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Hot or not? The 10% rule in sentinel lymph node biopsy for malignant melanoma revisited☆

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Summary *Background:* The surgeon needs a practical rule to follow when deciding whether to excise a lymph node during sentinel node biopsy (SLNB). The "10% rule" dictates that all nodes with a radiation count of greater than 10% of the hottest node and all blue nodes should be removed, and this study observes the effects of following this rule in SLNB in melanoma.
Methods: We reviewed the records of 665 patients with primary melanoma who underwent sentinel lymph node over a 5-year period (2007–2011).
Results: 2064 nodes were identified in 898 nodal basins in 665 patients. 141 (21%) patients had at least one positive sentinel node. 105 positive nodal basins were identified in which more than one sentinel node was removed. In 18 of these, a less radioactive node was positive for tumour when the most radioactive node was negative. Of 175 positive nodes 157 (90%) contained blue dye staining. For cases in which the positive sentinel node was not the hottest node, the positive node had apparent blue dye staining in all 18 cases (100%), and was the second hottest node in the basin.
Conclusion: In this series removing just the hottest node and all blue nodes would not have missed a single positive basin and would have resulted in a 38% reduction in the number of nodes removed compared to those taken following the 10% rule, without changing the staging in any patient.

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Introduction

Introduced by Morton et al. in 1992, sentinel lymph node biopsy (SLNB) has become standard of care in lymph node basin staging in malignant melanoma.[1] A sentinel lymph node is the first draining node on a direct lymphatic channel from the primary tumour site. The sentinel lymph nodes are identified by intradermal injection of a vital blue dye, a radioactive tracer, or both around the site of the primary tumour. Pre-operative lymphoscintigraphy as well as intra-operative gamma probe localization and visualization of the blue dye increase the diagnostic accuracy of the sentinel node procedure.[2]

The radiocolloids are only partially filtered in the sentinel nodes, so secondary nodes are seen to have some degree of radioactivity, which would have not been detected with blue dye alone. Some of these were found to be positive for tumour presence.[3–5] A number of early studies sought to define the sentinel node in terms of absolute radiation count, in vivo or ex vivo radiation count relative to the background radioactivity, or relative to the most radioactive node in the basin.[5–9]

Since McMasters' paper analysing the results of the Sunbelt Melanoma Trial in 2001[9] the "10% rule" has been widely followed. That is that all blue nodes and all nodes containing 10% or more of the radioactive count of the ex vivo count of the hottest node should be removed and considered a sentinel node, along with any macroscopically abnormal nodes. While this approach reduces the risk of missing a positive node with a low radiation count compared to hotter negative nodes in the lymphatic basin, it may result in a large number of nodes being removed during the sentinel lymph node biopsy procedure. This study aims to re-evaluate the 10% rule by retrospectively examining the outcomes of 665 patients undergoing SLNB over a 5-year period for malignant melanoma.

Materials & methods

A retrospective review was performed of 665 consecutive patients undergoing sentinel lymph node biopsy for malignant melanoma between January 2006 and December 2011. All patients with American Joint Committee on Cancer[10] stage 1B or greater melanoma, who had no clinically detectable nodal, regional or distant metastases, and were medically fit to undergo a completion lymphadenectomy should the result of SLNB be positive were offered sentinel lymph node biopsy.

After informed consent was obtained patients underwent sentinel node localization using triple method identification; dynamic lymphoscintigraphy, intra-operative gamma probe localization and intra-dermal Patent Blue V injection. All patients underwent lymphoscintigraphy with ^{99m}Tc-human serum albumin colloid (nanocoll GE Healthcare). Four depots of 0.2 mL of radiocolloid was injected intradermally around the primary melanoma biopsy site on the morning of surgery or the evening prior. Dynamic scanning was carried out with a planar dual-head gamma camera (Siemens). Images were taken every 10 s for 10 min post-injection followed by multiple static images up to 90 min post-injection. A mark was made on the skin overlying the node(s) and the depth estimated.

The pre-operative lymphoscintogram was used as a guide to the location, and number of nodes, to be removed. Radioactivity in the nodes was measured intraoperatively using a hand-held gamma probe (Neoprobe®, Neoprobe Corp., Ohio, USA). Pre-operatively 0.5–1 mL of Patent Blue V dye (Guerbet Laboratories Ltd., Solihull, UK) was injected in the dermis around the excision site. Ex-vivo counts of the removed sentinel nodes were obtained and blue dye staining was recorded. All nodes containing blue dye staining and/or 10% or more of the radioactive count of the hottest node were removed.

Sentinel nodes underwent hematoxylin& eosin staining at multiple levels followed by immunohistochemical staining for S100 protein. The pathology of each sentinel node was correlated with the node count/hottest node count and blue dye status.

Statistical analysis was performed with Student's *t*-test. Significance was determined at $p \leq 0.05$.

Results

The demographics of the study group are represented in Table 1. There were 665 patients in total; 318 male and 347 female. The mean age was 54 years. A total of 2064 nodes were sampled (median, 3/patient). The mean and median tumour thicknesses were 2.36 mm and 1.70 mm respectively. The mean Breslow thickness in the node positive group was 2.7 mm, significantly greater than the node negative group, which was 2.1 mm ($p < 0.05$).

141 patients had at least one positive sentinel node (21.5%). These 141 patients had nodes sampled from 190 lymph node basins. 115 patients had only one basin sampled whereas18 patients had nodes taken from 2 basins, another6 patients had 3 lymphatic basins sampled, and 2 patients had nodes taken from 4 basins. Nodal metastases were found in 143 basins in these 141 patients.

In 105 basins more than one sentinel node was removed – the cohort of interest in this study. In 18 of these 105 basins a less radioactive node was positive for disease when another, more radioactive, node was negative for disease. Overall, in

Table 1 Study demographics.

	All cases	Negative	Positive
Number of cases (%)	665	524 (79)	141 (21)
Sex (%)			
Male	318 (48)	235 (45)	83 (58)
Female	347 (52)	289 (55)	58 (42)
Mean age	54.42	54.93	52.26
Breslow thickness (mm)	Number (%)		
0–1.0 (T1)	69 (10.5)	62 (12)	7 (5)
1.01–2.0 (T2)	320 (48)	267 (51)	53 (38.5)
2.01–4.0 (T3)	192 (29)	134 (25)	58 (40.5)
>4 (T4)	84 (12.5)	61 (12)	23 (16)
Mean number of nodes sampled	3.1	3.05	3.3
Median number of nodes sampled	3	3	3