph node metastasis. When the histological diagnosis had been established by excisional biopsy, patients were included only if the margins of excision were narrow (<5.0 mm); patients whose margins of excision were wide were excluded because of the likelihood that the excision had disrupted the cutaneous lymphatic drainage pathways. Patients with midline lesions (located between the midpupillary sagittal planes) also were excluded, because of the high likelihood that their lesions had bilateral lymphatic drainage.

In addition to physical examination, all patients underwent ultrasonography of the head and neck to confirm the absence of lymphadenopathy. A metastatic workup also was performed, which consisted of a chest x-ray and serum alkaline phosphatase and lactate dehydrogenase levels, according to institutional guidelines for evaluating patients with stage I or II cutaneous melanoma.

PREOPERATIVE LYMPHOSCINTIGRAPHY

Preoperative lymphoscintigraphy was performed by injecting 1 mL of technetium Tc 99m-labeled sulfur colloid intradermally around the primary lesion or biopsy scar in a 4-quadrant fashion. Using a gamma camera with a low-energy, high-resolution collimator, dynamic images of the head and neck region were obtained, beginning 15 minutes after injection and continuing every 30 minutes thereafter, until the SLNs were visualized. At that point, transmission images of the head and neck region were obtained. Radioactive markers were placed on the external occipital protuberance, mastoid tip, mandibular angle, mentum, thyroid notch, and supra-softal notch to help demonstrate the anatomical orientation of the visualized lymph nodes.

INTRAOPERATIVE LYMPHATIC MAPPING

One to 2 hours before the anticipated time of surgery, the patient was taken to the nuclear medicine suite, where Tc 99m sulfur colloid was injected intradermally around the primary site in a 4-quadrant fashion. After the patient was transported to the operating room and general anesthesia was induced, approximately 1 mL of isosulfan blue dye was infiltrated around the lesion or biopsy scar, keeping the dye within the anticipated margins of resection to avoid permanent tattooing of the skin. The area of the injection was massaged to facilitate passage of the dye into the cutaneous lymphatics. Immediately thereafter, the patient’s head and neck were prepared and draped in a sterile fashion, and the primary tumor was excised with appropriate margins.

Next, the handheld gamma probe was used to localize the SLNs transcervically, to determine the type of skin incision to perform for the lymphatic dissection. This was accomplished by angling the probe away from the primary site and using a collimator to decrease the background radioactivity. In some cases, localization of the SLNs was guided by the images obtained from preoperative lymphoscintigraphy.

After the appropriate skin incision was made and the skin flaps were elevated, the SLNs were identified by the presence of blue dye or by their concentration of radio-labeled colloid. Each SLN was marked with a silk suture and left in situ. When a SLN could not be identified specifically within its nodal basin, because of its small size, encasement by fibrolymphatic tissue, or other factors, the general area of the SLN was marked with a suture. A comprehensive nodal dissection then was performed, removing levels I through V. For posterior lesions, levels II through V were dissected, as drainage to level I was unlikely. The parotid, postauricular, and suboccipital lymphatics were dissected as clinically indicated.

Following completion of the dissection, each previously marked SLN was separated from its basin ex vivo, using the gamma probe to help identify the SLN precisely if it had not taken up blue dye. The maximal counts per second were recorded, and the SLNs were submitted for histological processing. To ensure that the SLN harvest was complete, particularly when 1 or more lymphatic basins were preserved (eg, level I or the parotid, postauricular, or suboccipital nodes), the head and neck were checked again with the gamma probe, to verify that no additional areas of increased radioactivity remained.

Following surgery, the patients were hospitalized for 1 to 3 days, depending on the extent of the lymphatic dissection. Before discharge, they were seen by a physical therapist, who prescribed standard neck and shoulder exercises that are recommended at M.D. Anderson Cancer Center for all patients who have undergone neck dissections.

HISTOLOGICAL ANALYSIS

After the SLNs were isolated, the neck dissection specimen was separated into levels, based on the SLN’s anatomical location, and the non-SLNs were identified. The SLNs and non-SLNs were fixed in 10% formalin and embedded in separate paraffin blocks. One section from each SLN was prepared, stained with hematoxylin-eosin, and examined by light microscopy. If the initial examination of the SLNs did not detect metastatic disease, the SLNs were sectioned serially in 5.0-mm increments and stained with hematoxylin and eosin. In addition, immunohistochemical staining to detect melanoma markers S-100 and HMB-45 was performed.

For the non-SLNs, each node was bivalved, and 1 section was prepared and then stained with hematoxylin-eosin. At our institution, this has been an effective method for screening a large number of lymph nodes for metastatic disease.
RESULTS

Of the 43 patients who underwent intraoperative lymphatic mapping and SLN identification, 35 were men and 8 were women. The mean age was 55 years (range, 24-76 years). Most of the primary tumors were distributed throughout the scalp (18 [42%]), face (10 [23%]), and neck (9 [21%]), while 6 (14%) were located on the ear. The mean thickness of the lesions was 2.1 mm (range, 0.8-5.5 mm), with a median Clark level of IV, and 4 tumors were ulcerated. One patient had a lesion that was more than 4.0 mm thick (5.5 mm), but this patient was part of the pilot investigation that was performed before establishing the study protocol.

PREOPERATIVE LYMPHOSCINTIGRAPHY

Preoperative lymphoscintigraphy identified putative SLNs in 65 nodal basins. Twenty-nine (45%) of these basins later were found to contain a SLN during intraoperative lymphatic mapping. Despite the placement of external markers to facilitate localization of SLNs on the lymphoscintigram, difficulty was encountered when trying to identify the precise location of the lymph nodes that concentrated radiolabeled colloid. Furthermore, in 20 patients (47%), the radioactive signal from the primary site obscured the signal from a nearby SLN on the lymphoscintigram, and in 5 patients (12%), the lymphoscintigram falsely identified a SLN in a nodal basin that was adjacent to the primary site.

INTRAOPERATIVE LYMPHATIC MAPPING

One or more SLNs were found in 42 (98%) of the 43 patients. One hundred fifty-five SLNs (range, 1-7) were identified in 94 nodal basins (range, 1-4), with a mean of 3.6 sentinel nodes and 2.2 basins per patient. Most of the SLNs were identified with the gamma probe, all of which had scintillation counts that were at least 10-fold higher than the background counts. In 12 patients (28%), blue dye was seen in 1 or more SLNs, but most of these SLNs also concentrated radiolabeled colloid. Only 4 patients (9%) had a blue SLN that did not concentrate radiolabeled colloid.

Sentinel nodes were located in the parotid gland in 19 patients (44%), necessitating superficial parotidectomy, and they were distributed throughout nonadjacent nodal basins in 18 (42%). In addition, SLNs were identified in nodal basins that would not have been predicted clinically in 10 patients (23%), based on the location of the primary tumor (Table 1).

A SLN could not be identified in 1 patient, whose primary tumor was located on the temporal scalp and had been excised previously with narrow margins. Because the pathological analysis of the excised scar revealed extensive dermal fibrosis, it is possible that the radiolabeled colloid and blue dye could not diffuse adequately into the dermal lymphatics. Interestingly, a “hot” spot was seen in the inferior aspect of level V on the preoperative lymphoscintigram, which presumably represented diffusion of radiolabeled colloid into a SLN. Contrary to this finding, a micrometastasis was identified in level II after histological analysis of the neck dissection contents, suggesting that this region served as the primary drainage site for the temporal melanoma, rather than lower level V.

Sentinel lymph nodes that concentrated radiolabeled colloid were numbered according to their proximity to the primary tumor. For example, the lymph node with high scintillation counts that was located closest to the primary site was identified as the first SLN. Based on this classification system, the first or second SLNs that were identified in patients with positive SLNs often did not contain metastatic disease. In addition, no correlation was seen between the scintillation counts of the SLNs and their disease status (Table 2). In essence, those SLNs with the highest counts were not more likely to harbor a micrometastasis.

HISTOLOGICAL ANALYSIS

Nine patients (21%) had micrometastatic disease in 1 or more SLNs. Thirteen positive SLNs were identified (1.4 SLNs per patient), although most of the patients had only 1 positive SLN. Two positive SLNs were identified in 1 patient, and another had 3 positive SLNs. Routine histological analysis with hematoxylin and eosin staining identified metastasis in 10 of the 13 positive SLNs, whereas immunohistochemistry was necessary to identify metastatic disease in the remaining 3 SLNs. In most of the patients, the foci of metastatic disease measured 4.0 mm or less. Extracapsular tumor extension was seen in only 1 of the positive SLNs.

The mean thickness of the primary tumors in these patients was 2.6 mm (range, 1.9-3.5 mm), only 1 of whom had a lesion that measured less than 2.0 mm in thickness. This patient’s tumor was not ulcerated and had no other adverse histological features that would suggest a tendency to metastasize, such as lymphovascular invasion.

Three of the 9 patients with positive SLNs also had positive non-SLNs, which were located in a basin that contained a positive SLN in 2 of these patients. No patient who had negative sentinel nodes had a positive non-sentinel node (false-negative incidence, 0).

Table 1. Primary Sites and Location of Clinically Unpredicted Sentinel Lymph Nodes (SLNs)

<table>
<thead>
<tr>
<th>Location of Primary</th>
<th>Unpredicted SLN Locations</th>
<th>Expected SLN Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear</td>
<td>Supraclavicular</td>
<td>Parotid gland, level II</td>
</tr>
<tr>
<td>Cheek</td>
<td>Inferior level V</td>
<td>Parotid gland</td>
</tr>
<tr>
<td>Ear</td>
<td>Level IV</td>
<td>Parotid gland, level I</td>
</tr>
<tr>
<td>Parietal scalp</td>
<td>Inferior level V</td>
<td>Level II, postauricular</td>
</tr>
<tr>
<td>Occipital scalp</td>
<td>Supraclavicular, level IV</td>
<td>Postauricular, parotid gland</td>
</tr>
<tr>
<td>Temporal scalp</td>
<td>Inferior level V, level IV</td>
<td></td>
</tr>
<tr>
<td>Ear</td>
<td>Level IV</td>
<td></td>
</tr>
<tr>
<td>Parietal scalp</td>
<td>Supraclavicular</td>
<td>Superior level V, level II</td>
</tr>
</tbody>
</table>


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Intraoperative lymphatic mapping accurately identifies SLNs for head and neck cutaneous melanomas. Unlike previous studies that have addressed this issue, the accuracy was confirmed histologically in each patient, through a comprehensive dissection of the regional lymphatics. We also have identified problems that are inherent to SLN biopsy in the head and neck region and offer an alternative technique.

In this study, preoperative lymphoscintigraphy correctly identified the location of only 101 (65%) of the SLNs that were found during intraoperative lymphatic mapping. However, preoperative lymphoscintigraphy was helpful for identifying drainage to the parotid or axillary nodal basins, particularly for lesions with ambiguous drainage patterns. This assisted surgical planning and preparation, affording the opportunity for the attending surgeon to discuss with the patient the type of lymphatic dissection and its associated risks. In addition, when the lymphoscintigram identified a potential SLN in the axilla, preoperative consultation with a surgical oncologist could be obtained. As we gain more experience with lymphatic mapping for head and neck cutaneous melanomas, preoperative lymphoscintigraphy may become unnecessary, sparing the patient from the discomfort of the colloid injection and from the lengthy time required to obtain a satisfactory lymphoscintigram.

Because of the close proximity of head and neck cutaneous melanomas to the regional lymphatic basins, the radioactive signal from the primary tumor may obscure that from SLNs in nearby nodal basins. Therefore, we excised the melanomas before intraoperative identification of SLNs, to decrease the background radioactivity from the primary site. Despite this, the background counts remained high, which interfered with precise SLN identification in many patients and would have made SLN biopsy difficult, if that had been the goal of our study. However, the nodal basins in which the SLNs were located and the general area of the SLNs could be identified easily.

Radiolabeled colloid concentrated in the SLNs in 39 (91%) of the patients, while isosulfan blue dye was seen in only 12 (28%) of the patients. One patient had an allergic reaction to isosulfan blue, which was treated successfully with epinephrine and diphenhydramine hydrochloride, and the procedure was not terminated. Only 4 patients had a blue SLN that did not concentrate radiolabeled colloid. Overall, the use of the blue dye did not facilitate SLN identification in our patient population to a significant degree. Because of the risk of anaphylaxis, the routine use of isosulfan blue may not be justified in all patients who undergo intraoperative lymphatic mapping.

A SLN could not be identified intraoperatively in only 1 patient, who had a primary tumor on the temporal scalp. After a modified radical neck dissection was performed, a micrometastasis was found in level II. The inability to identify a SLN intraoperatively may have been due to inadequate diffusion of the radioactive colloid or blue dye into the dermal lymphatics, secondary to fibrosis that developed after excisional biopsy of the primary tumor.

Most patients in this study had at least 3 SLNs that were located in 2 or more nodal basins. Furthermore, many patients had SLNs that were located in nonadjacent nodal basins, such as in levels II and IV. We believe that the multiplicity of the SLNs and their widespread distribution is a function of the complexity of the head and neck lymphatic system. Nevertheless, one could argue that the elapsed time between injection of the radiolabeled colloid and blue dye and subsequent isolation of SLNs after a comprehensive nodal dissection was too prolonged, thereby allowing diffusion of these tracers into secondary lymph nodes that falsely were identified as SLNs. However, because the SLNs were identified and marked with a suture immediately after elevation of the skin flaps, the possibility of incorrectly identifying secondary lymph nodes as SLNs was minimized. Although primary tumor resection and skin flap elevation increased the time between injection and SLN identification, these procedures generally were accomplished in less than 30 minutes. Therefore, it is unlikely that this slight delay allowed sufficient time for diffusion of the tracers into secondary lymph nodes.

A SLN was identified within the parotid gland in almost half of the patients, for which superficial parotidectomy was performed. In many instances, the SLNs

Table 2. Scintillation Counts of Sentinel Lymph Nodes (SLNs) in Patients With a Positive Micrometastasis in a SLN

<table>
<thead>
<tr>
<th>Patient</th>
<th>First</th>
<th>Second</th>
<th>Third</th>
<th>Fourth</th>
<th>Fifth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9000</td>
<td>4500</td>
<td>18000</td>
<td>8500 (+)</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>8000 (+)</td>
<td>6500</td>
<td>4000</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>3</td>
<td>17000</td>
<td>29000</td>
<td>19000 (+)</td>
<td>14000</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>3500 (+)</td>
<td>11000</td>
<td>4300</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>5</td>
<td>9000</td>
<td>12000</td>
<td>17200</td>
<td>8200 (+)</td>
<td>8200</td>
</tr>
<tr>
<td>6</td>
<td>2300</td>
<td>1800</td>
<td>3100 (+)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>7</td>
<td>6000</td>
<td>1400 (+)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>8</td>
<td>1620</td>
<td>1200</td>
<td>4790 (+)</td>
<td>3800 (+)</td>
<td>900 (+)</td>
</tr>
<tr>
<td>9</td>
<td>2800 (+)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Plus sign indicates positive for metastatic disease; NA, not available.
were small, often measuring 3.0 to 4.0 mm in greatest dimension, and they were difficult to identify precisely in vivo and to isolate ex vivo. Moreover, the SLNs frequently were embedded within a matrix of fibrofatty tissue, further contributing to this difficulty. Because these circumstances would render in vivo isolation and excision of most parotid SLNs problematic, we recommend a superficial parotidectomy rather than a SLN biopsy, to avoid injuring branches of the facial nerve. In addition, if a parotid SLN were found to be positive after SLN biopsy, reoperation would be associated with an increased risk of facial nerve injury, because of inflammation and fibrosis caused by the previous lymph node “plucking.”

These characteristics of the parotid SLNs also applied to other SLNs in the head and neck region. Although the general area of the SLNs could be identified easily while they were in situ, SLNs could not be identified precisely in many patients, regardless of the nodal basin in which they were located. Similar to the parotid SLNs, the small size of the SLNs and their encasement by fibrolymphatic tissue impeded their specific in vivo identification, rendering SLN biopsy impractical and potentially hazardous, particularly if the SLN were located in the vicinity of an important anatomical structure (eg, the spinal accessory nerve or hypoglossal nerve). Furthermore, high residual background radioactivity at the primary site also interfered with precise in vivo SLN identification. Therefore, we recommend resection of the entire sentinel nodal basin (sentinel basin lymphadenectomy), with isolation of the SLN ex vivo, to reduce operative morbidity and facilitate identification and isolation of SLNs.

Because of the multiplicity of the SLNs and their nodal basins, application of the technique of sentinel basin lymphadenectomy requires thoughtful consideration. When SLNs are located in adjacent nodal levels, we recommend dissection of the levels in continuity, using an appropriate skin incision. If the nodal basins are not adjacent to each other, dissection of the intervening levels should be considered, to help avoid missing in-transit metastases. Depending on the number and distribution of the sentinel nodal basins, this approach potentially could result in an extensive lymphatic dissection (ie, an elective posterolateral neck dissection or other selective neck dissection), but in skilled hands, the associated morbidity should be low.11 Furthermore, even if sentinel basin lymphadenectomy results in a more comprehensive dissection, its advantage over routine elective dissection is that SLNs are identified and targeted specifically for histological, immunohistochemical, and molecular analyses for detection of micrometastases.

According to current practice, metastatic disease detected through SLN biopsy indicates the need for a formal, therapeutic lymphatic dissection.2,4,12 When the primary tumor is located in the head and neck, this would entail a modified radical neck dissection. Because our proposed technique of dissecting the entire lymphatic basin in which a SLN is located results in complete surgical resection of the involved basin, only a completion neck dissection would be required when micrometastatic disease is found. This would involve removal of the remaining, surgically undisturbed nodal basins, which is technically easier and potentially safer than performing a comprehensive neck dissection after several nodal basins have been violated during SLN biopsy. Moreover, after further investigation, sentinel basin lymphadenectomy may eliminate the need for a completion nodal dissection in a subset of patients, such as those who require radiotherapy based on pathological findings (eg, multiple lymph node metastases). Removing the need for a second and more extensive operative procedure reduces morbidity and avoids delays in the administration of adjuvant therapy.

Although adjuvant systemic therapy for stage III melanomas has not been shown definitively to improve overall survival,13,14 it is possible that new, efficacious treatment strategies will be developed in the future. In addition, postoperative hypofractionated radiotherapy enhances locoregional control in patients with regional metastases from head and neck primary tumors.15-17 Therefore, SLN identification and resection potentially will play a key role in the multidisciplinary management of patients with melanomas of intermediate thickness, by allowing early detection of occult nodal metastases and subsequent institution of adjuvant therapy, without the morbidity of an elective nodal dissection.12 This could lead to increased disease-free and overall survival rates, thereby improving quality of life for many patients. Although SLN biopsy accomplishes the same goals, sentinel basin lymphadenectomy appears to be the superior procedure in the head and neck region.

Based on the results of this study, we recommend SLN identification and sentinel basin lymphadenectomy for patients who have head and neck cutaneous melanoma of intermediate thickness and no clinical evidence of regional lymphadenopathy, particularly when the primary tumor is 2.0 mm or more in thickness. Despite the increased operative time and overnight hospitalization required, this technique warrants investigation in a prospective trial, because of its technical advantages and potential benefits. After further study, SLN identification and sentinel basin lymphadenectomy may replace the current trend of SLN biopsy in patients with head and neck cutaneous melanoma.

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